CA-01

EMAILED TO Rec'nt
DATE 9/3/12 INT P

Queensland Government

Employee Movement Form - Permanent

Privacy disclaimer:
The collection of personal information on this form is authorised under the Public Service Act 2008. Your personal information will not be disclosed to other parties without your consent unless required by law. Use of personal information on this form is restricted to those involved in the authorisation and processing of this form.

This form is to be completed to document changes to an existing employee's position, status or terms of employment. Please complete all sections indicating N/A where relevant. Employees inherit the characteristics of the positional information (including cost centre). Employees must be moved into a position which is costed appropriately.

Employee Details

Person ID: [redacted]

Personnel assignment number:

Please indicate (✓) here if you work in more than one position in QLD Health. ☐

Title: Ms

Family name: ALLEN

First name/s: Catherine

Proposed Position

Position Number: [redacted]

Position title: Managing Scientist DNA Analysis FSS

Start date: 07-03-2012

Classification: HP7

Probationary Period: months

Organisational unit number: [redacted]

Organisational unit name: FSS Managing Scientists

Facility address: FSS, 39 Kessels Rd Coopers Plains

Job advertisement reference (if applicable): H11CSS08359 Open Merit

Concurrent/Aggregate: Indicate (✓) here if the employee will continue to hold their existing position in conjunction with the proposed position ☐

New Employment and Payroll Details

Appointment type

Internal temporary employee ☐ Internal permanent employee ☑ Other public sector employee ☐ Priority placement employee ☐

Employment basis

Full-time ☑ Casual ☐ Other ☐ Please Specify

Part-time ☐ No. part-time hours/fortnight (hh:mm):

First Day Contact Name

First day contact phone number

Award/EBA name: Health Practitioner (Queensland Health) Certified Agreement (No.2) 2011

Staff Movement Details

Reason for vacancy: Relinquishment

Work Contract

Working arrangements		Shift arrangements		Recreation leave accrual		Reason for additional weeks leave	
19 day month (ADO accrual)	☐	Single shift only	☑	Four weeks / annum	☐	Working public holidays	☐
Standard hours (non ADO accrual	☑	Two shifts	☐	Five weeks / annum	☐	Continuous shift work	☐
Variable working hours	☐	Continuous shift work	☐	Six weeks / annum	☐	Working with radium (radiographers only)	☐
Nine day fortnight	☐	12 hour shift arrangement applies	☐				

Special conditions (e.g. RANIP Nurses, etc.). Please refer to the Payroll and Rostering Intranet Site (PARIS) for more information.

Work Schedule

Please indicate (✓) here if this employee works either: A cyclic roster (where the roster pattern repeats at regular intervals e.g. fortnightly / monthly) ☑ OR A non-cyclic roster (a roster pattern that varies from one cycle to the next) ☐

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Employee Reference

Person ID [redacted]

Personnel assignment number

Please complete the table below using 24 hour time format (e.g. 07:00 - 15:30) to advise the employee's roster for their initial two week period of employment.

Week one

Day	Start time (hh:mm)	End time (hh:mm)	Meal break* Start time (hh:mm)	Meal break* End time (hh:mm)	Total daily hours
Monday	08:00	16:06	12:00	12:30	07:36
Tuesday	08:00	16:06	12:00	12:30	07:36
Wednesday	08:00	16:06	12:00	12:30	07:36
Thursday	08:00	16:06	12:00	12:30	07:36
Friday	08:00	16:06	12:00	12:30	07:36
Saturday					
Sunday					
				Total weekly hours	38

Week two

Day	Start time (hh:mm)	End time (hh:mm)	Meal break* Start time (hh:mm)	Meal break* End time (hh:mm)	Total daily hours
Monday	08:00	16:06	12:00	12:30	07:36
Tuesday	08:00	16:06	12:00	12:30	07:36
Wednesday	08:00	16:06	12:00	12:30	07:36
Thursday	08:00	16:06	12:00	12:30	07:36
Friday	08:00	16:06	12:00	12:30	07:36
Saturday					
Sunday					
				Total weekly hours	38

*Where a paid meal break applies, please insert N/A for meal break start and end times.

Pre-Employment Checks

Criminal History Check completed* (Please attach a copy of email confirmation) ☑

If Criminal History Check not required, please insert reason below

*In accordance with Queensland Health Criminal Checking policy, no offer of employment can be made until completion of a relevant criminal history check (refer Queensland Health policy IRM 3.12-1 for exclusions)

Blue Card (if applicable) ☐ Status Expiry date

Other (if applicable) ☐ Please specify Status

Qualification Payments

Does the employee possess any approved qualifications that will entitle them to additional payment(e.g. relevant AQF qualifications) under Queensland Health policy?

No ☐ Yes ☐ If yes, please provide details here:

Supervisor Certification

I certify that I have:

- (where the employee has been appointed to a position from another work unit) successfully negotiated the release date with the line manager of the employee's substantive position
- informed this employee of any changes to their FBT Concession Eligibility status as a consequence of this variation to their employment contract
- discussed with this employee the consequences of this change to their position, employment status, terms of employment and/or roster, and
- informed the employee where this change applies to a temporary employee moving between temporary assignments, of any impact (i.e. the ending or likelihood of extension of their previous contract) as a consequence of accepting appointment to this proposed position.

Supervisor's signature | Date | Area code (07) | Contact number

Supervisor's full name (please print): **Refer to Delegate** | Supervisor's position title

Employee Certification

I accept the appointment to this position and confirm my acceptance of the change in terms of employment contained in this form.
Further, I certify that I have been:

- informed by my line manager of the consequences of any change to the FBT Concession Eligibility status that may result from this variation to my employment contract, and
- made aware of the consequences of this change to my position, employment status, terms of employment and/or roster. I also acknowledge that where the proposed position is of a temporary nature, the contract may be ended by my line manager with two weeks' notice.

Em [redacted] Date 09/03/12

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Queensland Government

Employee Movement Form - Permanent

Employee Details

Person ID [redacted]

Personnel assignment number

Delegate Approval

I, the authorised Delegate for Appointments, approve:
- any increase above the position's AFT as a consequence of this appointment, and
- the above appointment subject to the receipt of acceptable criminal history report (where necessary) in accordance with Section 67 of the Public Service Act 2008 / Section 24 of the Health Services Act 1991 [delete whichever is not applicable].

Delegate's signature [redacted]

Date 4/3/12

Area code (07)

Contact number [redacted]

Delegate's full name (please print): **Greg Shaw**

Delegate's position title: **Senior Director FSS**

Processing Area Use Only

Processor's signature | Date | Reviewer's signature | Date | Processed fortnight ending

CA-02

Curriculum Vitae
Cathie Allen

Telephone: [redacted]
Email: [redacted]

QUALIFICATIONS

Master of Science, Forensic Science
Graduated 2002
Awarded 'Academic Excellence' award for the year 2002
Griffith University, Brisbane

Master Of Science, Qualifying Year (Pass)
Graduated 1995
Department of Microbiology, University of Queensland
A survey of the Heat-Stable enterotoxin gene in *Vibrio* and related genera in the local aquatic environment.

Bachelor of Science (Microbiology Major)
Graduated 1994
University of Queensland
St Lucia, Brisbane, Queensland 4072

AWARDS

Personal: Academic Excellence - Master of Science degree
Laboratory: Silver Award and the Collaboration Award for the 2010 ACT Institute of Public Administration of Australia, Prime Minister's Excellence Awards; Best Practice in State Government Award for the 2010 Queensland Institute of Public Administration of Australia Public Sector Awards – jointly with the Queensland Police Service

Professional Development - Certificate IV in Project Management 2008, Expert Evidence Training, Leadership Effectiveness Program

EMPLOYMENT HISTORY

Managing Scientist – Police Services Stream
January 2013 – Present
Queensland Health Forensic & Scientific Services
39 Kessels Road, Coopers Plains Q 4108

- Provide strategic management across a large Forensic DNA Analysis and Forensic Chemistry service (approx. 110 staff members), which provides a state-wide service.
- Provide leadership and mentoring to the Forensic DNA Analysis and Forensic Chemistry teams
- Ensure appropriate training and resource levels within the teams and co-ordinate the use of resources according to dynamic workloads
- Present Police Services Stream reports to the Forensic and Scientific Services leadership team and the Executive Director

- Manage key relationships with internal and external stakeholders to improve delivery of high-quality forensic biology and chemistry services
- Ensure the overall quality of the work and results produced within both forensic teams meets the certification and accreditation requirements
- Chair the Forensic DNA Analysis team meeting, Forensic DNA Analysis Management Team meeting and other meetings as appropriate
- Support, initiate and develop priority projects and their leaders
- Foster and develop a culture and infrastructure to ensure continuous improvement
- Represent the laboratory within the forensic science industry
- Manage the performance appraisal and development of staff
- Manage the Forensic DNA Analysis and Forensic Chemistry contribution to the Memorandum of Understanding with the Queensland Police Service
- Oversee the Forensic DNA Analysis and Forensic Chemistry budget and staff resources

Role of Managing Scientist – DNA Analysis Unit
July 2008 – January 2013
DNA Analysis Unit

- Provide strategic management across a large forensic DNA Analysis service (75 staff members), which provides a state-wide service.
- Provide leadership and mentoring to the DNA Analysis team
- Ensure appropriate training and resource levels within the team and co-ordinate the use of resources according to dynamic workloads
- Present DNA Analysis progress reports to the Forensic and Scientific Services executive and the Senior Director
- Manage key relationships with internal and external stakeholders to improve delivery of high-quality forensic biology services
- Ensure the overall quality of the work and results produced within DNA Analysis exceeds the certification and accreditation requirements
- Chair the DNA Analysis team meeting, DNA Analysis Management Team meeting and other meetings as appropriate
- Support, initiate and develop priority projects and their leaders
- Managed and liaised with project staff on the 2008 $7.5mil Refurbishment Project, which was on time and on budget
- Foster and develop a culture and infrastructure to ensure continuous improvement
- Represent the laboratory within the Forensic Science Industry
- Manage the performance appraisal and development of staff
- Manage the DNA Analysis contribution to the Memorandum of Understanding with the Queensland Police Service
- Maintain the DNA Analysis budget and staff resources

Team Leader – Volume Crime Team
July 2006 – July 2008
DNA Analysis Unit

- Supervise two Senior Scientists and twenty-three scientists within the team
- Provide direction and support for the Senior Scientists in the management of their sub-teams
- Prepare and present Volume Crime key performance indicators and issues to the Managing Scientist
- Monitor and manage performance

- Prepare Statement of Witness reports and provide expert testimony for all level in the Court System
- Peer Review Statement of Witness reports
- Supervise the maintenance and use of the National Criminal Investigation DNA Database, in line with legislative and client requirements
- Management results for ongoing cases for clients
- Interpret DNA profiles for client reporting
- Represent the Volume Crime Team at meetings with internal and external clients
- Liaison with Clients (who include Queensland Police Service, Judicial Officers, DNA Results management unit staff, Senior Forensic and Scientific Services staff)

Previous positions with the DNA Analysis Unit (formerly known as Forensic Biology)
Senior Scientist – Analytical Team within Volume Crime Team
July 2004 – July 2006
Queensland Health Scientific Services (name changed to Queensland Health Forensic & Scientific Services)

To effectively manage the resources of the Analytical team while providing a quality client focused forensic biology service. To provide expert advice to the Team Leader and Managing Scientist on matters pertaining to the output of the laboratory. To implement innovation and support the changing environment of Forensic Sciences.

- Provide resources necessary for smooth day-to-day running of the Analytical team
- Identify bottlenecks and provide solutions, technology and support to overcome any issues and continue to improve our service
- Provide training, professional development and support for new staff members in all areas of Forensic biology
- Provide expert advice to staff, managers and clients
- Address Opportunities for Quality Improvement, implement any changes required to Standard Operating Procedures and provide training where necessary

Casework Scientist
August 2002 – July 2004

The role of a Forensic Scientist is to provide impartial and independent service to clients which include: the Queensland Community, Queensland Police Service, Department of Public Prosecutions, the tiers of Judicial System, the Coroner and other industry organisations.

- Perform a wide variety of analyses and case examinations to satisfy the clients' requirements for timeliness and quality
- Issue statements of analysis and be responsible for the matters contained therein.
- Attend to the completion of all administrative details in relation to analysis and reporting within a timely manner
- Attend courts of law in Queensland (and other states as necessary) as required, and provide expert testimony on work performed personally and by others in the laboratory and other matters
- Advise and assist the work unit supervisor and other colleagues within the section as required
- Provide scientific knowledge and expertise in the appraisal of exhibits for receival

Laboratory Technician

August 1999 – August 2002

To participate in the provision of analytical, advisory and expert evidence services by Queensland Health Scientific Services to its clients. To ensure Quality Assurance is maintained to the appropriate standards to fulfill NATA requirements.

Techniques Used:

- DNA Extraction using Chelex
- DNA Quantitation using either ACES or Quantiblot
- DNA Amplification
- Use of the ABI 377 Genescan and related software
- Receival of exhibits
- Intelligence Database casework

Research Assistant
October, 1998 – August, 1999
Sir Albert Sakzewski Virus Research Centre
Royal Childrens' Hospital, Herston, Queensland, 4006

Experimental Scientist/Microbiologist
December 1997 – October, 1998
Food Science Australia
(Joint Venture of Afisc and CSIRO)
Cannon Hill, Brisbane, Queensland, 4170

Research Assistant
December 1996 – December 1997
Molecular Virology Laboratory
Department of Microbiology, University of Queensland
St Lucia, Brisbane, Queensland, 4072

Microbiologist
July 1995 – November 1996
Inghams Enterprises, Quality Assurance Laboratory
Springwood, Brisbane, Queensland, 4127

Managing Scientist - Police Services Stream Duty Statement

1 Purpose

The purpose of this duty statement is to describe the role of the Managing Scientist with Police Services Stream, Forensic and Scientific Services Leadership Team.

2 Scope

This duty statement shall apply to Police Services Stream.

3 Definitions

Nil

4 Actions

The Managing Scientist - Police Services Stream is responsible for providing leadership, management and innovation in Forensic Chemistry and Forensic DNA Analysis, including the implementation of strategic and operational planning, monitoring, evaluating, and reporting systems.

The role is accountable for establishing and maintaining effective working relationships with all relevant government and non-government agencies to provide a quality, client focused Forensic Chemistry and Forensic DNA Analysis service. This role actively pursues quality, innovation, integration, and standardisation in efficient service delivery whilst promoting the values and interests of FSS.

The Managing Scientist - Police Services Stream leads and inspires a multidisciplinary team, establishes management and reporting systems, provides strategic advice on a state, national and international level, manages key relationships, ensures compliance to international standards, and provides ethical decision making in the achievement of organisational goals.

Strategic Direction:

- Provide high level leadership and strategic management across a large forensic DNA Analysis service and a forensic Chemistry service, both of which provide a State-wide service.
- Contribute to strategic level management processes, applying high level clinical knowledge to challenge existing protocols and advocating authoritatively for the forensic DNA Analysis and forensic chemistry services on a State-wide basis in the development of new policy.

- Participate and advocate for the forensic DNA analysis and forensic chemistry services in setting State-wide and National standards of performance, safety, and inter-departmental coordination.
- Participate in establishing broad criteria for the development of professional standards, education or research in the forensic DNA analysis and forensic chemistry services on a State-wide and National basis through membership on national advisory bodies.

Leadership / Work Unit Management

- Accountable for all aspects of operational management and development of people and facilities within Forensic DNA Analysis and Forensic Chemistry, including;
- Developing and implementing strategic direction
- Facilitating staff development, performance appraisal and other general people management issues
- Accountable for the administration, direction and control of the asset management and financial management of multiple cost centres.
- Responsible for solving large scale complex forensic service or work-flow problems through recognised expertise, high level interpretation of existing forensic service delivery systems, professional standards and other pertinent external considerations.

Communication / Team Participation

- Provide authoritative counsel to advise and inform strategic level management processes across forensic services operating within a State-wide service.
- Accountable for the effects of all policy generated from within the position's jurisdiction and provide associated professional counsel to relevant stakeholders.
- Utilise high level negotiation and conflict management skills to advocate with stakeholders in securing resources or other outcomes for Forensic DNA Analysis and Forensic Chemistry, Forensic and Scientific Services.

5 Records

Nil

6 Associated Documentation

Nil

7 References

Nil

8 Amendment History

Revision	Date	Author/s	Amendments
1	17 Oct 2006	R Smith	First Issue
2	14 Nov 2007	T Nurthen	No Information
3	9 December 2008	J Howes	No Information

4	5 Aug 2013	C Allen	Changed from CaSS to HSSA, moved document to Managing Scientist for update responsibility
5	6 Jan 2015	C Allen	Updated with new HSQ template and added responsibilities associated with Forensic Chemistry
6	18 Jan 2021	C Allen	Updated with new template.
7	28 Feb 2022	C Allen	Updated with new template, added more description into Section 4 to be consistent with the FSS Governance document (20033).

9 Appendices

Nil

Queensland Government

CA-04

Clinical and Statewide Services Division
Role Description

Job ad reference:	[redacted]
Role title:	Managing Scientist
Status: (Permanent/Temporary) (Full-time/ Part-Time) (Casual)	Permanent Full Time
Unit/Branch:	DNA Analysis Unit
Division/District:	Forensic and Scientific Services Clinical and Statewide Services Division
Location:	Coopers Plains
Classification level:	HP7
Salary level:	$4936.30 per fortnight, $128,785 per annum
Closing date:	12 September 2011
Contact:	Greg Shaw
Telephone:	[redacted]
Online applications:	www.health.qld.gov.au/workforus or www.smartjobs.qld.gov.au
Fax application:	[redacted]
Post application:	Recruitment Services - Corporate & Statewide, Locked Mail Bag [redacted]
Deliver application:	

About our organisation

Queensland Health's mission is 'creating dependable health care and better health for all Queenslanders'. Within the context of this organisation, there are **four core values** that guide our behaviour:

- **Caring for People:** Demonstrating commitment and consideration for people in the way we work.
- **Leadership:** We all have a role to play in leadership by communicating a vision, taking responsibility and building trust among colleagues. Queensland Health applies the National Health Service (NHS) Leadership Qualities Framework.
- **Respect:** Showing due regard for the feelings and rights of others.
- **Integrity:** Using official positions and power properly.

Purpose

- Provide effective high level leadership, management, strategic direction and advocacy in the management of the DNA Analysis unit, Forensic and Scientific Services.
- Provide authoritative and strategic forensic biological and analytical counsel to Queensland Health and key stakeholders ensuring expert knowledge remains current and includes the latest developments.
- Establish and maintain effective working relationships with all relevant government and non-government agencies, both intra-jurisdictional and inter-jurisdictional, to provide a quality client focused forensic biology service, through agreed mechanisms.
- To investigate innovation in the field and support the changing environment of Forensic Services, while promoting the values and interests of Queensland Health Forensic and

Scientific Services.

Your key responsibilities

- Fulfil the responsibilities of this role in accordance with Queensland Health's core values, as outlined above.
- Provide strategic direction and advice on a state, national and international level on issues associated with forensic DNA Analysis training, development, direction, needs, client interfaces, risk management, business development and also on the coordination of forensic DNA Analysis services provided to the Queensland Police Service and the Department of Justice and Attorney Generals.
- Contribute to strategic level management processes, applying high level knowledge to challenge existing protocols and advocating authoritatively for forensic DNA Analysis services in the development of new policy.
- Participate and proactively advocate for the forensic DNA analysis services in setting state and national standards of performance, safety and inter-departmental coordination, through membership on national advisory bodies.
- Monitor and influence the development of relevant legislation that may impact on forensic DNA analysis services, both in Queensland and Nationally.
- Accountable for all aspects of operational management and development of people and facilities within the DNA Analysis unit, including, but not limited to:
    - Ethical decision making in the achievement of organisational goals
    - Direction and control of the asset management and financial management of one or more cost centres
    - Effects of all policy generated from within Queensland and provide associated professional counsel to relevant stakeholders
    - Facilitate staff development, performance appraisal and associated human resource management
- Responsible for solving complex forensic service or work-flow problems through recognised expertise, high level interpretation of existing forensic service delivery systems, professional standards, established change management procedures and other pertinent external considerations.
- Utilise high level negotiation and conflict management skills to advocate with staff and stakeholders in securing resources, resolving issues or other outcomes for the DNA Analysis unit.

Qualifications/Professional registration/Other requirements

- The successful applicant must hold a tertiary qualification, or equivalent, in science from a recognised university or tertiary institution.
- In some circumstances and following consultation, Queensland Health staff may be required to participate in 24 hour shift, on-call or weekend roster arrangements.

Are you the right person for the job?

You will be assessed on your ability to demonstrate the following key attributes. Within the context of the responsibilities described above, the ideal applicant will be someone who can demonstrate the following:

- Demonstrated expert understanding and knowledge of complex forensic DNA analysis services and the factors which are critical to effective service delivery at an organisational, state and national level.
- Demonstrated competence to provide leadership and conceptual, analytical and innovative management skills to implement, support and manage organisational change within a service delivery organisation, involving diverse work units.
- Demonstrated competence in liaising with business clients and stakeholders within and outside the organisation, together with a demonstrated high level of oral and written communication

skills associated with the provision of high level briefings and advice
- Demonstrated ability to supervise and manage staff in line with quality human resource management practices including employment equity, anti-discrimination, workplace health and safety, and ethical behaviour and demonstrated commitment to their implementation.

How to apply

Please provide the following information to the panel to assess your suitability:

- **Your current CV or resume, including referees**. Applicants must seek approval prior to nominating a person as a referee. Referees should have a thorough knowledge of your work performance and conduct, and it is preferable to include your current/immediate past supervisor. By providing the names and contact details of your referee/s you consent for these people to be contacted by the selection panel. Please note: your referees may be contacted at any time during the recruitment process. If you do not wish for a referee to be contacted, please indicate this on your resume and contact the selection panel chair to discuss.

- **A short statement (maximum 1–2 pages)** on how your experience, abilities, knowledge and personal qualities are relevant for the role, taking into account the key responsibilities and attributes noted in the 'Are you the right person for the job?' section.

About the Clinical and Statewide Services Division

Working in Clinical and Statewide Services (CaSS) is an opportunity to creatively and productively contribute to improving the provision of health services to the people of Queensland. CaSS is a learning organisation, committed to developing our people through training, support and leadership programs. We offer challenging opportunities to allow you to explore your potential. CaSS promotes a healthy balance between your work and personal life, provides flexible work hours, paid parental leave and study leave options.

We look forward to working with you!

CaSS is a division of Queensland Health that aims to deliver safe, sustainable and appropriate services to enhance health care throughout Queensland. It provides these services through

- Pathology Queensland
- Medication Services Queensland
- Statewide Health Services
- Radiology Support
- Forensic and Scientific Services
- Biomedical Technology Services
- Queensland Blood Management Programme

http://www.health.qld.gov.au/qhcss/

Pre-employment screening

Pre-employment screening, including criminal history and discipline history checks, may be undertaken on persons recommended for employment. The recommended applicant will be required to disclose any serious disciplinary action taken against them in public sector employment.

Roles providing health, counselling and support services mainly to children will require a Blue Card. Please refer to the Information Package for Applicants for details of employment screening and other employment requirements.

Disclosure of Previous Employment as a Lobbyist

Applicants will be required to give a statement of their employment as a lobbyist within one (1) month of taking up the appointment. Details are available at
http://www.psc.qld.gov.au/library/document/policy/lobbyist-disclosure-policy.pdf

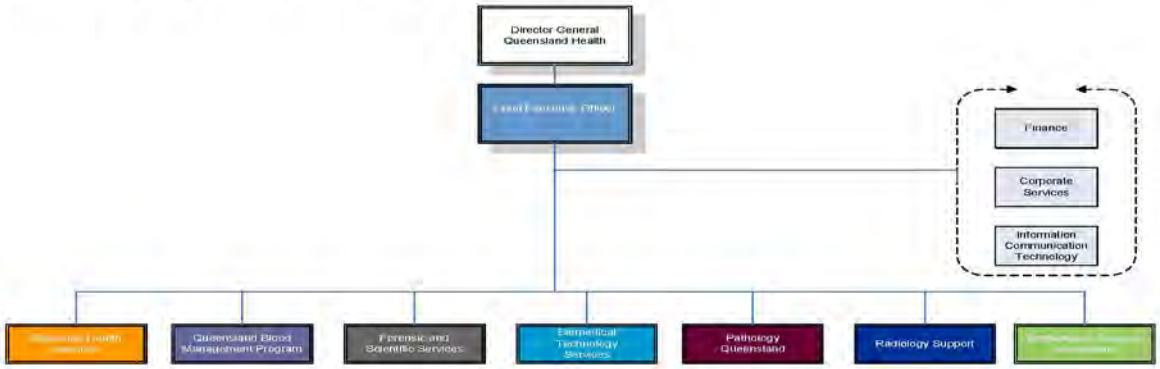
Probation

Employees who are permanently appointed to Queensland Health may be required to undertake

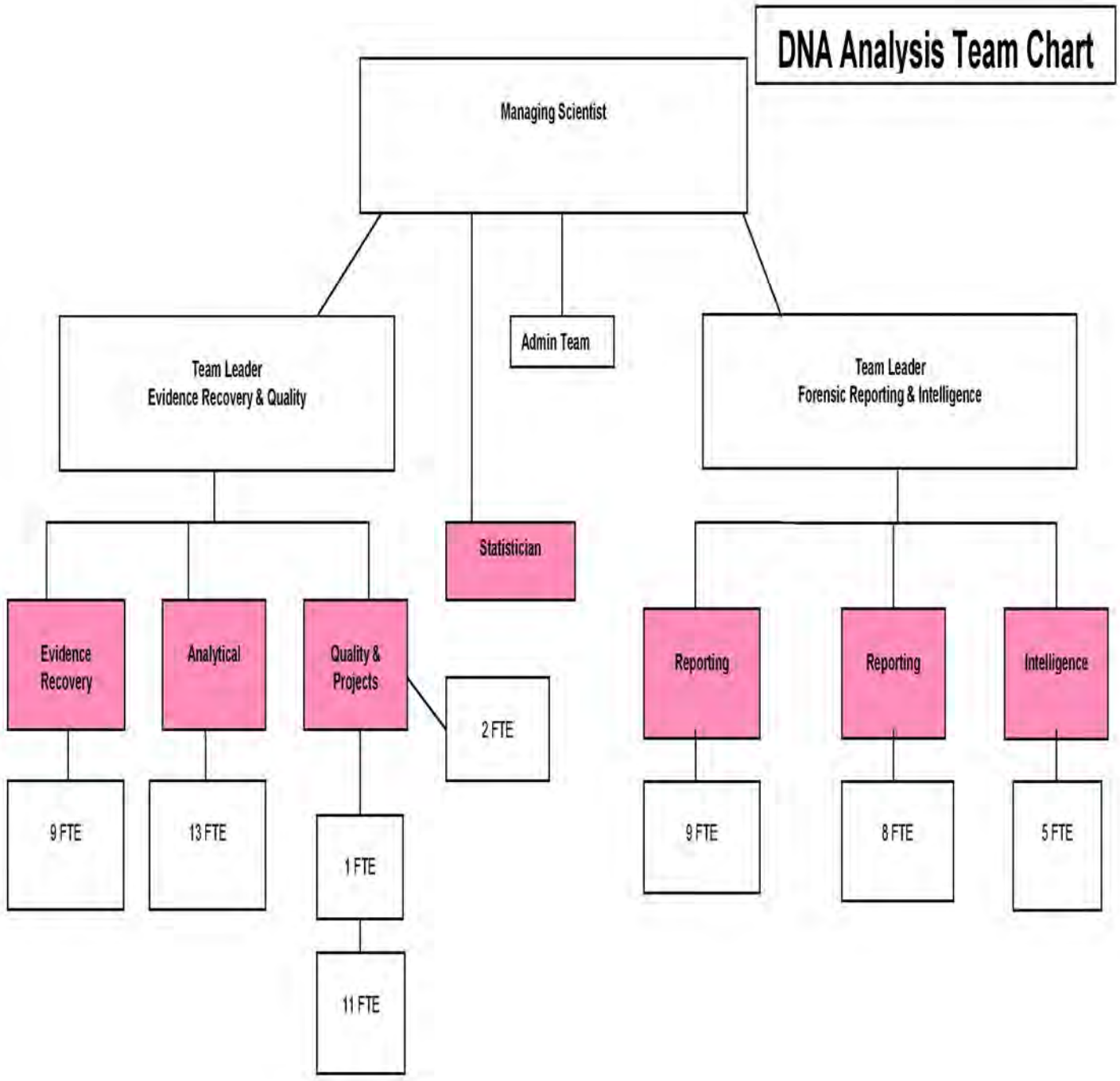
a period of probation appropriate to the appointment. For further information, refer to Probation HR Policy B2 http://www.health.qld.gov.au/hrpolicies/resourcing/b_2.pdf

Organisational chart

Clinical and Statewide Services Division



March 2010


DNA Analysis Team Chart
Managing Scientist
Team Leader
Evidence Recovery & Quality
Admin Team
Team Leader
Forensic Reporting & Intelligence
Statistician
Evidence Recovery
Analytical
Quality & Projects
2 FTE
Reporting
Reporting
Intelligence
9 FTE
13 FTE
1 FTE
11 FTE
9 FTE
8 FTE
5 FTE

CA-05

Queensland Health

Business case for change

Department of Health – 8 August 2022 release

About this document

This document is a new business case for change and has been informed by previous business case documents released since May 2022. This document takes into consideration evidence-based feedback provided throughout the previous business case documents.

This new business case for change document proposes an organisational structure that supports a progressive and collaborative health system manager that responds to challenges and opportunities into the future. This document outlines all of the proposed structural changes and supporting rationale to provide employees the opportunity to have a voice in shaping the future of the department.

Document sections:

Business case document:

- Pages 1 – 6 outline the background, about this document, vision for change, principles, rationale for change and benefits.
- Pages 7 – 33 include the summary of proposed realignments by division for section one with the proposed change and the supporting rationale that outlines the reasons or basis for the proposed change.
- Pages 34 – 35 provide an overview of the proposed new divisions that will be created and provide context for the boards of management function and membership.
- Pages 36 – 55 section two defines consolidation and integration of corporate support functions including the consultation process that has been undertaken, the proposed functional model, human resource and finance branch rationale and alignment.
- Pages 56 – 60 articulate the proposed options, recommendation for this business case, instructions on how to provide feedback and where people can seek assistance through this change process.

Attachments:

- Attachment 1 – video transcripts of the DG videos on the vision for change and the principles outlined in this document.
- Attachment 2 – current and proposed future organisational charts including consolidation and integration of corporate support functions
- Attachment 3 – outlines a list of impacted positions by division, branch, unit and position and what the proposed impact is.

How to read this document:

The document is structured in two sections, the first section outlines the business case for change proposal for the overarching organisational structure. The second section of the document outlines corporate support functions consolidation and integration.

It is important to note that the proposed organisational structure changes are outlined at a divisional, branch, unit or positional level. If a branch is proposed to be realigned, it is assumed that all positions reporting to the most senior position are moving unless otherwise stated. For example, if a branch or unit is proposed to be split and realigned to different divisions, proposed changes are outlined at a positional level.

To understand the proposed changes, please refer to the relevant division which outlines the proposed changes for that division. Please also refer to the impacted positions by division table that outlines the proposed changes at a positional level.

Background

The Department of Health has learned many lessons responding to the COVID-19 pandemic and the potential that was unleashed in responding to such high-evolving circumstances. Phase one of an organisational change process commenced in March 2021 to review the department's structure to ensure it was aligned to the health system needs now and into the future.

In November 2021 the Executive Leadership Team (ELT) decided to take more time to consider the proposal for the future of the department before proceeding with the phase two business case document. The Acting Director-General (A/DG) commenced phase two of the business case for change in May 2022. Since May 2022, extensive consultation and engagement activities have occurred across the department—enabling our employees, union partners and other stakeholders to participate in, and engage with, this change process.

On 20 July 2022, Together Queensland and the department attended the Queensland Industrial Relations Commission (QIRC). There were a series of recommendations made by Commissioner McLennan for the department to consider. One such recommendation was for the department to replace the decision document released on 5 July 2022, with a new business case for change document– this is that document.

Vision for change

The department needs to lead and build sustainability for the change and challenges we are going to have inside our health system going forward. Through the COVID-19 pandemic we have demonstrated that we can rapidly respond to a challenging and changing environment. It is critical that the department continues to be responsive, and has a structure that supports the vision:

"To be a cohesive health system manager that supports the delivery of high-quality and compassionate healthcare to Queenslanders. To continue to be good stewards of health system resources by focusing on improving service delivery so that we can maintain and build confidence in the community".

Click on the above video to listen to the vision. Transcript is available in Attachment 1.

Principles

To align with the vision for change, there are five principles guiding the proposed changes, including how the department is structured and how employees operate and behave in the system in the future:

5. Effective health capital management

Enhance the speed for delivery and the effectiveness of capital infrastructure projects to align with clinical service planning and commissioning

1. Functions working collaboratively, not in competition

The creation of well-structured functions that allow for 'source of truth information' to be used consistently across departments

4. 'Clinical service need' versus 'clinical service support'

Working collectively as a network rather than as different components for the HHSs to ensure we are collaboratively providing the clinical service support in the most effective way

2. Accountability in the right place

This is about ensuring that there is separation between the area that plans for the clinical service from the area that then commissions or funds activity

3. Strong strategy and policy

The separation of responsibility for doing public policy of health (not public health policy) for Queensland. We aim to be leaders in policy and strategy at a State and Commonwealth level

Click on the above video to listen to the principles for change. Transcript is available in Attachment 1.

Rationale for change

Over the past decade, the department has navigated constant change in how it, as the system manager, has been structured to deliver outcomes—from a centralised model to one that devolved accountabilities and responsibilities to local hospitals and health services. Moreover, balancing financial sustainability and health outcomes has become the focus in recent years, exacerbated by the challenges created through the COVID-19 pandemic. Today, co-contributing social, economic and environmental factors are propelling us towards an unsustainable health system.

We have a unique opportunity to continue the good work that we saw when we came together as a united, collaborative and connected health system during the COVID-19 pandemic. The proposed organisational structure outlined in this new business case for change is responsive to our future challenges and increasing pressures on the health system. Queensland Health, along with Government and industry partners, have supported multiple programs, reviews and investment aimed at shifting the way services are delivered to meet sustainability challenges.

Now is the time to consolidate and prioritise these outcomes, to focus on the strategic thinking that all learning organisations must do, and to plan for a future of delivering more sustainable and enhanced patient care. For example the 15-year health capital program will deliver more beds and services to Queenslanders. This is not only about increasing bed capacity within our hospital and health services, this is also about how we obtain and build a sustainable workforce, how we align our workforce to deliver care safely, in the right place, at the right time. We know that increasing beds does not only impact on our clinical frontline workforce, it also requires additional workforce for clinical and non-clinical support functions.

We need to consider and confirm contemporary models of care for the system by reimagining the traditional care models and understand the role of alternate care models to support both in-hospital and out-of-hospital care. As a system we need to define and implement the key enablers that create an environment for a change across the system by focusing on strategy, policy, planning, funding ICT, capital, culture, and relationships for the future.

This business case is about functional design. The focus in this document is to ensure that we are aligning our functions and people in a way that supports a progressive and collaborative health system manager into the future and addresses some of the known challenges (stated above) we currently experience. We require the right structure, with the right people, in the right roles doing the right things. From a functional design perspective our department faces challenges which manifests in:

- duplication of effort and/or inconsistencies, which leads to an inefficient system manager
- decentralised functions, contributing to a lack of coordination across the department, which could be improved by centralisation
- limited availability and strategic use of rich information to support transparency and real-time decision making
- delayed decision making due to process inefficiency and layered governance structures.

To achieve the vision for change and by applying the five principles outlined above, various functions across the department are proposed to be realigned, integrated and consolidated to ensure we grow functional capability, are consistent in how we deliver functions and continue to strengthen our capacity as a system.

More detailed rationale has been provided for each of the proposed division in the sections below.

Benefits

The proposed structure (found in attachment 2 - organisational charts) has been designed by applying the five principles above, to provide benefits for employees and the whole system, including:

- **Fostering functional collaboration; reducing silos and isolation by placing complementary functions together.** This will result in increased integration between teams and functions, with employees and the organisation able to realise the benefits of working together—avoiding duplication of effort, freeing up resources to go towards other priority activities, maximising access to specialised resources (e.g. bringing systems into eHQ) and removing competition for these scarce resources.
- **Ensuring reliable information is readily available from a 'single source of truth'**. Ensuring consistent data increases trust and confidence in Queensland Health and the integrity of the information that is made available.
- **Providing greater support and development opportunities** for employees by consolidating and joining functions creating, ultimately making these functions more resilient and sustainable.
- **Bringing confidence into decision making by making accountabilities** more independent of one another and mitigating potential conflicts of interest (e.g. separating of health system planning and funding functions to deliver capital infrastructure projects).
- **Creating system collaboration** and increasing input from frontlines services in investment decisions by introducing of boards of management—ensuring services are delivered in the right place, at the right time, with the right resources.
- **Better participation and strengthened partnership** at the national, state and other government agency-levels by establishing a dedicated division for policy development and system strategy.
- **Removing duplication and waste** overall, supporting more efficient operations and financial sustainability.

Section One

Summary of proposed realignments

Healthcare Purchasing and System Performance Division (HPSP)

Proposed change	Rationale
The Deputy Director-General (DDG) HPSP position is proposed to continue to report to the Chief Operating Officer.	The service provider functions of the department including HPSP, Queensland Ambulance Service (QAS) and the Integrated Scientific and Clinical Prevention Services Division (ISCPSD) will be led by the Chief Operating Officer (COO). The alignment of these functions under the COO will bring the service provider components together to collaborate and function as a network to deliver on community and health system needs.
Funding Strategy and Intergovernmental Policy Branch is proposed to be realigned to the Strategy, Policy and Reform (SPR) Division.	The Funding Strategy and Intergovernmental Policy Branch provides advice on emerging and priority state-wide health service, system and clinical policy issues. The Branch coordinates Queensland Health's contribution to a range of intra-governmental and intergovernmental policy priorities and represents the Department's interests in relevant policy forums which is directly aligned to the remit of SPR. The division leads, directs and coordinates activities to support and assist the health system to deliver safe, responsive, quality health services for Queenslanders. It is also responsible for the interaction of policy and strategy at both the State and Commonwealth Government levels.
System Planning Branch is proposed to be realigned to the new Clinical Planning and Service Strategy (CPSS) Division.	CPSS is a proposed new division bringing together clinical, workforce and mental health planning functions to improve health services available to the Queensland community. Therefore, the functions of the System Planning Branch align with the remit of this new Division, having better functional alignment with CPSS.
Office of Rural and Remote Health is proposed to be realigned to Clinical Excellence Queensland (CEQ).	The Office of Rural and Remote Health is established to provide a focus on supporting statewide policy, strategy and planning for rural and remote health services and work closely with the other clinical streams within CEQ in the delivery of sustainable rural and remote health services.
Healthcare Analysis Team, from Healthcare Improvement Unit, CEQ, is proposed to be realigned to HPSP	The Healthcare Analysis Team is proposed to realign to HPSP to create a single source of data reporting within one division by bringing together information, reporting and analysis

Proposed change	Rationale
	functions. This will also strengthen access to data and information that informs decision-making.
Statistical Services Branch, CEQ, is proposed to be realigned to HPSP.	Statistical Services Branch collect, processes, analyses and disseminates statistics on the health of Queenslanders and their use of health services. Functional alignment within HPSP with other reporting similar reporting functions will create a single source of data reporting within one division. This will also strengthen access to data and information that informs decision-making.
Mental Health, Alcohol and Other Drugs Branch (MHAODB), CEQ is proposed to be realigned as per the following: • Strategy Planning and Partnerships Unit is proposed to be realigned to the new CPSS Division. It is proposed to be renamed to Mental Health, Alcohol and Other Drugs Strategy and Planning Branch • Clinical Systems Support team of the Clinical Systems Collections and Performance Unit is proposed to be realigned to eHQ • All remaining teams within the MHAODB are proposed to remain with CEQ.	• The Strategy Planning and Partnerships Unit undertakes system wide planning for MHAODB and is best aligned to support broader system wide clinical planning. • The proposed move to the Digital Health Branch will align the responsibility for the support functions of key clinical platforms to a single point of accountability. This will ensure clinically informed decision making and oversight provide clinical solutions are built safely, used safely and are used to improve safety across the system. • The remaining functions for MHAOD Branch are best aligned to CEQ
System Performance Reporting Branch is proposed to be re-established and will include the Healthcare Analysis Team from the Healthcare Improvement Unit (HIU) in CEQ. The branch is proposed to report to the DDG HPSP.	System Performance Branch prepares and publishes regular reports on the performance of the Queensland public health system, including safety and quality, effectiveness, efficiency and responsiveness of the health system to meet the needs of the people of Queensland. System Performance Reporting Branch is proposed to be re-established to create a single source of data reporting within one division by bringing together information, reporting and analysis functions. This will also strengthen access to data and information that informs decision-making.

Clinical Excellence Queensland (CEQ)

Proposed change	Rationale
The Assistant DDG and Chief Clinical Information Officer (CCIO) position is proposed to be repurposed to a fulltime CCIO position and is proposed to be integrated with the ED Digital Health position in eHealth Queensland and report to the DDG eHQ.	The business case proposed all digital programs are housed in one division. The driver is to ensure that we have effective clinical oversight of delivery, use and adoption of enterprise clinical systems to improve patient safety and quality healthcare. To achieve this, digital health should be embedded in robust safety and quality frameworks, underpinned by strong clinical governance which will be provided by OCCIO to allow alignment between clinical innovation and digital transformation.
Patient Safety Quality and Improvement Service is proposed to be renamed Patient Safety and Quality.	This Patient Safety Quality and Improvement Service proposed renaming is based on branch feedback. The name change is to increase ease of use and is a return to the original name.
Allied Health Professions Office of Queensland is proposed to be renamed Office of the Chief Allied Health Officer	The Allied Health Profession Office of Queensland name change is to standardise the names of the professional offices within CEQ.
MHAODB is proposed to be realigned as per the following: • Strategy Planning and Partnerships Unit is proposed to be realigned to the new CPSS. It is proposed to be renamed Mental Health, Alcohol and Other Drugs Strategy and Planning Branch • Clinical Systems Support team is proposed to be realigned to eHQ • All remaining teams within the MHAODB are proposed to remain within CEQ.	• The Strategy Planning and Partnerships Unit undertakes system wide planning (amongst other functions) for MHAODB and is best aligned to the support broader system wide clinical planning • The proposed move to the Digital Health Branch will align the responsibility for the support functions of key clinical platforms to a single point of accountability. This will ensure clinically informed decision making and oversight provide clinical solutions are built safely, used safely, and are used to improve safety across the system • The remaining functions for MHAOD Branch are best aligned to CEQ.
HIU is proposed to be realigned as per the following: • Healthcare Analysis team is proposed to be realigned to HPSP • Health Systems team is proposed to be realigned to eHQ in the Digital Health Branch • CCIO and OCCIO to eHQ • Telehealth team from CEQ (HIU) and the Telehealth team from eHQ are proposed to be realigned with the Digital Health Branch in eHQ	• The Healthcare Analysis Team is proposed to realign to HPSP to create a single source of data reporting within in one division by bringing together information, reporting and analysis functions. This will also strengthen access to data and information that informs decision-making. • CCIO and OCCIO are proposed to realign to eHQ to ensure all digital programs are housed in one division. The driver is to ensure that we have effective clinical oversight of delivery, use and adoption of enterprise clinical systems to improve patient safety and quality healthcare. To achieve this, digital health should be

Proposed change	Rationale
• Clinical Excellence Engage team has been identified under section two of the business case consolidation and integration as a corporate support function and is proposed to be realigned Strategic Communications Branch • All remaining teams within the HIU are proposed to remain with CEQ.	embedded in robust safety and quality frameworks, underpinned by strong clinical governance which will be provided by OCCIO. To allow alignment between clinical innovation and digital transformation. • Telehealth is a clinical, front facing service which best aligns with the focus and functions of the proposed Digital Health Branch. The Digital Health Branch focus is on clinically led clinical solutions, ensuring they are built safely, used safely and are being used by staff to improve safety across the department and HHS ecosystem. The proposed branch will increase clinical capability and connection into eHQ and will play a key role ensuring eHQ decision making is clinically informed. • CEQ engage realignment is proposed to allow equity of access to CEQ and will be outlined in section 2 - consolidation and integration of this document.
Healthcare Improvement Fellowship Team has been proposed to be realigned to Clinical Planning and Service Strategy	The movement of Healthcare Improvement Fellowship Team is to ensure all leadership and improvement programs are co-located. This program will complement the existing suite of leadership and improvement courses already offered by CLE. It also aligns well with the focus of the CPSS Division to enable the cultivation of future generations of healthcare workers with innovation and implementation skills.
Statistical Services Branch is proposed to be realigned from CEQ to HPSP.	Statistical Services Branch collect, processes, analyses and disseminates statistics on the health of Queenslanders and their use of health services. Functional alignment within HPSP with other reporting similar reporting functions will create a single source of data reporting within one division. This will also strengthen access to data and information that informs decision-making.
Centre for Leadership Excellence is proposed to be realigned to CPSS and report to the Assistant DDG.	CPSS is a proposed new division bringing together clinical, workforce and mental health planning functions to improve health services available to the Queensland community. The key functions the Centre for Leadership Excellence provide will strengthen the portfolio offered in CPSS and will be critical to the ongoing development of the workforce across the health system. The Workforce Strategy Branch is also proposed to join the CPSS, bringing focus to one of our most significant challenges facing health service delivery – our workforce.

Proposed change	Rationale
Chief Medical Officer and Healthcare Regulation Branch is proposed to be realigned from the PD to CEQ (see PD table for detail) • Clinical Forensic Medicine Unit within Forensic and Scientific Services is proposed to be realigned with the Chief Medical Officer (See PD for detail) • Credentialing Committee is proposed to be realigned to the Chief Medical Officer (See PD for details) • Medical Advisory and Prevocational Accreditation Unit is proposed to realign to CPSS with the ADDG of Workforce Strategy • Medication Services Queensland is proposed to realign with the Healthcare Regulation Branch to Integrated Scientific, Clinical and Prevention Services Division (IPSCPSD) • All other units within Healthcare Regulation Branch are proposed to be realigned to ISCPSD	The Chief Medical Officer realignment is to bring all professional bodies within a single unit to increase collaboration and alignment. The Chief Medical Officer realignment is to bring all professional bodies within a single unit to increase collaboration and alignment.
OCCIO is proposed to be realigned to eHQ and report to the Executive Director of Digital Health / CCIO (See CEQ for detail).	The driver to realign OCCIO to eHQ is to ensure that there is effective clinical oversight of delivery, use and adoption of enterprise clinical systems to improve patient safety and quality healthcare. To achieve this, digital health should be embedded in robust safety and quality frameworks, underpinned by strong clinical governance which will be provided by OCCIO. In addition, this will provide alignment between clinical innovation and digital transformation.
The existing Manager Policy and Executive Support Correspondence Coordinator position is proposed to be evaluated and proposed to lead a newly created team. The team is proposed to be renamed Clinical Priority Oversight Team.	The Clinical Priority Oversight Team is proposed to be created and will be accountable for the implementation of clinical policy. For clarity, developing policy and legislation will be undertaken by the SPR and the implementation remit will sit with CEQ.

Queensland Ambulance Service (QAS)

Proposed change	Rationale
The Commissioner position is proposed to continue to functionally report to the Chief Operating Officer in the future state structure.	The service provider functions of the department including HPSP, QAS and Integrated Scientific and Clinical Prevention Services Division (ISCPSD) will be led by the COO. The alignment of these functions under the COO will bring the service provider components together to collaborate and function as a network to deliver on community and health system needs.
System Planning is proposed to be realigned to CPSS.	The proposed realignment of System Planning is to create a liaison point within CPSS. The business partnership arrangement will increase the coordination and collaboration between QAS and CPSS system planning and will provide a link to the tactical services within QAS.
Aeromedical and Retrieval Services and Disaster Management are proposed to be realigned as per the following: • Aeromedical and Retrieval Services is proposed to be realigned to QAS and proposed to be renamed Retrieval Services Queensland. • Disaster Management is proposed to be realigned to the Office of the COO. For the duration of the COVID-19 response, the Deputy Chief Health Officer Operations will remain reporting to the Chief Health Officer.	• QAS and Aeromedical Retrieval Services provide out of hospital coordination and logistics. The functions of these areas are heavily linked and provide a similar state-wide function. The realignment of Aeromedical Retrieval Services to QAS will provide the opportunity for increased collaboration and innovation that will benefit both Branches and the community for the future. • Disaster Management function focuses on business continuity and sustainability. The proposed realignment aims to strengthen the linkage with operations to create system responsiveness and business continuity. This function aligns with the COO role as the function includes areas outside the remit of the Chief Health Officer.

Prevention Division (PD)

Proposed change	Rationale
The DDG position is proposed to be abolished in the proposed future state structure.	The DDG role is proposed to be abolished as the PD is proposed to be abolished.
Aeromedical and Retrieval Services and Disaster Management are proposed to be realigned as per the following: • Aeromedical and Retrieval Services is proposed to be realigned to QAS and proposed to be renamed Retrieval Services Queensland. • Disaster Management is proposed to be realigned to the Office of the Chief Operating Officer. For the duration of the COVID-19 response, the Deputy Chief Health Officer Operations will remain reporting to the Chief Health Officer.	• QAS and Aeromedical Retrieval Services provide out of hospital coordination and logistics. The functions of these areas are heavily linked and provide a similar state-wide function. The realignment of Aeromedical Retrieval Services to QAS will provide the opportunity for increased collaboration and innovation that will benefit both Branches and the community for the future. • Disaster Management function focuses on business continuity and sustainability. The proposed realignment aims to strengthen the linkage with operations to create system responsiveness and business continuity. This function aligns with the COO role as the function includes areas outside the remit of the Chief Health Officer.
Area of Need function is proposed to be realigned to CPSS with no proposed position impacts.	The Area of Need function coordinates the declaration process that allows employers that are unable to fill vacant medical practitioner positions with suitably qualified Australian or New Zealand trained medical practitioners, to recruit international medical graduates (IMG). It also ensures that every attempt is made to fill vacancies with qualified Australian and New Zealand trained medical practitioners so they are not disadvantaged. CPSS is a proposed new division bringing together clinical, workforce and mental health planning functions to improve health services available to the Queensland community and the Area of Need function is closely aligned to planning workforce requirements.
The Chief Medical Officer and Healthcare Regulation Branch is proposed to be realigned as per the following: • The Chief Medical Officer is proposed to be realigned to CEQ • Medical Advisory and Prevocational Accreditation Unit is proposed to realign to CPSS and report to the ADDG of Workforce Strategy • Medication Services Queensland is proposed to realign with the Healthcare Regulation Branch to Integrated	• Based on the functions performed by the units within the Chief Medical Officer and Healthcare Regulation Branch, the proposed realignments will create better functional alignment. • The Chief Medical Officer realignment is to bring all professional bodies within a single unit to increase collaboration and alignment. • The Medical Advisory and Prevocational Accreditation Unit provides the necessary degree of separation and independence of Prevocational Accreditation from HHS

Proposed change	Rationale
Scientific, Clinical and Prevention Services Division (IPSCPSD). • All other units within Healthcare Regulation Branch are proposed to be realigned to ISCPSD	functions. This will best support the delivery of accreditation and quality assurance services, for prevocational training that are free from undue influence and minimise the risk of apprehended bias with satisfactory separation from service delivery with subsequent clear delineation of responsibilities and accountabilities. Additionally, such arrangement is likely to best satisfy the Australian Medical Council and AHPRA's requirements for independence of the accreditation functions. • Medications Services Queensland maintains a cohesive and consistent response to Medicines management at a systems level. Any separation of what is currently, a consolidated medicines function, creates risks in enabling a timely and comprehensive response to the growing amount of medicines-related policy matters. It is proposed that MSQ remain with HRB and that further work be done on exploring opportunities to enhance the existing collaboration between HRB and CEQ in the area of medicines.
Pathology Queensland and Forensic and Scientific Services is proposed to be realigned as per the following: • Pathology Queensland is proposed to be realigned with ISCPSD • Forensic and Scientific Services is proposed to be realigned with ISCPSD • Clinical Forensic Medicine Unit within Forensic and Scientific Services is proposed to be realigned with the Chief Medical Officer in CEQ.	• Pathology Queensland and Forensic and Scientific Services aligned with ISCPSD to integrate alongside other key scientific and clinical prevention health services and functions. • The realignment to the Chief Medical Officer will provide the Clinical Forensic Medicine Unit with strong clinical governance. The Clinical Forensic Medicine Unit provides clinical services here and now by working within health services and requires nursing and clinical governance. The patient service, patient care and the governance provided within CEQ will strengthen the unit's ability to work with the Chief Medical Officer and Chief Nursing Officer to manage the scale of work. The unit functions include dealing with complex scenarios and issues which will be supported by CEQ and the support framework.
Communicable Diseases Branch is proposed to be realigned with ISCPSD.	ISCPSD is proposed to bring together key system support functions in the surveillance, prevention, and control of communicable diseases in Queensland—leading the state-wide planning and coordination of programs and

Proposed change	Rationale
	services to prevent, or control, health-related diseases, and promote the overall wellbeing of Queenslanders.
Infection Prevention and Control Function is proposed to be realigned with Communicable Diseases Branch in ISCPSD.	Infection Prevention and Control is discharged at HHS level, with the department taking on a policy and whole of state role that aids the discharge at HHSs. This will be a network function with state-wide coordination and policy.
Health Protection Branch is proposed to be realigned with the ISCPSD.	The proposed realignment of the Health Protection Branch to ISCPSD will bring together key system support functions in the surveillance, prevention and control of communicable diseases in Queensland—leading the state-wide planning and coordination of programs and services to prevent, or control, health-related diseases, and promote the overall wellbeing of Queenslanders.
Office of Precision Medicine and Research is proposed to be realigned from PD to CPSS.	The realignment is proposed based on the functions performed by the Office of Precision Medicine and Research. These functions include the development and support of clinical models. The CPSS focus is to position Queensland Health for responsiveness to future needs and innovation. The focus for the Office of Precision Medicine and Research is how Queensland Health can improve for the future.
Preventive Health Branch is proposed to be realigned as per the following: • Preventive Health Branch is proposed to be realigned to Strategy, Policy and Reform Division • Cancer Screening Unit is to be realigned to ISCPSD and is to be renamed Cancer Screening Branch.	Preventive Health Branch provides expertise, leadership and innovation to improve policy, systems and programs related to disease prevention, population cancer screening and health promotion. Public health epidemiology, information system maintenance and public health data management are also key services. The proposed realignment of the Preventive Health Branch is to align the policy functions with the transformation and reform agenda within SPR and the functional elements of the Cancer Screening Unit and Public Health with the ISCPSD to integrate with similar system support functions.
Voluntary Assisted Dying Unit is proposed to be realigned to Strategy, Policy and Reform Division.	Voluntary Assisted Dying Unit is focused on the development of the policy which aligns with SPR until January 1 2023. Once the policy position for Voluntary Assisted Dying is developed and finalised, the policy will shift from development to implementation and the project will move to CEQ which focuses on the implementation of clinical policy.

Proposed change	Rationale
Quarantine Fee Waiver Branch is proposed to be realigned from PD to Finance Branch.	The Quarantine Fee Waiver Branch function is transactional finance activity which during the COVID-19 response hosted in PD. Due to the nature of fee recovery, this function is better aligned with the Finance Branch as we transition back to normal health service operations.
Credentialing Committee is proposed to be realigned to the Chief Medical Officer in CEQ.	The alignment of the Credentialing Committee function following the abolishment of PD is proposed to realign to the Chief Medical Officer to provide oversight.
Clinical Services Capability Framework Governance function is proposed to be realigned to CPSS within the System Planning Branch.	Previously overseen by the DDG PD which is proposed to be abolished, the CSCF committee brings nominated people together with a focus on strategic needs and governance including patient safety and quality. The alignment with System Planning Branch within CPSS is to provide a nominated lead to bring together the relevant areas.

Aboriginal and Torres Strait Islander Health Division

Proposed change	Rationale
The DDG Aboriginal and Torres Strait Islander Health Division position is proposed to be renamed to Chief First Nations Health Officer.	• This change in position title to the Chief First Nations Health Officer will be more consistent with other organisations, government agencies and First Nations leadership across Australia. • References to both 'Aboriginal and Torres Strait Islander' peoples and 'First Nations' references—noting that both Aboriginal peoples and Torres Strait Islander peoples are First Nations people in Queensland. • We recognise the importance that people can continue to use the terms 'Aboriginal and Torres Strait Islander' and 'First Nations' in our drive to equity. • Within the department and in-line with the principles of change for the business case, we will start to see more accountability located logically, with every division having greater responsibility for the delivery of improved First Nations health outcomes.
The Aboriginal and Torres Strait Islander Health Division is proposed to be renamed the Office of the Chief First Nations Health Officer.	This change in name, along with the renaming of the Chief First Nations Health Officer will be more consistent with other organisations, government agencies and First Nations leadership across the country. We will continue to appropriately use 'Aboriginal and Torres Strait Islander' references along with 'First Nations' references – noting that both Aboriginal peoples and Torres Strait Islander peoples are First Nations people in Queensland. We recognise the importance that people can continue to use the terms 'Aboriginal and Torres Strait Islander' and 'First Nations' in our drive to equity.
The proposed changes outlined below are to streamline reporting, accountability for individual roles: • The Correspondence Coordinator position is proposed to change reporting line to the Manager, Office of the Chief First Nations Health Officer • The Senior Project Officer position is proposed to change reporting line to the Manager Office of the Chief First Nations Health Officer • The Principal Policy and Planning Officer (Position Number 30492262) is proposed to change reporting line to the Manager, Cultural Reform (Position Number 32054934)	• The Correspondence Coordinator reporting line change is proposed to increase the support for the correspondence officer. The proposed change will streamline the function and accountability and support staff in the office. • The Senior Project Officer position is a temporary vacant role and will not continue. • The Principal Policy and Planning Officer reporting line change is to strengthen the capacity of cultural capability and to support the health equity reform agenda. The proposed change redistributes resource to support the division and organisation. • The Investment Team provides Making Tracks funding and supports the division. The

Proposed change	Rationale
• The Investment Team is proposed to move from the Strategy Branch to the Office of the Chief First Nations Health Officer • The Manager, Investment Team position is proposed to change reporting line to the Director, Office of the Chief First Nations Health Officer	proposed alignment aims to elevate the team and align with the division. This will provide an increase in collaboration and visibility of the team moving forward.

eHealth Queensland (eHQ)

Proposed change	Rationale
The DDG eHQ position is proposed to continue to report to the DG through an advisory board.	The position will continue to report to the DG through a Board of Management. Boards of management will seek to further embed networked governance in Queensland Health, with the Department and HHSs advancing cooperative partnerships and strive toward the achievement of collective system goals, and increased trust and reciprocity. The board of management will be accountable for the strategy, investment decisions, operational performance and reporting against key performance indicators. The boards will comprise representation from the Executive Leadership Team, HHSs and independent external expertise. There will be a strong emphasis on industry expertise across these boards of management to bring external perspectives in to inform how the system works.
The Assistant DDG and Chief Clinical Information Officer (CCIO) position is proposed to be repurposed to a fulltime CCIO position and is proposed to be integrated with the ED Digital Health position in eHealth Queensland and report to the DDG eHQ.	The business case proposed all digital programs are housed in one division. The driver is to ensure that we have effective clinical oversight of delivery, use and adoption of enterprise clinical systems to improve patient safety and quality healthcare. To achieve this, digital health should be embedded in robust safety and quality frameworks, underpinned by strong clinical governance which will be provided by OCCIO to allow alignment between clinical innovation and digital transformation.
The following Branches are proposed to be renamed to better demonstrate their proposed focus and functions: • Digital Strategy and Transformation Branch is proposed to be renamed Strategy, Architecture and Information Services Branch • Digital Solutions Delivery Branch is proposed to be renamed Delivery Services Branch • Technology Services Branch is proposed to be renamed Enterprise Technology Services Branch • Information and Technology Services Branch is proposed to be renamed Digital Health Branch • Corporate Services Branch is proposed to be renamed Operations and Performance Branch	• Strategy, Architecture and Information Services Branch will focus on ensuring consolidation of reporting functions across the division, ICT strategy and architecture and ensuring all data in the department is accurate, accessible and protected. • Delivery Services Branch will focus on ensuring delivery for all functions of eHQ is delivered from a single branch, introduces heightened responsibility for delivery impacts to customers with a single point of accountability. • Collocation of all management and support for enterprise technology services within a single branch, introduces heightened responsibility for enterprise service impacts with a single point of accountability. • Digital Health Branch will focus on clinically led clinical solutions, ensuring they are built safely, used safely and are being used by staff to improve safety across the

Proposed change	Rationale
	department and HHS ecosystem. The proposed branch will increase clinical capability and connection into eHQ and will play a key role in ensuring eHQ Decision making is clinically informed. • Operations and Performance Branch will focus on providing operational oversight of the division in terms of measuring the delivery of the strategic agenda, ensuring issues are addressed and that eHQ remains accountable to the board in terms of performance.
Digital Solutions Delivery Branch existing functions are proposed to be realigned to the Delivery Services Branch	Delivery Services Branch will focus on ensuring delivery for all functions of eHQ is delivered from a single branch, introduces heightened responsibility for delivery impacts to customers with a single point of accountability.
Digital Strategy and Transformation Branch existing functions are proposed to be realigned as per the following: • Digital Services Management is proposed to be realigned to Operations and Performance Branch • The Chief Information Officer Rural and Remote position is proposed to be realigned to the Enterprise Technology Services Branch • All remaining teams in the Digital Strategy and Transformation Branch are proposed to be realigned to Strategy, Architecture and Information Branch	• Improves the alignment between Digital Service Management, Commercial Strategy and Customer Value and Engagement to support the delivery of sustainable services. • Heightens the accountability of Enterprise Technology Services Branch in terms of its role to provide enterprise technology services to rural and remote Hospital and Health Services and enables the Rural and Remote CIO role to proactively working with the branch to ensure services are delivered safely and efficiently. • Remaining functions support the revised focus on the proposed branch.
Information and Technology Services (ITS) existing functions are proposed to be realigned as per the following: • ITS Delivery Office is proposed to be realigned to Delivery Services Branch • CISSU Service Desk team is proposed to be realigned to Enterprise Technology Services Branch • The Office of the General Manager Information Technology Services, including Governance, Risk and Assurance ITS, are proposed to be realigned across multiple branches (Operations and Performance Branch and Office of the DDG).	• Aligns with the focus on end-to-end accountability for delivery of the proposed Delivery Service Branch and ensure delivery is approached consistently across eHQ. • All support desk functions moving under Enterprise Technology Services Branch to provide alignment and consistency of incident management and business processes to best support the system. • Realignment based on consolidation of functional groups to improve consistency of service and create communities of practice to support the division. • Remaining functions support the revised focus on the proposed branch.

Proposed change	Rationale
• All remaining teams in Information and Technology Services are proposed to be realigned to the Digital Health Branch	
Technology Services Branch existing functions are proposed to be realigned as per the following: • ieMR Applications team is proposed to be realigned to the Digital Health Branch • Reporting Services, currently in DAS, is proposed to be realigned to Strategy and Architecture Branch • The RIVeR application support team, currently in DAS, is proposed to be realigned to Digital Health Branch • All remaining teams in the Technology Services Branch are proposed to be realigned to Enterprise Technology Services Branch	• The proposed move to the Digital Health Branch will align the responsibility for the support functions of key clinical platforms to a single point of accountability. This will ensure clinically informed decision making and oversight provide clinical solutions are built safely, used safely and are used to improve safety across the system. • Proposed move supports the consolidation of system data and information services within a single branch to provide heightened responsibility of these services and provide customers a single point of accountability. • The proposed move to the Digital Health Branch will align the responsibility for the support functions of key clinical platforms to a single point of accountability. This will ensure clinically informed decision making and oversight provide clinical solutions are built safely, used safely and are used to improve safety across the system. • Functions support the revised focus on the proposed branch and will support the technology transformation and digital modernisation agenda.
Customer Services Branch will be disbanded. The existing functions are proposed to be realigned as per the following: • Digital Partnerships team, including Customer Service FFS, is proposed to be realigned to Delivery Services Branch • Presentation and Printing team is proposed to be realigned to Enterprise Technology Services Branch • Service Management and Improvement team is proposed to be realigned to Enterprise Technology Services Branch • Digital Service Centre team is proposed to be realigned to Enterprise Technology Services Branch • Customer Value and Engagement team is proposed to be realigned to the Operations and Performance Branch • The Office of the Executive Director Customer Services is proposed to be	• Customer Service is a key accountability for all branches and all this change emphasises that all branches are responsible for being the voice of the customer. The proposed team movements are expected to introduce additional benefits. The key principle of collaboration across branches applies and teams that are currently which work closely together should continue to collaborate regardless of any changes. • This proposed change emphasises the role of the Digital Partnerships Teams in terms of knowing customers and as a key eHQ support team to deliver innovation into Hospital and Health Services and the move will provide opportunity for early engagement and involvement of DPTs to support the successful transition of projects from delivery to operations. • Provides a key enterprise service that will be best leveraged from within the proposed Enterprise Technology Services Branch.

Proposed change	Rationale
realigned to the revised functions within the Office of the DDG • The Executive Director Customer Services role is proposed to be abolished	• The proposed move recognises the key role Service Management and Improvement in providing a platform service as well as managing service improvement in relation to enterprise technology teams underpinning ICT towers and is best aligned to the focus of the proposed Enterprise Technology Services Branch. • All support desk functions moving under Enterprise Technology Services Branch to provide alignment and consistency of incident management and business processes to best support the system. • The team provides a key business relationship role ensuring underpinning account structure supports the whole division which best aligns with the focus of the proposed Operations and Performance Branch. • Recommended realignment to support consolidating eHQ's executive support functions to bring together a collective community of practice. • Abolishing this position aligns with overall reduction in the number of branches being proposed for eHQ.
Health Systems Branch, within Healthcare Improvement Unit, is proposed to be realigned from CEQ to eHQ within the Digital Health Branch (see CEQ table for detail)	The proposed move to the Digital Health Branch will align the responsibility for the support functions of key clinical platforms to a single point of accountability. This will ensure clinically informed decision making and oversight provide clinical solutions are built safely, used safely and are used to improve safety across the system.
Contractor Engagement Team, within Human Resources Branch, is proposed to be realigned from CSD to eHQ within the Operations and Performance Branch (see CSD table for detail)	This unit does not provide a general HR advisory function and provides a specific service to eHQ. The move under Phase 1 of the BC4C did not align with the intent and it is proposed to be returned to eHQ.
In addition to the above, all branches are proposed to have the following existing functions realigned as per the following: • Executive Director or General Manager support functions including all Branch/Business Managers, Senior Executive Support Officers and Business Support roles located in Executive Director or General Manager Offices will be centralised under the new unit	Consolidating eHQ's executive support functions to bring together a collective community of practice across the diverse division to provide improved professional support for teams so that they in turn can provide enhanced service to the teams that they support.

Proposed change	Rationale
'Executive Services and Governance' in the Office of the DDG	
MHAODB is proposed to be realigned as per the following (See CEQ for detail): • Clinical Systems Support team is proposed to be realigned to eHQ	The proposed move to the Digital Health Branch will align the responsibility for the support functions of key clinical platforms to a single point of accountability. This will ensure clinically informed decision making and oversight provide clinical solutions are built safely, used safely and are used to improve safety across the system.
Software Asset Management team is proposed to be realigned to eHQ (See CSD for detail)	Based on the functions performed by the Software Asset Management Team, the proposed realignment will create a better functional alignment.
OCCIO is proposed to be realigned to eHQ and report to the Executive Director of Digital Health / CCIO (See CEQ for detail).	OCCIO is proposed to realign to eHQ to ensure all digital programs are housed in one division. The driver is to ensure that we have effective clinical oversight of delivery, use and adoption of enterprise clinical systems to improve patient safety and quality healthcare. To achieve this, digital health should be embedded in robust safety and quality frameworks, underpinned by strong clinical governance which will be provided by OCCIO. To allow alignment between clinical innovation and digital transformation.
Telehealth team from CEQ (HIU) and the Telehealth team from eHQ are proposed to be realigned with the Digital Health Branch in eHQ (see CEQ for details).	Telehealth is a clinical front facing service which best aligns with the focus and functions of the proposed Digital Health Branch.
Office of the DDG, with existing functions, is proposed to remain with revised team names to reflect proposed branch structure Current ODDG function is proposed to be realigned to a newly established unit Executive Services and Governance Media and Communications is proposed to be renamed to Digital Performance Support	• Reflects increased focus supporting the broader division and representative of the new reporting lines, ensuring branch level support roles achieve better support, oversight and increased coordination across the division. • Renaming this unit emphasises proposed focus supporting project delivery and the delivery of performance support products to customers to support use and adoption of ICT systems.

Corporate Services Division (CSD)

Proposed change	Rationale
Corporate Facilities team within the previous Capital and Asset Services Branch is proposed to remain with CSD and report to the ODDG.	Corporate Facilities team provide corporate services (e.g. floor space) and does not align with the capital delivery functions in HCD. This proposed realignment is to ensure accountability and alignment with CSD.
Investment Assurance Committee team members within the previous Capital and Asset Services Branch is proposed to remain with CSD.	Investment Assurance Committee team provides assurance over capital projects. By remaining in CSD the team can maintain independence as part of the three arm infrastructure approach: Commissioning arm, Clinical needs assessment arm and Infrastructure delivery arm.
Workforce Strategy Branch is proposed to be realigned to the new CPSS and report to the ADDG Workforce Strategy.	The Workforce Strategy Branch is responsible for leading and developing key processes to support a sustainable and capable health workforce. This includes leading strategic workforce development, and identifying and developing opportunities for clinical enhancements, extended scope capabilities and clinical education and training. The branch links closely with HHSs, Clinical Chiefs and networks, professional boards and educators as well as the Commonwealth. CPSS is a proposed new division bringing together clinical, workforce and mental health planning functions to improve health services available to the Queensland community. The Workforce Strategy Branch will bring focus to one of our most significant challenges facing health service delivery – our workforce and ensure alignment with planning and service strategy functions.
Ethical Standards Unit within Human Resources Branch is proposed to be realigned to the Office of the DG (ODG) with a functional dotted reporting line to the Executive Director of the ODG.	The alignment to the DG and ODG is proposed to support the principal of separation and segregation of duties; and will also signal the confidentiality and seriousness of matters referred to the Ethical Standards Unit.
Contractor Engagement Team, within Human Resources Branch, is proposed to be realigned from CSD to eHQ within the Operations and Performance Branch.	The Contractor Engagement Team undertakes recruitment for ICT specialised contractor roles and the best fit for this team would be in the eHQ Contracts and Procurement team.
The interim COVID-19 Supply Chain Surety Division is proposed to be abolished and all branches within the interim division is proposed to be realigned to CSD (see CSCSD table for detail).	During the COVID-19 pandemic response phase, an interim division was established. As we transition back to normal health service operations this division is being abolished.
The Manager Carparking is proposed to be realigned to Finance Branch (see Health Capital Division (HCD) for detail).	Manager Carparking function includes policy setting position around state-wide carpark

Proposed change	Rationale
	tariffs and aligns to revenue within the Finance branch.
Asset Management and Purchasing team within Finance Branch is proposed to be realigned as per the following: • Management accountant and manager position is proposed to remain in Finance Branch • The finance Officer Assets and Purchasing is proposed to be realigned to eHQ.	In line with the functional assessments of the roles within the Asset Management and Purchasing team it has been identified that these roles are largely eHQ specific, have limited finance functions and predominantly perform an ICT and management function for eHQ.
Work Health and Safety Unit is proposed to be created within the Human Resource Branch.	The purpose of establishing a dedicated Work Health and Safety Unit is to acknowledge that this high priority portfolio carries with it significant risk to the organisation, and the DG, if health and safety is not appropriately led and managed.
Business Partnerships and Improvement Branch (BPIB) is proposed to be disestablished with all teams proposed to be realigned to other branches and divisions within the department. Name changes are proposed as per the following: • Executive Director BPIB is proposed to be retitled to Executive Director Governance and Information Management, leading the newly titled Governance and Information Management Branch (Corporate Services Division). • Project and Branch Support Officer Position is proposed to be realigned to the newly titled Governance and Information Management Branch, Corporate Services Division. BPIB team is proposed to be realigned as per the following: • Portfolio Management is proposed to be realigned to the Office of the DDG in Corporate Services Division • Priority Projects is proposed to be realigned to the Office of the DDG Corporate Services Division • Customer Experience is proposed to be realigned to the Office of the General Manager Integrated Scientific, Clinical & Prevention Services Division in Integrated Scientific, Clinical & Prevention Services Division	Rationale for the BPIB name changes are: • Renaming the ED, BPIB role to ED, Governance and Information Management Branch will better align the job title to the remit of the role. • Realigning the Project and Branch Support Officer to the Governance and Information Management Branch will provide the branch with support across all teams. Rationale for the BPIB team realignment are: • Portfolio Management and Priority Projects will be amalgamated and will focus on supporting the whole of CSD with improvement projects and reporting. This team will also provide support for Corporate Networks and Partnerships (e.g. Women's Network). • Customer Experience realigning with the Integrated Scientific, Clinical & Prevention Services Division ensures the services provided to the service delivery areas of the branch continue (e.g. Pathology Queensland and Biomedical Technology Services) • Change and Culture Leadership currently undertakes numerous Organisational Development (OD) activities. An OD function closely aligns with Strategic HR Management and needs to work very closely and collaboratively with other HR SMEs and functions. • Mental Health Court Registry moving to Legal Branch will ensure there is better

Proposed change	Rationale
• Change and Culture Leadership is proposed to be realigned to the HR Branch in Corporate Services Division. • Mental Health Court Registry is proposed to be realigned to the Legal Branch in Corporate Services Division • Communication and Engagement Manager is proposed to realign to Strategic Communications Branch in accordance with the consolidation and integration.	alignment and support of the function in the one branch • Rationale for consolidation and integration is outlined below.
Risk, Assurance and Information Management Branch (RAIM) are proposed to be realigned as per the following: • Risk, Assurance and Information Management Branch is proposed to be renamed to Governance and Information Management Branch. • Governance and Risk positions within current Department divisions are proposed to be realigned to a newly titled Governance and Information Management Branch (currently Risk, Assurance and Information Management Branch), Corporate Services Division. • Director Risk and Business Continuity position is proposed to be renamed to Director Risk, Business Continuity and Fraud. • Manager Corporate Planning and Governance position is proposed to be renamed to Manager Governance and Planning.	• The proposed name change to Governance and Information Management will better align the branch name to the function of the team. • The proposed realignment of positions is to ensure consistency of approach to risk management across the department and the ability to cross cover when vacancies arrive • The Director name change will better align the job title to the remit of the role • Manager corporate planning and governance name change is to reflect the departmental wide service function.
As part of the consolidation and integration process, Business Services is proposed to be realigned under a newly created Business Services Branch within Corporate Services Division. • All business services leads are proposed to report to a newly titled Director Business Services (proposed to be renamed from Director Governance and Engagement) which will report to the DDG, Corporate Services Division. • All business services positions which currently report to the business services leads (listed in the table below) are also proposed to realign with their respective lead.	The proposed creation of a Business Services Branch is to provide a standalone branch to lead business services across the department due to functions having touch points across multiple corporate functions.

Proposed change	Rationale
Strategic Initiatives and Planning is proposed to be realigned to the General Manager ISCPS.	• The function of the Strategic Initiatives and Planning align within the remit of the General Manager of ISCPSD. The newly formed ISCPS will be led by a new General Manager position reporting to a new ISCPS Board of Management. • ISCPS brings together key system support functions in the surveillance, prevention and control of communicable diseases in Queensland—leading the statewide planning and coordination of programs and services to prevent, or control, health-related diseases, and promote the overall wellbeing of Queenslanders.
Software Asset Management team is proposed to be realigned to eHQ.	Based on the functions performed by the Software Asset Management Team, the proposed realignment will create a better functional alignment.

COVID-19 Supply Chain Surety Division (CSCSD) (interim)

Proposed change	Rationale
The interim CSCSD is proposed to be abolished and all branches within the interim division to be realigned to CSD.	During the COVID-19 pandemic response phase, an interim division was established. As we transition back to normal health service operations this division is being abolished.
COVID-19 Supply Chain Surety Division is proposed to be split into two Branches. COVID-19 Supply Chain Surety is proposed to be a branch in Corporate Services Division. • COVID-19 Supply Chain Surety is proposed to be renamed to Supply Chain Surety. The branch is proposed to be led by the Executive Director Supply Chain. • Executive Director Supply Chain is proposed to report to the DDG Corporate Services Division • The Branch is proposed to include all current functions (Central Pharmacy, Supply Chain Services, Group Linen Services and Operations) and any aspects of the Queensland Government Critical Supply Reserve Program (QGCSR) at program end.	• Creation of a branch based on the functions performed by the current COVID-19 Supply Chain Surety and the removal of references to COVID-19. • Create a Branch focussed solely on the logistics functions performed by the Department to ensure greater integration
Strategic Procurement is proposed to be a branch in Corporate Services Division. Rationale: a strategic procurement branch created to provide end-to-end procurement. • Strategic Procurement is proposed to be renamed System Procurement Branch • The branch is proposed to be led by the Chief Procurement Officer • The Chief Procurement Officer role is proposed to be renamed the Queensland Health Chief Procurement Officer • The Queensland Health Chief Procurement Officer is proposed to report to the DDG Corporate Services Division.	Proposed to increase the prominence of the procurement function within the Department and across the system and reinforce that this is for the 'system'.
The functions within Finance Transactional Services (FTS) that do not provide core accounts payable functions are proposed to be realigned to the Finance Branch under Financial Accounting and Systems Operations.	The functions in FTS that do not provide core accounts payable functions and are more aligned to the services and functions performed within Finance Branch and the delegation of the CFO.
Accounts payable functions of FTS are proposed to be realigned to the proposed System Procurement Branch.	The proposed realignment with the System Procurement Branch is to bring together the functions that make up the end-to-end procurement process.

COVID-19 Response Division (CRD) (interim)

It is recognised that the CRD (interim) will continue in the immediate term and that concurrent planning will be undertaken to transition some COVID functions into the new organisational structure. Some temporary functions currently delivered by the CRD will cease, others will be realigned and continue for the duration of the pandemic. The new Office of the CHO will lead strategy and engagement to drive population health outcomes for all Queenslanders and ensure the Chief Health Officer to be able to discharge their regulatory and statutory obligations. Six new permanent positions will be created to deliver the functions of the new Office. To enable this the following proposed changes will take effect when appropriate.

Proposed change	Rationale
The Chief Health Officer is proposed to lead a newly formed permanent Office of the Chief Health Officer reporting to the DG.	• The new Office of the CHO will lead strategy and engagement to drive population health outcomes for all Queenslanders and ensure the Chief Health Officer to be able to discharge their regulatory and statutory obligations. • The Chief Health Officer will retain oversight for the public health components of the COVID pandemic response operating through a networked governance model.
• The existing temporary COVID-19 Response System Lead position will report to the Chief Operating Officer All temporary positions reporting to the COVID-19 Response System Lead will continue to report to this position. • The Deputy Chief Health Officers will lead the closure and transition of functions within their respective branches in CRD. • Existing COVID Operations and Disaster Management Functions, including temporary and permanent functions that are currently in CRD, will be accountable to the Chief Operating Officer. • Temporary functions in the COVID Public Health Branch will transition to ISCPSD. • Temporary functions in the COVID Governance Branch will be scaled down. A small temporary function will continue in the new Office of the CHO for the duration required to respond to the pandemic.	• The transition of some existing temporary functions into the new organisational structure will provide continuity and alignment with proposed business as usual areas. • This transition will occur with existing resources funded through the National Partnership Agreement for COVID-19. • This would more appropriately align operational functions in the proposed new organisational structure. This will enable effective forward response to future COVID waves, and pandemic planning and readiness.
Temporary functions in the COVID-19 Vaccination Taskforce Branch will be integrated into the ISCPS Division	• The transition of remaining temporary functions into the new organisational structure will provide continuity and alignment with proposed business as usual areas.

Proposed change	Rationale
	• This transition will occur with existing resources funded through the National Partnership Agreement for COVID-19. • This would more appropriately align operational functions in the proposed new organisational structure.

Strategy, Policy and Reform Division (SPR) (interim)

Proposed change	Rationale
The Associate Director-General SPR position is proposed to continue and to report to the DG.	The business case proposes a SPR division be retained within the final proposed structure.
Strategic Communications Branch is proposed to remain within SPR.	The business case proposes a SPR division be retained within the final proposed structure.
Social Policy, Legislation and Statutory Agencies is proposed to be renamed to System Policy Branch.	The Social Policy, Legislation and Statutory Agencies name change will better align the branch name to the function of team.
System Governance Strategy Branch is proposed to be a newly created branch.	The proposed branch will provide ongoing support for the health system governance including establishing efficient governance structures and supporting integrated governance between Hospital and Health Services, Queensland Health and other statutory agencies across Queensland Government.
Funding Strategy and Intergovernmental Policy Branch is proposed to be realigned from HPSP to SPR (see HPSP table for detail).	The Funding Strategy and Intergovernmental Policy Branch provides advice on emerging and priority state-wide health service, system and clinical policy issues. The Branch coordinates Queensland Health's contribution to a range of intra-governmental and intergovernmental policy priorities and represents the Department's interests in relevant policy forums which is directly aligned to the remit of SPR. The division leads, directs and coordinates activities to support and assist the health system to deliver safe, responsive, quality health services for Queenslanders. It is also responsible for the interaction of policy and strategy at both the State and Commonwealth Government levels.
Preventive Health Branch is proposed to be realigned as per the following: • Preventive Health Branch is proposed to be realigned to Strategy, Policy and Reform Division • Cancer Screening Unit is to be realigned to ISCPSD and is to be renamed Cancer Screening Branch.	Preventive Health Branch provides expertise, leadership and innovation to improve policy, systems and programs related to disease prevention, population cancer screening and health promotion. Public health epidemiology, information system maintenance and public health data management are also key services. The proposed realignment of the Preventive Health Branch is to align the policy functions with the transformation and reform agenda within SPR and the functional elements of the Cancer Screening Unit and Public Health with the ISCPSD to integrate with similar system support functions.
The Office of Hospital Sustainability is proposed to be realigned to SPR (see HCD table for detail).	The Office of Hospital Sustainability does not have a delivery component. The office functions

Proposed change	Rationale
	include policy functions that are for the broader health system and are better aligned with SPR.
Voluntary Assisted Dying Unit is proposed to be realigned to Strategy, Policy and Reform Division.	Voluntary Assisted Dying Unit is focused on the development of the policy which aligns with SPR until January 1 2023. Once the policy position for Voluntary Assisted Dying is developed and finalised, the policy will shift from development to implementation and the project will move to CEQ which focuses on the implementation of clinical policy.

Office of the DG (ODG)

Proposed change	Rationale
Ethical Standards Unit within Human Resources Branch is proposed to be realigned from CSD to the ODG, reporting directly to the DG with operational reporting to the Executive Director ODG (see CSD table for detail)	The alignment to the DDG and ODG is proposed according to the principal of separation and segregation of duties.

Health Capital Division (HCD) (interim)

Proposed change	Rationale
The HCD will move from an interim division to a retained division. The DDG HCD is proposed to continue to report to the DG through an advisory Board of Management.	The position will continue to report to the DG through a Board of Management. Boards of management will seek to further embed networked governance in Queensland Health, with the Department and HHSs advancing cooperative partnerships and strive toward the achievement of collective system goals, and increased trust and reciprocity. The board of management will be accountable for the strategy, investment decisions, operational performance and reporting against key performance indicators. The boards will comprise representation from the Executive Leadership Team, HHSs and independent external expertise. There will be a strong emphasis on industry expertise across these boards of management to bring external perspectives in to inform how the system works.
Biomedical Technology Services is proposed to be realigned to ISCPSD.	• BTS provides a statewide clinical support service along with the other branches proposed to be realigned to ISCPSD. Reassurance of public health and scientific services, this work is very aligned. In previous divisions they did not feel like they had a specific focus, in the new division they will get a specific focus on BTS. • By realigning, segregation of responsibility can be achieved. • BTS is supporting clinical care, note the feedback regarding the connection with CASB and capital, valued the relationship with CASB, we need to be able to work across silos, even though they are not reporting to HCD, they can still maintain a connection with CASB.
The newly created HCD consists of Capital Planning, Infrastructure Delivery, and Planning Assets and Support. The interim Health Capital Division structure has been realigned as per the table outlined in attachment 3: impacted positions by divisions.	• The proposed alignment of the interim structure to ideal end state including the creation of 3 Executive Director positions which are required as the nature of work has changed. • The 3 Executive Director positions and functions are centralised due to the increase output expected from this team. • Capital planning functions involve business case development for any projects in the pipeline • Infrastructure and delivery functions involve larger projects and capacity expansion projects • Planning and support have a function in the base programs and foundations of the division

Proposed change	Rationale
Master planning positions are proposed to be realigned to System Planning Unit in CPSS.	The Master Planning function for service needs assessment has a broader planning perspective then delivery and is within the remit of CPSS. CPSS contains functions that plan clinical services in collaboration with HHSs and key stakeholders throughout the health system. The function
The Office of Hospital Sustainability is proposed to be realigned to SPR.	The Office of Hospital Sustainability does not have a delivery component. The office functions include policy functions that are for the broader health system and are better aligned with SPR.
The Manager Carparking is proposed to be realigned to Finance Branch.	Realigned to revenue within the Finance branch as the Manager Carparking function includes policy setting position around state-wide carpark tariffs.
Corporate Facilities team within the previous Capital and Asset Services Branch is proposed to remain with CSD (see CSD table for detail).	Corporate Facilities team provide corporate services (e.g. floor space etc) and do not align with capital delivery functions. This proposed realignment is to ensure accountability alignment with CSD.
Investment Assurance Committee team members within the previous Capital and Asset Services Branch is proposed to remain with CSD (see CSD table for detail).	Investment Assurance Committee team provides assurance over capital projects. By remaining in CSD the team can maintain independence as part of the three-arm infrastructure approach: Commissioning arm, Clinical needs assessment arm and Infrastructure delivery arm.

Proposed new divisions and boards of management

The new divisions proposed in the future state structure are outlined below:

Clinical Planning and Service Strategy (CPSS) Division

The newly formed CPSS division will be led by a new DDG position reporting to the DG. Clinical Planning and Service Strategy will delivery clinical, workforce and mental health planning functions to improve health services available to the Queensland community. The CPSS division is also responsible for developing preventative and rural and remote health measures to foster improved health outcomes for those who most need it, as well as administering and governing voluntary assisted dying within Queensland ensuring Queenslanders have access to legal means to assist the end of life.

The CPSS division is proposed to contain functions that plan clinical services in collaboration with HHSs and key stakeholders throughout the health system. This division will look broadly across clinical functions and demographic data, including population growth and labour demand to best inform the departments allocation of health service funding and purchasing.

Integrated Scientific, Clinical and Prevention Services (ISCPS) Division

The newly formed ISCPS division will be led by a new General Manager position reporting to a new ISCPS division Board of Management.

The ISCPS division brings together key system support functions in the surveillance, prevention and control of communicable diseases in Queensland—leading the statewide planning and coordination of programs and services to prevent, or control, health-related diseases, and promote the overall wellbeing of Queenslanders.

- Communicable Diseases—investigating, preventing and controlling communicable diseases in Queensland
- Health Protection—safeguarding the community from potential harm or illness, including a strong regulatory focus on environmental hazards, water quality, fluoridation, food safety and standards, radiation health and chemical safety
- Pathology Queensland—a statewide comprehensive diagnostic pathology service, providing tailored services and support to HHSs based on clinical need
- Forensic and Scientific Services (FSS)—providing comprehensive forensic, public health and environmental science testing, analysis and solutions. FSS investigates and responds to public health threats, epidemics, civil emergencies, criminal investigations and coronial enquiries
- Biomedical Technology Services—providing preventive maintenance, medical device repair, asset management and safety advice to support the delivery of quality healthcare.

Strategy, Policy and Reform (SPR) Division

The interim SPR division is proposed to be transitioned to a division within the new structure and be led by an Associate DG (ADG) reporting directly to the DG. This division will drive the strategic agenda for health in Queensland - from developing policies and legislation to guide and protect the health of the community, to designing communications activities, campaigns and strategies to engage and empower Queenslanders, and leading and managing Queensland Health's system sustainability reform.

Some key functions of the SPR division will range from developing policies and legislation to guide and protect the health of the community, to designing communications activities, campaigns and strategies to engage and empower Queenslanders, to leading and managing Queensland Health's system sustainability reform.

The SPR division leads, directs and coordinates activities to support and assist the health system to deliver safe, responsive, quality health services for Queenslanders, and is also responsible for the interaction of policy and strategy at both the State and Commonwealth Government levels. The SPR division will also be responsible for developing preventive health measures to foster improved health outcomes for those who most need it. This new division separates these functions from the current Office of the DG.

Health Capital Division

The interim Health Capital division is proposed to be transitioned to a division within the new structure and be led by a new DDG position reporting through a Health Capital Board of Management to the DG.

Health Capital Division delivers an end-to-end capital infrastructure process. This includes all capital planning, business cases, construction and maintenance programs and managing these through government processes for Queensland Health in partnership with Hospital and Health Services.

The Health Capital Division will be instrumental in transforming the department's capital infrastructure function to achieve an accelerated capital program.

Boards of management for Integrated Scientific, Clinical and Prevention Services, eHealth Queensland, and Health Capital

Three boards are proposed over Integrated Scientific, Clinical and Prevention Services, eHQ and Health Capital Division.

Previous reviews into Queensland Health (Hunter Review 2015, Advice on Queensland Health's governance framework 2019) have recommended the implementation of boards of management in those functions that serve a support role as a provider of key components to our system and agency.

Boards of management will seek to further embed networked governance in Queensland Health, with the Department and HHSs advancing cooperative partnerships and strive toward the achievement of collective system goals, and increased trust and reciprocity.

The board of management will be accountable for the strategy, investment decisions, operational performance and reporting against key performance indicators.

The boards will comprise representation from the Executive Leadership Team, HHSs and independent external expertise. There will be a strong emphasis on industry expertise across these boards of management to bring external perspectives in to inform how the system works.

Section Two

Corporate support functions consolidation and integration

A note about consolidation and integration:

Consolidation and integration of corporate support functions requires:

- the identification of roles that perform these tasks
- confirmation that the roles sit outside the functional branch

In some cases, identification of these roles can be straightforward. To assist in the accurate identification of the roles in scope numerous methods were undertaken, these included:

- meetings with Senior members of staff (e.g., Directors of the divisional offices)
- a review of role titles
- workshops with functional groups
- survey data
- self-identification

This is a large organisation and there may be instances where a role has been identified by one or more of the above-mentioned methods and it is not correct.

If your role has been identified in the consolidation and integration section as performing one of the in-scope functions and you believe this is an error, please complete this form.

Please note if you have previously raised your role as being an error, you will still need to complete this form

Throughout the business case for change process, an overarching principle has been to ensure functions are working collaboratively, not in competition with one another. In line with this principle, consolidation and integration of certain horizontal corporate support functions has been discussed throughout phase two of the business case for change. The proposed approach and model for the delivery of corporate support functions is open for consultation and feedback.

There are several functions currently operating across the department (within multiple divisions and branches) and in some cases, also have a central branch/team located separately as well. This is typically called a decentralised model of service, meaning there are employees across the department providing these services who are not sitting in the central function, with no reporting line or association to that central function. These functions include:

- human resources
- communications and media
- finance
- risk and governance
- business services.

While these functions provide a high level of service to the areas in which they reside, there are inconsistencies in tools and templates, service delivery levels and in some instances, inconsistent guidance and messaging between these separate roles and the central function. This can be

caused by the same work being performed in different areas using different methods, result in varying advice for the same question.

Additionally, for employees in these positions, there can be little or no backfill or opportunity for growth and development.

The employees who do this work across the divisions are in the best position to present and discuss the different models of organising these horizontal functions across the department, and this conversation began with those employees during the phase two consultation period. This included via workshops, meetings with stream leads, meetings with ELT and an all-staff survey to understand their desire for different models of service.

Initial feedback and insights show there is support for building a model and structure which creates greater consistency and provides an opportunity to deliver a better service for the department.

Consultation process

Workshops

Employees were invited to attend a series of workshops to discuss the integration and consolidation of the different corporate support functions. They could self-select which, and how many, workshops to attend based on the nature of their work and services they provide.

A total of eight workshops were held from 7–9 June 2022.

Function		Date	Approximate Number of Participates
1	Risk and Governance	7 June 2022	65
2	Communications and Media session 1	7 June 2022	65
3	Change management	7 June 2022	37
4	Generalist Human Resources Advice	8 June 2022	125
5	Finance session 1	8 June 2022	84
6	Business Services	9 June 2022	95
7	Finance session 2	9 June 2022	55
8	Communications and Media session 2	9 June 2022	23

The workshops discussed how corporate support functions across the Department of Health could be better connected, with attendees responding to three broad questions:

1. How is the service or function currently being delivered?
2. What is working well and what are any opportunities for improvement?
3. How can the function or service be delivered better in the future?

In addition to the above workshops, a separate data and analytics workshop was held on 22 June 2022 to discuss the department's analytics role and function, and how the different parts of the

organisation that have analytics capacity can work better together to ensure a single source of truth.

Over 20 people across the department attended and contributed to the conversation, revealing that further conversations with this group are needed.

Survey

On 21 June 2022, a survey was released to all departmental employees seeking their feedback on the consolidation and integration of corporate support functions, before closing on 27 June 2022. A total of 157 staff responded to the survey during this time. The purpose of the survey was to gather more data from people who provide the in-scope services but also from those that are customers of these services. The survey asked questions about the consistency of services and what is most valued in relation to how services are delivered. There was also an open text field for additional comments.

The information gathered during the workshop sessions and the survey have contributed to the proposed future model and structure.

Key considerations for the proposed model

"It is proposed that roles that perform HR, Finance, Communications and Media, Risk and Governance and Business Services functions and do not currently report into the central function will be proposed to have their reporting line changed to the centre. In the case of business services a central branch is proposed to be created".

The feedback from employees revealed that many were supportive of exploring consolidation and integration but acknowledged there was significant work required to decide on the most appropriate model. The workshops and survey findings were categorised by four key themes, these are outlined below:

- Consistent advice—having the same answer to the same question, regardless of where the question is being asked.
- Collaboration—an ability to reach into expertise for advice and to build knowledge across the department.
- Reduce duplication—realising that having multiple roles performing the same function is inefficient.
- Co-located with client area—allowing for greater understanding of client issues and needs and being able to build relationships.

The proposed model is intended to have the following benefits:

- corporate functions will be working collaboratively, with everyone connected to a larger centralised team, while still supporting their client areas
- functional resilience and sustainability within the system manager
- employees working in these functions will have with greater team support and development opportunities, including clearer promotion and career pathways

- better connection between people and functions, reducing duplication of work and supporting a single 'source of functional truth' for information
- greater employee access to opportunities by ensuring smaller or isolated teams have better support for backfill and leave arrangements by being connected to the central hub.

See over page an overview of the current and proposed operating models.

Current corporate support functions model

Features

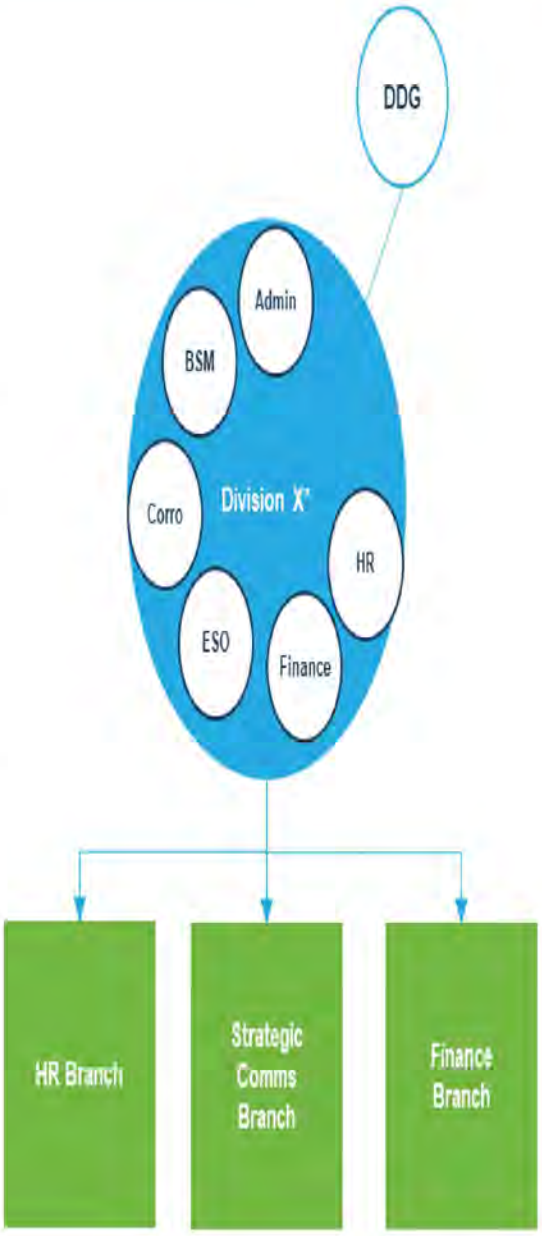
- Roles provide services directly to the customer (e.g. DDG or division)
- Advice ranges from basic to complex, based on employee skill, knowledge and experience
- Imbalance in both functions performed and the location of the roles
- Seek assistance from central hub if greater or different skillset required
- Services are provided on needs basis

Advantages

- Clear line of sight of responsibility
- Ability of customer (division) to direct resources based on divisional need and priorities
- Faster decision making due
- Faster and better-quality response to customer needs
- Better job satisfaction and identity for empowered employees

Disadvantages

- Lack of consistent advice and service offering
- People dependant rather than role dependant
- Lack of development opportunities
- Generalist advice or providing the advice that is wanted rather than what is needed
- Duplication of effort and resources



Not representative of the roles in all divisions and it is illustrative only

In the current state the customer has access to horizontal functions within the division and also access to the horizontal functions located centrally.

Proposed corporate support functions model

Features

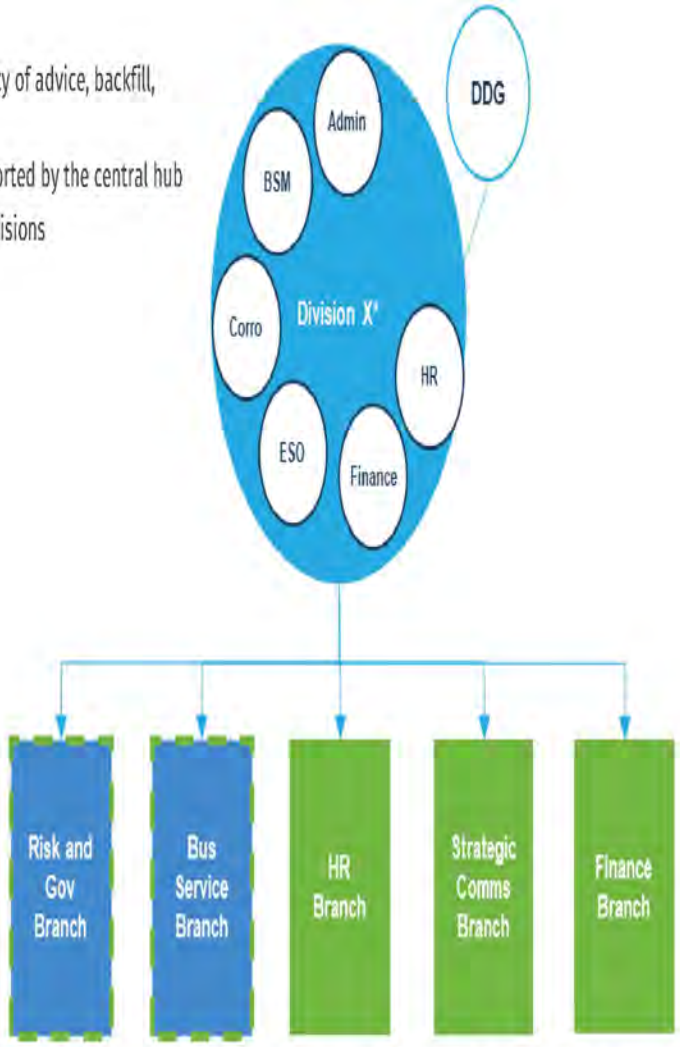
- Roles provide service to the division
- Roles will have access to, and support from, 'the centre' regarding consistency of advice, backfill, professional development and career progression
- Customer (e.g. DDG or division) has access to role/s within the division supported by the central hub
- Opportunity roles to be equally shared across the department and within divisions
- Service delivered on a needs basis

Advantages

- Moves beyond the person and focuses on the role
- Allows for backfill, growth and consistency of advice
- Reduces duplication of roles within the department
- Allows for resources to take a system wide view
- Better connections across the department
- Increased capability across the whole system

Disadvantages

- Reduced ability to control output quality
- Requires undertaking of services with strong governance
- May result in loss of organically grown in-house skills in key areas
- Potential to have a decrease in services given a decrease in control
- Increased points of control for the employee in the role



**Not agreed, this is proposed for feedback and it is illustrative only*

The proposed future state is a model where the reporting line is to the centre branch and the role is aligned to the client or division.

Implications of proposed model

Generally, if you currently provide any of the functions in scope, you will continue to do so in the location you are in and where possible to the same client area. Noting that based on the final structure client group allocations will need to be resolved to ensure equitable access to corporate support services for all divisions.

For example, if you currently provide a corporate support service to PD, as this Division is proposed to be abolished, your reporting line is proposed to be realigned to the central function and your client group allocation will be resolved through implementation upon finalisation of the proposed structure.

A key implication of the proposed model is that employees who currently deliver corporate support functions and report to the division in which they are located, will have a change in reporting line to the central function. However, they will remain in their current physical location.

As such, the consolidation and integration are only intended to impact reporting lines, with accommodation and current work locations to remain constant in most cases. There may be some instances where a change in working location is required (e.g. corporate support functions supporting a new division). If this need arises, impacted employees will be consulted with as per industrial requirements.

The table below identifies some initial questions you may be asking yourself when reading this. In addition to this, there will be opportunity to provide feedback during the feedback phase, and also a workshop during this feedback phase to understand more of what this consolidation means.

Implementation planning considerations

The implementation of the consolidation and integration body of work will occur over the next 6–12 months, following the implementation of the new organisational structure.

Throughout this time, there will be discussions around creating consistency in service provision as well as how the proposed model will be implemented across the department. This will also consider where roles reside across divisions and branches, and should any changes be required; these changes will be discussed with the impacted employees.

The following types of activities will be undertaken to consolidate and integrate corporate support functions and apply the proposed model:

Capability assessment	• Understanding the current skills and expertise • Developing a consistent service offering • Developing a professional development program
Culture	• Ways of working • Identifying behaviours that support culture • Developing management and leadership training
Workforce management	• Determining client group allocation and distribution • Understanding resourcing and capacity requirements
Systems and establishment	• Identifying cost centres, workflow and systems • Establishment cleanse and workforce management • Identifying policy changes
Change management and support	• Developing the change management activities to support this program
Organisational structure	• Identifying and implementing reporting line changes • Determining governance arrangements
Client group allocation	• During implementation, client group allocations will be reviewed. Where any changes are proposed, individual conversations will be held.

Answers to common questions

Question	Answer
Who will approve my leave requests?	Your new line manager in the central function will be responsible for approving your leave requests. However, you are responsible for informing your client when you're on leave.
Will I move location?	Initially no, you will not move location. However, with a revision of reporting line, there may be opportunities to provide services across a wider array of clients. Should any location changes be identified during implementation, these will be discussed with the individual roles affected.
What if my role has been identified as performing an in scope activity and I don't believe it performs that function	This is a large organisation and there may be instances where a role has been identified by one or more of the above-mentioned methods and it is not correct. If your role has been identified in the consolidation and integration section as performing one of the in scope functions and you believe this is an error, please complete this form. Please note if you have previously raised this error, you will still need to complete this form.
Will I lose my job?	No, maintaining job security is a key priority
Doesn't this mean I will have multiple bosses?	No, your new reporting line into the central function will be to your line manager. You will still work closely with your divisional leadership but these roles will not have any management responsibility for you.
When will this happen?	It is anticipated this consolidation and integration will occur over the 6 to 12 months following business case for change implementation.

Human Resources Branch: Consolidation and Integration

Phase 1 of the Business Case for Change brought together the Department of Health's (the department) HR areas (eHQ People and Culture, the former HSQ HR Directorate and HR Branch), Workforce Strategy Branch and the Ethical Standards Unit under the management of the Chief HR Officer (CHRO) as a 'Workforce Collective'. Although technically aligned, we are not fully integrated or functionally consolidated.

Before full integration and consolidation was undertaken, several workshops exploring our strengths, weaknesses, opportunities, and challenges were undertaken in order to understand our HR/Workforce Service opportunities better and inform our integration and consolidation.

Key insights and feedback gathered from our staff and customers included (but are not limited to):

In terms of HR functions that,

- There is duplication of functions and inefficiencies across the HR functions
- Work still remains largely siloed, not aligned or integrated, creating inconsistency issues
- Insufficient time for proactive and strategic work and innovative practice
- There is a lack of awareness from within and outside the branch on what our functions and services are

Our customers have said:

- speed and responsiveness of HR is slow
- they are sometimes receiving varying and conflicting advice
- they have difficulty engaging with HR (no front door, uncertainty of how and who they engage with in HR)
- they are not always getting adequate support.

As such, the way we are organised and delivering our services right now, could be enhanced. We must review how we are structured, collaborate more, and develop further the way we deliver our services to the organisation.

The department's business case for change – phase 2 proposes:

- Workforce Strategy Branch be realigned to the new Clinical Planning and Services Strategy Division
- Ethical Standards Unit be realigned to the Office of the Director General
- The Contractor Engagement Team with HR Services (eHQ), Corporate Services Division be realigned to eHQ
- The medical credentialling function within HR Services (ex HSQ), Corporate Services be realigned with other credentialling functions to Clinical Excellence Queensland

Proposed HR structure rationale

Research is highlighting the need for HR to transform the way in which it delivers services. Whilst there is no one right way to transform there is mounting evidence for the need for HR to: be more strategic; be flexible, adaptable, and agile in their approach; engage in new ways of problem solving; design creative people solutions; leverage people analytics to inform service development; place the wellbeing of employees at the centre; create future-focused policy; and build robust and proactive HR operations and service delivery teams. Research is also showing that HR can be most effectively optimised by creating separate spaces for strategic and operational activities.

We acknowledge that this type of transformation can take time. As such, the proposed HR Branch structure is about beginning the journey to transforming our services for the future. It will require all of HR to build new capabilities and develop services and approaches to support the realisation of HR transformation goals for the future.

As a result of customer feedback, HR Branch reflections, and the principles for an HR structure derived from feedback, feedback and input from the Human Resources Branch, alongside global research into the future of HR, some key rationale for the proposed HR structure for the Business Case for Change 2022 is as follows:

1. Consolidation of HR functions

Integrating and consolidating the HR functions spread across the HR Branch will create efficiencies and optimise the services we provide. Fully aligning the eHQ People and Culture functions, ex-HSQ HR Directorate functions and the department's HR Branch functions together will provide centralised support for all of the department's customers and the proposed new divisions.

Bringing together our functions will strengthen our collaboration with each other and the business and provide better functional resilience. A centralised HR function encourages consistency, coordination, better knowledge sharing, capacity to move resources quickly and flexibly, optimisation of processes and continuous improvement. It allows us to leverage the diverse skills and strengths we possess across all HR functions but also helps us provide more easily professional development and growth opportunities for our HR staff.

2. Oversight over HR Branch operational planning, progress against objectives, and executive policy and contracts – Office of the CHRO

It is proposed that the Office of the CHRO house a *HR Governance team* and the *Executive Policy and Contracts* team.

HR Governance is a central support function. Primarily this work supports the CHRO in HR Branch operational planning, risk management and provides a secretariat to executive committees. As such, this work is better aligned with the Office of the CHRO. It may on occasion support the establishment and monitoring of special HR Branch projects.

The ***Executive Policy and Contracts*** team is proposed to remain in the Office of the CHRO. It is responsible for managing executive employment and policy for Queensland Health. The team works on confidential employment matters at the executive level, including providing advice to the Minister, Director General, Hospital and Health Boards, Health Service Chief Executives and other Queensland Health executives relating to executive employment. Remaining in the Office of CHRO means that the CHRO can have a clear line of sight of this work.

3. Growing our HR analytics and insights capacity and transforming our systems for the future – HR Business Intelligence

The workforce is a key focus area for Queensland Health into the future. The proposal aims to recognise all of our key services in their own right and deliver a structure that enables us to deliver transformative work to support the organisations future direction. It also provides greater clarity to our customers.

There is growing demand for HR analytics and insights to support the organisation, the system, and other HR units in their decision making and practices, to improve organisational effectiveness and people performance. This will require growing our analytics and insights capacity and supporting the workforce in building their data literacy.

Reporting, data management and analytics and reporting are distinctly different functions, which require different skills sets. But there is a critical connection between these components that must be aligned to deliver an efficient and effective service under a clear strategy.

Our systems support key HR business process both statewide and within the department. Ensuring that we have the right support model in place is critical to maintaining and enhancing system functionality and a high-quality customer service. Business requirements is also a key component of this function. Acknowledging this as a separate function allows us to provide a better service to our customers and supports a best practice approach.

With increasing demands and reliance on workforce data, bringing focus to the quality and integrity of the data and reports we provide to the business is critical. By way of example, the same question should receive the same answer – a single source of truth building trust and confidence. We must also meet our customers' expectations around speed of access to information.

4. Growing our strategic leadership, systemic problem-solving abilities, organisational effectiveness, and talent – Organisational Development, Change and Talent

Establishing an ***Organisational Development, Change and Talent (ODCT)*** unit for the department is about creating a dedicated space in HR for strategic and systemic thinking and implementation. The ODCT unit will focus on creating overarching people and culture strategies in order to create a workplace and workforce for the future in the department. The purpose of establishing the ODCT is to design solutions, foster change and organisational improvements. It brings together the aspects of HR, culture and organisational development that have broad organisational remits.

It is proposed that the *Organisational Change and Culture* team (from Business Partnerships and Improvement Branch) be realigned to the HR Branch. This team currently undertakes numerous OD activities. An OD function closely aligns with strategic HR management and needs to work very closely and collaboratively with other HR SMEs and functions.

The ***Organisational Development and Change*** team will focus on the organisational system (including but not limited to: organisational design, leadership and management practices, employee experiences -physical and psychological, work environment, performance management, workplace relationships and behaviours, organisational culture and wellbeing, employee meaning, values and purpose, diversity and inclusion practices, job design, workload management, capability and competencies, recognition, employee engagement and resilience, flexible working practices). This team will be structured around three sub-teams.

Critical to creating an effective organisation is building organisational capability, developing leaders and ensuring that diversity and inclusion practices are embedded throughout the organisation. As such, ***Organisational Development and Diversity*** sub-team and a ***Leadership Capability*** sub-team will focus on growing strategic leadership and Organisational effectiveness.

Leading, managing, and supporting change is central to OD and all improvement initiatives. As such, a dedicated ***Organisational Change*** sub-team is proposed to be included. It is also proposed that this team stay within HR Branch because of the important industrial obligations we are required to meet, and that many levers and expertise for effective change management are found in HR (e.g. people and leadership development, people management, culture, behaviour change expertise). The role of this team is to provide advice and support to the organisation regarding change and improvement, creating resources and guidance materials, coaching change managers and fostering new ways of problem solving. The team provides advice on leading and implementing different types of changes e.g. behaviour change, systemic change, structural change or smaller changes and improvements. It also aims to create consistency of change practice across

the department. The team does not however project manage change processes across the organisation.

The ***Workforce Planning and Development*** team provides space for a strategic approach to ensuring that we have the right workforce to successfully navigate our future. It requires an understanding of our possible futures, the types of skills and jobs we require, and optimising our workforce structures for the future. It also requires a strategy to attract and retain our talent and needs to ensure there is a talent pipeline for our current workforce. WPT aims to ensure that jobs are designed well, achieve our strategic and business objectives, encourage safe practices and maximise our talent potential. In order to achieve these goals a ***Workforce Planning and Attraction*** *sub-team*, inclusive of job design and evaluation, and a ***Talent and Development*** *sub-team* is proposed to be included. This team focuses on setting strategy and best practice and contemporary standards in the recruitment space, it does not manage recruitment processes (with the exception of executive recruitment). The MO3/MO4 advancement function is included in this stream.

In line with the overarching principle of this business case for change to ensure functions are working collaboratively, with a focus on consolidation and integration of functions currently operating across the different divisions and branches, it was identified that a function performed by the Centre for Leadership Excellence (CLE), Clinical Excellence Queensland (CEQ), i.e. providing development programs to employees within CEQ was aligned to the functions of the Human Resources Branch. Therefore, it is proposed that a position be realigned from CLE to the Human Resources Branch. It is proposed that the position for realignment be identified through a closed expression of interest to CLE employees only. In addition, it was identified that CLE also delivered a HR program to Hospital and Health Services, it is proposed that this remains with CLE as a component of a broader learning series, however, the Human Resources Branch and CLE would strengthen collaboration and input on course content.

5. Need for system-wide health and safety leadership – Health and Safety

The purpose of establishing a dedicated ***Health and Safety (HaS)*** unit is to acknowledge that this high priority portfolio carries with it significant risk to the organisation and the DG if health and safety is not appropriately led and managed. The COVID-19 pandemic also highlighted the importance of state-wide leadership to the Queensland Health system regarding workplace health and safety.

It is envisioned that this team will provide strategic and statewide leadership and guidance on all matters pertaining to health and safety, including: designing policy architecture to enable and inform the delivery of operational health and safety services and wellbeing initiatives; provide expert advice on the identification and management of physical and psychosocial risks and hazards to the organisation and operational health and safety teams; providing specialist advice and services to Hospital and Health Services (HHSs); monitoring, evaluation and compliance; maintaining close relationships with key partners including HR, Risk and Governance, Legal, and Patient Safety teams. This team will build, drive and improve our overall safety culture

The ***System Leadership and Advisory*** team under this stream of work will focus on providing health and safety leadership and guidance to the whole Queensland Health system. This includes providing strategic direction, expert advice and implementation of initiatives designed to improve health and safety outcomes and safety culture. This team will be able to provide specialist advice to the department and HHSs in areas such as: occupational health and hygiene; asbestos, biosafety, chemicals, noise; ergonomics & human factors; manual handling, patient handling, safe design; health management; biological hazards e.g. Covid; fatigue; rehabilitation and injury management; industrial safety, plant, electrical; operational road maps, plans, and assurance frameworks.

The ***Monitoring, Evaluation and Compliance*** team will focus on having strategies, systems and processes that monitor, measure and evaluate system performance with regards to meeting health and safety obligations and the identification of real and emerging risks. This includes contributing to system level risk management and compliance activities.

It is critical for these teams to work collaboratively and across streams of work to maximise expertise and workloads.

6. Providing a direct-to-client service – HR Advisory Services

The creation of a dedicated direct-to-client advisory service for general/operational HR Advice and support is in direct response to customer feedback regarding concerns about accessing quality HR advice easily and receiving adequate support from HR.

The ***HR Advisory Service*** unit addresses the imperative for HR to build a robust operational delivery team. It allows HR practitioners to focus on understanding client business needs and their unique contexts and challenges, therefore providing quality HR advice and support to the business. It is our aim to provide the best possible service to our clients. The business case for change proposes new divisions, and we must ensure the entire organisation is supported by HR.

Whilst there are many pros to centralisation, one of the challenges of a centralised function is that teams can lose business intelligence and knowledge, especially in a large diverse organisation. The creation of the HR Advisory Service unit balances this out by focusing on understanding the diverse needs of the business and building on-the-ground business intelligence. This is critical knowledge to share with all HR Branch units in order to design better services for our clients.

The HR Advisory Services unit will partner with client portfolios in the provision and delivery of tactical, operational and advisory services in HR, employee relations, industrial relations, work health and safety, rehabilitation and injury management, recruitment services and *my*HR service support. They will also be required to build and maintain effective relationships with a range of external agencies, union partners, and internal HR Branch teams and members.

Proposed to be Included in this function are the following teams: *HR Operations and Recruitment Services* team; and a *Health, Safety and Rehabilitation* Team.

The ***HR Operations and Recruitment Services*** team will be led by a Director oversighting two sub-teams.

The ***Recruitment and myHR Services*** sub-team focuses on advisory and operational support to a range of clients across the department. Recruitment will provide a range of advisory and support services to clients including recruitment advice and options in accordance with policies and Directives, job evaluations, job advertising, vacancy administration and pre/post compliance processes, and recruitment training for line managers and panel chairs. This team will also provide medical recruitment services for relevant divisions; and will also manage community recovery coordination as required. The medical credentialling function is proposed to transfer to CEQ, bringing together all clinical credentialling functions; it is not proposed that the associated resources move this function.

The Business System Administrators in *my*HR Services will support employees and line managers with the *my*HR workflow solution through the provision of advice and expertise in relation to the forms workflow system and local business processes and practices. The team is a central contact point for Payroll Portfolio in relation to forms workflow queries and support.

The ***HR Operations*** team will deliver advisory and operational HR services to client portfolios on people management matters, coaching and guidance on a broad range of HR and employee relations matters in accordance with awards, legislation, standards, regulations, directives,

policies, and guidelines to improve people management capability and business results across the department. This team will be a pivotal connector between the new divisions and the HR Branch. The team will provide contemporary advice to divisions across the department on all aspects of effective people management work practices that emphasise the achievement of customer objectives. The team will liaise and partner with the People Performance (Statewide) team on complex cases, policy advice, performance management, industrial relations advocacy and representation.

The ***Health, Safety and Rehabilitation*** (HSR) sub-team will provide a contemporary and professional integrated HSR service across the department that encompasses work health and safety, rehabilitation and return to work, risk and hazard management, and HSR governance matters such as policies, procedures, mandatory training and reporting. This team will work closely with the HaS unit to ensure alignment to the department's Safety Management System to achieve consistency of strategies, service delivery arrangements and performance outcomes. The team will collaborate and partner with the HaS unit and seek advice and guidance on strategic and state-wide policies, procedures and other matters pertaining to health and safety.

In addition, it was noted that some functions performed by Business Services Officer may better align to this Unit, in particular the management of temporary and casual to permanent conversions and higher duties conversions. This function is already performed by the HR / People and Culture teams from eHQ and ex HSQ; this will ensure this function is managed in a standard and consistent way across the Department.

7. Providing guidance to the whole QH system regarding workforce relations, complex case management, creating future focused HR policy and standards development – Workforce Relations and Policy

Creating a ***Workforce Relations and Policy*** (WRP) unit will create a leader of expertise that can create the policy and industrial architecture for the state as well as be a leader of expertise, collaborating and coordinating expertise from across the system to transform strategy to operations.

The team will provide expert interpretation and advice on complex case management, policy and industrial and employment relations to People and Culture/Workforce/HR teams in HHSs and the department and build the capability of individuals and the system.

Additionally, the team will lead disputation resolution and tribunal conciliation and hearings that are of significance i.e. that are sensitive in nature, set a precedent or have implications for more than one HHS. This disputation may be individual or collective in nature.

As the DG's representative, the WRP unit leads enterprise bargaining negotiations on behalf of Queensland Health and does this by working with stakeholders to review, prepare and undertake bargaining with our industrial partners. The unit also leads the implementation of agreements once they are certified.

It is proposed that the ***Statewide People and Performance*** team be aligned with the WRP unit due to its focus on providing specialist advice across all of Queensland Health. This team advises on complex conduct and performance matters including those that are lodged with external bodies such as the Queensland Industrial Relations Commission (QIRC), Queensland Human Rights Commission (QHRC), Queensland Ombudsman and Australian Human Rights Commission (AHRC). This team will also work closely with the ***HR Operations*** team providing advice and guidance when required. The People and Performance team will also focus on building capability across the HR practitioner network through coaching and training.

8. Flexibility, adaptability, collaboration and new ways of working

Finally, the HR leadership team believes that it is important to develop new ways of working within the branch that encourages flexibility, adaptability, collaboration, and cross-team working. This means that although we must have clarity on the functional roles of each team, our team boundaries are not rigid, nor do we want them to be rigid. The nature of all our work is that it overlaps with other teams in HR.

We hope our structure helps us work flexibly with and across teams when required, and that we always consider how another team in HR might contribute insight and expertise to our area of work. We are going to have to explore new ways of problem solving together, through understanding our business needs, our employee experiences, the systemic challenges, strategic imperatives, and the different expert perspectives we bring to our work. We will continue to improve and develop ourselves and our services now and into the future through reflective practice and communities of practice and expertise.

Finance Branch: Consolidation and Integration

Background and Context

As part of Corporate Services Division, the work produced in Finance Branch supports and enables the business to deliver many critical services and outcomes that are essential for the effective delivery of hospital and health services and the performance of Queensland Health.

The Business Case for Change process has enabled Finance Branch the opportunity to assess how it may be better structured to perform its functions and, where necessary, streamline and improve existing processes and outputs. The work undertaken by Finance Branch was in accordance with organisational expectations that the proposed functional alignment was developed within existing resources.

Finance Branch has been on the Business Case for Change journey since March 2021. Phase one outcomes saw new functions and services realigned into the Branch with the addition of the Financial Management team from eHealth Queensland (eHQ) and the Finance Directorate team from the former Health Support Queensland (HSQ). While these new functions and existing business functions within Finance Branch have evolved to better align to organisational goals, it is noted that each function is not fully consolidated into Finance Branch. Without consolidation of these functions into the Branch, it is noted that continued operations in this manner may limit staff development and business synergy opportunities.

Phase two represents the opportunity for consolidation. Phase two also proposes that Finance Branch continues to grow by welcoming back components of the Finance Transactional Services (FTS) Unit as well as potentially several other finance related positions from across the department.

Finance Branch Vision and Principles

Work has been undertaken to redefine Finance Branch's vision and create working principles in line with organisational expectations. These are:

Vision

"We will be the leader of system financial policy and management and will work collaboratively to achieve value for money, consistent and sustainable outcomes."

Principles

- We seek to become a valued and trusted advisor to all stakeholders
- We will ensure value for money outcomes by being financially and resource prudent
- We will work collaboratively to ensure that our services are coordinated, connected and not in competition
- We will be responsive to our stakeholders' needs and enquiries, and
- We will provide service excellence and ensure compliance with all of our statutory obligations.

Finances Branch's vision statement seeks to establishes the strategic intent for the Branch to which the proposed Business Units can work towards. The working principles provide direction and establish the expected manner in which staff work.

Rationale

In alignment with the foundations for strategic change in the health system, it is recognised that Finance Branch needs to move towards a structure with stronger functional alignment. By having the right functional structure, Finance Branch can better align its most important resource (people)

to support processes and outputs required for decision making and to support the department in its role as system leader in an efficient and effective manner.

Noting the new functions from phase one (eHQ and HSQ), those proposed from phase two (FTS etc.) and the existing functions within Finance Branch, a functional assessment process was undertaken. Function assessment led to function grouping within the Business Units and where practical, re-alignment of reporting lines. 'Like' skill sets were identified and 'like' functions, being output and ways of working, were also identified. Like skills and outputs were grouped together, and a proposed functional structure developed. Importantly, this approach will allow Finance Branch to better leverage the diverse skills and strengths across the Branch and enable better professional development and growth opportunities.

A number of factors and considerations were made in the development of the proposed functional structure including: consolidation of functions to support clarity of tasks and purpose; grouping of like staff skills; grouping of like ways of working; alignment to vision and ways of workings; achievement of consistency of practices and processes within teams and units; better utilisation of staff skill sets; opportunity to grow and develop staff; improvement of and better alignment of analytics and training opportunities; and improved communication and coordination within and across the Branch. These factors, when working in alignment to the Vision, and within the proposed functional structure, will drive benefits.

Benefits

Benefits identified should the proposed Finance Branch structure be supported, include:

- delivering a fit-for-purpose structure
- providing clarity around functional responsibilities
- improving integration and collaboration within and across Units, Branches and Divisions
- removing duplication to allow for efficiency, innovation and productivity
- fostering a system-wide view to support skill-sharing, capability uplift, professional development and career progression, and
- facilitating workforce agility and helping sustain resource constraints.

Finance Branch Business Units

The proposed functional structure will consist of four Business Units and two key functions (it is noted that the quarantine fee functions are limited life, with accounts receivable teams to be re-absorbed over time, where appropriate, into the proposed Accounts Receivable function). Each proposed Business Unit and new function is identified with their function and intent of working discussed below.

It is acknowledged that some of the proposed functions and proposed Business Unit names may only have minimal staff impact, however, the name of the function or business unit has been changed. The change in naming convention was undertaken to assist in providing necessary function differentiation. The proposed functional structure of Finance Branch will consist of the following business units and underlying functions:

Financial Budget, Assessment and Performance Unit (formerly Budget and Analysis)

This Business Unit will lead the organisation for State Budget financial matters, cost modelling and analysis. It will be the trusted source for Queensland Health's cost assessment that informs policy direction.

It will comprise of three functions, Budget; Financial Performance Monitoring and Analysis; and Cost Assessment and Advisory that will all need to work collaboratively and effectively across the organisation to achieve success.

Financial Policy, Controls & Advisory Unit (formerly Statutory and Advisory Services)

This Business Unit will provide valued strategic advice that informs financial policy direction, whilst proactively managing operations to achieve value for money outcomes in a timely manner.

Comprising of four functions, Financial Policy; Revenue Policy; Taxation; and Insurance these functions will need to have a strong focus on collaboration with Hospital and Health Services and the Department to ensure clarity and effective implementation of relevant advice.

Financial Accounting and System Operations (formerly Finance Transactional Services)

This Business Unit will perform system operations and service functions that deliver

high-quality products that are timely, accurate and compliant to all statutory obligations.

There will be four functions within this unit, Financial Accounting; Asset Accounting; System Operations; and Accounts Receivable that need to have a strong service focus. Critical services within these functions must be accurate and timely, and advice prepared must be performed collegiately to ensure effective implementation.

This subset of functions from within the current Finance Transactional Services unit is proposed to move back into Finance Branch. This move is proposed given its alignment to:

- specific provision of services that have unique departmental service delivery functions (i.e. Accounts Receivable, specifically relating to Pathology). This approach will ensure a dedicated focus on these unique departmental level service functions.
- support a State-wide approach for statutory obligation and compliance work relating to financial and asset management to ensure clarity and consistency of approach across the system. This consistent approach can be uniformly managed and communicated to impacted stakeholders under the guidance of the Chief Finance Officer, including banking and corporate card.

It is noted that Accounts Payable is excluded from the proposed Finance Branch structure as it is proposed to remain within Procurement to enable the effective delivery of the end-to-end Procure-to-Pay function.

Finance Solutions

This Business Unit will seek to collectively improve data quality, provide insights and drive better decision making.

The three functions within this unit, Data Insights; Support and Training; and Projects; must work together and collaboratively across the organisation to ensure that data insights are meaningful, training is targeted, and the identification and reporting of issues and solutions supports productive outcomes.

Financial Business Partnering

As a function reporting direct to the Chief Finance Officer, this function will seek to provide strategic financial management and meaningful reporting that provides insights and drives improved decision-making. With service offerings across a breadth of stakeholders, consistency of reporting approach will be critical to become a trusted advisor.

Consolidating this function into Finance Branch will support a better flow of macro financial information to be provided and used to inform decision-making. This improved intelligence will also provide greater context to staff and support improved outputs for stakeholders. Outcomes expected include; increased collaboration, reduced duplication, enhanced document and reporting quality, in addition to consistency of advice and approach.

New services are also proposed to come in from other areas (i.e. Health Capital Division, HPSP and QGCSR) that preform financial tasks that align to, and will be enhanced by working within Finance Branch. These functions are identified to align to Financial Business Partnering to leverage the above-mentioned benefits.

Consolidating this function also provides greater opportunity for staff development, career progression opportunities, cross and up-skilling for staff. Further, this proposed function will also lead to opportunities to better distribute workload evenly, manage leave arrangements without placing additional workload pressure on individuals, and develop succession plans, which is identified as a challenge under the current structure.

Office of the Chief Finance Officer

This function will also report to the Chief Finance Officer and support them in their duties across the breadth of daily, project and strategic responsibilities. It will provide support and services across the Branch and will be a central point of coordination and communication and help drive professional development and enhancement of Branch culture. The Office will drive consistency of reporting and a focused effort to streamline and improve overall Finance Branch operations and performance.

Quarantine Fee Functions

It is noted that these functions (Waiver and Recovery) are limited life due to the nature of the COVID-19 Pandemic and existing government quarantine policy arrangements. Both functions are proposed to come into Finance Branch, with separate reporting lines due to the financial nature of their transactions.

Feedback and Next Steps

Efforts to provide quality feedback improves the level of conversation that all parties have when considering any potential alignment of function, leading to better decision-making. All feedback received is welcome, and staff are encouraged to continue to provide their feedback through formal channels in accordance with the consultation processes.

It is acknowledged that the release of a Phase two decision will be by no means the end of the journey, and that investment in staff upskilling and organisational culture will be required. It is also recognised that finetuning, and where evidenced, role assessment may be required. Further changes, for example, to team names, position titles and team structures, may be required as Finance Branch continues to grow and there is demonstrated need for change to cater for any future outcomes as part of other functional consolidation and integration reviews. Furthermore, physical location of staff is expected to remain the same pending any proposed changes flowing from the potential future organisational accommodation plan.

Options

There are two options to be considered:

1. No change (not recommended)
2. Proposed future state structure change

Option 1	No change
What	• While no change to current organisational structure is an option, findings and evidence indicate that 'no change' is not a sustainable option for the future of the Department of Health.
Scope	• Department of Health
Benefits	• Nil additional benefits. • Limitation of employee change fatigue, as there is no further organisational structure change to take place. • No disruption to employees or current work programs.
Implications	• Employee dissatisfaction due to an expectation of phase two changes.
Risks	• Missed opportunity to achieve a sustainable Department of Health structure. • Current inefficiencies and interim arrangements continue until further notice. • Employee dissatisfaction at the execution of this change process, which results in no significant change. • Loss of trust/credibility in leadership and decision makers.

Option 2 (Recommended)	Proposed future state structure
What	• This option proposes aligning the organisation's functions to a new structure that improves system sustainability and better enables the health system manager to respond to challenges and opportunities. • Where possible, whole branches are realigned to the proposed structure. • Changes to executive roles to align with the proposed structure. • A single source of truth for information that supports well-structured functions.

Option 2 (Recommended)	Proposed future state structure
Scope	**Abolish divisions and realign functions for:** • Prevention Division • COVID-19 Supply Chain Surety Division. **[Upon stand down of the pandemic] Abolish division and realign branches within:** • COVID-19 Response Division. **Establish new divisions/office:** • Clinical Planning and Service Strategy Division • Integrated Scientific, Clinical and Prevention Services Division • Office of the Chief First Nations Health Officer (previously Aboriginal and Torres Strait Islander Health Division). **Convert interim division to permanent:** • Health Capital Division • Strategy, Policy and Reform Division. **Realign:** • Functions across the department • Office of the Chief Health Officer • Office of the Director-General • Office of the Chief Operating Officer. **Create three boards of management:** • eHQ Board of Management • Health Capital Board of Management • Integrated Scientific, Clinical and Prevention Services Board of Management. **Undertake Consolidation and Integration** • of corporate support functions including implementation of the proposed model.

Option 2 (Recommended)	Proposed future state structure
Benefits	• Fosters functional collaboration and reduces silos/isolation that lead to duplication and inefficiencies. • Reliable information is readily available from a 'single source of truth'. • Enables better collaboration between teams and functions, with employees and the organisation able to realise the benefits of working together. • Greater support and development opportunities created through resilient and sustainable functions. • Separates health system planning and funding functions so that accountabilities are more independent of one another. • Greater system collaboration in investment decisions by introducing boards of management in key areas. • Establishing a dedicated division for policy development and system strategy to collaborate at national, state and other government agency-levels. • Greater end-to-end collaboration with HHSs and key stakeholders to deliver capital infrastructure projects.
Implications	• Divisional leadership positions to be reviewed and evaluated in line with the proposed changes to the organisational structure. • Proposed changes to divisions may require reporting line changes. • Employees impacted by the proposed change may experience changes to senior leadership positions. • The COVID-19 Response Division will remain as an interim division for the duration of the pandemic.
Risks	• Possible change fatigue impacting willingness of employees to participate in engagement and consultation. • The change process, if not implemented correctly, may not resolve current issues or challenges and/or may create additional issues or challenges. • Employees disagree with the proposed change.

Recommendation

It is recommended that Option 2 is progressed for the following reasons:

- Strongest alignment to the overarching vision and guiding principles
- Strongest alignment to the Department of Health strategic intent
- Strongest opportunity for the overall benefits to government.

Next steps

Date	Activity
8 August 2022	Business case for change released
8 August 2022	Consultation opens—business case for change
8 August 2022	Business case for change provided to relevant unions
5 September 2022	Consultation closes—business case for change
19 September 2022	Decision and implementation plan released

If Option 1 is pursued, then no further steps will be undertaken.

If Option 2 is pursued, an implementation timeline and plan will be released on 19 September 2022.

Supporting our people through change

We appreciate this may be a difficult time for our people. The following support activities are offered to support employees and we encourage all of our people to seek assistance if required. Below outlines the support that is available to you:

1. Benestar (Employee Assistance Service) This confidential service can be accessed through self-referral to Benestar, the external service provider. Services are available 24 hours a day, seven days per week
   - [redacted]
   - Visit the Benestar website (access codes to access Benehub wellbeing resources on Benestar's website, ID: DOHQ and Token: DOHQ01
   - Employee support and counselling – Queensland Health

2. Priority one (Employee assistance service – for QAS staff only)
   - Available 24 hour a day, seven days per week
   - Telephone: 1800 805 980

3. Your line manager and executive leadership team
4. Your union delegates.

Feedback contacts

Genuine consultation is vitally important to ensuring that we are able to collaboratively build a future structure that is able to support us in achieving the vision for the department. The feedback that you provide will go directly to the DG for consideration and decision with the Executive Leadership Team where appropriate. We invite you provide your feedback by close of business on **5 September 2022** for it to be considered.

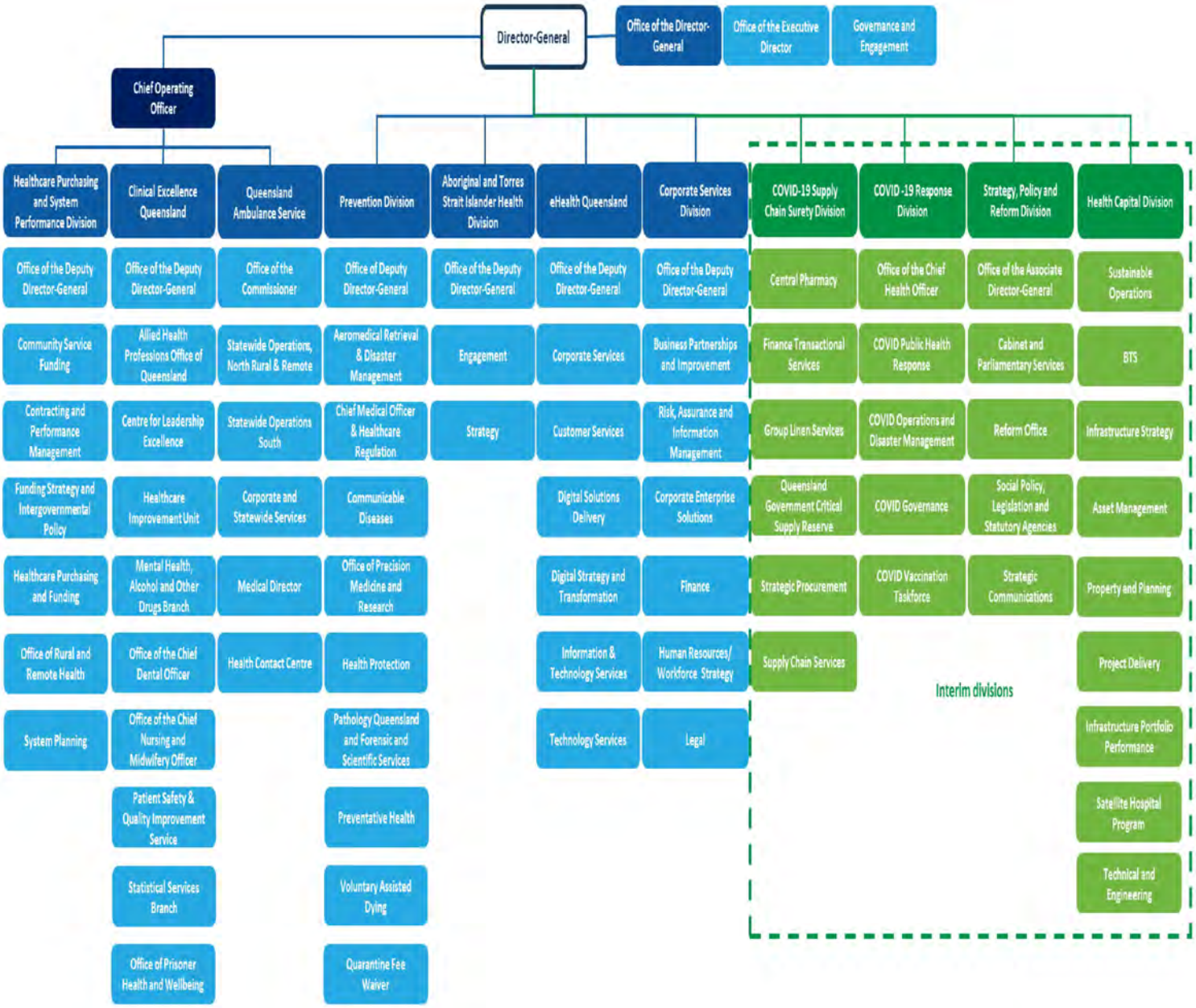
For this business case feedback **will only be accepted** via the online feedback form

We understand that not everybody has access to a computer, we do not want to take away the opportunity for you to provide feedback. If you are unable to provide feedback electronically, talk to your line manager about accessing a printed copy of the feedback form which is located on QHEPS. Hardcopy feedback forms can be provided at request.

CA-06

Attachment 2 – Organisational Charts

Department of Health Queensland
Current Organisational Structure

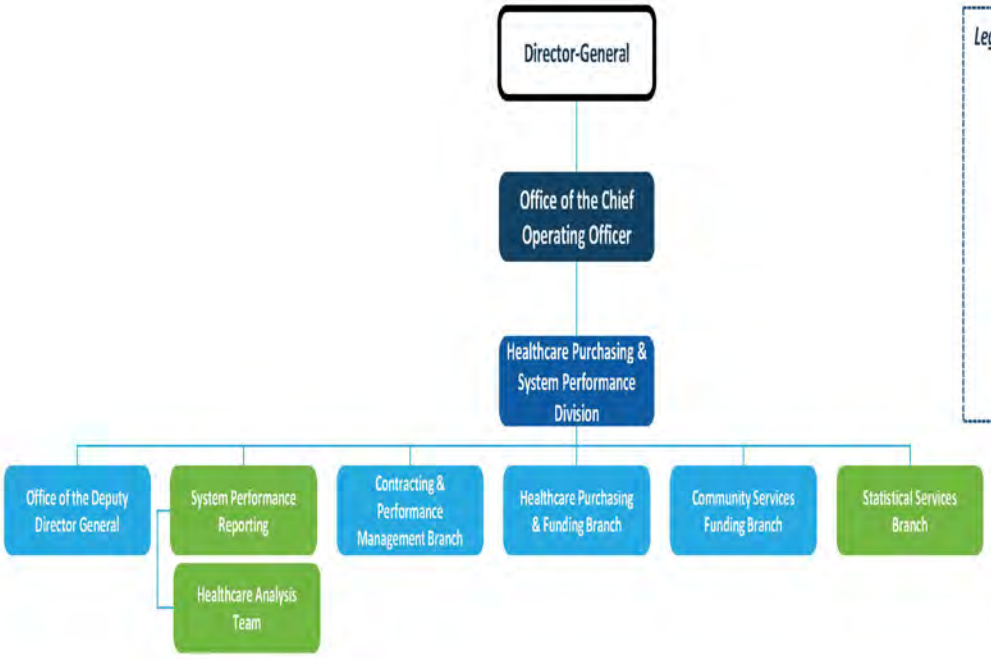


Department of Health Queensland
Proposed Organisational Structure

Note* = Name Change

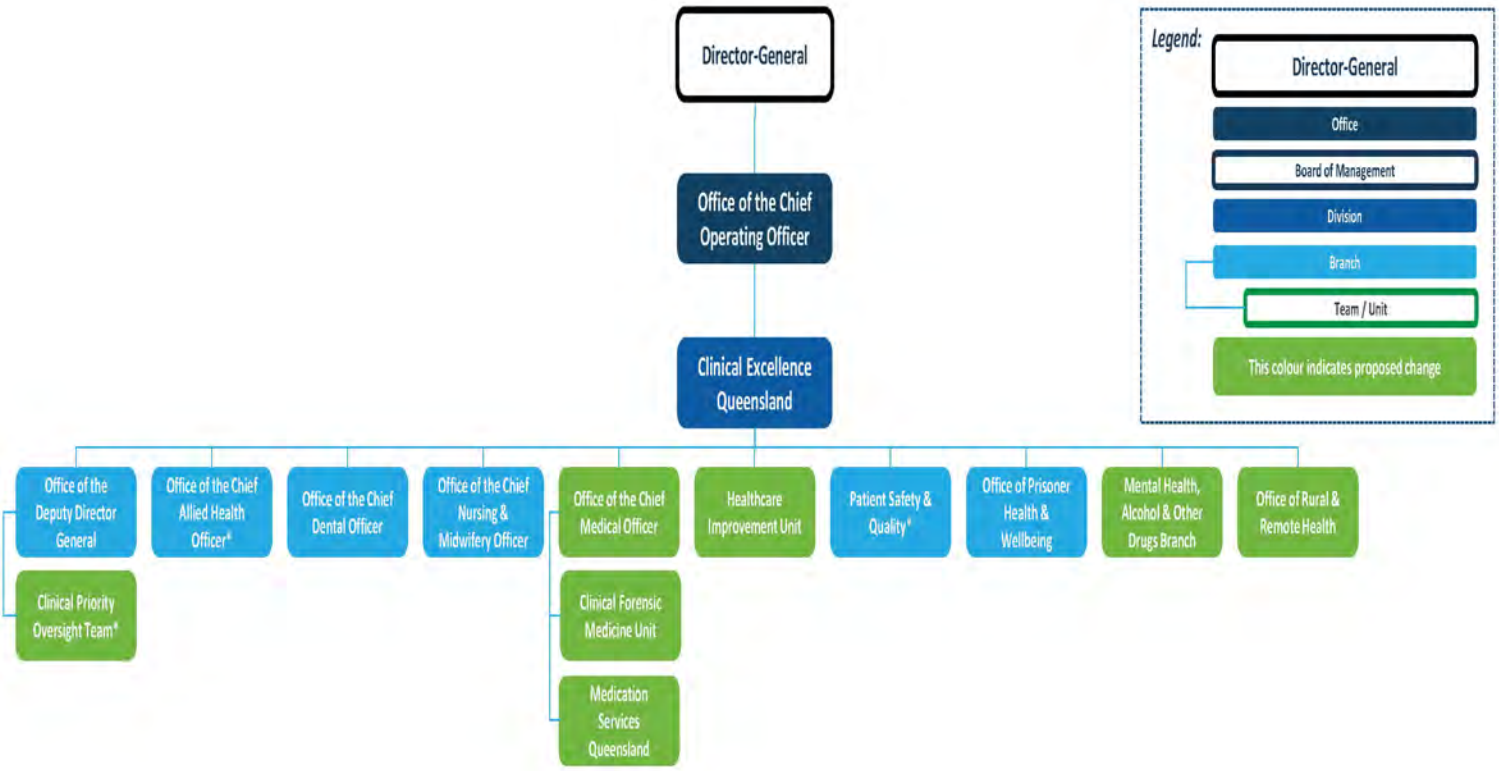
Healthcare Purchasing & System Performance Division
Proposed Organisational Structure

Note* = Name Change



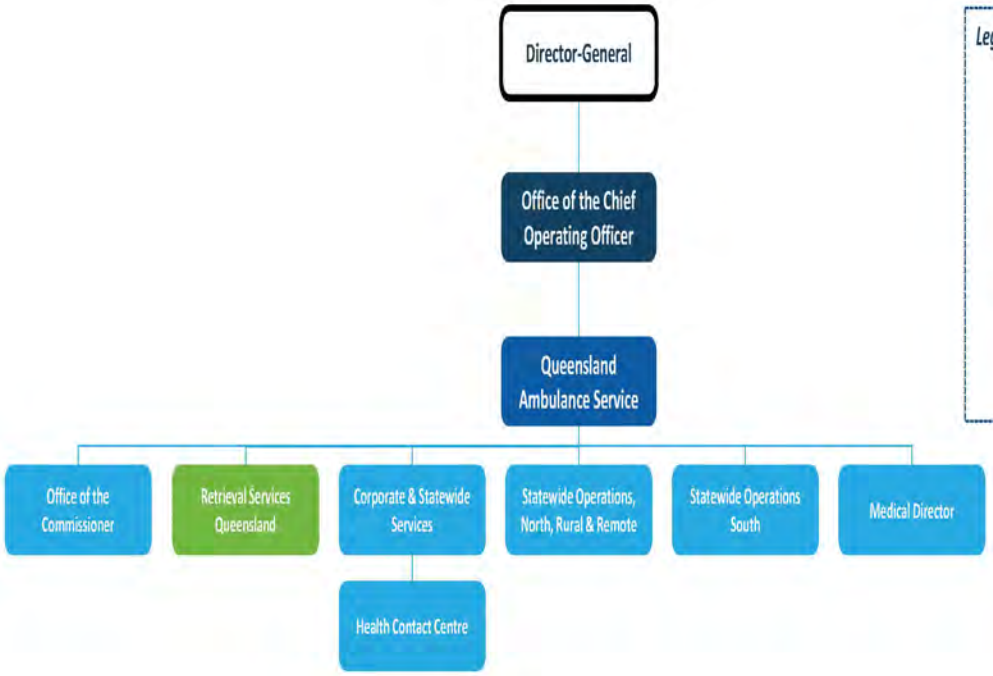
Clinical Excellence Queensland Division
Proposed Organisational Structure

Note* = Name Change



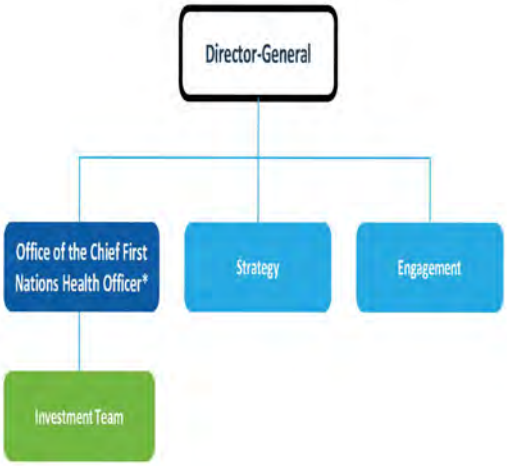
Queensland Ambulance Service Division
Proposed Organisational Structure

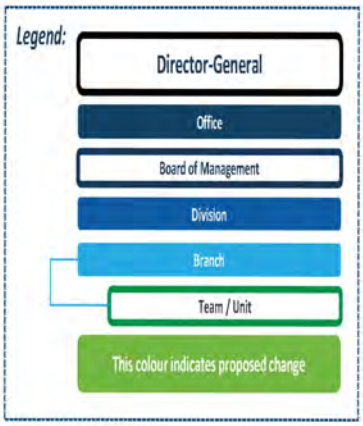
Note* = Name Change



Office of the Chief First Nations Health Officer*
Proposed Organisational Structure

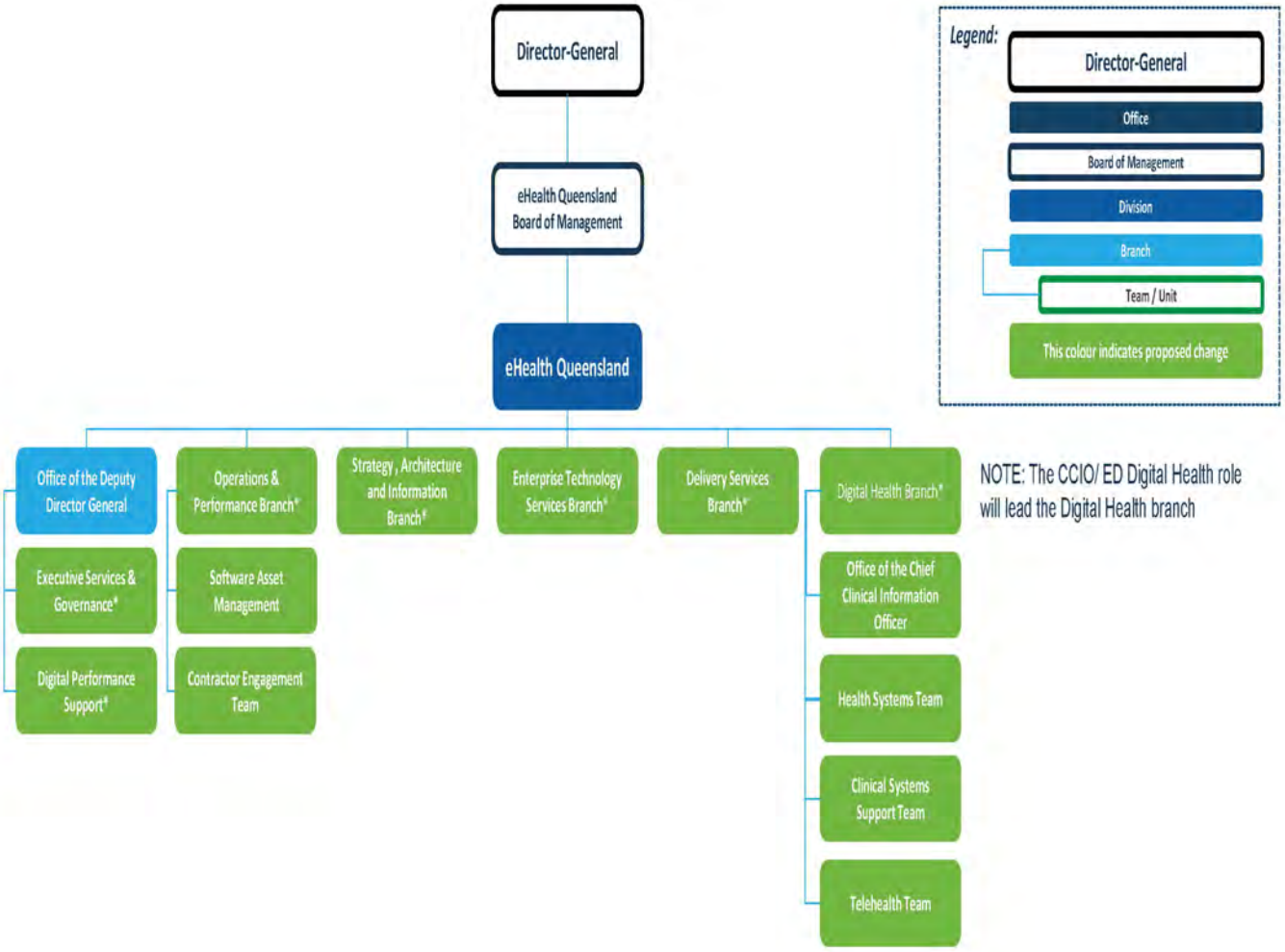
Note* = Name Change





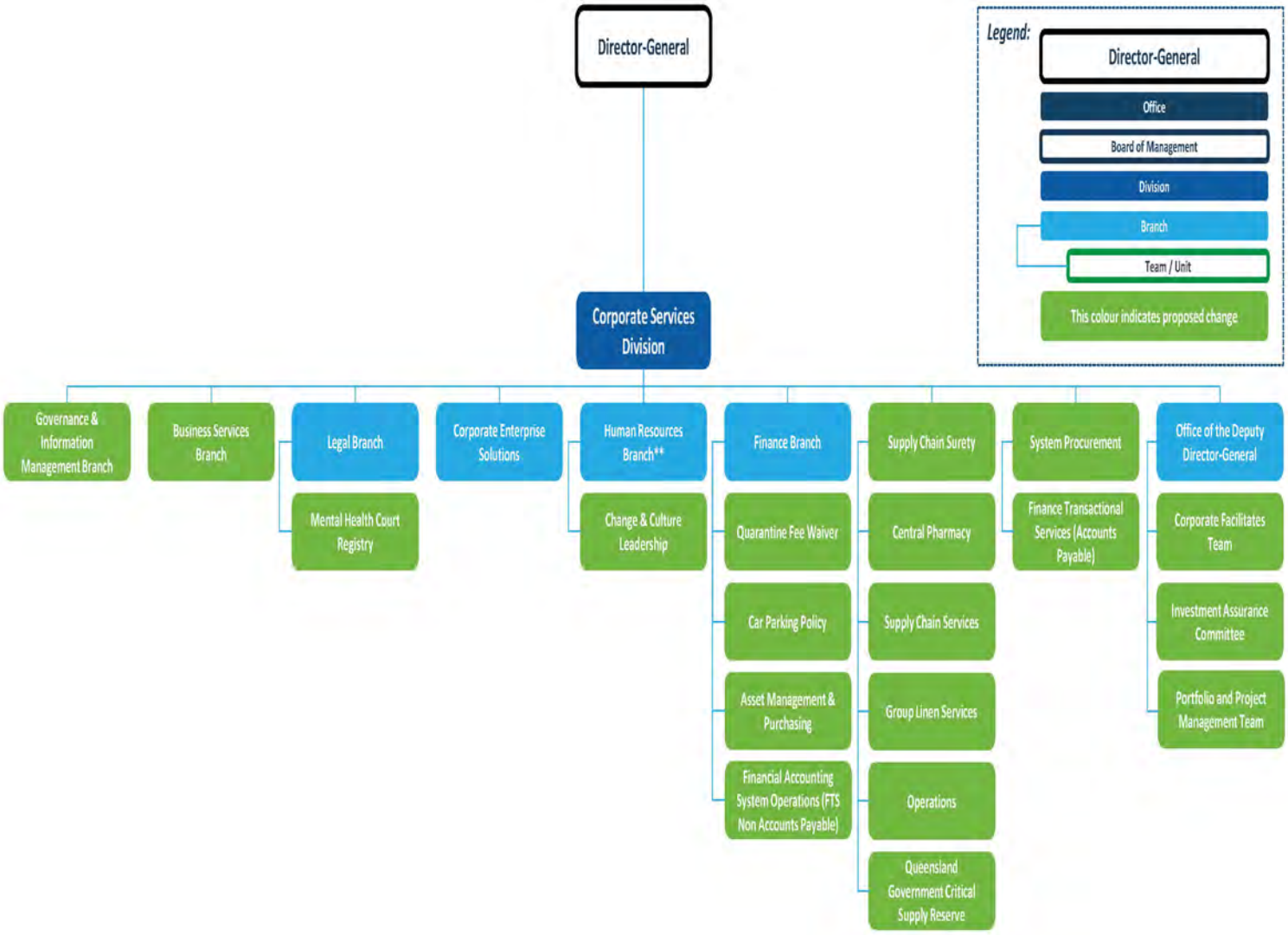
eHealth Queensland Division
Proposed Organisational Structure

Note* = Name Change



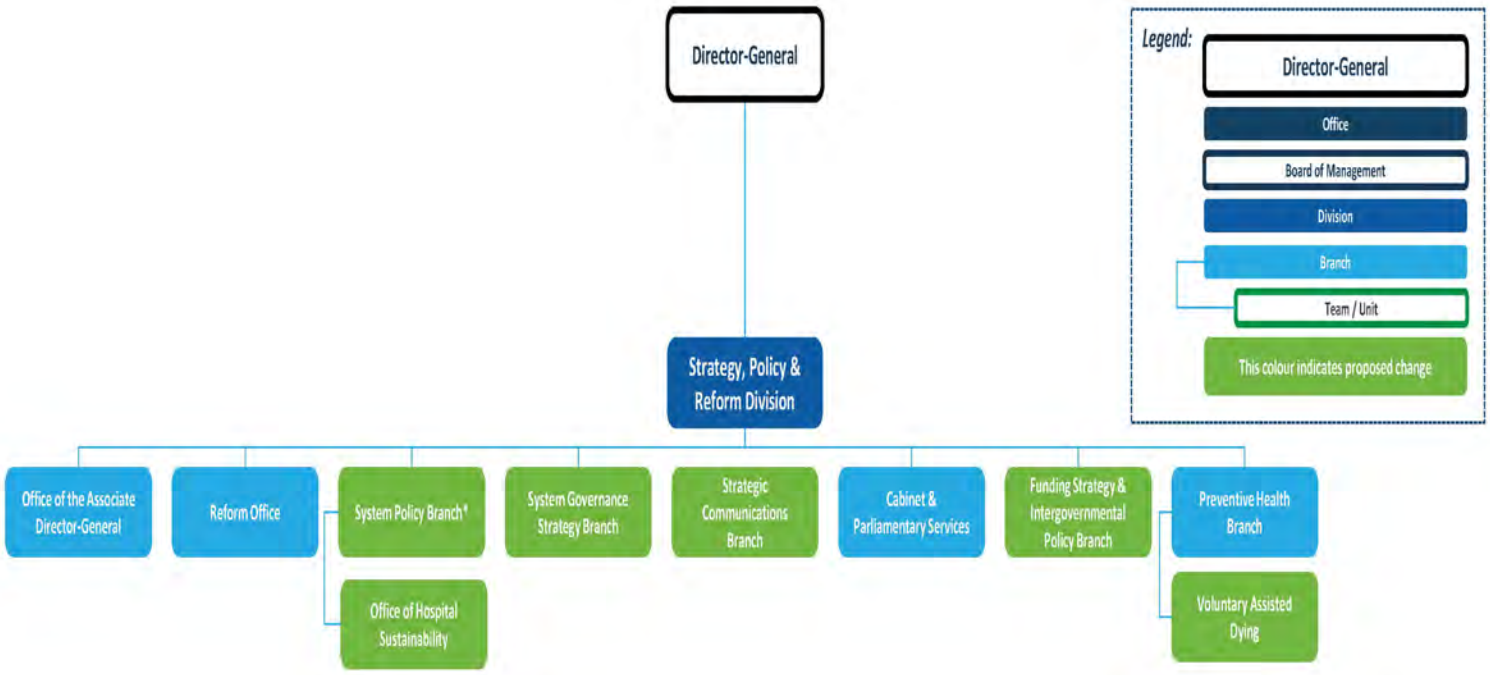
Corporate Services Division
Proposed Organisational Structure

Note* = Name Change
**= *See Section 2, Human Resources*



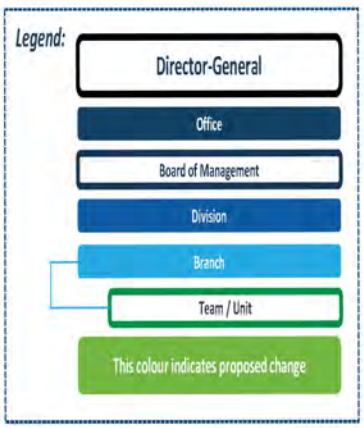
Strategy, Policy & Reform Division
Proposed Organisational Structure

Note* = Name Change

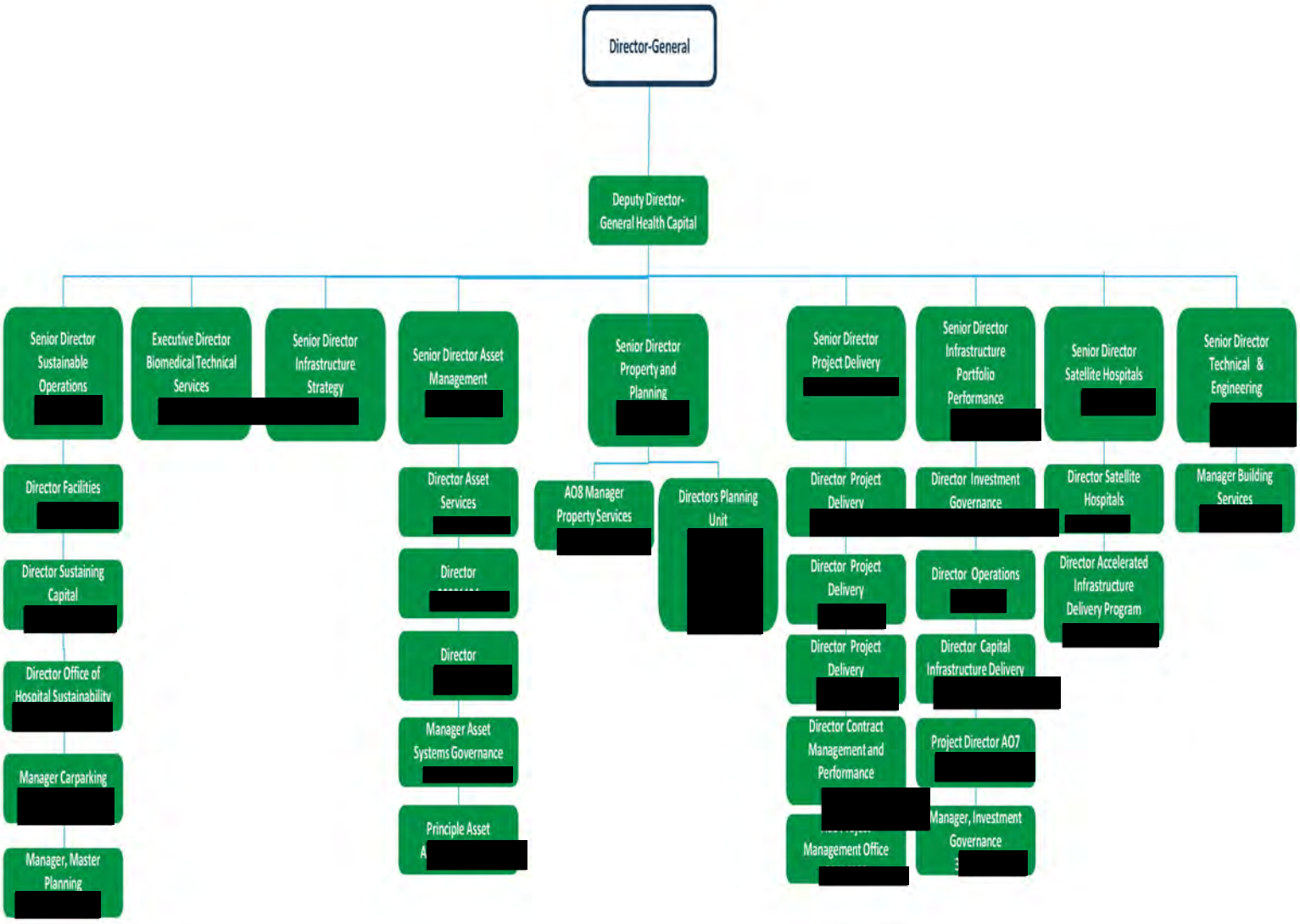


Office of the Chief Operating Officer
Proposed Organisational Structure

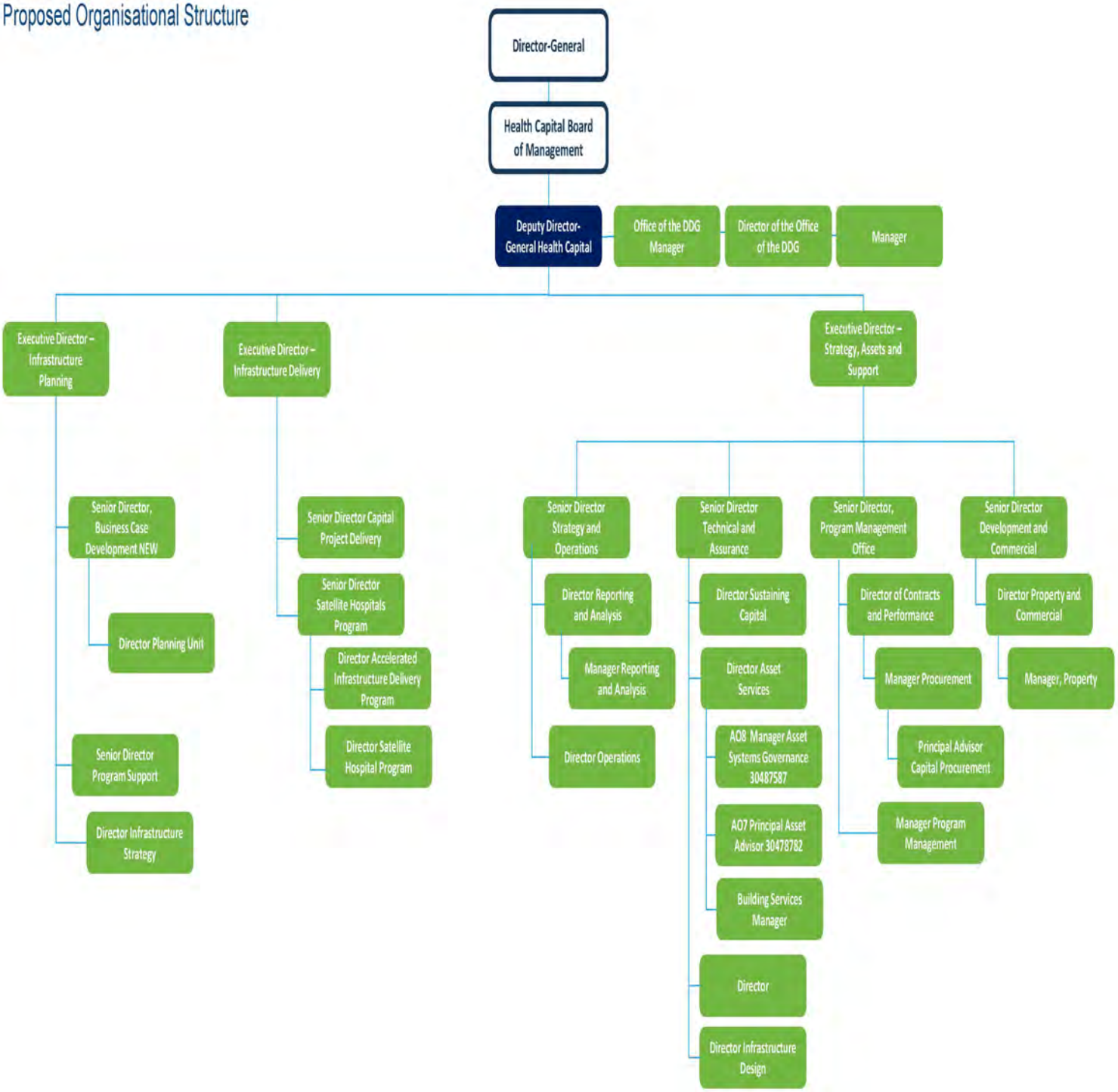
Note* = Name Change

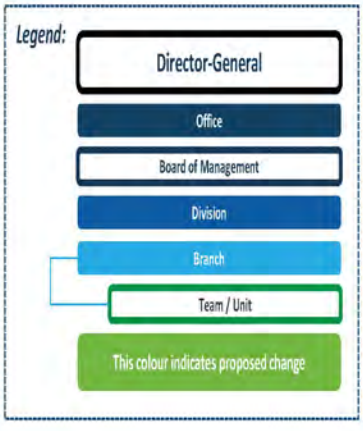


Health Capital Division
Current state Organisational Structure



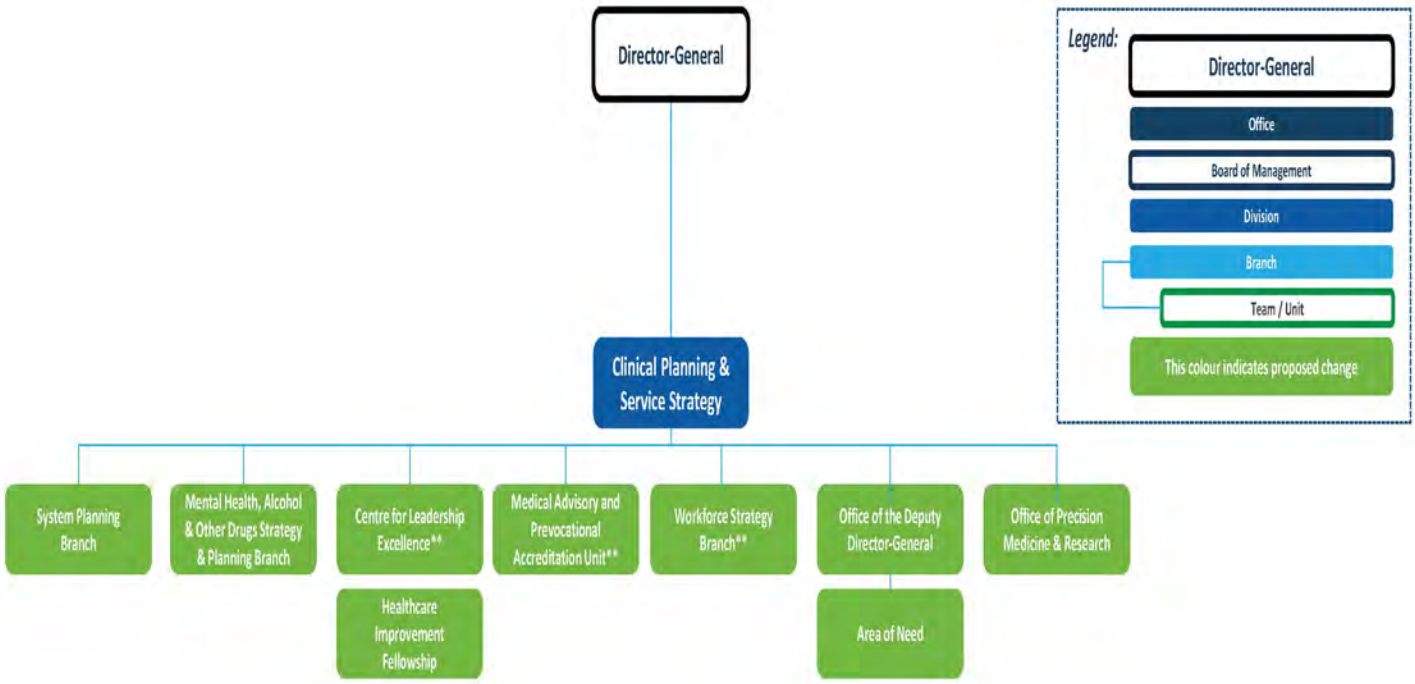
Health Capital Division
Proposed Organisational Structure





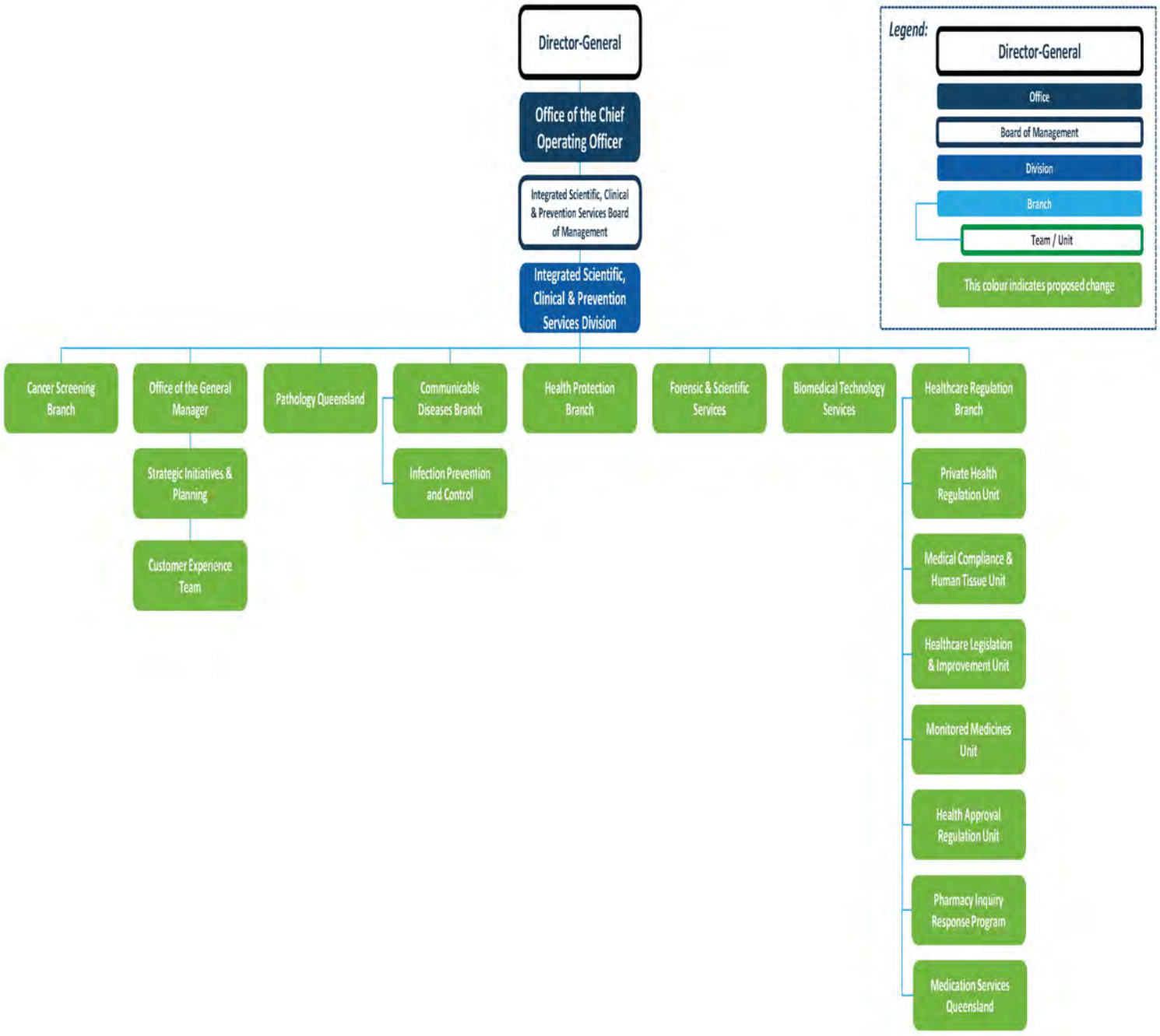
Clinical Planning & Service Strategy Division
Proposed Organisational Structure

Note* = Name Change
Note** = Reports to the new role ADDG Workforce Strategy



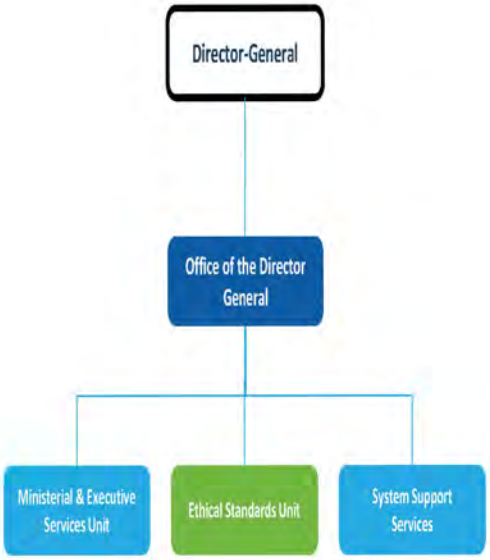
Integrated Scientific, Clinical & Prevention Services Division*
Proposed Organisational Structure

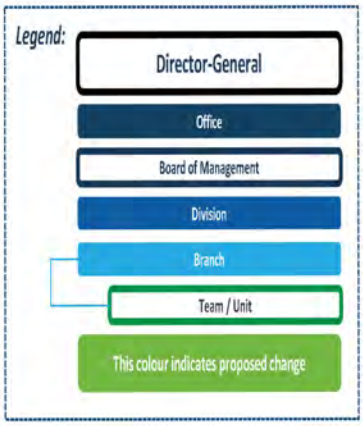
Note* = Name Change



Office of the Director General
Proposed Organisational Structure

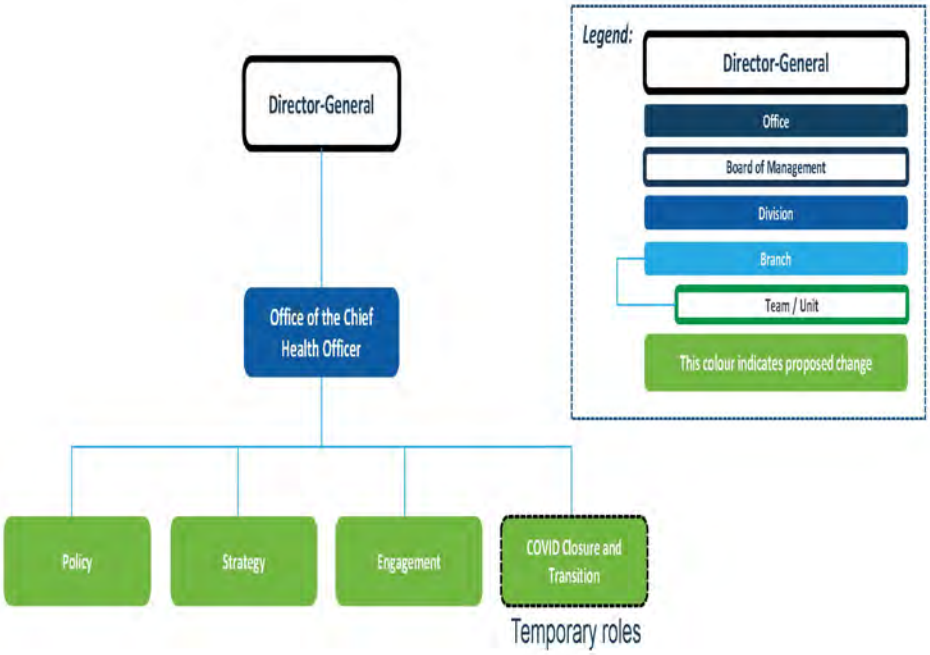
Note* = Name Change





Office of the Chief Health Officer
Proposed Organisational Structure

Note* = Name Change



Section 2

Consolidated and Integration

Organisational Structures

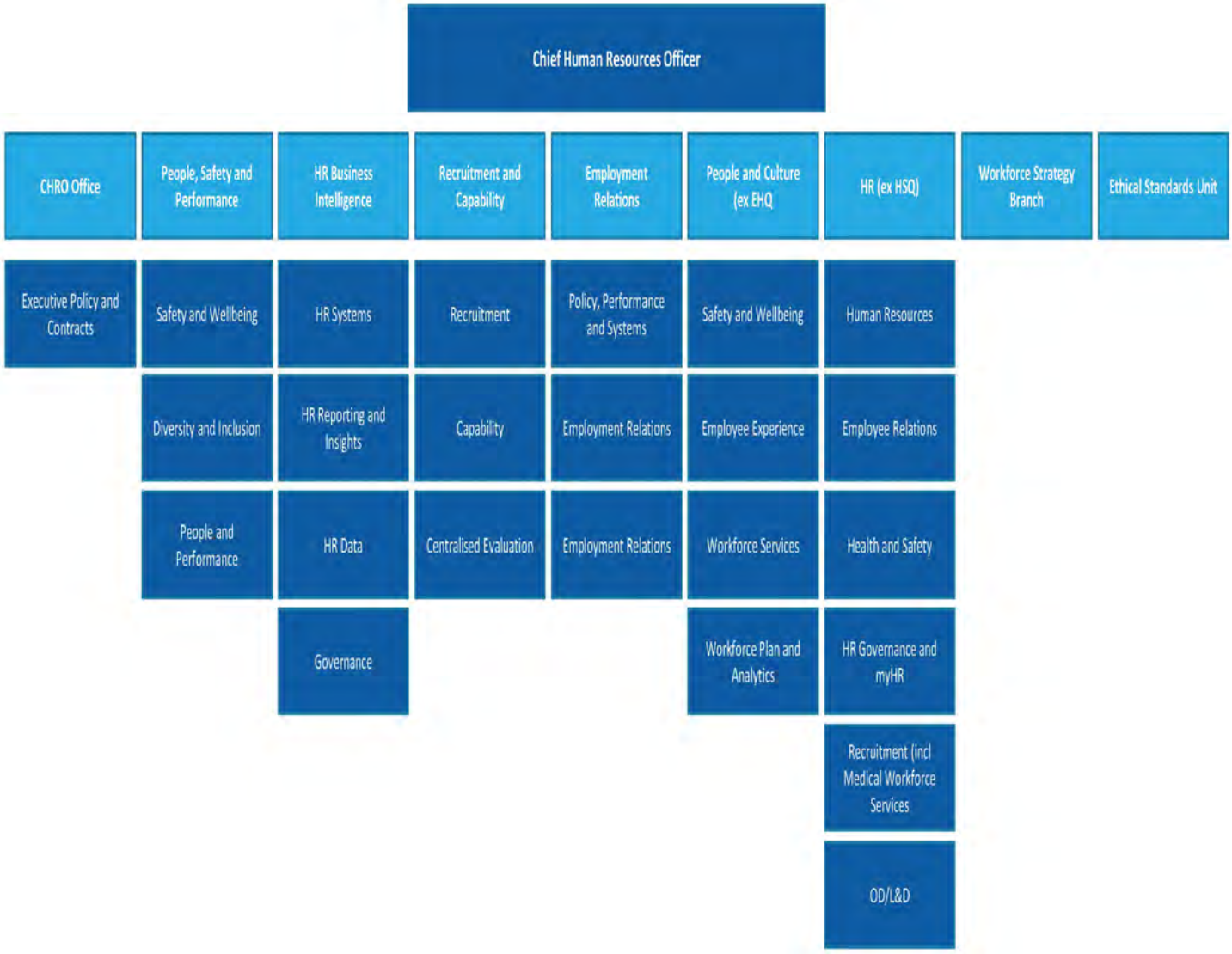
Queensland Health

Human Resources

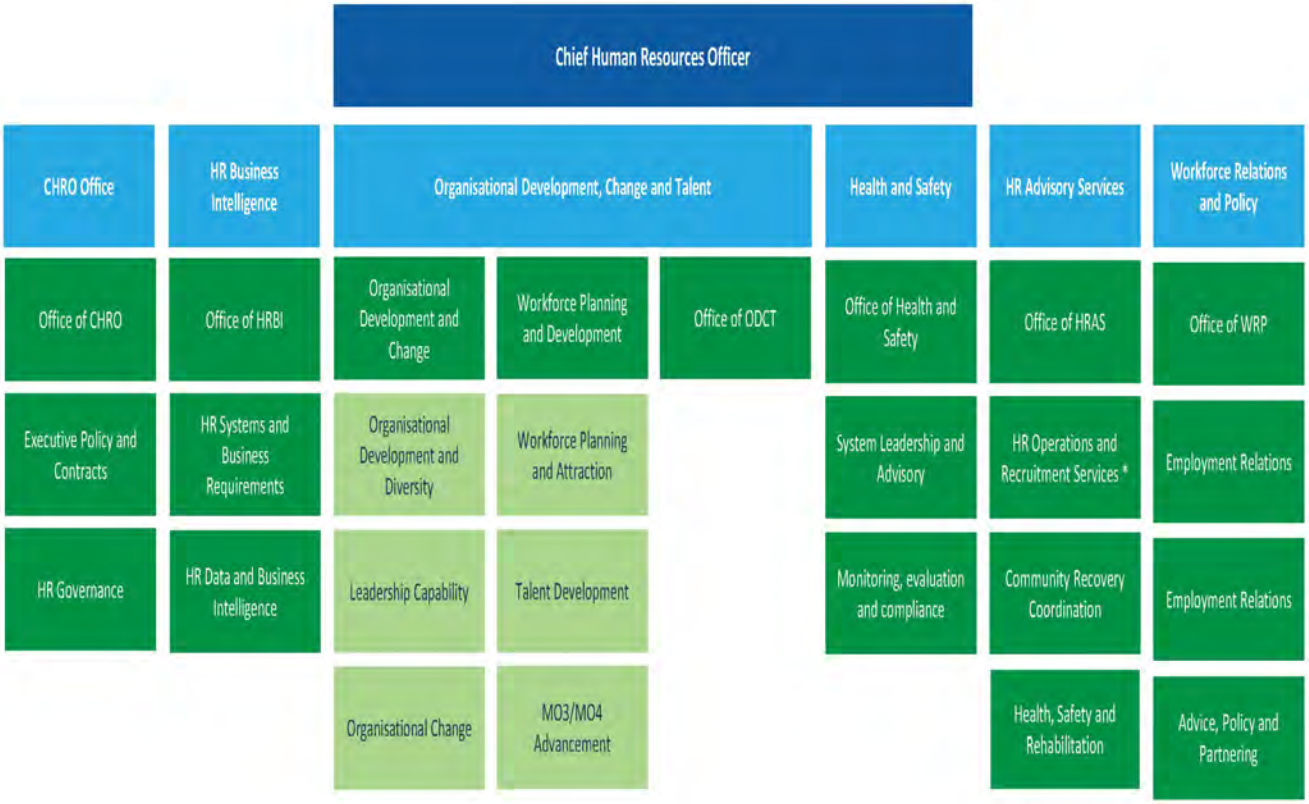
Organisational Structures

Queensland Government

Human Resources Branch
Current Organisational Structure



Human Resources Branch
Proposed Organisational Structure



Workforce Strategy Branch is proposed to move to Clinical Planning and Service Strategy Division

Ethical Standards Unit is proposed to move to ODG

Contractor Engagement Team is proposed to move to eHQ

*** Medical credentialing function** is proposed to move to Clinical Excellence Queensland

Human Resources Branch

Office of the Chief Human Resources Officer

Current Structure

- Executive Policy and Contracts
  - Director (SO) [redacted]
  - Principal Advisor (AO7) [redacted]
  - Senior Advisor (AO6) [redacted]
  - Senior Advisor (AO6) [redacted]

Proposed Structure

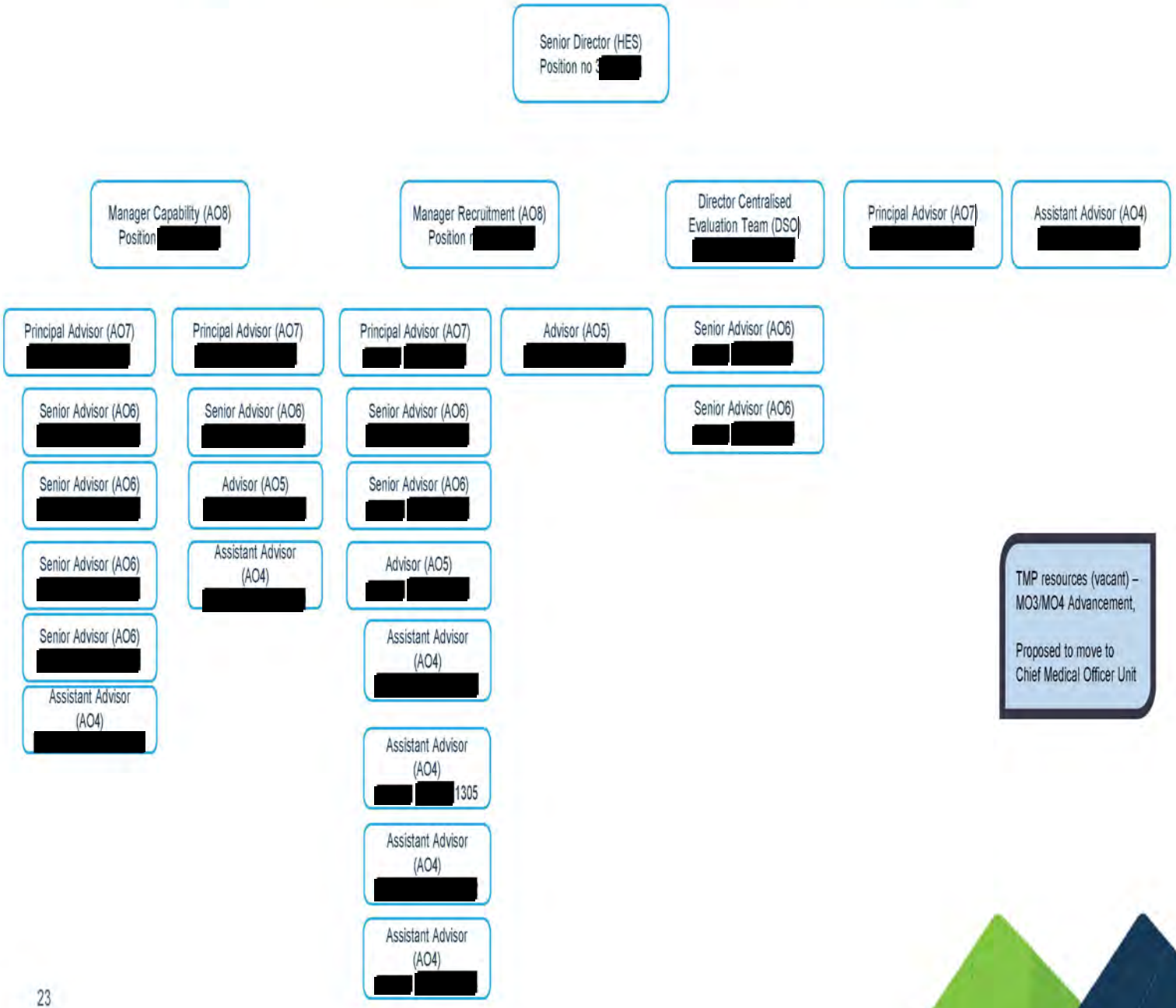
- Executive Policy and Contracts
  - Director (SO) [redacted]
  - Principal Advisor (AO7) [redacted]
  - Senior Advisor (AO6) [redacted]
  - Senior Advisor (AO6) [redacted]
- HR Governance
  - Manager (AO8) [redacted]
  - HR Governance Advisor (AO5) [redacted]

Relinquished Officer [redacted]

Seconded Out [redacted]

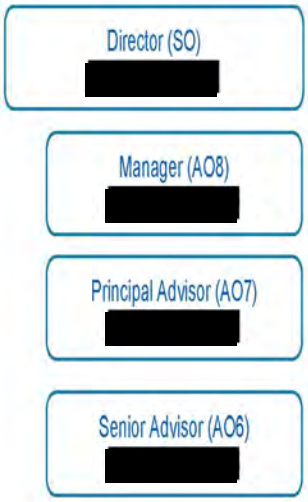
Human Resources Branch

Current structure – Recruitment and Capability Unit



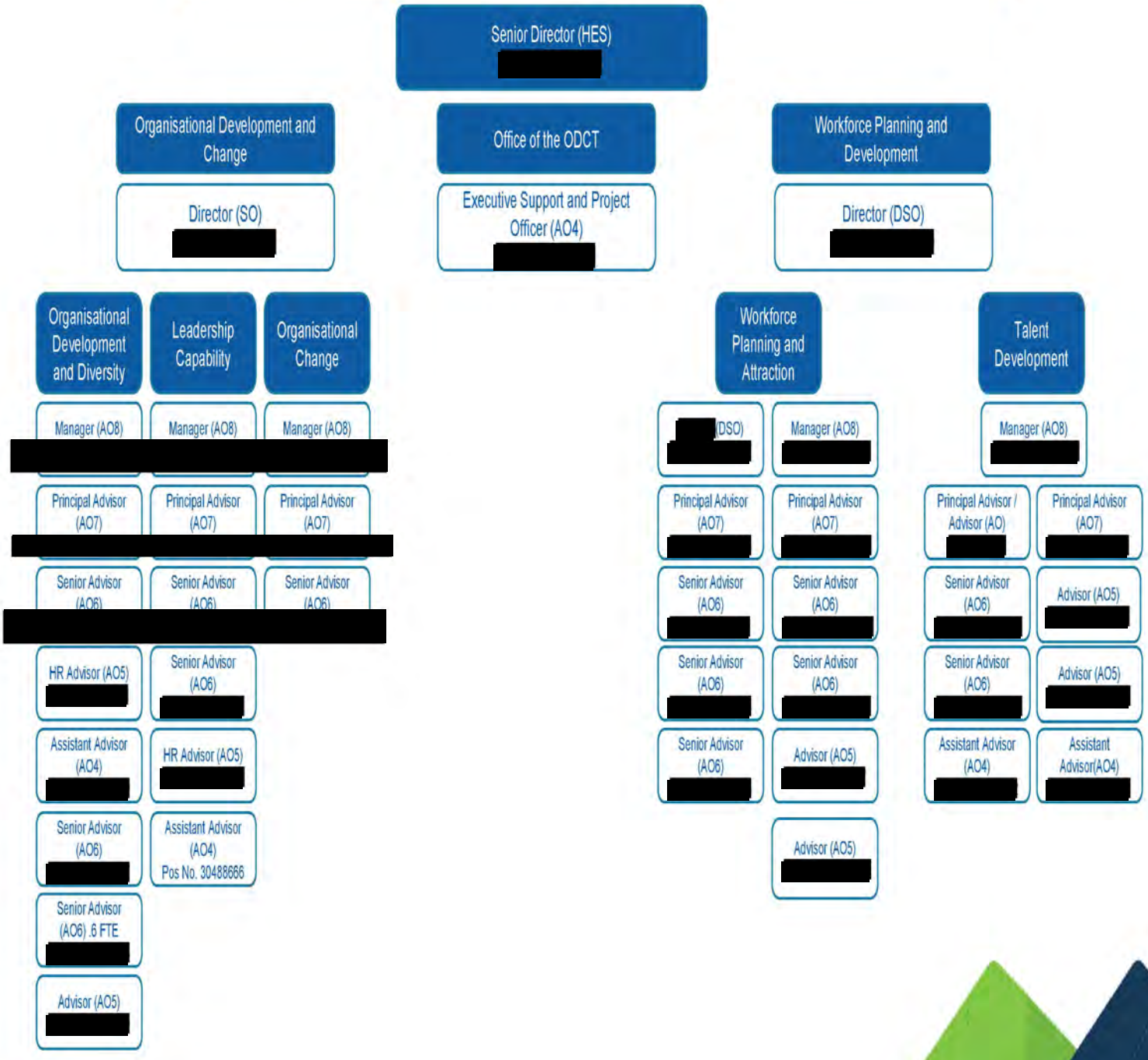
Business Partnership and Improvement Branch

Current structure – Change and Culture Leadership Unit

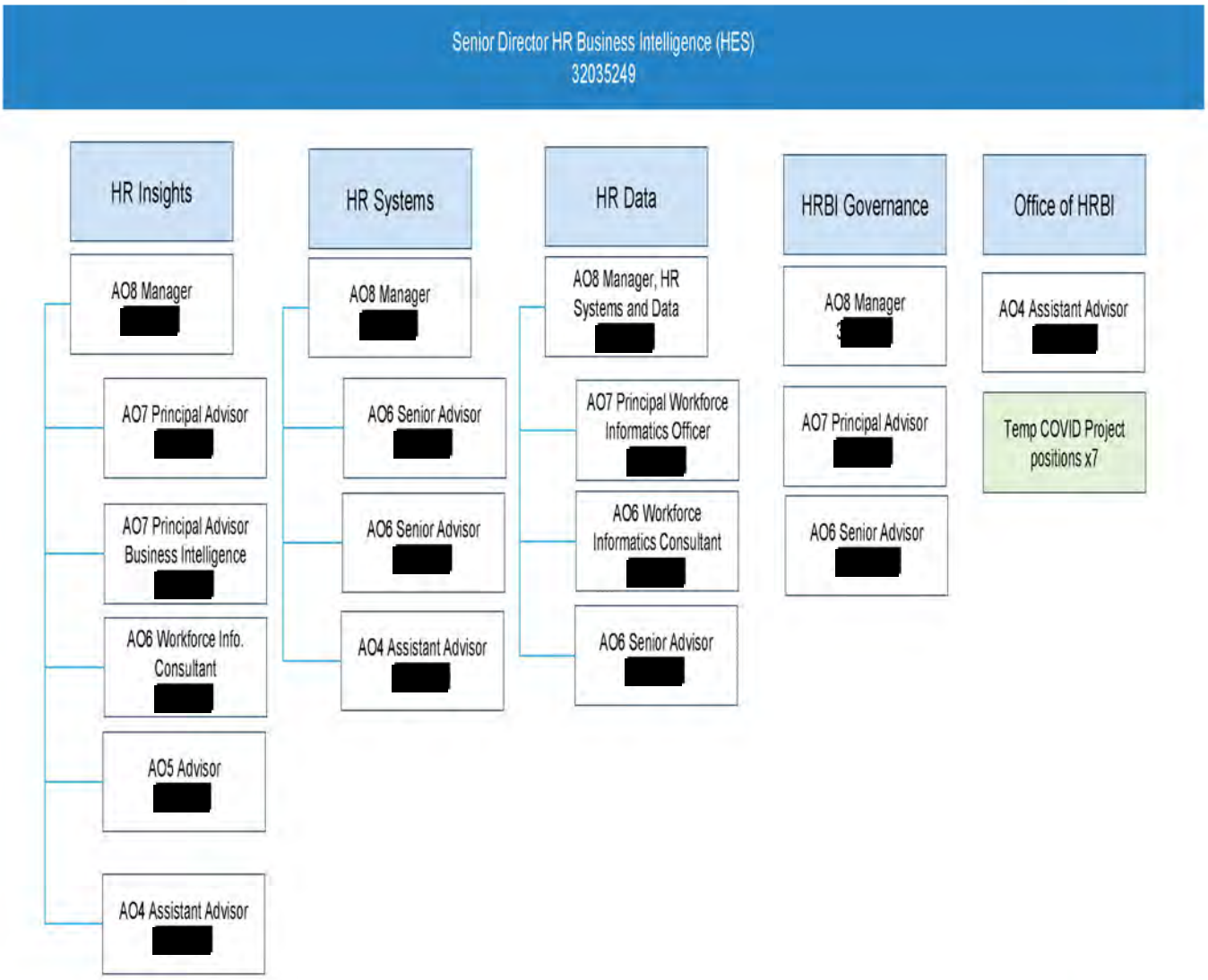


Human Resources Branch

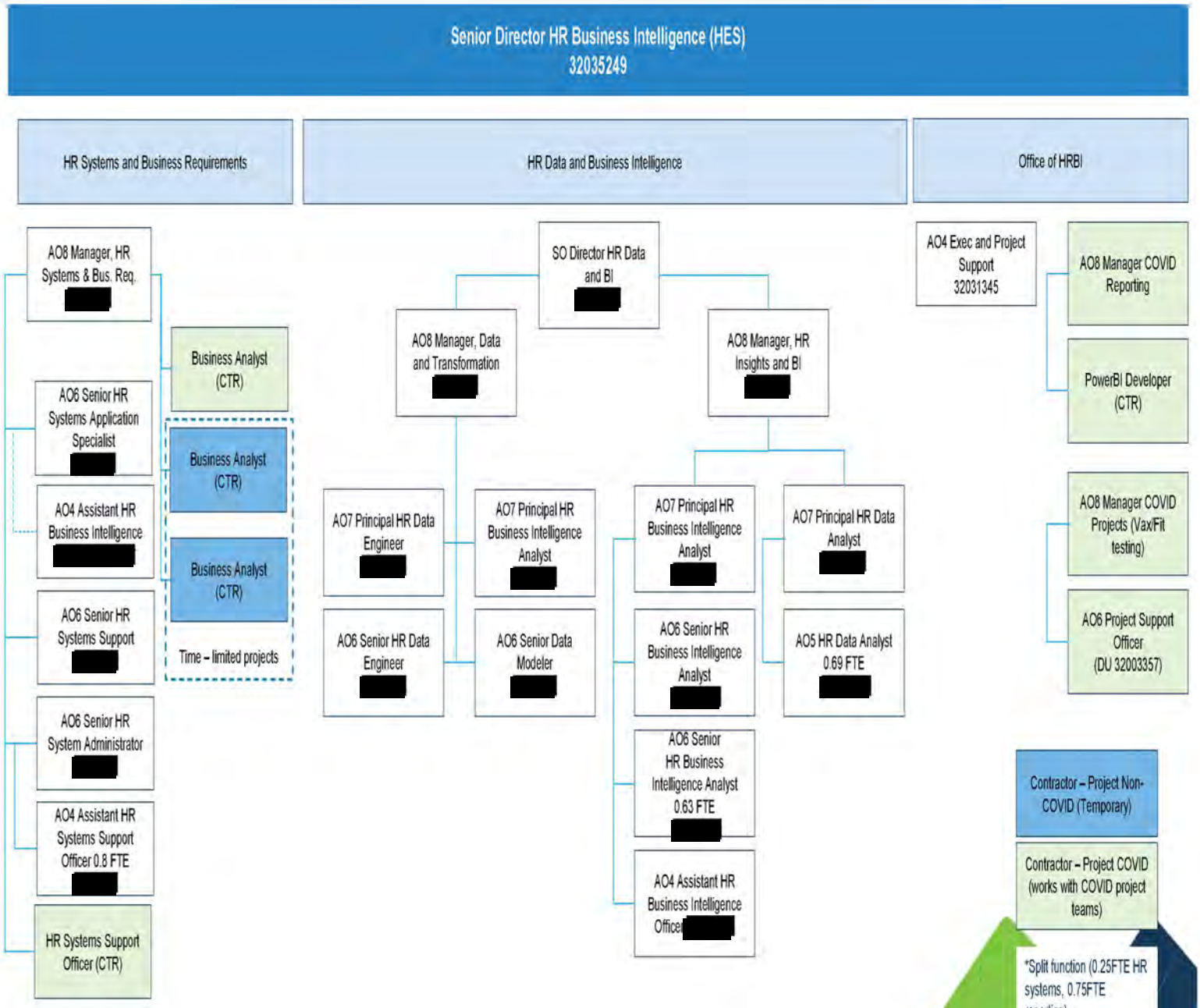
Proposed Structure – Organisational Development, Change and Talent



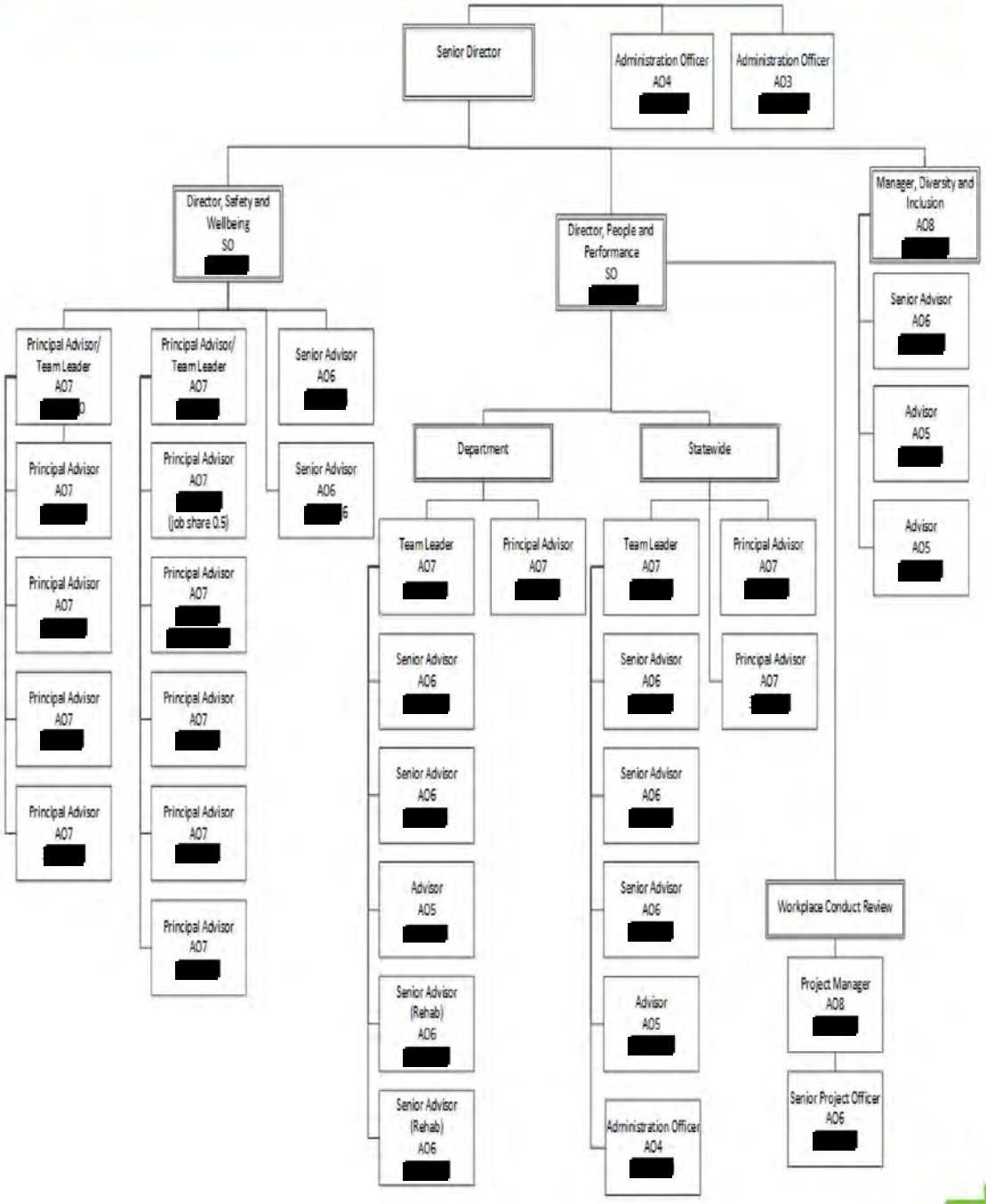
Current structure – HR Business Intelligence



Proposed structure – HR Business Intelligence

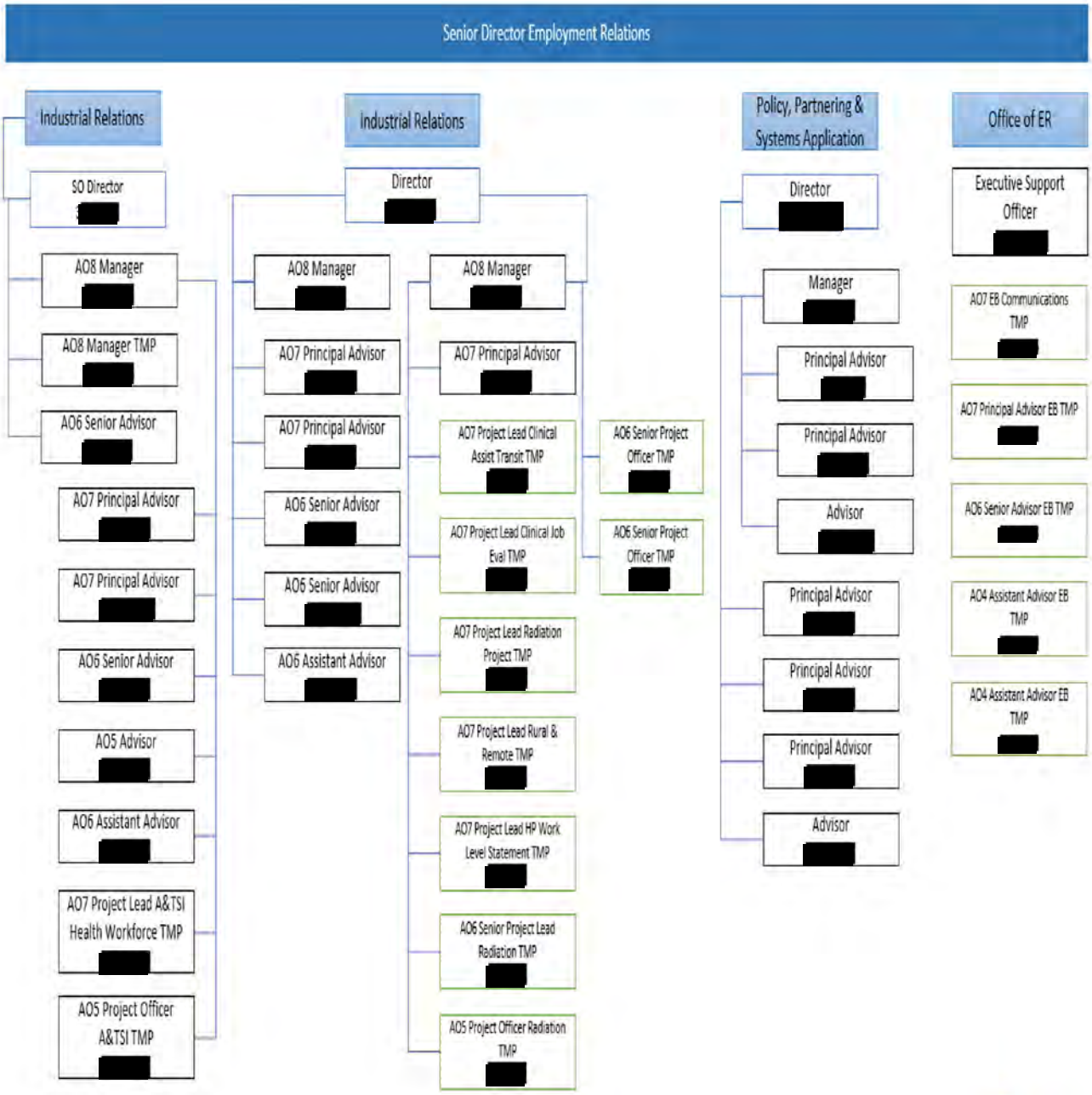


Current structure – People, Safety and Performance



Proposed structure – Health and Safety

Current structure – Employment Relations



Human Resources Branch

Workforce Relations and Policy

Senior Director
Workforce Relations and Policy (HES2)
[redacted]

Employment Relations

Change to team title only

Employment Relations

Change to team title only

Advice, Policy and Partnering

Change to team title only

People and Performance

Director (SO)
[redacted]

- Team Leader (AO7) [redacted]
- Senior Advisor (AO6) [redacted]
- Senior Advisor (AO6) [redacted]
- Senior Advisor (AO6) [redacted]
- Senior Advisor (AO6) [redacted]
- Senior Advisor (AO6) [redacted]
- Senior Advisor (AO6) [redacted]
- Advisor (AO5) [redacted]
- Principal Advisor (AO7) [redacted]
- [redacted]
- AO7 HR Principal Advisor [redacted]
- Project Manager – Workplace Conduct (AO8) (TMP) [redacted]
- Senior Project Officer – Workplace Conduct (AO6) (TMP) [redacted]
- Asst Project Officer temp (COVID AO4) [redacted]

Office of WRP

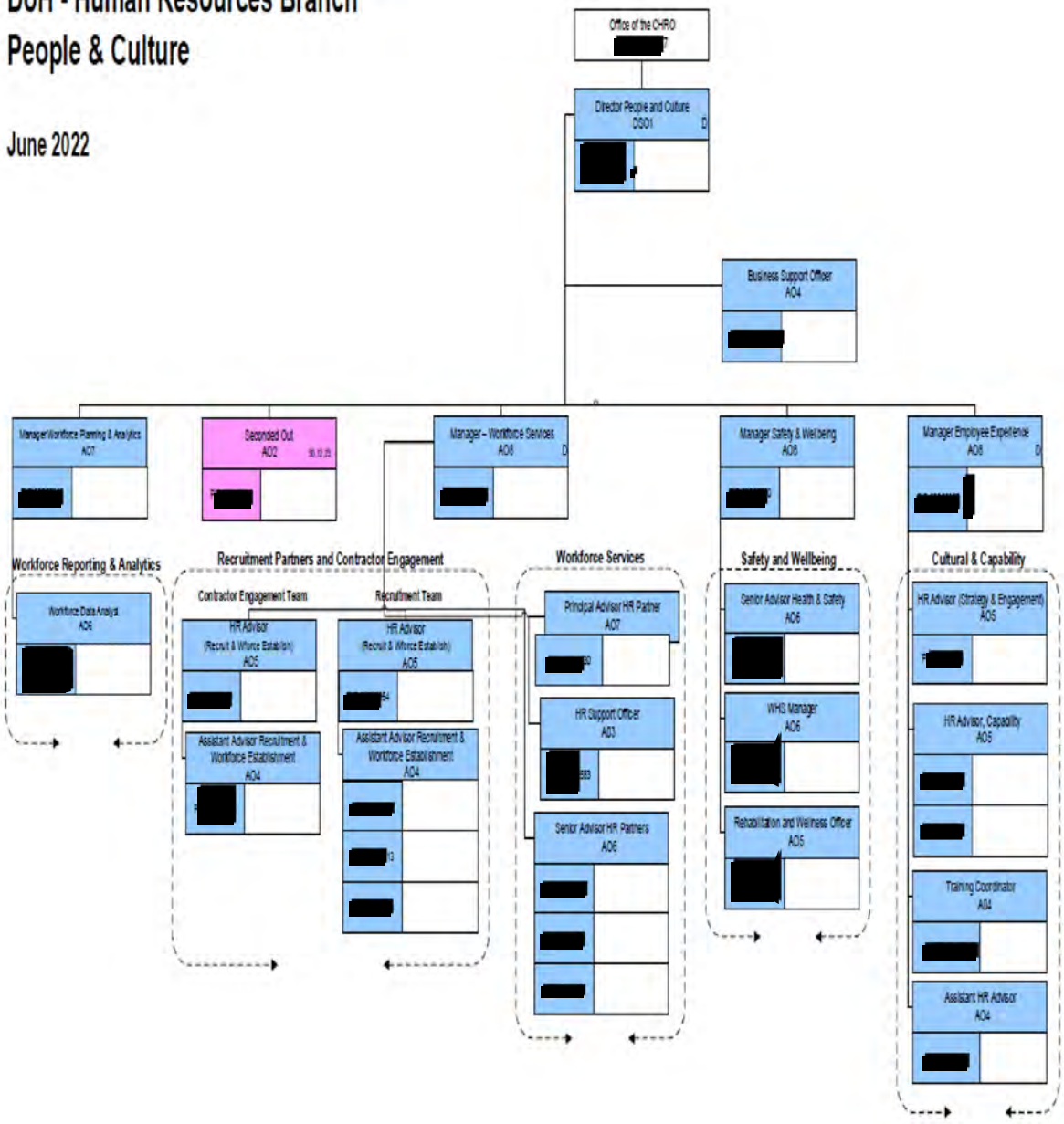
Existing plus -

- Advisor (AO5) [redacted]
- Administration Officer (AO3) [redacted]

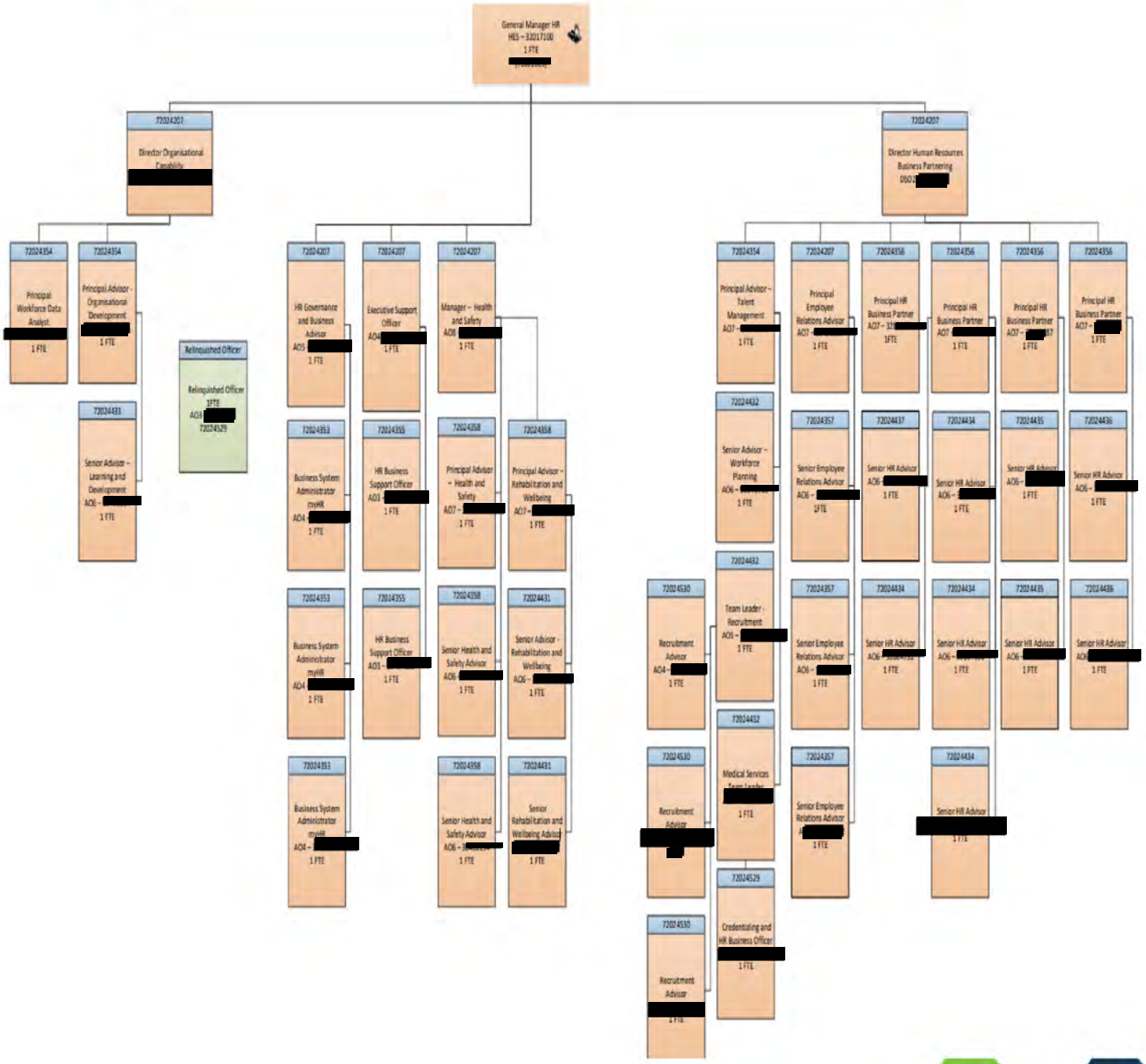
Current structure – People and Culture eHealth Queensland

DoH - Human Resources Branch
People & Culture

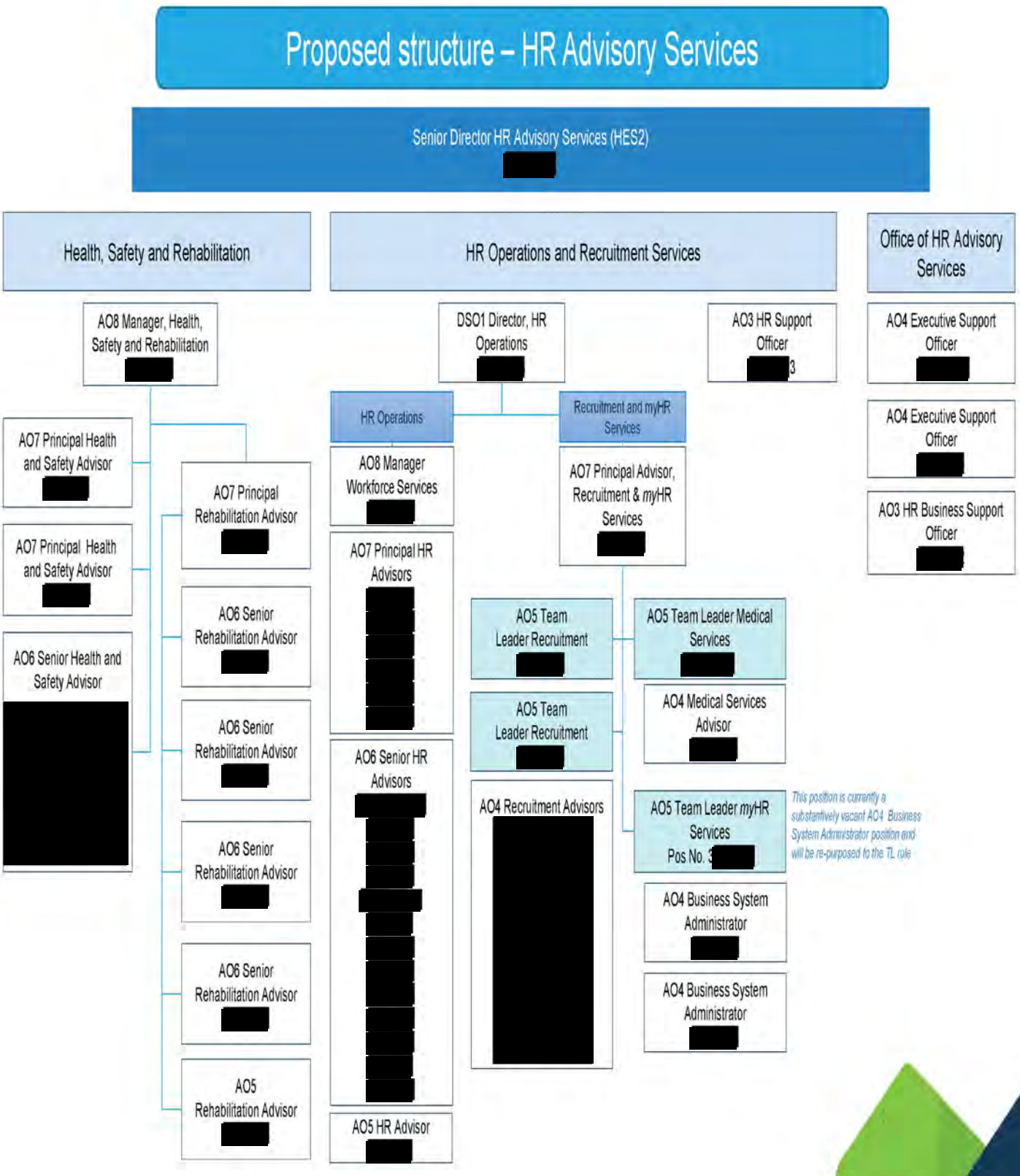
June 2022



Current structure – Health Support Queensland Human Resources



Proposed structure – HR Advisory Services



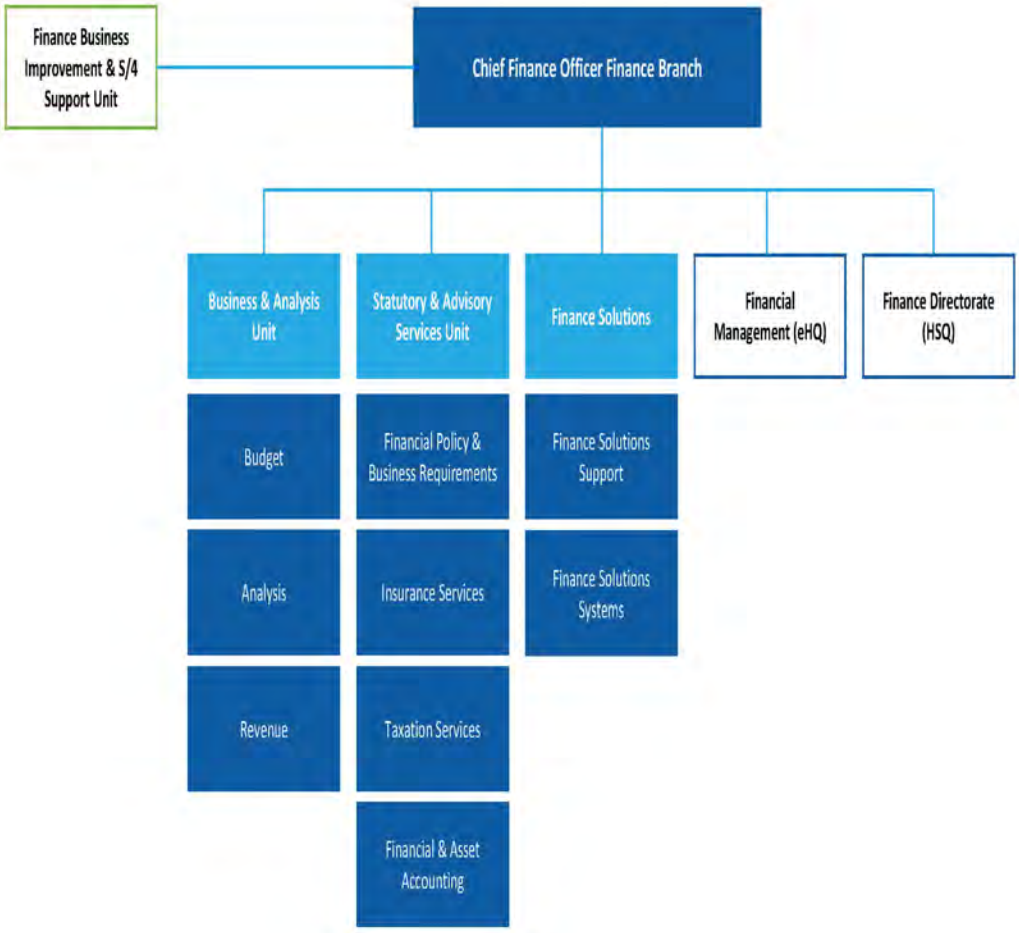
Queensland Health

Finance

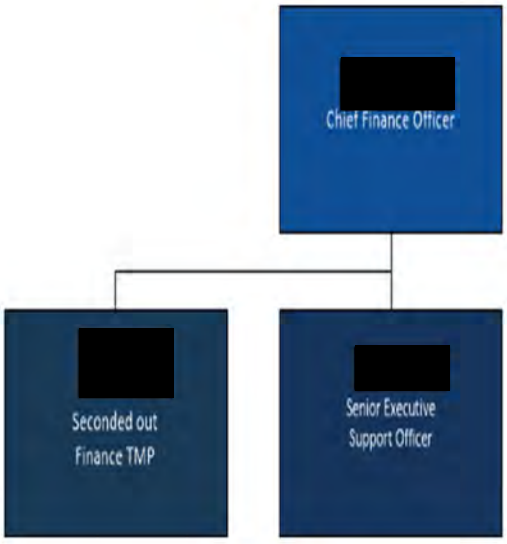
Organisational Structures

Queensland Government

Finance Branch
Current Organisational Structure



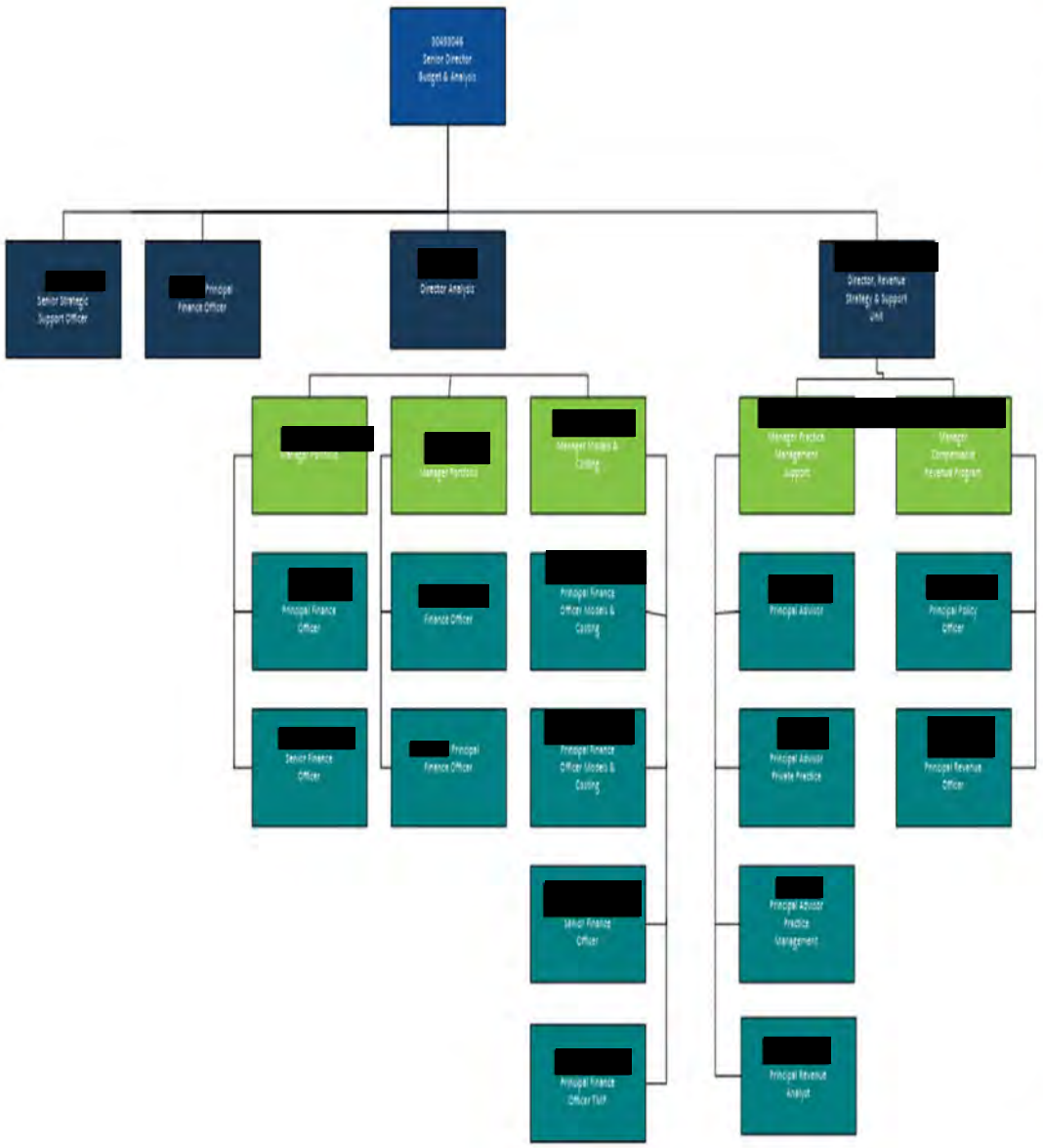
Finance Branch - Executive
Current Organisational Structure



Position	Position Title
Executive and Project	
[redacted]	Chief Finance Officer
	Senior Executive Support Officer
	Seconded out Finance TMP
	Seconded out Finance TMP

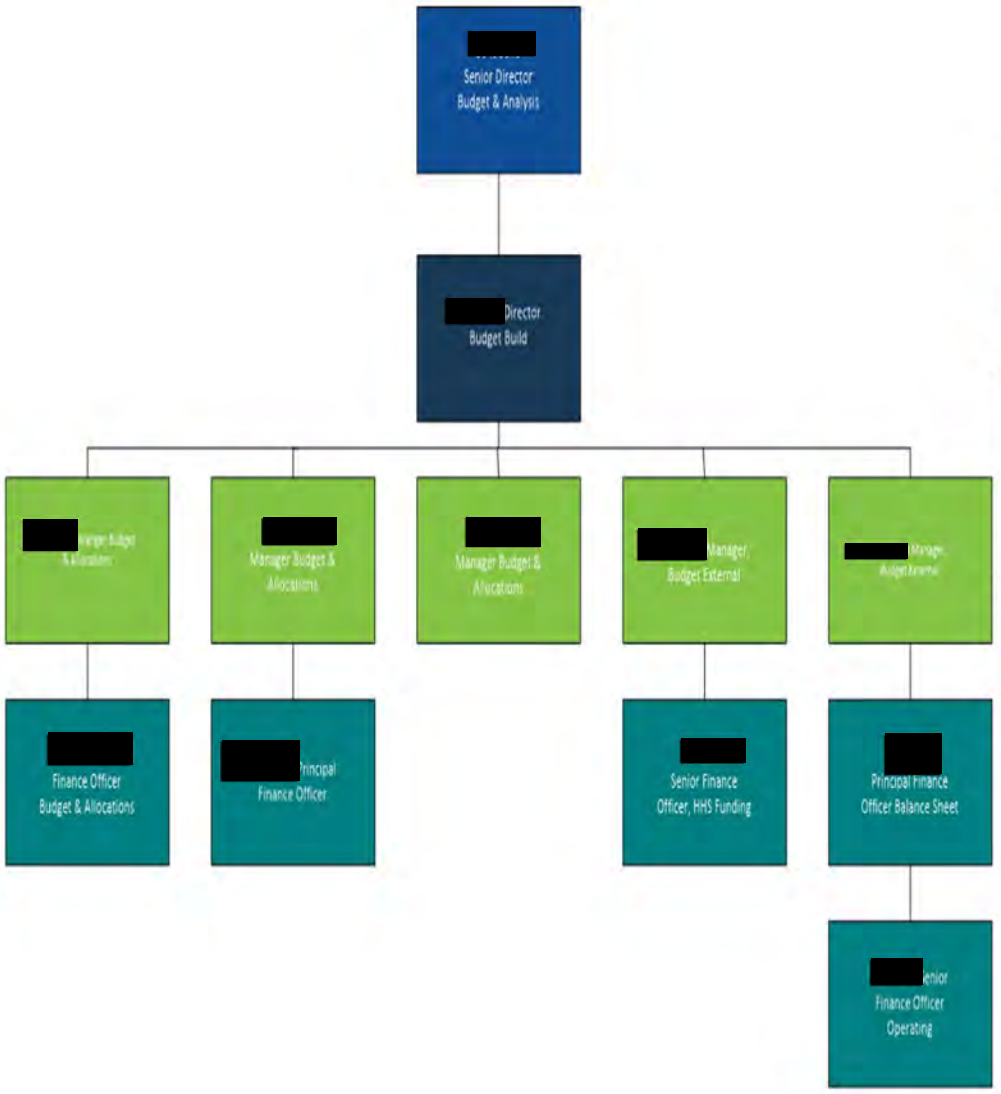
Finance Branch – Budget and Analysis Unit (Revenue Team and Analysis Team)

Current Organisational Structure



Position	Position Title
[redacted]	Senior Director, Budget & Analysis
	Principal Finance Officer
	Senior Strategic Support Officer
Analysis Team	
[redacted]	Director, Analysis
Financial Performance Monitoring Team	
[redacted]	Manager, Portfolio
	Manager, Portfolio
	Principal Finance Officer
	Senior Finance Officer
	Finance Officer
	Principal Finance Officer
Models and Costing Team	
[redacted]	Manager, Models & Costing
	Principal Finance Officer, Models & Costing
	Principal Finance Officer, Models & Costing
	Senior Finance Officer
	Principal Finance Officer TMP
Revenue Team	
[redacted]	Director, Revenue Strategy & Support Unit
Practice Management Program Team	
[redacted]	Manager, Practice Management Support
	Principal Advisor 19(2)
	Principal Advisor - Private Practice
	Principal Advisor, Practice Management
	Principal Revenue Analyst
Compensable Revenue Team	
[redacted]	Manager, Compensable Revenue Program
	Principal Policy Officer
	Principal Revenue Officer (GP Clause)
	Principal Revenue Officer

Finance Branch – Budget and Analysis Unit (Budget Team)
Current Organisational Structure



Position	Position Title
Budget Team	
[redacted]	Director, Budget Build
Budget Build Internal Team	
[redacted]	Manager, Budget & Allocations
	Manager, Budget & Allocations
	Manager, Budget & Allocations
	Principal Finance Officer
[redacted]	Finance Officer, Budget & Allocations
Budget Build External Team	
[redacted]	Manager, Budget External
	Manager, Budget External
	Principal Finance Officer, Balance Sheet
	Senior Finance Officer, HHS Funding
	Senior Finance Officer, Operating

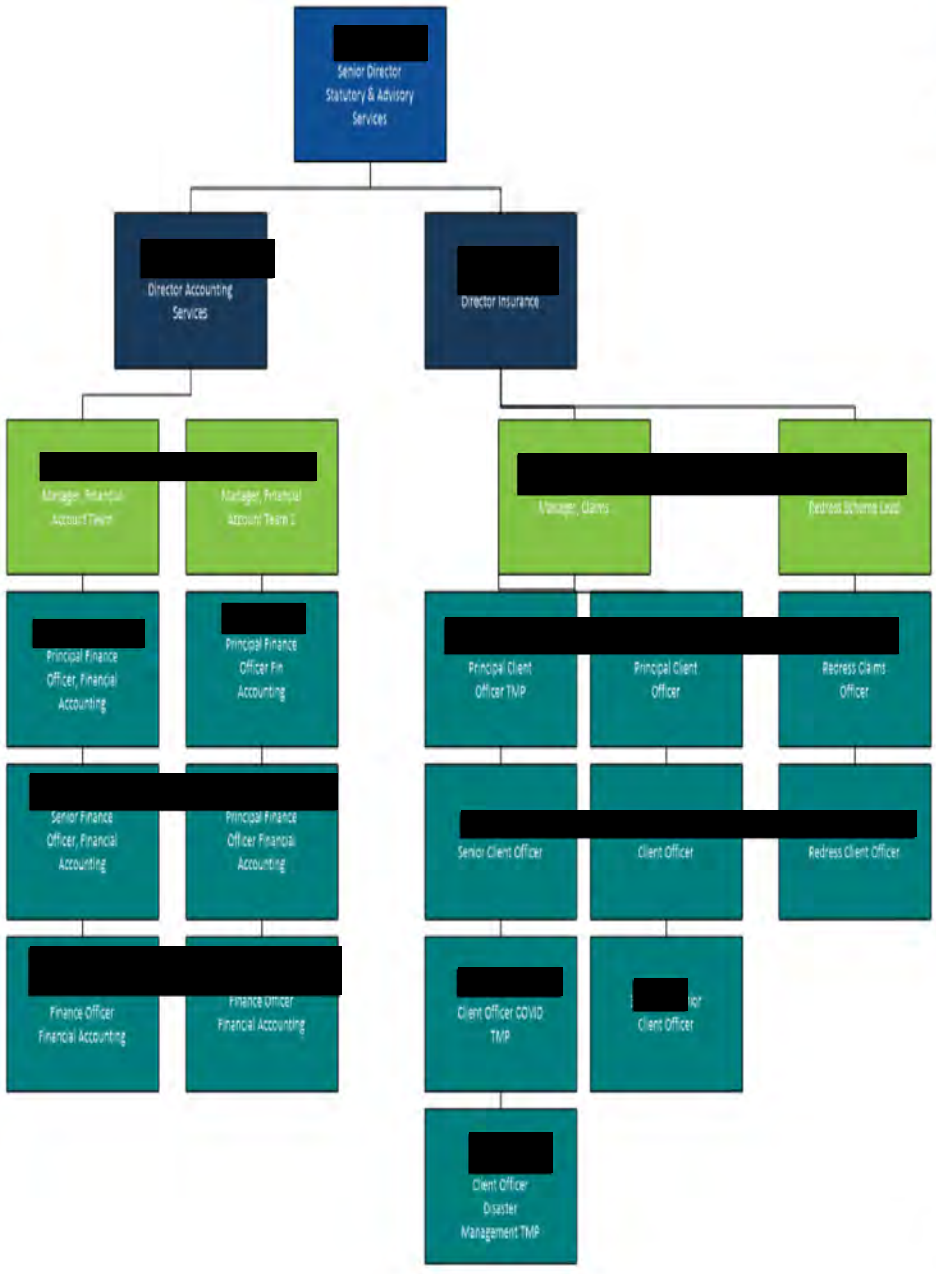
Finance Branch – Statutory and Advisory Services Unit (Taxation Team and Financial Policy and Business Requirements)

Current Organisational Structure

Position	Position Title
Statutory and Advisory Services	
[redacted]	Senior Director, Statutory and Advisory Services
	Senior Finance Officer
Taxation Team	
[redacted]	Director, Taxation
GST Team	
[redacted]	Manager, GST
	Principal Finance Officer, Taxation
	Senior Finance Officer Taxation, GST
FBT Team	
[redacted]	Manager, FBT
	Principal Finance Officer, Taxation
	Principal Finance Officer, FBT
	Principal Finance Officer, FBT
Financial Policy and Business Requirements	
[redacted]	Director, Financial Policy & Business Requirements
	Manager, Financial Legislation & Policy
Financial Policy Team	
[redacted]	Manager, Financial Policy and Compliance
	Principal Finance Officer, Financial Control
	Principal Finance Off, Financial Policy
	Principal Finance Officer, Legislation & Policy
Finance Business Requirements	
[redacted]	Manager Finance Business Requirements
	Principal Finance Officer
	Principal Finance Officer (Finance Business Req)
	Senior Finance Officer Financial Systems
	Policy Officer

Finance Branch – Statutory and Advisory Services Unit (Financial and Asset Accounting Team and Insurance Services)

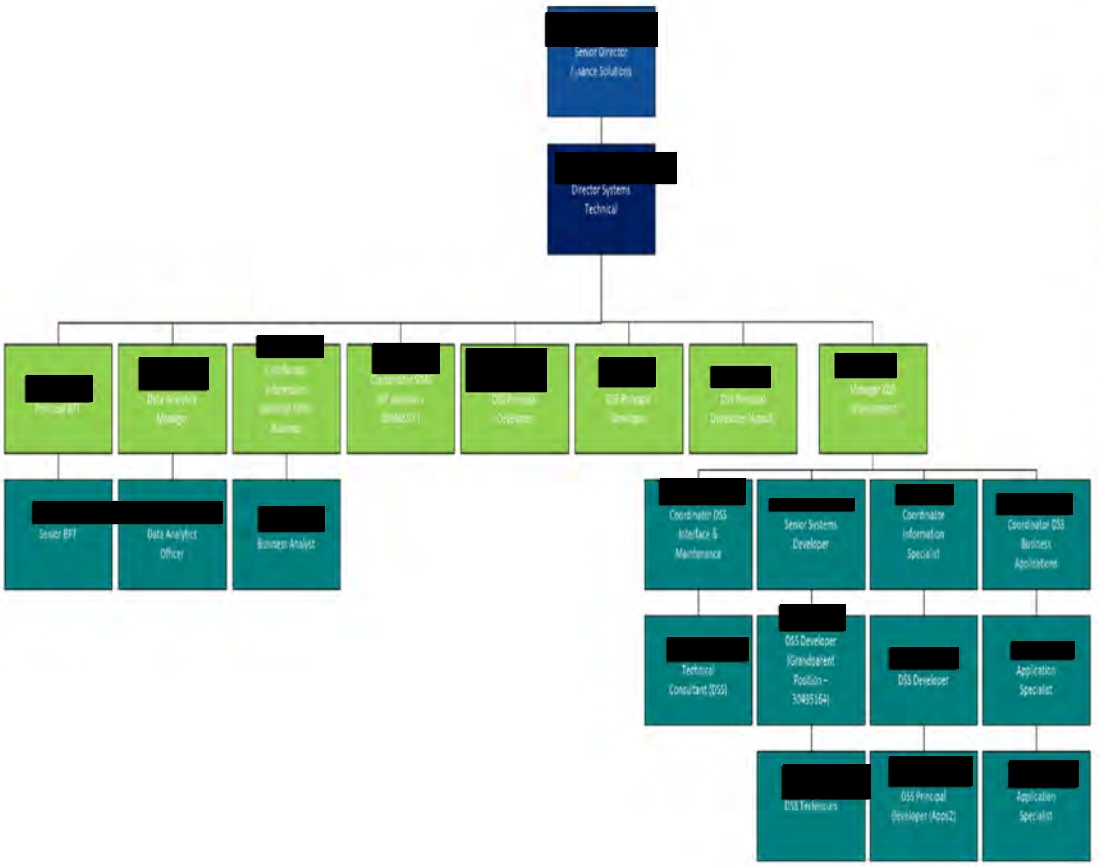
Current Organisational Structure



Position	Position Title
Financial Accounting Services Team	
[redacted]	Director, Accounting Services
Financial Accounting Team 1	
[redacted]	Manager, Financial Accounting
	Principal Finance Officer, Fin Accounting
	Senior Finance Officer, Fin Accounting
	Finance Officer, Financial Accounting
Financial Accounting Team 2	
[redacted]	Manager, Financial Account Team 2
	Principal Finance Officer, Fin Accounting
	Principal Finance Officer, Fin Accounting
	Finance Officer, Financial Accounting
Insurance Team	
[redacted]	Director Insurance
	Manager, Claims
	Principal Client Officer
	Principal Client Officer TMP
	Senior Client Officer
	Client Officer Disaster Management TMP
	Senior Client Officer
	Client Officer
	Client Officer Covid TMP
	Redress Scheme Lead
	Redress Claims Officer
	Redress Client Officer

Finance Branch – Financial Solutions (Systems Team)

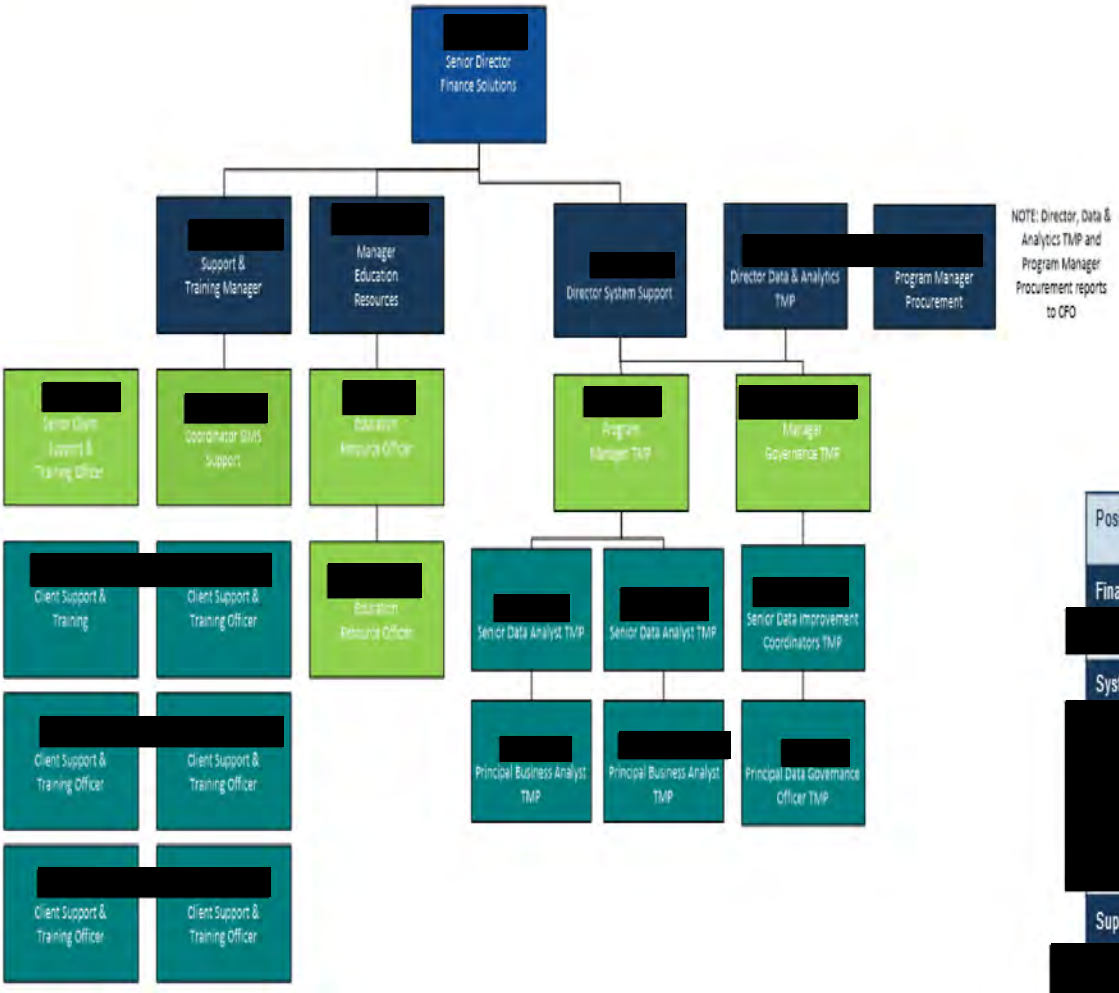
Current Organisational Structure



Position	Position Title
Systems Technical	
[redacted]	Director, Systems Technical
Principal BPT	
[redacted]	Principal BPT
	Senior BPT
Data Analytics Manager	
[redacted]	Data Analytics Manager
	Data Analytics Officer
Technical Staff	
[redacted]	DSS Principal Developer
	DSS Principal Developer
	DSS Principal Developer (Apps 3)
	Coordinator SIMS *Coordinator SIMS (GP Clause)*
Technical Manager	
[redacted]	Manager, DSS Development
	Coordinator DSS Interface & Maintenance
	Technical Consultant (DSS)
	DSS Principal Developer (Apps 2)
	Coordinator DSS Business Applications
	DSS Developer *DSS Developer (GP Clause)*
	DSS Developer
	Application Specialist
	Application Specialist
	Senior Systems Developer
	Coordinator Information Specialist
	DSS Technician
Technical Information Lead	
[redacted]	Coordinator Information Specialist Other Business
	Business Analyst

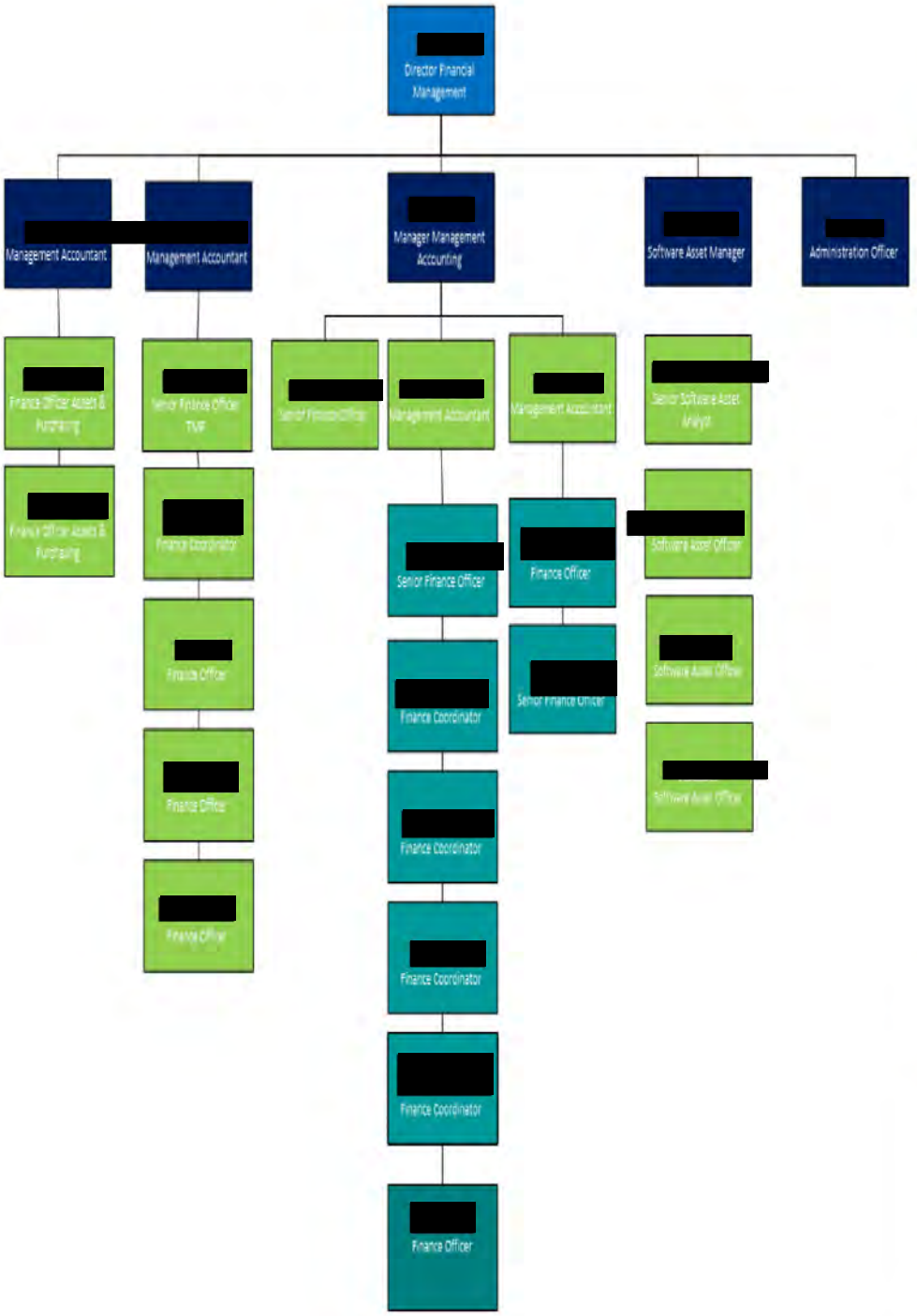
Finance Branch – Financial Solutions (Support Team and Finance Business Intelligence Team)

Current Organisational Structure



Position	Position Title
Finance Solutions	
[redacted]	Senior Director, Finance Solutions
Systems Support	
[redacted]	Director, System Support
	Manager, Education Resources
	Education Resource Officer
	Education Resource Officer
Support and Training Manager	
[redacted]	Support & Training Manager
	Coordinator SIMS Support
	Senior Client Support & Training Officer
	Client Support & Training Officer
	Client Support & Training Officer
	Client Support & Training Officer
	Client Support & Training Officer
	Client Support & Training Officer
	Client Training & Support Officer

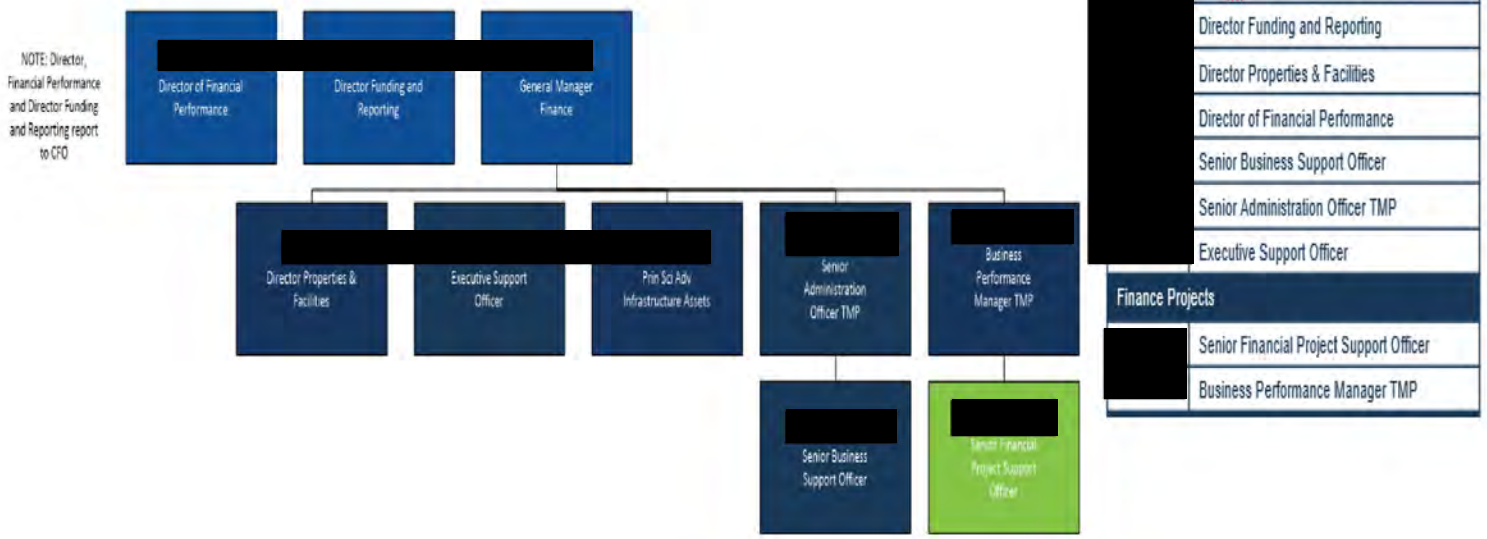
Finance Branch – eHealth Financial Management
Current Organisational Structure



Position	Position Title
eHealth Financial Management	
[redacted]	Director, Financial Management
Administration Management	
[redacted]	Manager, Management Accounting
	Software Asset Manager
	Management Accountant
	Management Accountant
	Administration Officer
Software Asset Management	
[redacted]	Senior Software Asset Analyst
	Software Asset Officer
	Software Asset Officer
	Software Asset Officer
Financial Accounting	
[redacted]	Senior Finance Officer TMP
	Finance Coordinator
	Finance Officer
	Finance Officer
	Finance Officer
Funding and Budget Maintenance	
[redacted]	Senior Finance Officer
	Finance Officer
Management Accounting and Reporting	
[redacted]	Senior Finance Officer
	Finance Coordinator
	Finance Coordinator
	Finance Coordinator
	Finance Coordinator
	Finance Officer

Finance Branch – Finance Directorate (HSQ) – (Finance Directorate Team and Projects Team)

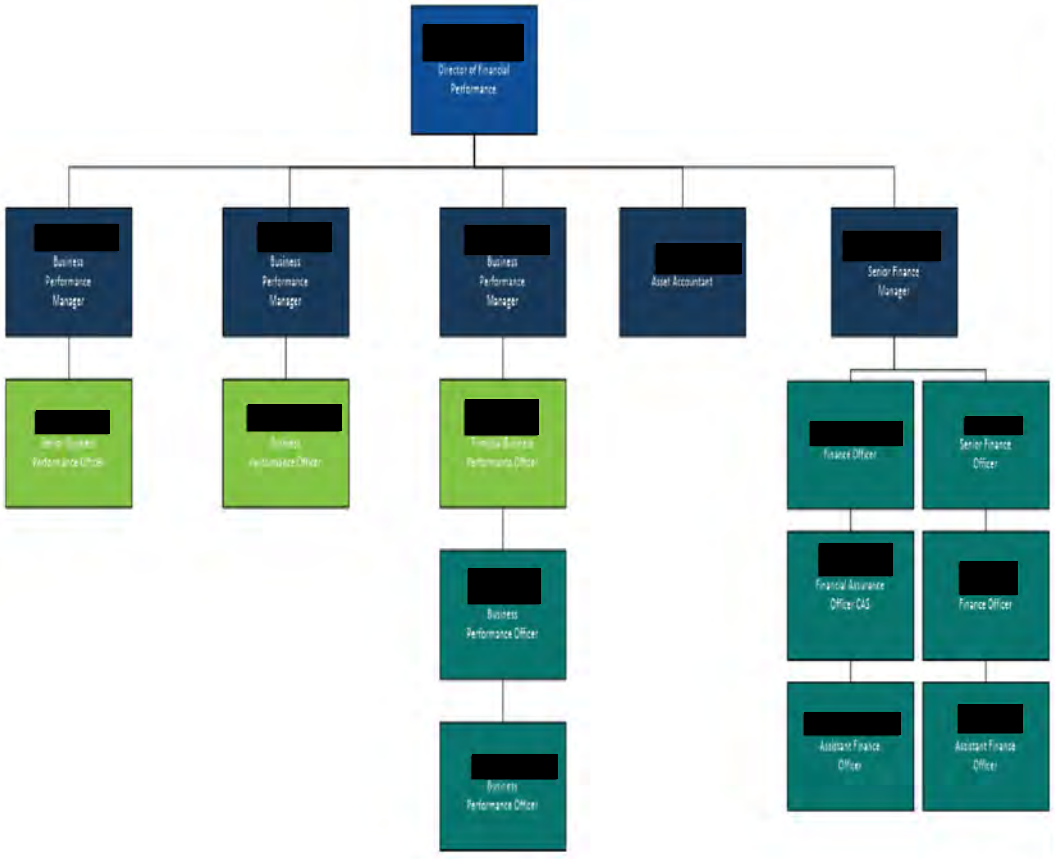
Current Organisational Structure



Position	Position Title
Finance Directorate	
[redacted]	General Manager Finance
	Prin Sci Adv Infrastructure Assets
	Director Funding and Reporting
	Director Properties & Facilities
	Director of Financial Performance
	Senior Business Support Officer
	Senior Administration Officer TMP
	Executive Support Officer
Finance Projects	
[redacted]	Senior Financial Project Support Officer
	Business Performance Manager TMP

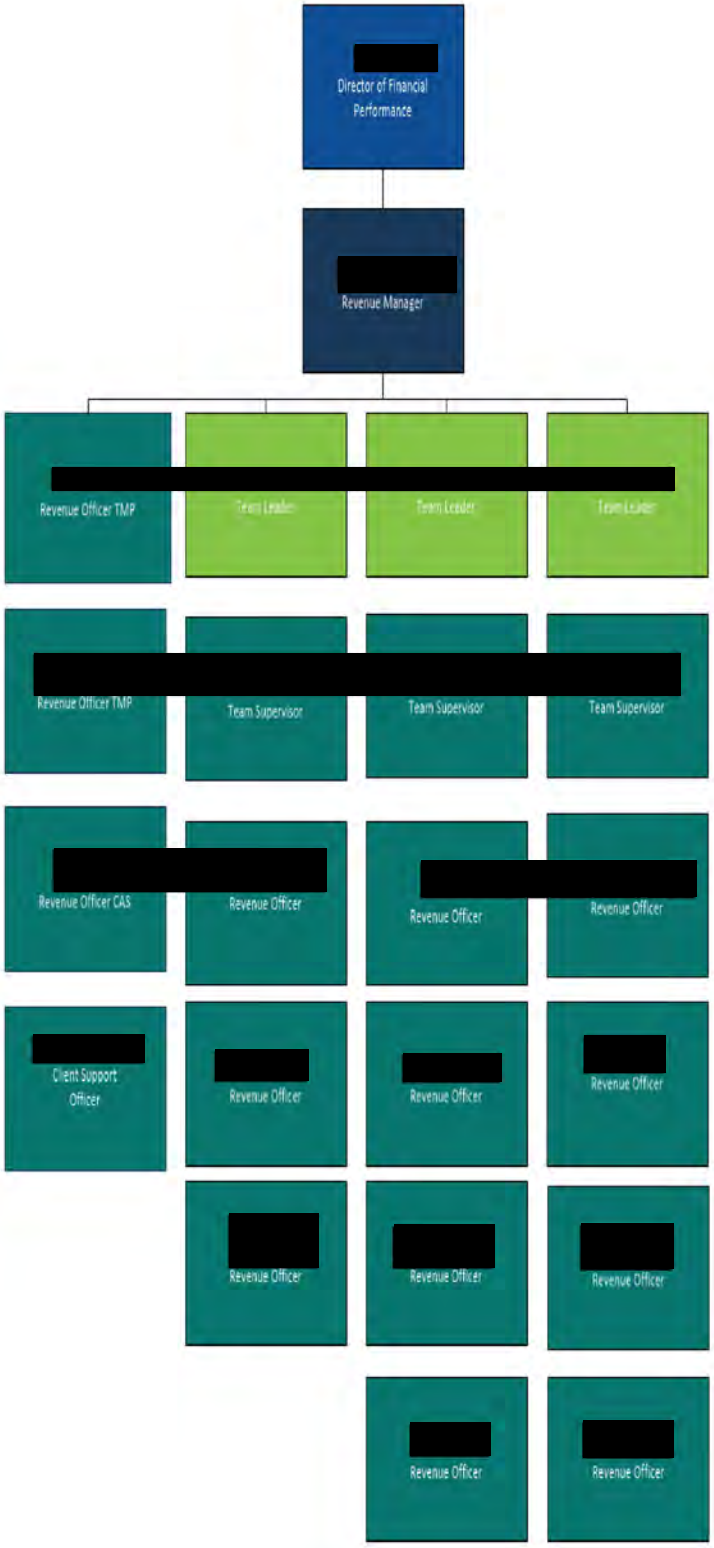
Finance Branch – Finance Directorate (HSQ) – (Financial Performance Team)

Current Organisational Structure



Position	Position Title
Finance Financial Performance	
[redacted]	Senior Finance Manager
	Business Performance Manager
	Business Performance Manager
	Business Performance Manager
	Assistant Finance Officer
	Assistant Finance Officer
	Senior Finance Officer
	Finance Officer
	Finance Officer
	Financial Assurance Officer CAS
	Asset Accountant
	Business Performance Officer
	Senior Business Performance Officer
	Business Performance Officer
	Business Performance Officer
	Principal Business Performance Officer

Finance Branch – Finance Directorate (HSQ) – (Finance Revenue Team)
Current Organisational Structure



Position	Position Title
Finance Revenue Team	
[redacted]	Revenue Manager
	Revenue Officer
	Team Supervisor
	Revenue Officer
	Revenue Officer
	Team Supervisor
	Revenue Officer
	Revenue Officer
	Revenue Officer
	Team Supervisor
	Team Leader
	Team Leader
	Team Leader
	Revenue Officer
	Revenue Officer
	Revenue Officer
	Revenue Officer
	Revenue Officer
	Revenue Officer TMP
	Revenue Officer TMP
	Client Support Officer
	Revenue Officer CAS

Finance Branch - Proposed Organisational Mapping - Impacted positions only

The following pages detail the proposed organisational mapping of each impacted position within the proposed business units for Finance Branch.

Individual current position numbers and current position titles are identified. Positions impacted are defined as those whose proposed position has an impact to their current reporting line, current team or current division.

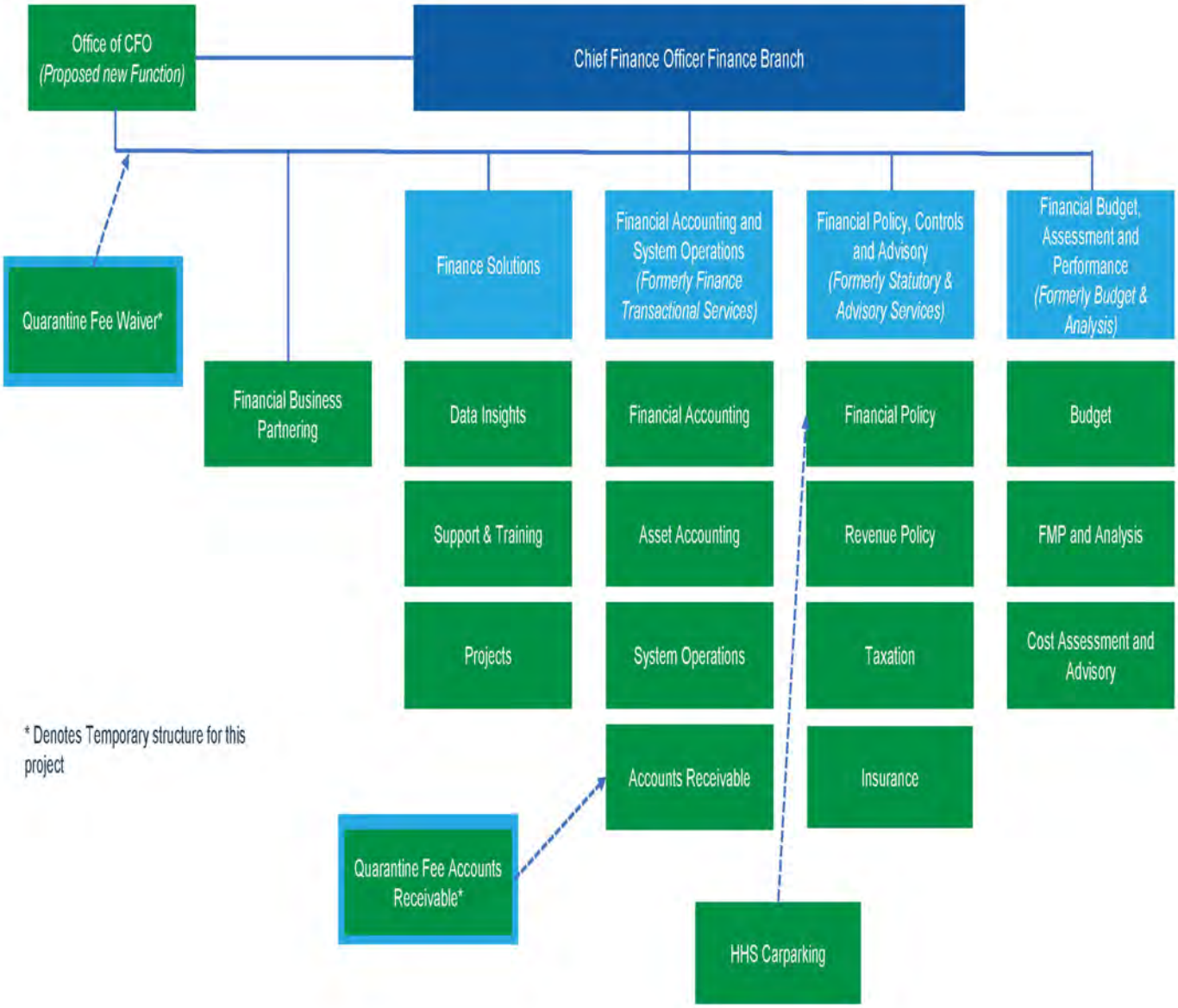
Changes to a Business Unit/Team name is not considered an impact.

Colour coding for existing units/teams has been used to help identify positions (e.g. Orange for eHealth Queensland). Items with no colour reflect changes to existing Finance Branch positions.

Colour coding is consistent throughout the document.

Impacted positions are captured within the mapping tables and within the proposed function. Greater detail on changes to reporting lines may then be found in the Positions Impact table.

Finance Branch
Proposed Organisational Structure



* Denotes Temporary structure for this project

Finance Branch – Finance Solutions
Proposed Organisational Structure

Position Impacted	Position Title
Projects	
[redacted]	Data Governance SME TMP
	Principal Data Governance Officer TMP
	Senor Data Improvement Coordinators TMP
	Celonis Strategic Manager TMP
	Business Value Architect TMP
	Principal Data Analyst TMP
	Senior Data Analyst TMP
	Senior Data Analyst TMP
Support and Training	
[redacted]	System Trainer
Data Insights	
[redacted]	Coordinator Information Specialist Other Business
	Coordinator Information Specialist
	Business Analyst
	DSS Principal Developer
	DSS Principal Developer
	DSS Principal Developer (Apps 3)
	Coordinator SIMS (GP Clause)
	DSS Technician

Finance Branch – Financial Accounting and System Operations (currently Finance Transactional Services)

Proposed Organisational Structure

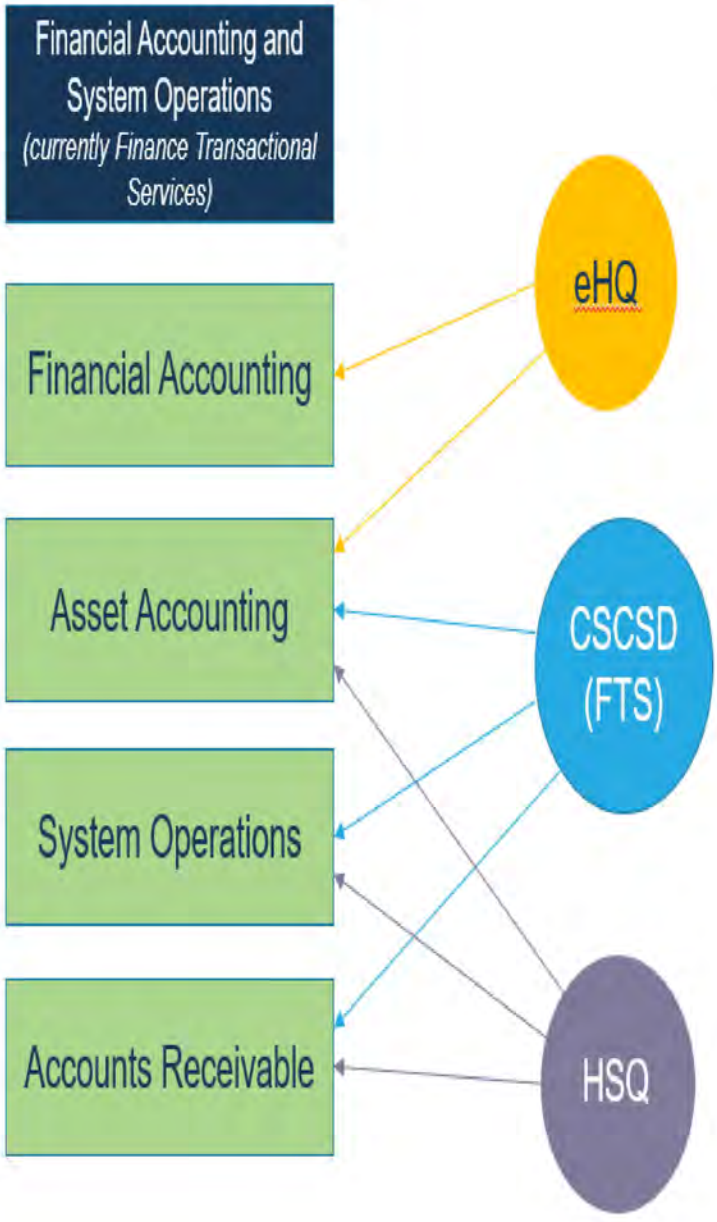
* Excludes Quarantine Fee AR team

Position Impacted	Position Title
Financial Accounting	
[redacted]	Director, Accounting Services
	Manager, Financial Accounting
	Principal Finance Officer, Fin Accounting
	Senior Finance Officer, Fin Accounting
	Finance Officer, Financial Accounting
	Management Accountant
	Senior Finance Officer TMP
	Finance Coordinator
	Finance Officer
	Finance Officer
	Finance Officer
Asset Accounting	
[redacted]	Manager, Financial Account Team 2
	Principal Finance Officer, Fin Accounting
	Principal Finance Officer, Fin Accounting
	Finance Officer, Financial Accounting
[redacted]	Management Accountant
	Asset Accountant
	Finance Officer, Assets
	Finance Officer, Assets
Systems Operations	
[redacted]	Director of Financial Performance
	Senior Finance Manager
	Assistant Finance Officer
	Assistant Finance Officer
	Senior Finance Officer
	Finance Officer
	Finance Officer
	Financial Assurance Officer CAS

Position Impacted	Position Title
Systems Operations cont...	
[redacted]	Manager State-wide Finance Services
	Team Lead, Card Compliance
	Finance Officer
	Senior Finance Officer Banking
	Senior Finance Officer
	Finance Officer
	Banking Officer Quaran. Contractor TMP
	Principal Systems Officer
	Senior Systems Officer
	Finance Officer
	Systems Officer
	Senior Systems Officer
	Assistant Systems Officer
	Systems Officer
	Systems Officer
	Assistant Systems Officer
	Senior Banking Officer
	Banking Officer
	Manager Finance Business Centre
	Principal Finance Officer
	Senior Finance Officer
	Finance Officer
	Assistant Finance Officer GL

Finance Branch – Financial Accounting and System Operations (currently Finance Transactional Services)

Proposed Organisational Structure



Position Impacted	Position Title
Accounts Receivable	
[redacted]	Revenue Manager
	Revenue Officer
	Team Supervisor
	Revenue Officer
	Revenue Officer
	Team Supervisor
	Revenue Officer
	Revenue Officer
	Revenue Officer
	Team Supervisor
	Team Leader
	Team Leader
	Team Leader
	Revenue Officer
	Revenue Officer
	Revenue Officer
	Revenue Officer
	Revenue Officer
	Revenue Officer TMP
	Revenue Officer TMP
	Revenue Officer CAS
	Finance Officer, AR
	Assistant Finance Officer, AR

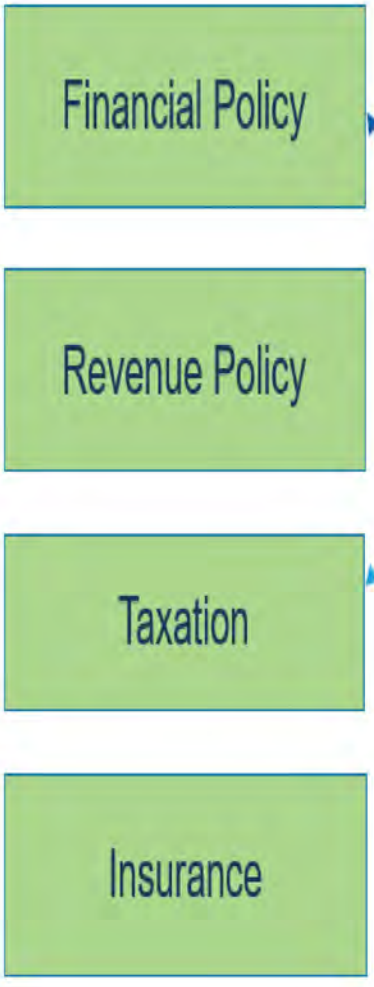
Finance Branch – Financial Accounting and System Operations (Currently Finance Transactional Services)

Proposed Organisational Structure

Position Impacted	Position Title
Accounts Receivable Quarantine Fee	
[redacted]	Accts Receivable Team Ld Quarantine TMP
	Finance Officer Quarantine TMP
	FTS Contractor Quarantine TMP
	Assistant Finance Officer Quarantine TMP
	Assistant Finance Officer Quarantine TMP
	Assistant Finance Officer Quarantine TMP
	Assistant Finance Officer Quarantine TMP
	Assistant Finance Officer Quarantine TMP

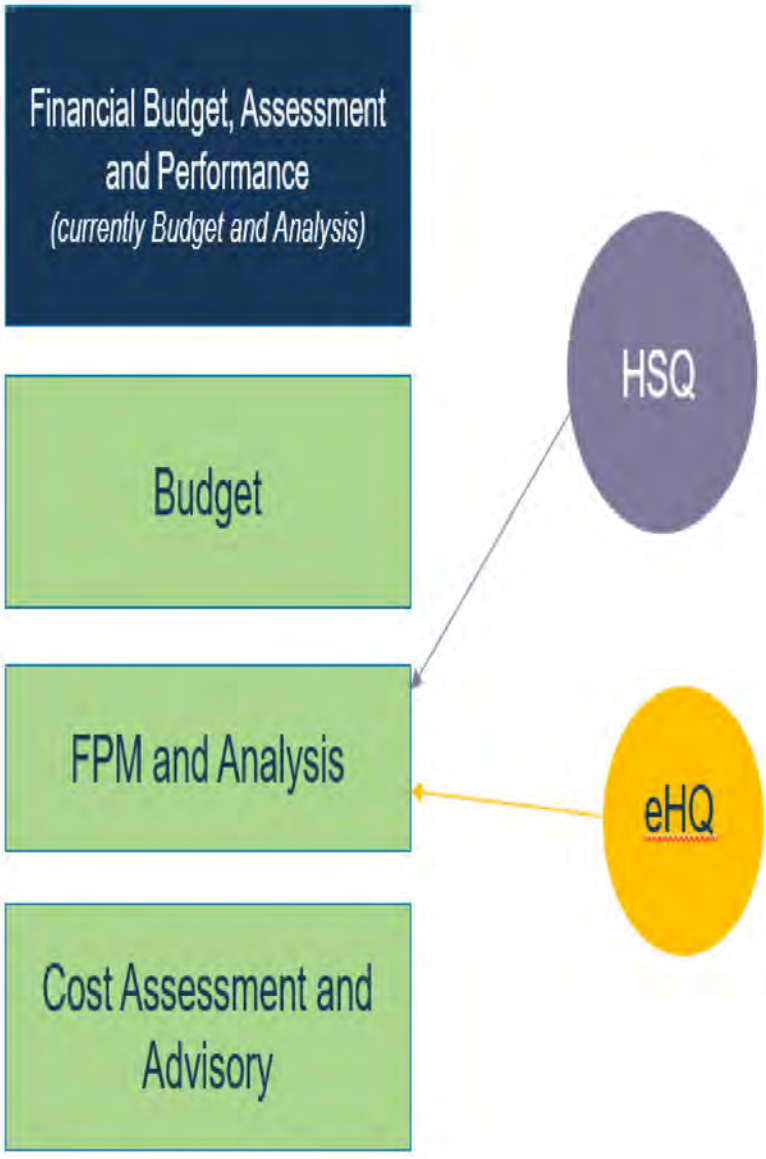
Finance Branch – Financial Policy, Controls and Advisory (Currently Statutory and Advisory Services)

Current Organisational Structure



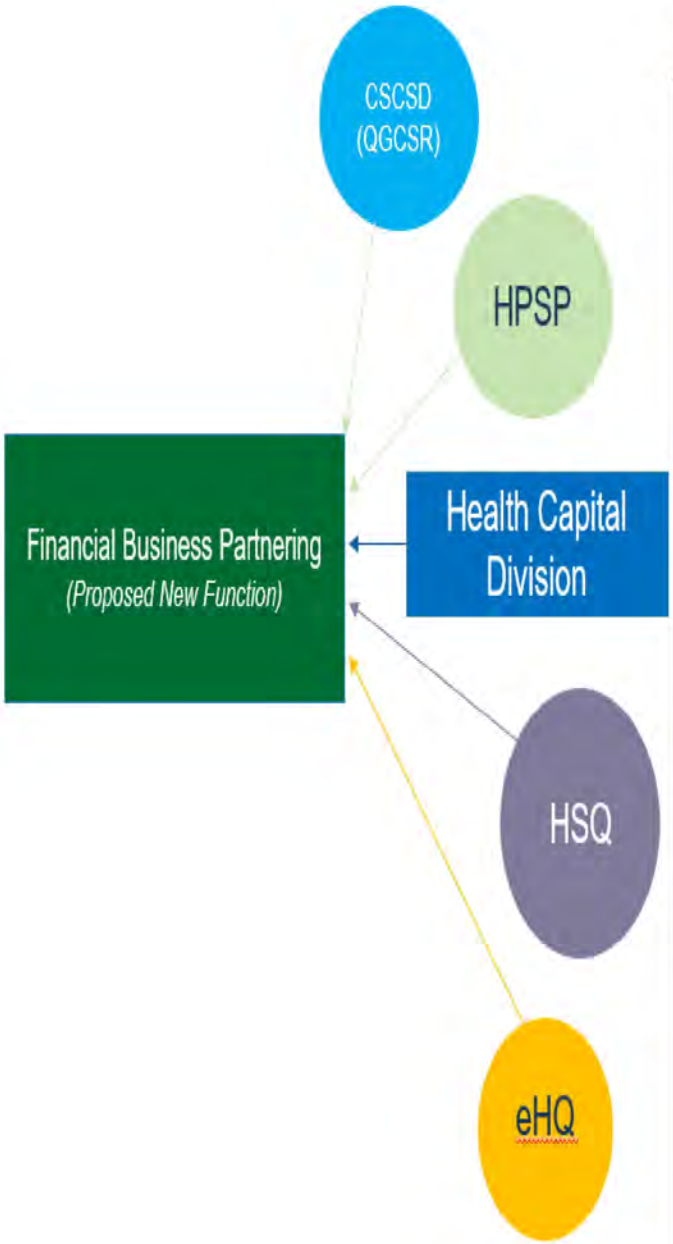
Position Impacted	Position Title
Financial Policy	
[redacted]	MANAGER, CAR PARKING
Revenue Policy	
[redacted]	Director, Revenue Strategy & Support Unit
	Manager, Practice Management Support
	Principal Advisor 19(2)
	Principal Advisor - Private Practice
	Principal Advisor, Practice Management
	Principal Revenue Analyst
	Manager, Compensable Revenue Program
	Principal Policy Officer
	Principal Revenue Officer Principal Revenue Officer (GP Clause)
Taxation	
[redacted]	Senior Finance Officer AR

Finance Branch – Financial Business Partnering



Position Impacted	Position Title
Financial Performance Monitoring and Analysis	
[redacted]	Manager Financial Legislation & Policy
	Manager, Management Accounting
	Management Accountant
	Management Accountant
	Senior Finance Officer
	Manager Funding and Reporting
	Finance Officer
	Business Performance Officer
	Principal Business Performance Officer
	Business Performance Officer
	Senior Business Performance Officer
Cost Assessment and Advisory	
[redacted]	Manager, Models & Costing
	Principal Finance Officer, Models & Costing
	Principal Finance Officer, Models & Costing
	Senior Finance Officer
	Principal Finance Officer TMP
	Principal Finance Officer

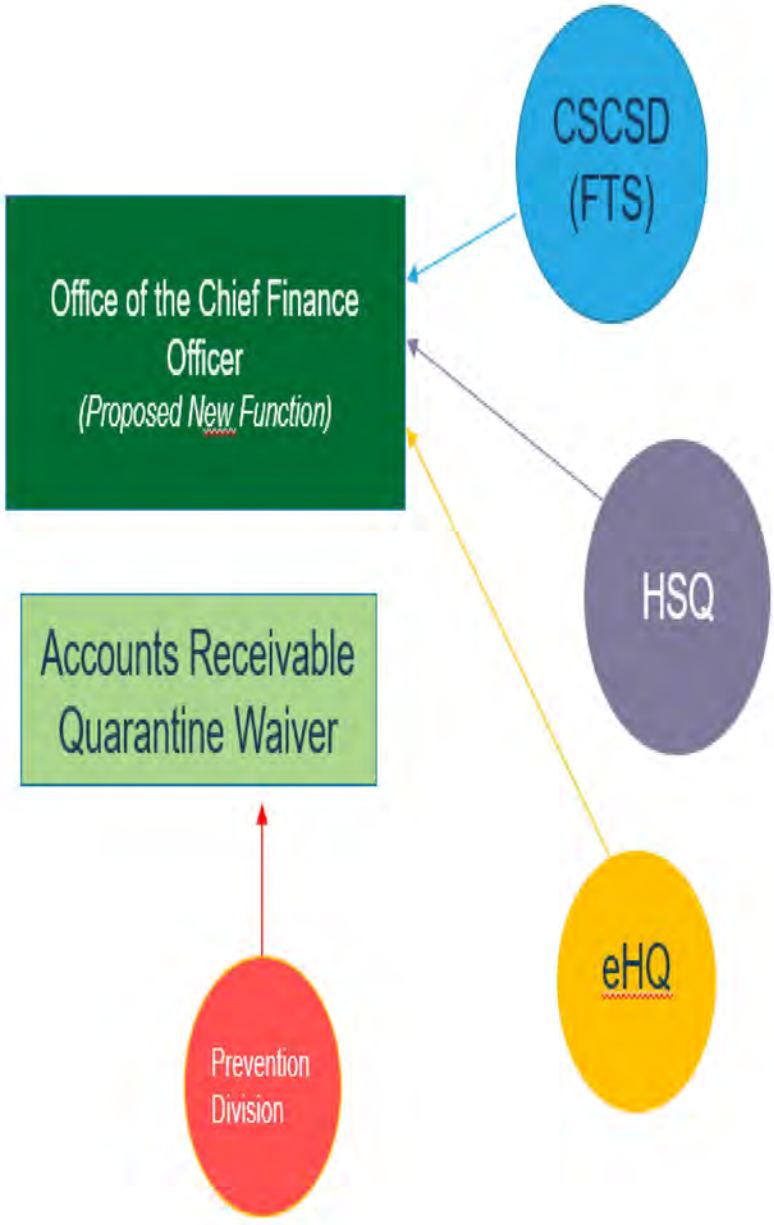
Finance Branch – Financial Business Partnering



Position Impacted	Position Title
[redacted]	Director Funding and Reporting
	Director, Financial Management
	Business Performance Manager
	Senior Business Performance Officer
	Business Performance Manager
	Business Performance Officer
	Business Performance Officer
	Principal Business Performance Officer
	Business Performance Manager
	Business Performance Officer
	Principal Business Performance Officer
	Principal Business Performance Officer
	Senior Business Performance Officer
	Seconded Out TMP
	Business Performance Manager
	Assistant Finance Officer
	Administration Officer
	Finance Offficer WMSO
	Senior Finance Officer
	Administration Officer CES Finance CAS
	Senior Finance Officer
	Senior Finance Officer
	Finance Coordinator
	Finance Coordinator
	Finance Coordinator
	Finance Coordinator
	Principal Finance Officer TMP

Position Impacted	Position Title
[redacted]	Principal Finance Officer
	Manager HHS Financial Performance
	Principal Service Agreement Officer
	Manager Capital Budgets & Accounting
	PRINCIPAL ADVISOR
	PRINCIPAL ADVISOR
	ADVISOR CIDU
	ADVISOR CIDU
	ASSISTANT ADVISOR
	ADMIN OFFICER TRANSACTIONAL

Finance Branch – Office of the Chief Finance Officer



Position Impacted	Position Title
[redacted]	Senior Strategic Support Officer
	Senior Executive Support Officer
[redacted]	Executive Support Officer
	Administration Officer
	Senior Director, Budget & Analysis
	Senior Director, Statutory and Advisory Services
	Senior Director, Finance Transactional Services
Accounts Receivable Quarantine Waiver	
32068514	Executive Director Quarantine Fee Recovery

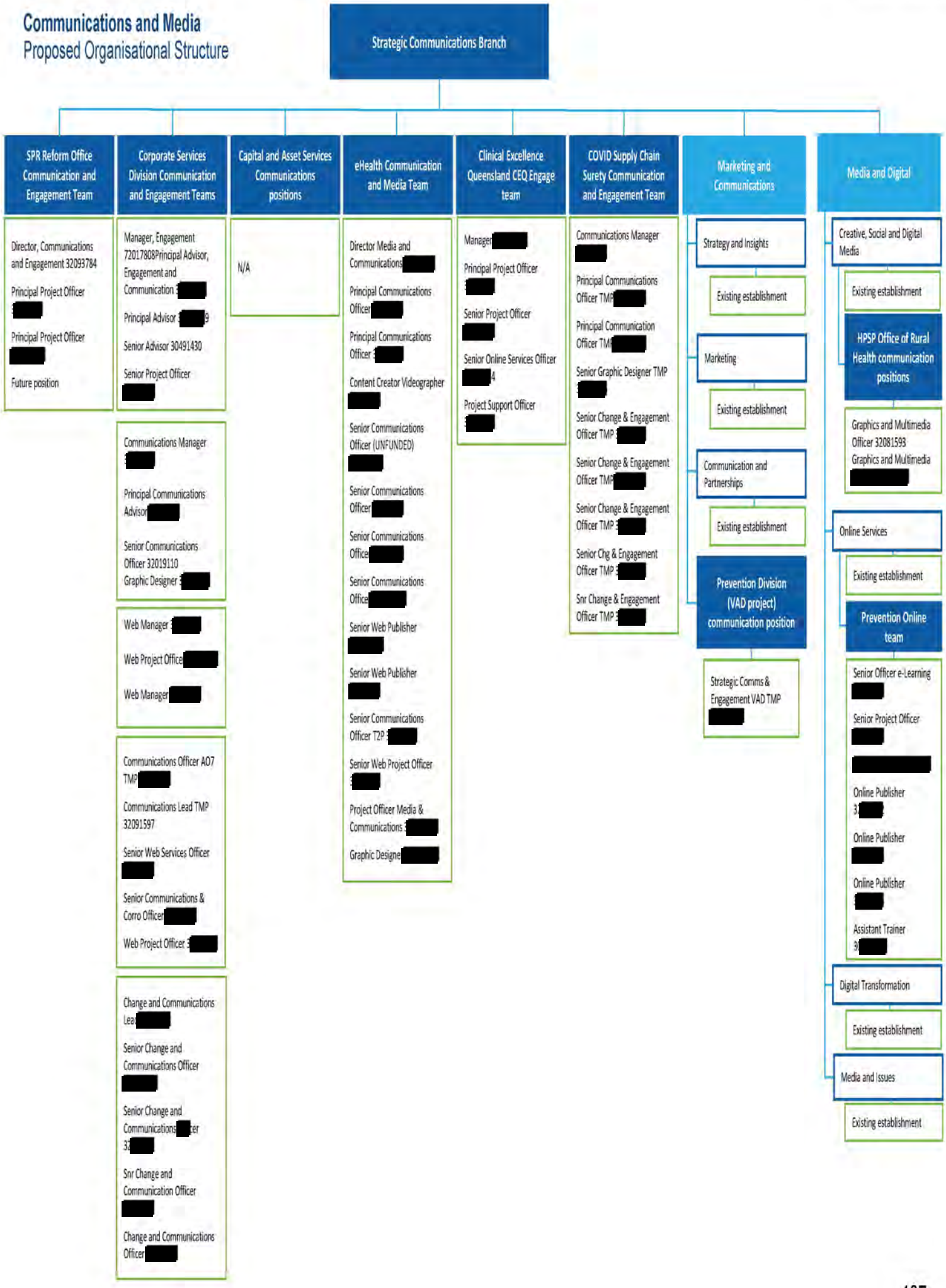
Queensland Health

Communications and Media

Proposed Organisational Structures

Queensland Government

Communications and Media
Proposed Organisational Structure



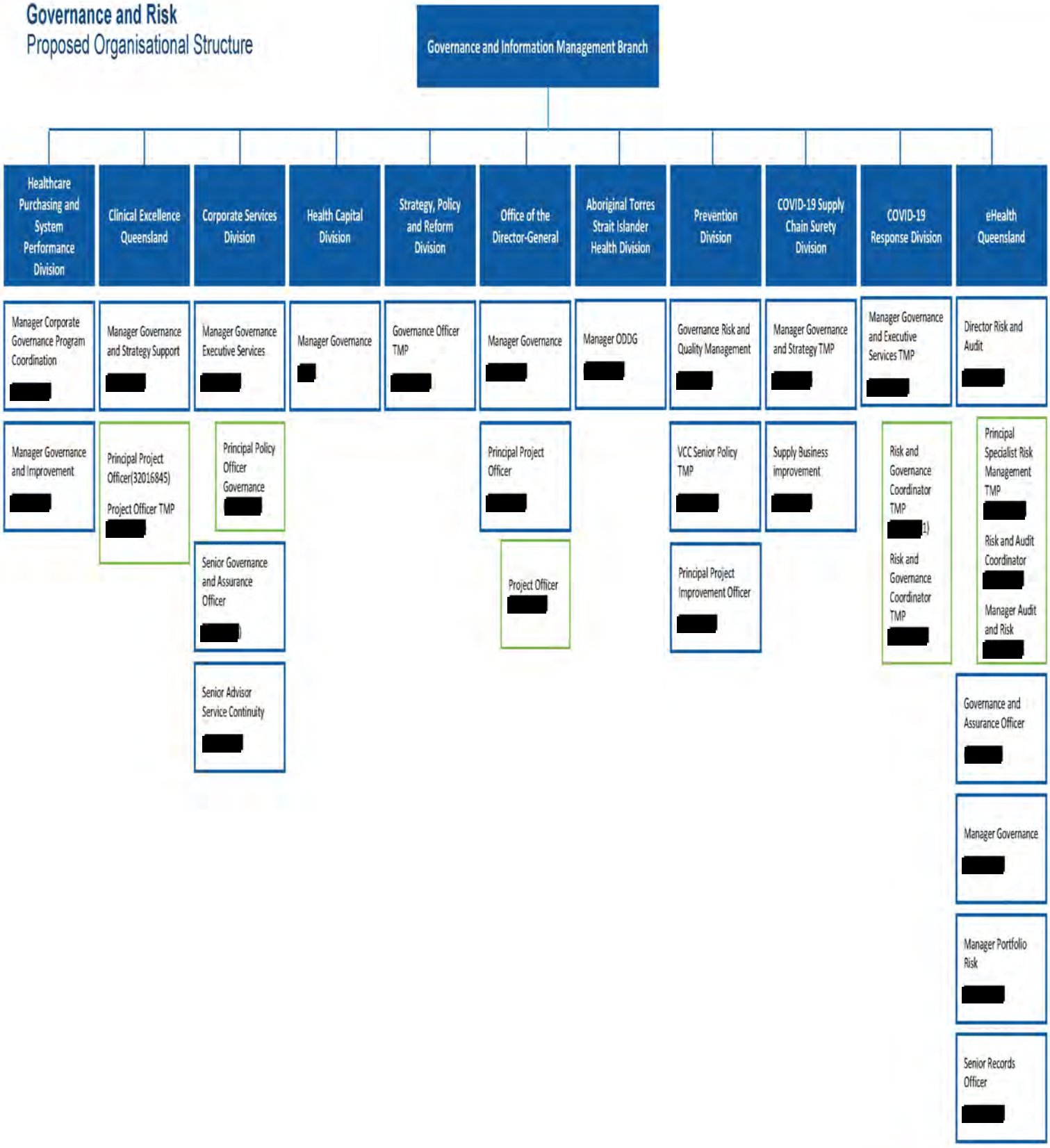
Queensland Health

Governance and Risk

Proposed Organisational Structures

Queensland Government

Governance and Risk
Proposed Organisational Structure



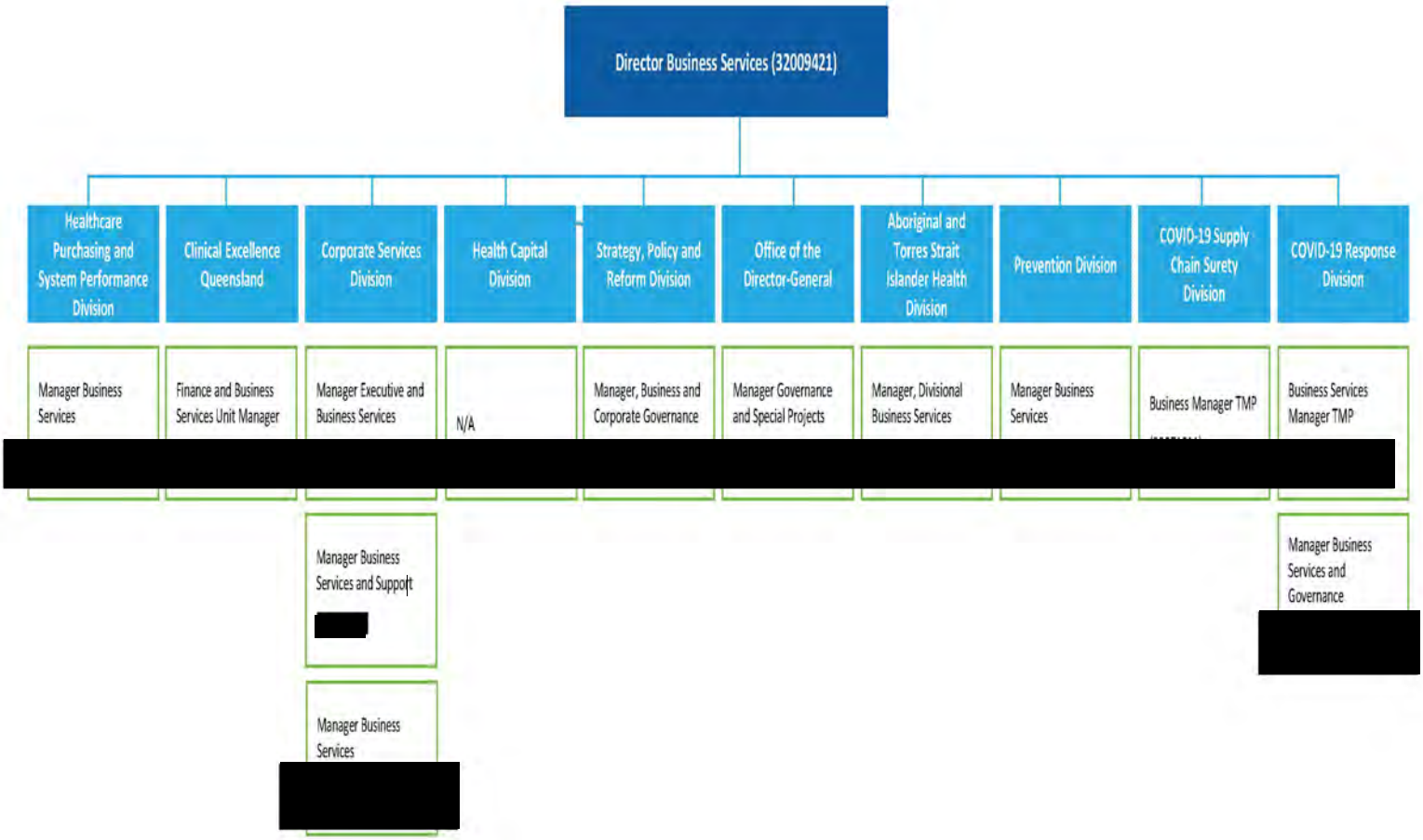
Queensland Health

Business Services

Proposed Organisational Structures

Queensland Government

Business Services
Proposed Organisational Structure



Attachment 3: Impacted positions

Section 1: Impacted Positions by division

Healthcare Purchasing and System Performance Division (HPSP)

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Office of the Deputy Director-General		Healthcare Purchasing and System Performance	Office of the Deputy Director-General	Healthcare Purch & Sys Perf Div		Deputy Director-General Healthcare Purch & System Perf Div		Chief Operating Officer	Continued reporting line.
Funding Strategy and Intergovernmental Policy		Strategy, Policy and Reform	Funding Strategy and Intergovernmental Policy			Senior Director Fund Strat & Gov Policy		Associate Director-General	Change of division. New reporting line. All positions within this branch are moving.
System Planning		Clinical Planning and Service Strategy	System Planning Branch			Senior Director System Planning Branch		New Deputy Director-General - Clinical Planning and Service Strategy Division	Change of division. New reporting line. All positions within this branch are moving.
Office of Rural and Remote Health		Clinical Excellence Queensland	Office of Rural and Remote Health			Executive Director Rural & Remote Health		Deputy Director-General Clinical Excellence Division	Change of division. New reporting line. All positions within this branch are moving.

Clinical Excellence Queensland

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Office of the Deputy Director-General		Clinical Excellence Queensland	Office of the Deputy Director-General			Deputy Director-General Clinical Excellence Division		Chief Operating Officer	Continued reporting line.
Office of the Deputy Director-General		eHealth Queensland	Digital Health Branch			Assistant Deputy Director-General & Chief Clinical Information Officer		Deputy Director-General eHealth Queensland	The Assistant DDG role is proposed to be abolished. The Chief Clinical Information Officer (CCIO) position is proposed to be repurposed to a fulltime CCIO position and is proposed to be integrated with the ED Digital Health position in eHealth Queensland and report to the DDG eHQ. Position title change to Executive Director Digital Health / CCIO.
Patient Safety Quality and Improvement Service		Clinical Excellence Queensland	Patient Safety and Quality						Change of name.
Allied Health Professions Office of Queensland		Clinical Excellence Queensland	Office of the Chief Allied Health Officer						Change of name.
Mental Health, Alcohol and Other Drugs	Strategy Planning and Performance Unit	Clinical Planning and Service Strategy	Mental Health, Alcohol and Other Drugs Strategy and Planning Branch			Senior Director MHAODB		New Deputy Director-General - Clinical Planning and Service Strategy Division	Change of division. Change of branch and unit name. New reporting line. All positions within this branch are moving.
Mental Health, Alcohol and Other Drugs	Clinical Systems Collections team in the Clinical Systems Collections and Performance Unit	eHealth Queensland	Digital Health Branch			Manager Clinical System Support		Executive Director Digital Health / CCIO	Change of division. New reporting line. All positions that report to this position are moving.
Healthcare Improvement Unit	Healthcare Analysis Team	Healthcare Purchasing and System Performance		Healthcare Analysis Team		Manager		Senior Director System Performance Reporting	Change of division. New reporting line. All positions that report to this position are moving.
Healthcare Improvement Unit	Health Systems	eHealth Queensland	Digital Health	Health Systems		Director		Executive Director Digital Health/CCIO	Change of division. New reporting line. All positions within this branch are moving.
Healthcare Improvement Unit	Telehealth	eHealth Queensland	Digital Health	Telehealth		Principal Technology Officer		Executive Director Digital Health / CCIO	Change of division. New reporting line. All positions that report to this position are moving.
Healthcare Improvement Unit	Telehealth	eHealth Queensland	Digital Health	Telehealth		Principal Program Officer MRF		Executive Director Digital Health / CCIO	Change of division. New reporting line. All positions that report to this position are moving.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Healthcare Improvement Unit	Telehealth	eHealth Queensland	Digital Health	Telehealth	[redacted]	Principal Project Officer	[redacted]	Executive Director Digital Health / CCIO	Change of division. New reporting line. All positions that report to this position are moving.
Healthcare Improvement Unit	Telehealth	eHealth Queensland	Digital Health	Telehealth		Principal Project Officer		Executive Director Digital Health / CCIO	Change of division. New reporting line. All positions that report to this position are moving.
Healthcare Improvement Unit	Telehealth	eHealth Queensland	Digital Health	Telehealth		Assistant Project Officer		Executive Director Digital Health / CCIO	Change of division. New reporting line. All positions that report to this position are moving.
Clinical Excellence Queensland	CEQ Engage	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Manager		Senior Director SCB	Change to new Division
ODDG CEQ	ODDG CEQ	Clinical Excellence Queensland	ODDG CEQ	ODDG CEQ		Senior Executive Support Officers Senior Coordinator Team Leader		Director ODDG CEQ	New reporting line.
Statistical Services		Healthcare Purchasing and System Performance	Statistical Services			Executive Director Statistical Services		Deputy Director-General Healthcare Purch & System Perf Div	Change of division. New reporting line.
Centre for Leadership Excellence						Executive Director CLE			Position to be abolished.
Centre for Leadership Excellence		Clinical Planning and Service Strategy	Centre for Leadership Excellence	Centre for Leadership Excellence		Senior Director		New Assistant Deputy Director-General - Clinical Planning and Service Strategy	Change to new division. New reporting line. All positions reporting to this position are also moving.
Healthcare Improvement Unit	Healthcare Improvement Fellowship	Clinical Planning and Service Strategy	Centre for Leadership Excellence			Nursing Director Improvement Fellowship		Senior Director	Change of division. New reporting line. All positions that report to this position are moving.
Office of the CCIO		eHealth Queensland	Digital Health	Office of the CCIO				Executive Director Digital Health / CCIO	Change of division. New reporting line.
New	New	Clinical Excellence Queensland	Office of the Chief Medical Officer	Office of the Chief Medical Officer		Chief Medical Officer		DDG Clinical Excellence Division	Role to be created
New	New	Clinical Excellence Queensland	Office of the Deputy Director-General	ODDG Clinical Priority Oversight Team		Manager Clinical Priority Oversight Team		Director ODDG CEQ	Role to be evaluated. Org unit re-named.

Queensland Ambulance Service

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
QAS	Office of the DG				[redacted]	QAS Commissioner	[redacted]	Chief Operating Officer	Continued reporting line.
System Planning	Queensland Ambulance Service	Clinical Planning and Service Strategy	System Planning			Project Officer		Senior Director System Planning Branch	Change of division. New reporting line.
System Planning	Queensland Ambulance Service	Clinical Planning and Service Strategy	System Planning			Project Officer		Senior Director System Planning Branch	Change of division. New reporting line.

Prevention Division

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Office of the Deputy Director-General	Office of the CHO & Deputy Director-General Business Svs		Office of the Deputy Director-General	Office of the CHO & Deputy Director-General Business Svs	[redacted]	CHO & Deputy Director-General Prevention Health Division TMP	[redacted]		Decoupling the responsibilities for Director-General Prevention Health Division from the CHO.
Aeromedical and Retrieval and Disaster Management	Retrieval Services Queensland	Queensland Ambulance Service	Aeromedical Retrieval Services	Retrieval Services Queensland		Executive Director Aeromedical Retrieval & Disaster Mgt		QAS Commissioner	Change of division. New reporting line. Position and Branch name change. All positions within the Aeromedical Retrieval Service are moving.
Aeromedical and Retrieval and Disaster Management	Disaster Management	Office of the COO	Disaster Management	Disaster Management		Deputy State Health Coordinator		Chief Operating Officer	Change of division. New reporting line. All positions within this branch are moving.
Chief Medical Officer and Healthcare Regulation	Medical Advisory and Prevocational Accreditation Unit	Clinical Planning and Service Strategy	Direct report to A/DDG Workforce - Clinical Planning and Service Strategy	Medical Advisory and Prevocational Accreditation Unit		Director Medical Advisory and Prevocational Accreditation Unit		New Assistant Director-General Workforce - Clinical Planning and Service Strategy	Change of division. New reporting line. All positions reporting to this position are moving.
Chief Medical Officer and Healthcare Regulation	Medication Services Queensland	Integrated Scientific, Clinical and Prevention Services Division	Healthcare Regulation Branch	Medication Services Queensland		Director Medication Services Queensland		Exec Dir Healthcare Regulation Branch (Currently Exec Dir CMO & Healthcare Reg Branch)	Change of division. New reporting line. All positions within this branch are moving.
Chief Medical Officer and Healthcare Regulation		Integrated Scientific, Clinical and Prevention Services Division	Healthcare Regulation Branch			Exec Dir Healthcare Regulation Branch (Currently Exec Dir CMO & Healthcare Reg Branch)		General Manager - Integrated Scientific, Clinical and Prevention Services	Change of division. New reporting line. Change of position title. All positions within this branch are moving.
Pathology Queensland and Forensic and Scientific Services	Pathology Queensland and Forensic and Scientific Services	Integrated Scientific, Clinical and Prevention Services	Pathology Queensland	Pathology Queensland		General Manager Pathology Queensland		New General Manager Integrated Scientific, Clinical and Prevention Services	Change to new division. New reporting line. All positions within this branch are moving.
Pathology Queensland and Forensic and Scientific Services	Pathology Queensland and Forensic and Scientific Services	Integrated Scientific, Clinical and Prevention Services	Forensic and Scientific Services	Forensic and Scientific Services		Executive Forensic and Scientific Services		New General Manager Integrated Scientific, Clinical and Prevention Services	Change to New division. New reporting line. All positions within this branch are moving.
Pathology Queensland and Forensic and Scientific Services	Clinical Forensic Medicine Unit	Clinical Excellence Queensland	Office of the Chief Medical Officer	Clinical Forensic Medicine Unit		Director CFMU FSS		Chief Medical Officer	Change of division. New reporting line. All positions within this branch are moving.
Communicable Diseases	Communicable Diseases	Integrated Scientific, Clinical and Prevention Services	Communicable Diseases	Communicable Diseases		Executive Director Communicable Diseases		New General Manager Integrated Scientific, Clinical and Prevention Services	Change to New division. New reporting line. All positions within this branch are moving.
Health Protection	Health Protection	Integrated Scientific, Clinical and Prevention Services	Health Protection	Health Protection		Executive Director HPB		New General Manager Integrated Scientific, Clinical and Prevention Services	Change to New division. New reporting line. All positions within this branch are moving.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Office of Precision Medicine & Research	HIIRO Leadership Team	Clinical Planning and Service Strategy	Office of Precision Medicine & Research			Director Health & Med Research GP Clause		Executive Director OPMR	Change of reporting line.
Office of Precision Medicine & Research	Office of Precision Medicine & Research	Clinical Planning and Service Strategy	Office of Precision Medicine & Research	Office of Precision Medicine & Research		Executive Director OPMR		New Deputy Director-General - Clinical Planning and Service Strategy	Change to new division. New reporting line. All positions within OPMR are moving.
Preventive Health	Preventive Health	Strategy, Policy and Reform	Prevention Strategy Branch	Preventive Health		Exec Director Preventative Health Unit		New Associate Director-General - Strategy, Policy and Reform	Change to new division New reporting line. All positions within this branch are moving.
Quarantine Fee Waiver	Quarantine Fee Waiver	Corporate Services Division	Finance Branch	Quarantine Fee Waiver		Exec Director Quarantine Fee Recovery		CFO	Change of division. New reporting line. All positions reporting to this position are also moving.
Prevention Division	COVID-19 Recovery	Chief Operating Officer	COVID-19 Recovery			Registrar TMP		COVID-19 Response System Lead TMP	Change of division. New reporting line.
Prevention Division	COVID-19 Recovery	Chief Operating Officer	COVID-19 Recovery			Senior Medical Officer TMP		COVID-19 Response System Lead TMP	Change of division. New reporting line.
Prevention Division	Office of Precision Medicine & Research	Clinical Planning and Service Strategy	Office of Precision Medicine & Research			Manager Conversion		Director Health & Med Research GP Clause	Change of division. New reporting line.
Prevention Division		Chief Operating Officer	COVID-19 Recovery			Senior Medical Officer		COVID-19 Response System Lead TMP	Change of division. New reporting line.
Prevention Division		Chief Operating Officer	COVID-19 Recovery			CHOB Contractor		COVID-19 Response System Lead TMP	Change of division. New reporting line.
Office of the Chief Health Officer		Integrated Scientific, Clinical and Prevention Services	Office of the Deputy Director-General			Senior Director Office of the Chief Health Officer		New General Manager - Integrated Scientific, Clinical and Prevention Services	Change of division. New reporting line. All positions reporting to this position are also moving.
Preventive Health	Cancer Screening Unit	Integrated Scientific, Clinical and Prevention Services Division	Cancer Screening Branch			Director		General Manager - Integrated Scientific, Clinical and Prevention Services	Change of division. New reporting line. All positions within this unit are moving.
Prevention Division	Voluntary Assisted Dying	Strategy, Policy and Reform Division	Preventive Health Branch	Voluntary Assisted Dying		Project Executive Director VAD TMP		Exec Director Preventative Health Unit	Change of division. All position are also moving.

Aboriginal and Torres Strait Islander Health Division

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Office of the Deputy Director-General		Office of First Nations Health	Office of the Chief First Nations Health Officer						Division name change.
Office of the Deputy Director-General		Office of First Nations Health	Office of the Chief First Nations Health Officer			Senior Project Offic TMP		Manager, Governance	Change of reporting line.
Office of the Deputy Director-General		Office of First Nations Health	Office of the First Nations Health Officer			Correspondence Coordinator		Manager, Governance	Change of reporting line.
Engagement		Office of First Nations Health	Engagement and Monitoring						Branch name change.
Strategy		Office of First Nations Health	Strategy and Policy						Branch name change.
Strategy		Office of First Nations Health	Strategy and Policy	Cultural Reform		Principal Policy and Planning Officer		Manager, Cultural Capability	Change of reporting line.
Strategy	Investment	Office of First Nations Health	Office of the Chief First Nations Health Officer	Strategic Investment		Manager		Director, Office of the Chief First Nations Health Officer	Change of reporting line. Unit Name change.
Strategy	Investment	Office of First Nations Health	Office of the Chief First Nations Health Officer	Strategic Investment		Principal Policy and Planning Officer		Manager, Project Management Office, (Office of the Chief First Nations Health Officer)	Change of reporting line. Unit Name change.
Strategy	Investment	Office of First Nations Health	Office of the Chief First Nations Health Officer	Strategic Investment		Senior Policy and Planning Officer		Manager, Project Management Office (Office of the Chief First Nations Health Officer)	Change of reporting line. Unit Name change.

eHealth Queensland

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Corporate Services		eHealth Queensland	Operations and Performance		[redacted]		[redacted]		Branch name change.
Corporate Services		eHealth Queensland	Operations and Performance			Executive Director Operations and Performance			Role title change
Corporate Services	Corporate Services Management	eHealth Queensland	ODDG	Executive Services and Governance		Branch Manager		Director Executive Services and Governance	Changed reporting line.
Corporate Services	Office of the EDCS	eHealth Queensland	ODDG	Executive Services and Governance		Senior Executive Support Officer		Branch Manager	Changed reporting line.
Corporate Services	Office of the EDCS	eHealth Queensland	ODDG	Executive Services and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Customer Services						Executive Director Customer Services			Abolish position
Customer Service	Digital Partnership	eHealth Queensland	Delivery Services	Digital Partnerships		Director Digital Partnerships		Executive Director Delivery Services	Changed reporting line.
Customer Service	Service Management and Improvement	eHealth Queensland	Enterprise Technology Services	Service Management and Improvement		Director Service Management & Improvement		Executive Director Enterprise Technology Services	Changed reporting line.
Customer Service	Presentation and Printing	eHealth Queensland	Enterprise Technology Services	Presentation and Printing		Manager Presentation		Senior Director Digital Application Serv	Changed reporting line.
Customer Service	Digital Service Centre Team	eHealth Queensland	Enterprise Technology Services	Digital Service Centre Team		Director		Executive Director Enterprise Technology Services	Changed reporting line.
Customer Service	Customer Value and Engagement	eHealth Queensland	Operations and Performance	Customer Value and Engagement		Director Customer Value and Engagement		Executive Director Operations and Performance	Changed reporting line.
Customer Service	Customer Service Management	eHealth Queensland	ODDG	Executive Services and Governance		Branch Manager		Director Executive Services and Governance	Changed reporting line.
Customer Service	Office of the ED Customer Services	eHealth Queensland	ODDG	Executive Services and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Customer Service	Office of the ED Customer Services	eHealth Queensland	ODDG	Executive Services and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Customer Service	Office of the ED Customer Services	eHealth Queensland	ODDG	Executive Services and Governance		Senior Executive Support Officer		Branch Manager	Changed reporting line.
Customer Service	Office of the ED Customer Services	eHealth Queensland	ODDG	Digital Performance Support		Training and Development Officer		Director Digital Performance Support	Changed reporting line.
Digital Solutions Delivery		eHealth Queensland	Delivery Services						Branch name change.
Digital Solutions Delivery		eHealth Queensland	Delivery Services			Executive Director Delivery Services			Role title change
Digital Solutions Delivery	Office of the Executive Director	eHealth Queensland	ODDG	Executive Services and Governance		Senior Business Support Officer		Branch Manager	Changed reporting line.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	[redacted]	Position Title	Change and Effect
Digital Solutions Delivery	Office of the Executive Director	eHealth Queensland	ODDG	Executive Services and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Digital Solutions Delivery	Office of the Executive Director	eHealth Queensland	ODDG	Executive Services and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Digital Solutions Delivery	Office of the Executive Director	eHealth Queensland	ODDG	Executive Services and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Digital Solutions Delivery	Services Management	eHealth Queensland	ODDG	Executive Services and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Digital Solutions Delivery	Office of the Executive Director	eHealth Queensland	ODDG	Executive Services and Governance		Assistant Business Support Officer		Branch Manager	Changed reporting line.
Digital Solutions Delivery	Office of the Executive Director	eHealth Queensland	ODDG	Executive Services and Governance		Senior Executive Support Officer		Branch Manager	Changed reporting line.
Digital Solutions Delivery	Office of the Executive Director	eHealth Queensland	ODDG	Executive Services and Governance		Senior Executive Support Officer		Branch Manager	Changed reporting line.
Digital Solutions Delivery	DSDB Senior Management	eHealth Queensland	ODDG	Executive Services and Governance		Branch Manager		Director Executive Services and Governance	Changed reporting line.
Digital Strategy and Transformation		eHealth Queensland	Strategy, Architecture and Information Services						Branch name change.
Digital Strategy and Transformation		eHealth Queensland	Strategy, Architecture and Information Services			Executive Director Strategy, Architecture and Information Services			Role title change
Digital Strategy and Transformation	CDS&T Management	eHealth Queensland	Enterprise Technology Services			CIO Rural and Remote		Executive Director Enterprise Technology Services	Change of reporting line.
Digital Strategy and Transformation	Digital Services Management	eHealth Queensland	Operations and Performance	Digital Services Management		Senior Director Digital Services Mngmt		Executive Director Operations and Performance	Changed reporting line.
Digital Strategy and Transformation	CDS&T Management	eHealth Queensland	ODDG	Executive Services and Governance		Branch Manager		Director Executive Services and Governance	Changed reporting line.
Digital Strategy and Transformation	DSTB Business Support Unit	eHealth Queensland	ODDG	Executive Services and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Digital Strategy and Transformation	DSTB Business Support Unit	eHealth Queensland	ODDG	Executive Services and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Digital Strategy and Transformation	DSTB Business Support Unit	eHealth Queensland	ODDG	Executive Services and Governance		Senior Executive Support Officer		Branch Manager	Changed reporting line.
Information & Technology Services		eHealth Queensland	Digital Health						Branch name change.
Information & Technology Services		eHealth Queensland	Digital Health			Executive Director Digital Health			Abolish Position.
Information & Technology Services	ITS Delivery Office	eHealth Queensland	Delivery Services	Delivery Office		Delivery Director		Senior Director Digital Solutions	Changed reporting line.
Information & Technology Services	CISSU Service Desk	eHealth Queensland	Enterprise Technology Services	CISSU Service Desk		Team Leader Service Desk		Director Digital Service Centre	Changed reporting line.
Information & Technology Services	Governance, Risk and Assurance ITS	eHealth Queensland	Operations and Performance	Commercial Strategy		Governance and Assurance Manager		Director Commercial Strategy	Changed reporting line.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Information & Technology Services	Office of the GMITS	eHealth Queensland	ODDG	Executive Service and Governance		Business Manager		Director Executive Services and Governance	Changed reporting line.
Information & Technology Services	Office of the GMITS	eHealth Queensland	Operations and Performance	ICT Contracts and Procurement		Contract Manager		Director Contracts and Procurement	Changed reporting line.
Information & Technology Services	Office of the GMITS	eHealth Queensland	Operations and Performance	Office of the ED		Senior Records Officer		Branch Manager	Changed reporting line.
Information & Technology Services	Governance Risk & Assurance ITS	eHealth Queensland	Operations and Performance	Risk and Audit		ICT Governance Officer		Director Risk and Audit	Changed reporting line.
Information & Technology Services	Office of the GMITS	eHealth Queensland	ODDG	Executive Service and Governance		Business Support Officer		Business Manager	Changed reporting line.
Technology Services		eHealth Queensland	Enterprise Technology Services						Branch name change.
Technology Services		eHealth Queensland	Enterprise Technology Services			Executive Director Enterprise Technology Services			Role title change
Technology Services	ieMR Applications	eHealth Queensland	Digital Health	Digital Health Solutions		Senior Director Digital Health Solutions		Executive Director Digital Health / CCIO	Changed reporting line / Change role title
Technology Services	Technology Services Management Team	eHealth Queensland	ODDG	Executive Service and Governance		Branch Manager		Director Executive Services and Governance	Changed reporting line.
Technology Services	Technology Services Coordination	eHealth Queensland	ODDG	Executive Service and Governance		Senior Business Support Officer		Branch Manager	Changed reporting line.
Technology Services	Technology Services Business Support	eHealth Queensland	ODDG	Executive Service and Governance		Business Support Officer		Branch Manager	Changed reporting line.
Technology Services	Technology Services Management Team	eHealth Queensland	ODDG	Executive Service and Governance		Senior Executive Support Officer		Branch Manager	Changed reporting line.
Technology Services	Digital Application Services	eHealth Queensland	Digital Health			Technical Delivery Manager		Senior Director Digital Health Solutions	Changed reporting line.
Technology Services	Digital Application Services	eHealth Queensland	Strategy, Architecture and Information	Reporting Service		Manager Business Intelligence and Data Analytics		Executive Director Strategy, Architecture and Information	Changed reporting line.
Technology Services	Telehealth	eHealth Queensland	Digital Health	Telehealth		Applications Manager		Executive Director Digital Health / CCIO	Change of division.
Office of the Deputy Director-General		eHealth Queensland				Deputy Director-General eHealth Queensland			Reporting to the DG through the eHealth Queensland Board of Management
Office of the Deputy Director-General	Media and Communications	eHealth Queensland	ODDG	Digital Performance Support					Unit name change
Office of the Deputy Director-General	Media and Communications	eHealth Queensland	ODDG	Digital Performance Support		Director Digital Performance Support		Senior Director SCB	Role title Change. Change to new division reporting line.
Office of the Deputy Director-General		eHealth Queensland	ODDG	Executive Service and Governance					Unit Creation

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title		Position Title	Change and Effect
Office of the Deputy Director-General		eHealth Queensland	ODDG	Executive Servic and Governance		Director Executive Services and Governance			Role title Change
Customer Service	Office of the ED Customer Services	eHealth Queensland	Enterprise Technology Services	Service Management an Improvement		Continuous Improvement Specialist		Continuous Improvement Manager	Changed reporting line.
Customer Service	Office of the ED Customer Services	eHealth Queensland	Enterprise Technology Services	Service Management an Improvement		Application Specialist (SNOW)		Continuous Improvement Manager	Changed reporting line.
Customer Service	Office of the ED Customer Services	eHealth Queensland	Delivery Services	Digital Partnerships		Application Specialist		Director Digital Partnerships	Changed reporting line.
Customer Service	Office of the ED Customer Services	eHealth Queensland	Delivery Services	Digital Partnerships		Application Specialist		Director Digital Partnerships	Changed reporting line.
Customer Service	Office of the ED Customer Services	eHealth Queensland	Enterprise Technology Services	Service Management an Improvement		Principal Busines Change Officer		Director Service Management & Improvement	Changed reporting line.
Customer Service	Office of the ED Customer Services	eHealth Queensland	ODDG	Executive Servic and Governance		Administration Officer		Branch Manager	Changed reporting line.

Corporate Services Division

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
CSD	CSD				[redacted]	Deputy Director-General Corp Services	[redacted]		Continue reporting to Director-General.
Corporate Services Division	Business Partnerships and Improvement Branch	Corporate Services Division	Governance and Information Management Branch	Office of the Executive Director		Project and Branch Support Officer		Executive Director, Governance and Information Management	Change to branch title.
Human Resources Branch	Office of the CHRO	Clinical Planning and Service Strategy	Workforce Strategy Branch			Senior Director Workforce Strategy Branch		New ADDG – Workforce Strategy	Change to new division New reporting line. All positions reporting to this position have also moved.
Human Resources Branch	Ethical Standards Unit	Office of the Director-General	Ethical Standards			Director Ethical Standards Unit		Director-General TMP	Change of division. New reporting line. All positions reporting to this position have also moved.
Human Resources Branch	eHQ People and Culture	eHealth Queensland	Operations and Performance	Contractor Engagement		HR Advisor (Recruit and Wforce establishment)		Director Contracts and Procurement	Change to new division, New reporting line. All positions reporting to this position have also moved.
Corporate Services Division	Business Partnerships and Improvement Branch	Corporate Services Division	Governance and Information Management Branch	Office of the Executive Director		Executive Director, Governance and Information Management (currently Executive Director BPIB)		Deputy Director-General, Corporate Services Division	Change to position title. Change to branch title.
Corporate Services Division	Business Partnerships and Improvement Branch	Strategy Policy and Reform Division	Strategic Communications Branch			Communication and Engagement Manager		Senior Director Strategic Communication	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Business Partnerships and Improvement Branch	Corporate Services Division	Human Resources Branch			Director Change and Culture Leadership		Chief Human Resources Officer	Change to new branch. New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Business Partnerships and Improvement Branch	Corporate Services Division	Legal Branch			Registrar Mental Health Court		Chief Legal Counsel	Change to new branch. New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Business Partnerships and Improvement Branch	Corporate Services Division	Office of the Deputy Director-General			Manager Portfolio Management		Director Portfolio and Project Management	Change to new branch. New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Business Partnerships and Improvement Branch	Corporate Services Division	Office of the Deputy Director-General			Director Portfolio and Project Management (Currently Director Priority Projects)		Deputy Director-General, Corporate Services Division	Change to new branch. New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Business Partnerships and Improvement Branch	Strategy Policy and Reform Division	Strategic Communications Branch			Communications Manager		Senior Director Strategic Communication	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Corporate Services Division	Business Partnerships and Improvement Branch	Strategy Policy and Reform Division	Strategic Communications Branch			Web Manager		Senior Director Strategic Communication	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Business Partnerships and Improvement Branch	Integrated Scientific, Clinical & Prevention Services	Office of the General Manager			Customer Relationship Manager		Senior Director	Change to new branch. New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Business Partnerships and Improvement Branch	Integrated Scientific, Clinical & Prevention Services	Office of the General Manager			Manager Strategic Initiatives & Planning		Senior Director	Change to new branch. New reporting line.
Corporate Services Division	Finance Branch	eHealth Queensland	Operations and Performance	Software Asset Management		Finance Officer Assets & Purchasing		Digital Asset Strategic Manager	Change of division. New reporting line.
Corporate Services Division	Finance Branch	eHealth Queensland	Operations and Performance	Software Asset Management		Finance Officer Assets & Purchasing		Digital Asset Strategic Manager	Change of division. New reporting line.
Corporate Services Division	Finance Branch	eHealth Queensland	Operations and Performance	Software Asset Management		Software Asset Manager		Senior Director Digital Services Mngmt	Change of division. New reporting line.
Corporate Services Division	Finance Branch	eHealth Queensland	Operations and Performance			Finance Officer		Executive Director Corporate Services	Change to new division. New reporting line.
Corporate Services Division	Finance Branch	eHealth Queensland	Operations and Performance			Finance Officer		Executive Director Corporate Services	Change to new division. New reporting line.

COVID-19 Supply Chain Surety Division (interim)

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
		Corporate Services Division	Supply Chain Surety			Executive Director Supply Chain Sure		Deputy Director-General Corporate Services Division	New reporting line. Change of position title.
Strategic Procurement		Corporate Services Division	System Procurement			Queensland Healt Chief Procurement Officer		Deputy Director-General Corporate Services Division	Change of division. New branch created. All positions within this branch have also moved.
Supply Chain Services		Corporate Services Division	Supply Chain Surety	Supply Chain Services		Director Supply Ch Operations		Executive Director Supply Chain Surety	Change of division. New branch created. All positions within this branch have also moved.
Finance Transactional Services		Corporate Services Division	System Procurement	Finance Transactional Services		Snr Director Finan Trans Services		Queensland Health Chief Procurement Officer	Change of division. New branch created. All positions within this branch have also moved.
Central Pharmacy		Corporate Services Division	Supply Chain Surety	Central Pharmacy		Executive Director Central Pharmacy		Executive Director Supply Chain Surety	Change of division. New branch created. All positions within this branch have also moved.
Queensland Government Critical Supply Reserve		Corporate Services Division	Supply Chain Surety	Queensland Government Critical Supply Reserve		Executive Director QGCSR Program		Executive Director Supply Chain Surety	Change of division. New branch created. All positions within this branch have also moved.
Group Linen Services		Corporate Services Division	Supply Chain Surety	Group Linen Services		Director Group Lin Services		Executive Director Supply Chain Surety	Change of division. New branch created. All positions within this branch have also moved.
Finance Transactional Services (accounts payable functions)		Corporate Services Division	System Procurement			Manager AP Servic South Qld		Queensland Health Chief Procurement Officer	Change to new division. New reporting line.
Finance Transactional Services (non-accounts payable functions)		Corporate Services Division	Finance Branch	Financial Accounting and System Operations		Snr Director Finan Trans Services		Chief Finance Officer	Change to new division. New reporting line.
Finance Transactional Services		Corporate Services Division	System Procurement	Accounts Payable		Manager AP Servic South QLD		Queensland Health Chief Procurement Officer	Change to new division. New reporting line.
Finance Transactional Services		Corporate Services Division	System Procurement	Accounts Payable		AP Change Manage		Queensland Health Chief Procurement Officer	Change to new division. New reporting line.
Finance Transactional Services		Corporate Services Division	System Procurement	Accounts Payable		Senior Reporting Analyst		AP Change Manager	Change to new division. New reporting line.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Finance Transactional Services		Corporate Services Division	System Procurement	Accounts P	[redacted]	Lead AP	[redacted]	AP Change Manager	Change to new division. New reporting line.
Finance Transactional Services		Corporate Services Division	Finance Branch		[redacted]	r Director, ce Transactional ces	[redacted]	Chief Finance Officer	Change to new division. New reporting line.

COVID-19 Response Division (interim)

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Office of the CHO		Office of the CHO						Chief Health Officer	New office established. New reporting line.
COVID-19 Ops & Disaster Management Branch		Office of the COO	Disaster Prevention and Response	Office of the CO		eputy Chief Health fficer TMP		Chief Health Officer	Change of division. New branch created with change of reporting line. All positions reporting to this position have also moved.
COVID-19 Vaccination Taskforce & VCC		Office of the COO	Vaccination			ate Director COVID- Vac Program		Chief Health Officer	Change of division. New branch created with change of reporting line. All positions reporting to this position have also moved.
COVID-19 Health System Response		Office of the COO	COVID-19 Recovery			OVID-19 Response stem Lead TMP		Chief Operating Officer	Change of division. New branch created with change of reporting line. All positions reporting to this position have also moved.
		NEW Office of the Chief Health Officer				enior Director		Chief Health Officer	Role to be created
		NEW Office of the Chief Health Officer				enior Epidemiologist		Chief Health Officer	Role to be created
		NEW Office of the Chief Health Officer				anager, Policy nalysis & ordination		Senior Director	Role to be created
		NEW Office of the Chief Health Officer				anager, Policy nalysis & ordination		Senior Director	Role to be created
		NEW Office of the Chief Health Officer				incipal Policy fficer, Secretariat & gagement		Senior Director	Role to be created
		NEW Office of the Chief Health Officer				ecutive Support / rrespondence fficer		Senior Director	Role to be created

Strategy, Policy and Reform Division (interim)

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
SPR Division						Associate Director-General		Director-General	Continue to report to the Director-General
SPR Division	Social Policy, Legislation, Statutory Agencies	SPR	System Policy Branch						New branch created and name change of existing branch.
Office of Hospital Sustainability		Strategy Policy & Reform	System Policy Branch		[redacted]	Director	[redacted]	Senior Director Social Policy Legislation and Statutory Agencies	Change of reporting line

Office of the Director-General Division

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
System Governance and Strategy branch	System Governance Support Unit	Office of the Director-General	System Support Services Branch	System Support Services Unit	[redacted]	Director System Support Services			Branch and position title name change.

Health Capital Division (interim)

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
CSD		Health Capital Division	Strategy, Assets & Support		[redacted]	Executive Director, Strategy, Assets & Support	[redacted]	New Deputy Director-General - Health Capital Division	Change to new division. New reporting line. New position name. All positions reporting to this position have also moved.
		Health Capital Division	Infrastructure Planning			Executive Director, Infrastructure Planning		New Deputy Director-General - Health Capital Division	
		Health Capital Division	Infrastructure Delivery			Executive Director, Infrastructure Delivery		New Deputy Director-General - Health Capital Division	
CASB	Sustainable Operations	Health Capital Division	Strategy, Assets and Support			Senior Director Sustainable Operations		New Executive Director – Strategy, Assets & Support	New reporting line. Position title change to Senior Director Strategy and Operations.
CASB	Sustainable Operations	CSD		Asset Property Facilities Management (Corporate Facilities)		Director Corporate Facilities		Executive Director Corporate Governance and Strategy	New reporting line. All positions reporting to this position have also moved.
Capital and Asset Services Branch	Capital Infrastructure (Investment Assurance Committee)	CSD				Director Assurance Administration		Executive Director Corporate Governance and Strategy	New reporting line. All positions reporting to this position have also moved.
Capital and Asset Services Branch	ISIB Investment (Investment Assurance Committee)	CSD				Manager		Director Assurance Administration	New reporting line.
CASB	Sustainable Operations	Health Capital Division	Strategy, Assets and Support	Technical and Assurance		Director Sustaining Capital		Senior Director Technical Assurance	New reporting line. All positions reporting to this position have also moved.
CASB	Sustainable Operations	Strategy, Policy and Reform	Office of Hospital Sustainability			Director Office of Hospital Sustainability		Senior Director Social Policy, Legislation and Statutory Authorities	Change to new division. All position reporting to this position are also moving.
CASB	Sustainable Operations	Corporate Services	Finance	Financial Polic Controls and Advisory		Manager, Car Parking		Director, Financial Policy & Business Requirements	Change to new division Change in reporting line
CASB	Sustainable Operations	CPSS	System Planning Branch			Manager Master Planning		Director System Planning Branch	Change to new division. All positions reporting have also moved.
CASB	BTS	Integrated Scientific and Clinical Prevention Services Division	Biomedical Technology Services			Executive Director BTS		New General Manager – Integrated Scientific and Clinical Services	Change to new division. New reporting line. All positions reporting to this position have also moved.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
CASB	Infrastructure Strategy	Health Capital Division	Strategy, Assets and Support		[redacted]	Senior Director Infrastructure Strategy	[redacted]	New Executive Director – Strategy, Assets & Support	New reporting line. The position name will change to Senior Director Technical and Assurance.
CASB	Asset Management	Health Capital Division	Strategy, Assets and Support			Senior Director Asset Management			This role is proposed to be abolished.
CASB	Asset Management	Health Capital Division	Strategy, Assets and Support			Director Asset Services		Senior Director Technical and Assurance	New reporting line. All positions reporting to this position have also moved.
CASB	Asset Management	Health Capital Division	Strategy, Assets and Support			Director		Senior Director Strategy and Operations	Reporting line change. Position title change to Director Reporting and Analysis.
CASB	Asset Management	Health Capital Division	Strategy, Assets and Support			Director		Senior Director Technical and Assurance	New reporting line.
CASB	Asset Management	Health Capital Division	Strategy, Assets and Support			Manager Assets Systems Governance		Director Asset Services	New reporting line.
CASB	Asset Management	Health Capital Division	Strategy, Assets and Support			Principal Assets Advisor		Director Asset Services	New reporting line.
CASB	Property and Planning	Health Capital Division	Infrastructure Planning			Senior Director Property and Planning		New Executive Director Infrastructure Planning	New reporting line. Change of position title to Senior Director Program Support.
CASB	Property and Planning	Health Capital Division	Infrastructure Planning			Manager Property Services		Senior Director Development and Commercial	New reporting line. All positions reporting are also moving.
CASB	Property and Planning	Health Capital Division	Infrastructure Planning			Director (Multiple)		Senior Director Business Case Development	New reporting lines. All position reporting to these positions are moving. Change to position titles to Director Capital Planning.
CASB	Infrastructure Portfolio Performance	Health Capital Division	Infrastructure Planning			Director Capital Delivery		Senior Director Business Case Development	New reporting line. Change to position title Director Capital Planning
CASB	Capital Project Delivery	Health Capital Division	Strategy, Assets and Support			Director Contract Management and Performance		Senior Director Program Management Officer	New reporting lines. All position reporting to these positions are moving.
CASB	Capital Project Delivery	Health Capital Division	Strategy, Assets and Support			Manager Program Management Office		Senior Director Program Management Officer	New reporting lines. All position reporting to these positions are moving.
CASB	Infrastructure Portfolio Performance	Health Capital Division	Strategy, Assets and Support			Senior Director Infrastructure Portfolio Performance		New Executive Director –Strategy, Assets & Support	New reporting line. All positions reporting to this position have also moved (except for the IAC positions – see table above for detail). Change position title to Senior Director Development and Commercial.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Proposed Division	Branch	Unit	[redacted]	osition Title	Position ID	Position Title	Change and Effect
CASB	Infrastructure Portfolio Performance	Health Capital Division	Strategy, Assets and Support			irector Operat		Senior Director Strategy and Operations	New reporting lines. All position reporting to these positions are moving.
CASB	Infrastructure Portfolio Performance	Health Capital Division	Infrastructure Planning			roject Director		Director Infrastructure Planning	New reporting lines.
CASB	Technical and Engineering	Health Capital Division	Strategy, Assets and Support			enior Director ngineering and echnical Servi		Senior Director Technical and Assurance	New reporting line. All positions reporting to this position have also moved. Change position title to Director Infrastructure Design.
CASB	Technical and Engineering	Health Capital Division	Strategy, Asset and Support			uilding Service anager		Director Asset Services	New reporting line.
CASB	Capital Project Delivery	Health Capital Division	Infrastructure Delivery			enior Director atellite Hospit rogram		New Executive Director Infrastructure Delivery	New reporting line. All positions reporting are also moving.
CASB	Capital Project Delivery	Health Capital Division	Infrastructure Delivery			enior Director, apital Project elivery		New Executive Director Infrastructure Delivery	New reporting line. All positions reporting are also moving.
		Health Capital Division	Strategy, Asset and Support			enior Director rogram Manag fficer		New Executive Director –Strategy, Assets & Support	New position. Direct report outlined above.
		Health Capital Division	Infrastructure Planning			enior Director usiness Case evelopment		New Executive Director Infrastructure Planning	New position. Direct report outlined above.
CASB	Infrastructure Portfolio Performance	Health Capital Division	Strategy, Asset and Support			rincipal Adviso apital Procure		Manager Procurement	New reporting line.

Section 2: Impacted Positions Consolidation and Integration

Human Resources

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Branch	Unit	Division	Unit	Team	Position ID	Position Title	Position ID	Position Title	Change and Effect
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	Work Health and Safety	[redacted]	Senior Director Health and Safety	[redacted]	Chief HR Officer	Position repurposed to Senior Director Work Health and safety Repurposed - Senior Director People, Safety and Performance (HES) - 32022007
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Organisational Development, Change and Talent		Senior Director Recruitment and Capability		Chief HR Officer	Position repurposed to Senior Director Organisational Development, Change and Talent
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Advisory Services		General Manager Human Resources		Chief HR Officer	Position repurposed to Senior Director Human Resources Advisory Service
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Organisational Development, Change and Talent		Assistant Advisor (ESO)		Senior Director Organisational Development, Change and Talent	Change to Unit name Change of position title to Executive and Project Support Officer
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Workforce Planning and Talent		Principal Advisor		Director Workforce Planning and Evaluation	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Leadership Capability		Manager Capability		Director Organisational Development and Change	Change to Unit name Change in reporting line Change of position title to Manager Leadership Capability Change to number of direct reports
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Leadership Capability		Principal Advisor		Manager Leadership Capability	Change to Unit name Change to number of direct reports
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Diversity and Inclusion		Senior Advisor		Manager Organisational Development and Diversity	Change of Unit Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Leadership Capability		Senior Advisor		Manager Leadership Capability	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Workforce Planning and Talent		Senior Advisor		Manager Organisational Change	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Leadership Capability		Senior Advisor		Manager Leadership Capability	Change to Unit name Change in reporting line

Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Leadership Capability	[redacted]	Assistant Advisor	Manager Leadership Capability	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Workforce Planning and Talent		Principal Advisor	Manager Talent Development	Change to Unit name Change to number of direct reports
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Learning and Development		Senior Advisor	Manager Talent Development	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Workforce Planning and Talent		Advisor	Manager Talent Development	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Organisational Development		Assistant Advisor	Manager Organisational Development and Diversity	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Job Design and Evaluation		Director Centralised Evaluation Team	Director Workforce Planning and Development	Change to Unit name Change to number of direct reports Change of position title to Director Workforce Planning and Evaluation
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Job Design and Evaluation		Senior Advisor	Director Workforce Planning and Evaluation	Change to Unit name
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Job Design and Evaluation		Senior Advisor	Director Workforce Planning and Evaluation	Change to Unit name
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Workforce Planning and Talent		Manager Recruitment	Director Workforce Planning and Development	Change to Unit name Change in reporting line Change to position title to Manager Attraction Change to number of direct reports
Human Resources	Recruitment and Capability	Corporate Services	HR Advisory Services	Recruitment and myHR Services		Principal Advisor	Director HR Operations	Change of Unit Change in reporting line Change in position title to Principal Advisor Recruitment and myHR Services Team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Workforce Planning and Talent		Senior Advisor	Manager Attraction	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Workforce Planning and Talent		Senior Advisor	Manager Attraction	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	Office of the Chief HR Officer	Office of the Chief HR Office		Advisor	Manager Attraction	Change to Unit name Change in reporting line

Human Resources	Recruitment and Capability	Corporate Services	Organisational Development, Change and Talent	Job Design and Evaluation	[redacted]	Advisor	[redacted]	Senior Director Workforce Relations and Policy	Change to Unit name Change in reporting line
Human Resources	Recruitment and Capability	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	Assistant Advisor	[redacted]	Principal Advisor	Change of Unit Change of position title to Recruitment Advisors Change in reporting line and Team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Recruitment and Capability	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	Assistant Advisor	[redacted]	Principal Advisor	Change of Unit Change of position title to Recruitment Advisors Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Recruitment and Capability	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	Assistant Advisor	[redacted]	Principal Advisor	Change of Unit Change of position title to Recruitment Advisors Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Recruitment and Capability	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	Assistant Advisor	[redacted]	Principal Advisor	Change of Unit Change of position title to Recruitment Advisors Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	Manager, Health, Safety and Rehabilitation	[redacted]	Senior Director HR Advisory Services	Change to Unit name Change of position title to Manager, Health, Safety and Rehabilitation Change reporting line
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	Principal Health and Safety Advisor	[redacted]	Manager, Health, Safety and Rehabilitation	Change to Unit name Change in team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	Senior Health and Safety Advisor	[redacted]	Manager, Health, Safety and Rehabilitation	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	Senior Health and Safety Advisor	[redacted]	Manager, Health, Safety and Rehabilitation	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	Principal Rehabilitation Adviso	[redacted]	Manager, Health, Safety and Rehabilitation	Change to Unit name Change of position title to Principal Rehabilitation Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	Senior Rehabilitation Advisor	[redacted]	Principal Rehabilitation Advisor	Change to Unit name

Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	Senior Rehabilitation Advisor	[redacted]	Principal Rehabilitation Advisor	Change to Unit name
Human Resources	Human Resources (former HSQ)	Corporate Services	Workforce Relations and Policy	Statewide People and Performance	[redacted]	Principal Employee Relations Advisor	[redacted]	Director People and Performance	Change of Unit Change in reporting line Change to position title to Principal Advisor Change to number of direct reports
Human Resources	Human Resources (former HSQ)	Corporate Services	Workforce Relations and Policy	Statewide People and Performance	[redacted]	Senior Employee Relations Advisor	[redacted]	Team Leader People and Performance	Change of Unit Change in reporting line Change to position title to Senior Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	Workforce Relations and Policy	Statewide People and Performance	[redacted]	Senior Employee Relations Advisor	[redacted]	Team Leader People and Performance	Change of Unit Change in reporting line Change to position title to Senior Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	Workforce Relations and Policy	Statewide People and Performance	[redacted]	Senior Employee Relations Advisor	[redacted]	Team Leader People and Performance	Change of Unit Change in reporting line Change to position title to Senior Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	Organisational Development, Change and Talent	Talent and Learning	[redacted]	Director Organisational Capability	[redacted]	Senior Director Organisational Development, Change and Talent	Change of Unit Change in reporting line Position repurposed - change in position title to Director, Workforce Planning and Development
Human Resources	Human Resources (former HSQ)	Corporate Services	Office of the Chief HR Officer	HR Governance	[redacted]	HR Governance and Business Advisor	[redacted]	Manager HR Governance	Change to Unit name Change in reporting line Change in position title to HR Governance Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	Business System Administrator myHR	[redacted]	Team Leader myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations Repurpose AO4 position to AO5 Team Leader myHR Services
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	Business System Administrator myHR	[redacted]	Team Leader myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	Business Systems Administrator myHR	[redacted]	Principal Advisor Recruitment and myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations Repurpose AO4 position to AO5 Team Leader myHR Services
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	Principal HR Business Partner	[redacted]	Director HR Operations	Change to Unit name Change of position title to Principal HR Advisor Change in reporting line and team to

					[redacted]		[redacted]		be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	enior HR Advisor	[redacted]	Director HR Operations	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	enior HR Advisor	[redacted]	Director HR Operations	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	enior HR Advisor	[redacted]	Director HR Operations	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	rincipal HR Business artner	[redacted]	Director HR Operations	Change to Unit name Change of position title to Principal HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	enior HR Advisor	[redacted]	Director HR Operations	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	rincipal HR Business artner	[redacted]	Director HR Operations	Change to Unit name Change of position title to Principal HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	enior HR Advisor	[redacted]	Director HR Operations	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	enior HR Advisor	[redacted]	Director HR Operations	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	enior HR Advisor	[redacted]	Director HR Operations	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Operations	[redacted]	enior HR Advisor PQ MP	[redacted]	Director HR Operations	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations

Human Resources	Human Resources (former HSQ)	Corporate Services	Organisational Development, Change and Talent	Organisational Change	[redacted]	rincipal Advisor - rganisational evelopment	[redacted]	Manager Organisational Change	Change of Unit Change in reporting line Change to number of direct reports Change of position title to Principal Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	Organisational Development, Change and Talent	Leadership Capability	[redacted]	enior Advisor earning & evelopment	[redacted]	Manager Talent Development	Change of Unit Change in reporting line Change of position title to Senior Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	Organisational Development, Change and Talent	Learning and Development	[redacted]	rincipal Advisor alent Management	[redacted]	Manager Attraction	Change of Unit Change in reporting line Change to number of direct reports Change of position title to Principal Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	Organisational Development, Change and Talent	Workforce Planning and Talent	[redacted]	enior Advisor orkforce Planning	[redacted]	Director Workforce Planning and Evaluation	Change of Unit Change in reporting line Change of position title to Senior Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	ecruitment Team eader	[redacted]	Principal Advisor Recruitment and myHR Services	Change to Unit name Change of position title to Team Leader Recruitment Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	edical Services Team eader	[redacted]	Principal Advisor Recruitment and myHR Services	Change to Unit name Change of position title to Team Leader Medical Services Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	ecruitment Advisor	[redacted]	Principal Advisor Recruitment and myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	ecruitment Advisor	[redacted]	Principal Advisor Recruitment and myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	ecruitment Advisor	[redacted]	Principal Advisor Recruitment and myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	redentialing and HR usiness Officer	[redacted]	Team Leader Medical Services	Change to Unit name Change of position title to Medical Services Advisor
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Advisory Services	[redacted]	xecutive Support fficer	[redacted]	Senior Director HR Advisory Services	Change to Unit name

					[redacted]			
Human Resources	Human Resources (former HSQ)	Corporate Services	HR Advisory Services	HR Advisory Services		HR Business Support Officer	Executive Support Officer	Change to Unit name
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	HR Operations		Director People and Culture	Senior Director HR Advisory Services	Change to Unit name Change to position title to Director HR Operations Change to number of direct reports - to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	HR Advisory Services		Business Support Officer	Senior Director HR Advisory Services	Change to Unit name Change in reporting line Change of position title to Executive Support Officer
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	HR Operations		Manager Workforce Services	Director HR Operations	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	HR Operations		Prin Advisor HR Partners	Director HR Operations	Change to Unit name Change of position title to Principal HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	HR Operations		Snr Advisor HR Partners	Director HR Operations	Change to Unit name Change of position title to Senior HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	HR Operations		Senior Advisor HR Partners	Director HR Operations	Change to Unit name Change of position to Senior HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	HR Operations		Snr Advisor HR Partners	Director HR Operations	Change to Unit name Change of position title to Senior HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	HR Operations		HR Support Officer	Director HR Operations	Change to Unit name Change in reporting line
Human Resources	People and Culture (former eHQ)	Corporate Services	Work Health and Safety	Monitoring, Evaluation and Compliance		Manager Monitoring, Evaluation and Compliance	Senior Director Health and Safety	Change of Unit Change of reporting line Change of position title to Manager Monitoring, Evaluation and Compliance

Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	WH&S Manager	Manager, Health, Safety and Rehabilitation	Change of Unit Change of position title to Senior Health and Safety Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation		Rehabilitation & Wellness Officer	Principal Advisor Health and Safety	Changes to Unit name Change in reporting line Change of position title to Rehabilitation Advisor
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation		Senior Advisor Health and Safety	Manager, Health, Safety and Rehabilitation	Changes to Unit name Change in Reporting line Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People and Culture (former eHQ)	Corporate Services	Organisational Development, Change and Talent	Learning and Development		Manager Employee Experience	Director Workforce Planning and Development	Change of Unit Change in reporting line Change of position title to Manager Talent Development Change to number of direct reports
Human Resources	People and Culture (former eHQ)	Corporate Services	Organisational Development, Change and Talent	Organisational Development		HR Advisor Strategy & Engagement	Manager Organisational Development and Diversity	Change of Unit Change in reporting line
Human Resources	People and Culture (former eHQ)	Corporate Services	Organisational Development, Change and Talent	Leadership Capability		HR Advisor Capability	Manager Leadership Capability	Change of Unit Change in reporting line
Human Resources	People and Culture (former eHQ)	Corporate Services	Organisational Development, Change and Talent	Learning and Development		Training Coordinator	Manager Talent Development	Change of Unit Change in reporting line Change of position title to Assistant Advisor
Human Resources	People and Culture (former eHQ)	Corporate Services	Organisational Development, Change and Talent	Organisational Change		Assistant HR Advisor	Manager Talent Development	Change of Unit Change in reporting line
Human Resources	People and Culture (former eHQ)	Corporate Services	Organisational Development, Change and Talent	Workforce Planning and Talent		HR Advisor	Manager Attraction	Change of Unit Change in reporting line
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Business Intelligence	HR Business Intelligence		Manager Workforce Planning & Analytics	Manager HR Insights and Business Intelligence	Change of Unit Change in reporting line Change of title to Principal HR Business Intelligence Analyst
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Business Intelligence	HR Business Intelligence		Workforce Data Analyst	Principal HR Business Intelligence Analyst	Change of Unit Change of title to Senior HR Business Intelligence Analyst
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services		HR Advisor Recruit & Wforce Establish	Principal Advisor Recruitment and myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations

								Change of position name to Team Leader Recruitment
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	ssist Advisor Recruit Vforce Establish	Principal Advisor Recruitment and myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations Change of position name to Recruitment Advisor
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	sst Advisor Recruit & Vforce Establish	Principal Advisor Recruitment and myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations Change of position name to Recruitment Advisor
Human Resources	People and Culture (former eHQ)	Corporate Services	HR Advisory Services	Recruitment and myHR Services	[redacted]	sst Advisor Recruit Vforce Estab Capab	Principal Advisor Recruitment and myHR Services	Change to Unit name Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations Change of position name to Recruitment Advisor
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	System Leadership and Advisory Services	[redacted]	irector System eadership and dvisory Services	Senior Director, Health and Safety	Change of Unit Change in reporting line Change to number of direct reports Change of position title to Director, System Leadership and Advisory Services
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	enior Advisor	Manager, Health, Safety and Rehabilitation	Change of Unit Change in reporting line Change of position title to Senior Health and Safety Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	enior Advisor	Manager, Health, Safety and Rehabilitation	Change of Unit Change in reporting line Change of position title to Senior Health and Safety Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	Monitoring, Evaluation and Compliance	[redacted]	rincipal Advisor	Manager, Monitoring, Evaluation and Compliance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	System Leadership and Advisory Services	[redacted]	rincipal Advisor	Director, System Leadership and Advisory Services	Change of Unit Change in reporting line

Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	Monitoring, Evaluation and Compliance	[redacted]	Principal Advisor	Manager, Monitoring, Evaluation and Compliance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	System Leadership and Advisory Services		Principal Advisor	Director, System Leadership and Advisory Services	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	Monitoring, Evaluation and Compliance		Principal Advisor	Manager, Monitoring, Evaluation and Compliance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	System Leadership and Advisory Services		Principal Advisor	Director, System Leadership and Advisory Services	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	Monitoring, Evaluation and Compliance		Principal Advisor	Manager, Monitoring, Evaluation and Compliance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	System Leadership and Advisory Services		Principal Advisor	Director, System Leadership and Advisory Services	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	System Leadership and Advisory Services		Principal Advisor	Director, System Leadership and Advisory Services	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation		Principal Advisor	Manager, Health, Safety and Rehabilitation	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance		Director, People and Performance	Senior Director, Workforce Relations and Policy	Change of Unit Change in reporting line Change of position title to Director, People and Performance Change to number of direct reports
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance		Principal Advisor	Director, People and Performance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance		Team Leader, Statewide People and Performance	Director, People and Performance	Change of Unit Change in reporting line Change of position title to Team Leader People and Performance Change to number of direct reports Role to be evaluated
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	HR Operations		Team Leader	Director HR Operations	Change of Unit Change of position title to Principal HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance		Principal Advisor	Director, People and Performance	Change of Unit Change in reporting line

Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance	[redacted]	[redacted] Senior Advisor	Team Leader People and Performance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance	[redacted]	[redacted] Senior Advisor	Team Leader People and Performance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	HR Operations	[redacted]	[redacted] Senior Advisor	Director, HR Operations	Change of Unit Change of position title to Senior HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance	[redacted]	[redacted] Advisor	Team Leader People and Performance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Office of WRP	[redacted]	[redacted] MP Assistant Project Officer	Director People and Performance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	[redacted] Senior Advisor	Principal Rehabilitation Advisor	Change of Unit Change in reporting line Change of position title to Senior Rehabilitation Advisor
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	Health, Safety and Rehabilitation	[redacted]	[redacted] Senior Advisor	Principal Rehabilitation Advisor	Change of Unit Change in reporting line Change of position title to Senior Rehabilitation Advisor
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	HR Operations	[redacted]	[redacted] Senior Advisor	Director, HR Operations	Change of Unit Change of position title to Senior HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	HR Operations	[redacted]	[redacted] Advisor	Director, HR Operations	Change of Unit Change of position title HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People, Safety and Performance	Corporate Services	Office of the CHRO	HR Governance	[redacted]	[redacted] Manager Diversity and Inclusion	Chief HR Officer	Change of Unit Change in reporting line Change of position title to Manager HR Governance
Human Resources	People, Safety and Performance	Corporate Services	Organisational Development, Change and Talent	Diversity and Inclusion	[redacted]	[redacted] Senior Advisor	Manager Organisational Development and Diversity	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Organisational Development, Change and Talent	Diversity and Inclusion	[redacted]	[redacted] Advisor	Manager Organisational Development and Diversity	Change of Unit Change in reporting line

Human Resources	People, Safety and Performance	Corporate Services	Organisational Development, Change and Talent	Learning and Development	[redacted]	[redacted] Advisor	Manager Talent Development	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Work Health and Safety	Work Health and Safety		[redacted] ssistant Advisor	Senior Director, Health and Safety	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Office of WRP		[redacted] dministration Officer	Senior Director, Workforce Relations and Policy	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	HR Advisory Services	HR Operations		[redacted] Principal Advisor	Director HR Operations	Change of Unit Change of position title to Principal HR Advisor Change in reporting line and team to be determined in line with new DoH divisions and portfolio allocations
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance		[redacted] MP Senior Project Officer - Workplace Conduct	Project Manager - Workplace Conduct	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance		[redacted] MP Project Manager - Workplace Conduct	Director People and Performance	Change of Unit Change in reporting line
Human Resources	People, Safety and Performance	Corporate Services	Workforce Relations and Policy	Statewide People and Performance		[redacted] enior Advisor	Team Leader People and Performance	Change of Unit Change in reporting line
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		[redacted] Manager	Senior Director HR Business Intelligence	Change in position title to Manager, HR Insights and Business Intelligence Change to number of direct reports
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		[redacted] Manager HR Systems and Data	Director HR Data and Business Intelligence	Change in position title to Manager, HR Data and Transformation Change to number of direct reports
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		[redacted] Manager	Senior Director HR Business Intelligence	Change in position title to Manager, HR Systems and Business Requirements
Human Resources	HR Business Intelligence	Corporate Services	Organisational Development, Change and Talent	Organisational Development		[redacted] Manager	Director Organisational Development and Change	Change of Unit Change in reporting line Change to number of direct reports Change of position title to Manager Organisational Development and Diversity
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		[redacted] enior Advisor	Manager, HR Systems and Business Requirements	Change in reporting line Change in function Change in position title to Senior HR Systems Support
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		[redacted] Principal Advisor	Senior Director HR Business Intelligence	Change in reporting line Position repurposed to Director, HR Data and Business Intelligence Change in direct reports
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence	[redacted] 30495165	[redacted] Workforce nformation Consultant	Manager HR Data and Transformation	Change of position title to Senior HR Data Engineer

Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence	[redacted]	Senior Advisor	Manager HR Data and Transformation	Change of position title to Senior Data Modeler
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Principal Workforce Informatics Officer	Manager HR Data and Transformation	Change of position title to Principal HR Data Engineer
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Senior Advisor	Manager HR Systems and Business Requirements	Change of title to Senior HR Systems Application Specialist
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Project Support Officer	Senior HR System Administrator	Change in reporting line Change of position title to Assistant HR Systems Support Officer
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Senior Advisor	Manager HR Systems and Business Requirements	Change of position title to Senior HR System Administrator Change in the number of direct reports
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Principal Advisor Business Intelligence	Manager HR Data and Transformation	Change of reporting line Change of position title to Principal HR Business Intelligence Analyst
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Workforce Information Consultant	Principal HR Business Intelligence Analyst	Change in reporting line Change of title to Senior HR Business Intelligence Analyst
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Assistant Advisor	Principal HR Business Intelligence Analyst	Change in reporting line Change of title to Assistant HR Business Intelligence Analyst
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Principal Advisor	Manager HR Insights and Business Intelligence	Change in reporting line Change of title to Principal HR Data Analyst
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Advisor	Principal HR Data Analyst	Change in reporting line Change of title to HR Data Analyst
Human Resources	HR Business Intelligence	Corporate Services	HR Business Intelligence	HR Business Intelligence		Assistant Advisor	Senior Director HR Business Intelligence	Change of position title to Executive and Project Support
RELINQUISHED AND/OR SECONDED OUT								
Human Resources	Human Resources Directorate (former HSQ)	Corporate Services	Office of the Chief HR Officer	Office of the Chief HR Officer		Relinquished Officer	Chief HR Officer	Change of Unit Change in reporting line
Human Resources	People and Culture (former eHQ)	Corporate Services	Office of the Chief HR Officer	Office of the Chief HR Officer		Seconded Out	Chief HR Officer	Change of Unit Change in reporting line
MOVEMENT OUT								
Human Resources	People and Culture (former eHQ)	eHQ				HR Advisor Contractor Engagement Team		Move to eHQ Division
Human Resources	People and Culture (former eHQ)	eHQ				Assistant Advisor Contractor Engagement Team		Move to eHQ Division
TO BE ABOLISHED (vacant and unfunded)								

Human Resources	Human Resources Directorate (former HSQ)	Corporate Services			[redacted]	Principal Workforce Data Analyst		To be abolished
Human Resources	Human Resources Directorate (former HSQ)	Corporate Services				Director HR Business Partnering		To be abolished
Human Resources	Human Resources Directorate (former HSQ)	Corporate Services				Principal HR Business Partner		To be abolished
Human Resources	Human Resources (former HSQ)	Corporate Services				HR Business Support Officer		Position to be abolished. MOHRI and funding to be transferred to HR Business Intelligence to offset 32031345
MOVEMENT IN								
Business Partnership and Improvement	Change and Culture Leadership	Corporate Services	Organisational Development, Change and Talent	Organisational Development and Change		Director, Change and Culture Leadership	Senior Director Organisational Development, Change and Talent	Change to Branch Change to Unit name Change in reporting line Change to number of direct reports Change in position title to Director Organisational Development and Change
Business Partnership and Improvement	Change and Culture Leadership	Corporate Services	Organisational Development, Change and Talent	Organisational Change		Manager	Director Organisational Development and Change	Change to Branch Change to Unit name Change in reporting line Change to number of direct reports Change of position title to Manager Organisational Change
Business Partnership and Improvement	Change and Culture Leadership	Corporate Services	Organisational Development, Change and Talent	Organisational Development		Principal Advisor	Manager Organisational Development and Diversity	Change to Branch Change to Unit name Change in reporting line
Business Partnership and Improvement	Change and Culture Leadership	Corporate Services	Organisational Development, Change and Talent	Organisational Development		Senior Advisor	Manager Organisational Development and Diversity	Change to Branch Change to Unit name Change in reporting line
Centre for Leadership Excellence		Clinical Excellence Queensland	Organisational Development, Change and Talent	Talent Development		Position to be identified through an Expression of Interest process	Manager Talent Development	Change to Branch Change to Unit name Change in reporting line

Finance

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Finance Branch	Budget and Analysis	Corporate Services	Finance	New Function - Office of the Chief Finance Officer	[redacted]	Senior Strategic Support Officer	[redacted]	Chief Finance Officer	Change in Unit Change in reporting line
Finance Branch	Office of the Chief Finance Officer	Corporate Services	Finance	New Function - Office of the Chief Finance Officer		Senior Executive Support Officer		Senior Strategic Support Officer	Change in reporting line.
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function - Office of the Chief Finance Officer		Executive Support Officer		Senior Strategic Support Officer	Change in Unit Change in reporting line
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	New Function - Office of the Chief Finance Officer		Administration Officer		Senior Strategic Support Officer	Change in Unit Change in reporting line
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Director Funding and Reporting		Chief Finance Officer	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Director, Financial Management		Chief Finance Officer	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Business Performance Manager		Director Funding and Reporting	Change in Unit Change in reporting line
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Senior Business Performance Officer		Business Performance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Business Performance Manager		Director Funding and Reporting	Change in Unit Change in reporting line
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Business Performance Officer		Business Performance Manager	Change in Unit

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering	[redacted]	Business Performance Officer	[redacted]	Business Performance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Principal Business Performance Officer		Business Performance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Business Performance Manager		Director Funding and Reporting	Change in Unit Change in reporting line
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Business Performance Officer		Business Performance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Principal Business Performance Officer		Director Funding and Reporting	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Principal Business Performance Officer		Director, Financial Management	Change in Unit Change in reporting line
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Senior Business Performance Officer		Director Funding and Reporting	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Seconded Out TMP		Director Funding and Reporting	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Business Performance Manager		Director Funding and Reporting	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Assistant Finance Officer		Business Performance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering		Administration Officer		Business Performance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial		Finance Officer WMSO		Business Performance Manager	Change in Unit

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
				Business Partnering	[redacted]		[redacted]		
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering	[redacted]	Senior Finance Officer	[redacted]	Business Performance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	New Function – Financial Business Partnering	[redacted]	Administration Officer CES Finance CAS	[redacted]	Business Performance Manager	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	New Function – Financial Business Partnering	[redacted]	Senior Finance Officer	[redacted]	Director, Financial Management	Change in Unit Change in reporting line
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	New Function – Financial Business Partnering	[redacted]	Senior Finance Officer	[redacted]	Director, Financial Management	Change in Unit Change in reporting line
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	New Function – Financial Business Partnering	[redacted]	Finance Coordinator	[redacted]	Director, Financial Management	Change in Unit Change in reporting line
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	New Function – Financial Business Partnering	[redacted]	Finance Coordinator	[redacted]	Director, Financial Management	Change in Unit Change in reporting line
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	New Function – Financial Business Partnering	[redacted]	Finance Coordinator	[redacted]	Director, Financial Management	Change in Unit Change in reporting line
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	New Function – Financial Business Partnering	[redacted]	Finance Coordinator	[redacted]	Director, Financial Management	Change in Unit Change in reporting line
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Budget, Assessment and Performance	[redacted]	Senior Director, Budget & Analysis	[redacted]	Chief Finance Officer	Change in position title to Senior Director, Financial Budget, Assessment and Performance
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Policy Controls and Advisory	[redacted]	Senior Director, Statutory and Advisory Services	[redacted]	Chief Finance Officer	Change in position title to Senior Director, Financial Policy Controls and Advisory
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Director, Accounting Services	[redacted]	Senor Director, Financial Accounting and System Operations	Change in Unit Change in reporting line All positions reporting to this impacted position are also realigning

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Accounting and System Operations		Manager, Financial Accounting		Director, Accounting Services	Change in Unit
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Accounting and System Operations		Principal Finance Officer, Fin Accounting		Manager, Financial Accounting	Change in Unit Change in reporting line
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Accounting and System Operations		Senior Finance Officer, Fin Accounting		Manager, Financial Accounting	Change in Unit
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Accounting and System Operations		Finance Officer, Financial Accounting		Manager, Financial Accounting	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Accounting and System Operations		Management Accountant		Manager, Financial Accounting	Change in Unit Change in reporting line All positions reporting to this impacted position are also realigning
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Accounting and System Operations		Senior Finance Officer TMP		Management Accountant	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Accounting and System Operations		Finance Coordinator		Management Accountant	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Accounting and System Operations		Finance Officer		Management Accountant	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Accounting and System Operations		Finance Officer		Management Accountant	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Accounting and System Operations		Finance Officer		Management Accountant	Change in Unit
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Accounting and System Operations		Manager, Financial Account Team 2		Director, Accounting Services	Change in Unit
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Accounting and		Principal Finance Officer, Fin Accounting		Manager, Financial Account Team 2	Change in Unit Change in reporting line

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
				System Operations					
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Accounting and System Operations		Principal Finance Officer, Fin Accounting	3	Manager, Financial Account Team 2	Change in Unit
Finance Branch	Statutory and Advisory Services	Corporate Services	Finance	Financial Accounting and System Operations		Finance Officer, Financial Accounting	3	Manager, Financial Account Team 2	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Accounting and System Operations		Management Accountant	3	Manager, Financial Account Team 2	Change in Unit Change in reporting line
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Asset Accountant	3	Manager, Financial Account Team 2	Change in Unit Change in reporting line
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Director of Financial Performance	3	Senior Director, Financial Accounting & System Operations	Change in Unit Change in reporting line
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Senior Finance Manager	3	Director of Financial Performance	Change in Unit All positions reporting to this impacted position are also realigning
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Assistant Finance Officer	3	Senior Finance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Assistant Finance Officer	3	Senior Finance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Senior Finance Officer	3	Senior Finance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Finance Officer	3	Senior Finance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Finance Officer	3	Senior Finance Manager	Change in Unit

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Financial Assurance Officer CAS		Senior Finance Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Revenue Manager		Director of Financial Performance	Change in Unit Change in reporting line All positions reporting to this impacted position are also realigning
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Revenue Officer		Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Team Supervisor		Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Revenue Officer		Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Revenue Officer		Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Team Supervisor		Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Revenue Officer		Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Revenue Officer		Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Revenue Officer		Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations		Team Supervisor		Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and		Team Leader		Revenue Manager	Change in Unit

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
				System Operations	[redacted]		[redacted]		
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Team Leader	3[redacted]	Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Team Leader	3[redacted]	Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Revenue Officer	3[redacted]	Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Revenue Officer	3[redacted]	Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Revenue Officer	3[redacted]	Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Revenue Officer	3[redacted]	Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Revenue Officer TMP	3[redacted]	Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Revenue Officer TMP	3[redacted]	Revenue Manager	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Revenue Officer CAS	3[redacted]	Revenue Manager	Change in Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Policy Controls and Advisory	[redacted]	Director, Revenue Strategy & Support Unit	3[redacted]	Senior Director, Financial Policy Controls and Advisory	Change in Unit Change in reporting line All positions reporting to this impacted position are also realigning

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Policy Controls and Advisory		Manager, Practice Management Support	3	Director, Revenue Strategy & Support Unit	Change in Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Policy Controls and Advisory		Principal Advisor 19(2)	3	Manager, Practice Management Support	Change in Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Policy Controls and Advisory		Principal Advisor - Private Practice	3	Manager, Practice Management Support	Change in Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Policy Controls and Advisory		Principal Advisor, Practice Management	3	Manager, Practice Management Support	Change in Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Policy Controls and Advisory		Principal Revenue Analyst	3	Director, Revenue Strategy & Support Unit	Change in Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Policy Controls and Advisory		Manager, Compensable Revenue Program	3	Director, Revenue Strategy & Support Unit	Change in Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Policy Controls and Advisory		Principal Policy Officer	3	Manager, Compensable Revenue Program	Change in Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Policy Controls and Advisory		Principal Revenue Officer Principal Revenue Officer (GP Clause)	3	Manager, Compensable Revenue Program	Change in Unit
Finance Branch	Financial Policy Controls and Advisory	Corporate Services	Finance	Financial Budget, Assessment and Performance		Manager Financial Legislation & Policy	3	Director, Analysis	Change in Unit Change in reporting line
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Manager, Management Accounting	3	Director, Analysis	Change in Unit Change in reporting line
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Management Accountant	3	Manager, Management Accounting	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Management Accountant	3	Manager, Management Accounting	Change in Unit
Finance Branch	Financial Management (eHQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Senior Finance Officer	3	Management Accountant	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Manager Funding and Reporting	3	Director, Analysis	Change in Unit Change in reporting line
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Finance Officer	3	Manager Funding and Reporting	Change in Unit

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Business Performance Officer	3	Manager Funding and Reporting	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Principal Business Performance Officer	3	Manager Funding and Reporting	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Business Performance Officer	3	Manager Funding and Reporting	Change in Unit
Finance Branch	Finance Directorate (former HSQ)	Corporate Services	Finance	Financial Budget, Assessment and Performance		Senior Business Performance Officer	3	Manager Funding and Reporting	Change in Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Budget, Assessment and Performance		Manager, Models & Costing	3	Senior Director, Financial Budget, Assessment and Performance	Change in team within Unit Change in reporting line All positions reporting to this impacted position are also realigning
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Budget, Assessment and Performance		Principal Finance Officer, Models & Costing	3	Manager, Models & Costing	Change in team within Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Budget, Assessment and Performance		Principal Finance Officer, Models & Costing	3	Manager, Models & Costing	Change in team within Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Budget, Assessment and Performance		Senior Finance Officer	3	Manager, Models & Costing	Change in team within Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Budget, Assessment and Performance		Principal Finance Officer TMP	3	Manager, Models & Costing	Change in team within Unit
Finance Branch	Budget and Analysis	Corporate Services	Finance	Financial Budget, Assessment and Performance		Principal Finance Officer	3	Manager, Models & Costing	Change in team within Unit Change in reporting line
Finance Branch	Finance Business Intelligence	Corporate Services	Finance	Finance Solutions		Data Governance SME TMP	3	Director, System Support	Change in Unit
Finance Branch	Finance Business Intelligence	Corporate Services	Finance	Finance Solutions		Principal Data Governance Officer TMP	3	Data Governance SME TMP	Change in Unit
Finance Branch	Finance Business Intelligence	Corporate Services	Finance	Finance Solutions		Senor Data Improvement Coordinators TMP	3	Data Governance SME TMP	Change in Unit
Finance Branch	Finance Business Intelligence	Corporate Services	Finance	Finance Solutions		Celonis Strategic Manager TMP	3	Director, System Support	Change in Unit
Finance Branch	Finance Business Intelligence	Corporate Services	Finance	Finance Solutions		Business Value Architect TMP	3	Celonis Strategic Manager TMP	Change in Unit

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Finance Branch	Finance Business Intelligence	Corporate Services	Finance	Finance Solutions	[redacted]	Principal Data Analyst TMP	[redacted]	Celonis Strategic Manager TMP	Change in Unit
Finance Branch	Finance Business Intelligence	Corporate Services	Finance	Finance Solutions		Senior Data Analyst TMP		Director, System Support	Change in Unit
Finance Branch	Finance Business Intelligence	Corporate Services	Finance	Finance Solutions		Senior Data Analyst TMP		Director, System Support	Change in Unit
Finance Branch	Finance Branch	Corporate Services	Finance	Finance Solutions		Coordinator Information Specialist Other Business		Data Analytics Manager	Change in team within Unit Change in reporting line
Finance Branch	Finance Branch	Corporate Services	Finance	Finance Solutions		Coordinator Information Specialist		Data Analytics Manager	Change in team within Unit Change in reporting line
Finance Branch	Finance Branch	Corporate Services	Finance	Finance Solutions		Business Analyst		Coordinator Information Specialist Other Business	Change in team within Unit
Finance Branch	Finance Solutions	Corporate Services	Finance	Finance Solutions		DSS Principal Developer		Manager, DSS Development	Change in reporting line
Finance Branch	Finance Solutions	Corporate Services	Finance	Finance Solutions		DSS Principal Developer		Manager, DSS Development	Change in reporting line
Finance Branch	Finance Solutions	Corporate Services	Finance	Finance Solutions		DSS Principal Developer (Apps 3)		Manager, DSS Development	Change in reporting line
Finance Branch	Finance Solutions	Corporate Services	Finance	Finance Solutions		Coordinator SIMS (GP Clause)		Manager, DSS Development	Change in reporting line
Finance Branch	Finance Solutions	Corporate Services	Finance	Finance Solutions		DSS Technician		Manager, DSS Development	Change in reporting line

MOVEMENTS IN									
EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Prevention Division		Corporate Services	Finance	**New Function** - Office of the Chief Finance Officer	[redacted]	Executive Director Quarantine Fee Recovery	[redacted]	Chief Finance Officer	Change to new division Change in reporting line All positions reporting to this impacted position are also realigning. Pending details

COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Senior Director, Finance Transactional Services	[redacted]	Chief Finance Officer	Change to new Division Change in reporting line Change in position title to Senor Director, Financial Accounting and System Operations

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	**Branch/Unit**	**Proposed Division**	**Branch**	**Unit**	**Position ID**	**Position Title**	**Position ID**	**Position Title**	**Change and Effect**
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Accts Receivable Team Ld Quarantine TMP	[redacted]	Director of Financial Performance	Change to new division Change in reporting line All positions reporting to this impacted position are also realigning
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Finance Officer Quarantine TMP	[redacted]	Accts Receivable Team Ld Quarantine TMP	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	FTS Contractor Quarantine TMP	[redacted]	Accts Receivable Team Ld Quarantine TMP	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Assistant Finance Officer Quarantine TMP	[redacted]	Accts Receivable Team Ld Quarantine TMP	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Assistant Finance Officer Quarantine TMP	[redacted]	Accts Receivable Team Ld Quarantine TMP	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Assistant Finance Officer Quarantine TMP	[redacted]	Accts Receivable Team Ld Quarantine TMP	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Assistant Finance Officer Quarantine TMP	[redacted]	Accts Receivable Team Ld Quarantine TMP	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Assistant Finance Officer Quarantine TMP	[redacted]	Accts Receivable Team Ld Quarantine TMP	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Finance Officer, Assets	[redacted]	Manager, Financial Account Team 2	Change to new division Change in reporting line
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Finance Officer, Assets	[redacted]	Manager, Financial Account Team 2	Change to new division Change in reporting line
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Manager State-wide Finance Services	[redacted]	Director of Financial Performance	Change to new division Change in reporting line All positions reporting to this impacted position are also realigning

COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Team Lead, Card Compliance	[redacted]	Manager State-wide Finance Services	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Finance Officer	[redacted]	Team Lead, Card Compliance	Change to new division

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	enior Finance Officer anking	3	Manager State-wide Finance Services	Change to new division All positions reporting to this impacted position are also realigning
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	enior Finance Officer	3	Senior Finance Officer Banking	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	nance Officer	3	Senior Finance Officer Banking	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	anking Officer uaran. Contractor MP	3	Senior Finance Officer Banking	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	incipal Systems fficer	3	Manager State-wide Finance Services	Change to new division All positions reporting to this impacted position are also realigning
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	enior Systems fficer	3	Principal Systems Officer	Change to new division All positions reporting to this impacted position are also realigning
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	nance Officer	3	Senior Systems Officer	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	stems Officer	3	Senior Systems Officer	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	enior Systems fficer	3	Principal Systems Officer	Change to new division All positions reporting to this impacted position are also realigning
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	ssistant Systems fficer	3	Senior Systems Officer	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	stems Officer	3	Senior Systems Officer	Change to new division

COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Systems Officer	Senior Systems Officer	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Assistant Systems Officer	Senior Systems Officer	Change to new division

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations	[redacted]	Senior Banking Officer	[redacted]	Manager State-wide Finance Services	Change to new division All positions reporting to this impacted position are also realigning
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations		Banking Officer		Senior Banking Officer	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations		Manager Finance Business Centre		Director of Financial Performance	Change to new division Change in reporting line
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations		Principal Finance Officer		Manager Finance Business Centre	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations		Senior Finance Officer		Principal Finance Officer	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations		Finance Officer		Senior Finance Officer	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations		Assistant Finance Officer GL		Senior Finance Officer	Change to new division
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations		Finance Officer, AR		Revenue Manager	Change to new division Change in reporting line
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Accounting and System Operations		Assistant Finance Officer, AR		Revenue Manager	Change to new division Change in reporting line
COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Financial Policy Controls and Advisory		Senior Finance Officer AR		Director, Taxation	Change to new division Change in reporting line
COVID-19 Supply Chain Surety Division	Qld Government Critical Supply Reserve (QGCSR)	Corporate Services	Finance	**New Function** – Financial Business Partnering		Principal Finance Officer TMP		Director, Funding & Reporting	Change to new division Change in reporting line.

COVID-19 Supply Chain Surety Division	Finance Transactional Services	Corporate Services	Finance	Finance Solutions	[redacted]	System Trainer	[redacted]	Support & Training Manager	Change to new division Change in reporting line
Healthcare Purchasing and System Performance Division	Contracting and Performance Management	Corporate Services	Finance	**New Function** – Financial Business Partnering	[redacted]	Manager HHS Financial Performance	[redacted]	Director, Financial Management	Change to new division Change in reporting line All positions reporting to this impacted position are also realigning

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Healthcare Purchasing and System Performance Division	Contracting and Performance Management	Corporate Services	Finance	**New Function** – Financial Business Partnering	[redacted]	Principal Service Agreement Officer	[redacted]	Manager HHS Financial Performance	Change to new division
Healthcare Purchasing and System Performance Division	Community Services Funding Branch	Corporate Services	Finance	**New Function** – Financial Business Partnering		Principal Finance Officer		Director, Financial Management	Change to new division Change in reporting line
Health Capital Division	Capital & Asset Services Branch	Corporate Services	Finance	Financial Policy Controls and Advisory		Manager, Car Parking		Director, Financial Policy & Business Requirements	Change to new division Change in reporting line
Health Capital Division	Capital & Asset Services Branch	Corporate Services	Finance	**New Function** – Financial Business Partnering		Manager Capital Budgets & Accounting		Director, Financial Management	Change to new division. Change in reporting line All positions reporting to this impacted position are also realigning
Health Capital Division	Capital & Asset Services Branch	Corporate Services	Finance	**New Function** – Financial Business Partnering		PRINCIPAL ADVISOR		Manager Capital Budgets & Accounting	Change to new Division
Health Capital Division	Capital & Asset Services Branch	Corporate Services	Finance	**New Function** – Financial Business Partnering		PRINCIPAL ADVISOR		Manager Capital Budgets & Accounting	Change to new Division
Health Capital Division	Capital & Asset Services Branch	Corporate Services	Finance	**New Function** – Financial Business Partnering		ADVISOR CIDU		Manager Capital Budgets & Accounting	Change to new Division
Health Capital Division	Capital & Asset Services Branch	Corporate Services	Finance	**New Function** – Financial Business Partnering		ASSISTANT ADVISOR		Manager Capital Budgets & Accounting	Change to new Division
Health Capital Division	Capital & Asset Services Branch	Corporate Services	Finance	**New Function** – Financial Business Partnering		ADMIN OFFICER TRANSACTIONAL		Manager Capital Budgets & Accounting	Change to new Division

MOVEMENTS OUT

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Finance Branch	Financial Management (eHQ)	eHQ	Operations and Performance	Software Asset Management	[redacted]	Software Asset Manager	[redacted]	Senior Director Digital Services Mngmt	Move to eHQ. New reporting line All positions reporting to this impacted position are also realigning
Finance Branch	Financial Management (eHQ)	eHQ	Operations and Performance	Software Asset Management		Senior Software Asset Analyst		Software Asset Manager	Move to eHQ Division
Finance Branch	Financial Management (eHQ)	eHQ	Operations and Performance	Software Asset Management		Software Asset Officer		Software Asset Manager	Move to eHQ Division
Finance Branch	Financial Management (eHQ)	eHQ	Operations and Performance	Software Asset Management		Software Asset Officer		Software Asset Manager	Move to eHQ Division
Finance Branch	Financial Management (eHQ)	eHQ	Operations and Performance	Software Asset Management		Software Asset Officer		Software Asset Manager	Move to eHQ Division
Finance Branch	Financial Management (eHQ)	eHQ	Operations and Performance			Finance Officer		Executive Director Corporate Services	Move to eHQ Division New reporting line
Finance Branch	Financial Management (eHQ)	eHQ	Operations and Performance			Finance Officer		Executive Director Corporate Services	Move to eHQ Division New reporting line
Finance Branch	Financial Management (eHQ)	eHQ	Operations and Performance	Software Asset Management		Finance Officer		Digital Asset Strategic Manager	Move to eHQ Division New reporting line
Finance Branch	Financial Management (eHQ)	eHQ	Operations and Performance	Software Asset Management		Finance Officer Assets & Purchasing		Digital Asset Strategic Manager	Move to eHQ Division New reporting line

Business Services

- Business services leads within current department divisions are proposed to be realigned to a newly created Business Services Branch within Corporate Services Division.
- All business services leads are proposed to report to a newly titled Director Business Services (proposed to be renamed from Director Governance and Engagement) which will report to the Deputy Director-General, Corporate Services Division.
- All business services positions that currently report to the business services leads (listed in the table below) are also proposed to realign with their respective lead.
- All business services staff will remain primarily located with their current division/branch/unit/team and continue to provide business services to their current client/s.
- Following implementation of the business case for change, a detailed review of roles, responsibilities, and processes will be undertaken for business services across the department, led by the newly titled Director Business Services.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Aboriginal and Torres Strait Islander Health Division	Office of the Deputy Director-General	Corporate Services Division	NEW Business Services Branch		[redacted]	Manager, Divisional Business Services	[redacted]	Director Business Services	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
Clinical Excellence Queensland	Office of the Deputy Director-General	Corporate Services Division	NEW Business Services Branch			Finance and Business Services Unit Manager		Director Business Services	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Office of the Deputy Director-General	Corporate Services Division	NEW Business Services Branch			Manager Executive & Business Services		Director Business Services	New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Corporate Enterprise Solutions	Corporate Services Division	NEW Business Services Branch			Manager Business Services & Support		Director Business Services	New reporting line. All positions reporting to this impacted position are also realigning.
Corporate Services Division	Office of the Deputy Director-General	Corporate Services Division	NEW Business Services Branch			Manager Business Services		Director Business Services	New reporting line. All positions reporting to this impacted position are also realigning.
COVID-19 Response Division	Office of the Chief Health Officer	Corporate Services Division	NEW Business Services Branch			Business Services Manager TMP		Director Business Services	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
COVID-19 Response Division	Vaccination Taskforce	Corporate Services Division	NEW Business Services Branch			Manager Business Services & Governance TMP		Director Business Services	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
COVID-19 Supply Chain Surety Division	Qld Government Critical Supply Reserve (QGCSR)	Corporate Services Division	NEW Business Services Branch			Business Manager TMP		Director Business Services	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
Healthcare Purchasing and System Performance Division	Office of the Deputy Director-General	Corporate Services Division	NEW Business Services Branch			Manager Business Services		Director Business Services	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
Office of the Director-General	Office of the Executive Director	Corporate Services Division	NEW Business Services Branch			Director Business Services (Currently Director Governance & Engagement)		DDG CORPORATE SERVICES DIVISION	Change to new division. New reporting line. Change in position title.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	[redacted]	sition Title	Position ID	Position Title	Change and Effect
Office of the Director-General	Office of the Executive Director	Corporate Services Division	NEW Business Services Branch			nager Governance Special Projects		tor Business ces	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
Prevention Division	Office of the Deputy Director-General	Corporate Services Division	NEW Business Services Branch			nager Business rvices		tor Business ces	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.
Strategy Policy and Reform Division	Office of the Deputy Director-General	Corporate Services Division	NEW Business Services Branch			nager, Business d Corporate vernance		tor Business ces	Change to new division New reporting line. All positions reporting to this impacted position are also realigning.

Communications and Media

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Clinical Excellence Queensland	CEQ Engage	Strategy, Policy and Reform	Strategic Communications Branch	N/A	[redacted]	Manager	[redacted]	Senior Director SCB	Change to new Division New reporting line All positions within this team are moving, including: • 30478320 • 32010564 • 30494142 • 30481554
Corporate Services	Communication and Engagement	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Manager, Engagement		Senior Director SCB	Change to new Division New reporting line All positions within this team are moving, including: • 32051069 • 30490029 • 30491430 • 32031556
Corporate Services	Communication and Engagement	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Communications Manager		Senior Director SCB	Change to new Division New reporting line All positions within this team are moving, including: 32038080 32019110 32025413
Corporate Services	Communication and Engagement	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Web Manager		Senior Director SCB	Change to new Division New reporting line All positions within this team are moving, including: 30489788 30496909
Corporate Services	Communication and Engagement	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Communications Officer A07 TMP		Director of Marketing and Communications	Change to new Division New reporting line
Corporate Services	Communication and Engagement	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Communications Lead TMP		Director of Marketing and Communications	Change to new Division New reporting line
Corporate Services	Communication and Engagement	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Senior Communications & Corro Officer		Director of Marketing and Communications	Change to new Division New reporting line
Corporate Services	Corporate Enterprise Solutions	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Change and Communications Lead		Senior Director SCB	Change to new Division New reporting line All positions within this team are moving including: • 32089452 • 32089392 • 32063890 • 32054014
Corporate Services	Business Partnerships and	Strategy, Policy and Reform Division	Strategic Communications Branch			Principal Advisor		Communication and Engagement Manager	Change to new division. New reporting line.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
	Improvement Branch								
COVID Supply Chain Surety	Communication and Engagement	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Communications Manager		Senior Director SCB	Change to new Division New reporting line All positions within this team are moving, along with Engagement positions, including • 32071801 • 32071014 • 32081646 • 32093265 • 32093266 • 32093267 • 32079075 • 32080952
eHealth	Communication and Media	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Director Media and Communications		Senior Director SCB	Change to new Division New reporting line All positions within this team are moving, including: • 32003293 • 30496456 • 32054974 • 32001051 • 32002098 • 32001418 • 32000927 • 32057103 • 30472948 • 30477191 • 32056147 • 32000924 • 30478305
Healthcare Purchasing and System Performance	Office of Rural Health	Strategy, Policy and Reform	Strategic Communications Branch	Creative, Social and Digital Media		Graphics and Multimedia Officers		Manager Creative, Social and Digital Media	Change to new Division New reporting line
Prevention	Online team	Strategy, Policy and Reform	Strategic Communications Branch	Online Services		Senior Officer e-Learning, Project Officers, Online Publishers and Assistant Trainer		Manager Online Services	Change to new Division New reporting line
Prevention	VAD project team	Strategy, Policy and Reform	Strategic Communications Branch	Marketing and Communications		Strategic Comms & Engagement VAD TMP		Director, Marketing and Communications	Change to new Division New reporting line
Strategy, Policy and Reform	Reform Office	Strategy, Policy and Reform	Strategic Communications Branch	N/A		Director, Communications and Engagement		Senior Director SCB	New reporting line All positions within this team are moving, including: • 32092452 • 32093901

Governance and Risk

- Governance and Risk positions within current department divisions are proposed to be realigned to a newly titled Governance and Information Management Branch (currently Risk, Assurance and Information Management Branch), Corporate Services Division.
- All staff listed in the table below will remain primarily located with their current division/branch/unit/team and continue to provide governance and risk functions to/for their current client/s and services.
- Risk, Assurance and Information Management Branch is proposed to be renamed to Governance and Information Management Branch.
- Director Risk and Business Continuity position is proposed to be renamed to Director Risk and Fraud.
- Manager Corporate Planning and Governance position is proposed to be renamed to Manager Governance and Planning.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Aboriginal and Torres Strait Islander Health Division	Office of the Deputy Director-General	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Manager ODDG		Director, Risk and Fraud	Change to new division New reporting line.
Clinical Excellence Queensland	Office of the Deputy Director-General	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Manager Governance and Strategy Support		Director, Governance	Change to new division New reporting line.
Clinical Excellence Queensland	Office of the Deputy Director-General	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Principal Project Officer		Manager Governance and Strategy Support	Change to new division
Clinical Excellence Queensland	Office of the Deputy Director-General	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Project Officer TMP		Manager Governance and Strategy Support	Change to new division
Corporate Services Division	Risk, Assurance and Information Management Branch	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Senior Governance Advisor		Director, Risk and Fraud (currently Director Risk and Business Continuity)	New reporting line. Change to branch title.
Corporate Services Division	Risk, Assurance and Information Management Branch	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Principal Governance Advisor		Manager, Governance and Planning (currently Manager Corporate Planning & governance)	New reporting line. Change to branch title.
Corporate Services Division	Risk, Assurance and Information Management Branch	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Principal Policy Advisor		Manager, Governance and Planning	New reporting line. Change to branch title.
Corporate Services Division	Risk, Assurance and Information Management Branch	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Strategy and Planning Officer		Manager, Governance and Planning	New reporting line. Change to branch title.
Corporate Services Division	Risk, Assurance and Information Management Branch	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Governance Advisor		Manager, Governance and Planning	New reporting line. Change to branch title.
Corporate Services Division	Risk, Assurance and Information Management Branch	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Principal Fraud Control and Govern Officer		Director, Risk and Fraud	New reporting line. Change to branch title.
Corporate Services Division	Corporate Enterprise Solutions	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Senior Governance and Assurance Officer		Manager, Governance and Planning	Change to new branch. New reporting line.
Corporate Services Division	Corporate Enterprise Solutions	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Senior Advisor Service Continuity		Director, Risk and Fraud	Change to new branch. New reporting line.
Corporate Services Division	Office of the Deputy Director-General	Corporate Services Division	Governance and Information Management	Governance Ris Planning and Fraud		Manager Governance Executive Services		Director, Governance	Change to new branch. New reporting line.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Corporate Services Division	Office of the Deputy Director-General	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud	[redacted]	Principal Policy Officer Governance	[redacted]	Manager Governance Executive Services	Change to new branch.
COVID-19 Response Division	COVID Governance	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Risk and Governance Coordinator TMP		Manager Governance and Executive Services TMP	Change to new division New reporting line.
COVID-19 Response Division	COVID Governance	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Risk and Governance Coordinator TMP		Manager Governance and Executive Services TMP	Change to new division New reporting line.
COVID-19 Response Division	COVID Governance	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Manager Governance and Executive Services TMP		Director Governance	Change to new division New reporting line.
COVID-19 Supply Chain Surety Division	Qld Government Critical Supply Reserve (QGCSR)	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Manager Governance and Strategy TMP		Director Governance	Change to new division New reporting line.
COVID-19 Supply Chain Surety Division	Supply Chain Services	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Supply Business Improvement		Director Governance	Change to new division New reporting line.
eHealth Queensland	Corporate Services	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Director Risk and Audit		Executive Director, Governance and Information Management (currently Executive Director BPIB)	Change to new division New reporting line.
eHealth Queensland	Technology Services	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Principal Specialist Risk Management TMP		Director Risk and Audit	Change to new division New reporting line.
eHealth Queensland	Corporate Services	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Risk and Audit Coordinator		Director Risk and Audit	Change to new division New reporting line.
eHealth Queensland	Information Technology Services	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Governance and Assurance Officer		Manager, Governance and Planning	Change to new division New reporting line.
eHealth Queensland	Corporate Services	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Manager Audit and Risk		Director Risk and Audit	Change to new division New reporting line.
eHealth Queensland	Digital Solutions Delivery	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Manager Governance		Director Governance	Change to new division New reporting line.
eHealth Queensland	Digital Strategy and Transformation	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Manager Portfolio Risk		Director, Risk and Fraud	Change to new division New reporting line.
eHealth Queensland		Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Senior Records Officer		Principal Information Management	Change to new division New reporting line.
Health Capital Division	Office of the Deputy Director-General	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Manager Governance		Director, Risk and Fraud	Change to new division New reporting line.
Healthcare Purchasing and System Performance Division	Rural and Remote Health	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Manager Corporate Governance Program Coordination		Director Governance	Change to new division New reporting line.

EXISTING		PROPOSED			IMPACTED POSITIONS		NEW REPORTING		
Division/Branch	Branch/Unit	Proposed Division	Branch	Unit	Position ID	Position Title	Position ID	Position Title	Change and Effect
Healthcare Purchasing and System Performance Division	Office of the Deputy Director-General	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud	[redacted]	Manager Governanc and Improvement	[redacted]	Director Governance	Change to new division New reporting line.
Office of the Director-General	Office of the Executive Director	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Manager Governanc		Director, Governance	Change to new division New reporting line.
Office of the Director-General	Office of the Executive Director	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Project Officer		Principal Project Officer	Change to new division New reporting line.
Office of the Director-General	Office of the Executive Director	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Principal Project Officer		Manager, Governance and Planning	Change to new division New reporting line.
Prevention Division	Vaccination Taskforce	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		VCC Senior Policy TM		Director, Risk and Fraud	Change to new division New reporting line.
Strategy Policy and Reform Division	Office of the Associate Director-General	Corporate Services Division	Governance and Information Management	Governance Risk Planning and Fraud		Governance Officer TMP		Manager, Governance and Planning	Change to new division New reporting line.

BCFC Process Framework

Task	Timing
BUSINESS CASE RELEASE	
1. New Business Case for Change (BCFC) is developed, shared and consulted with ELT and union partners for identification of errors prior to release	Prior to release
2. The new BCFC is released to staff and unions partners via a special broadcast email and published on QHEPS/QAS intranet	Friday 8 August 2022
3. TQ to provide email invitation to DoH to distribute to QH staff regarding Together briefing on BCFC and advise that all staff can attend in paid time	TBA
OPERATIONALISATION – BUSINESS CASE	
4. Recurring meetings between parties to be established to collaboratively and respectfully discuss where there are opportunities for both parties to invest effort to help embed the change.	Ongoing (weekly to commence)
5. Minutes and actions will be circulated post meeting to attendees. **The minutes will capture any actions assigned in the meeting and these will be covered off at the start of the meeting.**	Ongoing
6. Engagement processes developed to support engagement across Divisions to include: • An ELT member to be aligned to each division **including for each new division** • Each ELT member to hold a divisional forum post the release of the business case to discuss the business case proposal and to answer questions	As required

Task	Timing
• Each ELT member to meet with their leadership team to discuss the BCFC document to ensure that leaders are able to answer questions and support their teams • Where identified through the feedback, ad hoc meetings led by the respective ELT member will be held with Divisions, Branches and Units where additional clarification is required on the why the proposed changes and the benefits. **These will be focused on allowing and encouraging rigorous yet respectful discussion of the relative pros and cons of approaches.** • **A role of the ELT or leadership team member will be to document any feedback from members and for this to be provided to the BCFC project plan.**	
7. Feedback received will be reviewed progressively over the consultation period. • Feedback and our response to the feedback will be shared at the regular union meeting. • Where an employee is individually impacted by feedback resulting in a change from the BCFC, **genuine** consultation will occur with that employee. **The employee is welcome to be accompanied by a support person which may be their union rep.** • Where a team is impacted by feedback resulting in a change from the BCFC, **genuine** consultation will occur with that team.	During consultation period
8. Following the consultation period, and prior to finalising the next document, we will share the feedback with ELT and union partners	Following consultation period
9. Release date of the decision and implementation plan document will be outlined in the business case for change document	As outlined in BCFC
10. Final decision and implementation plan document will be released to staff and unions via email and publish on QHEPS/QAS intranet	As outlined in BCFC
11. Engagement processes developed to support engagement across Divisions following the release of the final decision and implementation plan document to include leadership by the DG-DDG-and Divisional Executives to deliver briefings to Divisions **and Branches** regarding the scope of changes in the final decision and implementation plan **and to address concerns raised**. These are designed to enable staff engagement via direct questions as well as via written comment/questions. These communication and engagements sessions will involve:	During consultation period

Task	Timing
• Each ELT member to hold a divisional forum post the release of the final decision and implementation plan document to answer questions and to discuss the decisions and rationale • Each ELT member to meet with their leadership team to discuss the final decision and implementation plan document to ensure that leaders are able to answer questions and support their teams • Where significant change is identified ad hoc meetings led by the respective ELT member will be held with Divisions, Branches and Units where additional clarification is required.	
ACCESS TO INFORMATION	
12. QH maintain and develop QHEPS/QAS intranet site, including information that allows the staff to access information regarding the new BCFC and final decision and implementation plan document to assist in developing deeper understanding of the proposed change. QH will also from time to time publish information such as FAQs on key issues and matters regarding process.	Ongoing
REVIEW AND EVALUATION	
13. QH is committed to reviewing the outcome of the change proposed in the BCFC. We will incorporate into existing processes evaluation and assessment criteria. For example, through the Department's operational plan, working for Queensland, pulse surveys and other already established mechanisms. We are supportive of engaging with stakeholders in the development of the measures (where required). QH will develop a draft term of reference (ToR) for a process and outcome review of BCFC and provide these to union partners for feedback and consideration.	Following delivery of the BCFC

CA-09

Cathie Allen

From: DG Connect
Sent: Friday, 26 August 2022 10:01 AM
Subject: Queensland Health executive appointments

Having trouble viewing this email? View Online

DG Connect

Shaun Drummond

Acting Director-General
Queensland Health

Dear colleagues

Following recent recruitment processes, I am pleased to confirm a number of appointments to executive positions in Queensland Health.

The calibre of applications for all positions was outstanding, coming from local, national and international candidates. The excellent response highlights that Queensland Health can attract the best talent as we continue to evolve and grow as a system.

The appointments are:

- Dr David Rosengren – Chief Operating Officer
- Melissa Carter – Deputy Director-General, Healthcare Purchasing and System Performance Division
- Dr Helen Brown – Deputy Director-General, Clinical Excellence Queensland
- Haylene Grogan – Chief First Nations Health Officer
- Damian Green – Deputy Director-General, eHealth Queensland
- Jasmina Joldić – Associate Director-General, Strategy, Policy and Reform Division
- Colleen Jen – Deputy Director-General, Clinical Planning and Service Strategy
- David Sinclair – Deputy Director-General, Corporate Services Division
- Joe Occhino – Assistant Deputy Director-General, Workforce Strategy

They are joined by existing members of the executive team:

- Dr John Gerrard – Chief Health Officer
- Priscilla Radice – Deputy Director-General, Health Capital Division
- Craig Emery – Queensland Ambulance Service Commissioner
- Professor Keith McNeil – Chief Medical Officer
- Luan Sadikaj – Chief Finance Officer
- Nick Steele, who will transition into the role of General Manager, Integrated Scientific, Clinical and Prevention Services Division

Back row L-R: *Luan Sadikaj, David Sinclair, Helen Brown, Jasmina Joldić, David Rosengren, Craig Emery, Melissa Carter, Joe Occhino*

Front row L-R: *Damian Green, Keith McNeil, Shaun Drummond, Haylene Grogan, Priscilla Radice, John Gerrard, Colleen Jen, Nick Steele*

An announcement about appointments to the positions of Queensland Health Director-General and Executive Director, Office of the Director-General will be made in due course.

Following this, we will formally convene an Executive Leadership Team (ELT).

I look forward to working closely with the new executives as they commence in their roles over the coming weeks, and please join me in congratulating each of them on their appointments.

Kind regards

Shaun Drummond
Acting Director-General

Queensland Health

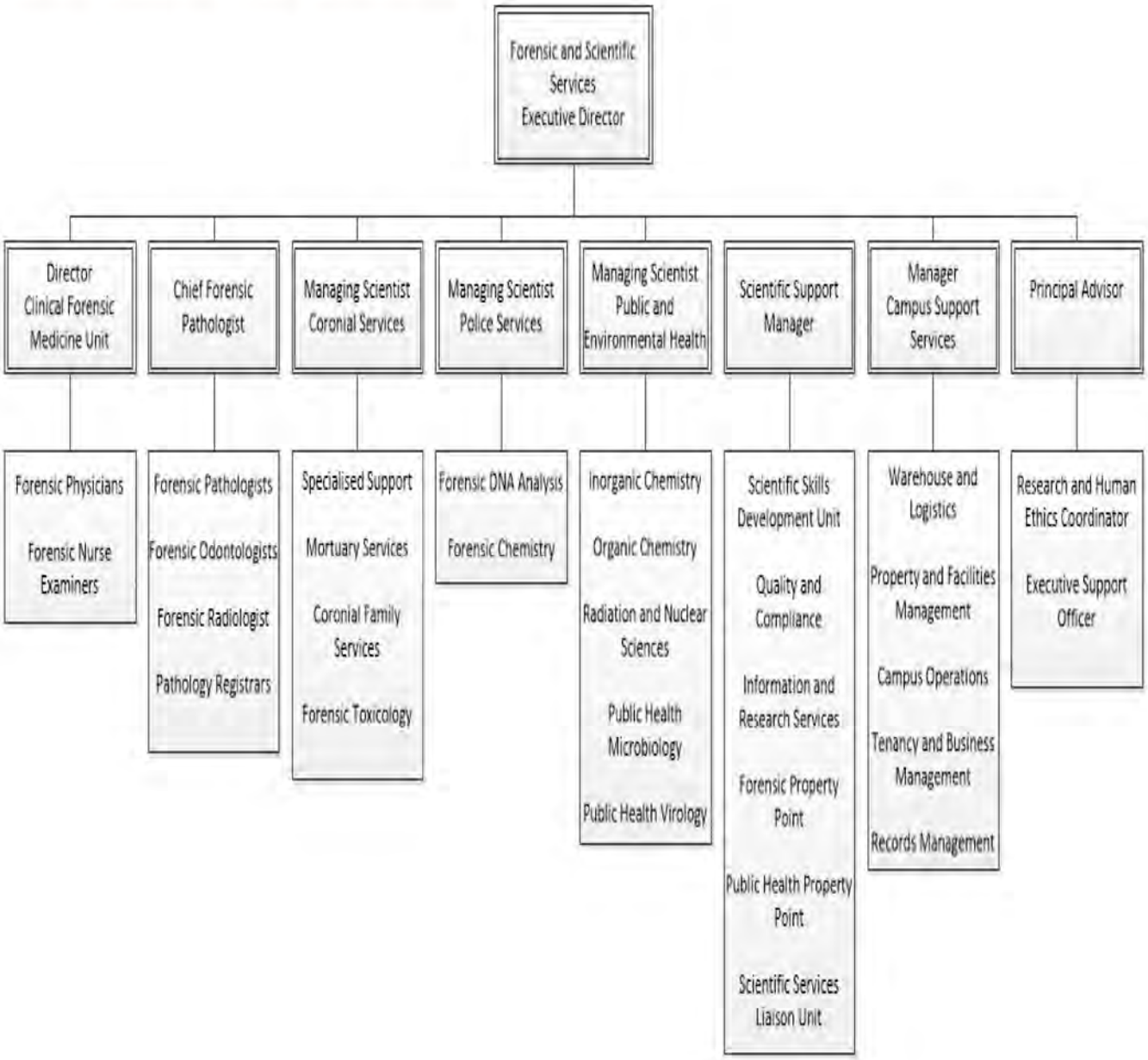
Queensland Government

33 Charlotte Street, Brisbane QLD 4000

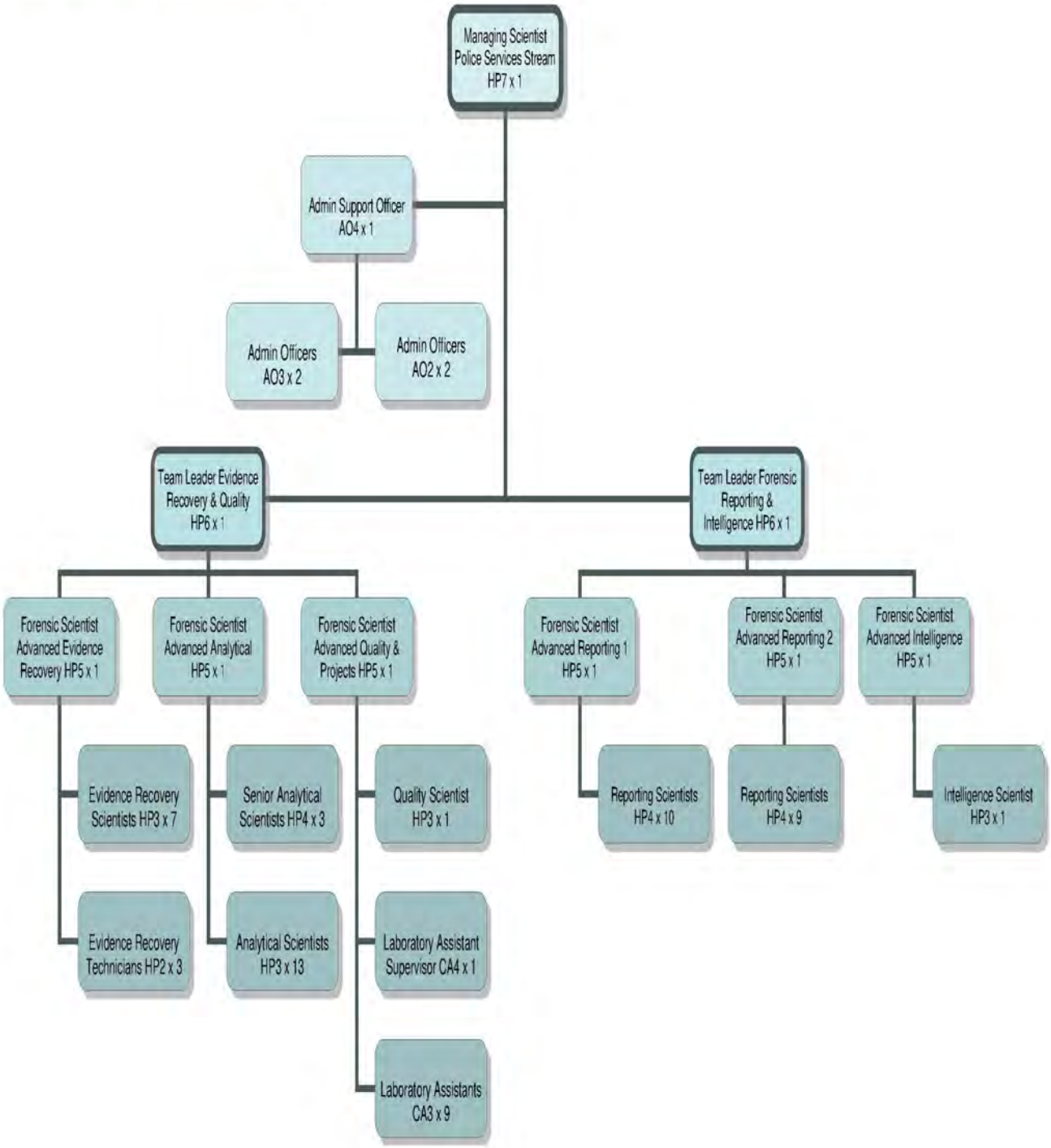
Queensland Government

CA-10

Forensic and Scientific Services Organisational Chart



Forensic DNA Analysis Team Chart



CA-11

Queensland Health

Forensic and Scientific Services

Police Services Stream Duty Statements – Administration

1 Purpose

The purpose of these duty statements is to describe the role of Administration personnel within Police Services Stream

2 Scope

These duty statements shall apply to Police Services Stream.

3 Definitions

Nil

4 Actions

Administration Support Officer

Coordinate and provide confidential administrative support to the Managing Scientist, Police Services Stream. This support includes -

- Communication between internal and external clients on behalf of the Managing Scientist.
- Supervision of the administrative staff in the delivery of professional and client focussed support to both the Forensic DNA Analysis Team and the Forensic Chemistry Team.
- Coordinate Career Success Plans (CSP) for Forensic DNA Analysis administrative staff and assist as required in CSP for Administration Officer, Forensic Chemistry.
- Representation of Administration Team to Management Team as required, including Management Review Reporting.
- Diary Management including coordination of meetings and providing minute support.
- Management of HR forms for staff of Forensic DNA Analysis including guidance to staff on HR issues, utilising myHR.
- S4 Hana – requestor of maintenance to office equipment, building / electrical faults for staff / visitor safety. Ordering of stocks / consumables as required.
- Update responsibility for Forensic DNA Analysis administration procedures in QIS2.
- The storage and archiving of forensic case related records.
- Mail distribution including the forwarding of scientific statements.
- Assist in compilation of articles for presentation in Forensic DNA Analysis newsletter.
- Office reception duties.

Administration Officer
Forensic DNA Analysis and Forensic Chemistry

Coordinate and provide confidential administrative support to the Team Leaders / Chief Chemist, and the teams. This support includes –

- Communication between internal and external clients on behalf of the Team Leaders, Chief Chemist.
- Diary Management including coordination of meetings and providing minute support.
- Management of HR forms for staff of Forensic DNA Analysis including guidance to staff on HR issues, utilising myHR.
- Auditor for fortnightly HR documentation for the relevant team.
- S4 Hana – requestor of maintenance to office equipment, building / electrical faults for staff / visitor safety. Ordering of stocks / consumables as required and reconciliation of accounts for such.
- Case management duties including the creation, storage and archiving of forensic case related records.
- Update responsibility for Forensic DNA Analysis / Forensic Chemistry administration procedures in QIS2.
- Mail distribution including the forwarding of scientific statements.
- Assist in compilation of articles for presentation in Forensic DNA Analysis newsletter.
- Office reception duties.

Administrative Officer
Provide administrative support to all sections of Forensic DNA Analysis. This support includes-

- Reception duties for Forensic DNA Analysis with respect to internal and external clients.
- Case management duties including the creation, storage and archiving of forensic case related records.
- Maintenance of office equipment and administrative supplies for Forensic DNA Analysis.
- Assisting with maintenance of Forensic DNA Analysis administration procedures on QIS2 as required.
- Recording of statistics of daily workflow.
- Ongoing management of LIMS work lists.
- Mail distribution including the forwarding of scientific statements.
- Management of HR forms for staff of Forensic DNA Analysis including guidance to staff on HR issues.
- Assist in compilation of articles for presentation in Forensic DNA Analysis newsletter.

5 Records

Nil

6 Associated Documentation

Nil

7 References

Nil

8 Amendment History

Version	Date	Author/s	Amendments
1	18 June 2006	R Smith	First Issue
2	30 Aug 2007	R Smith	No Information
3	1 April 2008	R Smith	No Information
4	23 Aug 2010	W Harmer	Moved into new format. Updated with DNA Analysis Unit.
5	7 Nov 2013	W Harmer	Updated with new name and new template.
6	9 June 2015	W Harmer	Updated with new template.
7	29 June 2018	W Harmer	Changed AUSLAB to LIMS
8	30 April 2020	W Harmer	Review of duties undertaken, include reference to S4Hana and myHR.
9	16 February 2022	W Harmer	Review to include Admin Officer in Forensic Chemistry – now collectively Police Services Stream

9 Appendices

Nil

Queensland Health
Forensic and Scientific Services

Forensic Reporting and Intelligence Team – Duty Statements

1 Purpose

To provide a framework for duties performed by members of the Forensic Reporting and Intelligence Team (FRIT) within Forensic DNA Analysis

2 Scope

This document applies to all members of the FRIT within Forensic DNA Analysis. Duties may vary from this document according to business requirements.

3 Definitions

DMU	DNA Management Unit
OQI	Opportunity for Quality Improvement (Queensland Health's equivalent of Non-Conformances and Corrective Actions)
CSP	Career Success Plan
FRIT	Forensic Reporting and Intelligence Team
KPI	Key Performance Indicator
NCIDD	National Criminal Investigation DNA Database
NIFA	NCIDD-Integrated Forensic Application
QPS	Queensland Police Service
SMU	Sample Management Unit
SOP	Standard Operating Procedure
SSDU	Scientific Skills Development Unit
SSLU	Scientific Services Liaison Unit
TAT	Turnaround Time
TM	Training Module

4 Team Leader – Forensic Reporting and Intelligence Team

4.1 Reporting structure

The Team Leader (HP6) of the FRIT reports to the Managing Scientist – Police Services Stream.

4.2 Duties

- Manage and develop the FRIT within Forensic DNA Analysis.
- Assist Managing Scientist (Police Services) in setting strategic direction for Forensic DNA Analysis.

- Monitor training and resource levels in the team in line with QIS 31010, and co-ordinate the use of resources according to dynamic workloads.
- Continue to develop training programs within FRIT in collaboration with Senior Scientists, especially concerning the training and development of new court Reporting Scientists.
- Participate in moot court evaluations on staff to evaluate competence in providing court evidence.
- Conduct team meetings and lead discussions on profile interpretation, method development and court reports where necessary.
- Present FRIT progress reports to senior management.
- Provide scientific advice and support to the FRIT sub-team leaders, and court Reporting Scientists and Scientists within, and outside of FRIT.
- Provide support to Quality and Projects team, including undertaking Proficiency Tests when allocated.
- Participate in FSS Training Co-ordinator's meetings as directed by SSDU where necessary.
- Provide advice and assistance to FRIT sub-team leaders at case conferences when required.
- Provide scientific advice to QPS officers or legal parties on matters of collection, sampling, testing and explanations of DNA profile interpretations when required.
- Provide expert testimony on reported cases, and on cases peer reviewed when required. Provide expert testimony on cases when the Reporting Scientist and Peer Reviewer are both absent when required.
- Liaise with SSLU and QPS DMU when necessary to co-ordinate the allocation of priority cases to case scientists.
- Keep abreast of current literature as it relates to current and emerging technologies.
- Participate in Quality Program including using QIS2 appropriately to maintain a high standard of quality in the laboratory, completing TMs, following (and writing and updating where appropriate) SOPs, and reviewing documentation in QIS2 and within the Change Management Framework where required.
- Record tallies according to KPIs and collate for FRIT.
- Conduct tours for external parties where required.
- Attend meetings with QPS or other external agencies as a representative of Forensic DNA Analysis where required.
- Deliver presentations to clients, or other external groups, and internal groups where required.
- Conduct CSPs on sub-team leaders.

5 Senior Scientist – Forensic Reporting and Intelligence Team

5.1 Reporting Structure

The Senior Scientist (HP5) within the FRIT reports to the Team Leader – FRIT.

5.2 Duties

- Manage and develop FRIT sub-team within Forensic DNA Analysis.
- Monitor training and resource level in the sub-team in line with QIS 31010 and co-ordinate the use of resources according to dynamic workloads.
- Assist Team Leader in setting strategic direction for FRIT.

- Undertake casework duties according to competencies including profile data analysis, preparation of statements and peer review of all case and sample type, upload profiles to NCIDD, link reporting and reviewing, and NIFA uploading and reporting.
- Co-ordinate workflow to enable a Quality Service of short TAT on casework (including case management and statement reporting, and link reporting).
- Continue to develop training programs within team, especially concerning the training and development of new court Reporting Scientists.
- Participate in moot court evaluations on staff to evaluate competence in providing court evidence.
- Conduct team meetings and lead discussions on profile interpretation, method development and court reports.
- Provide scientific advice, support and mentoring to court Reporting Scientists and Scientists performing case management and NCIDD and NIFA tasks.
- Liaise with SSLU, QPS DMU when necessary to co-ordinate the allocation and/or priority of cases, and to seek feedback on processes implemented.
- Provide advice and assistance at case conferences where required.
- Provide advice to QPS and legal parties on casework where required.
- Provide expert testimony on reported cases, and on cases peer reviewed when required. Provide expert testimony on cases when the Reporting Scientist and Peer Reviewer are both absent when required.
- Provide support to Quality and Projects team, including undertaking Proficiency Tests when allocated.
- Provide support to other FRIT sub-teams and promote cohesion between teams.
- Commit to and lead continuous improvement strategies.
- Lead research and development initiatives when required including completing actions as designated at the management meetings.
- Keep abreast of current literature as it relates to current and emerging technologies.
- Participate in Quality Program including using QIS2 appropriately to maintain a high standard of quality in the laboratory, completing TMs, following (and writing and updating where appropriate) SOPs, and reviewing documentation in QIS2 and within the Change Management Framework where required.
- Participate in and lead specific projects within the Change Management Framework when required.
- Participate in rostered tasks as directed by Team Leader (eg. Quality Flag checking)
- Monitor sub-team performance and provide Team Leader with progress reports of performance of sub-team.
- Record tallies according to KPIs and collate for sub-team.
- Conduct tours for external parties where required.
- Attend meetings with QPS or other external agencies as a representative of Forensic DNA Analysis where required.
- Deliver presentations to clients, or other external groups, and internal groups where required.
- Conduct CSPs on staff under line management when required.

6 Reporting Scientist – Forensic Reporting and Intelligence Team

6.1 Reporting Structure

The Reporting Scientist (HP4) within the FRIT reports to the Senior Scientist within FRIT.

6.2 Duties

- Prepare and peer review statements for court on all sample and case type, including Intelligence Reports.
- Undertake casework duties according to competencies including profile data analysis, preparation of statements and peer review of all case and sample type, upload profiles to NCIDD, link reporting and reviewing, and NIFA uploading and reporting.
- Assist Senior Scientist in continuous improvement of workflow arrangements.
- Provide expert testimony on reported cases, and on cases peer reviewed when required. Provide expert testimony on cases when the Reporting Scientist and Peer Reviewer are both absent when required.
- Provide advice and assistance at case conferences where required.
- Provide advice to QPS and legal parties on casework where required.
- Commit to continuous improvement strategies.
- Provide support to other teams and promote cohesion between teams.
- Participate in research and development initiatives and change management projects.
- Participate in Proficiency Tests when allocated.
- Participate in moot court evaluations on colleagues to evaluate competence in providing court evidence when required.
- Keep abreast of current literature as it relates to current and emerging technologies.
- Participate in Quality Program including using QIS2 appropriately to maintain a high standard of quality in the laboratory, completing TMs, following (and writing and updating where appropriate) SOPs, and reviewing documentation in QIS2 and within the Change Management Framework where required.
- Participate in and lead specific projects within the Change Management Framework when required.
- Participate in rostered tasks as directed by Senior Scientist or Team Leader
- Record tallies according to KPIs.
- Deliver presentations to clients, or other external groups, and internal groups where required.
- Conduct tours for external parties where required.

7 Scientist – Forensic Reporting and Intelligence Team (within Intelligence Team)

7.1 Reporting Structure

The Scientist (HP3) within the FRIT reports to the Senior Scientist of the Intelligence Team within FRIT.

7.2 Duties

- Perform DNA interpretations (profile data analysis) according to competencies.
- Use NCIDD and provide Intelligence to QPS via uploading and reporting via the link process.
- Write Intelligence Reports where appropriate.
- Participate in research and development initiatives and change management projects.
- Provide support to other teams and promote cohesion between teams.

- Participate in quality initiatives including following SOP's and undertaking Proficiency Tests when allocated.
- Participate in Quality Program including using QIS2 appropriately to maintain a high standard of quality in the laboratory, completing TMs, following (and writing and updating where appropriate) SOPs, and reviewing documentation in QIS2 and within the Change Management Framework where required.
- Participate in and lead specific projects within the Change Management Framework when required.
- Commit to continuous improvement strategies.
- Participate in rostered tasks as directed by Senior Scientist or Team Leader
- Record tallies according to KPIs.
- Conduct tours for external parties where required.
- Deliver presentations to clients, or other external groups, and internal groups where required.

8 Associated Documentation

QIS: 31010 – Forensic DNA Analysis Capability Development Program

9 References

Nil

10 Amendment History

Version	Date	Updated By	Amendments
1	11 Oct 2006	K Weller/ R Smith	First version – Major Crime
2	17 Dec 2007	J Howes	Major Crime update
3	09 May 2011	J Howes	Major update to duties performed including Title change in document
4	17 Dec 2012	J Howes	General update including header
5	16 July 2014	J Howes	Changed PADs to PDPs and expanded into words, edited header
6	11 Jan 2016	J Howes	New template
7	25 July 2017	J Howes	Updated header, removed 'case manager' and replaced with PDA, replaced CTS with Proficiency
8	02 Jan 2019	J Howes	No change required
9	13 May 2022	J Howes	Updated template, included amendment history and format updated, removed duplicates where found.

Queensland Health
Forensic and Scientific Services

Forensic DNA Analysis - Evidence Recovery & Quality Team Duty Statements

1 Purpose

To provide a framework for duties performed by members of the Evidence Recovery & Quality Team within Forensic DNA Analysis

2 Scope

This document applies to all members of the Evidence Recovery & Quality Team within Forensic DNA Analysis. Duties may vary from this document according to business requirements.

3 Abbreviations

DRMU	DNA Results Management Unit
OQI	Opportunity for Quality Improvement (Queensland Health's equivalent of Non-Conformances and Corrective Actions)
CSP	Career Success Plan
QHFSS	Queensland Health Forensic and Scientific Services
QPS	Queensland Police Service
SMU	Sample Management Unit
SOP	Standard Operating Procedure
SSLU	Scientific Services Liaison Unit
TMs	Training Modules

4 Team Leader – Evidence Recovery & Quality Team

4.1 Reporting structure

The Team Leader (HP6) of the Evidence Recovery & Quality Team reports to the Managing Scientist – Police Services Stream.

4.2 Duties

- Manage and develop the Evidence Recovery (ERT), Analytical (AT) and Quality and Projects Teams within Forensic DNA Analysis
- Provide direction and support for senior scientists within the Evidence Recovery, Analytical and Quality and Projects Teams including, but not limited to: conflict management, problem solving, strategic direction, project development, training and resources
- Monitor training and resource levels within the Evidence Recovery and Quality Team, and coordinate resources to ensure workflow is efficient and turnaround times are maintained

- Present weekly Evidence Recovery and Quality Team progress reports to the Managing Scientist
- Assist the Managing Scientist in setting strategic direction for Forensic DNA Analysis, and contribute to the planning and implementation of strategies to ensure organisational goals are achieved
- Undertake case work duties when required, including result management and review, statement preparation and review, Intelligence report preparation and review
- Provide expert testimony on reported cases where required
- Participate in the Quality Program, including using QIS2 appropriately to maintain a high standard of quality in the laboratory, including updating and reviewing SOP's, approving OQI's, monitoring reviews and notifications of staff within sub-teams
- Chair Forensic DNA Analysis and Management Team meetings where required
- Provide high level scientific services to QPS, DPP and other clients
- Liaise with Clients (QPS, Judicial Officers, QPS DRMU, QHFSS Senior Management) regarding priority samples, collection, sampling, DNA testing, additional testing, and explanations of DNA profile interpretation
- Manage feedback from clients in relation to communication, work processes, turnaround times (including complaints), and developing actions and process improvements
- Represent Forensic DNA Analysis at meetings with internal and external clients
- Provide guidance and feedback in relation to projects conducted and implemented within Forensic DNA Analysis
- Monitor work practices within Forensic DNA Analysis to improve services provided in line with best practice
- Conduct CSP's for the senior scientists of the Analytical, Evidence Recovery and Quality and Projects teams
- Provide support and advice to the Team Leader of the Reporting and Intelligence Team
- Provide scientific advice and support to all staff within Forensic DNA Analysis.
- Present to staff and clients as required
- Conduct tours for external parties where required
- Perform higher duties in the position of Managing Scientist when required

5 Senior Scientist – Evidence Recovery Team

5.1 Reporting structure

The Evidence Recovery Team senior scientist (HP5) reports to the Team Leader – Evidence Recovery & Quality Team

5.2 Duties

5.2.1 Management and Development of team

- Co-ordinate sample processing and sample prioritisation, and provide trouble-shooting, assist the team with issues that may arise in sample processing
- Allocate or re-allocate resources when required; e.g., delegate specific tasks to complete urgent processing
- Review work completed by staff and provide timely and relevant feedback
- Co-ordinate and / or chair regular team meetings, provide a forum for discussing issues, changes and research and development projects
- Establish and maintain Key Performance Indicators (KPIs) and other associated metrics and provide progress reports on team performance (weekly report, monthly report, quarterly reviews) to the team leader and management team

- Co-ordinate or conduct as appropriate the creation, updating and reviewing of standard operating procedures, training modules and training delivery plans relevant to the team
- Co-ordinate, record and / or conduct as appropriate calibration and preventative maintenance or servicing of equipment used by the team
- Co-ordinate and / or conduct environmental monitoring of laboratory areas, including monitoring / reviewing of the results and carrying out appropriate actions that may arise from the results
- Participate in internal and external proficiency testing [Collaborative Trial Testing (CTS)] as required
- Keep abreast of current literature as it relates to new and emerging technologies
- Manage, lead and / or provide support for research into process improvements, verification or validation of new and/or alternative technologies and techniques

5.2.2 Management and Development of Staff

- To develop and train staff within the team, providing both encouragement and support to aid in their professional development
- Establish and maintain training plans in accordance with the Forensic DNA Analysis Capability Development Plan
- Undertake CSP sessions with each team member
- Mentor and provide advice to staff within the team and across Forensic DNA Analysis in aspects of the duties undertaken by the team as required
- Develop and nurture strong professional relationships within the team and with other Forensic DNA Analysis staff
- Establish and maintain a duty roster on a weekly, and if required, daily basis
- Check and sign time-sheets for staff

5.2.3 Internal and External Liaison and Support

- Liaise with Scientific Services Liaison Unit (SSLU), Queensland Police Services (QPS) Sample Management Unit (SMU), QPS DNA Results Management Unit (DRMU) and QPS Investigating Officers (I/O) and Scientific Officers to co-ordinate examinations, gather further information to establish suitable examination strategies and clarify information about specific items and provide non-conformance feedback as required
- Provide advice to clients concerning sample collection hierarchy, collection techniques and priority of testing
- Present to the laboratory and external clients and associated professionals as part of further education
- Liaise with Forensic DNA Analysis Management team regarding specific issues surrounding the team

5.2.4 Other duties

- Participate as an active member of the Forensic DNA Analysis Management Team
- Manage and report results in line with current competency

6 Scientist – Evidence Recovery Team

6.1 Reporting structure

The ERT scientists (HP3) report to the ERT senior scientist

6.2 Duties

6.2.1 Laboratory duties

- Examination of items: Perform and record in an accurate, concise and contemporaneous manner, the examination of items submitted to Forensic DNA Analysis, including (but not limited to) whole items, sexual assault investigation kits (SAIKs) and in-tube items according to standard operating procedures. This includes the development and review of appropriate examination strategies for complex items (e.g. SAIK), the performance of presumptive and confirmatory testing, a range of sampling techniques, and the use of photographic equipment
- Entry and review of results of examination into laboratory information system
- Participate in internal and external proficiency testing [Collaborative Trial Testing (CTS)] as required
- Active involvement and adherence to anti-contamination processes associated to examinations
- Equipment maintenance and calibration as required
- Environmental cleaning and sampling

6.2.2 Non-laboratory duties

- Maintain QIS2 events including revision of SOPs, TMs and forms associated to team tasks
- Participate and assist with Internal Audits
- Assist in investigation of adverse events as directed by the senior scientist
- Investigate non-conformance by clients and provide feedback as directed by senior scientist
- Participate in projects as directed by the senior scientist
- Perform case management on samples in accordance with current competence
- Maintain accurate time-sheets

6.2.3 Involvement in continued professional development

- Involvement in the CSP process
- Maintenance of scientific knowledge and awareness of new / emerging technologies as it pertains to daily duties as well as other areas within Forensic DNA Analysis through electronic journals, project reports, news articles and other relevant publications
- Provide training to scientists, technicians or other staff as directed by the senior scientist in line with competence
- Self manage work/life balance

6.2.4 Communications

- Commitment to be dynamic in the daily and weekly roster; e.g., help fellow team members when own duties complete
- Liaise with Scientific Services Liaison Unit (SSLU), Queensland Police Services (QPS) Sample Management Unit (SMU), to gather further information to establish suitable examination strategies and clarify information about specific items
- When directed by the senior scientist, provide advice to clients and associated professionals

- Present information to team and other Forensic DNA Analysis staff and / or external clients as directed by senior scientist
- Develop and nurture strong professional relationships within the team and with other Forensic DNA Analysis staff
- Actively participate in team meetings and Forensic DNA Analysis meetings and represent the team in meetings held by other teams as directed
- Attend court and give evidence of fact as required

7 Forensic Technician – Evidence Recovery Team

7.1 Reporting structure

The Forensic Technicians (HP2) report to the ERT senior scientist

7.2 Duties

7.2.1 Laboratory duties

- Examination of items: Perform and record in an accurate, concise and contemporaneous manner, the examination of in-tube items submitted to Forensic DNA Analysis, manual intervention of in-tube items where sub-sampling is not required, and the use of photographic equipment to record details of in-tube items
- Entry and review of results of in-tube examination into laboratory information system
- Active involvement and adherence to anti-contamination processes associated to examinations
- Sampling of Reference Blood FTA cards for DNA extraction
- Staining of slides for spermatozoa microscopy
- Assist the Analytical team with making internal positive control samples
- Preparation and Registration of reagents as required
- Equipment maintenance and calibration as required
- Environmental cleaning and sampling
- Assist with the collection and transport of liquid nitrogen

7.2.2 Non-laboratory duties

- Data entry using the STRmix software
- Assist the Analytical Team with weekly stocktaking as required
- Maintain QIS2 events including revision of SOPs, TMs and forms associated to team tasks,
- Participate and assist with Internal Audits
- Assist in investigation of adverse events as directed by the senior scientist
- Investigate non-conformance by clients and provide feedback as directed by senior scientist
- Maintain accurate time-sheets
- Destruction of reference samples requested by QPS

7.2.3 Involvement in continued professional development

- Involvement in the CSP process
- Maintenance of knowledge and awareness of new / emerging technologies as it pertains to daily duties as well as other areas within Forensic DNA Analysis through electronic journals, project reports, news articles and other relevant publications
- Provide training to other technical and non-technical staff as directed by the senior scientist in line with competence
- Self manage work/life balance

7.2.4 Communications

- Commitment to be dynamic in the daily and weekly roster; eg, help fellow team members when own duties complete
- Develop and nurture strong professional relationships within the team and with other Forensic DNA Analysis staff
- Actively participate in team meetings and Forensic DNA Analysis meetings and represent the team in meetings held by other teams as directed
- Attend court and give evidence of fact as required

8 Senior Scientist – Analytical Team

8.1 Reporting structure

The Analytical Team senior scientist (HP5) reports to the Team Leader – Evidence Recovery & Quality Team

8.2 Duties

8.2.1 Management and Development of team

- Co-ordinate sample processing and sample prioritisation, and provide trouble-shooting. Assist the team for issues that may arise in sample processing
- Allocate or re-allocate resources when required; e.g., delegate specific tasks to complete urgent processing
- Review work completed by staff and provide timely and relevant feedback
- Co-ordinate and / or chair regular team meetings, provide a forum for discussing issues, changes and research and development projects
- Establish and maintain Key Performance Indicators (KPIs) and other associated metrics and provide progress reports on team performance (weekly report, monthly report, quarterly reviews) to the team leader and management team
- Co-ordinate or conduct as appropriate the creation, updating and reviewing of standard operating procedures, training modules and training delivery plans relevant to the team
- Co-ordinate, record and / or conduct as appropriate calibration and preventative maintenance or servicing of equipment used by the team
- Co-ordinate and / or conduct environmental monitoring of laboratory areas, including monitoring / reviewing of the results and carrying out appropriate actions that may arise from the results
- Participate in internal and external proficiency testing [Collaborative Trial Testing (CTS)] as required
- Keep abreast of current literature as it relates to new and emerging technologies
- Manage, lead and / or provide support for research into process improvements, verification or validation of new and/or alternative technologies and techniques
- Delegate tasks as necessary

8.2.2 Management and Development of Staff

- To develop and train staff within the team, providing both encouragement and support to aid in their professional development
- Establish and maintain training plans in accordance with the Forensic DNA Analysis Capability Development Plan
- Undertake CSP sessions with each team member
- Mentor and provide advice to staff within the team and across Forensic DNA Analysis in aspects of the duties undertaken by the team as required

- Develop and nurture strong professional relationships within the team and with other Forensic DNA Analysis staff
- Establish and maintain a duty roster on a weekly, and if required, daily basis
- Check and sign time-sheets for staff

8.2.3 Internal and External Liaison and Support

- Liaise with Scientific Services Liaison Unit (SSLU), Queensland Police Services (QPS) Sample Management Unit (SMU), QPS DNA Results Management Unit (DRMU) regarding issues around instruments and analytical techniques
- Provide advice to clients concerning sample collection, collection techniques and priority of testing
- Liaise with service providers with respect to laboratory instrument and consumable pricing, servicing and supply
- Present to the laboratory and external clients and associated professionals as part of further education
- Liaise with Forensic DNA Analysis Management team regarding specific issues surrounding the team

8.2.4 Other duties

- Participate as an active member of the Forensic DNA Analysis Management Team
- Manage and report results in line with current competency

9 Senior Analytical Scientist (HP4) – Analytical Team

9.1 Reporting structure

The Senior Analytical Scientists (HP4) report to the Senior Scientist – Analytical Team

9.2 Primary duties

The primary duties of the Senior Scientist – Analytical Team are the same as those described under Scientist (HP3) – Analytical Team below. The Senior Scientist (HP4) – Analytical have additional duties as outlined immediately below.

9.3 Additional duties

- Assist the senior scientist (HP5) in maintaining staff rosters (rotating staff through various tasks).
- Assist the senior scientist (HP5) in ensuring work is planned out for the following day (ensuring sufficient / the right mix of batches are entered into the electronic workflow diary).
- Provide assistance in the provision of advice to team members within and external to the Analytical team in the absence of the senior scientist (HP5) (e.g. when HP5 is on sick leave, course attendance or other reasons for temporary unavailability)
- Assist the senior scientist (HP5) in the coordination of training
- Perform the majority of updating of Training Module (TM) and Training Delivery Plan (TDP) documents. Standard Operating Procedures (SOP) are to be updated by all HP staff, and any HP staff may also update a TM or TDP as delegated by the senior scientist (HP5)
- Management of monthly Environmental Monitoring, including finalisation and reporting results
- Manage the testing / QC of reagents and controls within the AT
- Investigating of OQI's as delegated by the senior scientist (HP5)

- Assist the senior scientist (HP5) in the area of laboratory instrumentation. This also may include liaising with service engineers, completing maintenance requests and other such assistance as required
- Provide a project mentoring role within the Analytical team. With a goal that all smaller projects would be carried out by pairing a HP3 staff member with a HP4 staff member. Large projects would be staffed appropriately depending on the type and nature of the project, any research funding made available etc. This would be done after appropriate management level consultation
- The senior scientist (HP4) staff is to meet weekly with the senior scientist (HP5) to provide updates on project progress, roadblocks, issues etc.
- Monitor stocktaking, provide assistance with and where competency is available carry out purchasing and supply of consumables for Forensic DNA Analysis laboratory using S/4HANA

10 Scientist – Analytical Team

10.1 Reporting structure

The Analytical scientists (HP3) report to the Senior Scientist – Analytical Team

10.2 Duties

10.2.1 General Laboratory Duties

- To ensure the Analytical Team (AT) runs smoothly on a daily, monthly and yearly basis
- To ensure the continued output of quality results from the Analytical section within desired timeframes
- To assist in the trouble-shooting of technical issues that may arise in the day-to-day running of the Analytical section and implement any change management as required
- Carry out monthly laboratory cleaning and environmental sampling

10.2.2 Automated DNA extraction tasks

- Ensure there are sufficient batches prepared and ready for automated DNA extractions i.e. both lysate and extract Nunc Bank-It™ tubes have been sorted and sequence checked
- Perform DNA extractions using the QIAsymphony
- Maintenance and Calibration of QIAsymphony

10.2.3 Manual DNA extraction tasks

- Prepare samples for automated DNA extraction i.e. performing pre-lysis of samples for QIAsymphony
- Perform DNA extractions using Maxwell16, Organic extractions & Nucleospin extractions
- Carry out post-extraction processing of DNA extracts including Microcons, Nucleospin clean-ups, dilutions and transfers/pooling

10.2.4 Pre-PCR tasks

- Perform quantification and amplification of DNA extracts that have been processed by both manual and automated extraction methods using the Pre-PCR Hamilton STARlet instruments
- Carry out QC testing of Quantifiler Trio, PowerPlex 21 when necessary
- Make standards for quantification of DNA extracts and test them when required

- Perform manual quantification and amplification of DNA extracts as required
- Calibration and Maintenance of Hamilton STARlet instruments

10.2.5 Capillary Electrophoresis tasks

- Prepare samples/plates for capillary electrophoresis
- Run plates on the 3500xL Genetic Analyser
- Perform the CEQ check of CE batches after completion of the run
- Create batches for and perform capillary electrophoresis of re-genescan samples and/or samples to be rerun
- Running quantification batches, checking QC parameters and exporting results
- Maintenance and calibration as required of 3500xL Genetic Analysers, 7500, Quant Studio 5 & Proflex instruments

10.2.6 Non-laboratory duties

- To verify or validate as required new and/or alternative technologies/techniques, or assist with the identification of alternative technologies/techniques that may be considered for verification/validation and participate as required in research leading to potential process improvements
- Reviewing of "No DNA detected" and "DNA insufficient" results electronically
- Use Forensic Register batch dashboard, KPI data and workflow diary to monitor workload and workflow of the AT
- Maintain QIS2 events including revision of SOPs, TMs and forms associated to team tasks,
- Participate and assist with Internal Audits
- Assist in investigation of adverse events as directed by the senior scientist
- Investigate non-conformance by clients and provide feedback as directed by senior scientist
- Record KPI data as relevant to daily tasks
- Participate in internal and external proficiency testing [Collaborative Trial Testing (CTS)] as required
- Maintain stock levels in each rostered area and check that it is sufficient for the week; email "FSS DNAorders" with items to be ordered as required
- Maintain accurate time-sheets
- Peer review of QC results

10.2.7 Involvement in continued professional development

- Involvement in the CSP process
- Maintenance of scientific knowledge and awareness of new / emerging technologies as it pertains to daily duties as well as other areas within Forensic DNA Analysis through electronic journals, project reports, news articles and other relevant publications
- Provide training to scientists, technicians or other staff as directed by the senior scientist in line with competence
- Self manage work/life balance

10.2.8 Communications

- Commitment to be dynamic in the daily and weekly roster; eg, help fellow team members when own duties complete
- Liaise with service providers with respect to laboratory instrument servicing or maintenance as directed
- When directed by the senior scientist, provide advice to clients and associated professionals

- Present information to team and other Forensic DNA Analysis staff and / or external clients as directed by senior scientist
- Develop and nurture strong professional relationships within the team and with other Forensic DNA Analysis staff
- Actively participate in team meetings and Forensic DNA Analysis meetings and represent the team in meetings held by other teams as directed
- Attend court and give evidence of fact as required

11 Senior Scientist – Quality and Projects Team

11.1 Reporting structure

The Quality and Projects Team senior scientist (HP5) reports to the Team Leader – Evidence Recovery & Quality Team

11.2 Duties

11.2.1 Management and Development of team

- Co-ordinate sample processing and sample prioritisation, and provide trouble-shooting. Assist the team for issues that may arise in sample processing
- Allocate or re-allocate resources when required; e.g., delegate specific tasks to complete urgent processing
- Review work completed by staff and provide timely and relevant feedback
- Co-ordinate and / or chair regular team meetings, provide a forum for discussing issues, changes and research and development projects
- Establish and maintain Key Performance Indicators (KPIs) and other associated metrics and provide progress reports on team performance (weekly report, monthly report, quarterly reviews) to the team leader and management team
- Co-ordinate or conduct as appropriate the creation, updating and reviewing of standard operating procedures, training modules and training delivery plans relevant to the team.
- Co-ordinate, record and / or conduct as appropriate calibration and preventative maintenance or servicing of equipment used by the team
- Co-ordinate and / or conduct environmental monitoring of laboratory areas, including monitoring / reviewing of the results and carrying out appropriate actions that may arise from the results
- Participate in internal and external proficiency testing [Collaborative Trial Testing (CTS)] as required
- Keep abreast of current literature as it relates to new and emerging technologies
- Manage, lead and / or provide support for research into process improvements, verification or validation of new and/or alternative technologies and techniques
- Delegate tasks as necessary

11.2.2 Management and Development of Staff

- To develop and train staff within the team, providing both encouragement and support to aid in their professional development
- Establish and maintain training plans in accordance with the Forensic DNA Analysis Capability Development Plan
- Undertake CSP sessions with each team member
- Mentor and provide advice to staff within the team and across Forensic DNA Analysis in aspects of the duties undertaken by the team as required
- Develop and nurture strong professional relationships within the team and with other Forensic DNA Analysis staff
- Establish and maintain a duty roster on a weekly, and if required, daily basis

- Check and sign time-sheets for staff

11.2.3 Internal and External Liaison and Support

- Liaise with Scientific Services Liaison Unit (SSLU), Queensland Police Services (QPS) Sample Management Unit (SMU), QPS DNA Results Management Unit (DRMU) and QPS Investigating Officers (I/O) and Scientific Officers in particular regarding quality matters and those pertaining to reference sample processing
- Provide advice to clients concerning sample collection hierarchy, collection techniques and priority of testing
- Present to the laboratory and external clients and associated professionals as part of further education
- Liaise with Forensic DNA Analysis Management team regarding specific issues surrounding the team

11.2.4 Other duties

- Manage and report results in line with current competency
- Co-ordinate Accreditation and Certification Audit Preparation
- Provide regular Quality updates to all Forensic DNA Analysis staff
- Management of OQIs
- Document Control
- Scheduling and co-ordination Internal Audits
- Co-ordination of Instrument & Method Validation
- Change Management Processes
- Management of QPS Environmental samples
- Review of Forensic DNA Analysis environmental monitoring program
- Co-ordination of External and Internal Proficiency Testing programs
- Monitoring of laboratory Calibrations
- Presentation of Management Review Reports
- Interpret and Identify Trends
- Interpret and provide advice regarding the requirements of the standards and guidelines applicable to Forensic DNA Analysis
- Maintenance of a quality manual
- Perform internal investigations
- Co-ordinate Quality Induction and Training for Forensic DNA Analysis staff
- Co-ordinate projects within Forensic DNA Analysis

12 Scientist – Quality and Projects Team

12.1 Reporting structure

The Quality and Projects Team scientist (HP3) reports to the Senior Scientist – Quality and Projects Team

12.2 Duties

- Provide support to the Quality and Projects Senior Scientist and assist with the co-ordination of the Quality system within Forensic DNA Analysis
- Management of OQIs
- Document Control
- Co-ordination of Internal Audits
- Contribute to Instrument & Method Validations
- Change Management Processes
- Management of QPS Environmental samples

- Review of Forensic DNA Analysis environmental monitoring program
- Co-ordination of External and Internal Proficiency Testing Programs,
- Calibrations
- Maintenance of a quality manual
- Data compilation for Quality Reporting and Management Reviews;
- Interpret and Identify trends
- Assist with Interpretation and providing advice regarding the requirements of the standards and guidelines applicable to Forensic DNA Analysis;
- Perform internal investigations
- Conduct Quality Training sessions
- Assist with Forensic DNA Analysis Accreditation and Certification Audit Preparations
- Participate in Quality Induction Training
- Attend and contribute to regular team meetings
- Assist and co-ordinate projects within Forensic DNA Analysis
- Attend court and give evidence of fact as required

13 Laboratory Assistant Supervisor – Quality and Projects Team

13.1 Reporting structure

The Laboratory Assistant Supervisor (CA4) reports to the Senior Scientist – Quality and Projects Team

13.2 Primary duties

- Provide direction and support to laboratory assistants
- Manage rostering of laboratory assistants
- Chair Laboratory Assistant team meetings
- Monitor Key Performance Indicators and report to Supervising Scientist weekly
- Monitor the Logs such as the Issues Log used by scientific staff to communicate issues with samples
- Allocate tasks and reassign, where necessary, Laboratory Assistants to ensure critical work is completed
- Act as the liaison between scientific staff and Laboratory Assistants
- Assist with the production and review of Standard Operating Procedures and Training Modules
- Co-ordinate calibrations and ensure completion in a timely manner
- Problem solve and report outcomes to Supervising Scientist
- Escalate problems when necessary
- Implement quality improvement strategies
- Co-ordinate the training of Laboratory Assistants
- Maintain Training Gap Analysis data for Laboratory Assistants
- Fulfil S/4HANA requisitioning officer duties and liaise with suppliers, where necessary
- Monitor work unit reagents and assign staff to re-stock as required
- Participate in general quality activities, e.g. OQI generation
- Record and escalate client feedback
- May participate in other duties as required, e.g. assist other units, cross-training
- Train and mentor other staff as required
- Other tasks as assigned by senior and supervisory staff

13.3 Additional duties

In addition to the duties outlined above, the Laboratory Assistant Supervisor will carry out duties as outlined under laboratory assistant below.

14 Laboratory Assistant – Quality and Projects Team

14.1 Reporting structure

The Laboratory Assistants (CA3) report to the Laboratory Assistant supervisor and Senior Scientist – Quality and Projects Team

14.2 Duties

14.2.1 Laboratory duties

- Active involvement and adherence to anti-contamination processes within laboratory and reagent preparation and storage areas
- Use of Laboratories information systems that include Forensic Register
- Reference FTA sample processing
- Equipment maintenance and calibration as required
- Assist with the environmental cleaning of the laboratory
- General cleaning of labware
- Reagent & Kit preparation and registration
- Pick-up, delivery and movement of drums of cleaning products
- Waste Management – including removal of biohazardous waste wheelie bins, glass and plastic recycling bins and other laboratory waste
- Preparation/Processing of samples including short and long term storage of samples
- Assisting scientists with sample batch management
- Coronial/Evidence blood preparation
- Control preparation
- Stock management including loading and unloading of stock from trollies, and storage of stock/materials
- In-tube item processing: Record in an accurate, concise and contemporaneous manner, the packaging of in-tube items submitted to Forensic DNA Analysis, including the use of photographic equipment to record details of in-tube items, provide an initial assessment of the suitability of in-tube items for routine processing, and register and record item details in the LIMS

14.2.2 Non-laboratory duties

- Maintain QIS2 events including revision of SOPs, TMs and forms associated to team tasks
- Participate and assist with Internal Audits
- Assist with the compilation of audit trails & information for Evidentiary Certificates
- Maintenance and calibration of instruments and equipment
- Assist in investigation of adverse events as directed by the senior scientist
- Record KPI data / daily statistics as relevant to daily tasks
- Maintain accurate time-sheets
- Collection of data and records
- Monitoring/recording of fridge/freezer temperatures
- Scanning of records/batch paperwork
- Assistance with case file management
- PDF profiles, including upload to Forensic Register
- Coordination and management of Sexual Assault Investigation Kits

14.2.3 Involvement in continued professional development

- Involvement in the CSP process
- Provide training to other as directed by the senior scientist in line with competence
- Self manage work/life balance

14.2.4 Communications

- Provide support and Assist scientific and administrative staff across all areas of Forensic DNA Analysis
- Commitment to be dynamic in the daily and weekly roster; e.g., help fellow team members when own duties complete
- Develop and nurture strong relationships within the team and with other Forensic DNA Analysis staff
- Actively participate in team meetings and Forensic DNA Analysis meetings and represent the team in meetings held by other teams as directed
- Liaising with external/internal clients
- Attend court and give evidence of fact as required

15 Associated Documentation

QIS: 17091 – The organisation and management of Forensic DNA Analysis

QIS: 31010 – Forensic DNA Analysis Capability Development Program

16 Amendment History

Version	Date	Updated By	Amendments
1	Oct 2006	M Gardam	Document created
2	April 2004	R Smith	Document update
3	June 2008	A Pippia	Document modified from "Volume Crime Team" to "Evidence Recovery Team" and associated changes with roles / team structures
4	May 2012	A Pippia	Complete document revision
5	November 2013	L Ryan	Document format updated
6	May 2015	A McNevin	Document expanded in scope to include all of Evidence Recovery and Quality team; changed to HSQ template; rewording of some duties and headings for consistency across ER&Q team; addition of some duties / descriptors and removal of duplications
7	August 2018	A McNevin	Removed references to AUSLAB, other minor updates to ensure relevance to current procedures and practices
8	July 2019	K Scott	Additions to OO duties, replace PDP with CSP
9	June 2022	K Scott	Update header, replace OO with CA, update equipment and minor text edits

Queensland Health
HealthSupport Queensland

Role description

Job ad reference	Insert HSQ Number	**Classification**	A02
Role title	Administrative Officer	**Salary**	Insert Salary
Status	Permanent, Full Time.	**Closing date**	Insert Closing Date
Unit/branch	Forensic DNA Analysis Forensic & Scientific Services		
		Contact name	Wendy Harmer
Location	[redacted]	**Contact number**	[redacted]

If you have difficulties applying, please contact Health Support Queensland Recruitment on [redacted]

Why work for us?

At Health Support Queensland (HSQ), you will be part of an organisation who helps care for Queenslanders.

We know it is important for people to work in an organisation that provides more than just a job. In joining HSQ, you will embark on a journey to help us realise our vision of being 'Australia's best healthcare support partner'.

Once you join us, we will expect you to exemplify the HSQ fundamental principles of ICARE:

- Integrity—being honest and ethical in everything we say and do.
- Customers and patients first—putting customers and patients at the centre of everything we do.
- Accountability—taking personal responsibility for our actions.
- Respect—being considerate, recognising our differences and looking out for each other.
- Engagement—actively investing in positive outcomes by partnering with others.

Purpose of the role

Provide professional and client focussed administrative support and assistance to the team members in Forensic DNA Analysis and Managing Scientist – Police Services Stream.

The Administrative Officer in Forensic DNA Analysis reports to the Administration Support Officer.

Your key responsibilities will include:

Fulfil the responsibilities of this role in accordance with ICARE and the Queensland Public Service values (QPS) along with the following accountabilities:

- Adhere to defined service quality standards, health and safety policies and procedures relating to the work being undertaken to ensure high quality, safe services and workplaces.
- Ensure work practices align with Department of Health's Records Management Policy, Standards and Procedures.
- Provide efficient and reliable keyboard and data entry skills, whilst keeping informed of new developments in this area, and utilising contemporary software packages including but not limited to:
  - Microsoft Programs
  - myHR
  - Forensic Register
  - AUSLAB
- Perform case management duties including tracking files, basic problem solving, and corrections (e.g. accuracy of client supplied data / identifiers and transcription checking) using Laboratory Information Management System, in accordance with quality assurance guidelines.
- Co-ordinate administrative aspects of Forensic DNA Analysis, including but not limited to:
  - Preparation of email correspondence, and documents as required
  - Establish and maintain an effective office records system
  - Assist in the procurement process associated with the ordering of general office supplies.
  - Maintain office equipment maintenance and consumables.
- Meet the deadlines and work priorities of the workplace in cooperation with other team members as directed by the Administration Support Officer. Work autonomously and show initiative in solving basic problems within established guidelines in the absence of the Administration Support Officer.
- Attend to telephone and reception inquiries from internal and external clients of the laboratory and direct requests to appropriate officer/s as required. Maintain a sound knowledge of the department's functions in order to deliver an effective client focussed service.
- Comply with NATA/ISO accreditation/certification requirements including performing quality control procedures, assisting with preparation of procedure manuals and completion of relevant statistics. Comply with and utilise procedures, policies, regulations, and standards which impact upon the position including the Department of Health Code of Conduct, contemporary human resource management requirements and practices, such as workplace health and safety, equal employment opportunity and anti-discrimination policy.

What are we looking for?

You will be assessed on your ability to demonstrate the following key capabilities, knowledge and experience. Within the context of the responsibilities described under 'your key responsibilities', the ideal applicant will be someone who can demonstrate the following:

- Proven ability in keyboard and data entry skills including a sound knowledge of contemporary word processing and data entry systems including knowledge of or the ability to rapidly acquire knowledge of available information systems relevant to the duties of the position.

- Ability to prioritise tasks, meet deadlines and work successfully, both individually and as a member of a multi-disciplinary team.
- Ability to communicate effectively both orally and in writing to effectively liaise with a broad range of clients.
- A demonstrated commitment to the principles of quality management and continuous quality improvement.
- Ability to actively participate in a working environment supporting quality human resource management practices including employment equity, anti-discrimination, occupational health and safety and ethical behaviour.

Vaccine Preventable Diseases (VPD) requirements

- It is a condition of employment for this role for the employee to be, and remain, vaccinated against the following vaccine preventable diseases during their employment: Hepatitis B
- Existing staff that are engaged prior to 1 July 2016 are not subject to this condition of employment unless they apply for a role with VPD requirements that is with a different Queensland Health entity (i.e. a Hospital and Health Service (HHS) to HSQ).

What is on offer?

- Up to 12.75% employer superannuation contribution
- Annual leave loading 17.5%
- Employee Assistance Program
- Work/life balance, variety and flexibility

How to apply

Please provide the following information to the panel to assess your suitability:

- **Your current CV or resume,** including the names and contact details of two referees. Referees should have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current, immediate or past supervisor
- **A short statement (Max 2 pages)** that gives details of your skills, experience and knowledge as required on the role description under the heading 'what are we looking for?'

About Health Support Queensland

HSQ is an organisational Division of the Department of Health and delivers a range of support services to enable the delivery of frontline health services. HSQ provides services to all Queensland Hospital and Health Services (HHSs), to other government agencies and to commercial clients. The current services provided by HSQ include pathology services, procurement and logistics for health-related equipment, products and services, biomedical technology services, forensic and scientific services, linen and laundry services, medicines management, 13 HEALTH, radiology support and payroll.

Forensic and Scientific Services

Forensic and Scientific Services (FSS) is a hub of co-located laboratories at Coopers Plains in

Brisbane. We are ready to respond to civil emergencies, crime and potential threats to our health, environment and our economy with tailor-made, smart scientific solutions.

Our scientists offer highly specialised analytical services and expert advice in the complex fields of Public Health Science and Forensic Science. Scientifically diverse, our organisation has cutting edge capabilities in:

- chemical analysis
- environmental health
- health physics
- communicable diseases (microbiology)
- forensic pathology
- DNA analysis, and
- forensic medicine

Police Services Stream

This stream encompasses both the Forensic DNA Analysis work unit and Forensic Chemistry work unit. Forensic DNA Analysis provides analytical and advisory services principally to the Queensland Police Service in the areas of evidence examination, DNA analysis and result interpretation culminating in expert advice and evidence.

We look forward to working with you!

Visit the website for more information: http://www.health.qld.gov.au/qhcss/default.asp

Vision for the public service

To be a government of the 21st century, one government that is connected and working together to deliver smarter, simpler outcomes that are responsive to the needs of Queenslanders now and for the future. We will create opportunities in partnership that are all about positive outcomes rather than just service delivery and regulation.

To enable this vision, the Queensland Public Sector is transforming from a focus on compliance to a values-led way of working. The following five QPS values, underpin behaviours that will support and enable better ways of working and result in better outcomes for Queenslanders.

Customers first

Know your customers
Deliver what matters
Make decisions with empathy

Ideas into action

Challenge the norm and suggest solutions
Encourage and embrace new ideas
Work across boundaries

Unleash potential

Expect greatness
Lead and set clear expectations
Seek, provide and act on feedback

Be courageous

Own your actions, successes and mistakes
Take calculated risks
Act with transparency

Empower people

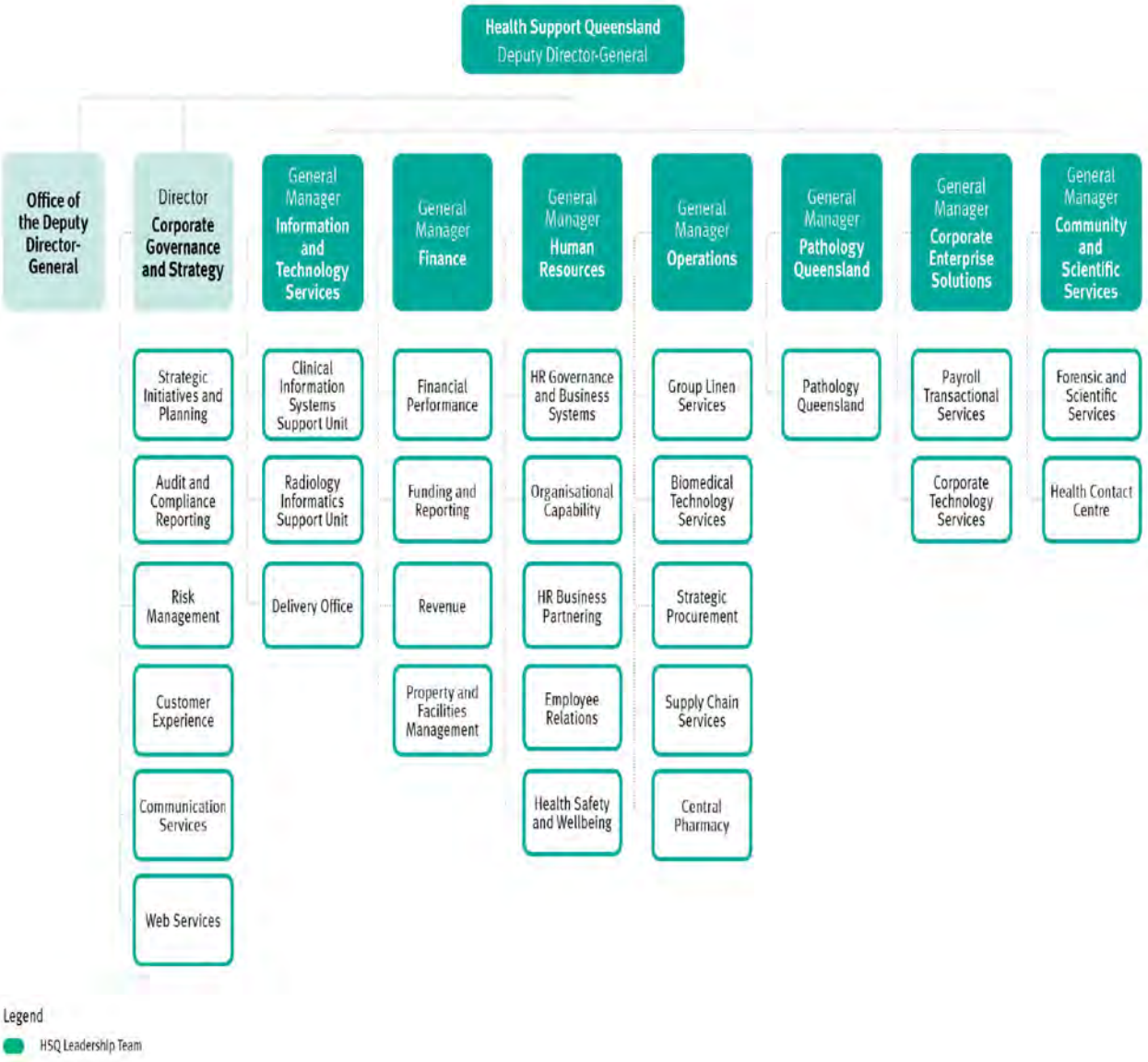
Lead, empower and trust
Play to everyone's strengths
Develop yourself and those around you

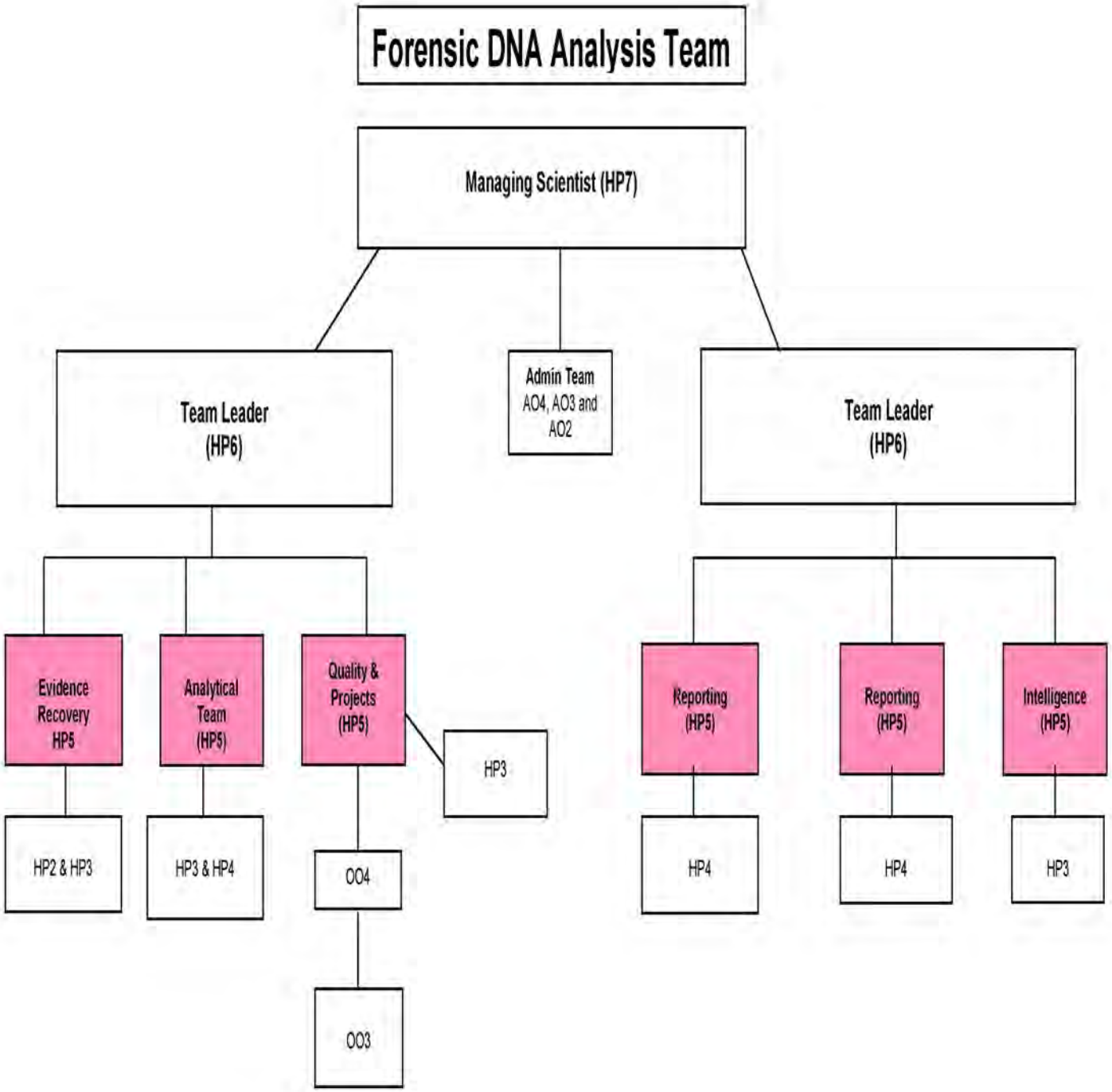
Additional information for applicants

- For details regarding salary information, leave entitlements, flexible working arrangements and other benefits, visit the Queensland Health website.
- All relevant health professionals (including registered nurses and medical officers) who in the course of their duties formulate a reasonable suspicion that a child or youth has been abused or neglected in their home or community environment, have a legislative and a duty of care obligation to immediately report such concerns to Child Safety Services, Department of Communities.
- Pre-employment screening, including criminal history and disciplinary history checks, may be undertaken on persons recommended for employment. Roles providing health, counselling and support services mainly to children will require a Blue Card.
- Employees who are permanently appointed to HSQ may be required to undertake a period of probation appropriate to the appointment.
- Applicants will be required to give a statement of their employment as a lobbyist within one month of taking up the appointment. Details are available at the Public Service Commission Lobbyist Disclosure Policy
- Applicants may be required to disclose any pre-existing illness or injury, which may impact on their ability to perform the role. Details are available in *Section 571 of the Workers' Compensation and Rehabilitation Act 2003*.
- Hepatitis B vaccination or proof that you are not susceptible to hepatitis B is a condition of employment for all staff that will have direct contact with patients of who during their work may be exposed to bodily fluids or blood, or contaminated sharps.
- Roles that interact face-to-face with patients, or the work location is in a clinical area (i.e. a ward, emergency department or outpatient clinic), or frequently or regularly requires attendance in clinical areas, require evidence of vaccination or proof that you are not susceptible to these vaccine preventable diseases:
    - measles, mumps, rubella (MMR)
    - varicella (chicken pox)
    - pertussis (whooping cough)
    - hepatitis B
- Additional vaccinations including Japanese Encephalitis and Rabies may also be required.

NOTE that subsequent evidence must be provided of future vaccination in respect of pertussis (whooping cough) as recommended in *The Australian Immunisation Handbook*.

- Travel may be a requirement.
- Applications will remain current for 12 months and may be considered for other vacancies which may include an alternative employment basis (temporary, full time, part time).


Health Support Queensland
Deputy Director-General
Office of the Deputy Director-General
Director Corporate Governance and Strategy
General Manager Information and Technology Services
General Manager Finance
General Manager Human Resources
General Manager Operations
General Manager Pathology Queensland
General Manager Corporate Enterprise Solutions
General Manager Community and Scientific Services
Strategic Initiatives and Planning
Audit and Compliance Reporting
Risk Management
Customer Experience
Communication Services
Web Services
Clinical Information Systems Support Unit
Radiology Informatics Support Unit
Delivery Office
Financial Performance
Funding and Reporting
Revenue
Property and Facilities Management
HR Governance and Business Systems
Organisational Capability
HR Business Partnering
Employee Relations
Health Safety and Wellbeing
Group Linen Services
Biomedical Technology Services
Strategic Procurement
Supply Chain Services
Central Pharmacy
Pathology Queensland
Payroll Transactional Services
Corporate Technology Services
Forensic and Scientific Services
Health Contact Centre
Legend
HSQ Leadership Team


Forensic DNA Analysis Team
Managing Scientist (HP7)
Team Leader (HP6)
Admin Team AO4, AO3 and AO2
Team Leader (HP6)
Evidence Recovery HP5
Analytical Team (HP5)
Quality & Projects (HP5)
HP3
Reporting (HP5)
Reporting (HP5)
Intelligence (HP5)
HP2 & HP3
HP3 & HP4
OO4
HP4
HP4
HP3
OO3

Queensland Government
Queensland Health

CaSS | Clinical and Statewide Services
safe | sustainable | appropriate

Queensland Health www.health.qld.gov.au/workforus

Job ad reference:	
Role title:	Administration Support Officer
Status:	Full time
Unit/Branch:	DNA Analysis Unit
Division/District:	Clinical and Statewide Services
Location:	Coopers Plains
Classification level:	AO4
Salary level:	This position does not attract PBI status
Closing date:	
Contact:	Wendy Harmer
Telephone:	[redacted]
Online applications:	www.health.qld.gov.au/workforus or http://smartjobs.govnet.qld.gov.au
Fax application:	[redacted]
Post application:	Recruitment Services, Locked Mail Bag 7004, Chermside Centre, Chermside QLD 4032
Deliver application:	*Internal applicants only* Level 4, Leichhardt Court, 831 Gympie Road, Chermside, QLD 4032

Delegate Approval:

Greg Shaw

Senior Director

Signature:

Date

About our organisation

Queensland Health's mission is 'creating dependable health care and better health for all Queenslanders'. Within the context of this organisation, there are **four core values** that guide our behaviour:

- **Caring for People:** Demonstrating commitment and consideration for people in the way we work.
- **Leadership:** We all have a role to play in leadership by communicating a vision, taking responsibility and building trust among colleagues.
- **Respect:** Showing due regard for the feelings and rights of others.
- **Integrity:** Using official positions and power properly.

Purpose of role

- To plan, coordinate, manage, monitor and evaluate the provision of administrative support to DNA Analysis, Forensic & Scientific Services.
- Provide professional and client focused administrative support and assistance to Managing Scientist, DNA Analysis.

Staffing and budget responsibilities

- Coordinates the work of a team of Administrative Officers. Administration Support Officer reports to Managing Scientist, DNA Analysis Unit.
- Nil budget responsibilities.

Key accountabilities

- Fulfil the accountabilities of this role in accordance with Queensland Health's core values, as outlined above.
- Ensure work practices align with Queensland Health Records Management Policy, Standards and Procedures.

- Provide confidential administrative support to the Managing Scientist, DNA Analysis including well developed communication skills to enable effective interaction with internal and external clients / stakeholders. This includes diary management for Managing Scientist and other senior members of DNA Analysis. Monitor incoming correspondence, papers and reports to determine priorities and direct to appropriate action officers.
- Supervise and manage administrative support staff responsible to this position including preparation of rosters, management of workloads, organisation of relief where appropriate, recruitment and selection of administrative support staff, conduct performance planning and review, conduct training, and ensuring duties are completed efficiently and within timeframes.
- Foster teamwork and accountability through monitoring, evaluating, setting goals and priorities, delegation, negotiation and team building.
- Coordination of team meetings, including preparation of meeting documentation, distribution of action items and follow up of outstanding action items. Manage conference room and catering bookings. Coordinate travel arrangements for department staff including travel for court appearances and meetings, interstate and overseas travel submissions.
- High level ability to identify and resolve issues where procedures are not defined. Maintain knowledge of IRM's that affect staff and assist with completion of forms etc, for example Maternity Leave, Recruitment, HR issues. Assist department staff with pay enquiries through liaison with payroll staff. Provide training, induction and orientation for new staff.
- Participate in the development, implementation, review and maintenance of internal systems, processes and work practices. Identify areas for improvement and recommend / implement enhancements to existing practice. Review, create and approve standard operating procedures, perform training, induction and orientation of new staff including scientific staff within department.
- Proficient and competent to train in numerous case / records management systems including AUSLAB, RecFind, Digital Data Store, FACTS. Responsible for record management systems within department.
- Assist in cost centre management, generate reports from maintenance and repairs and coordination of such, provide responsible for purchasing stationery supplies for unit utilising FAMMIS.

Qualifications/Professional registration/Other requirements

Nil

Key skill requirements/competencies

- Demonstrated high level organisational skills including office management, staff supervision and teamwork.
- Demonstrated experience meeting organisational objectives including organising and delegating work, solving day to day challenges, meeting deadlines and establishing priorities.
- Demonstrated high level of communication, both written and verbal, negotiation and interpersonal skills in the management and support of a multidisciplinary environment.
- Demonstrated knowledge of computerised patient information management systems and contemporary software packages which assist with the provision of administrative support to patient services.

- Demonstrated ability to supervise and manage staff in line with quality human resource management practices including employment equity, anti discrimination, occupational health and safety, and ethical behaviour.

How to apply

A short response (maximum 1-2 pages) on how your experience, abilities, knowledge and personal qualities are relevant to this role, taking into account the Key Skill Requirements / Competencies.

ABOUT CLINICAL AND STATEWIDE SERVICES (CASS)

Working in CaSS is an opportunity to creatively and productively contribute to improving the provision of health services to the people of Queensland. CaSS is a learning organisation, committed to developing our people through training, support and leadership programs. We offer challenging opportunities to allow you to explore your potential. CaSS promotes a healthy balance between your work and personal life, provides flexible work hours, paid parental leave and study leave options.

We look forward to working with you!

CaSS is a division of Queensland Health that aims to deliver safe, sustainable and appropriate services to enhance health care throughout Queensland. It provides these services through

- Pathology Queensland
- Medication Services Queensland
- Statewide Health Services
- Radiology Support
- Forensic and Scientific Services
- Biomedical Technology Services
- Queensland Blood Management Programme

Forensic and Scientific Services (FSS) is a hub of co-located laboratories at Coopers Plains in Brisbane. We are ready to respond to civil emergencies, crime and potential threats to our health, environment and our economy with tailor-made, smart scientific solutions.

Our scientists offer highly specialised analytical services and expert advice in the complex fields of Public Health Science and Forensic Science. Scientifically diverse, our organisation has cutting-edge capabilities in:

- chemical analysis
- environmental health
- health physics
- communicable diseases (microbiology)
- forensic pathology
- DNA Analysis, and
- forensic medicine

Visit the website for more information: http://www.health.qld.gov.au/qhcss/

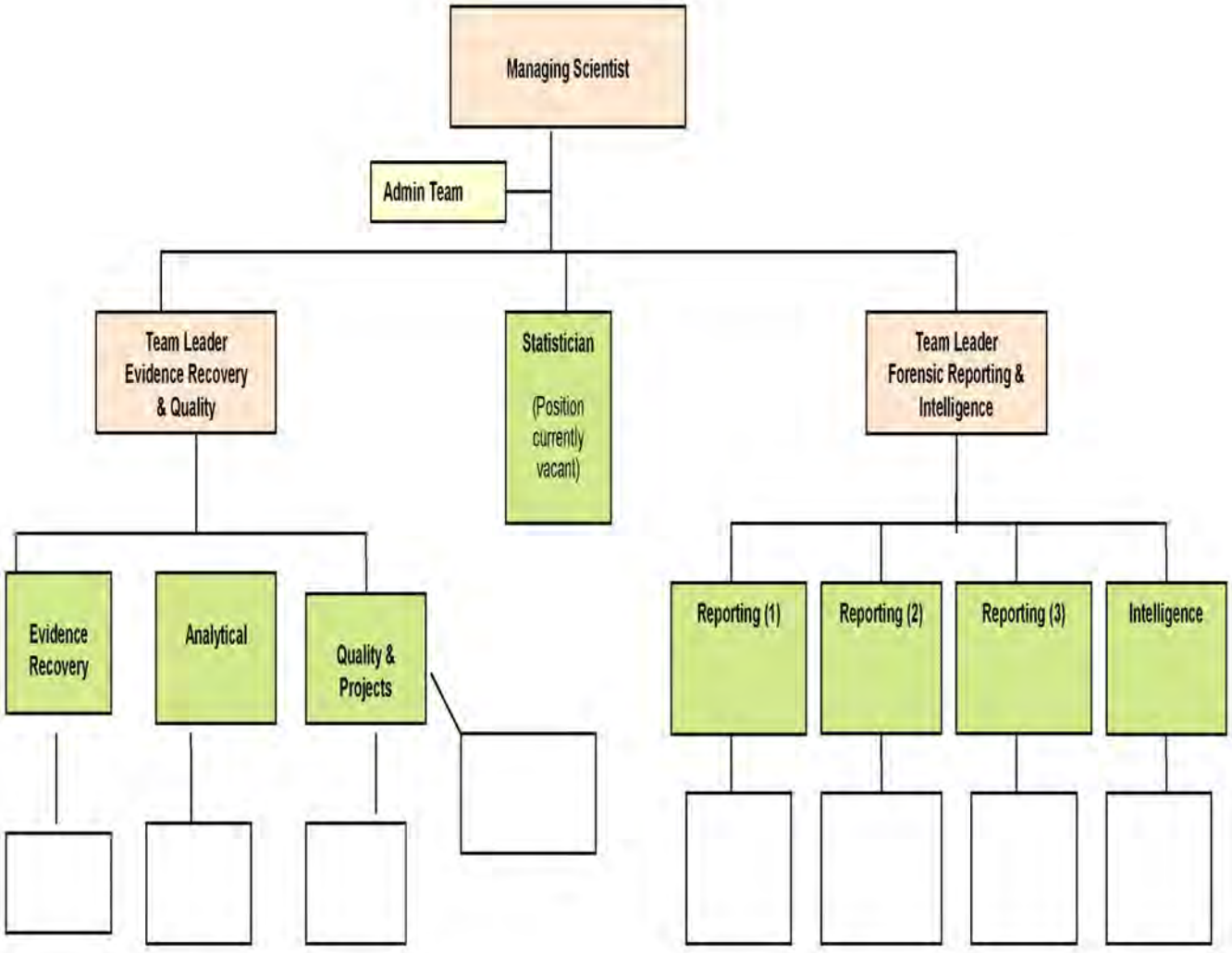
DNA Analysis Unit provides independent and impartial, high quality scientific, research, advisory and expert witnessing services in the discipline of forensic DNA analysis to meet the needs of the Queensland Government and the community. Clients include the Departments of Police, Justice and Attorney General, Medical and Legal Practitioners and the Courts.

Pre-Employment screening

Pre-employment screening, including a criminal history check, may be undertaken on persons recommended for employment. Please refer to the Information Package for Applicants for details of employment screening and other employment requirements.

Organisational chart

DNA Analysis Team Chart



Queensland Health

Role description

Job ad reference:	HSQ417731	**Unit/branch:**	Forensic DNA Analysis, Forensic and Scientific Services
Role title:	Laboratory Assistant	**Location:**	Coopers Plains
Status:	Permanent Full-time	**Closing date:**	Monday 16 May 2022
Classification:	CA3	**Contact name:**	Michael Goodrich
Salary range:	$61,464 - $64,613 per annum plus superannuation and Government benefits	**Phone:**	[redacted]

Department of Health

The Department of Health has a diverse set of responsibilities, and a common purpose of creating better health care for Queenslanders. The department is responsible for the overall management of the public health system in Queensland. We strongly believe in the need to work with people that value the goals of our organisation and who will thrive in our workplace.

To enable this vision, the Queensland Public Sector is transforming from a focus on compliance to a values-led way of working. The following five values underpin behaviours that will support and enable better ways of working and result in better outcomes for Queenslanders.


Customers First


Ideas into action


Unleash potential


Be courageous


Empower people

About Forensic and Scientific Services

Forensic and Scientific Services (FSS) is a hub of co-located laboratories at Coopers Plains in Brisbane. We are ready to respond to civil emergencies, crime and potential threats to our health, environment and our economy with tailor-made, smart scientific solutions.

Our scientists offer highly specialised analytical services and expert advice in the complex fields of Public Health Science and Forensic Science. Scientifically diverse, our organisation has cutting-edge capabilities in:

- Chemical analysis;
- Environmental health
- Health physics;
- Communicable diseases (microbiology);

- Forensic Pathology;
- Forensic Chemistry
- Forensic DNA Analysis, and
- Forensic medicine

Police Services Stream

This stream encompasses both the Forensic DNA Analysis work unit and Forensic Chemistry work unit. Forensic DNA Analysis provides analytical and advisory services principally to the Queensland Police Service in the areas of evidence examination, DNA analysis and result interpretation culminating in expert advice and evidence.

We look forward to working with you!

Visit the website for more information: http://www.health.qld.gov.au/qhcss/default.asp

Purpose of the role

- Deliver a state-wide forensic biology and DNA service
- Apply standard operating procedures to the testing of forensic specimens and samples in the Forensic DNA Analysis laboratory.
- To ensure that all laboratory practices comply with Forensic & Scientific Services requirements in providing an effective and efficient service.
- To comply with NATA/ISO accreditation/certification requirements including performing quality control procedures.

The Laboratory Assistant in Forensic DNA Analysis reports to the Senior Scientist.

Your key responsibilities

You will be required to fulfil the responsibilities of this role in accordance with the Queensland Public Service values.

- Adhere to defined service quality standards, health and safety policies and procedures relating to the work being undertaken to ensure high quality, safe services and workplaces.
- Prepare general laboratory samples received for testing by scientific and technical staff.
- Perform simple measurements and laboratory procedures under close supervision as required, including sample preparation and processing in accordance with the laboratory's policies and practices, including Workplace Health and Safety and Quality Assurance requirements.
- Ensure laboratory equipment and consumable stocks are maintained.
- Comply with safe laboratory practices including the disposal of laboratory waste and planned equipment maintenance.
- Actively participate in the activities of the multi-speciality team, including participating in the introduction of new technologies or processes in the work area.
- Comply with regulatory accreditation/certification of the National Association of Testing Authority/International Standardisation Organisation (NATA/ISO) including performing quality control procedures, assisting with preparation of procedure manuals and completion of relevant records and statistics.
- Comply with and utilise procedures, policies, regulations and standards which impact upon the position in line with contemporary human resources management requirements and practices, such as workplace health and safety, equal employment opportunity, anti-discrimination and ethical behaviour.

Key competencies (role specific criteria)

You will be assessed on your ability to demonstrate the following:

- Demonstrated knowledge and skills in basic laboratory processes and practices including, but not limited to: use of computers, use and maintenance of laboratory equipment, reagent preparation, assisting in the preparation of samples for testing by scientific staff, and the keeping and maintenance of concise and accurate records.
- Demonstrated knowledge of or the ability to rapidly acquire knowledge of available information system relevant to the duties of the position (eg. a laboratory information management system).
- Ability to work within a multi-skilled team, to communicate effectively with peers and professional/technical staff, including the ability to follow detailed operational instructions. Demonstrated interpersonal skills for working within a busy team and environment.
- A demonstrated commitment to the principles of quality management and continuous quality improvement, and an ability to follow detailed instructions.
- Ability to actively and successfully participate in a working environment supporting quality human resource management practices including employment equity, anti-discrimination, occupational health and safety and ethical behaviour.

Qualifications, registrations and other requirements

- Provision of a DNA sample is required for inclusion on a staff elimination database to comply with accreditation requirements.
- Candidate will be required to underake frequent manual handling, bending and lifting.
- In some circumstances and following consultation, Queensland Health staff may be required to participate in 24-hour shift, on-call or weekend roster arrangements
- It may be a condition of employment for this role for the employee to be, and remain, vaccinated against one or more of the following vaccine preventable diseases during their employment (Health Employment Directive No. 01/16): measles, mumps, rubella (MMR),varicella (chicken pox),pertussis (whooping cough), hepatitis B, tuberculosis
- COVID-19 Vaccination may be required—It may be a condition of employment for this role for the employee to be, and remain, vaccinated against COVID-19 (Health Employment Directive No. 12/21 and Queensland Health Human Resources Policy B70).
- Please detail any visa conditions you may have if you are not a permanent resident of Australia.
- We understand that some people may require adjustments to the workplace or the way the work is performed. All applicants are encouraged to advise the panel of any support or reasonable adjustments (i.e. building access, wheelchair access, interpreting services etc.) that may be required.

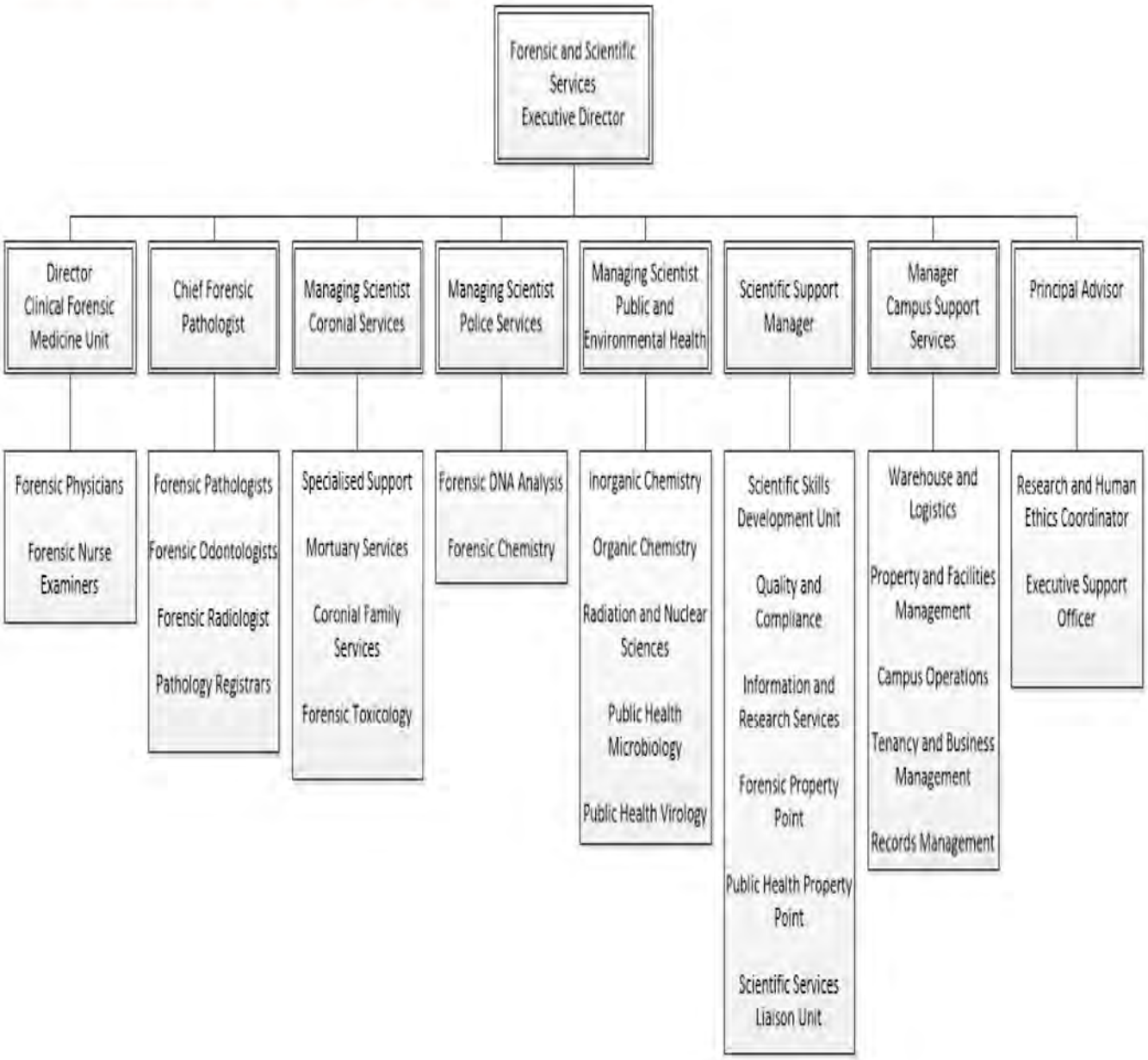
Additional Information

Please provide the following information to the panel to assess your suitability:

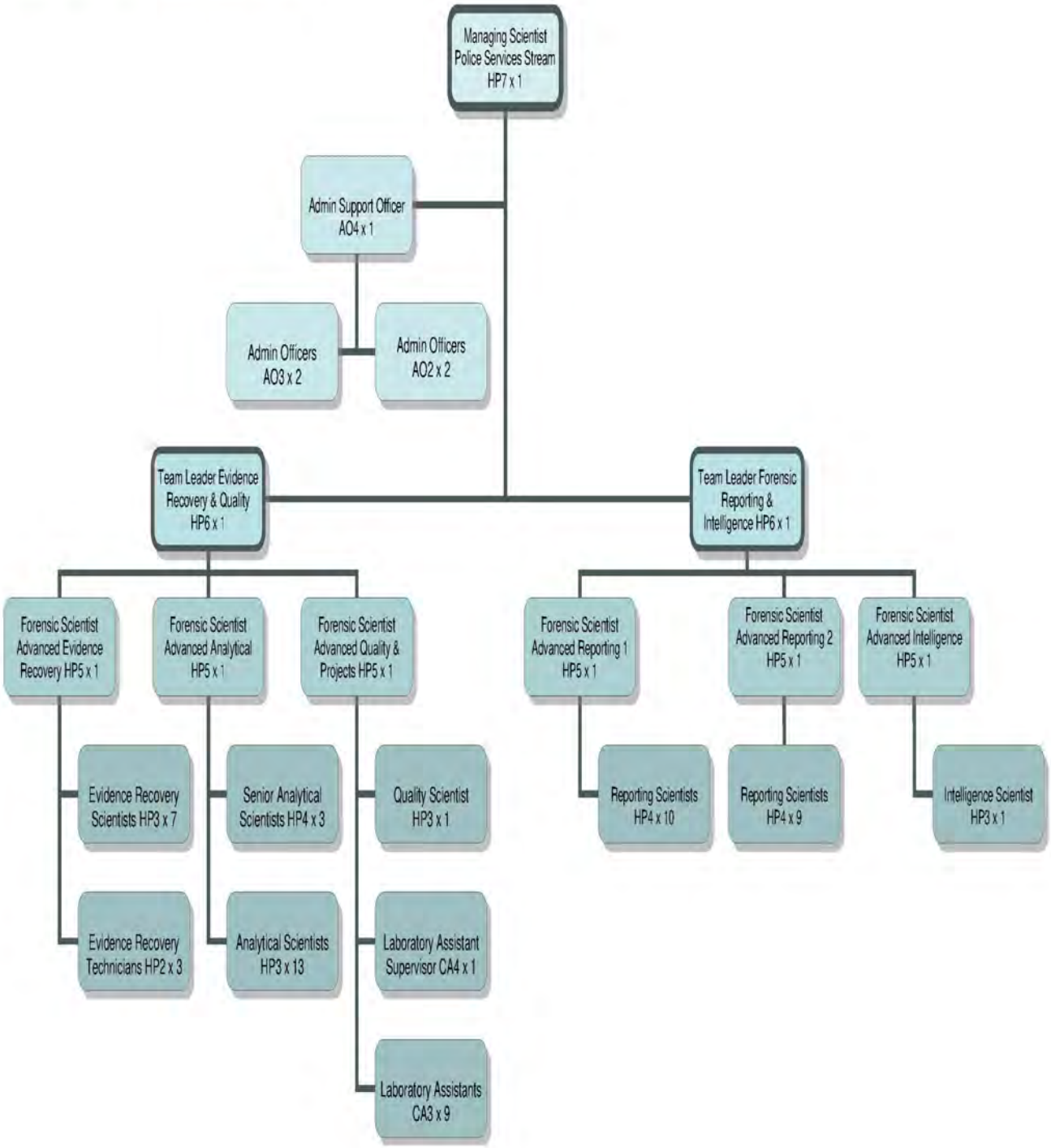
- Your **resume**, including the names and contact details of two referees who have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current, immediate or past supervisor.
- A **short statement (maximum two pages)** that gives details of your skills, experience and knowledge as required on the role description under the heading 'key competencies (role specific criteria)'.

Discover more about our work, our people and employment opportunities at Queensland Health.

Forensic and Scientific Services Organisational Chart



Forensic DNA Analysis Team Chart



Queensland Government

Health Services Support Agency

Queensland Health www.health.qld.gov.au/workforus

Job ad reference:	
Role title:	Forensic Scientist - Advanced
Status: (Permanent/Temporary) (Full-time/ Part-Time) (Casual)	Permanent Full Time. Please note future vacancies of a temporary, full time and part time nature may also be filled through this recruitment process.
Unit/Branch:	Forensic DNA Analysis
Division/Hospital and Health Service:	Forensic and Scientific Services Health Services Support Agency
Location:	Coopers Plains
Classification level:	HP
Salary level:	
Closing date:	
Contact:	Cathie Allen
Telephone:	[redacted]
Online applications:	www.health.qld.gov.au/workforus or www.smartjobs.qld.gov.au
Fax application:	
Post application:	
Deliver application:	

About our organisation

Queensland Health's purpose is to provide safe, sustainable, efficient, quality and responsive health services for all Queenslanders. Our behaviour is guided by Queensland Health's commitment to high levels of ethics and integrity and the following **five core values**:

- **Caring for People:** We will show due regard for the contribution and diversity of all staff and treat all patients and consumers, carers and their families with professionalism and respect.
- **Leadership:** We will exercise leadership in the delivery of health services and in the broader health system by communicating vision, aligning strategy with delivering outcomes, taking responsibility, supporting appropriate governance and demonstrating commitment and consideration for people.
- **Partnership:** Working collaboratively and respectfully with other service providers and partners is fundamental to our success.
- **Accountability, efficiency and effectiveness:** We will measure and communicate our performance to the community and governments. We will use this information to inform ways to improve our services and manage public resources effectively, efficiently and economically.
- **Innovation:** We value creativity. We are open to new ideas and different approaches and seek to continually improve our services through our contributions to, and support of, evidence, innovation and research.

Purpose

Provide authoritative advice applying an expert level of knowledge, skills and experience in the area of forensic biology to all clients and stakeholders and operate as a State-wide reference point for forensic advice and advocacy with respect to quality and projects. To manage scientists and laboratory assistants within the Quality and Projects Team the provision of an integrated, comprehensive, cost effective and quality forensic service in line with the policies, guidelines and strategies of Forensic and Scientific Services. To make an active contribution to continuous improvement in provision of DNA analysis services through leadership of, and/or participation in research and project teams.

Your key responsibilities

- Fulfil the responsibilities of this role in accordance with Queensland Health's core values, as outlined above.
- As a recognised forensic expert and DNA Analyst, demonstrates a specialist level of knowledge, skills and experience and clinical leadership within Forensic DNA Analysis, Forensic and Scientific Services and is recognised for servicing at a state-wide level. Duties are performed through the independent application of forensic expertise and the use of established specialised techniques, to facilitate complex, critical discipline specific clinical decisions with minimal supervision.
- As a recognised forensic expert and DNA Analyst, demonstrates high level clinical leadership, judgement, experience and specialist skills (including the provision of training and education) in the undertaking and supervision of change management, project methodology and quality management practices within the multi-speciality discipline of forensic biology within the Forensic DNA Analysis Unit, Forensic and Scientific Services.
- Accountable for providing independent high level forensic services, based on work performed by others, to all key stakeholders incorporating the interpretation of results, the use of information relating to the National Criminal Investigation DNA Database, and the provision of expert testimony on work performed within the laboratory in accordance with legislative requirements. Apply expertise within the discipline of forensic biology to participate in problem solving large-scale and/or complex scientific service or work-flow problems.
- Demonstrated high level management skills, especially in the areas of operational management and resource allocation with respect to new and existing samples, to be processed within an agreed timeframe as required by state wide clients.
- Provide specialist clinical advice to peers and relevant stakeholders regarding service delivery, on a state wide level, demonstrating involvement and participate in providing strategic direction to DNA Analysis and key stakeholders.
- Applies high level evidence and judgement in advising senior management, clients and relevant stakeholders on quality service improvements and project management to ensure that the Forensic DNA Analysis unit complies with all relevant legislative, administrative and professional standards to meet NATA/ISO accreditation/certification requirements.
- Demonstrated ability to manage a medium sized team, including high level interpersonal skills including conflict management, ensuring that the team works cooperatively and with effective communication with clients internal and external to the laboratory, chairing weekly team meetings and being involved in the decision making process as part of the Forensic DNA Analysis Management Team.
- Accountable for the co-ordination of internal and external research projects within the DNA Analysis Unit of significant scope and clinical importance to Queensland Health, with outcomes influencing forensic DNA Analysis Unit processes and standards of forensic science with Australia.
- Ensure the development of scientific knowledge and expertise by supporting active learning and professional development of DNA Analysis Unit staff under your line management.
- Represent the Forensic DNA Analysis laboratory on relevant and appropriate internal and external committees and forums, including providing specialist advice with respect to laboratory information management systems. Represent the Forensic DNA Analysis

laboratory group (Forensic & Scientific Services) which includes participation in decision making and strategic planning at a state-wide level.

- Represents Queensland Health at a state-wide level in the provision of expert forensic scientific evidence in all tiers within the court system.
- Responsible for a high level of formal daily management of a medium-sized discipline-specific professional team. Responsibilities include performance appraisal, assistance with performance management, training of Laboratory Assistants (OO3) and Scientists (HP3 and HP4) staff, maintenance of appropriate standard operating procedures, appropriate management of allocated resources, assistance and input into strategic planning at a Department level and responsibility for the monitoring of professional standards and quality outcomes from staff and work unit.

Qualifications/Professional registration/Other requirements

- The successful applicant must hold a tertiary qualification, or equivalent, in science from a recognised university or tertiary institution.
- In some circumstances and following consultation, Queensland Health staff may be required to participate in 24 hour shift, on-call or weekend roster arrangements.
- Appointment to this position requires proof of qualification and if applicable registration or membership with the appropriate registration authority or association. Certified copies of the required information must be provided to the appropriate supervisor/manager, prior to commencement of clinical duties.

Are you the right person for the job?

You will be assessed on your ability to demonstrate the following key attributes. Within the context of the responsibilities described above, the ideal applicant will be someone who can demonstrate the following:

- Demonstrated extensive expertise and understanding of the contemporary discipline of forensic biology, with demonstrated abilities in a range of relevant procedures, techniques, instrumentation and quality assurance systems, including the use of computer systems.
- Demonstrated extensive expertise and implementation of the principles of quality management and continuous quality improvement and a contemporary knowledge of NATA/ISO accreditation/certification.
- Demonstrated expertise and skills in enhancement and configuration of a laboratory information management system (eg AUSLAB), with appropriate change management framework to achieve an efficient workflow for a high through-put laboratory.
- Demonstrated ability to solve scientific problems, generate ideas and innovations, introduce new technology and actively participate in the processes of change and continuous improvement, using project management methodology to achieve outcomes.
- Demonstrated interpersonal skills for working in a team both as a member and as a leader; the ability to consult and communicate scientific/technical information effectively both orally and in writing including presentation of expert testimony in a court of law.
- Demonstrated ability to supervise and manage staff in line with quality human resource management practices with particular reference to employment equity, anti-discrimination, occupational health and safety and ethical behaviour.

How to apply

Please provide the following information to the panel to assess your suitability:

- Your current CV or resume, including referees. You must seek approval prior to nominating a person as a referee. Referees should have a thorough knowledge of your work performance and conduct, and it is preferable to include your current/immediate past supervisor. By providing the names and contact details of your referee/s you consent for these people to be contacted by the selection panel. If you do not wish for a referee to be contacted, please indicate this on your resume and contact the selection panel chair to discuss.
- A short statement (maximum 2 pages) on how your experience, abilities, knowledge and personal qualities are relevant for the role, taking into account the key responsibilities and attributes noted in the 'Are you the right person for the job?' section.

About the Health Services Support Agency

Working in the Health Services Support Agency (HSSA) is an opportunity to creatively and productively contribute to improving the provision of health services to the people of Queensland. HSSA is a learning organisation, committed to developing our people through training, support and leadership programs. We offer challenging opportunities to allow you to explore your potential. HSSA promotes a healthy balance between your work and personal life, provides flexible work hours, paid parental leave and study leave options.

We look forward to working with you!

HSSA is a division of Queensland Health that aims to deliver safe, sustainable and appropriate services to enhance health care throughout Queensland. It provides these services through

- Diagnostic and Scientific Services
- Procurement Logistics and Health Technology Services
- Clinical Support Services

http://www.health.qld.gov.au/hssa/home.htm

Pre-employment screening

Pre-employment screening, including criminal history and discipline history checks, may be undertaken on persons recommended for employment. The recommended applicant will be required to disclose any serious disciplinary action taken against them in public sector employment. In addition, any factors which could prevent the recommended applicant complying with the requirements of the role are to be declared.

Roles providing health, counselling and support services mainly to children will require a Blue Card, unless otherwise exempt. Please refer to the Information Package for Applicants for details of employment screening and other employment requirements.

Salary Packaging

To find out whether or not your work unit is eligible for the Public Hospital Fringe Benefits Tax (FBT) Exemption Cap please refer to the Salary Packaging Information Booklet for Queensland Health employees available from the Queensland Health Salary Packaging Bureau Service Provider – RemServ at http://www.remserv.com.au. For further queries regarding salary packaging RemServ's Customer Care Centre may be contacted via telephone on 1300 30 40 10.

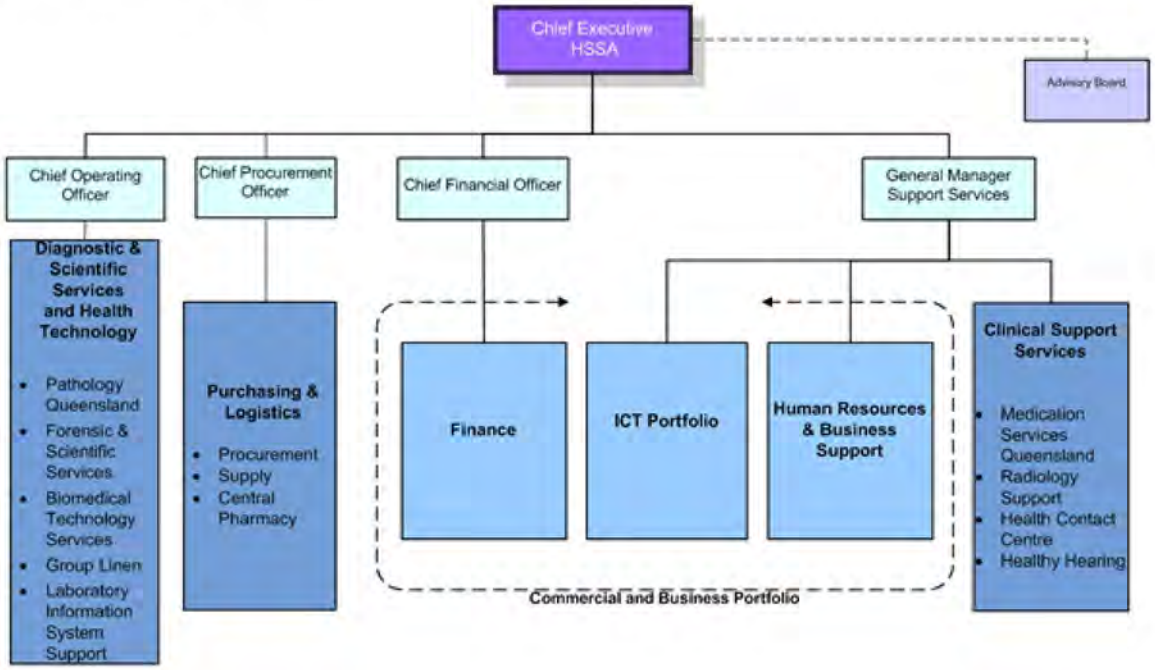
Disclosure of Previous Employment as a Lobbyist

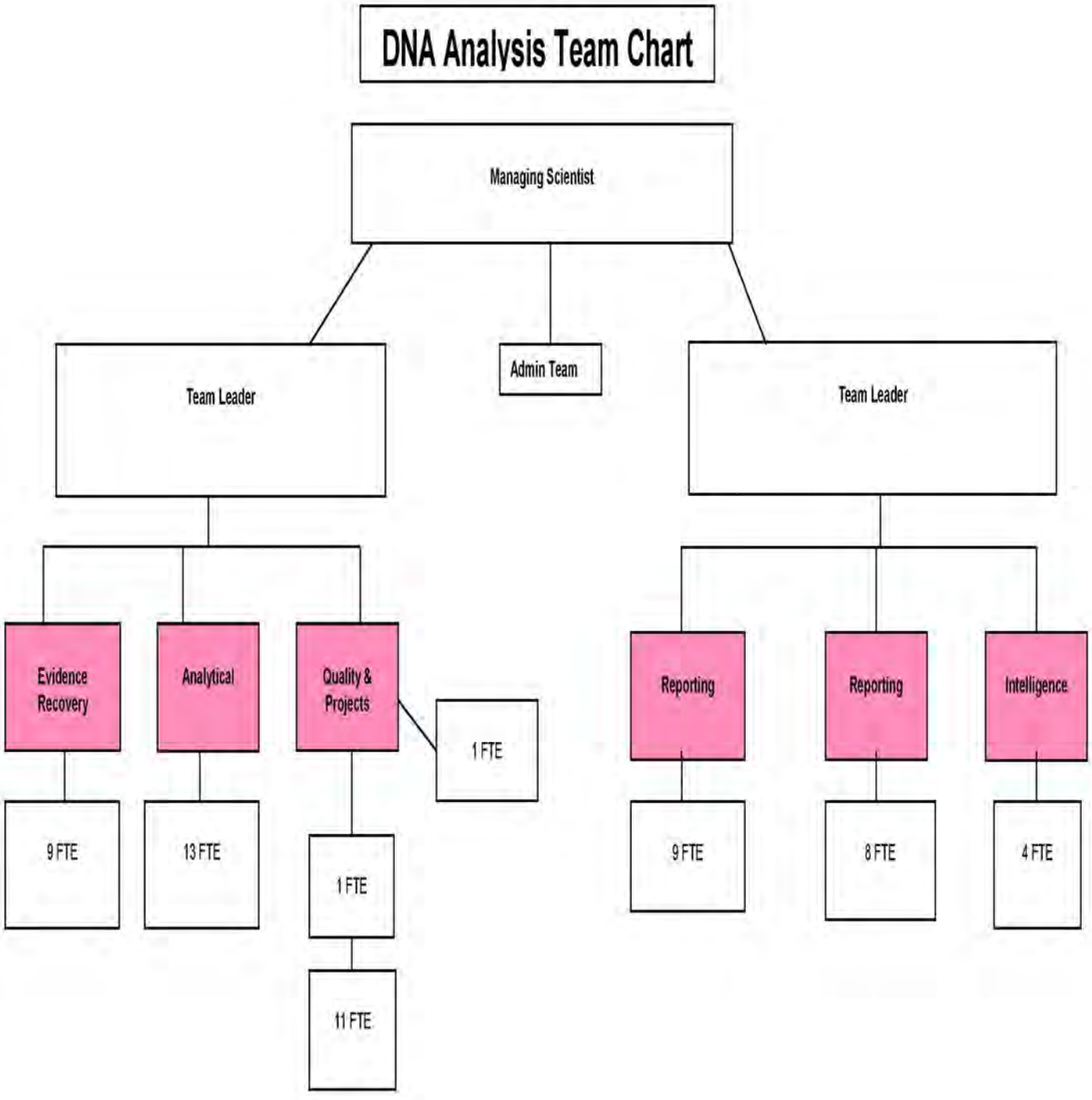
Applicants will be required to give a statement of their employment as a lobbyist within one (1) month of taking up the appointment. Details are available at http://www.psc.qld.gov.au/library/document/policy/lobbyist-disclosure-policy.pdf.

Probation

Employees who are permanently appointed to Queensland Health may be required to undertake a period of probation appropriate to the appointment. For further information, refer to Probation HR Policy B2 http://www.health.qld.gov.au/qhpolicy/docs/pol/qh-pol-197.pdf.

Organisational Chart




DNA Analysis Team Chart
Managing Scientist
Team Leader
Admin Team
Team Leader
Evidence Recovery
Analytical
Quality & Projects
1 FTE
Reporting
Reporting
Intelligence
9 FTE
13 FTE
1 FTE
11 FTE
9 FTE
8 FTE
4 FTE

Queensland Government

Clinical and Statewide Services Division
Role Description

Job ad reference:	CSS08359
Role title:	Managing Scientist
Status: (Permanent/Temporary) (Full-time/ Part-Time) (Casual)	Permanent Full Time
Unit/Branch:	DNA Analysis Unit
Division/District:	Forensic and Scientific Services Clinical and Statewide Services Division
Location:	Coopers Plains
Classification level:	HP7
Salary level:	$4936.30 per fortnight, $128,785 per annum
Closing date:	12 September 2011
Contact:	Greg Shaw
Telephone:	[redacted]
Online applications:	www.health.qld.gov.au/workforus or www.smartjobs.qld.gov.au
Fax application:	[redacted]
Post application:	Recruitment Services - Corporate & Statewide, Locked Mail Bag 7004, Chermside Centre, CHERMSIDE QLD 4032
Deliver application:	

About our organisation

Queensland Health's mission is 'creating dependable health care and better health for all Queenslanders'. Within the context of this organisation, there are **four core values** that guide our behaviour:

- **Caring for People:** Demonstrating commitment and consideration for people in the way we work.
- **Leadership:** We all have a role to play in leadership by communicating a vision, taking responsibility and building trust among colleagues. Queensland Health applies the National Health Service (NHS) Leadership Qualities Framework.
- **Respect:** Showing due regard for the feelings and rights of others.
- **Integrity:** Using official positions and power properly.

Purpose

- Provide effective high level leadership, management, strategic direction and advocacy in the management of the DNA Analysis unit, Forensic and Scientific Services.
- Provide authoritative and strategic forensic biological and analytical counsel to Queensland Health and key stakeholders ensuring expert knowledge remains current and includes the latest developments.
- Establish and maintain effective working relationships with all relevant government and non-government agencies, both intra-jurisdictional and inter-jurisdictional, to provide a quality client focused forensic biology service, through agreed mechanisms.
- To investigate innovation in the field and support the changing environment of Forensic Services, while promoting the values and interests of Queensland Health Forensic and

Scientific Services.

Your key responsibilities

- Fulfil the responsibilities of this role in accordance with Queensland Health's core values, as outlined above.
- Provide strategic direction and advice on a state, national and international level on issues associated with forensic DNA Analysis training, development, direction, needs, client interfaces, risk management, business development and also on the coordination of forensic DNA Analysis services provided to the Queensland Police Service and the Department of Justice and Attorney Generals.
- Contribute to strategic level management processes, applying high level knowledge to challenge existing protocols and advocating authoritatively for forensic DNA Analysis services in the development of new policy.
- Participate and proactively advocate for the forensic DNA analysis services in setting state and national standards of performance, safety and inter-departmental coordination, through membership on national advisory bodies.
- Monitor and influence the development of relevant legislation that may impact on forensic DNA analysis services, both in Queensland and Nationally.
- Accountable for all aspects of operational management and development of people and facilities within the DNA Analysis unit, including, but not limited to:
    - Ethical decision making in the achievement of organisational goals
    - Direction and control of the asset management and financial management of one or more cost centres
    - Effects of all policy generated from within Queensland and provide associated professional counsel to relevant stakeholders
    - Facilitate staff development, performance appraisal and associated human resource management
- Responsible for solving complex forensic service or work-flow problems through recognised expertise, high level interpretation of existing forensic service delivery systems, professional standards, established change management procedures and other pertinent external considerations.
- Utilise high level negotiation and conflict management skills to advocate with staff and stakeholders in securing resources, resolving issues or other outcomes for the DNA Analysis unit.

Qualifications/Professional registration/Other requirements

- The successful applicant must hold a tertiary qualification, or equivalent, in science from a recognised university or tertiary institution.
- In some circumstances and following consultation, Queensland Health staff may be required to participate in 24 hour shift, on-call or weekend roster arrangements.

Are you the right person for the job?

You will be assessed on your ability to demonstrate the following key attributes. Within the context of the responsibilities described above, the ideal applicant will be someone who can demonstrate the following:

- Demonstrated expert understanding and knowledge of complex forensic DNA analysis services and the factors which are critical to effective service delivery at an organisational, state and national level.
- Demonstrated competence to provide leadership and conceptual, analytical and innovative management skills to implement, support and manage organisational change within a service delivery organisation, involving diverse work units.
- Demonstrated competence in liaising with business clients and stakeholders within and outside the organisation, together with a demonstrated high level of oral and written communication

skills associated with the provision of high level briefings and advice
- Demonstrated ability to supervise and manage staff in line with quality human resource management practices including employment equity, anti-discrimination, workplace health and safety, and ethical behaviour and demonstrated commitment to their implementation.

How to apply

Please provide the following information to the panel to assess your suitability:

- **Your current CV or resume, including referees**. Applicants must seek approval prior to nominating a person as a referee. Referees should have a thorough knowledge of your work performance and conduct, and it is preferable to include your current/immediate past supervisor. By providing the names and contact details of your referee/s you consent for these people to be contacted by the selection panel. Please note: your referees may be contacted at any time during the recruitment process. If you do not wish for a referee to be contacted, please indicate this on your resume and contact the selection panel chair to discuss.

- **A short statement (maximum 1–2 pages)** on how your experience, abilities, knowledge and personal qualities are relevant for the role, taking into account the key responsibilities and attributes noted in the 'Are you the right person for the job?' section.

About the Clinical and Statewide Services Division

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We look forward to working with you!

CaSS is a division of Queensland Health that aims to deliver safe, sustainable and appropriate services to enhance health care throughout Queensland. It provides these services through

- Pathology Queensland
- Medication Services Queensland
- Statewide Health Services
- Radiology Support
- Forensic and Scientific Services
- Biomedical Technology Services
- Queensland Blood Management Programme

http://www.health.qld.gov.au/ghcss/

Pre-employment screening

Pre-employment screening, including criminal history and discipline history checks, may be undertaken on persons recommended for employment. The recommended applicant will be required to disclose any serious disciplinary action taken against them in public sector employment.

Roles providing health, counselling and support services mainly to children will require a Blue Card. Please refer to the Information Package for Applicants for details of employment screening and other employment requirements.

Disclosure of Previous Employment as a Lobbyist

Applicants will be required to give a statement of their employment as a lobbyist within one (1) month of taking up the appointment. Details are available at
http://www.psc.qld.gov.au/library/document/policy/lobbyist-disclosure-policy.pdf

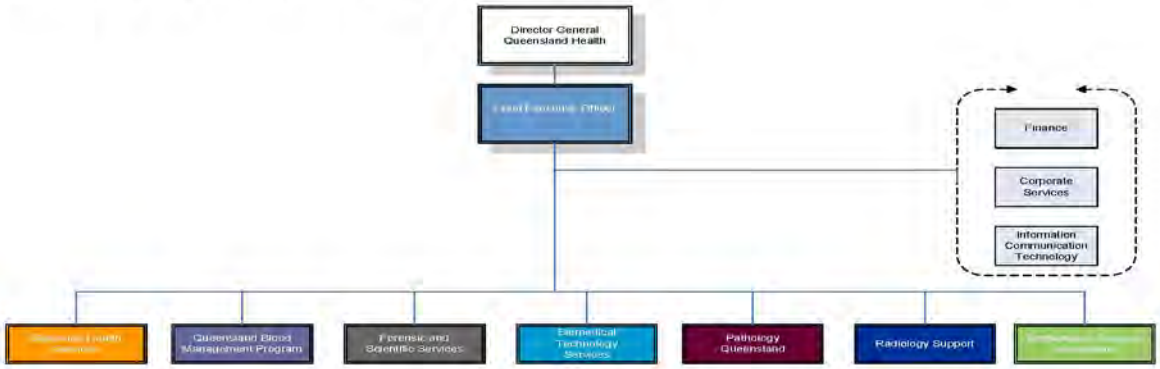
Probation

Employees who are permanently appointed to Queensland Health may be required to undertake

a period of probation appropriate to the appointment. For further information, refer to Probation HR Policy B2 http://www.health.qld.gov.au/hrpolicies/resourcing/b_2.pdf

Organisational chart

Clinical and Statewide Services Division



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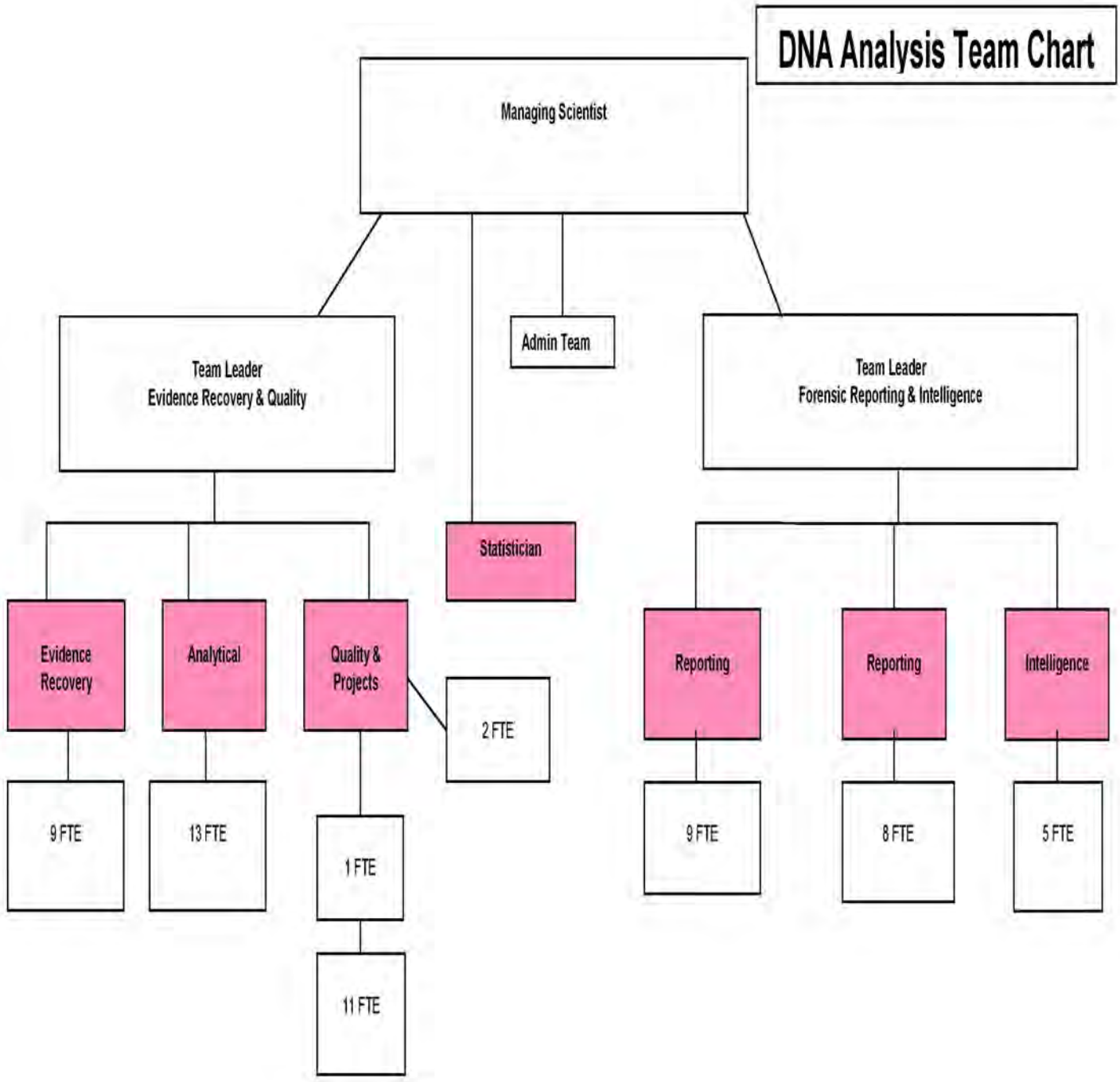

DNA Analysis Team Chart
Managing Scientist
Team Leader
Evidence Recovery & Quality
Admin Team
Team Leader
Forensic Reporting & Intelligence
Statistician
Evidence Recovery
Analytical
Quality & Projects
2 FTE
Reporting
Reporting
Intelligence
9 FTE
13 FTE
1 FTE
11 FTE
9 FTE
8 FTE
5 FTE

Department of Health

Role description

Health Services Support Agency

Role details

Job ad reference	H14HSS123645	**Classification**	HP5
Role title	Forensic Scientist - Advanced	**Salary**	$106820 - $111459 Per Annum
Status	Permanent Full Time	**Closing date**	Thursday 19 June 2014
Unit/Branch	Forensic DNA Analysis Police Services Stream Forensic and Scientific Services		
Commercialised Business Unit	Health Services Support Agency	**Contact name**	Cathie Allen
Location	Coopers Plains	**Contact number**	[redacted]

If you have difficulties applying online, please contact HSSA Recruitment on [redacted]

Vision for the public service

To be a government of the 21st century, one government that is connected and working together to deliver smarter, simpler outcomes that are responsive to the needs of Queenslanders now and for the future. We will create opportunities in partnership that are all about positive outcomes rather than just service delivery and regulation.

To enable this vision, the Queensland Public Service (QPS) is transforming from a compliance focus to a more values-led way of working. The following **five values statements** underpin behaviours that will support and enable better ways of working and result in better outcomes for Queenslanders.

- **Customers first:** Know your customers. Deliver what matters. Make decisions with empathy.
- **Ideas into action:** Challenge the norm and suggest solutions. Encourage and embrace new ideas. Work across boundaries.
- **Unleash potential:** Expect greatness. Lead and set clear expectations. Seek, provide and act on feedback.
- **Be courageous:** Own your actions, successes and mistakes. Take calculated risks. Act with transparency.
- **Empower People:** Lead, empower and trust. Play to everyone's strengths. Develop yourself and those around you.

Your opportunity

Provide authoritative advice applying an expert level of knowledge, skills and experience in the area of Forensic Biology and operate as a State-wide reference point for forensic advice and advocacy. To manage the Forensic and Scientific Services, DNA Analysis Unit – to ensure the provision of an integrated, comprehensive, cost effective and quality forensic service in line with the policies, guidelines and strategies of Forensic and Scientific Services.

Your role

- Fulfil the responsibilities of this role in accordance with QPS values as outlined above.
- As a recognised forensic expert and DNA Analyst (or ability to become a DNA Analyst), demonstrates a specialist level of knowledge, skills and experience and clinical leadership within Forensic DNA Analysis, Forensic and Scientific Services and is recognised for servicing at a state-wide level. Duties are performed through the independent application of forensic expertise and the use of established specialised techniques, to facilitate complex, critical discipline specific clinical decisions with minimal supervision.
- As a recognised forensic expert and DNA Analyst, demonstrates high level clinical leadership, judgement, experience and specialist skills (including the provision of training and education) in the undertaking and supervision of project methodology, change management following completion of a project, and quality management practices within the multi-speciality discipline of forensic biology within Forensic DNA Analysis unit of Forensic and Scientific Services.
- Accountable for providing independent high level forensic services, based on work performed by others, to all key stakeholders incorporating the interpretation of results, the use of information relating to the National Criminal Investigation DNA Database, and the provision of expert testimony on work performed within the laboratory in accordance with legislative requirements.
- Apply expertise within the discipline of forensic biology to participate in problem solving large-scale and/or complex scientific service or work-flow problems, with respect to projects and quality outcomes from routine processes.
- Demonstrated high level management skills, especially in the areas of operational management and resource allocation with respect to new and existing samples, to be processed within an agreed timeframe as required by state wide clients.
- Provide specialist clinical advice to peers and relevant stakeholders regarding service delivery, on a state wide level, demonstrating involvement and participate in providing strategic direction to DNA Analysis and key stakeholders.
- Applies high level evidence and judgement in advising senior management, clients and relevant stakeholders on quality service improvements and project management to ensure that the Forensic DNA Analysis unit complies with all relevant legislative, administrative and professional standards to meet NATA/ISO accreditation/certification requirements.
- Demonstrated ability to manage a medium sized team, including high level interpersonal skills including conflict management, ensuring that the team works cooperatively and with effective communication with clients internal and external to the laboratory, chairing weekly team meetings and being involved in the decision making process as part of the Forensic DNA Analysis Management Team.
- Accountable for the co-ordination of internal and external research projects within the DNA Analysis Unit of significant scope and clinical importance to Queensland Health, with outcomes influencing forensic DNA Analysis Unit processes and standards of forensic science with Australia.
- Ensure the development of scientific knowledge and expertise by supporting active learning and professional development of DNA Analysis Unit staff under your line management.

- Represent the Forensic DNA Analysis laboratory on relevant and appropriate internal and external committees and forums, including providing specialist advice with respect to laboratory information management systems. Represent the Forensic DNA Analysis laboratory group (Forensic & Scientific Services) which includes participation in decision making and strategic planning at a state-wide level.
- Represents Queensland Health at a state-wide level in the provision of expert forensic scientific evidence in all tiers within the court system.
- Responsible for a high level of formal daily management of a medium-sized team consisting of operational support staff and 1x HP3. Responsibilities include performance appraisal, assistance with performance management, training of Laboratory Assistants (OO4 and OO3) and Scientists (HP3) staff, maintenance of appropriate standard operating procedures, appropriate management of allocated resources, assistance and input into strategic planning at a Department level and responsibility for the monitoring of professional standards and quality outcomes from staff and work unit.

Mandatory qualifications/Professional registration/Other requirements

- The successful applicant must hold a tertiary degree (or equivalent) qualification in science from a recognised university or tertiary institution.
- In some circumstances and following consultation, Queensland Health staff may be required to participate in 24 hour shift, on-call or weekend roster arrangements.
- Appointment to this position requires proof of qualification and if applicable registration or membership with the appropriate registration authority or association. Certified copies of the required information must be provided to the appropriate supervisor/manager, prior to commencement of clinical duties.

How you will be assessed?

You will be assessed on your ability to demonstrate the following key capabilities, knowledge and experience. Within the context of the responsibilities described above under 'Your role', the ideal applicant will be someone who can demonstrate the following:

- Demonstrated extensive expertise and understanding of the contemporary discipline of forensic biology, with demonstrated abilities in a range of relevant procedures, techniques, instrumentation and quality assurance systems, including the use of computer systems.
- Demonstrated extensive expertise and implementation of the principles of quality management and continuous quality improvement and a contemporary knowledge of NATA/ISO accreditation/certification.
- Demonstrated expertise and skills in enhancement and configuration of a laboratory information management system (eg AUSLAB), with appropriate change management framework to achieve an efficient workflow for a high through-put laboratory.
- Demonstrated ability to solve scientific problems, generate ideas and innovations, introduce new technology and actively participate in the processes of change and continuous improvement, using project management methodology to achieve outcomes.
- Demonstrated interpersonal skills for working in a team both as a member and as a leader; the ability to consult and communicate scientific/technical information effectively both orally and in writing including presentation of expert testimony in a court of law.
- Demonstrated ability to supervise and manage staff in line with quality human resource management practices with particular reference to employment equity, anti-discrimination, occupational health and safety and ethical behaviour.

Your application

Please provide the following information to the panel to assess your suitability:

- **Your current CV or resume, including the names and contact details of two referees**. Referees should have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current/immediate/past supervisor
- **A short statement (maximum 1–2 pages)** on how your experience, abilities, knowledge and personal qualities are relevant for the role, taking into account the key responsibilities and attributes noted in the 'How you will be assessed?' section.

Your employer— Health Services Support Agency

The Health Services Support Agency (HSSA) is a commercialised business unit of Queensland Health that delivers a wide range of diagnostic, scientific, technical, logistical and clinical support services that assist our clients to deliver quality, safe and affordable patient and community care.

Working in the HSSA is an opportunity to creatively and productively contribute to improving the provision of health services to the people of Queensland. The HSSA is a learning organisation, committed to developing our people through training, support and leadership programs. We offer challenging opportunities to allow you to explore your potential. The HSSA promotes a healthy balance between your work and personal life, provides flexible work hours, paid parental leave and study leave options.

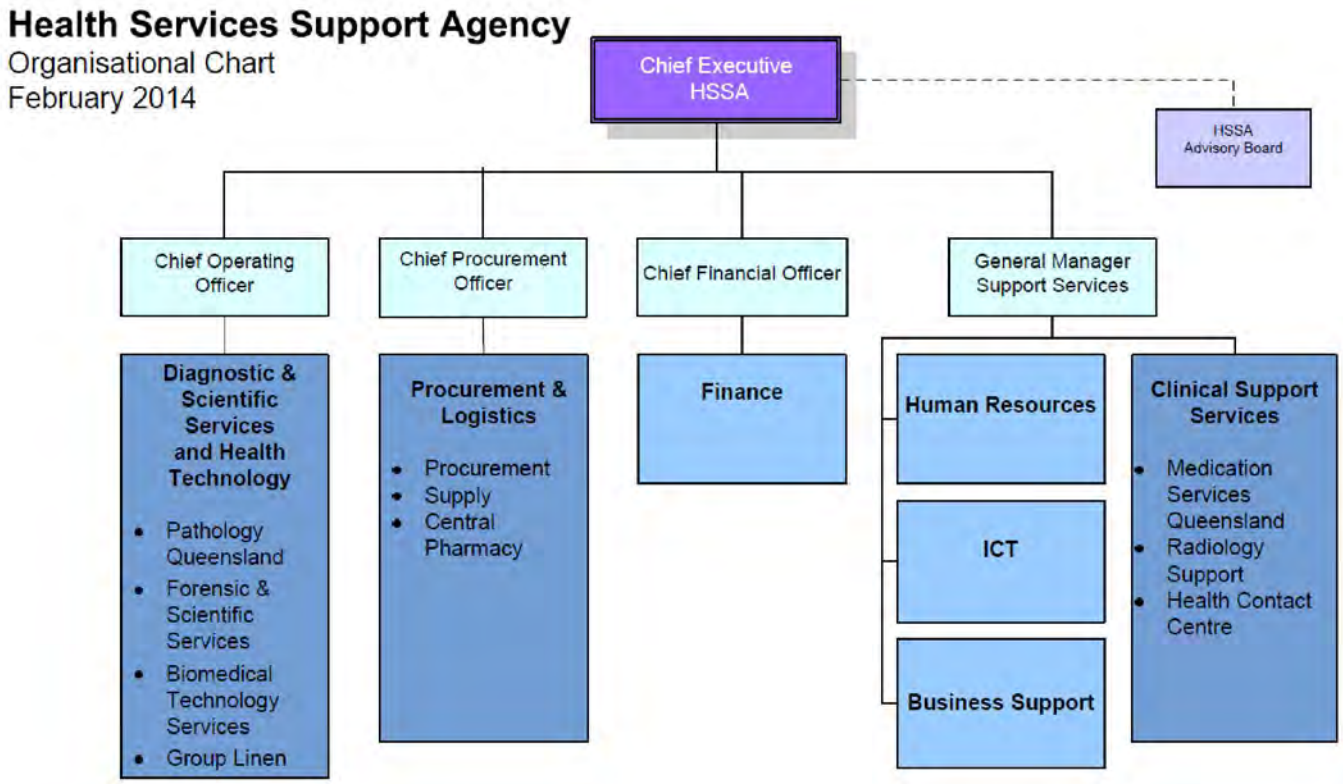
We look forward to working with you!

Visit the website for more information: http://www.health.qld.gov.au/hssa.

Additional information

- Permanent and temporary vacancies longer than 12 months remain current for 12 months OR Temporary vacancies less than 12 months remain current for vacancy duration
- Future vacancies of a temporary, full-time and part-time nature may also be filled through this recruitment process.
- Pre-employment screening, including criminal history and discipline history checks, may be undertaken on persons recommended for employment. Roles providing health, counselling and support services mainly to children will require a blue card, unless otherwise exempt.
- Employees who are permanently appointed to Queensland Health may be required to undertake a period of probation appropriate to the appointment.
- All relevant health professionals, who in the course of their duties formulate a reasonable suspicion that a child or youth has been abused or neglected in their home/community environment, have a legislative and a duty of care obligation to immediately report such concerns to Child safety services, Department of Communities.
- Applicants will be required to give a statement of their employment as a lobbyist (http://www.psc.qld.gov.au/publications/assets/policies/lobbyist-disclosure-policy.pdf) within one month of taking up the appointment.

Organisational Chart



Queensland Government

Clinical and Statewide Services Division
Role Description

Job ad reference:	
Role title:	Team Leader - Forensic Scientists
Status: (Permanent/Temporary) (Full-time/ Part-Time) (Casual)	Permanent Full Time. Please note future vacancies of a temporary, full time and part time nature may also be filled through this recruitment process.
Unit/Branch:	DNA Analysis Unit
Division/District:	Forensic and Scientific Services Clinical and Statewide Services Division
Location:	Coopers Plains
Classification level:	HP6 (CJEU benchmark of generic RD Jedii reference 1717)
Salary level:	
Closing date:	
Contact:	Cathie Allen
Telephone:	[redacted]
Online applications:	www.health.qld.gov.au/workforus or www.smartjobs.qld.gov.au
Fax application:	[redacted]
Post application:	Recruitment Services - Corporate & Statewide, Locked Mail Bag [redacted]
Deliver application:	

About our organisation

Queensland Health's purpose is to provide safe, sustainable, efficient, quality and responsive health services for all Queenslanders. Our behaviour is guided by Queensland Health's commitment to high levels of ethics and integrity and the following **five core values**:

- **Caring for People:** We will show due regard for the contribution and diversity of all staff and treat all patients and consumers, carers and their families with professionalism and respect.
- **Leadership:** We will exercise leadership in the delivery of health services and in the broader health system by communicating vision, aligning strategy with delivering outcomes, taking responsibility, supporting appropriate governance and demonstrating commitment and consideration for people.
- **Partnership:** Working collaboratively and respectfully with other service providers and partners is fundamental to our success.
- **Accountability, efficiency and effectiveness:** We will measure and communicate our performance to the community and governments. We will use this information to inform ways to improve our services and manage public resources effectively, efficiently and economically.
- **Innovation:** We value creativity. We are open to new ideas and different approaches and seek to continually improve our services through our contributions to, and support of, evidence, innovation and research.

Purpose

Provide authoritative advice applying an expert level of knowledge, skills and experience in the area of Forensic Biology and operate as a State-wide reference point for forensic advice and advocacy. To manage the Forensic and Scientific Services, DNA Analysis Unit – to ensure the provision of an integrated, comprehensive, cost effective and quality forensic service in line with the policies, guidelines and strategies of Forensic and Scientific Services.

Your key responsibilities

- Fulfil the responsibilities of this role in accordance with Queensland Health's core values, as outlined above.
- Operationally manage one of the two large teams within the DNA Analysis Unit, QHFSS, including responsibility for facilitating staff development, performance appraisal and other human resource management issues. Ensure that the DNA Analysis Unit meet all relevant legislative, administrative and professional standards to exceed NATA/ISO accreditation/certification requirements and to manage the quality of scientific practice within the multi speciality team.
- Collaborate with other scientific line managers and teams to ensure the role and operations of the DNA Analysis Unit are strategically integrated with those of Clinical and Statewide Services (CaSS) to achieve its service delivery goals and to lead the development of service improvement initiatives to ensure the provision of quality scientific services to clients and stakeholders. Facilitate close and collaborative partnerships with state-wide clients and stakeholders to ensure an effective delivery of client focused scientific services.
- Provide strategic planning and management of the DNA Laboratory, including forecasting of space, staff and equipment needs in the future as the service develops in order to meet the needs of the clients and develop business plans and monitor the implementation of initiatives to ensure achievement of the FSS and CaSS objectives.
- As a state wide recognised forensic expert and DNA Analyst, demonstrate a specialist level of knowledge, skills and experience in the field of Forensic Biology. Duties are performed through the independent application of forensic expertise and the use of established specialised techniques, to facilitate complex, critical discipline specific clinical decisions with minimal supervision. Lead the development of professional forensic standards and scientific practices across the State, by the provision of training delivery to internal and external stakeholders.
- Accountable for providing independent high level forensic services to all key stakeholders incorporating the interpretation of results, the use of information relating to the National Criminal Investigation DNA Database, and the provision of expert testimony on work performed within the laboratory in accordance with legislative requirements. Apply expertise within the discipline of forensic biology discipline to solve large-scale and/or complex scientific service or work-flow problems.
- Professionally lead the delivery of forensic services within one of the DNA Analysis multi-speciality teams, providing expert forensic advice to health practitioners' in order to deliver effective forensic services within a large facility.
- Represent the DNA Analysis Laboratory on relevant and appropriate internal and external committees and forums, including for example, the DNA Innocence Working Party.
- Ensure staff work as part of a cooperative team with effective communication between colleagues and clients internal and external to the laboratory. Utilise high level negotiation and conflict management skills to advocate with stakeholders in securing resources for Forensic and Scientific Services.
- Support the development of scientific knowledge and expertise through representation at both internal and external forums of Forensic and Scientific Services.

Qualifications/Professional registration/Other requirements

- The successful applicant must hold a tertiary qualification, or equivalent, in science from a recognised university or tertiary institution.
- In some circumstances and following consultation, Queensland Health staff may be required to

participate in 24 hour shift, on-call or weekend roster arrangements.

- Appointment to this position requires proof of qualification and if applicable registration or membership with the appropriate registration authority or association. Certified copies of the required information must be provided to the appropriate supervisor/manager, prior to the commencement of clinical duties.

Are you the right person for the job?

You will be assessed on your ability to demonstrate the following key attributes. Within the context of the responsibilities described above, the ideal applicant will be someone who can demonstrate the following:

- Demonstrated extensive expertise in contemporary forensic biology practice, including procedures, techniques, instrumentation and quality assurance with particular reference to forensic DNA analysis, with proven ability to provide authoritative expert advice (including provision of expert testimony) to line management, clients and in court.
- Demonstrated ability to contribute to effective leadership and management of a scientific laboratory in complex service delivery environment.
- Demonstrated commitment to continuous improvement; ability to implement best practice laboratory processes, including automation and robotics; and to lead change management processes in a forensic biology laboratory in line with NATA/ISO accreditation certification requirements.
- Demonstrated interpersonal skills in negotiation, consultation and communication and effectiveness in responding to the needs of the management, clients and staff in an environment of change.
- Demonstrated ability to supervise and manage staff in line with quality human resource management practices with particular reference to employment equity, anti-discrimination, occupational health and safety and ethical behaviour.

How to apply

Please provide the following information to the panel to assess your suitability:

- **Your current CV or resume, including referees**. Applicants must seek approval prior to nominating a person as a referee. Referees should have a thorough knowledge of your work performance and conduct, and it is preferable to include your current/immediate past supervisor. By providing the names and contact details of your referee/s you consent for these people to be contacted by the selection panel. Please note: your referees may be contacted at any time during the recruitment process. If you do not wish for a referee to be contacted, please indicate this on your resume and contact the selection panel chair to discuss.

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- Radiology Support
- Forensic and Scientific Services
- Biomedical Technology Services

- Queensland Blood Management Programme

http://www.health.qld.gov.au/qhcss/

Pre-employment screening

Pre-employment screening, including criminal history and discipline history checks, may be undertaken on persons recommended for employment. The recommended applicant will be required to disclose any serious disciplinary action taken against them in public sector employment.

Roles providing health, counselling and support services mainly to children will require a Blue Card. Please refer to the Information Package for Applicants for details of employment screening and other employment requirements.

Salary Packaging

To confirm your eligibility for the Public Hospital Fringe Benefits Tax (FBT) Exemption Cap please contact the Queensland Health Salary Packaging Bureau Service Provider – RemServ via telephone [redacted] or http://www.remserv.com.au.

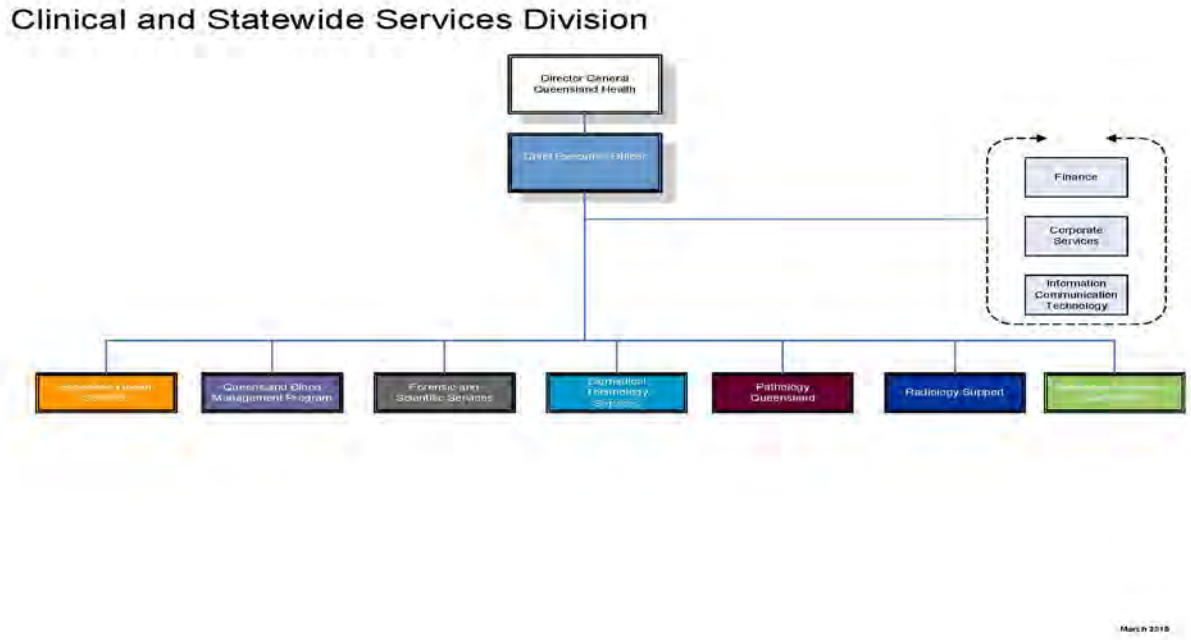
Disclosure of Previous Employment as a Lobbyist

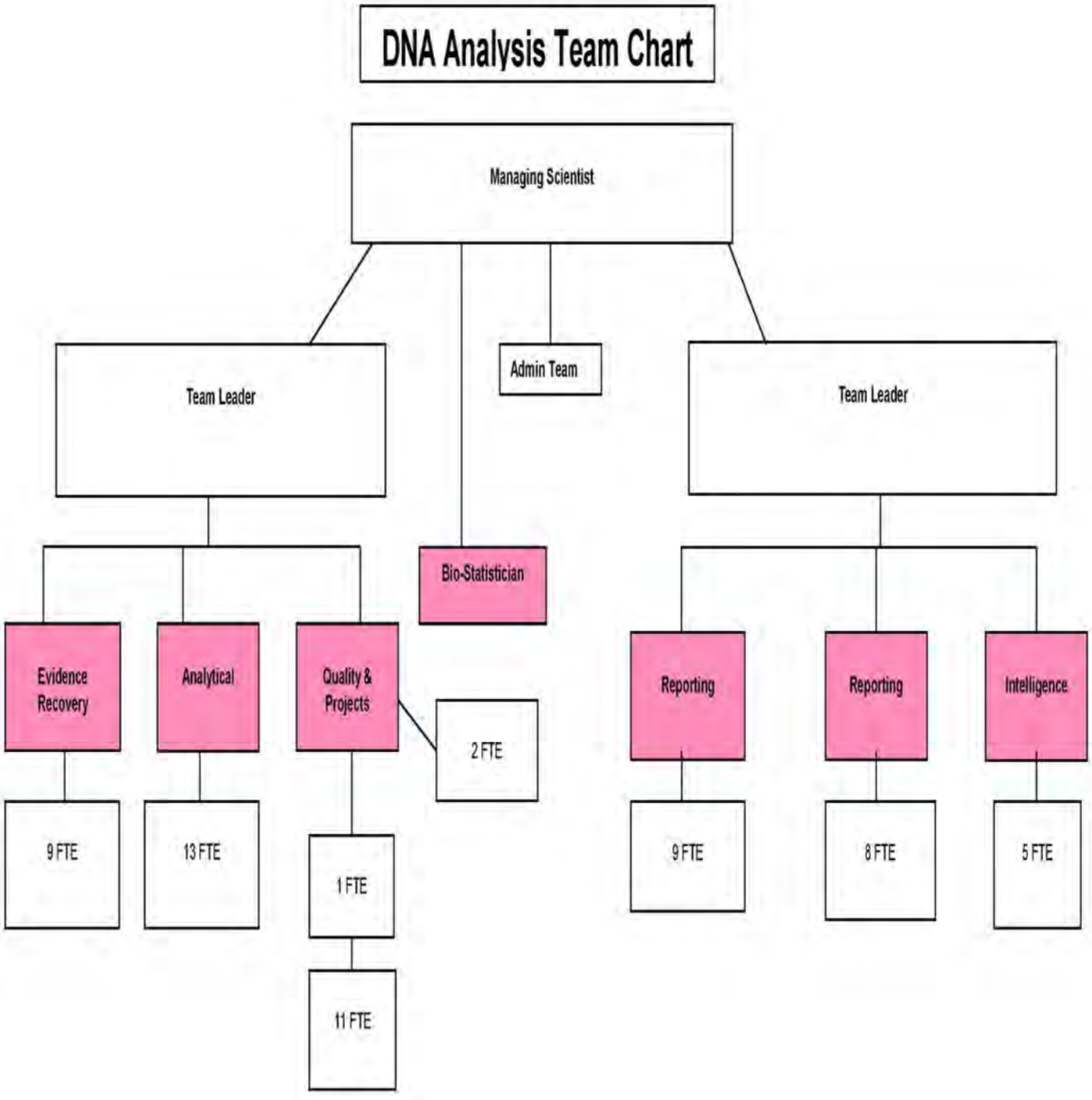
Applicants will be required to give a statement of their employment as a lobbyist within one (1) month of taking up the appointment. Details are available at http://www.psc.qld.gov.au/library/document/policy/lobbyist-disclosure-policy.pdf

Probation

Employees who are permanently appointed to Queensland Health may be required to undertake a period of probation appropriate to the appointment. For further information, refer to Probation HR Policy B2 http://www.health.qld.gov.au/hrpolicies/resourcing/b_2.pdf

Organisational chart




DNA Analysis Team Chart
Managing Scientist
Team Leader
Admin Team
Team Leader
Bio-Statistician
Evidence Recovery
Analytical
Quality & Projects
2 FTE
Reporting
Reporting
Intelligence
9 FTE
13 FTE
1 FTE
11 FTE
9 FTE
8 FTE
5 FTE

Queensland Health
HealthSupport Queensland

Role description

Job ad reference	HSQ353934	**Classification**	AO3
Role title	Administration Officer	**Salary**	$65427 - $73126 per annum plus superannuation and government benefits
Status	Permanent, Full Time	**Closing date**	Wednesday 28th October 2020
Unit/branch	Forensic DNA Analysis, Forensic & Scientific Services		
		Contact name	Wendy Harmer
Location	Coopers Plains	**Contact number**	[redacted]

If you have difficulties applying please contact Health Support Queensland Recruitment on [redacted]

Why work for us?

At Health Support Queensland (HSQ), you will be part of an organisation who helps care for Queenslanders.

We know it is important for people to work in an organisation that provides more than just a job. In joining HSQ, you will embark on a journey to help us realise our vision of being 'Australia's best healthcare support partner'.

Once you join us, we will expect you to exemplify the HSQ fundamental principles of ICARE:

- Integrity—being honest and ethical in everything we say and do.
- Customers and patients first—putting customers and patients at the centre of everything we do.
- Accountability—taking personal responsibility for our actions.
- Respect—being considerate, recognising our differences and looking out for each other.
- Engagement—actively investing in positive outcomes by partnering with others.

Purpose of the role

Provide a professional, confidential and client focussed administrative and secretarial support service within a laboratory environment to the team members and the Team Leaders of Forensic DNA Analysis.

The Administration Officer in Forensic DNA Analysis reports to the Administration Support Officer.

Your key responsibilities will include:

Fulfil the responsibilities of this role in accordance with ICARE and the Queensland Public Service (QPS) values along with the following accountabilities:

- Adhere to defined service quality standards, health and safety policies and procedures relating to the work being undertaken to ensure high quality, safe services and workplaces.
- Maintain accuracy and efficiency through exemplary keyboard and data entry skills utilising contemporary software packages including but not limited to Microsoft Word, Microsoft Excel, Microsoft Power Point.
- High level skills required in the use of laboratory information management systems (Forensic Register, myHR and Quality Information System) including, but not limited to:
    - Input of data to meet accreditation and legislative requirements
    - Management of laboratory documents and upload into QIS2
    - Access appropriate data to provide information for statistical reports.
    - Case Management and tracking and storage of relevant files
    - Generation of data for issuing of invoices
- Provide assistance to laboratory staff through the management and organisation of administrative aspects of Forensic DNA Analysis, including but not limited to:
    - Distribution of laboratory analytical reports to clients through electronic means.
    - Preparation of confidential letters, memos and correspondence.
    - Manage agenda, venue and equipment coordination, minute recording/distribution for meetings on behalf of the Team Leaders.
    - Assist with the preparation of scientific reports as required.
- Establish and maintain an effective office records system (includes file storage and retrieval) and operate computerised databases.
- Work with a high degree of independence on a regular basis whilst utilising discretion in instances where the Administration Support Officer or Team Leaders are absent.
- Provide the first point of client contact for the unit and attend to telephone and reception enquiries from internal and external laboratory clients including monitoring access of visitors / contractors.
- Prioritise workload to ensure that stringent timeframes of the team are satisfied.
- Assist the team with human resource administrative paperwork including collation of timesheets for approval and completion of time and attendance records within myHR.
- Examine incoming correspondence and determine actions and priorities and, where necessary, prepare appropriate replies for consideration and/or dispatch.
- Manage consumable and stationery replacements through S4HANA and office supply vendor.
- Participation in other core administration duties as operationally required.

What are we looking for?

You will be assessed on your ability to demonstrate the following key capabilities, knowledge and experience. Within the context of the responsibilities described under 'your key responsibilities', the ideal applicant will be someone who can demonstrate the following:

- Possession of exemplary keyboard and data entry skills including a comprehensive knowledge of contemporary word processing and data entry systems. Knowledge of and or the ability to rapidly acquire knowledge of laboratory information systems (Forensic Register, myHR and QIS2) relevant to the duties of the position.
- Demonstrated ability to provide high level administrative support to a division or work unit including the ability to work autonomously, utilise discretion in the absence of the Team Leader, meet deadlines and establish work priorities whilst maintaining strict confidentiality of information.
- Demonstrated high level communication and interpersonal skills to effectively liaise with a broad range of clients and the ability to accurately prepare routine and complex correspondence.

- Ability to actively participate in a laboratory working environment supporting quality human resource management practices including employment equity, anti-discrimination, occupational health and safety and ethical behaviour.

Mandatory qualifications, professional registrations or other requirements

- Provision of a DNA sample will be required for use on the staff DNA elimination database to comply with accreditation requirements.
- In some circumstances and following consultation, Department of Health staff may be required to participate in 24 hour shift, on-call or weekend roster arrangements.

Vaccine Preventable Diseases (VPD) requirements

- It is a condition of employment for this role for the employee to be, and remain, vaccinated against the following vaccine preventable diseases during their employment: Hepatitis A & B, Measles, Mumps, Pertussis, Rubella and Varicella.
- Additional vaccinations including Japanese Encephalitis and Rabies may also be required for this position.
- Existing staff that are engaged prior to 1 July 2016 are not subject to this condition of employment unless they apply for a role with VPD requirements that is with a different Queensland Health entity (i.e. a Hospital and Health Service (HHS) to HSQ).

What is on offer?

- Up to 12.75% employer superannuation contribution
- Annual leave loading 17.5%
- Employee Assistance Program
- Work/life balance, variety and flexibility
- Salary packaging

How to apply

Please provide the following information to the panel to assess your suitability:

- **Your current CV or resume,** including the names and contact details of two referees. Referees should have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current, immediate or past supervisor
- **A short statement (Max 2 pages)** that gives details of your skills, experience and knowledge as required on the role description under the heading 'what are we looking for?'
-

About Health Support Queensland

HSQ is an organisational Division of the Department of Health and delivers a range of support services to enable the delivery of frontline health services. HSQ provides services to all Queensland Hospital and Health Services (HHSs), to other government agencies and to commercial clients. The current services

provided by HSQ include: pathology services, procurement and logistics for health-related equipment, products and services, biomedical technology services, forensic and scientific services, linen and laundry services, medicines management, 13 HEALTH, radiology support and payroll.

Forensic and Scientific Services

Forensic and Scientific Services (FSS) is a hub of co-located laboratories at Coopers Plains in Brisbane. We are ready to respond to civil emergencies, crime and potential threats to our health, environment and our economy with tailor-made, smart scientific solutions.

Our scientists offer highly specialised analytical services and expert advice in the complex fields of Public Health Science and Forensic Science. Scientifically diverse, our organisation has cutting edge capabilities in:

- chemical analysis
- environmental health
- health physics
- communicable diseases (microbiology)
- forensic pathology
- DNA analysis, and
- forensic medicine

Police Services Stream

This stream encompasses both the Forensic DNA Analysis work unit and Forensic Chemistry work unit. Forensic DNA Analysis provides analytical and advisory services principally to the Queensland Police Service in the areas of evidence examination, DNA analysis and result interpretation culminating in expert advice and evidence.

We look forward to working with you!

Visit the website for more information: http://www.health.qld.gov.au/qhcss/default.asp

Vision for the public service

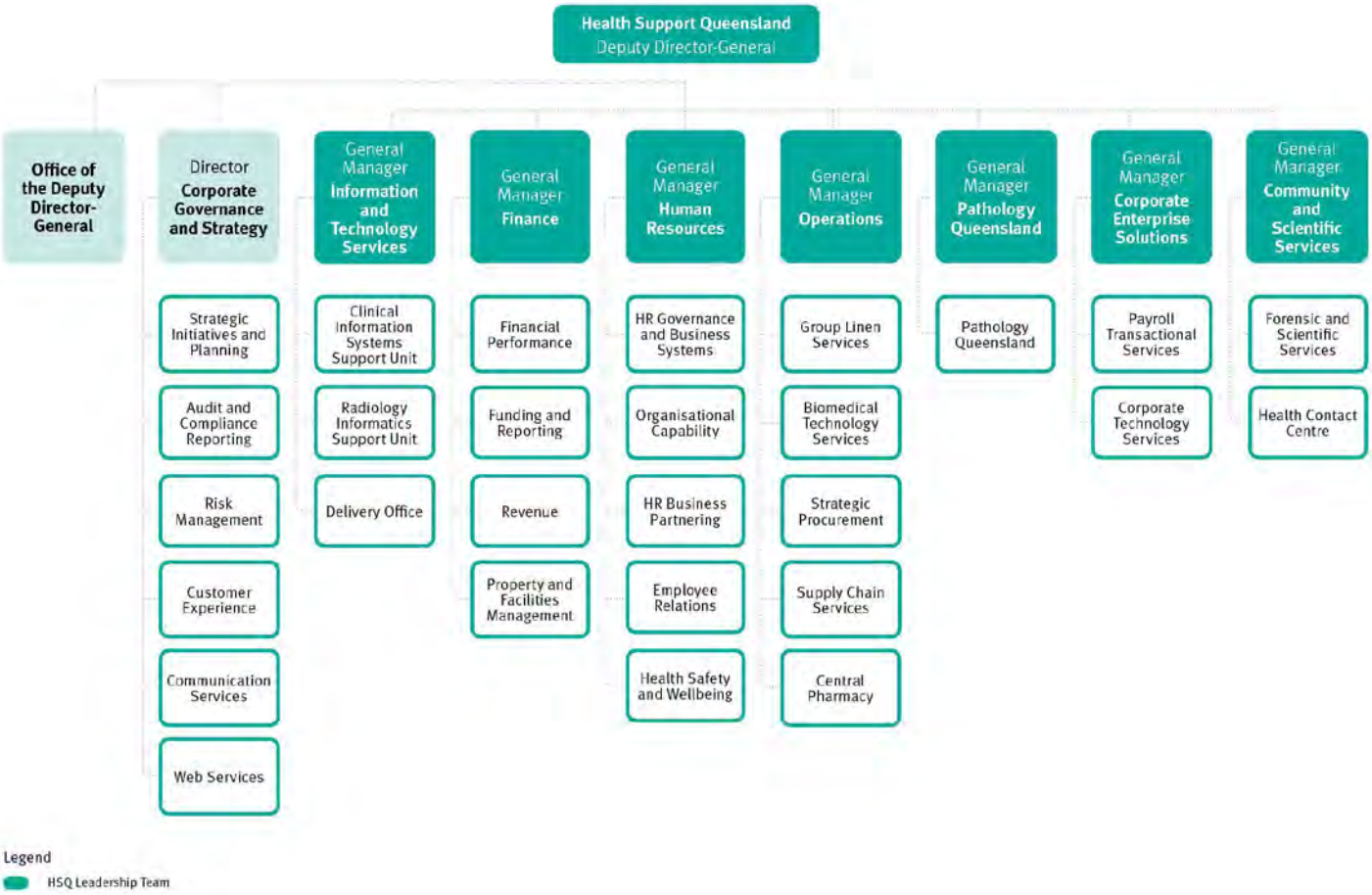
To be a government of the 21st century, one government that is connected and working together to deliver smarter, simpler outcomes that are responsive to the needs of Queenslanders now and for the future. We will create opportunities in partnership that are all about positive outcomes rather than just service delivery and regulation.

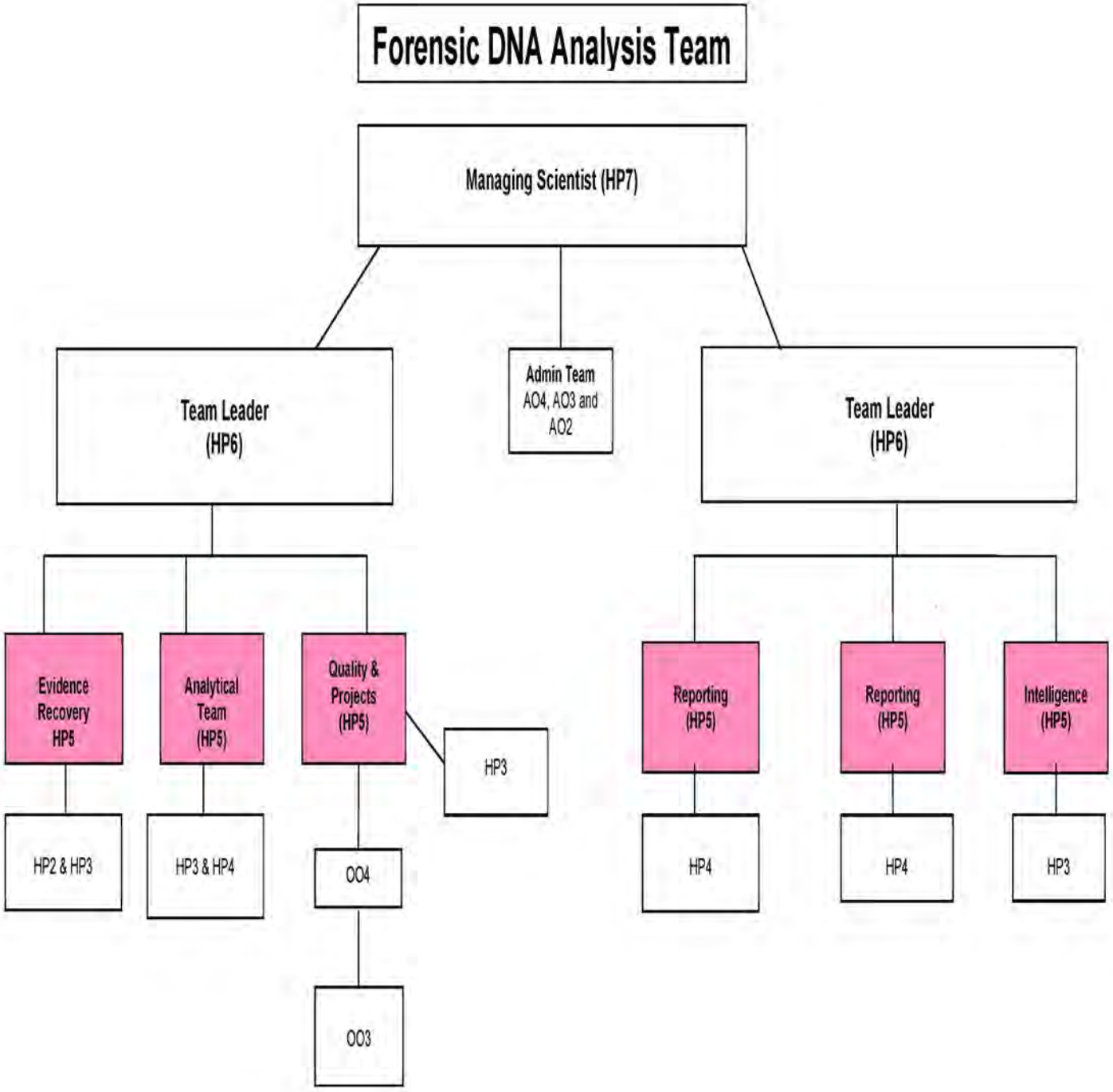
To enable this vision, the Queensland Public Sector is transforming from a focus on compliance to a values-led way of working. The following five QPS values, underpin behaviours that will support and enable better ways of working and result in better outcomes for Queenslanders.





Customers first	Ideas into action	Unleash potential	Be courageous	Empower people
Know your customers	Challenge the norm and suggest solutions	Expect greatness	Own your actions, successes and mistakes	Lead, empower and trust
Deliver what matters	Encourage and embrace new ideas	Lead and set clear expectations	Take calculated risks	Play to everyone's strengths
Make decisions with empathy	Work across boundaries	Seek, provide and act on feedback	Act with transparency	Develop yourself and those around you


Health Support Queensland
Deputy Director-General
Office of the Deputy Director-General
Director Corporate Governance and Strategy
General Manager Information and Technology Services
General Manager Finance
General Manager Human Resources
General Manager Operations
General Manager Pathology Queensland
General Manager Corporate Enterprise Solutions
General Manager Community and Scientific Services
Strategic Initiatives and Planning
Audit and Compliance Reporting
Risk Management
Customer Experience
Communication Services
Web Services
Clinical Information Systems Support Unit
Radiology Informatics Support Unit
Delivery Office
Financial Performance
Funding and Reporting
Revenue
Property and Facilities Management
HR Governance and Business Systems
Organisational Capability
HR Business Partnering
Employee Relations
Health Safety and Wellbeing
Group Linen Services
Biomedical Technology Services
Strategic Procurement
Supply Chain Services
Central Pharmacy
Pathology Queensland
Payroll Transactional Services
Corporate Technology Services
Forensic and Scientific Services
Health Contact Centre
Legend
HSQ Leadership Team


Forensic DNA Analysis Team
Managing Scientist (HP7)
Team Leader (HP6)
Admin Team AO4, AO3 and AO2
Team Leader (HP6)
Evidence Recovery HP5
Analytical Team (HP5)
Quality & Projects (HP5)
HP3
Reporting (HP5)
Reporting (HP5)
Intelligence (HP5)
HP2 & HP3
HP3 & HP4
OO4
HP4
HP4
HP3
OO3

Additional information for applicants

- For details regarding salary information, leave entitlements, flexible working arrangements and other benefits, visit the Queensland Health website.
- All relevant health professionals (including registered nurses and medical officers) who in the course of their duties formulate a reasonable suspicion that a child or youth has been abused or neglected in their home or community environment, have a legislative and a duty of care obligation to immediately report such concerns to Child Safety Services, Department of Communities.
- Pre-employment screening, including criminal history and disciplinary history checks, may be undertaken on persons recommended for employment. Roles providing health, counselling and support services mainly to children will require a Blue Card.
- Employees who are permanently appointed to HSQ may be required to undertake a period of probation appropriate to the appointment.
- Applicants will be required to give a statement of their employment as a lobbyist within one month of taking up the appointment. Details are available at the Public Service Commission Lobbyist Disclosure Policy
- Applicants may be required to disclose any pre-existing illness or injury, which may impact on their ability to perform the role. Details are available in *Section 571 of the Workers' Compensation and Rehabilitation Act 2003*.
- Hepatitis B vaccination or proof that you are not susceptible to hepatitis B is a condition of employment for all staff that will have direct contact with patients of who during their work may be exposed to bodily fluids or blood, or contaminated sharps.
- Roles that interact face-to-face with patients, or the work location is in a clinical area (i.e. a ward, emergency department or outpatient clinic), or frequently or regularly requires attendance in clinical areas, require evidence of vaccination or proof that you are not susceptible to these vaccine preventable diseases:
    - measles, mumps, rubella (MMR)
    - varicella (chicken pox)
    - pertussis (whooping cough)
    - hepatitis B
- Additional vaccinations including Japanese Encephalitis and Rabies may also be required.

NOTE that subsequent evidence must be provided of future vaccination in respect of pertussis (whooping cough) as recommended in *The Australian Immunisation Handbook*.

- Travel may be a requirement.
- Applications will remain current for 12 months and may be considered for other vacancies which may include an alternative employment basis (temporary, full time, part time).

Queensland Health

Role description

Job ad reference:	HSQ420091	**Unit/branch:**	Forensic DNA Analysis Forensic and Scientific Services
Role title:	Analytical Senior Scientist	**Location:**	Coopers Plains
Status:	Permanent Full Time	**Closing date:**	Friday, 27th May 2022
Classification:	HP4	**Contact name:**	Luke Ryan
Salary range:	$115 049 - $123 799 per annum plus superannuation	**Phone:**	[redacted]

Department of Health

The Department of Health has a diverse set of responsibilities, and a common purpose of creating better health care for Queenslanders. The department is responsible for the overall management of the public health system in Queensland. We strongly believe in the need to work with people that value the goals of our organisation and who will thrive in our workplace.

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Our scientists offer highly specialised analytical services and expert advice in the complex fields of Public Health Science and Forensic Science. Scientifically diverse, our organisation has cutting-edge capabilities in:

- Chemical analysis;
- Environmental health
- Health physics;
- Communicable diseases (microbiology);
- Forensic Pathology;
- Forensic Chemistry
- Forensic DNA Analysis, and
- Forensic medicine

Police Services Stream

This stream encompasses both the Forensic DNA Analysis work unit and Forensic Chemistry work unit. Forensic DNA Analysis provides analytical and advisory services principally to the Queensland Police Service in the areas of evidence examination, DNA analysis and result interpretation culminating in expert advice and evidence.

We look forward to working with you!

Visit the website for more information: http://www.health.qld.gov.au/qhcss/default.asp

Purpose of the role

- To deliver a state wide forensic biological and DNA service including the provision of expert opinion and testimony.
- To actively participate in delivering significant scientific and service delivery improvements.
- To supervise and coordinate scientific judgement in the analysis of forensic specimens and samples in the Forensic DNA Analysis Laboratory leading to the provision of test results and advice to clients and stakeholders where appropriate.
- To ensure that all laboratory practices comply with Forensic & Scientific Services requirements in providing an effective and efficient service.

The Analytical Senior Scientist in Forensic DNA Analysis reports to the Analytical Forensic Scientist - Advanced, Forensic DNA Analysis.

Your key responsibilities

You will be required to fulfil the responsibilities of this role in accordance with the Queensland Public Service values.

- Demonstrates expertise, knowledge and skills to engage in research and validation projects with minimal supervision, using evidence-based practice to make critical decisions to assess novel methodologies or facilitate the initiating, planning, evaluating and implementation of complex innovative technologies at a state-wide level.
- Demonstrates and applies well developed scientific judgement in the analysis of forensic specimens and samples and the provision of advice within Forensic DNA Analysis, Forensic and Scientific Services and to key stakeholders state-wide.
- Undertakes and supervises forensic testing and related duties following well established accredited forensic protocols and standards within Forensic DNA Analysis in accordance with prescribed professional and ethical standards and supervise the development of scientific practices, procedures and protocols within the Forensic DNA Analysis work area.
- Responsible for monitoring and reporting clinical work practices and outcomes within Forensic DNA Analysis and initiating, planning and evaluating scientific and service delivery improvement activities.
- Responsible for providing expert technical advice within the specific area of expertise to relevant stakeholders regarding standards and clinical services of a complex nature
- Provide general clinical and technical advice to professional and operational supervisors and relevant service managers regarding service delivery, equipment, technology and the prioritisation and development of clinical services.
- Ensure the development of scientific knowledge and expertise by supporting active learning and professional development of Forensic DNA Analysis staff.
- Provide clinical practice supervision to HP3 level assistants and clinical support staff, to ensure the maintenance of professional clinical standards.
- Adhere to defined service quality standards, health and safety policies and procedures relating to the work being undertaken to ensure high quality, safe services and workplaces.
- Ensure work practices align with Queensland Health Records Management Policy, Standards and Procedures.

- Ensure that Forensic DNA Analysis complies with all relevant legislative, administrative and professional standards to meet NATA/ISO accreditation/certification requirements.
- Utilises and applies a high level of interpersonal skills, ensuring the team works cooperatively and with effective communication within Forensic DNA Analysis.

Key competencies (role specific criteria)

You will be assessed on your ability to demonstrate the following:

- Demonstrated ability to perform and to train others in a range of relevant forensic procedures, techniques, instrumentation and quality assurance systems including the use of computer systems.
- Demonstrated ability to solve scientific problems and apply scientific rationale in the analysis and interpretation of forensic samples, without supervision.
- Demonstrated interpersonal skills for working in a team, both as a member and a leader, with demonstrated ability to communicate effectively with staff and clients.
- Demonstrated ability to actively participate in the process of change and continuous improvement, including participation in and management of projects.
- Demonstrated high level of ability to consult and communicate scientific/technical information, both orally and in writing, including the potential presentation of expert testimony in a court of law.
- Ability to supervise and manage staff in line with quality human resource management practices to ensure the maintenance of professional and ethical standards.
- Demonstrated commitment to the principles of quality management, continuous quality improvement and a contemporary knowledge of NATA/ISO accreditation/certification.

Qualifications, registrations and other requirements

- The successful applicant must hold a tertiary qualification, with a Bachelor Degree as a minimum, or equivalent, in science from a recognised university or tertiary institution.
- Appointment to this position requires proof of qualification. Certified copies of the required information must be provided to the appropriate supervisor/ manager, prior to commencement of duties.
- Provision of a DNA sample is required for inclusion on a staff elimination database to comply with accreditation requirements.
- Please detail any visa conditions you may have if you are not a permanent resident of Australia.
- We understand that some people may require adjustments to the workplace or the way the work is performed. All applicants are encouraged to advise the panel of any support or reasonable adjustments (i.e. building access, wheelchair access, interpreting services etc.) that may be required.

Vaccine Preventable Diseases (VPD) requirements

- It will be a condition of employment for this role for the employee to be, and remain, vaccinated against one or more of the following vaccine preventable diseases during their employment (Health Employment Directive No. 01/16): measles, mumps, rubella (MMR),varicella (chicken pox),pertussis (whooping cough),hepatitis B, tuberculosis
- Additional vaccinations including Japanese Encephalitis and Rabies may also be required for this position.
- Existing staff that are engaged prior to 1 July 2016 are not subject to this condition of employment unless they apply for a role with VPD requirements that is with a different Queensland Health entity (i.e. one HHS to another HHS, department to a HHS, or HHS to department).
- It may be a condition of employment for this role for the employee to be, and remain, vaccinated against COVID-19 (Health Employment Directive No. 12/21 and Queensland Health Human Resources Policy B70.)

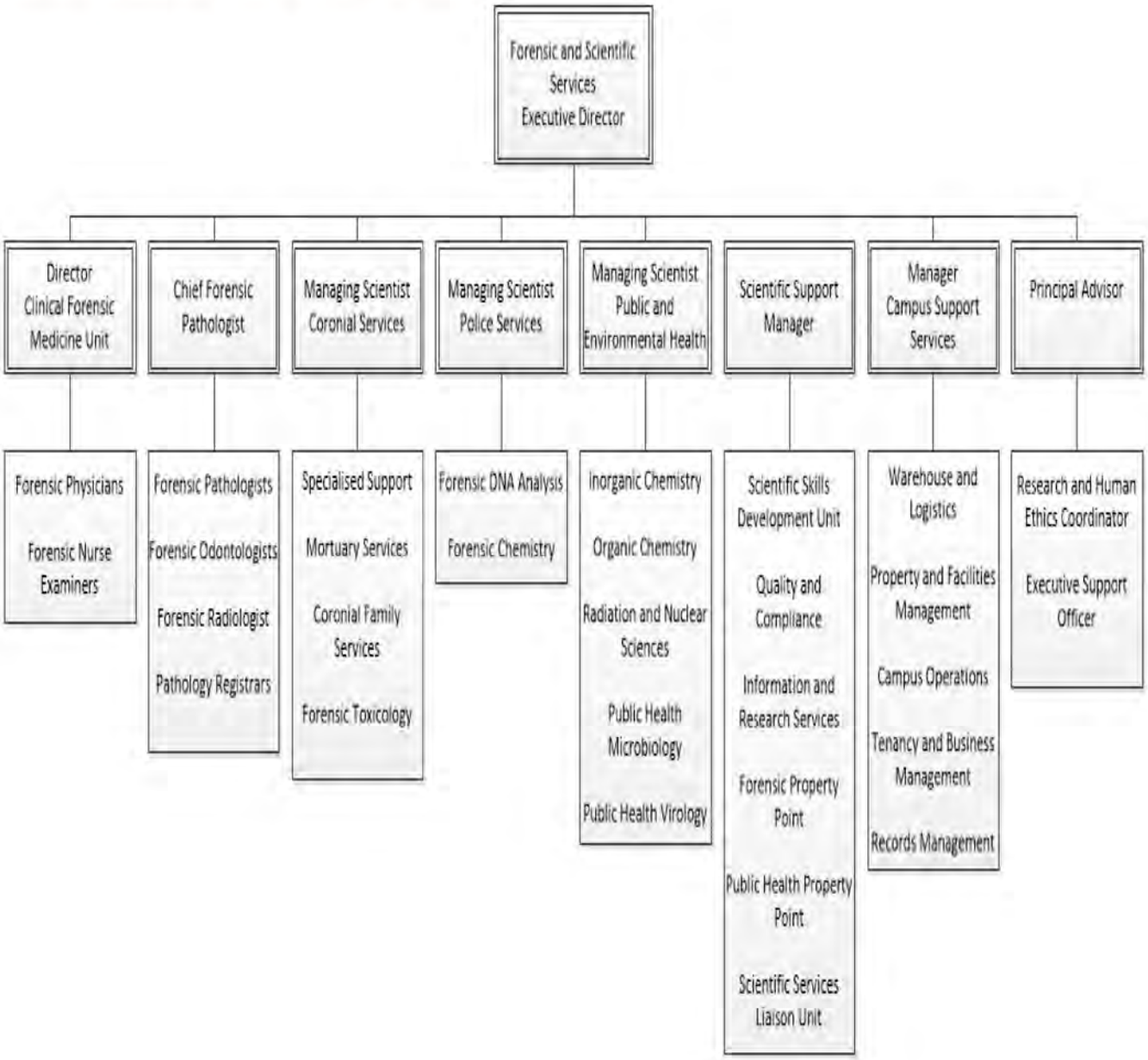
Additional Information

Please provide the following information to the panel to assess your suitability:

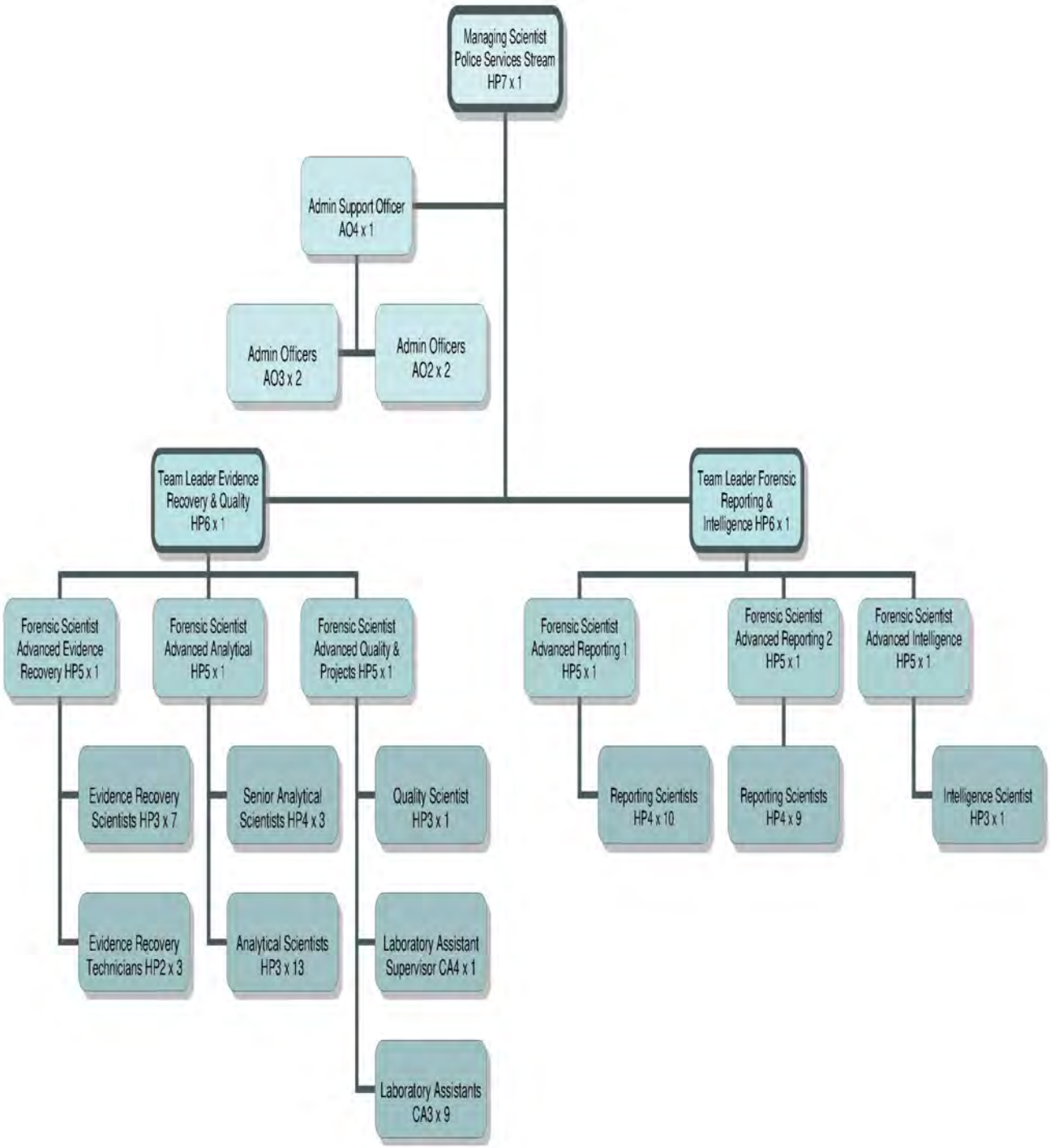
- Your **resume**, including the names and contact details of two referees who have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current, immediate or past supervisor.
- A **short statement (maximum two pages)** that gives details of your skills, experience and knowledge as required on the role description under the heading 'key competencies (role specific criteria)'.

Discover more about our work, our people and employment opportunities at Queensland Health.

Forensic and Scientific Services Organisational Chart



Forensic DNA Analysis Team Chart



Queensland Health

Role description

Job ad reference:	HSQ430432	**Unit/branch:**	Forensic DNA Analysis, Forensic and Scientific Services
Role title:	Forensic Scientist	**Location:**	Coopers Plains
Status:	Permanent Full-time	**Closing date:**	Thursday, 21st July 2022
Classification:	HP3	**Contact name:**	Allison Lloyd
Salary range:	$70 958 - $104 295 per annum plus superannuation	**Phone:**	[redacted]

Department of Health

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Customers First


Ideas into action


Unleash potential


Be courageous


Empower people

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- Chemical analysis;
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- Health physics;
- Communicable diseases (microbiology);
- Forensic Pathology;
- Forensic Chemistry
- Forensic DNA Analysis, and
- Forensic medicine

Police Services Stream

This stream encompasses both the Forensic DNA Analysis work unit and Forensic Chemistry work unit. Forensic DNA Analysis provides analytical and advisory services principally to the Queensland Police Service in the areas of evidence examination, DNA analysis and result interpretation culminating in expert advice and evidence.

We look forward to working with you!

Visit the website for more information: http://www.health.qld.gov.au/qhcss/default.asp

Purpose of the role

- Deliver a state wide forensic biology and DNA service
- Apply independent scientific judgement in the analysis of forensic specimens and samples in the Forensic DNA Analysis laboratory, leading to the provision of test results and advice to clients and stakeholders where appropriate
- Apply standard operating procedures to the testing of forensic specimens and samples in the Forensic DNA Analysis laboratory.
- To ensure that all laboratory practices comply with Forensic & Scientific Services requirements in providing an effective and efficient service.
- To comply with NATA/ISO accreditation/certification requirements including performing quality control procedures.
- The HP3 Forensic Scientist in the Forensic DNA Analysis Team reports to the HP5 Senior Scientist of the respective team.

Your key responsibilities

You will be required to fulfil the responsibilities of this role in accordance with the Queensland Public Service values.

- Adhere to defined service quality standards, health and safety policies and procedures relating to the work being undertaken to ensure high quality, safe services and workplaces.
- Provide professional level analytical services in relation to forensic DNA Analysis and interpretation for Queensland Health Forensic and Scientific Services commensurate with level of analytical experience.
- Undertake forensic DNA testing and related duties using well established accredited protocols, standards and instrumentation within a multi-speciality team in accordance with prescribed professional and ethical standards, with level of supervision decreasing and professional accountability increasing commensurate with level of analytical experience.
- Commensurate with level of experience in role, provide training and education and clinical practice supervision for less experienced practitioners with the guidance of senior staff; assist in the development of forensic and scientific practices, procedures and protocols within the Forensic DNA Analysis work area and participate in quality and service improvement activities.
- Responsible for providing the results of forensic DNA analysis and interpretation to senior staff and key stakeholders, including information relating to the National Criminal Investigation DNA Database and the provision of expert testimony in court on work performed if required.
- Actively participate in the activities of the multi-speciality team, including participating in the introduction of new technologies or processes in the work area.
- Develop scientific knowledge and expertise through active learning within the team and by engaging in professional development activities.
- Work cooperatively and communicate effectively within the Forensic DNA Analysis team and with clients and stakeholders, both internal and external to the laboratory. Provide test results and advice on matters pertaining to complex technical matters for less senior staff members, clients and key stakeholders.

- Participate in the process of quality and service improvement activities in accordance with NATA/ISO accreditation/certification that enhance the delivery of Forensic DNA Analysis services provided to clients and key stakeholders.
- Actively participate in the activities of the multi-speciality team, including participating in the introduction of new technologies or processes in the work area.
- Provide direction to assistant and support staff, including operational and administrative staff.
- Comply with and utilise procedures, policies, regulations and standards which impact upon the position in line with contemporary human resources management requirements and practices, such as workplace health and safety, equal employment opportunity, anti-discrimination and ethical behaviour.

  Utilises and applies a high level of interpersonal skills, ensuring the team works cooperatively and with effective communication within DNA Analysis

Key competencies (role specific criteria)

You will be assessed on your ability to demonstrate the following:

- Demonstrated abilities in a range of relevant procedures, techniques, instrumentation and quality assurance systems including the use of computer systems and laboratory information management systems.
- Demonstrated ability to work within a multi-speciality team, and without direct supervision, to produce an effective work output. Proven ability to solve complex scientific and technical problems by selecting and applying standard procedures.
- Well-developed interpersonal skills, with the ability to communicate effectively by written or verbal means with staff and clients and present expert testimony in a court of law.
- Demonstrated ability to develop collaborative working relationships with key stakeholders and team members and ability to effectively communicate and influence staff.
- Demonstrated commitment to the principles of quality management and continuous quality improvement. Knowledge of the basis of laboratory Quality Control and Quality Assurance programs and ability to apply such knowledge.
- Ability to actively participate in the processes of change and continuous improvement
- Ability to actively and successfully participate in a working environment supporting quality human resource management practices including employment equity, anti-discrimination, occupational health and safety and ethical behaviour

Qualifications, registrations and other requirements

- The successful applicant must hold a tertiary qualification, or equivalent, in science from a recognised university or tertiary institution.
- Provision of a DNA sample will be required for use on the staff DNA elimination database to comply with accreditation requirements.
- In some circumstances and following consultation, Department of Health staff may be required to participate in 24-hour shift, on-call or weekend roster arrangements.
- Please detail any visa conditions you may have if you are not a permanent resident of Australia.
- We understand that some people may require adjustments to the workplace or the way the work is performed. All applicants are encouraged to advise the panel of any support or reasonable adjustments (i.e. building access, wheelchair access, interpreting services etc.) that may be required.

Vaccine Preventable Diseases (VPD) requirements

- It may be a condition of employment for this role for the employee to be, and remain, vaccinated against COVID-19 (Health Employment Directive No. 12/21 and Queensland Health Human Resources Policy B70.)
- It will be a condition of employment for this role for the employee to be, and remain, vaccinated against one or more of the following vaccine preventable diseases during their employment: Hepatitis A & B, Measles, Mumps, Pertussis, Rubella and Varicella.
- Additional vaccinations including Japanese Encephalitis and Rabies may also be required for this position.
- Existing staff that are engaged prior to 1 July 2016 are not subject to this condition of employment unless they apply for a role with VPD requirements that is with a different Queensland Health entity (i.e. one HHS to another HHS, department to a HHS, or HHS to department).

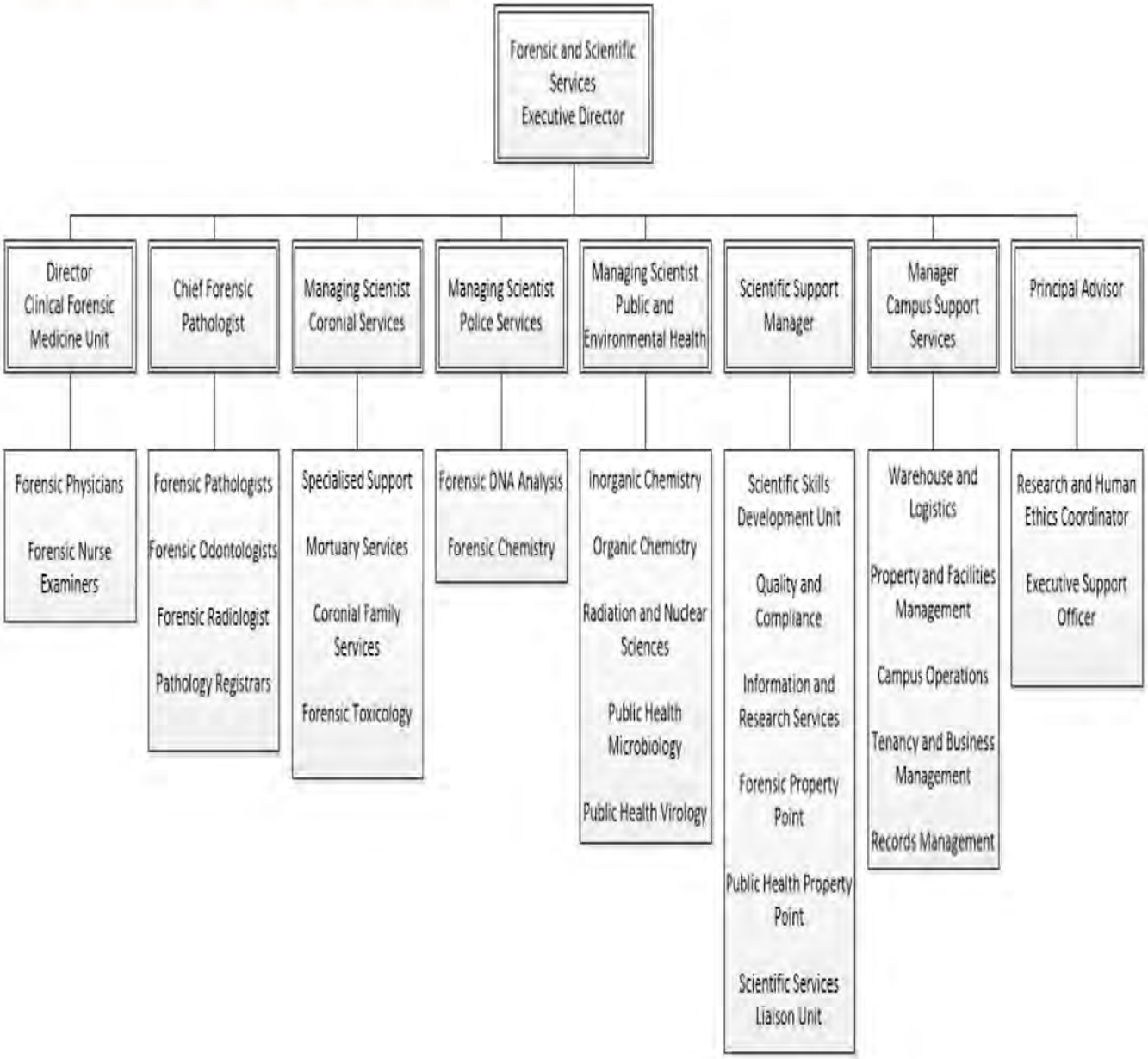
Additional Information

Please provide the following information to the panel to assess your suitability:

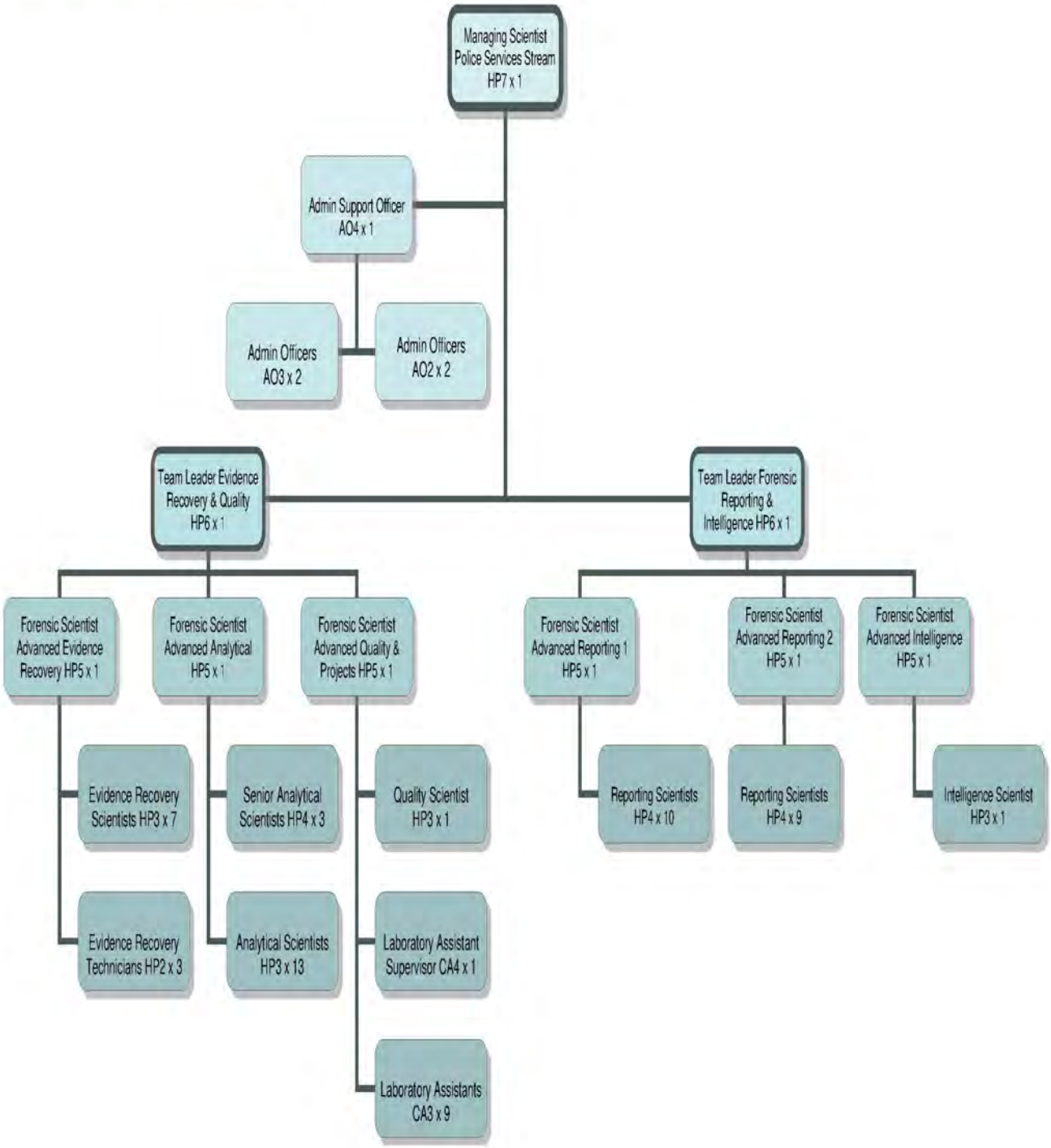
- Your **resume**, including the names and contact details of two referees who have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current, immediate or past supervisor.
- A **short statement (maximum two pages)** that gives details of your skills, experience and knowledge as required on the role description under the heading 'key competencies (role specific criteria)'.

Discover more about our work, our people and employment opportunities at Queensland Health.

Forensic and Scientific Services Organisational Chart



Forensic DNA Analysis Team Chart



Queensland Health
Forensic and Scientific Services

Managing Scientist - Police Services Stream Duty Statement

1 Purpose

The purpose of this duty statement is to describe the role of the Managing Scientist with Police Services Stream, Forensic and Scientific Services Leadership Team.

2 Scope

This duty statement shall apply to Police Services Stream.

3 Definitions

Nil

4 Actions

The Managing Scientist - Police Services Stream is responsible for providing leadership, management and innovation in Forensic Chemistry and Forensic DNA Analysis, including the implementation of strategic and operational planning, monitoring, evaluating, and reporting systems.

The role is accountable for establishing and maintaining effective working relationships with all relevant government and non-government agencies to provide a quality, client focused Forensic Chemistry and Forensic DNA Analysis service. This role actively pursues quality, innovation, integration, and standardisation in efficient service delivery whilst promoting the values and interests of FSS.

The Managing Scientist - Police Services Stream leads and inspires a multidisciplinary team, establishes management and reporting systems, provides strategic advice on a state, national and international level, manages key relationships, ensures compliance to international standards, and provides ethical decision making in the achievement of organisational goals.

Strategic Direction:

- Provide high level leadership and strategic management across a large forensic DNA Analysis service and a forensic Chemistry service, both of which provide a State-wide service.
- Contribute to strategic level management processes, applying high level clinical knowledge to challenge existing protocols and advocating authoritatively for the forensic DNA Analysis and forensic chemistry services on a State-wide basis in the development of new policy.

- Participate and advocate for the forensic DNA analysis and forensic chemistry services in setting State-wide and National standards of performance, safety, and inter-departmental coordination.
- Participate in establishing broad criteria for the development of professional standards, education or research in the forensic DNA analysis and forensic chemistry services on a State-wide and National basis through membership on national advisory bodies.

Leadership / Work Unit Management

- Accountable for all aspects of operational management and development of people and facilities within Forensic DNA Analysis and Forensic Chemistry, including;
- Developing and implementing strategic direction
- Facilitating staff development, performance appraisal and other general people management issues
- Accountable for the administration, direction and control of the asset management and financial management of multiple cost centres.
- Responsible for solving large scale complex forensic service or work-flow problems through recognised expertise, high level interpretation of existing forensic service delivery systems, professional standards and other pertinent external considerations.

Communication / Team Participation

- Provide authoritative counsel to advise and inform strategic level management processes across forensic services operating within a State-wide service.
- Accountable for the effects of all policy generated from within the position's jurisdiction and provide associated professional counsel to relevant stakeholders.
- Utilise high level negotiation and conflict management skills to advocate with stakeholders in securing resources or other outcomes for Forensic DNA Analysis and Forensic Chemistry, Forensic and Scientific Services.

5 Records

Nil

6 Associated Documentation

Nil

7 References

Nil

8 Amendment History

Revision	Date	Author/s	Amendments
1	17 Oct 2006	R Smith	First Issue
2	14 Nov 2007	T Nurthen	No Information
3	9 December 2008	J Howes	No Information

4	5 Aug 2013	C Allen	Changed from CaSS to HSSA, moved document to Managing Scientist for update responsibility
5	6 Jan 2015	C Allen	Updated with new HSQ template and added responsibilities associated with Forensic Chemistry
6	18 Jan 2021	C Allen	Updated with new template.
7	28 Feb 2022	C Allen	Updated with new template, added more description into Section 4 to be consistent with the FSS Governance document (20033).

9 Appendices

Nil

Queensland Government

Health Services Support Agency
Forensic and Scientific Services

Queensland Health www.health.qld.gov.au/workforus

Job ad reference:	
Role title:	Operational Staff Supervisor
Status: (Permanent/Temporary) (Full-time/ Part-Time) (Casual)	Permanent Full-Time. Please note future vacancies of a temporary, full time and part time nature may also be filled through this recruitment process.
Unit/Branch:	DNA Analysis
Division/Hospital and Health Service:	Department of Health Forensic and Scientific Services Health Services Support Agency
Location:	[redacted]
Classification level:	OO4
Salary level:	
Closing date:	
Contact:	Thomas Nurthen
Telephone:	[redacted]
Online applications:	www.health.qld.gov.au/workforus or www.smartjobs.qld.gov.au
Fax application:	
Post application:	
Deliver application:	

About our organisation

Queensland Health's purpose is to provide safe, sustainable, efficient, quality and responsive health services for all Queenslanders. Our behaviour is guided by Queensland Health's commitment to high levels of ethics and integrity and the following **five core values**:

- **Caring for People:** We will show due regard for the contribution and diversity of all staff and treat all patients and consumers, carers and their families with professionalism and respect.
- **Leadership:** We will exercise leadership in the delivery of health services and in the broader health system by communicating vision, aligning strategy with delivering outcomes, taking responsibility, supporting appropriate governance and demonstrating commitment and consideration for people.
- **Partnership:** Working collaboratively and respectfully with other service providers and partners is fundamental to our success.
- **Accountability, efficiency and effectiveness:** We will measure and communicate our performance to the community and governments. We will use this information to inform ways to improve our services and manage public resources effectively, efficiently and economically.
- **Innovation:** We value creativity. We are open to new ideas and different approaches and seek to continually improve our services through our contributions to, and support of, evidence, innovation and research.

Purpose

- To facilitate effective service delivery of DNA Analysis samples to external clients.
- To co-ordinate the performance of routine tasks, assist where necessary, under the direction and supervision of a Health Practitioner.

Your key responsibilities

- Fulfil the responsibilities of this role in accordance with Department of Health's core values, as outlined above.
- Ensure work practices align with Queensland Health Records Management Policy, Standards and Procedures.
- The Operational Staff Supervisor reports to the Senior Scientist – Quality and Project, within DNA Analysis and as such has line management responsibility for the staff within the Laboratory Assistant team.
- Manage the roster of Laboratory Assistants
- Chair the Laboratory Assistants meeting, including the maintenance of accurate minutes
- Monitor Key Performance Indicators and report to Supervising Scientist weekly
- Monitor the Logs such as the Issues Log used by scientific staff to communicate issues with samples
- Allocate tasks and reassign, where necessary, Laboratory Assistants to ensure critical work is completed
- Act as the liaison between scientific staff and Laboratory Assistants
- Assist with the production and review of Standard Operating Procedures
- Liaise with suppliers, where necessary
- Co-ordinate calibrations and ensure completion in a timely manner
- Problem solve and report outcomes to Supervising Scientist
- Escalate problems when necessary
- Implement quality improvement strategies
- Co-ordinate the training of Laboratory Assistants
- Maintain Training Gap Analysis data for Laboratory Assistants
- Monitor work unit reagents and assign staff to re-stock as required
- Participate in general quality activities, e.g. OQI generation
- Record and escalate client feedback
- May participate in other duties as required, e.g. assist other units, cross-training
- Train and mentor more less experienced staff as required
- Other tasks as assigned by senior and supervisory staff

Qualifications/Professional registration/Other requirements

- While not mandatory, a relevant qualification would be well regarded.
- In some circumstances and following consultation, Department of Health staff may be required to participate in 24 hour shift, on-call or weekend roster arrangements.

Are you the right person for the job?

You will be assessed on your ability to demonstrate the following key attributes. Within the context of the responsibilities described above, the ideal applicant will be someone who can demonstrate the following:

- Demonstrated knowledge and skills in basic laboratory processes and practices and the ability to work in a multi-skilled team, performing routine tasks within a scientific laboratory.
- Demonstrated ability to comply with the laboratory's policies and practices, including Workplace Health and Safety and continuous quality improvement requirements.
- Demonstrated high level computer literacy skills in a number of computer software packages.
- Proven ability to solve problems, show initiative and manage time effectively in the workplace.
- Demonstrated ability to supervise and mentor operational officers, in a complex and demanding work environment.
- Proven ability to communicate effectively with peers and professional/technical staff, including the ability to follow detailed operational instructions to meet the client's expectations.
- A demonstrated commitment to the principles of quality management and continuous quality improvement, including the initiation and evaluation of quality improvement activities.

- Ability to actively participate in a working environment supporting quality human resource management practices including employment equity, anti-discrimination, occupational health and safety and ethical behaviour.

How to apply

Please provide the following information to the panel to assess your suitability:

- Your current CV or resume, including referees. You must seek approval prior to nominating a person as a referee. Referees should have a thorough knowledge of your work performance and conduct, and it is preferable to include your current/immediate past supervisor. By providing the names and contact details of your referee/s you consent for these people to be contacted by the selection panel. If you do not wish for a referee to be contacted, please indicate this on your resume and contact the selection panel chair to discuss.
- **A short response** (maximum 1–2 pages) on how your experience, abilities, knowledge and personal qualities would enable you to achieve the key accountabilities and meet the key skill requirements.

About the Hospital and Health Service/Division/Branch/Unit

Working in HSSA is an opportunity to creatively and productively contribute to improving the provision of health services to the people of Queensland. HSSA is a learning organisation, committed to developing our people through training, support and leadership programs. We offer challenging opportunities to allow you to explore your potential. HSSA promotes a healthy balance between your work and personal life, provides flexible work hours, paid parental leave and study leave options.

We look forward to working with you!

HSSA is a division of Department of Health that aims to deliver safe, sustainable and appropriate services to enhance health care throughout Queensland. It provides these services through

- Pathology Queensland
- Medication Services Queensland
- Statewide Health Services
- Radiology Support
- Forensic and Scientific Services
- Biomedical Technology Services
- Queensland Blood Management Programme

Forensic and Scientific Services (FSS) is a hub of co-located laboratories at Coopers Plains in Brisbane. We are ready to respond to civil emergencies, crime and potential threats to our health, environment and our economy with tailor-made, smart scientific solutions.

Our scientists offer highly specialised analytical services and expert advice in the complex fields of Public Health Science and Forensic Science. Scientifically diverse, our organisation has cutting-edge capabilities in:

- chemical analysis
- environmental health
- health physics
- communicable diseases (microbiology)
- forensic pathology
- DNA analysis, and
- forensic medicine

Visit the website for more information: http://www.health.qld.gov.au/qhcss/

Pre-employment screening

Pre-employment screening, including criminal history and discipline history checks, may be undertaken on persons recommended for employment. The recommended applicant will be required to disclose any serious disciplinary action taken against them in public sector

employment. In addition, any factors which could prevent the recommended applicant complying with the requirements of the role are to be declared.

Roles providing health, counselling and support services mainly to children will require a Blue Card, unless otherwise exempt. Please refer to the Information Package for Applicants for details of employment screening and other employment requirements.

Salary Packaging

To find out whether or not your work unit is eligible for the Public Hospital Fringe Benefits Tax (FBT) Exemption Cap please refer to the Salary Packaging Information Booklet for Queensland Health employees available from the Queensland Health Salary Packaging Bureau Service Provider – RemServ at http://www.remserv.com.au. For further queries regarding salary packaging RemServ's Customer Care Centre may be contacted via telephone on 1300 30 40 10.

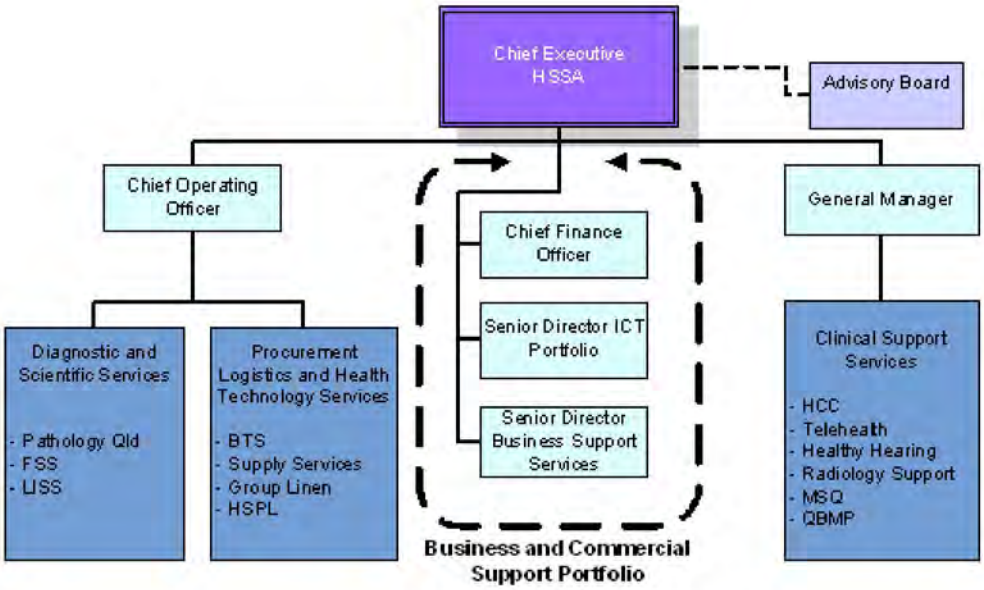
Disclosure of Previous Employment as a Lobbyist

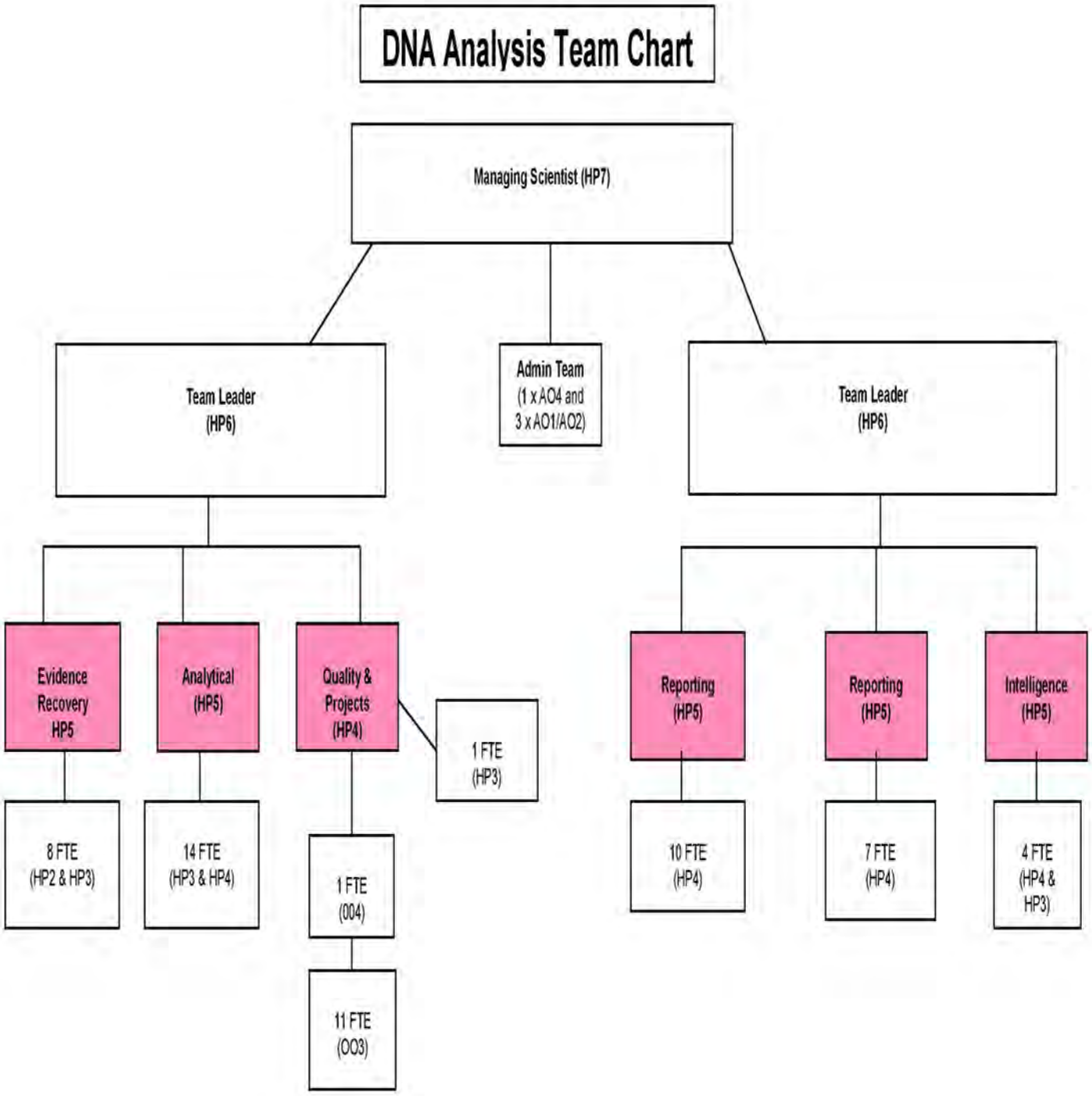
Applicants will be required to give a statement of their employment as a lobbyist within one (1) month of taking up the appointment. Details are available at http://www.psc.qld.gov.au/library/document/policy/lobbyist-disclosure-policy.pdf.

Probation

Employees who are permanently appointed to Queensland Health may be required to undertake a period of probation appropriate to the appointment. For further information, refer to Probation HR Policy B2 http://www.health.qld.gov.au/qhpolicy/docs/pol/qh-pol-197.pdf.

Organisational Chart




DNA Analysis Team Chart
Managing Scientist (HP7)
Team Leader (HP6)
Admin Team (1 x AO4 and 3 x AO1/AO2)
Team Leader (HP6)
Evidence Recovery HP5
Analytical (HP5)
Quality & Projects (HP4)
1 FTE (HP3)
Reporting (HP5)
Reporting (HP5)
Intelligence (HP5)
8 FTE (HP2 & HP3)
14 FTE (HP3 & HP4)
1 FTE (004)
11 FTE (003)
10 FTE (HP4)
7 FTE (HP4)
4 FTE (HP4 & HP3)

Queensland Health

Role description

Job ad reference:	Recruitment to insert number	**Unit/branch:**	Forensic DNA Analysis, Forensic and Scientific Services
Role title:	Forensic Technician	**Location:**	Coopers Plains
Status:	Fixed Term Temporary	**Closing date:**	Recruitment to insert closing date (day of week, DD, MONTH, YYYY)
Classification:	HP2	**Contact name:**	Paula Brisotto
Salary range:	Insert Salary ($ - $ per annum/fortnight/hour plus superannuation)	**Phone:**	[redacted]

Department of Health

The Department of Health has a diverse set of responsibilities, and a common purpose of creating better health care for Queenslanders. The department is responsible for the overall management of the public health system in Queensland. We strongly believe in the need to work with people that value the goals of our organisation and who will thrive in our workplace.

To enable this vision, the Queensland Public Sector is transforming from a focus on compliance to a values-led way of working. The following five values underpin behaviours that will support and enable better ways of working and result in better outcomes for Queenslanders.

About Forensic and Scientific Services

Forensic and Scientific Services (FSS) is a hub of co-located laboratories at Coopers Plains in Brisbane. We are ready to respond to civil emergencies, crime and potential threats to our health, environment and our economy with tailor-made, smart scientific solutions.

Our scientists offer highly specialised analytical services and expert advice in the complex fields of Public Health Science and Forensic Science. Scientifically diverse, our organisation has cutting-edge capabilities in:

- Chemical analysis;
- Environmental health
- Health physics;

- Communicable diseases (microbiology);
- Forensic Pathology;
- Forensic Chemistry
- Forensic DNA Analysis, and
- Forensic medicine

Police Services Stream

This stream encompasses both the Forensic DNA Analysis work unit and Forensic Chemistry work unit. Forensic DNA Analysis provides analytical and advisory services principally to the Queensland Police Service in the areas of evidence examination, DNA analysis and result interpretation culminating in expert advice and evidence.

We look forward to working with you!

Visit the website for more information: http://www.health.qld.gov.au/qhcss/default.asp

Purpose of the role

- Deliver a state wide forensic biology and DNA service
- Apply standard operating procedures to the analysis of forensic specimens and samples in the Forensic DNA Analysis laboratory, leading to the provision of test results and advice to supervisors, clients and stakeholders where appropriate.
- To ensure that all laboratory practices comply with Forensic & Scientific Services requirements in providing an effective and efficient service.

The Forensic Technician in Forensic DNA Analysis reports to the Senior Scientist.

Your key responsibilities

You will be required to fulfil the responsibilities of this role in accordance with the Queensland Public Service values.

- Adhere to defined service quality standards, health and safety policies and procedures relating to the work being undertaken to ensure high quality, safe services and workplaces.
- Provide technical services in relation to forensic DNA Analysis and interpretation for Forensic and Scientific Services commensurate with level of laboratory experience.
- Undertake forensic DNA testing and related duties using well established accredited protocols, standards and instrumentation within a multi-speciality team in accordance with prescribed professional and ethical standards, with level of supervision decreasing and professional accountability increasing commensurate with level of laboratory experience.
- Deliver routine technical/clinical services and undertake a range of tasks of increasing complexity under the direction and general supervision of more senior practitioners (including but not limited to processing general laboratory samples and basic histology processes).
- Commensurate with level of experience in role, provide training and education for less experienced practitioners with the guidance of senior staff; assist in the development of forensic and scientific practices, procedures and protocols within the Forensic DNA Analysis work area and participate in quality and service improvement activities.
- Responsible for providing the results of forensic DNA Analysis to senior staff and key stakeholders including information relating to the National Criminal Investigation DNA Database, and the provision of DNA testimony in court on work performed if required.
- Actively participate in the activities of the multi-speciality team, including participating in the introduction of new technologies or processes in the work area.
- Demonstrates ability to participate in the multi-speciality team and a level of knowledge and skills in the given technical domain, with the ability to undertake complex tasks in the Forensic DNA Analysis laboratory with minimal clinical practice supervision, within sphere of responsibility.

- Develop scientific knowledge and expertise through active learning within the team where basic guidance and instruction on technical and clinical matters can support less experienced staff. Develop scientific knowledge and expertise by engaging in professional development activities.
- Work cooperatively and communicate effectively within the Forensic DNA Analysis team and with clients and stakeholders, both internal and external to the laboratory. Provide test results and advice on matters pertaining to technical matters for less senior staff members, clients and key stakeholders.
- Provide guidance to less experienced staff, such as operational and administrative staff.
- Participate in the process of quality and service improvement activities in accordance with National Association of Testing Authorities and International Standardisation Organisation (NATA/ISO) accreditation/certification that enhance the delivery of forensic DNA Analysis services provided to clients and key stakeholders.

Key competencies (role specific criteria)

You will be assessed on your ability to demonstrate the following:

- Knowledge of, or ability to quickly acquire knowledge of, forensic DNA testing and related duties. Proven abilities in a range of accredited, relevant protocols, standards, instrumentation and quality assurance systems and the ability to apply such knowledge.
- Proven ability to work within a multi-speciality team, with and without direct supervision, to produce an effective work output. Proven ability to solve scientific and technical problems by selecting and applying standard procedures.
- Well-developed interpersonal skills, with the ability to communicate effectively with staff and clients.
- Demonstrated knowledge of the basis of laboratory Quality Control and Quality Assurance programs and ability to apply such knowledge, including continuous quality improvement.
- Commitment and motivation to effectively contribute to organisational goals, including supporting quality human resource management practices and ethical behaviour.

Qualifications, registrations and other requirements

- The successful applicant must hold at least a science oriented Associate Diploma (generally graduating prior to the year 2000), or a Diploma or Advanced Diploma (or equivalent) (year 2000 onwards), tertiary or equivalent formal qualification/s in science and/or extensive operational experience in a scientific field.
- Appointment to this position requires proof of qualification. Certified copies of the required information must be provided to the appropriate supervisor/ manager, prior to commencement of laboratory duties.
- Provision of a DNA sample is required for inclusion on a staff elimination database to comply with accreditation requirements.
- Please detail any visa conditions you may have if you are not a permanent resident of Australia.
- We understand that some people may require adjustments to the workplace or the way the work is performed. All applicants are encouraged to advise the panel of any support or reasonable adjustments (i.e. building access, wheelchair access, interpreting services etc.) that may be required.

Vaccine Preventable Diseases (VPD) requirements

- It will be a condition of employment for this role for the employee to be, and remain, vaccinated against one or more of the following vaccine preventable diseases during their employment: Hepatitis A & B, Measles, Mumps, Pertussis, Rubella and Varicella.
- Additional vaccinations including Japanese Encephalitis and Rabies may also be required for this position.
- Existing staff that are engaged prior to 1 July 2016 are not subject to this condition of employment unless they apply for a role with VPD requirements that is with a different Queensland Health entity (i.e. one HHS to another HHS, department to a HHS, or HHS to department).

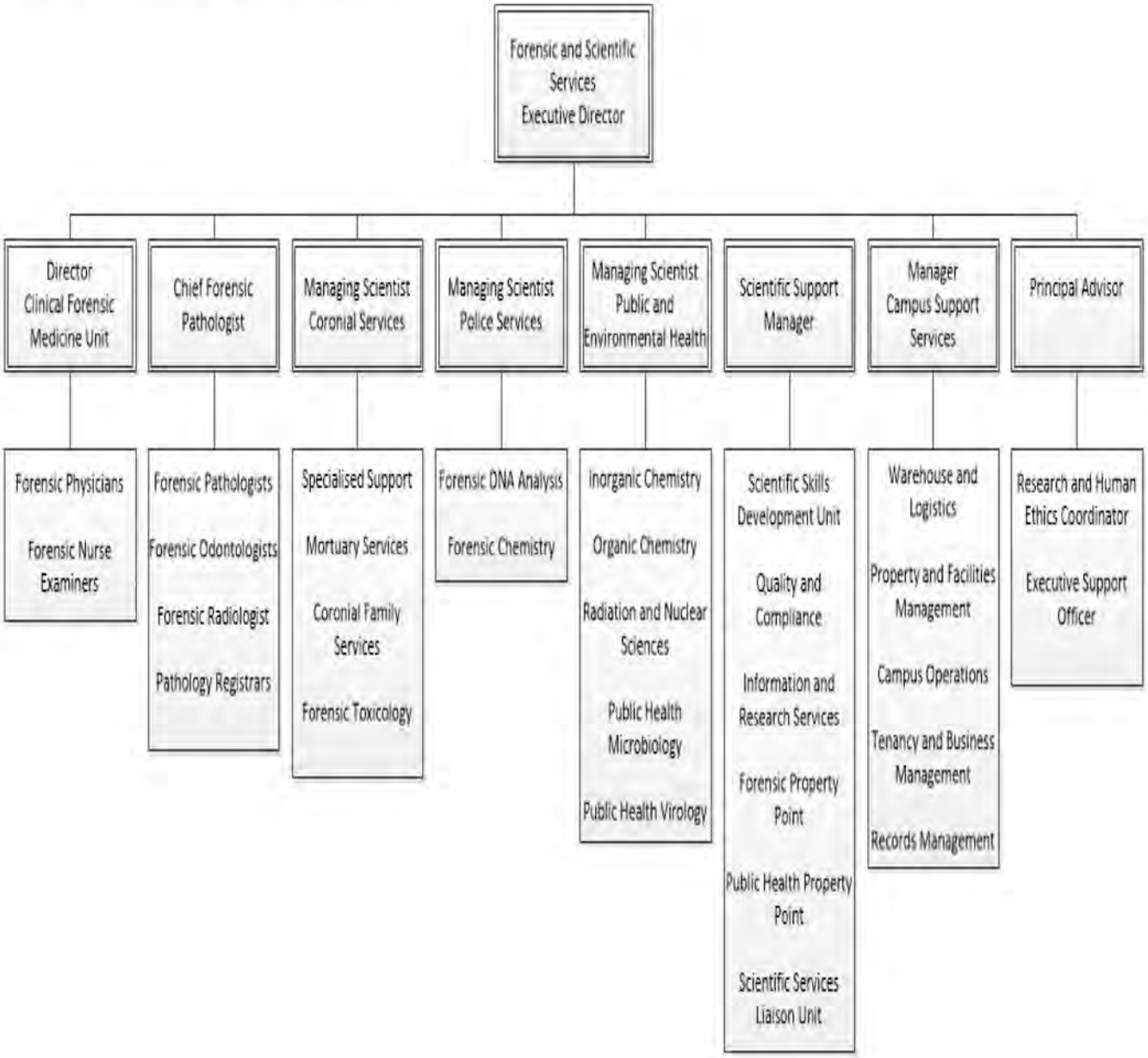
Additional Information

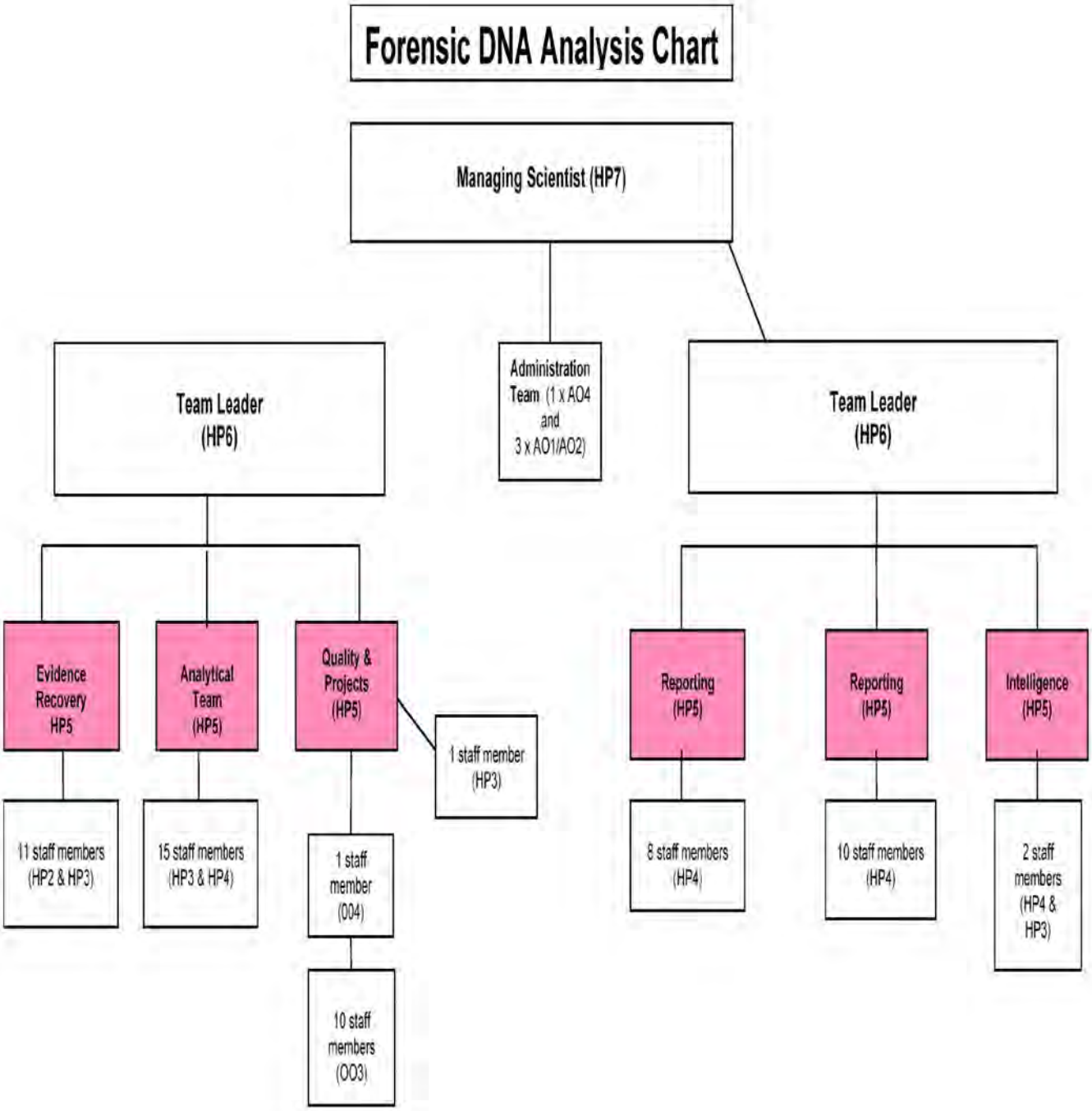
Please provide the following information to the panel to assess your suitability:

- Your **resume**, including the names and contact details of two referees who have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current, immediate or past supervisor.
- A **short statement (maximum two pages)** that gives details of your skills, experience and knowledge as required on the role description under the heading 'key competencies (role specific criteria)'.

Discover more about our work, our people and employment opportunities at Queensland Health.

Forensic and Scientific Services Organisational Chart




Forensic DNA Analysis Chart
Managing Scientist (HP7)
Team Leader (HP6)
Administration Team (1 x AO4 and 3 x AO1/AO2)
Team Leader (HP6)
Evidence Recovery HP5
Analytical Team (HP5)
Quality & Projects (HP5)
1 staff member (HP3)
Reporting (HP5)
Reporting (HP5)
Intelligence (HP5)
11 staff members (HP2 & HP3)
15 staff members (HP3 & HP4)
1 staff member (004)
10 staff members (003)
8 staff members (HP4)
10 staff members (HP4)
2 staff members (HP4 & HP3)

Queensland Health
HealthSupport Queensland

Role description

Job ad reference:	Recruitment team will insert HSQ number	**Unit/branch:**	Forensic DNA Analysis, Forensic and Scientific Services
Role title:	Forensic Scientist	**Location:**	Coopers Plains
Status:	Temporary Full-time position (for up to 9 months)	**Closing date:**	Recruitment to insert closing date (Day of week, DD/MM/YYYY)
Classification:	HP3	**Contact name:**	Kirsten Scott
Salary range:	$34.83 - $51.32 p/h plus superannuation	**Phone:**	[redacted]

Health Support Queensland—*helping care for Queenslanders*

Health Support Queensland (HSQ) is an organisational division of the Department of Health and delivers a range of support services to enable the delivery of frontline health services.

We deliver a wide range of diagnostic, scientific, clinical support and payroll services to enable the delivery of frontline healthcare.

Once you join us, we will expect you to exemplify the HSQ fundamental principles of ICARE:

- **I**ntegrity—being honest and ethical in everything we say and do.
- **C**ustomers and patients first—putting customers and patients at the centre of everything we do.
- **A**ccountability—taking personal responsibility for our actions.
- **R**espect—being considerate, recognising our differences and looking out for each other.
- **E**ngagement—actively investing in positive outcomes by partnering with others.

About Forensic and Scientific Services

Forensic and Scientific Services (FSS) is a hub of co-located laboratories at Coopers Plains in Brisbane. We are ready to respond to civil emergencies, crime and potential threats to our health, environment and our economy with tailor-made, smart scientific solutions.

Our scientists offer highly specialised analytical services and expert advice in the complex fields of Public Health Science and Forensic Science. Scientifically diverse, our organisation has cutting edge capabilities in:

- chemical analysis
- environmental health
- health physics
- communicable diseases (microbiology)
- forensic pathology
- DNA analysis, and
- forensic medicine

Police Services Stream

This stream encompasses both the Forensic DNA Analysis work unit and Forensic Chemistry work unit. Forensic DNA Analysis provides analytical and advisory services principally to the Queensland Police Service

in the areas of evidence examination, DNA analysis and result interpretation culminating in expert advice and evidence.

We look forward to working with you!

Visit the website for more information: http://www.health.qld.gov.au/qhcss/default.asp

Purpose of the role

- Deliver a state wide forensic biology and DNA service
- Apply independent scientific judgement in the analysis of forensic specimens and samples in the Forensic DNA Analysis laboratory, leading to the provision of test results and advice to clients and stakeholders where appropriate
- Apply standard operating procedures to the testing of forensic specimens and samples in the Forensic DNA Analysis laboratory.
- To ensure that all laboratory practices comply with Forensic & Scientific Services requirements in providing an effective and efficient service.
- To comply with NATA/ISO accreditation/certification requirements including performing quality control procedures.
- The HP3 Forensic Scientist in the Forensic DNA Analysis Team reports to the HP5 Senior Scientist of the respective team.

Your key responsibilities

You will be required to fulfil the responsibilities of this role in accordance with HSQ's fundamental principles of **ICARE** and the Queensland Public Service values.

- Adhere to defined service quality standards, health and safety policies and procedures relating to the work being undertaken to ensure high quality, safe services and workplaces.
- Provide professional level analytical services in relation to forensic DNA Analysis and interpretation for Queensland Health Forensic and Scientific Services commensurate with level of analytical experience.
- Undertake forensic DNA testing and related duties using well established accredited protocols, standards and instrumentation within a multi-speciality team in accordance with prescribed professional and ethical standards, with level of supervision decreasing and professional accountability increasing commensurate with level of analytical experience.
- Commensurate with level of experience in role, provide training and education and clinical practice supervision for less experienced practitioners with the guidance of senior staff; assist in the development of forensic and scientific practices, procedures and protocols within the Forensic DNA Analysis work area and participate in quality and service improvement activities.
- Responsible for providing the results of forensic DNA analysis and interpretation to senior staff and key stakeholders, including information relating to the National Criminal Investigation DNA Database and the provision of expert testimony in court on work performed if required.
- Actively participate in the activities of the multi-speciality team, including participating in the introduction of new technologies or processes in the work area.
- Develop scientific knowledge and expertise through active learning within the team and by engaging in professional development activities.
- Work cooperatively and communicate effectively within the Forensic DNA Analysis team and with clients and stakeholders, both internal and external to the laboratory. Provide test results and advice on matters pertaining to complex technical matters for less senior staff members, clients and key stakeholders.

- Participate in the process of quality and service improvement activities in accordance with NATA/ISO accreditation/certification that enhance the delivery of Forensic DNA Analysis services provided to clients and key stakeholders.
- Actively participate in the activities of the multi-speciality team, including participating in the introduction of new technologies or processes in the work area.
- Provide direction to assistant and support staff, including operational and administrative staff.
- Comply with and utilise procedures, policies, regulations and standards which impact upon the position in line with contemporary human resources management requirements and practices, such as workplace health and safety, equal employment opportunity, anti-discrimination and ethical behaviour.
- Utilises and applies a high level of interpersonal skills, ensuring the team works cooperatively and with effective communication within DNA Analysis.

Key competencies (role specific criteria)

You will be assessed on your ability to demonstrate the following:

- Demonstrated abilities in a range of relevant procedures, techniques, instrumentation and quality assurance systems including the use of computer systems and laboratory information management systems.
- Demonstrated ability to work within a multi-speciality team, and without direct supervision, to produce an effective work output. Proven ability to solve complex scientific and technical problems by selecting and applying standard procedures.
- Well-developed interpersonal skills, with the ability to communicate effectively by written or verbal means with staff and clients and present expert testimony in a court of law.
- Demonstrated ability to develop collaborative working relationships with key stakeholders and team members and ability to effectively communicate and influence staff.
- Demonstrated commitment to the principles of quality management and continuous quality improvement. Knowledge of the basis of laboratory Quality Control and Quality Assurance programs and ability to apply such knowledge.
- Ability to actively participate in the processes of change and continuous improvement
- Ability to actively and successfully participate in a working environment supporting quality human resource management practices including employment equity, anti-discrimination, occupational health and safety and ethical behaviour

Qualifications, registrations and other requirements

- The successful applicant must hold a tertiary qualification, or equivalent, in science from a recognised university or tertiary institution.
- Provision of a DNA sample will be required for use on the staff DNA elimination database to comply with accreditation requirements.
- In some circumstances and following consultation, Department of Health staff may be required to participate in 24-hour shift, on-call or weekend roster arrangements.
- Please detail any visa conditions you may have if you are not a permanent resident of Australia.
- We understand that some people may require adjustments to the workplace or the way the work is performed. All applicants are encouraged to advise the panel of any support or reasonable adjustments (i.e. building access, wheelchair access, interpreting services etc.) that may be required.

Vaccine Preventable Diseases (VPD) requirements

- It will be a condition of employment for this role for the employee to be, and remain, vaccinated against one or more of the following vaccine preventable diseases during their employment: Hepatitis A & B, Measles, Mumps, Pertussis, Rubella and Varicella.
- Additional vaccinations including Japanese Encephalitis and Rabies may also be required for this position.
- Existing staff that are engaged prior to 1 July 2016 are not subject to this condition of employment unless they apply for a role with VPD requirements that is with a different Queensland Health entity (i.e. one HHS to another HHS, department to a HHS, or HHS to department).

Additional Information

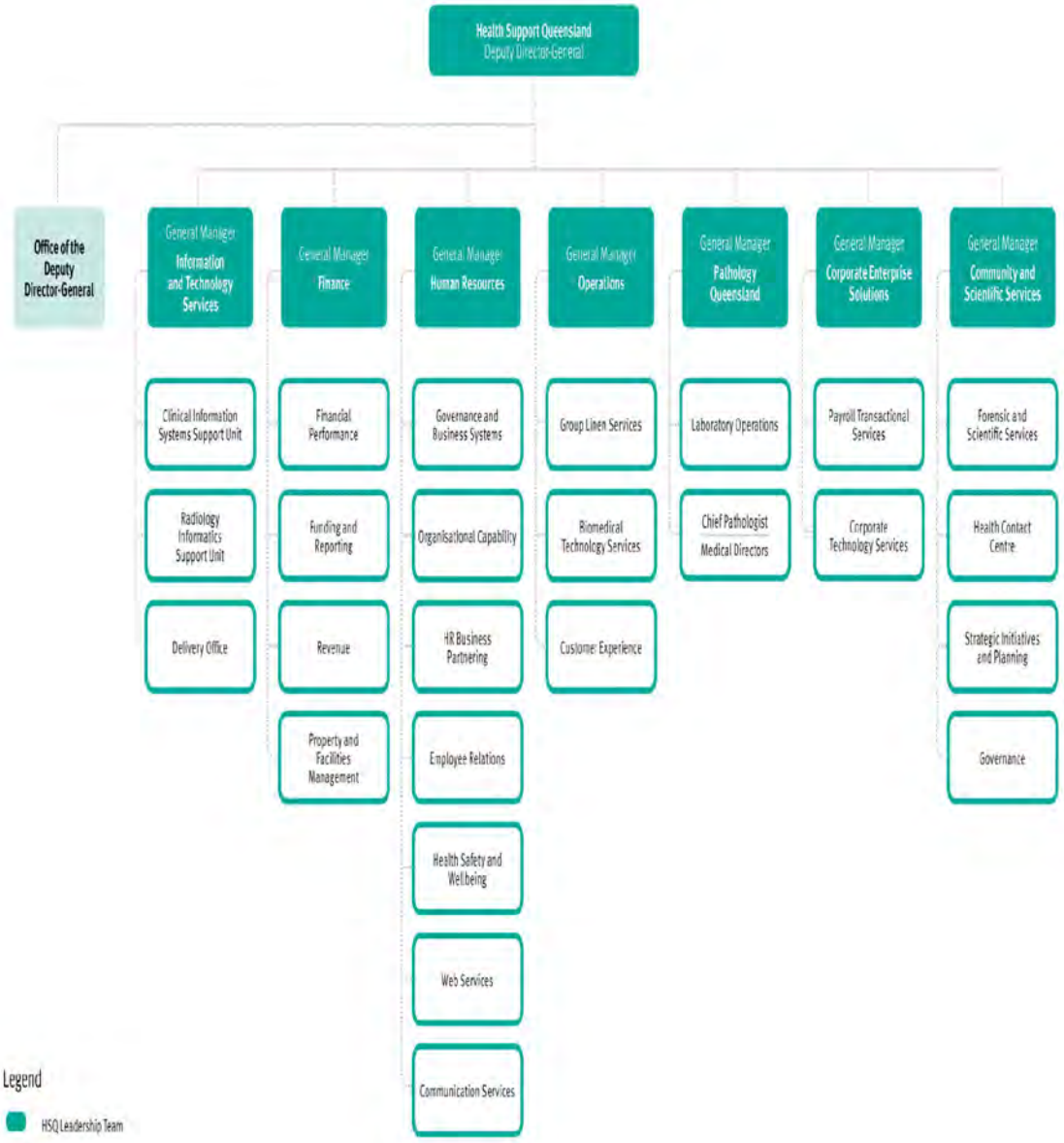
Please provide the following information to the panel to assess your suitability:

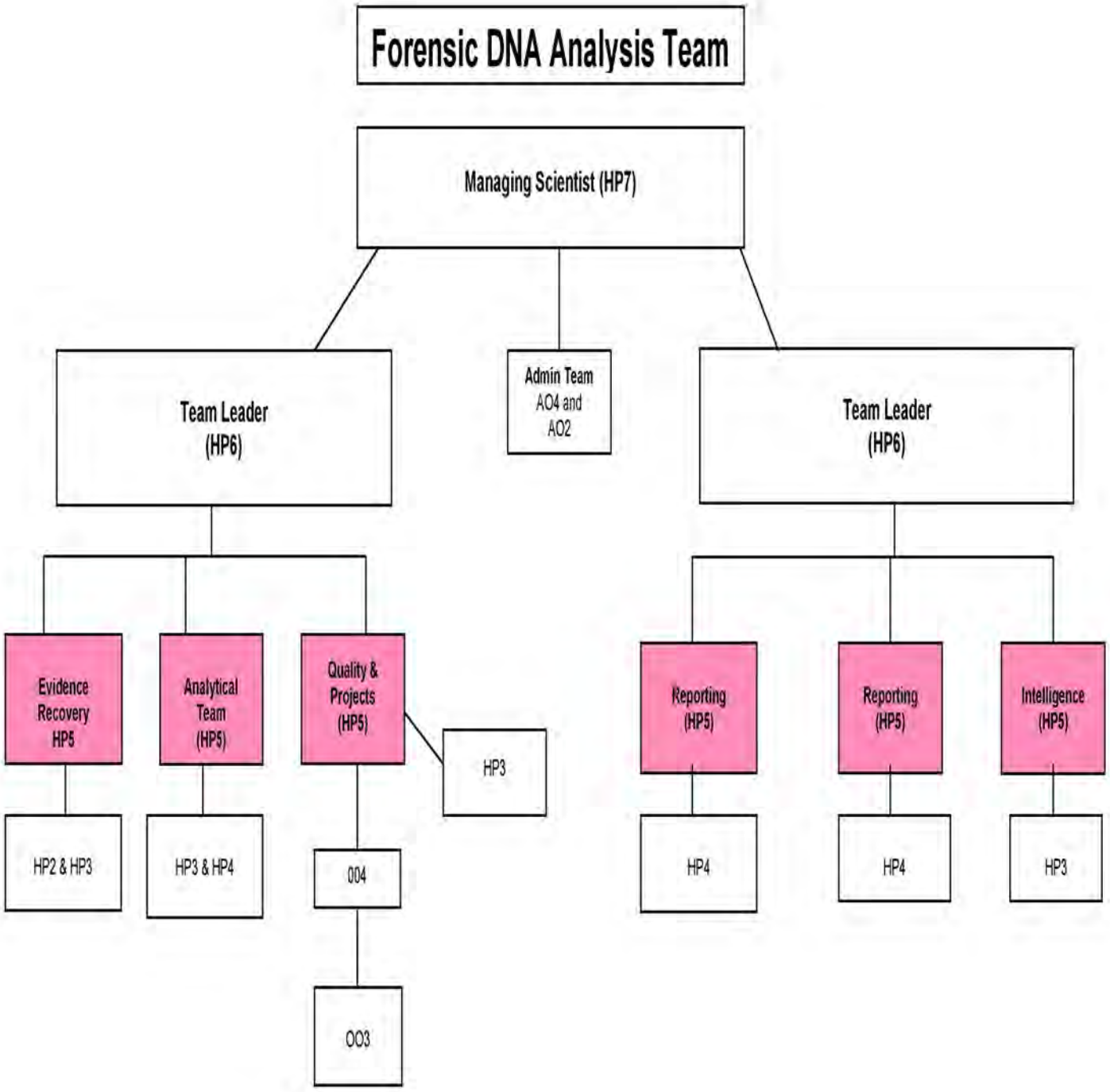
- Your **resume**, including the names and contact details of two referees who have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current, immediate or past supervisor.
- A **short statement (maximum two pages)** that gives details of your skills, experience and knowledge as required on the role description under the heading 'key competencies (role specific criteria)'.

Discover more about HSQ, our people and employment opportunities at Health Support Queensland.

Health Support Queensland Organisational Chart

Organisational structure




Forensic DNA Analysis Team
Managing Scientist (HP7)
Team Leader (HP6)
Admin Team AO4 and AO2
Team Leader (HP6)
Evidence Recovery HP5
Analytical Team (HP5)
Quality & Projects (HP5)
HP3
Reporting (HP5)
Reporting (HP5)
Intelligence (HP5)
HP2 & HP3
HP3 & HP4
004
HP4
HP4
HP3
OO3

Queensland Health

Role description

Job ad reference:	Recruitment to insert number	**Unit/branch:**	Forensic DNA Analysis, Forensic and Scientific Services
Role title:	Reporting Scientist	**Location:**	Coopers Plains
Status:	Permanent Full-time	**Closing date:**	Recruitment to insert closing date (day of week, DD, MONTH, YYYY)
Classification:	HP4	**Contact name:**	
Salary range:	Insert Salary ($ - $ per annum/fortnight/hour plus superannuation)	**Phone:**	

Department of Health

The Department of Health has a diverse set of responsibilities, and a common purpose of creating better health care for Queenslanders. The department is responsible for the overall management of the public health system in Queensland. We strongly believe in the need to work with people that value the goals of our organisation and who will thrive in our workplace.

To enable this vision, the Queensland Public Sector is transforming from a focus on compliance to a values-led way of working. The following five values underpin behaviours that will support and enable better ways of working and result in better outcomes for Queenslanders.


Customers First


Ideas into action


Unleash potential


Be courageous


Empower people

About Forensic and Scientific Services

Forensic and Scientific Services (FSS) is a hub of co-located laboratories at Coopers Plains in Brisbane. We are ready to respond to civil emergencies, crime and potential threats to our health, environment and our economy with tailor-made, smart scientific solutions.

Our scientists offer highly specialised analytical services and expert advice in the complex fields of Public Health Science and Forensic Science. Scientifically diverse, our organisation has cutting-edge capabilities in:

- Chemical analysis;
- Environmental health
- Health physics;

- Communicable diseases (microbiology);
- Forensic Pathology;
- Forensic Chemistry
- Forensic DNA Analysis, and
- Forensic medicine

Police Services Stream

This stream encompasses both the Forensic DNA Analysis work unit and Forensic Chemistry work unit. Forensic DNA Analysis provides analytical and advisory services principally to the Queensland Police Service in the areas of evidence examination, DNA analysis and result interpretation culminating in expert advice and evidence.

We look forward to working with you!

Visit the website for more information: http://www.health.qld.gov.au/qhcss/default.asp

Purpose of the role

- Deliver a state wide forensic biology and DNA service including the provision of expert opinion and testimony.
- To supervise and coordinate scientific judgement in the analysis of forensic specimens and samples in the Forensic DNA Analysis Laboratory leading to the provision of test results and advice to clients and stakeholders where appropriate.
- To ensure that all laboratory practices comply with Forensic & Scientific Services requirements in providing an effective and efficient service.

The Reporting Scientist in Forensic DNA Analysis reports to the Senior Scientist, Forensic DNA Analysis.

Your key responsibilities

You will be required to fulfil the responsibilities of this role in accordance with the Queensland Public Service values.

- Apply well developed scientific judgement in the analysis of forensic specimens and samples and the provision of advice within Forensic DNA Analysis, Forensic and Scientific Services and to key stakeholders state-wide.
- Utilise high levels of knowledge and clinical skills in exercising independent professional judgement in problem solving and forensic case management, handling an increasingly complex caseload beyond that of routine forensic DNA analysis with infrequent need for direct clinical practice supervision.
- Responsible for providing the results of Forensic DNA Analysis and interpretation to senior staff and key stakeholders with respect to the National Criminal Investigation DNA Database, including the provision of Statement of Witness documents and provision of expert testimony in court on work performed within the laboratory as a designated DNA Analyst.
- Supervise forensic testing and related duties following well established accredited forensic protocols and standards within Forensic DNA Analysis in accordance with prescribed professional and ethical standards and supervise the development of scientific practices, procedures and protocols within the Forensic DNA Analysis work area.
- Responsible for monitoring and reporting clinical work practices and outcomes within Forensic DNA Analysis and initiating, planning and evaluating scientific and service delivery improvement activities.
- Responsible for providing expert technical advice within the specific area of expertise to relevant stakeholders regarding standards and clinical services of a complex nature

- Provide general clinical and technical advice to professional and operational supervisors and relevant service managers regarding service delivery, equipment, technology and the prioritisation and development of clinical services.
- Ensure the development of scientific knowledge and expertise by supporting active learning and professional development of Forensic DNA Analysis staff.
- Provide clinical practice supervision to HP3 level assistants and clinical support staff, to ensure the maintenance of professional clinical standards.
- Adhere to defined service quality standards, health and safety policies and procedures relating to the work being undertaken to ensure high quality, safe services and workplaces.
- Ensure work practices align with Queensland Health Records Management Policy, Standards and Procedures.
- Work cooperatively and communicate effectively within the Forensic DNA Analysis team and with clients and stakeholders, both internal and external to the laboratory. Provide test results and advice on matters pertaining to technical matters for less senior staff members, clients and key stakeholders.
- Utilises and applies a high level of interpersonal skills, ensuring the team works cooperatively and with effective communication within Forensic DNA Analysis.
- Ensure that Forensic DNA Analysis complies with all relevant legislative, administrative and professional standards to meet NATA/ISO accreditation/certification requirements.

Key competencies (role specific criteria)

You will be assessed on your ability to demonstrate the following:

- Demonstrated abilities in a range of relevant procedures, techniques, instrumentation and quality assurance systems including the use of computer systems.
- Ability to actively participate in the processes of change and continuous improvement.
- Demonstrated ability to solve scientific problems and apply scientific rationale in the analysis and interpretation of forensic samples, without supervision.
- Demonstrated knowledge of, or ability to rapidly acquire knowledge of, contemporary statistical interpretation of forensic DNA profiles, including the use of statistical software.
- Demonstrated interpersonal skills for working in a team, both as a member and a leader, with demonstrated ability to communicate effectively with staff and clients.
- Demonstrated high level of ability to consult and communicate scientific/technical information, both orally and in writing, including the potential presentation of expert testimony in a court of law.
- Demonstrated commitment to the principles of quality management, continuous quality improvement and a contemporary knowledge of NATA/ISO accreditation/certification.
- Ability to supervise and manage staff in line with quality human resource management practices to ensure the maintenance of professional and ethical standards.

Qualifications, registrations and other requirements

- The successful applicant must hold a tertiary qualification, with a Bachelor Degree as a minimum, or equivalent, in science from a recognised university or tertiary institution.
- Appointment to this position requires proof of qualification. Certified copies of the required information must be provided to the appropriate supervisor/ manager, prior to commencement of duties.
- Provision of a DNA sample is required for inclusion on a staff elimination database to comply with accreditation requirements.
- Please detail any visa conditions you may have if you are not a permanent resident of Australia.

- We understand that some people may require adjustments to the workplace or the way the work is performed. All applicants are encouraged to advise the panel of any support or reasonable adjustments (i.e. building access, wheelchair access, interpreting services etc.) that may be required.

Vaccine Preventable Diseases (VPD) requirements

- It will be a condition of employment for this role for the employee to be, and remain, vaccinated against one or more of the following vaccine preventable diseases during their employment: Hepatitis A & B, Measles, Mumps, Pertussis, Rubella and Varicella.
- Additional vaccinations including Japanese Encephalitis and Rabies may also be required for this position.
- Existing staff that are engaged prior to 1 July 2016 are not subject to this condition of employment unless they apply for a role with VPD requirements that is with a different Queensland Health entity (i.e. one HHS to another HHS, department to a HHS, or HHS to department).

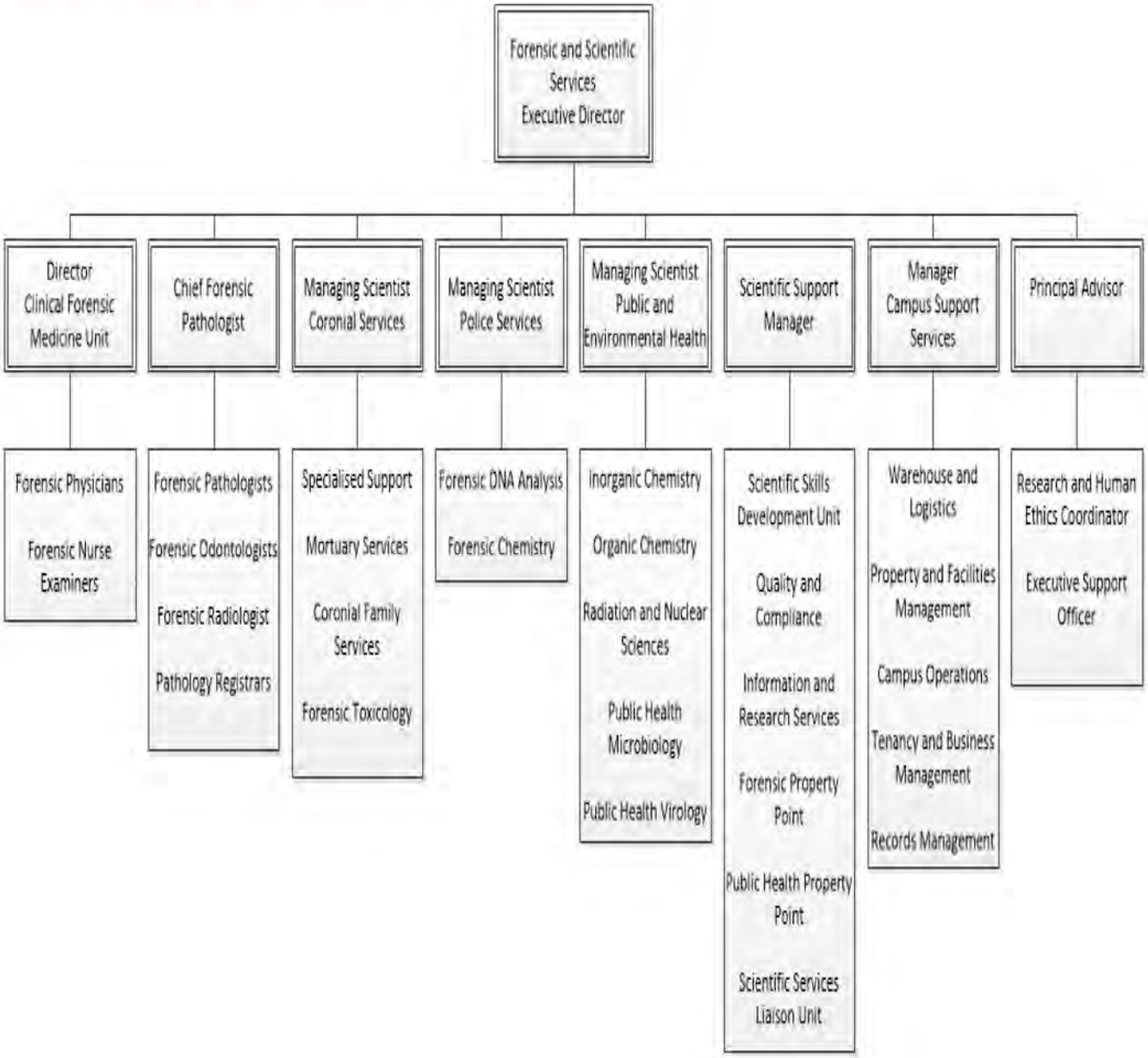
Additional Information

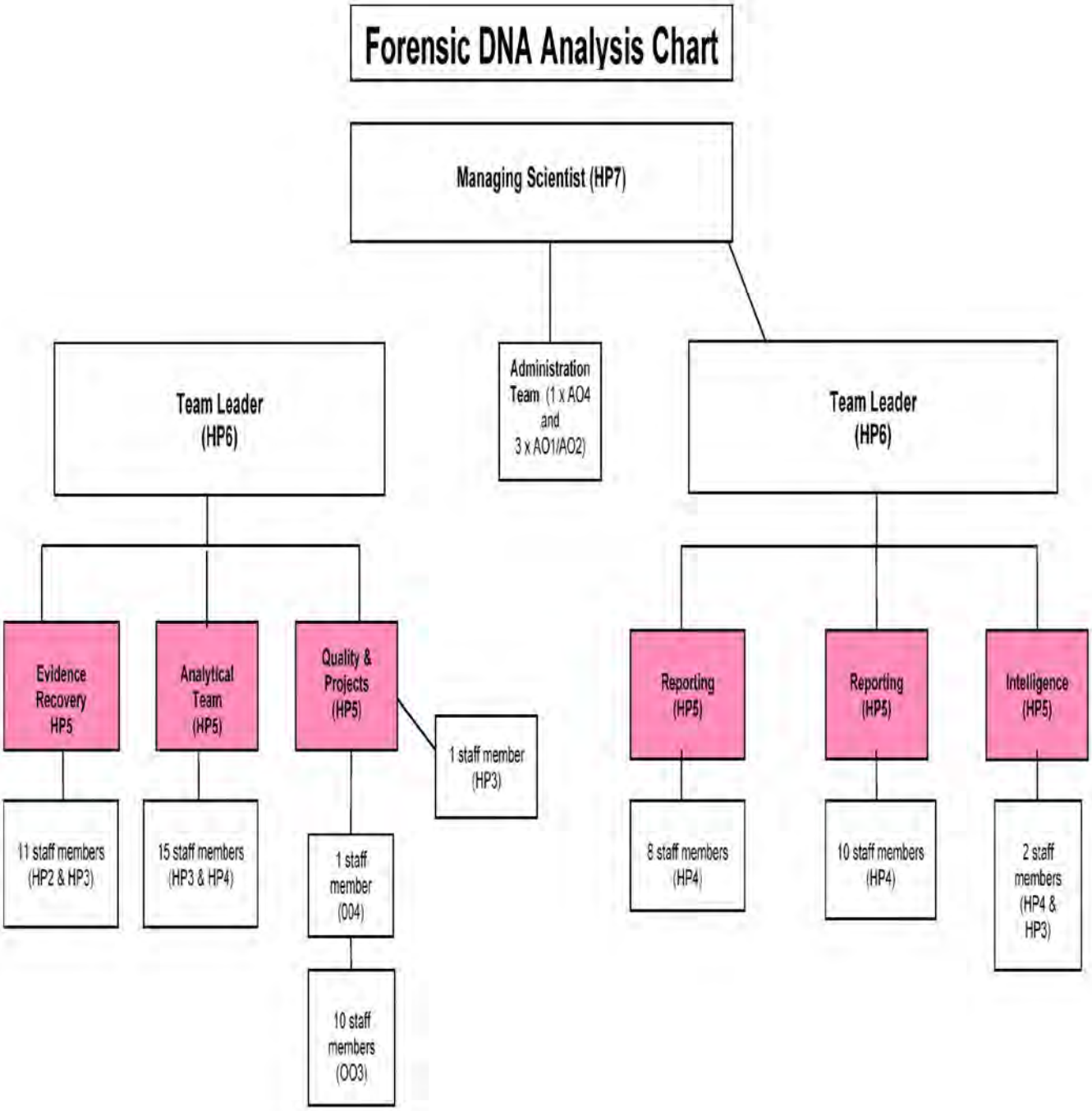
Please provide the following information to the panel to assess your suitability:

- Your **resume**, including the names and contact details of two referees who have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current, immediate or past supervisor.
- A **short statement (maximum two pages)** that gives details of your skills, experience and knowledge as required on the role description under the heading 'key competencies (role specific criteria)'.

Discover more about our work, our people and employment opportunities at Queensland Health.

Forensic and Scientific Services Organisational Chart




Forensic DNA Analysis Chart
Managing Scientist (HP7)
Team Leader (HP6)
Administration Team (1 x AO4 and 3 x AO1/AO2)
Team Leader (HP6)
Evidence Recovery HP5
Analytical Team (HP5)
Quality & Projects (HP5)
1 staff member (HP3)
Reporting (HP5)
Reporting (HP5)
Intelligence (HP5)
11 staff members (HP2 & HP3)
15 staff members (HP3 & HP4)
1 staff member (004)
10 staff members (003)
8 staff members (HP4)
10 staff members (HP4)
2 staff members (HP4 & HP3)

CA-12

Queensland Health
Forensic and Scientific Services

The Organisation and Management of Forensic DNA Analysis

1 Purpose and Scope

The purpose of this document is to describe the organisation and communication framework for Forensic DNA Analysis. This document applies all staff within Forensic DNA Analysis.

2 Definitions

Nil

3 Actions

3.1 Organisational Charts

- The Forensic DNA analysis organisational chart can be found in G:\ForBiol\AAA Administration\Master Documents\Team Chart and is called 'Forensic DNA Analysis Team Chart_(date)'. This is updated as required.
- The appendix contains a general overview of the organisational chart.

3.2 Roles and Responsibilities

- Role descriptions for each position within Forensic DNA Analysis are available on G:\ForBiol\AAA Administration\Forensic DNA Analysis Role Descriptions These role descriptions are updated as required.

  Managing Scientist
  Team Leader Forensic Scientist
  Forensic Scientist Advanced
  Senior Scientist
  Scientist
  Technician
  Laboratory Assistant Supervisor
  Laboratory Assistant/Clinical Assistant
  Administrative Officer

- Duty statements describing specific duties and responsibilities for staff in each team can be accessed via QIS2 (refer to associated documents below).

3.3 Internal Communication

- Minutes from all internal meetings are available on G drive.
- Sub Teams hold meetings to discuss agenda items. Sub Team members are advised of the meeting and the agenda items.
- A Forensic DNA Analysis team meeting is scheduled once per month with appointments sent to all team members. At this meeting, agenda items affecting the whole team are discussed, however if no agenda items have been submitted or the agenda items can be dealt with in another format, the meeting will be cancelled.
- A "Change Register – Minor Changes and emerging or novel practices" is maintained to record details of changes made to processes and procedures.

4 Records

Nil

5 Associated Documents

22012 DNA Analysis Duty Statement - Managing Scientist
23127 Forensic DNA Analysis Duty Statements – Administration
24122 Forensic Reporting and Intelligence Team - Duty Statements Forensic DNA Analysis
24274 Forensic DNA Analysis - Evidence Recovery and Quality Team Duty Statements

6 Amendment History

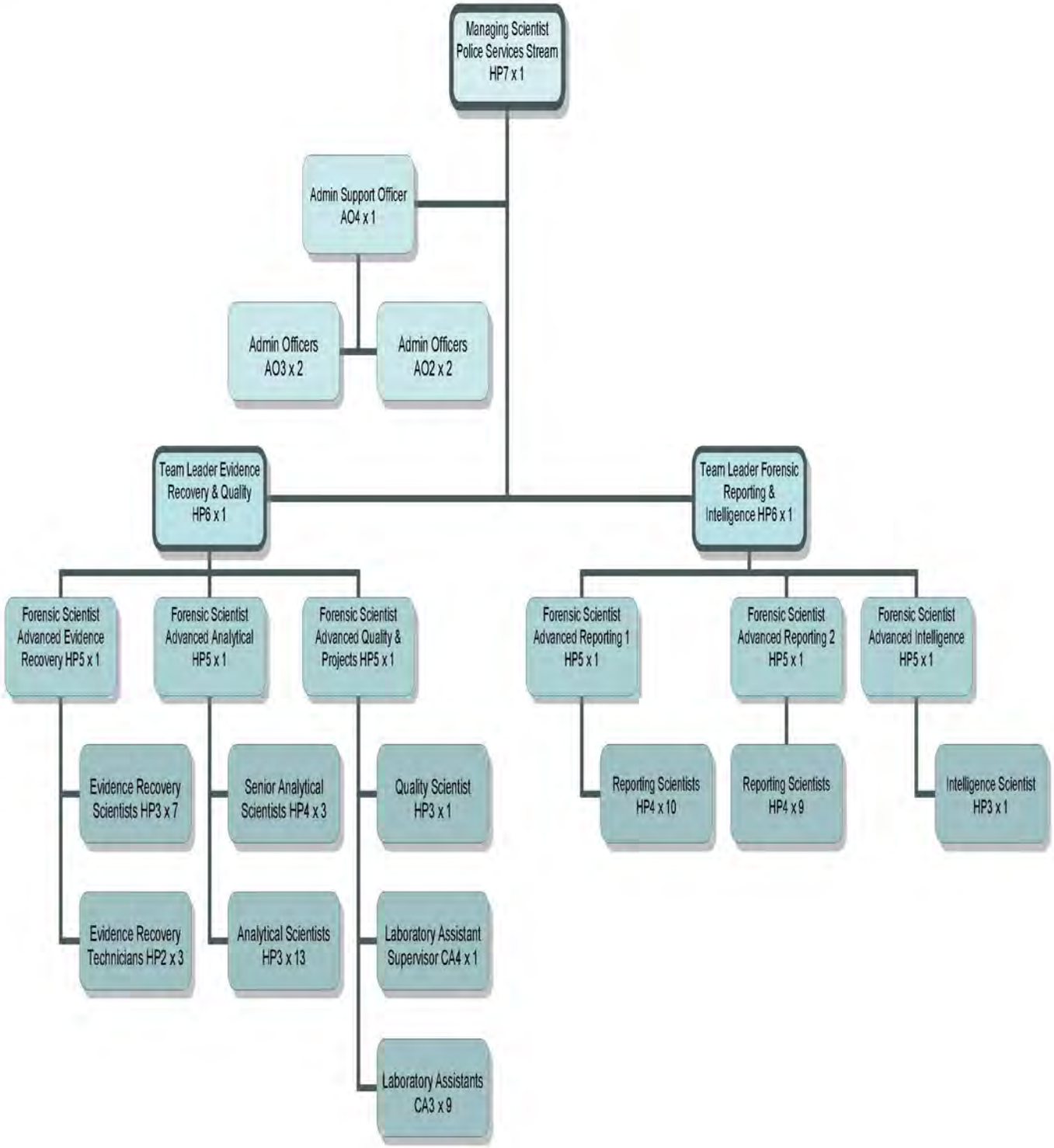
Version	Date	Author/s	Amendments
1	17 Apr 2001	V Ientile	New Guideline
2	24 Apr 2001	V Ientile	
3	18 Jul 2001	V Ientile	Changes made to org charts
4	04 Apr 2002	V Ientile	Changes made to org charts
5	17 Nov 2003	L Freney	Changes made to org charts, update document numbers, refer to AUSLAB
6	27 Jan 2004	L Freney	Changes to org charts
7	6 May 2004	V Ientile	Changes to org charts
8	23 Jan 2005	V Ientile	Removed attachments, hyperlinked organizational charts
9	10 Aug 2006	V Ientile	Complete Re-write
10	18 Oct 2006	V Ientile	Fixed link to org chart
11	20 Mar 2007	M Gardam	Changed links to org chart
11	April 2008	QIS2 Migration Project	Headers and Footers new format. Amended Business references
12	3 August 2009	C Allen, T Nurthen	Updated to name to DNA Analysis, removed references to QHEPS, added organisational chart, added Associated documents
13	27 March 2012	K Scott	Update document headings, organisational structure and associated documentation
14	12 April 2013	K Scott	Update header, hyperlinks, organisational chart and minor text edits.
15	06 Nov 2014	K Scott	Update header, hyperlinks, organisational chart and minor text edits.
16	04 May 2016	K Scott	Update associated documents

17	11 Dec 2017	K Scott	Update hyperlinks and network locations. Minor changes to internal communications.
18	29 Mar 2022	A Ryan	Update header and organisational chart.

7 Appendices

1 Forensic DNA Analysis Team Chart

7.1 Forensic DNA Analysis Team Chart



CA-13

MEMORANDUM OF UNDERSTANDING

BETWEEN

The State of Queensland through Queensland Health, Queensland Health Scientific Services, Forensic Sciences

Queensland Government
Queensland Health

DNA Signed Jan 2001

AND

The State of Queensland through the Queensland Police Service

QUEENSLAND POLICE

COPY

This **MEMORANDUM OF UNDERSTANDING** is made at Brisbane on the day of 2000.

11

BETWEEN

The State of Queensland through Queensland Department of Health, Queensland Health Scientific Services, Forensic Sciences, 39 Kessels Road, Coopers Plains, Brisbane.

AND

The State of Queensland through the Queensland Police Service, 200 Roma Street, Brisbane.

1 EXPLANATION OF TERMS

1.1 "DNA" means Deoxyribonucleic Acid.

1.2 "MAJOR INCIDENT" For the purpose of this MOU a major incident also includes a major disaster where victim identification may be required using DNA profiling.

1.3 "MANAGER QHSS" This term used within this MOU relates to the Manager QHSS or the manager's delegate.

1.4 "MOU" means Memorandum of Understanding.

1.5 "NATA" means National Association of Testing Authorities.

1.6 "O/C" means Officer in Charge.

1.7 "QHSS" means Queensland Health Scientific Services, Forensic Sciences.

1.8 "QPS" means Queensland Police Service.

2 INTRODUCTION

2.1 This MOU has been developed to clarify the roles and responsibilities of both of the parties to this memorandum and to facilitate the development of formal arrangements, which will ensure the effective use of DNA profiling technology.

11

2.2 The QHSS and the QPS agree that this MOU does not create any legal relations between them. However the matters set out in this MOU are agreed in principle between the parties.

3 OBJECTIVES

3.1 The primary objective of this MOU is to establish the framework under which Queensland Police Service will provide funding to Queensland Health for forensic person sampling using DNA technology.

3.2 Additional objectives are:

3.2.1 To develop a positive and collaborative working relationship between the QHSS and the QPS in relation to the use of DNA profiling technology for the purpose of police enquiries and investigations.

3.2.2 To develop a funding model reinforced by the principle of financial equity and consistent with sound financial management practices, as prescribed in the *Financial Management Standard 1997.*

3.2.3 To minimise the administrative complexity of processing payments.

3.2.4 To ensure timing constancy in the provision of funds each quarter.

3.2.5 To achieve a high level of transparency in all transactions.

4 RECITALS

4.1 The QHSS will provide forensic scientific services to the QPS with the intention of identifying individuals using the evidentiary application of DNA profiles.

4.2 The QPS intends to use the DNA profile information supplied by the QHSS to assist in police enquiries and investigations.

4.3 The QHSS undertakes to provide forensic scientific services in a NATA accredited environment, in accordance with the prerequisites of the national DNA system.

11

5 GENERAL ROLES AND RESPONSIBILITIES

The following particulars outline the general roles and responsibilities of each party to this MOU.

5.1 The mission of Queensland Health is "Helping people to better health and wellbeing."

5.2 The guiding principles and role of Queensland Health are:

5.2.1 Prevention, health promotion and early intervention.

5.2.2 Evidence-based clinical practice.

5.2.3 Partnership with all health-care providers (including private sector and non-government bodies).

5.2.4 Managing the public health risks of Queenslanders.

5.3 The mission of the QPS is "To serve the people of Queensland by protecting life and property, preserving peace and safety, preventing crime and upholding the law in a manner which has regard for the public good and the rights of the individual."

5.4 The guiding principles of the QPS are:

5.4.1 Provide a corruption free policing service to the Queensland community, based on integrity, fairness, equity, professionalism and accountability.

5.4.2 In partnership with the Queensland community, as well as with other law enforcement agencies, provide responsive policing services to meet the Service's statutory responsibility to preserve peace and good order and to prevent, detect and investigate breaches of the law by the use of problem solving approaches.

5.4.3 Help create a safe environment for all Queensland residents and visitors.

11

5.4.4 Employ effective and efficient management systems which provide maximum support to operational police and all other staff through:

5.4.4.1 Human resource management practices which value the contribution of all staff members.

5.4.4.2 Education and training programs which support and enhance the capacities of all staff.

5.4.4.3 Corporate management practices, which provide the information systems and administrative support structures required to ensure a well, equipped and well-informed Police Service.

6 FUNDING MODEL

6.1 Cost Recovery

6.1.1 The per sample costs for each biological person sample processed by Queensland Health are as follows:
2000/2001 - $85.93
2001/2002 - $90.22
2002/2003 - $89.65

The projections of sample volume are:
2000/2001 – 13,900
2001/2002 – 26,010
2002/2003 – 28,320

6.1.2 The Queensland Police Service and Queensland Health agree to undertake a review and renegotiation of per sample cost and projections of sample volume, if necessary, at the end of each financial year incorporated by this MOU. Additional funding requests to Queensland Treasury, if required, will be initiated by Queensland Police Service.

11

6.2 Each payment to Queensland Health by Queensland Police Service will be made prospectively by the commencement of each quarter. Now paid monthly!

6.3 A quarterly acquittal process will be conducted to reconcile the payments made to the samples processed throughout the period.

7 OPERATIONAL ASPECTS OF MEMORANDUM

7.1 The fiscal years incorporated by this MOU are 2000/2001, 2001/2002, 2002/2003.

7.2 The MOU will take effect from the date of execution of the Memorandum by the last party to sign it, and will continue until either party withdraws from the memorandum by written notice to the other party.

7.3 Both parties must agree in writing to any alterations to this MOU. Any proposed alteration shall be raised and addressed through the Commissioner, QPS and the Director-General, Queensland Health.

7.4 Should either party (the first party) form the view that the other party (the second party) is not complying in any respect with any of the provisions of this MOU. The first party shall notify the second party in writing and request the second party to attend a meeting to resolve the issue. The second party shall cooperate with the first party in a genuine attempt to resolve the dispute.

7.5 The parties agree to respect the policy and legislative requirements of either party and that any joint service provision will reflect those requirements. Those policy and legislative requirements include:

7.5.1 Queensland Police Service Code of Conduct.

7.5.2 Queensland Police Service Operational Procedures Manual.

11

7.5.3 *Police Powers and Responsibilities Act 2000* including the Responsibilities Code.

7.5.4 *Police Service Administration Act 1990.*

7.5.5 *Criminal Code Act 1899.*

7.6 Forensic samples obtained by QPS during the course of investigations for evidentiary purposes remain the property of QPS during investigations.

7.7 The QHSS will overview the initial sampling procedures and certify in writing to the QPS that the procedure is in accordance with NATA protocols and will protect the integrity of any samples.

7.8 The QHSS will provide advice to the QPS on packaging and transport of DNA person samples obtained from arrested persons, prisoners and from consenting persons.

7.9 The QHSS will provide advice to QPS on packaging and transport of samples relating to the DNA database.

7.10 The QHSS will provide advice to the QPS DNA Unit as to quality of samples received.

7.11 The O/C of the QPS DNA Unit will develop a suitable person sample delivery procedure and schedule in conjunction with the Manager QHSS.

7.12 The QHSS shall guarantee that they have the capacity to provide DNA profiles to a minimum of Twenty Thousand person samples per annum.

7.13 The Commissioner of the Queensland Police Service authorises the Director General of Queensland Health to keep and maintain a DNA database for the purpose of recording any information obtained by a DNA analysis of a DNA sample. The DNA database that is kept and maintained by the Director-

General of Queensland Health is approved for that use by the Commissioner of the Queensland Police Service.

7.13.1 A DNA database approved under paragraph 7.13 may include a database established by agreement between the Commonwealth and the States for keeping information, including DNA information, obtained by Commonwealth and State law enforcement agencies and is for use only for investigations being conducted by those agencies.

7.13.2 The Commissioner may arrange for information obtained by a DNA analysis of either of the following, held by the commissioner, to be included in the database. A sample including blood taken before or after the commencement of this MOU or a thing a police officer reasonably suspects is evidence of the commission of an offence.

7.13.3 It is lawful for the Commissioner to use the DNA database for any investigation being conducted by a police officer for the police service or a declared law enforcement agency.

7.14 The QHSS will provide advice to the QPS on training issues in relation to the collection of samples and data for a DNA database.

7.15 The QHSS will notify the results of any DNA profile matches to the QPS DNA Unit. These profile matches include those profiles that are presently stored on the QHSS database, including person to person matches, person to crime scene matches and crime scene to crime scene matches

7.16 The QHSS will provide the DNA Unit with information in relation to any DNA profile matches within forty-eight hours of a match being confirmed. The QHSS will restrict this information to the QPS DNA Unit except where a task force or

major operation is current and awaiting the result of a specific DNA profiling.

7.17 The agreed maximum turn around time in relation to person samples is ten working days.

7.18 Where a task force or major operation is currently deployed then the QHSS and the O/C QPS DNA Unit shall liaise with each in order to facilitate direct contact between the QHSS and the chief investigator concerning any relevant DNA profile.

7.19 DNA profile information that is recorded pursuant to Section 317 of the *Police Powers and Responsibilities Act* and held by the Forensic Biology Section, QHSS is for law enforcement purposes only.

7.20 The QHSS will provide adequate security of any exhibits used for DNA profiling and any data and electronic systems used to store that DNA profile. This security will also include physical protection of buildings as required.

7.19 The QHSS will develop a satisfactory procedure of removing DNA profiles from the searchable records of the DNA database in accordance with section 316 of the *Police Powers and Responsibilities Act.*

7.20 The QHSS will provide to the QPS DNA Unit, on or before, the fifth day of each month an activity statement detailing the number of DNA samples received and the number of profiles obtained during the preceding month.

7.21 As in 7.20, the QHSS will supply to the QPS on a monthly basis, an activity statement detailing the number and the reasons for the non-profiling of any samples.

7.22 Upon a request of the O/C QPS DNA Unit the QHSS will provide to that unit any information in order to identify a person that has a DNA profile from a person sample obtained from matching profiles stored within the QHSS database. Any data stored within the QHSS database is done so in an interim

arrangement pending the commencement of the national DNA system, CrimTrac.

7.23 On the commencement of the National DNA system, CrimTrac, the QHSS will provide the QPS with DNA matching reports on a person to person basis, person to crime scene basis or crime scene to crime scene basis.

7.24 The QPS will continue to work towards providing QPS Intranet access to the QHSS in order to provide intranet email advice to the O/C QPS DNA Unit.

7.25 The QHSS will provide a contact person in the event of any major incident or major disaster where identification using DNA profiling may be required.

7.26 The QHSS and the QPS will agree on any necessary procedures in the event of any major incident or major disaster.

7.27 In matters relating to priority:

7.27.1 The O/C QPS DNA Unit will from time to time request the Manager QHSS to give priority over the QHSS current DNA profiling work load in relation to an urgent crime scene sample or person sample.

7.27.2 When a request, as detailed in paragraph 7.27.1 is made the Manager QHSS, depending on resource implications, will give that priority to the relevant crime scene sample or person sample.

7.28 The O/C QPS DNA Unit will give prior advice, where applicable, to the Manager QHSS in relation to any screening operations that are currently in action or about to commence.

8 TERMS OF AGREEMENT

In a spirit of cooperation between the QHSS and the QPS, the parties agree as follows:

8.19 To participate in regular meetings designed to improve service delivery in issues impacting on their respective responsibilities.

8.20 To develop protocols and operational procedures to improve coordination of services in relation to DNA profiling.

8.21 To develop clear lines of communication between the QHSS and the QPS.

8.22 To work together to identify needs and develop strategies for future initiatives.

8.23 To cooperate in the preparation and presentation of training packages relating to the collection of samples and data for the DNA database that will be applicable and complimentary to both agencies.

SIGNED BY:

[redacted]

R ATKINSON
COMMISSIONER
QUEENSLAND POLICE SERVICE
8 / / ~~2000~~ 2001

[redacted]

(DR) R L STABLE
DIRECTOR GENERAL
QUEENSLAND HEALTH
21 / 1 / ~~2000~~ 2001

CA-14

Cathie Allen

From: Cathie Allen
Sent: Friday, 24 June 2022 4:40 PM
To: Troy O'Malley; Neville.DavidH; Rechelle Cook
Cc: McNab.BruceJ[OSC]; Lara Keller; Peter Culshaw
Subject: RE: QHFSS access to DNA TAT stats

Thanks Troy. I can confirm that I'm able to view the stats in the FR.

Cheers
Cathie

Cathie Allen BSc, MSc (Forensic Science) (She/Her*)
Managing Scientist

Social Chair, Organising Committee for 25th International Symposium of the
Australian and New Zealand Forensic Science Society (ANZFSS), Brisbane, 11 – 15 Sept 2022

Police Services Stream, Forensic & Scientific Services
Prevention Division, Queensland Health
[redacted]

Queensland Health acknowledges the Traditional Owners of the land, and pays respect to Elders past, present and future.

*If you're wondering about the use of pronouns She/Her on this signature block, I encourage you to read some resources available here

From: Troy O'Malley [redacted]
Sent: Friday, 24 June 2022 2:00 PM
To: Neville.DavidH [redacted]; Rechelle Cook [redacted]
Cc: McNab.BruceJ[OSC] [redacted]; Cathie Allen [redacted]; Lara Keller [redacted]; Peter Culshaw [redacted]
Subject: RE: QHFSS access to DNA TAT stats

Inspector

QHFSS now have access to view the DNA TAT stats (QHFSS Link below):

https://164.112.251.241/main/statscf11/stats_summary_rmt.cfm?DISP=DNATAT&View=DNA%20TAT

Troy

Troy O'Malley
Managing Director - Forensic Software and Services
[redacted]
www.bdna.com.au

From: [redacted]
Sent: Thursday, 23 June 2022 2:08 PM
To: Troy O'Malley[redacted]; Rechelle Cook [redacted]
Cc: McNab.BruceJ[OSC] [redacted]; Cathie Allen [redacted]; Lara Keller[redacted]; Peter Culshaw [redacted]
Subject: QHFSS access to DNA TAT stats

Hi Troy and Rechelle

Could you please give QHFSS access to view the TAT stats viewable through the link below:

http://forensics.prds.qldpol/main/statscf11/stats_summary_rmt.cfm?DISP=DNATAT&View=DNA%20TAT

This would be very helpful for them to monitor operations

Cheers

David Neville
Inspector
Biometrics
Forensic Services Group
Operations Support Command
[redacted]

CA-15

Cathie Allen

From: Neville.DavidH[OSC] <[redacted]
Sent: Monday, 2 November 2020 9:39 AM
To: McNab.BruceJ[OSC]; John Doherty; Cathie Allen
Subject: RE: FSG/QHFSS Catch Up
Attachments: tats chart.docx

Hi All
I have enclosed a chart of current TAT for noting only;

Cheers

David

-----Original Appointment-----
From: De Marco.JennaL[OSC] **On Behalf Of** McNab.BruceJ[OSC]
Sent: Monday, 2 November 2020 09:10
To: [redacted]; Neville.DavidH[OSC]; [redacted]
Subject: FSG/QHFSS Catch Up
When: Monday, 2 November 2020 11:00-12:00 (UTC+10:00) Brisbane.
Where: Microsoft Teams Meeting

Good morning,

Bi-monthly meetings between FSG and QHFSS.

Please contact Supt McNab office if this reoccurrence needs to be rescheduled.

Agenda/papers to be provided before each meeting.

Join Microsoft Teams Meeting

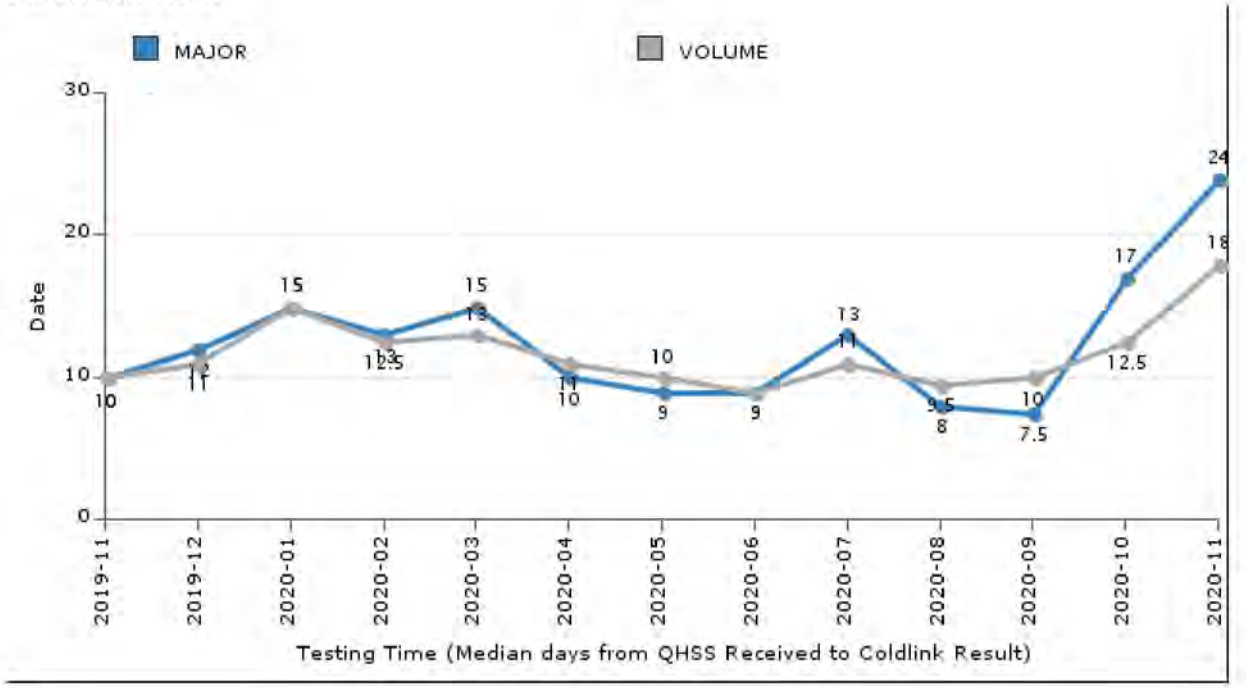
Learn more about Teams | Meeting options

Queensland Police Service

Help | Legal

CA-16

Current TAT Trend



Comparison with other States.

State	Vic	NSW	SA	WA	Tas
Routine TAT	Average 16 days	10-15 days	10-15 days	5-8 weeks	Unable to determine

CA-17

Queensland Health

Forensic and Scientific Services

Quality Commitment

At Forensic and Scientific Services (FSS) the pursuit of excellence is an organisation-wide objective. All
our employees demonstrate a real commitment to continuously improve the quality of our services and
products. We engage with our customers to understand and respond to their needs.

FSS will reliably provide quality products and services to its customers. To achieve this aim, we will;

- **Respect and comply with our quality commitments** by producing and supplying products and services that conform to the relevant specifications and meet contractual and regulatory requirements.
- **Focus on our customers** by ensuring that our products and services deliver the accuracy and timeliness expected by our customers.
- **Achieve operational excellence** through the development, implementation and continual improvement of systems in all aspects of our organisation.
- **Seek relevant certification and accreditation** of our management systems where appropriate to the requirements of all applicable standards.
- **Reduce variation and waste** by ensuring that the right measures guide process management decisions
- **Maintain productive management systems**, to the international standards detailed in the quality manual, to ensure they are relevant and contribute to the efficient and reliable operation of the business.
- **Integrate quality objectives into our business** to ensure that the needs and requirements of users are met.
- **Hold employees accountable** for maintaining the quality of work in their area and carrying out their duties in accordance with this commitment.
- **Source economical and reliable products** from suppliers with the objective of getting the best combination of value and quality for our customers.
- **Establish a robust system** of risk oversight, management and internal controls.
- **Deliver expert reference and analytical services.**
- **Provide efficient cost-effective services** to clients.

The objectives outlined in our business plans will be used to measure our success in effectively implementing this commitment

HealthSupport Queensland

Management Review Procedure – Health Support Queensland (HSQ)

1 Purpose

To provide guidance for the periodic maintenance and review of the management systems throughout HSQ.

Management Review is the key process used for coordinating improvement efforts throughout HSQ. Management is required to periodically review the whole quality system to ensure that it is still aligned with the required standards; the HSQ Quality Policy and continues to be suitable for the organisation. It is an opportunity to not only review those issues relating to the Quality System but to ensure that other environmental factors that may impact on the organisation and the way it operates are reviewed . Outcomes from the Management Review should feed into organisational plans and priorities.

2 Scope

This procedure shall apply to management reviews at all levels throughout HSQ. Refer to the HSQ Governance Manual 14473

The individual branches which make up HSQ have responsibility for the review maintenance and improvement of that part of the Quality System under their supervision.

Reports on quality system activities may be produced at all levels of the organisation from the "Management Review" module in QIS, (refer QIS User Manual – Reports 26214)

This information, where relevant shall be considered at Service, Department & work area level meetings where appropriate.

3 Definitions

QIS Quality Information System

4 Actions

4.1 General Information

HSQ exists in a complex environment and is constantly impacted by changes from a multitude of sources. The Management Review process is an excellent opportunity to perform a broad environmental scan and ensure actions are in place where required.

Each service shall determine and document the form and structure of the management review process for their area of responsibility.

As well as a Management Review meeting, regular management meetings shall be conducted as required, the purpose, objectives, attendees, frequency, reporting structure,

mandatory topics to be covered and how outcomes will be communicated and followed up should be documented.

4.2 Frequency

Each branch shall determine the frequency of these meetings and ensure they are regularly scheduled. The frequency shall be determined to ensure that critical areas of management, in particular the contribution to patient care and client satisfaction are addressed.

4.3 Matters considered in the review- Inputs

In addition to matters relating directly to the appropriate level of management, the following issues shall be considered, where relevant, at reviews at all levels:

- Implementation of quality related issues/objectives arising from organisational plans
- Status of Key Performance Indicators
- Reports from managerial or supervisory staff
- Customer service issues, including client complaints
- Opportunities for Quality Improvement (OQI's), their status (open or closed) and the effectiveness of corrective action taken. Refer to 13965 for details of the escalation procedures for OQIs
- Outcomes of internal audits (e.g. usefulness, progress with schedule, new/urgent issues which require audit)
- Assessments by external accrediting and certifying bodies, status and improvement opportunities.
- Document control – including new documents and number overdue for review
- Recommendations for improvement to the quality system
- Results of Proficiency Testing (appropriate action taken , sign off of non-conformances)
- Major changes in organisation and management resources or processes
- Identification and minimization of risk
- Staff training & professional development status
- Occupational Health and Safety issues as applicable
- Operational issues as applicable
- Ensure TGA Licensed Laboratories consider the requirements of section 113 of Australian Code of Good Manufacturing Practice for human blood and blood component, human tissues and human cellular therapy products

4.4 Documentation

An agenda shall be developed for management reviews at all levels.

The results of any meeting shall be documented in the minutes of the meeting within which it was tabled. These minutes shall include any objectives and associated action plans. (Pathology Queensland Refer QIS 26883)

Staff shall be informed of meeting outcomes as appropriate

Records of all reviews shall be retained for a period of time in accordance with legislative requirement

4.5 Management Review Outputs

The objective of the Management review meeting is to obtain feedback on how the management system is functioning; to identify risks and to make appropriate plans to ensure that the laboratory's aims, behaviours, procedures and strategies remain aligned. The output of the Management Review meeting should be improvement focused.

The Chair of the Management Review meeting shall ensure that the decisions made shall be documented and records of the review retained. Decisions are required for:

- Improvement of the Quality Management System and its processes
  - Performance improvement objectives e.g. OQI status/audits etc.
- Improvements related to processes
  - Performance objectives e.g. TAT
- Mitigation plans for identified risks
- Resource efficiency and needs

The decisions made at the meetings should be periodically reviewed and progress tracked throughout the year e.g. at Management meetings

5 Records

Management review records

6 Associated Documents

QIS 14473 HSQ Governance Manual
QIS 26214 QIS User Manual – Reports
QIS 19588 Pathology Queensland Laboratory Manual Template
QIS 26883 Pathology Queensland Management Review template

7 References

ISO 9001 Quality Management Systems Requirements
AS/ISO 15189 Medical Laboratories – Particular Requirements for Quality and Competence
AS/ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

8 Amendment History

Version	Date	Updated By	Amendments
1-7	Various	Various	See previous versions
8	April 2010	K Watson	Updated 4.1 difference between Management Review and Management Meetings. Included section 4.5 Management Review Outputs. Included Section 9.1 Branch Reporting Key from Feb 2010 management Review Report. Added reference to standards. Removed reference to Manager Planning and Quality and replaced with Quality Manager (CaSS). Changed approver
9	Sept 2011	K Watson	Updated Branch reporting key
10	Oct 2012	K Watson	Updated to new template changed CaSS references to HSQ.
11	June 2017	H Gregg	New Template. Replaced references to HSSA. Added dot point in section 4.3 to reference TGA requirements. Removed reference to archived documents and branch reporting key

Queensland Health
Forensic and Scientific Services

Forensic DNA Analysis Management Team
Management Review – Agenda

Date:
Time:
Venue:
Meeting Commenced at:

Secretariat:
File location:
G:\ForBiol\Forensic DNA Analysis Team Meetings\Forensic DNA Analysis Management\Management Review

Name	Initials	Position	Attending
Committee Members			
		Managing Scientist, PSS	
		Team Leader, Forensic DNA Analysis	
		Team Leader, Forensic DNA Analysis	
		Senior Forensic Scientist	
		Senior Forensic Scientist	
		Senior Forensic Scientist	
		Senior Forensic Scientist	
		Senior Forensic Scientist	
		Administration Support Officer	
Participants			
Guests -			

Preparation materials:

Prior to the management review meeting, management members are to prepare materials on the following topics. These materials are then collated by Quality team and distributed prior to the meeting so that they can be discussed.

1. Corrective Actions (OQIs and Adverse Events).
   - Status of OQIs (number opened/closed/pending etc)
   - Was the action taken appropriate?
   - What evidence is there of the effectiveness of the actions taken?

- Are there any trends/concerns that require follow up?

2. Stakeholder Issues/Complaints Status
   - Reviewed/analysed appropriately and in a satisfactory time frame
   - Corrective and Preventive Action generated?(OQI)
   - Are there any trends/concerns that require follow up?
3. NATA Assessments
   - Have all minor non-conformances and conditions from the last assessments been actioned?
   - Have all the observations been reviewed and actions taken where appropriate?
   - Have the actions taken been effective and sustainable?
   - Have the results of inspections at other laboratories been reviewed to ensure no adverse implications?
4. Internal Audit Program
   - Are internal audits performed as per the internal audit schedule? Is the scope adequate?
   - Are OQIs being raised and actioned appropriately from these audits?
   - Has the internal audits identified any significant risks to the business?
   - Has there been sufficient external input into the audits undertaken?
5. Proficiency Testing
   - Status of Proficiency Testing (number started/completed/pending etc)
   - Results of Proficiency Testing (results reported on time, accurate, and followed up)
   - New Proficiency tests (new to market, new scope of testing)
6. Risk Assessments: Status of Risk assessments (number started/closed/pending etc)
7. Occupational Health and Safety: Status of OHS (number of events etc) and trends
8. Document Control
   - Document Activity from QIS
   - Are documents being actioned in a timely manor
   - Are there any areas of concern?
9. Quality Improvements and Projects
   - Trend analysis on in-house quality controls
   - Status of Quality Improvements and Projects (number started/closed/pending etc)
   - Include minor change register review
   - What are the outcomes of the improvements and projects?
   - Future needs and directions?
10. Training and Professional Development: Current status and future needs
11. Supplier performance
    - Status of Supplier performance issue (number of issues observed/actioned/pending etc)
    - Instrument Servicing (significant issues)
12. Key Performance Indicators (KPIs): Review trends, have targets been met?
13. Finance: Budget status
14. Strategic Plans
    - Status and outcomes of improvement projects
    - Significant stakeholder enquiries and projects
    - Impending changes that could affect management system integrity
    - Key business objectives

Item	Topic	Lead	Paper Attached
1	**Welcome and apologies**	Chair	
1.1	**Acknowledgement of Country** I would like to acknowledge the Yuggera peoples and Turrbal peoples as the Traditional and Cultural Custodians of the lands	Chair	

	upon which we meet today Meanjin Brisbane and pay respect to Elder's past, present and emerging.		
1.2	**Confirmation of attendees and apologies**	Chair	N/A
1.3	**Conflicts of Interest** <<Enter NIL conflicts of interest to be noted>>or list		
2	**Standing Agenda Items**		
2.1	**Previous meeting** - Previous meeting minutes are endorsed by email vote and stored with minutes in network location. - Business arising from previous minutes <<Enter NIL or list>>		
2.2	**From review prepared materials discuss the following** Are there any areas of deficiency we need to address immediately? Are there any concerning trends that we need to review in more depth? Are we distributing our resources efficiently? Does anything need to change? What have we done that is new? Is it working well? Is there something we need to do more of? Is there something we need to do less of? Is there anything we need to change to make the management review more effective?		

Meeting closed at:

Internal Audit Procedure

1 Purpose

The performance of internal audits is an essential part of a quality system and is a requirement of ISO 9001 (clause 9.2), ISO 17025 (clause 8.8) and AS ISO 15189 (clause 4.14).

This document describes the procedure to follow to perform internal audits throughout Forensic and Scientific Services (FSS), Biomedical Technology Services (BTS) and Pathology Queensland (PQ). These audits aim to identify critical processes of the organisation, associated risks and the effectiveness of controls. They also seek to identify improvements and whether all requirements of relevant standards are met.

Unless made private, all audits on QIS2 are available for viewing by all staff (see 3.9 below).

2 Scope

This procedure applies to all staff throughout FSS, BTS and PQ who manage and perform internal audits, both scheduled & unscheduled.

Reference is made at various points to QIS2 (the Quality Information System). This procedure does not describe in detail how to manage audits in QIS2. Information on this can be found in the help files of QIS2 and in the User Manual Audits (document 26210). It also does not discuss auditing techniques in detail. Such matters are dealt with in auditor training courses.

3 Definitions

Acronyms –

- NATA: National Association of Testing Authorities
- BSI: British Standards Institution
- TGA: Therapeutic Goods Administration

Clinical Pathway audit – Audit performed which directly relates to a set clinical pathway i.e. a set path that identifies the expected course of events for the majority of patients.

Compliance with standard audit – An audit carried out to check compliance with a particular standard such as ISO 17025, ISO 9001, AS/ISO 15189, TGA or other regulatory requirements.

Compliance with documentation audit – An audit to assess compliance with documented policies or procedures, or to assess the accuracy of a documented procedure or method.

External Agency audit – An audit or review carried out by an external agency for compliance, benchmarking or improvement purposes. Auditors or reviewers might include government or non-government agencies.

Follow-up audit – Audit conducted to determine whether recommendations made as a result of a previous audit or OQI have been implemented and are effective.

Location-based audit – These audits examine a chosen part of the organisation (e.g. Organic Chemistry laboratory, Central Specimen Reception) for a wide range of relevant activities (e.g. installations, support services, computer systems, training, environmental monitoring, maintenance, calibration, etc.).

Operational Review audit – A review of operational activities, functions and/or structures.

Process – Any activity or set of activities, which uses resources to transform inputs into outputs. ISO 9001 definition – "a set of interrelated or interacting activities which transforms inputs into outputs". Examples: specimen reception, investigating food complaints, payroll and leave processing, illicit drug analysis.

Process audit – An audit of an entire process or a part thereof. A process audit may encompass a number of standards and documents. Process audits focus on:

- the critical elements of a process,
- potential risks and their consequences,
- associated controls,
- interactions with other processes and activities; and
- potential improvements.

Private Audit – Functionality in QIS2 that allows the details of the audit to remain private. A private viewer is appointed if there is a security risk if the information is generally available. If a private viewer is nominated, only those users nominated can view the audit.

Quality Administrator/ Audit Administrator – is scoped to an organisational unit (OU – e.g. Organic Chemistry) and special privileges only apply within that OU. Quality Administrators can perform all functions in the OQI and Audit modules. Audit Administrators can perform all functions in the Audit module only.
The role of the Quality or Audit Administrator is

- to assist their Line Manager and others within their organisational unit to manage their audit events

Their responsibilities are

- to comply with the requirements of this document and any other relevant standards, and
- to obtain appropriate authorisation to perform functions on someone else's behalf.

Queensland Health audit – Carried out by another Queensland Health Division or Business Unit e.g. Audit and Operational Review, Information Division, etc

Risk Management audit – An audit scheduled to assess risk around a particular process or location.

Workplace Health and Safety audit – A workplace health and safety inspection.

4 Actions

4.1 General

Topics audited should be selected on the basis of risk, that is, the likelihood of something going wrong and the consequences if it does. The greater the risk, the more important it is to audit a particular issue.

The overall audit program will concentrate on process audits but will include other audit types as required by each individual work area. Individual audit schedules will be

developed in conjunction with the managers of each work area. Auditors are generally selected by the work area manager and must be selected to retain independence of the area they are auditing. Progress against the schedules is monitored by the work area managers, quality managers or delegates.

Further details for Pathology Queensland audit management is documented in QIS document 25032. Further details for Biomedical Technology Services technical audit management is documented in QIS document 24827.

4.2 Scheduling of the audit program

When formulating an audit program, the Quality Manager or delegate shall consult with managers and team leaders in each work area regarding audit needs. Factors to be considered include:

- the importance of the process or activity to the organisation and its stakeholders.
- the degree of risk (a combination of probability of something going wrong and severity of the consequences) associated with it;
- the complexity of the process or activity (which determines how much of it can be audited at the one time);
- newness of the activity and experience level of the staff involved.
- results of previous audits and any history of past problems.
- possible overlap with other audits or assessments by external bodies.
- the resources available for auditing.
- issues raised in OQIs, or trends arising from OQIs
- benefit to the business

Once consensus is reached audit details will be scheduled on QIS2. Lead auditors will need to be assigned to enter the audit in QIS2 but can be changed later if necessary due to changed circumstances.

A minimum of three-month audits should be scheduled in advance. The schedule should be reviewed regularly and updated as required.

The audit schedule for areas accredited as a Proficiency Testing Scheme Provider shall ensure that all areas of the quality management system are covered over a three-year period (eg first year – planning, second year – operation, third year – data/reporting).

The Quality Manager or delegate has an overarching responsibility for monitoring the timeliness of audits conducted within the schedule and reporting problem areas to the relevant management committee. However, managers within each work area are responsible for ensuring audits are completed within an appropriate timeframe. This may require consultation with assigned auditors and managers in other areas to prioritise resources.

Individuals given the Quality/Audit Administrator role in QIS2 can assist the individuals in 4.2 to monitor audit progress. They are not responsible for ensuring audits are completed.

4.3 Auditors

All auditors shall be trained in auditing techniques. The Quality Manager or delegate are responsible for arranging training and maintaining a record of this. Inexperienced auditors should not be required to perform an audit without the assistance of an experienced colleague.

Auditors shall not audit their own work but should preferably have some general knowledge of the subject matter of the audit. Where possible, auditors should not be requested to do more than 2 or 3 audits per year.

Certain audits (e.g. some in the IT area) may require specialised knowledge, and expertise from outside the organisation may be sought.

4.4 Audit preparation

Each audit will be unique and thus the auditor should become familiar with relevant parts of the process, prioritise what should be examined and customise a checklist.

The auditor must get in touch with the designated audit contact prior to the audit to arrange a convenient date and time. It will sometimes be necessary to have a pre-audit meeting to discuss:

- the scope and general format of the audit.
- when it will take place.
- who will be the main auditee and what other staff are likely to be involved.
- what local documentation exists (e.g. procedures or test methods) relevant to the audit.
- what other documents (e.g. standards) may need to be consulted.

QIS2 contains both a blank checklist template (19145) and a general process checklist (19130), which can be downloaded and edited to suit. Checklists for each of the standards are also on QIS2 and are referenced during audit training. Another possible source of relevant questions includes NATA pre-assessment checklists for the field of accreditation concerned.

4.5 Conduct of the audit

The checklist is used as a guide during the audit. Notes should be taken at the time of the audit so that details are not forgotten. Points to consider when auditing include:

- where relevant, interview not only the main auditee but other staff as well.
- try to see objective evidence where possible, using multiple sources where necessary.
- generally, examine only those records relevant to the timeframe of the audit.
- discuss any apparent problems found at the time of the audit, so that there are no "surprises" when the audit report is issued, and misunderstandings are avoided.
- give due credit when things are done well.
- recommend improvements where possible.

4.6 Audit reporting and follow-up

Audit findings and recommendations must be recorded in QIS2 as soon as possible after the audit has taken place. If any significant non-conformances or potential problems or improvements are found, it will probably be necessary to raise one or more Opportunities for Quality Improvement (OQI). These may not necessarily be directed to the audit contact, particularly in the case of higher-level problems.

There is provision in QIS2 for these OQIs to be linked to the audit. Similarly, if auditing has been done against any of the other resources available in QIS2 (reminders, calibrations, previous audits, controlled documents), these can be linked to the audit report via 'associations'. Other records (not in QIS2) that were also audited can be linked to the audit report via 'records'. Suggested changes or improvements to controlled documents in QIS2 are managed by adding a comment to the relevant document.

Where possible, before exiting an audit, an agreement regarding the audit findings and terms (including timeframes for action) of any OQIs raised should be achieved with the audit contact. There is provision for the audit contact to acknowledge the audit report electronically. Any significant disagreements must be recorded in QIS2 and should be referred to the Quality Manager or relevant manager if they cannot be resolved.

OQIs resulting from the audit are to be investigated, actioned and followed up according to OQI management procedure (13965)

4.7 Unscheduled audits

An unscheduled audit shall be undertaken when events indicate that there is a significant problem or potential risk. This could result, for example, from investigation of a client complaint.

An unscheduled audit shall be carried out and reported in QIS2 as soon as possible.

4.8 Management review

In addition to being able to view reports on individual audits, managers have access to the audit program status via QIS2. Management review of internal audits shall be a standing item at management committee meetings and shall include discussion of;

- results/outcomes from audits and any actions arising
- outstanding audits and plan around completion of the audit
- review of the audit schedule to ensure continuing relevance (e.g. based on resources, operational changes and identified risks)

The Quality Manager shall also report to the Management Committee any issues requiring action on their part.

5 Records

Audit schedules (in QIS2)
Audit checklists (to be retained in accordance with the General Retention and Disposal Schedule for Administrative Records)
Audit reports (In QIS2)
OQI's arising from audits (in QIS2)
Comments on documents (in QIS2)
Minutes of management committee meetings (to be retained in accordance with the General Retention and Disposal Schedule for Administrative Records)

6 Associated Documentation

26210	User Manual Audits
13965	OQI Management
25032	Pathology Queensland Generic Audit schedule
21071	Pathology Queensland Compliance to Standards Audit Checklist
19145	Audit Checklist – Blank Template
19130	Audit checklist - general

7 References

ISO 9001 Quality Management Systems - requirements
ISO 17025 General requirements for the competence of testing and calibration laboratories

AS ISO 15189 Medical laboratories – Particular requirements for quality and competence
ISO Guide 34 General requirements for the competence of reference material producers

8 Amendment History

Version	Date	Updated By	Amendments
1-11	Various	H Gregg	See previous versions
12	Mar 2011	H Gregg	Section 4.1.2 added new Chemical testing requirement that audit schedule must cover both management and technical requirements
13	Jan 2013	H Gregg	Updated to HSSA, removed branch specific details
14	Aug 2014	H Gregg	Updated to HSQ. Added plan to ensure all QMS is covered for PT accreditation
15	Sep 2016	H Gregg	Added ISO 17043 and ISO Guide 34 to sections 1 and 7. Updated title of doc 21071 New headers and footers
16	Feb 2019	H Gregg	General update
17	July 2019	H Gregg	Removed reference to ISO 17043
18	July 2021	H Gregg	Removed reference to HSQ

HealthSupport Queensland

Opportunity for Quality Improvement (OQI) Management Procedure (HSQ)

1 Purpose

Continuous improvement is the underlying principle of the HSQ Clinical Governance and Quality program. This procedure describes the management of an "Opportunity for Quality Improvement" (OQI) arising within the organization and is designed to address the applicable requirements of ISO 9001: section 8.5, ISO 17025: sections 79 and 8.7 and ISO 15189: sections 4.8 - 4.12. The procedure documents the steps to be taken to investigate and action incidents that do not conform to established policies, processes and procedures. In addition, this procedure details the steps to be taken if the non-conformance results in the recall of a therapeutic good.

2 Scope

This document covers creation, investigation, action, follow-up and approval of OQIs. This procedure applies to all HSQ employees except CISSU staff.

Where applicable this procedure is to be used in conjunction with the Queensland Health Clinical Incident Management policies and procedures and the HSQ Risk Management Framework

3 Definitions

Actioner	The person responsible for investigating and actioning the OQI.
Adverse event	Means an event arising from the use of a medical device that might lead, or might have led, to the death or serious deterioration in the state of health of a patient, a user of the medical device or another person.
Approver	The person responsible for approving the OQI (normally the Actioners Line Manager)
BTS	Biomedical Technology Services
Clinical Incident	An event or circumstance which could have, or did, lead to unintended harm to a person
CISSU	Clinical Information Systems Support Unit
Creator	The person responsible for raising the OQI
FSS	Forensic and Scientific Services
HR	Human Resources
HSQ	Health Support Queensland
IMS	Incident Management System
Issue Register	List of issues or situations requiring resolution. Registers are maintained at a low level (e.g. team/laboratory), and pose negligible/low risk
NATA	National Association of Testing Authorities
OQI	Opportunity for Quality Improvement

Non-conformance	Something that happens that does not conform to established policies, processes or procedures. Other terms used include, *adverse event*, *error*, *non-conformity*.
Participant	A person whose name is specified in a field in an OQI
PQ	Pathology Queensland
Private Viewer	A person appointed when there is a security risk if the information is made generally available. If a Private Viewer is nominated, only they and the OQI participants can view the OQI.
QH	Queensland Health
QIS	Quality Information System
Quality Administrator	The person who can perform all functions in the OQI module
RCA	Root Cause Analysis a collective term that describes a wide range of approaches, tools, and techniques used to help identify what, how, and why an event occurred, so the cause(s) of the problem can be identified, and steps can be taken to prevent future occurrences.
RiskMan	Incident Management System
SAC	Severity assessment code, the measurement of consequences associated with a clinical incident. The SAC score (1,2,3) is used to determine the appropriate level of analysis, action and escalation of clinical incidents.
SAC 1	Death or likely permanent harm which is not reasonable expected [by the treating clinician(s), patient or family] as an outcome of healthcare.
SAC 2	Temporary harm which is not reasonably expected as an outcome of healthcare.
SAC 3/4	Minimal or no harm event which is not reasonably expected as an outcome of healthcare. Reference: Clinical Incident Management Implementation Standard (CIMIS)
Task Assignee	The person who receives and completes a task
TAT	Turnaround time
TGA	Therapeutic Goods Administration.
WH&S	Workplace Health and Safety

4 Actions

4.1 General Information

This procedure does not cover the in-depth instructions for recording OQIs in QIS. That information is contained in document 26209http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=10001 QIS^2 User's Manual – Opportunity for Quality Improvement (OQI).

OQIs are process and system focused. They are about making permanent improvements to the way we do things. They shall not be used to blame or confront people and do not replace good communication, management, process and policy. They do not replace the QH grievance procedures and should not be used to advise managers and supervisors of HR issues with other staff members.

Instances that present themselves as opportunities to improve processes and systems arise from many sources including during routine work and audits (internal and external). An indication of what should and shouldn't be managed as an OQI is described below and a quick reference guide is available in Appendix 9

Workplace Health and Safety Incidents must be reported in RiskMan. Clinical incidents that relate to an HHS must also be raised in RiskMan.

All staff may raise an OQI and wherever possible have access to the records in QIS; however, a degree of judgment needs to be exercised in deciding what resources to expend on corrective and preventive action and associated record keeping. Examples of what should be classified as an OQI are detailed below.
An OQI **must** be raised for:

- Complaints from external clients (external to HSQ) – if a client or external party expresses displeasure, irritation or anger over an issue where accepted service levels, or behavior have, or are perceived to have been breached. This does not include general enquiries about completion dates if agreed TATs have not been exceeded. In addition, any RiskMan Customer Feedback incidents reported against Pathology Queensland must be treated as a non-conformance and entered in QIS as an OQI and categorised as a complaint. The RiskMan reference number must be included in the OQI title to assist with traceability.
- **Clinical incidents**:
  - PQ episodes of non-conforming results that have had or with the potential for an Adverse Clinical Event shall be recorded in QIS. If a RiskMan incident is raised by an HSS staff member to PQ for action, the incident must be raised as an OQI. The RiskMan reference number must be included in the OQI title to assist with traceability. QIS 23422 - Amendment or Deletion of Patient Results outlines how to manage a Clinical incident. Records of investigation and actions taken must be recorded in QIS and where applicable, include relevant information in the applicable sections of the RiskMan Incident refer Appendix 8. If required RiskMan HSQ web site, and RiskMan Management Procedure QIS 34517 have additional information.

    Note: For SAC1 events the General Manager Pathology Queensland, Executive Director Laboratory Operations, Quality Manager, Chief Pathologist, relevant Discipline Director and Principal Chief Scientist, and Operations Managers **must** be notified as soon as possible and copied in to all related communications.
  - FSS clinical incidents are recorded in RiskMan and managed as per QIS 35201.
- Conditions identified during external audits/assessments/quality assurance processes by NATA/BSI or other Regulatory Authorities (TGA) e.g. major or minor non-conformances, or a material, product or service that fails to meet one or more of the applicable specifications.

  A quality risk assessment is required to be carried out for any actions that are implemented for TGA work

  Note: When PQ staff are notified of a TGA related recall by a supplier or the TGA, the "TGA Recall, Hazards and Safety Alerts Procedure, Pathology Queensland", shall be followed (QIS 27956).
- When continuity of evidence has been significantly compromised.
- Where there is a significant deviation from the documented process.
- PQ staff must raise an OQI for any non-conformances relating to therapeutic goods or any critical material used in the collection, handling, processing and testing of the manufactured product.
- PQ staff must raise an OQI for any adverse clinical event relating to the use of an in-house IVDs. Refer to Appendix 7 for legislated time frames and TGA reporting obligations

- All episodes of non-conforming results with the potential for an Adverse Clinical Event shall be recorded in QIS (for PQ or FSS to action) or RiskMan (for HHS to action).
  - For PQ, refer to Amendment or Deletion of Patient Results 23422. Staff must notify the Discipline Director, the Quality Manager and any other staff as necessary regarding the occurrence.
  - For FSS, refer to document 35201 for management of adverse events
- Non-compliances identified during internal audits
- EQAP, collaborative or external proficiency trial where outliers or problems/trends with test methods have been identified.

An OQI **can** be raised for:

- Problems that occur internally (within HSQ). For example:
  - Breakdowns in communication that lead to errors or a reduced level of service
  - Problems with specimen referral between laboratories or service delivery problems between teams or work units.
- Issues arising from an audit (recommendations);
- Compliments or praise received from clients external to the work unit.
- Suggestions for improvements from staff members.
- Actions from specific improvement initiatives such as the staff survey strategies.
- Problems with suppliers of goods and services to HSQ – these may be directed to the Procurement Manager who will use the information in both; addressing the issue, and as an information source in any future negotiations. In these instances, the supplier should be provided with a copy of the OQI details for them to have the right of reply. Their response can then be added to the OQI for completeness.
- Unintended Human Error (non-cognitive error) – an example in a laboratory setting is a scientist who enters "positive" instead of "negative" as a laboratory result. Note however that "human error" is not a root cause and that the attribution of "unintended human error" does not signify an end point where we cease looking for further explanations. "Human error" is a consequence of deeper underlying issues and is just the starting point to look more deeply into the features of people's tools, tasks and operational/organisational environment that could have caused them to make otherwise inexplicable decisions. [15] Explanations may lie in mental fatigue, fixation on certain information or events, heightened stress levels, concentration issues e.g. distractions, conflicting goals (turnaround time versus safety/quality), etc. The point is not to find where people went wrong, it is to understand why their assessments and actions made sense to them at the time (given their knowledge, focus of attention, their objectives, and objectives of the organisation).
- Environment – this is often used as a cause and effect category. An example could be where the air-conditioner breaks down and the resulting increase in temperature causes the biochemistry analyzer to malfunction or break down.
- Mitigation of risk – when things might go wrong.

Issues registers can be used at the team/laboratory level for negligible and low risk issues where an OQI does not need to be created. Issues registers shall be reviewed on a regular basis (e.g. at each team/lab meeting) and if any systematic issues are detected, an OQI shall be raised. The use of issues registers can be used for recording the circumstances listed above and may assist with determining when an OQI should be raised.

OQIs should **not** be used for:

- **Routine maintenance issues** with equipment until the problem becomes systemic, calamitous or a regular occurrence that requires a root cause analysis.
- **Minor methodology or QC errors** until the problem becomes systemic, calamitous or a regular occurrence that requires a root cause analysis.
- **Ministerials** unless systematic issues are detected and/or it relates to a Clinical incident or significant complaint. Ministerials are managed and recorded at the Office of the Chief Executive.
- **Grievances regarding other staff.** These should be lodged according to standard HR process.
- **Software problem reporting.** For the reporting of these problems, use the relevant systems – e.g. Help Desk [redacted].)
- **Complaints received by the Animal Ethics Committee (AEC).** These are dealt with according to FSS – Animal Ethics Committee Terms of Reference and Operational Procedures 10642

With very sensitive or confidential issues, or where there is a need to name individuals, it is possible to limit access of the OQI details via the use of the 'private viewers' functionality in QIS (See QIS² User Manual – Opportunities for Quality Improvement 26209).

Although the primary purpose of the OQI system is to record information on situations that require changes to systems or processes, the OQI database can also be used as an information resource. When a problem is encountered, such as an instrument malfunction that is difficult to overcome, details of the nature of the problem, the root cause and the solution can form the basis of an OQI. Staff encountering similar difficulties at a later date can benefit from the previous work that was done.

Personal Information

Please note: staff, patient, client or offender/complainant/suspect names must not be recorded in the OQI module on QIS. Recording personal information in this manner does not meet the requirements of the Privacy Principles contained in Information Standard 42A (IS42A) that sets out the privacy regime for the Queensland Health. Furthermore, revealing the identity of a person who has received a public sector health service contravenes Section 63 of the Health Services Act 1991. However, staff names can be used in Compliment OQIs.

When identifying, investigating and actioning OQIs that relate to laboratory results, de-identified information such as Auslab or laboratory numbers shall be used to provide traceability.

4.2 Initiating or Creating an OQI

When creating an OQI in QIS, important points to note are:

- Title and a description of the OQI – keep it simple, brief and to the point but ensure that the whole issue can be understood. Cross reference any related RiskMan incidents
- The source of the OQI – For example an internal problem, as the result of an audit, or a suggestion.

- An attempt made to classify what needs fixing/changing.
- Your location details.
- The person who you believe is responsible for taking appropriate action, known as the 'actioner'. It is important to ensure that this person is in a position in which they have the authority or knowledge to progress the issue.
- You may also add Private Viewers and Notifiees; however, these fields are not mandatory. It is suggested that the creator's line manager be added as a Notifiee, if the creator's line manager and the actioner's line manager are not the same person.

Private Viewer: Please note that the use of private viewers should be discretionary, as populating this field limits the view of the OQI to the creator, actioner, actioner's line manager and private viewer only. If other staff are required to be kept abreast of the OQI's progress, please use the notifiees field instead.

It is a common courtesy to communicate with the person to whom you will be assigning the OQI. In this way, issues are bought to their attention sooner, any misunderstandings can be talked through and the OQI can be assigned to the appropriate person if the original actioner feels that it is beyond their control.

4.3 Assignment Acceptance/Rejection

Once an OQI is created, it is sent to the 'actioner' who can either accept or reject the OQI assignment. If the 'actioner' accepts the assignment, then the 'actioner' takes responsibility for the investigation and action stages of the OQI. If the 'actioner' rejects the assignment, a comment is mandatory to inform the creator of the reasons for the rejection. The comment should also nominate an alternate 'actioner'.

4.4 Edit an OQI

If an OQI assignment is rejected by an 'actioner', the creator can change the name of the 'actioner' and resubmit the OQI to the Assignment stage.

If an OQI is rejected by the 'actioner' as being unnecessary (as per details listed in Section 4.1), then the 'creator' can delete the OQI.

If an OQI is rejected by the 'actioner' as being unnecessary, but the 'creator' would prefer the issue be recorded, the 'creator' can:

- escalate the OQI to the actioner's line manager.
- escalate the OQI to the relevant Quality Manager if applicable.
- raise the OQI to themselves as 'actioner'.

4.5 Investigating an OQI

Principles of the investigation

The investigation should be thorough and credible.

To be considered **thorough**, the root cause analysis must include the following approach: [5, 6, 7]

- Inquiry into all areas appropriate to the specific type of event.

- The analysis (i.e. investigation) repeatedly asks a series of "why ..." questions (as well as how, when, and what, and may include questions such as 'what is the relevance?'), until it identifies the systemic causal factors associated with each step in the sequence that led to the adverse event.
- The analysis focuses on systems and processes, not solely on individual performance.
- A determination of the human and other factors most directly associated with the event and the process(es) and systems related to its occurrence
- Identification of risk points and their potential contributions to this type of event.
- A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

To be considered **credible**, the root cause analysis must meet the following standards: [5, 6, 7]

- The individuals most closely involved in the process and systems under review must participate in the root cause analysis.
- The root cause analysis must be internally consistent; that is, it must not contradict itself or leave obvious questions unanswered.
- For SAC1 events, the analysis must include consideration of any relevant literature.

A Thorough Investigation [9,10,11,12,13]

To enquire into all areas appropriate to the specific type of event. The following should be considered (not everything will be applicable) – see Appendix 2 for further detail:

- What happened?
- Training and Competency
- Work Environment / Fatigue / Scheduling (Rostering)
- Equipment and Information Technology
- Communication
- Policies, Procedures and Guidelines

For OQI's raised on Pathology Queensland a risk assessment, based on the Department of Health's Risk Analysis Matrix should be performed and recorded in the *Investigation* stage of the OQI. The actions taken as a result of the investigation should be commensurate with the level of the identified risk, see worked example in Appendix 4.

When investigating the reasons why an OQI has arisen it is essential to determine the real "root cause". For example, it may be tempting to attribute the cause to a one-off mistake; however, it is more probable that the real cause is due to:

- inappropriate or inadequate training,
- problems with communication,
- inadequate or incorrect documentation, or
- an ambiguous, confusing or ineffective process

Unless the real cause is dealt with, there is every chance there will be a recurrence of the situation.

Some OQIs can take an extended period to determine the root cause. Dated notes should be added as progress reports to the investigation text field until finalized. This will indicate that things are still ongoing and that the OQI is not being ignored.

Writing Causal Statements [9, 10, 11, 12, 13]

Causal statements are frequently included in root cause analysis. These are succinct statements that can be included at the end of the investigation to summaries the investigation and show a clear link between the contributing factors and the incident/outcome. Contributory factor statements need to focus on process and system vulnerability rather than the action of individuals. See Appendix 3 for further guidance.

1. Causal statements must clearly show the 'cause and effect' relationship.
2. Use specific and accurate descriptors for what occurred, rather than negative and vague words.
3. Human errors must have a preceding cause.
4. Violations of procedure are not root causes but must have a preceding cause.
5. Failure to act is only causal when there is a pre-existing duty to act.

4.6 Actioning an OQI

A **corrective / preventive action** plan will be considered **acceptable** if it:

- Identifies and implements actions to eliminate or control systems hazards or vulnerabilities. The actions must be applied to all relevant Laboratories/areas within the organisation

OQI investigators/actioners should, where possible, attempt to identify actions that are likely to reduce the risk or prevent the event from recurring and if that is not possible, reduce the severity or consequences if it should recur.

When taking action in response to an OQI it is often necessary to take corrective action immediately, however, it is also essential to address the root cause of the problem (as identified in the investigation phase) and make permanent changes to systems and processes, e.g. change methodology, train/retrain staff or revise a form to ensure ease of use. This is "preventive action" and aims to stop the same situation arising in the future.

Reprimanding people, retraining people, rewriting policies, etc. [8]

The most popular recommendations to come out of 'human error' investigations (in industries ranging from construction to oil & gas to healthcare) are retraining people or rewriting a policy, however:

- Reprimanding people involved in the incident typically prevents learning from that incident. While it may provide the illusion that others will learn to be more careful, it is likely to make people want to hide errors.
- Retraining the people involved will have limited reach into the organisation but is relevant where training has been inadequate. Performance could be symptomatic of deeper problems and issues that all your people or similar practitioners are exposed to.

- Writing an extra procedure often only deals with the latest "hole" uncovered by the mishap may simplistically assume one best method (as specified in the procedure) is the remedy. Where a procedure is not documented at all, then the creation of a procedure is justified.
- Adding just a little bit more technology may create new work for people, new error opportunities and new pathways to breakdown.

Linking actions to the causation

OQI actions sometimes fail to clearly show a link between the proposed actions and the causative factors.

Each action/intervention should be clearly linked to one or more causative factors. For example; if the staff member was trained, competent, experienced and knowledgeable about the expected workflow, impact of the error and policies/procedures, there is little logic in recommending training.

Weak risk-reduction strategies

- **Reminders**
  The available evidence points to the endemic tendency of investigators to settle for administrative and perhaps 'weaker' solutions (such as reminders) rather than those that address the latent causes, such as poorly designed technology or defective operational systems.[15]

- **Reminders to try harder and watch out better** [14]
  While raising awareness can be meaningful in the absence of other possibilities for safety intervention, the effects of such campaigns tend to wear off quickly. A reminder to try harder and watch out better, particularly during times of high workload, is a poor substitute for developing skills to cope.
- **Telling people to be more vigilant, to try harder, or not to make errors** [8]
  Telling people to be more vigilant (verbally, or with memo's and emails) does nothing to remove the problem, certainly not in the medium or longer term. Instead it is necessary to understand why it made sense for a staff member to do what they did, given the conditions in which they worked. The remedy does not lie in telling people not to make errors. The focus must be on fixing the process by addressing the gaps in tools and environment in which people work.

TGA Recall Required

If the investigation and corrective action of a PQ non-conforming event identifies that a TGA recall needs to be considered, the Discipline Director shall notify the General Manager laboratory Operations prior to the initiation of any notification to the relevant sponsor or TGA. If it is agreed through consultation with the sponsor and the TGA Recall Co-ordinator that Pathology Queensland shall initiate the Recall, follow the process outlined in Appendix 5

Assigning Tasks

Some OQIs require various tasks to be completed as part of the action process. It is the responsibility of the actioner to assign tasks to relevant staff, and to ensure that tasks are

completed in a timely manner. If tasks have been assigned, an OQI cannot be finalized until all tasks have been completed.

Business Case Required

For OQIs that turn out to be complex or resource intensive, a business case and project management process might be required. In this case it is acceptable to advise that this avenue has been pursued to progress the OQI and an audit scheduled for a suitable time to follow up on the effectiveness of the action.

Promises are Not Actions

In all other cases, the action shall be carried out before the OQI is submitted for follow-up. In this way it stays on the events of the person who still has a responsibility to do something with it. Promises are not actions.

For Forensic and Scientific Services, the action shall include a re-evaluation of the risks associated with the process. This should be recorded in the action box of the OQI.

4.7 OQI Checklist (Appendix 6)

Appendix 6, the OQI checklist includes a variety of checks that should be carried out when reviewing your investigation and actions. Many of these have been covered in the previous text of this procedure, however some may be being presented for the first time. You are encouraged to review this checklist before completing your investigation and action.

4.8 Following up and accepting an OQI

Once the OQI has been actioned, the OQI returns to the person who created it. This communicates that:

- the issue has been resolved in some manner, and
- creates an obligation to follow up to ensure that the actions been appropriate and effective.

It is possible at this stage that the OQI creator does not believe the action is enough/correct and may explain their reasons for rejecting the action and send it back to the actioner.

It is not enough to accept promises of action unless real progress has been made in implementation.

4.9 Approving an OQI

After the creator accepts the action taken, the OQI will divert to the line manager of the person who has actioned it. A decision needs to be made from a management perspective whether the action has been effective. If effective action has been taken, the OQI can be accepted and closed as Approved. If the OQI line manager does not believe the action is enough/correct they must reject it and explain their reasons why. It will then automatically be sent back to the actioner to address. In some cases, it may be impossible to take effective action, for example, due to insufficient resources or legislative reasons. In this case the OQI may be accepted with comment and closed as Rejected or Abandoned. It may be necessary to begin a new OQI process from the outcome of the current OQI, and in this case the OQI is accepted and closed as New. When the new OQI is created, cross-referencing occurs between the OQIs.

4.10 Create an Audit from an OQI

An audit can be scheduled from an OQI to ensure that the solution is effective over time. The creator and the actioner both have the ability to create an audit from the findings of an OQI, by using the New Audit action button on the OQI.

4.11 Timeframes for Addressing OQIs

The following guidelines shall apply for progressing an OQI from investigation to action to follow-up.

- An entry to the investigation field shall be made no longer than one week from the creation date to at least explain the approach that will be taken to address the issue.
    - The investigation field of the OQI can be updated as progress is made in addressing the issue. Once an investigation is complete, the OQI moves to the action stage.
- When the issue is finalised, and all tasks and actions have been taken, the action can be completed.
    - This will move the OQI back to the creator for follow-up and should occur within 30 days of the creation of the OQI.
- Follow-up shall occur at a time that will be able to verify the success of the implementation of the action.
    - This might be immediately or might require weeks or a few months to ensure effectiveness.
    - Provided there is an adequate record of intentions, and the follow-up is expedited as soon as possible, there is no need to rush the close out of the OQI.

Note: For OQI's raised by PQ, actions should be defined within 30 days and the OQI must be closed within 90 days unless there is an operational reason that prevents this. If the OQI relates to a clinical incident it must be investigated and escalated immediately.

Complaints shall be managed as outlined in the HSQ Feedback management framework HSQ-OP-FW-00001. Whenever possible, the laboratory shall acknowledge receipt of the complaint within 5 days and provide the complainant with progress reports and the outcomes and give formal notice at the end of the complaint handling to the complainant. This should be recorded in the OQI. Complaints must be investigated and actioned within 30 days wherever possible.

4.12 Management Review

The Management Review module allows the status of OQIs to be obtained at all levels of the organisation. Managers at all levels shall monitor issues within their own area and follow up on issues that appear to be stalled. They can then make decisions on resourcing, priorities and responsibilities to ensure the best possible outcome for the organisation.

The designated responsible officer within each Group Laboratory/Department/BTS Site/FSS team/Branch shall analyse the OQIs on a monthly basis and report any critical issues and the proposed or completed actions at least monthly. These issues shall be reported to the next level of management via the most efficient means e.g. Management meetings. These in turn will be escalated to the service executive meetings or HSQ executive by the chair of the committee, if deemed appropriate.

NOTE: The PQ Quality Manager shall prepare a monthly OQI status report for review at the Pathology Queensland Quality Committee (PQQC).

4.13 Roles and Responsibilities of the Quality Administrator

The role of the Quality Administrator is to help Line Mangers and others in their work area to manage events, and to assist in the management of OQIs, audits, and reminders within their scoped Organisational Unit.

The responsibilities of the Quality Administrator include complying with the requirements of the standards and relevant HSQ procedures and obtaining appropriate authorization to perform various functions.

5 Records

OQI records in QIS
Risk assessment documentation as required.
Meeting minutes where issues have been escalated and actions assigned.

6 Associated Documentation

QIS^2 User Manual – Opportunities for Quality Improvement	26209
Amendment or Deletion of Patient Results	23422
TGA Recall, Hazards and Safety Alerts Procedure, Pathology Queensland	27956
HSQ Risk Management Framework https://qheps.health.qld.gov.au/hsq-staff/about/controlled-docs/searchable-list	
Quality Risk Assessment Procedure (TGA)	31813
RiskMan Management Procedure	34517
OQI Investigation and Analysis Toolkit	31001

7 References

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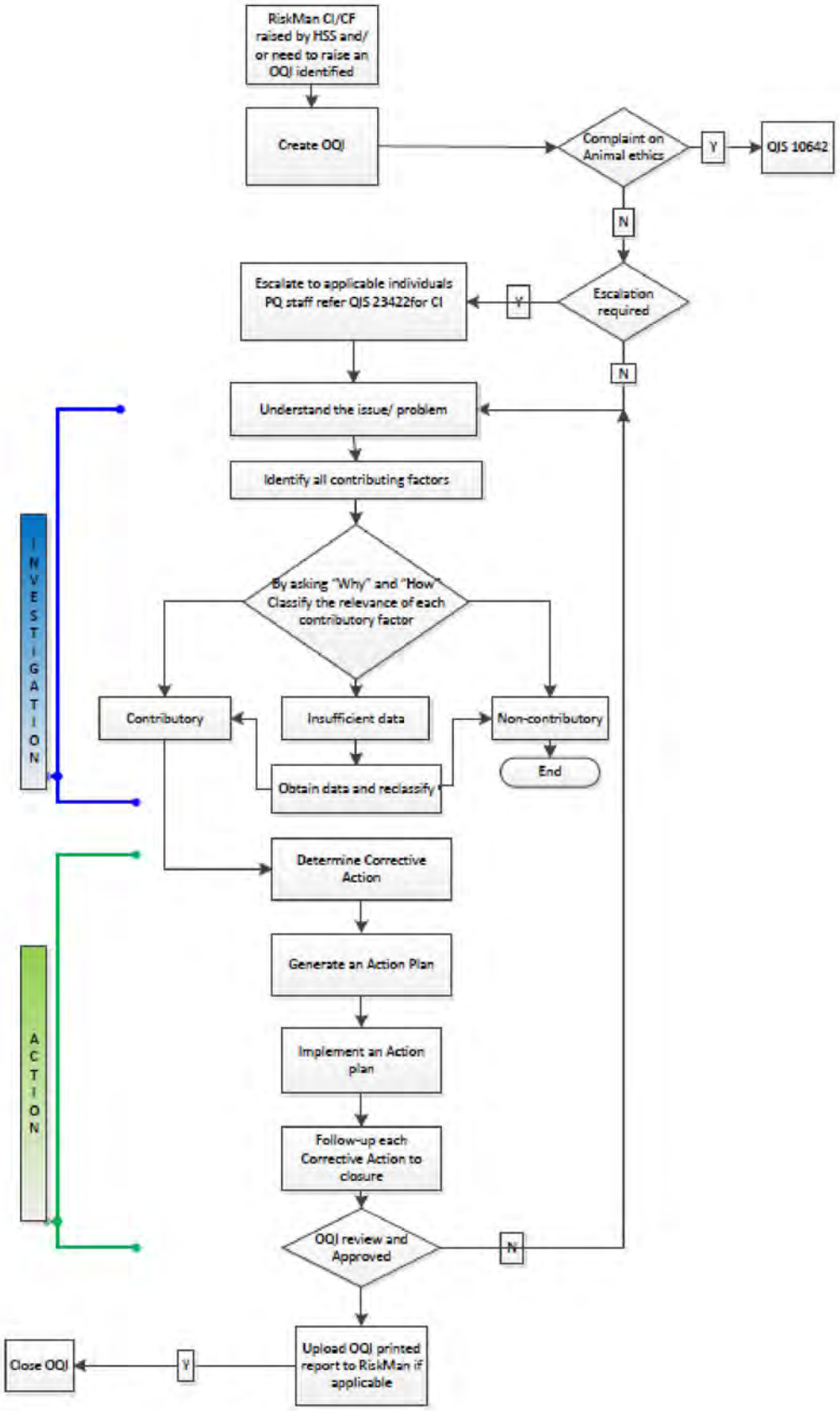
8 Amendment History

Revision	Date	Author/s	Amendment
0	Sep 1998	N Douglas	New format. Deletion of specific keywords. Requirement to monitor effectiveness of OQI's
1	Dec 2001	S.Nilsen S.Anderson	Conversion to QHPSS-wide document & QIS references
2	Feb 2003	S.Nilsen	Addition to scope-Problems and complaints with suppliers of goods and services to QHPSS; Addition to 4.1 Problems and complaints regarding suppliers to QHPSS may also be directed to the Materials Manager who will use the information in both addressing the issue and then in any future contract negotiations.
3	May 2004	S.Nilsen	Addition to scope re. logging conditions from NATA/BSI audits & privacy issues wrt names in OQI's
4	Jan 2007	S.Nilsen	Almost a total rewrite. Addition of a more rigorous governance and management review process, timeframes for action and examples and responsibility matrix. Change over to HSQ.
QIS² Edition			
Version	**Date**	**Updated By**	**Amendments**
6	Apr 2009	C. Della	Amended to reflect QIS² functionality.
7	Jul 2010	C. Della	Update Standards, what OQI can be used for, new committee names
8	Oct 2011	C Della	Minor changes to Section 4.1; additional information to Sections 4.3 and 4.4; All HSQ branches added to 9.1; clinical incident process added to 9.3
9	Nov 2011	C Della	Additional information to Section 4.1
10	Sept 2012	H Gregg	Inclusion of Issues Registers to Section 4.1, update to include HSQ, remove Appendix A,B
11	Nov 2014	M Hardwick	HSQ template and minor editorial changes
12	Nov 2015	M Hardwick	Changes to purpose and scope and various sections changed to address PQ specific directions.
13	Jul 2016	M Hardwick	Added TGA risk assessment. Updated amendment history table. Added doc 31813 Deleted dot point 1 in section 2 and appendix 2
14	Nov 2017	M Hardwick	Changes made to reflect use of RiskMan to capture clinical incidents and customer feedback
15	March 2018	M Hardwick	Updated references in section 1 Purpose to reflect current standards Updated section 4.10

Revision	Date	Author/s	Amendment
16	Feb 2020	D Burns M Hardwick	Major revision to: 1. include additional information to support investigation and action activities 2. Revise when to raise an OQI and how incidents must be handled in QIS and RiskMan 3. Update references and delete archived referenced documents 4. Update definitions 5. Include adverse event (post market) reporting relating to the use of their in-house IVDs Staff should read the whole document rather than individual changed sections, so they are familiar with requirements

Appendix 1: OQI Flow Chart



Appendix 2: A Thorough Investigation 9,10,11,12,13

To enquire into all areas appropriate to the specific type of event. The following (bolded) factors should be considered (not everything will be applicable):

What happened?

- Check what happened.
- Several questions are likely to arise naturally from the discussion(s) with the individuals most closely involved in the issue.

Training and Competency

- If relevant, review the initial training and competency records as well as ongoing (e.g. annual) assessments of competency.
- Are they complete?
- Do training and competency records cover the tasks, equipment, IT, safety checks, labelling checks, etc. involved in this incident / error?
- Are training records and competencies sufficiently comprehensive to include the specific tasks that may have contributed to the current incident / error (or are they too general in nature)?
- Is the employee the only person with this performance problem?
- Does the staff member feel training was adequate?
- Does the staff member feel frequency of exposure to the task or abnormality is an issue?

Work Environment / Fatigue / Scheduling (Rostering)

- If considered relevant, review the roster and assess whether fatigue could have been anticipated.
  - Consider frequency of being rostered to perform that task,
  - Did the roster allow the opportunity to get adequate sleep?
  - Did the staff member actually get adequate sleep?
  - Do you think fatigue was a factor?
    - Be aware that people are not good at assessing their own levels of alertness. If they are not experiencing symptoms of extreme fatigue like head nods, slow eye blinking or micro-sleeps, then they will probably say they are not fatigued because there are no overt cues to tell them they are fatigued
    - Fatigue levels range across a spectrum from wide awake to fully asleep, so questions such as "How fatigued are/were you?" may be better than "Were you fatigued?" which asks people to answer "yes" or "no" and forces people to choose between wide awake and almost asleep.
    - Self-assessment of fatigue is more accurate when people are experiencing high levels of fatigue.
- Consider whether elements of organisational culture contribute to the error e.g. organisational focus on productivity or turnaround times, financial/resource constraints, or organisational priorities?
- Were enough staff on hand for the workload at the time, for example, was workload too high, too low, or was there the wrong mix of staff?

- Note: this is not an invitation for unsubstantiated claims. It can be easy to assert that people got stressed; that there was high workload and that things got out of hand because of it. But this does not mean or explain very much .... What you can do is make an inventory of the demands in a situation, and the resources that people had available to cope with these demands. This is one way to handle your evidence.[16]

- Were distractions an issue? (provide details if relevant),
- Did the layout of the laboratory hinder the work from being carried out without issues?
- Did any physical environmental factors such as; noise, vibration, or lighting (for instance) contribute to the levels of environmental stress?
- Did any environmental factors such as; delays in getting samples, patient transfer, or levels of urgency communicated by other staff contribute to the levels of stress?

Equipment and Information Technology

- Did equipment contribute to the work not going as planned?
- Did the equipment display any alert or warning signals/messages?
- Was the staff member trained appropriately to operate the equipment involved in the adverse event / close call?
- Was the staff member trained appropriately to operate the software (e.g. Laboratory Information System) involved in the adverse event / close call?
    - Did the software (e.g. LIS) display any alert or warning signals / messages?
        a) If yes, what was the response to each of these warnings or messages?
        b) If one or more alert or warning messages were displayed and were overridden or dismissed by the staff member, why were the messages overridden or dismissed?
        c) If there were multiple warnings or messages, what prevented the staff member from responding appropriately?

Communication

- Was communication with supervisors or other laboratory staff adequate?
- Was adequate supervision provided for inexperienced staff?
- Was communication between laboratory staff and other front-line staff (e.g. hospital staff), adequate?
- Was communication of potential risk factors provided to the people who needed to know?
- Has this happened before, to the person involved in this issue or anyone else, and was anything done to prevent it from happening again?
- Do staff feel they can speak up or make suggestions if they are aware of any problems in the workplace?

Policies, Procedures and Guidelines

- Was the staff member aware of the policies and procedures (e.g. laboratory methods) that relate to this event?
    - If not, why not?
- Were there written, up-to-date policies and procedures in the laboratory that addressed the work processes related to the adverse event or close call?

- Were the relevant policies and procedures clear, understandable, and readily available to the staff that needed them?
- Were the relevant policies and procedures referred to?
    - If the policies and procedures were not used, what got in the way of their usefulness to staff?
- Were the policies and procedures adhered to?
    - If not, why not?
- Did the staff member perform all the safety checks (e.g. checking specimen details/labelling) described in the procedures, including multiple checks where required?
    - If not, why not?

Appendix 3: Writing Causal Statements 9, 10, 11, 12, 13

8.1 Causal statements must clearly show the 'cause and effect' relationship.

The statement should show the link between your root cause and the adverse outcome. Each link should be clear to the investigation team and others.

Incorrect: The scientist was fatigued.

Correct: The level of the scientist's fatigue increased the likelihood of the instructions being misread, which led to incorrect data entry and subsequent incorrectly labelled red cells.

8.2 Use specific and accurate descriptors for what occurred, rather than negative and vague words.

Words like "poorly", "carelessness" and "complacency" are bad choices because they are broad, negative judgments that do little to describe the actual conditions or behaviours that led to the mishap.

Incorrect: The procedure was poorly written.

Correct: The procedure was not indexed, used a font that was difficult to read, did not include tables or flowcharts, and as a result, the document was rarely used.

8.3 Human errors must have a preceding cause.

Identify the preceding cause(s) not the human error. Most mishaps involve at least one human error. Unfortunately, the discovery that a human has made an error does little to aid the prevention process. You must investigate to determine WHY the human error occurred. It can be a system-induced error (e.g. step not included in the procedure) or an at-risk behaviour (completing a task by memory, instead of using a checklist). For every human error in your causal chain, you must have a corresponding cause. It is the cause of the error, not the error itself, which leads us to productive prevention strategies.

Incorrect: The scientist did not check the label on the unit of blood.

Correct: The level of urgency caused the scientist to rush and take shortcuts, resulting in the label on the unit of blood not being checked.

8.4 Violations of procedure are not root causes but must have a preceding cause.

Identify the preceding cause(s) not the human error.

Procedural violations are not directly manageable. Instead, it is the cause of the procedural violation we are trying to manage. If a staff member is violating a procedure because it is the local norm, the incentives that created the norm will have to be addressed. If the staff member is missing steps in a procedure because he or she is not aware of the formal checklist, work on education.

Incorrect: The staff member did not follow the procedure for issuing blood products.

Correct: Noise and distractions in the laboratory, and pressures to quickly complete the issuing of blood increased the probability of bypassing the checking step; this resulted in the wrong unit being dispensed.

8.5 Failure to act is only causal when there is a pre-existing duty to act.

We can all find ways in which our investigated mishap would not have occurred – but this is not the purpose of causal investigation. Instead, we need to find out why this mishap occurred in the system as it was at the time the error occurred.

The duty to perform may arise from standard operating procedures, guidelines for practice, or other duties to provide patient care.

Incorrect: The scientist did not check for urgent orders every half hour, which led to a delay in the availability of blood, increasing the likelihood of delaying the operation.

Correct: The absence of an established procedure requiring checks for urgent orders every half hour, increased the likelihood that urgent orders would be missed or delayed, which led to a delay in the operation.

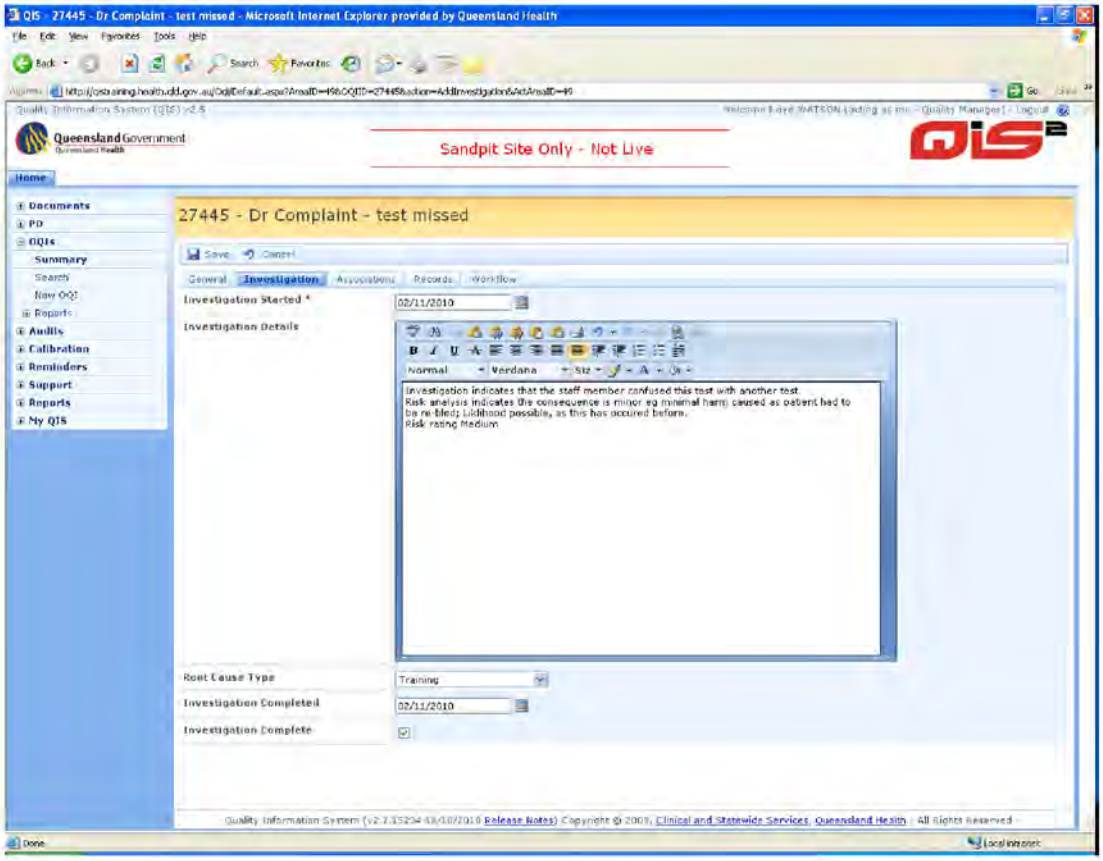
Appendix 4: Recoding Risk Rating in OQI

An example of how a risk rating can be used in an OQI is demonstrated below. During the investigation of an OQI, document the risk rating if relevant

Subject: An OQI raised after testing staff notice that a requested test was missed.

Investigation

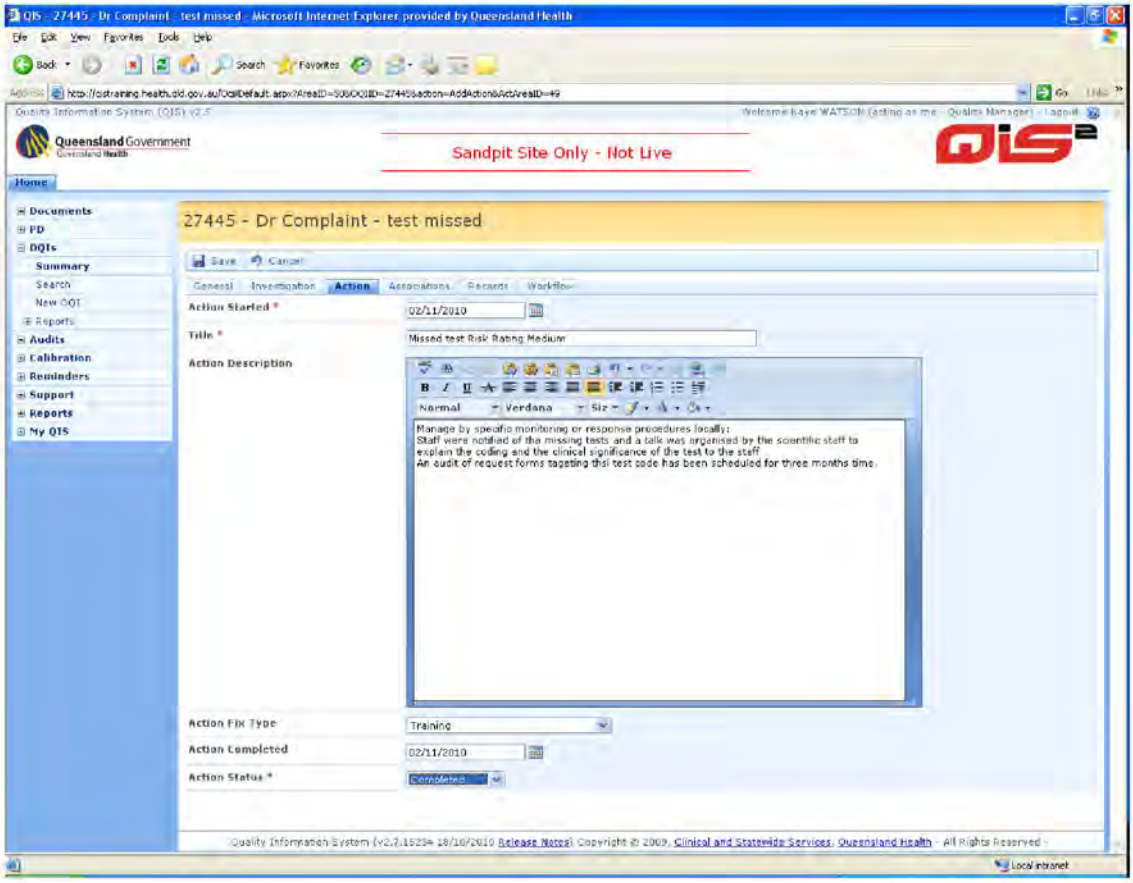
Investigation indicates that the staff member confused this test with another test.
Risk analysis indicates the consequence is *minor* e.g. minimal harm caused as patient had to be re-bled, causing minor interruption to routine; Likelihood *possible*, as this has occurred previously.
Risk rating Medium



Action required for a medium risk is to: *Manage by specific monitoring or response procedures locally*

Action Title
Missed Test - Risk Rating Medium
Document the Risk Rating in the Title on the OQI Action Tab)

Action:
Staff were notified of the missing tests and a talk was organised by the scientific staff to explain the coding and the clinical significance of the test to the staff
An audit of request forms targeting this test code has been scheduled for three months' time, audit #1234



Appendix 5: Pathology Queensland Product Recall Procedure for TGA related Tests

Where the investigation and corrective action of a non-conforming event (occurrence) is evaluated as outlined above and the committee decides that a recall may be necessary, the Discipline Director shall notify the General Manager laboratory Operations prior to the initiation of any notification to the relevant sponsor or TGA.

In most cases due to the nature of the manufacturing license(s) held by Pathology Queensland, the notification to the sponsor of non–conforming results will result in the sponsor initiating a product recall. However, if it is agreed through consultation with the sponsor and the TGA Recall Co-ordinator that Pathology Queensland shall initiate the Recall, the following procedure shall be followed.

8.6 Notification to the Co-ordinator

Recalls must be reported as soon as possible to [redacted] and by telephone or facsimile to the Australian Recall coordinator telephone [redacted] Mobile [redacted] Facsimile [redacted]

Recalls may be initiated based on potential harm to consumers as a result of analysis or testing of samples of therapeutic goods or through the discovery of a non -conformance. No recall regardless of level shall be undertaken without consultation with the Australian Recall Co-ordinator and without agreement on the required strategy.

Information sent with the notification must be sufficient to allow adequate assessment of the problem.

The Human Blood and Tissue Recall Reporting Form (Uniform Recall Procedure for Therapeutic Goods) shall be used to recall any human blood and tissue products). Electronic copies are available from the TGA website http://www.tga.gov.au/problem/recallbt.pdf.

8.7 Assessment of Recall

The nature of the deficiency in the product, the incidence of complaint(s) (refer RiskMan data), consumer safety etc., and must all be considered when assessing a recall and the strategy to be used. The classification and level of recall and strategy shall be decided in consultation with the TGA Recall Co-ordinator and the sponsor if relevant.

8.8 Recall

Letters explaining the recall shall be written by the Discipline Director or General Manager laboratory Operations as appropriate. Before any recall letters are sent to the relevant sponsor, they shall be submitted to the Australian Recall Co-ordinator for approval first.

8.9 Notification to the Federal Minister Responsible for Consumer Affairs

Where a re-call is safety related, (i.e. there is a risk of injury or harm to patients), there is a legal requirement under the Commonwealth Trade Practices Act 1974 for the sponsor to notify the Commonwealth minister via the ACCC within two days of taking recall action. The notification must:

- State the goods are subject to recall, and
- Set out the nature of the defect in, or dangerous characteristic of the goods.

Refer to Section M of the *Uniform Recall Procedure for Therapeutic Goods* for details.

8.10 Progress of Recall and Report

At two and six weeks after the implementation of a recall or at other agreed times, the sponsor shall provide the Australian Recall Co-ordinator with an interim and a final report on the recall.
The report must contain the following information:

a The circumstances leading to the recall,
b The consequent actions taken,
c The extent of the distribution of the relevant batch,
d The result of the recall,
e Confirmation that customers have received their letter,
f The method of disposal of the recalled goods, and
g Action proposed to be implemented in future to prevent recurrence of the problem.

8.11 Follow up action

The effectiveness of the recall shall be monitored by the Australian Recall Co-ordinator.

Appendix 6: OQI Checklist

1. Does the investigation provide in-depth understanding of the events being investigated by continuously asking "why did this (or that) happen" until all root causes have been identified?
2. Does the investigation focus primarily on systems and processes rather than individual performance or in any way placing blame on individuals?
3. Is an accurate sequence of events important in understanding what actually happened; if so, is the sequence of events accurately described?
4. Does the investigation enquire into all areas appropriate to the specific type of event (e.g. training, communication, etc.)?
    a. Were issues relating to staff training or staff competency a factor in this event?
    b. Was equipment involved in this event in any way?
    c. Was a lack in information or misinterpretation a factor in this event?
    d. Was communication a factor in this event?
    e. Were appropriate rules/policies/procedures – or the lack thereof – a factor in this event?
    f. Was fatigue/scheduling (roster) a factor in this event?
    g. Was information technology involved in this event in any way?
    h. Were environmental factors involved in this event in any way?
    This could be the physical environment or the non-physical environment e.g. organisational focus on productivity or turnaround times, financial/resource constraints, or organisational priorities?
5. Is the investigation/action internally consistent; that is, it must not contradict itself or leave obvious questions unanswered.
6. Does the investigation uncover "real life" conditions to illustrate what happened or does it rely too much on what is written in policies and procedures that just describe what should have happened?
7. Does the investigation identify risk points and their potential contributions to this type of event?
8. Does the investigation identify system and process changes needed to improve performance and reduce the risk of a similar event recurring i.e. does the investigation link the causation to the actions?
9. Does the investigation use non-judgemental language?
10. Is the investigation unnecessarily long or contain unnecessary detail e.g. includes pages and pages of emails copied and pasted into the OQI?
    a. In these cases, the OQI should summarise the correspondence / information rather than provide unnecessary detail.

Appendix 7: Pathology Queensland Adverse Event Reporting for In-house IVDs

As manufacturers of in-house IVD medical devices, laboratories have responsibilities for adverse event (post market) reporting relating to the use of their in-house IVDs. The National Pathology Accreditation Advisory Council (NPAAC) standard Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (IVDs) and the Regulatory requirements for in-house IVDs TGA guidance document provides information on the necessary monitoring and post market activities for in-house IVD manufacturers. The Therapeutic Goods (Medical Devices) Regulations 2002 prescribe the mandatory obligations to report the details of events associated with their device(s) that have resulted, or could have resulted, in serious injury or death to the TGA.

When to report	
Represents a serious threat to public health	**Within two (2) days** of becoming aware of the issue
Led to the death, or a serious deterioration in the state of health, of a person* *a patient, a user of the device, or another person	**Within ten (10) days** of becoming aware of the event
Where a recurrence might lead to the death or a serious deterioration in the state of health, of a person* *a patient, a user of the device, or another person	**Within thirty (30) days** of becoming aware of the event

Any adverse events related to in-house IVDs must be reported by the Quality manager or delegate through the TGA Business Services portal by completing the medical device incident report form. For assistance on completing this form refer to the User guidance on how to submit a report.

The user guidance provides instruction on how to continue editing the initial report should the laboratory's internal investigation into the incident be ongoing.

The sponsor assigns a 'Report Type' in most cases as an 'Initial' report. The Report Type then proceeds directly to 'Awaiting Final' in cases in which the sponsor is expected to provide additional information. The report is then designated as a 'Final' when this information is received.

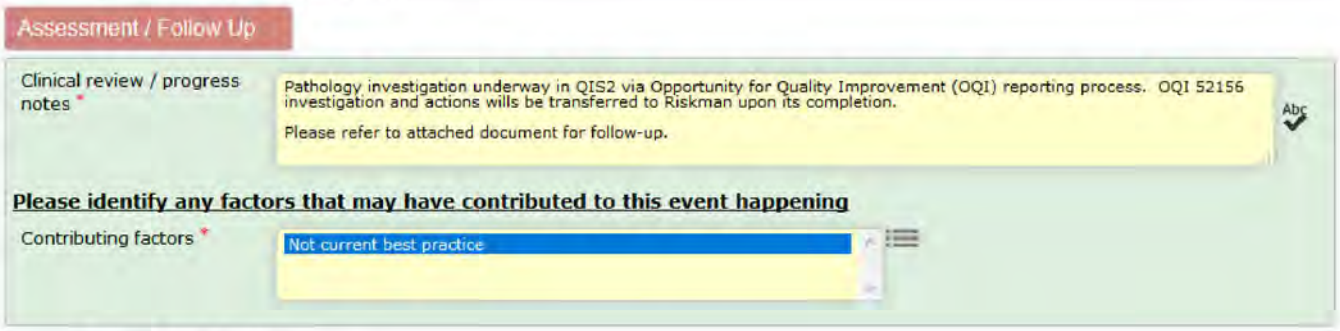
The TGA reviews the report at the initial stage and once the report is finalised. Generally, when the report is finalised the TGA will determine if additional information is required, and if so, will request this information by email. In some cases, such as when there is a serious threat to public health, additional information may be requested at the initial stage of the report. If the TGA does not require any further information, the report will be closed.

The TGA and the National Association of Testing Authorities (NATA) formed a Memorandum of Understanding (MoU) that describes the interaction, role and responsibilities of both parties in relation to the regulation of in-house IVDs. Under this MoU, the TGA is obligated to inform NATA of any adverse events that are reported to the TGA in relation to in-house IVDs.

Appendix 8: How to action an HSS raised RiskMan Incident

- Raise OQI to address the complaint / event and include the Riskman ID in the title of the OQI (for Quality Dept tracking and traceability);
- Ensure the Open/Clinical Disclosure section of the Riskman is completed by clinical staff (add Journal action and call/email the person who raised the Riskman);
- Record in the Assessment / Follow-up section of the Riskman that the Pathology investigation is underway and to refer to the attached document for the follow-up report;
- Print the approved / final OQI report and upload in the "Documents" section of the Riskman;

- Remember to select appropriate contributing factors in the Riskman Assessment / Follow-up section (root cause/s);



- Close the Riskman.

Appendix 9: When to create an OQI Quick Guide

Incident Category	MUST Raise OQI	MAY Raise OQI	DO NOT Raise OQI	Comment
Audit - Internal				
Non-compliances	✓			
Recommendations		✓		
Clinical incidents				
Non-conforming results that have had, or with the potential for, an adverse clinical event	✓			
In-house IVD adverse event	✓			Any relating to use of an In-house IVD
RiskMan incident - HHS raised	✓			
Complaints				
Animal Ethics Committee (AEC) complaint			✓	
Behaviour breach (actual or perceived)	✓			
RiskMan customer feedback incidents	✓			HHS reported
Service breach (actual or perceived)	✓			
Staff grievance			✓	
Compliments				
Internal or externally identified exceptional service or behaviour		✓		
Critical material issues				
Non-conformances	✓			Non-conformances relating to therapeutic goods or any critical material used in the collection, handling, processing and testing of the manufactured product.
EQAP				
EQAP - where outliers or problems/trends with test methods have been identified	✓			EQAP collaborative or external proficiency trials.
External Accreditation Agency findings				
Audit conditions/non-conformances	✓			
Audit observations or improvement suggestions		✓		
Internal Processes				
Deviations from documented process	✓			Significant deviations only.
Improvement suggestions		✓		
Loss of traceability	✓			
Systemic Issues/trends	✓			
Low risk non systemic issues		✓		
Routine equipment maintenance issues			✓	
Non systemic minor methodology or QC errors			✓	

Queensland Health
Forensic and Scientific Services

Procedure for the Use and Maintenance of the Forensic DNA Analysis Elimination Databases

1 Purpose and scope

This document describes the use and maintenance of the Forensic Register Elimination Databases within Forensic DNA Analysis. This procedure applies to all Forensic DNA Analysis staff; however, the Forensic DNA Analysis Quality Team has update responsibility for these databases.

2 Definitions

FR: Forensic Register

FR Staff Database: A database that contains all staff, QPS, visitor, contractor, validation, project and unknown profiles. This database is internal within the FR.

OQI: Opportunity for Quality Improvement.

PICF: Participant Information and Consent Form

PP21: Powerplex®21.

Staff Database: A database that contains all staff, visitor, contractor, validation, project and unknown profiles. This is a locked Excel file (accessible to the Senior Scientist Quality and Projects and Managing Scientist).

Staff Database Key: Database that identifies the linkage between sample barcode and the sample donor's name. This is a locked Excel file (accessible to the Senior Scientist Quality and Projects and Managing Scientist). This database was not required post-implementation of FR and has been archived.

3 Principle

The Staff database contains records of Profiler/Cofiler and/or Powerplex®21 DNA profiles taken from:

- Forensic DNA Analysis staff members
- DNA donors for validation and projects
- Visitors / Work Experience / Contractors who have had access to the Forensic DNA Analysis laboratory
- QPS Scenes of Crime and Scientific Staff

The results of all DNA profiles obtained from casework and reference samples are screened and compared against these staff databases to detect potential contamination events.

The comparison stringency for the Staff database is:

- Match at least 12 alleles
- 0 or 1 mismatch

4 Sample Collection

4.1 Collection of Staff, Visitors and Contractor Samples (Sample ID - FBSTF)

DNA profiling of all Forensic DNA Analysis staff, contractors and visitors to the Forensic DNA Analysis laboratories is performed as part of Quality Control and Anti-Contamination procedures. A DNA sample must be taken - prior to entry to a laboratory space. The collection and registration of these samples is coordinated through the Quality Team. Consent forms are to be printed and given to the person being sampled to read and sign before a sample is taken (required forms: QIS 34241, QIS 34242 and QIS 34243). Completed forms are stored in a locked cabinet in Rm 6103.

4.2 Collection of Validation/Project Samples (Sample ID - FBSTF)

Staff in Forensic DNA Analysis may also be invited to provide biological samples for validations and/or projects. Notice may be given at a staff meeting that samples are required; however invitations must be emailed to participants with an attached relevant PICF (QIS 33333, QIS 33334 and QIS 33335). Consent is usually sought by the Senior Scientist (Quality and Projects); however, staff can ask to liaise with a scientist of the same gender. Participation is voluntary.

Collection of the staff sample for a project requires the use of the following consent forms QIS 33333, QIS 33334 or QIS 33335. Consent forms are to be printed and given to the person being sampled to read and sign before a sample is taken. The collection and registration of these samples is coordinated through the Quality Team. Completed forms are stored in a locked cabinet in Rm 6103.

4.3 QPS Elimination Samples (Sample ID - QPSTF)

As part of their anti-contamination processes, the Queensland Police Service collects samples from a number of their staff for addition to the Staff database. The collection of these samples is coordinated through the Queensland Police Service. Registration of these samples ***must*** be performed by a Quality Team staff member.

4.4 Unknown Profiles (Sample ID - FBUNK)

DNA profiles containing ≥12 alleles that have been obtained from quality investigations within the laboratory, and cannot be attributed to a source, are registered as FBUNK samples.

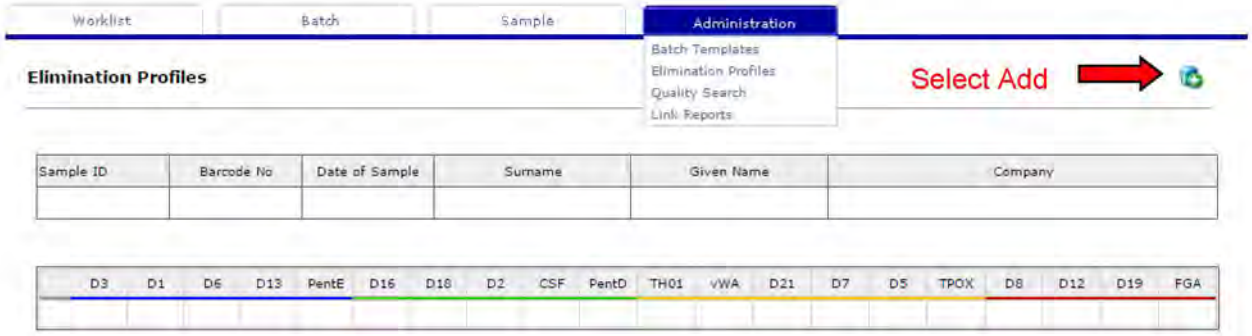
5 Sample Registration and Addition to the Elimination database

Samples are registered in the Forensic Register by the Quality Team. Access to add and/or delete staff samples from the Forensic Register staff database is limited to Quality Team (and senior managers). The Staff database (Elimination Profiles) function in the FR is located in the Sample Management section of FR under the administration tab in the Elimination Profiles menu (Refer to section 5.1).

5.1 Registration of samples for processing

Where samples are taken from staff, contractor or visitors they will be registered.

1. In the Sample Management section of FR under the administration tab in the Elimination Profiles menu select add



2. Select the appropriate sample ID prefix (as per section 4), to enter a barcode and complete sample details as displayed below and save

Example data entry FBSTF

Example data entry FBUNK

Sample ID	Barcode No	Date of Sample	Surname	Given Name	Company
FBUNK000038	[redacted]	12/08/2010	UNKNOWN PROFILE 22 (OQI#26465)	Unknown Profile	Forensic DNA Analysis

Example data entry QPS

Sample ID	Barcode No	Date of Sample	Surname	Given Name	Company
QPSTF000000004	[redacted]	15/07/2008	QPS	QPS	QPS

3. Store the sample in Forensic Register
4. If a FBSTF or FBUNK sample add it to the Staff database
5. The sample will auto-add to the FTA worklist for processing

Exhibit Testing

Date / Time	Technique	
21/04/2017 07:29	FTAAMP [WL]	723210418 FTA 3500xl

6. After processing the sample will require the following:
    a. Check PDF of profile
    b. Copy down profile in PDA page, untick the NCIDD box and save (as below). This auto-adds it to the FR Staff Elimination database.
    c. Add a "Profile review" if the sample in on the PDA [WL]
    d. Add the profile to the staff database (Excel)
    e. Reviewer will check records (as per a-d above), add a note to FR to the Elimination sample e.g. "Checked by KDS 29/11/2017". Validate the Result line and the Profile review

Exhibit Detail

Exhibit Detail			
Barcode No:	[redacted]	Forensic No:	QPRIME No:
Category	FBSTF	FBSTF FBSTF	
Batch No			

Profile Analysis

Barcode	DNA Extraction & Post Ext.	µL	DNA Quantification	ng/µL	STR Amplification	SV1	TV1	SV2	TV2	Capillary Electrophoresis
[redacted]					RFTAAMP20170519-01 D01					RCE20170519-02 D01

Profile Record

Amel	D3	D1	D6	D13	PentE	D16	D18	D2	CSF	PentD	TH01	vWA	D21	D7	D5	TPOX	D8	D12	D19	FGA
X,Y	15,16	11,12	12,20	8,11	11,16	11,11	14,16	17,22	10,14	12,14	6,8	14,17	30,31.2	11,12	12,12	8,8	14,15	19,20	13,15	26,26
[redacted]																				

Elimination Profiles

Sample ID	Barcode No	Date of Sample	Surname	Given Name	Company
[redacted]					

Notes

	D3	D1	D6	D13	PentE	D16	D18	D2	CSF	PentD	TH01	vWA	D21	D7	D5	TPOX	D8	D12	D19	FGA
X,Y	15,16	11,12	12,20	8,11	11,16	11,11	14,16	17,22	10,14	12,14	6,8	14,17	30,31.2	11,12	12,12	8,8	14,15	19,20	13,15	26,26

5.2 Manual addition of profiles

Manual loading of profiles to the FR database will be required in some circumstances for FBUNK samples, or in circumstances where a DNA profile is provided directly to the laboratory. Samples can be manually loaded as follows:

From the drop-down list select the correct Sample ID prefix (FBSTF, QPSTF or FBUNK – Refer to section 4.1-4.4)

Complete entry of all fields displayed: barcode, date, surname, given name and company. Notes are not mandatory. Profile can then be manually entered. "0" is to be entered where no data is available (Refer below). Then save the record.

5.3 Destruction of staff samples

Every 3-6 months elimination samples that have been profiled should be identified, and the physical sample destroyed (FTA card and extracts if applicable). A list of elimination samples for destruction is compiled by the quality team and given to the operational team to locate the physical samples. When located the samples are to be sent to the FR location of "Destroyed". Quality then confirms all appropriate items are destroyed and a comment is added to the sample e.g. profile available, physical sample destroyed. The date of destruction should also be entered into the staff database. Another quality scientist must then review these destructions.

Staff, contractors and visitors must have their profile removed from the staff database approximately 2 years after last access. See Appendix 1 for a guide on how to do this.

6 Maintenance of Elimination Databases

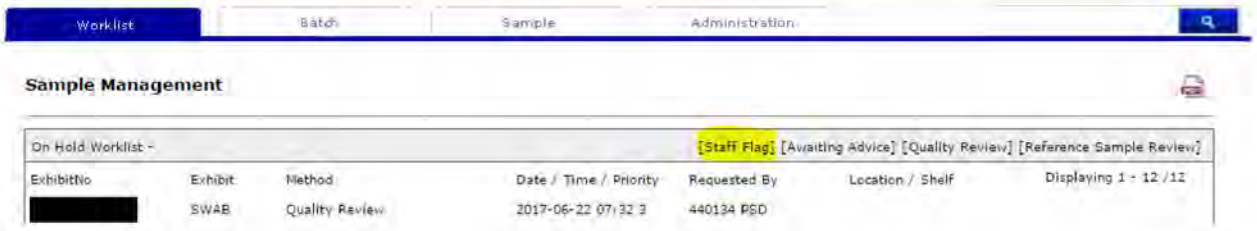
- Every profile that is added must be sequence checked by a second person. This check is to be detailed in the notes field on addition of the profile
- Approximately 2 years after leaving the laboratory Staff/Contractors/Visitors & Project Donors will be removed from active searching in the Elimination Databases. Date of last entry is recorded in the electronic visitor log (refer to G:\ForBiol\AAA Administration\Visitors Log). The visitors log automatically flags people who have not entered the laboratory in 2 years as needing a DNA induction.
- QPS FTA cards and extracts will be destroyed once a full profile has been obtained. The relevant QPS DNA profile will be removed from active searching upon receiving written notification from the QPS.

7 QFLAG Process – From Plate Reading Result Upload

Any potential 'staff flag' identified at loading of genemapper results is quarantined in the Forensic Register to the "On-Hold" - "Staff Flag" worklist. It is the responsibility of Senior Scientists to review these potential matches and either release them as suitable to report, or alternatively to refer them to the Quality Team for further action.

7.1 First review of 'Staff Flag' by Senior Scientist (HP5-HP6)

Senior staff rostered on to QFLAG each week are to review samples on the Forensic Register "On-Hold" - "Staff Flag" worklist. These samples are potential matches to staff samples after plate reading results are loaded. They will appear on the worklist as follows:



For each sample on the worklist (for recently loaded plates) Action as follows:

1. Select the barcode of the sample/Sub-ID from the worklist
2. In the exhibit testing table select "Review" from near the QA Fail CE batch – if you are on the sample management page as below:

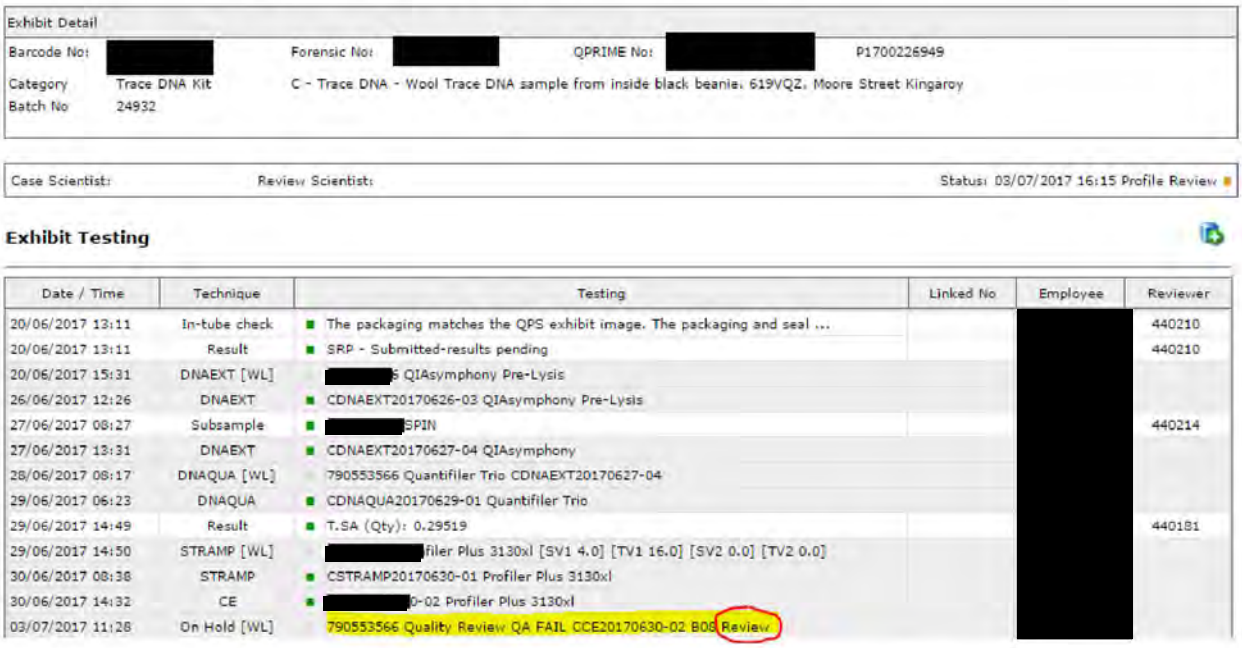


Exhibit Detail

Barcode No: [redacted] Forensic No: [redacted] QPRIME No: [redacted] P1700226949

Category Trace DNA Kit C - Trace DNA - Wool Trace DNA sample from inside black beanie, 619VQZ, Moore Street Kingaroy

Batch No 24932

Case Scientist: Review Scientist: Status: 03/07/2017 16:15 Profile Review

Exhibit Testing

Date / Time	Technique	Testing	Linked No	Employee	Reviewer
20/06/2017 13:11	In-tube check	The packaging matches the QPS exhibit image. The packaging and seal ...		[redacted]	440210
20/06/2017 13:11	Result	SRP - Submitted-results pending			440210
20/06/2017 15:31	DNAEXT [WL]	[redacted] QIAsymphony Pre-Lysis			
26/06/2017 12:26	DNAEXT	CDNAEXT20170626-03 QIAsymphony Pre-Lysis			
27/06/2017 08:27	Subsample	[redacted] SPIN			440214
27/06/2017 13:31	DNAEXT	CDNAEXT20170627-04 QIAsymphony			
28/06/2017 08:17	DNAQUA [WL]	790553566 Quantifiler Trio CDNAEXT20170627-04			
29/06/2017 06:23	DNAQUA	CDNAQUA20170629-01 Quantifiler Trio			
29/06/2017 14:49	Result	T.SA (Qty): 0.29519			440181
29/06/2017 14:50	STRAMP [WL]	[redacted] filer Plus 3130xl [SV1 4.0] [TV1 16.0] [SV2 0.0] [TV2 0.0]			
30/06/2017 08:38	STRAMP	CSTRAMP20170630-01 Profiler Plus 3130xl			
30/06/2017 14:32	CE	[redacted] 0-02 Profiler Plus 3130xl			
03/07/2017 11:28	On Hold [WL]	790553566 Quality Review QA FAIL CCE20170630-02 B08 Review			

Or if on the Case Management Management Page Select the plate co-ordinate from the near the QA Fail CE batch as below:

30/06/2017 14:32	CE	CCE20170630-02 Profiler Plus 3130xl	440214
03/07/2017 11:28	On Hold [WL]	790553566 Quality Review CCE20170630-02 B08	440137

3. This will display the sample profile and corresponding potential elimination matches in the Elim Profile Table as follows:

Quality Review Table

Sample	Batch ID / Comment	D3	vWA	FGA	Amel	D8	D21	D18	D5	D13	D7
[redacted]	20170630-02 COMPLEX	15,16,17,18	14,16,17,18	20,21,22,22.2,23,24	X,Y	13,14,15,	28,29,30,30.2,31.2,32.2	12,14,15,16	9,10,11,12,13,	8,9,11,12,13,14	8,10,11,12

Elim Profile Table

Elimination	Match	D3	vWA	FGA	Amel	D8	D21	D18	D5	D13	D7
[redacted]	B08 [16 2]	[redacted]									
	B08 [16 2]										

4. Compare the sample profile (may be a sub-ID) to the Elimination profile/s. The PDF of the profile for the sample is accessed by selecting the plate position near the sample number (e.g. B08)

Quality Review Table

Sample	Batch ID / Comment
[redacted]	[redacted]

5. Decide if the sample profile is a match to the Staff Elimination Profile. Action as follows:

a.) Release the result if not considered a match. Actions required:

- Addition of a notation stating that it is not considered a match. The notation auto-validates and removes the sample from the "On-Hold" worklist. All notations should start with "QFLAG" e.g. QFLAG complex mixed profile unsuitable for QFLAG.

  NOTE: If it is a sub-ID ensure the test is added to the Sub-ID barcode

- Manually add the sample to PDA worklist "Profile Data Analysis" - "GeneMapper IDX" for standard case management. Generally, the Source Batch/Rack ID will autofill (from previous CE batch), however if it does not autofill, or requires update it will need to be manually entered (Sub-ID will require manual overwrite).

Worklist

Technique*	Method	Source Batch / Rack ID	Position
Profile Data Analysis ▼	GeneMapper IDX ▼	[redacted]	C01

440134 PSD 03:26 PM 02/06/2017 164.112.251.224

The exhibit testing page should then display the notation – indication result release and the re-addition to to PDA [WL]

02/06/2017 15:23	Notation	[redacted]	QFLAG pass	600154	440134
02/06/2017 15:30	PDA [WL]		GeneMapper IDX [redacted]2 C01	440134	

b.) If the result is considered a match. Add a PDA note "QFLAG being investigated". Then leave the sample on the list and the Quality Team will review the result and action as required. If necessary, quality will contact QPS (Refer section 7.2). Please do **not** add a notation – as this will incorrectly remove it from the on-hold list

7.2 Second review of 'staff flag' by Senior Scientist Quality and Projects

For quality flags it is the responsibility of the Senior Scientist Quality (or delegate) to investigate and/or exclude the match. Once the 'staff flag' has been investigated the Senior Scientist and/or Quality Officer can then:

a.) Release the result if not considered a match. Refer to Section 7.1; Point 5 (a).

b.) If the result is considered a match: refer to section 7.2.1. or 7.2.2 as applicable

7.2.1 For QPS staff sample matches:

1. Add a test of "Result" as below where the linked number refers to the laboratory number of the QPS staff elimination sample.

Testing / Analysis

Process*	Date	SubID	SubType	Equipment No
Result ▼	21/04/2017 06:44		▼	

Police Report	Linked No.
QFIH - Quality flag identified, on hold awaiting advice from QPS ▼	[redacted]

[redacted] This "Result" exhibit testing line is to be validated by a Team Leader or Senior Scientist. Validated line displays with a green square. (Note: If sample is on PDA [WL] a profile review will also be required)

Result	■ QFIH - Quality flag identified, on hold awaiting advice from QPS	123456789	440134	440137

3. Prepare and send an Intel report to QPS – Refer to QIS 34308; Using a text template located in I:\Quality & Projects\Intelligence reports (if applicable)
4. QPS will reply to the Intel report with either:

a. **Suitable to report**. Action as per Section 7.1; Point 5 (a).
b. **Considered a contamination event**. Action as follows:
    i. Addition of a notation stating that "QPS confirm contamination event". The notation auto-validates and removes the sample from the "On-Hold" worklist
    ii. Addition of a notation stating "Refer to Intel report sent to QPS as attached". Add PDF of Intel report as an attachment.
    iii. Addition of a notation stating "Results suitable/not suitable to report as per QPS". Add PDF of the QPS email as an attachment
    iv. Add a test of "Result" as below

Testing / Analysis

Process*	Date	SubID	SubType	Equipment No
Result ▼	06/06/2017 11:26		▼	

Police Report	Linked No.
QCFRQ - Quality control failure, refer to QPS ▼	

    v. This "Result" exhibit testing line is to be validated by a Team Leader or Senior Scientist. The validated line displays with a green square

7.2.2 For internal staff sample matches:

1. Addition of a notation stating that it is considered a match, sample is Quality Failed (after investigation is conducted)

Testing / Analysis

Process*	Date	SubID	SubType	Equipment No
Notation ▼	02/06/2017 15:55		▼	

Notes
Quality Fail [redacted] cted.

2. Add a test of "Result" as below. (Note: If sample is on PDA [WL] a profile review will also be required)

Testing / Analysis

Process*	Date	SubID	SubType	Equipment No
Result ▼	02/06/2017 16:05		▼	

Police Report	Linked No.
QCF - Quality control failure - results not reportable ▼	

Notes
Match to [redacted] noted. Refer to QQI= for investigation notes

3. This result line is to be validated by a Team Leader or Senior Scientist. The validated result line displays with a green square.

8 QFLAG Process – After deconvolution (from STR mix)

After STR mix deconvolution and profile copy down during case management; The PDA page may display additional matches to staff profiles (that were not detected at genemapper results upload). These matches will display below the profile that has been copied down. Refer below as an example:

Profile Analysis

440121 CAUNT,E

Barcode	DNA Extraction & Post Ext.	µL	DNA Quantification	ng/µL	STR Amplification	SV1	TV1	SV2	TV2	Capillary Electrophoresis	Include
[redacted]											

Profile Interpretation

Contributors	Profile	STRmix™	Notes
○1 ○2 ◉3 ○4 ○5	○CX ○NP ○PU ☐ST		Match to staff sample - sent to quality

	D3	D1	D6	D13	PentE	D16	D18	D2	CSF	PentD	TH01	vWA	D21	D7	D5	TPOX	D8	D12	D19	FGA
1	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
2	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	9,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
3	0,0	0,0	19,0	12,0	0,0	13,0	15,0	20,21	0,0	0,0	0,0	16,0	28,28	8,13	11,0	8,12	0,0	0,0	12,12.2	0,0

Profile Record

Amel	D3	D1	D6	D13	PentE	D16	D18	D2	CSF	PentD	TH01	vWA	D21	D7	D5	TPOX	D8	D12	D19	FGA
	0,0	0,0	19,0	12,0	0,0	13,0	15,0	20,21	0,0	0,0	0,0	16,0	28,28	8,13	11,0	8,12	0,0	0,0	12,12.2	0,0
FBSTF002004																☐+ CPT	☐+ NCIDD			

Where a potential match is detected the case manager is to add a "Result" process and add the sample to the "On Hold – Quality Review" Worklist for quality to action.

Testing / Analysis

Process*	Date	SubID	SubType	Equipment No
Result ▼	06/06/2017 11:56		▼	

Police Report	Linked No.
▼	

Notes
Attachment: Choose File No file chosen

Storage Box ID	Position	Tube Lot No	Volume (µL)	Priority
				○1 ◉2 ○3

Worklist

Technique*	Method	Source Batch / Rack ID	Position
On Hold ▼	Quality Review ▼		

440134 PSD 11:56 AM 06/06/2017 164.1 [redacted]

It will display in the exhibit testing as follows:

15/05/2017 12:26	PDA [WL]	GeneMapper IDX CCE20170512-01 H04
01/06/2017 14:52	Result	[redacted]
01/06/2017 14:53	On Hold [WL]	Quality Review

A sample that is manually added to "On-Hold" "Quality Review" (usually from the PDA page) will add to the On-Hold [Staff] filter for quality to action. Quality will action the potential match as outlined in section 7.2. However, given the Result test is pre-existing, the result can be

edited (and does not need to be added new). Note: If the sample is on PDA [WL] a profile review will also be required.

9 External Database searching

FBUNK profiles (derived from controls) are to be sent to manufacturers with Elimination databases for searching purposes, and the outcome recorded in the Staff Database Maintenance Spreadsheet.

Annual emails are to be sent to the manufacturers without elimination databases to inquire if they have developed / made available elimination databases in the preceding 12-month period. Manufacturers that currently have Elimination databases (and what their preferred method of communication is) include:

- Promega – Compile profiles into a spreadsheet. Combined FBUNK profiles will only be searched if there is sufficient overlap between runs. Stringency for Promega searching is 16 alleles (excluding amel). Compile .fsa / .hid files and corresponding ladder files. Compile list of relevant reagents. Fill out form FRM21338 (found I:\Quality & Projects\Staff Database\External DNA Database Searches\Promega database search). Then email all docs/files to Promega (include techservice).
- Life Tech – Email a spreadsheet containing a list of profiles and relevant reagents.
- QIAGEN – Complete the following form (Note: you must register as a QIAGEN user to be able to access the form). https://www.qiagen.com:443/au/feedbackform/surveyform/sedrequest?sc_mode=normal
- Eppendorf https://www.eppendorf.com/AU-en/service-support/quality-regulatory-affairs/purity-grades/forensic-dna-grade/

Refer to I:\Quality & Projects\Staff Database\External DNA Database Searches for details

10 Records

The staff database is located:
I:\Quality & Projects\Staff Database\Staff Database Maintenance Spreadsheet - to use.xlsx

11 Associated documents

17154 Procedure for Quality Practice in Forensic DNA Analysis
22857 Anti-contamination Procedure
30800 Investigating Adverse Events in Forensic DNA Analysis
33744 Forensic Register Training Manual

12 Amendment history

Version	Date	Author/s	Amendments
1	15/06/2017	Kirsten Scott	First Issue
2	5/07/2017	Kirsten Scott	Update On-Hold list to new "Staff Flag" filter, include manual addition of Quality review [WL], addition of Elim Profile Table for QFLAGs
3	04/12/2017	Kirsten Scott	Minor changes to addition of elimination samples to database. Addition of Intel reports and QPS emails as notations. QFLAG notation updates. Inclusion of

			manufactures in section 9. Remove Appendix – FTA drying
4	23/05/2019	Kirsten Scott	General review, removal archived databases
5	21/04/2020	Chelsea Savage	Added appendix 1. Updated sections 5.3 and 9.
6	05/11/2021	Abbie Ryan	Updated to new template.

13 Appendices

1 Appendix 1 Deletion of profiles

13.1

Appendix 1

Deletion of profiles

Any staff member / visitor / contractor who hasn't visited Forensic DNA Analysis in over 2 years is to have their profile deleted from the staff database. Profiles must be deleted from the Forensic Register and/or AUSLAB and the Staff Database Maintenance Spreadsheet (I:\Quality & Projects\Staff Database)

- Check last entry in visitors log (G:\ForBiol\AAA Administration\Visitors Log) for all visitors / contractors.
- Email DNA Admin regarding ex-staff member finish dates
- Email Campus Operations regarding ex-security guard finish dates

↓

Blank out profile in the Staff Database Maintenance Spreadsheet with the comment 'Deleted – not visited the laboratory in >2 years as at XXXX (Deleted by ___)' with XXXX being the date that the profile was deleted and ___ being the staff member who deleted the profile.

↓

Check date the profile was uploaded.

- Before the 15th July 2017 - profile needs to be deleted from AUSLAB **and** Forensic Register.
- After the 15th July 2017 the profile does not exist in AUSLAB and therefore only needs to be deleted from the Forensic Register.
- If unsure or the upload date is around the 15th July 2017 – check both LIMS.

↙ ↘

AUSLAB

1. Hash out all profiles (may include any of the following: profiler, cofiler and PP21). Save the hashed-out profile to the front page and validate this page.
2. If a DEST destruction page is present, fill this out and validate it. If a DEST destruction page is not present, order one through the shift+F10 page.
3. Ensure all pages are validated
4. Ensure there are no locations (all physical samples should have previously been destroyed)
5. Delete all images

Forensic Register

1. Enter into the sample through the elimination samples section of the FR
2. In the notes field, add the comment 'profile deleted – not visited the lab in >2 years as at XXX date (initial, date)', with XXX being the date the profile was deleted
3. Click the red cross in the top right corner of the page. Another page will appear – click 'Delete Record'. The profile will now be deleted from the FR.
4. Ensure the FTA card and any extracts have been sent to 'destroyed'.

↘ ↙

Complete the audit tab in the Staff Database Maintenance Spreadsheet.

↓

This record must now be peer-reviewed by another Scientist.

Queensland Health
Forensic and Scientific Services

Environmental Monitoring

Table of Contents

1 Purpose and Scope

The purpose of this document is to provide guidelines for the environmental monitoring of the Forensic DNA Analysis laboratory; and for profile data analysis of environmental samples belonging to Forensic DNA Analysis, commercial clients or the Queensland Police Service (QPS). The procedure applies to all staff within Forensic DNA Analysis.

Environmental Monitoring shall apply to all laboratory and examination areas in which processing of items requiring Forensic DNA Analysis is performed. These areas include (but are not limited to) the Forensic DNA Analysis laboratory, QPS forensic laboratories, and areas where dual examinations or Coronial/DVI/Skeletal Remains testing is conducted.

Where equipment, consumables, work areas, clothing or staff come into contact with an exhibit/DNA sample, there is a possibility that DNA may transfer from these objects to another exhibit/DNA sample. Environmental sampling is used to monitor the levels of environmental DNA, facilitating the management of risk/s associated with DNA transfer and/or contamination of exhibits/DNA samples. Risk is assessed according to the probability that a contamination would occur, the frequency of exposure to the risk, and the possible consequences of the contamination. The level of risk determines the level of investigation required in the event of a profile being obtained from the environmental monitoring samples.

2 Definitions

DVI	Disaster Victim Identification
FR	Forensic Register
QPS	Queensland Police Service

3 Registration of environmental cases and samples

3.1 Background: Forensic DNA Analysis Laboratory

The purpose of environmental sampling is to monitor the environment for incidental/accidental DNA contamination (from staff, DNA samples, exhibits or other sources) to detect events that may detrimentally impact on sample processing/profiling within the Forensic DNA Analysis laboratory. It also assesses the efficacy of cleaning procedures within the Forensic DNA Analysis laboratories.

All staff may be required to assist in environmental cleaning. Environmental monitoring involves the sampling of areas that may come into direct or indirect contact with exhibits/DNA samples during processing. These areas are sampled as they have the potential to cause contamination e.g. contamination of subsequent samples as a result of contact with contaminated benches or pipettes etc. If contamination has been detected in previous month's monitoring, the Quality Officer may ask for a specific area to be tested to ensure that new cleaning procedures have been effective.

Environmental sampling shall be conducted on a monthly basis, usually before the deep clean (but after the routine daily clean). At least once a year, environmental sampling will be completed both before and after cleaning (i.e. pre and post clean sampling). Ten samples are to be taken in the Analytical laboratory section, and ten samples taken in the Evidence Recovery section of the laboratory for submission monthly. An attempt should be made to sample from different areas each month which may include (but is not limited to):

Examination Laboratories

- Rooms 6123, 6124 (plus entry/exits), 6122 and 6117
- Examination surfaces - stainless steel benches, fume hoods, & desk tops

- Laboratory fixtures - metal drying rails, fridges
- Examination equipment - cameras, microscopes, instruments & pens
- Furniture – chairs, fridges, fridge handles, cupboard handles
- Keyboards, touch screens & label printers
- Tape Dispensers / Brown Paper dispensers
- Label Printers

DNA Suite & Analytical Section

- Rooms 3188, 3189, 3190, 3191, 3194 and 3196
- Robotic Platforms*
- Fixtures – benches, fume hoods, biohazard cabinets
- Equipment – centrifuges, vortex, hot blocks, pipettes
- Furniture – chairs, fridges, fridge handles, cupboard handles
- Keyboards, touch screens, label printers, phones

Environmental Sampling of Robotic Platforms to be performed by authorised analytical staff.

3.2 Registration of a Forensic DNA Analysis 'Environmental Sampling Case' in FR

The registration of environmental cases in FR will be performed by a quality team staff member. One case will be created each year for Evidence Recovery environmental sampling, and another case for Analytical environmental sampling.

To register a case:

1. Select Case Files Menu option
2. Select the add button
3. Select job type of Environmental Control
4. Quality officer to add their employee number to the IO Employee No field
5. Case information is to be added. In the **Subject/Complainant** field add "Environmental Sampling YYYY" (where YYYY is the current year) and in the **Location** field enter the name of the laboratory area to which it relates (eg. Evidence Recovery or Analytical). Save the record.
6. On saving the case information, a unique FR number will be generated. This FR number will be used for all samples taken from that location (e.g. Evidence Recovery) for the calendar year.
7. Once quality has registered a case file for environmental sampling it is communicated to the Senior Scientist of the relevant team (i.e. Evidence Recovery or Analytical) using a request task function. The relevant teams Senior Scientists staff number is added to the Case Officer Field, and a comment can be added.
8. The Senior Scientist will receive a notification to their Personal Work List.

3.3 Registration of Commercial 'Environmental Sampling Case' in FR

The registration of environmental cases in FR for commercial clients can be performed by quality, or by HP2/HP3 Evidence Recovery staff as required. Each commercial client must have separate FR cases. In most cases it is desirable to have individual FR cases for each delivery from the same client (dependant on sample numbers). To register a case use details as provided in section 3.2 above.

For registration of commercial ENVM samples refer to section 3.5 in addition to the following requirements:

- Each sample must have an analytical note "Quant and Hold" added
- If samples come pre-barcoded/numbered from the client - the paperwork needs to be scanned and stored as a PDF in case file notation. The hardcopy of the paperwork is to be given to the quality team

- Descriptions for samples should exactly reflect the information provided by the client for clarity
- Where sending validation samples (containing blood) to external commercial providers the envelope may require "Exempt human specimen" labelling on the envelope

3.4 Environmental Sampling Process

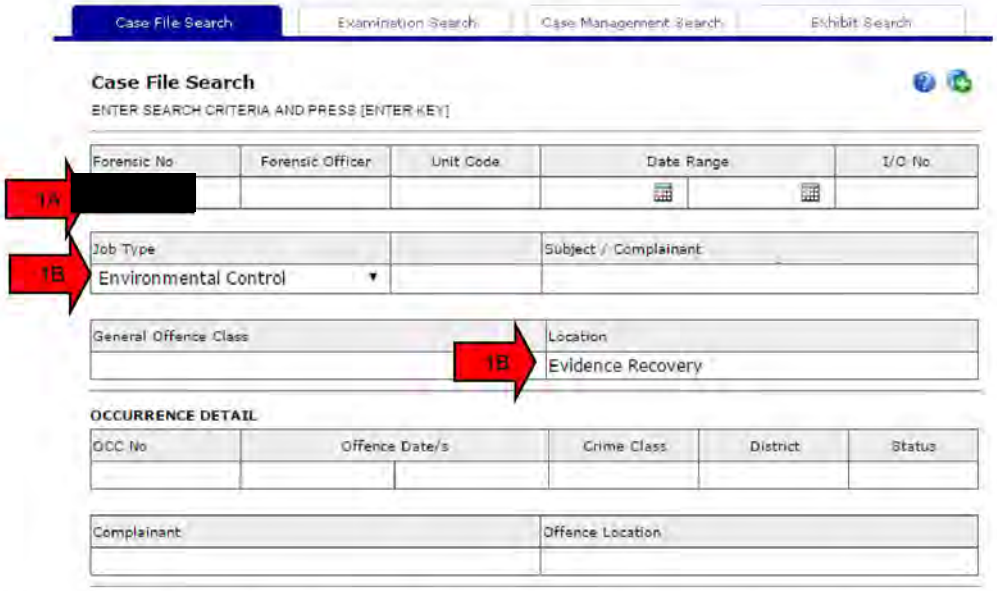
The staff member allocated to perform environmental sampling must wear full PPE in line with Anti-contamination procedure QIS 22857, and will sample areas within the laboratory using standard sampling procedures as detailed in QIS 33800 (Examination of Items).

No examination notes are required for environmental sampling. Sampling scientists are to label each swab casing with: a description of the sampled area and a barcode - as they sample each laboratory area. The swab heads are then broken into 2mL tubes and the tubes labelled with a corresponding barcode. Scientists then register the samples in Forensic Register from the barcode and sampling description on each of the swab casings. On completion of all registrations, the swab casings can be discarded.

3.5 Registration of Environmental Samples

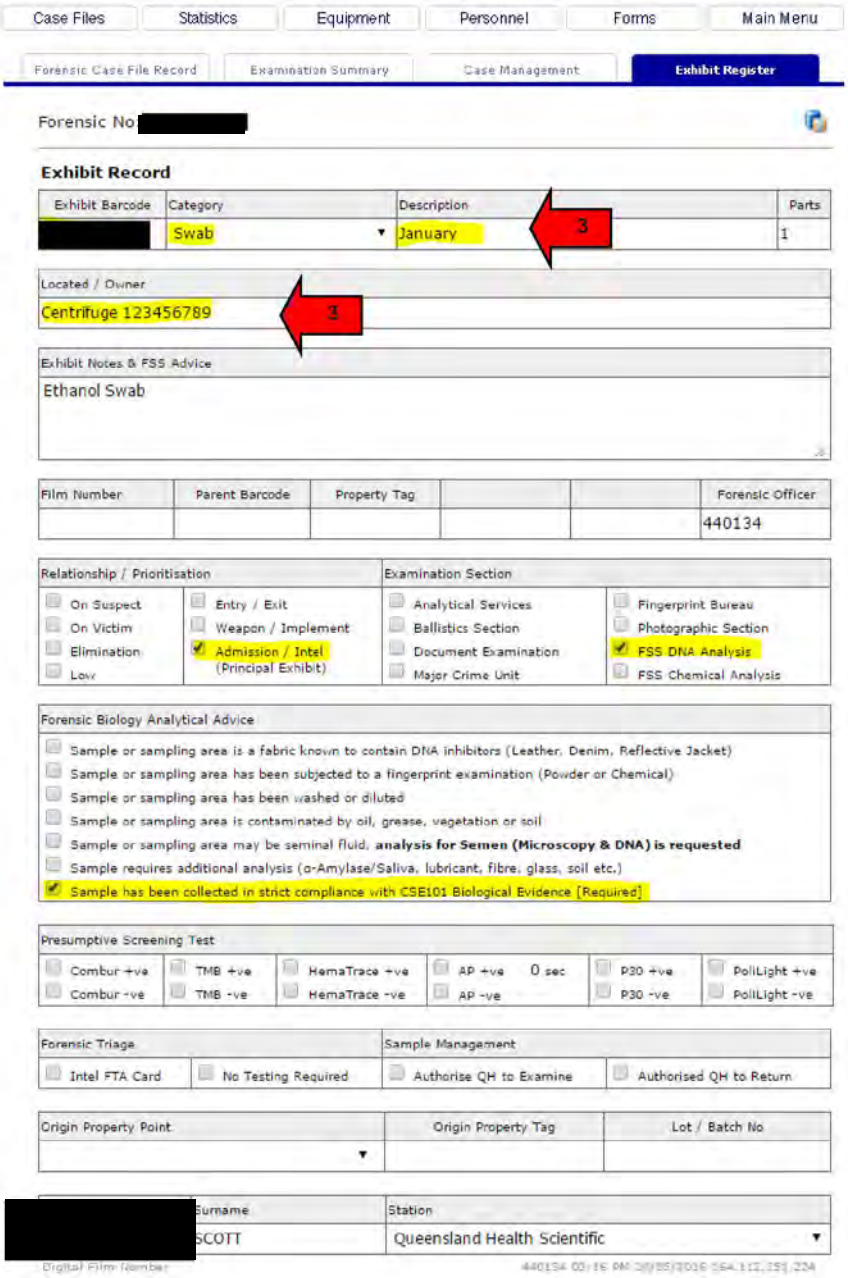
The registration of samples in Forensic Register will be performed by the sampling scientist. For registration of Forensic DNA Analysis samples refer below, for registration of commercial samples refer also to section 3.3 for detailed requirements.

1. The sampling Scientist will locate the relevant environmental case either by:
   A. entering the FR number directly on the case file search field
      OR
   B. entering the Job Type of "Environmental Control" with the appropriate location (e.g. Evidence Recovery or Analytical)



2. Each team can then register new samples (as required) from the exhibit register tab, using the add button.

3. Registration of samples requires completion of the fields as highlighted below. The Description field must refer to the Month (of the sampling), and the Located/Owner is to refer to the location that the sample was taken from.



4. After registration of the samples, make an addition to the exhibit testing table to add the sample to the appropriate extraction worklist for processing.

5. After registration all samples can be viewed from the Exhibit Register Tab.

4 Cleaning

Routine cleaning (before and after exhibit examinations) in the Evidence Recovery laboratory, and (before and after DNA sample processing) in the Analytical laboratory is standard practice, and is to be conducted as outlined in the Anti-Contamination Procedure

(QIS 22857). In addition to routine daily cleaning, a monthly environmental clean of all work areas and equipment should be completed (after sampling is complete). All work areas and equipment should be cleaned with 0.5%(w/v) bleach, or if bleach is not suitable for an item of equipment, it should be cleaned with Trigene.

5 Environmental Sampling – results and reporting

5.1 Profile Data Analysis

When Forensic DNA Analysis environmental sample profile results, and QPS environmental samples are available for management they will be available on the Case Work PP21 Profile data analysis worklist.

Analytical and Evidence Recovery environmental sample profile data analysis requires:

- Management of samples as per QIS 33773 - Procedure for Profile Data Analysis using the Forensic Register
- Order re-works (e.g. Microcons, re-amplifications) only where the rework is likely to increase the available information for investigation and matching purposes.
  For example: *Order a microcon rework for partial profiles to obtain additional alleles - as investigations into the source/s of DNA will be more informative.*
- Do not rework *complex mixtures – as they are not suitable for comparison purposes. For a detailed procedure on ordering reworks refer to QIS 33773 - Procedure for Profile Data Analysis using the Forensic Register.*

When final profiles have been obtained for each sample:

For samples without a profile:

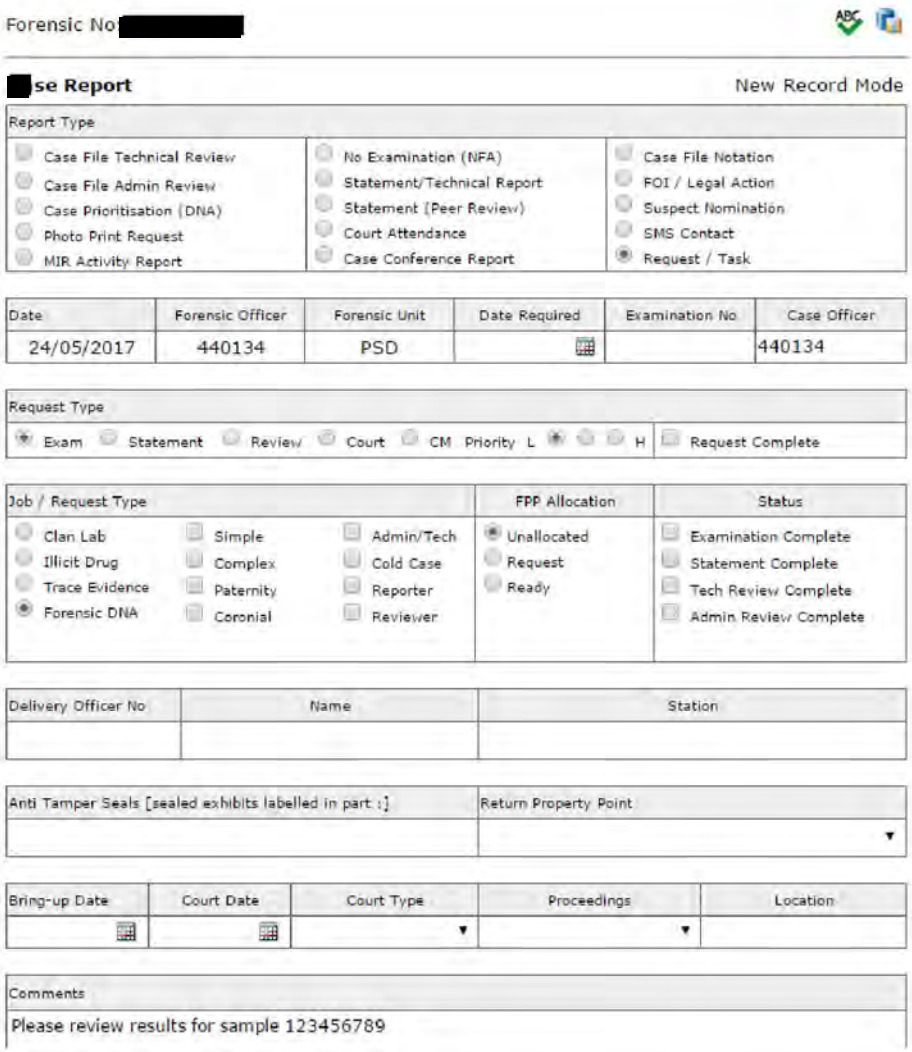
- Evidence Recovery/Analytical staff are to follow QIS 33773 in summary:
  - On the PDA page, in the profile field select "NP" (No Profile), no profile copy down is required.
  - Add the "ENV-No DNA profile" result line to the sample, and a profile review
  - Senior Scientist or another ER/Analyt team member (competent in profile data analysis) is to validate the test as per QIS 33773.

For samples with a profile <6 alleles:

- Capillary Electrophoresis – carry over (CE-CO) check is to be completed
- Evidence Recovery/Analytical staff are to follow QIS 33773 in summary:
  - On the PDA page, in the profile field select "PU" (Partial Unsuitable), no profile copy down is required.
  - Add the "ENV-Partial profile unsuitable for comparison purposes" result line, and a profile review
  - Senior Scientist or another ER/Analyt team member (competent in profile data analysis) is to validate the test as per QIS 33773.

For samples with a profile >6 alleles:

- Evidence Recovery/Analytical staff are to send a communication to the Senior Scientist of Quality and Projects using a request task function. The Senior Scientist Quality and Projects staff number must be added to the Case Officer Field, and a comment requesting the quality search is to be added. The Senior Scientist Quality and Projects will receive the notification on their personal worklist.



Forensic No [redacted]

[redacted]se Report — New Record Mode

Report Type		
Case File Technical Review	No Examination (NFA)	Case File Notation
Case File Admin Review	Statement/Technical Report	FOI / Legal Action
Case Prioritisation (DNA)	Statement (Peer Review)	Suspect Nomination
Photo Print Request	Court Attendance	SMS Contact
MIR Activity Report	Case Conference Report	Request / Task

Date	Forensic Officer	Forensic Unit	Date Required	Examination No	Case Officer
24/05/2017	440134	PSD			440134

Request Type										
Exam	Statement	Review	Court	CM	Priority	L			H	Request Complete

Job / Request Type			FPP Allocation	Status
Clan Lab	Simple	Admin/Tech	Unallocated	Examination Complete
Illicit Drug	Complex	Cold Case	Request	Statement Complete
Trace Evidence	Paternity	Reporter	Ready	Tech Review Complete
Forensic DNA	Coronial	Reviewer		Admin Review Complete

Delivery Officer No	Name	Station

Anti Tamper Seals [sealed exhibits labelled in part :]	Return Property Point

Bring-up Date	Court Date	Court Type	Proceedings	Location

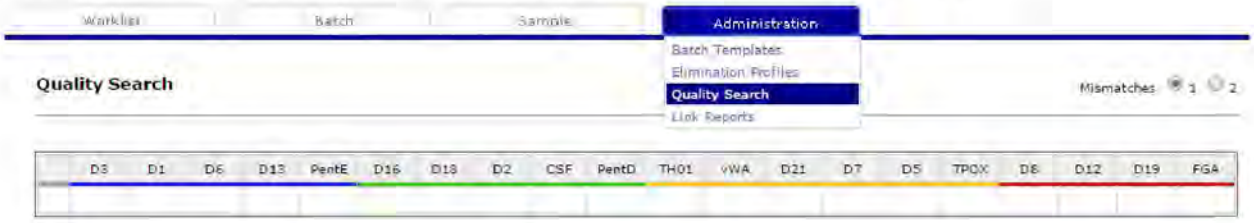
Comments
Please review results for sample 123456789

- Quality staff will complete CE-CO checks as required, and a quality review as per section 5.2 Quality review of results. An appropriate result line will be added as per QIS 33773, Evidence Recovery/Analytical staff Senior Scientist or team member (competent in profile data analysis) will then validate the test as per QIS 33773
  - **Complex**: Where the profile is considered complex, select CX in the PDA page, no copy down of results is required. Result line "ENVM-Complex mixture unsuitable for interp or comparison" is to be added, with the addition of a profile review.
  - **>6 alleles suitable to report:** Where the profile is suitable to report, select the appropriate number of contributors on the PDA page, copy down a profile, select an appropriate result line and add a profile

5.2 Quality review of results

For any Forensic DNA Analysis environmental monitoring sample that contains a profile send a request task (containing the barcode of the sample) to the Senior Scientist Quality and Projects. The quality team will assess if the profiles are suitable for matching purposes, and will add an appropriate result line for the findings/investigation (e.g. ENVM-Partial profile unsuitable for comparison purposes, ENVM-complex mixed profile unsuitable for interp or comparison).

In cases where the environmental sample profile is suitable for matching purposes, a quality search is to be conducted by Quality in the Forensic Register as below:



- If an unknown profile (usually single source and >12 alleles) is identified, it should be added to the DNA Analysis Elimination databases. Refer to QIS 34281 for details on FBUNK-unknown profile registration.

Quality checks can provide data to determine the source of a contamination/s. If a sample is found to match staff, or to match a previously profiled FTA or exhibit, a detailed investigation will be completed by the quality team, and an OQI may be raised. Considerations for raising an OQI include:

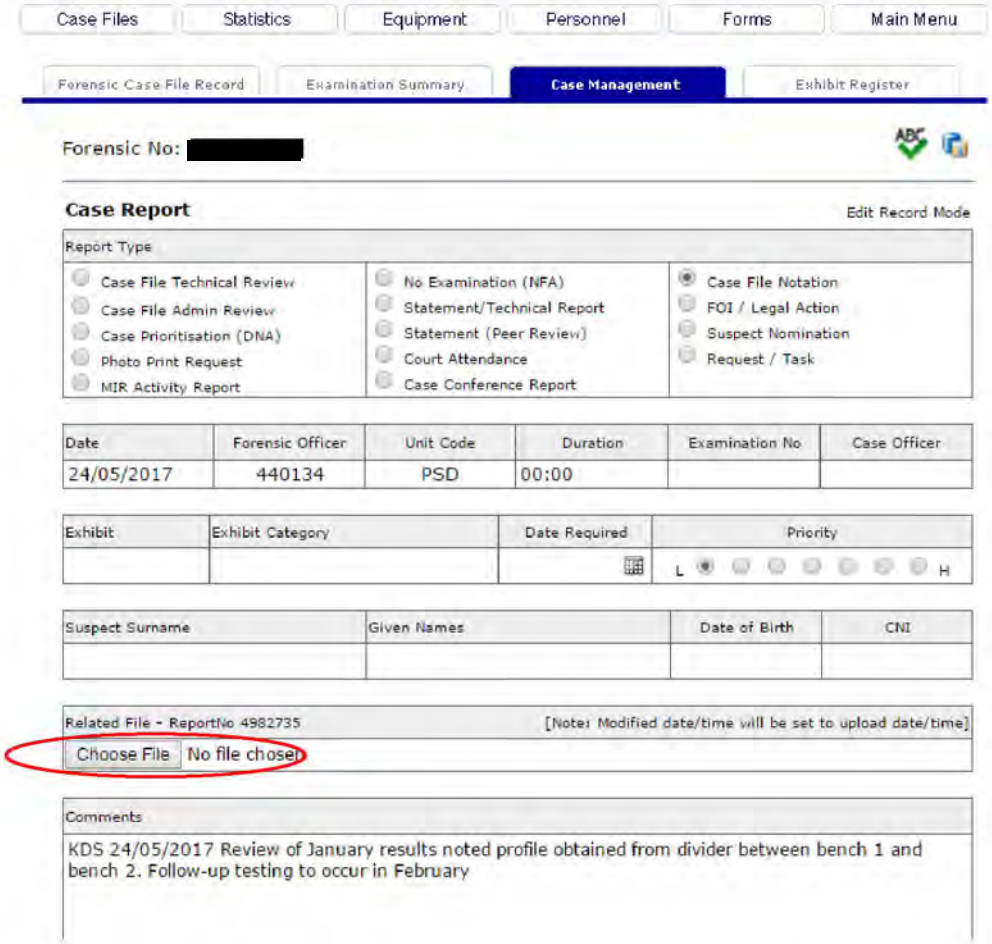
- What is the likelihood of contamination occurring (Is the sample open/exhibit unpacked when in contact with this possible contamination source?
- What impact has/will this contamination have on the sampling/testing process?
- Has this occurred previously?

The quality team will review the Forensic DNA Analysis environmental sampling cases every 6 months. Quality review will assess:

- Source and type of staff matches obtained
- Suitability of laboratory areas sampled
- Profiles obtained from similar/re-occurring laboratory areas.
- Overall profile outcomes to determine effectiveness of cleaning
- Preventative measures implemented (if applicable).

5.3 Review of monthly cases

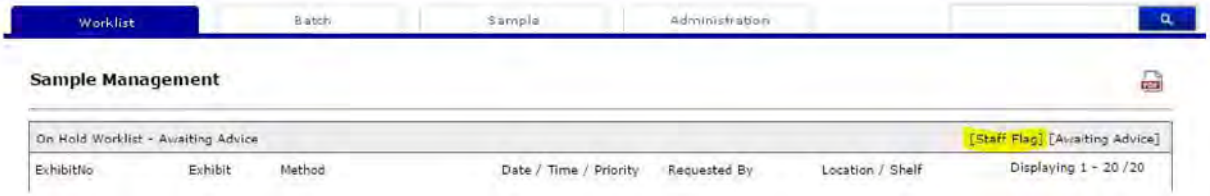
- On completion of the management of each months' environmental samples, each team (Evidence Recovery and Analytical) should review the results of the case (this may include discussions in team meetings and/or the preparation of a report reviewing the results).
- (Optional) From the Case Management Tab - create a case file notation to record any actions required after reviewing environmental results. This may include areas to target for environmental sampling for the next month, changes in cleaning practices etc. Report as outlined above can be added to the case file notation.



5.4 Quality Flag checking

When potential staff matches are identified by the Quality Flag Checker, the usual workflow for Quality flags applies to environmental samples as per QIS 34281.

- Quality flags will usually be detected at plate reading result upload the QFLAG will be on the On-Hold Worklist – Staff Flag list



Quality team will action these samples, for review by the individual teams

- If a quality flag is detected at profile data analysis stage it will be actioned as per QIS 34281

6 QPS Forensic Laboratories

6.1 Background

The purpose of environmental sampling, is to monitor the environment, for incidental/accidental DNA contamination (from staff, exhibits or other sources) to detect

events that may detrimentally impact on sample processing, and sample profiling. It also assesses the efficacy of cleaning procedures within the QPS forensic laboratories. QPS have been advised to sample areas that may come into direct or indirect contact with exhibits/person samples, to have monthly environmental sampling, and to sample both before and after a deep clean at least once a year.

6.2 Registration of the QPS Environmental 'Case'

QPS create a single case registration for ALL environmental samples taken in a calendar year. The case registration follows the following format: QP(yy)00000000; where (yy) represents the current calendar year. For example QP2200000000 refer to samples from the 2022 calendar year. The FR numbers within the QP are specific to QPS laboratories.

6.3 Processing & Suitability Assessment of QPS Environmental Samples

- QPS environmental samples are received by Property Point in the same way as casework samples.
- Property Point staff track the environmental samples to a designated 'Environmental Samples' box, which is then transported and tracked in FR to the Forensic DNA Analysis Exhibit Room.
- QPS Environmental samples are processed by sampling scientists or technicians in the Evidence Recovery team that are competent in Examination of In-tube Samples (QIS 33800)
- Standard analytical processes are applied to QPS environmental samples and for samples with <0.0088 ng/µL results are reported as per QIS#34045. If the quantity of DNA is >0.0088 ng/µL then profile DNA Analysis occurs as detailed in section 6.4

6.4 Profile Data Analysis

QPS Environmental samples are managed by the analytical/quality teams. When QPS environmental sample results are available for profile data analysis they will be available on the Case Work PP21 Profile data analysis worklist (as per section 5.1)

- Generally QPS environmental samples are **profiled once only**, with reworks only ordered for purposes of investigation, on request by QPS, or in some instances where the profile would likely be suitable for matching purposes with a rework (e.g. single source profile with several alleles and a quantitation value >LOR).

Any QPS environmental monitoring sample which results in a partial, full or mixture profile will be assessed by the quality team for its suitability for matching purposes. In cases where the environmental sample profile is suitable for matching purposes, quality searches will be conducted by the quality team.

- Senior Scientist Quality and Projects (or delegate) is to validate the results lines from the Review Worklist - Results.

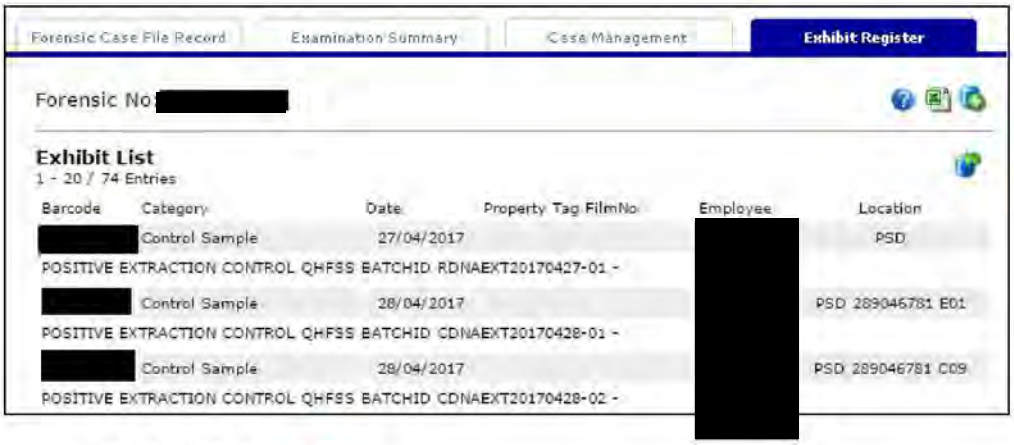
7 Cross-contamination Check of Robotic Platforms

7.1 Registering positive and negative controls

Positive and negative controls are required to be registered when creating cross-contamination check batches for robotic platforms (e.g. soccerball for QIAsymphony® and STARlet or zebra for Maxwell®).

1. Enter into a recent extraction batch in the FR as per QIS 34034 Forensic DNA Analysis Workflow Procedure.

2. Enter into the positive control barcode and copy the FR number.
3. Paste the FR number into the **search** field on the top right of the page and **Enter**.
4. Click **Exhibit Register**.



5. Click the **Add Exhibit** icon.
6. Enter in an unused barcode number into the **Exhibit Barcode** field and choose *Control Sample* from the **Category** drop down box.
7. Type "Positive Extraction Control" in **Description** field and "FSS" in **Located / Owner** field.
8. Type a brief description (e.g. Maxwell A contamination check or QIA A contamination check) into the **Exhibit Notes & FSS Advice** field.
9. Check the *Admission / Intel* box in the **Relationship / Prioritisation** field and ensure the *FSS DNA Analysis* box is checked in the **Examination Section**.
10. Check the *Sample has been collected in strict compliance with CSE101 Biological Evidence [Required]* box in the **Forensic Biology Analytical Advice** field.
11. Enter FR user number into **Delivery Officer Rego** field.
12. Click the **Save** icon.
13. Repeat steps 2 – 13 for the negative control on the extraction batch (ensure "Negative Extraction Control" is typed as the description).

7.2 Soccerball cross-contamination batches for QIAsymphony® SP

Soccerball testing is performed every 6 months on the QIAsymphony® SP to monitor cross-contamination during DNA extraction. A set of positive and negative controls are extracted on the SP and they then progress to amplification and the results are documented and saved in I:\AAA Analytical\Audits and Reviews\QIAsymphony.

1. Register 8 positive extraction controls and 80 negative extraction controls as per Section 7.1.

2. Create 4 QIAsymphony pre-lysis batches as per QIS 34034 Forensic DNA Analysis Workflow Procedure and manually add 2 positive and 20 negative extraction controls to each QIAsymphony pre-lysis batch.

3. Perform QIAsymphony® pre-lysis procedure on the batches as per QIS 34132 DNA Extraction and Quantitation of Samples using the QIAsymphony® SP and AS – FR.

4. Once the 4 batches are lysed, store the samples into a FR QIAsymphony® storage box (96 well rack) as per Table 1.

Table 1 Storage rack configuration for soccerball cross-contamination batch for the SP module.

	1	2	3	4	5	6	7	8	9	10	11	12
A	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg
B	Pos	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
C	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Pos
D	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
E	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg
F	Pos	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
G	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Pos
H	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg

5. Create a QIAsymphony® four pre-lysis SP extraction batch as per QIS 34034 Forensic DNA Analysis Workflow Procedure.

6. Ensure the FR plate map is in the order shown in Table 2.

Table 2 Layout for soccerball cross-contamination batch for the SP module.

	1	2	3	4	5	6	7	8	9	10	11	12
A	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg
B	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg
C	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
D	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg
E	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg
F	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
G	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg
H	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg

7. Perform QIAsymphony® extraction procedure as per QIS 34132 DNA Extraction and Quantitation of Samples using the QIAsymphony® SP and AS.

8. Progress all controls through routine quantification and amplification processing.

7.3 Soccerball cross-contamination batches for QIAsymphony® AS

Soccerball testing is performed every 6 months on the QIAsymphony® AS to monitor cross-contamination during DNA quantification setup. A set of positive and negative controls that have been extracted on a SP cross-contamination batch are selected to prepare a quantification batch on the AS and the results are documented and saved in I:\AAA Analytical\Audits and Reviews\QIAsymphony.

1. Select 74 negative control extracts from the SP cross-contamination batch that have No DNA Profile results. All 12 positive control extracts from the SP cross-contamination batch will be included in the AS cross-contamination batch.

2. Create a quantification batch as per QIS 34034 Forensic DNA Analysis Workflow Procedure and manually add all 12 positive controls and the 74 selected negative controls in the order shown in Table 3.

Table 3 Layout for soccerball cross-contamination check batch for the AS module.

	1	2	3	4	5	6	7	8	9	10	11	12
A	STD 1	STD 5	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos
B	STD 1	STD 5	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg
C	STD 2	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg
D	STD 2	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg
E	STD 3	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
F	STD 3	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg
G	STD 4	Pos	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg
H	STD 4	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg

3. Perform quantification procedure as per QIS 34132 DNA Extraction and Quantitation of Samples using the QIAsymphony® SP and AS.

4. All controls are assessed according to the quantification result. Those with unexpected results are progressed to routine amplification processing.

7.4 Zebra Contamination Batches for Maxwell

Zebra testing is performed every 6 months on all Maxwell®16 and Maxwell® FSC instruments to monitor cross-contamination during DNA extraction. A set of positive and negative controls are extracted and then progress through routine quantification and amplification. The results are documented and saved in I:\AAA Analytical\Audits and Reviews\AAA Maxwell.

1. Register a total of 5 positive controls and 9 negative controls as per Section 7.1.

2. Create a Maxwell extraction batch as per QIS 34034 Forensic DNA Analysis Workflow Procedure and manually add the newly registered positive and negative controls in the order shown in Table 4.

Table 4 Sample layout in FR for zebra cross-contamination Maxwell batch.

	1	2	3	4	5	6	7	8	9	10	11	12
A	Pos	Neg	Neg	Pos	Neg	Neg	Pos	Neg	Neg	Pos	Neg	Neg
B	Pos	Neg	Neg	Pos								

3. Perform extraction as per QIS 34044 DNA IQ Method of Extraction Using Maxwell®16 or QIS 35605 DNA IQ Extraction Using the Maxwell® FSC.

4. All samples are then progressed through routine quantification and amplification.

7.5 Soccerball cross-contamination batches for STARlets (Pre-PCR & CE)

Soccerball testing is performed every 6 months on the Pre-PCR & CE STARlet instruments to monitor cross-contamination. A set of positive and negative controls are prepared for

amplification (STARlet A & B) and prepared for CE (STARlet C). The results documented and saved in I:\AAA Analytical\Audits and Reviews\Starlets.

Note: Registration of new positive and negative controls is **not required**.

Note: A minimum of 75 µL of diluted Promega 2800M Control (0.03 ng/µL) and a minimum of 60 µL of in-house positive control (0.03 ng/µL) is required for each cross-contamination batch performed. If the volume of either of these positive controls is low, please prepare more as per Section 7.5.1.

1. Create a validation amplification batch from a previous contamination check amplification batch as per QIS 34034 Forensic DNA Analysis Workflow Procedure.

The following steps are performed in the Clean Reagent Room (Room 3188)

2. Prepare PP21 amplification Master Mix using currently validated reagents according to Table 5 and refrigerate in Room 3194 until required.

Table 5 Volume required of each PP21 reagent for STARlet cross-contamination check batches

PowerPlex21 Master Mix Preparation Table		
Reagent	**N**	**Volume Required**
5 µL of Master Mix	96	480 µL
5 µL of Primer Pair	96	480 µL

3. Record the lot numbers of the Master Mix reagents for the cross-contamination check batch in FR.

The following Steps are to be carried out in the Pre-PCR (Room 3194)

4. Double click on the Method Manager Icon  on the computer desktop.
5. From the Method Manager home screen (Figure 1) select "TESTING"  .

Figure 1 Method Manager home screen.

6. From the Method Manager TESTING screen (Figure 2), open the "Layout"  for the "Cross Contamination Check" method.

Figure 2 Method Manager Testing Screen.

7. Decontaminate and place all the required labware onto the loading shelf in the designated track positions as outlined in the layout (Figure 3). The 0.5 mL and 2 mL sample carriers require blue inserts in each tube position. Load clean 50 µL tips into the tip carrier on **Tracks 8-13**.

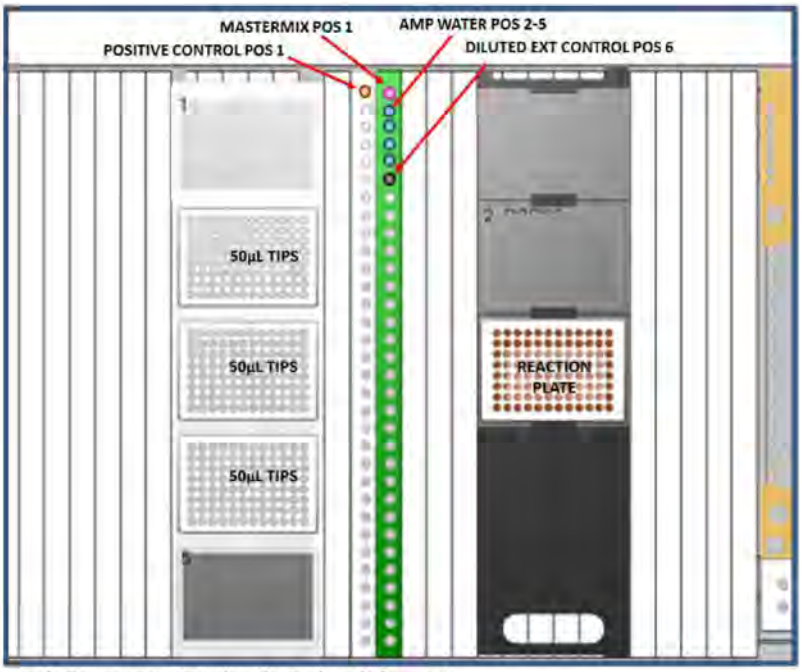


Figure 3 Cross contamination check layout.

8. Vortex the Master Mix, In-house positive control and diluted Promega 2800M Control for 5 seconds. Spin the tubes briefly in a microcentrifuge to ensure no liquid is trapped in the lids.

9. Place the Promega 2800 Control in position 1 of the sample carrier in **Track 15**.

10. In the sample carrier in **Track 16**, place the Master Mix in position 1, place four Amplification Water aliquots in positions 2 to 5 and place the In-house positive control in position 6.

11. After ensuring that all the necessary labware has been positioned on the loading deck, close the Layout and click **Run** Run on the TESTING screen of the Method Manager.

12. A prompt will appear to check the deck layout. Select "Continue".

13. A prompt will appear to load the plate and sample carriers onto the deck. Select "OK" to load the carriers.

14. A prompt will appear to update the 50 µL tip counter. Highlight all available tips in red and select "OK" to load the tip carrier.

Note: The method will prepare the cross contamination check amplification batch in a soccerball pattern as per Table 6. Replace the amplification water aliquots as prompted within the method.

Table 6 Amplification (and CE) batch layout for Soccerball cross contamination check for Pre-PCR STARlets.

	1	2	3	4	5	6	7	8	9	10	11	12
A	Pos	Ladder	Neg	Neg	Ladder	Neg	Neg	Ladder	Neg	Neg	Ladder	Neg
B	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
C	Neg	Pos (In-house)	Neg	Neg	Pos (Promega)	Neg	Neg	Pos (In-house)	Neg	Neg	Pos (Promega)	Neg
D	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
E	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
F	Neg	Pos (Promega)	Neg	Neg	Pos (In-house)	Neg	Neg	Pos (Promega)	Neg	Neg	Pos (In-house)	Neg
G	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
H	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg

15. Enter into the Contamination Check batch in FR and record reagents, consumables and equipment. Check "Batch Prepared".

16. When prompted, select "Continue" to unload the plate and sample carriers, seal the amplification plate with a foil seal and centrifuge for 1 minute at 2000 rpm.

17. Transfer the plate to the PCR/CE room (3196). The amplification is run according the routine Casework thermocycling parameters.

18. Save and upload the batch STARlet trace file to FR.

19. Once amplification is complete, perform the routine CE set-up for the contamination check of STARlet C as per QIS 34062 Capillary Electrophoresis Setup.

7.5.1 Preparation of positive controls for STARlet cross-contamination batch

If the prepared stock tubes of Promega 2800M full volume control or in-house positive control are low or consumed perform the following steps:

1. Prepare 2800M Promega control at a final concentration of 0.03 ng/µL as per QIS 34514 Preparation and Testing of Quantification Standards, In-House DNA Controls, Quantification Kits and Amplification Kits.

2. Prepare In-house positive control at a final concentration of 0.03 ng/µL as per Preparation and Testing of Quantification Standards, In-House DNA Controls, Quantification Kits and Amplification Kits (34514).

8 References

Nil

9 Associated Documents

22857 - Anti-contamination Procedure
33800 - Examination of Items (Forensic Register)
33773 - Procedure for Profile Data Analysis using the Forensic Register.
34281 - Procedure for the Use and Maintenance of the Forensic DNA Analysis Elimination Databases

10 Amendment History

Version	Date	Author/s	Amendments
1	24 May 2017	Kirsten Scott	First Issue
2	24 Jan 2019	Kirsten Scott	Add information for commercial ENVM work – section 3.3. Add information for CX and >6 allele ENVM result management – section 5.1. Add TOC, remove excess screen shots, update header titles
3	24 July 2020	Kirsten Scott	Add the "Exempt human specimen" details for packaging. Remove excess screen shots, update analytical details
4	8 Feb 2022	Alanna Darmanin & Kirsten Scott	Transferred to current template. Added Section 7 for cross-contamination check methods for all Analytical robotic platforms. Remove some screenshots, minor text updates

HealthSupport
Queensland
Forensic and Scientific Services

Proficiency Testing in Forensic DNA Analysis

1 Purpose and scope

To monitor the performance of the Forensic DNA Analysis laboratory against our own requirements in terms of quality control and quality assurance procedures, and against the performance of peer laboratories. This procedure shall apply to all Forensic DNA Analysis staff that are competent and currently performing examination, analytical processes and case management/reporting duties in Forensic DNA Analysis.

2 Definitions

ANZPAA - Australia and New Zealand Policing Advisory Agency
BPB - Brown paper bag
CTS - Collaborative Testing Services (USA)
FR – Forensic Register
NIFS - National Institute of Forensic Science (Australia)
STC - Said to contain

3 Allocation of Case Files – Proficiency Schedule

Proficiency tests assess an individual's ability to examine, process or case manage/report results within the Forensic DNA Analysis laboratory. A record of the external proficiency and internal proficiency participants is held in I:\Quality & Projects\Proficiency\Proficiency Roster, and is maintained by the Quality and Projects Team. An attempt should be made to include all scientists in at least one proficiency test each year (external or internal), and those that are able to report/review parentage proficiency tests will be required to undertake this test in addition to the routine proficiency test. Scientists that have not previously participated in an external proficiency test should be assigned a mentor (an experienced examining or reporting scientist as applicable) to assist them through the process. Each year on the construction of the proficiency roster, the staff (deemed competent for assessment) is to be reviewed by the appropriate senior staff member e.g. Team leader FRIT to review reporters and reviewers

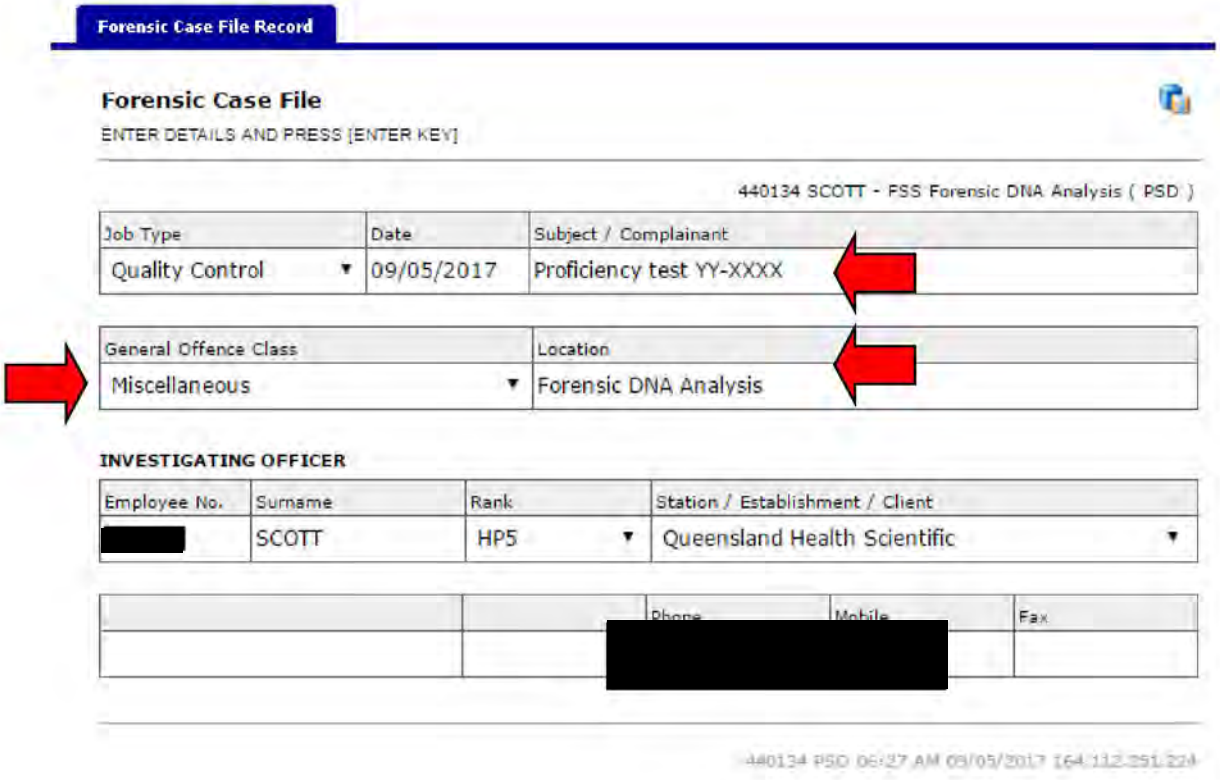
The majority of external CTS proficiency tests are performed by a sampling scientist and two reporting scientists (one scientist to report results, and one to review results). Occasionally, the Forensic DNA Analysis laboratory receives Body Fluid Identification Testing CTS; these tests are for sampling scientists only. Similarly, the Forensic DNA Analysis laboratory may occasionally receive DNA Database - Saliva Testing CTS tests. These tests contain reference samples only. These tests are processed by CA staff and can be reported and reviewed by those competent in reference profile data analysis.

4 Proficiency Case File Registration

All Proficiency cases should be paperless within the FR. However, if a hard copy case file is created, all pages are to have the FR number included.

The registration of proficiency cases in FR will be performed by a quality team staff member. To register a case:

1. Select Case Files Menu option
2. Select the add button
3. Select job type of "Quality Control"
4. Quality officer to add their employee number to the case registration. Press the save button.
5. Case information is to be added. In the **Subject/Complainant** field add "Proficiency test YY-XXXX" (where YY is the year and XXXX is the CTS test number e.g. 17-5703). Select 'Miscellaneous' under "General Offence Class' and in the **Location** field enter "Forensic DNA Analysis". Save the record. On saving the case information, a unique FR number will be generated.



Forensic Case File Record

Forensic Case File

ENTER DETAILS AND PRESS [ENTER KEY]

440134 SCOTT - FSS Forensic DNA Analysis (PSD)

Job Type	Date	Subject / Complainant
Quality Control	09/05/2017	Proficiency test YY-XXXX

General Offence Class	Location
Miscellaneous	Forensic DNA Analysis

INVESTIGATING OFFICER

Employee No.	Surname	Rank	Station / Establishment / Client
[redacted]	SCOTT	HP5	Queensland Health Scientific

		Phone	Mobile	Fax
		[redacted]		

440134 PSD 06:27 AM 09/05/2017 164.112.251.224

5 Proficiency Exhibit Registration

Proficiency tests are usually received as a BPB - STC a number of items (e.g. Item 1, Item 2 etc.). To simplify registration Quality team will directly register only the BPB as an exhibit.

1. Item / exhibit registration is from the exhibit register tab. Click the add button.

2. Enter the following information
   - Barcode of Item/exhibt
   - Select appropriate category type for the item = Bag.
   - Enter "1 x BPB" and CTS number into the description (eg. CTS 17-5704 1 x BPB)
   - Enter 'Forensic DNA Analysis' into the 'Located/Owner' box
   - Tick: 'Low', 'FSS DNA Analysis' and 'Sample has been collected……'
   - Enter your FR personnel ID number and save

   Note: Check to see if the exhibit is registered as **Priority 2**. (This should be automatic, but if not, add a "Notation" and change the priority in the same step).

3. Assign the exhibit a location by clicking the add button above the 'Exhibit Movement' table (scan entry) and store to exhibit room shelf 699 (**FDNA-EXSH-0699**).

   Note: Place the registered exhibit barcode onto the CTS BPB before placing the BPB on shelf 699. Remaining barcodes to be stapled to BPB.

6 Scenario and Item Description

1. The information required for each CTS is sent via email when the CTS itself has been sent. The participant code, webcode and due date are contained within the email, and the scenario and item description are attached to the email as a PDF.

   Note: If the case scenario and details are not included, data sheets are to be downloaded from the CTS portal and saved to the relevant CTS test folder. Downloading of data sheets from the CTS portal can be done a couple of ways, depending on your level of access. Either print from the status box in the Master Group main page, or through the Data Entry Library, by finding the test in the relevant year and clicking on DNA Analysis participant code link and using the print function.

2. Create a folder for the CTS in I:\Quality & Projects\Proficiency\Reports, and save the PDF into this folder.

3. Attach the PDF as a "Case File Notation" – access the "Case Management" tab and select "Case File Notation". Add the exhibit barcode into the Exhibit field and add appropriate comments. (The Exhibit Category field will automatically populate once the page is saved). Save page. The PDF can be attached by updating the page and choosing file in the Related File field.

   Note: Only one PDF can be uploaded per Case File Notation at one time, so multiple updates are required to attach more than one PDF. (e.g. the cover letter and the worksheets can be added to the same Case File Notation – however, they need to be uploaded separately.)

7 Case Allocation

1. Quality team are to Allocate the CTS test in the CTS portal – Refer to Appendix B

   Note: If a test has been incorrectly allocated or needs re-allocating – contact NIFS [redacted]

2. Allocate the case to a reporter via a request task function
   - From the case management tab request task
   - Check the "CM" box in the Request Type field
   - Check the "Reporter" box in the Job/Request Type field
   - Add the CTS due date to the "Date Required" field
   - Add the relevant Scientists staff number is added to the Case Officer Field, add CTS due date, and a comment

     e.g. "CTS 17-XXXX allocated
     Due date 16/05/2017
     Reporter: Jane Smith
     Reviewer: John Doe"

3. Allocate the case to a reviewer via a request task function
   - From the case management tab request task
   - Check the "Review" box in the Request Type field
   - Check the "Reviewer" box in the Job/Request Type field
   - Add the CTS due date to the "Date Required" field
   - Add the relevant Senior Scientists staff number is added to the Case Officer Field, add CTS due date, and a comment

     e.g. "CTS 17-XXXX allocated
     Due date 16/05/2017
     Reporter: Jane Smith
     Reviewer: John Doe"

4. Notify Senior Scientist Evidence of their allocated test by addition to FR personal list via a request task function.
   - From the case management tab request task
   - Check the "Exam" box in the Request Type field
   - Add the relevant Senior Scientists staff number is added to the Case Officer Field, add CTS due date, and a comment

     e.g. "CTS 17-XXXX allocated
     Due date 16/05/2017
     Reporter: Jane Smith
     Reviewer: John Doe"

5. Send 3 x appointments to the quality team. Set 1 appointment for the due date with the title 'CTS XX-XXXX due today'. Another appointment is to be set 1 week before the due date with the title 'CTS XX-XXXX due in 1 week'. The third appointment is to be set 2 weeks before the due date with the title 'CTS XX-XXXX' due in 2 weeks.

6. Write the CTS number, barcode, and due date on the quality board.

7. Enter the required information into the proficiency roster.

8 Examination

The examination, registration is to be completed by a scientist deemed competent in the examination of items.

There are three types of external proficiency tests received within the laboratory and examined by Evidence Recovery as follows:

1. involves the investigation of biological fluids/material based on the relevant history and subsequent submission of samples, if required, for DNA analysis.
2. does not require screening for the presence of biological fluids/materials and involves the submission of a sample from the substrates received for DNA analysis.
3. involves the investigation of biological fluids/material based on the relevant history without the subsequent submission of samples i.e. no DNA analysis is required.

All proficiencies should be examined and sampled as per the Examination of Items Standard Operating Procedure QIS 33800, and if applicable the appropriate presumptive and/or confirmatory test procedures.

Note: Reference samples must be registered as "Category = Reference".

Note: For proficiency cases only:

- Images taken of BPB – to be loaded as a notation under Item 1
- Sub-samples taken from Item exhibits, will need to be given exhibit status (via registration)

For **DNA Database - Saliva Testing CTS** only: processing will be completed by CA staff competent in FTA processing. After allocation of barcodes to each FTA, FTA cards are to be tracked to an FTA transfer box (for CA processing) and added to the Direct Amp FTA – FTA 3500xL worklist. Processing will be completed as per QIS 34035 .

8.1 CTS tracking – REF and CW samples

The following steps are to be followed for the tracking and examination of CTS cases:

1. Allocated HP3 opens the brown paper bag and registers the contents
2. Reference samples are tracked to the Ref Sampling box (403508484) (or directly to EX15 if the allocated HP2 is ready to sample)
3. HP3 examines the casework samples as per QIS 33800 and performs appropriate presumptive and/or confirmatory tests as required
4. HP2 samples reference samples as per QIS 33800
5. All samples to be stored to the CTS completed storage box when complete. Note: it is not necessary for the HP2 staff to track reference samples back to the original CTS packaging.
6. For parentage CTS tests, individual envelopes are to the tracked to the FTA sampling box, and are to be stored when complete by CA staff as completed FTA's. The outer packaging is to be stored to the CTS completed storage box.

9 Storage of Exhibits

After sampling is complete, seal the exhibits and store to storage box 723211753.

10 Case Management

Cases shall be managed in accordance with the procedure 33773 Procedure for Profile Data Analysis using the Forensic Register. Each proficiency test is treated in the same way as a casework casefile that includes reference samples. An **exception** to this is that NCIDD uploads are not required for CTS samples. The case manager/reporter should ensure that the "NCIDD" box on the PDA page remains unticked and that the appropriate result lines (excluding NCIDD uploads are used). Each test will have a case manager/reporter and a peer reviewer.

- The case managing scientist should monitor the progress of testing and ensure that after sampling all samples progress as required.
- Ensure that any reference profiles provided with the case file information are used.
- If required, an extension may be sought. The reporting scientist should contact the Quality & Projects team for extension requests. Any extension should be communicated to all participants.

11 Reporting Proficiency Cases

1. Complete Forensic Register entries. CTS results **should also be electronically entered into the CTS portal (refer to Appendix C)**, which can be accessed at http://www.cts-portal.com/
   NOTE: Must use Microsoft Edge browser for the CTS portal

1. Reporting requirements as follows:
   a. Appropriate presumptive and confirmatory tests are indicated
   b. DNA interpretation is completed as per 33773 (with NCIDD exception as per Section 9) or 25303 for paternity tests. Please ensure appropriate datasets are used (e.g. NIST).
   c. The results obtained for each sample are entered into the proficiency paperwork, and as EXH lines.
   d. Enter results and submit for review via the CTS portal (Refer to Appendix C).

2. After the report has been completed, the reviewing scientist shall:
   a. Review Forensic Register entries
   b. Review CTS portal entries
   c. Once review is accepted, email pdf of the results to the Quality team [redacted] (Refer to Appendix C)
   d. Submit results directly to CTS (Refer to Appendix C)

3. Quality and Projects Team will then:
   a. Save the pdf containing the results to the relevant proficiency folder in I drive.
   b. Upload the pdf of the results as a 'Case File Notation'
   c. Upload a copy of the automatic submission email as a "Case File Notation"

Note: In instances where the CTS test has been granted an extension, submission is not possible through the CTS portal, and the following steps are to be taken:

- Reporter:
  - Complete DNA Interpretation as per 33773. (with the NCIDD exception as mentioned in Section 9).
  - Enter results into the proficiency paperwork and the Forensic Register.

- Reviewer
  - Review paperwork and Forensic Register entries.
  - Submit paperwork to Quality and Projects Team.

- Quality and Projects Team:
  - Scan paperwork and upload to the Forensic Register as a "Case File Notation".
  - Email the results to NIFS.

12 Review of Proficiency Results

The Quality Team will review all proficiency tests as follows:

1. Manufacturer's information is received via email, which includes how the exhibits were created (including donors/biological material used) and the results (compiled from predistrubution laboratories and at least 10 participants).

2. Compare the results received in the manufacturers information versus the results generated by our laboratory.

3. A report of all participating laboratory's results is also forwarded to the Forensic DNA Analysis laboratory for comparative purposes. These are useful if our laboratory generates results that do not align with the manufacturers information.

4. An OQI should be generated for any results from our laboratory that do not align with the results from the majority of the other participating laboratories.

5. All associated reports shall be uploaded as Case File Notations.

6. Follow up to be added as a Case File Notation (template as per Appendix A)

   - Ensure that the casefile barcode is added to the "Exhibit Field"
   - Add the Manufacturers Information PDF to this Case File Notation
   - Update this Case File Notation with the method of feedback (once done)

7. In the event of a discrepant result, a "please explain" letter is generated by NIFS. It is the responsibility of the Quality and Projects Team to initially investigate and address these communications.

Outcomes

All proficiency test outcomes are to be reported to all staff at the monthly Forensic DNA Analysis Team Meetings.

13 Records

- Electronic CTS paperwork is stored in I:\Quality & Projects\Proficiency\Reports, and in the Forensic Register as a Case File Notation

- Reports from NIFS/ANZPAA are stored in I:\Quality & Projects\Proficiency\Reports, and within the Forensic Register as Case File Notations.
- Forensic Register records to be complete

14 References

Nil

15 Associated documents

33773 Procedure for profile Data Analysis using the Forensic Register
33800 Examination of Items (Forensic Register)
34035 Forensic Register FTA Processing
33744 Forensic Register Training Manual
34006 Procedure for the release of Results using the Forensic Register

16 Amendment history

Version	Date	Author/s	Amendments
1	9 May 2017	Kirsten Scott	First Issue
2	9 October 2017	Kerry-Anne Lancaster	Addition of paperless CTS workflow and required changes to processes. Removed references to Internal Proficiency tests. Images are to be loaded against Item 1 (no longer against casefile). Slight change in order of review steps in CTS portal. Only the BPB is to be registered by Quality. Minor formatting changes.
3	21 March 2018	Kerry-Anne Lancaster	Able to add multiple documents against the one case file notation. Added in extra steps for Quality for follow up and amended Appendix A to reflect this. Explicitly stated the reference samples must be registered as "reference". Addition of extra screenshots to Appendix B for reviewers. Added steps on submission of CTS tests that have been granted an extension.
4	5 February 2019	Kerry-Anne Lancaster	In the task/request for reporters and reviewers – due date added in the date required field, and appropriate request type check box ticked. For reporting – NCIDD upload is not required – box to be unticked prior to saving PDA page. If a hard copy of the test is required – all pages are to be marked with FR number. Addition of sample tracking steps for ER team. Information added as to how to re-allocate tests and download data sheets. Addition of worklist required for samples for Saliva database tests.
5	2 April 2020	Chelsea Savage	Edited screen shot in 16.2.3. Added points 5, 6 and 7 to section 6. Removed details

			regarding creating statements from section 10. Other minor edits and removal of screenshots. Section 3 - Addition of a yearly review of competent staff for proficiency testing.
6	14 April 2021	Chelsea Savage	CTS's are now being received paperless – updates to section 4 – 6 to reflect this. Added QIS document number for Paternity tests – section 11. Separate Appendix B and C to clarify actions by Quality Team and actions by reporters/reviewers. Removed PPE from definitions. Added new email contact for NIFS. Amendments to section 12. Result PDFs no longer need to be forwarded to FSS Quality Advisor (Section 11). Change 'OO' staff to 'CA' staff. Update section 8.1 regarding CTS storage.

17 Appendices

1 Appendix A Proficiency Test Results Follow-up template
2 Appendix B CTS portal instructions for the Quality Team
3 Appendix C Instructions for entering, reviewing & submitting results via CTS portal

17.1 Appendix A

Proficiency Tests

Results Follow Up Template

Proficiency Test #:

Reporting Case FR#:

Date Received:

Date Due:

Date Submitted:

Reported by:

Reviewed by (and date):

Results Acceptable: YES / NO **(if NO) Team Leader notified:** YES / N/A

Comments:

OQI Required: YES / NO **OQI #:**

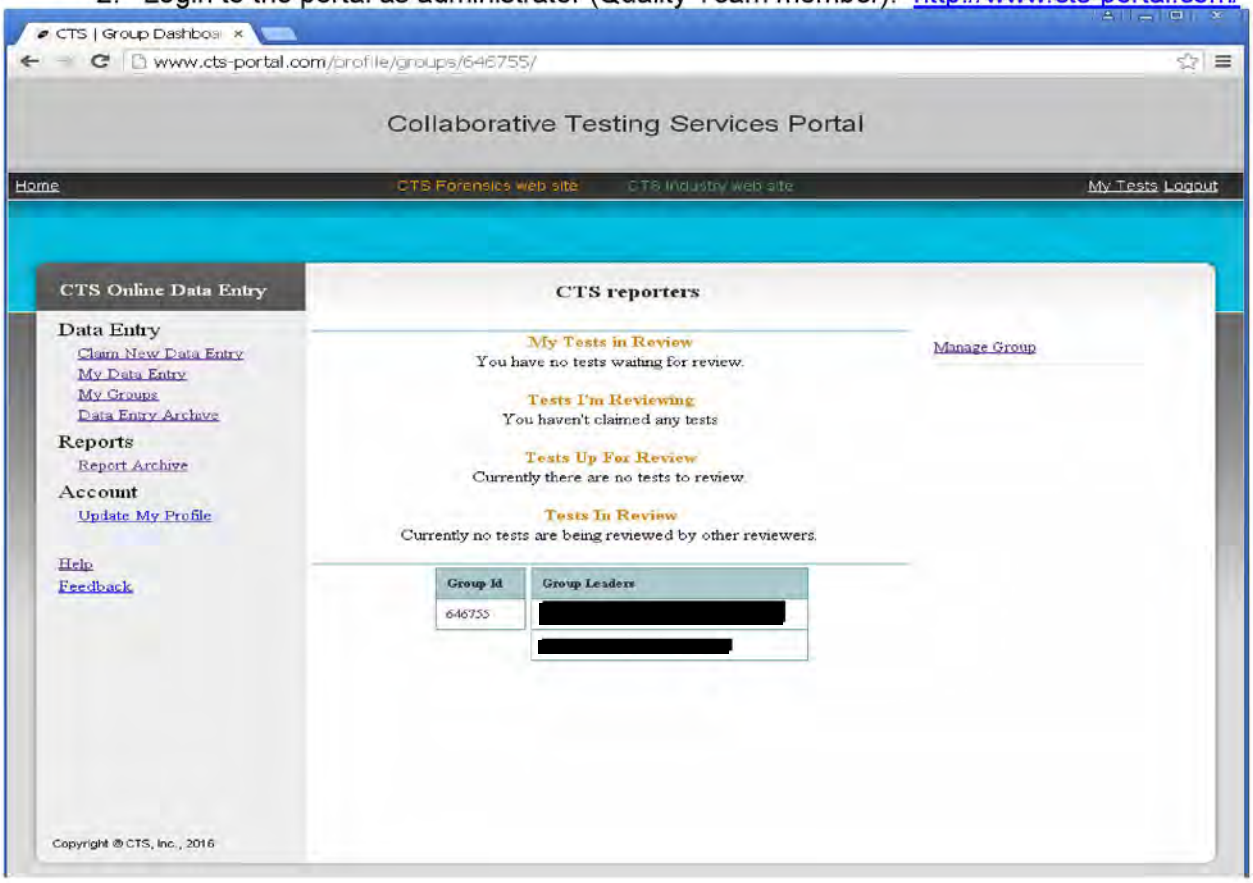
Results feedback to Forensic DNA Analysis staff: YES / NO (and how) – eg. Team meeting or email.

17.2 Appendix B: CTS portal instruction for the Quality Team

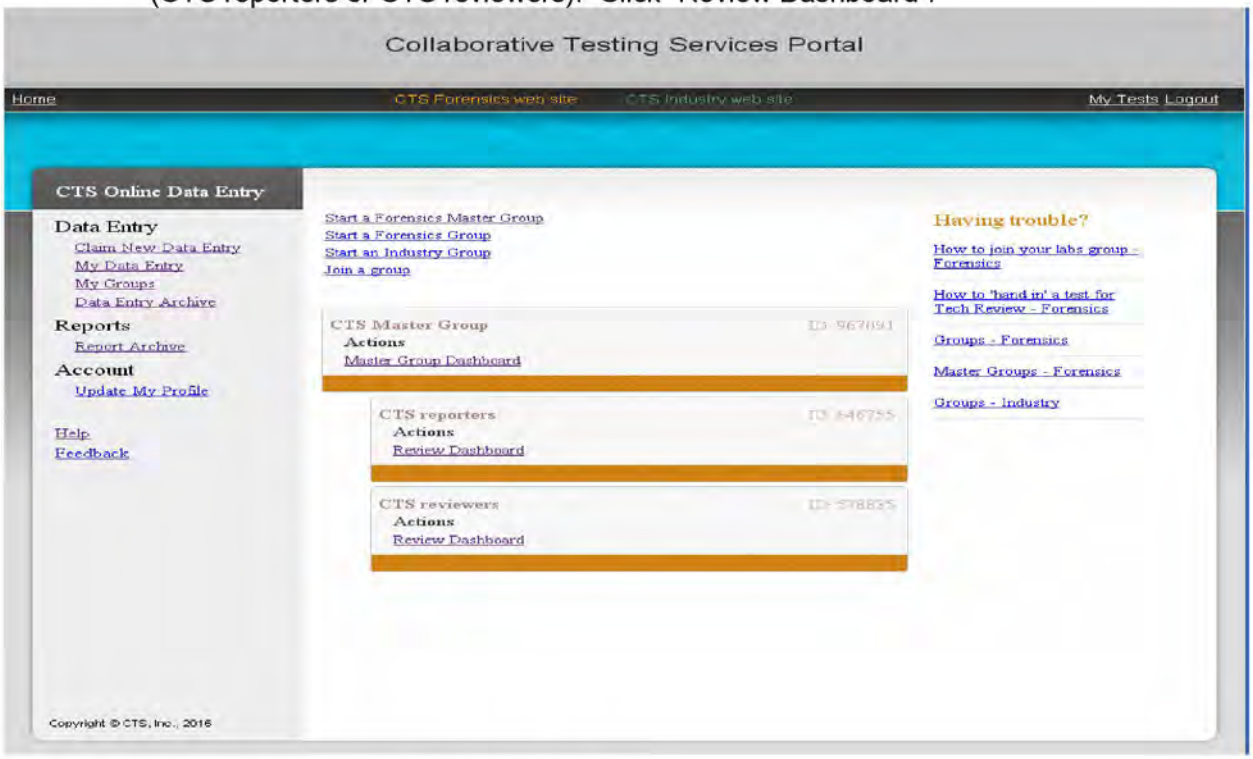
NOTE: Must use Microsoft Edge browser for the CTS portal

17.2.1 To invite reporters/reviewers to the CTS portal group (Quality Team Action)

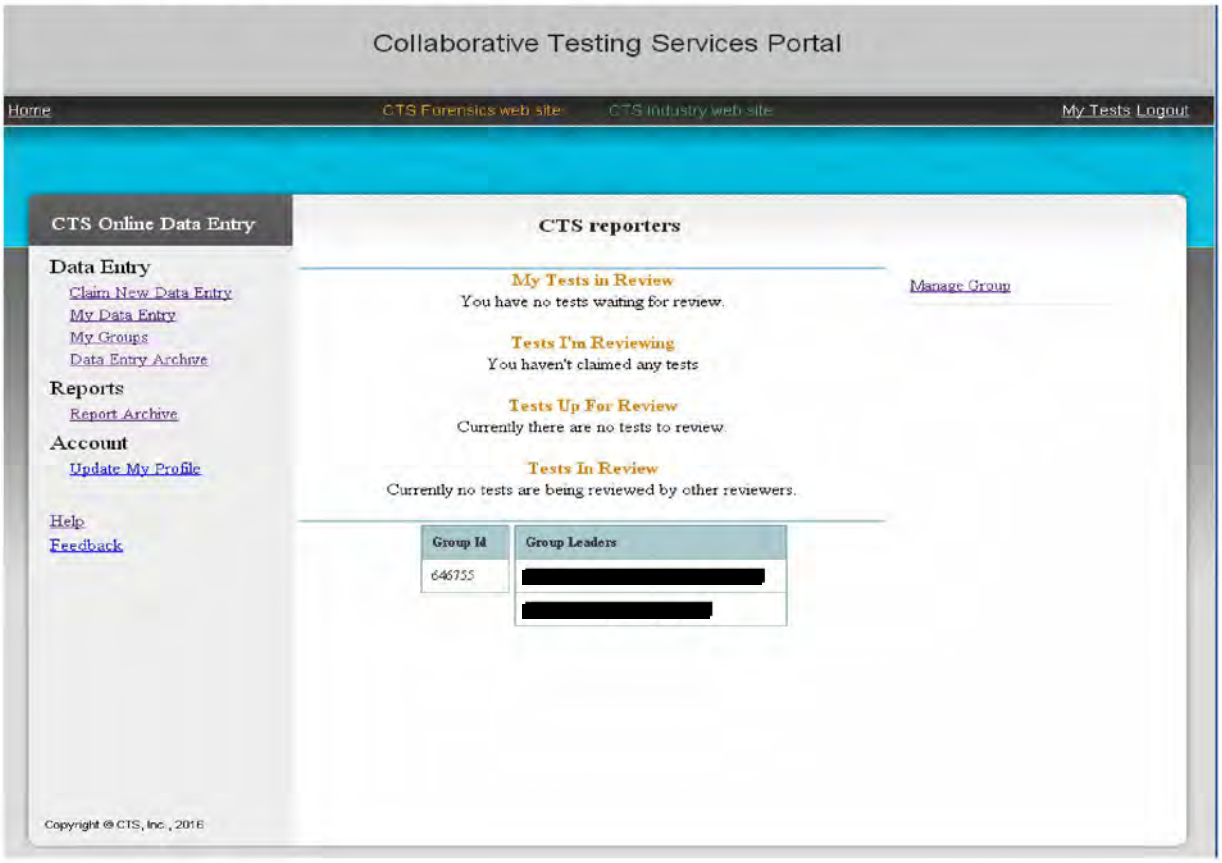
2. Login to the portal as administrator (Quality Team member). http://www.cts-portal.com/



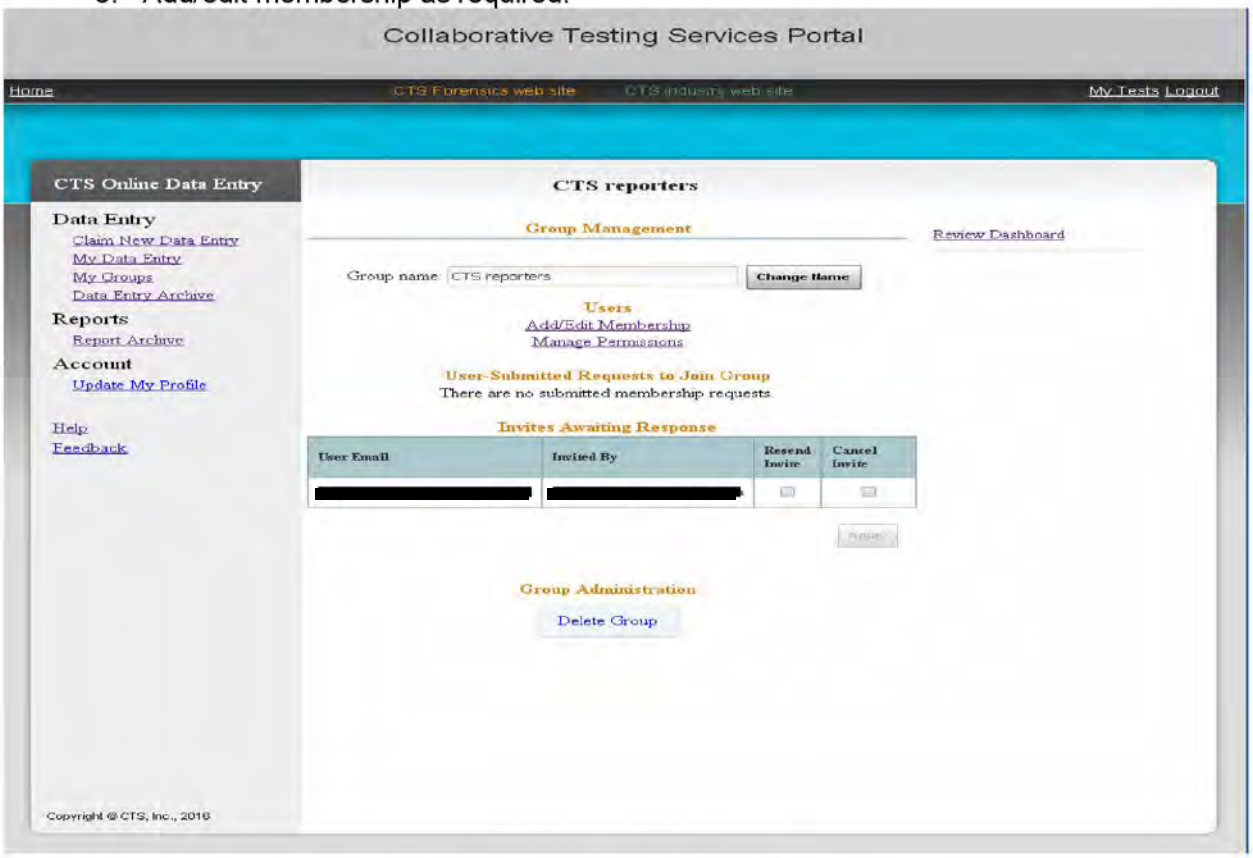
3. Select "My Groups" on the far left, then choose a group to action from the centre panel (CTS reporters or CTS reviewers). Click "Review Dashboard".



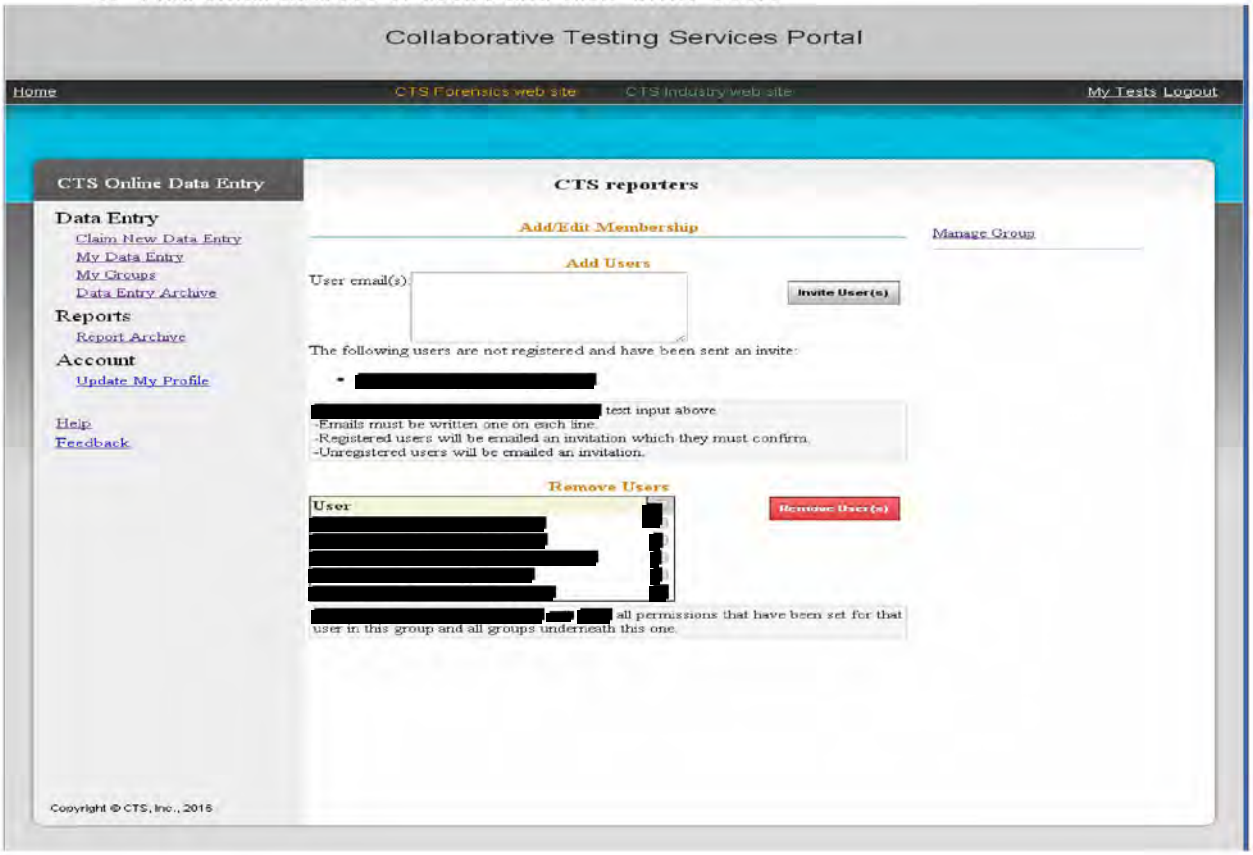
4. Select "Manage Group" on the far right.



5. Add/edit membership as required.

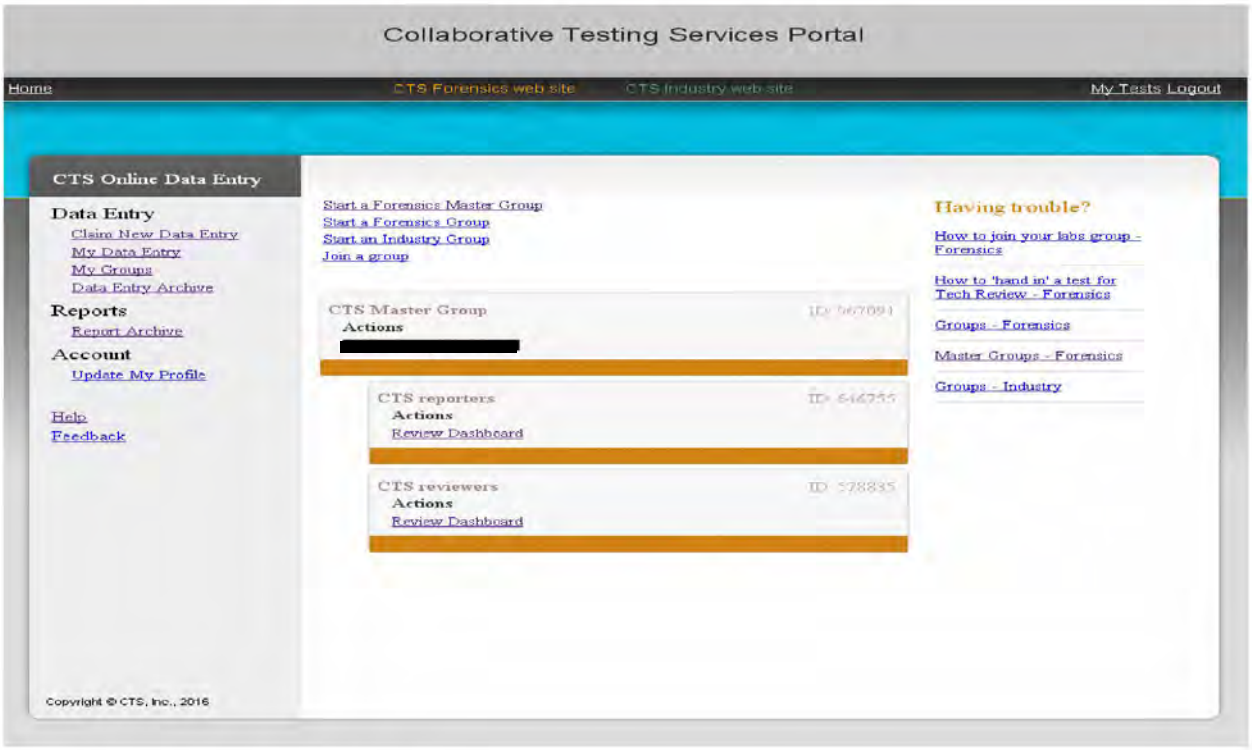


6. Add email address of user/s and click "Invite Users"

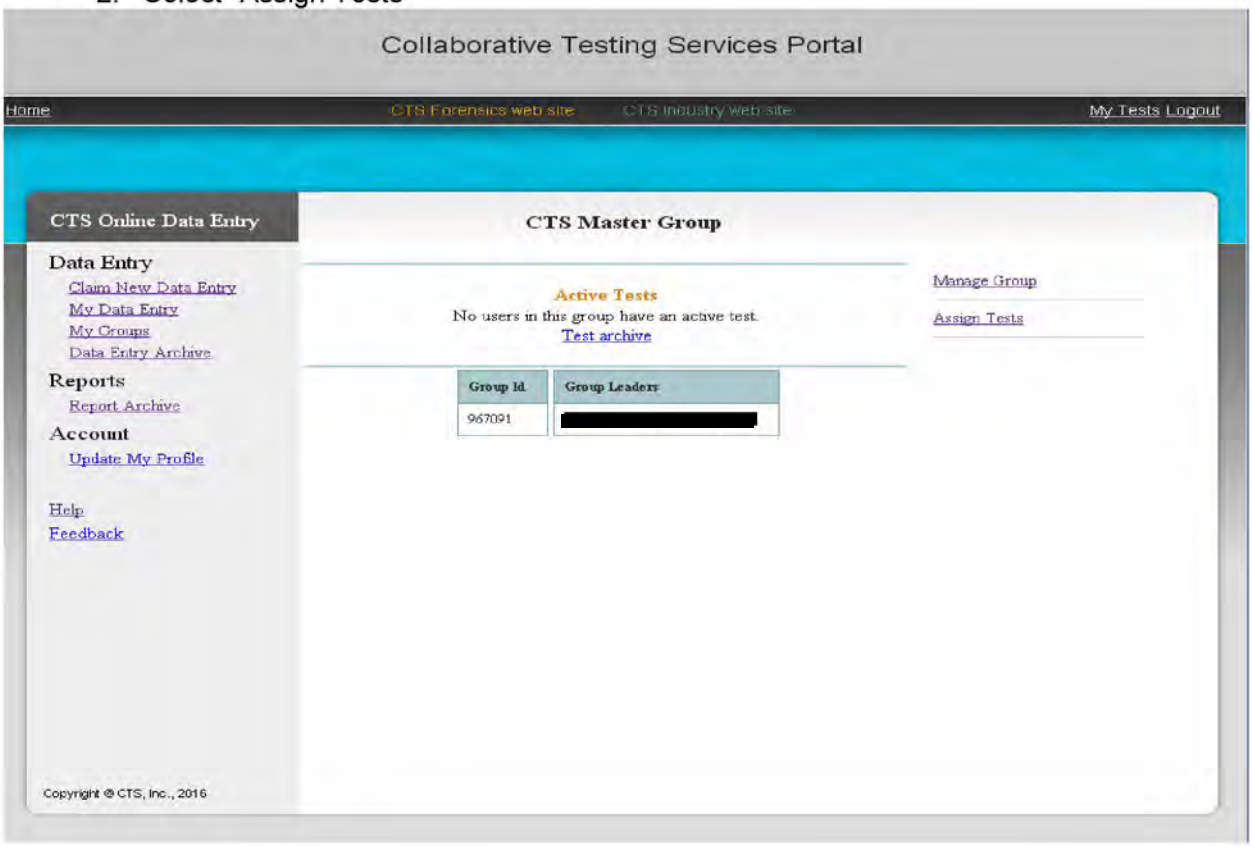


17.2.2 Assign/Allocate CTS test (Quality Team Action)

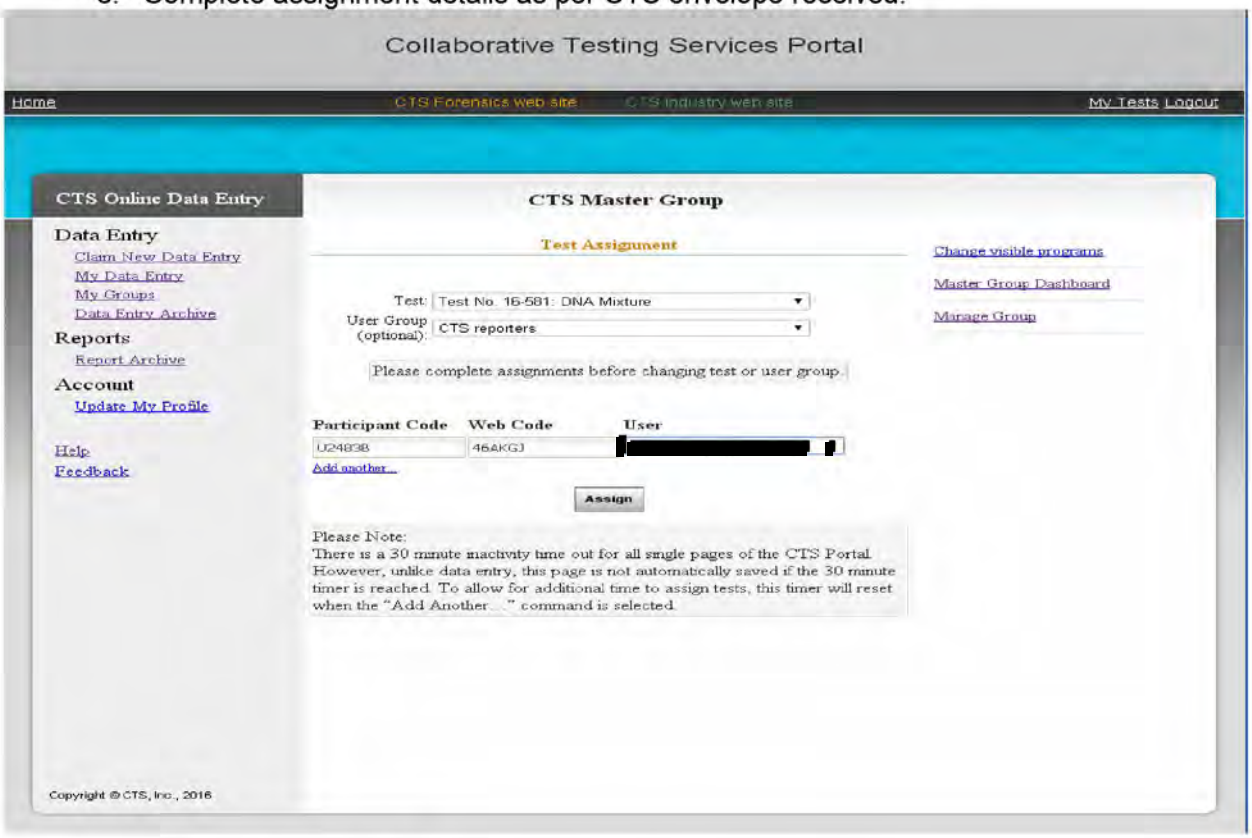
1. Select "Master Group" Dashboard



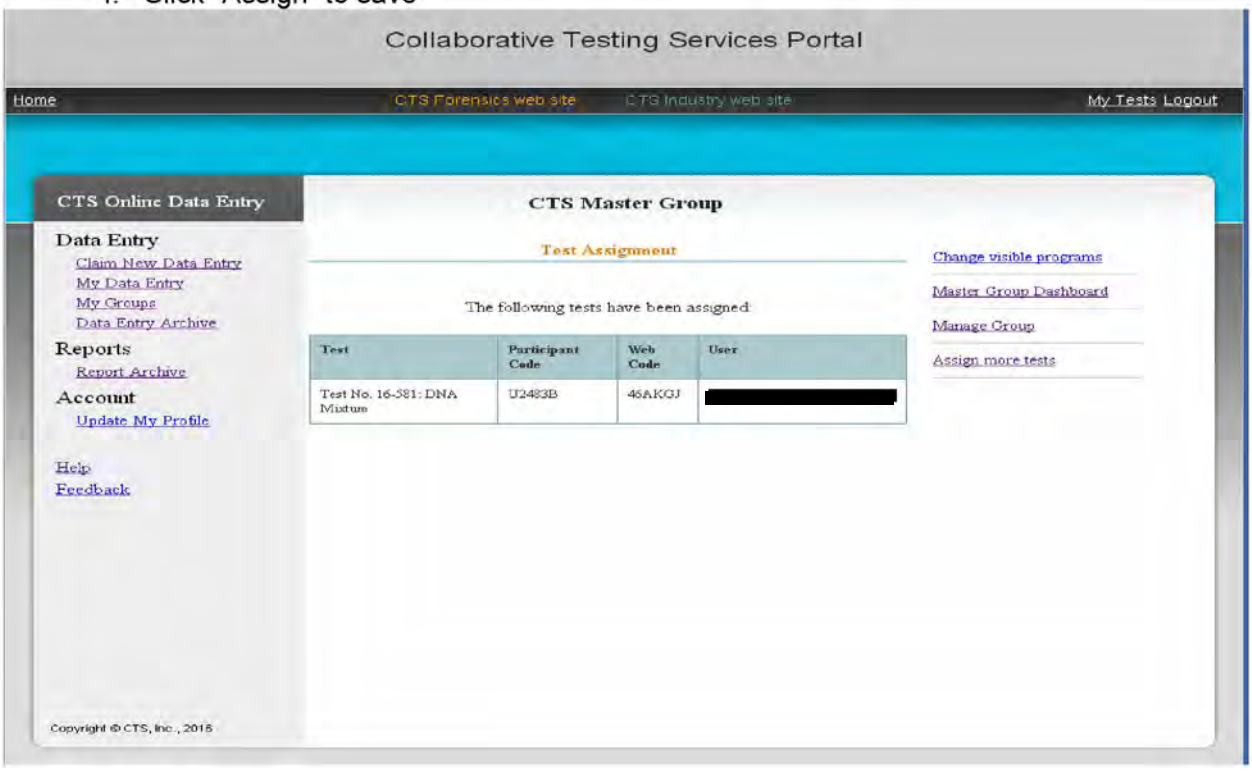
2. Select "Assign Tests"



3. Complete assignment details as per CTS envelope received.



4. Click "Assign" to save



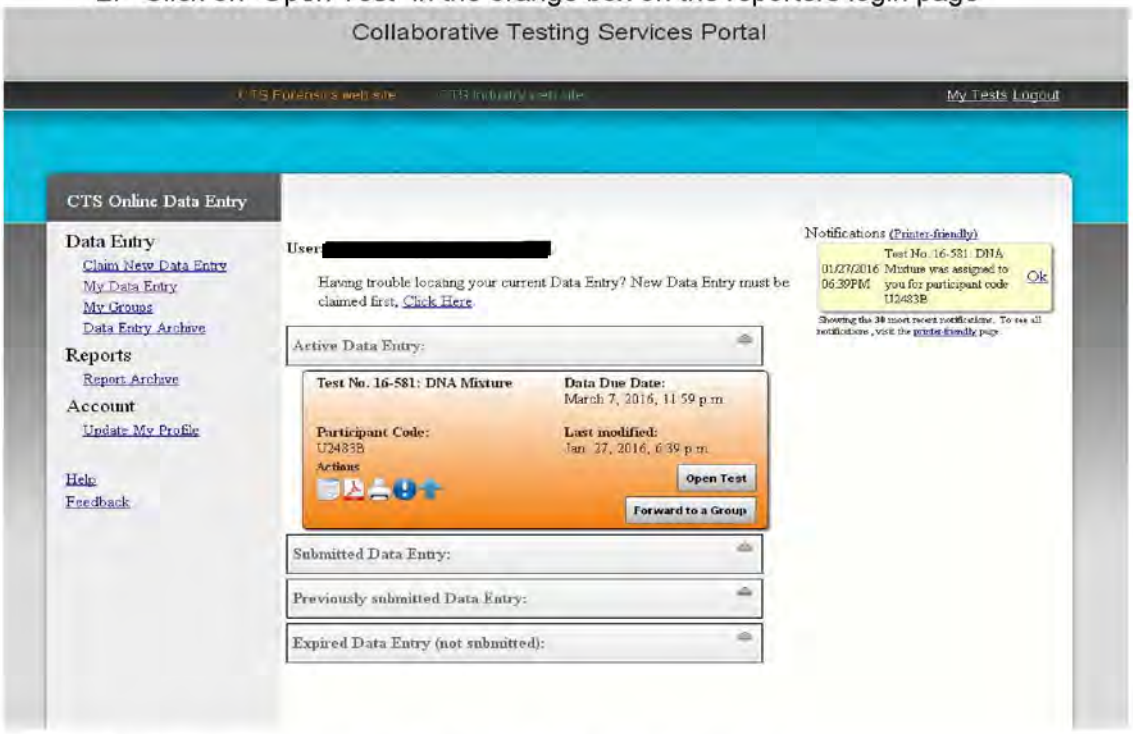
17.3 Appendix C: Instructions for entering, reviewing and submitting results via CTS portal

Access the CTS portal using the following link http://www.cts-portal.com/, and login using your QH email and password.

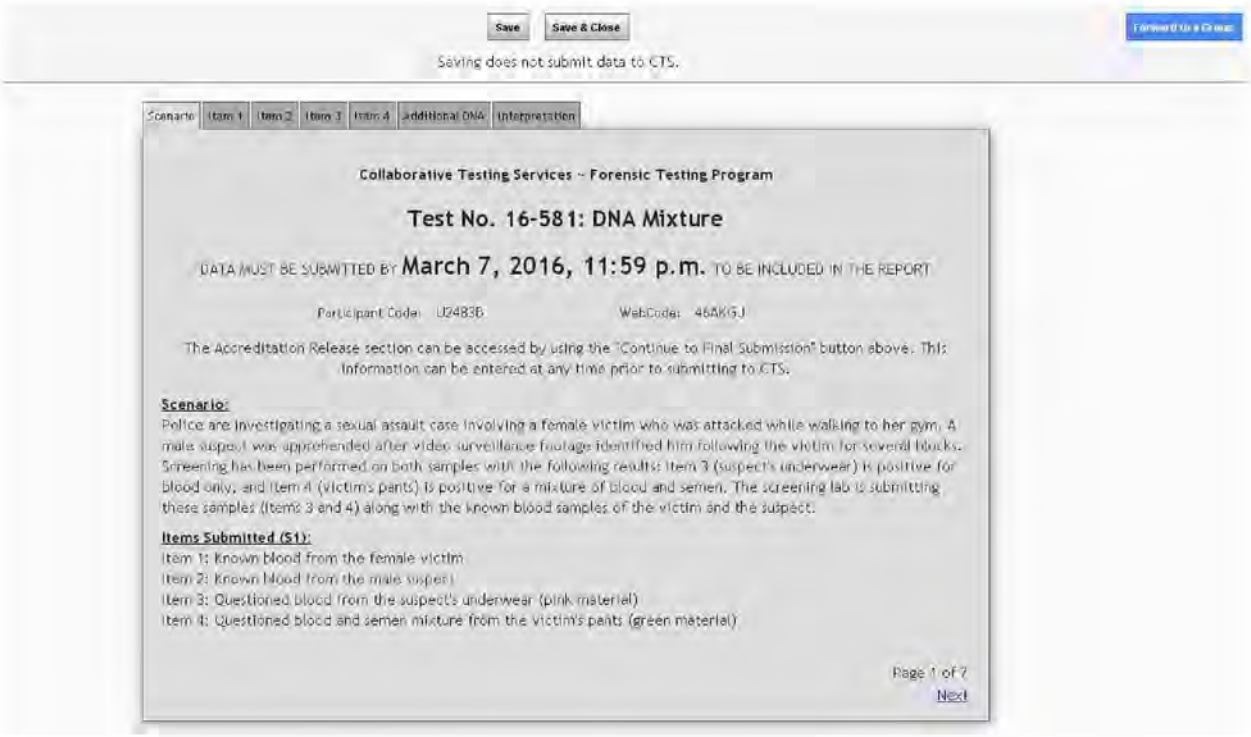
17.3.1 Entering results for a CTS test (Reporting Scientist Action)

NOTE: Must use Microsoft Edge browser for the CTS portal

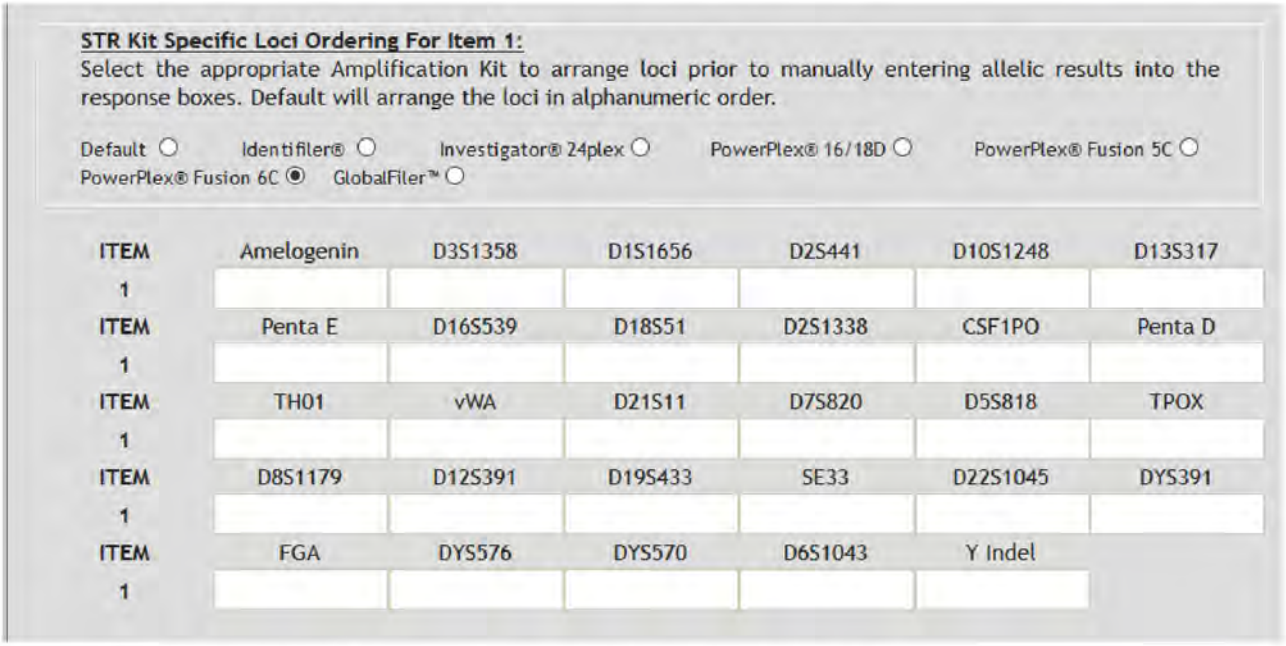
1. When results are ready for upload the electronic CTS form is to be completed
2. Click on "Open Test" in the orange box on the reporters login page



3. The Electronic Form appears as below. Click 'Next'.


Save
Save & Close
Saving does not submit data to CTS.
Scenario
Item 1
Item 2
Item 3
Item 4
Additional DNA
Interpretation
Collaborative Testing Services – Forensic Testing Program
Test No. 16-581: DNA Mixture
DATA MUST BE SUBMITTED BY March 7, 2016, 11:59 p.m. TO BE INCLUDED IN THE REPORT
Participant Code: U24836
WebCode: 46AKGJ
The Accreditation Release section can be accessed by using the "Continue to Final Submission" button above. This information can be entered at any time prior to submitting to CTS.
Scenario:
Police are investigating a sexual assault case involving a female victim who was attacked while walking to her gym. A male suspect was apprehended after video surveillance footage identified him following the victim for several blocks. Screening has been performed on both samples with the following results: Item 3 (suspect's underwear) is positive for blood only, and Item 4 (victim's pants) is positive for a mixture of blood and semen. The screening lab is submitting these samples (Items 3 and 4) along with the known blood samples of the victim and the suspect.
Items Submitted (S1):
Item 1: Known blood from the female victim
Item 2: Known blood from the male suspect
Item 3: Questioned blood from the suspect's underwear (pink material)
Item 4: Questioned blood and semen mixture from the victim's pants (green material)
Page 1 of 2
Next

4. Select "PowerPlex@Fusion 6C" to order loci appropriately (note that D6 is at the end).



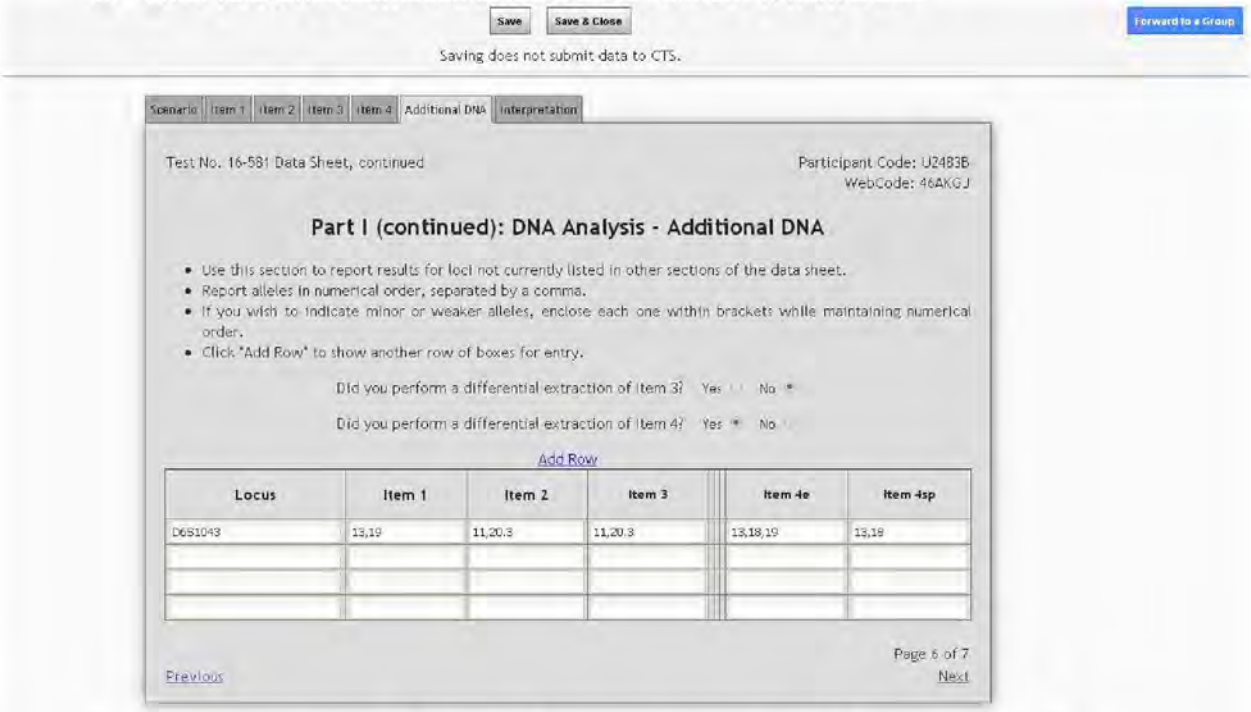
STR Kit Specific Loci Ordering For Item 1:

Select the appropriate Amplification Kit to arrange loci prior to manually entering allelic results into the response boxes. Default will arrange the loci in alphanumeric order.

Default ○ Identifiler® ○ Investigator® 24plex ○ PowerPlex® 16/18D ○ PowerPlex® Fusion 5C ○
PowerPlex® Fusion 6C ◉ GlobalFiler™ ○

ITEM 1	Amelogenin	D3S1358	D1S1656	D2S441	D10S1248	D13S317
ITEM 1	Penta E	D16S539	D18S51	D2S1338	CSF1PO	Penta D
ITEM 1	TH01	vWA	D21S11	D7S820	D5S818	TPOX
ITEM 1	D8S1179	D12S391	D19S433	SE33	D22S1045	DYS391
ITEM 1	FGA	DYS576	DYS570	D6S1043	Y Indel	

5. Enter relevant information into each tab i.e. Item 1, Item 2 etc



Save | Save & Close | Forward to a Group

Saving does not submit data to CTS.

Scenario | Item 1 | Item 2 | Item 3 | Item 4 | Additional DNA | Interpretation

Test No. 16-581 Data Sheet, continued — Participant Code: U2483B, WebCode: 46AKGJ

Part I (continued): DNA Analysis - Additional DNA

- Use this section to report results for loci not currently listed in other sections of the data sheet.
- Report alleles in numerical order, separated by a comma.
- If you wish to indicate minor or weaker alleles, enclose each one within brackets while maintaining numerical order.
- Click "Add Row" to show another row of boxes for entry.

Did you perform a differential extraction of Item 3? Yes ○ No ◉

Did you perform a differential extraction of Item 4? Yes ◉ No ○

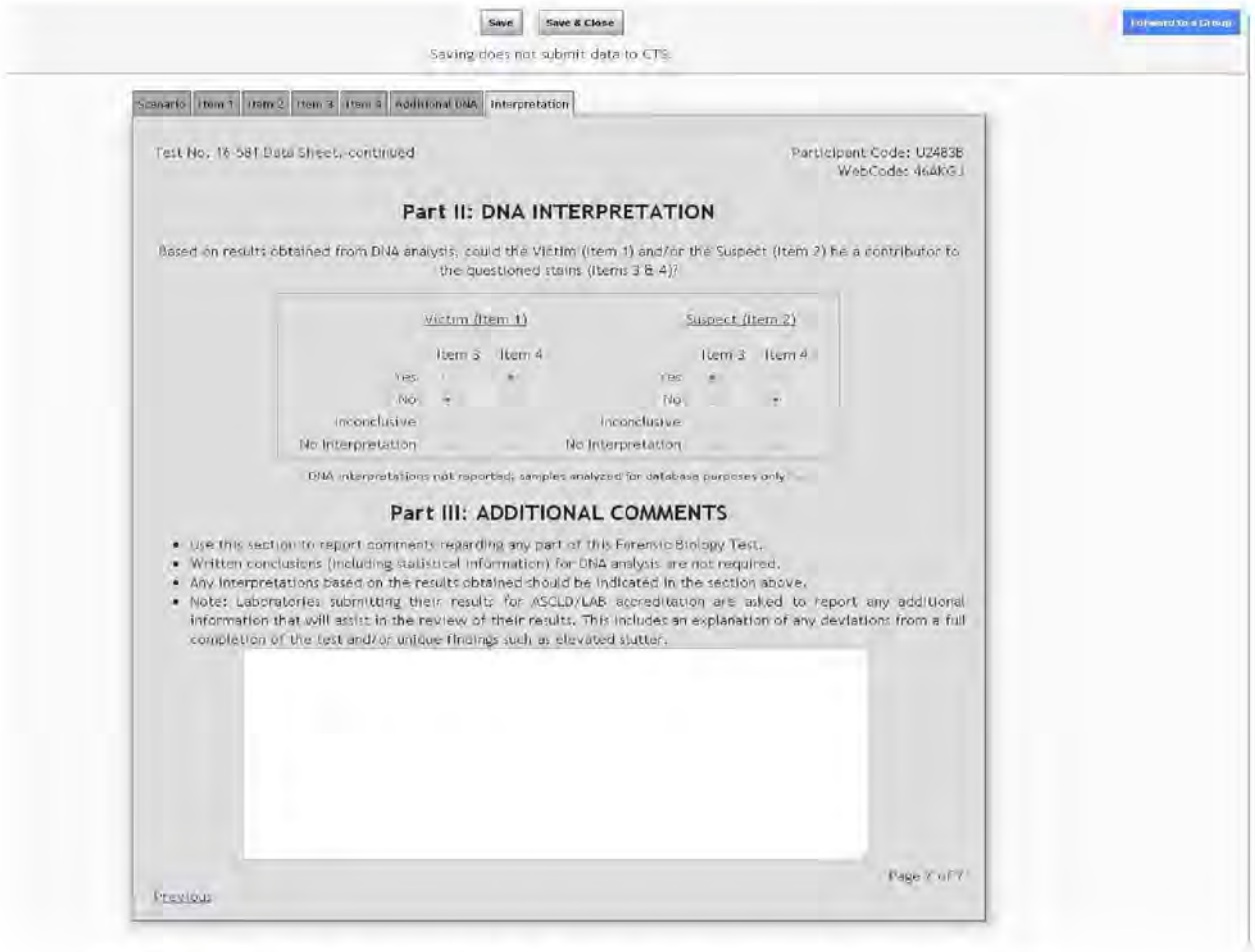
Add Row

Locus	Item 1	Item 2	Item 3	Item 4e	Item 4sp
D6S1043	13,19	11,20.3	11,20.3	13,18,19	13,19

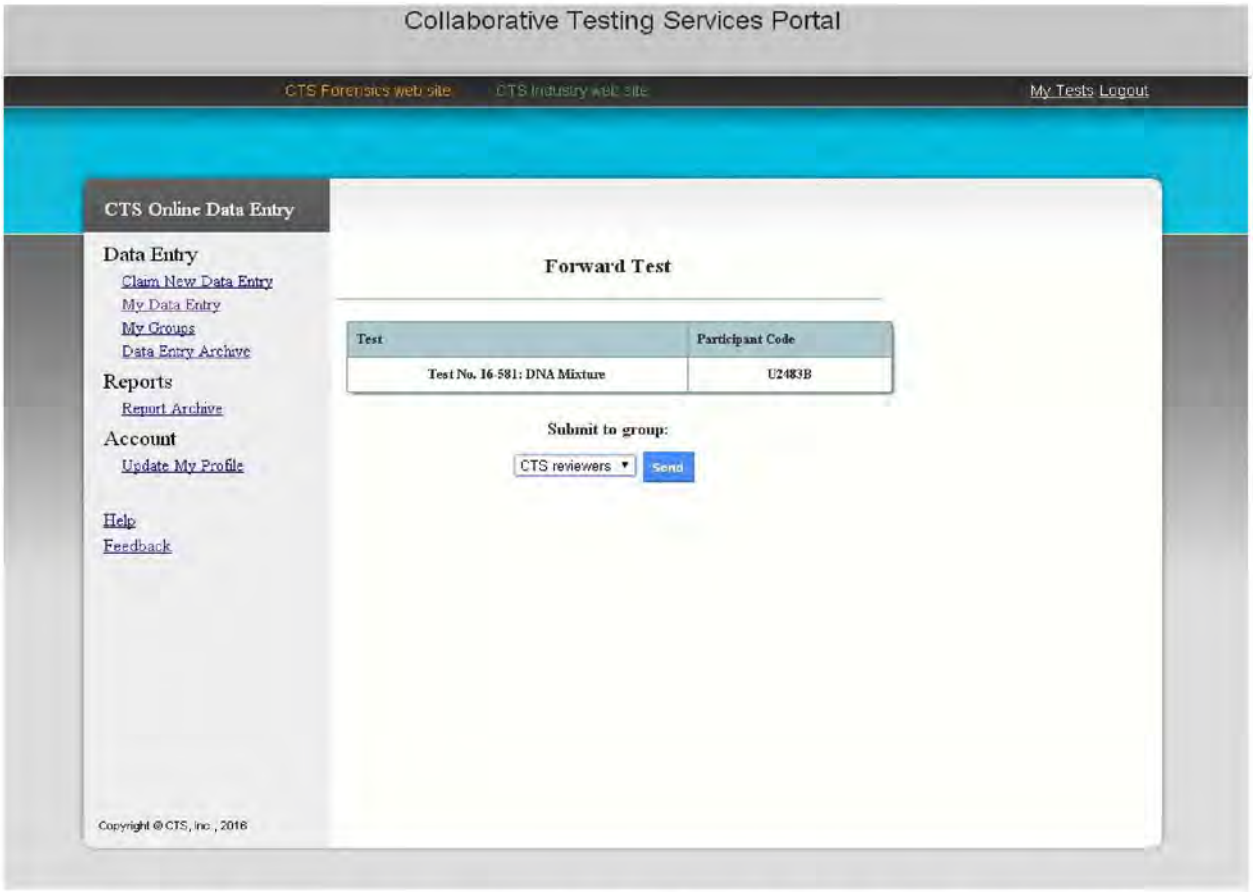
Page 6 of 7

Previous Next

6. After completing data entry (including interpretation), click "Save" and then click "Forward to Group" (in the top right corner)



7. Select ‘CTS Reviewers’ from the dropdown menu and then click ‘send’.



CTS Reporting has now been completed and is ready for review. Reporter transfers the case file to the reviewer. The Quality Team is notified that the CTS has progressed to review.

CTS Online Portal Notification

[redacted]

Sent: Wed 10/02/2016 2:35 PM
To: Kirsten Scott

CTS

The following message is from Collaborative Testing Services' online Portal.

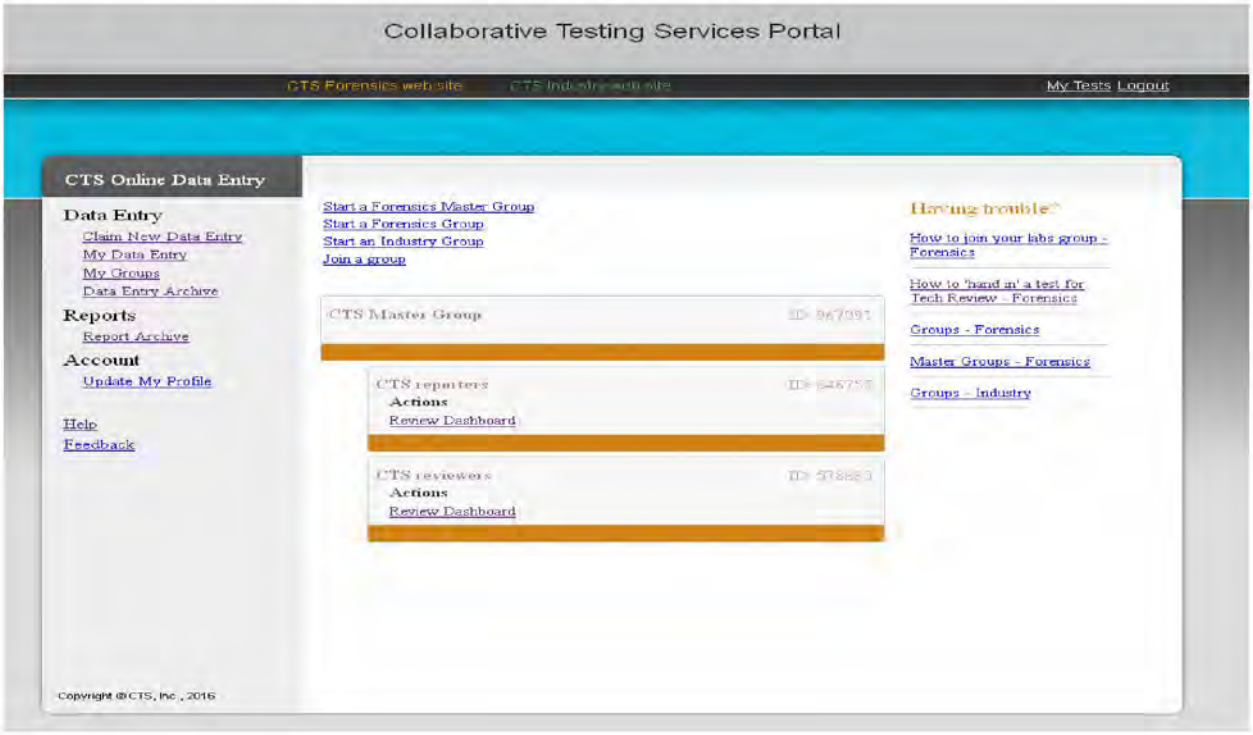
Test No. 16-581: DNA Mixture, for participant code U2483B, has been forwarded to the group CTS reviewers.

Collaborative Testing Services
[redacted]

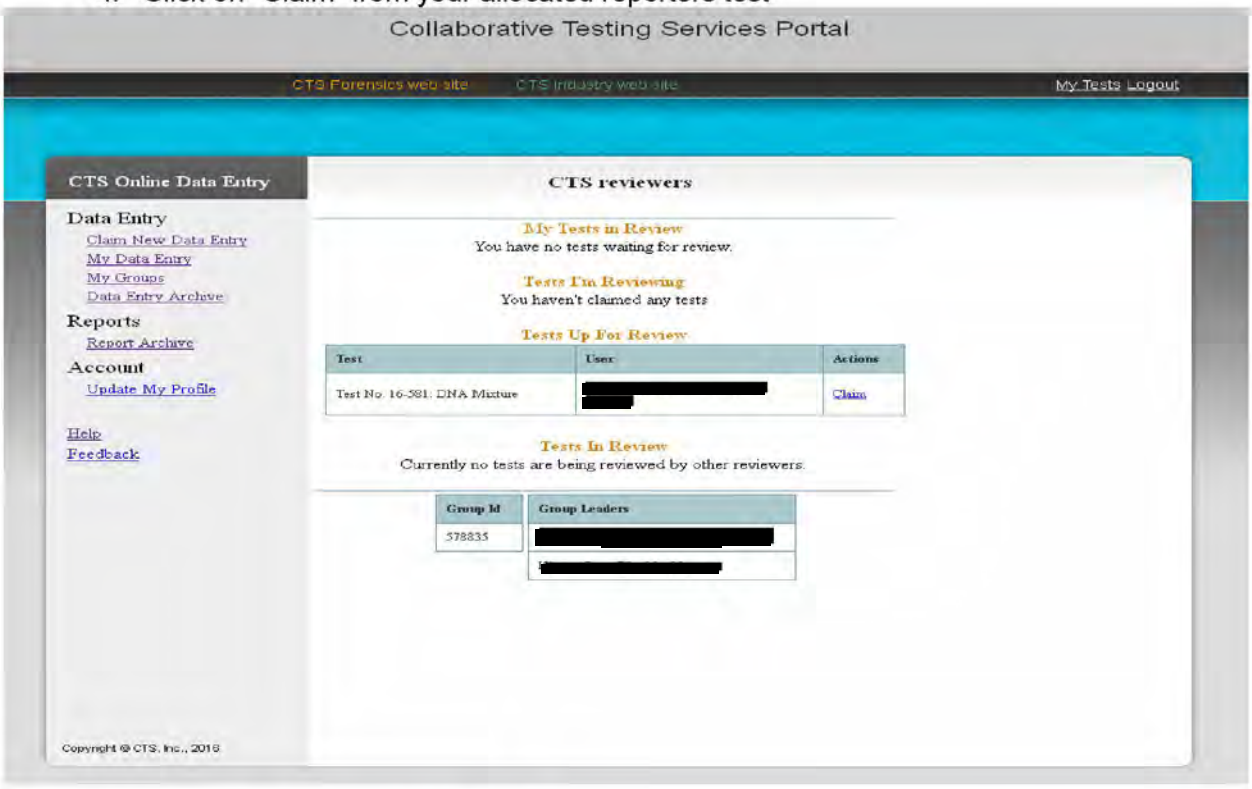
17.3.2 Reviewing and submission of results for a CTS test (Reviewing Scientist Action)

NOTE: Must use Microsoft Edge browser for the CTS portal

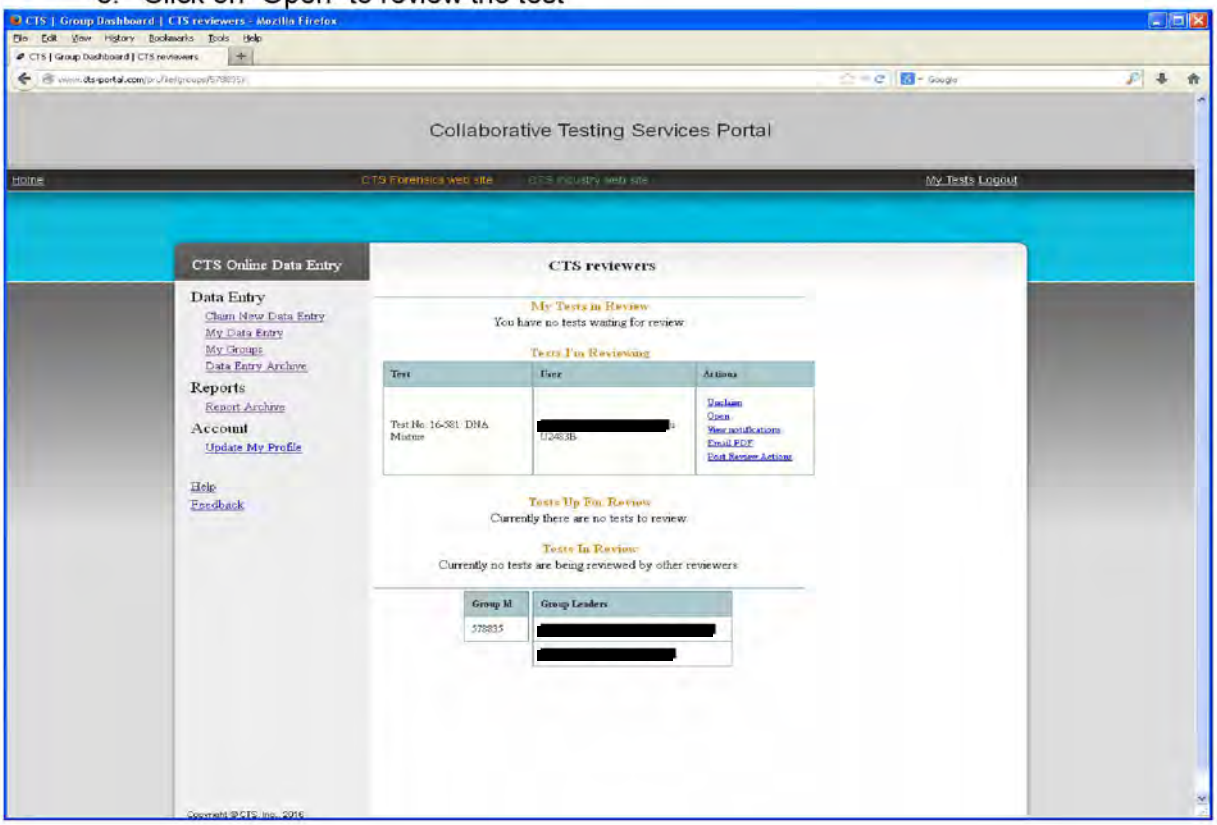
1. When results are ready for review, the reporter will transfer the case file to the reviewer.
2. The reviewer logs into the CTS portal and selects “My Groups” from the left panel.
3. Click on the CTS Reviewers “Review Dashboard”



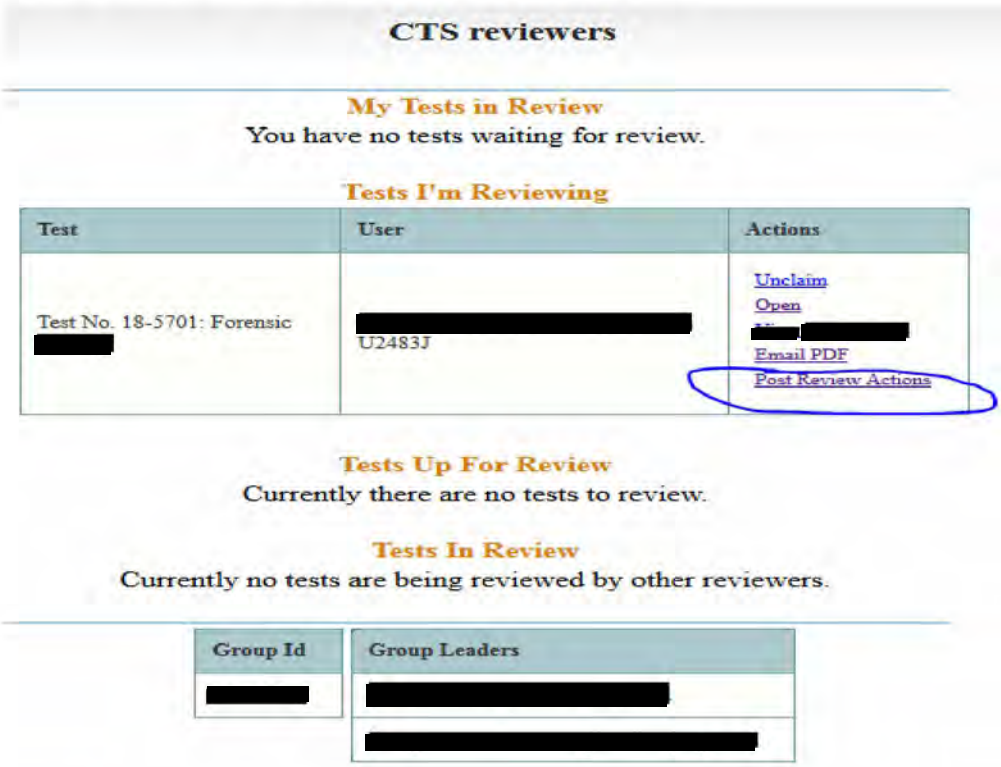
4. Click on "Claim" from your allocated reporters test



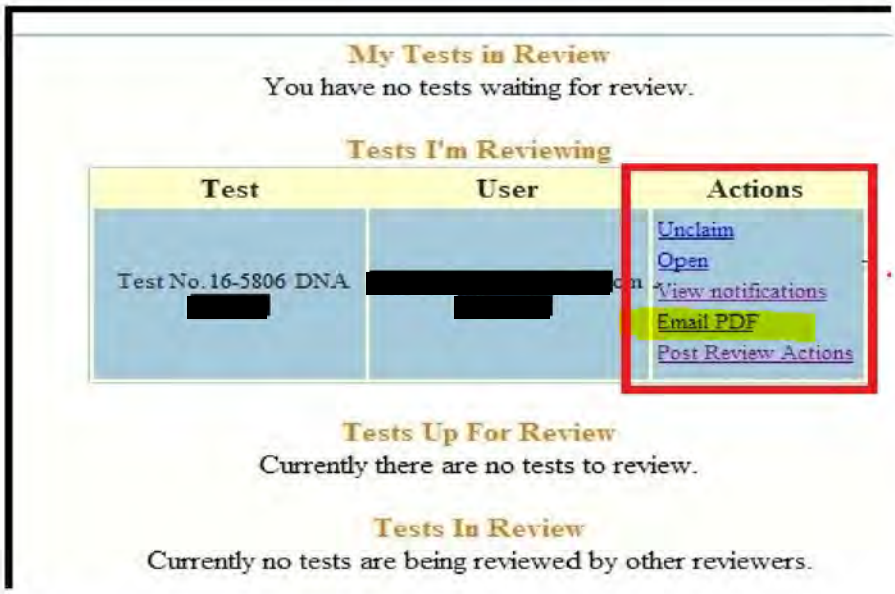
5. Click on "Open" to review the test



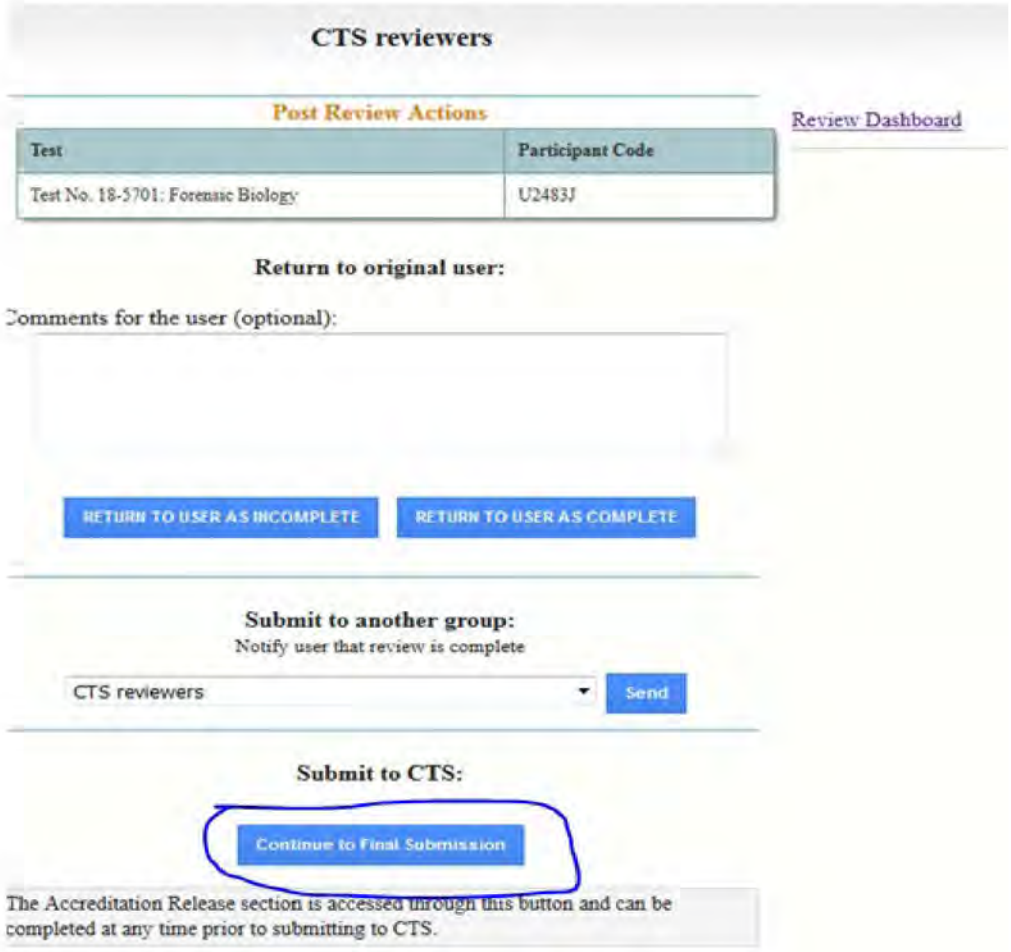
6. **If the review is <u>not</u> OK**, click on "Post Review Actions", then click on "Return to User as Incomplete", this will send the test back to the reporter for corrections. Follow steps 1-5 to re-review the test once completed by the reporter.



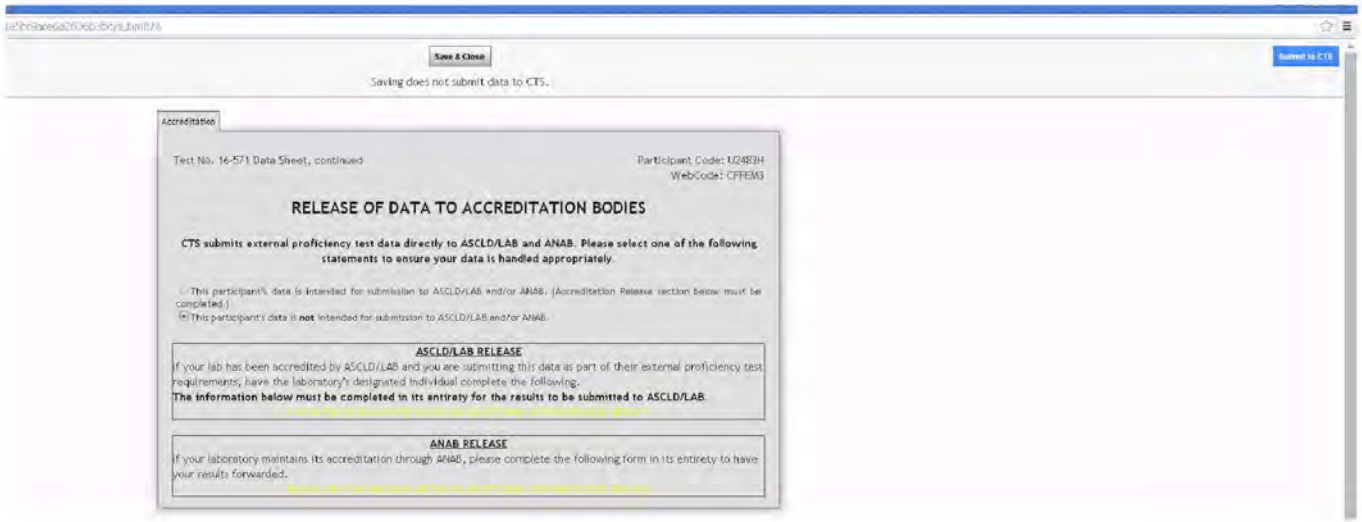
7. **If review is OK**, Click on "Email PDF" and send the results to the Quality Team [redacted]



8. If the review is OK, click on "Continue to Final Submission" under Submit to CTS.

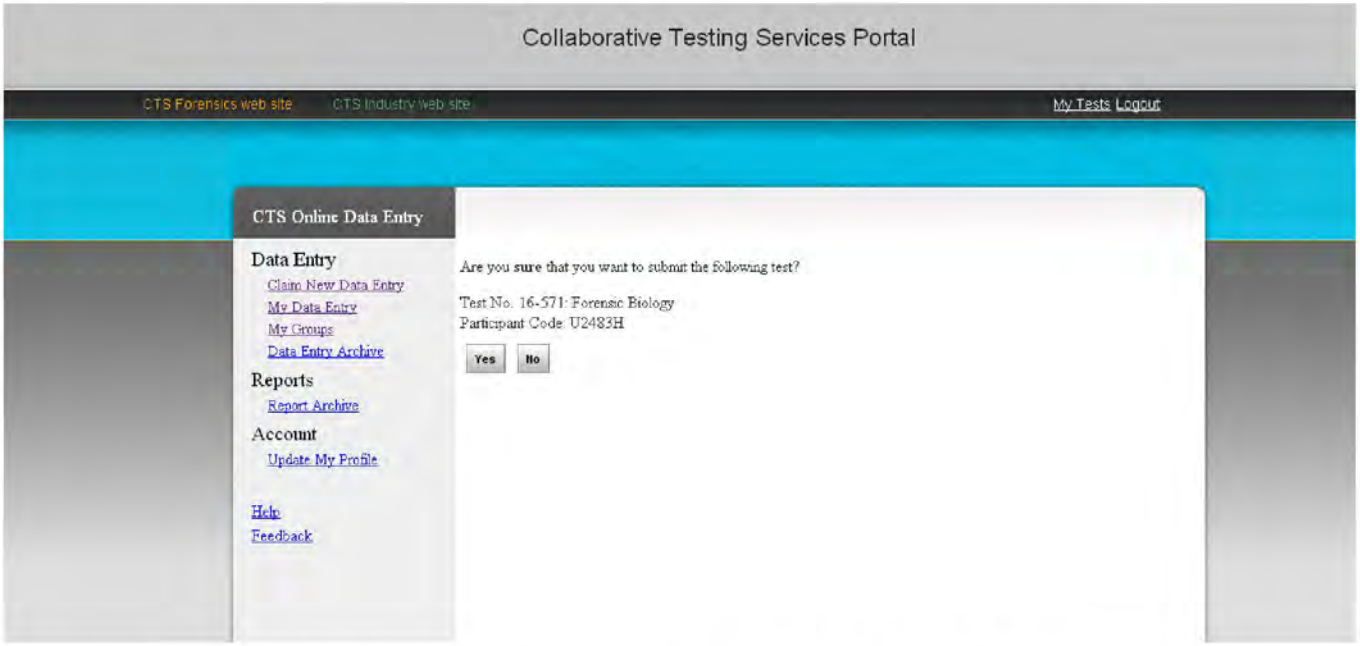


9. Check the box "This participants data is **not** intended for submission to ASCLD/LAB and/or ANAB"

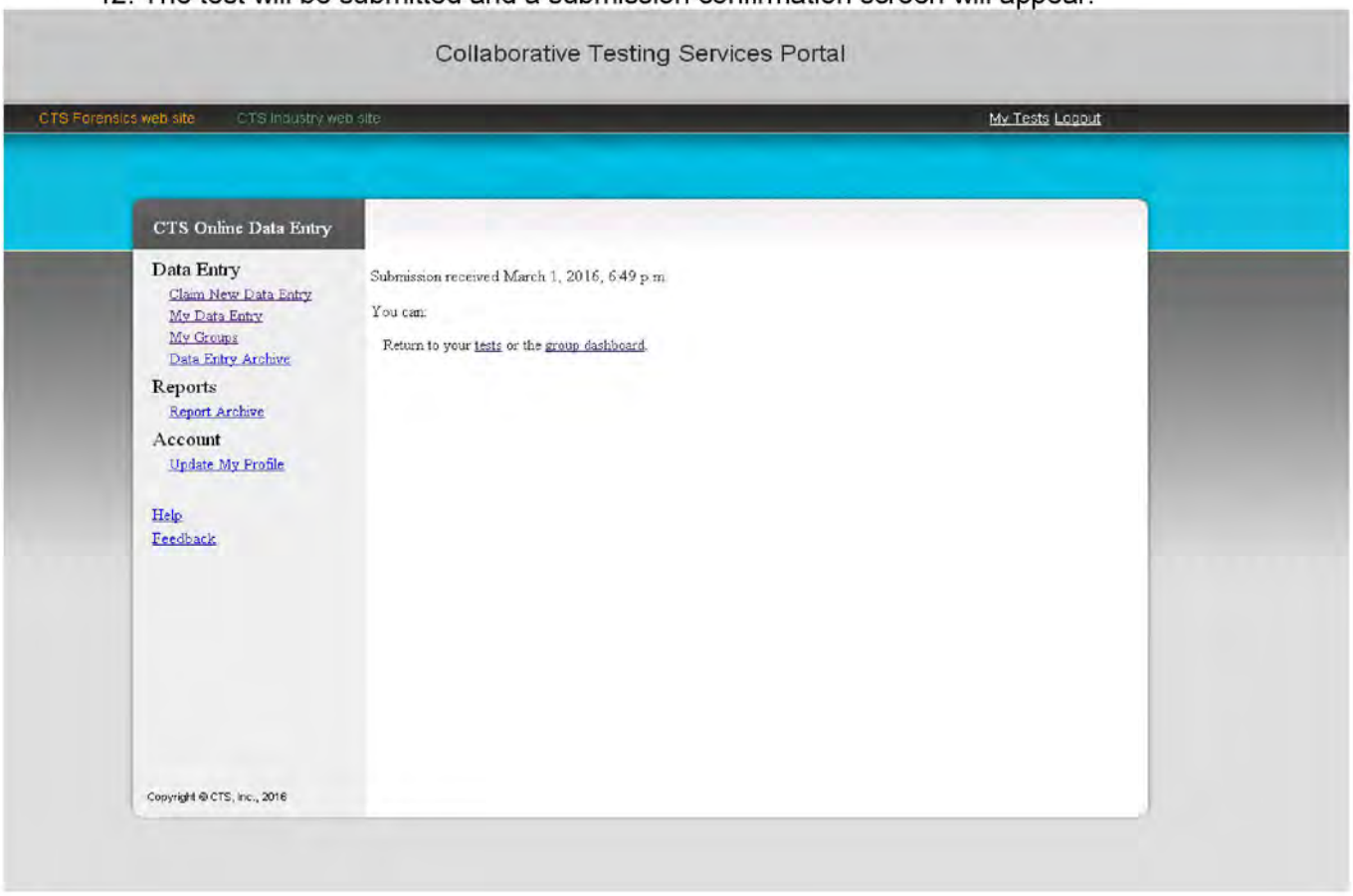


10. Click "Submit to CTS" in the top right corner.

11. Check the test details and click "Yes" – you are sure you want to submit the test



12. The test will be submitted and a submission confirmation screen will appear.



The Quality Team is notified that the test has been submitted for review.

From: [redacted]
To: Kerry-Anne Lancaster
Cc:
Subject: CTS Online Portal Notification

CTS

The following message is from Collaborative Testing Services' online Portal.

The group CTS reviewers has submitted Test No. 16-571: Forensic Biology, participant code U2483H, to CTS.

Collaborative Testing Services

[redacted]

Queensland Health
Forensic and Scientific Services

Investigating Adverse Events in Forensic DNA Analysis

Contents

1 Purpose

The purpose of this document is to provide guidelines around standard investigation protocols and result acceptance criteria for adverse events in Forensic DNA Analysis. The procedure outlines the key considerations in an investigation, the required actions and the necessary documentation for issues that may interfere with the quality of results within Forensic DNA Analysis.

These guidelines have been developed in complement to the OQI process (QIS 13965) and the Procedure for Quality Practice in Forensic DNA Analysis (QIS 17154).

2 Scope

This procedure applies to all staff within Forensic DNA Analysis. This document has attempted to cover key quality issues that may arise from adverse events in sample preparation, in screening of exhibits for biological fluids and in DNA profiling; however it cannot cover all possible adverse events. Where an event occurs which is outside the scope of this document, consult Senior Scientists and Team Leaders for guidance. This document does not cover adverse events that relate to workplace health and safety.

3 Definitions

For a comprehensive list of abbreviations refer to QIS 23849 Common Forensic DNA Analysis Terms and Acronyms.

Adverse Event: Any event or occurrence which brings into question a procedure or result

AI: Allelic imbalance

AP: Acid phosphatase

CE: Capillary electrophoresis

DNA Profiling techniques: All procedures, analytical instruments and consumables used in the process of obtaining a DNA profile (including extraction, quantification, amplification, capillary electrophoresis and profile interpretation)

EREF: Extraction FTA sample

FR: Forensic Register

PDA: Profile Data Analysis

OQI: Opportunity for Quality Improvement

QPS: Queensland Police Service

ReCE: Sample or batch is re-prepared and analysed again on the 3500*xl*

SD: Standard deviation

TMB: Tetramethylbenzidine

4 Evidence recovery – presumptive testing quality control

4.1 Tetramethylbenzidine (TMB) presumptive screening

Tetramethylbenzidine (TMB) is a presumptive test for blood used within Forensic DNA Analysis (refer to QIS 17190 for testing methodology). Before the reagent can be used for casework, both positive and negative controls must pass quality control criteria.

The positive TMB control is a known blood sample. A positive control pass is the appearance of the blue-green colour developing in < 5 seconds. A colour change in 5-20 seconds should be considered inconclusive and the test repeated, if after repetition it is still inconclusive this should be considered a fail (refer below). A positive control fail is the absence of the blue-green colour change, or the appearance of the blue-green colour developing > 20 seconds. If a colour change occurs after the addition of TMB only (without hydrogen peroxide) it is also a failed test.

The negative control for TMB is performed on a substrate that does not react to TMB (e.g. clean filter paper). A negative control pass is the absence of a blue-green colour developing in 10 seconds, with a negative control fail being the development of a blue-green colour within 10 seconds.

If the positive or negative controls fail, the TMB and hydrogen peroxide reagents should be re-prepared and the controls re-tested. If the new reagent preparation has passing TMB controls, the chemical test is acceptable for use. If the newly prepared reagents fail the quality criteria for TMB positive and negative controls, notify the Senior Scientist Evidence Recovery. New reagents may need to be purchased and new positive controls prepared for testing.

4.2 Acid Phosphatase (AP) presumptive screening

Acid phosphatase (AP) is a presumptive test for seminal fluid used within Forensic DNA Analysis (refer to QIS 17186 for testing methodology). Before the reagent can be used for casework, both positive and negative controls must pass.

The positive AP control is a known semen sample. A positive control pass is the development of a purple colouration within 5 seconds. A positive control fail is purple colouration developing > 5 seconds or the absence of the purple colour change after 5 seconds.

The negative control for AP is performed on a substrate that does not react to AP (e.g. clean filter paper). A negative control pass is the absence of a purple colouration within 2 minutes. A negative control fail is the development of a purple colouration within 2 minutes.

In cases where the positive or negative controls fail, the AP reagent should be re-prepared and the controls retested. If the new reagent preparation has passed AP controls, the reagent is acceptable for use. If the newly prepared reagent fails the quality criteria for AP positive and negative controls, notify the Senior Scientist Evidence Recovery. New reagents may need to be purchased and new positive controls prepared for testing.

4.3 Phadebas presumptive screening

Phadebas is a presumptive test for saliva used within Forensic DNA Analysis. The laboratory utilises both a supernatant (liquid), and a paper based testing procedure (refer to QIS 33998 for methodologies). Positive and negative controls must both pass for the test results to be accepted and reported.

The Phadebas positive control is a known saliva sample, and the negative control is Nanopure water. The criteria for positive and negative controls are different for the supernatant and paper tests, as outlined below.

Phadebas paper test:

A positive control pass is the development of pale blue zones on the blank side of the Phadebas paper at 40 minutes. On the spotted/treated side of the paper the blue spots appear dissolved or smudged. A positive control fail would be the absence of the pale blue zones on the blank side of the paper, and/or the absence of the dissolved/smudged blue spots on the treated side at 40 minutes.

A negative control pass is indicated by no colour change on either side of the paper (at 40 min.), with a negative control fail occurring if the Phadebas paper develops pale blue zones or dissolved/smudged areas on the treated side of the paper at 40min.

For Phadebas paper based testing, the positive and negative controls should be processed prior to use on casework samples, as a control failure would constitute an unacceptable risk to the exhibit.

If a positive control fails for the Phadebas paper, the paper should be retested with the saliva of a different staff member used as the positive control. If the second control passes, the results can be accepted (as individual staff may have differing levels of amylase). If the second positive control does not pass, notify the Senior Scientist Evidence Recovery, as new Phadebas paper may need to be purchased.

If the negative control for the Phadebas paper test fails, fresh nanopure water should be obtained and the negative control retested. If the retested negative control passes, the Phadebas test can be performed on casework samples. If the negative control still fails an investigation will be required. The investigation should consider the area in which the test was performed (e.g. laboratory bench), the equipment (spray bottles) and the water used for possible contribution of amylase and/or the function of the Phadebas paper. Casework samples are not able to be processed until both the positive and negative controls pass.

Phadebas supernatant test:

A positive control pass is indicated by a blue coloured supernatant in the positive control sample after processing, with a positive control fail indicated by the absence of a blue colouration in the supernatant.

A negative control pass is indicated by a clear and colourless supernatant in the negative control sample after processing, and a negative control fail occurring if the supernatant is blue in colour.

In the Phadebas supernatant testing procedure a positive and negative control are processed prior to casework samples being tested, this ensures that the reagents are suitable for use (i.e. reagent controls).

If the positive control fails for the Phadebas supernatant test, it should be retested with the saliva of a different staff member. If the second control passes, the results can be accepted (as individual staff may have differing levels of amylase). If the second positive control does not pass, in consultation with the Senior Scientist Evidence Recovery an investigation may be required and/or new Phadebas tablets may need to be purchased.

If the negative control for the Phadebas supernatant test fails, in consultation with the Senior Scientist Evidence Recovery and Senior Scientist Quality and Projects an investigation should be initiated. The investigation should examine the environment, processing procedure, labware and reagents used in testing for possible sources of amylase. Until the positive and negative reagent controls pass, no casework samples can be processed.

If the first set of controls pass (reagent controls), the positive and negative controls are re-run with the casework samples (as methodology controls). On completion of the batch the pass/fail status of the controls determines if the casework Phadebas results can be accepted and reported.

4.4 ABAcard p30 seminal fluid presumptive screening

ABAcard® p30 test (Abacus Diagnostics Inc.) detects p30 and is a presumptive test for seminal fluid used within Forensic DNA Analysis (refer to QIS 17185 for testing methodology). The ABAcard® device has two result areas within the device window; the control "C" area and the test "T" area.

On completion of the test, a pink line in the "C" area is a positive control pass, and indicates that the test is functional. On test completion a pink line in the "T" test result area is a positive test result i.e. presumptive positive for seminal fluid. The absence of a pink line in the "T" test area is a negative test result i.e. presumptive negative for seminal fluid.

For valid use of the ABAcard® test, the positive control line must be apparent on completion of the test, and the test must not be used after the expiration date. If there is no pink line visible in the "C" control area of the test, it is inconclusive and the test should be repeated. If the second ABAcard® test fails (i.e. no pink line visible in the control area) notify the Senior Scientist Evidence Recovery. New test kits may need to be purchased.

5 Sample preparation/processing – adverse event investigations

Adverse events can occur during sample preparation and/or processing. This procedure is not able to provide a comprehensive coverage of all possible adverse occurrences, but will outline the four most critical types of events which may occur and would require investigation. These include:

- Incorrect labelling (refer section 5.1)
- Sample cross contamination (refer section 5.2)
- Incorrect use of reagents (refer section 5.3)
- Dropping of sample (refer section 5.4)

Minor adverse events which do not require corrective actions and/or investigation must be detailed in sample notations (e.g. incorrect storage of an exhibit) or a batch notes if required. Significant adverse events, or adverse events for which corrective action is needed will require an investigation to be completed (an OQI may also be required) in addition to the sample notations.

5.1 Incorrect labelling event

Where there are labelling discrepancies on samples delivered to Forensic DNA Analysis from QPS, an investigation by Forensic DNA Analysis staff is **not** required as these labelling issues are reported back to QPS for their investigation by one of either two processes, depending on the severity of the discrepancy.

1. If the labelling discrepancy undermines the identification or the source of the sample (e.g. incorrect VIN), then the sample will be placed on hold (by adding to the "On Hold - Awaiting Advice" worklist) and a task will be sent to QPS for investigation and clarification. After QPS have investigated these occurrences, they will communicate any additional action/s back to Forensic DNA Analysis via a task. Only once the issue has been investigated and clarified can processing of the sample continue.

2. If the labelling discrepancy is minor (e.g. a typographical error), then the "Labelling Discrepancy" quality issue box will be checked during examination (or in-tube check) and, upon validation, a result line detailing the discrepancy will be automatically sent to QPS. A task will also be sent to QPS detailing discrepancy details. However, processing of the sample is able to continue without feedback from QPS.

Where labelling discrepancies have occurred during the processing of exhibits, sub-samples or DNA extract tubes within Forensic DNA Analysis, an investigation is required. Labelling discrepancies may occur as a result of incorrect data entry, barcode misprinting or from the application of an incorrect barcode to a tube. The Senior Scientist Evidence Recovery, Senior Scientist Analytical or Senior Scientist Quality and Projects must be notified of any instances of labelling discrepancies. Investigations into these occurrences will depend on the nature of each event, however strategies and considerations for an investigation into mislabelling should include:

- An examination of the FR exhibit testing table to determine when the affected sample's labels were printed and the staff member who printed it (information on samples processed at the same time or day can be obtained from the FR). Using the information from FR exhibit testing tables, from discussions with staff, and from examination or batch notes, it should be possible to determine the number of potential labelling errors that may have occurred. The information may be of use to determine how the mislabelling happened. For example: if a mislabelling occurred during examination, other samples processed by that sampling scientist, or other sample barcodes printed at the same time could potentially be affected.
- A review of the documentation/records which relates to the processing of the sample is required (e.g. examination notes, sample notations and batch notes) to see if the correct identity of the sample can be established.
- A confirmation of sample type should be completed as an identity check and/or to provide additional information to an investigation. For example if examination notes and/or exhibit details indicate that sample barcode 123456789 should be associated to a swab, but on retrieving the sample it is noted to contain a cigarette butt, a sample/barcode switch should be investigated.
- An assessment of the FR exhibit movement of the sample may be informative. In situations where barcode labels have been switched (between two items), incorrectly printed, or duplicate labels printed, evidence on the time at which this occurred may be obtained from FR exhibit movement and storage records.

Corrective actions and documentation:

In **all** cases of mislabelling, sample notations, and/or tasks must describe the issue and if applicable, the corrective action (e.g. OQI). Where an investigation is required, it must be

detailed in an OQI or in the adverse events log I:\Adverse Events Forensic DNA Analysis (refer to section 8.2.3). The OQI number / Adverse event log number must be added as a notation against all affected samples.

Upon conclusion of the investigation, if the sample can be positively identified the result may be reported after the completion of corrective actions and documentation as described above. If the sample **cannot** be positively identified, it may be failed in consultation with the Senior Scientist Quality and Projects or a Team Leader. Where a sample is failed it should be re-sampled/re-extracted if possible. If it is not possible to positively identify or reprocess the sample, a result line and/or communications with QPS must indicate a quality failure for the sample. Communications to QPS on sample failures will only occur in consultation with the Senior Scientist Quality and Projects or a Team Leader. An Intel report may be required for this communication (refer to QIS 34308). Where a re-extraction of the spin basket has occurred, any Intel report relating to this must include the barcode/s of the spin basket (re-extract) as these will be reported in FR.

5.2 Sample cross contamination

Sample cross-contamination can occur between exhibits, between DNA samples or from staff to exhibits/samples. The type of contamination that has occurred will determine how/when the contamination is detected and how it will be investigated. Cross contamination will usually only be detected after profiling.

Detection of staff contamination of samples can be identified at:
- Plate reading - when the results are uploaded into the FR and are automatically searched against Staff Elimination Profiles to identify potential matches between samples and Forensic DNA Analysis staff, QPS staff or FBUNK profiles.
- Profile Data Analysis – when a profile is entered into the Profile Record table of the PDA page, analysts are able to search against the FR database with the Staff Elimination profiles the first group of samples that is checked (other checks include reference and unknown samples as well as Intel samples external to the case).

Detection of sample-to-sample contaminations can be identified by:
- Profile Data Analysis and reporting processes
- Link creation/confirmation
- Incorrect profile in positive or negative controls

Detection of staff to sample or sample-to-sample contaminations may also be identified from quality searches (as performed by the Quality Team - refer section 13).

Where a cross contamination event is suspected a Senior Scientist or Team Leader should be consulted and the following actions should be considered:

- If a possible **contamination event of an exhibit/DNA sample by a staff member** is identified (at results upload, profile data analysis processes or by quality search) FR records including exhibit testing tables, and/or examinations should be reviewed to establish if the staff member has had contact with the exhibit/DNA during processing i.e. during examination, DNA extraction etc. If there is no evidence that the staff member has contacted the sample, an analytical investigation is required (refer to section 8). For environmental monitoring samples which contain a possible staff match refer to QIS 34280 for required actions.

- If a **contamination between exhibits is suspected**, FR records should be reviewed to establish who has handled the exhibits, when they were processed/moved, and where

the exhibits have been located/examined. This information should enable any potential cross contamination events - due to physical proximity (time/place/staff handling) to be identified. The possibility of transfer of DNA from exhibit to equipment (e.g. tweezers) and equipment on to the next exhibit should also be considered (swabbing and profiling the equipment may assist an investigation). If there is no evidence of physical proximity of the exhibits under investigation, an analytical investigation will be required (refer to section 8).

- If a **contamination between DNA samples is suspected**, an analytical investigation is required (refer to section 8).

Corrective actions and documentation:

In **all** cases of cross-contamination, sample notations must be added to all affected samples. Sample notations must record the adverse event and if applicable the corrective action (e.g. OQI). The investigation should be detailed in an OQI, in sample notations and in I:\Adverse Events Forensic DNA Analysis (Refer to section 8.2.3).

Upon conclusion of the investigation, if it is determined that the sample/s have not been contaminated the results may be reported after the completion of all documentation as described above. If the investigation has determined that the sample has been contaminated, the sample may be failed in consultation with the Senior Scientist Quality and Projects or a Team Leader. When a sample (or sub-sample) is failed the item should be re-sampled/re-extracted and profiled if possible. If reprocessing the item is not possible then a quality failure must be reported for the item/sample by a result line and/or by communications to QPS. Such communications to QPS on sample failures may only occur in consultation with the Senior Scientist Quality and Projects and a Team Leader. An Intel report may be required for this communication (refer to QIS 34308). Where a re-extraction of the spin basket has occurred, any Intel report relating to this must include the barcode/s of the spin basket (re-extract) as these will be reported in FR.

5.3 Incorrect use of reagents

The incorrect use of reagents during the preparation of samples, or in the completion of a presumptive screening test, has the potential to detrimentally impact on further presumptive testing, DNA extraction and/or profiling results. If incorrect reagent usage is suspected, an investigation is required and the Senior Scientist Evidence Recovery, Senior Scientist Analytical or Senior Scientist Quality and Projects should be advised. The investigation into incorrect reagent usage should include:

- A check of the labelling on the reagents used for sample processing. Ensure that the correct reagent has been used, and that the reagent has not expired.
- Review all the reagents/consumable that have been used for the processing of the sample - as shown in the FR batches. A check of other samples processed with the same reagent/s, is required to determine if the reagent has functioned (as expected) on previously tested samples. The "Batch history" table for the reagent/consumable will show all batches that have used that reagent/consumable.
- If the reagent is specific to a presumptive test, repeat the presumptive test with the suspected incorrect reagent (and if possible a known functional reagent) with the presumptive tests positive and negative controls (Refer to section 4). The function of the test on the controls - may provide information on the correct function of the reagents and/or the presumptive test.
- Note any unusual test results or test performance issues

- Ensure that the correct procedure has been used (refer to active QIS document as applicable)

Before any further testing is conducted, reagents should be re-prepared (if applicable), purchased (if applicable) and/or retested with positive and negative controls. All quality controls (positive and negative) must pass the criteria as outlined in section 4, section 8 and/or section 9 before further testing can be conducted on casework/reference samples.

Corrective actions and documentation:

In **all** cases of incorrect reagent usage notes (sample notations and batch notes) must record the adverse event and if applicable the corrective action (e.g. OQI). The investigation must be detailed in an OQI, batch notes (with a batch comment of "See Batch"), in sample notations and/or in I:\Adverse Events Forensic DNA Analysis (refer to section 8.2.3).

Upon conclusion of the investigation, if it is determined that the sample/s have not been adversely affected, the results may be reported after the completion of the documentation as described above. If it is determined that the sample has been adversely affected by incorrect use of reagents, but still has some evidentiary value, the impact of the event of the sample should be described in sample notations and/or PDA notes. Any compromised result should be reported to QPS via an Intel report written in collaboration with a Team Leader.

If the sample is no longer suitable for reporting due to the adverse event the sample may be failed in consultation with the Senior Scientist Quality and Projects and a Team Leader. If possible, a sample (or sub-sample) that has failed should be re-sampled/re-extracted and profiled. If it is not possible to reprocess the item/sample, a quality failure must be reported for the sample by a result line and/or by communications to QPS. Such communications to QPS on sample failures will only occur in consultation with the Senior Scientist Quality and Projects and a Team Leader. An Intel report may be required for this communication (refer to QIS 34308). Where a re-extraction of the spin basket has occurred, any Intel report relating to this must include the barcode/s of the spin basket (re-extract) as these will be reported in FR.

5.4 Dropped sample

In the case where an exhibit/subsample/substrate is dropped during processing the minimum requirements are:

- A sample notation must be added by the operator
- An entry into the Adverse events log is to be made (or an OQI raised)
- Additional corrective actions (depending on scenario) as below :

Drop in Evidence Recovery Laboratory:

- If the exhibit/subsample is dropped on the floor, the exhibit will be quality failed. The "Quality control failure – results not reportable" result line will be sent to QPS - due to the compromised sample integrity, and an Intel report from a Team Leader is to be sent to the Inspector QPS DRMU (refer to QIS 34308).
- If the exhibit/subsample is dropped on a non-cleaned space (Keyboard/Gown etc.), an Intel report from a Team Leader is to be sent to the Inspector QPS DRMU to ask for advice on if processing is required (refer to QIS 34308).

- If the exhibit/subsample is dropped on a clean space (e.g. Petrie dish), sample is to be submitted for processing.

Note: if only part of an exhibit is dropped (e.g. 1 out of 5 fingernails), follow the relevant steps listed above.

Drop in Analytical Laboratory:

- If the subsample/substrate is dropped pre-spinning (e.g. transfer to spin basket) the lysate component that is unaffected is to continue through processing (on the current batch). Analytical to note the volume of unaffected lysate as a sample notation.
- If the lysate or substrate is potentially affected:
    - For Lysate – Analytical to create a "MISC" subsample and process the lysate (on a separate batch) under that lab number with an Analytical note ("Hold after extraction"). A sample notation is also to be added detailing steps of the event, and should be added to the adverse events log with an OQI if applicable. An Intel report from a Team Leader is to be sent to the Inspector QPS DRMU (refer to QIS 34308).
    - For Substrate – Analytical to turn "SPIN" subsample into an exhibit and process on a separate batch with an Analytical note ("Hold after extraction"). A sample notation is also to be added detailing steps of the event, and should be added to the adverse events log with an OQI if applicable. An Intel report from a Team Leader is to be sent to the Inspector QPS DRMU (refer to QIS 34308). Where a re-extraction of the spin basket has occurred, any Intel report relating to this must include the barcode/s of the spin basket (re-extract) as these will be reported in FR.
- If the subsample/substrate is dropped post spinning. Store the dropped substrate with sample notations and continue to extract unaffected lysate.

6 Casework extraction and amplification batches: results acceptance criteria

Plate reading comments for controls auto-trigger batch status updates on uploading of results at capillary electrophoresis stage. All extraction, post-extraction, and amplification (STR and Direct Amp) batches will have their statuses updated in this manner. The status update will be dependent on both the positive and negative control (where applicable) result and will be either "**PASS**", PASS with "**EXTN <3pks**" batch comment, or "**INV**". Batches with an "INV" comment will need to be investigated further and will be listed at the top of the FR Batch Dashboard.

Microcon and dilution batches contain a negative extraction control only. For microcon and dilution batches, the negative control must pass (refer to Figure 2) for the batch to pass. If the negative control is NSD (No Sizing Data) then the batch is passed. If the negative control has ≤ 2 alleles above the LOD then the batch is passed with the batch comment "EXTN<3peaks". If the negative control has > 2 alleles above LOD, Analytical staff ReCE the CE plate (or control sample) to confirm the profile is reproducible, before initiating an investigation.

All other casework extraction batches contain a minimum of one positive and one negative extraction control. If the positive control within a batch is not the expected full profile and/or if the negative control has > 2 alleles above LOD, Analytical staff ReCE the plate (or control sample) to confirm the profile is reproducible before initiating an investigation. For an extraction batch to pass, **both the positive and negative controls must pass** as

determined by the quality criteria indicated in Figure 1 (positive control criteria) and Figure 2 (negative control criteria).

All amplification batches contain one positive and one negative amplification control. If the positive control within a batch is not the expected full profile and/or if the negative control is not NSD, Analytical staff ReCE the plate (or control sample) to confirm the profile is reproducible before initiating an investigation. For an amplification batch to pass, **both the positive and negative controls must pass** as determined by the quality criteria indicated in Figure 1 (positive control criteria) and Figure 2 (negative control criteria).

In some rare circumstances, where the amplification batch positive control fails, it may be possible to use a sample as a "positive control" if that particular sample has been previously profiled and the profile results for the sample in this batch match its previous profile. This approach requires consultation with the Senior Scientist Analytical, Senior Scientist Quality and Projects or Team Leader.

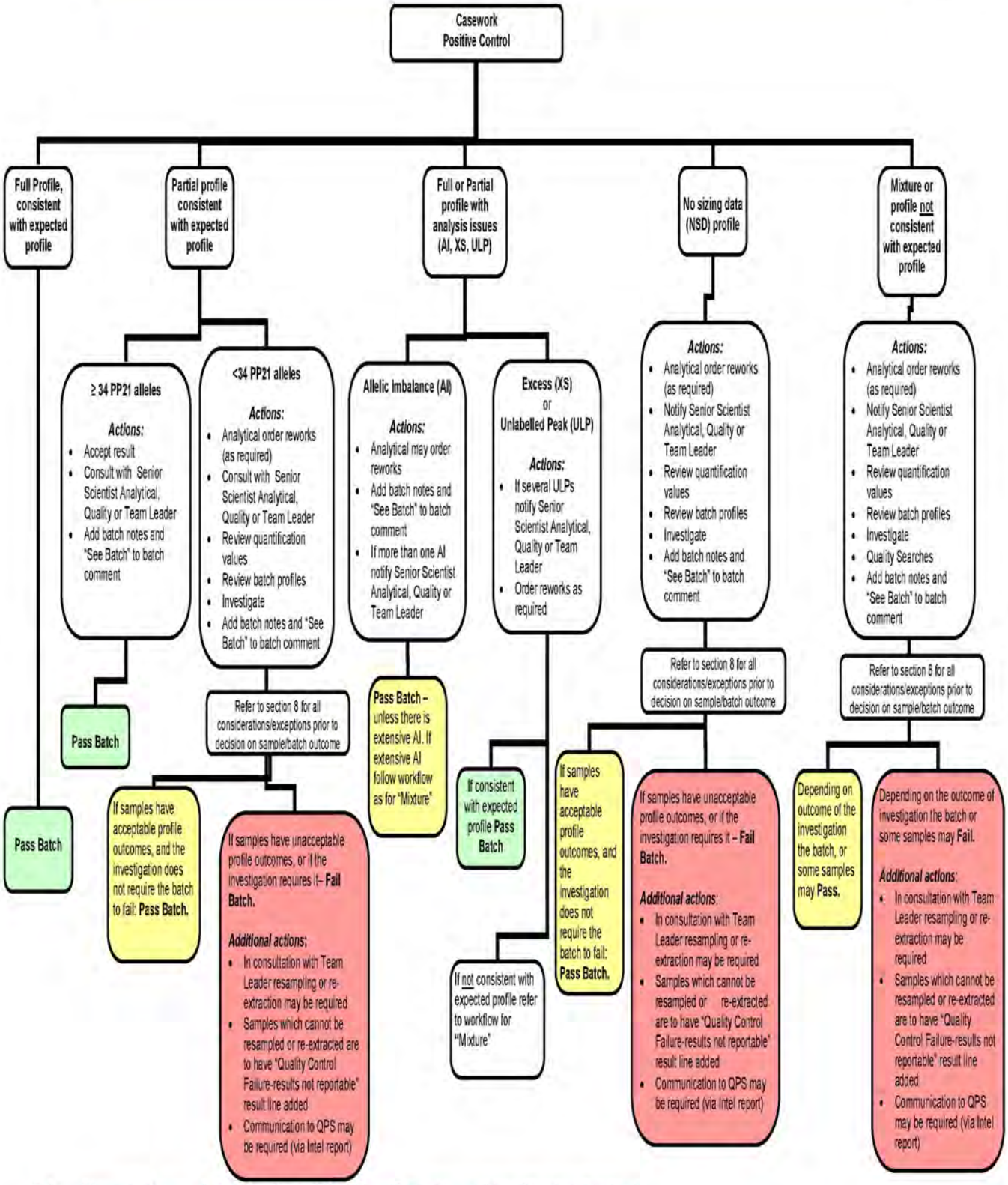
Where the positive and/or negative control profile is not ideal (i.e. partial positive control, and not NSD for the negative control) there are specific actions which must be completed, and batch details assessed before the batch can be passed. Figure 1 and Figure 2 outline the required actions and batch considerations which must be made prior to passing or failing a batch. The actions and considerations are dependent on the control profile/s results (i.e. partial profile, excess, or a mixture profile).

Note: the actions and batch check details in Figure 1 and Figure 2 are brief, for full details of requirements for each action refer section 8, and Appendix A and Appendix B.

7 Quantification batches: results acceptance criteria

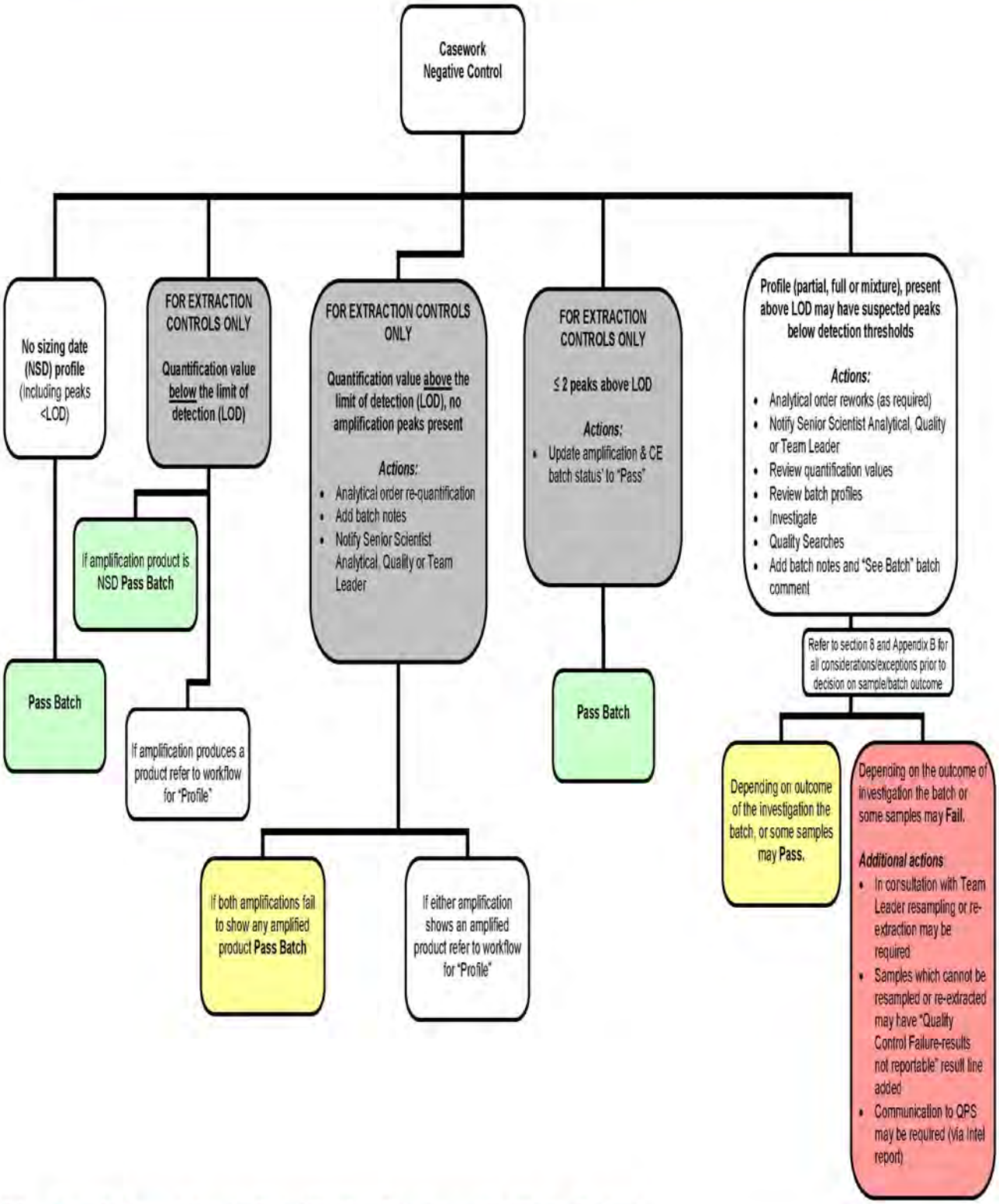
Quantification batches have several quality criteria which need to be assessed to determine if the batch is passed or failed (refer to Figure 3). In circumstances where quality criteria/thresholds are not met, the batch requires review and is to be discussed with the Senior Scientist Analytical (or Team Leader/Senior Scientist Quality and Projects) to determine batch outcome.

An initial evaluation of the extraction negative controls occurs during the quantification process (refer to section 6, and Figure 2 for additional information on extraction control quality guidelines). The quality control criteria and actions for quantification values in extraction negative controls are also detailed in the Quantification of Extracted DNA standard operating procedure (refer to QIS 34045).



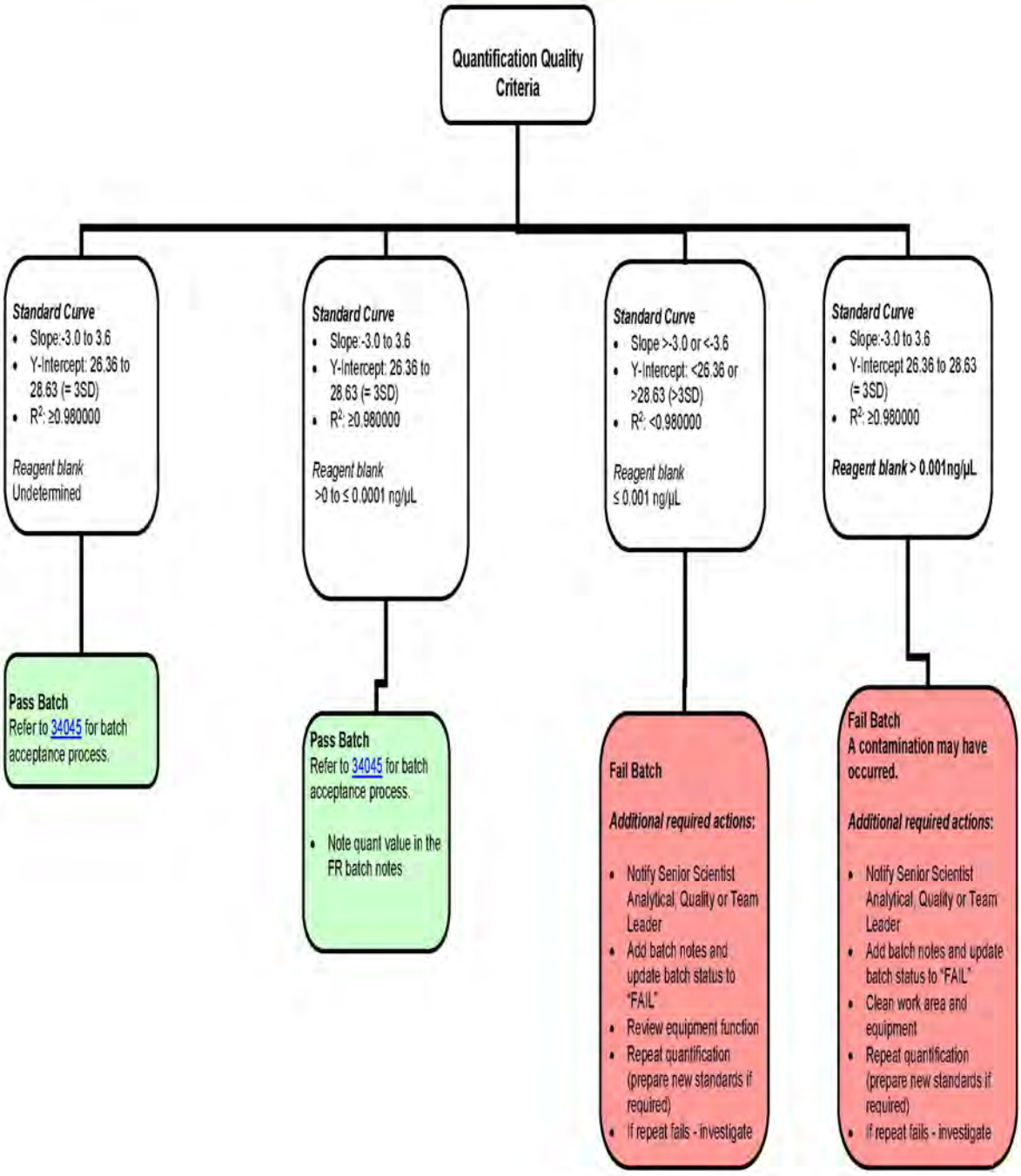
7.1 Figure 1: Casework Positive Control Workflow (Extraction and Amplification Batches).

N.B. Flowchart contains brief details of the actions and batch checks required - refer to section 8 for full details.



7.2 Figure 2: Casework Negative Control Workflow (Extraction and Amplification Batches).

Amplification negative controls are not processed through quantification - quantification values do not apply. N.B. Flowchart contains brief details of the actions and batch checks required - refer to section 8 and Appendix B for full details.



Note: Quant Trio assesses SAT, LAT and Y-Target values. Currently Forensic DNA Analysis only uses the SAT standard curve in assessing quantification batches. **IF** LAT and Y-Target standard curves are not within accepted range, refer to QIS 34045 for further actions.

7.3 Figure 3: Quantification quality criteria and required actions.

N.B. Flowchart contains brief details of the actions and batch checks required - refer to section 8 for full details.

8 Investigations into adverse analytical events including controls outside acceptance criteria

An investigation is required in cases where unexpected profile/s are obtained from positive controls, DNA is detected in negative controls (from extraction or amplification batches) or a laboratory processing event has occurred which has the potential to cause a DNA contamination event. Investigations into potential contamination events will be conducted in consultation with the Senior Scientist Analytical and the Senior Scientist Quality and Projects. Where possible, all results from batches under investigation should be placed on-hold until the outcome of the investigation is complete.

All batches under investigation should have a batch status of "INV" and should remain at this status until investigations are complete. Investigations should include the actions as described in Sections 8.1-8.7. On completion of the investigation the batch status will be updated to either "FAIL" or "PASS" with a "See Batch" comment as determined by the outcome of the investigation.

8.1 Repetition of CE results prior to investigation

The increasing number of capillaries on newer CE instruments means that the capillaries are physically located in close proximity to each other. This may result in the following phenomena:

Cross talk
This is where a small amount of fluorescence or light absorption from one capillary appears in an adjacent capillary - this source of the excess fluorescence is typically overloaded (highly excess) sample that results in off scale data (e.g. NAD XS).

Signal interference
This is similar to cross talk, but the transfer of the fluorescence is not from an adjacent capillary but from one in the same injection. Again this may be the result of an extremely excess sample.

In both instances, the cross talk or signal interference peak will appear in the affected sample as low level and usually off bin. However, it should be noted that they may, at times, appear in bins, and may slightly shift basepair size on re-preparation or re- running of the plate.

If either cross talk or signal interference is suspected, it can be confirmed by ordering a re-capillary electrophoresis (ReCE) of the sample; whereby the sample is rerun through CE away from the excess sample. If the ReCE sample results in a profile that is clear from extra peaks, cross talk or signal interference, then the issue is confirmed – showing that the extra peaks are due to a capillary electrophoresis issue only and the clear ReCE result is suitable for reporting.

If the positive control within a batch does not pass (shown in yellow/red) in Figure 1 and/or the negative control within a batch does not pass (shown in yellow/red) in Figure 2, Analytical staff will re-run or re-prepare the plate to confirm the profile outcome (i.e. is it reproducible), before an investigation is initiated (also consider CE carry-over, cross talk or signal interference as a possible source of unexpected alleles - particularly in negative controls). Other adverse events may require ReCE to confirm the adverse event is reproducible, before an investigation is initiated.

Analytical staff will order reworks on controls as per standard operating procedures QIS 34064 and QIS 34131 where it is indicated as necessary by the workflows in Figure 1 and Figure 2. Analytical staff should consider quantification values of the controls, the quantification values of the samples on the batch and profiling results before ordering the rework/s. Where an investigation is required, additional reworks may be requested by the staff who are completing the investigation (refer to section 8.6).

8.2 Investigation process

8.2.1 Results management

For samples or batches under investigation, where possible **no results should be released until the investigation deems it suitable to do so** (part or all of the results may be released after the investigation – depending on the outcome). This may require the following actions:

- Update Batch Status to "INV" (Investigation)
- Where possible do not upload results until the investigation is complete. If the batch is failed as a result of the investigation the results are not to be uploaded.
- "DO NOT USE" may be added to the result of applicable samples (where the plate has been released, but results of the marked samples are not to be used).
- Samples that have a batch at "INV" status will be under the INV filter on the PDA worklist and will be quarantined from OK samples.
- Adding sample notations and batch notes. Batch notes should indicate that an investigation is required. For analytical investigations, also refer to QIS 34064 for additional information on sample notations and batch notes.
- If results have been reported discuss required actions with Senior Scientist Quality and Projects and the Team Leaders.
- Senior Scientist should email details of the investigation to the Management Team.

8.2.2 Required actions and considerations in investigations

Investigations should include the following steps:

- Batch notes must be used to detail the investigation process (refer to section 8.3).
- Batch Status updates as appropriate.
- Entries into the Adverse event log I:\Adverse Events Forensic DNA Analysis
- Review of batch notes, sample notations or examinations to evaluate if there have been any processing issues which may have affected samples or batches that are under investigation.
- Review the controls that relate to the sample/batches under investigation to ensure they meet quality criteria as detailed in Figure 1 - 5 as applicable.
- Review the batch profiles (refer to section 8.5) and quantification values if useful (refer to section 8.4).
- It may be useful in some circumstances, to check the function/programming of the equipment that was used (e.g. was the correct program used on the thermal cycler (Thermal cycler log file will be uploaded against the amplification batch); was the performance of the Genetic Analyzer suitable for interpretation).
- A check of the controls, chemicals/kits, consumables and reagents that have been used may be useful (information located in batches and FR Supply Batch History) including:

- correct control for the batch (e.g. the correct FTA amp control selected)
- expiry date of reagents/kit
- has the reagent/kit functioned on a previous and a subsequent batch
- in cases of contamination, consider reagents/chemical as a possible source
- any notes recorded against reagents and consumables that may be relevant (e.g. "PP21 amp kit to be used for Reference samples only")

- In consultation with Team Leaders and Senior Scientist Quality and Projects order reworks (e.g. microcons, re-amplification, re-extractions) if they will provide additional information to the investigation. Refer to section 8.6 for rework strategies for investigation purposes. However before reworks are ordered the amount of sample available for testing should be carefully considered. Additional quality searches (refer section 14) and batch checks may be required on reworked samples.
- Complete quality search if applicable (refer section 14). There may be instances where a quality search is completed at the beginning of an investigation and then repeated after rework results have been obtained.

Raising an OQI should be considered, particularly in instances of a significant or reoccurring adverse event. If an OQI has been raised – the findings of the investigation will be recorded within QIS2.

8.2.3 Documentation of investigation

On completion of the investigation, detailed batch notes (refer section 8.3), an entry into the adverse events log (I:\Adverse Events Forensic DNA Analysis) and/or sample notations should be completed for all affected samples.

Where results are released for interpretation (and there have been unexpected processing issues or profiling results for the sample/batch) notes should include: a description of the adverse event, the investigation that was completed, the corrective actions completed (if applicable), the impact of the event on the sample/s, and the considerations that are required for the interpretation of the profile/s as a result of the issue.

Where results are not suitable for release notes should include: a description of the adverse event, the investigation that was completed, the corrective actions completed (if applicable) and the impact of the event on the sample/s. A clear statement that the results are not suitable for interpretation or reporting should be made.

Failed samples/batches will need to be repunched/reworked or failed (if they are reference samples), or reworked/re-extracted/re-sampled or failed (if they are casework). Failure of samples will occur only in consultation with a Team Leader/Senior Scientist Analytical/Senior Scientist Quality and Projects, and may require additional communications with the QPS. If needed, supporting data and information for investigations into adverse events can be stored to network drive I:\Adverse Events Forensic DNA Analysis. Issue/s and findings (including OQIs) may also be discussed in relevant team meetings to alert staff to quality issue/s.

At any time a process has potentially resulted in a loss of sample or sub-optimal extraction process, an Intel report, in consultation with a Team Leader, is required. When suitable, re-extraction of the spin-basket should be ordered.

8.3 Batch notes

Batch notes must:

- Be entered in a timely way.

- Should start with initials (of person entering notes) and date (when entry is made).
- Should be added progressively if the batch is under investigation. For example if a batch is on hold pending the results of an investigation, the batch note entry must state that the batch is under investigation. As reworks are ordered for the purpose of investigation, the details of the reworks and the implications of the findings of the rework/s should be stated in the batch notes.
- For analytical investigations refer to QIS 34064 for additional information on sample notations and batch notes.
- Clearly state if the batch fails, passes (with no quality issues) or passes (but has been affected by one or more quality issues which are detailed in the batch notes and have a batch comment of "See Batch").
- If there is a quality issue with the batch – the batch notes must clearly state what the issue is, the action/s taken (i.e. investigation details), and the outcome of the actions/investigations.
- If there is a quality issue with the batch – the final Batch Status must be either "Pass" with a batch comment of "See Batch", or "Fail".
- Where the negative control on a batch has a quantification value, the batch notes must state the quantification value obtained from the negative control, and state if that value is >or< the limit of detection (LOD), or limit of reporting (LOR).
- If an OQI is raised as a result of findings/investigations, the notes, and sample notations (for all samples on the batch) should have the OQI number entered into the notes.

8.4 Review quantification values (controls and samples)

Reviews of quantification values of individual samples and/or a batch is beneficial when:

- a quantification batch is under investigation - due to the controls not meeting the quality criteria as described in Figure 3
- a negative control has a quantification value (particularly >LOD)
- an adverse event has occurred that impacts significantly on DNA yield
- an adverse event has occurred and the quantity of DNA in the samples adversely affected would inform the investigation.
- to determine if reworks should be ordered for investigation purposes

A review of a quantification batch requires a scientist to make an assessment of the expected quantification values (based on sample type and previous quantification results) in comparison with the quantification values obtained from the sample/batch under investigation.

8.5 Review batch profiles (controls and samples)

Where an unexpected profile has been obtained in a control, or there has been an adverse event on a batch which has required investigation, a check of the profiles from the other samples and controls in the batch is required. This check is usually completed in Genemapper ID-X so that peaks below reporting threshold can be reviewed/assessed. All controls that related to a batch and/or samples under investigation should be reviewed to ensure they meet acceptable quality criteria (refer to Figures 1-5 as applicable).

For casework and extracted reference samples that have been processed on an automated platform this batch check may include a Full Batch Check at lowered thresholds (refer to QIS 34006).

For FTA reference batches - the batch review should include a visual inspection of the plate to ensure the correct location and number of spots is present in each well (Refer to section 11 for FTA investigations).

The purpose of the batch review is to:

- Identify any additional quality issues on the batch/plate (if present)
- Establish possible sources of unexpected alleles within a control/sample that may have sourced from within the batch/es in which the sample/controls have been processed (if applicable).
- To assess if an event has impacted on some or all of the controls/samples (e.g. poor amplification)

Examples of batch reviews:

- Where a negative control contains a part or full profile, the review of the batch would aim to determine if any samples from within that batch could have contributed to the alleles that have been observed in the negative control.
- Where a negative control contains a part or full profile, the review of the batch would aim to determine if that profile (full or partial) can be found across any other samples (e.g. possible reagent or consumable contamination).
- If a positive amplification control was NSD the batch check would determine if it is the control only, or the entire batch that failed to amplify.
- If an FTA or FTA control produced a mixture profile, the batch review would be searching for the source of the additional alleles from FTAs processed on the same batch/plate.

Instances where adverse events impact on casework samples are more difficult to investigate, and may require mixture interpretation to determine if cross-contamination within batches has occurred.

8.6 Rework strategies for investigation purposes

Reworks including microcons, nucleospin clean-ups, re-extractions or re-amplifications should be requested if they will provide additional information to the investigation. However before reworks are ordered the amount of sample available for testing should be carefully considered. Examples of the use of reworks for investigations include:

Improving profiles for quality searches/match purposes:
- A microcon may be ordered to increase the number of alleles present in a partial/below threshold profile
- Re-amplifications at higher DNA concentrations to increase available alleles

Reworks to establish time/source of contamination/s:
- A re-preparation at CE may establish if a contamination occurred at/prior to amplification (if the result is reproducible) or occurred during CE (if the result is not reproducible)
- A re-amplification may establish if a contamination occurred at/prior to extraction (if result is reproducible) or occurred during amplification (if result is not reproducible)
- A re-extraction/re-punch may establish if a contamination occurred during extraction

The quantification values for samples under investigation should be considered. Samples with low quantification values may not produce uniform profiling results - due to the stochastic effect of PCR. Samples with high quantification values should profile consistently. Additional quality searches (refer section 14) and batch checks may be required on reworked samples.

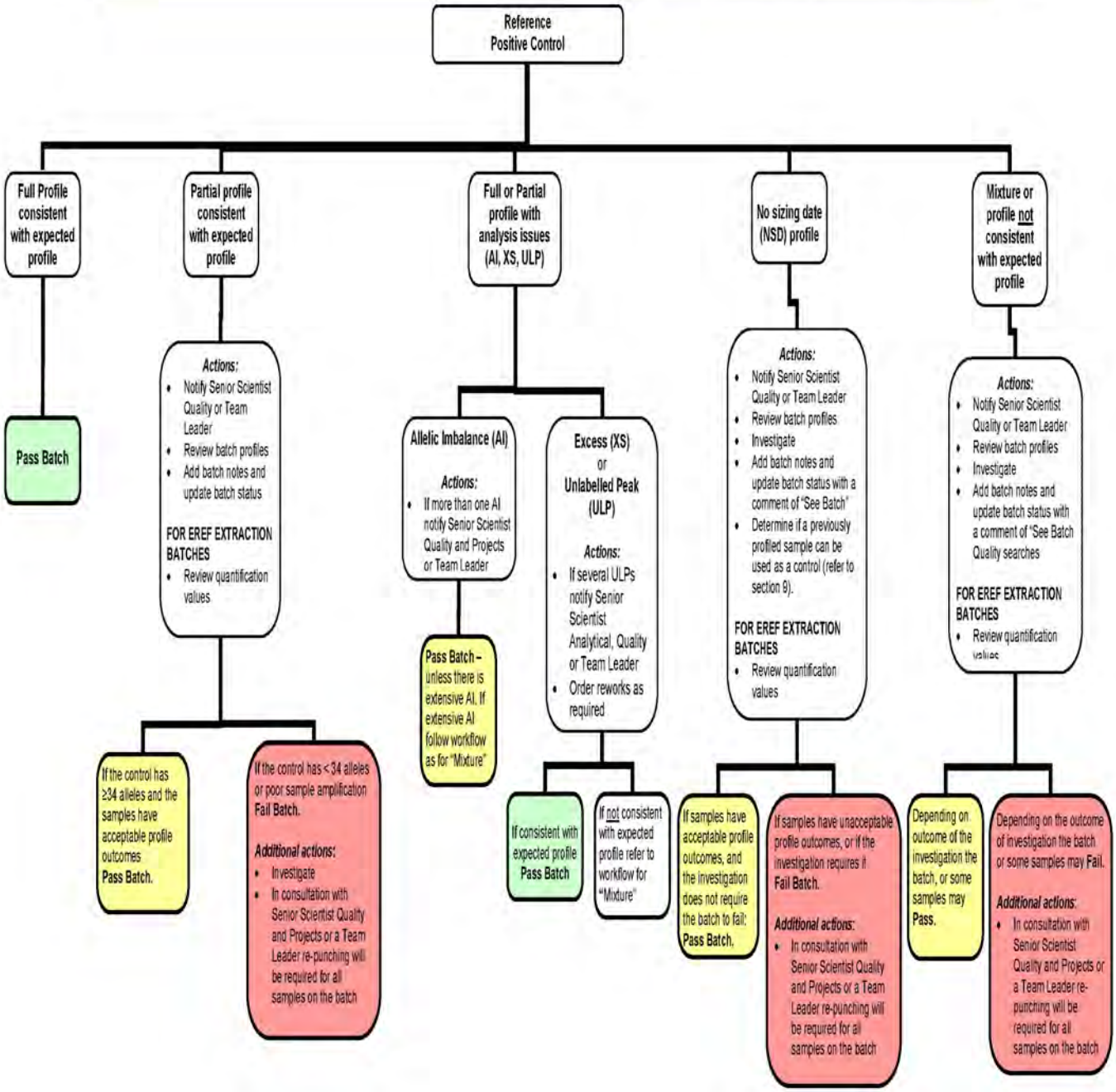
9 Direct STR Amp FTA reference batch controls: results acceptance criteria

Direct STR Amp FTA reference batches (this does not include EREF batches – Refer to section 10 for EREF samples) contain one positive and one negative amplification control. If the positive control within a batch is not the expected full profile and/or the negative control is not No Sizing Data (NSD), Analytical staff ReCE the control or the plate to confirm the profile is reproducible, before initiating an investigation. For an FTA batch to pass, **both a positive and negative control must pass** as determined by the quality criteria indicated in Figure 4 and Figure 5.

In some rare circumstances, where the batch positive control fails, it may be possible to use a sample as a "positive control", if that particular sample has been previously profiled and the profile results for the sample in this batch match its previous profile. This approach requires consultation with the Team Leader and Senior Scientist Quality and Projects.

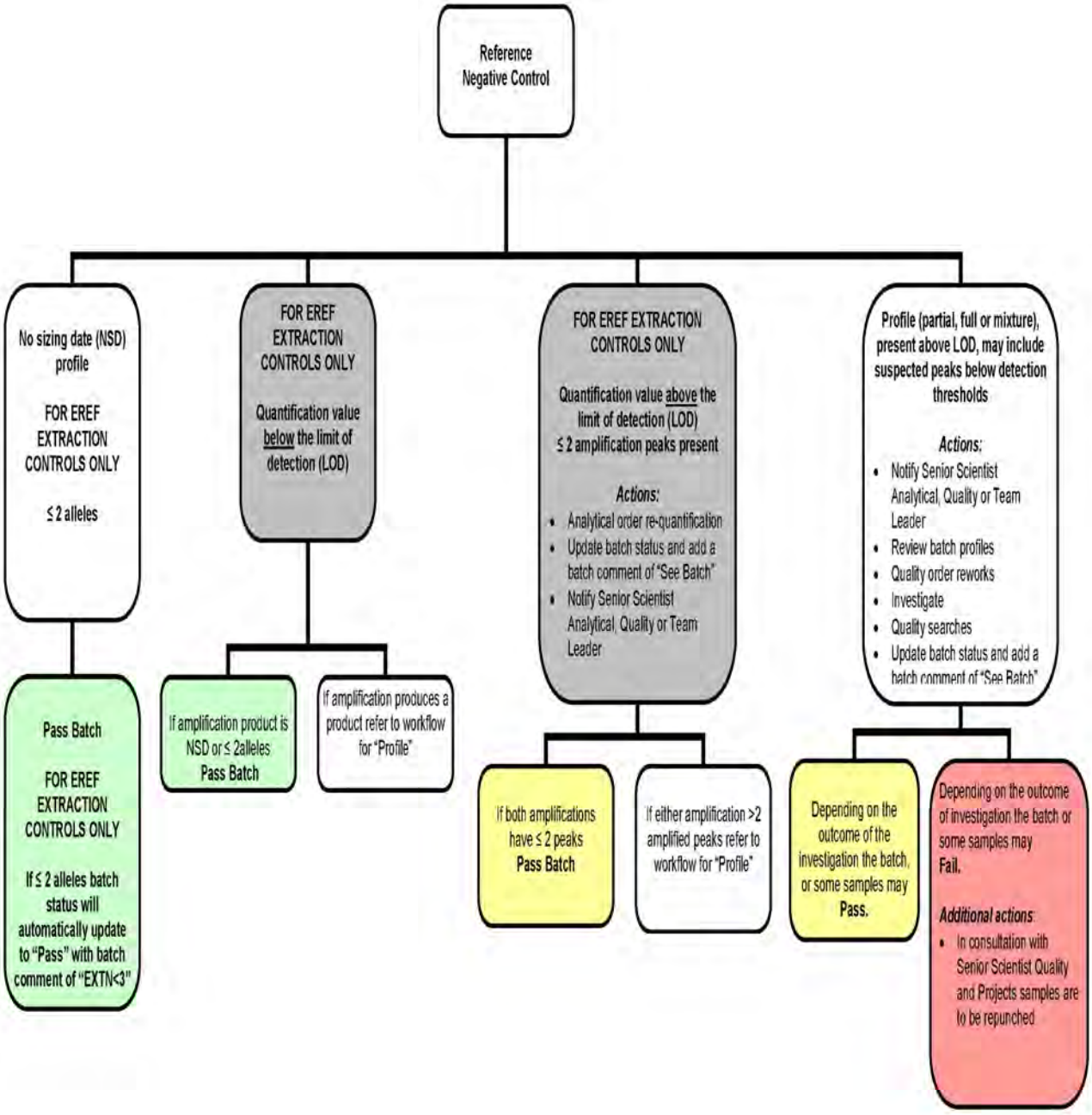
Where the positive and/or negative control profile is not ideal (i.e. do not obtain the expected full profile for the positive control and NSD for the negative control) there are specific actions which must be completed, and batch details assessed before the batch can be passed. Figure 4 and Figure 5 outline the actions and batch considerations which must be made prior to passing or failing a batch. The actions and considerations are dependent on the control profile/s results (i.e. partial profile, excess, or a mixture profile).

Note: Figure 4 and Figure 5 contain brief actions and batch check details. For full details of requirements for each action refer to section 8 and section 11.



9.1 Figure 4: Reference Positive Control Workflow (EREF Extraction, EREF Amplification and FTA Batches).

N.B. Flowchart contains brief details of the actions and batch checks required - refer to section 8 for full details.



9.2 Figure 5: Reference Negative Control Workflow (EREF Extraction, EREF Amplification and FTA Batches).

Amplification negative controls are not processed through quantification - quantification values do not apply. N.B. Flowchart contains brief details of the actions and batch checks required - refer to section 8 for full details.

10 Extraction FTA (EREF) batch controls: results acceptance criteria

FTA samples which are processed through a Maxwell extraction process - are Extraction FTA samples (EREF). EREF punch batches contain a negative control only, and do not contain a positive control on the batch. EREF differ from standard FTA processing, as the samples are processed through an extraction batch, a quantification batch and an amplification batch - each of which have specific controls. EREF sample quality guidelines and required actions for each step of processing are listed in Table 1. In circumstances where an EREF batch fails (as a result of not meeting the quality criteria) adequate batch notes and sample notations are required, and an investigation should be initiated (refer to section 8 and section 11). Where a significant or reoccurring quality issue is identified an OQI should be raised.

Table 1: Extraction FTA (EREF) batches: quality criteria and required actions.

Batch Type	Control	Actions
Punching batch	Negative Control	EREF negative control pass/fail batch status and required actions are the same as those for standard FTA Negative Controls **Refer to Figure 5** for workflow
Extraction Batch	Positive Control	EREF positive control pass/fail batch status and required actions are the same as those for standard FTA Positive Controls **Refer to Figure 4** for workflow
	Negative Control	EREF negative control pass/fail batch status and required actions are the same as those for standard FTA Negative Controls **Refer to Figure 5** for workflow
Quantification Batch		EREF batch control pass/fail batch status and required actions – Refer to **Figure 3** for workflow.
Amplification Batch	Positive Control	EREF positive control pass/fail batch status and required actions are the same as those for standard FTA Positive Controls Refer to **Figure 4** for workflow
	Negative Control	EREF negative control pass/fail batch status and required actions are the same as those for standard FTA Negative Controls Refer to **Figure 5** for workflow

11 Investigation processes for adverse events in FTA processing

An investigation is required in cases where a mixed profile results from an FTA sample, an unexpected profile is obtained from a positive control, DNA is detected in a negative control or a laboratory processing event has occurred which has the potential to cause a DNA contamination. In each case, the adversely affected control/sample should undergo a ReCE to confirm the adverse event is reproducible, before an investigation is initiated.

Investigations into potential contamination events will be conducted in consultation with the Senior Scientist Quality and Projects or Team Leader. Where possible, all results from batches under review should be placed on-hold until the outcome of the investigation is complete.

For EREF batches: If an EREF extraction, quantification or amplification batch fails – only the samples on the affected batch/es will be failed. These failed samples will likely be distributed over several plate reading batches. For failed EREF batches, results for only some samples will be acceptable. In these instances, all failed samples should be given the comment of "DoNotUse" and relevant reworks ordered prior to the plate being released

for reading and result upload. This differs from FTA plates which are processed together during punching, amplification and plate reading.

All investigations should include the following actions:

- **Ensure results are not incorrectly utilised or reported**. Refer to Section 8.2.1 for results management guidelines
- Check all positive and negative control samples meet quality guidelines (refer to Figure 4 and Figure 5).
- Review examinations, batch notes and sample notations to evaluate if there have been any processing issues which may have affected samples or batches that are under investigation.
- For Direct STR Amp FTA batches only - visually inspect the plate for the correct number of punch spots in each well.
- Batch profiles must be checked - refer to section 8.5. For EREF batches a review of quantification results may also be required (refer to section 8.4).
- It may be useful in some circumstances, to check the function and or programming of the equipment that was used (e.g. was the correct program used on the thermal cycler, was the performance of the Genetic Analyzer suitable for interpretation).
- A check of the controls, chemicals/kits, reagents and consumables that have been used may be useful (information located on batches and FR Supply Batch History) including:
    - correct control for the batch (e.g. the correct FTA control card punched)
    - expiry date of reagents/kit
    - has the reagent/kit functioned on a previous and subsequent batch
    - in cases of contamination, consider reagents/chemical as a possible source
- For EREF investigations order reworks (e.g. microcons, re-amplification, re-punch etc.) if they will provide additional information to the investigation. Refer to section 8.6 for rework strategies for investigation purposes. Additional quality searches and batch checks may be required on reworked samples.
- Complete quality search if applicable (refer section 14). There may be instances where a quality search is completed at the beginning of an investigation and then repeated after rework results have been obtained.
- Raising an OQI should be considered, particularly in instances of a significant or reoccurring adverse event. If an OQI has been raised – the findings of the investigation will be recorded within QIS.
- All investigation findings must be documented as per section 8.2.3
- On completion of the investigation: ensure all affected reference samples have been reprocessed, such that reportable results are available.
- All Direct STR Amp FTA plate investigations to be logged in I:\Adverse Events DNA Analysis\FTA Plate Issues.xls
- Failing a batch
    - Ensure the FTAAMP and RCE batches have their batch status updated
    - Add a sample notation to the sample
    - Export and delete the project from GMIDX

12 Investigation into reference sample mixture profiles

Reference samples are expected to be single source samples. An investigation is required in cases where a mixed profile is obtained from an FTA sample. The investigation will aim to determine if a DNA contamination has occurred within the Forensic DNA Analysis Laboratory or if the sample that was submitted to Forensic DNA Analysis (as a reference sample) was not a single source specimen.

A mixture in a reference sample may result from occurrences such as: CE issues (cross talk/signal interference/carryover), an FTA card contamination, BSD punch carryover, FTA spots moving within a plate, consumable/labware contamination, reagent contamination, cross contamination during extraction/quantification/amplification, or in very rare circumstances it may be the correct profile for a person.

Before an investigation is initiated the adversely affected plate/sample should undergo a ReCE to confirm the adverse event is reproducible. While it is usual practice for the entire plate to be ReCE for investigation purposes, if cross-talk or signal interference (refer section 8.1) is suspected there may be no value in repreparing and rerunning the whole plate, as the extra peaks will more than likely be replicated as the same samples are prepped and run in the same order (in proximity to excess samples). Where low level extra peaks are suspected to be either cross talk or signal interference a ReCE will be ordered on the affected sample. This enables the CE result to be assessed for the sample/s in a different array of samples. This will allow cross-talk/signal interference to be identified.

Investigations into potential contamination events will be conducted in consultation with the Senior Scientist Quality and Projects. Where possible, all results from batches under review should be placed on-hold until the outcome of the investigation is complete.

If the ReCE confirms that the result is reproducible, the following ***initial investigation steps are required:***

- Review batch notes and sample notations to evaluate if there have been any processing issues which may have affected the sample.
- For FTA batches visually inspect the plate (not applicable to EREF batches) for the correct number of punch spots in each well.
- Batch profiles must be checked - refer to section 8.5.
- Check all positive and negative control samples meet quality guidelines (refer to Figure 4 and Figure 5).
- Check to see if a profile has previously been obtained from another submission to confirm correct profile.
- Check for any another unusual or problematic profiles on the batch
- Complete quality search (refer section 14).

12.1 Investigation actions for FTA samples with a reproducible mixture

If on completion of the initial investigation actions above (section 12) it is determined that there are multiple quality issues with the plate (i.e. multiple samples on the plate contain mixtures, control failures) the plate should be **failed**. For a failed batch refer to section 11 for investigation processes and required actions.

- If there is only one sample on the plate/batch that is a mixture, but the source of the mixture is not able to be determined, after completion of the initial investigations actions above (section 12), a repunch (appropriate rework) of the sample which has produced the mixture profile should be requested. The plate/batch on which the mixture sample

was processed should be placed on hold pending the results of the rework. Ensure that adequate batch notes are entered against the batch and that a sample notation is added to the affected sample. Ensure investigations are added to the FTA issues log, located I:\Adverse Events DNA Analysis\FTA Plate Issues.xls

If the repunch of the sample confirms the mixture profile, and there are no additional mixtures or analysis issues identified during the batch profiles check (refer to section 8.5), in consultation with Senior Scientist Quality and Projects - the batch may be **passed**. All investigation findings must be documented as per section 8.2.3. The affected mixed DNA profile must be marked "DoNotUse" in the GMID-X plate reading comment, prior to the batch being released to read. The batch can be passed as the mixture has been confirmed as the correct profile for that FTA card, and not as a result of a sample/batch processing issue. However, due to the FTA card producing a mixture profile, it is not suitable as a reference sample and as such an Intel report is to be sent to QPS (in consultation with a Team Leader), and the sample "FTP" Failed to profile.

If the repunch is single source in consultation with Senior Scientist Quality and Projects the following batch dependant actions are to occur:

For **FTA Batches** – the batch will be **Failed**, as a contamination event has occurred on the batch, and there is no way to determine which samples are impacted by the contamination event, and thus which profiles are correct.

For a rework batch (**RUN, OSD or RPT**), batch notes are required, with "See Batch" in the comment field. Only some samples maybe released from these plates as follows:

- if the sample on the affected plate has confirming previous profile the rework profile can be released to report, or rework.
- if the sample does not have a confirming previous profile an additional rework is required, prior to reporting the reference result.

For a failed batch refer to section section 11 for investigation processes and required actions.

12.2 Investigation actions for EREF samples with a reproducible mixture

If a mixture profile in an EREF sample is reproducible (after ReCE) but the initial investigation actions above (section 12) are not able to determine the source/cause of the mixture profile the following actions are required:

Order a re-extraction (EREF) of the mixture FTA sample (under another child barcode) and a re-amplification from the initial EREF sample to determine if the contamination has occurred prior to extraction, during extraction or during amplification. Where possible the batches on which the mixture sample was processed should be placed on hold pending the rework results.

If a re-punch (new EREF), re-extraction and re-amplification confirm the mixture profile and there are no additional quality issues identified during the initial investigation actions above (section 12), in consultation with Senior Scientist Analytical or Senior Scientist Quality and Projects - the batch may be **Passed**. The affected mixed DNA profile must be marked "DoNotUse" in the GMID-X plate reading comment/s, prior to the batches being released to read. The batch can be passed as the mixture has been confirmed as the correct profile for that FTA card, and it is not a result of a sample/batch processing issue. However, due to the FTA card producing a mixture profile, it is not suitable as a reference sample and as

such an Intel report is to be sent to QPS (in consultation with a Team Leader), and the sample "FTP" Failed to profile.

If the re-amplification confirms the mixture profile, but the re-extraction (under new EREF) is single source, further investigation will be required as the initial EREF BSD punch batch or reference exaction batch has been impacted by a contamination issue. In this case all samples in the affected BSD/extraction batch/es need to have a confirming re-extraction (under new EREF barcodes) before being reported. The reworks will be ordered as a corrective action from the investigation. Investigation notes, findings and corrective actions are to be completed on the batch/es that were affected.

If the re-extraction and re-amplification is single source it is most likely that the contamination event has occurred during the amplification process. In this case an investigation into the amplification batch must be conducted, to look for the source of the contamination and any other quality issues. As a minimum all samples on the affected amplification batch must be reworked for a confirming profile (ordered as a corrective action from the investigation). Investigation notes, findings and corrective actions are to be completed on the batch/es that were affected.

If an EREF extraction, quantification or amplification batch fails – only the samples on the affected batch/es will be failed. These failed samples will likely be distributed over several plate reading batches. For failed EREF batches, results can be uploaded, with affected profiles having the "DoNotUse" comment added.

13 Capillary Electrophoresis Batches: fixes for missed batch steps

In the FR, CE batches require a name recorded against the "Read" field in "Batch Info" area of the batch. This ensures that a result is recorded against each sample, and that when PDFs are uploaded, the sample moves to the PDA list for profile data analysis.

If the status of the CE batch is changed to "PASS" before the results are uploaded and saved, no name is recorded against "Read" field and samples do not progress. To fix this:

- Change the batch status to "INV" and "Save"
- Then check the "CEQ" box and "Save" (this puts the status at "Read")
- Enter into the results screen and "Save" (this will add a name to the "Read" field and record a result in the exhibit testing table)
- Then change the batch status to "PASS"

If caught before the PDFs have been uploaded, the PASS status will put the batch onto the list for PDFing.

If PDFs have already been uploaded, enter into the PDF icon and "Save". This will re-file the PDFs against the samples and add them to the PDA list if needed. The PDF page needs to be re-saved so the samples progress to the PDA list.

14 Quality searches

Quality searches are to be performed when the source of an unexpected profile is not able to be determined (e.g. a profile in a negative control that does not match a sample on a batch). Quality searches can only be completed by the Managing Scientist or by Quality and Projects. If a quality search is required, a copy of the profile requiring a search will be required. The quality search may identify possible sources of the unknown profile, and can inform investigations.

A quality search consists of a search against Forensic DNA Analysis staff, QPS staff, the unknown profiles database and a search against all casework and all reference samples that have been processed within Forensic DNA Analysis. Where possible, individual amplification products/reworks will be quality searched separately, however if there are insufficient alleles in one amplification product - a combined profile may be required for searching purposes. The exact number of alleles required for a quality search cannot be exactly defined - as it is in part is determined by the relative rarity of the alleles. As a general guideline <8 alleles are not suitable for quality searching >10 alleles are suitable for searching, within the 8-10 allele range the outcome of the quality search is dependent on the loci/alleles available. If staff are unsure of a profiles suitability for quality searching, submit the profile to Quality for consideration. Profiles for quality searches are usually limited to single source profiles, that when matched against mixtures, are used to see if they are present in the mixture. Complex unsuitable mixtures will be excluded from any quality search results.

The quality searching/matching criteria in the FR are as follows:

- Plate reading
    - Single mismatch only – adds to the On-hold/Staff Flag list
- Full Quality Search
    - Can toggle to 1 or 2 mismatches
    - Must contain a minimum of 8 alleles
    - Exclude any mixtures where there are greater than 8 alleles

When performing a quality search in the FR, two alleles need to be included for each loci. If there is only one allele to search, it needs to be searched as "allele,0" – e.g. search an 11 as "11,0".

If the request to perform a quality search is received as a "Task" in the FR, the task should be sent back to the requestor containing the results of the quality search once the quality search has been completed.

In cases where the source of an unknown profile is not able to be determined, the unknown profile will be uploaded to the Staff Elimination database as an "Unknown Profile" (if the profile has ≥12 alleles) maintained by the quality team. This will ensure that any future occurrences of this profile can be identified. Where profiles are suitable (e.g. control profiles) – unknown profiles may be submitted to manufactures for searching against their staff databases.

Where the quality team have conducted a quality search, a sample notation detailing the outcome of the search will be added against the relevant barcode.

15 Investigating a sample which has different profiling results

Where a casework or a reference sample is profiled twice and the two resulting profiles do not match, ReCE of both amplified profiles (refer to QIS 34131) should be ordered (Note: alleles present in a mixture may vary between amplifications). After ReCE:

If it is confirmed that both sample profiles are the same:

- Advise Senior Scientist Quality and Projects
- Investigate incorrect CE result (refer to section 8 for casework, section 11 for reference samples)
- Ensure that no incorrect profiles have been reported.

If it is confirmed that the sample profiles are different:

- Advise Senior Scientist Quality and Projects
- Order re-extraction (casework) or re-punch (reference) of the sample.
- Investigate incorrect CE result (refer to section 8 for casework, section 11 for reference samples)
- View samples to ensure they have been correctly labelled
- Ensure that no incorrect profiles have been reported.

All investigation processes, actions and reporting in relation to this type of adverse event will be as described section 8 for casework, section 11 for reference samples.

16 Records

- FR batch notes, case notes and sample notations (as appropriate) will detail results from adverse events, adverse event investigation/s and outcomes of investigations.
- OQIs within QIS may be used: particularly in instances of a significant adverse event.
- For minor adverse events they may be recorded in the Adverse Events Log (I:\Adverse Events DNA Analysis\adverse Event log.xls) (as an alternative to an OQI).
- If needed, supporting data and information for investigations into adverse events can be stored to network drive I:\Adverse Events Forensic DNA Analysis.
- Investigations into reference batch failures are recorded in I:\Adverse Events DNA Analysis\FTA Plate Issues.xls, in addition to batch audit entries.

17 Communication

- All OQIs must have the DNA Management team added as a notifiee
- Staff are to notify their line manager for all adverse events
- The Team leader and Senior Scientist Quality and Projects are to be notified for all adverse events which may impact on results

18 Associated documentation

QIS: 13965 Opportunities for Quality Improvement (OQIs) Management Procedure (HSQ)
QIS: 17154 Procedure for Quality Practice in Forensic DNA Analysis
QIS: 17186 The acid phosphatise screening test for seminal stains
QIS: 17190 Tetramethylbenzidine screening test for blood
QIS: 31001 OQI Investigation and Analysis Toolkit
QIS: 33998 Phadebas Test for Saliva
QIS: 34006 Procedure for the Release of Results using the Forensic Register
QIS: 34035 Forensic Register FTA Processing
QIS: 34045 Quantification of Extracted DNA using the Quantifiler® Trio DNA Quantification Kit
QIS: 34052 Amplification of Extracted DNA using the PowerPlex21 System
QIS: 34064 Miscellaneous Analytical Procedures and Tasks
QIS: 34131 Capillary Electrophoresis Quality (CEQ) Check
QIS: 34280 Environmental Monitoring
QIS: 34308 Procedure for Intelligence Reports and Interstate/Interpol Requests in the Forensic Register

QIS: 34312 Operation and Maintenance of the Applied Biosystems 3500 Series Genetic Analyzers

19 References

ABAcard® p30 Test for the Forensic Identification of Semen. Technical Information sheet. Abacus Diagnostics, Inc.

20 Amendment history

Version	Date	Updated By	Amendments
1	5 April 2012	K Scott	First Issue
2	4 Sept 2013	K Scott	Update header and footer. Update location for storage of adverse event documentation, hyperlinks and replace 9FTAR with REF21
3	13 March 2015	A Darmanin	Changed to HSQ template. Added reference to QIS 17185 in section 4.4. Updated hyperlinks. Removed reference to AUSLAB staff match. Removed EB check as a routine process. Added references to batch GII. In Section 6 and Figure 2 updated that ≤ 2 alleles are acceptable in negative extraction controls. In Section 6 separated extraction and amplification batch quality pass criteria. In Section 9 removed reference to 2 positive amplification controls. Updated EFTA to EREF. Added QIS 32882 to Section 15.
4	25 Oct 2016	K Scott	Add section 5.4 – dropped sample, addition of cross-talk/signal interference to section 8.1. Edit section 15. Inclusion of investigation checklists (Appendix A & B)
5	7 Sept 2017	K Lancaster	Removed references to AUSLAB and updated to Forensic Register. Updated SOPs to FR equivalents. Changes as per comments.
6	05 Apr 2019	K Lancaster	Added section for CE batches. Added criteria for quality searches. Removed P+ references. Updated hyperlinks. Updated quant values in Figure 3. Changes as per comments. Changed minimum number of alleles for quality searching to 8. Changed partial positive control acceptance to ≥34 alleles
7	22 Sep 2020	C Savage	Removed information regarding spin basket barcode in Intel Reports in section 8.2.3. Additional minor changes. Added Section 17 -

			Communication.
8	22 Feb 2022	K Scott	Add appendix C & D, edit section 5.4 & 12 and Fig 3 - criteria for acceptance. Remove references to 3130xl. Update header

21 Appendices

1 Appendix A Investigation Checklist – items for consideration
2 Appendix B Negative Extraction Control Investigation Checklist
3 Appendix C Duplicate barcode considerations
4 Appendix D Root cause analysis fact sheet

21.1 Appendix A: Investigation Checklist – items for consideration

Initial Investigation Actions:

- ☐ Update batch status to "INV" (Investigation)
- ☐ Perform actions to hold affected results/samples pending investigation outcomes (e.g. hold plates from reading, mark samples "DoNotUse", add sample notations etc).
- ☐ Check for CE issues in sample/control (Cross-talk, Signal interference, and CE carry-over)
- ☐ Review plate as a whole – general outcomes for controls and samples
- ☐ Review technical aspects as required (e.g. thermal cycler programs, reagent usage etc.).
- ☐ ReCE samples/controls – if these reworks are informative
- ☐ Add sample "On hold" worklist (if applicable)
- ☐ Order additional reworks – as applicable to the investigation
- ☐ Add initial batch notes and/or sample notations as needed.
- ☐ Quality searches (if applicable)
- ☐ Record the issue/investigation in either Adverse Events Log, FTA Plate Issue Log or raise an OQI

Actions when reworks are available:

- ☐ Assess rework results
- ☐ Order additional reworks if required
- ☐ Quality searches (if applicable)
- ☐ Update batch notes with findings and/or sample notations as needed
- ☐ Update the issue/investigation in either Adverse Events Log, FTA Plate Issue Log or raise an OQI

Finalisation of Investigation:

- ☐ Finalise rework results
- ☐ Quality searches (if applicable)
- ☐ Release acceptable results (e.g. release plates, batch status, update sample notations etc)
- ☐ Results not suitable for release to be communicated to QPS (eg. Intel report), and finalised in FR appropriately
- ☐ Finalise batch notes (Outcome of investigation and consequences for reporting of samples). This is likely to include a summary of the following information
    - Are peaks confirmed on reworks
    - Is there sufficient information for matching purposes
    - Does it match anything on the batch
    - Results of quality search (if applicable), and FBUNK load (if applicable)
    - Source/method of contamination if known. If not known, state is it not known and provide possible/potential sources or reasons
    - State which samples are suitable for reporting, which are not suitable for reporting or caveats on samples that can be reported (if applicable)
    - Where there has been a technical issue an indication of the likely impact on sample quantity/quality should be provided
    - Where corrective actions have been taken state what these are.
- ☐ Finalise the investigation in the Adverse Events Log/FTA Plate Issue Log and/or the OQI. This will include the information as above and may include preventative actions.
- ☐ Update batch status (e.g. "PASS" - with "See Batch" comment, or "FAIL")
- ☐ Add a sample notation to remove the sample from the "On Hold" worklist (as required)

21.2 Appendix B: Negative Casework Extraction Control Investigation Checklist

Blue text – actions to be completed by CEQ checker
Black text – actions to be completed by Senior Scientist

Where there is < 3 peaks present in an extraction negative control

☐ Add "OK PP" to the UD1 comment

(this will then automatically update the status of the extraction batch (along with a passing positive control) to "PASS" (with "EXTN<3" comment) on uploading of CE results.

Where there is ≥ 3 peaks present in an extraction negative control

Initial Investigation Actions:

- ☐ If CEQ checker suspects the peaks are possibly due to cross talk, signal interference or carry over, they are to order a ReCE to confirm.
- ☐ If peaks are not due to cross talk, signal interference or carry over, the batch is to be reprepared (reprep)
- ☐ CEQ checker adds a batch note detailing reason for ReCE or reprep and enters an appropriate comment in the batch comment
- ☐ If peaks are no longer present after ReCE, CEQChecker adds "Quality Pass" to the UD1 comment and passes and finalises batch
- ☐ If peaks are still present on reprep, CEQChecker enters a batch note against CE batch: "EXTN Lab No XXXX has peaks at Locus [allele] investigation to follow" and updates batch status to "INV"
- ☐ Plate to be given to Senior Scientist for investigation
- ☐ Using ReCE reworks check for CE issues in the control (Artefacts, Cross-talk, Signal interference, and CE carry-over)
- ☐ Review plate as a whole – general outcomes for controls and samples
- ☐ Order additional reworks (as applicable) to see if the peaks are reproducible from the extract (e.g. re-amplification or microcon)
- ☐ Initial batch check – see if peaks in the control match any sample co-processed with the control
- ☐ Quality search (if > 8 alleles)
- ☐ Results/samples may be held pending investigation outcomes (e.g. hold plates from reading), however this is not generally the case as samples are effectively quarantined via a batch status of "INV" (investigation), and later workflows are more efficient if plates have already been read. In some instances case managers may have been able to order additional reworks while the initial result is still under "investigation" hold.
- ☐ May be necessary to record the investigation in either Adverse Events Log or raise an OQI. The adverse event number or OQI number must appear in the batch audit entry.

Note: Batches that are under investigation are displayed both in a table at the top of the FR Batch Dashboard page and under the "INV" filter on PDA worklists.

Actions when reworks are available:

- ☐ Assess rework results
- ☐ Order additional reworks if required
- ☐ Quality searches (if applicable) – with multiple reworks quality searching <8 alleles may be possible (Refer to section 14 for details)
- ☐ Additional batch check – see if peaks in the control match any sample co-processed with the control
- ☐ Update extraction batch and/or amplification audit entries with findings as needed

Finalisation of Investigation:

- ☐ Finalise rework results
- ☐ Quality searches (if applicable) – with multiple reworks quality searching <8 alleles may be possible (Refer to section 14 for details)
- ☐ Release acceptable results (if plates are on hold)
- ☐ Results not suitable for release to be communicated to QPS (eg. Intel report), and finalised in FR appropriately
- ☐ Finalise batch audit entries (Outcome of investigation and consequences for reporting of samples). This is likely to include a summary of the following information
    - Are peaks confirmed on reworks
    - The findings of the search against the extraction, quant and amp batches and any actions
    - The findings of the Quality search and any actions
    - The FBUNK number (if appropriate)
    - Whether there is any evidence that the peaks are the result of drop in or contamination (possibly low level contamination). If no source identified, the contamination could be environmental, consumables, labware, reagents.
    - State which samples are suitable for reporting, which are not suitable for reporting or caveats on samples that can be reported (if applicable)
    - Where corrective actions have been taken state what these are.
    - Example of wording used: *"123456789 – compared all profiles to each of their respective batches. No source could be found.*

    Due to the low level DNA profiles obtained from negative control 123456789, the sporadic nature of the DNA profiles obtained after each amplification is not unexpected (only a few of the peaks were consistent between amplifications). Given this, the extract cannot be definitively identified as the true source of the contamination; however this is the most likely explanation. The source of these contaminant peaks is not known and therefore the mechanism for this contamination cannot be determined, however some possible explanations are: the low level contaminant peaks could be the result of environmental, consumable, reagents or labware contaminants. Results from this extraction can be released for reporting."

- ☐ Finalise the investigation in the Adverse Events Log and/or the OQI (if applicable). This will include the information as above and may include preventative actions. Where an OQI is raised the OQI number must appear in the batch audit entry.

21.3 Appendix C: Duplicate barcode considerations

Where Queensland Police Service (QPS) have used a single barcode twice (duplicate barcode) e.g. once for a fingerprint and the same barcode for a reference submission the following actions should be considered and completed as required. Some actions must be completed by QPS, and some by Forensic DNA Analysis.

Scenario 1: AUSLAB only processed sample (barcode has been processed with tests and reporting in AUSLAB ONLY and NOT in FR) and the reference sample suitable for destruction. This does not apply to samples processed/tested in FR, or to reference samples that must be retained in AUSLAB in these cases see Scenario 2 below.

A. If QPS are aware of the duplicate at time of destruction.

- QPS is to request the destruction by email, and NOT manually trigger a destruction (as per standard destruction process).
- QPS is to request bdna to remove the DNA profile from the barcode (if it is present in FR).
- Forensic DNA Analysis staff to action the destruction in AUSLAB only, by manual addition of the DEST test code.
- Forensic DNA Analysis to add a specimen note to AUSLAB to state duplicate barcode, actioned in AUSLAB only.
- Storage must stay in AUSLAB (NOT to be stored in FR at any time)

B. If QPS are unaware of duplicate at time of destruction.

- QPS is to request from bdna the removal of the destruction in the FR
- QPS is to request bdna to remove the DNA profile from the barcode (if it is present in FR)
- Forensic DNA Analysis must NOT action the destruction in FR, we need to wait for its removal by bdna
- Forensic DNA Analysis staff to action the destruction in AUSLAB only, by manual addition of the DEST test code.
- Forensic DNA Analysis to add a specimen note to AUSLAB to state duplicate barcode, actioned in AUSLAB only.
- Storage must stay in AUSLAB (NOT to be stored in FR at any time)

Scenario 2: Shared records in FR. Correction requirements, where reference sample needs to be re-barcoded.

- QPS to register the new barcode YYYYYYYYY (to be assigned to the item that was a duplicate)
- QPS to advise Forensic DNA Analysis of re-barcoding requirements. We will need an email that advises the following: FTA (barcode XXXXXXXXX, UR/Person number, Name) has been re-barcoded by QPS to YYYYYYYYYY. Please update Queensland Health Records, and physically re-barcode all items
- If any FR records have been blended (from the two items) as a result of the duplicate barcode QPS will need to request a correction of records with bdna. This may include removal of records under barcode XXXXXXXXX (it may be only a historical epg, or removal from Forensic DNA Analysis worklists if applicable), or may involve complex movement of records from XXXXXXXXX across to the new barcode YYYYYYYYY if some testing has been completed under the duplicate record.
- Forensic DNA Analysis is to add specimen notes to AUSLAB to state that it is a duplicate barcode, and that it has been re-barcoded by QPS from barcode XXXXXXXXX to YYYYYYYYY, and is now stored and recorded in FR under barcode YYYYYYYYY
- Forensic DNA Analysis to ensure the new barcode is registered in FR, and store a copy of the email advice RE: rebarcoding in FR as a notation

- Forensic DNA Analysis to re-barcode the physical FTA card/DNA Extract/Blood with the new barcode (and Sub-IDs if required) as advised by QPS. This must be sequence checked by a second operator. Quality team can help with this action.
- Forensic DNA Analysis is to remove the items from AUSLAB storage (with appropriate notes)
- Forensic DNA Analysis to store all re-barcoded items in FR
- Forensic DNA Analysis to make edits/changes/updates to NCIDD and link records as required.

21.4 Appendix D: Root cause analysis fact sheet (sourced from the 2020 FSS management review)

Background: When investigating an OQI, NATA has asked us to determine the "root cause". This fact sheet will help staff to identify the root cause(s) and connect actions to these.

Root cause analysis: Every mistake has a "root cause". Unless the real cause is dealt with, there is every chance the mistake will re-occur.

Use the three questions below to identify the root cause.

1. What happened? Clearly identify the error made.

2. How did this happen? Identify the issue that caused the error.
   - Was the training and competency of the staff performing the task complete? Adequate?
   - Is the task infrequently performed?
   - Was fatigue, stress or workload a factor?
   - Were there distractions?
   - Did the layout of the work area contribute? Did the physical environment contribute?
   - Did the equipment contribute?
   - Was communication adequate? To the right people?
   - Is there a SOP? Is it up to date? Is it clearly written? If the SOP was not followed, why?
   - Was the error introduced from outside the laboratory? (e.g. Incorrect instructions from customer, wrong value for reference sample supplied by manufacturer)

3. What underlying situation created this issue that caused the error?
   - Working a six-day week for 12 hours a day = fatigue
   - Task only done once a year = low level of competency
   - Poorly written SOP = procedure not followed
   - Wrongly labelled reference sample = external error

Documenting the root cause – causal statements
It is important to document the root cause in the 'investigation' section of the OQI, and this is best done using causal statements. These are succinct statements used to summarise the investigation and show a clear link between the contributing factors and the incident/outcome. Causal statements;

- clearly show the 'cause and effect' relationship. For example – 'The level of the scientist's fatigue increased the likelihood of the instructions being misread, which led to incorrect data entry' instead of 'The scientist was fatigued'
- use specific and accurate descriptors of what occurred. For example – 'The procedure was not indexed, and did not include tables or flowcharts, and as a result, the document was rarely used' instead of 'The procedure was poorly written'.
- human error must have a preceding cause: For example – 'The level of urgency caused the scientist to rush and take shortcuts, resulting in the label not being checked' instead of 'The scientist did not check the label'
- violations of procedure must have a preceding cause: For example – 'Noise and distractions in the laboratory, and pressures to quickly complete the work increased the probability of bypassing the checking step; this resulted in the wrong result being issued' instead of 'The staff member did not follow the procedure'.

Actioning an OQI
Actions should prevent the event from recurring and if that is not possible, reduce the severity or consequences if it should recur. OQI actions must clearly show a link between the actions and the

causative factors. Each action/intervention can be clearly linked to one or more causative factors. For example:
If the staff member was not trained in how to perform a procedure, your action must clearly explain what training has been done, "staff member trained using QIS training module 12345", not "staff member trained".
If the staff member is fatigued from long hours your action might be "three other staff members trained to perform procedures so working hours can be shortened", not "staff member reminded to tell supervisor when they are tired". Reminders and telling staff to be more vigilant have limited effect.

HealthSupport
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Procedure for Quality Practice in Forensic DNA Analysis

Contents

1 Purpose

Laboratory technical accreditation (under ISO 17025) requires documentation of all policies and procedures that are critical to the proper functioning of Forensic DNA Analysis. The purpose of this document is to provide an "electronic index" to the principal Forensic DNA Analysis quality documents.

2 Scope

This document is to be used by all Forensic DNA Analysis Staff as well as clients and external assessors of the quality management system.

3 Definitions

CSP Career Success Plan
HSQ Health Support Queensland
FSS Forensic and Scientific Services
QIS Quality Information System
QPS Queensland Police Service

Refer also to Common Forensic DNA Analysis Terms and Acronyms (QIS 23849)

4 Organisational overview

Address:
Blocks 3 Level 1 & 6 Level 1
39 Kessels Road
Coopers Plains 4108

Postal address:
[redacted]

4.1 Organisational overview

FSS routinely operates Monday to Friday from 7:30 am to 4:30 pm. The hours of operation may change depending on client requirements including overtime and/or weekend work.

4.2 Clients

The Forensic DNA Analysis Organisational Structure is documented in Organisation and Management of Forensic DNA Analysis (QIS 17091). Forensic DNA Analysis is to comply with the procedures and policies outlined in the FSS Quality Management System Guide (QIS 19259)

5 Quality management system

Forensic DNA Analysis is committed to continual improvement through the implementation and maintenance of the quality management system, and by conformance to the ISO 17025 standard.

5.1 Corrective/preventative action and complaints

QIS2 is used for documentation of corrective and non-conforming actions. Specific instructions for adverse events are documented in the appropriate standard operating procedures detailed in Table 1. Notes are used in the LIMS system to document corrective actions for a sample/s. Non-conforming work from QPS is recorded in results lines and/or Intel reports.

Table 1 Standard Operating Procedures for corrective/preventative action and complaints.

QIS #	Title	Description
13965	Opportunities for Quality Improvement (OQIs) Management procedure	Describes the management of an OQI arising within the organisation.
30800	Investigating Adverse Events in Forensic DNA Analysis Unit	Guidelines for investigations into adverse events, and result acceptance criteria in the Forensic DNA Analysis Unit Laboratory

5.2 Risk Assessment Follow-up

Risk assessments in Forensic DNA Analysis are to be completed by following the FSS risk assessment procedure 29106 with the 29100 risk assessment forms. In Forensic DNA Analysis the follow-up actions from risk assessments will be flagged as due via a QIS OQI function.

5.3 Management review

Forensic DNA Analysis Management Team conducts biannual Management Review using template QIS 28801 as per the HSQ document QIS 10010 Management Review Procedure. The minutes of these meetings are kept on a network drive: Management Review.

5.4 Client feedback

Forensic DNA Analysis seeks formal and informal feedback from the Queensland Police Service electronically, (through the use of email and phone meetings), and face to face (via meetings, conferences, working groups etc.). Minutes, issues logs, and OQI's are used to record client feedback.

Where negative feedback is received from a client, the Management team/Managing Scientist/Team Leader will assess the seriousness of the issue/s raised in the feedback. If the feedback is deemed to be a complaint an OQI must be raised. All complaints received from the client require an OQI to be raised.

5.5 Business continuity

Table 2 Standard Operating Procedure for business continuity.

QIS #	Title	Description
27210*	Business Continuity Plan - Forensic DNA Analysis	Provides information for use by the Business Recovery Manager following a Business Continuity Emergency.

**Private Viewer documents – hyperlink with appropriate login only*

6 Personnel

6.1 Confidentiality

All Forensic DNA Analysis staff are governed by the Department of Health Code of Conduct for the Queensland Public Service, the HSQ Analytical Services Framework QIS 14475 and the policy on appropriate use of E-mail and Internet.

6.2 Security

All visitors to Forensic DNA Analysis are recorded on an Electronic Visitors Log and are subject to procedures listed in Table 3.

Table 3 Standard Operating Procedures for security in Forensic DNA Analysis.

QIS #	Title	Description
17146	Internal Security and Access to the Forensic DNA Analysis	Describes the procedures used to control access to the Forensic DNA Analysis Unit to ensure the integrity of exhibits and DNA samples.
17048	Electronic Visitors Log (for Forensic DNA Analysis)	Form for visitors to sign when entering the Forensic DNA Analysis Unit.

6.3 Communication

All Forensic DNA Analysis teams hold regular meetings with staff. The all Forensic DNA Analysis Unit meetings are held on the first Thursday of the month. Meeting Attendance for Forensic DNA Analysis is recorded on the Meeting Attendance form.

- Forensic DNA Analysis Team minutes
- Analytical Team minutes
- Operational Team Minutes
- Evidence Recovery Team Minutes
- Forensic Reporting and Intelligence Team minutes
- Reporting 1 minutes
- Reporting 2 minutes
- Intelligence Team minutes
- Management Team minutes (will be available to staff after minutes are confirmed)

Emails or Faxes can be used to communicate between various departments and clients in and outside of Forensic DNA Analysis. The Forensic DNA Analysis Facsimile Transmission Sheet template is to be used, and the multifunction printer located in Administration area is able to fax. The QPS communication issues log records discussions / advice from QPS where no case is available.

6.4 Duty statements

The duty statements for each team are documented in QIS2 as outlined in Table 4.

Table 4 Duty statements for each team in Forensic DNA Analysis.

QIS #	Title	Description
22012	DNA Analysis Duty Statement – Managing Scientist	To describe the duties of the Forensic DNA Analysis Managing Scientist.
24274	Forensic DNA Analysis - Evidence Recovery and Quality Team Duty Statements	To provide a framework for duties performed by members of the Evidence Recovery & Quality Team within Forensic DNA Analysis
23127	Forensic DNA Analysis Unit Duty	To describe the duties of the Forensic DNA

	Statements – Administration	Analysis Administration staff.
24122	Forensic Reporting and Intelligence Team –Duty Statements Forensic DNA Analysis	To describe the duties of the Forensic DNA Analysis Senior Scientist & Scientists: Forensic Reporting & Intelligence.

6.5 Orientation and induction

New staff that commence in the Forensic DNA Analysis participate in the campus wide induction and department specific inductions. The documents that relate to Inductions are listed in Table 5.

Table 5 Standard Operating Procedures and checklists for orientation and induction.

QIS #	Title	Description
17088	Procedure for recording handwriting specimens in Forensic DNA Analysis	Procedure for documenting the Forensic DNA Analysis Staff handwriting specimens & form
17147	Forensic DNA Analysis Orientation & Induction Checklist	Checklist to ensure that all new staff members within Forensic DNA Analysis are provided with an adequate introduction to the section, its facilities, activities and requirements.
21964	Forensic DNA Analysis Induction Presentation	Position and leave entitlements, security, timesheets, WHS First Aid & Fire Safety, Impartiality, Confidentiality, Anti-contamination, Quality, Lab Structure, Professional Bodies, Requisitions, Training.
31010	Forensic DNA Analysis Capability Development Program	Forensic DNA Analysis Capability Development Program. Learning Pathways for all positions in sub-teams within Forensic DNA Analysis..

6.6 General

Table 6 Standard Operating Procedure for Forensic DNA Analysis Administrative Duties

QIS #	Title	Description
24125	Forensic DNA Analysis Administrative HR Duties	Outlines the specific procedures used in completing various HR-Related tasks.

6.7 Learning and development

The Scientific Skills Development Unit provides information and co-ordinates learning and development opportunities for all staff at Forensic and Scientific Services (Forensic and Scientific Services Learning and Development Guidelines 23651) in accordance with the Queensland Government Orientation, Induction and Mandatory Training Policy G6 and Performance and Development Policy G9.

6.8 Career Success Plan (CSP)

The resources for CSPs are available from https://qheps.health.qld.gov.au/hsq-staff/hr/training/csp. All original CSP records are kept locked in locked filing cabinet within Forensic DNA Analysis Rm 6103.

6.9 Safety

Forensic DNA Analysis staff comply with FSS Workplace Health and Safety QIS 10744 and Workplace Health and Safety in Forensic DNA Analysis QIS 23945. One member of the Forensic DNA Analysis staff is nominated as a Workplace Health & Safety representative and participates in the Workplace Health and Safety Committee.

In addition Forensic DNA Analysis has 2 Area Wardens and 3 Wardens. Each block has its own Area Warden and designated evacuation route. Staff are allocated "evacuation buddies" as listed in Forensic DNA Analysis Emergency Evacuation.

Forensic DNA Analysis has 4 First Aid officers.

Each standard operating procedure has specific requirements for Health and Safety related to that procedure. FSS campus specific procedures are listed in Table 7.

Table 7 Standard Operating Procedures for Workplace Health and Safety.

QIS #	Title	Description
10744	Laboratory Safety General Guidelines	To provide general guidance regarding safe practices in the workplace and to promote health and safety of persons and property.
16006	Walk In Cold Room and Freezer General Use and Safety	To provide general guidance regarding safe practices for the use of the walk in freezer/fridge in Forensic DNA Analysis.
17149	Procedure for Waste Disposal in Forensic DNA Analysis	The purpose of this document is to describe waste management procedure for Forensic DNA Analysis.
17195	Spill Control	This procedure describes the steps that should be taken in the clean up of both biological and chemical spills.
25352	Eyewash Station and Safety Shower- Record of Flushing	Form for recording details of flushing of eyewash stations and safety showers.

7 Testing

7.1 Subcontracting of work

Forensic DNA Analysis does not carry out routine subcontracting of work. In the event that it does occur guidelines are described within standard operating procedure Guideline on Subcontracting of Work (QIS 17103).

7.2 Accommodation and environmental conditions

Forensic DNA Analysis has specific requirements regarding accommodation and environmental conditions in which casework and reference samples are processed. These conditions are outlined in Table 8.

Table 8 Standard Operating Procedures for accommodation and environmental conditions.

QIS #	Title	Description
22857	Anti-contamination Procedure	Describes the anti-contamination practices for examinations, equipment use, storage, waste disposal, cleaning within Forensic DNA Analysis.
34280	Environmental Monitoring	Describe environmental monitoring and provides guidelines for the Environmental testing to be carried out within Forensic DNA

		Analysis.

7.3 Internal quality control

Specific standard operating procedures contain requirements for internal quality control and rules for their acceptance/rejection. Key points are listed below in addition to the procedures are outlined in Table 9.

- All examinations conducted by the Evidence Recovery team are reviewed.
- Sequence checks are performed within the Forensic DNA Analysis. It must be performed whenever a sample, DNA extract or PCR product is transferred from one tube, plate or rack to another. A sequence check may be performed using the FR, manual cross referencing, or by using the STORstar instrument.
- Within Forensic DNA Analysis internal Quality controls are prepared by Forensic DNA Analysis staff.
- Training Modules are used within Forensic DNA Analysis to standardise training and to document competency.
- Quality Flag checking is described in QIS 34281; this procedure is to detect gross contamination that could have occurred at collection or during processing of the sample.
- Data of enduring value is to be stored in a location where the Information Division can maintain back-ups and security e.g. to G:, I: or P:drive as these are backed up each day
- Date format for use throughout the laboratory is dd/mm/yyyy.

Table 9 Standard Operating Procedures for internal quality control.

QIS #	Title	Description
34006	Procedure for the release of results using the Forensic Register	Describes the correct format for statements or reports issued from Forensic DNA Analysis.
34514	Preparation & Testing of Quantification Standards, In-house Controls, Quantification Kits and Amplification Kits	Describe the method required to prepare Standards and Quality Controls included in Extraction processes performed within the Analytical Section of Forensic DNA Analysis.
30800	Investigating Adverse Events in Forensic DNA Analysis Unit	Guidelines for investigations into adverse events, and result acceptance criteria in the Forensic DNA Analysis Unit Laboratory

7.4 Proficiency testing

Participation in proficiency testing is coordinated by the National Institute of Forensic Science (NIFS) through the FSS Quality Office. Samples and reports that are received by the Quality Office are forwarded to Quality & Projects Team in Forensic DNA Analysis. Forensic DNA Analysis participates in the CTS Collaborative Testing Services DNA Testing proficiency program. The standard operating procedure for proficiency testing is outlined in Table 10.

Table 10 Standard Operating Procedure for proficiency testing in Forensic DNA Analysis.

QIS #	Title	Description
34114	Proficiency Testing in Forensic DNA Analysis - FR	Describes the process for proficiency testing within Forensic DNA Analysis.

7.5 Elimination DNA sampling

Elimination DNA samples are taken from:

- All staff that work in Forensic DNA Analysis;
- Personnel nominated by Queensland Police Service; and
- Contractors, engineers and other people who enter the DNA or examination suites.

DNA profiles and person records (i.e. names and company etc.) are stored in the Forensic Register and are accessible only to quality staff and the managing scientist (by specific FR login). All potential matches to staff are checked as per the documents outlined in Table 11.

Table 11 Standard Operating Procedures for elimination DNA sampling.

QIS #	Title	Description
34281	Procedure for Use and Maintenance of the Forensic DNA Analysis Elimination Database	This document describes the use and maintenance of the Elimination Databases within Forensic DNA Analysis.
33333	Participant Information and Consent Form (PICF) - Common Biological Samples	This Participant Information Sheet and Consent Form (PICF) explains why staff samples are collected and how they are used.
33334	Participant Information and Consent Form (PICF) - Semen Samples	This Participant Information Sheet and Consent Form (PICF) explains why staff samples are collected and how they are used
33335	Participant Information and Consent Form (PICF) - Vaginal Samples	This Participant Information Sheet and Consent Form (PICF) explains why staff samples are collected and how they are used
34112	STR Fragment Analysis of PowerPlex21 profiles using GeneMapper ID-X software - FR	Describes the procedure for analysing results using the GeneMapper ID-X software

7.6 Receipt, storage and disposal of testing material

Exhibits, Samples and specimens are delivered to the Forensic Property Point. Receipt, storage and disposal procedures are listed in Table 12.

Table 12 Standard Operating Procedures for receipt, storage and disposal of testing material.

QIS #	Title	Description
17116	Processing DNA Exhibits/Samples in the Forensic Sciences Property Point	Detail the process to be followed for processing DNA crime scene, reference and coronial exhibits in the Forensic Sciences Property Point.
25459	Dual Analysis of Forensic Exhibits	Procedure for receipting forensic exhibits that require analysis by 2 laboratories.

8 Change management

Table 13 Standard Operating Procedures and guidelines for change management.

QIS #	Title	Description
22871	Procedure for Change Management in Forensic DNA Analysis	This document describes the change management procedure that is to be used within Forensic DNA Analysis, to ensure that all process changes and projects occur in a controlled and timely manner..

23401	Forensic DNA Analysis Validation Guidelines	Describes validation and its use within Forensic DNA Analysis.
23402	Writing Guidelines for Validation and Change Management Reports	The purpose of this document is to provide Forensic DNA Analysis staff with guidelines for writing the final report - after completion of either a validation or change management project.
22872	Project Plan Form for Change Management in Forensic DNA Analysis	It is a template to be used for the submission project plans
31052	Forensic DNA Analysis Unit Change Management Budget	Budget tracker used in conjunction with QIS 22872
31543	Initial Request Form for Change Management in Forensic DNA Analysis	Change requests initiated by Forensic DNA Analysis staff are to be recorded on the Initial Request form
31548	Minor Process Change Form for Change Management in Forensic DNA Analysis	Minor changes to be recorded in this form

9 Equipment

9.1 Equipment inventory

An equipment inventory is available using the Forensic Register - for all equipment requiring calibration.

9.2 Calibration and maintenance of equipment

The equipment verification and maintenance procedures used in the Forensic DNA Analysis are listed in Table 14.

Table 14 Standard Operating Procedures and documents for calibration and maintenance of equipment.

QIS #	Title	Description
33315	Procedure for verification and Maintenance of equipment	Describes the various procedures used to verify and maintain equipment in Forensic DNA Analysis
N/A	Equipment records	Electronic copies of verifications, calibrations and equipment maintenance is available
N/A	Risk Analysis Critical and Non-Critical Equipment	Risk assessment for all equipment in Forensic DNA Analysis

10 Purchasing

The Managing Scientist and Team Leaders of Forensic DNA Analysis have a financial delegation as per roles and responsibilities of the position. Purchasing by Forensic DNA Analysis is governed by the procedures outline in Table 15.

Table 15 Standard Operating Procedures and documents for purchasing and stocktake.

QIS #	Title	Description
24138	Ordering System Procedures – (Forensic DNA Analysis)	Forensic DNA Analysis specific procedures
19259	FSS Quality Management System Guide	Procedures specific to purchasing at FSS
N/A	Asset Stocktake	Yearly asset stock takes
N/A	Consumable stocktake	Yearly consumable stocks takes
N/A	Queensland Health Purchasing Policies and Procedures,	Policies and procedures that apply to whole of QLD health.

11 References

Nil

12 Associated documentation

Nil

13 Amendment history

Version	Date	Author/s	Amendments
1	18 Jul 2000	V Ientile	
2	21 May 2001	V Ientile	
3	4 Sep 2001	V Ientile	
4	20 Feb 2003	V Ientile	Updated CTS section & int prof procedures, removed reference to Monthly Checks and Ref Blood Processing, these are no longer done.
5	20 Feb 2003	V Ientile	Add external proficiency reviewed by quality manager, section 4. Changes to internal proficiency testing, Section 5, Add Section 7.
6	24 Jan 2005	V Ientile	
7	29 Sep 2005	M Gardam	Changed Quality Manager to Quality Supervisor, added details regarding the Change Management process
9	26 Oct 2005	M Gardam	Included a storage position for CTS Samples
10	29 Jul 2006	M Gardam	Included sample ID check and sequence check. Added details regarding QC dots. Added location of Minor Change Log.
11	28 Jul 2007	M Gardam/N Govind	Included Audit Trail and OQI Notification. Changes made to Internal Quality Procedures. Amalgamated 17163 and 17154.
11	Apr 2008	QIS2 Migration Project	Headers and Footers changed to new CaSS format. Amended Business references from QHSS to FSS, QHPSS to CaSS and QHPS to Pathology Queensland
12	16 Sep 2010	Thomas Nurthen	Major re-write – re-aligned to FSS Quality Guide
13	28 Aug 2012	Kirsten Scott	Header changed to new HSSA format. Update all documents and links.
14	03 Sept 2013	Kirsten Scott	Update all documents and hyperlinks. Remove references to ISO9001. Update section 7.4 to reflect ISO17025 (July 2013) 5.9.1
15	12 March 2015	A Darmanin	Transfer to HSQ template. Section 6.8 changed PAD to PDP. Updated hyperlinks, current documents and policies. Added titles to Tables. Replaced QIS 17121 with the Meeting Attendance form. Removed reference to QIS

			documents 26854 and 31546. Added equipment risk analysis spreadsheet.
16	17 Nov 2015	K Scott	Addition of risk assessment follow-up process to section 5, QIS documents 31389, 33333, 33334, 33335 and update section 6.4
17	10 Oct 2016	K Scott	Add date format to section 7.3. Add additional communication information to section 5.4. Section 5.1 update from AUSLAB to LIMs. Table 5 remove archived document 31853 Update section 6.8, 10 and Appendix A title.
18	4 April 2018	K Scott	Update documents, hyperlinks and minor text updates section 6.3, 6.4, 6.5, 6.9, 7.2, 7.3 and 7.5
19	23 Oct 2019	C Savage	Updated phone and fax numbers in section 2. Replaced PDP with CSP – section 3 and 6.8. Updated table 11. Updated communications. Updated process for risk assessment follow-up and deleted appendix 1.
20	5 May 2020	C Savage	Remove reference to QIS#17119 in table 9 – this SOP has been archived. Equipment list removed from table 14 – this has been archived and all equipment is now in the FR.

Queensland Health
Forensic and Scientific Services

Quality Management System Guide

1 Purpose

Quality systems certification (under ISO 9001) and laboratory technical accreditation (under ISO 17025, ISO 15189 and ISO 17034) requires documentation of all policies and procedures that are critical to the proper functioning of Forensic and Scientific Services (FSS).

The purpose of this guide is to provide an "electronic index" to the principal documents in QIS that describe the quality management system as it applies to FSS. Details of the accreditation, certification and approvals held by FSS are detailed in section 7. This section also details the exclusions for certification against ISO 9001.

2 Scope

This guide is designed to be used by all staff at Forensic and Scientific Services, as well as clients and external assessors of the quality management system.

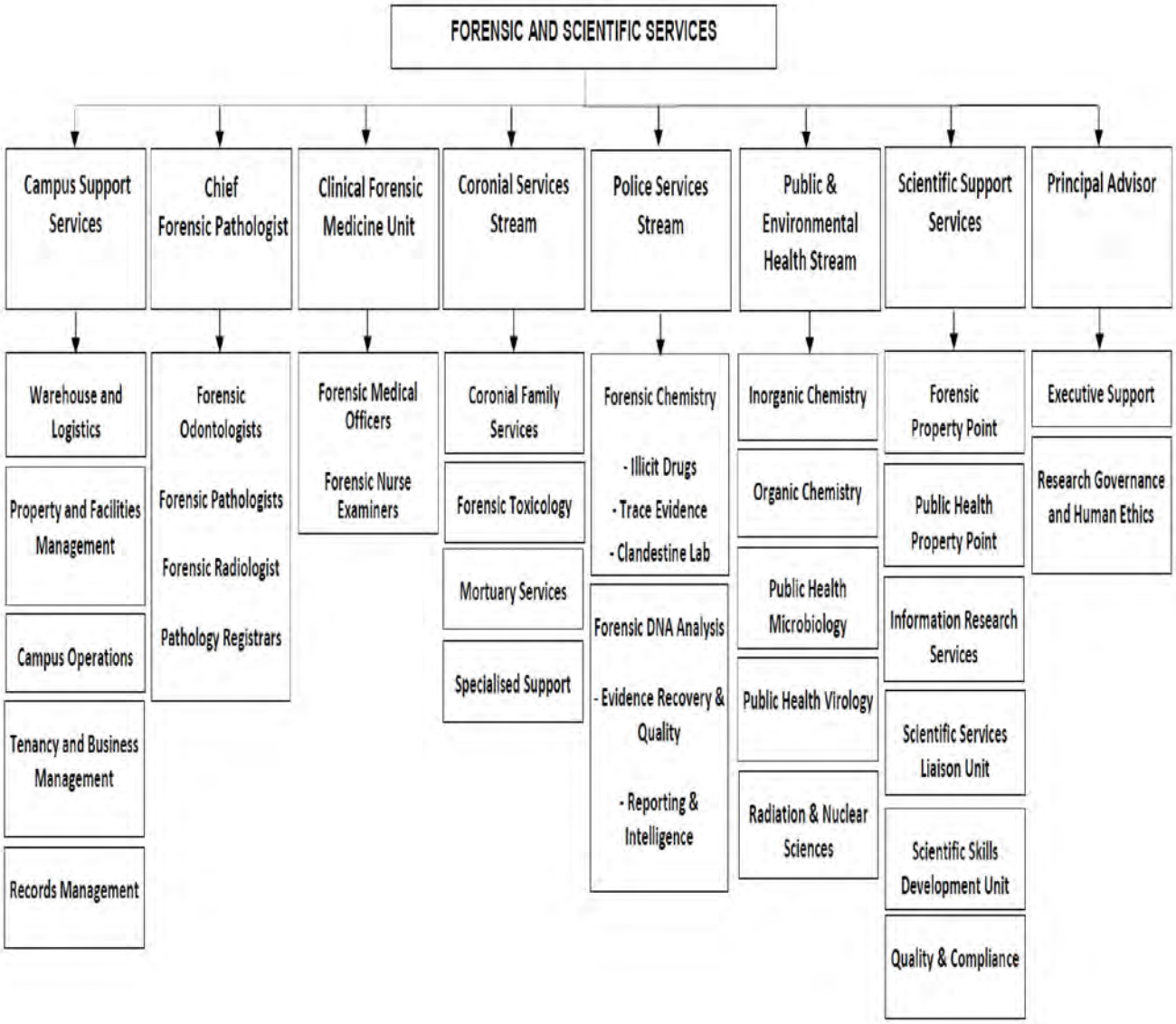
3 Definitions

Nil

4 Organisation overview

Forensic and Scientific Services (FSS) is Australia's most comprehensive forensic and public health science facility. We provide expert analysis, advice, teaching and research as a vital part of the government response to threats to public health and the environment, epidemics, civil emergencies, criminal investigations and coroners' inquiries into reportable deaths.

The Forensic and Scientific Services (FSS) organisational structure is below.


FORENSIC AND SCIENTIFIC SERVICES
Campus Support Services
Chief Forensic Pathologist
Clinical Forensic Medicine Unit
Coronial Services Stream
Police Services Stream
Public & Environmental Health Stream
Scientific Support Services
Principal Advisor
Warehouse and Logistics
Property and Facilities Management
Campus Operations
Tenancy and Business Management
Records Management
Forensic Odontologists
Forensic Pathologists
Forensic Radiologist
Pathology Registrars
Forensic Medical Officers
Forensic Nurse Examiners
Coronial Family Services
Forensic Toxicology
Mortuary Services
Specialised Support
Forensic Chemistry
- Illicit Drugs
- Trace Evidence
- Clandestine Lab
Forensic DNA Analysis
- Evidence Recovery & Quality
- Reporting & Intelligence
Inorganic Chemistry
Organic Chemistry
Public Health Microbiology
Public Health Virology
Radiation & Nuclear Sciences
Forensic Property Point
Public Health Property Point
Information Research Services
Scientific Services Liaison Unit
Scientific Skills Development Unit
Quality & Compliance
Executive Support
Research Governance and Human Ethics

Our key streams are;

- Coronial Services
- Police Services
- Public and Environmental Health
- Clinical Forensic Medicine

The units within each stream, and the corresponding services provided by these units is detailed below;

Coronial Services	
Forensic Toxicology	• Biological specimen testing for alcohol, drugs and poisons • Testing for coronial, criminal and road safety matters
Forensic Pathology	• Provides autopsy and specialised services to assist coroners and bereaved families during deaths that have been reported to a coroner under the *Coroners Act 2003*. These examinations help to determine the cause and circumstances of death and assist in identifying the deceased. • The following specialised services are integral in assisting forensic pathologists to determine the cause of death as well as providing counselling and information about the coronial process: - mortuary services - forensic histology - forensic odontology - forensic skeletal examination - coronial family services
Police Services	
Forensic DNA Analysis	• DNA profiling • court attendance and delivery of expert evidence in court • accident and crime scene evidence analysis
Forensic Chemistry	• Illicit drug analysis • Clandestine laboratory analysis and remediation • Physical evidence examination • Oil spill comparisons
Public and Environmental Health	
Organic Chemistry	• Testing for organic and pesticide contaminants in recycled and drinking water, biological specimens and foods • Air analysis for volatile organic compounds • Algae identification and toxin analysis • Food testing to determine safety, chemical composition and compliance • Molecular testing to determine the identity and country of origin of foodstuffs
Inorganic Chemistry	• Testing for metal and inorganic compounds in the environment, consumer products, biological materials and food • Environmental monitoring of nutrients

Public Health Microbiology	• Food and water microbiology • Reference microbiology • Molecular epidemiology • Reference and research of Leptospirosis
Public Health Virology	• Serology diagnostic laboratory • Molecular diagnostic laboratory • Virus culture • Research entomology
Radiation and Nuclear Science	• radiation assessments for public and environmental health programs • contaminated land assessment and radiological baseline studies • radiation testing of food, water and soil • radiation survey meter calibration • waste disposal and transport of radioactive substances • radiation safety training • compliance testing and certification of radiation sources, equipment and premises.
Clinical Forensic Medicine Unit	
• obtain, document and interpret medical evidence from victims of crime, alleged offenders and examination of adult sexual assault victims • provide toxicological advice to the Coroner and courts in relation to suspicious deaths and driving matters • provide expert evidence and appear in court • examine the treatment of police detainees • support the Office of the State Coroner to investigate healthcare-related deaths.	

These services are supported by;

- Scientific Support Services
- Campus Support Services
- Research and Development

The corresponding services provided by these units is detailed below;

Scientific Support Services	
Quality	responsible for managing, maintaining and improving all aspects the FSS quality system including accreditation, certification and any regulatory and legislative requirements relating to these issues. The role provides authoritative, professional advice and assistance to management, supervisors and employees on quality systems issues
Scientific Skills Development Unit	• Facilitates the development of a learning culture across all business units at FSS. • Responsible for leading the design, development, implementation and evaluation of competency-based training programs across FSS. • Delivers scientific and related training • facilitating and coordinating the provision of other training

	development services • facilitates implementation of court training for scientists providing evidence in court
Information and Research Services (IRS)	Provides information and research support to FSS services, including literature searches, electronic journals and databases, eprints (FSS staff publications), access to Australian Standards and lending services
Public Health Property Point	responsible for receiving, registering, tracking, storing, coding, allocating and delivering public health samples to the scientific business units at FSS
Forensic Property Point	responsible for receiving, registering, tracking, storing, coding, allocating and delivering forensic exhibits to the scientific business units at FSS
Scientific Services Liaison Unit	responsible for the effective liaison between FSS and key clients such as Queensland Police, and Department of Justice and Attorney-General. The unit ensure correct case allocation to the Forensic scientists and is responsible for court scheduling etc
Campus Support Services	
Operational Support Services	responsible for contract management and delivery of cleaning, security, grounds, waste and hygiene services. The area is also responsible for vehicle fleet management, internal courier service and a centralised warehouse, tracking all incoming and outgoing freight for laboratories; as well as the commencement of the asset lifecycle process
Tenancy and Business Management	responsible for business management and information (finance, billing, fleet vehicle transactions, petty cash, coordinating business case process, purchase requisitions) as well as executive and administrative support; providing relief to laboratories for admin functions and secretariat functions to executive management
Records Management	responsible for right to information (RTI) request for records and supporting the QH Legal Unit. The area is also responsible for managing all corporate records information in relation to strategic, operational, financial and decision making into FSS funding, revenue and resources. The unit provides advice and training to laboratories across the campus to capture, manage, archive and lawfully destroy records in compliance to Public Records Act 2002
Property and Facilities Management	responsible for the maintenance of campus buildings and related infrastructure, and for coordinating contractors brought on site to complete works
Research and Development	
• provides assistance to FSS staff with application and approval documentation • monitors and reviews project progress and budget • assists with collation and submission of grant applications • to facilitates training in research and development areas	

- liaises with Legal and Administrative Law Unit (LALU), universities and other government departments for administration of cross-jurisdictional projects and contracts
- facilitates Site Specific Assessment for projects requiring ethical approval
- Facilitates FSS Human Research Ethics Committee

Address: [redacted]

Fax: [redacted]

Phone:

Postal address: [redacted]

Website: www.health.qld.gov.au/fss

Hours of Operation

FSS routinely operates Monday – Friday 0830 - 1630. Some laboratories operate extended hours or have on-call arrangements.

Clients

The client base includes the Department of Health, Queensland Police Service, Coroners Court of Queensland, Department of Justice and Attorney-General, other government departments and the private sector.

Governance

The FSS Governance Manual (20033) provides an overview of the corporate governance processes of FSS, including organisational and committee structures as well as outlining reporting procedures and requirements. It also profiles the organisations senior management responsibilities.

Clinical governance processes at FSS are detailed in QIS document 35201.

Business Continuity

Each unit has a Business Continuity plan, which is governed by the FSS Business Continuity Management Framework (27063).

Disaster Management

The FSS Disaster Management Plan (28736) is a functional sub-plan for the Queensland Health Disaster and Emergency Management Arrangements. The plan provides for an all hazards, all agencies, and comprehensive approach to emergency management.

Planning

The FSS Operational Plan identifies the core activities that will be undertaken, and details key performance indicators for these activities. It is supported by operational plans for each stream. There is regular monitoring and reporting against these operational plans by relevant management and the plan is aligned to FSS business objectives and the FSS quality commitment.

Quality Policy
The Quality Management System of FSS is governed by the FSS Quality Commitment (33322). These processes are regularly reviewed by the FSS Quality Manager for ongoing relevance.

The FSS Quality Management System supports several accreditations, certifications and approvals as listed in section 7 of this document. FSS management is committed to continual improvement through the implementation and maintenance of the quality management system, and conformance to the relevant standards and guidelines that pertain to the organisation.

5 Personnel

Confidentiality
FSS staff are governed by the Queensland Public Service Code of Conduct, and section 3 of the Analytical Services Framework 14475. Conflicts of interest are managed according to risk.

Orientation and Induction
All new staff participate in a site induction on day one of employment, and are referred to the Campus Operations Manual (28335). All staff are required to complete their area induction and mandatory training within 3 months of employment.

All FSS staff are required to have current mandatory training. Details of mandatory training requirements are found on the SSDU website.

Position Descriptions
Each position within FSS has a documented position description, available from Campus Support Services. Position Descriptions are used in the recruitment and selection process, and for annual career success plans (CSP). Further information about the CSP, and links to relevant documentation can be found at https://qheps.health.qld.gov.au/hsq-staff/hr/training/csp.

Communication
If supervisors are not onsite, their contact details or arrangements for supervision is available in the relevant service area. All supervisors ensure clear communication of planned absences to the relevant staff in the relevant service.

Training and Competency of Staff
The Scientific Skills Development Unit (SSDU) coordinates the training needs and professional development of FSS staff. Competency is assessed via completion of training modules or statement of competence (these are currently transitioning to iLearn) and on-going assessment is through annual CSPs. Hard copy records are currently kept for each individual and will be stored electronically in iLearn once the organisation transitions to this platform. CSPs are recorded in the Professional Development module of QIS (29249). The Professional Development module of QIS is also used to record qualifications, experience and other professional development activities such as publications and conference attendance (26208).

The FSS Learning and Development Guidelines (23651) describes the framework for FSS staff learning and development. The effectiveness of training is evaluated as outlined in section 4 of this document, and through the following;

- Feedback forms
- Debrief sessions for trainers
- Monthly trainers' meetings
- Training delivery plans

- Comments and suggestions for improvements on training modules
- Opportunity to provide feedback in training module
- FSS Training email
- Evaluations performed by SSDU training coordinator

Continuing Education and Professional Development
The continuing education and professional development of FSS staff is supported by SSDU and Information and Research Services.
The SSDU facilitates course and conference attendance. Details are available via their website.
Services offered by Information and Research Services can be accessed through their website.
Other resources are available through QHEPS.

Procedures specific for FSS are;

QIS #	Title	Description
10675	FSS - Application for Professional Activity Leave	Application for Professional Activity Leave to attend Conferences, Seminars, Meetings, Training Courses and Project Related Travel where financial outlays by FSS and/or leave of absence for staff are involved

Safety
The occupational health and safety of FSS staff is facilitated by the FSS Infection Control team, and Safety and Wellbeing Advisors.

QIS #	Title	Description
10744	Laboratory safety general guidelines	Details the requirements for safe practices in laboratories
28958	Environmental and Waste Management Plan	This document outlines site requirements for staff, tenants and contractors relating to waste management

6 Administration

The following procedures are related to administrative activities performed within FSS

QIS #	Title	Description
19981	Business Case Management at FSS Standard Operating Procedure (SOP)	Procedure for preparation and approval of business cases, change initiatives and project proposals at Forensic and Scientific Services
33350	Procedure for managing Q Contracts at FSS	Outlines the roles and responsibilities for users, and provides the business rules for use

Team Meetings
It is recommended that teams have formal meetings at regular intervals. Formal meetings may not be necessary for very small teams.
The agenda should include;

- Previous actions/business arising
- WHS issues
- Communication from relevant management meetings
- Suggestions for improvement
- Customer feedback
- Audits, OQI's, documents, calibrations

Records include the agenda, list of attendees, and minutes/action list. These must be available to relevant staff.

7 Testing

Testing performed within FSS is governed by the Analytical Services Framework 14475.

Regulatory Compliance
FSS holds the following accreditation, certification and approvals;

Certifying Body	Details	Field of Testing	Relevant Lab(s)	Standard/Act
NATA	Accreditation Number 41	Environment	Organic Chemistry Inorganic Chemistry RNSu Microbiology	ISO 17025
NATA	Accreditation Number 41	Legal	Forensic DNA Analysis Forensic Chemistry Forensic Toxicology	ISO 17025
NATA	Accreditation Number 41	Food and Beverage	Microbiology Organic Chemistry Inorganic Chemistry RNSu	ISO 17025
NATA	Accreditation Number 41	Human testing for workplace and/or community screening	Inorganic Chemistry Organic Chemistry	ISO 17025
NATA	Accreditation Number 41	Materials	Inorganic Chemistry	ISO 17025
NATA	Accreditation Number 41	Agribusiness	Organic Chemistry RNSu	ISO 17025
NATA	Accreditation Number 41	Healthcare, Pharmaceutical and Media Products	Microbiology	ISO 17025
NATA	Accreditation Number 41	Human Pathology	Forensic Pathology Microbiology Virology Organic Chemistry	ISO 15189
BSI	Certificate Number FS 609174	N/A	Radiation and Nuclear Sciences Excludes NATA accredited labs, Scientific Support Services, Research, Campus Support Services, IT/LIMS support, OHS, and services provided externally by Qld Govt	ISO 9001
Dept of Agriculture and Water Resources	Approval Number Q0322, Q1755, Q1761, Q2808, Q2822, Q2823, Q2824	Approval of Place for Quarantine	Various	Biosecurity Act
OGTR	Certification Number 275, 277, 1432 and 2157 IBC Number 418	N/A	Various	Gene Technology Act
DPI	Facility Number 51	Animal Ethics	N/A	Code of Practice for Care and Use of Animals for Scientific Purposes
WHO	Accreditation	World Health Organisation	Leptospirosis	
FAO	Accreditation	Food and Agricultural Organisation	Leptospirosis	
OIE	Accreditation	Office of International Epizooties	Leptospirosis	

Certificates are displayed in the level 1 foyer, and copies are available from the FSS Quality Unit.
Details of the Scope of Accreditation/Certification are available from the NATA website.

Risk based thinking is applied to all quality processes at FSS. Staff identify possible risks associated with services provided by the work area and implement controls to mitigate these risks to an acceptable level. Document 35294 can be used to implement this process.

Receipt, Storage and Disposal of Testing Material
Samples/exhibits are delivered either to the Public Health or Forensic Property Points. Bodies are received directly by the mortuary. Work areas have their own specific documented procedures on sample/specimen receipt, handling, preservation and storage according to circumstances. Inadequately labelled specimens and incomplete request forms are referred to the requestor where possible, and to the appropriate lab for management if necessary.

Medical/clinical testing samples may be relabelled on receipt if they are deemed irreplaceable. Irreplaceable samples are defined as samples that cannot be recollected (e.g. coronial sample or food outbreak investigation) or are extremely difficult to recollect (e.g. paediatric CSF).

Samples/exhibits are retained and disposed of in accordance with the relevant retention schedules or jurisdictional requirement. FSS does not return specimens to patients/clients due to public health reasons.

The following are receipt, storage and disposal procedures specific to FSS.

QIS #	Title	Description
16165	Procedure for Biological Samples	Explains the process of receiving biological samples
25390	Procedure for Water Samples	Explains receipt and registration of water samples
25511	Miscellaneous Samples	Describes the preparation, chain of custody and dispatch of Legal samples, toxicology samples, food samples and drugs for destruction
14077	FSS – Legal Analysis	Describes the procedures applying to the handling and testing of legal samples.

Requests
The following are specimen/exhibit request procedures specific to FSS

QIS #	Title	Description
10629	FSS Procedure for Review and Acceptance of Work.	Defines the type of information to be obtained from and imparted to clients when considering accepting work from them, as well as to stipulate issues to be considered and records to be kept.
14078	FSS - Intralaboratory Requests	Describes the system for submitting test items for analysis to another section within the laboratory
10650	Mandatory Criteria for Acceptance of Syringes and Needles	Defines the conditions under which hypodermic syringes and needles will be accepted for analysis for drugs or infectious agents.

Test Methods
The following are procedures specific to FSS

QIS #	Title	Description
20302	FSS – Methods Template	Template for test methods, including all headings likely to be applicable
10662	FSS - Guidelines for Method Validation	Provides information on how to determine the various parameters used to validate quantitative methods (primarily those used in the physical sciences)
20089	FSS Infrequent Testing Guideline	Provides a guideline to FSS laboratories that perform infrequent tests, to ensure the competency of the analyst performing the test, and the currency of the methodology used.
30767	FSS standards for Analytical Spreadsheets	Describes the minimum standards to be followed by FSS for analytical spreadsheets

Test methods used by the laboratory are detailed in separate test methods managed in the Quality Information System (QIS). Acceptance criteria for test results are contained in these test methods.

Staff are authorised to develop, modify, verify or validate methods in specific capability development pathways. Where not included, staff who are deemed competent in the performance of a test method may perform this task with the appropriate approval of the relevant line manager.

Internal QC
Specific methods contain requirements for internal quality control and rules for their acceptance/rejection, suggested actions, and responsibilities for recalling and resuming work.
Failures of internal QC must be reported to a senior responsible scientist for evaluation. For medical testing these issues must be escalated to the designated person if a significant clinical risk is identified. Responsibility for the resumption of work lies with the senior responsible scientist (in consultation with the designated person for clinical testing).

Reports
Test reports issued by FSS are NATA endorsed where possible.

FSS has received Crown Law advice that electronically signed analyst certificates are admissible as evidence in court proceedings.

Electronic signatures (e-signatures) are stored in the LIMS and are linked to the individual's unique login. Use of LIMS for e-signatures ensures that they are kept secure and prevents unauthorised use, as the signature appearing on the certificate is the login of the person validating the result (F6). The LIMS also maintains an audit trail for all activities performed in the system. E-signatures shall not be used for offline reports.

Results are not issued to patients unless approved by the Medical Microbiologist.

Verbal results issued by FSS staff should be recorded in the LIMS where it is can be easily identified by other staff members that the result has been provided (e.g. Auslab specimen notes).

The following are procedures specific to reports issued by FSS laboratories

QIS #	Title	Description
10623	FSS - Laboratory Report Format and Content	Defines requirements for the format and content of laboratory reports issued by FSS
14076	Test Records	Ensures that laboratory records contain the appropriate information for all tests and that they are consistently handled in a manner that retains their integrity without loss or damage
26993	Procedure for authorising staff to release results for NATA accredited tests	Outlines the procedure for authorising staff to release results for NATA accredited tests
29024	Use of offline Forensic reporting templates	Describes the use of offline templates for statement of witness and certificate of analysis for laboratories reporting in the forensic division of AUSLAB
29125	Use of offline Public Health reporting templates	Contains instructions on the use of offline reporting templates in FSS Public Health laboratories
34485	Critical values for Public Health Microbiology and Virology	Outlines the critical values relevant to Public Health Microbiology and Virology

Proficiency Testing

Team leaders, in conjunction with the Medical Microbiologist for medical testing, are responsible for ensuring that proficiency testing (PT) samples and results are handled in accordance with NATA accreditation requirements (e.g. mimic normal testing processes, are reviewed, and corrective action taken where appropriate). They are also responsible for maintaining records of participation for an appropriate period. Staff must participate in relevant PT at least once every 2 years. Acceptable performance criteria are taken from the proficiency testing provider (e.g. Z score >2), and outliers are investigated as OQI's. Failures must be reported to the team leader and Medical Microbiologist (for medical testing results) as soon as possible.

PT with a requirement to have one point of contact for enrolment (e.g. NIFS, PTA-Chemical) are coordinated through the FSS Quality Office. For these, the FSS Quality Office is responsible for organising participation and forwarding PT results to relevant areas.
Programs where only one laboratory is participating are organised directly by the lab. Selection of PT providers is informed by details available on the NATA website

Laboratories are encouraged to participate in accredited schemes and as broad a range of proficiency testing activities as practicable and available. Labs must participate in proficiency testing in accordance with the frequency stipulated by NATA.

Referral laboratories

Document 30736 details the procedure for selection of referral laboratories, and includes the procedure for approval of external laboratories who analyse referred legal samples.

8 Records

Records at FSS are created, retained and disposed of according to the Records Management Policy, Standards and Guidelines. Procedures specific for FSS are

QIS #	Title	Description
10625	FSS – Records creation, retention and disposal	Provides details of procedures to be followed to manage records at FSS
28965	Key to FSS Onsite Records	Provides information to FSS employees on where the onsite storage facilities are located, who has control and ownership of the facility and how to access records
23201	Destruction of Ephemeral (Information Only) Records	Ensures that all FSS records deemed ready for destruction are destroyed in a controlled, secure environment in compliance with the QH Records Management Policy
14080	Records Management Data Entry Standards	Describes procedure to enter data consistently and accurately into QH recordkeeping application system
19781	RecFind Searching Procedures	Provides RecFind (or RecQuery) users with procedures to successfully search for data within the systems
27115	Corporate File Management	Describes the process for Corporate File Management including, file creation, applying disposal timeframes, managing physical files and recording movement of files
27131	Destruction of QH Records (FSS)	Describes the process for approving the destruction or extension of records retention

9 Purchasing

Purchasing by FSS is governed by the Department of Health policies. Procedures specific to purchasing at FSS are detailed below

QIS #	Title	Description
10628	Procedure for engaging and evaluating vendors/suppliers of consumables	Describes how to engage and evaluate suppliers and vendors of consumables.
10622	Verification of Consumables within the Work Group	Describes procedures for ascertaining whether consumables are fit for purpose. Labelling and record keeping are included.

10 Equipment

Equipment Inventory
An Equipment Inventory is available using the Calibration module of the Quality Information System (QIS) or the Forensic Register (FR).

Calibration and Maintenance of Equipment
Calibration and checking intervals are detailed by NATA in the Reference and General Equipment tables. These intervals are reflected in the Calibration module of QIS. Calibration and checking of equipment are supported by other quality assurance activities conducted by the laboratory such as performance of internal quality control checks, routine use of spikes, routine use of reference material, and participation in external quality assurance programs. These additional checks are an immediate indication of the validity of the test results, and an indicator of the correct functioning of the equipment used.

FSS determines if a piece of equipment requires calibration based on its criticality to the final result. Calibration may be performed externally by a NATA accredited facility, or internally by in-house methods assessed by NATA as 'in-house calibrations. POVA that

are externally calibrated have a calibration interval of at least every 2 years. Equipment that does not require traceability to be established is checked internally.

NATA currently requires class A volumetric glassware to be externally calibrated every 10 years by an ISO 17025 accredited organisation. FSS has determined that where the contribution of the error of the glassware to the overall uncertainty of the method is not significant, then the requirement for external calibration could be replaced with an internal verification (as per QIS 10668). Error of the glassware is defined as the error on the calibration certificate. Such a decision should be documented in a risk assessment.

For example, an analytical method has a minimum uncertainty of ± 25%. The method uses an A grade 10mL volumetric flask, and the error for this flask is ± 0.04mL, which is ± 0.4%. This is less than 2% of the total uncertainty for the method, and thus is not considered significant, and an internal verification is sufficient. Table 1 summarises this, and can be used as a risk assessment record;

Method	Method MU	Glassware error	Proportion MU from glassware	Decision Ver/Cal
Method ABC	25%	0.4%	2%	Verification

Each decision will be different as each method will have larger or smaller measurement uncertainty, and different glassware will be used (and the error is higher with small volumetric glassware compared with larger volumetric glassware). These two variables determine the contribution that glassware makes to MU, and whether it is significant. Note also, that the error will need to be added if a number of volumetrics are used in a single procedure.

Each section is required to determine what constitutes a significant contribution on the part of their glassware, taking into account the total uncertainty of the method, the proportion of uncertainty that the glassware contributes, and documenting the decision in a risk assessment. In general, a contribution from the glassware of greater than 20% to the total uncertainty would be considered to be significant.

Equipment is maintained in accordance with the guidelines contained in QIS 26325. Procedures that apply to equipment commonly in use at FSS are detailed below;

QIS #	Title	Description
10666	Balance Verification and Assessment	Describes the on use, monthly and six-monthly verification checks of electronic balances.
10668	Procedure for acceptance checking and calibration of volumetric glassware	Describes the procedure for conducting acceptance checks and full calibrations of items of glassware used in situations where volumetric errors could contribute significantly to analytical errors
10669	Verification of Environmentally Controlled Enclosures (ECE)	Describes the procedure for checking environmentally controlled enclosures.
33955	Procedure for thermometer checks using the Fluke 7103 micro bath	Describes the procedure to check thermometers using the Fluke 7103 Micro Bath
10671	Procedure for In-House Calibration and Verification of Piston Operated Volumetric Apparatus (POVA)	Describes the gravimetric method for performing in-house calibrations or verifying critical POVA

10672	The Verification of Timing Devices	The purpose of this procedure is to ensure that stopwatches and other timing devices which require precise verification are checked in accordance with ISO 17025 and NATA requirements

11 Research

Research conducted at FSS is coordinated through the Research and Development Office. FSS supports research through the following

QIS #	Title	Description
10642	FSS Animal Ethics Committee Terms of Reference and Operational Procedures	Describes the terms of reference and operational procedures for the FSS Animal Ethics Committee
10643	FSS - Institutional Biosafety Committee	Defines the functions and terms of reference of the Forensic and Scientific Services Institutional Biosafety Committee (FSS-IBC), which deals with genetic manipulation issues.
10664	FSS - Human Ethics Committee Functions and Terms of Reference	Describes the composition and operation of the Human Ethics Committee
14079	FSS Medical Advisory Committee – Functions and Terms of Reference	Describes the composition and operation of the Committee, whose principal role is to put into place procedures to be followed in the event of an accident, or exposure of staff to bacterial, viral or rickettsial agents, in the FSS PC3 or PC4 suites

12 Quality Management System

The Quality Management System is coordinated through the QIS (Quality Information System) database. Flowcharts detailing how to use QIS are contained in the Quality Information System user manuals (26207 – 26214, 29249).

Quality Indicators

Quality indicators are mapped against the quality commitment

Indicator	Commitment component
Audits overdue	Respect and comply with quality commitment
Critical OQI's open >30 days	Focus on customers
External agency audit major non-conformances open >30 days	Relevant accreditation and certification Productive management systems
%CSP open	Hold employees accountable
Monthly budget reports	Reduce variation and waste
Risks monitored and managed	Robust system

Document Control

The Procedure for Document Management 10003 outlines the control, development, publication, review/amendment and withdrawal of all documents. Documents are classified according to the hierarchy as detailed in the Document Hierarchy, Document Types and

Document Authorisation Requirements 24756. The recommended review period for FSS documents is 24 months.
QIS allows for access to documents to be limited through the private viewers functionality. The use of this functionality to protect the content of documents is not encouraged, however it is recognised that FSS deals with issues of an extremely sensitive nature, and the protection of documents is necessary in some cases. Authorisation for protection of documents lies with the relevant Managing Scientist or Unit Manager. Guidelines for FSS Units for the types of documents that should be protected are detailed below

FSS Unit	Guideline
Public and Environmental Health	Security Sensitive or commercial-in-confidence
Coronial Services	Security Sensitive
Police Services	Security Sensitive
Campus Support Services	No need for password protected documents identified
Scientific Support	No need for password protected documents identified
Client Support and Liaison	No need for password protected documents identified

Corrective/Preventive Action and Complaints
The procedure for Management of Opportunities for Quality Improvement (OQI) 13965 describes the creation and resolution of OQI's as well as the timeframes and escalation process surrounding them. Complaints involving the provision of medical pathology services must be sighted by the Medical Microbiologist. This includes the response to the complaint.

Adverse events resulting from the use of in-house IVDs are to be reported by phone and follow up email to the Medical Microbiologist, relevant Supervising Scientist and Managing Scientist as soon as possible. Reporting to the TGA is to occur in accordance with the timeframes set out in the NPAAC 'Requirements for the development and use of in-house diagnostic medical devices'.

Adverse events and near misses are to be recorded as a clinical incident in RiskMan to ensure detection of trends. FSS has an open disclosure policy that allows for a discussion with a patient (and/or their support person(s)) about a patient safety incident.

Internal Audit
The Internal Audit Procedure 10636 describes the procedure followed to perform internal audits. These audits aim to identify critical processes of the organisation, associated risks and the effectiveness of controls. They also seek to identify improvements and whether all requirements of relevant standards are met.

Internal Auditor Training is conducted at FSS by the Quality Manager, with content provided in iLearn. Training is conducted in accordance with the Internal Auditor Training Module (24740). A list of trained auditors can be obtained from the FSS Quality Manager or iLearn.

Specific fields in QIS are used to identify the criteria and scope of an audit, and this is included in internal auditor training. Criteria should include relevant NATA requirements, standard operating procedures, areas of risk, recent changes to methodology etc. The scope of the audit should describe the extent and boundaries of the audit and consider the activities to be audited based on risk. It is not necessary that internal audits cover all elements in depth each year, and audit topics should be based on risk. At least one audit should be performed in each section per annum.

The internal audit procedure is supplemented by numerous audit checklists available on QIS. It is intended that these checklists are used as a guide for auditors to develop their own process audit checklist.

QIS #	Title
19130	Audit checklist - general
20088	ISO 9001 checklist
20030	ISO/IEC 17025 checklist
20032	AS/ISO 15189 checklist

An audit schedule can be obtained from the Quality Information System (QIS).

Management Review

The Management Review Procedure 10010 describes the process by which management formally conducts periodic, independent reviews of the management system.
Management review is performed on at least an annual basis (usually in the last quarter of each year). A report is provided to the FSS Leadership Team for endorsement.

Monthly status reports (including relevant quality indicators) are provided by the FSS Quality Manager to FSS Leadership Team. The risk register and budget reports are provided separately.

Management review is also part of regular team meetings.

Client Feedback

FSS strives to actively seek feedback, both positive and negative, from its clients. This is facilitated through the Scientific Services Liaison Unit (28520). Feedback is sought both formally and informally, electronically (email and phone meetings), and face to face (via meetings, conferences, working groups etc). Minutes, issues logs, and OQI's are used to record client feedback.

FSS will advise clients in advance if information is made publicly available, and if confidential information is required to be released.

13 Amendment History

Version	Date	Updated by	Amendments
0-24	Various	Various	See archived versions
25	December 2020	H Gregg	Organisational chart and hyperlinks updated. TGA approval removed, and ISO9001 scope updated. Added verbal results to be clearly identified in LIMS. Updated OGTR certification numbers. Updated to reflect transition to iLearn.
26	Dec 2021	H Gregg	Updated organisational chart, remove reference to HSQ and RMP accreditation, amended services for Forensic Pathology. Updated FSS website, list of internal auditors and reference to PDP

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HealthSupport Queensland

Role description

Job ad reference	Insert job ad reference	**Classification**	HP6
Role title	Quality Manager	**Salary**	Insert salary range
Status	Permanent Fulltime	**Closing date**	Insert closing date
Unit/Branch	Quality and Compliance		
Commercialised Business Unit	Forensic and Scientific Services	**Contact name**	Paul Csoban
Location	Coopers Plains	**Contact number**	[redacted]

If you have difficulties applying online, please contact HSQ Recruitment on [redacted]

Vision for the public service

To be a government of the 21st century, one government that is connected and working together to deliver smarter, simpler outcomes that are responsive to the needs of Queenslanders now and for the future. We will create opportunities in partnership that are all about positive outcomes rather than just service delivery and regulation.

To enable this vision, the Queensland Public Service (QPS) is transforming from a compliance focus to a more values-led way of working. The following **five values statements** underpin behaviours that will support and enable better ways of working and result in better outcomes for Queenslanders.

- **Customers first:** Know your customers. Deliver what matters. Make decisions with empathy.
- **Ideas into action:** Challenge the norm and suggest solutions. Encourage and embrace new ideas. Work across boundaries.
- **Unleash potential:** Expect greatness. Lead and set clear expectations. Seek, provide and act on feedback.
- **Be courageous:** Own your actions, successes and mistakes. Take calculated risks. Act with transparency.
- **Empower People:** Lead, empower and trust. Play to everyone's strengths. Develop yourself and those around you.

Your opportunity

To manage the Quality and Compliance Unit at Forensic and Scientific Services, maintain and improve the organisations quality management system, learning and development framework, and lead business critical projects for FSS.

Your role

- Fulfil the responsibilities of this role in accordance with Queensland Health's core values, as outlined above.
- Provide operational leadership and management to ensure FSS complies with all relevant certification, accreditation, regulatory and legislative requirements. Be an active member of the FSS Leadership Team, providing expert advice, consultation and direction on quality management system and compliance issues and informing decision making.
- Apply laboratory knowledge and problem solving skills in a complex scientific environment to provide high level specialised advice to the FSS Executive Director about the quality management system and learning and development framework.
- Apply program and project management knowledge and experience to manage business critical projects for FSS as directed by the Executive Director
- Regularly review business processes across FSS and develop, implement and evaluate initiatives to improve performance and productivity. Advise FSS Executive Director on corrective and preventive action, and risk minimisation strategies.
- Supervise and manage staff of the Scientific Skills Development Unit in line with human resource management practices
- Lead the development and delivery of training activities on quality issues, including accreditation & certification requirements, and business improvement techniques and tools. Develop associated competencies, in order to ensure FSS staff are knowledgeable and able to implement learnings.
- Identify and proactively manage FSS organisational risks, and provide consultative advice to service line management on risk minimisation strategies
- Facilitate the development and enactment of FSS Strategic and Operational Plans, and report on the performance and achievement of these plans
- Manage other business improvement initiatives for the Executive Director (eg client survey, staff survey, clinical governance)
- Work in partnership with the FSS Research Governance and Human Ethics officer, and the FSS Information Research Services manager, to deliver improved and integrated performance outcomes for the FSS Executive Director
- Lead the development of a learning culture at FSS, and manage the learning and development framework for competency based training
- Monitor and contribute to national and international future directions in quality, compliance, and learning and development, ensuring that the organisational performance benchmarks favourably against comparable organisations. Ensure the operations of the Quality and Compliance Unit effectively supports FSS business needs and strategic and operational plans
- Manage the financial accountabilities of the position in accordance with financial management practices
- Work autonomously and exercise judgement to establish work priorities and meet deadlines.

Mandatory qualifications/professional registration/other requirements

- Mandatory possession of a tertiary qualification in Science
- While not mandatory, a relevant qualification in project management, risk management, education or learning and development would be well regarded

- It is a condition of employment for this role for the employee to be, and remain, vaccinated against the following vaccine preventable diseases during their employment: hepatitis A, hepatitis B.

How you will be assessed?

You will be assessed on your ability to demonstrate the following key capabilities, knowledge and experience. Within the context of the responsibilities described above under 'Your role', the ideal applicant will be someone who can demonstrate the following:

- High level knowledge of scientific and laboratory practice.
- Expert knowledge and understanding of the legislation, regulations and standards that apply to a multidisciplinary laboratory organisation
- Proven ability to lead an organisational quality management system and provide high level authoritative counsel to executive management in relation to organisational compliance
- Demonstrated project management knowledge and experience, with demonstrated ability to plan, coordinate and prioritise tasks to achieve project outcomes
- Demonstrated experience in managing staff in a scientific skills training unit and leading a learning and development framework in a complex environment
- Advanced negotiation, consultation, communication and interpersonal skills to build and develop stakeholder relationships, and lead the organisational quality and learning culture.
- High level organisational skills, ability to work autonomously, and demonstrated ability to motivate others
- Well-developed analytical and human management skills that enable identification and resolution of issues

Your application

Please provide the following information to the panel to assess your suitability:

- **Your current CV or resume, including the names and contact details of two referees**. Referees should have a thorough knowledge of your capabilities, work performance and conduct within the previous two years, and it is preferable to include your current/immediate/past supervisor
- **A short statement (maximum 1–2 pages)** on how your experience, abilities, knowledge and personal qualities are relevant for the role, taking into account the key responsibilities and attributes noted in the 'How you will be assessed?' section.

Your employer— Health Support Queensland

Health Support Queensland (HSQ) is an organisational Division of the Department of Health and delivers a range of support services to enable the delivery of frontline health services. HSQ provides services to all Queensland Hospital and Health Services (HHSs), to other government agencies and to commercial clients.

The current services provided by HSQ include: pathology services , procurement and logistics for health related equipment, products and services, biomedical technology services, forensic and scientific services, linen and laundry services, medicines management, 13HEALTH , radiology support and payroll.

HSQ has a staff complement of approximately 4,000 full-time equivalents (FTEs) and has an operating budget of approximately $900 million for the financial year 14/15. HSQ handles the procurement of approximately $1 billion worth of goods on behalf of the Queensland public health system.

The Chief Executive Officer is accountable for the day-to-day operation and performance of HSQ. The HSQ Advisory Board has been established to assist the Chief Executive Officer and the Director-General, Department of Health in setting the strategic direction of HSQ.

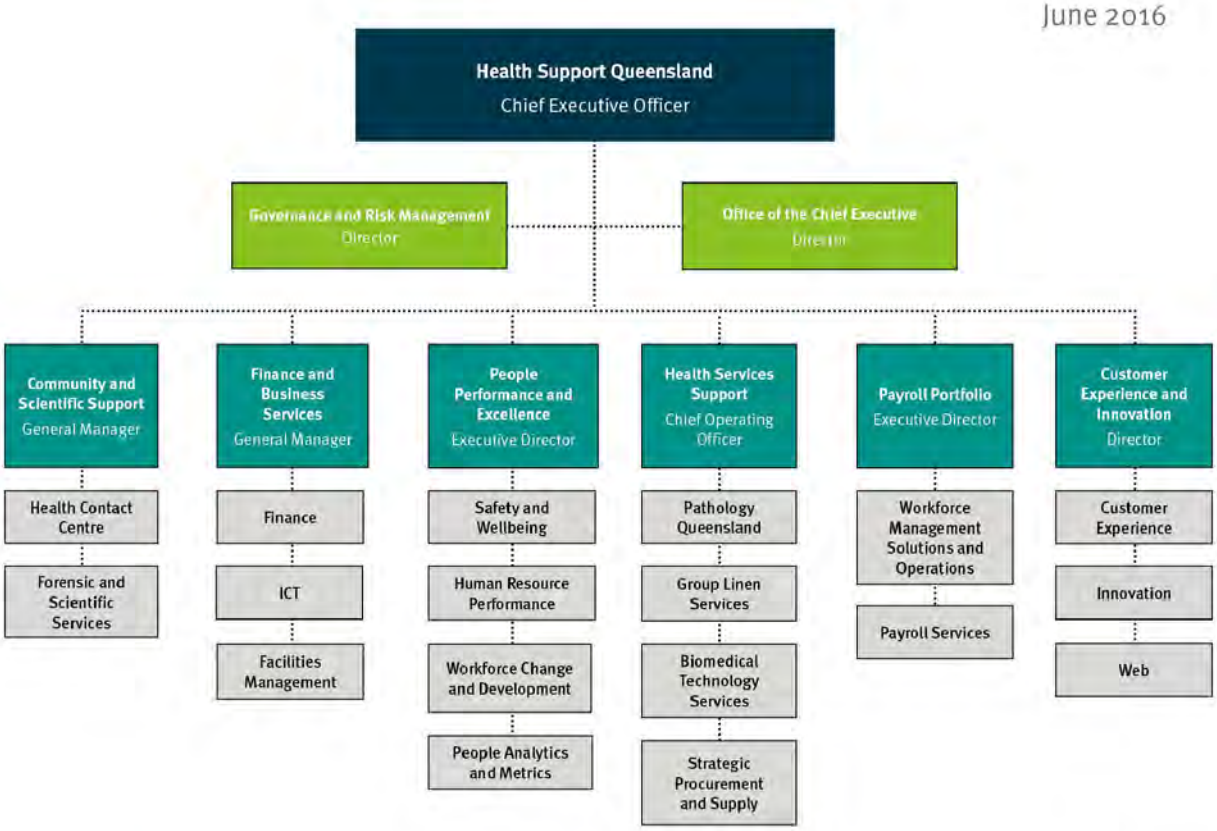
Additional information

- Permanent and temporary vacancies longer than 12 months remain current for 12 months OR Temporary vacancies less than 12 months remain current for vacancy duration
- Future vacancies of a temporary, full-time and part-time nature may also be filled through this recruitment process.
- Pre-employment screening, including criminal history and discipline history checks, may be undertaken on persons recommended for employment. Roles providing health, counselling and support services mainly to children will require a blue card, unless otherwise exempt.
- Employees who are permanently appointed to Queensland Health may be required to undertake a period of probation appropriate to the appointment.
- All relevant health professionals, who in the course of their duties formulate a reasonable suspicion that a child or youth has been abused or neglected in their home/community environment, have a legislative and a duty of care obligation to immediately report such concerns to Child safety services, Department of Communities.
- Applicants will be required to give a statement of their employment as a lobbyist (http://www.psc.qld.gov.au/publications/assets/policies/lobbyist-disclosure-policy.pdf) within one month of taking up the appointment.
- Applicants may be required to disclose any current pre-existing illness or injury which may impact on their ability to perform the role. Details are available in section 571 of the *Workers' Compensation and Rehabilitation Act 2003* (http://www.justice.qld.gov.au/fair-and-safe-work/workers-compensation-and-rehabilitation/workers-compensation-and-rehabilitation-legislation/workers-compensation-and-rehabilitation-act-2003).

- Employees of Health Support Queensland are to actively participate in a working environment supporting quality human resource management practices including employment equity, anti-discrimination, occupational health and safety and ethical behaviour.

Organisational Chart

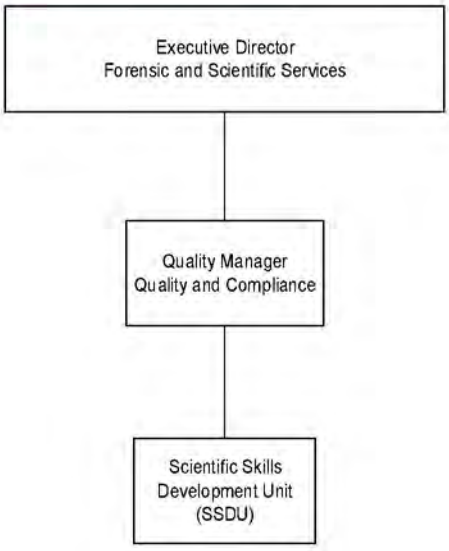
June 2016



HealthSupport Queensland

Queensland Government

Quality and Compliance Organisational Chart



CA-19

Police Services

	Actual FY2016	Actual FY2017	Actual FY2018	Actual FY2019	Actual FY2020	Actual FY2021	Actual YTD April 2022	Budget Stage 1 FY2023
Operating (Surplus)/Deficit	**8,380,297**	**9,345,052**	**8,927,417**	**8,666,974**	**9,260,265**	**10,580,138**	**8,778,286**	**1,218,507**
Revenue	***-5,483,245***	***-4,702,324***	***-4,926,874***	***-4,833,605***	***-4,901,175***	***-4,589,750***	***-3,744,683***	***-14,341,706***
Appropriation								-9,541,705
Grants And Contributions	-1,473				-71,160	-118,383	-45,494	
Own Source Revenue	-5,481,772	-4,702,324	-4,926,874	-4,833,605	-4,830,015	-4,471,367	-3,699,190	-4,800,000
Expenses	***13,863,542***	***14,047,376***	***13,854,292***	***13,500,579***	***14,161,440***	***15,169,888***	***12,477,476***	***15,560,213***
Labour Expenses	10,769,027	10,766,496	10,855,469	10,683,690	11,209,550	11,750,338	9,732,094	12,565,024
Non Labour Expenses	2,651,174	2,783,782	2,459,149	2,263,161	2,337,758	2,717,062	2,127,703	2,274,326
Depreciation & Amortisation	443,342	497,098	539,674	553,728	614,132	702,488	617,679	720,863

POS_ID	POS_PAYPOINT_ID	POS_DS	Total
[redacted]	HP3	SCIENTIST	0.60
	HP3	SCIENTIST	1.00
	HP3	CHEMIST	1.00
	HP3	CHEMIST	1.00
	HP3	CHEMIST	1.00
	HP4	CHEMIST SENIOR	0.79
	HP4	SENIOR CHEMIST	1.00
	HP3	CHEMIST	1.00
	HP3	CHEMIST	1.00
	HP3	CHEMIST	1.00
	HP3	CHEMIST	1.00
	HP5	SUPERVISING CHEMIST CLANDESTINE LABS	1.00
	HP3	CHEMIST	1.00
	HP3	TECHNICIAN SENIOR LABORATORY	0.50
	HP3	TECHNICIAN SENIOR LABORATORY	1.00
	HP5	CHEMIST SUPERVISOR ILLICIT DRUGS	1.00
	HP4	CHEMIST SENIOR	1.00
	HP6	CHIEF CHEMIST FORENSIC CHEMISTRY	1.00
	HP2	TECHNICIAN	1.00
	HP2	TECHNICIAN	1.00
	HP3	CHEMIST	1.00
	HP3	SENIOR LABORATORY TECHNICIAN	1.00
	HP3	CHEMIST	1.00
	AO3	ADMINISTRATION OFFICER	1.00
	HP5	FORENSIC SCIENTIST ADVANCED	1.00
	AO2	ADMINISTRATIVE OFFICER	1.00
	HP6	TEAM LEADER FORENSIC REPORTING & INTEL	1.00
	HP4	REPORTING SCIENTIST	1.00
	HP3	SCIENTIST	0.50
	HP3	SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	0.73
	CA3	LABORATORY ASSISTANT	0.00
	CA3	LABORATORY ASSISTANT	1.00
	AO4	ADMINISTRATION SUPPORT OFFICER	1.00
	HP3	SCIENTIST	1.00

[redacted]	HP5	FORENSIC SCIENTIST ADVANCED	1.00
	HP5	FORENSIC SCIENTIST ADVANCED	1.00
	HP5	FORENSIC SCIENTIST ADVANCED	1.00
	HP3	SCIENTIST	1.00
	HP3	CHEMIST	0.50
	HP4	CHEMIST SENIOR	1.00
	HP4	SENIOR CHEMIST FIELD ANALYST	1.00
	HP3	CHEMIST	1.00
	HP3	SCIENTIST	1.00
	HP2	FORENSIC TECHNICIAN	1.00
	HP3	SCIENTIST	1.00
	HP3	SCIENTIST	1.00
	HP3	SCIENTIST	0.80
	HP3	SCIENTIST	1.00
	HP7	MANAGING SCIENTIST POLICE SERVICES	1.00
	HP5	SUPERVISING CHEMIST TRACE EVIDENCE	1.00
	HP5	FORENSIC SCIENTIST ADVANCED	0.00
	HP4	REPORTING SCIENTIST	1.00
	HP6	TEAM LEADER EVIDENCE RECOVERY QUALITY	1.00
	HP4	SENIOR SCIENTIST	1.00
	HP5	FORENSIC SCIENTIST ADVANCED	1.00
	HP4	REPORTING SCIENTIST	0.80
	HP2	FORENSIC TECHNICIAN	0.00
	CA4	LABORATORY ASSISTANT SUPERVISOR	1.00
	HP3	CHEMIST	0.40
	HP3	SCIENTIST	0.57
	HP3	SCIENTIST	0.90
	HP4	CHEMIST SENIOR	1.00
	AO2	ADMINISTRATIVE OFFICER	1.00
	AO3	ADMINISTRATIVE OFFICER	1.00
	HP4	REPORTING SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	0.77
	HP4	REPORTING SCIENTIST	1.00
	HP3	SCIENTIST	1.00
	CA3	LABORATORY ASSISTANT	1.00
	CA3	LABORATORY ASSISTANT	1.00
	CA3	LABORATORY ASSISTANT	1.00
	CA3	LABORATORY ASSISTANT	1.00
	CA3	LABORATORY ASSISTANT	1.00
	CA3	LABORATORY ASSISTANT	1.00

[redacted]	CA3	LABORATORY ASSISTANT	1.00
	CA3	LABORATORY ASSISTANT	1.00
	CA3	LABORATORY ASSISTANT	0.00
	HP3	SCIENTIST	1.00
	HP3	SCIENTIST	1.00
	HP3	SCIENTIST	1.00
	HP3	SCIENTIST	1.00
	HP3	CHEMIST	1.00
	HP3	CHEMIST	1.00
	HP3	CHEMIST	1.00
	HP4	SENIOR CHEMIST FIELD ANALYST	1.00
	HP4	SENIOR CHEMIST FIELD ANALYST	1.00
	HP4	SENIOR CHEMIST FIELD ANALYST	1.00
	HP3	SCIENTIST	1.00
	HP3	SCIENTIST	1.00
	HP3	SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	1.00
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	HP4	REPORTING SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	0.60
	HP4	REPORTING SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	1.00
	HP4	SENIOR SCIENTIST	0.00
	HP4	SENIOR SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	1.00
	HP4	REPORTING SCIENTIST	1.00
	HP2	FORENSIC TECHNICIAN	1.00
	HP3	SCIENTIST	1.00
	HP3	CHEMIST	1.00
	HP3	CHEMIST	1.00
	HP3	CHEMIST	0.00
Grand Total			99.46

CA-20

Actual -Police DNA Services

	Actual						
	2016	2017	2018	2019	2020	2021	2022
Revenue	**-5,393,599**	**-4,602,839**	**-4,787,564**	**-4,604,736**	**-4,614,830**	**-4,240,017**	**-4,494,892**
Qld Police Block Funding	-3,000,000	-3,000,000	-3,000,000	-3,000,000	-3,000,000	-3,000,000	-3,000,000
Own Source Revenue	-2,393,599	-1,602,839	-1,787,564	-1,604,736	-1,614,830	-1,240,017	-1,494,892
Expenses	**9,119,189**	**9,572,229**	**9,025,763**	**8,824,649**	**9,431,855**	**10,054,015**	**10,095,018**
Labour Expenses	6,675,328	6,771,334	6,772,913	6,640,128	7,120,333	7,532,180	7,448,273
Non Labour Expenses	2,288,429	2,574,296	2,011,518	1,963,577	2,068,761	2,253,400	2,385,641
Depreciation & Amortisation	155,432	226,599	241,331	220,945	242,762	268,435	261,105
Expenses (excl. Depreciation)	8,963,757	9,345,630	8,784,432	8,603,704	9,189,093	9,785,580	9,833,913

Budget -Police DNA Services

	Budget						
	2016	2017	2018	2019	2020	2021	2022
Revenue	**-5,450,004**	**-5,000,004**	**-4,299,996**	**-4,946,398**	**-4,618,034**	**-4,554,676**	**-4,458,260**
Qld Police Block Funding	-3,000,000	-3,000,000	-3,000,000	-3,000,000	-3,000,000	-3,000,000	-3,000,000
Own Source Revenue	-2,450,004	-2,000,004	-1,299,996	-1,946,398	-1,618,034	-1,554,676	-1,458,260
Expenses	**8,767,820**	**9,476,988**	**9,169,322**	**9,432,665**	**9,077,364**	**9,173,965**	**9,717,603**
Labour Expenses	6,359,616	7,298,299	7,380,658	7,418,686	7,016,265	7,316,539	7,418,593
Non Labour Expenses	2,249,888	1,990,453	1,554,208	1,770,662	1,843,641	1,602,392	2,014,707
Depreciation & Amortisation	158,316	188,236	234,456	243,317	217,458	255,034	284,303
Expenses (excl. Depreciation)	8,609,504	9,288,752	8,934,866	9,189,348	8,859,906	8,918,931	9,433,300

Depreciation comes in the form of State funding, and at the end of each financial year actuals are matched with budget.

FTE	60.56	60.09	58.25	57.56	57.95	61.12	59.15

FTE	62.19	66.79	68.36	65.10	60.83	62.56	62.48

Additional FTE data is provided on Sheet 2 - this is slightly different to the data here due to the method of collation and aggregation. 57.48

Background

The Department traditionally receives funding based on prior year budgets with increases in budgets based on additional own source revenue (OSR) received, CBRC (Cabinet Budget Review Committee) funding decisions or other (internal Queensland Health or HSQ as the former managing body) approved briefs / business cases

Budget rebasing across HSQ occurred in FY2019 areas were funded based on prior year spend escalated by 2.5% for enterprising bargaining and Non-labour CPI.

Following that all budgets were based on prior year spend and adjusted for any formal budget changes that had been approved

This provides the funding base for the overall facility with further activities locally to devolve the budget across the services within FSS.

Revenue sources are a combination of appropriation (state funding) and OSR. State funding has been held at the facility level (FSS) with no formal allocation below that. To enable reporting at the Police DNA level monthly performance management focused on actuals against budget for both OSR and expenditure.

Own Source Revenue Budgets

OSR budgets are locally set with reviews done in September and January. Prior year is used as a guide for setting OSR budgets and adjusted for known changes

Additional OSR above budget provides additional revenue to support costs associated with the delivery of activities that generate the revenue which are above Business as usual

$3M in funding is recovered from the MOU with QPS, the remainder is revenue charged based on activity. The $3M has been consistent for some time.

OSR peaked at $5.4M in FY2016 (this was up $0.8M from 2015), reduced to $5M ($450K Lower) in FY2017 and has remained between $4.4M and $5M

Labour Budgets

Teams have a positional labour profile (staffing establishment). FTE's are budgeted at the positional level and adjusted for known changes - eg where staff are on various forms of leaving (including Maternity) and relief arrangements as determined.

Budgets are developed in the departmental budget tool (BPT). Labour budgets are built at the positional level according to current wage rates.

Non Labour Budgets

Non labour budgets are based on prior year spends and adjustments made for known contractual changes or other business decisions

Depreciation

Depreciation is matched for actual expenses

Budget Finalisation

Once initial work ups for budgets are done, areas are required to ensure the total of all areas align to the facility total. Local decisions are made where activities are required to reduce estimates in line with budgets

Budgets are reported against, in that monthly reporting occurs against the budget that had been set. From September each year, forecasting is undertaken to determine any pressures or issues with budgets.

Specific Budget adjustments

FY2020-21 - Employers received an EB sign on bonuses of $1,250 per FTE as a one off payment. This impacted all busines line budgets and actuals based on amounts paid. This was approx $77K for this business line

FY2020-21 / FY2021-22 - All EB agreements were "deferred" by 12 months. This impacted budgets with an adjustment to state base revenue.

FY2018-19 / FY2019-20 Whilst the department did not receive formal EB increases or non-labour escalation, the rebasing of the budget at the top level provided for 2.5% escalation with funding internally supported.

Budgeted FTE for Position DNA across teams and function

Row Labels	FY2015-16	FY2016-17	FY2017-18	FY2018-19	FY2019-20	FY2020-21	FY2021-22
Budgeted FTE	62.00	66.54	68.36	65.16	60.74	62.63	62.40
Admin	-	3.97	4.00	3.97	3.97	3.99	3.97
Laboratory Based Team	18.07	36.68	37.55	35.43	33.85	33.47	33.39
Forensic Scientist	18.07	20.33	21.14	20.27	20.08	20.24	20.15
Forensic Technician	-	2.86	3.00	2.90	2.98	2.01	2.00
Laboratory Assistant	-	9.75	10.00	8.95	8.53	8.47	8.49
Laboratory Assistant Supervisor	-	1.00	1.00	1.00	0.98	0.98	0.98
Senior Scientist	-	2.74	2.41	2.31	1.29	1.78	1.77
Reporting Based team	43.93	25.89	26.80	25.76	22.91	25.17	25.04
Management	8.45	8.68	8.89	8.68	8.30	7.98	7.97
Reporting Scientist	-	17.21	17.91	17.08	14.61	17.18	17.07
Budget not at position level	35.48	-	-	-	-	-	-

Actual FTE for Position DNA across teams and function

Row Labels	FY2015-16	FY2016-17	FY2017-18	FY2018-19	FY2019-20	FY2020-21	FY2021-22
QH FTE	61.80	62.02	60.60	58.14	59.29	62.68	59.81
Admin	3.96	3.97	3.54	3.95	3.73	3.75	3.97
Admin	3.96	3.97	3.54	3.95	3.73	3.75	3.97
Permanent	3.21	3.55	3.54	3.70	2.79	3.12	3.97
Temporary	0.75	0.42	-	0.26	0.95	0.63	-
Laboratory Based Team	33.35	33.17	33.29	31.57	31.94	33.45	30.67
Forensic Scientist	18.94	18.68	18.37	18.03	18.11	18.65	16.62
Permanent	17.95	18.22	17.57	17.18	17.14	18.36	16.62
Temporary	0.99	0.46	0.80	0.85	0.97	0.29	-
Forensic Technician	1.98	2.48	3.02	2.89	2.96	3.03	2.66
Permanent	0.97	2.06	3.02	2.89	2.96	3.03	2.22
Temporary	1.00	0.42	-	-	-	-	0.44
Laboratory Assistant	8.63	8.71	8.67	7.43	7.47	8.13	7.64
Permanent	7.81	6.11	5.20	5.13	5.34	5.98	7.57
Temporary	0.82	2.60	3.46	2.30	2.13	2.14	0.08
Laboratory Assistant Supervisor	1.04	1.02	1.05	0.98	1.00	1.03	1.02
Permanent	1.04	1.02	1.05	0.92	0.89	1.03	1.02
Temporary	-	-	-	0.06	0.10	-	-
Senior Scientist	2.76	2.27	2.18	2.24	2.41	2.62	2.74
Permanent	2.76	2.27	2.18	2.24	2.41	2.62	2.74
Reporting Based team	24.49	24.89	23.78	22.62	23.62	25.48	25.17
Management	9.18	9.43	9.15	8.30	9.39	9.15	8.71
Permanent	9.18	9.39	9.15	8.30	9.39	9.15	8.71
Temporary	-	0.04	-	-	-	-	-
Reporting Scientist	15.31	15.46	14.63	14.31	14.23	16.33	16.46
Permanent	15.31	15.35	14.63	14.31	14.23	16.33	16.46
Temporary	-	0.10	-	-	-	-	-

FTE Types: Standard / Non Standard

QH Standard FTE (previously provided) aligns to the labour costs.
It includes the following:
* Base wages
* Sick leave, Professional development leave and family leave
* Overtime FTE

QH Non-Standard FTE relates to leave payments covered by levies
Long Service Leave
Annual Leave

The levies are paid as part of the normal pay costs and actual leave taken (including on termination) has minimal impact on the expenditure FTE on Termination can be inflated for people who are paid out high leave balances

Traditional budget for each position / employee would align to:
0.92 FTE Standard
0.08 FTE Non-Standard
Data reported is based on **Standard FTE** uplifted to the 1 FTE metric.

DNA have been under (or in line with) their budget FTE across each FY
Budgeted FTE did increase in FY2016-17 and followed increases in OSR
FTE budgets for FY2021 and FY2022 are in line with the 2016 FTE.

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

Queensland Health

Accreditation Number 41 Forensic and Scientific Services

Site Number 14171 **Forensic and Scientific Services**

Contact Summary

Address

Liaison Unit

39 Kessels Road

COOPERS PLAINS

QLD 4108

AUSTRALIA

Phone

Mobile

Email

Web

Contact

[redacted]

Site Availability Services conditionally available to external clients

Site Supervision

Site Scope Last Modified: 17/01/2019

Scope (AC = Accreditation Status, AU= Authorisation Status, D = Do Not Publish)

ISO/IEC 17025

Legal

Service	Product	Determination	Technique	Procedure	AC	AU
Analysis of controlled substances	Clandestine drug facility - Investigation	Drug identification; Presumptive testing	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; Inductively coupled plasma (ICP); Ion chromatography (IC); LC-MS; Quantitation of drugs and associated compounds by UPLC-PDA; Raman spectroscopy; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures	D	Auth
Analysis of controlled substances	Any item received	Drug identification; Presumptive testing	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; LC-MS; Quantitation of drugs and associated compounds by UPLC-PDA; Spot test; Visual examination	In-house procedures	D	Auth

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

Forensic biology - Examination of biological material	Any item received	Collection, location and identification of biological material	Acid phosphatase test; Microscopic examination; p30 test; Phadebas Forensic Press test; Tetramethylbenzidine (TMB) test for blood	In-house procedures	D	Auth
Forensic biology - Examination of biological material	Hair	Examination of hair	Microscopic examination; Visual examination	In-house procedures	D	Auth
Forensic chemistry/criminalistics	Any item received	Explosives; Propellants	Flow injection analyser (FIA); Fourier transform infrared spectroscopy (FTIR); GC-MS; Gravimetric; Inductively coupled plasma (ICP); Infrared (IR) microscopy; Ion chromatography (IC); LC-MS; Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Solid phase microextraction (SPME) GC-MS; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures	D	Auth
Forensic chemistry/criminalistics	Any item received	Miscellaneous comparisons; Polymer analysis; Tape; Textile fibre examination	Comparison microscopy; GC-MS; Gravimetric; Infrared (IR) microscopy; Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Polarised light microscopy; Thin layer chromatography (TLC); UV-vis microscopy; Visual examination; X-ray fluorescence (XRF)	In-house procedures	D	Auth

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

Forensic chemistry/criminalistics	Any item received	Cosmetics, oils and lotions; General chemical analysis; General physical examination; Lubricants; Miscellaneous comparisons; Screening, interpretation and reporting of textile damage; Unknown substance identification	Comparison microscopy; Flow injection analyser (FIA); Fourier transform infrared spectroscopy (FTIR); GC-FID; GC-FPD; GC-MS; Gravimetric; Inductively coupled plasma (ICP); Infrared (IR) microscopy; Ion chromatography (IC); LC-MS; Liquid chromatography (LC); Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Polarised light microscopy; Solid phase microextraction (SPME) GC-MS; Spot test; Thin layer chromatography (TLC); UV-vis microscopy; Visual examination; X-ray fluorescence (XRF)	In-house procedures	D	Auth
Forensic toxicology	Blood; Body fluids; Hair; Liver; Lung; Oral fluid; Plasma; Serum; Urine; Viscera; Vitreous humor	Alcohol testing; Coronial toxicology; Drugs in drivers; Drugs in living persons; Drugs of abuse	Enzyme linked immunosorbent assay (ELISA); GC-FID; GC-MS; Haemoximeter; Immunoassay; LC-ESI-MS-MS; LC-MS-MS; LC-QTOF; LC-UV; Precipitation LC-MS	In-house procedures	D	Auth
Genetic analysis	Biological material	DNA profiling for criminal case work - Direct comparison; DNA profiling for relationship testing	Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser; FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction; Polymerase chain reaction (PCR); QIAGEN QIAsymphony extraction	In-house procedures	D	Auth
Genetic analysis	Biological material	DNA profiling for relationship testing	Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser; FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction; Polymerase chain reaction (PCR); QIAGEN QIAsymphony extraction	In-house procedures	D	Auth

CA-22

Kirsten Scott

From: Kirsty Putsey [redacted]
Sent: Tuesday, 16 March 2021 12:02 PM
To: Kirsten Scott; Helen Gregg
Subject: RE: Forensic DNA Analysis - request reduction is scope of NATA accreditation

Dear Kirsten & Helen

Please be advised that Examination of Hair has been withdrawn from your scope of accreditation for site 14171. The changes have been made effect today and will be live on our website from tomorrow.

Please let me know if I can assist with anything further.

Kind Regards,

Kirsty Putsey

Accreditation Manager
Forensic and Life Sciences

National Association of Testing Authorities (NATA)
www.nata.com.au

[redacted]

From: Kirsten Scott [mailto[redacted]
Sent: Friday, 12 March 2021 1:48 PM
To: Kirsty Putsey
Cc: Paula Brisotto; Justin Howes; Cathie Allen; Helen Gregg; Chelsea Savage
Subject: Forensic DNA Analysis - request reduction is scope of NATA accreditation

Dear Kirsty,

Forensic DNA Analysis would like to request a reduction in their scope of accreditation.
We would like to remove "Examination of hair" from our scope, and for that to be applied/effective as soon as it is able to be processed please.

We will be reviewing our processes in light of this change.

Please advise if you require further details or information.

Thanks
Kirsten Scott

Kirsten Scott PhD BSc(Hons) DipMn GDipEd GCEd
Senior Scientist Quality and Projects

Forensic DNA Analysis, Police Services Stream
Forensic & Scientific Services, Health Support Queensland, Queensland Health

[redacted]

Integrity | Customers and patients first | Accountability | Respect | Engagement

Queensland Health acknowledges the Traditional Owners of the land, and pays respect to Elders past, present and emerging.

CA-23

NATIONAL ASSOCIATION OF TESTING AUTHORITIES AUSTRALIA

REPORT ON ASSESSMENT

FACILITY:	Queensland Health Forensic and Scientific Services
SITE:	Forensic and Scientific Services
Accreditation NO:	41
SITE NO:	14171
DATE OF VISIT:	14 December 2020
AUTHORISED REPRESENTATIVE:	Ms Helen Gregg
LEAD ASSESSOR:	Ms Kirsty Putsey
CLIENT COORDINATOR:	Mr Peter Hastil
JOB NUMBER:	74911
ASSESSMENT TYPE:	Surveillance visit (in-office assessment)
IN-OFFICE ASSESSMENT TIME (HR):	18 hours
RESPONSE DUE DATE: *(refer to page 2)*	13 January 2021
SIGNED ON BEHALF OF: **JENNIFER EVANS, CEO**	[redacted]
NAME:	Ms Kirsty Putsey
DATE:	16 December 2020

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

CODING OF ASSESSMENT FINDINGS

Assessment findings are recorded as nonconformities and observations. Each finding is coded with a cross reference to the relevant clause number of the accreditation standard(s).

Responses to any nonconformities are to be recorded in the *Facility Response* section with reference to any supporting evidence. Responses to all nonconformities must be provided by the due date indicated on the front page of the report. In the case that any nonconformity has not been able to be addressed, the reason why and a progress summary is still required to be provided by the due date.

The accreditation status of the facility will be confirmed once all nonconformities have been satisfactorily addressed. The accreditation status of currently accredited facilities will be reviewed should there be significant delays in satisfactorily addressing any nonconformity.

Findings are coded as follows:

Code	Explanation
C **(Major nonconformity)**	May include, but not limited to, the following: • An issue that contributes directly, or has the potential to contribute directly, to the reliability of test results (e.g. inadequate staff training, calibration deficiency, inadequate quality control). This is irrespective of whether the issue is random/infrequent or systemic; • An issue, that whilst it does not contribute directly to the reliability of test results, is systemic (i.e. the same deficiency has occurred on at least a number of occasions); • An issue that contributes directly to how results may be interpreted by the client (e.g. sampling deficiencies); • An issue that has been raised previously as a minor nonconformity but has not been fully or appropriately addressed. A response is required on major nonconformities, including the cause analysis, the action taken and supporting evidence.
M **(Minor nonconformity)**	May include, but not limited to, the following: • An issue is random or infrequent (e.g. only a few staff training records have been found to be out of date); • An issue that does not contribute directly to the reliability of test results but is still a criterion for accreditation (e.g. all staff have received appropriate training for an updated method but

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

	this has not been recorded). For initial assessments and variation visits, minor nonconformities must be addressed as per major nonconformities. For all other visits, the cause analysis and action taken or planned to be taken is required. Supporting evidence does not need to be submitted as this will be reviewed at the following assessment visit. Responses to minor conditions raised in relation to the transition of accreditation from the one version of a Standard to a new version of the same Standard, e.g. ISO/IEC 17025:2005 to ISO/IEC 17025:2017 or ISO Guide 34 to 17034:2016, must include supporting evidence of the action taken. Such minor conditions are written with the year of the new Standard in brackets e.g. M (2017).
Observation	This may be a recommendation, information, clarification, a reminder or flag for follow-up/review at the next assessment. Observations do not require a response.

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

GENERAL COMMENTS

As part of NATA's response to the COVID-19 pandemic, a remote surveillance activity was performed in-lieu of the scheduled onsite visit. The purpose of this remote assessment was to monitor the facility's continuing fulfilment of ISO/IEC 17025:2017 and the applicable NATA Accreditation Criteria (NAC) for its scope of accreditation.

This included a complete review of the facility's management system together with a review of records relating to the activities performed by its scope of accreditation.

Verification of action taken on the findings coded "M" from the previous assessment, conducted on 4 December 2018, was also reviewed as part of this visit and the findings included in this report.

Queensland Health Forensic and Scientific Services holds corporate accreditation. A document review of the corporate management system was conducted on 30 September 2020 to 1 October 2020.

The facility was found to comply with the criteria of General Accreditation Criteria: Corporate Accreditation.

The facility has implemented a management system in accordance with Option A.

The facility is operating at a standard that demonstrates it is competent to perform the activities for which accreditation is held. There are, however, matters detailed in this report where the facility does not comply with the criteria for accreditation which must be addressed. Once these matters are satisfactorily addressed, a recommendation to maintain accreditation can be made.

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

VARIATIONS TO THE SCOPE OF ACCREDITATION

A copy of the complete scope of accreditation is available on the NATA website

Additions

Nil

Deletions

Nil

Amendments

Nil

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

ASSESSMENT FINDING

(Nonconformity)

Clause No:	6.3.4	**Finding Code:**	M

Finding:

Toxicology

The facility must ensure appropriate visitor records are maintained, e.g. visitor register records for August 2020 do not always contain the complete date entries.

FACILITY RESPONSE

(Response must be provided by the due date indicated on the front page of this report. The nonconformity must be addressed at each applicable site if corporate accreditation is held. This must be reflected in the cause analysis and action taken).

Cause Analysis:

Action taken (attach supporting evidence):

NATA Review

Finding close-out date:		**Staff name:**	

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.5.2	**Finding Code:**	M

Finding:

Forensic Biology

All amendments to records must be signed and dated by the operator responsible for the change, e.g. Forensic DNA Analysis Workflow Procedure - Training Module for N. French.

FACILITY RESPONSE

(Response must be provided by the due date indicated on the front page of this report. The nonconformity must be addressed at each applicable site if corporate accreditation is held. This must be reflected in the cause analysis and action taken).

Cause Analysis:

Action taken (attach supporting evidence):

NATA Review

Finding close-out date:		**Staff name:**	

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

ASSESSMENT FINDING

(Observations)

Clause No:	Finding:
6.4.8	The facility is reminded that an appropriate label must be attached to equipment when intermediate checks are found to indicate the item does not function within with working range for the instrument, e.g. POVA CO128 checks for 100ul range demonstrate unsuitability. The facility could also consider any samples that may have been impacted if this instrument was used at this range prior detection.
7.7.2	The facility has performed in the following internal proficiency testing programs; • Forensic Biology (CTS DNA Parentage, Forensic Biology, DNA - Blood, Body Fluid Identification, DNA - Mixture, DNA Database - Saliva, DNA - Semen); • Illicit Drugs (NMI, CTS Drug Analysis, FTS Drug Analysis); • Clandestine Laboratories (FTS Unknown ID, NMI Unknown ID, Remediation) • Criminalistics (FTS Explosives, Forensics Assurance Fibres, FTS Deference Sprats, CWALN, CTS Tape, FTS Chemical ID Inhalants, Metals, Inorganic, FTS Physical Matching, FTS Textile Damage, FTS Lubricant); • Toxicology (FASS Alcohol in Drivers, Drugs in Drivers, Drugs in Oral Fluid, PM Toxicology, CAP, Drugs in Hair). Participation and performance were reviewed and found to be satisfactory.

CA-24

National Association of Testing Authorities, Australia

3 September 2020

Ms Helen Gregg
Quality Manager
Queensland Health
Forensic and Scientific Services
[redacted]

Dear Helen

ACCREDITATION NO.: 41
FACILITY NAME: Queensland Health - Forensic and Scientific Services
SITE NO.: 14171
SITE NAME: Forensic and Scientific Services

We are undertaking our assessments via in-office means so I have the below list of additional documents required for the Forensic and Scientific Services (Site 14171).

As this site holds accreditation for a number of services, please provide the documents/records for each of the following units (one sample traceability sufficient for laboratory records):

1. Controlled Substances
2. Forensic Biology (examination of biological material)
3. Forensic Chemistry/Criminalistics
4. Forensic Toxicology
5. Genetic Analysis

Requested Documentation/Records

- evidence that minor non-conformities ('Ms') raised at the previous on-site assessments have been addressed;
- supervision arrangements & visits, including evidence of technical control (e.g. visitor registers, key registers);
- authorisation of personnel, qualifications and monitoring for any new staff and any staff undergoing cross-training (since last assessment);
- maintenance of competency for infrequently performed activities;
- verification data for methods (e.g. new equipment / instrument introduced where there is no change to the scope of accreditation necessary);
- completed worksheets and calculations (including evidence of tech and admin review casefile per discipline, instrument spectrums/graphs not required);
- equipment checks and maintenance records and external calibrations (relevant to sample traceability);
- environmental monitoring (contamination monitoring, cleaning registers etc.);

- corrective actions, including trend analysis / summaries and actions taken as necessary (some examples from each unit since last assessment);
- proficiency testing summaries, including evidence of review and outlier corrective actions taken as necessary;
- reports issued example (can be redacted for confidentiality if required);
- internal audits, including non-conformities identified and the corrective actions taken (one example per unit since last assessment);
- management review.

After all the information needed is supplied and I have completed the review, I will put together an interim report as normal and we will conduct a scheduled phone/video conversation to perform the exit meeting.

I will be in touch soon to check the progress and assist where I can with any clarifications. The requested documentation would be appreciated by 24 September 2020.

Kind regards,

Ms Kirsty Putsey

Senior Client Coordinator

CA-25

NATIONAL ASSOCIATION OF TESTING AUTHORITIES AUSTRALIA

REPORT ON ASSESSMENT

FACILITY:	Queensland Health Forensic and Scientific Services
SITE:	Forensic and Scientific Services
Accreditation NO:	41
SITE NO:	14171
DATE OF VISIT:	14 December 2020
AUTHORISED REPRESENTATIVE:	Ms Helen Gregg
LEAD ASSESSOR:	Ms Kirsty Putsey
CLIENT COORDINATOR:	Mr Peter Hastil
JOB NUMBER:	74911
ASSESSMENT TYPE:	Surveillance visit (in-office assessment)
IN-OFFICE ASSESSMENT TIME (HR):	18 hours
RESPONSE DUE DATE: *(refer to page 2)*	13 January 2021
SIGNED ON BEHALF OF: **JENNIFER EVANS, CEO**	
NAME:	Ms Kirsty Putsey
DATE:	16 December 2020

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

CODING OF ASSESSMENT FINDINGS

Assessment findings are recorded as nonconformities and observations. Each finding is coded with a cross reference to the relevant clause number of the accreditation standard(s).

Responses to any nonconformities are to be recorded in the *Facility Response* section with reference to any supporting evidence. Responses to all nonconformities must be provided by the due date indicated on the front page of the report. In the case that any nonconformity has not been able to be addressed, the reason why and a progress summary is still required to be provided by the due date.

The accreditation status of the facility will be confirmed once all nonconformities have been satisfactorily addressed. The accreditation status of currently accredited facilities will be reviewed should there be significant delays in satisfactorily addressing any nonconformity.

Findings are coded as follows:

Code	Explanation
C **(Major nonconformity)**	May include, but not limited to, the following: • An issue that contributes directly, or has the potential to contribute directly, to the reliability of test results (e.g. inadequate staff training, calibration deficiency, inadequate quality control). This is irrespective of whether the issue is random/infrequent or systemic; • An issue, that whilst it does not contribute directly to the reliability of test results, is systemic (i.e. the same deficiency has occurred on at least a number of occasions); • An issue that contributes directly to how results may be interpreted by the client (e.g. sampling deficiencies); • An issue that has been raised previously as a minor nonconformity but has not been fully or appropriately addressed. A response is required on major nonconformities, including the cause analysis, the action taken and supporting evidence.
M **(Minor nonconformity)**	May include, but not limited to, the following: • An issue is random or infrequent (e.g. only a few staff training records have been found to be out of date); • An issue that does not contribute directly to the reliability of test results but is still a criterion for accreditation (e.g. all

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

	staff have received appropriate training for an updated method but this has not been recorded). For initial assessments and variation visits, minor nonconformities must be addressed as per major nonconformities. For all other visits, the cause analysis and action taken or planned to be taken is required. Supporting evidence does not need to be submitted as this will be reviewed at the following assessment visit. Responses to minor conditions raised in relation to the transition of accreditation from the one version of a Standard to a new version of the same Standard, e.g. ISO/IEC 17025:2005 to ISO/IEC 17025:2017 or ISO Guide 34 to 17034:2016, must include supporting evidence of the action taken. Such minor conditions are written with the year of the new Standard in brackets e.g. M (2017).
Observation	This may be a recommendation, information, clarification, a reminder or flag for follow-up/review at the next assessment. Observations do not require a response.

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

GENERAL COMMENTS

As part of NATA's response to the COVID-19 pandemic, a remote surveillance activity was performed in-lieu of the scheduled onsite visit. The purpose of this remote assessment was to monitor the facility's continuing fulfilment of ISO/IEC 17025:2017 and the applicable NATA Accreditation Criteria (NAC) for its scope of accreditation.

This included a complete review of the facility's management system together with a review of records relating to the activities performed by its scope of accreditation.

Verification of action taken on the findings coded "M" from the previous assessment, conducted on 4 December 2018, was also reviewed as part of this visit and the findings included in this report.

Queensland Health Forensic and Scientific Services holds corporate accreditation. A document review of the corporate management system was conducted on 30 September 2020 to 1 October 2020.

The facility was found to comply with the criteria of General Accreditation Criteria: Corporate Accreditation.

The facility has implemented a management system in accordance with Option A.

The facility is operating at a standard that demonstrates it is competent to perform the activities for which accreditation is held. There are, however, matters detailed in this report where the facility does not comply with the criteria for accreditation which must be addressed. Once these matters are satisfactorily addressed, a recommendation to maintain accreditation can be made.

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

VARIATIONS TO THE SCOPE OF ACCREDITATION

A copy of the complete scope of accreditation is available on the NATA website

Additions

Nil

Deletions

Nil

Amendments

Nil

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

ASSESSMENT FINDING

(Nonconformity)

Clause No:	6.3.4	**Finding Code:**	M

Finding:

Toxicology

The facility must ensure appropriate visitor records are maintained, e.g. visitor register records for August 2020 do not always contain the complete date entries.

FACILITY RESPONSE

(Response must be provided by the due date indicated on the front page of this report. The nonconformity must be addressed at each applicable site if corporate accreditation is held. This must be reflected in the cause analysis and action taken).

Cause Analysis:

OQI 54406:

Visitor log was inspected for completeness. There were a number of pages that were filled out correctly and completely (e.g. 16/6/2020, 21/7/2020 and 19/8/2020). incomplete records are due to staff not checking that the record has been filled out correctly, and visitors/contractors being in a hurry to complete the record

Action taken (attach supporting evidence):

A reminder email has been sent to staff from the Quality manager to remind staff to fill in this record correctly and completely.

Could you please ensure visitors and contractors complete the register in its entirety with complete dates (e.g. 11/2/2021) and they are signed in and signed out by an authorising staff member.

NATA Review

Finding close-out date:		**Staff name:**	

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.5.2	**Finding Code:**	M

Finding:

Forensic Biology

All amendments to records must be signed and dated by the operator responsible for the change, e.g. Forensic DNA Analysis Workflow Procedure - Training Module for N. French.

FACILITY RESPONSE

(Response must be provided by the due date indicated on the front page of this report. The nonconformity must be addressed at each applicable site if corporate accreditation is held. This must be reflected in the cause analysis and action taken).

Cause Analysis:

OQI 54407:

Unintended human error. The standard operating procedure outlines the process, and as such no procedural change or additional preventative is required to address this non-conformance.

Action taken (attach supporting evidence):

The missing initial and date has been added by the original trainer that made the record (as at 25.02.2021). Refer to "I:\Adverse Events DNA Analysis\OQI 54407 - NATA minor non-conformance (amendment records)" for a copy of the corrected training record.

The standard operating procedure we utilise QIS#14076 version 8 – Test Records (FSS) requires that "*Any mistakes made in recorded data shall not be erased or deleted but shall be altered by crossing out the error and entering the correct value alongside. Corrections shall be initialled and dated by the person making them. Where relevant, the time of amendment shall also be included. Hand written corrections shall be made using permanent ink*"; as such no procedural change or additional preventative is required to address this non-conformance.

All staff in Forensic DNA Analysis have been made aware of the NATA non-compliance as a reminder of the requirement.

NATA Review

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

Finding close-out date:		**Staff name:**	

NATA Report on Assessment	Accreditation No:	41
	Site No:	14171
	Job No:	74911

ASSESSMENT FINDING

(Observations)

Clause No:	Finding:
6.4.8	The facility is reminded that an appropriate label must be attached to equipment when intermediate checks are found to indicate the item does not function within with working range for the instrument, e.g. POVA CO128 checks for 100ul range demonstrate unsuitability. The facility could also consider any samples that may have been impacted if this instrument was used at this range prior detection.
7.7.2	The facility has performed in the following internal proficiency testing programs; • Forensic Biology (CTS DNA Parentage, Forensic Biology, DNA - Blood, Body Fluid Identification, DNA - Mixture, DNA Database - Saliva, DNA - Semen); • Illicit Drugs (NMI, CTS Drug Analysis, FTS Drug Analysis); • Clandestine Laboratories (FTS Unknown ID, NMI Unknown ID, Remediation) • Criminalistics (FTS Explosives, Forensics Assurance Fibres, FTS Deference Sprats, CWALN, CTS Tape, FTS Chemical ID Inhalants, Metals, Inorganic, FTS Physical Matching, FTS Textile Damage, FTS Lubricant); • Toxicology (FASS Alcohol in Drivers, Drugs in Drivers, Drugs in Oral Fluid, PM Toxicology, CAP, Drugs in Hair). Participation and performance were reviewed and found to be satisfactory.

CA-26

National Association of Testing Authorities, Australia

15 March 2021

Ms Helen Gregg
Quality Manager
Queensland Health
Forensic and Scientific Services
[redacted]

Dear Ms Gregg

Accreditation No: 41
Facility Name: Queensland Health
Forensic and Scientific Services
Site No: 14171
Site Name: Forensic and Scientific Services

I am pleased to inform you that the accreditation of your facility has been maintained. Accreditation is for a period as defined in the Sixth schedule of the NATA Rules, being continued in accordance with Regulation R.32.

Maintenance of accreditation is dependent on adherence to the current NATA General Accreditation Criteria, NATA Specific Accreditation Criteria and the NATA Rules.

Should the Members Portal have been utilised in relation to this activity, please ensure that you have copies of documents lodged in the 'My Jobs' folder for your permanent records. The associated job folder and its contents will be removed in due course.

Scope of Accreditation

Your current scope of accreditation is available on the NATA website.

Next Visit Type

Your facility is next scheduled for a Reassessment in June 2022.

Endorsement of Reports

We continue to encourage you to apply the NATA endorsement to your reports whenever possible. This will enhance the standing of your facility with your clients and help to promote increased recognition of accreditation and NATA throughout the community. If you have any queries about the most appropriate means of reproducing the NATA endorsement or material for advertising your NATA accreditation, please contact NATA Communications on 1800 621 666.

Reports issued by your facility may also include the Accredited CAB Combined ILAC MRA Mark. To apply for the Mark, please contact NATA's Quality Manager in our Melbourne office.

Authorised Representative

Your rights and responsibilities as your facility's Authorised Representative are stated in the Associations Rules. Copies of these and other appropriate publications, e.g. the Charter of Service and NATA General Accreditation Criteria: *Responsibilities of Authorised Representatives* are available from the NATA website www.nata.com.au.

At this time I take the opportunity to remind you that you are our point of contact with your organisation and hence our source of formal advice regarding your organisation. I therefore ask you to advise me within 14 days if:

- The name or ownerships of your facility changes;
- Changes in duties or departures of key staff occur; or
- Significant changes occur to the functions or accommodation of your facility.

I also remind you that on behalf of the accredited facility, you are responsible for ensuring that all NATA's Accreditation Criteria continue to be met including:

- NATA's requirements for the content and endorsements of the test documents;
- That the NATA emblem is not misused;
- All fees and charges are promptly paid.

NATA also enters into agreements with other parties. Where NATA has an agreement with or from the Commonwealth or a State Government or where the Association is engaged in accreditation in conjunction with or on behalf of one or more other Stakeholders, NATA may pass information otherwise privileged under the NATA Rules, to the party concerned. Additionally, agreements may contain other

obligations/undertaking of NATA which may have an impact on your facility. The following are given as examples of such agreements.

Agreement	Party/ies	Scope
Memorandum of Understanding	State of Tasmania	Facilities accredited by NATA, public or private, and conducting testing, measurement, inspection or related activities for the State of Tasmania.
Memorandum of Understanding	State of Victoria	Facilities accredited by NATA, public or private, and conducting testing, measurement, inspection or related activities, reference material producers, proficiency testing scheme providers for the State of Victoria.
Memorandum of Understanding	Dept. of Industry, Innovation, Climate Change, Science, Research and Tertiary Education	Concerns raised by the Commonwealth agencies with regard to facilities accredited by NATA or NATA's MRA Partners.

A full listing of agreements and the obligations/undertakings placed on NATA by the agreement in question can be viewed on the NATA website by clicking on the About Us tab/structure/formal agreements. You should be aware that the contents of one or more of these agreements may be relevant to your accreditation(s).

On behalf of NATA, may I take this opportunity to thank you and your staff for the cooperation and hospitality during the recent activity of your facility. If you have any queries with the information contained in this letter please contact your client coordinator Peter Hastil at our Brisbane office.

Yours sincerely

[redacted]

for
Jennifer Evans
CHIEF EXECUTIVE OFFICER

CA-27

NATIONAL ASSOCIATION OF TESTING AUTHORITIES AUSTRALIA

INTERIM REPORT ON ASSESSMENT

Facility:	Queensland Health Forensic and Scientific Services
Site:	Forensic and Scientific Services
Accreditation No:	41
Site No:	14171
Dates of Visit:	25-28 July 2022 08-09 August 2022
Authorised Representative:	Ms Helen Gregg
Technical Assessors:	Assoc Prof Dimitri Gerostamoulos (25-26 July) Ms Kahlee Redman (25-26 July) Ms Julie McCall (27-28 July) Mr Ben Painter (08-09 August)
Lead Assessors:	Ms Madelen Chikhani Ms Kirsty Putsey
Client Coordinator:	Peter Hastil
Job Number:	82214
Assessment Type:	Reassessment
On-Site Time (hr):	Day 1: 7.5 Day 2: 6 Day 3: 7.25 Day 4: 6 Day 5: 7 Day 6: 5.5
Response Due Date: *(refer to page 2)*	*Four weeks from date of confirmed report*
Signed on behalf of: **Jennifer Evans, CEO**	[redacted]

Name:	Ms Madelen Chikhani
Date:	28 July 2022

The contents of this report are subject to review and may be modified.

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	Job No:	82214

CODING OF ASSESSMENT FINDINGS

Assessment findings are recorded as nonconformities and observations. Each finding is coded with a cross reference to the relevant clause number of the accreditation standard(s).

Responses to any nonconformities are to be recorded in the *Facility Response* section with reference to any supporting evidence. Responses to all nonconformities must be provided by the due date indicated on the front page of the report. In the case that any nonconformity has not been able to be addressed, the reason why and a progress summary is still required to be provided by the due date.

The accreditation status of the facility will be confirmed once all nonconformities have been satisfactorily addressed. The accreditation status of currently accredited facilities will be reviewed should there be significant delays in satisfactorily addressing any nonconformity.

Findings are coded as follows:

Code	Explanation
C **(Major nonconformity)**	May include, but not limited to, the following: • An issue that contributes directly, or has the potential to contribute directly, to the reliability of test results (e.g. inadequate staff training, calibration deficiency, inadequate quality control). This is irrespective of whether the issue is random/infrequent or systemic; • An issue, that whilst it does not contribute directly to the reliability of test results, is systemic (i.e. the same deficiency has occurred on at least a number of occasions); • An issue that contributes directly to how results may be interpreted by the client (e.g. sampling deficiencies); • An issue that has been raised previously as a minor nonconformity but has not been fully or appropriately addressed. A response is required on major nonconformities, including the cause analysis, the action taken and supporting evidence.
M **(Minor nonconformity)**	May include, but not limited to, the following: • An issue is random or infrequent (e.g. only a few staff training records have been found to be out of date); • An issue that does not contribute directly to the reliability of test results but is still a criterion for accreditation (e.g. all

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	staff have received appropriate training for an updated method but this has not been recorded). For initial assessments and variation visits, minor nonconformities must be addressed as per major nonconformities. For all other visits, the cause analysis and action taken or planned to be taken is required. Supporting evidence does not need to be submitted as this will be reviewed at the following assessment visit. Responses to minor nonconformities raised in relation to the transition of accreditation from the one version of a Standard to a new version of the same Standard must include supporting evidence of the action taken. Such minor nonconformities are written with the year of the new Standard in brackets e.g. M (2017).
Observation	This may be a recommendation, information, clarification, a reminder or flag for follow-up/review at the next assessment. Observations do not require a response.

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GENERAL COMMENTS

The purpose of this reassessment was to monitor the facility's continuing fulfilment of ISO/IEC 17025:2017 and the applicable NATA Accreditation Criteria (NAC) for its scope of accreditation. This included a review of the facility's technical competence together with a review of select elements of its management system.

Verification of action taken on the findings coded "M" from the previous assessment, conducted on 14 December 2020, was also reviewed as part of this visit and the findings included in this report.

The facility has implemented a management system in accordance with Option A.

Queensland Health Forensic and Scientific Services holds corporate accreditation. A document review of the corporate management system was conducted on 30 September 2020 to 1 October 2020.

The facility was found to comply with the criteria of General Accreditation Criteria: Corporate Accreditation.

The facility is operating at a standard that demonstrates it is competent to perform the activities for which accreditation is held. There are, however, matters detailed in this report where the facility does not comply with the criteria for accreditation which must be addressed. Once these matters are satisfactorily addressed, a recommendation to continue accreditation can be made.

Abbreviations

LAD Specific Accreditation Criteria
ISO/IEC 17025 Application Document
Legal (including Forensic Science) - Appendix

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VARIATIONS TO THE SCOPE OF ACCREDITATION

A copy of the complete scope of accreditation is available on the NATA website.

Additions

Nil

Deletions

Nil

Amendments

ISO 17025 Legal				
Service	**Product**	**Determination**	**Technique**	**Procedure**
Analysis of controlled substances	Clandestine drug facility - Investigation	Drug identification; Presumptive testing	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; Inductively coupled plasma (ICP); Ion chromatography (IC); LC-MS; Quantitation of drugs and associated compounds by UPLC-PDA; Raman spectroscopy; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures
Analysis of controlled substances	Any item received	Drug identification; Presumptive testing	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; LC-MS; Quantitation of drugs and associated compounds by UPLC-PDA; Spot test; Visual examination	In-house procedures
Forensic chemistry/criminalistics	Any item received	Explosives; Propellants	Flow injection analyser (FIA); Fourier transform infrared spectroscopy (FTIR); GC-MS; GC-MS - Solid phase microextraction (SPME); Gravimetric; Inductively coupled plasma (ICP); Infrared microscopy; Ion chromatography (IC); LC-MS; Macroscopic examination; MicroFourier transform infrared spectroscopy (FTIR); Microscopic examination; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures

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Forensic toxicology	Blood; Body fluids; Hair; Liver; Lung; Oral fluid; Plasma; Serum; Urine; Viscera; Vitreous humor	Blood; Body fluids; Hair; Liver; Lung; Oral fluid; Plasma; Serum; Urine; Viscera; Vitreous humor	Enzyme linked immunosorbent assay (ELISA); GC-FID; GC-MS; Haemoximeter; Immunoassay; LC-ESIMS-MS; LC-MS-MS; LC-QTOF; LC-UV; Precipitation LC-MS	In-house procedures
Genetic analysis	Biological material	DNA profiling for criminal case work - Direct comparison; DNA profiling for relationship testing	Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser; FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction; Polymerase chain reaction (PCR); QIAGEN QIAsymphony extraction	In-house procedures
Genetic analysis	Biological material	DNA profiling for relationship testing	Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser; FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction; Polymerase chain reaction (PCR); QIAGEN QIAsymphony extraction	In-house procedures

Are now represented as:

ISO 17025 **Legal**				
Service	**Product**	**Determination**	**Technique**	**Procedure**
Analysis of controlled substances	Clandestine drug facility - Investigation	Collection; Drug and chemical identification; ~~Drug identification~~; Drug quantitation; Presumptive testing	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; Inductively coupled plasma (ICP); Ion chromatography (IC); LC-MS; Quantitation of drugs and associated compounds by UPLC-PDA; Raman spectroscopy; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures
Analysis of controlled substances	Any item received	Drug identification; Drug purity;	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; LC-MS;	In-house procedures

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		Drug quantitation; Presumptive testing	Quantitation of drugs and associated compounds by UPLC-PDA; Spot test; Visual examination	
Forensic chemistry/criminalistics	Any item received	Explosives; Propellants	Flow injection analyser (FIA); Fourier transform infrared spectroscopy (FTIR); GC-MS; GC-MS - Solid phase microextraction (SPME); Gravimetric; Inductively coupled plasma (ICP); Infrared microscopy; Ion chromatography (IC); LC-MS; Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Raman spectroscopy; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures
Forensic toxicology	Blood; Body fluids; Hair; Liver; Lung; Oral fluid; Plasma; Serum; Urine; Viscera; Vitreous humor	Blood; Body fluids; Hair; Liver; Lung; Oral fluid; Plasma; Serum; Urine; Viscera; Vitreous humor	Enzyme linked immunosorbent assay (ELISA); GC-FID; GC-MS; Haemoximeter; Immunoassay; LC-ESI-MS-MS; LC-MS - Liquid liquid extraction; LC-MS - Solid phase extraction; LC-MS-MS; LC-MS-MS - Supported liquid extraction; LC-QTOF; LC-UV; ~~Precipitation LC-MS~~; Protein precipitation LC-MS	In-house procedures
Genetic analysis	Biological material	DNA profiling for criminal case work - Direct comparison; ~~DNA profiling for relationship testing~~	~~Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser;~~ Capillary electrophoresis (CE); DNA concentration; DNA extraction; DNA quantitation; Fragment analysis; ~~FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction~~; Polymerase chain reaction (PCR); ~~QIAGEN QIAsymphony extraction~~	In-house procedures
Genetic analysis	Biological material	DNA profiling for relationship testing	~~Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser;~~ Capillary electrophoresis (CE); DNA concentration;	In-house procedures

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			DNA extraction; DNA quantitation; Fragment analysis; ~~FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction;~~ Polymerase chain reaction (PCR); ~~QIAGEN QIAsymphony extraction~~	

Following discussions with the facility, amendments have been made as represented above; deletions have been struck through and additions are in blue.

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	6.3.4 (LAD)	**Finding Code:**	M

Finding:

Forensic Chemistry and Toxicology

The facility must ensure appropriate visitor records are maintained, e.g. several entries are not completed in the "Visitor/Contractor Register for Forensic Chemistry/Toxicology Laboratories".

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	6.4.1 (LAD)	**Finding Code:**	M

Finding:

Toxicology, Illicit Drugs and Clandestine Laboratories

Reagents must be labelled with sufficient information to allow traceability back to its original preparation. The laboratories were unable to demonstrate traceability of reagents on assessment. Reagents decanted into smaller working bottles on benches could not be traced back to original bulk working solutions as batch numbers or preparation dates are not recorded on the bottles.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	6.4.8	**Finding Code:**	M

Finding:

Toxicology

All equipment which has a defined period of validity shall be labelled to allow the user to readily identify the period of validity. There were no preparation or expiry dates on several bottles including "Mobile Phase A (GHB Hair)" and "Mobile Phase B (GHB Hair)".

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	6.4.13 a-h)	**Finding Code:**	M

Finding:

Toxicology

The facility must retain records which can influence laboratory activities. Records for several equipment were either not easily accessible or inadequate on assessment, for example, LCMS 8050B, GCMS G7081B and GCMS no. 10338648.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.2.1.1 (LAD)	**Finding Code:**	M

Finding:

Illicit Drugs

Examination methods used must be accepted in the field or supported by data. The weight of the calculated drug must not be reported to an accuracy greater than the least accurate measurement. In casefiles where purity analysis was performed, a purity with accuracy of three significant figures was reported, but in most instances, the calculated weight was reported to a value with higher accuracy.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.2.1.3	**Finding Code:**	C

Finding:

Clandestine Laboratories

Procedure no. 21474 states that where sample size permits, two samplings are to be tested to ensure results correspond to the exhibit. Casefile [redacted] contained a bulk liquid in which cocaine was detected, and it appears that only one extract was run, which is not compliant with standard operating procedures. The facility must follow the instructions in their procedure for these types of exhibits.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

NATA Report on Assessment	Accreditation No:	41
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	Job No:	82214

ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.2.2.1	**Finding Code:**	C

Finding:

Toxicology

The laboratory must have a validated method for analysis of drugs in hair. Drug Analysis of Hair Specimens (33718v3) is a partly validated method. GHB is not validated as part of this method and the validation method lacks significant aspects of method validation, including but not limited to linearity, selectivity, and autosampler stability. The laboratory must review all GHB positive cases and must withdraw all positive GHB reports. Drugs listed in Appendix B "the list of drugs covered by the hair testing method" are not all included in the validation, for example, heroin, MDPV and PMA.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.4.2	**Finding Code:**	M

Finding:

Illicit Drugs

The laboratory must record unique and unambiguous identification of calibration standards, for example, standard with electronic identification 22WS033 was physically labelled as 21WS033.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.4.4 (LAD)	**Finding Code:**	M

Finding:

Forensic Chemistry

The laboratory must ensure case continuity is maintained when internally transferring samples to laboratories not using the Forensic Register, for example, in [redacted] the request form was not signed by the external IRMS operator.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.5.1 (LAD)	**Finding Code:**	M

Finding:

Toxicology

The total number of pages in casefiles must be clearly identified. No casefiles observed on assessment had a total number of pages indicated including casefiles [redacted] and [redacted]

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

NATA Report on Assessment	Accreditation No:	41
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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.5.1 (LAD)	**Finding Code:**	M

Finding:

Toxicology

The facility must record the acceptance criteria for non-conforming results and a reason when a test result is rejected, for example, ion ratio 'failing' for drugs using method 32059 in casefile [redacted] (pages 6 and 13).

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.5.1 (LAD)	**Finding Code:**	M

Finding:

Toxicology

The laboratory must record batch numbers or preparation dates of critical reagents used for quantitative analyses, for example, ammonia solution and dichloromethane (method 26178v11).

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.5.1 (LAD)	**Finding Code:**	M

Finding:

Illicit Drugs and Clandestine Laboratories

Technical records must include batch numbers or preparation dates of critical reagents. This is not being recorded by the laboratories.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.5.1 (LAD)	**Finding Code:**	M

Finding:

Illicit Drugs

The laboratory must record a reason when a test result is rejected, for example, the calculated weight in casefile [redacted] or sample ID [redacted].

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.8.1.2	**Finding Code:**	C

Finding:

Toxicology

The laboratory must adhere to the limits of reporting as per the specific method, for example chlorpheniramine is reported at a concentration less than the limit of reporting in casefile [redacted].

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	7.11.6	**Finding Code:**	M

Finding:

Illicit Drugs

The laboratory must check data transfers in an appropriate and systematic manner. Total weight of drugs recorded on examination worksheets were not verified in most casefiles.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	8.3.2 c)	**Finding Code:**	M

Finding:

Illicit Drugs and Clandestine Laboratories

The laboratory must ensure that the current revision status of documents is identified, for example:

- 18042v7 ("valid from" date in footer does not match amendment history table)
- 17979v9 (footer indicates version 9 but amendment history table stops at revision 7 due to duplication in version numbers)

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Nonconformity)

Clause No:	8.7.1 a)	**Finding Code:**	M

Finding:

Toxicology

When a non-conformity occurs, the laboratory shall take action and address the consequences. During autotune no. 5977, high water levels were noted in GCMS no. 10338648, and no action was taken.

FACILITY RESPONSE

(The response must be provided by the due date indicated on the front page of this report)

If the facility holds corporate accreditation, is the nonconformity relevant to other sites?	Yes		No	

Cause Analysis:

(Where "Yes" was indicated above, the cause analysis must also address the applicable sites)

Action taken (attach supporting evidence):

(Where "Yes" was indicated above, the action taken must also address the applicable sites)

NATA Review

Finding close-out date:		**Staff name:**	

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ASSESSMENT FINDING

(Observations)

Clause No:	Finding:
4.1.4	DNA The laboratory may consider reviewing risks to its impartiality on an on-going basis, for example, the use of "insufficient DNA was detected during the initial processing of this sample and was not examined further" in their reports. It is recommended that the laboratory clarifies this statement to ensure that its intent is clearly understood.
6.3.1	Toxicology Whilst the NATA audit does not constitute a WHS inspection, it is recommended that the mouldy vents in the toxicology laboratory are cleaned.
6.3.1	Clandestine Laboratories The laboratory is commended for their "Clan Lab Chemical Storage" area for being well set up with good segregation of chemicals.
6.4.13	Illicit Drugs The laboratory is commended for their comprehensive standards database.
7.2.1.1	DNA It is recommended that the laboratory reviews page 19 of "Procedure for Case Management" (document no. 17117v21) to correct any content errors, for example "incorrect" results.
7.7.1 (LAD)	DNA For best practice, the laboratory may consider reprocessing the original reagent blanks associated with evidentiary samples if upgrading to different typing kits.
7.7.1	Illicit Drugs and Clandestine Laboratories For best practice, where identification is based on mass spectral data, the laboratory should consider ensuring any variation in ion ratio between standard and sample are appropriate.
7.7.2	The laboratory is enrolled in proficiency testing programs which cover all areas of testing. The laboratory's participation is satisfactory. Proficiency testing results were reviewed and found to be satisfactory.
7.11.3	Toxicology An improved case management system is recommended for the Toxicology Laboratory to reduce workarounds using excel spreadsheets.
8.8.2	For best practice, it is recommended that the facility includes the review of casefiles in its internal audits.

CA-28

NATIONAL ASSOCIATION OF TESTING AUTHORITIES AUSTRALIA

REPORT ON REASSESSMENT

FACILITY:	Queensland Health Forensic and Scientific Services
SITE:	Forensic and Scientific Services
ACCREDITATION NO:	41
CORPORATE SITE NO:	14171
DATE OF VISIT:	26 - 29 November 2018 (Forensic Chemistry, DNA) 3 - 4 December 2018 (Toxicology)
AUTHORISED REPRESENTATIVE:	Ms H Gregg
TECHNICAL ASSESSORS:	Ms H Brown
	Dr H Salouros
	Dr D Abarno
	Ms M Grist
LEAD ASSESSORS:	Ms K Putsey
CLIENT COORDINATOR:	Mr P Hastil
RESPONSE DATE (to Conditions for Accreditation):	15 January 2019

[redacted]

Signed on behalf of	JENNIFER EVANS CHIEF EXECUTIVE OFFICER
Name	Kirsty Putsey
Date	18 December 2018

Time on-site:

26/11 – 8hrs, 27/11 – 8rs, 28/11 – 8hrs,
29/11 – 7hrs, 3/12 – 8hrs, 4/12 – 7hrs

Codes used in this report:	
O = Observation.	This may be a recommendation, information/clarification on activities or a reminder or flag for follow-up/review at the next assessment.
M = Minor Condition.	A description of the action taken or intended must be provided. Supporting evidence of this action will not be required as it will be reviewed at the next assessment. **Responses to any minor conditions raised in relation to the transition of accreditation from the 2005 version of ISO/IEC 17025 to the 2017 version must include supporting evidence of the action taken. Such minor conditions will be coded in the report as M (2017).**
C = Condition.	A response on action taken is required with supporting evidence provided.
All responses must be provided by the response due date.	

GENERAL COMMENTS

The purpose of this reassessment was to monitor the facility's continuing compliance with the requirements for accreditation. This included a complete review of the facility's technical competence together with a limited review of management system requirements.

The visit was conducted against ISO/IEC 17025:2017 and the criteria documents in the NATA Accreditation Criteria (NAC) package(s) relevant to the facility's scope of accreditation.

A formal document review of the management system documentation was last conducted on 15 July 2015.

Queensland Health Forensic and Scientific Services holds corporate accreditation.

Accordingly the response to this report must also include assurance that the conditions have been addressed at all sites, where relevant.

The facility was found to comply with the *General Accreditation Criteria: Corporate Accreditation.*

Verification of action taken on the findings coded "M" from the previous assessment, conducted on 21 – 23 March 2017, was also reviewed as part of this visit and the findings included in this report.

NATA Report on Assessment **Accreditation No. 41 / Corp Site No. 14171**

SCOPE OF ACCREDITATION

Variations to the Scope of Accreditation

Additions

Note: Additional activities will not be recommended for accreditation until all the conditions contained in this report have been satisfactorily addressed. This includes provision of supporting evidence for those conditions coded M directly related to the requested extension(s).

Nil

Deletions

Nil

Editorial Revision

Inclusion of determinations for forensic chemistry/criminalistics omitted when the scope of accreditation was transitioned. Forensic toxicology editorial modifications were also made onsite.

Other Comments

Nil

NATA Report on Assessment **Accreditation No. 41 / Corp Site No. 14171**

ASSESSMENT FINDINGS

Clause No.	Code	Surveillance Visit Findings	Action taken by facility and NATA review (with reference to supporting evidence)	NATA close-out
4. General requirements				
4.1		Impartiality		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
4.2		Confidentiality		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
5. Structural requirements				
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
6. Resource requirements				
6.1		General		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
6.2		Personnel		
6.2.2	M	Trace Evidence Competence requirements for each function involved in testing activities must be documented, e.g. explosives and chemical identification.		
6.2.5	M	Trace Evidence Evidence must be maintained in staff training records to support how and when ongoing competency is achieved. Such records must be retained when staff employment ceases.		

NATA Report on Assessment **Accreditation No. 41 / Corp Site No. 14171**

Clause No.	Code	Surveillance Visit Findings	Action taken by facility and NATA review (with reference to supporting evidence)	NATA close-out
6.3		Facilities and environmental conditions		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
6.4		Equipment		
6.4.1	M	Controlled Substances All reagents must be appropriately labelled, e.g. T-Butanol and methanol in the synthesis room with hand-written labels only.		
6.4.3	O	Toxicology It is strongly recommended that the facility consider including an additional staff members contact details on the critical fridges and freezers to ensure contact can be made if required.		
6.4.13	M	Trace Evidence Evidence of verification that equipment conforms to specified requirements must be maintained, e.g. GC/MS-FID-FPD.		
6.5		Metrological traceability		
6.5.2	M	Controlled Substances Measurement results must be traceable to SI units through the use of certified reference materials, e.g. where a CRM is available this must be used to make Working Standards.		
6.6		Externally provided products and service		
6.6.2	M	Toxicology The security of schedule eight drug standards must be maintained in the laboratory at all times, e.g. refrigerator 10 with inadequate lock.		

Clause No.	Code	Surveillance Visit Findings	Action taken by facility and NATA review (with reference to supporting evidence)	NATA close-out
6.6.2 Cont.	O	Toxicology It is recommended that the process in place for recording the use of powder standards be applied to liquid standards (e.g. partial ampoule usage records).		
7. Process requirements				
7.1	O	Review of requests, tenders and contracts Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
7.2		Selection. Verification and validation of methods		
7.2.1.2	M_1	Controlled Substances The following documents must be updated: • 21474 section 5.8 to include the peptide digestion analysis; • 18063 to include guidance around running samples at a higher concentration and using FTIR for samples where no drug (or compound) is detected; • 18063 section 7.1 to ensure form 24009 is completed for both internal and external testing requests.		
	M_2	Trace Evidence The following documents must be updated: • 18125 remove reference to adhesive tape; • 18133 remove reference to section 9.6.5; • 18558 section 8.3 to refer to appendix 10.2; • 18558 appendix 10.2 notes incorrectly references 10.1; • 27241 amendment history and footer do not match; • 27881 references outdated NATA classes of tests;		

NATA Report on Assessment **Accreditation No. 41 / Corp Site No. 14171**

Clause No.	Code	Surveillance Visit Findings	Action taken by facility and NATA review (with reference to supporting evidence)	NATA close-out
7.2.1.2 Cont.		• 27238 page 5 reference to hexane extract should reflect methanol extract; • 26552 section 10.15 correct reference to 'below the line' for peak labelling; • 26552 include bench calibration check; • 30932 section 5.4.11 storage cages update to WV31 and WV1.		
	M_3	<u>Toxicology</u> Further information must be included procedures 32059, 17383 and 21337 to ensure appropriate instrument checks are conducted with defined objective parameters that are fit for purpose. Records to support these checks must also be maintained.		
	O	<u>Trace Evidence</u> It is recommended that section 8.1 be updated in procedure 18558 to remove the requirement to complete use history for all reference materials. The current practice of completing this form for CRMs is deemed sufficient.		
7.3		<u>Sampling</u>		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
7.4		<u>Handling test or calibration items</u>		
7.4.1	M	<u>Trace Evidence</u> All exhibit movement history must recorded and traceable, e.g. 1800063100.		

NATA Report on Assessment **Accreditation No. 41 / Corp Site No. 14171**

Clause No.	Code	Surveillance Visit Findings	Action taken by facility and NATA review (with reference to supporting evidence)	NATA close-out
7.4.1 Cont.	O_1	Controlled Substances It is recommended that the property point exhibit vault be closed at all times and the exhibit box used for holding received items be further secured in the closed vault. It is noted that this area is monitored by CCTV and a minimum of two staff members at all times.		
	O_2	Controlled Substances It is recommended that the two stage process involving the transfer and receipt of exhibits be conducted sequentially by the involved staff members.		
	O_3	Forensic Biology/DNA Testing The practice of answering mobile phones in the laboratory could be reconsidered.		
	O_4	Trace Evidence The facility is reminded that all cages used for storing explosives must be appropriately labelled as per 30932.		
7.5		Technical records		
7.5.1	O_1	Controlled Substances It is recommended that the expiry date for Working Standards be incorporated on the excel Quant spreadsheet. This modification could be referenced in procedure 34194.		
	O_2	The facility is reminded that the appropriate court testimony evaluation form is to be used when monitoring is conducted, e.g. real and/or moot testimony.		

NATA Report on Assessment **Accreditation No. 41 / Corp Site No. 14171**

Clause No.	Code	Surveillance Visit Findings	Action taken by facility and NATA review (with reference to supporting evidence)	NATA close-out
7.6		Evaluation of measurement uncertainty		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
7.7		Ensuring the validity of results		
		Forensic Biology/DNA Testing		
7.7.1	O	It is recommended that the challenge sample used when checking STRmix™ installation be expanded to cover the increased number of settings in the updated version.		
7.7.2	O	The facility participates in the applicable external proficiency testing programs, e.g. CTS, NMI, FTS, WA Chem Centre, CWALN, FASS NSW and CAP. The investigations into outliers were reviewed and found to be satisfactory.		
7.8		Reporting of results		
		Controlled Substances		
7.8.1.2	M	Reported results must be accurate, e.g. report 5674167 exhibit 90666-633-1 reported N-isopropyl benzylamine as 'detected' rather than 'indicated'.		
7.9		Complaints		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
7.10		Nonconforming work		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		

Clause No.	Code	Surveillance Visit Findings	Action taken by facility and NATA review (with reference to supporting evidence)	NATA close-out
7.11		Control of data and information management		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
8. Management system requirements				
8.1.1		General		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
8.1.2		Option A		
	O	The facility has established and implemented a management system in accordance with Option A. Refer to clauses 8.2 to 8.9 for specific assessment findings.		
8.1.3		Option B		
	O	Not applicable. Refer to clause 8.1.2.		
8.2		Management system documentation (Option A)		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
8.3		Control of management system documentation (Option A)		
		Forensic Biology/DNA Testing		
8.3.2	M_1	All outdated references must be updated, e.g. 25303 obsolete NATA documents and texts within the reference list (Buckleton, 2005).		

Clause No.	Code	Surveillance Visit Findings	Action taken by facility and NATA review (with reference to supporting evidence)	NATA close-out
8.3.2 Cont.	M_2	Trace Evidence and Toxicology All templates that are used for testing activities must be controlled, e.g. gravimetric instrument spreadsheets (trace) and the saliva THC and amphetamines quantitation by LCMS batch worksheets (toxicology).		
	M_3	Toxicology All obsolete documents must be removed from use and replaced with the current version, e.g. 17286 (version 5 still in use) and 23852 (version 4 still in use).		
	O	Forensic Biology/DNA Testing The facility is reminded that all hyperlinks in documents must be kept up to date, e.g. 25303.		
8.4		Control of record (Option A)		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
8.5		Actions to address risks and opportunities (Option A)		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
8.6		Improvement (Option A)		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
8.7		Corrective actions (Option A)		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		

NATA Report on Assessment **Accreditation No. 41 / Corp Site No. 14171**

Clause No.	Code	Surveillance Visit Findings	Action taken by facility and NATA review (with reference to supporting evidence)	NATA close-out
8.8		Internal audits (Option A)		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		
8.9		Management reviews (Option A)		
	O	Assessed and found to be satisfactory as per the purpose of the visit detailed on page 2 of the report.		

CA-29

National Association of Testing Authorities, Australia

18 December 2018

Ms Helen Gregg
Principal Quality Advisor
Queensland Health
[redacted]

Dear Helen

ACCREDITATION NO 41
Queensland Health - Forensic and Scientific Services
Forensic and Scientific Services

Please find attached the confirmed report on the reassessment of the above facility, conducted on 26 - 29 November 2018 and 3 - 4 December 2018. This reviewed report differs from the interim report provided at the conclusion of the visit as follows:

Clause 7.2.1.2 M_1 point 2 Controlled Substances	Removed from report. Please see considerations below based on Accreditation Advisory Committee (AAC) review.

Some editorial changes have also been made.

Reporting of a compound as detected/indicated when a CRM is unavailable

The approach is considered satisfactory with one caveat regarding not being able to identify positional isomers where reference materials for all isomers are not available. In the interests of transparency such instances should be accompanied by a disclaimer e.g. *other positional isomers cannot be excluded.*

Also consider a disclaimer where IDs are made not using reference materials as there are instances where commercial and in-house libraries have had inaccurate entries e.g. *a certified reference material was not available to confirm substance identity and identification is based on information contained within a reference library.*

A recommendation to continue accreditation will be made when the conditions in the attached report have been satisfactorily addressed.

The matters requiring attention were discussed with you and your staff during the reassessment and are coded "C" and "M" in the report. The report also includes some recommendations for your consideration and these are coded 'O'.

A response detailing the actions taken, or intended, together with relevant cross-referenced supporting documents on the above matters is requested by 15 January 2019.

Failure to address the conditions raised by the response date may result in the suspension of all or part of your facility's accreditation.

To facilitate the review of your response, please complete the relevant column of the "Assessment Findings" pages of the report and submit these with your supporting documentation. An electronic version of the report is also available on request if you are not accessing the Members Portal. Please note submissions should be presented as a simple collated package. A reference to the relevant attachment should be included to link the documentary evidence with the particular clause. Similarly, it should be ensured that each attachment is clearly identified to link it to the clause or condition.

If you are accessing the Members Portal, please note that individual Portal uploads are limited to 150MB. A confirmation list of the documents lodged will be provided by the Portal.

If you will be providing your submission via email, please ensure that the email is less than 10 MB. NATA staff will contact you when the submission is received. If you do not receive confirmation of receipt within two weeks, please contact me.

Finally, I would like to thank you for the cooperation and hospitality given to the assessment team. If you have any queries please contact me in our Sydney office.

Yours sincerely

[redacted]

Kirsty Putsey
Senior Client Coordinator

CA-30

Cathie Allen

From:	Kirsten Scott
Sent:	Thursday, 1 September 2022 11:45 AM
To:	Samantha Granato; Helen Gregg; Cathie Allen; Paula Brisotto; Justin Howes; Chelsea Savage
Subject:	RE: Action - 18/9/2022 NATA Forensic Audit Assessment findings for Action.
Attachments:	DG Memo - Urgent Amendment to Standard Operating Procedure required.pdf; 17117V21.5.doc

Sam and Helen,

Please find attached the Forensic DNA Analysis response to the observations noted in the NATA final report.

*Observation 4.1.4 **DNA** The laboratory may consider reviewing risks to its impartiality on an on-going basis, for example, the use of "insufficient DNA was detected during the initial processing of this sample and was not examined further" in their reports. It is recommended that the laboratory clarifies this statement to ensure that its intent is clearly understood.*

The use of "insufficient DNA was detected during the initial processing of this sample and was not examined further" in reports is currently being reviewed by the Commission of Inquiry into Forensic DNA Testing in Queensland; As such the use/application of this phrase and similar terminology is currently being informed by the commission process, and directives from Queensland Heath Executive. The attached Queensland Health Memorandum outlines an urgent amendment to be made to a Standard Operating Procedure regarding the reporting of this type of sample. The wording outlined in the Memo has been added to the SOP and will be used to ensure witness statements are clear that further analysis may be possible in some cases. Until the completion of the commission the laboratory will not make any additional changes other than those required by Queensland Health Executive and the Commission.

*Observation 7.2.1.1 **DNA** It is recommended that the laboratory reviews page 19 of "Procedure for Case Management" (document no. 17117v21) to correct any content errors, for example "incorrect" results.*

QIS#17117 is currently in review (refer attached 17117V21.5) and has been edited; Section 6.5.2 (previously page 19) relating to incorrect results has been expanded and clarified, and will be available at the publication of the next version of the document.

*Observation 7.7.1 **DNA** For best practice, the laboratory may consider reprocessing the original reagent blanks associated with evidentiary samples if upgrading to different typing kits.*

Forensic DNA Analysis intends on implementing this practice for Y-Filer testing if/when it is validated and implemented.

It is not a standard/common practice for the laboratory to upgrade autosomal casework samples from Profiler to PP21 amplification, and as such routine profiling of negative controls for autosomal work is not required. In the rare circumstance this does/could occur it would be at the discretion of the case scientist to consider this additional rework/s if they deemed it useful for the interpretation of results. Some upgrade of reference samples from Profiler to PP21 does occur, this is so that STRmix analysis can be completed on older reference samples. Given that reference samples by nature must be single source for acceptance and reporting there is little/no risk that any contamination - if present would not be detected. As such for reference sample re-processing it is not deemed necessary to profile the negative control associated with the sample.

Kirsten

From: Samantha Granato [redacted]
Sent: Wednesday, 24 August 2022 11:23 AM
To: Daniel Smart [redacted]; Jenny McGowan [redacted]; Tony Peter [redacted] Mark Stephenson [redacted] Lesley Sharp [redacted]>; Peter Culshaw [redacted]; Sean Davis [redacted] Kirsten Scott [redacted]; Paula Brisotto [redacted] Justin Howes [redacted] Chelsea Savage [redacted]
Cc: Helen Gregg [redacted]; Samantha Granato [redacted]
Subject: Action - 18/9/2022 NATA Forensic Audit Assessment findings for Action.

Please find attached the final report. All of Major and Minor non conformances have been added in QIS as OQI's to the respective Team Leaders/Quality Coordinator to action.

Please Note - This reviewed report differs from the interim report provided at the conclusion of the visit as follows:

- Clause 7.4.2 Changed to clause 6.4.13 b)
- Clause 7.2.1.1 Clause 7.5.1 (LAD)
- Changed to clause 7.5.1 Changed from M to C
- Some editorial changes have also been made.

Reminder that all OQI's require Root Cause analysis to identify the deeper issues and to address the nonconformities identified, Responses are required back via QIS **before the 18th September** so that I can issue the final report back via the **Nata by the 21st September 2022.**

All Observation will be added to QIS by end of day as suggestions – these do no go back to NATA, so have lower priority to action.

The amended scope of accreditation will be available on the NATA website most likely by the end of the week, so please check.

Any problems or errors in QIS please just let me know.

Sam

Samantha Granato

A/Quality Manager

Forensic and Scientific Services
Prevention Division, Queensland Health

[redacted]

Chat with me on Teams

Queensland Health acknowledges the Traditional Owners of the land, and pays respect to Elders past, present and emerging.

CA-31

Department of Health

Queensland Government

MEMORANDUM

To: Helen Gregg, A/Executive Director, Forensic and Scientific Services

Copies to: Professor Keith McNeil, Deputy Director-General and Chief Medical Officer, Prevention Division and Chief Clinical Information

From: Shaun Drummond, Acting Director-General

Enquiries to: David Harmer, Senior Director, Social Policy and Legislation Branch. [redacted]

Subject: Urgent amendment to Standard Operating Procedure required

File Ref: [redacted]

It has been brought to my attention that the following wording is currently used in witness statements where DNA was in the range 0.001ng/uL (LOD) - 0.0088ng/uL:

'insufficient DNA for analysis' or 'insufficient DNA for further processing'

This wording may convey the impression that further processing or analysis is not possible. To avoid this impression and ensure witness statements make clear that further analysis may be possible in some cases, please immediately amend the Standard Operating Procedure and other guidance for staff to require that the following alternative text is used in witness statements:

Low levels of DNA were detected in this sample and it was not submitted for further DNA profiling.

The sample may have insufficient DNA to result in a DNA profile suitable for interpretation. It is possible that further testing may result in an interpretable DNA profile in some cases.

If there is a requirement to clarify witness statements already submitted that use the descriptions '*insufficient DNA for analysis' or 'insufficient DNA for further processing',* use the above wording in any clarifying statement.

Please share this memorandum with Forensic DNA Analysis Unit staff.

Should you require further information, the Department of Health's contact is Mr David Harmer, Senior Director, Social Policy and Legislation Branch on telephone [redacted]

[redacted]

Shaun Drummond
Acting Director-General
05/08/2022

CA-32

Queensland Health
Forensic and Scientific Services

Procedure for Case Management

1 Purpose

The purpose of this procedure is to describe the components of a case record, processes involved in compiling and completing a case record and tracking of case records.

2 Scope

This procedure shall apply to all Forensic DNA Analysis staff that case manage any component of a case record.

3 Definitions

AUSLAB	Laboratory Information System (routinely used prior to the FR)
Case managing scientist	The scientist(s) that has (or have) been involved in the assessment of results and compilation of the case file in preparation for statement writing or peer review.
Case record	All information relating to a particular case. This can include all case histories, receipts, communication with clients, examination notes, Analytical data, internal communications, results and reports.
CE	Capillary Electrophoresis
DAD	DNA Analysis Database
DNA Master	Repository of DNA profiling information prior to FR
DNA Mgt	DNA Management Unit – A QPS Unit that transfers the exhibit results and link results from the Forensic Register to QPRIME. They also perform quality checks on the validity of the information/results received.
EPG	Electropherogram
Examining scientist	The scientist/s who has/have examined exhibits for a case.
FR	Forensic Register – Laboratory Information Management System since July 2017.
GMIDX	GeneMapper ID-X, software used for allele designation after capillary electrophoresis
In tube	An item that has been sub-sampled by the QPS and submitted to the laboratory in a tube ready for analysis.
LR	Likelihood Ratio
NCIDD	National Criminal Investigation DNA Database
OLA	Off ladder allele
PDA	Profile Data Analysis – page in the FR to record the DNA profile interpretation and actions
Profiler Plus	AmpF*l*STR® Profiler Plus®: The amplification kit made by Life Technologies
PP21	PowerPlex® 21 system kit
Paperless	A type of case that does not involve a traditional paper case file.
PowerPlex® 21 system kit	The amplification kit made by Promega that is currently used for all samples.
QFLAG	Quality checking procedure to investigate potential staff and elimination database matches

QPRIME	Queensland Police Records and Information Management Exchange (Post 2008)
Reporting Scientist	The scientist who is responsible for writing a Statement of Witness outlining the results of a case and for presenting evidence in a court of law.
RFU	Relative Flourescent unit (a measure of peak heights in electropherograms)
SCI	QPS Scientific Officer
SOCO	QPS Scenes of Crimes Officer
SSLU	Scientific Services Liaison Unit
StatsPWG	Statistics Project Working Group
STRmix™	A statistical program used during case management to interpret certain types of DNA profiles.
UKN	Unknown DNA profile
ULP	Unlabelled allele
VAR	Variant allele
XOVER	Cross over allele, allele migrates into an adjacent marker bin.

4 Case file overview

Since the 1st of September 2009, low priority Volume Crime cases have been treated as 'paperless' and therefore do not have case files. In April 2010, paperless case management and review was expanded to also include all cases of both high and low priority (Volume and Major Crime) and some Sexual Assault cases except for cases involving excessive numbers of crime scene/reference samples or complex profiles. In April 2015 all cases are initially managed as paperless cases.

Case files are generally created

- At the time of case management (for complex cases) or
- When a statement is requested or
- When a case manager/reporter deems it necessary for efficient case management.

For cases previously managed paperlessly that become reactivated upon receipt of further items, they may be considered for conversion to a paper file. Case and examination notes (when the case was managed paperlessly) are stored in 'Paperless' folders stored in Evidence Recovery, Reporting and Admin areas.

As of 20 September 2021, case files will only be prepared by Admin team for all Sexual Assault cases and case considered to be Category 3, unless specifically requested.

If a case has been converted from paperless to paper, it is not necessary to annotate all of the EPGs with the item description or interpretations unless a statement has been requested. At such a time, the reporting scientist may continue with EPGs not being annotated as long as the casefile also includes a printout of the relevant PDA page from the FR.

4.1 How to create a case file

To request a casefile to be created, email [redacted] with instructions. Admin edit the Statement Request/Task that a casefile is being created, assign a barcode for the casefile and create a storage location (see QIS 33773 and 34248).

4.2 Additional Elements of a case file

Upon completion, a case file may also contain:

1. Examination notes
2. Diagrams, photographs and/or photocopies
3. Statistical calculations.
4. Copies of results (GeneMapper ID-X printouts).
    a. As a minimum, reference samples require the final/reported profile. Casework samples should have all EPGs printed.
5. Interpretations of results
6. Copy of statement or intelligence report
7. Records of any internal or external communication relating to the case, e.g. Casefile Notations, Requests/Tasks or emails.
8. STRmix™ output files/report. STRmix™ v2.7 and beyond, it is not recommended to include the STRmix™ report, rather a printout of the PDA page with the EPG is sufficient.

4.3 Handwritten results and corrections within a case file

As is required by NATA ISO 17025 - as case notes etc. are subject to subpoenas; no pencil is to be used in the case file (unless used in diagrams or pictorial representations).

Any calculations, interpretations or changes to notes or results must be initialled and dated by the person performing the action.

4.4 Case file storage and movement

Case files are required to be kept indefinitely as per accreditation requirements.

Exhibits are not to be stored in the case file. This includes external proficiency samples. Original QPS property tags or reference sample envelopes are also NOT to be stored in the case file.

Case file movements are to be recorded in the FR. If a case previously managed within AUSLAB is reactivated, remove the tracking from AUSLAB, create a casefile in the FR (using the same barcode) and track in the FR.

Active case files are stored with the case analyst or in a designated storage location for the work area.

Upon completion, scientists should transfer cases to Admin via the FR. Administration assistance slips are available to attach to the front of the case file to direct the storage of the file or to outline any further administrative tasks that need to be performed prior to storage. Admin In-Tray – Casefile Finish is the location from which administrative staff will track case files (sequentially) into the compactus or another designated storage location. No further administrative tasks will be carried out on these cases.

If a casefile in the custody of the case scientist is taken out of the laboratory for court, or for court preparation, movement of the casefile should be recorded as a casefile notation in the FR.

5 Workflows

5.1 Priorities

Table 1 details the DNA priorities that are used in Forensic DNA Analysis. These are not to be confused with case priorities eg. one sample may be processed as Priority 1, but the case as a whole is Priority 2 (Major Crime).

Table 1 - DNA Priorities in Forensic DNA Analysis

Priority	Description	CW Use	Ref Use
1	Urgent	Urgent	Priority/investigation
2	High Pri	Major crime	High priority
3	Low Pri	Volume	Normal

Urgent (5-day Turnaround (TAT)) cases are specifically allocated to a case scientist and/or reporting scientist as they arrive into the department. The Managing Scientist and Team Leaders will be notified of the arrival of an urgent case by email and appropriate notes will be entered. A supervising scientist will allocate to an appropriate case manager. This does not mean that the case managing scientist will necessarily become the reporting scientist should a statement be required, however this is preferred to maintain consistency in reporting.

P1 samples must be managed as soon as results become available and reviewed as soon as results are interpreted. To ensure there is no delay in QPS being informed of 5-day TAT results as soon as they are available, a workflow has been created for samples that are expected to be completed on a Friday (see QIS 23968, 33773 and 34006).

5.2 PowerPlex®21 system kit vs AmpFℓSTR® Profiler Plus® case management

Since the end of testing with AmpFℓSTR® Profiler Plus® (Profiler Plus) in January 2018, all samples are received and processed with PowerPlex®21 system kit (PP21).

This does not mean the reporting method for Profiler Plus samples is invalid; therefore, in consultation with a senior scientist, samples may be re-processed with PP21 for case consistency or only newly received items will be processed and reported with PP21 and STRmix™.

5.3 STRmix™ versions

The date of first installation and processing of cases with various versions of STRmix™ are listed in Table 2 below.

Table 2 – STRmix™ version use

Date case received	Decon	LR (at time of receival)	LR (New comparison)
19 Dec 2012	v1.05	v1.05	v2.0.6
1 July 2014	v2.0.1	v2.0.1	v2.7.0
30 Jan 2015	v2.0.6	v2.0.6	v2.7.0
16 Jan 2019	v2.6.0	v2.6.0	v2.7.0
24 June 2019	v2.6.2	v2.6.2	v2.7.0
10 Feb 2020	v2.7.0	v2.7.0	v2.7.0

13 May 2021	V2.8.0	V2.8.0	V2.8.0

If new samples are received for cases that had other samples in the case previously analysed with earlier STRmix™ versions, they are to be analysed with the current version of STRmix™. Discussion with a Senior Scientist on whether to migrate previously reported samples to the current version should be held. Some considerations include reporting in statements with the previously-used version and declare the differences between samples (if there are others processed with different versions), or convert the profiles to a format amenable to the current STRmix™ version.

5.4 Case management workflows

For the process to allocate samples and/or cases, see QIS 33773.

For worklists and information on how these are populated, refer to QIS 33773.

Allocation of cases to a particular scientist usually only happens if a statement is required, the case is large or has been assigned an Operation by QPS. These cases will otherwise be routinely case managed by the competent case managers. However, to reduce the amount of double handling by case managers, individual samples initially case managed by a particular person will be completed by the same person. This includes reworking and STRmix™ deconvolutions.

Unallocated paper case files may be stored in the filing cabinets stored in the far end of the reporting area in Block 3.

Internal controls, external and internal proficiency (where applicable), internal and external environmental monitoring samples are case managed by the Analytical, Evidence recovery and Quality teams.

Various tools may be employed to assist in meeting timeframes and to cover absence such as scheduling Outlook appointments or tasks.

6 Case management

The purpose of case management is to collate and report any DNA results that have been obtained and to prepare the case file for a statement (if required) or for peer review. To achieve this, the case managing scientist may be required to:

1. Assess DNA results to determine whether reworking is required to improve or confirm results.
2. Enter final Exhibit reports via the Profile Data Analysis (PDA) page in the FR.
3. Compile case file.

6.1 Check quality

Samples should not be progressed or reported until the various quality checks that are in place have been completed. These checks are designed to identify potential issues with samples before they are reported to the QPS.

6.1.1 Batch statuses

Check that the statuses of the processing batches are fully completed (see QIS 33773).

If there has been an issue noted during processing of a sample, the Analytical staff member/delegate will enter a status of 'See batch'. The case managers (PDA operator and reviewer) **MUST** check the batch audit and add a Sample Note to detail that they have deemed the sample OK to report.
It is acceptable that the note is added by the PDA operator or reviewer. If there is a critical element to a Batch that could affect the sample processing or interpretation strategy, and there is no note added by the PDA operator, then a discussion between the PDA operator and reviewer should occur.

Results can be released prior to the batches being formally 'passed'. In these instances, the PDA operator and reviewer will need to check the relevant batches and added a comment or sample notation to describe this.

6.1.2 Casefile Notations

Check Case Management tab in the FR for Casefile Notations and Request/Tasks (and UR notes for cases processed with AUSLAB) for relevant information related to the case. This may include information such as allocation to an individual case manager/reporter, court timeframes, communication with DNA Management etc.

6.1.3 Notations

Check for relevant information in the Exhibit Testing tables for notations and Analytical Notes (see QIS 33773), and Specimen Notes for cases processed with AUSLAB.

6.2 Check case information

Case information may be relevant to only particular samples or the whole case. This information may be used to guide the case manager's choice of processing and reporting.

6.2.1 Check for reference samples associated to the case

The presence or absence of reference samples may affect the workflow path a sample takes. If reference samples have been received for a case, these will be compared against all single source DNA profiles, and all interpretable mixed DNA profiles to generate a LR.

See QIS 33773 and 34006.

6.2.2 Check for case allocation

It is necessary to check if a case has been allocated to a particular case manager or reporter before case managing a sample.
Check the Case Management tab in the FR for details or on the PDA page, it can be viewed in the 'Case Scientist' field. See QIS 33773.
In AUSLAB (if some or all of the case was processed with AUSLAB (pre July 2017), it may be recorded in the UR notes and/or the CS page.

6.2.3 Check for paper file/case notes.

Check the Exhibit Register for a barcode created for a casefile to enable storage and tracking (see QIS 33773).

6.2.4 Check ownership of item

Ownership of an item may be required before interpretation of a DNA profile or an exhibit is sampled. If unknown, send a Request/Task to the SOCO or SCI in the first instance to obtain this information. If a response is not received in a timely manner, send a Request/Task to QPS DNA Management for the information.

6.2.5 Finalising samples no longer required

See QIS 34006.

6.3 Assess results

All samples have alleles designated as per QIS 34112.

When results become available for a sample, an assessment needs to be made as to whether reworks are required or whether sufficient information has already been obtained. This can be performed as each result becomes available. Not all results need to be available at the same time for these assessments to take place.

If viewing a case via AUSLAB and with samples processed with Profiler Plus, the EPGs were saved to AUSLAB as jpegs, or if they were samples from major crime cases, they had their EPGs saved to the P drive.

If the case was processed before implementation of the FR, the EPG PDF will be stored on the network.

To assess the stutter percentages, a worksheet or macro may be used to perform the calculation checks (see QIS 35008 or QIS 35406). The former requires manual addition of the alleles and peak heights to calculate the stutters, and the latter spreadsheet uses a macro to calculate the stutters after importation of the STRmix™ text file generated by the FR.

If performing a multi-kit analysis of stutter, QIS 36045 may be used.

6.3.1 Assess the number of contributors to the DNA profile

The number of contributors to a DNA profile is required to perform interpretation. Counting the number of alleles at each locus (above and below Limit of Reporting threshold, above Limit of Detection) is the first step in assessing the number of contributors.

However, counting called alleles alone may not be suitable in determining the number of contributors due to the presence of PCR artefacts such as stutter. Allelic imbalance (AI) also known as heterozygote balance (Hb) can also be used as an indication of the number of contributors. Forensic DNA Analysis does not have a threshold for AI for casework DNA profiles because STRmix™ is designed to model the heterozygote balance as a continuous system. Although internal validation studies (Nurthen et al 2013) indicate that the calculated

AI threshold varies depending on the DNA input, the values detailed in the study can be used as a guide.

See Appendix 1 for a workflow designed within the internal Change Management project #149 to assist in deciding on a reasonable number of contributors to the DNA profile. Note that the stochastic range in RFU values will be different depending on the CE instrument. The workflow is a guide only.

The validated stutter thresholds (as published in QIS 34112) are used as a guide to aid in the determination of number of contributors to a DNA profile.

6.3.2 Assess the overall quality of the DNA profile

The quality of the DNA profile in conjunction with the number of contributors will determine if a DNA profile is suitable for interpretation.
The following factors should be considered

1. Whether a reasonable assumption of the number of contributors can be made.
2. The degradation slope (the tendency for higher molecular weight loci to have lower peak heights compared with smaller molecular weight loci).
3. The total amount of DNA input used in the amplification
4. Adverse events affecting the sample.

6.3.3 Check VAR/OLA/ULP/XOVER calculations

If a variant and/or off ladder allele or stutter has been observed on a GeneMapper ID-X (GMIDX) profile it is not necessary to re-amplify to confirm its presence.

For mixed DNA profiles with variant and/or off ladder alleles, the repeat of these samples is at the case manager/reporter's discretion. Things to consider include whether the profile with variant and/or off ladder alleles has already had this questioned allele confirmed, matches a deconvoluted contribution, or if the sample description suggests the mixed DNA profile could be conditioned on the reference DNA profile (with variant and/or off ladder alleles).

A case manager must independently perform the calculation for allele designation including if the calculated allele falls in the stutter position. Refer to QIS 33773.

Variant/OLA/ULP/crossover calculations do not require checking if the DNA profile has been assessed as unsuitable for interpretation.

If there are broad peaks observed in the EPG and the sample has not been Re-CE'd, the case manager may order a Re-CE. This is especially important if the DNA profile is to be assessed by STRmix™, or if the case manager determines that the broad peak could be masking other peaks such that it may affect the number of contributors assessment.

6.3.4 NAD samples

If a sample is flagged as No Analysed Data (NAD) at CE quality checking stage, the sample will be re-prepared by Analytical staff.

6.3.5 Edit DNA profiles

See QIS 33773 and 34006.

6.3.6 Rework DNA extract if necessary.

For processes relating to ordering reworks, see 33773.

See Appendix 2 for information on reworking strategies and considerations when assessing sample information and profiles.

If a sample was completed in DNAMaster/DAD and AUSLAB, any subsequent reworks that are required are requested in the FR.

As of 30 June, 2019, any rework on a previously reported Major Crime (Priority 2) result is not to be ordered without Managing Scientist or Executive Director authorisation. A MS Form can be used to provide information to the Managing Scientist of Executive Director to assess the reasons for the rework, and the potential risks associated with proceeding (or not proceeding) with a requested rework. This form can be accessed via Office 365, then selecting MS Forms. The operator fills out the details in the DNA Rework Authorisation form. After submission, the form then goes to the Team Leader for consideration and endorsement prior to the Managing Scientist (or Executive Director) for final consideration.

In 2008, QPS in conjunction with Forensic DNA Analysis decided that for Low priority Volume Crime (Priority 3) cases, samples are only to be reworked via re-amplification, or Re-CE'ing until 12 alleles are obtained (National Criminal Investigation DNA Database-NCIDD uploading threshold). NucleoSpin cleanups or Microcon concentrations are not to be ordered on low priority samples, unless in exceptional circumstances. Other valid reasons for reworking these samples include investigations of adverse events or if other quality issues are suspected.

If a partial profile or NSD profile is obtained for a sample, an assessment should be made as to whether reworking that sample will be beneficial or if there are other profiles within the case that satisfy reporting requirements.

Amplification products are not kept indefinitely. The availability of a PCR product should be checked prior to ordering a Re-CE. For more recent batches, the Analytical Section enters audit notes against the amplification batch when the PCR product has been discarded.

Rework strategies:

Any process that is likely to exhaust all the DNA extract is required to have written approval from QPS to proceed prior to the process being conducted. The aim is to not exhaust samples, and only to do so with QPS approval in writing.

If it is determined that a better profile is required, the following should be considered when determining the best rework strategy:

1. **The type of sample**
   e.g. blood versus cells. Due to the generally high number of nucleated white cells in whole blood, a DNA profile is usually obtained from such samples. If a DNA profile is not obtained, this may be due to insufficient nucleated cells in the sample, or

could indicate an issue with the efficacy of the processing, or it could be that the sample is inhibited. Reworks may assist in obtaining an interpretable profile.

2. The Quantitation value

The quantitation value is displayed in the FR. The quantitation value is an estimate and should be assessed in conjunction with other factors. Sample workflows based on the quantitation value are listed below:

1. PP21 samples with a quantitation value <0.001 ng/µL will not be further processed and will be reported post-quant with the result line 'No DNA detected', regardless of priority.
2. Samples reported as 'No DNA detected' or 'DNA insufficient for further processing' prior to 6 June 2022 can be requested by QPS for further processing via the Request/Task system to the senior scientist of the Analytical section.
3. Priority 1 and 2 PP21 samples with an initial quantitation value of between 0.001ng/µL and 0.0088ng/µL are automatically-microconned to 35µL. If a scientist considers the DNA profile obtained would benefit from a second amplification, a Request/ Task should be sent to the relevant Forensic Officer.

As per direction on 19 August 2022, issued as a Memorandum from the A/Director-General Qld Health, Priority 2 samples in the range 0.001ng/uL to 0.0088ng/µL will undergo an automatic Microcon concentration step to 35uL. If the scientist considers it might be beneficial for a second amplification after the Microcon process, written approval is required from QPS due to point that there would be a full consumption of the DNA extract after this second process. See Appendix 3.

To seek approval from QPS, a Request/Task should be sent to the relevant Forensic Officer, with the relevant crime scene barcode linked. Suggested wording for the Request/ Task should be:

Hello, a DNA profile has been obtained from the linked crime scene sample. I am seeking approval for additional work to be undertaken on the sample, in an attempt to obtain a suitable DNA profile for interpretation. Please be advised if this additional work is approved, the DNA extract will be consumed. This means there will be no opportunity for further processing in this laboratory, or elsewhere if alternative technologies are under consideration. We understand that consultation with the Investigating Officer may be necessary and will await the outcome of those discussions. Once finalised, please advise via return Request/Task if the additional work is approved. If approval is not provided, the DNA profile obtained will be reported.

When sending the Request/Task, the exhibit result line 'SOHAA – Sample on hold, awaiting advice' should be added, and validated by a second operator.

When QPS respond, the exhibit result line 'TRQ – Testing restarted on advice from QPS' should be added irrespective of whether approval for further processing has been granted or not. The result will either be reported based on the one amplification result, or will be reported after the further processing.

Priority 1 samples in the range 0.001ng/uL to 0.0088ng/µL will have an automatic Microcon concentration to 35uL prior to amplification.

Samples reported as 'No DNA detected' or 'DNA insufficient for further processing' prior to 6 June, 2022 can be requested by QPS for further processing via the Request/Task system to the senior scientist of the Analytical section. For these samples, they will have an automatic microcon concentration prior to amplification.

Priority 3 samples continue to not have reworks performed unless in exceptional circumstances. If requested to be restarted, the exhibit result line of 'TRQ- Testing Restarted upon QPS advice' should be added as a result. After the final result is obtained, these are entered as per standard arrangement. 'Sample undergone further processing (SUFP)' does not need to be added if TRQ has been previously added. If the TRQ line had not been added at point of request, SUFP should be added at the same time as the final results.

A partial or NSD profile from a sample with a high quantitation value may indicate inhibition or may be due to degradation. The Degradation Index is available within the Quantification data and provides an indication that degraded DNA may be present. It should be noted that while quantitation values can be used as an indicator for the presence of inhibitory compounds in an extracted sample, lack of inhibition in a quantitation amplification (as indicated by the IPCCT and possibly the CT as well) does not necessarily mean there will be no inhibition in an STR amplification. This is because different primers, target DNA and amplification conditions are used in each reaction and this could result in inhibition to one reaction and not the other. Also, 2 µL of extracted sample is added to a quantitation amplification, whereas in an STR amplification the sample may be diluted before being added (which would decrease the concentration of any inhibitory substances in the amplification reaction). Up to 15 µL of DNA extract can be used for a PP21 amplification (which would change the relative concentration of inhibitory substances in the amplification reaction). Further information on DNA quantification is found in QIS 34045.

3. The number of alleles obtained

A full DNA profile is the aim of any DNA amplification, but a partial DNA profile does not necessarily need to be reworked.

The minimum number of alleles required to upload to NCIDD is 12 alleles. Samples below this stringency, but above 6 alleles, may be loaded to NCIDD under special circumstances and searched against the database (refer to QIS 34246 and 33773).

If an assumption of a single contributor has been determined, partial DNA profiles do not have to be reworked to obtain a full DNA profile.

4. Examination notes

Certain substances are known to be inhibitory to the PCR process. This includes a variety of commonly encountered substances, such as dyes used in clothing (particularly denim dyes) and some biological material (in particular, the haem in blood). If managing a case where semen samples were extracted with Chelex – for example, if the case is reactivated for further processing - these samples were sometimes observed to return an NSD profile after initial extraction with no indication of inhibition. Performing a NucleoSpin clean up was noted to improve the chances of obtaining an interpretable DNA profile for these samples.

5. **Offence Details (if available)**
   Information from the QPS entered into the FR, present on item packaging, or from case conferences may assist in determining the evidential value of a particular item.

6. **Results already obtained**
   If multiple samples have been submitted for an item and one or more full profiles or mixtures have already been obtained there may be no need to continue reworking other samples from that same item. A partial 'matching' profile is often sufficient if other better profiles already exist for the same item. This must be considered carefully and in the context of the case. If it is a possibility that there may be a different profile present, such as in the case of multiple offenders, then reworks should be considered.

6.4 Manage samples

The sample management tab in the FR contains the worklists relevant to PDA entry and review (see 33773 and 33744).

Cases are not usually allocated to an individual case manager/reporter. The exception to this rule may be some urgent cases, QPS operations, linked cases or sensitive matters. Samples are case managed by staff from the worklists in the FR.

Cases with paper files may have EPGs annotated with the results and interpretations, although if the PDA page is also printed, this may be not required (see 33773). If annotated, as a minimum, the type of DNA profile, e.g. single source matching UKM1 is required. These annotations need to be signed and dated by the case manager.

6.4.1 Interpret

6.4.1.1 Paired Kinship/Paternity Trios

Any samples for Paternity trios etc. are interpreted as detailed in QIS 25303.

Reporting of the analysis outcomes is detailed in QIS 34006 and QIS 34308.

6.4.1.2 PP21 interpretation

Statistics for PP21 results are generated by the STRmix™ program as outlined in QIS 35007.

If a sample has replicate amplifications they must all be included in the STRmix™ deconvolution unless they have a particular processing issue such as excess peak heights and pull up, a Re-CE has been performed, or the runs are not consistent with each other (at the discretion of the case manager). A Re-CE and the source amplification results cannot be included in the same deconvolution as they come from the same amplification, a choice as to the best or most appropriate run must be made by the case manager and replaces the less informative result. At a minimum, a Sample Note should be added to explain why particular amplifications were not included.

All reference samples received for a particular case are to be compared against all interpretable mixtures (to generate a Likelihood Ratio - LR) and single source samples within a case.

The number of contributors will have been determined as per section 6.3.1 above.

STRmix™ V2.7 and beyond uses a stratified approach to reporting the Likelihood Ratio where the relative proportions of the population are factored into the final LR.

Single source DNA profiles

Deconvolution with STRmix™ is required if:

1. The sample is the first single source DNA profile that matches a reference sample and needs to be loaded to NCIDD, or
2. The sample requires loading to NCIDD (e.g. UNK), and/or
3. This DNA profile has less than 32 allelic peaks. The count of peaks is such that homozygous loci are counted as one peak. It is only through STRmix that single-peak loci are determined to be homozygous.

LR generation with STRmix™ is not required for single source DNA profiles:

1. If a reference sample does not match the single source sample.
2. If a matching reference sample has previously had an LR generated (and the new interpretation would not be more probative).
3. If the single source DNA profile has 32 or more allelic peaks, the sample can be reported with the appropriate result line (as per QIS 34229) and doesn't require deconvolution and an LR generated as per the recommendations in the document 'The determination of the threshold number of alleles, above which single source DNA profiles can confidently be ascribed a likelihood ratio in excess of 100 billion.' [Parry et al 2014] and further Risk Assessment after moving to STRmix™ V2.7.0.

If a single source DNA profile has one peak at a locus and another peak is visible sub threshold, STRmix™ may designate the locus as a homozygote (with a ≥99 % weighting), the case manager should consider ordering a rework in an attempt to amplify the second peak.

Homozygote alleles for single source samples that will not be loaded to NCIDD do not require editing in the FR PDA page.

A mixed DNA profile would be reported as a single source profile with sub-threshold peaks using the appropriate exhibit result line in the following circumstances:

1. If the only indication of a mixture is a labelled Y peak at Amelogenin or
2. If the only indication of a mixture is a labelled Y peak at Amelogenin and sub-threshold peaks that do not affect the called alleles.

This is done because STRmix™ cannot 'see' Amelogenin or sub-threshold peaks and the low-level contribution does not affect the interpretation of the 'single source' profile.

Further guidelines on Single Source interpretation is located in Appendix 2.

Mixed DNA profiles (two, three, four person mixtures)

Deconvolution with STRmix™ is not required if:

1. The case does not have any reference samples and the profile is not likely to be deconvoluted by STRmix™ into contributions for NCIDD, or
2. The case does not have any reference samples and if the DNA profile is likely to be deconvoluted into a contribution that matches an already reported unknown in the case.

If reference samples are later received then the deconvolution will be run and these reference sample profiles will be compared against the mixture and the LRs reported back via exhibit result lines.

Deconvolution with STRmix™ is required for all other two, three and four person mixtures.

Deconvolutions of mixed DNA profiles may run for extended periods of time. Additional support is provided by other staff in Forensic DNA Analysis (mostly Forensic Technicians) to run deconvolutions on dedicated STRmix™ computers. This releases Reporting Scientists' computers for other tasks.

To have another staff member run a deconvolution, see QIS 33773.

Conditioning mixtures

It may be possible to condition mixtures from intimate swabs and items (said to have come from a person). The decision to condition is at the discretion of the case manager (and reviewer). Additional information regarding ownership may be required.

Table 3 – Quick reference when to use STRmix™

Scenario	Decon	LR
SS <32 & matches assumed known contributor	No	No
SS <32 & matches a reference sample	Yes	Yes
SS <32 & new Unknown profile & NCIDD	Yes	N/A
SS <32 & matches an Unknown profile	No	N/A
First SS >32 DNA profile & matches a reference sample & NCIDD	Yes	No*
First SS >32 DNA profile & matches a reference sample no NCIDD	No	No*
SS >32 DNA profile & new Unknown profile & NCIDD	Yes	No
Subsequent SS >32 DNA profile and matches a reference sample/Unknown profile	No	No*
2P to 4P & no reference samples & not likely to resolve for NCIDD	No	N/A
2P to 4P cond & no other reference samples & not likely to resolve for NCIDD	No	N/A
2P to 4P & reference samples	Yes	Yes

*Where matching a reference samples, a Likelihood Ratio is not calculated in these instances, but they are reported in the FR as >100 billion favouring contribution.

STRmix™ results output

After the STRmix™ deconvolution and/or reference comparison has been completed and processed, the following quality checks must be performed on each result produced by STRmix™.

1. STRmix™ version
2. Casework sample number is correct
3. Reference sample number (if any) is correct
4. Number of contributors assumed to be present is correct
5. Casework DNA profile (correct allelic designations entered and correct run(s) have been included)
6. Individual locus LRs appear have an intuitive fit
7. Check all loci had successfully deconvoluted (component interpretation complete)
8. Check that the Diagnostic tools are all performing to expectation
9. Settings values (especially check full vs. half variances)

10. Reference DNA profile (correct allelic designations entered)
11. The overall LR is reasonable given the reference and casework DNA profiles

It is important when a STRmix™ analysis is carried out, that the results are interpreted by examining the weightings of various genotypes and the DNA profile(s) observed. There are instances when the results obtained do not intuitively seem correct. Sometimes (particularly if the model must account for drop-in) the failure of the Markov chain to properly converge means that some parameters will not have optimised properly. Examples of this are:

1. Large LRs are obtained for each locus, except one where the LR is low or 0
2. The mixture proportions do not reflect what is observed
3. The degradation does not reflect what is observed
4. Genotype combinations do not reflect all likely allele sets (especially likely if sub-threshold peaks are present at a locus)
5. The probability of dropout at a particular locus has been given a low value but sub-threshold peaks are clearly visible in the DNA profile.

Effectively, a zero LR means that the genotype of the POI has not been accepted by the MCMC at any time through the course of the analysis. Common causes for making a genotype an unlikely contributor are large dropouts, drop-ins or imbalances, or when the peak heights at a locus exceed the general degradation slope (and are therefore penalised). If further iterations are chosen, then the MCMC will have more opportunity to accept the less supported genotypes, however a reference sample with a poor fit to the DNA profile will still have a low LR for a particular locus or loci. It is best practice to attempt to resolve the mixture biologically first, that is through rework, prior to resorting to increased iterations.

It is possible that the deconvolution does not fit with the intuitive assessment of the DNA profile, e.g. there is a clear major profile but the deconvolution has not resolved C1 (Contributor 1) to ≥99%. There are a number of reasons why this may occur including there being insufficient accepts to enable STRmix to converge on the best probability space. In this instance, the user can increase the number of burnin accepts and post-burnin accepts by a factor of 2 (to 20,000 and 100,000 respectively) in the run settings when setting up the deconvolution.

If it is noted that the EPG has a plate reading error, such as a stutter peak that has been inappropriately removed or an artefact that has been left in, then the sample can be edited in the FR and EPGs manually edited as per QIS 33773.

It is not necessary for STRmix™ v2.6 (and beyond) cases to have the STRmix™ report printed and included in the casefiles. A printout of the PDA page and EPG is sufficient. All cases have the pdfs imported and retained in the FR (see QIS 33773).

Repeated Analysis

Each time a DNA profile is analysed using STRmix™ the results will vary slightly. This is a natural consequence of the random nature of the Monte Carlo property. To be as unbiased as possible, each analysis should only ever be run once and the result reported. If a STRmix™ result has been generated for a DNA profile at case management stage, then that same result should be the one used for statement writing. If additional reference samples are received in the case, the reference sample(s) should be run against all original deconvolutions for all samples in the case where mixtures are present. The exception to this is when an analysis has produced a result that requires further investigation and hence further analysis or if the underlying assumptions made about the profile have changed (eg. a two-person mix is reassessed as being a three-person mix).

Consequently, if at review or at a subsequent stage in reporting it is decided that a different number of contributors better fits the DNA profile, the deconvolution for that sample can be rerun using the new assumption. Case-managers/Reporters should discuss any decision to change a reviewed result with the original operator/s. For High Priority samples, if a rework after a result has been released, this will need Managing Scientist or Executive Director approval (see 6.3.6).

If multiple analyses have been conducted, then only the STRmix™ results from the most appropriate analysis should be reported (e.g. the higher number of acceptances or the more appropriate number of contributors). If there are printouts of the STRmix™ results in the casefile, the previous results will need to be removed.

The electronic STRmix™ results from the multiple analyses that are not used must be moved into a sub-folder labelled "Do not use" in the case folder in the STRmix™ results folder.

Use of Ignore Loci function

In certain circumstances a particular locus or loci may be dropped from the interpretation. These include where a Tri-allele pattern has been observed in a reference profile and inconsistent sizing of an allele is observed. See QIS 35007.

If a case has a reference sample with a mutation, all scene profiles within the case (except single-source profiles that do not match the reference sample in question) should have the loci removed from the interpretation. If the reference sample is received after the initial deconvolution was performed, the deconvolutions should be repeated with the relevant locus/loci ignored.

Amended Results

If an amended result is required to be released, this should be accompanied by an Intelligence Report (in most circumstances as per QIS 33773) and cleared by the Managing Scientist or Executive Director prior to release.

6.4.1.3 Profiler Plus interpretation

Since January 2018, Profiler Plus DNA profiles were no longer produced by Forensic DNA Analysis. Samples may still be added to statements (if requested) and reported in a binary fashion. This difference should be explained in the statement of witness.

Samples that are processed with Profiler Plus are not interpreted using STRmix™ as this system has not been validated for use with Profiler Plus data.

See QIS 33773 for the use of the FR in reporting Profiler Plus DNA profile interpretation results.

6.5 Report Results

All results are to be communicated as outlined in QIS 23968 and 34308.

Statements and intelligence reports are to be prepared according to QIS 34006 and 34308.

For cases processed and previously reported via AUSLAB, all new items received and/or updated interpretations should be reported via the FR.

If a sample cannot be explained by one of the result lines available, an intelligence letter should be sent to QPS to outline the interpretation. See QIS 34308.

When reporting 4p mixture interpretations where the LR is in the in the range 2-1million favouring contribution, a result is acceptable to be reported via Request/Task in the FR by using the following process:

- PDA Reviewer to ask for the Request/Task when reviewing the sample,
- Using a template (below), case manager/reporter to direct a Task to the reviewer with the information,
- PDA Reviewer directs to Sgt DNA Results Management Unit at same time as reviewing.

- Template to use:
- *Sample barcode: XXXXXXXXX*

- *Result reported: Mixed DNA profile*
- *LR reported: Mix – Support for contribution 2 to 1 million: Person barcode YYYYYYYYY*
- *Actual LR: [number]: Person barcode YYYYYYYYY*

6.5.1 Exhibit Result lines

See QIS 33773 and 34006 for details on how to report result lines in the FR.

For urgent/Priority 1 samples only, an interim exhibit report may be entered.

6.5.2 Exhibit Result line updates and amendments

Exhibit result lines may require updating after additional information is available or additional testing has been completed. Commonly, these lines are updated after a reference sample for the case has been received and new information needs to be sent back to QPS eg. the profile is now to be 'conditioned'.

If the DNA profile has undergone further work and the result line 'SUFP: sample undergone further processing' has been used, the final interpretation result lines need to be added to the FR at the same time and supersede the previous result lines. This means all lines need to be added that are relevant to the updated DNA profile interpretation.

If an incorrect result is detected, the result line must be marked as 'incorrect' by Senior Scientists or Team Leaders. See QIS 33773 and 34006.

The correct result should be added and reviewed at the same time as marking the previous result as 'incorrect', (see QIS 34006).

If an Intelligence Report is required to be sent to the QPS Inspector of DNA Management Unit to explain an incorrect or amended result, this report needs to be initially sent to the Managing Scientist for awareness. See 34308 for a template for this report.

6.5.3 Suspect checks

If a suspect check has been requested by QPS for a reference sample profiled in Profiler Plus and the sample is not intuitively excluded from the mixture, the reference sample needs to be reworked in PP21 to increase the amount of data available for comparison.

Instructions for reworking reference samples are documented in QIS 34245.

Suspect checks have reserved Exhibit result lines for reporting; refer to QIS 34229.

LR reports from STRmix™ for Suspect Checks need to be retained in the FR. These can be attached as a sample notations for the crime scene sample, or attached to the Result line pertaining to the LR outcome for the comparison.

6.5.4 Samples with undetermined quantitation values or insufficient DNA

It is understood by QPS that samples reported post-quant as 'No DNA Detected' and for samples reported prior to 6 June 2022 as 'DNA Insufficient for further processing' can be requested for processing at any time.

This request for further processing is made by the QPS sending a Request/Task to the Senior Scientist of the Analytical section to reactivate the sample for processing.

Similarly, case managers may at their discretion order a rework in cases where low quants for samples are obtained.

6.5.5 Paternity Samples

For paternity cases, results are reported via the barcode for the child (see QIS 33773).

If the putative father sample is an intelligence sample, the relevant result line would be 'Intel report required for further Interpretation'. The Intel Report is issued as per QIS 34308.

6.5.6 Using Coronial samples as Reference Samples in Exhibit results.

If a sample has been processed with casework conditions is to be used as a reference sample, it needs to be deconvoluted in STRmix™ because there is no homozygote threshold. This deconvoluted DNA profile is used as the reference in all comparisons.

6.5.7 Using Covert samples to compare to DNA profiles

Covert samples are ones that have been identified by the QPS as being taken in lieu of a official reference sample. Covert samples are treated as crime scene samples and can present to the laboratory as items such as straw swabs, swabs of drink containers and cigarette butts, among others.

The DNA profiles obtained from these covert samples may be requested to be compared to specific, or all crime scene samples. The results of these comparisons should be entered in an Intelligence Report and issued to QPS DNA Management Section, unless specifically informed otherwise.

See QIS 34308, 33773 and 34006.

6.5.8 Intuitive Exclusions

Mixed DNA profiles assumed to be from two contributors may have reference samples intuitively excluded where alleles are higher than 250RFU.

Scientists interpretating these profiles may select to run all reference sample comparisons through STRmix; however intuitive exclusions should be considered first.

The following should be considered when performing an intuitive exclusion:

- Peaks in stutter position should not be used in isolation to exclude
- It is best to intuitively exclude on peaks that are distinct and isolated from those in stutter position and they must be above 250RFU

7 NCIDD

Case managers are responsible for choosing a representative profile for each unique profile seen within a case for upload to NCIDD. These profiles must have at least 12 alleles for NCIDD matching.

To upload an allele to NCIDD for PP21 samples, a 99% deconvolution is required at a locus as per the Statistics Project Working Group (StatsPWG) recommendations.

- ≥99% deconvolution at all PP21 loci is known as a 'full' NCIDD load
- ≥99% deconvolution at ≥ 12 PP21 loci is known as an 'Intel' NCIDD load.

In certain circumstances, a profile with less than 12 alleles (including sub-threshold information) can be loaded to NCIDD, and any matches will be reported back to QPS via an Intelligence report written by the case scientist or Intelligence Team member. This is an

intel/upload process and is not for court purposes. Intel/NCIDD work does not get heard in court unless special authorisation is given by the Judge/Justice due to potential to prejudice court.

Only one representative DNA profile is loaded to NCIDD for a person in a case. Profiles that match known deceased persons or complainants in sexual assault cases are not to be uploaded to NCIDD. By the same rationale, unknown DNA profiles previously loaded to NCIDD that match known deceased and sexual assault victims are also removed from NCIDD. Refer to QIS 34246 and 33773.

7.1 Conditioned DNA profiles loading to NCIDD

After a mixed DNA profile has been conditioned in STRmix™, the deconvolution will list that each conditioned allele has been deconvoluted to 100%, a conditioned component of a mixed DNA profile can be loaded to NCIDD provided that :

- The upload alleles are able to be visually separated (i.e. major or minor)
- Upload matching alleles in an even mixture where there is a strong representation

Do not upload contributions from low level mixed minors where we may be confident enough to condition but not load to NCIDD.

8 Peer review

All results must be peer reviewed prior to release to the QPS. Peer review can be at a sample level or case level, Technical or Administrative (see QIS 34322 and 34006).

Peer review of 'No DNA detected' is usually performed by a competent Analytical Section staff member.

8.1 Difference of Scientific Opinion

Through the review process, either at PDA stage or statement stage, a difference of scientific opinion between competent scientists may occur.

Refer to QIS 36061 for workflow arrangements should this be experienced.

9 Reference sample management

Refer to QIS 34245.

10 Case Managing a file with a 'Just in Case' SAIK

'Just in Case' (JIC) kits are sexual assault investigation kits that are distributed to Pathology Queensland (PQ) Laboratories and are used in instances where a patient has disclosed a sexual assault but are not ready to involve police. A forensic examination can be requested "Just in Case" a police complaint may be made at a later date.

The JIC kits include swabs in a tamper evident bag (similar to standard SAIKs), pathology request form, JIC consent form and chain of custody form.

The JIC kits are registered in AUSLAB (Pathology) by Pathology Queensland and received at Forensic Property Point (FPP), FSS within AUSLAB (Pathology) and electronically tracked.

FSS will hold the JIC kits for 12 months, at which time they will be destroyed if the complaint has not progressed.

If the complaint progresses, the JIC kits will be registered in the Forensic Register (FR) by the Queensland Police Service using a barcode allocated by FPP. This may be different to the Pathology Queensland allocated barcode, as FR cannot currently accept the series 2 ten digit barcodes. The AUSLAB audit trail and notation in the FR will link these barcodes.

FPP will enter into the FR the delivery officer details as per the initial AUSLAB (Pathology) entry, with appropriate notes regarding the date and time fhe samples were originally received. The AUSLAB (Pathology) audit trail will be scanned to the FR. NB. the test code "TRAIL" in AUSLAB will output the entire audit trail for the case into a report.

At statement stage, the original barcode assigned by Pathology QLD and date received at FPP should be listed as received date and barcode with (SAIK [identifier]) listed next to it.

Testing will proceed through standard examination and analysis within Forensic DNA Analysis.

The consent form, pathology request form and Chain of Custody form will be scanned into the FR.

Refer to https://qheps.health.qld.gov.au/hsq/forensics/response-to-sexual-assault for more information.

11 File compilation

11.1 Suggested order of pages (from top to bottom)

1. Case file particulars page (QIS 34307)
2. Copy of final statement (if written)
3. Most recent printout of casefile notations, emails*
4. Exhibit Register list
5. Reference samples – receipt page then profile
6. QP127 (if available)
7. Examination notes:
    i. Description of item
    ii. Diagrams
8. Photos/photocopies/packaging/envelope images*
9. DNA profiles (EPGs)
10. Statistical calculations (if applicable)#

* these items are not required to be printed if the case is not going to court
# STRmix™ v2.6.0 (and beyond) deconvolution and likelihood Ratio reports are not necessary for casefiles. The PDA page may be substituted as it displays the LRs.

11.2 Page numbering

Only cases that are going to court (Statements of Witness or Evidentiary Certificates) need to be page numbered. Assistance is available from the Administrative Team for page numbering.

1. The Case File Particulars page is always Page 1 (except upon reactivation when the additional Case File Particulars page will be numbered page 1 and the original Case File Particulars page will be renumbered as the next consecutive number in the case file).
2. Case Files are numbered from the back of the case file to the front.
3. Number and initial each page, including the reverse of the page if both sides have been used.
4. Ensure the Case number is recorded on each page.
5. Write the total number of pages on the front of the case file and initial and date as indicated.

For those cases that aren't going to court, the total number of pages simply needs to be counted and noted on the front of the case file, that is, each individual page does not need to be numbered.

11.3 Statement compilation

Refer to QIS 34006 for the correct format for statements or reports issued by Forensic DNA Analysis.

11.4 Preparing a case file for peer review

Prior to submitting a case file for final review or prior to a statement being issued, the following is required:

- Ensure that all items/exhibits have been examined or prioritised appropriately.
- Ensure that appropriate reworks have been performed.
- Establish whether further testing needs to be performed
- Ensure that all samples are finalised
- Samples that have been reported as 'No DNA detected' or 'DNA insufficient for further processing' need to be documented in the case file. This can be done by either printing the PDA page, annotation of the receipt or annotation of the packaging image.
- All profiles have been printed and included in the case file. It is not necessary for EPGs within a casefile to be labelled, instead a copy of the PDA page can be printed to accompany the EPG(s). The PDA page contains all of the sample and interpretation information and can be associated with the EPG via its barcode.
- Ensure that appropriate profiles have been selected for upload to NCIDD. Only one example of each profile is to be loaded to the database.
- Ensure that the reference sample receipt is printed for each evidence sample (AUSLAB only).
- If there are multiple EPGs for a particular reference sample, only the reported profile need be printed and annotated as the final profile.
- Ensure that all evidence samples associated with the case are present.
- STRmix™ printouts for all cases that used this program for statistical calculations. It is not necessary to print the report for STRmix™ v2.6.0 (or beyond) as it contains a large number of pages; a printout of the PDA page and EPG is sufficient.

- For Profiler Plus cases: if a statement has been requested, ensure that profiles requiring a genotype frequency have had the statistical calculation performed through the Kinship program (see QIS 25368) and that the results are printed and included in the file. Any mixture interpretation pages, including Popstats where appropriate, must be included in the casefile.

12 Working Remotely

See QIS 34006 for writing and reviewing statements from a location other than at work (eg. working from home).

In these situations, printed casefiles with all contents may not be necessary unless a court requirement eventuates. Casefiles will be needed to be created to contain, at the very least, the hard-copy of the Statement of Witness to enable tracking to occur in the FR.

At times where actions are performed (or not performed) that differ to the standard approach to casefile compilation, these actions should be recorded as casefile notations in the FR.

13 Case file management off-site

When case files are required for court appearances they should be tracked to the Reporting Scientist in the FR.

If a file is taken off-site (in exceptional circumstances eg. flight for court evidence outside Brisbane), then a casefile notation should be added to the FR to detail this occurrence.

14 Reactivated cases and cases requiring updated interpretations and testing in external laboratories

14.1 Reactivated and Cold Case Management

On occasion, some cases require further work after they have been finalised and reviewed. In compiling cases that were previously managed with AUSLAB, it is recommended to print UR notes and any associated communications for the reactivated case, and commence tracking within the FR (QIS 33773).

An assessment of previously reported and uploaded profiles should be undertaken. In July 2007, it was decided (in conjunction with QPS) that all crime scene profiles (except Known Deceased and complainants in sexual assault cases) would be uploaded. Prior to this any crime scene sample that matched a complainant profile for any case type was uploaded to NCIDD.

New evidence samples received for a case which has been profiled using Profiler Plus will be profiled using PP21. It should be discussed with a Senior Scientist or Team Leader and in consultation with DNA Management as to whether the case is transitioned to PP21 profiling.

Any interstate person samples submitted for analysis by the DNA Management Section (QPS) that have been obtained from people located interstate are to be treated as Evidence samples (as per advice from the QPS).

If a case is reactivated for attention, a Request/Task is usually sent to the Team Leader. The case may already have been allocated to an existing staff member or can be considered for allocation to a new case manager.

The reactivation may be for a number of reasons including, but not limited to:

- Check into property holdings at FSS;
- Check into any remnants of testing still held at FSS (ie. spin baskets, extracts);
- Check into what volumes of extracts may remain for consideration of profiling at FSS, or at an external facility;
- Seeking advice on potential for external testing (extract volume and reference sample dependent);
- Request for a copy of the casefile as held at FSS (QIS 34248).

If samples were quantified prior to 04 November, 2015, they would not have been processed with Quant-Trio. These samples would benefit from a re-Quant with Quant-Trio so that the indicators of Degradation and Y-Quant are obtained.

If new samples are received for these Cold Cases, these are usually accompanied by a request for 'Quant and Hold' (see QIS 33773 and 34006).

In some instances, it may be possible upon consultation with QPS Homicide Cold Case Investigation Team Forensic Co-Ordinator to pool samples from the same parent item. Consideration of whether to pool prior to profiling, or after profiling can be discussed. DNA profiling of the sample/s may be before, or after a microcon post-extraction step. Pooling samples may hinder the ability to obtain a usable DNA profile if one sample is complex, or has raised a Quality Flag.

14.2 Testing in other laboratories

Consideration of further profiling interstate or overseas can be made:

- Highly sensitive DNA profiling, using Minifiler and LCN technology, may assist degraded or low-level DNA profiles. The Institute of Environmental Science and Research (ESR) in New Zealand offers this testing.

- Y-STR profiling is performed in most other Australian jurisdictions, and in New Zealand. This technology may be useful if there are male reference DNA profiles, and the DNA profile has a quant value associated to the Y-Quant from Quant-Trio.

- Mitochondrial DNA profiling may be useful if the sample is likely to be single-sourced. This technology is useful for samples that are highly degraded or aged eg. recovered skeletal remains. Currently, Victorian Institute of Forensic Medicine (VIFM) offer this profiling service. This technology may be useful if there are males or females from the same maternal lineage.

If testing for certain samples has been approved to be conducted in other jurisdictions, the appropriate discussions and authorisations with QPS DNA Management should be retained in the FR.

Approvals and packaging process is outlined in QIS 30917.

If a casework sample is processed in another jurisdiction, it should be reported in a statement by that testing laboratory. Reference sample data (including EPG) may be requested by this reporting jurisdiction, which can be sent via DNA Management Unit.

If a casework sample is processed in QLD and Reference sample data is received from another jurisdiction, this should be reported to DNA Management Unit via Intelligence Report.

15 Records

1. Case file records – the location of paper case files is recorded in the FR, or for pre-FR cases, this is recorded in AUSLAB.
2. Paperless case examination notes - all but the current folder is stored in Block 3 Reporting.
3. Batch paper records - Filing Storage area (room 6112) or the Exhibit Room (room 6106)
4. DAD-Prior to AUSLAB Batch Functionality, all results obtained were loaded into an Excel spreadsheet known as DNAmaster. In 2008 these results were transferred to the DNA Analysis Database (DAD).
5. AUSLAB
6. Electropherogram pdf/jpeg files for samples:
   - Genotyper profiles are located in J:\User3100\Results Finalised\PRE-LIMS and I:\User3100\AAARESULTS FINALISED\POST-LIMS
   - As of the 16th February 2009, results have been analysed using GeneMapper ID-X. GeneMapper ID-X profiles are located in P:\Profile PDFs and only accessible from computers with GeneMapper ID-X installed (contains all DNA profile results from 16th February 2009 until June 2012).
   - As of July 2012, all DNA profile results are located in O:\Profile PDFs (accessible from all network PCs).
7. STRmix™ result files are stored on a network drive - I:\STRmix Results\

16 Associated Documentation

QIS: 17168 – Procedure for Single Source DNA Profile Statistics

QIS: 23968 – Forensic DNA Analysis Communications Procedure

QIS: 25368 – Kinship Software – Genotype Frequency Module

QIS: 25581 – Kinship Software - Paired Kinship and Paternity Trio/Missing Child Modules

QIS 30917 – Forensic DNA Analysis – Procedure for external transfer of samples and subsamples

QIS: 32139 - STRmix™ Report macro

QIS: 33744 – Forensic Register Training Manual

QIS: 33773 – Procedure for Profile Data Analysis using the Forensic Register

QIS: 34006 – Procedure for Release of Results using the Forensic Register

QIS: 34045 - Quantification of Extracted DNA using the Quantifiler® Trio DNA Quantification Kit.

QIS 34307 – Forensic DNA Analysis - Case File Particulars

QIS: 34112 – STR Fragment Analysis of PowerPlex 21 profiles using GeneMapper ID-X software – FR

QIS: 34229 - Explanations of Exhibit Results for FR

QIS: 34245 – Reference Sample Result Management

QIS: 34246 – Uploading and Actioning on NCIDD - FR

QIS: 34248 - Administrative Team - Case File related duties using the Forensic Register

QIS 34308 – Procedure for Intelligence Reports and Interstate/Interpol Requests in the Forensic Register.

QIS 34322 – Technical and Administrative Review of Records Created in the Forensic Register

QIS 35007 – Use of STRmix Software

QIS 35008 – Allele specific stutter threshold worksheet

QIS 35406 – STRmix Stutter Calculator

QIS 36045 – Multi-kit stutter calculator

QIS 36061 – Procedure for Resolving DNA Profile Interpretation Differences of Opinion

17 References

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Adamson, A, James, C, Caunt, E, McNevin, A and Cathie Allen (2021) Verification of STRmix v2.8.0

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McNevin A, Caunt E & Allen C. (2019) Verification of STRmix™ V2.6.2.

Morgan, R., & Caunt E. (2015) Development of Guidelines for Mixed PowerPlex® 21 DNA Profiles within Forensic DNA Analysis_version 2 (Change Management #149).

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Parry R, Caunt, E & Allen C. (2012) Verification of the DNA profile module of STRmix™ using the Promega PowerPlex® 21 system.

Parry R, Caunt, E & Allen C. (2013) Verification of the DNA profile module of STRmix™ for Full Volume Amplifications using the Promega PowerPlex® 21 system.

Parry R, Howes J, & Allen C. (2014) The determination of the threshold number of alleles, above which single source DNA profiles can confidently be ascribed a likelihood ratio in excess of 100 billion.

Parry R, Caunt E, & Lloyd A. (2020) 4p Mixture Discussion Paper

Police Powers and Responsibilities Act 2000, Current as of 22 September 2014

Police Powers and Responsibilities Regulation 2012, Current as of 22 September 2014

18 Amendment History

Revision	Date	Updated By	Amendments
1	11 Nov 1998	V Ientile	
2	28 Mar 2001	V Ientile	
3	11 Jun 2001	V Ientile	
4	18 Jul 2001	V Ientile	
5	08 Jan 2002	V Ientile	9(3) – Completed case codes for FACTS
6	21 Nov 2002	V Ientile	Changes to section 9, completing a case
7	19 Nov 2003	V Ientile L Freney	Refer to AUSLAB. Remove FACTS in many places

8	07 Jun 2005	M Gardam	Included requirements for paperwork in case file ie No loose pages
9	03 Aug 2006	M Gardam	List of reference articles added
10	25 Sep 2006	M Gardam	Off site case file management, compilation of case file, case management.
11	13 Feb 2007	L Weston	Update with processes for AUSLAB
12	Apr 2008	QIS2 Migration Project	Headers and Footers changed to new CaSS format. Amended Business references from QHSS to FSS, QHPSS to CaSS and QHPS to Pathology Queensland
Version	**Date**	**Updated by**	**Amendments**
12	10 Apr 2008	J Connell	Transferred section on preparing case file for presumptive EXR/EXH validation to Examination of Items SOP
13	12 Feb 2009	K Lee	Major rewrite; Inserted subheadings and table of contents; changed order of information to reflect current processes; expanded on reworking information and other processes undertaken as part of case management; added information regarding dilutions and requesting processing of samples sub-sampled in analytical; summarised finalisation requirements for samples with extra barcodes; added examples for entering final EXR lines. Hyperlinked associated documents.
14	28 Oct 2009	K Lee	Updated with reference to GeneMapper *ID-X* software; changed "Pre/Post LIMS" references to "Pre/Post AUSLAB Batch Functionality"; removed unnecessary flow charts; updated hyperlinks and associated documents; introduced paperless case management; re-arranged for better flow and grammatical correctness; Introduced more definitions; included instruction on locating profiles for printing.
15	27 Jan 2012	K Pippia	Introduced new worklists; added section on reworking evidence samples; added VOLUND process; addressed changes in processes since last update; removed references to re-Genescanning and introduced references to re-reads;

			updated hyperlinks; addressed comments raised against last revision; updated FBNLR process
16	12 Nov 2012	Alicia Quartermain, Emma Caunt, Justin Howes	Updated all processes to include implementation of PowerPlex®21 and STRmix™
17	Jan 2015	Thomas Nurthen	Incorporation of updated workflows, major rewrite , New template
18	August 2015	Thomas Nurthen	Fixed typos, referenced new document for number of contributors, additional steps for FBNLR process, added NCIDD removal process, updated STRmix versions, NCIDD load requirements
19	07 April 2017	Justin Howes	Changed example on p41 to [9, NR]; added information to 5.4 regarding strmix instructions; added eg Profiler Plus to PP21 to 9.3; section 6.3.6 – added info on Profiler Plus and microcon instructions; changed LOD Quant from 0.00214ng/uL to 0.001ng/uL; added information to 6.5.3 re incorrects; added first line to Table 6;added information to 6.2.5 on no further work process; added Appendix 3 – Intuitive Exclusion Guide and details to 6.4.1.2; changed 19977 to 33407; fixed title of 24126 and hyperlinking throughout; edited amendment history versions/revisions to align with QIS.
20	24 December 2018	Justin Howes	Major revision due to implementation of FR and other new SOPs (for the FR).
21	17 February 2021	Justin Howes	Updated definition list; changed EXH to result; changed statswg to statsPWG; added 35406 and 35008 to associated docs and details to 6.3; updated title of no. contributors guidelines document; added details to 6.3.1; 6.3.4 edited to remove the requirement for reamps;added authorisations to 6.3.6; removed App 17.2 (intuitive exclusion guide); replaced 're-run' with re-CE'; added 35007 and 30917 to assoc docs, removed 31523; removed details on no. iterations for STRmix in 6.4.1.2; edited the title of mixed profiles to include four-person mixtures; added Sections on remote, cold cases and off-site; added info on broad peaks

			to 6.3.3; 6.5.2 added info on further processing; added information on increasing iterations; removed 17038 and replaced with 34307; added reference to Intel Report template for amended results in 6.5; updated formatting, added information to section 4.4 and removed numbers; edited 11.1 to remove AUSLAB references; removed checklist (was App 19.1); added contributors workflow to appendix; added reworking strategies to appendix; add information to 6.3.6 and 6.1.1, updated reference list, updated workding in 6.4.1.2; added section 6.5.7, edited wording in section 12 (remote working),6.1.1 and 6.5.3.
22	19 August 2022	Justin Howes	New template, updated as per comments on v21, added new information regarding DIFP to 6.3.2, removed App1, updated section 10, add ref to strmix v2.8, added guidelines to App2, edited 6.3.6 as per DG memo, added App 3 workflow

19 Appendices

1 Considerations in assessing samples for reworks
2 Guidelines for Single Source DNA profile interpretation
3 Processing Workflow for Priority 1 and Priority 2 samples

19.1 Considerations in assessing samples for reworks

Reworks are required for case work samples for several reasons including optimisation of profiles, confirming information and assessing the impact of quality issues.

Any process that is likely to exhaust all the DNA extract is required to have written approval from QPS to proceed prior to the process being conducted. The aim is to not exhaust samples, and only to do so with QPS approval in writing.

Below is a brief set of options to consider when deciding to rework a sample and choosing an appropriate rework strategy. This set of options will not cover every scenario and each sample should be considered on its own merit and within its own case. Samples may exhibit more than one issue that might warrant a rework. In this case select the one that will overcome the majority of issues in one go for maximum efficiency.

Problem/Profile Type	Rework Strategy/Considerations
Quality Issue noted in Batch Notes - Reduced Volume Post PCR	Refer to the Report on Observed Reduction in Volume Post-PCR (Brisotto et al 2020). The wells commonly affected are A01, A012, H01 and H012. A reduced remaining volume may impact on the rework able to be ordered. If a suboptimal amplification (amp) is obtained due to reduced amp volumes, consider a re-quantification (quant) or re-amp as an appropriate strategy.
- Other batch issue affecting the sample	Only rework if necessary in order to confirm a profile after a quality issue has been found to impact the sample. The best rework strategy will be dependent on the issue affecting the batch and the possible implications of the batch issue itself. Consider that re-extracting the spin basket may be best option. If the profile is considered unsuitable for interpretation, a rework or re-extraction may not assist. Consult a Senior Scientist if in doubt.
Quantification - Quant issue	If the profile seems inconsistent with the quant value or if the quant value is unexpected given other results or testing (such as numerous spermatozoa present), consider a re-quant as the best option. A profile with an inaccurate quant might be able to be identified in a sample with a strong quant with low degradation however with a poor quality or low level profile. Check the quant batch to assess the IPCCt value. A particularly low value (< 27) can be a contributing factor as this does not flag (as it does if it is a high IPCCt). If IPCCt value is low and degradation high, a

	re-quant should be ordered. If the IPCCt value appears to be low, a Nucleospin clean-up is still an available option for reworking. Note that Quantification of samples is only an estimation of the amount of DNA present within a sample and the true value can vary. A re-quant will use less extract and is more likely to obtain an accurate profile. Microconning a sample with an incorrect quant value can consume the entire extract and potentially obtain an uninformative profile that is unsuitable for interpretation.
- Low quant	A profile displaying limited information due to the low level of DNA present might benefit from a re-amp at maximum volume. If the sample has already been amplified at the maximum volume, consider concentrating the sample via microcon to 35ul (a microcon to full can be a helpful option for low level single source profiles). As of 19 August 2022, if performing a microcon to full, this will need prior approval from QPS as this process will exhaust the DNA extract. When considering a microcon, bear in mind that the optimal amplification DNA input is approximately 500pg or 0.033ng/ul quant value. A sample with a quant value less than 0.03 is more likely to benefit from a microcon. The presence of multiple peaks at loci in a low quant profile does not in itself mean that the microconned profile will be complex, it could lead to a clean mixed profile that might be interpreted. This should be considered within the case context.
CE issues	
- Poor Baseline and/or Pull Up	A profile with an unclean baseline can create difficulty in interpretation particularly if pull-up is interfering with true alleles and causing uncertainty as to the number of contributors to the profile. A re-CE is the best first option. A re-amp might be useful if the re-CE doesn't fix the issue.
- Artefacts such as ULPs or VARs etc.	It is no longer policy within DNA Analysis to confirm unlabelled peaks or variant alleles unless there are questions raised as to their accuracy. A re-CE can confirm whether they are truly present however a re-amp will confirm the allele designations.
- Broad Peaks	Broad peaks are peaks considered to be wider than

	standard. Broad peaks can interfere with STRmix™ deconvolutions of mixed profiles. A mixed DNA profile with labelled broad peaks will require a re-CE before being processed through STRmix™. A re-CE is preferable due to reduced costs and faster turn arounds however a re-amp is a second alternative. If the profile is considered complex or unsuitable for interpretation, a rework is not necessary. Note that a single source profile displaying broad peaks that also requires STRmix™ deconvolution does not necessarily require a rework. This is because STRmix™ will assign the broad peaks correctly to the one contributor without much penalty. If the sample has broad peaks and is not being reworked, add a sample note on the PDA page that broad peaks have been observed however are not affecting the overall interpretation.
Degradation	Degradation of a sample can vary from nil to extreme. The greater the degradation, the less the certainty of the interpretation or number of contributors to the profile. Degradation can be identified by taking the quant value into account along with the severity of the slopes of peaks from left to right of the profile. Provided inhibition has not been detected (low/high IPCCt value), re-amplifying using above optimal volume input (but below what might saturate the amplification) may assist. If the Degradation Index is significant, consider if the IPCCt value is appearing satisfactory. A re-quant may be necessary.
Amplification Issues - Preferential Amplification - Poor Amplification	Preferential amplification is noted by the ski slope effect from left to right across the profile in conjunction with an indication of degradation as per the Degradation Index. Whilst this is relatively rare within casework samples, it can be negated by re-amplifying at slightly lower volumes than previous. Poor amplifications might occur for a number of reasons including bad injections or pipetting issues. They can generally be identified after a good quality profile followed by a poor quality profile after a re-amp. First consider a re-CE or else re-amp at the same volume. A poor amp can be used for information but may not be particularly useful as part

	of a STRmix™ deconvolution.
Determination of Number of Contributors	
- Single Source Profiles	Consider that single source profiles only require 12 alleles and preferably as many P+ alleles as possible to be loaded to NCIDD. Therefore a partial single source may not require reworking depending on the sample and case. If the profile is low level and falls within the stochastic range, a re-amp might be beneficial to confirm any high stutters or potentially interfering sub threshold information.
- Two Contributor Profiles	Refer to the Number of Contributor Guidelines (Morgan R and Caunt E, 2015 – Change Management #149) for reworking to determine the number of contributors to a profile. In general terms, re-amps are the most appropriate rework for reproducibility. However if both contributors are clearly present across all loci, there may be no need to rework unless the profile is within stochastic range or STRmix™ might have a better chance at deconvolution with extra runs.
- Three Contributor Profiles	Refer to the Number of Contributor Guidelines for reworking to determine the number of contributors to a profile. In general terms, re-amps are the most appropriate rework for reproducibility. If a profile is assessed as 3 contributors, a re-amp might help to assess if drop out has occurred.
- Four Contributor Profiles	Refer to the Number of Contributor Guidelines for reworking to determine the number of contributors to a profile. In general terms, re-amps are the most appropriate rework for reproducibility
- Uncertain Contributor Profiles	Refer to the Number of Contributor Guidelines for reworking to determine the number of contributors to a profile. In general terms, re-amps are the most appropriate rework for reproducibility. Two additional re-amps (if necessary) are considered appropriate.
- Complex profiles	Complex profiles should not be reworked unless it is considered that the profile is complex due to other amplification or quantification issues.
- General Mixed profiles	There is NO NEED to rework a profile unless there is good reason to do so. Consider the risks of doing so. Does the number of contributors assessed correlate with the appearance of the profile, rather than just counting the number of peaks? If not, consider a

	rework to see if an extra contributor might be involved or to allow STRmix™ more certainty. Remember that the assumption of the number of contributors to a mixed profile is the minimum number of contributors to reasonably explain the DNA profile. Note that the Number of Contributor Guidelines are GUIDELINES ONLY and interpretation can occur without added reworks.

19.2 Guidelines on Single source DNA profile interpretation

Recommendations

(see G:\ForBiol\AAA Forensic Reporting & Intel\AAA Reporting guidelines\Proposed SS guidelines\SS High stutter guidelines_Final)

• Samples with a single peak in stutter position above threshold (labelled or unlabelled) can be interpreted as single source profiles.

• For the purposes of determining whether a peak in stutter position can be considered as high stutter, we recommend the use of the STRmix™ maximum allowable thresholds which are 30% for -1 rpt stutter and 10% for +1 rpt stutter. This means that a peak in stutter position can be considered to be high stutter up to 30% of the parent allele height for -1 rpt stutter and up to 10% of the parent allele height for +1 rpt stutter.

• Samples with multiple high stutters can be interpreted as single source, however if either of the high stutters are above the STRmix maximum allowable thresholds we recommend that theses samples are interpreted as mixed samples.

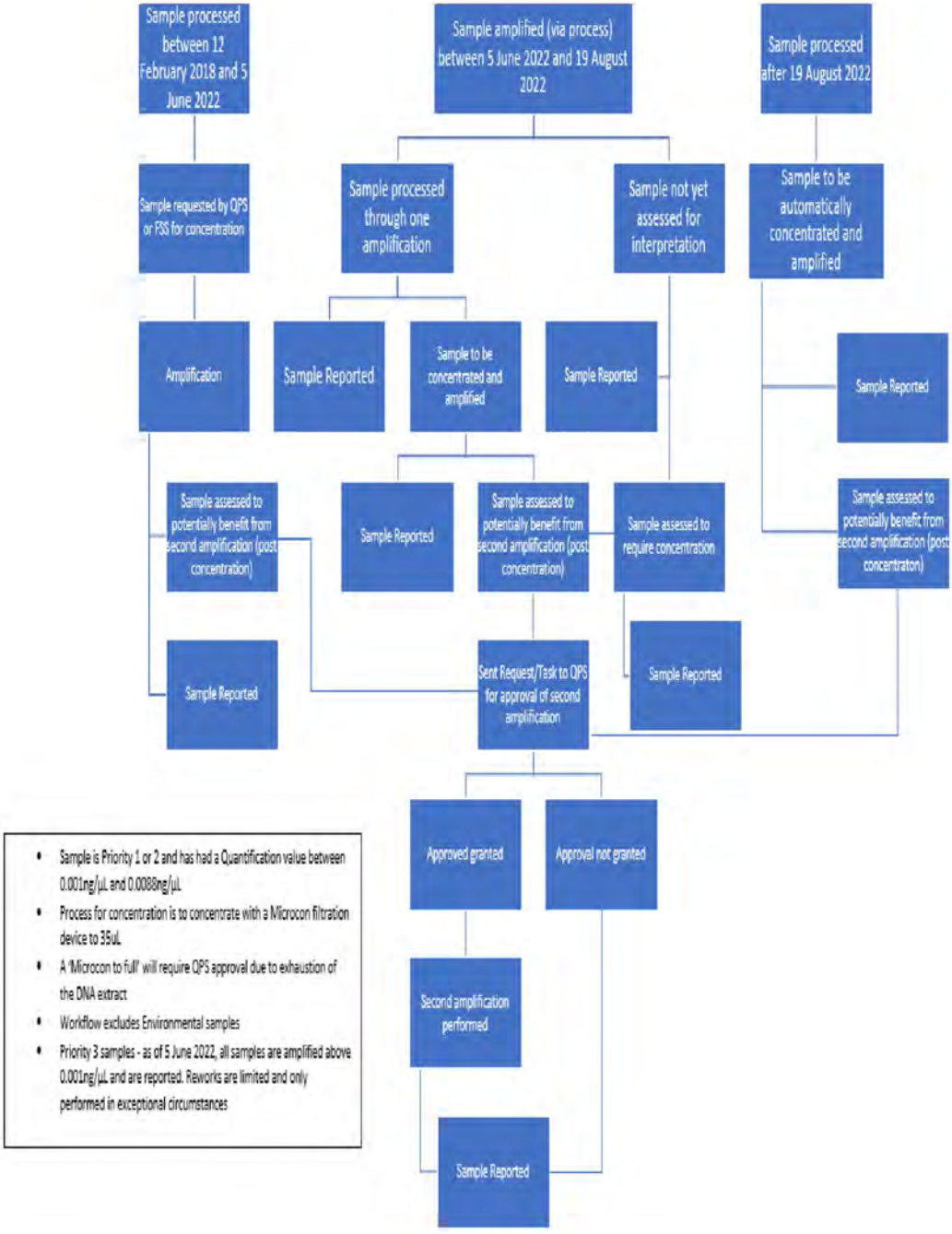
• High -2 rpt stutter is to be left labelled. STRmix™ is not modelling -2 rpt stutter but will model these peaks as drop in if they are below 250 RFU.

• These recommendations are for the determination of single source verses two contributor mixtures only. They are not intended for use for mixtures with greater than two contributors.

Queensland Health

Forensic and Scientific Services

19.3 Processing Workflow for Priority 1 and Priority 2 samples



Scope of Accreditation

issued as CA-33

National Association of Testing Authorities, Australia

Queensland Health

Accreditation Number 41 Forensic and Scientific Services

Site Number 14171 **Forensic and Scientific Services**

Contact Summary

Address	**Phone**	[redacted]
Liaison Unit	**Mobile**	
39 Kessels Road	**Email**	[redacted]
	Web	[redacted]
COOPERS PLAINS	**Contact**	
QLD 4108	**Site Availability**	Services conditionally available to external clients
AUSTRALIA	**Site Supervision**	

Site Scope Last Modified: 17/01/2019

Scope (AC = Accreditation Status, AU= Authorisation Status, D = Do Not Publish)

ISO/IEC 17025

Legal

Service	Product	Determination	Technique	Procedure	AC	AU
Analysis of controlled substances	Clandestine drug facility - Investigation	Drug identification; Presumptive testing	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; Inductively coupled plasma (ICP); Ion chromatography (IC); LC-MS; Quantitation of drugs and associated compounds by UPLC-PDA; Raman spectroscopy; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures	D	Auth
Analysis of controlled substances	Any item received	Drug identification; Presumptive testing	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; LC-MS; Quantitation of drugs and associated compounds by UPLC-PDA; Spot test; Visual examination	In-house procedures	D	Auth

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

Forensic biology - Examination of biological material	Any item received	Collection, location and identification of biological material	Acid phosphatase test; Microscopic examination; p30 test; Phadebas Forensic Press test; Tetramethylbenzidine (TMB) test for blood	In-house procedures	D	Auth
Forensic biology - Examination of biological material	Hair	Examination of hair	Microscopic examination; Visual examination	In-house procedures	D	Auth
Forensic chemistry/criminalistics	Any item received	Explosives; Propellants	Flow injection analyser (FIA); Fourier transform infrared spectroscopy (FTIR); GC-MS; Gravimetric; Inductively coupled plasma (ICP); Infrared (IR) microscopy; Ion chromatography (IC); LC-MS; Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Solid phase microextraction (SPME) GC-MS; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures	D	Auth
Forensic chemistry/criminalistics	Any item received	Miscellaneous comparisons; Polymer analysis; Tape; Textile fibre examination	Comparison microscopy; GC-MS; Gravimetric; Infrared (IR) microscopy; Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Polarised light microscopy; Thin layer chromatography (TLC); UV-vis microscopy; Visual examination; X-ray fluorescence (XRF)	In-house procedures	D	Auth

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

Forensic chemistry/criminalistics	Any item received	Cosmetics, oils and lotions; General chemical analysis; General physical examination; Lubricants; Miscellaneous comparisons; Screening, interpretation and reporting of textile damage; Unknown substance identification	Comparison microscopy; Flow injection analyser (FIA); Fourier transform infrared spectroscopy (FTIR); GC-FID; GC-FPD; GC-MS; Gravimetric; Inductively coupled plasma (ICP); Infrared (IR) microscopy; Ion chromatography (IC); LC-MS; Liquid chromatography (LC); Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Polarised light microscopy; Solid phase microextraction (SPME) GC-MS; Spot test; Thin layer chromatography (TLC); UV-vis microscopy; Visual examination; X-ray fluorescence (XRF)	In-house procedures	D	Auth
Forensic toxicology	Blood; Body fluids; Hair; Liver; Lung; Oral fluid; Plasma; Serum; Urine; Viscera; Vitreous humor	Alcohol testing; Coronial toxicology; Drugs in drivers; Drugs in living persons; Drugs of abuse	Enzyme linked immunosorbent assay (ELISA); GC-FID; GC-MS; Haemoximeter; Immunoassay; LC-ESI-MS-MS; LC-MS-MS; LC-QTOF; LC-UV; Precipitation LC-MS	In-house procedures	D	Auth
Genetic analysis	Biological material	DNA profiling for criminal case work - Direct comparison; DNA profiling for relationship testing	Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser; FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction; Polymerase chain reaction (PCR); QIAGEN QIAsymphony extraction	In-house procedures	D	Auth
Genetic analysis	Biological material	DNA profiling for relationship testing	Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser; FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction; Polymerase chain reaction (PCR); QIAGEN QIAsymphony extraction	In-house procedures	D	Auth

CA-34

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

Queensland Health

Accreditation Number 41 Forensic and Scientific Services

Site Number 14171 **Forensic and Scientific Services**

Contact Summary

Address	**Phone**	[redacted]
Liaison Unit	**Mobile**	
39 Kessels Road	**Email**	[redacted]
	Web	[redacted]
COOPERS PLAINS	**Contact**	
QLD 4108	**Site Availability**	Services conditionally available to external clients
AUSTRALIA	**Site Supervision**	

Site Scope Last Modified: 16/01/2019

Scope (AC = Accreditation Status, AU= Authorisation Status, D = Do Not Publish)

ISO/IEC 17025 (2017)

Legal

Service	Product	Determination	Technique	Procedure	AC	AU
Analysis of controlled substances	Clandestine drug facility - Investigation	Drug identification; Presumptive testing	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; Inductively coupled plasma (ICP); Ion chromatography (IC); LC-MS; Quantitation of drugs and associated compounds by UPLC-PDA; Raman spectroscopy; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures	D	Auth

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

ISO/IEC 17025 (2017)

Legal

Service	Product	Determination	Technique	Procedure	AC	AU
Analysis of controlled substances	Any item received	Drug identification; Presumptive testing	Fourier transform infrared spectroscopy (FTIR); GC-IR; GC-MS; LC-MS; Quantitation of drugs and associated compounds by UPLC-PDA; Spot test; Visual examination	In-house procedures	O	Auth
Forensic biology - Examination of biological material	Any item received	Collection, location and identification of biological material	Acid phosphatase test; Microscopic examination; p30 test; Phadebas Forensic Press test; Tetramethylbenzidine (TMB) test for blood	In-house procedures	O	Auth
Forensic chemistry/criminalistics	Any item received	Explosives; Propellants	Flow injection analyser (FIA); Fourier transform infrared spectroscopy (FTIR); GC-MS; GC-MS - Solid phase microextraction (SPME); Gravimetric; Inductively coupled plasma (ICP); Infrared microscopy; Ion chromatography (IC); LC-MS; Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Spot test; Thin layer chromatography (TLC); Visual examination; X-ray fluorescence (XRF)	In-house procedures	O	Auth

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

ISO/IEC 17025 (2017)

Legal

Service	Product	Determination	Technique	Procedure	AC	AU
Forensic chemistry/criminalistics	Any item received	Miscellaneous comparisons; Polymer analysis; Tape; Textile fibre examination	Comparison microscopy; GC-MS; Gravimetric; Infrared microscopy; Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Polarised light microscopy; Thin layer chromatography (TLC); UV-vis microscopy; Visual examination; X-ray fluorescence (XRF)	In-house procedures	O	Auth
Forensic chemistry/criminalistics	Any item received	Cosmetics, oils and lotions; General chemical analysis; General physical examination; Lubricants; Miscellaneous comparisons; Screening, interpretation and reporting of textile damage; Unknown substance identification	Comparison microscopy; Flow injection analyser (FIA); Fourier transform infrared spectroscopy (FTIR); GC-FID; GC-FPD; GC-MS; GC-MS - Solid phase microextraction (SPME); Gravimetric; Inductively coupled plasma (ICP); Infrared microscopy; Ion chromatography (IC); LC-MS; Liquid chromatography (LC); Macroscopic examination; Micro-Fourier transform infrared spectroscopy (FTIR); Microscopic examination; Polarised light microscopy; Spot test; Thin layer chromatography (TLC); UV-vis microscopy; Visual examination; X-ray fluorescence (XRF)	In-house procedures	O	Auth

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

ISO/IEC 17025 (2017)

Legal

Service	Product	Determination	Technique	Procedure	AC	AU
Forensic toxicology	Blood; Body fluids; Hair; Liver; Lung; Oral fluid; Plasma; Serum; Urine; Viscera; Vitreous humor	Alcohol testing; Coronial toxicology; Drugs in drivers; Drugs in living persons; Drugs of abuse	Enzyme linked immunosorbent assay (ELISA); GC-FID; GC-MS; Haemoximeter; Immunoassay; LC-ESI-MS-MS; LC-MS-MS; LC-QTOF; LC-UV; Precipitation LC-MS	In-house procedures	◊	Auth
Genetic analysis	Biological material	DNA profiling for criminal case work - Direct comparison; DNA profiling for relationship testing	Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser; FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction; Polymerase chain reaction (PCR); QIAGEN QIAsymphony extraction	In-house procedures	◊	Auth
Genetic analysis	Biological material	DNA profiling for relationship testing	Applied Biosystems 3130XL DNA analyser; Applied Biosystems 3500XL DNA analyser; FTA cards; Maxwell 16 capillary electrophoresis; Microcon; NucleoSpin; PCR - 9700 Life Technologies; Phenol chloroform isoamyl alcohol (PCIA) extraction; Polymerase chain reaction (PCR); QIAGEN QIAsymphony extraction	In-house procedures	◊	Auth

Scope of Accreditation

issued by

National Association of Testing Authorities, Australia

ISO/IEC 17025 (2017)

Legal

Service	Product	Determination	Technique	Procedure	AC	AU

CA-35

ASSESSMENT INFORMATION DOCUMENT

Your facility is due for a reassessment.

This Assessment Information Document seeks specific background information from facilities on the current scope of NATA accreditation, any changes required, and the specific resources available to meet the requested changes.

Some sections may not apply to your facility. Please cross-reference relevant sections from your management system documentation where appropriate.

Please upload a completed copy of this Assessment Information Document and required documents/records as detailed in covering letter to the NATA Portal or email to:

Ms Madelen Chikhani at [redacted]
By: **09 April 2022**

Delays or failure to provide the requested information may result in delays to the accreditation process.

The personal information collected in this document and other management system documentation supplied for the assessment briefing is used for conducting the assessment, reporting on the assessment and the process of continuing accreditation. It may be disclosed to NATA staff members, all of whom have signed confidentiality agreements. Aggregated data gathered from the assessment process may also be provided to third parties in a de-identified format. It may also be disclosed to agencies to which NATA has a legal obligation or with which NATA has formal agreement.

Personal information collected such as name, business telephone and mobile phone numbers and email address of the Authorised Representative or the Site Contact may be made available to enquiries requiring the service of NATA accredited facilities. The Site Contact details may be included in the NATA website directory.

NATA's Privacy Policy contains information on access and correction to the personal information held by NATA and the compliant process associated with breaches of the Australian Privacy Principles. NATA's Privacy Policy is available from the NATA website, www.nata.com.au.

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

FACILITY DETAILS

In preparation for the accreditation activity, please review the information below to confirm (or change) the details of your facility and the site to be assessed. Use the shaded boxes to provide corrected or changed details.

FACILITY (the name in which accreditation is held)	
Accreditation No: 41	
Facility Name: Queensland Health Forensic and Scientific Services	
Facility Trading Name (see note 1):	
ABN or ACN: 66-329-169-412	
Mailing Address: [redacted]	
Street address (if different from above): [redacted]	
Facility web address (optional): www.health.qld.gov.au	
Phone: [redacted]	
INVOICING DETAILS (for all sites under your facility)	
Mailing address: [redacted]	
Phone: [redacted]	
Email: [redacted]	

The following details are specific to your Facility's Authorised Representative.

(The rights and responsibilities of the Authorised Representative are outlined in the *General Accreditation Criteria: Responsibilities of authorised representatives*, available on the NATA website.)

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Authorised Representative: Ms Helen Gregg	To change the appointed Authorised Representative please complete the Facility Details Update (FDU) form available from the NATA website.
Position: Quality Manager	
Direct Phone: [redacted]	
Email: [redacted]	
SITE DETAILS	
Site No: 14171	
Site Name: Forensic and Scientific Services	
Site Trading Name (see note 1):	
Availability of services: Services conditionally available to external clients	☐ Services available to external clients ☐ Services conditionally available to external clients ☐ Services not available to external clients
Street address (physical location): Liaison Unit [redacted]	
Site Contact (full name including title):	
Phone: [redacted]	
Mobile:	
Indicate the Site Contact's primary contact number: ☐ Phone ☐ Mobile	
Email: [redacted]	
Do you wish to publish the Site contact information on NATA's website directory? ☐ Yes ☒ No (The name of the contact person and preferred phone number and email address will be listed in our records as the person to contact with enquiries about the Site's activities (i.e. from potential clients) and may be listed on the NATA website.)	

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Note 1: Trading name(s) (optional)

Providing this information indicates the applicant is seeking approval to issue reports in its trading name(s), in addition to the name of the Facility. Trading names may be provided for a Facility and/or for individual Sites.

In order to able to issue reports in a trading name the following criteria need to be met.

- There must be a clear and reasonable link between the name of the Facility and the trading name(s) supplied, such as an ownership link or a link by virtue of a registered trading name;
- Activities reported in a trading name(s) will have been performed by the staff of the accredited Facility/accredited Site to which the trading name(s) applies, using the same techniques and procedures s those covered by the Scope(s) of Accreditation of the applicable accredited Facility/accredited Site;
- The scope of reporting applicable to the trading name(s) is the same as or a subset of the Scope of Accreditation of the applicable accredited Facility/accredited Site.

Should trading name(s) be provided you will be contacted to further explore this option.

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

NATA SCOPE OF ACCREDITATION

A copy of your current scope of accreditation is attached.

☒ Annotate this scope to indicate the approximate frequency of all laboratory activities.

		2020		2021				2022		
	Quarter	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar (in part)	Total	Weekly average
Forensic Biology Examination of biological materials	InTube samples	4938	4727	5461	5210	5457	5423	4756	35972	404.18
	Items examined (not SAIK)	1447	1281	1445	1415	1544	1461	1340	9933	111.61
	SAIKs	96	81	121	112	128	117	104	759	8.53
	Phadebas Supernatant	199	104	141	95	177	143	99	958	10.76
	Microscopic	1142	684	742	734	961	733	687	5683	63.85
	Presumptive TMB/AP/p30/Phadebas paper	462	356	566	531	697	574	482	3668	41.21
Genetic Analysis	Extraction (Reference Maxwell)	1074	714	839	825	545	595	382	4974	55.89
	Extraction (Diff Lysis, incl Supernatant)	673	457	689	663	876	706	637	4701	52.82
	Extraction (Casework Maxwell)	1250	917	956	1022	690	876	536	6247	70.19
	Extraction (QIAsymphony)	1826	1689	1927	2140	1903	1917	2536	13938	156.61
	Extraction (PCIA - Bones)	5	10	11	10				36	0.69
	Integrated (QIA extraction and quantification)	4248	4032	4536	4320	4464	4752	3168	29520	331.69
	Post Extraction processing (Nucleospin, Microcon)	398	403	362	242	310	386	245	2346	26.36
	Quantifications	10374	9275	10258	10004	9820	10554	7821	68106	765.24
	Amplifications (PCR)	9983	8590	8485	9003	7627	8143	6161	57992	651.60
	Capillary Electrophoresis (3130, 3500)	15316	13210	14219	15491	12566	13371	9180	93353	1048.91

Animal health facilities only: please also complete the attached Supplement document.

Changes to the scope of accreditation

Surveillance visit: Additions will not normally be considered during a surveillance visit as such visits will not include a technical assessor. Where requested a decision will be made as to how best to meet the request without compromising the aim and focus of the surveillance visit. Accordingly, a variation visit may be arranged concurrently or as a separate visit once all information concerning the request has been considered. Charges will be incurred to accommodate the variation visit in accordance with NATA's Fee Schedule current at the time. Please be aware that any extensions to scope of accreditation may also result in an increase to your annual membership fees.

Reassessment: Any requests for additional activities to be added to the scope of accreditation as part of a scheduled reassessment will only be accommodated where such requests do not compromise the purpose of the reassessment (to review the existing scope of accreditation to determine ongoing compliance with the accreditation criteria). Where additional resources and time are required to accommodate the request, a concurrent variation visit may be arranged, and charges will be levied in accordance with the current Fee Schedule available from the NATA website. Please be aware that any extensions to scope of accreditation may also result in an increase to your annual membership fees.

Do you wish to request additions or deletions or editorial amendments to the scope of accreditation?

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Note: Changes to calibration and measurement capability (CMC) may be considered as additions to the scope of accreditation.

☐ Yes. Please complete the Application for changes to the scope of accreditation form available from the NATA website.

☒ No

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Regulatory requirements applicable to laboratory activities

Are any of your laboratory activities covered by your scope of accreditation subject to, or used by your customers to meet, regulatory requirements? For example, do you test products covered by Consumer Safety Law, WHS regulations, trade measurement, food regulation, etc.?

☐ Yes

☒ No

If yes, please indicate this by annotating the attached copy of your current scope of accreditation specifically identifying the relevant regulation (including regulatory body and/or regulatory ruling), standard or other applicable document as appropriate. For example:

- Testing of children's nightwear for flammability in accordance with AS/NZS 1249:2003
- Testing of trolley jacks in accordance with Consumer Protection Notice No. 10:2008 (ACCC)

Testing of human specimens

Are any of your laboratory activities covered by your scope of accreditation on human samples?

☒ Yes

Testing is carried out on human samples. However, these samples are used in legal investigations and not for clinical testing purposes. As such they do not come under the framework for In Vitro Diagnostic Medical Devices.

☐ No

If yes, please annotate this on the attached scope of accreditation. Note that such testing may be subject to the Therapeutic Goods Administration (TGA) In-Vitro Diagnostic (IVD) medical device Framework and assessed against the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for the Development and use of In-House In Vitro Diagnostic Medical Devices.*

Sampling

Since your previous assessment, are there changes to any sampling conducted covered by your NATA scope of accreditation?

☐ Yes. Please complete the Application for changes to the scope of accreditation form available from the NATA website.

☒ No

☐ Not applicable

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Off-Site Laboratory Activities

Since your previous assessment, has your facility commenced performing laboratory activities off-site, for example, field testing or at clients' premises, and do you require this to be covered by your scope of accreditation?

Note: Refer to relevant documents in the NATA Accreditation Criteria (NAC) package applicable to your scope of accreditation, available from the NATA website, for any specific requirements for such laboratory activities.

☐ Yes. Please complete the Application for changes to the scope of accreditation form available from the NATA website.

☒ No

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

STAFF

In the following spaces provided (or on a separate sheet if is insufficient room), list the current facility staff. Please also indicate whether any staff work on a shift or part-time basis.

Staff responsible for quality management
Part-time staff (as at 07/04/2022)
Extended leave (as at 07/04/2022)

Name and qualifications	Position (Please also specifically identify staff responsible for technical and quality management)	Date started in the facility
ACEDO, Pierre [BSc]	Scientist	2006
ADAMSON, Angela [BSc (Hons)]	Reporting Scientist	2003
AGUILERA, Maria [BSc]	Scientist	2006
ALLEN, Catherine [BSc, MSc (For Sc)]	Managing Scientist	1999
ANDERSEN, Belinda [B Biomed Sc, GDFor]	Senior Scientist	2005
ANGUS, Chantal [BA (Hons)]	Laboratory Assistant	2017
AVDIC, Kevin [HNC Chem]	Forensic Technician	2014
BRADY, Susan [BAppSc. (Biotech); Grad.Dip. (For Inv)]	Scientist - Leave	2004
BRISOTTO, Paula [BSc, MSc (For Sc)]	Team Leader	2001
BROOKS, Julie	Laboratory Assistant	2016
CALDWELL, Valerie [B.AppSc. (Med Sc)]	Scientist	2006
CAUNT, Emma [BSc (Hons)]	Reporting Scientist	2007
CHANG, Cindy [BSc; PGDip Clin Biochem]	Scientist	2001
CHENG, Amy [BSc]	Scientist	2006
CIPOLLONE , Melissa [B.AppSc.]	Scientist	2006
CONNOLLY, Yvonne [BA, DipBus; Cert II &Cert III B.Admin]	Administration	2014
DARMANIN, Alanna [BA, BSc (Hons); MSc For Arch & Crime Scene Investigation, Cert Forensic Statistics]	Scientist	2010
DWYER, Tegan [BForSc]	Reporting Scientist	2010
EBA, Ryu	Laboratory Assistant	2011
ENTWISTLE, Josie [BSc BA]	Reporting Scientist	2005
ESTREICH, Kim	Laboratory Assistant	2019
FARRELLY, Lisa [BAppSc]	Scientist	2013
FINCH, Patricia [BSc]	Reporting Scientist - Leave	2002
FRENCH, Naomi [Cert IV Lab Tech]	Laboratory Assistant	2019
GALLAGHER, Claire [B.Tech. PG.Cert]	Reporting Scientist	2006
GOODRICH, Michael	Laboratory Assistant Supervisor	2010
GULLIVER, Maddison	Laboratory Assistant	2021
HARMER, Wendy [Cert II BA, DipMgt]	Administration	2005
HART, Michael [City and Guilds Level 3 (UK); Cert IV Lab Tech] DipLabTech	Forensic Technician	2014
HUNT, Matthew [BSc (Hons)]	Reporting Scientist	2009
HOWES, Justin [BSc, BA, MSc (For Sc), DipMgt]	Team Leader	2005
JAMES, Cassandra [BSc MSc (For Sc)]	Reporting Scientist	2016
JOHNSTONE, Sharon [BSc; MSc (For Sc), DipMgt]	Forensic Scientist Advanced	1999

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Name and qualifications	Position (Please also specifically identify staff responsible for technical and quality management)	Date started in the facility
KAITY, Adam [BSc (Hons I); PhD]	Scientist	2008
KELLER, Angelina [BAgSci (Hons), MSc (ForSc)]	Reporting Scientist	2004
LANCASTER, Kerry-Anne [B.AppSc, GDip For Inv]	Reporting Scientist	2005
LE, Lai-Wan [BSc (Med Lab), MSc (For Sc)]	Scientist	2005
LLOYD, Allison [B.AppSc; MSc (For Sc)]	Forensic Scientist Advanced	2006
LUNDIE, Generosa [BSc (Biomed Sc)]	Scientist	2006
MARGETTS, Michelle [BSc For Sc, Cert IV Lab Tech, DipLabTech]	Scientist	2011
MATHIESON, Megan [B.HSc., B.BioMedSc, GDFor]	Reporting Scientist	2005
McINDOE, Phillip [BTecONC]	Laboratory Assistant	2019
McKEAN, Sandra	Laboratory Assistant	2008
McNEVIN, Allan [B. AppSc. (Med Lab Sc)]	Reporting Scientist	2004
MICIC, Biljana [BSc]	Scientist	2005
MOELLER, Ingrid [BSc (Hons), PhD]	Reporting Scientist	2004
MORGAN, Amy [B.AppSc]	Scientist	2014
MORTON, Kristina [BSc For Sc.]	Scientist	2020
NICOLETTI, Deborah [BSc (MLS)]	Reporting Scientist	2005
NURTHEN, Thomas [BSc (Hons)]	Reporting Scientist	2004
NYDAM, Sharelle [BSc (Hons)]	Scientist	2014
PARRY, Rhys [BSc (Hons)]	Reporting Scientist	2006
PENDLEBURY-JONES, Victoria	Administration	2015
PIPPIA, Adriano [B. AppSc.]	Reporting Scientist	2000
PROWSE, Tara [B. AppSc.]	Scientist	2009
QUARTERMAIN, Alicia [BHSc, MSc (For Sc)]	Reporting Scientist	2005
RIKA, Kylie [BSc, PGDipFor, DipMgt]	Forensic Scientist Advanced	2005
ROSELT, Nicole [B.For Sc. & BCCJ]	Scientist	2016
RYAN, Abigail [BSc (Hons) For Sc]	Scientist	2008
RYAN, Luke [BSc, MSc (For Sc), Dip Gov(Sec),DipMgt]	Forensic Scientist Advanced	2013
SANDERSON, Suzanne	Laboratory Assistant	2006
SAVAGE, Chelsea [B.For Sc. & BCCJ]	Scientist (Quality)	2015
SCOTT, Kirsten [BSc (Hons). PhD. GCEd, GDEd., DipMgt]	Forensic Scientist Advanced – Quality and Projects	2007
SEYMOUR-MURRAY ,Janine [B. AppSc.]	Scientist	2006
TAYLOR ,Penelope [BSc (Hons)]	Reporting Scientist	2001
WAIARIKI, Stephanie [BSc For Sc, DipLabTech]	Laboratory Assistant	2022
WILLIAMS, Helen [B. AppSc. (Med Lab Sc), PGDip (Biotech)]	Scientist	2003
WILSON, Jacqueline [B.AppSc. MSc]	Reporting Scientist	2006

Note: NATA will list individuals in the Report on Assessment where there is a regulatory framework or is covered in a Deed of Agreement, Memorandum of Understanding or other binding agreement with a third party. If this is applicable to any of your laboratory activities, indicate in the table any nominated individuals or changes to nominated individuals who are authorised to release results under such an arrangement, including the arrangement in place. Please provide resumes for any new individuals not previously listed.

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ENSURING THE VALIDITY OF RESULTS

Has your facility participated in any proficiency tests, measurement audits or inter-laboratory comparison programs since your last assessment?

Refer to the *General Accreditation Criteria: Proficiency testing* document available from the NATA website for the policy on participation in such programs.

☒ Yes

☐ No

If yes, please provide details in the table below. Records of participation in these programs must be available for review during the NATA assessment, together with details of action taken in response to unsatisfactorily performance.

Name of provider, program and activities undertaken	Frequency of program	Last date of participation
CTS Collaborative Testing Services	38 tests in total	March 2022
FB5701 Forensic Biology	1	Jan 2021
FB5801 DNA-Mixture	1	Jan 2021
FB5840 DNA Database - Saliva	3	Feb 2021
FB5870 DNA Parentage	3	Feb 2021
FB5702 Forensic Biology	1	March 2021
FB5802 DNA-Semen	1	March 2021
FB5781 Body Fluid Identification	1	March 2021
FB5703 Forensic Biology	1	April 2021
FB5803 DNA-Blood	1	April 2021
FB5871 DNA Parentage	3	May 2021
FB5704 Forensic Biology	1	July 2021
FB5804 DNA-Semen	1	July 2021
FB5843 DNA Database - Saliva	3	July 2021
FB5872 DNA Parentage	2	Aug 2021
FB5705 Forensic Biology	1	Sept 2021
FB5805 DNA-Blood	1	Sept 2021

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[redacted]

Body Fluid Identification	1	Sept 2021
Forensic Biology	1	Oct 2021
DNA-Mixture	1	Oct 2021
– Forensic Biology	1	Jan 2022
– DNA-Mixture	1	Jan 2022
DNA Database - Saliva	3	Feb 2022
DNA Parentage	2	Feb 2022
Forensic Biology	1	March 2022
DNA-Semen	1	March 2022
Body Fluid Identification	1	March 2022

☒ If yes to the above, please provide a summary of your facility's performance in proficiency testing programs or inter-laboratory comparisons. This should include matrices/analytes covered and any outliers recorded (including actions taken).

All tests (mixture, semen, database, standard, parentage and body fluid) were consistent with manufacturers information with the exception of test FB5781 Body Fluid Identification test (March 2021). For this non-conformance OQI#55008 refers – see below for details and actions (Refer attached).

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Report for QIS OQI as of 11/03/2022 1:37:20 PM

Report for QIS OQI -

55008 CTS 21-5781 non-conformance

OQI Details

Status	Closed Approved
Subject	CTS results submitted by Forensic DNA Analysis for items 3 and 6 were not consistent with manufacturers information as provided by CTS.
Source of OQI	EQAP/Collaborative/Proficiency Test
Date Identified	22/06/2021

OQI Creator Contact Details

Creator	Abigail RYAN
Organisational Unit/s	Quality and Projects
Service/s	Forensic and Scientific Service
Site Location/s	Coopers Plains

Investigator/Actioner Contact Details

Actioner	Allan MCNEVIN
Organisational Unit/s	Evidence Recovery
Service/s	Forensic and Scientific Service
Site Location/s	Coopers Plains

Investigation Details

Investigation Completed 03/08/2021 **Root Cause Type** | None - No Problem

Investigation Details

Item 3

Based on the scenario provided, the examiner and peer reviewer had not considered testing the Item for the possible presence of saliva. The swab was stained with what appeared to be blood, which tested positive for the presumptive presence of blood. On review, the scenario does not provide any clear indication that item should have been tested for saliva. The testing carried out in FSS Forensic DNA Analysis is consistent with that reported by other laboratories, with 136 of 244 laboratories that responded to the CTS reporting saliva as "Not Tested".

The item was re-examined for the presence of saliva and tested positive.

Item 6

The item tested was black and pink in colour. The area of the item that tested positive for Phadebas was part of the fabric that was entirely black. The material did not appear faded, and there was no visual indication of the presence of blood. The scenario provided did not strongly indicate which body fluids the item should be tested for, so it was tested for the presence of semen and saliva, and visually inspected for the presence of blood. Of the 244 laboratories that responded to the CTS there were 15 laboratories that reported the

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item as negative for blood, 1 as inconclusive for blood and 15 that did not test the item for blood.

The item was re-examined for the presence of blood. It was noted that there was no visual indication of the presence of blood. The examiner did not recall any discolouration of the Phadebas test paper at the time of initial examination that may have provided some indication that blood was present. A TMB test was conducted on the area previously to be determined as Phadebas positive, and a positive result was obtained. The area which in which the DNA was located was an area of fabric with an intense black colour (i.e. not visibly faded in any way). At present, the laboratory does not have any validated protocols for observing for biological fluids under alternative light sources. This kind of testing is performed by QPS, and subsamples of possible blood staining are usually submitted as in-tube items. However, items requested for Saliva testing are usually submitted as whole items.

Preformed By Allan MCNEVIN

Action Details

Action Complete 03/08/2021 **Action Fix Type** No Action PossibleOutcomes

Title **Action Description** The testing of CTS tests does not perfectly correlate with routine processes. This is not unexpected as the CTS test has to cater to a larger number of laboratories with varying workflow practices. With respect to Item 3, for our laboratory, the testing of swabs is usually performed when swabs are submitted as "in-tube" samples, where the swab head is submitted inside a tube ready for DNA extraction. Testing for blood on these items is performed by QPS prior to submission to FSS. It is incumbent on the officer submitting the item for testing to request any additional testing (semen, saliva). Generally, case history information is either not provided, or only provided in relation to the specific items submitted for testing, and the laboratory staff are not called on to decide whether additional testing is required. As the sample type and location of Item 3, and the scenario provided would not flag any immediate thoughts of the need for saliva testing, it is not considered necessary that further actions are required to be carried out with respect to the results obtained from this specific test.

For Item 6, it is unclear what could have been done different, as on re-examination, there was no visible blood staining, most likely due to the intense colouration of the fabric being tested. At present, the laboratory does not have any validated protocols for observing for biological fluids under alternative light sources. This kind of testing is performed by QPS, and subsamples of possible blood staining are usually submitted as in-tube items. However, items requested for Saliva testing are usually submitted as whole items. At this stage, no actions as a result of the findings of this OQI have been determined.

The outcomes from this OQI to be discussed with the team next team meeting.

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status Accepted

4/08/2021 8:24:52 AM Abigail RYAN:

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Follow-up Status	
Comment	Accept investigation and actions as written
Approver	Paula BRISOTTO
Approval/Rejection Date	04/08/2021
Approval/Rejection Comment	4/08/2021 1:23:26 PM Paula BRISOTTO: Approved of investigation and actions

Associations

No Associations found

Records

No Records found

55008 CTS 21-5781 non-conformance

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MONTH	CTS Proficiency Testing Schedule 2021 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 58x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should NOT be used for sampling scientists.										
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted	Follow-up completed	Feedback presented
January	FB5701 Forensic Biology	[redacted]			Kerry-Anne Lancaster	Reporter	15/01/2021	8/03/2021	16/02/2021	7/04/2021	11/05/2021
					Matthew Hunt	Reviewer					
					Kristina Morton	Sampler					
					Mike Hart	Reference sampler					
	FB5801 DNA-Mixture				Kylie Rika	Reporter	15/01/2021	8/03/2021	5/03/2021	7/04/2021	11/05/2021
					Anne Finch	Reviewer					
					Valerie Caldwell	Sampler					
					Mike Hart	Reference sampler					
February	FB5840 DNA Database - Saliva				Sharelle Nydam	Reporter	11/02/2021	8/03/2021	4/03/2021	29/04/2021	11/05/2021
					Helen Williams	Reviewer					
					Valerie Caldwell	Sampler					
					Phillip Mcindoe	Reference sampler					
	FB5840 DNA Database - Saliva				Lisa Farrelly	Reporter	11/02/2021	8/03/2021	8/03/2021	29/04/2021	11/05/2021
					Biljana Micic	Reviewer					
					Valerie Caldwell	Sampler					
					Phillip Mcindoe	Reference sampler					
	FB5840 DNA Database - Saliva				Megan Mathieson	Reporter	11/02/2021	8/03/2021	4/03/2021	29/04/2021	11/05/2021
					Tara Prowse	Reviewer					
					Valerie Caldwell	Sampler					
					Phillip Mcindoe	Reference sampler					
	FB5870 DNA Parentage				Angelina Keller	Reporter	25/02/2021	19/04/2021 (extension to 03/05/2021)	15/04/2021	11/05/2021	11/05/2021
					Rhys Parry	Reviewer					
					Helen Williams	Sampler					
					Mike Hart	Reference sampler					
	FB5870 DNA Parentage				Penelope Taylor	Reporter	25/02/2021	19/04/2021 (extension to 03/05/2021)	15/04/2021	11/05/2021	11/05/2021
					Ingrid Moeller	Reviewer					
					Helen Williams	Sampler					
					Michelle Margetts	Reference sampler					
	FB5870 DNA Parentage				Jacqui Wilson	Reporter	25/02/2021	19/04/2021 (extension to 03/05/2021)	13/04/2021	11/05/2021	11/05/2021
					Adrian Pippia	Reviewer					
					Cindy Chang	Sampler					
					Kevin Avdic	Reference sampler					

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MONTH	CTS Proficiency Testing Schedule 2021 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 58x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should NOT be used for sampling scientists.										
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted	Follow-up completed	Feedback presented
March	FB5702 Forensic Biology	[redacted]			Thomas Nurthen	Reporter	8/03/2021	3/05/2021	27/04/2021	25/05/2021	6/08/2021
					Sharon Johnstone	Reviewer					
					Abbie Ryan	Sampler					
					Michelle Margetts	Reference sampler					
	FB5802 DNA - Semen				Ingrid Moeller	Reporter	8/03/2021	3/05/2021	29/04/2021	25/05/2021	6/08/2021
					Deborah Nicoletti	Reviewer					
					Valerie Caldwell	Sampler					
					Michelle Margetts	Reference sampler					
	FB5781 Body Fluid Identification				Sharon Byrne	Reporter	8/04/2021	24/05/2021	11/05/2021	4/08/2021	6/08/2021
					Allan McNevin	Reviewer					
					Abbie Ryan	Sampler Item 1					
					Kristina Morton	Sampler Item 2					
					Valerie Caldwell	Sampler Item 3					
					Helen Williams	Sampler Item 4					
					Cindy Chang	Sampler Item 5					
					Janine Seymour-Murray	Sampler Item 6					
April	FB5703 Forensic Biology				Allison Lloyd	Reporter	28/04/2021	21/06/2021	15/06/2021	13/07/2021	6/08/2021
					Angela Adamson	Reviewer					
					Janine Seymour-Murray	Sampler					
					Mike Hart	Reference sampler					
	FB5803 DNA - Blood				Justin Howes	Reporter	11/05/2021	21/06/2021	15/06/2021	13/07/2021	6/08/2021
					Josie Entwistle	Reviewer					
					Kristina Morton	Sampler					
					Kevin Avdic	Reference sampler					
May	FB5871 (a) DNA Parentage				Justin Howes	Reporter	11/06/2021	2/08/2021	12/07/2021	24/08/2021	30/09/2021
					Emma Caunt	Reviewer					
					Abbie Ryan	Sampler					
					Michelle Margetts	Reference sampler					
	FB5871 (b) DNA Parentage				Josie Entwistle	Reporter	11/06/2021	2/08/2021	19/07/2021	24/08/2021	30/09/2021
					Sharon Johnstone	Reviewer					
					Abbie Ryan	Sampler					
					Mike Hart	Reference sampler					
	FB5871 (c) DNA Parentage				Thomas Nurthen	Reporter	11/06/2021	2/08/2021	16/07/2021	24/08/2021	30/09/2021
					Kylie Rika	Reviewer					
					Abbie Ryan	Sampler					
					Kevin Avdic	Reference sampler					

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MONTH	CTS Proficiency Testing Schedule 2021 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 58x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should NOT be used for sampling scientists.											
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted	Follow-up completed	Feedback presented
July	FB5704 Forensic Biology	[redacted]		[redacted]	Emma Caunt	Reporter	16/07/2021	7/09/2021	24/08/2021	30/09/2021	30/09/2021
					Angelina Keller	Reviewer					
					Kristina Morton	Sampler					
					Michelle Margetts	Reference sampler					
	FB5804 DNA-Semen				Adrian Pippia	Reporter	16/07/2021	7/09/2021	2/09/2021	30/09/2021	30/09/2021
					Alicia Quartermain	Reviewer					
					Valerie Caldwell	Sampler					
					Michelle Margetts	Reference sampler					
	FB5843 (a) DNA Database - Saliva				Generosa Lundie	Reporter	29/07/2021	27/09/2021	26/08/2021	19/10/2021	2/12/2021
					Sharelle Nydam	Reviewer					
					Valerie Caldwell	Sampler					
					Julie Brooks	Reference sampler					
	FB5843 (b) DNA Database - Saliva				Pierre Acedo	Reporter	29/07/2021	27/09/2021	31/08/2021	19/10/2021	2/12/2021
					Megan Mathieson	Reviewer					
					Michelle Margetts	Sampler					
					Julie Brooks	Reference sampler					
	FB5843 (c) DNA Database - Saliva				Melissa Cipollone	Reporter	29/07/2021	27/09/2021	24/08/2021	19/10/2021	2/12/2021
					Lisa Farrelly	Reviewer					
					Michelle Margetts	Sampler					
					Julie Brooks	Reference sampler					
August	FB5872 (a) DNA Parentage				Claire Gallagher	Reporter	10/09/2021	25/10/2021	7/10/2021	17/11/2021	2/12/2021
					Jacqui Wilson	Reviewer					
					Helen Williams	Sampler					
					Louise Benincasa	Reference sampler					
	FB5872 (b) DNA Parentage				Ingrid Moeller	Reporter	10/09/2021	25/10/2021	18/10/2021	17/11/2021	2/12/2021
					Kylie Rika	Reviewer					
					Helen Williams	Sampler					
					Louise Benincasa	Reference sampler					

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MONTH	CTS Proficiency Testing Schedule 2021 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 58x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should **NOT** be used for sampling scientists.										
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted	Follow-up completed	Feedback presented
September	FB5705 Forensic Biology	[redacted]			Penny Taylor	Reporter	20/09/2021	8/11/2021	18/10/2021	2/12/2021	2/12/2021
					Allan McNevin	Reviewer					
					Helen Williams	Sampler					
					Louise Benincasa	Reference sampler					
	FB5805 DNA-Blood				Angela Adamson	Reporter	20/09/221	8/11/2021	21/10/2021	2/12/2021	2/12/2021
					Cassie James	Reviewer					
					Cindy Chang	Sampler					
					Louise Benincasa	Reference sampler					
	FB5782 Body Fluid Identification				Valerie Caldwell	Reporter	1/10/2021	22/11/2021	9/11/2021	4/01/2022	11/01/2022
					Allison Lloyd	Reviewer					
					Janine Seymour-Murray	Sampler Item 1					
					Cindy Chang	Sampler Item 2					
					Kristina Morton	Sampler Item 3					
					Michelle Margetts	Sampler Item 4					
					Kristina Morton	Sampler Item 5					
					Helen Williams	Sampler Item 6					
October	FB5706 Forensic Biology				Matthew Hunt	Reporter	2/11/2021	20/12/2021	9/12/2021	11/01/2022	11/01/2022
					Rhys Parry	Reviewer					
					Michelle Margetts	Sampler					
					Louise Benincasa	Reference sampler					
	FB5806 DNA-Mixture				Claire Gallagher	Reporter	2/11/2021	20/12/2021	8/12/2021	11/01/2022	11/01/2022
					Jacqui Wilson	Reviewer					
					Janine Seymour-Murray	Sampler					
					Louise Benincasa	Reference sampler					

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MONTH	CTS Proficiency Testing Schedule 2022 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 58x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should **NOT** be used for sampling scientists.								
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted
January	FB5701 Forensic Biology	[redacted]			Luke Ryan	Reporter	18/01/2022	7/03/2022	10/02/2022
					Allison Lloyd	Reviewer			
					Valerie Caldwell	Sampler			
					Kevin Avdic	Reference sampler			
	FB5801 DNA-Mixture				Kerry-Anne Lancaster	Reporter	18/01/2022	7/03/2022	1/03/2022
					Deborah Nicoletti (Rogers)	Reviewer			
					Helen Williams	Sampler			
					Mike Hart	Reference sampler			
February	FB5840 (A) DNA Database - Saliva				Helen Williams	Reporter	10/02/2022	4/04/2022	
					Pierre Acedo	Reviewer			
					Janine Seymour-Murray	Sampler			
					Kim Estreich	Reference sampler			
	FB5840 (B) DNA Database - Saliva				Biljana Micic	Reporter	10/02/2022	4/04/2022	9/03/2022
					Kirsten Scott	Reviewer			
					Kristina Morton	Sampler			
					Madison Gulliver	Reference sampler			
	FB5840 (C) DNA Database - Saliva				Tara Prowse	Reporter	10/02/2022	4/04/2022	6/03/2022
					Abbie Ryan	Reviewer			
					Amy Morgan	Sampler			
					Madison Gulliver	Reference sampler			
	FB5870 (A) DNA Parentage				Alicia Quartermain	Reporter	24/02/2022	18/04/2022	
					Angelina Keller	Reviewer			
					Cindy Chang	Sampler			
					Mike Hart	Reference sampler			
	FB5870 (B) DNA Parentage				Adrian Pippia	Reporter	24/02/2022	18/04/2022	
					Rhys Parry	Reviewer			
					Michelle Margetts	Sampler			
					Mike Hart	Reference sampler			
March	FB5702 Forensic Biology				Justin Howes	Reporter	10/03/2022	2/05/2022	
					Josie Entwistle	Reviewer			
					Valerie Caldwell	Sampler			
						Reference sampler			
	FB5802 DNA - Semen				Sharon Johnstone	Reporter	10/03/2022	2/05/2022	
					Thomas Nurthen	Reviewer			
					Helen Williams	Sampler			
						Reference sampler			
	FB5781 Body Fluid Identification					Reporter			
						Reviewer			
						Sampler Item 1			
						Sampler Item 2			
						Sampler Item 3			
						Sampler Item 4			
						Sampler Item 5			
						Sampler Item 6			

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EQUIPMENT

Equipment includes, but is not limited to, measuring instruments, reference standards and analytical systems.

Note: Refer to the *General Accreditation Criteria: Equipment assurance, in-house calibration and equipment verification*, available from the NATA website, for further information.

Please complete the table below (or attach a separate sheet) indicating whether the equipment is calibrated in-house or externally.

Calibration of equipment is necessary when:

- the measurement accuracy of measurement uncertainty affects the validity of reported results; and/or
- the equipment is required to establish the metrological traceability of reported results.

Where calibration of equipment is deemed not necessary, it is still required that the facility ensure equipment has been verified that it conforms with specified requirements (e.g. method requirements; manufacturer's requirements).

Equipment description	Calibrated		
	In-house		Externally
	Yes	Procedure (as per Methods Manual, national or international standard, etc)	Yes
Genetic Analysers: Forensic DNA Analysis currently has two 3500xl instruments in use, these are listed below. Also listed is the 3130xl instrument that was taken out of use on 15/02/2021. To be suitable for use the Genetic Analysis must meet annual service requirements and continue to pass internal spectral checks			
200418261 ; 3130 (B) - Analyser , 3130xl			Yes
200418262 ; 3500 (A) - Analyser , 3500xL			Yes
200418263 ; 3500 (B) - Analyser , 3500xL			Yes
QuantStudio: has 6 monthly maintenance, and 2 yearly calibration check by an external provider. The instruments are suitable for use if they pass internal monthly and external checks.			
200420763 QuantStudio 5 A			Yes
200420764 QuantStudio 5 B			Yes
ARTEL instruments: Forensic DNA Analysis has two ARTEL instruments (PCS and an MVS), both instruments use Dual dye photometry to enable verification of POVAs and pipetting robotics. The MVS instrument can do multichannel POVA up to 200uL and pipetting robotics, the PCS can do single channel POVAs to 5000uL. Both the MVS and PCS instruments are calibrated prior to use, using either a plate or calibration solutions (refer QIS#31956 and 26628). All reagents, consumables and calibration plate/solutions of the MVS and PCS systems are traceable back to the NIST Standard. The MVS calibrations plates are sent out to external providers			

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200418246 ; ARTEL MVS Calibration Plate			Yes
200418247 ; ARTEL MVS Calibration Plate			Yes
Balance: Receives 1 year service and 3 year NATA calibration by an external provider. Monthly and six monthly checks are completed internally. The balance is deemed suitable for use if it meets all NATA calibration/servicing requirements and continues to pass internal 1 & 6 monthly checks.			
200418260 ; Balance , Electronic XS105DU			Yes
BSD FTA punching instrument receives annual servicing by an external provider. No calibration is required. Instrument is suitable for use if servicing finds no issues with instrument function			
200422004 ; BSD 600 Ascent A2			Yes
Centrifuges: Within Forensic DNA Analysis we have both critical centrifuges and non-critical centrifuges. Centrifuges which are used for DNA extraction, microcon, nucleospin processing, semen testing or phadebas supernatant testing are deemed critical. Critical centrifuges are calibrated externally. They must pass external calibration to be suitable for use.			
200418244 ; Centrifuge , Eppendorf 5424			Yes
200418251 ; Centrifuge , Eppendorf 5424			Yes
200421429 ; Centrifuge , Eppendorf 5425			Yes
200422136 ; Centrifuge , Eppendorf 5425			Yes
200422137 ; Centrifuge , Eppendorf 5425			Yes
200422138 ; Centrifuge , Eppendorf 5425			Yes
200422139 ; Centrifuge , Eppendorf 5430			Yes
200421645 ; Centrifuge , Eppendorf 5804			Yes
200418255 ; Centrifuge , 333506			Yes
200419296 ; Centrifuge , 333506			Yes
200418254 ; Centrifuge , Sigma 41640			Yes
200418255 ; Centrifuge , Labogene 1248			Yes
Hamilton: Liquid handling platforms used for PCR set-up and CE set-up. Instruments have three monthly internal verifications using ARTEL to criteria given in QIS#26628 (MVS) which is relative inaccuracy and co-efficient of variation below 10% for ≤10µL and below 5% for ≥11µL, plus 6 monthly preventative maintenance by an external provider. The instrument is suitable for use if it meets both internal verifications and external servicing.			
200418618 ; Liquid Handler , Hamilton STARlet (B)	Yes	QIS#26628	Service
200418619 ; Liquid Handler , Hamilton STARlet (A)	Yes	QIS#26628	Service
200418620 ; Liquid Handler , Hamilton STARlet (C)	Yes	QIS#26628	Service

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Microscopes: receive annual servicing by an external provider. No calibration is required. Instrument is suitable for use if servicing finds no issues with function			
200418265 Microscope , Olympus BX41			Service
200418266 Microscope , Olympus BX41			Service
200418267 Microscope , Olympus BX41			Service
200418268 Microscope , Olympus BX41			Service
200420451 Microscope , Nikon Eclipse Ci-L			Service
200421945 Microscope , Nikon Eclipse Ci-L			Service
POVAs have been assessed as non-critical pieces of equipment. The checks that are in place to ensure pipettes are within range and suitable for use include: positive and negative controls on batches, initial NATA calibration certificates and internal 3 monthly checks with traceable ARTEL equipment and reagents. To be suitable for use POVAs must - pass initial NATA calibration and 3 monthly internal verifications using ARTEL to criteria given in QIS#26628 (MVS) and QIS#31956 (PCS) which is relative inaccuracy and co-efficient of variation below 10% for ≤10µL and below 5% for ≥11µL			
200418336 POVA 0.5-10ul , Thermo Finnpipette	Yes	QIS#31956 or QIS#26628	Initial
200418338 ; POVA 0.5-10ul , Thermo Finnpipette	Yes		Initial
200422696 ; POVA 0.5-10ul , Eppendorf Research Plus	Yes		Initial
200422697 ; POVA 0.5-10ul , Eppendorf Research Plus	Yes		Initial
200422884 ; POVA 0.5-10ul , Eppendorf Research Plus	Yes		Initial
200422761 ; POVA 0.5-10ul , Eppendorf Research Plus	Yes		Initial
200418341 ; POVA 1-10ul , Thermo Finnpipette	Yes		Initial
200418326 ; POVA 1-10ul , Thermo Finnpipette	Yes		Initial
200418327 ; POVA 1-10ul , Thermo Finnpipette	Yes		Initial
200418330 ; POVA 1-10ul , Thermo Finnpipette	Yes		Initial
200418294 ; POVA 1-10ul Cliptip , Thermo	Yes		Initial
200421793 POVA 1-10ul Cliptip , Thermo	Yes		Initial
200422690 POVA 10-100ul , Eppendorf Research Plus	Yes		Initial
200422691 POVA 10-100ul , Eppendorf Research Plus	Yes		Initial
200422692 POVA 10-100ul , Eppendorf Research Plus	Yes		Initial

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200422694 ; POVA 10-100ul , Eppendorf Research Plus	Yes	QIS#31956 or QIS#26628	Initial
200422632 ; POVA 100-1000ul , Eppendorf Research Plus	Yes		Initial
200422633 ; POVA 100-1000ul , Eppendorf Research Plus	Yes		Initial
200422634 ; POVA 100-1000ul , Eppendorf Research Plus	Yes		Initial
200422635 ; POVA 100-1000ul , Eppendorf Research Plus	Yes		Initial
200422636 ; POVA 100-1000ul , Eppendorf Research Plus	Yes		Initial
200422637 ; POVA 100-1000ul , Eppendorf Research Plus	Yes		Initial
200422638 ; POVA 100-1000ul , Eppendorf Research Plus	Yes		Initial
200418337 ; POVA 100-1000ul , Thermo Finnpipette	Yes		Initial
200418335 ; POVA 100-1000ul , Thermo Finnpipette	Yes		Initial
200418292 ; POVA 100-1000ul , Thermo Finnpipette	Yes		Initial
200419868 ; POVA 100-1000ul , Socorex Calibra 822	Yes		Initial
200422444 ; POVA 100-1000ul , Socorex Calibra 822	Yes		Initial
200422602 ; POVA 100-1000ul , Socorex Acura 825	Yes		Initial
200422603 ; POVA 100-1000ul , Socorex Acura 826	Yes		Initial
200420148 ; POVA 100-1000ul Clip Tip , Thermo	Yes		Initial
200420149 ; POVA 100-1000ul Clip Tip , Thermo	Yes		Initial
200418291 ; POVA 100-1000ul Clip Tip , Thermo	Yes		Initial
200418295 ; POVA 100-1000ul Clip Tip , Thermo	Yes		Initial
200421992 POVA 100-1000ul Clip Tip , Thermo	Yes		Initial
200421993 POVA 100-1000ul Clip Tip , Thermo	Yes		Initial
200418298 ; POVA 100-1000ul Cliptip , Thermo	Yes		Initial
200418299 ; POVA 100-1000ul Cliptip , Thermo	Yes		Initial
200418300 ; POVA 100-1000ul Cliptip , Thermo	Yes		Initial
200421767 POVA 100-1000ul Cliptip, Thermo	Yes		Initial

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200418334 ; POVA 2-20ul , Thermo Finnpipette	Yes	QIS#31956 or QIS#26628	Initial
200418342 ; POVA 2-20ul , Socorex Acura 825	Yes		Initial
200418332 ; POVA 2-20ul , Eppendorf Research	Yes		Initial
200422676 ; POVA 2-20ul , Eppendorf Research Plus	Yes		Initial
200422677 ; POVA 2-20ul , Eppendorf Research Plus	Yes		Initial
200422678 ; POVA 2-20ul , Eppendorf Research Plus	Yes		Initial
200422679 ; POVA 2-20ul , Eppendorf Research Plus	Yes		Initial
200418331 ; POVA 20-200ul , Eppendorf Research	Yes		Initial
200422727 ; POVA 20-200ul, Eppendorf Research Plus	Yes		Initial
200422728 ; POVA 20-200ul, Eppendorf Research Plus	Yes		Initial
200422729 ; POVA 20-200ul, Eppendorf Research Plus	Yes		Initial
200422730 ; POVA 20-200ul, Eppendorf Research Plus	Yes		Initial
200422731 ; POVA 20-200ul, Eppendorf Research Plus	Yes		Initial
200422732 ; POVA 20-200ul, Eppendorf Research Plus	Yes		Initial
200422885 ; POVA 20-200ul, Eppendorf Research Plus	Yes		Initial
200418343 ; POVA 20-200ul , Socorex Acura 825	Yes		Initial
200422601 ; POVA 20-200ul , Socorex Acura 825	Yes		Initial
200422604 ; POVA 20-200ul , Socorex Acura 826	Yes		Initial
200422879 ; POVA 20-200ul , Socorex Calibra 822	Yes		Initial
200422880 ; POVA 20-200ul , Socorex Calibra 822	Yes		Initial
200422881 ; POVA 20-200ul , Socorex Calibra 822	Yes		Initial
200418319 ; POVA 20-200ul , Thermo Finnpipette	Yes		Initial
200420814 ; POVA 20-200ul , Thermo Finnpipette	Yes		Initial
200418320 ; POVA 20-200ul , Thermo Finnpipette	Yes		Initial
200418317 POVA 20-200ul Cliptip , Thermo	Yes		Initial

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200418309 ; POVA 20-200ul Cliptip , Thermo	Yes		Initial
200418310 ; POVA 20-200ul Cliptip , Thermo	Yes		Initial
200421794 ; POVA 20-200ul Cliptip , Thermo	Yes		Initial
200418312 ; POVA 20-200ul Cliptip , Thermo	Yes		Initial
200418313 ; POVA 20-200ul Cliptip , Thermo	Yes		Initial
200418314 ; POVA 20-200ul Cliptip , Thermo	Yes		Initial
200418306 ; POVA 20-200ul Cliptip , Thermo	Yes		Initial
200420138 ; POVA 20-200ul Cliptip , Thermo	Yes		Initial
200419811 ; POVA 20-200uL Cliptip , Thermo	Yes		Initial
200418321 ; POVA 5-50ul , Thermo Finnpipette	Yes		Initial
200418339 ; POVA 5-50ul , Sealpette	Yes		Initial
200418328 ; POVA 5-50ul , Thermo Finnpipette	Yes		Initial
200421986 ; POVA 5-50ul , Thermo Finnpipette	Yes		Initial
200418329 ; POVA 5-50ul , Thermo Finnpipette	Yes		Initial
200418307 ; POVA 5-50ul Cliptip , Thermo	Yes		Initial
200418308 ; POVA 5-50ul Cliptip , Thermo	Yes	QIS#31956 or QIS#26628	Initial
200418304 ; POVA 5-50ul Cliptip , Thermo	Yes		Initial
200418305 ; POVA 5-50ul Cliptip , Thermo	Yes		Initial
200418302 ; POVA 5-50ul Cliptip , Thermo	Yes		Initial
200420053 ; POVA 5-50uL Cliptip , Thermo	Yes		Initial
200420103 ; POVA 30-30ul Multi Channel , Thermo	Yes	QIS#26628	Initial
200418315 ; POVA 1-10ul Multi Channel , Thermo	Yes		Initial
200418316 ; POVA 1-10ul Multi Channel , Thermo	Yes		Initial
200419981 ; POVA 50-300uL Multi Channel , Labsystems Finnpipette	Yes		Initial
200420015 ; POVA Ranin AutoRep E	Yes		Initial
200420462 ; POVA Multipipette E3 , Eppendorf	Yes		Initial

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200421847 ; POVA Multipipette E3 , Eppendorf	Yes	QIS#26628	Initial
200422610 ; POVA Multipipette Repeater , Eppendorf	Yes		Initial
200422611 ; POVA Multipipette Repeater , Eppendorf	Yes		Initial
200420450 ; POVA Multipipette Plus , Eppendorf	Yes		Initial
QIAsymphony instrument has two parts SP and AS modules. Both modules are serviced annually by an external provider. The AS module will also have 3 monthly verifications for dispensing volumes using the ARTEL MVS instrument. The QIAsymphony will be suitable for use if servicing finds no issues with instrument function and if 3-monthly checks in the ARTEL pass criteria given in QIS#26628 (MVS).			
200418249 ; QIAsymphony AS A , QIAsymphony AS	Yes	QIS#26628	Service
200420328 ; QIAsymphony AS B , QIAsymphony AS	Yes	QIS#26628	Service
200418248 ; QIAsymphony SP A , QIAsymphony SP	N/A	N/A	Service
200420192 ; QIAsymphony SP B , QIAsymphony SP	N/A	N/A	Service
Thermal cyclers: Forensic DNA Analysis previously used six 9700 thermal cyclers, these were taken out of use on 10/01/2022. They have been replaced with six Proflex thermalcyclers that were implemented on 10/01/2022. Annual checks by an external provider, and internal weekly cycle and rate checks. The instruments are suitable for use if they pass external annual checks and weekly internal checks.			
200418274 ; Thermal Cycler (B) , ABI 9700			Service
200418275 ; Thermal Cycler (C) , ABI 9700			Service
200418276 ; Thermal Cycler (D) , ABI 9700			Service
200418277 ; Thermal Cycler (E) , ABI 9700			Service
200418278 ; Thermal Cycler (F) , ABI 9700			Service
200418279 ; Thermal Cycler (G) , ABI 9700			Service
200420445 ; Thermalcycler Proflex 1 Base, Thermo 200422684 ; Thermalcycler Proflex 1 Samp Block, Thermo			Service
200420446 ; Thermalcycler Proflex 2 Base, Thermo 200422685 ; Thermalcycler Proflex 2 Samp Block, Thermo			Service
200420447 ; Thermalcycler Proflex 3 Base, Thermo 200422686 ; Thermalcycler Proflex 3 Samp Block, Thermo			Service
200420448 ; Thermalcycler Proflex 4 Base, Thermo 200422687 ; Thermalcycler Proflex 4 Samp Block, Thermo			Service
200420449 ; Thermalcycler Proflex 5 Base, Thermo 200422688 ; Thermalcycler Proflex 5 Samp Block,			Service

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Thermo			
200420576 ; Thermalcycler Proflex 6 Base, Thermo 200422689 ; Thermalcycler Proflex 6 Samp Block, Thermo			Service
Thermometers: Within Forensic DNA Analysis we have both critical and non-critical thermometers. Fridges and freezers within Forensic DNA Analysis are monitored by a BMS system (with alarms), however in addition to the BMS many fridges and freezers have non-critical thermometers in them for easy of user observation only. Non-critical thermometers are not included below. Thermometers that are deemed critical are those used for DNA extraction water-baths, nucleospin clean-ups and the CE denaturation blocks. Critical thermometers are checked internally every six months (single point) and a full check completed every 5 years. Thermometers are deemed suitable for use if they pass all internal checks (as per QIS#10670)			
200419950 ; Thermometer - Alcohol 24 , Alcohol/Glass 76mm Part/Immer	Yes	QIS#10670	
200419951 ; Thermometer - Alcohol 25 , Alcohol/Glass 76mm Part/Immer	Yes	QIS#10670	
200418670 ; Thermometer - Alcohol 32 , Alcohol/Glass 76mm Part/Immer	Yes	QIS#10670	
200418668 ; Thermometer - Alcohol 9 , Alcohol/Glass 76mm Part/Immer	Yes	QIS#10670	
Timers: Within Forensic DNA Analysis we have both critical and non-critical timers. Timers that are used to remind staff to return to samples post-denaturation, or during extraction are non-critical (non-critical timers are not listed below). Timers that are used for making a "result" reading on presumptive tests (AP and PSA) are deemed critical. Timers that are deemed critical are checked internally every 6 months against the National Measurement Institute (NMI) WebTimer, they must pass this internal check to be suitable for use (as per QIS#10672)			
200420325 ; Timer 2 , Electronic	Yes	QIS#10672	
200418259 ; Timer 34 , Electronic	Yes	QIS#10672	
200420501 ; Timer 4 , Electronic	Yes	QIS#10672	
200418257 ; Timer 7 , Electronic	Yes	QIS#10672	
200421923 ; Timer 41, Lab Co	Yes	QIS#10672	
200422531 ; Timer 42, Lab Co	Yes	QIS#10672	

☒ * For facilities performing in-house calibrations: please provide a copy of the test method and statement of capability of each in-house calibration identified above.

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SUBCONTRACTING, AGENCY OR FRANCHISING ARRANGEMENTS

Since your previous assessment, does your facility now operate under formal subcontracting, agency or franchising agreement with another organisation which you have not advised NATA of?

☐ Yes

☒ No

Note: While we do not sub-contract out any work from Forensic DNA Analysis to an external group, we do complete small scale commercial work (validations and environmental sample monitoring) for external organisations such as ARUMA.

If yes, please provide details of the arrangement and the principal organisation.

Note: As per *clause 5.3* the laboratory cannot claim conformity with ISO/IEC 17025 for externally provided laboratory activities on an ongoing basis.

TEST REPORTS, SAMPLING REPORTS AND CALIBRATION CERTIFICATES

☒ Please provide an example copy of a recently completed test report and/or sampling report and/or calibration certificate.

Note: Refer to the *General Accreditation Criteria: use of the NATA emblem, NATA endorsement and references to accreditation*, available from the NATA website, for criteria relating to endorsing reports.

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Queensland Government

Forensic and Scientific Services

STATEMENT OF WITNESS

Peer Reviewed..... (Yes/No)

Case Analyst.. [redacted] .....

Peer Analyst.. [redacted] .....

Date Issued..23/07/2021.....

Client Reference : [redacted]
Report Number : 6964592

QUEENSLAND)
TO WIT)

I, Allan Russell MCNEVIN, of Brisbane in the State of Queensland, do solemnly and sincerely declare that:-

1. I am employed by Queensland Health Forensic and Scientific Services (QHFSS) at Coopers Plains, Brisbane.
2. I hold the position of scientist in the Forensic DNA Analysis laboratory of QHFSS.
3. I was awarded a Bachelor of Applied Science from Queensland University of Technology.
4. I am a member of the Australian and New Zealand Forensic Science Society.
5. This is my statement in relation to the alleged offence that Occurrence Number [redacted] refers. The defendant in this matter is [redacted] The complainant in this matter is [redacted]

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STATEMENT OF WITNESS Client Reference : [redacted]

6. Laboratory records show that on 8 April 2021, S/CONST BRETT ANTHONY WINNETT delivered the following 17 items:

[redacted]

7. Laboratory records show that on 13 April 2021, STELLA CONDOLEON delivered the following reference sample:

[redacted]

8. Laboratory records show that on 15 April 2021, S/SGT STEPHAN PAUL FOXOVER delivered the following reference sample:

[redacted]

9. The results of the scientific examinations conducted in the laboratory are as follows:

[redacted]

The DNA profile of [redacted] has been determined from the reference sample.

[redacted]

The DNA profile of [redacted] has been determined from the reference sample.

[redacted] - **EXH A- DRIED RED STAIN 1CM X 1CM [SWBL] from the vehicle keys in the loungeroom**

The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

It is estimated that the mixed DNA profile obtained is approximately 14 times more likely to have occurred if [redacted] had not contributed DNA rather than if she had.

[redacted] - **EXH B- DRIED RED STAIN 3CM X 3CM [SWBL] from the checked shirt in the main bedroom**

The mixed DNA profile obtained from this sample indicates the presence of DNA from three contributors. Since this sample is said to have been collected from an item of clothing belonging to [redacted] it would not be unexpected to find DNA which could have come from him.

In order to interpret this mixed DNA profile an assumption of DNA from three contributors, one of whom is [redacted] has been made. The DNA profile of [redacted] has been compared to this mixed DNA profile, to assess whether or not she may have contributed DNA along with [redacted]

Based on statistical analysis, it is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

The results relate solely to the item(s) and/or sample(s) as received. Allan Russell MCNEVIN [redacted] Date 23 July 2021

NATA Accredited Laboratory 41 Accredited for compliance with ISO/IEC 17025 - Testing

[redacted]

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STATEMENT OF WITNESS Client Reference : [redacted]

[redacted] **EXH C- DRIED RED STAIN 3CM X 3CM [SWBL] from the checked shirt in the main bedroom**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. Since this sample is said to have been collected from an item of clothing belonging to [redacted], it would not be unexpected to find DNA which could have come from him.

In order to interpret this mixed DNA profile an assumption of DNA from two contributors, one of whom is [redacted] has been made. The DNA profile of [redacted] has been compared to this mixed DNA profile, to assess whether or not she may have contributed DNA along with [redacted]

Based on statistical analysis, it is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] **- EXH K- EXCISED DRIED RED STAIN 2CMX2CM [FABRIC] from the checked shirt in the main bedroom**
The mixed DNA profile obtained from this sample indicates the presence of DNA from three contributors. Since this sample is said to have been collected from an item of clothing belonging to [redacted], it would not be unexpected to find DNA which could have come from him.

In order to interpret this mixed DNA profile an assumption of DNA from three contributors, one of whom is [redacted] has been made. The DNA profile of [redacted] has been compared to this mixed DNA profile, to assess whether or not she may have contributed DNA along with [redacted]

Based on statistical analysis, it is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] **- EXH D- INVISIBLE STAIN [SWBL] from the steering wheel**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

It is estimated that the mixed DNA profile obtained is approximately 16000 times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] **- EXH E- DRIED RED STAIN 1CM X 1CM [SWBL] from the handbrake**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

The results relate solely to the item(s) and/or sample(s) as received. Allan Russell MCNEILLY [redacted]

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[redacted]

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STATEMENT OF WITNESS Client Reference : [redacted]

[redacted] can be excluded as having contributed DNA to this mixed DNA profile.

[redacted] - **EXH I- STAIN INVISIBLE [SWBL] From the Iphone case in the loungeroom**

The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

It is estimated that the mixed DNA profile obtained is approximately 3 times more likely to have occurred if [redacted] had not contributed DNA rather than if she had.

[redacted] - **EXH L-EXCISED FABRIC WITH DRIED RED STAIN 1CM X1CM [FABRIC] from the cloth in the drivers side door**

The DNA profile obtained from this sample matches the DNA profile of [redacted]. Based on statistical analysis, it is estimated that the DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

[redacted] - **JB1 - BLOOD SWAB 20CMX2CM DRY RED STAIN [SWBL] on front stairs railing**

The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

It is estimated that the mixed DNA profile obtained is approximately 1.2 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

[redacted] - **JB2 - BLOOD SWAB 8CMX4CM DRY RED STAIN [SWBL] on lamp on bedside table in front bedroom**

The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

The results relate solely to the item(s) and/or sample(s) as received. Allan Russell MCNEVIN [redacted] Date 23 July 2021

NATA Accredited Laboratory 41 Accredited for compliance with ISO/IEC 17025 - Testing

[redacted]

STATEMENT OF WITNESS Client Reference [redacted]

It is estimated that the mixed DNA profile obtained is approximately 30 times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

[redacted] - **JB3 - BLOOD SWAB 20CMX13CM DRY RED STAIN [SWBL] on right side of doona on bed in front bedroom**

The DNA profile obtained from this sample matches the DNA profile of [redacted] Based on statistical analysis, it is estimated that the DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] - **JB4 - BLOOD SWAB 2.5CMX2CM DRY RED STAIN [SWBL] on right side of doona on bed in front bedroom**

The DNA profile obtained from this sample matches the DNA profile of [redacted] Based on statistical analysis, it is estimated that the DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

[redacted] - **JB5 - BLOOD SWAB 1.5CMX2CM DRY RED STAIN [SWBL] on pillow on floor on right side of bed**

The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] - **JB6 - BLOOD SWAB 2CMX2CM WET RED STAIN [SWBL] on bathroom tile floor**

The DNA profile obtained from this sample matches the DNA profile of [redacted] Based on statistical analysis, it is estimated that the DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] - **JB7 - BLOOD SWAB 20CMX4CM DRY RED STAIN [SWBL] on kitchen fridge door**

The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

It is estimated that the mixed DNA profile obtained is approximately 2 times more likely to have occurred if [redacted] had not contributed DNA rather than if he had.

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STATEMENT OF WITNESS Client Reference : [redacted]

[redacted] **- JB9 - BLOOD SWAB 5CM X 3CM DRY RED STAIN [SWBL] on handle of knife**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

It is estimated that the mixed DNA profile obtained is approximately 1100 times more likely to have occurred if [redacted] had not contributed DNA rather than if he had.

[redacted] **- JB10 - BLOOD SWAB 4CM X 2CM DRY RED STAIN [SWBL] on blade of knife**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

It is estimated that the mixed DNA profile obtained is approximately 580 million times more likely to have occurred if [redacted] had not contributed DNA rather than if he had.

The results relate solely to the item(s) and/or sample(s) as received. Allan Russell MCNEVIN [redacted] Date 23 July 2021

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[redacted]

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

STATEMENT OF WITNESS Client Reference [redacted]

APPENDIX

Procedural and technical overview of DNA profiling at Forensic DNA Analysis, Forensic and Scientific Services

Forensic Biologist

It is a forensic biologist's role to:

1. Report on the examination of items submitted in relation to a case for the presence of possible biological material. If identified, a sample of the biological material is analysed in an attempt to obtain a DNA profile.

2. Report on the DNA profiles obtained from samples submitted by the Queensland Police Service (QPS) in relation to a case.

Any DNA profiles that are obtained from these samples are compared with the DNA profile obtained from an individual's reference sample to assess whether or not the individual may be a contributor of DNA. Where multiple reference DNA profiles are analysed for a case, they are all genetically different to each other unless otherwise specified. That is, they all possess differing allelic designations – see the *DNA Profiling* section below.

Examinations

Unless otherwise stated, the examinations of items for biological material were conducted by staff within the QPS. Sub-samples from these items were forwarded to Forensic and Scientific Services (FSS), for the purposes of conducting DNA analysis.

The descriptions of items and/or samples submitted to Forensic DNA Analysis by the QPS, and listed within this Statement, are derived from the descriptions entered by the QPS into the Forensic Register.

Receipt details are listed for items reported in this statement, including reference samples where relevant. The period of testing on these items is from the date of the first submission, to the date of this Statement. Details of specific dates of testing are retained within the Laboratory Information Management System (LIMS). Where relevant, any items that are still in progress at the time of issuing this Statement are identified and final results will be reported in an addendum Statement.

Forensic DNA Analysis operates under the agreement that the QPS are responsible for item prioritisation, sample selection, selection of screening/sampling methods, anti-contamination procedures and the application of Standard Operating Procedures (SOPs) on work undertaken on the items/samples prior to submission to the Forensic DNA Analysis laboratory. As such, forensic biologists may not be able to provide information or opinion on possible biological origin of DNA profiles that may be obtained from these samples.

At the discretion of the QPS, some items may be submitted to this laboratory for the purposes of both examination and DNA profiling. These examinations are performed in accordance with the SOPs of this laboratory. For these items, contemporaneous notes are made during the examination by the examining scientist and these notes form part of the casefile.

Forensic DNA Analysis casefiles and any samples remaining are available for independent examination and / or testing upon request.

As a representative of the laboratory, I am only able to comment on the processes performed within Forensic DNA Analysis.

STATEMENT OF WITNESS Client Reference [redacted]

Chain of Custody

All Forensic DNA Analysis case files and exhibits are electronically tracked, monitored, and securely stored to ensure that appropriate chain of custody and continuity measures are maintained. The QPS case number and sample submission information is provided from the QPS via an electronic interface to FSS, and this information is cross-checked against labelling on the exhibit packaging prior to processing.

Entry into Forensic DNA Analysis is restricted to authorised persons only, via electronic proximity access cards. Forensic DNA Analysis forms part of a Queensland Health campus site wherein access is controlled and monitored by a security team. Records of visitors to Forensic DNA Analysis are retained.

Accreditation

Forensic DNA Analysis first achieved accreditation by the National Association of Testing Authorities (NATA) to conduct forensic DNA analyses in 1998, and has continuously maintained NATA accreditation since this date. NATA ensures continued compliance with the accreditation requirements through routine reassessment (every 3 years) and an intermediate surveillance visit (at approximately 18 months between reassessment surveys).

NATA accredited facilities are assessed against best international practices based on the ISO/IEC 17025 standard. Laboratories are deemed able to competently perform testing and analysis activities if the laboratory demonstrates that it meets compliance with the standard within the scope of their accreditation.

The parameters assessed during accreditation include:

- Organisation and management
- Quality management system
- Personnel
- Evidence management
- Methods and procedures
- Quality control and Proficiency Testing
- Equipment
- Reporting of results
- Procurement of services and supplies
- Accommodation and safety
- Security and access

For details of the current ISO/IEC 17025 Standard, refer to *Standards Australia*.

http://www.nata.com.au

DNA Profiling

Deoxyribonucleic acid (DNA) is a complex chemical found in almost all cells of the human body. It carries genetic information that determines the physical and chemical characteristics of a person. Forensic DNA Analysis uses two main systems for the generation of DNA profiling results. In this case, the PowerPlex® 21 System was used, which examines 21 regions (loci) of DNA, 20 of which contain highly variable short tandem repeats (STRs). The 21st region gives an indication as to the genolypic sex of the donor (for details see Table 1). The generation of a DNA profile involves a method known as the polymerase chain reaction (PCR), which is used to produce numerous copies of these specific regions of the DNA. In this way, minimal amounts of DNA isolated from small or degraded samples can be increased to a level where the DNA can be detected, profiled, and compared with DNA profiles from other samples.

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STATEMENT OF WITNESS Client Reference : [redacted]

The individual components (alleles) of a DNA profile are represented by a series of peaks on a graph that are measured and given a designation, using standard sizing ladders. A person will have two alleles (represented graphically as peaks) for each locus, one inherited from the biological mother and one inherited from the biological father. However, if the same allele is inherited from both parents, only one peak will be graphically represented at that locus.

A DNA profile obtained from biological material such as blood, semen, saliva, hair or cellular material (eg. touch DNA) can be compared with the DNA profile obtained from the reference sample from any person.

Table 1: PowerPlex® 21 system, list of loci

Abbreviated Name	Scientific Name	Chromosomal Name
Amel	AMELOGENIN	Sex (X and Y)
D3	D3S1358	3
D1	D1S1656	1
D6	D6S1043	6
D13	D13S317	13
Penta E	Penta E	15
D16	D16S539	16
D18	D18S51	18
D2	D2S1338	2
CSF	CSF1PO	5
Penta D	Penta D	21
TH01	TH01	11
vWA	HUMVWAFA31/A	12
D21	D21S11	21
D7	D7S820	7
D5	D5S818	5
TPOX	TPOX	2
D8	D8S1179	8
D12	D12S391	12
D19	D19S433	19
FGA	HUMFIBRA	4

Statistical Analysis of DNA Profiles

STRmix™ is an expert statistical DNA profile analysis system developed and validated in Australia and New Zealand. Forensic DNA Analysis uses the STRmix™ software to assist in the interpretation of DNA profiles and the calculation of likelihood ratios for DNA profiles generated using the PowerPlex® 21 system.

DNA profiles are initially assessed to determine the number of contributors. This value will be the minimum number of people that are required to reasonably explain the observed profile, however, it is noted that there is always the possibility that the profile is a result of a different number of contributors.

As such, if there is no indication of a contribution by more than one person, then a DNA profile is described as being from a "single contributor". If less than 40 alleles are present in a DNA profile, this is referred to as a "partial" or "incomplete" DNA profile. If there are indications of two or more contributors, then a DNA profile is described as being a "mixed" DNA profile.

STATEMENT OF WITNESS Client Reference : [redacted]

DNA Profiles Assumed To Originate From One Person (Single Source)

A person can be excluded as a possible source of the biological material if the alleles of the crime-scene DNA profile are different from the corresponding alleles of the person's reference DNA profile. If the corresponding alleles of the crime-scene DNA profile contain the same information, then that person, along with any other person who has the same corresponding alleles as the crime-scene DNA profile, can be considered as a potential contributor of the DNA.

The evidential significance of such a finding is assessed by considering two competing propositions:

Proposition 1: The crime-scene DNA originated from the person of interest.

Proposition 2: The crime-scene DNA originated from someone other than, and unrelated to, the person of interest.

The resultant figure (termed the 'Likelihood Ratio') compares the two opposing propositions. The likelihood ratio describes how likely the DNA profile obtained from the biological material is to have occurred if Proposition 1 were true (the DNA originated from the person of interest) rather than if Proposition 2 were true (the DNA originated from someone other than, and unrelated to, the person of interest).

The likelihood ratio is calculated by taking into account the characteristics of the DNA profile and the frequency of occurrence of the individual alleles that make up the DNA profile.

If less than the 20 STR regions of DNA are observed in a DNA profile, the likelihood ratio will be smaller than the likelihood ratio calculated for a full DNA profile obtained from the same individual. In other words, the more incomplete a DNA profile is, the greater the likelihood that the obtained DNA profile could have come from someone other than, and unrelated to the person of interest.

DNA Profiles Assumed To Originate From More Than One Person (Mixed DNA Profiles)

In order to assess whether a person may or may not have contributed to a mixed DNA profile, a set of competing propositions (similar to the single source DNA profile example) are considered. For example, for a two-person mixture:

Proposition 1: The crime-scene DNA originated from the person of interest and an unknown person, unrelated to the person of interest.

Proposition 2: The crime-scene DNA originated from two unknown people, both unrelated to the person of interest.

The likelihood ratio provides a statistical assessment of the possibility that the DNA profile obtained was the result of a DNA contribution by the person of interest.

The likelihood ratio will not always favour Proposition 1 (the DNA originated from the person of interest and an unknown person unrelated to the person of interest). The likelihood ratio could favour Proposition 2 (the DNA originated from two unknown people unrelated to the person of interest).

In certain circumstances, if the ownership of an item is established or if the sample was collected from an identified person's body, then it is possible to make the reasonable assumption that the identified person has contributed DNA to the resultant mixed DNA profile. In these cases, a mixed DNA profile can be 'conditioned' on the DNA profile of the assumed contributor, such that the presence of the alleles corresponding with the assumed contributor's reference DNA profile can be factored into the statistical interpretation. This may facilitate a more meaningful statistical analysis of potential second and/or third contributors to the DNA profile. In this situation, the likelihood ratio is based on the following propositions:

Proposition 1: the DNA has originated from the assumed contributor and the person of interest.

Proposition 2: the DNA has originated from the assumed contributor and an unknown individual, unrelated to the person of interest.

DNA profiles with an uncertain number of contributors

Forensic DNA Analysis is currently validated for the interpretation of DNA profiles with 1-4 contributors. Once the assessment of the number of contributors has been made, this information is used in the STRmix™ analysis.

When a DNA profile is deemed unsuitable for interpretation it may be described as 'complex'. This can occur under the following circumstances:

- When a DNA profile could have a large number of contributors and therefore it is difficult to exclude individuals and/or determine whether a person could be a potential contributor to the DNA profile
- When there is very limited information available and/or the quality of the profile is poor.

It is important to note that should further information be received that renders the assumptions used in an analysis invalid, the DNA profile will require additional statistical interpretation.

Datasets Used in Statistical Analyses

Three validated datasets consisting of DNA profiles obtained from individuals of the Australian Caucasian, Aboriginal, and South-East Asian populations are used to calculate the likelihood ratio. A population correction factor, θ (theta), is applied to all likelihood ratio calculations in order to correct for the common genetic ancestry of people within a particular population (sharing of DNA components inherited from a common ancestor). In Forensic DNA Analysis, a likelihood ratio that represents a stratified population statistic is reported irrespective of whether the DNA profile of interest is single source or a mixed DNA profile.

The likelihood ratio is calculated using all three datasets and the relative proportions of each ethnic grouping in the overall Australian population based on data sourced from the Australian Bureau of Statistics. This calculation, which is known as stratification, allows for the possibility that a random unknown person, unrelated to the person of interest, from anywhere in Australia could have contributed to the DNA profile obtained. Therefore, the likelihood ratio is not dependent on the ethnicity of the person of interest, but it is representative of the relative proportion of the person of interest's ethnic population within the larger Australian population.

Theta cannot account for close blood relatives. Closely related people, such as siblings, will have a greater chance of sharing similar components within their DNA profiles. However, due to the nature of parental DNA recombination during conception, the probability that two siblings would share the same 40 alleles would be very small. As this relationship becomes more distant, the probability of two relatives having the same DNA profile becomes smaller still. If it were thought that a close blood relative might have been a contributor of DNA, the most meaningful approach to interpretation would be to submit the reference sample from the relative in question for DNA analysis and subsequent direct comparison to the crime-scene DNA profile.

Often the calculated likelihood ratio produces numbers of thousands (1000s) or even millions (1000,000s) of billions. To avoid the use of potentially confusing mathematical terminology, a "ceiling figure" for the likelihood ratio of 100 billion is used (this is called "truncation"). For example, a calculated likelihood ratio of "150 000 billion times more likely", would be reported as "greater than 100 billion times more likely". The actual calculated figure can be provided upon request.

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Touch DNA / Transfer of DNA

When a person touches a surface, it is possible for their DNA to be transferred onto that surface. This transferred DNA can often be recovered (sampled) by a swab, tape lift, or excision depending upon the nature of the surface in question, and the sample can then be subjected to DNA profiling.

This transferred DNA can originate from cells or cellular material within sweat and/or oils on the skin. The generation of a DNA profile will depend on many factors. These include the amount of DNA transferred, the nature of the surface being touched, and the amount of genetic material available for transfer. The persistence of any transferred genetic material to a surface will depend largely upon the nature of the surface and the conditions the surface has been subjected to in the time between deposition and recovery of the DNA. For example, DNA could be lost from the surface by washing or mechanical action such as abrasion.

It therefore follows that the inability to obtain a DNA profile from a touched surface does not necessarily mean that a person has not had contact with the surface. It is possible for a person to contact a surface without a detectable amount of their DNA being transferred or subsequently recovered for analysis.

JUSTICES ACT 1886

I acknowledge by virtue of Section 110A (6C) (c) of the Justices Act 1886 that:

(i) This written statement by me dated 23 July 2021 and contained in the pages numbered 1 to 12 is true to the best of my knowledge and belief; and

(ii) I make it knowing that, I would be liable to prosecution for stating anything that I know is false.

..... [redacted] .....

Allan Russell MCNEVIN

Signed at BRISBANE on 23 July 2021

The results relate solely to the item(s) and/or sample(s) as received. Allan Russell MCNEVIN ..... [redacted] ..... Date 23 July 2021

NATA Accredited Laboratory 41 Accredited for compliance with ISO/IEC 17025 - Testing

[redacted]

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ASSESSMENT INFORMATION DOCUMENT

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PROCEDURES

☒ Please provide a list and copy of all non-standard test or calibration or inspection procedures (including in-house procedures) covered by the scope of accreditation.

Equipment Documents:
#10670 Procedure for Thermometer Checks
#10672 The Verification of Timing Devices
#26628 Verifications using the ARTEL MVS
#31956 Verifications using the ARTEL PCS Pipette Calibration System
#33315 Procedure for Verification and Maintenance of Equipment

Major Forensic DNA Analysis procedures:
#17091 Organisation and Management in Forensic DNA Analysis
#17117 Procedure for Case management
#17146 Internal Security and Access to Forensic DNA Analysis
#17154 Procedure for Quality Practice in Forensic DNA Analysis
#22871 Procedure for Change Management in Forensic DNA Analysis
#28801 DNA Analysis Unit Management Review template
#30800 Investigating Adverse Events in Forensic DNA Analysis
#33773 Procedure for Profile Data Analysis using the Forensic Register
#33800 Examination of Items
#34006 Procedure for the release of results using the Forensic Register
#34035 Forensic Register FTA Processing
#34229 Explanations of Exhibit Results for FR
#34245 Reference Sample Result Management
#34247 Creating and Reviewing Links - FR
#34281 Procedure for the Use and Maintenance of the Forensic DNA Analysis Elimination Databases

Additional minor documents can be provided on request

☒ Please provide an example of an estimation of measurement uncertainty (MU) and a list of the procedures for which MU estimates have been made.

Documents:
#10670 Procedure for Thermometer Checks
#10672 The Verification of Timing Devices

Changes to least uncertainties of measurement:

☒ Not applicable. There are no changes to least uncertainties of measurement.

☐ If there are changes to least uncertainties of measurement, provide uncertainty calculations and supporting data for their derivation.

Note: Changes to calibration and measurement capability (CMC) may be considered as additions to the scope of accreditation. Please complete the Application for changes to the scope of accreditation form available from the NATA website.

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

WORKPLACE HEALTH & SAFETY

Assessments are conducted by a team comprising of NATA staff and voluntary technical assessors. This team will need to attend your premises to have discussions with your staff and to observe activities covered by your scope of accreditation being performed.

To prepare for the assessment and to ensure the health and safety of the assessment team while on-site (including any field work), please respond to the following:

General issues

Issue	Yes	No
Have relevant WHS requirements been implemented, including provision of appropriate amenities for the NATA assessment team (e.g. washrooms, potable water supply)?	☒	☐
Does your facility, or a site to be visited, have a company alcohol and testing policy which the NATA assessment team would be subject to? **If yes, please attach a copy of the policy.**	☐	☒
In response to the COVID-19 pandemic		
Does your facility comply with government guidelines pertaining to social distancing in addition to other provisions such as hand sanitation facilities and visitor register (to allow for contact tracing)?	☒	☐
Can your facility provide COVID-19 PPE, as required?	☒	☐
Will the assessment team be subject to additional measures to those of relevant health directives relating to COVID? **If yes, please provide detail in the space below or on a separate sheet.**	☐	☒
Additional measures:		

Specific hazards

Location	Hazard	Precaution
e.g. Abattoir *e.g. Radiography laboratory*	*Q Fever* *Radiation*	*Vaccination required* *Film badge*
All laboratory areas	Contaminations of exhibits	PPE required
All laboratory areas	Standard chemical use	PPE required
All laboratory areas	Biological hazard	PPE required

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

MANAGEMENT SYSTEM

☒ Please provide a copy of your facility's current management system documentation and any associated management system procedures.

Refer to document #19259 – FSS Quality Management System Guide
Additional documents can be provided on request.

ISO/IEC 17025:2017 requires the facility to implement a management system in accordance with either Option A or Option B.

Option A requires clauses 8.2 to 8.9 of the Standard to be addressed.

Option B requires that a management system to be implemented in accordance with ISO 9001.

Your facility has established a management system in accordance with which option of the standard?

☒ Option A
☐ Option B

If the management system established is in accordance with Option A, it will be assessed against clauses 8.2 to 8.9 of the Standard.

If the management system established is in accordance with Option B, the records to be reviewed on-site by the NATA Lead Assessor may be reduced subject to the following:

1) the management system is certified by a certification body (CB) accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA);

2) the CB's accreditation covers ISO/IEC 17021 Parts 1 and 3. If Part 3 is not specifically listed in the CB's scope of accreditation, then it must be clear that its accreditation covers the certification of Quality Management Systems (QMS) to ISO 9001 (which may be included in the scope of accreditation or other documentation provided by the accreditation body signatory to the IAF MLA);

3) copies of the most recent certification audit report(s) issued by the CB covering your facility's management system in full is (are) provided to NATA;

4) confirmation from the CB of the close out of any non-conformities raised during certification audits is provided to NATA;

5) the certification of the management system covers the laboratory activities proposed to be covered by your NATA scope of accreditation.

Evidence in support of 1) to 5) is requested to be submitted with a copy of your facility's management system documentation. The latter is required to allow the assessment team to familiarise itself with your system. The records to be reviewed on-site will be dependent on the extent of the evidence provided and the extent of the audits performed by the CB.

Should evidence supporting points 1) to 5) not be provided, NATA will assess your management system in accordance with Option A (i.e. clauses 8.2 to 8.9 of the Standard).

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Queensland Health

Role description

Job ad reference:	HSQ 385742	**Unit/branch:**	Forensic and Scientific Services
Role title:	Executive Director Forensic and Scientific Services	**Location:**	Coopers Plains
Status:	3-month higher duties opportunity, with the possibility of extension	**Closing date:**	7th September 2021
Classification:	HES2H	**Contact name:**	Brett Bricknell
Salary range:	$217,986 to $235,654 Total Remuneration Per Annum	**Phone:**	[redacted]

Department of Health

The Department of Health has a diverse set of responsibilities, and a common purpose of creating better health care for Queenslanders. The department is responsible for the overall management of the public health system in Queensland. We strongly believe in the need to work with people that value the goals of our organisation and who will thrive in our workplace.

To enable this vision, the Queensland Public Sector is transforming from a focus on compliance to a values-led way of working. The following five values underpin behaviours that will support and enable better ways of working and result in better outcomes for Queenslanders.

About Forensic and Scientific Services

Forensic and Scientific Services (FSS) provides highly specialised analysis, interpretation, advice and research to public and private sector clients in forensic, environmental and public health sciences. This includes a broad remit of state-wide services which is summarised below.

As part of the implementation of Phase One of the Department of Health's Business Case for Significant Change, Forensic and Services in June 2021 was formally merged with Queensland's Statewide public pathology service Pathology Queensland. This new larger pathology, forensic and scientific services entity was also realigned from being part of the now defunct Health Support Queensland to Queensland Health's Prevention Division.

Forensic Services

We provide specialised services and expert advice to the Queensland Police Service (QPS) and the Coroner's Court of Queensland. Our services include clinical forensic medicine including the examination of victims and

alleged perpetrators, forensic biology including DNA profiling and analysis to support crime investigations, forensic toxicology involving the analysis, detection, and interpretation of drugs, alcohol, poisons and other substances, forensic chemical testing and evidence examination, coronial autopsies and examinations, and the provision of expert evidence and opinions to the Queensland Police Service and Coroner's Court of Queensland.

Scientific Services

We provide specialised services and expert advice to a range of public and private sector clients. Our services include public and environmental health sciences including organic chemistry, inorganic chemistry, microbiology, virology, and radiation and nuclear sciences. We provide tailored method development, project testing programs, custom scoping and analysis, and expert consultancy services across the state. This includes water testing, food and beverage testing, environmental testing, disease investigation and analysis, whole genome sequencing, and radiometric analysis and post-incident remediation. We are routinely involved in research projects, collaborations, and publications.

Purpose of the role

The Executive Director Forensic and Scientific Services (FSS) is accountable to the General Manager Pathology Queensland and Forensic and Scientific services to effectively manage, lead and optimise the state-wide operations of Forensic and Scientific Services, ensuring the provision of high-quality, cost-effective, and client-centred service delivery. This is an opportunity to lead a highly specialised state-wide service which plays an integral role in supporting frontline health service delivery, population health and safety, and civil justice in Queensland.

Your key responsibilities

You will be required to fulfil the responsibilities of this role in accordance with the Queensland Public Service values.

- Adhere to defined service quality standards, health and safety policies and procedures relating to the work being undertaken to ensure high quality, safe services, and workplaces.
- Fulfil the responsibilities of this role in accordance with the Queensland Public Service values.
- Lead and manage the operations of the Forensic and Scientific Services business to ensure the delivery of performance targets and operational objectives.
- Champion continual improvements in business processes and professional practices as well as service innovation so that services are delivered more effectively and efficiently year-on-year.
- Implement successful change management and continuous improvement initiatives.
- Actively contribute to the strategic management and continuous improvement of the system by participating in key governance groups and undertaking sponsorship and senior responsible officer roles for project and research work.
- Develop comprehensive annual service forecasts and budgets, business cases and business plans to optimise effectiveness and value-for-money.
- Ensure effective management and monitoring of FSS budget and establishment in accordance with statutory responsibilities, departmental policies and procedures, and organisational priorities.
- Management of FSS campus, facilities, and medical technology.
- Establish and maintain strong relationships with clients and stakeholders including internal Queensland Health partners and external organisations such as other government departments and agencies and industry representatives and networks.
- Foster an engaged and productive workforce and a professional environment that promotes values-based behaviour, staff wellbeing, skills development, professional growth, and continuous improvement.
- Represent Queensland Health in internal and external capacities including engagement activities and media activities.

- Provide expert advice to the Executive Leadership Team, Chief Executive Officer and proposed HSQ Reference Board of HSQ and other senior stakeholders on forensic and scientific services matters.
- Ensure that all relevant legislation and regulatory obligations are met including industry accreditations such as that by the National Association of Testing Authorities.
- Ensure ethical decision making in the management and achievement of organisational goals.
- Adhere to defined service quality standards, occupational health and safety policies and procedures relating to the work being undertaken to ensure high-quality, safe services and workplaces.

Key competencies (role specific criteria)

You will be assessed on your ability to demonstrate the following:

- Proven ability to support and lead staff through significant organisational change, ensuring at the same time that they remain focused on delivering on their core duties and responsibilities.
- Expertise in contemporary applied public health science principles.
- Proven ability in the leadership of a diverse and complex scientific services organisation.
- Strong track record of developing, implementing, and evaluating scientific business and service models to deliver measurable outcomes.
- Proven ability to manage scientific resources and programs effectively, efficiently, and ethically.
- Highly developed interpersonal, negotiation and communication skills and the demonstrated ability to foster effective and productive relationships with a variety of stakeholders.

Qualifications, registrations, and other requirements

- Bachelor of Applied Science degree or an equivalent qualification is highly desirable.
- Postgraduate qualifications in business administration, public sector management or equivalent is highly desirable.
- Travel across the greater Brisbane area will be a requirement of this role. Therefore, the ability to operate a class C vehicle and an appropriate licence endorsement is required. Some intrastate and interstate travel may also be required.

Vaccine Preventable Diseases (VPD) requirements

- It will be a condition of employment for this role for the employee to be, and remain, vaccinated against one or more of the following vaccine preventable diseases during their employment: SARS-CoV-2, Hepatitis A & B, Measles, Mumps, Pertussis, Rubella and Varicella.
- Additional vaccinations including Japanese Encephalitis and Rabies may also be required for this position.
- Existing staff that are engaged prior to 1 July 2016 are not subject to this condition of employment unless they apply for a role with VPD requirements that is with a different Queensland Health entity (i.e. one HHS to another HHS, department to a HHS, or HHS to department).

Additional Information

Please refer to the instructions in the accompanying internal Expression of Interest, noting that this temporary opportunity is, for short term practical and business continuity purposes, limited to existing staff of Pathology Queensland and Forensic and Scientific Services.

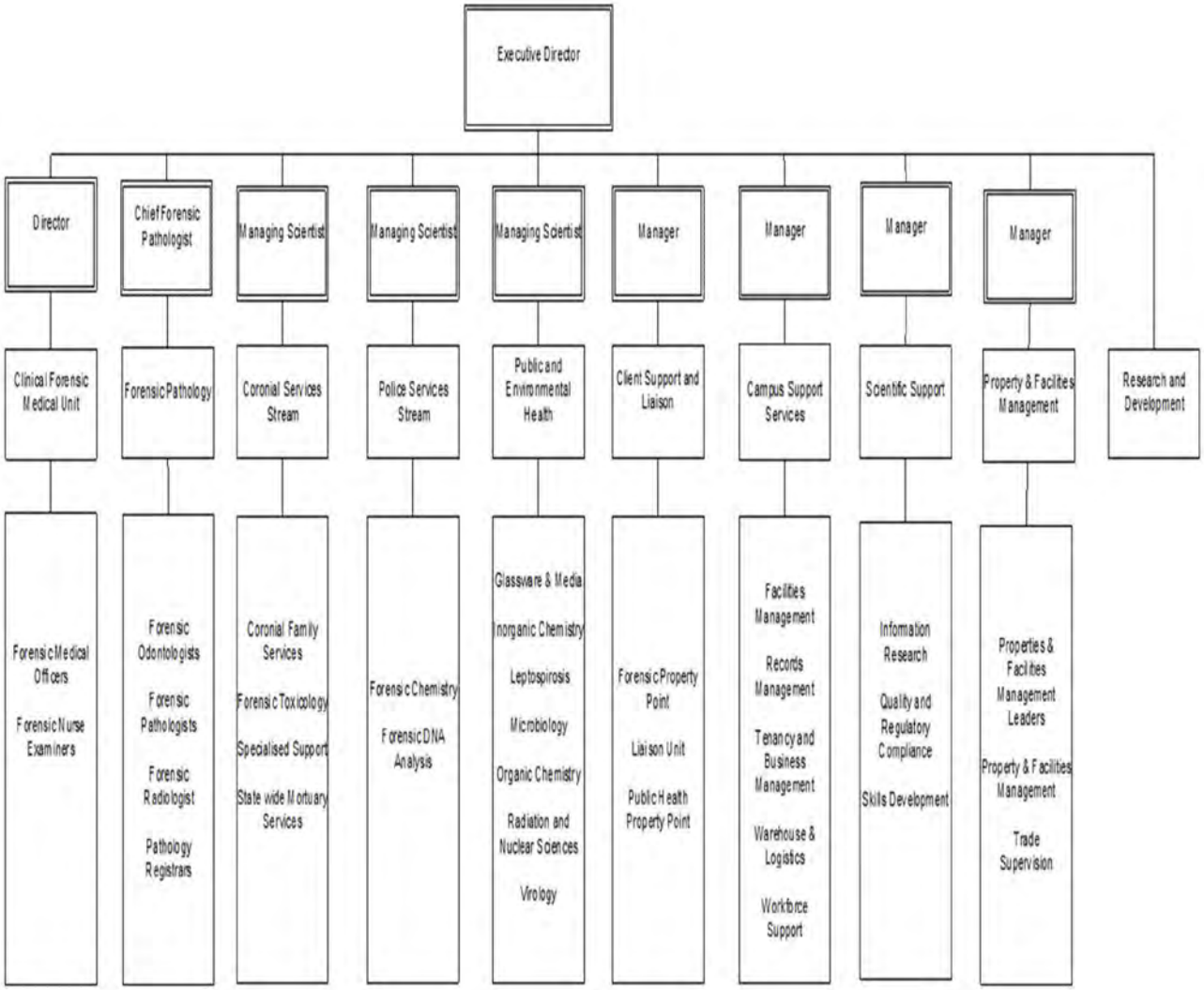
Any enquiries regarding this position should be directed to Brett Bricknell, General Manager, Pathology Queensland and Forensic and Scientific Services on [redacted]

In submitting your Expression of Interest, please provide the following information to the panel to assess your suitability:

- Your **resume**, including the names and contact details of two referees who have a thorough knowledge of your capabilities, work performance and conduct within the previous two years. This should if at all possible, include your current, immediate, or past supervisor.
- A short (no more than one page) **covering letter** informing the panel of your skills, personal qualities, and motivation for applying.

Discover more about our work, our people and employment opportunities at Queensland Health.

Forensic and Scientific Services – Executive Director direct reports/functional areas



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HealthSupport Queensland
Forensic and Scientific Services

Appointment of Analysts for Police Services Stream

1 Purpose

This document describes the procedures for the appointment of Analysts with Police Services Stream. It describes the procedure for the appointment of DNA Analysts under the Evidence Act 1977 (Section 133A) within Forensic DNA Analysis and the procedure for the appointment or cancellation of Analysts in Forensic Chemistry under either the Drugs Misuse Act 1986 or the Transport Operations (Marine Pollution) Act and Regulations 1995.

2 Scope

This procedure shall apply to DNA Analysts in Forensic DNA Analysis and to Analysts in Forensic Chemistry.

3 Definitions

Nil

4 Actions

4.1 Analyst Appointment for Forensic DNA Analysis

1. Managing Scientist - Police Services Stream is to prepare a "Briefing Note for Approval" for submission to the Director-General, Queensland Health, via FSS Corro email.

   Refer Appendix 1 for example wording to be used in conjunction with the current template for the Briefing Note obtained from http://qheps.health.qld.gov.au/corro-templates/home.htm.

   The Briefing Note must include:
   - Instrument of Appointment
   - Schedule of nominated persons, qualifications and statement of competency
   - Copies of qualifications
   - Excerpt of Evidence Act 1977 Section 133A

2. Once approval has been obtained (signed brief will be returned via FSS Corro email), the Managing Scientist will request publication of the Analyst's name in the Government Gazette.
   - Gazette request is to be emailed to [redacted]
   - Gazette information to be provided on letter head, with contents as follows:

Department of Health
Brisbane, [insert date]

It is notified that, pursuant to DNA Analysts Section 133A *Evidence Act 1977*, each of the persons whose name appears in the schedule hereunder have been approved as DNA Analysts:

[insert name]
[insert name]

[insert name]
Director General of Health

3. Payment for the Gazette publication is via credit card.

4. Gazette will forward a proof. Proof will need to be approved prior to publication, and the Gazette will also advise of the date of publication.

5. On publication in the Gazette, a copy of the publication is to be retained with the Managing Scientist, and the appointed staff member is to be advised.

6. Details of the appointment will need to be added to the PD Module of QIS2 under the 'Other' tab.

7. The staff member is to organise for DNA Analyst to appear on their statements in the Forensic Register.

4.2 Analyst appointment for Forensic Chemistry under the Drugs Misuse Act 1986 Queensland

1. After the successful completion of training and assessment, the Chief Chemist of Forensic Chemistry or delegate will contact the Office of General Counsel, Department of Justice and Attorney General by email or phone to request the person to be appointed as an analyst under the Drugs Misuse Act Queensland. The purpose of this call is to establish a contact person to send the relevant documentation.

2. The Chief Chemist or delegate will provide the nominee's educational qualifications (including a statement regarding the assessment undertaken against the Mandatory Qualifications for a Chemist guideline QIS#35204), current criminal history check, type of training and length of training in writing to the Managing Scientist – Police Services Stream.

3. After peer review of the relevant evidence regarding the nominee, the Managing Scientist will forward the relevant documents to the nominated contact person in the Office of General Counsel.

4. The Office of General Counsel will notify the Managing Scientist once approved and when it will appear in the gazette. The Managing Scientist will forward this onto the Chief Chemist.

5. The Chief Chemist will issue a letter of authority to the appointed analyst enabling the staff member to issue reports in the relevant areas under their own hand. The electronic copies of this letter of authority will be sent all staff of Forensic Chemistry, the Managing Scientist – Police Services and the Executive Director, FSS.

6. The original letter of authority is placed in the analyst's training folder.

4.3 Analyst appointment for Forensic Chemistry under The Transport Operations (Marine Pollution) Act and Regulations 1995

1. After the successful completion of training and assessment, a staff member will be nominated to become an Analyst. The Chief Chemist or delegate will provide information about the nominee's educational qualifications (including a statement regarding the assessment undertaken against the Mandatory Qualifications for a Chemist guideline QIS#35204), experience, current criminal history check, type of training and length of training in writing to the Managing Scientist.
2. After peer review of the relevant evidence regarding the nominee, the Managing Scientist will forward the relevant documents to the Manager (Compliance), Maritime Safety Queensland via email [redacted] requesting the nominee be appointed as an Analyst under the "Transport Operations (Marine Pollution) Act 1995' and Regulation 2018.
3. If the nominee has been accepted for appointment, Maritime Safety Queensland will issue the letter of appointment, which will be sent electronically to the Managing Scientist. The Managing Scientist will forward this to the Chief Chemist.
4. The Chief Chemist will issue the letter of authority to the appointed analyst enabling the staff member to issue reports in the relevant areas under their own hand.
5. A copy of the letter of appointment is to be placed in the analyst's training folder.

4.4 Analyst cancellation for Forensic Chemistry under the Drugs Misuse Act 1986 Queensland

The Chief Chemist will annually review the list of gazetted analysts. The name/s of persons who are no longer employed by FSS will be sent to Office of General Counsel, Department of Justice and Attorney General requesting the cancellation of the appointment as Analyst.

4.5 Analyst cancellation for Forensic Chemistry under The Transport Operations (Marine Pollution) Act and Regulations 1995

When an appointed analyst is no longer employed by FSS, the Chief Chemist contacts Maritime Safety Queensland requesting the cancellation of the appointment as Analyst.

5 Records

Hard-copy records of requests and approvals are retained in a central location within the office of the Managing Scientist, Police Services Stream. Electronic records are saved to G:\ForBiol\DNA Analysts or P:\Quality Management\Letters of Authority\DMA gazettal. Copies of records are kept in Analyst's training folders.

6 Associated Documentation

Nil

7 References

Nil

8 Amendment History

Version	Date	Updated By	Amendments
1	11 Aug 2015	J Howes/K Scott	New document
2	26 July 2017	J Howes	Edited wording in 4.7, added link to QHEPS for current Briefing Note template and added information to refer to example wording in Appendix 1 for Briefing Note.
3	31 July 2018	J Howes	Removed point 7 of 4.1 as it referred to AUSLAB; changed 'except' to 'excerpt' in 4.1 paragraph 1.
4	14 October 2019	J Howes and C Allen	Addition of Forensic Chemistry Analyst Appointment and Cancellation document (#33349) to create a Police Services Stream document. Updated wording as appropriate throughout the document based on feedback from Supervising Chemists regarding portions for Forensic Chemistry.

9 Appendices

1 Template and example wording for Forensic DNA Analysis – Briefing note for approval
2 Template and example wording for Forensic Chemistry – Letter of Authority

9.1 Template and example wording for Forensic DNA Analysis – Briefing note for approval

NB. See http://qheps.health.qld.gov.au/corro-templates/home.htm for active templates.

Briefing Note for Approval

Director-General

Requested by: **Date requested:** **Action required by:**

SUBJECT: Appointment of a DNA Analyst

Proposal

That the Director-General:

Approve the appointment of _[insert name]_, employed as a Scientist by Forensic DNA Analysis (FSS), as a DNA Analyst pursuant to Section 133A *Evidence Act 1977* and the publication of the approved DNA Analyst in the Government Gazette.

Sign the instrument of appointment at Attachment 1

Note that Section 133A of the *Evidence Act 1977* specifies that the Director-General, as 'The chief executive of the department in which the Hospital and health Boards Act 2011 is administered' may appoint a public service officer as a DNA Analyst, if satisfied that the officer has the necessary qualifications and experience (see excerpt at Attachment 5)

Urgency

1. Routine

Headline Issues

2. The top issue is:
   - DNA Evidentiary Certificates are only admissible in court if signed by a gazetted DNA Analyst.

Blueprint How does this align with the Blueprint for Better Healthcare in Queensland?

- This aligns with enhancement of efficiency by allowing all court reporting, forensic scientists to issue a DNA Evidentiary certificate.

Key issues

4. There is a legislative requirement for an approved DNA Analyst to issue a DNA Evidentiary Certificate upon request from either the Office of the Director of Public Prosecutions or Defence Counsel.
5. There is an operational benefit in all DNA Analysis scientists, who report results to the court, being appointed and gazetted as DNA Analysts so that they are able to issue a DNA Evidentiary Certificate.
6. The appointment and gazettal of the DNA Analysts is the culmination of the internal training program for reporting scientists.
7. The scientists for which approval is being sought for appointment as DNA Analysts have been assessed and deemed by the Managing Scientist, Police Services Stream, FSS, as competent reporting officers and meet the requirements to report and present the results of DNA analyses in court as expert witnesses (Attachment 2)

Background

8. Section 95A of the *Evidence Act 1977* describes the admission of a DNA Evidentiary Certificate as evidence in a criminal trial and requires a DNA Analyst to sign the DNA Evidentiary Certificate.
9. _[insert name]_ holds the position of Scientist, Forensic DNA Analysis and has a _[insert qualification]_. _[insert name]_has successfully fulfilled all laboratory competencies to provide expert evidence in court and is recommended for appointment as a DNA Analyst.

Consultation

10. Gazettal of the DNA Analyst will notify stakeholders

Financial implications

11. There are no financial implications.

Legal implications

12. If the appointment of _[insert name]_is not approved, they will not be able to comply with the legislative requirements for issuing a DNA Evidentiary Certificate and will not be able to issue Statements of Witness for a large proportion of cases.

Attachments

13. Attachment 1: Instrument of Appointment – DNA Analyst section *133A Evidence Act 1977*
Attachment 2: Schedule of nominated persons, qualifications and statement of competency
Attachment 3: _[insert name]_qualifications
Attachment 4: Excerpt of the *Evidence Act 1977* – section 133A

Recommendation
That the Director-General:

Approve the appointment of _[insert name]_, employed as a Scientist by Forensic DNA Analysis (FSS), as a DNA Analyst pursuant to Section 133A *Evidence Act 1977* and the publication of their appointments in the Government Gazette.

Sign the instrument of appointment at Attachment 1

Note that Section 133A of the *Evidence Act 1977* specifies that the Director-General, as 'The chief executive of the department in which the Hospital and health Boards Act 2011 is administered' may appoint a public service officer as a DNA Analyst, if satisfied that the officer has the necessary qualifications and experience (see excerpt at Attachment 5)

APPROVED/NOT APPROVED **NOTED**

Insert name
Director-General

/ /

To Minister's Office for Approval ☐
for Noting ☐

Director-General's comments

Author	Cleared by: (SD/Dir)	Content verified by: (CEO/DDG/Div Head)
Insert name	Insert name	Insert name
Managing Scientist	Senior Director	Chief Executive
Police Services Stream	Forensic and Scientific Services	Health Services Support Agency
Insert phone number	Insert phone number	Insert phone number
Insert date	Insert phone number	Insert phone number
	Insert date	

Attachment 1:

INSTRUMENT OF APPOINTMENT

DNA ANALYST

Section 133A *Evidence Act 1977*

I, **[insert name], Chief Executive of the Department of Health,** hereby appoint the persons named in the schedule herein as DNA Analysts under section 133A *Evidence Act 1977.*

Dated at Brisbane this ..... day of ....., 20__.

_____

DIRECTOR GENERAL
QUEENSLAND HEALTH

SCHEDULE

Insert name	Insert name

Attachment 2:

Schedule of Nominated Officers, Qualifications, Years of Relevant Forensic Experience and Statement of Competency

Name	Qualifications	Years of experience

The officers listed in the above schedule have been assessed and signed off as competent reporting officers and meet the requirements to report and present the results of DNA analyses in court as expert witnesses.
Detailed records of competency components are stored in each officer's training portfolio and can be accessed upon request.

Managing Scientist
Police Services Stream
Forensic and Scientific Services

9.2 Template and example wording for Forensic Chemistry – Letter of Authority

Department of Health	Queensland Government

MEMORANDUM

To:	XXXX		
Copies to:	XXXX, Managing Scientist, Police Services Stream		
From:	XXXX Chief Chemist, Forensic Chemistry	**Contact No:**	[redacted]
		Fax No:	
Subject:	Drugs Misuse Act Authorisation		
		File Ref:	

By virtue of your successful completion of your training and the associated training modules together with your verbal assessment in the analysis of illicit drug related matters, you are deemed competent to conduct analysis and provide opinion based evidence within the scope of the abovementioned areas from [Date].

In conjunction with your Appointment of Analyst for the purposes of the Drugs Misuse Act 1986 on [Date of Gazettal], you are hereby authorised to provide reports and expert evidence in the above specified areas under your name.

XXXX
Chief Chemist, Forensic Chemistry
[Date]

CA-38

Queensland Health
Forensic and Scientific Services

Forensic and Scientific Services
Learning and Development (L&D) Framework

1 Purpose

This document outlines the Learning and Development (L&D) framework at Forensic and Scientific Services (FSS).

2 Definitions

Competency based training and assessment: seeks to determine whether a person can do a task or group of tasks and how well they can do them. It recognises that the best way to determine a person's competence is to assess them using their knowledge and skills in an on-the-job situation. Competency based training (CBT) is ideally not time based - as soon as the trainee can demonstrate they have the required abilities and knowledge, they can be deemed competent. This caters to all learners so they can work at their required pace based on their current skills and abilities.

Re-evaluation: a recorded activity collating objective and subjective evidence to determine ongoing (continued) competency. If a re-evaluation is inconclusive or unsupported, additional re-assessment(s) is to be conducted.

Re-assessment: assessment of a trainee again at a required interval. This may be a full module of training and assessment, or a smaller predetermined assessment that focuses on key skills.

Capability Develop Program (CDP): contains the associated learning pathways for each position within the work unit.

Learning Pathway: the minimum core competencies specific to a position. It is a list of the training modules required to be completed by the individual(s) in the position.

Training Modules: competency-based training and assessment documents published in QIS2

Courses: competency-based training and assessment in iLearn

Competent to train (CTT): Staff delivering training must have a completed competency statement indicating competent to train status (CTT) and authorisation (in hard copy or in iLearn where possible) by their respective line manager using QIS 23948.

3 Orientation and Induction

Orientation and Inductions are completed in accordance of QIS 23643 Induction Management and HR Policy G6.

4 Development of training

Training will be developed by the business units as required. Development of training will generally involve a number of people over an agreed time period. Usually, a person will be allocated the task of designing the training to a prescribed scope, as determined by the training needs analysis or learning pathway of the area.

Training must be approved prior to its use in the business unit. Approval should be based on the suitability of the material to adequately deliver and record the training and assessment activities necessary for the staff member to become competent.

5 Review of training

Training is generally reviewed every 12-18 months and should consider changes to standard operating procedures. Ideally, review of training material occurs when the SOP is updated. Changes are managed through QIS2 and iLearn.

All staff, including trainees, managers and trainers, are able to comment and constructively improve the training via the comments tab of the training module in QIS2, or via the 'Training and assessment feedback' section of the course in iLearn.

The QIS2 update responsibility (UR) person or the iLearn course owner is responsible for ensuring that adequate consultation has occurred before the updated training is approved for use.

It is best practice to have a subject matter expert (SME) as the course owner/UR, but if this not possible, then it should be a competent or competent to train person.

Competent or competent to train person(s) should be reviewers of training modules or courses, and at a minimum, should be included on the QIS2 notification list. This ensures that changes to training are delivered consistently and review is transparent.

Suggestions to maintain the validity of training include:

- alignment to key performance criteria (KPC) and standard operating procedures/methods/tasks
- collaboration with staff that deliver and assess training to decide the technical knowledge required of the trainee
- collaboration with SSDU and/or area training coordinators to ensure training is relevant, there is no duplication of effort, ensure the right people and area are completing the training, and there are no gaps in skills or requirements
- collaboration with external agencies to provide insight into how they train in their area, and ensure there is no duplication of effort or re-creation of training content
- reviewing risk assessments relevant to the training scope and incorporate within the training to mitigate risk during training/assessment and when performing the task once competent
- reviewing non-conformances (OQIs) to identify training needs

All training resources (PowerPoints, flowcharts, diagrams, videos etc.) should be version controlled where possible so there is traceability of changes made to the training materials. At this stage, this does not necessarily include uploading to QIS2, but at a minimum a version number in the footer and an amendment history is recommended.

When a training module or course is due for review, all associated training resources are also to be reviewed.

6 Role/Position Specific Training

6.1 Capability Development Program (CDP) and learning pathways

The Capability Development Program template (QIS 31908) collates the learning pathways for each department.

Learning pathways are the minimum core competencies specific to a position and are a representation of the training modules required to be completed by the individual(s) in the position.

It is the responsibility of the team leader to develop a learning pathway for any employee that does not align to the pre-determined learning pathways contained in the CDP (e.g. temporary employee, student, project work, higher duties). Learning pathways should be reviewed by the training co-ordinator to ensure they are sufficient, valid and specific to the work that will be assigned.

All training and assessment activities outlined in a relevant learning pathway should be made available to the trainee who holds that position. Note: this will include external courses (including costing) if applicable.

6.2 Training Modules

In the majority of FSS business units, training is progressed via competency-based training and assessment modules (training modules) that cover the specific task, process or techniques. Training modules may be linked to one or more procedures or methods and are used to gain competency and an authorisation to perform work unsupervised, consistent with accreditation requirements. Training modules are created on a standard template (QIS 23277).

6.3 Training and Assessment

Training and assessment is aligned to each of the key performance criteria (KPC) within the training module. Assessment can be performed according to a selection of options as outlines in appendix 1 of QIS 23277 XYZ Training module template, and summarised below;

- Skills and Ability (Part A) assessment – observation and review of the trainee performing the associated process or technique
- Knowledge (Part B) assessment - evidence of underpinning knowledge via written and/or oral questions. Written assessment is recorded on the Training module assessment form (QIS 24899). Written feedback from the trainer is also recorded in this document.

If competency is not achieved, then additional training and assessment can be conducted until competency is awarded. SSDU should be consulted for assistance.

6.4 Delivery of training

All training within the learning pathway will be delivered by a trainer that has been deemed 'Competent to Train (CTT) for the training delivered.

During the initial CSP (conducted in the first 3 weeks) the learning pathway should be discussed with the trainee in detail. At each stage of the CSP cycle, performance and progression of training and development should be aligned to the relevant learning pathway.

It is the responsibility of the direct report to ensure that the trainee is progressing through the pathway at the appropriate times (as defined by the training module), and to identify any remedial training that may be necessary.

Recognition of Prior Learning from other organisations can be documented by documenting the evidence of fewer skills and abilities i.e. if a module requires the trainee to complete 4 observations and after a minimum of one, the trainer is satisfied, then this can be justified by documenting the reason for the reduced number of assessments.

Once an employee has completed all the training requirements of the required learning pathway, a PD achievement will be added to the competency section of QIS2.

6.5 Recognition of Current Competency (RCC)

Staff trained prior to the implementation of training modules (September 2005), or who develop new training modules can be awarded a Recognition of Current Competency (RCC) statement based on the provision of relevant evidence, using QIS 23948

6.6 Evaluation of Continued Competency

If there are significant changes to a training module (determined by risk), staff that are competent in the previous version should undergo training in the revised portion of the training module. Staff that have been involved in the associated change process can complete a competency statement (QIS 23948) to recognise current competence. Where a training module has been migrated to an iLearn course, this should be conducted and recorded in iLearn.

Evaluation of continued competency should be performed on a regular basis as determined by the departments capability development program and be recorded in the employee's training records. Processes include but are not limited to:

- CSP review cycle where training and professional development is discussed and recorded
- Proficiency testing
- Peer review
- Court testimony monitoring and evaluation (iLearn - Provision of Court Testimony)
- Viva (oral questioning and panel discussions)

7 Learning and Development activities

Professional development aims to enhance the skills, knowledge and abilities beyond the requirements of the current position, in order to meet future business objectives and/or career aspirations of the staff member.

Professional development activities may be facilitated through:

- Internal and external training courses, workshops and seminars
- Advisory meetings
- Conferences
- Queensland Health programs
- Higher education

7.1 Internal and external training courses

A range of internal and externally facilitated training activities are listed in iLearn
An application for professional activity leave (QIS 10675) may be necessary in your work unit to attend external training courses.

7.2 Advisory meetings

Meetings may include Standards Australia, NATA assessments, Special Advisory Groups (SAG), Special Interest Groups (SiG), National Institute of Forensic Sciences (NIFS), other work-related committee meetings and medical meetings that involve staff leave of absence and/or travel bookings.

Project related travel includes work to complete a specific project such as field work for collection of samples, monitoring and surveillance or provision of training which involves travel bookings and/or staff leave of absence. An application for professional activity leave (QIS 10675) is required as these meetings are recorded as client advisory activities.

7.3 Conferences

Conference leave is prescribed by HR Policy C50 Seminar and Conference Leave - Within and Outside Australia a Whole-of-Government policy that sets the rules for all government departments. Approval required:

- Local – Applications for attendance at local conferences (within Queensland) must be approved by the EDFSS (for FSS staff) or the DDG HSQ (for SES and DES Officers).
- Interstate - Applications for attendance at interstate conferences must be approved by DDG HSQ.
- Overseas - Minister for Health

The completion of the application for professional activity leave (QIS 10675) is also required. Attach any supporting documentation such as an invitation to present a paper, a copy of the conference program, registration form or similar material, if available. Overseas travel also requires a ministerial briefing note at least 10 weeks prior to travel.

7.4 Queensland Health Staff development programs

Register for any of the QH Staff development programs via iLearn.

7.4.1 Leadership Development Program

Refer to Department of Health Learning Gateway for communication, management and leadership courses.

7.4.2 Employee training and development education Incentive Funding

This initiative is a state-wide training and incentive fund administered by Cunningham Centre on behalf of Queensland Health. Under this initiative, Admin Officers A02-A05 and Operational Officers 002-005 are eligible and may apply for funding up to $1,800 to attain a certificate qualification relevant to their role. Please contact [redacted] to assist in determining the available qualifications

Operational Officers - Interested employees must complete and submit an expression of interest to be considered for this initiative. Please note that only the current version of the expression of interest available on the website will be accepted. It is important that you read the Implementation Guide which contains more specific details regarding this initiative.

Administrative Employees - Interested employees must complete and submit an expression of interest to be considered for this initiative. It is important that you read the Implementation Guide which contains more specific details regarding this initiative.

7.5 Higher education

7.5.1 Staff identified

The Study and Research Assistance Scheme (SARAS) is used by Queensland Health to promote organisational and personnel development and to assist and encourage employees to undertake courses and research which:

- Directly contribute to the achievement of departmental goals
- Meet specific work needs above the officer's personal vocational development
- Develop the officers' personal skills for vocation within Queensland Health
- Develop the officers' personal skills for general application within the Queensland Public Service.

HR Policy G10 SARAS prescribes financial support and/or leave assistance that may be approved. All SARAS applications are managed by respective work units.

7.5.2 FSS identified

Where knowledge gaps occur, university or vocational training programs (non-award subjects) may be used to supplement the workplace skills of a staff member.

The program is not intended to replace the use of FSS requisite training modules but to value add (for example, pharmacokinetics, statistics).
Note: in this case, the subjects or program would fall outside the SARAS guidelines

The cost of the program/subjects will be paid by FSS. Time to complete the subject is to be negotiated with the respective Team Leader. If the staff member does not complete or fails a given subject, a cost recovery process may be pursued.

8 Funding Sources

8.1 Professional Development Allowance and Leave (PDA /PDL)

Professional Development allowance and leave is generally available for Queensland Health employees in the medical, nursing and health practitioner fields. It allows eligible employees to take leave to participate in professional development activities such as study, forums and workshops. For more information refer to C42 Health Practitioners - Professional Development Allowance and Leave

8.2 Other

FSS funds are at the discretion of cost centre manager.

9 External Partnerships

9.1 Visiting student and scientific practitioner placements program

FSS participates in Queensland Health's ongoing partnership with the education sector by way of student placements. This collaboration assists to identify and train future health workers. Student placements refer to students enrolled in gaining a qualification with a registered training organisation (university or vocational training provider), and do not include individuals outside this scope. Additionally, visiting scientific practitioners from other organisations may be hosted. FSS does not facilitate work experience for secondary school students.

Further details are found in Visiting student and scientific practitioner placements (QIS 27576). To initiate a student placement, email [redacted]

10 Feedback

It is a requirement that staff attending external courses or conferences communicate their learnings and other important information to the broader FSS community. Staff will be required to disseminate this information through formal or informal presentations at team meetings.

11 Records

A personal training portfolio (green folder) contains all paper-based training records. The training portfolio should be available at FSS at any time for review and remains the property of FSS. If the staff member leaves the organisation, a copy of these records can be provided to the staff member by SSDU.

Details of completed paper-based training modules should be added to the PD Module in QIS2 under the Competency or Course tabs. No expiry dates are required for individual entries, except where there are regulatory requirements for re-assessment.

Once an employee has completed all the training requirements of a learning pathway, a PD achievement will be added to the competency section of QIS2 – Competency QIS Number and the description should state the area and/or position that they have achieved competence in (including appendix number and area/position title).

iLearn records of completion are no longer required to be filed in employee issued training portfolios. Managers have access to view these records via the relevant DSS workboards or the staff member via iLearn.

Records should include:

- the results of assessment from training modules
- details and dates of relevant recognised academic qualifications after sighting of original or certified document
- records of participation in professional development activities

On-going competency shall be assumed unless shown to be otherwise. This shall be recorded in the CSP documentation.

If an employee is no longer active in the area/position then the team leader will "expire" the QIS2 event (recording details of decision). If they return to the area then a training needs analysis should be conducted on the trainee to determine the level of training required to be refreshed/re-trained in the area.

If an employee moves into a different area/position, it is the responsibility of the new team leader to determine competency status renewal in conjunction with the previous team leader.

12 Associated Documentation

10675 Application for professional leave activity
23277 XYZ training module template
23947 Guideline to writing a statement of competence using RPL or RCC methodology
23948 Competency statement
24899 Training module assessment form
27576 Visiting student and scientific practitioner placements at FSS
31908 Capability Development Program template

13 Amendment History

Version	Date	Author(s)	Amendments
0-8	Refer to QIS2	Refer to QIS2	Refer to QIS2
9	17 July 2017	P Clausen S Granato	Updated links and titles of associated documents Amended some roles and responsibilities in section 3 and added to Appendix 12. Section 8.2 Evaluation indicators removed as already in operation plans
10	02 Mar 2020	P Clausen	Updated links and titles of associated documents. Checked various DoH and Cunningham Centre programs were still in place. Wording amendments in Appendix, section 12, to assist and clarify Roles and Responsibilities.
11	May 2021	SSDU	Addition of iLearn for SSDU facilitated training, removal of SERC, general revision.
11	Sept 2021	D Johnston	Updated header design

14 Appendix – Roles and Responsibilities

14.1 Scientific Skills Development Unit (SSDU)

SSDU works in partnership with internal stakeholders including the FSS Leadership team, team leaders, managers/supervisors, training coordinators, trainers, individual employees and other Queensland Health learning and development groups.

The role of SSDU is to:

- Facilitate the development of a learning culture across all business units using flexible, realistic and cost-effective methodology
- Lead, manage and coordinate the planning, design, development, delivery, assessment and evaluation of competency-based training and learning pathways facilitated by a dedicated capability development program
- Deliver scientific and related training
- Develop, document, implement and maintain systems to record competency-based training outcomes across FSS
- Provide guidance for managers and staff regarding the Study and Research Assistance Scheme (SARAS)
- Coordinate visiting student and scientific practitioner placements
- Coordinate training sessions and workshops
- Facilitate and coordinate the provision of other training and development services to FSS
- Support staff in pursuing further education and advancement.
- Promote engagement in targeted training programs (Administrative and Operational staff)

14.2 FSS Leadership

- Endorse and contribute to the maintenance of a learning culture as detailed in this framework (QIS 23651)
- Provide ongoing leadership to training coordinators and trainers
- Review Scientific Support report to the leadership team for items for noting or action to ensure learning and development initiatives are supported and met

14.3 Supervisor & Team Leader

- Endorse and advocate the FSS Learning and Development framework (QIS 23651)
- Ensure any new staff member or student undergoes a site and local induction on the first day of employment as per the induction website
- Monitor G6 mandatory training and renewals for compliance.
- Ensure trainees are supervised whilst undergoing training, and any staff member or student is provided with a competent trainer.
- Manage training and professional development of staff through Career Success Plans (CSP). The CSP should be conducted within the first 21 days of employment and then yearly for re-evaluation of learning.
- Ensure all training records are completed contemporaneously, including relevant comments and feedback within the training module or competency statements with reference to the appropriate evidence.
- Manage the authorisation of staff to perform work by completing the authorisation section of training modules and providing comments and feedback within an agreed period.
- Monitor the capability matrix to identify training needs and skills gaps, as well as succession planning requirements for the business unit
- Liaise and collaborate as required with SSDU on learning and development training needs/requirements, issues, concerns, compliance, career development and/or succession planning opportunities.

- Manage the review of SARAS applications, targeted training expression of interest and/or student/visiting practitioner placements by completing the required paperwork and liaising with SSDU as required.
- Ensure training coordinators provide updates in team meetings on all relevant L&D activities, initiatives and changes.
- Manage the development and maintenance of competency-based training modules within the business unit.
- Contribute to the development, implementation and evaluation of the units Capability Development Program including the associated learning pathways.
- Allocate time for training coordinators and or delegates to attend training coordinators meetings.
- Provide guidance, direction and coaching to support training coordinators and trainers in fulfilling their duties.

14.4 Training Coordinators

- Advocate the FSS Learning and Development framework (QIS 23651)
- Complete (FSS) Delivery of FSS Training and Assessment
- Provide updates in team meetings on all relevant L&D activities, initiatives and changes.
- Gain feedback from trainers and trainees on learning pathways, training modules and other learning and development initiatives.
- Monitor the capability matrix to identify training needs and skills gaps
- Monitor G6 mandatory training and renewals for compliance in conjunction with supervisor/team leader.
- Liaise with supervisor to determine the training requirements of all unit staff
- Assist supervisor/ manager in the allocation of a competent trainer to deliver training using competency-based training module(s) for the unit.
- Audit training records, portfolio's and QIS^2/iLearn records as part of the business area's audit schedule.
- Complete all records contemporaneously and record all feedback and comments within the training module, iLearn course or competency statements with required evidence.
- Coordinate the development, maintenance and review of competency-based training modules, model answers and learning pathways in the respective unit (utilising the capability matrix).
- Assist in the development, implementation and evaluation of learning pathways relevant to the unit.
- Provide guidance, direction and coaching to assist trainers in fulfilling their duties.
- Assist and ensure assessment has been completed and the trainee's knowledge and skills are captured (scoped to the training module).
- Assist trainers maintain training records, portfolio's and QIS^2/iLearn records.
- Ensure that all trainers are competent to train and possess a competency statement for relevant workplace skills.
- Assist staff in completing competency statements as required with reference to appropriate evidence.
- Attend any scheduled meetings with SSDU, and training coordinators meetings.

14.5 Trainers

- Advocate the FSS Learning and Development framework (QIS 23651)
- Complete (FSS) Delivery of FSS Training and Assessment
- Deliver training only in workplace skills where deemed competent to train and possessing a CTT statement.
- Assess the trainee's knowledge and skill (scoped to the training module)
- Provide guidance, direction and supervision of trainee until competency is achieved.

- Mark assessments utilising version-controlled model answers to ensure answers provided by the trainee are current, specific, valid and authentic.
- Provide sufficient, appropriate and valid feedback of assessments, within two weeks.
- Allow trainees to provide evaluations and comment throughout training and assessment activities.
- Provide ongoing coaching and support. Monitor staff progress as required.
- Complete all records contemporaneously and record all feedback and comments within the training module, iLearn course or competency statements with required evidence
- Maintain the training records, portfolios and QIS²/iLearn records in conjunction with the department training co-ordinator, where applicable.
- Collaborate with supervisor and training co-ordinator to determine the training requirements of staff and/or the need to update/change any training resources, modules or assessment.
- Assist in the development, implementation and evaluation of learning pathways relevant to the unit.
- Consult with the training co-ordinator, SSDU team member and/or line manager with any concerns about the training and assessment process.

14.6 Trainees

- Develop knowledge and skills to enhance performance in the current position.
- Be responsible for own learning outcomes.
- Progress through the learning pathway of allocated training modules and/or training courses by completing all tasks as directed by the trainer, at appropriate times, in a timely manner.
- Complete assessment activities in a timely manner and ensuring responsibility for ownership of responses.
- Read comments written by assessor and seek feedback where required.
- Provide constructive feedback to improve a given training session/module/program.
- Undergo re-evaluation at designated times where directed.
- Ensure work is not performed unsupervised and results are not released until relevant competency has been achieved and authorised.
- Ensure training is recorded at the time of delivery and assessment, and that all relevant records are completed.

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HealthSupport Queensland

Management of professional development and training records in QIS2

1 Purpose

The recording of staff professional development is a requirement of ISO 9001 (clause 7.2), ISO 17025 (clause 6.2), AS ISO 15189 (clause 5.1) and ISO 17034 (clause 6.1). This procedure describes the recording of Professional Development activities within the Quality Information System (QIS), and outlines mandatory entries.

2 Scope

This document describes the business rules for using the QIS Professional Development module.

This procedure applies to all HSQ staff.

3 Definitions

Competency – A competency is a training module with a QIS document number

Conference and Visit – A conference or something you have attended

Course – An external training course which doesn't have a QIS document number.

Language – If you can speak, read or write a language

Presentation – A presentation either oral or in a poster/written form about a subject relevant to the organisation e.g. At a conference of a seminar

Professional Membership – A record of participation or a qualification that you have received by a professional organisation.

Publication – A formal publication of a paper, book or article relating to your work or studies.

Qualification – Formal qualifications from a recognised training institute e.g. University or TAFE

Registration – Formal registration from an external body

Other – Anything which does not fit into one of the categories above

4 Mandatory Entries

Career success plan (CSP) dates must be entered into the Professional Development module of QIS.

5 QIS Administrators

QIS administrators are users that have special privileges. They help managers and staff to enter their professional development activities into QIS. The three types of administrator for the PD module are

- Credentialing Administrator
- PAD Administrator
- Training Administrator

The administrator role is scoped to an organisation unit (OU) and special access applies only within that OU. The administrator should obtain appropriate authorisation (preferably in writing) to perform all tasks.

5.1 Credentialing Administrator

Credentialing Administrators can enter, verify and renew clinician qualifications and scope of clinical practice within their OU. The role of the Credentialing Administrator is to assist their OU to manage its credentialing and scope of clinical practice obligations.

Credentialing administrator access is granted upon application to the QIS2 Senior Systems Support Officer.

5.2 Training Administrator

Training Administrators can enter, verify and renew staff Professional Development (PD) needs and achievements within their OU. The role of the Training Administrator is to assist their Line Manager and others within their organisational unit to add PD needs and achievements, and to verify PD needs (either as a trainer or on behalf of their line manager).

Training administrator access is granted upon successful completion of the QIS 26221 Training Administrator Competency Assessment tool.

5.3 PAD Administrator

PAD Administrators can enter, verify and renew staff Career Success Plans (CSP) records within their OU. The role of the PAD Administrator is to assist their line manager and others within their organisational unit to manage their CSP records in QIS.

PAD administrator access is granted upon successful completion of the QIS 28629 PAD Administrator Competency Assessment tool.

6 Actions

6.1 Professional Development and Credentialing Activities

QIS 26208 *User manual professional development manual* provides specific instructions on how to complete the tasks listed below

6.1.1 Creation

All staff can enter their own PD records into QIS. The QIS Administrators listed in section 4, and the individuals line manager, are also able to enter staff PD records into QIS.

Records may be entered as a need (i.e. a PD activity not yet completed) or a PD Achievement (i.e. completed).

When adding PD achievements requiring renewal (e.g. registrations etc), you must enter an expiry date, as well as an expiry notification period. This will ensure the staff member and their line manager receives a QIS event notifying them that the achievement is due for renewal.

6.1.2 Verification

Once PD needs are completed, they are verified by the staff members Line Manager, or a Training or Credentialing Administrator. The staff member is responsible for proving to the

person verifying the record that the achievement has been achieved (e.g. certificate of completion etc).

6.1.3 Renewal

If an achievement requires renewal, the staff member and their line manager will receive a QIS event (renew achievement) when the notification period has been reached.

The staff member is responsible for renewing the achievement and updating QIS. The renewal is verified by the staff members Line Manager, or a Training or Credentialing Administrator with the appropriate access. The staff member is responsible for proving to the person verifying the record that the achievement has been achieved (e.g. certificate of completion etc).

6.2 Career Success Plan (CSP) Activities

QIS 29249 – *QIS2 User Manual – Professional Development – PAD* provides specific instructions on how to complete the tasks listed below

6.2.1 Creation

The Line Manager is responsible for conducting a CSP on their staff members. This responsibility may be delegated to another individual who has knowledge of the staff members performance (PAD Assessor). Once the CSP has been conducted, the line manager must create a CSP record in QIS, nominating the appropriate person as the PAD Assessor. CSPs may also be entered into QIS by a PAD Administrator.

If the CSP is to be reviewed in 6-months, a 'mid-term review' period should be set. CSPs must be conducted annually, so a review period no longer than 12 months must be entered.

Due to the confidential nature of a CSP, it is only necessary to add to QIS the date the CSP was conducted. Do not enter personal CSP details into QIS.

6.2.2 Review

Depending on the review period set, the staff member and their line manager (or PAD Assessor) will receive an event when the CSP is due for review. Once the review has been conducted, the line manager/PAD assessor should update QIS. The record may also be updated by an appropriately scoped PAD Administrator.

Once a review has been entered in QIS, the staff member will receive an event to 'acknowledge' the review. Only the staff member can perform this action.

6.2.3 Renewal

Once the CSP has reached its annual review date, the Line Manager/PAD assessor will receive an event that the CSP is due for renewal (renew PAD). Renewal entails closing the 'old' CSP and creating a 'new' CSP for the upcoming year. The line manager/PAD assessor should update QIS; however, this may also be updated by an appropriately scoped PAD Administrator.

7 Records

QIS database

8 Associated Documentation

QIS: 26208 – QIS Professional Development User Manual

QIS: 29249 – QIS2 User Manual – Professional Development – PAD

QIS: 28629 - PAD Administrator Competency Assessment Tool

QIS: 26221 - Training Administrator Competency Assessment Tool

HR Policy G9 – Performance and development

9 References

ISO 9001 Section 7.2 Human Resources
ISO 17025 Section 6.2 Personnel
AS ISO 15189 Section 5.1 Personnel

10 Amendment History

Version	Date	Author/s	Amendment
1-4	Various	H Gregg	See previous versions
5	June 2014	H Gregg	Change of title to reflect purpose of document. Addition of reference to relevant administrator training modules
6	Sept 2016	H Gregg	New headers. Added ISO Guide 34 and ISO 17043 to section 1
7	Apr 2019	H Gregg	Updated terminology of PAD to PDP. Updated section 1 ISO17025 & ISO 17034 clauses and added reference to HR Policy G9.
8	Jul 2019	H Gregg	Removed reference to ISO 17043
9	Apr 2020	A Hardman	General revision

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Document Number	Title	Version	Document Status	Organisational Unit Scope	Service Scope	Site/Location Scope	Update Responsibility	Document Abstract	URL
[redacted]	Paternity and Paired Kinship Statistics - Training Module	10	Active	DNA Analysis	Forensic and Scientific Service	All	Justin HOWES	After successful completion of this module the staff member wil be able to perform paternity/ paried kinship calculations	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=9008&DocumentInstanceID=131446
	CE Quality Check of Samples from CE Genetic Analyzers Training Module	9	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	To outline the training and competency requirements for new staff in the analysis of person samples run on the 3130xl Genetic Analyzer.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=15996&DocumentInstanceID=134335
	Examination of Items - Training Module	15	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	1 Examine items to identify potential sources of DNA. 2 Determine when/if screening tests are required. 3 Make detailed case notes regarding descriptions of items and actions taken during the examinations. 4 Identify the risks of cross contamination.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=16000&DocumentInstanceID=131239
	Acid Phosphatase Screening - Training Module	13	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	Training module in performing the Acid Phosphatase screening test for seminal fluid. Elemnts of Competency include; WH&S, Constituents of Semen, Principle of test, Actions, and Interpretation.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=16002&DocumentInstanceID=131233
	Examination of Microscopy Slides for Spermatozoa - Training module	11	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	? Examination of items and the preparation of microscope slides ? Staining of microscope slides ? Examination of stained microscope slides for the detection of spermatozoa and other cellular components, and	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=16003&DocumentInstanceID=131257
	Processing of FTA Reference Samples Training Module	12	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Chantal ANGUS	After successful completion of assessment of this module, the staff member will have provided the required evidence for demonstration of knowledge in the processes of:- FTA Reference Samples Reference Blood Processing (Blood Clothing); & Processing of FTA Reference samples (Buccal & Blood samples)	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=17125&DocumentInstanceID=128828
	STR PCR Amplification - Training Module	14	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	To outline the training and competency requirements for staff in the amplification of samples using AmpFISTR Profiler Plus and PowerPlex 21 systems.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=17210&DocumentInstanceID=128827
	Training Module - NucleoSpin Extraction	12	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	To outline the training and competency requirements for Forensic Biology staff in the extraction of samples using the NucleoSpin method.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=20966&DocumentInstanceID=133265
	Forensic DNA Analysis Induction Presentation	13	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Chelsea SAVAGE	Information for new starters in Forensic DNA Analysis including: * Position & Leave entitlements; * Security; * Timesheets; * WHS, First Aid & Fire Safety; * Impartiality & Confidentiality; * Anti-Contamination; * Quality; * Professional Bodies; * Training.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=21064&DocumentInstanceID=128277

Document Number	Title	Version	Document Status	Organisational Unit Scope	Service Scope	Site/Location Scope	Update Responsibility	Document Abstract	URL
[redacted]	raining Module - Tetramethylbenzidine creening Test for Blood	11	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	To outline the training and competency requirements for staff performing the Tetramethylbenzidine Screening test for blood.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=22593&DocumentInstanceID=121624
	he Phadebas Test for Saliva - Training Module	10	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	To outline the training and competency requirements for DNA Analysis staff when screening for Saliva using the Phadebas test.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=22594&DocumentInstanceID=131280
	echnical Review - Training Module	10	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Justin HOWES	Competency based training module - Technical Review.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=22858&DocumentInstanceID=131088
	oncentration of DNA Extract using Microcon Centrifugal Filter Devices Training Module	10	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	Microcon Centrifugal Filter Devices employ Amicons low binding, anisotropic, hydrophilic regenerated cellulose membrane. The low-adsorption characteristics of the YM membrane and the devices component parts, together with an inverted recovery spin, combine to yield high recovery rates (typically >95% of the sample, with concentration factors as high as 100x).	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=23516&DocumentInstanceID=129253
	BAcard p30 Test - Training Module	9	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Kristina MORTON	1. This training module outlines the competency and assessment necessary to use the ABAcard p30 Test for Prostate Specific Antigen (PSA). 2. The ABAcard p30 Test has been designed for the detection of PSA in blood samples collected from patients with prostate cancer. 3. It uses a solid phase immunochromatographic format for the qualitative detection of PSA. 4. It has been validated for use with forensic casework stains and swabs. 5. To be used when an acid phosphatase positive stain is suspected of being azoospermic.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=23608&DocumentInstanceID=135723
	election & Preparation of Bone & Teeth or DNA Testing - Training Module	9	Active	Forensic Reporting and Intelligence	Forensic and Scientific Service	Coopers Plains	Valerie CALDWELL	The details involved in assessing / examining and preparing bone & tissue samples for DNA testing.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=23622&DocumentInstanceID=133721
	dministrative Officer - Forensic DNA nalysis Training Module	12	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Wendy HARMER	After successful completion of assessment of this module the staff member will have provided evidence of required knowledge in administrative tasks in Forensic DNA Analysis, Forensic Biology.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=23742&DocumentInstanceID=135666
	raining Module - Uploading Profiles to CIDD, Creating and Reviewing Links	12	Active	Evidence Recovery and Quality	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	Refer to SOP 22619 Creating and Reviewing Links and SOP 23890 Uploading and Actioning Samples on NCIDD	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=23839&DocumentInstanceID=136535

Document Number	Title	Version	Document Status	Organisational Unit Scope	Service Scope	Site/Location Scope	Update Responsibility	Document Abstract	URL
[redacted]	Miscellaneous Tasks For Laboratory Assistants - Training Module	8	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Kirsten SCOTT	A structured approach in the training of staff when preparing reagents used in DNA Analysis Department. Including: - the receipt and storage of chemicals, reagents and test kits into the DNA Analysis laboratory. - preparation of reagents in the DNA Analysis laboratory. - disposal of reagents in DNA Analysis laboratory.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=23865&DocumentInstanceID=131093
	Basics of DNA Profile Interpretation - Training Module	8	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Emma CAUNT	After successful completion of assessment of this module the staff member will have provided evidence of required knowledge and skill in the basic principles of DNA profile interpretation in Forensic DNA Analysis.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=24234&DocumentInstanceID=126104
	Automated Dilution & Automated Testquant of Standards Training Module	9	Active	Analytical	Forensic and Scientific Service	Coopers Plains	Luke RYAN	After successful completion of assessment of this module the staff member will have provided evidence of required knowledge in the dilution of controls and standards on theSTARlet and the subsequent testing of the controls and standards for quality purposes in DNA Analysis, FSS.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=24253&DocumentInstanceID=133378
	Case Management of Casework Samples Training Module	7	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Justin HOWES	After successful completion of assessment of this module the staff member will have provided evidence of required knowledge in Case Management in Forensic DNA Analysis.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=24276&DocumentInstanceID=121545
	Genotype Frequency Module in Kinship - Training module	6	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Sharon JOHNSTONE	Records the training assessment and describes Key Performance Criteria and levels of competency.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=25301&DocumentInstanceID=131055
	Paired Kinship and Paternity Trio Modules in Kinship - Training module	6	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Sharon JOHNSTONE	Records the training assessment and describes Key Performance Criteria and levels of competency	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=25582&DocumentInstanceID=131056
	Use of the DNA Analysis Database Interface (DADI) Training Module	6	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Sharon JOHNSTONE	Records the training assessment and describes Key Performance Criteria and levels of competency	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=25584&DocumentInstanceID=133023
	Use of the STORstar unit for automated sequence checking Training Module	9	Active	Analytical	Forensic and Scientific Service	Coopers Plains	Chantal ANGUS	After successful completion of assessment of this module the staff member will have provided evidence of required knowledge and ability in the automated sequence checking of DNA extract tubes and transfer of liquid or samples using the automat.it STORstar system (Process Analysis & Automation Ltd. Hampshire. UK) in FSS DNA Analysis.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=25745&DocumentInstanceID=132574

Document Number	Title	Version	Document Status	Organisational Unit Scope	Service Scope	Site/Location Scope	Update Responsibility	Document Abstract	URL
[redacted]	Procedure for STR Analysis using GeneMapper® ID-X - Training Module	11	Active	Analytical	Forensic and Scientific Service	Coopers Plains	Kerry-Anne LANCASTER	After successful completion of assessment of this module the staff member will have provided evidence of required knowledge in procedure for the acceptance of Profiler, COfiler and PowerPlex21 results in DNA Analysis Laboratory.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=26048&DocumentInstanceID=132271
	Calibrations using the Artel MVS Training Module	8	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Biljana MICIC	To outline the training and competency requirements for staff in the use of the Artel MVS in the calibration of pipetting performance on the MicroLab STARlet and QIA Symphony instruments, and for the calibration of multi and single channel pipettes for volumes <350uL.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=27668&DocumentInstanceID=128015
	Examination of in-tube Samples - Training Module	8	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	1. Register items received from the Queensland Police Service in a tube for analytical processing. 2. Identify whether a sample is ready for extraction or requires manual intervention. 3. Identify the risks of contamination. 4. Identify probelms and carry out corrective actions.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=27744&DocumentInstanceID=131318
	Analytical Processes for Reporting Scientists - Training Module	7	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	Analytical Processes for Reporting Scientists This document is a training module for new Reporting Scientists to complete that covers the observation of Analytical processes (Part A) and written questions (Part B). The overall aim is for the trainee to develop enough knowledge of the processes to communicate the theory in lay terms to a court of law.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=28078&DocumentInstanceID=127575
	Evidence Recovery for Reporting Scientists - Training module	5	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Valerie CALDWELL	Evidence Recovery for Reporting Scientists	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=28079&DocumentInstanceID=134107
	Intelligence Processes for Reporting Scientists ? Training module	6	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	Intelligence Processes for Reporting Scientists	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=28080&DocumentInstanceID=132133
	DNA Statement Writing - Training Module	8	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Justin HOWES	DNA Statement Writing - Training Module - This training module is designed to cover all aspects of DNA Statement writing that are required before being signed off as a competent Reporting Scientist.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=28182&DocumentInstanceID=131300
	DNA Extraction using the Maxwell® Instrument Training Module	7	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	After successful completion of training and assessment in this module, the staff member will have provided evidence of required knowledge, skills and abilities in extraction DNA IQ? extraction using the Maxwell® 16 in DNA Analysis.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=29345&DocumentInstanceID=129202

Document Number	Title	Version	Document Status	Organisational Unit Scope	Service Scope	Site/Location Scope	Update Responsibility	Document Abstract	URL
[redacted]	STRmix? Training Module	3	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Emma CAUNT	This document details the requirements for sign off in the use of STRmix	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=31476&DocumentInstanceID=127360
	Examination of sexual cases training module	5	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Michelle MARGETTS	Training Module for the Examination of Sexual Cases Forensic DNA Analysis	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=32143&DocumentInstanceID=133388
	Using the Artel PCS® for Calibrations and Verifications Training Module	6	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Chantal ANGUS	Artel PCS® system for calibrations in the DNA Analysis Laboratory	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=32445&DocumentInstanceID=133051
	DVI and Coronial Casework for Reporting Scientists - Training Module	2	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Jacqui WILSON	training module to provide evidence of required knowledge, skills and abilities in DVI and Coronial Casework for Reporting Scientists in Forensic DNA Analysis.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=32555&DocumentInstanceID=120033
	STRmix? Data Entry for Case Management ? Training Module	5	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	Document outlining the training requirements for basic operation of the STRmix Software system.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=32618&DocumentInstanceID=133354
	Operation and Maintenance of the Applied Biosystems 3500 Series Genetic Analyzers - Training Module	5	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	Maintaining the 3500 Series Genetic Analyzers Preparation of plates to run on the 3500 Series Genetic Analyzers	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=32883&DocumentInstanceID=133761
	Quantification of Extracted DNA using the Quantifiler® Trio Quantification Kit ? Training Module	5	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	After successful completion of training and assessment in this module, the staff member named below, will have provided evidence of required knowledge, skills and abilities in ? Maintaining the QS5 Real Time PCR System. ? Quantitation of DNA extracts using the Life Technologies/Thermo Fisher Scientific Quantifiler® Trio DNA Quantification kit; ? Performing manual and automated setup of Microlab® STARlet and LabElite® Integrated I.D. Capper? instruments.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=33406&DocumentInstanceID=128913
	Operation and Maintenance of the QIAsymphony SP and AS- Training Module	6	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	Operation and Maintenance of the QIAsymphony SP and AS modules	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=33757&DocumentInstanceID=133266
	DNA Extraction and Quantitation of casework and reference samples using the QIAsymphony SP and AS Training Module	5	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	DNA extraction and quantitation of casework and reference samples using the QIAsymphony SP and AS training module	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=33759&DocumentInstanceID=129417
	Microlab STARlet and LabElite Integrated I.D. Capper Training Module	4	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	Training module for use and operation of ML STARlet and LE DeCapper Instruments.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=34054&DocumentInstanceID=134084
	Validation of Examinations - Training module	5	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Janine SEYMOUR-MURRAY	To provide evidence of required knowledge, skills and abilities in validations of examinations in Forensic DNA Analysis Laboratory	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=34316&DocumentInstanceID=133866

Document Number	Title	Version	Document Status	Organisational Unit Scope	Service Scope	Site/Location Scope	Update Responsibility	Document Abstract	URL
[redacted]	Basic Programming for Microlab STARlet and LabElite Integrated I.D. Capper using Venus Software Training Module	3	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	Training module for staff learning Basic Programming for Microlab® STARlet and LabElite® Integrated I.D. Capper? using Venus Software.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=34628&DocumentInstanceID=133113
	Capillary Electrophoresis Setup Training Module	2	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Luke RYAN	To outline the training and competency requirements for staff in the manual and automated prepping of plates for capillary electrophoresis on the 3130xl and 3500xL Genetic Analyzers.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=35063&DocumentInstanceID=131474
	Destruction of FTA reference samples - Training Module	1	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	Destruction of FTA reference samples - Training Module	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=35148&DocumentInstanceID=120010
	Reference Sample Profile Management - Training Module	1	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Allison LLOYD	Reference sample PDA Training Module to ensure standardisation of training and performance of reference sample PDA in the Forensic Register. The training module contains elements of quality control, use of worklists, profile checks and amendments, ordering of reworks and calculations.	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=35254&DocumentInstanceID=122543
	Gradual Exposure Training Checklist	1	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Paula BRISOTTO	Gradual Exposure Training Checklist	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=36071&DocumentInstanceID=131796
	NIFA for Familial, DVI and Missing Persons searching ? Training module	1	Active	DNA Analysis	Forensic and Scientific Service	Coopers Plains	Sharon JOHNSTONE	NIFA for Familial, DVI and Missing Persons searching ? Training module	http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=36082&DocumentInstanceID=134483

CA-41

Queensland Health
Forensic and Scientific Services

FSS Police Services Forensic DNA Analysis Orientation and Induction Checklist

Name: _____ Team: _____

Start Date: _____ End Date*: *Temp staff only _____

This checklist is to be completed in adjacent with the Orientation and Induction iLearn course.

Activity	Self-paced iLearn tasks and face-to-face discussions	Facilitator – name, sign & date	Inductee – initial, sign & date
Key policies, systems and procedures with **Line Manager** *~0900 -1030 Mon*	Key Policies, Systems and Procedures Line Manager discussion topics		
Stream tour with **Managing Scientist** *~1045 -1130 Mon*	Managing Scientist discussion topics		
Workplace Health and Safety with **Area Warden** and **Workplace Health and Safety Rep** *~1145 -1245 Mon*	Workplace Health and Safety Area Warden discussion topics Workplace Health and Safety Rep discussion topics		
Provision of ID/ EAC with **Campus Ops** *1330 -1400 Mon (note this is a fixed apt)*	Provision of ID/ EAC **You must have completed all Workplace Health and Safety tasks and discussions PRIOR to attending this appointment. Please print and bring your FEP certificate.*		
Local induction with **Line Manager** *~0900 - 1030 Tues*	Local Induction Line Manager discussion topics		
Quality with **Quality Representative** *~0900 - 0930 Wed*	Quality Quality Rep discussion topics		
Training with **Training Coordinator** *~0930 – 1000 Wed*	Training Training Coordinator discussion topics		

Orientation Agenda and Discussion Topics

Day 1 – FSS Orientation

Activity + Facilitator	Discussion Topics
Key policies, systems, and procedures with **Line Manager**	***Associated documents that require reading*** ☐ Job description / duty statements ☐ Awards and agreements – Employment conditions ☐ Overview of Forensic DNA Analysis team functions ☐ Roles and responsibilities ☐ Business hours ☐ Clients ☐ Business continuity statement ☐ Employee Assistance Service ☐ Salary packaging ☐ Superannuation ☐ Together Union membership ☐ Set-up timesheet and discussion ☐ Wages – first pay – streamline/myHR ☐ Upload commencement and tax form into myHR ☐ MyHR – Leave forms – applying for leave Getting started guide ☐Tours of Block 3 and Block 6 work areas ☐ Lockers (including where spare keys are kept – as applicable) ☐ Meet Team Leader FRIT ☐ Meet Team Leader ER & Quality ☐ QIS 36071 V__ Gradual Exposure Training Checklist
Stream tour with **Managing Scientist**	☐ Police Services Structure / Values / Clients / Strategic Direction and QHEPS resources ☐ Workplace behaviour/employee complaints ☐ Police Services tour / Meet Executive Director
Workplace Health and Safety with **Area/ Deputy Warden**	Emergency board presentation – board # (list all) _____ ☐ Evacuation routes / exits and signs ☐ Emergency plan procedures ☐ Emergency equipment ☐ ECO members (where possible introduce) ☐ WIP phones ☐ Add person to emergency contact list ☐ Assist the staff member to complete Fire and Evacuation Program *Note: This presentation is to be done at all relevant emergency boards that the staff member works, resides or occupies near for more than 2 weeks of 10 hours/week over a 3-month period) – please ensure FEP is also done for each of these locations also.*

Activity + Facilitator	Discussion Topics
Workplace Health and Safety with **Workplace Health and Safety Rep / Team Leader**	☐ Location and use of safety shower and eyewash stations ☐ Laboratory safety guidelines ☐ Clean / dirty areas ☐ Use and supply of PPE ☐ Accessing Chem Alert / SDS ☐ Consumption of food and drink in the laboratory. ☐ Hazardous exhibits / samples ☐ Storage of chemicals ☐ Use of fume & biohazard cupboards ☐ Waste management – i.e.: biohazards, sharps and general rubbish/ confidentiality bins / shredders ☐ First aid kits / supplies / rooms ☐ Spill containment / kits ☐ Working after hours ☐ Reporting of incidents i.e. Risk Man ☐ Freezer alarms

Day 2 – Local Induction

Activity + Suggested Facilitator	Suggested Discussion Topics
Local Induction continued with ***Line Manager***	☐ Equipment types ☐ Equipment / maintenance log books ☐ External equipment repair / maintenance ☐ S/4HANA maintenance requests ☐ Ordering of consumables ☐ Controlled fridge temperature monitoring ☐ Duress alarms ☐ Network drives/ use of H and C drives/ Internet access ☐ Self-service centre ☐ Scanning / faxing/ photocopying ☐ Recording phone messages ☐ Phone logs / Notations ☐ Password confidentiality ☐ Absences (Phone Admin) ☐ Use of electronics (mobile, iPods) ☐ Issues logs ☐ Mail management / distribution ☐ Notice boards ☐ Staff meetings / minutes ☐ Case/result enquiries referral

Activity + Suggested Facilitator	Suggested Discussion Topics
	☐ Disclosure of information ☐ Release of results ☐ Privacy and confidentiality ☐ Visitors to area ☐ External communications ☐ Turnaround times ☐ Changes to records – line, sign and date ☐ Contemporaneous notes ☐ LIM audit trails ☐ Movement of case files ☐ Archiving ☐ Glassware washing ☐ Computer software validation. ☐Explanation and demonstration of ordering system (if applicable) ☐Receipt of item protocol (if applicable)

Day 3 – Local Induction cont.

Activity + Suggested Facilitator	Suggested Discussion Topics
Quality discussion with ***Quality Representative***	☐ Forensic DNA Analysis - consent form ☐ Document Control / Notification lists ☐ Opportunities for Quality Improvement (OQI) / Self service centre ☐ Audits ☐ Anti-contamination procedures ☐ Design and function of the DNA suite ☐ Continuity ☐ Forensic Accreditation ISO 9001 / ISO 17025 – supp req's ☐ Management review ☐ Verification of consumables ☐ Calibrations / verifications / checks ☐ Method Validation / verifications ☐ Collaborative trials / Proficiency tests ☐ Peer review ☐ Meet Quality and Compliance Manager (Block 1, level 1) ***Complete*** ☐ Take DNA Sample ☐ Sign Signature Register

Activity + Suggested Facilitator	Suggested Discussion Topics
Training discussion with ***Training Coordinator***	☐ Learning pathway ☐ Authorisation to perform work ☐ Booking training course/s via the training calendar (iLearn) ☐ Training Portfolio • sign front page • record retention • records to be kept / location of green folders / not taking home / not sharing content. ☐ QIS² PD Records ☐ Court training program

Once all activities and tasks above are completed please upload this signed checklist here.

Your induction doesn't end here! What's next?

Wednesday 1300 – 1500: Infection and Prevention Control Training
See your appointment with FSS_Training for more information

Week Two: Check In with SSDU (online survey)
You will receive an email with a link to complete this survey

Week Two- Eight: *Mandatory Training*
Use this link to access and complete all required Mandatory Training

Week Three: *Career Success Plan (CSP)*
See your appointment with your line manager for more information

Week Eight: Check In with SSDU (online survey)
You will receive an email with a link to complete this survey

Six Months: Check In with SSDU (online survey)
You will receive an email with a link to complete this survey

Queensland Health

Forensic and Scientific Services

Forensic DNA Analysis Induction

Queensland Government

Position Requirements

- We are paid through the HRBC Payroll team (located at Chermside). Email: [redacted]

- For more information regarding the payroll and rostering system, you can visit the Payroll and Rostering Intranet Site (PARIS): http://qheps.health.qld.gov.au/paris/home.htm

- Standard Work Hours
  - HP: 7.6 a day, 38 hours per week.
  - AO: 7.6 a day, 38 hours per week.
  - CA: 8 a day, 40 per week (2 hours per week goes towards an RDO)

TOIL

- Some staff can accrue TOIL (time off in lieu) - if you work over the standard work hours, but this requires prior approval from your manager.

- An employee cannot take more TOIL than they have accrued i.e. an employee cannot go into negative TOIL

- For TOIL leave - no forms are required. An email to the generic Admin account [redacted] from a line manager - approving the leave is required.

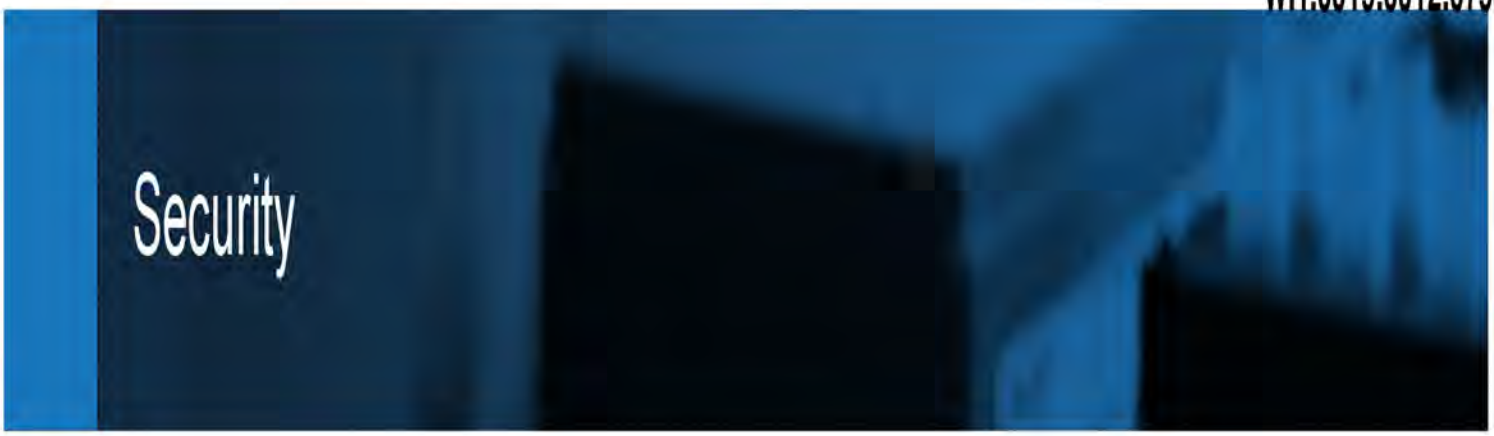
Leave

- Full time staff will accrue 20 days of recreation leave and 10 sick leave days per year. For part time staff, recreation and sick leave will be pro rata.

- If you are going to be absent you must call the Admin Team on [redacted] between 8am-9am, and advise them what type of leave you will be taking. The Admin team will forward a message to your line manager.

- You will require a Doctor's certificate for sick leave that is >3 days leave.

- For most leave types (including sick and recreation), a form must be completed and submitted in myHR (including part days). For RDOs and SARAS, or if you are working under a GRTW – admin will complete an AVAC form.



Security

- The building is surrounded by motion sensors and Closed Circuit Television Cameras and provides 24hr security.
- Forensic DNA Analysis is also monitored and all exhibits are stored in a room or freezer where access is via your proximity card.
- If you do work outside the hours of 6am – 6pm, or on a weekend, you must sign in and out at the security desk at the front entrance.
- You must wear your ID at all times.
- Free parking is available on site and on the road on Middle Street.

Time sheets

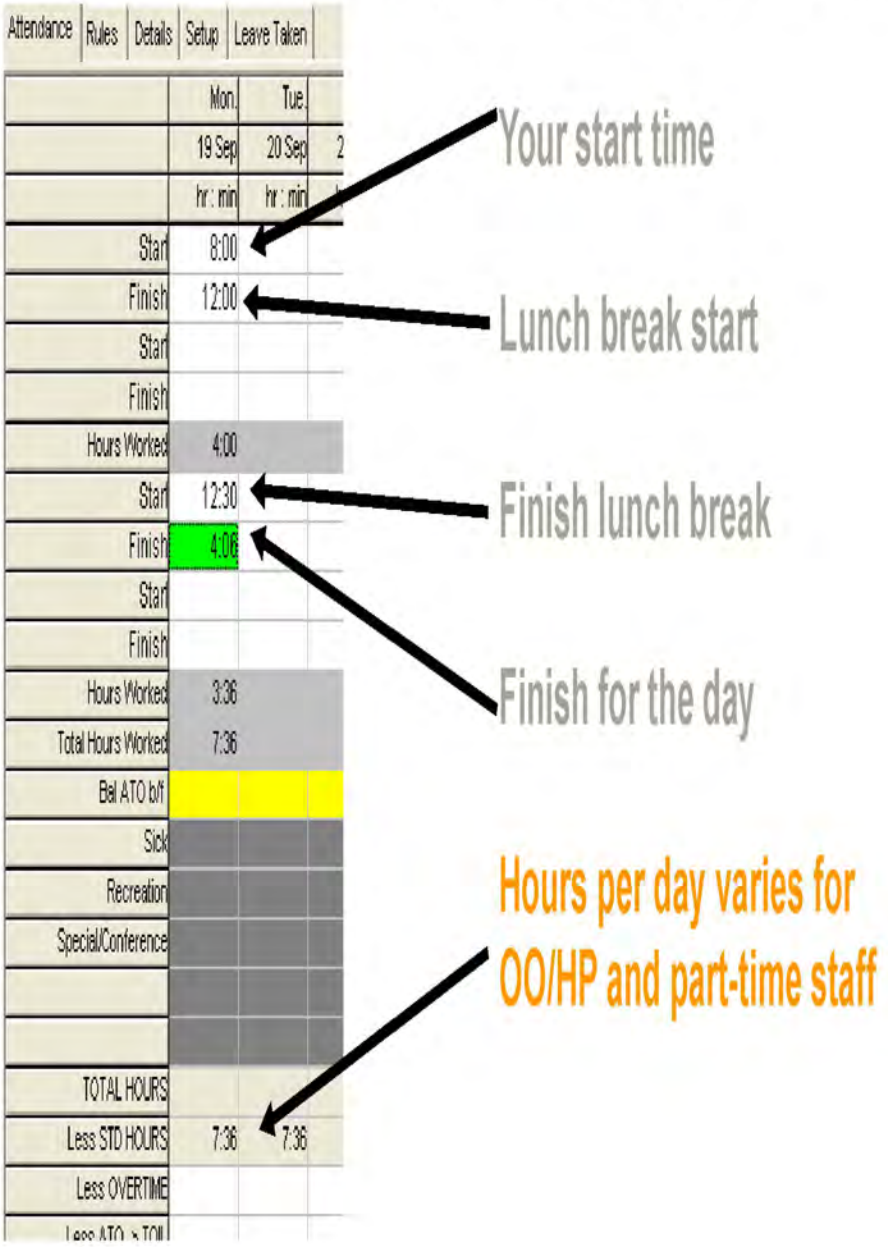
- **Each person fills out their own time sheet and it is based on the 'honesty' system – you fill in the hours you do.**

Time sheets are to be filled in daily:

- No password protection
- Start time is to be entered on arrival at work
- Fill in the time you go to lunch, the time you get back from lunch
- Finish time is to be entered before leaving work
- Lunch break is to be taken between the 3rd and 6th hour of work. You are also entitled to an additional 2 x 10min breaks.
  - If you work a ½ day only one 10 min is to be taken

Time sheet example

- If you right click with the mouse, you can enter any leave taken.



Workplace Health and Safety, First Aid and Fire Safety

Occupational Health and Workplace Safety

- It is the duty of all staff to ensure that the work place is maintained in a safe and proper manner, for others, as well as themselves.

- Kristina Morton is the current Workplace Health and Safety representative for Forensic DNA Analysis.

- It is a OHS requirement that incidents and near misses be documented and investigated using RiskMan. This needs to be completed as soon as practical after the incident (within 24 hours is the expectation).

First Aid

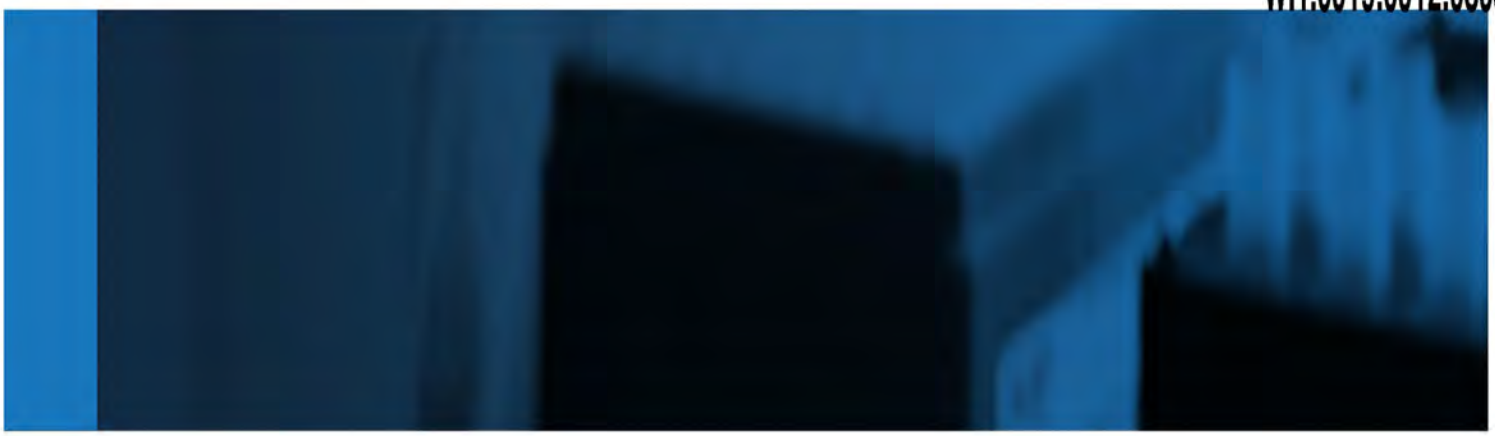
- FSS has several trained First Aid Officers throughout the site.
- In the event of an accident, a First Aid Officer should be called to render assistance.
- In Forensic DNA Analysis there are a number of First Aid Officers – refer to the laminated sheets on display around the laboratory (one is located at the fire board).
- You will be shown the locations of the first aid kits in your walk through

Fire Safety

- There is a fire alarm system installed within the building and it is tested regularly.

- Forensic DNA Analysis has an area warden, and deputy area warden in block 3 and in block 6 – refer to the list located at the fire board.

- They will take you on a walk through the lab and show you where the fire extinguishes are located, where the exits are located and indicate what the emergency response procedure is

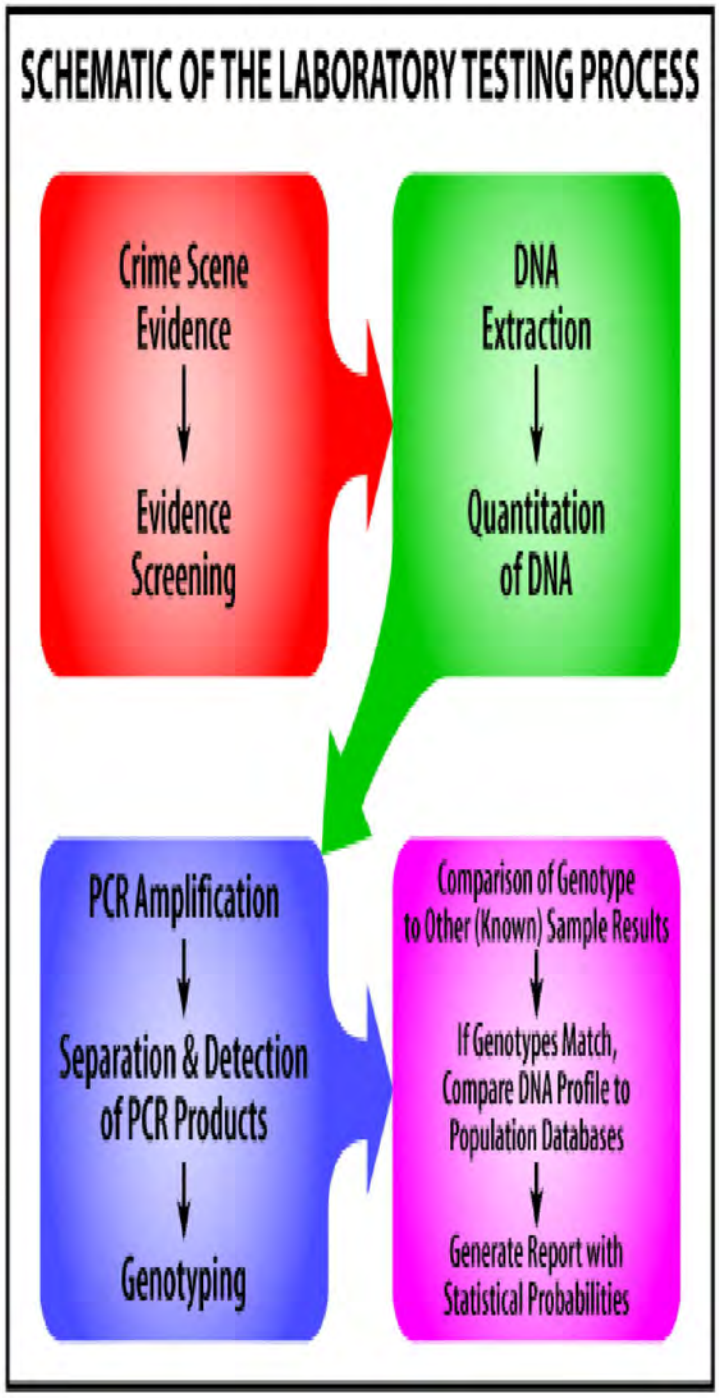


Forensic DNA Analysis Laboratory

What is the role of the Forensic DNA Analysis Laboratory?

- To analyse for legal purposes, human biological fluids for the purpose of identification.
- Typically within Forensic DNA Analysis these samples consist of (but aren't limited to) blood, semen, saliva & bone.
- Generally these fluids are deposited during the commission of violent crimes against a person including homicide, rape and assault and property crimes including break and enters.

Forensic DNA Analysis



Who are our clients?

Queensland Police Service(QPS)/Courts

- Identification of the origin of the sample (semen or saliva etc.)
- DNA analysis to link the material to a known person
- DNA analysis for upload to the National Criminal Investigation DNA Database

Office of the Director of Public Prosecutions

- Each and every one of us is accountable for the work we do, we can be called to court to explain our actions as requested.
- Reporting Scientists write statements for the court and regularly give evidence

Coroner

- Identification of remains prior to release for burial. Remains are analysed and the DNA profiles compared against profiles from ante-mortem samples or living relatives.

DVI (Disaster Victim Identification) via QPS/AFP

- Following international protocols such as those used for the Bali Bombings and the Tsunami, remains are analysed and the DNA profiles compared against profiles from ante-mortem samples or living relatives

Impartiality

- Objectivity and Impartiality should be maintained at all times .
- We have multiple clients including the QPS, the DPP, the Judicial System and other Forensic Laboratories.
- We make ourselves available to all parties in legal proceedings
- There are processes (for example peer review) in place to ensure that conscious or sub-conscious bias is not an issue

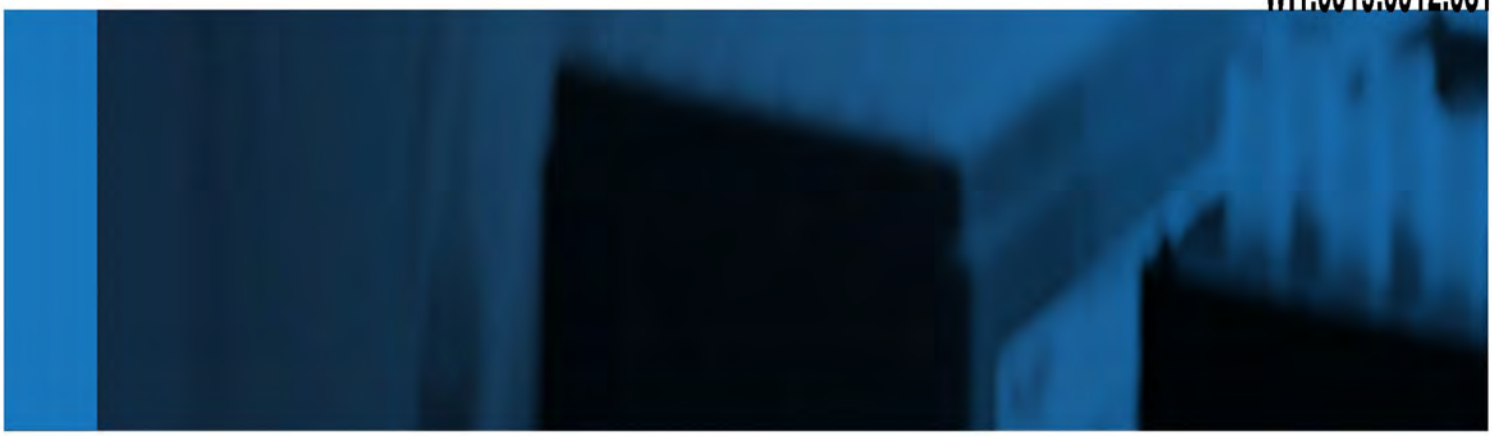
Confidentiality

- Confidentiality should be maintained at all times (refer to the Code of Conduct for the Queensland Public Service).
  - Cafe
  - 'water cooler' conversations

- Requests for information (i.e. overview of process or SOPs etc.) from other areas on campus, other labs in Queensland or other laboratories across the country - these requests must be authorised for release of information by the Managing Scientist.
- Any requests by the media for comments in relation to the laboratory or particular cases or processes must be referred to the Strategic Communications Work Unit https://qheps.health.qld.gov.au/csd/business/comms

Anti-contamination

- Laboratory Anti-contamination Policy
  - Distinction between 'clean' and 'dirty' areas
  - PPE
  - Environmental Monitoring
  - Use of controls (positive and negative)
- Staff Reference Samples



Quality

NATA Accreditation

- NATA is the National Association of Testing Authorities. NATA accreditation provides internationally recognised means of evaluating the competence of organisations to perform specific tests, calibrations, measurements and inspections.

- Forensic DNA Analysis is a ISO17025 accredited laboratory

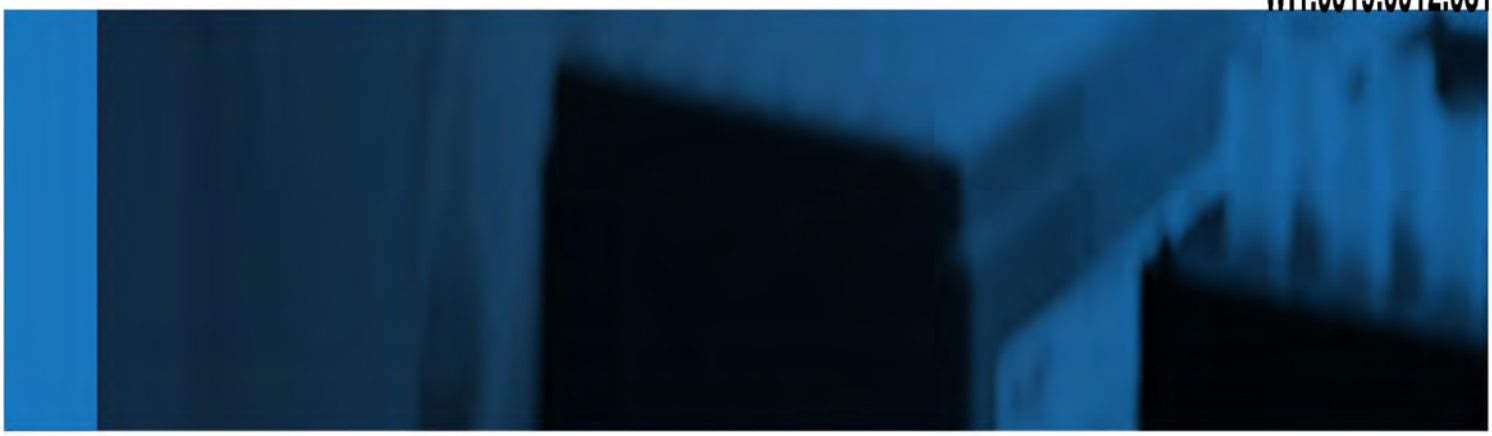
- The Senior Scientist for the Quality and Projects Team is the Quality Advisor for the Forensic DNA Analysis laboratory.

Professional Bodies and Associations

- Forensic DNA Analysis staff members come into contact with many different organisations and people. Some are listed below:
  - Justice Department
  - FMO's (Forensic Medical Officers)/GMO's (Government Medical Officers)
  - Forensic Toxicology, Forensic Pathology, Forensic Chemistry
  - Interstate forensic laboratories
  - NIFS (National Institute of Forensic Sciences)
  - NATA (National Association of Testing Authorities)
  - QPS – Queensland Police Service
  - Universities and students
  - Independent barristers
  - SSLU (Scientific Services Liaison Unit), Property office
  - CRIMTRAC
  - Interpol

The Australian and New Zealand Forensic Science Service (ANZFSS)

- Some staff in Forensic DNA Analysis are members of ANZFSS but it is not compulsory.
- ANZFSS has a dedicated Code of Ethics which all members are bound by.
- Forensic DNA Analysis laboratory is also bound by these ethics.
- Further information can be obtained from the members within the laboratory or also from the ANZFSS or NIFS websites.



Computers

Computer Programs

- The ***Standard Operating Environment*** **(SOE)**, is a standard maintainable desktop computer hardware and software platform for all computer workstations in the Department of Health.

- The SOE Project is part of the Workstation Management Program (WMP) which was established to develop and implement key workstation initiatives that will provide a managed workstation environment and create an ongoing structure to maintain that environment into the future.

- This means that any computer you log into will always contain the same programs and desktop.

- The major point with SOE is that you must log out when you walk away from a computer you were logged into. If you do not log out the computer will shut down after ten minutes and your password must be entered to unlock that computer.

Computer Programs

- Outlook is used for email and it is monitored by filter software to ensure that email is being used in accordance with professional, ethical, moral and public accountability standards.

- The Director–General encourages the use of electronic mail and the internet services appropriately and for official purposes, and not to divulge passwords to anyone.

- By logging onto a computer you acknowledge that you will adhere to these guidelines.

Computer Programs

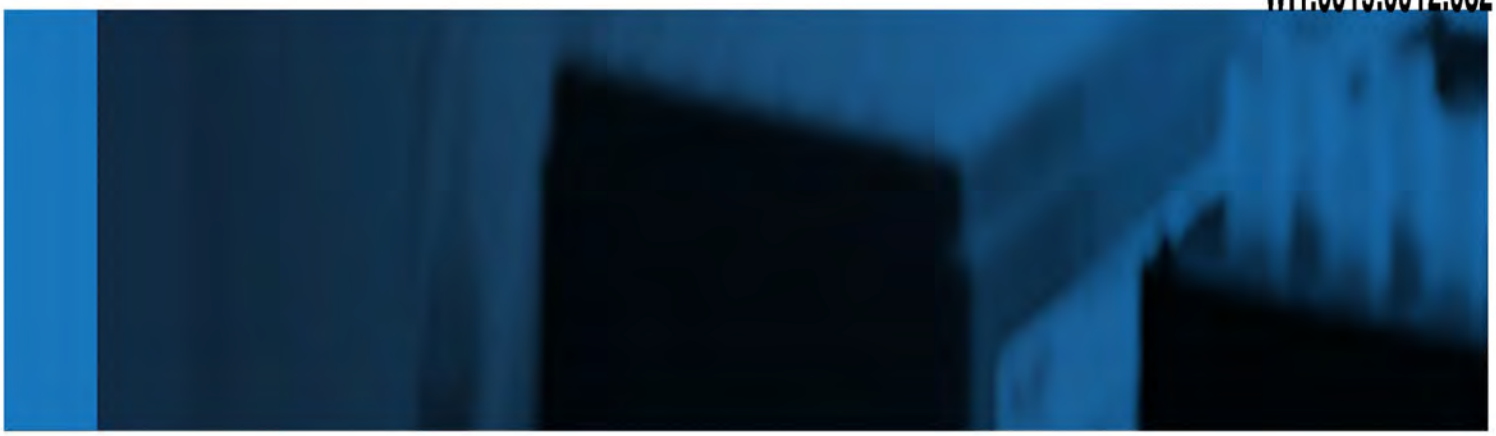
- QIS2 is the Quality Information System that is used to access standard operating procedures, calibration information, your professional development information and OQI's (opportunities for quality improvement).

- Internet access is available on all computers within Forensic DNA Analysis. Guidelines for appropriate use are available at: https://www.health.qld.gov.au/system-governance/policies-standards/doh-policy/standard/qh-imp-032-1.pdf

Computer Programs
AUSLAB/Forensic Register

- **Forensic Register** and **AUSLAB** are the Laboratory's information management systems (LIMS)

- LIMS is used for:
  - All samples and cases are registered
  - Batches are created
  - All results are stored and reported
  - Case Management is recorded
  - Communication between SSLU/Courts/QPS is recorded
  - Casefiles and exhibits are electronically tracked



Training Framework

Training Procedures and Competence Tests

- For each method we perform in the laboratory, there is an associated training procedure and competency test.

- For each type of position within Forensic DNA Analysis - the required training is outlined in the QIS #31010 Capability Development Program document

- In the next few weeks you will be working through a number of these competency tests, including training modules and competency tests for Forensic Register, QIS and role specific tasks

What to expect

- The next few weeks will contain a lot of information but this induction process is designed to slowly introduce you to the work processes within Forensic DNA Analysis and help you move into your new roles as quickly as possible.

Forensic DNA Analysis Area Inductions

- Management Team
- Administration
- Evidence Recovery
- Analytical
- Reporting
- Intelligence
- Quality and Projects
- Coronial Cases and DVI
- General Information

Management Team

The management team consists of :

- Managing Scientist
- 2x Team Leaders

  (Evidence Recovery & Quality; Forensic Reporting and Intelligence)
- 6x Senior Scientists

  (Evidence Recovery, Analytical, Quality & Projects, Reporting 1, Reporting 2 and Intelligence)
- 1x Admin Support Officer

- Management team meets once a week
- If you feel that an issue requires the attention of the management team – please discuss it with your line manager

Administration Team

The administration team perform many duties within the Forensic DNA Analysis laboratory, some of which include:

- Reception duties for Forensic DNA Analysis with respect to internal and external clients
- Storage and archiving of forensic case related records
- Management of Forensic Register work lists
- Mail distribution including forwarding of scientific statements
- Management of HR forms
- Case file compilation and storage

Evidence Recovery Team

- Evidence Recovery Team is comprised of HP2 Technicians and HP3 Scientists
- The Evidence Recovery Team examines items for the presence of biological fluids and submits samples to best address the allegations at hand. The team also handles the processing of samples examined by the Queensland Police Service (QPS) and submitted in-tube. These items or cases are split into the following categories:
  - In-tubes

    Samples taken by QPS from alleged crime scenes
  - Sexual Assault

    Sexual assaults in which a SAIK has been taken
  - Small items samples such as

    fabric, cig butts etc.

Evidence Recovery Team

Examinations include:

Visual examination – documentation of packaging, general description of item, visible damage and staining (documentation includes notes, diagrams and photos)

Screening tests - blood, semen, saliva

Blood:

- Distinctive visual appearance (red to red brown, shiny, crusty, dilute)
- Presumptive chemical screening test (Tetramethyl benzidine – TMB) positive reaction = immediate colour change from colourless to intense blue/green

Semen:

- May have visible appearance (white, crusty, stiffening of fabric substrate)
- Presumptive chemical screening test (acid phosphatase - AP)
- Microscopy is used to visualise presence of sperm
- Prostate Specific Antigen presumptive test for seminal fluid

Saliva

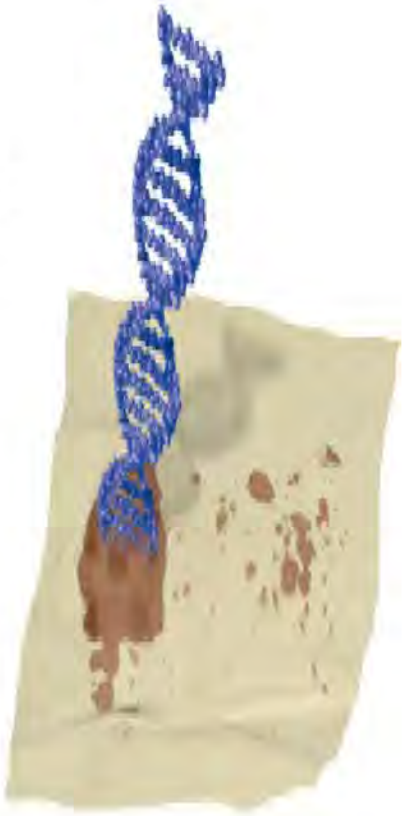
- Visual examination (may have clear whitish staining)
- Presumptive chemical screening test (Phadebas)

Analytical Team

The Analytical Team generates DNA profiles from;

- ✓ In-tube samples submitted by QPS
- ✓ Samples submitted from exhibits by the Evidence Recovery Team
- ✓ Reference blood and buccal samples collected by QPS

- Crime scene samples are processed in a different time and space to reference samples
- DNA profiling is a complex process with each step taking hours to complete
- Quality steps are essential at each stage to ensure sample integrity and continuity



Analytical Team

Extraction

- Most extractions performed in Forensic DNA Analysis are DNAIQ Extractions, and QIAsymphony extractions.
- The majority of DNAIQ Extractions are automated.

Quantitation

- Is used to quantify the total amount of amplifiable human DNA in a samples using a real-time PCR assay.
- Automation is also involved in Quantitation set-up and pre-PCR amplification set-up.

Amplification

- PP21 multiplex amplification reaction targets 20 different regions of STR sequence DNA as well as enabling gender typing.
- A positive and negative control is included in every batch of samples.

Capillary Electrophoresis

- Casework and Reference samples are run on a 3500xL Genetic Analyser and results interpreted using Genemapper® *ID-X* Software

Analytical Team

Concentration

- The Microcon method is used for samples where the yield of DNA is not sufficient to obtain a DNA profile
- Microcon Centrifugal Filter Devices employ the low-adsorption characteristics of the membrane and the device's component parts, together with an inverted recovery spin to produce high recovery rates

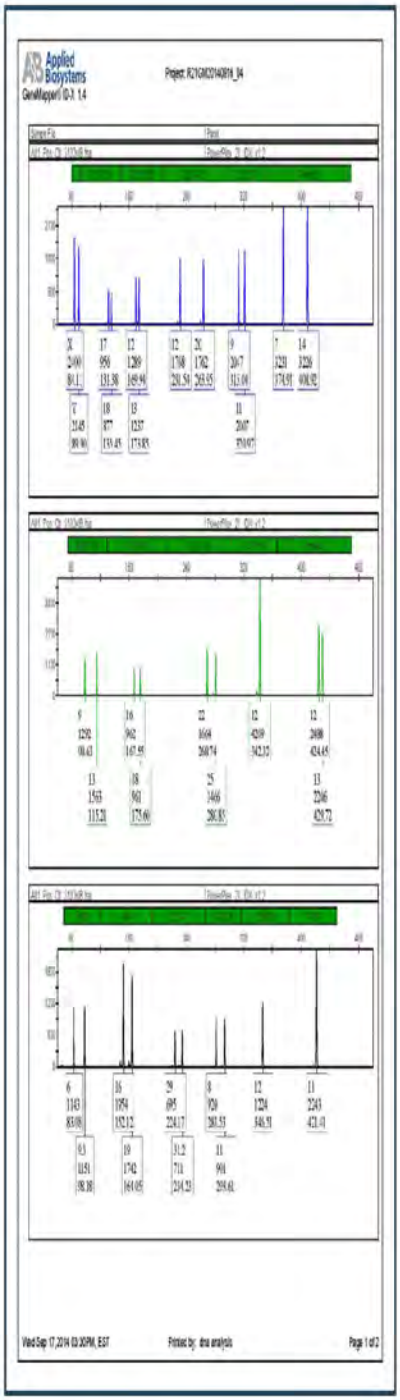
Purification

- The NucleoSpin extraction method is used on samples with a high proportion of contaminants or inhibitors.
- Unlike the Microcon method, it is not used to concentrate extracted DNA.

Reporting Team

The Reporting Team is made up of Reporting Scientists divided into two teams. They perform a number of duties including:

- Collating and interpreting results
- Preparing statements for court
- Attending court and providing expert testimony



Intelligence Team

The Intelligence Team is made up of Scientists and they perform a number of duties including:

- Collating and interpreting results
- Uploading DNA profiles to National Criminal Investigation DNA Database (NCIDD)
- Searching against the database for links (matches)

Intelligence Team (NCIDD)

ACIC National Criminal Investigation DNA Database contains profiles from samples collected from crime scenes and from convicted offenders. In some circumstances, controlled by legislation, profiles from suspects and volunteers may be compared with other profiles on the database.

It enables us to:

- compare DNA profiles from crime scenes with profiles of convicted offenders, suspects and volunteers;
- compare DNA profiles from convicted offenders, and where legislation allows, suspects, with profiles from unsolved crime scenes for which they may not previously have been suspects;
- match DNA profiles from two or more crime scenes, thereby linking seemingly unrelated police investigations.

While some States and Territories already have their own DNA databases, ACIC national DNA database allows the fight against crime to be taken Australia-wide.

Quality and Projects Team

The Quality and Projects Team is made up of Scientists and Laboratory Assistants.

Lab assistants support other teams in Forensic DNA Analysis through the following duties:

- FTA punching
- Registration of samples submitted by the QPS in-tube
- Batch creation
- Reagent preparation and stock maintenance

Quality and Projects Team - Scientists

Scientists within the team perform a number of duties including:

- Experimental design and research
- Validation studies and protocol design
- Maintenance of the laboratory quality system

Coronials & DVI

- **CORONIAL EXAMINATION**: The analysis of human remains for the purposes of identification e.g. If remains are found in bushland.

- **DVI** : Disaster Victim Identification. This includes identifications such as the of victims of the Lockhardt River Plane Crash in Northern Qld. It follows the international protocols as used in Bali (Bombings) and Thailand (Tsunami).

- All coronial and DVI work performed in the Forensic DNA Analysis laboratory is conducted in designated laboratory space to reduce the risk of contamination.

- Work is performed for the QPS and the Coroner.

Scientific Services Liaison Unit (SSLU)

- SSLU act as a liaison between Forensic DNA Analysis Case Scientists and QPS Investigating officers, the Office of the Director of Public Prosecutions and the courts.

- SSLU are responsible for helping with non-scientific matters such as prioritising testing of items as per QPS Request, negotiating court dates and general case liaison.

QPS DNA Results Management Unit (DRMU)

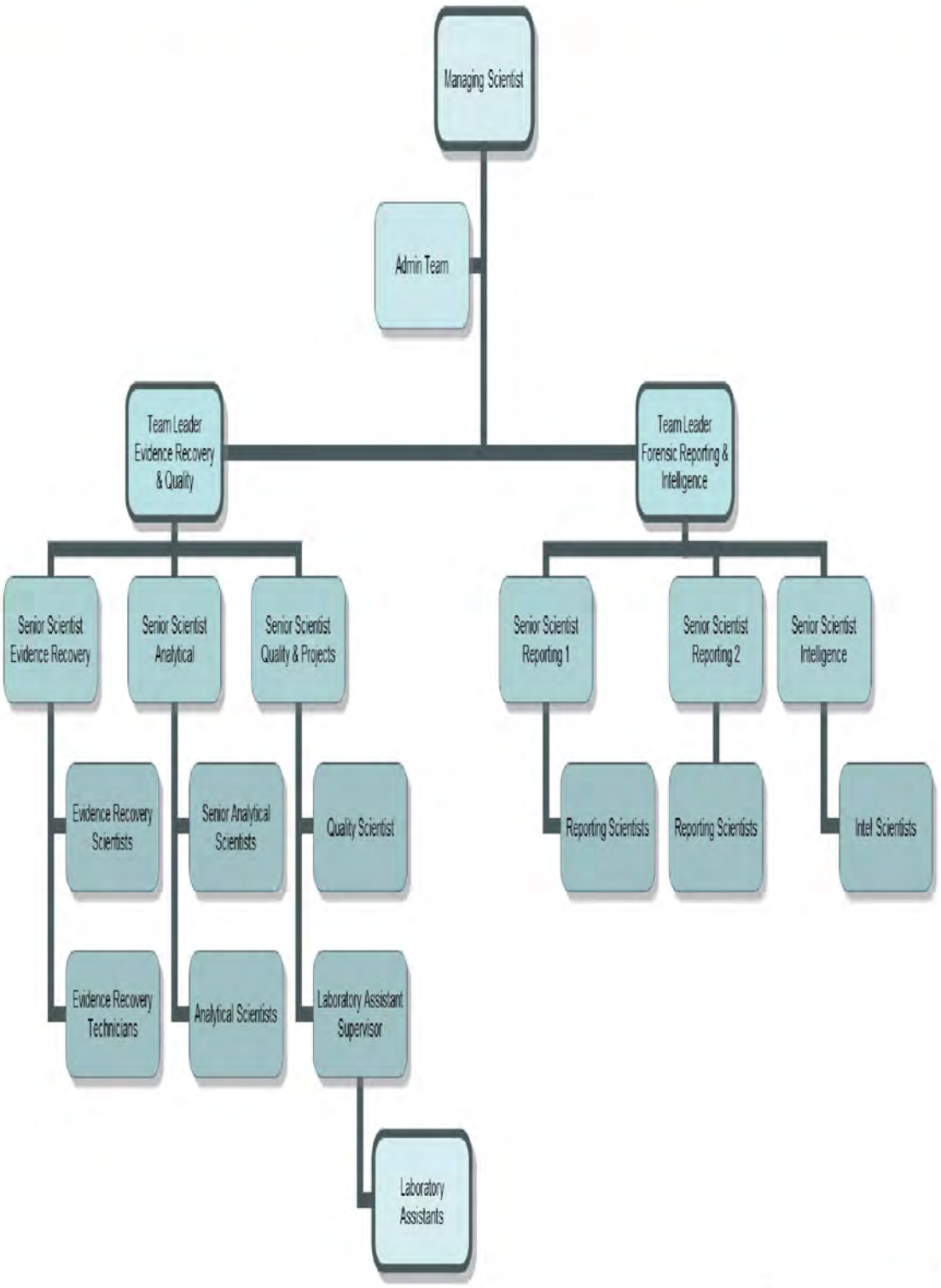
- Department of the Queensland Police Service that handle all Forensic DNA Analysis Results.
- Only DRMU, Scenes of Crime Officers (SOCOs) and Scientific Officers have access to the Forensic Register.
- In order for QPS to see the results, DRMU conduct quality checks and release the information to the IO (Investigating Officer).

Results

- Results over the telephone
  - The only instance where results can be given to QPS DRMU over the phone is where the result has already been validated.
  - Any enquiries from IOs should be referred to QPS DRMU, as DRMU perform their own quality checks prior to releasing results to IOs. We cannot tell if these have been completed.

- Guidelines for general information over the phone
  - Sub sample information, item descriptions and other non-results information can be given to QPS.
  - Explanations of results are best handled by the relevant case scientist.

Forensic DNA Analysis Team Chart



WELCOME TO
Forensic DNA Analysis

Version	Date	Author(s)	Amendments
12	31 May 2019	Kirsten Scott	Remove P+, SMANZFL & Crimtrac references, add to confidentiality, update hyperlinks and email addresses.
13	02 Dec 2020	Chelsea Savage	Addition of myHR
14	09 June 2022	Chelsea Savage	Change 'OO' to 'CA'. Update WH&S officer. Update 3130xL to 3500xL for casework samples. Change template. Update payroll email. Include AVAC information for GRTW. Update frequency of management team meetings.

Forensic DNA Analysis
Capability Development Program

This Capability Development Program (CDP) contains the associated learning pathways for Forensic DNA Analysis. A learning pathway is comprised of the minimum core skills and competencies specific to an area and / or position.

Learning pathways are flexible and can be tailored for the trainee and the work they will be performing. Management and use of this CDP is in accordance with:
QS 75051 - Competence Development Guideline

Learning Pathway Key

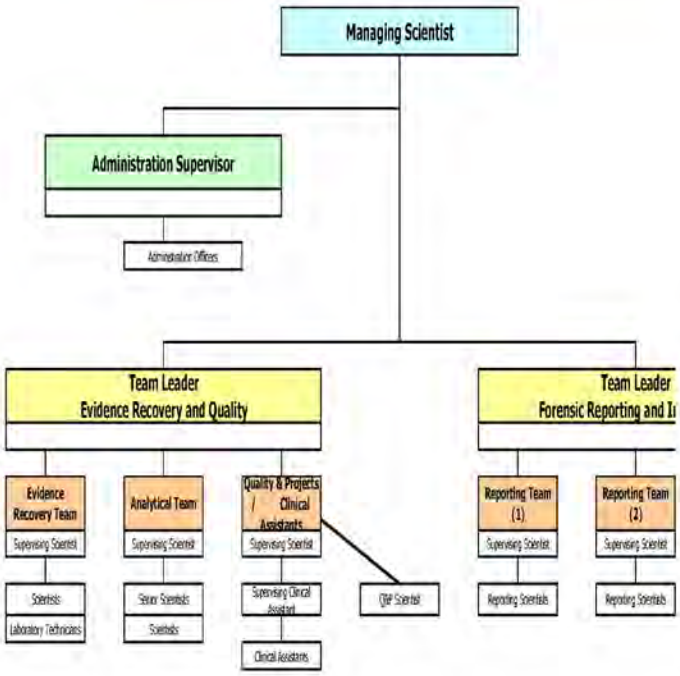
	Department of Health / Corporate / Policy / Legislative
	Workplace Health and Safety
	Quality
	IT Systems
	Scientific & Professional Development
A	Assigned - Line Manager Assigned as not all staff in the role are required to complete this training
U	Upskill - suggested upskilling for this position to be discussed in CSP
P	Partial – not required to complete all EC/KPC see pathway detailing requirements to be completed
	Team specific training modules

Learning Pathways

	Role / Position	Classification
1	Team Leader	HP6
2	Supervisor - Administration Team	AO4
2.1	Administration Officer	AO1-3
3	Supervising Scientist - Evidence Recovery	HP5
3.1	Scientist - Evidence Recovery	HP3
3.2	Laboratory Technician - Evidence Recovery	HP2
4	Supervising Scientist - Quality and Projects	HP5
4.1	Scientist - Quality and Projects	HP3
4.2	Supervising Clinical Assessor	CA4
4.3	Clinical Assistant	CA3
5	Supervising Scientist - Analytical	HP5
5.1	Senior Scientist - Analytical	HP4
5.2	Scientist - Analytical	HP3
6	Supervising Scientist - Reporting	HP5
6.1	Reporting Scientist - Reporting Team	HP4
7	Supervising Scientist - Intelligence	HP5
7.1	Scientist - Intelligence	HP3

Q/S2 Edition			
Version	**Date**	**Updated By**	**Amendments**
1	27-Apr-12	J. Howes	First issue as Reporting Scientist Learning Pathway
2	11-Jul-14	J. Howes and P. Clausen	First issue as overarching document
3	6-May-16	J. Howes	New template, updated all appendices
4	11-Apr-18	J. Howes	New template (31908v5) used. Updated LPs, especially since FR implementation. Added Org chart and Record of re-evaluation as per template.
5	16-Mar-20	J Howes	Updated LPs based on supervisor's paper-based feedback, moved Red Text box to KEY, change grey to clear when non-essential
6	12-Apr-22	J Howes	Major revision to fit to new Excel format

Forensic DNA Analysis Team Chart



Course Catalogue	Course Type.	Duration
FSS Orientation and Induction	Blended	3 months
QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	3 days
DoH Expenditure Delegations Framework	Self Paced	30 minutes
Beginner Guide to the Queensland Procurement Policy	Self Paced	1 hour
Procurement 101	Self Paced	1 hour
Probity in Procurement - Queensland Health	Self Paced	1 hour
Introduction to Procurement and Planning	Self Paced	1 hour
Introduction to Good Practice Social Procurement	Self Paced	1 hour
Driving a vehicle for work induction	Self Paced	30 minutes
FMPM and Financial Governance 2021	Self Paced	30 minutes
HSQ Delivered Panel Chair and Hiring Manager Training	Face 2 Face	1 hour
Introduction to Good Practice Contract Management	Self Paced	30 minutes
Contract Management – Extensions and Variations	Self Paced	1 hour
Mortuary Awareness	blended	1 hour
Queensland Health and the Human Rights Act	Self Paced	30 minutes
Research & Governance Induction	Self Paced	10 minutes
Risk Management	Self Paced	30 minutes
Site Tenants and Visitors Induction	Blended	1 hour
2021 Radiation Protection and Safety	Self Paced	30 minutes
Advanced Resuscitation	Face 2 Face - External provider	1/2 day - renew yearly
(FSS) Building Specific General Evacuation/ First Response Instructions - General	Self Paced	30 minutes - renew yearly
(FSS) Building Specific General Evacuation/ First Response Instructions - ECO members	Self Paced	30 minutes - renew yearly
Cardiopulmonary Resuscitation (CPR) or Advanced Resus or Low Voltage Rescue	Face 2 Face - External provider	1/2 day - renew yearly
Chemical Spill Response	Self Paced	30 minutes
Dangerous Goods Packaging (Air) – Shippers of Infectious Sub and Dry Ice (Cat A and B)	Self Paced	2 hours - Renew every 2 years
Dangerous Goods Packaging (Road / Rail) – Shippers of Infectious Substances (Cat A and B)\	Self Paced	2 hours
Dangerous Goods Packaging (Road / Rail) – Shippers of Chemicals	Face 2 Face - External provider	Recommended every 2 years
Emergency Control Organisation (Scenarios) includes Practical Fire Extinguisher training	Self Paced	2 hours
First Aid training	Blended	1 day - renew 3 yearly
Health and Safety Representative training	Face 2 Face - External provider	5 Days 1 Day- renew 3 yearly
Health and Safety Risk Assessments	Class Room	1 month
Low Voltage Rescue	Face 2 Face - External provider	Renew yearly
Operation of ELSA	Blended	2 weeks
Qualitative Respirator Fit Test Evaluator	Blended	1 month
Safe Handling Liquid Nitrogen	Blended	1 month
Risk Management	Self Paced	30 minutes
RiskMan	Self Paced	30 minutes
WHS Incident Response and Investigations	Self Paced	30 minutes

	Course Catalogue	Course Type.	Duration
	Waste Management	*Self Paced*	*30 minutes*
	Balance Verifications	*Blended*	*1 month*
	Clinical Governance	*Self Paced*	*1 hours*
	DAWE AA Accredited Person	*Self Paced*	*2 hours*
	Internal Auditor Training	*Blended*	*1 month*
	POVA Verification	*Blended*	*1 month*
	Release of results	*Self Paced*	*1 hour*
	Thermometer/ Data Logger Verification	*Blended*	*1 month*

	Course Catalogue	Course Type.	Duration
	Understanding ISO 15189	Self Paced	1 hour
	Understanding ISO 17025	Self Paced	1 hour
	Adobe Software	Self Paced	30 minutes
	AUSLAB Corrections (Forensic/Public Health/Pathology	Blended	2 weeks
	DSS New User - System Navigation	Self Paced	30 minutes
	EndNote	Face 2 Face	3 Hours
	Microsoft Office 365	Self Paced	Various
	Microsoft Office Coaching	Face 2 Face	1 hour
	QIS2 Basics	Self Paced	30 minutes
	QIS2: Documents Advanced	Self Paced	30 minutes
	QIS2: OQIs	Self Paced	30 minutes
	QIS2: Professional Development	Self Paced	30 minutes
	QIS 2 Management Reports	Self Paced	30 minutes
	QIS 2 Document Administrator	Self Paced	2 hours
	QIS 2 OQI Administrator	Self Paced	2 hours
	QIS 2 Audit Administrator	Self Paced	2 hours
	QIS 2 Calibration Administrator	Self Paced	2 hours
	QIS 2 PAD Administrator	Self Paced	2 hours
	QIS 2 Training Administrator	Self Paced	2 hours
	RecFind/RecQuery	F2F with Records	2 Hours
	S/4HANA Delegations and Workflow	Self Paced	1 Hour
	S/4HANA Extended Warehouse Management	Self Paced	1 Hour
	S/4HANA Foundation	Self Paced	1 Hour
	S/4HANA General Ledger	Self Paced	1 Hour
	S/4HANA Inventory Management	Self Paced	1 Hour
	S/4HANA Master Data Governance	Self Paced	1 Hour
	S/4HANA Operational Procurement	Self Paced	1 Hour
	S/4HANA SME Uplift Program	Self Paced	1 Hour
	S4HANA - AP-M00: Accounts Payable - Functional Overview	Self Paced	1 Hour
	IWFM mYHr Manager Self Service	Self Paced	1 Hour
	IWFM myHR Support Groups	Self Paced	1 Hour
	Payroll Services myHR Worklist Manager	Self Paced	1 Hour
	Standard Movements	Self Paced	1 Hour
	Forensic Register Training	Blended	2 x 2 hour session
	Career Success Plans	Self Paced	2 hours
	Delivery of FSS Training and Assessment	Blended	2 months
	Introduction to Legislation	Blended	2 hours
	Provision of Court Testimony	Blended	Part A +B 2 months / yearly

	Course Catalogue	Course Type.	Duration
	Performance Practice Program	Virtual	3 days
	Managers Toolbox (not graded)	Self Paced	N/A
	Forensic DNA Training Modules	**Type**	**Duration**
	Admin TM		
	QIS 23742: Administrative Officer - Forensic DNA Analysis	Face 2 Face	See document for details
	Evidence Recovery TM		
	QIS 16000: Examination of Items	Face 2 Face	See document for details
	QIS 16002: Acid Phosphatase Screening	Face 2 Face	See document for details
	QIS 16003: Examination of Microscopy Slides ...	Face 2 Face	See document for details
	QIS 22593: TMB Screening test for Blood	Face 2 Face	See document for details
	QIS 22594: The Phadebas Test for Saliva	Face 2 Face	See document for details
	QIS 23608: ABAcard p30	Face 2 Face	See document for details
	QIS 23622: Selection & Prep of Bone and Teeth for DNA Testing	Face 2 Face	See document for details
	QIS 27744: Examination of in tube samples	Face 2 Face	See document for details
	QIS 28079: Evidence Recovery for Reporting Scientists	Face 2 Face	See document for details
	QIS 32143: Examination of Sexual cases	Face 2 Face	See document for details
	QIS 34316: Validation of Examinations	Face 2 Face	See document for details
	QIS 35148: Destruction of FTA Reference Samples	Face 2 Face	See document for details
	Quality and Projects TM		
	QIS 17125: Processing of FTA Reference Samples	Face 2 Face	See document for details
	QIS 23885: Miscellaneous Tasks for Laboratory Assistants	Face 2 Face	See document for details
	QIS 24106: Verification of Timing Devices	Face 2 Face	See document for details
	QIS 25266: Forensic DNA Analysis Workflow Procedure	Face 2 Face	See document for details
	QIS 25745: Use of the STORstar unit for automated sequence checking	Face 2 Face	See document for details
	QIS 27668: Calibrations using the Artel MVS ®	Face 2 Face	See document for details
	QIS 32445: Using the Artel PCS for Calibrations and Verifications	Face 2 Face	See document for details
	Analytical TM		
	QIS 17210: STR PCR Amplification	Face 2 Face	See document for details
	QIS 15996: CE Quality Check of Samples from CE Genetic Analyzers	Face 2 Face	See document for details
	QIS 20966: Nucleospin Extraction	Face 2 Face	See document for details
	QIS 23516: Concentration of DNA Extract using Microcon Centrifugal Filter Devices	Face 2 Face	See document for details
	QIS 24253: Automated dilution & Automated Testquant of Standards Operation	Face 2 Face	See document for details
	QIS 28078: Analytical Processes for Reporting Scientists	Face 2 Face	See document for details
	QIS 29345: DNA Extraction using the Maxwell 16 Instrument	Face 2 Face	See document for details
	QIS 32445: Using the Artel PCS for Calibrations and Verifications	Face 2 Face	See document for details
	QIS 32883: Operation and Maintenance of AB 3500 Series Genetic Analyser	Face 2 Face	See document for details
	QIS 33406: Quantification of Extracted DNA using Quantifiler Trio Quant Kit	Face 2 Face	See document for details
	QIS 33757: Operation and Maintenance of the QIAsymphony SP and AS	Face 2 Face	See document for details

	Course Catalogue	Course Type.	Duration
	QIS 33759: DNA Extraction and Quant of casework and reference samples using the QIAsymphony SP and AS SP and AS	Face 2 Face	See document for details
	QIS 34628: Basic programming for Microlab STARlet and LABElie Integrated I.D. Capper using Venus S	Face 2 Face	See document for details
	QIS 35063: Capillary Electrophoresis Setup	Face 2 Face	See document for details
	Reporting TM		
	QIS 24276: Case Management	Face 2 Face	See document for details
	QIS 31476: STR Mix	Face 2 Face	See document for details
	QIS 32618: STRmix Data Entry for Case Management	Face 2 Face	See document for details
	QIS 28182: DNA Statement Writing	Face 2 Face	See document for details
	QIS 24234: DNA Statistics	Face 2 Face	See document for details
	QIS 25301: Kinship	Face 2 Face	See document for details
	QIS 35254: Reference Sample Profile Management	Face 2 Face	See document for details
	QIS 22858: Technical Review	Face 2 Face	See document for details
	QIS 23622: Selection & Prep of Bone and Teeth for DNA Testing	Face 2 Face	See document for details
	QIS 32555: DVI and Coronial Casework for Reporting Scientists	Face 2 Face	See document for details
	QIS 24276: Case Management	Face 2 Face	See document for details
	QIS 36287: Body Fluid, Trace and Opinion Evidence Provision in Forensic DNA Analysis	Face 2 Face	See document for details
	QIS 9009: Paternity and Paired Kinship Statistics	Face 2 Face	See document for details
	Intelligence TM		
	QIS 23839: Uploading Profiles to NCIDD, Creating & Reviewing Links	Face 2 Face	See document for details
	QIS 25582: Paired Kinship & Paternity Trio / Missing Child in Kinship	Face 2 Face	See document for details
	QIS 25584: Use of DNA Analysis Database Interface (DADI)	Face 2 Face	See document for details
	QIS 26048: GeneMapper IDX Plate Reading	Face 2 Face	See document for details
	QIS 28080: Intelligence Processes for Reporting Scientists	Face 2 Face	See document for details

1 **Team Leader Learning Pathway** **Name**

	Training	Type	Duration	
	FSS Orientation and Induction	*Blended*	*3 months*	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	*Blended*	*3 days*	
	HSQ Delivered Panel Chair and Hiring Manager Training	*Face 2 Face*	*1 hour*	
	S/4HANA Foundation	*Self Paced*	*1 Hour*	
	S/4HANA Delegations and Workflow	*Self Paced*	*1 Hour*	
	IWFM mYHr Manager Self Service	*Self Paced*	*1 Hour*	
	IWFM myHR Support Groups	*Self Paced*	*1 Hour*	
	Payroll Services myHR Worklist Manager	*Self Paced*	*1 Hour*	
	DoH Expenditure Delegations Framework	*Self Paced*	*30 minutes*	
	Beginner Guide to the Queensland Procurement Policy	*Self Paced*	*1 hour*	
	Risk Management	*Self Paced*	*30 minutes*	
	Risk Management	*Self Paced*	*30 minutes*	
	RiskMan	*Self Paced*	*30 minutes*	
	Career Success Plans	*Self Paced*	*2 hours*	
	Managers Toolbox (not graded)	*Self Paced*	*N/A*	
	Competence – Evidence Recovery Supervising Scientist - learning pathway QIS 31010 Appendi	*1 year re-evaluation*		A
	Competence – Quality & Projects Supervising Scientist - learning pathway QIS 31010 Appendix	*1 year re-evaluation*		A
	Competence – Analytical Section Supervising Scientist - learning pathway QIS 31010 Appendix	*1 year re-evaluation*		A
	Competence – Reporting Team Supervising Scientist - learning pathwayQIS 31010 Appendix 6	*1 year re-evaluation*		A
	Competence - Intelligence Team Supervising Scientist - learning pathway QIS 31010 Appendix 7	*1 year re-evaluation*		A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010 - Appendix 1 - Competent - Forensic DNA Analysis Team Leader Learning Pathway
Re-Evaluation 1 Year

2 Administration Supervisor Learning Pathway **Name**

	Training	Type	Duration	
	FSS Orientation and Induction	*Blended*	*3 months*	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	*Blended*	*3 days*	
	QIS 23742: Administrative Officer - Forensic DNA Analysis	*Face 2 Face*	*See document for details*	
	Managers Toolbox (not graded)	*Self Paced*	*N/A*	
	QIS2 Basics	*Self Paced*	*30 minutes*	
	QIS2: Documents Advanced	*Self Paced*	*30 minutes*	
	QIS2: OQIs	*Self Paced*	*30 minutes*	
	QIS2: Professional Development	*Self Paced*	*30 minutes*	
	Microsoft Office 365 (Outlook, Word, Excel)	*Self Paced (Not Graded)*	*N/A*	
	EndNote	*Face 2 Face*	*3 Hours*	
	DSS New User - System Navigation	*Self Paced*	*30 minutes*	A
	S/4HANA Foundation	*Self Paced*	*1 Hour*	
	S4HANA - AP-M00: Accounts Payable - Functional Overview	*Self Paced*	*1 Hour*	
	S/4HANA Operational Procurement	*Self Paced*	*1 Hour*	
	IWFM myHr Manager Self Service	*Self Paced*	*1 Hour*	
	IWFM myHR Support Groups	*Self Paced*	*1 Hour*	
	Payroll Services myHR Worklist Manager	*Self Paced*	*1 Hour*	
	eDRMS with FSS Records	*F2F with Records*	*2 Hours*	
	Delivery of FSS Training and Assessment	*Blended*	*2 months*	
	Career Success Plans	*Self Paced*	*2 hours*	
	WHS Incident Response and Investigations	*Self Paced*	*30 minutes*	
	Procurement 101	*Self Paced*	*1 hour*	
	HSQ Delivered Panel Chair and Hiring Manager Training	*Face 2 Face*	*1 hour*	
	Health and Safety Risk Assessments	*Class Room*	*1 month*	A
	Internal Auditor Training	*Blended (optional)*	*1 month*	A
	Understanding ISO 17025	*Self Paced (optional)*	*1 hour*	A
	Performance Practice Program	*Virtual*	*3 days*	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010 - Appendix 2 - Competent - Forensic DNA Analysis Admin Supervisor Learning Pathway
Re-Evaluation 1 Year

2.1 Administration Officer Learning Pathway **Name**

	Training	Type	Duration	
	FSS Orientation and Induction	*Blended*	*3 months*	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	*Blended*	*3 days*	
	QIS 23742: Administrative Officer - Forensic DNA Analysis	*Face 2 Face*	*See document for details*	
	QIS2 Basics	*Self Paced*	*30 minutes*	
	QIS2: Documents Advanced	*Self Paced*	*30 minutes*	
	QIS2: OQIs	*Self Paced*	*30 minutes*	
	QIS2: Professional Development	*Self Paced*	*30 minutes*	
	Microsoft Office 365 (Outlook, Word, Excel)	*Self Paced*	*Various*	A
	eDRMS with FSS Records	*F2F with Records*	*2 Hours*	
	EndNote	*Face 2 Face*	*3 Hours*	A
	DSS New User - System Navigation	*Self Paced*	*30 minutes*	A
	S/4HANA Foundation	*Self Paced*	*1 Hour*	
	S4HANA - AP-M00: Accounts Payable - Functional Overview	*Self Paced*	*1 Hour*	
	Understanding ISO 17025	*Self Paced*	*1 hour*	
	Delivery of FSS Training and Assessment	*Blended*	*2 months*	A
	Internal Auditor Training	*Blended*	*1 month*	A
	Understanding ISO 15189	*Self Paced*	*1 hour*	A
	Health and Safety Risk Assessments	*Class Room*	*1 month*	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010 - Appendix 2.1 - Competent - Forensic DNA Analysis - Administration Officer Learning Pathway

Re-Evaluation 1 year

3 **Supervising Scientist - Evidence Recovery Learning Pathway** Name

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	See document for details	
	QIS 26048: GeneMapper IDX Plate Reading	Face 2 Face	See document for details	A
	Competent – ER Scientist - learning pathway QIS 31010 Appendix 3.1 mini Part B only	Yearly	See document for details	
	QIS 31010: Competence – Reporting Scientist (HP4) - learning pathway	Face 2 Face	See document for details	
	HSQ Delivered Panel Chair and Hiring Manager Training	Face 2 Face	1 hour	
	Delivery of FSS Training and Assessment	Blended	2 months	A
	Managers Toolbox (not graded)	Self Paced	N/A	
	Career Success Plans	Self Paced	2 hours	
	Risk Management	Self Paced	30 minutes	
	RiskMan	Self Paced	30 minutes	
	WHS Incident Response and Investigations	Self Paced	30 minutes	
	Health and Safety Risk Assessments	Class Room	1 month	A
	QIS2 Basics	Self Paced	30 minutes	
	QIS2 Documents Advanced	Self Paced	30 minutes	
	QIS2 OQIs	Self Paced	30 minutes	
	QIS2 Professional Development	Self Paced	30 minutes	
	QIS 2 Management Reports	Self Paced	30 minutes	
	Understanding ISO 17025	Self Paced	1 hour	
	Internal Auditor Training	Blended	1 month	A
	Mortuary Awareness	Blended	1 hour	A
	Performance Practice Program	Virtual	3 days	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010 - Appendix 3 - Competent -Evidence Recovery Supervising Scientist Learning Pathway
Re-Evaluation 1 Year

3.1 Scientist - Evidence Recovery Learning Pathway **Name**

	Training	Type	Duration	
	FSS Orientation and Induction	*Blended*	*3 months*	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	*Blended*	*See document for details*	
	QIS 27744: Examination of in tube samples	*Face 2 Face*	*See document for details*	
	QIS 22593: TMB Screening test for Blood	*Face 2 Face*	*See document for details*	
	QIS 16000: Examination of Items	*Face 2 Face*	*See document for details*	
	QIS 22594: The Phadebas Test for Saliva	*Face 2 Face*	*See document for details*	
	QIS 34316: Validation of Examinations	*Face 2 Face*	*See document for details*	
	QIS 16002: Acid Phosphatase Screening	*Face 2 Face*	*See document for details*	
	QIS 16003: Examination of Microscopy Slides...	*Face 2 Face*	*See document for details*	
	QIS 23608: ABAcard p30	*Face 2 Face*	*See document for details*	
	QIS 32143: Examination of Sexual cases	*Face 2 Face*	*See document for details*	
	QIS 28048: GeneMapper IDX Plate Reading	*Face 2 Face*	*See document for details*	
	QIS 31476: STRMix	*Face 2 Face*	*See document for details*	A
	QIS 32618: STRmix Data Entry for Case Management	*Face 2 Face*	*See document for details*	A
	QIS 35254: Reference Sample Profile Management	*Face 2 Face*	*See document for details*	A
	QIS 24276: Case Management	*Face 2 Face*	*See document for details*	A
	Release of results	*Self Paced*	*1 hour*	A
	QIS 35148: Destruction of FTA Reference Samples	*Face 2 Face*	*See document for details*	A
	Safe Handling Liquid Nitrogen	*Blended*	*1 month*	A
	Operation of ELSA	*Blended*	*2 weeks*	A
	QIS 23622: Selection & Prep of Bone and Teeth for DNA Testing	*Face 2 Face*	*See document for details*	A
	Provision of Court Testimony	*Blended*	*Part A +B 2 months / yearly*	A
	Internal Auditor Training	*Blended*	*1 month*	A
	Understanding ISO 15189	*Self Paced*	*1 hour*	A
	Understanding ISO 17025	*Self Paced*	*1 hour*	
	Delivery of FSS Training and Assessment	*Blended*	*2 months*	A
	Mortuary Awareness	*blended*	*1 hour*	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010 - Appendix 3.1 - Competent - ER Scientist Learning Pathway
Re-Evaluation 1 Year

3.2 Laboratory Technician - Evidence Recovery Learning Pathway

Name

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	See document for details	
	QIS 27744: Examination of in tube samples	Face 2 Face	See document for details	
	QIS 16000: Examination of Items	Face 2 Face	See document for details	P
	QIS 35148: Destruction of FTA Reference Samples	Face 2 Face	See document for details	
	QIS 32618: STRmix Data Entry for Case Management	Face 2 Face	See document for details	
	Balance Verifications	Blended	1 month	A
	Thermometer/ Data Logger Verification	Blended	1 month	A
	QIS 32445: Using the Artel PCS for Calibrations and Verifications	Face 2 Face	See document for details	
	QIS 27668: Calibrations using the Artel MVS ®	Face 2 Face	See document for details	
	QIS 24106: Verification of Timing Devices	Face 2 Face	See document for details	A
	Internal Auditor Training	Blended	1 month	A
	Understanding ISO 15189	Self Paced	1 hour	A
	Understanding ISO 17025	Self Paced	1 hour	
	Delivery of FSS Training and Assessment	Blended	2 months	A
	Operation of ELSA	Blended	2 weeks	
	Provision of Court Testimony	Blended	Part A +3 2 months / yearly	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010 - Appendix 3.2 - Competent - Laboratory Technician Learning Pathway
Re-Evaluation 1 Year

4 **Supervising Scientist - Quality & Projects Learning Pathway** **Name**

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	See document for details	
	Competent – Q&P Scientist - learning pathway QIS 31010 Appendix 4.1	Yearly	N/A	
	HSQ Delivered Panel Chair and Hiring Manager Training	Face 2 Face	1 hour	
	Delivery of FSS Training and Assessment	Blended	2 months	A
	Performance Practice Program	Virtual	3 days	A
	Managers Toolbox (not graded)	Self Paced	N/A	
	Career Success Plans	Self Paced	2 hours	
	Risk Management	Self Paced	30 minutes	
	RiskMan	Self Paced	30 minutes	
	WHS Incident Response and Investigations	Self Paced	30 minutes	
	Health and Safety Risk Assessments	Class Room	1 month	A
	QIS2 Basics	Self Paced	30 minutes	
	QIS2 Documents Advanced	Self Paced	30 minutes	
	QIS2 OQIs	Self Paced	30 minutes	
	QIS2 Professional Development	Self Paced	30 minutes	
	Understanding ISO 17025	Self Paced	1 hour	
	Internal Auditor Training	Blended	1 month	A
	QIS 28048: GeneMapper IDX Plate Reading	Face 2 Face	See document for details	A
	QIS 2 Document Administrator	Self Paced	2 hours	
	QIS 2 OQI Administrator	Self Paced	2 hours	
	QIS 2 Audit Administrator	Self Paced	2 hours	
	QIS 2 Calibration Administrator	Self Paced	2 hours	
	QIS 2 PAD Administrator	Self Paced	2 hours	
	QIS 2 Training Administrator	Self Paced	2 hours	
	QIS 2 Management Reports	Self Paced	30 minutes	

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010- Appendix 4 - Competent - Supervising Scientist - Quality & Projects Learning Pathway
Re-Evaluation 1 Year

4.1 Scientist - Quality & Projects Learning Pathway **Name**

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147_Forensic DNA Analysis Orientation & Induction checklist	Blended	See document for details	
	QIS 26048_GeneMapper IDX Plate Reading	Face 2 Face	See document for details	
	Understanding ISO 17025	Self Paced	1 hour	
	QIS2_Documents Advanced	Self Paced	30 minutes	
	QIS 2 Document Administrator	Self Paced	2 hours	
	Risk Management	Self Paced	30 minutes	
	RiskMan	Self Paced	30 minutes	
	Health and Safety Risk Assessments	Class Room	1 month	A
	Internal Auditor Training	Blended	1 month	A
	QIS 31476_STRMix	Face 2 Face	See document for details	A
	QIS 24276_Case Management	Face 2 Face	See document for details	A
	QIS 22858_Technical Review	Face 2 Face	See document for details	A, P
	Release of results	Self Paced	1 hour	
	Operation of ELSA	Blended	2 weeks	A
	Safe Handling Liquid Nitrogen	Blended	1 month	A
	Provision of Court Testimony	Blended	Part A +8.2 months / yearly	A

QIS 31010- Appendix 4.1 - Competent - Quality & Projects Scientist Learning Pathway
Re-Evaluation 1 Year

Shift + R will put a tick in Column A - this is useful to keep track of your training
You can add your completion date to the duration column to track your training also

4.2 Supervising Clinical Assistant Learning Pathway Name

	Training	Type	Duration
	FSS Orientation and induction	Blended	3 months
	QIS 17147 Forensic DNA Analysis Orientation & induction checklist	Blended	See document for details
	Competence – Appendix 4.3 Clinical Assistant Learning Pathway	Hands	N/A
	Delivery of FSS Training and Assessment	Blended	2 months
	SHAHANA Foundation	Self Paced	1 Hour
	SHAHANA Operational Procurement	Self Paced	1 Hour
	QIS2 Professional Development	Self Paced	30 minutes
	Career Success Plans	Self Paced	2 hours

Shift + R will put a tick in Column A - this is useful to keep track of your training
You can add your completion date to the duration column to track your training also

QIS 11010 - Appendix 4.2 - Competent - Unit - Supervising Clinical Assistant Learning Pathway
Re-Evaluation 1 Year

4.3 Clinical Assistant Learning Pathway

Name

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	3 days	
	QIS 17125: Processing of FTA Reference Samples	Face 2 Face	See document for details	
	QIS 27744: Examination of in vitro samples	Face 2 Face	See document for details	
	QIS 29735: Use of the STORStar unit for automated sequence checking	Face 2 Face	See document for details	
	QIS 29268: Forensic DNA Analysis Workflow Procedure	Face 2 Face	See document for details	
	Reliance Verifications	Blended	1 month	
	QIS 24106: Verification of Timing Devices	Face 2 Face	See document for details	
	QIS 32445: Using the Axtel PCS for Calibrations and Verifications	Face 2 Face	See document for details	
	Thermometer Data Logger Verification	Blended	1 month	
	Internal Auditor Training	Blended	1 month	
	Quantification of HLSA	Blended	2 weeks	
	Safe Handling Liquid Nitrogen	Blended	1 month	
	Mindfulness Awareness	Self Paced	30 minutes	
	Provision of Court Testimony	Blended	Part A + B 3 months / yearly	
	QIS 29345: GeneMapper IDX Plate Revising	Face 2 Face	See document for details	
	QIS 25984: Use of DNA Analysis Database Interface (DADI)	Face 2 Face	See document for details	
	QIS 28869: Miscellaneous Tasks for Laboratory Assistants	Face 2 Face	See document for details	
	QIS2 Bluejay	Self Paced	30 minutes	
	QIS2: Documents Advanced	Self Paced	30 minutes	
	QIS2: CQN	Self Paced	30 minutes	
	Internal Auditor Training	Blended	1 month	
	Health and Safety Risk Assessments	Class Room	1 month	
	Understanding ISO 17025	Self Paced	1 hour	
	Delivery of FSS Training and Assessment	Blended	3 months	
	RiskMan	Self Paced	30 minutes	

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also.

QIS 31030- Appendix 4.3 - Competent - Clinical Assistant Learning Pathway
Re-Evaluation 1 Year

5 Supervising Scientist - Analytical Learning Pathway

Name

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	2 months	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	See document for details	
	Competent – Analytical Scientist - learning pathway QIS 31010 Appendix 5.1	Yearly	N/A	
	QIS 31513: Reporting Scientist (MPS) - learning pathway Appendix 8.1	Face 2 Face (min every 5 years)	See document for details	A
	QIS 16996: CE Quality Check - AB 3130xl Genetic Analyser	Face 2 Face	See document for details	
	QIS 26349: GeneMapper IDX Plate Reading	Face 2 Face	See document for details	A
	HSQ Delivering Fitness Chair and Hiring Manager Training	Face 2 Face	1 hour	
	Delivery of FSS Training and Assessment	Blended	3 months	A
	Performance Practice Program	Virtual	3 days	A
	Managers Toolbox (to be created)	Self Paced	N/A	
	Career Success Plans	Self Paced	3 hours	
	Risk Management	Self Paced	30 minutes	
	RiskMan	Self Paced	30 minutes	
	OMS Incident Response and Investigations	Self Paced	30 minutes	
	Health and Safety Risk Assessments	Class Room	1 month	A
	QMS Basics	Self Paced	30 minutes	
	QMS2: Documents Advanced	Self Paced	30 minutes	
	QMS2: CAPA	Self Paced	30 minutes	
	QMS2: Professional Development	Self Paced	30 minutes	
	QMS 2 Management Reports	Self Paced	30 minutes	
	Understanding ISO 17025	Self Paced	1 hour	
	Internal Auditor Training	Blended	1 month	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010 - Appendix 5 - Competent - Supervising Scientist - Analytical Team Learning Pathway
Re-Evaluation 1 Year

5.1 Senior Scientist - Analytical Learning Pathway Name

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	See document for details	
	QIS 27668: Calibrations using the Artel MVS®	Face 2 Face	See document for details	
	QIS 29345: DNA Extraction using the Maxwell® Instrument	Face 2 Face	See document for details	
	QIS 23516: Concentration of DNA Extract using Microcon Centrifugal Filter Devices	Face 2 Face	See document for details	
	QIS 22866: Nucleospin Extraction	Face 2 Face	See document for details	
	QIS 31406: Quantification of Extracted DNA using Quantifiler Trio Quant Kit	Face 2 Face	See document for details	
	QIS 17210: STR PCR Amplification	Face 2 Face	See document for details	
	QIS 33445: Using the Artel PCS for Calibrations and Verifications	Face 2 Face	See document for details	
	QIS 34054: Mirrorkit STARlet and LabElite- integrated I.D. Capper	Face 2 Face	See document for details	
	QIS 33757: Operation and Maintenance of the QIAsymphony SP and AS	Face 2 Face	See document for details	
	QIS 33759: DNA Extraction and Quant of casework and reference samples using the QIAsymphony SP and AS SP and AS	Face 2 Face	See document for details	
	QIS 24053: Automated dilution & Automated Transport of Standards Operation	Face 2 Face	See document for details	
	QIS 32885: Operation and Maintenance of AB 3500 Series Genetic Analyser	Face 2 Face	See document for details	
	QIS 35901: Capillary Electrophoresis Setup	Face 2 Face	See document for details	
	QIS 15896: CE Quality Check of Samples from CE Genetic Analyzers	Face 2 Face	See document for details	
	QIS 26048: GeneMapper DX Plate Reading	Face 2 Face	See document for details	A
	QIS 22859: Technical Review	Face 2 Face	See document for details	A
	QIS 24076: Case Management	Face 2 Face	See document for details	A
	Health and Safety Risk Assessments	Class Room	1 month	A
	Release of results	Self Paced	1 hour	A
	Delivery of FSS Training and Assessment	Blended	2 months	A
	Understanding ISO 17025	Self Paced	1 hour	
	Balance Verifications	Blended	1 month	A
	Internal Auditor Training	Blended	1 month	A
	Pre-Advice of Court Testimony	Blended	Part A +B 2 months 1 yearly	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 33010 - Appendix 5.1- Competent - Senior Scientist Analytical Team Learning Pathway
Re-Evaluation 1 Year

5.2 Scientist - Analytical Learning Pathway

Name

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147: Forensic DNA Analysis Orientation & induction checklist	Blended	See document for details	
	QIS 26245: DNA Extraction using the Maxwell 16 instrument	Face 2 Face	See document for details	
	QIS 23916: Concentration of DNA Extract using Microcon Centrifugal Filter Devices	Face 2 Face	See document for details	
	QIS 22666: Nucleospin Extraction	Face 2 Face	See document for details	
	QIS 33406: Quantification of Extracted DNA using Quantifiler Trio Quant Kit	Face 2 Face	See document for details	
	QIS 17210: STR PCR Amplification	Face 2 Face	See document for details	
	QIS 34054: Microlab STARlet and LabElite Integrated I.D. Copper	Face 2 Face	See document for details	
	QIS 33757: Operation and Maintenance of the QIAsymphony SP and AS	Face 2 Face	See document for details	
	QIS 33759: DNA Extraction and Quant of casework and reference samples using the QIAsymphony SP and AS SP and AS	Face 2 Face	See document for details	
	QIS 24253: Automated dilution & Automated Testpoint of Standards Operation	Face 2 Face	See document for details	
	QIS 32681: Operation and Maintenance of AB 3500 Series Genetic Analyser	Face 2 Face	See document for details	
	QIS 35963: Capillary Electrophoresis Setup	Face 2 Face	See document for details	
	QIS 15996: CE Quality Check of Samples from CE Genetic Analysers	Face 2 Face	See document for details	
	QIS 26049: GeneMapper IDX Plate Reading	Face 2 Face	See document for details	A
	QIS 22658: Technical Review	Face 2 Face	See document for details	P
	QIS 24276: Case Management	Face 2 Face	See document for details	A
	Health and Safety Risk Assessments	Class Room	1 month	A
	Release of results	Self Paced	1 hour	A
	Delivery of FSS Training and Assessment	Blended	3 months	A
	Understanding ISO 17025	Self Paced	1 hour	
	Balance Verifications	Blended	1 month	A
	Internal Auditor Training	Blended	1 month	A
	Provision of Court Testimony	Blended	Part A +0-2 events / yearly	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 33030 - Appendix 5.2 - Competent - Scientist Analytical Team Learning Pathway
Re-Evaluation 1 Year

QIS 17147: Forensic DNA Analysis Orientation & Induction checklist
QIS 25112: Risk Assessment Basic
QIS 25745: Use of the STORStar unit for automated sequence checking
QIS 33757: Operation and Maintenance of the QIAsymphony SP and AS
QIS 35608: Capillary Electrophoresis Setup
QIS 15599: Operation and Maintenance of AB 3130xl Genetic Analyser
QIS 15996: CE Quality Check - ABI 3130xl Genetic Analyser
QIS 27772: Delivery of FSS Training and Assessment
Understanding ISO 15189
Understanding ISO 17025
QIS 23916: Conc. Of DNA Extract using Microcon
QIS 27668: Calibrations using the Artel MVS
QIS 26945: DNA IQ Extraction using the Maxwell 16
QIS 22666: Nucleospin Extraction Calibrations
QIS 33406: Quantification of Extracted DNA using Quantifiler Trio Quant Kit
QIS 17210: STR PCR Amplification
QIS 34054: Microlab STARlet and LabElite Integrated I.D. Copper
QIS 33757: Operation and Maintenance of the QIAsymphony SP and AS
QIS 33759: DNA Extraction and Quantification of casework and reference samples using the QIAsymphony SP and AS SP and AS
QIS 24253: Automated dilution & Automated Testpoint of Standards Operation
QIS 16689: Requirements for Releasing Results
QIS 26049: GeneMapper IDX Plate Reading
QIS 24276: Case Management Nucleospin
QIS 24743: Internal Auditor Training
QIS 20025: Balance Verification
QIS 33758: Forensic Register Fundamentals
QIS 34259: Forensic Register Case File
QIS 23758: Moot CourtCourt Provision of Court Evidence (Main)
QIS 23668: Intro to QUD Court System
QIS 33010: Competence - Analytical Section Scientist - learning pathway

6 Supervising Scientist - Reporting Learning Pathway

Name

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	See document for details	
	Competent – Reporting Scientist - training pathway QIS 31210 Appendix 6.1	Yearly	N/A	
	HSQ Delivered Panel Chair and Hiring Manager Training	Face 2 Face	1 hour	
	Delivery of FSS Training and Assessment	Blended	3 months	A
	Performance Practice Program	Virtual	3 days	A
	Managers Toolbox (exit gradeg)	Self Paced	N/A	
	Career Success Plans	Self Paced	2 hours	
	Risk Management	Self Paced	30 minutes	
	RiskMan	Self Paced	30 minutes	
	WHS: Incident Response and Investigations	Self Paced	30 minutes	
	Health and Safety Risk Assessments	Class Room	1 month	A
	QIS2 Basics	Self Paced	30 minutes	
	QIS2: Documents Advanced	Self Paced	30 minutes	
	QIS2: CQIs	Self Paced	30 minutes	
	QIS2: Professional Development	Self Paced	30 minutes	
	QIS 2 Management Reports	Self Paced	30 minutes	
	Understanding ISO 17025	Self Paced	1 hour	
	Internal Auditor Training	Blended	1 month	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010 - Appendix 6 - Competent - Supervising Scientist Reporting Team Learning Pathway
Re-Evaluation 1 Year

6.1 Reporting Scientist -Reporting Learning Pathway

Name

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	See document for details	
	QIS 26248: GeneMapper IDX Plate Reading	Face 2 Face	See document for details	A
	QIS 28078: Evidence Recovery for Reporting Scientists	Face 2 Face	See document for details	
	QIS 28078: Analytical Processes for Reporting Scientists	Face 2 Face	See document for details	
	QIS 28080: Intelligence Processes for Reporting Scientists	Face 2 Face	See document for details	
	QIS 24276: Case Management	Face 2 Face	See document for details	
	Release of results	Self Paced	1 hour	
	QIS 31479: STR Mix	Face 2 Face	See document for details	
	QIS 28182: DNA Statement Writing	Face 2 Face	See document for details	
	QIS 24264: Basics of DNA Profile Interpretation	Face 2 Face	See document for details	
	QIS 26287: Body Fluid, Trace and Opinion Evidence Provision in Forensic DNA Analysis	Face 2 Face	See document for details	
	QIS 25321: Kinship	Face 2 Face	See document for details	A
	QIS 25584: DADI	Face 2 Face	See document for details	A
	QIS 32454: Reference Sample Profile Management	Face 2 Face	See document for details	
	QIS 22658: Technical Review	Face 2 Face	See document for details	
	QIS 23622: Selection & Prep of Bone and Tooth for DNA Testing	Face 2 Face	See document for details	A
	QIS 32555: DVI and Concealed Casework for Reporting Scientists	Face 2 Face	See document for details	A
	QIS 25580: Paired Kinship & Paternity Trio / Missing Child in Kinship	Face 2 Face	See document for details	A
	QIS 9029: Paternity and Paired Kinship Statistics	Face 2 Face	See document for details	A
	Operation of ELSA	Blended	2 weeks	A
	Safe Handling Liquid Nitrogen	Blended	1 month	A
	Health and Safety Risk Assessments	Class Room	1 month	A
	Delivery of FSS Training and Assessment	Blended	3 months	A
	Provision of Court Testimony	Blended	Part A +0.5 months /yearly	
	Internal Auditor Training	Blended	1 month	A
	Understanding ISO 17025	Self Paced	1 hour	

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 33100 - Appendix 6.1 - Competent - Reporting Scientist Learning Pathway
Re-Evaluation 1 Year

Understanding ISO 15189
Understanding ISO 17025
QIS 17147: Forensic DNA Analysis Orientation & Induction checklist
QIS 23758: Moot Court/Court Provision of Court Evidence (Exam)
QIS 28549: Intro to QLD Court System
QIS 27772: Delivery of FSS Training and Assessmnet
QIS 29112: Risk Assessment Basic
Risk Management
RiskMan
QIS 26742: Internal Auditor Training
QIS 26248: GeneMapper IDX Plate Reading
QIS 33758: Forensic Register Fundamentals
QIS 34258: Forensic Register Case File
QIS 28078: Evidence Recovery for Reporting Scientists
QIS 28078: Analytical Processes for Reporting Scientists
QIS 28080: Intelligence Processes for Reporting Scientists
QIS 11729: Report Writing and Examination of Plan
QIS 24276: Case Management
QIS 30859: Requirements for Reporting Results
QIS 31479: STR Mix
QIS 28182: DNA Statement Writing
QIS 24264: DNA Statistics
QIS 25321: Kinship
QIS 25584: DADI
QIS 32454: Reference Sample Profile Management
QIS: Requirement for ngm-MF (Using ngm Licensing Specification Limitations to ISO Level 3 SWG Guidelines)
QIS 22658: Technical Review
QIS 22958: Technical Review
QIS 23622: Selection & Prep of Bone and Tooth for DNA Testing
QIS 32555: DVI and Concealed Casework for Reporting Scientists
QIS 25580: Paired Kinship & Paternity Trio / Missing Child in Kinship
QIS 9029: Paternity and Paired Kinship Statistics
QIS 29679: Handling Liquid Nitrogen
Dangerous Goods Packaging - Infectious Substances
QIS 34249: Mortuary Awareness (QIS 30370)
QIS 30370: ELSA Operation
QIS 33010: Competence - Reporting Scientist- learning pathway

7 Supervising Scientist - Intelligence Learning Pathway

Name

	Training	Type	Duration	
	FSS Orientation and Induction	Blended	3 months	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	Blended	See document for details	
	Competent – Reporting Scientist - learning pathway QIS 31010 Appendix 7.1	Yearly	N/A	
	QIS 28048: GeneMapper IDX Plate Reading	Face 2 Face	See document for details	A
	HSQ Delivered Panel Chair and Hiring Manager Training	Face 2 Face	1 hour	
	Delivery of FSS Training and Assessment	Blended	2 months	A
	Performance Practice Program	Virtual	3 days	A
	Managers Toolbox (not graded)	Self Paced	N/A	
	Career Success Plans	Self Paced	2 hours	
	Risk Management	Self Paced	30 minutes	
	RiskMan	Self Paced	30 minutes	
	WHS Incident Response and Investigations	Self Paced	30 minutes	
	Health and Safety Risk Assessments	Class Room	1 month	A
	QIS2 Basics	Self Paced	30 minutes	
	QIS2 Documents Advanced	Self Paced	30 minutes	
	QIS2 OQIs	Self Paced	30 minutes	
	QIS2 Professional Development	Self Paced	30 minutes	
	QIS 2 Management Reports	Self Paced	30 minutes	
	Understanding ISO 17025	Self Paced	1 hour	
	Internal Auditor Training	Blended	1 month	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010 - Appendix 7- Competent - Supervising Scientist Intelligence Team Learning Pathway
Re-Evaluation 1 Year

7.1 Scientist - Intelligence Learning Pathway **Name**

	Training	Type	Duration	
	FSS Orientation and Induction	*Blended*	*3 months*	
	QIS 17147: Forensic DNA Analysis Orientation & Induction checklist	*Blended*	*See document for details*	
	QIS 26048: GeneMapper IDX Plate Reading	*Face 2 Face*	*See document for details*	A
	QIS 23839: Uploading Profiles to NCIDD, Creating & Reviewing Links	*Face 2 Face*	*See document for details*	
	QIS 25584: Use of the DNA Analysis Database Interface	*Face 2 Face*	*See document for details*	
	QIS 35148: Destruction of FTA Reference Samples	*Face 2 Face*	*See document for details*	
	QIS 24276: Case Management	*Face 2 Face*	*See document for details*	P
	QIS 32618: STRmix Data Entry for Case Management	*Face 2 Face*	*See document for details*	A
	QIS 22858: Technical Review	*Face 2 Face*	*See document for details*	P
	QIS 31476: STR Mix	*Face 2 Face*	*See document for details*	A
	QIS 35254: Reference Sample Profile Management	*Face 2 Face*	*See document for details*	
	Release of results	*Self Paced*	*1 hour*	
	Delivery of FSS Training and Assessment	*Blended*	*2 months*	A
	Provision of Court Testimony	*Blended*	*Part A +6 2 months / yearly*	A
	Internal Auditor Training	*Blended*	*1 month*	A
	Understanding ISO 17025	*Self Paced*	*1 hour*	
	Health and Safety Risk Assessments	*Class Room*	*1 month*	A

Shift + R will put a tick in Column A - this is useful to keep track of your training

You can add your completion date to the duration column to track your training also

QIS 31010- Appendix 7.1 - Competent - Scientist Intelligence Team Learning Pathway
Re-Evaluation 1 Year

Record of Re-evaluation

This record of re-evaluation is to be completed in conjunction with CSP and stored in the employee's training portfolio. If the employee is cross-trained or trained in on-call, they are to discuss their re-evaluation with the relevant trainer or Line Manager prior to the completion of this form.

Employee Name:

Learning pathway(s) re-evaluated: (specify role name and or appendix number)

Re-evaluation criteria is evaluated by relevant team leader and may require a combination of criteria as determined by the team leader. Re-evaluation expectations should be discussed with all relevant team leaders prior to CSP.

Training Module / Rolepathway Appendix	Original Competency Sign off date	Date of Re-evaluation	Name of Line Manager Authorising Re-Evaluation	Criteria

Criteria Examples - add / Remove as necessary

1 - Perform work continuously
2 - Participation in QAP's / Proficiency Testing
3 - Participate on roster (including weekends)
4 - Re-read SOP's and record versions
5 - Quality management (audits, SOP, TM, validation/verification)
8 - Inhouse mools

CA-42

Queensland Health
Forensic and Scientific Services

Competency statement

Name	
Statement Type	Recognition of Current Competence (RCC) - recognise the current competence of staff where competency was achieved prior to training modules being developed and / or Competent to Train (CTT) authorise a staff to train and assess using the competency based training and assessment framework or Re-evaluation of competence - Re-evaluate current competency as part of the PDP process
For	Learning Pathway – Training Module -

Associated Knowledge Skills and Abilities	DETAILS OF SUPPORTING EVIDENCE
☐ Experience in the area	*<For Example, Commenced Activity/Employment on DATE and # of years working in area)*
☐ Participation in Proficiency Testing Program or Blind Trial	*<For Example, Proficiency Program or Blind Trial Identifier, Role of involvement, RESULT, Date>*
☐ Author, Co-Author or Contributor to Standard Operating Procedure	*<For Example, Co-Author of SOP 12345, TITLE, Date>*
☐ Author, Co-Author or Contributor to Training Module	*<For Example, Author of Training Module 12346, TITLE, Date>*
☐ Involvement in Validation or Method Development Activities	*<For Example, Reviewing Officer, Validation Documentation, METHOD/INSTRUMENT, Date>*
☐ Train the Trainer ☐ Delivery of a workplace skill QIS 27771 ☐ Cert IV in Training and assessment	*<<Enter Dates completed or attach QIS PD entry>>* *<<Attach verified copy of Qualification*
☐ Lecturer or Tutor at Tertiary Institution	*<e.g, guest lecturer, SUBJECT, University, Date>*
☐ Participation in Quality Assurance Activities	*<For Example, Activity & Involvement, DATE>*
☐ Involvement in Client Advisory Activities	*<For Example, on Advisory Board for XYZ Legislation, DATE>*
☐ Performance meets or exceeds work unit expectations for area of work	*<For Example, have observed processes, have obtained personal accounts from third parties – peers, supervisors, DATE>*
☐ Court Evidence	*<For Example, As at DATE, case identifiers for X records or detail where to find this information, and or number of cases >*
☐ OTHER (as detailed)	*<Add Details>*

The above supporting evidence is appended to this document:

Authorisation by Line Manager

I ..... recognise that .....
(Line Manager or Delegate) (Trainee)

has the current competence to perform work and or deliver training & assessment.

having the required knowledge, skills and abilities associated with the above Training Module or Learning Pathway

The reason for my recommendation is:

☐ The staff member provided adequate evidence of competence.

Further comments if required:

.....

.....

.....

Line Manager signature & date ..../...../ 20...

Acknowledged by Trainee

Name: Signature: Date completed:

Reviewed by Department / SSDU Training Coordinator

Name: Signature: Date completed:

☐ Entered in QIS² as Competent, Competent to Train or Competency Renewal.

Human Resources Policy

Health practitioners and dental officers – Professional development allowance and leave

Policy Number: C42 (QH-POL-146)

Publication date: June 2020

Purpose: To outline entitlements and processes for the professional development allowance and professional development leave as outlined in clauses 31 and 32 of the Health Practitioners and Dental Officers (Queensland Health) Certified Agreement (No. 2) 2016.

Application: This policy applies to all Queensland Health permanent and eligible temporary health practitioners and dental officers, who work 15.2 hours or more per fortnight.

Delegation: The 'delegate' is as listed in the relevant Department of Health Human Resource (HR) Delegations Manual, or Hospital and Health Services Human Resource (HR) Delegations Manual, as amended from time to time.

Legislative or other authority:

- Health Practitioners and Dental Officers (Queensland Health) Award – State 2015
- Health Practitioners and Dental Officers (Queensland Health) Certified Agreement (No.2) 2016

Related policy or documents:

- Self-education – FBT fact sheet
- Aggregate and concurrent HR Policy C47 (QH-POL-301)
- Employee complaints HR Policy E12 (QH-POL-140)

Policy subject:

1 Policy

Queensland Health expects all health practitioner (HP) and dental officer (DO) employees to use their professional development allowance for professional development.

Approval for further professional development funding and leave is at the line manager's discretion and is dependent on proof of expenditure of the employee's professional development allowance on approved professional development activities.

1.1 Professional development allowance

From 14 September 2015, temporary employees with greater than 12 month's continuous service are eligible for the professional development allowance (PDA).

All eligible permanent and temporary employees are entitled to the PDA as follows:

Category	From 17/10/2017	From 17/10/2018
Category A	$2,208	$2,263
Category B	$2,760	$2,829
All other employees	$1,655	$1,696

Attachment Two details the allowances paid at each facility.

The allowance is paid fortnightly through the payroll system and taxed as part of gross income. Payment is made during periods of paid leave, but is not to be included when calculating leave loading, penalty rates or overtime.

Eligible part-time employees working at least 15.2 hours per fortnight are entitled to PDA on a pro rata basis.

It is envisaged that employees will fully expend the allowance in the derivation of income and as such, employees may be able to claim an income tax deduction for eligible self-education expenses they incur using the PDA. Employees are to seek independent financial advice regarding their personal taxation.

The PDA is not included in superannuable salary or in ordinary time earnings (OTE).

1.2 Paid professional development leave entitlement

Paid professional development leave (PDL) is conferred in addition to current entitlements, assistance or Queensland Health obligations as contained in various policies such as conference leave, SARAS and other Queensland Health learning and development initiatives.

From 1 September 2007, permanent employees accrue PDL hours each fortnight at a rate that after one full year of employment, an employee will have accrued three days.

From 14 September 2015, the following temporary employees are eligible for PDL:

- employees with greater than 12 month's continuous service

- employees with greater than six months continuous service provided a performance plan is in place for that employee to support professional development activities with the employer to meet reasonable professional development activity costs.

Eligible part-time employees working at least 15.2 hours per fortnight accrue PDL on a pro rata basis.

The PDL is paid at the ordinary rate of pay.

Any component of the PDL entitlement not accessed after two years is forgone. The leave component is not cashable.

When an employee moves temporarily to a classification stream other than the HP or DO stream, their entitlement will be held in reserve in accordance with this policy for a two year period. Such employees will not accrue nor have access to PDL entitlement until they return to their respective HP or DO stream.

When an employee is permanently appointed to a non-HP or DO classification stream, they forego any accrued PDL.

1.3 Part-time employees

Eligible part-time employees working a minimum of 15.2 hours per fortnight have their PDA and PDL entitlement calculated on a pro rata basis.

The calculation of the proportionate entitlement is based on actual ordinary hours worked, including paid leave, as a proportion of full-time hours.

For example, on 17 October 2017, a non-category A or B HP or DO employee, who works two days per week (30.4 hours per fortnight), has their entitlement calculated on the following basis:

- PDA – 30.4/76 of $1,655 = $662 per annum, i.e. $25.37 per fortnight.

History:

June 2020	• Policy: – formatted as part of the HR Policy review – amended to update naming conventions – application amended as a result of changes to the Hospital and Health Boards (Changes to Prescribed Services) Amendment Regulation 2019 – amended to replace aggregate and concurrent criteria with reference to the Aggregate and concurrent HR Policy C47 (Attachment One, section 5).
October 2018	• Policy formatted as part of the HR Policy review • Policy amended to: – update references and naming conventions – incorporate provisions for eligible temporary employees – include aggregate and concurrent arrangements.
April 2014	• Policy reviewed as part of the Queensland Ambulance Service (QAS) HR Policy Integration project • Policy not applicable to QAS employees.
February 2014	• Policy formatted as part of the HR Policy Simplification project. • Policy amended to update references and naming conventions.

April 2010	• Policy amended so section 5 References to reflect Self Education – FBT Fact Sheet • Attachment one amended to correctly reflect districts and facilities.
November 2008	• Developed as a result of the implementation of the Health Practitioners (Queensland Health) Certified Agreement (No.1) 2007.

Attachment One – Appropriate use and management of professional development allowance and leave

The following information is provided as the minimum mandatory standard practice, procedure or process to enable satisfactory compliance with this Queensland Health HR policy.

Local guidelines/procedures may be developed to facilitate implementation of this policy. Any local guidelines/procedures must be consistent with this policy and standard practice and ensure employee entitlements continue to be met.

Examples of relevant professional development activities include but are not limited to:

- study support additional to that provided under SARAS
- higher education courses or tuition fees
- expenses incurred for conferences, seminars, workshops or forums
- items to support study relevant to clinical practice, e.g. text books
- short courses
- professional association professional development events and membership fees
- professional library membership
- reasonable travel and accommodation costs associated with professional development attendance.

The use of PDA is not suitable for:

- payment of registration fees with the Australian Health Practitioner Regulation Authority (AHPRA)
- attendance at Queensland Health mandatory training
- competency attainment
- activities for industrial relations education leave.

1 Management of professional development allowance

Managers use the performance and development (PAD) process to plan appropriate professional development requirements and opportunities in consultation with the health practitioner (HP) or dental officer (DO).

Queensland Health provides the PDA specifically for employees to use for professional development activities. It is recommended that HPs/DOs and line managers document and review a summary of this expenditure on an annual basis. Managers are encouraged to undertake this review.

Evidence of professional development expenditure within the previous 12 months (to an amount equivalent to the employee's PDA) is to be provided by the employee when requesting additional departmental funding for professional development purposes (refer Attachment Three).

2 Management of professional development leave

Professional development leave (PDL) is an entitlement, and while having regard for the maintenance of service provision, line managers are not to unreasonably refuse employee access to PDL.

Leave may be taken on an hourly basis subject to agreement.

All reasonable travel time associated with accessing the PDL is treated as paid work time (rostered hours) on the basis of no more than eight hours at the ordinary rate for each day of travel.

When an employee takes PDL at a time which falls outside of ordinary hours, on a weekend, or at a time that would normally attract a shift allowance, the payment for leave is at single time and does not attract overtime, penalty rates or shift allowance. Managers and employees need to plan PDL to ensure the entitlement is taken and paid at ordinary rate of pay only. There is no entitlement for PDL to be paid at any rate other than single time.

3 Accrual

Employees accrue hours each fortnight, so after one full year of employment an employee will have three days (pro rata for part-time) accrued. The leave entitlement is accrued over a 24 month period, commencing from either 1 September 2007 for existing employees, or the start date for employees who commence after 1 September 2007.

The leave component of the entitlement accrues during periods of permanent full-time and permanent part-time employment and paid leave in the HP/DO streams, as well as the following temporary arrangements:

- temporary employees with greater than 12 months continuous service
- temporary employees with greater than six months continuous service provided a performance plan is in place for that employee.

Employees do not accrue the entitlement during periods of unpaid leave, including proportionate leave (i.e. the purchased leave period).

During periods of half pay leave, PDL accrues at the normal rate, i.e. employees accrue the full entitlement rather than accrue half the entitlement.

In order to allow employees to use their leave entitlements from the date of commencement, employees are allowed to have a negative balance of no more than 24 hours (or a projection of 12 hours for a part-time employee). At the end of the year (i.e. either 1 September or anniversary date) employees are expected to have a nil or positive balance. If an employee has a negative balance at the anniversary date, the leave taken in the upcoming year is adjusted accordingly.

Line managers are to be mindful of the hours an employee is working when approving professional development activities to minimise the risk of employees accruing a large negative leave balance.

4 Travel

All reasonable travel time (as approved) associated with accessing PDL is treated as paid work time on the basis of no more than eight hours single time for each day of travel.

When a HP/DO travels at a time which falls outside of the ordinary hours, on a weekend or at a time that would normally attract a shift allowance, the payment for travel is at the ordinary rate of pay, and does not attract overtime, penalty rates or shift allowance. This also applies when an employee would have been ordinarily rostered to work at that time.

When a HP/DO uses their professional development entitlements, they are not bound by the Queensland Health travel policy. This enables freedom of choice and cost minimisation to HP/DOs, therefore:

- travel bookings cannot be made through the Queensland Health travel hub service for any travel associated with professional development
- HP/DOs are required to book and pay for any travel or accommodation costs themselves
- costs associated with travel, accommodation cancellation or changes are the responsibility of the HP/DO

- travel insurance is the responsibility of the HP/DO and travel is not covered under the Queensland Health insurance arrangements
- approval for overseas travel claimed and pre-approved as PDL does not require any existing permission process.

The employee's line manager determines and approves reasonable travel time. Reasonable travel time constitutes the amount of time spent in transit including time travelling to and from airports, as well as the most economical and practical route to and from an activity (event).

5 Aggregate and concurrent arrangements

Employees working in multiple positions may be engaged in an aggregate or a concurrent employment arrangement. Refer Aggregate and concurrent HR Policy C47.

The professional development package is treated differently subject to the specific employment arrangements, and classification streams.

Engagements are to be considered collectively for the purpose of determining the appropriate employment conditions for each engagement.

Employees engaged in an **aggregate** employment arrangement are assigned a singular Employee ID number that is used to identify them as a Queensland Health employee. As such, any eligible HP or DO will accrue PDL as a singular balance, and paid PDA on a singular employee ID. Eligible employees on higher duties will continue to accrue PDA and PDL.

As the employee has one combined balance, a temporary eligible employee engaged in multiple temporary engagements of the same stream, will accrue PDA and PDL from the initial eligible temporary engagement, and continue to be eligible to receive the professional development package for the multiple engagements subject to continuous engagement.

Communication between line managers of HP or DO employees engaged in aggregate arrangements are strongly recommended to ensure appropriate monitoring and management of entitlements.

Employees engaged in a **concurrent** employment arrangement are assigned a singular Employee ID number that is used to identify them as a Queensland Health employee; however, they will also be assigned an additional personnel assignment number (PAN) that will be used to identify and link them to each of their individual engagements. As such, any eligible HP or DO will accrue PDL as multiple and separate balances, and paid PDA on each PAN. Eligible employees on higher duties will continue to accrue PDA and PDL.

In the event a temporary eligible employee is engaged in multiple temporary engagements of the same stream, PDA and PDL will accrue from the initial eligible temporary engagement, and continue to be eligible to receive the professional development package for the multiple temporary engagements subject to continuous engagement.

6 Grievance process

Normal grievance procedures apply to this policy. For further information please refer to Employee complaints HR Policy E12.

Attachment Two – Categories for health practitioner and dental officer professional development allowance

Hospital and Health Service	Facility		
	Non category A and B	**Category A**	**Category B**
Cairns and Hinterland	• Cairns • Gordonvale • Ravenshoe • Yarrabah	• Atherton • Babinda • Herberton • Innisfail • Malanda • Mareeba • Millaa Millaa • Douglas Shire (Mossman) • Tully	• Chillagoe • Croydon • Dimbulah • Forsayth • Georgetown • Mt Garnet
Central Queensland	• Duaringa • Gladstone • Mt Morgan • Ogmore • Rockhampton • Yeppoon	• Baralaba • Biloela • Blackwater • Capella • Cracow • Dingo • Emerald • Gemfields • Moura • Springsure • Theodore • Woorabinda	
Central West			• Alpha • Aramac • Barcaldine • Blackall • Boulia • Isisford • Jundah • Longreach • Muttaburra • Tambo • Windorah • Winton
Children's Health Queensland	• Queensland Children's Hospital		

Hospital and Health Service	Facility		
	Non category A and B	Category A	Category B
Darling Downs	• Oakey • Toowoomba	• Cherbourg • Chinchilla • Dalby • Glenmorgan • Goondiwindi • Inglewood • Jandowae • Kingaroy • Meandarra • Miles • Millmerran • Moonie • Murgon • Nanango • Stanthorpe • Tara • Taroom • Texas • Wandoan • Warwick • Wondai	
Gold Coast	• Gold Coast • Robina		
Mackay	• Mackay • Marlborough • Sarina • St Lawrence	• Bowen • Clermont • Collinsville • Dysart • Moranbah • Proserpine	
Metro North	• Caboolture • Kilcoy • RBWH • Redcliffe • Prince Charles		
Metro South	• Beaudesert • Dunwich • Logan • Princess Alexandra • Queen Elizabeth II • Redland • Wynnum		

Hospital and Health Service	Facility		
	Non category A and B	Category A	Category B
North West			• Mt Isa • Burketown • Camooweal • Cloncurry • Dajarra • Doomadgee • Julia Creek • Karumba • Mornington Island • Normanton
South West		• Bollon • Dirranbandi • Injune • Mitchell • Mungundi • Roma • St George • Surat • Wallumbilla	• Augathella • Charleville • Cunnamulla • Morven • Quilpie • Thargomindah
Sunshine Coast	• Caloundra • Gympie • Maleny • Nambour		
Torres and Cape		• Cooktown	• Aurukun • Bamaga • Coen • Hopevale • Kowanyama • Laura • Lockhart River • Mapoon • Pormpuraaw • Thursday Island • Weipa • Wujal Wujal
Townsville	• Magnetic Island • Townsville	• Ayr • Charters Towers • Home Hill • Ingham	• Hughenden • Richmond • Palm Island
West Moreton	• Boonah • Esk • Gatton • Ipswich • Laidley		

Hospital and Health Service	Facility		
	Non category A and B	Category A	Category B
Wide Bay	• Bundaberg • Childers • Gin Gin • Hervey Bay • Maryborough • Mount Perry	• Biggenden • Eidsvold • Gayndah • Monto • Mundubbera	

Attachment Three – Record of professional development activities

Health practitioners and dental officers are encouraged to complete this activity record on an annual/regular basis, and this is to accompany the employee's performance and development (PAD) plan.

Activity undertaken	**Provider of activity**	**Learning outcome**	**Costs associated (employee/Queensland Health)**
Examples: seminars, conferences, short courses, workshops, tertiary training, professional membership fees	**Examples:** training provider, university, name of professional organisation	**Examples:** enhancement of current skill set, higher qualifications	**Examples:** costs met by employee, costs met by work unit

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Instrument, Equipment & Software List – Forensic DNA Analysis 2022

Instruments

Instrument	Purpose	Implementation	Responsible Person	Position
Maxwell 16	DNA Extraction – Priority 3 Blood swabs	22/08/2011	Allan McNevin	Senior Scientist – Analytical Team
	DNA Extraction – Tapelifts and Priority 1 swabs.	14/09/2011	Allan McNevin	Senior Scientist – Analytical Team
	DNA Extraction – Fabrics, scrapings, cigarette butts, paper, FTA and chewing gum	26/09/2011	Allan McNevin	Senior Scientist – Analytical Team
	DNA Extraction – fingernail and hair	16/01/2012	Allan McNevin	Senior Scientist – Analytical Team
	DNA Extraction – Differential Lysis	27/02/2012	Allan McNevin	Senior Scientist – Analytical Team
	DNA Extraction - tissue	28/08/2013	Allan McNevin	Senior Scientist – Analytical Team
	DNA Extraction – Retain Supernatant	13/06/2018	Luke Ryan	Senior Scientist – Analytical Team
Maxwell FSC	DNA Extraction	19/06/2020	Luke Ryan	Senior Scientist – Analytical Team
BSD Ascent	FTA card sampling	16/11/2020	Kirsten Scott	Senior Scientist – Quality & Projects
Artel MVS and PCS	Enable verification of POVAs and pipetting robotics	MVS 2009 PCS 2013 Retrospectively validated in 2016.	Kirsten Scott	Senior scientist – Quality & Projects
QIAsymphony SP/AS	SP Module - DNA Extraction	21/11/2016	Luke Ryan	Senior Scientist – Analytical Team
	AS Module -Quantification assay preparation	10/07/2017	Luke Ryan	Senior Scientist – Analytical Team

	SP Module – Bone extraction	13/04/2018	Luke Ryan	Senior Scientist – Analytical Team
	SP Module – Teeth extraction	20/10/2020	Luke Ryan	Senior Scientist – Analytical Team
ID STARlet	PCR and Quantification preparation	17/01/2017	Luke Ryan	Senior Scientist – Analytical Team
ID STARlet	Capillary electrophoresis setup	20/05/2019	Luke Ryan	Senior Scientist – Analytical Team
QuantStudio 5	DNA quantification	15/02/2019	Luke Ryan	Senior Scientist – Analytical Team
Proflex (6 x instruments)	PCR amplification	10/01/2022	Luke Ryan	Senior Scientist – Analytical Team
3500xL	Capillary Electrophoresis – Reference FTA direct amplification (PowerPlex 21)	04/03/2015	Luke Ryan	Senior Scientist – Analytical Team
	Capillary Electrophoresis – Extracted reference samples (PowerPlex 21)	07/07/2015	Luke Ryan	Senior Scientist – Analytical Team
	Capillary Electrophoresis – Casework samples (PowerPlex 21)	15/02/2021	Luke Ryan	Senior Scientist – Analytical Team

Equipment

Equipment	Purpose	Implementation	Position responsible
Storstar	Batch preparation/sequence checking	June 2008	Managing Scientist – Forensic Biology
Thermomixer	Heating and agitating during DNA Extraction	21/11/2016	Senior Scientist – Analytical Team
Tube and Plate Centrifuges	Spinning samples tubes and plates during DNA extraction, quantification assay setup, PCR setup, and Capillary Electrophoresis plate setup.	Various	Senior Scientist – Analytical Team
Microscopes	Microscopic identification of spermatozoa	Various	Senior Scientist – Evidence Recovery Team

Vortexes	Vortexing sample tubes, reagent tubes for DNA extraction, quantification assay setup, PCR setup, and Capillary Electrophoresis plate setup.	Various	Senior Scientist – Analytical Team
Pipettes/POVAs (Piston Operated Volumetric Apparatus)	Pipetting samples and reagents for DNA extraction, quantification assay setup, PCR setup, and Capillary Electrophoresis plate setup.	Various	Senior Scientist – Analytical Team

Software

Software	Purpose	Implementation	Responsible Person	Position
STRmix	Statistical interpretation of DNA results	03/02/2012	Emma Caunt & Rhys Parry	Reporting Scientists
Data Collection Software v4	3500xL operating system	21/06/2021	Luke Ryan	Senior Scientist – Analytical
VENUS	ID STARlet operating system	17/01/2017	Luke Ryan	Senior Scientist – Analytical Team
Forensic Register	Laboratory Information Management System	15/06/2017	Cathie Allen	Managing Scientist – Police Services Stream
Genemapper	Analysis of Capillary Electrophoresis results	16/02/2009	Thomas Nurthen	Senior Scientist – Quality
Overlord	Storstar operating system	13/02/2007	Vanessa Ientile	Managing Scientist – Forensic Biology

Software used for historical cases only (not in routine use)

Software	Purpose
Popstats	A Statistical program used to determine a likelihood ratio using two different hypotheses (defence and prosecution). Used where mixtures cannot be divided into major or minor components. Can also be used to condition on a known contributor.
Genotyper	ABI software used to read results generated on the 3100/3130.

AUSLAB	Former Laboratory Information Management System (2003-2007).
DADI	The Forensic DNA Analysis Database Interface is used to maintain the data stored within the Forensic DNA Analysis Database (DAD) and to provide results management functions.

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ASSESSMENT INFORMATION DOCUMENT

Your facility is due for a reassessment.

This Assessment Information Document seeks specific background information from facilities on the current scope of NATA accreditation, any changes required, and the specific resources available to meet the requested changes.

Some sections may not apply to your facility. Please cross-reference relevant sections from your management system documentation where appropriate.

Please upload a completed copy of this Assessment Information Document and required documents/records as detailed in covering letter to the NATA Portal or email to:

Ms Madelen Chikhani at [redacted]
By: **09 April 2022**

Delays or failure to provide the requested information may result in delays to the accreditation process.

The personal information collected in this document and other management system documentation supplied for the assessment briefing is used for conducting the assessment, reporting on the assessment and the process of continuing accreditation. It may be disclosed to NATA staff members, all of whom have signed confidentiality agreements. Aggregated data gathered from the assessment process may also be provided to third parties in a de-identified format. It may also be disclosed to agencies to which NATA has a legal obligation or with which NATA has formal agreement.

Personal information collected such as name, business telephone and mobile phone numbers and email address of the Authorised Representative or the Site Contact may be made available to enquiries requiring the service of NATA accredited facilities. The Site Contact details may be included in the NATA website directory.

NATA's Privacy Policy contains information on access and correction to the personal information held by NATA and the compliant process associated with breaches of the Australian Privacy Principles. NATA's Privacy Policy is available from the NATA website, www.nata.com.au.

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

FACILITY DETAILS

In preparation for the accreditation activity, please review the information below to confirm (or change) the details of your facility and the site to be assessed. Use the shaded boxes to provide corrected or changed details.

FACILITY (the name in which accreditation is held)	
Accreditation No: 41	
Facility Name: Queensland Health Forensic and Scientific Services	
Facility Trading Name (see note 1):	
ABN or ACN: 66-329-169-412	
Mailing Address: [redacted]	
Street address (if different from above): [redacted]	
Facility web address (optional): www.health.qld.gov.au	
Phone: [redacted]	
INVOICING DETAILS (for all sites under your facility)	
Mailing address: [redacted]	
Phone: [redacted]	
Email: [redacted]	

The following details are specific to your Facility's Authorised Representative.

(The rights and responsibilities of the Authorised Representative are outlined in the *General Accreditation Criteria: Responsibilities of authorised representatives*, available on the NATA website.)

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Authorised Representative: Ms Helen Gregg	To change the appointed Authorised Representative please complete the Facility Details Update (FDU) form available from the NATA website.
Position: Quality Manager	
Direct Phone: [redacted]	
Email: [redacted]	
SITE DETAILS	
Site No: 14171	
Site Name: Forensic and Scientific Services	
Site Trading Name (see note 1):	
Availability of services: Services conditionally available to external clients	☐ Services available to external clients ☐ Services conditionally available to external clients ☐ Services not available to external clients
Street address (physical location): Liaison Unit [redacted]	
Site Contact (full name including title):	
Phone: [redacted]	
Mobile:	
Indicate the Site Contact's primary contact number: ☐ Phone ☐ Mobile	
Email: [redacted]	
Do you wish to publish the Site contact information on NATA's website directory? ☐ Yes ☒ No (The name of the contact person and preferred phone number and email address will be listed in our records as the person to contact with enquiries about the Site's activities (i.e. from potential clients) and may be listed on the NATA website.)	

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Note 1: Trading name(s) (optional)

Providing this information indicates the applicant is seeking approval to issue reports in its trading name(s), in addition to the name of the Facility. Trading names may be provided for a Facility and/or for individual Sites.

In order to able to issue reports in a trading name the following criteria need to be met.

- There must be a clear and reasonable link between the name of the Facility and the trading name(s) supplied, such as an ownership link or a link by virtue of a registered trading name;
- Activities reported in a trading name(s) will have been performed by the staff of the accredited Facility/accredited Site to which the trading name(s) applies, using the same techniques and procedures s those covered by the Scope(s) of Accreditation of the applicable accredited Facility/accredited Site;
- The scope of reporting applicable to the trading name(s) is the same as or a subset of the Scope of Accreditation of the applicable accredited Facility/accredited Site.

Should trading name(s) be provided you will be contacted to further explore this option.

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

NATA SCOPE OF ACCREDITATION

A copy of your current scope of accreditation is attached.

☒ Annotate this scope to indicate the approximate frequency of all laboratory activities.

		2020		2021				2022		
	Quarter	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar (in part)	Total	Weekly average
Forensic Biology Examination of biological materials	InTube samples	4938	4727	5461	5210	5457	5423	4756	35972	404.18
	Items examined (not SAIK)	1447	1281	1445	1415	1544	1461	1340	9933	111.61
	SAIKs	96	81	121	112	128	117	104	759	8.53
	Phadebas Supernatant	199	104	141	95	177	143	99	958	10.76
	Microscopic	1142	684	742	734	961	733	687	5683	63.85
	Presumptive TMB/AP/p30/Phadebas paper	462	356	566	531	697	574	482	3668	41.21
Genetic Analysis	Extraction (Reference Maxwell)	1074	714	839	825	545	595	382	4974	55.89
	Extraction (Diff Lysis, incl Supernatant)	673	457	689	663	876	706	637	4701	52.82
	Extraction (Casework Maxwell)	1250	917	956	1022	690	876	536	6247	70.19
	Extraction (QIAsymphony)	1826	1689	1927	2140	1903	1917	2536	13938	156.61
	Extraction (PCIA - Bones)	5	10	11	10				36	0.69
	Integrated (QIA extraction and quantification)	4248	4032	4536	4320	4464	4752	3168	29520	331.69
	Post Extraction processing (Nucleospin, Microcon)	398	403	362	242	310	386	245	2346	26.36
	Quantifications	10374	9275	10258	10004	9820	10554	7821	68106	765.24
	Amplifications (PCR)	9983	8590	8485	9003	7627	8143	6161	57992	651.60
	Capillary Electrophoresis (3130, 3500)	15316	13210	14219	15491	12566	13371	9180	93353	1048.91

Animal health facilities only: please also complete the attached Supplement document.

Changes to the scope of accreditation

Surveillance visit: Additions will not normally be considered during a surveillance visit as such visits will not include a technical assessor. Where requested a decision will be made as to how best to meet the request without compromising the aim and focus of the surveillance visit. Accordingly, a variation visit may be arranged concurrently or as a separate visit once all information concerning the request has been considered. Charges will be incurred to accommodate the variation visit in accordance with NATA's Fee Schedule current at the time. Please be aware that any extensions to scope of accreditation may also result in an increase to your annual membership fees.

Reassessment: Any requests for additional activities to be added to the scope of accreditation as part of a scheduled reassessment will only be accommodated where such requests do not compromise the purpose of the reassessment (to review the existing scope of accreditation to determine ongoing compliance with the accreditation criteria). Where additional resources and time are required to accommodate the request, a concurrent variation visit may be arranged, and charges will be levied in accordance with the current Fee Schedule available from the NATA website. Please be aware that any extensions to scope of accreditation may also result in an increase to your annual membership fees.

Do you wish to request additions or deletions or editorial amendments to the scope of accreditation?

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Amendments as follows:

As advised by K.Scott in email 25 May 2018 and 31 May 2018 to Lyndon Thomas (NATA):

- QIAsymphony (DNA extraction) technique - to be added to DNA profiling for criminal casework and DNA profiling for relationship testing
- 3500xl capillary electrophoresis to be added to DNA profiling for criminal casework and DNA profiling for relationship testing
- Microcon to be added to DNA profiling for criminal casework and DNA profiling for relationship testing
- Nucleospin to be added to DNA profiling for criminal casework and DNA profiling for relationship testing

As advised by K.Scott in email 25 July 2018 and 7 August 2018 to Lyndon Thomas (NATA):

- Maxwell 16 is a DNA extraction process and not capillary electrophoresis technique

Instrument and software changes since last NATA visit in December 2020:

- February 2021 - 3130xl CE instruments removed from use. 3500xL use ongoing.
- May 2021 - Implementation of STRmix v2.8 (project #231)
- June 2021 – Verification of DCS v4 on 3500xL (project #223)
- January 2022 - Forensic DNA Analysis replaced the AB 9700 PCR machines with AB Proflex PCR machines (project #199)

Other changes:

- Feb 2021 – Verification of commercial H&E stain (project #220)
- March 2021 - Removal of "Hair examination" from NATA scope of accreditation

New projects currently in progress:

- Y-Filer (project #206)
- Verifiler (project #213)
- Ion Chef and S5 – MPS (Project #216)

Note: Changes to calibration and measurement capability (CMC) may be considered as additions to the scope of accreditation.

☐ Yes. Please complete the Application for changes to the scope of accreditation form available from the NATA website.

☒ No

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Regulatory requirements applicable to laboratory activities

Are any of your laboratory activities covered by your scope of accreditation subject to, or used by your customers to meet, regulatory requirements? For example, do you test products covered by Consumer Safety Law, WHS regulations, trade measurement, food regulation, etc.?

☐ Yes

☒ No

If yes, please indicate this by annotating the attached copy of your current scope of accreditation specifically identifying the relevant regulation (including regulatory body and/or regulatory ruling), standard or other applicable document as appropriate. For example:

- Testing of children's nightwear for flammability in accordance with AS/NZS 1249:2003
- Testing of trolley jacks in accordance with Consumer Protection Notice No. 10:2008 (ACCC)

Testing of human specimens

Are any of your laboratory activities covered by your scope of accreditation on human samples?

☒ Yes

Testing is carried out on human samples. However, these samples are used in legal investigations and not for clinical testing purposes. As such they do not come under the framework for In Vitro Diagnostic Medical Devices.

☐ No

If yes, please annotate this on the attached scope of accreditation. Note that such testing may be subject to the Therapeutic Goods Administration (TGA) In-Vitro Diagnostic (IVD) medical device Framework and assessed against the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for the Development and use of In-House In Vitro Diagnostic Medical Devices.*

Sampling

Since your previous assessment, are there changes to any sampling conducted covered by your NATA scope of accreditation?

☐ Yes. Please complete the Application for changes to the scope of accreditation form available from the NATA website.

☒ No

☐ Not applicable

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Off-Site Laboratory Activities

Since your previous assessment, has your facility commenced performing laboratory activities off-site, for example, field testing or at clients' premises, and do you require this to be covered by your scope of accreditation?

Note: Refer to relevant documents in the NATA Accreditation Criteria (NAC) package applicable to your scope of accreditation, available from the NATA website, for any specific requirements for such laboratory activities.

☐ Yes. Please complete the Application for changes to the scope of accreditation form available from the NATA website.

☒ No

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

STAFF

In the following spaces provided (or on a separate sheet if is insufficient room), list the current facility staff. Please also indicate whether any staff work on a shift or part-time basis.

Staff responsible for quality management
Part-time staff (as at 07/03/2022)
Extended leave (as at 07/03/2022)

Name and qualifications	Position (Please also specifically identify staff responsible for technical and quality management)	Date started in the facility
ACEDO, Pierre [BSc]	Scientist	2006
ADAMSON, Angela [BSc (Hons)]	Reporting Scientist	2003
AGUILERA, Maria [BSc]	Scientist	2006
ALLEN, Catherine [BSc, MSc (For Sc)]	Managing Scientist	1999
ANDERSEN, Belinda [B Biomed Sc, GDFor]	Senior Scientist	2005
ANGUS, Chantal [BA (Hons)]	Laboratory Assistant	2017
AVDIC, Kevin [HNC Chem]	Forensic Technician	2014
BRADY, Susan [BAppSc. (Biotech); Grad.Dip. (For Inv)]	Scientist - Leave	2004
BRISOTTO, Paula [BSc, MSc (For Sc)]	Team Leader	2001
BROOKS, Julie	Laboratory Assistant	2016
CALDWELL, Valerie [B.AppSc. (Med Sc)]	Scientist	2006
CAUNT, Emma [BSc (Hons)]	Reporting Scientist	2007
CHANG, Cindy [BSc; PGDip Clin Biochem]	Scientist	2001
CHENG, Amy [BSc]	Scientist	2006
CIPOLLONE , Melissa [B.AppSc.]	Scientist	2006
CONNOLLY, Yvonne [BA, DipBus; Cert II &Cert III B.Admin]	Administration	2014
DARMANIN, Alanna [BA, BSc (Hons); MSc For Arch & Crime Scene Invest, Cert For Stat]	Scientist	2010
DWYER, Tegan [BForSc]	Reporting Scientist	2010
EBA, Ryu	Laboratory Assistant	2011
ENTWISTLE, Josie [BSc BA]	Reporting Scientist	2005
ESTREICH, Kim	Laboratory Assistant	2019
FARRELLY, Lisa [BAppSc]	Scientist	2013
FINCH, Patricia [BSc]	Reporting Scientist - Leave	2002
FLANAGAN Cecilia [Cert IV Lab Tech; Cert II Gov]	Administration	2021
FRENCH, Naomi [Cert IV Lab Tech]	Laboratory Assistant	2019
GALLAGHER, Claire [B.Tech. PG.Cert]	Reporting Scientist	2006
GOODRICH, Michael	Laboratory Assistant Supervisor	2010
GULLIVER, Maddison	Laboratory Assistant	2021
HARMER, Wendy [Cert II BA, DipMgt]	Administration	2005
HART, Michael [City and Guilds Level 3 (UK); Cert IV Lab Tech] DipLabTech	Forensic Technician	2014
HUNT, Matthew [BSc (Hons)]	Reporting Scientist	2009
HOWES, Justin [BSc, BA, MSc (For Sc), DipMgt]	Team Leader	2005
JAMES, Cassandra [BSc MSc (For Sc)]	Reporting Scientist	2016

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

Name and qualifications	Position (Please also specifically identify staff responsible for technical and quality management)	Date started in the facility
JOHNSTONE, Sharon [BSc; MSc (For Sc), DipMgt]	Forensic Scientist Advanced	1999
KAITY, Adam [BSc (Hons I); PhD]	Scientist	2008
KELLER, Angelina [BAgSci (Hons), MSc (ForSc)]	Reporting Scientist	2004
LANCASTER, Kerry-Anne [B.AppSc, GDip For Inv]	Reporting Scientist	2005
LE, Lai-Wan [BSc (Med Lab), MSc (For Sc)]	Scientist	2005
LLOYD, Allison [B.AppSc; MSc (For Sc)]	Forensic Scientist Advanced	2006
LUNDIE, Generosa [BSc (Biomed Sc)]	Scientist	2006
MARGETTS, Michelle [BSc For Sc, Cert IV Lab Tech, DipLabTech]	Scientist	2011
MATHIESON, Megan [B.HSc., B.BioMedSc, GDFor]	Reporting Scientist	2005
McINDOE, Phillip [BTecONC]	Laboratory Assistant	2019
McKEAN, Sandra	Laboratory Assistant	2008
McNEVIN, Allan [B. AppSc. (Med Lab Sc)]	Reporting Scientist	2004
MICIC, Biljana [BSc]	Scientist	2005
MOELLER, Ingrid [BSc (Hons), PhD]	Reporting Scientist	2004
MORGAN, Amy [B.AppSc]	Scientist	2014
MORTON, Kristina [BSc For Sc.]	Scientist	2020
NICOLETTI, Deborah [BSc (MLS)]	Reporting Scientist	2005
NURTHEN, Thomas [BSc (Hons)]	Reporting Scientist	2004
NYDAM, Sharelle [BSc (Hons)]	Scientist	2014
PARRY, Rhys [BSc (Hons)]	Reporting Scientist	2006
PENDLEBURY-JONES, Victoria	Administration	2015
PIPPIA, Adriano [B. AppSc.]	Reporting Scientist	2000
PROWSE, Tara [B. AppSc.]	Scientist	2009
QUARTERMAIN, Alicia [BHSc, MSc (For Sc)]	Reporting Scientist	2005
RIKA, Kylie [BSc, PGDipFor, DipMgt]	Forensic Scientist Advanced	2005
ROSELT, Nicole [B.For Sc. & BCCJ]	Scientist	2016
RYAN, Abigail [BSc (Hons) For Sc]	Scientist	2008
RYAN, Luke [BSc, MSc (For Sc), Dip Gov(Sec),DipMgt]	Forensic Scientist Advanced	2013
SANDERSON, Suzanne	Laboratory Assistant	2006
SAVAGE, Chelsea [B.For Sc. & BCCJ]	Scientist (Quality)	2015
SCOTT, Kirsten [BSc (Hons). PhD. GCEd, GDEd., DipMgt]	Forensic Scientist Advanced – Quality and Projects	2007
SEYMOUR-MURRAY, Janine [B. AppSc.]	Scientist	2006
TAYLOR, Penelope [BSc (Hons)]	Reporting Scientist	2001
WAIARIKI, Stephanie [BSc For Sc, DipLabTech]	Laboratory Assistant	2022
WILLIAMS, Helen [B. AppSc. (Med Lab Sc), PGDip (Biotech)]	Scientist	2003
WILSON, Jacqueline [B.AppSc. MSc]	Reporting Scientist	2006

Note: NATA will list individuals in the Report on Assessment where there is a regulatory framework or is covered in a Deed of Agreement, Memorandum of Understanding or other binding agreement with a third party. If this is applicable to any of your laboratory activities, indicate in the table any nominated individuals or changes to nominated individuals who are authorised to release results under such an arrangement, including the arrangement in place. Please provide resumes for any new individuals not previously listed.

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ENSURING THE VALIDITY OF RESULTS

Has your facility participated in any proficiency tests, measurement audits or inter-laboratory comparison programs since your last assessment?

Refer to the *General Accreditation Criteria: Proficiency testing* document available from the NATA website for the policy on participation in such programs.

☒ Yes

☐ No

If yes, please provide details in the table below. Records of participation in these programs must be available for review during the NATA assessment, together with details of action taken in response to unsatisfactorily performance.

Name of provider, program and activities undertaken		Frequency of program	Last date of participation
CTS Collaborative Testing Services		38 tests in total	March 2022
[redacted]	Forensic Biology	1	Jan 2021
	DNA-Mixture	1	Jan 2021
	DNA Database - Saliva	3	Feb 2021
	DNA Parentage	3	Feb 2021
	Forensic Biology	1	March 2021
	DNA-Semen	1	March 2021
	Body Fluid Identification	1	March 2021
	Forensic Biology	1	April 2021
	DNA-Blood	1	April 2021
	DNA Parentage	3	May 2021
	Forensic Biology	1	July 2021
	DNA-Semen	1	July 2021
	DNA Database - Saliva	3	July 2021
	DNA Parentage	2	Aug 2021
	Forensic Biology	1	Sept 2021
	DNA-Blood	1	Sept 2021

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[redacted]	Body Fluid Identification	1	Sept 2021
	Forensic Biology	1	Oct 2021
	DNA-Mixture	1	Oct 2021
	– Forensic Biology	1	Jan 2022
	– DNA-Mixture	1	Jan 2022
	DNA Database - Saliva	3	Feb 2022
	DNA Parentage	2	Feb 2022
	Forensic Biology	1	March 2022
	DNA-Semen	1	March 2022
	Body Fluid Identification	1	March 2022

☒ If yes to the above, please provide a summary of your facility's performance in proficiency testing programs or inter-laboratory comparisons. This should include matrices/analytes covered and any outliers recorded (including actions taken).

All tests (mixture, semen, database, standard, parentage and body fluid) were consistent with manufacturers information with the exception of test [redacted] Body Fluid Identification test (March 2021). For this non-conformance OQI#55008 refers – see below for details and actions (Refer attached).

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Report for QIS OQI as of 11/03/2022 1:37:20 PM

Report for QIS OQI -

55008 CTS 21-5781 non-conformance

OQI Details

Status	Closed Approved
Subject	CTS results submitted by Forensic DNA Analysis for items 3 and 6 were not consistent with manufacturers information as provided by CTS.
Source of OQI	EQAP/Collaborative/Proficiency Test
Date Identified	22/06/2021

OQI Creator Contact Details

Creator	Abigail RYAN
Organisational Unit/s	Quality and Projects
Service/s	Forensic and Scientific Service
Site Location/s	Coopers Plains

Investigator/Actioner Contact Details

Actioner	Allan MCNEVIN
Organisational Unit/s	Evidence Recovery
Service/s	Forensic and Scientific Service
Site Location/s	Coopers Plains

Investigation Details

Investigation Completed 03/08/2021 **Root Cause Type** | None - No Problem

Investigation Details

Item 3

Based on the scenario provided, the examiner and peer reviewer had not considered testing the Item for the possible presence of saliva. The swab was stained with what appeared to be blood, which tested positive for the presumptive presence of blood. On review, the scenario does not provide any clear indication that item should have been tested for saliva. The testing carried out in FSS Forensic DNA Analysis is consistent with that reported by other laboratories, with 136 of 244 laboratories that responded to the CTS reporting saliva as "Not Tested".

The item was re-examined for the presence of saliva and tested positive.

Item 6

The item tested was black and pink in colour. The area of the item that tested positive for Phadebas was part of the fabric that was entirely black. The material did not appear faded, and there was no visual indication of the presence of blood. The scenario provided did not strongly indicate which body fluids the item should be tested for, so it was tested for the presence of semen and saliva, and visually inspected for the presence of blood. Of the 244 laboratories that responded to the CTS there were 15 laboratories that reported the

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item as negative for blood, 1 as inconclusive for blood and 15 that did not test the item for blood.

The item was re-examined for the presence of blood. It was noted that there was no visual indication of the presence of blood. The examiner did not recall any discolouration of the Phadebas test paper at the time of initial examination that may have provided some indication that blood was present. A TMB test was conducted on the area previously to be determined as Phadebas positive, and a positive result was obtained. The area which in which the DNA was located was an area of fabric with an intense black colour (i.e. not visibly faded in any way). At present, the laboratory does not have any validated protocols for observing for biological fluids under alternative light sources. This kind of testing is performed by QPS, and subsamples of possible blood staining are usually submitted as in-tube items. However, items requested for Saliva testing are usually submitted as whole items.

Preformed By Allan MCNEVIN

Action Details

Action Complete 03/08/2021 **Action Fix Type** No Action PossibleOutcomes

Title **Action Description** The testing of CTS tests does not perfectly correlate with routine processes. This is not unexpected as the CTS test has to cater to a larger number of laboratories with varying workflow practices. With respect to Item 3, for our laboratory, the testing of swabs is usually performed when swabs are submitted as "in-tube" samples, where the swab head is submitted inside a tube ready for DNA extraction. Testing for blood on these items is performed by QPS prior to submission to FSS. It is incumbent on the officer submitting the item for testing to request any additional testing (semen, saliva). Generally, case history information is either not provided, or only provided in relation to the specific items submitted for testing, and the laboratory staff are not called on to decide whether additional testing is required. As the sample type and location of Item 3, and the scenario provided would not flag any immediate thoughts of the need for saliva testing, it is not considered necessary that further actions are required to be carried out with respect to the results obtained from this specific test.

For Item 6, it is unclear what could have been done different, as on re-examination, there was no visible blood staining, most likely due to the intense colouration of the fabric being tested. At present, the laboratory does not have any validated protocols for observing for biological fluids under alternative light sources. This kind of testing is performed by QPS, and subsamples of possible blood staining are usually submitted as in-tube items. However, items requested for Saliva testing are usually submitted as whole items. At this stage, no actions as a result of the findings of this OQI have been determined.

The outcomes from this OQI to be discussed with the team next team meeting.

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status Accepted

4/08/2021 8:24:52 AM Abigail RYAN:

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Follow-up Status	
Comment	Accept investigation and actions as written
Approver	Paula BRISOTTO
Approval/Rejection Date	04/08/2021
Approval/Rejection Comment	4/08/2021 1:23:26 PM Paula BRISOTTO: Approved of investigation and actions

Associations

No Associations found

Records

No Records found

55008 CTS 21-5781 non-conformance

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MONTH	CTS Proficiency Testing Schedule 2021 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 58x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should NOT be used for sampling scientists.										
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted	Follow-up completed	Feedback presented
January	FB5701 Forensic Biology	U2483H (DRL6HU)	734420086	[redacted]	Kerry-Anne Lancaster	Reporter	15/01/2021	8/03/2021	16/02/2021	7/04/2021	11/05/2021
					Matthew Hunt	Reviewer					
					Kristina Morton	Sampler					
					Mike Hart	Reference sampler					
	FB5801 DNA-Mixture	U2483B (66EQGJ)	734420075		Kylie Rika	Reporter	15/01/2021	8/03/2021	5/03/2021	7/04/2021	11/05/2021
					Anne Finch	Reviewer					
					Valerie Caldwell	Sampler					
					Mike Hart	Reference sampler					
February	FB5840 DNA Database - Saliva	U2483A (TJZYT2)	734420126		Sharelle Nydam	Reporter	11/02/2021	8/03/2021	4/03/2021	29/04/2021	11/05/2021
					Helen Williams	Reviewer					
					Valerie Caldwell	Sampler					
					Phillip Mcindoe	Reference sampler					
	FB5840 DNA Database - Saliva	U2483B (PYM6C7)	734420137		Lisa Farrelly	Reporter	11/02/2021	8/03/2021	8/03/2021	29/04/2021	11/05/2021
					Biljana Micic	Reviewer					
					Valerie Caldwell	Sampler					
					Phillip Mcindoe	Reference sampler					
	FB5840 DNA Database - Saliva	U2483C (KQQJJB)	734420146		Megan Mathieson	Reporter	11/02/2021	8/03/2021	4/03/2021	29/04/2021	11/05/2021
					Tara Prowse	Reviewer					
					Valerie Caldwell	Sampler					
					Phillip Mcindoe	Reference sampler					
	FB5870 DNA Parentage	U2483D (4U9CDR)	734420191		Angelina Keller	Reporter	25/02/2021	19/04/2021 (extension to 03/05/2021)	15/04/2021	11/05/2021	11/05/2021
					Rhys Parry	Reviewer					
					Helen Williams	Sampler					
					Mike Hart	Reference sampler					
	FB5870 DNA Parentage	U2483E (ZBP94V)	734420206		Penelope Taylor	Reporter	25/02/2021	19/04/2021 (extension to 03/05/2021)	15/04/2021	11/05/2021	11/05/2021
					Ingrid Moeller	Reviewer					
					Helen Williams	Sampler					
					Michelle Margetts	Reference sampler					
	FB5870 DNA Parentage	U2483F (P47438)	734420215		Jacqui Wilson	Reporter	25/02/2021	19/04/2021 (extension to 03/05/2021)	13/04/2021	11/05/2021	11/05/2021
					Adrian Pippia	Reviewer					
					Cindy Chang	Sampler					
					Kevin Avdic	Reference sampler					

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MONTH	CTS Proficiency Testing Schedule 2021 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 59x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should NOT be used for sampling scientists.										
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted	Follow-up completed	Feedback presented
March	FB5702 Forensic Biology	U2483J (A3ET8Y)	734421534	[redacted]	Thomas Nurthen	Reporter	8/03/2021	3/05/2021	27/04/2021	25/05/2021	6/08/2021
					Sharon Johnstone	Reviewer					
					Abbie Ryan	Sampler					
					Michelle Margetts	Reference sampler					
	FB5802 DNA - Semen	U2483C (F432XC)	734421523		Ingrid Moeller	Reporter	8/03/2021	3/05/2021	29/04/2021	25/05/2021	6/08/2021
					Deborah Nicoletti	Reviewer					
					Valerie Caldwell	Sampler					
					Michelle Margetts	Reference sampler					
	FB5781 Body Fluid Identification	U2483J (N2WC37)	734421697		Sharon Byrne	Reporter	8/04/2021	24/05/2021	11/05/2021	4/08/2021	6/08/2021
					Allan McNevin	Reviewer					
					Abbie Ryan	Sampler Item 1					
					Kristina Morton	Sampler Item 2					
					Valerie Caldwell	Sampler Item 3					
					Helen Williams	Sampler Item 4					
					Cindy Chang	Sampler Item 5					
					Janine Seymour-Murray	Sampler Item 6					
April	FB5703 Forensic Biology	U2483C (VC4W2T)	734422037		Allison Lloyd	Reporter	28/04/2021	21/06/2021	15/06/2021	13/07/2021	6/08/2021
					Angela Adamson	Reviewer					
					Janine Seymour-Murray	Sampler					
					Mike Hart	Reference sampler					
	FB5803 DNA - Blood	U2483A (T7GVJV)	734422313		Justin Howes	Reporter	11/05/2021	21/06/2021	15/06/2021	13/07/2021	6/08/2021
					Josie Entwistle	Reviewer					
					Kristina Morton	Sampler					
					Kevin Avdic	Reference sampler					
May	FB5871 (a) DNA Parentage	U2483F (LWRCQC)	734422634		Justin Howes	Reporter	11/06/2021	2/08/2021	12/07/2021	24/08/2021	30/09/2021
					Emma Caunt	Reviewer					
					Abbie Ryan	Sampler					
					Michelle Margetts	Reference sampler					
	FB5871 (b) DNA Parentage	U2483G (NH7JEA)	734422640		Josie Entwistle	Reporter	11/06/2021	2/08/2021	19/07/2021	24/08/2021	30/09/2021
					Sharon Johnstone	Reviewer					
					Abbie Ryan	Sampler					
					Mike Hart	Reference sampler					
	FB5871 (c) DNA Parentage	U2483H (U8G223)	734422656		Thomas Nurthen	Reporter	11/06/2021	2/08/2021	16/07/2021	24/08/2021	30/09/2021
					Kylie Rika	Reviewer					
					Abbie Ryan	Sampler					
					Kevin Avdic	Reference sampler					

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MONTH	CTS Proficiency Testing Schedule 2021 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 58x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should NOT be used for sampling scientists.										
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted	Follow-up completed	Feedback presented
July	FB5704 Forensic Biology	U2483H (EDF9XV)	734422700	[redacted]	Emma Caunt	Reporter	16/07/2021	7/09/2021	24/08/2021	30/09/2021	30/09/2021
					Angelina Keller	Reviewer					
					Kristina Morton	Sampler					
					Michelle Margetts	Reference sampler					
	FB5804 DNA-Semen	U2483B (TMZ6CF)	734422711		Adrian Pippia	Reporter	16/07/2021	7/09/2021	2/09/2021	30/09/2021	30/09/2021
					Alicia Quartermain	Reviewer					
					Valerie Caldwell	Sampler					
					Michelle Margetts	Reference sampler					
	FB5843 (a) DNA Database - Saliva	U2483A (JU3HK8)	734422733		Generosa Lundie	Reporter	29/07/2021	27/09/2021	26/08/2021	19/10/2021	2/12/2021
					Sharelle Nydam	Reviewer					
					Valerie Caldwell	Sampler					
					Julie Brooks	Reference sampler					
	FB5843 (b) DNA Database - Saliva	U2483B (ZZD2YQ)	734422744		Pierre Acedo	Reporter	29/07/2021	27/09/2021	31/08/2021	19/10/2021	2/12/2021
					Megan Mathieson	Reviewer					
					Michelle Margetts	Sampler					
					Julie Brooks	Reference sampler					
	FB5843 (c) DNA Database - Saliva	U2483C (T3JWLX)	734422755		Melissa Cipollone	Reporter	29/07/2021	27/09/2021	24/08/2021	19/10/2021	2/12/2021
					Lisa Farrelly	Reviewer					
					Michelle Margetts	Sampler					
					Julie Brooks	Reference sampler					
August	FB5872 (a) DNA Parentage	U2483D (8U9NZ2)	734422788		Claire Gallagher	Reporter	10/09/2021	25/10/2021	7/10/2021	17/11/2021	2/12/2021
					Jacqui Wilson	Reviewer					
					Helen Williams	Sampler					
					Louise Benincasa	Reference sampler					
	FB5872 (b) DNA Parentage	U2483E (M6VY6K)	734422799		Ingrid Moeller	Reporter	10/09/2021	25/10/2021	18/10/2021	17/11/2021	2/12/2021
					Kylie Rika	Reviewer					
					Helen Williams	Sampler					
					Louise Benincasa	Reference sampler					

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MONTH	CTS Proficiency Testing Schedule 2021 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 58x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should **NOT** be used for sampling scientists.										
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted	Follow-up completed	Feedback presented
September	FB5705 Forensic Biology	U2483E (QVYXG6)	734422808	[redacted]	Penny Taylor	Reporter	20/09/2021	8/11/2021	18/10/2021	2/12/2021	2/12/2021
					Allan McNevin	Reviewer					
					Helen Williams	Sampler					
					Louise Benincasa	Reference sampler					
	FB5805 DNA-Blood	U2483E (GN3BZL)	734422817		Angela Adamson	Reporter	20/09/221	8/11/2021	21/10/2021	2/12/2021	2/12/2021
					Cassie James	Reviewer					
					Cindy Chang	Sampler					
					Louise Benincasa	Reference sampler					
	FB5782 Body Fluid Identification	U2483C (WC673Z)	734422826		Valerie Caldwell	Reporter	1/10/2021	22/11/2021	9/11/2021	4/01/2022	11/01/2022
					Allison Lloyd	Reviewer					
					Janine Seymour-Murray	Sampler Item 1					
					Cindy Chang	Sampler Item 2					
					Kristina Morton	Sampler Item 3					
					Michelle Margetts	Sampler Item 4					
					Kristina Morton	Sampler Item 5					
					Helen Williams	Sampler Item 6					
October	FB5706 Forensic Biology	U2483J (7ZY8UX)	734422894		Matthew Hunt	Reporter	2/11/2021	20/12/2021	9/12/2021	11/01/2022	11/01/2022
					Rhys Parry	Reviewer					
					Michelle Margetts	Sampler					
					Louise Benincasa	Reference sampler					
	FB5806 DNA-Mixture	U2483E (W2NHWG)	734422906		Claire Gallagher	Reporter	2/11/2021	20/12/2021	8/12/2021	11/01/2022	11/01/2022
					Jacqui Wilson	Reviewer					
					Janine Seymour-Murray	Sampler					
					Louise Benincasa	Reference sampler					

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MONTH	CTS Proficiency Testing Schedule 2022 CTS Proficiency Tests 57x require sample screening CTS Proficiency Tests 58x are sample specific and pre-screened. No screening techniques are required and therefore this set of proficiencies should **NOT** be used for sampling scientists.								
	CTS type	Participant Number (Web Code)	Lab Number(s)	FR Number	Staff	Role	Received Date	Due Date	Date Submitted
January	FB5701 Forensic Biology	U2483H (N8NME3)	723188457	[redacted]	Luke Ryan	Reporter	18/01/2022	7/03/2022	10/02/2022
					Allison Lloyd	Reviewer			
					Valerie Caldwell	Sampler			
					Kevin Avdic	Reference sampler			
	FB5801 DNA-Mixture	U2483C (N6KUNN)	723188468		Kerry-Anne Lancaster	Reporter	18/01/2022	7/03/2022	1/03/2022
					Deborah Nicoletti (Rogers)	Reviewer			
					Helen Williams	Sampler			
					Mike Hart	Reference sampler			
February	FB5840 (A) DNA Database - Saliva	U2483A (WQ67FR)	734422951		Helen Williams	Reporter	10/02/2022	4/04/2022	
					Pierre Acedo	Reviewer			
					Janine Seymour-Murray	Sampler			
					Kim Estreich	Reference sampler			
	FB5840 (B) DNA Database - Saliva	U2483B (2R36HM)	734422960		Biljana Micic	Reporter	10/02/2022	4/04/2022	9/03/2022
					Kirsten Scott	Reviewer			
					Kristina Morton	Sampler			
					Madison Gulliver	Reference sampler			
	FB5840 (C) DNA Database - Saliva	U2483C (9FMNQG)	734422974		Tara Prowse	Reporter	10/02/2022	4/04/2022	6/03/2022
					Abbie Ryan	Reviewer			
					Amy Morgan	Sampler			
					Madison Gulliver	Reference sampler			
	FB5870 (A) DNA Parentage	U2483C (89L29P)	734423057		Alicia Quartermain	Reporter	24/02/2022	18/04/2022	
					Angelina Keller	Reviewer			
					Cindy Chang	Sampler			
					Mike Hart	Reference sampler			
	FB5870 (B) DNA Parentage	U2483D (3ZPFEV)	734423068		Adrian Pippia	Reporter	24/02/2022	18/04/2022	
					Rhys Parry	Reviewer			
					Michelle Margetts	Sampler			
					Mike Hart	Reference sampler			
March	FB5702 Forensic Biology	U2483H (D7F66V)	734423181		Justin Howes	Reporter	10/03/2022	2/05/2022	
					Josie Entwistle	Reviewer			
					Valerie Caldwell	Sampler			
						Reference sampler			
	FB5802 DNA - Semen	U2483C (U3C4P3)	734423190		Sharon Johnstone	Reporter	10/03/2022	2/05/2022	
					Thomas Nurthen	Reviewer			
					Helen Williams	Sampler			
						Reference sampler			
	FB5781 Body Fluid Identification					Reporter			
						Reviewer			
						Sampler Item 1			
						Sampler Item 2			
						Sampler Item 3			
						Sampler Item 4			
						Sampler Item 5			
						Sampler Item 6			

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EQUIPMENT

Equipment includes, but is not limited to, measuring instruments, reference standards and analytical systems.

Note: Refer to the *General Accreditation Criteria: Equipment assurance, in-house calibration and equipment verification*, available from the NATA website, for further information.

Please complete the table below (or attach a separate sheet) indicating whether the equipment is calibrated in-house or externally.

Calibration of equipment is necessary when:

- the measurement accuracy of measurement uncertainty affects the validity of reported results; and/or
- the equipment is required to establish the metrological traceability of reported results.

Where calibration of equipment is deemed not necessary, it is still required that the facility ensure equipment has been verified that it conforms with specified requirements (e.g. method requirements; manufacturer's requirements).

Equipment description	Calibrated		
	In-house		Externally
	Yes	Procedure (as per Methods Manual, national or international standard, etc)	Yes
Genetic Analysers: Forensic DNA Analysis currently has two 3500xl instruments in use, these are listed below. Also listed is the 3130xl instrument that was taken out of use on 15/02/2021. To be suitable for use the Genetic Analysis must meet annual service requirements and continue to pass internal spectral checks			
200418261 ; 3130 (B) - Analyser , 3130xl			Yes
200418262 ; 3500 (A) - Analyser , 3500xL			Yes
200418263 ; 3500 (B) - Analyser , 3500xL			Yes
QuantStudio: has 6 monthly maintenance, and 2 yearly calibration check by an external provider. The instruments are suitable for use if they pass internal monthly and external checks.			
200420763 QuantStudio 5 A			Yes
200420764 QuantStudio 5 B			Yes
ARTEL instruments: Forensic DNA Analysis has two ARTEL instruments (PCS and an MVS), both instruments use Dual dye photometry to enable verification of POVAs and pipetting robotics. The MVS instrument can do multichannel POVA up to 200uL and pipetting robotics, the PCS can do single channel POVAs to 5000uL. Both the MVS and PCS instruments are calibrated prior to use, using either a plate or calibration solutions (refer QIS#31956 and 26628). All reagents, consumables and calibration plate/solutions of the MVS and PCS systems are traceable back to the NIST Standard. The MVS calibrations plates are sent out to external providers			

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200418246 ; ARTEL MVS Calibration Plate			Yes
200418247 ; ARTEL MVS Calibration Plate			Yes
Balance: Receives 1 year service and 3 year NATA calibration by an external provider. Monthly and six monthly checks are completed internally. The balance is deemed suitable for use if it meets all NATA calibration/servicing requirements and continues to pass internal 1 & 6 monthly checks.			
200418260 ; Balance , Electronic XS105DU			Yes
BSD FTA punching instrument receives annual servicing by an external provider. No calibration is required. Instrument is suitable for use if servicing finds no issues with instrument function			
200422004 ; BSD 600 Ascent A2			Yes
Centrifuges: Within Forensic DNA Analysis we have both critical centrifuges and non-critical centrifuges. Centrifuges which are used for DNA extraction, microcon, nucleospin processing, semen testing or phadebas supernatant testing are deemed critical. Critical centrifuges are calibrated externally. They must pass external calibration to be suitable for use.			
200418244 ; Centrifuge , Eppendorf 5424			Yes
200418251 ; Centrifuge , Eppendorf 5424			Yes
200421429 ; Centrifuge , Eppendorf 5425			Yes
200422136 ; Centrifuge , Eppendorf 5425			Yes
200422137 ; Centrifuge , Eppendorf 5425			Yes
200422138 ; Centrifuge , Eppendorf 5425			Yes
200422139 ; Centrifuge , Eppendorf 5430			Yes
200421645 ; Centrifuge , Eppendorf 5804			Yes
200418255 ; Centrifuge , 333506			Yes
200419296 ; Centrifuge , 333506			Yes
200418254 ; Centrifuge , Sigma 41640			Yes
200418255 ; Centrifuge , Labogene 1248			Yes
Hamilton: Liquid handling platforms used for PCR set-up and CE set-up. Instruments have three monthly internal verifications using ARTEL to criteria given in QIS#26628 (MVS) which is relative inaccuracy and co-efficient of variation below 10% for ≤10µL and below 5% for ≥11µL, plus 6 monthly preventative maintenance by an external provider. The instrument is suitable for use if it meets both internal verifications and external servicing.			
200418618 ; Liquid Handler , Hamilton STARlet (B)	Yes	QIS#26628	Service
200418619 ; Liquid Handler , Hamilton STARlet (A)	Yes	QIS#26628	Service
200418620 ; Liquid Handler , Hamilton STARlet (C)	Yes	QIS#26628	Service

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Microscopes: receive annual servicing by an external provider. No calibration is required. Instrument is suitable for use if servicing finds no issues with function					
200418265	Microscope , Olympus BX41				Service
200418266	Microscope , Olympus BX41				Service
200418267	Microscope , Olympus BX41				Service
200418268	Microscope , Olympus BX41				Service
200420451	Microscope , Nikon Eclipse Ci-L				Service
200421945	Microscope , Nikon Eclipse Ci-L				Service
POVAs have been assessed as non-critical pieces of equipment. The checks that are in place to ensure pipettes are within range and suitable for use include: positive and negative controls on batches, initial NATA calibration certificates and internal 3 monthly checks with traceable ARTEL equipment and reagents. To be suitable for use POVAs must - pass initial NATA calibration and 3 monthly internal verifications using ARTEL to criteria given in QIS#26628 (MVS) and QIS#31956 (PCS) which is relative inaccuracy and co-efficient of variation below 10% for ≤10µL and below 5% for ≥11µL					
200422695	POVA 10-100u , Eppendorf Research Plus	I10767K	Yes	QIS#3156 or QIS#26628	Initial
200422728	POVA 20-200uL , Eppendorf Reasearch Plus	G42714K	Yes		Initial
200422731	POVA 20-200uL , Eppendorf Reasearch Plus	G42713K	Yes		Initial
200422884	POVA 0.5-10uL , Eppendorf Research Plus	J54217K	Yes		Initial
200422761	POVA 0.5-10uL , Eppendorf Research Plus	J54848K	Yes		Initial
200422696	POVA 0.5-10uL , Eppendorf Research Plus	G37613K	Yes		Initial
200422697	POVA 0.5-10uL , Eppendorf Research Plus	G37615K	Yes		Initial
200418338	POVA 0.5-10ul , Thermo Finnpipette	V22491	Yes		Initial
200418327	POVA 1-10ul , Thermo Finnpipette	FK26794	Yes		Initial
200418330	POVA 1-10ul , Thermo Finnpipette	FK26795	Yes		Initial
200418341	POVA 1-10ul , Thermo Finnpipette	V22491	Yes		Initial
200421793	POVA 1-10ul Cliptip , Thermo	NH47298	Yes		Initial
200418294	POVA 1-10ul Cliptip , Thermo	KH30542	Yes		Initial
200418315	POVA 1-10ul Multi Channel , Thermo	JH92826	Yes		Initial
200422690	POVA 10-100uL , Eppendorf Research Plus	I10323K	Yes		Initial

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200422691	POVA 10-100uL , Eppendorf Research Plus	H15260K	Yes	QIS#3156 or QIS#26628	Initial
200422692	POVA 10-100uL , Eppendorf Research Plus	I10319K	Yes		Initial
200422693	POVA 10-100uL , Eppendorf Research Plus	I10766K	Yes		Initial
200422694	POVA 10-100uL , Eppendorf Research Plus	H15277K	Yes		Initial
200422633	POVA 100-1000uL , Eppendorf Research Plus	R12542J	Yes		Initial
200422634	POVA 100-1000uL , Eppendorf Research Plus	R12384J	Yes		Initial
200422635	POVA 100-1000uL , Eppendorf Research Plus	R11936J	Yes		Initial
200422636	POVA 100-1000uL , Eppendorf Research Plus	R12624J	Yes		Initial
200422637	POVA 100-1000uL , Eppendorf Research Plus	R12137J	Yes		Initial
200422638	POVA 100-1000uL , Eppendorf Research Plus	R12253J	Yes		Initial
200418335	POVA 100-1000ul , Thermo Finnpipette	CH32624	Yes		Initial
200422602	POVA 100-1000uL , Socorex Acura 825	31022454	Yes		Initial
200422603	POVA 100-1000uL , Socorex Acura 826	31021420	Yes		Initial
200419868	POVA 100-1000ul , Socorex Calibra 822	9063000	Yes		Initial
200420149	POVA 100-1000ul Clip Tip , Thermo	JH91415	Yes		Initial
200421992	POVA 100-1000ul Clip Tip , Thermo	RH15216	Yes		Initial
200418298	POVA 100-1000ul Cliptip , Thermo	JH91419	Yes		Initial
200418300	POVA 100-1000ul Cliptip , Thermo	JH91424	Yes		Initial
200418334	POVA 2-20ul , Thermo Finnpipette	CH45188	Yes		Initial
200418342	POVA 2-20ul , Socorex Acura 825	14051150	Yes		Initial
200422676	POVA 2-20uL , Eppendorf Research Plus	Q48353J	Yes		Initial
200422677	POVA 2-20uL , Eppendorf Research Plus	Q48385J	Yes		Initial
200422678	POVA 2-20uL , Eppendorf Research plus	Q48435J	Yes		Initial
200422679	POVA 2-20uL , Eppendorf Research Plus	Q48386J	Yes		Initial

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200422680	POVA 2-20uL , Eppendorf Research Plus	J35823B	Yes	QIS#3156 or QIS#26628	Initial
200422681	POVA 2-20uL , Eppendorf Research Plus	J35801B	Yes		Initial
200422682	POVA 2-20uL , Eppendorf Research Plus	J35800B	Yes		Initial
200422727	POVA 20-200uL , Eppendorf Reasearch Plus	G42318K	Yes		Initial
200422601	POVA 20-200uL , Socorex Acura 825	31012305	Yes		Initial
200422729	POVA 20-200uL , Eppendorf Reasearch Plus	G42676K	Yes		Initial
200422730	POVA 20-200uL , Eppendorf Reasearch Plus	G42675K	Yes		Initial
200422879	POVA 20-200uL , Socorex Calibra 822	9062270	Yes		Initial
200422880	POVA 20-200uL , Socorex Calibra 822	10012061	Yes		Initial
200422881	POVA 20-200uL , Socorex Calibra 822	9062274	Yes		Initial
200422885	POVA 20-200uL , Eppendorf Research Plus	G42369K	Yes		Initial
200422732	POVA 20-200uL , Eppendorf Reasearch Plus	G42656K	Yes		Initial
200418343	POVA 20-200ul , Socorex Acura 825	14073513	Yes		Initial
200422604	POVA 20-200uL , Socorex Acura 826	30111077	Yes		Initial
200418331	POVA 20-200ul , Eppendorf Research	2022626	Yes		Initial
200418320	POVA 20-200ul , Thermo Finnpipette	JH10553	Yes		Initial
200418310	POVA 20-200ul Cliptip , Thermo	JH74655	Yes		Initial
200418313	POVA 20-200ul Cliptip , Thermo	KH09750	Yes		Initial
200419811	POVA 20-200uL Cliptip , Thermo	KH09754	Yes		Initial
200421986	POVA 5-50uL , Thermo Finnpipette	GH71377	Yes		Initial
200418321	POVA 5-50ul , Thermo Finnpipette	GH71376	Yes		Initial
200418328	POVA 5-50ul , Thermo Finnpipette	GH35698	Yes		Initial
200418329	POVA 5-50ul , Thermo Finnpipette	GH27001	Yes		Initial
200418339	POVA 5-50ul , Sealpette	EL16316	Yes		Initial

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200418305	POVA 5-50ul Cliptip , Thermo	JH75442	Yes	QIS#3156 or QIS#26628	Initial
200418307	POVA 5-50ul Cliptip , Thermo	JH75445	Yes		Initial
200420053	POVA 5-50uL Cliptip , Thermo	JH75443	Yes		Initial
200419981	POVA 50-300uL Multi Channel , Labsystems Finnpipette	E43203	Yes	QIS#26628	Initial
200421847	POVA Multipette E3 , Eppendorf	K18155I	Yes	QIS#26628	Initial
200422610	POVA Multipette Repeater , Eppendorf Multipette M4	M48200J	Yes	QIS#26628	Initial
200422611	POVA Multipette Repeater , Eppendorf Multipette M4	M46990J	Yes	QIS#26628	Initial
QIAsymphony instrument has two parts SP and AS modules. Both modules are serviced annually by an external provider. The AS module will also have 3 monthly verifications for dispensing volumes using the ARTEL MVS instrument. The QIAsymphony will be suitable for use if servicing finds no issues with instrument function and if 3-monthly checks in the ARTEL pass criteria given in QIS#26628 (MVS).					
200418249 ; QIAsymphony AS A , QIAsymphony AS			Yes	QIS#26628	Service
200420328 ; QIAsymphony AS B , QIAsymphony AS			Yes	QIS#26628	Service
200418248 ; QIAsymphony SP A , QIAsymphony SP			N/A	N/A	Service
200420192 ; QIAsymphony SP B , QIAsymphony SP			N/A	N/A	Service
Thermal cyclers: Forensic DNA Analysis previously used six 9700 thermal cyclers, these were taken out of use on 10/01/2022. They have been replaced with six Proflex thermal cyclers that were implemented on 10/01/2022. Annual checks by an external provider, and internal weekly cycle and rate checks. The instruments are suitable for use if they pass external annual checks and weekly internal checks.					
200418274 ; Thermal Cycler (B) , ABI 9700					Service
200418275 ; Thermal Cycler (C) , ABI 9700					Service
200418276 ; Thermal Cycler (D) , ABI 9700					Service
200418277 ; Thermal Cycler (E) , ABI 9700					Service
200418278 ; Thermal Cycler (F) , ABI 9700					Service
200418279 ; Thermal Cycler (G) , ABI 9700					Service
200420445 ; Thermalcycler Proflex 1 Base, Thermo 200422684 ; Thermalcycler Proflex 1 Samp Block, Thermo					Service

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200420446 ; Thermalcycler Proflex 2 Base, Thermo 200422685 ; Thermalcycler Proflex 2 Samp Block, Thermo			Service
200420447 ; Thermalcycler Proflex 3 Base, Thermo 200422686 ; Thermalcycler Proflex 3 Samp Block, Thermo			Service
200420448 ; Thermalcycler Proflex 4 Base, Thermo 200422687 ; Thermalcycler Proflex 4 Samp Block, Thermo			Service
200420449 ; Thermalcycler Proflex 5 Base, Thermo 200422688 ; Thermalcycler Proflex 5 Samp Block, Thermo			Service
200420576 ; Thermalcycler Proflex 6 Base, Thermo 200422689 ; Thermalcycler Proflex 6 Samp Block, Thermo			Service
Thermometers: Within Forensic DNA Analysis we have both critical and non-critical thermometers. Fridges and freezers within Forensic DNA Analysis are monitored by a BMS system (with alarms), however in addition to the BMS many fridges and freezers have non-critical thermometers in them for easy of user observation only. Non-critical thermometers are not included below. Thermometers that are deemed critical are those used for DNA extraction water-baths, nucleospin clean-ups and the CE denaturation blocks. Critical thermometers are checked internally every six months (single point) and a full check completed every 5 years. Thermometers are deemed suitable for use if they pass all internal checks (as per QIS#10670)			
200419950 ; Thermometer - Alcohol 24 , Alcohol/Glass 76mm Part/Immer	Yes	QIS#10670	
200419951 ; Thermometer - Alcohol 25 , Alcohol/Glass 76mm Part/Immer	Yes	QIS#10670	
200418670 ; Thermometer - Alcohol 32 , Alcohol/Glass 76mm Part/Immer	Yes	QIS#10670	
200418668 ; Thermometer - Alcohol 9 , Alcohol/Glass 76mm Part/Immer	Yes	QIS#10670	
Timers: Within Forensic DNA Analysis we have both critical and non-critical timers. Timers that are used to remind staff to return to samples post-denaturation, or during extraction are non-critical (non-critical timers are not listed below). Timers that are used for making a "result" reading on presumptive tests (AP and PSA) are deemed critical. Timers that are deemed critical are checked internally every 6 months against the National Measurement Institute (NMI) WebTimer, they must pass this internal check to be suitable for use (as per QIS#10672)			
200420325 ; Timer 2 , Electronic	Yes	QIS#10672	
200418259 ; Timer 34 , Electronic	Yes	QIS#10672	
200420501 ; Timer 4 , Electronic	Yes	QIS#10672	
200418257 ; Timer 7 , Electronic	Yes	QIS#10672	
200421923 ; Timer 41, Lab Co	Yes	QIS#10672	
200422531 ; Timer 42, Lab Co	Yes	QIS#10672	

☒ * For facilities performing in-house calibrations: please provide a copy of the test method and statement of capability of each in-house calibration identified above.

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SUBCONTRACTING, AGENCY OR FRANCHISING ARRANGEMENTS

Since your previous assessment, does your facility now operate under formal subcontracting, agency or franchising agreement with another organisation which you have not advised NATA of?

☐ Yes

☒ No

Note: While we do not sub-contract out any work from Forensic DNA Analysis to an external group, we do complete small scale commercial work (validations and environmental sample monitoring) for external organisations such as ARUMA.

If yes, please provide details of the arrangement and the principal organisation.

Note: As per *clause 5.3* the laboratory cannot claim conformity with ISO/IEC 17025 for externally provided laboratory activities on an ongoing basis.

TEST REPORTS, SAMPLING REPORTS AND CALIBRATION CERTIFICATES

☒ Please provide an example copy of a recently completed test report and/or sampling report and/or calibration certificate.

Note: Refer to the *General Accreditation Criteria: use of the NATA emblem, NATA endorsement and references to accreditation*, available from the NATA website, for criteria relating to endorsing reports.

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Queensland Government

Forensic and Scientific Services

STATEMENT OF WITNESS

Peer Reviewed.....(Yes)/No

Case Analyst.[redacted]....

Peer Analyst..[redacted]....

Date Issued..23/07/2021.....

Client Reference : [redacted]
Report Number : 6964592

QUEENSLAND)
TO WIT)

I, Allan Russell MCNEVIN, of Brisbane in the State of Queensland, do solemnly and sincerely declare that:-

1. I am employed by Queensland Health Forensic and Scientific Services (QHFSS) at Coopers Plains, Brisbane.
2. I hold the position of scientist in the Forensic DNA Analysis laboratory of QHFSS.
3. I was awarded a Bachelor of Applied Science from Queensland University of Technology.
4. I am a member of the Australian and New Zealand Forensic Science Society.
5. This is my statement in relation to the alleged offence that Occurrence Number [redacted] refers. The defendant in this matter is [redacted] The complainant in this matter is [redacted]

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STATEMENT OF WITNESS Client Reference : [redacted]

6. Laboratory records show that on 8 April 2021, S/CONST BRETT ANTHONY WINNETT delivered the following 17 items:

[redacted]

7. Laboratory records show that on 13 April 2021, STELLA CONDOLEON delivered the following reference sample:

[redacted]

8. Laboratory records show that on 15 April 2021, S/SGT STEPHAN PAUL FOXOVER delivered the following reference sample:

[redacted]

9. The results of the scientific examinations conducted in the laboratory are as follows:

[redacted]

The DNA profile of [redacted] has been determined from the reference sample.

[redacted]

The DNA profile of [redacted] has been determined from the reference sample.

[redacted] **EXH A- DRIED RED STAIN 1CM X 1CM [SWBL] from the vehicle keys in the loungeroom**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

It is estimated that the mixed DNA profile obtained is approximately 14 times more likely to have occurred if [redacted] had not contributed DNA rather than if she had.

[redacted] **- EXH B- DRIED RED STAIN 3CM X 3CM [SWBL] from the checked shirt in the main bedroom**
The mixed DNA profile obtained from this sample indicates the presence of DNA from three contributors. Since this sample is said to have been collected from an item of clothing belonging to [redacted] it would not be unexpected to find DNA which could have come from him.

In order to interpret this mixed DNA profile an assumption of DNA from three contributors, one of whom is [redacted] has been made. The DNA profile of [redacted] has been compared to this mixed DNA profile, to assess whether or not she may have contributed DNA along with [redacted]

Based on statistical analysis, it is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

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STATEMENT OF WITNESS Client Reference : [redacted]

[redacted] **EXH C- DRIED RED STAIN 3CM X 3CM [SWBL] from the checked shirt in the main bedroom**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. Since this sample is said to have been collected from an item of clothing belonging to [redacted], it would not be unexpected to find DNA which could have come from him.

In order to interpret this mixed DNA profile an assumption of DNA from two contributors, one of whom is [redacted] has been made. The DNA profile of [redacted] has been compared to this mixed DNA profile, to assess whether or not she may have contributed DNA along with [redacted]

Based on statistical analysis, it is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] **- EXH K- EXCISED DRIED RED STAIN 2CMX2CM [FABRIC] from the checked shirt in the main bedroom**
The mixed DNA profile obtained from this sample indicates the presence of DNA from three contributors. Since this sample is said to have been collected from an item of clothing belonging to [redacted], it would not be unexpected to find DNA which could have come from him.

In order to interpret this mixed DNA profile an assumption of DNA from three contributors, one of whom is [redacted] has been made. The DNA profile of [redacted] has been compared to this mixed DNA profile, to assess whether or not she may have contributed DNA along with [redacted]

Based on statistical analysis, it is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] **- EXH D- INVISIBLE STAIN [SWBL] from the steering wheel**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

It is estimated that the mixed DNA profile obtained is approximately 16000 times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] **- EXH E- DRIED RED STAIN 1CM X 1CM [SWBL] from the handbrake**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

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STATEMENT OF WITNESS Client Reference : [redacted]

[redacted] can be excluded as having contributed DNA to this mixed DNA profile.

[redacted] **- EXH I- STAIN INVISIBLE [SWBL] From the Iphone case in the loungeroom**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

It is estimated that the mixed DNA profile obtained is approximately 3 times more likely to have occurred if [redacted] had not contributed DNA rather than if she had.

[redacted] **EXH L-EXCISED FABRIC WITH DRIED RED STAIN 1CM X1CM [FABRIC] from the cloth in the drivers side door**
The DNA profile obtained from this sample matches the DNA profile of [redacted]. Based on statistical analysis, it is estimated that the DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

[redacted] **- JB1 - BLOOD SWAB 20CMX2CM DRY RED STAIN [SWBL] on front stairs railing**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

It is estimated that the mixed DNA profile obtained is approximately 1.2 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

[redacted] **- JB2 - BLOOD SWAB 8CMX4CM DRY RED STAIN [SWBL] on lamp on bedside table in front bedroom**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

The results relate solely to the item(s) and/or sample(s) as received. Allan Russell MCNEVIN [redacted] Date 23 July 2021

NATA Accredited Laboratory 41 Accredited for compliance with ISO/IEC 17025 - Testing

[redacted]

ASSESSMENT INFORMATION DOCUMENT

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STATEMENT OF WITNESS Client Reference [redacted]

It is estimated that the mixed DNA profile obtained is approximately 30 times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

[redacted] **- JB3 - BLOOD SWAB 20CMX13CM DRY RED STAIN [SWBL] on right side of doona on bed in front bedroom**

The DNA profile obtained from this sample matches the DNA profile of [redacted] Based on statistical analysis, it is estimated that the DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] **JB4 - BLOOD SWAB 2.5CMX2CM DRY RED STAIN [SWBL] on right side of doona on bed in front bedroom**

The DNA profile obtained from this sample matches the DNA profile of [redacted] Based on statistical analysis, it is estimated that the DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

[redacted] **- JB5 - BLOOD SWAB 1.5CMX2CM DRY RED STAIN [SWBL] on pillow on floor on right side of bed**

The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if he had not.

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] **- JB6 - BLOOD SWAB 2CMX2CM WET RED STAIN [SWBL] on bathroom tile floor**

The DNA profile obtained from this sample matches the DNA profile of [redacted] Based on statistical analysis, it is estimated that the DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

[redacted] **- JB7 - BLOOD SWAB 20CMX4CM DRY RED STAIN [SWBL] on kitchen fridge door**

The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

It is estimated that the mixed DNA profile obtained is approximately 2 times more likely to have occurred if [redacted] had not contributed DNA rather than if he had.

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STATEMENT OF WITNESS Client Reference : [redacted]

[redacted] **- JB9 - BLOOD SWAB 5CM X 3CM DRY RED STAIN [SWBL] on handle of knife**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

It is estimated that the mixed DNA profile obtained is approximately 1100 times more likely to have occurred if [redacted] had not contributed DNA rather than if he had.

[redacted] **- JB10 - BLOOD SWAB 4CM X 2CM DRY RED STAIN [SWBL] on blade of knife**
The mixed DNA profile obtained from this sample indicates the presence of DNA from two contributors. As such, an assumption of two contributors has been made for statistical analysis.

Each of the reference DNA profiles associated to this case has been compared with this mixed DNA profile separately, in order to assess whether or not any of them may have contributed DNA.

Based on statistical analysis, the results are as follows:

It is estimated that the mixed DNA profile obtained is greater than 100 billion times more likely to have occurred if [redacted] had contributed DNA rather than if she had not.

It is estimated that the mixed DNA profile obtained is approximately 580 million times more likely to have occurred if [redacted] had not contributed DNA rather than if he had.

The results relate solely to the item(s) and/or sample(s) as received. Allan Russell MCNEVIN [redacted] Date 23 July 2021

NATA Accredited Laboratory 41 Accredited for compliance with ISO/IEC 17025 - Testing

[redacted]

APPENDIX

Procedural and technical overview of DNA profiling at Forensic DNA Analysis, Forensic and Scientific Services

Forensic Biologist

It is a forensic biologist's role to:

1. Report on the examination of items submitted in relation to a case for the presence of possible biological material. If identified, a sample of the biological material is analysed in an attempt to obtain a DNA profile.

2. Report on the DNA profiles obtained from samples submitted by the Queensland Police Service (QPS) in relation to a case.

Any DNA profiles that are obtained from these samples are compared with the DNA profile obtained from an individual's reference sample to assess whether or not the individual may be a contributor of DNA. Where multiple reference DNA profiles are analysed for a case, they are all genetically different to each other unless otherwise specified. That is, they all possess differing allelic designations – see the *DNA Profiling* section below.

Examinations

Unless otherwise stated, the examinations of items for biological material were conducted by staff within the QPS. Sub-samples from these items were forwarded to Forensic and Scientific Services (FSS), for the purposes of conducting DNA analysis.

The descriptions of items and/or samples submitted to Forensic DNA Analysis by the QPS, and listed within this Statement, are derived from the descriptions entered by the QPS into the Forensic Register.

Receipt details are listed for items reported in this statement, including reference samples where relevant. The period of testing on these items is from the date of the first submission, to the date of this Statement. Details of specific dates of testing are retained within the Laboratory Information Management System (LIMS). Where relevant, any items that are still in progress at the time of issuing this Statement are identified and final results will be reported in an addendum Statement.

Forensic DNA Analysis operates under the agreement that the QPS are responsible for item prioritisation, sample selection, selection of screening/sampling methods, anti-contamination procedures and the application of Standard Operating Procedures (SOPs) on work undertaken on the items/samples prior to submission to the Forensic DNA Analysis laboratory. As such, forensic biologists may not be able to provide information or opinion on possible biological origin of DNA profiles that may be obtained from these samples.

At the discretion of the QPS, some items may be submitted to this laboratory for the purposes of both examination and DNA profiling. These examinations are performed in accordance with the SOPs of this laboratory. For these items, contemporaneous notes are made during the examination by the examining scientist and these notes form part of the casefile.

Forensic DNA Analysis casefiles and any samples remaining are available for independent examination and / or testing upon request.

As a representative of the laboratory, I am only able to comment on the processes performed within Forensic DNA Analysis.

STATEMENT OF WITNESS Client Reference [redacted]

Chain of Custody

All Forensic DNA Analysis case files and exhibits are electronically tracked, monitored, and securely stored to ensure that appropriate chain of custody and continuity measures are maintained. The QPS case number and sample submission information is provided from the QPS via an electronic interface to FSS, and this information is cross-checked against labelling on the exhibit packaging prior to processing.

Entry into Forensic DNA Analysis is restricted to authorised persons only, via electronic proximity access cards. Forensic DNA Analysis forms part of a Queensland Health campus site wherein access is controlled and monitored by a security team. Records of visitors to Forensic DNA Analysis are retained.

Accreditation

Forensic DNA Analysis first achieved accreditation by the National Association of Testing Authorities (NATA) to conduct forensic DNA analyses in 1998, and has continuously maintained NATA accreditation since this date. NATA ensures continued compliance with the accreditation requirements through routine reassessment (every 3 years) and an intermediate surveillance visit (at approximately 18 months between reassessment surveys).

NATA accredited facilities are assessed against best international practices based on the ISO/IEC 17025 standard. Laboratories are deemed able to competently perform testing and analysis activities if the laboratory demonstrates that it meets compliance with the standard within the scope of their accreditation.

The parameters assessed during accreditation include:

- Organisation and management
- Quality management system
- Personnel
- Evidence management
- Methods and procedures
- Quality control and Proficiency Testing
- Equipment
- Reporting of results
- Procurement of services and supplies
- Accommodation and safety
- Security and access

For details of the current ISO/IEC 17025 Standard, refer to *Standards Australia*.

http://www.nata.com.au

DNA Profiling

Deoxyribonucleic acid (DNA) is a complex chemical found in almost all cells of the human body. It carries genetic information that determines the physical and chemical characteristics of a person. Forensic DNA Analysis uses two main systems for the generation of DNA profiling results. In this case, the PowerPlex® 21 System was used, which examines 21 regions (loci) of DNA, 20 of which contain highly variable short tandem repeats (STRs). The 21st region gives an indication as to the genotypic sex of the donor (for details see Table 1). The generation of a DNA profile involves a method known as the polymerase chain reaction (PCR), which is used to produce numerous copies of these specific regions of the DNA. In this way, minimal amounts of DNA isolated from small or degraded samples can be increased to a level where the DNA can be detected, profiled, and compared with DNA profiles from other samples.

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STATEMENT OF WITNESS Client Reference : [redacted]

The individual components (alleles) of a DNA profile are represented by a series of peaks on a graph that are measured and given a designation, using standard sizing ladders. A person will have two alleles (represented graphically as peaks) for each locus, one inherited from the biological mother and one inherited from the biological father. However, if the same allele is inherited from both parents, only one peak will be graphically represented at that locus.

A DNA profile obtained from biological material such as blood, semen, saliva, hair or cellular material (eg. touch DNA) can be compared with the DNA profile obtained from the reference sample from any person.

Table 1: PowerPlex® 21 system, list of loci

Abbreviated Name	Scientific Name	Chromosomal Name
Amel	AMELOGENIN	Sex (X and Y)
D3	D3S1358	3
D1	D1S1656	1
D6	D6S1043	6
D13	D13S317	13
Penta E	Penta E	15
D16	D16S539	16
D18	D18S51	18
D2	D2S1338	2
CSF	CSF1PO	5
Penta D	Penta D	21
TH01	TH01	11
vWA	HUMVWAFA31/A	12
D21	D21S11	21
D7	D7S820	7
D5	D5S818	5
TPOX	TPOX	2
D8	D8S1179	8
D12	D12S391	12
D19	D19S433	19
FGA	HUMFIBRA	4

Statistical Analysis of DNA Profiles

STRmix™ is an expert statistical DNA profile analysis system developed and validated in Australia and New Zealand. Forensic DNA Analysis uses the STRmix™ software to assist in the interpretation of DNA profiles and the calculation of likelihood ratios for DNA profiles generated using the PowerPlex® 21 system.

DNA profiles are initially assessed to determine the number of contributors. This value will be the minimum number of people that are required to reasonably explain the observed profile, however, it is noted that there is always the possibility that the profile is a result of a different number of contributors.

As such, if there is no indication of a contribution by more than one person, then a DNA profile is described as being from a "single contributor". If less than 40 alleles are present in a DNA profile, this is referred to as a "partial" or "incomplete" DNA profile. If there are indications of two or more contributors, then a DNA profile is described as being a "mixed" DNA profile.

STATEMENT OF WITNESS Client Reference : [redacted]

DNA Profiles Assumed To Originate From One Person (Single Source)

A person can be excluded as a possible source of the biological material if the alleles of the crime-scene DNA profile are different from the corresponding alleles of the person's reference DNA profile. If the corresponding alleles of the crime-scene DNA profile contain the same information, then that person, along with any other person who has the same corresponding alleles as the crime-scene DNA profile, can be considered as a potential contributor of the DNA.

The evidential significance of such a finding is assessed by considering two competing propositions:

Proposition 1: The crime-scene DNA originated from the person of interest.

Proposition 2: The crime-scene DNA originated from someone other than, and unrelated to, the person of interest.

The resultant figure (termed the 'Likelihood Ratio') compares the two opposing propositions. The likelihood ratio describes how likely the DNA profile obtained from the biological material is to have occurred if Proposition 1 were true (the DNA originated from the person of interest) rather than if Proposition 2 were true (the DNA originated from someone other than, and unrelated to, the person of interest).

The likelihood ratio is calculated by taking into account the characteristics of the DNA profile and the frequency of occurrence of the individual alleles that make up the DNA profile.

If less than the 20 STR regions of DNA are observed in a DNA profile, the likelihood ratio will be smaller than the likelihood ratio calculated for a full DNA profile obtained from the same individual. In other words, the more incomplete a DNA profile is, the greater the likelihood that the obtained DNA profile could have come from someone other than, and unrelated to the person of interest.

DNA Profiles Assumed To Originate From More Than One Person (Mixed DNA Profiles)

In order to assess whether a person may or may not have contributed to a mixed DNA profile, a set of competing propositions (similar to the single source DNA profile example) are considered. For example, for a two-person mixture:

Proposition 1: The crime-scene DNA originated from the person of interest and an unknown person, unrelated to the person of interest.

Proposition 2: The crime-scene DNA originated from two unknown people, both unrelated to the person of interest.

The likelihood ratio provides a statistical assessment of the possibility that the DNA profile obtained was the result of a DNA contribution by the person of interest.

The likelihood ratio will not always favour Proposition 1 (the DNA originated from the person of interest and an unknown person unrelated to the person of interest). The likelihood ratio could favour Proposition 2 (the DNA originated from two unknown people unrelated to the person of interest).

In certain circumstances, if the ownership of an item is established or if the sample was collected from an identified person's body, then it is possible to make the reasonable assumption that the identified person has contributed DNA to the resultant mixed DNA profile. In these cases, a mixed DNA profile can be 'conditioned' on the DNA profile of the assumed contributor, such that the presence of the alleles corresponding with the assumed contributor's reference DNA profile can be factored into the statistical interpretation. This may facilitate a more meaningful statistical analysis of potential second and/or third contributors to the DNA profile. In this situation, the likelihood ratio is based on the following propositions:

STATEMENT OF WITNESS Client Reference : [redacted]

Proposition 1: the DNA has originated from the assumed contributor and the person of interest.

Proposition 2: the DNA has originated from the assumed contributor and an unknown individual, unrelated to the person of interest.

DNA profiles with an uncertain number of contributors

Forensic DNA Analysis is currently validated for the interpretation of DNA profiles with 1-4 contributors. Once the assessment of the number of contributors has been made, this information is used in the STRmix™ analysis.

When a DNA profile is deemed unsuitable for interpretation it may be described as 'complex'. This can occur under the following circumstances:

- When a DNA profile could have a large number of contributors and therefore it is difficult to exclude individuals and/or determine whether a person could be a potential contributor to the DNA profile
- When there is very limited information available and/or the quality of the profile is poor.

It is important to note that should further information be received that renders the assumptions used in an analysis invalid, the DNA profile will require additional statistical interpretation.

Datasets Used in Statistical Analyses

Three validated datasets consisting of DNA profiles obtained from individuals of the Australian Caucasian, Aboriginal, and South-East Asian populations are used to calculate the likelihood ratio. A population correction factor, θ (theta), is applied to all likelihood ratio calculations in order to correct for the common genetic ancestry of people within a particular population (sharing of DNA components inherited from a common ancestor). In Forensic DNA Analysis, a likelihood ratio that represents a stratified population statistic is reported irrespective of whether the DNA profile of interest is single source or a mixed DNA profile.

The likelihood ratio is calculated using all three datasets and the relative proportions of each ethnic grouping in the overall Australian population based on data sourced from the Australian Bureau of Statistics. This calculation, which is known as stratification, allows for the possibility that a random unknown person, unrelated to the person of interest, from anywhere in Australia could have contributed to the DNA profile obtained. Therefore, the likelihood ratio is not dependent on the ethnicity of the person of interest, but it is representative of the relative proportion of the person of interest's ethnic population within the larger Australian population.

Theta cannot account for close blood relatives. Closely related people, such as siblings, will have a greater chance of sharing similar components within their DNA profiles. However, due to the nature of parental DNA recombination during conception, the probability that two siblings would share the same 40 alleles would be very small. As this relationship becomes more distant, the probability of two relatives having the same DNA profile becomes smaller still. If it were thought that a close blood relative might have been a contributor of DNA, the most meaningful approach to interpretation would be to submit the reference sample from the relative in question for DNA analysis and subsequent direct comparison to the crime-scene DNA profile.

Often the calculated likelihood ratio produces numbers of thousands (1000s) or even millions (1000,000s) of billions. To avoid the use of potentially confusing mathematical terminology, a "ceiling figure" for the likelihood ratio of 100 billion is used (this is called "truncation"). For example, a calculated likelihood ratio of "150 000 billion times more likely", would be reported as "greater than 100 billion times more likely". The actual calculated figure can be provided upon request.

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Touch DNA / Transfer of DNA

When a person touches a surface, it is possible for their DNA to be transferred onto that surface. This transferred DNA can often be recovered (sampled) by a swab, tape lift, or excision depending upon the nature of the surface in question, and the sample can then be subjected to DNA profiling.

This transferred DNA can originate from cells or cellular material within sweat and/or oils on the skin. The generation of a DNA profile will depend on many factors. These include the amount of DNA transferred, the nature of the surface being touched, and the amount of genetic material available for transfer. The persistence of any transferred genetic material to a surface will depend largely upon the nature of the surface and the conditions the surface has been subjected to in the time between deposition and recovery of the DNA. For example, DNA could be lost from the surface by washing or mechanical action such as abrasion.

It therefore follows that the inability to obtain a DNA profile from a touched surface does not necessarily mean that a person has not had contact with the surface. It is possible for a person to contact a surface without a detectable amount of their DNA being transferred or subsequently recovered for analysis.

JUSTICES ACT 1886

I acknowledge by virtue of Section 110A (6C) (c) of the Justices Act 1886 that:

(i) This written statement by me dated 23 July 2021 and contained in the pages numbered 1 to 12 is true to the best of my knowledge and belief; and

(ii) I make it knowing that, I would be liable to prosecution for stating anything that I know is false.

..... [redacted] .....

Allan Russell MCNEVIN

Signed at BRISBANE on 23 July 2021

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 41 Site No: 14171 Job No: 82214

PROCEDURES

☒ Please provide a list and copy of all non-standard test or calibration or inspection procedures (including in-house procedures) covered by the scope of accreditation.

Major Equipment Documents:
#10670 Procedure for Thermometer Checks
#10672 The Verification of Timing Devices
#26628 Verifications using the ARTEL MVS
#31956 Verifications using the ARTEL PCS Pipette Calibration System
#33315 Procedure for Verification and Maintenance of Equipment

Major Forensic DNA Analysis procedures:
#17091 Organisation and Management in Forensic DNA Analysis
#17117 Procedure for Case management
#17146 Internal Security and Access to Forensic DNA Analysis
#17154 Procedure for Quality Practice in Forensic DNA Analysis
#22871 Procedure for Change Management in Forensic DNA Analysis
#28801 DNA Analysis Unit Management Review template
#30800 Investigating Adverse Events in Forensic DNA Analysis
#33773 Procedure for Profile Data Analysis using the Forensic Register
#33800 Examination of Items
#34006 Procedure for the release of results using the Forensic Register
#34035 Forensic Register FTA Processing
#34229 Explanations of Exhibit Results for FR
#34245 Reference Sample Result Management
#34247 Creating and Reviewing Links - FR
#34281 Procedure for the Use and Maintenance of the Forensic DNA Analysis Elimination Databases

Additional minor documents can be provided on request

☒ Please provide an example of an estimation of measurement uncertainty (MU) and a list of the procedures for which MU estimates have been made.

Documents:
#10670 Procedure for Thermometer Checks
#10672 The Verification of Timing Devices

Changes to least uncertainties of measurement:

☒ Not applicable. There are no changes to least uncertainties of measurement.

☐ If there are changes to least uncertainties of measurement, provide uncertainty calculations and supporting data for their derivation.

Note: Changes to calibration and measurement capability (CMC) may be considered as additions to the scope of accreditation. Please complete the Application for changes to the scope of accreditation form available from the NATA website.

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WORKPLACE HEALTH & SAFETY

Assessments are conducted by a team comprising of NATA staff and voluntary technical assessors. This team will need to attend your premises to have discussions with your staff and to observe activities covered by your scope of accreditation being performed.

To prepare for the assessment and to ensure the health and safety of the assessment team while on-site (including any field work), please respond to the following:

General issues

Issue	Yes	No
Have relevant WHS requirements been implemented, including provision of appropriate amenities for the NATA assessment team (e.g. washrooms, potable water supply)?	☒	☐
Does your facility, or a site to be visited, have a company alcohol and testing policy which the NATA assessment team would be subject to? **If yes, please attach a copy of the policy.**	☐	☒
In response to the COVID-19 pandemic		
Does your facility comply with government guidelines pertaining to social distancing in addition to other provisions such as hand sanitation facilities and visitor register (to allow for contact tracing)?	☒	☐
Can your facility provide COVID-19 PPE, as required?	☒	☐
Will the assessment team be subject to additional measures to those of relevant health directives relating to COVID? **If yes, please provide detail in the space below or on a separate sheet.**	☐	☒
Additional measures:		

Specific hazards

Location	Hazard	Precaution
e.g. Abattoir *e.g. Radiography laboratory*	*Q Fever* *Radiation*	*Vaccination required* *Film badge*
All laboratory areas	Contaminations of exhibits	PPE required
All laboratory areas	Standard chemical use	PPE required
All laboratory areas	Biological hazard	PPE required

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MANAGEMENT SYSTEM

☒ Please provide a copy of your facility's current management system documentation and any associated management system procedures.

Refer to document #19259 – FSS Quality Management System Guide
Additional documents can be provided on request.

ISO/IEC 17025:2017 requires the facility to implement a management system in accordance with either Option A or Option B.

Option A requires clauses 8.2 to 8.9 of the Standard to be addressed.

Option B requires that a management system to be implemented in accordance with ISO 9001.

Your facility has established a management system in accordance with which option of the standard?

☒ Option A
☐ Option B

If the management system established is in accordance with Option A, it will be assessed against clauses 8.2 to 8.9 of the Standard.

If the management system established is in accordance with Option B, the records to be reviewed on-site by the NATA Lead Assessor may be reduced subject to the following:

1) the management system is certified by a certification body (CB) accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA);

2) the CB's accreditation covers ISO/IEC 17021 Parts 1 and 3. If Part 3 is not specifically listed in the CB's scope of accreditation, then it must be clear that its accreditation covers the certification of Quality Management Systems (QMS) to ISO 9001 (which may be included in the scope of accreditation or other documentation provided by the accreditation body signatory to the IAF MLA);

3) copies of the most recent certification audit report(s) issued by the CB covering your facility's management system in full is (are) provided to NATA;

4) confirmation from the CB of the close out of any non-conformities raised during certification audits is provided to NATA;

5) the certification of the management system covers the laboratory activities proposed to be covered by your NATA scope of accreditation.

Evidence in support of 1) to 5) is requested to be submitted with a copy of your facility's management system documentation. The latter is required to allow the assessment team to familiarise itself with your system. The records to be reviewed on-site will be dependent on the extent of the evidence provided and the extent of the audits performed by the CB.

Should evidence

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	supporting points 1) to 5) not be provided, NATA will assess your management system in accordance with Option A (i.e. clauses 8.2 to 8.9 of the Standard).

CA-46

Queensland Government
Queensland Health

EXTENDED INTERNAL PROSPECTIVE VALIDATION OF THE ABI PRISM®7000/ QUANTIFILER SYSTEM

Vojtech HLINKA, Iman MUHARAM, and Cathie ALLEN

20th of July, 2006

Queensland Government
Queensland Health

Extended Internal Prospective Validation of the ABI Prism® 7000/Quantifiler System (Forensic Biology)

Vojtech HLINKA, Iman MUHARAM, and Cathie ALLEN

20th of July, 2006

1 TABLES

Table 1: Table of contents.

Table 2: List of figures

Table 3: List of tables.

Table 4: Table of terms and abbreviations.

Term/abbreviation	Definition
EPC	External positive control. The control utilised was AmpℓFSTR Control DNA 9947A. This consists of 0.10ng/μL of human cell line DNA in 0.05%NaN_3 and buffer (Applied Biosystems 1997:1-7).
Promega female control (Promega Human Genomic DNA female control)	Control produced from Human Genomic DNA, Female. Part No. G152A Size 100μg. Each lot number varies in concentration.
Promega male control (Promega Human Genomic DNA Male control)	Control produced from Human Genomic DNA, Male. Part No. G147A. Size 100μg. Each lot number varies in concentration. It is typically diluted to a high concentration of 1ng/μL and a low concentration of 0.1ng/μL.
Promega Male Standard (Promega Human Genomic DNA Male Standard)	Standard produced by a serial dilution from Promega Human Genomic DNA, Male. Part No. G147A. Size 100μg. The known concentration values (see table 14) are used to estimate unknown concentrations.
Quantifiler Standard	Standard produced by a serial dilution from 200ng/μL of ABI's Quantifiler Human DNA Standard. It is produced from the human cell line 9947A and the known concentration values (see table 14) are used to estimate unknown concentrations.
Roche Standard	Standard produced by a serial dilution from 200ng/μL Human Genomic DNA from Roche (Cat. No. 1691 112)

2 PURPOSE

The purpose of this document is to provide information regarding the internal prospective extended validation of the integrated ABI Prism® 7000 Sequence Detection System (SDS) and the Quantifiler Human DNA Quantitation Kit System (Quantifiler) and its use within Forensic Biology. It is a prospective validation given that this document focuses on the validation of modifications such as the use of Promega Human Genomic DNA Male as the run standard (Promega Male Standard). It is an additional document to the original internal validation of the Quantifiler System by Forensic Biology at Queensland Health Scientific Services (QHSS) (Ientile *et al.* 2004), the internal retrospective validation of the Quantifiler System by QHSS (Hlinka *et al.* 2006), and the developmental validation performed and published by Applied Biosystems (ABI) in 2003.

3 SCOPE

Validation is intended to demonstrate (according to QIS 10663R2):

(a) That the method is technically sound and appropriate for the purpose to which it is to be applied.
(b) Variations to the method are technically justified and supported by documented evidence.
(c) Limitations associated with the method.

Validation also requires that the following are fit for the purpose before they are used by the laboratory to generate results [as outlined in QIS (23401R0)]:

(a) test methods.
(b) processes.
(c) computer systems/information management systems.
(d) laboratory equipment.

4 BACKGROUND

The internal extended validation of the ABI Prism® 7000/Quantifiler System was conducted as a prospective validation because the revisions to the protocol affect the results produced and this required validation before the changes were implemented. Revisions made include

(a) Introducing the Promega Male Standard as a replacement for the Quantifiler standard given that its use will ensure that Quantifiler nanograms will be more consistent with real nanograms. In other words the ng/μL concentration of DNA samples as determined by Quantifiler will be more representative of the actual values.
(b) The use of single rather than duplicate reactions for each sample being tested.

4.1 HOW DOES QUANTIFILER QUANTITATE DNA?

The ABI 7000/Quantifiler real-time PCR system (Quantifiler system) detects and measures a fluorescent signal that increases during PCR. This fluorescent signal is known as the normalised reporter signal (Rn) and is "the emission intensity of the reporter dye divided by the emission intensity of the passive reference dye measured in each cycle" (QIAGEN 2004:12). The main measurement obtained for each sample on a run is a threshold cycle (C_t) or CT value. This is a cycle number value at which the fluorescent signal crosses the value of the threshold setting (see figure 1). The CT value depends on the amount of starting template and the efficiency of the system.

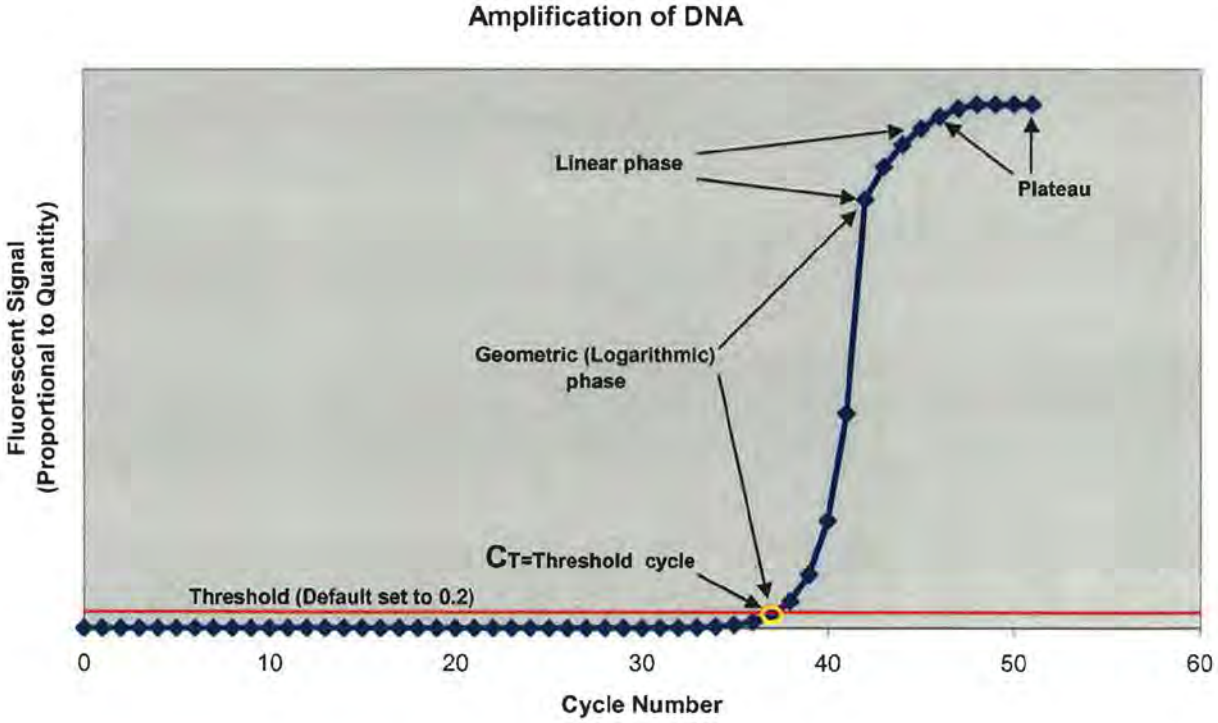

Figure 1: Amplification of DNA during real-time PCR. The cycle at which the fluorescent signal crosses the set threshold is the threshold cycle (CT). Note the different phases of an amplification plot.

In the Quantifiler system it is assumed that because the amplicons are designed and optimised for efficiencies approaching 100%, that the efficiency can be assumed to equal 100% (Applied Biosystems 2003:1-14). In theory, a difference between two samples of one CT equals a two-fold increase in initial template amount. The three-fold concentration increase from standard 8 through to standard 1 found in the Quantifiler standards (see table 14) should therefore have CT differences equal to one and a half.

In the Quantifiler system a CT value from a sample of unknown quantity is compared to CT values obtained from standard samples of known concentration. A series of standards for absolute quantitation is run on each plate. QIAGEN (2004:13) state that it is common for at least five

different concentrations to be used to generate a standard curve. The samples of unknown quantity have the same master mix as the samples of known quantity that are being quantified. Quantifiler has eight standards that are made up from one vial by serial dilution. The final concentrations are approximately 50ng/μL for STD1, 16.67ng/μL for STD2, 5.56ng/μL for STD3, 1.85ng/μL for STD4, 0.62ng/μL for STD5, 0.21ng/μL for STD6, 0.069ng/μL for STD7, and 0.022ng/μL for STD8. The CTs produced from the standards on a run should be in the geometric (logarithmic) phase of amplification and are graphed on a logarithmic graph (see figure 2). A regression line is produced by calculating a line of best fit through the data points produced by the standard. A regression line is only accepted if the closeness of fit between the standard curve regression line and individual CT data points of the standards is high. The closeness of fit is measured by the coefficient of determination in linear regression (R^2 value) where 1.00 indicates a perfect fit. A value above 0.98 is deemed acceptable. The standard regression line formula is then utilised to work out Quantifiler values of samples of unknown concentration based on the CT values obtained given a specific slope and Y-intercept. The formula for the regression line is y=mx + c where m is the slope and c is the Y-intercept when x = 0. X is equal to the log of the Quantifiler value and y equals the CT value. The Y-intercept is defined as the CT value when x=0. Therefore, CT value of the Y-intercept corresponds to where the Quantifiler value is 1ng/μL since the $\log_{10}(1)=0$. In summary, the regression line formula (CT={Slope x Log_{10}(Quantifiler Value)}+ Yintercept) used to work out Quantifiler values can be re-written as

$$\text{Quantifiler Value}=10^{(\{\text{CT-Yintercept}\}/\text{Slope})}$$

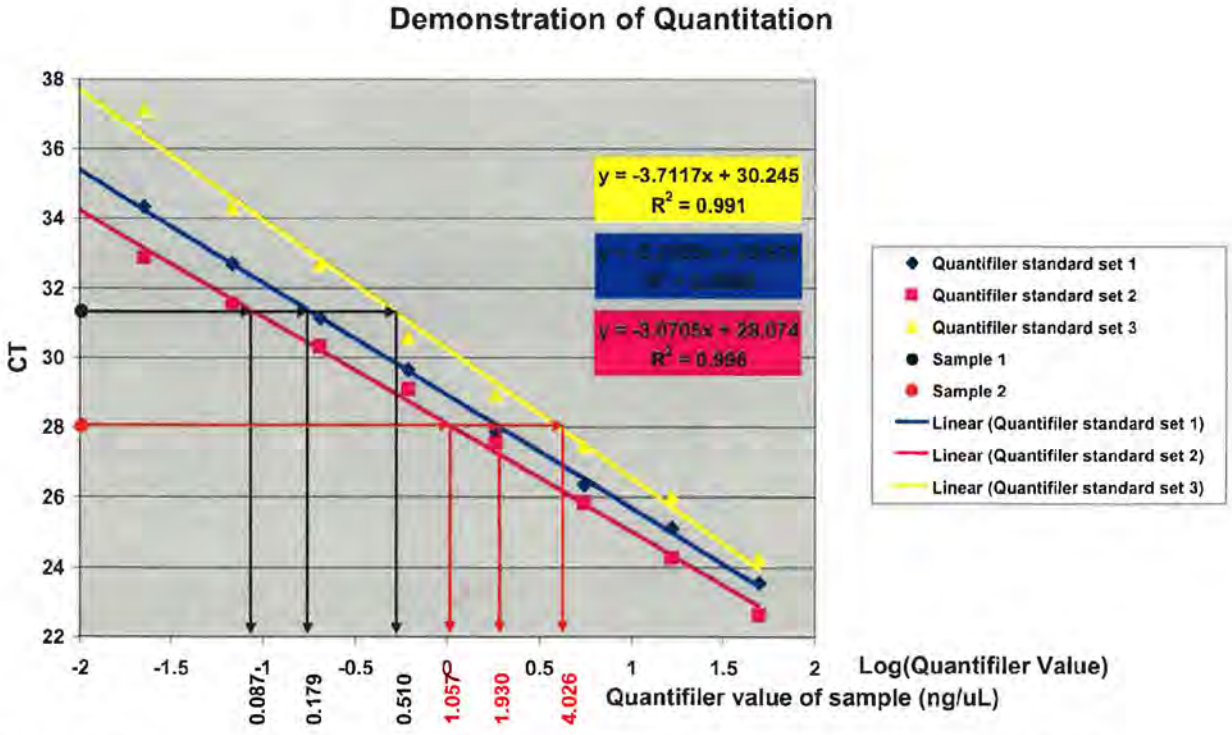

Figure 2: Demonstration of Quantitation. A single CT value can have a number of different Quantifiler values depending on where the Quantifiler standard lies.

In a similar way that a CT can give multiple Quantifiler values given the slope and Y-intercept conditions, the reverse is also true. A single Quantifiler value across different slope and Y-intercept conditions will theoretically give a variety of different CT values, but should also consistently give the same value under the same conditions when the system is quantifying accurately. This is demonstrated in tables 5 and 6.

Table 5: Ideal CT values for 0.1ng/μL under different slope and y-intercept values.

CT Values										
Quant value=0.1ng/μL	Slope									
Y-Intercept	-3.6	-3.5	-3.4	-3.3	-3.2	-3.1	-3.0	-2.9	-2.8	-2.7
30.0	33.6	33.5	33.4	33.3	33.2	33.1	33.0	32.9	32.8	32.7
29.9	33.5	33.4	33.3	33.2	33.1	33.0	32.9	32.8	32.7	32.6
29.8	33.4	33.3	33.2	33.1	33.0	32.9	32.8	32.7	32.6	32.5
29.7	33.3	33.2	33.1	33.0	32.9	32.8	32.7	32.6	32.5	32.4
29.6	33.2	33.1	33.0	32.9	32.8	32.7	32.6	32.5	32.4	32.3
29.5	33.1	33.0	32.9	32.8	32.7	32.6	32.5	32.4	32.3	32.2
29.4	33.0	32.9	32.8	32.7	32.6	32.5	32.4	32.3	32.2	32.1
29.3	32.9	32.8	32.7	32.6	32.5	32.4	32.3	32.2	32.1	32.0
29.2	32.8	32.7	32.6	32.5	32.4	32.3	32.2	32.1	32.0	31.9
29.1	32.7	32.6	32.5	32.4	32.3	32.2	32.1	32.0	31.9	31.8
29.0	32.6	32.5	32.4	32.3	32.2	32.1	32.0	31.9	31.8	31.7
28.9	32.5	32.4	32.3	32.2	32.1	32.0	31.9	31.8	31.7	31.6
28.8	32.4	32.3	32.2	32.1	32.0	31.9	31.8	31.7	31.6	31.5
28.7	32.3	32.2	32.1	32.0	31.9	31.8	31.7	31.6	31.5	31.4
28.6	32.2	32.1	32.0	31.9	31.8	31.7	31.6	31.5	31.4	31.3
28.5	32.1	32.0	31.9	31.8	31.7	31.6	31.5	31.4	31.3	31.2
28.4	32.0	31.9	31.8	31.7	31.6	31.5	31.4	31.3	31.2	31.1
28.3	31.9	31.8	31.7	31.6	31.5	31.4	31.3	31.2	31.1	31.0
28.2	31.8	31.7	31.6	31.5	31.4	31.3	31.2	31.1	31.0	30.9
28.1	31.7	31.6	31.5	31.4	31.3	31.2	31.1	31.0	30.9	30.8
28.0	31.6	31.5	31.4	31.3	31.2	31.1	31.0	30.9	30.8	30.7

Table 6: Ideal CT values for 1.0ng/μL under different slope and y-intercept values.

CT Values										
Quant value=1.0ng/μL	Slope									
Y-Intercept	-3.6	-3.5	-3.4	-3.3	-3.2	-3.1	-3.0	-2.9	-2.8	-2.7
30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
29.9	29.9	29.9	29.9	29.9	29.9	29.9	29.9	29.9	29.9	29.9
29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8
29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7
29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6
29.5	29.5	29.5	29.5	29.5	29.5	29.5	29.5	29.5	29.5	29.5
29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4
29.3	29.3	29.3	29.3	29.3	29.3	29.3	29.3	29.3	29.3	29.3
29.2	29.2	29.2	29.2	29.2	29.2	29.2	29.2	29.2	29.2	29.2
29.1	29.1	29.1	29.1	29.1	29.1	29.1	29.1	29.1	29.1	29.1
29.0	29.0	29.0	29.0	29.0	29.0	29.0	29.0	29.0	29.0	29.0
28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9
28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8
28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7
28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
28.5	28.5	28.5	28.5	28.5	28.5	28.5	28.5	28.5	28.5	28.5
28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4
28.3	28.3	28.3	28.3	28.3	28.3	28.3	28.3	28.3	28.3	28.3
28.2	28.2	28.2	28.2	28.2	28.2	28.2	28.2	28.2	28.2	28.2
28.1	28.1	28.1	28.1	28.1	28.1	28.1	28.1	28.1	28.1	28.1
28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0

The slope of a standard curve is an indication of PCR reaction efficiency. At a slope of –3.322 the PCR has an efficiency of 100% (Applied Biosystems 2003). A lower slope (more negative number e.g. –3.55) is indicative of reduced efficiency while a higher slope (more positive number e.g. –2.9) is indicative of efficiency appearing greater than 100% (QIAGEN 2004:13). Due to experimental limitations most standard slopes do not reach 100% efficiency (QIAGEN 2004:13). Values greater than 100% can occur when samples are measured in the non-linear phase of the logarithmic graph or in the presence of inhibitors (QIAGEN 2004:13). To ensure a slope is valid, QIAGEN (2004:13) set the ideal range for the value between –3.3 and –3.8. However, ABI state a typical slope should be between –2.9 and –3.3 with an average of –3.1 (Applied Biosystems 2003:5-5). According to Pfaffl (2004:11), a typical slope will only vary by 2-3% on repeated runs of the same standard, while the Y-intercept will vary by about 10%. As a result the Y-intercept is harder to replicate (Pfaffl 2004:11). At maximum, the same standard producing an average slope of –3.1 would vary from –3.007 to –3.193 on different runs by applying a 3% variance. A detection of a two-fold difference over a range of target concentrations was observed as a result of standard curve correlation with samples of unknown quantity (Pfaffl 2004:11, Rasmussen 2001).

5 METHOD VALIDATION

The two types of method validation were as follows

a. Developmental Validation
This was an independent external validation presented in Applied Biosystems (2003) but later published by Green *et. al.* 2005 in a peer-reviewed journal. The 2005 publication concluded that the Quantifiler system is accurate, precise and reproducible.

b. Internal Validation
The original internal QHSS validation of Quantifiler in June, 2004, concluded that an actual concentration of 1ng of template was suitable for Profiler and COfiler amplifications. In the third quarter of 2004 there was a high rate of reworks and this was investigated. After a detailed review in January, 2005, of results from the use of controls and alternative standards, the amount of DNA template used for amplifications was increased from 1 Quantifiler nanogram to 2 Quantifiler nanograms which was still within the ABI recommended range of 1 to 2.5 nanograms for Profiler and COfiler. A positive control was now introduced in each Quantifiler run for quality assurance purposes. After the discovery that Quantifiler inaccuracy is largely due to differences in the concentration of standards, two approaches were taken. The first approach was the introduction of testing and validating each Quantifiler standard as it was made up for use. The second approach focused on the validation of standards other than the supplied Quantifiler standards.

5.1 RECOMMENDED RANGES FOR USING THE PROMEGA MALE STANDARD

The expected ranges for the Promega Male Standard were determined by making up and testing nine sets of the standards. Five standards were tested on the 1.8.2005 and four were tested on the 4.3.2006. The results from the nine standards are presented in table 7. These were used to calculate the recommended acceptability criteria presented in table 8. Data analysis indicated that the closer the y-intercept is to the mean, the more accurate the result. A y-intercept within one standard deviation will therefore provide more accurate results than a y-intercept within two standard deviations. We recommend that when a standard is made, then when it is tested, the result for the y-intercept should be within the one standard deviation before it is utilised for the quantitation of samples. Allowing for natural variation, two standard deviations for the y-intercept are acceptable for normal Quantifiler runs. Once the standard regularly comes up at between the maximum one standard deviation (28.189706) and two standard deviation y-intercept values (28.367930), the standard will typically have degraded due to regular usage and a new standard should be made and tested. While a typical Quantifiler standard from the kit has a recommended lifetime of about two weeks, it appears that the Promega Male Standard has a longer lifetime. One Promega Male Standard made on the 1.8.2005 (Standard B) was within the one standard deviation originally when tested on the 1.8.2005. However, after being used on several Quantifiler runs, it was re-used on the 21.4.2006. Therefore, at 7 months and 3 weeks of age it still produced y-intercept results within two standard deviations. This indicates that the Promega Male Standard can be stored at 4 degrees Celsius for up to approximately 6 months after being made without being used, and still produce results within two standard deviations. However, for increased accuracy, it is recommended that the standards that have passed the slope, y-intercept and R^2 criteria are stored at 4 degrees Celsius, while the y-intercept is still within the one standard deviation.

Table 7: Typical Promega Male Standard distribution. Slope, y-intercept and r2 values of nine different standards are provided as a guide to what should be expected.

Plate ID	Standard	Slope	Y-Intercept	R2
Testquant_010805	A	-3.116899	28.225719	0.993405
Testquant_010805	B	-3.004052	27.912193	0.995207
Testquant_010805	C	-2.996166	27.794958	0.997555
Testquant_010805	D	-2.942776	27.823851	0.995839
Testquant_010805	E	-3.089615	27.913212	0.998925
Testquant_040306_PromSTD	A	-3.053439	28.287077	0.99683
Testquant_040306_PromSTD	B	-3.181063	28.177837	0.998396
Testquant_040306_PromSTD	C	-3.031986	28.01162	0.998955
Testquant_040306_PromSTD	D	-2.963965	27.956869	0.993889
	Mean	-3.042218	28.011482	0.996556
	Standard Deviation (StdDev)	0.076585	0.178224	0.002098
	Minimum at 1 StdDev		27.833258	
	Maximum at 1 StdDev		28.189706	
	CT difference at 1 standard deviations		0.356448	
	Minimum at 2 StdDev		27.655034	
	Maximum at 2 StdDev		28.367930	
	CT difference at 2 standard deviations		0.712896	

Table 8: Acceptable ranges for the Promega Male Standard. When a Promega Male Standard is made and used the following guidelines should be utilised. The y-intercept should be in the one standard deviation when a standard is made-up and tested for suitability. Under normal run conditions a Y-intercept of two standard deviations is acceptable for general use.

	Minimum Value	Maximum Value	Acceptance Purpose
Slope	-3.3	-2.9	Runs and standards
Y-Intercept (1 Standard Deviation)	27.833258	28.189706	Standards
Y-Intercept (2 Standard Deviation)	27.655034	28.367930	Runs
R2	>0.98		Runs and standards

5.2 ASSESSMENT OF ACCURACY/TRUENESS, BIAS, AND PRECISION (REPEATABILITY AND REPRODUCIBILITY) OF CONTROLS

5.2.1 PROMEGA FEMALE CONTROL

5.2.1.1 DEFINITION AND COMPLIANCE GUIDELINES FOR ACCURACY/TRUENESS

Accuracy is the closeness of agreement between the test result and the "true" or accepted value. Accuracy is determined by replicate analysis of a reference material of known composition (QIS 10663R2). Validation of accuracy complies with DAB (2000:8.1.3.1.2), SWGDAM (2004:3.2), and NATA (2004:2.1, 2.2, 2.4 and 2.4.2) guidelines.

5.2.1.2 DEFINITION AND COMPLIANCE GUIDELINES FOR PRECISION (REPEATABILITY AND REPRODUCIBILITY)

Precision is the closeness of agreement between independent replicate test results. There are two measures of precision, repeatability and reproducibility. High precision does not necessarily reflect high accuracy (QIS 10663R2). It is a requirement of QIS 23401R0 to assess precision of a system.

Repeatability is a measure of the maximum acceptable difference between two test results obtained at the same time by the same analyst under identical conditions on the same material. Normally, repeatability is calculated at the 95% confidence level (and two correctly obtained results will not differ from one another by more than the repeatability value in more than 1 in 20 cases) (QIS 10663R2). Measuring repeatability follows DAB (2000:8.1.3.1.1), SWGDAM (2004:3.2), and NATA (2004:2.4.1) guidelines.

Reproducibility is a measure of the maximum acceptable difference between two test results obtained on the same material by different analysts at different times. Normally, reproducibility is calculated at the 95% confidence level. This value of reproducibility is the one generally used to estimate the limits of uncertainty of a result (QIS 10663R2). In-house reproducibility is required by QIS document 23401R0, and according to DAB (2000:8.1.3.1.2), SWGDAM (2004:3.2), and NATA (2004:2.1, 2.2, and 2.4) guidelines.

5.2.1.3 METHOD

To assess the accuracy, bias, repeatability and limited in-house reproducibility of the Quantifiler system using Promega Human Genomic DNA Male for the standard, dilutions of a known control were made, tested, and the results compared to the true or expected values. Promega Human Genomic DNA Female control was used like Certified Reference Material (CRM) and was diluted in house to 0.1ng/μL and 1.0ng/μL. Both Promega Human Genomic DNA Male and Female come with product certificates and with a guaranteed concentration that is measured spectrophotometrically from three readings that agree within 10 percent (Stevens pers. com. 2006). Due to previous results showing uneven heating on the ABI 7000 thermal block, positions A11 and A12 were omitted and should not be used in future Quantifiler runs (quants) because they result in inconsistent results.

5.2.1.4 RESULTS AND DISCUSSION

See table 9 for the analysis results of CT values produced from the different controls. The CV is less than 1.03% and 95% confidence levels are less than 2.06%. The low percentage values are indicative that the system has high precision. The highest repeatability value was 0.5837 CTs for the 0.1ng/μL Promega Female control and 0.3135 CTs for the 1.0ng/μL Promega Female control. The highest repeatability value for the EPC (0.1ng/μL) was under 1.4348 CTs. The student's t-test for accuracy failed for some controls in some plate runs where the t-test statistic T_0 exceeded the 5% critical values. Therefore, the system is not always accurate and the obtained CT values can be significantly different to the true or expected CT values.

Table 10 contains the analysis of the Quantifiler value data (ng/μL). The CV is less than 22.34% and 95% confidence levels are less than 44.68%. The moderate percentage values show an intermediate spread of values relative to the mean value, indicating moderate precision with DNA concentrations. The highest repeatability value was 0.0638ng/μL for the 0.1ng/μL Promega Female control and 0.2770ng/μL for the 1.0ng/μL Promega Female control. The highest repeatability value for the EPC (0.1ng/μL) was 0.1241ng/μL. The student's t-test for accuracy failed for some controls in some plate runs where the t-test statistic T_0 exceeded the 5% critical values. Therefore, the system is not always accurate and the obtained Quantifiler values can be significantly different to the true or expected values. This could largely be because the y-intercept values for the standards being used were all in the second standard deviation rather than the first standard deviation (see table 8 for more details). Y-intercept values within one standard deviation would have produced more accurate results.

Reproducibility values for CT and Quantifiler values are presented in tables 11 and 12. It is possible to see that there is good in-house reproducibility, although the distribution is broader for the 0.1ng/μL controls than for the 1ng/μL controls. Similarly, the amplification volumes at two standard deviations can also be quite broad for the same control.

When duplicate controls are run, the controls must be within the 95% confidence interval of two standard deviations and within the repeatability value calculated. Thus the 0.1ng/μL Promega Female control CT must be between 30.5237 and 31.5324 and the two values must be within 0.5837 CTs to be acceptable. The 1.0ng/μL Promega Female control CT must be between 27.8097 and 28.3251 and the two values must be within 0.3135 CTs to be acceptable. The CT repeatability figures and ranges for the controls were based on the most extreme values obtained from different sets of data.

With Quantifiler values, the ranges shift based on the slope and y-intercept values obtained from each standard. This is visible in table 10 where higher y-intercept values generally produced higher ranges. With Quantifiler values, the 0.1ng/μL Promega Female control quantified between the two standard deviations and the maximum difference in the two values must be within 0.0634ng/μL to be acceptable. The 1.0ng/μL Promega Female control Quantifiler value must be between the two standard deviations and the two values must be within 0.2770ng/μL to be acceptable. The Quantifiler value repeatability figures and ranges for the controls were based on the most extreme values obtained with the y-intercept being between 28.191647 and 28.331522. Because the acceptable range for the y-intercept is between 27.655034 and 28.367930, it is likely that in reality the ranges can shift to lower values. It is possible to see with this data that the repeatability value

ranges change as the slope conditions change. Slope conditions towards more extreme values such as -3.3 or -2.9 would also affect the range causing it to shift.

The EPC was reproducible at a CT range of 30.6033 to 31.4592 with duplicate values having to be within 0.6358 CTs of each other. Similarly, 0.1ng/μL Promega Female control was reproducible at a CT range of 30.6899 to 31.4082 with two duplicate values in a run having to be within 0.5006 CTs of each other. 1.0ng/μL Promega Female control was reproducible at a CT range of 27.9174 to 28.2628 with two duplicate values in a run having to be within 0.2407 CTs of each other.

The EPC was reproducible with a Quantifiler value range of 0.0862 and 0.1680ng/μL and duplicate values having to be within 0.0608ng/μL of each other. Similarly, 0.1ng/μL Promega Female control was reproducible with a Quantifiler value range of 0.0910 to 0.1599ng/μL with two duplicate values in a run having to be within 0.0480ng/μL of each other. 1.0ng/μL Promega Female control was reproducible with a Quantifiler value range of 0.9801 to 1.2678ng/μL and with two duplicate values in a run having to be within 0.2005ng/μL of each other.

While the above reproducibility data results in tables 11 and 12 having different controls and standards over two operators, reproducibility data using the same controls and standards over two operators produced very similar results compared to the data discussed. This is also presented in tables 11 and 12.

Table 9: CT values of run controls with T-test analysis and repeatability values. The CV (<1.03%) and 95% confidence levels (<2.06%) are low in percentage values showing a low spread of values relative to the mean value (high precision). The highest repeatability value was 0.5837 CTs for 0.1ng/μL Promega Female control and 0.3135 CTs for 1.0ng/μL Promega Female control. The highest repeatability value for the EPC (0.1ng/μL) was under 1.4348 CTs. The student's t-test for accuracy failed for some controls in some plate runs (shown in red) where the t-test statistic T_o exceeded the 5% critical values. Therefore, the system is not always accurate and the obtained CT values can be significantly different to the true or expected values.

		Testquant_04 0306_femDN A1	Testquant_04 0306_femDN A2	Testquant_11 0306_femDN A1	Testquant_11 0306_femDN A2	Testquant_13 0306_femDN A1	Testquant_14 0306_femDN A2
	Slope	-3.126940	-3.103814	-3.004527	-3.062368	-3.112569	-3.138381
Quantifiler	Yintercept	28.307346	28.331522	28.191647	28.211411	28.225107	28.194588
value (ng/uL)	R2	0.995381	0.994705	0.993650	0.996977	0.996648	0.997523
0.1	0.1ng/uL expected CT	31.434286	31.435336	31.196174	31.273779	31.337676	31.332969
1	1.0 ng/uL expected CT	28.307346	28.331522	28.191647	28.211411	28.225107	28.194588
EPC 0.1ng/uL	Mean	30.9700	30.9725	31.1150	31.0250	30.9800	31.1250
	StdDev	0.1175	0.2360	0.1287	0.3188	0.2507	0.1555
	CV	0.38%	0.76%	0.41%	1.03%	0.81%	0.50%
	95% confidence interval (± percent)	0.76%	1.52%	0.83%	2.06%	1.62%	1.00%
	Minimum range (mean-2xStdDev)	30.7351	30.5005	30.8576	30.3874	30.4785	30.8141
	Maximum range (mean+2xStdDev)	31.2049	31.4445	31.3724	31.6626	31.4815	31.4359
	Sample number	4	4	4	4	4	4
	Degrees of freedom (d.f.)	3	3	3	3	3	3
	5% critical values for Degrees of freedom (n-1)	3.1824	3.1824	3.1824	3.1824	3.1824	3.1824
	T-test statistic To	7.9045	3.9225	1.2613	1.5607	2.8531	2.6756
	Repeatability (r)	0.5287	1.0621	0.5793	1.4348	1.1285	0.6997
Promega Female 0.1ng/uL	Mean	31.1258	30.9225	31.1592	31.0614	31.0058	31.0194
	StdDev	0.2033	0.1994	0.1508	0.2001	0.1637	0.1510
	CV	0.65%	0.64%	0.48%	0.64%	0.53%	0.49%
	95% confidence interval (± percent)	1.31%	1.29%	0.97%	1.29%	1.06%	0.97%
	Minimum range (mean-2xStdDev)	30.7192	30.5237	30.8575	30.6612	30.6784	30.7174
	Maximum range (mean+2xStdDev)	31.5324	31.3213	31.4608	31.4616	31.3333	31.3215
	Sample number	36	36	36	36	36	36
	Degrees of freedom (d.f.)	35	35	35	35	35	35
	5% critical values for Degrees of freedom (n-1)	2.0301	2.0301	2.0301	2.0301	2.0301	2.0301
	T-test statistic To	9.1037	15.4298	1.4721	6.3689	12.1605	12.4507
	Repeatability (r)	0.5837	0.5725	0.4330	0.5745	0.4701	0.4336
Promega Female 1.0ng/uL	Mean	28.1311	28.0744	28.1431	28.0281	28.0639	28.1000
	StdDev	0.0789	0.0760	0.0910	0.1092	0.0774	0.0809
	CV	0.28%	0.27%	0.32%	0.39%	0.28%	0.29%
	95% confidence interval (± percent)	0.56%	0.54%	0.65%	0.78%	0.55%	0.58%
	Minimum range (mean-2xStdDev)	27.9734	27.9225	27.9610	27.8097	27.9090	27.9383
	Maximum range (mean+2xStdDev)	28.2889	28.2264	28.3251	28.2465	28.2188	28.2617
	Sample number	36	36	36	36	36	36
	Degrees of freedom (d.f.)	35	35	35	35	35	35
	5% critical values for Degrees of freedom (n-1)	2.0301	2.0301	2.0301	2.0301	2.0301	2.0301
	T-test statistic To	13.4058	20.2562	3.2031	10.0743	12.4922	7.0183
	Repeatability (r)	0.2265	0.2162	0.2613	0.3135	0.2223	0.2321

Table 10: Quantifiler values obtained with the Promega Male Standard with T-test analysis and repeatability values. The CV (<22.34%) and 95% confidence levels (<44.68%) are moderate in percentage values showing an intermediate spread of values relative to the mean value (moderate precision). The highest repeatability value was 0.0638ng/μL for 0.1ng/μL Promega Female control and 0.2770ng/μL for 1.0ng/μL Promega Female control. The highest repeatability value for the EPC (0.1ng/μL) was 0.1241ng/μL. The student's t-test for accuracy failed for some controls in some plate runs (shown in red) where the t-test statistic To exceeded the 5% critical values. Therefore, the system is not always accurate and the obtained Quantifiler values can be significantly different to the true or expected values.

		Testquant_04 0306_femDN A1	Testquant_04 0306_femDN A2	Testquant_11 0306_femDN A1	Testquant_11 0306_femDN A2	Testquant_13 0306_femDN A1	Testquant_14 0306_femDN A2
Quantifiler value	Slope	-3.126940	-3.103814	-3.004527	-3.062368	-3.112569	-3.138381
	Yintercept	28.307346	28.331522	28.191647	28.211411	28.225107	28.194588
	R2	0.995381	0.994705	0.993650	0.996977	0.996648	0.997523
EPC 0.1ng/uL	Mean	0.1413	0.1428	0.1066	0.1233	0.1318	0.1170
	StdDev	0.0128	0.0276	0.0104	0.0275	0.0232	0.0135
	CV	9.09%	19.32%	9.76%	22.34%	17.62%	11.53%
	95% confidence interval (± percent)	18.18%	38.65%	19.52%	44.68%	35.24%	23.06%
	Minimum range (mean-2xStdDev)	0.1156	0.0876	0.0858	0.0682	0.0853	0.0900
	Maximum range (mean+2xStdDev)	0.1669	0.1979	0.1273	0.1784	0.1782	0.1440
	Sample number	4	4	4	4	4	4
	Degrees of freedom (d.f.)	3	3	3	3	3	3
	5% critical values for Degrees of freedom (n-1)	3.1824	3.1824	3.1824	3.1824	3.1824	3.1824
	T-test statistic To	8.4242	3.0995	1.2597	1.6919	2.7354	2.5202
	Repeatability (r)	0.0578	0.1241	0.0468	0.1240	0.1045	0.0607
Promega Female 0.1ng/uL	Mean	0.1268	0.1479	0.1036	0.1188	0.1288	0.1266
	StdDev	0.0182	0.0221	0.0118	0.0189	0.0165	0.0138
	CV	14.36%	14.93%	11.39%	15.87%	12.82%	10.88%
	95% confidence interval (± percent)	28.73%	29.87%	22.79%	31.74%	25.64%	21.77%
	Minimum range (mean-2xStdDev)	0.0904	0.1038	0.0800	0.0811	0.0958	0.0991
	Maximum range (mean+2xStdDev)	0.1633	0.1921	0.1272	0.1565	0.1619	0.1542
	Sample number	36	36	36	36	36	36
	Degrees of freedom (d.f.)	35	35	35	35	35	35
	5% critical values for Degrees of freedom (n-1)	2.0301	2.0301	2.0301	2.0301	2.0301	2.0301
	T-test statistic To	8.8378	13.0200	1.8107	5.9850	10.4796	11.6853
	Repeatability (r)	0.0523	0.0634	0.0339	0.0541	0.0474	0.0396
Promega Female 1.0ng/uL	Mean	1.1400	1.2108	1.0404	1.1517	1.1277	1.0733
	StdDev	0.0662	0.0697	0.0692	0.0965	0.0630	0.0610
	CV	5.80%	5.76%	6.66%	8.38%	5.59%	5.69%
	95% confidence interval (± percent)	11.61%	11.51%	13.31%	16.75%	11.17%	11.37%
	Minimum range (mean-2xStdDev)	1.0077	1.0714	0.9019	0.9587	1.0017	0.9512
	Maximum range (mean+2xStdDev)	1.2723	1.3503	1.1788	1.3446	1.2537	1.1954
	Sample number	36	36	36	36	36	36
	Degrees of freedom (d.f.)	35	35	35	35	35	35
	5% critical values for Degrees of freedom (n-1)	2.0301	2.0301	2.0301	2.0301	2.0301	2.0301
	T-test statistic To	12.6569	18.1470	3.4973	9.4334	12.1630	7.2067
	Repeatability (r)	0.1899	0.2001	0.1988	0.2770	0.1808	0.1752

Table 11: In-house CT reproducibility and expected CT value ranges.

CT	Data source	Combined Standard Deviation	Combined degrees of freedom	T-value (2-sided, 95% confidence level)	In-house reproducibility (Rw) (CT)	Overall mean	Minimum range (mean - 2xStdDev)	Maximum range (mean + 2xStdDev)
EPC 0.1ng/uL	6 plates with two sets of data (different controls and standards, 2 operators)	0.2140	18	2.1009	0.6358	31.0313	30.6033	31.4592
EPC 0.1ng/uL	4 plates with one data set (Same controls and standards, 2 operators)	0.2265	12	2.1788	0.6980	31.0613	30.6082	31.5143
Promega Female 0.1ng/uL	6 plates with two sets of data (different controls and standards, 2 operators)	0.1796	210	1.9713	0.5006	31.0490	30.6899	31.4082
Promega Female 0.1ng/uL	4 plates with one data set (Same controls and standards, 2 operators)	0.1676	140	1.9771	0.4687	31.0615	30.7262	31.3967
Promega Female 1.0ng/uL	6 plates with two sets of data (different controls and standards, 2 operators)	0.0864	210	1.9713	0.2407	28.0901	27.9174	28.2628
Promega Female 1.0ng/uL	4 plates with one data set (Same controls and standards, 2 operators)	0.0905	140	1.9771	0.2530	28.0838	27.9028	28.2647

Table 12: In-house Quantifiler value reproducibility and expected Quantifiler value ranges using the Promega Male Standard.

Quantifiler value	Data source	Combined Standard Deviation	Combined degrees of freedom	T-value (2-sided, 95% confidence level)	In-house reproducibility (Rw) (ng/uL)	Overall mean	Minimum range (mean - 2xStdDev)	Maximum range (mean + 2xStdDev)	Maximum amplification volume	Minimum amplification volume
EPC 0.1ng/uL	6 plates with two sets of data (different controls and standards, 2 operators)	0.0205	18	2.1009	0.0608	0.1271	0.0862	0.1680	11.6056	5.9511
EPC 0.1ng/uL	4 plates with one data set (Same controls and standards, 2 operators)	0.0199	12	2.1788	0.0614	0.1197	0.0798	0.1595	12.5307	6.2698
Promega Female 0.1ng/uL	6 plates with two sets of data (different controls and standards, 2 operators)	0.0172	210	1.9713	0.0480	0.1254	0.0910	0.1599	10.9873	6.2552
Promega Female 0.1ng/uL	4 plates with one data set (Same controls and standards, 2 operators)	0.0155	140	1.9771	0.0433	0.1195	0.0885	0.1504	11.2971	6.6485
Promega Female 1.0ng/uL	6 plates with two sets of data (different controls and standards, 2 operators)	0.0719	210	1.9713	0.2005	1.1240	0.9801	1.2678	1.0203	0.7888
Promega Female 1.0ng/uL	4 plates with one data set (Same controls and standards, 2 operators)	0.0738	140	1.9771	0.2064	1.0983	0.9506	1.2459	1.0519	0.8026

5.2.1.4.1 EXAMPLE OF RESULTS USING PROMEGA MALE STANDARD WITH CONTROLS

An example of the effects of the slope and y-intercept values from the Promega Male standard on Quantifiler values of controls is presented in table 13. Standard A, with the highest y-intercept value produced the highest results, while the lowest y-intercept values were produced the lowest Quantifiler concentration values. The effect of the difference in slope value is visible where Quantifiler standard C produced the lowest buccal control concentration (in ng/μL), while Quantifiler standard D produced the lowest EPC concentrations (in ng/μL). With the acceptable range for the y-intercept being between 27.655034 and 28.367930, even more extreme values can be expected with more extreme y-intercept conditions.

Table 13: An example of Quantifiler values from controls with five different Promega Male Standards run on the same plate. The results show values obtained on Testquant_010805 from buccal controls with an estimated concentration of approximately 1ng/μL and EPCs of 0.1ng/μL. Standard A produced the highest and most inaccurate results (yellow background), but these are still acceptable given that the standard slope, y-intercept and r2 values pass the criteria in table 8. The values with the green background were the lowest values produced.

Standard	A	B	C	D	E	CT
Slope	-3.116899	-3.004052	-2.996166	-2.942776	-3.089615	
Y-Intercept	28.225719	27.912193	27.794958	27.823851	27.913212	
R2	0.993405	0.995207	0.997555	0.995839	0.998925	
BuCtl C B11 Quantity	**1.39**	1.11	1.01	1.03	1.10	27.78
BuCtl C B12 Quantity	1.36	1.08	0.991	1.01	1.08	27.81
BuCtl C C11 Quantity	**1.39**	1.11	1.01	1.04	1.11	27.78
BuCtl C C12 Quantity	1.38	1.10	1.01	1.03	1.10	27.79
BuCtl C D11 Quantity	1.33	1.05	0.963	0.984	1.05	27.84
BuCtl C D12 Quantity	1.24	0.987	**0.902**	0.921	0.988	27.93
EPC E11 Quantity	**0.176**	0.130	0.118	0.116	0.137	30.58
EPC E12 Quantity	0.132	0.0961	0.0872	0.0854	0.103	30.97
EPC F11 Quantity	0.131	0.0956	0.0868	0.0850	0.102	30.98
EPC F12 Quantity	0.124	0.0899	0.0816	**0.0797**	0.0961	31.06
EPC C G11 Quantity	0.132	0.0960	0.0872	0.0853	0.102	30.97
EPC C G12 Quantity	0.137	0.0996	0.0905	0.0886	0.106	30.92

5.3 ACCURACY AND PRECISION (REPEATABILITY and REPRODUCIBILITY) OF STANDARDS

5.3.1 METHOD

Quantifiler standard, Promega Human Genomic DNA Male, Promega Human Genomic DNA Female and Human Genomic DNA from Roche (Cat. No. 1691 112) were diluted based on the DNA concentrations provided by the manufacturer to the expected concentrations below in table 14. These were run with the EPC and a Buccal control (approximately 1.0ng/μL buccal cell extract from an FTA) and the results were analysed utilising the Promega Male Standard. The standards created were run according to the platemap in figure 3 over two plates (Testquant_130905 and Testquant_140905).

Table 14: Human DNA standard concentrations. Standards 1 to 8 are shown with their respective true or expected concentrations.

Human DNA Standard Concentrations	
Standard #	[DNA] ng/µl
1	50.00
2	16.70
3	5.560
4	1.850
5	0.620
6	0.210
7	0.068
8	0.023

	1	2	3	4	5	6	7	8	9	10	11	12
A	Quantifiler STD#1 50 ng/µL	Quantifiler STD#1 50 ng/µL	Promega Male STD#1 50 ng/µL	Promega Male STD#1 50 ng/µL	Promega Female STD#1 50 ng/µL	Promega Female STD#1 50 ng/µL	Promega Female STD#1 50 ng/µL	Roche STD#1 50 ng/µL	Roche STD#1 50 ng/µL	Roche STD#1 50 ng/µL	X	X
B	Quantifiler STD#2 16.7ng/µL	Quantifiler STD#2 16.7ng/µL	Promega Male STD#2 16.7ng/µL	Promega Male STD#2 16.7ng/µL	Promega Female STD#2 16.7ng/µL	Promega Female STD#2 16.7ng/µL	Promega Female STD#2 16.7ng/µL	Roche STD#2 16.7ng/µL	Roche STD#2 16.7ng/µL	Roche STD#2 16.7ng/µL	Promega Male 1 ng/µL	Promega Male 1 ng/µL
C	Quantifiler STD#3 5.56ng/µL	Quantifiler STD#3 5.56ng/µL	Promega Male STD#3 5.56ng/µL	Promega Male STD#3 5.56ng/µL	Promega Female STD#3 5.56ng/µL	Promega Female STD#3 5.56ng/µL	Promega Female STD#3 5.56ng/µL	Roche STD#3 5.56ng/µL	Roche STD#3 5.56ng/µL	Roche STD#3 5.56ng/µL	Promega Male 1 ng/µL	Promega Male 1 ng/µL
D	Quantifiler STD#4 1.85ng/µL	Quantifiler STD#4 1.85ng/µL	Promega Male STD#4 1.85ng/µL	Promega Male STD#4 1.85ng/µL	Promega Female STD#4 1.85ng/µL	Promega Female STD#4 1.85ng/µL	Promega Female STD#4 1.85ng/µL	Roche STD#4 1.85ng/µL	Roche STD#4 1.85ng/µL	Roche STD#4 1.85ng/µL	EPC	EPC
E	Quantifiler STD#5 0.62ng/µL	Quantifiler STD#5 0.62ng/µL	Promega Male STD#5 0.62ng/µL	Promega Male STD#5 0.62ng/µL	Promega Female STD#5 0.62ng/µL	Promega Female STD#5 0.62ng/µL	Promega Female STD#5 0.62ng/µL	Roche STD#5 0.62ng/µL	Roche STD#5 0.62ng/µL	Roche STD#5 0.62ng/µL	EPC	EPC
F	Quantifiler STD#6 0.21ng/µL	Quantifiler STD#6 0.21ng/µL	Promega Male STD#6 0.21ng/µL	Promega Male STD#6 0.21ng/µL	Promega Female STD#6 0.21ng/µL	Promega Female STD#6 0.21ng/µL	Promega Female STD#6 0.21ng/µL	Roche STD#6 0.21ng/µL	Roche STD#6 0.21ng/µL	Roche STD#6 0.21ng/µL	Buccal control	Buccal control
G	Quantifiler STD#7 0.068ng/µL	Quantifiler STD#7 0.068ng/µL	Promega Male STD#7 0.068ng/µL	Promega Male STD#7 0.068ng/µL	Promega Female STD#7 0.068ng/µL	Promega Female STD#7 0.068ng/µL	Promega Female STD#7 0.068ng/µL	Roche STD#7 0.068ng/µL	Roche STD#7 0.068ng/µL	Roche STD#7 0.068ng/µL	Buccal control	Buccal control
H	Quantifiler STD#8 0.023ng/µL	Quantifiler STD#8 0.023ng/µL	Promega Male STD#8 0.023ng/µL	Promega Male STD#8 0.023ng/µL	Promega Female STD#8 0.023ng/µL	Promega Female STD#8 0.023ng/µL	Promega Female STD#8 0.023ng/µL	Roche STD#8 0.023ng/µL	Roche STD#8 0.023ng/µL	Roche STD#8 0.023ng/µL	H2O	H2O

Figure 3: A platemap with four different standard dilutions run against each other (Testquant_130905 and Testquant_140905).

5.3.2 RESULTS AND DISCUSSION

By comparing the mean CT values of the different standards in table 15, it is clearly evident that the Quantifiler Human DNA standard is a clear outlier, with mean CT values approximately one CT higher than the Promega Male Standard and even greater for the other standards. Therefore, the Quantifiler Human DNA standard was not consistent with the data from the other diluted controls run as standards. This is reflected in the Quantifiler values produced as shown in figures 4 and 5. A comparison of these results to other results and published data (table 18 and figure 7) show that the Quantifiler standards typically have higher CT values than the Promega Male, Promega Female and Roche standards.

Using the Promega Male Standard, the Quantifiler standard dilution concentrations were the lowest. This confirms that if the Quantifiler standard was used, the other controls would be significantly over-estimated. As a result, the Promega Male Standard is more suitable for DNA quantitation. The suitability of the Promega Male Standard is further confirmed in figure 6, where we demonstrate that the EPC and buccal controls tested were also near the true or expected values.

When the Promega Male standard was used to quantitate dilutions of the Promega Human Genomic DNA Female, there was only a 19.68% difference between resulting and expected values (see table 16). This supports that the Promega Male standard is suitable for quantitation. In table 17, it is possible to see that the Promega Male standard will not always produce a statistically accurate result based on student T-tests, even for the combined results from two plates. The distribution of the Quantifiler values for a specific concentration can miss the true or expected value completely in one run while produce statistically accurate results in another run. This is why we recommend the Quantifiler system for estimation rather than an accurate method for determining DNA concentrations. In other words, the estimated DNA concentrations will not always cluster and be distributed through the true or expected values at the 95% confidence interval. Most of the stochastic effects were present for low concentrations (dilutions at standard 7 and 8 concentrations) of the Promega Human Genomic DNA Female.

According to Applied Biosystems (2006)

"The real-time PCR assay specification targets a specific Ct value with an allowable variance of ±0.32 Ct. This specification results in a maximum allowable difference of 0.64 Ct between two qualifying lots of DNA standard with a resulting possible 1.56-fold concentration difference."

However, the concentration difference observed with the Quantifiler standard used compared to the Promega Human Genomic DNA and Roche Human Genomic DNA dilutions was approximately one CT with a 2 to 2.22-fold concentration increase. Comparing our data (table 15) to the published data (Applied Biosystems 2003:6-4), the difference in CTs was greater than the maximum allowable 0.64 CTs. As a result, the CT values can also change significantly from one system to another.

Table 15: Human DNA standard CT and IPC CT values. The CT values and standard deviations for standards one to eight and their IPCs are found in this table. Note that the Quantifiler Human DNA standards are typically higher by approximately one CT value.

Sample Name	CT Means	CT StdDev	IPC CT Means	IPC CT StdDev
Quantifiler STD#1	23.833	0.161	26.873	0.231
Promega Male STD#1	22.658	0.084	27.730	0.462
Promega Female STD#1	22.550	0.043	28.990	0.605
Roche STD#1	22.390	0.083	29.043	0.387
Quantifiler STD#2	25.318	0.082	26.905	0.108
Promega Male STD#2	24.258	0.034	26.983	0.075
Promega Female STD#2	24.182	0.046	27.368	0.225
Roche STD#2	23.980	0.033	27.937	0.251
Quantifiler STD#3	27.003	0.081	26.933	0.068
Promega Male STD#3	26.005	0.069	26.878	0.103
Promega Female STD#3	25.792	0.087	27.065	0.092
Roche STD#3	25.560	0.046	27.177	0.048
Quantifiler STD#4	28.475	0.105	26.985	0.026
Promega Male STD#4	27.505	0.114	26.915	0.054
Promega Female STD#4	27.288	0.035	26.967	0.115
Roche STD#4	27.145	0.071	27.045	0.049
Quantifiler STD#5	29.835	0.146	27.070	0.052
Promega Male STD#5	28.955	0.152	26.995	0.041
Promega Female STD#5	28.642	0.101	27.112	0.079
Roche STD#5	28.500	0.213	27.095	0.082
Quantifiler STD#6	31.200	0.189	27.083	0.071
Promega Male STD#6	30.140	0.085	27.075	0.082
Promega Female STD#6	30.032	0.074	27.135	0.063
Roche STD#6	30.013	0.096	27.187	0.043
Quantifiler STD#7	32.475	0.168	27.203	0.108
Promega Male STD#7	31.353	0.225	27.103	0.046
Promega Female STD#7	31.187	0.132	27.172	0.055
Roche STD#7	31.313	0.219	27.200	0.064
Quantifiler STD#8	34.233	0.110	27.230	0.089
Promega Male STD#8	32.850	0.448	27.223	0.081
Promega Female STD#8	32.600	0.442	27.268	0.047
Roche STD#8	32.485	0.285	27.320	0.049
Promega 1ng/uL	27.995	0.118	27.168	0.059
EPC	31.160	0.120	27.211	0.062
Buccal control	28.033	0.056	27.194	0.076
H2O	Undetermined	Undetermined	27.418	0.026

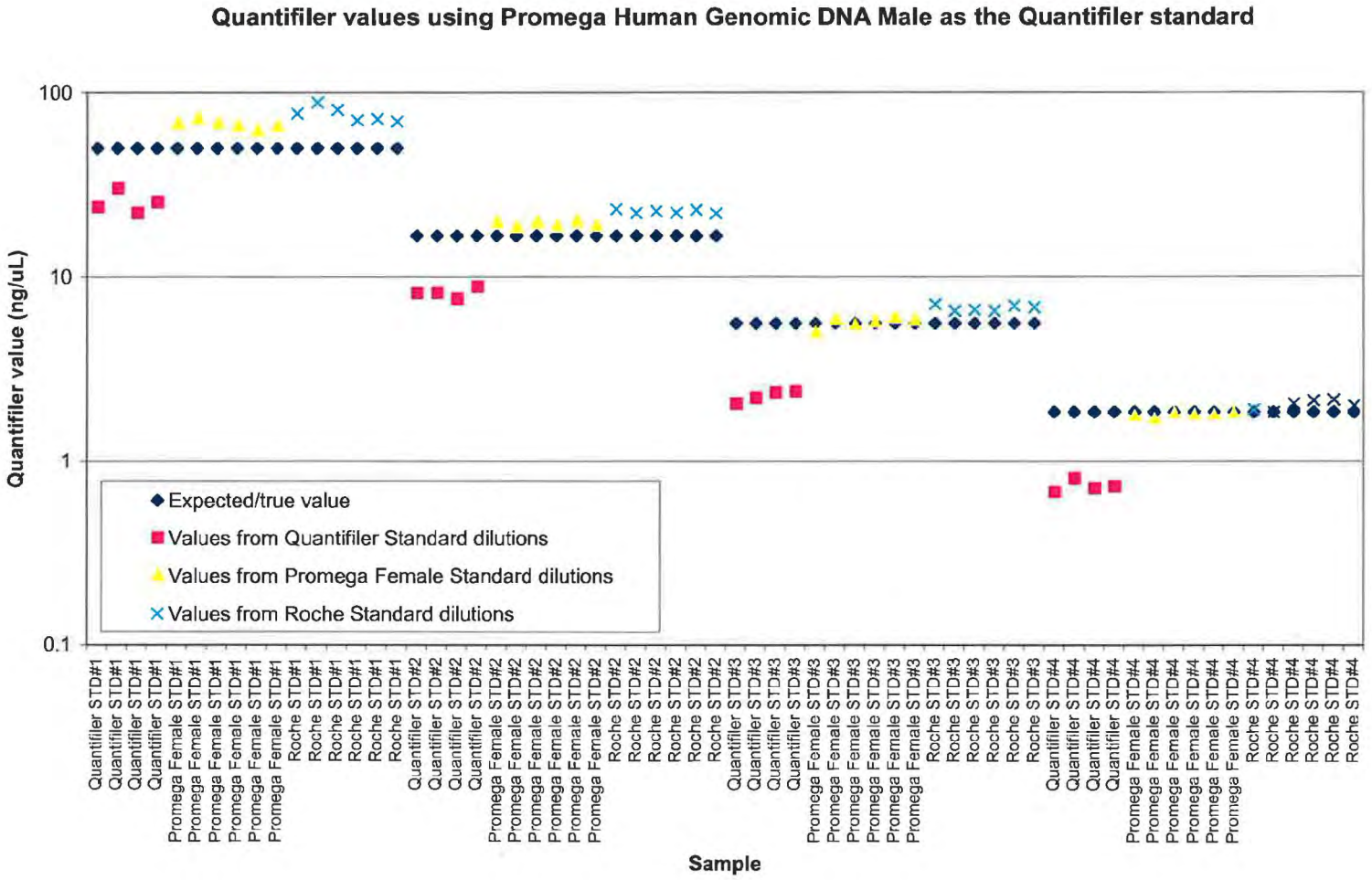

Figure 4: Quantifiler values using Promega Human Genomic DNA Male as the Quantifiler standard. The values of the Quantifiler Human DNA standards come out lower than the true or expected values, while the Promega Female standard dilutions and Roche standard dilutions are nearer to the expected or true value.

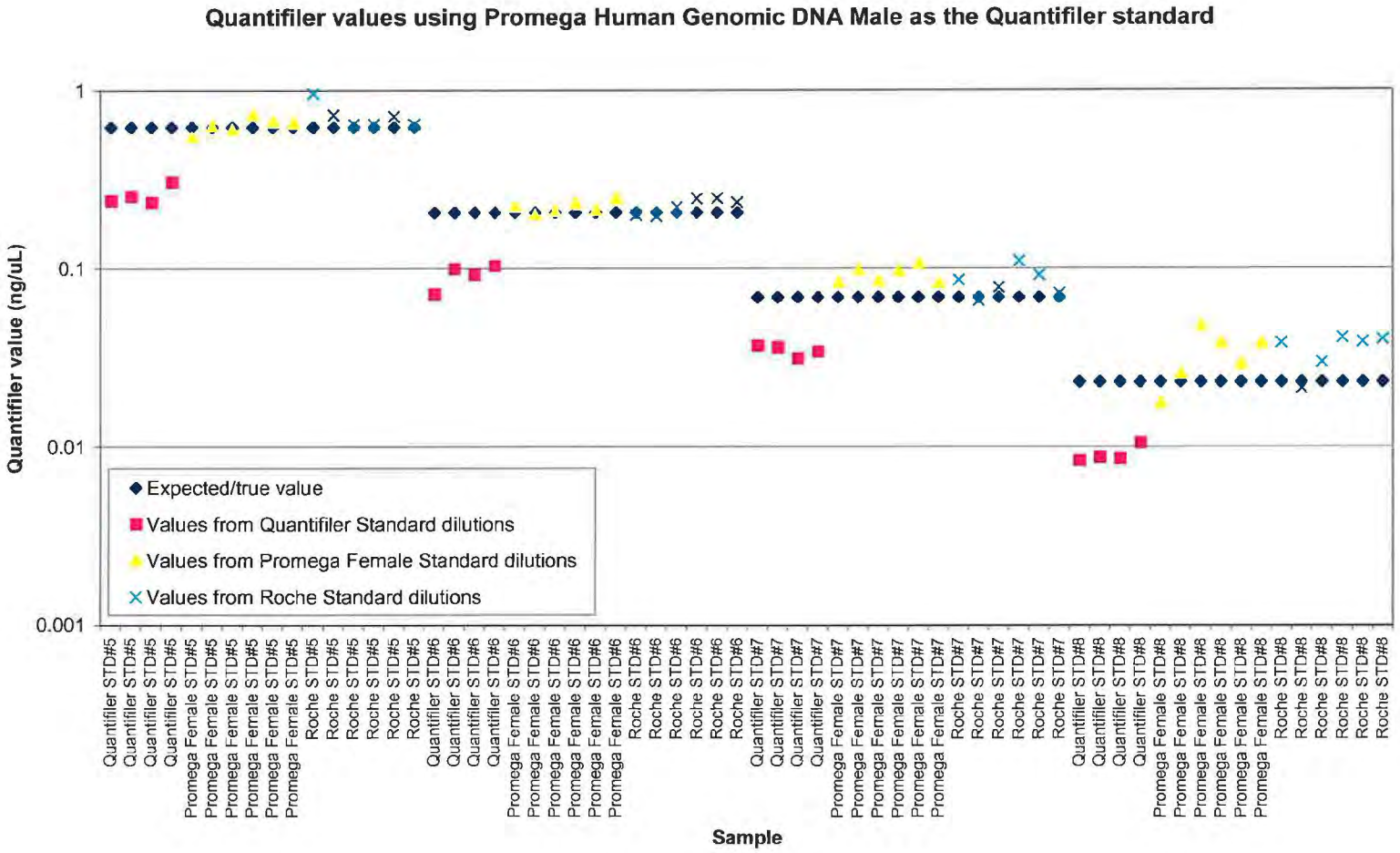

Figure 5: Quantifiler values using Promega Human Genomic DNA Male as the Quantifiler standard. The values of the Quantifiler Human DNA standards come out lower than the true or expected values, while the Promega Female standard dilutions and Roche standard dilutions are nearer to the expected or true value.

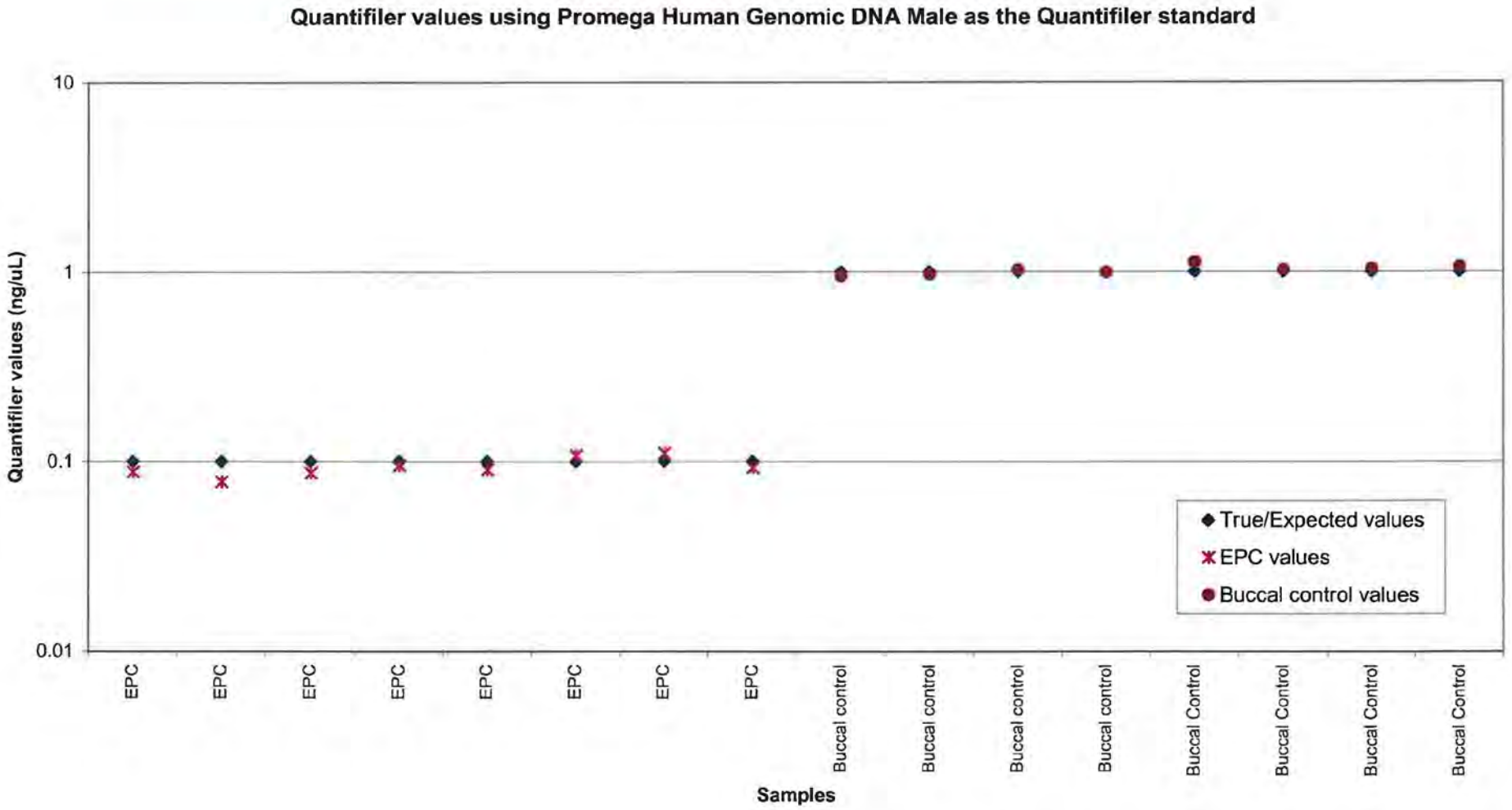

Figure 6: Quantifiler values of controls using Promega Human Genomic DNA Male as the Quantifiler standard. The EPC and buccal control values are near to the expected or true value.

Table 16: Promega Female standard Quantifiler values obtained using the Promega Male standard. An overall mean difference between the resulting and expected Quantifiler values was 19.68%.

Sample Name	Given concentration (ng/uL)	Log expected concentration	Quantifiler value	Log resulting concentration	Difference
Promega Female STD#1	50.00	1.70	68.46	1.84	36.92%
Promega Female STD#1	50.00	1.70	72.47	1.86	44.94%
Promega Female STD#1	50.00	1.70	68.49	1.84	36.98%
Promega Female STD#1	50.00	1.70	66.40	1.82	32.80%
Promega Female STD#1	50.00	1.70	62.05	1.79	24.10%
Promega Female STD#1	50.00	1.70	66.09	1.82	32.18%
Promega Female STD#2	16.67	1.22	19.87	1.30	19.20%
Promega Female STD#2	16.67	1.22	18.59	1.27	11.52%
Promega Female STD#2	16.67	1.22	19.76	1.30	18.54%
Promega Female STD#2	16.67	1.22	18.75	1.27	12.48%
Promega Female STD#2	16.67	1.22	20.11	1.30	20.64%
Promega Female STD#2	16.67	1.22	18.93	1.28	13.56%
Promega Female STD#3	5.56	0.75	5.00	0.70	10.07%
Promega Female STD#3	5.56	0.75	5.88	0.77	5.76%
Promega Female STD#3	5.56	0.75	5.50	0.74	1.08%
Promega Female STD#3	5.56	0.75	5.71	0.76	2.70%
Promega Female STD#3	5.56	0.75	6.00	0.78	7.91%
Promega Female STD#3	5.56	0.75	5.81	0.76	4.50%
Promega Female STD#4	1.85	0.27	1.78	0.25	3.78%
Promega Female STD#4	1.85	0.27	1.71	0.23	7.57%
Promega Female STD#4	1.85	0.27	1.84	0.26	0.54%
Promega Female STD#4	1.85	0.27	1.80	0.26	2.70%
Promega Female STD#4	1.85	0.27	1.80	0.26	2.70%
Promega Female STD#4	1.85	0.27	1.85	0.27	0.00%
Promega Female STD#5	0.620	-0.21	0.550	-0.26	11.29%
Promega Female STD#5	0.620	-0.21	0.636	-0.20	2.58%
Promega Female STD#5	0.620	-0.21	0.609	-0.22	1.77%
Promega Female STD#5	0.620	-0.21	0.726	-0.14	17.10%
Promega Female STD#5	0.620	-0.21	0.665	-0.18	7.26%
Promega Female STD#5	0.620	-0.21	0.655	-0.18	5.65%
Promega Female STD#6	0.206	-0.69	0.221	-0.66	7.28%
Promega Female STD#6	0.206	-0.69	0.202	-0.69	1.94%
Promega Female STD#6	0.206	-0.69	0.211	-0.68	2.43%
Promega Female STD#6	0.206	-0.69	0.231	-0.64	12.14%
Promega Female STD#6	0.206	-0.69	0.213	-0.67	3.40%
Promega Female STD#6	0.206	-0.69	0.247	-0.61	19.90%
Promega Female STD#7	0.0686	-1.16	0.0833	-1.08	21.43%
Promega Female STD#7	0.0686	-1.16	0.0981	-1.01	43.00%
Promega Female STD#7	0.0686	-1.16	0.0844	-1.07	23.03%
Promega Female STD#7	0.0686	-1.16	0.0965	-1.02	40.67%
Promega Female STD#7	0.0686	-1.16	0.1060	-0.97	54.52%
Promega Female STD#7	0.0686	-1.16	0.0822	-1.09	19.83%
Promega Female STD#8	0.0230	-1.64	0.0175	-1.76	23.91%
Promega Female STD#8	0.0230	-1.64	0.0254	-1.60	10.43%
Promega Female STD#8	0.0230	-1.64	0.0476	-1.32	106.96%
Promega Female STD#8	0.0230	-1.64	0.0379	-1.42	64.78%
Promega Female STD#8	0.0230	-1.64	0.0289	-1.54	25.65%
Promega Female STD#8	0.0230	-1.64	0.0378	-1.42	64.35%
				Mean difference	**19.68%**

Table 17: Analysis of Promega Female standard Quantifiler values obtained using the Promega Male standard. With the CV and 95% confidence interval values it is possible to see that most stochastic effects are present at concentrations around standards 7 (0.0686ng/μL) and 8 (0.023ng/μL). The T-test statistic (To) failed to pass Standards 1 and 2 for accuracy, showing that Quantifiler values obtained within one plate will not always be accurate and can be significantly different to true or expected values. When values are combined from the two plates, then not all of the values produced are accurate. Within plate repeatability and between plate reproducibility values are also shown.

Standard	STD1	STD1	STD2	STD2	STD3	STD3	STD4	STD4	STD5	STD5	STD6	STD6	STD7	STD7	STD8	STD8
Given concentration (ng/uL)	50	50	16.67	16.67	5.56	5.56	1.85	1.85	0.62	0.62	0.206	0.206	0.0686	0.0686	0.023	0.023
Average Quantifiler value (ng/uL)	69.81	64.85	19.41	19.26	5.46	5.84	1.78	1.82	0.60	0.68	0.2113	0.2303	0.0886	0.0949	0.0302	0.0349
Standard deviation of Quantifiler value	2.307	2.427	0.709	0.739	0.441	0.147	0.065	0.029	0.044	0.038	0.0095	0.0170	0.0082	0.0120	0.0156	0.0052
CV	3.30%	3.74%	3.66%	3.83%	8.08%	2.52%	3.66%	1.59%	7.35%	5.64%	4.50%	7.38%	9.31%	12.62%	51.73%	14.82%
95% confidence interval (± percent)	6.61%	7.49%	7.31%	7.67%	16.17%	5.04%	7.32%	3.18%	14.70%	11.27%	8.99%	14.77%	18.61%	25.25%	103.46%	29.64%
Minimum range (mean-2*StdDev)	65.19	59.99	17.99	17.79	4.58	5.55	1.65	1.76	0.51	0.61	0.19	0.20	0.07	0.07	0.00	0.02
Maximum range (mean-2*StdDev)	74.42	69.70	20.83	20.74	6.34	6.13	1.91	1.87	0.69	0.76	0.23	0.26	0.11	0.12	0.06	0.05
Sample number	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Degree of freedom (d.f.)	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
T-value (2-sided,95% confidence interval)	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027	4.3027
T-test statistic To	14.6733	10.5957	5.5819	6.0804	0.3924	3.2922	1.9522	2.0000	0.8533	2.7942	0.9719	2.4778	4.2011	3.8023	0.7954	3.9775
Repeatability (r) (ng/uL)	14.0351	14.7676	4.3185	4.4951	2.6856	0.8964	0.3959	0.1757	0.2676	0.2339	0.0578	0.1035	0.0502	0.0729	0.0950	0.0314
Combined mean	67.3267		19.3350		5.6500		1.7967		0.6402		0.2208		0.0918		0.0325	
Combined standard deviation	1.1838		0.3621		0.1645		0.0252		0.0206		0.0069		0.0051		0.0058	
Combined CV	1.7582%		1.8728%		2.9116%		1.4007%		3.2257%		3.1195%		5.6043%		17.8743%	
Combined 95% confidence interval (± percent)	0.0352		0.0375		0.0582		0.0280		0.0645		0.0624		0.1121		0.3575	
Combined minimum range (Combined mean - 2*CombinedStdDev)	64.9592		18.6108		5.3210		1.7463		0.5989		0.2071		0.0815		0.0209	
Combined maximum range (mean - 2*StdDev)	69.6942		20.0592		5.9790		1.8470		0.6815		0.2346		0.1020		0.0441	
Combined sample number	6		6		6		6		6		6		6		6	
Combined degrees of freedom	4		4		4		4		4		4		4		4	
Combined t-value (2-sided,95% confidence interval)	2.7765		2.7765		2.7765		2.7765		2.7765		2.7765		2.7765		2.7765	
Combined t-test statistic to	36.8532		18.0276		1.3401		5.1911		2.3922		5.2742		11.6280		4.0107	
Reproducibility (Rw) (ng/uL)	4.6480		1.4218		0.6459		0.0988		0.0811		0.0270		0.0202		0.0228	

Table 18: Comparison of CT values and distributions of Human DNA Control standards. The orange rows show the results from the samples run on Testquant_130905 and Testquant_140905. The QHSS standard (in blue) is the accumulative result of long-term data while the Promega Male standard (Promega Human Genomic DNA Male standard) are the results obtained from another set of data. The ADFS (ADFS accessed online 11th March, 2005) and ABI standards (Applied Biosystems 2003) are Quantifiler Human DNA standards where CT values were obtained from published references. As is clearly visible, all of the Quantifiler standards (QHSS, QHSS2, ADFS and ABI have higher CT values than the Promega Male, Promega Female and Roche standards.

Standard type	Mean CT	1 StdDev Minimum	1 StdDev Maximum	2 StdDev Minimum	2 StdDev Maximum	3 StdDev Minimum	3 StdDev Maximum
QHSS STD1	23.50	23.25	23.75	23.00	24.00	22.75	24.25
QHSS2 STD1	23.83	23.67	23.99	23.51	24.15	23.35	24.31
ADFS STD1	23.28	23.16	23.40	23.04	23.52	22.92	23.64
ABI STD1	23.09	22.99	23.19	22.89	23.29	22.79	23.39
Promega Male STD1	22.60	22.46	22.74	22.32	22.88	22.18	23.02
Promega Male2 STD1	22.66	22.57	22.74	22.49	22.83	22.40	22.91
Promega Female STD1	22.55	22.51	22.59	22.46	22.64	22.42	22.68
Roche STD1	22.39	22.31	22.47	22.22	22.56	22.14	22.64
QHSS STD2	25.12	24.88	25.36	24.65	25.59	24.41	25.83
QHSS2 STD2	25.32	25.24	25.40	25.15	25.48	25.07	25.56
ADFS STD2	24.74	24.56	24.92	24.38	25.10	24.20	25.28
ABI STD2	24.64	24.47	24.81	24.30	24.98	24.13	25.15
Promega Male STD2	24.18	24.09	24.27	24.00	24.37	23.90	24.46
Promega Male2 STD2	24.26	24.22	24.29	24.19	24.33	24.16	24.36
Promega Female STD2	24.18	24.14	24.23	24.09	24.27	24.04	24.32
Roche STD2	23.98	23.95	24.01	23.91	24.05	23.88	24.08
QHSS STD3	26.62	26.37	26.87	26.12	27.12	25.86	27.38
QHSS2 STD3	27.00	26.92	27.08	26.84	27.17	26.76	27.25
ADFS STD3	26.19	26.05	26.33	25.91	26.47	25.77	26.61
ABI STD3	26.19	26.03	26.35	25.87	26.51	25.71	26.67
Promega Male STD3	25.77	25.60	25.94	25.43	26.11	25.26	26.28
Promega Male2 STD3	26.01	25.94	26.07	25.87	26.14	25.80	26.21
Promega Female STD3	25.79	25.70	25.88	25.62	25.97	25.53	26.05
Roche STD3	25.56	25.51	25.61	25.47	25.65	25.42	25.70
QHSS STD4	28.18	27.98	28.40	27.74	28.62	27.52	28.84
QHSS2 STD4	28.48	28.37	28.58	28.26	28.69	28.16	28.79
ADFS STD4	27.59	27.46	27.72	27.33	27.85	27.20	27.98
ABI STD4	27.67	27.50	27.84	27.33	28.01	27.16	28.18
Promega Male STD4	27.34	27.09	27.59	26.85	27.83	26.60	28.08
Promega Male2 STD4	27.51	27.39	27.62	27.28	27.73	27.16	27.85
Promega Female STD4	27.29	27.25	27.32	27.22	27.36	27.18	27.39
Roche STD4	27.15	27.07	27.22	27.00	27.29	26.93	27.36
QHSS STD5	29.65	29.36	29.94	29.08	30.22	28.79	30.51
QHSS2 STD5	29.84	29.69	29.98	29.54	30.13	29.40	30.27
ADFS STD5	29.09	28.84	29.34	28.59	29.59	28.34	29.84
ABI STD5	29.09	28.92	29.26	28.75	29.43	28.58	29.60
Promega Male STD5	28.70	28.49	28.90	28.29	29.11	28.08	29.31
Promega Male2 STD5	28.96	28.80	29.11	28.65	29.26	28.50	29.41
Promega Female STD5	28.64	28.54	28.74	28.44	28.84	28.34	28.95
Roche STD5	28.50	28.29	28.71	28.07	28.93	27.86	29.14
QHSS STD6	31.11	30.80	31.42	30.49	31.73	30.18	32.04
QHSS2 STD6	31.20	31.01	31.39	30.82	31.58	30.63	31.77
ADFS STD6	30.38	30.19	30.57	30.00	30.76	29.81	30.95
ABI STD6	30.31	30.12	30.50	29.93	30.69	29.74	30.88
Promega Male STD6	30.00	29.84	30.16	29.68	30.32	29.52	30.48
Promega Male2 STD6	30.14	30.05	30.23	29.97	30.31	29.88	30.40
Promega Female STD6	30.03	29.96	30.11	29.88	30.18	29.81	30.25
Roche STD6	30.01	29.92	30.11	29.82	30.21	29.73	30.30
QHSS STD7	32.69	32.26	33.12	31.82	33.56	31.39	33.99
QHSS2 STD7	32.48	32.31	32.64	32.14	32.81	31.97	32.98
ADFS STD7	31.65	31.37	31.93	31.09	32.21	30.81	32.49
ABI STD7	31.90	31.62	32.18	31.34	32.46	31.06	32.74
Promega Male STD7	31.37	31.04	31.70	30.72	32.02	30.39	32.35
Promega Male2 STD7	31.35	31.13	31.58	30.90	31.80	30.68	32.03
Promega Female STD7	31.19	31.05	31.32	30.92	31.45	30.79	31.58
Roche STD7	31.31	31.09	31.53	30.88	31.75	30.66	31.97
QHSS STD8	34.31	33.68	34.94	33.05	35.57	32.43	36.19
QHSS2 STD8	34.23	34.12	34.34	34.01	34.45	33.90	34.56
ADFS STD8	33.67	32.82	34.52	31.97	35.37	31.12	36.22
ABI STD8	33.45	32.97	33.93	32.49	34.41	32.01	34.89
Promega Male STD8	32.80	32.36	33.23	31.93	33.66	31.50	34.09
Promega Male STD8	32.85	32.40	33.30	31.95	33.75	31.50	34.20
Promega Female STD8	32.60	32.16	33.04	31.72	33.48	31.28	33.92
Roche STD8	32.49	32.20	32.77	31.91	33.06	31.63	33.34

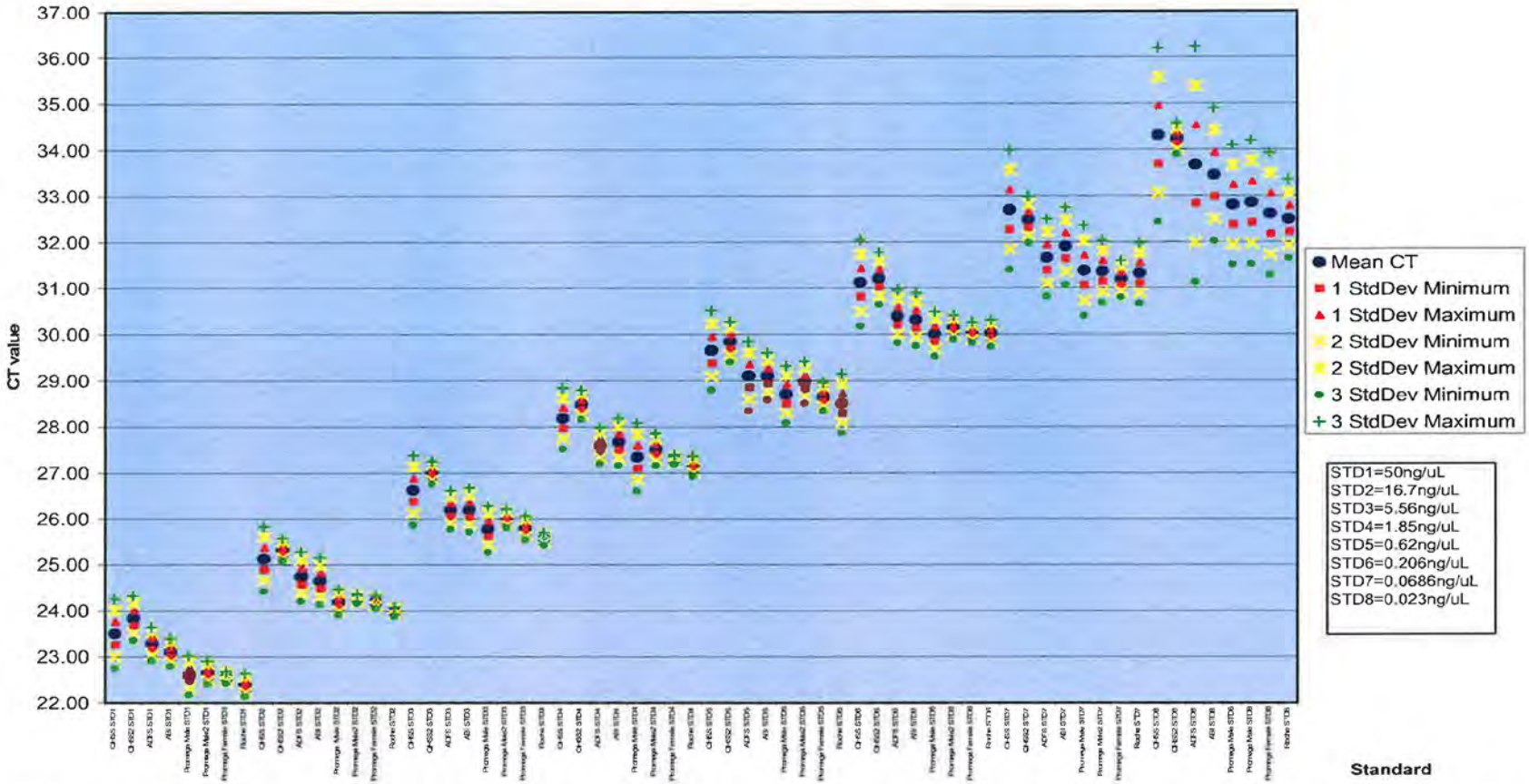

Figure 7: Comparison of CT values and distributions of Human DNA Control standards. QHSS2, Promega Male2, Promega Female and Roche standard results are from the dilutions run on Testquant_130905 and Testquant_140905. The QHSS standard is the accumulative result of long-term data while the Promega Male standard results are the results obtained from another set of data. The ADFS (ADFS accessed online 11th March, 2005) and ABI standards (Applied Biosystems 2003) are Quantifiler Human DNA standards where CT values were obtained from published references. As is clearly visible, all of the Quantifiler standards (QHSS, QHSS2, ADFS and ABI have higher CT values than the Promega Male, Promega Female and Roche standards. A general difference of approximately 1 CT is observable between the QHSS standard and the Promega Male standard.

5.3.3 LONG-TERM REPRODUCIBILITY

At this stage there is no long-term reproducibility data. This component is to be analysed once the system is operational and quality controls can be analysed to determine long-term reproducibility. Because singlicate controls are going to be run in the long-term, we recommend that on a regular basis (e.g. once a week) one plate has the controls in duplicate. This will enable degrees of freedom to be used in establishing 'non-biased' statistical reproducibility values for the long-term.

5.3.4 LINEAR CALIBRATION FUNCTION GRAPH ANALYSIS

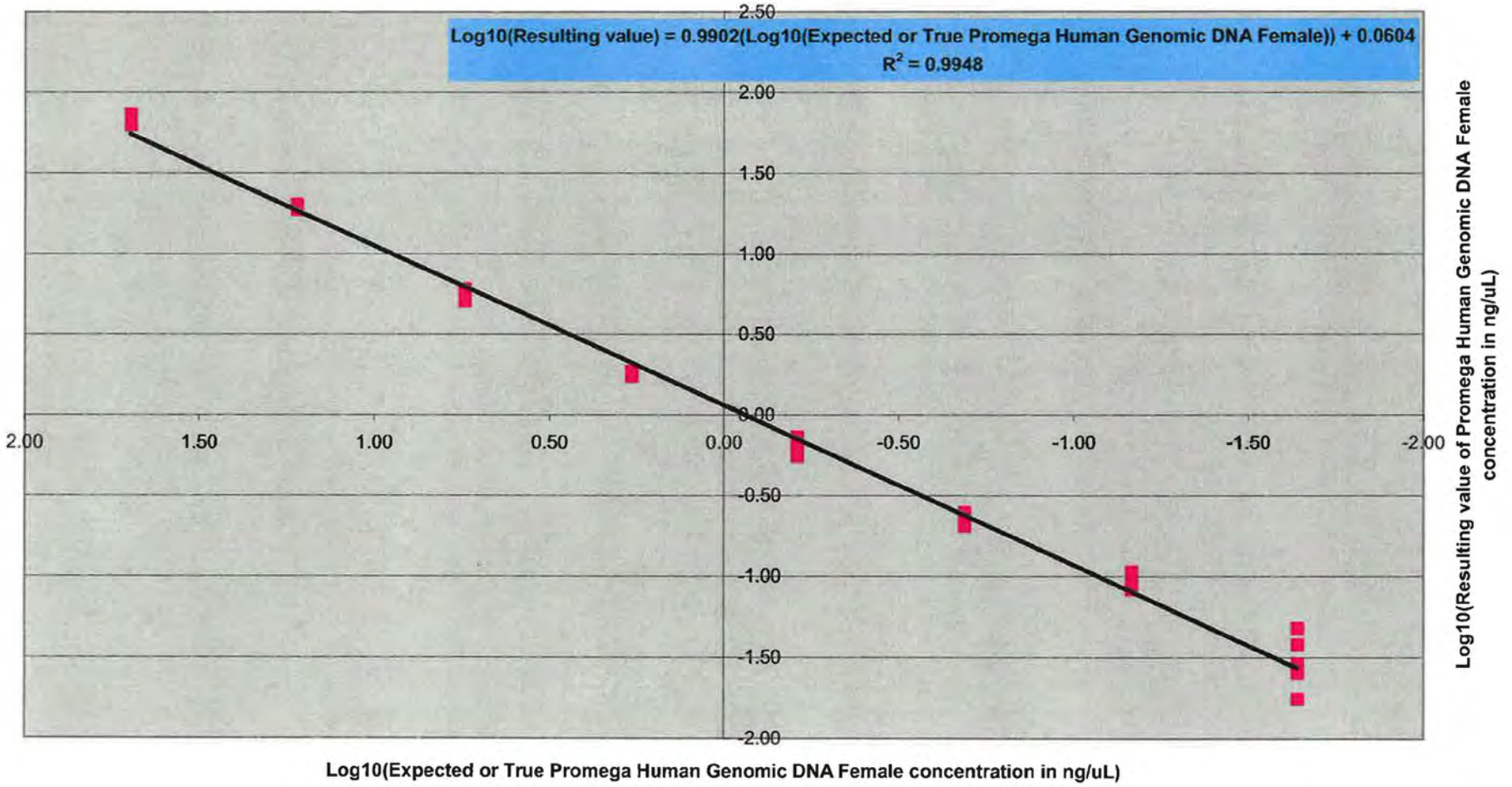

Figure 8: Linearity graph of Promega Human Genomic DNA Female dilution series using the Promega Male standard.

5.3.4.1 LINEARITY (LINEAR RESPONSE RANGE)

The linear response range is the range of concentrations between which the method produces a linear calibration line (QIS 10663R2) and is required by NATA guidelines (2004:2.2). Promega Human Genomic DNA Female concentration values ranging from 0.023ng/μL to 50ng/μL produced a linear calibration line using Promega Human Genomic DNA Male as the Quantifiler standard. This data is presented in figure 8. The correlation coefficient (R2) was 0.9948 for the linear response range.

5.3.4.2 POTENTIAL BIAS FROM LINEARITY ANALYSIS

A positive y-intercept (+0.0604) is indicative of a bias using Promega Human Genomic DNA Female in relation to using the Promega Human Genomic DNA Male as the Quantifiler Standard (see QIS 10662R2). This is equivalent to a calibration factor of approximately 1.1492. In other words:

Quantifiler value ≈ (Promega Human Genomic DNA Female true or expected value) x 1.1492

Therefore, there was a slight bias of approximately 14.9% in increasing Quantifiler values relative to the expected or true value of the female control. This is reflective of a difference in the dilutions between the batches of Male and Female Promega Human Genomic DNA used. Unlike the Quantifiler standard from ABI, where a bias of approximately 0.3458 was observed (a calibration factor of approximately 2.22 relative to the Promega Human Genomic DNA Male), the results from the Promega Male standard appear far more accurate.

It is expected that the bias will change due to slight differences between one standard and the next but it is expected to fluctuate around approximately the zero value.

5.3.4.3 SENSITIVITY

Sensitivity is the slope of the calibration function graph (QIS 10663R2). It is required by QIS 23401R0 and SWGDAM (2004:2.3) and NATA (2004:2.3) guidelines. Because the mean slope (0.9902) is almost equal to unity (1), this indicates that on average the method is highly sensitive.

5.3.4.4 STOCHASTIC EFFECTS

The laboratory must conduct studies that ensure the reliability and integrity of results. For PCR-based assays, studies must address the stochastic effects and levels (QIS 23401R0). The stochastic effects are visible in the ranges observed with the standard deviations. The levels of stochastic effects using Promega Human Genomic DNA Male as the Quantifiler standard is observed in figures 4, 5, 7 and 8. Most stochastic effects were observable at the lower concentration levels observed for standard 7 and 8. This is at the concentration of 0.068ng/μL and 0.023ng/μL. The increase in stochastic effects at these concentrations is reflected in the increasing CV and 95% confidence interval values (see table 17).

5.4 ACCURACY OF PROMEGA MALE STANDARD- INDEPENDENT TESTING

A spectrophotometric reading were taken of one Promega Male standard. The reading was taken with a Cary 1E UV-Visible Spectrophotometer (from Varian) at Investigative Chemistry, QHSS (thanks to Willy Gore), and calibrated against TE background (mean=0.0089 units). For the calculation 1 A260 unit was taken to be 50μg/mL.

5.4.1 RESULT

The Promega Human Genomic DNA Male STD1 (50ng/μL) produced a spectrophotometric result of 51.5±1.67ng/μL. Therefore the spectrophotometric reading result was consistent with the manufacturer's tests that Promega Human Genomic DNA Male was accurate.

5.5 REPRODUCIBILITY (EXTERNAL)

External reproducibility is defined as a measure of the maximum acceptable difference between two test results obtained on the same material by different laboratories. Normally, inter-laboratory laboratory reproducibility is calculated at the 95% confidence level. It is most conveniently determined in collaborative trials (QIS 10663R2).

Reproducibility between different laboratories was not measured or calculated at the 95% confidence level. No collaborative trials were set up for this purpose. However, a collaborative trial was set up between Forensic Science South Australia (FSSA), PathWest in Western Australia and QHSS to examine the variation in Quantifiler results from a set of 24 samples. It is important to note that both FSSA and PathWest have the ABI 7500 SDS and not the ABI 7000 SDS used by QHSS. We were also the last to receive the samples and had a few volumes that were just above the 4μL required for this analysis. Although the samples were in O-ring vials, evaporation may have resulted in concentrating some of the lower volumes. We analysed the samples in duplicate with both the Promega Male standard and the Quantifiler standard being run on the same plate. PathWest used the Promega Female standard and the Quantifiler standard (which they term the ABI standard) whereas FSSA utilised the Promega K562 (another Female control) standard. Therefore, the Quantifiler data differences could largely be due to the differences in the systems used as well as differences in the condition of the samples.

Table 19 contains the Quantifiler concentrations resulting from the three different laboratories. A comparison of the differences in the values is presented in table 20. The lowest differences observed were within QHSS comparing the calibrated Quantifiler results with the Promega Male standard results. We believe that the data demonstrates that reproducibility values are higher across labs than within the QHSS lab itself. In other words, although the 95% confidence intervals from one lab to another will be different and have a different mean depending on the system used, across the labs tested the 95% confidence interval range would be greater than estimated within QHSS for our purposes.

Table 19. Quantifiler concentration results from different laboratories. The blue colour denotes where a Promega standard was used whereas the yellow colour denotes where the Quantifiler (ABI) standard was used.

Sample	FSSA (Promega std)	PathWest (Promega std)	QLD (Promega Human DNA Control Male Std result 1	QLD (Promega Human DNA Control Male Std result 2	QLD (ABI std)/2 result 1	QLD (ABI std)/2 result 2	QLD (ABI std)/2.22 result 1	QLD (ABI std)/2.22 result 2	QLD (ABI std) result 1	QLD (ABI std) result 2	PathWest (ABI std) result 1	PathWest (ABI std) result 2
1	200.000	260.78	284.71	228.66	317.61	254.32	286.13	229.12	635.21	508.64	907.45	720.31
2	50.000	58.02	92.82	93.23	101.99	102.44	91.88	92.29	203.97	204.88	184.10	170.94
3	12.500	17.38	14.83	12.75	15.89	13.64	14.32	12.29	31.78	27.28	39.91	37.64
4	3.125	4.65	5.04	4.85	5.33	5.12	4.80	4.61	10.65	10.23	9.04	9.76
5	0.781	1.34	1.75	1.58	1.82	1.65	1.64	1.48	3.63	3.29	2.63	2.49
6	0.195	0.368	0.446	0.432	0.456	0.442	0.411	0.398	0.912	0.883	0.644	0.493
7	0.049	0.115	0.117	0.110	0.117	0.110	0.105	0.099	0.234	0.220	0.148	0.0987
8	0.012	0.0343	0.0220	0.0089	0.0216	0.0067	0.0195	0.0060	0.0432	0.0134	0.0276	0.0366
9	0.013	0.0114	0.0261	0.0190	0.0256	0.0186	0.0231	0.0167	0.0512	0.0371	0.0467	0.0234
10	0.050	0.0447	0.0411	0.0335	0.0407	0.0331	0.0367	0.0298	0.0814	0.0662	0.0664	0.0654
11	0.042	0.059	0.0548	0.0594	0.0545	0.0590	0.0491	0.0532	0.109	0.118	0.0872	0.0695
12	0.025	0.026	0.0307	0.0158	0.0302	0.0155	0.0272	0.0139	0.0604	0.0309	0.0651	0.0668
13	0.104	0.0935	0.0835	0.0955	0.0835	0.0955	0.0752	0.0860	0.167	0.191	0.158	0.0909
14	0.036	0.0455	0.0300	0.0313	0.0295	0.0309	0.0266	0.0278	0.0590	0.0617	0.0396	0.0421
15	0.016	0.0223	0.0337	0.0472	0.0332	0.0468	0.0299	0.0421	0.0664	0.0935	0.023	0.0257
16	0.054	0.0885	0.0763	0.0922	0.0760	0.0920	0.0685	0.0829	0.152	0.184	0.151	IPC fail
17	0.008	0.0215	0.0319	0.0328	0.0315	0.0324	0.0284	0.0292	0.0630	0.0648	0.0326	0.0325
18	0.035	0.0584	0.0845	0.0763	0.0845	0.0760	0.0761	0.0685	0.169	0.152	0.1	0.0975
19	0.023	0.0695	0.0607	0.0618	0.0605	0.0615	0.0545	0.0554	0.121	0.123	0.108	0.112
20	0.034	0.0528	0.0646	0.0416	0.0645	0.0411	0.0581	0.0370	0.129	0.0822	0.0794	0.0815
21	0.01	0.0199	0.0213	0.0197	0.0209	0.0194	0.0188	0.0174	0.0418	0.0387	0.027	0.0222
22	0.052	0.139	0.159	0.170	0.160	0.172	0.144	0.155	0.320	0.343	0.183	0.15
23	0.025	0.0397	0.120	0.0984	0.121	0.0985	0.109	0.0887	0.241	0.197	0.109	0.0695
24	0.037	0.0565	0.0624	0.0409	0.0620	0.0405	0.0559	0.0364	0.124	0.0809	0.0584	0.0783

Table 20. Differences in Quantifiler concentration values across three laboratories.

	Promega Standard						Quantifiler (ABI) Standard						Promega vs Quantifiler (ABI) standard					
	Difference FSSA Promega Std to QLD Promega Std result 1	Difference FSSA Promega Std to QLD Promega Std result 2	Difference PathWest Promega Std to QLD Promega Std result 1	Difference PathWest Promega Std to QLD Promega Std result 2	Difference FSSA Promega Std to QLD Promega Std mean result	Difference PathWest Promega Std to QLD Promega Std mean result	Difference PathWest (ABI std) result 1 to QLD (ABI std mean)	Difference PathWest (ABI std) result 2 to QLD (ABI std mean)	Difference QLD (ABI std result 1) to PathWest (ABI std) result 1	Difference QLD (ABI std result 2) to PathWest (ABI std) result 1	Difference QLD (ABI std result 1) to PathWest (ABI std) result 2	Difference QLD (ABI std result 2) to PathWest (ABI std) result 2	Difference QLD (ABI Std mean/2) to QLD Promega Std mean result	Difference QLD (ABI Std mean/2 22) to QLD Promega Std mean result	Difference QLD (ABI std)/2 result 1 to QLD Promega Std mean	Difference QLD (ABI std)/2 result 2 to QLD Promega Std mean	Difference QLD (ABI std)/2 22 result 1 to QLD Promega Std mean	Difference QLD (ABI std)/2 22 result 2 to QLD Promega Std mean
Mean	44.50%	43.51%	23.44%	40.85%	41.36%	24.97%	29.57%	36.39%	49.23%	49.76%	68.43%	66.90%	2.37%	8.99%	11.77%	10.09%	10.24%	15.26%
Overall mean		44.01%		32.15%				32.90%		49.50%		67.66%				10.93%		12.75%
Sample																		
1	29.75%	12.53%	8.41%	14.05%	22.08%	1.60%	58.67%	25.94%	30.00%	43.95%	11.81%	29.39%	11.41%	0.37%	23.73%	0.92%	11.47%	10.74%
2	46.13%	46.37%	37.49%	37.77%	46.25%	37.63%	9.94%	16.38%	10.79%	11.29%	19.32%	19.85%	9.88%	1.01%	9.63%	10.12%	1.23%	0.79%
3	15.71%	1.96%	17.19%	36.31%	9.35%	26.03%	35.15%	27.46%	20.37%	31.65%	15.57%	27.52%	7.07%	3.54%	15.23%	1.09%	3.81%	10.89%
4	38.00%	35.57%	7.74%	4.12%	36.80%	5.97%	13.41%	6.51%	17.81%	13.16%	9.12%	4.82%	5.56%	4.90%	7.68%	3.44%	2.99%	6.81%
5	55.37%	50.57%	23.43%	15.19%	53.09%	19.52%	23.99%	28.03%	38.02%	25.10%	45.78%	32.13%	3.90%	6.39%	9.01%	1.20%	1.79%	10.99%
6	56.28%	54.86%	17.49%	14.81%	55.58%	16.17%	28.25%	45.07%	41.61%	37.11%	84.99%	79.11%	2.22%	7.91%	3.87%	0.57%	6.42%	9.40%
7	58.12%	55.45%	1.71%	4.55%	56.83%	1.32%	34.80%	56.52%	58.11%	48.65%	137.08%	122.90%	0.00%	9.91%	3.08%	3.08%	7.13%	12.69%
8	45.45%	73.66%	55.91%	396.38%	16.98%	137.29%	2.47%	29.33%	56.52%	51.45%	18.03%	63.39%	2.11%	11.81%	49.43%	53.65%	34.62%	58.24%
9	50.19%	31.58%	56.32%	40.00%	42.35%	49.45%	5.78%	47.00%	9.64%	20.56%	118.80%	58.55%	2.11%	11.81%	13.53%	17.74%	2.28%	25.89%
10	21.65%	49.25%	8.76%	33.43%	34.05%	19.84%	10.03%	11.38%	22.59%	0.30%	24.46%	1.22%	1.07%	10.88%	9.12%	11.26%	1.70%	20.05%
11	23.36%	29.29%	7.66%	0.67%	26.44%	3.33%	23.17%	38.77%	25.00%	35.32%	56.83%	69.78%	0.61%	10.46%	4.55%	3.33%	14.01%	6.91%
12	18.57%	58.23%	15.31%	64.56%	7.53%	11.83%	42.61%	46.33%	7.22%	52.53%	9.58%	53.74%	1.83%	11.56%	29.89%	33.55%	17.02%	40.13%
13	24.55%	8.90%	11.98%	2.09%	16.20%	4.47%	11.73%	49.22%	5.70%	20.89%	83.72%	110.12%	0.00%	9.91%	6.70%	6.70%	15.95%	3.87%
14	20.00%	15.02%	51.67%	45.37%	17.46%	48.45%	34.38%	30.24%	48.99%	55.81%	40.14%	46.56%	1.55%	11.31%	3.75%	0.65%	13.29%	9.32%
15	52.52%	66.10%	33.83%	52.75%	60.44%	44.87%	71.23%	67.85%	188.70%	306.52%	158.37%	263.81%	1.17%	10.97%	17.92%	15.57%	26.06%	4.12%
16	29.23%	41.43%	15.99%	4.01%	35.91%	5.04%	10.12%	IPC fail	0.66%	21.85%	IPC fail	IPC fail	0.30%	10.18%	9.79%	9.20%	18.73%	1.62%
17	74.92%	75.61%	32.60%	34.45%	75.27%	33.54%	48.98%	49.14%	93.25%	98.77%	93.85%	99.38%	1.24%	11.02%	2.63%	0.15%	12.28%	9.77%
18	58.58%	54.13%	30.89%	23.46%	56.47%	27.36%	37.69%	39.25%	69.00%	52.00%	73.33%	55.90%	0.19%	10.08%	5.10%	5.47%	5.32%	14.84%
19	62.11%	62.78%	14.50%	12.46%	62.45%	13.47%	11.48%	8.20%	12.04%	13.89%	8.04%	9.82%	0.41%	10.28%	1.22%	0.41%	11.01%	9.54%
20	47.37%	18.27%	18.27%	26.92%	35.97%	0.56%	24.81%	22.82%	62.47%	3.53%	58.28%	0.86%	0.56%	10.42%	21.47%	22.60%	9.43%	30.27%
21	53.05%	49.24%	6.57%	1.02%	51.22%	2.93%	32.92%	44.84%	54.81%	43.33%	88.29%	74.32%	1.83%	11.56%	1.95%	5.61%	8.15%	14.96%
22	67.30%	69.41%	12.58%	18.24%	68.39%	15.50%	44.80%	54.75%	74.86%	87.43%	113.33%	128.67%	0.76%	9.23%	2.74%	4.26%	12.37%	6.08%
23	79.17%	74.59%	66.92%	59.65%	77.11%	63.64%	50.23%	68.26%	121.10%	80.73%	246.76%	183.45%	0.27%	9.66%	10.35%	9.80%	0.59%	18.74%
24	40.71%	9.54%	9.46%	38.14%	28.36%	9.39%	43.00%	23.57%	112.33%	38.53%	58.37%	3.32%	0.82%	10.65%	20.04%	21.68%	8.14%	29.45%

5.6 LOWER LIMIT OF DETECTION (LOD) AND LIMIT OF REPORTING/QUANTITATION (LOR/LOQ)

The lower limit of detection (LOD) is the lowest concentration of analyte that can be reliably distinguished from zero, but not necessarily quantified, by the test method. It is the lowest value that is greater than the uncertainty associated with it. This is most commonly taken to be the concentration at which there is only a 5% chance that the result obtained will be within the range normally obtained for zero concentration. There are different approaches for estimating this, but the most common is to take the concentration corresponding to 3 times the standard deviation of the result obtained from the analysis of blanks (QIS 10663R2). This determination follows NATA guidelines (2004:2.5).

The lowest recorded Quantifiler value was worked out by using the Quantifiler standard from the kit. This was by examining DNAMaster on the 22.2.06 and eliminating undetermined or zero values. The lowest value was 0.000363ng/μL from DNA#81908 (Sample identification barcode 195520211). Such a low value is not expected to produce an STR profile with Profiler. According to Andrew Masel (pers. comm. to Iman Muharam 16.05.05) "anything greater than a Ct of 37-38 won't produce a STR anyway so it doesn't really matter that it is picking up in the order of 1-2 cells and remember the lowest size std is about 4 cells." A single diploid human cell contains approximately 6.4pg.

Table 21: The lowest Quantifiler standard values obtained in DNAMaster for values above zero out of a total of 18329 samples.

Quantifiler value	DNA number	Barcode
0.000363	81908	[redacted]
0.000441	74557	
0.000463	70228	
0.000589	70401	
0.000623	72259	
0.000672	74585	
0.000695	81403	

The Limit of Reporting or Quantitation (LOR/LOQ) is the lowest concentration of analyte that can be determined with acceptable repeatability and accuracy by the test method. This is the lowest concentration that can be determined with an acceptable level of uncertainty. Depending on the level of certainty required (e.g. whether or not the analysis is for legal purposes), this is usually taken as 6 or 10 times the limit of detection (QIS 10663R2) or 3 times the limit of detection according to NATA guidelines (2004:2.5).

The data available on the LOD and LOR/LOQ are based on the use of Promega Human Genomic DNA Male as the Quantifiler standard. They were calculated when there was background present in the system. Applied Biosystems (2005) have acknowledged the presence of contamination/background in their Quantifiler kits and recommend that each laboratory should "establish a Ct value above which a positive result represents only background DNA." If we account for contamination inherent in the Quantifiler kits, the LOD and LOQ can be determined. Rather than a CT value we have expressed this as a concentration value. The highest figures

obtained were 0.00467ng/μL for the LOD and 0.0467ng/μL for the LOR/LOQ using Promega Human Genomic DNA Male as the Quantifiler standard. This was with a slope of -3.137673, Y-intercept of 28.300249 and R2 of 0.996778. These figures were calculated based on currently known levels of background contamination. With the assumption that Applied Biosystems does not alter its quality control procedures and higher concentration levels of contaminants are not introduced into reagents during manufacture in the future, the figures are valid.

Table 22: LOD and LOR/LOQ data for samples using Promega Human Genomic DNA Male as the Quantifiler standard.

Sample number	30	13
Positive result (amplified) sample number	13	13
Mean (ng/uL)	0.000786	0.00181
1 Standard deviation	0.00110	0.000953
LOD method 1 (95% confidence interval) ($2s_0$) (Applied Biosystems 2003:6-7) (ng/uL)	0.00299	0.00372
LOD method 2 (95% confidence interval) ($3s_0$)(QIS 10662R2, NATA 2004) (ng/uL)	0.00409	0.00467
LOR/LOQ method1 (3x LOD) using $2s_0$ (ng/uL)	0.00896	0.0112
LOR/LOQ method2 (3x LOD) using $3s_0$ (ng/uL)	0.0123	0.0140
LOR/LOQ method3 (10x LOD) using $3s_0$ (QIS 10663R2) (ng/uL)	0.0409	0.0467

	1	2	3	4	5	6	7	8	9	10	11	12
A	STD#1 50 ng/µL	STD#1 50 ng/µL	Reagent blank Y3	Reagent blank Y3	Reagent blank Y4	Reagent blank Y4	Reagent blank Y5	Reagent blank Y5	OMIT	OMIT	OMIT	OMIT
B	STD#2 16.7ng/µL	STD#2 16.7ng/µL	Nanopure H2O Y3	Nanopure H2O Y3	Nanopure H2O Y4	Nanopure H2O Y4	Nanopure H2O Y5	Nanopure H2O Y5	OMIT	OMIT	OMIT	OMIT
C	STD#3 5.56ng/µL	STD#3 5.56ng/µL	Promega Female 1ng/µL Y3	Promega Female 1ng/µL Y3	Promega Female 1ng/µL Y4	Promega Female 1ng/µL Y4	Promega Female 1ng/µL Y5	Promega Female 1ng/µL Y5	OMIT	OMIT	OMIT	OMIT
D	STD#4 1.85ng/µL	STD#4 1.85ng/µL	Promega Female 0.1ng/µL Y3	Promega Female 0.1ng/µL Y3	Promega Female 0.1ng/µL Y4	Promega Female 0.1ng/µL Y4	Promega Female 0.1ng/µL Y5	Promega Female 0.1ng/µL Y5	OMIT	OMIT	OMIT	OMIT
E	STD#5 0.62ng/µL	STD#5 0.62ng/µL	EPC Y3	EPC Y3	EPC Y4	EPC Y4	EPC Y5	EPC Y5	OMIT	OMIT	OMIT	OMIT
F	STD#6 0.21ng/µL	STD#6 0.21ng/µL	Reagent blank Y3	Reagent blank Y3	Reagent blank Y4	Reagent blank Y4	Reagent blank Y5	Reagent blank Y5	OMIT	OMIT	OMIT	OMIT
G	STD#7 0.068ng/µL	STD#7 0.068ng/µL	Reagent blank Y3	Reagent blank Y3	Reagent blank Y4	Reagent blank Y4	Reagent blank Y5	Reagent blank Y5	OMIT	OMIT	OMIT	OMIT
H	STD#8 0.023ng/µL	STD#8 0.023ng/µL	Reagent blank Y3	Reagent blank Y3	Reagent blank Y4	Reagent blank Y4	Reagent blank Y5	Reagent blank Y5	OMIT	OMIT	OMIT	OMIT

Figure 9: A platemap of Testquant_210406. The orange colour indicates where amplified product was detected. The values obtained were used to calculate the LOD and LOR/LOQ. Three batches of reagent mix (Y3, Y4 and Y5) were tested. These kits were found to contain background contamination during investigation in April, 2004.

5.7 WORKING RANGE AND SAMPLE DISTRIBUTION

Working range determination is a requirement of NATA (2004:2.6). The minimum acceptable working concentration based on the LOD is 0.00467ng/μL while the minimum acceptable working concentration beyond any reasonable doubt is the LOR/LOQ of 0.0467ng/μL (10xLOD). The maximum acceptable working concentration is the value of the standard with the highest concentration. This is equal to 50ng/μL (STD1). It is recommended that values beyond 50ng/μL be diluted and requantified and the dilution used for amplification. Samples above 50ng/μL can produce IPC CT results outside of the normal 20-30 range because large amounts of DNA overload the system and affect the efficiency of the Quantifiler IPC reaction. Two samples in the collaborative trial producing mean Quantifiler values of 93.03 and 256.69ng/μL using the Promega Male standard produced IPC CT values of 31.54 and 35.91 respectively.

5.8 CONTAMINATION

The laboratory must demonstrate that its procedures minimise contamination that would compromise the integrity of the results (QIS 23401R0). The laboratory should employ appropriate controls and implement quality practices to assess contamination and demonstrate that its procedure minimises contamination (QIS 23401R0).

The mean observable contamination out of all the samples where readings were obtained when using Promega Human Genomic DNA Male as a standard was approximately 0.00181ng/μL with one standard deviation at 0.000953ng/μL. If we account for contamination inherent in the Quantifiler kits and set the means as the baseline for the LOD and LOQ, the highest figures obtained were 0.00467ng/μL for the LOD and 0.0467ng/μL for the LOR/LOQ. This means that we can be confident that anything higher than 0.00467ng/μL is not likely to be a contaminant but a real result. For legal, commercial or statutory applications the amount of freedom is increased in the LOR/LOQ so that we can be confident "beyond reasonable doubt" that anything over 0.0467ng/μL is not likely to be a contaminant but a real result.

5.9 SELECTIVITY

5.9.1 SELECTIVITY-SPECIES SPECIFICITY

Selectivity is the ability of the test method to measure an analyte accurately in the presence of potentially interfering substances (QIS 10663R2). It is tested by comparing results for samples containing impurities with results for samples without impurities (QIS 10662R2). It is a NATA guideline to test species specificity (2004:2.1). Following the advice of Cathie Allen (pers. comm. with Hlinka and Muharam 2005), it was agreed that species specificity would not be included in this validation. This is because species specificity was already tested in the developmental validation by Applied Biosystems (2003) and it was found that Quantifiler Human Kit amplified DNA from higher ape DNA samples including gorilla, chimpanzee,

orangutan, macaque as well as humans. However, other species including cat, dog, pig, cow, mouse, rabbit, hampster, rat, chicken, fish, horse, sheep, and deer did not produce amplified product (Applied Biosystems 2003).

Two samples of dog blood were analysed as a part of the Outsourcing Project at Forensic Biology, QHSS. These consisted of dog blood on fabric (DNA# Sample ID) and dog blood on wood (DNA# , ID). After chelex extraction, both failed to amplify on Quantifiler and produced undetermined values (0ng/μL) with the Quantifiler standard. This agreed with the dog results from Applied Biosystems (2003).

5.9.2 SELECTIVITY-INHIBITORS

The Quantifiler system uses an internal positive control (IPC) to determine if the measurement is potentially accurate. If there are inhibitors present, the IPC will generally be outside the recommended CT range of 20-30. We have not rigorously tested the system by comparing results for samples containing inhibitors with results for samples without impurities.

It should be noted that the lack of inhibition in Quantifiler is not necessarily an indication that the Profiler amplification will not be inhibited. This is primarily because the systems are different and a greater sample per total reaction volume is used in Profiler. An example of this is shown in table 23. Note that this data was also obtained using the Quantifiler standard rather than the Promega Male standard.

Table 23: Examples of samples which were not inhibited in Quantifiler but were inhibited at the amplification stage.

Sample No#	Sample Type	Quant# and Quant Value	Result in Amp	CW#	Other Amp Volumes	Reamp Results	Notes
	Blood swab	QF#269 Quant= 0.08 IPC 27.31, 27.43	NSD @ 20uL	CW#558	5uL PP (12 all-14 inc. Amel.) in CW#549	3uL PP (8 inc. Amel.) in CW#576 5uL PP (8 inc. Amel.) in CW#576 10uL PP (2 inc. Amel.) in CW#576	Later results=greater inhibition/degradation?
	Diff. Lysis	QF#265 Quant= 0.25 IPC 27.43, 27.49	NSD@10uL	CW#545		3uL PP (8 inc. Amel.) in CW#608 4uL PP (13 inc. Amel.) in CW#592 8uL PP (7 inc. Amel.) in CW#592	3uL sample could have greater inhibition or degradation being a later sample or the concentration could be less optimal with the ideal between 4 and 8.

It was interesting to note that at higher concentrations (≥5.56ng/μL or the concentration of standard three and above) of the various genomic samples, including the Promega Male standard, the mean IPC CT values increased (see figure 10 and table 20). This indicates a potential but very weak form of partial inhibition from the Promega and Roche genomic samples at concentration levels of ≥5.56ng/μL. The effect was not observed for the Quantifiler standard which was linear throughout. Samples above 50ng/μL can be outside the CT range of 20-30 because large amounts of DNA overload the system and affect the efficiency of the Quantifiler IPC reaction (refer to section 5.7).

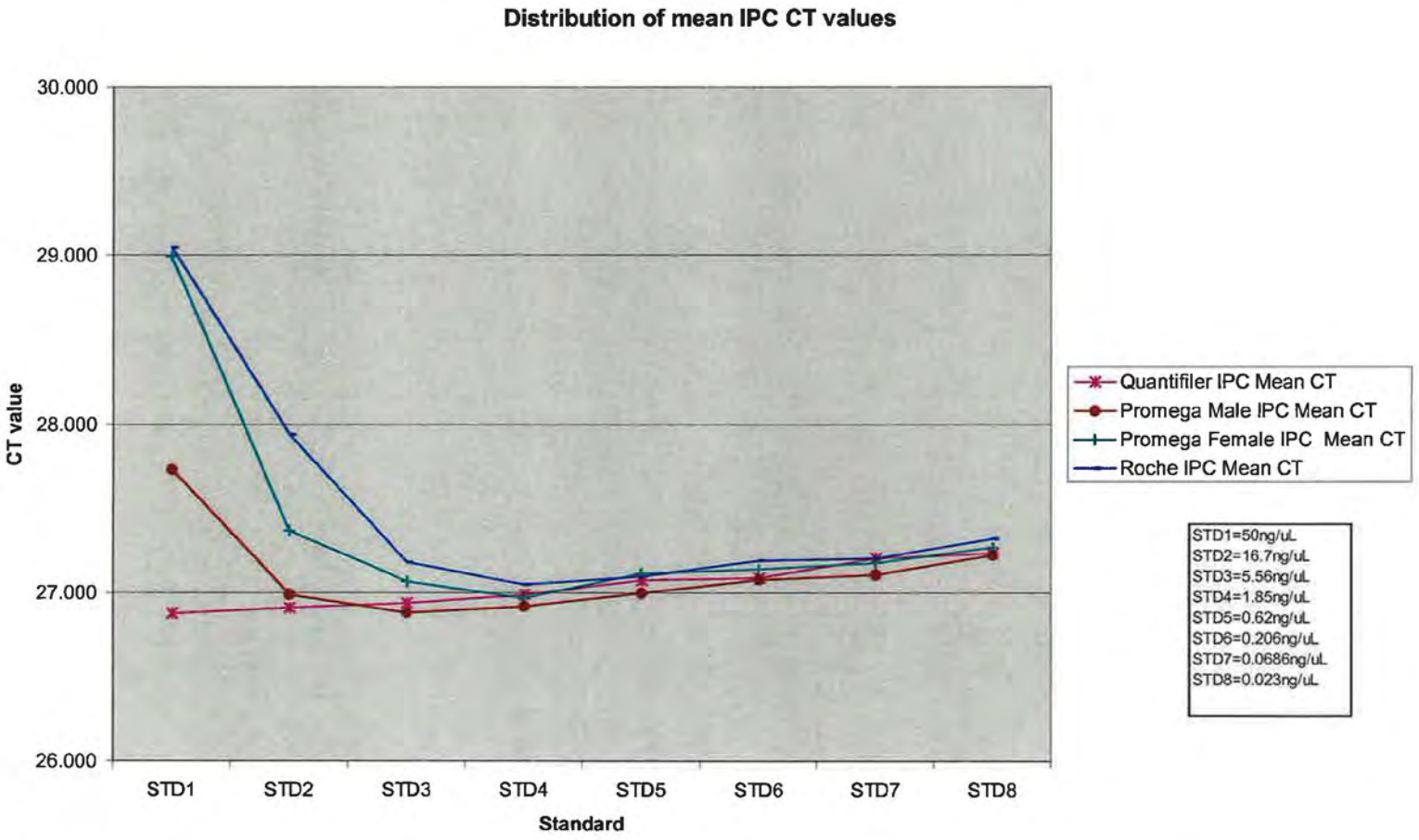

Figure 10: Distribution of mean IPC values for the four types of Human DNA control samples tested.

5.10 VALIDATION OF THE PROMEGA MALE STANDARD (QUANTIFILER STANDARD RESULTS VERSUS PROMEGA STANDARD RESULTS)

5.10.1 PROBATIVE SAMPLES (QUANTIFILER STANDARD RESULTS VERSUS PROMEGA MALE STANDARD RESULTS)

The testing of the method and modifications of the method on probative and non-probative samples is required according to DAB (2000: 8.1.3.1) and SWGDAM (2004: 3.1) guidelines. A total of 127 probative samples were analysed with both the Quantifiler standard and the Promega Male standard. However, only the values determined from the Quantifiler standard were actually used for amplification with Profiler Plus. The final Profiler Plus results from these samples at 50μL reactions are presented in table 33 and figure 11. Similarity in Quantifiler concentration and amplification volumes was compared, but the initial Profiler amplifications consisted of an estimated amount of 2 Quantifiler nanograms. We have shown in the validation of the Quantifiler standard that 1 Promega Male standard nanogram is equivalent to approximately 2.22 or 2 Quantifiler standard nanograms. This result was confirmed with the probative sample data presented in figures 23 to 25. The difference in DNA concentrations (Quantity in ng/μL) showed the least mean difference in all three tables with the Quantifiler standard concentrations divided by 2.22 and the Promega Male standard concentration. Therefore, while the Quantifiler Human DNA Standard result needed to be calibrated, the Promega Male standard results did not.

The sample volumes and amplification volumes, as well as actual accepted amplification volumes were also compared (see figures 26, 27 and 28) for individual results from each duplicate while the same was done with the mean Quantifiler results (see figures 29, 30 and 31) which were used for the initial Profiler amplifications. The greatest differences were observed between the uncalibrated Quantifiler Human DNA standard results and Promega Male standard results producing a mean difference of 112.7474% for the amplification volumes of full profile samples. The smallest resulting mean difference was with the Quantifiler standard at 2.22ng and Promega Human Genomic DNA Male control at 1ng for full profile samples at 10.9356%. With the samples resulting in full profiles, the rounded Quantifiler standard result amplification volumes at 2ng produced the smallest mean difference with the actual accepted volumes. The actual accepted volumes were the volumes accepted as the most optimal results out of up to three amplifications and not necessarily what was originally calculated as the ideal volume for the initial PCR based on the Quantifiler results. The result was obviously biased by 2ng being the original amplification target. The mean difference of the rounded Promega Male standard amplification volume and actual accepted amplification volume was 14.3081% for full profile results (see table 24). This mean percentage is so low that the full profile results should not be significantly affected when Promega Male standard is utilised instead of the Quantifiler Human DNA standard.

With partial profile and mixture results (table 25), similar results as for the full profiles are visible. However, the differences of the rounded Promega Male standard amplification volume and accepted amplification volume are greater with a mean difference of 27.8991%. However, the mean difference of the Promega Male standard to Quantifiler Human DNA standard concentration/2.22 was only 10.6833%.

With resulting profiles producing no-size data (NSD) and non-reportable (NR) profiles, most of the samples were amplified at maximum sample volumes of 20μL in 50μL Profiler Plus reactions. Quantifiler values were still comparable with the mean difference of the Promega Male standard and the Quantifiler Human DNA standard concentration/2.22 at only 13.3795%.

Table 24: Comparison of Quantifiler and Promega Male standard concentration results for full profile probative samples. The quantity shown is in ng/μL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 11.31%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 13.9%. Duplicate results are presented.

Full profile samples								
Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega Male standard	Difference of Quantifiler standard/2 and the Promega Male standard	Difference of Quantifiler standard/2.22 and the Promega Male standard
[redacted]	28.63	1.480	0.740	0.667	0.647	128.75%	[illegible]	3.04%
	28.54	1.570	0.785	0.707	0.690	127.54%	[illegible]	2.49%
	31.07	0.246	0.123	0.111	0.106	132.08%	[illegible]	4.54%
	31.02	0.254	0.127	0.114	0.110	130.91%	[illegible]	4.01%
	28.62	1.490	0.745	0.671	0.652	128.53%	[illegible]	2.94%
	28.62	1.490	0.745	0.671	0.652	128.53%	[illegible]	2.94%
	29.38	0.849	0.425	0.382	0.370	129.46%	[illegible]	3.36%
	29.3	0.901	0.451	0.406	0.393	129.26%	[illegible]	3.27%
	30.18	0.479	0.240	0.216	0.208	130.29%	[illegible]	3.73%
	30.01	0.536	0.268	0.241	0.233	130.04%	[illegible]	3.62%
	31.16	0.229	0.115	0.103	0.099	131.31%	[illegible]	4.20%
	31.03	0.253	0.127	0.114	0.110	130.00%	[illegible]	3.60%
	28.2	2.020	1.010	0.910	0.888	127.48%	[illegible]	2.47%
	27.88	2.570	1.285	1.158	1.130	127.43%	[illegible]	2.45%
	31.28	0.210	0.105	0.095	0.091	131.79%	[illegible]	4.41%
	31.61	0.165	0.083	0.074	0.071	132.07%	[illegible]	4.53%
	28.15	2.110	1.055	0.950	0.926	127.86%	[illegible]	2.64%
	28.19	2.050	1.025	0.923	0.898	128.29%	[illegible]	2.83%
	29.54	0.758	0.379	0.341	0.330	129.70%	[illegible]	3.47%
	29.62	0.715	0.358	0.322	0.312	129.17%	[illegible]	3.23%
	30.24	0.452	0.226	0.204	0.196	130.61%	[illegible]	3.88%
	30.46	0.384	0.192	0.173	0.167	129.94%	[illegible]	3.58%
	25.81	12.940	6.470	5.829	6.120	111.44%	[illegible]	4.76%
	25.67	14.270	7.135	6.428	6.780	110.47%	[illegible]	5.19%
	31.66	0.204	0.102	0.092	0.079	157.58%	[illegible]	16.03%
	32.02	0.157	0.079	0.071	0.060	159.93%	[illegible]	17.09%
	28.3	2.210	1.105	0.995	0.962	129.73%	[illegible]	3.48%
	28.29	2.230	1.115	1.005	0.968	130.37%	[illegible]	3.77%
	29.18	1.200	0.600	0.541	0.509	135.76%	[illegible]	6.20%
	29.04	1.310	0.655	0.590	0.555	136.04%	[illegible]	6.32%
	22.39	146.530	73.265	66.005	77.620	88.78%	[illegible]	14.96%
	22.41	143.880	71.940	64.811	76.150	88.94%	[illegible]	14.88%
	31.95	0.166	0.083	0.075	0.064	159.78%	[illegible]	17.02%
	31.87	0.176	0.088	0.079	0.068	159.59%	[illegible]	16.93%
	28.08	2.580	1.290	1.162	1.130	128.32%	[illegible]	2.85%
	28.13	2.490	1.245	1.122	1.090	128.44%	[illegible]	2.90%
	29.45	0.975	0.488	0.439	0.408	138.97%	[illegible]	7.64%
	29.49	0.949	0.475	0.427	0.397	139.04%	[illegible]	7.68%
	28.6	1.790	0.895	0.806	0.769	132.77%	[illegible]	4.85%
	28.57	1.830	0.915	0.824	0.787	132.53%	[illegible]	4.74%
	30.73	0.395	0.198	0.178	0.158	150.00%	[illegible]	12.61%
	30.69	0.407	0.204	0.183	0.163	149.69%	[illegible]	12.47%
	29.02	1.320	0.660	0.595	0.562	134.88%	[illegible]	5.80%
	29.09	1.260	0.630	0.568	0.534	135.96%	[illegible]	6.29%
	29.18	1.190	0.595	0.536	0.501	137.52%	[illegible]	6.99%
	29.25	1.120	0.560	0.505	0.473	136.79%	[illegible]	6.66%
	29.73	0.800	0.400	0.360	0.332	140.96%	[illegible]	8.54%
	29.78	0.771	0.386	0.347	0.319	141.69%	[illegible]	8.87%
	31.24	0.274	0.137	0.123	0.108	153.70%	[illegible]	14.28%
	31.48	0.231	0.116	0.104	0.090	155.53%	[illegible]	15.10%
	19.18	2011.980	1005.990	906.297	883.530	127.72%	[illegible]	2.58%
	19.18	2015.100	1007.550	907.703	884.910	127.72%	[illegible]	2.58%
	19.18	2019.860	1009.930	909.847	887.020	127.71%	[illegible]	2.57%
	19.17	2033.770	1016.885	916.113	893.180	127.70%	[illegible]	2.57%
	19.2	1981.270	990.635	892.464	869.930	127.75%	[illegible]	2.59%
	19.25	1911.490	955.745	861.032	839.040	127.82%	[illegible]	2.62%
	17.89	5365.580	2682.790	2416.928	2375.890	125.83%	[illegible]	1.73%
	18.46	3483.560	1741.780	1569.171	1536.890	126.66%	[illegible]	2.10%
	18.11	4534.020	2267.010	2042.351	2004.810	126.16%	[illegible]	1.87%
	18.42	3605.070	1802.535	1623.905	1590.960	126.60%	[illegible]	2.07%
	19.06	2200.160	1100.080	991.063	968.900	127.55%	[illegible]	2.50%
	18.92	2461.300	1230.650	1108.694	1082.690	127.33%	[illegible]	2.40%
	18.14	4448.710	2224.355	2003.923	1966.770	126.19%	[illegible]	1.89%
	19.09	2157.550	1078.775	971.869	948.020	127.58%	[illegible]	2.52%
	19.1	2131.920	1065.960	960.324	938.660	127.61%	[illegible]	2.53%
	19.07	2192.490	1096.245	987.608	963.500	127.55%	[illegible]	2.50%
	30.12	0.482	0.241	0.217	0.197	144.67%	[illegible]	10.21%
	30.17	0.464	0.232	0.209	0.190	144.21%	[illegible]	10.00%
	30.06	0.504	0.252	0.227	0.206	144.66%	[illegible]	10.21%
	30.11	0.486	0.243	0.219	0.199	144.22%	[illegible]	10.01%
	26.11	10.270	5.135	4.626	4.310	138.28%	[illegible]	7.33%
	26.05	10.710	5.355	4.824	4.500	138.00%	[illegible]	7.21%
	27.01	5.150	2.575	2.320	2.150	139.53%	[illegible]	7.90%
	26.96	5.370	2.685	2.419	2.240	139.73%	[illegible]	7.99%
	25.77	13.230	6.615	5.959	5.570	137.52%	[illegible]	6.99%
	25.84	12.600	6.300	5.676	5.300	137.74%	[illegible]	7.09%
	30.58	0.334	0.167	0.150	0.196	70.41%	[illegible]	23.24%
	30.52	0.348	0.174	0.157	0.204	70.59%	[illegible]	23.16%
	28.92	1.090	0.545	0.491	0.643	69.52%	[illegible]	23.64%
	28.88	1.120	0.560	0.505	0.665	68.42%	[illegible]	24.13%
	29.81	0.577	0.289	0.260	0.340	69.71%	[illegible]	23.56%

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Full profile samples

Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2.22	Quantity Promega Standard	Difference of Quantifiler standard and the Promega standard	Difference of Quantifiler standard/2 and the Promega standard	Difference of Quantifiler standard/2.22 and the Promega standard
[redacted]	29.84	0.567	0.284	0.255	0.334	69.76%	15.12%	23.53%
	30.26	0.418	0.209	0.188	0.245	70.61%	14.69%	23.15%
	30.33	0.399	0.200	0.180	0.234	70.51%	14.74%	23.19%
	28.15	1.880	0.940	0.847	1.120	67.86%	16.07%	24.39%
	28.15	1.890	0.945	0.851	1.120	68.75%	15.63%	23.99%
	29.49	0.724	0.362	0.326	0.427	69.56%	15.22%	23.62%
	29.43	0.755	0.378	0.340	0.445	69.66%	15.17%	23.58%
	28.91	1.100	0.550	0.495	0.648	69.75%	15.12%	23.53%
	28.91	1.090	0.545	0.491	0.646	68.73%	15.63%	24.00%
	25.08	16.750	8.375	7.545	10.100	65.84%	17.06%	25.30%
	25.03	17.310	8.655	7.797	10.450	65.65%	17.18%	25.38%
	29.25	0.862	0.431	0.388	0.509	69.35%	15.32%	23.72%
	29.16	0.921	0.461	0.415	0.544	69.30%	15.35%	23.74%
	30.52	0.348	0.174	0.157	0.204	70.59%	14.71%	23.16%
	30.4	0.379	0.190	0.171	0.223	69.96%	15.02%	23.44%
	28.08	1.970	0.985	0.887	1.170	68.38%	15.81%	24.15%
	28.22	1.800	0.900	0.811	1.070	68.22%	15.89%	24.22%
	27.61	2.760	1.380	1.243	1.640	68.29%	15.85%	24.19%
	27.49	3.020	1.510	1.360	1.800	67.78%	16.11%	24.42%
	27.67	2.590	1.295	1.167	1.400	85.00%	7.50%	16.67%
	27.7	2.530	1.265	1.140	1.370	84.67%	7.66%	16.81%
	30.45	0.338	0.169	0.152	0.178	89.89%	5.06%	14.47%
	30.2	0.405	0.203	0.182	0.214	89.25%	5.37%	14.75%
	24.08	35.690	17.845	16.077	19.960	78.81%	10.60%	19.46%
	24.09	35.450	17.725	15.968	19.820	78.86%	10.57%	19.43%
	28.44	1.480	0.740	0.667	0.792	86.87%	6.57%	15.82%
	28.54	1.370	0.685	0.617	0.733	86.90%	6.55%	15.81%
	29.07	0.929	0.465	0.418	0.496	87.30%	6.35%	15.63%
	29.19	0.849	0.425	0.382	0.452	87.83%	6.08%	15.39%
	25.52	12.470	6.235	5.617	6.880	81.25%	9.37%	18.36%
	25.85	9.800	4.900	4.414	5.390	81.82%	9.09%	18.10%
	29.05	0.946	0.473	0.426	0.505	87.33%	6.34%	15.62%
	28.96	1.010	0.505	0.455	0.539	87.38%	6.31%	15.59%
	28.24	1.710	0.855	0.770	0.917	86.48%	6.76%	16.00%
	28.43	1.480	0.740	0.667	0.794	86.40%	6.80%	16.04%
	30.02	0.463	0.232	0.209	0.245	88.98%	5.51%	14.87%
	30.01	0.468	0.234	0.211	0.248	88.71%	5.65%	15.00%
	31.56	0.151	0.076	0.068	0.079	92.36%	3.82%	13.35%
	31.26	0.187	0.094	0.084	0.098	91.60%	4.20%	13.69%
	28.01	2.010	1.005	0.905	1.090	84.40%	7.80%	16.94%
	28.05	1.950	0.975	0.878	1.050	85.71%	7.14%	16.34%
	28.28	1.660	0.830	0.748	0.891	86.31%	6.85%	16.08%
	28.39	1.530	0.765	0.689	0.821	86.36%	6.82%	16.05%
	26.86	4.680	2.340	2.108	2.550	83.53%	8.24%	17.33%
	26.87	4.650	2.325	2.095	2.530	83.79%	8.10%	17.21%
	25.84	9.910	4.955	4.464	5.450	81.83%	9.08%	18.09%
	25.88	9.570	4.785	4.311	5.260	81.94%	9.03%	18.05%
	29.25	0.817	0.409	0.368	0.435	87.82%	6.09%	15.40%
	29.38	0.741	0.371	0.334	0.394	88.07%	5.95%	15.28%
	29.49	0.682	0.341	0.307	0.362	88.40%	5.80%	15.14%
	29.57	0.643	0.322	0.290	0.342	88.01%	5.99%	15.31%
	30.19	0.410	0.205	0.185	0.216	89.81%	5.09%	14.50%
	30.17	0.417	0.209	0.188	0.220	89.55%	5.23%	14.62%
	31.91	0.116	0.058	0.052	0.060	92.37%	3.81%	13.35%
	31.68	0.138	0.069	0.062	0.072	92.47%	3.77%	13.30%
	30.29	0.380	0.190	0.171	0.201	89.05%	5.47%	14.84%
	30.25	0.391	0.196	0.176	0.208	89.81%	5.10%	14.50%
	30.5	0.325	0.163	0.146	0.171	90.06%	4.97%	14.39%
	30.64	0.294	0.147	0.132	0.155	89.68%	5.16%	14.56%
	26.18	9.740	4.870	4.387	4.090	138.14%	19.07%	7.27%
	25.82	12.800	6.400	5.766	5.390	137.48%	18.74%	6.97%
	29.56	0.904	0.452	0.407	0.377	139.79%	19.89%	8.01%
	29.42	1.000	0.500	0.450	0.419	138.66%	19.33%	7.51%
	28.41	2.040	1.020	0.919	0.886	130.25%	15.12%	3.72%
	28.37	2.110	1.055	0.950	0.915	130.60%	15.30%	3.87%
	27.23	4.700	2.350	2.117	2.120	121.70%	10.85%	0.14%
	27.22	4.740	2.370	2.135	2.140	121.50%	10.75%	0.23%
	30.18	0.472	0.236	0.213	0.205	130.24%	15.12%	3.71%
	30.24	0.452	0.226	0.204	0.196	130.61%	15.31%	3.88%
	28.89	1.220	0.610	0.550	0.535	128.04%	14.02%	2.72%
	28.81	1.300	0.650	0.586	0.569	128.47%	14.24%	2.91%
	29.19	0.976	0.488	0.440	0.426	129.11%	14.55%	3.20%
	29.5	0.780	0.390	0.351	0.340	129.41%	14.71%	3.34%
	29.11	0.952	0.476	0.429	0.563	69.09%	15.45%	23.83%
	28.77	1.210	0.605	0.545	0.719	68.29%	15.86%	24.19%
	27.33	3.360	1.690	1.523	2.010	68.16%	15.92%	24.25%
	27.18	3.750	1.875	1.689	2.240	67.41%	16.29%	24.59%
	26.16	9.880	4.940	4.450	4.150	138.07%	19.04%	7.24%
	26.08	10.510	5.255	4.734	4.410	138.32%	19.16%	7.35%
	27.83	2.670	1.335	1.203	1.170	128.21%	14.10%	2.80%
	27.75	2.830	1.415	1.275	1.240	128.23%	14.11%	2.80%
					Mean	**110.33%**	**13.99%**	**11.31%**

Table 25: Comparison of Quantifiler and Promega Male standard concentration results for probative samples that resulted in partial profiles and mixtures. The quantity shown is in ng/μL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 14.09%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 16.56%. Duplicate results are presented.

Partial Profiles and Mixtures									
Result	Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2 .22	Quantity Promega Standard	Difference of Quantifiler standard and the Promega standard	Difference of Quantifiler standard/2 and the Promega standard	Difference of Quantifiler standard/2 .22 and the Promega standard
X,Y+24 mixture	[redacted]	28.88	1.470	0.735	0.662	0.625	135.20%	17.60%	5.95%
X,Y+24 mixture		28.88	1.460	0.730	0.658	0.623	134.35%	17.17%	5.56%
X,Y+22 Mixture		31.05	0.239	0.120	0.108	0.140	70.71%	14.64%	23.10%
X,Y+22 Mixture		31.04	0.240	0.120	0.108	0.140	71.43%	14.29%	22.78%
X,Y+21 mixture		29.35	1.050	0.525	0.473	0.441	138.10%	19.05%	7.25%
X,Y+21 mixture		29.58	0.889	0.445	0.400	0.370	140.27%	20.14%	8.23%
X,Y+19 Mixture		27.68	2.620	1.310	1.180	1.560	67.95%	16.03%	24.35%
X,Y+19 Mixture		27.66	2.680	1.340	1.207	1.590	68.55%	15.72%	24.08%
X,NR+18 Mixture		31.35	0.189	0.095	0.085	0.077	145.77%	22.89%	10.71%
X,NR+18 Mixture		31.74	0.141	0.071	0.064	0.057	146.94%	23.47%	11.23%
X,NR+17 mixture		31.84	0.136	0.068	0.061	0.079	71.93%	14.03%	22.55%
X,NR+17 mixture		32.02	0.119	0.060	0.054	0.070	71.22%	14.39%	22.87%
X,Y+17		30.49	0.468	0.234	0.211	0.189	147.62%	23.81%	11.54%
X,Y+17		30.27	0.547	0.274	0.246	0.223	145.29%	22.65%	10.49%
X,X+16		30.15	0.421	0.211	0.190	0.222	89.64%	5.18%	14.58%
X,X+16		29.71	0.581	0.291	0.262	0.308	88.64%	5.68%	15.03%
X,Y+16		32.1	0.101	0.051	0.045	0.052	93.12%	3.44%	13.01%
X,Y+16		31.94	0.114	0.057	0.051	0.059	92.24%	3.88%	13.40%
X,Y+16 Mixture		29.24	0.941	0.471	0.424	0.387	143.15%	21.58%	9.53%
X,Y+16 Mixture		29.38	0.847	0.424	0.382	0.348	143.39%	21.70%	9.64%
X,Y+16 Mixture		30.94	0.259	0.130	0.117	0.105	146.67%	23.33%	11.11%
X,Y+16 Mixture		30.78	0.292	0.146	0.132	0.119	145.38%	22.69%	10.53%
X,X+14		33.27	0.043	0.022	0.019	0.022	95.02%	2.49%	12.15%
X,X+14		33.28	0.043	0.021	0.019	0.022	94.55%	2.73%	12.37%
X,Y+12 on 813		30.18	0.474	0.237	0.214	0.206	130.10%	15.05%	3.65%
X,Y+12 on 813		30.11	0.498	0.249	0.224	0.216	130.56%	15.28%	3.85%
X,Y+11		30.24	0.427	0.214	0.192	0.251	70.12%	14.94%	23.37%
X,Y+11		30.4	0.381	0.191	0.172	0.224	70.09%	14.96%	23.38%
X,Y+11 (10uL on CW#869)		30.21	0.433	0.217	0.195	0.254	70.47%	14.76%	23.21%
X,Y+11 (10uL on CW#869)		30.27	0.418	0.209	0.188	0.245	70.61%	14.69%	23.15%
X,Y+8 on CW#869(20uL)		32	0.121	0.061	0.055	0.071	71.63%	14.18%	22.69%
X,Y+8 on CW#869(20uL)		32.11	0.112	0.056	0.050	0.065	71.78%	14.11%	22.62%
X,Y+6		32.35	0.096	0.048	0.043	0.041	132.85%	16.42%	4.89%
X,Y+6		32.44	0.089	0.045	0.040	0.038	133.16%	16.58%	5.03%
X,Y+3		32.92	0.063	0.031	0.028	0.027	133.46%	16.73%	5.16%
X,Y+3		33.17	0.052	0.026	0.024	0.022	133.48%	16.74%	5.17%
X,Y+1		32.41	0.091	0.045	0.041	0.053	72.38%	13.81%	22.35%
X,Y+1		32.32	0.097	0.049	0.044	0.056	72.29%	13.85%	22.39%
X,Y+1		32.54	0.083	0.042	0.037	0.036	133.05%	16.53%	4.98%
X,Y+1		32.18	0.108	0.054	0.049	0.047	131.76%	15.88%	4.40%
X,Y+1		32.43	0.090	0.045	0.040	0.039	132.64%	16.32%	4.79%
X,Y+1		32.08	0.116	0.058	0.052	0.050	131.54%	15.77%	4.30%
X,0+0		33.76	0.046	0.023	0.021	0.017	175.45%	37.72%	24.08%
X,0+0		33.43	0.058	0.029	0.026	0.021	172.77%	36.38%	22.87%
X,X+0		32.06	0.110	0.055	0.050	0.044	147.75%	23.87%	11.60%
X,X+0		32.38	0.086	0.043	0.039	0.035	148.13%	24.06%	11.77%
X,NR+ 0		32.29	0.099	0.049	0.044	0.057	72.08%	13.96%	22.49%
X,NR+ 0		32.51	0.084	0.042	0.038	0.049	72.39%	13.80%	22.35%
						Mean	111.83%	16.56%	14.09%

Table 26: Comparison of Quantifiler and Promega Male standard concentration results for probative samples that resulted in non-reportable profiles and NSDs. The quantity shown is in ng/μL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 13.38%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 18.30%. Duplicate results are presented.

NR profiles and NSDs									
	Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2.22	Quantity Promega Standard	Difference of Quantifiler standard and the Promega standard	Difference of Quantifiler standard/2 and the Promega standard	Difference of Quantifiler standard/2.22 and the Promega standard
NR profile	[redacted]	34.33	0.020	0.010	0.009	0.008	150.97%	25.48%	13.05%
NR profile		33.88	0.028	0.014	0.012	0.011	150.00%	25.00%	12.61%
NR profile		36.42	0.004	0.002	0.002	0.002	153.85%	26.92%	14.35%
NR profile		37.18	0.002	0.001	0.001	0.001	155.47%	27.73%	15.07%
NR profile		35.81	0.006	0.003	0.003	0.003	153.20%	26.60%	14.05%
NR profile		35.74	0.007	0.003	0.003	0.003	153.23%	26.62%	14.07%
NR profile		33.85	0.033	0.016	0.015	0.019	73.40%	13.30%	21.89%
NR profile		34.58	0.019	0.010	0.009	0.011	74.77%	12.61%	21.27%
NR profile		32.3	0.098	0.049	0.044	0.057	72.06%	13.97%	22.50%
NR profile		32.85	0.066	0.033	0.030	0.038	72.40%	13.80%	22.34%
NR profile		33.76	0.035	0.017	0.016	0.020	73.13%	13.43%	22.01%
NR profile		34.16	0.026	0.013	0.012	0.015	73.51%	13.25%	21.84%
NR profile		35.67	0.008	0.004	0.004	0.004	137.14%	18.57%	6.82%
NR profile		35.57	0.009	0.004	0.004	0.004	136.70%	18.35%	6.62%
NR profile		32.44	0.090	0.045	0.040	0.038	133.07%	16.54%	4.99%
NR profile		33.06	0.057	0.028	0.025	0.024	133.88%	16.94%	5.35%
NSD		35.21	0.012	0.006	0.005	0.005	135.29%	17.65%	5.99%
NSD		35.15	0.012	0.006	0.005	0.005	136.89%	18.45%	6.71%
NSD		33.24	0.050	0.025	0.022	0.021	133.49%	16.75%	5.18%
NSD		33.41	0.044	0.022	0.020	0.019	133.69%	16.84%	5.27%
NSD		34.16	0.025	0.013	0.011	0.011	134.58%	17.29%	5.67%
NSD		34.49	0.020	0.010	0.009	0.008	135.71%	17.86%	6.18%
NSD		36.08	0.006	0.003	0.003	0.003	137.74%	18.87%	7.09%
NSD		37.21	0.003	0.001	0.001	0.001	139.64%	19.82%	7.95%
NSD		35.09	0.013	0.006	0.006	0.005	136.50%	18.25%	6.53%
NSD		36.79	0.004	0.002	0.002	0.002	138.56%	19.28%	7.46%
NSD		33.65	0.050	0.025	0.022	0.018	175.00%	37.50%	23.87%
NSD		33.31	0.063	0.032	0.028	0.023	171.98%	35.99%	22.51%
NSD		33.05	0.076	0.038	0.034	0.028	169.15%	34.57%	21.24%
NSD		32.95	0.081	0.041	0.037	0.030	168.65%	34.32%	21.01%
NSD		Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD		Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD		34.62	0.025	0.012	0.011	0.009	184.25%	42.12%	28.04%
NSD		34.63	0.025	0.012	0.011	0.009	184.08%	42.04%	27.96%
NSD		34.07	0.037	0.018	0.017	0.013	178.79%	39.39%	25.58%
NSD		33.78	0.045	0.023	0.020	0.016	175.61%	37.80%	24.15%
NSD		34.56	0.026	0.013	0.012	0.009	183.22%	41.61%	27.58%
NSD		35.04	0.019	0.009	0.008	0.006	187.71%	43.86%	29.60%
NSD		35.85	0.006	0.003	0.003	0.002	153.31%	26.65%	14.10%
NSD		Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD		32.73	0.066	0.033	0.030	0.027	148.50%	24.25%	11.94%
NSD		32.59	0.074	0.037	0.033	0.030	148.31%	24.16%	11.85%
NSD		39.02	0.001	0.000	0.000	0.000	106.15%	3.07%	7.14%
NSD		37.16	0.002	0.001	0.001	0.001	102.44%	1.22%	8.81%
NSD		36.07	0.006	0.003	0.002	0.003	100.00%	0.00%	9.91%
NSD		34.95	0.013	0.006	0.006	0.006	99.05%	0.47%	10.34%
NSD		37.12	0.003	0.001	0.001	0.001	102.36%	1.18%	8.85%
NSD		35.33	0.009	0.005	0.004	0.005	98.95%	0.52%	10.38%
NSD		32.26	0.095	0.047	0.043	0.038	148.03%	24.02%	11.73%
NSD		33.18	0.047	0.023	0.021	0.019	148.94%	24.47%	12.13%
NSD		Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD		Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD		37.08	0.003	0.001	0.001	0.001	102.29%	1.15%	8.88%
NSD		35.77	0.007	0.003	0.003	0.003	99.42%	0.29%	10.17%
NSD		33.45	0.043	0.022	0.020	0.025	73.20%	13.40%	21.98%
NSD		34.6	0.019	0.010	0.009	0.011	75.23%	12.39%	21.07%
NSD		35.87	0.008	0.004	0.003	0.004	75.45%	12.27%	20.97%
NSD		35.04	0.014	0.007	0.006	0.008	74.56%	12.72%	21.37%
						Mean	118.85%	18.30%	13.38%

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Table 27: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for probative samples that resulted in full profiles. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 11.31%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 13.90%. Duplicate results are presented.

Full profile results															
Sample Name	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Actual accepted amplification volume	Difference of Promega standard to Quantifiler standard quantity amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 amplification volumes	Difference of rounded Quantifiler standard amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2.22 amplification volume and actual accepted amplification volume	Difference of rounded Promega standard amplification volume and actual accepted amplification volume
[redacted]	128.75%	14.37%	3.04%	0.7000	1.0000	2.0000	2.0000	1.0000	185.7143%	100.0000%	0.0000%	30.0000%	0.0000%	100.0000%	100.0000%
	127.54%	13.77%	2.49%	0.6000	1.0000	1.0000	1.0000	1.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	132.08%	16.04%	4.54%	4.0000	8.0000	9.0000	9.0000	8.0000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	130.91%	15.45%	4.01%	4.0000	8.0000	9.0000	9.0000	8.0000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	128.53%	14.26%	2.94%	0.7000	1.0000	1.0000	2.0000	1.0000	185.7143%	100.0000%	100.0000%	30.0000%	0.0000%	0.0000%	100.0000%
	128.53%	14.26%	2.94%	0.7000	1.0000	1.0000	2.0000	1.0000	185.7143%	100.0000%	100.0000%	30.0000%	0.0000%	0.0000%	100.0000%
	129.46%	14.73%	3.36%	1.0000	2.0000	3.0000	3.0000	2.0000	200.0000%	50.0000%	0.0000%	50.0000%	0.0000%	50.0000%	50.0000%
	129.26%	14.63%	3.27%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
	130.29%	15.14%	3.73%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	130.04%	15.02%	3.62%	2.0000	4.0000	4.0000	4.0000	4.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	131.31%	15.66%	4.20%	4.0000	9.0000	10.0000	10.0000	8.0000	150.0000%	11.1111%	0.0000%	50.0000%	12.5000%	25.0000%	25.0000%
	130.00%	15.00%	3.60%	4.0000	8.0000	9.0000	9.0000	8.0000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	127.46%	13.74%	2.47%	0.5000	1.0000	1.0000	1.0000	0.9000	100.0000%	0.0000%	0.0000%	44.4444%	11.1111%	11.1111%	11.1111%
	127.43%	13.72%	2.45%	0.4000	0.8000	0.9000	0.9000	0.9000	125.0000%	12.5000%	0.0000%	55.5556%	11.1111%	0.0000%	0.0000%
	131.79%	15.89%	4.41%	5.0000	10.0000	11.0000	11.0000	11.0000	120.0000%	10.0000%	0.0000%	54.5455%	9.0909%	0.0000%	0.0000%
	132.07%	16.03%	4.53%	6.0000	12.0000	13.0000	14.0000	11.0000	133.3333%	16.6667%	7.6923%	45.4545%	9.0909%	18.1818%	27.2727%
	127.86%	13.93%	2.64%	0.5000	0.9000	1.0000	1.0000	1.0000	100.0000%	11.1111%	0.0000%	50.0000%	10.0000%	0.0000%	0.0000%
	128.29%	14.14%	2.83%	0.5000	1.0000	1.0000	1.0000	1.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	129.70%	14.85%	3.47%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	129.17%	14.58%	3.23%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	130.61%	15.31%	3.88%	2.0000	4.0000	5.0000	5.0000	5.0000	150.0000%	25.0000%	0.0000%	60.0000%	20.0000%	0.0000%	0.0000%
	129.94%	14.97%	3.58%	3.0000	5.0000	6.0000	6.0000	5.0000	100.0000%	20.0000%	0.0000%	40.0000%	0.0000%	20.0000%	20.0000%
	111.44%	5.72%	4.76%	0.0800	0.2000	0.2000	0.2000	0.1600	150.0000%	0.0000%	0.0000%	20.0000%	100.0000%	100.0000%	100.0000%
	110.47%	5.24%	5.19%	0.0700	0.1000	0.2000	0.1000	0.1600	42.8571%	0.0000%	50.0000%	32.0000%	0.0000%	100.0000%	0.0000%
	157.58%	28.79%	16.03%	5.0000	10.0000	11.0000	13.0000	11.0000	160.0000%	30.0000%	18.1818%	54.5455%	9.0909%	0.0000%	18.1818%
	159.93%	29.97%	17.09%	6.0000	13.0000	14.0000	17.0000	11.0000	183.3333%	30.7692%	21.4286%	45.4545%	18.1818%	27.2727%	54.5455%
	129.73%	14.86%	3.48%	0.5000	0.9000	1.0000	1.0000	0.9000	100.0000%	11.1111%	0.0000%	44.4444%	0.0000%	11.1111%	11.1111%
	130.37%	15.19%	3.77%	0.4000	0.9000	1.0000	1.0000	0.9000	150.0000%	11.1111%	0.0000%	55.5556%	0.0000%	11.1111%	11.1111%
	135.76%	17.88%	6.20%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	136.04%	18.02%	6.32%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	88.78%	5.61%	14.96%	0.0070	0.0100	0.0200	0.0100	0.0100	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	88.94%	5.53%	14.89%	0.0070	0.0100	0.0200	0.0100	0.0100	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	159.76%	29.89%	17.02%	6.0000	12.0000	13.0000	16.0000	12.0000	166.6667%	33.3333%	23.0769%	50.0000%	0.0000%	8.3333%	33.3333%
	159.59%	29.79%	16.93%	6.0000	11.0000	13.0000	15.0000	12.0000	150.0000%	36.3636%	15.3846%	50.0000%	8.3333%	8.3333%	25.0000%
	128.32%	14.16%	2.85%	0.4000	0.8000	0.9000	0.9000	0.8000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	128.44%	14.22%	2.90%	0.4000	0.8000	0.9000	0.9000	0.8000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	138.97%	19.49%	7.64%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	139.04%	19.52%	7.68%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
	132.77%	16.38%	4.85%	0.6000	1.0000	1.0000	1.0000	1.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	132.53%	16.26%	4.74%	0.5000	1.0000	1.0000	1.0000	1.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	150.00%	25.00%	12.61%	3.0000	5.0000	6.0000	6.0000	5.0000	100.0000%	20.0000%	0.0000%	40.0000%	0.0000%	20.0000%	20.0000%
	149.69%	24.85%	12.47%	2.0000	5.0000	5.0000	6.0000	5.0000	200.0000%	20.0000%	20.0000%	60.0000%	0.0000%	0.0000%	20.0000%
	134.88%	17.44%	5.80%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	135.96%	17.98%	6.29%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	137.52%	18.76%	6.99%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	136.79%	18.39%	6.66%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	140.96%	20.48%	8.54%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	141.09%	20.55%	8.67%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	153.70%	26.85%	14.28%	4.0000	7.0000	8.0000	9.0000	8.0000	125.0000%	28.5714%	12.5000%	50.0000%	12.5000%	0.0000%	12.5000%
	155.53%	27.77%	15.10%	4.0000	9.0000	10.0000	11.0000	8.0000	175.0000%	22.2222%	10.0000%	50.0000%	12.5000%	25.0000%	37.5000%
	127.72%	13.86%	2.58%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.72%	13.86%	2.58%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.71%	13.86%	2.57%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.70%	13.85%	2.57%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.75%	13.88%	2.59%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.82%	13.91%	2.62%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	125.83%	12.92%	1.73%	0.0002	0.0004	0.0004	0.0004	0.0005	100.0000%	0.0000%	0.0000%	60.0000%	20.0000%	20.0000%	20.0000%
	126.66%	13.33%	2.10%	0.0003	0.0006	0.0006	0.0007	0.0005	133.3333%	16.6667%	16.6667%	40.0000%	20.0000%	20.0000%	40.0000%
	126.16%	13.08%	1.87%	0.0002	0.0004	0.0005	0.0005	0.0005	150.0000%	25.0000%	0.0000%	60.0000%	20.0000%	0.0000%	0.0000%
	126.60%	13.30%	2.07%	0.0003	0.0006	0.0006	0.0006	0.0005	100.0000%	0.0000%	0.0000%	40.0000%	20.0000%	20.0000%	20.0000%
	127.56%	13.77%	2.50%	0.0005	0.0009	0.0010	0.0010	0.0009	100.0000%	11.1111%	0.0000%	44.4444%	0.0000%	11.1111%	11.1111%
	127.33%	13.67%	2.40%	0.0004	0.0008	0.0009	0.0009	0.0009	125.0000%	12.5000%	0.0000%	55.5556%	11.1111%	0.0000%	0.0000%
	126.19%	13.10%	1.89%	0.0002	0.0004	0.0005	0.0005	0.0006	150.0000%	25.0000%	0.0000%	66.6667%	33.3333%	16.6667%	16.6667%
	127.56%	13.79%	2.52%	0.0005	0.0009	0.0010	0.0010	0.0006	100.0000%	11.1111%	0.0000%	16.6667%	50.0000%	66.6667%	66.6667%
	127.61%	13.80%	2.53%	0.0005	0.0009	0.0010	0.0010	0.0009	100.0000%	11.1111%	0.0000%	44.4444%	0.0000%	11.1111%	11.1111%
	127.55%	13.78%	2.50%	0.0005	0.0009	0.0010	0.0010	0.0009	100.0000%	11.1111%	0.0000%	44.4444%	0.0000%	11.1111%	11.1111%
	144.67%	22.34%	10.21%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	144.21%	22.11%	10.00%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	144.66%	22.33%	10.21%	2.0000	4.0000	4.0000	5.0000	4.0000	150.0000%	25.0000%	25.0000%	50.0000%	0.0000%	0.0000%	25.0000%
	144.22%	22.11%	10.01%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	138.28%	19.14%	7.33%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	138.00%	19.00%	7.21%	0.0900	0.2000	0.2000	0.2000	0.2000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	139.53%	19.77%	7.90%	0.2000	0.4000	0.4000	0.5000	0.4000	150.0000%	25.0000%	25.0000%	50.0000%	0.0000%	0.0000%	25.0000%
	139.73%	19.87%	7.99%	0.2000	0.4000	0.4000	0.4000	0.4000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	137.52%	18.76%	6.99%	0.0800	0.2000	0.2000	0.2000	0.2000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	137.74%	18.87%	7.09%	0.0800	0.2000	0.2000	0.2000	0.2000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	70.41%	14.80%	23.24%	3.0000	6.0000	7.0000	5.0000	6.0000	66.6667%	16.6667%	28.5714%	50.0000%	0.0000%	16.6667%	16.6667%
	70.59%	14.71%	23.16%	3.0000	6.0000	6.0000	5.0000	6.0000	66.6667%	16.6667%	16.6667%	50.0000%	0.0000%	0.0000%	16.6667%
	69.52%	15.24%	23.64%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	68.42%	15.79%	24.13%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	69.71%	15.15%	23.56%	2.0000	3.0000	4.0000	3.0000	3.0000	50.0000%	0.0000%	25.0000%	33.3333%	0.0000%	33.3333%	0.0000%
	69.76%	15.12%	23.53%	2.0000	4.0000	4.0000	3.0000	3.0000	50.0000%	25.0000%	25.0000%	33.3333%	33.3333%	33.3333%	0.0000%

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Extended Internal Prospective Validation of the ABI Prism® 7000/Quantifiler System (Forensic Biology)

Full profile results

Sample Name	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Actual accepted amplification volume	Difference of Promega standard to Quantifiler standard quantity amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 amplification volumes	Difference of rounded Quantifiler standard amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2 amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2.22 amplification volume and actual accepted amplification volume	Difference of rounded Promega standard amplification volume and actual accepted amplification volume
[redacted]	70.61%	14.69%	23.15%	2.0000	5.0000	5.0000	4.0000	5.0000	100.0000%	20.0000%	20.0000%	60.0000%	0.0000%	0.0000%	20.0000%
	70.51%	14.74%	23.19%	3.0000	5.0000	6.0000	4.0000	5.0000	33.3333%	20.0000%	33.3333%	40.0000%	0.0000%	20.0000%	20.0000%
	67.86%	16.07%	24.39%	0.5000	1.0000	1.0000	0.9000	1.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
	68.75%	15.63%	23.99%	0.5000	1.0000	1.0000	0.9000	1.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
	69.56%	15.22%	23.62%	1.0000	3.0000	3.0000	2.0000	3.0000	100.0000%	33.3333%	33.3333%	66.6667%	0.0000%	0.0000%	33.3333%
	69.66%	15.17%	23.58%	1.0000	3.0000	3.0000	2.0000	3.0000	100.0000%	33.3333%	33.3333%	66.6667%	0.0000%	0.0000%	33.3333%
	69.75%	15.12%	23.53%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	68.73%	15.63%	24.00%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	65.84%	17.08%	25.30%	0.0600	0.1000	0.1000	0.1000	0.1000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	65.65%	17.18%	25.38%	0.0600	0.1000	0.1000	0.1000	0.1000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	69.35%	15.32%	23.72%	1.0000	2.0000	3.0000	2.0000	2.0000	100.0000%	0.0000%	33.3333%	50.0000%	0.0000%	50.0000%	0.0000%
	69.30%	15.35%	23.74%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	70.59%	14.71%	23.18%	3.0000	6.0000	6.0000	5.0000	5.0000	66.6667%	16.6667%	16.6667%	40.0000%	20.0000%	20.0000%	0.0000%
	69.96%	15.02%	23.44%	3.0000	5.0000	6.0000	4.0000	5.0000	33.3333%	20.0000%	33.3333%	40.0000%	0.0000%	20.0000%	20.0000%
	88.38%	15.81%	24.15%	0.5000	1.0000	1.0000	0.9000	1.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
	68.22%	15.89%	24.22%	0.6000	1.0000	1.0000	0.9000	1.0000	50.0000%	10.0000%	10.0000%	40.0000%	0.0000%	0.0000%	10.0000%
	68.29%	15.85%	24.19%	0.4000	0.7000	0.8000	0.6000	0.7000	50.0000%	14.2857%	25.0000%	42.8571%	0.0000%	14.2857%	14.2857%
	67.78%	16.11%	24.42%	0.3000	0.7000	0.7000	0.6000	0.7000	100.0000%	14.2857%	14.2857%	57.1429%	0.0000%	0.0000%	14.2857%
	85.90%	7.50%	16.67%	0.4000	0.8000	0.9000	0.7000	0.8000	75.0000%	12.5000%	22.2222%	50.0000%	0.0000%	12.5000%	12.5000%
	84.67%	7.66%	16.81%	0.4000	0.8000	0.9000	0.7000	0.8000	75.0000%	12.5000%	22.2222%	50.0000%	0.0000%	12.5000%	12.5000%
	89.89%	5.06%	14.47%	3.0000	6.0000	7.0000	6.0000	5.0000	100.0000%	0.0000%	14.2857%	40.0000%	20.0000%	40.0000%	20.0000%
	89.25%	5.37%	14.75%	2.0000	5.0000	5.0000	5.0000	5.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	78.81%	10.60%	19.46%	0.0300	0.0600	0.0600	0.0500	0.0600	66.6667%	16.6667%	16.6667%	50.0000%	0.0000%	0.0000%	16.6667%
	78.86%	10.57%	19.43%	0.0300	0.0600	0.0600	0.0500	0.0600	66.6667%	16.6667%	16.6667%	50.0000%	0.0000%	0.0000%	16.6667%
	86.87%	6.57%	15.82%	0.7000	1.0000	2.0000	1.0000	1.0000	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	86.90%	6.55%	15.81%	0.7000	1.0000	2.0000	1.0000	1.0000	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	87.30%	6.35%	15.63%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	87.83%	6.08%	15.39%	1.0000	2.0000	3.0000	2.0000	2.0000	100.0000%	0.0000%	33.3333%	50.0000%	0.0000%	50.0000%	0.0000%
	91.25%	9.37%	16.36%	0.0600	0.2000	0.2000	0.1000	0.2000	25.0000%	50.0000%	50.0000%	60.0000%	0.0000%	0.0000%	50.0000%
	81.82%	9.09%	18.10%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	87.33%	6.34%	15.62%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	87.38%	6.31%	15.59%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	86.48%	6.76%	16.00%	0.6000	1.0000	1.0000	1.0000	1.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	86.40%	6.80%	16.04%	0.7000	1.0000	2.0000	1.0000	1.0000	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	88.98%	5.51%	14.87%	2.0000	4.0000	5.0000	4.0000	4.0000	100.0000%	0.0000%	20.0000%	50.0000%	0.0000%	25.0000%	0.0000%
	88.71%	5.65%	15.00%	2.0000	4.0000	5.0000	4.0000	4.0000	100.0000%	0.0000%	20.0000%	50.0000%	0.0000%	25.0000%	0.0000%
	92.38%	3.82%	13.35%	7.0000	13.0000	15.0000	13.0000	12.0000	85.7143%	0.0000%	13.3333%	41.6667%	8.3333%	25.0000%	8.3333%
	91.60%	4.20%	13.69%	5.0000	11.0000	12.0000	10.0000	12.0000	100.0000%	9.0909%	16.6667%	58.3333%	8.3333%	0.0000%	16.6667%
	84.40%	7.80%	16.94%	0.5000	1.0000	1.0000	0.9000	1.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
	85.71%	7.14%	16.34%	0.5000	1.0000	1.0000	1.0000	1.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	86.31%	6.85%	16.08%	0.6000	1.0000	1.0000	1.0000	1.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	86.38%	6.82%	16.05%	0.7000	1.0000	1.0000	1.0000	1.0000	42.8571%	0.0000%	0.0000%	30.0000%	0.0000%	0.0000%	0.0000%
	83.53%	8.24%	17.33%	0.2000	0.4000	0.5000	0.4000	0.4000	100.0000%	0.0000%	20.0000%	50.0000%	0.0000%	25.0000%	0.0000%
	83.79%	8.10%	17.21%	0.2000	0.4000	0.5000	0.4000	0.4000	100.0000%	0.0000%	20.0000%	50.0000%	0.0000%	25.0000%	0.0000%
	81.83%	9.08%	18.09%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	81.94%	9.03%	18.05%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	87.82%	6.09%	15.40%	1.0000	2.0000	3.0000	2.0000	3.0000	100.0000%	0.0000%	33.3333%	66.6667%	33.3333%	0.0000%	33.3333%
	88.07%	5.96%	15.28%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	88.40%	5.80%	15.14%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	88.01%	5.99%	15.31%	2.0000	3.0000	3.0000	3.0000	3.0000	50.0000%	0.0000%	0.0000%	33.3333%	0.0000%	0.0000%	0.0000%
	89.81%	5.09%	14.50%	2.0000	5.0000	5.0000	5.0000	10.0000	150.0000%	0.0000%	0.0000%	80.0000%	50.0000%	50.0000%	50.0000%
	89.55%	5.23%	14.62%	2.0000	5.0000	5.0000	5.0000	10.0000	150.0000%	0.0000%	0.0000%	80.0000%	50.0000%	50.0000%	50.0000%
	92.37%	3.81%	13.35%	9.0000	17.0000	19.0000	17.0000	18.0000	88.8889%	0.0000%	10.5263%	43.7500%	6.2500%	18.7500%	6.2500%
	92.47%	3.77%	13.30%	7.0000	14.0000	16.0000	14.0000	16.0000	100.0000%	0.0000%	12.5000%	56.2500%	12.5000%	0.0000%	12.5000%
	89.93%	5.47%	14.84%	3.0000	5.0000	6.0000	5.0000	5.0000	66.6667%	0.0000%	16.6667%	40.0000%	0.0000%	20.0000%	0.0000%
	89.81%	5.10%	14.50%	3.0000	5.0000	6.0000	5.0000	5.0000	66.6667%	0.0000%	16.6667%	40.0000%	0.0000%	20.0000%	0.0000%
	90.06%	4.97%	14.39%	3.0000	6.0000	7.0000	6.0000	7.0000	100.0000%	0.0000%	14.2857%	57.1429%	14.2857%	0.0000%	14.2857%
	89.68%	5.16%	14.56%	3.0000	7.0000	8.0000	6.0000	7.0000	100.0000%	14.2857%	25.0000%	57.1429%	0.0000%	14.2857%	14.2857%
	138.14%	19.07%	7.27%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	137.48%	18.74%	6.97%	0.0800	0.2000	0.2000	0.2000	0.2000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	139.79%	19.86%	8.01%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
	138.66%	19.33%	7.51%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	130.25%	15.12%	3.72%	0.5000	1.0000	1.0000	1.0000	1.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	130.60%	15.30%	3.87%	0.5000	0.9000	1.0000	1.0000	1.0000	100.0000%	11.1111%	0.0000%	50.0000%	10.0000%	0.0000%	0.0000%
	121.70%	10.85%	0.14%	0.2000	0.4000	0.5000	0.5000	0.4000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	121.50%	10.75%	0.23%	0.2000	0.4000	0.5000	0.5000	0.4000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	130.24%	15.12%	3.71%	2.0000	4.0000	5.0000	5.0000	10.0000	150.0000%	25.0000%	0.0000%	80.0000%	60.0000%	50.0000%	50.0000%
	130.61%	15.31%	3.88%	2.0000	4.0000	5.0000	5.0000	10.0000	150.0000%	25.0000%	0.0000%	80.0000%	60.0000%	50.0000%	50.0000%
	128.04%	14.02%	2.72%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	128.47%	14.24%	2.91%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	129.11%	14.55%	3.20%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	129.41%	14.71%	3.34%	1.0000	3.0000	3.0000	3.0000	2.0000	200.0000%	0.0000%	0.0000%	50.0000%	50.0000%	50.0000%	50.0000%
	69.09%	15.45%	23.83%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	68.29%	15.86%	24.19%	0.8000	2.0000	2.0000	1.0000	2.0000	25.0000%	50.0000%	50.0000%	60.0000%	0.0000%	0.0000%	50.0000%
	68.16%	15.92%	24.25%	0.3000	0.6000	0.7000	0.5000	0.6000	66.6667%	16.6667%	28.5714%	50.0000%	0.0000%	16.6667%	16.6667%
	67.41%	16.29%	24.59%	0.3000	0.5000	0.6000	0.4000	0.6000	33.3333%	20.0000%	33.3333%	50.0000%	16.6667%	0.0000%	33.3333%
	138.07%	19.04%	7.24%	0.1000	0.2000	0.2000	0.2000	0.3000	100.0000%	0.0000%	0.0000%	66.6667%	33.3333%	33.3333%	33.3333%
	138.32%	19.16%	7.35%	0.1000	0.2000	0.2000	0.2000	0.3000	100.0000%	0.0000%	0.0000%	66.6667%	33.3333%	33.3333%	33.3333%
	128.21%	14.10%	2.80%	0.4000	0.7000	0.8000	0.6000	0.7000	125.0000%	28.5714%	12.5000%	42.8571%	0.0000%	14.2857%	28.5714%
	128.23%	14.11%	2.80%	0.4000	0.7000	0.8000	0.8000	0.7000	100.0000%	14.2857%	0.0000%	42.8571%	0.0000%	14.2857%	14.2857%
	110.33%	**13.90%**	**11.31%**						**112.7474%**	**11.3492%**	**10.9356%**	**50.2195%**	**5.7880%**	**14.2419%**	**14.3081%**

Table 28: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for probative samples that resulted in partial profiles and mixtures. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 14.09%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 16.56%. Duplicate results are presented.

Partial profiles and mixtures																	
Result	Sample Name	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Actual accepted amplification volume	Difference of Promega standard to Quantifiler standard quantity amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 amplification volumes	Difference of rounded Quantifiler standard amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2.22 amplification volume and actual accepted amplification volume	Difference of rounded Promega standard amplification volume and actual accepted amplification volume
X,Y+24 mixture	[redacted]	135.29%	17.60%	5.85%	0.7000	1.0000	2.0000	2.0000	1.0000	185.7143%	100.0000%	0.0000%	30.0000%	0.0000%	100.0000%	100.0000%
X,Y+24 mixture		134.35%	17.17%	5.56%	0.7000	1.0000	2.0000	2.0000	1.0000	185.7143%	100.0000%	0.0000%	30.0000%	0.0000%	100.0000%	100.0000%
X,Y+22 Mixture		70.71%	14.64%	23.10%	4.0000	8.0000	9.0000	7.6000	8.0000	75.0000%	12.5000%	22.2222%	50.0000%	0.0000%	12.5000%	12.5000%
X,Y+22 Mixture		71.43%	14.29%	22.78%	4.0000	8.0000	9.0000	7.6000	8.0000	75.0000%	12.5000%	22.2222%	50.0000%	0.0000%	12.5000%	12.5000%
X,Y+21 mixture		136.10%	19.05%	7.25%	1.0000	2.0000	2.0000	2.6000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
X,Y+21 mixture		140.27%	20.14%	8.23%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
X,Y+19 Mixture		67.85%	16.03%	24.35%	0.4000	0.4000	0.8000	0.8000	0.8000	50.0000%	25.0000%	25.0000%	50.0000%	0.0000%	0.0000%	25.0000%
X,Y+19 Mixture		68.55%	15.72%	24.09%	0.4000	0.7000	0.8000	0.8000	0.8000	50.0000%	14.2857%	25.0000%	50.0000%	12.5000%	0.0000%	25.0000%
X,NR+18 Mixture		145.77%	22.89%	10.71%	5.0000	11.0000	12.0000	13.0000	12.0000	160.0000%	18.1818%	8.3333%	58.3333%	8.3333%	0.0000%	8.3333%
X,NR+18 Mixture		149.94%	23.47%	11.23%	7.0000	14.0000	16.0000	18.0000	12.0000	157.1429%	28.5714%	12.5000%	41.6667%	16.6667%	33.3333%	50.0000%
X,NR+17 mixture		71.93%	14.03%	22.55%	7.0000	15.0000	16.0000	13.6000	16.0000	85.7143%	13.3333%	16.7500%	56.2500%	6.2500%	0.0000%	18.7500%
X,NR+17 mixture		71.22%	14.39%	22.87%	8.0000	17.0000	19.0000	14.0000	16.0000	75.0000%	17.6471%	26.3158%	50.0000%	6.2500%	18.7500%	12.5000%
X,Y+17		147.62%	23.81%	11.54%	2.0000	4.0000	5.0000	5.0000	2.0000	150.0000%	25.0000%	0.0000%	0.0000%	100.0000%	150.0000%	150.0000%
X,Y+17		145.26%	22.65%	10.48%	2.0000	4.0000	4.0000	4.0000	2.0000	100.0000%	0.0000%	0.0000%	0.0000%	100.0000%	100.0000%	100.0000%
X,X+16		89.64%	5.18%	14.58%	2.0000	5.0000	5.0000	5.0000	12.0000	150.0000%	0.0000%	0.0000%	83.3333%	58.3333%	58.3333%	58.3333%
X,X+16		88.64%	5.68%	15.03%	2.0000	3.0000	4.0000	3.0000	12.0000	50.0000%	0.0000%	25.0000%	83.3333%	75.0000%	66.6667%	75.0000%
X,Y+16		90.12%	3.44%	13.01%	10.0000	20.0000	20.0000	19.0000	15.0000	90.0000%	5.0000%	5.0000%	33.3333%	33.3333%	33.3333%	26.6667%
X,Y+16		92.24%	3.86%	13.40%	9.0000	18.0000	19.0000	17.0000	15.0000	88.8889%	5.5556%	10.5263%	40.0000%	20.0000%	26.6667%	13.3333%
X,Y+16 Mixture		143.15%	21.58%	9.53%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
X,Y+16 Mixture		143.39%	21.70%	9.64%	1.0000	2.0000	3.0000	3.0000	2.0000	200.0000%	50.0000%	0.0000%	50.0000%	0.0000%	50.0000%	50.0000%
X,Y+15 Mixture		146.67%	23.33%	11.11%	4.0000	8.0000	9.0000	10.0000	12.0000	150.0000%	25.0000%	11.1111%	66.6667%	33.3333%	25.0000%	16.6667%
X,Y+15 Mixture		145.38%	22.69%	10.53%	3.0000	7.0000	8.0000	8.0000	12.0000	166.6667%	14.2857%	0.0000%	75.0000%	41.6667%	33.3333%	33.3333%
X,X+14		96.02%	2.49%	12.15%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
X,X+14		94.55%	2.73%	12.37%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
X,Y+12 on 813		130.16%	15.05%	3.65%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
X,Y+12 on 813		130.56%	15.28%	3.85%	2.0000	4.0000	4.0000	5.0000	4.0000	150.0000%	25.0000%	25.0000%	50.0000%	0.0000%	0.0000%	25.0000%
X,Y+11		70.12%	14.94%	23.37%	2.0000	5.0000	5.0000	4.0000	7.0000	100.0000%	20.0000%	20.0000%	71.4286%	28.5714%	28.5714%	42.8571%
X,Y+11		70.09%	14.96%	23.36%	3.0000	5.0000	6.0000	4.0000	7.0000	33.3333%	20.0000%	33.3333%	57.1429%	28.5714%	14.2857%	42.8571%
X,Y+11 (10uL on CW#869		70.47%	14.76%	23.21%	2.0000	5.0000	5.0000	4.6000	10.0000	100.0000%	20.0000%	20.0000%	80.0000%	50.0000%	50.0000%	60.0000%
X,Y+11 (10uL on CW#869		70.61%	14.69%	23.15%	2.0000	5.0000	5.0000	4.0000	10.0000	100.0000%	20.0000%	20.0000%	80.0000%	50.0000%	50.0000%	60.0000%
X,Y+8 on CW#869(20uL)		71.63%	14.18%	22.69%	8.0000	17.0000	18.0000	14.0000	20.0000	75.0000%	17.6471%	22.2222%	60.0000%	15.0000%	10.0000%	30.0000%
X,Y+8 on CW#869(20uL)		71.78%	14.11%	22.62%	9.0000	18.0000	20.0000	15.0000	20.0000	66.6667%	16.6667%	25.0000%	55.0000%	10.0000%	0.0000%	25.0000%
X,Y+6		132.85%	16.42%	4.89%	10.0000	20.0000	20.0000	20.0000	20.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
X,Y+6		133.16%	16.58%	5.03%	11.0000	20.0000	20.0000	20.0000	20.0000	81.8182%	0.0000%	0.0000%	45.0000%	0.0000%	0.0000%	0.0000%
X,Y+3		133.46%	16.73%	5.16%	10.0000	20.0000	20.0000	20.0000	20.0000	25.0000%	0.0000%	0.0000%	20.0000%	0.0000%	0.0000%	0.0000%
X,Y+3		133.48%	16.74%	5.17%	19.0000	20.0000	20.0000	20.0000	20.0000	5.2632%	0.0000%	0.0000%	5.0000%	0.0000%	0.0000%	0.0000%
X,Y+1		72.38%	13.81%	22.35%	11.0000	20.0000	20.0000	19.0000	20.0000	72.7273%	5.0000%	5.0000%	45.0000%	0.0000%	0.0000%	5.0000%
X,Y+1		72.29%	13.85%	22.39%	10.0000	20.0000	20.0000	18.0000	20.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
X,Y+1		130.05%	16.53%	4.98%	12.0000	20.0000	20.0000	20.0000	20.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
X,Y+1		131.76%	15.88%	4.40%	9.0000	19.0000	20.0000	20.0000	20.0000	122.2222%	5.2632%	0.0000%	55.0000%	5.0000%	0.0000%	0.0000%
X,Y+1		132.84%	16.33%	4.79%	11.0000	20.0000	20.0000	20.0000	19.0000	81.8182%	0.0000%	0.0000%	42.1053%	5.2632%	5.2632%	5.2632%
X,Y+1		131.54%	15.77%	4.30%	9.0000	17.0000	19.0000	20.0000	19.0000	122.2222%	17.6471%	5.2632%	52.6316%	10.5263%	0.0000%	5.2632%
X,X+0		175.49%	37.72%	24.08%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
X,X+0		172.77%	36.38%	22.87%	17.0000	20.0000	20.0000	20.0000	20.0000	17.6471%	0.0000%	0.0000%	15.0000%	0.0000%	0.0000%	0.0000%
X,X+0		147.76%	23.87%	11.60%	9.0000	18.0000	20.0000	20.0000	20.0000	122.2222%	11.1111%	0.0000%	55.0000%	10.0000%	0.0000%	0.0000%
X,X+0		149.13%	24.06%	11.77%	12.0000	20.0000	20.0000	20.0000	20.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
X,NR+0		72.08%	13.96%	22.49%	10.0000	20.0000	20.0000	17.0000	20.0000	70.0000%	15.0000%	15.0000%	50.0000%	0.0000%	0.0000%	15.0000%
X,NR+0		72.39%	13.80%	22.35%	12.0000	20.0000	20.0000	20.0000	20.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	Mean	111.9263%	16.5020%	14.0949%						96.2663%	16.5666%	10.6533%	44.9214%	15.8958%	20.9070%	27.8991%

Table 29: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for probative samples that resulted in non-reportable or NSD profiles. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 13.38%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 18.30%. Duplicate results are presented.

NR and NSD profile results																	
Result	Sample Name	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Actual accepted amplification volume	Difference of Promega standard to Quantifiler standard quantity amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 amplification volumes	Difference of rounded Quantifiler standard amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2.22 amplification volume and actual accepted amplification volume	Difference of rounded Promega standard amplification volume and actual accepted amplification volume
NR profile	[redacted]	150.97%	25.48%	13.05%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		150.00%	25.00%	12.61%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		153.65%	26.92%	14.35%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		155.47%	27.73%	15.07%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		153.30%	26.66%	14.05%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		153.23%	26.62%	14.07%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		73.40%	13.39%	21.69%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		74.77%	12.61%	21.22%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		72.66%	13.97%	22.50%	16.0000	29.0000	29.0000	18.0000	29.0000	80.0000%	0.0000%	19.0000%	50.0000%	0.0000%	0.0000%	16.0000%
NR profile		72.46%	13.80%	22.34%	15.0000	29.0000	29.0000	29.0000	29.0000	93.3333%	0.0000%	0.0000%	24.0000%	0.0000%	0.0000%	0.0000%
NR profile		73.13%	13.43%	22.01%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		73.51%	13.25%	21.84%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		137.14%	18.57%	6.82%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		136.76%	18.39%	6.62%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		133.97%	16.54%	4.99%	11.0000	29.0000	29.0000	20.0000	20.0000	81.8182%	0.0000%	0.0000%	45.0000%	0.0000%	0.0000%	0.0000%
NR profile		133.85%	16.84%	5.35%	18.0000	29.0000	29.0000	29.0000	20.0000	11.1111%	0.0000%	0.0000%	10.0000%	0.0000%	0.0000%	0.0000%
NSD		135.29%	17.65%	5.99%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		136.89%	18.45%	6.71%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		133.49%	16.75%	5.18%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		133.69%	16.84%	5.27%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		134.58%	17.29%	5.67%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		136.71%	17.86%	6.18%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		137.74%	18.87%	7.09%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		139.64%	19.82%	7.95%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		136.50%	18.25%	6.53%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		138.58%	19.29%	7.46%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		175.00%	37.50%	23.87%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		171.98%	35.99%	22.61%	16.0000	29.0000	29.0000	20.0000	20.0000	25.0000%	0.0000%	0.0000%	30.0000%	0.0000%	0.0000%	0.0000%
NSD		169.15%	34.57%	21.24%	13.0000	29.0000	29.0000	29.0000	20.0000	53.8462%	0.0000%	0.0000%	35.0000%	0.0000%	0.0000%	0.0000%
NSD		168.63%	34.32%	21.01%	12.0000	29.0000	29.0000	29.0000	20.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		184.23%	42.12%	29.84%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		184.08%	42.04%	27.96%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		176.79%	39.39%	25.58%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		175.61%	37.80%	24.16%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		183.22%	41.61%	27.58%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		187.71%	43.60%	29.60%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		163.31%	26.65%	14.10%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		148.50%	24.25%	11.94%	15.0000	29.0000	29.0000	29.0000	29.0000	33.3333%	0.0000%	0.0000%	25.0000%	0.0000%	0.0000%	0.0000%
NSD		148.31%	24.16%	11.85%	16.0000	29.0000	29.0000	29.0000	29.0000	42.8571%	0.0000%	0.0000%	30.0000%	0.0000%	0.0000%	0.0000%
NSD		106.15%	3.97%	7.14%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		102.44%	1.22%	8.61%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		100.00%	0.00%	9.91%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		99.65%	0.47%	10.34%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		102.36%	1.18%	8.85%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		99.95%	0.52%	10.38%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		148.03%	24.02%	11.73%	11.0000	29.0000	29.0000	29.0000	29.0000	81.8182%	0.0000%	0.0000%	45.0000%	0.0000%	0.0000%	0.0000%
NSD		148.94%	24.47%	12.13%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		102.29%	1.15%	8.86%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		99.42%	0.29%	10.17%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		73.29%	13.48%	21.98%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		76.23%	12.39%	21.07%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		76.45%	12.22%	20.97%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		74.56%	12.72%	21.37%	29.0000	29.0000	29.0000	29.0000	29.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
	Mean	118.8539%	18.3037%	13.3795%						8.7894%	0.1724%	0.1724%	5.6034%	0.0000%	0.0000%	0.1724%

In tables 30-32, comparisons of the same data but this time off average results from the duplicates are shown. The rounded amplification volumes account for the pipetting limit of 1µL. In other words, the rounding macro has to round sample volumes to the nearest 1µL and not volumes with decimal places. Where amounts are under 1ng of input template for Profiler or Cofiler due to rounding, the macro then rounds up to the next 1µL of sample volume. Although the original macro used by Forensic Biology did not round up the volumes for sample template amounts that were under 1ng, we recommend that updated versions that round sample volumes for pipetting do include the algorithm to be able to do so.

The difference of Promega Male standard and Quantifiler standard values/2 sample volumes, which are the theoretical unrounded volumes, was 13.08% for full profiles (table 30), 15.38% for partial profiles and mixtures (table 31) and 15.4% for NR or NSD profiles (table 32). In other words, the use of the Promega male standard was similar to using the Quantifiler standard value/2 method.

Table 30: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for probative samples that resulted in full profiles. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

Full profile results								
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 rounded amplification volumes	Difference of rounded average Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded average Promega standard amplification volume and actual accepted amplification volume
[redacted]	1.3115	1.4959	12.33%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	8.0000	9.2593	13.60%	8.0000	9.0000	11.1111%	0.0000%	12.5000%
	1.3423	1.5337	12.48%	1.0000	2.0000	50.0000%	0.0000%	100.0000%
	2.2857	2.6212	12.80%	2.0000	3.0000	33.3333%	0.0000%	50.0000%
	3.9409	4.5351	13.10%	4.0000	5.0000	20.0000%	0.0000%	25.0000%
	8.2988	9.5694	13.28%	8.0000	10.0000	20.0000%	0.0000%	25.0000%
	0.8715	0.9911	12.07%	0.9000	1.0000	10.0000%	0.0000%	11.1111%
	10.6667	12.3686	13.76%	11.0000	12.0000	8.3333%	0.0000%	9.0909%
	0.9615	1.0965	12.31%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	2.7155	3.1153	12.83%	3.0000	3.0000	0.0000%	0.0000%	0.0000%
	4.7847	5.5096	13.16%	5.0000	6.0000	16.6667%	0.0000%	20.0000%
	0.1470	0.1550	5.18%	0.1000	0.2000	50.0000%	0.0000%	100.0000%
	11.0803	14.3266	22.66%	11.0000	14.0000	21.4286%	0.0000%	27.2727%
	0.9009	1.0363	13.06%	0.9000	1.0000	10.0000%	0.0000%	11.1111%
	1.5936	1.8797	15.22%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.0138	0.0130	5.90%	0.0100	0.0100	0.0000%	0.0000%	0.0000%
	11.6959	15.1860	22.98%	12.0000	15.0000	20.0000%	0.0000%	25.0000%
	0.7890	0.9009	12.43%	0.8000	0.9000	11.1111%	0.0000%	12.5000%
	2.0790	2.4845	16.32%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	1.1050	1.2853	14.03%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	4.9875	6.2305	19.95%	5.0000	6.0000	16.6667%	0.0000%	20.0000%
	1.5504	1.8248	15.04%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	1.7316	2.0534	15.67%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	2.5461	3.0722	17.12%	3.0000	3.0000	0.0000%	0.0000%	0.0000%
	7.9208	10.0806	21.43%	8.0000	10.0000	20.0000%	0.0000%	25.0000%
	0.0010	0.0011	12.17%	0.0010	0.0010	0.0000%	0.0000%	0.0000%
	0.0010	0.0011	12.17%	0.0010	0.0010	0.0000%	0.0000%	0.0000%
	0.0010	0.0012	12.20%	0.0010	0.0010	0.0000%	0.0000%	0.0000%
	0.0005	0.0005	11.57%	0.0005	0.0005	0.0000%	0.0000%	0.0000%
	0.0005	0.0006	11.84%	0.0005	0.0006	16.6667%	0.0000%	20.0000%
	0.0009	0.0010	12.06%	0.0009	0.0010	10.0000%	0.0000%	11.1111%
	0.0006	0.0007	11.76%	0.0006	0.0007	14.2857%	0.0000%	16.6667%
	0.0009	0.0011	12.12%	0.0009	0.0010	10.0000%	0.0000%	11.1111%
	4.2283	5.1680	18.18%	4.0000	5.0000	20.0000%	0.0000%	25.0000%
	4.0404	4.9383	18.18%	4.0000	5.0000	20.0000%	0.0000%	25.0000%
	0.1907	0.2270	16.02%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	0.3802	0.4556	16.54%	0.4000	0.5000	20.0000%	0.0000%	25.0000%
	0.1549	0.1840	15.83%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	5.8651	5.0000	17.30%	6.0000	5.0000	20.0000%	0.0000%	16.6667%
	1.8100	1.5291	18.37%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	3.4965	2.9674	17.83%	3.0000	3.0000	0.0000%	0.0000%	0.0000%
	4.8960	4.1754	17.26%	5.0000	4.0000	25.0000%	0.0000%	20.0000%
	1.0610	0.8929	18.83%	1.0000	0.9000	11.1111%	0.0000%	10.0000%
	2.7045	2.2936	17.92%	3.0000	2.0000	50.0000%	0.0000%	33.3333%
	1.8265	1.5456	18.17%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.1174	0.0973	20.67%	0.1000	0.1000	0.0000%	0.0000%	0.0000%
	2.2434	1.8993	18.12%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	5.5021	4.6838	17.47%	6.0000	5.0000	20.0000%	20.0000%	0.0000%
	1.0610	0.8929	18.83%	1.0000	0.9000	11.1111%	0.0000%	10.0000%
	0.6920	0.5814	19.03%	0.7000	0.6000	16.6667%	0.0000%	14.2857%
	0.7813	0.7220	8.20%	0.8000	0.7000	14.2857%	0.0000%	12.5000%
	5.3636	5.1020	5.52%	5.0000	5.0000	0.0000%	0.0000%	0.0000%
	0.0562	0.0503	11.84%	0.0600	0.0500	20.0000%	0.0000%	16.6667%
	1.4035	1.3115	7.02%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	2.2497	2.1097	6.64%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.1796	0.1630	10.19%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	2.0450	1.9157	6.75%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	1.2539	1.1689	7.27%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	4.2965	4.0568	5.91%	4.0000	4.0000	0.0000%	0.0000%	0.0000%
	11.8343	11.3572	4.20%	12.0000	11.0000	9.0909%	0.0000%	8.3333%
	1.0101	0.9346	8.08%	1.0000	0.9000	11.1111%	0.0000%	10.0000%
	1.2539	1.1682	7.34%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	0.4287	0.3937	8.90%	0.4000	0.4000	0.0000%	0.0000%	0.0000%
	0.2053	0.1867	9.96%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	2.5674	2.4125	6.42%	3.0000	2.0000	50.0000%	0.0000%	33.3333%
	3.0189	2.8409	6.26%	3.0000	3.0000	0.0000%	0.0000%	0.0000%
	4.8368	4.5872	5.44%	5.0000	5.0000	0.0000%	50.0000%	50.0000%
	15.7480	15.1515	3.94%	16.0000	15.0000	6.6667%	0.0000%	6.2500%
	5.1681	4.9140	5.58%	5.0000	5.0000	0.0000%	0.0000%	0.0000%
	6.4620	6.1350	5.33%	6.0000	6.0000	0.0000%	14.2857%	14.2857%
	0.1775	0.2110	15.85%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	2.1008	2.5126	16.39%	2.0000	3.0000	33.3333%	0.0000%	50.0000%
	0.9639	1.1105	13.20%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	0.4237	0.4695	9.75%	0.4000	0.5000	20.0000%	0.0000%	25.0000%
	4.3290	4.9875	13.20%	4.0000	5.0000	20.0000%	60.0000%	50.0000%
	1.5873	1.8116	12.38%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	2.2779	2.6110	12.76%	2.0000	3.0000	33.3333%	0.0000%	50.0000%
	1.8501	1.5501	18.59%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.5610	0.4706	19.21%	0.6000	0.5000	20.0000%	0.0000%	16.6667%
	0.1962	0.2336	16.04%	0.2000	0.2000	0.0000%	33.3333%	33.3333%
	0.7273	0.8209	12.36%	0.7000	0.8000	12.5000%	0.0000%	14.2857%
Mean			13.08%			10.2940%	2.1928%	13.6101%

Table 31: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for probative samples that resulted in partial profiles and mixtures. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

Partial profiles and mixtures								
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 rounded amplification volumes	Difference of rounded average Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded average Promega standard amplification volume and actual accepted amplification volume
[redacted]	1.3652	1.6026	14.81%	1.0000	2.0000	50.0000%	0.0000%	100.0000%
	8.3507	7.1429	16.91%	8.0000	7.0000	14.2857%	0.0000%	12.5000%
	2.0629	2.4661	16.35%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.7547	0.6349	18.87%	0.8000	0.6000	33.3333%	0.0000%	25.0000%
	12.1212	14.9254	18.79%	12.0000	15.0000	20.0000%	0.0000%	25.0000%
	15.6863	13.4590	16.55%	16.0000	13.0000	23.0769%	0.0000%	18.7500%
	3.9409	4.8544	18.82%	4.0000	5.0000	20.0000%	100.0000%	150.0000%
	3.9920	3.7736	5.79%	4.0000	4.0000	0.0000%	66.6667%	66.6667%
	18.6047	17.9211	3.81%	19.0000	18.0000	5.5556%	26.6667%	20.0000%
	2.2371	2.7211	17.79%	2.0000	3.0000	33.3333%	0.0000%	50.0000%
	7.2595	8.9286	18.69%	7.0000	9.0000	22.2222%	41.6667%	25.0000%
	46.5658	45.3515	2.68%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	4.1152	4.7393	13.17%	4.0000	5.0000	20.0000%	0.0000%	25.0000%
	4.9505	4.2105	17.57%	5.0000	4.0000	25.0000%	28.5714%	42.8571%
	4.7004	4.0080	17.27%	5.0000	4.0000	25.0000%	50.0000%	60.0000%
	17.1674	14.7384	16.48%	17.0000	15.0000	13.3333%	15.0000%	25.0000%
	21.6216	25.1889	14.16%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	34.7524	40.5680	14.34%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	21.3333	18.3824	16.05%	20.0000	18.0000	11.1111%	0.0000%	10.0000%
	20.9205	24.3013	13.91%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	19.4363	22.5479	13.80%	19.0000	20.0000	5.0000%	0.0000%	5.2632%
	38.4246	52.6316	26.99%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	20.3978	25.2845	19.33%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	21.8699	18.8324	16.13%	20.0000	19.0000	5.2632%	0.0000%	5.0000%
Mean			**15.38%**			**13.6048%**	**13.6905%**	**27.7515%**

Table 32: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for probative samples that resulted in non-reportable or NSD profiles. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

NR and NSD profile results									
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 rounded amplification volumes	Difference of rounded average Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded average Promega standard amplification volume and actual accepted amplification volume
[redacted]	85.1064	106.5530	20.13%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	647.2492	823.3841	21.39%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	307.9292	389.8635	21.02%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	76.9231	66.8896	15.00%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	24.3754	20.9864	16.15%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	65.5738	56.8182	15.41%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	232.5581	275.4821	15.58%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	27.3785	31.9489	14.31%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	168.0672	198.4127	15.29%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	42.9185	50.1253	14.38%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	89.0869	104.7120	14.92%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	456.1003	543.4783	16.08%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	244.6483	289.8551	15.60%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	35.5240	48.5437	26.82%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	25.4291	34.1880	25.62%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	20.0000	20.0000	0.00%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	80.4829	114.3511	29.62%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	48.7805	67.5676	27.80%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	89.8876	128.1230	29.84%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	652.5285	826.4463	21.04%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	28.6533	35.5872	19.48%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	1279.1813	1299.5452	1.57%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	220.7506	220.0220	0.33%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	331.6750	331.1258	0.17%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	28.3086	35.1494	19.46%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	20.0000	20.0000	0.00%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	419.7272	420.1681	0.10%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	64.1026	55.7103	15.06%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	184.1621	161.0306	14.36%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
Mean			**15.40%**			**0.0000%**	**0.0000%**	**0.0000%**

Table 33: Final results using the Quantifiler standard after an estimated 2ng was used for the initial Profiler amplification.

Amplification results	Sample number
Full profiles	81
Partial profiles	24
No size data (NSD)	21
Non reportable (NR) profile	8
SUBTOTAL	**126**
Unamplified (inhibition present)	1
TOTAL	**127**

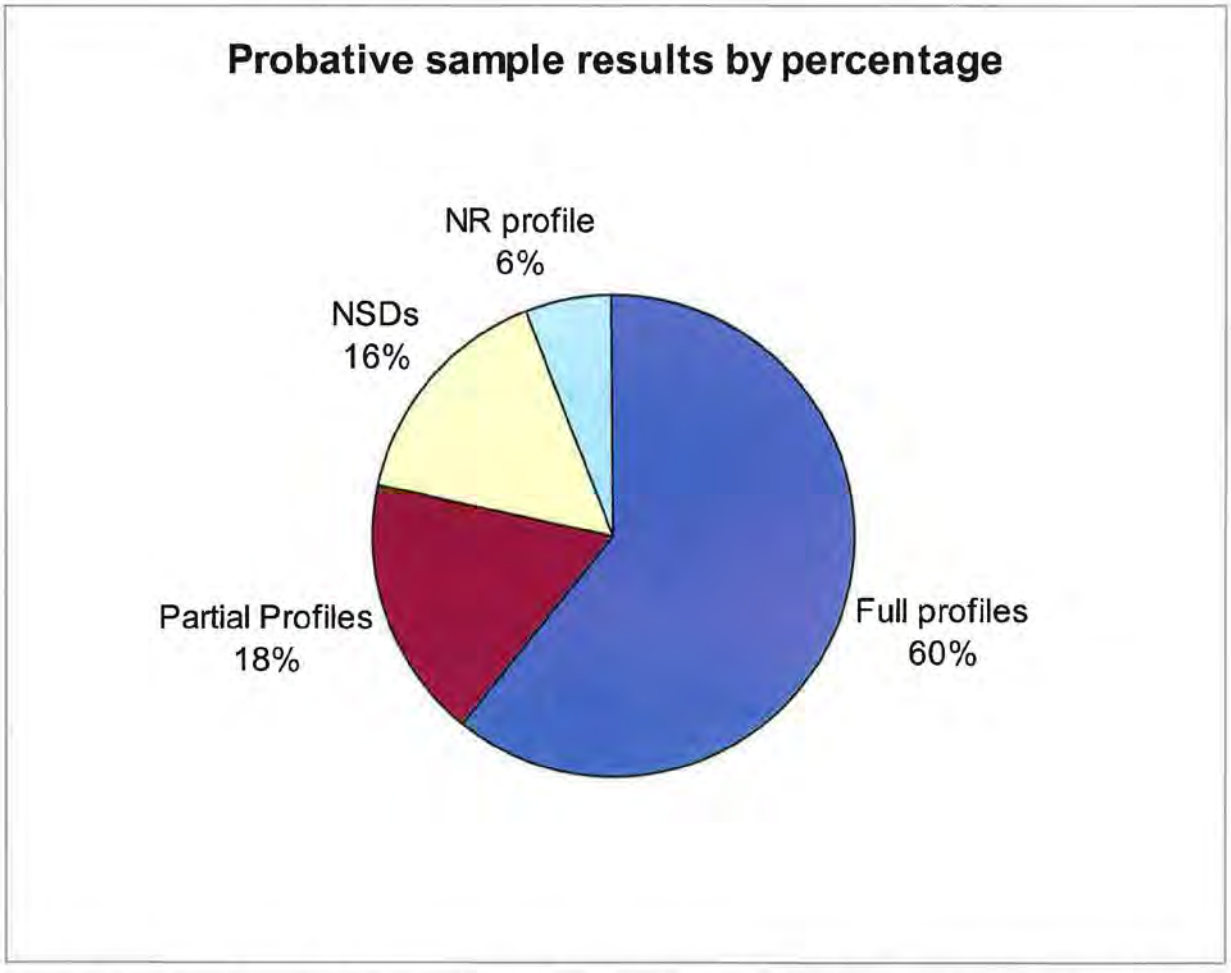

Figure 11: Final results for probative samples using the Quantifiler standard after an estimated 2ng was used for the initial Profiler amplification.

In table 34, the differences between using the Quantifiler Human DNA standard and the Promega Male standard for estimating probative sample concentration are summarised. Clearly, the most optimal nanogram amount for the Quantifiler Human DNA standard (approximately 2ng) is approximately double to that of the Promega Male standard (approximately 1ng). This is due to the approximate two-fold bias inherent in the results when using the Quantifiler standard.

Table 34: A comparison of probative sample results with the Promega Male standard and Quantifiler standard.

Probative Sample results						
Final Result		Optimal ng amount using Quantifiler Standard	Optimal ng using Promega Standard			
Full	**Mean**	**2.064747679**	**0.996119346**			
PP	**Mean**	**2.124316667**	**1.057872917**			
Full+PP	**Mean**	**2.078363448**	**1.010234448**			
		No rounding				
Final Result		Difference 1ng Promega to 1ng Quantifiler	Difference 1ng Promega to 2ng Quantifiler	Difference 1ng Promega to 2.22ng Quantifiler	Difference 1ng Promega to 2.35ng Quantifiler	Difference 1ng Promega to 2.5ng Quantifiler
Full	**Mean**	**110.33%**	**13.90%**	**11.31%**	**11.93%**	**16.09%**
PP	**Mean**	**111.83%**	**16.56%**	**14.09%**	**13.35%**	**16.07%**
		Rounding due to macro				
Final Result		Difference 1ng Promega to 1ng Quantifiler	Difference 1ng Promega to 2ng Quantifiler	Difference 1ng Promega to 2.22ng Quantifiler	Difference 1ng Promega to 2.35ng Quantifiler	Difference 1ng Promega to 2.5ng Quantifiler
Full	**Mean**	**112.75%**	**11.35%**	**10.94%**	**10.20%**	**14.38%**
PP	**Mean**	**96.27%**	**16.57%**	**10.68%**	**10.80%**	**10.66%**

5.10.2 NON-PROBATIVE SAMPLES (QUANTIFILER STANDARD RESULTS VERSUS PROMEGA MALE STANDARD RESULTS)

The testing of the method and modifications of the method on non-probative samples is required according to DAB (2000: 8.1.3.1) and SWGDAM (2004: 3.1) guidelines. A total of 67 non-probative samples were analysed with both the Quantifiler standard and the Promega Male standard. The final profiling results from these samples are presented in table 44 and figure 12. Similarity in Quantifiler concentration and amplification volumes was compared, but the initial Profiler Plus amplifications consisted of an estimated amount of 2 Quantifiler nanograms. We have shown in the validation of the Quantifiler standard that 1 Promega Male standard nanogram is equivalent to approximately 2.22 or 2 Quantifiler standard nanograms. This result was confirmed with the non-probative sample data presented in figures 33 to 35. While the Quantifiler Human DNA Standard result needed to be calibrated, the Promega Male standard results did not.

The sample volumes and amplification volumes, as well as actual accepted amplification volumes were also compared for individual results from each duplicate while the same was done with the mean Quantifiler results which were used for the initial Profiler Plus amplifications. The greatest differences were observed between the uncalibrated Quantifiler Human DNA standard results and Promega Male standard results producing a mean difference of 109.8% for the sample volumes of full profile samples (see table 38). The smallest resulting mean difference was with the Quantifiler standard at 2ng and Promega Male control at 1ng for full profile samples at 6.27% (see table 35). With the samples resulting in full profiles, the rounded Quantifiler standard result amplification volumes at 2ng produced the smallest mean difference with the actual accepted volumes. The actual accepted volumes were the volumes accepted as the most optimal results out of up to three amplifications and not necessarily what was originally calculated as the ideal volume for the initial PCR based on the Quantifiler results. The result was obviously biased by 2ng being the original amplification target.

With partial profile and mixture results (table 36), similar results as for the full profiles are visible. The mean difference of the Promega Male standard to Quantifiler Human DNA standard concentration/2.22 Quantifiler values was only 16.06% and the mean difference of the Promega Male standard to Quantifiler Human DNA standard concentration/2 Quantifiler values was higher at 24.42%. The highest mean difference at 143.24% was the mean difference of the Promega Male standard to the uncalibrated Quantifiler standard Quantifiler values. With the sample volumes, the same difference percentage values were obtained whether a full profile, partial profile, mixture, No Size Data (NSD) profile or a Non-Reportable profile as for the Quantifiler value differences. In terms of amplification volumes, Promega Male standard to Quantifiler Human DNA standard concentration/2.22 had the lowest difference at 7.79%, followed by Promega Male standard to Quantifiler Human DNA standard concentration/2 at 14.93%. The greatest differences were observed between the uncalibrated Quantifiler Human DNA standard amplification volumes and Promega Male standard amplification volumes producing a mean difference of 107.47% (see table 39)

With resulting profiles producing no-size data (NSD) and non-reportable (NR) profiles (see tables 37 and 40), most of the samples were amplified at maximum sample volumes of 20µL in 50µL Profiler Plus reactions. The least overall difference with the NSD and NR samples was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 2.48%). The Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng is also comparable with a mean difference of 3.65%.

Table 35: Comparison of Quantifiler and Promega Male standard concentration results for full profile non-probative samples. The quantity shown is in ng/μL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 6.27%). The Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng is also comparable with a mean difference of 7.75%. Duplicate results are presented.

Full profile								
Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/ 2	Quantity Quantifiler standard/ 2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega male standard quantities	Difference of Quantifiler standard/2 and the Promega male standard quantities	Difference of Quantifiler standard/2 .22 and the Promega male standard quantities
[redacted]	28.82	1.2400	0.6200	0.5586	0.6280	97.45%	1.27%	11.06%
	29.04	1.0400	0.5200	0.4685	0.5330	95.12%	2.44%	12.11%
	28.29	1.8700	0.9350	0.8423	0.9260	101.94%	0.97%	9.03%
	28.28	1.8800	0.9400	0.8468	0.9340	101.28%	0.64%	9.33%
	28.06	2.2400	1.1200	1.0090	1.1000	103.64%	1.82%	8.27%
	28.09	2.1800	1.0900	0.9820	1.0800	101.85%	0.93%	9.08%
	28.25	1.9200	0.9600	0.8649	0.9540	101.26%	0.63%	9.34%
	28.40	1.7100	0.8550	0.7703	0.8530	100.47%	0.23%	9.70%
	27.20	4.3300	2.1650	1.9505	2.0700	109.18%	4.59%	5.78%
	27.08	4.7600	2.3800	2.1441	2.2600	110.62%	5.31%	5.13%
	25.29	19.0000	9.5000	8.5586	8.4700	124.32%	12.16%	1.05%
	25.39	17.6900	8.8450	7.9685	7.9100	123.64%	11.82%	0.74%
	28.48	1.6100	0.8050	0.7252	0.8070	99.50%	0.25%	10.13%
	28.25	1.9200	0.9600	0.8649	0.9510	101.89%	0.95%	9.06%
	26.25	9.0400	4.5200	4.0721	4.1700	116.79%	8.39%	2.35%
	26.32	8.6100	4.3050	3.8784	3.9800	116.33%	8.17%	2.55%
	28.11	2.1500	1.0750	0.9685	1.0600	102.83%	1.42%	8.64%
	28.11	2.1500	1.0750	0.9685	1.0600	102.83%	1.42%	8.64%
	27.40	3.7100	1.8550	1.6712	1.7800	108.43%	4.21%	6.11%
	27.49	3.4500	1.7250	1.5541	1.6700	106.59%	3.29%	6.94%
	27.70	2.9400	1.4700	1.3243	1.4300	105.59%	2.80%	7.39%
	27.95	2.4300	1.2150	1.0946	1.1900	104.20%	2.10%	8.02%
	27.41	3.6900	1.8450	1.6622	1.7700	108.47%	4.24%	6.09%
	27.43	3.6200	1.8100	1.6306	1.7400	108.05%	4.02%	6.29%
	28.66	1.4000	0.7000	0.6306	0.7030	99.15%	0.43%	10.29%
	28.75	1.3100	0.6550	0.5901	0.6600	98.48%	0.76%	10.59%
	28.00	2.3400	1.1700	1.0541	1.1500	103.48%	1.74%	8.34%
	28.05	2.2500	1.1250	1.0135	1.1100	102.70%	1.35%	8.69%
	26.53	7.2900	3.6450	3.2838	3.4000	114.41%	7.21%	3.42%
	26.56	7.1200	3.5600	3.2072	3.3200	114.46%	7.23%	3.40%
	27.28	4.0800	2.0400	1.8378	1.9500	109.23%	4.62%	5.75%
	27.25	4.1700	2.0850	1.8784	1.9900	109.55%	4.77%	5.61%
	29.19	0.9300	0.4650	0.4189	0.4770	94.97%	2.52%	12.18%
	29.09	1.0100	0.5050	0.4550	0.5140	96.50%	1.75%	11.49%
	27.74	2.8600	1.4300	1.2883	1.3900	105.76%	2.88%	7.32%
	27.58	3.2300	1.6150	1.4550	1.5600	107.05%	3.53%	6.73%
	27.04	4.9200	2.4600	2.2162	2.3300	111.16%	5.58%	4.88%
	27.08	4.7500	2.3750	2.1396	2.2600	110.18%	5.09%	5.33%
	29.63	0.6620	0.3310	0.2982	0.3450	91.88%	4.06%	13.57%
	29.30	0.8500	0.4250	0.3829	0.4380	94.06%	2.97%	12.58%
	25.74	12.9800	6.4900	5.8468	6.2200	108.68%	4.34%	6.00%
	25.80	12.4100	6.2050	5.5901	5.9300	109.27%	4.64%	5.73%
	28.10	2.4600	1.2300	1.1081	1.0900	125.69%	12.84%	1.66%
	28.04	2.5500	1.2750	1.1486	1.1400	123.68%	11.84%	0.76%
	29.69	0.8000	0.4000	0.3604	0.3390	135.99%	17.99%	6.30%
	29.44	0.9510	0.4755	0.4284	0.4060	134.24%	17.12%	5.51%
	27.16	4.7700	2.3850	2.1486	2.1900	117.81%	8.90%	1.89%
	27.14	4.8300	2.4150	2.1757	2.2100	118.55%	9.28%	1.55%
	30.00	0.6420	0.3210	0.2892	0.2700	137.78%	8.89%	7.11%
	30.07	0.6100	0.3050	0.2748	0.2550	139.22%	19.61%	7.75%

Full profile

Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/ 2	Quantity Quantifiler standard/ 2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega male standard quantities	Difference of Quantifiler standard/2 and the Promega male standard quantities	Difference of Quantifiler standard/2 .22 and the Promega male standard quantities
[redacted]	30.23	0.5450	0.2725	0.2455	0.2270	140.09%	20.04%	8.15%
	30.51	0.4480	0.2240	0.2018	0.1850	142.16%	21.08%	9.08%
	27.30	4.3100	2.1550	1.9414	1.9600	119.90%	9.95%	0.95%
	27.44	3.9100	1.9550	1.7613	1.7800	119.66%	9.83%	1.05%
	28.26	2.1900	1.0950	0.9865	0.9710	125.54%	12.77%	1.59%
	28.22	2.2500	1.1250	1.0135	0.9970	125.68%	12.84%	1.66%
	28.09	2.4700	1.2350	1.1126	1.1000	124.55%	12.27%	1.15%
	28.11	2.4400	1.2200	1.0991	1.0800	125.93%	12.96%	1.77%
	29.66	0.8150	0.4075	0.3671	0.3460	135.55%	17.77%	6.10%
	29.73	0.7780	0.3890	0.3505	0.3290	136.47%	18.24%	6.52%
	28.61	1.7100	0.8550	0.7703	0.7500	128.00%	14.00%	2.70%
	28.86	1.4400	0.7200	0.6486	0.6260	130.03%	15.02%	3.62%
	28.46	1.9100	0.9550	0.8604	0.8390	127.65%	13.83%	2.55%
	28.52	1.8200	0.9100	0.8198	0.8000	127.50%	13.75%	2.48%
	28.77	1.5300	0.7650	0.6892	0.6690	128.70%	14.35%	3.02%
	29.01	1.2900	0.6450	0.5811	0.5590	130.77%	15.38%	3.95%
	28.45	1.9200	0.9600	0.8649	0.8440	127.49%	13.74%	2.47%
	28.51	1.8300	0.9150	0.8243	0.8050	127.33%	13.66%	2.40%
	30.33	0.5110	0.2555	0.2302	0.2120	141.04%	20.52%	8.58%
	30.46	0.4650	0.2325	0.2095	0.1930	140.93%	20.47%	8.53%
	29.10	1.2200	0.6100	0.5495	0.5240	132.82%	16.41%	4.88%
	29.26	1.0800	0.5400	0.4865	0.4660	131.76%	15.88%	4.40%
	27.51	3.0800	1.5400	1.3874	1.5700	96.18%	1.91%	11.63%
	27.69	2.6900	1.3450	1.2117	1.3700	96.35%	1.82%	11.55%
	25.67	11.8800	5.9400	5.3514	6.1200	94.12%	2.94%	12.56%
	25.71	11.5500	5.7750	5.2027	5.9500	94.12%	2.94%	12.56%
	24.02	39.8800	19.9400	17.9640	20.7000	92.66%	3.67%	13.22%
	24.08	38.1700	19.0850	17.1937	19.8100	92.68%	3.66%	13.21%
	30.45	0.3560	0.1780	0.1604	0.1790	98.88%	0.56%	10.41%
	30.29	0.4020	0.2010	0.1811	0.2030	98.03%	0.99%	10.80%
	29.47	0.7310	0.3655	0.3293	0.3700	97.57%	1.22%	11.01%
	29.66	0.6350	0.3175	0.2860	0.3210	97.82%	1.09%	10.89%
	26.20	8.0700	4.0350	3.6351	4.1500	94.46%	2.77%	12.41%
	26.21	8.0000	4.0000	3.6036	4.1100	94.65%	2.68%	12.32%
	30.38	0.3760	0.1880	0.1694	0.1890	98.94%	0.53%	10.39%
	30.29	0.4010	0.2005	0.1806	0.2020	98.51%	0.74%	10.58%
	28.59	1.4000	0.7000	0.6306	0.7110	96.91%	1.55%	11.30%
	28.65	1.3300	0.6650	0.5991	0.6770	96.45%	1.77%	11.51%
	31.31	0.1900	0.0950	0.0856	0.0953	99.37%	0.31%	10.19%
	31.23	0.2010	0.1005	0.0905	0.1010	99.01%	0.50%	10.36%
	30.11	0.4570	0.2285	0.2059	0.2310	97.84%	1.08%	10.88%
	30.01	0.4940	0.2470	0.2225	0.2490	98.39%	0.80%	10.63%
	27.27	3.6700	1.8350	1.6532	1.8800	95.21%	2.39%	12.07%
	27.34	3.5000	1.7500	1.5766	1.7900	95.53%	2.23%	11.92%
	29.07	0.9790	0.4895	0.4410	0.4960	97.38%	1.31%	11.09%
	29.04	1.0000	0.5000	0.4505	0.5090	96.46%	1.77%	11.50%
	29.55	0.6920	0.3460	0.3117	0.3500	97.71%	1.14%	10.94%
	29.71	0.6150	0.3075	0.2770	0.3110	97.75%	1.13%	10.92%
	31.61	0.1520	0.0760	0.0685	0.0763	99.21%	0.39%	10.26%
	32.01	0.1130	0.0565	0.0509	0.0566	99.65%	0.18%	10.07%
	26.33	7.3100	3.6550	3.2928	3.7500	94.93%	2.53%	12.19%
	26.24	7.8400	3.9200	3.5315	4.0300	94.54%	2.73%	12.37%
	29.07	0.9820	0.4910	0.4423	0.4980	97.19%	1.41%	11.18%
	29.18	0.9040	0.4520	0.4072	0.4580	97.38%	1.31%	11.09%
	25.76	11.1100	5.5550	5.0045	5.7200	94.23%	2.88%	12.51%
	25.85	10.4200	5.2100	4.6937	5.3600	94.40%	2.80%	12.43%
	30.48	0.3500	0.1750	0.1577	0.1760	98.86%	0.57%	10.42%
	30.50	0.3430	0.1715	0.1545	0.1730	98.27%	0.87%	10.69%
	28.93	1.3700	0.6850	0.6171	0.5940	130.64%	15.32%	3.89%
	28.82	1.4800	0.7400	0.6667	0.6440	129.81%	14.91%	3.52%
					Mean	109.80%	6.27%	7.75%

Table 36: Comparison of Quantifiler and Promega Male standard concentration results for partial profile non-probative samples. The quantity shown is in ng/μL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 16.06%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 24.42%. Duplicate results are presented. Values ≤0.1ng/μL are amplified with Profiler Plus at a full sample volume of 20μL in a 50μL reaction.

Partial profiles								
Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/ 2	Quantity Quantifiler standard/ 2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega male standard quantities	Difference of Quantifiler standard/2 and the Promega male standard quantities	Difference of Quantifiler standard/2 .22 and the Promega male standard quantities
[redacted]	31.84	0.1750	0.0875	0.0788	0.0695	151.80%	25.90%	13.42%
[redacted]	31.90	0.1680	0.0840	0.0757	0.0665	152.63%	26.32%	13.80%
[redacted]	32.06	0.1500	0.0750	0.0676	0.0592	153.38%	26.69%	14.13%
[redacted]	32.38	0.1200	0.0600	0.0541	0.0466	157.51%	28.76%	16.00%
[redacted]	32.39	0.1190	0.0595	0.0536	0.0463	157.02%	28.51%	15.77%
[redacted]	33.98	0.0389	0.0195	0.0175	0.0144	170.14%	35.07%	21.68%
[redacted]	30.40	0.3620	0.1810	0.1631	0.1940	86.60%	6.70%	15.95%
[redacted]	30.63	0.3040	0.1520	0.1369	0.1640	85.37%	7.32%	16.50%
[redacted]	32.62	0.1010	0.0505	0.0455	0.0392	157.65%	28.83%	16.06%
[redacted]	32.83	0.0872	0.0436	0.0393	0.0335	160.30%	30.15%	17.25%
					Mean	**143.24%**	**24.42%**	**16.06%**

Table 37: Comparison of Quantifiler and Promega Male standard concentration results for non-probative samples resulting in NSDs. The quantity shown is in ng/μL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 2.48%). The Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng is also comparable with a mean difference of 3.65%. Duplicate results are presented.

NSDs								
Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/ 2	Quantity Quantifiler standard/ 2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega male standard quantities	Difference of Quantifiler standard/2 and the Promega male standard quantities	Difference of Quantifiler standard/2 .22 and the Promega male standard quantities
[redacted]	33.97	0.0228	0.0114	0.0103	0.0139	64.03%	17.99%	26.11%
[redacted]	33.55	0.0315	0.0158	0.0142	0.0189	66.67%	16.67%	24.92%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
					Mean	**9.34%**	**2.48%**	**3.65%**

Table 38: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for non-probative samples that resulted in full profiles. The least overall difference in sample volumes was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 6.27%). The Promega Male standard result at 1ng and Quantifiler standard sample volume result at 2.22ng is also comparable with a mean difference of 7.75%. Duplicate results are presented.

Full profile results																
Sample Name	Quantity Quantifiler standard	Quantity Promega Male standard	Sample volume Quantifiler standard quantity	Sample volume Quantifiler standard quantity/ 2	Sample volume Quantifiler standard quantity/ 2.22	Sample volume Promega standard	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Difference of Quantifiler standard quantity to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2 to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2.22 to Promega standard amplification volumes
[redacted]	1.2400	0.6280	0.81	1.61	1.79	1.59	97.45%	1.27%	11.06%	0.8000	2.000	2.000	2.000	150.00%	0.00%	0.00%
	1.0400	0.5330	0.96	1.92	2.13	1.88	95.12%	2.44%	12.11%	1.0000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	1.8700	0.9260	0.53	1.07	1.19	1.08	101.94%	0.97%	9.03%	0.5000	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.8800	0.9340	0.53	1.06	1.18	1.07	101.26%	0.64%	9.33%	0.5000	1.000	1.000	1.000	100.00%	0.00%	0.00%
	2.2400	1.1000	0.45	0.89	0.99	0.91	103.64%	1.82%	8.27%	0.4000	0.900	1.000	0.900	125.00%	0.00%	10.00%
	2.1800	1.0800	0.46	0.92	1.02	0.93	101.85%	0.93%	9.08%	0.5000	0.900	1.000	0.900	80.00%	0.00%	10.00%
	1.9200	0.9540	0.52	1.04	1.16	1.05	101.26%	0.63%	9.34%	0.5000	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.7100	0.8530	0.58	1.17	1.30	1.17	100.47%	0.23%	9.70%	0.6000	1.000	1.000	1.000	66.67%	0.00%	0.00%
	4.3300	2.0700	0.23	0.46	0.51	0.48	109.18%	4.59%	5.78%	0.2000	0.500	0.500	0.500	150.00%	0.00%	0.00%
	4.7600	2.2600	0.21	0.42	0.47	0.44	110.62%	5.31%	5.13%	0.2000	0.400	0.500	0.400	100.00%	0.00%	20.00%
	19.0000	8.4700	0.05	0.11	0.12	0.12	124.32%	12.16%	1.05%	0.0500	0.100	0.100	0.100	100.00%	0.00%	0.00%
	17.6900	7.9100	0.06	0.11	0.13	0.13	123.64%	11.82%	0.74%	0.0600	0.100	0.100	0.100	66.67%	0.00%	0.00%
	1.6100	0.8070	0.62	1.24	1.38	1.24	99.50%	0.25%	10.13%	0.6000	1.000	1.000	1.000	66.67%	0.00%	0.00%
	1.9200	0.9510	0.52	1.04	1.16	1.05	101.89%	0.95%	9.06%	0.5000	1.000	1.000	1.000	100.00%	0.00%	0.00%
	9.0400	4.1700	0.11	0.22	0.25	0.24	116.79%	8.39%	2.35%	0.1000	0.200	0.200	0.200	100.00%	0.00%	0.00%
	8.6100	3.9800	0.12	0.23	0.26	0.25	116.33%	8.17%	2.55%	0.1000	0.200	0.300	0.300	200.00%	50.00%	0.00%
	2.1500	1.0600	0.47	0.93	1.03	0.94	102.83%	1.42%	8.64%	0.5000	0.900	1.000	0.900	80.00%	0.00%	10.00%
	2.1500	1.0600	0.47	0.93	1.03	0.94	102.83%	1.42%	8.64%	0.5000	0.900	1.000	0.900	80.00%	0.00%	10.00%
	3.7100	1.7800	0.27	0.54	0.60	0.56	108.43%	4.21%	6.11%	0.3000	0.500	0.600	0.600	100.00%	20.00%	0.00%
	3.4500	1.6700	0.29	0.58	0.64	0.60	106.59%	3.29%	6.94%	0.3000	0.600	0.600	0.600	100.00%	0.00%	0.00%
	2.9400	1.4300	0.34	0.68	0.76	0.70	105.59%	2.80%	7.39%	0.3000	0.700	0.800	0.700	133.33%	0.00%	12.50%
	2.4300	1.1900	0.41	0.82	0.91	0.84	104.20%	2.10%	8.02%	0.4000	0.800	0.900	0.800	100.00%	0.00%	11.11%
	3.6900	1.7700	0.27	0.54	0.60	0.56	108.47%	4.24%	6.09%	0.3000	0.500	0.600	0.600	100.00%	20.00%	0.00%
	3.6200	1.7400	0.28	0.55	0.61	0.57	108.05%	4.02%	6.29%	0.3000	0.600	0.600	0.600	100.00%	0.00%	0.00%
	1.4000	0.7030	0.71	1.43	1.59	1.42	99.15%	0.43%	10.29%	0.7000	1.000	2.000	1.000	42.86%	0.00%	50.00%
	1.3100	0.6600	0.76	1.53	1.69	1.52	98.48%	0.76%	10.59%	0.8000	2.000	2.000	2.000	150.00%	0.00%	0.00%
	2.3400	1.1500	0.43	0.85	0.95	0.87	103.48%	1.74%	8.34%	0.4000	0.900	0.900	0.900	125.00%	0.00%	0.00%
	2.2500	1.1100	0.44	0.89	0.99	0.90	102.70%	1.35%	8.69%	0.4000	0.900	1.000	0.900	125.00%	0.00%	10.00%
	7.2900	3.4000	0.14	0.27	0.30	0.29	114.41%	7.21%	3.42%	0.1000	0.300	0.300	0.300	200.00%	0.00%	0.00%
	7.1200	3.3200	0.14	0.28	0.31	0.30	114.46%	7.23%	3.40%	0.1000	0.300	0.300	0.300	200.00%	0.00%	0.00%
	4.0800	1.9500	0.25	0.49	0.54	0.51	109.23%	4.62%	5.75%	0.2000	0.500	0.500	0.500	150.00%	0.00%	0.00%
	4.1700	1.9900	0.24	0.48	0.53	0.50	109.55%	4.77%	5.61%	0.2000	0.500	0.500	0.500	150.00%	0.00%	0.00%
	0.9300	0.4770	1.08	2.15	2.39	2.10	94.97%	2.52%	12.16%	1.0000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	1.0100	0.5140	0.99	1.98	2.20	1.95	96.50%	1.75%	11.49%	1.0000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	2.8600	1.3900	0.35	0.70	0.78	0.72	105.76%	2.88%	7.32%	0.3000	0.700	0.800	0.700	133.33%	0.00%	12.50%
	3.2300	1.5800	0.31	0.62	0.69	0.64	107.05%	3.53%	6.73%	0.3000	0.600	0.700	0.600	100.00%	0.00%	14.29%
	4.9200	2.3300	0.20	0.41	0.45	0.43	111.16%	5.58%	4.88%	0.2000	0.400	0.500	0.400	100.00%	0.00%	20.00%
	4.7500	2.2600	0.21	0.42	0.47	0.44	110.18%	5.09%	5.33%	0.2000	0.400	0.500	0.400	100.00%	0.00%	20.00%
	0.6620	0.3450	1.51	3.02	3.35	2.90	91.88%	4.06%	13.57%	2.0000	3.000	3.000	3.000	50.00%	0.00%	0.00%
	0.8500	0.4380	1.18	2.35	2.61	2.28	94.06%	2.97%	12.58%	1.0000	2.000	3.000	2.000	100.00%	0.00%	33.33%
	12.9800	6.2200	0.08	0.15	0.17	0.16	108.68%	4.34%	6.00%	0.0800	0.200	0.200	0.200	150.00%	0.00%	0.00%
	12.4100	5.9300	0.08	0.16	0.18	0.17	109.27%	4.64%	5.73%	0.0800	0.200	0.200	0.200	150.00%	0.00%	0.00%
	2.4600	1.0900	0.41	0.81	0.90	0.92	125.69%	12.84%	1.66%	0.4000	0.800	0.900	0.900	125.00%	12.50%	0.00%
	2.5500	1.1400	0.39	0.78	0.87	0.88	123.68%	11.84%	0.76%	0.4000	0.800	0.900	0.900	125.00%	12.50%	0.00%
	0.8000	0.3390	1.25	2.50	2.78	2.95	135.99%	17.99%	6.30%	1.0000	3.000	3.000	3.000	200.00%	0.00%	0.00%
	0.9510	0.4060	1.05	2.10	2.33	2.46	134.24%	17.12%	5.51%	1.0000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	4.7700	2.1900	0.21	0.42	0.47	0.46	117.81%	8.90%	1.69%	0.2000	0.400	0.500	0.500	150.00%	25.00%	0.00%
	4.8300	2.2100	0.21	0.41	0.46	0.45	118.55%	9.28%	1.55%	0.2000	0.400	0.500	0.500	150.00%	25.00%	0.00%
	0.6420	0.2700	1.56	3.12	3.46	3.70	137.78%	18.89%	7.11%	2.0000	3.000	3.000	4.000	100.00%	33.33%	33.33%
	0.6100	0.2550	1.64	3.28	3.64	3.92	139.22%	19.61%	7.75%	2.0000	3.000	4.000	4.000	100.00%	33.33%	0.00%

Queensland Government
Queensland Health

Extended Internal Prospective Validation of the ABI Prism® 7000/Quantifiler System (Forensic Biology)

Full profile results

Sample Name	Quantity Quantifiler standard	Quantity Promega Male standard	Sample volume Quantifiler standard quantity	Sample volume Quantifiler standard quantity/ 2	Sample volume Quantifiler standard quantity/ 2.22	Sample volume Promega standard	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Difference of Quantifiler standard quantity to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2 to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2.22 to Promega standard amplification volumes
	0.5450	0.2270	1.83	3.67	4.07	4.41	140.09%	20.04%	8.15%	2.000	4.000	4.000	4.000	100.00%	0.00%	0.00%
	0.4480	0.1850	2.23	4.46	4.96	5.41	142.16%	21.06%	9.08%	2.000	4.000	5.000	5.000	150.00%	25.00%	0.00%
	4.3100	1.9600	0.23	0.46	0.52	0.51	119.90%	9.95%	0.95%	0.200	0.500	0.500	0.500	150.00%	0.00%	0.00%
	3.9100	1.7800	0.26	0.51	0.57	0.56	119.66%	9.83%	1.05%	0.300	0.500	0.600	0.600	100.00%	20.00%	0.00%
	2.1900	0.9710	0.46	0.91	1.01	1.03	125.54%	12.77%	1.59%	0.500	0.900	1.000	1.000	100.00%	11.11%	0.00%
	2.2500	0.9970	0.44	0.89	0.99	1.00	125.68%	12.84%	1.66%	0.400	0.900	1.000	1.000	150.00%	11.11%	0.00%
	2.4700	1.1000	0.40	0.81	0.90	0.91	124.55%	12.27%	1.15%	0.400	0.800	0.900	0.900	125.00%	12.50%	0.00%
	2.4400	1.0800	0.41	0.82	0.91	0.93	125.93%	12.96%	1.77%	0.400	0.800	0.900	0.900	125.00%	12.50%	0.00%
	0.8150	0.3460	1.23	2.45	2.72	2.89	135.55%	17.77%	6.10%	1.000	2.000	3.000	3.000	200.00%	50.00%	0.00%
	0.7760	0.3290	1.29	2.57	2.85	3.04	136.47%	18.24%	6.52%	1.000	3.000	3.000	3.000	200.00%	0.00%	0.00%
	1.7100	0.7500	0.58	1.17	1.30	1.33	128.00%	14.00%	2.70%	0.600	1.000	1.000	1.000	66.67%	0.00%	0.00%
	1.4400	0.6260	0.69	1.39	1.54	1.60	130.03%	15.02%	3.62%	0.700	1.000	2.000	2.000	185.71%	100.00%	0.00%
	1.9100	0.8390	0.52	1.05	1.16	1.19	127.65%	13.83%	2.55%	0.500	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.8200	0.8000	0.55	1.10	1.22	1.25	127.50%	13.75%	2.48%	0.500	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.5300	0.6690	0.65	1.31	1.45	1.49	126.70%	14.35%	3.02%	0.700	1.000	1.000	1.000	42.86%	0.00%	0.00%
	1.2900	0.5590	0.78	1.55	1.72	1.79	130.77%	15.38%	3.95%	0.800	2.000	2.000	2.000	150.00%	0.00%	0.00%
	1.9200	0.8440	0.52	1.04	1.16	1.18	127.49%	13.74%	2.47%	0.500	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.8300	0.8050	0.55	1.09	1.21	1.24	127.33%	13.66%	2.40%	0.500	1.000	1.000	1.000	100.00%	0.00%	0.00%
	0.5110	0.2120	1.96	3.91	4.34	4.72	141.04%	20.52%	8.58%	2.000	4.000	4.000	5.000	150.00%	25.00%	25.00%
	0.4650	0.1930	2.15	4.30	4.77	5.18	140.93%	20.47%	8.53%	2.000	4.000	5.000	5.000	150.00%	25.00%	0.00%
	1.2200	0.5240	0.82	1.64	1.82	1.91	132.82%	16.41%	4.86%	0.800	2.000	2.000	2.000	150.00%	0.00%	0.00%
	1.0800	0.4660	0.93	1.85	2.06	2.15	131.76%	15.88%	4.40%	0.900	2.000	2.000	2.000	122.22%	0.00%	0.00%
	3.0800	1.5700	0.32	0.65	0.72	0.64	96.18%	1.91%	11.63%	0.300	0.600	0.700	0.600	100.00%	0.00%	14.29%
	2.6900	1.3700	0.37	0.74	0.83	0.73	96.35%	1.82%	11.55%	0.400	0.700	0.800	0.700	75.00%	0.00%	12.50%
	11.8800	6.1200	0.08	0.17	0.19	0.16	94.12%	2.94%	12.56%	0.080	0.200	0.200	0.200	150.00%	0.00%	0.00%
	11.5500	5.9500	0.09	0.17	0.19	0.17	94.12%	2.94%	12.56%	0.090	0.200	0.200	0.200	122.22%	0.00%	0.00%
	39.8800	20.7000	0.03	0.05	0.06	0.05	92.66%	3.67%	13.22%	0.030	0.050	0.060	0.050	66.67%	0.00%	16.67%
	38.1700	19.8100	0.03	0.05	0.06	0.05	92.68%	3.66%	13.21%	0.030	0.050	0.060	0.050	66.67%	0.00%	16.67%
	0.3560	0.1790	2.81	5.62	6.24	5.59	98.88%	0.56%	10.41%	3.000	6.000	6.000	6.000	100.00%	0.00%	0.00%
	0.4020	0.2030	2.49	4.98	5.52	4.93	98.03%	0.99%	10.80%	2.000	5.000	6.000	5.000	150.00%	0.00%	16.67%
	0.7310	0.3700	1.37	2.74	3.04	2.70	97.57%	1.22%	11.01%	1.000	3.000	3.000	3.000	200.00%	0.00%	0.00%
	0.6350	0.3210	1.57	3.15	3.50	3.12	97.82%	1.09%	10.89%	2.000	3.000	3.000	3.000	50.00%	0.00%	0.00%
	8.0700	4.1500	0.12	0.25	0.28	0.24	94.46%	2.77%	12.41%	0.100	0.200	0.300	0.200	100.00%	0.00%	33.33%
	8.0000	4.1100	0.13	0.25	0.28	0.24	94.65%	2.68%	12.32%	0.100	0.300	0.300	0.200	100.00%	33.33%	33.33%
	0.3760	0.1890	2.66	5.32	5.90	5.29	98.94%	0.53%	10.39%	3.000	5.000	6.000	5.000	66.67%	0.00%	16.67%
	0.4010	0.2020	2.49	4.99	5.54	4.95	98.51%	0.74%	10.58%	2.000	5.000	6.000	5.000	150.00%	0.00%	16.67%
	1.4000	0.7110	0.71	1.43	1.59	1.41	96.91%	1.55%	11.30%	0.700	1.000	2.000	1.000	42.86%	0.00%	50.00%
	1.3300	0.6770	0.75	1.50	1.67	1.48	96.45%	1.77%	11.51%	0.800	2.000	2.000	1.000	25.00%	50.00%	50.00%
	0.1900	0.0953	5.26	10.53	11.68	10.49	99.37%	0.31%	10.19%	5.000	11.000	12.000	10.000	100.00%	9.09%	16.67%
	0.2010	0.1010	4.98	9.95	11.04	9.90	99.01%	0.50%	10.36%	5.000	10.000	11.000	10.000	100.00%	0.00%	9.09%
	0.4570	0.2310	2.19	4.38	4.86	4.33	97.84%	1.08%	10.88%	2.000	4.000	5.000	4.000	100.00%	0.00%	20.00%
	0.4940	0.2490	2.02	4.05	4.49	4.02	98.39%	0.80%	10.63%	2.000	4.000	4.000	4.000	100.00%	0.00%	0.00%
	3.6700	1.8800	0.27	0.54	0.60	0.53	95.21%	2.39%	12.07%	0.300	0.500	0.600	0.500	66.67%	0.00%	16.67%
	3.5000	1.7900	0.29	0.57	0.63	0.56	95.53%	2.23%	11.92%	0.300	0.600	0.600	0.600	100.00%	0.00%	0.00%
	0.9790	0.4960	1.02	2.04	2.27	2.02	97.38%	1.31%	11.09%	1.000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	1.0000	0.5090	1.00	2.00	2.22	1.99	96.46%	1.77%	11.50%	1.000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	0.6920	0.3500	1.45	2.89	3.21	2.86	97.71%	1.14%	10.94%	1.000	3.000	3.000	3.000	200.00%	0.00%	0.00%
	0.6150	0.3110	1.63	3.25	3.61	3.22	97.75%	1.13%	10.92%	2.000	3.000	4.000	3.000	50.00%	0.00%	25.00%
	0.1520	0.0763	6.58	13.16	14.61	13.11	99.21%	0.39%	10.26%	7.000	13.000	15.000	13.000	85.71%	0.00%	13.33%
	0.1130	0.0566	8.85	17.70	19.65	17.67	99.65%	0.18%	10.07%	9.000	18.000	20.000	18.000	100.00%	0.00%	10.00%
	7.3100	3.7500	0.14	0.27	0.30	0.27	94.93%	2.53%	12.19%	0.100	0.300	0.300	0.300	200.00%	0.00%	0.00%
	7.8400	4.0300	0.13	0.26	0.28	0.25	94.54%	2.73%	12.37%	0.100	0.300	0.300	0.200	100.00%	33.33%	33.33%
	0.9820	0.4980	1.02	2.04	2.26	2.01	97.19%	1.41%	11.18%	1.000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	0.9040	0.4580	1.11	2.21	2.46	2.18	97.38%	1.31%	11.09%	1.000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	11.1100	5.7200	0.09	0.18	0.20	0.17	94.23%	2.88%	12.51%	0.090	0.200	0.200	0.200	122.22%	0.00%	0.00%
	10.4200	5.3800	0.10	0.19	0.21	0.19	94.40%	2.80%	12.43%	0.100	0.200	0.200	0.200	100.00%	0.00%	0.00%
	0.3500	0.1760	2.86	5.71	6.34	5.68	98.86%	0.57%	10.42%	3.000	6.000	6.000	6.000	100.00%	0.00%	0.00%
	0.3430	0.1730	2.92	5.83	6.47	5.78	98.27%	0.87%	10.69%	3.000	6.000	6.000	6.000	100.00%	0.00%	0.00%
	1.3700	0.5940	0.73	1.46	1.62	1.68	130.64%	15.32%	3.89%	0.700	1.000	2.000	2.000	185.71%	100.00%	0.00%
	1.4800	0.6440	0.68	1.35	1.50	1.55	129.81%	14.91%	3.52%	0.700	1.000	2.000	2.000	185.71%	100.00%	0.00%
						Mean	109.80%	6.27%	7.75%					115.03%	7.72%	6.57%

Table 39: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for non-probative samples that resulted in partial profiles. The least overall difference in sample volumes was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 16.06%). The Promega Male standard result at 1ng and Quantifiler standard sample volume result at 2ng is also comparable with a mean difference of 24.42%. Duplicate results are presented.

Partial profiles																
Sample Name	Quantity Quantifiler standard	Quantity Promega Male standard	Sample volume Quantifiler standard quantity	Sample volume Quantifiler standard quantity/ 2	Sample volume Quantifiler standard quantity/ 2.22	Sample volume Promega standard	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quanlity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Difference of Quantifiler standard quantity to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2 to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2.22 to Promega standard amplification volumes
[redacted]	0.1750	0.0695	5.71	11.43	12.69	14.39	151.80%	25.90%	13.42%	6	11	13	14	133.33%	27.27%	7.69%
[redacted]	0.1680	0.0665	5.95	11.90	13.21	15.04	152.63%	26.32%	13.80%	6	12	13	15	150.00%	25.00%	15.38%
[redacted]	0.1500	0.0592	6.67	13.33	14.80	16.89	153.38%	26.69%	14.13%	7	13	15	17	142.86%	30.77%	13.33%
[redacted]	0.1200	0.0466	8.33	16.67	18.50	21.46	157.51%	28.76%	16.00%	8	17	19	20	150.00%	17.65%	5.26%
[redacted]	0.1190	0.0463	8.40	16.81	18.66	21.60	157.02%	28.51%	15.77%	8	17	19	20	150.00%	17.65%	5.26%
[redacted]	0.0389	0.0144	25.71	51.41	57.07	69.44	170.14%	35.07%	21.68%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.3620	0.1940	2.76	5.52	6.13	5.15	86.60%	6.70%	15.95%	3	6	6	5	66.67%	16.67%	16.67%
[redacted]	0.3040	0.1640	3.29	6.58	7.30	6.10	85.37%	7.32%	16.50%	3	7	7	6	100.00%	14.29%	14.29%
[redacted]	0.1010	0.0392	9.90	19.80	21.98	25.51	157.65%	28.83%	16.06%	10	20	20	20	100.00%	0.00%	0.00%
[redacted]	0.0872	0.0335	11.47	22.94	25.46	29.85	160.30%	30.15%	17.25%	11	20	20	20	81.82%	0.00%	0.00%
						Mean	143.24%	24.42%	16.06%					107.47%	14.93%	7.79%

Table 40: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for non-probative samples that resulted in NSDs. The least overall difference in sample volumes was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 2.48%). The Promega Male standard result at 1ng and Quantifiler standard sample volume result at 2.22ng is also comparable with a mean difference of 3.65%. Duplicate results are presented.

NSDs																
Sample Name	Quantity Quantifiler standard	Quantity Promega Male standard	Sample volume Quantifiler standard quantity	Sample volume Quantifiler standard quantity/ 2	Sample volume Quantifiler standard quantity/ 2.22	Sample volume Promega standard	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quanlity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Difference of Quantifiler standard quantity to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2 to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2.22 to Promega standard amplification volumes
[redacted]	0.0228	0.0139	43.86	87.72	97.37	71.94	64.03%	17.99%	26.11%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0315	0.0189	31.75	63.49	70.48	52.91	66.67%	16.67%	24.92%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
						Mean	9.34%	2.48%	3.65%					0.00%	0.00%	0.00%

In tables 41-43, comparisons of the same data but this time off average results from the duplicates are shown. The rounded amplification volumes account for the pipetting limit of 1μL. In other words, the rounding macro has to round sample volumes to the nearest 1μL and not volumes with decimal places. Where amounts are under 1ng of input template for Profiler or Cofiler due to rounding, the macro then rounds up to the next 1μL of sample volume.

Table 41: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for non-probative samples that resulted in full profiles. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

Full profile results						
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard rounded amplification volumes
[redacted]	1.75	1.72	1.84%	2.00	2.00	0.00%
	1.07	1.08	0.80%	1.00	1.00	0.00%
	0.90	0.92	1.36%	0.90	0.90	0.00%
	1.10	1.11	0.44%	1.00	1.00	0.00%
	0.44	0.46	4.73%	0.40	0.50	20.00%
	0.11	0.12	10.71%	0.10	0.10	0.00%
	1.13	1.14	0.40%	1.00	1.00	0.00%
	0.23	0.25	7.65%	0.20	0.20	0.00%
	0.93	0.94	1.40%	0.90	0.90	0.00%
	0.56	0.58	3.63%	0.60	0.60	0.00%
	0.74	0.76	2.42%	0.70	0.80	12.50%
	0.55	0.57	3.97%	0.50	0.60	16.67%
	1.48	1.47	0.59%	1.00	1.00	0.00%
	0.87	0.88	1.53%	0.90	0.90	0.00%
	0.28	0.30	6.73%	0.30	0.30	0.00%
	0.48	0.51	4.48%	0.50	0.50	0.00%
	2.06	2.02	2.16%	2.00	2.00	0.00%
	0.66	0.68	3.12%	0.70	0.70	0.00%
	0.41	0.44	5.07%	0.40	0.40	0.00%
	2.65	2.55	3.57%	3.00	3.00	0.00%
	0.16	0.16	4.29%	0.20	0.20	0.00%
	0.80	0.90	10.98%	0.80	0.90	11.11%
	2.28	2.68	14.91%	2.00	3.00	33.33%
	0.42	0.45	8.33%	0.40	0.50	20.00%
	3.19	3.81	16.13%	3.00	4.00	25.00%
	4.03	4.85	17.02%	4.00	5.00	20.00%
	0.49	0.53	9.00%	0.50	0.50	0.00%
	0.90	1.02	11.35%	0.90	1.00	10.00%
	0.81	0.92	11.20%	0.80	0.90	11.11%
	2.51	2.96	15.25%	3.00	3.00	0.00%
	1.27	1.45	12.63%	1.00	1.00	0.00%
	1.07	1.22	12.12%	1.00	1.00	0.00%
	1.42	1.63	12.91%	1.00	2.00	50.00%
	1.07	1.21	12.05%	1.00	1.00	0.00%
	4.10	4.94	17.01%	4.00	5.00	20.00%
	1.74	2.02	13.91%	2.00	2.00	0.00%
	0.69	0.68	1.91%	0.70	0.70	0.00%
	0.17	0.17	3.03%	0.20	0.20	0.00%
	0.05	0.05	3.81%	0.05	0.05	0.00%
	5.28	5.24	0.79%	5.00	5.00	0.00%
	2.93	2.89	1.17%	3.00	3.00	0.00%
	0.25	0.24	2.80%	0.20	0.20	0.00%
	5.15	5.12	0.64%	5.00	5.00	0.00%
	1.47	1.44	1.68%	1.00	1.00	0.00%
	10.23	10.19	0.41%	10.00	10.00	0.00%
	4.21	4.17	0.95%	4.00	4.00	0.00%
	0.56	0.54	2.37%	0.60	0.50	20.00%
	2.02	1.99	1.57%	2.00	2.00	0.00%
	3.06	3.03	1.15%	3.00	3.00	0.00%
	15.09	15.05	0.30%	15.00	15.00	0.00%
	0.26	0.26	2.71%	0.30	0.30	0.00%
	2.12	2.09	1.38%	2.00	2.00	0.00%
	0.19	0.18	2.93%	0.20	0.20	0.00%
	5.77	5.73	0.72%	6.00	6.00	0.00%
	1.40	1.62	13.12%	1.00	2.00	50.00%
Mean			**5.62%**			**5.81%**

Table 42: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for non-probative samples that resulted in partial profiles. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

Partial profiles						
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard rounded amplification volumes
[redacted]	11.6618	14.7059	20.70%	12.0000	15.0000	20.00%
	14.8148	18.9036	21.63%	15.0000	19.0000	21.05%
	25.3325	32.9489	23.12%	20.0000	20.0000	0.00%
	6.0060	5.5866	7.51%	6.0000	6.0000	0.00%
	21.2540	27.5103	22.74%	20.0000	20.0000	0.00%
Mean			**19.14%**			**8.21%**

Table 43: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for non-probative samples that resulted in NSDs. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

NSDs						
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard rounded amplification volumes
[redacted]	73.66	60.98	20.81%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
Mean			**2.97%**			**0.00%**

Table 44: Final results using the Quantifiler standard after an estimated 2ng was used for the initial Profiler amplification.

Amplification results	Sample number
Full profiles	55
Partial profiles	5
No size data (NSDs)	7
SUBTOTAL	**67**
Non-reportable (NR) profile	0
Unamplified (inhibition present)	0
TOTAL	**67**

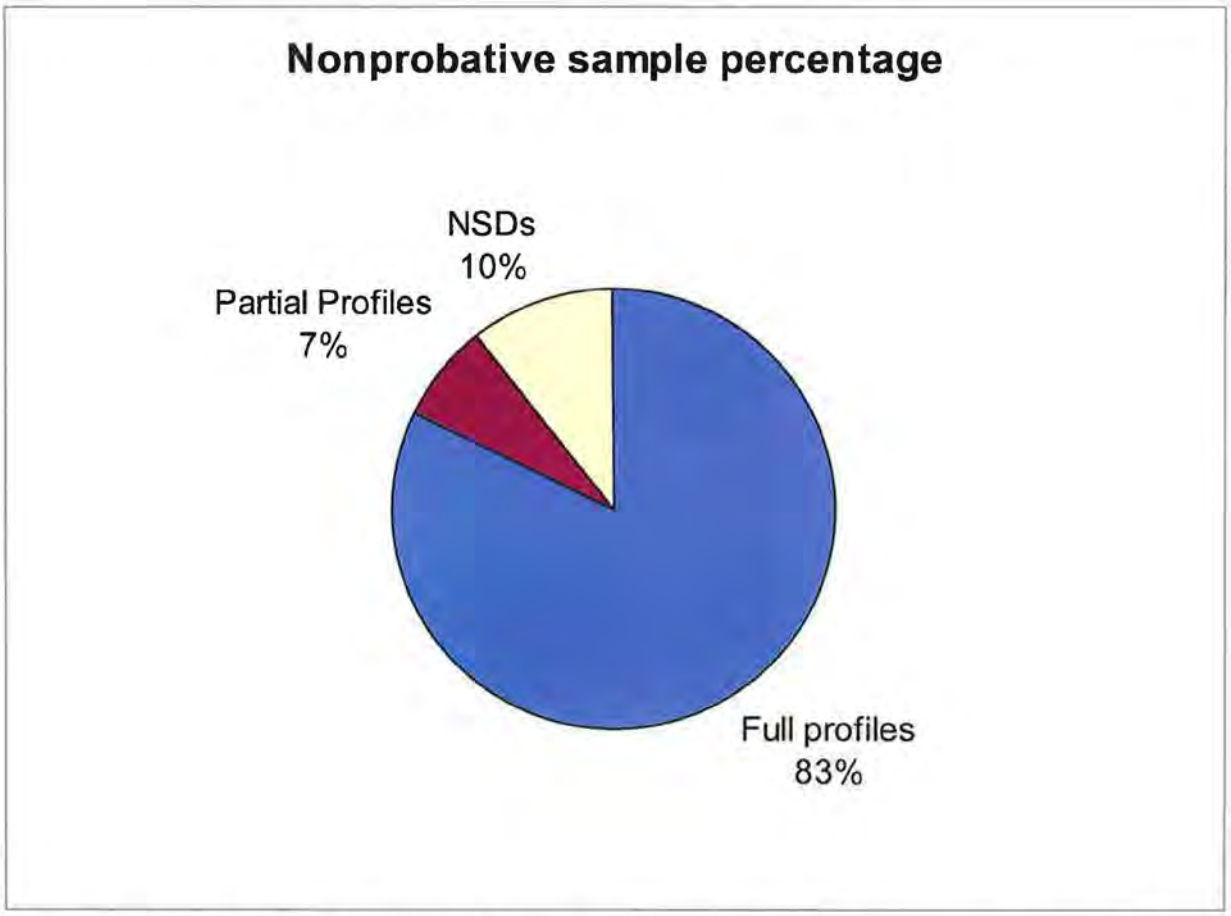

Figure 12: Final results for non-probative samples using the Quantifiler standard after an estimated 2ng was used for the initial Profiler amplification.

In table 45, the differences between using the Quantifiler Human DNA standard and the Promega Male standard for estimating probative sample concentration are summarised. Clearly, the most optimal nanogram amount for the Quantifiler Human DNA standard (approximately 2ng at 1.95ng) is approximately double to that of the Promega Male standard (approximately 1ng at 0.92ng).

Overall, the least difference was between the Quantifiler Human DNA standard concentrations divided by 2 and 2.22 and the Promega Male standard. For partial profiles the difference was lower between the Quantifiler Human DNA standard concentrations divided by 2.5 and the Promega Male standard. This is most likely an artefact of small sample number since only five partial profile results were produced from 67 samples.

Table 45: A comparison of non-probative sample results with the Promega Male standard and Quantifiler standard.

Non-probative sample results			
Final result		Optimal ng amount using Quantifiler Standard	Optimal ng using Promega Standard
Full profile	**Mean**	**1.95**	**0.93**
Partial profile	**Mean**	**1.91**	**0.80**
Full and partial profiles	**Mean**	**1.95**	**0.92**

No rounding						
Final result		Difference 1ng Promega to 1ng Quantifiler	Difference 1ng Promega to 2ng Quantifiler	Difference 1ng Promega to 2.22ng Quantifiler	Difference 1ng Promega to 2.35ng Quantifiler	Difference 1ng Promega to 2.5ng Quantifiler
Full profile	**Mean**	**109.80%**	**6.27%**	**7.75%**	**10.99%**	**16.08%**
Partial profile	**Mean**	**143.24%**	**24.42%**	**16.06%**	**11.85%**	**7.54%**
Full and partial profiles	**Mean**	**112.59%**	**7.79%**	**8.44%**	**11.06%**	**15.37%**

Rounding						
Final result		Difference 1ng Promega to 1ng Quantifiler	Difference 1ng Promega to 2ng Quantifiler	Difference 1ng Promega to 2.22ng Quantifiler	Difference 1ng Promega to 2.35ng Quantifiler	Difference 1ng Promega to 2.5ng Quantifiler
Full profile	**Mean**	**115.03%**	**7.72%**	**6.57%**	**9.69%**	**13.64%**
Partial profile	**Mean**	**107.47%**	**14.93%**	**7.79%**	**6.28%**	**5.36%**

5.10.3 ROUNDING MACRO

The original macro that was used with our Quantifiler output file to convert concentrations into amplification volumes for Profiler Plus and COfiler, was designed by Tim Gardam. The pipetting dilutions are rounded off to the nearest µL which occasionally results in less than the goal of approximately 1ng being added to Profiler Plus and COfiler. Because Profiler Plus and COfiler require between 1 and 2.5ng of template, samples that are theoretically lower than 1ng can be compensated for by rounding up the pipetting dilution to the next µL, unless the sample is already amplified at the maximum volume of 20µL. This means that at the most you may double the volume of some samples, although the final theoretical concentration should still be less than approximately 2ng.

The probative and non-probative amplification profile plots from the ABI3100 were examined for samples where the volume of samples would have been doubled due to the application of the compensatory macro. The greatest peak heights in each amp plot where doubling would have occurred were doubled to approximate the increase in DNA template and determine if the amounts could potentially produce excess profiles. Excess profiles were defined as those with peaks over 4500 RFU being produced after doubling the actual peak heights obtained following the application of Tim's macro. The results of this analysis are presented in tables 47 and 48. About 4.80% of the probative samples and 4.48% of the non-probative samples had the potential to produce excess profiles with the Promega Male Standard.

Table 46: An example of the effects of rounding for pipetting and a compensatory method. The probative samples below show the effects of rounding to the nearest μL. The boldened samples are those where less than 1ng of DNA is added due to rounding or where the maximum amount of DNA has been added. Because Profiler Plus requires between 1 and 2.5ng, this can be compensated for by adding one more μL for samples that are under the 1ng amount (except for samples that are already being amplified at the maximum volume-shown in red). The maximum effect is visible for samples where the volumes have been doubled (shown in pink).

	Tris-Ea macro (adds +1ng added due to rounding)					Compensatory macro (not <1ng unless amplified at maximum volume)					
Sample Name	svol1	TEvol1	svol2	TEvol2	Quantity DNA (ng)	svol1	TEvol1	svol2	TEvol2	Quantity DNA (ng)	Percent of original
	1	19	0	0	0.668500000	2	18	0	0		200%
	1	19	0	0	0.912000000	2	18	0	0		200%
	1	19	0	0	0.965000000	2	18	0	0		200%
	1	19	1	99	0.768850000	1	19	2	98		200%
	1	19	0	0	0.778000000	2	18	0	0		200%
	1	19	1	999	0.684220000	1	19	2	998		200%
	1	19	1	999	0.890100000	1	19	2	998		200%
	1	19	1	999	0.854485000	1	19	2	998		200%
	1	19	1	999	0.950080000	1	19	2	998		200%
	1	19	0	0	0.762500000	2	18	0	0		200%
	1	19	0	0	0.855500000	2	18	0	0		200%
	1	19	0	0	0.856000000	2	18	0	0		200%
	1	19	0	0	0.900500000	2	18	0	0		200%
	2	18	0	0	0.974000000	3	17	0	0		150%
	2	18	0	0	0.805000000	3	17	0	0		150%
	1	19	2	8	0.681000000	1	19	3	7		150%
	2	18	0	0	0.872000000	3	17	0	0		150%
	2	18	0	0	0.948000000	3	17	0	0		150%
	2	18	0	0	0.829000000	3	17	0	0		150%
	1	19	2	8	0.948000000	1	19	3	7		150%
	1	19	2	8	0.856000000	1	19	3	7		150%
	2	18	0	0	0.811000000	3	17	0	0		150%
	3	17	0	0	0.963000000	4	16	0	0		133%
	3	17	0	0	0.976500000	4	16	0	0		133%
	4	16	0	0	0.950000000	5	15	0	0		125%
	4	16	0	0	0.998000000	5	15	0	0		125%
	4	16	0	0	0.958000000	5	15	0	0		125%
	4	16	0	0	0.986000000	5	15	0	0		125%
	5	15	0	0	0.980000000	6	14	0	0		120%
	1	19	5	95	0.994500000	1	19	5	94		120%
	5	15	0	0	0.967500000	6	14	0	0		120%
	1	19	6	4	0.945000000	1	19	7	3		117%
	6	14	0	0	0.963000000	7	13	0	0		117%
	6	14	0	0	0.978000000	7	13	0	0		117%
	1	19	7	3	0.969500000	1	19	8	2		114%
	7	13	0	0	0.980000000	8	12	0	0		114%
	1	19	8	2	0.984000000	1	19	9	1		113%
	9	11	0	0	0.972000000	10	10	0	0		111%
	1	19	9	1	0.999000000	1	19	10	0		111%
	1	19	9	1	0.963000000	1	19	10	0		111%
	10	10	0	0	0.992000000	11	9	0	0		110%
	11	9	0	0	0.968550000	12	8	0	0		109%
	12	8	0	0	0.970200000	13	7	0	0		108%
	13	7	0	0	0.955900000	14	6	0	0		108%
	15	5	0	0	0.990000000	16	4	0	0		107%
	14	6	0	0	0.977200000	15	5	0	0		107%
	15	5	0	0	0.987750000	16	4	0	0		107%
	20	0	0	0	0.794000000	20	0	0	0		100%
	20	0	0	0	0.441000000	20	0	0	0		100%
	2	18	0	0	1.304000000	2	18	0	0		100%
	3	17	0	0	1.144500000	3	17	0	0		100%
	5	15	0	0	1.102500000	5	15	0	0		100%
	10	10	0	0	1.045000000	10	10	0	0		100%
	1	19	0	0	1.009000000	1	19	0	0		100%
	6	14	0	0	1.089000000	6	14	0	0		100%
	1	19	2	8	1.290000000	1	19	2	8		100%
	2	18	0	0	1.064000000	2	18	0	0		100%
	2	18	0	0	1.096000000	2	18	0	0		100%
	1	19	1	999	1.024795000	1	19	1	999		100%
	5	15	0	0	1.012500000	5	15	0	0		100%
	1	19	5	5	1.097500000	1	19	5	5		100%
	1	19	2	8	1.087000000	1	19	2	8		100%
	5	15	0	0	1.000000000	5	15	0	0		100%
	2	18	0	0	1.308000000	2	18	0	0		100%
	3	17	0	0	1.011000000	3	17	0	0		100%
	1	19	9	1	1.008000000	1	19	9	1		100%
	2	18	0	0	1.294000000	2	18	0	0		100%
	1	19	1	9	1.027500000	1	19	1	9		100%
	2	18	0	0	1.053000000	2	18	0	0		100%
	5	15	0	0	1.067500000	5	15	0	0		100%
	1	19	9	1	1.008000000	1	19	9	1		100%
	1	19	6	4	1.032000000	1	19	6	4		100%
	1	19	2	8	1.227000000	1	19	2	8		100%
	2	18	0	0	1.044000000	2	18	0	0		100%
	1	19	4	6	1.016000000	1	19	4	6		100%
	1	19	2	8	1.071000000	1	19	2	8		100%
	3	17	0	0	1.056000000	3	17	0	0		100%
	5	15	0	0	1.060000000	5	15	0	0		100%
	5	15	0	0	1.017500000	5	15	0	0		100%
	3	17	0	0	1.194000000	3	17	0	0		100%
	1	19	5	5	1.085000000	1	19	5	5		100%
	5	15	0	0	1.002500000	5	15	0	0		100%
	2	18	0	0	1.104000000	2	18	0	0		100%
	3	17	0	0	1.149000000	3	17	0	0		100%
	2	18	0	0	1.282000000	2	18	0	0		100%
	1	19	5	5	1.062500000	1	19	5	5		100%
	2	18	0	0	1.248000000	2	18	0	0		100%
	15	5	0	0	1.005000000	15	5	0	0		100%
	5	15	0	0	1.030000000	5	15	0	0		100%
	4	16	0	0	1.060000000	4	16	0	0		100%
	18	2	0	0	1.004400000	18	2	0	0		100%
	3	17	0	0	1.102500000	3	17	0	0		100%
	9	11	0	0	1.008000000	9	11	0	0		100%
	5	15	0	0	1.055000000	5	15	0	0		100%
	15	5	0	0	1.017750000	15	5	0	0		100%

Table 47: Probative sample rounding correction effects. The table demonstrates the number of probative samples where a doubling of volume would occur due to rounding correction for samples originally less than 1ng. This is the most extreme effect of rounding up to the next μL. For example, where 1μL becomes 2μL in a sample dilution. Most effects would not be as extreme (e.g. 5μL becomes 6μL).

	Shared	Other	Total	Potential excess profiles	Percentage of total samples
Promega Male standard	5	8	13	6	4.80%
Quantifiler standard	5	9	14	9	7.10%

Table 48: Non-probative sample rounding correction effects. The table demonstrates the number of non-probative samples where a doubling of volume would occur due to rounding correction for samples originally less than 1ng. This is the most extreme effect of rounding up to the next μL. For example, where 1μL becomes 2μL in a sample dilution. Most effects would not be as extreme (e.g. 5μL becomes 6μL).

	Shared	Other	Total	Potential excess profiles	Percentage of total samples
Promega Male standard	9	1	10	3	4.48%
Quantifiler standard	9	2	11	3	4.48%

5.11 SINGLICATE VERSUS DUPLICATE SAMPLE RUNS

In this section we investigated whether it is valid to run single rather than duplicate reactions in adjacent wells. One of our previous observations was that most differences are observed between non-adjacent positions on the block and between different runs rather than adjacent horizontal positions.

Duplicates sometimes resulted in different amplification volumes being calculated and therefore on that basis could be termed to be significant differences. However, since the differences in the amplification volumes are typically quite small they should usually result in similar Profiler and COfiler results and therefore not be significantly different.

5.11.1 SINGLICATES VERSUS DUPLICATES FOR PROBATIVE SAMPLE DATA

In table 49, it is clear that the mean duplicate differences in the Quantifiler concentrations were low using the Promega Male standard for probative samples (9.7% for full profile samples and 13.5% for partial profile samples). Mean duplicate percentages in the Quantifiler concentrations were high (92% for full profiles and 88% for partial profiles) using the Promega Male standard for probative samples. Therefore, the use of single reactions would be valid.

Table 49: Mean results for Quantifiler probative sample data for duplicates.

Final Result	Duplicate Differences in Quantifiler Quant values	Duplicate Differences in Promega Quant values	Duplicate lower ratio Quantifiler Quant values	Duplicate lower ratio Promega Quant values	Duplicate Differences in Quantifiler Quant values to Maximum	Duplicate Differences in Quantifiler Quant values to Minimum	Duplicate Differences in Promega Quant values to Maximum	Duplicate Differences in Promega Quant values to Minimum	Ratio
Full	9.58%	9.70%	0.92	0.92	8.12%	10.12%	8.21%	10.25%	0.92
Partial profile	13.33%	13.50%	0.88	0.88	12.13%	14.81%	12.28%	15.06%	0.88

Mean duplicate differences in the amplification volumes were low using the Promega Male standard for probative samples and incorporating rounding (11.40% for full profile samples and 9.33% for partial profile samples). Mean duplicate percentages in the amplification volumes incorporating rounding were high (91% for full profiles and 92% for partial profiles) using the Promega Male standard for probative samples. This also supports the use of single reactions would be valid (see table 50).

Table 50: Mean results for amplification volume probative sample data for duplicates.

Final Result	Duplicate difference Quantifiler 2ng incorporating rounding	Duplicate difference Quantifiler 2ng without rounding	Duplicate difference Promega 1ng incorporating rounding	Duplicate difference Promega 1ng without rounding	Duplicate lower ratio Quantifiler 2ng incorporating rounding	Duplicate lower ratio Quantifiler 2ng without rounding	Duplicate lower ratio Promega 1ng incorporating rounding	Duplicate lower ratio Promega 1ng without rounding
Full	7.28%	8.66%	11.40%	8.76%	0.94	0.92	0.91	0.92
Partial profile	7.42%	13.61%	9.33%	13.83%	0.94	0.88	0.92	0.88

5.11.2 SINGLICATES VERSUS DUPLICATES FOR NON-PROBATIVE SAMPLE DATA

Table 51: Mean results for Quantifiler non-probative sample data for duplicates.

Final result	Duplicate Differences in Quantifiler Quant values	Duplicate Differences in Promega Quant values	Duplicate lower ratio Quantifiler Quant values	Duplicate lower ratio Promega Quant values
Full profile	8.43%	8.38%	0.92	0.92
Partial profile	54.00%	57.68%	0.76	0.75

In table 51, it is clear that the mean duplicate differences in the Quantifiler concentrations were generally low using the Promega Male standard for non-probative samples (8.38% for full profile samples) although the partial profiles results produced a skewed mean duplicate difference of 57.68%. This was most likely due to the low sample number of only five samples for the partial profile results, where one sample may have had a pipetting error associated with it (see table 39). Mean duplicate percentages in the Quantifiler concentrations were high (92% for full profiles and 75% for partial profiles) using the Promega Male standard for non-probative samples. Therefore, the use of single reactions would be valid.

Mean duplicate differences in the amplification volumes were low using the Promega Male standard for non-probative samples and incorporating rounding (9.14% for full profile samples and 7.67% for partial profile samples). Mean duplicate percentages in the amplification volumes incorporating rounding were high (92% for full profiles and 92% for partial profiles) using the Promega Male standard for probative samples. This also supports the use of single reactions would be valid (see table 52).

Table 52: Mean results for amplification volume non-probative sample data for duplicates.

Final result	Duplicate difference Quantifiler 2ng incorporating rounding	Duplicate difference Quantifiler 2ng without rounding	Duplicate difference Promega 1ng incorporating rounding	Duplicate difference Promega 1ng without rounding	Duplicate lower ratio Quantifiler 2ng incorporating rounding	Duplicate lower ratio Quantifiler 2ng without rounding	Duplicate lower ratio Promega 1ng incorporating rounding	Duplicate lower ratio Promega 1ng without rounding
Full profile	**8.96%**	**8.05%**	**9.14%**	**7.99%**	**0.92**	**0.92**	**0.92**	**0.92**
Partial profile	**12.23%**	**24.20%**	**7.67%**	**24.90%**	**0.88**	**0.76**	**0.92**	**0.75**

5.12 TRAINING (QUALIFYING TEST)

Before the method is introduced the analyst performs a qualifying test. The qualifying test is administered internally and uses types of samples that the laboratory routinely analyses. This testing is required by QIS document 23401R0 and follows DAB (2000:8.1.3.3) and SWGDAM (2004:3.7) guidelines. QIS document 22622 outlines the training required for the qualifying test.

5.13 MAINTENANCE

5.13.1 PERFORMANCE CHECKS

Regular performance checks are required according to SWGDAM (2004:5) guidelines. These are documented in QIS document 23130 and recorded in QIS document 23131.

5.13.2 QUALITY CHECKS

Several quality checks should be followed to ensure that the Quantifiler system is operating effectively. These checks include-

(a) Testing of Promega Male standards when they are made. This testing will be detailed in QIS document 23446. It ensures that the standards made conform with acceptable guidelines.
(b) Testing of Quantifiler batches/kits. Although a regular process there is no current SOP in QIS.
(c) Testing of controls. Following any dilution or tube transfer of stock control solutions, it is recommended that they are tested to determine their accuracy.

5.14 RISK ASSESSMENT

The level and scope of validation required for a particular method/process must be pre-determined and justifiable (QIS 23401R0). Such justification shall be documented along with risk assessments performed (QIS 23401R0). The following factors need to be considered:

(a) Its criticality to the final result (QIS 23401R0). Because DNA amount is being estimated and the sample volumes used for each estimation are low (2μL for a single reaction and 4μL for duplicate reactions), the Quantifiler system is generally believed to be low risk. Reworks of Quantifiler runs are low. If there is a bad run the risk is higher for samples where there are low volumes. The Quantifiler system is generally believed to be non-critical to the final profile result because amplified DNA is reworked based on the initial profiling results. However, more accurate estimation using the Quantifiler system does help to reduce further reworks at the amplification stage where typically greater volumes are used.
(b) The complexity of design or operation (QIS 23401R0). Although of medium complexity the quality system in place ensures that operation is carried out in an efficient and effective manner.

(c) Existing data from this validation shows that it is preferable to use Promega Male standard rather than the Quantifiler standard to obtain more accurate results.
(d) Whether the validation required is prospective or if it has already been in use for some time (retrospective validation) (QIS 23401R0). The current validation is prospective.

5.15 DOCUMENTATION

Validation must be documented according to DAB (2000:8.1.3). Policies/methods for the interpretation of data are to be documented (NATA 2002 5.4.1). This validation project was started before QIS document 23401R0 so there is no formal validation plan (QIS 23401R0) or formal validation protocol. This validation is recorded in the validation register with the unique number of 20 (QIS 23401R0). This document consists of the validation summary report (QIS 23401R0). Raw data or interim results tables not included in the final report (QIS 23401R0) are available from the server.

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7 AMENDMENT HISTORY

Table 53: Amendment history

Revision	Date	Author/s	Amendments
0	15 May 2005	Vojtech Hlinka	First Draft

COMPLETED BY

PERSON	ROLE	SIGNATURE
Vojtech Hlinka	**Project Leader**	[redacted] 20.7.06
Cathie Allen	**Project Leader**	[redacted] 21.7.06.
Iman Muharam	**Associate**	[redacted] 02-08-06

Queensland Government
Queensland Health

Pathology & Scientific Services
Biomedical Technology Services

Validation Acceptance

Validation file title: Extended Internal Prospective Validation of the ABI Prism®7000/Quantifiler System (Forensic Biology)

Purpose:
Second Validation Report supporting validation of the Promega Male Standard.
Completed as part of the DNA Processing Improvement/Quantifiler Project.

The following are included as part of this validation file:

Validation Plan:	**YES / (NO)**
Validation Protocol:	**YES / (NO)**
Validation Summary Report:	**(YES) / NO**
Raw Data:	**YES / (NO)**

Comments:

Refer to **Change No.** 13 for details of training and documentation update responsibility.

Chief Scientist Approval (signature and date): [redacted] 24.7.06

Note: This form is to be placed in the front of all validation files as a record that the validation has been reviewed and approved.

Validation documents filed and Validation Log updated (signature/date) : [redacted] 26/06/06
Quality Officer

Queensland Government
Queensland Health

EXTENDED INTERNAL RETROSPECTIVE VALIDATION OF THE ABI PRISM®7000/ QUANTIFILER SYSTEM

Vojtech HLINKA, Iman MUHARAM, and Cathie ALLEN

9th of August, 2006

Queensland Government
Queensland Health

Extended Internal Retrospective Validation of the ABI Prism® 7000/Quantifiler System (Forensic Biology)

Vojtech HLINKA, Iman MUHARAM, and Cathie ALLEN

9th of August, 2006

1 TABLES

Table 1: Table of contents

Table 2: List of figures

Table 3: List of tables

Table 4: Table of terms and abbreviations

Term/abbreviation	Definition
ABI	Applied Biosystems
CT/C_T	Threshold cycle
EPC	External positive control. The control utilised was AmpℓFSTR Control DNA 9947A. This consists of 0.10ng/µL of human cell line DNA in 0.05%NaN_3 and buffer (Applied Biosystems 1997:1-7).
Promega female control (Promega Human Genomic DNA female control)	Control produced from Human Genomic DNA, Female. Part No. G152A Size 100µg. Each lot number varies in concentration.
Promega male control (Promega Human Genomic DNA Male control)	Control produced from Human Genomic DNA, Male. Part No. G147A. Size 100µg. Each lot number varies in concentration. It is typically diluted to a high concentration of 1ng/µL and a low concentration of 0.1ng/µL.
Promega Male Standard (Promega Human Genomic DNA Male Standard)	Standard produced by a serial dilution from Promega Human Genomic DNA, Male. Part No. G147A. Size 100µg. The known concentration values (see table 14) are used to estimate unknown concentrations.
QIS	Quality Information System
Quantifiler Standard	Standard produced by a serial dilution from 200ng/µL of ABI's Quantifiler Human DNA Standard. Known concentration values (see table 14) are used to estimate unknown concentrations.
Roche Standard	Standard produced by a serial dilution from 200ng/µL Human Genomic DNA from Roche (Cat. No. 1691 112)

2 PURPOSE

The purpose of this document is to provide information regarding the internal extended retrospective validation of the integrated ABI Prism® 7000 Sequence Detection System (SDS) and Quantifiler Human DNA Quantitation Kit System (Quantifiler) and its use within Forensic Biology. It is a retrospective validation given that this document focuses on results based on accumulated historical data for a piece of equipment/process already in use and it also provides additional/extended data to that provided in the original internal validation. It is an additional document to the original internal validation of the Quantifiler System by Queensland Health Scientific Services (QHSS 2004), the Extended Internal Prospective Validation of the ABI Prism® 7000/Quantifiler System (Forensic Biology) (Hlinka *et al.* 2006) and the developmental validation performed and published by Applied Biosystems (ABI) in 2003.

3 SCOPE

Validation is intended to demonstrate:

(a) That the method is technically sound and appropriate for the purpose to which it is to be applied (QIS 10663R2).
(b) Variations to the method are technically justified and supported by documented evidence (QIS 10663R2).
(c) Limitations associated with the method (QIS 10663R2).

Validation also requires that the following are fit for the purpose before they are used by the laboratory to generate results:

(a) test methods (QIS 23401R0).
(b) processes (QIS 23401R0).
(c) computer systems/information management systems (QIS 23401R0).
(d) laboratory equipment (QIS 23401R0).

4 BACKGROUND

The internal extended validation of the ABI Prism® 7000 SDS/Quantifiler System was conducted as a retrospective validation because the validation was based on accumulated historical data for a piece of equipment/process already in operational use. A specific modification that was validated and could be classed as prospective was the change to using 2 Quantifiler nanograms for amplifications instead of using 1 Quantifiler nanogram template amount. Using the Quantifiler standard to quantify samples, we have validated the use of 2 Quantifiler nanograms for amplifications with the AmpFLSTR Profiler Plus PCR Amplification Kit and AmpFLSTR COfiler PCR Amplification Kit where 1 to 2.5ng of DNA is recommended (Applied Biosystems 1997:1-9, Applied Biosystems 1998: 1-9). However, this approach is subject to the diligent screening and testing of Quantifiler standards received from Applied Biosystems to check for conformance.

4.1 HOW DOES QUANTIFILER QUANTITATE DNA?

The ABI 7000/Quantifiler real-time PCR system (Quantifiler system) detects and measures a fluorescent signal that increases during PCR. This fluorescent signal is known as the normalised reporter signal (Rn) and is "the emission intensity of the reporter dye divided by the emission intensity of the passive reference dye measured in each cycle" (QIAGEN 2004:12). The main measurement obtained for each sample on a run is a threshold cycle (C_t) or CT value. This is a cycle number value at which the fluorescent signal crosses the value of the threshold setting (see figure 1). The CT value depends on the amount of starting template and the efficiency of the system.

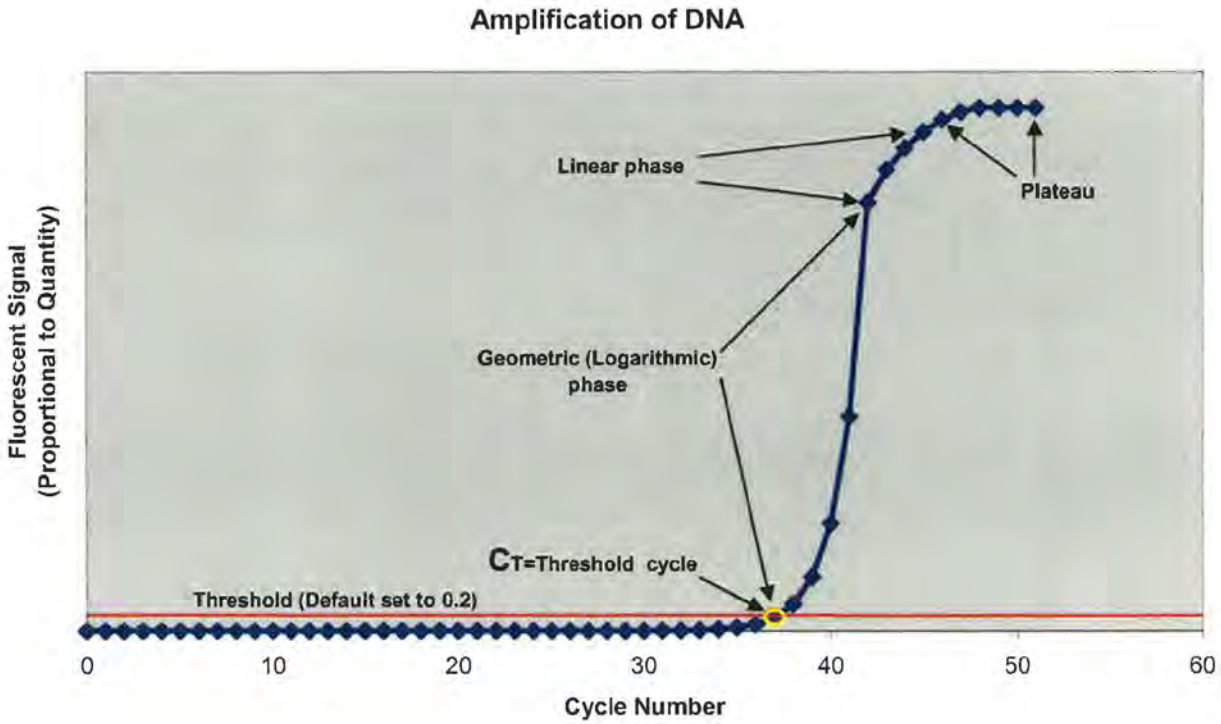

Figure 1: Amplification of DNA during real-time PCR. The cycle at which the fluorescent signal crosses the set threshold is the threshold cycle (CT). Note the different phases of an amplification plot.

In the Quantifiler system it is assumed that because the amplicons are designed and optimised for efficiencies approaching 100%, that the efficiency can be assumed to equal 100% (Applied Biosystems 2003:1-14). In theory, a difference between two samples of one CT equals a two-fold increase in initial template amount. The three-fold concentration increase from standard 8 through to standard 1 found in the Quantifiler standards (see table 14) should therefore have CT differences equal to one and a half.

In the Quantifiler system a CT value from a sample of unknown quantity is compared to CT values obtained from standard samples of known concentration. A series of standards for absolute quantitation is run on each plate. QIAGEN (2004:13) state that it is common for at least five different concentrations to be used to generate a standard curve. The samples of unknown quantity have the same master mix as the samples of known quantity that are being quantified. Quantifiler has eight standards that are made up from one vial by

serial dilution. The final concentrations are approximately 50ng/µL for STD1, 16.67ng/µL for STD2, 5.56ng/µL for STD3, 1.85ng/µL for STD4, 0.62ng/µL for STD5, 0.21ng/µL for STD6, 0.069ng/µL for STD7, and 0.022ng/µL for STD8. The CTs produced from the standards on a run should be in the geometric (logarithmic) phase of amplification and are graphed on a logarithmic graph (see figure 2). A regression line is produced by calculating a line of best fit through the data points produced by the standard. A regression line is only accepted if the closeness of fit between the standard curve regression line and individual CT data points of the standards is high. The closeness of fit is measured by the coefficient of determination in linear regression (R^2 value) where 1.00 indicates a perfect fit. A value above 0.98 is deemed acceptable. The standard regression line formula is then utilised to work out Quantifiler values of samples of unknown concentration based on the CT values obtained given a specific slope and Y-intercept. The formula for the regression line is y=mx + c where m is the slope and c is the Y-intercept when x = 0. X is equal to the log of the Quantifiler value and y equals the CT value. The Y-intercept is defined as the CT value when x=0. Therefore, CT value of the Y-intercept corresponds to where the Quantifiler value is 1ng/µL since the $\log_{10}(1)=0$. In summary, the regression line formula (CT={Slope x Log_{10}(Quantifiler Value)}+ Yintercept) used to work out Quantifiler values can be re-written as

$$\text{Quantifiler Value}=10^{(\{CT-Y\text{intercept}\}/\text{Slope})}$$

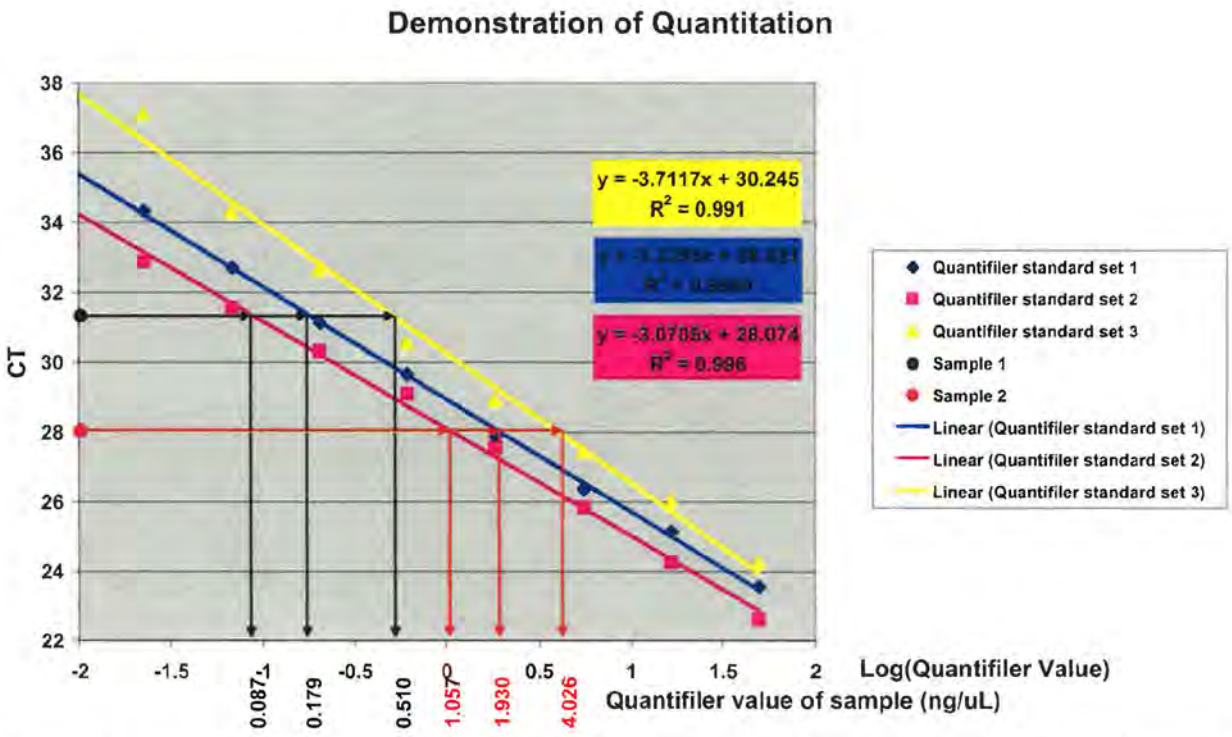

Figure 2: Demonstration of Quantitation. A single CT value can have a number of different Quantifiler values depending on where the Quantifiler standard lies.

In a similar way that a CT can give multiple Quantifiler values given the slope and Y-intercept conditions, the reverse is also true. A single Quantifiler value across different slope and Y-intercept conditions will theoretically give a variety of different CT values, but should also consistently give the same value under the same conditions when the system is quantifying accurately. This is demonstrated in tables 5 and 6.

Table 5: Ideal CT values for 0.1ng/µL under different slope and y-intercept values.

CT Values										
Quant value=0.1ng/uL	Slope									
Y-Intercept	-3.6	-3.5	-3.4	-3.3	-3.2	-3.1	-3.0	-2.9	-2.8	-2.7
30.0	33.6	33.5	33.4	33.3	33.2	33.1	33.0	32.9	32.8	32.7
29.9	33.5	33.4	33.3	33.2	33.1	33.0	32.9	32.8	32.7	32.6
29.8	33.4	33.3	33.2	33.1	33.0	32.9	32.8	32.7	32.6	32.5
29.7	33.3	33.2	33.1	33.0	32.9	32.8	32.7	32.6	32.5	32.4
29.6	33.2	33.1	33.0	32.9	32.8	32.7	32.6	32.5	32.4	32.3
29.5	33.1	33.0	32.9	32.8	32.7	32.6	32.5	32.4	32.3	32.2
29.4	33.0	32.9	32.8	32.7	32.6	32.5	32.4	32.3	32.2	32.1
29.3	32.9	32.8	32.7	32.6	32.5	32.4	32.3	32.2	32.1	32.0
29.2	32.8	32.7	32.6	32.5	32.4	32.3	32.2	32.1	32.0	31.9
29.1	32.7	32.6	32.5	32.4	32.3	32.2	32.1	32.0	31.9	31.8
29.0	32.6	32.5	32.4	32.3	32.2	32.1	32.0	31.9	31.8	31.7
28.9	32.5	32.4	32.3	32.2	32.1	32.0	31.9	31.8	31.7	31.6
28.8	32.4	32.3	32.2	32.1	32.0	31.9	31.8	31.7	31.6	31.5
28.7	32.3	32.2	32.1	32.0	31.9	31.8	31.7	31.6	31.5	31.4
28.6	32.2	32.1	32.0	31.9	31.8	31.7	31.6	31.5	31.4	31.3
28.5	32.1	32.0	31.9	31.8	31.7	31.6	31.5	31.4	31.3	31.2
28.4	32.0	31.9	31.8	31.7	31.6	31.5	31.4	31.3	31.2	31.1
28.3	31.9	31.8	31.7	31.6	31.5	31.4	31.3	31.2	31.1	31.0
28.2	31.8	31.7	31.6	31.5	31.4	31.3	31.2	31.1	31.0	30.9
28.1	31.7	31.6	31.5	31.4	31.3	31.2	31.1	31.0	30.9	30.8
28.0	31.6	31.5	31.4	31.3	31.2	31.1	31.0	30.9	30.8	30.7

Table 6: Ideal CT values for 1.0ng/µL under different slope and y-intercept values.

CT Values										
Quant value=1.0ng/uL	Slope									
Y-Intercept	-3.6	-3.5	-3.4	-3.3	-3.2	-3.1	-3.0	-2.9	-2.8	-2.7
30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
29.9	29.9	29.9	29.9	29.9	29.9	29.9	29.9	29.9	29.9	29.9
29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8
29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7
29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6
29.5	29.5	29.5	29.5	29.5	29.5	29.5	29.5	29.5	29.5	29.5
29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4
29.3	29.3	29.3	29.3	29.3	29.3	29.3	29.3	29.3	29.3	29.3
29.2	29.2	29.2	29.2	29.2	29.2	29.2	29.2	29.2	29.2	29.2
29.1	29.1	29.1	29.1	29.1	29.1	29.1	29.1	29.1	29.1	29.1
29.0	29.0	29.0	29.0	29.0	29.0	29.0	29.0	29.0	29.0	29.0
28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9
28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8
28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7
28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
28.5	28.5	28.5	28.5	28.5	28.5	28.5	28.5	28.5	28.5	28.5
28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4
28.3	28.3	28.3	28.3	28.3	28.3	28.3	28.3	28.3	28.3	28.3
28.2	28.2	28.2	28.2	28.2	28.2	28.2	28.2	28.2	28.2	28.2
28.1	28.1	28.1	28.1	28.1	28.1	28.1	28.1	28.1	28.1	28.1
28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0

The slope of a standard curve is an indication of PCR reaction efficiency. At a slope of –3.322 the PCR has an efficiency of 100% (Applied Biosystems 2003). A lower slope (more negative number e.g. –3.55) is indicative of reduced efficiency while a higher slope (more positive number e.g. –2.9) is indicative of efficiency appearing greater than 100% (QIAGEN 2004:13). Due to experimental limitations most standard slopes do not reach 100% efficiency (QIAGEN 2004:13). Values greater than 100% can occur when samples are measured in the non-linear phase of the logarithmic graph or in the presence of inhibitors (QIAGEN 2004:13). To ensure a slope is valid, QIAGEN (2004:13) set the ideal range for the value between –3.3 and –3.8. However, ABI state a typical slope should be between –2.9 and –3.3 with an average of –3.1 (Applied Biosystems 2003:5-5). According to Pfaffl (2004:11), a typical slope will only vary by 2-3% on repeated runs of the same standard, while the Y-intercept will vary by about 10%. As a result the Y-intercept is harder to replicate (Pfaffl 2004:11). At maximum, the same standard producing an average slope of –3.1 would vary from –3.007 to –3.193 on different runs by applying a 3% variance. A detection of a two-fold difference over a range of target concentrations was observed as a result of standard curve correlation with samples of unknown quantity (Pfaffl 2004:11, Rasmussen 2001).

5 METHOD VALIDATION

The two types of method validation were as follows

a. Developmental Validation
This was an independent external validation presented in Applied Biosystems (2003) but later published by Green *et. al.* 2005 in a peer-reviewed journal. The 2005 publication concluded that the Quantifiler system is accurate, precise and reproducible.

b. Internal Validation
The original internal validation of Quantifiler in June, 2004, concluded that 1ng of template was enough for Profiler and COfiler amplifications. In the third quarter of 2004 there was a high rate of reworks and this was investigated. After a detailed review in January, 2005 of results from the use of controls and alternative standards, the amount of DNA template used for amplifications was increased from 1 Quantifiler nanogram to 2 Quantifiler nanograms which was still within the ABI recommended range of 1 to 2.5 nanograms for Profiler and COfiler. A positive control was now introduced in each Quantifiler run for quality assurance purposes. After the discovery that Quantifiler inaccuracy is largely due to differences in the concentration of standards, two approaches were taken. The first approach was the introduction of testing and validating each Quantifiler standard as it was made up for use. That is the subject of this document. The second approach focused on the validation of standards other than the supplied Quantifiler standards. The second approach is the subject of the Extended Internal Prospective Validation of the ABI Prism ®7000/Quantifiler System (Forensic Biology) report (Hlinka *et al.* 2006).

5.1 RECOMMENDED RANGES FOR USING THE QUANTIFILER STANDARD

The expected ranges for the Quantifiler Standard were determined by analyzing the results from 196 Quantifiler runs ranging from QF# 83 (5.10.2004) to QF#264 (14.4.2005) and QF#365 (26.7.05) to QF#386 (22.8.2005). This is the data that was used to setup the original criteria for the recommended operational ranges of the Quantifiler Standard. The results are biased in that the same standard was typically used for runs for up to two weeks. The number of standards made up from different batches and lots also varied.

Table 7: Typical Quantifiler Standard distribution. Mean slope, y-intercept and r2 values of from 196 Quantifiler runs are provided as a guide to what should be expected.

	Y-intercept	Slope	R2
Mean	29.006	-3.197080934	0.995578199
Standard deviation	0.227	0.112843373	0.002938243
Minimum value	28.582		
Maximum value	29.825		
CT difference (Max.-min. value)	1.244		
Minimum value at 1 Standard deviation	28.779		
Maximum value at 1 Standard deviation	29.233		
CT difference at 1 Standard deviation	0.454		
Minimum value at 2 Standard deviations	28.552		
Maximum value at 2 Standard deviations	29.460		
CT difference at 2 Standard deviations	0.907		

Table 8: Acceptable ranges for the Quantifiler Standard. When a Quantifiler Standard is made and used the following guidelines should be utilised. The y-intercept should be in the one standard deviation when a standard is made-up and tested for suitability. Under normal run conditions a Y-intercept of two standard deviations is acceptable for general use.

	Minimum value	Maximum value	Acceptance Purpose
Slope	-3.3	-2.9	Runs and standards
Y-Intercept (1 Standard Deviation)	28.77	29.23	Standards
Y-Intercept (2 Standard Deviations)	28.55	29.46	Runs
R2	0.98	1	Runs and standards

Another set of data to work out an expected range was based on Testquant data from the 18th of May, 2005 to the 20th of May, 2006. This is where a single standard that was made up was only run once for the data compilation. However, it is still biased by some lot numbers and batches being present in number more than others.

Table 9: Typical Quantifiler Standard distribution derived from Testquant data. Mean slope, y-intercept and r2 values from 139 standards are provided as a guide to what should be expected.

	Y-intercept	Slope	R_2
Mean	28.960595	-3.067032	0.995101
Standard Deviation	0.312775	0.128373	0.003404
Population (n)	139		
Minimum value	28.176086		
Maximum value	29.671104		
Y-intercept CT difference	1.495018		
Minimum value at 1 Standard deviation	28.647821		
Maximum value at 1 Standard deviation	29.273370		
Y-intercept CT difference	0.625549		
Minimum value at 2 Standard deviation	28.335046		
Maximum value at 2 Standard deviation	29.586145		
Y-intercept CT difference	1.251099		

Table 10. Acceptable ranges for the Quantifiler Standard derived from Testquant data. When a Quantifiler Standard is made and used the following guidelines could be utilised. The y-intercept should be in the one standard deviation when a standard is made-up and tested for suitability. Under normal run conditions a Y-intercept of two standard deviations is acceptable for general use.

	Minimum value	Maximum value	Acceptance/Purpose
Slope	-3.3	-2.9	Runs and standards
Y-intercept (1 Standard Deviation)	28.64	29.27	Standards
Y-intercept (2 Standard Deviation)	28.33	29.59	Runs
R2	0.98	1	Runs and standards

According to ABI quality control procedures (Applied Biosystems 2006), the maximum allowable CT difference between two qualifying lots of DNA standard is 0.64. However, from the historical data from Forensic biology (QHSS), it is clear that this is exceeded and that at a 95% confidence interval (2 standard deviations) a difference of 1.25 CTs was observed. This means that there is approximately a maximum 2.38 theoretical concentration difference possible by using different standards at a 95% confidence interval. By using the maximum and minimum values for the Y-intercept, this figure rises to 2.81. With the tighter criteria being applied a 0.907 theoretical difference at a 95% confidence interval (2 standard deviations) is observed. This means the maximum theoretical concentration difference by using different standards is

approximately 1.866065983. These figures do not take into account slope differences or sample pipetting differences and sample PCR result differences.

5.2 ASSESSMENT OF ACCURACY/TRUENESS, BIAS, AND PRECISION (REPEATABILITY AND REPRODUCIBILITY) OF CONTROLS

5.2.1 PROMEGA MALE CONTROL (DILUTION SERIES)

5.2.1.1 DEFINITION AND COMPLIANCE GUIDELINES FOR ACCURACY/TRUENESS

Accuracy is the closeness of agreement between the test result and the "true" or accepted value. Accuracy is determined by replicate analysis of a reference material of known composition (QIS 10663R2). Validation of accuracy complies with DAB (2000:8.1.3.1.2), SWGDAM (2004:3.2), and NATA (2004:2.1, 2.2, 2.4 and 2.4.2) guidelines.

5.2.1.2 DEFINITION AND COMPLIANCE GUIDELINES FOR PRECISION (REPEATABILITY AND REPRODUCIBILITY)

Precision is the closeness of agreement between independent replicate test results. There are two measures of precision- repeatability and reproducibility. High precision does not necessarily reflect high accuracy (QIS 10663R2). It is a requirement of QIS (23401R0) to assess precision of a system.

Repeatability is a measure of the maximum acceptable difference between two test results obtained at the same time by the same analyst under identical conditions on the same material. Normally, repeatability is calculated at the 95% confidence level (and two correctly obtained results will not differ from one another by more than the repeatability value in more than 1 in 20 cases) (QIS 10663R2). Measuring repeatability follows DAB (2000:8.1.3.1.1), SWGDAM (2004:3.2), and NATA (2004:2.4.1) guidelines.

Reproducibility is a measure of the maximum acceptable difference between two test results obtained on the same material by different analysts at different times. Normally, reproducibility is calculated at the 95% confidence level. This value of reproducibility is the one generally used to estimate the limits of uncertainty of a result (QIS 10663R2). In-house reproducibility is required by QIS document 23401R0, and according to DAB (2000:8.1.3.1.2), SWGDAM (2004:3.2), and NATA (2004:2.1, 2.2, and 2.4) guidelines.

5.2.1.3 METHOD

To assess the accuracy, bias, repeatability and limited in-house reproducibility of the Quantifiler system, dilutions of a known control were made, tested, and the results compared to the true or expected values. Promega Human Genomic DNA Control (Male) G147A, otherwise referred to here as the Promega Male control, was used as a Certified Reference Material (CRM) and was diluted in house to 0.05ng/µL, 0.1ng/µL, 0.25ng/µL, 0.5ng/µL, 1ng/µL, 2ng/µL, and 10ng/µL. Due to previous results showing uneven heating on the ABI 7000 thermal block, positions A11 and A12 were omitted and should not be used in future quants (Quantifiler runs) because they result in inconsistent results.

Lot#19402901 of the Promega Male control was used. The DNA was supplied in a concentration of 150ng/µL. Using the 1000µL Eppendorf Research Pipettor (Serial Number 3325731) and TE^{-4} (batch VH2.2.05), the serial dilution in table 10 was made on the 7th of April, 2005.

Table 11. Dilution of Promega Male control.

Dilution	Final concentration (ng/µL)	Volume of previous vial (ng/µL)	Volume of TE (ng/µL)	Total (ng/µL)	Remainder (after taking out volume for next dilution) (ng/µL)
1 in 5	30	213	852	1065	801
1 in 5	6	264	1056 (2x528)	1320	800
1 in 3	2	520	1040 (2x520)	1560	800
1 in 2	1	760	760	1520	800
1 in 2	0.5	720	720	1440	800
1 in 2	0.25	640	640	1280	800
2 in 5	0.1	480	720	1200	800
1 in 2	0.05	400	400	800	800

112 samples of 0.05ng/µL were run on three plates (18 samples on Testquant_140705RW, 18 samples on Testquant_130705, 76 samples on Testquant0_05_160705).

112 samples of 0.1ng/µL were run on three plates (18 samples on Testquant_140705RW, 18 samples on Testquant_130705, 76 samples on Testquant_270705).

36 samples of 0.25ng/µL were run on two plates (18 samples on Testquant_140705RW, 18 samples on Testquant_130705).

36 samples of 0.5ng/µL were run on two plates (18 samples on Testquant_140705RW, 18 samples on Testquant_130705).

16 samples of 1ng/µL were run on four plates (4 samples on Testquant_140705RW, 4 samples on Testquant_130705, 4 samples on Testquant_160705, 4 samples on Testquant_150705).

72 samples of 2ng/µL were run on two plates (36 samples on Testquant_160705, 36 samples on Testquant_150705).

148 samples of 10ng/µL were run on three plates (36 samples on Testquant_160705, 36 samples on Testquant_150705, 76 samples on Testquant_10_160705 with A11 and A12 omitted).

The accuracy of the Quantifiler system was assessed using a typical student's T-test (see QIS 10662R2). This is where the distribution of experimental values are compared against the expected or 'true' value. Normally, a 95% confidence level is used where there is a 1 in 20 chance of the critical value being exceeded if there is no bias. The 2-sided T-test was applied for a set of same concentrations run on the same plate by the same analyst. The 2-sided T-test was also applied in this way over several plates to assess in-house reproducibility by the same analyst. Combined results of all the plates for the same sets of concentrations were analysed with the 2-sided T-test to measure overall accuracy. Furthermore, precision was measured using the 95% Confidence Interval method (Applied Biosystems 2003). This is where the mean standard deviation for one same concentration set is multiplied by 2, the answer is divided by the mean Quantifiler quantity of the identical concentration set, and the final answer converted to a percentage figure. The distribution of the same concentration sets over various plates was graphed to demonstrate these to the reader.

	1	2	3	4	5	6	7	8	9	10	11	12
A	**STD#1 50 ng/µL**	**STD#1 50 ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.25ng/µL	Promega 0.25ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL	Reagent blank	Reagent blank
B	**STD#2 16.7ng/µL**	**STD#2 16.7ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.25ng/µL	Promega 0.25ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL	Promega 1.0ng/µL	Promega 1.0ng/µL
C	**STD#3 5.56ng/µL**	**STD#3 5.56ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.25ng/µL	Promega 0.25ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL	Promega 1.0ng/µL	Promega 1.0ng/µL
D	**STD#4 1.85ng/µL**	**STD#4 1.85ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.25ng/µL	Promega 0.25ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL
E	**STD#5 0.62ng/µL**	**STD#5 0.62ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.25ng/µL	Promega 0.25ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL
F	**STD#6 0.21ng/µL**	**STD#6 0.21ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.25ng/µL	Promega 0.25ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL	Promega 0.25ng/µL	Promega 0.25ng/µL
G	**STD#7 0.068ng/µL**	**STD#7 0.068ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.25ng/µL	Promega 0.25ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL
H	**STD#8 0.023ng/µL**	**STD#8 0.023ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.25ng/µL	Promega 0.25ng/µL	Promega 0.5ng/µL	Promega 0.5ng/µL	NegCtl	NegCtl

Figure 3. Format of Testquant_140705RW and Testquant_130705.

	1	2	3	4	5	6	7	8	9	10	11	12
A	**STD#1 50 ng/µL**	**STD#1 50 ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL
B	**STD#2 16.7ng/µL**	**STD#2 16.7ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL
C	**STD#3 5.56ng/µL**	**STD#3 5.56ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL
D	**STD#4 1.85ng/µL**	**STD#4 1.85ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL
E	**STD#5 0.62ng/µL**	**STD#5 0.62ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL
F	**STD#6 0.21ng/µL**	**STD#6 0.21ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL
G	**STD#7 0.068ng/µL**	**STD#7 0.068ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL
H	**STD#8 0.023ng/µL**	**STD#8 0.023ng/µL**	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	Promega 0.05ng/µL	NegCtl	NegCtl

Figure 4. Format of Testquant0_05_160705. Results from A11 and A12 were omitted for analysis.

	1	2	3	4	5	6	7	8	9	10	11	12
A	**STD#1 50 ng/µL**	**STD#1 50 ng/µL**	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL
B	**STD#2 16.7ng/µL**	**STD#2 16.7ng/µL**	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL
C	**STD#3 5.56ng/µL**	**STD#3 5.56ng/µL**	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL
D	**STD#4 1.85ng/µL**	**STD#4 1.85ng/µL**	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL
E	**STD#5 0.62ng/µL**	**STD#5 0.62ng/µL**	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL
F	**STD#6 0.21ng/µL**	**STD#6 0.21ng/µL**	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL
G	**STD#7 0.068ng/µL**	**STD#7 0.068ng/µL**	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL
H	**STD#8 0.023ng/µL**	**STD#8 0.023ng/µL**	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	Promega 0.1ng/µL	NegCtl	NegCtl

Figure 5. Format of Testquant_270705.

	1	2	3	4	5	6	7	8	9	10	11	12
A	**STD#1 50 ng/µL**	**STD#1 50 ng/µL**	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Reagent blank	Reagent blank
B	**STD#2 16.7ng/µL**	**STD#2 16.7ng/µL**	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 1.0ng/µL	Promega 1.0ng/µL
C	**STD#3 5.56ng/µL**	**STD#3 5.56ng/µL**	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 1.0ng/µL	Promega 1.0ng/µL
D	**STD#4 1.85ng/µL**	**STD#4 1.85ng/µL**	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL
E	**STD#5 0.62ng/µL**	**STD#5 0.62ng/µL**	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL
F	**STD#6 0.21ng/µL**	**STD#6 0.21ng/µL**	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL
G	**STD#7 0.068ng/µL**	**STD#7 0.068ng/µL**	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL
H	**STD#8 0.023ng/µL**	**STD#8 0.023ng/µL**	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 2.0ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	NegCtl	NegCtl

Figure 6. Format of Testquant_160705 and Testquant_150705.

	1	2	3	4	5	6	7	8	9	10	11	12
A	**STD#1 50 ng/µL**	**STD#1 50 ng/µL**	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL
B	**STD#2 16.7ng/µL**	**STD#2 16.7ng/µL**	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL
C	**STD#3 5.56ng/µL**	**STD#3 5.56ng/µL**	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL
D	**STD#4 1.85ng/µL**	**STD#4 1.85ng/µL**	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL
E	**STD#5 0.62ng/µL**	**STD#5 0.62ng/µL**	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL
F	**STD#6 0.21ng/µL**	**STD#6 0.21ng/µL**	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL
G	**STD#7 0.068ng/µL**	**STD#7 0.068ng/µL**	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL
H	**STD#8 0.023ng/µL**	**STD#8 0.023ng/µL**	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	Promega 10ng/µL	NegCtl	NegCtl

Figure 7. Format of Testquant_10_160705. Results from A11 and A12 were omitted for analysis.

5.2.1.4 RESULTS

The CT and Quantifiler value data was analysed separately in section 5.2.1.4.1 and 5.2.1.4.2 respectively. Run data relevant to the main data is shown in table 12.

Table 12. Y-intercept, slope and r2 data for the plates run.

Relevant data

Plate ID	Yintercept	Slope	R2
Testquant_140705RW	29.304394	-3.124207	0.991935
Testquant_130705	29.110334	-2.942568	0.993637
Testquant0_05_160705	29.279089	-3.184713	0.995971
Testquant_270705	29.154394	-3.105385	0.998756
Testquant_160705	29.152035	-2.997561	0.997300
Testquant_150705	29.086424	-2.969740	0.993439

5.2.1.4.1 CT RESULTS AND ANALYSIS RESULTS

In figures 8 to 14, we present a visual comparison of the distribution of the CT values at various concentrations and across different plates. It is possible to see that with the larger sample numbers, the distributions are relatively similar and therefore were generally reproducible under the standard parameters utilised. The results and analysis of the data are summarized in table 13. At the 95% confidence interval the largest CV was 1.97%. Therefore, the distributions are very tight. This demonstrates that the system has a reasonably high level of precision for each run.

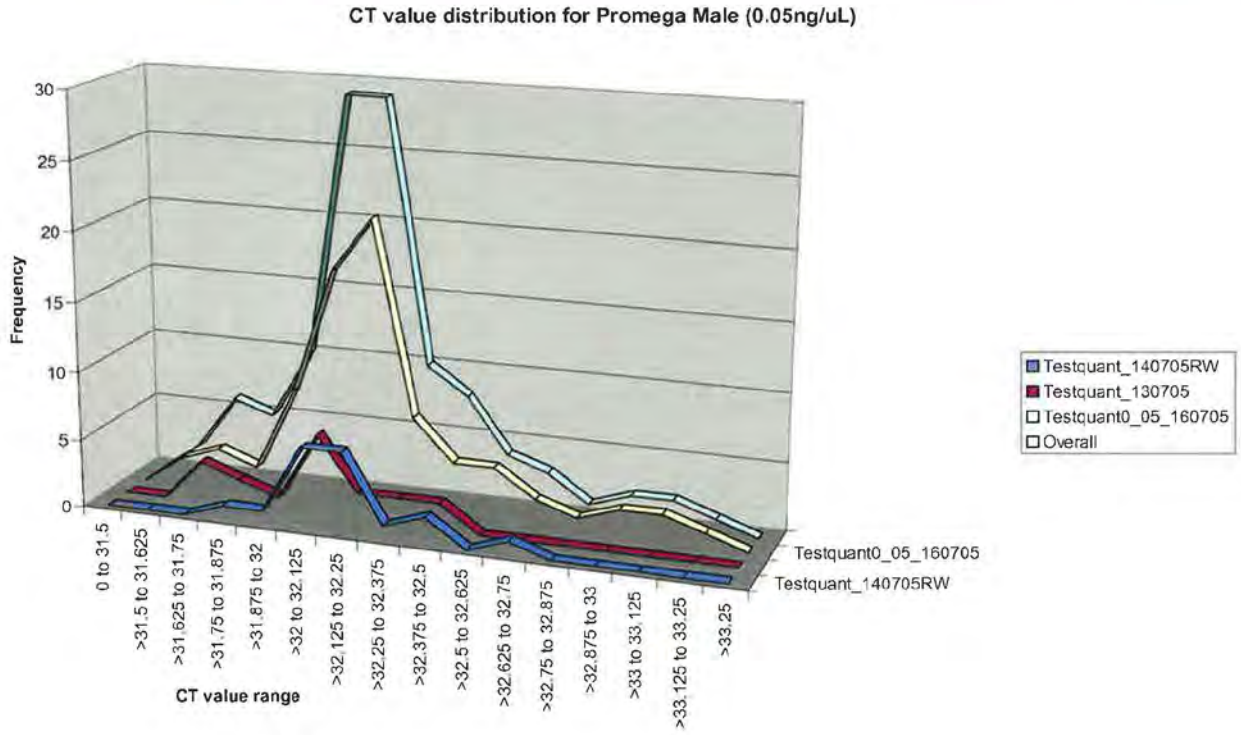

Figure 8. CT value distribution for Promega Male control (0.05ng/µL).

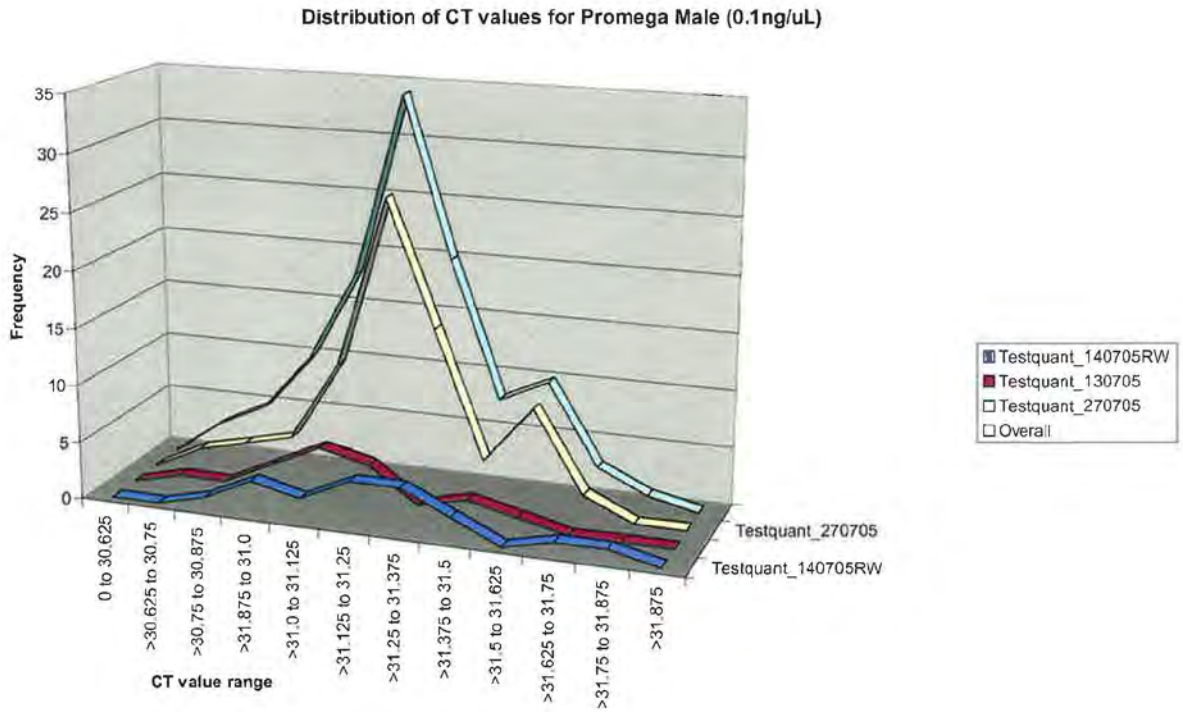

Figure 9. Distribution of CT values for Promega Male control (0.1ng/µL).

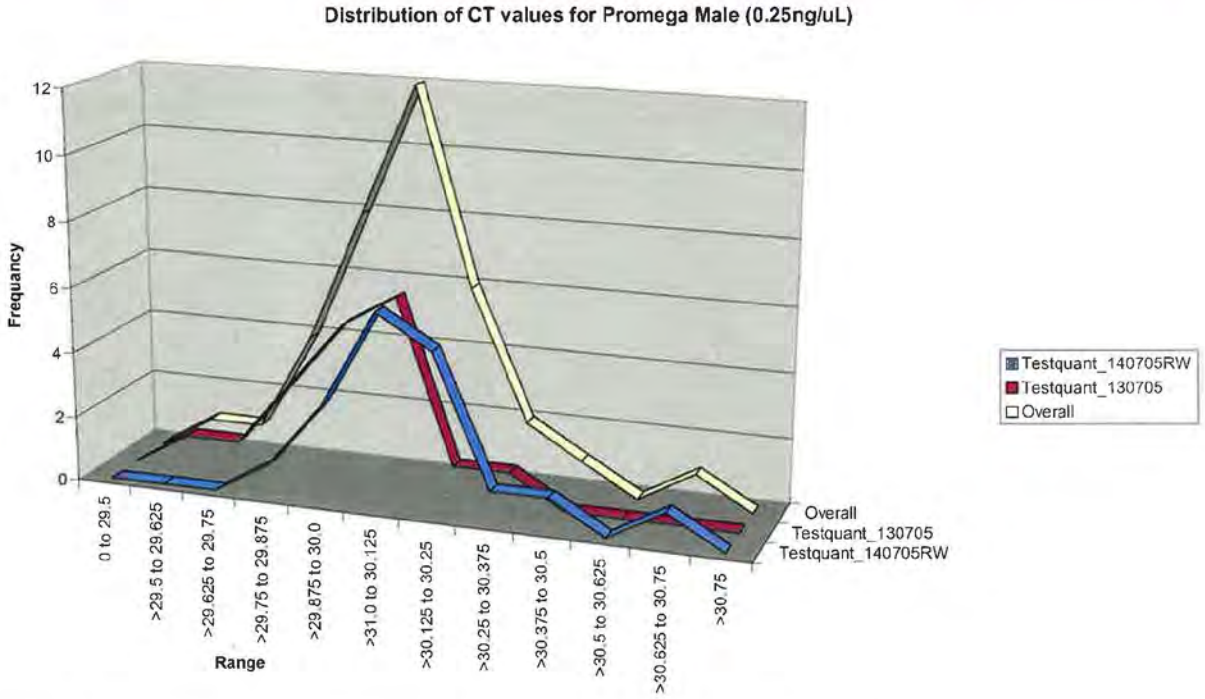

Figure 10. Distribution of CT values for Promega Male control (0.25ng/µL).

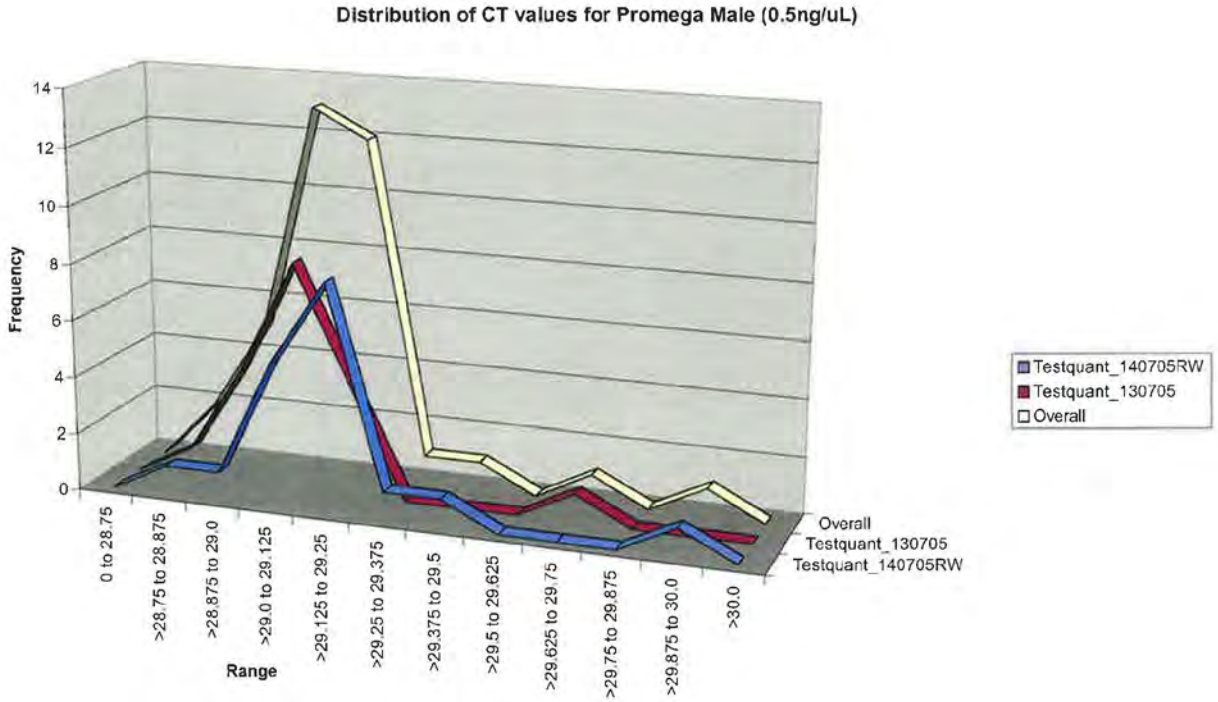

Figure 11. Distribution of CT values for Promega Male control (0.5ng/µL).

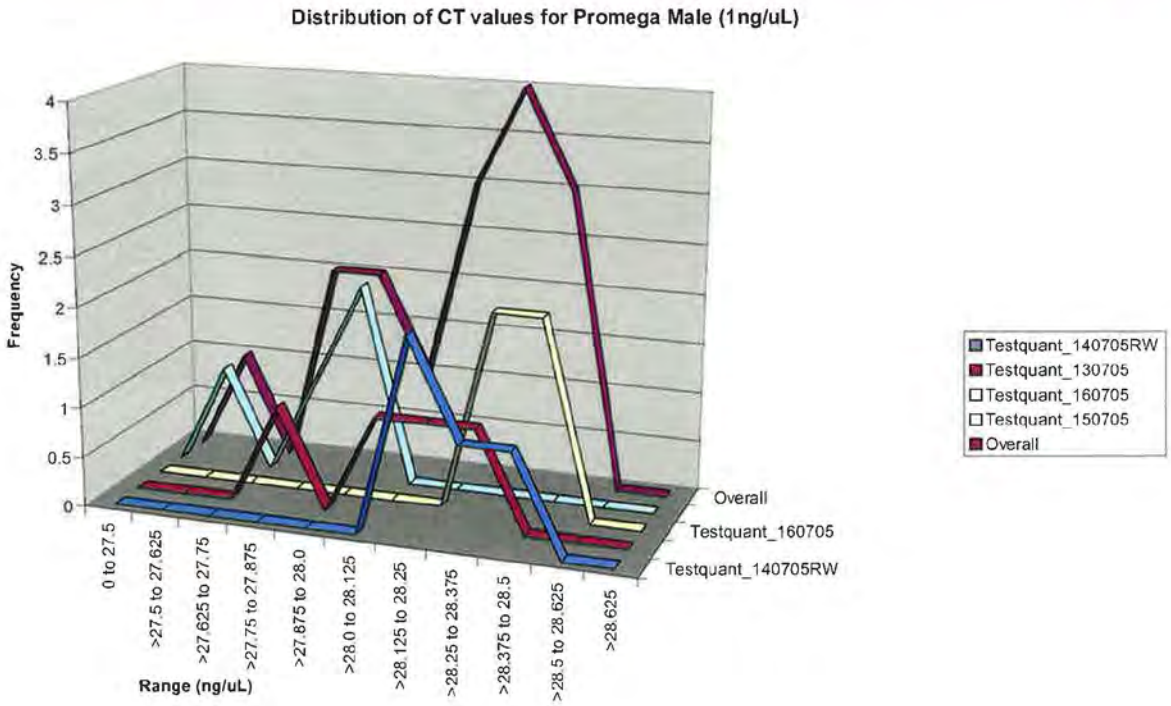

Figure 12. Distribution of CT values for Promega Male control (1.0ng/µL).

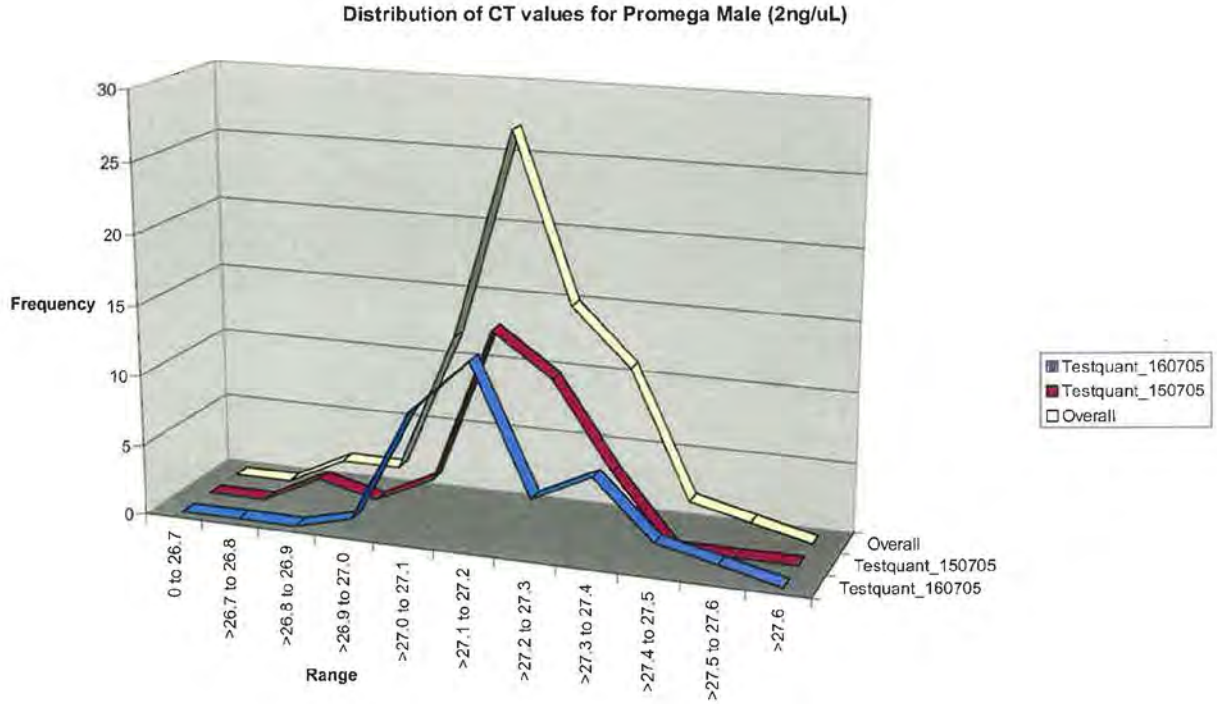

Figure 13. Distribution of CT values for Promega Male control (2ng/µL).

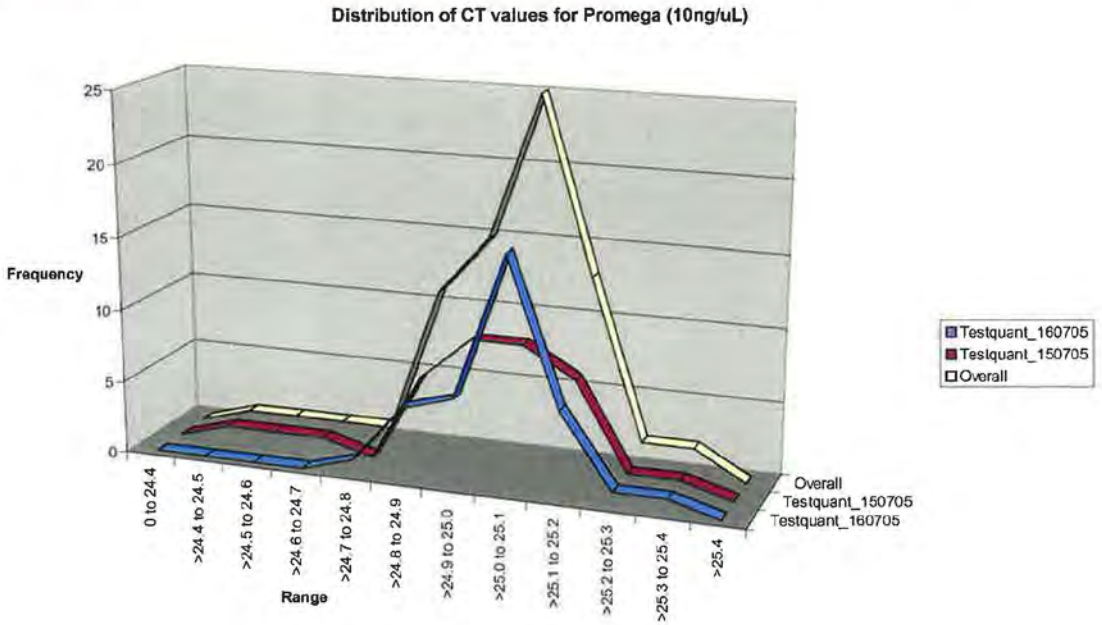

Figure 14. Distribution of CT values for Promega Male control (10ng/µL).

Table 13. CT results from various concentrations of Promega Male control.

		Normal (No calibration)				
True/ Expected Concentration ng/uL						
0.05		Overall	Testquant_140705RW	Testquant_130705	Testquant0_05_160705	
	Mean CT	32.1800893	32.165	32.0511111	32.21421053	
	1 StdDev CT value	0.29384833	0.21018899	0.22954915	0.317188748	
	CV	0.91%	0.65%	0.72%	0.98%	
	95% confidence interval	1.83%	1.31%	1.43%	1.97%	
0.1		Overall	Testquant_140705RW	Testquant_130705	Testquant_270705	
	Mean CT	31.2097321	31.2427778	31.125	31.22197368	
	1 StdDev CT value	0.2202679	0.26374688	0.21041276	0.209443833	
	CV	0.71%	0.84%	0.68%	0.67%	
	95% confidence interval	1.41%	1.69%	1.35%	1.34%	
0.25		Overall	Testquant_140705RW	Testquant_130705		
	Mean CT	30.0547222	30.145	29.9644444		
	1 StdDev CT value	0.21203081	0.21836963	0.16617575		
	CV	0.71%	0.72%	0.55%		
	95% confidence interval	1.41%	1.45%	1.11%		
0.5		Overall	Testquant_140705RW	Testquant_130705		
	Mean CT	29.1358333	29.1838889	29.0877778		
	1 StdDev CT value	0.2167866	0.23250905	0.19443903		
	CV	0.74%	0.80%	0.67%		
	95% confidence interval	1.49%	1.59%	1.34%		
1		Overall	Testquant_140705RW	Testquant_130705	Testquant_160705	Testquant_150705
	Mean CT	28.148125	28.265	28.1	28.3975	27.83
	1 StdDev CT value	0.25527028	0.13478378	0.178699	0.103400516	0.160831174
	CV	0.91%	0.48%	0.64%	0.36%	0.58%
	95% confidence interval	1.81%	0.95%	1.27%	0.73%	1.16%
2		Overall	Testquant_160705	Testquant_150705		
	Mean CT	27.1901389	27.1961111	27.1841667		
	1 StdDev CT value	0.13237264	0.14057591	0.12534239		
	CV	0.49%	0.52%	0.46%		
	95% confidence interval	0.97%	1.03%	0.92%		
10		Overall	Testquant_160705	Testquant_150705		
	Mean CT	25.0030556	25.0280556	24.9780556		
	Mean CT	0.15383033	0.11119659	0.18534631		
	CV	0.62%	0.44%	0.74%		
	95% confidence interval	1.23%	0.89%	1.48%		

5.2.1.4.2 QUANTIFILER VALUE DATA AND ANALYSIS RESULTS

5.2.1.4.2.1 ACCURACY AND QUANTIFILER VALUE DISTRIBUTION GRAPHS

In figures 15 to 21, we present a visual comparison of the distribution of the Quantifiler concentration values at various concentrations and across different plates. It is possible to see that the distributions are relatively broad and not that accurate, with mean Quantifiler values approximately twice the expected concentrations. In figures 22 to 24 this inaccuracy is presented in terms of the means and standard deviations. A correction factor applied to the concentration data (figure 24) shows that the mean correction factor is approximately between 2 and 2.5. Stochastic effects appear greatest towards the lower concentrations (Standards 7 and 8) as shown in figure 24. The increase with 1ng/µL (figure 24) is most likely a result of a low sample number being run on more plates than the other concentrations.

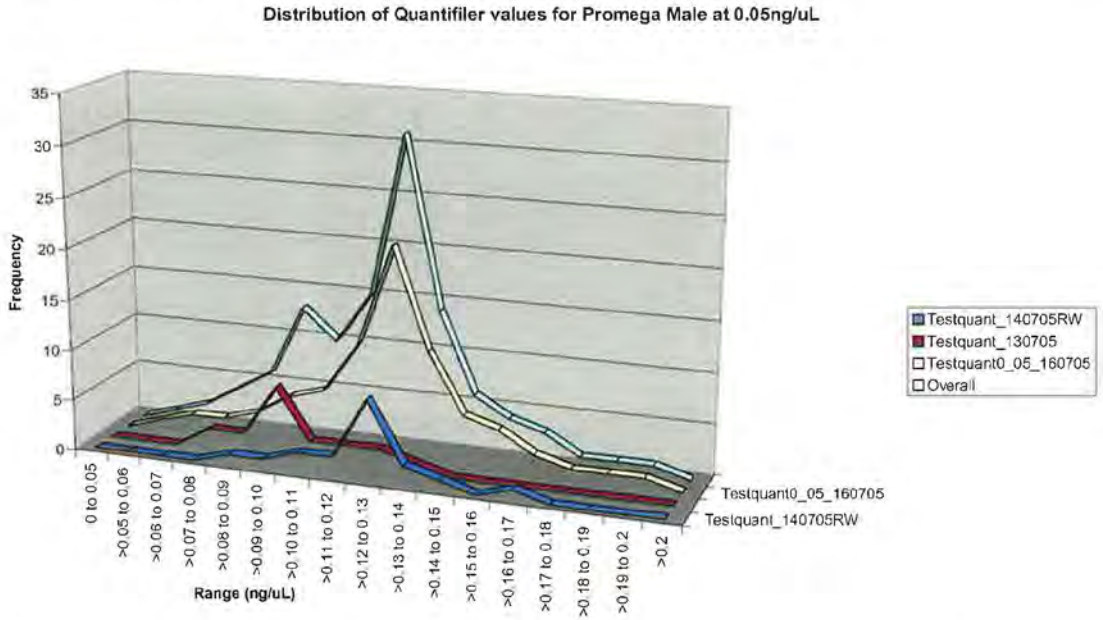

Figure 15. Distribution of Quantifiler values for Promega Male control at (0.05ng/µL).

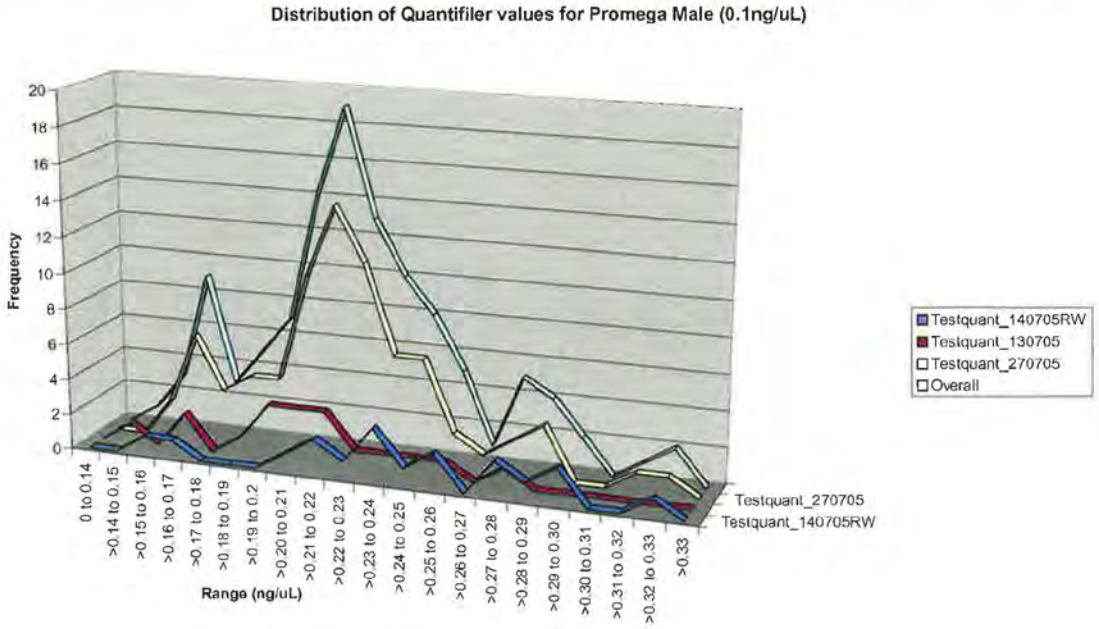

Figure 16. Distribution of Quantifiler values for Promega Male control (0.1ng/µL).

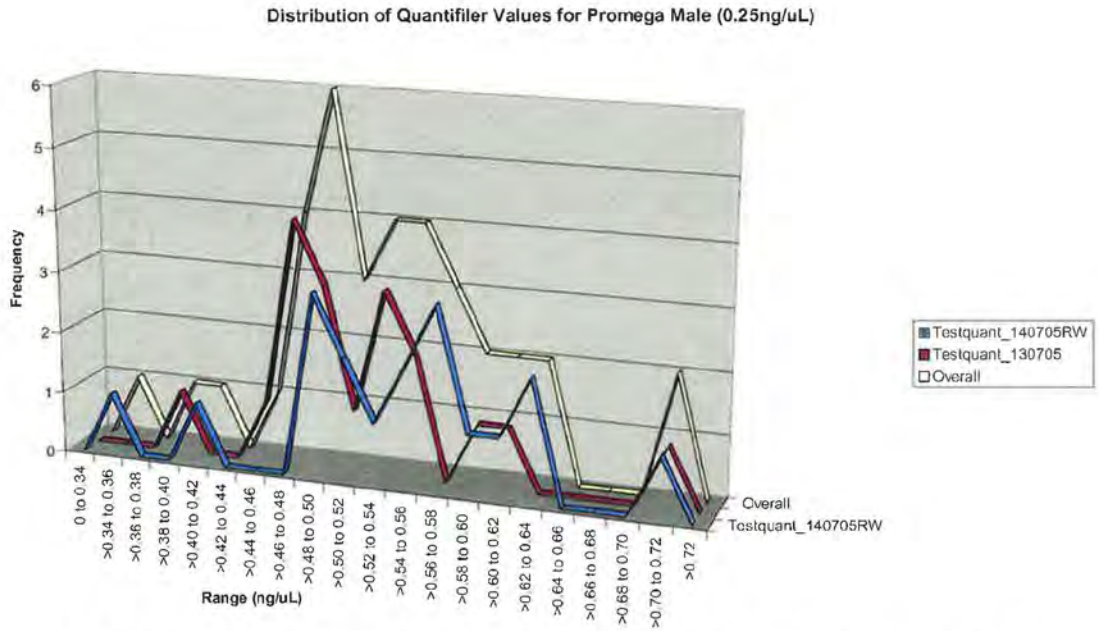

Figure 17. Distribution of Quantifiler values for Promega Male control (0.25ng/µL).

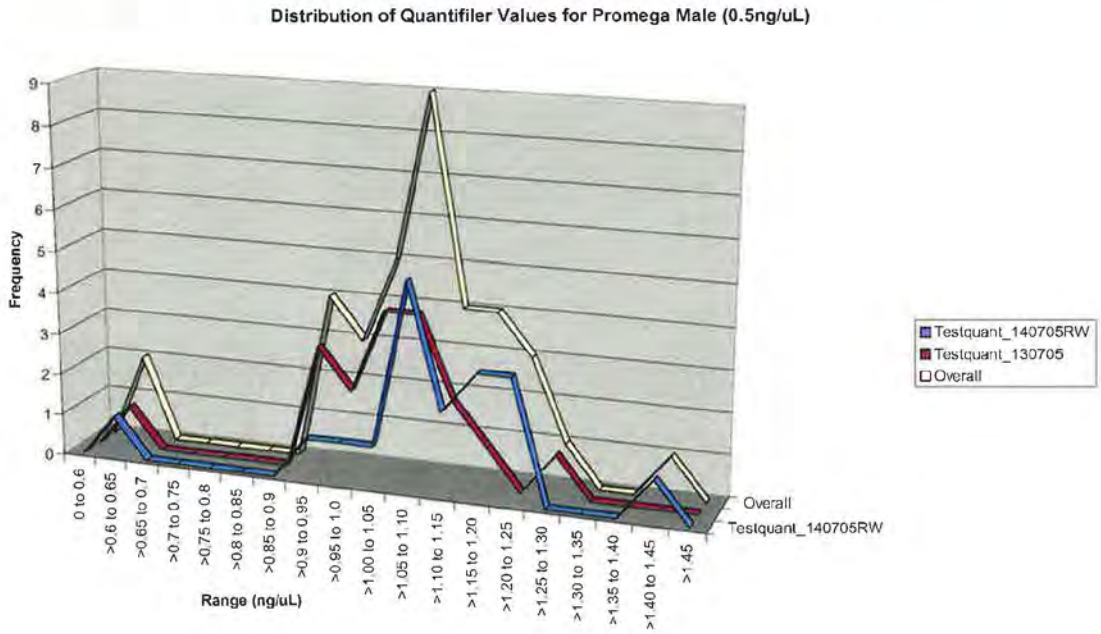

Figure 18. Distribution of Quantifiler values for Promega Male control (0.5ng/µL).

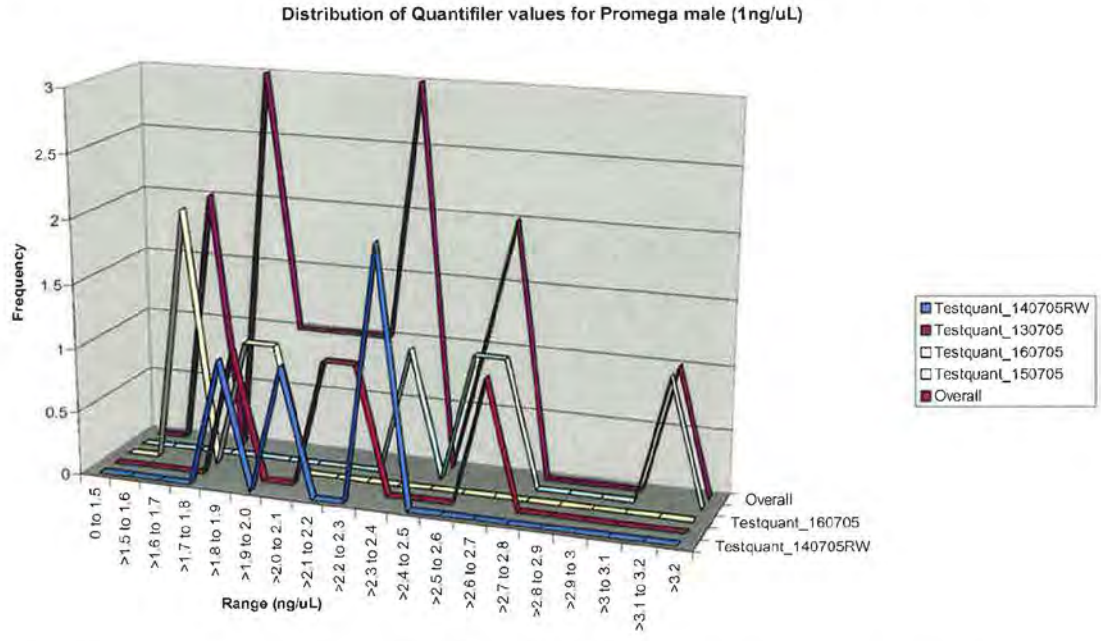

Figure 19. Distribution of Quantifiler values for Promega Male control (1ng/µL).

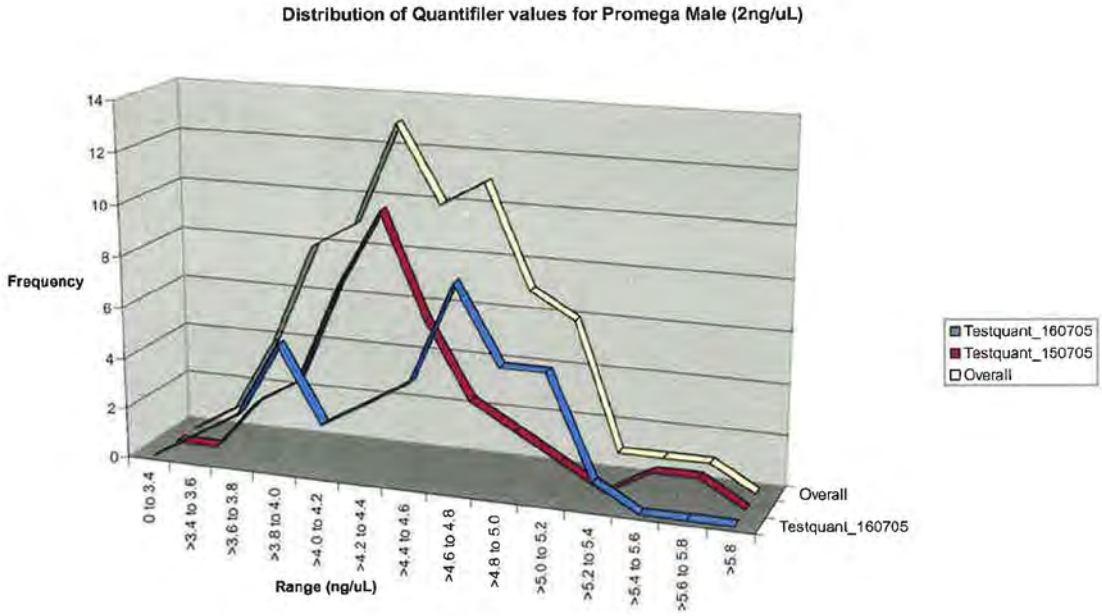

Figure 20. Distribution of Quantifiler values for Promega Male control (2ng/µL).

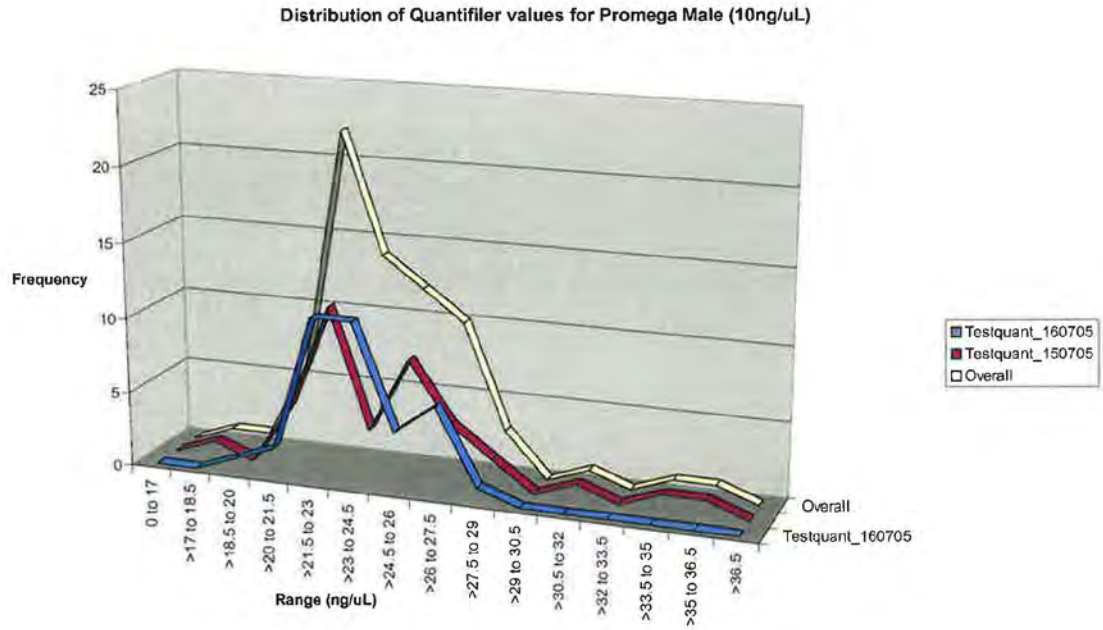

Figure 21. Distribution of Quantifiler values for Promega Male control (10ng/µL).

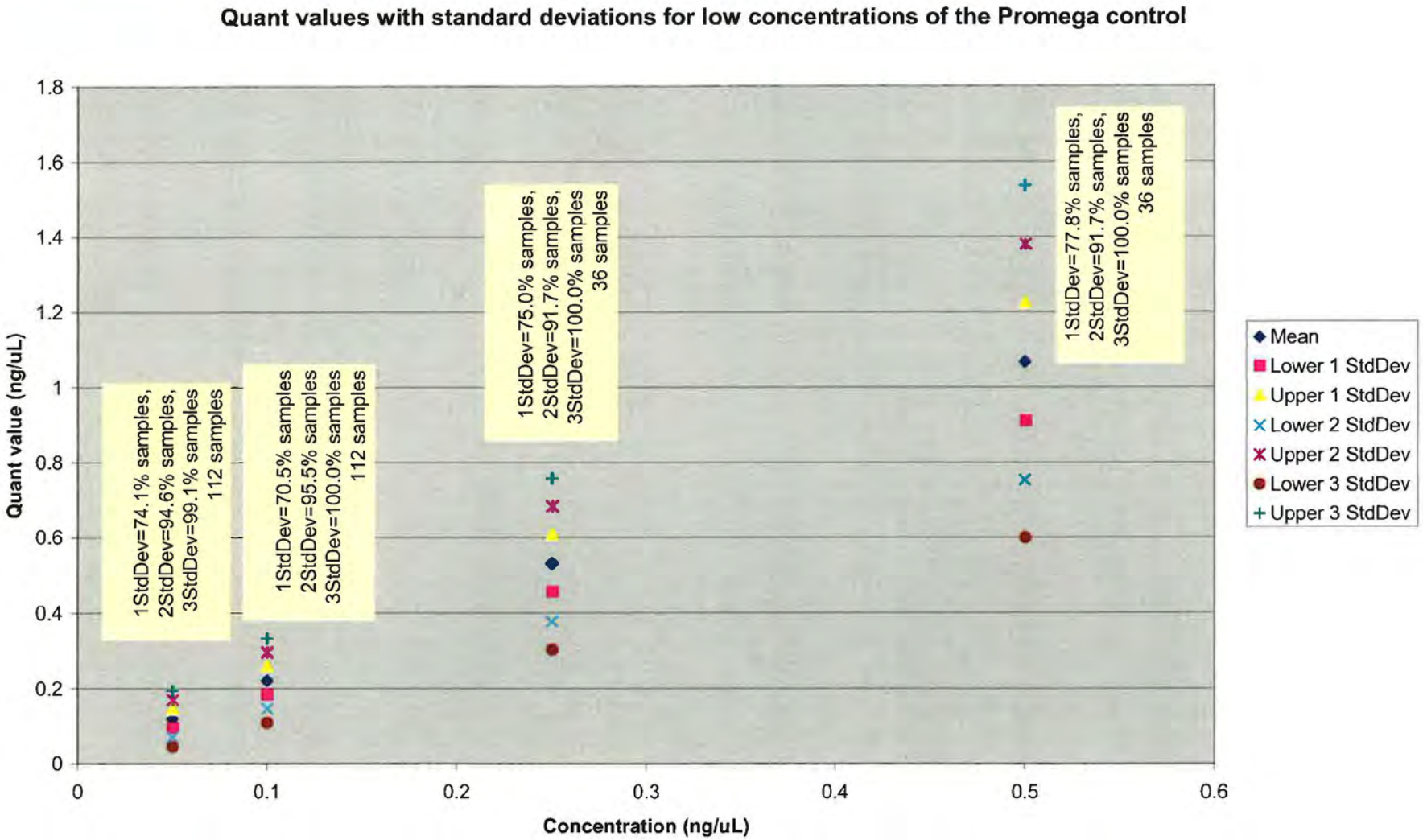

Figure 22. Quant values with standard deviations for low concentrations of the Promega Male control.

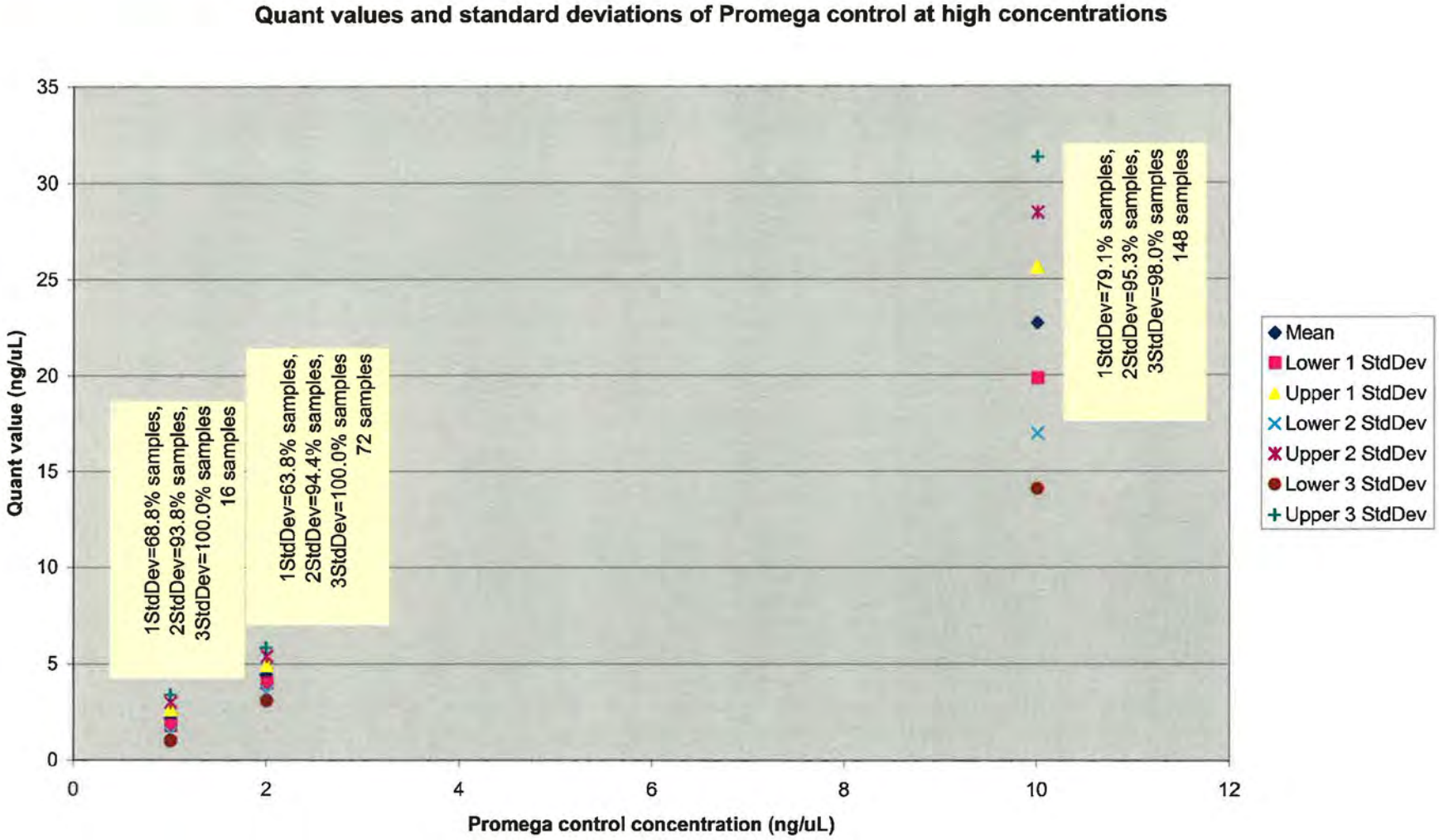

Figure 23. Quant values with standard deviations for high concentrations of the Promega Male control.

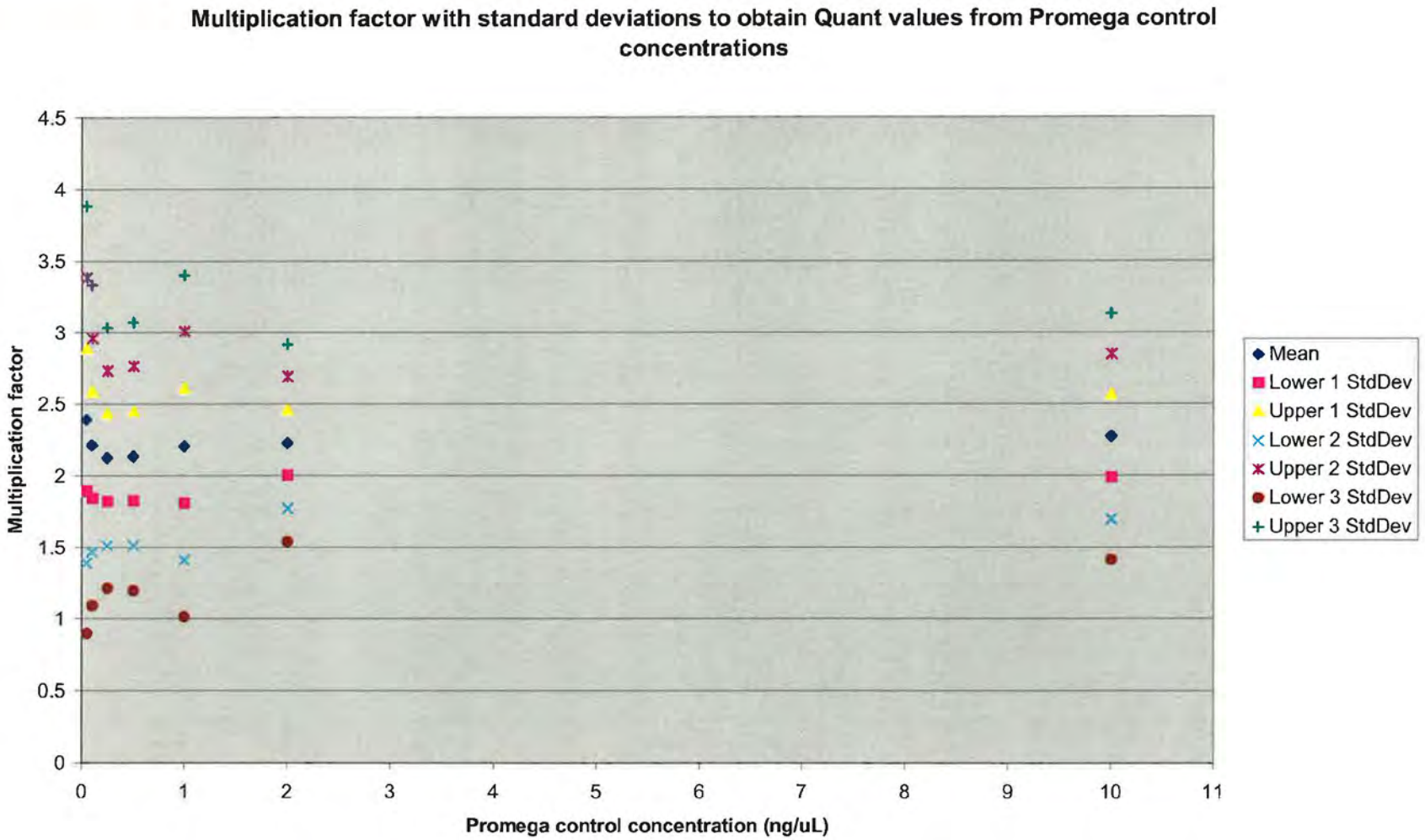

Figure 24. Multiplication factor with standard deviations to obtain Quantifiler values from Promega Male control concentrations.

5.2.1.4.2.2 ACCURACY AND PRECISION (REPEATABILITY): 95% CONFIDENCE INTERVAL AND T-TEST ANALYSIS OF QUANTIFILER RESULTS

In table 14, the Student T-test (two-sided) was used to determine the statistical accuracy of the Quantifiler system at a 95% confidence interval. It was found that no Promega Male control concentration resulted in Quantifiler values that produced an accurate distribution. This demonstrates that with the Quantifiler standard used from Applied Biosystems, the system was not accurate. This was also consistently the case when other Quantifiler standards from Applied Biosystems were employed in other Quantifiler runs, as reflected by the control values run on plates. Furthermore, Applied Biosystems has admitted that calibration, because of the standard not being consistently produced, is sometimes required (Applied Biosystems 2006). In fact, we have shown that the standard consistently requires some form of calibration or correction of the final Quantifiler results.

Table 14. T-test analysis of Quantifiler results (no calibration). The red colour highlights that all of the sample results that failed the T-test for accuracy. Therefore the system is not always accurate and the obtained Quantifiler values can be significantly different to true or expected values.

True/ Expected Concentration (ng/uL)	Calibration type	Normal (No calibration)				
0.05		Overall	Testquant_140705RW	Testquant_130705	TestquantI0_05_160705	
	Mean Quant value	0.11933304	0.12277222	0.1017	0.122694737	
	1 StdDev Quant value	0.02490517	0.01820717	0.01830407	0.026038453	
	CV	20.87%	14.83%	18.00%	21.22%	
	95% Confidence Interval (2 standard deviations)	41.74%	29.66%	36.00%	42.44%	
	Test Statistic to	29.4616535	16.9374083	11.9833778	24.53854331	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.1		Overall	Testquant_140705RW	Testquant_130705	Testquant_270705	
	Mean Quant value	0.22109821	0.24377778	0.20888889	0.218618421	
	1 StdDev Quant value	0.03734764	0.04463915	0.03348202	0.034541942	
	CV	16.89%	18.31%	16.03%	15.80%	
	95% Confidence Interval (2 standard deviations)	33.78%	36.62%	32.06%	31.60%	
	Test Statistic to	34.3149993	13.635778	13.7977461	29.69726691	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.25		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	0.53030556	0.54411111	0.5165		
	1 StdDev Quant value	0.07599993	0.08164694	0.06943999		
	CV	14.33%	15.01%	13.44%		
	95% Confidence Interval (2 standard deviations)	28.66%	30.01%	26.89%		
	Test Statistic to	22.1294057	15.2829711	16.2626031		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
0.5		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	1.06702778	1.10661111	1.02744444		
	1 StdDev Quant value	0.15629084	0.16771514	0.13727397		
	CV	14.65%	15.16%	13.36%		
	95% Confidence Interval (2 standard deviations)	29.29%	30.31%	26.72%		
	Test Statistic to	31.7881766	18.345985	18.501305		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
1		Overall	Testquant_140705RW	Testquant_130705	Testquant_160705	Testquant_150705
	Mean Quant value	2.206875	2.1575	2.2225	1.7875	2.66
	1 StdDev Quant value	0.39859284	0.21546461	0.31951787	0.140328999	0.338132124
	CV	18.06%	9.99%	14.38%	7.85%	12.71%
	95% Confidence Interval (2 standard deviations)	36.12%	19.97%	28.75%	15.70%	25.42%
	Test Statistic to	12.1119966	10.7412236	7.65216429	11.2378452	9.818647101
	Sample number	16	4	4	4	4
	5% critical values for Degrees of freedom (n-1)	2.131	3.182	3.182	3.182	3.182
2		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	4.45569444	4.51805556	4.3933333		
	1 StdDev Quant value	0.45833387	0.47033009	0.44376957		
	CV	10.29%	10.41%	10.10%		
	95% Confidence Interval (2 standard deviations)	20.57%	20.82%	20.20%		
	Test Statistic to	46.4630562	33.1228344	32.3561085		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		
10		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	24.1295833	23.8369444	24.4222222		
	1 StdDev Quant value	3.00525007	2.03279515	3.74335076		
	CV	12.45%	8.53%	15.33%		
	95% Confidence Interval (2 standard deviations)	24.91%	17.06%	30.66%		
	Test Statistic to	30.8546501	40.841378	23.1164443		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		

5.2.1.4.2.3 PRECISION (IN-HOUSE REPRODUCIBILITY)

In-house reproducibility values (see QIS 10662R2) were calculated in ng/µL and are highlighted in yellow in table 15. According to expectation, the lower concentrations had lower reproducibility values. Relative reproducibility values, which are a ratio of the reproducibility value over the overall mean of the relevant concentration, demonstrated a general trend towards increasing with the lower concentration values. Therefore, the range of reproducibility at the lower concentrations (i.e. 0.05ng/µL and 0.1ng/µL) was higher relative to the overall mean of those concentrations.

Table 15. In-house Quantifiler value reproducibility.

ng/uL	Overall Mean	Combined StdDev Sc	Degrees of freedom	t-value (2-sided,95% confidence interval)	Reproducibility Rw (ng/uL)	Relative reproducibility (Rw/Overall Mean)	Relative lower range limit	Relative upper range limit
0.05	0.119	0.024	109	1.982	0.067	0.561	0.052	0.186
0.1	0.221	0.036	109	1.982	0.101	0.458	0.120	0.322
0.25	0.530	0.076	34	2.032	0.218	0.411	0.312	0.748
0.5	1.067	0.153	34	2.032	0.440	0.413	0.627	1.507
1	2.207	0.266	12	2.179	0.819	0.371	1.388	3.026
2	4.456	0.457	70	1.994	1.290	0.289	3.166	5.745
10	24.130	3.012	70	1.994	8.496	0.352	15.634	32.625

5.2.1.4.2.4 STOCHASTIC EFFECTS

The laboratory must conduct studies that ensure the reliability and integrity of results. For PCR-based assays, studies must address the stochastic effects and levels (QIS 23401R0). An assessment of stochastic effects is also required according to QIS 23401R0. The stochastic effects are due to the ranges observed with the standard deviations (see figures 25 and 26). The levels of stochastic effects using the Quantifiler standard is observed in the graph showing the range in correction factors for different control sample concentrations (Figure 24). Most stochastic effects were observable at the lower concentration scale at 0.05ng/µL and 0.1ng/µL. This can be seen in the relative reproducibility figures (Rw/Overall mean) in Table 15, as well as in the graph showing multiplication factors being broadest in the lowest concentrations (Figure 24).

5.2.1.4.2.5 LINEAR CALIBRATION FUNCTION GRAPH ANALYSIS

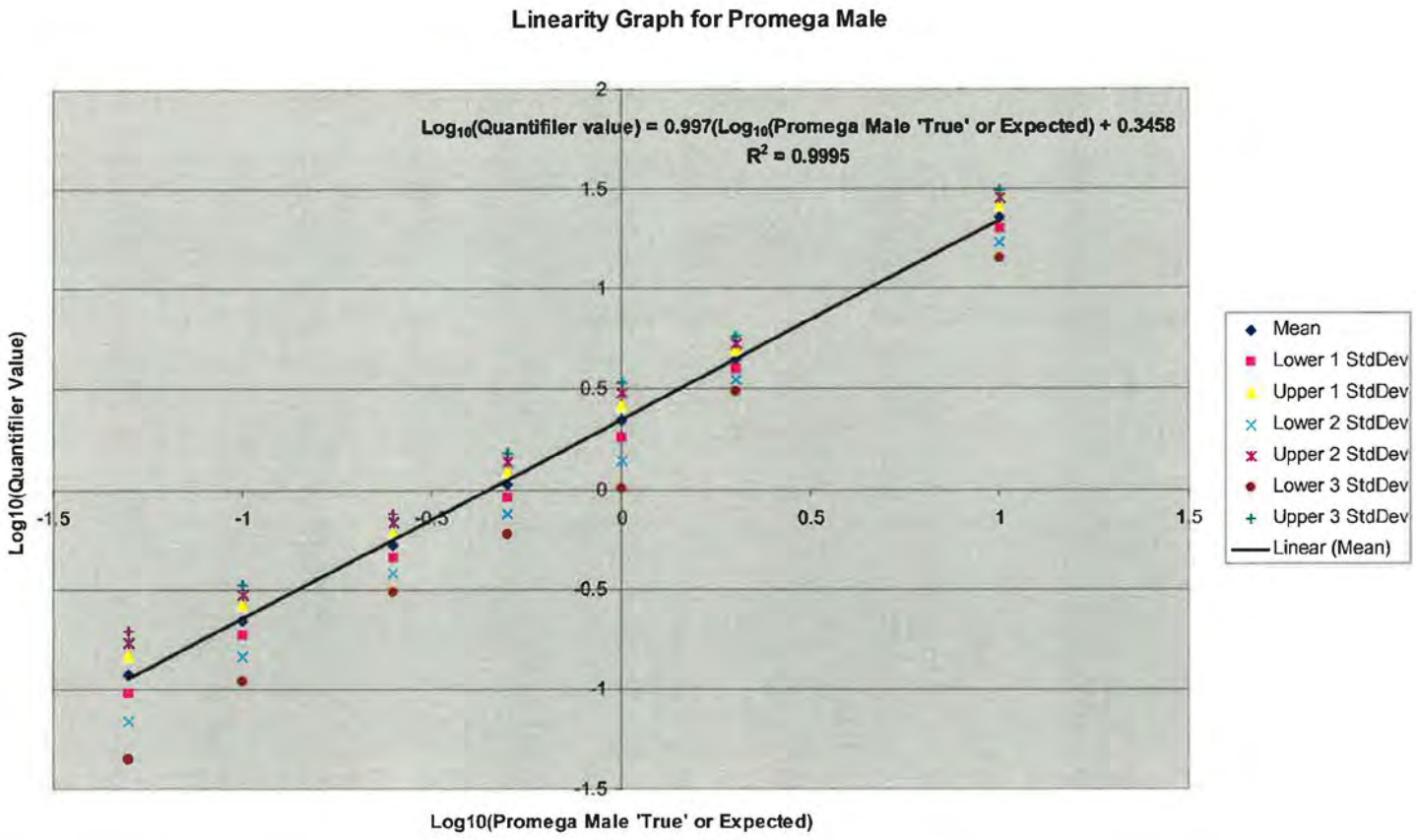

Figure 25. Linearity graph for the Promega Male control derived from mean values.

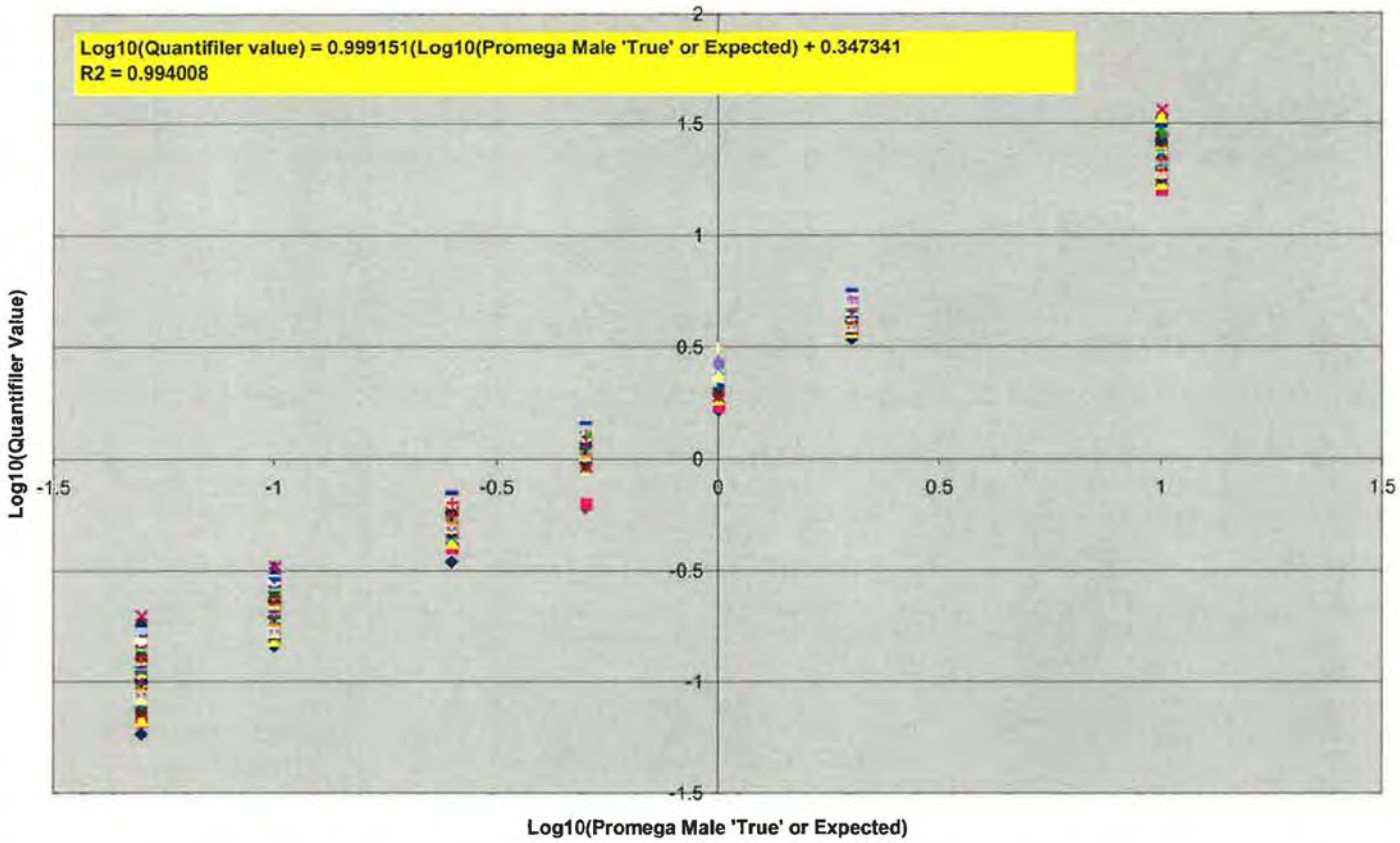

Figure 26. Linearity graph for the Promega Male control using individual points. The equation was calculated externally in Microsoft Excel and is very similar to that calculated in figure 25.

5.2.1.4.2.5.1 LINEARITY (LINEAR RESPONSE RANGE)

Linearity is the range of concentrations between which the method produces a linear calibration line (QIS 10663R2). This is required by NATA (2004:2.2) guidelines. Promega Male control concentration values ranging from 0.05ng/µL to 10ng/µL produced a linear calibration line using the Quantifiler standard based on the mean result from each concentration range. The correlation coefficient (R2) was 0.9995 (see figure 25) and 0.994008 (see figure 26) for the linear response range as calculated from the mean values and individual values respectively. A value as near as possible to unity (between 0.98 and 1.00) indicates that the system is linear between the concentration values tested.

5.2.1.4.2.5.2 POTENTIAL BIAS FROM LINEARITY ANALYSIS

A positive y-intercept (+0.3458 in figure 20 and +0.347341 in figure 21) is indicative of bias using the Quantifiler Standard in relation to the Promega Male control (see QIS 10662R2). This is equal to correction factors of about 2.217 and 2.225 respectively. By rigorous analysis of data from controls run on plates from Testquants and standard runs, it was found that while most Quantifiler standard lot and batch numbers fluctuated around the 2-fold correction factor, there were also some lots and batches where Quantifiler values of controls could not be reproduced in at the typical distribution. Therefore, with the use of the Quantifiler standard and linear calibration methods, it is essential to maintain the same level of bias by testing lots and batches and selecting only those that produce a bias similar to that obtained from the majority of the lots and batches from historical data..

5.2.1.4.2.5.3 SENSITIVITY

Sensitivity is the slope of the calibration function graph (QIS 10663R2). It is required by QIS 23401R0 and SWGDAM (2004:2.3) and NATA (2004:2.3) guidelines. Because the mean slopes (approximately 0.997 in figure 25 and approximately 0.999 in figure 26) are almost equal to unity (1), this indicates that on average the method is highly sensitive.

5.2.2 PROMEGA MALE CONTROL {ACCURACY AND PRECISION (REPEATABILITY AND REPRODUCEABILITY)}: 1ng/µL CONCENTRATION

1 ng/µL Promega Male control was run across several plates to examine distribution

(a) between operators

(b) between two different lots of Quantifiler standards

(c) overall distribution by plate position

The Promega Male control is suitable as a quality control check to accept or reject the performance of the recommended ABI Quantifiler Standards because it is derived from human blood and is similar to standard genomic casework and reference samples. Examination of range and correction factor is limited by the small numbers of plates run and may only reflect the conditions pertained to the set of Quantifiler reagents and standards utilized.

5.2.2.1 METHOD

1. Quantifiler Human DNA Standard was prepared according to SOP 21963R0 "Real Time PCR Quantification of Human DNA using Quantifiler Human DNA Quantification Kit (Applied Biosystems)" using $T_{10}E_{0.1}$-glycogen (5mL TE + 5µL glycogen 20mg/mL) as the recommended diluent.

2. Dilution volumes for the Quantifiler Human DNA Standard followed the instructions as described in SOP 219630 (= each standard requires 100µL DNA), two tubes of DNA standard were required to create the two sets of DNA standards as outlined.

   Quantifiler Human DNA Standard $T_{10}E_{0.1}$-glycogen = lot#0406006 (U2)
   Quantifiler Human DNA Standard $T_{10}E_{0.1}$-glycogen = lot#0412010 (V2)

3. It must be noted that the labels on Quantifiler Human DNA Standard tubes indicate neither DNA concentration nor volume of solution. However, the product insert for the Quantifiler kit claims that the Human DNA Standard is at a concentration of 200ng/µL. The method for creating the DNA standard dilution series in SOP 219630 assumes or implies a Human DNA Standard stock concentration of 200ng/µL (the actual stock concentration is not listed in the SOP).

Table 16. DNA concentration of the DNA standards used in the Quantifiler assay.

Quantifiler Human DNA Standard Concentrations	
Standard #	[DNA] ng/µl
1	50.00
2	16.70
3	5.560
4	1.850
5	0.620
6	0.210
7	0.068
8	0.023

4. Operator 1 did serial dilutions of the Quantifiler Standard from two lots (U2 and V2).

5. TE-4 used for eluting DNA was autoclaved in-house TE (batch USP grade VH 21.1.05).

6. Promega Male control (G147A, lot#18797901, Promega Corp., Madison, WI, USA) was diluted on the 4th of March, 2005 from the in-tube concentration of 177ng/µL to 100ng/µL by adding 150µL of DNA (using Socorex pipettor serial#14073619) to 115.5µL of TE-4 (using Socorex pipettor serial#14073619) to make a total volume of 265.5µL in a sterile 1.5mL tube. This was vortexed and briefly centrifuged. A SealPette (serial#EL67674) was then used to add 15µL of the 100ng/µL DNA to 1485µL of TE-4 (1000µL and 485µL using Eppendorf pipette serial#3325731) in a sterile 1.5mL tube to make a total of 1500µL of 1ng/µL DNA. This was vortexed and briefly centrifuged and left overnight in the refrigerator at 4 degrees Celsius for equilibration.

7. A Quantifiler reaction was set up on a 96-well plate, using the ABI Prism® 7000 SDS instrument (Applied Biosystems, Foster City, CA, USA). The ABI Sequence Detection System software allows the analysis of data to compare samples to DNA standards within the same run (after completion of the quantification reaction). For more detailed information on the Quantifiler reaction, refer to SOP 21963R0 and references therein.

8. Operator 1 made up the serial dilutions of two standards of different lot numbers that were used throughout this set of experiments. Two operators each ran two plates, one with one standard and the other with the other standard to quantify 1ng/µL of the Promega male control. These four plates were replicated one more time. The Quantifiler format in figure 27 was followed.

	1	2	3	4	5	6	7	8	9	10	11	12
A	**STD#1 50 ng/µL**	**STD#1 50 ng/µL**	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL
B	**STD#2 16.7ng/µL**	**STD#2 16.7ng/µL**	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL
C	**STD#3 5.56ng/µL**	**STD#3 5.56ng/µL**	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL
D	**STD#4 1.85ng/µL**	**STD#4 1.85ng/µL**	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL
E	**STD#5 0.62ng/µL**	**STD#5 0.62ng/µL**	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL
F	**STD#6 0.21ng/µL**	**STD#6 0.21ng/µL**	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL
G	**STD#7 0.068ng/µL**	**STD#7 0.068ng/µL**	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL
H	**STD#8 0.023ng/µL**	**STD#8 0.023ng/µL**	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	Promega 1ng/µL	NegCtl	NegCtl

Figure 27. Format of the eight plates. Completed by operator 1 and operator 2 (four plates each) and utilizing Quantifiler Standard U2 and V2 (four plates each).

5.2.2.2 RESULTS

From a total of 624 samples of 1ng/µL of the Promega male control quantified over 8 plates, the average mean concentration obtained was 1.88ng/µL with Quantifiler values ranging from 0.21 to 4.72ng/µL. The actual Quantifiler values obtained are shown in table 17 and the analysis of this data is shown in table 18. The majority of samples (98.9%) were within 3 standard deviations having a range of 1.10-2.66ng/µL. 90.2% of samples were within 1.25 standard deviations with a range of 1.56-2.24ng/µL. See tables 19 and 20 for other ranges. The mean results were graphed (see Figure 28) to demonstrate the distribution across the plate. Other distributions of the data are also presented in figures 29, 30, 31 and 32. Values obtained solely based on individual operators and standards are presented in tables 21 to 24.

Table 17. Table of Quantifiler value results from Promega Male control at 1ng/µL. The red colour denotes where potential pipetting errors may have occurred.

QFVAL_OP1_STDU_PLATE1_050305

Position	1	2	3	4	5	6	7	8	9	10	11	12
A			2.17	2.07	2.00	1.96	2.03	1.92	1.69	1.73	2.81	2.72
B			1.76	1.97	1.74	1.90	1.77	1.82	1.81	1.84	1.56	1.68
C			1.75	1.86	1.74	1.86	2.08	2.14	1.86	1.87	2.05	1.68
D			1.61	1.82	2.02	2.10	1.76	1.80	1.80	1.96	1.89	1.67
E			1.63	1.91	1.73	2.23	1.93	2.05	2.05	1.90	1.74	1.71
F			1.93	1.90	1.95	1.95	2.00	2.01	1.83	1.98	1.67	1.66
G			1.73	1.80	1.80	1.80	1.76	2.06	1.76	1.46	1.61	1.67
H			1.65	1.90	1.79	1.78	1.71	1.68	1.67	1.77		

QFVAL_OP2_STDU_PLATE1_050305

Position	1	2	3	4	5	6	7	8	9	10	11	12
A			1.90	2.24	1.76	1.78	1.67	1.65	1.55	1.71	1.33	1.22
B			2.18	2.21	2.29	2.01	1.81	1.78	1.69	1.73	1.75	1.79
C			2.03	2.10	2.32	2.11	2.13	2.07	2.07	1.82	1.74	1.71
D			1.71	1.80	1.93	2.18	1.93	1.89	1.82	1.94	1.76	1.33
E			1.66	1.92	2.07	2.03	1.74	1.85	1.86	1.82	1.67	1.48
F			2.14	2.26	1.98	1.88	1.76	1.84	1.62	1.67	1.44	1.76
G			1.63	2.05	1.98	1.85	1.87	1.70	0.21	1.78	1.65	1.69
H			1.76	1.96	1.67	1.72	1.60	1.71	1.74	1.68		

QFVAL_OP1_STDU_PLATE2_070305

	1	2	3	4	5	6	7	8	9	10	11	12
A			2.04	2.07	2.25	1.98	1.82	1.81	1.98	1.60	1.59	1.68
B			1.86	2.03	1.58	2.02	1.94	2.03	1.94	1.87	1.78	1.81
C			1.70	1.80	1.85	2.12	1.96	1.89	1.72	1.80	1.86	1.72
D			1.55	1.87	2.02	2.06	1.82	2.23	1.85	2.16	2.25	1.88
E			1.58	1.76	2.03	2.09	1.89	1.94	1.78	1.61	2.19	1.84
F			1.58	2.03	1.94	1.86	2.14	1.96	2.09	1.85	1.80	1.82
G			1.87	1.98	2.12	1.95	1.80	2.09	1.82	1.79	1.88	1.74
H			1.78	2.17	1.86	1.89	1.88	1.95	1.76	1.95		

QFVAL_OP2_STDU_PLATE2_080305

	1	2	3	4	5	6	7	8	9	10	11	12
A			2.20	1.89	2.04	1.88	1.86	1.86	1.98	1.81	1.85	1.75
B			1.88	1.89	1.65	1.92	1.99	1.92	1.82	1.93	1.89	1.84
C			1.98	2.09	2.20	2.30	2.36	2.02	1.98	1.89	1.94	1.88
D			1.51	1.98	2.45	2.21	2.31	1.95	1.99	1.94	1.93	1.89
E			1.72	1.82	2.18	2.26	1.88	2.25	1.92	1.95	1.83	1.80
F			2.13	2.25	2.16	2.21	1.98	1.98	2.40	2.06	1.84	1.86
G			1.92	1.91	1.96	2.26	1.97	1.94	1.89	1.81	1.94	1.97
H			1.86	2.08	1.6	1.69	1.89	1.93	1.8	1.89		

QFVAL_OP1_STDV_PLATE1_070803

	1	2	3	4	5	6	7	8	9	10	11	12
A			1.90	2.27	1.78	1.63	1.62	1.73	2.03	1.77	1.50	2.35
B			1.63	1.80	1.90	1.93	1.73	1.92	1.84	1.68	1.74	1.57
C			1.65	1.61	1.85	1.64	2.01	1.96	1.69	1.72	1.50	1.76
D			1.60	1.60	1.68	1.64	1.75	1.85	1.69	1.85	1.76	1.75
E			1.58	1.65	1.68	2.11	1.71	2.02	1.72	1.78	1.68	1.78
F			1.87	1.74	1.88	1.68	1.86	1.67	1.83	1.86	1.72	1.51
G			1.70	1.97	1.96	1.93	1.87	1.80	1.60	1.59	1.67	1.60
H			1.78	1.71	1.96	1.93	2.04	1.88	1.68	1.71		

QFVAL_OP2_STDV_PLATE1_050305

	1	2	3	4	5	6	7	8	9	10	11	12
A			2.18	2.13	1.82	2.63	1.82	1.77	1.71	1.84	1.72	4.72
B			1.82	1.91	2.33	2.17	2.01	2.10	2.09	1.88	1.84	1.77
C			1.75	1.82	2.06	2.12	2.26	2.00	2.22	2.04	2.01	1.87
D			1.59	1.78	1.84	1.97	1.81	2.20	2.16	2.11	1.98	1.85
E			1.52	1.73	1.80	1.93	1.95	1.76	1.87	2.26	1.76	1.94
F			1.90	2.43	1.95	2.14	1.93	1.75	2.00	2.11	1.85	2.11
G			2.13	2.09	2.02	2.06	2.07	2.12	1.75	1.81	1.65	1.92
H			1.87	2.05	1.84	2.11	1.72	2.09	1.88	1.80		

QFVAL_OP1_STDV_PLATE2_080305

	1	2	3	4	5	6	7	8	9	10	11	12
A			2.05	2.13	1.79	1.59	1.81	1.82	1.88	1.74	2.84	4.12
B			1.77	2.32	2.18	2.21	1.87	1.81	2.18	1.96	1.50	1.76
C			1.75	1.88	1.77	2.12	1.91	1.77	2.04	1.97	1.80	2.07
D			1.69	1.79	1.87	2.15	1.90	1.90	1.99	1.76	1.76	1.63
E			1.58	1.81	2.20	1.80	2.19	1.44	1.82	2.03	1.80	1.73
F			1.87	1.76	1.75	1.89	1.79	1.71	1.83	1.71	1.64	1.79
G			1.71	1.69	1.73	1.87	1.65	1.88	1.77	1.73	1.74	1.68
H			1.94	2.01	1.81	1.78	1.80	1.91	1.64	1.90		

QFVAL_OP2_STDV_PLATE2_090305

	1	2	3	4	5	6	7	8	9	10	11	12
A			1.84	1.98	1.73	1.86	1.51	1.77	1.64	1.72	1.34	2.04
B			2.28	2.08	2.17	1.88	1.93	1.65	1.90	1.83	1.71	1.51
C			1.77	2.02	2.01	1.84	2.05	1.87	1.87	1.76	1.59	1.18
D			1.67	1.95	1.73	1.91	1.96	1.89	1.85	1.76	1.79	1.84
E			1.50	1.79	2.00	1.75	1.86	1.93	1.75	1.81	1.81	1.40
F			1.91	1.84	2.04	2.26	1.79	2.24	1.82	1.73	1.54	1.95
G			2.03	1.85	2.01	1.85	1.76	2.01	1.91	1.84	1.63	1.76
H			1.74	1.86	1.88	1.86	1.78	1.85	1.71	1.77		

Table 18. Analysed Quantifiler values from Promega Male control at 1ng/µL. The differing results at positions F11 and G9 are most likely the result of pipetting errors made in setting up plate QFVAL_OP2_STDU_PLATE1_050305. Otherwise, positions A11 and A12 produce the most disparate results with the highest overall 95% confidence intervals and standard deviations.

Overall mean by position

Position	1	2	3	4	5	6	7	8	9	10	11	12
A			2.04	2.10	1.90	1.91	1.77	1.79	1.81	1.74	1.87	2.58
B			1.90	2.03	1.98	2.01	1.88	1.88	1.91	1.84	1.72	1.72
C			1.80	1.90	1.98	2.01	2.10	1.97	1.93	1.86	1.81	1.73
D			1.62	1.82	1.94	2.03	1.91	1.96	1.89	1.94	1.89	1.73
E			1.60	1.80	1.96	2.03	1.89	1.91	1.85	1.90	1.81	1.71
F			1.92	2.03	1.96	1.98	1.91	1.90	1.93	1.86	1.66	1.81
G			1.84	1.92	1.95	1.95	1.84	1.95	1.59	1.73	1.72	1.76
H			1.80	1.97	1.80	1.85	1.80	1.88	1.74	1.81		

Overall standard deviation by position

	1	2	3	4	5	6	7	8	9	10	11	12
A			0.142	0.126	0.183	0.322	0.161	0.082	0.182	0.073	0.614	1.234
B			0.221	0.173	0.299	0.125	0.103	0.144	0.159	0.095	0.132	0.119
C			0.134	0.166	0.209	0.213	0.151	0.119	0.181	0.107	0.195	0.257
D			0.069	0.117	0.239	0.187	0.181	0.161	0.146	0.147	0.169	0.188
E			0.072	0.090	0.201	0.187	0.147	0.238	0.106	0.193	0.164	0.182
F			0.175	0.259	0.118	0.200	0.131	0.190	0.236	0.160	0.068	0.180
G			0.177	0.133	0.125	0.150	0.132	0.148	0.585	0.133	0.124	0.127
H			0.090	0.144	0.116	0.135	0.135	0.132	0.078	0.096		

Overall 95% Confidence Interval

	1	2	3	4	5	6	7	8	9	10	11	12
A			13.96%	11.98%	19.26%	33.67%	18.26%	9.16%	20.14%	8.33%	65.63%	66.86%
B			23.25%	17.07%	30.25%	12.45%	10.98%	15.35%	16.69%	10.30%	15.36%	13.90%
C			14.94%	17.50%	21.19%	21.19%	14.46%	12.08%	18.71%	11.52%	21.54%	29.70%
D			8.60%	12.86%	24.60%	18.46%	18.99%	16.40%	15.41%	15.15%	17.89%	21.79%
E			9.03%	9.95%	20.45%	18.44%	15.51%	24.95%	11.43%	20.41%	18.15%	21.30%
F			18.23%	25.61%	12.08%	20.17%	13.74%	20.05%	24.48%	17.18%	59.67%	19.95%
G			19.28%	13.89%	12.84%	15.41%	14.32%	15.22%	71.11%	15.38%	14.36%	14.50%
H			10.00%	14.62%	12.89%	14.65%	15.04%	14.08%	9.01%	10.60%		

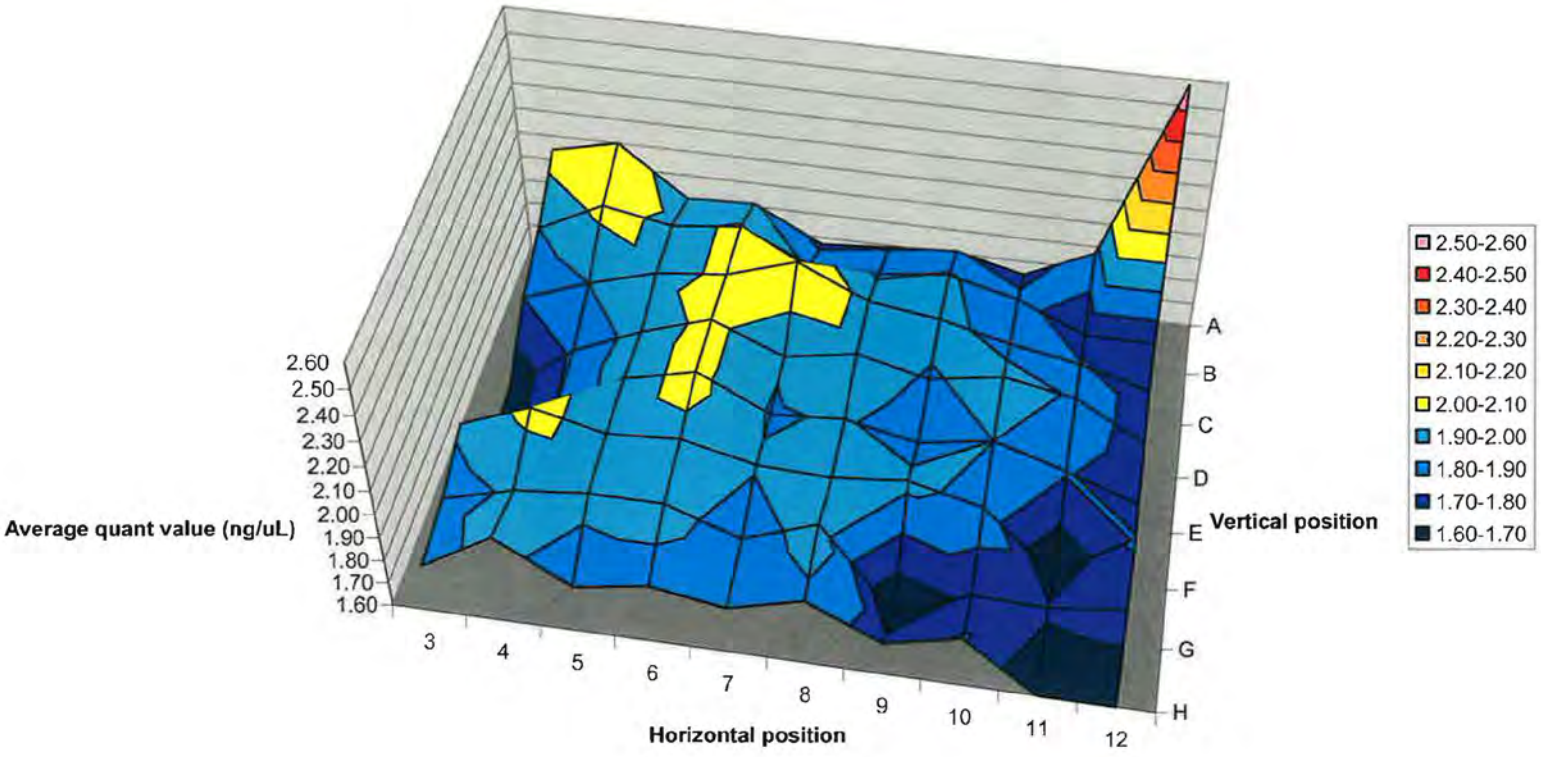

Figure 28. Average Quantifiler values of 1ng/µL Promega Male control over 8 plates by well position. Positions H11 and H12 were negative controls that produced undetermined results.

Table 19. Range of values for the Promega Male control.

This data does not take into account the mean or standard deviation				Total number of samples	624
				1% of samples	6.24 samples
Number samples missing in range	Range of values		Number of samples in range	Percentage of samples	Percentage of samples missed
	Minimum	Maximum			
0	0.21	4.72	624	100%	0%
6	1.22	2.81	618	99%	1%
12	1.34	2.45	612	98%	2%
19	1.46	2.35	605	97%	3%
25	1.50	2.32	599	96%	4%
31	1.51	2.29	593	95%	5%
36	1.50	2.25	588	94.2%	5.8%
29	1.25	2.25	595	95.4%	4.6%

Table 20. Range of values for the Promega Male control using standard deviation values.

				StdDev	0.26
				Mean	1.88
Standard deviation	Range of values		Number of samples in range	Percentage of samples	Percentage of samples missed
	Minimum	Maximum			
1.000	1.62	2.14	520	83.3%	16.7%
1.250	1.56	2.21	563	90.2%	9.8%
1.500	1.49	2.27	595	95.4%	4.6%
1.625	1.46	2.30	600	96.2%	3.8%
1.750	1.43	2.34	605	97.0%	3.0%
2.000	1.36	2.40	609	97.6%	2.4%
3.000	1.10	2.66	617	98.9%	1.1%
7.000	0.06	3.70	622	99.7%	0.3%

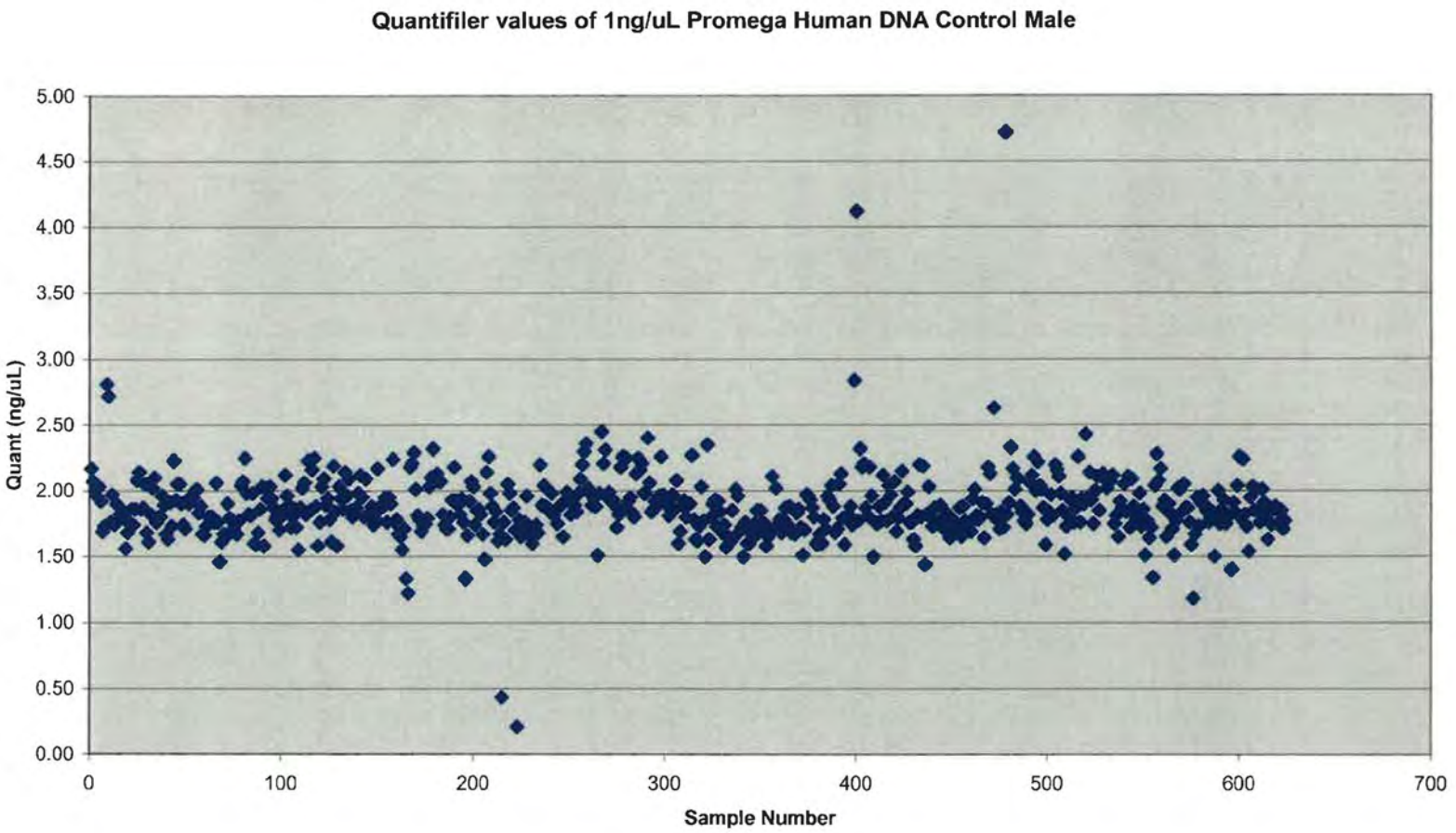

Figure 29. Quantifiler values of 1ng/µL Promega Male control.

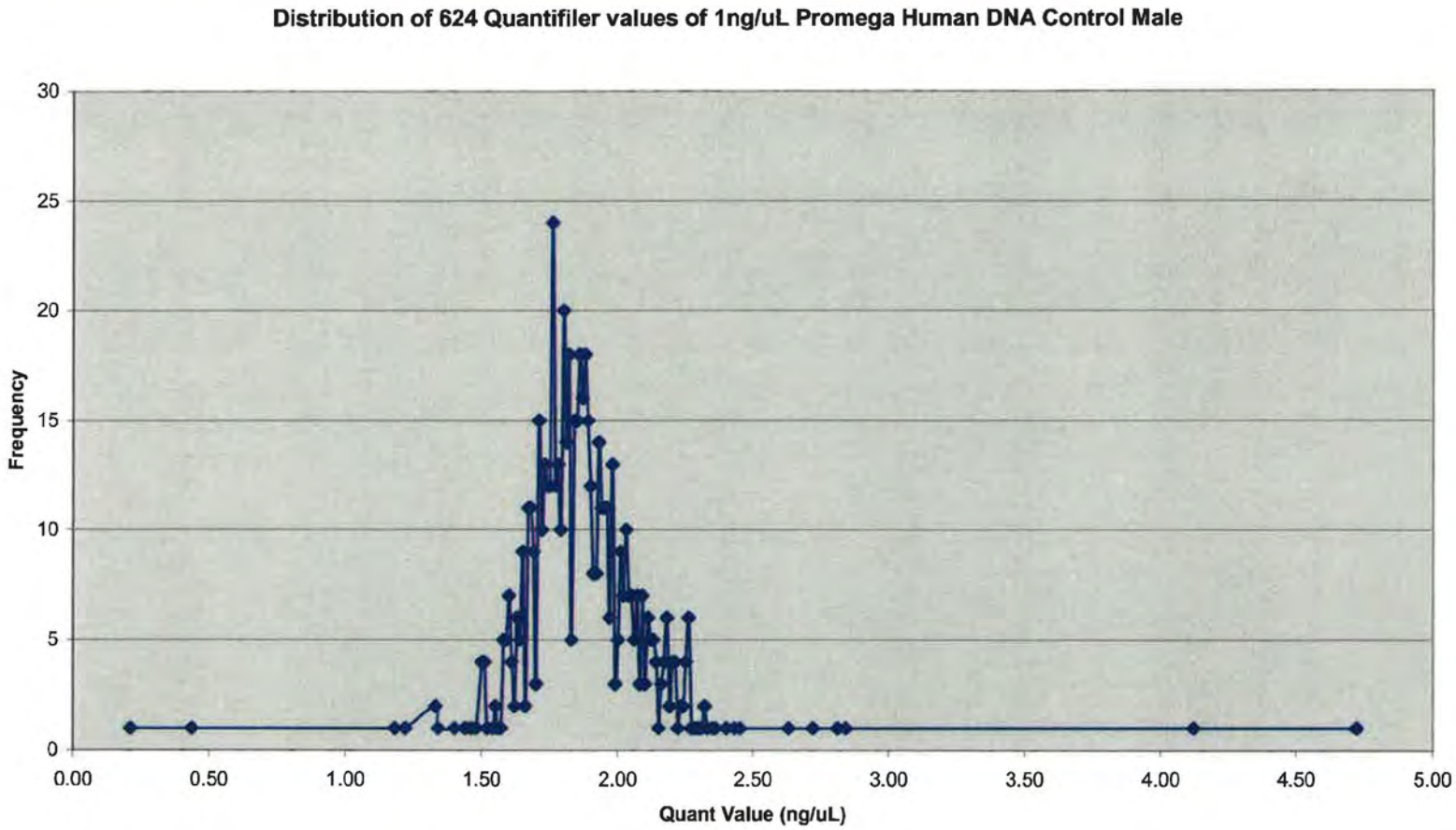

Figure 30. Distribution of 624 Quantifiler values of 1ng/µL Promega Male control.

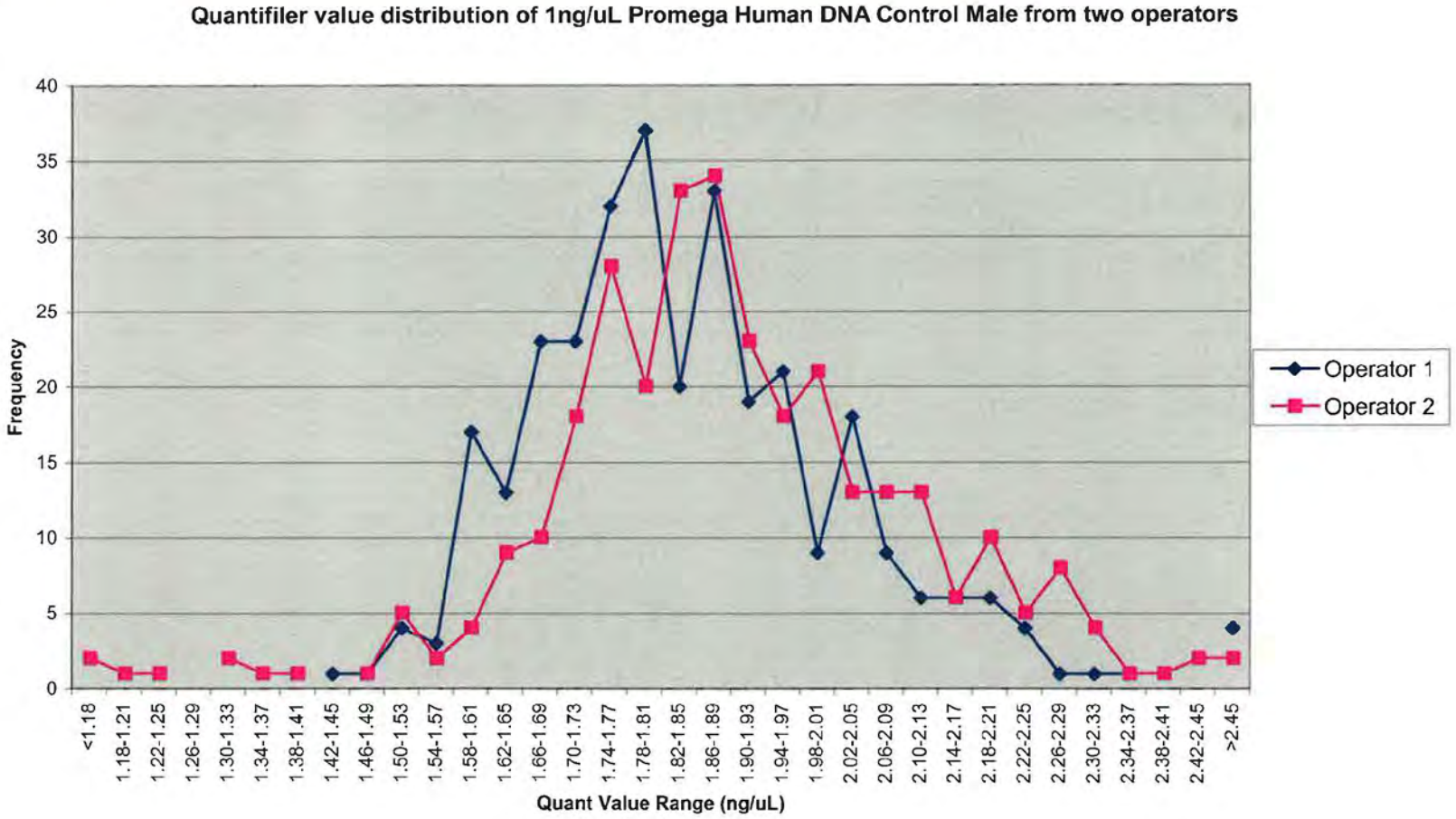

Figure 31. Quantifiler value distribution of 1ng/µL Promega Male control from two operators.

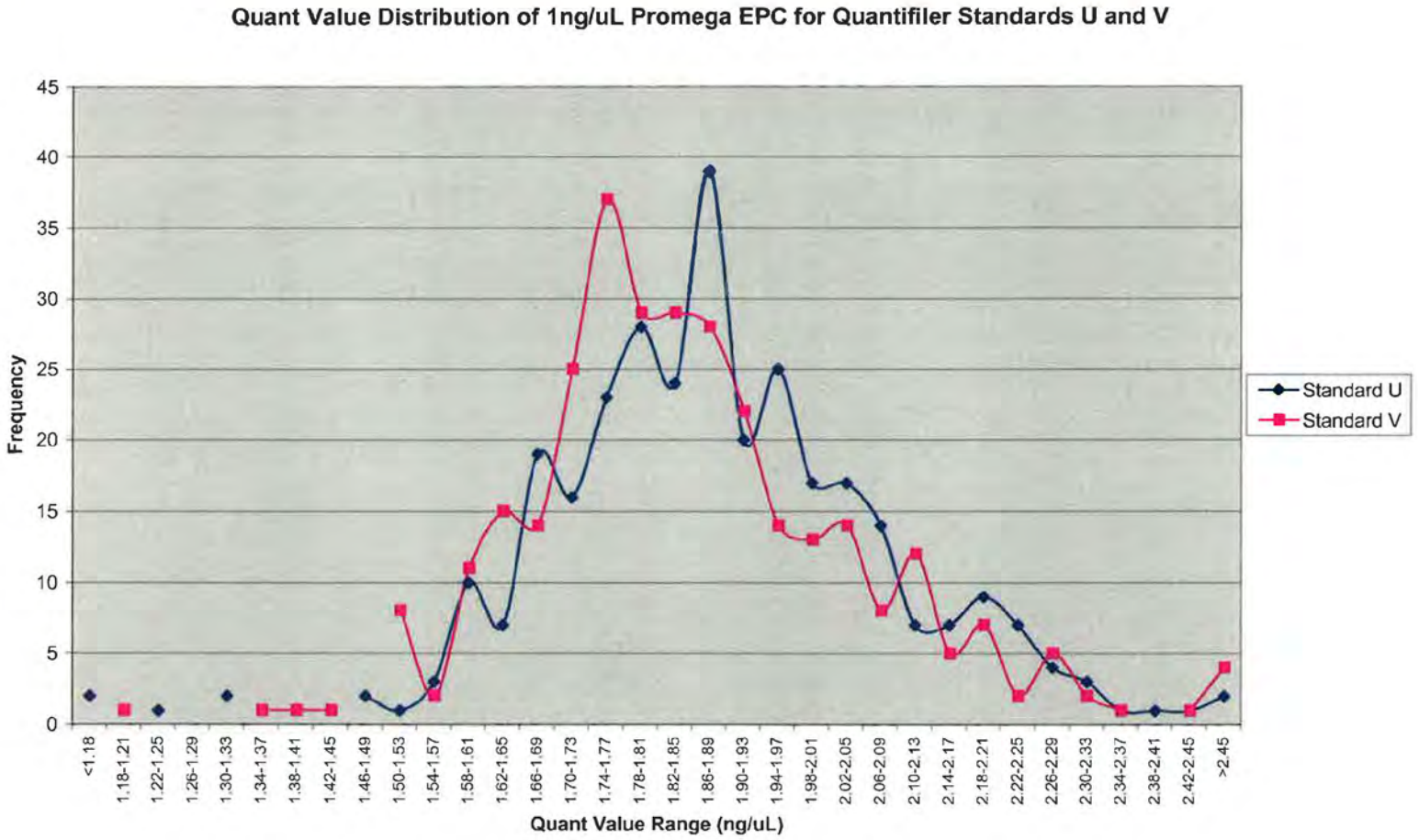

Figure 32. Quantifiler value distribution of 1ng/µL Promega Male control using standards U and V.

Table 21. Table for Promega Male control values for operator 1.

			Total number of samples	312
			Standard Deviation (StdDev)	0.23
			Mean Quantifiler value	1.86
Standard Deviation	Range in values		Values in range	Percentage in range
	Minimum	Maximum		
1	1.63	2.09	242	77.6%
2	1.40	2.32	307	98.4%
3	1.17	2.55	310	99.4%

Table 22. Table for Promega Male control values for operator 2.

			Total number of samples	312
			Standard Deviation (StdDev)	0.29
			Mean Quantifiler value	1.90
Standard Deviation	Range in values		Values in range	Percentage in range
	Minimum	Maximum		
1	1.61	2.19	263	84.3%
2	1.32	2.48	306	98.1%
3	1.03	2.77	309	99.0%

Table 23. Table for Promega Male control Quantifiler standard U values.

			Total Samples	312
			StdDev	0.24
	Range of values		Mean Quantifiler value	1.88
StdDev	Minimum	Maximum	Values in range	Percentage in range
1	1.64	2.12	251	80.4%
2	1.40	2.36	303	97.1%
3	1.16	2.60	308	98.7%

Table 24. Table for Promega Male control Quantifiler standard V values.

			Total Samples	312
			StdDev	0.29
	Range in values		Mean Quantifiler value	1.87
StdDev	Minimum	Maximum	Values in range	Percentage in range
1	1.58	2.16	271	86.9%
2	1.29	2.45	307	98.4%
3	1.00	2.74	309	99.0%

5.2.2.3 DISCUSSION

A few observations were made about the data.

(a) The values obtained from Quantifiler Standard U and Standard V produced similar results when 312 results of each were compared to each other.

(b) Minor operator differences were observed. The mean value for operator 2 (1.90ng/µL) was higher than the mean for operator 1 (1.86ng/µL), with both means producing values closer to twice the amount of 1ng/µL. However, operator 2 also had a larger standard deviation (0.29 compared to 0.24) and broader ranges (1.00-2.74ng/µL compared to 1.16-2.60ng/µL) at three standard deviations.

(c) Positions A11 and A12 produced the most disparate values showing that heating of the 96-well block is not homogeneous. Some edge positions (C12, D12) also produced disparate values to the rest of the data but only once out of the eight plate runs. It is possible that there are differences in how different plates are contacting the heat block because of manufacturing differences and the way users place them into position within the machine. There is also a potential convectional problem where the heat from the lamp may not be distributed evenly and resulting in edge aberrations. However, the differences expected from this factor would depend on the age as well as the heating properties of individual lamps. Here the same lamp was used over two days so it is unlikely to be a contributing factor. A Precision Plate Holder was obtained to hold the plates better in position and for further testing.

The same set of data was reanalysed with positions A11 and A12 omitted. The other corner positions contain the Quantifiler Standards and the TE negative control and therefore remain untested.

5.2.2.4 REANALYSIS

By removing A11 and A12, there are less outliers found in the distribution of Quantifiler results (compare figures 29-32 to figures 33-36). This has helped to tighten the standard deviations (compare tables 20-24 to tables 26-30).

Table 25. Range of values for the Promega Male control omitting positions A11 and A12.

This data does not take into account the mean or standard deviation				Total number of samples	608
				1% of samples	6.08 samples
Number of samples missing in range	Range of values		Number of samples in range	Percentage of samples	Percentage of samples missed
	Minimum	Maximum			
0	0.21	2.63	608	100%	0%
6	1.33	2.40	602	99%	1%
12	1.46	2.32	596	98%	2%
18	1.50	2.30	590	97%	3%
24	1.51	2.27	584	96%	4%
30	1.51	2.26	578	95%	5%
27	1.50	2.25	581	96.1%	3.90%
22	1.25	2.25	586	95.7%	4.30%

Table 26. Range of values for the Promega Male control omitting positions A11 and A12 and using standard deviation values.

				StdDev	0.21
				Mean	1.87
Standard Deviation	Range of values		Number of samples in range	Percentage of Samples	Percentage of samples missed
	Minimum	Maximum			
1.000	1.66	2.08	463	76.2%	23.8%
1.250	1.61	2.13	515	84.7%	15.3%
1.500	1.56	2.19	553	91.0%	9.0%
1.625	1.53	2.21	564	92.8%	7.2%
1.750	1.50	2.24	577	95.0%	5.0%
2.000	1.45	2.29	592	97.4%	2.6%
3.000	1.24	2.58	604	99.3%	0.7%
7.000	0.40	3.34	607	99.8%	0.2%

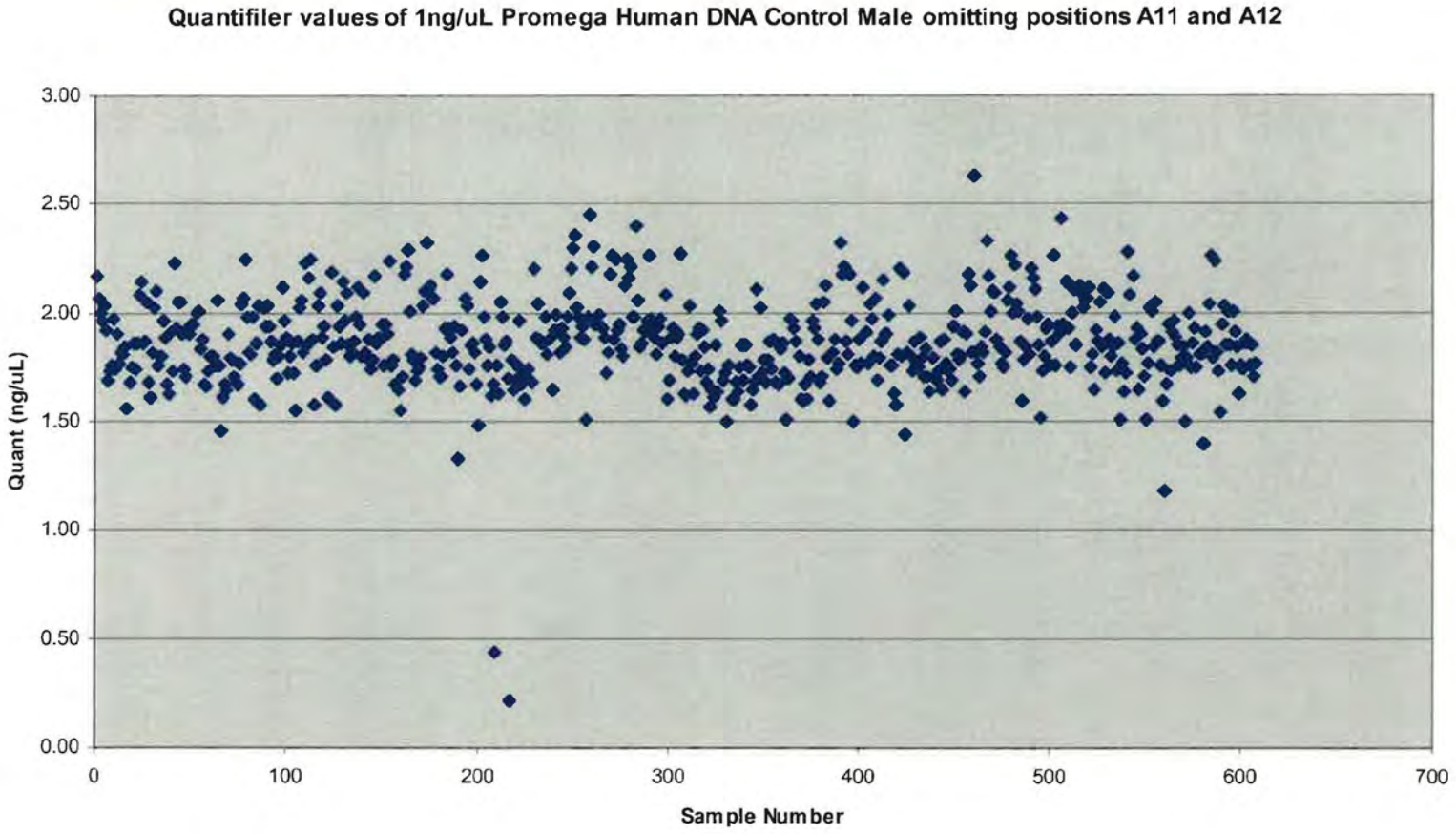

Figure 33. Quantifiler values of 1ng/µL Promega Male control omitting positions A11 and A12.

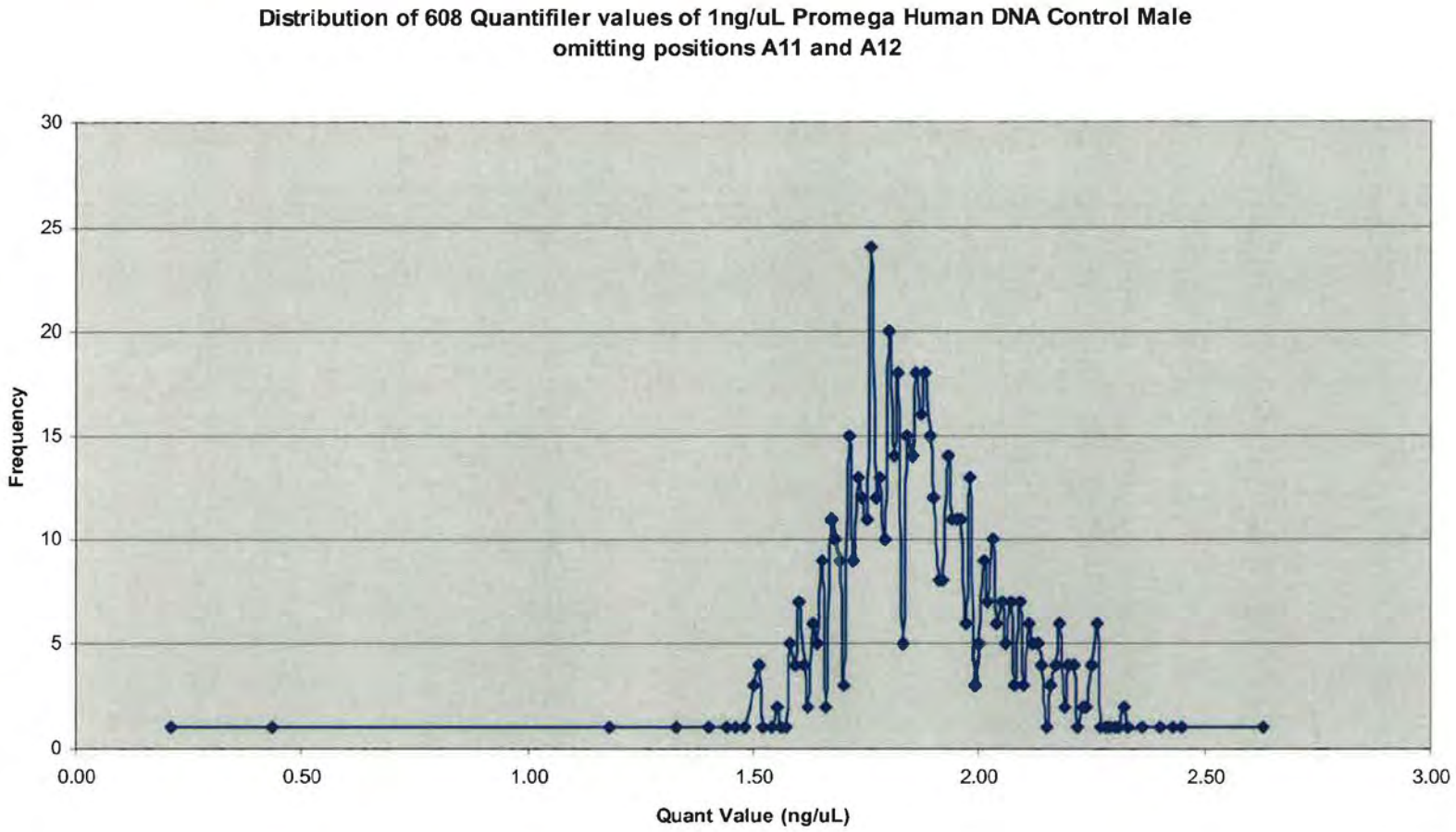

Figure 34. Distribution of 608 Quantifiler values of 1ng/µL Promega Male control omitting positions A11 and A12.

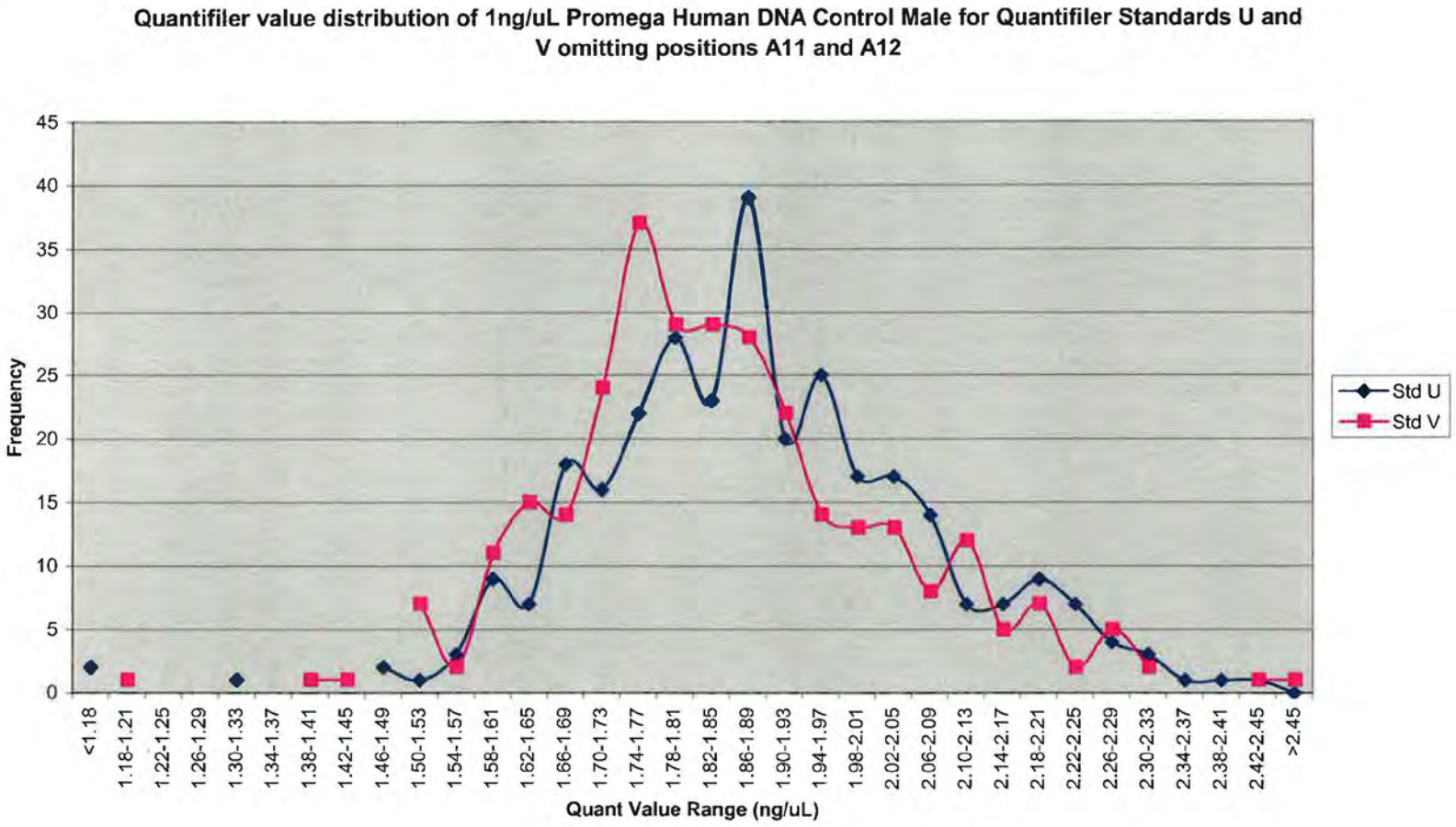

Figure 35. Quantifiler value distribution of 1ng/µL Promega Male control for Quantifiler standards U and V omitting positions A11 and A12.

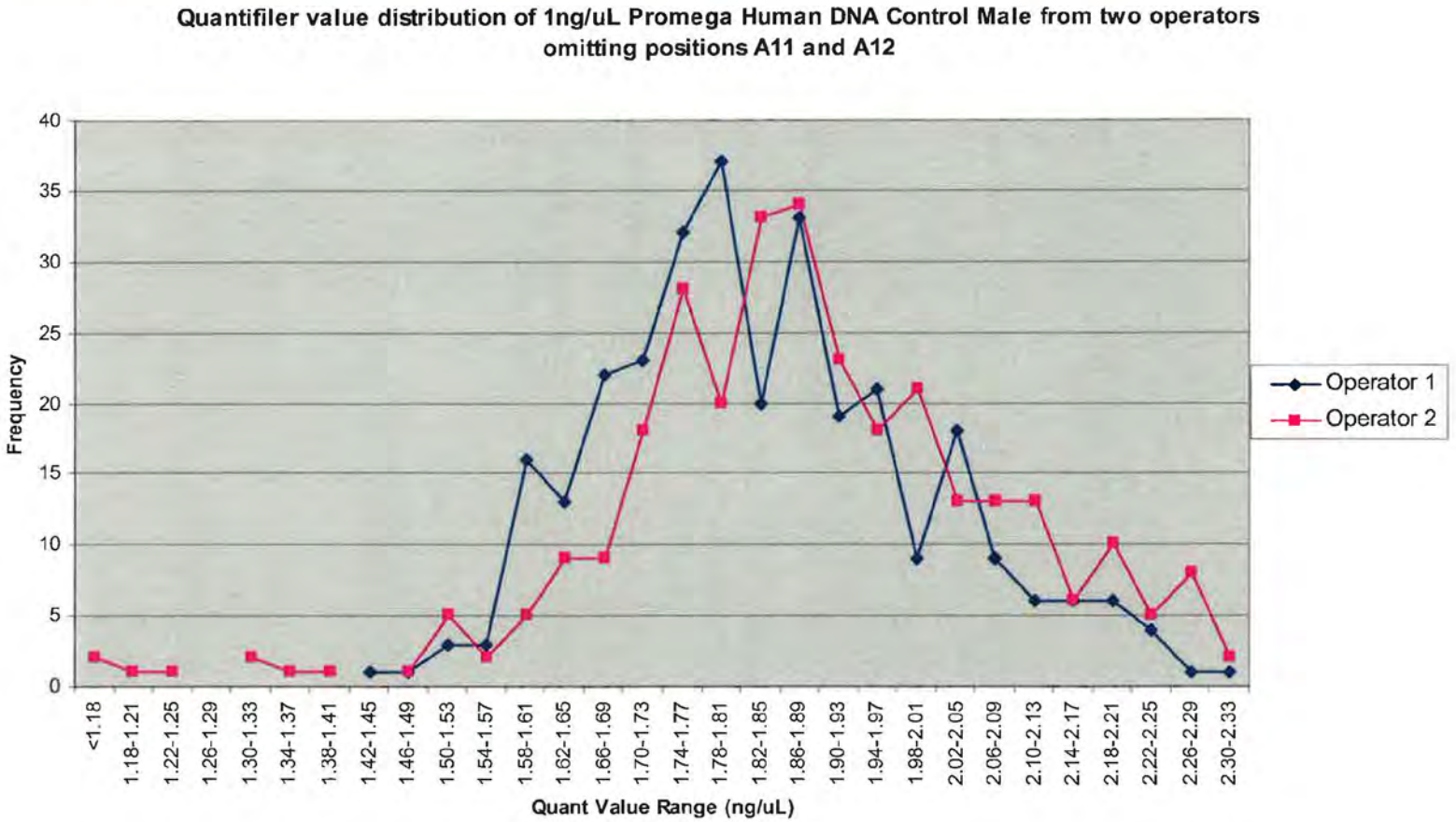

Figure 36. Quantifiler value distribution of 1ng/µL Promega Male control from two operators omitting positions A11 and A12.

Table 27. Table for 1ng/µL Promega Male control values for operator 1 omitting positions A11 and A12.

			Total sample number	304
			Standard Deviation (StdDev)	0.17
			Mean Quantifiler value	1.84
Standard deviation	Range in values		Values in range	Percentage in range
	Minimum	Maximum		
1	1.67	2.01	215	70.7%
2	1.50	2.18	292	96.1%
3	1.33	2.35	304	100.0%

Table 28. Table for 1ng/µL Promega Male control values for operator 2 omitting positions A11 and A12.

			Total sample number	304
			Standard Deviation (StdDev)	0.24
			Mean Quantifiler value	1.89
Standard deviation	Range in values		Values in range	Percentage in Range
	Minimum	Maximum		
1	1.65	2.13	249	81.9%
2	1.41	2.37	296	97.4%
3	1.17	2.61	302	99.3%

Table 29. Promega Male control (1ng/µL) Quantifiler value distribution for Quantifiler Standard U and omitting positions A11 and A12.

			Total sample number	304
			Standard deviation	0.22
			Mean Quantifiler value	1.88
deviation	Range in values			
(StdDev)	Minimum	Maximum	Values in range	Percentage in range
1	1.66	2.10	241	79.3%
2	1.44	2.32	298	98.0%
3	1.22	2.54	302	99.3%

Table 30. Promega Male control (1ng/µL) Quantifiler value distribution for Quantifiler Standard V and omitting positions A11 and A12.

			Total sample number	304
			Standard deviation	0.19
			Mean Quantifiler value	1.85
deviation	Range in values			
(StdDev)	Minimum	Maximum	Values in range	Percentage in range
1	1.66	2.04	220	72.4%
2	1.47	2.23	291	95.7%
3	1.28	2.42	301	99.0%

5.2.2.5 BETWEEN OPERATOR REPRODUCIBILITY

The data between the two operators was reproducible with a Quantifiler concentration reproducibility (95% confidence interval, 2-sided) value of 0.578ng/µL and Quantifiler CT reproducibility (95% confidence interval, 2-sided) value of 0.538CTs. This data is presented in table 31.

Table 31. Between operator reproducibility.

	OP1	OP2
Degrees of freedom	303	303
Mean Quant	1.84	1.89
StdDev Quant	0.17	0.24
Mean CT	27.970	28.028
StdDev CT	0.116	0.248
	Quant	CT
Combined StdDev Sc	0.208	0.193598
Degrees of freedom	606	606
t-value (2-sided,95%)	1.964	1.964
Rw (Within lab reproducibility)	0.578	0.538

5.2.2.6 BETWEEN QUANTIFILER STANDARD LOT REPRODUCIBILITY

The data from the two different standard lots was also reproducible with a Quantifiler concentration reproducibility (95% confidence interval, 2-sided) value of 0.572ng/µL and Quantifiler CT reproducibility (95% confidence interval, 2-sided) value of 0.542CTs. This data is presented in table 32.

Table 32. Between Quantifiler standard lot reproducibility. The differences resulting from using lot#0406006, batch U, vial 2 and lot#0412010, batch V, vial 2.

	U	V
Degrees of freedom	303	303
Mean Quant	1.88	1.85
StdDev Quant	0.22	0.19
Mean CT	28.01	27.98
StdDev CT	0.239	0.137
	Quant	**CT**
Combined StdDev Sc	0.206	0.195
Degrees of freedom	606	606
t-value (2-sided,95%)	1.964	1.964
Rw (Within lab reproducibility)	0.572	0.542

5.2.2.7 BETWEEN PLATE REPRODUCIBILITY AND REPEATABILITY

The data from the eight plates is presented in table 33. Quant and CT repeatability by plate was generally similar with the exception of the plate QFVAL_OP2_STDU_PLATE1_050305 which had the greater standard deviations. Mean values were still approximately similar ranging from 27.926 to 28.095 for the mean CT and 1.773 to 1.972 for the mean quant values.

Reproducibility was 0.524CTs for the CT value and 0.543ng/µL for the Quantifiler value. Repeatability was generally slightly higher for operator 2 than operator 1, showing that there is a minor difference in distribution from the two operators.

Table 33. Reproducibility and repeatability between plates.

Plate	Sample number	Mean CT	StdDev CT	Mean Quant	StdDev Quant	Degrees of freedom	t-value (2-sided, 95%)	CT repeatability by plate (r)	Quant repeatability by plate (r)
QFVAL_OP1_STDU_PLATE1_050305	76	27.951	0.113	1.839	0.152	75	1.992	0.319	0.427
QFVAL_OP1_STDU_PLATE2_070305	76	27.981	0.116	1.902	0.162	75	1.992	0.326	0.456
QFVAL_OP2_STDU_PLATE1_050305	76	28.095	0.422	1.810	0.320	75	1.992	1.188	0.901
QFVAL_OP2_STDU_PLATE2_080305	76	28.023	0.125	1.972	0.179	75	1.992	0.352	0.503
QFVAL_OP1_STDV_PLATE1_070503	76	27.966	0.107	1.773	0.150	75	1.992	0.301	0.422
QFVAL_OP1_STDV_PLATE2_080305	76	27.980	0.126	1.846	0.175	75	1.992	0.354	0.493
QFVAL_OP2_STDV_PLATE1_050305	76	27.926	0.137	1.960	0.193	75	1.992	0.385	0.543
QFVAL_OP2_STDV_PLATE2_090305	76	28.067	0.140	1.830	0.182	75	1.992	0.395	0.513

	CT	Quant
Combined StdDev Sc	0.189	0.196
Combined degrees of freedom	600	600
t-value (2-sided, 95%)	1.964	1.964
Rw	0.524	0.543

5.2.3 PROMEGA MALE CONTROL {ACCURACY AND PRECISION (REPEATABILITY)}: 1ng/µL CONCENTRATION ACCURACY AND PRECISION (REPEATABILITY)

5.2.3.1 AIM

The aim of this experiment was to compare amplification at corner wells and vertical edges with and without the Precision Plate Holder for ABI 7000 SDS (Applied Biosystems).

5.2.3.2 METHOD

1. Quantifiler Human DNA Standard was prepared according to SOP 21963R0 "Real Time PCR Quantification of Human DNA using Quantifiler Human DNA Quantification Kit (Applied Biosystems)" using $T_{10}E_{0.1}$-glycogen (5mL TE + 5µL glycogen 20mg/mL) as the recommended diluent.

2. It must be noted that the labels on Quantifiler Human DNA Standard tubes indicate neither DNA concentration nor volume of solution. However, the product insert for the Quantifiler kit claims that the Human DNA Standard is at a concentration of 200ng/µL. The method for creating the DNA standard dilution series in SOP 219630 assumes or implies a Human DNA Standard stock concentration of 200ng/µL (the actual stock concentration is not listed in the SOP).

3. TE^{-4} used for eluting DNA was autoclaved in-house TE (batch VH 2.2.05).

4. Promega Male control (G147A, lot#18797901, Promega Corp., Madison, WI, USA) was received on the 24th of February, 2005 and diluted on the 4th of April, 2005 from the in-tube concentration of 177ng/µL to 100ng/µL by adding 150µL of DNA (using Socorex pipettor serial#14073619) to 115.5µL of TE^{-4} (using Socorex pipettor serial#14073619) to make a total volume of 265.5µL in a sterile 1.5mL tube. This was vortexed and briefly centrifuged. 100µL was removed with the Socorex pipettor (serial#14073619) to another 1.5mL tube. The 100µL was diluted with 900µL of TE^{-4} using Eppendorf pipette (serial#3325731) to make a total of 1000µL of 10ng/µL DNA. This was vortexed and briefly centrifuged. 100µL was removed with the Socorex pipettor (serial#14073619) to another 1.5mL tube. The 100µL was diluted with 900µL of TE^{-4} using Eppendorf pipette (serial#3325731) to make a total of 1000µL of 1ng/µL DNA. This was vortexed and briefly centrifuged.

5. A Quantifiler reaction was set up on a 96-well plate (see figure 37), and run on the ABI Prism® 7000 SDS instrument (Applied Biosystems, Foster City, CA, USA). The ABI Sequence Detection System software allows the analysis of data to compare samples to DNA standards within the same run (after completion of the quantification reaction). For more detailed information on the Quantifiler reaction, refer to SOP 21963R0 and references therein.

	1	2	3	4	5	6	7	8	9	10	11	12
A	Promega 1ng/µL	Promega 1ng/µL	X	X	Promega 1ng/µL	**STD#1 50 ng/µL**	**STD#1 50 ng/µL**	Promega 1ng/µL	X	X	Promega 1ng/µL	Promega 1ng/µL
B	Promega 1ng/µL	X	X	X	Promega 1ng/µL	**STD#2 16.7ng/µL**	**STD#2 16.7ng/µL**	Promega 1ng/µL	X	X	X	Promega 1ng/µL
C	Promega 1ng/µL	X	X	X	Promega 1ng/µL	**STD#3 5.56ng/µL**	**STD#3 5.56ng/µL**	Promega 1ng/µL	X	X	X	Promega 1ng/µL
D	Promega 1ng/µL	X	X	NegCtl	Promega 1ng/µL	**STD#4 1.85ng/µL**	**STD#4 1.85ng/µL**	Promega 1ng/µL	NegCtl	X	X	Promega 1ng/µL
E	Promega 1ng/µL	X	X	X	Promega 1ng/µL	**STD#5 0.62ng/µL**	**STD#5 0.62ng/µL**	Promega 1ng/µL	X	X	X	Promega 1ng/µL
F	Promega 1ng/µL	X	X	X	Promega 1ng/µL	**STD#6 0.21ng/µL**	**STD#6 0.21ng/µL**	Promega 1ng/µL	X	X	X	Promega 1ng/µL
G	Promega 1ng/µL	X	X	X	Promega 1ng/µL	**STD#7 0.068ng/µL**	**STD#7 0.068ng/µL**	Promega 1ng/µL	X	X	X	Promega 1ng/µL
H	Promega 1ng/µL	Promega 1ng/µL	X	X	Promega 1ng/µL	**STD#8 0.023ng/µL**	**STD#8 0.023ng/µL**	Promega 1ng/µL	X	X	Promega 1ng/µL	Promega 1ng/µL

Figure 37. Platemap for analysing the edges and the corners.

5.2.3.3 RESULTS

It was found that without the Precision Plate Holder from Applied Biosysetms, the corner positions A11 and A12 produced the most extreme values (see table 34). Therefore, when running a plate without the Precision Plate Holder, it is essential that these corner wells are omitted. Positions D1 and E1 produced the lowest mean values. Quantifiler standards #4 and #5 are run at these positions and may result in the Y-intercept being slightly lower. As a result, the "ravine" or "dip" in the middle of the left side may explain some of the bias observed with the Quantifiler system that is not due to the manufacture of the standards (see figure 39). Thus controls run elsewhere on the plate based on the standards being in the left two lanes may typically produce higher Quantifiler values than what is expected.

Table 34. Results with and without the Precision Plate Holder. The cells highlighted in red indicate the more extreme values obtained. The use of the Precision plate also resulted in some high standard deviations and overall 95% confidence intervals but appears to have removed the inconsistency with positions A11 and A12.

QF_VAL_PRECPLT_WOUT02_070405

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	2.09	2.63			2.31			2.08			1.78	1.80
B	2.01				2.06			2.15				2.14
C	2.02				2.47			2.44				2.09
D	1.88				2.51			2.45				2.06
E	1.96				2.70			2.43				2.12
F	2.05				2.35			2.30				2.16
G	2.20				2.25			2.14				2.17
H	2.03	2.09			2.23			2.20			2.24	2.05

QF_VAL_PRECPLT_WOUT01_050405

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	2.02	2.24			2.04			2.41			1.78	1.89
B	2.11				2.26			2.29				2.10
C	2.02				2.81			2.35				2.36
D	1.84				2.45			2.48				2.21
E	1.71				2.58			2.61				2.31
F	2.47				2.37			2.18				2.42
G	1.79				2.17			2.46				1.93
H	2.16	2.45			2.55			2.17			2.20	2.12

Overall mean by position

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	2.01	2.44			2.48			2.35			1.97	1.93
B	2.06				2.49			2.27				2.12
C	2.02				2.64			2.40				2.09
D	1.86				2.48			2.47				2.14
E	1.88				2.62			2.53				2.22
F	2.26				2.36			2.24				2.29
G	2.00				2.21			2.27				2.05
H	2.10	2.27			2.49			2.19			2.22	2.09

Overall standard deviation by position

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	0.01	0.28			0.22			0.22			0.01	0.05
B	0.07				0.26			0.17				0.03
C	0.00				0.24			0.06				0.02
D	0.03				0.04			0.01				0.11
E	0.04				0.12			0.11				0.13
F	0.30				0.01			0.08				0.18
G	0.29				0.06			0.18				0.17
H	0.09	0.25			0.21			0.07			0.03	0.03

Overall 95% Confidence Interval

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	1.41%	22.85%			16.56%			20.79%			1.69%	1.79%
B	0.67%				23.05%			14.95%				2.67%
C	0.00%				18.21%			5.31%				1.78%
D	3.64%				3.42%			1.19%				9.94%
E	4.20%				9.19%			8.54%				12.13%
F	25.28%				1.20%			7.58%				18.04%
G	29.06%				9.12%			16.36%				16.36%
H	8.78%	22.43%			17.66%			1.94%			2.55%	4.78%

QF_VAL_PRECPLT_WITH01_050405

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	1.95	2.40			2.39			2.42			2.06	2.35
B	1.99				2.40			2.21				2.11
C	1.58				2.58			2.56				2.23
D	1.96				2.58			2.51				2.43
E	1.99				2.71			2.69				2.52
F	1.97				2.47			2.50				2.29
G	2.26				2.43			2.44				2.30
H	2.16	2.14			2.56			2.31			2.50	2.13

QF_VAL_PRECPLT_WITH02_070405

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	2.14	2.56			3.01			2.15			2.24	2.33
B	1.71				2.23			2.13				1.97
C	2.09				2.80			2.48				2.15
D	1.61				2.73			2.61				2.29
E	1.69				2.54			2.19				2.08
F	2.00				2.18			2.20				2.25
G	1.47				2.64			2.33				2.14
H	2.18	2.25			2.16			2.18			2.21	2.05

Overall mean by position

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	2.03	2.48			2.83			2.29			2.10	2.34
B	1.85				2.32			2.18				2.04
C	1.84				2.69			2.52				2.24
D	1.78				2.66			2.56				2.34
E	1.83				2.63			2.40				2.45
F	1.99				2.33			2.33				2.32
G	2.43				2.24			2.39				2.22
H	2.13	2.20			2.36			2.26			2.40	2.09

Overall standard deviation by position

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	0.13	0.11			0.50			0.19			0.13	0.01
B	0.29				0.12			0.04				0.10
C	0.43				0.16			0.09				0.13
D	0.06				0.11			0.07				0.12
E	0.19				0.12			0.25				0.10
F	0.07				0.21			0.21				0.10
G	0.04				0.29			0.08				0.13
H	0.04	0.08			0.28			0.09			0.27	0.08

Overall 95% Confidence Interval

Position	1	2	3	4	5	6	7	8	9	10	11	12
A	13.14%	9.12%			29.93%			16.71%			11.84%	1.21%
B	21.40%				10.29%			3.89%				9.71%
C	29.21%				11.58%			4.49%				11.38%
D	7.93%				7.69%			3.52%				10.68%
E	20.92%				9.16%			24.21%				8.08%
F	2.14%				17.64%			18.05%				8.59%
G	5.25%				24.68%			6.52%				10.19%
H	3.96%	7.08%			23.97%			8.19%			22.39%	5.41%

With the utilization of the Precision Plate Holder, the "ravine" or "dip" observed on the left-hand side was still present (also see figure 42), and position C1 now produced extreme overall standard deviation and overall 95% Confidence Interval. A5 also produced extreme values. The problems with positions A11 and A12 were not replicated with the Precision Plate Holder. Therefore, while the Precision Plate Holder appeared to have resolved the issue with A11 and A12, it had wider and more extreme values for positions that were non-problematic without the Precision Plate Holder. Some of the samples outside of one and two standard deviations are presented in table 35. In Figure 38, it is possible to see that A11 and A12 (green and red-lined amplification plots) are in fact outliers. These were corrected in Figure 41. In figures 40 and 43, it is possible to see that the higher values were generally in the middle of the plate, while the lower values concentrated around the edges and corners (with the exception of A11 and A12). It is therefore clear that the plate may not be homogeneous or even in heat distribution, although the system did pass the TaqMan® RNase P 96-Well Instrument Verification Plate test from Applied Biosystems (data not shown) and the system is routinely calibrated by Applied Biosystems.

We recommend that the system is run without the Precision Plate Holder but omitting positions A11 and A12. Standards should be run on the left hand side two columns because there is data to support how they are expected to perform from the validation data in this document.

Table 35. Analysis of results with and without the Precision Plate Holder.

Plate Holder	No	No	Yes	Yes
Date	5/04/2005	7/04/2005	5/04/2005	7/04/2005
Mean	2.30	2.20	2.30	2.24
Standard Deviation	0.372	0.272	0.272	0.286
Minimal Value in Range	1.71	1.66	1.56	1.65
Maximum Value in Range	3.89	2.70	2.71	3.01
1 StdDev Minimum Value in Range	1.93	1.93	2.03	1.95
1 StdDev Maximum Value in Range	2.67	2.47	2.57	2.53
2 StdDev Minimum Value in Range	1.56	1.66	1.76	1.67
2 StdDev Maximum Value in Range	3.04	2.74	2.84	2.81
Positions below range in 1 StdDev	A11, D1, E1, G1	D1, E1, A11, A12	A1,B1,C1,D1,E1,F1	B1, D1, E1
Positions below range in 2 StdDev	0	0	C1, D1	D1
Positions above range in 1 StdDev	A12, C5	A2, B5, D5, D8, E5	C5, D5, E5, E8, H11	A2, A5, C5, D5, D8, E5
Positions above range in 2 StdDev	A12	0	0	A5

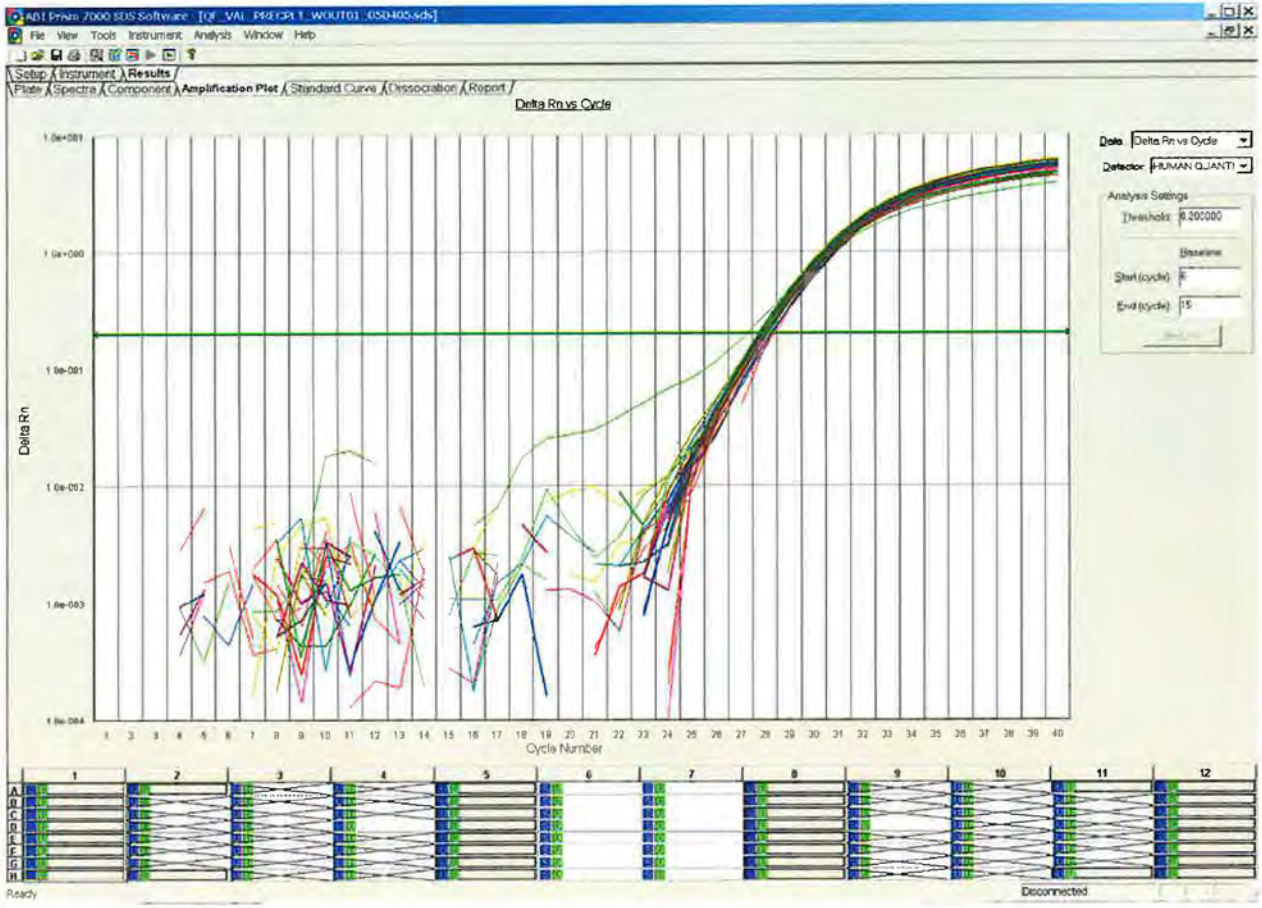

Figure 38. An amplification plot without the Precision Plate Holder. Note that the amplification plots from positions A11 and A12 are the green and red outliers.

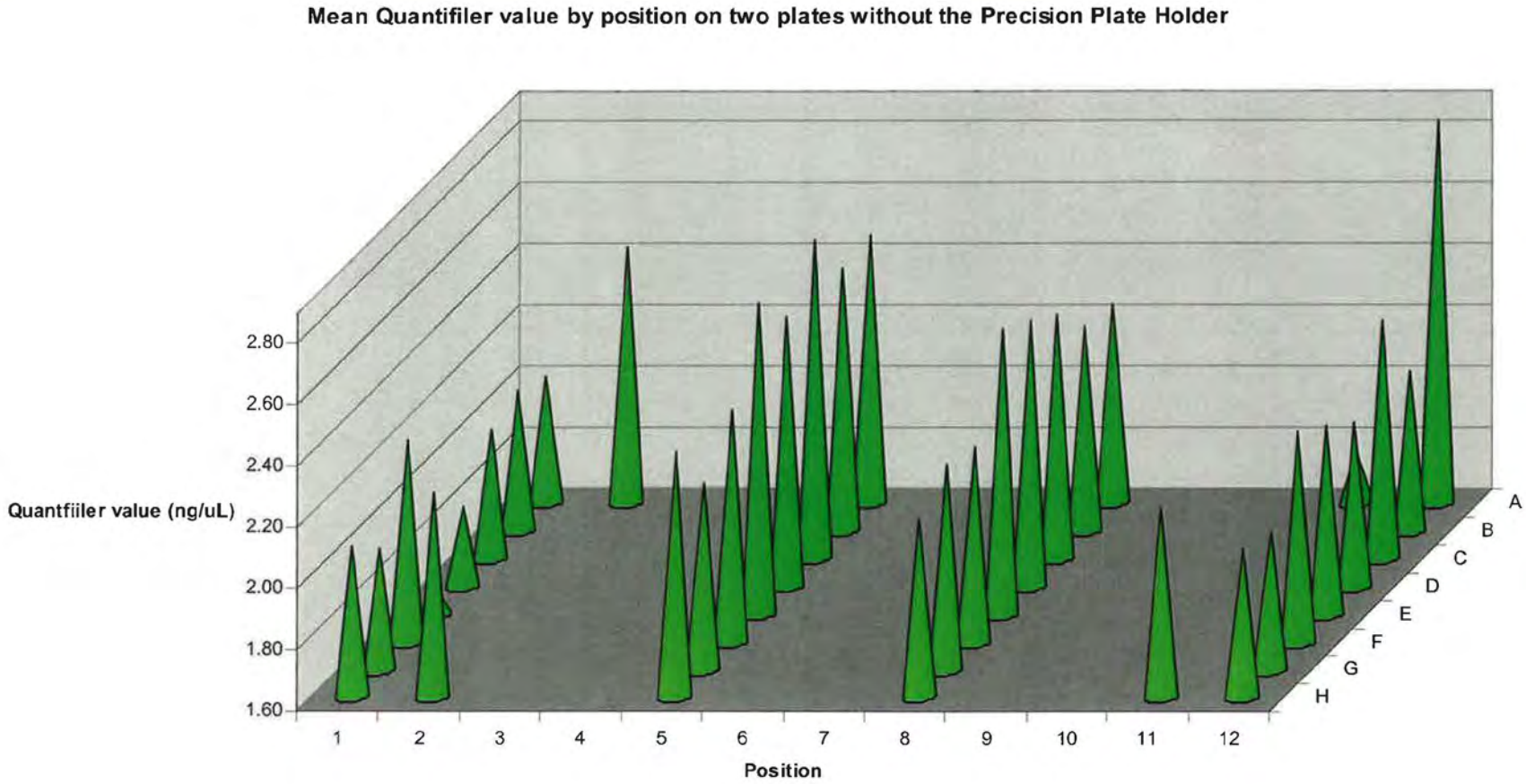

Figure 39. Mean Quantifiler value by position from two plates without the Precision Plate Holder.

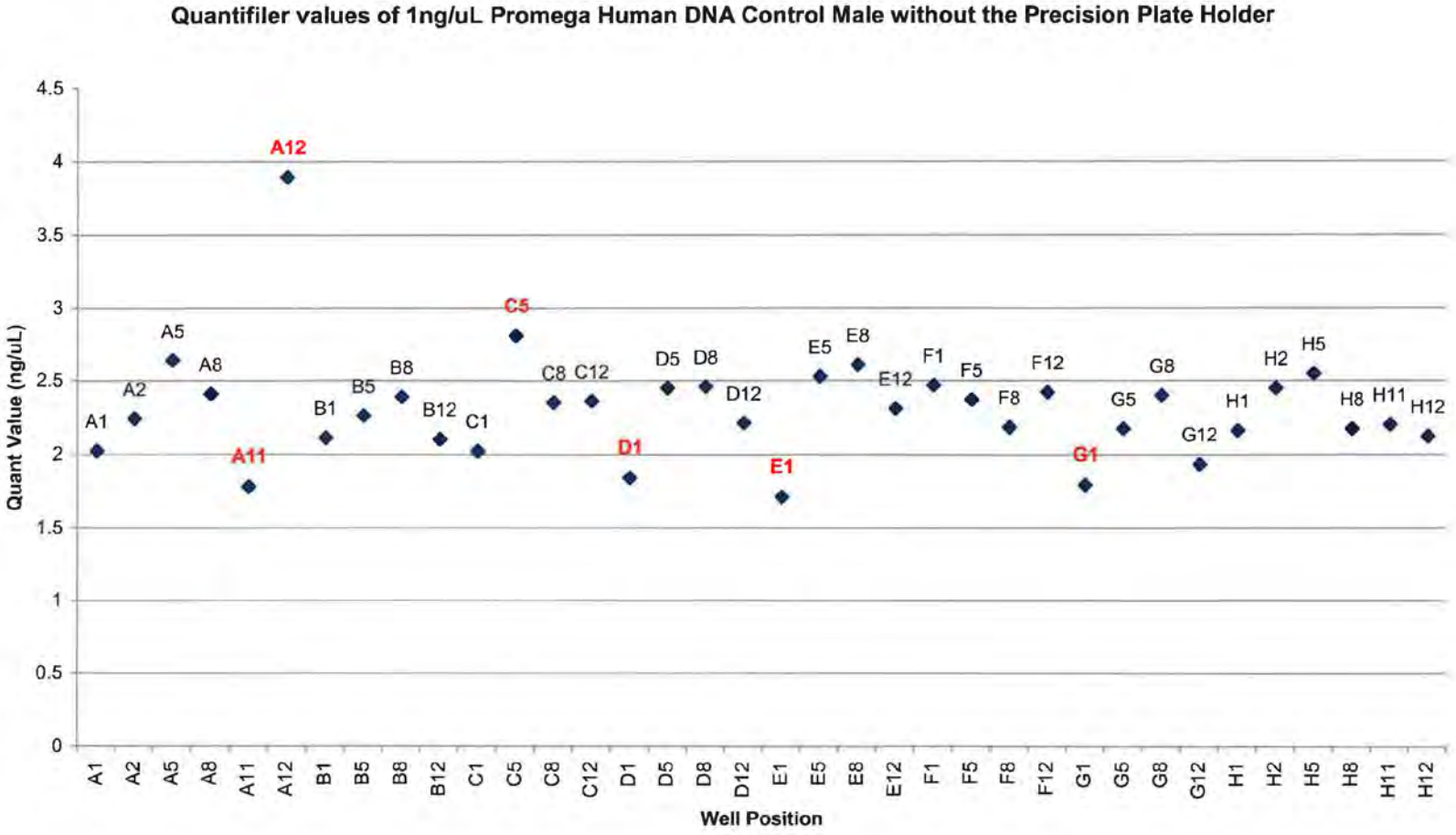

Figure 40. Quantifiler values of 1ng/µL Promega Male control without the Precision Plate Holder.

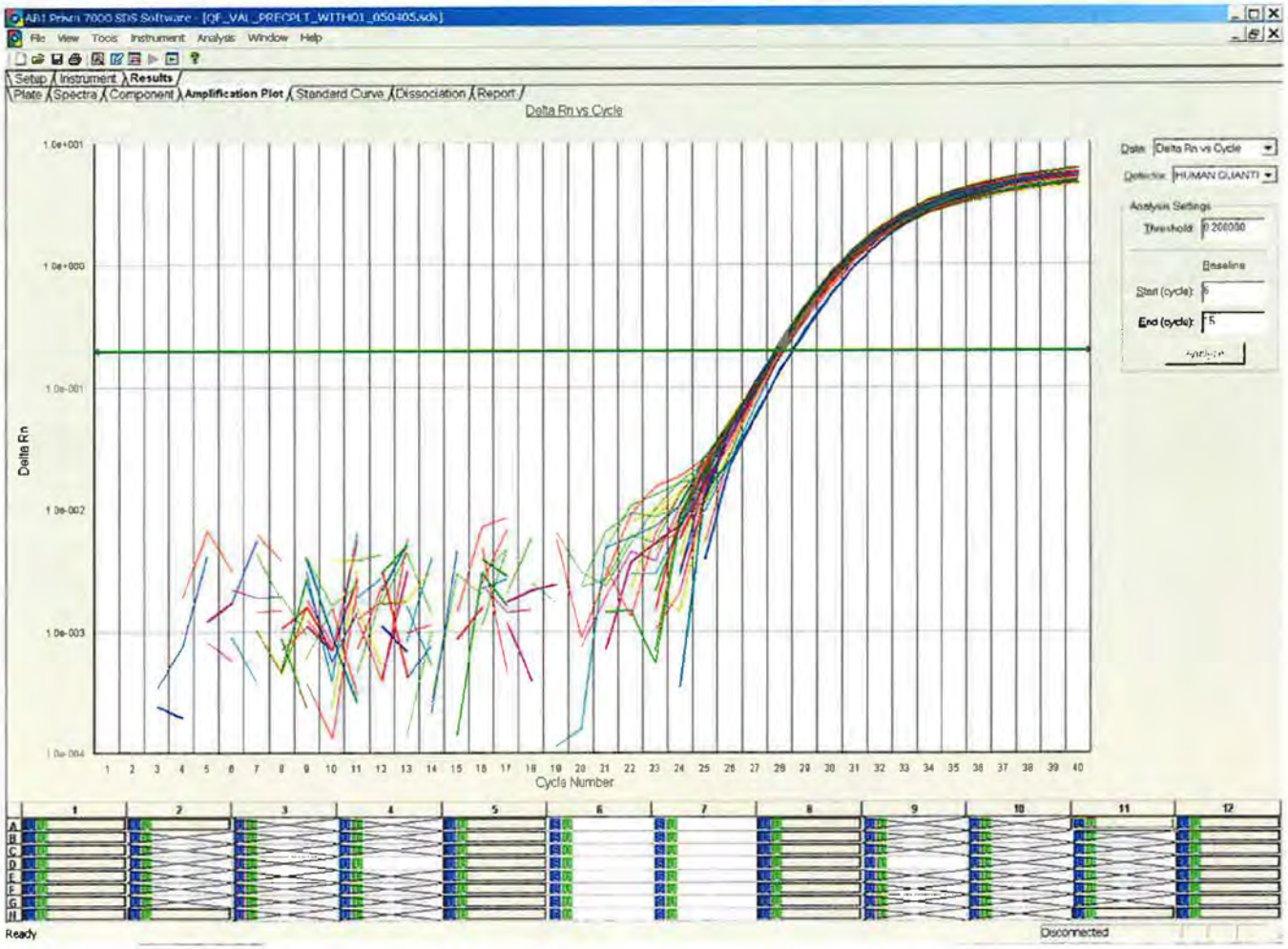

Figure 41. An amplification plot with the Precision Plate Holder.

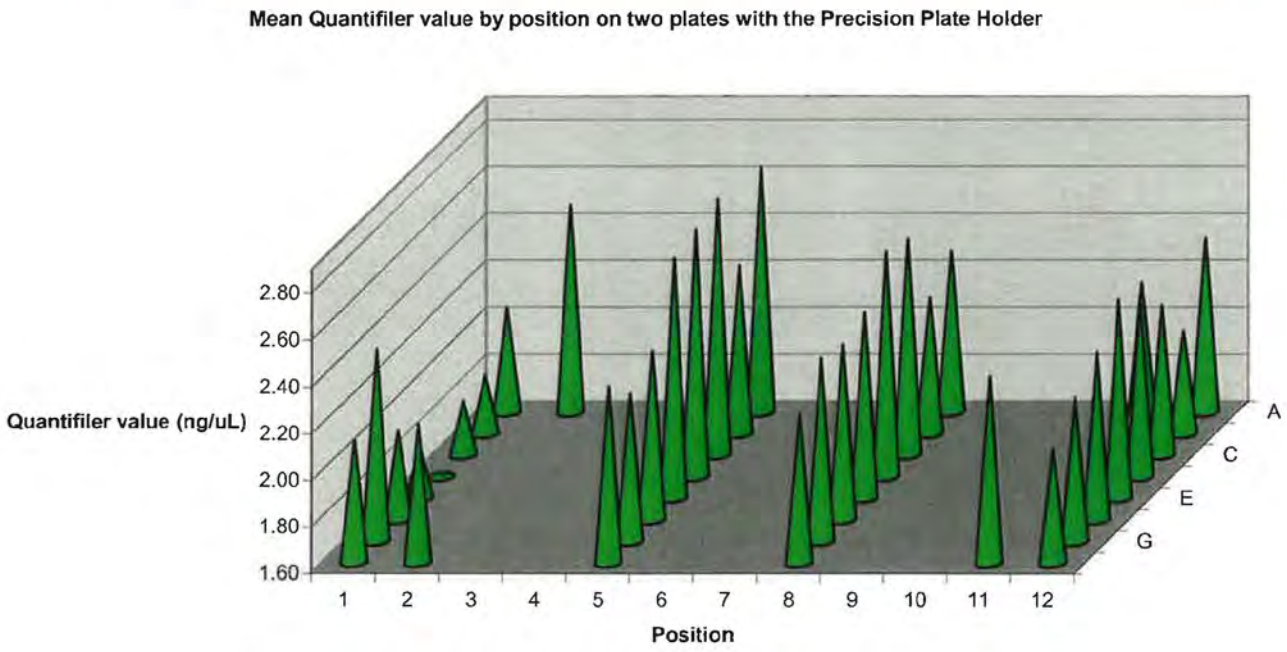

Figure 42. Mean Quantifiler value of 1ng/µL Promega Male control by position on two plates with the Precision Plate Holder.

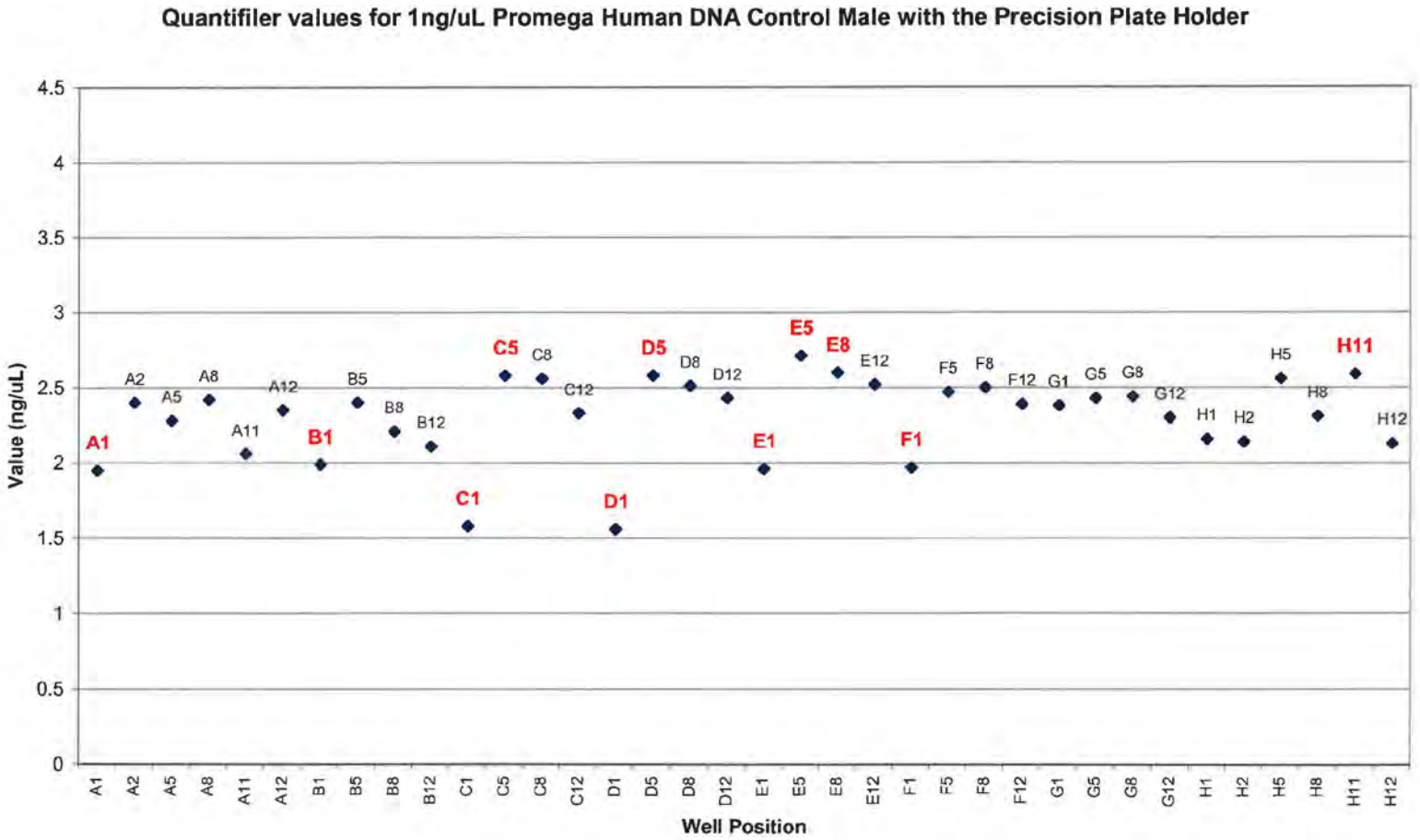

Figure 43. Quantifiler values for 1ng/µL Promega Male control with the Precision Plate Holder.

5.3 ACCURACY AND REPEATABILITY OF STANDARDS

5.3.1 METHOD

Quantifiler standard, Promega Male control, Promega Female control and a Roche control were diluted according to provided DNA concentrations to the expected concentrations below in table 36. These were run on two plates with the EPC, 1ng/µL Promega male control and a Buccal control (approximately 1.0ng/µL buccal cell extract from an FTA card) following the platemap format in figure 44. The results were analysed with respect to each of the four standards.

Table 36. Human DNA standard concentrations.

Human DNA Standard Concentrations	
Standard #	[DNA] ng/µl
1	50.00
2	16.70
3	5.560
4	1.850
5	0.620
6	0.210
7	0.068
8	0.023

	1	2	3	4	5	6	7	8	9	10	11	12
A	Quantifiler STD#1 50 ng/µL	Quantifiler STD#1 50 ng/µL	Promega Male STD#1 50 ng/µL	Promega Male STD#1 50 ng/µL	Promega Female STD#1 50 ng/µL	Promega Female STD#1 50 ng/µL	Promega Female STD#1 50 ng/µL	Roche STD#1 50 ng/µL	Roche STD#1 50 ng/µL	Roche STD#1 50 ng/µL	X	X
B	Quantifiler STD#2 16.7ng/µL	Quantifiler STD#2 16.7ng/µL	Promega Male STD#2 16.7ng/µL	Promega Male STD#2 16.7ng/µL	Promega Female STD#2 16.7ng/µL	Promega Female STD#2 16.7ng/µL	Promega Female STD#2 16.7ng/µL	Roche STD#2 16.7ng/µL	Roche STD#2 16.7ng/µL	Roche STD#2 16.7ng/µL	Promega Male 1 ng/µL	Promega Male 1 ng/µL
C	Quantifiler STD#3 5.56ng/µL	Quantifiler STD#3 5.56ng/µL	Promega Male STD#3 5.56ng/µL	Promega Male STD#3 5.56ng/µL	Promega Female STD#3 5.56ng/µL	Promega Female STD#3 5.56ng/µL	Promega Female STD#3 5.56ng/µL	Roche STD#3 5.56ng/µL	Roche STD#3 5.56ng/µL	Roche STD#3 5.56ng/µL	Promega Male 1 ng/µL	Promega Male 1 ng/µL
D	Quantifiler STD#4 1.85ng/µL	Quantifiler STD#4 1.85ng/µL	Promega Male STD#4 1.85ng/µL	Promega Male STD#4 1.85ng/µL	Promega Female STD#4 1.85ng/µL	Promega Female STD#4 1.85ng/µL	Promega Female STD#4 1.85ng/µL	Roche STD#4 1.85ng/µL	Roche STD#4 1.85ng/µL	Roche STD#4 1.85ng/µL	EPC	EPC
E	Quantifiler STD#5 0.62ng/µL	Quantifiler STD#5 0.62ng/µL	Promega Male STD#5 0.62ng/µL	Promega Male STD#5 0.62ng/µL	Promega Female STD#5 0.62ng/µL	Promega Female STD#5 0.62ng/µL	Promega Female STD#5 0.62ng/µL	Roche STD#5 0.62ng/µL	Roche STD#5 0.62ng/µL	Roche STD#5 0.62ng/µL	EPC	EPC
F	Quantifiler STD#6 0.21ng/µL	Quantifiler STD#6 0.21ng/µL	Promega Male STD#6 0.21ng/µL	Promega Male STD#6 0.21ng/µL	Promega Female STD#6 0.21ng/µL	Promega Female STD#6 0.21ng/µL	Promega Female STD#6 0.21ng/µL	Roche STD#6 0.21ng/µL	Roche STD#6 0.21ng/µL	Roche STD#6 0.21ng/µL	Buccal control	Buccal control
G	Quantifiler STD#7 0.068ng/µL	Quantifiler STD#7 0.068ng/µL	Promega Male STD#7 0.068ng/µL	Promega Male STD#7 0.068ng/µL	Promega Female STD#7 0.068ng/µL	Promega Female STD#7 0.068ng/µL	Promega Female STD#7 0.068ng/µL	Roche STD#7 0.068ng/µL	Roche STD#7 0.068ng/µL	Roche STD#7 0.068ng/µL	Buccal control	Buccal control
H	Quantifiler STD#8 0.023ng/µL	Quantifiler STD#8 0.023ng/µL	Promega Male STD#8 0.023ng/µL	Promega Male STD#8 0.023ng/µL	Promega Female STD#8 0.023ng/µL	Promega Female STD#8 0.023ng/µL	Promega Female STD#8 0.023ng/µL	Roche STD#8 0.023ng/µL	Roche STD#8 0.023ng/µL	Roche STD#8 0.023ng/µL	H2O	H2O

Figure 44. A platemap of Testquant_130905 and Testquant_140905.

5.3.2 RESULTS

CT means for the samples and their IPCs as well as their standard deviations were calculated and are presented in table 37. It was found that Quantifiler standards #1 to #8 had the highest CT values out of all the standard types created and that the Applied Biosystems Quantifiler standard was a clear outlier compared to the genomic DNA standards tested. In table 39 and figure 49, the CT values and distributions were compared to those from complementary data and published sources (ADFS 2005 and Applied Biosystems 2003). Even the published ADFS and ABI standards produced higher CT values than those from the genomic samples.

A comparison of the Quantifiler values obtained (in table 38) demonstrates that the Quantifiler standard is a clear outlier with a mean difference of 158% to the 'true' or 'expected' concentration. The Human genomic DNA standards produced values nearer to what was expected, with a mean difference of 28-29% of the "true' or 'expected' values. That the Quantifiler standard is an outlier is further demonstrated in the linear (Figures 47 and 48) and logarithmic (Figures 45 and 46) distribution graphs of the results.

In figure 50 we present the linearity analysis of the four standards tested. These graphs were made based on mean Quantifiler values for each of the standards. Of interest is the difference in the constants which can be related back to the Y-intercept values. We document that the Quantifiler standard had a constant of 22.482 while the Promega male standard had a constant of 21.5. That is a difference of approximately 1 CT, accounting for the doubling effect that has been observed in the results. Another interesting feature is that m or the slopes range from 1.422 to 1.4588. In theory, a difference of 1 CT between adjacent standards should equal double the concentration, whereas 1.5 CTs should equal the three-fold difference expected in the 1 in 3 dilutions of the standards. The fact that m is lower than 1.5 may indicate that there is a slight loss of DNA of approximately between 2.7-5.2% between each standard made up by serial dilution. This could be a loss due to DNA adhering to the pipette tips. Alternatively or additionally, the Quantifiler system may have a bias where one CT difference does not exactly represent a doubling of concentration.

Mean IPC CT values (table 37 and Figure 51) were typically the lowest for the Quantifiler standard, especially for standard #1 and #2. These are the higher concentration standards. Therefore, there may be some inhibition from the genomic Human DNA standards at the higher concentrations. This is indicative that the IPC system should not be utilized for genomic Human DNA control samples over 50ng/µL in concentration because of inhibitors inherent in the samples and because of the genomic Human DNA samples amplified outcompeting the IPC reaction at higher concentrations.

Table 37. Human DNA standard CT and IPC CT values. The CT values and standard deviations for standards one to eight and their IPCs are found in this table. Note that the Quantifiler Human DNA standards are typically higher by approximately one CT value.

Sample Name	CT Means	CT StdDev	IPC CT Means	IPC CT StdDev
Quantifiler STD#1	23.833	0.161	26.873	0.231
Promega Male STD#1	22.658	0.084	27.730	0.462
Promega Female STD#1	22.550	0.043	28.990	0.605
Roche STD#1	22.390	0.083	29.043	0.387
Quantifiler STD#2	25.318	0.082	26.905	0.108
Promega Male STD#2	24.258	0.034	26.983	0.075
Promega Female STD#2	24.182	0.046	27.368	0.225
Roche STD#2	23.980	0.033	27.937	0.251
Quantifiler STD#3	27.003	0.081	26.933	0.068
Promega Male STD#3	26.005	0.069	26.878	0.103
Promega Female STD#3	25.792	0.087	27.065	0.092
Roche STD#3	25.560	0.046	27.177	0.048
Quantifiler STD#4	28.475	0.105	26.985	0.026
Promega Male STD#4	27.505	0.114	26.915	0.054
Promega Female STD#4	27.288	0.035	26.967	0.115
Roche STD#4	27.145	0.071	27.045	0.049
Quantifiler STD#5	29.835	0.146	27.070	0.052
Promega Male STD#5	28.955	0.152	26.995	0.041
Promega Female STD#5	28.642	0.101	27.112	0.079
Roche STD#5	28.500	0.213	27.095	0.082
Quantifiler STD#6	31.200	0.189	27.083	0.071
Promega Male STD#6	30.140	0.085	27.075	0.082
Promega Female STD#6	30.032	0.074	27.135	0.063
Roche STD#6	30.013	0.096	27.187	0.043
Quantifiler STD#7	32.475	0.168	27.203	0.108
Promega Male STD#7	31.353	0.225	27.103	0.046
Promega Female STD#7	31.187	0.132	27.172	0.055
Roche STD#7	31.313	0.219	27.200	0.064
Quantifiler STD#8	34.233	0.110	27.230	0.089
Promega Male STD#8	32.850	0.448	27.223	0.081
Promega Female STD#8	32.600	0.442	27.268	0.047
Roche STD#8	32.485	0.285	27.320	0.049
Promega 1ng/uL	27.995	0.118	27.168	0.059
EPC	31.160	0.120	27.211	0.062
Buccal control	28.033	0.056	27.194	0.076
H2O	Undetermined	Undetermined	27.418	0.026

Table 38. Quantifiler values resulting from using four different standards. The greatest difference was obtained by using the Quantifiler standard. This was gave a mean difference of 158% compared to the expected or 'true' concentration.

		Quantifiler	Promega Male	Promega Female	Roche	Quantifiler	Promega Male	Promega Female	Roche
Sample Name	Expected concentration (ng/uL)	Quantity	Quantity	Quantity	Quantity	Difference	Difference	Difference	Difference
Quantifiler STD#1	50		23.84	21.18	17.73		52%	58%	65%
Quantifiler STD#1	50		30.18	26.79	22.27		40%	46%	55%
Quantifiler STD#1	50		22.19	20.08	17.86		56%	60%	64%
Quantifiler STD#1	50		25.32	22.99	20.42		49%	54%	59%
Promega Male STD#1	50	122.85		52.3	42.6	146%		5%	15%
Promega Male STD#1	50	136.08		58.04	47.12	172%		16%	6%
Promega Male STD#1	50	126.35		54.02	47.48	153%		8%	5%
Promega Male STD#1	50	140.68		60.37	52.99	181%		21%	6%
Promega Female STD#1	50	141.89	68.46		49.11	184%	37%		2%
Promega Female STD#1	50	150.01	72.47		51.88	200%	45%		4%
Promega Female STD#1	50	141.95	68.49		49.13	184%	37%		2%
Promega Female STD#1	50	143.81	66.4		54.2	188%	33%		8%
Promega Female STD#1	50	134.47	62.05		50.6	169%	24%		1%
Promega Female STD#1	50	143.16	66.09		53.94	186%	32%		8%
Roche STD#1	50	159.33	77.07	68.14		219%	54%	36%	
Roche STD#1	50	181.79	88.19	77.93		264%	76%	56%	
Roche STD#1	50	166.76	80.75	71.38		234%	62%	43%	
Roche STD#1	50	153.22	70.78	65.93		206%	42%	32%	
Roche STD#1	50	155.62	71.9	67		211%	44%	34%	
Roche STD#1	50	151.06	69.77	64.97		202%	40%	30%	

		Quantifiler	Promega Male	Promega Female	Roche	Quantifiler	Promega Male	Promega Female	Roche
Sample Name	Expected concentration (ng/uL)	Quantity	Quantity	Quantity	Quantity	Difference	Difference	Difference	Difference
Quantifiler STD#2	16.67		8.11	7.24	6.26		51%	57%	62%
Quantifiler STD#2	16.67		8.13	7.26	6.28		51%	56%	62%
Quantifiler STD#2	16.67		7.54	6.64	5.99		55%	60%	64%
Quantifiler STD#2	16.67		8.76	7.75	6.97		47%	54%	58%
Promega Male STD#2	16.67	39.4		16.43	13.87	136%		1%	17%
Promega Male STD#2	16.67	39.22		16.36	13.81	135%		2%	17%
Promega Male STD#2	16.67	38.47		15.8	14.1	131%		5%	15%
Promega Male STD#2	16.67	40.7		16.75	14.93	144%		0%	10%
Promega Female STD#2	16.67	42.3	19.87		14.87	154%	19%		11%
Promega Female STD#2	16.67	39.63	18.59		13.95	138%	12%		16%
Promega Female STD#2	16.67	42.07	19.76		14.79	152%	19%		11%
Promega Female STD#2	16.67	41.05	18.75		15.06	146%	12%		10%
Promega Female STD#2	16.67	44.01	20.11		16.17	164%	21%		3%
Promega Female STD#2	16.67	41.45	18.93		15.21	149%	14%		9%
Roche STD#2	16.67	49.35	23.26	20.67		196%	40%	24%	
Roche STD#2	16.67	46.99	22.13	19.66		182%	33%	18%	
Roche STD#2	16.67	48.12	22.67	20.14		189%	36%	21%	
Roche STD#2	16.67	48.48	22.17	20.07		191%	33%	20%	
Roche STD#2	16.67	50.33	23.03	20.86		202%	38%	25%	
Roche STD#2	16.67	48.19	22.04	19.95		189%	32%	20%	

		Quantifiler	Promega Male	Promega Female	Roche	Quantifiler	Promega Male	Promega Female	Roche
Sample Name	Expected concentration (ng/uL)	Quantity	Quantity	Quantity	Quantity	Difference	Difference	Difference	Difference
Quantifiler STD#3	5.56		2.04	1.83	1.65		63%	67%	70%
Quantifiler STD#3	5.56		2.19	1.96	1.77		61%	65%	68%
Quantifiler STD#3	5.56		2.34	2	1.83		58%	64%	67%
Quantifiler STD#3	5.56		2.37	2.03	1.86		57%	63%	67%
Promega Male STD#3	5.56	10.08		4.1	3.61	81%		26%	35%
Promega Male STD#3	5.56	10.54		4.29	3.77	90%		23%	32%
Promega Male STD#3	5.56	10.26		4.03	3.66	85%		28%	34%
Promega Male STD#3	5.56	11.4		4.5	4.07	105%		19%	27%
Promega Female STD#3	5.56	10.97	5		3.93	97%	10%	100%	29%
Promega Female STD#3	5.56	12.84	5.88		4.59	131%	6%	100%	17%
Promega Female STD#3	5.56	12.03	5.5		4.3	116%	1%	100%	23%
Promega Female STD#3	5.56	12.62	5.71		4.52	127%	3%		19%
Promega Female STD#3	5.56	13.27	6		4.76	139%	8%		14%
Promega Female STD#3	5.56	12.85	5.81		4.6	131%	4%		17%
Roche STD#3	5.56	15.41	7.08	6.32		177%	27%	14%	
Roche STD#3	5.56	14.2	6.51	5.82		155%	17%	5%	
Roche STD#3	5.56	14.37	6.59	5.89		158%	19%	6%	
Roche STD#3	5.56	14.39	6.51	5.72		159%	17%	3%	
Roche STD#3	5.56	15.3	6.93	6.09		175%	25%	10%	
Roche STD#3	5.56	15	6.79	5.97		170%	22%	7%	

		Quantifiler	Promega Male	Promega Female	Roche	Quantifiler	Promega Male	Promega Female	Roche
Sample Name	Expected concentration (ng/uL)	Quantity	Quantity	Quantity	Quantity	Difference	Difference	Difference	Difference
Quantifiler STD#4	1.85		0.675	0.608	0.567		64%	67%	69%
Quantifiler STD#4	1.85		0.8	0.721	0.669		57%	61%	64%
Quantifiler STD#4	1.85		0.705	0.586	0.544		62%	68%	71%
Quantifiler STD#4	1.85		0.723	0.601	0.558		61%	68%	70%
Promega Male STD#4	1.85	3.27		1.3	1.19	77%		30%	36%
Promega Male STD#4	1.85	3.8		1.52	1.38	105%		18%	25%
Promega Male STD#4	1.85	3.15		1.19	1.09	70%		36%	41%
Promega Male STD#4	1.85	3.46		1.31	1.21	87%		29%	35%
Promega Female STD#4	1.85	3.98	1.78		1.44	115%	4%		22%
Promega Female STD#4	1.85	3.84	1.71		1.39	108%	8%		25%
Promega Female STD#4	1.85	4.13	1.84		1.5	123%	1%		19%
Promega Female STD#4	1.85	4.01	1.8		1.4	117%	3%		24%
Promega Female STD#4	1.85	4.01	1.8		1.4	117%	3%		24%
Promega Female STD#4	1.85	4.13	1.85		1.44	123%	0%		22%
Roche STD#4	1.85	4.26	1.9	1.71		130%	3%	8%	
Roche STD#4	1.85	4.11	1.84	1.65		122%	1%	11%	
Roche STD#4	1.85	4.59	2.05	1.84		148%	11%	1%	
Roche STD#4	1.85	4.75	2.13	1.82		157%	15%	2%	
Roche STD#4	1.85	4.79	2.15	1.83		159%	16%	1%	
Roche STD#4	1.85	4.46	2	1.71		141%	8%	8%	

		Quantifiler	Promega Male	Promega Female	Roche	Quantifiler	Promega Male	Promega Female	Roche
Sample Name	Expected concentration (ng/uL)	Quantity	Quantity	Quantity	Quantity	Difference	Difference	Difference	Difference
Quantifiler STD#5	0.62		0.24	0.217	0.209		61%	65%	66%
Quantifiler STD#5	0.62		0.254	0.23	0.221		59%	63%	64%
Quantifiler STD#5	0.62		0.234	0.189	0.178		62%	70%	71%
Quantifiler STD#5	0.62		0.305	0.248	0.233		51%	60%	62%
Promega Male STD#5	0.62	1.13		0.444	0.419	82%		28%	32%
Promega Male STD#5	0.62	1.32		0.516	0.484	113%		17%	22%
Promega Male STD#5	0.62	1.02		0.37	0.346	65%		40%	44%
Promega Male STD#5	0.62	1.14		0.416	0.388	84%		33%	37%
Promega Female STD#5	0.62	1.27	0.55		0.466	105%	11%		25%
Promega Female STD#5	0.62	1.46	0.636		0.536	135%	3%		14%
Promega Female STD#5	0.62	1.4	0.609		0.514	126%	2%		17%
Promega Female STD#5	0.62	1.63	0.726		0.56	163%	17%		10%
Promega Female STD#5	0.62	1.5	0.665		0.513	142%	7%		17%
Promega Female STD#5	0.62	1.48	0.655		0.505	139%	6%		19%
Roche STD#5	0.62	2.17	0.953	0.858		250%	54%	38%	
Roche STD#5	0.62	1.66	0.726	0.655		168%	17%	6%	
Roche STD#5	0.62	1.47	0.642	0.579		137%	4%	7%	
Roche STD#5	0.62	1.45	0.643	0.533		134%	4%	14%	
Roche STD#5	0.62	1.6	0.712	0.592		158%	15%	5%	
Roche STD#5	0.62	1.45	0.643	0.533		134%	4%	14%	

		Quantifiler	Promega Male	Promega Female	Roche	Quantifiler	Promega Male	Promega Female	Roche
Sample Name	Expected concentration (ng/uL)	Quantity	Quantity	Quantity	Quantity	Difference	Difference	Difference	Difference
Quantifiler STD#6	0.206		0.0713	0.0649	0.0648		65%	68%	69%
Quantifiler STD#6	0.206		0.099	0.0899	0.0889		52%	56%	57%
Quantifiler STD#6	0.206		0.0916	0.0723	0.0688		56%	65%	67%
Quantifiler STD#6	0.206		0.103	0.0819	0.0778		50%	60%	62%
Promega Male STD#6	0.206	0.423		0.163	0.158	105%		21%	23%
Promega Male STD#6	0.206	0.466		0.18	0.174	126%		13%	16%
Promega Male STD#6	0.206	0.489		0.174	0.163	137%		16%	21%
Promega Male STD#6	0.206	0.506		0.18	0.169	146%		13%	18%
Promega Female STD#6	0.206	0.519	0.221		0.194	152%	7%		6%
Promega Female STD#6	0.206	0.476	0.202		0.177	131%	2%		14%
Promega Female STD#6	0.206	0.496	0.211		0.185	141%	2%		10%
Promega Female STD#6	0.206	0.526	0.231		0.176	155%	12%		15%
Promega Female STD#6	0.206	0.484	0.213		0.162	135%	3%		21%
Promega Female STD#6	0.206	0.562	0.247		0.188	173%	20%		9%
Roche STD#6	0.206	0.47	0.2	0.181		128%	3%	12%	
Roche STD#6	0.206	0.463	0.197	0.178		125%	4%	14%	
Roche STD#6	0.206	0.518	0.221	0.2		151%	7%	3%	
Roche STD#6	0.206	0.561	0.247	0.2		172%	20%	3%	
Roche STD#6	0.206	0.564	0.248	0.201		174%	20%	2%	
Roche STD#6	0.206	0.534	0.235	0.19		159%	14%	8%	

		Quantifiler	Promega Male	Promega Female	Roche	Quantifiler	Promega Male	Promega Female	Roche
Sample Name	Expected concentration (ng/uL)	Quantity	Quantity	Quantity	Quantity	Difference	Difference	Difference	Difference
Quantifiler STD#7	0.0686		0.0364	0.0332	0.0339		47%	52%	51%
Quantifiler STD#7	0.0686		0.0357	0.0326	0.0332		48%	52%	52%
Quantifiler STD#7	0.0686		0.0309	0.0237	0.0229		55%	65%	67%
Quantifiler STD#7	0.0686		0.0337	0.026	0.025		51%	62%	64%
Promega Male STD#7	0.0686	0.154		0.0582	0.0584	124%		15%	15%
Promega Male STD#7	0.0686	0.184		0.0697	0.0695	168%		2%	1%
Promega Male STD#7	0.0686	0.24		0.0833	0.0791	250%		21%	15%
Promega Male STD#7	0.0686	0.185		0.0634	0.0604	170%		8%	12%
Promega Female STD#7	0.0686	0.2	0.0833		0.0753	192%	21%		10%
Promega Female STD#7	0.0686	0.234	0.0981		0.0882	241%	43%		29%
Promega Female STD#7	0.0686	0.202	0.0844		0.0762	194%	23%		11%
Promega Female STD#7	0.0686	0.221	0.0965		0.0726	222%	41%		6%
Promega Female STD#7	0.0686	0.243	0.106		0.08	254%	55%		17%
Promega Female STD#7	0.0686	0.189	0.0822		0.0617	176%	20%		10%
Roche STD#7	0.0686	0.206	0.0861	0.0783		200%	26%	14%	
Roche STD#7	0.0686	0.158	0.0658	0.0599		130%	4%	13%	
Roche STD#7	0.0686	0.187	0.078	0.071		173%	14%	3%	
Roche STD#7	0.0686	0.252	0.11	0.0876		267%	60%	28%	
Roche STD#7	0.0686	0.21	0.0917	0.0724		206%	34%	6%	
Roche STD#7	0.0686	0.166	0.0722	0.0567		142%	5%	17%	

		Quantifiler	Promega Male	Promega Female	Roche	Quantifiler	Promega Male	Promega Female	Roche
Sample Name	Expected concentration (ng/uL)	Quantity	Quantity	Quantity	Quantity	Difference	Difference	Difference	Difference
Quantifiler STD#8	0.023		0.0083	0.00762	0.00812		64%	67%	65%
Quantifiler STD#8	0.023		0.00864	0.00793	0.00845		62%	66%	63%
Quantifiler STD#8	0.023		0.00851	0.00634	0.00621		63%	72%	73%
Quantifiler STD#8	0.023		0.0104	0.00775	0.00757		55%	66%	67%
Promega Male STD#8	0.023	0.089		0.0333	0.0339	287%		45%	47%
Promega Male STD#8	0.023	0.0576		0.0214	0.0221	150%		7%	4%
Promega Male STD#8	0.023	0.0665		0.0221	0.0213	189%		4%	7%
Promega Male STD#8	0.023	0.0409		0.0133	0.013	78%		42%	43%
Promega Female STD#8	0.023	0.0433	0.0175		0.0167	88%	24%		27%
Promega Female STD#8	0.023	0.0625	0.0254		0.0239	172%	10%		4%
Promega Female STD#8	0.023	0.116	0.0476		0.0439	404%	107%		91%
Promega Female STD#8	0.023	0.0876	0.0379		0.0282	281%	65%		23%
Promega Female STD#8	0.023	0.067	0.0289		0.0214	191%	26%		7%
Promega Female STD#8	0.023	0.0873	0.0378		0.0281	280%	64%		22%
Roche STD#8	0.023	0.0927	0.0381	0.0347		303%	66%	51%	
Roche STD#8	0.023	0.0523	0.0212	0.0194		127%	8%	16%	
Roche STD#8	0.023	0.0726	0.0296	0.0271		216%	29%	18%	
Roche STD#8	0.023	0.0938	0.0407	0.0315		308%	77%	37%	
Roche STD#8	0.023	0.0891	0.0386	0.0298		287%	68%	30%	
Roche STD#8	0.023	0.0918	0.0398	0.0308		299%	73%	34%	

		Quantifiler	Promega Male	Promega Female	Roche	Quantifiler	Promega Male	Promega Female	Roche
Sample Name	Expected concentration (ng/uL)	Quantity	Quantity	Quantity	Quantity	Difference	Difference	Difference	Difference
Promega 1ng/uL	1	2.22	0.977	0.88	0.811	122%	2%	12%	19%
Promega 1ng/uL	1	2.22	0.978	0.88	0.812	122%	2%	12%	19%
Promega 1ng/uL	1	2.15	0.946	0.852	0.787	115%	5%	15%	21%
Promega 1ng/uL	1	2.27	0.997	0.898	0.828	127%	0%	10%	17%
Promega 1ng/uL	1	2.88	1.28	1.08	0.998	188%	28%	8%	0%
Promega 1ng/uL	1	2.32	1.03	0.868	0.802	132%	3%	13%	20%
Promega 1ng/uL	1	2.53	1.13	0.947	0.874	153%	13%	5%	13%
Promega 1ng/uL	1	2.39	1.06	0.893	0.825	139%	6%	11%	18%
EPC	0.1	0.211	0.088	0.08	0.0794	111%	12%	20%	21%
EPC	0.1	0.187	0.078	0.071	0.0707	87%	22%	29%	29%
EPC	0.1	0.208	0.0868	0.0789	0.0783	108%	13%	21%	22%
EPC	0.1	0.227	0.0949	0.0863	0.0854	127%	5%	14%	15%
EPC	0.1	0.207	0.0904	0.0714	0.068	107%	10%	29%	32%
EPC	0.1	0.246	0.107	0.0852	0.0809	146%	7%	15%	19%
EPC	0.1	0.252	0.11	0.0875	0.0831	152%	10%	13%	17%
EPC	0.1	0.212	0.0926	0.0732	0.0696	112%	7%	27%	30%
Buccal control	1	2.15	0.946	0.852	0.787	115%	5%	15%	21%
Buccal control	1	2.2	0.967	0.871	0.803	120%	3%	13%	20%
Buccal control	1	2.31	1.02	0.918	0.845	131%	2%	8%	16%
Buccal control	1	2.25	0.991	0.892	0.823	125%	1%	11%	18%
Buccal Control	1	2.5	1.12	0.938	0.866	150%	12%	6%	13%
Buccal Control	1	2.28	1.02	0.852	0.788	128%	2%	15%	21%
Buccal Control	1	2.3	1.03	0.86	0.795	130%	3%	14%	21%
Buccal Control	1	2.39	1.06	0.893	0.825	139%	6%	11%	18%
					Mean difference	158%	28%	29%	29%

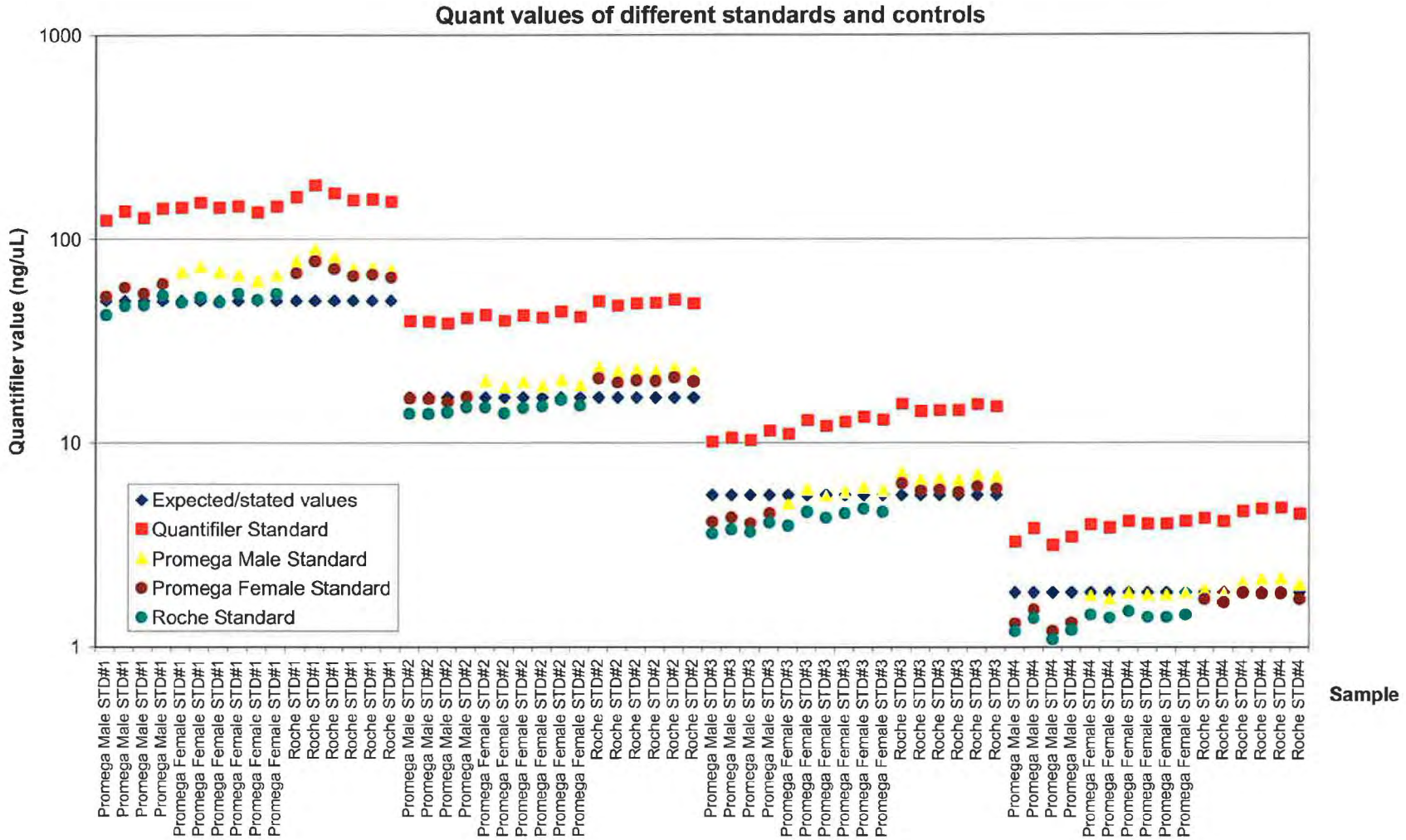

Figure 45. Logarithmic graph with Quantifiler values of high concentration samples.

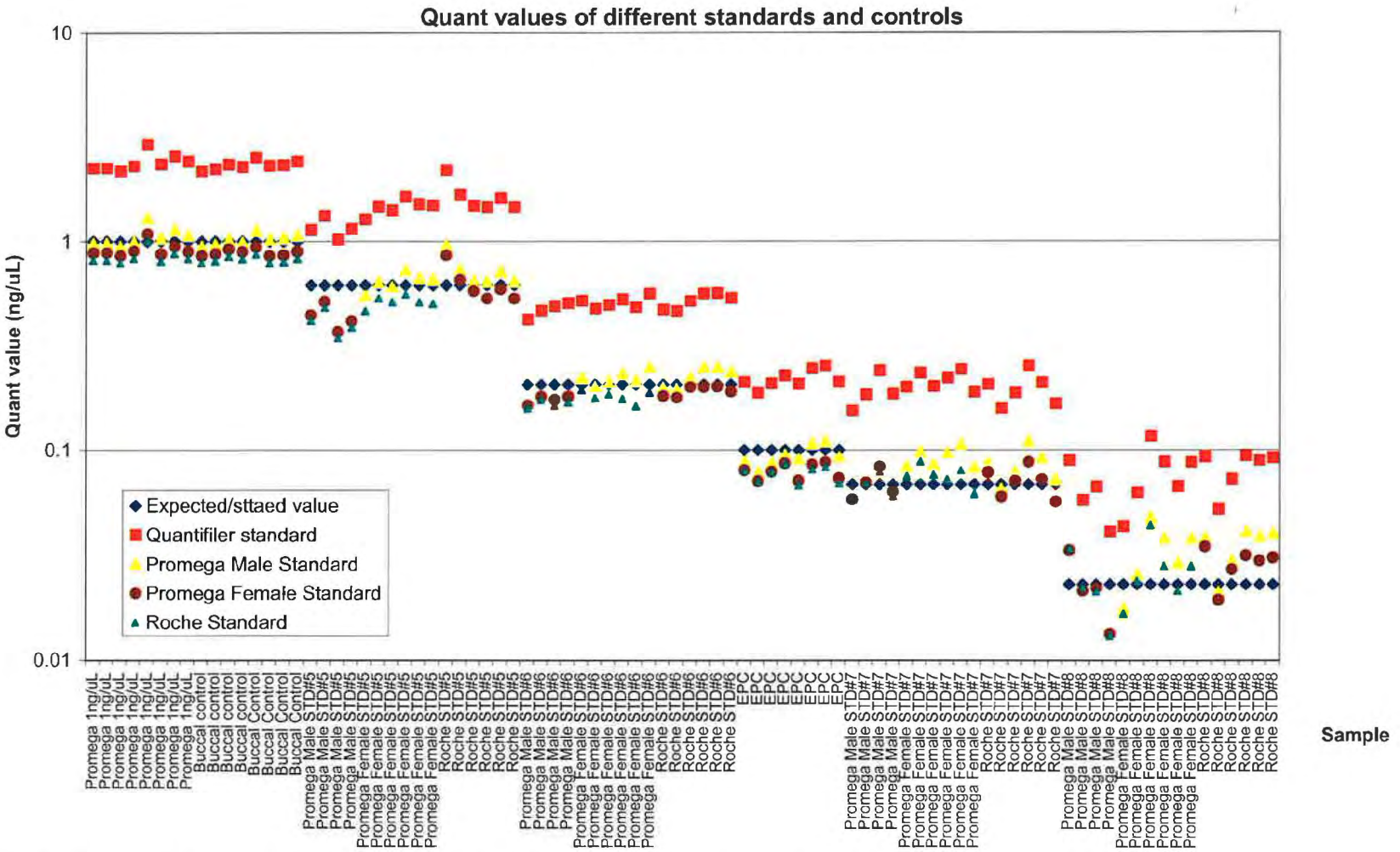

Figure 46. Logarithmic graph with Quantifiler values of low concentration samples.

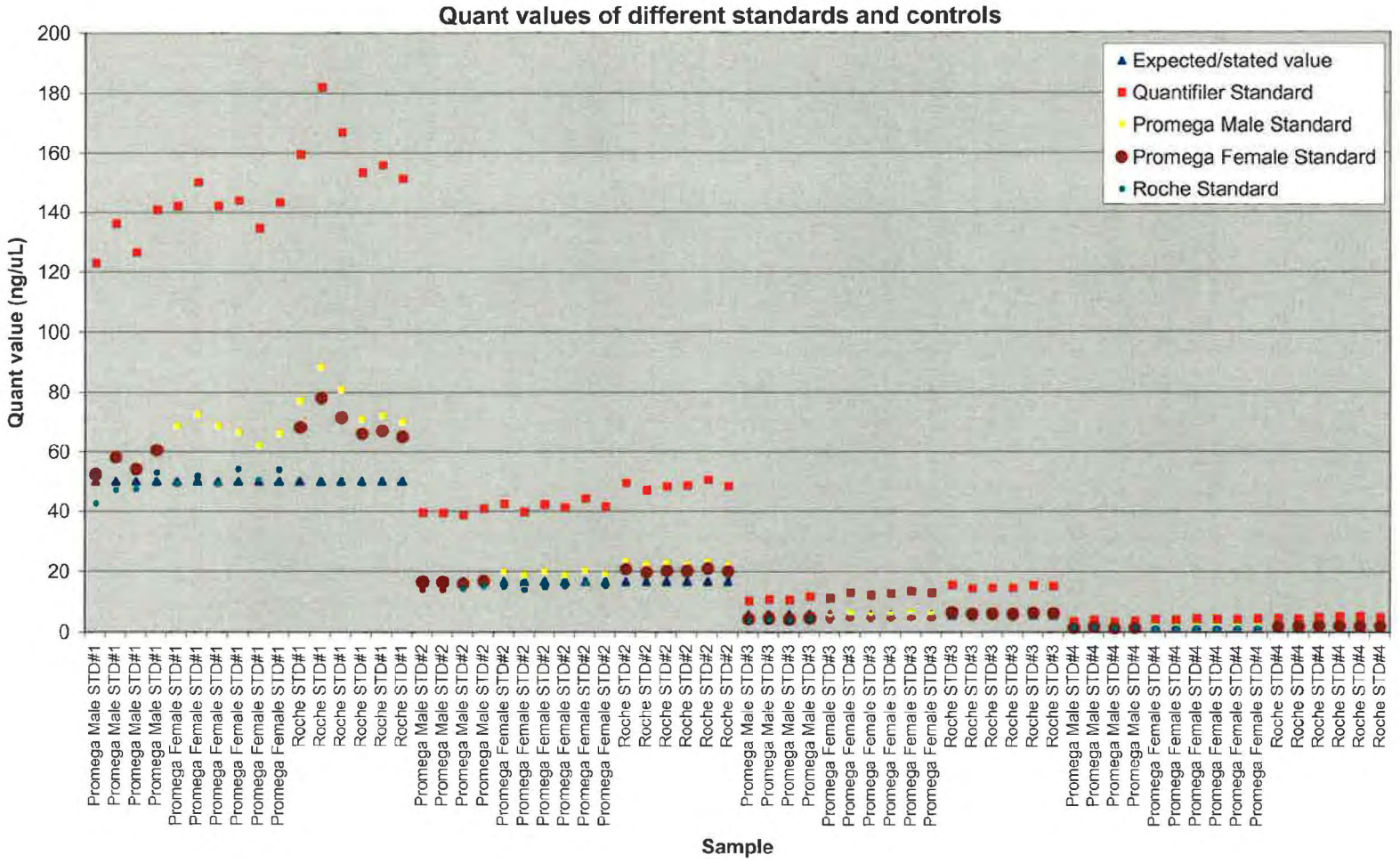

Figure 47. Linear graph with Quantifiler values of high concentration samples.

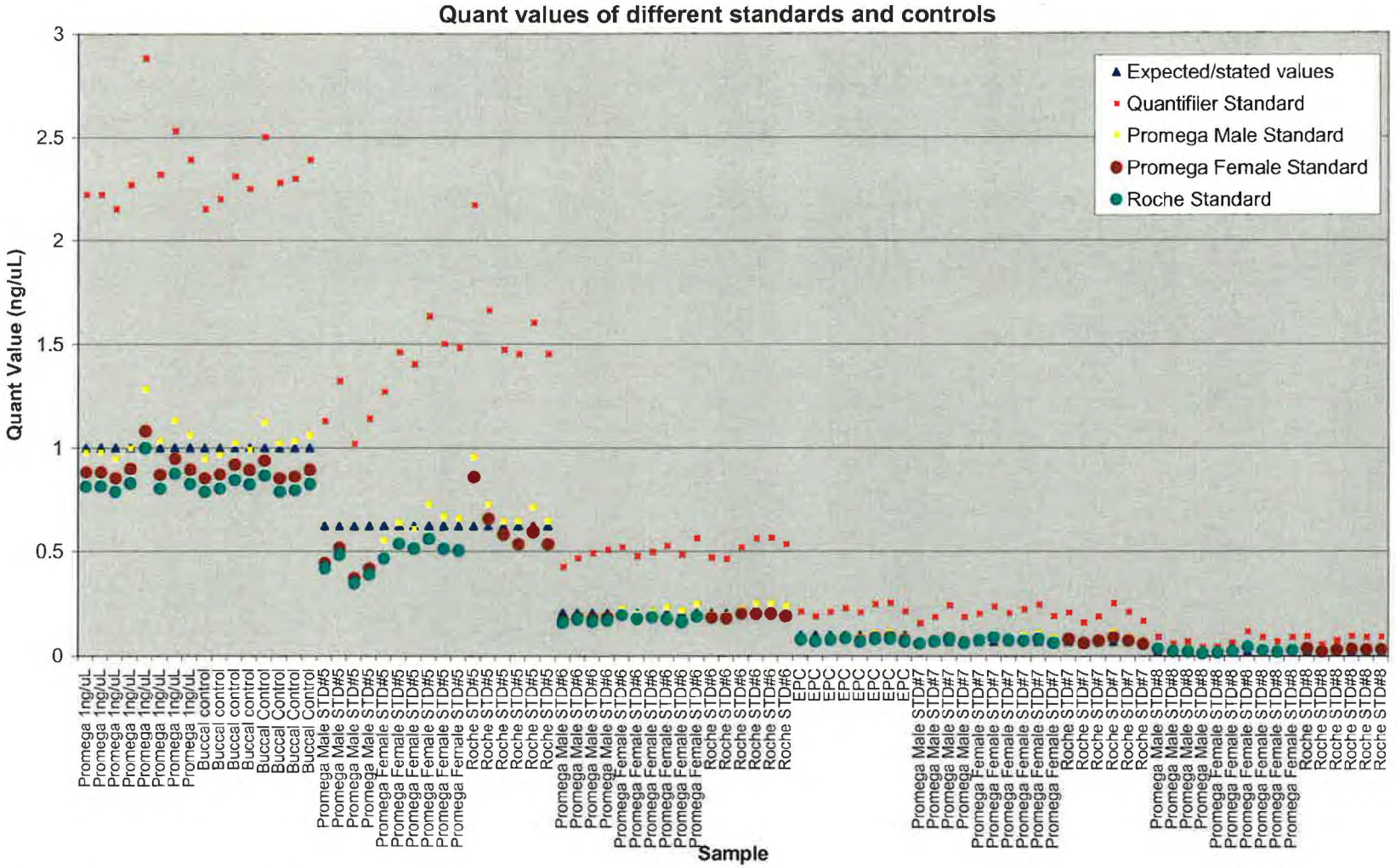

Figure 48. Linear graph with Quantifiler values of low concentration samples.

Table 39. Comparison of CT values and distributions of Human DNA Control standards. The orange rows show the results from the samples run on Testquant_130905 and Testquant_140905. The QHSS standard (in blue) is the accumulative result of long-term data while the Promega Male standard (Promega Human Genomic DNA Male standard) are the results obtained from another set of data. The ADFS (ADFS accessed online 11th March, 2005) and ABI standards (Applied Biosystems 2003) are Quantifiler Human DNA standards where CT values were obtained from published references. As is clearly visible, all of the Quantifiler standards (QHSS, QHSS2, ADFS and ABI have higher CT values than the Promega Male, Promega Female and Roche standards.

Standard type	Mean CT	1 StdDev Minimum	1 StdDev Maximum	2 StdDev Minimum	2 StdDev Maximum	3 StdDev Minimum	3 StdDev Maximum
QHSS STD1	[illegible]	23.75	23.75	[illegible]	[illegible]	22.75	24.25
QHSS2 STD1	23.83	23.67	23.99	23.51	24.15	23.35	24.31
ADFS STD1	23.28	23.16	23.40	23.04	23.52	22.92	23.64
ABI STD1	23.09	22.99	23.19	22.89	23.29	22.79	23.39
Promega Male STD1	22.60	22.46	22.74	22.32	22.88	22.18	23.02
Promega Male2 STD1	22.66	22.57	22.74	22.49	22.83	22.40	22.91
Promega Female STD1	22.65	22.51	22.59	22.46	22.84	22.42	22.68
Roche STD1	22.39	22.31	22.47	22.22	22.56	22.14	22.64
QHSS STD2	25.12	24.88	25.36	24.65	[illegible]	[illegible]	25.83
QHSS2 STD2	25.32	25.24	25.40	25.15	25.48	25.07	25.56
ADFS STD2	24.74	24.56	24.92	24.38	25.10	24.20	25.28
ABI STD2	24.64	24.47	24.81	24.30	24.98	24.13	25.15
Promega Male STD2	24.18	24.09	24.27	24.00	24.37	23.90	24.46
Promega Male2 STD2	24.26	24.22	24.29	24.19	24.33	24.16	24.36
Promega Female STD2	24.18	24.14	24.23	24.09	24.27	24.04	24.32
Roche STD2	23.98	23.95	24.01	23.91	24.05	23.88	24.08
QHSS STD3	26.62	26.37	26.87	26.12	27.12	25.88	27.38
QHSS2 STD3	27.00	26.92	27.08	26.84	27.17	26.76	27.25
ADFS STD3	26.19	26.05	26.33	25.91	26.47	25.77	26.61
ABI STD3	26.19	26.03	26.35	25.87	26.51	25.71	26.67
Promega Male STD3	25.77	25.60	25.94	25.43	26.11	25.26	26.28
Promega Male2 STD3	26.01	25.94	26.07	25.87	26.14	25.80	26.21
Promega Female STD3	25.79	25.70	25.88	25.62	25.97	25.53	26.05
Roche STD3	25.56	25.51	25.61	25.47	25.65	25.42	25.70
QHSS STD4	28.18	27.96	[illegible]	[illegible]	[illegible]	27.52	28.84
QHSS2 STD4	28.48	28.37	28.58	28.26	28.69	28.16	28.79
ADFS STD4	27.59	27.46	27.72	27.33	27.85	27.20	27.98
ABI STD4	27.67	27.50	27.84	27.33	28.01	27.16	28.18
Promega Male STD4	27.34	27.09	27.59	26.85	27.83	26.60	28.08
Promega Male2 STD4	27.51	27.39	27.62	27.28	27.73	27.16	27.85
Promega Female STD4	27.29	27.25	27.32	27.22	27.36	27.18	27.39
Roche STD4	27.15	27.07	27.22	27.00	27.29	26.93	27.36
QHSS STD5	29.65	29.36	29.94	29.08	[illegible]	[illegible]	30.51
QHSS2 STD5	29.84	29.69	29.98	29.54	30.13	29.40	30.27
ADFS STD5	29.09	28.84	29.34	28.59	29.59	28.34	29.84
ABI STD5	29.09	28.92	29.26	28.75	29.43	28.58	29.60
Promega Male STD5	28.70	28.49	28.90	28.29	29.11	28.08	29.31
Promega Male2 STD5	28.96	28.80	29.11	28.65	29.26	28.50	29.41
Promega Female STD5	28.64	28.54	28.74	28.44	28.84	28.34	28.95
Roche STD5	28.50	28.29	28.71	28.07	28.93	27.86	29.14
QHSS STD6	31.11	30.80	31.42	30.49	31.73	30.18	32.04
QHSS2 STD6	31.20	31.01	31.39	30.82	31.58	30.63	31.77
ADFS STD6	30.38	30.19	30.57	30.00	30.76	29.81	30.95
ABI STD6	30.31	30.12	30.50	29.93	30.69	29.74	30.88
Promega Male STD6	30.00	29.84	30.16	29.68	30.32	29.52	30.48
Promega Male2 STD6	30.14	30.05	30.23	29.97	30.31	29.88	30.40
Promega Female STD6	30.03	29.96	30.11	29.88	30.18	29.81	30.25
Roche STD6	30.01	29.92	30.11	29.82	30.21	29.73	30.30
QHSS STD7	32.69	32.26	33.12	31.82	33.56	31.39	33.99
QHSS2 STD7	32.48	32.31	32.64	32.14	32.81	31.97	32.98
ADFS STD7	31.65	31.37	31.93	31.09	32.21	30.81	32.49
ABI STD7	31.90	31.62	32.18	31.34	32.46	31.06	32.74
Promega Male STD7	31.37	31.04	31.70	30.72	32.02	30.39	32.35
Promega Male2 STD7	31.35	31.13	31.58	30.90	31.80	30.68	32.03
Promega Female STD7	31.19	31.05	31.32	30.92	31.45	30.79	31.58
Roche STD7	31.31	31.09	31.53	30.88	31.75	30.66	31.97
QHSS STD8	34.31	33.68	34.94	33.06	35.57	32.43	36.19
QHSS2 STD8	34.23	34.12	34.34	34.01	34.45	33.90	34.56
ADFS STD8	33.67	32.82	34.52	31.97	35.37	31.12	36.22
ABI STD8	33.45	32.97	33.93	32.49	34.41	32.01	34.89
Promega Male STD8	32.80	32.36	33.23	31.93	33.66	31.50	34.09
Promega Male STD8	32.85	32.40	33.30	31.95	33.75	31.50	34.20
Promega Female STD8	32.60	32.16	33.04	31.72	33.48	31.28	33.92
Roche STD8	32.49	32.20	32.77	31.91	33.06	31.63	33.34

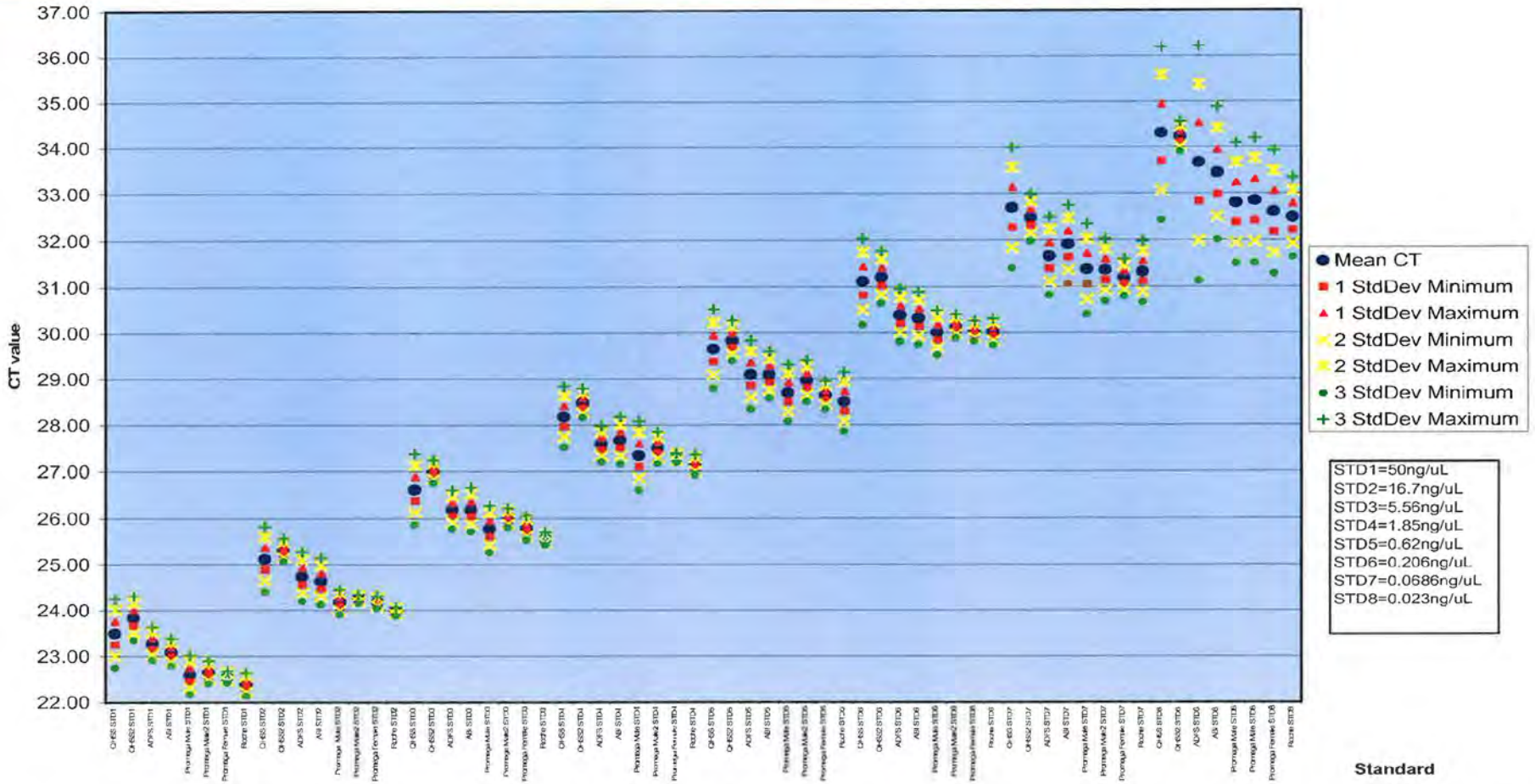

Figure 49. Comparison of CT values and distributions of Human DNA Control standards. QHSS2, Promega Male2, Promega Female and Roche standard results are from the dilutions run on Testquant_130905 and Testquant_140905. The QHSS standard is the accumulative result of long-term data while the Promega Male standard results are the results obtained from another set of data. The ADFS (ADFS accessed online 11th March, 2005) and ABI standards (Applied Biosystems 2003) are Quantifiler Human DNA standards where CT values were obtained from published references. As is clearly visible, all of the Quantifiler standards (QHSS, QHSS2, ADFS and ABI have higher CT values than the Promega Male, Promega Female and Roche standards. A general difference of approximately 1 CT is observable between the QHSS standard and the Promega Male standard.

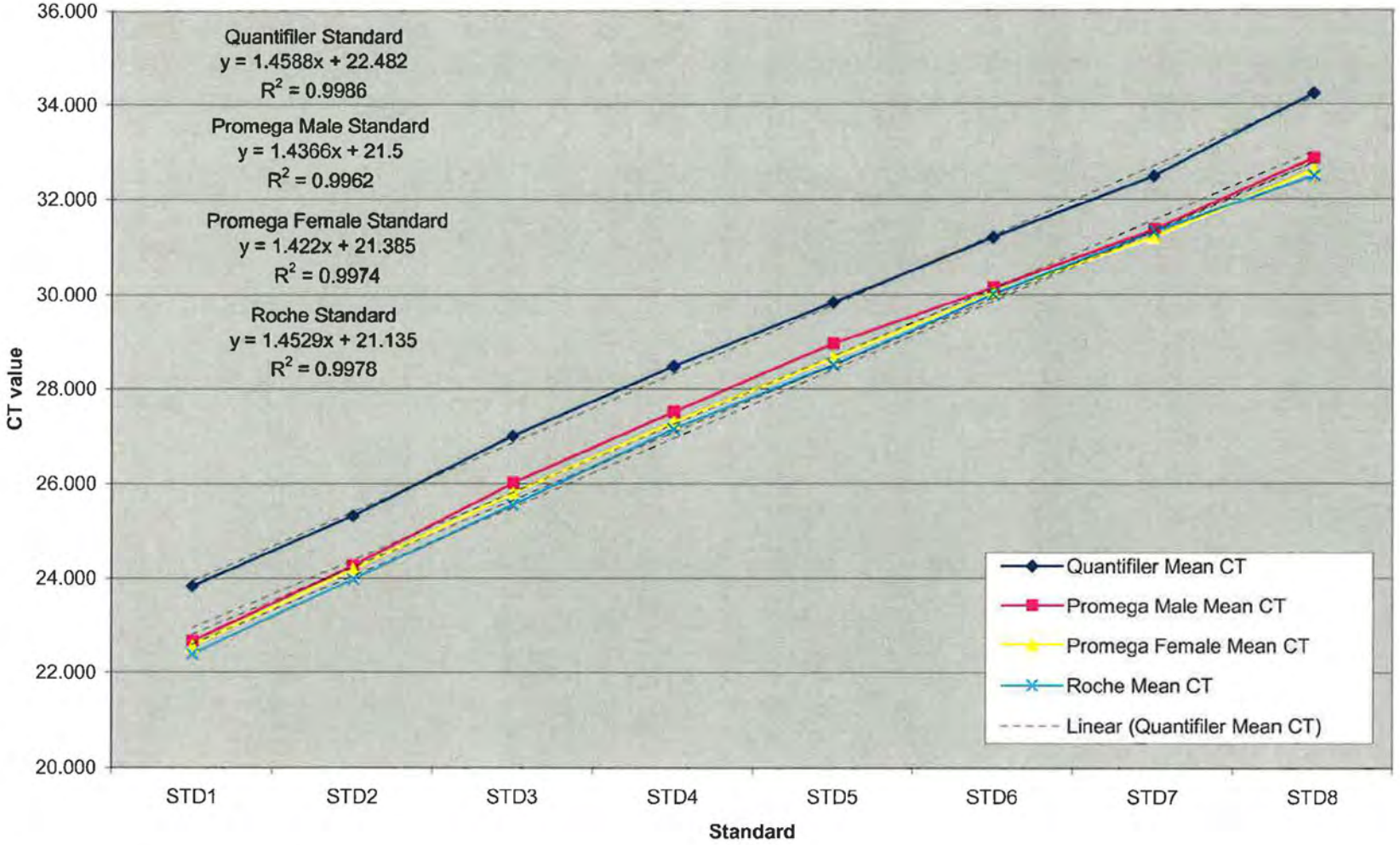

Figure 50. Linearity graph for the four standards.

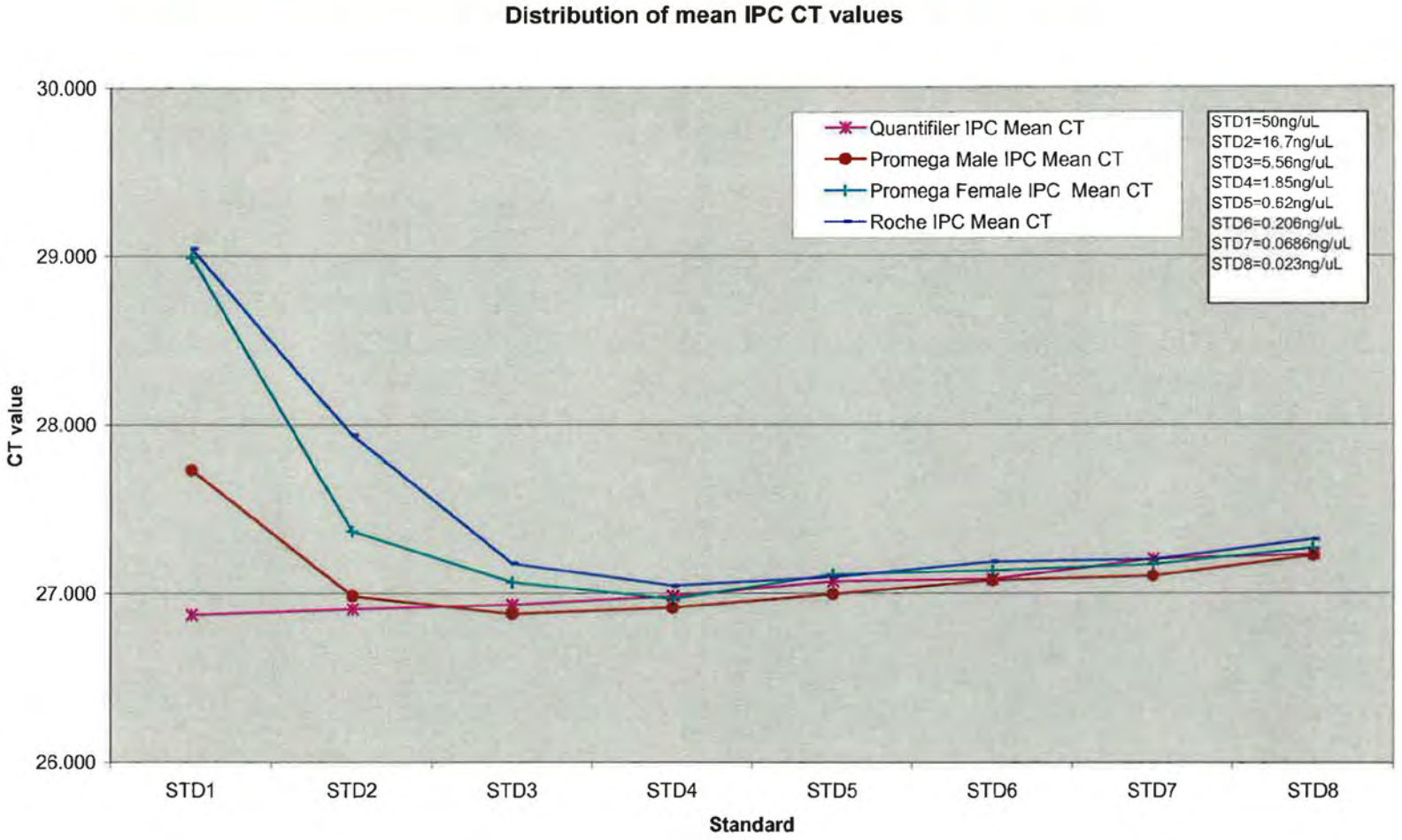

Figure 51. Distribution of mean IPC CT values.

5.4 LONG-TERM REPRODUCIBILITY (CONTROLS AND QUANTIFILER STANDARD)

The main process changes introduced at QHSS were the use of controls on every Quantifiler run (EPC and Promega Male control), the use of established guidelines such as expected Y-intercept ranges, slope and r2 values. Before any process changes (see table 40), the system varied in mean EPC value from 0.138 to 0.252ng/µL. The actual concentration of the EPC according to Applied Biosystems is 0.1ng/µL. After introducing Testquants of Standards (see table 41) to check a standard is acceptable before it is utilized, the EPC value range was tighter with the EPC between 0.192 and 0.229ng/µL. At this time the Promega Male control (at 1ng/µL) was introduced and mean values ranged from 1.89 to 2.22. With a different batch sets and lots being applied and the checking of ranges introduced in the QF QC Log (see table 42), the values ranged from 0.208 to 0.262 for the mean EPC and 2.03 to 2.72 for the mean Promega Male control at 1ng/µL.

Table 40. Long-term reproducibility data before process changes. Note that the y-intercept, slope and r2 means were derived per EPC value.

Before Process changes						
Quantifiler Standard made on	Mean Y-Intercept [CT at Quant=1] Acceptable range 2StdDev 28.55-29.46	Mean Slope Acceptable range -3.3 to -2.9	Mean r2 Acceptable range ≥0.98	Mean EPC Value	Mean Promega Value	Quantifiler Standard Batch
4.1.05	29.192160	-3.377780	0.995629	0.252	NA	0406006
8.11.04	29.432280	-3.272630	0.992560	0.233	NA	0403005
29.3.05	29.147820	-3.182540	0.995804	0.224	NA	0412010 V3+V4
22.11.04	29.168110	-3.245060	0.996486	0.221	NA	0403005
5.10.04	29.171820	-3.259660	0.994687	0.212	NA	0402004
6.12.04	28.987310	-3.148140	0.994837	0.202	NA	0406006
17.1.05	28.873570	-3.201330	0.995211	0.197	NA	0406006
14.3.05	28.826450	-3.176730	0.995676	0.177	NA	0403005 D1
1.2.05	28.724820	-3.235730	0.995082	0.177	NA	0402004
7.4.05	28.814600	-3.101720	0.996541	0.175	NA	0412010 Y1
28.2.05	28.862240	-3.161780	0.996631	0.167	NA	0406006 W2
17.2.05	28.780070	-3.143940	0.995921	0.163	NA	0406006
22.10.04	28.902460	-3.147810	0.995502	0.158	NA	0402004
20.12.04	28.813510	-3.081460	0.996848	0.138	NA	0406006

Table 41. Long-term reproducibility data after applying Testquant of Standards process. Note that the y-intercept, slope and r2 means were derived per EPC value.

After Process improvement (Standard Testquants but not checking ranges in QFQCLog)						
Quantifiler Standard made on	**Mean Y-Intercept [CT at Quant=1] Acceptable range 2StdDev 28.55-29.46**	**Mean Slope Acceptable range -3.3 to -2.9**	**Mean r2 Acceptable range ≥0.98**	**Mean EPC Value**	**Mean Promega Value**	**Quantifiler Standard Batch**
6.7.05	29.214905	-3.090170	0.996316	0.229	2.22	0503012 D5
27.6.05	28.961467	-3.175749	0.995673	0.214	1.95	0403005 E7
10.6.05	28.932707	-3.148387	0.994808	0.207	1.92	0403005 E5
18.5.05	28.960197	-3.119111	0.995674	0.205	2.01	0406006 I2
18.5.05	28.989796	-3.055342	0.991136	0.193	1.95	0406006 N3
30.5.05	28.956872	-3.134285	0.996408	0.192	1.89	0406006 L3

Table 42. Long-term reproducibility data after applying Testquant of Standards process and checking ranges in the QF QC Log. Note that the y-intercept, slope and r2 means were derived per EPC value.

After Process improvement (Standard Testquants and checking ranges in QFQCLog)						
Quantifiler Standard made on	Mean Y-Intercept [CT at Quant=1] Acceptable range 2StdDev 28.55-29.46	Mean Slope Acceptable range -3.3 to -2.9	Mean r2 Acceptable range ≥0.98	Mean EPC Value	Mean Promega Value	Quantifiler Standard Batch
19.9.05	29.276109	-3.150469	0.996956	0.262	2.60	0503012 I10
3.10.05	29.351458	-3.146003	0.995245	0.250	2.64	0503012 I16
17.10.05	29.286532	-3.121781	0.995420	0.247	2.72	0503012 I17
22.8.05	29.074191	-3.178229	0.996110	0.244	2.03	0503012 I2
25.7.05	29.129660	-3.090196	0.996438	0.243	2.15	0503012 E3
16.01.06	29.194165	-3.154871	0.995841	0.242	2.38	0507015 K10
6.7.05	29.351814	-3.164174	0.995103	0.241	2.31	0503012 D5
14.11.05	29.141799	-3.170734	0.996624	0.231	2.24	0507015 K1
25.7.05	29.192492	-3.122426	0.996061	0.229	2.16	0503012 E2
25.7.05	29.102238	-3.164359	0.996099	0.227	2.07	0503012 F7
19.9.05	29.231785	-3.071752	0.996350	0.225	2.54	0503012 I9
31.10.05	29.035192	-3.179748	0.996378	0.221	2.15	0507015 L3
5.9.05	29.204120	-3.174353	0.995593	0.219	2.44	0503012 I6
12.12.05	28.955695	-3.156146	0.995869	0.219	2.16	0507015 L14
03.01.06	29.004436	-3.184334	0.995925	0.217	2.10	0507015 L8
28.11.05	28.969172	-3.171995	0.997100	0.213	2.07	0507015 L5
30.01.06	28.960926	-3.159467	0.996347	0.208	2.15	0406006 K1

In Figures 52 and 53 we show how the control values have changed over time. Before process changes the values concentrated around 0.2ng/µL for the EPC. Initial values for the Promega Male control at 1ng/µL also concentrated at approximately 2ng/µL initially. However, the values still fluctuated by using different batches and lots of Quantifiler standards. After process changes, there was an increase in the mean concentrations obtained and initial fluctuation appeared to be reduced. The statistical analysis showed that the overall mean EPC value was approximately double to the 'true' or 'expected' value at 0.214ng/µL and the Promega Male control at 1ng/µL produced a mean of 2.217ng/µL (see tables 43 and 44). The EPC reproducibility range at 95% confidence (0.128 to 0.299ng/µL) and Promega Male control reproducibility range at 95% confidence (1.777 to 2.657ng/µL) is reflective of the typical sample distribution range where values could usually be reproduced.

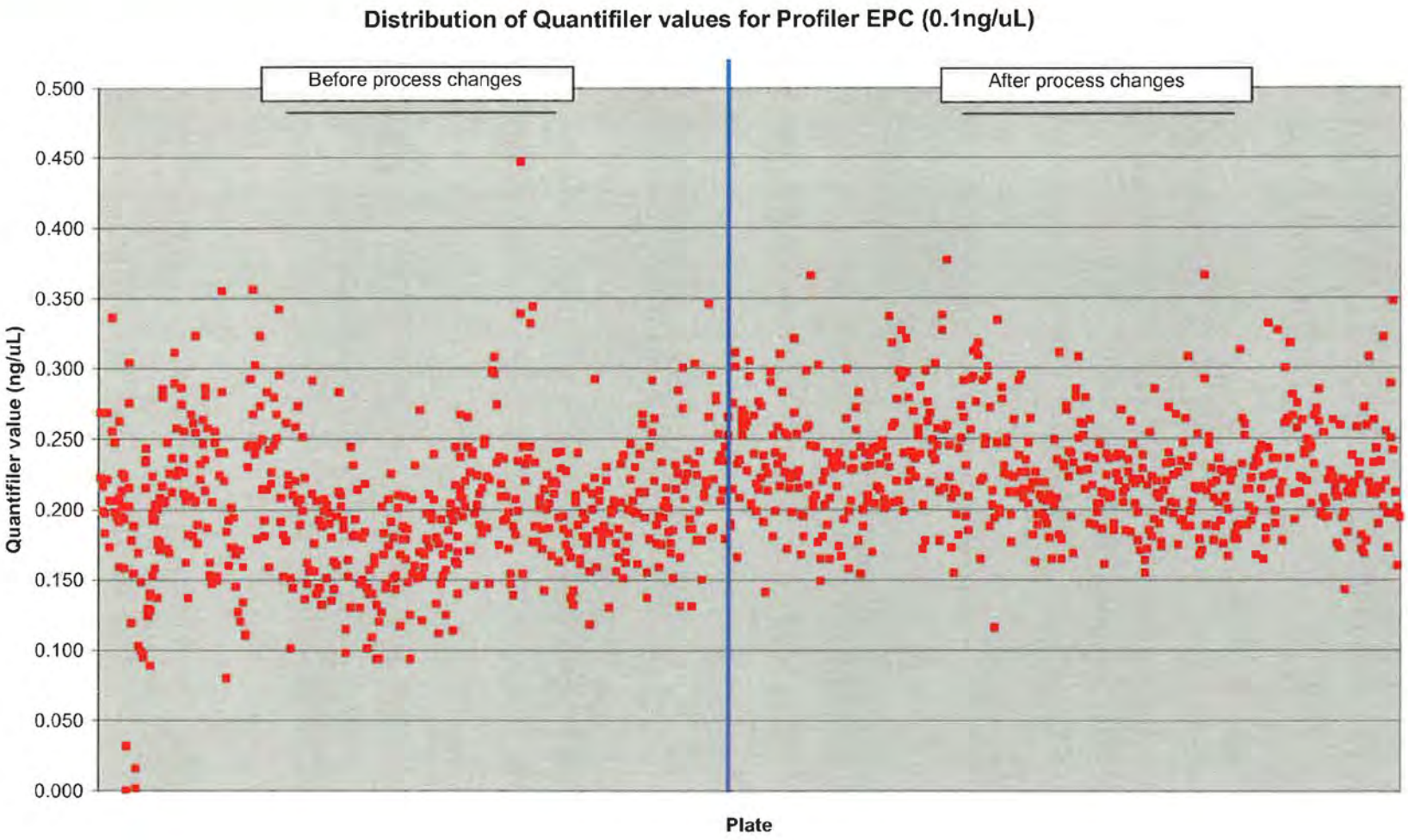

Figure 52. Distribution of Quantifiler values (ng/µL) for 0.1ng/µL EPC before and after process changes. The values are shown per plate run in chronological order. Plates ranging from QF#83_05-10-04 to QF#350_120705(CW) (before the changes) and QF#351_140705(CW) to QF#640_160206(CW) (after changes) are represented.

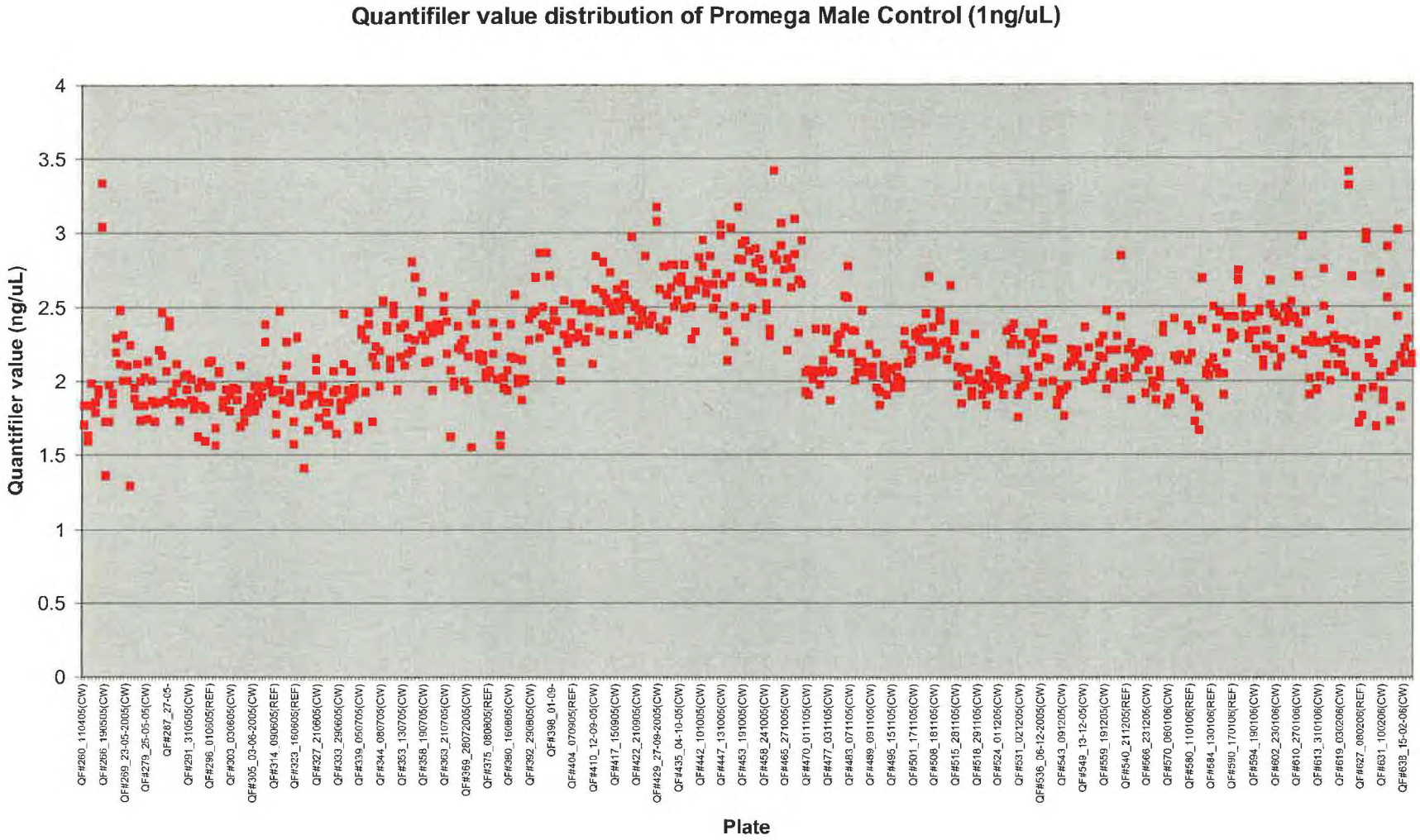

Figure 53. Quantifiler value (ng/µL) distribution for 1ng/µL Promega Male control.

Table 43. EPC statistics.

EPC 0.1ng/uL	Sample number	1128
	Plate number	546
	Overall mean	0.214
	Combined degrees of freedom (df)	582
	t-value (2-sided, 95% confidence interval)	1.964
	Combined StdDev (Sc)	0.031
	Reproducibility (Rw) by plate	0.0855
	Relative reproducibility (Rw/overall mean)	0.400
	Relative lower range limit	0.128
	Relative upper range limit	0.299

Table 44. 1ng/µL Promega Male control statistics.

Promega Male 1ng/uL	Sample number	750
	Plate number	375
	Overall mean Quantifiler value	2.217
	Combined degrees of freedom (df)	375
	t-value (2-sided, 95% confidence interval)	1.966
	Combined StdDev (Sc)	0.158
	Reproducibility (Rw) by plate	0.440
	Relative reproducibility (Rw/overall mean)	0.199
	Relative lower range limit	1.777
	Relative upper range limit	2.657

With additional batches and lots obtained it was found that the Quantifiler standard and the values it produced were very difficult to reproduce even at a 1.72 to 3.0ng/µL range for the Promega Male control at 1ng/µL (tables 45 and 46). The batch and lot number data was obtained by running the EPC and 1ng/µL Promega Male controls on Testquants of Standards and analysing the results. This analysis had less bias than the data from normal Quantifiler runs, since outlying standard values are not removed and each standard is only run once after it is made. In tables 45 and 46, we show that some lot number results for different standards were not reproducible compared to each other and the overall reproducibility value was high. This means that to maintain a suitable level of reproducibility, where the reproducibility value is as low as possible, rejection of Quantifiler standards that do not produce typical baseline results is essential. A low reproducibility value ensures a tighter distribution of control and sample concentration values (i.e. higher reproducibility).

Table 45. Summary of Testquant results by batch number. In general, Quantifiler values resulting from the same lot number are similar, with most batches producing approximately double the concentration value of expected results. With the Testquant procedure, Quantifiler Standard outliers (e.g. blue, pink or orange-coloured batches) that are not producing approximately double the concentration values expected could be removed from use in casework and reference Quantifiler runs.

Operator number	TestQuant number	Lot Number	Batch number	Total vials	Mean Y-Intercept [CT at Quant=1] Acceptable range 1StdDev 28.77-29.23 2StdDev 28.55-29.46	Y-intercept StdDev	Minimum 2 StdDev (95% CI)	Maximum 2 StdDev (95% CI)	Mean Slope Acceptable range -3.3 to -2.9	Slope StdDev	Mean r2 Acceptable range >0.98	r2 StdDev	Promega Sample Number	EPC Sample Number	1ng/uL Promega Mean (ng/uL)	Promega StdDev	0.1ng/uL EPC Mean	EPC StdDev
1	2	0602018	Y	3	28.478726	0.119939	28.358787	28.598665	-3.070512	0.107193	0.997929	0.000929	6	6	1.282	0.091	0.146	0.0183
4	6	0602018	X	8	28.482052	0.191604	28.290448	28.673657	-3.022454	0.118604	0.994658	0.005407	16	16	1.412	0.153	0.135	0.0435
5	7	0602018	V	8	28.646189	0.175128	28.471061	28.821317	-3.148948	0.120990	0.995959	0.001916	16	16	1.494	0.199	0.164	0.0491
4	5	0510016	W	5	28.985246	0.374852	28.611394	29.361098	-3.041177	0.136262	0.995915	0.002215	10	10	2.012	0.617	0.188	0.0719
5	8	0507015	U	10	28.997031	0.167306	28.829723	29.164339	-3.122360	0.131020	0.995172	0.003170	20	20	2.023	0.337	0.205	0.0482
3	5	0507015	T	7	29.006698	0.179398	28.827300	29.186096	-3.105198	0.096062	0.996682	0.001155	14	14	2.066	0.321	0.205	0.0358
1	4	0507015	R	7	29.182391	0.129035	29.053356	29.311425	-3.207651	0.071323	0.996592	0.002289	14	14	2.329	0.265	0.275	0.0539
4	5	0507015	L	11	28.878342	0.123062	28.755280	29.001403	-3.151215	0.077473	0.996682	0.001551	22	22	1.961	0.237	0.218	0.0335
4	4	0507015	K	9	28.822362	0.118701	28.703661	28.941063	-3.041408	0.139535	0.995750	0.002856	18	18	1.790	0.265	0.192	0.0380
1	4	0506014	S	8	29.456878	0.150106	29.306772	29.606984	-3.005163	0.111296	0.991636	0.005629	16	16	2.931	0.263	0.295	0.0436
2	4	0506014	Q	6	29.389914	0.204245	29.185669	29.594158	-3.109960	0.120347	0.993536	0.005132	12	12	3.067	0.523	0.350	0.0543
3	3	0506014	N	4	29.223918	0.170793	29.053125	29.394711	-2.972843	0.111464	0.994226	0.003586	8	8	2.816	0.221	0.237	0.0169
3	2	0505013	M	2	28.697520	0.024691	28.672829	28.722211	-2.986995	0.062070	0.992860	0.000262	4	4	1.798	0.436	0.200	0.0114
2	2	0505013	J	3	29.017669	0.190380	28.827290	29.208049	-3.138222	0.089033	0.994803	0.001085	6	6	1.858	0.429	0.246	0.0536
3	5	0503012	I	17	29.097706	0.211359	28.886347	29.309065	-3.039012	0.129569	0.994287	0.004050	34	34	2.233	0.321	0.220	0.0531
1	1	0503012	H	2	29.326475	0.057655	29.268819	29.384130	-3.178899	0.026857	0.994728	0.001096	4	4	2.440	0.083	0.262	0.0213
1	1	0503012	F	2	29.157309	0.098239	29.059069	29.255548	-3.057713	0.025584	0.996582	0.000824	4	0	2.450	0.183	EPC not obtained	
1	1	0503012	E	3	29.052445	0.082329	28.970116	29.134774	-2.974728	0.115177	0.996197	0.002650	6	6	2.138	0.090	0.174	0.0247
1	1	0503012	D	5	29.020751	0.096818	28.923933	29.117568	-2.994571	0.071776	0.994535	0.001508	10	10	2.126	0.145	0.188	0.0259
1	1	0412010	X	2	29.164420	0.015077	29.149343	29.179497	-3.176580	0.081416	0.995699	0.003836	4	4	2.668	0.134	0.303	0.0173
1	1	0406006	P	2	28.839257	0.237546	28.601710	29.076803	-2.960307	0.005079	0.997064	0.000142	4	4	1.943	0.296	0.180	0.0277
2	2	0406006	O	2	28.912683	0.173233	28.739449	29.085916	-3.222941	0.256027	0.996027	0.001653	4	4	2.158	0.575	0.236	0.0643
1	1	0406006	N	2	28.989329	0.160418	28.828911	29.149747	-2.970125	0.007270	0.997398	0.001050	4	4	2.190	0.362	0.212	0.0282
1	1	0406006	M	3	28.380780	0.177291	28.203489	28.558071	-2.859183	0.107768	0.989484	0.002529	6	6	2.027	0.361	0.147	0.0256
1	1	0406006	L	1	28.357681		28.357681	28.357681	-2.914488		0.994048		2	2	1.960	0.297	0.149	0.0212
1	1	0406006	K	2	28.836067	0.120582	28.715485	28.956649	-3.102119	0.032528	0.997772	0.000100	4	4	2.023	0.241	0.255	0.0447
1	1	0406006	I	1	28.897871		28.897871	28.897871	-2.997110		0.995925		2	2	2.016	0.318	0.200	0.0212
1	2	0403005	E	4	28.665796	0.189916	28.475880	28.855711	-2.927845	0.046859	0.994102	0.003407	8	8	1.828	0.315	0.170	0.0330

Table 46. Summary of Testquant results by lot number. While most lot numbers produced Quantifiler values of approximately double the expected concentrations, a few outliers highlighted in green, pink and orange were present. With the use of Testquants of Standards, it was possible to avoid the use of such outliers.

Operator number	TestQuant number	Lot Number	Total vials	Mean Y-Intercept [CT at Quant=1] Acceptable range 1StdDev 28.77-29.23 2StdDev 28.55-29.46	Y-intercept StdDev	Minimum 2 StdDev (95% CI)	Maximum 2 StdDev (95% CI)	Mean Slope (Acceptable range -3.3 to -2.9)	Slope StdDev	Mean r^2 (Acceptable range ≥0.98)	r^2 StdDev	Promega Sample Number	EPC Sample Number	1ng/µL Promega Mean (ng/µL)	Promega StdDev	0.1ng/µL EPC Mean (ng/µL)	EPC StdDev
5	9	0602018	19	28.550637	0.186582	28.364055	28.737220	-3.08330268	0.126602	0.995722	0.003773	38	38	1.426	0.179	0.149	0.0444
4	5	0510016	5	28.986246	0.374852	28.611394	29.361098	-3.041177	0.136262	0.995915	0.002215	10	10	2.012	0.617	0.188	0.0719
6	19	0507015	49	28.962658	0.182222	28.780436	29.144880	-3.123854	0.115858	0.996134	0.002346	88	88	2.015	0.325	0.216	0.0491
3	11	0506014	18	29.382788	0.187709	29.195078	29.570497	-3.032913	0.121899	0.992845	0.004936	36	36	2.951	0.366	0.301	0.0600
4	3	0505013	5	28.889610	0.221412	28.668198	29.111022	-3.077731	0.108570	0.994026	0.001318	10	10	1.834	0.408	0.228	0.0472
3	8	0503012	29	29.099643	0.181876	28.917767	29.281520	-3.035637	0.116328	0.994716	0.003297	58	54	2.228	0.270	0.212	0.0496
1	1	0412010	2	29.164420	0.015077	29.149343	29.179497	-3.176580	0.081416	0.995699	0.003838	4	4	2.658	0.134	0.303	0.0173
2	4	0406006	11	28.734812	0.284248	28.450564	29.019061	-3.000010	0.153275	0.994996	0.003502	26	26	2.052	0.339	0.197	0.0524
1	2	0403005	4	28.665796	0.189916	28.475880	28.855711	-2.927845	0.046859	0.994102	0.003407	8	8	1.828	0.315	0.170	0.0330

Table 47. Quantifiler Standard data from Testquants of Standards. The data from Testquants reflects that the CT difference for the Y-intercept between different Quantifiler Standards is much higher than the maximum allowable difference of 0.64 CTs published by Applied Biosystems (2006).

Total population	
Minimum	28.176086
Maximum	29.671104
Y-intercept CT difference	1.495018
Mean	28.9605954
Standard Deviation	0.31277464
1 StdDev Min	28.6478207
1 StdDev Max	29.27337
Y-intercept CT difference at 1 StdDev	0.62554929
2 StdDev Min	28.3350461
2 StdDev Max	29.5861447
Y-intercept CT difference at 2 StdDev	1.25109857

In Table 47, we can see a Y-intercept difference of up to approximately 2.82-fold in concentrations by using different standards and at the 95% confidence level, up to a 2.38-fold concentration difference. The Y-intercept distribution has a CV of 1.08% or a 95% confidence interval of 2.16% (2 standard deviations). Therefore, while the distribution of the Y-intercept is broad for Quantitation purposes, it has a reasonable distribution when compared to the mean Y-intercept value. From Tables 45 and 46 it is evident that validation using standards from only a few lot numbers may not be appropriate, given that there is so much variation in DNA concentration from one Quantifiler standard lot to another. Clearly, the Y-intercept distribution of lot 0602018 (95% confidence interval range of approximately 28.36-28.74) will not provide reproducible data with the application of the standard from lot 0506014 (95% confidence interval range of approximately (29.20-29.57). These two lots had a mean Y-intercept difference of 0.83 CTs so that the correction factor for reproducible results would be approximately 1.78. This validation provided the means to test for standards to ascertain whether or not they fall in the mean distribution and criteria were established to ensure tighter reproducibility, especially in the Y-intercept values. This, however, has the disadvantage that not every lot or batch obtained from ABI will be suitable for making standards that will maintain a suitable level of reproducibility.

5.5 ACCURACY OF PROMEGA MALE AND QUANTIFILER STANDARDS- INDEPENDENT TESTING

Spectrophotometric readings were taken of a variety of lots of Quantifiler standards and one Promega Male standard. Readings were taken with a Cary 1E UV-Visible Spectrophotometer (from Varian) at Investigative Chemistry, QHSS (thanks to Willy Gore) and calibrated against TE background (mean=0.0089 units). A 1mL cuvette and a glass pipettor were utilised for loading the samples into the cuvette. The pipettor and cuvette were rinsed twice with TE before re-use. For the calculations, 1 A260 unit was taken to be 50µg/mL (50ng/µL). Comparisons of the A260 data were made with concentration values obtained from a Quantifiler run on the 20th of December 2004. The run included three Quantifiler standards and a Promega Male standard to produce values for comparison.

5.5.1 RESULTS

Table 48. A260 and Quantifiler results of Promega Male control and Quantifiler standard samples.

		A260 Percentage of stated value			Quantifiler percentage of stated value (50ng/uL)				
Sample	Stated concentration (ng/uL) of original vial	Original vial	STD1 (50ng/uL)	Overall mean (A260 value of STD1 and original)	Promega Standard values Quant 20.12.04	Mean Quantifiler standard percentage	E Standard values Quant 20.12.04	I Standard values Quant 20.12.04	T Standard values Quant 20.12.04
Promega	177	95.06%	103.00%	99.03%		199.33%	175.86%	204.02%	218.10%
B	200	79.63%	90.34%	84.99%	74.84%	122.55%	109.00%	127.00%	131.66%
E	200	69.04%	87.66%	78.35%	70.44%	121.61%		119.66%	123.56%
G	200	81.25%	93.34%	87.30%	64.24%	104.98%	93.60%	109.22%	112.12%
I	200	105.63%	93.00%	99.32%	67.24%	107.82%	97.98%		117.66%
L	200	59.63%	84.66%	72.15%	70.58%	115.51%	102.84%	119.88%	123.80%
M	200	107.25%	81.66%	94.46%	56.92%	92.89%	82.98%	96.94%	98.74%
T	200	59.88%	101.00%	80.44%	69.80%	110.14%	101.70%	118.58%	
Mean of non-promega samples				85.28%	67.72%	110.79%			
Standard deviation of non-promega samples				9.39%	5.77%	10.34%			

A mean difference of 43.06% was observed between the Promega Male and Quantifiler standards with the Promega Male standard producing values 17.56% lower than the mean A260 value and the Quantifiler standards producing values 25.50% higher than the mean A260 value (see table 48). This is indicative that the Quantifiler standard could have lower amount of copies of the target DNA gene and potentially contains more other DNA than in a genomic sample such as the Promega Male control. Quantifiler values of the Promega Male control sample original and 50ng/µL dilution were approximately double to the expected or stated values, and the A260 readings approximated the expected or stated values. In other words the amount of human DNA detected with the Quantifiler system is approximately 43% to 50% different between using the Promega Male and Quantifiler standards. The average A260 reading for Quantifiler STD#1 samples B, E, G, I, L, M and T was 45.12±4.86ng/µL (45.12±(standard deviation of 3.19 + error margin of 1.67ng/µL). Both the Promega Male and Quantifiler standard samples appear to indicate values near to the expected or stated values according to A260 values, although the Quantifiler standards overestimated the amount of DNA present in the Promega Male control samples. The Promega Male standard used in this case underestimated the amount of DNA present in the Quantifiler standard samples when compared to the expected values.

5.6 REPRODUCIBILITY (EXTERNAL)

External reproducibility is a measure of the maximum acceptable difference between two test results obtained on the same material by different laboratories. Normally, inter-laboratory reproducibility is calculated at the 95% confidence level. It is most conveniently determined in collaborative trials (QIS 10663R2).

Reproducibility between different laboratories was not measured or calculated at the 95% confidence level. No collaborative trials were set up for this purpose. However, a collaborative trial was set up between Forensic Science South Australia (FSSA), PathWest in Western Australia and QHSS to examine the variation in Quantifiler results from a set of 24 samples. It is important to note that both FSSA and PathWest have the ABI 7500 SDS and not the ABI 7000 SDS used by QHSS. We were also the last to receive the samples and had a few volumes that were just above the 4µL required for this analysis. Although the samples were in O-ring vials, evaporation may have resulted in concentrating some of the lower volumes. We analysed the samples in duplicate with both the Promega Male standard and the Quantifiler standard being run on the same plate. PathWest used the Promega Female standard and the Quantifiler standard (which they term the ABI standard) whereas FSSA utilised the Promega K562 (another Female control) standard. Therefore, the Quantifiler data differences could largely be due to the differences in the systems used as well as differences in the condition of the samples.

Table 49 contains the Quantifiler concentrations resulting from the three different laboratories. A comparison of the differences in the values is presented in table 50. The lowest differences observed were within QHSS comparing the calibrated Quantifiler results with the Promega Male standard results. We believe that the data demonstrates that reproducibility values are higher across labs than within the QHSS lab itself. In other words, although the 95% confidence intervals from one lab to another will be different and have a different mean depending on the system used, across the labs tested the 95% confidence interval range would be greater than estimated within QHSS for our purposes.

Table 49.Quantifiler concentration results from different laboratories. The blue colour denotes where a Promega Male standard was used, whereas the yellow colour denotes where the Quantifiler (ABI) standard was used.

Sample	FSSA (Promega std)	PathWest (Promega std)	QLD (Promega Human DNA Control Male Std result 1	QLD (Promega Human DNA Control Male Std result 2	QLD (ABI std)/2 result 1	QLD (ABI std)/2 result 2	QLD (ABI std)/2.22 result 1	QLD (ABI std)/2.22 result 2	QLD (ABI std) result 1	QLD (ABI std) result 2	PathWest (ABI std) result 1	PathWest (ABI std) result 2
1	200.000	260.78	284.71	228.66	317.61	254.32	286.13	229.12	635.21	508.64	907.45	720.31
2	50.000	58.02	92.82	93.23	101.99	102.44	91.88	92.29	203.97	204.88	184.10	170.94
3	12.500	17.38	14.83	12.75	15.89	13.64	14.32	12.29	31.78	27.28	39.91	37.64
4	3.125	4.65	5.04	4.85	5.33	5.12	4.80	4.61	10.65	10.23	9.04	9.76
5	0.781	1.34	1.75	1.58	1.82	1.65	1.64	1.48	3.63	3.29	2.63	2.49
6	0.195	0.368	0.446	0.432	0.456	0.442	0.411	0.398	0.912	0.883	0.644	0.493
7	0.049	0.115	0.117	0.110	0.117	0.110	0.105	0.099	0.234	0.220	0.148	0.0987
8	0.012	0.0343	0.0220	0.0069	0.0216	0.0067	0.0195	0.0060	0.0432	0.0134	0.0276	0.0366
9	0.013	0.0114	0.0261	0.0190	0.0256	0.0186	0.0231	0.0167	0.0512	0.0371	0.0467	0.0234
10	0.050	0.0447	0.0411	0.0335	0.0407	0.0331	0.0367	0.0298	0.0814	0.0662	0.0664	0.0654
11	0.042	0.059	0.0548	0.0594	0.0545	0.0590	0.0491	0.0532	0.109	0.118	0.0872	0.0695
12	0.025	0.026	0.0307	0.0158	0.0302	0.0155	0.0272	0.0139	0.0604	0.0309	0.0651	0.0668
13	0.104	0.0935	0.0835	0.0955	0.0835	0.0955	0.0752	0.0860	0.167	0.191	0.158	0.0909
14	0.036	0.0455	0.0300	0.0313	0.0295	0.0309	0.0266	0.0278	0.0590	0.0617	0.0396	0.0421
15	0.016	0.0223	0.0337	0.0472	0.0332	0.0468	0.0299	0.0421	0.0664	0.0935	0.023	0.0257
16	0.054	0.0885	0.0763	0.0922	0.0760	0.0920	0.0685	0.0829	0.152	0.184	0.151	IPC fail
17	0.008	0.0215	0.0319	0.0328	0.0315	0.0324	0.0284	0.0292	0.0630	0.0648	0.0326	0.0325
18	0.035	0.0584	0.0845	0.0763	0.0845	0.0760	0.0761	0.0685	0.169	0.152	0.1	0.0975
19	0.023	0.0695	0.0607	0.0618	0.0605	0.0615	0.0545	0.0554	0.121	0.123	0.108	0.112
20	0.034	0.0528	0.0646	0.0416	0.0645	0.0411	0.0581	0.0370	0.129	0.0822	0.0794	0.0815
21	0.01	0.0199	0.0213	0.0197	0.0209	0.0194	0.0188	0.0174	0.0418	0.0387	0.027	0.0222
22	0.052	0.139	0.159	0.170	0.160	0.172	0.144	0.155	0.320	0.343	0.183	0.15
23	0.025	0.0397	0.120	0.0984	0.121	0.0985	0.109	0.0887	0.241	0.197	0.109	0.0695
24	0.037	0.0565	0.0624	0.0409	0.0620	0.0405	0.0559	0.0364	0.124	0.0809	0.0584	0.0783

Table 50. Differences in Quantifiler concentration values across three laboratories.

	Promega Standard						Quantifiler (ABI) Standard						Promega vs Quantifiler (ABI) standard					
	Difference FSSA Promega Std to QLD Promega Std result 1	Difference FSSA Promega Std to QLD Promega Std result 2	Difference PathWest Promega Std to QLD Promega Std result 1	Difference PathWest Promega Std to QLD Promega Std result 2	Difference FSSA Promega Std to QLD Promega Std mean result	Difference PathWest Promega Std to QLD Promega Std mean result	Difference PathWest (ABI std) result 1 to QLD (ABI std mean)	Difference PathWest (ABI std) result 2 to QLD (ABI std mean)	Difference QLD (ABI std result 1) to PathWest (ABI std) result 1	Difference QLD (ABI std result 2) to PathWest (ABI std) result 1	Difference QLD (ABI std result 1) to PathWest (ABI std) result 2	Difference QLD (ABI std result 2) to PathWest (ABI std) result 2	Difference QLD (ABI Std mean/2) to QLD Promega Std mean result	Difference QLD (ABI Std mean/2.22) to QLD Promega Std mean result	Difference QLD (ABI std)/2 result 1 to QLD Promega Std mean	Difference QLD (ABI std)/2 result 2 to QLD Promega Std mean	Difference QLD (ABI std)/2.22 result 1 to QLD Promega Std mean	Difference QLD (ABI std)/2.22 result 2 to QLD Promega Std mean
Mean	44.50%	43.51%	23.44%	40.85%	41.36%	24.97%	29.57%	36.39%	49.23%	49.76%	68.43%	66.90%	2.37%	8.99%	11.77%	10.09%	10.24%	15.26%
Overall mean		44.01%		32.15%				32.90%		49.50%		67.66%				10.93%		12.75%
Sample																		
1	29.75%	12.53%	8.41%	14.05%	22.08%	1.60%	58.67%	25.94%	30.00%	43.95%	11.81%	29.39%	11.41%	0.37%	23.73%	0.92%	11.47%	10.74%
2	46.13%	46.37%	37.49%	37.77%	46.25%	37.63%	9.94%	16.38%	10.79%	11.29%	19.32%	19.85%	9.88%	1.01%	9.63%	10.12%	1.23%	0.79%
3	15.71%	1.96%	17.19%	36.31%	9.35%	26.03%	35.15%	27.46%	20.37%	31.65%	15.57%	27.52%	7.07%	3.54%	15.23%	1.09%	3.81%	10.89%
4	38.00%	35.57%	7.74%	4.12%	36.80%	5.97%	13.41%	6.51%	17.81%	13.16%	9.12%	4.82%	5.56%	4.90%	7.68%	3.44%	2.99%	6.81%
5	55.37%	50.57%	23.43%	15.19%	53.09%	19.52%	23.99%	28.03%	38.02%	25.10%	45.78%	32.13%	3.90%	6.39%	9.01%	1.20%	1.79%	10.99%
6	56.28%	54.86%	17.49%	14.81%	55.58%	16.17%	28.25%	45.07%	41.61%	37.11%	84.99%	79.11%	2.22%	7.91%	3.87%	0.57%	6.42%	9.40%
7	58.12%	55.45%	1.71%	4.55%	56.83%	1.32%	34.80%	56.52%	58.11%	48.65%	137.08%	122.90%	0.00%	9.91%	3.08%	3.08%	7.13%	12.69%
8	45.45%	73.66%	55.91%	396.38%	16.98%	137.29%	2.47%	29.33%	56.52%	51.45%	18.03%	63.39%	2.11%	11.81%	49.43%	53.65%	34.62%	58.24%
9	50.19%	31.58%	56.32%	40.00%	42.35%	49.45%	5.78%	47.00%	9.64%	20.56%	118.80%	58.55%	2.11%	11.81%	13.53%	17.74%	2.28%	25.89%
10	21.65%	49.25%	8.76%	33.43%	34.05%	19.84%	10.03%	11.38%	22.59%	0.30%	24.46%	1.22%	1.07%	10.88%	9.12%	11.26%	1.70%	20.05%
11	23.36%	29.29%	7.66%	0.67%	26.44%	3.33%	23.17%	38.77%	25.00%	35.32%	56.83%	69.78%	0.61%	10.46%	4.55%	3.33%	14.01%	6.91%
12	18.57%	58.23%	15.31%	64.56%	7.53%	11.83%	42.61%	46.33%	7.22%	52.53%	9.58%	53.74%	1.83%	11.56%	29.89%	33.55%	17.02%	40.13%
13	24.55%	8.90%	11.98%	2.09%	16.20%	4.47%	11.73%	49.22%	5.70%	20.89%	83.72%	110.12%	0.00%	9.91%	6.70%	6.70%	15.95%	3.87%
14	20.00%	15.02%	51.67%	45.37%	17.46%	48.45%	34.38%	30.24%	48.99%	55.81%	40.14%	46.56%	1.55%	11.31%	3.75%	0.65%	13.29%	9.32%
15	52.52%	66.10%	33.83%	52.75%	60.44%	44.87%	71.23%	67.85%	188.70%	306.52%	158.37%	263.81%	1.17%	10.97%	17.92%	15.57%	26.06%	4.12%
16	29.23%	41.43%	15.99%	4.01%	35.91%	5.04%	10.12%	IPC fail	0.66%	21.85%	IPC fail	IPC fail	0.30%	10.18%	9.79%	9.20%	18.73%	1.62%
17	74.92%	75.61%	32.60%	34.45%	75.27%	33.54%	48.98%	49.14%	93.25%	98.77%	93.85%	99.38%	1.24%	11.02%	2.63%	0.15%	12.28%	9.77%
18	58.58%	54.13%	30.89%	23.46%	56.47%	27.36%	37.69%	39.25%	69.00%	52.00%	73.33%	55.90%	0.19%	10.08%	5.10%	5.47%	5.32%	14.84%
19	62.11%	62.78%	14.50%	12.46%	62.45%	13.47%	11.48%	8.20%	12.04%	13.89%	8.04%	9.82%	0.41%	10.28%	1.22%	0.41%	11.01%	9.54%
20	47.37%	18.27%	18.27%	26.92%	35.97%	0.56%	24.81%	22.82%	62.47%	3.53%	58.28%	0.86%	0.56%	10.42%	21.47%	22.60%	9.43%	30.27%
21	53.05%	49.24%	6.57%	1.02%	51.22%	2.93%	32.92%	44.84%	54.81%	43.33%	88.29%	74.32%	1.83%	11.56%	1.95%	5.61%	8.15%	14.96%
22	67.30%	69.41%	12.58%	18.24%	68.39%	15.50%	44.80%	54.75%	74.86%	87.43%	113.33%	128.67%	0.76%	9.23%	2.74%	4.26%	12.37%	6.08%
23	79.17%	74.59%	66.92%	59.65%	77.11%	63.64%	50.23%	68.26%	121.10%	80.73%	246.76%	183.45%	0.27%	9.66%	10.35%	9.80%	0.59%	18.74%
24	40.71%	9.54%	9.46%	38.14%	28.36%	9.39%	43.00%	23.57%	112.33%	38.53%	58.37%	3.32%	0.82%	10.65%	20.04%	21.68%	8.14%	29.45%

5.7 LOWER LIMIT OF DETECTION (LOD) AND LIMIT OF REPORTING/QUANTITATION (LOR/LOQ)

The lower limit of detection (LOD) is the lowest concentration of analyte that can be reliably distinguished from zero, but not necessarily quantified, by the test method. It is the lowest value that is greater than the uncertainty associated with it. This is most commonly taken to be the concentration at which there is only a 5% chance that the result obtained will be within the range normally obtained for zero concentration. There are different approaches for estimating this, but the most common is to take the concentration corresponding to 3 times the standard deviation of the result obtained from the analysis of blanks (QIS 10663R2). This approach is compliant with NATA guidelines (2004:2.5).

The lowest recorded Quantifiler value was worked out by examining DNAMaster on the 22.2.06 and eliminating undetermined or zero values (refer to table 51). The lowest value was 0.000363 from DNA [redacted] Such a low value is not expected to produce an STR profile with Profiler. According to Andrew Masel from Applied Biosystems (pers. comm. to Iman Muharam 16.05.05) "anything greater than a Ct of 37-38 won't produce a STR anyway so it doesn't really matter that it is picking up in the order of 1-2 cells and remember the lowest size std is about 4 cells." A single diploid human cell contains approximately 6.4pg.

Table 51. The lowest Quantifiler values obtained in DNAMaster out of a total of 18329 samples.

Quant value	DNA number	Barcode
0.000363	[redacted]	[redacted]
0.000441		
0.000463		
0.000589		
0.000623		
0.000672		
0.000695		

The Limit of Reporting or Quantitation (LOR/LOQ) is the lowest concentration of analyte that can be reliably distinguished from zero, but not necessarily quantified by the test method. This is the lowest concentration that can be determined with an acceptable level of uncertainty associated with it. This is most commonly taken to be the concentration at which there is only a 5% chance that the result obtained will be within the range normally obtained for zero concentration. There are different approaches for estimating this, but the most common is to take the concentration corresponding to 3 times the standard deviation of the result obtained from the analysis of blanks (QIS 10663R2). This determination follows NATA guidelines (2004:2.5).

For determining the LOD and LOQ, reagent sets with and without expected contamination present from manufacture were utilized. Some of the reagent mixes were not opened until the Quantifiler run (Testquant_130405) was performed. Reagent set V had no contamination present and was known to be sterile. However reagent sets from Y were expected to be contaminated based on one of the vials previously producing background level readings. The occurrence of background levels/contamination was confirmed through the manufacturer (Applied Biosystems 2005). The plate was run according to the format presented in figure 54. The results were analysed and are presented in table 52.

If we account for contamination inherent in the Quantifiler kits and set the means as the baseline for the LOD and LOQ, the highest figures obtained were 0.007242ng/µL for the LOD and 0.07242ng/µL for the LOR/LOQ. The LOR of 0.021725ng/µL is compliant with NATA guidelines. The data produced is presented in table 52.

Table 52. LOD and LOR/LOQ data for samples using the Quantifiler standard.

Sample number	58	16
Positive results (contaminated) sample number	16	16
Mean (ng/uL)	0.000751	0.002722
1 StdDev	0.001450	0.001507
LOD method1 (95% confidence interval; ($2s_0$) (Applied Biosystems 2003:6-7) (ng/uL)	0.003651	0.005735
LOD method2 95% confidence (3s0) (QIS 10662R2, NATA 2004) (ng/uL)	0.005102	0.007242
LOR/LOQ method1 (3x LOD) using $2s_0$ (ng/uL)	0.010954	0.017205
LOR/LOQ method2 (3x LOD) using 3s0 (ng/uL)	0.015305	0.021725
LOR/LOQ method3 (10x LOD) using $3s_0$ (QIS 10663R2) (ng/uL)	0.051017	0.072416

	Lot V reagents + primers				Lot Y3 reaction mix		Lot Y4 reaction mix		Lot Y5 reaction mix		Lot Y6 reaction mix		
	1	2	3	4	5	6	7	8	9	10	11	12	
A	**STD#1 50 ng/uL**	**STD#1 50 ng/uL**	Reagent Blank (V)	Reagent Blank (V)	Reagent Blank (Y3-12)	Reagent Blank (Y3-12)	Reagent Blank (Y4-12)	Reagent Blank (Y4-12)	Reagent Blank (Y5-12)	Reagent Blank (Y5-12)	Reagent Blank (Y6-12)	Reagent Blank (Y6-12)	Y12 primers
B	**STD#2 16.7ng/uL**	**STD#2 16.7ng/uL**	NanoH2O New 060405 (V)	NanoH2O New 060405 (V)	NanoH2O New 060405 (Y3-12)	NanoH2O New 060405 (Y3-12)	NanoH2O New 060405 (Y4-12)	NanoH2O New 060405 (Y4-12)	NanoH2O New 060405 (Y5-12)	NanoH2O New 060405 (Y5-12)	NanoH2O New060405 (Y6-12)	NanoH2O New060405 (Y6-12)	
C	**STD#3 5.56ng/uL**	**STD#3 5.56ng/uL**	NanoH2O 230305 (V)	NanoH2O 230305 (V)	NanoH2O 230305 (Y3-12)	NanoH2O 230305 (Y3-12)	NanoH2O 230305 (Y4-12)	NanoH2O 230305 (Y4-12)	NanoH2O 230305 (Y5-12)	NanoH2O 230305 (Y5-12)	NanoH2O 230305 (Y6-12)	NanoH2O 230305 (Y6-12)	
D	**STD#4 1.85ng/uL**	**STD#4 1.85ng/uL**	NanoH2O 070405 (V)	NanoH2O 070405 (V)	Promega 1ng/uL (Y3-12)	Promega 1ng/uL (Y3-12)	Promega 1ng/uL (Y4-12)	Promega 1ng/uL (Y4-12)	Promega 1ng/uL (Y5-12)	Promega 1ng/uL (Y5-12)	Promega 1ng/uL (Y6-12)	Promega 1ng/uL (Y6-12)	
E	**STD#5 0.62ng/uL**	**STD#5 0.62ng/uL**	Promega 1ng/uL (V)	Promega 1ng/uL (V)	Reagent Blank (Y3-15)	Reagent Blank (Y3-15)	Reagent Blank (Y4-15)	Reagent Blank (Y4-15)	Reagent Blank (Y5-15)	Reagent Blank (Y5-15)	Reagent Blank (Y6-15)	Reagent Blank (Y6-15)	Y15 primers
F	**STD#6 0.21ng/uL**	**STD#6 0.21ng/uL**	EPC K5 (V)	EPC K5 (V)	NanoH2O New 060405 (Y3-15)	NanoH2O New 060405 (Y3-15)	NanoH2O New 060405 (Y4-15)	NanoH2O New 060405 (Y4-15)	NanoH2O New 060405 (Y5-15)	NanoH2O New 060405 (Y5-15)	NanoH2O New 060405 (Y6-15)	NanoH2O New 060405 (Y6-15)	
G	**STD#7 0.068ng/uL**	**STD#7 0.068ng/uL**	TE-4 (V)	TE-4 (V)	NanoH2O 230305 (Y3-15)	NanoH2O 230305 (Y3-15)	NanoH2O 230305 (Y4-15)	NanoH2O 230305 (Y4-15)	NanoH2O 230305 (Y5-15)	NanoH2O 230305 (Y5-15)	NanoH2O 230305 (Y6-15)	NanoH2O 230305 (Y6-15)	
H	**STD#8 0.023ng/uL**	**STD#8 0.023ng/uL**	BLANK (no reagent)	BLANK (no reagent)	Promega 1ng/uL (Y3-15)	Promega 1ng/uL (Y3-15)	Promega 1ng/uL (Y4-15)	Promega 1ng/uL (Y4-15)	Promega 1ng/uL (Y5-15)	Promega 1ng/uL (Y5-15)	Promega 1ng/uL (Y6-15)	Promega 1ng/uL (Y6-15)	

Figure 54. Testquant_130405 (13 April 2005). The orange colour indicates where amplified product was detected. The values obtained were used to calculate the LOD and LOR/LOQ. Five batches of reagent mix (V, Y3, Y4, Y5 and Y6) were tested from a total of nine master mixes. Reagent mixes Y3, Y4 and Y5 were found to contain background fluorescent product which was interpreted as contamination or background inherent in the kits.

5.8 WORKING RANGE AND SAMPLE DISTRIBUTION

Working range determination is a requirement of NATA (2004:2.6). The minimum acceptable working concentration based on the LOD is 0.007242ng/µL while the minimum acceptable working concentration beyond any reasonable doubt is the LOR/LOQ of 0.07242ng/µL (10X the LOD) or 0.021725ng/µL (3X the LOD). The maximum acceptable working concentration is the value of the standard with the highest concentration. This is equal to 50ng/µL (STD1). It is recommended that values beyond 50ng/µL be diluted and re-quantified and the dilution used for amplification. In Figure 55, it is clear that less than 1% of samples historically produced values greater than 50ng/µL. 18% of samples produced values below the LOD (0.00742ng/µL), while approximately 37% of samples produced values below and including the LOR/LOQ of 0.07242ng/µL (10X LOD). Under 26% of samples would produce values under the NATA LOR/LOQ of 0.021725ng/µL (3X LOD) based on historical data.

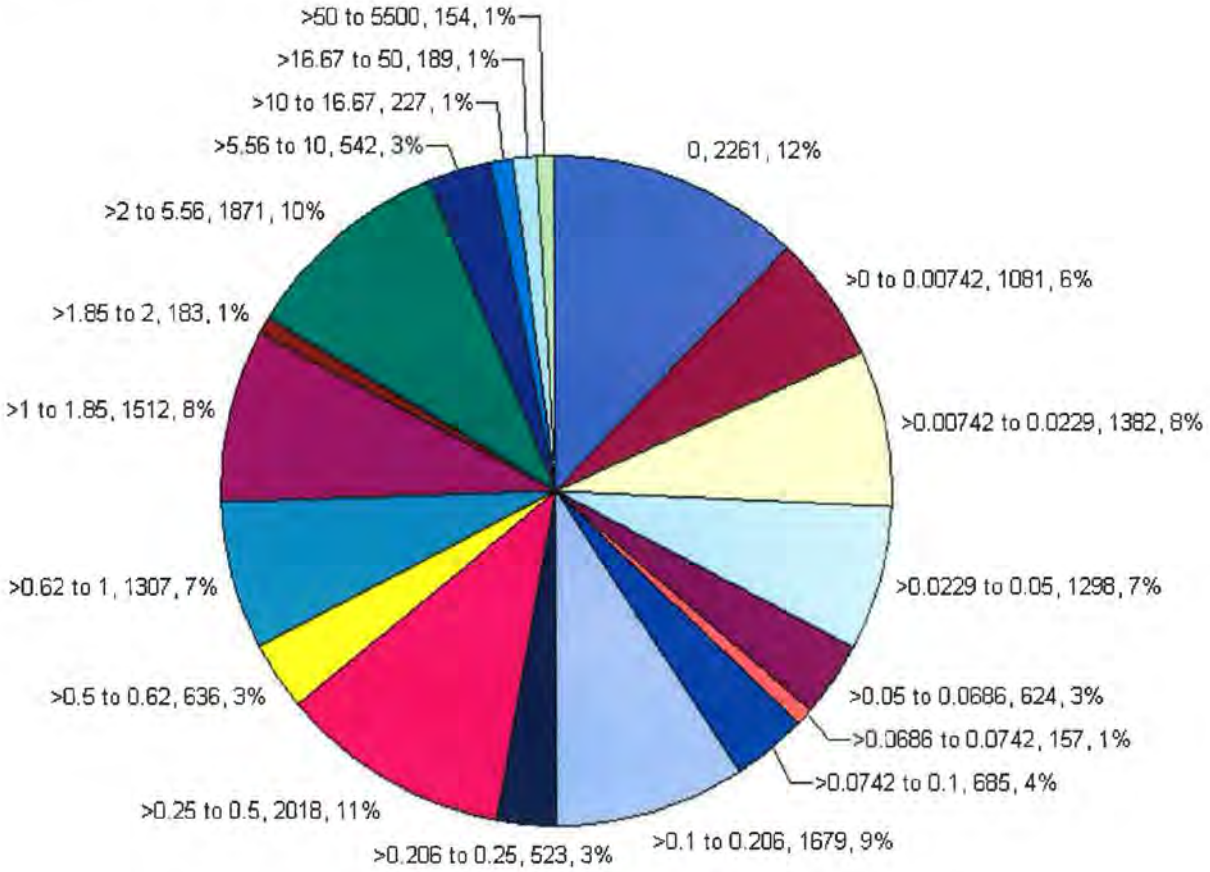

Figure 55. Distribution of Quantifiler values for 18329 reference and casework sample.

5.9 CONTAMINATION

The laboratory must demonstrate that its procedures minimize contamination that would compromise the integrity of the results (QIS 23401R0). The laboratory should employ appropriate controls and implement quality practices to assess contamination and demonstrate that its procedure minimizes contamination (QIS 23401R0).

From ABI, the mean observable contamination out of all the samples where readings were obtained was approximately 0.00272ng/µL with one standard deviation at 0.001572ng/µL. If we account for contamination inherent in the Quantifiler kits and set the means as the baseline for the LOD and LOQ, the highest figures obtained were 0.007242ng/µL for the LOD and 0.07242ng/µL for the LOR/LOQ (10X LOD). This means that we can be confident that anything higher than 0.007242ng/µL is not likely to be a contaminant but a real result. For legal, commercial or statutory applications the amount of freedom is increased in the LOR/LOQ so that we can be confident "beyond reasonable doubt" that anything over 0.07242ng/µL(10X LOD) following QIS 10663R2 or 0.021725ng/µL(3X LOD) following NATA (2004) and QIS 10662R2 is not likely to be a contaminant but a real result.

5.10 SELECTIVITY

5.10.1 SELECTIVITY-SPECIES SPECIFICITY

Selectivity is the ability of the test method to measure an analyte accurately in the presence of potentially interfering substances (QIS 10663R2). It is tested by comparing results for samples containing impurities with results for samples without impurities (QIS 10662R2) and complies with NATA guidelines (2004:2.1). Following the advice of Cathie Allen (pers. comm. with Hlinka and Muharam 2005), it was agreed that species specificity would not be included in this validation. This is because species specificity was already tested in the developmental validation by Applied Biosystems (2003) and it was found that Quantifiler Human Kit amplified DNA from higher ape DNA samples including gorilla, chimpanzee, orangutan, macaque as well as humans. However, other species including cat, dog, pig, cow, mouse, rabbit, hamster, rat, chicken, fish, horse, sheep, and deer did not produce amplified product (Applied Biosystems 2003).

Two samples of dog blood were analysed as a part of the Outsourcing Project at Forensic Biology, QHSS. These consisted of dog blood on fabric (DNA [redacted], Sample ID [redacted]) and dog blood on wood (DNA# [redacted] ID [redacted]). After chelex extraction, both failed to amplify on Quantifiler and produced undetermined values (0ng/µL) with the Quantifiler standard. This agreed with the dog results from Applied Biosystems (2003).

5.10.2 SELECTIVITY-INHIBITORS

The Quantifiler system uses an internal positive control (IPC) to determine if the measurement is potentially accurate. If there are inhibitors present, the IPC will generally be outside the recommended CT range of 20-30. We have not rigorously tested the system by comparing results for samples containing inhibitors with results for samples without impurities.

It should be noted that the lack of inhibition in Quantifiler is not necessarily an indication that the Profiler amplification will not be inhibited. This is primarily because the systems are different and a greater sample per total reaction volume is used in Profiler. An example of this is shown in table 53.

Table 53. Examples of samples that were not inhibited in Quantifiler but were inhibited at the amplification stage.

Sample No#	Sample Type	Quant# and Quant Value	Result in Amp	CW#	Other Amp Volumes	Reamp Results	Notes
[redacted]	Blood swab	QF#269 Quant= 0.08 IPC 27.31, 27.43	NSD @ 20uL	CW#558	5uL PP (12 all-14 inc. Amel.) in CW#549	3uL PP (8 inc. Amel.) in CW#576 5uL PP (8 inc. Amel.) in CW#576 10uL PP (2 inc. Amel.) in CW#576	Later results=greater inhibition/degradation?
[redacted]	Diff. Lysis	QF#265 Quant= 0.25 IPC 27.43, 27.49	NSD@10uL	CW#545		3uL PP (8 inc. Amel.) in CW#608 4uL PP (13 inc. Amel.) in CW#592 8uL PP (7 inc. Amel.) in CW#592	3uL sample could have greater inhibition or degradation being a later sample or the concentration could be less optimal with the ideal between 4 and 8.

It was interesting to note that at higher concentrations (≥5.56ng/µL or the concentration of standard three and above) of the various genomic samples, including the Promega Male standard, the mean IPC CT values increased (see figure 51 and table 37). This indicates a potential but very weak form of partial inhibition from the Promega and Roche genomic samples at concentration levels of ≥5.56ng/µL. The effect was not observed for the Quantifiler standard which was linear throughout. Samples above 50ng/µL can be outside the CT range of 20-30 because large amounts of DNA overload the system and affect the efficiency of the Quantifiler IPC reaction.

5.11 INTEGRATION WITH PROFILER PLUS

5.11.1 PROBATIVE, NONPROBATIVE AND KNOWN SAMPLE TESTING

Evaluation and test of the method and comparison to those from reference samples (QIS 23401R0). When previous typing results are available, consistency within the limits of the respective assays should be assessed (QIS 23401R0). This is consistent with DAB (2000:8.1.3.1.3) and SWGDAM (2004:3.1) guidelines. Because the optimal amount of input DNA with Profiler Plus is 1 to 2.5ng of template, we investigated whether 1 or 2ng of input template is more suitable.

5.11.1.1 PROBATIVE AND NON-PROBATIVE PROFILER AMPLIFICATION RESULTS USING THE QUANTIFILER STANDARD AT 1ng VERSUS 2ng

For this investigation, 1 versus 2 Quantifiler nanograms was evaluated. This differs from 'true' nanograms because the Quantifiler system generally over-estimates the amount of DNA present. Two casework and one reference plate were run to compare the difference. It was found that the 2 Quantifiler ng for input into Profiler Plus generally produced better results and this is demonstrated in table 54.

Table 54. A comparison of results from different input amounts for Profiler Plus.

RUN ID	Number of samples with partial profiles	Number of samples with allelic imbalances	Total number of allelic imbalances	Samples of better quality
CW#274 1ng	28	11	15	6 of 37
CW#274 2ng	7	7	7	28 of 37
REF#81 1ng	2	12	15	2 of 37
REF#81 2ng	1	1	1	35 of 37
CW#273 1ng	12	8	8	4 of 38
CW#273 2ng	6	7	10	26 of 38

5.11.1.2 PROFILER AMPLIFICATION RESULTS FOR QUANTIFILER STANDARD AND PROMEGA MALE CONTROL DILUTED SAMPLES

In this section, the Promega Male control and Quantifiler Standard that had both been diluted were run at different concentrations to evaluate the optimal template amount based on 'expected' or 'stated' values obtained from manufacturers. As is shown in table 55, it was found that the Promega Male control amplified better from an 'expected' value of 1.0 and 2.0ng or approximately 2.0 and 4.0 Quantifiler nanograms respectively. 2.0ng 'expected' and approximate Quantifiler nanograms also produced a better result than 1.0ng. While it was not the case here, possibly because the Promega Male control is a mixture, we believe that a profile from a single-source control may occasionally result in excessive peak heights at approximately 4.0 Quantifiler nanograms or 2.0 'true' or 'expected' nanograms. The profiles from these samples are presented in figures 56-60.

Table 55. Results from analysing samples with Profiler Plus with different input amounts.

Sample	Volume by diluted concentration	True/expected value	Approximate Quantifiler value	Allele count
Promega Male	0.5µL x 1ng/µL	0.5ng	1.0ng	X,Y+22
Promega Male	1.0µL x 1ng/µL	1.0ng	2.0ng	X,Y+46
Promega Male	2.0µL x 1ng/µL	2.0ng	4.0ng	X,Y+48
Quantifiler Standard	2.0µL X 0.5ng/µL	1.0ng	1.0ng	X,Y+18
Quantifiler Standard	4.0µL X 0.5ng/µL	2.0ng	2.0ng	X,Y+18

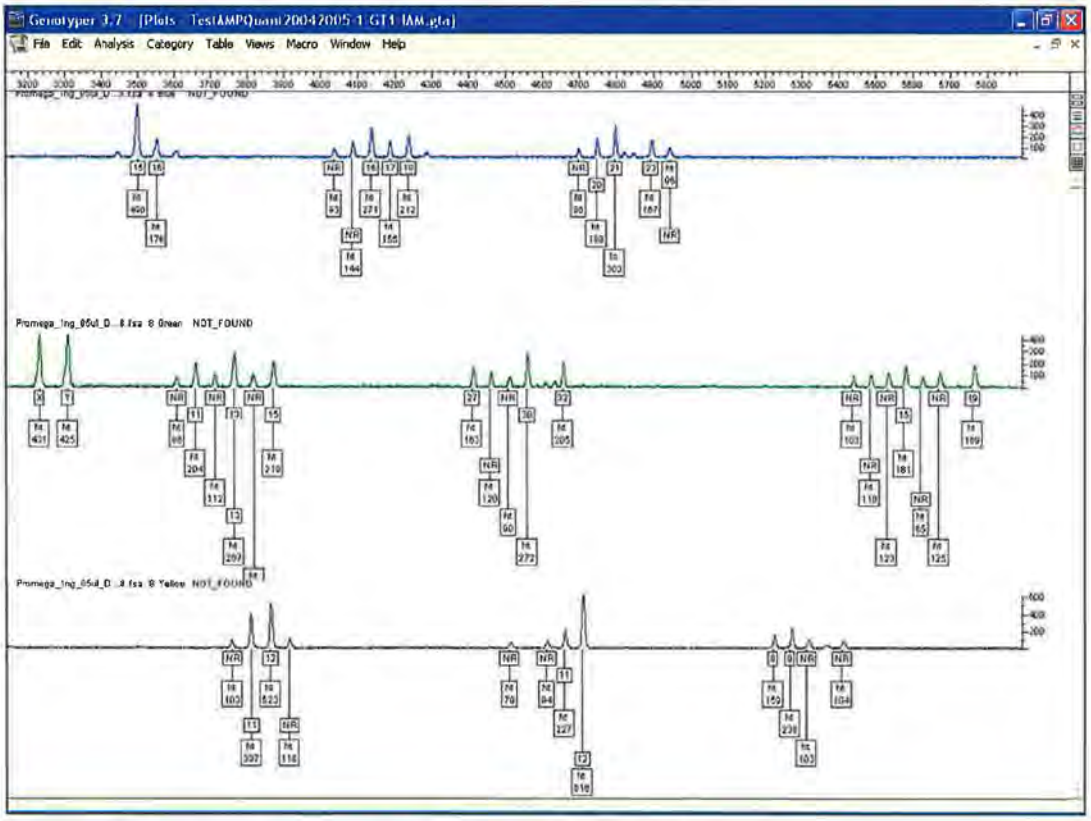

Figure 56. Promega Male control at 0.5ng on Profiler Plus.

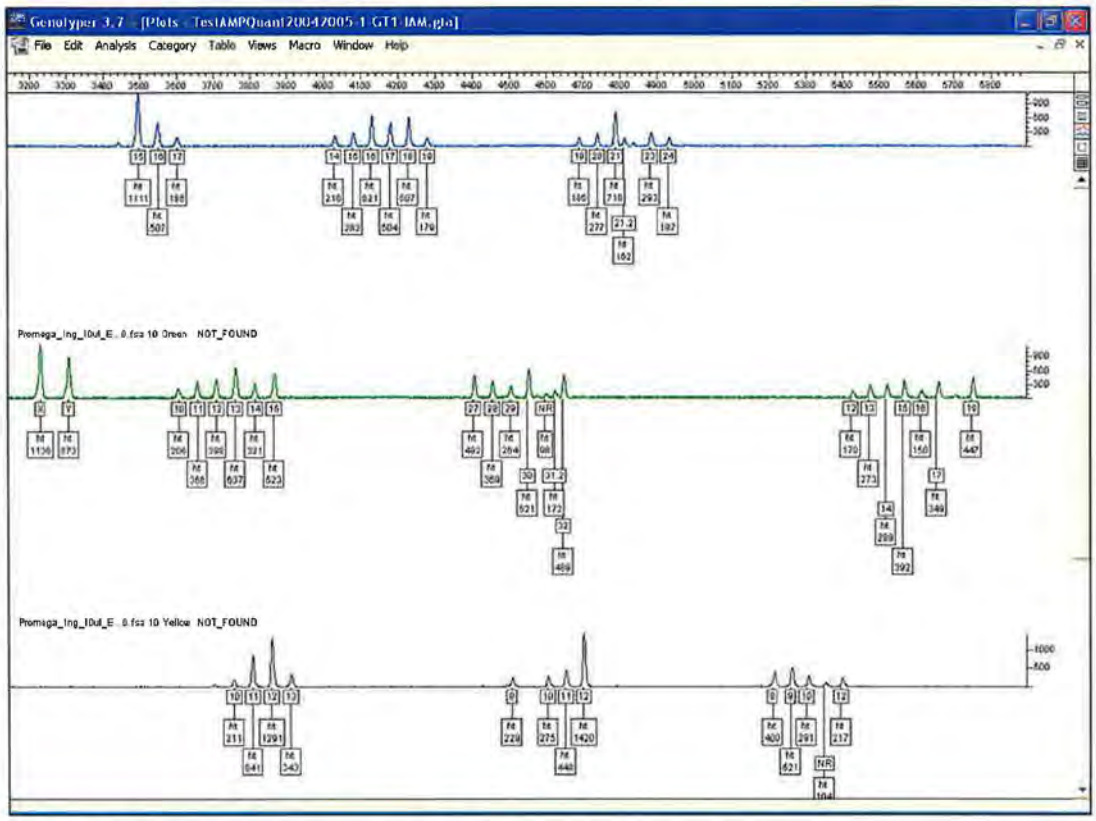

Figure 57. Promega Male control at 1.0ng on Profiler Plus.

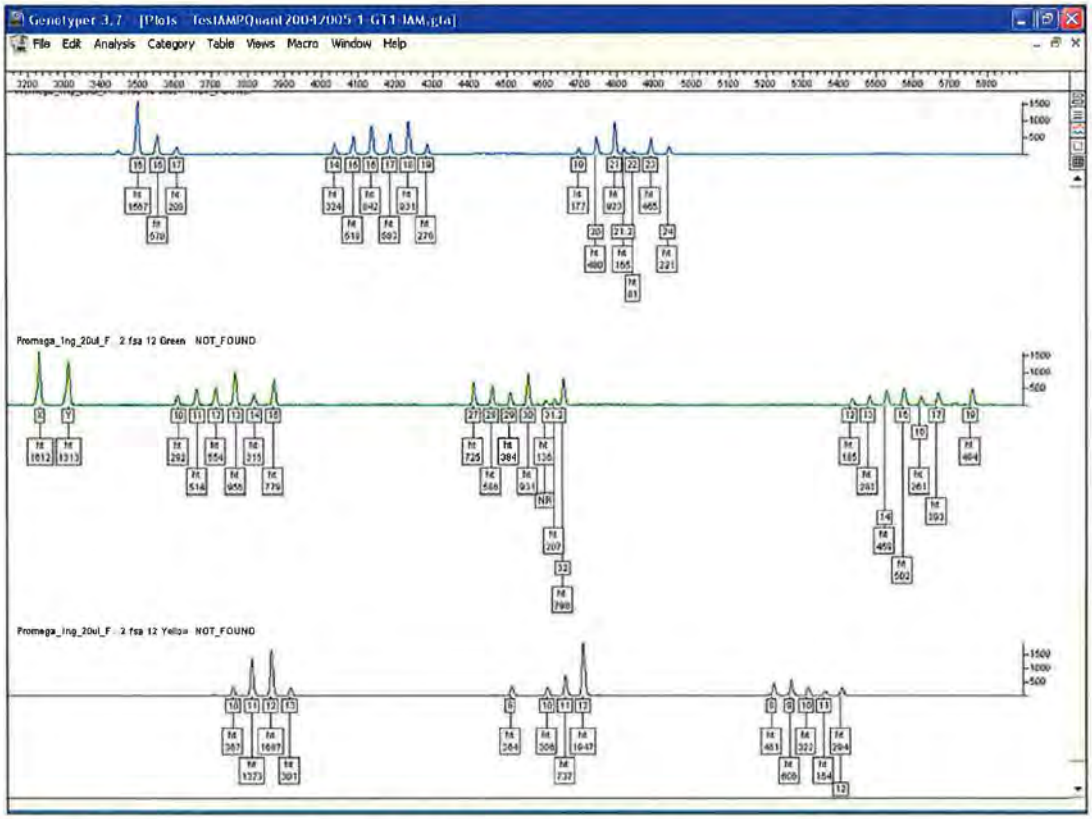

Figure 58. Promega Male control at 2.0ng on Profiler Plus.

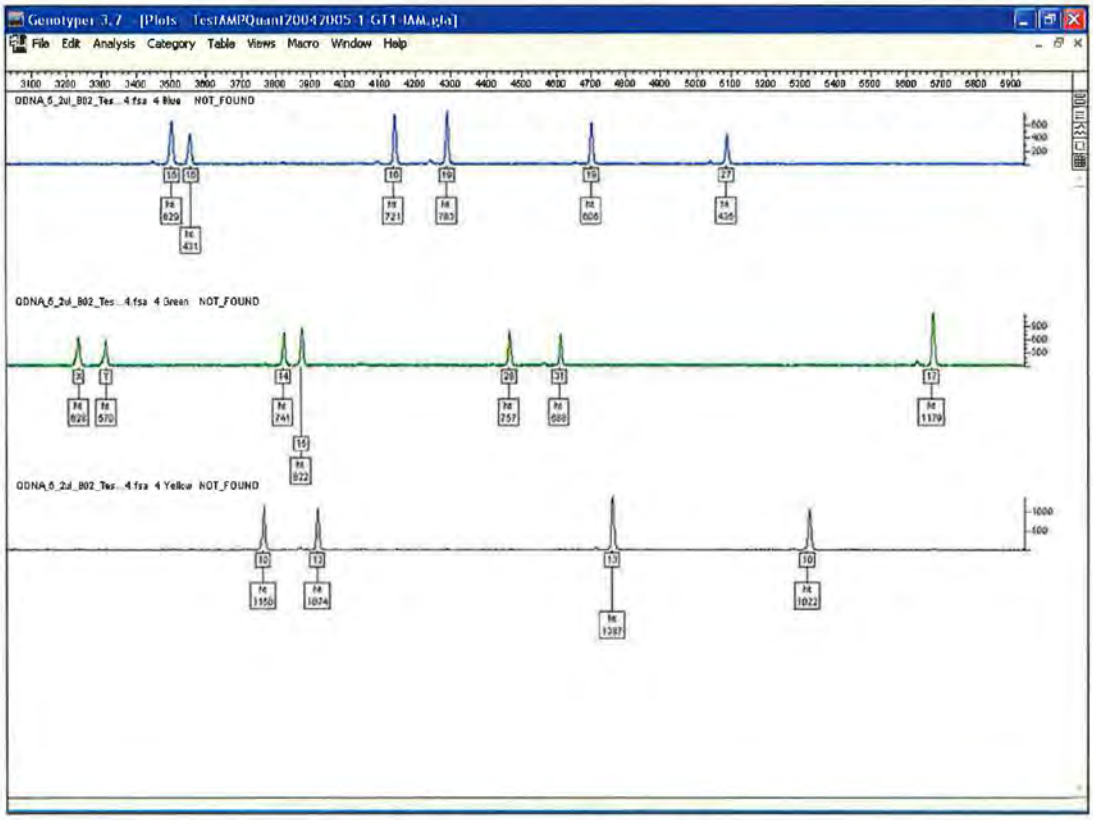

Figure 59. Quantifiler standard at 1.0ng on Profiler Plus.

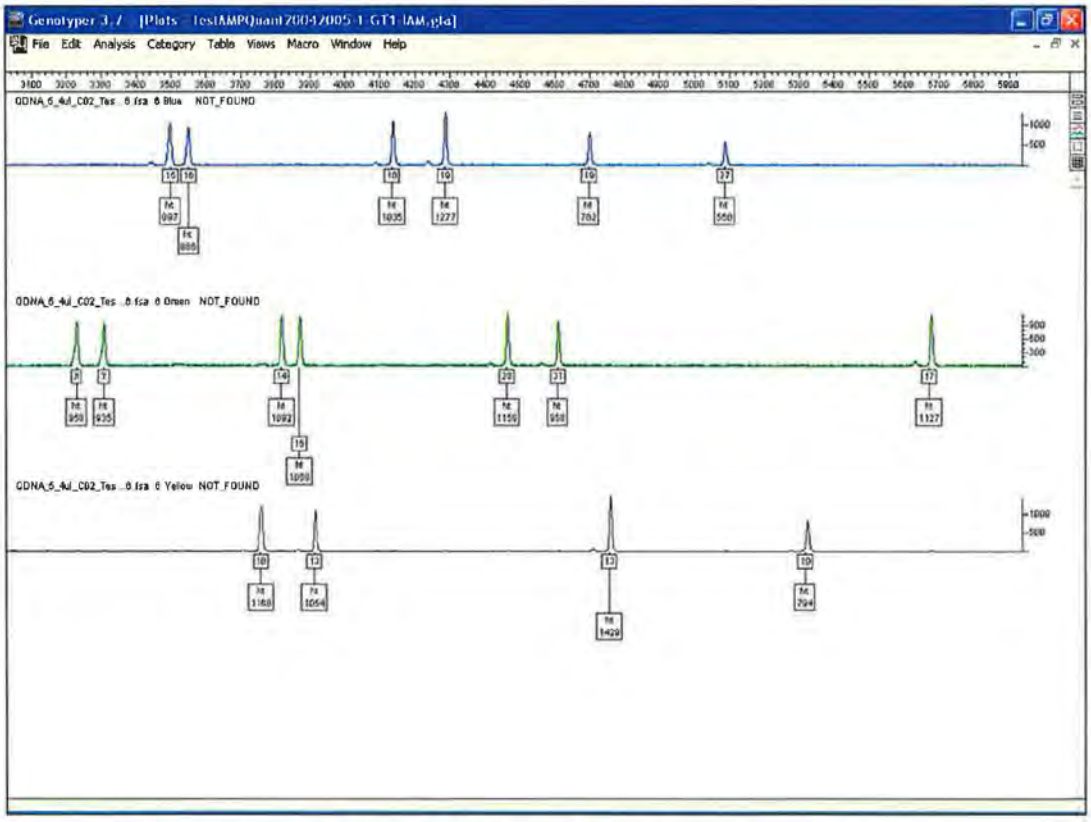

Figure 60. Quantifiler standard at 2.0ng on Profiler Plus.

5.12 MODIFICATIONS

Modifications have to be documented and validated according to DAB (2000:8.1.3.1) and SWGDAM (2004:3.1) guidelines. The following modifications were validated:

(a) Integration of results with Profiler using the Quantifiler standard

A number of different correction factors were evaluated to determine if accuracy in estimation with the Quantifiler could be increased. Various linear and logarithmic calibration methods were tested and the final methods selected for validation were two linear calibration methods where 2.22 Quantifiler nanograms equals approximately 1 true/real nanogram and, rounding down, where 2 Quantifiler nanograms equals approximately 1 true/real nanogram. This is essentially a modification in the paradigm of thinking in terms of Quantfiler nanograms not being the same as true/real nanograms. If we incorrectly assume that 1 Quantifiler nanogram equals a true/real nanogram then a modification to using 2.22 or 2 Quantifiler nanogram amounts for amplification would not be classed as a modification because Profiler requires the true/real nanograms to lie between 1 and 2.5ng.

5.12.1 VALIDATION OF MODIFICATIONS

5.12.1.1 VALIDATION OF CALIBRATION METHODS USING THE QUANTIFILER STANDARD

5.12.1.1.1 BACKGROUND TO LINEAR CALIBRATION METHODS

5.12.1.1.1.1 LINEAR CALIBRATION OF 2.22

The Quantifiler value/2.22 linear calibration method was developed from the equations obtained from the graphs in figures 25 and 26.

Equation 1

$\text{Log}_{10}(\text{Quantifiler value}) = 0.997(\text{Log}_{10}(\text{Promega Male control 'True' or Expected}) + 0.3458$
$R^2 = 0.9995$

Equation 2

$\text{Log}_{10}(\text{Quantifiler value}) = 0.99915(\text{Log}_{10}(\text{Promega Male control 'True' or Expected}) + 0.347341$
$R^2 = 0.9995$

From equation 1 obtained above

(a) Quantifiler value ≈ Promega Male control 'True' or Expected x $10^{(0.3458)}$

(b) Quantifiler value ≈ Promega Male control 'True' or Expected x $10^{(0.3458)}$

(c) Quantifiler value ≈ Promega Male control 'True' or Expected x **2.217**

From equation 2 obtained above

(a) Quantifiler value ≈ Promega Male control 'True' or Expected x $10^{(0.347341)}$

(b) Quantifiler value ≈ Promega Male control 'True' or Expected x **2.225**

Averaging 2.217 and 2.225 to 2.22 and rounding to two decimal places we obtain the approximate correction factor below:

Quantifiler value ≈ Promega Male control 'True' or Expected x 2.22

A linear correction factor of approximately 2.22 is obtained for converting the Promega Male control 'True' or 'Expected' value to the Quantifiler value. The Quantifiler value/2.22 linear calibration method is based on mean results and thus does not take the distributions into account.

5.12.1.1.1.2 LINEAR CALIBRATION OF 2

Rounding down 2.22 to 2 we obtain the approximate

Quantifiler value ≈ Promega Male control 'True' or Expected x 2

The Quantifiler value/2 linear calibration method is based on the mean results and thus does not take distributions into account. This is the recommended linear calibration method since it is simple for calculation purposes and because it is equivalent to adding 2 Quantifiler nanograms instead of 1 Quantifiler nanogram. It has been utilized by Forensic Biology at QHSS but also relies on regulating the selection and use of standards and reagents to maintain the approximate 1:2 ratio of 'expected' nanograms to Quantifiler nanograms.

5.12.1.1.2 REANALYSIS OF PROMEGA MALE CONTROL DATA WITH LINEAR CALIBRATION (INCLUDING T-TEST ANALYSIS)

Results from the Promega Male controls run at different concentrations on a variety of plates were reanalyzed by dividing the Quantifiler results by 2. In Table 56, it is possible to see that the T-test statistic values (To) are much lower than in the uncalibrated data. Furthermore, a few concentrations on specific plates sometimes pass the T-test (95% confidence interval) for accuracy. Therefore, the linear calibration method of Quantifiler value/2 as an estimation method where the distributions fluctuate and are occasionally accurate. This is what can be expected of a system used as for estimation purposes.

In figures 61 to 65, the distributions of Quantifiler values/2 were converted into theoretical amplification volumes for Quantifiler. These values are different to actual values where a maximum of 20µL is added to a Profiler or Cofiler PCR amplification vial. The 0.1ng/µL Promega Male control would, for example, be amplified at between approximately between 6 and 14µL based on Quantifiler values/2 method (see figure 62).

With the linear calibration method of division by 2.22, more results passed the T-test for accuracy and the T-test statistic values (To) were lower than for the division by 2 method (indicating greater accuracy). This data is presented in table 57. Again, the linear calibration method of Quantifiler value/2.22 as an estimation method where the distributions fluctuate and are occasionally accurate. This is what can be expected of a system used as for estimation purposes. With the reagents and standard used for this set of experiments, the mean values fluctuated around 2.22. However, the use of a different lot of standard could potentially result in values with a mean of less than 2 for the correction factor. The use of the linear calibration method of Quantifiler value/2 is supported by long-term data from Testquants of Standards for different batches and lots of Quantifiler standard, where the mean values for the controls appear to fluctuate around the 2-fold concentration values.

Table 56. T-test analysis of Quantifiler results (linear calibration of division by 2). The red colour highlights the sample results that failed the T-test for accuracy. Therefore the system is not always accurate and the obtained Quantifiler values can be significantly different to true or expected values.

		Linear Calibration				
True/ Expected Concentration	Calibration type	Division by 2				
0.05		Overall	Testquant_140705RW	Testquant_130705	Testquant0_05_160705	
	Mean Quant value	0.05966652	0.06138611	0.05085	0.061347368	
	1 StdDev Quant value	0.01245258	0.00910358	0.00915203	0.013019227	
	Test Statistic to	8.21522816	5.30639138	0.39403755	7.598305795	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.1		Overall	Testquant_140705RW	Testquant_130705	Testquant_270705	
	Mean Quant value	0.11054911	0.12188889	0.10444444	0.109309211	
	1 StdDev Quant value	0.01867382	0.02231957	0.01674101	0.017270971	
	Test Statistic to	5.97349073	4.16077337	1.12634662	4.698972325	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.25		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	0.26515278	0.27205556	0.25825		
	1 StdDev Quant value	0.03799997	0.04082347	0.03471999		
	Test Statistic to	2.392546	2.29215699	1.00811614		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
0.5		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	0.53351389	0.55330556	0.51372222		
	1 StdDev Quant value	0.07814542	0.08385757	0.06863699		
	Test Statistic to	2.57319404	2.69690994	0.84820825		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
1		Overall	Testquant_140705RW	Testquant_130705	Testquant_160705	Testquant_150705
	Mean Quant value	1.1034375	1.07875	1.11125	0.939	1.33
	1 StdDev Quant value	0.19929642	0.10773231	0.15975893	0.118025421	0.1690661
	Test Statistic to	2.07605336	1.461957	1.39272337	1.033675618	3.9037994
	Sample number	16	4	4	4	4
	5% critical values for Degrees of freedom (n-1)	2.131	3.182	3.182	3.182	3.182
2		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	2.22784722	2.25902778	2.19666667		
	1 StdDev Quant value	0.22916693	0.23516505	0.22188478		
	Test Statistic to	8.4364169	6.60883362	5.31807536		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		
10		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	12.0647917	11.9184722	12.2111111		
	1 StdDev Quant value	1.50262504	1.01639757	1.87167538		
	Test Statistic to	11.6598205	11.3251287	7.08812372		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		

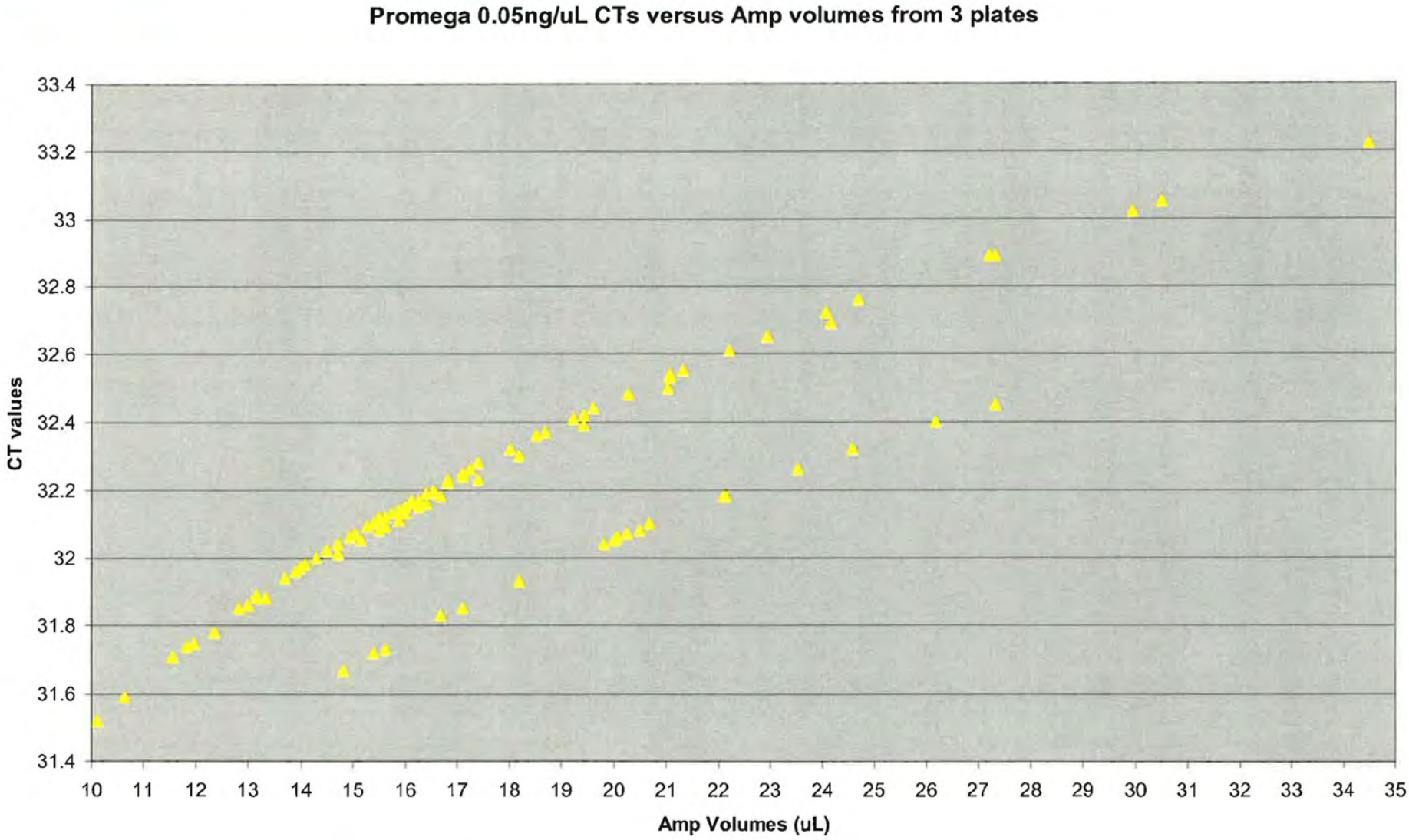

Figure 61. 0.05ng/µL Promega Male control CTs versus amplification volumes from 3 plates.

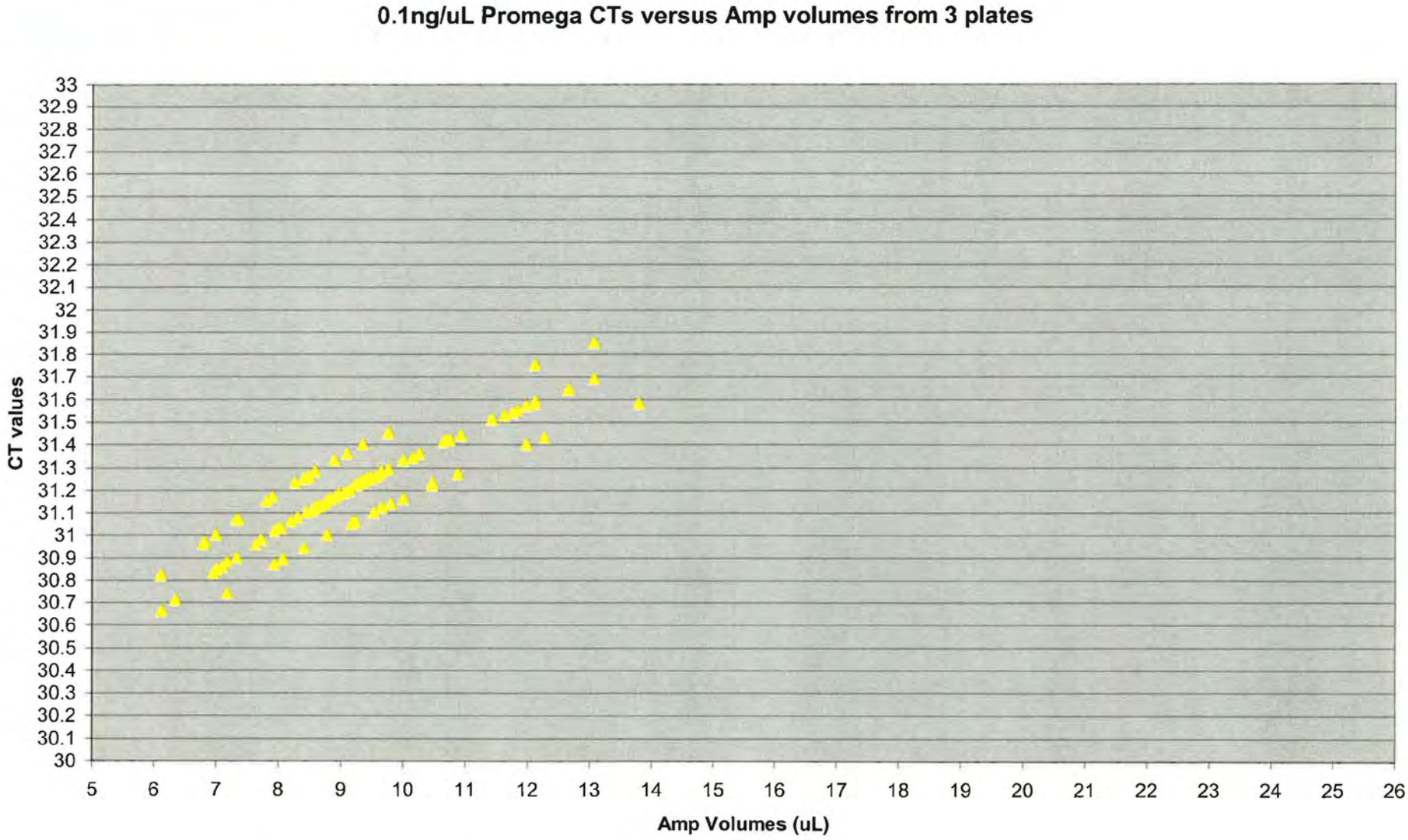

Figure 62. 0.1ng/µL Promega Male control CTs versus amplification volumes from 3 plates.

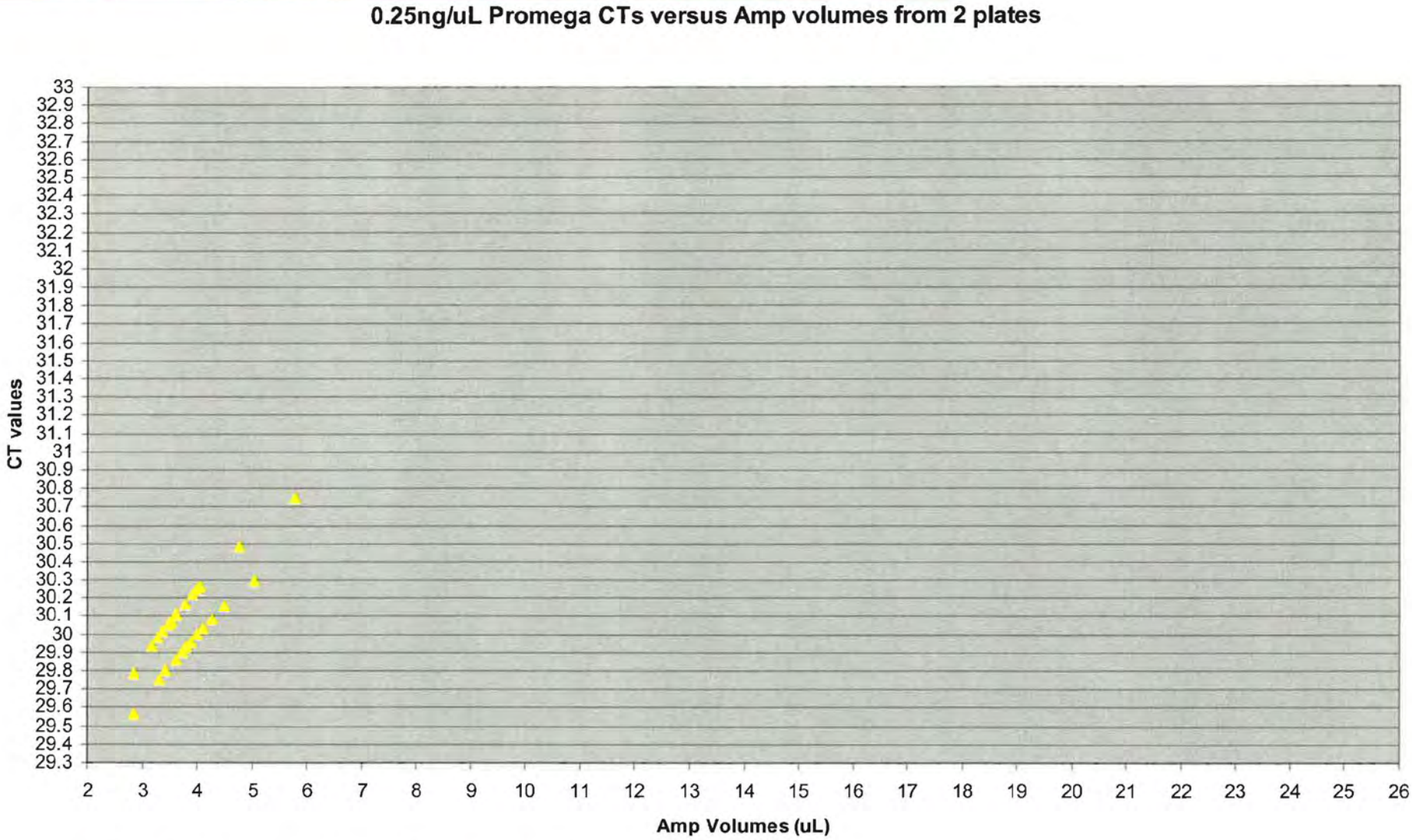

Figure 63. 0.25ng/µL Promega Male control CTs versus amplification volumes from 2 plates.

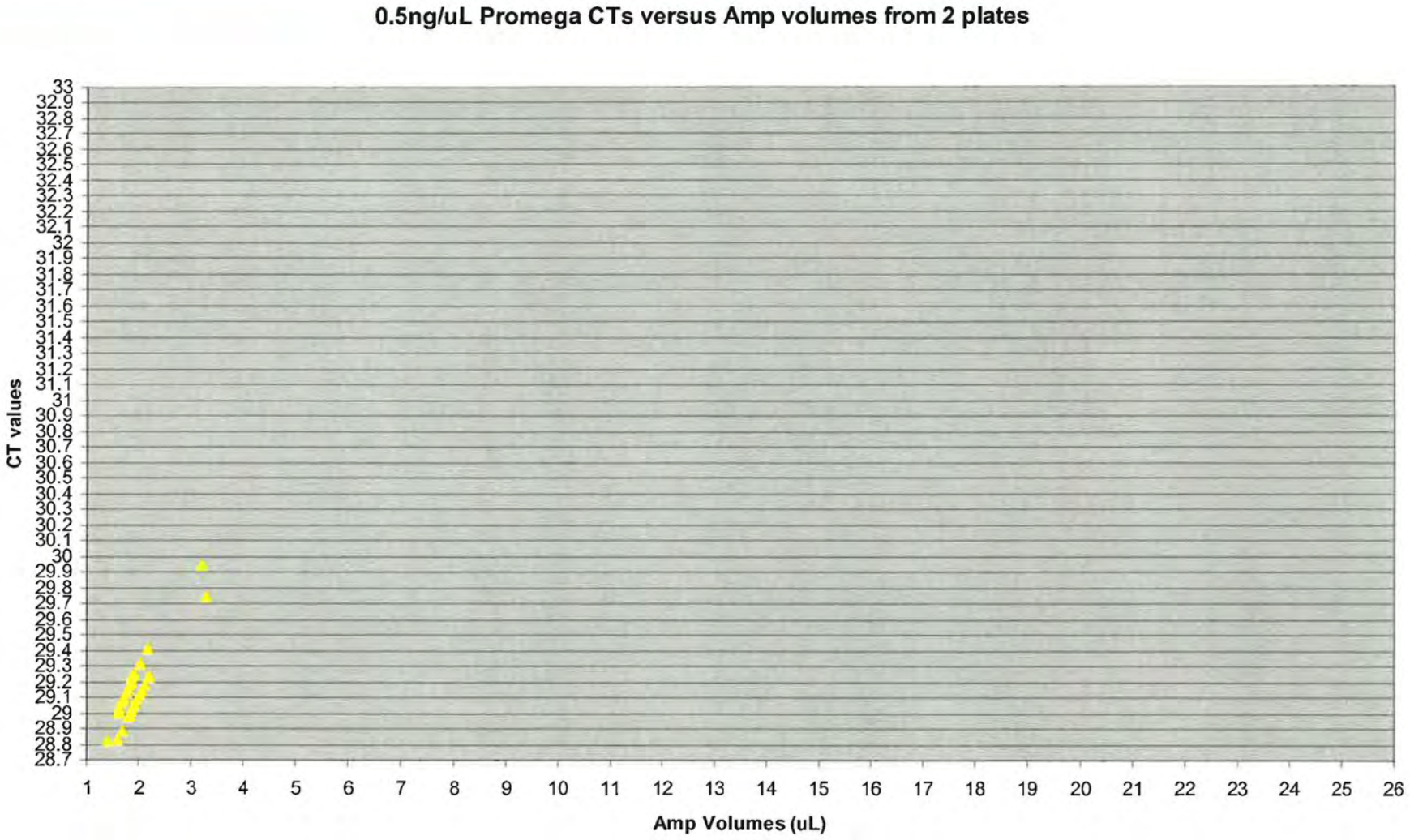

Figure 64. 0.5ng/µL Promega Male control CTs versus amplification volumes from 2 plates.

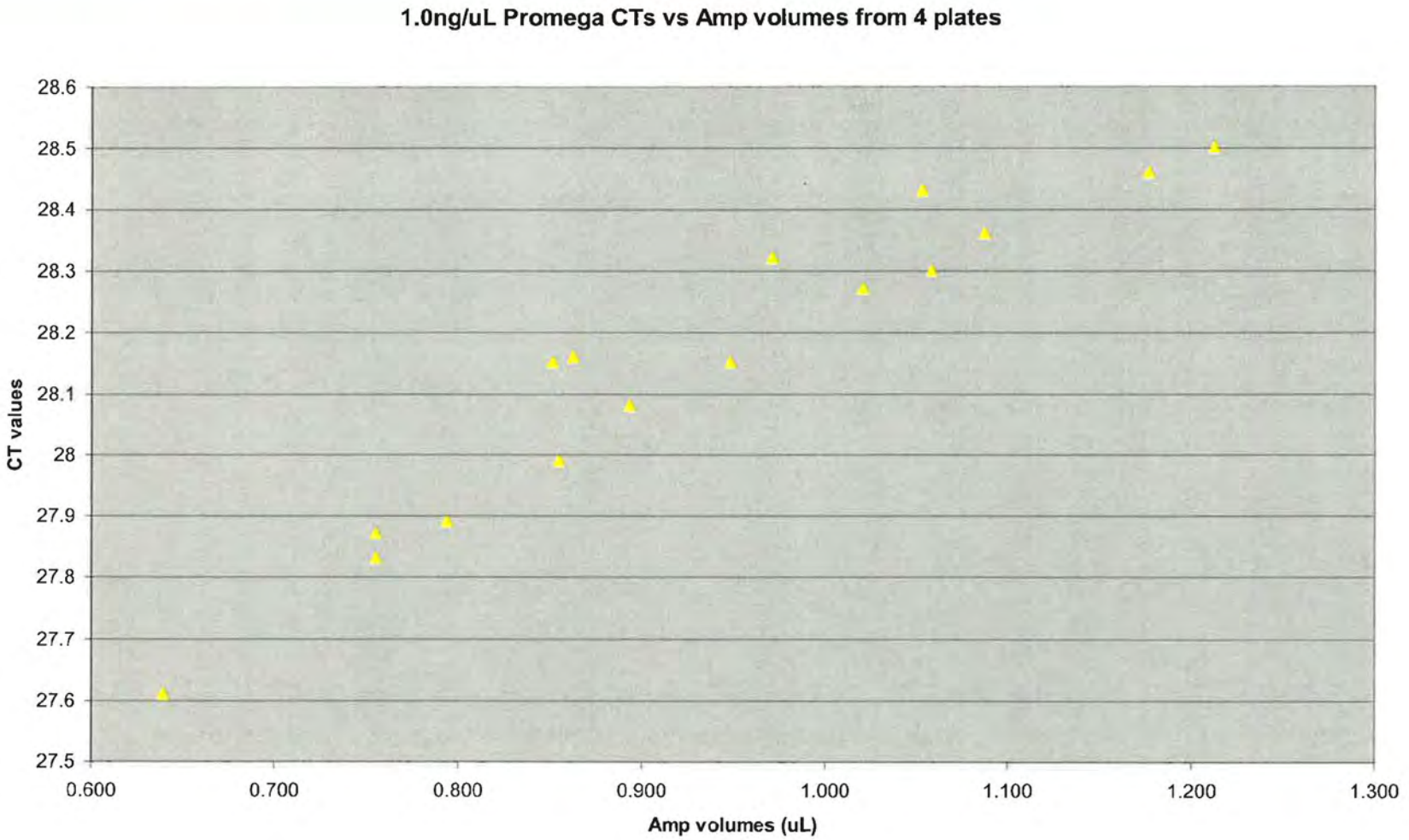

Figure 65. 1.0ng/µL Promega Male control CTs versus amplification volumes from 4 plates.

Table 57. T-test analysis of Quantifiler results (linear calibration of division by 2.22). The red colour highlights that all of the sample results that failed the T-test for accuracy. Therefore the system is not always accurate and the obtained Quantifiler values can be significantly different to true or expected values.

		Linear calibration				
True/ Expected Concentration	Calibration type	Division by 2.22				
0.05		Overall	Testquant_140705RW	Testquant_130705	Testquant0_05_160705	
	Mean Quant value	0.05375362	0.0553028	0.04581081	0.0552679	
	1 StdDev Quant value	0.01121854	0.00820143	0.00824507	0.01172903	
	Test Statistic to	3.54097466	2.74316744	2.15561717	3.9154535	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.1		Overall	Testquant_140705RW	Testquant_130705	Testquant_270705	
	Mean Quant value	0.09959379	0.10980981	0.09409409	0.09847677	
	1 StdDev Quant value	0.01682326	0.02010772	0.01508199	0.01555943	
	Test Statistic to	0.25553431	2.06982635	1.66136127	0.85345292	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.25		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	0.23887638	0.2450951	0.23265766		
	1 StdDev Quant value	0.0342342	0.0367779	0.03127927		
	Test Statistic to	1.94956314	0.56582212	2.35227089		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
0.5		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	0.48064314	0.49847347	0.46281281		
	1 StdDev Quant value	0.07040128	0.07554736	0.06183512		
	Test Statistic to	1.6497021	0.08572773	2.55149283		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
1		Overall	Testquant_140705RW	Testquant_130705	Testquant_160705	Testquant_150705
	Mean Quant value	0.99408784	0.97184685	1.00112613	0.80518018	1.1981982
	1 StdDev Quant value	0.17954632	0.09705613	0.14392697	0.06321036	0.15231177
	Test Statistic to	0.13171336	0.58014166	0.01564858	5.16417372	2.60253297
	Sample number	16	4	4	4	4
	5% critical values for Degrees of freedom (n-1)	2.131	3.182	3.182	3.182	3.182
2		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	2.00706957	2.03516016	1.97897898		
	1 StdDev Quant value	0.2064567	0.2118604	0.1998962		
	Test Statistic to	0.29055627	0.99575456	0.63095809		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		
10		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	10.8691817	10.7373624	11.001001		
	1 StdDev Quant value	1.35371625	0.91567349	1.68619404		
	Test Statistic to	5.44815144	4.83160671	3.56187122		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		

5.12.1.1.3 LOGARITHMIC CALIBRATION

While a logarithmic calibration system was not utilized by QHSS, it was considered as a possible alternative to linear calibration/correction of the Quantifiler data. The logarithmic calibration methods are run-specific because they utilize run-specific data, specifically the Y-intercept and slope. The approach of using run-specific logarithmic calibration was considered too complex for routine work by QHSS Forensic Biology management.

Where a standard is used which contains the correct concentrations, the following theoretical equation is suitable:

$$\text{Quantifiler Value} = 10^{(\{CT-Yintercept\}/Slope)}$$

That is the equation utilised by Quantifiler. However, when the slope has a lower or higher Y-intercept value due to a lower or higher concentration of the Quantifiler standard, a correction which we have termed the Ycorrection is required for the Y-intercept. This is represented in the equations below.

(a) $\text{Quantifiler Value} = 10^{(\{CT-Yintercept+Ycorrection\}/Slope)}$

(b) $\text{Quantifiler Value} = 10^{(\{CT-Yintercept\}/Slope)} \times 10^{(Ycorrection/Slope)}$

(c) $\text{Quantifiler Value} = 10^{(\{CT-Yintercept\}/Slope)} \times \text{Correction factor}$

5.12.1.1.3.1 CHANGE IN CT=0.99 LOGARITHMIC CALIBRATION METHOD

In this calibration method the mean change in CT of the Y-intercept between the Quantifiler standard and the Promega Male standard is taken into account (change in CT=98.2) and further supported by data (not shown) where change in CT of approximately 0.99 produced the most accurate results for controls. The difference of approximately 1 CT also accounts for the doubling effect accounted for in the linear calibration model. This method is represented by the equations below.

(a) $\text{Quantifiler Value} = 10^{(\{CT-Yintercept+Ycorrection\}/Slope)}$

(b) $\text{Quantifiler Value} = 10^{(\{CT-Yintercept+0.99\}/Slope)}$

(c) $\text{Quantifiler Value} = 10^{(\{CT-Yintercept/Slope)\})} \times 10^{(0.99/Slope)}$

The change in CT=0.99 method or ΔCT=0.99 was applied to the Promega Male controls diluted at various concentrations and a T-test for accuracy was conducted. This data is presented in table 58. The ΔCT=0.99 method was also applied to controls (EPC and Promega Male control at 1ng/μL) run on normal Quantifiler runs and the results were tabulated against the Quantifiler value/2 and ΔCT=(Y-intercept-28.05) methods in tables 60 to 62.

5.12.1.1.3.2 CHANGE IN CT=(YINTERCEPT-28.05) LOGARITHMIC CALIBRATION METHOD

The change in CT value=(Yintercept-28.05) or ΔCT=(Yintercept-28.05) calibration method takes a mean value for the Quantifiler standard Y-intercept being approximately one CT less than the actual mean Y-intercept value. The difference of approximately 1 CT also accounts for the doubling effect accounted for in the linear calibration model. This method is represented by the following equations:

(a) Quantifiler Value=$10^{(\{CT-Yintercept\}/Slope)}$

(b) Quantifiler Value=$10^{(\{CT-28.05\}/Slope)}$

(c) Quantifiler Value=$10^{(\{CT-Yintercept+[Yintercept-28.05]\}/Slope)}$

(d) Quantifiler Value=$10^{(\{CT-Yintercept/Slope)} \times 10^{([Yintercept-28.05]/Slope)}$

The ΔCT=(Yintercept-28.05) was applied to the Promega Male controls diluted at various concentrations and a T-test for accuracy was conducted. This data is presented in table 59. The ΔCT=(Yintercept-28.05) method was also applied to controls (EPC and Promega Male control at 1ng/μL) run on normal Quantifiler runs and the results were tabulated against the Quantifiler value/2 and ΔCT=0.99 methods in tables 60 to 62.

While the ΔCT=0.99 assumes a difference of approximately 1 CT in the Y-intercept values, the ΔCT=(Yintercept-28.05) method does not make this assumption and calibrates the results to a theoretical and 'representative' mean standard.

5.12.1.1.3.3 RESULTS AND ANALYSIS (T-TEST ANALYSIS)

Both the ΔCT=0.99 and ΔCT=(Yintercept-28.05) methods resulted in data similar to the Quantifiler value/2 and Quantifiler value/2.22 calibrations. The T-tests demonstrated that no calibration was always accurate for the distributions obtained from the Promega Male controls run at various concentrations. The ΔCT=(Yintercept-28.05) method had the tighter distribution for values obtained from controls presented in tables 60 to 62 and could be an alternative method of choice where differing concentrations of standards are resulting in more variability than other factors. If another model or machine was utilized, the figure of 28.05 would need to be adjusted to suit the different operational and physical conditions. A potential future direction could be to combine the different calibration methods and utilize them to determine the most likely concentration for the sample being analyzed. However, every method tested served only as an estimation of concentration rather than an accurate determination.

With the choice of a more reliable standard, the need for calibration can be avoided. This had been suggested initially by Iman Muharam when the DNA Processing Improvement Project/Quantifiler Project was being developed. The Extended Internal Prospective Validation of the ABI Prsim®7000/Quantifiler System (Forensic Biology) report is focused on the validation of the Promega Male control as a replacement for the Quantifiler (Applied Biosystems) standard.

Table 58. T-test analysis of Quantifiler results (Logarithmic calibration of change in CT=0.99). The red colour highlights the sample results that failed the T-test for accuracy. Therefore the system is not always accurate and the obtained Quantifiler values can be significantly different to true or expected values.

		Logarithmic calibration				
True/ Expected Concentration	Calibration type	(Change in CT=0.99)				
0.05		Overall	Testquant_140705RW	Testquant_130705	Testquant0_05_160705	
	Mean Quant value	0.05774139	0.0591861	0.0468684	0.0599744	
	1 StdDev Quant value	0.01245307	0.00877732	0.00843542	0.01272785	
	Test Statistic to	6.5788719	4.44022858	1.57505514	6.83165033	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.1		Overall	Testquant_140705RW	Testquant_130705	Testquant_270705	
	Mean Quant value	0.10555881	0.11752052	0.09626635	0.10492662	
	1 StdDev Quant value	0.01818173	0.02151966	0.01543017	0.01657852	
	Test Statistic to	3.23560813	3.45420205	1.02659401	2.59066093	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.25		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	0.25016708	0.26230537	0.2380288		
	1 StdDev Quant value	0.03743595	0.0393604	0.03200139		
	Test Statistic to	0.02677921	1.32639072	1.58710339		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
0.5		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	0.50348649	0.53347567	0.47349732		
	1 StdDev Quant value	0.07774385	0.0808522	0.06326265		
	Test Statistic to	0.26907542	1.75660301	1.77737336		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
1		Overall	Testquant_140705RW	Testquant_130705	Testquant_160705	Testquant_150705
	Mean Quant value	1.0345401	1.04008874	1.02793218	0.83555981	1.23457967
	1 StdDev Quant value	0.18318413	0.10387129	0.14770407	0.0655953	0.15693648
	Test Statistic to	0.75421595	0.77189248	0.37821813	5.01377958	2.98948546
	Sample number	16	4	4	4	4
	5% critical values for Degrees of freedom (n-1)	2.131	3.182	3.182	3.182	3.182
2		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	2.0584753	2.09695471	2.01999589		
	1 StdDev Quant value	0.21334185	0.21829322	0.20403931		
	Test Statistic to	2.32574793	2.66489377	0.58800108		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		
10		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	11.1461986	11.0633861	11.229011		
	1 StdDev Quant value	1.38060286	0.94347652	1.7211426		
	Test Statistic to	7.04461618	6.76255977	4.28446167		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		

Table 59. T-test analysis of Quantifiler results (Logarithmic calibration of change in CT=Yintercept-28.05). The red colour highlights the sample results that failed the T-test for accuracy. Therefore the system is not always accurate and the obtained Quantifiler values can be significantly different to true or expected values.

		Logarithmic calibration				
True/ Expected Concentration	Calibration type	Change in CT=Yintercept-28.05				
0.05		Overall	Testquant_140705RW	Testquant_130705	Testquant0_05_160705	
	Mean Quant value	0.04919334	0.04870709	0.0443586	0.05045357	
	1 StdDev Quant value	0.01000666	0.00722328	0.00798371	0.01070733	
	Test Statistic to	0.8531205	0.75940138	2.99790786	0.36929585	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.1		Overall	Testquant_140705RW	Testquant_130705	Testquant_270705	
	Mean Quant value	0.09559607	0.09671329	0.0911113	0.09639364	
	1 StdDev Quant value	0.01553472	0.01770957	0.01460389	0.0152303	
	Test Statistic to	3.00017231	0.7873902	2.58229397	2.06427178	
	Sample number	112	18	18	76	
	5% critical values for Degrees of freedom (n-1)	1.982	2.110	2.110	1.992	
0.25		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	0.22057305	0.33702396	0.22528239		
	1 StdDev Quant value	0.03127295	0.03239156	0.03028772		
	Test Statistic to	5.64582782	11.3983805	3.46239103		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
0.5		Overall	Testquant_140705RW	Testquant_130705		
	Mean Quant value	0.4435822	0.71268255	0.44814161		
	1 StdDev Quant value	0.06255417	0.06653717	0.05987495		
	Test Statistic to	5.4114188	13.5613776	3.67460042		
	Sample number	36	18	18		
	5% critical values for Degrees of freedom (n-1)	2.030	2.110	2.110		
1		Overall	Testquant_140705RW	Testquant_130705	Testquant_160705	Testquant_150705
	Mean Quant value	0.94471198	0.85593904	0.96531855	0.76665885	1.19093148
	1 StdDev Quant value	0.19361295	0.08548068	0.13930504	0.06018626	0.15138804
	Test Statistic to	1.14223803	3.37050838	0.49792094	7.75396752	2.52241165
	Sample number	16	4	4	4	4
	5% critical values for Degrees of freedom (n-1)	2.131	3.182	3.182	3.182	3.182
2		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	2.10294185	2.02281751	2.18306619		
	1 StdDev Quant value	0.22877764	0.21057553	0.220511		
	Test Statistic to	3.81807658	0.65014718	4.98114427		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		
10		Overall	Testquant_160705	Testquant_150705		
	Mean Quant value	11.4038752	10.6722434	12.135507		
	1 StdDev Quant value	1.62995299	0.9101202	1.86008706		
	Test Statistic to	7.30835576	4.43178888	6.88840992		
	Sample number	72	36	36		
	5% critical values for Degrees of freedom (n-1)	1.994	2.030	2.030		

Table 60. Application of calibration methods to control results obtained before process changes. Note that the Y-intercept, slope and r^2 means were derived per EPC value.

Before Process changes							Values adjusted with correction algorithms					
Quantifiler Standard made on	Mean Y-Intercept [CT at Quant=1] Acceptable range 2StdDev 28.55-29.46	Mean Slope Acceptable range -3.3 to -2.9	Mean r2 Acceptable range ≥0.98	Mean EPC Value	Mean Promega Value	Quantifiler Standard Batch	EPC (0.99 ΔCT)	EPC (Yintercept-28.05)	EPC (Quant value/2)	Promega (ΔCT =0.99)	Promega (Yintercept-28.05)	Promega (Quant value/2)
4.1.05	29.192160	-3.377780	0.995629	0.252	NA	0406006	0.128	0.116	0.126	NA	NA	NA
8.11.04	29.432280	-3.272630	0.992560	0.233	NA	0403005	0.116	0.088	0.117	NA	NA	NA
29.3.05	29.147820	-3.182540	0.995804	0.224	NA	0412010 V3+V4	0.109	0.101	0.112	NA	NA	NA
22.11.04	29.168110	-3.245060	0.996486	0.221	NA	0403005	0.109	0.100	0.111	NA	NA	NA
5.10.04	29.171820	-3.259660	0.994687	0.212	NA	0402004	0.105	0.096	0.106	NA	NA	NA
6.12.04	28.987310	-3.148140	0.994837	0.202	NA	0406006	0.098	0.102	0.101	NA	NA	NA
17.1.05	28.873570	-3.201330	0.995211	0.197	NA	0406006	0.097	0.109	0.099	NA	NA	NA
14.3.05	28.826450	-3.176730	0.995676	0.177	NA	0403005 D1	0.086	0.101	0.089	NA	NA	NA
1.2.05	28.724820	-3.235730	0.995082	0.177	NA	0402004	0.088	0.110	0.089	NA	NA	NA
7.4.05	28.814600	-3.101720	0.996541	0.175	NA	0412010 Y1	0.084	0.099	0.088	NA	NA	NA
28.2.05	28.862240	-3.161780	0.996631	0.167	NA	0406006 W2	0.081	0.092	0.084	NA	NA	NA
17.2.05	28.780070	-3.143940	0.995921	0.163	NA	0406006	0.079	0.095	0.082	NA	NA	NA
22.10.04	28.902460	-3.147810	0.995502	0.158	NA	0402004	0.077	0.085	0.079	NA	NA	NA
20.12.04	28.813510	-3.081460	0.996848	0.138	NA	0406006	0.066	0.078	0.069	NA	NA	NA

Table 61. Application of calibration methods to control results obtained after process changes (Testquant of standards but not checking ranges in the QF QC Log). Note that the Y-intercept, slope and r^2 means were derived per EPC value.

After Process improvement (Standard Testquants but not checking ranges in QFQCLog)							Values adjusted with correction algorithms					
Quantifiler Standard made on	Mean Y-Intercept [CT at Quant=1] Acceptable range 2StdDev 28.55-29.46	Mean Slope Acceptable range -3.3 to -2.9	Mean r2 Acceptable range ≥0.98	Mean EPC Value	Mean Promega Value	Quantifiler Standard Batch	EPC (0.99 ΔCT)	EPC (Yintercept-28.05)	EPC (Quant value/2)	Promega (ΔCT =0.99)	Promega (Yintercept-28.05)	Promega (Quant value/2)
6.7.05	29.214905	-3.090170	0.996316	0.229	2.22	0503012 D5	0.110	0.096	0.115	1.062	0.932	1.110
27.6.05	28.961467	-3.175749	0.995673	0.214	1.95	0403005 E7	0.104	0.111	0.107	0.951	1.007	0.975
10.6.05	28.932707	-3.148387	0.994808	0.207	1.92	0403005 E5	0.100	0.109	0.104	0.931	1.007	0.960
18.5.05	28.960197	-3.119111	0.995674	0.205	2.01	0406006 I2	0.099	0.105	0.103	0.968	1.027	1.005
18.5.05	28.989796	-3.055342	0.991136	0.193	1.95	0406006 N3	0.092	0.095	0.097	0.925	0.960	0.975
30.5.05	28.956872	-3.134285	0.996408	0.192	1.89	0406006 L3	0.093	0.099	0.096	0.913	0.971	0.945

Table 62. Application of calibration methods to control results obtained after process changes (Testquant of standards and checking ranges in the QF QC Log). Note that the Y-intercept, slope and r^2 means were derived per EPC value.

After Process improvement (Standard Testquants and checking ranges in QFQCLog)							Values adjusted with correction algorithms					
Quantifiler Standard made on	Mean Y-Intercept [CT at Quant=1] Acceptable range 2StdDev 28.55-29.46	Mean Slope Acceptable range -3.3 to -2.9	Mean r2 Acceptable range ≥0.98	Mean EPC Value	Mean Promega Value	Quantifiler Standard Batch	EPC (0.99 ΔCT)	EPC (Yintercept-28.05)	EPC (Quant value/2)	Promega (ΔCT =0.99)	Promega (Yintercept-28.05)	Promega (Quant value/2)
19.9.05	29.276109	-3.150469	0.996956	0.262	2.60	0503012 I10	0.127	0.107	0.131	1.261	1.061	1.300
3.10.05	29.351458	-3.146003	0.995245	0.250	2.64	0503012 I16	0.121	0.096	0.125	1.279	1.018	1.319
17.10.05	29.286532	-3.121781	0.995420	0.247	2.72	0503012 I17	0.119	0.099	0.123	1.312	1.094	1.362
22.8.05	29.074191	-3.178229	0.996110	0.244	2.03	0503012 I2	0.119	0.116	0.122	0.991	0.967	1.015
25.7.05	29.129660	-3.090196	0.996438	0.243	2.15	0503012 E3	0.116	0.109	0.122	1.028	0.962	1.075
16.01.06	29.194165	-3.154871	0.995841	0.242	2.38	0507015 K10	0.118	0.105	0.121	1.157	1.033	1.191
6.7.05	29.351814	-3.164174	0.995103	0.241	2.31	0503012 D5	0.117	0.093	0.121	1.124	0.896	1.155
14.11.05	29.141799	-3.170734	0.996624	0.231	2.24	0507015 K1	0.112	0.104	0.115	1.090	1.012	1.118
25.7.05	29.192492	-3.122426	0.996061	0.229	2.16	0503012 E2	0.110	0.099	0.115	1.041	0.930	1.080
25.7.05	29.102238	-3.164359	0.996099	0.227	2.07	0503012 F7	0.110	0.106	0.114	1.007	0.963	1.035
19.9.05	29.231785	-3.071752	0.996350	0.225	2.54	0503012 I9	0.107	0.093	0.113	1.209	1.047	1.270
31.10.05	29.035192	-3.179748	0.996378	0.221	2.15	0507015 L3	0.108	0.108	0.110	1.048	1.051	1.073
5.9.05	29.204120	-3.174353	0.995593	0.219	2.44	0503012 I6	0.107	0.095	0.110	1.190	1.056	1.220
12.12.05	28.955695	-3.156146	0.995869	0.219	2.16	0507015 L14	0.107	0.113	0.110	1.047	1.113	1.078
03.01.06	29.004436	-3.184334	0.995925	0.217	2.10	0507015 L8	0.106	0.109	0.108	1.026	1.053	1.050
28.11.05	28.969172	-3.171995	0.997100	0.213	2.07	0507015 L5	0.104	0.110	0.107	1.009	1.062	1.035
30.01.06	28.960926	-3.159467	0.996347	0.208	2.15	0406006 K1	0.101	0.107	0.104	1.044	1.106	1.074

5.13 VALIDATION OF THE QUANTIFILER STANDARD (QUANTIFILER STANDARD RESULTS VERSUS PROMEGA MALE STANDARD RESULTS)

5.13.1 PROBATIVE SAMPLES (QUANTIFILER STANDARD RESULTS VERSUS PROMEGA MALE STANDARD RESULTS)

The testing of the method and modifications of the method on probative and non-probative samples is required according to DAB (2000: 8.1.3.1) and SWGDAM (2004: 3.1) guidelines. A total of 127 probative samples were analysed with both the Quantifiler standard and the Promega Male standard. However, only the values determined from the Quantifiler standard were actually used for amplification with Profiler Plus. Similarity in Quantifiler concentration and amplification volumes was compared, but the initial Profiler amplifications consisted of an estimated amount of 2 Quantifiler nanograms. We have shown in the validation of the Quantifiler standard that 1 Promega Male standard nanogram is equivalent to approximately 2.22 or 2 Quantifiler standard nanograms. This result was confirmed with the probative sample data presented. The difference in DNA concentrations (Quantity in ng/µL) showed the least mean difference in all three tables with the Quantifiler standard concentrations divided by 2.22 and the Promega Male standard concentration. Therefore, while the Quantifiler Human DNA Standard result needed to be calibrated, the Promega Male standard results did not.

The sample volumes and amplification volumes, as well as actual accepted amplification volumes were also compared for individual results from each duplicate while the same was done with the mean Quantifiler results which were used for the initial Profiler Plus amplifications. The greatest differences were observed between the uncalibrated Quantifiler Human DNA standard results and Promega Male standard results producing a mean difference of 112.7474% for the amplification volumes of full profile samples (see table 66). The smallest resulting mean difference was with the Quantifiler standard at 2.22ng and Promega Male control at 1ng for full profile samples at 10.9356% (see table 63). With the samples resulting in full profiles, the rounded Quantifiler standard result amplification volumes at 2ng produced the smallest mean difference with the actual accepted volumes. The actual accepted volumes were the volumes accepted as the most optimal results out of up to three amplifications and not necessarily what was originally calculated as the ideal volume for the initial PCR based on the Quantifiler results. The results were obviously biased by 2ng being the original amplification target.

With partial profile and mixture results (table 64), similar results as for the full profiles are visible. However, the differences of the rounded Promega Male standard amplification volume and accepted amplification volume are greater with a mean difference of 27.8991% (see table 67). The mean difference of the Promega Male standard to Quantifiler Human DNA standard concentration/2.22 was only 10.6833% (see table 67).

With resulting profiles producing no-size data (NSD) and non-reportable (NR) profiles (table 65), most of the samples were amplified at maximum sample volumes of 20µL in 50µL Profiler Plus reactions. Quantifiler values were still comparable with the mean difference of the Promega Male standard and the Quantifiler Human DNA standard concentration/2.22 at only 13.3795% (see table 68).

In tables 69-71, comparisons of the same data but this time off average results from the duplicates are shown. The rounded amplification volumes account for the pipetting limit of 1µL. In other words, the rounding macro has to round sample volumes to the nearest 1µL and not volumes with decimal places. Where amounts are under 1ng of input template for Profiler or Cofiler due to rounding, the macro then rounds up to the next 1µL of sample volume. Although the original macro used by Forensic Biology did not round up the volumes for sample template amounts that were under 1ng, we recommend that updated versions that round sample volumes for pipetting do include the algorithm to be able to do so.

The difference of Promega Male standard and Quantifiler standard values/2 sample volumes, which are the theoretical unrounded volumes, was 13.08% for full profiles (table 69), 15.38% for partial profiles and mixtures (table 70) and 15.4% for NR or NSD profiles (table 71). In other words, the use of the Quantifiler standard value/2 method was similar to using the Promega Male standard.

Table 63. Comparison of Quantifiler and Promega Male standard concentration results for full profile probative samples. The quantity shown is in ng/μL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 11.31%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 13.9%. Duplicate results are presented.

Full profile samples								
Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega Male standard	Difference of Quantifiler standard/2 and the Promega Male standard	Difference of Quantifiler standard/2.22 and the Promega Male standard
[redacted]	28.63	1.480	0.740	0.667	0.947	128.75%	14.37%	3.04%
	28.54	1.570	0.785	0.707	0.690	127.54%	13.77%	2.49%
	31.07	0.246	0.123	0.111	0.106	132.08%	16.04%	4.54%
	31.02	0.254	0.127	0.114	0.110	130.91%	15.45%	4.01%
	28.62	1.490	0.745	0.671	0.652	128.53%	14.22%	2.94%
	28.62	1.490	0.745	0.671	0.652	128.53%	14.26%	2.94%
	29.38	0.849	0.425	0.382	0.370	129.46%	14.73%	3.36%
	29.3	0.901	0.451	0.406	0.393	129.26%	14.63%	3.27%
	30.16	0.479	0.240	0.216	0.208	130.29%	15.14%	3.73%
	30.01	0.536	0.268	0.241	0.233	130.04%	15.02%	3.62%
	31.16	0.229	0.115	0.103	0.099	131.31%	15.68%	4.20%
	31.03	0.253	0.127	0.114	0.110	130.00%	15.06%	3.60%
	28.2	2.020	1.010	0.910	0.888	127.48%	13.74%	2.47%
	27.68	2.570	1.285	1.158	1.130	127.43%	13.72%	2.45%
	31.28	0.210	0.105	0.095	0.091	131.79%	15.89%	4.41%
	31.61	0.165	0.083	0.074	0.071	132.07%	15.03%	4.53%
	28.15	2.110	1.055	0.950	0.926	127.86%	13.93%	2.64%
	28.19	2.050	1.025	0.923	0.898	128.29%	14.14%	2.83%
	29.54	0.758	0.379	0.341	0.330	129.70%	14.85%	3.47%
	29.62	0.715	0.358	0.322	0.312	129.17%	14.53%	3.23%
	30.24	0.452	0.226	0.204	0.196	130.61%	15.31%	3.88%
	30.46	0.384	0.192	0.173	0.167	129.94%	14.97%	3.58%
	25.81	12.940	6.470	5.829	6.120	111.44%	5.72%	4.76%
	25.67	14.270	7.135	6.428	6.780	110.47%	5.24%	5.19%
	31.66	0.204	0.102	0.092	0.079	157.58%	28.73%	16.03%
	32.02	0.157	0.079	0.071	0.060	159.93%	29.97%	17.09%
	28.3	2.210	1.105	0.995	0.962	129.73%	14.86%	3.46%
	28.29	2.230	1.115	1.005	0.968	130.37%	15.19%	3.77%
	29.16	1.200	0.600	0.541	0.509	135.76%	17.83%	6.20%
	29.04	1.310	0.655	0.590	0.555	136.04%	18.02%	6.32%
	22.39	146.530	73.265	66.005	77.620	88.78%	5.81%	14.96%
	22.41	143.880	71.940	64.811	76.150	88.94%	5.53%	14.89%
	31.95	0.166	0.083	0.075	0.064	159.78%	29.80%	17.02%
	31.87	0.176	0.088	0.079	0.068	159.59%	29.75%	16.93%
	28.08	2.580	1.290	1.162	1.130	128.32%	14.16%	2.85%
	28.13	2.490	1.245	1.122	1.090	128.44%	14.22%	2.90%
	29.45	0.975	0.488	0.439	0.408	138.97%	19.49%	7.64%
	29.49	0.949	0.475	0.427	0.397	139.04%	19.52%	7.68%
	28.6	1.790	0.895	0.806	0.769	132.77%	16.45%	4.85%
	28.57	1.830	0.915	0.824	0.787	132.53%	16.32%	4.74%
	30.73	0.395	0.198	0.178	0.158	150.00%	25.00%	12.61%
	30.69	0.407	0.204	0.183	0.163	149.69%	24.85%	12.47%
	29.02	1.320	0.660	0.595	0.562	134.88%	17.44%	5.80%
	29.09	1.260	0.630	0.568	0.534	135.96%	17.95%	6.29%
	29.18	1.190	0.595	0.536	0.501	137.52%	18.70%	6.99%
	29.25	1.120	0.560	0.505	0.473	136.79%	18.35%	6.66%
	29.73	0.800	0.400	0.360	0.332	140.96%	20.43%	8.54%
	29.78	0.771	0.386	0.347	0.319	141.69%	20.85%	8.87%
	31.24	0.274	0.137	0.123	0.108	153.70%	23.95%	14.28%
	31.48	0.231	0.116	0.104	0.090	155.53%	27.77%	15.10%
	19.18	2011.980	1005.990	906.297	883.530	127.72%	13.85%	2.58%
	19.18	2015.100	1007.550	907.703	884.910	127.72%	13.85%	2.58%
	19.18	2019.860	1009.930	909.847	887.020	127.71%	13.85%	2.57%
	19.17	2033.770	1016.885	916.113	893.180	127.70%	13.85%	2.57%
	19.2	1981.270	990.635	892.464	869.930	127.75%	13.85%	2.59%
	19.25	1911.490	955.745	861.032	839.040	127.82%	13.91%	2.62%
	17.89	5365.580	2682.790	2416.928	2375.890	125.83%	12.9%	1.73%
	18.46	3483.560	1741.780	1569.171	1536.890	126.66%	12.59%	2.10%
	18.11	4534.020	2267.010	2042.351	2004.810	126.16%	13.05%	1.87%
	18.42	3605.070	1802.535	1623.905	1590.960	126.60%	13.30%	2.07%
	19.06	2200.160	1100.080	991.063	966.900	127.55%	13.77%	2.50%
	18.92	2461.300	1230.650	1108.694	1082.690	127.33%	13.67%	2.40%
	18.14	4448.710	2224.355	2003.923	1966.770	126.19%	13.10%	1.89%
	19.09	2157.550	1078.775	971.869	948.020	127.58%	13.79%	2.52%
	19.1	2131.920	1065.960	960.324	936.660	127.61%	13.80%	2.53%
	19.07	2192.490	1096.245	987.608	963.500	127.55%	13.76%	2.50%
	30.12	0.482	0.241	0.217	0.197	144.67%	22.34%	10.21%
	30.17	0.464	0.232	0.209	0.190	144.21%	22.11%	10.00%
	30.06	0.504	0.252	0.227	0.205	144.66%	22.93%	10.21%
	30.11	0.486	0.243	0.219	0.199	144.22%	22.11%	10.01%
	26.11	10.270	5.135	4.626	4.310	138.28%	19.14%	7.33%
	26.05	10.710	5.355	4.824	4.500	138.00%	19.00%	7.21%
	27.01	5.150	2.575	2.320	2.150	139.53%	19.77%	7.90%
	26.96	5.370	2.685	2.419	2.240	139.73%	19.87%	7.99%
	25.77	13.230	6.615	5.959	5.570	137.52%	18.76%	6.99%
	25.84	12.600	6.300	5.676	5.300	137.74%	18.87%	7.09%
	30.58	0.334	0.167	0.150	0.196	70.41%	14.80%	23.24%
	30.52	0.348	0.174	0.157	0.204	70.59%	14.71%	23.16%
	28.92	1.090	0.545	0.491	0.643	69.52%	15.24%	23.64%
	28.88	1.120	0.560	0.505	0.665	68.42%	15.79%	24.13%
	29.81	0.577	0.289	0.260	0.340	69.71%	14.98%	23.56%

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Full profile samples

Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2.22	Quantity Promega Standard	Difference of Quantifiler standard and the Promega standard	Difference of Quantifiler standard/2 and the Promega standard	Difference of Quantifiler standard/2.22 and the Promega standard
[redacted]	29.84	0.567	0.284	0.255	0.334	69.76%	15.12%	23.63%
	30.26	0.418	0.209	0.188	0.245	70.61%	14.69%	23.15%
	30.33	0.399	0.200	0.180	0.234	70.51%	14.74%	23.19%
	28.15	1.880	0.940	0.847	1.120	67.86%	16.07%	24.39%
	28.15	1.890	0.945	0.851	1.120	68.75%	15.63%	23.99%
	29.49	0.724	0.362	0.326	0.427	69.56%	15.22%	23.62%
	29.43	0.755	0.378	0.340	0.445	69.66%	15.17%	23.58%
	28.91	1.100	0.550	0.495	0.648	69.75%	15.12%	23.53%
	28.91	1.090	0.545	0.491	0.646	68.73%	15.63%	24.00%
	25.08	16.750	8.375	7.545	10.100	65.84%	17.08%	25.30%
	25.03	17.310	8.655	7.797	10.450	65.65%	17.18%	25.38%
	29.25	0.862	0.431	0.388	0.509	69.35%	15.32%	23.72%
	29.16	0.921	0.461	0.415	0.544	69.30%	15.35%	23.74%
	30.52	0.348	0.174	0.157	0.204	70.59%	14.71%	23.16%
	30.4	0.379	0.190	0.171	0.223	69.96%	15.02%	23.44%
	28.08	1.970	0.985	0.887	1.170	68.38%	15.81%	24.15%
	28.22	1.800	0.900	0.811	1.070	68.22%	15.89%	24.22%
	27.61	2.760	1.380	1.243	1.640	68.29%	15.85%	24.19%
	27.49	3.020	1.510	1.360	1.800	67.78%	16.11%	24.42%
	27.67	2.590	1.295	1.167	1.400	85.00%	7.50%	16.67%
	27.7	2.530	1.265	1.140	1.370	84.67%	7.66%	16.81%
	30.45	0.338	0.169	0.152	0.178	89.89%	5.06%	14.47%
	30.2	0.405	0.203	0.182	0.214	89.25%	5.37%	14.76%
	24.08	35.690	17.845	16.077	19.960	78.81%	10.60%	19.46%
	24.09	35.450	17.725	15.968	19.820	78.86%	10.57%	19.43%
	28.44	1.480	0.740	0.667	0.792	86.87%	6.57%	15.82%
	28.54	1.370	0.685	0.617	0.733	86.90%	6.55%	15.81%
	29.07	0.929	0.465	0.418	0.496	87.30%	6.35%	15.63%
	29.19	0.849	0.425	0.382	0.452	87.83%	6.08%	15.39%
	25.52	12.470	6.235	5.617	6.880	81.25%	9.37%	18.36%
	25.85	9.800	4.900	4.414	5.390	81.82%	9.09%	18.10%
	29.05	0.946	0.473	0.426	0.505	87.33%	6.34%	15.62%
	28.96	1.010	0.505	0.455	0.539	87.38%	6.31%	15.59%
	28.24	1.710	0.855	0.770	0.917	86.48%	6.76%	16.00%
	28.43	1.480	0.740	0.667	0.794	86.40%	6.80%	16.04%
	30.02	0.463	0.232	0.209	0.245	88.98%	5.51%	14.87%
	30.01	0.468	0.234	0.211	0.248	88.71%	5.65%	15.00%
	31.56	0.151	0.076	0.068	0.079	92.36%	3.82%	13.35%
	31.26	0.187	0.094	0.084	0.098	91.60%	4.20%	13.69%
	28.01	2.010	1.005	0.905	1.090	84.40%	7.80%	16.94%
	28.05	1.950	0.975	0.878	1.060	85.71%	7.14%	16.34%
	28.28	1.660	0.830	0.748	0.891	86.31%	6.85%	16.08%
	28.39	1.530	0.765	0.689	0.821	86.36%	6.82%	16.05%
	26.86	4.680	2.340	2.108	2.550	83.53%	8.24%	17.33%
	26.87	4.650	2.325	2.095	2.530	83.79%	8.10%	17.21%
	25.84	9.910	4.955	4.464	5.450	81.83%	9.08%	18.09%
	25.88	9.570	4.785	4.311	5.260	81.94%	9.03%	18.05%
	29.25	0.817	0.409	0.368	0.435	87.82%	6.09%	15.40%
	29.38	0.741	0.371	0.334	0.394	88.07%	5.96%	15.28%
	29.49	0.682	0.341	0.307	0.362	88.40%	5.80%	15.14%
	29.57	0.643	0.322	0.290	0.342	88.01%	5.99%	15.31%
	30.19	0.410	0.205	0.185	0.216	89.81%	5.09%	14.50%
	30.17	0.417	0.209	0.188	0.220	89.55%	5.23%	14.62%
	31.91	0.116	0.058	0.052	0.060	92.37%	3.81%	13.35%
	31.68	0.138	0.069	0.062	0.072	92.47%	3.77%	13.30%
	30.29	0.380	0.190	0.171	0.201	89.05%	5.47%	14.84%
	30.25	0.391	0.196	0.176	0.206	89.61%	5.10%	14.50%
	30.5	0.325	0.163	0.146	0.171	90.06%	4.97%	14.39%
	30.64	0.294	0.147	0.132	0.155	89.68%	5.16%	14.56%
	26.18	9.740	4.870	4.387	4.090	138.14%	19.07%	7.27%
	25.82	12.800	6.400	5.766	5.390	137.48%	18.74%	6.97%
	29.56	0.904	0.452	0.407	0.377	139.79%	19.89%	8.01%
	29.42	1.000	0.500	0.450	0.419	138.66%	19.33%	7.51%
	28.41	2.040	1.020	0.919	0.886	130.25%	15.12%	3.72%
	28.37	2.110	1.055	0.950	0.915	130.60%	15.30%	3.87%
	27.23	4.700	2.350	2.117	2.120	121.70%	10.95%	0.14%
	27.22	4.740	2.370	2.135	2.140	121.50%	10.75%	0.23%
	30.18	0.472	0.236	0.213	0.205	130.24%	15.12%	3.71%
	30.24	0.452	0.226	0.204	0.196	130.61%	15.31%	3.88%
	28.89	1.220	0.610	0.550	0.535	128.04%	14.02%	2.72%
	28.81	1.300	0.650	0.586	0.569	128.47%	14.24%	2.91%
	29.19	0.976	0.488	0.440	0.426	129.11%	14.56%	3.20%
	29.5	0.780	0.390	0.351	0.340	129.41%	14.71%	3.34%
	29.11	0.952	0.476	0.429	0.563	69.09%	15.45%	23.83%
	28.77	1.210	0.605	0.545	0.719	68.29%	15.86%	24.19%
	27.33	3.380	1.690	1.523	2.010	68.16%	15.92%	24.25%
	27.18	3.750	1.875	1.689	2.240	67.41%	16.29%	24.59%
	26.16	9.880	4.940	4.450	4.150	138.07%	19.04%	7.24%
	26.08	10.510	5.255	4.734	4.410	138.32%	19.16%	7.35%
	27.83	2.670	1.335	1.203	1.170	128.21%	14.10%	2.80%
	27.75	2.830	1.415	1.275	1.240	128.23%	14.11%	2.80%
					Mean	110.33%	13.90%	11.31%

Table 64: Comparison of Quantifiler and Promega Male standard concentration results for probative samples that resulted in partial profiles and mixtures. The quantity shown is in ng/µL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 14.09%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 16.56%. Duplicate results are presented.

Partial Profiles and Mixtures									
Result	Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2.22	Quantity Promega Standard	Difference of Quantifiler standard and the Promega standard	Difference of Quantifiler standard/2 and the Promega standard	Difference of Quantifiler standard/2.22 and the Promega standard
X,Y+24 mixture	[redacted]	28.88	1.470	0.735	0.662	0.625	135.20%	17.60%	5.95%
X,Y+24 mixture		28.88	1.460	0.730	0.658	0.623	134.35%	17.17%	5.56%
X,Y+22 Mixture		31.05	0.239	0.120	0.108	0.140	70.71%	14.64%	23.10%
X,Y+22 Mixture		31.04	0.240	0.120	0.108	0.140	71.43%	14.29%	22.78%
X,Y+21 mixture		29.35	1.050	0.525	0.473	0.441	138.10%	19.05%	7.25%
X,Y+21 mixture		29.58	0.889	0.445	0.400	0.370	140.27%	20.14%	8.23%
X,Y+19 Mixture		27.68	2.620	1.310	1.180	1.560	67.95%	16.03%	24.35%
X,Y+19 Mixture		27.66	2.680	1.340	1.207	1.590	68.55%	15.72%	24.08%
X,NR+18 Mixture		31.35	0.189	0.095	0.085	0.077	145.77%	22.89%	10.71%
X,NR+18 Mixture		31.74	0.141	0.071	0.064	0.057	146.94%	23.47%	11.23%
X,NR+17 mixture		31.84	0.136	0.068	0.061	0.079	71.93%	14.03%	22.55%
X,NR+17 mixture		32.02	0.119	0.060	0.054	0.070	71.22%	14.39%	22.87%
X,Y+17		30.49	0.468	0.234	0.211	0.189	147.62%	23.81%	11.54%
X,Y+17		30.27	0.547	0.274	0.246	0.223	145.29%	22.65%	10.49%
X,X+16		30.15	0.421	0.211	0.190	0.222	89.64%	5.18%	14.58%
X,X+16		29.71	0.581	0.291	0.262	0.308	88.64%	5.68%	15.03%
X,Y+16		32.1	0.101	0.051	0.045	0.052	93.12%	3.44%	13.01%
X,Y+16		31.94	0.114	0.057	0.051	0.059	92.24%	3.88%	13.40%
X,Y+16 Mixture		29.24	0.941	0.471	0.424	0.387	143.15%	21.58%	9.53%
X,Y+16 Mixture		29.38	0.847	0.424	0.382	0.348	143.39%	21.70%	9.64%
X,Y+16 Mixture		30.94	0.259	0.130	0.117	0.105	146.67%	23.33%	11.11%
X,Y+16 Mixture		30.78	0.292	0.146	0.132	0.119	145.38%	22.69%	10.53%
X,X+14		33.27	0.043	0.022	0.019	0.022	95.02%	2.49%	12.15%
X,X+14		33.28	0.043	0.021	0.019	0.022	94.55%	2.73%	12.37%
X,Y+12 on 813		30.18	0.474	0.237	0.214	0.206	130.10%	15.05%	3.65%
X,Y+12 on 813		30.11	0.498	0.249	0.224	0.216	130.56%	15.28%	3.85%
X,Y+11		30.24	0.427	0.214	0.192	0.251	70.12%	14.94%	23.37%
X,Y+11		30.4	0.381	0.191	0.172	0.224	70.09%	14.96%	23.38%
X,Y+11 (10uL on CW#869)		30.21	0.433	0.217	0.195	0.254	70.47%	14.76%	23.21%
X,Y+11 (10uL on CW#869)		30.27	0.418	0.209	0.188	0.245	70.61%	14.69%	23.15%
X,Y+8 on CW#869(20uL)		32	0.121	0.061	0.055	0.071	71.63%	14.18%	22.69%
X,Y+8 on CW#869(20uL)		32.11	0.112	0.056	0.050	0.065	71.78%	14.11%	22.62%
X,Y+6		32.35	0.096	0.048	0.043	0.041	132.85%	16.42%	4.89%
X,Y+6		32.44	0.089	0.045	0.040	0.038	133.16%	16.58%	5.03%
X,Y+3		32.92	0.063	0.031	0.028	0.027	133.46%	16.73%	5.16%
X,Y+3		33.17	0.052	0.026	0.024	0.022	133.48%	16.74%	5.17%
X,Y+1		32.41	0.091	0.045	0.041	0.053	72.38%	13.81%	22.35%
X,Y+1		32.32	0.097	0.049	0.044	0.056	72.29%	13.85%	22.39%
X,Y+1		32.54	0.083	0.042	0.037	0.036	133.05%	16.53%	4.98%
X,Y+1		32.18	0.108	0.054	0.049	0.047	131.76%	15.88%	4.40%
X,Y+1		32.43	0.090	0.045	0.040	0.039	132.64%	16.32%	4.79%
X,Y+1		32.08	0.116	0.058	0.052	0.050	131.54%	15.77%	4.30%
X,0+0		33.76	0.046	0.023	0.021	0.017	175.45%	37.72%	24.08%
X,0+0		33.43	0.058	0.029	0.026	0.021	172.77%	36.38%	22.87%
X,X+0		32.06	0.110	0.055	0.050	0.044	147.75%	23.87%	11.60%
X,X+0		32.38	0.086	0.043	0.039	0.035	148.13%	24.06%	11.77%
X,NR+ 0		32.29	0.099	0.049	0.044	0.057	72.08%	13.96%	22.49%
X,NR+ 0		32.51	0.084	0.042	0.038	0.049	72.39%	13.80%	22.35%
						Mean	111.83%	16.56%	14.09%

Table 65: Comparison of Quantifiler and Promega Male standard concentration results for probative samples that resulted in non-reportable profiles and NSDs. The quantity shown is in ng/µL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 13.38%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 18.30%. Duplicate results are presented.

NR profiles and NSDs									
	Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2 .22	Quantity Promega Standard	Difference of Quantifiler standard and the Promega standard	Difference of Quantifiler standard/2 and the Promega standard	Difference of Quantifiler standard/2 .22 and the Promega standard
NR profile	[redacted]	34.33	0.020	0.010	0.009	0.008	150.97%	25.48%	13.05%
NR profile	[redacted]	33.88	0.028	0.014	0.012	0.011	150.00%	25.00%	12.61%
NR profile	[redacted]	36.42	0.004	0.002	0.002	0.002	153.85%	26.92%	14.35%
NR profile	[redacted]	37.18	0.002	0.001	0.001	0.001	155.47%	27.73%	15.07%
NR profile	[redacted]	35.81	0.006	0.003	0.003	0.003	153.20%	26.60%	14.05%
NR profile	[redacted]	35.74	0.007	0.003	0.003	0.003	153.23%	26.62%	14.07%
NR profile	[redacted]	33.85	0.033	0.016	0.015	0.019	73.40%	13.30%	21.89%
NR profile	[redacted]	34.58	0.019	0.010	0.009	0.011	74.77%	12.61%	21.27%
NR profile	[redacted]	32.3	0.098	0.049	0.044	0.057	72.06%	13.97%	22.50%
NR profile	[redacted]	32.85	0.066	0.033	0.030	0.038	72.40%	13.80%	22.34%
NR profile	[redacted]	33.76	0.035	0.017	0.016	0.020	73.13%	13.43%	22.01%
NR profile	[redacted]	34.16	0.026	0.013	0.012	0.015	73.51%	13.25%	21.84%
NR profile	[redacted]	35.67	0.008	0.004	0.004	0.004	137.14%	18.57%	6.82%
NR profile	[redacted]	35.57	0.009	0.004	0.004	0.004	136.70%	18.35%	6.62%
NR profile	[redacted]	32.44	0.090	0.045	0.040	0.038	133.07%	16.54%	4.99%
NR profile	[redacted]	33.06	0.057	0.028	0.025	0.024	133.88%	16.94%	5.35%
NSD	[redacted]	35.21	0.012	0.006	0.005	0.005	135.29%	17.65%	5.99%
NSD	[redacted]	35.15	0.012	0.006	0.005	0.005	136.89%	18.45%	6.71%
NSD	[redacted]	33.24	0.050	0.025	0.022	0.021	133.49%	16.75%	5.18%
NSD	[redacted]	33.41	0.044	0.022	0.020	0.019	133.69%	16.84%	5.27%
NSD	[redacted]	34.16	0.025	0.013	0.011	0.011	134.58%	17.29%	5.67%
NSD	[redacted]	34.49	0.020	0.010	0.009	0.008	135.71%	17.86%	6.18%
NSD	[redacted]	36.08	0.006	0.003	0.003	0.003	137.74%	18.87%	7.09%
NSD	[redacted]	37.21	0.003	0.001	0.001	0.001	139.64%	19.82%	7.95%
NSD	[redacted]	35.09	0.013	0.006	0.006	0.005	136.50%	18.25%	6.53%
NSD	[redacted]	36.79	0.004	0.002	0.002	0.002	138.56%	19.28%	7.46%
NSD	[redacted]	33.65	0.050	0.025	0.022	0.018	175.00%	37.50%	23.87%
NSD	[redacted]	33.31	0.063	0.032	0.028	0.023	171.98%	35.99%	22.51%
NSD	[redacted]	33.05	0.076	0.038	0.034	0.028	169.15%	34.57%	21.24%
NSD	[redacted]	32.95	0.081	0.041	0.037	0.030	168.65%	34.32%	21.01%
NSD	[redacted]	Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD	[redacted]	Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD	[redacted]	34.62	0.025	0.012	0.011	0.009	184.25%	42.12%	28.04%
NSD	[redacted]	34.63	0.025	0.012	0.011	0.009	184.08%	42.04%	27.96%
NSD	[redacted]	34.07	0.037	0.018	0.017	0.013	178.79%	39.39%	25.58%
NSD	[redacted]	33.78	0.045	0.023	0.020	0.016	175.61%	37.80%	24.15%
NSD	[redacted]	34.56	0.026	0.013	0.012	0.009	183.22%	41.61%	27.58%
NSD	[redacted]	35.04	0.019	0.009	0.008	0.006	187.71%	43.86%	29.60%
NSD	[redacted]	35.85	0.006	0.003	0.003	0.002	153.31%	26.65%	14.10%
NSD	[redacted]	Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD	[redacted]	32.73	0.066	0.033	0.030	0.027	148.50%	24.25%	11.94%
NSD	[redacted]	32.59	0.074	0.037	0.033	0.030	148.31%	24.16%	11.85%
NSD	[redacted]	39.02	0.001	0.000	0.000	0.000	106.15%	3.07%	7.14%
NSD	[redacted]	37.16	0.002	0.001	0.001	0.001	102.44%	1.22%	8.81%
NSD	[redacted]	36.07	0.006	0.003	0.002	0.003	100.00%	0.00%	9.91%
NSD	[redacted]	34.95	0.013	0.006	0.006	0.006	99.05%	0.47%	10.34%
NSD	[redacted]	37.12	0.003	0.001	0.001	0.001	102.36%	1.18%	8.85%
NSD	[redacted]	35.33	0.009	0.005	0.004	0.005	98.95%	0.52%	10.38%
NSD	[redacted]	32.26	0.095	0.047	0.043	0.038	148.03%	24.02%	11.73%
NSD	[redacted]	33.18	0.047	0.023	0.021	0.019	148.94%	24.47%	12.13%
NSD	[redacted]	Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD	[redacted]	Undetermined	0.000	0.000	0.000	0.000	0.00%	0.00%	0.00%
NSD	[redacted]	37.08	0.003	0.001	0.001	0.001	102.29%	1.15%	8.88%
NSD	[redacted]	35.77	0.007	0.003	0.003	0.003	99.42%	0.29%	10.17%
NSD	[redacted]	33.45	0.043	0.022	0.020	0.025	73.20%	13.40%	21.98%
NSD	[redacted]	34.6	0.019	0.010	0.009	0.011	75.23%	12.39%	21.07%
NSD	[redacted]	35.87	0.008	0.004	0.003	0.004	75.45%	12.27%	20.97%
NSD	[redacted]	35.04	0.014	0.007	0.006	0.008	74.56%	12.72%	21.37%
						Mean	118.85%	18.30%	13.38%

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Table 66: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for probative samples that resulted in full profiles. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 11.31%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 13.90%. Duplicate results are presented.

Full profile results																
Sample Name	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Actual accepted amplification volume	Difference of Promega standard to Quantifiler standard quantity amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 amplification volumes	Difference of rounded Quantifiler standard amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2 amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2.22 amplification volume and actual accepted amplification volume	Difference of rounded Promega standard amplification volume and actual accepted amplification volume
[redacted]	128.75%	14.37%	3.94%	0.7000	1.0000	2.0000	2.0000	1.0000	185.7143%	100.0000%	0.0000%	30.0000%	0.0000%	100.0000%	100.0000%
	127.54%	13.77%	2.49%	0.6000	1.0000	1.0000	1.0000	1.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	132.08%	16.04%	4.54%	4.0000	8.0000	9.0000	9.0000	8.0000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	130.91%	15.45%	4.01%	4.0000	8.0000	9.0000	9.0000	8.0000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	128.53%	14.26%	2.94%	0.7000	1.0000	1.0000	2.0000	1.0000	185.7143%	100.0000%	100.0000%	30.0000%	0.0000%	0.0000%	100.0000%
	128.53%	14.26%	2.94%	0.7000	1.0000	1.0000	2.0000	1.0000	185.7143%	100.0000%	100.0000%	30.0000%	0.0000%	0.0000%	100.0000%
	129.46%	14.73%	3.36%	1.0000	2.0000	3.0000	3.0000	2.0000	200.0000%	50.0000%	0.0000%	50.0000%	0.0000%	50.0000%	50.0000%
	129.26%	14.63%	3.27%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
	130.29%	15.14%	3.73%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	130.04%	15.02%	3.62%	2.0000	4.0000	4.0000	4.0000	4.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	131.31%	15.66%	4.20%	4.0000	9.0000	10.0000	10.0000	8.0000	150.0000%	11.1111%	0.0000%	50.0000%	12.5000%	25.0000%	25.0000%
	130.00%	15.00%	3.60%	4.0000	8.0000	9.0000	9.0000	8.0000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	127.48%	13.74%	2.47%	0.5000	1.0000	1.0000	1.0000	0.9000	100.0000%	0.0000%	0.0000%	44.4444%	11.1111%	11.1111%	11.1111%
	127.43%	13.72%	2.45%	0.4000	0.8000	0.9000	0.9000	0.9000	125.0000%	12.5000%	0.0000%	55.5556%	11.1111%	0.0000%	0.0000%
	131.79%	15.89%	4.41%	5.0000	10.0000	11.0000	11.0000	11.0000	120.0000%	10.0000%	0.0000%	54.5455%	9.0909%	0.0000%	0.0000%
	132.07%	16.03%	4.53%	6.0000	12.0000	13.0000	14.0000	11.0000	133.3333%	16.6667%	7.6923%	45.4545%	9.0909%	18.1818%	27.2727%
	127.86%	13.93%	2.64%	0.5000	0.9000	1.0000	1.0000	1.0000	100.0000%	11.1111%	0.0000%	50.0000%	10.0000%	0.0000%	0.0000%
	128.29%	14.14%	2.83%	0.5000	1.0000	1.0000	1.0000	1.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	129.70%	14.85%	3.47%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	129.17%	14.58%	3.23%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	130.61%	15.31%	3.88%	2.0000	4.0000	5.0000	5.0000	5.0000	150.0000%	25.0000%	0.0000%	60.0000%	20.0000%	0.0000%	0.0000%
	129.94%	14.97%	3.58%	3.0000	5.0000	6.0000	6.0000	5.0000	100.0000%	20.0000%	0.0000%	40.0000%	0.0000%	20.0000%	20.0000%
	111.44%	5.72%	4.76%	0.0600	0.2000	0.2000	0.2000	0.1000	150.0000%	0.0000%	0.0000%	20.0000%	100.0000%	100.0000%	100.0000%
	110.47%	5.24%	5.19%	0.0700	0.1000	0.2000	0.1000	0.1000	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	157.58%	28.79%	16.03%	5.0000	10.0000	11.0000	13.0000	11.0000	160.0000%	30.0000%	18.1818%	54.5455%	9.0909%	0.0000%	18.1818%
	159.93%	29.97%	17.09%	6.0000	13.0000	14.0000	17.0000	11.0000	183.3333%	30.7692%	21.4286%	45.4545%	18.1818%	27.2727%	54.5455%
	129.73%	14.86%	3.48%	0.5000	0.9000	1.0000	1.0000	0.9000	100.0000%	11.1111%	0.0000%	44.4444%	0.0000%	11.1111%	11.1111%
	130.37%	15.19%	3.77%	0.4000	0.9000	1.0000	1.0000	0.9000	150.0000%	11.1111%	0.0000%	55.5556%	0.0000%	11.1111%	11.1111%
	135.76%	17.88%	6.20%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	136.04%	18.02%	6.32%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	88.78%	5.61%	14.98%	0.0070	0.0100	0.0200	0.0100	0.0100	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	88.94%	5.53%	14.89%	0.0070	0.0100	0.0200	0.0100	0.0100	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	159.78%	29.89%	17.02%	6.0000	12.0000	13.0000	16.0000	12.0000	166.6667%	33.3333%	23.0769%	50.0000%	8.3333%	8.3333%	33.3333%
	159.59%	29.79%	16.93%	6.0000	11.0000	13.0000	15.0000	12.0000	150.0000%	36.3636%	15.3846%	50.0000%	8.3333%	8.3333%	25.0000%
	128.32%	14.16%	2.85%	0.4000	0.8000	0.9000	0.9000	0.8000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	128.44%	14.22%	2.90%	0.4000	0.8000	0.9000	0.9000	0.8000	125.0000%	12.5000%	0.0000%	50.0000%	0.0000%	12.5000%	12.5000%
	138.97%	19.49%	7.64%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	139.04%	19.52%	7.68%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
	132.77%	16.38%	4.85%	0.6000	1.0000	1.0000	1.0000	1.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	132.53%	16.26%	4.74%	0.5000	1.0000	1.0000	1.0000	1.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	150.00%	25.00%	12.61%	3.0000	5.0000	6.0000	6.0000	5.0000	100.0000%	20.0000%	0.0000%	40.0000%	0.0000%	20.0000%	20.0000%
	149.69%	24.85%	12.47%	2.0000	5.0000	5.0000	6.0000	5.0000	200.0000%	20.0000%	20.0000%	60.0000%	0.0000%	0.0000%	20.0000%
	134.88%	17.44%	5.80%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	135.96%	17.98%	6.29%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	137.52%	18.76%	6.99%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	136.79%	18.39%	6.66%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	140.96%	20.48%	8.54%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	141.09%	20.55%	8.87%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	153.70%	26.85%	14.28%	4.0000	7.0000	8.0000	9.0000	8.0000	125.0000%	28.5714%	12.5000%	50.0000%	12.5000%	0.0000%	12.5000%
	155.53%	27.77%	15.10%	4.0000	9.0000	10.0000	11.0000	8.0000	175.0000%	22.2222%	10.0000%	50.0000%	12.5000%	25.0000%	37.5000%
	127.72%	13.86%	2.58%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.72%	13.86%	2.58%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.71%	13.86%	2.57%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.70%	13.85%	2.57%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.75%	13.88%	2.59%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	127.82%	13.91%	2.62%	0.0005	0.0010	0.0010	0.0010	0.0010	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	125.83%	12.92%	1.73%	0.0002	0.0004	0.0004	0.0004	0.0005	100.0000%	0.0000%	0.0000%	60.0000%	20.0000%	20.0000%	20.0000%
	126.66%	13.33%	2.10%	0.0003	0.0006	0.0006	0.0007	0.0005	133.3333%	16.6667%	16.6667%	40.0000%	20.0000%	20.0000%	40.0000%
	126.16%	13.08%	1.87%	0.0002	0.0004	0.0005	0.0005	0.0005	150.0000%	25.0000%	0.0000%	60.0000%	20.0000%	0.0000%	0.0000%
	126.60%	13.30%	2.07%	0.0003	0.0005	0.0006	0.0006	0.0005	100.0000%	0.0000%	0.0000%	40.0000%	20.0000%	20.0000%	20.0000%
	127.55%	13.77%	2.50%	0.0005	0.0009	0.0010	0.0010	0.0009	100.0000%	11.1111%	0.0000%	44.4444%	0.0000%	11.1111%	11.1111%
	127.33%	13.67%	2.40%	0.0004	0.0008	0.0009	0.0009	0.0009	125.0000%	12.5000%	0.0000%	55.5556%	11.1111%	0.0000%	0.0000%
	126.19%	13.10%	1.89%	0.0002	0.0004	0.0005	0.0005	0.0005	150.0000%	25.0000%	0.0000%	66.6667%	33.3333%	16.6667%	16.6667%
	127.58%	13.79%	2.52%	0.0005	0.0009	0.0010	0.0010	0.0006	100.0000%	11.1111%	0.0000%	16.6667%	50.0000%	66.6667%	66.6667%
	127.91%	13.80%	2.53%	0.0005	0.0009	0.0010	0.0010	0.0009	100.0000%	11.1111%	0.0000%	44.4444%	0.0000%	11.1111%	11.1111%
	127.56%	13.78%	2.50%	0.0005	0.0009	0.0010	0.0010	0.0009	100.0000%	11.1111%	0.0000%	44.4444%	0.0000%	11.1111%	11.1111%
	144.67%	22.34%	10.21%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	144.21%	22.11%	10.00%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	144.66%	22.33%	10.21%	2.0000	4.0000	4.0000	5.0000	4.0000	150.0000%	25.0000%	25.0000%	50.0000%	0.0000%	0.0000%	25.0000%
	144.22%	22.11%	10.01%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	138.28%	19.14%	7.33%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	138.00%	19.00%	7.21%	0.0900	0.2000	0.2000	0.2000	0.2000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	139.53%	19.77%	7.90%	0.2000	0.4000	0.4000	0.5000	0.4000	150.0000%	25.0000%	25.0000%	50.0000%	0.0000%	0.0000%	25.0000%
	139.73%	19.87%	7.99%	0.2000	0.4000	0.4000	0.4000	0.4000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	137.52%	18.76%	6.99%	0.0800	0.2000	0.2000	0.2000	0.2000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	137.74%	18.87%	7.08%	0.0800	0.2000	0.2000	0.2000	0.2000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	70.41%	14.80%	23.24%	3.0000	6.0000	7.0000	5.0000	6.0000	66.6667%	16.6667%	28.5714%	50.0000%	0.0000%	16.6667%	16.6667%
	70.59%	14.71%	23.16%	3.0000	6.0000	6.0000	5.0000	6.0000	66.6667%	16.6667%	16.6667%	50.0000%	0.0000%	0.0000%	16.6667%
	69.52%	15.24%	23.64%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	68.42%	15.79%	24.13%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	69.71%	15.15%	23.56%	2.0000	3.0000	4.0000	3.0000	3.0000	50.0000%	0.0000%	25.0000%	33.3333%	0.0000%	33.3333%	0.0000%
	69.76%	15.12%	23.53%	2.0000	4.0000	4.0000	3.0000	3.0000	50.0000%	25.0000%	25.0000%	33.3333%	33.3333%	33.3333%	0.0000%

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Full profile results

Sample Name	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Actual accepted amplification volume	Difference of Promega standard to Quantifiler standard quantity amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 amplification volumes	Difference of rounded Quantifiler standard amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2.22 amplification volume and actual accepted amplification volume	Difference of rounded Promega standard amplification volume and actual accepted amplification volume
[redacted]	70.61%	14.69%	23.15%	2.0000	5.0000	5.0000	4.0000	5.0000	100.0000%	20.0000%	20.0000%	60.0000%	0.0000%	0.0000%	20.0000%
	70.51%	14.74%	23.19%	3.0000	5.0000	6.0000	4.0000	5.0000	33.3333%	20.0000%	33.3333%	40.0000%	0.0000%	20.0000%	20.0000%
	67.86%	16.07%	24.39%	0.5000	1.0000	1.0000	0.9000	1.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
	68.75%	15.63%	23.96%	0.5000	1.0000	1.0000	0.9000	1.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
	69.56%	15.22%	23.62%	1.0000	3.0000	3.0000	2.0000	3.0000	100.0000%	33.3333%	33.3333%	66.6667%	0.0000%	0.0000%	33.3333%
	69.66%	15.17%	23.58%	1.0000	3.0000	3.0000	2.0000	3.0000	100.0000%	33.3333%	33.3333%	66.6667%	0.0000%	0.0000%	33.3333%
	69.75%	15.12%	23.53%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	68.73%	15.63%	24.00%	0.9000	2.0000	2.0000	2.0000	2.0000	122.2222%	0.0000%	0.0000%	55.0000%	0.0000%	0.0000%	0.0000%
	65.84%	17.08%	25.30%	0.0500	0.1000	0.1000	0.1000	0.1000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	65.65%	17.18%	25.38%	0.0500	0.1000	0.1000	0.1000	0.1000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	69.35%	15.32%	23.72%	1.0000	2.0000	3.0000	2.0000	2.0000	100.0000%	0.0000%	33.3333%	50.0000%	0.0000%	50.0000%	0.0000%
	69.30%	15.35%	23.74%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	70.59%	14.71%	23.16%	3.0000	6.0000	6.0000	5.0000	5.0000	66.6667%	16.6667%	16.6667%	40.0000%	20.0000%	20.0000%	0.0000%
	69.96%	15.02%	23.44%	3.0000	5.0000	6.0000	4.0000	5.0000	33.3333%	20.0000%	33.3333%	40.0000%	0.0000%	20.0000%	20.0000%
	68.35%	15.81%	24.15%	0.5000	1.0000	1.0000	0.9000	1.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
	68.22%	15.89%	24.22%	0.6000	1.0000	1.0000	0.9000	1.0000	50.0000%	10.0000%	10.0000%	40.0000%	0.0000%	0.0000%	10.0000%
	68.29%	15.85%	24.19%	0.4000	0.7000	0.8000	0.6000	0.7000	50.0000%	14.2857%	25.0000%	42.8571%	0.0000%	14.2857%	14.2857%
	67.78%	16.11%	24.42%	0.3000	0.7000	0.7000	0.6000	0.7000	100.0000%	14.2857%	14.2857%	57.1429%	0.0000%	0.0000%	14.2857%
	80.90%	7.50%	16.67%	0.4000	0.8000	0.9000	0.7000	0.8000	75.0000%	12.5000%	22.2222%	50.0000%	0.0000%	12.5000%	12.5000%
	84.97%	7.66%	16.81%	0.4000	0.8000	0.9000	0.7000	0.8000	75.0000%	12.5000%	22.2222%	50.0000%	0.0000%	12.5000%	12.5000%
	89.89%	5.06%	14.47%	3.0000	6.0000	7.0000	6.0000	5.0000	100.0000%	0.0000%	14.2857%	40.0000%	20.0000%	40.0000%	20.0000%
	89.25%	5.37%	14.75%	2.0000	5.0000	5.0000	5.0000	5.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	78.81%	10.60%	19.46%	0.0300	0.0600	0.0600	0.0500	0.0600	66.6667%	16.6667%	16.6667%	50.0000%	0.0000%	0.0000%	16.6667%
	78.86%	10.57%	19.43%	0.0300	0.0600	0.0600	0.0500	0.0600	66.6667%	16.6667%	16.6667%	50.0000%	0.0000%	0.0000%	16.6667%
	86.87%	6.57%	15.82%	0.7000	1.0000	2.0000	1.0000	1.0000	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	86.90%	6.55%	15.81%	0.7000	1.0000	2.0000	1.0000	1.0000	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	87.30%	6.35%	15.63%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	87.83%	6.08%	15.39%	1.0000	2.0000	3.0000	2.0000	2.0000	100.0000%	0.0000%	33.3333%	50.0000%	0.0000%	50.0000%	0.0000%
	81.25%	9.37%	18.36%	0.0800	0.2000	0.2000	0.1000	0.2000	25.0000%	50.0000%	50.0000%	60.0000%	0.0000%	0.0000%	50.0000%
	81.82%	9.09%	18.10%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	87.33%	6.34%	15.62%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	87.36%	6.31%	15.59%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	86.48%	6.76%	16.00%	0.6000	1.0000	1.0000	1.0000	1.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	86.40%	6.80%	16.04%	0.7000	1.0000	2.0000	1.0000	1.0000	42.8571%	0.0000%	50.0000%	30.0000%	0.0000%	100.0000%	0.0000%
	88.96%	5.51%	14.87%	2.0000	4.0000	5.0000	4.0000	4.0000	100.0000%	0.0000%	20.0000%	50.0000%	0.0000%	25.0000%	0.0000%
	88.71%	5.65%	15.00%	2.0000	4.0000	5.0000	4.0000	4.0000	100.0000%	0.0000%	20.0000%	50.0000%	0.0000%	25.0000%	0.0000%
	92.36%	3.82%	13.35%	7.0000	13.0000	15.0000	13.0000	12.0000	85.7143%	0.0000%	13.3333%	41.6667%	8.3333%	25.0000%	8.3333%
	91.60%	4.20%	13.69%	5.0000	11.0000	12.0000	10.0000	12.0000	100.0000%	9.0909%	16.6667%	58.3333%	8.3333%	0.0000%	16.6667%
	84.40%	7.80%	16.94%	0.5000	1.0000	1.0000	0.9000	1.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
	85.71%	7.14%	16.34%	0.5000	1.0000	1.0000	1.0000	1.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	86.31%	6.85%	16.08%	0.6000	1.0000	1.0000	1.0000	1.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	86.36%	6.82%	16.05%	0.7000	1.0000	1.0000	1.0000	1.0000	42.8571%	0.0000%	0.0000%	30.0000%	0.0000%	0.0000%	0.0000%
	83.53%	8.24%	17.33%	0.2000	0.4000	0.5000	0.4000	0.4000	100.0000%	0.0000%	20.0000%	50.0000%	0.0000%	25.0000%	0.0000%
	83.79%	8.10%	17.21%	0.2000	0.4000	0.5000	0.4000	0.4000	100.0000%	0.0000%	20.0000%	50.0000%	0.0000%	25.0000%	0.0000%
	81.83%	9.08%	18.09%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	81.94%	9.03%	18.05%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	87.92%	6.09%	15.40%	1.0000	2.0000	3.0000	2.0000	3.0000	100.0000%	0.0000%	33.3333%	66.6667%	33.3333%	0.0000%	33.3333%
	88.07%	5.96%	15.28%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	88.40%	5.80%	15.14%	1.0000	3.0000	3.0000	3.0000	3.0000	200.0000%	0.0000%	0.0000%	66.6667%	0.0000%	0.0000%	0.0000%
	88.01%	5.99%	15.31%	2.0000	3.0000	3.0000	3.0000	3.0000	50.0000%	0.0000%	0.0000%	33.3333%	0.0000%	0.0000%	0.0000%
	89.81%	5.09%	14.50%	2.0000	5.0000	5.0000	5.0000	10.0000	150.0000%	0.0000%	0.0000%	60.0000%	50.0000%	50.0000%	50.0000%
	89.55%	5.23%	14.62%	2.0000	5.0000	5.0000	5.0000	10.0000	150.0000%	0.0000%	0.0000%	80.0000%	50.0000%	50.0000%	50.0000%
	92.37%	3.81%	13.35%	9.0000	17.0000	19.0000	17.0000	16.0000	88.8889%	0.0000%	10.5263%	43.7500%	6.2500%	18.7500%	6.2500%
	92.47%	3.77%	13.30%	7.0000	14.0000	16.0000	14.0000	16.0000	100.0000%	0.0000%	12.5000%	56.2500%	12.5000%	0.0000%	12.5000%
	89.05%	5.47%	14.84%	3.0000	5.0000	6.0000	5.0000	5.0000	66.6667%	0.0000%	16.6667%	40.0000%	0.0000%	20.0000%	0.0000%
	89.81%	5.10%	14.50%	3.0000	5.0000	6.0000	5.0000	5.0000	66.6667%	0.0000%	16.6667%	40.0000%	0.0000%	20.0000%	0.0000%
	90.06%	4.97%	14.39%	3.0000	6.0000	7.0000	6.0000	7.0000	100.0000%	0.0000%	14.2857%	57.1429%	14.2857%	0.0000%	14.2857%
	89.58%	5.16%	14.56%	3.0000	7.0000	8.0000	6.0000	7.0000	100.0000%	14.2857%	25.0000%	57.1429%	0.0000%	14.2857%	14.2857%
	138.14%	19.07%	7.27%	0.1000	0.2000	0.2000	0.2000	0.2000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	137.48%	18.74%	6.97%	0.0800	0.2000	0.2000	0.2000	0.2000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	139.79%	19.89%	8.01%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
	138.66%	19.33%	7.51%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	130.25%	15.12%	3.72%	0.5000	1.0000	1.0000	1.0000	1.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	130.60%	15.30%	3.87%	0.5000	0.9000	1.0000	1.0000	1.0000	100.0000%	11.1111%	0.0000%	50.0000%	10.0000%	0.0000%	0.0000%
	121.70%	10.85%	0.14%	0.2000	0.4000	0.5000	0.5000	0.4000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	121.50%	10.75%	0.23%	0.2000	0.4000	0.5000	0.5000	0.4000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
	130.24%	15.12%	3.71%	2.0000	4.0000	5.0000	5.0000	10.0000	150.0000%	25.0000%	0.0000%	80.0000%	60.0000%	50.0000%	50.0000%
	130.61%	15.31%	3.88%	2.0000	4.0000	5.0000	5.0000	10.0000	150.0000%	25.0000%	0.0000%	80.0000%	60.0000%	50.0000%	50.0000%
	128.04%	14.02%	2.72%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	128.47%	14.24%	2.91%	0.8000	2.0000	2.0000	2.0000	2.0000	150.0000%	0.0000%	0.0000%	60.0000%	0.0000%	0.0000%	0.0000%
	129.11%	14.55%	3.20%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	129.41%	14.71%	3.34%	1.0000	3.0000	3.0000	3.0000	2.0000	200.0000%	0.0000%	0.0000%	50.0000%	50.0000%	50.0000%	50.0000%
	69.09%	15.45%	23.83%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
	68.29%	15.85%	24.19%	0.8000	2.0000	2.0000	1.0000	2.0000	25.0000%	50.0000%	50.0000%	60.0000%	0.0000%	0.0000%	50.0000%
	68.16%	15.92%	24.25%	0.3000	0.6000	0.7000	0.5000	0.6000	66.6667%	16.6667%	28.5714%	50.0000%	0.0000%	16.6667%	16.6667%
	67.41%	16.29%	24.59%	0.3000	0.5000	0.6000	0.4000	0.6000	33.3333%	20.0000%	33.3333%	50.0000%	16.6667%	0.0000%	33.3333%
	138.07%	19.04%	7.24%	0.1000	0.2000	0.2000	0.2000	0.3000	100.0000%	0.0000%	0.0000%	66.6667%	33.3333%	33.3333%	33.3333%
	138.32%	19.16%	7.35%	0.1000	0.2000	0.2000	0.2000	0.3000	100.0000%	0.0000%	0.0000%	66.6667%	33.3333%	33.3333%	33.3333%
	128.21%	14.10%	2.80%	0.4000	0.7000	0.8000	0.6000	0.7000	125.0000%	28.5714%	12.5000%	42.8571%	0.0000%	14.2857%	28.5714%
	128.23%	14.11%	2.80%	0.4000	0.7000	0.8000	0.8000	0.7000	100.0000%	14.2857%	0.0000%	42.8571%	0.0000%	14.2857%	14.2857%
Mean	**110.33%**	**13.90%**	**11.31%**						**112.7474%**	**11.3492%**	**10.9356%**	**50.2195%**	**5.7880%**	**14.2419%**	**14.3081%**

Table 67: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for probative samples that resulted in partial profiles and mixtures. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 14.09%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 16.56%. Duplicate results are presented.

Partial profiles and mixtures																	
Result	Sample Name	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Actual accepted amplification volume	Difference of Promega standard to Quantifiler standard quantity amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 amplification volumes	Difference of rounded Quantifiler standard amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2.22 amplification volume and actual accepted amplification volume	Difference of rounded Promega standard amplification volume and actual accepted amplification volume
X,Y+24 mixture	[redacted]	125.26%	17.60%	5.95%	9.7000	1.0000	2.0000	2.0000	1.0000	185.7143%	100.0000%	0.0000%	30.0000%	0.0000%	100.0000%	100.0000%
X,Y+24 mixture		134.35%	17.17%	5.56%	9.7000	1.0000	2.0000	2.0000	1.0000	185.7143%	100.0000%	0.0000%	30.0000%	0.0000%	100.0000%	100.0000%
X,Y+22 Mixture		70.71%	14.64%	23.10%	4.0000	8.0000	9.0000	7.0000	8.0000	75.0000%	12.5000%	22.2222%	50.0000%	0.0000%	12.5000%	12.5000%
X,Y+22 Mixture		71.45%	14.29%	22.78%	4.0000	8.0000	9.0000	7.0000	8.0000	75.0000%	12.5000%	22.2222%	50.0000%	0.0000%	12.5000%	12.5000%
X,Y+21 mixture		138.10%	19.05%	7.25%	1.0000	2.0000	2.0000	2.0000	2.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
X,Y+21 mixture		140.27%	20.14%	8.23%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
X,Y+19 Mixture		67.85%	16.03%	24.35%	0.4000	0.8000	0.8000	0.6000	0.8000	50.0000%	25.0000%	25.0000%	50.0000%	0.0000%	0.0000%	25.0000%
X,Y+19 Mixture		66.55%	15.72%	24.08%	0.4000	0.7000	0.8000	0.6000	0.8000	50.0000%	14.2857%	25.0000%	50.0000%	12.5000%	0.0000%	25.0000%
X,NR+18 Mixture		145.77%	22.89%	10.71%	5.0000	11.0000	12.0000	13.0000	12.0000	160.0000%	18.1818%	8.3333%	58.3333%	9.3333%	0.0000%	8.3333%
X,NR+18 Mixture		146.94%	23.47%	11.23%	7.0000	14.0000	16.0000	18.0000	12.0000	157.1429%	28.5714%	12.5000%	41.6667%	16.6667%	33.3333%	50.0000%
X,NR+17 mixture		71.93%	14.63%	22.55%	7.0000	15.0000	16.0000	13.0000	16.0000	85.7143%	13.3333%	18.7500%	56.2500%	6.2500%	0.0000%	18.7500%
X,NR+17 mixture		71.22%	14.39%	22.87%	8.0000	17.0000	19.0000	14.0000	16.0000	75.0000%	17.6471%	26.3158%	50.0000%	6.2500%	18.7500%	12.5000%
X,Y+17		147.62%	23.81%	11.54%	2.0000	4.0000	5.0000	5.0000	2.0000	150.0000%	25.0000%	0.0000%	0.0000%	100.0000%	150.0000%	150.0000%
X,Y+17		145.29%	22.65%	10.46%	2.0000	4.0000	4.0000	4.0000	2.0000	100.0000%	0.0000%	0.0000%	0.0000%	100.0000%	100.0000%	100.0000%
X,X+16		89.64%	5.18%	14.56%	2.0000	5.0000	5.0000	5.0000	12.0000	150.0000%	0.0000%	0.0000%	83.3333%	58.3333%	58.3333%	58.3333%
X,X+16		88.64%	5.68%	15.03%	2.0000	3.0000	4.0000	3.0000	12.0000	50.0000%	0.0000%	25.0000%	83.3333%	75.0000%	66.6667%	75.0000%
X,Y+16		93.12%	3.44%	13.61%	16.0000	20.0000	20.0000	19.0000	15.0000	90.0000%	5.0000%	5.0000%	33.3333%	33.3333%	33.3333%	26.6667%
X,Y+16		92.24%	3.88%	13.40%	9.0000	18.0000	19.0000	17.0000	15.0000	88.8889%	5.5556%	10.5263%	40.0000%	20.0000%	26.6667%	13.3333%
X,Y+16 Mixture		143.15%	21.58%	9.53%	1.0000	2.0000	2.0000	3.0000	2.0000	200.0000%	50.0000%	50.0000%	50.0000%	0.0000%	0.0000%	50.0000%
X,Y+16 Mixture		143.39%	21.70%	9.64%	1.0000	2.0000	3.0000	3.0000	2.0000	200.0000%	50.0000%	0.0000%	50.0000%	0.0000%	50.0000%	50.0000%
X,Y+16 Mixture		148.67%	23.33%	11.11%	4.0000	8.0000	9.0000	10.0000	12.0000	150.0000%	25.0000%	11.1111%	66.6667%	33.3333%	25.0000%	16.6667%
X,Y+16 Mixture		149.38%	22.69%	10.53%	3.0000	7.0000	8.0000	8.0000	12.0000	166.6667%	14.2857%	0.0000%	75.0000%	41.6667%	33.3333%	33.3333%
X,X+14		95.92%	2.49%	12.15%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
X,X+14		94.55%	2.73%	12.37%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
X,Y+12 on 813		130.19%	15.65%	3.65%	2.0000	4.0000	5.0000	5.0000	4.0000	150.0000%	25.0000%	0.0000%	50.0000%	0.0000%	25.0000%	25.0000%
X,Y+12 on 813		130.56%	15.28%	3.65%	2.0000	4.0000	4.0000	5.0000	4.0000	150.0000%	25.0000%	25.0000%	50.0000%	0.0000%	0.0000%	25.0000%
X,Y+11		70.12%	14.64%	23.37%	2.0000	5.0000	5.0000	4.0000	7.0000	100.0000%	20.0000%	20.0000%	71.4286%	28.5714%	28.5714%	42.8571%
X,Y+11		70.09%	14.96%	23.38%	3.0000	5.0000	6.0000	4.0000	7.0000	33.3333%	20.0000%	33.3333%	57.1429%	28.5714%	14.2857%	42.8571%
X,Y+11 (10uL on CW#869		70.47%	14.76%	23.21%	2.0000	5.0000	5.0000	4.0000	10.0000	150.0000%	20.0000%	20.0000%	80.0000%	50.0000%	50.0000%	60.0000%
X,Y+11 (10uL on CW#869		70.61%	14.89%	23.15%	2.0000	5.0000	5.0000	4.0000	10.0000	150.0000%	20.0000%	20.0000%	80.0000%	50.0000%	50.0000%	60.0000%
X,Y+8 on CW#869(20uL)		71.63%	14.18%	22.65%	8.0000	17.0000	18.0000	14.0000	20.0000	75.0000%	17.6471%	22.2222%	60.0000%	15.0000%	10.0000%	30.0000%
X,Y+8 on CW#869(20uL)		71.78%	14.11%	22.62%	9.0000	18.0000	20.0000	15.0000	20.0000	66.6667%	16.6667%	25.0000%	55.0000%	10.0000%	0.0000%	25.0000%
X,Y+6		132.85%	16.42%	4.89%	10.0000	20.0000	20.0000	20.0000	20.0000	100.0000%	0.0000%	0.0000%	50.0000%	0.0000%	0.0000%	0.0000%
X,Y+6		133.16%	16.58%	5.03%	11.0000	20.0000	20.0000	20.0000	20.0000	81.8182%	0.0000%	0.0000%	45.0000%	0.0000%	0.0000%	0.0000%
X,Y+3		133.46%	16.73%	5.18%	16.0000	20.0000	20.0000	20.0000	20.0000	25.0000%	0.0000%	0.0000%	20.0000%	0.0000%	0.0000%	0.0000%
X,Y+3		133.48%	16.74%	5.17%	19.0000	20.0000	20.0000	20.0000	20.0000	5.2632%	0.0000%	0.0000%	5.0000%	0.0000%	0.0000%	0.0000%
X,Y+1		72.38%	13.81%	22.35%	11.0000	20.0000	20.0000	19.0000	20.0000	72.7273%	5.0000%	5.0000%	45.0000%	0.0000%	0.0000%	5.0000%
X,Y+1		72.29%	13.85%	22.39%	10.0000	20.0000	20.0000	18.0000	20.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
X,Y+1		133.93%	16.53%	4.98%	12.0000	20.0000	20.0000	20.0000	20.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
X,Y+1		133.76%	15.88%	4.40%	9.0000	19.0000	20.0000	20.0000	20.0000	122.2222%	5.2632%	0.0000%	55.0000%	5.0000%	0.0000%	0.0000%
X,Y+1		132.64%	16.32%	4.79%	11.0000	20.0000	20.0000	20.0000	19.0000	81.8182%	0.0000%	0.0000%	42.1053%	5.2632%	5.2632%	5.2632%
X,Y+1		131.54%	15.77%	4.30%	9.0000	17.0000	19.0000	20.0000	19.0000	122.2222%	17.6471%	5.2632%	52.6316%	10.5263%	0.0000%	5.2632%
X,0+0		175.45%	37.72%	24.08%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
X,0+0		172.77%	36.38%	22.87%	17.0000	20.0000	20.0000	20.0000	20.0000	17.6471%	0.0000%	0.0000%	15.0000%	0.0000%	0.0000%	0.0000%
X,X+0		147.75%	23.87%	11.60%	9.0000	18.0000	20.0000	20.0000	20.0000	122.2222%	11.1111%	0.0000%	55.0000%	10.0000%	0.0000%	0.0000%
X,X+0		148.13%	24.06%	11.77%	12.0000	20.0000	20.0000	20.0000	20.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
X,NR+0		72.08%	13.99%	22.49%	10.0000	20.0000	20.0000	17.0000	20.0000	70.0000%	15.0000%	15.0000%	50.0000%	0.0000%	0.0000%	15.0000%
X,NR+0		72.39%	13.80%	22.35%	12.0000	20.0000	20.0000	20.0000	20.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
	Mean	111.8202%	16.5420%	14.0949%						96.2663%	16.5668%	10.6833%	44.9214%	15.0958%	20.9970%	27.8991%

Table 68: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for probative samples that resulted in non-reportable or NSD profiles. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 13.38%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 18.30%. Duplicate results are presented.

NR and NSD profile results

Result	Sample Name	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Actual accepted amplification volume	Difference of Promega standard to Quantifiler standard quantity amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 amplification volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 amplification volumes	Difference of rounded Quantifiler standard amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded Quantifiler standard/ 2.22 amplification volume and actual accepted amplification volume	Difference of rounded Promega standard amplification volume and actual accepted amplification volume
NR profile	[redacted]	150.97%	25.48%	13.05%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		150.00%	25.00%	12.61%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		153.89%	26.92%	14.35%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		156.47%	27.73%	15.07%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		153.20%	26.60%	14.05%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		153.23%	26.62%	14.07%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		72.40%	13.30%	21.89%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		74.77%	12.81%	21.27%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		72.06%	13.97%	22.50%	10.0000	20.0000	20.0000	18.0000	20.0000	80.0000%	10.0000%	10.0000%	50.0000%	0.0000%	0.0000%	10.0000%
NR profile		72.40%	13.80%	22.34%	15.0000	20.0000	20.0000	20.0000	20.0000	33.3333%	0.0000%	0.0000%	25.0000%	0.0000%	0.0000%	0.0000%
NR profile		73.13%	13.43%	22.01%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		73.51%	13.25%	21.84%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		137.14%	18.57%	6.82%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		136.76%	18.35%	6.62%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NR profile		139.07%	16.54%	4.89%	11.0000	20.0000	20.0000	20.0000	20.0000	81.8182%	0.0000%	0.0000%	45.0000%	0.0000%	0.0000%	0.0000%
NR profile		133.88%	18.94%	5.35%	18.0000	20.0000	20.0000	20.0000	20.0000	11.1111%	0.0000%	0.0000%	10.0000%	0.0000%	0.0000%	0.0000%
NSD		135.29%	17.65%	5.99%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		136.89%	18.45%	6.71%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		133.49%	16.75%	5.16%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		133.69%	16.84%	5.27%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		134.58%	17.29%	5.67%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		135.71%	17.86%	6.16%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		137.74%	18.87%	7.09%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		139.64%	19.82%	7.95%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		136.50%	18.25%	6.53%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		138.56%	19.28%	7.46%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		175.00%	37.50%	23.87%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		171.98%	35.99%	22.51%	16.0000	20.0000	20.0000	20.0000	20.0000	25.0000%	0.0000%	0.0000%	20.0000%	0.0000%	0.0000%	0.0000%
NSD		169.15%	34.57%	21.24%	13.0000	20.0000	20.0000	20.0000	20.0000	53.8462%	0.0000%	0.0000%	35.0000%	0.0000%	0.0000%	0.0000%
NSD		168.65%	34.32%	21.01%	12.0000	20.0000	20.0000	20.0000	20.0000	66.6667%	0.0000%	0.0000%	40.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		184.25%	42.12%	28.04%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		184.08%	42.04%	27.96%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		178.70%	39.35%	25.58%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		176.61%	37.80%	24.15%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		183.22%	41.61%	27.56%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		187.71%	43.86%	29.60%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		153.31%	26.65%	14.10%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		148.50%	24.25%	11.94%	15.0000	20.0000	20.0000	20.0000	20.0000	33.3333%	0.0000%	0.0000%	25.0000%	0.0000%	0.0000%	0.0000%
NSD		148.31%	24.16%	11.85%	14.0000	20.0000	20.0000	20.0000	20.0000	42.8571%	0.0000%	0.0000%	30.0000%	0.0000%	0.0000%	0.0000%
NSD		106.15%	3.07%	7.14%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		102.44%	1.22%	8.81%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		109.00%	0.00%	9.91%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		89.05%	0.47%	10.34%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		102.36%	1.18%	8.65%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		98.95%	0.52%	10.38%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		148.03%	24.02%	11.73%	11.0000	20.0000	20.0000	20.0000	20.0000	81.8182%	0.0000%	0.0000%	45.0000%	0.0000%	0.0000%	0.0000%
NSD		148.94%	24.47%	12.13%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		0.00%	0.00%	0.00%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		102.29%	1.15%	8.88%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		99.42%	0.29%	10.17%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		73.26%	13.40%	21.58%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		75.23%	12.39%	21.07%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		75.45%	12.27%	20.97%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
NSD		74.56%	12.72%	21.37%	20.0000	20.0000	20.0000	20.0000	20.0000	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
	Mean	116.8530%	18.3037%	13.3795%						9.7894%	0.1724%	0.1724%	5.6034%	0.0000%	0.0000%	0.1724%

Table 69: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for probative samples that resulted in full profiles. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

Full profile results								
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 rounded amplification volumes	Difference of rounded average Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded average Promega standard amplification volume and actual accepted amplification volume
[redacted]	1.3115	1.4959	12.33%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	8.0000	9.2593	13.60%	8.0000	9.0000	11.1111%	0.0000%	12.5000%
	1.3423	1.5337	12.46%	1.0000	2.0000	50.0000%	0.0000%	100.0000%
	2.2857	2.6212	12.80%	2.0000	3.0000	33.3333%	0.0000%	50.0000%
	3.9409	4.5351	13.10%	4.0000	5.0000	20.0000%	0.0000%	25.0000%
	8.2988	9.5694	13.28%	8.0000	10.0000	20.0000%	0.0000%	25.0000%
	0.8715	0.9911	12.07%	0.9000	1.0000	10.0000%	0.0000%	11.1111%
	10.6667	12.3686	13.76%	11.0000	12.0000	8.3333%	0.0000%	9.0909%
	0.9615	1.0965	12.31%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	2.7155	3.1153	12.83%	3.0000	3.0000	0.0000%	0.0000%	0.0000%
	4.7847	5.5096	13.16%	5.0000	6.0000	16.6667%	0.0000%	20.0000%
	0.1470	0.1550	5.18%	0.1000	0.2000	50.0000%	0.0000%	100.0000%
	11.0803	14.3266	22.66%	11.0000	14.0000	21.4286%	0.0000%	27.2727%
	0.9009	1.0363	13.06%	0.9000	1.0000	10.0000%	0.0000%	11.1111%
	1.5936	1.8797	15.22%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.0138	0.0130	5.90%	0.0100	0.0100	0.0000%	0.0000%	0.0000%
	11.6959	15.1860	22.98%	12.0000	15.0000	20.0000%	0.0000%	25.0000%
	0.7890	0.9009	12.43%	0.8000	0.9000	11.1111%	0.0000%	12.5000%
	2.0790	2.4845	16.32%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	1.1050	1.2853	14.03%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	4.9875	6.2305	19.95%	5.0000	6.0000	16.6667%	0.0000%	20.0000%
	1.5504	1.8248	15.04%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	1.7316	2.0534	15.67%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	2.5461	3.0722	17.12%	3.0000	3.0000	0.0000%	0.0000%	0.0000%
	7.9208	10.0806	21.43%	8.0000	10.0000	20.0000%	0.0000%	25.0000%
	0.0010	0.0011	12.17%	0.0010	0.0010	0.0000%	0.0000%	0.0000%
	0.0010	0.0011	12.17%	0.0010	0.0010	0.0000%	0.0000%	0.0000%
	0.0010	0.0012	12.20%	0.0010	0.0010	0.0000%	0.0000%	0.0000%
	0.0005	0.0005	11.57%	0.0005	0.0005	0.0000%	0.0000%	0.0000%
	0.0005	0.0006	11.64%	0.0005	0.0006	16.6667%	0.0000%	20.0000%
	0.0009	0.0010	12.06%	0.0009	0.0010	10.0000%	0.0000%	11.1111%
	0.0006	0.0007	11.76%	0.0006	0.0007	14.2857%	0.0000%	16.6667%
	0.0009	0.0011	12.12%	0.0009	0.0010	10.0000%	0.0000%	11.1111%
	4.2283	5.1680	18.18%	4.0000	5.0000	20.0000%	0.0000%	25.0000%
	4.0404	4.9383	18.18%	4.0000	5.0000	20.0000%	0.0000%	25.0000%
	0.1907	0.2270	16.02%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	0.3802	0.4556	16.54%	0.4000	0.5000	20.0000%	0.0000%	25.0000%
	0.1549	0.1840	15.83%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	5.8651	5.0000	17.30%	6.0000	5.0000	20.0000%	0.0000%	16.6667%
	1.8100	1.5291	18.37%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	3.4965	2.9674	17.83%	3.0000	3.0000	0.0000%	0.0000%	0.0000%
	4.8980	4.1754	17.26%	5.0000	4.0000	25.0000%	0.0000%	20.0000%
	1.0610	0.8929	18.83%	1.0000	0.9000	11.1111%	0.0000%	10.0000%
	2.7045	2.2936	17.92%	3.0000	2.0000	50.0000%	0.0000%	33.3333%
	1.8265	1.5456	18.17%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.1174	0.0973	20.67%	0.1000	0.1000	0.0000%	0.0000%	0.0000%
	2.2434	1.8893	18.12%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	5.5021	4.6838	17.47%	6.0000	5.0000	20.0000%	20.0000%	0.0000%
	1.0610	0.8929	18.83%	1.0000	0.9000	11.1111%	0.0000%	10.0000%
	0.6920	0.5814	19.03%	0.7000	0.6000	16.6667%	0.0000%	14.2857%
	0.7813	0.7220	8.20%	0.8000	0.7000	14.2857%	0.0000%	12.5000%
	5.3836	5.1020	5.52%	5.0000	5.0000	0.0000%	0.0000%	0.0000%
	0.0562	0.0503	11.84%	0.0600	0.0500	20.0000%	0.0000%	16.6667%
	1.4035	1.3115	7.02%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	2.2497	2.1097	6.64%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.1796	0.1630	10.19%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	2.0450	1.9157	6.75%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	1.2539	1.1689	7.27%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	4.2965	4.0568	5.91%	4.0000	4.0000	0.0000%	0.0000%	0.0000%
	11.8343	11.3572	4.20%	12.0000	11.0000	9.0909%	0.0000%	8.3333%
	1.0101	0.9346	8.08%	1.0000	0.9000	11.1111%	0.0000%	10.0000%
	1.2539	1.1682	7.34%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	0.4287	0.3937	8.90%	0.4000	0.4000	0.0000%	0.0000%	0.0000%
	0.2053	0.1867	9.96%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	2.5674	2.4125	6.42%	3.0000	2.0000	50.0000%	0.0000%	33.3333%
	3.0189	2.8409	6.26%	3.0000	3.0000	0.0000%	0.0000%	0.0000%
	4.8368	4.5872	5.44%	5.0000	5.0000	0.0000%	50.0000%	50.0000%
	15.7480	15.1515	3.94%	16.0000	15.0000	6.6667%	0.0000%	6.2500%
	5.1881	4.9140	5.58%	5.0000	5.0000	0.0000%	0.0000%	0.0000%
	6.4620	6.1350	5.33%	6.0000	6.0000	0.0000%	14.2857%	14.2857%
	0.1775	0.2110	15.88%	0.2000	0.2000	0.0000%	0.0000%	0.0000%
	2.1008	2.5126	16.39%	2.0000	3.0000	33.3333%	0.0000%	50.0000%
	0.9639	1.1105	13.20%	1.0000	1.0000	0.0000%	0.0000%	0.0000%
	0.4237	0.4695	9.75%	0.4000	0.5000	20.0000%	0.0000%	25.0000%
	4.3290	4.9875	13.20%	4.0000	5.0000	20.0000%	60.0000%	50.0000%
	1.5873	1.8116	12.38%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	2.2779	2.6110	12.76%	2.0000	3.0000	33.3333%	0.0000%	50.0000%
	1.8501	1.5601	18.59%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.5610	0.4706	19.21%	0.6000	0.5000	20.0000%	0.0000%	16.6667%
	0.1962	0.2336	16.04%	0.2000	0.2000	0.0000%	33.3333%	33.3333%
	0.7273	0.8299	12.36%	0.7000	0.8000	12.5000%	0.0000%	14.2857%
Mean			**13.08%**			**10.2940%**	**2.1928%**	**13.6101%**

Table 70: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for probative samples that resulted in partial profiles and mixtures. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

Partial profiles and mixtures								
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 rounded amplification volumes	Difference of rounded average Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded average Promega standard amplification volume and actual accepted amplification volume
[redacted]	1.3652	1.6026	14.81%	1.0000	2.0000	50.0000%	0.0000%	100.0000%
	8.3507	7.1429	16.91%	8.0000	7.0000	14.2857%	0.0000%	12.5000%
	2.0629	2.4661	16.35%	2.0000	2.0000	0.0000%	0.0000%	0.0000%
	0.7547	0.6349	18.87%	0.8000	0.6000	33.3333%	0.0000%	25.0000%
	12.1212	14.9254	18.79%	12.0000	15.0000	20.0000%	0.0000%	25.0000%
	15.6863	13.4590	16.55%	16.0000	13.0000	23.0769%	0.0000%	18.7500%
	3.9409	4.8544	18.82%	4.0000	5.0000	20.0000%	100.0000%	150.0000%
	3.9920	3.7736	5.79%	4.0000	4.0000	0.0000%	66.6667%	66.6667%
	18.6047	17.9211	3.81%	19.0000	18.0000	5.5556%	26.6667%	20.0000%
	2.2371	2.7211	17.79%	2.0000	3.0000	33.3333%	0.0000%	50.0000%
	7.2595	8.9286	18.69%	7.0000	9.0000	22.2222%	41.6667%	25.0000%
	46.5658	45.3515	2.68%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	4.1152	4.7393	13.17%	4.0000	5.0000	20.0000%	0.0000%	25.0000%
	4.9505	4.2105	17.57%	5.0000	4.0000	25.0000%	28.5714%	42.8571%
	4.7004	4.0080	17.27%	5.0000	4.0000	25.0000%	50.0000%	60.0000%
	17.1674	14.7384	16.48%	17.0000	15.0000	13.3333%	15.0000%	25.0000%
	21.6216	25.1889	14.16%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	34.7524	40.5680	14.34%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	21.3333	18.3824	16.05%	20.0000	18.0000	11.1111%	0.0000%	10.0000%
	20.9205	24.3013	13.91%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	19.4363	22.5479	13.80%	19.0000	20.0000	5.0000%	0.0000%	5.2632%
	38.4246	52.6316	26.99%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	20.3978	25.2845	19.33%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	21.8699	18.8324	16.13%	20.0000	19.0000	5.2632%	0.0000%	5.0000%
Mean			**15.38%**			**13.6048%**	**13.6905%**	**27.7515%**

Table 71: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for probative samples that resulted in non-reportable or NSD profiles. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

NR and NSD profile results								
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Promega standard to average Quantifiler standard quantity/ 2 rounded amplification volumes	Difference of rounded average Quantifiler standard/2 amplification volume and actual accepted amplification volume	Difference of rounded average Promega standard amplification volume and actual accepted amplification volume
[redacted]	85.1064	106.5530	20.13%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	647.2492	823.3841	21.39%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	307.9292	389.8635	21.02%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	76.9231	66.8896	15.00%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	24.3754	20.9864	16.15%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	65.5738	56.8182	15.41%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	232.5581	275.4821	15.58%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	27.3785	31.9489	14.31%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	168.0672	198.4127	15.29%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	42.9185	50.1253	14.38%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	89.0869	104.7120	14.92%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	456.1003	543.4783	16.08%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	244.6483	289.8551	15.60%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	35.5240	48.5437	26.82%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	25.4291	34.1880	25.62%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	20.0000	20.0000	0.00%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	80.4829	114.3511	29.62%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	48.7805	67.5676	27.80%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	89.8876	128.1230	29.84%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	652.5285	826.4463	21.04%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	28.6533	35.5872	19.48%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	1279.1813	1299.5452	1.57%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	220.7506	220.0220	0.33%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	331.6750	331.1258	0.17%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	28.3086	35.1494	19.46%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	20.0000	20.0000	0.00%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	419.7272	420.1681	0.10%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	64.1026	55.7103	15.06%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
	184.1621	161.0306	14.36%	20.0000	20.0000	0.0000%	0.0000%	0.0000%
Mean			**15.40%**			**0.0000%**	**0.0000%**	**0.0000%**

With a 2ng of template amount used for the initial Profiler Plus reactions, the majority of probative samples resulted in full profiles (see table 72 and figure 66). With full and partial profile results combined, successful results were obtained from 78% of the probative samples. The remaining 22% results may be attributed to a number of reasons, including none or too little DNA being present in the samples themselves.

Table 72: Final results using the Quantifiler standard after an estimated 2ng was used for the initial Profiler amplification.

Amplification results	Sample number
Full profiles	81
Partial profiles	24
No size data (NSD)	21
Non reportable (NR) profile	8
SUBTOTAL	**126**
Unamplified (inhibition present)	1
TOTAL	**127**

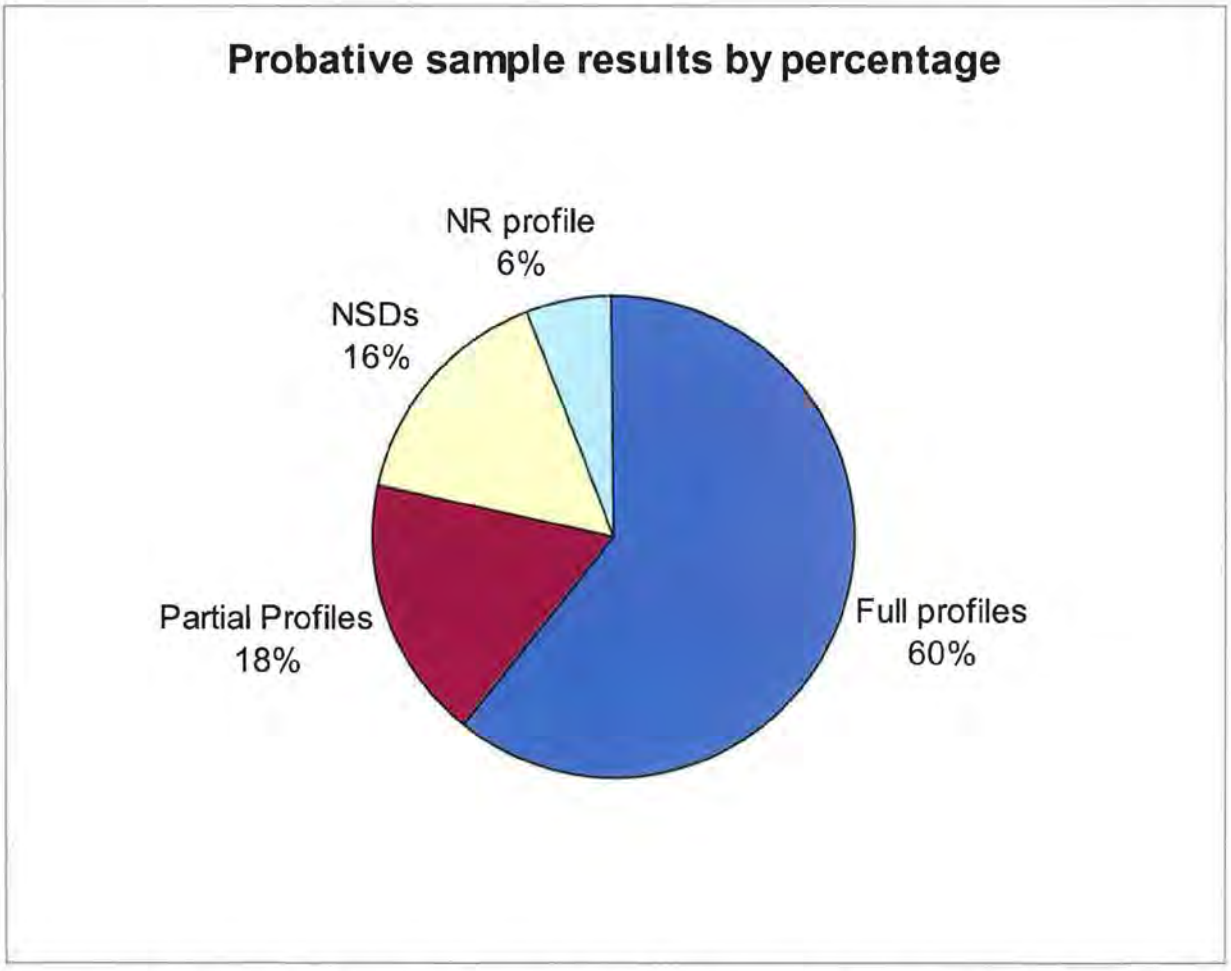

Figure 66: Final results for probative samples using the Quantifiler standard after an estimated 2ng was used for the initial Profiler amplification.

In table 73, the differences between using the Quantifiler Human DNA standard and the Promega Male standard for estimating probative sample concentration are summarised. Clearly, the most optimal nanogram amount for the Quantifiler Human DNA standard (approximately 2ng) is approximately double to that of the Promega Male standard (approximately 1ng). This is due to the approximate two-fold bias inherent in the results when using the Quantifiler standard.

Table 73: A comparison of probative sample results with the Promega Male standard and Quantifiler standard.

Probative Sample results						
Final Result		Optimal ng amount using Quantifiler Standard	Optimal ng using Promega Standard			
Full	**Mean**	**2.064747679**	**0.996119346**			
PP	**Mean**	**2.124316667**	**1.057872917**			
Full+PP	**Mean**	**2.078363448**	**1.010234448**			
		No rounding				
Final Result		Difference 1ng Promega to 1ng Quantifiler	Difference 1ng Promega to 2ng Quantifiler	Difference 1ng Promega to 2.22ng Quantifiler	Difference 1ng Promega to 2.35ng Quantifiler	Difference 1ng Promega to 2.5ng Quantifiler
Full	**Mean**	**110.33%**	**13.90%**	**11.31%**	**11.93%**	**16.09%**
PP	**Mean**	**111.83%**	**16.56%**	**14.09%**	**13.35%**	**16.07%**
		Rounding due to macro				
Final Result		Difference 1ng Promega to 1ng Quantifiler	Difference 1ng Promega to 2ng Quantifiler	Difference 1ng Promega to 2.22ng Quantifiler	Difference 1ng Promega to 2.35ng Quantifiler	Difference 1ng Promega to 2.5ng Quantifiler
Full	**Mean**	**112.75%**	**11.35%**	**10.94%**	**10.20%**	**14.38%**
PP	**Mean**	**96.27%**	**16.57%**	**10.68%**	**10.80%**	**10.66%**

5.13.2 NON-PROBATIVE SAMPLES (QUANTIFILER STANDARD RESULTS VERSUS PROMEGA MALE STANDARD RESULTS)

The testing of the method and modifications of the method on non-probative samples is required according to DAB (2000: 8.1.3.1) and SWGDAM (2004: 3.1) guidelines. A total of 67 non-probative samples were analysed with both the Quantifiler standard and the Promega Male standard. Similarity in Quantifiler concentration and amplification volumes was compared, but the initial Profiler Plus amplifications consisted of an estimated amount of 2 Quantifiler nanograms. We have shown in the validation of the Quantifiler standard that 1 Promega Male standard nanogram is equivalent to approximately 2.22 or 2 Quantifiler standard nanograms. While the Quantifiler Human DNA Standard result needed to be calibrated, the Promega Male standard results did not.

The sample volumes and amplification volumes, as well as actual accepted amplification volumes were also compared for individual results from each duplicate while the same was done with the mean Quantifiler results which were used for the initial Profiler Plus amplifications. The greatest differences were observed between the uncalibrated Quantifiler Human DNA standard results and Promega Male standard results producing a mean difference of 109.8% for the sample volumes of full profile samples (see table 77). The smallest resulting mean difference was with the Quantifiler standard at 2ng and Promega Male control at 1ng for full profile samples at 6.27% (see table 74). With the samples resulting in full profiles, the rounded Quantifiler standard result amplification volumes at 2ng produced the smallest mean difference with the actual accepted volumes. The actual accepted volumes were the volumes accepted as the most optimal results out of up to three amplifications and not necessarily what was originally calculated as the ideal volume for the initial PCR based on the Quantifiler results. The result was obviously biased by 2ng being the original amplification target.

With partial profile and mixture results (table 75), similar results as for the full profiles are visible. The mean difference of the Promega Male standard to Quantifiler Human DNA standard concentration/2.22 Quantifiler values was only 16.06% and the mean difference of the Promega Male standard to Quantifiler Human DNA standard concentration/2 Quantifiler values was higher at 24.42%. The highest difference at 143.24% was the mean difference of the Promega Male standard to the uncalibrated Quantifiler standard Quantifiler values. With the sample volumes, the same difference percentage values were obtained whether a full profile, partial profile, mixture, No Size Data (NSD) profile or a Non-Reportable profile as for the Quantifiler value differences. In terms of amplification volumes, Promega Male standard to Quantifiler Human DNA standard concentration/2.22 had the lowest difference at 7.79%, followed by Promega Male standard to Quantifiler Human DNA standard concentration/2 at 14.93%. The greatest differences were observed between the uncalibrated Quantifiler Human DNA standard amplification volumes and Promega Male standard amplification volumes producing a mean difference of 107.47% (see table 78)

With resulting profiles producing no-size data (NSD) and non-reportable (NR) profiles (see tables 76 and 79), most of the samples were amplified at maximum sample volumes of 20µL in 50µL Profiler Plus reactions. The least overall mean difference with the NSD and NR samples was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 2.48%). The Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng is also comparable with a mean difference of 3.65%.

In tables 80-82, comparisons of the same data but this time off average results from the duplicates are shown. The rounded amplification volumes account for the pipetting limit of 1µL. In other words, the rounding macro has to round sample volumes to the nearest 1µL and not volumes with decimal places. Where amounts are under 1ng of input template for Profiler or Cofiler due to rounding, the macro then rounds up to the next 1µL of sample volume. Although the original macro used by Forensic Biology did not round up the volumes for sample template amounts that were under 1ng, we recommend that updated versions that round sample volumes for pipetting do include the algorithm to be able to do so.

Table 74: Comparison of Quantifiler and Promega Male standard concentration results for full profile non-probative samples. The quantity shown is in ng/µL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 6.27%). The Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng is also comparable with a mean difference of 7.75%. Duplicate results are presented.

Full profile								
Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/ 2	Quantity Quantifiler standard/ 2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega male standard quantities	Difference of Quantifiler standard/2 and the Promega male standard quantities	Difference of Quantifiler standard/2 .22 and the Promega male standard quantities
[redacted]	28.82	1.2400	0.6200	0.5586	0.6280	97.45%	1.27%	11.06%
	29.04	1.0400	0.5200	0.4685	0.5330	95.12%	2.44%	12.11%
	28.29	1.8700	0.9350	0.8423	0.9260	101.94%	0.97%	9.03%
	28.28	1.8800	0.9400	0.8468	0.9340	101.28%	0.64%	9.33%
	28.06	2.2400	1.1200	1.0090	1.1000	103.64%	1.82%	8.27%
	28.09	2.1800	1.0900	0.9820	1.0800	101.85%	0.93%	9.08%
	28.25	1.9200	0.9600	0.8649	0.9540	101.26%	0.63%	9.34%
	28.40	1.7100	0.8550	0.7703	0.8530	100.47%	0.23%	9.70%
	27.20	4.3300	2.1650	1.9505	2.0700	109.18%	4.59%	5.78%
	27.08	4.7600	2.3800	2.1441	2.2600	110.62%	5.31%	5.13%
	25.29	19.0000	9.5000	8.5586	8.4700	124.32%	12.16%	1.05%
	25.39	17.6900	8.8450	7.9685	7.9100	123.64%	11.82%	0.74%
	28.48	1.6100	0.8050	0.7252	0.8070	99.50%	0.25%	10.13%
	28.25	1.9200	0.9600	0.8649	0.9510	101.89%	0.95%	9.06%
	26.25	9.0400	4.5200	4.0721	4.1700	116.79%	8.39%	2.35%
	26.32	8.6100	4.3050	3.8784	3.9800	116.33%	8.17%	2.55%
	28.11	2.1500	1.0750	0.9685	1.0600	102.83%	1.42%	8.64%
	28.11	2.1500	1.0750	0.9685	1.0600	102.83%	1.42%	8.64%
	27.40	3.7100	1.8550	1.6712	1.7800	108.43%	4.21%	6.11%
	27.49	3.4500	1.7250	1.5541	1.6700	106.59%	3.29%	6.94%
	27.70	2.9400	1.4700	1.3243	1.4300	105.59%	2.80%	7.39%
	27.95	2.4300	1.2150	1.0946	1.1900	104.20%	2.10%	8.02%
	27.41	3.6900	1.8450	1.6622	1.7700	108.47%	4.24%	6.09%
	27.43	3.6200	1.8100	1.6306	1.7400	108.05%	4.02%	6.29%
	28.66	1.4000	0.7000	0.6306	0.7030	99.15%	0.43%	10.29%
	28.75	1.3100	0.6550	0.5901	0.6600	98.48%	0.76%	10.59%
	28.00	2.3400	1.1700	1.0541	1.1500	103.48%	1.74%	8.34%
	28.05	2.2500	1.1250	1.0135	1.1100	102.70%	1.35%	8.69%
	26.53	7.2900	3.6450	3.2838	3.4000	114.41%	7.21%	3.42%
	26.56	7.1200	3.5600	3.2072	3.3200	114.46%	7.23%	3.40%
	27.28	4.0800	2.0400	1.8378	1.9500	109.23%	4.62%	5.75%
	27.25	4.1700	2.0850	1.8784	1.9900	109.55%	4.77%	5.61%
	29.19	0.9300	0.4650	0.4189	0.4770	94.97%	2.52%	12.18%
	29.09	1.0100	0.5050	0.4550	0.5140	96.50%	1.75%	11.49%
	27.74	2.8600	1.4300	1.2883	1.3900	105.76%	2.88%	7.32%
	27.58	3.2300	1.6150	1.4550	1.5600	107.05%	3.53%	6.73%
	27.04	4.9200	2.4600	2.2162	2.3300	111.16%	5.58%	4.88%
	27.08	4.7500	2.3750	2.1396	2.2600	110.18%	5.09%	5.33%
	29.63	0.6620	0.3310	0.2982	0.3450	91.88%	4.06%	13.57%
	29.30	0.8500	0.4250	0.3829	0.4380	94.06%	2.97%	12.58%
	25.74	12.9800	6.4900	5.8468	6.2200	108.68%	4.34%	6.00%
	25.80	12.4100	6.2050	5.5901	5.9300	109.27%	4.64%	5.73%
	28.10	2.4600	1.2300	1.1081	1.0900	125.69%	12.84%	1.66%
	28.04	2.5500	1.2750	1.1486	1.1400	123.68%	11.84%	0.76%
	29.69	0.8000	0.4000	0.3604	0.3390	135.99%	17.99%	6.30%
	29.44	0.9510	0.4755	0.4284	0.4060	134.24%	17.12%	5.51%
	27.16	4.7700	2.3850	2.1486	2.1900	117.81%	8.90%	1.89%
	27.14	4.8300	2.4150	2.1757	2.2100	118.55%	9.28%	1.55%
	30.00	0.6420	0.3210	0.2892	0.2700	137.78%	18.89%	7.11%
	30.07	0.6100	0.3050	0.2748	0.2550	139.22%	19.61%	7.75%

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Full profile

Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/ 2	Quantity Quantifiler standard/ 2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega male standard quantities	Difference of Quantifiler standard/2 and the Promega male standard quantities	Difference of Quantifiler standard/2 .22 and the Promega male standard quantities
[redacted]	30.23	0.5450	0.2725	0.2455	0.2270	140.09%	20.04%	8.15%
	30.51	0.4480	0.2240	0.2018	0.1850	142.16%	21.08%	9.08%
	27.30	4.3100	2.1550	1.9414	1.9600	119.90%	9.95%	0.95%
	27.44	3.9100	1.9550	1.7613	1.7800	119.66%	9.83%	1.05%
	28.26	2.1900	1.0950	0.9865	0.9710	125.54%	12.77%	1.59%
	28.22	2.2500	1.1250	1.0135	0.9970	125.68%	12.84%	1.66%
	28.09	2.4700	1.2350	1.1126	1.1000	124.55%	12.27%	1.15%
	28.11	2.4400	1.2200	1.0991	1.0800	125.93%	12.96%	1.77%
	29.66	0.8150	0.4075	0.3671	0.3460	135.55%	17.77%	6.10%
	29.73	0.7780	0.3890	0.3505	0.3290	136.47%	18.24%	6.52%
	28.61	1.7100	0.8550	0.7703	0.7500	128.00%	14.00%	2.70%
	28.86	1.4400	0.7200	0.6486	0.6260	130.03%	15.02%	3.62%
	28.46	1.9100	0.9550	0.8604	0.8390	127.65%	13.83%	2.55%
	28.52	1.8200	0.9100	0.8198	0.8000	127.50%	13.75%	2.48%
	28.77	1.5300	0.7650	0.6892	0.6690	128.70%	14.35%	3.02%
	29.01	1.2900	0.6450	0.5811	0.5590	130.77%	15.38%	3.95%
	28.45	1.9200	0.9600	0.8649	0.8440	127.49%	13.74%	2.47%
	28.51	1.8300	0.9150	0.8243	0.8050	127.33%	13.66%	2.40%
	30.33	0.5110	0.2555	0.2302	0.2120	141.04%	20.52%	8.58%
	30.46	0.4650	0.2325	0.2095	0.1930	140.93%	20.47%	8.53%
	29.10	1.2200	0.6100	0.5495	0.5240	132.82%	16.41%	4.88%
	29.26	1.0800	0.5400	0.4865	0.4660	131.76%	15.88%	4.40%
	27.51	3.0800	1.5400	1.3874	1.5700	96.18%	1.91%	11.63%
	27.69	2.6900	1.3450	1.2117	1.3700	96.35%	1.82%	11.55%
	25.67	11.8800	5.9400	5.3514	6.1200	94.12%	2.94%	12.56%
	25.71	11.5500	5.7750	5.2027	5.9500	94.12%	2.94%	12.56%
	24.02	39.8800	19.9400	17.9640	20.7000	92.66%	3.67%	13.22%
	24.08	38.1700	19.0850	17.1937	19.8100	92.68%	3.66%	13.21%
	30.45	0.3560	0.1780	0.1604	0.1790	98.88%	0.56%	10.41%
	30.29	0.4020	0.2010	0.1811	0.2030	98.03%	0.99%	10.80%
	29.47	0.7310	0.3655	0.3293	0.3700	97.57%	1.22%	11.01%
	29.66	0.6350	0.3175	0.2860	0.3210	97.82%	1.09%	10.89%
	26.20	8.0700	4.0350	3.6351	4.1500	94.46%	2.77%	12.41%
	26.21	8.0000	4.0000	3.6036	4.1100	94.65%	2.68%	12.32%
	30.38	0.3760	0.1880	0.1694	0.1890	98.94%	0.53%	10.39%
	30.29	0.4010	0.2005	0.1806	0.2020	98.51%	0.74%	10.58%
	28.59	1.4000	0.7000	0.6306	0.7110	96.91%	1.55%	11.30%
	28.65	1.3300	0.6650	0.5991	0.6770	96.45%	1.77%	11.51%
	31.31	0.1900	0.0950	0.0856	0.0953	99.37%	0.31%	10.19%
	31.23	0.2010	0.1005	0.0905	0.1010	99.01%	0.50%	10.36%
	30.11	0.4570	0.2285	0.2059	0.2310	97.84%	1.08%	10.88%
	30.01	0.4940	0.2470	0.2225	0.2490	98.39%	0.80%	10.63%
	27.27	3.6700	1.8350	1.6532	1.8800	95.21%	2.39%	12.07%
	27.34	3.5000	1.7500	1.5766	1.7900	95.53%	2.23%	11.92%
	29.07	0.9790	0.4895	0.4410	0.4960	97.38%	1.31%	11.09%
	29.04	1.0000	0.5000	0.4505	0.5090	96.46%	1.77%	11.50%
	29.55	0.6920	0.3460	0.3117	0.3500	97.71%	1.14%	10.94%
	29.71	0.6150	0.3075	0.2770	0.3110	97.75%	1.13%	10.92%
	31.61	0.1520	0.0760	0.0685	0.0763	99.21%	0.39%	10.26%
	32.01	0.1130	0.0565	0.0509	0.0566	99.65%	0.18%	10.07%
	26.33	7.3100	3.6550	3.2928	3.7500	94.93%	2.53%	12.19%
	26.24	7.8400	3.9200	3.5315	4.0300	94.54%	2.73%	12.37%
	29.07	0.9820	0.4910	0.4423	0.4980	97.19%	1.41%	11.18%
	29.18	0.9040	0.4520	0.4072	0.4580	97.38%	1.31%	11.09%
	25.76	11.1100	5.5550	5.0045	5.7200	94.23%	2.88%	12.51%
	25.85	10.4200	5.2100	4.6937	5.3600	94.40%	2.80%	12.43%
	30.48	0.3500	0.1750	0.1577	0.1760	98.86%	0.57%	10.42%
	30.50	0.3430	0.1715	0.1545	0.1730	98.27%	0.87%	10.69%
	28.93	1.3700	0.6850	0.6171	0.5940	130.64%	15.32%	3.89%
	28.82	1.4800	0.7400	0.6667	0.6440	129.81%	14.91%	3.52%
					Mean	**109.80%**	**6.27%**	**7.75%**

Table 75: Comparison of Quantifiler and Promega Male standard concentration results for partial profile non-probative samples. The quantity shown is in ng/μL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 16.06%). The Promega Male standard result at 1ng and Quantifiler standard result at 2ng is also comparable with a mean difference of 24.42%. Duplicate results are presented. Values ≤0.1ng/μL are amplified with Profiler Plus at a full sample volume of 20μL in a 50μL reaction.

Partial profiles								
Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega male standard quantities	Difference of Quantifiler standard/2 and the Promega male standard quantities	Difference of Quantifiler standard/2.22 and the Promega male standard quantities
[redacted]	31.84	0.1750	0.0875	0.0788	0.0695	151.80%	25.90%	13.42%
[redacted]	31.90	0.1680	0.0840	0.0757	0.0665	152.63%	26.32%	13.80%
[redacted]	32.06	0.1500	0.0750	0.0676	0.0592	153.38%	26.69%	14.13%
[redacted]	32.38	0.1200	0.0600	0.0541	0.0466	157.51%	28.76%	16.00%
[redacted]	32.39	0.1190	0.0595	0.0536	0.0463	157.02%	28.51%	15.77%
[redacted]	33.98	0.0389	0.0195	0.0175	0.0144	170.14%	35.07%	21.68%
[redacted]	30.40	0.3620	0.1810	0.1631	0.1940	86.60%	6.70%	15.95%
[redacted]	30.63	0.3040	0.1520	0.1369	0.1640	85.37%	7.32%	16.50%
[redacted]	32.62	0.1010	0.0505	0.0455	0.0392	157.65%	28.83%	16.06%
[redacted]	32.83	0.0872	0.0436	0.0393	0.0335	160.30%	30.15%	17.25%
					Mean	**143.24%**	**24.42%**	**16.06%**

Table 76: Comparison of Quantifiler and Promega Male standard concentration results for non-probative samples resulting in NSDs. The quantity shown is in ng/μL. The least overall difference was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 2.48%). The Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng is also comparable with a mean difference of 3.65%. Duplicate results are presented.

NSDs								
Sample Name	CT	Quantity Quantifiler standard	Quantity Quantifiler standard/2	Quantity Quantifiler standard/2.22	Quantity Promega Male standard	Difference of Quantifiler standard and the Promega male standard quantities	Difference of Quantifiler standard/2 and the Promega male standard quantities	Difference of Quantifiler standard/2.22 and the Promega male standard quantities
[redacted]	33.97	0.0228	0.0114	0.0103	0.0139	64.03%	17.99%	26.11%
[redacted]	33.55	0.0315	0.0158	0.0142	0.0189	66.67%	16.67%	24.92%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
[redacted]	Undetermined	0.0000	0.0000	0.0000	0.0000	0.00%	0.00%	0.00%
					Mean	**9.34%**	**2.48%**	**3.65%**

Table 77: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for non-probative samples that resulted in full profiles. The least overall difference in sample volumes was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 6.27%). The Promega Male standard result at 1ng and Quantifiler standard sample volume result at 2.22ng is also comparable with a mean difference of 7.75%. Duplicate results are presented.

Full profile results																	
Sample Name	Quantity Quantifiler standard	Quantity Promega Male standard	Sample volume Quantifiler standard quantity	Sample volume Quantifiler standard quantity/ 2	Sample volume Quantifiler standard quantity/ 2.22	Sample volume Promega standard	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Difference of Quantifiler standard quantity to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2 to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2.22 to Promega standard amplification volumes
[redacted]	1.2400	0.6280	0.81	1.61	1.79	1.59	97.45%	1.27%	11.06%	0.8000	2.000	2.000	2.000	150.00%	0.00%	0.00%
	1.0400	0.5330	0.96	1.92	2.13	1.88	95.12%	2.44%	12.11%	1.0000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	1.8700	0.9260	0.53	1.07	1.19	1.08	101.94%	0.97%	9.03%	0.5000	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.8800	0.9340	0.53	1.06	1.18	1.07	101.28%	0.64%	9.33%	0.5000	1.000	1.000	1.000	100.00%	0.00%	0.00%
	2.2400	1.1000	0.45	0.89	0.99	0.91	103.64%	1.82%	8.27%	0.4000	0.900	1.000	0.900	125.00%	0.00%	10.00%
	2.1800	1.0800	0.46	0.92	1.02	0.93	101.85%	0.93%	9.08%	0.5000	0.900	1.000	0.900	80.00%	0.00%	10.00%
	1.9200	0.9540	0.52	1.04	1.16	1.05	101.26%	0.63%	9.34%	0.5000	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.7100	0.8530	0.58	1.17	1.30	1.17	100.47%	0.23%	9.70%	0.6000	1.000	1.000	1.000	66.67%	0.00%	0.00%
	4.3300	2.0700	0.23	0.46	0.51	0.48	109.18%	4.59%	5.78%	0.2000	0.500	0.500	0.500	150.00%	0.00%	0.00%
	4.7600	2.2600	0.21	0.42	0.47	0.44	110.62%	5.31%	5.13%	0.2000	0.400	0.500	0.400	100.00%	0.00%	20.00%
	19.0000	8.4700	0.05	0.11	0.12	0.12	124.32%	12.16%	1.05%	0.0500	0.100	0.100	0.100	100.00%	0.00%	0.00%
	17.6900	7.9100	0.06	0.11	0.13	0.13	123.64%	11.82%	0.74%	0.0600	0.100	0.100	0.100	66.67%	0.00%	0.00%
	1.6100	0.8070	0.62	1.24	1.38	1.24	99.50%	0.25%	10.13%	0.6000	1.000	1.000	1.000	66.67%	0.00%	0.00%
	1.9200	0.9510	0.52	1.04	1.16	1.05	101.89%	0.95%	9.06%	0.5000	1.000	1.000	1.000	100.00%	0.00%	0.00%
	9.0400	4.1700	0.11	0.22	0.25	0.24	116.79%	8.39%	2.35%	0.1000	0.200	0.200	0.200	100.00%	0.00%	0.00%
	8.6100	3.9900	0.12	0.23	0.26	0.25	116.33%	8.17%	2.55%	0.1000	0.200	0.300	0.300	200.00%	50.00%	0.00%
	2.1500	1.0500	0.47	0.93	1.03	0.94	102.83%	1.42%	8.64%	0.5000	0.900	1.000	0.900	80.00%	0.00%	10.00%
	2.1500	1.0800	0.47	0.93	1.03	0.94	102.83%	1.42%	8.64%	0.5000	0.900	1.000	0.900	80.00%	0.00%	10.00%
	3.7100	1.7800	0.27	0.54	0.60	0.58	108.43%	4.21%	6.11%	0.3000	0.500	0.600	0.600	100.00%	20.00%	0.00%
	3.4500	1.6700	0.29	0.58	0.64	0.60	106.59%	3.29%	6.94%	0.3000	0.600	0.600	0.600	100.00%	0.00%	0.00%
	2.9400	1.4300	0.34	0.68	0.76	0.70	105.59%	2.80%	7.39%	0.3000	0.700	0.800	0.700	133.33%	0.00%	12.50%
	2.4300	1.1900	0.41	0.82	0.91	0.84	104.20%	2.10%	8.02%	0.4000	0.800	0.900	0.800	100.00%	0.00%	11.11%
	3.6900	1.7700	0.27	0.54	0.60	0.56	108.47%	4.24%	6.09%	0.3000	0.500	0.600	0.600	100.00%	20.00%	0.00%
	3.6200	1.7400	0.28	0.55	0.61	0.57	108.05%	4.02%	6.29%	0.3000	0.600	0.600	0.600	100.00%	0.00%	0.00%
	1.4000	0.7030	0.71	1.43	1.59	1.42	99.15%	0.43%	10.29%	0.7000	1.000	2.000	1.000	42.86%	0.00%	50.00%
	1.3100	0.6600	0.76	1.53	1.69	1.52	98.48%	0.76%	10.59%	0.8000	2.000	2.000	2.000	150.00%	0.00%	0.00%
	2.3400	1.1500	0.43	0.85	0.95	0.87	103.48%	1.74%	8.34%	0.4000	0.900	0.900	0.900	125.00%	0.00%	0.00%
	2.2500	1.1100	0.44	0.89	0.99	0.90	102.70%	1.35%	8.69%	0.4000	0.900	1.000	0.900	125.00%	0.00%	10.00%
	7.2900	3.4000	0.14	0.27	0.30	0.29	114.41%	7.21%	3.42%	0.1000	0.300	0.300	0.300	200.00%	0.00%	0.00%
	7.1200	3.3200	0.14	0.28	0.31	0.30	114.46%	7.23%	3.40%	0.1000	0.300	0.300	0.300	200.00%	0.00%	0.00%
	4.0800	1.9500	0.25	0.49	0.54	0.51	109.23%	4.62%	5.75%	0.2000	0.500	0.500	0.500	150.00%	0.00%	0.00%
	4.1700	1.9900	0.24	0.48	0.53	0.50	109.55%	4.77%	5.61%	0.2000	0.500	0.500	0.500	150.00%	0.00%	0.00%
	0.9300	0.4770	1.08	2.15	2.39	2.10	94.97%	2.52%	12.18%	1.0000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	1.0100	0.5140	0.99	1.98	2.20	1.95	96.50%	1.75%	11.49%	1.0000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	2.8600	1.3900	0.35	0.70	0.78	0.72	105.76%	2.88%	7.32%	0.3000	0.700	0.800	0.700	133.33%	0.00%	12.50%
	3.2300	1.5600	0.31	0.62	0.69	0.64	107.05%	3.53%	6.73%	0.3000	0.600	0.700	0.600	100.00%	0.00%	14.29%
	4.9200	2.3300	0.20	0.41	0.45	0.43	111.16%	5.58%	4.88%	0.2000	0.400	0.500	0.400	100.00%	0.00%	20.00%
	4.7500	2.2600	0.21	0.42	0.47	0.44	110.18%	5.09%	5.33%	0.2000	0.400	0.500	0.400	100.00%	0.00%	20.00%
	0.6620	0.3450	1.51	3.02	3.35	2.90	91.88%	4.06%	13.57%	2.0000	3.000	3.000	3.000	50.00%	0.00%	0.00%
	0.8500	0.4380	1.18	2.35	2.61	2.28	94.06%	2.97%	12.58%	1.0000	2.000	3.000	2.000	100.00%	0.00%	33.33%
	12.9800	6.2200	0.08	0.15	0.17	0.16	108.68%	4.34%	6.00%	0.0800	0.200	0.200	0.200	150.00%	0.00%	0.00%
	12.4100	5.9300	0.08	0.16	0.18	0.17	109.27%	4.64%	5.73%	0.0800	0.200	0.200	0.200	150.00%	0.00%	0.00%
	2.4600	1.0900	0.41	0.81	0.90	0.92	125.69%	12.84%	1.66%	0.4000	0.800	0.900	0.900	125.00%	12.50%	0.00%
	2.5500	1.1400	0.39	0.78	0.87	0.88	123.68%	11.84%	0.76%	0.4000	0.800	0.900	0.900	125.00%	12.50%	0.00%
	0.8000	0.3390	1.25	2.50	2.78	2.95	135.99%	17.99%	6.30%	1.0000	3.000	3.000	3.000	200.00%	0.00%	0.00%
	0.9510	0.4060	1.05	2.10	2.33	2.46	134.24%	17.12%	5.51%	1.0000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	4.7700	2.1900	0.21	0.42	0.47	0.46	117.61%	8.90%	1.89%	0.2000	0.400	0.500	0.500	150.00%	25.00%	0.00%
	4.8300	2.2100	0.21	0.41	0.46	0.45	118.55%	9.28%	1.55%	0.2000	0.400	0.500	0.500	150.00%	25.00%	0.00%
	0.6420	0.2700	1.56	3.12	3.46	3.70	137.78%	18.89%	7.11%	2.0000	3.000	3.000	4.000	100.00%	33.33%	33.33%
	0.6100	0.2550	1.64	3.28	3.64	3.92	139.22%	19.61%	7.75%	2.0000	3.000	4.000	4.000	100.00%	33.33%	0.00%

Queensland Government
Queensland Health

Extended Internal Retrospective Validation of the ABI Prism® 7000/Quantifiler System (Forensic Biology)

Full profile results

Sample Name	Quantity Quantifiler standard	Quantity Promega Male standard	Sample volume Quantifiler standard quantity	Sample volume Quantifiler standard quantity/ 2	Sample volume Quantifiler standard quantity/ 2.22	Sample volume Promega standard	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Difference of Quantifiler standard quantity to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2 to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2.22 to Promega standard amplification volumes
[redacted]	0.5450	0.2270	1.83	3.67	4.07	4.41	140.09%	20.04%	8.15%	2.000	4.000	4.000	4.000	100.00%	0.00%	0.00%
	0.4480	0.1850	2.23	4.46	4.96	5.41	142.16%	21.08%	9.08%	2.000	4.000	5.000	5.000	150.00%	25.00%	0.00%
	4.3100	1.9600	0.23	0.46	0.52	0.51	119.90%	9.95%	0.95%	0.200	0.500	0.500	0.500	150.00%	0.00%	0.00%
	3.9100	1.7800	0.26	0.51	0.57	0.56	119.66%	9.83%	1.05%	0.300	0.500	0.600	0.600	100.00%	20.00%	0.00%
	2.1900	0.9710	0.46	0.91	1.01	1.03	125.54%	12.77%	1.59%	0.500	0.900	1.000	1.000	100.00%	11.11%	0.00%
	2.2500	0.9970	0.44	0.89	0.99	1.00	125.68%	12.84%	1.66%	0.400	0.900	1.000	1.000	150.00%	11.11%	0.00%
	2.4700	1.1000	0.40	0.81	0.90	0.91	124.55%	12.27%	1.15%	0.400	0.800	0.900	0.900	125.00%	12.50%	0.00%
	2.4400	1.0800	0.41	0.82	0.91	0.93	125.93%	12.96%	1.77%	0.400	0.800	0.900	0.900	125.00%	12.50%	0.00%
	0.6150	0.3460	1.23	2.45	2.72	2.89	135.55%	17.77%	6.10%	1.000	2.000	3.000	3.000	200.00%	50.00%	0.00%
	0.7780	0.3290	1.29	2.57	2.85	3.04	136.47%	18.24%	6.52%	1.000	3.000	3.000	3.000	200.00%	0.00%	0.00%
	1.7100	0.7500	0.58	1.17	1.30	1.33	128.00%	14.00%	2.70%	0.600	1.000	1.000	1.000	66.67%	0.00%	0.00%
	1.4400	0.6260	0.69	1.39	1.54	1.60	130.03%	15.02%	3.62%	0.700	1.000	2.000	2.000	185.71%	100.00%	0.00%
	1.9100	0.8390	0.52	1.05	1.16	1.19	127.65%	13.83%	2.55%	0.500	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.8200	0.8000	0.55	1.10	1.22	1.25	127.50%	13.75%	2.48%	0.500	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.5300	0.6690	0.65	1.31	1.45	1.49	128.70%	14.35%	3.02%	0.700	1.000	1.000	1.000	42.86%	0.00%	0.00%
	1.2900	0.5590	0.78	1.55	1.72	1.79	130.77%	15.38%	3.95%	0.800	2.000	2.000	2.000	150.00%	0.00%	0.00%
	1.9200	0.8440	0.52	1.04	1.16	1.18	127.49%	13.74%	2.47%	0.500	1.000	1.000	1.000	100.00%	0.00%	0.00%
	1.8300	0.8050	0.55	1.09	1.21	1.24	127.33%	13.66%	2.40%	0.500	1.000	1.000	1.000	100.00%	0.00%	0.00%
	0.5110	0.2120	1.96	3.91	4.34	4.72	141.04%	20.52%	8.58%	2.000	4.000	4.000	5.000	150.00%	25.00%	25.00%
	0.4650	0.1930	2.15	4.30	4.77	5.18	140.93%	20.47%	8.53%	2.000	4.000	5.000	5.000	150.00%	25.00%	0.00%
	1.2200	0.5240	0.82	1.64	1.82	1.91	132.82%	16.41%	4.88%	0.800	2.000	2.000	2.000	150.00%	0.00%	0.00%
	1.0800	0.4660	0.93	1.85	2.06	2.15	131.76%	15.86%	4.40%	0.900	2.000	2.000	2.000	122.22%	0.00%	0.00%
	3.0800	1.5700	0.32	0.65	0.72	0.64	96.18%	1.91%	11.63%	0.300	0.600	0.700	0.600	100.00%	0.00%	14.29%
	2.6900	1.3700	0.37	0.74	0.83	0.73	96.35%	1.82%	11.55%	0.400	0.700	0.800	0.700	75.00%	0.00%	12.50%
	11.8800	6.1200	0.08	0.17	0.19	0.16	94.12%	2.94%	12.56%	0.080	0.200	0.200	0.200	150.00%	0.00%	0.00%
	11.5500	5.9500	0.09	0.17	0.19	0.17	94.12%	2.94%	12.56%	0.090	0.200	0.200	0.200	122.22%	0.00%	0.00%
	39.8800	20.7000	0.03	0.05	0.06	0.05	92.66%	3.67%	13.22%	0.030	0.050	0.060	0.050	66.67%	0.00%	16.67%
	38.1700	19.8100	0.03	0.05	0.06	0.05	92.68%	3.66%	13.21%	0.030	0.050	0.060	0.050	66.67%	0.00%	16.67%
	0.3560	0.1790	2.81	5.62	6.24	5.59	98.88%	0.56%	10.41%	3.000	6.000	6.000	6.000	100.00%	0.00%	0.00%
	0.4020	0.2030	2.49	4.98	5.52	4.93	98.03%	0.99%	10.80%	2.000	5.000	6.000	5.000	150.00%	0.00%	16.67%
	0.7310	0.3700	1.37	2.74	3.04	2.70	97.57%	1.22%	11.01%	1.000	3.000	3.000	3.000	200.00%	0.00%	0.00%
	0.6350	0.3210	1.57	3.15	3.50	3.12	97.82%	1.09%	10.89%	2.000	3.000	3.000	3.000	50.00%	0.00%	0.00%
	8.0700	4.1500	0.12	0.25	0.28	0.24	94.46%	2.77%	12.41%	0.100	0.200	0.300	0.200	100.00%	0.00%	33.33%
	8.0000	4.1100	0.13	0.25	0.28	0.24	94.65%	2.68%	12.32%	0.100	0.300	0.300	0.200	100.00%	33.33%	33.33%
	0.3760	0.1890	2.66	5.32	5.90	5.29	98.94%	0.53%	10.39%	3.000	5.000	6.000	5.000	66.67%	0.00%	16.67%
	0.4010	0.2020	2.49	4.99	5.54	4.95	98.51%	0.74%	10.58%	2.000	5.000	6.000	5.000	150.00%	0.00%	16.67%
	1.4000	0.7110	0.71	1.43	1.59	1.41	96.91%	1.55%	11.30%	0.700	1.000	2.000	1.000	42.86%	0.00%	50.00%
	1.3300	0.6770	0.75	1.50	1.67	1.48	96.45%	1.77%	11.51%	0.800	2.000	2.000	1.000	25.00%	50.00%	50.00%
	0.1900	0.0953	5.26	10.53	11.68	10.49	99.37%	0.31%	10.19%	5.000	11.000	12.000	10.000	100.00%	9.09%	16.67%
	0.2010	0.1010	4.96	9.95	11.04	9.90	99.01%	0.50%	10.36%	5.000	10.000	11.000	10.000	100.00%	0.00%	9.09%
	0.4570	0.2310	2.19	4.38	4.86	4.33	97.84%	1.08%	10.88%	2.000	4.000	5.000	4.000	100.00%	0.00%	20.00%
	0.4940	0.2490	2.02	4.05	4.49	4.02	98.39%	0.80%	10.63%	2.000	4.000	4.000	4.000	100.00%	0.00%	0.00%
	3.6700	1.8800	0.27	0.54	0.60	0.53	95.21%	2.39%	12.07%	0.300	0.500	0.600	0.500	66.67%	0.00%	16.67%
	3.5000	1.7900	0.29	0.57	0.63	0.56	95.53%	2.23%	11.92%	0.300	0.600	0.600	0.600	100.00%	0.00%	0.00%
	0.9790	0.4960	1.02	2.04	2.27	2.02	97.38%	1.31%	11.09%	1.000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	1.0000	0.5090	1.00	2.00	2.22	1.96	96.46%	1.77%	11.50%	1.000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	0.6920	0.3500	1.45	2.89	3.21	2.86	97.71%	1.14%	10.94%	1.000	3.000	3.000	3.000	200.00%	0.00%	0.00%
	0.6150	0.3110	1.63	3.25	3.61	3.22	97.75%	1.13%	10.92%	2.000	3.000	4.000	3.000	50.00%	0.00%	25.00%
	0.1520	0.0763	6.58	13.16	14.61	13.11	99.21%	0.39%	10.26%	7.000	13.000	15.000	13.000	85.71%	0.00%	13.33%
	0.1130	0.0566	8.85	17.70	19.65	17.67	99.65%	0.18%	10.07%	9.000	18.000	20.000	18.000	100.00%	0.00%	10.00%
	7.3100	3.7500	0.14	0.27	0.30	0.27	94.93%	2.53%	12.19%	0.100	0.300	0.300	0.300	200.00%	0.00%	0.00%
	7.8400	4.0300	0.13	0.26	0.28	0.25	94.54%	2.73%	12.37%	0.100	0.300	0.300	0.200	100.00%	33.33%	33.33%
	0.9820	0.4980	1.02	2.04	2.26	2.01	97.19%	1.41%	11.18%	1.000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	0.9040	0.4580	1.11	2.21	2.46	2.18	97.38%	1.31%	11.09%	1.000	2.000	2.000	2.000	100.00%	0.00%	0.00%
	11.1100	5.7200	0.09	0.18	0.20	0.17	94.23%	2.88%	12.51%	0.090	0.200	0.200	0.200	122.22%	0.00%	0.00%
	10.4200	5.3600	0.10	0.19	0.21	0.19	94.40%	2.80%	12.43%	0.100	0.200	0.200	0.200	100.00%	0.00%	0.00%
	0.3500	0.1760	2.86	5.71	6.34	5.68	98.86%	0.57%	10.42%	3.000	6.000	6.000	6.000	100.00%	0.00%	0.00%
	0.3430	0.1730	2.92	5.83	6.47	5.76	98.27%	0.87%	10.69%	3.000	6.000	6.000	6.000	100.00%	0.00%	0.00%
	1.3700	0.5940	0.73	1.46	1.62	1.68	130.64%	15.32%	3.89%	0.700	1.000	2.000	2.000	185.71%	100.00%	0.00%
	1.4800	0.6440	0.68	1.35	1.50	1.55	129.81%	14.91%	3.52%	0.700	1.000	2.000	2.000	185.71%	100.00%	0.00%
						Mean	109.80%	6.27%	7.75%					115.03%	7.72%	6.57%

Table 78: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for non-probative samples that resulted in partial profiles. The least overall difference in sample volumes was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2.22ng (mean difference of 16.06%). The Promega Male standard result at 1ng and Quantifiler standard sample volume result at 2ng is also comparable with a mean difference of 24.42%. Duplicate results are presented.

Partial profiles

Sample Name	Quantity Quantifiler standard	Quantity Promega Male standard	Sample volume Quantifiler standard quantity	Sample volume Quantifiler standard quantity/ 2	Sample volume Quantifiler standard quantity/ 2.22	Sample volume Promega standard	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Difference of Quantifiler standard quantity to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2 to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2.22 to Promega standard amplification volumes
[redacted]	0.1750	0.0695	5.71	11.43	12.69	14.39	151.80%	25.90%	13.42%	6	11	13	14	133.33%	27.27%	7.69%
[redacted]	0.1680	0.0665	5.95	11.90	13.21	15.04	152.63%	26.32%	13.80%	6	12	13	15	150.00%	25.00%	15.38%
[redacted]	0.1500	0.0592	6.67	13.33	14.80	16.89	153.38%	26.60%	14.13%	7	13	15	17	142.86%	30.77%	13.33%
[redacted]	0.1200	0.0466	8.33	16.67	18.50	21.46	157.51%	28.76%	16.00%	8	17	19	20	150.00%	17.65%	5.26%
[redacted]	0.1100	0.0463	8.40	16.81	18.66	21.60	157.02%	28.51%	15.77%	8	17	19	20	150.00%	17.65%	5.26%
[redacted]	0.0389	0.0144	25.71	51.41	57.07	69.44	170.14%	35.07%	21.68%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.3620	0.1940	2.76	5.52	6.13	5.15	86.60%	6.70%	15.95%	3	6	6	5	66.67%	16.67%	16.67%
[redacted]	0.3040	0.1640	3.29	6.58	7.30	6.10	85.37%	7.32%	16.50%	3	7	7	6	100.00%	14.29%	14.29%
[redacted]	0.1010	0.0392	9.90	19.80	21.98	25.51	157.65%	28.83%	16.06%	10	20	20	20	100.00%	0.00%	0.00%
[redacted]	0.0872	0.0335	11.47	22.94	25.46	29.85	160.30%	30.15%	17.25%	11	20	20	20	81.82%	0.00%	0.00%
						Mean	**143.24%**	**24.42%**	**16.06%**					**107.47%**	**14.93%**	**7.79%**

Table 79: Comparison of Quantifiler and Promega Male standard sample and amplification volumes for non-probative samples that resulted in NSDs. The least overall difference in sample volumes was observed between the Promega Male standard result at 1ng and Quantifiler standard result at 2ng (mean difference of 2.48%). The Promega Male standard result at 1ng and Quantifiler standard sample volume result at 2.22ng is also comparable with a mean difference of 3.65%. Duplicate results are presented.

NSDs

Sample Name	Quantity Quantifiler standard	Quantity Promega Male standard	Sample volume Quantifiler standard quantity	Sample volume Quantifiler standard quantity/ 2	Sample volume Quantifiler standard quantity/ 2.22	Sample volume Promega standard	Difference of Promega standard to Quantifiler standard quantity sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2 sample volumes	Difference of Promega standard to Quantifiler standard quantity/ 2.22 sample volumes	Rounded amplification volume for Quantifiler standard quantity	Rounded amplification volume for Quantifiler standard quantity/ 2	Rounded amplification volume for Quantifiler standard quantity/ 2.22	Rounded amplification volume for Promega standard quantity	Difference of Quantifiler standard quantity to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2 to Promega standard amplification volumes	Difference of Quantifiler standard quantity/ 2.22 to Promega standard amplification volumes
[redacted]	0.0228	0.0139	43.86	87.72	97.37	71.94	64.03%	17.99%	26.11%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0315	0.0189	31.75	63.49	70.48	52.91	66.67%	16.67%	24.92%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
[redacted]	0.0000	0.0000	20.00	20.00	20.00	20.00	0.00%	0.00%	0.00%	20	20	20	20	0.00%	0.00%	0.00%
						Mean	**9.34%**	**2.48%**	**3.65%**					**0.00%**	**0.00%**	**0.00%**

Table 80: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for non-probative samples that resulted in full profiles. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

Full profile results						
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard rounded amplification volumes
[redacted]	1.75	1.72	1.84%	2.00	2.00	0.00%
	1.07	1.08	0.80%	1.00	1.00	0.00%
	0.90	0.92	1.36%	0.90	0.90	0.00%
	1.10	1.11	0.44%	1.00	1.00	0.00%
	0.44	0.46	4.73%	0.40	0.50	20.00%
	0.11	0.12	10.71%	0.10	0.10	0.00%
	1.13	1.14	0.40%	1.00	1.00	0.00%
	0.23	0.25	7.65%	0.20	0.20	0.00%
	0.93	0.94	1.40%	0.90	0.90	0.00%
	0.56	0.58	3.63%	0.60	0.60	0.00%
	0.74	0.76	2.42%	0.70	0.80	12.50%
	0.55	0.57	3.97%	0.50	0.60	16.67%
	1.48	1.47	0.59%	1.00	1.00	0.00%
	0.87	0.88	1.53%	0.90	0.90	0.00%
	0.28	0.30	6.73%	0.30	0.30	0.00%
	0.48	0.51	4.48%	0.50	0.50	0.00%
	2.06	2.02	2.16%	2.00	2.00	0.00%
	0.66	0.68	3.12%	0.70	0.70	0.00%
	0.41	0.44	5.07%	0.40	0.40	0.00%
	2.65	2.55	3.57%	3.00	3.00	0.00%
	0.16	0.16	4.29%	0.20	0.20	0.00%
	0.80	0.90	10.98%	0.80	0.90	11.11%
	2.28	2.68	14.91%	2.00	3.00	33.33%
	0.42	0.45	8.33%	0.40	0.50	20.00%
	3.19	3.81	16.13%	3.00	4.00	25.00%
	4.03	4.85	17.02%	4.00	5.00	20.00%
	0.49	0.53	9.00%	0.50	0.50	0.00%
	0.90	1.02	11.35%	0.90	1.00	10.00%
	0.81	0.92	11.20%	0.80	0.90	11.11%
	2.51	2.96	15.25%	3.00	3.00	0.00%
	1.27	1.45	12.63%	1.00	1.00	0.00%
	1.07	1.22	12.12%	1.00	1.00	0.00%
	1.42	1.63	12.91%	1.00	2.00	50.00%
	1.07	1.21	12.05%	1.00	1.00	0.00%
	4.10	4.94	17.01%	4.00	5.00	20.00%
	1.74	2.02	13.91%	2.00	2.00	0.00%
	0.69	0.68	1.91%	0.70	0.70	0.00%
	0.17	0.17	3.03%	0.20	0.20	0.00%
	0.05	0.05	3.81%	0.05	0.05	0.00%
	5.28	5.24	0.79%	5.00	5.00	0.00%
	2.93	2.89	1.17%	3.00	3.00	0.00%
	0.25	0.24	2.80%	0.20	0.20	0.00%
	5.15	5.12	0.64%	5.00	5.00	0.00%
	1.47	1.44	1.68%	1.00	1.00	0.00%
	10.23	10.19	0.41%	10.00	10.00	0.00%
	4.21	4.17	0.95%	4.00	4.00	0.00%
	0.56	0.54	2.37%	0.60	0.50	20.00%
	2.02	1.99	1.57%	2.00	2.00	0.00%
	3.06	3.03	1.15%	3.00	3.00	0.00%
	15.09	15.05	0.30%	15.00	15.00	0.00%
	0.26	0.26	2.71%	0.30	0.30	0.00%
	2.12	2.09	1.38%	2.00	2.00	0.00%
	0.19	0.18	2.93%	0.20	0.20	0.00%
	5.77	5.73	0.72%	6.00	6.00	0.00%
	1.40	1.62	13.12%	1.00	2.00	50.00%
Mean			**5.62%**			**5.81%**

Table 81: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for non-probative samples that resulted in partial profiles. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

Partial profiles						
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard rounded amplification volumes
[redacted]	11.6618	14.7059	20.70%	12.0000	15.0000	20.00%
	14.8148	18.9036	21.63%	15.0000	19.0000	21.05%
	25.3325	32.9489	23.12%	20.0000	20.0000	0.00%
	6.0060	5.5866	7.51%	6.0000	6.0000	0.00%
	21.2540	27.5103	22.74%	20.0000	20.0000	0.00%
Mean			**19.14%**			**8.21%**

Table 82: Comparison of Quantifiler and Promega Male standard average sample and amplification volumes for non-probative samples that resulted in NSDs. The results resulting from averaging the duplicate Quantifiler values showing minor differences between the average Promega Male standard result at 1ng and average Quantifiler standard result at 2ng.

NSDs						
Sample Name	Sample volume of average Quantifiler standard value /2	Sample volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard sample volumes	Rounded amplification volume of average Quantifiler standard value /2	Rounded amplification volume of average Promega standard value	Difference of average Quantifiler standard quantity/ 2 to average Promega standard rounded amplification volumes
[redacted]	73.66	60.98	20.81%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
	20.00	20.00	0.00%	20.00	20.00	0.00%
Mean			**2.97%**			**0.00%**

The difference of Promega Male standard and Quantifiler standard values/2 sample volumes in tables 80-82, which are the theoretical unrounded volumes, was 5.62% for full profiles (table 80), 19.14% for partial profiles and mixtures (table 81) and 2.97% for NR or NSD profiles (table 82). In other words, the use of the Quantifiler standard value/2 method was similar to using the Promega Male standard. We expect the higher result for the partial profiles was largely due to the low sample number and stochastic effects associated with low concentrations. The NSD results are more similar because most samples that had undetermined or 0ng/μL concentrations had pre-set sample volumes at maximum concentration (20μL).

With a 2ng of template amount used for the initial Profiler Plus reactions, the majority of non-probative samples resulted in full profiles (see table 83 and figure 67). 83 percent of non-probative samples resulted in full profiles. The remaining 17% of results may be attributed to a number of reasons, including none or too little DNA being present in the samples themselves.

Table 83: Final results using the Quantifiler standard after an estimated 2ng was used for the initial Profiler amplification.

Amplification results	Sample number
Full profiles	55
Partial profiles	5
No size data (NSDs)	7
SUBTOTAL	**67**
Non-reportable (NR) profile	0
Unamplified (inhibition present)	0
TOTAL	**67**

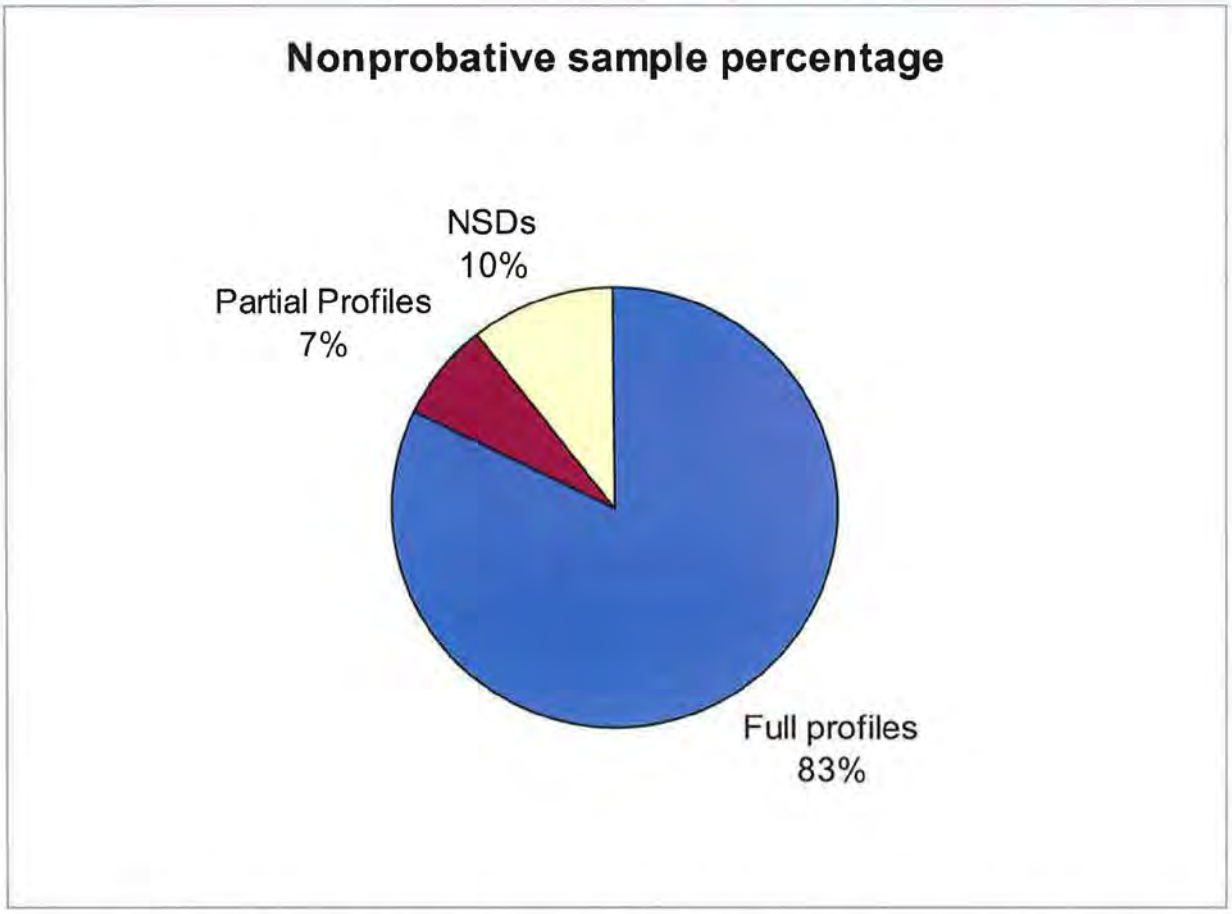

Figure 67: Final results for non-probative samples using the Quantifiler standard after an estimated 2ng was used for the initial Profiler amplification.

In table 84, the differences between using the Quantifiler Human DNA standard and the Promega Male standard for estimating probative sample concentration are summarised. Clearly, the most optimal nanogram amount for the Quantifiler Human DNA standard (approximately 2ng at 1.95ng) is approximately double to that of the Promega Male standard (approximately 1ng at 0.92ng).

Overall, the least difference was between the Quantifiler Human DNA standard concentrations divided by 2 and 2.22 and the Promega Male standard. For partial profiles the difference was lower between the Quantifiler Human DNA standard concentrations divided by 2.5 and the Promega Male standard. This is most likely an artefact of small sample number since only five partial profile results were produced from 67 samples.

Table 84: A comparison of non-probative sample results with the Promega Male standard and Quantifiler standard.

Non-probative sample results			
Final result		Optimal ng amount using Quantifiler Standard	Optimal ng using Promega Standard
Full profile	**Mean**	**1.95**	**0.93**
Partial profile	**Mean**	**1.91**	**0.80**
Full and partial profiles	**Mean**	**1.95**	**0.92**

No rounding						
Final result		Difference 1ng Promega to 1ng Quantifiler	Difference 1ng Promega to 2ng Quantifiler	Difference 1ng Promega to 2.22ng Quantifiler	Difference 1ng Promega to 2.35ng Quantifiler	Difference 1ng Promega to 2.5ng Quantifiler
Full profile	**Mean**	**109.80%**	**6.27%**	**7.75%**	**10.99%**	**16.08%**
Partial profile	**Mean**	**143.24%**	**24.42%**	**16.06%**	**11.85%**	**7.54%**
Full and partial profiles	**Mean**	**112.59%**	**7.79%**	**8.44%**	**11.06%**	**15.37%**

Rounding						
Final result		Difference 1ng Promega to 1ng Quantifiler	Difference 1ng Promega to 2ng Quantifiler	Difference 1ng Promega to 2.22ng Quantifiler	Difference 1ng Promega to 2.35ng Quantifiler	Difference 1ng Promega to 2.5ng Quantifiler
Full profile	**Mean**	**115.03%**	**7.72%**	**6.57%**	**9.69%**	**13.64%**
Partial profile	**Mean**	**107.47%**	**14.93%**	**7.79%**	**6.28%**	**5.36%**

5.14 TRAINING (QUALIFYING TEST)

Before the method is introduced the analyst performs a qualifying test. The qualifying test is administered internally and uses types of samples that the laboratory routinely analyses. This testing is required by QIS document 23401R0 and follows DAB (2000:8.1.3.3) and SWGDAM (2004:3.7) guidelines. QIS document 22622 outlines the training required for the qualifying test.

5.15 MAINTENANCE

5.15.1 PERFORMANCE CHECKS

Regular performance checks are required according to SWGDAM (2004:5) guidelines. These are documented in QIS document 23130 and recorded in QIS document 23131.

5.15.2 QUALITY CHECKS

Several quality checks should be followed to ensure that the Quantifiler system is operating effectively. These checks include-

(a) Testing of Quantifiler standards when they are made. This testing was detailed in QIS document 23446. It ensures that the standards made conform with acceptable guidelines.
(b) Testing of Quantifiler batches/kits.
(c) Testing of controls. Following any dilution or tube transfer of stock control solutions, it is recommended that they are tested to determine their accuracy.

5.16 RISK ASSESSMENT

The level and scope of validation required for a particular method/process must be pre-determined and justifiable (QIS 23401R0). Such justification shall be documented along with risk assessments performed (QIS 23401R0). The following factors need to be considered:

(a) Its criticality to the final result (QIS 23401R0). Because DNA amount is being estimated and the sample volumes used for each estimation are low (2µL for a single reaction and 4µL for duplicate reactions), the Quantifiler system is generally believed to be low risk. Reworks of Quantifiler runs are low. If there is a bad run the risk is higher for samples where there are low volumes. The Quantifiler system is generally believed to be non-critical to the final profile result because amplified DNA is reworked based on the initial profiling results. However, more accurate estimation using the Quantifiler system does help to reduce further reworks at the amplification stage where typically greater volumes are used.
(b) The complexity of design or operation (QIS 23401R0). Although of medium complexity the quality system in place ensures that operation is carried out in an efficient and effective manner.
(c) As a published method, the existing method has been accepted by the general scientific community. Existing data shows that it is preferable to use the Promega Male rather than Quantifiler standards to obtain more accurate results.
(d) Whether the validation required is prospective or if it has already been in use for some time (retrospective validation) (QIS 23401R0). The current validation is retrospective.

5.17 SUMMARY AND RECOMMENDATIONS

In this validation we have demonstrated the benefits and limitations with using the Quantifiler system, especially the Quantifiler standards. We have shown that the Quantifiler system can be utilized but must adhere to strict quality control procedures to maintain a level of reproducibility. Most of this is associated with maintaining reproducibility with the standards. Because of the overestimation of DNA with the Quantifiler standards and lack of sufficient reproducibility for our purposes, we recommend the replacement of the Quantifiler standard with a genomic control such as the Promega Male control trialed here as a standard. This would ensure more accurate results and avoidance of using calibration methods. The Extended Internal Prospective Validation of the ABI® 7000/Quantifiler System (Forensic Biology) is the subject of validating the use of the Promega Male standard.

Another recommendation made in this validation is to omit the use of the corner wells A11 and A12 in Quantifiler™ runs on the ABI Prism® 7000 SDS. It was found that the Precision Plate Holder did not add significant benefits. Results appeared to be better from not using the Precision Plate Holder and omitting the use of wells A11 and A12. Investigations into plate homogeneity resulted in demonstrating that the middle of the plate generally resulted in higher Quantifiler values, while the corners and sides typically produced lower values. Therefore, variation in Quantifiler values occurred both due to plate position (despite Applied Biosystems' TaqMan® RNase P 96-Well Instrument Verification Plate run being acceptable) and run-to-run differences.

In respect to the integration of Quantifiler with Profiler Plus and Cofiler, we recommend an algorithm to be used where sample volume amounts rounded off to less than 1ng of the recommended amplification template are rounded up to the next μL of sample volume. For example, at 1μL, if the template amount is 0.99ng, then the sample volume is increased to 2μL to give a template amount of 1.98ng. If a template threshold higher than 1ng is utilized, the risks are that the template amount that has been rounded up may rise over the 2.5ng threshold limit recommended by Applied Biosystems (1997, 1998).

5.18 DOCUMENTATION

Validation must be documented according to DAB (2000:8.1.3). Policies/methods for the interpretation of data are to be documented (NATA 2002 5.4.1). This validation project was started before QIS document 23401R0 so there is no formal validation plan (QIS 23401R0) or formal validation protocol. This validation is recorded in the validation register with the unique number of 20 (QIS 23401R0). This document consists of the validation summary report (QIS 23401R0). Raw data or interim results tables not included in the final report (QIS 23401R0) are available from the server or validation folders.

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7 AMENDMENT HISTORY

Revision	Date	Author/s	Amendments
0	15 May 2005	Vojtech Hlinka	First Draft

COMPLETED BY

PERSON	ROLE	SIGNATURE
Vojtech Hlinka	Project Leader	[redacted] 9.8.06
Cathie Allen	Project Leader	[redacted] 9.8.06.
Iman Muharam	Associate	[redacted] 09.08.06.

Queensland Government
Queensland Health

Pathology & Scientific Services
Biomedical Technology Services

Validation Acceptance

Validation file title: Extended Internal Retrospective Validation of the ABI Prism® 7000/Quantifiler System (Forensic Biology)

Purpose:
Validation of use of Quantifiler Standards showing limitations with historically-used method and reasons for the direction of using an alternative standard.

The following are included as part of this validation file:

Validation Plan:	**NO**
Validation Protocol:	**NO**
Validation Summary Report:	**YES**
Raw Data:	**YES**

Comments: Raw data submitted in two folders. Testquant analysis sheets can be found in Testquant folders.

Refer to **Change No.** 13 for details of training and documentation update responsibility.

Chief Scientist Approval (signature and date): [redacted] 9.8.06

Note: This form is to be placed in the front of all validation files as a record that the validation has been reviewed and approved.

Validation documents filed and Validation Log updated (signature/date) : _____
Quality Officer

#107

CA-47

HSSA | Health Services Support Agency

PowerPlex®21 – Amplification of Extracted DNA Validation

Megan Mathieson, Thomas Nurthen & Cathie Allen

DNA Analysis, Forensic & Scientific Services

December 2012

Queensland Government

Document details

Contact for enquiries and proposed changes

If you have any questions regarding this document or if you have a suggestion for improvements, please contact:

Contact officer: Thomas Nurthen
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Version history

Version	Date	Changed by	Description
1.0	14/12/2012		1st Issue

Document sign off

This document has been **approved** by:

Name	Position	Signature	Date
Cathie Allen	Managing scientist	[redacted]	17.12.12.

This document has been **endorsed** by: Approval provided verbally on 6.12.12.

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Justin Howes	Team Leader FRIT	[redacted]	14.12.12

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Contents

1 Abstract

To meet Queensland legislative requirements and core business needs, DNA Analysis has validated the PowerPlex® 21 system DNA profiling Kit. All Australian jurisdictions are expected to implement a new DNA profiling kit by the end of 2012. This project came about through the Australian and New Zealand Policing Advisory Agency (ANZPAA).

The loci within the AmpFℓSTR® Profiler Plus® and AmpFℓSTR® COfiler® kits, which are currently used in DNA Analysis, are represented within the PowerPlex® 21 system loci. This allows concordance of the kit for direct comparison and matching against existing AmpFℓSTR® Profiler Plus® crime scene and reference DNA profiles.

This validation has demonstrated that the PowerPlex® 21 system kit is fit for purpose for the amplification of extracted DNA samples processed in the DNA Analysis Unit. A limit of reporting threshold of 40RFU will be adopted for analysis of extracted DNA samples amplified at either 25µL or 12.5µL total PCR volumes.

The sensitivity of this next generation STR kit has greatly increased, however the increased sensitivity does not necessarily result in increased information. The results of this validation indicates that Promega's PowerPlex® 21 system is a very sensitive STR amplification kit, but to reduce the risk of type 2 errors (calling a heterozygous locus homozygous[1]) consideration needs to be given to restricting the range of DNA template added. Single source samples with DNA templates of greater than 0.5ng overload the PowerPlex® 21 system resulting in DNA profiles being unable to be interpreted. Generally samples with lower templates (reaching the often termed 'low copy number' level of 100-150pg) tend to exhibit enhanced stochastic effects as one would expect. Therefore, it should be considered whether samples around this input template level should be amplified given that interpretation of the results could be unwieldy. It would be possible to increase the template levels of samples that fall into this category by post extraction concentration or increase the total PCR volume.

At a total DNA input template of 0.5ng, for 25µL and 12.5µL total PCR volumes, all alleles were detected for the mixtures with ratios of 1:1, 2:1 and 5:1.

The results from this validation support that the Promega PowerPlex®21 System is suitable for analysis of short tandem repeats (STR).

2 Introduction

To meet Queensland legislative requirements and core business needs, DNA Analysis has validated the PowerPlex® 21 system DNA profiling Kit. All Australian jurisdictions are expected to implement a new DNA profiling kit by the end of 2012. This expectation has been directed by ANZPAA, which comprises a Police Commissioner from each jurisdiction.

The initial plan endorsed by the members of the Biological Specialist Advisory Group (BSAG) involved a series of experiments designed to enable each jurisdiction to choose an appropriate STR amplification kit but using the same methodology (national approach to STR kit validation)[2].

This plan included:

1. Sensitivity and amplification volume determination
2. Population studies
3. Concordance
4. Mixture studies
5. Baseline determinations, peak balance, stutter thresholds, minimum reporting threshold and probability of drop in. This last series of experiments were devised by the Statistics Scientific Working Group (StatSWG)[3].

The plans created by BSAG and StatSWG are a significant development with respect to STR validation and interpretation within Australia. In line with current research, these plans involve the move away from a binary approach to DNA profile interpretation to a continuous model. To achieve this, a new DNA profile interpretation software (STRmix™) has been developed by forensic DNA experts & statisticians from Australia and New Zealand forensic laboratories. The validation of the STRmix™ software will be covered in the STRmix™ validation document to be issued subsequent to this report.

The PowerPlex® 21 system[4] is a new short tandem repeat (STR) kit made available to the Australian forensic laboratories in early 2012. The kit has all of the nine loci amplified in AmpF*l*STR® Profiler Plus®[5] and the six loci amplified in AmpF*l*STR® COfiler®[6] and an additional seven loci. See Table 1 for kit loci.

Table 1 - Comparison of loci in three different kits

(dye colour indicated by colour text)

PowerPlex® 21 System	AmpFℓSTR® Profiler Plus®	AmpFℓSTR® COfiler®
AMEL	AMEL	AMEL
D3S1358	D3S1358	D3S1358
D1S1656		
D6S1043		
D13S317	D13S317	
Penta E		
D16S539		D16S539
D18S51	D18S51	
D2S1338		
CSF1PO		CSF1PO
Penta D		
TH01		TH01
vWA	vWA	
D21S11	D21S11	
D7S820	D7S820	D7S820
D5S818	D5S818	
TPOX		TPOX
D8S1179	D8S1179	
D12S391		
D19S433		
FGA	FGA	

The scope of this validation is to determine for the PowerPlex® 21 system, the limit of detection (LOD), limit of reporting (LOR), the optimal total PCR amplification volume, the range of DNA template, ensure concordance of the PowerPlex® 21 system against the AmpFℓSTR® Profiler Plus® and COfiler® kits, observe the performance of mixed DNA samples and create population datasets required for statistical calculations. Secondary to this, this validation provides the data necessary for STRmix™ validation.

3 Materials

The following materials were used within this validation:

- BSD Duet 600 Series II (BSD Robotics, Brisbane, QLD,AU)
- STORstar instrument (Process Analysis & Automation, Hampshire, GB)
- MultiPROBE II PLUS HT EX with Gripper Integration Platform (PerkinElmer, Downers Grove, IL, US)
- Sterile conductive filtered Roborack 25µL disposable tips (PerkinElmer, Downers Grove, IL, USA)
- 5804 centrifuge (Eppendorf AG, Hamburg, DE)
- 5424 centrifuge (Eppendorf AG, Hamburg, DE)
- Thermomixer (Eppendorf AG, Hamburg, DE)
- MixMate (Eppendorf AG, Hamburg, DE)

- Vortex (Ratek Instruments Pty Ltd, Melbourne, VIC, AU)
- Micro centrifuge (Tomy, Tokyo, JP)
- 1.5mL screw-cap tubes (Axygen Inc. Union City, CA, US)
- Pipettes (Eppendorf, Hamburg, DE and Thermo Fisher Scientific(Finnpipette), Waltham, MA, US)
- Pipette tips (VWR International LLC Radnor, PA, US and Molecular Bioproducts Inc., San Diego, CA, US)
- 96-well PCR plates(Axygen Inc. Union City, CA, US)
- 2.0mL sterile screw-cap tubes (Axygen Inc. Union City, CA, US)
- Plate septas (Axygen Inc. Union City, CA, US)
- Adhesive film (QIAGEN, Hilden, DE)
- FTA™ collection kits (Whatman™ GE Healthcare, Buckinghamshire, GB)
- Positive controls (DNA Analysis Unit, Brisbane, QLD, AU)
- TNE (DNA Analysis Unit, Brisbane, QLD, AU)
- Proteinase K (20mg/mL) (Sigma-Aldrich® Corporation, St Louis, MO, US)
- Dithiothreitol (Sigma-Aldrich® Corporation, St Louis, MO, US)
- Trigene (Medichem International, Kent, GB)
- Ethanol (Recochem Incorporated, Wynnum, QLD,AU)
- Bleach (Ionics Australasia Pty Ltd., Lytton, QLD, AU)
- Amphyl (Rickitt Benckiser Inc. Parsippany, NJ, US)
- Sarcosyl (Sigma-Aldrich® Corporation, St Louis, MO, US)
- Nanopure water (DNA Analysis Unit, Brisbane, QLD, AU)
- Quantifiler™ Human DNA Quantification kits (Life Technologies Applied Biosystems, Foster City, CA, US)
- AB 7500 Real Time PCR System (Life Technologies Applied Biosystems, Foster City, CA, US)
- GeneAmp® PCR system 9700 (Life Technologies Applied Biosystems, Foster City, CA, US)
- ABI 3130*xl* Genetic Analyzer (Life Technologies Applied Biosystems, Foster City, CA, US)
- Hi-Di™ Formamide (Life Technologies Applied Biosystems, Foster City, CA, US)
- 3130 POP-4™ Polymer (Life Technologies Applied Biosystems, Foster City, CA, US)
- Running Buffer (Life Technologies Applied Biosystems, Foster City, CA, US)

- DNA IQ™ Casework Pro Kit for Maxwell® 16 (Promega Corp., Madison, WI, US)
- Promega PowerPlex® 21 system (Promega Corp., Madison, WI, US)
- Promega CC5 Internal Lane Standard 500 (Promega Corp., Madison, WI, US)
- Promega PowerPlex 5 Dye Matrix Standard (Promega Corp., Madison, WI, US)
- Promega PowerPlex® 21 Allelic Ladder Mix (Promega Corp., Madison, WI, US)
- 2800M Control DNA, 10ng/µl (Promega Corp., Madison, WI, US)

Water amplification grade (Promega Corp., Madison, WI, US)

4 Methods

4.1 Sample Selection

All samples used in this validation were sourced from the internal DNA Analysis staff DNA database, Collaborative Testing Services (CTS) DNA testing samples, or reference samples that had the National Criminal Investigation DNA Database (NCIDD) categories of Volunteer Unlimited Purpose (VUP) or Suspect (SCT). Permission to use reference samples from NCIDD was obtained from the Queensland Police Service (QPS).

4.2 Selection of Sub-Population Samples

4.2.1 Aboriginal and Torres Strait Islanders Sub-Populations

Aboriginal samples:

Aboriginal samples previously profiled as part of the sub-population dataset for the validation of AmpFℓSTR® Profiler Plus® loci were recommended as the best samples to use for compilation of the Aboriginal sub-population dataset for the Promega PowerPlex®21 system. The samples are self-declared Aboriginal ethnicity and were collected over a number of years.

220 Aboriginal samples were randomly selected from the Aboriginal dataset (545 total) previously profiled with AmpFℓSTR® Profiler Plus®. Microsoft Excel RANDBETWEEN function was used and duplicates removed until 220 unique samples were identified for profiling.

These 220 samples were originally extracted using Chelex. The extracts for the 220 samples were viewed for sufficient volume. 201 samples with sufficient volume were identified and given new population dataset barcodes.

Torres Straits Islander samples:

A list of FTA™ samples previously profiled with AmpFℓSTR® Profiler Plus® resulting in a full profile and identified as self-declared Torres Strait Islander ethnicity in AUSLAB were compiled to be used for the Aboriginal sub population dataset.

599 samples were listed and after further filtering, including removing duplicates, 249 Torres Strait Islander samples remained. Of the 249 Torres Strait Islander samples listed 223 samples were randomly selected for processing. Samples were given new population dataset barcodes

4.2.2 Caucasian Sub-Population

A list of FTA™ samples previously profiled with AmpFℓSTR® Profiler Plus® resulting in a full profile and identified as Caucasian ethnicity in AUSLAB were compiled to be used for the Caucasian sub-population dataset.

From this list 210 samples were selected and 208 were selected for processing as two were deemed unsuitable. Samples were given new population database barcodes.

4.2.3 South East Asian Sub-Population

A list of FTA™ samples previously profiled with AmpFℓSTR® Profiler Plus® resulting in a full profile and identified as South East Asian ethnicity in AUSLAB were compiled to be used for the South East Asian population dataset.

157 samples were listed and after further filtering 141 South East Asian samples remained. These 141 samples were given new population database barcodes.

4.3 Collection Procedure for FTA™ Cards

Where staff samples were entirely consumed during processing, additional samples were collected. New FTA™ samples were collected using FTA™ Collection kits. A foam swab was used to collect buccal cells from each cheek for one minute then applied to the FTA™ card[7]. The FTA™ card was stored at room temperature until required.

4.4 FTA™ Punching Method

1. PCR Amplification mix was created as required.
2. 25µL (full) or 12.5µL (half) of PCR amplification mix was added to a clean 0.2mL 96 well PCR plate.
3. Plate was sealed and centrifuged to ensure PCR amplification mix was at the bottom of the wells.

4. Each FTA™ sample was punched with the 1.2mm diameter die into the 96 well PCR plate using the BSD Duet 600 Series II.
5. 1µL of 2800M control DNA was added to the Positive control well.
6. 1 x 1.2mm punch of a blank FTA™ card was added to the blank control well
7. Amplification mix without FTA™ card was used as a negative control.
8. The plate was sealed and centrifuged briefly to pull the FTA™ cards to the bottom of the plate wells.

4.5 FTA® Punching Method 2

1. 7.5µL of amplification grade water was added to the required wells.
2. Plate was sealed and centrifuged to ensure the water was at the bottom of the wells.
3. Each FTA® sample was punched with the 1.2mm diameter die into the 96 well PCR plate using the BSD Duet 600 Series II.
4. 1µL of 2800M control DNA was added to the Positive control well.
5. 1 x 1.2mm punch of a blank FTA® card was added to the blank control well
6. PCR Amplification mix without FTA® card was used as a negative control.
7. PCR Amplification mix was created as required and 5µL added to each well.
8. The plate was sealed and centrifuged briefly to pull the FTA® cards to the bottom of the plate wells.

4.6 Punching for Extraction

FTA™ samples were prepared for extraction by punching four paper spots of 3.2mm diameter into 1.5mL/2mL tubes using the BSD Duet 600 according to standard operating procedure 24823 V4.0 "FTA™ Processing and Work Instructions".

4.7 Extraction

FTA™ samples requiring DNA extraction were processed using the DNA IQ™ Casework Pro Kit for Maxwell®16 according to standard operating procedure 29344 V4.0 "DNA IQ™ Extraction using the Maxwell®16".

4.8 Preparation of DNA Stock Solutions

Samples used to make dilution series required a stock solution to be prepared. FTA™ samples were selected and punched in duplicate for

extraction (as outlined in section 4.6) then extracted (as outlined in section 4.7). The duplicate samples were pooled into a single tube and quantified twice (as outlined in section 4.9).

4.9 Procedure for Creating a Dilution Series

The samples used to make dilution series were diluted with amplification grade water provided with the Promega PowerPlex®21 System. Spreadsheets for calculating the normalisation and dilution series were written to outline the serial dilutions required to obtain the specified concentrations

4.10 Quantification

All preparations of reactions were performed using MultiPROBE II plus HT EX platform according to standard operating procedure 19977 V8.0 "Automated Quantification of Extracted DNA using the Quantifiler™ Human DNA Quantitation Kit".

4.11 Amplification Set up

For the experiments that used extracted DNA, all amplification reactions were performed using a MultiPROBE II plus HT EX platform. A new protocol called PowerPlex 21 amp setup v1.0 was created using WinPrep® software and utilised for amplifications at 25µL and 12.5µL total PCR volumes. The protocol is saved and stored on the C drive of the MultiPROBE II plus HT EX platform computer. Table 2 outlines the components of the amplification mix per sample.

Table 2 - Amplification mix per sample.

Kit components	Volumes (µL)	Volumes (µL)
Master Mix	5.0	2.5
Primer pair	5.0	2.5
Sample	15	7.5
Total Volume	25	12.5

4.12 Amplification Conditions

Table 3 lists the PCR cycling conditions used in this validation. All PCR reactions were carried out in 96 well plates (Axygen Inc.) on GeneAmp® 9700 thermal cyclers

Table 3 - PCR cycling conditions used for PowerPlex®21 system

PowerPlex® 21 Kit	Direct amp	Standard
GeneAmp 9700 mode	Max	Max
	25,26 or 27 cycles	30 cycles
Activation	96°C for 1 minute	96°C for 1 minute
Cycling	94°C for 10 seconds 59°C for 1 minute 72°C for 30 seconds	94°C for 10 seconds 59°C for 1 minute 72°C for 30 seconds
Extension	60°C for 20 minutes	60°C for 10 minutes
	4°C Soak	4°C Soak

4.13 DNA Fragment Analysis

The plates for DNA fragment analysis were prepared as recommended by the manufacturer, using a combination of Hi-Di™ formamide, size standard and sample as outlined below.

Formamide: size standard mixture composed of

[(2.0µl CC5 ILS 500) x (number of injections)] + [(10.0µl Hi-Di™ formamide) x (number of injections)]

Formamide: size standard mixture **12µL**

PCR product or allelic ladder **1µL**

The prepared plate was then centrifuged to remove bubbles, denatured at 95°C for 3 minutes then chilled in an ice block in the freezer for 3 minutes. The prepared plates were then run on a 3130*xl* Genetic Analyzer.

The PCR fragments were separated by capillary electrophoresis (CE) using a 3130*xl* Genetic Analyzer set up according to manufacturer recommendations outlined in Table 4.

Table 4 - CE Protocol conditions.

Injection time	Injection voltage	Run time
5s	3kV	1500s

4.14 Profile Interpretation 1

All DNA profiles were analysed with GeneMapper® ID-X v1.1.1. The analysis panel used was PowerPlex_21_IDX_v1.0. The thresholds were set as follows:

1. Heterozygote threshold was set at 40RFU
2. Limit of Detection (negative controls) was set at 16RFU
3. Individual locus stutter thresholds were set as per Promega PowerPlex® 21 Stutter filter
4. Homozygote threshold was set to 200RFU

4.15 Profile Interpretation 2

All DNA profiles were analysed with GeneMapper® ID-X v1.1.1. The analysis panel used was PowerPlex_21_IDX_v1.0. The rules were set as follows:

1. Samples were analysed at 1RFU.
2. All known alleles, forward and back stutter (+/-4bp or +/-5bp) of known alleles, known artefacts and spectral pull-up were removed. As defined by Promega artefact peaks in the N-2bp and/or N+2bp position at D1S1656, D6S1043, D13S317, vWA, D21S11, D7S820, D5S818, D12S391 and D18S51 loci and in the N-1bp position at Amelogenin were also removed.
3. Any peaks determined to be carry over peaks were also removed. Carry-over is defined as the physical transfer of DNA from one injection to the next.

4.16 Profile Interpretation 3

All samples were analysed with GeneMapper ID-X v1.1.1 with the stutter thresholds set to zero. The analysis panel used was PowerPlex_21_IDX_v1.1.

1. Samples were analysed at 20RFU
2. Loci where the two main alleles were one repeat apart were excluded from analysis.

5 Experimental Design

5.1 Sub-Population Datasets

As part of the national approach to implementation of next generation STR amplification kits, the creation of three national sub-population datasets was undertaken. Each jurisdiction contributed DNA profiles for each sub-population Caucasian, Aboriginal and South East Asian to Jo-Anne Bright (ESR) and John Buckleton (ESR) for analysis.

5.1.1 Aboriginal dataset

In this experiment 201 Aboriginal samples were transferred to appropriate tubes and the DNA concentrations determined as outlined in Method 4.10.

The samples were amplified with the recommended DNA template input of 0.5ng in a 25µL total PCR volume. Three plates were amplified using the PowerPlex®21 system kit with each plate including a positive amplification control (2800M DNA) and a negative amplification control (amplification grade water). The three plates were prepared as per Method 4.11.

Standard amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

5.1.2 Torres Strait Islander dataset

In this experiment 223 Torres Strait Islander samples were punched across three 96 well plates as outlined in section 4.4. Each sample had one spot punched, a total PCR volume of 12.5µL and was directly amplified at 26 PCR cycles.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

5.1.3 Caucasian dataset

In this experiment 208 Caucasian samples were punched across three 96 well plates as outlined in section 4.4. Each sample had two spots punched, a total PCR volume of 25µL and was directly amplified at 25 PCR cycles.

Caucasian samples that did not produce a full PowerPlex®21 profile were punched again using 2 spots, a total PCR volume of 25µL and was directly amplified at 26 PCR cycles.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

5.1.4 South East Asian dataset

In this experiment 141 South East Asian samples were punched across two 96 well plates as outlined in section 4.5. Each sample had one spot punched, a total PCR volume of 12.5µL and was directly amplified at 26 PCR cycles.

South East Asian samples that did not produce a full PowerPlex®21 profile were punched for extraction, extracted, quantified and amplified as outlined in Methods 4.6, 4.7, 4.8 and 4.10.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

5.2 Concordance

155 samples purchased from Collaborative Testing Services (CTS) as external Proficiency Tests were used to test the concordance of the PowerPlex® 21 system. These samples had previously been extracted, quantified and amplified with AmpFℓSTR® Profiler Plus® and AmpFℓSTR® COfiler® kits.

The samples were amplified with the recommended DNA template input of 0.5ng in a 12.5µL total PCR volume. Two plates were amplified using the PowerPlex®21 system kit with each plate including a positive amplification control (2800M DNA) and a negative amplification control (amplification grade water). The two plates were prepared as outlined in Method 4.11.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

The alleles obtained from these samples were compared with the CTS published alleles. Three loci could not be compared as CTS did not publish results for the D12S391, D1S1656 and D6S1043 loci.

5.3 Baseline Determination

To determine the limit of detection (LOD) and the limit of reporting (LOR), the baseline (background) was assessed.

Ten samples from the Caucasian sub-population dataset that exhibited high heterozygosity were used for baseline determination.

The samples were prepared as Methods 4.6, 4.7, 4.8, 4.9, 4.10, 4.11.

Ten samples diluted in ten steps (10x10) outlined in Table 5 were used for the baseline calculations. Each dilution set was amplified at 25µL and 12.5µL total PCR volumes.

50 negative samples were also amplified at 25µL and 12.5µL total PCR volumes.

Table 5 - Total DNA input for each dilution

Dilution	Total DNA (ng)
1	0.500
2	0.447
3	0.394
4	0.342
5	0.289
6	0.236
7	0.183
8	0.131
9	0.078
10	0.025

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13, 4.14 and 4.15.

The average peak height RFU (μ_{Pk}) for each dye channel was calculated using the AVERAGE function (Arithmetic mean) in Microsoft Excel. The standard deviation (σ_{Pk}) was calculated using the STDEV function in Microsoft Excel.

The thresholds were calculated as follows:

The limit of detection (LOD) was calculated from Equation 1[8].

Equation 1

$$\mathbf{LOD = \mu_{PK} + 3\sigma_{PK}}$$

The limit of reporting (LOR) also known as the analytical threshold (AT) was calculated from Equation 2[8].

Equation 2

$$\mathbf{LOR = \mu_{PK} + 10\sigma_{PK}}$$

5.4 Sensitivity 1

This experiment tested the sensitivity of PowerPlex® 21 system at amplification volumes of 25µL and 12.5µL for DNA template inputs from 4ng to 1pg.

Two staff (one male and one female) with the most heterozygous DNA profile processed with AmpFℓSTR® Profiler Plus® and AmpFℓSTR COfiler® kits were selected for testing[9]. Heterozygous loci provide more information with respect to allele drop out and peak balance.

FTA™ cards were collected, processed, extracted, stock solutions prepared, quantified and dilution series prepared as outlined in Methods 4.6, 4.7, 4.8, 4.9 and 4.10.

Each donor had 9 dilutions prepared as outlined in Table 6. These dilutions were amplified in duplicate with a total amplification volume of 25µL and 12.5µL. Each amplification plate included the kit positive control (2800M DNA) and a negative control (amplification grade water).

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.14.

Table 6 - Total DNA input for sensitivity 1

DNA Template Input (ng)
4
2
1
0.5
0.1
0.05
0.01
0.005
0.001

5.5 Sensitivity 2

To assess the differences between the two total PCR volumes with respect to low DNA extract concentrations a second sensitivity experiment was performed.

This experiment tested a dilution series of the same samples used in sensitivity 1 at low DNA templates outlined in table 7. Each dilution was amplified in duplicate at 25µL and 12.5µL.

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.14.

Table 7 - Concentration, DNA template input for each dilution.

Concentration (ng/µL)	Volume of sample added to 25 µL reaction volume	Total DNA template input (ng)	Volume of Sample added to 12.5 µL volume reaction	Total DNA template input (ng)
0.01	15	0.15	7.5	0.075
0.005	15	0.075	7.5	0.0375
0.0025	15	0.0375	7.5	0.01875
0.00125	15	0.01875	7.5	0.009375
0.000625	15	0.009375	7.5	0.004688
0.0003125	15	0.004688	7.5	0.002344
0.00015625	15	0.002344	7.5	0.001172
0.000078125	15	0.001172	7.5	0.000586

5.6 Drop In

50 negative samples were amplified alongside the 10 x10 data at 25µL and 12.5µL. Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.15.

The negative samples were analysed at 1RFU using GeneMapper ID-X v1.1.1 to determine if any peaks above 20RFU were present. Known artefacts, carry-over and pull-up were removed and not included in the analysis.

5.7 Stutter

To determine the thresholds for forward and back stutter peaks 342 samples from the Aboriginal data set, 10 x10, sensitivity 1 and sensitivity 2 were amplified at 25µL and 255 samples from 155 CTS samples, 10 x 10, sensitivity 1 and sensitivity 2 samples were amplified at 12.5µL.

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.16.

The stutter ratio (SR) was calculated for each locus as per Equation 3.

Equation 3

$$SR = E_S/E_A$$

SR = Stutter Ratio, E_S = Stutter Height, E_A = Allele Height

The stutter threshold (ST)[4] for each locus was calculated as per Equation 4.

Equation 4

$$ST = \mu_{SR} + 3\,\sigma_{SR}$$

ST = Stutter Threshold, μ_{SR} = average stutter ratio, σ_{SR} = standard deviation of stutter ratio.

The stutter results were also processed with a multiple regression analysis by Jo-Anne Bright for use within the STRmix™ validation and STRmix™ settings[10].

5.8 Peak Balance

The samples from the 10 x10 (section 5.4) were used to calculate peak height ratios and an allelic imbalance threshold to be used for reference samples and as a guide for determining the number of contributors to a mixture.

5.8.1 Peak Height Ratio and Allelic imbalance threshold

Peak height ratios for heterozygote loci (1127 alleles for 12.5µL and 1094 alleles for 25 µL total PCR volumes) were determined by dividing the lower peak height by the higher peak height. Loci where the two main alleles were one repeat apart or were homozygous were excluded from analysis.

The peak height ratio (PHR) was calculated for each locus as per equation 5 [11].

Equation 5

PHR = LPH / HPH

PHR = Peak Height Ratio, LPH = Lower Peak Height, HPH = Higher Peak Height

The average peak heights and standard deviation of peak height ratio were calculated using the Microsoft Excel AVERAGE and STDEV worksheet functions.

The allelic imbalance threshold (AI) was calculated as per Equation 6[12, 13]

Equation 6

$$AI_{TH} = \mu_{PHR} - 3\sigma_{PHR}$$

AI_{TH} = Allelic Imbalance threshold, μ_{PHR}= overall average PHR, σ_{PHR} = standard deviation of the PHR.

5.8.2 Homozygote threshold

The homozygote threshold is the threshold above which you can be confident that a heterozygote locus will not be incorrectly called as a homozygote locus. It was calculated using the following methods

Method 1 – As previously described in the internal validation[14] of peak heights and allelic imbalance thresholds and illustrated below:

Equation 7

$$Th_{Hom} = LOR \times (1 / AI_{TH}) \times 2$$

The LOR used for this calculation is from 5.3 and AI_{TH} was determined in 5.8.2.

Method 2 – As described in the Promega Internal validation guidelines[15] determined from a plot of allelic imbalance versus the lower RFU of a heterozygote pair. The homozygote threshold is assigned at the point at which there is a rapid drop off in peak height ratio.

5.9 Drop Out

To aid in determining the default total PCR volume and template DNA range a series of drop out analyses were performed on the 10 x 10 (section 5.4), sensitivity experiments (sections 5.3 & 5.5) and population datasets (section 5.2).

5.9.1 Drop out 1

The samples from the sensitivity 1 experiment (section 5.3) were used to determine at what RFU the partner of a heterozygote pair drops out. The data was interpreted as outlined in section 4.13. Homozygote peaks, excess samples and no size data were excluded from data analysis. Heat maps were used to summarise the data.

5.9.2 Drop out 2

Samples processed at 25µL and 12.5µL were analysed to determine the threshold when an allele most frequently drops out.

334 DNA profiles amplified at 25µL (from section 5.1.1, 5.3, 5.4 and 5.5) and 279 DNA profiles amplified at 12.5µL (from section 5.2, 5.3, 5.4 and 5.5) were analysed as outlined in Method 4.13.

Homozygote peaks, excess samples and no size data were excluded from both sets of data.

5.9.3 Drop out 3

The samples from the 10 x 10 (section 5.4) and sensitivity experiments (section 5.3 & 5.5) experiments (156 samples) were analysed to record the peak height at which a heterozygote paired allele was lost. The data was interpreted as outlined in Method 4.13.

Homozygote peaks, excess samples and no size data were excluded from data analysis.

5.10 Mixture Studies

In experiment 4 samples, two female and two male samples with high heterozygosity were selected, from the Caucasian dataset and CTS samples, to be combined to make mixed DNA samples. The samples were created as Methods 4.3, 4.4, 4.6, 4.7 and 4.10.

One female sample was combined with one male profile to create a two person mixture, the same female sample was combined with the two male samples to create a three person mixture and two female samples and two male samples were combined to create a four person mixture. The amount of sample required from each contributor to create the mixture ratio was calculated using excel spreadsheets . Varying contributor ratios were made for each of the mixture combinations as outlined in table 8. Each mixture combination was amplified in duplicate at a variety of DNA templates.

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.16.

Table 8 - Mixture ratios

Mixture Ratio	Template (ng)
Female:Male	
50:1	0.500
	0.250
	0.125
30:1	0.500
20:1	0.500
	0.250
	0.125
10:1	0.500
	0.125
5:1	0.500
	0.125
2:1	0.500
	0.06
1:1	0.500
Female:Male:Male	
20:10:1	0.500
	0.125
10:5:1	0.500
5:2:1	0.500
	0.125
Female:Male:Male:Female	
5:3:2:1	0.500
	0.125

The mixture ratio was calculated for each DNA profile and compared to the admixture ratio to determine whether there is any variability and whether the mixture ratio can be expected to hold across the profile.

The DNA profiles were analysed to determine at what ratio the minor contributor would be expected to drop out.

6 Results and Discussion

6.1 Population Datasets

Results were tabulated in the following format Unique Sample ID, Race ID, Marker, Allele 1 and Allele 2. Table 9 summarizes the number of profiles for each sub-population submitted for analysis.

Table 9 - Summary of number of profiles for each sub-population submitted.

	Caucasian	Aboriginal	SE Asian
DNA Analysis, FSS	**139**	**309**	**126**
Dataset total	**1707**	**1778**	**990**

Data generated for the three sub-population datasets were analysed by Jo Bright and John Buckleton and used in STRmix™ for statistical analysis[16, 17].

6.2 Concordance

All samples (number of alleles = 4644) tested were found to be concordant to the CTS reported DNA profiles. Table 10 displays the number of times a particular allele was seen at each locus within the laboratory.

Different DNA amplification kits may contain different primers for each locus. Comparison of allele calls (concordance) is required to ensure that each kit gives consistent allele designations, as mismatches or null alleles will affect matching on NCIDD or within a case. The current kits used by the DNA Analysis are AmpFℓSTR® Profiler Plus® and AmpFℓSTR COfiler® DNA amplification kits. Both of these use primers developed by, and manufactured by Life technologies. There are known issues with these kits such as a reverse primer binding mutation at the D8S1179 locus[18], vWA locus[19] and FGA locus[20]. The PowerPlex® 21 kit uses different primer sequences. All alleles tested were found to be concordant. As primer binding mutations and null alleles have been observed within DNA Analysis, any resulting mismatches on NCIDD will need to be retested using PowerPlex® 21.

Table 10 - Observed number of allele concordances

Allele Size	D3S1358	D13S317	Penta E	D16S539	D18S51	D2S1338	CSF1PO	Penta D	TH01	vWA	D21S11	D7S820	D5S818	TPOX	D8s1179	D19S433	FGA
2.2								5									
3.2								2									
5			17					5	1								
6									44					7			
7			32				4	5	75			4	3	4			
8		23	22	4			8	9	42			68	6	133	1		
9		21	10	44			4	48	50			28	13	34	4		
9.3									69								
10		11	25	26	2		69	31	3			80	19	13	11	1	
10.3									1								
11		79	26	83	2		77	45		1		65	91	65	14	6	
11.2																1	
12	1	86	40	78	37		93	51				26	100	11	37	26	
12.2																4	
13	1	48	27	46	30		16	44		3		9	15	1	96	72	
13.2																5	
14	41	20	15	2	38	1	1	8		28			3		71	67	
14.2																9	
15	84		12		42	1		3		43					43	23	
15.2																8	
16	56		13		48	14		1		63					10	5	
16.2																4	
17	67		10		36	46				67					1		
17.2																1	
18	36		6		18	19				57					1		4
18.2																1	
19	4		2		13	33				20							23
20			1		10	28				2							39
20.2																	2
21			2		5	19				2							35
22			2		2	13				1							56
22.2																	3
23					1	20											48
24						13											36
25						22											28
26						8					3						10
27						1					7						4
28											61						
29											47						1
29.2											1						
29.3											1						
30											78						
30.2											10						
31											18						
31.2											22						
32											5						
32.2											25						
33.2											9						
35											2						

6.3 Baseline Determination

The thresholds determined by the baseline experiments are the limit of detection (LOD) and limit of reporting (LOR). The use of thresholds for reporting is essentially a risk assessment[21], if the thresholds are set too low then labelling of artefacts and noise may occur, if set too high then real peaks will not be labelled and information will be lost[1, 11].

Type 1 errors are defined as false labelling of noise peaks. LODs calculated from negative samples may not be optimal for medium-high template samples, as the baseline will differ between positives and negative samples[22].

Type 2 errors are defined as false non-labelling of alleles. If the LOD is set too high, then low level samples may have a heterozygous locus called as a homozygous locus[1, 22-24].

The LOR is the threshold in which a peak can be confidently distinguished from the background fluorescence (baseline). Several methods can be used to determine this threshold.

For the method used here[8] the LOR is derived from the mean baseline plus ten standard deviations (Equation 2).

The LOD is the lowest signal that can be distinguished from the background fluorescence (baseline) and may vary between CE instruments.

Previously in DNA Analysis [14] baseline for the AmpF*l*STR® Profiler Plus® kit was determined using the BatchExtract software v0.16. The LOD was calculated using Equation 1. This approach of using the mean and three standard deviations would account for 99.73% of baseline fluorescence.

The files generated by GeneMapper ID-X v1.1.1 are not compatible with the BatchExtract software without modification. For this validation an equivalent process for measuring the baseline as described by Promega was used with some modifications to the types of samples used. For this validation samples containing DNA were used to determine baseline fluorescence.

Table 11 shows the results determined from the baseline calculations when the samples were amplified at 25µL. The highest average peak height (5.74RFU) and the highest standard deviation (3.21) was in the TMR (yellow) channel from run 2 on 3130xl A. The TMR (yellow) channel for run 2 on 3130xl A also yielded the highest LOD (15.37) and highest LOR (37.84). The LOD was rounded to 16RFU and the LOR was rounded to 40RFU and is to be used for all dye channels for samples amplified using a total amplification volume of 25µL.

Table 11 - Baseline results for amplifications at 25µL

		3130xl A run 1	3130xl A run 2	3130xl B run 1	3130xl B run 2	Overall 3130xl A & B run 1 & 2
Fluorescin (Blue)	μ_{PK}	2.33	2.58	1.90	1.68	2.11
	σ_{PK}	1.55	2.05	1.01	0.89	1.52
	LOD	6.99	8.73	4.93	4.36	6.68
	LOR	17.86	23.07	12.01	10.59	17.35
JOE (Green)	μ_{PK}	3.51	3.83	2.25	2.16	2.94
	σ_{PK}	2.34	2.62	1.04	1.29	2.12
	LOD	10.54	11.68	5.37	6.02	9.30
	LOR	26.94	29.99	12.65	15.02	24.14
TMR (Yellow)	μ_{PK}	5.29	5.74	3.33	3.07	4.32
	σ_{PK}	2.73	3.21	1.27	1.66	2.68
	LOD	13.47	15.37	7.15	8.05	12.37
	LOR	**32.55**	**37.84**	**16.06**	**19.66**	**31.16**
CXR (Red)	μ_{PK}	2.22	2.44	2.02	1.78	2.09
	σ_{PK}	1.36	1.54	0.89	1.01	1.35
	LOD	6.29	7.05	4.69	4.81	6.16
	LOR	15.79	17.79	10.93	11.88	15.63
CC5 (Orange)	μ_{PK}	1.76	1.99	1.14	1.36	1.66
	σ_{PK}	1.30	1.80	0.44	1.39	2.44
	LOD	5.68	7.38	2.47	5.52	9.00
	LOR	14.81	19.94	5.58	15.24	26.11
Overall	μ_{PK}	3.41	3.72	2.44	2.22	2.79
	σ_{PK}	2.45	2.80	1.33	1.39	2.29
	LOD	10.76	12.13	6.23	6.40	9.65
	LOR	**27.91**	**31.76**	**15.54**	**16.14**	**25.65**

Table 12 shows the results determined from the baseline calculations when the samples were amplified at 12.5µL. The highest average peak height (6.06RFU) was in the TMR (yellow) channel from the run on 3130xl A and the highest standard deviation (4.41) was in the JOE (green) channel from the run on 3130xl A. The TMR (yellow) channel for the run on 3130xl A yielded the highest LOD (18.50) and the JOE (green) channel yielded the highest LOR (48.60). It was noted on 3130xl A the baseline was raised more than expected compared to other baseline runs on the same instrument and baseline runs on 3130xl B. This could be due to a prolonged period between spectral calibrations, aging reagents and arrays and was taken into consideration when setting thresholds. With natural variations, the results from run to run and instrument may vary, by using the mean + 10SD for the LOR, although the baseline itself may shift, the LOR will always be greater than the LOD even if baseline is either increased or decreased on any given run. By using an "over all" result, the standard deviation is increased due to the difference in fluorescence between instruments, and this then gets factored into the overall LOR.

The highest overall LOD (15.70) was in the TMR (yellow) channel and was rounded to 16RFU and the highest overall LOR (42.27) was in the JOE (green) channel and was rounded to 40RFU.

In an effort to eliminate error and confusion a single LOD and LOR value is to be used for both instruments.

Table 12 - Baseline results for amplifications at 12.5µL

		3130xl A 12.5µL	3130xl B 12.5µL	Overall 3130xl A & B 12.5µL
Fluorescin (Blue)	μ_{PK}	3.10	2.19	2.64
	σ_{PK}	3.66	2.72	2.99
	LOD	14.07	10.36	11.59
	LOR	39.67	29.42	32.49
JOE (Green)	μ_{PK}	4.46	2.69	3.62
	σ_{PK}	4.41	2.86	3.86
	LOD	17.70	11.26	15.22
	LOR	48.60	31.28	42.27
TMR (Yellow)	μ_{PK}	6.06	3.58	4.83
	σ_{PK}	4.15	2.43	3.63
	LOD	18.50	10.88	15.70
	LOR	47.52	27.92	41.08
CXR (Red)	μ_{PK}	2.87	2.10	2.49
	σ_{PK}	2.32	1.28	1.93
	LOD	9.84	5.94	8.27
	LOR	26.11	14.90	21.75
CC5 (Orange)	μ_{PK}	2.38	1.66	2.02
	σ_{PK}	2.31	1.87	2.14
	LOD	9.33	7.26	8.84
	LOR	25.53	20.33	23.40
Overall	μ_{PK}	3.94	2.54	3.32
	σ_{PK}	3.87	2.46	3.30
	LOD	15.56	9.91	13.21
	LOR	42.68	27.10	36.28

μ_{PK} = Average peak height, σ_{PK} = Standard Deviation, LOD = limit of detection, LOR = Limit of Reporting

6.4 Sensitivity

All PCR amplification kits are optimised for a particular total reaction volume by the manufacturer; but it is commonplace to reduce the total PCR reaction volume to increase the sensitivity[25-28] and reduce processing costs[27]. Two sensitivity experiments were performed, in addition to the 10x10 (baseline determination) dataset.

To contrast and compare the effect of total PCR volume on DNA profiles, the same dilution series were amplified at two different total PCR volumes (25µL and 12.5µL) using 30 PCR cycles.

The results for the amplification of the two donors at 25µL and 12.5µL are summarised in tables 13 and 14 respectively.

Table 13 - Summary of the 2 donors amplified at 25µL

Donor 1 25µL	Template	Av No. Alleles	Av PH (RFU)	Max PH	Min PH	AV PHR
Donor1	4ng	N/A	NAD XS	N/A	N/A	N/A
Donor1	2ng	N/A	XS	N/A	N/A	N/A
Donor1	1ng	42	2512.56	4661.00	1456.00	90.47
Donor1	0.5ng	42	1347.65	2492.00	172.00	85.58
Donor1	0.1ng	42	277.47	506.00	119.00	78.78
Donor1	50pg	41	153.39	387.00	48.00	67.09
Donor1	10pg	17	46.86	108.00	20.00	79.08
Donor1	5pg	6.5	39.57	78.00	20.50	0.00
Donor1	1pg	1.5	33.83	43.00	27.00	0.00
Donor 2 25µL	**Template**	**Av No. Alleles**	**Av PH (RFU)**	**Av Max PH**	**Av Min PH**	**AV PHR**
Donor2	4ng	N/A	XS	N/A	N/A	N/A
Donor2	2ng	N/A	XS	N/A	N/A	N/A
Donor2	1ng	42	2790.81	5126.00	1461.00	89.19
Donor2	0.5ng	42	1344.10	2878.00	431.00	86.91
Donor2	0.1ng	42	292.72	698.00	88.00	74.55
Donor2	50pg	41.5	157.40	479.00	47.00	68.59
Donor2	10pg	24.5	69.69	171.00	14.25	69.60
Donor2	5pg	5.5	44.95	75.00	23.00	96.79
Donor2	1pg	6	33.62	55.00	20.00	94.85

Av = Average, PH = Peak Height, No. = Number, Max = Maximum, Min = Minimum, PHR = Peak Height Ratio

Table 14 - Summary of the 2 donors amplified at 12.5µL.

Donor 1 12.5µL	Template	Av No. Alleles	Av PH (RFU)	Max PH	Min PH	AV PHR
Donor1	4ng	N/A	NAD XS	N/A	N/A	N/A
Donor1	2ng	N/A	XS	N/A	N/A	N/A
Donor1	1ng	N/A	XS	N/A	N/A	N/A
Donor1	0.5ng	42	3132.96	6719.00	1590.00	84.41
Donor1	0.1ng	42	780.57	2444.00	180.00	74.66
Donor1	50pg	42	346.67	931.00	58.00	68.88
Donor1	10pg	27	91.95	406.00	21.00	49.76
Donor1	5pg	12	48.20	91.50	20.00	71.22
Donor1	1pg	4.5	35.80	51.00	22.00	88.24
Donor 2 12.5µL	**Template**	**Av No. Alleles**	**Av PH (RFU)**	**Av Max PH**	**Av Min PH**	**AV PHR**
Donor2	4ng	N/A	XS	N/A	N/A	N/A
Donor2	2ng	N/A	XS	N/A	N/A	N/A
Donor2	1ng	N/A	XS	N/A	N/A	N/A
Donor2	0.5ng	42	2878.80	6159.00	1281.00	78.29
Donor2	0.1ng	42	742.73	1612.00	140.00	68.12
Donor2	50pg	42	333.38	892.00	93.00	60.88
Donor2	10pg	25	82.33	249.00	21.00	59.05
Donor2	5pg	13.5	51.47	121.00	21.00	67.89
Donor2	1pg	0	0.00	0.00	0.00	0.00

The amplifications at 25µL total PCR volume with DNA templates of 4ng and 2ng for both donors gave excess profiles resulting in the profiles being unable to be interpreted. The results from the excess samples were excluded from the data analysis. The average number of alleles and the

average peak height was similar for both donors when processed with an amplification volume of 25µL.

The amplifications at 12.5µL with DNA templates of 4ng, 2ng, 1ng and one replicate of the 0.5ng for both donors gave excess results. The results from the excess samples were excluded from the data analysis. The average number of alleles and average peak height was similar for both donors when processed with an amplification volume of 12.5µL.

Figure 1 displays the average number of alleles and average peak height ratio obtained for each donor at each template amplified at 25µL and 12.5µL.

Figure 2 displays the average peak height and average peak height ratio at each DNA template amplified for 25µL and 12.5µL.

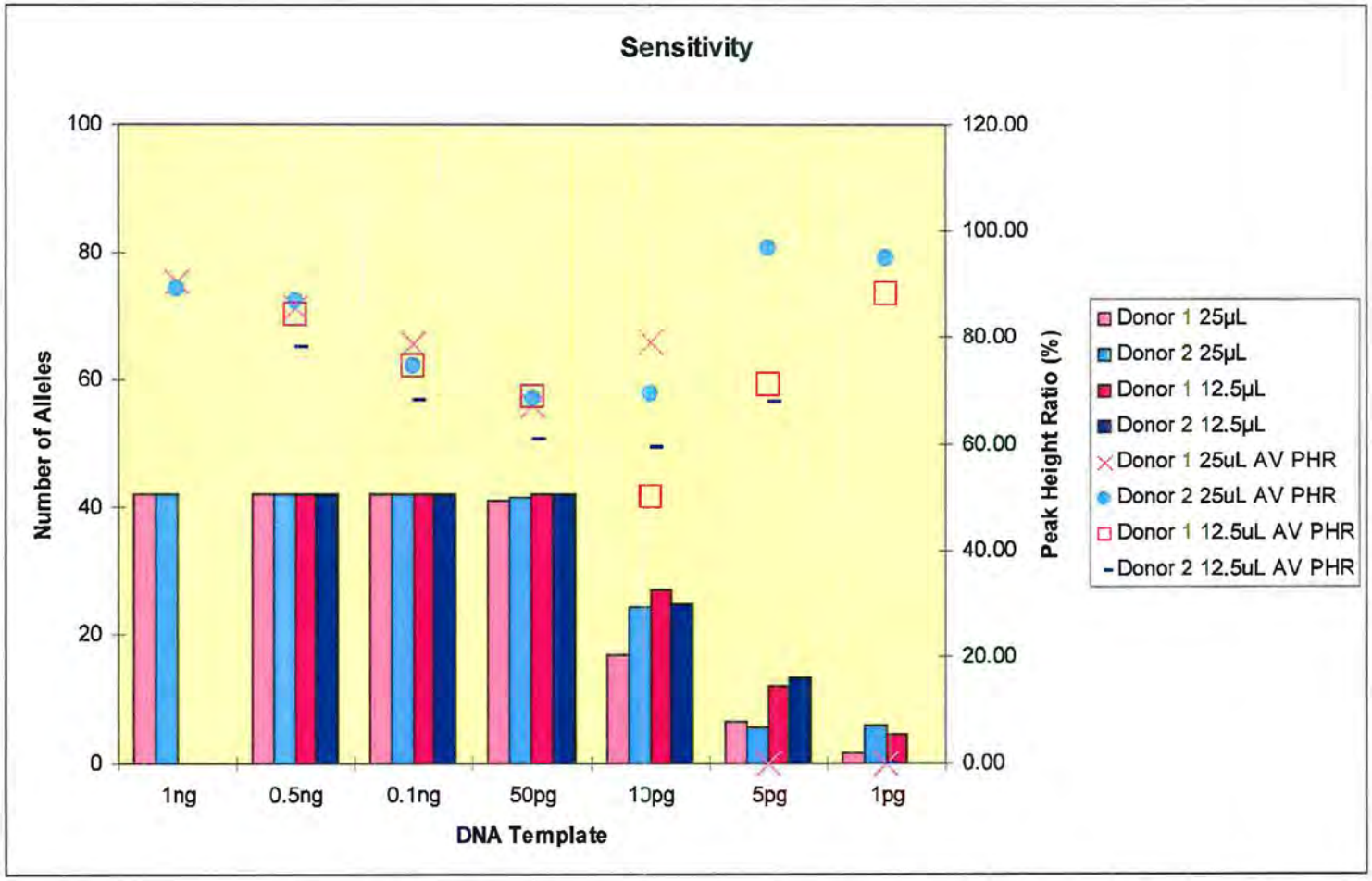


Figure 1 - Average number of alleles for each donor at each DNA template at amplification volumes of 25µL and 12.5µL. AV PHR = Average Peak Height Ratio

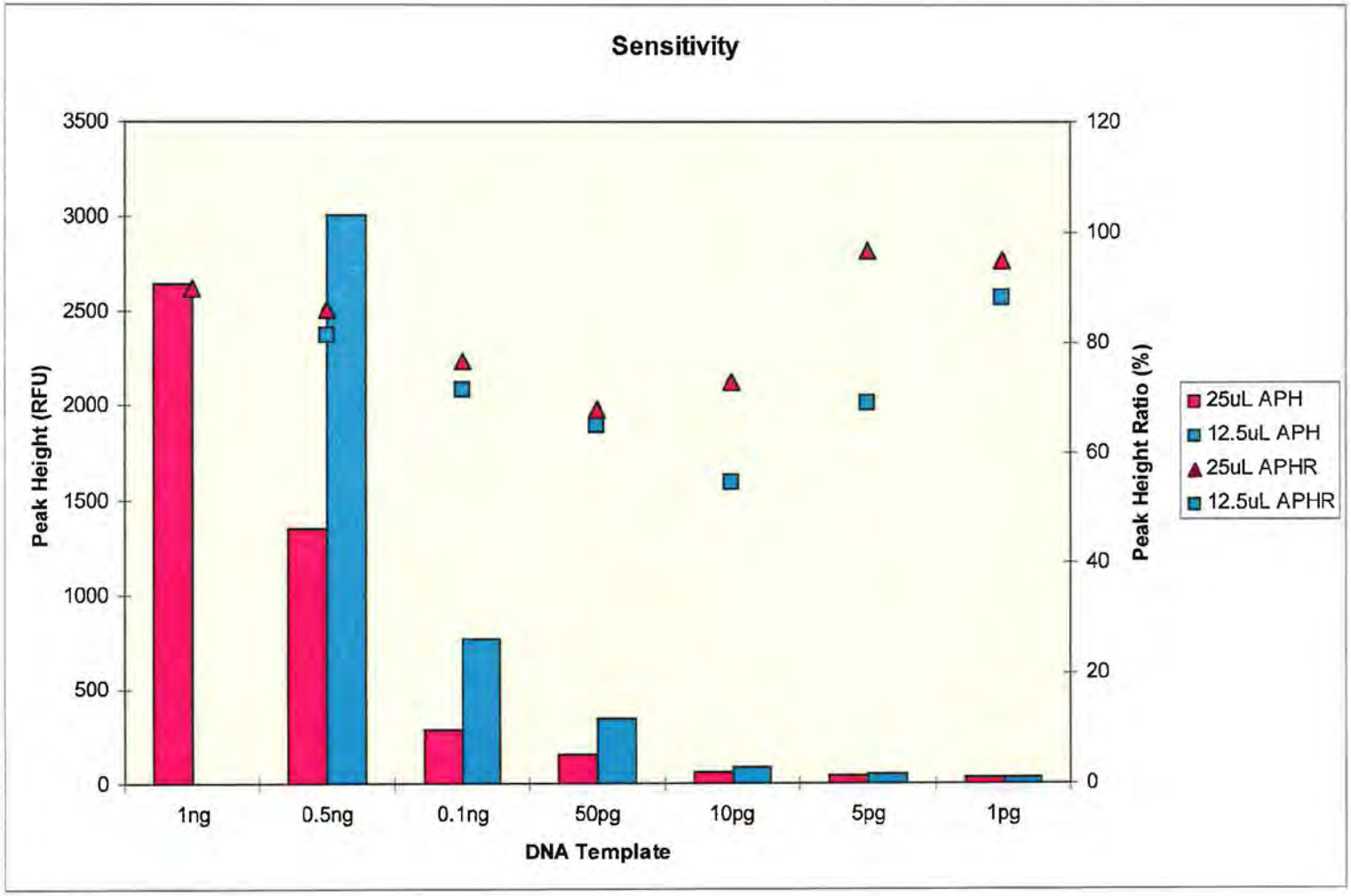


Figure 2 Average peak height and average peak height ratio for each DNA template

A full complement of alleles in the PowerPlex® 21 system was obtained for both donors at total DNA template inputs of 0.5ng and 0.1ng when amplified at both total PCR volumes. As expected the average number of alleles decreased as the DNA template decreased.

For both total PCR volumes, as the total DNA template decreased, the peak heights also decreased. The 12.5µL amplification gave higher peaks heights at the 0.5ng, 0.1ng and 50pg DNA template inputs compared with the 25µL amplification.

The average peak height ratio decreased as the DNA template decreased to 50pg. Below a DNA template of 50pg less heterozygote pairs were observed (as expected) which resulted in the peak height ratio becoming more variable and drop out being observed.

The samples from the 10x10 dataset ranged from template inputs of 0.5ng to 0.025ng. The results of these experiments are concordant with the first sensitivity experiment.

A full complement of alleles in the PowerPlex® 21 system was obtained for all samples between 0.5ng and 0.132ng DNA template inputs when amplified at both total PCR volumes.

The second sensitivity experiment was undertaken to enable direct comparison of the sample concentration when amplified at a total PCR volume of 25µL and 12.5µL rather than comparing the total DNA template input.

Figure 3 shows the results of low concentration samples amplified at 25µL and 12.5µL total PCR volumes with the vertical red line highlighting the limit of detection[29] (quantification) used for the AB 7500 Real Time PCR system. The numbers of alleles obtained at each concentration were counted using the LOR thresholds determined in section 6.4.

The DNA profiles exhibited increased allelic imbalance across different loci when the sample concentration dropped below 0.025ng/µL.

Overall the PowerPlex®21 system is a very sensitive STR amplification kit capable of detecting DNA amounts below what is generally considered low copy number (LCN). The data analyses indicate that the risk of type 2 errors will increase if the DNA template is too low for both total PCR volumes.

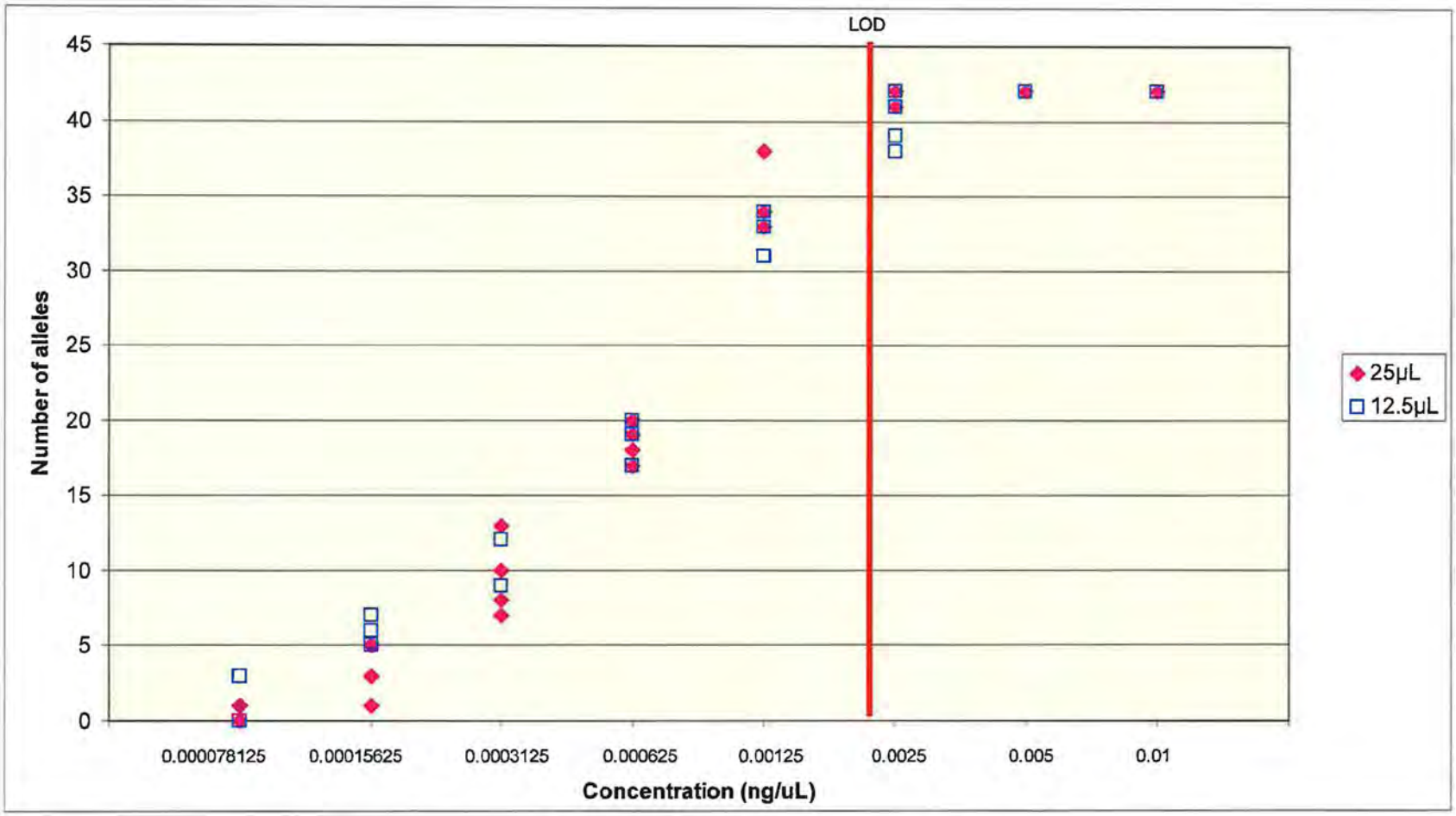


Figure 3 - Comparison of sample concentration vs allele count for 25µL and 12.5µL total PCR volumes.

6.5 Drop In

Allelic drop-in is due to spurious amplification products from unknown DNA, which makes allele drop-in a random event[30, 31]. The phenomenon of allelic drop-in is usually not reproducible and can be detected through testing samples multiple times[32].

For the 25µL amplifications processed on both 3130xl instruments 3 drop in events were noted. True drop-in alleles were seen in three negative controls at D16S539 as a 7 allele at 21RFU, D3S1358 as a 21 allele at 19RFU and at TH01 as a 5 allele at 19RFU.

For 12.5 µL amplifications on both 3130xl instruments no drop in events were noted.

Drop in data was sent to John Buckleton for fit to a Poisson distribution and tested. This data is required for STRmix™ validation and STRmix™ settings.

The rate of drop in events for 25µL volume amplifications (3 events in 1050 alleles above 15RFU) was calculated for STRmix™ by John Buckleton, see figure 4.

STRmix™ uses the model for drop-in ae-bx where the values for a and b are the drop-in parameters in STRmix™. John Buckleton's calculations determined that a=b=0.393. The maximum drop-in seen at any one locus is determined in RFU; this means that if two peaks were seen at one locus the drop-in would be the total height of both peaks. Since only one drop-in peak was observed at any one locus and the highest of these events was 21RFU, then our drop-in setting for STRmix™ would be 21RFU. Since our LOR was determined to be 40RFU, it seemed reasonable to set the drop-in level to 40RFU.

Although no drop-in events were observed for half volume amplifications, the same parameters will be applied.

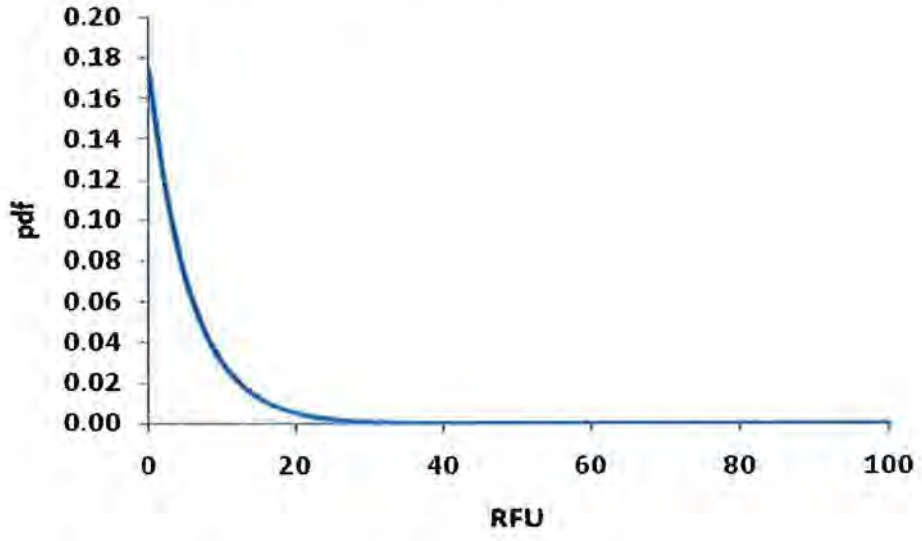


Figure 4 - Probability of Drop in for 25µL total PCR volume.

6.6 Stutter

Stutter peaks are Polymerase Chain Reaction (PCR) artefacts commonly observed in all STR analysis[4, 33]. They are usually observed as a peak one repeat unit smaller in size than the true allele peak[33]. The stutter mechanism has been attributed to slippage of the DNA strand during replication.

Over stutter is observed as a peak one repeat unit more in size than the true allele. Figure 5 shows an example of stutter and over stutter.

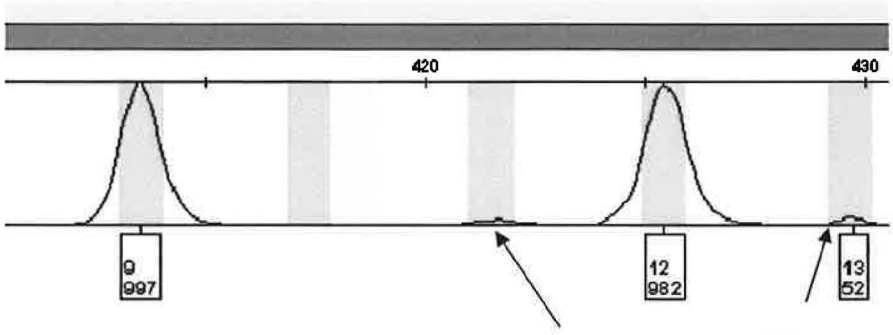


Figure 5 - Example of stutter and over stutter.

Promega supplied a stutter text file (using μ + 3σ[4]) for GeneMapper ID-X v.1.1.1. We have used the same calculation as it incorporates 99.73% of the data assuming normal distribution.

The data for the observed stutter ratios (forward and over) for samples amplified at 25μL are listed in table 15 and for 12.5μL are listed in table16.

Over stutter was observed for all loci when amplified at 25μL and therefore a threshold was able to be calculated for each locus. Over stutter was not observed for all loci when amplified at 12.5μL and therefore a threshold was only able to be calculated for those loci at which over stutter was observed. Over stutter will be continued to be monitored until enough data is obtained to review the thresholds set in this validation.

Most calculated stutter thresholds were higher than the Promega supplied stutter filter file both for 25μL and 12.5μL. The exceptions were D6S1043, D18D51, D2S1338, and Penta D for 25μL and D6S1043, Penta E, D18D51, D2S1338, and Penta D for 12.5uL.

When comparing the calculated stutter thresholds for the 25μL and 12.5μL total PCR volumes, they appear to be similar.

Table 15 - 25µL Calculated stutter thresholds.

Locus	μ_{SR}	σ_{SR}	Stutter Ratio (%)	μ_{OSR}	σ_{OSR}	Over stutter Ratio (%)
D3S1358	0.0868	0.0184	14.2	0.0131	0.0100	4.3
D1S1656	0.0910	0.0269	17.2	0.0183	0.0163	6.7
D6S1043	0.0685	0.0171	12.0	0.0164	0.0192	7.4
D13S317	0.0496	0.0228	11.8	0.0185	0.0184	7.4
Penta E	0.0457	0.0203	10.7	0.0113	0.0018	1.7
D16S539	0.0686	0.0173	12.1	0.0133	0.0099	4.3
D18S51	0.0873	0.0244	16.0	0.0144	0.0116	4.9
D2S1338	0.0878	0.0203	14.9	0.0196	0.0150	6.5
CSF1PO	0.0640	0.0244	13.7	0.0155	0.0096	4.4
Penta D	0.0245	0.0190	8.2	0.0306	0.0193	8.8
TH01	0.0325	0.0181	8.7	0.0085	0.0041	2.1
vWA	0.0782	0.0246	15.2	0.0157	0.0135	5.6
D21S11	0.0809	0.0199	14.1	0.0175	0.0177	7.1
D7S820	0.0485	0.0218	11.4	0.0207	0.0124	5.8
D5S818	0.0595	0.0202	12.0	0.0165	0.0132	5.6
TPOX	0.0381	0.0174	9.0	0.0235	0.0130	6.3
D8S1179	0.0790	0.0177	13.2	0.0176	0.0123	5.5
D12S391	0.0948	0.0311	18.8	0.0146	0.0128	5.3
D19S433	0.0666	0.0205	12.8	0.0211	0.0165	7.1
FGA	0.0702	0.0227	13.8	0.0182	0.0135	5.9

Stutter thresholds higher than the recommended stutter thresholds from Promega =

μ_{SR} = mean stutter ratio, σ_{SR} = standard deviation of stutter ratio, μ_{OSR} = mean over stutter ratio, σ_{OSR} = standard deviation of over stutter ratio

Table 16 - 12.5µL Calculated stutter thresholds.

Locus	μ_{SR}	σ_{SR}	Stutter Ratio (%)	μ_{OSR}	σ_{OSR}	Over stutter Ratio (%)
D3S1358	0.0880	0.0194	14.6	0.0113	0.0067	3.2
D1S1656	0.0909	0.0247	16.5	0.0138	0.0055	3.0
D6S1043	0.0738	0.0153	12.0	0.0141	0.0088	4.0
D13S317	0.0544	0.0197	11.3	0.0148	0.0070	3.6
Penta E	0.0389	0.0141	8.1	0.0289	0.0111	6.2
D16S539	0.0690	0.0195	12.8	0.0120	0.0049	2.7
D18S51	0.0827	0.0258	16.0	0.0167	0.0125	5.4
D2S1338	0.0909	0.0218	15.6	0.0298	0.0241	10.2
CSF1PO	0.0721	0.0258	14.9	0.0145	0.0071	3.6
Penta D	0.0262	0.0093	5.4	0.0324	0.0005	3.4
TH01	0.0252	0.0120	6.1	0.0071	0.0000	0.0
vWA	0.0836	0.0212	14.7	0.0149	0.0097	4.4
D21S11	0.0839	0.0199	14.4	0.0256	0.0132	6.5
D7S820	0.0508	0.0232	12.0	0.0250	0.0108	5.7
D5S818	0.0675	0.0230	13.7	0.0163	0.0139	5.8
TPOX	0.0346	0.0179	8.8	0.0145	0.0000	0.0
D8S1179	0.0818	0.0208	14.4	0.0173	0.0125	5.5
D12S391	0.1026	0.0313	19.6	0.0135	0.0083	3.8
D19S433	0.0689	0.0185	12.4	0.0129	0.0032	2.2
FGA	0.0700	0.0218	13.5	0.0192	0.0223	8.6

6.7 Peak Balance

6.7.1 Peak Height Ratio and Allelic Imbalance Threshold

Peak height ratio (PHR) is the ratio between the two peaks in a heterozygous pair. Under optimal conditions the amplification of a pair of alleles should result in equal peak heights however, input DNA, inhibitors and quality of DNA will affect the amplification [34, 35].

The method used in Equation 4 is recommended in the SWGDAM guidelines [11]and well represented in the literature [36], although other methods have been published by Kelly et al [37].

By assigning a threshold of the mean minus three standard deviations, this incorporates 99.73% of the data, resulting in a conservative threshold. This threshold was rounded up to the nearest RFU. Use of this method to produce a threshold is a low risk to reference samples, as samples that deviate would be reprocessed.

Table 17 shows the summary of PHR and AI_{Th} data calculated. The overall average PHR for 12.5µL and 25µL total PCR volumes are 78.9% and 80.4% respectively. These values are consistent with other kits listed in the literature [12, 38]. Although the average peak height ratios are similar to those reported in the literature, given the wide standard deviation

observed in our data, the calculated AI_{Th} of 31.1% for 12.5uL and 38.6% for 25uL reaction volumes are considered low.

Figures 6 and 7 display the data obtained from the 10 x10 experiments for 25µL and 12.5µL total PCR volumes respectively. For both total PCR volumes, as the amount of DNA input is decreased from the recommended 0.5ng template DNA, the average peak height ratio (μ_{PHR}) decreases and the standard deviation of the peak height ratio (σ_{PHR}) increases.

When the mean PHR are calculated for each DNA template, between 0.183ng and 0.5ng inputs there is no significant difference between total PCR volumes although the standard deviation is higher for the 12.5µL total PCR volume, resulting in a much lower threshold. Refer to table 17.

Figures 10 -19 show observed PHR for different template DNA amounts. The PHR range is separated into 0.1 increments plotted against number of allele pairs. Figure 10 is lowest template DNA amount. This shows that at the low template DNA range, the PHR varies unpredictably for both the 25µL and 12.5µL total PCR volumes. As the template DNA amount increases, the PHR converges towards the ideal of 1.0.

The μ_{PHR_25} at 25pg input was 0.736 and at 0.5ng input was 0.851 compared with the $\mu_{PHR\_12.5}$, at 25pg input was 0.598 and at 0.5ng was 0.832.

The results of our validation are consistent with previous published findings referring to low template DNA and reduced volume amplifications [13, 34, 39].

Stochastic effects were obvious in this experiment in data from templates below 0.132ng. Stochastic effects are the result of random, uneven amplification of heterozygous allele pairs from low template samples (SWGDAM 2010 interpretation) which is displayed by low peak heights or allele/locus dropout. At 0.132ng DNA template is approaching what is usually defined as low copy number (LCN) (~0.100ng to 0.150ng).

Supportive experimental data is displayed in Figure 20 AI_{TH} vs input graph, which displays a rapid drop off the AI_{TH} after 0.132ng DNA template. The calculated AI_{TH} drops below 0 for 0.02475ng DNA template because the standard deviation is so large. The rapid drop off is likely to increase the number of type 2 errors if AI_{TH} is used calculated from the entire dataset due to the large standard deviation. Exclusion of data from templates below 0.132ng increases the μ_{PHR} and decreases σ_{PHR}.

A multiple regression analysis was performed by Jo-Anne Bright, Duncan Taylor and John Buckleton to calculate the peak height variance for use in STRmix™[40].

The peak height ratios calculated here are for use with reference samples that have been amplified from extracted DNA and as a guideline to help determine the number of contributors for mixture interpretation as required for STRmix™ analysis.

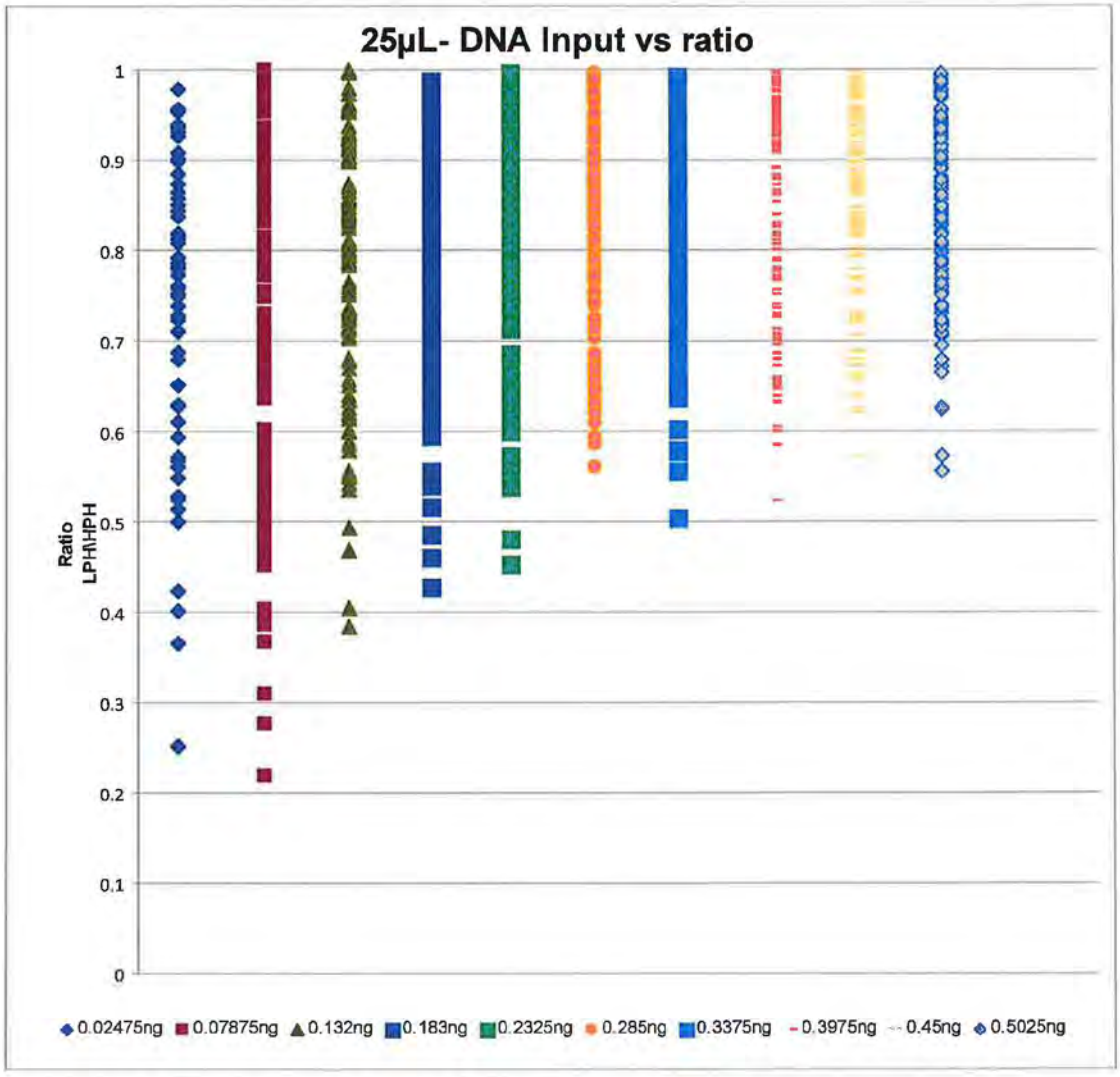


Figure 6 - 25µL total PCR volume, Peak balance vs total input DNA

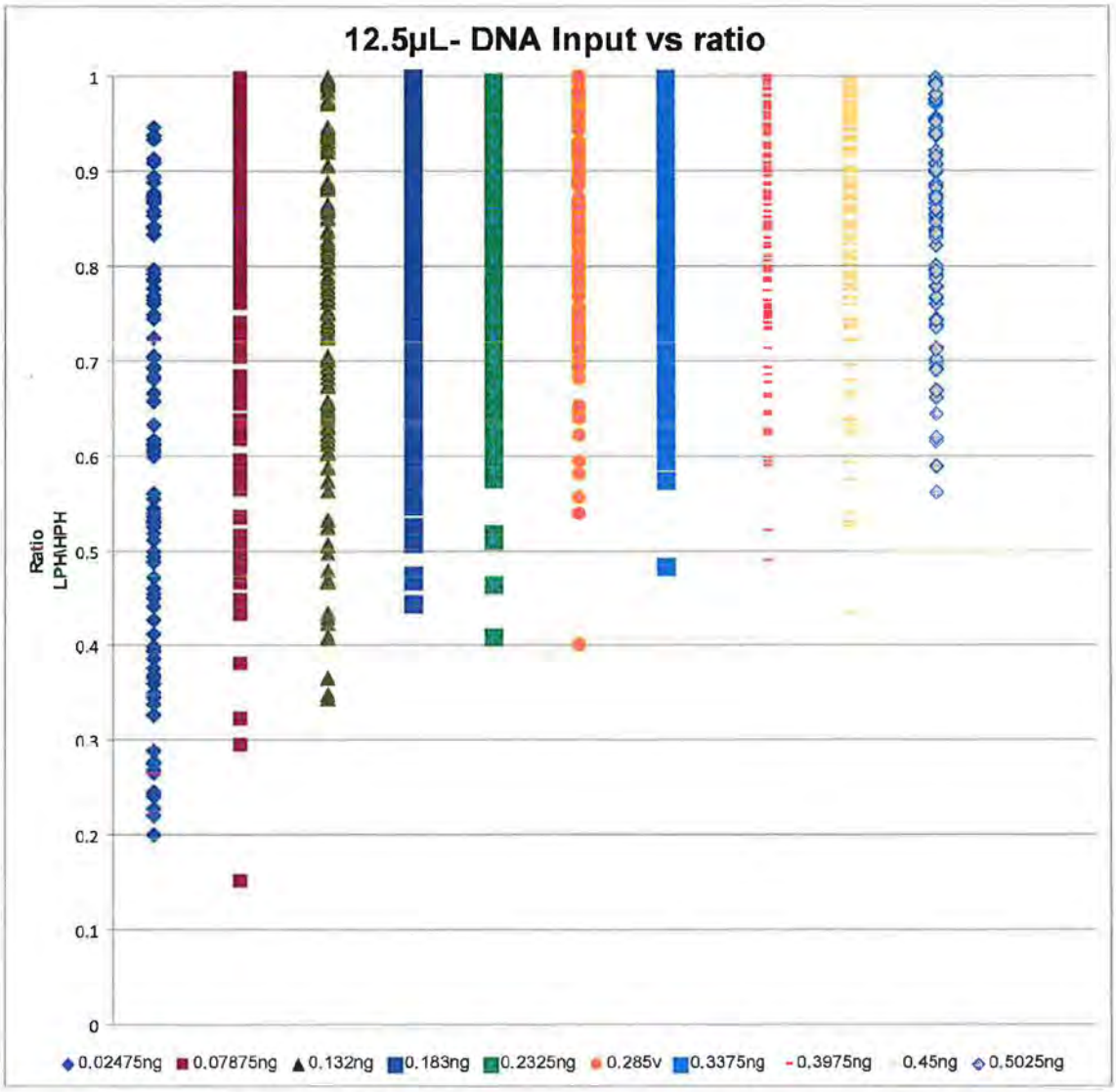


Figure 7 - 12.5µL Total PCR volume - Peak balance vs total input DNA.

Table 17 - Summary of calculated AI_{TH}.

	12.5µL			25µL		
	All Data	**0.132 - 0.50**	**0.183- 0.50**	**All Data**	**0.132 - 0.50**	**0.183- 0.50**
µ	0.789	0.814	0.825	0.804	0.824	0.830
σ	0.160	0.134	0.124	0.140	0.123	0.119
AI_{TH}	0.311	0.414	0.452	0.386	0.455	0.472

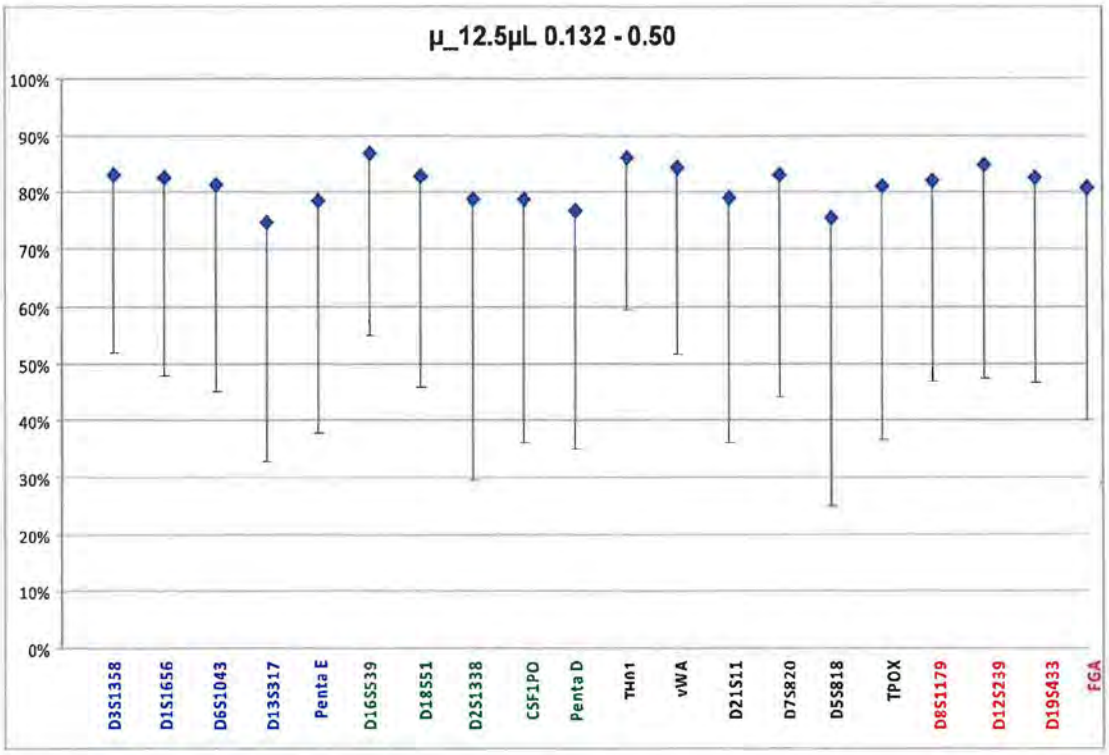


Figure 8 - 12.5µL total PCR volume µPHR per Loci

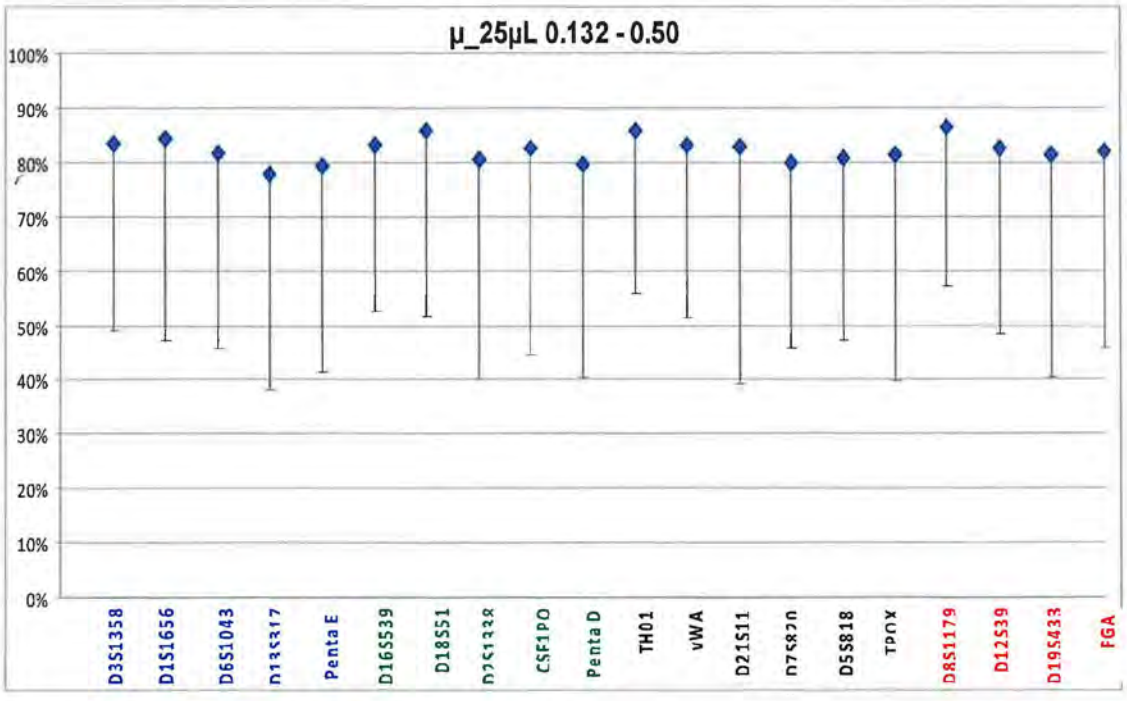


Figure 9 - 25µL total PCR volume µPHR per Loci

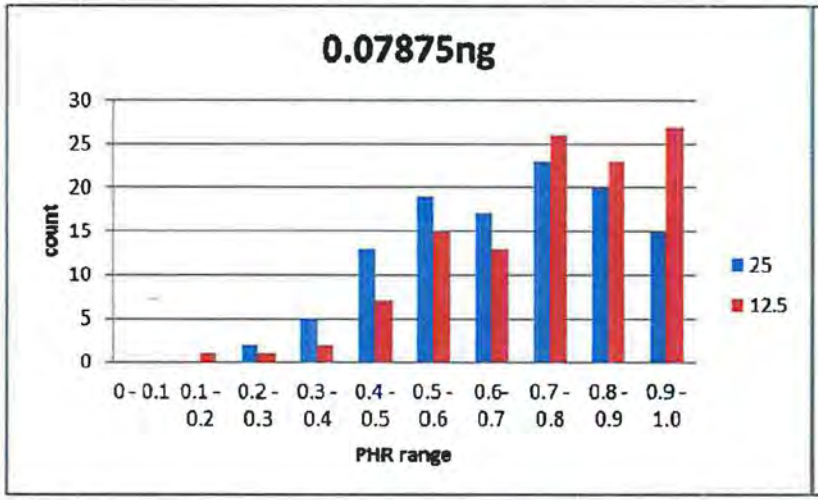


Figure 10 - The count of allele pairs per 0.1 PHR bin for 0.02475ng.

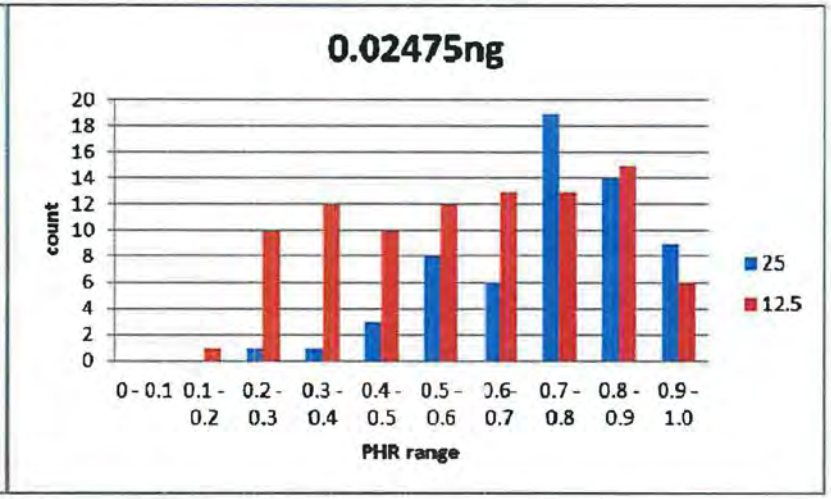


Figure 11 - The count of allele pairs per 0.1 PHR bin for 0.07875ng.

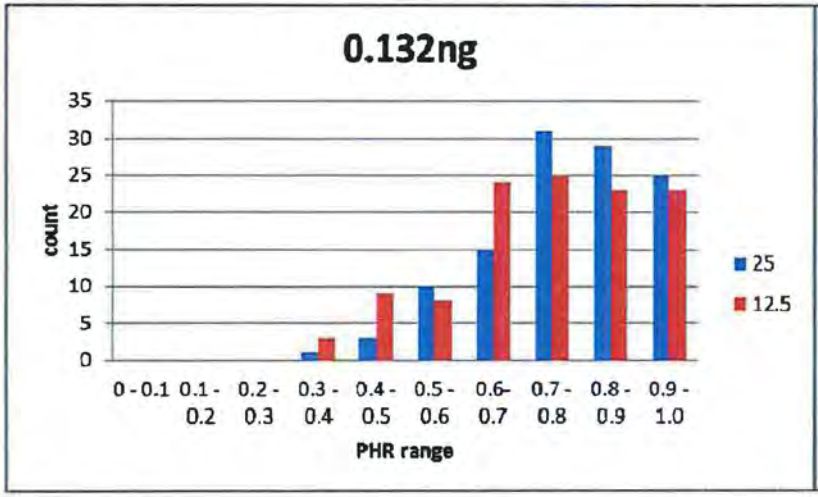


Figure 12 - The number of allele pairs per 0.1 PHR bin for 0.132ng.

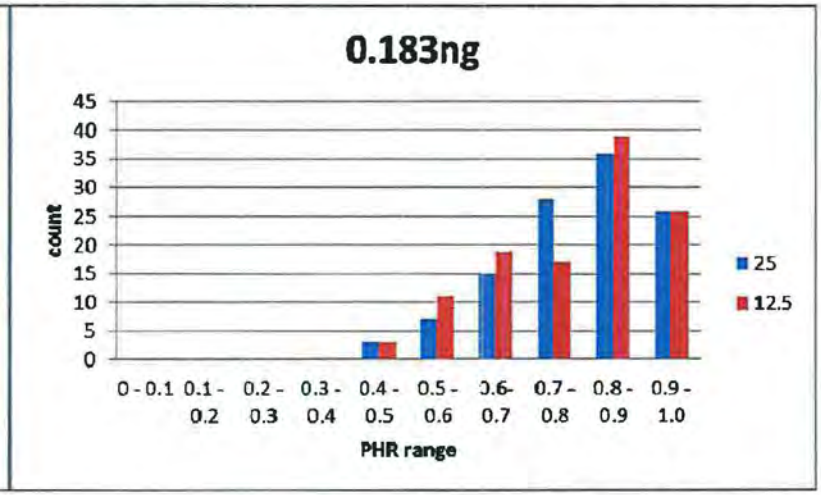


Figure 13 - The count of allele pairs per 0.1 PHR bin for 0.183ng.

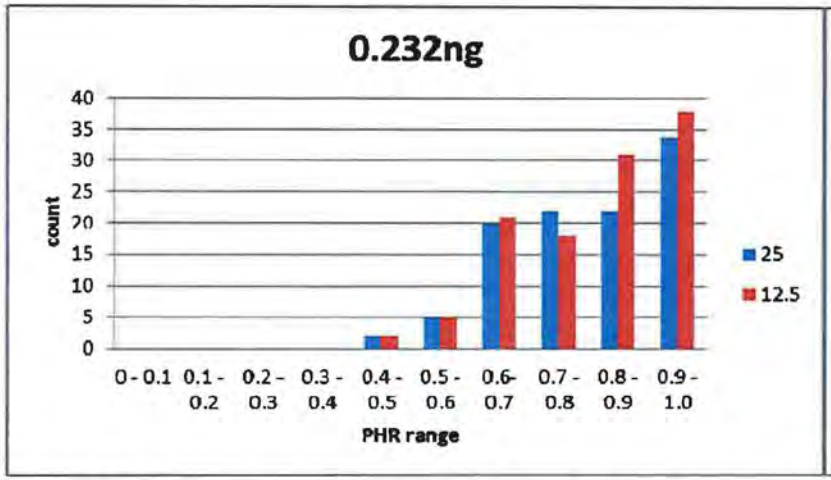


Figure 14 - The count of allele pairs per 0.1 PHR bin for 0.232ng.

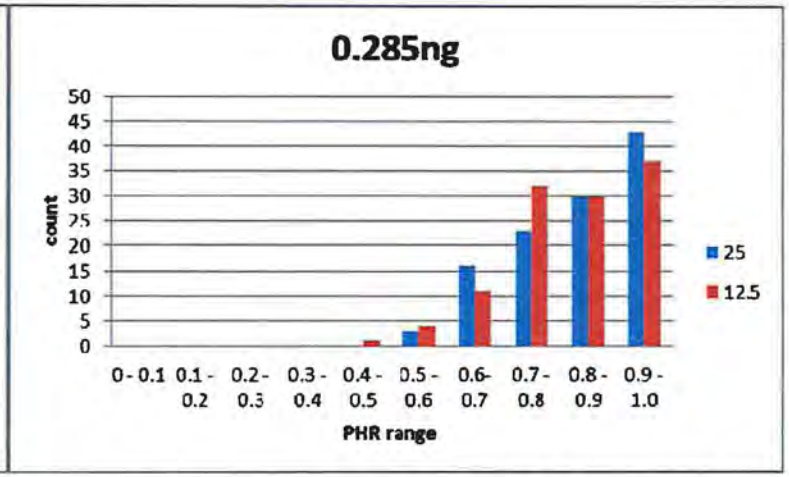


Figure 15 - The number of allele pairs per 0.1 PHR bin for 0.285ng.

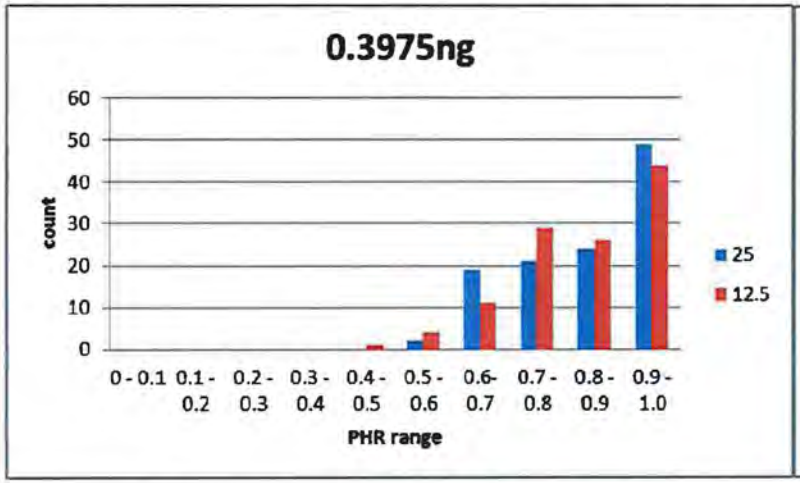


Figure 16 - The count of allele pairs per 0.1 PHR bin for 0.3375ng.

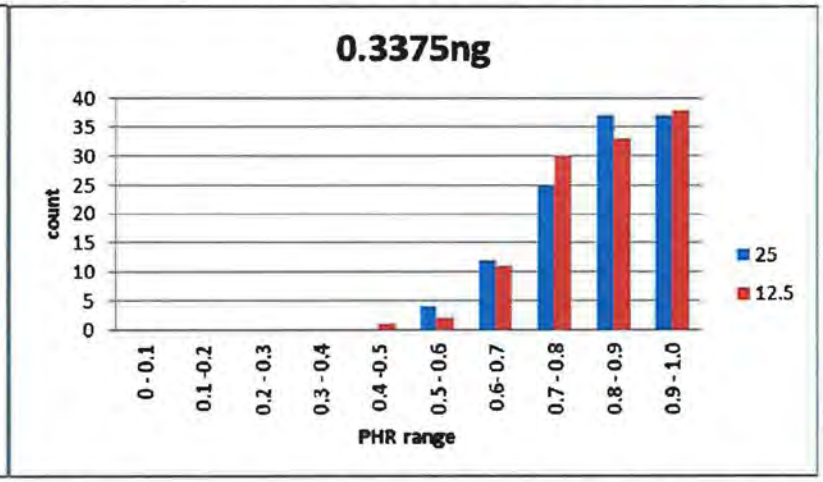


Figure 17 - The count of allele pairs per 0.1 PHR bin for 0.3975ng.

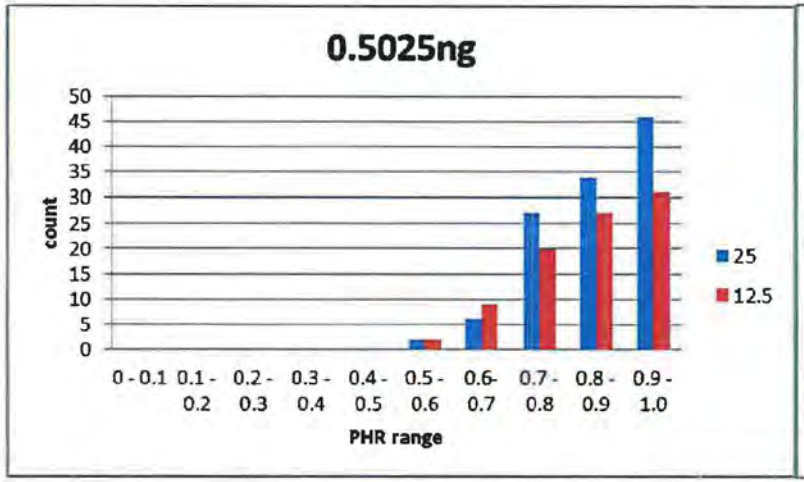


Figure 18 - The count of allele pairs per 0.1 PHR bin for 0.45ng.

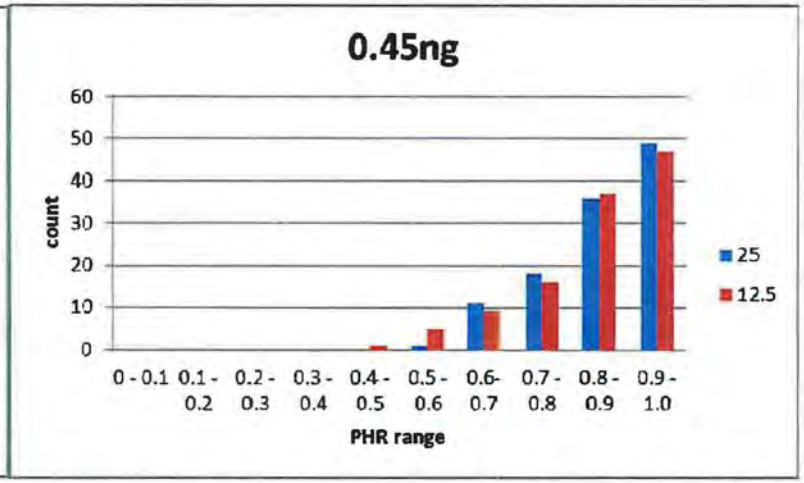


Figure 19 - The count of allele pairs per 0.1 PHR bin for 0.5025ng.

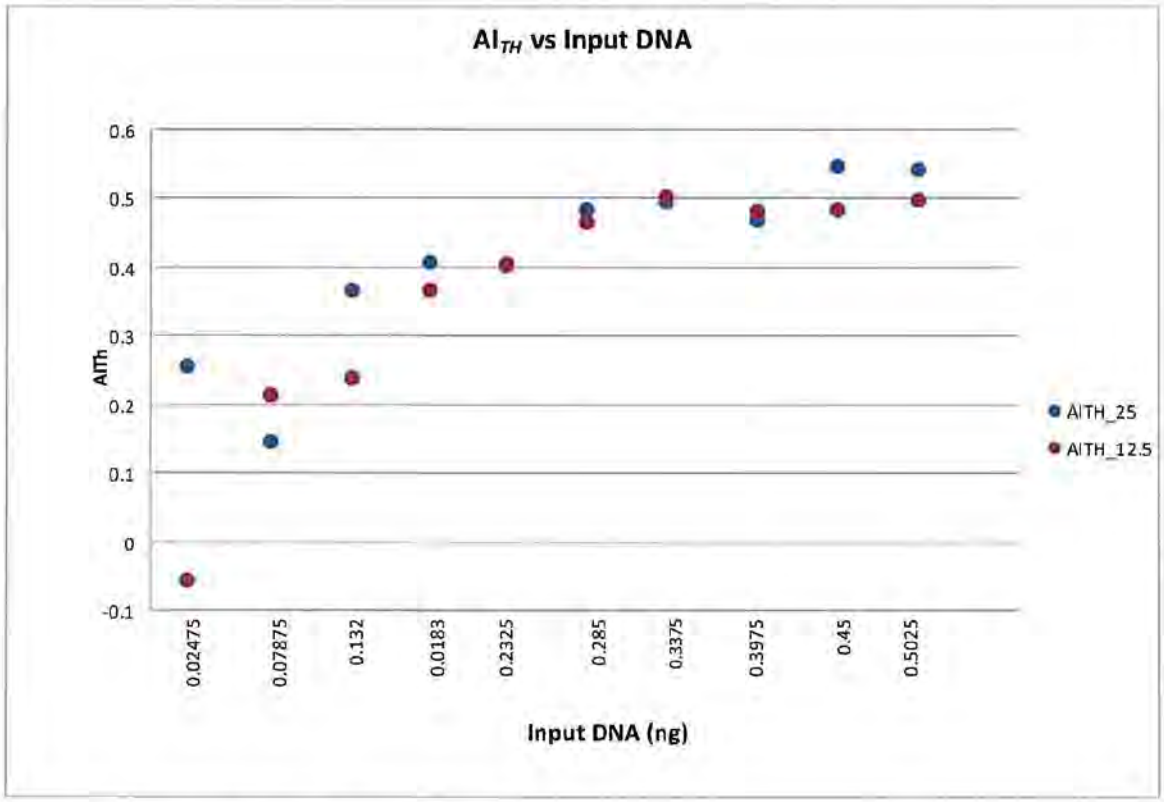


Figure 20 - Calculated AI_{TH} vs DNA template

6.7.2 Homozygote thresholds

The homozygote threshold is the threshold above which you can be confident that a heterozygote locus will not be incorrectly called as a homozygote locus.

Setting the homozygous threshold too high will result in excessive reworking of samples as a partial DNA profile would be called. Conversely, setting the threshold too low could result in false exclusions [1, 11, 23].

The method for determining the homozygote threshold varies in the literature. Traditionally, it had been arbitrarily designated at a particular level above the LOR. As already mentioned the risk of Type 1 and Type 2 errors should be balanced. Literature describes the setting of Th_{Hom} with respect to casework samples [21, 41, 42].

Previously in DNA Analysis, the Th_{Hom} was calculated as described in section 5.10 Equation 7. Using this method a figure of 176RFU for 25µL and 193FU for 12.5µL was calculated. These thresholds have been calculated excluding data below 0.132ng DNA template.

Another method of determining the Th_{Hom} is described in the Promega Internal Validation of STR systems reference manual[15]. This plots the peak height ratio for heterozygous loci against the lower RFU peak. The

threshold is defined as the point at which peak height ratio drops off significantly. Figures 21 and 22 display the data, the average AI_{TH} calculated for the range 0.132ng-0.5ng in section 6.7.1 for 25µL and 12.5µL respectively. An RFU that encompasses the majority of the data that falls below the average AI_{TH} calculated.

Unlike data reported in other publications[21, 43] there is not a rapid drop off of peak height ratios observed in the PowerPlex® 21 system, most likely due to the exclusion of the lower template data that exhibits extreme allelic imbalance. We have observed that the PowerPlex® 21 system loci tend to completely drop out completely compared to partially dropping out.

As both methods used give similar results, it is recommended the homozygote threshold be set at 200RFU for 25µL and 250RFU for 12.5µL.

These methods are subjective but when considered with the observed drop out data in Figures 23-32, Th_{Hom} of 200RFU would result in no type 2 errors. Additionally the threshold is more than three times the LOR threshold so Type 1 errors would also be addressed.

The homozygote threshold calculated in this validation will be used for extracted reference samples as case work samples do not require a homozygote threshold for STRmix™ analysis.

To ensure all of the thresholds set for this validation are appropriate a post implementation review of the thresholds will be performed. If the thresholds are found to be too conservative and have resulted in additional processing the review will provide an opportunity to re-adjust the thresholds based on empirical data.

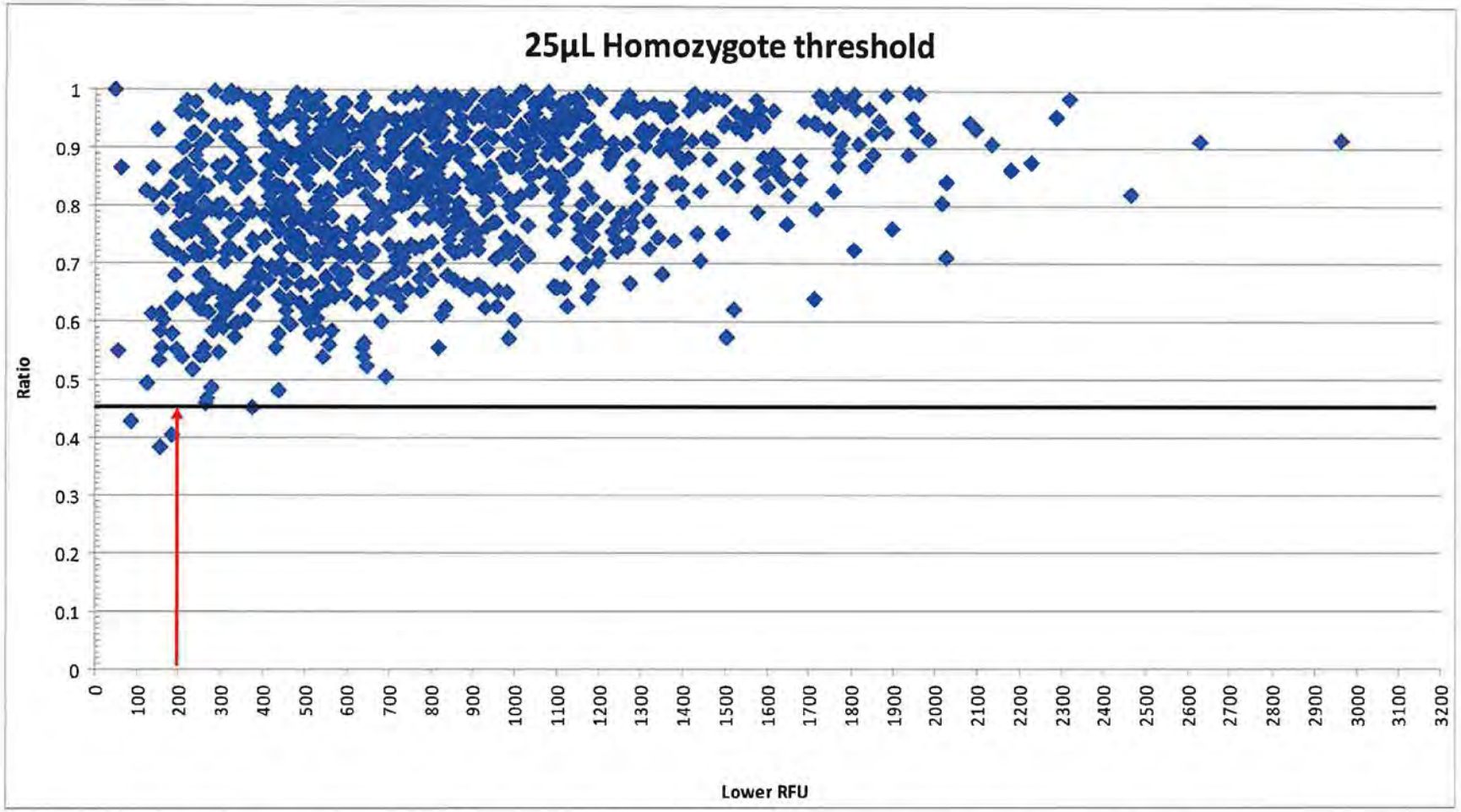


Figure 21 - Plot of the peak height ratio vs RFU of lower peak for 25µL. The black horizontal line is the AI_{TH}. The red vertical line is set to encompass the majority of points that fall below the AI_{TH}.

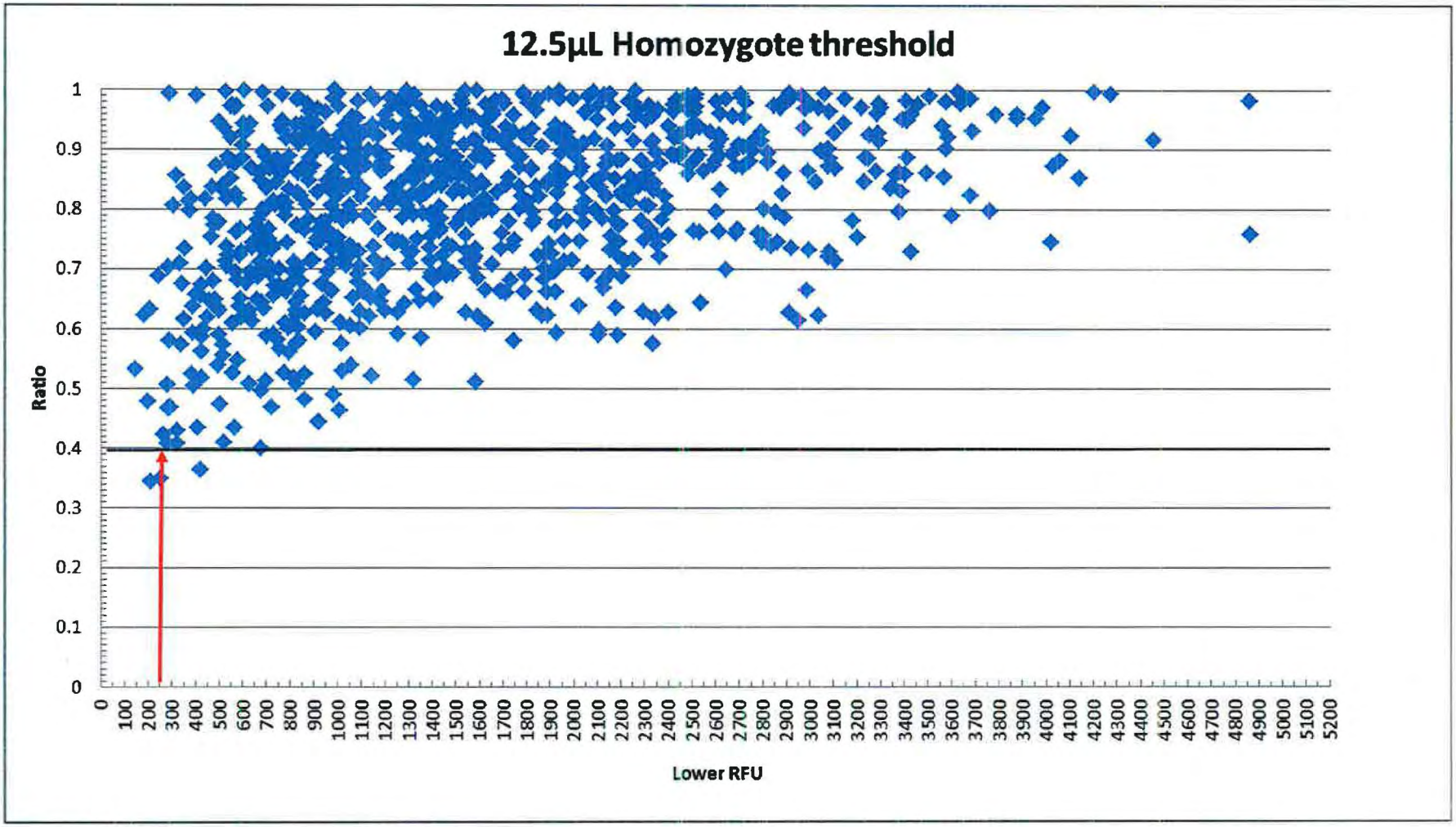


Figure 22 - Plot of the peak height ratio vs RFU of lower peak for 12.5µL. The black horizontal line is the AI_{TH}. The red vertical line is set to encompass the majority of points that fall below the AI_{TH}

6.8 Dropout Experiments

Allelic dropout is when one allele of a heterozygous pair has not appeared or has a very low peak height[44]. One cause of dropout is one allele of a heterozygous pair is preferentially amplified thus giving the false impression of a homozygous allele at a particular locus[31].

This experiment used sensitivity 1 data of the two donors from 1ng to 1pg the 4ng and 2ng data was excluded due to the excess nature of the profiles. The heat maps shown in figures 23, 24, 25 and 26 summarise the data to quickly compare the drop out events observed.

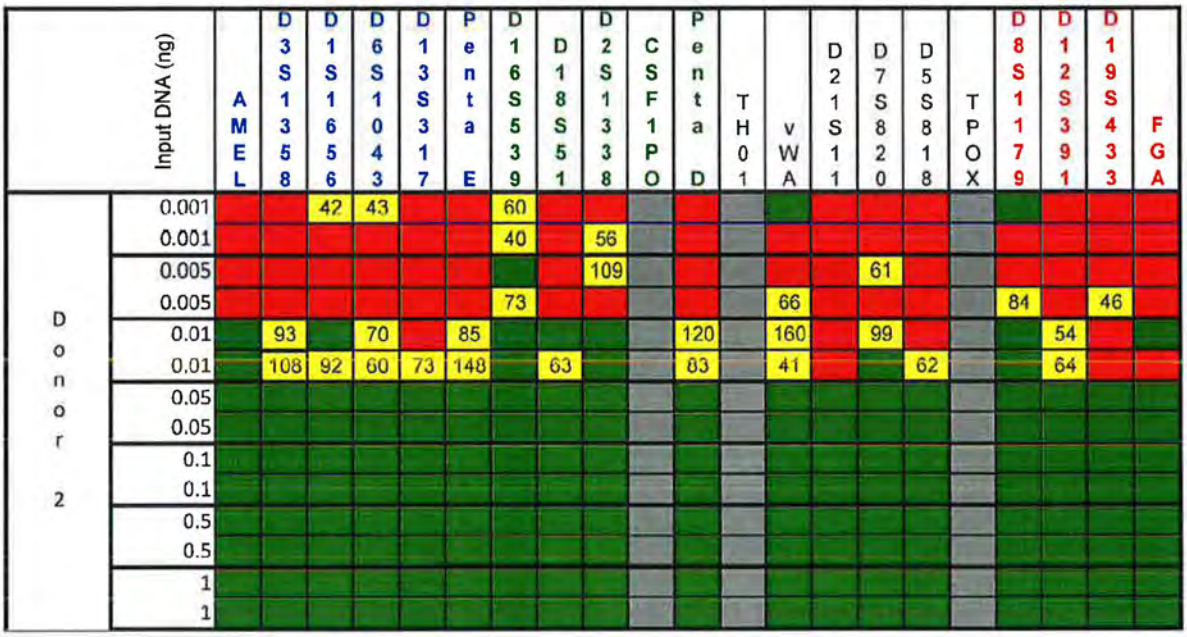
The data for the 25µL amplification shows 62 drop out events occurred across both donors from dilutions 0.001ng to 0.05ng. Figure 24 shows the highest peak height (RFU) where a heterozygous pair dropped out was at 160RFU for the 0.01ng dilution for donor 2 amplified at 25µL total PCR volume.

The data for the 12.5µL amplification shows 70 drop out events occurred across both donors from dilutions 0.001ng to 0.05ng. Figure 26 shows the highest peak height (RFU) where a heterozygous pair dropped out was at 399RFU for the 0.01ng dilution for donor 2.

Locus dropout
Allele dropout (surviving allele RFU)
Complete heterozygous locus
Homozygous locus

	Input DNA (ng)	AMEL	D3S1358	D1S1656	D6S1043	D13S317	PentaE	D16S539	D18S51	D2S1338	CSF1PO	PentaD	TH01	vWA	D21S11	D7S820	D5S818	TPOX	D8S1179	D12S391	D19S433	FGA
Donor 1	0.001										54											
	0.001								43													
	0.005	83												50		96					69	
	0.005	41		46		61								46				54	70			
	0.01	100	76	73						58	67	49		65	51		90	103	140			
	0.01	89								47			120		41	87	42		50	40	88	63
	0.05																131					
	0.05																					
	0.1																					
	0.1																					
	0.5																					
	0.5																					
	1																					
	1																					

Figure 23 - Heat map - Donor 1 - 25µL total PCR volume



Donor 2 – Input DNA (ng)	AMEL	D3S1358	D1S1656	D6S1043	D13S317	Penta E	D16S539	D18S51	D2S1338	CSF1PO	Penta D	TH01	vWA	D21S11	D7S820	D5S818	TPOX	D8S1179	D12S391	D19S433	FGA
	0.001			42	43			60														
	0.001							40		56												
	0.005									109					61							
	0.005							73					66					84		46		
	0.01		93		70		85					120		160		99				54		
	0.01		108	92	60	73	148		63			83		41			62			64		
	0.05																					
	0.05																					
	0.1																					
	0.1																					
	0.5																					
	0.5																					
	1																					
	1																					

Figure 24 - Heat map - Donor 2 - 25µL total PCR volume

Donor 1 – Input DNA (ng)	AMEL	D3S1358	D1S1656	D6S1043	D13S317	Penta E	D16S539	D18S51	D2S1338	CSF1PO	Penta D	TH01	vWA	D21S11	D7S820	D5S818	TPOX	D8S1179	D12S391	D19S433	FGA
	0.001				88					80								50		60		
	0.001										44					61						
	0.005	48							43	115				97	47				60			
	0.005	79		59						77		183	48	89	44	40			47			
	0.01		63			76				99		128		119			131		45	95		43
	0.01		126		49						56			120	53	161	162	42		52	80	
	0.05																					
	0.05																			277		
	0.1																					
	0.1																					
	0.5																					
	0.5																					
	1																					
	1																					

Figure 25 - Heat map - Donor 1 - 12.5µL total PCR volume

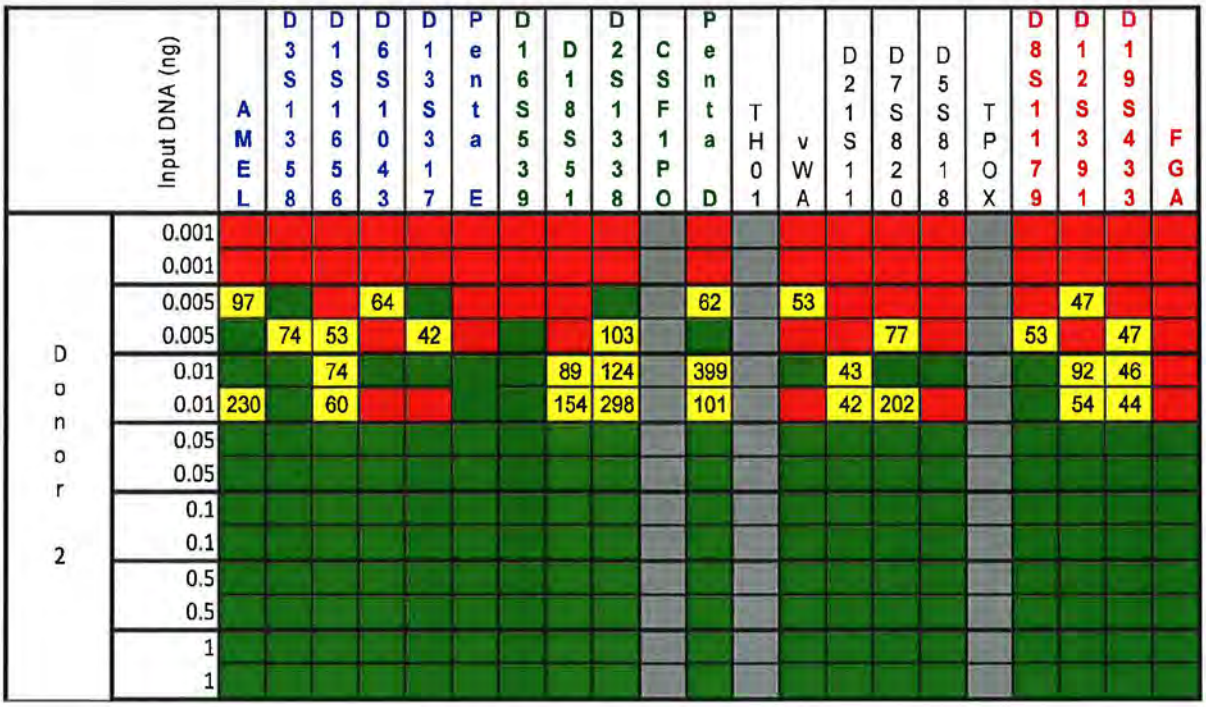


Figure 26 - Heat Map – Donor 2 - 12.5µL total PCR volume

6.8.1 Drop out 2

Analysis for drop out 2 used the data obtain from the Aboriginal dataset, 10 x10 and both sensitivity experiments for 25µL total PCR volume and the 10 x10, both sensitivity experiments and concordance for 12.5µL total PCR volume. The dropout 2 results are displayed in figures 27 and 28. Figure 27 shows the dropout events for all samples amplified at 25µL total PCR volume. Figure 28 shows the dropout events for all samples amplified at 12.5µL total PCR volume.

For both 25µL and 12.5µL total PCR volume amplifications there are more drop out events of whole loci compared with a single allele drop out event

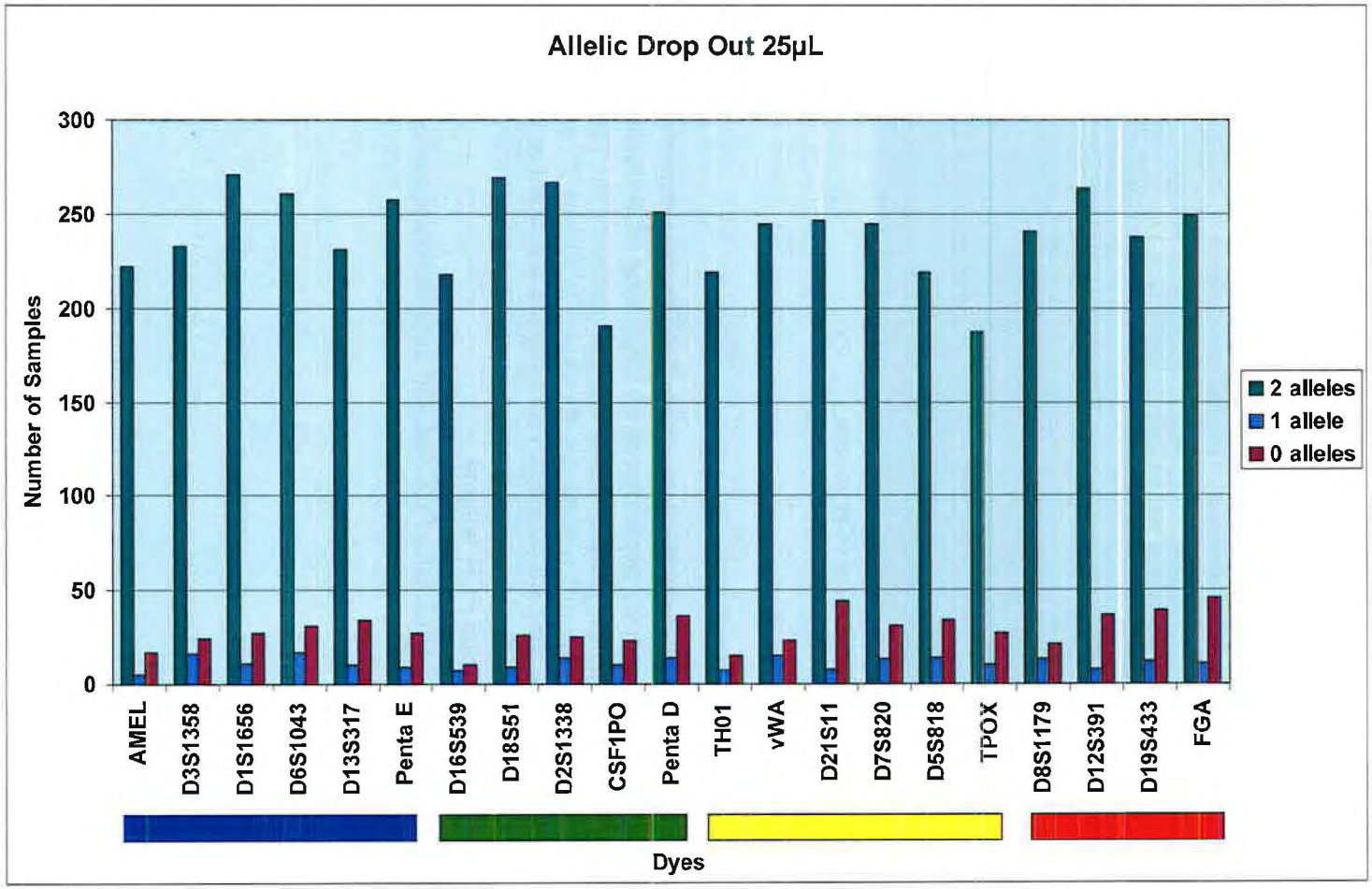


Figure 27 - Dropout events for samples amplified at 25µL

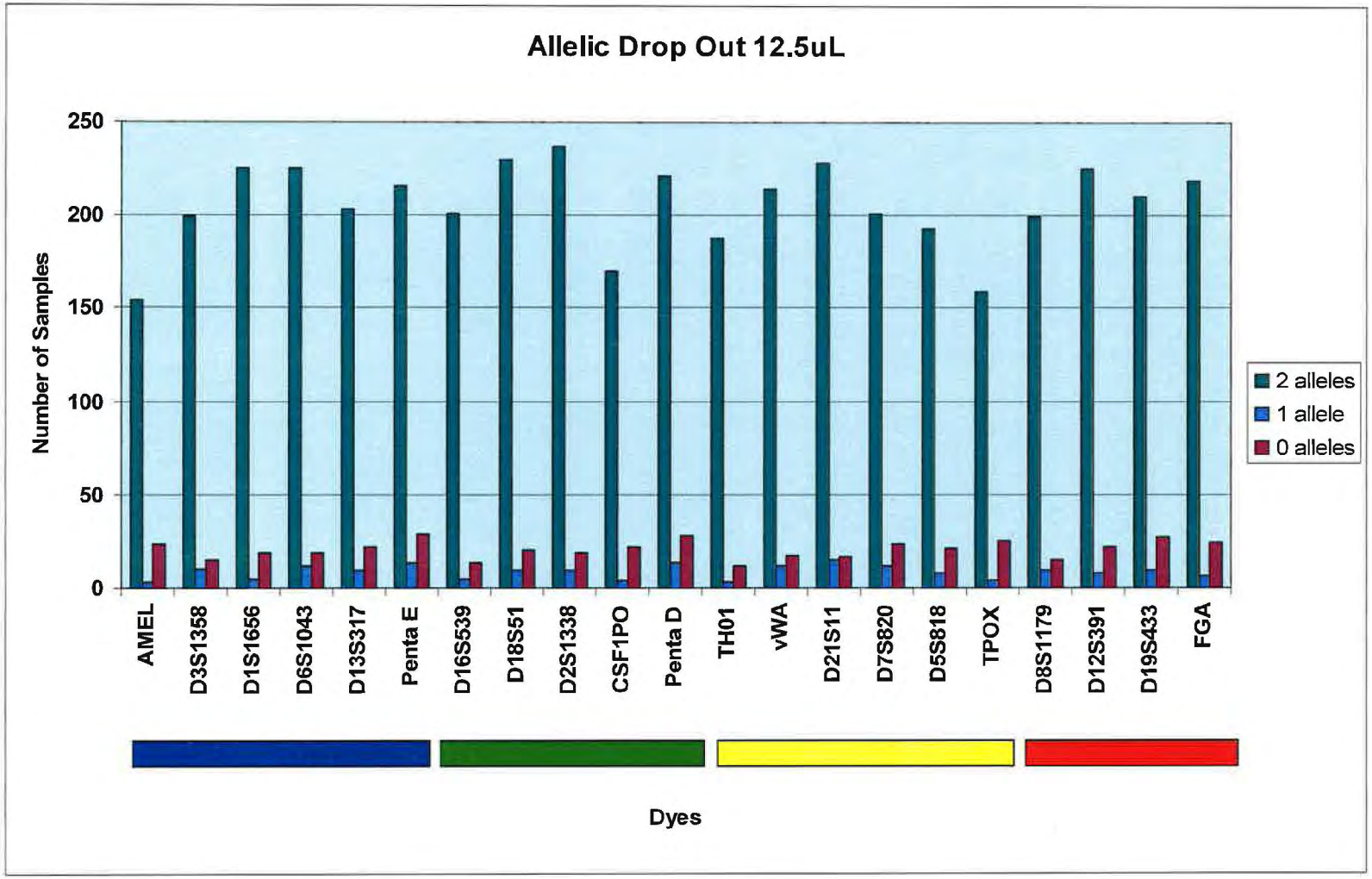


Figure 28 - Dropout events for samples amplified at 12.5µL

6.8.2 Drop out 3

Analysis for drop out 3 used the data from the baseline (10 x 10) and both sensitivity experiments at both 25µL and 12.5µL total PCR volume. There were 215 drop out events observed for the 25µL total PCR volume compared to198 drop out events observed at 12.5µL total PCR volume. Figure 29 shows the number of drop out events for a range of peak heights. This shows the majority of drop out events occur below 150RFU for 25µL total PCR volume and below 180RFU for 12.5µL total PCR volume.

Figures 30, 31 and 32 show the peak heights where one of the heterozygote pairs has dropout at each DNA template. Figure 30 shows one dropout event occurred at 226RFU for the 12.5µL total PCR volume at a DNA template of 0.131ng whereas 17 dropout events occurred at 25 µL total PCR volume at the same DNA template, however these dropout events occurred under 80RFU. The highest drop out seen for 12.5µL total PCR volume was at 234RFU at a DNA template of 0.025ng and for 25µL total PCR volume was at 106RFU. The total number of dropout events seen for the 10 x10 at 25µL total PCR volume was 68 and 30 at 12.5µL total PCR volume.

Figure 31 (Sensitivity 1) shows the highest drop out for 12.5µL total PCR volume was seen at 399RFU at a DNA template of 0.01ng and 160RFU at DNA template 0.01ng for the 25µL total PCR volume. The total number of dropout events seen for the sensitivity 1 experiment at 25µL total PCR volume was 58 and 66 at 12.5µL total PCR volume.

Figure 32 (Sensitivity 2) shows the highest drop out for 12.5µL total PCR volume was seen at 246RFU at a DNA template of 0.0094ng and 249RFU at a DNA template of 0.0375ng for the 25µL total PCR volume. The total number of dropout events seen for the sensitivity 2 experiment at 25µL total PCR volume was 89 and 102 at 12.5µL total PCR volume.

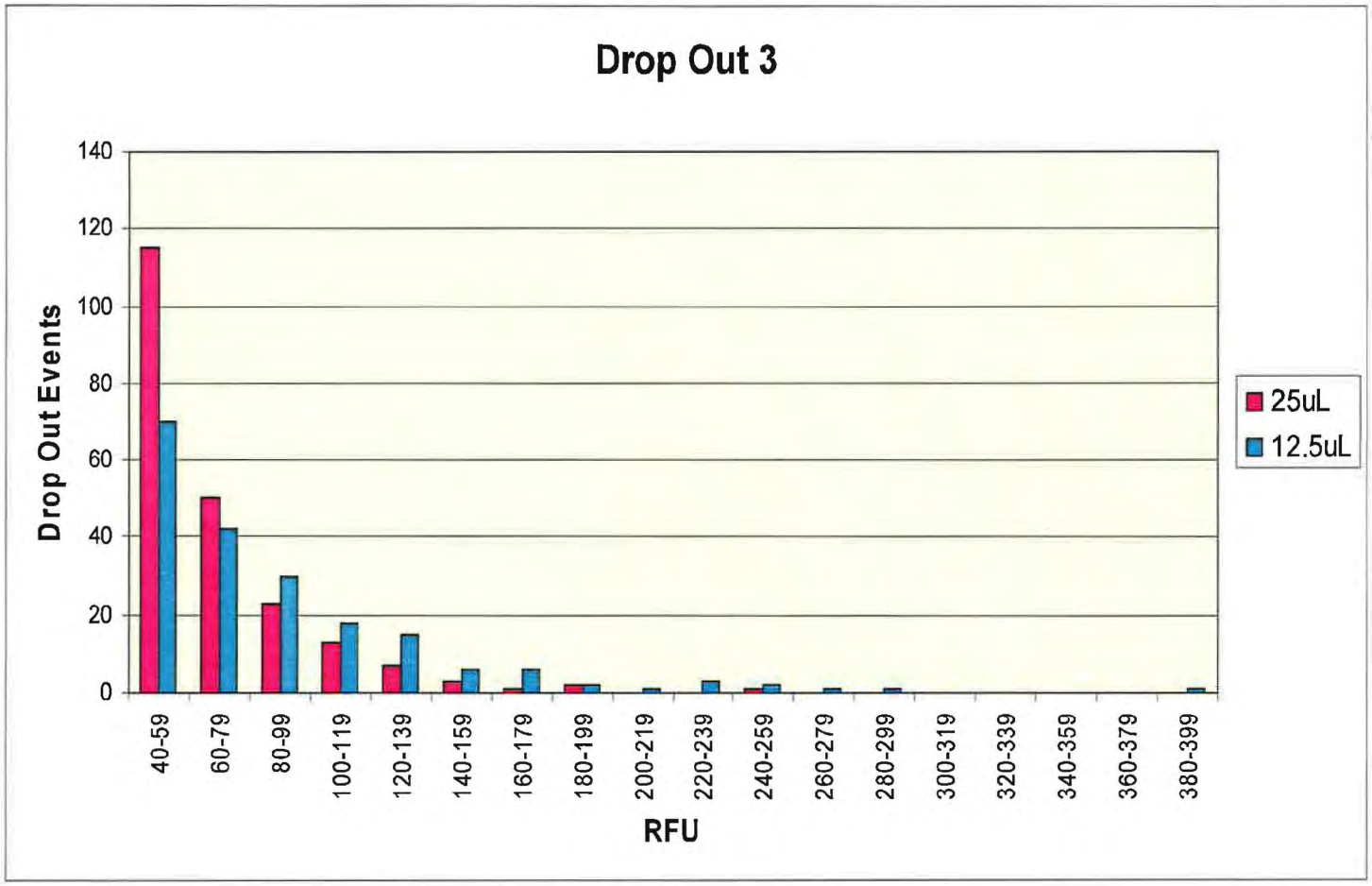


Figure 29 - Number of drop out events seen within peak height ranges at 25µL and 12.5µL amplifications

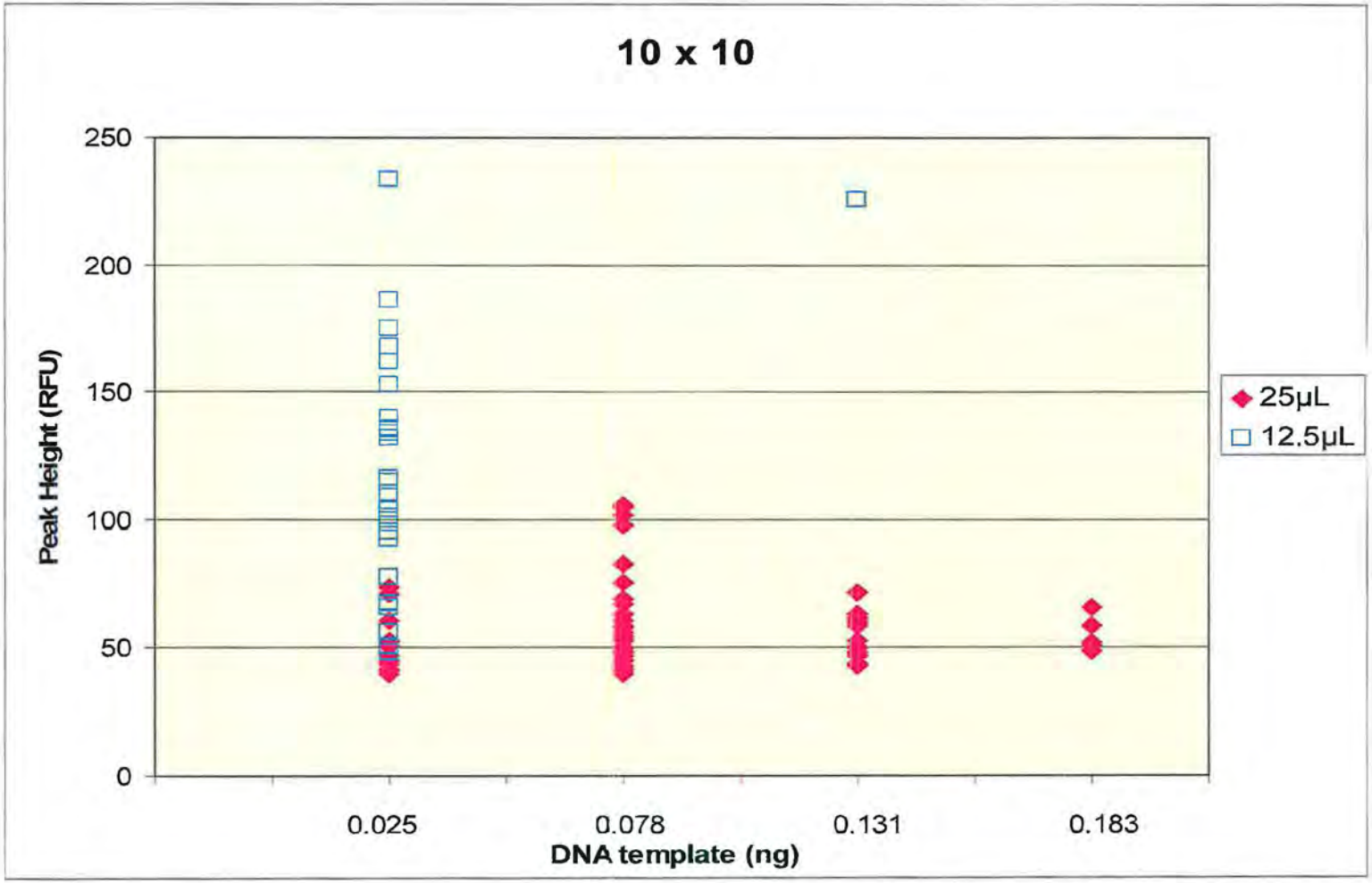


Figure 30 - Peak heights where the heterozygote pair has dropped out at different DNA templates for 12.5uL and 25uL using the baseline data (10 x10)

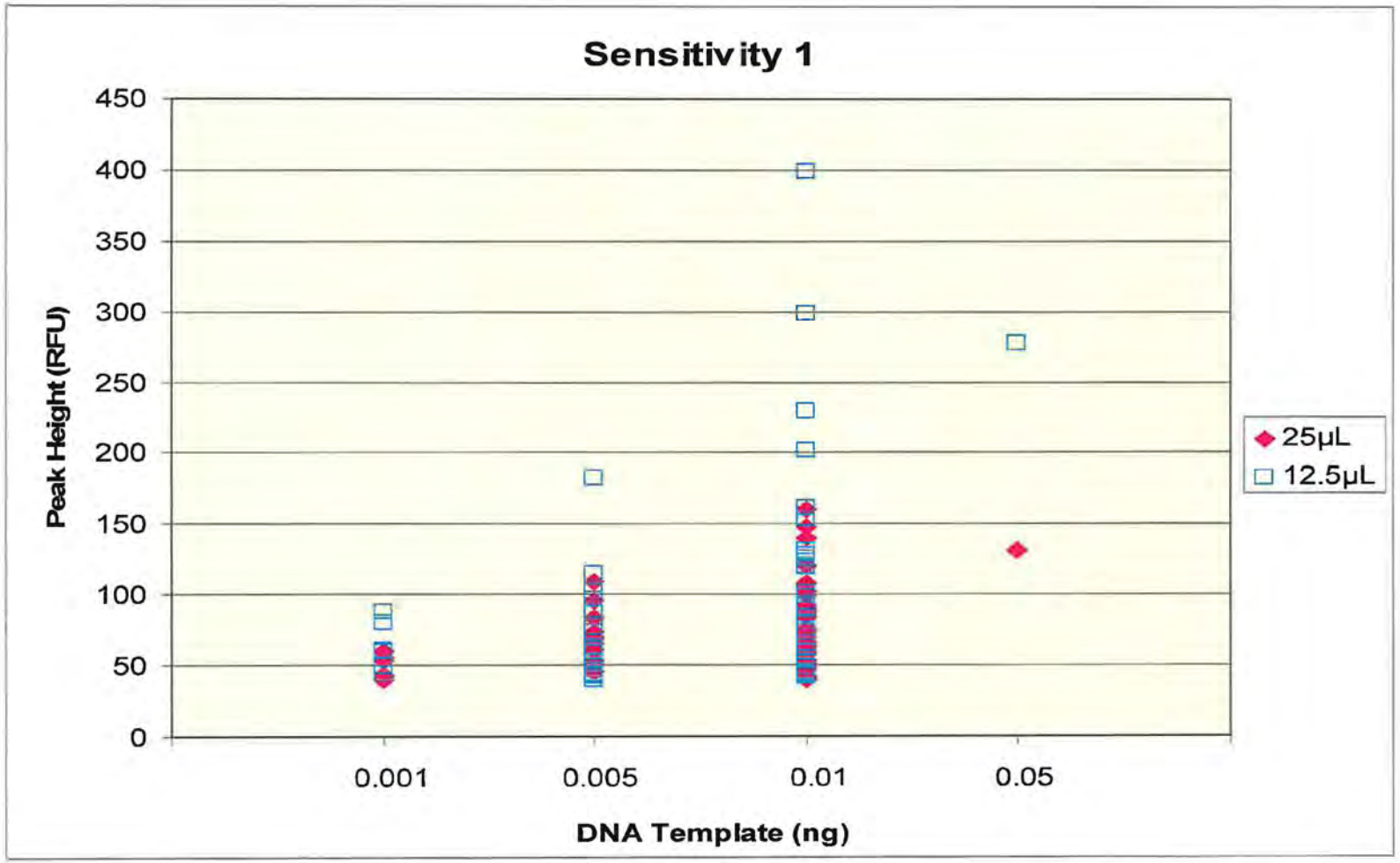


Figure 31 - Peak heights where the heterozygote pair has dropped out at different DNA templates for 12.5uL and 25uL using sensitivity 1 data

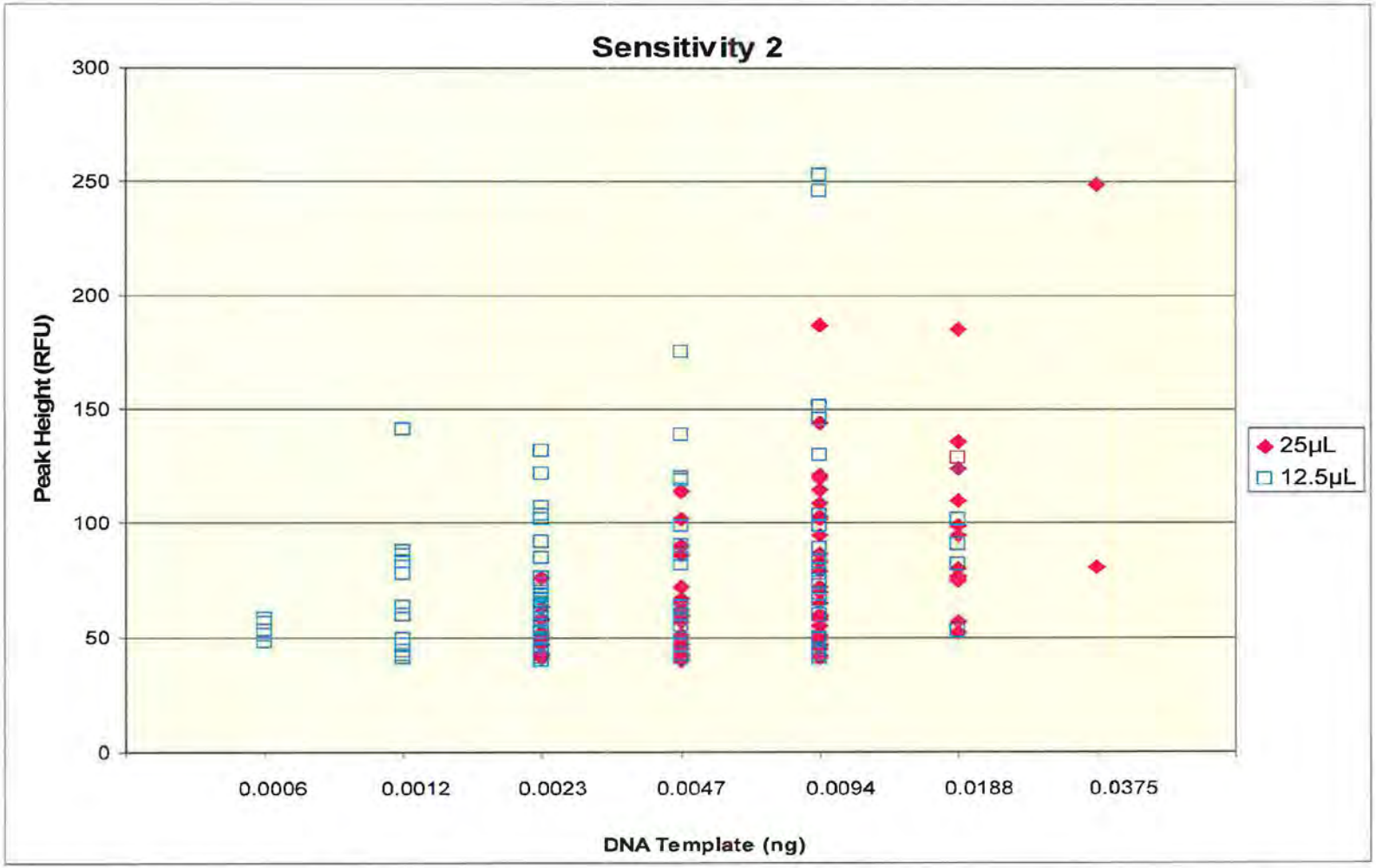


Figure 32 - Peak heights where the heterozygote pair has dropped out at different DNA templates for 12.5uL and 25uL using sensitivity 2 data

6.9 Mixture Studies

At a total input template of 0.5ng, for both 25µL and 12.5µL, all alleles were detected for the mixtures with ratios of 1:1, 2:1 and 5:1. Any allelic imbalance was observed at a level of greater than 40%.

When the template was decreased to 0.125ng for 5:1 mixtures, drop-out of the lower level contributor was observed for both 25µL and 12.5µL volumes. At this template level, allelic imbalance of down to 35% was observed for the lower level contributor at both 25µL and 12.5µL volumes, however, one of these peaks fell into the stutter position of the larger contributor.

When the template was decreased to 0.06ng for 2:1 mixtures, drop-out of the lower level contributor was observed for both 25µL and 12.5µL volume with the partner allele being as high as 562RFU. At this template level, allelic imbalance of down to 20% was observed for the lower level contributor and 23% for the higher level contributor.

For the remaining mixtures with ratios of 10:1, 20:1, 30:1 and 50:1 of varying template levels (maximum 0.5ng), the lower contributors exhibited, sometimes quite marked, stochastic variation. This included drop-out with peaks up to 392RFU and allelic imbalance as low as 20%.

The tables 16 and 17 show the approximate mixture ratio of the profile compared with the mixture ratio of the sample. For the 2 person mixtures this was averaged over all loci where there was no allele sharing between the two contributors and where the alleles did not fall into a stutter position. For the 3 person mixtures, the ratio was averaged over all loci where there was no allele sharing between the three contributors, however it was not possible to exclude loci where the alleles fell into stutter positions as there were no loci fulfilling this criteria. It was not possible to accurately calculate mixture ratios for the four person mixtures.

The data shows that the mixture ratio after DNA amplification is approximately equal to the mixture ratio of the initial sample for both 25µL and 12.5µL volumes at all ratios. The mixture ratio deviates more as the ratio increases most likely due to the stochastic effects of the lower contributor. The mixture ratios for the 25µL volume amp appear to be slightly lower than for the12.5µL volume amp.

Although mixture ratios have not been calculated for the four person mixtures, the alleles obtained are consistent with expected profiles.

Table 18 - 12.5µL total PCR volume mixture studies

Mixture Ratio of Sample	Total Input Template (ng)	Approximate Mixture Ratio of Profile
2 Person Mixtures		
1:1	0.500	1.2:1
2:1	0.500	2.2:1
	0.060	2.9:1
5:1	0.500	6.1:1
	0.125	6.1:1
10:1	0.500	12:1
	0.125	11:1
20:1	0.500	24:1
	0.250	16:1
	0.125	19:1
30:1	0.500	21:1
50:1	0.500	35:1
	0.250	49:1
	0.125	Unable to calculate
3 Person Mixtures		
5:2:1	0.500	4.2:1.3:1
	0.125	Unable to calculate
10:5:1	0.500	13:9.1:1
20:10:1	0.500	10:5.7:1
	0.125	Unable to calculate
4 Person Mixtures		
5:3:2:1	0.500	Unable to calculate
	0.125	Unable to calculate

Table 19 - 25µL total PCR mixture studies

Mixture Ratio of Sample	Total Input Template (ng)	Approximate Mixture Ratio of Profile
2 Person Mixtures		
1:1	0.500	1.2:1
2:1	0.500	1.8:1
	0.060	1.7:1
5:1	0.500	4.1:1
	0.125	4.8:1
10:1	0.500	8.5:1
	0.125	6.3:1
20:1	0.500	22:1
	0.250	17:1
	0.125	10:1
30:1	0.500	15:1
50:1	0.500	26:1
	0.250	9.2:1
	0.125	6.7:1
3 Person Mixtures		
5:2:1	0.500	2.9:1.5:1
	0.125	2.7:1.1:1
10:5:1	0.500	7.4:5.4:1
20:10:1	0.500	10:6.4:1
	0.125	10:4.7:1
4 Person Mixtures		
5:3:2:1	0.500	Unable to calculate
	0.125	Unable to calculate

7 Conclusion

The results from this validation support that Promega's PowerPlex®21 System is suitable for analysis of STRs.

Despite slight differences observed between the two 3130xl analysers, the use of single LOD and LOR of 16RFU and 40RFU is more practical for use in DNA Analysis.

The PowerPlex21® System displays full concordance with all alleles observed in testing being concordant.

The three national population datasets (Caucasian, Aboriginal and SE Asian) created collaboratively within Australia, have been externally validated and will be implemented in conjunction with STRmix™ for statistical interpretation.

12.5µL total PCR volumes gave higher peak heights than their 25µL counterparts at the same DNA template.

The PowerPlex®21 system is a very sensitive amplification kit when used at either the standard amplification volume (25µL) or reduced volume amplification (12.5µL); however the increased sensitivity does not necessarily result in more reliable information.

The two sensitivity experiments explored the range on DNA template inputs from very large inputs (4ng) to very small inputs (0.00059ng). Within this validation complete PowerPlex® 21 DNA profiles were obtained with as little as 0.01875ng of template DNA. However, the PHR data indicate that as the amount of template DNA decreases the μ_{PHR} decreases and σ_{PHR} increases. The risk of type 2 errors is greatly increased from template DNA amounts of less than 0.132ng for both 25µL and 12.5µL total PCR volumes, which is supported by the experimental drop out data.

The data presented within this report indicates that input templates less than 0.132ng total DNA (concentrations 0.0176ng/µL if using 12.5µL total PCR volume or 0.0088ng/µL for 25µL total PCR volume) may result in increased stochastic effects.

As previously documented in DNA Analysis[45, 46], the Quantifiler™ Human DNA Quantification kit gives an estimate of the DNA concentration. Careful consideration of the DNA profile is required before reporting because the precision within a quantification method and between different quantification methods may vary.

For the range of DNA templates specified above, significant differences between 12.5µL and 25µL total PCR volumes was not observed. The use of 12.5µL total amplification volume as the default protocol with DNA Analysis is indicated. The disadvantage of the 12.5µL total PCR volume are the physical constraints of the process i.e. a maximum of 7.5µL of sample can be used compared with 15µL for the 25µL total PCR volume. However, higher peak heights and the cost savings associated with reduced volume amplifications even with additional processes to increase the sample concentration, mitigate the disadvantage.

The implementation of PowerPlex® 21 for amplification of DNA extracts will coincide with the implementation of STRmix™. The combination of the two processes will apply a continuous biological model rather than a binary model to DNA interpretation. STRmix™ models stutter, drop out, heterozygote balance and homozygote threshold for case work samples.

The rate of drop in events has been calculated for both total PCR volumes and will be implemented in conjunction with STRmix™.

At a total input template of 0.5ng, for 25µL and 12.5µL total PCR volumes, all alleles were detected for the mixtures with ratios of 1:1, 2:1 and 5:1.

For the remaining mixtures with ratios of 10:1, 20:1, 30:1 and 50:1 of varying template levels (maximum 0.5ng), the lower contributors exhibited, sometimes quite marked, stochastic variation.

Mixture interpretation is beyond the scope of this validation and will be dealt with in the STRmix™ validation report.

8 Recommendations

1. A common LOD/LOR (16RFU/40RFU) will be used for both 3130xl instruments as outline in section 6.4.
2. The default total PCR volume will be 12.5µL. Samples can also be amplified at 25µL total PCR volume.
3. Initially samples with concentrations below 0.01ng/µL will not be routinely processed in the first instance. If necessary, these samples may undergo post extraction concentration via centrifugal filter concentration procedure to increase the concentration or re-amplify at 25µL total PCR volume.
4. Initially samples with concentrations between 0.01ng/µL and 0.0176ng/µL will not be routinely amplified. These samples are considered as candidates for post extraction concentration via centrifugal filter concentration procedure to increase the concentration to the point that stochastic effects are minimized.
5. Initially samples with concentrations between 0.0176ng/µL and 0.0244ng/µL will be amplified and assessed for stochastic effects during case management to ensure the suitability of these DNA profiles for reporting.
6. Samples with concentrations above 0.0244ng/µL will be routinely amplified.
7. AI_{TH} to be set at 40% and Hom_{TH} 250RFU for extracted reference, environmental and quality control samples amplified at 12.5µL total PCR volume.
8. AI_{TH} to be set at 45% and Hom_{TH} 200RFU for extracted reference, environmental and quality control samples amplified at 25µL total PCR volume.

9. Adoption of the national Caucasian, Asian and Aboriginal sub-population datasets that DNA Analysis contributed to as part of this validation for use within statistical calculations.
10. Adoption of the locus specific stutter filter as per results section.
11. Thresholds listed in 7 and 8 are to be used as a guidelines when assessing the number of contributors in a mixture.
12. A post implementation review should be performed to review the appropriateness of points 3 – 8. The review will at minimum examine the outcomes of samples amplified within 0.0176ng/µL and 0.0244ng/µL concentration range. Similarly, all of the extracted reference samples will be reviewed with regards to the AI_{TH} and homozygote threshold.

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HSSA | Health Services Support Agency

PowerPlex® 21-Direct Amplification of Reference FTA® samples validation

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Contents

1. Abstract

Since 1998, at DNA Analysis, Forensic and Scientific Services (FSS), in excess of 100,000 reference samples from; Suspects, Offenders and FTA® evidence samples have been processed with the AmpFℓSTR® Profiler Plus® PCR Amplification kit.

All Australian jurisdictions are expected to implement a new DNA profiling kit by the end of 2012.

This validation has demonstrated that the PowerPlex® 21 system is fit for purpose for the direct amplification of FTA® reference samples processed in the DNA Analysis. A limit of reporting threshold of 40RFU and homozygote threshold of 130RFU will be adopted for analysis of reference samples directly amplified

The implementation of this direct amplification method will decrease the time taken to process FTA® samples through more rapid cycling and no sample washing. Without the need for sample washing, the potential for cross contamination through reduction of washing steps and spots jumping wells is reduced.

The crossover of all of the AmpFℓSTR® Profiler Plus® and AmpFℓSTR COfiler® loci and PowerPlex® 21 system loci and the concordance of the kit allow for direct comparison and matching against existing AmpFℓSTR® Profiler Plus® crime scene and reference DNA profiles.

2. Introduction

Since 1998, at DNA Analysis, Forensic and Scientific Services (FSS), in excess of 100,000 reference samples from, Suspects, Serious Offenders and FTA® evidence samples have been processed with the AmpFℓSTR® Profiler Plus® PCR Amplification kit (Life Technologies). Initially reference DNA samples were stored on cloth or swabs then later on specially designed filter paper (FTA® paper) impregnated with chemicals to protect the DNA from microorganisms (1).

To overcome the limitations of the Profiler Plus® kit, after the FTA® cards are punched, they require washing with TE buffer to remove inhibitors prior to PCR amplification. Additionally, cards impregnated with blood require pre-treatment with NaOH to break down the Heme component of blood prior to washing. The method in use at FSS DNA Analysis is to amplify the washed FTA® cards in a 25µL total PCR reaction volume. This process is costly and lengthy takes approximately 60 minutes to wash alone.

To meet Queensland legislative requirements and core business needs, DNA Analysis has validated the PowerPlex® 21 system DNA profiling Kit. All Australian jurisdictions are expected to implement a new DNA profiling kit by the end of 2012. This expectation has been directed by the Australian and New Zealand Police Advisory Agency (ANZPAA) which comprises a Police Commissioner from each jurisdiction.

The PowerPlex® 21 system is a new short tandem repeat (STR) kit made available to the Australian forensic laboratories early in 2012. The kit has all of the nine loci amplified in AmpFℓSTR® Profiler Plus® and an additional 11 loci. Amongst these additional 11 loci are also the loci utilised in the COfiler® kit. Refer to Figure 1 for the loci present in each kit.

One advantage of the PowerPlex® 21 system is the ability to perform direct amplification and amplification from liquid DNA with the same kit. Direct amplification doesn't require washing of the FTA® cards as the multiplex has been optimised to tolerate large amounts of inhibitors without losing sensitivity. Direct amplification is also more time efficient for two reasons, as approximately half of the time required to process FTA® samples with AmpFℓSTR® Profiler Plus® is used in washing the FTA® cards, and the time taken on the thermal cycler is significantly less than AmpFℓSTR® Profiler Plus®.

PowerPlex® 21 System	AmpFℓSTR® Profiler Plus®	AmpFℓSTR® COfiler®
AMEL	AMEL	AMEL
D3S1358	D3S1358	D3S1358
D1S1656		
D6S1043		
D13S317	D13S317	
Penta E		
D16S539		D16S539
D18S51	D18S51	
D2S1338		
CSF1PO		CSF1PO
Penta D		
TH01		TH01
vWA	vWA	
D21S11	D21S11	
D7S820	D7S820	D7S820
D5S818	D5S818	
TPOX		TPOX
D8S1179	D8S1179	
D12S391		
D19S433		
FGA	FGA	

Figure 1 Comparison of loci within the amplification kits used in DNA Analysis

3. Scope and purpose

The purpose of this document is to describe the validation of the PowerPlex® 21 system for direct amplification of FTA® reference samples. This validation describes the experiments performed and the recommendations for processing reference samples and setting of analysis thresholds

4. Materials

The following materials were used within this validation:

- BSD Duet 600 Series II (BSD Robotics, Brisbane, QLD,AU)
- STORstar instrument (Process Analysis & Automation, Hampshire, GB)
- MultiPROBE II PLUS HT EX with Gripper Integration Platform (PerkinElmer, Downers Grove, IL, US)
- 5804 centrifuge (Eppendorf AG, Hamburg, DE)
- Vortex (Ratek Instruments Pty Ltd, Melbourne, VIC, AU)
- Micro centrifuge (Tomy, Tokyo, JP)
- 1.5mL screw-cap tubes (Axygen Inc. Union City, CA, US)
- pipettes (Eppendorf, Hamburg, DE and Thermo Fisher Scientific(Finnpipette), Waltham, MA, US)

- pipette tips (VWR International LLC Radnor, PA, US and Molecular Bioproducts Inc.,San Diego, CA, US)
- 96-well PCR plates(Axygen Inc. Union City, CA, US)
- 2.0mL sterile screw-cap tubes (Axygen Inc. Union City, CA, US)
- plate septas (Axygen Inc. Union City, CA, US)
- adhesive film (QIAGEN, Hilden, DE)
- FTA® collection kits (Whatman™ GE Healthcare, Buckinghamshire, GB)
- Reference positive controls (DNA Analysis, Brisbane, QLD, AU)
- TNE (DNA Analysis, Brisbane, QLD, AU)
- Proteinase K (20mg/mL) (Sigma-Aldrich® Corporation, St Louis, MO, US)
- Dithiothreitol (Sigma-Aldrich® Corporation, St Louis, MO, US)
- Trigene (Medichem International, Kent, GB)
- Ethanol (Recochem Incorporated, Wynnum, QLD,AU)
- Bleach (Ionics Australasia Pty Ltd., Lytton, QLD, AU)
- Amphyl (Rickitt Benckiser Inc. Parsippany, NJ, US)
- Sarcosyl (Sigma-Aldrich® Corporation, St Louis, MO, US)
- Nanopure water (DNA Analysis, Brisbane, QLD, AU)
- Quantifiler™ Human DNA Quantification kits (Life Technologies Applied Biosystems, Foster City, CA, US)
- AB 7500 Real Time PCR System (Life Technologies Applied Biosystems, Foster City, CA, US)
- GeneAmp PCR system 9700 (Life Technologies Applied Biosystems, Foster City, CA, US)
- ABI 3130xl Genetic Analyzer (Life Technologies Applied Biosystems, Foster City, CA, US)
- Hi-Di™ Formamide (Life Technologies Applied Biosystems, Foster City, CA, US)
- 3130 POP-4™ Polymer (Life Technologies Applied Biosystems, Foster City, CA, US)
- Running Buffer (Life Technologies Applied Biosystems, Foster City, CA, US)
- DNA IQ™ Casework Pro Kit for Maxwell® 16 (Promega Corp., Madison, WI, US)
- Promega PowerPlex® 21 system (Promega Corp., Madison, WI, US)
- Promega CC5 Internal Lane Standard 500 (Promega Corp., Madison, WI, US)
- Promega PowerPlex 5 Dye Matrix Standard (Promega Corp., Madison, WI, US)
- Promega PowerPlex® 21 Allelic Ladder Mix (Promega Corp., Madison, WI, US)
- 2800M Control DNA, 10ng/µl (Promega Corp., Madison, WI, US)
- Water amplification grade (Promega Corp., Madison, WI, US)

5. Methods

5.1. Sample selection

All samples used were sourced from either the internal DNA Analysis staff DNA database or reference samples that had the National Criminal Investigation DNA Database (NCIDD) categories of Volunteer Unlimited purpose (VUP) or Suspect (SCT). Permission to use reference samples from NCIDD was obtained from the Queensland Police Service (QPS).

5.2. Collection procedure for FTA® cards

Where staff samples were entirely consumed during processing, additional samples were collected. New FTA® samples were collected using FTA® Collection kits. A foam swab was used to collect buccal cells from each cheek for one minute then applied to the FTA® card. The FTA® card was stored at room temperature until required.

5.3. Punching for extraction

FTA® samples were prepared for extraction by punching four paper spots of 3.2mm diameter into 1.5mL/2mL tubes using the BSD Duet 600 according to standard operating procedure QIS 24823 "FTA® Processing and Work Instructions".

5.4. DNA Extraction

FTA® samples requiring DNA extraction were processed using the DNA IQ™ Casework Pro Kit for Maxwell® 16 according to the standard operating procedure QIS 29344 "DNA IQ™ Extraction using the Maxwell® 16".

5.5. DNA Quantification

All quantification reaction set ups were performed using MultiPROBE II plus HT EX with Gripper integration platform according to the standard operating procedure QIS 19977 "Automated Quantification of Extracted DNA using the Quantifiler™ Human DNA Quantitation Kit"

5.6. FTA® punching method 1

1. PCR Amplification mix was created as required.
2. 25µL or 12.5µL of PCR amplification mix was added to a clean 0.2mL 96 well PCR plate.
3. Plate was sealed and centrifuged to ensure PCR amplification mix was at the bottom of the wells.
4. Each FTA® sample was punched with the 1.2mm diameter die into the 96 well PCR plate using the BSD Duet 600 Series II.
5. 1µL of 2800M control DNA was added to the Positive control well.
6. 1 x 1.2mm punch of a blank FTA® card was added to the blank control well
7. Amplification mix without FTA® card was used as a negative control.
8. The plate was sealed and centrifuged briefly to pull the FTA® cards to the bottom of the plate wells.

5.7. FTA® punching method 2

1. 7.5µL of amplification grade water was added to the required wells.
2. Plate was sealed and centrifuged to ensure the water was at the bottom of the wells.
3. Each FTA® sample was punched with the 1.2mm diameter die into the 96 well PCR plate using the BSD Duet 600 Series II.
4. 1µL of 2800M control DNA was added to the Positive control well.

5. 1 x 1.2mm punch of a blank FTA® card was added to the blank control well
6. PCR Amplification mix without FTA® card was used as a negative control.
7. PCR Amplification mix was created as required and 5µL added to each well required.
8. The plate was sealed and centrifuged briefly to pull the FTA® cards to the bottom of the plate wells.

5.8. Amplification conditions

Table 1 lists the PCR cycling conditions as suggested by Promega (2).

Table 1 PowerPlex 21® PCR cycling conditions

PowerPlex® 21 Kit	Direct amp	Standard
GeneAmp 9700 mode	**Max**	**Max**
	25,26 or 27 cycles	**30 cycles**
Activation	**96°C for 1 minute**	**96°C for 1 minute**
Cycling	**94°C for 10 seconds**	**94°C for 10 seconds**
	59°C for 1 minute	**59°C for 1 minute**
	72°C for 30 seconds	**72°C for 30 seconds**
Extension	**60°C for 20 minutes**	**60°C for 10 minutes**
	4°C Soak	**4°C Soak**

5.9. DNA fragment capillary electrophoresis

Formamide: size standard mixture composed of
[(2.0 µL CC5 ILS 500) x (number of injections)] + [(10.0 µL Hi-Di™formamide) × (number of injections)]

1. Centrifuge plate to remove bubbles
2. Denature @ 95°C for 3 minutes
3. Chill in ice block in freezer for 3 minutes

The conditions recommended by the manufacturer were used for DNA fragment separation preparation below:

Formamide: size standard mixture	12 µL
PCR product or allelic ladder	1 µL

DNA fragment analysis conditions
The PCR fragments were separated by capillary electrophoresis (CE) using a 3130*xl* Genetic Analyzer set up according to manufacturer recommendations. Refer to Table 2.

Table 2 CE conditions

Injection time	Injection voltage	Run time
5s	**3kV**	**1500s**

5.10. Profile interpretation

All DNA profiles were initially analysed with GeneMapper® *ID-X* v1.1.1, using the PowerPlex_21_IDX_v1.0 panel. Thresholds were set as follows:

1. Limit of reporting was set to 50RFU
2. Homozygote threshold was set to 150RFU
3. Individual locus stutter thresholds were set as per Promega PowerPlex Stutter filter (see supplementary data for complete data)

6. Experimental Design

6.1. Direct FTA® amplification 25µL total PCR volume

The PowerPlex® 21 system kit has been developed to directly amplify DNA from an FTA® cards. This experiment tested this by following the manufacturers' standard parameters.
The internal DNA Analysis staff DNA database was previously queried for staff with the most heterozygous DNA profile processed with AmpFℓSTR® Profiler Plus® and AmpFℓSTR COfiler® kits (3). Five donors were selected.
The plate was prepared as in Method 5.6.

1. Figure 2 shows the FTA® plate layout (platemap) for this experiment.
2. 25µL total PCR volume was used
3. Table 3 outlines the volumes required for each reagent, extra reactions were included to account for wastage.
4. Each FTA® sample was punched in duplicate with one and two FTA® paper spot(s) of 1.2mm diameter into the 96 well PCR plate using the BSD Duet 600 Series II.
5. Plate was amplified using 25 PCR cycles.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 5.8, 5.9 & 5.10.

	1	2	3	4
A	Pos Ctl	**Ladder 1**	2-2 spot	**Ladder 2**
B	Neg Ctl	4-1 spot	3-2 spot	Empty
C	1-1 spot	4-1 spot	3-2 spot	Empty
D	1-1 spot	5-1 spot	4-2 spot	Empty
E	2-1 spot	5-1 spot	4-2 spot	Empty
F	2-1 spot	1-2 spot	5-2 spot	Empty
G	3-1 spot	1-2 spot	5-2 spot	Empty
H	3-1 spot	2-2 spot	Blank	Empty

Figure 2 25µL and 12.5µL volume plate maps

Table 3 Amplification mix for direct amplification at 25µL

Components	Vol/rxn	x	N of rxns	=	Final vol
Master Mix	5.0µL	**x**	25	=	125µL
Primer Pair	5.0µL	**x**	25	=	125µL
Water	15µL	**x**	25	=	375µL
Total	**25µL**	**x**	25	=	**625µL**

6.2. Direct FTA® amplification 12.5µL total PCR volume

The experimental design outlined in 6.1 was replicated in this experiment but using a reduced amplification volume.

This experiment tested the PowerPlex® 21 system at a reduced total reaction volume to see if sensitivity is increased and results are comparable to the 25µL total PCR volume.

The plate was prepared as in Method 5.6.

1. Figure 2 shows the FTA® plate map for this experiment.
2. 12.5µL total PCR volume was used
3. Table 4 outlines the volumes required for each reagent, extra reactions were included to account for wastage.
4. Each FTA® sample was punched in duplicate with one and two FTA® paper spot(s) of 1.2mm diameter into the 96 well PCR plate using the BSD Duet 600 Series II.
5. Plate was amplified using 25 PCR cycles.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 5.8, 5.9 & 5.10.

Table 4 Direct amplification PCR mix at 12.5µL

Components	Vol/rxn	x	N of rxns	=	Final
Master Mix	2.5µL	**x**	25	=	62.5µL
Primer Pair	2.5µL	**x**	25	=	62.5µL
Water	7.5µL	**x**	25	=	187.5µL
Total	**12.5**µL	**x**	25	=	**312.5µL**

6.3. PCR cycle variation

Six FTA® reference samples used for the Caucasian dataset experiments (4) were selected based on their first run PowerPlex® 21 DNA profiles. The criteria used were; one no size data (NSD), one low partial DNA profile (PP), one high partial DNA profile (PP),one full DNA profile (OK) one full DNA profile with allelic imbalance (OK AI@AMEL) and one excess DNA profile (XS). The low partial profile sample contained a total of 7 alleles above 50RFU and the high partial profile sample contained 42 alleles above 50RFU with 1 allele not reaching the homozygous threshold of 150RFU.

Initial results from the Caucasian dataset experiments (12.5µL total PCR volume, 25 PCR cycles, one 1.2mm spot) resulted in a high proportion of partial DNA profiles being obtained. This experiment was designed to test a range of those samples at three different PCR cycles to determine the most appropriate PCR cycle number.

Three plates were prepared as in Method 5.6.

1. Figure 3 shows the FTA® platemap for this experiment.
2. 12.5µL total PCR volume was used
3. Table 5 outlines the volumes required for each reagent, extra reactions were included to account for wastage.
4. Each FTA® sample was punched in duplicate with one FTA® paper spot(s) of 1.2mm diameter into the 96 well PCR plate using the BSD Duet 600 Series II.
5. Each plate was amplified at 25, 26 and 27 PCR cycles respectively.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 5.8, 5.9 & 5.10.

	1	2
A	Pos Ctl	**Ladder 1**
B	Blk Ctl	4 -1 spot
C	1 -1 spot	4 -1 spot
D	1 -1 spot	5 -1 spot
E	2 -1 spot	5 -1 spot
F	2 -1 spot	6 -1 spot
G	3 -1 spot	6 -1 spot
H	3 1 spot	Neg Ctl

Figure 3 PCR Cycle variation plate map

Components	Vol/rxn	x	N of rxns	=	Final
Master Mix	2.5µL	x	18	=	45µL
Primer Pair	2.5µL	x	18	=	45µL
Water	7.5µL	x	18	=	135µL
Total	**12.5**µL	x	18	=	**225µL**

Table 5 Direct amplification mix for PCR cycle variation

6.4. FTA® optimisation

The results obtained from the SE Asian Dataset samples (12.5µL total PCR volume, 26 PCR cycles and one 1.2mm spot) resulted in a high proportion of NSD and partial DNA profiles indicating extremely poor amplification. It was unclear as to whether the drop out was a result of too little DNA input, too much DNA input or inhibition from the FTA® cards. This experiment was designed to compare the three different PCR cycles and DNA input range to confirm the optimum conditions.

Ten FTA® samples used previously for the Caucasian dataset experiments (4) were processed with PowerPlex®21. They were selected based on their first run PowerPlex® 21 DNA profiles. The criteria used were, two no size data (NSD), two low partial DNA profiles (PP low), two high partial DNA profiles (PP High), two full DNA profiles (OK), 2x excess DNA profiles (XS).

Three plates were prepared as in Method 5.7. See discussion for explanation of Method 5.7.

1. Figure 4 shows the FTA® platemap for this experiment.
2. 12.5µL total PCR volume was used
3. Table 6 outlines the volumes required for each reagent, extra reactions were included to account for wastage.
4. Each FTA® sample was punched in duplicate with one and two FTA® paper spot(s) of 1.2mm diameter into the 96 well PCR plate using the BSD Duet 600 Series II.
5. Each plate was amplified at 25, 26 and 27 PCR cycles respectively

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 5.8, 5.9 & 5.10.

	1	2	3	4	5	6
A	Pos Ctl	**Ladder 1**	D -1 spot	**Ladder 2**	H -1 spot	**Ladder 3**
B	Neg Ctl	B -2 spot	D -2 spot	F -1 spot	H -1 spot	J -1 spot
C	A -1 spot	B -2 spot	D -2 spot	F -2 spot	H -2 spot	J -1 spot
D	A -1 spot	C -1 spot	E -1 spot	F -2 spot	H -2 spot	J -2 spot
E	A -2 spot	C -1 spot	E -1 spot	G -1 spot	I -1 spot	J -2 spot
F	A -2 spot	C -2 spot	E -2 spot	G -1 spot	I -1 spot	Empty
G	B -1 spot	C -2 spot	E -2 spot	G -2 spot	I -2 spot	Empty
H	B -1 spot	D -1 spot	F -1 spot	G -2 spot	I -2 spot	Empty

Figure 4 FTA optimisation plate map

Table 6 Direct amplification mix for FTA® optimisation at 12.5µL

Components	Vol/rxn	x	N of rxns	=	Final
Master Mix	2.5µL	x	45	=	112.5µL
Primer Pair	2.5µL	x	45	=	112.5µL
Total	**12.5**µL	x	45	=	**225µL**

6.5. Drop out

This experiment was designed to replicate real conditions that would ne encountered when performing direct amplification on FTA® cards; i.e. potential inhibition from the FTA® card. A dilution series of the Promega Positive control (2800M DNA) was created (see table 7) with each dilution added to a well containing a blank FTA® card. Three plates were created and amplified at 25, 26 and 27 cycles, respectively, to assess the number of drop out events. The 2800M DNA was used as its profile was known and it is heterozygous at all PowerPlex® 21 Loci except CSF1P0, D5S818 and TPOX loci (2)

The plate was prepared as in Method 5.7.

1. Figure 5 shows the FTA® platemap for this experiment.
2. Table 7 outlines the dilution series of the positive amplification control 2800M DNA.
3. 12.5µL total PCR volume was used
4. Table 8 outlines the volumes required for each reagent, extra reactions were included to account for wastage.
5. Each well containing the diluted positive control had a one 1.2mm spot blank FTA® card added using the BSD Duet 600 Series II.
6. 1 µL of each of these dilutions was added to the PCR plate
7. 1µL of 2800M control DNA was added to the Positive control well.
8. Negative control was amplification grade water.
9. The Plate was amplified using 25, 26 and 27 PCR cycles.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 5.8, 5.9 & 5.10.

	1	2
A	Pos	**Ladder 1**
B	Neg	0.2ng
C	10ng	0.2ng
D	10ng	0.1ng
E	5ng	0.1ng
F	5ng	0.05ng
G	1ng	0.05ng
H	1ng	BLANK

Figure 5 Drop out plate map

Table 7 Dilution series of 2800M DNA

Total DNA (ng)
10
5
1
0.2
0.1
0.05

Table 8 Direct amplification mix for drop out at 12.5µL

Components	Vol/rxn	x	N of rxns	=	Final
Master Mix	2.5µL	**x**	16	=	40µL
Primer Pair	2.5µL	**x**	16	=	40µL
Total	**12.5**µL	**x**	16	=	**80µL**

6.6. Drop out 2

In this experiment, results obtained for samples processed at 25 PCR cycles and 26 PCR cycles were analysed to determine the threshold when an allele most frequently drops out.

79 partial DNA profiles (from the Project#101, Caucasian plate 1 and 2) (2) were reanalysed using the thresholds calculated in 6.9, 6.10, 6.11 and 6.12. The data analysis involved counting how many of the 79 samples had one remaining allele of a heterozygote pair (this was counted as 1 drop out event) and noting the peak height of this allele. Homozygote peaks were excluded from the data analysis. A plot of the number of dropout events against peak height in category windows of 20RFU was created.

6.7. Drop out 3

In this experiment, all results available for samples processed at 25 PCR cycles and 26 PCR cycles were analysed to determine which loci drop out events are likely to occur.

205 samples processed using one 1.2mm FTA® spot, 25 PCR cycles and 12.5µL amplification reactions were analysed to determine how many times two, one and zero alleles at each locus occurred.
470 samples processed using one 1.2mm FTA® spot, 26 PCR cycles and 12.5µL amplification reactions were analysed to determine how many times two, one and zero alleles at each locus occurred.
Excess samples and no size data were excluded from both sets of data.

6.8. Concordance testing

This experiment was designed to test if all alleles called in PowerPlex® 21 are concordant with AmpFℓSTR® Profiler Plus® and AmpFℓSTR COfiler® loci. The PowerPlex® 21 kit was tested for concordance by amplification of completed Collaborative Testing Services (CTS) proficiency tests. CTS do not publish allele data for D1S1656, D12S391 and D6S1043 loci. These were excluded from the analysis. Forty four samples from previous CTS Proficiency tests with observed high heterozygosity were used for this experiment.
Whilst four of the samples were initially included in this experiment, testing could not be completed due to insufficient DNA extract. Therefore they were excluded on that basis.
Two of the samples had DNA extraction and DNA quantification performed as per Methods 5.3, 5.4 & 5.5.
The remaining 38 samples had DNA extracts after previously being processed.

1. Amplification of these samples was performed using the standard protocol as per Table 3.
2. The total PCR reaction volume was 25µL.

6.9. Baseline determination

To determine the limit of reporting and homozygote thresholds the baseline (background) must be assessed.

107 reference samples used for Population Datasets (4) were used for the baseline calculations. These samples were all amplified with one x 1.2mm FTA® card spot at 12.5µL final PCR reaction volume at 26 PCR cycles.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 5.8, 5.9 & 5.10.

Samples were analysed at 1RFU This experiment was designed to test if all alleles called in PowerPlex® 21 are concordant with AmpFℓSTR® Profiler Plus® and AmpFℓSTR COfiler® loci. The PowerPlex® 21 kit was tested for concordance by amplification of completed Collaborative Testing Services (CTS) proficiency tests. CTS do not publish allele data for D1S1656, D12S391 and D6S1043 loci. These were excluded from the analysis.
The average peak height RFU (μ_{Pk}) for each dye channel was calculated using the AVERAGE function (Arithmetic mean) in Microsoft Excel. The standard deviation (σ_{Pk}) was calculated using the STDEV function in Microsoft Excel.

6.10 Stutter threshold

To confirm if the stutter thresholds obtained from Promega agree with the observed data.
355 reference samples from six of the Population Dataset experiments (4) were reanalysed at 20RFU with the stutter thresholds in GeneMapper ID-*X* v1.1.1 set to zero. Alleles where the sister allele fell into the stutter position and where the two main alleles were one repeat apart were excluded from analysis.

The stutter ratio (SR) was calculated for each locus as per Equation 1:

Equation 1

$$SR = E_S \ / \ E_A$$

SR = Stutter Ratio, Es = Stutter Height, E_A = Allele Height
The stutter threshold (ST) for each locus was calculated as per Equation 2.

Equation 2

$$ST = \mu_{SR} + 3\,\sigma_{SR}$$

ST = Stutter threshold, µSR = average stutter ratio, σSR = standard deviation of stutter ratio

6.11 Allelic imbalance threshold and peak height ratio

Peak height ratios (PHR) for heterozygote loci were determined by dividing the lower peak height (LPH) by the higher peak height (HPH). Any samples with one repeat difference and homozygote peaks were excluded from analysis.

Equation 3

$$PHR = LPH/HPH$$

PHR = peak height ratio, LPH = lower peak height, HPH = higher peak height

Equation 4

$$AI_{TH} = \mu_{PHR} - 3\sigma_{PHR}$$

AI_{Th} = Allelic imbalance threshold, μ_{PHR} = overall average PHR & σ_{PHR} = standard deviation of the PHR.

The average PHR for each locus was plotted against the locus

6.12 Thresholds

Thresholds were calculated as follows:

The limit of detection (LOD) was calculated from Equation 5.

Equation 5

$$LOD = \mu_{PK} + 3\sigma_{PK}$$

The limit of reporting (LOR) (5) also known as the Analytical Threshold (AT) was calculated from equation 6.

Equation 6

$$LOR = \mu_{PK} + 10\sigma_{PK}$$

The homozygote threshold is the threshold above which you can be confident that a heterozygote locus will not be incorrectly called as a homozygote locus. It was calculated using the following methods.

Method 1 – As previously described (6) and illustrated below:

Equation 7

$$Th_{Hom} = LOR \times \frac{1}{AI_{Obs}} \times 2$$

The LOR used for this calculation was in 6.9 and the AI_{Obs} was determined in 6.10.

Method 2 – As described in the Promega Internal Validation guidelines (7) determined from a plot of the allelic imbalance vs the lower RFU. The homozygote threshold is assigned at the point at which there is a rapid drop off in peak height ratio.

Method 3 – Modified method as described in the presentation by Word (8). A plot of the allelic imbalance vs Higher RFU is used instead of the lower RFU. The homozygote threshold is assigned at the point at which there is a rapid drop off in peak height ratio.

7. Results

7.1. Direct FTA® amplification 25µL total PCR volume

The results for the direct FTA™ amplification with a total volume of 25µL is summarised in table 9. The average number of alleles varied across the 5 samples. Sample 2 and 5 displayed a lower number of average alleles and lower average peak heights compared to samples 1, 3 and 4 for both the 1 spot and 2 spot results. The average peak height ratio was consistent across all 5 samples for both the 1 spot and 2 spot results. Figure 6 shows the average peak height and average peak height ratio for each locus for both the 1 spot and 2 spot punches amplified with a total volume of 25µL.

Table 9 Summary of direct FTA™ amplification 25µL total PCR volume

	Av # Alleles	Av pk height (RFU)	Av Max pk Height	Av Min peak height	Av PHR %
Sample 1_1spot	42	651	982	325	93
Sample 2_1spot	13.5	62	73	39	93
Sample 3_1spot	41	181	304	90	93
Sample 4_1spot	41	146	253	65	90
Sample 5_1spot	23.5	70	111	51	94
Overall # alleles	32.2				
Overall av pk height		222			
Sample 1_2spot	42	383	744	184	91
Sample 2_2spot	37.5	213	475	55	93
Sample 3_2spot	42	476	365	121	94
Sample 4_2spot	42	364	652	199	93
Sample 5_2spot	41	168	409	86	92
Overall # alleles	40.9				
Overall av pk height		321			

7.2. Direct FTA® Amplification 12.5µL total PCR volume

The results for the direct FTA™ amplification with a total volume of 12.5µL is summarised in table 10. Sample 3 did not display a profile above the thresholds used for this experiment resulting in no results. The other 4 samples all displayed the same average number of alleles, which was a full complement of alleles across all loci. The average peak height ratio was also consistent across these 4 samples. Figure 7 shows the average peak height and average peak height ratio for each locus for both the 1 spot and 2 spot punches amplified with a total volume of 12.5µL. Figure 8 compares the average peak heights and average peak height ratios at each loci for 25µL and 12.5µL total amplification volumes. Figure 9 compares the average peak height and average peak height ratios of 1 spot and 2 spot punches amplified with a total volume of 25µL and 12.5µL.

Table 10 Summary of direct FTA® Amplification 12.5µL total PCR volume

	Av # Alleles	Av pk height (RFU)	Av Max pk Height	Av Min peak height	Av PHR %
Sample 1_1spot	42	1092	1765	439	93
Sample 2_1spot	42	352	740	194	92
Sample 3_1spot	0	0	0	0	0
Sample 4_1spot	42	582	938	253	93
Sample 5_1spot	42	265	540	151	92
Overall # alleles	33.6				
Overall av pk height		458			
Sample 1_2spot	42	1785	3164	762	93
Sample 2_2spot	40.5	1575	3836	652	90
Sample 3_2spot	0	0	0	0	0
Sample 4_2spot	42	764	1354	428	91
Sample 5_2spot	0	0	0	0	0
Overall # alleles	24.9				
Overall av pk height		825			

The results for the comparison of direct FTA® amplification 25µL and 12.5µL total PCR volume are summarised in Figures 8 & 9 below:

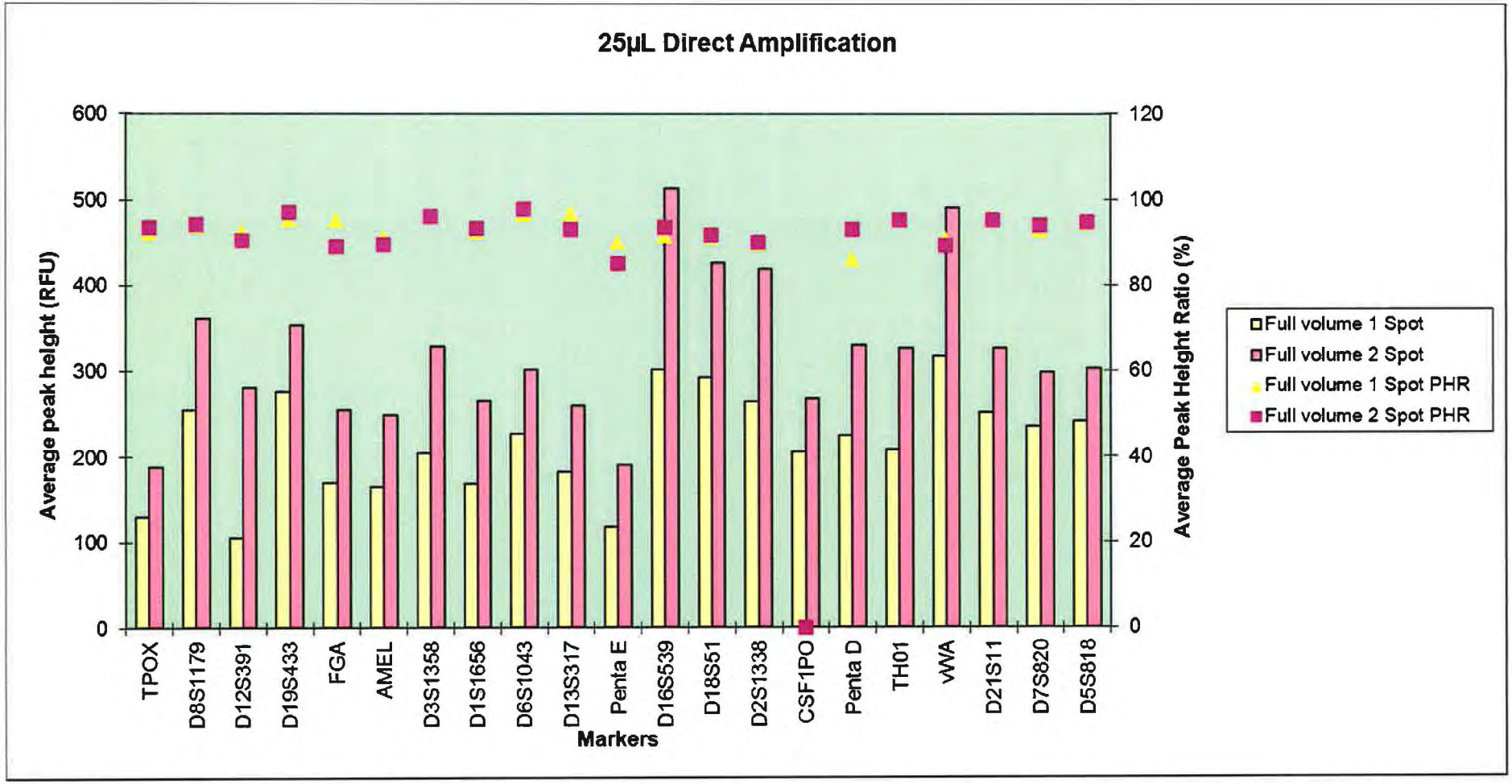


Figure 6 Direct FTA® amplification 25µL total PCR volume, average locus peak heights and peak height ratio. PHR = Peak height ratio. Full volume = 25µL

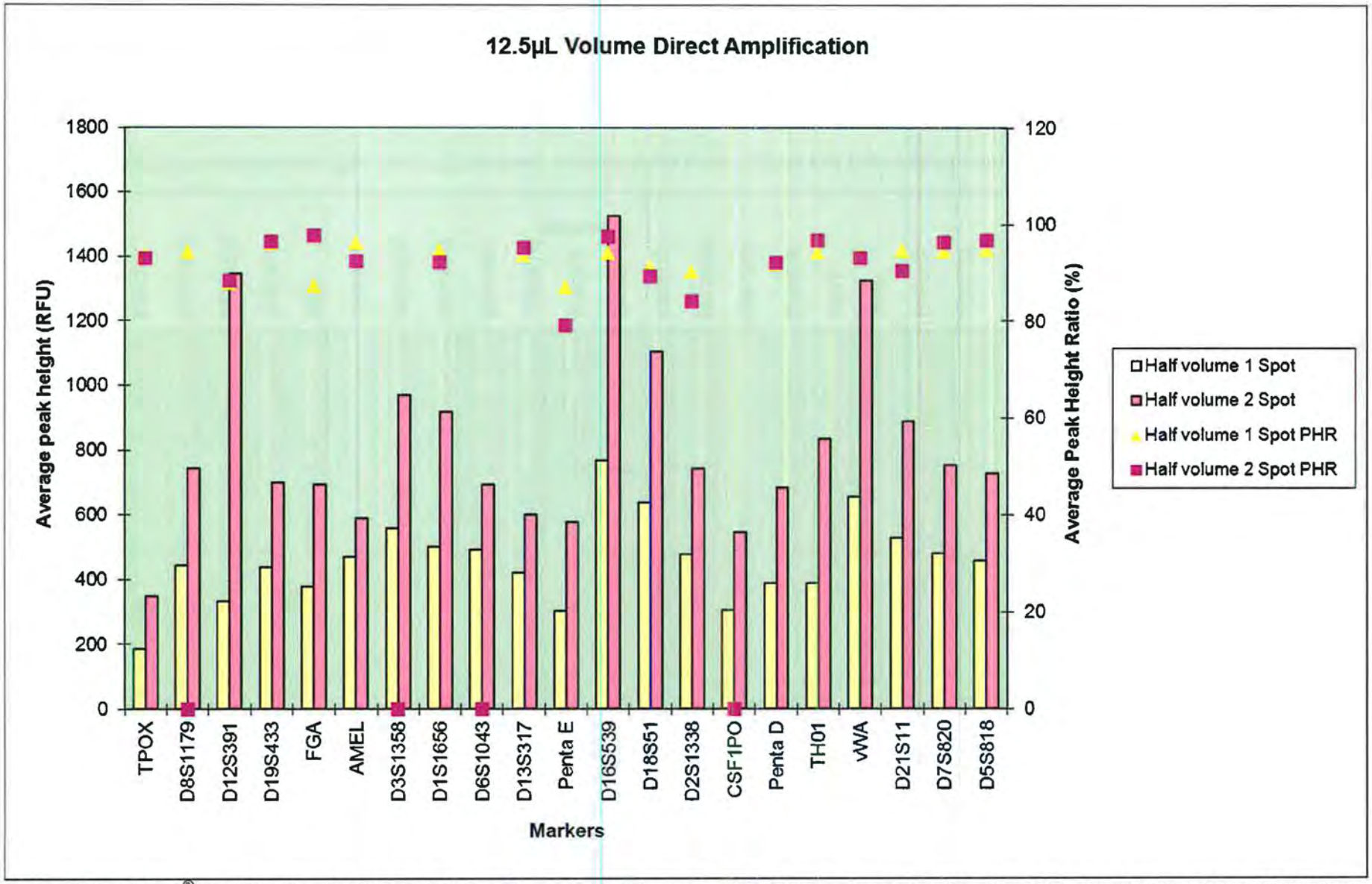


Figure 7 Direct FTA® amplification 12.5µL total PCR volume, average locus peak heights and peak height ratio. PHR = Peak height Ratio. Half volume = 12.5µL

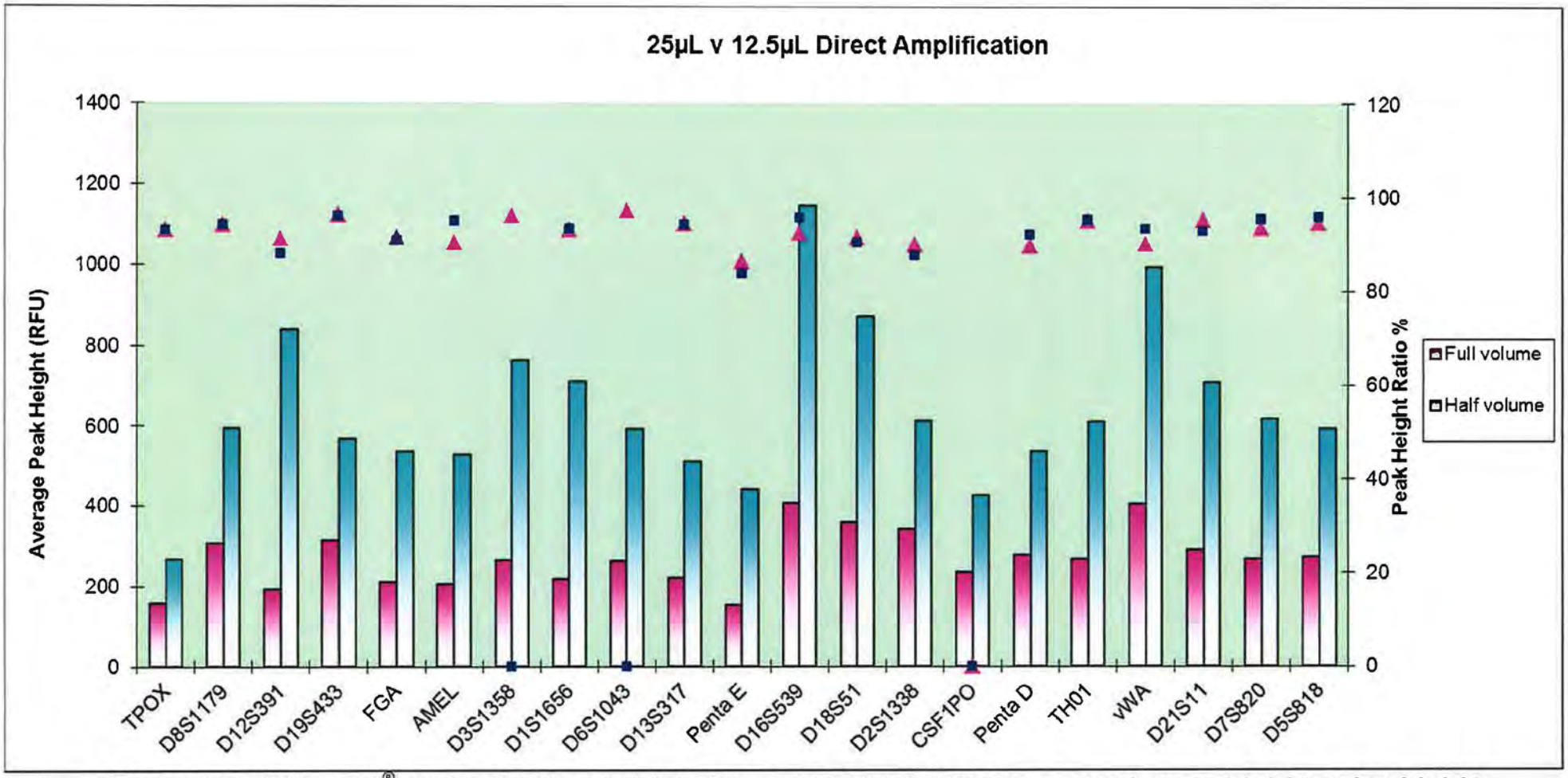


Figure 8 Comparison of Direct FTA® amplification 25µL total PCR volume vs 12.5µL total PCR volume, average locus peak heights and peak height ratio. Full = 25µL and Half = 12.5µL.

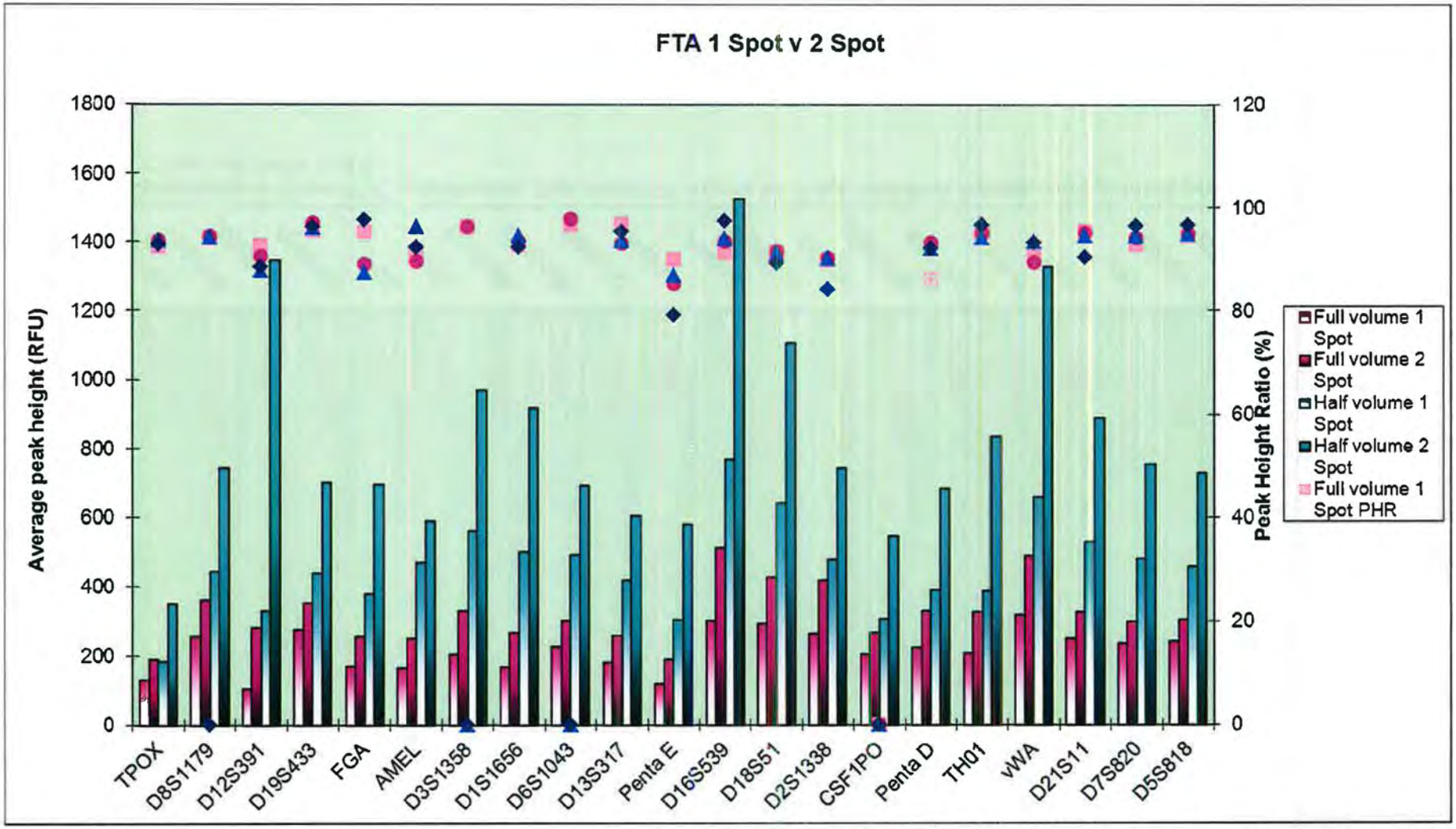


Figure 9 Comparison of 1 x 1.2mm spot vs 2 x 1.2mm spot, average locus peak height and peak height ratio. Full = 25µL and Half = 12.5µL. PHR = Peak height Ratio

7.3. PCR cycle variation

The results of the PCR cycle variation using 1 FTA™ spot and 12.5µL total amplification volume is summarised in table 11. The positive control showed as the cycle number increased the average peak height also increased. The NSD sample showed 27 cycles produced a higher average number of alleles and higher average peak heights compared to 25 and 26 cycles. Figure 10 shows the average peak height and average peak height ratio for each locus. This shows samples processed using 25 and 26 cycles have comparable average peak heights but the average peak height ratio is more consistent for 26 cycles. The samples processed at 27 cycles showed higher average peak heights with consistent peak height ratios.

Table 11 Summary of PCR cycle variation. PHR = Peak Height Ratio

Sample	Cycles	Average # Alleles	Average pk height (RFU)	Average Maximum pk height	Average Minimum peak height	Average PHR %
Positive Control	25	42	1169	3093	425	94
	26	42	2725	6636	1821	95
	27	42	5122	9689	2720	94
511920835 Just PP	25	42	227	648	102	93
	26	37	286	1061	50	89
	27	42	512	1472	206	91
511920744 Al@Amel	25	42	1330	4366	617	88
	26	42	2494	7376	61	88
	27	42	2584	7501	56	86
511920452 Very PP	25	42	1907	6356	1321	94
	26	42	1820	8696	330	93
	27	21	3499	8857	63	92
511921673 OK	25	41.5	213	887	80	91
	26	42	553	1999	248	92
	27	42	956	2522	425	90
511922527 NSD	25	19	67	161	51	80
	26	11	69	125	52	61
	27	31	667	2030	50	80
511921955 XS	25	42	1946	7164	450	92
	26	42	1181	3708	501	94
	27	42	2768	8647	66	87

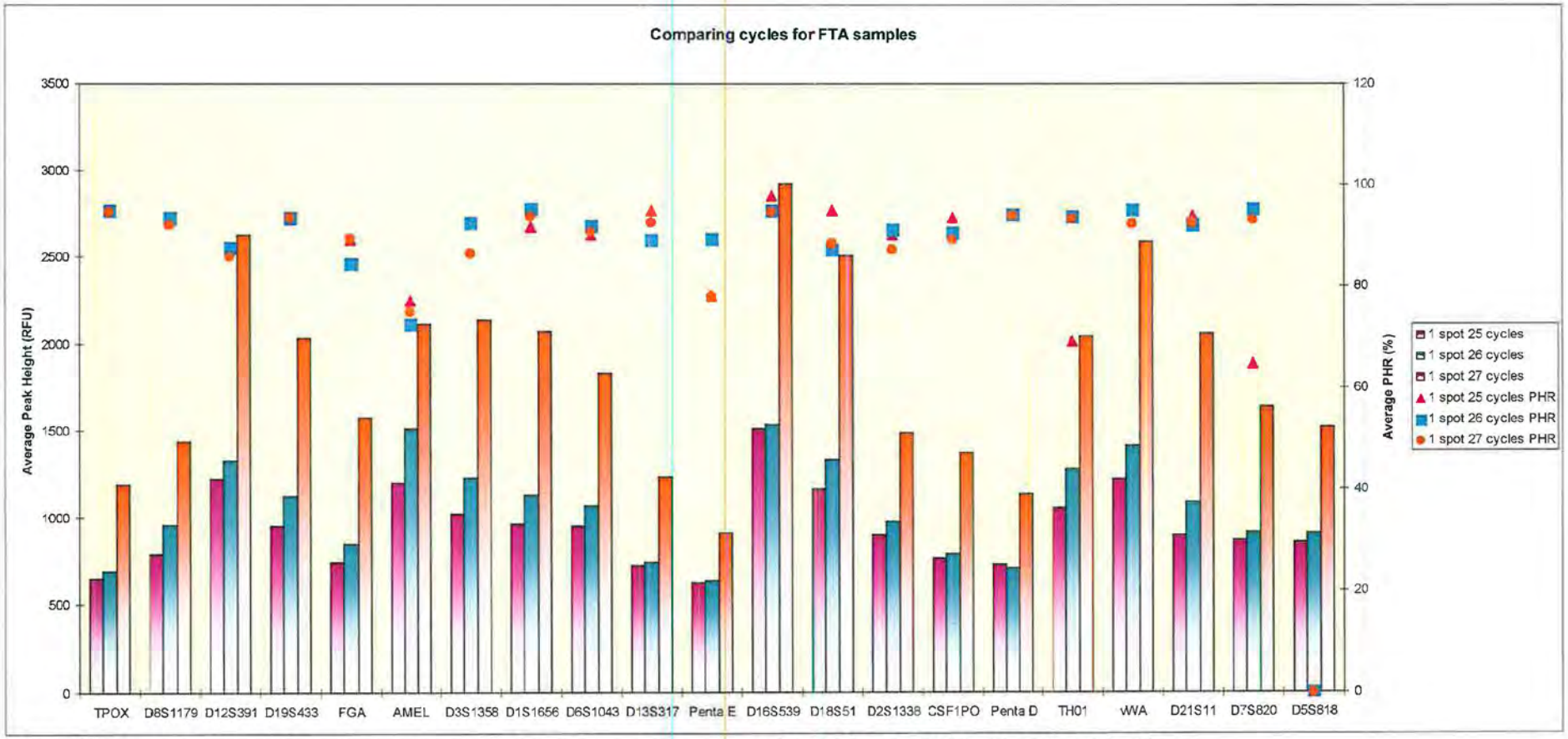


Figure 10 Comparison of PCR cycles, average peak height and average peak height ratio. PHR = Peak height ratio.

7.4. FTA® processing optimisation

The results of the optimisation experiment are listed in Table 12. Analysis method 1 had a LOR of 50 and Th_{Hom} as 150, Analysis Method 2 had a LOR of 40 and Th_{Hom} as 130. The results show there is a variance not only based on PCR cycle but also where the FTA™ card is punched as each of the duplicates gives a different result.

Table 12 FTA® processing optimisation, Comparison of alleles called for varied PCR cycles & analysis thresholds

		Analysis Method 1		Analysis Method 2	
		A	B	A	B
			Alleles called		
Sample 1	25	0	0	0	0
	26	0	0	0	0
	27	0	1	0	1
Sample 2	25	0	0	0	1
	26	0	0	0	0
	27	0	9	0	16
Sample 3	25	36	5	37	7
	26	19	34	26	36
	27	28	35	34	39
Sample 4	25	21	23	24	26
	26	29	36	30	40
	27	40	34	40	36
Sample 5	25	0	6	0	9
	26	0	0	0	1
	27	18	22	21	22
Sample 6	25	4	5	9	13
	26	24	3	27	9
	27	19	27	23	29
Sample 7	25	40	40	40	40
	26	40	40	40	40
	27	40	40	40	40
Sample 8	25	39	40	39	40
	26	40	40	40	40
	27	40	40	40	40
Sample 9	25	XS	NAD	XS	NAD
	26	XS	XS	XS	XS
	27	NAD XS	NAD XS	NAD XS	NAD XS
Sample 10	25	PA XS	PA XS	PA XS	PA XS
	26	PA XS	PA XS	PA XS	PA XS
	27	39*	PA XS	39*	PA XS

* Sample displayed PA XS

7.5. Drop out

The results obtained from the drop out experiments are shown in Figures 11 -13 as heat maps.

The heat maps show the PowerPlex 21 system is a balanced kit and indicates all or nothing in relation to drop out. The dilutions at 25 cycles had 7 drop out events, at 26 cycles there were 4 events and at 27 cycles there were 11 events.

Locus dropout
XX Allele dropout (surviving allele RFU)
Complete heterozygous locus
Homozygous locus

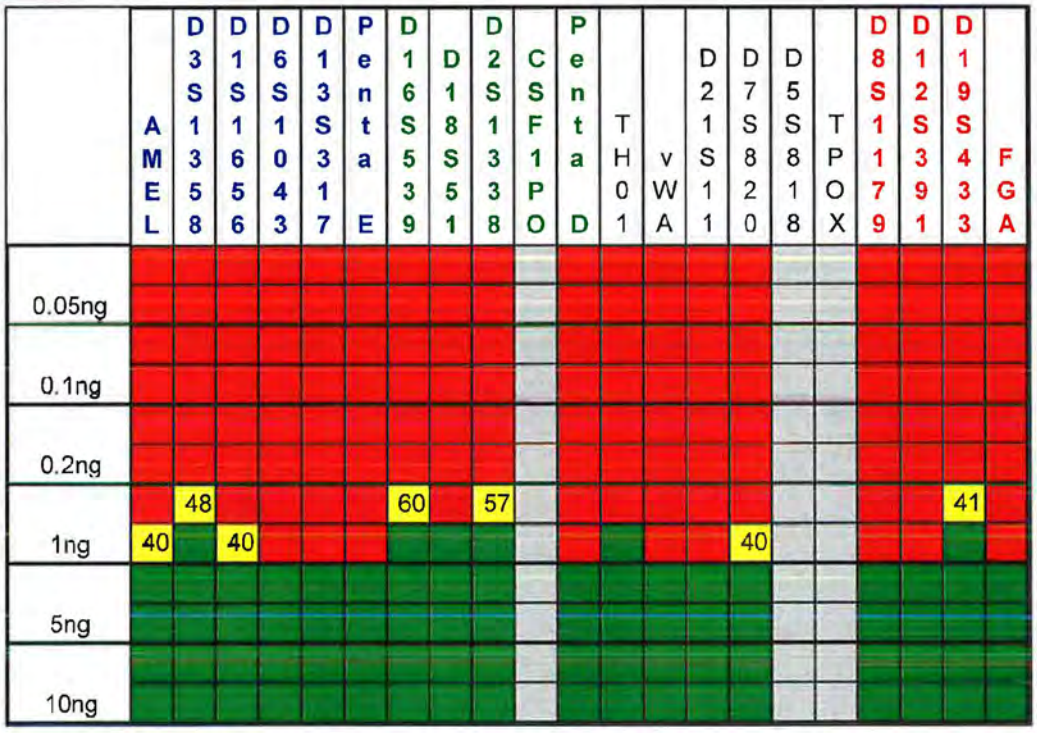


Figure 10 PowerPlex 21® system 25 PCR cycles Heat Map Positive control dilution

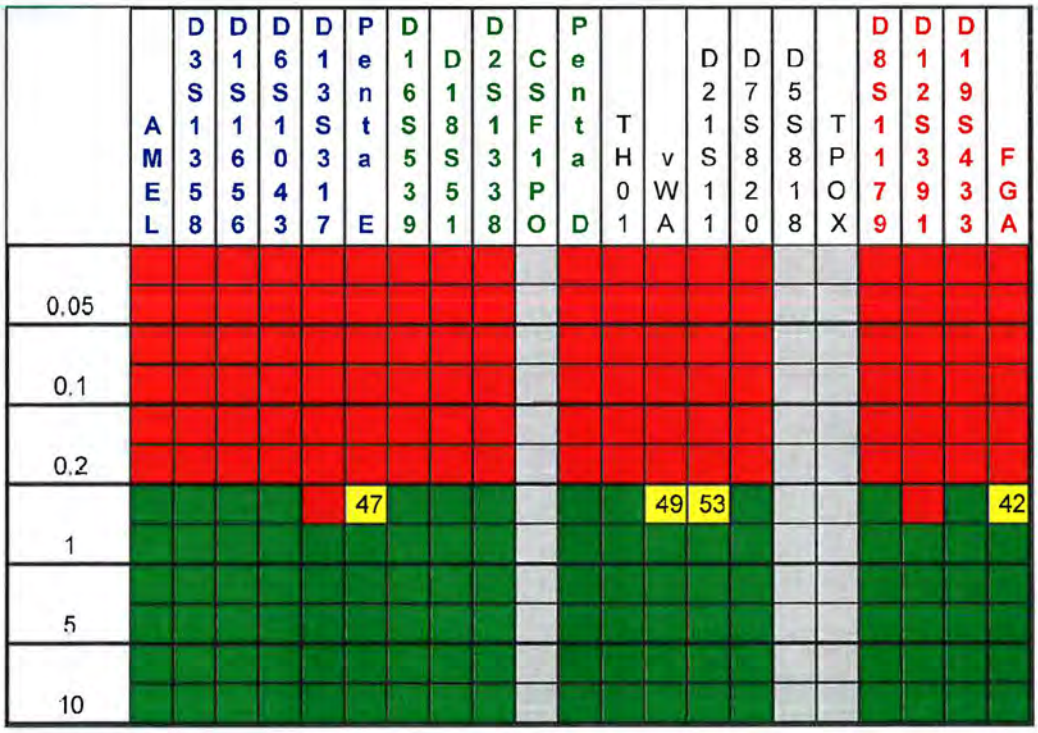


Figure 112 PowerPlex 21® system 26 PCR cycles Heat Map Positive control dilution

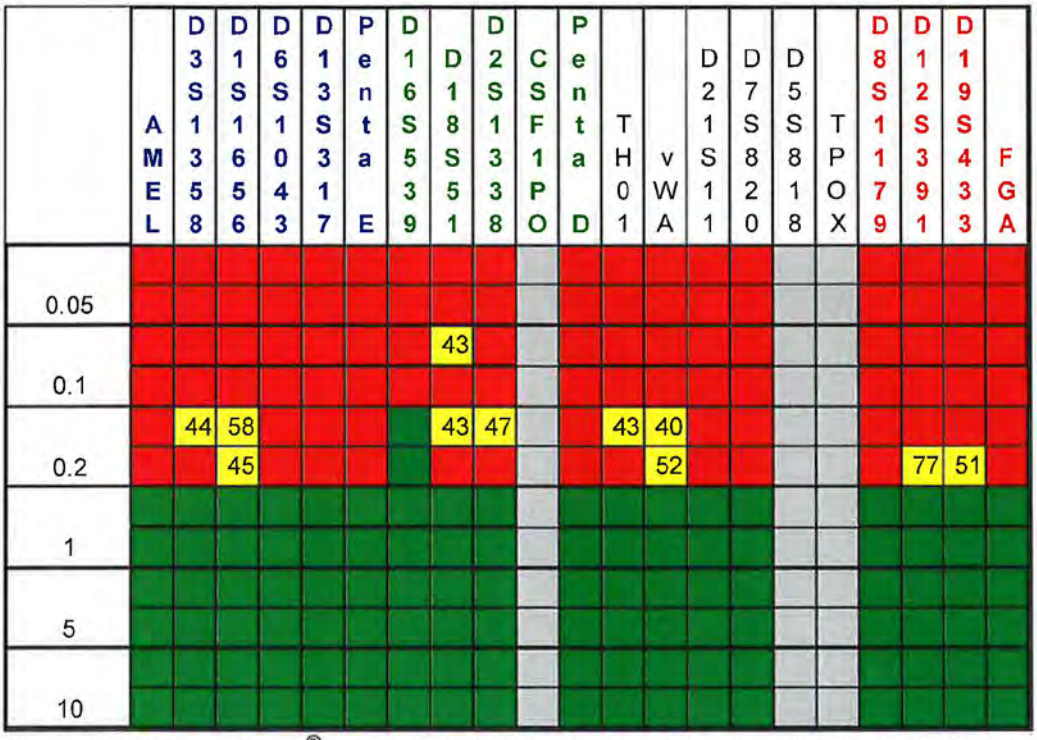


Figure 123 PowerPlex 21® system 27 PCR cycles Heat Map Positive control dilution

7.6. Drop out events 2

The results for drop out events 2 are summarised in figure 16. This showed there were a larger number of drop out events at 25 cycles compared to 26 cycles. The majority of the drop out events occurred within the 40-59 RFU range.

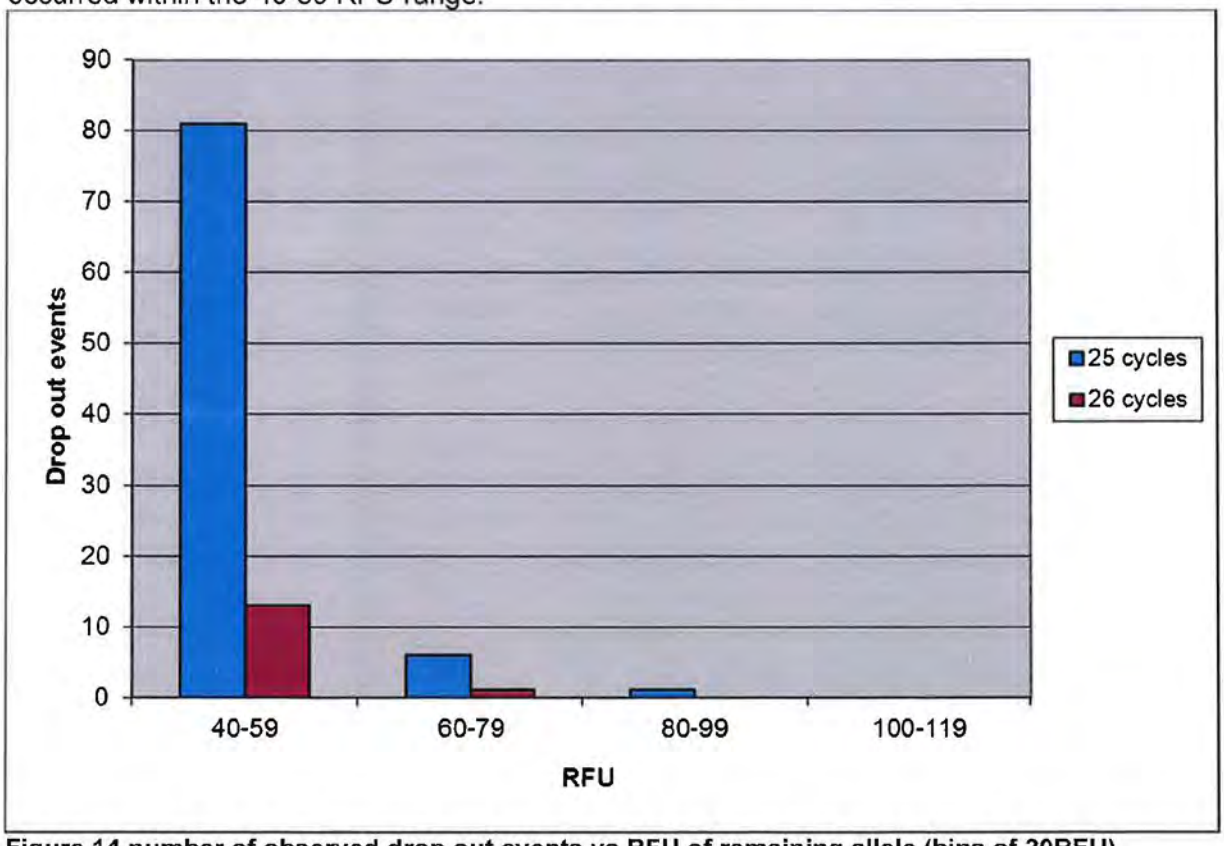


Figure 14 number of observed drop out events vs RFU of remaining allele (bins of 20RFU)

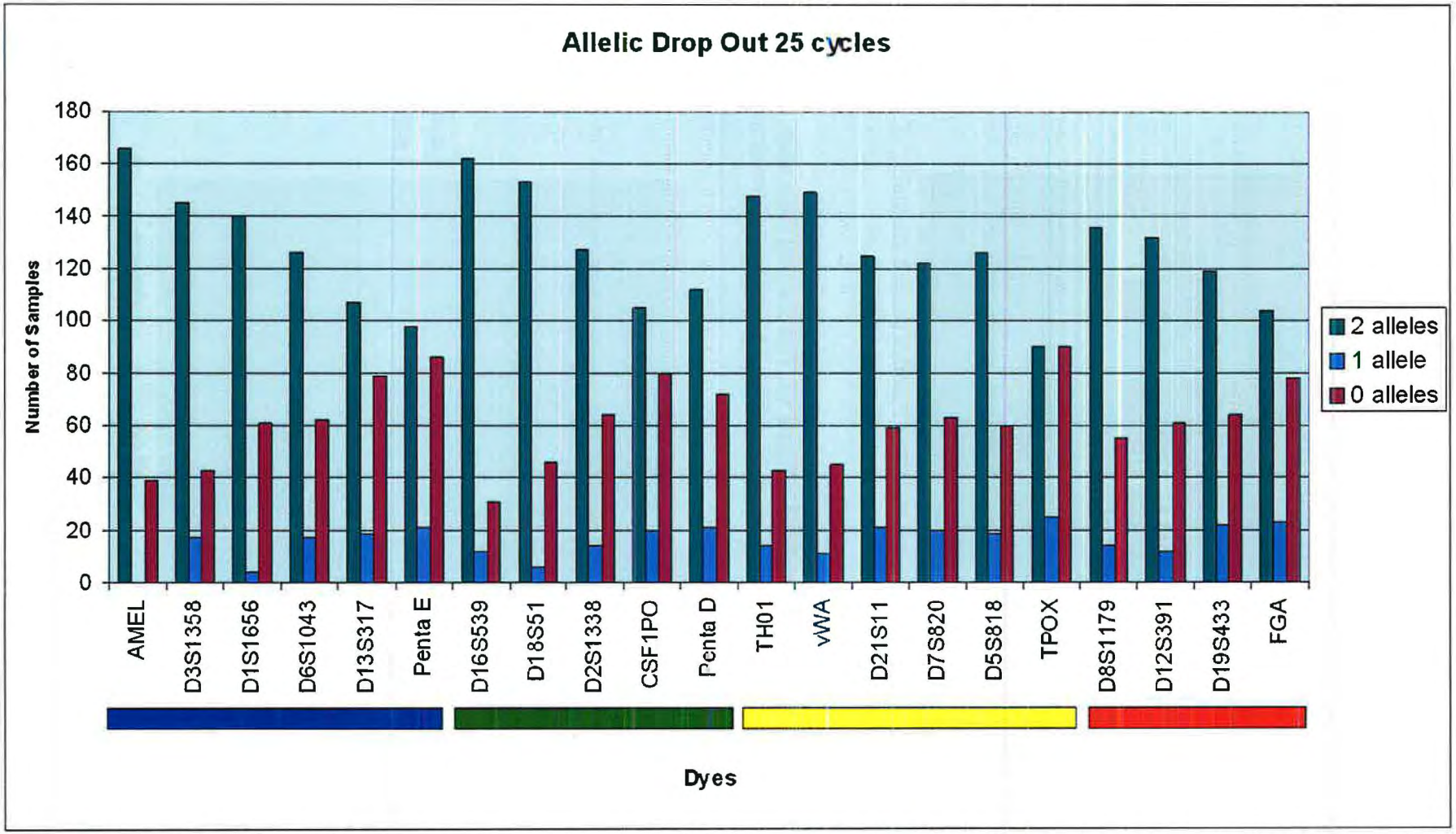


Figure 15 Observed number of alleles, partial drop out events and whole drop out events per locus for samples processed using 25 PCR cycles

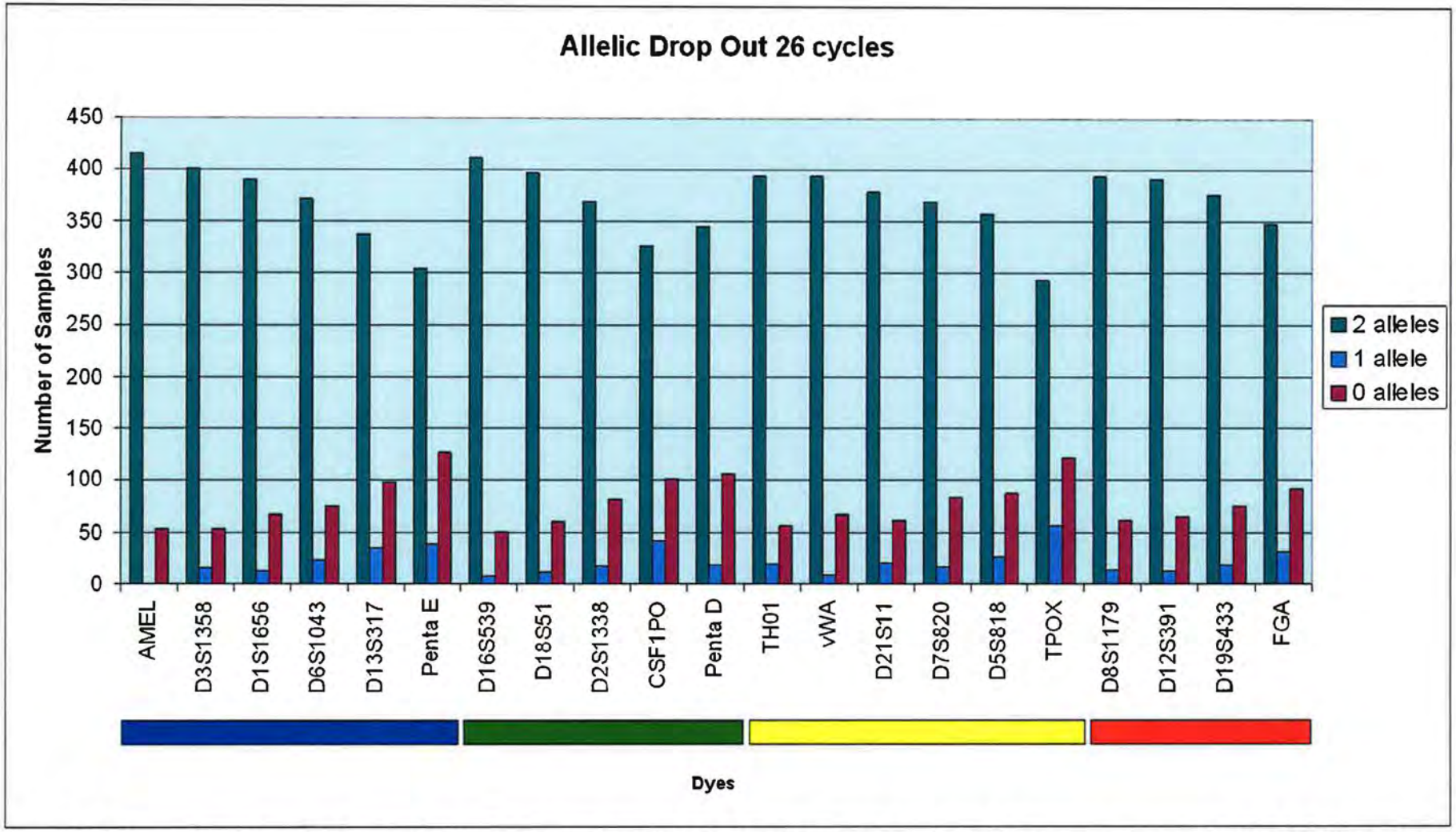


Figure 136 Observed number of alleles, partial drop out events and whole drop out events per locus for samples processed using 26 PCR cycles

7.7. Drop out 3

The results for drop put events 3 are displayed in figures 15 and 16. Figure 15 shows the drop out events for all FTA samples processed with 1 spot at 25 cycles. Figure 16 shows the drop out events for all FTA samples processed with 1 spot at 26 cycles.

7.8. Concordance

All samples (number of alleles = 1500) tested were found to be concordant to the CTS reported DNA profiles. Table 13 displays the number of times a particular allele was seen at each locus.

Table 13 observed number of allele concordances

Allele Size	D3	D13	Penta E	D16	D18	D2S	CSF1PO	Penta D	TH01	vWA	D21	D7	D5	TPOX	D8	D19	FGA
2.2								3									
5			9					2									
6									8					3			
7			9				1	2	29			5	3	1			
8		8	11	1			3	2	9			19	2	37	1		
9		8	1	10			2	19	18			15	7	17	3		
9.3									22								
10		2	9	4			19	15				20	10	4	3		
11		23	7	29	1		27	15				16	21	20	10	1	
12	1	26	9	23	6		31	11				7	28	4	16	13	
12.2																1	
13	1	11	8	17	10		3	13				4	13		20	25	
13.2																1	
14	13	8	2	2	11			3		10			2		20	19	
14.2																6	
15	21		5		19	1		1		12					10	13	
15.2																5	
16	22		6		14	3				19					3	2	
17	19		4		13	15				13							
18	8		4		6	5				24							3
19	1		1		4	13				6							5
20			1		1	12				2							5
21					1	9											13
22						8											14
22.2																	1
23						9											16
24						7											18
25						4											6
26											1						3
27																	1
28											18						1
29											11						
29.2											1						
29.3											1						
30											18						
30.2											5						
31											9						
31.2											6						
32											1						
32.2											7						
33.2											6						
35											2						

7.9. Baseline

The results of the baseline calculations are summarised in Table 14

Table 14 Summary of baseline results. The mean RFU is similar across all dye channels with TMR displaying the highest value. The JOE channel displays the highest standard deviation.

	Fluorescin (Blue) Samples (RFU)	JOE (Green) Samples (RFU)	TMR (Yellow) Samples (RFU)	CXR (Red) Samples (RFU)	CC5 (Orange) Samples (RFU)
μ_{Pk}	2	3	5	2	2
Max_{Pk}	112	121	56	65	14
Min_{Pk}	1	1	1	1	1
σ_{Pk}	2.6	3.5	2.3	1.4	1

Notes:

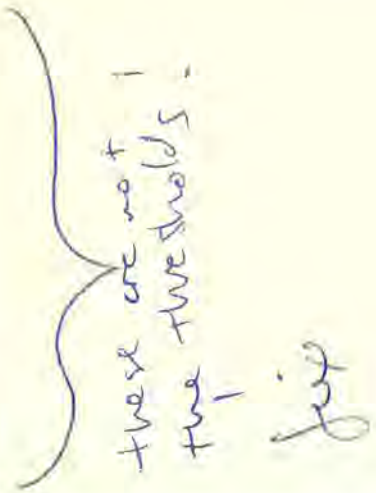
- Max value in blue due to D3[10] (possible) artefact more commonly seen in reference plates than in casework plates. D3 artefacts also seen at D3[8] and D3[9].
- Max value in green at 72bp prior to marker range. In samples with high RFU values, green dye has excess florescence in the 60-95bp range.

7.10. Stutter Threshold

The data for the observed stutter ratios (forward and over) are listed below in Table 15. For several loci, over stutter was not observed in the sample set used. Refer to the supplementary data for complete stutter information.

Table 15 Summary of observed mean locus specific stutter, mean over stutter and standard deviations. All results fell below the stutter thresholds given by Promega except for D1S1656 (15.5%) and D21S11 (15.2%).

	μ_{SR}	ST	μ_{OSR}	ST
D3S1358	0.0737	0.1113	0.0079	0.0
D1S1656	0.0808	0.1549	0.0138	0.0
D6S1043	0.0548	0.0859	0.0094	0.0
D13S317	0.0430	0.0920	0.0073	0.0
Penta E	0.0397	0.0867	0.0208	0.1
D16S539	0.0560	0.1008	0.0097	0.0
D18S51	0.0752	0.1371	0.0095	0.0
D2S1338	0.0739	0.1159	0.0102	N/A
CSF1PO	0.0484	0.0897	0.0105	0.0
Penta D	0.0155	0.0328	N/A	N/A
TH01	0.0250	0.0483	0.0064	0.0
vWA	0.0650	0.1305	0.0173	0.1
D21S11	0.0748	0.1524	0.0162	0.0
D7S820	0.0428	0.1036	0.0244	0.1
D5S818	0.0511	0.0958	0.0324	N/A
TPOX	0.0284	0.0647	N/A	N/A
D8S1179	0.0691	0.1148	0.0128	0.0
D12S391	0.0828	0.1537	0.0079	0.0
D19S433	0.0579	0.0988	N/A	N/A
FGA	0.0584	0.1041	0.0040	N/A



7.11. Allelic Imbalance threshold and Peak Height Ratios

The summary of the peak height data for each locus is listed below in Figure 17. Table 16 summarises the average and standard deviations for all data combined. Refer to Supplemental data for complete PHR data.

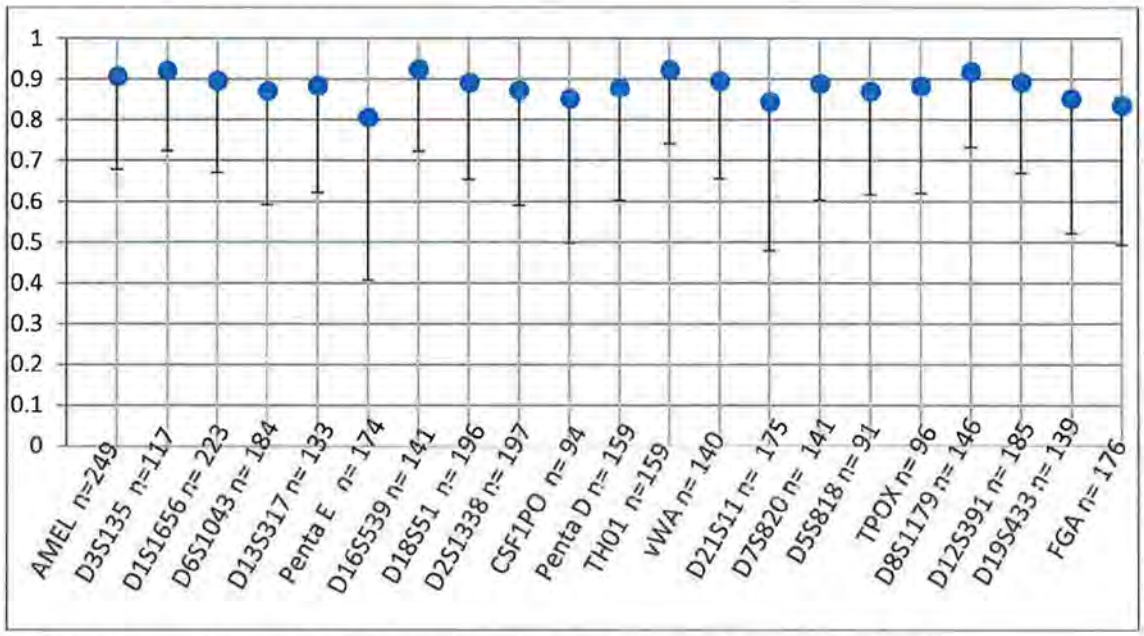


Figure 147 Observed average Peak height ratios per locus and locus specific AI_{TH}

Table 16 Average PHR and universal AI_{TH}

measure	value
μ_{PHR}	0.882
σ_{PHR}	0.096
AI_{Th}	0.595
n	3318

7.12. Thresholds

Table 17 summary of calculated dye channel LOD and LOR

measure	Fluorescin (Blue)	JOE (Green)	TMR (Yellow)	CXR (Red)	CC5 (Orange)	Adopted
	Samples	Samples	Samples	Samples	Samples	N/A
LOD	10	14	11	6	5	15
LOR	29	39	27	17	12	40

From the data listed in Table 17, the highest value was taken and rounded up to the nearest whole RFU. A LOD of 15RFU and LOR of 40RFU is recommended for use with direct amplification reference samples.

The results of the determined homozygote thresholds are given below.

Method 1-Th_{Hom} = 40 × 1/0.594 ×2 = **134**RFU

Method 2 – **130**RFU Refer to Figure 18 below.

Method 3 – **130**RFU Refer to Figure 19 below.

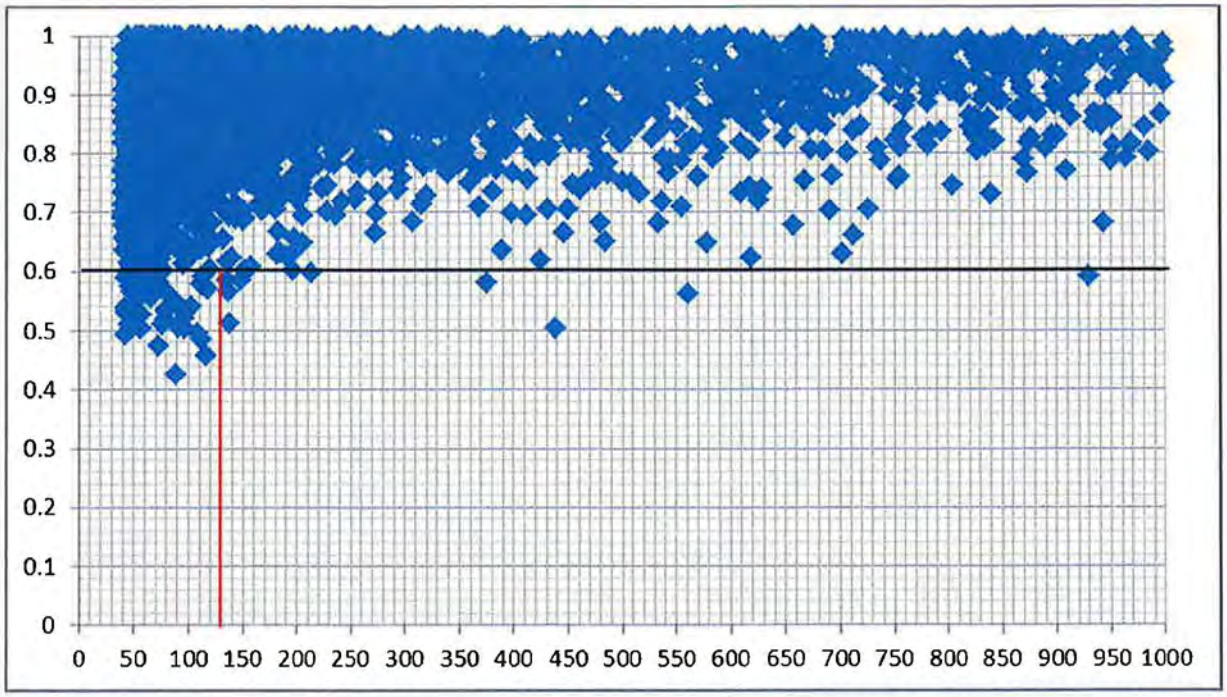


Figure 158 plot of the peak height ratio vs RFU of lower peak. The black horizontal line is the AI_{TH}. The red vertical line is set to encompass the majority of points that fall below the AI_{TH}.

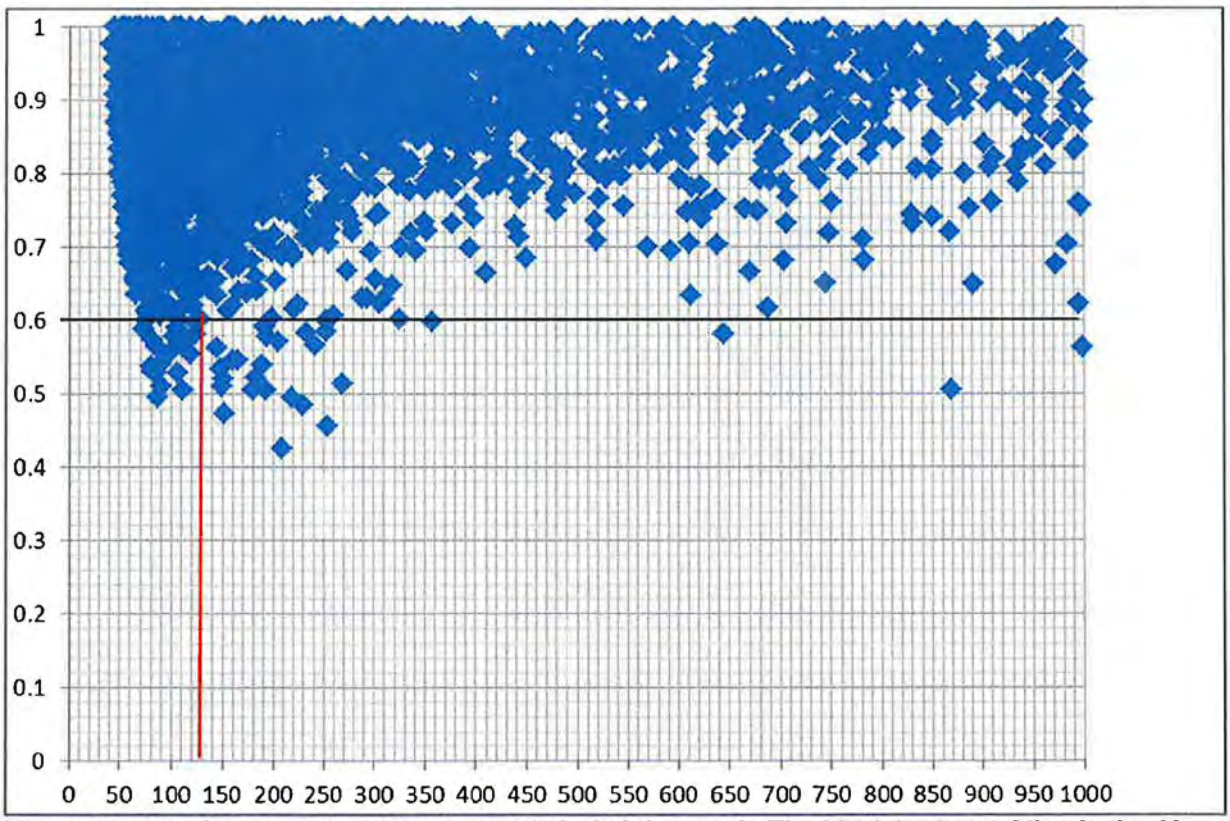


Figure 19 plot of the peak height ratio vs RFU of higher peak. The black horizontal line is the AI_{TH}. The red vertical line is set to encompass the majority of points that fall below the AI_{TH}.

8. Discussion

8.1. Comparison of direct FTA® amplification 25µL vs 12.5 total PCR volume and DNA input

All PCR amplification kits are optimised for a particular total reaction volume by the manufacturer; but it is commonplace to reduce the total PCR reaction volume to increase the sensitivity (9-12) and reduce processing costs (11). For the PowerPlex® 21 system, the optimised reaction volume is 25µL. All amplifications were performed at 25 PCR cycles as initially recommended by Promega (2).

Both methods used yielded good results. As expected, the reduced volume amplification increased the sensitivity of the PowerPlex® 21 system. Table 9 and Table 10 summarise the results of the 25µL (full volume) and 12.5µL (half volume) total volume PCR reactions. The decrease in total reaction volume did not appear to affect the peak balance of the samples tested.

Similarly, increasing the total DNA input into the PCR reaction resulted in increased peak heights. See Figure 6, Figure 7 , Figure 8 and Figure 9 for results. As previously determined, the reduced volume reactions produced larger peaks compared to the full volume reactions. When comparing one 1.2mm spots vs two1.2mm spots; the one spot samples did not yield peak heights as large as their two spot counterparts.

8.2. PCR Cycle variation

As mentioned above, each amplification kit is optimised to a set of conditions; this also includes the number of PCR cycles performed. The observation of a large number of partial DNA profiles for samples in the Caucasian dataset experiments suggested that 25 PCR cycles may not be sufficient for the range of quality of reference samples received. For these experiments the effect of PCR cycle number was investigated for determining the best first run PCR cycle and potential reworking methods if a full DNA profile is not obtained first time.

Three different PCR cycle numbers (25, 26 and 27 PCR cycles) for direct amplifications were compared to each other. The PCR cycles chosen are recommended alternative PCR cycle numbers by Promega (2) for optimisation in house. A fourth PCR cycle number (24 PCR cycles) was excluded because of the large number of partial DNA profiles obtained at 25 PCR cycles. Six samples that had been used for the Caucasian dataset were selected based on their initial PowerPlex® 21 result (25 PCR cycles, 12.5µL total PCR volume, one 1.2mm spot). These were representative of the range of quality of FTA® samples received.

Figure 10 and Table 11 summarises the results obtained from these experiments.

Some of the samples performed significantly better in this experiment than the previous direct amplification experiment. Typically, each 1.2mm spot of buccal FTA® contains ~3-5ng of DNA (10).The discrepancy between results can be attributed to the fact that FTA® samples will have DNA unevenly distributed on the FTA® card. This occurs because the process in which the buccal cells are collected may result in clumps of cells and consequently, when transferred to the FTA® card, uneven distribution (13, 14).

As expected and detailed in Table 11; the average RFU increases with each additional PCR cycle and consequently the number of alleles obtained also increases with the exception of two examples. The apparent failure to amplify can be attributed to DNA distribution and stochastic effects.

8.3. FTA Optimisation

The results obtained from the SE Asian Dataset samples (12.5µL total PCR volume, 26 cycles and one 1.2mm spot) exhibits extremely poor amplification. It was unclear as to whether the drop out was a result of too little DNA input, too much DNA input or inhibition from the FTA®

cards. This experiment was designed to compare the three PCR cycles and DNA input range to confirm the optimum conditions.

The variation in DNA distribution on the FTA® cards and the number of times these samples had been processed greatly affected the ability to obtain a full DNA profile.

The two spot samples used in this experiment exhibited very little amplification (and have been excluded from the table), most likely due to the lack of DNA input. These FTA® cards have had many spots removed prior to this experiment. Another possibility is that inhibition from the FTA® card itself may have prevented amplification (13, 15). Inhibitory substances can cause problems with direct amplification because there is no washing involved. Similarly, reduction in total PCR volume effectively concentrates any inhibitor present (12). However, we have already demonstrated that two 1.2mm spots can produce very good results.

Generally as the PCR cycle was increased the number of alleles called increased. See Table 12. Also as the amount of DNA input increased (that is the type of sample used. For example No size data vs full DNA profile) the number of alleles called increased. Table 12 also shows an increase in alleles called when the empirically derived thresholds are used for analysis instead of the Promega thresholds. The results from this experiment confirm that using 26 PCR cycles is appropriate for the first attempt at DNA profiling. 25 PCR cycles is appropriate for reworking samples with high DNA loads. 27 PCR cycles is appropriate for reworking samples with low DNA loads.

8.4. FTA® processing summary

The experiments carried out have compared the following parameters:

- Variations in total PCR volume (12.5µL vs 25µL)
- Variations in DNA input (one 1.2mm spot vs two 1.2mm spots)
- Variations in PCR cycle number (25, 26 and 27 PCR cycles)

Methods 5.6 and 5.7 describe two direct amplification methods. The method described in 5.6 is one of the methods described by Promega in the technical manual for PowerPlex® 21. The alternative method that was not tested, was to punch the FTA® samples into the 96 well PCR plate then add the amplification mix. This method was immediately determined to be a high cross contamination risk. This assessment was based on the frequent observation of spots jumping to adjacent wells by electrostatic interactions between the plastic plate and paper card.

The log of reference plate failures kept within the laboratory indicates the most frequent error or reason for failing a plate is contamination attributed to spot jumping.

The method described in 5.7 is the same method as 5.6 except that the amplification water that would otherwise been added to the amplification mix is added to the 96 well PCR plate separately to the other components. This method represents a compromise between potential waste of amplification reagents vs the risk of spots jumping. If a plate is abandoned because of excessive spot jumping, only amplification grade water would be wasted.

While the results show that the addition of two 1.2mm punches can increase the chance of obtaining a full DNA profile; the presence of two 1.2mm spots per well makes it harder to identify a spot jumping event when compared to absence of a spot if a single 1.2mm spot is used.

Results show that 26 PCR cycles, 12.5µL total volume and one 1.2mm FTA® spot is appropriate and recommended for initial processing of all FTA® samples including blood FTA® samples. The additional cycle (27 PCR cycles) is recommended for samples that do not obtain a full DNA profile first time. The 25 PCR cycle process will be used for samples that exhibit excess DNA profiles first time.

8.5. Drop out events

This experiment was designed to create a dilution series, and replicate the real conditions that would be encountered, i.e. potential inhibition from the FTA® card. Significant differences in peak height that could be attributed to the FTA® card were not observed at 10ng DNA input. This could be because there was a large of amount of DNA template so inhibition did not decrease the efficiency of the PCR or that the FTA® card did not contain significant inhibitor.

The heat maps shown in Figure 11, 12 & 13 indicate that whole loci in the PowerPlex® 21 system tend to drop out rather than a particular allele dropping out. The heat maps summarise the large amount of data to quickly compare the drop out events observed.

As the PCR cycles are increased the level of sensitivity is increased, however the DNA profile may not be usable. For example, at 27 PCR cycles and 0.2ng DNA input, partial DNA profiles are obtained but are not of sufficient stringency to be loaded to NCIDD.

This is confirmed by the data in Figure 14. The number of dropout events for heterozygous loci in the Caucasian dataset samples shows that no events of drop out were observed for heterozygous pairs for any RFU over 100RFU. As expected the 25 PCR cycle samples exhibit more dropout than the 26 PCR cycle samples.

This data agrees with the peak balance data observed – the min peak balance observed was ~40%, If for example an allele with the peak helght of 130RFU was observed, we would expect from the empirical data that the sister allele would have a height of no less than 50RFU. This is above the LOR

Figure 15 and Figure 16 show results of which loci tend drop out first. These results are in agreement with Figure 11, 12, 13 & 14. There are far more drop out events of whole loci compared with a single allele drop out event.

8.6. Concordance testing

Different DNA amplification kits may contain different primers for each locus. Comparison of allele calls (concordance) is required to ensure that each kit gives consistent allele designations between kits as mismatches or null alleles will affect matching on NCIDD or within a case. The current kits used by the DNA Analysis are AmpFℓSTR® Profiler Plus® and AmpFℓSTR COfiler® DNA amplification kits. Both of these are manufactured and use primers developed by Life technologies. There are known issues with these kits such as a reverse primer binding mutation at the D8S1179 locus (16) vWA locus (17) and FGA locus (18). The PowerPlex® 21 kit uses different primer sequences. All alleles tested were found to be concordant. As primer binding mutations and null alleles have been observed in the DNA Analysis, retesting of these reference samples and single mismatches would be required if the reference sample has been loaded to NCIDD.

8.7. Stutter threshold

Stutter peaks are PCR artefacts commonly observed in all STR analysis (2, 19) They are usually observed as a peak one repeat unit less in size than the true allele peak (19). The stutter mechanism has been attributed to slippage of the DNA strand during replication.

Over stutter is observed as a peak one repeat unit more in size than the true allele.

Refer to Figure 22 example of over stutter and stutter

For the GeneMapper *ID-X* v.1.1.1 stutter text file supplied (Promega use the mean + three standard deviations (2)) we have similarly used the same calculation as it incorporates 99.73% of the data assuming normal distribution.

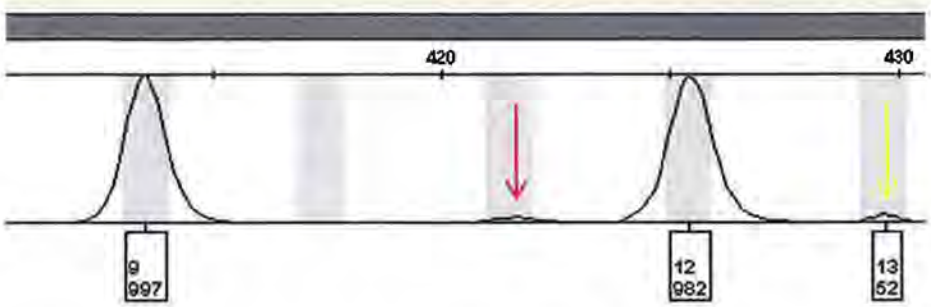


Figure 16- Example of stutter and over stutter. Red arrow indicates stutter -4 or -5 base pairs and the yellow arrow indicates stutter +4 or +5 base pairs.

Over stutter was not observed for all loci so a threshold cannot be determined from this validation. Observation of over stutter in reference samples must be examined on a sample by sample basis to determine if it can be attributed to over stutter, an extra peak or evidence of a mixture. A post implementation review has been scheduled in six months time. During this review, available data can be used to determine over stutter thresholds for all loci.

Most calculated stutter thresholds were less than the Promega supplied stutter filter file. The two exceptions as documented in Table 15 were D1S1656 (15.5% compared to Promega 15%) and D21S11 (15.2% compared to the Promega 13%). The stutter filter file that is used by GeneMapper *ID-X* v.1.1.1 was updated to incorporate the values for those two loci.

8.8. Allelic imbalance threshold and peak height ratio

Peak height ratio was calculated for all loci in the PowerPlex® 21 system. Figure 14 displays the average peak height ratio per locus. Table 16 summarises the results. Overall, the system displayed high peak balance within each locus and between loci. The lowest observed peak height ratio was 42%, while the mean peak height ratio was 88.2%.

The method used in Equation 3 is recommended in the SWGDAM guidelines (20) and well represented in the literature (21), although other methods have been published by Kelly et al (22).

By assigning a threshold of the mean minus three standard deviations, this incorporates 99.73% of the data, resulting in a conservative threshold. This threshold was rounded up to the nearest RFU. Use of this method to produce a threshold is a low risk to reference samples, as samples that deviate would be reprocessed. It is recommended that the AI_{TH} is set to 60%. Samples that exhibit low peak height ratios (<40%) should be assessed for signs of a mixture.

8.9. Thresholds

Thresholds other than Stutter and Allelic Imbalance that have already been described are:

- Limit of detection (LOD)
- Limit of reporting (LOR)
- Homozygote threshold (Th_{Hom})

The use of thresholds for reporting is essentially a risk assessment (23) , if the thresholds are set too low then labelling of artefacts and noise may occur , if set too high then real peaks will not be labelled and information will be lost (20, 24).

Type 1 errors are defined as false labelling of noise peaks. LODs calculated from negative samples may not be optimal for medium-high template samples as the baseline will differ between positives and negatives (24, 25).

Type 2 errors are defined as false non-labelling of alleles. If the LOD is set too high, then for low level samples may have a heterozygous locus called as a homozygous locus (24-27).

The LOR is the threshold in which a peak can be confidently distinguished from the background fluorescence (baseline). Several methods can be used to determine this threshold.

Literature regarding direct amplification of reference samples does not usually discuss how the thresholds are set for these types of samples. The methods and samples used to calculate the baseline in the literature vary. These range from use of negatives/blanks to linear regression of positive samples (5, 20, 28, 29).

A potential problem with direct amplification is the high variability of number of cells transferred to the FTA® paper. Creating a true dilution series is difficult because of this variability. It has also been reported that use of blank/negative samples for threshold determination could result in Type 1 errors for samples with low DNA amounts (25).

To overcome this issue, the limit of reporting threshold was determined for this validation from empirical data – that is a range of FTA® buccal samples that would contain different amounts of DNA. This would simulate a dilution series. This approach satisfies the guidelines from SWGDAM "*1.1. Analytical threshold: The Laboratory should establish an analytical threshold based on signal-to-noise analyses of internally derived empirical data.*" and "*3.1.1.2. While the application of an analytical threshold may serve to filter out some non-allelic peaks, the analytical threshold should be established based on signal-to-noise considerations (i.e., distinguishing potential allelic peaks from background). The analytical threshold should not be established for purposes of avoiding artifact labeling as such may result in the potential loss of allelic data.* " (20).

For the method used here the limit of reporting is derived from the mean baseline plus ten standard deviations (Equation 6).

The limit of detection is the lowest signal that can be distinguished from the background fluorescence (baseline) and may vary between CE instruments.

Previously in the DNA Analysis; baseline for the AmpFℓSTR® Profiler Plus® kit was determined using the BatchExtract software v0.1 (6). The LOD was calculated using Equation 5 above. This approach of using the mean and three standard deviations would account for 99.73% of baseline fluorescence.

The files generated by GeneMapper *ID-X* v1.1.1 are not compatible with the BatchExtract software without modification. For this validation an equivalent process for measuring the baseline as described by Promega was used with some modifications to the types of samples used (7).

Table 14 shows the results determined from the baseline calculations. The highest average RFU was for the yellow channel (5RFU) and the highest standard deviation was for the green channel (3.5RFU). Table 17 summarises the LODs and LORs calculated. The green channel yielded the highest LOR (39RFU). This figure was rounded up to 40RFU and is to be used as the LOR for all dye channels. These results are close to the LOD calculated for the casework samples (~40RFU) at 30 PCR cycles and 25µL total PCR volume. The samples used for the casework LOR were 10 samples diluted 10 times between 0.5ng to 25pg. This agreement would suggest that the samples used for the direct amplification baseline are appropriate and mimic a dilution series.

The homozygote threshold is the threshold above which you can be confident that a heterozygote locus will not be incorrectly called as a homozygote locus.

For reference samples setting the homozygous threshold too high will result in excessive reworking of samples as a partial DNA profile would be called. Conversely, setting the threshold too low could result in false exclusions when compared to crime scene samples (26).

The method for determining the homozygote threshold varies in the literature. Traditionally, it had been arbitrarily designated at a particular level above the LOR. As already mentioned the risk of Type 1 and Type 2 errors should be balanced. Literature describes the setting of Th_{Hom} with respect to casework samples not reference samples (7, 8, 23, 28). Some literature exists (10-13) describing the validation of amplification kits for reference sample purposes but fall short of describing a method used for the Th_{Hom}.

Previously in the DNA Analysis, the Th_{Hom} was calculated as described in 6.12 Equation 7. Using this method a figure of 134RFU was calculated.

Another method of determining the Th_{Hom} is described in the Promega Internal Validation of STR systems reference manual (7). This plots the peak height ratio for heterozygous loci against the lower RFU peak. The threshold is defined as the point at which peak height ratio drops off significantly. For Figure 10 which displays the data, the average AI_{TH} calculated was 0.595. An RFU that encompasses the majority of the data that falls below this line is ~130RFU.

A third method similar to method 2 has been modified from a presentation by Word (8) this instead plots the peak height ratio against the larger RFU peak height. Figure 10 displays the data, Despite only 23/40 points falling above 130RFU, 130RFU (17/40 point below) was taken to be the threshold because a definite cluster of data falls below 130RFU with the data points being quite dispersed above 150RFU. Unlike data reported in other publications (7, 23, 30), there is not a rapid drop off of peak height ratios observed in the PowerPlex® 21 system. We have observed that the PowerPlex® 21 system loci tend to completely drop out completely compared to partially dropping out

As all three methods used give similar results, it is recommended that homozygote threshold of 130RFU be set.

These methods are subjective but when considered with the observed drop out data in Figure , a Th_{Hom} of 130RFU would result in no type 2 errors. Additionally the threshold is more than three times the LOR threshold so Type 1 errors would also be addressed.

To ensure that the all of the thresholds set for this validation are appropriate a post implementation review of the thresholds is required. This would ensure that if the thresholds are too conservative and have resulted in additional processing that we have the opportunity to re-adjust the thresholds based on empirical data.

9. Recommendations

1. For 1st run FTA® samples the direct amplification parameters should be 26 PCR cycles, 1x 1.2mm spot in a 12.5µL total PCR reaction volume.
2. Reworking strategy A- FTA® samples (designated as partial or No size data) should be amplified with 27 PCR cycles, 1x 1.2mm spot in a 12.5µL total PCR reaction volume.
3. Reworking strategy B- FTA® samples (designated as excess) should be amplified with 25 PCR cycles, 1x 1.2mm spot in a 12.5µL total PCR reaction volume.
4. Reworking strategy C - FTA® samples (designated as Off ladder alleles and variants) should be amplified with 26 PCR cycles, 1x 1.2mm spot in a 12.5µL total PCR reaction volume.
5. Blood and buccal FTA® samples can be run together as no additional processing is required.
6. Six months after implementation of the PowerPlex® 21 system for direct amplification of reference samples; a review of the thresholds must be carried out to determine appropriateness of the thresholds set
7. Recommend re-amplification of previously profiled reference samples in PowerPlex® 21 system if there is any doubt that there is a null allele and primer binding mutations present.

Table 18- Summary of recommended direct FTA® processing methods

	1st Run	OSD	RUN	RPT
Cycles	26 cycles	25 cycles	27 cycles	26 cycles
DNA input	1x 1.2mm spot	1x 1.2mm spot	1x 1.2mm spot	1x1.2mm spot
Total PCR vol	12.5µL	12.5µL	12.5µL	12.5µL

Table 19- A summary of the recommended analysis thresholds. These are the thresholds that will applied in DNA Analysis for direct amplification of reference samples.

Parameter	Setting
LOD	15RFU
LOR	40RFU
Th_{Hom}	130RFU
AI_{TH}	60%

10. Conclusion

This validation has demonstrated that the PowerPlex® 21 system is fit for purpose for the direct amplification of FTA® reference samples processed in the DNA Analysis. The implementation of this direct amplification method will decrease the time taken to process FTA® samples through more rapid cycling and no sample washing. Without the need for sample washing, the potential for cross contamination through reduction of washing steps and spots jumping wells is reduced.

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Appendix A: Supplementary Data Index

CA-48

Analysis of the Australian Aboriginal and Asian Sub-Population Data for the PowerPlex® 21 Autosomal Short Tandem Repeat Loci

12 November 2012

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John Buckleton [redacted]

PREFACE

Data for the Australian Aboriginal and South Eastern Asian sub-populations were received in the form of MS EXCEL™ spreadsheets as part of a request to undertake a statistical analysis from the following laboratories. A summary of the participating the labs the number of samples is provided in Table 1.

Table 1: A summary of participating laboratories and number of samples analysed.

Laboratory	Aboriginal	Asian
Division of Analytical Laboratories, NSW	200	200
Forensic Science, South Australia	249	261
Forensic Services, Northern Territory Police	548	176
PathWest, Western Australia	198	199
Queensland Health Forensic & Scientific Services	309	126
Victorian Police Forensic Services Department	274	28
Total	1778	990

The data were checked for typographical and/or data entry errors and duplicate profiles. Twenty within-dataset and between-dataset duplicate profiles were removed from the Aboriginal data and 19 profiles from the Asian data prior to analysis.

The following abbreviations have been used intermittently throughout this report are summarised in Table 2.

Table 2: A list of abbreviations used in the text or tables of this report.

Full term	Abbreviation
Short tandem repeat	STR
Deoxyribonucleic Acid	DNA
PowerPlex 21	PP21
Hardy-Weinberg Equilibrium	HWE
Linkage Equilibrium	LE
Fisher's Exact Test	FET
Observed	Obs
Expected	Exp

INTRODUCTION

It is a requirement that forensic DNA profiling evidence be accompanied by an estimation of its weight, such that the court can assign an appropriate probative value during legal proceedings. There are various models by which this estimation can be made, but each relies on approximations of the allele frequencies in the relevant population, and some understanding of population genetic features that may influence the estimation process.

A dataset from the Aboriginal and South East Asian sub-populations of Australia has been compiled. The DNA profiles have been generated using the PowerPlex® 21 STR amplification kit. The Aboriginal sub-population dataset contained 1,778 profiles (N = 1778) from individuals who had self-declared their ethnic origin as Aboriginal and the Asian dataset contained 990 profiles (N = 990). Note that there are 20 STR within the PowerPlex® 21 multiplex plus Amelogenin.

These data have been examined in a manner that is consistent with the requirements of the international forensic community. The approach largely follows that outlined by Buckleton (2005)[1] and employs procedures developed by Weir.[2,3] The results of the statistical analysis are presented in the following sections:

1. Allele counts
2. Independence testing
3. Departures from Hardy-Weinberg Equilibrium

This is followed by general conclusions drawn from the data analysis.

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RESULTS OF DATA TESTING

1. ALLELE COUNTS

The allele counts for each of the 20 PowerPlex® 21 STR loci for the Aboriginal dataset is presented in Table 3 and for the Asian dataset in Table 4.

Table 3: Allele counts for the 20 PowerPlex® 21 STR loci for the Aboriginal sub-population.

Allele	CSF	D12	D13	D16	D18	D19	D1	D21	D2S	D3	D5	D6	D7	D8	FGA	Penta D	Penta E	TH01	TPOX	vWA
2.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-
5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	156	8	1	-
5.3	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
6	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1156	3	-
7	1	-	11	-	-	-	-	-	-	-	1	-	37	-	-	21	252	832	3	-
7.3	-	-	-	-	-	-	-	-	-	-	-	-	10	-	-	-	-	-	-	-
8	25	-	951	32	-	-	-	-	-	-	9	5	1056	26	-	232	21	477	1064	-
8.1	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
8.3	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-
9	53	-	204	220	1	-	-	-	-	-	198	6	348	29	-	821	28	603	1295	-
9.1	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
9.3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	449	-	-
10	787	-	190	325	17	5	23	-	-	-	671	81	735	177	-	480	154	26	164	-
10.1	-	-	-	-	-	-	-	-	-	-	10	-	-	-	-	-	-	-	-	-
10.3	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
11	1064	-	1071	1333	128	15	125	-	-	6	1042	899	793	291	-	796	222	1	872	-
11.1	-	-	-	-	-	-	-	-	-	-	3	-	1	-	-	-	-	-	-	-
11.2	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-
12	1263	-	801	1030	275	268	337	-	-	4	1062	761	470	507	-	665	305	-	73	-
12.1	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
13	282	-	221	512	602	1122	490	-	-	8	485	259	79	900	-	369	237	-	-	7
13.1	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
13.2	-	-	-	-	-	22	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13.3	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
14	33	4	77	94	577	1393	450	-	1	229	42	130	14	687	-	83	328	-	-	233

14.2	-	-	-	-	-	53	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14.3	-	-	-	-	-	-	8	-	-	-	-	-	-	-	-	-	-	-	-	-
15	5	185	6	9	469	427	610	-	5	1192	8	20	-	600	-	27	251	-	-	258
15.2	-	-	-	-	-	87	-	-	-	1	-	-	-	-	-	-	-	-	-	-
15.3	-	-	-	-	-	-	81	-	-	-	-	-	-	5	-	-	-	-	-	-
16	-	123	-	-	466	111	652	-	55	933	-	12	-	242	3	3	301	-	-	791
16.2	-	-	-	-	-	34	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16.3	-	-	-	-	-	-	95	-	-	-	-	-	-	-	-	-	-	-	-	-
17	-	549	-	-	334	9	270	-	391	734	-	91	-	74	12	5	347	-	-	1000
17.2	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17.3	-	45	-	-	-	-	205	-	-	-	-	-	-	-	-	-	-	-	-	-
18	-	795	-	-	289	2	79	-	242	391	-	283	-	12	101	-	257	-	-	798
18.2	-	-	-	-	-	2	-	-	-	-	-	2	-	-	-	-	-	-	-	-
18.3	-	46	-	-	-	-	73	-	-	-	-	14	-	-	-	-	-	-	-	-
19	-	550	-	-	194	-	32	-	851	50	-	331	-	-	219	-	195	-	-	382
19.1	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19.2	-	-	-	-	-	-	-	-	-	-	-	18	-	-	1	-	-	-	-	-
19.3	-	13	-	-	-	-	16	-	-	-	-	154	-	-	-	-	-	-	-	-
20	-	372	-	-	93	-	5	-	389	6	-	72	-	-	406	-	180	-	-	77
20.1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
20.2	-	-	-	-	-	-	-	-	-	-	-	18	-	-	6	-	-	-	-	-
20.3	-	-	-	-	-	-	-	-	-	-	-	198	-	-	-	-	-	-	-	-
21	-	307	-	-	63	-	-	-	150	2	-	18	-	-	484	-	125	-	-	7
21.1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21.2	-	-	-	-	-	-	-	-	-	-	-	5	-	-	12	-	-	-	-	-
21.3	-	1	-	-	-	-	-	-	-	-	-	138	-	-	-	-	-	-	-	-
22	-	250	-	-	33	-	-	-	217	-	-	-	-	-	596	-	63	-	-	1
22.2	-	3	-	-	-	-	-	-	-	-	-	1	-	-	20	-	-	-	-	-
22.3	-	-	-	-	-	-	-	-	-	-	-	24	-	-	1	-	-	-	-	-
23	-	160	-	-	7	-	-	-	464	-	-	-	-	-	547	-	37	-	-	-
23.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	13	-	-	-	-	-
23.3	-	-	-	-	-	-	-	-	-	-	-	8	-	-	-	-	-	-	-	-
24	-	86	-	-	3	-	-	-	389	-	-	-	-	-	566	-	24	-	-	-
24.2	-	-	-	-	-	-	-	1	-	-	-	-	-	-	7	-	-	-	-	-

24.3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
25	-	45	-	-	-	-	-	-	312	-	-	-	-	-	376	-	11	-	-	-
25.2	-	-	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-	-	-	-
26	-	6	-	-	1	-	-	5	65	-	-	-	-	-	143	-	3	-	-	-
26.1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
27	-	1	-	-	-	-	-	53	4	-	-	-	-	-	33	-	1	-	-	-
27.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
28	-	-	-	-	-	-	-	428	6	-	-	-	-	-	5	-	-	-	-	-
28.2	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	758	-	-	-	-	-	-	-	-	-	-	-	-
29.1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
29.2	-	-	-	-	-	-	-	7	-	-	-	-	-	-	-	-	-	-	-	-
29.3	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	723	-	-	-	-	-	-	-	-	-	-	-	-
30.2	-	-	-	-	-	-	-	134	-	-	-	-	-	-	-	-	-	-	-	-
31	-	-	-	-	-	-	-	203	-	-	-	-	-	-	-	-	-	-	-	-
31.2	-	-	-	-	-	-	-	403	-	-	-	-	-	-	-	-	-	-	-	-
32	-	-	-	-	-	-	-	49	-	-	-	-	-	-	-	-	-	-	-	-
32.1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
32.2	-	-	-	-	-	-	-	364	-	-	-	-	-	-	-	-	-	-	-	-
33	-	-	-	-	-	-	-	6	-	-	-	-	-	-	-	-	-	-	-	-
33.1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
33.2	-	-	-	-	-	-	-	160	-	-	-	-	-	-	-	-	-	-	-	-
34.2	-	-	-	-	-	-	-	25	-	-	-	-	-	-	-	-	-	-	-	-
35.2	-	-	-	-	-	-	-	76	-	-	-	-	-	-	-	-	-	-	-	-
36.2	-	-	-	-	-	-	-	53	-	-	-	-	-	-	-	-	-	-	-	-
37.2	-	-	-	-	-	-	-	38	-	-	-	-	-	-	-	-	-	-	-	-
38.2	-	-	-	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	-	-
39.2	-	-	-	-	-	-	-	12	-	-	-	-	-	-	-	-	-	-	-	-
40.2	-	-	-	-	-	-	-	8	-	-	-	-	-	-	-	-	-	-	-	-
R	-	-	-	-	2	-	-	2	-	-	-	-	-	-	-	2	3	-	-	-
F	42	12	20	1	2	1	4	7	15	-	23	7	9	6	3	47	53	4	81	2
Sum	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556	3556

Table 4: Allele counts for the 20 PowerPlex® 21 STR loci for the Asian sub-population.

Allele	CSF	D12	D13	D16	D18	D19	D1	D21	D2S	D3	D5	D6	D7	D8	FGA	Penta D	Penta E	TH01	TPOX	vWA
5	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	1	99	-	-	-
6	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	2	1	279	1	-
7	9	-	3	-	-	-	1	-	-	-	48	-	14	-	-	39	25	552	-	-
8	8	-	542	12	1	-	1	-	-	-	-	1	349	4	-	114	10	123	1055	-
9	73	-	256	433	-	5	-	-	-	-	115	4	122	5	-	678	26	802	220	-
9.1	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-
9.2	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
9.3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	135	-	-
10	460	-	259	277	5	2	4	-	-	-	417	60	325	280	-	290	95	84	69	-
10.3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
11	510	-	484	584	15	10	151	-	-	-	604	299	697	211	-	268	364	4	539	-
11.1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
12	707	-	317	437	108	98	99	-	-	3	483	292	385	239	-	306	227	-	63	-
12.1	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	1	-	-	-	-
12.2	-	-	-	-	-	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12.3	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
12.4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
13	161	-	93	203	289	542	172	-	-	6	287	244	68	406	1	178	121	-	1	2
13.2	-	-	-	-	1	73	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	36	1	21	30	391	497	199	-	-	80	17	261	11	347	-	66	163	-	-	449
14.2	-	-	-	-	-	218	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14.3	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-
15	5	23	1	3	407	153	553	-	-	613	1	31	-	303	-	16	175	-	-	83
15.1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
15.2	-	-	-	-	-	273	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15.3	-	-	-	-	-	-	17	-	-	-	-	-	-	-	-	-	-	-	-	-
16	-	26	-	-	300	32	400	-	41	665	-	4	-	157	2	4	149	-	-	340
16.2	-	-	-	-	-	57	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16.3	-	-	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	-	-	-
17	-	179	-	-	161	4	142	-	176	473	-	85	-	22	4	-	129	-	-	509
17.2	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-

17.3	-	4	-	-	-	-	129	-	-	-	-	-	-	-	-	-	-	-	-	-
18	-	406	-	-	102	1	23	-	192	129	-	308	-	6	38	-	125	-	-	402
18.1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18.2	-	-	-	-	-	3	-	-	-	-	-	6	-	-	-	-	-	-	-	-
18.3	-	8	-	-	-	-	43	-	-	-	-	1	-	-	-	-	1	-	-	-
19	-	356	-	-	75	-	4	-	357	9	-	276	-	-	139	-	88	-	-	147
19.1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19.3	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-
20	-	341	-	-	51	-	1	-	253	1	-	84	-	-	135	-	78	-	-	42
20.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-
20.3	-	-	-	-	-	-	2	-	-	-	-	3	-	-	-	-	-	-	-	-
21	-	249	-	-	35	-	-	-	64	1	-	11	-	-	229	-	39	-	-	5
21.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	15	-	-	-	-	-
22	-	161	-	-	23	-	-	-	129	-	-	-	-	-	370	-	27	-	-	-
22.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	13	-	-	-	-	-
23	-	129	-	-	11	-	-	-	334	-	-	-	-	-	308	-	9	-	-	-
23.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	18	-	-	-	-	-
24	-	60	-	-	5	-	-	-	290	-	-	-	-	-	344	-	4	-	-	-
24.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	19	-	-	-	-	-
24.3	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	-	25	-	-	-	-	-	-	126	-	-	-	-	-	186	-	2	-	-	-
25.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	13	-	-	-	-	-
26	-	3	-	-	-	-	-	1	12	-	-	-	-	-	95	-	-	-	-	-
26.1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-
26.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	-	-	-	-	-
27	-	1	-	-	-	-	-	19	4	-	-	-	-	-	31	-	-	-	-	-
28	-	-	-	-	-	-	-	129	-	-	-	-	-	-	10	-	-	-	-	-
28.2	-	-	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	433	-	-	-	-	-	-	-	-	-	-	-	-
29.2	-	-	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	511	-	-	-	-	-	-	-	-	-	-	-	-
30.2	-	-	-	-	-	-	-	47	-	-	-	-	-	-	-	-	-	-	-	-
30.3	-	-	-	-	-	-	-	5	-	-	-	-	-	-	-	-	-	-	-	-
31	-	-	-	-	-	-	-	200	-	-	-	-	-	-	-	-	-	-	-	-

31.2	-	-	-	-	-	-	-	144	-	-	-	-	-	-	-	-	-	-	-	-
32	-	-	-	-	-	-	-	52	-	-	-	-	-	-	-	-	-	-	-	-
32.2	-	-	-	-	-	-	-	294	-	-	-	-	-	-	-	-	-	-	-	-
33	-	-	-	-	-	-	-	8	-	-	-	-	-	-	-	-	-	-	-	-
33.2	-	-	-	-	-	-	-	110	-	-	-	-	-	-	-	-	-	-	-	-
34.2	-	-	-	-	-	-	-	14	-	-	-	-	-	-	-	-	-	-	-	-
37.2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-
38.2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-
39.2	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
R	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	1	-	-	-	-
F	11	5	3	-	-	-	-	-	2	-	7	1	5	-	3	15	22	-	32	1
Sum	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980	1980

2. INDEPENDENCE TESTING

For each locus and each pair of loci in the sample an exact test of allelic association was conducted. Significance levels (*p*-values) were generated empirically by the permutation procedure,[4] with 10,000 permutations (Table 4 and 5). This number is expected to give a 95% confidence interval of ±0.0043 for a *p*-value around 0.05.[5]

Table 5: Results of Fisher's Exact test for allelic association for each locus (HWE) for the Australian Aboriginal and Asian PP21 datasets. Values below 0.05 are shown in bold.

	Aboriginal		**Asian**	
Locus	***p*-value**	**-2ln(*p*) HWE**	***p*-value**	**-2ln(*p*) HWE**
CSF	0.09	4.93	0.91	0.20
D12	0.12	4.32	0.38	1.95
D13	0.46	1.57	0.16	3.62
D16	**0.00**	12.64	0.85	0.33
D18	**0.01**	10.48	0.22	3.05
D19	0.08	4.95	**0.00**	14.03
D1	**0.00**	NA	0.50	1.39
D21	**0.04**	6.65	0.54	1.22
D2	**0.01**	9.98	**0.01**	8.47
D3	0.38	1.96	0.88	0.25
D5	**0.03**	7.11	0.08	5.09
D6	0.12	4.25	0.89	0.23
D7	0.10	4.62	0.08	4.96
D8	0.83	0.37	0.16	3.70
FGA	0.40	1.83	0.41	1.79
PentaD	**0.00**	10.68	0.84	0.34
PentaE	**0.00**	NA	0.26	2.72
TH01	0.10	4.61	0.05	6.14
TPOX	**0.00**	NA	0.08	5.10
vWA	0.06	5.73	0.40	1.84
Sum[-2ln(*p*)]		96.67	-	66.41
***p*-value**		1.36E-06	-	5.43E-03

[4] Guo SW and Thompson EA. 1992. Performing the exact test of Hardy Weinberg proportion for multiple alleles. *Biometrics* 48:361-372.

[5] $\pm 1.96\sqrt{\frac{p(1-p)}{n}}$ from Evett IW and Weir BS (1998). *Interpreting DNA Evidence*. Sinauer Associates, Inc.: Sunderland, Ma.

Table 6: Results of Fisher's Exact test for allelic association for each pair of loci (LE) for the Australian Aboriginal and Asian PP21 datasets. Values below 0.05 are shown in bold.

	Aboriginal		Asian	
Locus	p-value	-2ln(p) LE	p-value	-2ln(p) LE
CSF/D12	0.56	0.90	0.07	5.27
CSF/D13	0.26	1.74	0.39	1.87
CSF/D16	0.09	6.49	0.15	3.81
CSF/D18	0.38	1.78	0.74	0.60
CSF/D19	0.08	1.55	0.97	0.06
CSF/D1	0.07	0.56	0.89	0.23
CSF/D21	**0.03**	1.64	0.77	0.53
CSF/D2	0.42	0.96	0.52	1.32
CSF/D3	0.36	4.77	0.51	1.35
CSF/D5	0.75	1.14	0.78	0.50
CSF/D6	0.33	0.35	0.78	0.49
CSF/D7	0.16	2.55	0.20	3.25
CSF/D8	**0.02**	0.22	0.13	4.06
CSF/FGA	0.49	3.77	0.72	0.65
CSF/PentaD	0.10	0.05	0.60	1.04
CSF/PentaE	0.19	5.80	0.31	2.32
CSF/TH01	**0.04**	0.71	0.37	2.00
CSF/TPOX	0.23	2.01	0.95	0.10
CSF/vWA	0.19	5.25	0.13	4.14
D12/D13	**0.00**	0.73	0.33	2.24
D12/D16	0.12	1.50	0.89	0.22
D12/D18	0.41	1.56	0.71	0.69
D12/D19	**0.01**	1.48	0.95	0.11
D12/D1	**0.00**	0.01	0.43	1.69
D12/D21	0.35	6.95	0.18	3.40
D12/D2	**0.00**	2.17	0.13	4.11
D12/D3	0.23	0.96	0.47	1.53
D12/D5	0.78	3.99	0.26	2.73
D12/D6	0.07	0.98	0.42	1.72
D12/D7	0.09	6.85	0.43	1.70
D12/D8	0.12	2.12	0.92	0.16
D12/FGA	0.07	0.63	0.96	0.08
D12/PentaD	0.34	0.52	0.43	1.67

D12/PentaE	0.34	0.08	0.19	3.34
D12/TH01	**0.02**	1.41	**0.02**	8.05
D12/TPOX	**0.02**	1.52	0.38	1.91
D12/vWA	0.19	1.18	0.36	2.07
D13/D16	**0.00**	2.50	0.73	0.62
D13/D18	0.64	2.14	0.11	4.45
D13/D19	0.05	1.30	0.18	3.48
D13/D1	**0.00**	0.91	**0.04**	6.21
D13/D21	0.67	0.52	0.23	2.96
D13/D2	0.12	0.92	0.66	0.83
D13/D3	0.27	0.83	0.65	0.85
D13/D5	**0.03**	0.51	0.43	1.68
D13/D6	0.96	4.77	0.41	1.77
D13/D7	**0.01**	0.49	0.40	1.83
D13/D8	0.58	4.42	0.59	1.07
D13/FGA	0.14	2.47	0.08	4.95
D13/PentaD	**0.01**	0.33	0.14	3.99
D13/PentaE	0.42	0.75	0.34	2.16
D13/TH01	**0.05**	1.30	0.14	3.87
D13/TPOX	0.08	2.40	0.47	1.50
D13/vWA	0.27	2.19	0.71	0.68
D16/D18	0.25	0.40	0.81	0.42
D16/D19	**0.03**	1.17	0.40	1.81
D16/D1	**0.03**	6.34	0.24	2.88
D16/D21	0.99	4.23	0.27	2.60
D16/D2	0.43	0.29	0.27	2.61
D16/D3	**0.01**	3.12	0.18	3.48
D16/D5	0.14	2.47	0.98	0.04
D16/D6	0.52	6.43	0.35	2.10
D16/D7	0.99	1.83	0.87	0.27
D16/D8	0.63	4.82	0.57	1.13
D16/FGA	0.25	3.59	0.91	0.18
D16/PentaD	0.12	3.98	0.52	1.31
D16/PentaE	0.06	0.27	0.67	0.80
D16/TH01	0.14	3.69	0.53	1.28
D16/TPOX	0.17	0.89	0.12	4.25
D16/vWA	0.35	3.12	0.25	2.77
D18/D19	0.23	3.83	0.70	0.71
D18/D1	0.08	3.36	0.60	1.01

D18/D21	**0.00**	0.62	0.06	5.73
D18/D2	0.60	7.42	0.76	0.54
D18/D3	0.43	0.26	0.46	1.54
D18/D5	0.34	3.02	0.48	1.46
D18/D6	**0.01**	5.88	0.19	3.29
D18/D7	0.55	7.19	0.86	0.29
D18/D8	0.09	1.18	0.45	1.62
D18/FGA	0.35	5.05	0.28	2.56
D18/PentaD	0.33	1.07	0.41	1.79
D18/PentaE	**0.01**	2.60	0.40	1.81
D18/TH01	**0.01**	1.45	**0.01**	10.27
D18/TPOX	**0.02**	0.33	0.38	1.94
D18/vWA	0.23	3.82	0.40	1.81
D19/D1	0.41	1.67	0.05	5.98
D19/D21	1.00	0.73	0.51	1.34
D19/D2	**0.05**	0.85	0.67	0.81
D19/D3	0.67	0.06	0.73	0.63
D19/D5	0.47	0.05	0.17	3.55
D19/D6	0.72	3.44	0.43	1.70
D19/D7	0.21	7.12	0.34	2.18
D19/D8	0.27	2.49	0.52	1.31
D19/FGA	0.11	2.52	**0.03**	7.18
D19/PentaD	**0.00**	0.74	0.89	0.24
D19/PentaE	**0.01**	0.77	0.63	0.93
D19/TH01	**0.00**	2.08	0.13	4.09
D19/TPOX	0.32	1.04	0.10	4.63
D19/vWA	0.05	0.76	0.56	1.17
D1/D21	0.20	1.95	0.33	2.22
D1/D2	**0.00**	2.33	0.43	1.70
D1/D3	**0.02**	1.94	**0.03**	6.95
D1/D5	0.17	3.85	0.70	0.72
D1/D6	0.21	6.21	0.25	2.78
D1/D7	**0.01**	0.15	**0.05**	6.19
D1/D8	**0.01**	2.72	0.72	0.65
D1/FGA	0.78	2.18	0.26	2.72
D1/PentaD	0.06	1.27	0.25	2.81
D1/PentaE	0.75	1.65	0.25	2.78
D1/TH01	**0.00**	3.34	0.52	1.29
D1/TPOX	**0.00**	1.07	**0.00**	13.82

D1/vWA	**0.00**	2.33	0.14	3.96
D21/D2	0.65	3.38	0.36	2.07
D21/D3	0.75	0.62	0.97	0.05
D21/D5	0.17	0.28	0.84	0.34
D21/D6	0.31	4.56	0.09	4.74
D21/D7	1.00	0.58	0.45	1.61
D21/D8	0.62	0.49	0.90	0.21
D21/FGA	0.17	6.77	0.35	2.10
D21/PentaD	0.53	1.98	0.34	2.13
D21/PentaE	0.69	0.49	0.81	0.43
D21/TH01	0.99	5.31	0.38	1.94
D21/TPOX	0.61	0.48	0.95	0.11
D21/vWA	0.06	1.70	0.08	5.06
D2/D3	**0.02**	0.56	0.94	0.13
D2/D5	0.31	1.35	0.73	0.63
D2/D6	0.25	1.09	0.57	1.12
D2/D7	0.06	0.57	**0.01**	8.88
D2/D8	0.71	1.64	0.29	2.51
D2/FGA	0.52	0.24	0.70	0.71
D2/PentaD	0.43	2.37	0.91	0.18
D2/PentaE	**0.01**	2.16	0.20	3.17
D2/TH01	0.10	0.74	0.19	3.32
D2/TPOX	**0.00**	0.07	**0.05**	6.00
D2/vWA	0.20	0.63	0.10	4.60
D3/D5	0.58	1.38	0.96	0.08
D3/D6	0.54	1.00	0.66	0.83
D3/D7	**0.03**	2.42	**0.05**	6.00
D3/D8	0.43	5.06	0.91	0.18
D3/FGA	0.57	1.15	0.40	1.84
D3/PentaD	0.16	0.03	0.72	0.66
D3/PentaE	0.15	0.25	0.86	0.30
D3/TH01	**0.00**	0.63	0.39	1.86
D3/TPOX	**0.01**	0.58	0.32	2.30
D3/vWA	0.92	2.21	0.60	1.04
D5/D6	0.14	0.72	0.19	3.27
D5/D7	0.55	0.40	0.85	0.32
D5/D8	0.29	1.12	0.05	5.92
D5/FGA	0.05	0.63	0.88	0.26
D5/PentaD	0.07	5.03	0.67	0.79

D5/PentaE	**0.00**	3.38	0.77	0.53
D5/TH01	0.16	0.91	0.97	0.05
D5/TPOX	**0.03**	0.05	0.72	0.66
D5/vWA	0.52	3.07	0.22	3.05
D6/D7	0.24	1.08	0.51	1.36
D6/D8	0.55	4.94	0.83	0.37
D6/FGA	**0.01**	0.87	0.25	2.76
D6/PentaD	0.20	1.15	0.11	4.48
D6/PentaE	0.80	2.09	0.28	2.55
D6/TH01	0.86	4.45	0.25	2.77
D6/TPOX	0.10	1.32	0.96	0.08
D6/vWA	0.15	2.52	0.11	4.50
D7/D8	0.24	1.39	0.55	1.19
D7/FGA	0.35	0.36	0.07	5.34
D7/PentaD	**0.01**	1.06	1.00	0.00
D7/PentaE	0.07	1.40	**0.02**	7.66
D7/TH01	**0.01**	2.82	0.41	1.76
D7/TPOX	0.05	2.16	0.94	0.13
D7/vWA	0.52	0.20	0.26	2.66
D8/FGA	0.41	0.36	**0.02**	7.76
D8/PentaD	**0.00**	0.80	0.46	1.53
D8/PentaE	0.18	3.65	0.72	0.65
D8/TH01	0.14	3.17	0.26	2.71
D8/TPOX	**0.00**	1.23	0.52	1.29
D8/vWA	0.91	8.88	0.24	2.82
FGA/PentaD	0.97	1.20	0.15	3.75
FGA/PentaE	0.10	0.76	**0.03**	6.95
FGA/TH01	0.20	2.52	0.28	2.57
FGA/TPOX	0.73	0.27	0.51	1.35
FGA/vWA	0.26	1.36	0.60	1.03
PentaD/PentaE	**0.05**	1.71	0.49	1.43
PentaD/TH01	**0.00**	1.62	0.10	4.55
PentaD/TPOX	0.10	4.87	0.07	5.22
PentaD/vWA	0.43	15.65	0.60	1.02
PentaE/TH01	0.54	4.61	0.32	2.28
PentaE/TPOX	**0.00**	1.11	0.07	5.25
PentaE/vWA	0.23	2.70	0.23	2.91
TH01/TPOX	**0.00**	0.58	0.10	4.51
TH01/vWA	0.20	0.51	0.85	0.32

TPOX/vWA	0.40	0.64	0.30	2.44
Sum[-2ln(p)]		835.79	-	444.47
***p*-value**		2.79E-36	-	1.25E-02

Entries with a p-value less than 0.05 are nominally 'significant.' This means that they would normally be interpreted as evidence for departure from independence. However in this dataset we have what is termed the 'multi-testing problem' which must be considered when interpreting the results. What this means is that we have performed many tests. In this case 20 Hardy-Weinberg and 190 linkage-equilibrium tests. About 5% of these are expected to give significant results by chance alone. There are various ways offered to deal with the multi-testing problem. Three of these are 1) the Bonferonni correction, 2) p-p plot or 3) the truncated product method.[6] The Bonferonni correction suffers from the handicap that it lowers the power of an already weak test.[7] For this reason the other two methods have been preferred. Graphical representations of the data are presented in Figures 1 through 4. These allow a level of visual comparison of the results of independence testing. If the hypotheses of Hardy-Weinberg and linkage equilibrium were true then the p-values should be distributed uniformly between 0 and 1; $p \sim U[0,1]$. As an example, the $x = y$ line in the p-p plots (Figures 1 - 4) represents equilibrium and deviations from that line can be seen as mild departures from equilibrium. The 95% confidence limit is also displayed on the p-p plots as the region within the two curved lines. In the p-p plot for the Australian Asian sub-population the data remains within the boundaries of this envelope. The Aboriginal population exhibits clear departures from expected p-values, and hence is neither in Hardy-Weinberg nor linkage equilibrium.

[6] Zaykin, D., Zhivotovsky, L. A. and Weir, B. S. (2002) Truncated product method for combining p-values. *Genetics and Epidemiology* 22: 170-185.

[7] Buckleton, J. S., Walsh, S. J. and Harbison, S. A. (2001) The fallacy of independence testing and the use of the product rule. *Science & Justice* 41: 81-84.

Figure 1: *p-p* plot for the LE tests on the Australian Aboriginal PP21 Dataset.

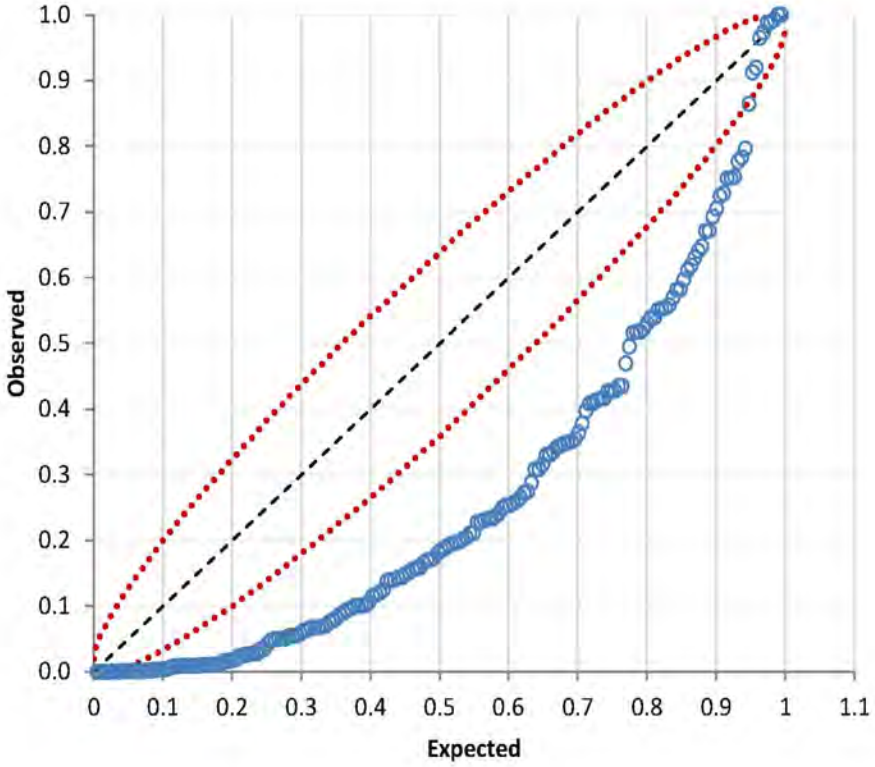


Figure 2: *p-p* plot for the HW tests on the Australian Aboriginal PP21 Dataset.

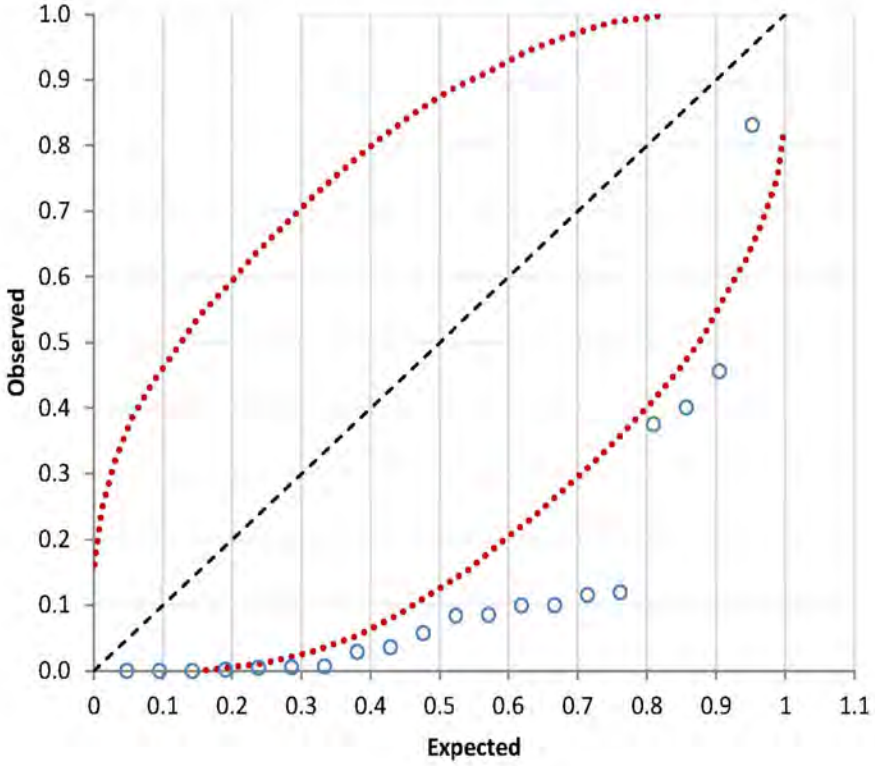


Figure 3: *p-p* plot for the LE tests on the Australian Asian PP21 Dataset.

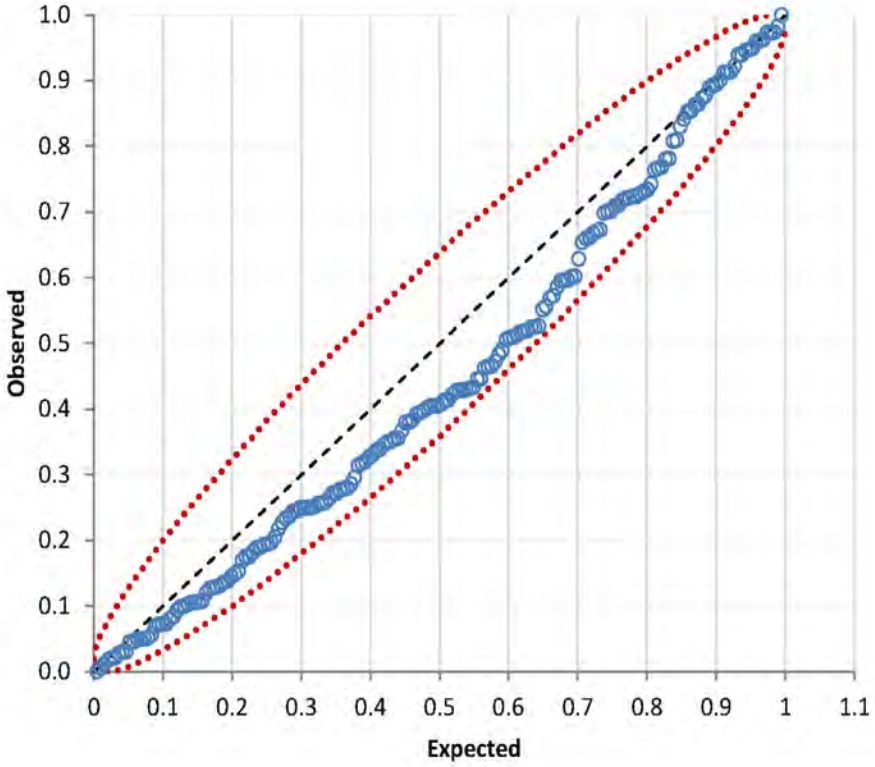
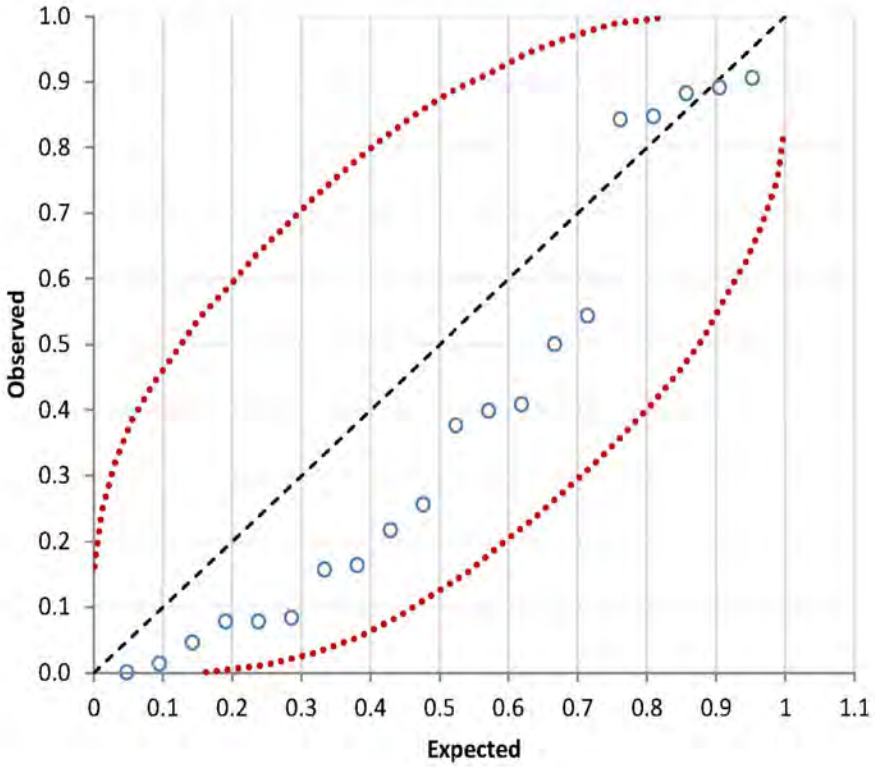


Figure 4: *p-p* plot for the HW tests on the Australian Asian PP21 Dataset.



The remaining method is the truncated product method of Zaykin, Zhivotovsky and Weir.[8] This involves forming the sum of $-2\ln(p)$ across, say, t independent tests (Table 4 and 5). This is expected to have a chi-square distribution with $2t$ degrees of freedom. Use of the chi-square distribution allows us to calculate the p-value for the null hypothesis that all 20 loci are in HWE, or that all 190 pairs of loci are in LE. It is important to note that these tests are not independent and hence the truncated product method can only be used as a guide.

The p-value for the HW tests would be deemed significant at the 5% significance level and as such would be taken as evidence for departure from HW.

Whilst Fisher's Exact Test is the method of choice for investigating departures from independence in this situation, it has limited power for samples of small or moderate size. The datasets analysed here are moderately sized by international standards. As such it is expected that Fisher's Exact Test would be expected to begin to find departures in the dataset if they were present.

3. DEPARTURES FROM EQUILIBRIUM

Whilst Fisher's exact test is acknowledged to be the most powerful for detecting departures from equilibrium it does not indicate which genotype or genotypes are contributing to the departure. This investigation is practical for HW using a Chi-square to indicate the departing genotypes. There are known patterns of departure from HW caused by subpopulations or admixture and these may occasionally be detected using the Chi-square.

Following independence testing on the Aboriginal dataset departures from HWE as indicated by low p-values were detected at the following loci:

- D16 (p=0.00)
- D18 (p=0.01)
- D1 (p=0.00)
- D21 (p=0.04)
- D2 (p=0.01)
- D5 (p=0.03)
- PentaD (p=0.00)
- PentaE (p=0.00)
- TPOX (p=0.00).

Within the Asian dataset departures from HWE were detected at D19 (p = 0.00) and D2 (p = 0.01). A check by partial Chi square of observed minus expected for each genotype

[8] *Ibid*, note 7, once again this explanation for the truncated product method follows Buckleton (2005) extensively.

produces a total of $n(n+1)\chi_1^2$ tests where n = number of alleles, each of which is nominally significant at a χ^2 value of 3.84. The pattern of departure showed no trends.

4. GENERAL CONCLUSIONS

The Australian Aboriginal and Asian sub-population datasets have been examined by a regime of statistical tests that meet the requirements of the international forensic community. The Aboriginal dataset shows clear evidence of departure from Hardy-Weinberg. The Asian dataset shows some indication of departure from Hardy-Weinberg.

As mentioned earlier, the results of independence are restricted in terms of their ability to inform us with respect to assumptions regarding a choice of population genetic model. This is due to the fact that formal testing procedures, when applied to databases of a few thousand individuals do not have sufficient power to show that the underlying populations are not in Hardy-Weinberg Equilibrium, or are not substructured or are admixed[9,10]. The datasets analysed here are moderately large by international standards and may be of a size that will reliably facilitate detection of any large departures from equilibrium. Regardless of the results of independence testing, our knowledge of the history of human populations leads us to expect that some level of admixture or substructure exists in all populations. With this in mind it is advised that balanced conclusions should be drawn from the testing of these datasets. An example may be; *"these tests cannot differentiate between the model of independence and the model of mild departure, therefore it is in the interests of balanced testimony to concede that mild departure may exist."*

For criminal investigations, it is recommended that multi-locus profile probabilities be calculated by the method of Balding and Nichols[11] (which appears as NRC recommendation 4.2; formulae 4.10a and 4.10b,[12] equations 4.20 in Evett and Weir[13] and equations 3.4 in Buckleton, Triggs and Walsh[14]). The Balding and Nichols formulae are commonly applied with conservative values of the inbreeding coefficient (θ or Fst).

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[9] See Triggs CM and Buckleton JS. (2002) Logical implications of applying the principles of population genetics to the interpretation of DNA profiling evidence. *Forensic Science International* 128: 108-114.

[10] Buckleton JS. (2004) Validating databases. In: Buckleton JS, Triggs CM and Walsh SJ (Eds). *Forensic DNA Evidence Interpretation*. CRC Press: Boca Raton, Fl., pp. 149-196.

[11] Balding DJ and Nichols RA. (1994) DNA profile match probability calculation: how to allow for population stratification, relatedness, database selection and single bands. *Forensic Science International* 64: 125-140.

[12] National Research Council (1996) The evaluation of forensic DNA evidence. *National Academy Press*, Washington, D.C.

[13] Evett IW and Weir BS. (1998) *Interpreting DNA Evidence*. Sinauer Associates, Inc., Sunderland, Ma.

[14] Buckleton JS, Triggs CM and Walsh SJ. (Eds.) (2005) *Forensic DNA Evidence Interpretation*. CRC Press, Boca Raton, Fl.

For non-criminal disputed parentage cases it is often less clear what the appropriate direction is in which to concede doubt. Under these circumstances, the product rule may be the better estimate.

The Australian Aboriginal and Asian population databases are of suitable size for the purpose of estimating allele frequencies.

Loci D12 and vWA are both on chromosome 12 and separated by approximately 12cM, which means that allelic inheritance from these two loci are not completely independent. On a population level the partial linkage of these two loci mean that they will take a longer time (i.e. a greater number of generations) to re-equilibrate after a population event (such as drastic increases or decreases in population size). As for Caucasians, Aboriginal and Asian populations are not known to have undergone recent population events and so it is not surprising that linkage disequilibrium was not detected between D12 and vWA in this data. Other studies have similarly found little evidence of linkage disequilibrium between these two loci in Caucasians at a population level[15,16,17]. We recommend that for the Australian Caucasian dataset D12 and vWA can be treated as independent for use in matching statistics for unrelated people but not for siblings, half siblings, cousins, uncle-nephew and some other relationships. When considering some pedigree analyses linkage should be taken into account. Refer to Gill et al for a full discussion[18].

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[15] Lewis O'Connor K, Hill CR, Vallone PM, Butler JM. (2012) Linkage disequilibrium analysis of D12S391 and vWA in U.S. population and paternity samples. *Forensic Science International:Genetics.* Article in press

[16] Lewis O'Connor K, Hill CR, Vallone PM, Butler JM. (2012) Corrigendum to "Linkage disequilibrium analysis of D12S391 and vWA in U.S. population and paternity samples". *Forensic Science International:Genetics.* Article in press

[17] Budowle B, Ge J, Chakraborty R, Eisenberg AJ, Green R, Mulero J, Lagace R, Hennessy L. (2011) Population genetic analyses of the NGM STR loci. *International Journal of Legal Medicine.* 125(1): 101-109.

[18] Gill P, Phillips C, McGovern C, Bright J, Buckleton J. (2012) An evaluation of potential allelic association between the STRs vWA and D12S391: Implications in criminal casework and applications to short pedigrees. *Forensic Science International:Genetics.* Article in press

Analysis of the Australian Caucasian Sub-Population Data for the PowerPlex® 21 Autosomal Short Tandem Repeat Loci

23 May 2012

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PREFACE

Data for the Australian Caucasian sub-population were received in the form of MS EXCEL™ spreadsheets as part of a request to undertake a statistical analysis from the following laboratories. A summary of the participating the labs the number of samples is provided in Table 1.

Table 1: A summary of participating laboratories and number of samples analysed.

Laboratory	Number of samples
Australian Federal Police, Canberra	223
Division of Analytical Laboratories, NSW	200
Forensic Science Service, Tasmania	201
Forensic Science, South Australia	355
Forensic Services, Northern Territory Police	189
PathWest, Western Australia	200
Queensland Health Forensic & Scientific Services	139
Victorian Police Forensic Services Department	200

The data were checked for typographical and/or data entry errors and duplicate profiles. Three within dataset and one between dataset duplicate profiles were deleted prior to analysis.

The following abbreviations have been used intermittently throughout this report are summarised in Table 2.

Table 2: A list of abbreviations used in the text or tables of this report.

Full term	Abbreviation
Short tandem repeat	STR
Deoxyribonucleic Acid	DNA
PowerPlex 21	PP21
Hardy-Weinberg Equilibrium	HWE
Linkage Equilibrium	LE
Fisher's Exact Test	FET
Observed	Obs
Expected	Exp

INTRODUCTION

It is a requirement that forensic DNA profiling evidence be accompanied by an estimation of its weight, such that the court can assign an appropriate probative value during legal proceedings. There are various models by which this estimation can be made, but each relies on approximations of the allele frequencies in the relevant population, and some understanding of population genetic features that may influence the estimation process.

A dataset from the Caucasian sub-population of Australia has been compiled. The DNA profiles have been generated using the PowerPlex® 21 STR amplification kit. The Caucasian sub-population dataset contained 1,707 profiles (N = 1707) from individuals who had self-declared their ethnic origin as Caucasian. Note that there are 20 STR within the PowerPlex® 21 multiplex plus Amelogenin.

These data have been examined in a manner that is consistent with the requirements of the international forensic community. The approach largely follows that outlined by Buckleton (2005)[1] and employs procedures developed by Weir.[2,3] The results of the statistical analysis are presented in the following sections:

1. Allele counts
2. Independence testing
3. Departures from Hardy-Weinberg Equilibrium

This is followed by general conclusions drawn from the data analysis.

[1] Buckleton JS. (2005) Validating databases. In: Buckleton JS, Triggs CM and Walsh SJ (Eds). *Forensic DNA Evidence Interpretation*. CRC Press: Boca Raton, Fl., pp. 157-196.
[2] Weir, B.S. (1996) *Genetic Data Analysis II*. Sinauer, Sunderland, Ma.
[3] Evett IW and Weir BS. (1998) *Interpreting DNA Evidence*. Sinauer Associates, Inc., Sunderland, Ma.

RESULTS OF DATA TESTING

1. ALLELE COUNTS

The allele counts for each of the 20 PowerPlex® 21 STR loci for the Caucasian dataset is presented in Table 2.

Table 3: Allele counts for the 20 PowerPlex® 21 STR loci for the Caucasian sub-population.

Allele	CSF	D12	D13	D16	D18	D19	D1	D21	D2S	D3	D5	D6	D7	D8	FGA	Penta D	Penta E	TH01	TPOX	vWA
2.2																8				
5																	273	10	1	
6			1													3	1	796	1	
6.3													1							
7	3		3								4		57			10	548	634	5	
7.3																			1	
8	17		420	62	1						6		551	65		64	51	333	1800	
8.3													1							
9	80		277	424	2		1				129	3	531	35		726	28	508	372	
9.1													3							
9.2					2															
9.3													1					1098		
10	900		233	203	31	3	3			1	235	44	925	318		410	307	27	201	
11	1014		1003	989	33	11	263			3	1249	1093	709	245		480	342		835	2
11.1													1							
11.3	2																			
12	1077		973	1018	502	253	448			1	1171	881	494	499		714	614		127	
12.1				1																
12.2			1			4														
13	238		329	612	407	861	205		2	13	566	273	104	1107		674	378		2	6
13.2						44														
13.3					1							1								
13.4																2				
14	39		148	94	560	1195	313			413	31	187	23	654		214	185		2	345
14.2						86														
14.3							18													
15	10	123	7	7	462	572	491		1	929	7	25		373	2	63	152			405

15.2						125														
15.3					1		236													
15.4																	1			
16		104			477	177	399		106	863		20		98		13	161			736
16.1							3													
16.2					1	46														
16.3		2					193													
17		381			433	15	175		698	665		174		13	1	5	163			894
17.1							3													
17.2						10														
17.3		68					442													
17.4																	1			
18		578			232	1	12		295	482		246		2	51	1	88			711
18.2						5														
18.3		69					175													1
18.4																	1			
19		400			151		3		382	43		321			234		35			256
19.1		1																		
19.2		1													1					
19.3		32					27													
20		371			68				451			111			472		20			48
20.2															8					
20.3		2					2					1								
21		388			26				109			20			616		13			7
21.2												1			11					
21.3												6								
22		382			14				115			1			603		5			
22.1															1					
22.2															43					
22.3															1					
23		284			7				391						503		2			
23.2															17					
23.3									1											
24		117			1				386						448					
24.2								9												
25		76			2			1	379						251					
25.2								3												

26		15						4	73						105					
26.2								1												
27		8						116	9						28					
28								528	1						3					
29								709												
29.2								5												
30								862												
30.2								107												
31								254												
31.2								318												
32								47												
32.2								320												
33								5												
33.2								104												
34.2								11												
35								1												
35.2								3												
39.2								2												
F	34	12	19	4		4	2	4	13	1	16	6	13	5	9	27	45	8	67	3
R						2			2						6					
n	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414	3414

An F indicates missing values where the genotype of the individual at that locus was not able to be determined reliably. R indicates a rare allele. The ten R values occur where triallelic patterns were observed (5 loci), for example due to trisomy or somatic mutation. The loci have been designated as R,R.

2. INDEPENDENCE TESTING

For each locus and each pair of loci in the sample an exact test of allelic association was conducted. Significance levels (*p*-values) were generated empirically by the permutation procedure,[4] with 10,000 permutations (Table 4 and 5). This number is expected to give a 95% confidence interval of ±0.0043 for a *p*-value around 0.05.[5]

Table 4: Results of Fisher's Exact test for allelic association for each locus (HWE) for the Australian Caucasian PP21 dataset. Values below 0.05 are shown in bold.

Locus	*p*-value	-2ln(*p*)
		HWE
CSF	0.53	1.26
D12	0.10	4.68
D13	0.26	2.72
D16	0.51	1.37
D18	0.25	2.74
D19	**0.04**	6.34
D1	0.97	0.07
D21	0.94	0.12
D2	0.29	2.49
D3	0.52	1.29
D5	0.25	2.80
D6	0.83	0.36
D7	0.87	0.29
D8	0.56	1.17
FGA	**0.01**	9.09
PentaD	0.17	3.57
PentaE	0.12	4.19
TH01	0.16	3.70
TPOX	0.35	2.13
vWA	1.00	0.00
Sum[-2ln(*p*)]		50.66
***p*-value**		0.12

[4] Guo SW and Thompson EA. 1992. Performing the exact test of Hardy Weinberg proportion for multiple alleles. *Biometrics* 48:361-372.

[5] $\pm 1.96\sqrt{\frac{p(1-p)}{n}}$ from Evett IW and Weir BS (1998). *Interpreting DNA Evidence*. Sinauer Associates, Inc.: Sunderland, Ma.

Table 5: Results of Fisher's Exact test for allelic association for each pair of loci (LE) for the Australian Caucasian PP21 dataset. Values below 0.05 are shown in bold.

Locus	p-value	-2ln(p)
		LE
CSF/D12	0.64	0.90
CSF/D13	0.42	1.74
CSF/D16	0.04	6.49
CSF/D18	0.41	1.78
CSF/D19	0.46	1.55
CSF/D1	0.76	0.56
CSF/D21	0.44	1.64
CSF/D2	0.62	0.96
CSF/D3	0.09	4.77
CSF/D5	0.56	1.14
CSF/D6	0.84	0.35
CSF/D7	0.28	2.55
CSF/D8	0.90	0.22
CSF/FGA	0.15	3.77
CSF/PentaD	0.97	0.05
CSF/PentaE	0.05	5.80
CSF/TH01	0.70	0.71
CSF/TPOX	0.37	2.01
CSF/vWA	0.07	5.25
D12/D13	0.70	0.73
D12/D16	0.47	1.50
D12/D18	0.46	1.56
D12/D19	0.48	1.48
D12/D1	1.00	0.01
D12/D21	**0.03**	6.95
D12/D2	0.34	2.17
D12/D3	0.62	0.96
D12/D5	0.14	3.99
D12/D6	0.61	0.98
D12/D7	**0.03**	6.85
D12/D8	0.35	2.12
D12/FGA	0.73	0.63
D12/PentaD	0.77	0.52
D12/PentaE	0.96	0.08
D12/TH01	0.50	1.41

D12/TPOX	0.47	1.52
D12/vWA	0.55	1.18
D13/D16	0.29	2.50
D13/D18	0.34	2.14
D13/D19	0.52	1.30
D13/D1	0.64	0.91
D13/D21	0.77	0.52
D13/D2	0.63	0.92
D13/D3	0.66	0.83
D13/D5	0.78	0.51
D13/D6	0.09	4.77
D13/D7	0.78	0.49
D13/D8	0.11	4.42
D13/FGA	0.29	2.47
D13/PentaD	0.85	0.33
D13/PentaE	0.69	0.75
D13/TH01	0.52	1.30
D13/TPOX	0.30	2.40
D13/vWA	0.33	2.19
D16/D18	0.82	0.40
D16/D19	0.56	1.17
D16/D1	**0.04**	6.34
D16/D21	0.12	4.23
D16/D2	0.87	0.29
D16/D3	0.21	3.12
D16/D5	0.29	2.47
D16/D6	**0.04**	6.43
D16/D7	0.40	1.83
D16/D8	0.09	4.82
D16/FGA	0.17	3.59
D16/PentaD	0.14	3.98
D16/PentaE	0.88	0.27
D16/TH01	0.16	3.69
D16/TPOX	0.64	0.89
D16/vWA	0.21	3.12
D18/D19	0.15	3.83
D18/D1	0.19	3.36
D18/D21	0.73	0.62
D18/D2	**0.02**	7.42

D18/D3	0.88	0.26
D18/D5	0.22	3.02
D18/D6	0.05	5.88
D18/D7	**0.03**	7.19
D18/D8	0.55	1.18
D18/FGA	0.08	5.05
D18/PentaD	0.59	1.07
D18/PentaE	0.27	2.60
D18/TH01	0.48	1.45
D18/TPOX	0.85	0.33
D18/vWA	0.15	3.82
D19/D1	0.43	1.67
D19/D21	0.69	0.73
D19/D2	0.65	0.85
D19/D3	0.97	0.06
D19/D5	0.98	0.05
D19/D6	0.18	3.44
D19/D7	**0.03**	7.12
D19/D8	0.29	2.49
D19/FGA	0.28	2.52
D19/PentaD	0.69	0.74
D19/PentaE	0.68	0.77
D19/TH01	0.35	2.08
D19/TPOX	0.59	1.04
D19/vWA	0.68	0.76
D1/D21	0.38	1.95
D1/D2	0.31	2.33
D1/D3	0.38	1.94
D1/D5	0.15	3.85
D1/D6	**0.04**	6.21
D1/D7	0.93	0.15
D1/D8	0.26	2.72
D1/FGA	0.34	2.18
D1/PentaD	0.53	1.27
D1/PentaE	0.44	1.65
D1/TH01	0.19	3.34
D1/TPOX	0.59	1.07
D1/vWA	0.31	2.33
D21/D2	0.18	3.38

D21/D3	0.73	0.62
D21/D5	0.87	0.28
D21/D6	0.10	4.56
D21/D7	0.75	0.58
D21/D8	0.78	0.49
D21/FGA	**0.03**	6.77
D21/PentaD	0.37	1.98
D21/PentaE	0.78	0.49
D21/TH01	0.07	5.31
D21/TPOX	0.79	0.48
D21/vWA	0.43	1.70
D2/D3	0.76	0.56
D2/D5	0.51	1.35
D2/D6	0.58	1.09
D2/D7	0.75	0.57
D2/D8	0.44	1.64
D2/FGA	0.89	0.24
D2/PentaD	0.31	2.37
D2/PentaE	0.34	2.16
D2/TH01	0.69	0.74
D2/TPOX	0.96	0.07
D2/vWA	0.73	0.63
D3/D5	0.50	1.38
D3/D6	0.61	1.00
D3/D7	0.30	2.42
D3/D8	0.08	5.06
D3/FGA	0.56	1.15
D3/PentaD	0.99	0.03
D3/PentaE	0.88	0.25
D3/TH01	0.73	0.63
D3/TPOX	0.75	0.58
D3/vWA	0.33	2.21
D5/D6	0.70	0.72
D5/D7	0.82	0.40
D5/D8	0.57	1.12
D5/FGA	0.73	0.63
D5/PentaD	0.08	5.03
D5/PentaE	0.18	3.38
D5/TH01	0.64	0.91

D5/TPOX	0.97	0.05
D5/vWA	0.22	3.07
D6/D7	0.58	1.08
D6/D8	0.08	4.94
D6/FGA	0.65	0.87
D6/PentaD	0.56	1.15
D6/PentaE	0.35	2.09
D6/TH01	0.11	4.45
D6/TPOX	0.52	1.32
D6/vWA	0.28	2.52
D7/D8	0.50	1.39
D7/FGA	0.83	0.36
D7/PentaD	0.59	1.06
D7/PentaE	0.50	1.40
D7/TH01	0.24	2.82
D7/TPOX	0.34	2.16
D7/vWA	0.90	0.20
D8/FGA	0.84	0.36
D8/PentaD	0.67	0.80
D8/PentaE	0.16	3.65
D8/TH01	0.20	3.17
D8/TPOX	0.54	1.23
D8/vWA	**0.01**	8.88
FGA/PentaD	0.55	1.20
FGA/PentaE	0.68	0.76
FGA/TH01	0.28	2.52
FGA/TPOX	0.87	0.27
FGA/vWA	0.51	1.36
PentaD/PentaE	0.43	1.71
PentaD/TH01	0.44	1.62
PentaD/TPOX	0.09	4.87
PentaD/vWA	**0.00**	15.65
PentaE/TH01	0.10	4.61
PentaE/TPOX	0.57	1.11
PentaE/vWA	0.26	2.70
TH01/TPOX	0.75	0.58
TH01/vWA	0.77	0.51
TPOX/vWA	0.73	0.64
Sum[-2ln(*p*)]		422.28

p-value	0.15

Entries with a *p*-value less than 0.05 are nominally 'significant.' This means that they would normally be interpreted as evidence for departure from independence. However in this dataset we have what is termed the 'multi-testing problem'. What this means is that we have performed many tests. In this case 20 Hardy-Weinberg and 190 linkage-equilibrium tests. About 5% of these are expected to give significant results by chance alone. There are various ways offered to deal with the multi-testing problem. Three of these are 1) the Bonferonni correction, 2) simple graphical examination or 3) the truncated product method.[6] The Bonferonni correction suffers from the handicap that it lowers the power of an already weak test.[7] For this reason the other two methods have been preferred. Graphical representations of the data are presented in Figures 1 and 2. These allow a level of visual comparison of the results of independence testing. If the hypotheses of Hardy-Weinberg and linkage equilibrium were true then the *p*-values should be distributed uniformly between 0 and 1; $p \sim U[0,1]$. As an example, the $x = y$ line in the *p-p* plots (Figures 1 and 2) represents equilibrium and deviations from that line can be seen as mild departures from equilibrium. The 95% confidence limit is also displayed on the *p-p* plots as the region within the two curved lines. In the *p-p* plot for the Australian Caucasian sub-population the data remains within the boundaries of this envelope.

[6] Zaykin, D., Zhivotovsky, L. A. and Weir, B. S. (2002) Truncated product method for combining p-values. *Genetics and Epidemiology* 22: 170-185.

[7] Buckleton, J. S., Walsh, S. J. and Harbison, S. A. (2001) The fallacy of independence testing and the use of the product rule. *Science & Justice* 41: 81-84.

Figure 1: *p-p* plot for the LE tests on the Australian Caucasian PP21 Dataset.

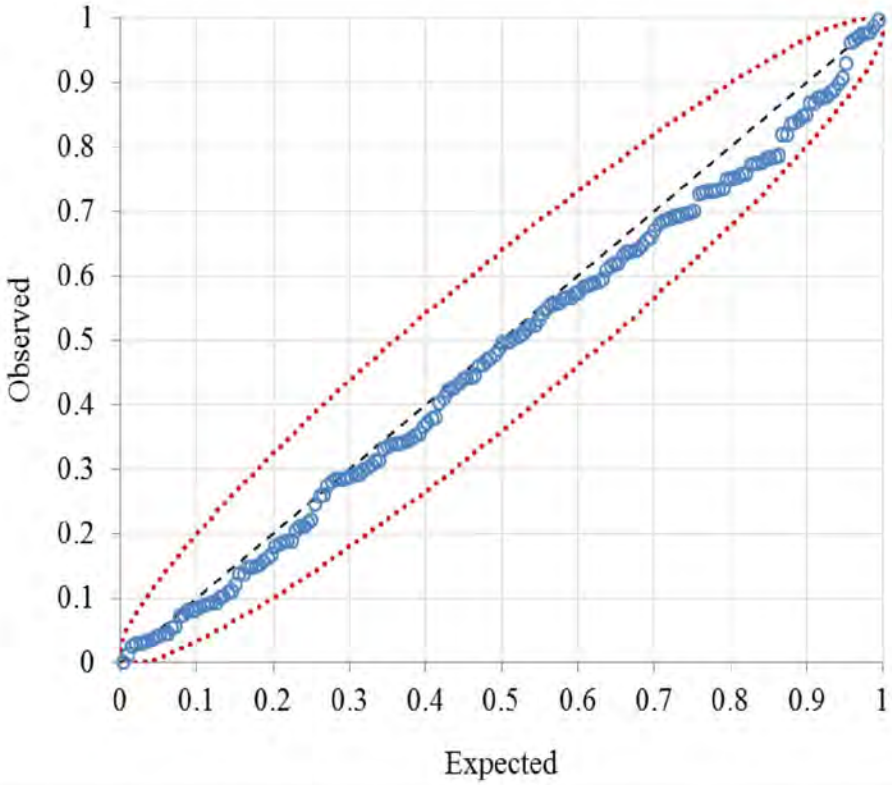
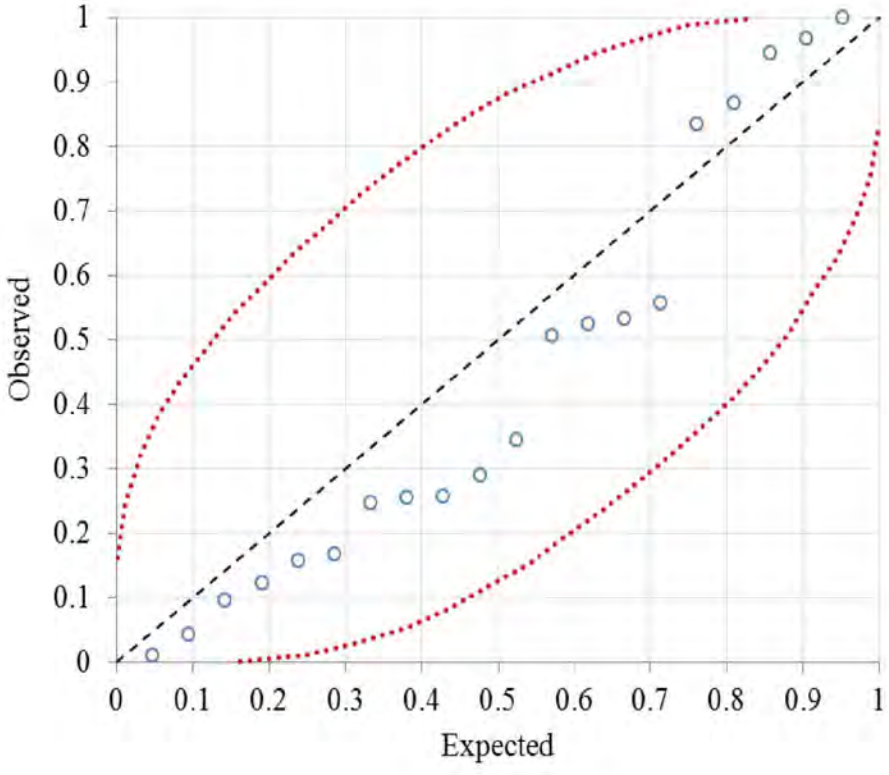


Figure 2: *p-p* plot for the HW tests on the Australian Caucasian PP21 Dataset.



The remaining method is the truncated product method of Zaykin, Zhivotovsky and Weir.[8] This involves forming the sum of $-2\ln(p)$ across, say, t independent tests (Table 3). This is expected to have a chi-square distribution with $2t$ degrees of freedom. Use of the chi-square distribution allows us to calculate the p-value for the null hypothesis that all 20 loci are in HWE, or that all 190 pairs of loci are in LE. It is important to note that these tests are not independent and hence the truncated product method can only be used as a guide.

The p-value for the HW tests would be deemed significant at the 5% significance level and as such would be taken as evidence for mild departure from HW.

Whilst Fisher's Exact Test is the method of choice for investigating departures from independence in this situation, it has limited power for samples of small or moderate size. The dataset analysed here is moderately sized by international standards. As such it is expected that Fisher's Exact Test would be expected to begin to find departures in the dataset if they were present.

3. DEPARTURES FROM EQUILIBRIUM

Whilst Fisher's exact test is acknowledged to be the most powerful for detecting departures from equilibrium it does not indicate which genotype or genotypes are contributing to the departure. This investigation is practical for HW using a Chi-square to indicate the departing genotypes. There are known patterns of departure from HW caused by subpopulations or admixture and these may occasionally be detected using the Chi-square. Following independence testing on the Australian Caucasian dataset departures from HWE were detected at D19 (p = 0.04) and FGA (p = 0.01). A check by Chi square of observed minus expected for each genotype produces a total of $n(n+1)\chi_1^2$ tests where n = number of alleles, each of which is nominally significant at a χ^2 value of 3.84. The pattern of departure showed no trends.

4. GENERAL CONCLUSIONS

The Australian Caucasian sub-population dataset have been examined by a regime of statistical tests that meet the requirements of the international forensic community. This dataset shows slight evidence for departure from Hardy-Weinberg.

As mentioned earlier, the results of independence are restricted in terms of their ability to inform us with respect to assumptions regarding a choice of population genetic model. This is due to the fact that formal testing procedures, when applied to databases of a few thousand individuals do not have sufficient power to show that the underlying

[8] *Ibid*, note 7, once again this explanation for the truncated product method follows Buckleton (2005) extensively.

populations are not in Hardy-Weinberg Equilibrium, or are not substructured or are admixed[9,10]. The dataset analysed here is moderately large by international standards and may be of a size that will reliably facilitate detection of any large departures from equilibrium. Regardless of the results of independence testing, our knowledge of the history of human populations leads us to expect that some level of admixture or substructure exists in all populations. With this in mind it is advised that balanced conclusions should be drawn from the testing of these datasets. An example may be; *"these tests cannot differentiate between the model of independence and the model of mild departure, therefore it is in the interests of balanced testimony to concede that mild departure may exist."*

For criminal investigations, it is recommended that multi-locus profile probabilities be calculated by the method of Balding and Nichols[11] (which appears as NRC recommendation 4.2; formulae 4.10a and 4.10b,[12] equations 4.20 in Evett and Weir[13] and equations 3.4 in Buckleton, Triggs and Walsh[14]). The Balding and Nichols formulae are commonly applied with conservative values of the inbreeding coefficient (θ or Fst).

For non-criminal disputed parentage cases it is often less clear what the appropriate direction is in which to concede doubt. Under these circumstances, the product rule may be the better estimate.

The Australian Caucasian population database is of suitable size for the purpose of estimating allele frequencies. If allele frequencies are going to be estimated using databases drawn from samples of individuals, it is recommended that the resulting estimates be adjusted for the induced sampling variation[15].

Loci D12 and vWA are both on chromosome 12 and separated by approximately 12cM, which means that allelic inheritance from these two loci are not completely independent. On a population level the partial linkage of these two loci mean that they will take a longer time (i.e. a greater number of generations) to re-equilibrate after a population event (such as drastic increases or decreases in population size). Caucasians are not known to have undergone recent population events and so it is not surprising that linkage disequilibrium was not detected between D12 and vWA in the analysis of the Australian Caucasian data. Other studies have similarly found little evidence of linkage

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[9] See Triggs CM and Buckleton JS. (2002) Logical implications of applying the principles of population genetics to the interpretation of DNA profiling evidence. *Forensic Science International* 128: 108-114.

[10] Buckleton JS. (2004) Validating databases. In: Buckleton JS, Triggs CM and Walsh SJ (Eds). *Forensic DNA Evidence Interpretation*. CRC Press: Boca Raton, Fl., pp. 149-196.

[11] Balding DJ and Nichols RA. (1994) DNA profile match probability calculation: how to allow for population stratification, relatedness, database selection and single bands. *Forensic Science International* 64: 125-140.

[12] National Research Council (1996) The evaluation of forensic DNA evidence. *National Academy Press*, Washington, D.C.

[13] Evett IW and Weir BS. (1998) *Interpreting DNA Evidence*. Sinauer Associates, Inc., Sunderland, Ma.

[14] Buckleton JS, Triggs CM and Walsh SJ. (Eds.) (2005) *Forensic DNA Evidence Interpretation*. CRC Press, Boca Raton, Fl.

[15] Buckleton JS and Curran JM. (2005) Sampling effects. In Buckleton JS, Triggs CM and Walsh SJ. (eds.), *Forensic DNA Evidence Interpretation*. CRC Press, Boca Raton, Fl, pp. 197-216.

disequilibrium between these two loci in Caucasians at a population level[16,17,18]. We recommend that for the Australian Caucasian dataset D12 and vWA can be treated as independent for use in matching statistics. Any linkage disequilibrium present between these two loci will be slight. When considering some pedigree analyses linkage should be taken into account. Refer to Gill et al for a full discussion[19].

[16] Lewis O'Connor K, Hill CR, Vallone PM, Butler JM. (2012) Linkage disequilibrium analysis of D12S391 and vWA in U.S. population and paternity samples. *Forensic Science International:Genetics.* Article in press

[17] Lewis O'Connor K, Hill CR, Vallone PM, Butler JM. (2012) Corrigendum to "Linkage disequilibrium analysis of D12S391 and vWA in U.S. population and paternity samples". *Forensic Science International:Genetics.* Article in press

[18] Budowle B, Ge J, Chakraborty R, Eisenberg AJ, Green R, Mulero J, Lagace R, Hennessy L. (2011) Population genetic analyses of the NGM STR loci. *International Journal of Legal Medicine.* 125(1): 101-109.

[19] Gill P, Phillips C, McGovern C, Bright J, Bucklteon J. (2012) An evaluation of potential allelic association between the STRs vWA and D12S391: Implications in criminal casework and applications to short pedigrees. *Forensic Science International:Genetics.* Article in press

CA-49

HSSA | Health Services Support Agency

Verification of the DNA Profile Analysis module of STRmix™ using the Promega PowerPlex®21 system

Proposal #105

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December 2012

Queensland Government

Document details

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Contents

1 Introduction

STRmix™ is a proprietary software solution for the consistent interpretation of DNA profiles. To meet Queensland legislative requirements and core business needs, DNA Analysis has performed a verification of STRmix™ for the interpretation of DNA profiles generated using the PowerPlex® 21 system DNA profiling kit. This change has been implemented across Australia and New Zealand under the direction of the Australian & New Zealand Police Advisory Agency (ANZPAA). STRmix™ was developed by Dr Duncan Taylor from FSSA and Jo-Anne Bright and Dr John Buckleton from Environmental Science & Research (ESR). It has been externally validated as a statistical model for DNA interpretation and has been endorsed by the Biological Specialist Advisory Group (BSAG).

Unlike binary DNA interpretation methods, STRMix™ uses a continuous model that accounts for drop-out, drop-in, stutter peak heights, peak height imbalance and possible mixed DNA sources. DNA profiles of between one and four contributors can be analysed. The software uses a Monte Carlo Markov Chain (MCMC) algorithm to deconvolute the various possible contributors of a mixed DNA profile, based on a mathematical model developed by Jo-Anne Bright, Dr Duncan Taylor and Dr John Buckleton (*STRmix™ V1.05 User's Manual*). This model provides a probabilistic weighting to indicate the "strengths" of the possible allelic combinations of a particular locus. These relative strengths are used to determine the likelihood of a particular DNA profile occurring, had a person of interest contributed DNA.

2 Aims

Ideally, when introducing a new methodology, a direct comparison between the existing and the novel method is performed. The current methods for statistical analysis of DNA profiles in QHFSS DNA Analysis are the Kinship and CODIS Popstats software packages. These calculate a match probability and a likelihood ratio respectively, however both are premised on the use of binary analysis methods using DNA profiles produced by the nine locus AmpFℓSTR® Profiler Plus® kit.

STRmix™ has been proposed as a means of analysing DNA profiles produced by the twenty STR locus Promega PowerPlex® 21 system. The continuous model employed by STRmix™ for analysing DNA profiles cannot be directly compared with the binary model of DNA profile analysis previously used by QHFSS DNA Analysis. As such, the significant differences between the two methodologies preclude a direct comparison of results. In order to address this issue, the following studies were performed using the STRmix™ software package in order to assess the suitability of this system as a reliable and reproducible means of deconvoluting DNA profiles and providing meaningful statistical weightings. Additional investigation was performed to determine the operating parameters, specific to the

QHFSS DNA Analysis analytical processes, which are necessary for the optimal operation of STRmix™.

STRmix™ requires parameters to be set in order to run. Where possible these settings have been decided at a national level using data provided from all jurisdictions. More information on the basic settings is provided in Appendix 2 of this report.

The specific aims of this project are:

1. Saturation Threshold

STRmix™ cannot accurately assess a DNA profile unless there is an appropriate (linear) relationship between the DNA input template and the RFU value produced. Due to the potential for the camera in the 3130xl to be overloaded by excessive signal, this relationship can become non-linear at higher template/rfu values. As such the maximum RFU value at which STRmix™ can perform properly needs to be determined as one of the operational settings for the software.

The expected peak height can be calculated from the observed stutter. The relationship between the expected peak height and the observed peak height should be linear with a gradient of approximately 1 as both values should be similar. The purpose of this study is to identify the RFU value at which this relationship starts to become non-linear thereby indicating that saturation of the camera has caused the true RFU value of the observed allele to be under-reported.

2. Determination of the Locus Amplification Variance

The purpose of the Model Maker component of STRmix™ software package is to determine the locus amplification variance. This variance is a critical value for the correct functioning of STRmix™. This report details the results produced by Model Maker.

3. Determination of the Variance Setting

Three different values for the variance were provided by Jo-Anne Bright, Dr John Buckleton and Dr Duncan Taylor (see Section 4-4.3 below). These values were derived from data produced by ten samples run at ten dilutions as well as the corresponding reference DNA data (see *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation*). This report details the testing carried out to determine which of the three variance values is appropriate for use in the analysis of both full (25µL total volume) and half (12.5µL total volume) volume DNA amplifications.

4. Single Source Deconvolution

This experiment will examine the ability of STRmix™ to deconvolute and produce likelihood ratios for single source DNA profiles consistently at a variety of dilutions/template quantities from both full and half volume amplifications.

5. Mixture Deconvolution

STRmix™ has the ability to deconvolute two, three and four person mixtures and it is critical that this can be done reliably. Consequently, this experiment assesses the ability of STRmix™ to accurately determine the possible DNA contributions of individuals to known mixtures. Various DNA contribution proportions and template quantities at both full and half volume amplification are examined.

6. Reproducibility of Results

It is paramount that STRmix™ provides consistent results when deconvoluting mixtures. Due to the random nature of the MCMC calculations, it is unlikely that multiple analyses of the same DNA profile will produce exactly the same result. However, repeated results should be within acceptable limits of one another. Accordingly, the ability of STRmix™ to generate reproducible DNA mixture deconvolution and likelihood ratio calculations are examined.

3 Materials

A number of resources are outlined in Section 3 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document. In addition to these resources, the following were required for the present verification:

- STRmix™ v1.05 software system
- Staff
- Computer time

4 Methods

Creation of mixed DNA profiles

The DNA profiles used in this validation were generated using the methods outlined in Section 4 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document.

Creation of input files

All of the DNA profiles required for this validation were exported from GeneMapper® ID-X v1.1.1 using the table settings detailed in Section 3 of the *STRmix™ V1.05 User's Manual.*

Determination of Variance

The variance values provided for DNA Analysis by Jo-Anne Bright & Dr. John Buckleton are detailed in Table 1 below.

Percentile	Variance Constant	
	Full volume	Half volume
50th	4.5	8.0
75th	6.7	11.2
90th	9.3	14.7

Table 1. Variance Values Determined by Jo-Anne Bright and Dr. John Buckleton for Half and Full Volum Amplification

4.1 Saturation Threshold

The 10x10 data described in Section 5.7 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document and additional data provided by other jurisdictions were provided to Jo-Anne Bright, Dr. Duncan Taylor and Dr. John Buckleton. From this data, locus-specific values (intercept and slope) for the linear relationship between stutter and allelic height were derived. These values are summarized below in Table 2.

Locus		Intercept	Slope
1	D3S1358	-0.0532	0.00875
2	D1S1656	0.0155	0.00469
3	D6S1043	0.0378	0.00208
4	D13S317	-0.063	0.0102
5	Penta E	-0.0185	0.00388
6	D16S539	-0.0549	0.0108
7	D18S51	-0.0462	0.00843
8	D2S1338	-0.013	0.00465
9	CSF1PO	-0.065	0.0114
10	Penta D	-0.012	0.00265
11	TH01	0.00607	0.00235
12	vWA	-0.136	0.0124
13	D21S11	-0.0811	0.00534
14	D7S820	-0.0606	0.0109
15	D5S818	-0.0748	0.0116
16	TPOX	-0.0334	0.00657
17	D8S1179	0.00787	0.00515
18	D12S391	-0.11	0.0104
19	D19S433	-0.0728	0.00997
20	FGA	-0.089	0.00707

Table 2. Locus Specific Values for all 20 Loci used for Calculation of the Expected Peak Height.

The observed peak heights and observed stutter heights of between approximately 100 and 450rfu (dependant on locus data) were recorded. This data was used to calculate the expected peak height from each of the stutter values using the equation (as per communication with Dr. Duncan Taylor):

$$E' = OS / (\text{slope} \times \text{allele value} + \text{intercept})$$

Where E' is the expected peak height
OS is the observed stutter height
Slope & Intercept as per Table 2

The observed peak height was plotted against the expected peak height for each data point.

4.2 Determination of Locus Amplification Variance

The 10x10 data described in Section 5.3 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document was analysed using the Model Maker module of STRmix™ as per Section 7.1 of the *STRmix™ v1.05 User's Manual*.

4.3 Determination of Variance Setting

Six of the mixed DNA profiles outlined in Section 5.10 of *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document were used for determining the variance setting for both full and half volume amplifications (see Table 3).

The six mixtures were analysed in STRmix™ using variances of 4.5, 6.7 and 9.3 for the full volume amplifications; and variances of 8.0, 11.2 and 14.7 for the half volume amplifications (see Table 1). The mixture deconvolution results were recorded and examined to determine whether or not STRmix™ had produced acceptable allelic pairings based on the known DNA contributions. The likelihood ratios (calculated using the Australian Caucasian dataset) were recorded and compared between the three variance settings at both full and half volume amplifications.

Mixture Ratio	Template (ng)
50:1	0.250
10:1	0.125
2:1	0.500
1:1	0.500
20:10:1	0.500
5:2:1	0.500

Table 3. Mixture Ratios and DNA Template Amounts used for the Determination of the Variance Values

4.4 Single Source Deconvolution

Section 5.3 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document details the samples that were generated to determine the baseline. One set of these samples was used for the single source deconvolution. To cover the smaller template levels, the 100pg and 50pg samples from Section 5.4 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* were also used. Table 4 lists the samples used for this experiment.

Each sample was analysed in STRmix™ for the full and half volume amplifications using variances of 9.3 and 14.7 respectively. The deconvoluted files and the likelihood ratios for each sample (calculated using the Australian Caucasian dataset) were examined to determine whether the profile was deconvoluted appropriately and that the correct genotype combinations were considered in the deconvolution. Additionally, to determine whether the likelihood ratios produced were intuitively appropriate for the DNA profile concerned.

Sample	Total DNA (ng)
1	0.500
2	0.447
3	0.394
4	0.342
5	0.289
6	0.236
7	0.183
8	0.131
9	0.078
10	0.025
11	0.100
12	0.050

Table 4. DNA Template used for Single-source Deconvolution.

4.5 Mixture Deconvolution

Section 5.10 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document details the mixed DNA profiles that were generated for the mixture studies and are detailed in Table 5 below. These mixtures were analysed in STRmix™ using a variance of 9.3 for full volume amplifications and 14.7 for half volume amplifications. The deconvoluted files and the likelihood ratios for each contributor (calculated using the Australian Caucasian dataset) were examined to determine whether the profile was deconvoluted appropriately; the correct genotype combinations were considered in the deconvolution; and to determine whether the likelihood ratios produced were intuitively appropriate for the DNA profile concerned.

Number of Contributors	Mixture Ratio	DNA Template (ng)		
2	50:1	0.500	0.250	0.125
	30:1	0.500	-	-
	20:1	0.500	0.250	0.125
	10:1	0.500	-	0.125
	5:1	0.500	-	0.125
	2:1	0.500	-	0.060
	1:1	0.500	-	-
3	20:10:1	0.500		0.125
	10:5:1	0.500	-	-
	5:2:1	0.500	-	0.125
4	5:3:2:1	0.500	-	0.125

Table 5. DNA Mixtures used for STRmix™ Validation Studies

4.6 Reproducibility of Results

The six mixtures used in Experiment 4.3 were also used to determine the reproducibility of the mixture deconvolution and the likelihood ratio output. These six mixtures were analysed separately in STRmix™ three times each for the full and half volume amplifications (Variance = 9.3 & 14.7 respectively). The likelihood ratios for each contributor were also calculated using the Australian Caucasian

dataset. The likelihood ratios were compared to determine whether the results were similar between analyses.

5 Results and Discussion

5.1 Saturation Threshold

Table 6 outlines the regression data results of the plots of expected versus observed peak height for each locus (see *Saturation Values Regression Data.xls* in I:\Change Management\Proposal #102\Stutter\ for raw values). There were no loci at which the linear relationship between the expected and observed peak heights failed, however it must be noted that only a few data points extended beyond 7000-8000rfu. In most cases, those that were present did not depart significantly from the regression gradient in any meaningful or predictable way. At the 7000-8000rfu heights, the DNA profiles had a tendency to demonstrate the effects of excess template and often possessed poor baseline integrity. As such, it was decided that 7000rfu was a suitable value for the saturation threshold.

Locus	Gradient	R^2	Locus	Gradient	R^2
D3S1358	1.04	0.97	TH01	0.87	0.75
D1S1656	1.08	0.92	vWA	0.95	0.78
D6S1043	0.97	0.92	D21S11	0.89	0.94
D13S317	0.95	0.90	D7S820	1.00	0.89
Penta E	0.84	0.75	D5S818	1.17	0.86
D16S539	0.94	0.98	TPOX	0.86	0.84
D18S51	0.97	0.97	D8S1179	0.94	0.93
D2S1338	1.05	0.97	D12S391	0.98	0.98
CSF1PO	0.96	0.94	D19S433	0.92	0.94
Penta D	0.46	0.46	FGA	0.90	0.94

Table 6. Gradients and R^2 Values for Lines of Fit of Expected vs. Observed Peak Height

5.2 Determination of Locus Amplification Variance

The values for the locus amplification variance produced from the 10x10 data by the Model Maker module of STRmix™ are:

- Half volume amplification = 0.033
- Full volume amplification = 0.030

The similarity in these values shows that the locus amplification variance is relatively stable between the two amplification volumes.

5.3 Determination of Variance Setting

The comparisons between the variances applied to the full and half volume amplifications showed that generally there was no difference between each value. However, one deconvolution (D16S539 of the 5:2:1 mixture - full volume amplification – 4.5 variance) failed to model the correct allelic pair representative of the known contributors. As such, a variance of 4.5 was deemed to be unsuitable for full volume amplifications. In all other cases, in both full and half volume amplification data, the true allelic set was considered as a valid genotype combination for every locus.

It was noted that the correct genotype combinations were not necessarily assigned the highest probability. This is expected with the model used, since STRmix™ will consider all of the possible genotype combinations that could make up this profile. The probabilities that were assigned were reasonable given the peak heights in the observed DNA profile. In general, where the correct genotype was a good fit to the profile, the probability decreased as the variance increased, which again was expected. However, this decrease did not appear to be large. Where the correct genotype was a poor fit to the observed profile, the probability increased as the variance increased. Again, this was expected and there did not appear to be a marked difference between values.

As the input template of the individual contributors decreased, the DNA profiles displayed significant stochastic effects (see also *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation)*. In these instances STRmix™ still considered the correct genotype combinations, albeit with a low probability. For example, the half volume 10:1 mixture with a total input template of 0.125ng displayed a drop-out peak at D1S1656 where the partner allele was 392rfu. STRmix™ did consider this drop-out event; however with a variance of 8 the correct genotype combination was given a weighting of only 6.63×10^{-4}. The weighting increased to 0.00415 with a variance of 14.7. It is considered that if the same profile was analysed again with a variance of 8 it is possible that the correct genotype combination will not be considered leading to a false exclusion. However, it is worth noting at this point that the input template of the contributor with which this drop-out event is associated is approximately 11pg. This sample would not be routinely amplified at the template level of 0.125ng according to the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document.

As there was no observable difference in the ability of the three variance values to accurately model the true allelic combination in preference to alternate combinations, the largest variance was chosen. It was decided based on the deconvolutions obtained, that the higher variances (Full=9.3, Half=14.7) gave a better statistical coverage of the possible allelic combinations that could be produced. It is noted though, that in doing so the probability space must be shared across a greater number of allelic combinations and therefore individual allelic probabilities for combinations that are a good fit to the observed profile will be lowered. It was expected that as the variance is increased, the number of genotype

combinations considered would increase due to the increased allowable variation in peak height.

The likelihood ratios for each of the contributors to each of the mixtures at each variance are detailed in Tables 7 and 8 below.

Mixture	Contributor	LR (Var 4.5)	LR (Var 6.7)	LR (Var 9.3)
1:1	1	3.86E+14	4.15E+14	3.79E+14
	2	2.09E+14	2.25E+14	2.06E+14
2:1	1	8.75E+25	1.23E+25	8.46E+23
	2	5.63E+25	6.78E+25	3.94E+23
10:1	1	8.45E+27	6.62E+27	4.59E+27
	2	1.40E+07	3.93E+07	1.44E+08
50:1	1	1.55E+28	1.55E+28	1.54E+28
	2	2.97E+03	2.02E+03	1.97E+03
5:2:1	1	7.09E+25	3.23E+25	8.44E+24
	2	2.31E+15	3.58E+14	3.09E+14
	3	4.86E+08	4.28E+07	5.24E+07
20:10:1	1	1.83E+26	8.54E+25	1.08E+25
	2	1.31E+26	5.19E+25	6.08E+24
	3	1.55E+07	1.94E+07	5.96E+06

Table 7. Likelihood Ratios Derived from Full Volume Amplifications

Mixture	Contributor	LR (Var 8)	LR (Var 11.2)	LR (Var 14.7)
1:1	1	4.24E+13	2.08E+14	3.62E+13
	2	8.21E+13	5.92E+14	1.03E+14
2:1	1	1.24E+28	1.08E+28	8.85E+27
	2	5.80E+27	4.11E+27	2.34E+27
10:1	1	1.51E+28	1.45E+28	1.35E+28
	2	6.96E+08	1.08E+10	6.85E+10
50:1	1	1.55E+28	1.54E+28	1.54E+28
	2	1.16E+00	8.90E-01	2.46E+00
5:2:1	1	6.26E+26	4.94E+26	3.71E+26
	2	8.41E+15	1.49E+15	1.23E+15
	3	4.66E+09	5.61E+08	7.58E+08
20:10:1	1	2.70E+27	2.16E+27	1.33E+27
	2	8.94E+26	7.49E+26	3.98E+26
	3	2.64E+02	4.45E+01	1.57E+02

Table 8. Likelihood Ratios Derived from Half Volume Amplifications

These tables demonstrate that the different variance values had no apparent significant effect on the likelihood ratios obtained for the known contributors to the DNA mixtures. Likelihood ratio values between contributors were representative of the quality of the DNA profile being analysed. DNA profiles where the "minor" contributor represented less than approximately one tenth of the "major" contributor produced significantly lower likelihood ratios than the "major" DNA profile. This was a reflection of the quality of the DNA profile whereby many of the

"minor" peaks had either dropped out or were masked by stutter and/or "major" peaks. The variation in likelihood ratios between the low-template "minor" DNA profiles (see 50:1, 20:10:1) in the half and full volume amplifications can be attributed largely to two factors. The first, that there is an observed difference in the peak heights of the DNA profiles between amplification types whereby half volume amplifications produce larger peaks than the full volume amplifications. This phenomenon means that dropout, which is more likely in low-template "minor" DNA profiles, is often assigned a lower likelihood in half volume amplifications. Secondly, the variance is larger in the half volume amplifications and accordingly the probabilities are reduced.

The results of both the likelihood ratios comparison and the analysis of the genotype probabilities show there are differences as the variance is increased, however this variation is minimal. The advantage of using a higher variance setting is that more stochastic variation is allowable within the model used by STRmix™. From experience, it is known that stochastic effects occur in casework and therefore need to be considered in routine DNA profile interpretation.

5.4 Single Source Deconvolution

The single source DNA profiles were analysed in STRmix™ with the following settings:

	Half Volume	Full Volume
Variance	14.7	9.3
Locus Amplification Variance	0.033	0.030

Table 9. Final Variance and Locus Amplification Variance Settings

For all of the single source profiles, the correct genotype combination was considered at all loci. As the template decreased, the stochastic effects (such as drop-out) of the profiles increased. Where drop-out had occurred, STRmix™ had listed it as an option, however it was generally not the most likely allelic combination. There were no instances of potential false exclusion. At loci where dropout had occurred, an allelic combination representing homozygous peaks was always given the highest probability. None of the deconvolutions failed to identify the possibility of drop-out, merely that it was assigned a lower probability.

For both full and half volume amplifications of sample 12, there was one locus where drop-out was observed. The combination representing a homozygous genotype was assigned a probability of ≥99%. This would lead to the incorrect genotype being loaded to NCIDD. Similarly, in the full volume amplification of sample 9, the combination at one locus where drop-out was observed, was

assigned a probability of 96.6% for the homozygous genotype. This is very near the level at which a genotype can be loaded to NCIDD. These samples would not be routinely amplified at the template level of 0.078 and 0.050ng according to the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document.

The likelihood ratios calculated for each of these DNA profiles are detailed in Table 10 below. These likelihood ratios are considered to be appropriate for the DNA profiles obtained.

The likelihood ratio for the full volume amplification of sample 10 is significantly lower than the likelihood ratios obtained for all of the other single source profiles. This is due to the high number of drop-out events observed in this sample.

Sample	Template (ng)	Half volume LR	Full volume LR
1	0.500	1.17E+26	1.10E+26
2	0.447	1.14E+26	1.10E+26
3	0.394	1.09E+26	1.18E+26
4	0.342	1.15E+26	1.10E+26
5	0.289	1.09E+26	1.09E+26
6	0.236	1.09E+26	1.13E+26
7	0.183	1.12E+26	1.12E+26
8	0.131	1.12E+26	1.11E+26
9	0.078	1.11E+26	5.93E+24
10	0.025	1.91E+21	2.13E+11
11	0.100	1.31E+24	1.35E+24
12	0.050	3.40E+21	1.25E+24

Table 10. Likelihood Ratios for Single Source Profiles

5.5 Mixture Deconvolution

The results for the mixture deconvolution studies are given in Appendix 1. At higher levels of template STRmix™ accurately listed the correct allelic combinations as possible genotypes and the likelihood ratios calculated intuitively fit with the profile. As the input template decreased, so did the template of the smaller contributors to the mixtures. In a number of samples where the smaller contributors had low template levels (especially for the half volume amplifications), the smaller contributor was excluded by STRmix™, despite them being known contributors. In at least one situation (5:2:1 at 0.125ng) this occurred because the relevant peak (10 at D16S539 – 92rfu) had been clicked off during plate-reading as post-stutter for the 9 peak (995rfu). It is interesting to note that the nearby 13 peak (2080 rfu) showed no indication of post-stutter.

It is suggested that the nature of post-stutter in low template samples be investigated further should these samples be deemed suitable for interpretation in the future. The failure of STRmix™ to successfully resolve these very low-template contributions may be a result of STRmix™ having insufficient iterations to fully explore the sample space. The inability of STRmix™ to list (-1,-1), that is double drop-out, as a legitimate alternative is suggestive of this. As such it is possible that these low-template mixtures would benefit from being run at 500K iterations. This phenomenon was not observed in the full volume amplification data. Increasing the number of iterations was not performed as currently QHFSS DNA Analysis will not be routinely amplifying samples with template levels this low.

The *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document discusses the stochastic effects observed with low template samples. This verification backs up the observation that DNA profiles derived from samples where the input template reaches the levels often described as 'low copy number' (100-150pg) might not be reliably interpreted (especially with respect to mixtures).

The four person mixtures with a total template of 0.5ng failed to deconvolute due to insufficient memory space of the computer. The four person mixtures with a total template of 0.125ng were able to be deconvoluted by STRmix™ without memory issues. However, it was not analysed beyond initial deconvolution. The principal reason for this is the extreme difficulty in reviewing the results. Unless there is a marked difference in the relative contributions of DNA, there is no way to reliably and meaningfully assess the probability weightings and allelic combinations. As such, the STRmix™ analysis has to be accepted at face value without an intuitive check by a scientist and this is not an acceptable option. In the future, with increased experience in analysing STRmix™ results, the interpretation of four-person mixtures can be re-assessed, but at this stage it is not recommended that four-person mixtures be reported.

5.6 Reproducibility of Results

The results of the reproducibility study are provided in Tables 11 and 12 below for half and full volume amplifications respectively. These results show little variation (less than one order of magnitude in all but one case) and indicate that the weightings obtained for successive STRmix™ deconvolutions are very similar. The notable exception to this trend is Contributor 2 of the 50:1 mixture in Table 9. In this case, the likelihood ratio changes from weakly supportive of inclusion to weakly supportive of exclusion. This is not unexpected in a DNA profile where there is a very poor fit to the observed profile, due largely to the loss of allelic information (Contributor 2 donating a theoretical 4pg of DNA to the mixture).

Mixture	Reference	LR1	LR2	LR3
1:1 (0-5ng)	Contributor 1	9.14E+13	3.61E+13	2.10E+14
	Contributor 2	2.39E+14	1.03E+14	1.31E+14
2:1 (0-5ng)	Contributor 1	9.12E+27	8.85E+27	8.90E+27
	Contributor 2	2.70E+27	2.34E+27	2.63E+27
5:2:1 (0-5ng)	Contributor 1	4.54E+26	3.71E+26	4.44E+26
	Contributor 2	1.15E+15	1.23E+15	1.06E+15
	Contributor 3	2.28E+08	7.58E+08	4.64E+08
10:1 (0-125ng)	Contributor 1	1.37E+28	1.35E+28	1.34E+28
	Contributor 2	8.30E+10	6.85E+10	3.15E+10
20:10:1 (0-5ng)	Contributor 1	1.41E+27	1.33E+27	1.09E+27
	Contributor 2	4.01E+26	3.98E+26	3.00E+26
	Contributor 3	158	157	248
50:1 (0-25ng)	Contributor 1	1.54E+28	1.54E+28	1.54E+28
	Contributor 2	5.74E-01	2.46	1.97

Table 11. Repeated Likelihood Ratios for DNA Mixtures at Half Volume Amplification

Mixture	Reference	LR (RM/JE)	LR (VarTest)	LR (Reprod.)
1:1 (0-5ng)	Contributor 1	3.43E+14	3.79E+14	3.23E+14
	Contributor 2	1.85E+14	2.06E+14	1.76E+14
2:1 (0-5ng)	Contributor 1	1.00E+24	8.46E+23	7.69E+23
	Contributor 2	4.78E+23	3.94E+23	3.72E+23
5:2:1 (0-5ng)	Contributor 1	8.58E+24	8.44E+24	6.86E+24
	Contributor 2	1.14E+14	3.09E+14	4.77E+13
	Contributor 3	4.42E+07	5.24E+07	1.12E+07
10:1 (0-125ng)	Contributor 1	4.38E+27	4.59E+27	3.87E+27
	Contributor 2	4.41E+07	1.44E+08	4.45E+07
20:10:1 (0-5ng)	Contributor 1	1.22E+25	1.08E+25	2.06E+25
	Contributor 2	6.49E+24	6.08E+24	1.10E+25
	Contributor 3	1.44E+07	5.96E+06	7.30E+06
50:1 (0-25ng)	Contributor 1	1.54E+28	1.54E+28	1.54E+28
	Contributor 2	635	1970	701

Table 12. Repeated Likelihood Ratios for DNA Mixtures at Full Volume Amplification

6 Conclusion

STRmix™ has been demonstrated to be a suitable means of analysing single-source and mixed DNA profiles. At template levels above approximately 0.125ng STRmix™ consistently identified the correct allelic combination as one of the likely contributions. These results are repeatable and the likelihood ratios produced were consistent between runs. Analysis difficulties arise with very low template contributions whereby the correct allelic combination is not modelled. This is most likely due to the increased stochastic effects observed with low-template DNA.

7 Recommendations

- STRmix™ is adopted for DNA profile interpretation and statistical calculations.
- Saturation threshold be set at 7000rfu.
- The maximum stutter be set at 0.3.
- The maximum drop-in be set at 40.
- Locus amplification variance and variance to be set according to Table 13 below:

	Full Volume	Half Volume
Locus Amplification Variance	0.030	0.033
Variance	9.3	14.7

Table 13. Variance Settings

- Deconvolutions on four-person mixtures are not performed at this time.
- The input template is considered before deciding whether a profile will be suitable for reliable interpretation.
- Should interpretation of low template samples be considered in the future, further investigations relating to post stutter and increasing the number of iterations should be performed.

8 Appendix 1 – Mixture Study Results

Half Volume Mixture	Template	Issues identified	C1 - LR	C2 -LR	C3 - LR	C4 - LR
5:3:2:1	0.5	Insufficient memory space				
	0.125	After examining profiles and results it has been decided that at this stage, 4-person mixtures will not be analysed	2.33E+13	9.33E+06	1.93E+03	1.85E-04
20:10:1	0.5	Major profile called correctly. Minor called and mini minor low probability as expected.	1.41E+27	4.01E+26	158	-
	0.125	combinations for D18 and D2 not found in GPD	6.69E+16	9.04E+08	0	-
10:5:1	0.5	Combination for Penta D not found in GPD, but present in component interp. Input genotypes found in component interps - usually highest %, but if not, are close to it.	1.52E+20	1.47E+19	9.97E+08	-
5:2:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	4.54E+26	1.15E+15	2.28E+08	-
	0.125	Legitimate allelic combinations not listed for lowest contribution at several loci, hence LR=0	1.17E+20	1.04E+12	0	-
50:1	0.5	Major profile called correctly. Minor profile called, but given very low probabilities at some loci. Probably due to lots of drop out and stochastic effects due to low template of minor	1.55E+28	215	-	-
	0.25	Major profile called correctly. Minor profile called, but given very low probabilities at some loci. Probably due to lots of drop out and stochastic effects due to low template of minor	1.54E+28	5.74E-01	-	-
	0.125	Major profile called correctly. Minor profile called, but given very low probabilities at some loci. Probably due to lots of drop out and stochastic effects due to low template of minor	1.55E+28	29.1	-	-
30:1	0.5	Major profile called correctly. Minor profile called, but given very low probabilities at some loci. Probably due to lots of drop out and stochastic effects due to low template of minor	1.55E+28	172	-	-
20:1	0.5	Drop-out not considered at TH01, therefore correct combination not considered	1.55E+28	0	-	-
	0.25	Drop-out given low probability	1.54E+28	2.83E+04	-	-
	0.125	Correct combinations considered. Low weightings where drop-out occurred	1.51E+28	168	-	-
10:1	0.5	Major profile called correctly. Minor profile called correctly but one locus gave very low probability such that it may not be duplicated. Probably due to stochastic effects due to low template of minor	1.55E+28	2.43E+18	-	-
	0.125	Major profile called correctly. Minor profile called, but given very low probabilities at some loci. Probably due to lots of drop out and stochastic effects due to low template of minor. Drop-out at 392rfu considered correctly in minor	1.37E+28	8.30E+10	-	-
5:1	0.5	Combinations found except for D12 where the only GPD combination does not include the second contributor. This meant the component interp. does not include the genotype for the second ref sample.	1.55E+28	0	-	-
	0.125	Combinations found. Major almost 100% at all loci, minor not always highest % but this is expected due to lower input template.	2.01E+27	1.59E+20	-	-
2:1	0.5	Profile correctly deconvoluted. Highest weightings assigned to correct combinations	9.12E+27	2.70E+27	-	-
	0.06	All correct combinations considered. Profile has drop-out at 562 rfu. Correct genotype considered but weightings so low may not be duplicated on second run. Very low template sample.	2.13E+23	3.29E+16	-	-
1:1	0.5	All correct combinations considered with good weightings	9.14E+13	2.39E+14	-	-

Table A1: Half Volume Amplification Results for Intuitive Checking

Full Volume Mixture	Template	Issues identified	C1 - LR	C2 -LR	C3 - LR	C4-LR
5:3:2:1	0.5	Insufficient memory space	-	-	-	-
	0.125	After examining profiles and results it has been decided that at this stage, 4-person mixtures will not be analysed	9.19E+10	2.98E+06	3.24E+04	4.91E-05
20:10:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.22E+25	6.49E+24	1.44E+07	-
	0.125	Profile considered by STRmix as 1:1:1 therefore low weightings assigned to correct combinations	6.61E+15	1.76E+09	3.68E-06	-
10:5:1	0.5	All correct combinations considered. Most loci had highest weightings assigned to the correct genotypes, or were reasonably close to this. Correct genotypes had lower weightings towards the higher MW loci due to the differences in degradation slope considered by STRmix. There didn't seem to be as large a difference in ratio between contributors 1 and 2 as might be expected.	1.49E+18	6.21E+17	9.44E+10	-
5:2:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	8.58E+24	1.14E+14	4.42E+07	-
	0.125	Mix considered as 1:1:1 therefore correct combinations given low weightings at some loci.	9.22E+14	4.56E+03	33.4	-
50:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.55E+28	5.39E+04	-	-
	0.25	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.54E+28	6.34E+02	-	-
	0.125	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.08E+28	5.39E+04	-	-
30:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.54E+28	1.41E+11	-	-
20:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.55E+28	1.48E+08	-	-
	0.25	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.54E+28	2.22E+05	-	-
	0.125	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.24E+28	3.25	-	-
10:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor".	1.55E+28	8.06E+14	-	-
	0.125	All correct combinations considered. Variations in weightings are due to the low template in "minor"	4.38E+27	4.41E+07	-	-
5:1	0.5	All correct combinations considered. All but one combination given the highest weighting	1.52E+28	8.00E+25	-	-
	0.125	All correct combinations considered. Mostly the highest weightings were assigned to the correct genotypes. Where correct genotypes had lower weightings there was drop-out related to the low template of the minor contributor.	3.15E+27	1.59E+20	-	-
2:1	0.5	All correct combinations considered with high weightings	1.00E+24	4.78E+23	-	-
	0.06	All the correct combinations were considered with good weightings. Variations in weightings are due to the low template.	2.37E+15	5.24E+08	-	-
1:1	0.5	All correct combinations considered with good weightings	3.43E+14	1.85E+14	-	-

Table A2: Full Volume Amplification Results for Intuitive Checking

9 Appendix 2 - Settings

9.1 Stutter

As described in Section 5.7 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples* validation document samples were selected for stutter analysis. This data was supplied to Jo-Anne Bright of ESR for analysis. There was no significant difference in stutter values between laboratories across Australia (*Variability In Powerplex® 21 Stutter Ratios Across Australian Laboratories*, Jo-Anne Bright, August 2012). Therefore the stutter data from the each of the laboratories was combined and a single stutter file created for use with STRmix™. DNA Analysis data (see Section 6.6 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples* validation document) shows that there appears to be no significant difference between the stutter values for full and half volume amplifications and therefore we propose the use of the same stutter file.

For the stutter setting, Jo-Anne Bright calculated that the maximum stutter observed in the data was 0.26. We propose a value of 0.3 for the stutter setting.

9.2 Drop-in

The drop-in parameters are discussed in Section 6.5 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples* validation document and will be set at a=b=0.393 The maximum observed drop-in at a locus was 21rfu, therefore we propose a value of 40rfu (equal to the detection threshold) for the drop-in setting. These values are based on the drop-in events observed for the full volume amplifications. Since no drop-in events were observed for the half volume amplifications, we propose the use of the same setting for both full and half volume amplifications.

9.3 MCMC accepts

The values for the MCMC accepts and Burnin accepts will be set at 50000 and 10000 respectively as recommended by Dr Duncan Taylor. These values can be increased to 500000 and 100000 respectively for more complex DNA profile analysis.

Emma Caunt - Re: STRmix verification report

From: Cathie Allen
To: Emma Caunt
Date: 11/12/2012 5:02 PM
Subject: Re: STRmix verification report
CC: Justin Howes
Attachments: Cathie Allen.vcf

Hi Emma

Thanks for the update.

I provide my sign off for the STRmix validation report by way of this email (as I will be away from work for the next few days). Upon my return on Monday, 17th of Dec, I will sign the hardcopy validation report.

Cheers
Cathie

Cathie Allen
Managing Scientist, DNA Analysis,
Forensic and Scientific Services

Health Services Support Agency | **Queensland Health**

PO Box 594
ARCHERFIELD Queensland 4108
Ph: [redacted]
Mob: [redacted]
Fax: [redacted]
Email: [redacted]
Web: www.health.qld.gov.au/fss/

Think before you print

>>> Emma Caunt 11/12/2012 4:00 pm >>>

Hi Cathie

The following paragraph has been added to the report to cover the 4 person mixtures:

The four person mixtures with a total template of 0.5ng failed to deconvolute due to insufficient memory space of the computer. The four person mixtures with a total template of 0.125ng were able to be deconvoluted by STRmix™ without memory issues. However, it was not analysed beyond initial deconvolution. The principal reason for this is the extreme difficulty in reviewing the results. Unless there is a marked difference in the relative contributions of DNA, there is no way to reliably and meaningfully assess the probability weightings and allelic combinations. As such, the STRmix™ analysis has to be accepted at face value without an intuitive check by a scientist and this is not an acceptable option. In the future, with increased experience in analysing STRmix™ results, the interpretation of four-person mixtures can be re-assessed, but at this stage it is not recommended that four-person mixtures be reported.

Thanks

Emma

HSSA | Health Services Support Agency

Verification of the DNA Profile Analysis module of STRmix™ for Full Volume Amplifications using the Promega PowerPlex®21 system

Proposal #105

Rhys Parry, Emma Caunt & Cathie Allen
DNA Analysis, Forensic & Scientific Services
March 2013

Queensland Government

Document details

Contact for enquiries and proposed changes

If you have any questions regarding this document or if you have a suggestion for improvements, please contact:

Contact officer: Rhys Parry
Title: Scientist
Phone: [redacted]
Email:

Version history

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1 Introduction

STRmix™ is a proprietary software solution for the consistent interpretation of DNA profiles. To meet Queensland legislative requirements and core business needs, DNA Analysis has performed a verification of STRmix™ for the interpretation of DNA profiles generated using the PowerPlex® 21 system DNA profiling kit. This change has been implemented across Australia and New Zealand under the direction of the Australian & New Zealand Police Advisory Agency (ANZPAA). STRmix™ was developed by Dr Duncan Taylor from FSSA and Jo-Anne Bright and Dr John Buckleton from Environmental Science & Research (ESR). It has been externally validated as a statistical model for DNA interpretation and has been endorsed by the Biological Specialist Advisory Group (BSAG).

Unlike binary DNA interpretation methods, STRMix™ uses a continuous model that accounts for drop-out, drop-in, stutter peak heights, peak height imbalance and possible mixed DNA sources. DNA profiles of between one and four contributors can be analysed. The software uses a Monte Carlo Markov Chain (MCMC) algorithm to deconvolute the various possible contributors of a mixed DNA profile, based on a mathematical model developed by Jo-Anne Bright, Dr Duncan Taylor and Dr John Buckleton (*STRmix™ V1.05 User's Manual*). This model provides a probabilistic weighting to indicate the "strengths" of the possible allelic combinations of a particular locus. These relative strengths are used to determine the likelihood of a particular DNA profile occurring, had a person of interest contributed DNA.

In December 2012, STRmix™ was implemented in DNA Analysis along with the *Promega PowerPlex®21* system. STRmix™ has been demonstrated to be a suitable means of analysing single-source and mixed half-volume amplified DNA profiles at template levels above approximately 0.125ng (see the *Verification of the DNA Profile Analysis module of STRmix™ using the Promega PowerPlex®21 system* report). During this verification analysis difficulties arose with very low template contributions in half volume amplifications whereby the correct allelic combinations were not modelled. This is thought to be due to the increased stochastic effects observed with low-template DNA.

As a result of this analysis issue, the validation report recommended the adoption of a binary interpretation method for DNA profiles. As such, contributions of DNA below 0.132ng of DNA template were deemed insufficient for analysis due to the potential interpretational difficulties. This approach was found to be unsuitable for use with STRmix™. The principal reason is that STRmix™ relies on a continuous analysis model for the interpretation of DNA profiles. The imposition of a binary threshold is incompatible with a continuous model as peaks below the threshold will still be analysed by the continuous model. This, therefore, invalidates the existence of the proposed threshold.

The initial analysis of the DNA profiles relied on the removal of n+4 stutter using plate-reader discretion. Additionally, there was no method for determining the

presence of n-8 stutter and consequently these latter peaks were left on, when in fact many should have been removed. Subsequent analysis (*PowerPlex®21 Amplification of Extracted DNA Validation v2.0*) has provided more accurate values for these artefacts, and this potentially affects the results of the mixture deconvolutions in the original STRmix™ validation study.

Accordingly, it was determined that the original DNA samples used in the validation study be reanalysed in order to determine whether or not using the new n+4 and n-8 stutter thresholds would lead to a different interpretational framework. This document combines the original validation material for full-volume amplifications with the updated STRmix™ validation analyses.

2 Aims

Ideally, when introducing a new methodology, a direct comparison between the existing and the novel method is performed. The current methods for statistical analysis of DNA profiles in FSS DNA Analysis are the Kinship and CODIS Popstats software packages. These calculate a match probability and a likelihood ratio respectively, however both are premised on the use of binary analysis methods using DNA profiles produced by the nine loci AmpFℓSTR® Profiler Plus® kit.

STRmix™ has been proposed as a means of analysing DNA profiles produced by the twenty STR loci, Promega PowerPlex® 21 system. The continuous model employed by STRmix™ for analysing DNA profiles cannot be directly compared with the binary model of DNA profile analysis previously used by QHFSS DNA Analysis. As such, the significant differences between the two methodologies preclude a direct comparison of results. In order to address this issue, the following studies were performed using the STRmix™ software package in order to assess the suitability of this system as a reliable and reproducible means of deconvoluting DNA profiles and providing meaningful statistical weightings. Additional investigation was performed to determine the operating parameters, specific to the QHFSS DNA Analysis analytical processes, which are necessary for the optimal operation of STRmix™.

STRmix™ requires parameters to be set in order to run. Where possible these settings have been decided at a national level using data provided from all jurisdictions. More information on the basic settings is provided in Appendix 2 of this report.

The specific aims of this project are:

1. Saturation Threshold

STRmix™ cannot accurately assess a DNA profile unless there is an appropriate (linear) relationship between the DNA input template and the RFU value produced.

Due to the potential for the camera in the 3130xl to be overloaded by excessive signal, this relationship can become non-linear at higher template/rfu values. As such the maximum RFU value at which STRmix™ can perform properly needs to be determined as one of the operational settings for the software.

The expected peak height can be calculated from the observed stutter. The relationship between the expected peak height and the observed peak height should be linear with a gradient of approximately 1 as both values should be similar. The purpose of this study is to identify the RFU value at which this relationship starts to become non-linear thereby indicating that saturation of the camera has caused the true RFU value of the observed allele to be under-reported.

2. Determination of the Locus Amplification Variance

The purpose of the Model Maker component of STRmix™ software package is to determine the locus amplification variance. This variance is a critical value for the correct functioning of STRmix™. This report details the results produced by Model Maker.

3. Determination of the Variance Setting

Three different values for the variance were provided by Jo-Anne Bright, Dr John Buckleton and Dr Duncan Taylor (see Section 4-4.3 below). These values were derived from data produced by ten samples run at ten dilutions as well as the corresponding reference DNA data (see *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation*). This report details the testing carried out to determine which of the three variance values is appropriate for use in the analysis of full (25µL total volume) volume DNA amplifications.

4. Single Source Deconvolution

This experiment will examine the ability of STRmix™ to deconvolute and produce likelihood ratios for single source DNA profiles consistently at a variety of dilutions/template quantities from full volume amplifications.

5. Mixture Deconvolution

STRmix™ has the ability to deconvolute two, three and four person mixtures and it is critical that this can be done reliably. Consequently, this experiment assesses the ability of STRmix™ to accurately determine the possible DNA contributions of individuals to known mixtures. Various DNA contribution proportions and template quantities for full volume amplification are examined.

6. Reproducibility of Results

It is paramount that STRmix™ provides consistent results when deconvoluting mixtures. Due to the random nature of the MCMC calculations, it is unlikely that multiple analyses of the same DNA profile will produce exactly the same result. However, repeated results should be within acceptable limits of one another.

Accordingly, the ability of STRmix™ to generate reproducible DNA mixture deconvolution and likelihood ratio calculations are examined.

3 Materials

A number of resources are outlined in Section 3 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document. In addition to these resources, the following were required for the present verification:

- STRmix™ v1.05 software system
- Staff
- Computer time

4 Methods

Creation of mixed DNA profiles

The DNA profiles used in this validation were generated using the methods outlined in Section 4 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document.

Creation of input files

All of the DNA profiles required for this validation were exported from GeneMapper® ID-X v1.1.1 using the table settings detailed in Section 3 of the *STRmix™ V1.05 User's Manual*.

Determination of Variance

The variance values provided for DNA Analysis by Jo-Anne Bright & Dr. John Buckleton are detailed in Table 1 below (see *I:\Change Management\Proposal#105 PowerPlex 21 Reporting and STRmix™\Choice of Variance.doc*)

Percentile	Variance Constant
50th	4.5
75th	6.7
90th	9.3

Table 1. Variance Values Determined by Jo-Anne Bright and Dr. John Buckleton for Full Volume Amplification

4.1 Saturation Threshold

The 10x10 data described in Section 5.7 (Baseline Determination) of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document and additional data provided by other jurisdictions were provided to Jo-Anne Bright, Dr. Duncan Taylor and Dr. John Buckleton. From this data, locus-specific values (intercept and slope) for the linear relationship between stutter and allelic height were derived. These values are summarized below in Table 2.

Locus		Intercept	Slope
1	D3S1358	-0.0532	0.00875
2	D1S1656	0.0155	0.00469
3	D6S1043	0.0378	0.00208
4	D13S317	-0.063	0.0102
5	Penta E	-0.0185	0.00388
6	D16S539	-0.0549	0.0108
7	D18S51	-0.0462	0.00843
8	D2S1338	-0.013	0.00465
9	CSF1PO	-0.065	0.0114
10	Penta D	-0.012	0.00265
11	TH01	0.00607	0.00235
12	vWA	-0.136	0.0124
13	D21S11	-0.0811	0.00534
14	D7S820	-0.0606	0.0109
15	D5S818	-0.0748	0.0116
16	TPOX	-0.0334	0.00657
17	D8S1179	0.00787	0.00515
18	D12S391	-0.11	0.0104
19	D19S433	-0.0728	0.00997
20	FGA	-0.089	0.00707

Table 2. Locus Specific Values for all 20 Loci used for Calculation of the Expected Peak Height.

The observed peak heights and observed stutter heights of between approximately 100 and 450rfu (dependant on locus data) were recorded. This data was used to calculate the expected peak height from each of the stutter values using the equation (as per communication with Dr. Duncan Taylor):

$$E' = OS / (\text{slope} \times \text{allele value} + \text{intercept})$$

Where E' is the expected peak height

OS is the observed stutter height

Slope & Intercept as per Table 2

The observed peak height was plotted against the expected peak height for each data point.

4.2 Determination of Locus Amplification Variance

The 10x10 data described in Section 5.3 (Baseline Determination) of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document was analysed using the Model Maker module of STRmix™ as per Section 7.1 of the *STRmix™ v1.05 User's Manual.*

4.3 Determination of Variance Setting

Six of the mixed DNA profiles outlined in Section 5.10 (Mixture Studies) of *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document were used for determining the variance setting for full volume amplifications (see Table 3).

The six mixtures were analysed in STRmix™ using variances of 4.5, 6.7 and 9.3 for the full volume amplifications (see Table 1). The mixture deconvolution results were recorded and examined to determine whether or not STRmix™ had produced acceptable allelic pairings based on the known DNA contributions. The likelihood ratios (calculated using the Australian Caucasian dataset) were recorded and compared between the three variance settings.

Mixture Ratio	Template (ng)
50:1	0.250
10:1	0.125
2:1	0.500
1:1	0.500
20:10:1	0.500
5:2:1	0.500

Table 3. Mixture Ratios and DNA Template Amounts used for the Determination of the Variance Values

4.4 Single Source Deconvolution

Section 5.3 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document details the samples that were generated to determine the baseline. One set of these samples was used for the single source deconvolution. To cover the smaller template levels, the 100pg and 50pg samples from Section 5.4 (Sensitivity 1) of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* were also used. Table 4 lists the samples used for this experiment.

Each sample was analysed in STRmix™ using a variance of 9.3. The deconvoluted files and the likelihood ratios for each sample (calculated using the Australian

Caucasian dataset) were examined to determine whether the profile was deconvoluted appropriately and that the correct genotype combinations were considered in the deconvolution. Additionally, to determine whether the likelihood ratios produced were intuitively appropriate for the DNA profile concerned.

Sample	Total DNA (ng)
1	0.500
2	0.447
3	0.394
4	0.342
5	0.289
6	0.236
7	0.183
8	0.131
9	0.078
10	0.025
11	0.100
12	0.050

Table 4. DNA Template used for Single-source Deconvolution.

4.5 Mixture Deconvolution

Section 5.10 (Mixture Studies) of the *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation* document details the mixed DNA profiles that were generated for the mixture studies and are detailed in Table 5 below. These mixtures were analysed in STRmix™ using a variance of 9.3. The deconvoluted files and the likelihood ratios for each contributor (calculated using the Australian Caucasian dataset) were examined to determine whether the correct genotype combinations were considered in the deconvolution; and to determine whether the likelihood ratios produced were intuitively appropriate for the DNA profile concerned.

Number of Contributors	Mixture Ratio	DNA Template (ng)		
2	50:1	0.500	0.250	0.125
	30:1	0.500	-	-
	20:1	0.500	0.250	0.125
	10:1	0.500	-	0.125
	5:1	0.500	-	0.125
	2:1	0.500	-	0.060
	1:1	0.500	-	-
3	20:10:1	0.500		0.125
	10:5:1	0.500	-	-
	5:2:1	0.500	-	0.125
4	5:3:2:1	0.500	-	0.125

Table 5. DNA Mixtures used for STRmix™ Validation Studies

4.6 Reproducibility of Results

The six mixtures used in Experiment 4.5 were also used to determine the reproducibility of the mixture deconvolution and the likelihood ratio output. These six mixtures were analysed separately in STRmix™ three times each (Variance = 9.3). The likelihood ratios for each contributor were also calculated using the Australian Caucasian dataset. The likelihood ratios were compared to determine whether the results were similar between analyses.

4.7 Concordance and Number of Contributors

A number of DNA profiles were observed in routine casework whereby the number of contributors to the "minor" DNA profile could not be readily determined. This effect is believed to be a result of the increased stochastic effects observed in low-level DNA contributions and sub-threshold artefacts such as n-8 stutter, n+4 stutter and pull-up. DNA profiles where the lowest template contribution yields peak heights similar to

that of the n-4 stutter of allelic peaks from the larger DNA contribution can also complicate the ability to readily assess the potential number of contributors. As STRmix™ relies on an assessment of the number of DNA contributors to a mixture for its probability calculations, the uncertainty in the number of contributors warranted further investigation. This effect is of particular concern where one contributor has donated DNA at a significantly greater level compared to the lesser contributor (eg. 10:1 ratio) and where the lesser contributions may be at or below the reporting threshold. While it is unlikely to have an effect on the successful deconvolution of the larger contribution, the number of assumed contributors can have an effect on the likelihood ratios generated for potentially matching reference samples to the low-template contribution. This is due to the probability space being shared by a greater or lesser range of potential genotype combinations. That is, if a lower number of contributors is assumed, the likelihood ratio of a true contributor will be greater than if the same mixture is assumed to have a larger number of contributors. Table 14 summarizes the theoretical effect of changing the assumed number of contributors to the mixture. The degree to which the likelihood ratio changes will also be influenced by: the population frequency of the matching alleles; the degradation slopes of the DNA profile; the ratio of the different contributions; and the relative allele heights (RFU values) of the contributing DNA profiles.

LR Outcome	Effect on LR	
	2P	3P
Support for Contribution	Higher	Lower
Support for Non-Contribution	Higher	Lower

Table 14: Theoretical Model for the Effect of Changing the Number of Contributors

The effect on likelihood ratio listed in Table 14 may seem obvious, but its significance is important and is not necessarily readily apparent. It should be noted that the effect of increasing the number of contributors is not to lower the likelihood ratio in an absolute sense, but rather, to drive the likelihood ratio towards ambiguity (LR=1).

The degree to which this effect occurs was investigated using the methods outlined below:

- Generating a constructed reference DNA profiles and comparing them to mixtures at varying degrees of concordance.
- Examining known mixtures and comparing drop-out rates with likelihood ratio values
- Changing the assumed number of contributors in the STRmix™ deconvolution in order to ascertain the effect on the derived likelihood ratio for faux reference samples at varying degrees of concordance.

In this study, mixed DNA profiles from the original validation study (50:1 0.5ng and 10:1 0.5ng) were analysed in STRmix™. A theoretical reference sample was generated by constructing an appropriately formatted text file for STRmix™. This was done to determine how altering the assumed number of contributors affects the statistical weightings generated by matching DNA reference samples. Additionally, this trial examined the possibility of obtaining a meaningful likelihood ratio supporting contribution with an adventitious match to a small number of low-level alleles. The faux reference sample was constructed such that it only matched at the alleles listed in Table 15. All other alleles did not match the alleles in the "major" contributor and nor did they fall in n-4 stutter position for any of the "major" peaks. Four analyses were run for each mixture. In the first trial, only one allele matched (D3 – 11) and in every subsequent run an allele was added such that in trial four there were four unique alleles [D3(11), D16(10), D8(10), and D3(19)].

4.8 T-tests

All t-tests were conducted using the Paired Sample for Two Means formula of the Data Analysis Module in Excel 2003. The settings were two-tailed alpha=0.05 and H_0= No expected change.

5 Results and Discussion

5.1 Saturation Threshold

Table 6 outlines the regression data results of the plots of expected versus observed peak height for each locus (see *Saturation Values Regression Data.xls* in I:\Change Management\Proposal #102\Stutter\ for raw values). There were no loci at which the linear relationship between the expected and observed peak heights failed, however it must be noted that only a few data points extended beyond 7000-8000rfu. In most cases, those that were present did not depart significantly from the regression gradient in any meaningful or predictable way. At the 7000-8000rfu heights, the DNA profiles had a tendency to demonstrate the effects of excess template and often possessed poor baseline integrity. As such, it was decided that 7000rfu was a suitable value for the saturation threshold.

Locus	Gradient	R^2	Locus	Gradient	R^2
D3S1358	1.04	0.97	TH01	0.87	0.75
D1S1656	1.08	0.92	vWA	0.95	0.78
D6S1043	0.97	0.92	D21S11	0.89	0.94
D13S317	0.95	0.90	D7S820	1.00	0.89
Penta E	0.84	0.75	D5S818	1.17	0.86
D16S539	0.94	0.98	TPOX	0.86	0.84
D18S51	0.97	0.97	D8S1179	0.94	0.93
D2S1338	1.05	0.97	D12S391	0.98	0.98
CSF1PO	0.96	0.94	D19S433	0.92	0.94
Penta D	0.46	0.46	FGA	0.90	0.94

Table 6. Gradients and R^2 Values for Lines of Fit of Expected vs. Observed Peak Height

5.2 Determination of Locus Amplification Variance

The values for the locus amplification variance produced from the 10x10 data by the Model Maker module of STRmix™ are:

- Full volume amplification = 0.030

5.3 Determination of Variance Setting

The comparisons between the variance settings for full volume amplifications showed that generally there was no difference between each value. However, one deconvolution (D16S539 of the 5:2:1 mixture - full volume amplification – 4.5 variance) failed to model the correct allelic pair representative of the known contributors. As such, a variance of 4.5, or lower, was deemed to be unsuitable for

analytical purposes. In all other cases, the true allelic set was considered as a valid genotype combination for every locus.

It was noted that the correct genotype combinations were not necessarily assigned the highest probability. This is expected with the model used, since STRmix™ will consider all of the possible genotype combinations that could make up this profile. The probabilities that were assigned were reasonable given the peak heights in the observed DNA profile. In general, where the correct genotype was a good fit to the profile, the probability decreased as the variance increased, which again was expected. However, this decrease did not appear to be large. Where the correct genotype was a poor fit to the observed profile, the probability increased as the variance increased. Again, this was expected and there did not appear to be a marked difference between values.

As the input template of the individual contributors decreased, the DNA profiles displayed stochastic effects (see also *PowerPlex® 21 - Amplification of Extracted DNA Samples Validation)*. In these instances STRmix™ still considered the correct genotype combinations, albeit with a lower probability.

As there was no observable difference in the ability of the three variance values to accurately model the true allelic combination in preference to alternate combinations, the largest variance was chosen. It was decided based on the deconvolutions obtained; that the higher variance (9.3) gave a better statistical coverage of the possible allelic combinations that could be produced and thus was more is more likely to account for any potential stochastic effects. It is noted though, that in doing so the probability space must be shared across a greater number of allelic combinations and therefore individual allelic probabilities for combinations that are a good fit to the observed profile will be lowered. It was expected that as the variance is increased, the number of genotype combinations considered would increase due to the increased allowable variation in peak height.

The likelihood ratios for each of the contributors to each of the mixtures at each variance are detailed in Tables 7 below.

This table demonstrates that the different variance values had no apparent effect on the likelihood ratios obtained for the known contributors to the DNA mixtures. Likelihood ratio values between contributors were representative of the quality of the DNA profile being analysed. DNA profiles where the "minor" contributor represented less than approximately one tenth of the "major" contributor produced significantly lower likelihood ratios than the "major" DNA profile. This was a reflection of the quality of the DNA profile whereby many of the "minor" peaks had either dropped out or were masked by stutter and/or "major" peaks.

Mixture	Contributor	LR (Var 4.5)	LR (Var 6.7)	LR (Var 9.3)
1:1	1	3.86E+14	4.15E+14	3.79E+14
	2	2.09E+14	2.25E+14	2.06E+14
2:1	1	8.75E+25	1.23E+25	8.46E+23
	2	5.63E+25	6.78E+25	3.94E+23
10:1	1	8.45E+27	6.62E+27	4.59E+27
	2	1.40E+07	3.93E+07	1.44E+08
50:1	1	1.55E+28	1.55E+28	1.54E+28
	2	2.97E+03	2.02E+03	1.97E+03
5:2:1	1	7.09E+25	3.23E+25	8.44E+24
	2	2.31E+15	3.58E+14	3.09E+14
	3	4.86E+08	4.28E+07	5.24E+07
20:10:1	1	1.83E+26	8.54E+25	1.08E+25
	2	1.31E+26	5.19E+25	6.08E+24
	3	1.55E+07	1.94E+07	5.96E+06

Table 7. Likelihood Ratios Derived from Full Volume Amplifications

The results of both the likelihood ratios comparison and the analysis of the genotype probabilities show there are differences as the variance is increased, however this variation is minimal. The advantage of using a higher variance setting is that more stochastic variation is allowable within the model used by STRmix™. From experience, it is known that stochastic effects are more likely to occur in casework and therefore need to be considered in routine DNA profile interpretation.

5.4 Single Source Deconvolution

The single source DNA profiles were analysed in STRmix™ using a Variance of 9.3 and a Locus Amplification Variance of 0.030.

For all of the single source profiles, the correct genotype combination was considered at all loci. As the template decreased, the stochastic effects (such as drop-out) of the profiles increased. Where drop-out had occurred, STRmix™ had listed it as an option, however it was generally not the most likely allelic combination. There were no instances of potential false exclusion. At loci where dropout had occurred, an allelic combination representing homozygous peaks was always given the highest probability. None of the deconvolutions failed to identify the possibility of drop-out, merely that it was assigned a lower probability.

The likelihood ratios calculated for each of these DNA profiles are detailed in Table 8 below. These likelihood ratios are considered to be appropriate for the DNA profiles obtained.

The likelihood ratio for sample 10 is significantly lower than the likelihood ratios obtained for all of the other single source profiles. This is due to the high number of drop-out events observed in this sample.

Sample	Template (ng)	Full volume LR
1	0.500	1.10E+26
2	0.447	1.10E+26
3	0.394	1.18E+26
4	0.342	1.10E+26
5	0.289	1.09E+26
6	0.236	1.13E+26
7	0.183	1.12E+26
8	0.131	1.11E+26
9	0.078	5.93E+24
10	0.025	2.13E+11
11	0.100	1.35E+24
12	0.050	1.25E+24

Table 8. Likelihood Ratios for Single Source Profiles

5.5 Mixture Deconvolution

The mixed DNA profiles were analysed in STRmix™ using a Variance of 9.3 and a Locus Amplification Variance of 0.030.

The results for the mixture deconvolution studies are given in Table A1 - Appendix 1. At higher levels of template STRmix™ accurately listed the correct allelic combinations as possible genotypes and the likelihood ratios calculated intuitively fit with the profile. As the input template decreased, so did the template of the smaller contributors to the mixtures. In two samples where the smaller contributors had low template, the likelihood ratio produced by STRmix™ indicated that non-contribution was more likely than contribution, despite them being known contributors. This is due to the larger number of drop-out alleles associated with these samples whereby the modelling of (-1,-1) genotype designations tends to support non-contribution.

There is a possibility that STRmix™ may fail to successfully resolve very low-template contributions as a result of STRmix™ having insufficient iterations to fully explore the sample space. The inability of STRmix™ to list (-1,-1), that is double drop-out, as a legitimate alternative is suggestive of lack of sufficient iterations. As such it is probable that these low-template mixtures would benefit from being run at 500K iterations. However, none of the full volume amplifications failed to be modelled with (-1,-1) as a genotype where it was legitimately an option. That being stated, it is paramount that the STRmix™ results file be checked to ensure that drop-out modelling (-1,-1) and/or (z,-1) designations have been made for loci where full or partial dropout has potentially occurred.

The four person mixtures with a total template of 0.5ng failed to deconvolute due to insufficient processing power of the computer. The four person mixtures with a total template of 0.125ng were able to be deconvoluted by STRmix™ without issue. The difference is most likely due to the increased amount of information required to be processed for the 0.5ng sample. However, because the 0.5ng DNA profile failed to be resolved a direct comparison of results is not possible. The 0.125ng mixture was not analysed beyond initial deconvolution. The principal reason for this is the extreme difficulty in reviewing the results. Unless there is a marked difference in the relative contributions of DNA, there is no way to reliably and meaningfully assess the probability weightings and allelic combinations. As such, the STRmix™ analysis has to be accepted at face value without an intuitive check by a scientist and this is not an acceptable option. In the future, with increased experience in analysing STRmix™ results, the interpretation of four-person mixtures can be re-assessed, but at this stage it is not recommended that four-person mixtures be reported.

5.6 Reproducibility of Results

The results of the reproducibility study are provided in Table 9 below. These results show little variation (less than one order of magnitude in all but one case) and indicate that the weightings obtained for successive STRmix™ deconvolutions are very similar.

Mixture	Reference	LR 1	LR 2	LR 3
1:1 (0-5ng)	Contributor 1	3.43E+14	3.79E+14	3.23E+14
	Contributor 2	1.85E+14	2.06E+14	1.76E+14
2:1 (0-5ng)	Contributor 1	1.00E+24	8.46E+23	7.69E+23
	Contributor 2	4.78E+23	3.94E+23	3.72E+23
5:2:1 (0-5ng)	Contributor 1	8.58E+24	8.44E+24	6.86E+24
	Contributor 2	1.14E+14	3.09E+14	4.77E+13
	Contributor 3	4.42E+07	5.24E+07	1.12E+07
10:1 (0-125ng)	Contributor 1	4.38E+27	4.59E+27	3.87E+27
	Contributor 2	4.41E+07	1.44E+08	4.45E+07
20:10:1 (0-5ng)	Contributor 1	1.22E+25	1.08E+25	2.06E+25
	Contributor 2	6.49E+24	6.08E+24	1.10E+25
	Contributor 3	1.44E+07	5.96E+06	7.30E+06
50:1 (0-25ng)	Contributor 1	1.54E+28	1.54E+28	1.54E+28
	Contributor 2	635	1970	701

Table 9. Repeated Likelihood Ratios for DNA Mixtures at Full Volume Amplification

5.7 Low-Template DNA Contributions to Mixtures

It is necessary for STRmix™ to be able to accurately deconvolute mixed DNA profiles and to ascribe appropriate likelihood ratios to potential contributors of low templates of DNA. As such, the same mixtures used in the *PowerPlex® 21* -

Amplification of Extracted DNA Samples Validation were re-read using GeneMapper® ID-X v1.1 using the most up-to-date values for n-8 and n+4 stutter (*see PowerPlex®21 Amplification of Extracted DNA Validation v2.0*) as both of these parameters have been reassessed since the original STRmix™ validation study. These mixtures were re-analysed using STRmix™ as per the original methodology. The results of the re-analysed deconvolutions are given below in Table 10. Drop-out was not observed for any of the larger contributions to the mixtures but was observed in many of the lesser contributions especially at low-template levels. Drop-in was not observed in any of the mixtures analysed in the study.

The likelihood ratios obtained from these analyses correspond well with the original likelihood ratios obtained (see Tables 7 & 9). The greyed-out results in the "LR Ref 3" column of Table 10 show that the likelihood ratio obtained was zero for an individual known to have not contributed DNA to the mixtures.

There were several variations in terms of the numbers of low-template alleles detected between the original and updated GeneMapper® ID-X reads. This was due to changes in the n-8 and n+4 stutter thresholds from the original analysis as can be seen from the variations in the counts of unique, shared and drop-out alleles in Table 16. The more accurate values for these stutter artefacts provides greater confidence in the DNA profile uploaded to STRmix™ being more representative of the true contributors. As such, these results confirm the corresponding outcomes of the original validation study as well as demonstrating that the new stutter artefact thresholds do not have an adverse effect on the ability of STRmix™ to accurately deconvolute mixed DNA profiles.

5.8 Low Template Concordance for Full Volume Mixtures

The two and three contributor full volume mixtures were analysed to examine how stochastic effects (drop-out and allelic imbalance) and allelic masking/sharing affects the obtained likelihood ratio for the lowest contribution of DNA (see Table 11 and 12 below). Unique alleles were deemed as those alleles that matched only the known contributor and did not fall in an n-4 stutter position. Shared alleles were designated as any alleles of the known contributor that fell in an n-4 stutter position to a larger peak or were the same as any of the alleles of the other known contributors. Any alleles that should have been present based on the reference DNA profile and for which there was no observed allele in the mixture EPG were considered to be dropped out.

The number of shared/masked alleles is equal to the 40 (total alleles possible) minus the sum of the drop-out and unique alleles. It should be noted that where alleles belonging to a known contributor lie in a stutter position, or in the same position as another known contributor, they have been considered as shared. STRmix™ is based on a probabilistic model and as such it is possible that it has considered some of these stutter-position peaks as more likely to be allelic and some as more likely to

be pure stutter dependant on the degradation slope of the low level DNA contribution. Assessing the exact nature of this effect was beyond the scope of this analysis.

Mixture	Template (pg)	LR Ref 1	LR Ref 2	LR Ref 3	Actual Template of lesser contribution (pg)
1:1	500	3.00E+14	1.60E+14	0.0	250
2:1	500	4.80E+24	2.10E+23	0.0	167
2:1	60	2.20E+15	1.90E+08	0.0	20
5:1	500	1.50E+28	1.00E+26	0.0	83
5:1	125	3.20E+27	1.40E+20	0.0	21
5:2:1	500	9.70E+24	5.10E+13	1.60E+07	63
5:2:1	125	1.60E+15	2.10E+03	1.00E+02	16
10:1	500	1.50E+28	3.60E+18	0.0	45
10:1	125	4.00E+27	1.00E+08	0.0	11
10:5:1	500	3.30E+18	1.60E+18	2.10E+11	31
20:1	500	1.50E+28	1.50E+07	0.0	24
20:1	250	1.50E+28	1.80E+05	0.0	12
20:1	125	1.20E+28	3.50E+00	0.0	6
20:10:1	500	1.50E+25	8.60E+24	3.40E+07	16
20:10:1	125	1.70E+16	1.10E+09	1.30E-07	4
30:1	500	1.50E+28	1.50E+09	0.0	16
50:1	500	1.50E+28	2.20E+03	0.0	10
50:1	250	1.50E+28	1.00E+02	0.0	5
50:1	125	1.00E+28	7.10E+01	0.0	2

Table 10: Likelihood Ratio Results from the Re-analysed Validation Mixtures

Table 11 below, represents a random cohort of the mixtures analysed. However, they demonstrate that the small changes in unique, shared and drop-out alleles do not

markedly affect the likelihood ratios obtained. As such, potential minor changes in stutter thresholds are very unlikely to adversely affect the ability of STRmix™ to accurately analyse mixtures. The differences observed can be affected by the random nature of the MCMC process and it is not possible to discern how much of an effect each element is having on the final likelihood ratio.

The lowest likelihood ratio for a two-person mixture is associated with the mixture possessing the highest number of drop-out alleles (50:1 using 0.25ng template) which would not be unexpected given the observed relationship discussed above. However, for three person mixtures the 20:10:1 mixture gave a likelihood ratio supporting non-contribution (1.3E-07) despite having relatively few dropped out alleles and a large proportion of potentially masked alleles. Therefore, it is evident that there is a significant effect on the obtained likelihood ratio other than unique and drop-out allele counts.

The level of statistical concordance with low template DNA contributions is illustrated by comparing the likelihood ratios obtained with the number of concordant alleles and the amount of DNA template used. Table 16 indicates that the low likelihood ratios obtained are reflective of the relative counts of unique and drop-out alleles. This adds confidence that the probability of adventitious matches generating a likelihood ratio supporting inclusion to a low-level DNA profile in a mixture is very low where only a few "matching" alleles are present. These DNA profiles have a high degree of concordance (unique plus shared alleles) which is extremely unlikely to occur for adventitious matching. For further discussion on likelihood ratios and adventitious matching see Section 8.4 below.

The data indicates that the likelihood ratio is at least partly based on the offset of the count of unique versus missing alleles. This is intuitively sound, in that unique alleles will increase the likelihood ratio supporting inclusion while missing alleles will tend to support non-inclusion. It is interesting to note that a similar likelihood ratio was obtained for the lesser DNA contributor in the 5:2:1 (500pg), 10:1 (125pg) and the 20:10:1 (500pg) mixtures, despite quite different levels of unique allelic correlation (7, 13, & 5 respectively). Thus, the 20:10:1 and the 5:2:1 mixtures had a greater amount of shared/masked alleles and these were considered as part of the STRmix™ analysis. Drop-out alleles produce likelihood ratios favouring support for non-contribution and consequently the high concordance of the unique alleles in the 10:1 mixture is offset by the large number of dropped-out alleles (14).

Mixture	Template (pg)	LR Ref 2	# of Unique C2 alleles	# of Drop-out C2 alleles	LR Ref 3	# of Unique C3 alleles	# of Drop-out C3 alleles	Actual Template of lesser contribution
1:1	500	1.60E+14	22	0	0.0			250
2:1	500	2.10E+23	20	0	0.0			167
2:1	60	1.90E+08	16	4	0.0			20
5:1	500	1.00E+26	22	0	0.0			83
5:1	125	1.40E+20	20	2	0.0			21
5:2:1	500	5.10E+13			1.60E+07	7	0	63
5:2:1	125	2.10E+03			1.00E+02	7	4	16
10:1	500	3.60E+18	17	2	0.0			45
10:1	125	1.00E+08	13	14	0.0			11
10:5:1	500	1.60E+18			2.10E+11	6	1	31
20:1	500	1.50E+07	9	12	0.0			24
20:1	250	1.80E+05	8	14	0.0			12
20:1	125	3.50E+00	1	28	0.0			6
20:10:1	500	8.60E+24			3.40E+07	5	2	16
20:10:1	125	1.10E+09			1.30E-07	2	7	4
30:1	500	1.50E+09	11	9	0.0			16
50:1	500	2.20E+03	6	16	0.0			10
50:1	250	1.00E+02	4	24	0.0			5
50:1	125	7.10E+01	5	22	0.0			2

Table 11: Unique and Drop-out Allele Counts for Re-analysed Full Volume Mixtures

Mixture	Reference	LR (Original Analysis)	Unique	Shared	Drop-out
5:2:1 (0.5ng)	Contributor 3	4.4E+07	7	33	0
10:1 (0.125ng)	Contributor 2	4.4E+07	15	11	14
20:10:1 (0.5ng)	Contributor 3	1.4E+07	5	32	3
50:1 (0.25ng)	Contributor 2	635	3	14	23
		LR (Updated Analysis)			
5:2:1 (0.5ng)	Contributor 3	1.6E+07	7	33	0
10:1 (0.125ng)	Contributor 2	1.0E+08	13	13	14
20:10:1 (0.5ng)	Contributor 3	3.4E+07	5	33	2
50:1 (0.25ng)	Contributor 2	71	4	15	21

Table 12. Concordance vs LR for Low-template DNA Contributions

The results in Tables 11 and 12 demonstrate that the amount of template, which is reflected in lower peak height values of the EPGs, has a much greater effect on the likelihood ratio obtained for the lesser contributor. This is most clearly indicated by the results of the 20:10:1 and 5:2:1 mixtures. In both sets of results, the counts for unique versus missing alleles are not that dissimilar, however there are radical differences in the likelihood ratios obtained. Again, this is not unexpected as the model employed by STRmix™ will assign lower probabilities to low rfu peaks due to the increased chance of drop-out and of allelic masking by larger peaks from other contributors. Consequently, the probability space is shared by a greater number of genotype combinations including single drop-out (-1) or full drop-out (-1,-1) possibilities. The lower the peak heights the greater this effect will be as the relationship between peak height and the probability assigned to drop-out is exponential (STRmix™ Manual v1.05 p58). That is, the smaller a peak is the more likely it is to have its corresponding heterozygotic allele drop-out.

5.9 Low-threshold Template and STRmix™ Mixture Proportions

The ability of STRmix™ to accurately determine the amount of DNA template contributed to a mixture by low-template contributors was examined by comparing the known amount of DNA with the predicted mixture proportion (see Table 13 below). The mixture percentage of the smallest DNA contribution calculated by STRmix™ was multiplied by the total template of DNA in the mixture to give the predicted template for the lesser DNA contribution. Although the difference between the actual template values and those predicted by STRmix™ appears quite similar, t-

test analysis shows there is a significant difference between the means ($p<0.05$). The major contributing factors to this difference are the 5:2:1 (125pg) and the 20:10:1 (125pg) samples. Given that full volume amplifications yield relatively lower average peak heights (compared to half volume amplifications) a greater degree of variance in these samples is not unexpected. The ability of STRmix™ or case-manager to deconvolute three person mixtures into component contributions is hampered by the increased stochastic effects seen in the lowest-template contributions and the relatively similar peak heights (~2:1) between contributors to these mixtures. This being stated, STRmix™ will still consider all genotypic combinations and provide a probability for them. As such, a known contributor to the lowest template DNA profile will still generate a likelihood ratio albeit potentially lower than if these contributions were able to be modelled more accurately.

Mixture	Total Template (pg)	Template of lesser DNA contribution	Template predicted by STRmix™
1:1	500	250	250
2:1	500	167	160
2:1	60	20	29
5:1	500	83	100
5:1	125	21	27
5:2:1	500	63	95
5:2:1	125	16	38
10:1	500	45	60
10:1	125	11	17
10:5:1	500	31	25
20:1	500	24	25
20:1	250	12	10
20:1	125	6	7
20:10:1	500	16	15
20:10:1	125	4	37
30:1	500	16	25
50:1	500	10	15
50:1	250	5	7
50:1	125	2	6

Table 13: Actual vs. Predicted DNA Template for Full Volume Mixtures

This data indicates that STRmix™ can be instructive in determining the likely amount of template contributed by low-level DNA contributions to a mixture. However, it should be noted that this is dependant on the quality of the input DNA and the EPG produced. Degraded DNA in a mixture especially, may not be accurately modelled by STRmix™ for low-template contributions due to the disparity in molecular weights of the DNA used for quantification and the DNA analysed for genotype determination. Additionally, this data increases confidence that stochastic effects are not adversely affecting the EPGs produced for the validation samples to any significant degree.

5.10 Concordance and Number of Contributors

Table 15 indicates that in order to have a likelihood ratio greater than one, at least four unique alleles would be required. Obviously, this is also dependant on the total template versus the template of the lesser contributor, the allelic frequencies of the unique alleles, and the relative allelic heights of the various contributors. However, the trend is observed in both the 50:1 and 10:1 studies performed. This result is supported by the data presented in Table 16. This data represents the results of a constructed reference sample compared to a routine casework sample. This data shows that for an approximately 10:1 mixed DNA sample, an adventitious match to three unique alleles produces a likelihood ratio that is still markedly less than one. Even when there was full concordance (albeit predominantly masked by larger alleles) a relatively low likelihood ratio supporting inclusion was produced.

Pk Ht Ratio	Allele Added	No. Alleles matching	2P LR	Support for Non-Contribution (2P)	3P LR	Support for Non-Contribution (3P)
50:1	D3(11)	1	2.5×10^{-3}	400	5.5×10^{-3}	181
	D16(10)	2	2.5×10^{-2}	40	5.0×10^{-2}	20
	D8(10)	3	4.1×10^{-1}	2.4	8.6×10^{-2}	11
	D3(19)	4	8.0	-	1.5	-
10:1	D3(11)	1	4.8×10^{-3}	208	5.8×10^{-2}	17
	D16(10)	2	4.6×10^{-3}	217	1.0×10^{-2}	100
	D8(10)	3	7.5×10^{-2}	13	3.8×10^{-2}	26
	D3(19)	4	8.8×10^{-1}	1.1	7.0×10^{-1}	1.4

Table 15: Concordance Results For Mixtures Analysed At Varying Degrees Of Concordance For Two And Three Contributors.

Concordance	2P	3P
2 unique alleles	2×10^{-3}	1.1×10^{-2}
2 unique alleles + 1 masked	5.4×10^{-3}	2.3×10^{-2}
2 unique alleles + 2 masked	1.1×10^{-2}	5.7×10^{-2}
2 unique alleles + 3 masked	3.2×10^{-2}	1.2×10^{-1}
3 unique alleles	8.4×10^{-4}	9.3×10^{-3}
3 unique alleles + 37 masked	12000	3300

Table 16: Likelihood Ratios Generated from Varying Degrees of Concordance in the Low-template DNA Contribution

A t-test analysis of the combined data of Tables 15 and 16 shows that altering the assumed number of contributors does not significantly affect the likelihood ratio obtained ($p>0.05$). Even though the effect of adding an extra potential contributor will be the same for all DNA profiles, it is suggested that this method only be applied to profiles where the lower-template contribution is likely to be of similar height to the n-4 stutter of the larger contribution. The average n-4 stutter height is 13% for the *Promega PowerPlex®21* system. Therefore ambiguity will begin to occur between true alleles and stutter alleles at a ratio of approximately 7:1 or greater.

5.11 Single Source Homozygotic Allele Designations

An identified risk of the STRmix™ analysis was the appropriate identification of truly homozygotic loci versus heterozygotic loci where, due to stochastic effects, one of the alleles had dropped out. It was proposed that NCIDD uploads be designated as (Z,NR) for loci where uncertainty occurred due to the low level of template in the analysis. STRmix™ does not account for template level, only the observed alleles and their associated peak heights and as such, is not able to accommodate stochastic effects beyond those associated with low-peak height. It is possible in low-template DNA profiles for the partner of a heterozygotic allele to drop out causing STRmix™ to model an artificially high probability of the locus being homozygotic. In order to determine the level of template at which this phenomenon occurs, the dilution series of full volume amplified samples 1-10 (see Section 5.4) consisting of 500, 447, 394, 342, 289, 236, 183, 131, 78, 25pg templates was analysed using STRmix™ and the genotype probabilities recorded. The contributor to this DNA profile was heterozygotic at all loci.

STRmix™ accurately modelled the heterozygotic alleles at all loci where allelic information was present indicating the presence of two alleles. This is not

unexpected. There were no examples in the sample examined of STRmix™ modelling a heterozygotic locus as homozygous at greater than 99% probability (the level required for NCIDD upload), however the 78pg DNA profile had one locus (Penta D) that had drop-out of one allele and was modelled as most probably homozygotic (96.6%). The 25pg DNA profile had 10 loci (D1, D6, D16, D2, CSF, TH01, D21, D7, D8, and D12) that had drop-out of one allele and were modelled as most likely to be homozygotic compared to (Z,-1) alternatives. The probabilities for the 25pg loci ranged from approximately 60% to 86%. Because the observed peaks are truly heterozygous, the same possibility for stochastic effects must be considered for if they were homozygous. Therefore if a single peak can drop out at 78pg then conceivably a homozygotic peak could present as a single peak at twice this height. As such it is recommended that for DNA profiles with template below 150pg potential homozygotic loci be uploaded to NCIDD as Z,NR designations. Additionally, the other aspects of the *Promega PowerPlex®21* system validation showed that stochastic effects were present at 132pg template and the 150pg value accords well with this observation. Using a Z,NR designation will prevent the possibility of false exclusion of potential matches on NCIDD as a result of stochastic aberrations affecting STRmix™ modelling.

6 Conclusion

STRmix™ has been demonstrated to be a suitable means of analysing single-source and mixed full volume amplified DNA profiles. At all template levels STRmix™ consistently identified the correct allelic combination as one of the likely contributions. These results are repeatable and the likelihood ratios produced were consistent between runs. Analysis difficulties can arise with very low template contributions whereby the likelihood ratio may support non-contribution for known contributors. This is most likely due to the increased stochastic effects observed with low-template DNA and to the probabilities assigned to drop-out (-1,-1) designations.

7 Recommendations for FULL (25µL) Volume Amplification

- STRmix™ is adopted for DNA profile interpretation and statistical calculations.
- Saturation threshold is set at 7000rfu.
- The maximum stutter is set at 0.3.
- The maximum drop-in is set at 40.
- Locus amplification variance and variance to be set to 0.030 and 9.3 respectively.
- Deconvolutions on four-person mixtures are not performed at this time.
- STRmix™ be used at the full range of observable DNA (ie >40rfu) irrespective of template.

- For low DNA templates complete and/or partial drop-out should be considered by STRmix™. That is it should have modelled (-1,-1) and/or (Z,-1) as appropriate. If this has not happened then the number of accept-iterations should be increased to 500K.
- If the number of contributors is uncertain but the DNA profile is still suitable for analysis, then the mixture should be modelled as "n+1" contributors (where n is the minimum number needed to explain the mixture). This has the effect of moving the likelihood ratio towards 1, however not by a significant amount. This process should only be considered for mixed DNA profiles where there is a marked ratio difference between the greater and lesser DNA contributions of around 7:1 or greater.
- NCIDD upload of homozygous peaks be limited to Z,NR designation where the DNA template of the DNA profile of interest is below 150pg.

8 Appendix 1 – Mixture Study Results

Full Volume Mixture	Template	Issues Identified	C1 - LR	C2 -LR	C3 - LR	C4-LR
5:3:2:1	0.5	Insufficient memory space	-	-	-	-
	0.125	After examining profiles and results it has been decided that at this stage, 4-person mixtures will not be analysed	9.19E+10	2.98E+06	3.24E+04	4.91E-05
20:10:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.22E+25	6.49E+24	1.44E+07	-
	0.125	Profile considered by STRmix as 1:1:1 therefore low weightings assigned to correct combinations	6.61E+15	1.76E+09	3.68E-06	-
10:5:1	0.5	All correct combinations considered. Most loci had highest weightings assigned to the correct genotypes, or were reasonably close to this. Correct genotypes had lower weightings towards the higher MW loci due to the differences in degradation slope considered by STRmix. There didn't seem to be as large a difference in ratio between contributors 1 and 2 as might be expected.	1.49E+18	6.21E+17	9.44E+10	-
5:2:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	8.58E+24	1.14E+14	4.42E+07	-
	0.125	Mix considered as 1:1:1 therefore correct combinations given low weightings at some loci.	9.22E+14	4.56E+03	33.4	-
50:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.55E+28	5.39E+04	-	-
	0.25	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.54E+28	6.34E+02	-	-
	0.125	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.08E+28	5.39E+04	-	-
30:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.54E+28	1.41E+11	-	-
20:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.55E+28	1.48E+08	-	-
	0.25	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.54E+28	2.22E+05	-	-
	0.125	All correct combinations considered. Variations in weightings are due to the low template in "minor"	1.24E+28	3.25	-	-
10:1	0.5	All correct combinations considered. Variations in weightings are due to the low template in "minor".	1.55E+28	8.06E+14	-	-
	0.125	All correct combinations considered. Variations in weightings are due to the low template in "minor"	4.38E+27	4.41E+07	-	-
5:1	0.5	All correct combinations considered. All but one combination given the highest weighting	1.52E+28	8.00E+25	-	-
	0.125	All correct combinations considered. Mostly the highest weightings were assigned to the correct genotypes. Where correct genotypes had lower weightings there was drop-out related to the low template of the minor contributor.	3.15E+27	1.59E+20	-	-
2:1	0.5	All correct combinations considered with high weightings	1.00E+24	4.78E+23	-	-
	0.06	All the correct combinations were considered with good weightings. Variations in weightings are due to the low template.	2.37E+15	5.24E+08	-	-
1:1	0.5	All correct combinations considered with good weightings	3.43E+14	1.85E+14	-	-

Table A1: Full Volume Amplification Results for Intuitive Checking

9 Appendix 2 - Settings

9.1 Stutter

As described in Section 5.7 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples* validation document samples were selected for stutter analysis. This data was supplied to Jo-Anne Bright of ESR for analysis. There was no significant difference in stutter values between laboratories across Australia (*Variability In Powerplex® 21 Stutter Ratios Across Australian Laboratories*, Jo-Anne Bright, August 2012). Therefore the stutter data from the each of the laboratories was combined and a single stutter file created for use with STRmix™. DNA Analysis data (see Section 6.6 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples* validation document) shows that there appears to be no significant difference between the stutter values for full and half volume amplifications and therefore we propose the use of the same stutter file.

For the stutter setting, Jo-Anne Bright calculated that the maximum stutter observed in the data was 0.26. We propose a value of 0.3 for the stutter setting.

9.2 Drop-in

The drop-in parameters are discussed in Section 6.5 of the *PowerPlex® 21 - Amplification of Extracted DNA Samples* validation document and will be set at a=b=0.393 The maximum observed drop-in at a locus was 21rfu, therefore we propose a value of 40rfu (equal to the detection threshold) for the drop-in setting. These values are based on the drop-in events observed for the full volume amplifications. Since no drop-in events were observed for the half volume amplifications, we propose the use of the same setting for both full and half volume amplifications.

9.3 MCMC accepts

The values for the MCMC accepts and Burnin accepts will be set at 50000 and 10000 respectively as recommended by Dr Duncan Taylor. These values can be increased to 500000 and 100000 respectively for more complex DNA profile analysis.

CA-50

Reference	Description	Project	Version 1	Version 2
5.1.1	Aboriginal & Torres Strait Islander dataset	101	Aboriginal-Torres Straits Results.xls	Project 107 - 5.1 v2.0.xls
5.1.2				
5.1.3	Caucasian dataset		Caucasian results.xls	
5.1.4	South East Asian dataset		PP21_SEAsian_Population data.xls	
5.2	Concordance	104	PowerPlex_21 to CTS manufacturer results comparison.xls	Project 107 - 5.2 v2.0.xls
			Powerplex21_Concordance_Allele Table_PowerPlex_21_IDX_v1.0.xls	
5.3	Baseline determination	102	Baseline_3130xlA-original.xlsx	Project 107 - 5.3 v2.0.xls
			Baseline_3130xlA.xlsx	
			Baseline 3130xl A_rerun.xls	
			Baseline_3130xlB - original.xlsx	
			Baseline_3130xlB.xlsx	
			Baseline 3130xl B_rerun.xls	
			Baseline 3130xl A Half.xls	
			Baseline 3130xl B Half.xls	
5.4	Sensitivity 1	100	DA for PowerPlex21_Exp1_Exp3_40RFUs	Project 107 - 5.4 v2.0.xls
5.5	Sensitivity 2		Low quant values.xls	Project 107 - 5.5 v2.0.xls
5.6	Drop in	105	Baseline_3130xlA-original.xlsx	Project 107 - 5.6 v2.0.xls
			Baseline_3130xlA.xlsx	
			Baseline 3130xl A_rerun.xls	
			Baseline_3130xlB - original.xlsx	
			Baseline_3130xlB.xlsx	
			Baseline 3130xl B_rerun.xls	
			Baseline 3130xl A Half.xls	
			Baseline 3130xl B Half.xls	
5.7	Stutter	102	10x10 CW data full volume - stutter data	Project 107 - 5.7 v2.0.xls
			12.5uL n-1_n+1 Summary	
5.8	Peak Balance	102	Alth_Homoth_summary.xls	Project 107 - 5.8 v2.0.xls
			Pk balance_both_final.xls	

Reference	Description	Project	Version 1	Version 2
			Alt_Homozygote_b_20130719.xls	
			PP21_10x10_half_B_20130722_Results Table_PowerPlex_21_IDX_v1.1.1.xlsx	
5.9.1	Drop out 1	102	Dropout1_heat maps.xls	Project 107 - 5.9 v2.0.xls
5.9.2	Drop out 2	102	Allelic drop out_full20130718.xls	
			Allelic drop out_half20130717.xls	
5.9.3	Drop out 3	102	Drop out20130718.xls	
5.10	Mixture studies	103	Mixtures_val_2012.xls	Project 107 - 5.10 v2.0.xls

Summary of PP21 validation batches

CE data folder (amp plate)	GM project ID	description	validation study used for	Project #	amp type	CE instrument	Injection time	Report	Report reference	Notes
Powerplex21_Exp1_25uL	Powerplex21_Exp1_25uL	Sensitivity experiments (2 donors 4ng - 0.001ng templates)	Sensitivity	100	full volume	3130xl A			5.4	used for final report
Powerplex21_Exp1_25uL	Powerplex21_Exp1_25uL	Sensitivity experiments (2 donors 4ng - 0.001ng templates)	Allelic drop out	102	full volume	3130xl A				
Powerplex21_Exp1_rsprop	Powerplex21_Exp1_rsprop	rsprop of sensitivity	Sensitivity	100	full volume	3130xl A				only done to look at run to run difference, not used in report
		?original ?rsprop run used	homozygote & All thresholds	102	full volume	3130xl A				used for final report
Powerplex21_Exp2	Powerplex21_Exp2	FTA sensivity samples	sensitivity	100	direct amp full volume	3130xl A				used for final report
Powerplex21_Exp2_rsprop	Powerplex21_Exp2_rsprop	FTA sensivity samples	sensitivity	100	direct amp full volume	3130xl A				only done to look at run to run difference, not used in report
		?original ?rsprop run used	homozygote & All thresholds	102	direct amp full volume	3130xl A				used for final report
Powerplex21_Exp3_12.5uL	Powerplex21_Exp3_12.5uL	Sensitivity experiments (2 donors 4ng - 0.001ng templates)	sensitivity	100	half volume	?				original amp done with incorrect dilutions. results not used
Powerplex21_Exp3_12.5uL_reamp	Powerplex21_Exp3_12.5uL_reamp	Sensitivity experiments (2 donors 4ng - 0.001ng templates)	sensitivity	100	half volume	3130xlA				used for final report
		Sensitivity experiments (2 donors 4ng - 0.001ng templates)	Allelic drop out	102	full volume	3130xl A				
Powerplex21_Exp3_12.5uL_rsprop	Powerplex21_Exp3_12.5uL_rsprop	rsprop of sensitivity	sensitivity	100	half volume	3130xlA				only done to look at run to run difference, not used in report
		?original ?rsprop run used	homozygote & All thresholds	102	half volume	3130xlA				used for final report
Powerplex21_Exp4_12.5uL	Powerplex21_Exp4_12.5uL	FTA sensivity samples	sensitivity	100	direct amp half volume	3130xlA				used for final report
Powerplex21_Exp4_rsprop	Powerplex21_Exp4_rsprop	rsprop of FTA sensitivity	sensitivity	100	direct amp half volume	3130xlA				only done to look at run to run difference, not used in report
		?original ?rsprop run used	homozygote & All thresholds	102	direct amp half volume	3130xlA				used for final report
PP21_serial_dil_plate1_full	PP21_serial_dil_plate1_full	additional sensitivity (0.01ng - 0.0000781*25ng) "bridging experi	sensitivity	100	full volume	3130xlA				used for final report
		additional sensitivity (0.01ng - 0.0000781*25ng) "bridging experi	Allelic drop out	102	full volume	3130xlA				
PP21_serial_dil_plate1_half	PP21_serial_dil_plate2_half	additional sensitivity "bridging experiment"	sensitivity	100	half volume	3130xlA				used for final report
		additional sensitivity "bridging experiment"	Allelic drop out	102	half volume	3130xlA				
PP21_Platte_1_Aboriginal	PP21_Platte_1_Aboriginal	samples for Aboriginal pop'n database	Allele freq, d'base	101	full volume	3130xlA				used for final report
	PP21_Platte_1_Aboriginal	samples for Aboriginal pop'n database	Allelic drop out	102	full volume	3130xl A				
	PP21_Platte_1_Aboriginal_stutter thresholds	samples for Aboriginal pop'n database	stutter thresholds	102	full volume	3130xlA				used for final report
	PP21_Platte_1_Aboriginal_stutter thresholds	samples for Aboriginal pop'n database	back stutter thresholds	102	full volume	3130xlA				used for final report
	PP21_Aboriginal_1_stutter thresholds	samples for Aboriginal pop'n database	* -2 repeat stutter thresholds	102	full volume	3130xlA				used in subsequent reports
PP21_Platte_2_Aboriginal	PP21_Platte_2_Aboriginal	samples for Aboriginal pop'n database	Allele freq, d'base	101	full volume	3130xlA				used for final report
	PP21_Platte_2_Aboriginal	samples for Aboriginal pop'n database	Allelic drop out	102	full volume	3130xlA				
	PP21_Platte_2_Aboriginal_stutter thresholds	samples for Aboriginal pop'n database	stutter thresholds	102	full volume	3130xlA				used for final report
	PP21_Platte_2_Aboriginal_stutter thresholds	samples for Aboriginal pop'n database	back stutter thresholds	102	full volume	3130xlA				used for final report
	PP21_Aboriginal_2_stutter thresholds	samples for Aboriginal pop'n database	* -2 repeat stutter thresholds	102	full volume	3130xlA				used in subsequent reports
PP21_Platte_3_Aboriginal	PP21_Platte_3_Aboriginal	samples for Aboriginal pop'n database	Allele freq, d'base	101	full volume	3130xlA				used for final report
	PP21_Platte_3_Aboriginal	samples for Aboriginal pop'n database	Allelic drop out	102	full volume	3130xlA				
	PP21_Platte_3_Aboriginal_stutter thresholds	samples for Aboriginal pop'n database	stutter thresholds	102	full volume	3130xlA				used for final report
	PP21_Platte_3_Aboriginal_stutter thresholds	samples for Aboriginal pop'n database	back stutter thresholds	102	full volume	3130xlA				used for final report
	PP21_Aboriginal_3_stutter thresholds	samples for Aboriginal pop'n database	* -2 repeat stutter thresholds	102	full volume	3130xlA				used in subsequent reports
PP21_Platte_4_Aboriginal	PP21_Platte_4_Aboriginal	samples for Aboriginal pop'n database - actually Torres St Isl.	Allele freq, d'base	101	direct amp half volume	?				used for Ab d'base, were originally labelled as SEAsian database samples as there was a mixup of what AUSLAB search criteria had been used
PP21_Platte_5_Aboriginal	PP21_Platte_5_Aboriginal	samples for Aboriginal pop'n database - actually Torres St Isl.	Allele freq, d'base	101	direct amp half volume	?				used for Ab d'base, were originally labelled as SEAsian database samples as there was a mixup of what AUSLAB search criteria had been used
PP21_Platte_6_Aboriginal	PP21_Platte_6_Aboriginal	samples for Aboriginal pop'n database - actually Torres St Isl.	Allele freq, d'base	101	direct amp half volume	?				used for Ab d'base, were originally labelled as SEAsian database samples as there was a mixup of what AUSLAB search criteria had been used
	Powerplex21_Caucasian_plate1	samples for Caucasian pop'n database	Allele freq, d'base	101	direct amp half volume	3130xl A				
		samples for Caucasian pop'n database	homozygote & All thresholds	102	direct amp full volume	3130xl A				
	Powerplex21_Caucasian_plate2	samples for Caucasian pop'n database	Allele freq, d'base	101	direct amp full volume	3130xl A				
		samples for Caucasian pop'n database	homozygote & All thresholds	102	direct amp full volume	3130xl A				
	Powerplex21_Caucasian_plate3	samples for Caucasian pop'n database	Allele freq, d'base	101	direct amp full volume	3130xl A				
Powerplex21_Caucasian_plate4	Powerplex21_Caucasian_plate4	samples for Caucasian pop'n database	Allele freq, d'base	101	direct amp half volume	3130xl B				done using different cycle numbers
		re-run of above	Allele freq, d'base	101	direct amp half volume	3130xl A				
		rsprop of above	Allele freq, d'base	101	direct amp half volume	3130xl B				
		unsure which run from above was used	homozygote & All thresholds	102	direct amp full volume	?				
Powerplex21_Caucasian_plate5	Powerplex21_Caucasian_plate5	samples for Caucasian pop'n database	Allele freq, d'base	101	direct amp half volume	3130xl B				done using different cycle numbers
		re-run of above	Allele freq, d'base	101	direct amp half volume	3130xl A				
		rsprop of above	Allele freq, d'base	101	direct amp half volume	3130xl B				
		unsure which run from above was used	homozygote & All thresholds	102	direct amp full volume	?				
Powerplex21_Caucasian_plate6	Powerplex21_Caucasian_plate6	samples for Caucasian pop'n database	Allele freq, d'base	101	direct amp half volume	3130xl B				done using different cycle numbers
		rsprop of above	Allele freq, d'base	101	direct amp half volume	3130xl A				
Powerplex21_Caucasian_plate7	Powerplex21_Caucasian_plate7	samples for Caucasian pop'n database	Allele freq, d'base	101	direct amp half volume	3130xl B				done using different cycle numbers
		rsprop of above	Allele freq, d'base	101	direct amp half volume	3130xl A				
Powerplex21_Caucasian_plate8	Powerplex21_Caucasian_plate8	samples for Caucasian pop'n database	Allele freq, d'base	101	direct amp half volume	3130xl B				done using different cycle numbers
		rsprop of above	Allele freq, d'base	101	direct amp half volume	3130xl A				
PP21_SEAsian_plate1	PP21_SEAsian_plate1	samples for SE Asian pop'n database	Allele freq, d'base	101	direct amp half volume	3130xl B				only samples that profiled used for database, other samples repeated on plates 3 & 5
		samples for SE Asian pop'n database	homozygote & All thresholds	102	direct amp half volume	3130xl B				
PP21_SEAsian_plate2	PP21_SEAsian_plate2	samples for SE Asian pop'n database	Allele freq, d'base	101	direct amp half volume	3130xl B				only samples that profiled used for database, other samples repeated on plates 4 & 6
		samples for SE Asian pop'n database	homozygote & All thresholds	102	direct amp half volume	3130xl B				
PP21_SEAsian_plate3	PP21_SEAsian_plate3	samples for SE Asian pop'n database	Allele freq, d'base	101	direct amp half volume	?				all NGD
PP21_SEAsian_plate4	PP21_SEAsian_plate4	samples for SE Asian pop'n database	Allele freq, d'base	101	direct amp half volume	?				all NGD
PP21_SEAsian_plate5	PP21_SEAsian_plate5	samples for SE Asian pop'n database	Allele freq, d'base	101	direct amp half volume	?				re-do of plate 3
PP21_SEAsian_plate6	PP21_SEAsian_plate6	samples for SE Asian pop'n database	Allele freq, d'base	101	direct amp half volume	?				re-do of plate 4
PP21_SEAsian_plate7	PP21_SEAsian_plate7	samples for SE Asian pop'n database	Allele freq, d'base	101	full volume	3130xl A				extracted samples that didn't work, used for database
	PP21_SEAsian_stutter thresholds	samples for SE Asian pop'n database ? Plates 1 & 2 combined	* -2 repeat stutter thresholds	102	full volume	3130xl A				used for stutter of stutter thresholds only
Powerplex21_plate1_102_full	Powerplex21_plate1_102_A	10 dilutions of 10 different REF samples	baseline	102	full volume	3130xl A				used for final report
Powerplex21_plate1_102_full	Powerplex21_plate1_102_B	10 dilutions of 10 different REF samples	baseline	102	full volume	3130xl B				used for final report
		10 dilutions of 10 different REF samples	stutter thresholds	102	full volume	3130xl B				used for final report
		10 dilutions of 10 different REF samples	Allelic drop out	102	full volume	3130xl B				
Powerplex21_plate2_102_full	Powerplex21_plate2_102_A	10 dilutions of 10 different REF samples	baseline	102	full volume	3130xl A				used for final report
Powerplex21_plate2_102_full	Powerplex21_plate2_102_B	10 dilutions of 10 different REF samples	baseline	102	full volume	3130xl B				used for final report
		10 dilutions of 10 different REF samples	stutter thresholds	102	full volume	3130xl B				used for final report
		10 dilutions of 10 different REF samples	Allelic drop out	102	full volume	3130xl B				
	Powerplex21_102_A_rerun	10 dilutions of 10 different REF samples	baseline	102	full volume	3130xl A				re-run of plate 1 and plate 2 on 3130xl A combined into one project, only used to confirm original run results
	Powerplex21_102_B_re-run	10 dilutions of 10 different REF samples	baseline	102	full volume	3130xl B				re-run of plate 1 and plate 2 on 3130xl B combined into one project, only used to confirm original run results
Powerplex21_plate1_102_half & Powerplex21_plate2_half	PowerPlex21_10x10_Half	10 dilutions of 10 different REF samples	baseline	102	half volume	3130xl A				used for final report
	PowerPlex21_10x10_Half_stutter thresholds	10 dilutions of 10 different REF samples	stutter thresholds	102	half volume	3130xl A				used for final report
		10 dilutions of 10 different REF samples	variance / model maker	105	half volume	3130xl A				used for final report (note, original run, not re-run data used)
		10x10 data, not sure which run	homozygote & All thresholds	102	half volume	?				
		10 dilutions of 10 different REF samples	Allelic drop out	102	half volume	3130xl A				
Powerplex21_plate1_102_half & Powerplex21_plate2_half	PP21_10x10_half_B	10 dilutions of 10 different REF samples	baseline	102	half volume	3130xl B				used for final report
Powerplex21_plate1_102 & Powerplex21_plate2_102	PP21_10x10	10 dilutions of 10 different REF samples	variance / model maker	105	full volume	3130xl A				used for final report (note, original run, not re-run data used)
		10x10 data, not sure which run	homozygote & All thresholds	102	full volume	?				
	Reference_Baseline_plate1	FTA samples for baseline data (Aboriginal pop'n samples)	baseline	102	direct amp half volume	3130xl A				
		as above	homozygote & All thresholds	102	direct amp half volume	3130xl A				
	Reference_Baseline_plate2	FTA samples for baseline data (? pop'n samples)	baseline	102	direct amp half volume	3130xl A				
		as above	homozygote & All thresholds	102	direct amp half volume	3130xl A				
PowerPlex21_Mixture	PowerPlex_Mixture	Mock mixtures of various ratios (only 2 and 3 person ratios)	mixture studies	103	full volume	3130xl A				original mixtures
PowerPlex21_Mixture & PP21_Mixture_Full	PP21_Mixture_Full	Mock mixtures of various ratios (2,3 and 4 person ratios)	mixture studies	103	full volume	3130xl A				additional mixtures requested later
	PP21_Mixture_Half	Mock mixtures of various ratios (2,3 and 4 person ratios)	mixture studies	103	half volume	3130xl A				additional mixtures requested later
PP21_CTS_plate 1_half & PP21_CTS_plate 2_half	PP21_CTS_Half	Old CTS samples	Concordance study	104	half volume	3130xl B				
	PP21_CTS_Half	Old CTS samples	Allelic drop out	102	half volume	3130xl B				
	PP21_CTS_stutter thresholds	Old CTS samples	stutter thresholds	102	half volume	3130xl B				
		Old CTS samples	* -2 repeat stutter thresholds	102	half volume	3130xl B				
		re-CE of above plate	* -2 repeat stutter thresholds	102	half volume	3130xl A				
RF21FCE20130212_01	FGMERF20130213_01 (also REFAMP_STUT	Old CTS samples	* -2 repeat stutter thresholds	102	full volume	3130xl A				
RF21FCE20130212_02	FGMERF20130214_01 (also REFAMP_STUT	Old CTS samples	* -2 repeat stutter thresholds	102	full volume	3130xl A				
RF21FCE20130213_01	FGMERF20130214_02 (also REFAMP_STUT	Old CTS samples	* -2 repeat stutter thresholds	102	full volume	3130xl A				
PowerPlex_Concordance	PowerPlex_Concordance	CTS samples	Concordance study	104	full volume	3130xl A				
	PowerPlex_Concordance_stutter	CTS samples	stutter thresholds	102	full volume	3130xl A				
		CTS samples	back stutter thresholds	103	full volume	3130xl A				
Powerplex21_plate1_102 & Powerplex21_plate2_102	PowerPlex21_102_full_20130225	10 dilutions of 10 different REF samples	baseline	102	full volume	3130xl B				re-run of baseline samples to check baseline of 3130xl B after change of major components
Powerplex21_plate1_102 & Powerplex21_plate2_102	PowerPlex21_102_full_20130225_48RFU	10 dilutions of 10 different REF samples	variance / model maker	102	full volume	3130xl B				re-run of baseline samples to check baseline of 3130xl B after change of major components
Powerplex21_plate1_102_half & Powerplex21_plate2_half	Powerplex21_102_half_20130222	10 dilutions of 10 different REF samples	baseline	102	half volume	3130xl B				re-run of baseline samples to check baseline of 3130xl B after change of major components
Powerplex21_plate1_102_half & Powerplex21_plate2_half	Powerplex21_102_half_20130222_48RFU	10 dilutions of 10 different REF samples	variance / model maker	102	half volume	3130xl B				re-run of baseline samples to check baseline of 3130xl B after change of major components

Report	Reference	Description	Project	injection time	CE instrument	GM project ID	PCR type	Results file	
PowerPlex®21 - Amplification of Extracted DNA Validation v2.0.doc	5.1.1	Aboriginal & Torres Strait Islander dataset	101	5s	3130xl A	PP21_Plate_1_Aboriginal	25µL	Aboriginal-Torres Straits Results.xls	
						PP21_Plate_2_Aboriginal	25µL		
						PP21_Plate_3_Aboriginal	25µL		
	5.1.2					PP21_Plate_4_Aboriginal	25µL		
						PP21_Plate_5_Aboriginal	25µL		
						PP21_Plate_6_Aboriginal	25µL		
	5.1.3	Caucasian dataset		5s	3130xl A	Powerplex21_Caucasian_plate1		Caucasian results.xls	
						Powerplex21_Caucasian_plate2			
						Powerplex21_Caucasian_plate3			
				3s	3130xl B	Powerplex21_Caucasian_plate4			
				5s	3130xl A	Powerplex21_Caucasian_plate5			
				5s	3130xl A	Powerplex21_Caucasian_plate6			
	5.1.4	South East Asian dataset		3s	3130xl B	PP21_SEAsian_plate1		PP21_SEAsian_Population data.xls	
						PP21_SEAsian_plate2			
						PP21_SEAsian_plate3			
						PP21_SEAsian_plate4			
				5s	3130xl A	PP21_SEAsian_plate5			
						PP21_SEAsian_plate6			
						PP21_SEAsian_plate7			
	5.2	Concordance	104	3s	3130xl B	PP21_CTS_Half	12.5µL	Not performed for 25µL	
	5.3	Baseline determination	102	5s	3130xl A	Powerplex21_plate1_102_A	25µL		Baseline 3130xl A_rerun.xls
				3s	3130xl B	Powerplex21_plate1_102_B	25µL		Baseline 3130xl B_rerun.xls
				5s	3130xl A	Powerplex21_plate2_102_A	25µL		Baseline_3130xlA.xlsx
				3s	3130xl B	Powerplex21_plate2_102_B	25µL		Baseline_3130xlA-original.xlsx
				5s	3130xl A	Powerplex21_102_A_rerun	25µL		Baseline_3130xlB - original.xlsx
				3s	3130xl B	Powerplex21_102_B_re-run	25µL		Baseline_3130xlB.xlsx
				5s	3130xl A	PowerPlex21_10x10_Half	12.5µL		Baseline 3130xl B Half.xls
				3s	3130xl B	PP21_10x10_half_B	12.5µL		Baseline 3130xl A Half.xls
						PowerPlex21_102_full_20130225	25µL		
						Powerplex21_102_half_20130222	12.5µL		
	5.4	Sensitivity 1	100	5s	3130xl A	Powerplex21_Exp1_25uL_ser	25µL	DA for PowerPlex21_Exp1_Exp3_40RFUs	
						Powerplex21_Exp3_12.5uL_reamp	12.5µL		
	5.5	Sensitivity 2				PP21_serial_dil_plate1_full	25µL	Low quant values.xls	
						PP21_serial_dil_plate1_half	12.5µL		
	5.6	Drop in							
	5.7	Stutter	102	5s	3130xl A	PP21_Plate_1_Aboriginal_stutter_20.ser	25µL		
						PP21_Plate_2_Aboriginal_stutter_20.ser			
						Powerplex21_Exp1_25uL.ser			
						PP21_serial_dil_plate1_full			
						PP21_10x10_Half_Stutter.ser	12.5µL		
				3s	3130xl B	PP21_CTS_Stutter.ser			
						PP21_CTS_Plate2.ser			
				5s	3130xl A	PP21_Aboriginal 1_Stutter.ser	25µL		
					3130xl A	PP21_Aboriginal 2_Stutter.ser			
					3130xl A	PP21_Aboriginal 3_Stutter.ser			
					3130xl A	PP21_REFAMP_Stutter.ser	725		
					3130xl A	PP21_SEAsian_Stutter.ser	725		
				3s	3130xl B	PP21_Stutter_Stutter_A	12.5µL		
				5s	3130xl A	PowerPlex_Concordance			
	5.8	Peak Balance	102	5s	3130xl A	Powerplex21_plate1_102_A	25µL	Alth_Hmoth_summary.xls	
						Powerplex21_plate2_102_A		Pk balance_both_final.xls	
						Powerplex21_plate1_102_half	12.5µL	Alth_Hmoth_summary.xls	
						Powerplex21_plate2_half		Pk balance_both_final.xls	
						Powerplex21_Exp1_25uL.ser	25µL		
						Powerplex21_Exp3_12.5uL_reamp	12.5µL		
						PP21_serial_dil_plate1_full	25µL		
						PP21_serial_dil_plate1_half	12.5µL		
	5.9.1	Drop out 1	102	5s	3130xl A	Powerplex21_Exp1_25uL.ser	25µL		
						Powerplex21_Exp3_12.5uL_reamp	12.5µL		
	5.9.2	Drop out 2	102	5s	3130xl A	PP21_Plate_1_Aboriginal	25µL	Allelic drop out_full.xls	Allelic drop out_full20130718.xls
						PP21_Plate_2_Aboriginal			
						PP21_Plate_3_Aboriginal			
				3s	3130xl B	Powerplex21_plate1_102_B			
						Powerplex21_plate2_102_B			
				5s	3130xl A	Powerplex21_Exp1_25uL.ser			
						PP21_serial_dil_plate1_full			
						Powerplex21_plate1_102_half			

			3s	3130xl A	Powerplex21_plate2_half	12.5µL	Allelic drop out_half.xls
					PP21_serial_dil_plate1_half		
					Powerplex21_Exp3_12.5uL_reamp		
			3s	3130xl B	PP21_CTS_plate1_Half		
					PP21_CTS_plate2_Half		
5.9.3	Drop out 3	102	5s	3130xl A	Powerplex21_Exp1_25uL_ser	25µL	Drop out.xls
					PP21_serial_dil_plate1_full		
			3s	3130xl B	Powerplex21_plate1_102_B		
					Powerplex21_plate2_102_B		
			5s	3130xl A	PP21_serial_dil_plate1_half	12.5µL	
					Powerplex21_Exp3_12.5uL_reamp		
					Powerplex21_plate1_102_half		
					Powerplex21_plate2_half		
5.10	Mixture studies	103	5s	3130xl A	PowerPlex_Mixture		
					PP21_Mixture_Full	25µL	
					PP21_Mixture_Half	12.5µL	
			3s	3130xl B	PP21_Mixture_Half_ReGs	12.5µL	
			3s	3130xl B	PP21_Mixture_Half_Reamp	12.5µL	
			5s	3130xl A	PP21_Mixture_Full_Feb 2013_40rfu	25µL	
					PP21_Mixture_Full_Feb 2013	25µL	
					PP21_Mixture_Half_20130111	12.5µL	

Report	Reference	Description	Project		CE instrument	GM project ID	PCR type	Results file
PowerPlex®21 (Amplification of Extracted DNA Validation)v2.0.doc	5.1.1	Aboriginal & Torres Strait Islander dataset	101	5s	3130xl A	PP21_Plate_1_Aboriginal	25µL	Aboriginal-Torres Straits Results.xls
						PP21_Plate_2_Aboriginal		
	5.1.2					PP21_Plate_3_Aboriginal		
						PP21_Plate_4_Aboriginal		
						PP21_Plate_5_Aboriginal		
						PP21_Plate_6_Aboriginal		
	5.1.3	Caucasian dataset			3130xl A	Powerplex21_Caucasian_plate1	25µL direct	Caucasian results.xls
						Powerplex21_Caucasian_plate2		
						Powerplex21_Caucasian_plate3		
				3s	3130xl B	Powerplex21_Caucasian_plate4		
				5s	3130xl A	Powerplex21_Caucasian_plate5		
						Powerplex21_Caucasian_plate6		
	5.1.4	South East Asian dataset		2s	3130xl B	PP21_SEAsian_plate1	12.5µL direct & 25µL	PP21_SEAsian_Population data.xls
						PP21_SEAsian_plate2		
						PP21_SEAsian_plate3		
						PP21_SEAsian_plate4		
				5s	3130xl A	PP21_SEAsian_plate5		
						PP21_SEAsian_plate6		
						PP21_SEAsian_plate7		
	5.2	Concordance	104	1s	3130xl B	PP21_CTS_Half	12.5µL	PowerPlex_21 to CTS manufacturer results comparison.xls
								Powerplex21_Concordance_Allele Table_PowerPlex_21_IDX_v1.0.xls
	5.3	Baseline determination	102	5s	3130xl A	Powerplex21_plate1_102_A	25µL	Baseline_3130xlA-original.xlsx
						Powerplex21_plate2_102_A		Baseline_3130xlA.xlsx
						Powerplex21_102_A_rerun		Baseline 3130xl A_rerun.xls
				3s	3130xl B	Powerplex21_plate1_102_B		Baseline_3130xlB - original.xlsx
						Powerplex21_plate2_102_B		Baseline_3130xlB.xlsx
						Powerplex21_102_B_re-run		Baseline 3130xl B_rerun.xls
				5s	3130xl A	PowerPlex21_10x10_Half	12.5µL	Baseline 3130xl A Half.xls
				3s	3130xl B	PP21_10x10_half_B		Baseline 3130xl B Half.xls
	5.4	Sensitivity 1	100	5s	3130xl A	Powerplex21_Exp1_25uL.ser	25µL	DA for PowerPlex21_Exp1_Exp3_40RFUs
						Powerplex21_Exp3_12.5uL_reamp	12.5µL	
	5.5	Sensitivity 2		5s	3130xl A	PP21_serial_dil_plate1_full	25µL	Low quant values.xls
						PP21_serial_dil_plate1_half	12.5µL	
	5.8	Drop in	102	5s	3130xl A	Powerplex21_plate1_102_A	25µL	Baseline_3130xlA-original.xlsx
						Powerplex21_plate2_102_A		Baseline_3130xlA.xlsx
						Powerplex21_102_A_rerun		Baseline 3130xl A_rerun.xls
				3s	3130xl B	Powerplex21_plate1_102_B		Baseline_3130xlB - original.xlsx
						Powerplex21_plate2_102_B		Baseline_3130xlB.xlsx
						Powerplex21_102_B_re-run		Baseline 3130xl B_rerun.xls
				5s	3130xl A	PowerPlex21_10x10_Half	12.5µL	Baseline 3130xl A Half.xls
				3s	3130xl B	PP21_10x10_half_B		Baseline 3130xl B Half.xls
	5.7	Stutter	102	5s	3130xl A	PP21_Plate_1_Aboriginal_stutter_20.ser	25µL	n-2 stutter 25uL Combined Results AKD-ARM data check 15-5-2013.xls
						PP21_Plate_2_Aboriginal_stutter_20.ser		Stutter Thresholds CASEWORK 10x10 full volume.xls
						Powerplex21_Exp1_25uL.ser		n-2 stutter Comparison - full v half volume-ARM15-5-2013.xls
						PP21_serial_dil_plate1_full		REFAMP & CTS results AKD-ARM data check 15-5-2013
						PP21_10x10_Half_Stutter.ser	12.5µL	n-2 stutter 12.5uL Combined Results AKD.xls
								12.5uL n-1_n+1 Summary.xls
								Stutter thresholds updated 20130516.doc
				5s	3130xl A	PP21_Aboriginal 1_Stutter.ser	25µL	Combined Results AKD
						PP21_Aboriginal 2_Stutter.ser		
						PP21_Aboriginal 3_Stutter.ser		
						PP21_REFAMP_Stutter.ser		
						PP21_SEAsian_Stutter.ser		
					3130xl B	PP21_Stutter_Stutter_A	12.5µL	
				3s	3130xl B	PP21_CTS_Stutter.ser	12.5uL	
	5.8	Peak Balance	102	5s	3130xl A	Powerplex21_plate1_102_A	25µL	Allh_Homoth_summary.xls
						Powerplex21_plate2_102_A		
						Powerplex21_plate1_102_half	12.5µL	
						Powerplex21_plate2_half		
						Powerplex21_Exp1_25uL.ser	25µL	
						Powerplex21_Exp3_12.5uL_reamp	12.5µL	Ph balance_toth Review

Report	Reference	Description	Project		CE instrument	GM project ID	PCR type	Results file
						PP21_serial_dil_plate1_full	25µL	Variance_pool_mat.xls
						PP21_serial_dil_plate1_half	12.5µL	
				3s	3130xl B	Powerplex21_plate1_102_B	25µL	All_Homozygote_b_20130719.xls
						Powerplex21_plate2_102_B		
						PP21_10x10_half_B_20130722.ser	12.5µL	PP21_10x10_half_B_20130722_Results Table_PowerPlex_21_IDX_v1.1.1.xlsx
	5.9.1	Drop out 1	102	5s	3130xl A	Powerplex21_Exp1_25uL.ser	25µL	Dropout1_heat maps.xls
						Powerplex21_Exp3_12.5uL_reamp	12.5µL	
	5.9.2	Drop out 2	102	5s	3130xl A	PP21_Plate_1_Aboriginal	25µL	Allelic drop out_full20130718.xls
						PP21_Plate_2_Aboriginal		
						PP21_Plate_3_Aboriginal		
						Powerplex21_Exp1_25uL.ser		
						PP21_serial_dil_plate1_full		
				3s	3130xl B	Powerplex21_plate1_102_B		
						Powerplex21_plate2_102_B		
				5s	3130xl A	Powerplex21_plate1_102_half	12.5µL	Allelic drop out_half20130717.xls
						Powerplex21_plate2_half		
						PP21_serial_dil_plate1_half		
						Powerplex21_Exp3_12.5uL_reamp		
				3s	3130xl B	PP21_CTS_plate1_Half		
						PP21_CTS_plate2_Half		
	5.9.3	Drop out 3	102	5s	3130xl A	Powerplex21_Exp1_25uL.ser	25µL	Drop out20130718.xls
						PP21_serial_dil_plate1_full		
						Powerplex21_plate1_102_A		
						Powerplex21_plate2_102_A		
					3130xl A	PP21_serial_dil_plate1_half	12.5µL	
						Powerplex21_Exp3_12.5uL_reamp		
						Powerplex21_plate1_102_half		
						Powerplex21_plate2_half		
	5.10.	Mixture studies	103		3130xl A	PowerPlex_Mixture	25µL	Mixtures_val_2012.xls
				5s		PP21_Mixture_Full	25µL	
				5s		PP21_Mixture_Half	12.5µL	
				3s	3130xl B	PP21_Mixture_Half_ReGs	12.5µL	
				3s	3130xl B	PP21_Mixture_Half_Reamp	12.5µL	

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PowerPlex®21 – Amplification of Extracted DNA Validation v2.0

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Forensic DNA Analysis, Forensic & Scientific Services

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Queensland Government

Document details

Contact for enquiries and proposed changes

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Version history

Version	Date	Changed by	Description
2.0	17/03/2014	Thomas Nurthen	Rewrite of stutter experiment design and results Rewrite to incorporate different injection times, additional reference

Document sign off

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Contents

1 Abstract

To meet Queensland legislative requirements and core business needs, DNA Analysis has validated the PowerPlex® 21 system DNA profiling Kit. All Australian jurisdictions are expected to implement a new DNA profiling kit by the end of 2012. This project came about through the Australian and New Zealand Policing Advisory Agency (ANZPAA).

The loci within the AmpFℓSTR® Profiler Plus® and AmpFℓSTR® COfiler® kits, which are currently used in DNA Analysis, are represented within the PowerPlex® 21 system loci. This allows concordance of the kit for direct comparison and matching against existing AmpFℓSTR® Profiler Plus® crime scene and reference DNA profiles.

This validation has demonstrated that the PowerPlex® 21 system kit is fit for purpose for the amplification of extracted DNA samples processed in the Forensic DNA Analysis laboratory. A limit of reporting threshold of 40 RFU will be adopted for analysis of extracted DNA samples amplified at either 25 µL or 12.5 µL total PCR volumes. This updated validation report supports the validity of samples processed with 5 s and 3 s injection times. However, the recommendation is that the 5 s injection time is the default injection time as it results in higher peak height RFU.

The sensitivity of this next generation STR kit has greatly increased, however the increased sensitivity does not necessarily result in increased information. The results of this validation indicates that Promega's PowerPlex® 21 system is a very sensitive STR amplification kit, but to reduce the risk of type 2 errors (calling a heterozygous locus homozygous[1]) consideration needs to be given to restricting the range of DNA template added. Single source samples with DNA templates of greater than 0.5ng overload the PowerPlex® 21 system resulting in DNA profiles being unable to be interpreted. Generally samples with lower templates (reaching the often termed 'low copy number' level of 100-150pg) tend to exhibit enhanced stochastic effects as one would expect. Therefore, it should be considered whether samples around this input template level should be amplified given that interpretation of the results could be unwieldy. It would be possible to increase the template levels of samples that fall into this category by post extraction concentration or increase the total PCR volume.

At a total DNA input template of 0.5 ng, for 25 µL and 12.5 µL total PCR volumes, all alleles were detected for the mixtures with ratios of 1:1, 2:1 and 5:1.

The results from this validation support that the Promega PowerPlex®21 System is suitable for analysis of short tandem repeats (STR).

2 Introduction

To meet Queensland legislative requirements and core business needs, DNA Analysis has validated the PowerPlex® 21 system DNA profiling Kit. All Australian jurisdictions are expected to implement a new DNA profiling kit by the end of 2012. This expectation has been directed by ANZPAA, which comprises a Police Commissioner from each jurisdiction.

The initial plan endorsed by the members of the Biological Specialist Advisory Group (BSAG) involved a series of experiments designed to enable each jurisdiction to choose an appropriate STR amplification kit but using the same methodology (national approach to STR kit validation)[2].

This plan included:

1. Sensitivity and amplification volume determination
2. Population studies
3. Concordance
4. Mixture studies
5. Baseline determinations, peak balance, stutter thresholds, minimum reporting threshold and probability of drop in. This last series of experiments were devised by the Statistics Scientific Working Group (StatSWG)[3].

The plans created by BSAG and StatSWG are a significant development with respect to STR validation and interpretation within Australia. In line with current research, these plans involve the move away from a binary approach to DNA profile interpretation to a continuous model. To achieve this, a new DNA profile interpretation software (STRmix™) has been developed by forensic DNA experts & statisticians from Australia and New Zealand forensic laboratories. The validation of the STRmix™ software will be covered in the STRmix™ validation document to be issued subsequent to this report.

The PowerPlex® 21 system[4] is a new short tandem repeat (STR) kit made available to the Australian forensic laboratories in early 2012. The kit has all of the nine loci amplified in AmpF*ℓ*STR® Profiler Plus®[5] and the six loci amplified in AmpF*ℓ*STR® COfiler®[6] and an additional seven loci. See Table 1 for kit loci.

Table 1 - Comparison of loci in three different kits

(dye colour indicated by colour text)

PowerPlex® 21 System	AmpFℓSTR® Profiler Plus®	AmpFℓSTR® COfiler®
AMEL	AMEL	AMEL
D3S1358	D3S1358	D3S1358
D1S1656		
D6S1043		
D13S317	D13S317	
Penta E		
D16S539		D16S539
D18S51	D18S51	
D2S1338		
CSF1PO		CSF1PO
Penta D		
TH01		TH01
vWA	vWA	
D21S11	D21S11	
D7S820	D7S820	D7S820
D5S818	D5S818	
TPOX		TPOX
D8S1179	D8S1179	
D12S391		
D19S433		
FGA	FGA	

The scope of this validation is to determine for the PowerPlex® 21 system, the limit of detection (LOD), limit of reporting (LOR), the optimal total PCR amplification volume, the range of DNA template, ensure concordance of the PowerPlex® 21 system against the AmpFℓSTR® Profiler Plus® and COfiler® kits, observe the performance of mixed DNA samples and create population datasets required for statistical calculations. Secondary to this, this validation provides the data necessary for STRmix™ validation.

3 Materials

The following materials were used within this validation:

- BSD Duet 600 Series II (BSD Robotics, Brisbane, QLD,AU)
- STORstar instrument (Process Analysis & Automation, Hampshire, GB)
- MultiPROBE II PLUS HT EX with Gripper Integration Platform (PerkinElmer, Downers Grove, IL, US)
- Sterile conductive filtered Roborack 25µL disposable tips (PerkinElmer, Downers Grove, IL, USA)
- 5804 centrifuge (Eppendorf AG, Hamburg, DE)
- 5424 centrifuge (Eppendorf AG, Hamburg, DE)
- Thermomixer (Eppendorf AG, Hamburg, DE)

- MixMate (Eppendorf AG, Hamburg, DE)
- Vortex (Ratek Instruments Pty Ltd, Melbourne, VIC, AU)
- Micro centrifuge (Tomy, Tokyo, JP)
- 1.5 mL screw-cap tubes (Axygen Inc. Union City, CA, US)
- Pipettes (Eppendorf, Hamburg, DE and Thermo Fisher Scientific(Finnpipette), Waltham, MA, US)
- Pipette tips (VWR International LLC Radnor, PA, US and Molecular Bioproducts Inc., San Diego, CA, US)
- 96-well PCR plates(Axygen Inc. Union City, CA, US)
- 2.0 mL sterile screw-cap tubes (Axygen Inc. Union City, CA, US)
- Plate septas (Axygen Inc. Union City, CA, US)
- Adhesive film (QIAGEN, Hilden, DE)
- FTA™ collection kits (Whatman™ GE Healthcare, Buckinghamshire, GB)
- Positive controls (DNA Analysis Unit, Brisbane, QLD, AU)
- TNE (DNA Analysis Unit, Brisbane, QLD, AU)
- Proteinase K (20 mg/mL) (Sigma-Aldrich® Corporation, St Louis, MO, US)
- Dithiothreitol (Sigma-Aldrich® Corporation, St Louis, MO, US)
- Trigene (Medichem International, Kent, GB)
- Ethanol (Recochem Incorporated, Wynnum, QLD,AU)
- Bleach (Ionics Australasia Pty Ltd., Lytton, QLD, AU)
- Amphyl (Rickitt Benckiser Inc. Parsippany, NJ, US)
- Sarcosyl (Sigma-Aldrich® Corporation, St Louis, MO, US)
- Nanopure water (DNA Analysis Unit, Brisbane, QLD, AU)
- Quantifiler™ Human DNA Quantification kits (Life Technologies Applied Biosystems, Foster City, CA, US)
- AB 7500 Real Time PCR System (Life Technologies Applied Biosystems, Foster City, CA, US)
- GeneAmp® PCR system 9700 (Life Technologies Applied Biosystems, Foster City, CA, US)
- ABI 3130*xl* Genetic Analyzer (Life Technologies Applied Biosystems, Foster City, CA, US)
- Hi-Di™ Formamide (Life Technologies Applied Biosystems, Foster City, CA, US)
- 3130 POP-4™ Polymer (Life Technologies Applied Biosystems, Foster City, CA, US)
- Running Buffer (Life Technologies Applied Biosystems, Foster City, CA, US)

- DNA IQ™ Casework Pro Kit for Maxwell® 16 (Promega Corp., Madison, WI, US)
- Promega PowerPlex® 21 system (Promega Corp., Madison, WI, US)
- Promega CC5 Internal Lane Standard 500 (Promega Corp., Madison, WI, US)
- Promega PowerPlex 5 Dye Matrix Standard (Promega Corp., Madison, WI, US)
- Promega PowerPlex® 21 Allelic Ladder Mix (Promega Corp., Madison, WI, US)
- 2800M Control DNA, 10ng/µl (Promega Corp., Madison, WI, US)
- Water, Amplification Grade (Promega Corp., Madison, WI, US)

4 Methods

4.1 Sample Selection

All samples used in this validation were sourced from the internal DNA Analysis staff DNA database, Collaborative Testing Services (CTS) DNA testing samples, or reference samples that had the National Criminal Investigation DNA Database (NCIDD) categories of Volunteer Unlimited Purpose (VUP) or Suspect (SCT). Permission to use reference samples from NCIDD was obtained from the Queensland Police Service (QPS).

4.2 Selection of Sub-Population Samples

4.2.1 Aboriginal and Torres Strait Islanders Sub-Populations

Aboriginal samples:

Aboriginal samples previously profiled as part of the sub-population dataset for the validation of AmpF*ℓ*STR® Profiler Plus® loci were recommended as the best samples to use for compilation of the Aboriginal sub-population dataset for the Promega PowerPlex®21 system. The samples are self-declared Aboriginal ethnicity and were collected over a number of years.

220 Aboriginal samples were randomly selected from the Aboriginal dataset (545 total) previously profiled with AmpF*ℓ*STR® Profiler Plus®. Microsoft Excel RANDBETWEEN function was used and duplicates removed until 220 unique samples were identified for profiling.

These 220 samples were originally extracted using Chelex. The extracts for the 220 samples were viewed for sufficient volume. 201 samples with sufficient volume were identified and given new population dataset barcodes.

Torres Straits Islander samples:

A list of FTA™ samples previously profiled with AmpF*l*STR® Profiler Plus® resulting in a full profile and identified as self-declared Torres Strait Islander ethnicity in AUSLAB were compiled to be used for the Aboriginal sub population dataset.

599 samples were listed and after further filtering, including removing duplicates, 249 Torres Strait Islander samples remained. Of the 249 Torres Strait Islander samples listed 223 samples were randomly selected for processing. Samples were given new population dataset barcodes

4.2.2 Caucasian Sub-Population

A list of FTA™ samples previously profiled with AmpF*l*STR® Profiler Plus® resulting in a full profile and identified as Caucasian ethnicity in AUSLAB were compiled to be used for the Caucasian sub-population dataset.

From this list 210 samples were selected and 208 were selected for processing as two were deemed unsuitable. Samples were given new population database barcodes.

4.2.3 South East Asian Sub-Population

A list of FTA™ samples previously profiled with AmpF*l*STR® Profiler Plus® resulting in a full profile and identified as South East Asian ethnicity in AUSLAB were compiled to be used for the South East Asian population dataset.

157 samples were listed and after further filtering 141 South East Asian samples remained. These 141 samples were given new population database barcodes.

4.3 Collection Procedure for FTA™ Cards

Where staff samples were entirely consumed during processing, additional samples were collected. New FTA™ samples were collected using FTA™ Collection kits. A foam swab was used to collect buccal cells from each cheek for one minute then applied to the FTA™ card[7]. The FTA™ card was stored at room temperature until required.

4.4 FTA™ Punching Method

1. PCR Amplification mix was created as required.
2. 25 µL (full) or 12.5 µL (half) of PCR amplification mix was added to a clean 0.2 mL 96 well PCR plate.
3. Plate was sealed and centrifuged to ensure PCR amplification mix was at the bottom of the wells.

4. Each FTA™ sample was punched with the 1.2 mm diameter die into the 96 well PCR plate using the BSD Duet 600 Series II.
5. 1 µL of 2800M Control DNA was added to the Positive control well.
6. 1 x 1.2 mm punch of a blank FTA™ card was added to the blank control well
7. Amplification mix without FTA™ card was used as a negative control.
8. The plate was sealed and centrifuged briefly to pull the FTA™ cards to the bottom of the plate wells.

4.5 FTA® Punching Method 2

1. 7.5 µL of Water, Amplification Grade was added to the required wells.
2. Plate was sealed and centrifuged to ensure the water was at the bottom of the wells.
3. Each FTA® sample was punched with the 1.2 mm diameter die into the 96 well PCR plate using the BSD Duet 600 Series II.
4. 1 µL of 2800M Control DNA was added to the Positive control well.
5. 1 x 1.2 mm punch of a blank FTA® card was added to the blank control well
6. PCR Amplification mix without FTA® card was used as a negative control.
7. PCR Amplification mix was created as required and 5 µL added to each well.
8. The plate was sealed and centrifuged briefly to pull the FTA® cards to the bottom of the plate wells.

4.6 Punching for Extraction

FTA™ samples were prepared for extraction by punching four paper spots of 3.2 mm diameter into 1.5 mL/2 mL tubes using the BSD Duet 600 according to standard operating procedure 24823 V4.0 "FTA™ Processing and Work Instructions".

4.7 Extraction

FTA™ samples requiring DNA extraction were processed using the DNA IQ™ Casework Pro Kit for Maxwell®16 according to standard operating procedure 29344 V4.0 "DNA IQ™ Extraction using the Maxwell®16".

4.8 Preparation of DNA Stock Solutions

Samples used to make dilution series required a stock solution to be prepared. FTA™ samples were selected and punched in duplicate for

extraction (as outlined in section 4.6) then extracted (as outlined in section 4.7). The duplicate samples were pooled into a single tube and quantified twice (as outlined in section 4.9).

4.9 Procedure for Creating a Dilution Series

The samples used to make dilution series were diluted with Water, Amplification Grade provided with the Promega PowerPlex®21 System. Spreadsheets for calculating the normalisation and dilution series were written to outline the serial dilutions required to obtain the specified concentrations

4.10 Quantification

All preparations of reactions were performed using MultiPROBE II plus HT EX platform according to standard operating procedure 19977 V8.0 "Automated Quantification of Extracted DNA using the Quantifiler™ Human DNA Quantitation Kit".

4.11 Amplification Set up

For the experiments that used extracted DNA, all amplification reactions were performed using a MultiPROBE II plus HT EX platform. A new protocol called PowerPlex® 21 amp setup v1.0 was created using WinPrep® software and utilised for amplifications at 25 µL and 12.5 µL total PCR volumes. The protocol is saved and stored on the C drive of the MultiPROBE II plus HT EX platform computer. Table 2 outlines the components of the amplification mix per sample.

Table 2 - Amplification mix per sample.

Kit components	Volumes (µL)	Volumes (µL)
PowerPlex® 21 5x Master Mix	5.0	2.5
PowerPlex® 21 5x Primer Pair	5.0	2.5
Sample	15	7.5
Total Volume	25	12.5

4.12 Amplification Conditions

Table 3 lists the PCR cycling conditions used in this validation. All PCR reactions were carried out in 96 well plates (Axygen Inc.) on GeneAmp® 9700 thermal cyclers

Table 3 - PCR cycling conditions used for PowerPlex®21 system

PowerPlex® 21 Kit	Direct amp	Standard
thermal cycler mode	Max	Max
	25,26 or 27 cycles	30 cycles
Activation	96 °C for 1 minute	96 °C for 1 minute
Cycling	94 °C for 10 seconds 59 °C for 1 minute 72 °C for 30 seconds	94 °C for 10 seconds 59 °C for 1 minute 72 °C for 30 seconds
Extension	60 °C for 20 minutes	60 °C for 10 minutes
	4 °C Soak	4 °C Soak

4.13 DNA Fragment Analysis

The plates for DNA fragment analysis were prepared as recommended by the manufacturer, using a combination of Hi-Di™ formamide, size standard and sample as outlined below.

Formamide: size standard mixture composed of

[(2.0 µl CC5 Internal Lane Standard 500) x (number of injections)] + [(10.0 µL Hi-Di™ formamide) x (number of injections)]

Formamide: size standard mixture **12 µL**

PCR product or allelic ladder **1 µL**

The prepared plate was then centrifuged to remove bubbles, denatured at 95 °C for 3 minutes then chilled in an ice block in the freezer for 3 minutes. The prepared plates were then run on a Applied Biosystems 3130*xl* Genetic Analyzer.

The PCR fragments were separated by capillary electrophoresis (CE) using a Applied Biosystems 3130*xl* Genetic Analyzer set up as outlined in Table 4.

Table 4 - CE Protocol conditions.

Injection time	Injection voltage	Run time
5 s	3 kV	1500 s
3 s	3 kV	1500 s

4.14 Profile Interpretation 1

All DNA profiles were analysed with GeneMapper® ID-X v1.1.1. The analysis panel used was PowerPlex_21_IDX_v1.0. The thresholds were set as follows:

1. Heterozygote threshold was set at 40 RFU
2. Limit of Detection (negative controls) was set at 16 RFU
3. Individual locus stutter thresholds were set as per Promega PowerPlex® 21 Stutter filter
4. Homozygote threshold was set to 200 RFU

4.15 Profile Interpretation 2

All DNA profiles were analysed with GeneMapper® ID-X v1.1.1. The analysis panel used was PowerPlex_21_IDX_v1.0. The rules were set as follows:

1. Samples were analysed at 1 RFU.
2. All known alleles, -1 repeat and +1 repeat stutter (+/-4 bp or +/-5 bp) of known alleles, known artefacts and spectral pull-up were removed. As defined by Promega artefact peaks in the N-2 bp and/or N+2 bp position at D1S1656, D6S1043, D13S317, vWA, D21S11, D7S820, D5S818, D12S391 and D18S51 loci and in the N-1 bp position at Amelogenin were also removed.
3. Any peaks determined to be CE carry over peaks were also removed. CE carry-over is defined as the physical transfer of DNA from one injection to the next.

4.16 Profile Interpretation 3

All samples were analysed with GeneMapper ID-X v1.1.1 with the stutter thresholds set to zero. The analysis panel used was PowerPlex_21_IDX_v1.1.

1. Samples were analysed at 20 RFU
2. Loci where the two main alleles were one repeat apart were excluded from analysis.

4.17 Profile Interpretation 4

All samples were analysed with GeneMapper ID-X v1.1.1 with the stutter thresholds set to zero. The analysis panel used was PowerPlex_21_IDX_v1.1.

1. Samples were analysed at 20 RFU
2. -2 repeat stutter peaks were recorded if they were distinct from baseline and not in a pull-up or +1 repeat stutter position.

5 Experimental Design

5.1 Sub-Population Datasets

As part of the national approach to implementation of next generation STR amplification kits, the creation of three national sub-population datasets was undertaken. Each jurisdiction contributed DNA profiles for each sub-population Caucasian, Aboriginal and South East Asian to Jo-Anne Bright (ESR) and John Buckleton (ESR) for analysis.

5.1.1 Aboriginal dataset

In this experiment 201 Aboriginal samples were transferred to appropriate tubes and the DNA concentrations determined as outlined in Method 4.10.

The samples were amplified with the recommended DNA template input of 0.5 ng in a 25 µL total PCR volume. Three plates were amplified using the PowerPlex®21 system kit with each plate including a positive amplification control (2800M Control DNA) and a negative amplification control (Water, Amplification Grade). The three plates were prepared as per Method 4.11.

Standard amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

5.1.2 Torres Strait Islander dataset

In this experiment 223 Torres Strait Islander samples were punched across three 96 well plates as outlined in section 4.4. Each sample had one spot punched, a total PCR volume of 12.5 µL and was directly amplified at 26 PCR cycles.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

5.1.3 Caucasian dataset

In this experiment 208 Caucasian samples were punched across three 96 well plates as outlined in section 4.4. Each sample had two spots punched, a total PCR volume of 25 µL and was directly amplified at 25 PCR cycles.

Caucasian samples that did not produce a full PowerPlex®21 profile were punched again using 2 spots, a total PCR volume of 25 µL and was directly amplified at 26 PCR cycles.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

5.1.4 South East Asian dataset

In this experiment 141 South East Asian samples were punched across two 96 well plates as outlined in section 4.5. Each sample had one spot punched, a total PCR volume of 12.5 µL and was directly amplified at 26 PCR cycles.

South East Asian samples that did not produce a full PowerPlex®21 profile were punched for extraction, extracted, quantified and amplified as outlined in Methods 4.6, 4.7, 4.8 and 4.10.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

5.2 Concordance

155 samples purchased from Collaborative Testing Services (CTS) as external Proficiency Tests were used to test the concordance of the PowerPlex® 21 system. These samples had previously been extracted, quantified and amplified with AmpF*l*STR® Profiler Plus® and AmpF*l*STR® COfiler® kits.

The samples were amplified with the recommended DNA template input of 0.5 ng in a 12.5 µL total PCR volume. Two plates were amplified using the PowerPlex®21 system kit with each plate including a positive amplification control (2800M DNA) and a negative amplification control (amplification grade water). The two plates were prepared as outlined in Method 4.11.

Amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13 and 4.14.

The alleles obtained from these samples were compared with the CTS published alleles. Three loci could not be compared as CTS did not publish results for the D12S391, D1S1656 and D6S1043 loci.

5.3 Baseline Determination

To determine the limit of detection (LOD) and the limit of reporting (LOR), the baseline (background) was assessed.

Ten samples from the Caucasian sub-population dataset that exhibited high heterozygosity were used for baseline determination.

The samples were prepared as Methods 4.6, 4.7, 4.8, 4.9, 4.10, 4.11.

Ten samples diluted in ten steps (10x10) outlined in Table 5 were used for the baseline calculations. Each dilution set was amplified at 25 µL and 12.5 µL total PCR volumes.

50 negative samples were also amplified at 25µL and 12.5µL total PCR volumes.

Table 5 - Total DNA input for each dilution

Dilution	Total DNA (ng)
1	0.500
2	0.447
3	0.394
4	0.342
5	0.289
6	0.236
7	0.183
8	0.131
9	0.078
10	0.025

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.12, 4.13, 4.14 and 4.15.

The average peak height RFU (μ_{Pk}) for each dye channel was calculated using the AVERAGE function (Arithmetic mean) in Microsoft Excel. The standard deviation (σ_{Pk}) was calculated using the STDEV function in Microsoft Excel.

The thresholds were calculated as follows:

The limit of detection (LOD) was calculated from Equation 1[8].

Equation 1

$$\mathbf{LOD = \mu_{PK} + 3\sigma_{PK}}$$

The limit of reporting (LOR) also known as the analytical threshold (AT) was calculated from Equation 2[8].

Equation 2

$$\mathbf{LOR = \mu_{PK} + 10\sigma_{PK}}$$

5.4 Sensitivity 1

This experiment tested the sensitivity of PowerPlex® 21 system at amplification volumes of 25 µL and 12. 5µL for DNA template inputs from 4 ng to 1 pg. These were all processed with a 5 s injection time.

Two staff (one male and one female) with the most heterozygous DNA profile processed with AmpFℓSTR® Profiler Plus® and AmpFℓSTR COfiler® kits were selected for testing[9]. Heterozygous loci provide more information with respect to allele drop out and peak balance.

FTA™ cards were collected, processed, extracted, stock solutions prepared, quantified and dilution series prepared as outlined in Methods 4.6, 4.7, 4.8, 4.9 and 4.10.

Each donor had 9 dilutions prepared as outlined in Table 6. These dilutions were amplified in duplicate with a total amplification volume of 25 µL and 12.5 µL. Each amplification plate included the kit positive control (2800M Control DNA) and a negative control (Water, Amplification Grade).

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.14.

Table 6 - Total DNA input for sensitivity 1

DNA Template Input (ng)
4
2
1
0.5
0.1
0.05
0.01
0.005
0.001

5.5 Sensitivity 2

To assess the differences between the two total PCR volumes with respect to low DNA extract concentrations a second sensitivity experiment was performed.

This experiment tested a dilution series of the same samples used in sensitivity 1 at low DNA templates outlined in Table 7. Each dilution was amplified in duplicate at 25 µL and 12.5 µL. These were all processed with a 5 s injection time.

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.14.

Table 7 - Concentration, DNA template input for each dilution.

Concentration (ng/µL)	Volume of sample added to 25 µL reaction volume	Total DNA template input (ng)	Volume of Sample added to 12.5 µL volume reaction	Total DNA template input (ng)
0.01	15	0.15	7.5	0.075
0.005	15	0.075	7.5	0.0375
0.0025	15	0.0375	7.5	0.01875
0.00125	15	0.01875	7.5	0.009375
0.000625	15	0.009375	7.5	0.004688
0.0003125	15	0.004688	7.5	0.002344
0.00015625	15	0.002344	7.5	0.001172
0.000078125	15	0.001172	7.5	0.000586

5.6 Drop In

50 negative samples were amplified alongside the baseline (10x10) samples at 25 µL and 12.5 µL. Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.15.

The negative samples were analysed at 1 RFU using GeneMapper ID-X v1.1.1 to determine if any peaks above 20 RFU were present. Known artefacts, carry-over and pull-up were removed and not included in the analysis.

5.7 Stutter

To determine the thresholds for -1repeat and +1repeat stutter peaks 342 samples from the Aboriginal data set, baseline samples (10 x10), sensitivity 1 and sensitivity 2 were amplified at 25µL and 255 samples from 155 CTS samples and baseline samples were amplified at 12.5 µL.

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.16.

The stutter ratio (SR) was calculated for each locus as per Equation 3.

Equation 3

$$SR = E_S/E_A$$

SR = Stutter Ratio, E_S = Stutter Height, E_A = Allele Height

The stutter threshold (ST)[4] for each locus was calculated as per Equation 4.

Equation 4

$$ST = \mu_{SR} + 3\,\sigma_{SR}$$

ST = Stutter Threshold, μ_{SR} = average stutter ratio, σ_{SR} = standard deviation of stutter ratio.

The stutter results were also processed with a multiple regression analysis by Jo-Anne Bright for use within the STRmix™ validation and STRmix™ settings[10].

To determine thresholds for -2 repeat stutter peaks, 243 samples (155 CTS and 88 reference samples) were amplified at 12.5 µL and 25 µL. Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.17.

The stutter ratio (SR) was calculated for each locus using Equations 5 & 6, modified versions of Equation 3.

Equation 5

$$SR = E_{S-2}/E_{S-1}$$

SR = Stutter Ratio, E_{S-2} = -2 repeat stutter Height, E_{S-1} = -1 repeat Stutter Height

Equation 6

$$SR = E_{S-2}/E_A$$

SR = Stutter Ratio, E_{S-2} = -2 repeat stutter Height, E_A = Allele Height

The -2 repeat stutter threshold (ST) [4] for each locus was calculated as per Equation 4 from the main allele peak.

5.8 Peak Balance

The samples from the baseline experiment (10 x10 in section 5.3) were used to calculate peak height ratios and an allelic imbalance threshold to be used for reference samples and as a guide for determining the number of contributors to a mixture.

5.8.1 Peak Height Ratio and Allelic imbalance threshold

Peak height ratios for heterozygote loci (1127 alleles for 12.5 µL and 1094 alleles for 25 µL total PCR volumes) were determined by dividing the lower peak height by the higher peak height. Loci where the two main alleles were one repeat apart or were homozygous were excluded from analysis.

The peak height ratio (PHR) was calculated for each locus as per equation 5 [11].

Equation 7

PHR = LPH / HPH

PHR = Peak Height Ratio, LPH = Lower Peak Height, HPH = Higher Peak Height

The average peak heights and standard deviation of peak height ratio were calculated using the Microsoft Excel AVERAGE and STDEV worksheet functions.

The allelic imbalance threshold (AI) was calculated as per Equation 6[12, 13]

Equation 8

$$AI_{TH} = \mu_{PHR} - 3\sigma_{PHR}$$

AI_{TH} = Allelic Imbalance threshold, μ_{PHR}= overall average PHR, σ_{PHR} = standard deviation of the PHR.

5.8.2 Homozygote threshold

The homozygote threshold is the threshold above which you can be confident that a heterozygote locus will not be incorrectly called as a homozygote locus. It was calculated using the following methods

Method 1 – As previously described in the internal validation[14] of peak heights and allelic imbalance thresholds and illustrated below:

Equation 9

$$Th_{Hom} = LOR \times (1 / AI_{TH}) \times 2$$

The LOR used for this calculation is from 5.3 and AI_{TH} was determined in 5.8.2.

Method 2 – As described in the Promega Internal validation guidelines[15] determined from a plot of allelic imbalance versus the lower RFU of a heterozygote pair. The homozygote threshold is assigned at the point at which there is a rapid drop off in peak height ratio.

5.9 Drop Out

To aid in determining the default total PCR volume and template DNA range a series of drop out analyses were performed on the baseline samples (section 5.4), sensitivity experiments (sections 5.3 & 5.5) and population datasets (section 5.2).

5.9.1 Drop out 1

The samples from the sensitivity 1 experiment (section 5.3) were used to determine at what RFU the partner of a heterozygote pair drops out. The data was interpreted as outlined in section 4.13. Homozygote peaks, excess samples and no size data were excluded from data analysis. Heat maps were used to summarise the data.

5.9.2 Drop out 2

Samples processed at 25 µL and 12.5 µL were analysed to determine the threshold when an allele most frequently drops out.

334 DNA profiles amplified at 25 µL (from section 5.1.1, 5.3, 5.4 and 5.5) and 279 DNA profiles amplified at 12.5µL (from section 5.2, 5.3, 5.4 and 5.5) were analysed as outlined in Method 4.13.

Homozygote peaks, excess samples and no size data were excluded from both sets of data.

Data was split between 3 s injection times and 5 s injection times

5.9.3 Drop out 3

The samples from the baseline samples (section 5.4) and sensitivity experiments (section 5.3 & 5.5) experiments (156 samples) were analysed to record the peak height at which a heterozygote paired allele was lost. The data was interpreted as outlined in Method 4.13.

Homozygote peaks, excess samples and no size data were excluded from data analysis.

Data was split between 3 s injection times and 5 s injection times

5.10 Mixture Studies 1

In experiment 4 samples, two female and two male samples with high heterozygosity were selected, from the Caucasian dataset and CTS samples, to be combined to make mixed DNA samples. The samples were created as Methods 4.3, 4.4, 4.6, 4.7 and 4.10.

One female sample was combined with one male profile to create a two person mixture, the same female sample was combined with the two male samples to create a three person mixture and two female samples and two male samples were combined to create a four person mixture. The amount of sample required from each contributor to create the mixture ratio was calculated using excel spreadsheets . Varying contributor ratios were made for each of the mixture combinations as outlined in Table 8. Each mixture combination was amplified in duplicate at a variety of DNA templates.

Amplification, amplification cycling conditions, DNA fragment analysis and profile interpretation was followed as outlined in Methods 4.11, 4.12, 4.13 and 4.16.

Table 8 - Mixture ratios

Mixture Ratio	Template (ng)
Female:Male	
50:1	0.500
	0.250
	0.125
30:1	0.500
20:1	0.500
	0.250
	0.125
10:1	0.500
	0.125
5:1	0.500
	0.125
2:1	0.500
	0.06
1:1	0.500
Female:Male:Male	
20:10:1	0.500
	0.125
10:5:1	0.500
5:2:1	0.500
	0.125
Female:Male:Male:Female	
5:3:2:1	0.500
	0.125

The mixture ratio was calculated for each DNA profile and compared to the admixture ratio to determine whether there is any variability and whether the mixture ratio can be expected to hold across the profile.

The DNA profiles were analysed to determine at what ratio the minor contributor would be expected to drop out.

6 Results and Discussion

6.1 Population Datasets

Results were tabulated in the following format Unique Sample ID, Race ID, Marker, Allele 1 and Allele 2. Table 9 summarises the number of profiles for each sub-population submitted for analysis. The total number refers to the size of the Australian combined sub-population datasets.

Table 9 - Summary of number of profiles for each sub-population submitted.

	Caucasian	Aboriginal	SE Asian
DNA Analysis, FSS	139	309	126
Dataset total	1707	1778	990

Data generated for the three sub-population datasets were analysed by Jo Bright and John Buckleton and used in STRmix™ for statistical analysis[16, 17].

6.2 Concordance

All samples (number of alleles = 4644) tested were found to be concordant to the CTS reported DNA profiles. Table 10 displays the number of times a particular allele was seen at each locus within the laboratory.

Different DNA amplification kits may contain different primers for each locus. Comparison of allele calls (concordance) is required to ensure that each kit gives consistent allele designations, as mismatches or null alleles will affect matching on NCIDD or within a case. The current kits used by the DNA Analysis are AmpFℓSTR® Profiler Plus® and AmpFℓSTR COfiler® DNA amplification kits. Both of these use primers developed by, and manufactured by Life technologies. There are known issues with these kits such as a reverse primer binding mutation at the D8S1179 locus[18], vWA locus[19] and FGA locus[20]. The PowerPlex® 21 kit uses different primer sequences. All alleles tested were found to be concordant. As primer binding mutations and null alleles have been observed within DNA Analysis, any resulting mismatches on NCIDD will need to be retested using PowerPlex® 21.

Table 10 - Observed number of allele concordances

Allele Size	D3S1358	D13S317	Penta E	D16S539	D18S51	D2S1338	CSF1PO	Penta D	TH01	vWA	D21S11	D7S820	D5S818	TPOX	D8s1179	D19S433	FGA
2.2								5									
3.2								2									
5			17					5	1								
6									44					7			
7			32				4	5	75			4	3	4			
8		23	22	4			8	9	42			68	6	133	1		
9		21	10	44			4	48	50			28	13	34	4		
9.3									69								
10		11	25	26	2		69	31	3			80	19	13	11	1	
10.3									1								
11		79	26	83	2		77	45		1		65	91	65	14	6	
11.2																1	
12	1	86	40	78	37		93	51				26	100	11	37	26	
12.2																4	
13	1	48	27	46	30		16	44		3		9	15	1	96	72	
13.2																5	
14	41	20	15	2	38	1	1	8		28			3		71	67	
14.2																9	
15	84		12		42	1		3		43					43	23	
15.2																8	
16	56		13		48	14		1		63					10	5	
16.2																4	
17	67		10		36	46				67					1		
17.2																1	
18	36		6		18	19				57					1		4
18.2																1	
19	4		2		13	33				20							23
20			1		10	28				2							39
20.2																	2
21			2		5	19				2							35
22			2		2	13				1							56
22.2																	3
23					1	20											48
24						13											36
25						22											28
26						8					3						10
27						1					7						4
28											61						
29											47						1
29.2											1						
29.3											1						
30											78						
30.2											10						
31											18						
31.2											22						
32											5						
32.2											25						
33.2											9						
35											2						

6.3 Baseline Determination

The thresholds determined by the baseline experiments are the limit of detection (LOD) and limit of reporting (LOR). The use of thresholds for reporting is essentially a risk assessment[21], if the thresholds are set too low then labelling of artefacts and noise may occur, if set too high then real peaks will not be labelled and information will be lost[1, 11].

Type 1 errors are defined as false labelling of noise peaks. LODs calculated from negative samples may not be optimal for medium-high template samples, as the baseline will differ between positives and negative samples[22].

Type 2 errors are defined as false non-labelling of alleles. If the LOD is set too high, then low level samples may have a heterozygous locus called as a homozygous locus[1, 22-24].

The LOR is the threshold in which a peak can be confidently distinguished from the background fluorescence (baseline). Several methods can be used to determine this threshold.

For the method used here[8] the LOR is derived from the mean baseline plus ten standard deviations (Equation 2).

The LOD is the lowest signal that can be distinguished from the background fluorescence (baseline) and may vary between CE instruments.

Previously in DNA Analysis [14] baseline for the AmpF*l*STR® Profiler Plus® kit was determined using the BatchExtract software v0.16. The LOD was calculated using Equation 1. This approach of using the mean and three standard deviations would account for 99.73% of baseline fluorescence.

The files generated by GeneMapper ID-X v1.1.1 are not compatible with the BatchExtract software without modification. For this validation an equivalent process for measuring the baseline as described by Promega was used with some modifications to the types of samples used. For this validation samples containing DNA were used to determine baseline fluorescence.

Table 11 shows the results determined from the baseline calculations when the samples were amplified at 25 µL. The highest average peak height (5.74 RFU) and the highest standard deviation (3.21) was in the TMR (yellow) channel from run 2 on 3130*xl* A. The TMR (yellow) channel for run 2 on 3130*xl* A also yielded the highest LOD (15.37) and highest LOR (37.84). The LOD was rounded to 16 RFU and the LOR was rounded to 40 RFU and is to be used for all dye channels for samples amplified using a total amplification volume of 25 µL.

Table 11 - Baseline results for amplifications at 25 µL

		3130*xl* A run 1	3130*xl* A run 2	3130*xl* B run 1	3130*xl* B run 2	Overall 3130*xl* A & B run 1 & 2
Fluorescin (Blue)	μ_{PK}	2.33	2.58	1.90	1.68	2.11
	σ_{PK}	1.55	2.05	1.01	0.89	1.52
	LOD	6.99	8.73	4.93	4.36	6.68
	LOR	17.86	23.07	12.01	10.59	17.35
JOE (Green)	μ_{PK}	3.51	3.83	2.25	2.16	2.94
	σ_{PK}	2.34	2.62	1.04	1.29	2.12
	LOD	10.54	11.68	5.37	6.02	9.30
	LOR	26.94	29.99	12.65	15.02	24.14
TMR (Yellow)	μ_{PK}	5.29	5.74	3.33	3.07	4.32
	σ_{PK}	2.73	3.21	1.27	1.66	2.68
	LOD	13.47	15.37	7.15	8.05	12.37
	LOR	**32.55**	**37.84**	**16.06**	**19.66**	**31.16**
CXR (Red)	μ_{PK}	2.22	2.44	2.02	1.78	2.09
	σ_{PK}	1.36	1.54	0.89	1.01	1.35
	LOD	6.29	7.05	4.69	4.81	6.16
	LOR	15.79	17.79	10.93	11.88	15.63
CC5 (Orange)	μ_{PK}	1.76	1.99	1.14	1.36	1.66
	σ_{PK}	1.30	1.80	0.44	1.39	2.44
	LOD	5.68	7.38	2.47	5.52	9.00
	LOR	14.81	19.94	5.58	15.24	26.11
Overall	μ_{PK}	3.41	3.72	2.44	2.22	2.79
	σ_{PK}	2.45	2.80	1.33	1.39	2.29
	LOD	10.76	12.13	6.23	6.40	9.65
	LOR	**27.91**	**31.76**	**15.54**	**16.14**	**25.65**

Table 12 shows the results determined from the baseline calculations when the samples were amplified at 12.5 µL. The highest average peak height (6.06 RFU) was in the TMR (yellow) channel from the run on 3130xl A and the highest standard deviation (4.41) was in the JOE (green) channel from the run on 3130*xl* A. The TMR (yellow) channel for the run on 3130*xl* A yielded the highest LOD (18.50) and the JOE (green) channel yielded the highest LOR (48.60). It was noted on 3130*xl* A the baseline was raised more than expected compared to other baseline runs on the same instrument and baseline runs on 3130*xl* B. This could be due to a prolonged period between spectral calibrations, aging reagents and arrays and was taken into consideration when setting thresholds. With natural variations, the results from run to run and instrument may vary, by using the mean + 10SD for the LOR, although the baseline itself may shift, the LOR will always be greater than the LOD even if baseline is either increased or decreased on any given run. By using an "over all" result, the standard deviation is increased due to the difference in fluorescence between instruments, and this then gets factored into the overall LOR.

The highest overall LOD (15.70) was in the TMR (yellow) channel and was rounded to 16 RFU and the highest overall LOR (42.27) was in the JOE (green) channel and was rounded to 40RFU.

In an effort to eliminate error and confusion a single LOD and LOR value is to be used for both instruments.

Table 12 - Baseline results for amplifications at 12.5 µL

		3130*x*l A 12.5 µL	3130*x*l B 12.5 µL	Overall 3130*x*l A & B 12.5 µL
Fluorescin (Blue)	μ_{PK}	3.10	2.19	2.64
	σ_{PK}	3.66	2.72	2.99
	LOD	14.07	10.36	11.59
	LOR	39.67	29.42	32.49
JOE (Green)	μ_{PK}	4.46	2.69	3.62
	σ_{PK}	4.41	2.86	3.86
	LOD	17.70	11.26	15.22
	LOR	48.60	31.28	42.27
TMR (Yellow)	μ_{PK}	6.06	3.58	4.83
	σ_{PK}	4.15	2.43	3.63
	LOD	18.50	10.88	15.70
	LOR	47.52	27.92	41.08
CXR (Red)	μ_{PK}	2.87	2.10	2.49
	σ_{PK}	2.32	1.28	1.93
	LOD	9.84	5.94	8.27
	LOR	26.11	14.90	21.75
CC5 (Orange)	μ_{PK}	2.38	1.66	2.02
	σ_{PK}	2.31	1.87	2.14
	LOD	9.33	7.26	8.84
	LOR	25.53	20.33	23.40
Overall	μ_{PK}	3.94	2.54	3.32
	σ_{PK}	3.87	2.46	3.30
	LOD	15.56	9.91	13.21
	LOR	42.68	27.10	36.28

μ_{PK} = Average peak height, σ_{PK} = Standard Deviation, LOD = limit of detection, LOR = Limit of Reporting

Additional baseline calculations have been performed since the initial validation was performed [25-28] as critical components of the ABI 3130xl instruments such as the lasers and IAD filters have been replaced. See Table 13 below.

Table 13 – Summary of baseline experiments

Instrument	Description	inj time (s)	μ peak height (RFU)	σ peak height (RFU)	LOD (RFU)	LOR (RFU)	PCR vol (μL)
3130xlA	Original	5	3.41	2.45	11	28	25
3130xlA	Original	5	3.32	3.30	13	36	12.5
3130xlA	Rerun	5	3.72	2.80	12	32	25
3130xlA	Post laser	5	3.34	2.47	11	28	25
3130xlA	Post laser	5	3.89	3.80	15	42	12.5
3130xlB	Original	3	2.44	1.33	6	16	25
3130xlB	Rerun	3	2.22	1.39	6	16	25
3130xlB	Post IAD filter	3	2.23	1.21	6	14	25
3130xlB	Post IAD filter	3	2.49	1.94	8	22	12.5
3130xlB	Injection time change	5	2.96	1.92	9	22	25
3130xlB	Injection time change	5	3.54	3.16	13	35	12.5
3130xlB	Post laser	5	3.78	2.91	12	33	25
3130xlB	Original	3	2.54	2.46	10	27	12.5

Although the results obtained from these experiments vary slightly from the initial validation all have been below the threshold set within this validation report.

6.4 Sensitivity

All PCR amplification kits are optimised for a particular total reaction volume by the manufacturer; but it is commonplace to reduce the total PCR reaction volume to increase the sensitivity[29-32] and reduce processing costs[31]. Two sensitivity experiments were performed, in addition to the baseline experiments.

To contrast and compare the effect of total PCR volume on DNA profiles, the same dilution series were amplified at two different total PCR volumes (25 μL and 12.5 μL) using 30 PCR cycles.

The results for the amplification of the two donors at 25 μL and 12.5 μL are summarised in Table 14 .

Table 14 - Summary of the 2 donors amplified at 25 µL and 12.5 µL (Supplementary data files specified in 10.6.1) $\mu_{Alleles}$ – average number of alleles called, μ_{PH} – the average peak height, Max_{PH}- maximum peak height, Min_{PH} – minimum peak height, μ_{PHR}- average peak height ratio

	Template (ng)	$\mu_{Alleles}$	μ_{PH} (RFU)	Max_{PH} (RFU)	Min_{PH} (RFU)	μ_{PHR} (RFU)
Donor1_25 µL	4	N/A	NAD XS	N/A	N/A	N/A
	2	N/A	XS	N/A	N/A	N/A
	1	42	2512.558	4661	1456	90.47371
	0.5	42	1347.647	2492	172	85.58243
	0.1	42	277.4744	506	119	78.77696
	0.05	41	153.3896	387	48	67.09085
	0.01	17	46.86111	108	20	79.08416
	0.005	6.5	39.57143	78	20.5	0
	0.001	1.5	33.83333	43	27	0
Donor2_25 µL	4	N/A	XS	N/A	N/A	N/A
	2	N/A	XS	N/A	N/A	N/A
	1	42	2790.808	5126	1461	89.18818
	0.5	42	1344.103	2878	431	86.90558
	0.1	42	292.7179	698	88	74.55354
	0.05	41.5	157.3974	479	47	68.58833
	0.01	24.5	69.69271	171	14.25	69.5993
	0.005	5.5	44.95455	75	23	93.58974
	0.001	6	33.61538	55	20	94.84848
Donor1_12.5 µL	4	N/A	NAD XS	N/A	N/A	N/A
	2	N/A	XS	N/A	N/A	N/A
	1	N/A	XS	N/A	N/A	N/A
	0.5	42	3132.963	6719	1590	84.41101
	0.1	42	780.5732	2444	180	74.65676
	0.05	42	346.6667	931	58	68.87677
	0.01	27	91.94737	406	21	49.76132
	0.005	12	48.19643	91.5	20	71.22325
	0.001	4.5	35.8	51	22	88.23529
Donor2_12.5 µL	4	N/A	XS	N/A	N/A	N/A
	2	N/A	XS	N/A	N/A	N/A
	1	N/A	XS	N/A	N/A	N/A
	0.5	42	2878.8	6159	1281	78.28704
	0.1	42	742.7313	1612	140	68.11695
	0.05	42	333.375	892	93	60.88416
	0.01	25	82.33	249	21	59.05469
	0.005	13.5	51.46552	121	21	67.89194
	0.001	0	0	0	0	0

The amplifications at 25 µL total PCR volume with DNA templates of 4 ng and 2 ng for both donors gave excess profiles resulting in the profiles being unable to be interpreted. The results from the excess samples were excluded from the data analysis. The average number of alleles and the average peak height was similar for both donors when processed with an amplification volume of 25 µL.

The amplifications at 12.5 µL with DNA templates of 4 ng, 2 ng, 1 ng and one replicate of the 0.5 ng for both donors gave excess results. The results from the excess samples were excluded from the data analysis. The average number of alleles and average peak height was similar for both donors when processed with an amplification volume of 12.5 µL.

Figure 1 displays the average number of alleles and average peak height ratio obtained for each donor at each template amplified at 25 µL and 12.5 µL.

Figure 2 displays the average peak height and average peak height ratio at each DNA template amplified for 25 µL and 12.5 µL.

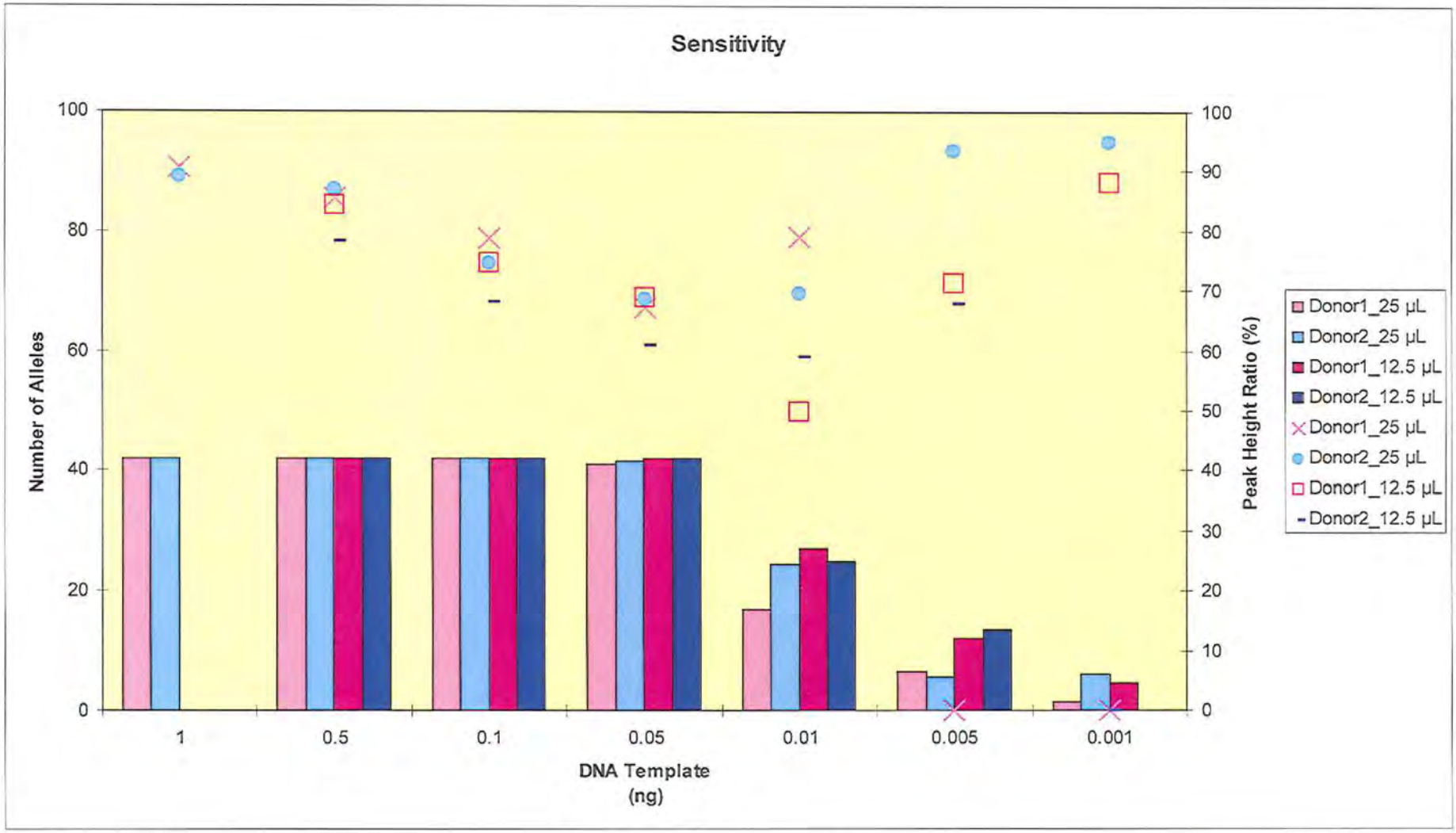


Figure 1 – Sensitivity results. The average number of alleles called (coloured bars) and average peak height ratio (coloured markers) for each donor and total PCR volume used.

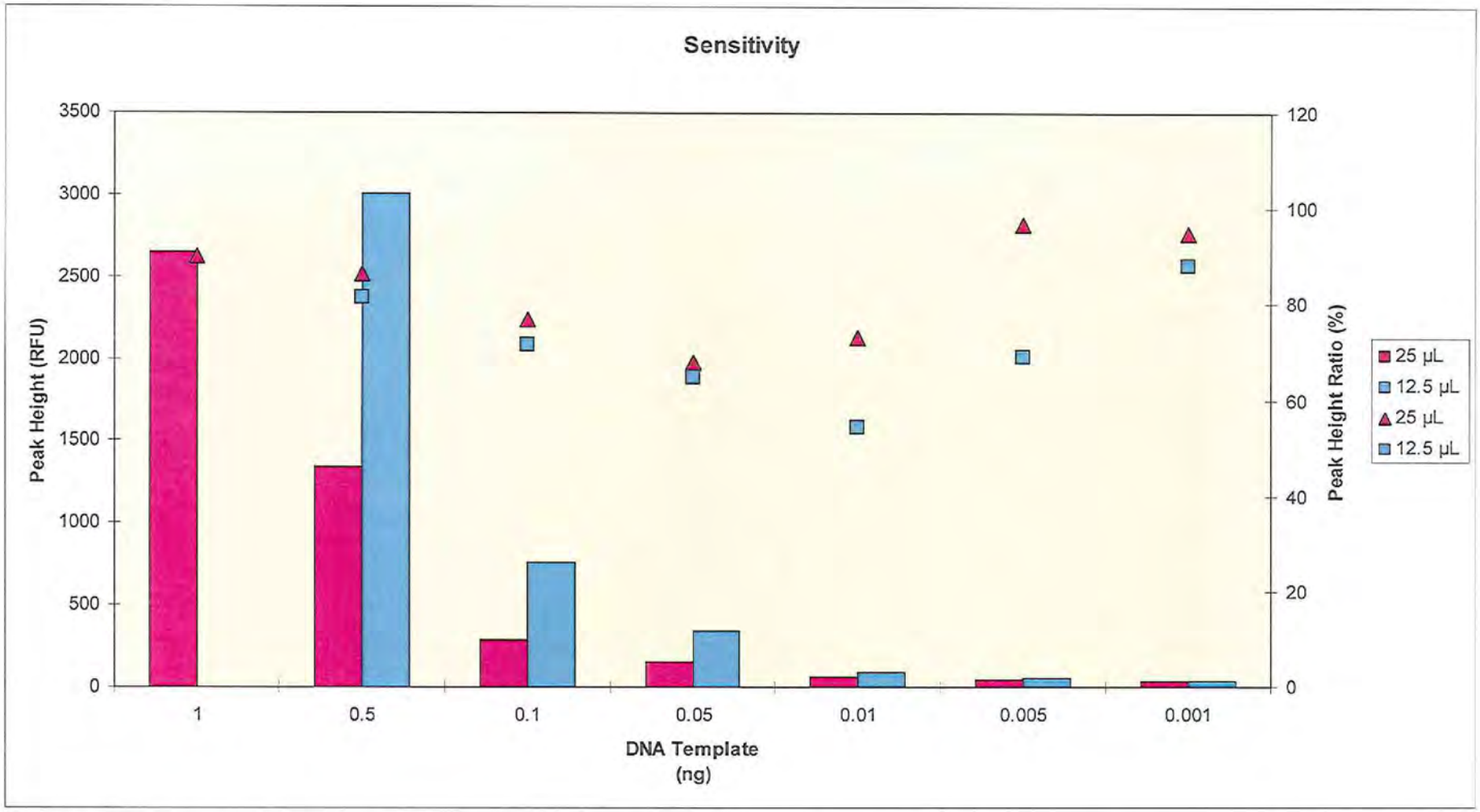


Figure 2 - Sensitivity results. The average peak height (coloured bars) and average peak height ratio (coloured markers) for each total PCR volume used.

A full complement of alleles in the PowerPlex® 21 system was obtained for both donors at total DNA template inputs of 0.5 ng and 0.1 ng when amplified at both total PCR volumes. As expected the average number of alleles decreased as the DNA template decreased.

For both total PCR volumes, as the total DNA template decreased, the peak heights also decreased. The 12.5 µL amplification gave higher peaks heights at the 0.5 ng, 0.1 ng and 50 pg DNA template inputs compared with the 25 µL amplification.

The average peak height ratio decreased as the DNA template decreased to 50 pg. Below a DNA template of 50 pg less heterozygote pairs were observed (as expected) which resulted in the peak height ratio becoming more variable and drop out being observed.

The samples from the baseline experiment ranged from template inputs of 0.5 ng to 0.025 ng. The results of these experiments are concordant with the first sensitivity experiment.

A full complement of alleles in the PowerPlex® 21 system was obtained for all samples between 0.5 ng and 0.132 ng DNA template inputs when amplified at both total PCR volumes.

The second sensitivity experiment was undertaken to enable direct comparison of the sample concentration when amplified at a total PCR volume of 25 µL and 12.5 µL rather than comparing the total DNA template input.

Figure 3 shows the results of low concentration samples amplified at 25 µL and 12.5 µL total PCR volumes with the vertical red line highlighting the limit of detection[33] (quantification) used for the AB 7500 Real Time PCR system. The numbers of alleles obtained at each concentration were counted using the LOR thresholds determined in section 6.4.

The DNA profiles exhibited increased allelic imbalance across different loci when the sample concentration dropped below 0.025 ng/µL.

Overall the PowerPlex®21 system is a very sensitive STR amplification kit capable of detecting DNA amounts below what is generally considered low copy number (LCN). The data analyses indicate that the risk of type 2 errors will increase if the DNA template is too low for both total PCR volumes.

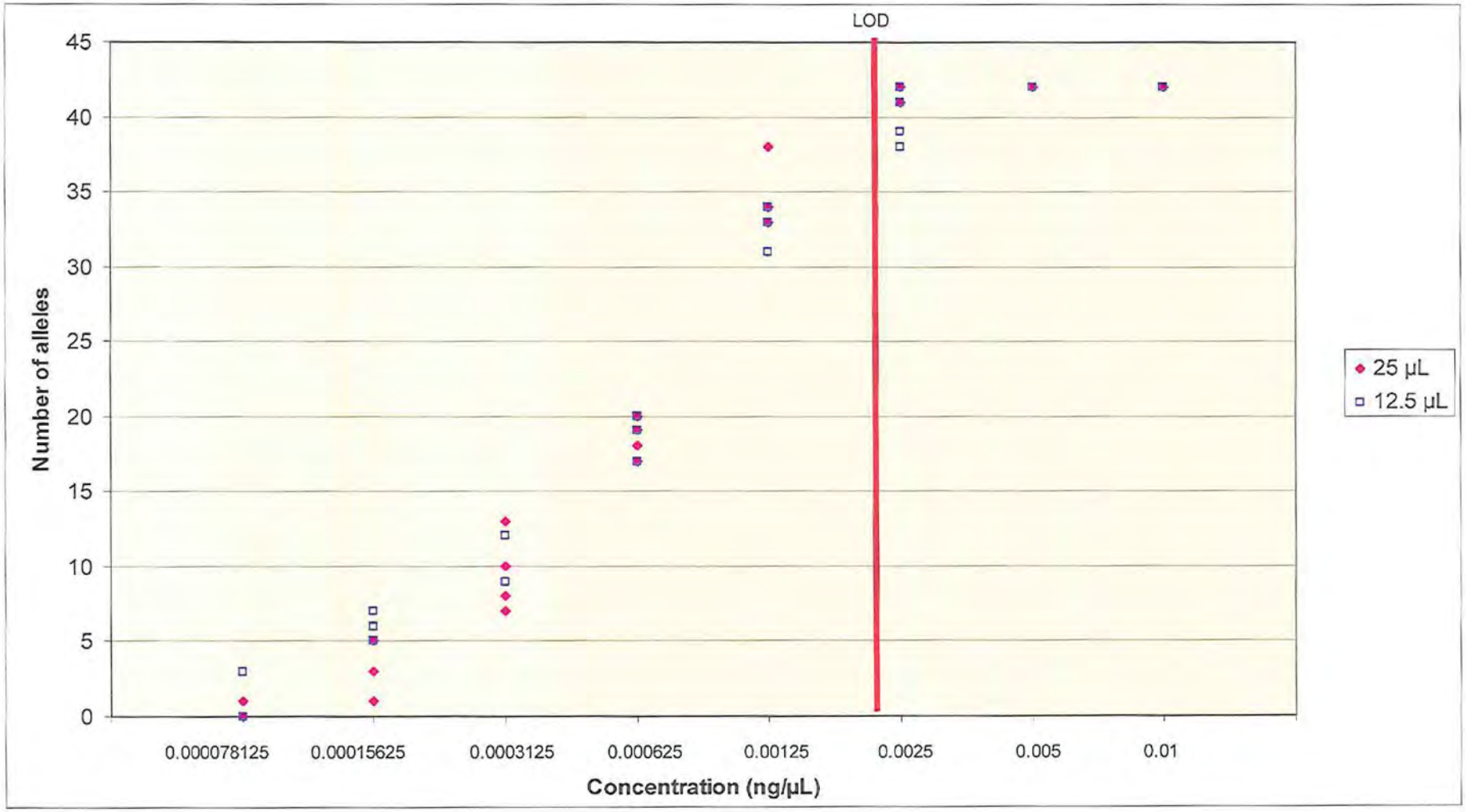


Figure 3 - Comparison of sample concentration vs allele count for 25 µL and 12.5 µL total PCR volumes. Please note the scale on the x axis is not linear.

6.5 Drop In

Allelic drop-in is due to spurious amplification products from unknown DNA, which makes allele drop-in a random event[34, 35]. The phenomenon of allelic drop-in is usually not reproducible and can be detected through testing samples multiple times[36].

For the 25 µL amplifications processed on both 3130xl instruments 3 drop in events were noted. True drop-in alleles were seen in three negative controls at D16S539 as a 7 allele at 21 RFU, D3S1358 as a 21 allele at 19 RFU and at TH01 as a 5 allele at 19 RFU.

For 12.5 µL amplifications on both 3130xl instruments no drop in events were noted.

Drop in data was sent to John Buckleton for fit to a Poisson distribution and tested. This data is required for STRmix™ validation and STRmix™ settings.

The rate of drop in events for 25µL volume amplifications (3 events in 1050 alleles above 15RFU) was calculated for STRmix™ by John Buckleton, see Figure 4.

STRmix™ uses the model for drop-in ae-bx where the values for a and b are the drop-in parameters in STRmix™. John Buckleton's calculations determined that a=b=0.393. The maximum drop-in seen at any one locus is determined in RFU; this means that if two peaks were seen at one locus the drop-in would be the total height of both peaks. Since only one drop-in peak was observed at any one locus and the highest of these events was 21 RFU, then our drop-in setting for STRmix™ would be 21 RFU. Since our LOR was determined to be 40 RFU, it seemed reasonable to set the drop-in level to 40 RFU.

Although no drop-in events were observed for half volume amplifications, the same parameters will be applied.

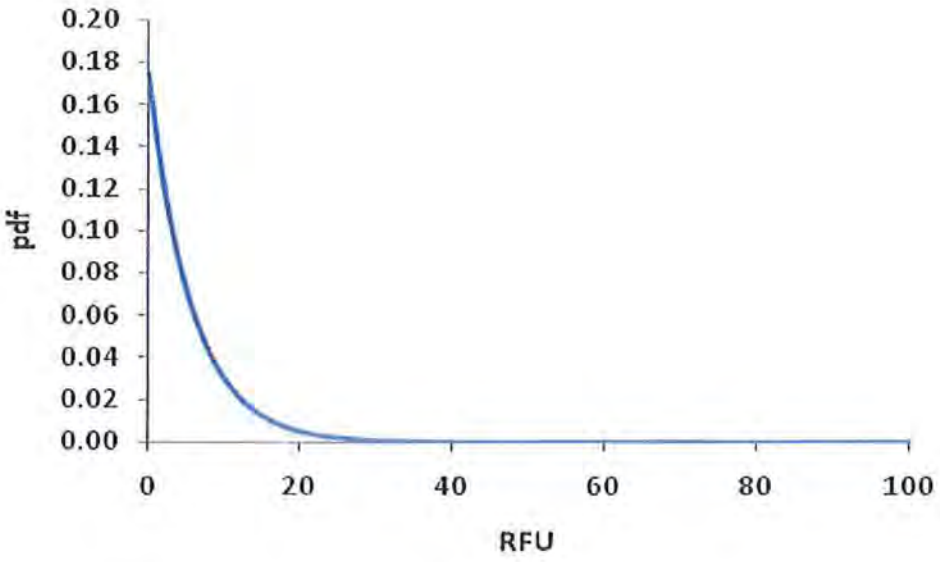


Figure 4 - Probability of Drop in for 25 µL total PCR volume.

6.6 Stutter

Stutter peaks are Polymerase Chain Reaction (PCR) artefacts commonly observed in all STR analysis[4, 37]. They are usually observed as a peak one repeat unit smaller (designated -1 repeat stutter or stutter) in size than the true allele peak [37, 38]. The slipped strand mispairing (SSM) model accounts for stutter formation via the looping out of either the template strand or the extending strand [38-40].

+1 repeat stutter (forward/over stutter) is observed as a peak one repeat unit more in size than the true allele [41, 42]. Figure 5 shows an example of -1 repeat stutter and +1 repeat stutter.

-2 repeat stutter (double back stutter) peaks are observed as a peak two repeat units less than the true allele [38, 41]. Figure 6 shows an example of -2 repeat stutter.

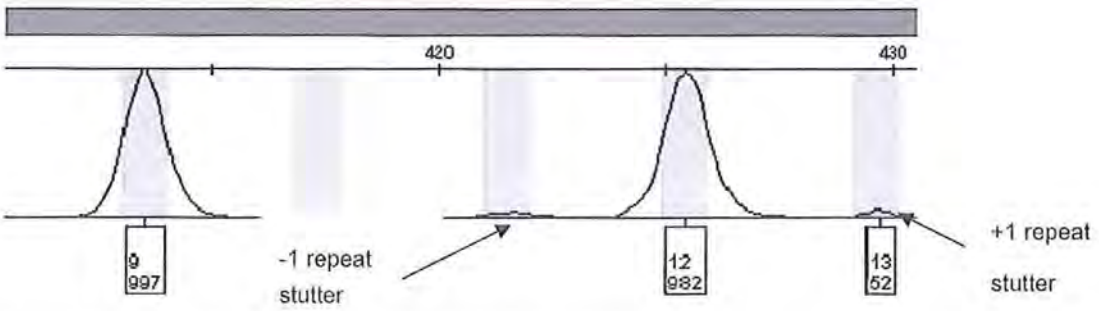


Figure 5 - Example of -1 repeat stutter and +1 repeat stutter.

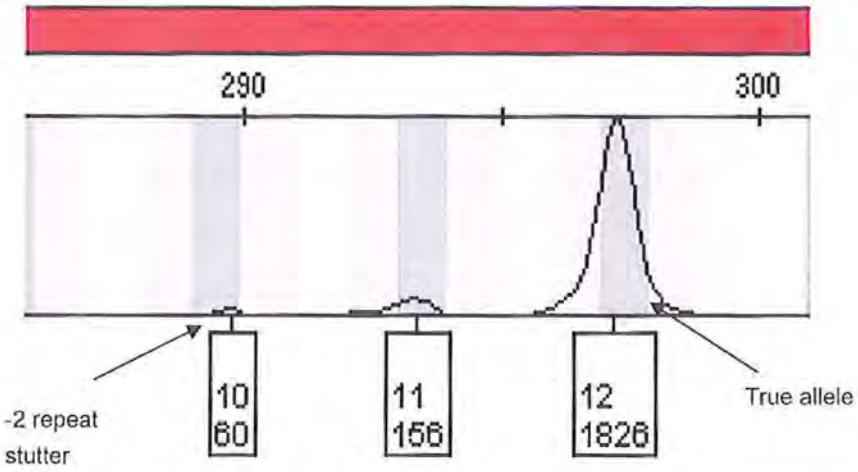


Figure 6 - Example of a -2 repeat stutter peak

The amount of stutter product formation is related to many different external factors including the type of repeat motif, the processivity of the DNA polymerase, template level and whether the allele contains interrupted repeats [38, 40, 42-44]

As evidenced by the results in Table 15 and Table 16, a different amount of stutter product formation is observed at different loci.

Promega supplied a stutter text file (using $\mu + 3\sigma$[4]) for GeneMapper ID-X v.1.1.1. We have used the same calculation as it incorporates 99.73% of the data assuming normal distribution.

The data for the observed stutter ratios (-1 repeat, +1 repeat and -2 repeat) for samples amplified at 25 µL and 12.5 µL are listed in Table 15 and Table 16 respectively.

+1 repeat stutter was observed for all loci when amplified at 25 µL and therefore a threshold was able to be calculated for each locus.

+1 repeat stutter was not observed for all loci when amplified at 12.5 µL and therefore a threshold was only able to be calculated for those loci at which +1 repeat stutter was observed. +1 repeat stutter will be continued to be monitored until enough data is obtained to review the thresholds set in this validation.

-2 repeat stutter was not observed for all loci when amplified at 12.5 µL and 25 µL, therefore a threshold was only able to be calculated at loci where at least two -2 repeat stutter peaks were observed. -2 repeat stutter will continue to be monitored until enough data is obtained to review the threshold set.

Most calculated -1 stutter thresholds were higher than the Promega supplied stutter filter file both for 25 µL and 12.5 µL as shown in Tables 15 and 16. The exceptions were D6S1043, D18D51, D2S1338, and Penta D for 25 µL and D6S1043, Penta E, D18D51, D2S1338, and Penta D for 12.5 uL.

When comparing the calculated stutter thresholds for the 25 µL and 12.5 µL total PCR volumes, they appear to be similar

Table 15 – 25 µL Calculated stutter thresholds.

Locus	n_{SR-2} repeat	μ_{SR-2} repeat	σ_{SR-2} repeat	-2 repeat Stutter Ratio (%)	n_{SR-1} repeat	μ_{SR-1} repeat	σ_{SR-1} repeat	-1 repeat Stutter Ratio (%)	n_{SR+1} repeat	μ_{SR+1} repeat	σ_{SR+1} repeat	+1 repeat stutter Ratio (%)
D3S1358	147	0.0095	0.0045	2.3	310	0.0868	0.0184	14.2	60	0.0131	0.0100	4.3
D1S1656	132	0.0125	0.0102	4.3	371	0.0910	0.0269	17.2	128	0.0183	0.0163	6.7
D6S1043	33	0.0097	0.0056	2.7	366	0.0685	0.0171	12.0	84	0.0164	0.0192	7.4
D13S317	14	0.0115	0.0076	3.4	200	0.0496	0.0228	11.8	39	0.0185	0.0184	7.4
Penta E	4	0.0165	0.0016	2.1	184	0.0457	0.0203	10.7	2	0.0113	0.0018	1.7
D16S539	108	0.0088	0.0040	2.1	270	0.0686	0.0173	12.1	118	0.0133	0.0099	4.3
D18S51	133	0.0103	0.0058	2.8	422	0.0873	0.0244	16.0	119	0.0144	0.0116	4.9
D2S1338	106	0.0114	0.0058	2.9	372	0.0878	0.0203	14.9	12	0.0196	0.0150	6.5
CSF1PO	29	0.0127	0.0080	3.7	190	0.0640	0.0244	13.7	54	0.0155	0.0096	4.4
Penta D	0	0.000	N/A	N/A	86	0.0245	0.0190	8.2	8	0.0306	0.0193	8.8
TH01	39	0.0087	0.0057	2.6	243	0.0325	0.0181	8.7	22	0.0085	0.0041	2.1
vWA	54	0.0116	0.0077	3.5	278	0.0782	0.0246	15.2	52	0.0157	0.0135	5.6
D21S11	58	0.0130	0.0091	4.0	322	0.0809	0.0199	14.1	120	0.0175	0.0177	7.1
D7S820	15	0.0102	0.0078	3.4	252	0.0485	0.0218	11.4	60	0.0207	0.0124	5.8
D5S818	20	0.0116	0.0039	2.3	214	0.0595	0.0202	12.0	51	0.0165	0.0132	5.6
TPOX	2	0.0096	0.0057	2.7	164	0.0381	0.0174	9.0	4	0.0235	0.0130	6.3
D8S1179	54	0.0116	0.0048	2.6	315	0.0790	0.0177	13.2	62	0.0176	0.0123	5.5
D12S391	146	0.0111	0.0056	2.8	376	0.0948	0.0311	18.8	45	0.0146	0.0128	5.3
D19S433	32	0.0101	0.0074	3.2	210	0.0666	0.0205	12.8	8	0.0211	0.0165	7.1
FGA	48	0.0116	0.0066	3.1	280	0.0702	0.0227	13.8	40	0.0182	0.0135	5.9

Stutter thresholds higher than the recommended stutter thresholds from Promega =

μ_{SR} = mean stutter ratio, σ_{SR} = standard deviation of stutter ratio, μ_{OSR} = mean over stutter ratio, σ_{OSR} = standard deviation of over stutter ratio

Table 16 - 12.5 µL Calculated stutter thresholds.

Locus		$\mu_{SR\ -2}$ repeat	$\sigma_{SR\ -2}$ repeat	-2 repeat Stutter Ratio (%)		$\mu_{SR\ -1}$ repeat	$\sigma_{SR\ -1}$ repeat	-1 repeat Stutter Ratio (%)		$\mu_{SR\ +1}$ repeat	$\sigma_{SR\ +1}$ repeat	+1 repeat stutter Ratio (%)
D3S1358	109	0.0113	0.0042	2.4	265	0.0880	0.0194	14.6	31	0.0113	0.0067	3.2
D1S1656	115	0.0102	0.0035	2.1	348	0.0909	0.0247	16.5	83	0.0138	0.0055	3.0
D6S1043	60	0.0073	0.0027	1.5	289	0.0738	0.0153	12.0	48	0.0141	0.0088	4.0
D13S317	20	0.0096	0.0047	2.4	172	0.0544	0.0197	11.3	11	0.0148	0.0070	3.6
Penta E	2	0.0103	0.0039	2.2	152	0.0389	0.0141	8.1	5	0.0289	0.0111	6.2
D16S539	23	0.0091	0.0061	2.8	238	0.0690	0.0195	12.8	40	0.0120	0.0049	2.7
D18S51	76	0.0117	0.0044	2.5	338	0.0827	0.0258	16.0	60	0.0167	0.0125	5.4
D2S1338	67	0.0105	0.0044	2.4	310	0.0909	0.0218	15.6	5	0.0298	0.0241	10.2
CSF1PO	49	0.0077	0.0072	2.9		0.0721	0.0258	14.9	41	0.0145	0.0071	3.6
Penta D	0	N/A	N/A	N/A	32	0.0262	0.0093	5.4	2	0.0324	0.0005	3.4
TH01	3	0.0075	0.0027	1.6	176	0.0252	0.0120	6.1	1	N/A	0.0000	N/A
vWA	18	0.0079	0.0037	1.9	222	0.0836	0.0212	14.7	11	0.0149	0.0097	4.4
D21S11	77	0.0088	0.0048	2.3	302	0.0839	0.0199	14.4	43	0.0256	0.0132	6.5
D7S820	21	0.0071	0.0022	1.4	179	0.0508	0.0232	12.0	6	0.0250	0.0108	5.7
D5S818	15	0.0090	0.0029	1.8	199	0.0675	0.0230	13.7	15	0.0163	0.0139	5.8
TPOX	1	N/A	N/A	N/A	169	0.0346	0.0179	8.8	1	N/A	0.0000	N/A
D8S1179	25	0.0095	0.0039	2.1	213	0.0818	0.0208	14.4	22	0.0173	0.0125	5.5
D12S391	156	0.0118	0.0058	2.9	382	0.1026	0.0313	19.6	16	0.0135	0.0083	3.8
D19S433	70	0.0083	0.0059	2.6	236	0.0689	0.0185	12.4		0.0129	0.0032	2.2
FGA	119	0.0087	0.0031	1.8	279	0.0700	0.0218	13.5		0.0192	0.0223	8.6

Stutter thresholds higher than the recommended stutter thresholds from Promega = ▭

μ_{SR} = mean stutter ratio, σ_{SR} = standard deviation of stutter ratio, μ_{OSR} = mean over stutter ratio, σ_{OSR} = standard deviation of over stutter ratio

6.7 Peak Balance

6.7.1 Peak Height Ratio and Allelic Imbalance Threshold

Peak height ratio (PHR) is the ratio between the two peaks in a heterozygous pair. Under optimal conditions the amplification of a pair of alleles should result in equal peak heights however, input DNA, inhibitors and quality of DNA will affect the amplification [45, 46].

The method used in Equation 4 is recommended in the SWGDAM guidelines [11]and well represented in the literature [44], although other methods have been published by Kelly et al [47].

By assigning a threshold of the mean minus three standard deviations, this incorporates 99.73% of the data, resulting in a conservative threshold. This threshold was rounded up to the nearest RFU. Use of this method to produce a threshold is a low risk to reference samples, as samples that deviate would be reprocessed.

Table 17 - Table 20 show the summary of PHR and AI_{Th} data calculated. The overall average PHR for 12.5µL- 5 s injection and 25 µL- 5 s injection total PCR volumes are 78.9% and 80.4% respectively. These values are consistent with other kits listed in the literature [12, 48]. Although the average peak height ratios are similar to those reported in the literature; given the wide standard deviation observed in our data, the calculated AI_{Th} of 31.4% for 12.5 µL (5 s injection) and 38.6% for 25 µL (5 s injection) reaction volumes are considered low.

The observed data for 3 s injection times are consistent with the 5 s injection times but slightly higher. The overall average PHR for 12.5 µL- 3s injection and 25 µL- 3 s injection total PCR volumes are 80.9% and 81.3% respectively; the calculated AI_{Th} are 39.8% and 41.5%.respectively .The differences in data is likely due to drop out of loci as the 3 s injection times have lower peak RFU.

Figure 7 - Figure 10 display the data obtained from the baseline experiments for 25 µL and 12.5 µL total PCR volumes and their respective injection times. For both total PCR volumes and both injection times, as the amount of DNA input is decreased from the recommended 0.5 ng template DNA, the average peak height ratio (μ_{PHR}) decreases and the standard deviation of the peak height ratio (σ_{PHR}) increases.

When the mean PHR are calculated for each DNA template, between 0.183 ng and 0.5 ng inputs there is no significant difference between total PCR volumes although the standard deviation is higher for the 12.5 µL total PCR volume, resulting in a much lower threshold. Refer to Tables 17 -20.

Figure 15 - Figure 33- The n of allele pairs per 0.1 PHR bin for 0.5025 ng 5 s inj. Figure 34 - The n of allele pairs per 0.1 PHR bin for 0.5025 ng 3 s inj. show observed PHR for different template DNA amounts. The PHR range is separated into 0.1 increments plotted against number of allele

pairs. Figure 15 - The n of allele pairs per 0.1 PHR bin for 0.02475 ng 5 s inj. Figure 16 - The n of allele pairs per 0.1 PHR bin for 0.02475ng 3 s inj.and Figure 15 - The n of allele pairs per 0.1 PHR bin for 0.02475 ng 5 s inj. Figure 16 - The n of allele pairs per 0.1 PHR bin for 0.02475ng 3 s inj. are the lowest template DNA amounts. This shows that at the low template DNA range, the PHR varies unpredictably for both the 25 µL (5 s inj) and 12.5 µL(5 s inj) total PCR volumes. The results for the both the 25 µL (3 s inj) and 12.5 µL(3 s inj) total PCR volumes show marked allelic drop out. As the template DNA amount increases, the PHR converges towards the ideal of 1.0.

The $\mu_{PHR\_25\_5s}$ at 25 pg input was 0.736 and at 0.5 ng input was 0.851 compared with the $\mu_{PHR\_12.5\_5\,s}$, at 25 pg input was 0.598 and at 0.5 ng was 0.832.

The $\mu_{PHR\_25\_3\,s}$ at 25 pg input was 0.971 and at 0.5 ng input was 0.842 compared with the $\mu_{PHR\_12.5\_3\,s}$, at 25 pg input was 0.735 and at 0.5 ng was 0.840. The high $\mu_{PHR\_25\_3\,s}$ at 25 pg is attributed to the extremely small sample size of 2 samples. This small sample size is too small to be reflective of the true result.

The results of our validation are consistent with previous published findings referring to low template DNA and reduced volume amplifications [13, 45, 49].

Stochastic effects were obvious in this experiment in data from templates below 0.132 ng. Stochastic effects are the result of random, uneven amplification of heterozygous allele pairs from low template samples (SWGDAM 2010 interpretation) which is displayed by low peak heights or allele/locus dropout. At 0.132 ng DNA template is approaching what is usually defined as low copy number (LCN) (~0.100 ng to 0.150 ng).

Supportive experimental data is displayed in & AI_{TH} vs input graph, which displays a rapid drop off the AI_{TH} after 0.132 ng DNA template. The calculated AI_{TH} drops below 0 for 0.02475 ng DNA template because the standard deviation is so large. The rapid drop off is likely to increase the number of type 2 errors if AI_{TH} is used calculated from the entire dataset due to the large standard deviation. Exclusion of data from templates below 0.132 ng increases the μ_{PHR} and decreases σ_{PHR}.

A multiple regression analysis was performed by Jo-Anne Bright, Duncan Taylor and John Buckleton to calculate the peak height variance for use in STRmix™[50].

The peak height ratios calculated here are for use with reference samples that have been amplified from extracted DNA and as a guideline to help determine the number of contributors for mixture interpretation as required for STRmix™ analysis.

Table 17- 25 µL 3 s inj summary

	25 µL 3 s inj All	25 µL 3 s inj 132 pg +	25 µL 3 s inj 183 pg +
µ	0.8125	0.8169	0.8213
σ	0.1325	0.1297	0.1292
AI_{Th}	41.49%	42.78%	43.38%
Th_{Hom}	193	187	184

Table 18 -25 µL 5 s inj summary

	25 µL 5 s inj All	25 µL 5 s inj 132 pg+	25 µL 5 s inj 183 pg+
µ	0.8042	0.8230	0.8298
σ	0.1393	0.1228	0.1194
AI_{Th}	38.63%	45.46%	47.17%
Th_{Hom}	207	176	170

Table 19-12.5 µL 3 s inj summary

	12.5 µL 3 s inj All	12.5 µL 3 s inj 132 pg+	12.5 µL 3 s inj 183 pg+
µ	0.8086	0.8171	0.8283
σ	0.1368	0.1291	0.1190
AI_{Th}	39.81%	42.99%	47.13%
Th_{Hom}	201	186	170

Table 20-12.5 µL 5 s inj summary

	12.5 µL 5 s inj All	12.5 µL 5 s inj 132 pg+	12.5 µL 5 s inj 183 pg+
µ	0.7894	0.8135	0.8239
σ	0.1586	0.1330	0.1240
AI_{Th}	31.36%	41.45%	45.19%
Th_{Hom}	255	193	177

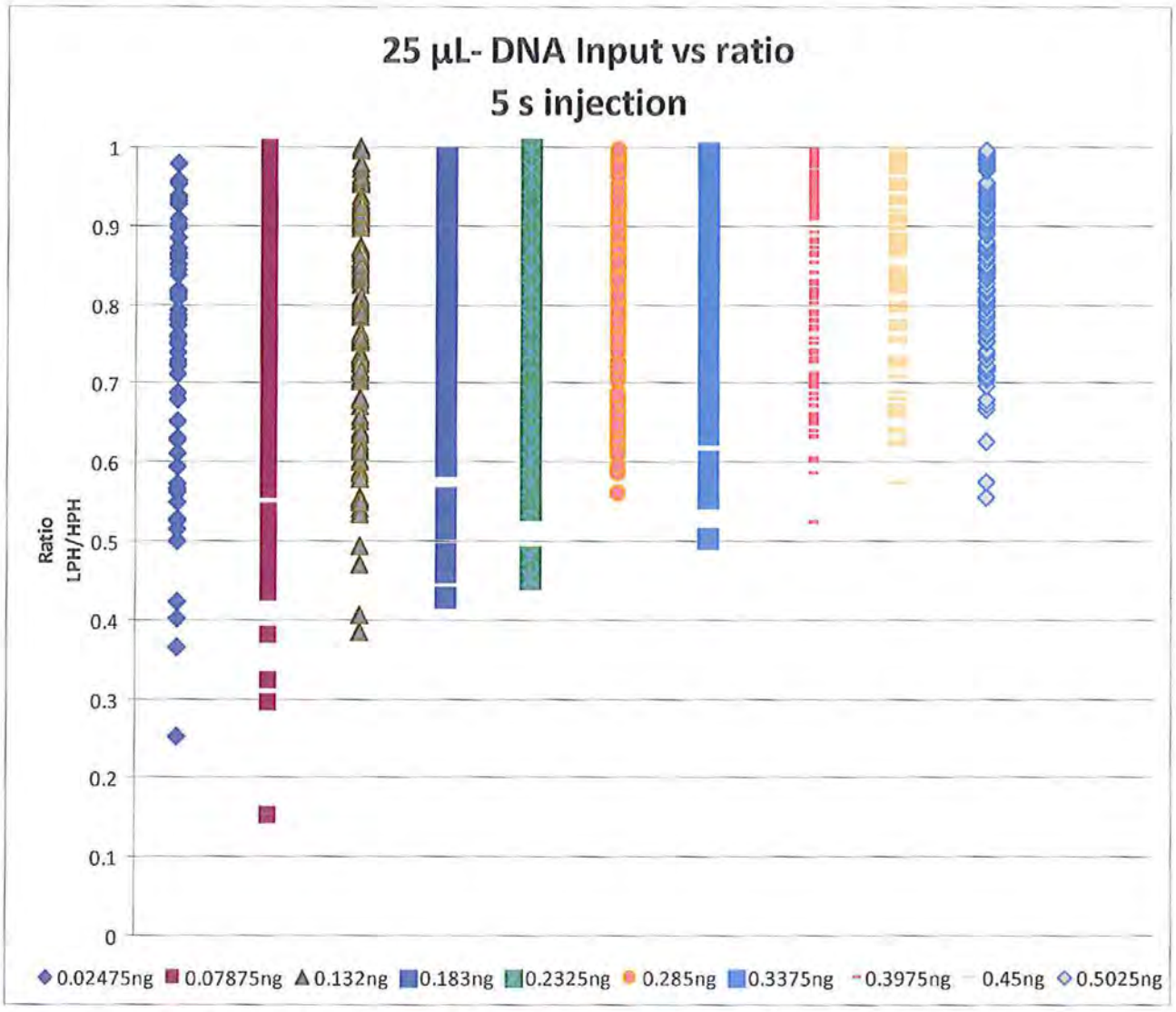


Figure 7 – 25 µL total PCR volume 5 s injection time, Peak balance vs total input DNA.

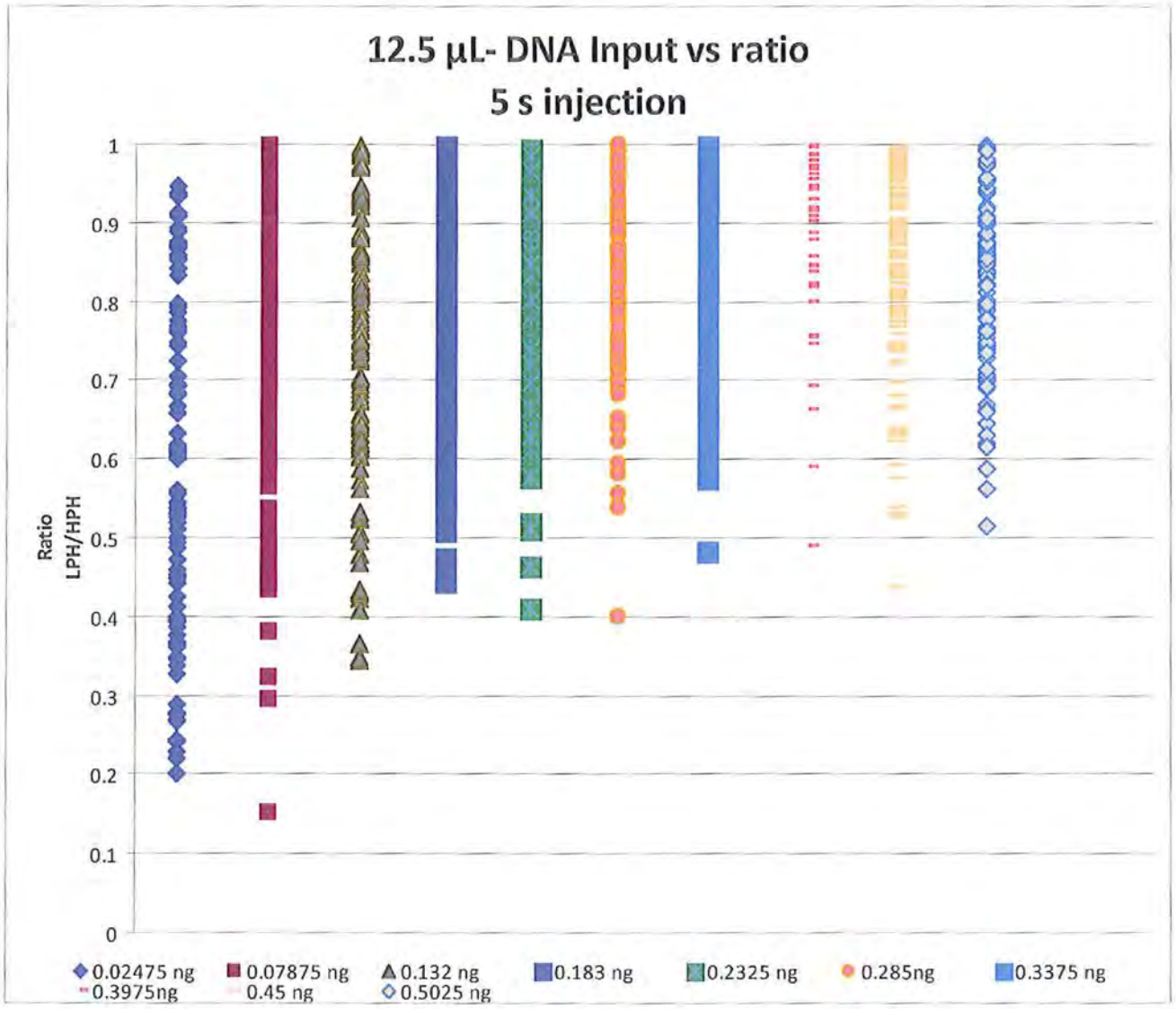


Figure 8 - 12.5 µL Total PCR volume 5 s injection time - Peak balance vs total input DNA.

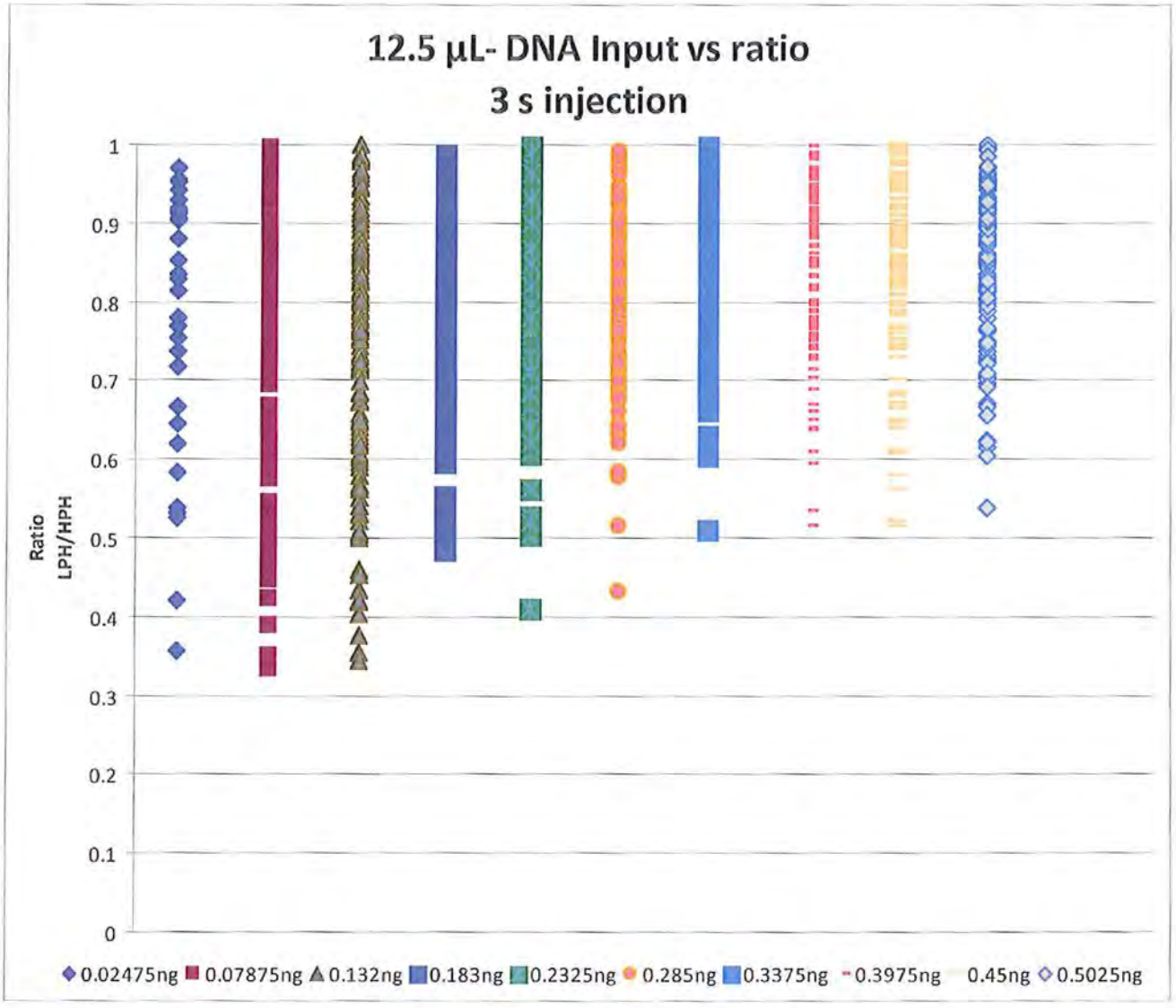


Figure 9 12.5 µL Total PCR volume 3 s injection time - Peak balance vs total input DNA.

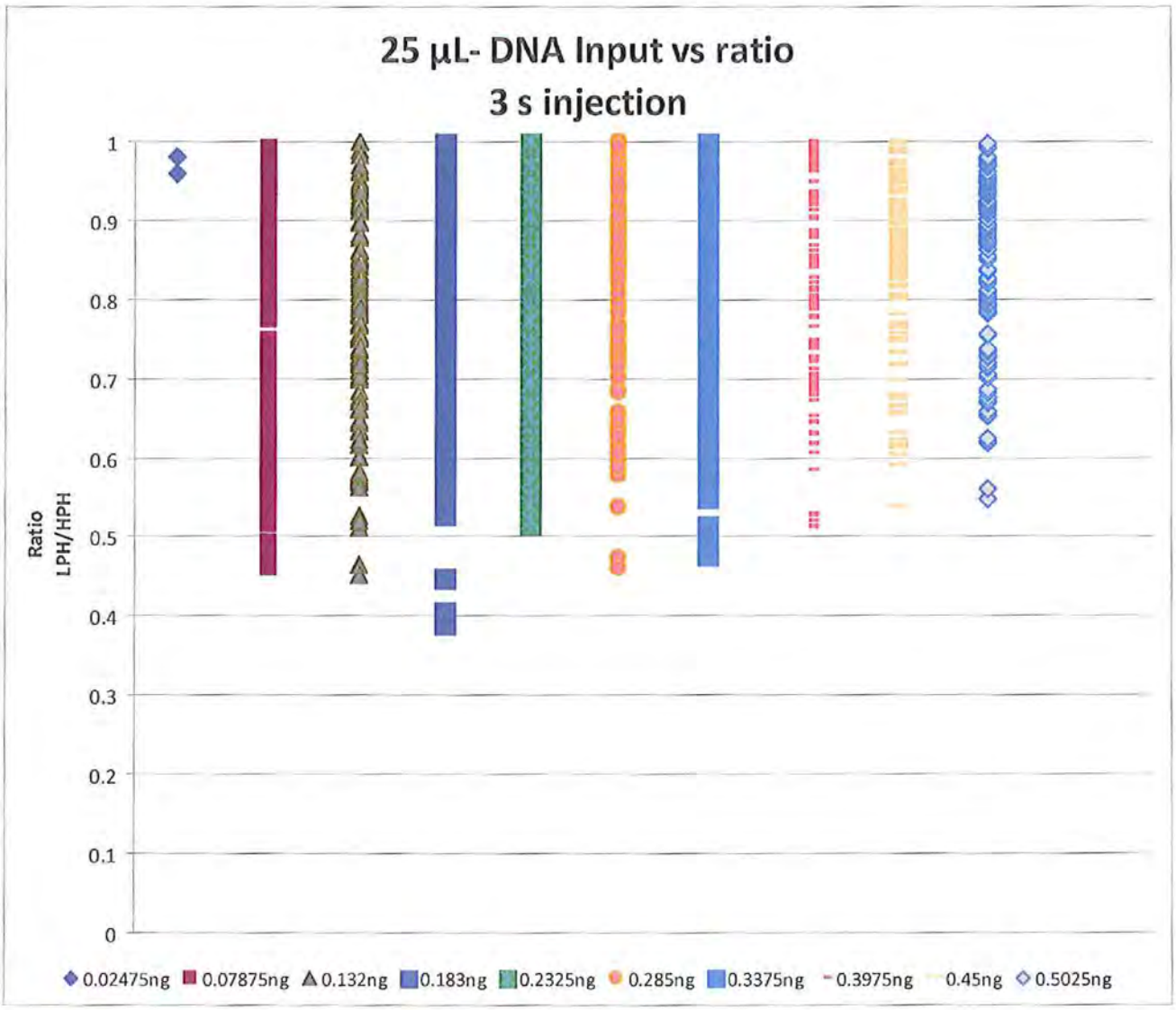


Figure 10 – 25 µL Total PCR volume 3 s injection time- Peak balance vs total input DNA.

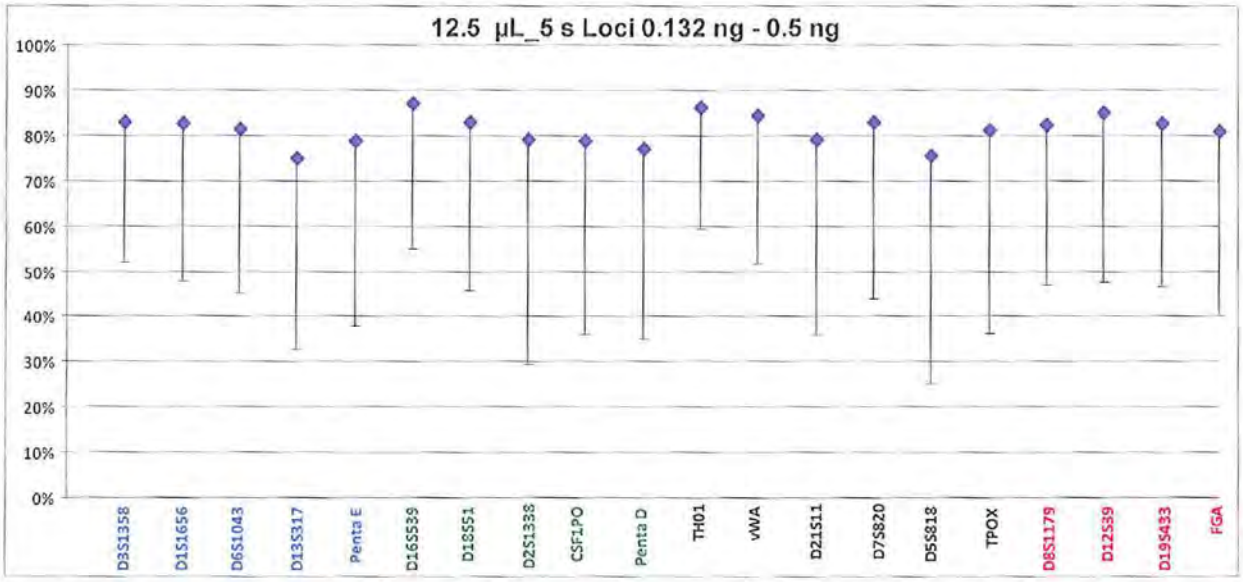


Figure 11 - 12.5 µL total PCR volume 5 s injection time µPHR per Loci. Error bars show minus 3 standard deviations

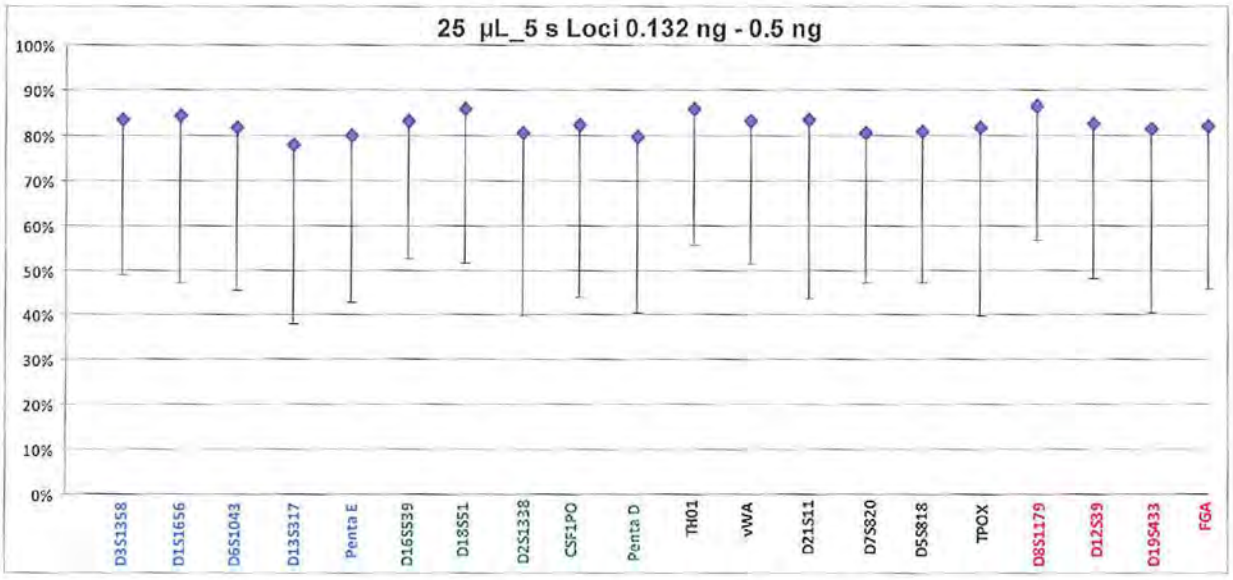


Figure 12 – 25 µL total PCR volume 5 s injection time - µPHR per Loci. Error bars show minus 3 standard deviations.

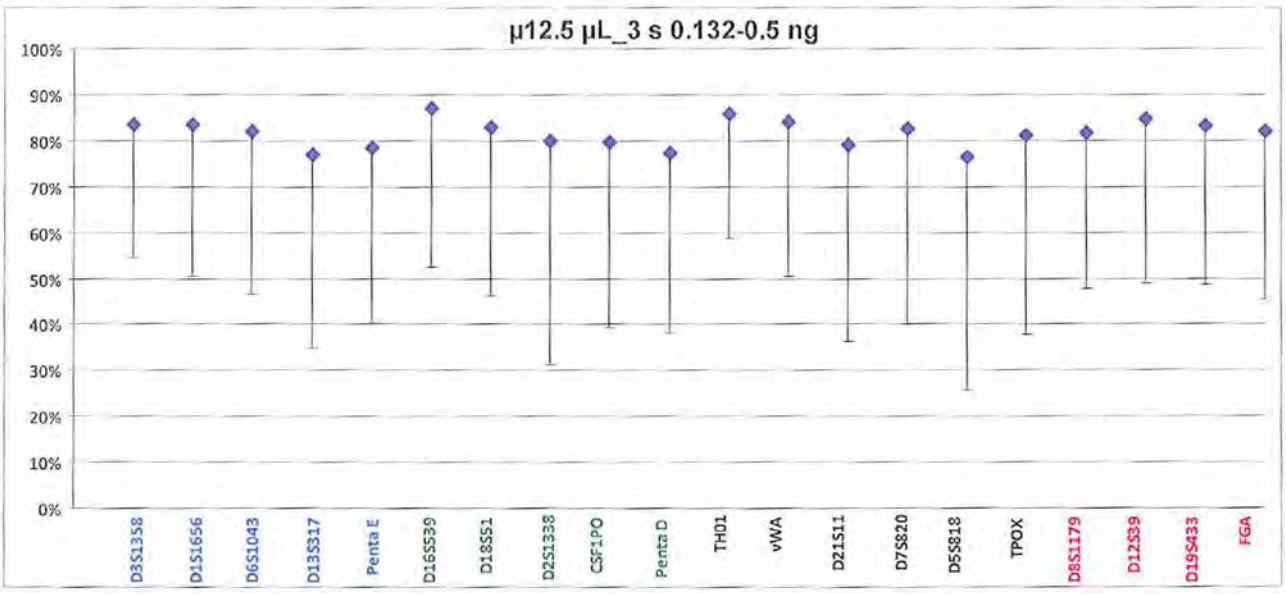


Figure 13 – 12.5 µL total PCR volume 3 s injection time - µPHR per Loci. Error bars show minus 3 standard deviations.

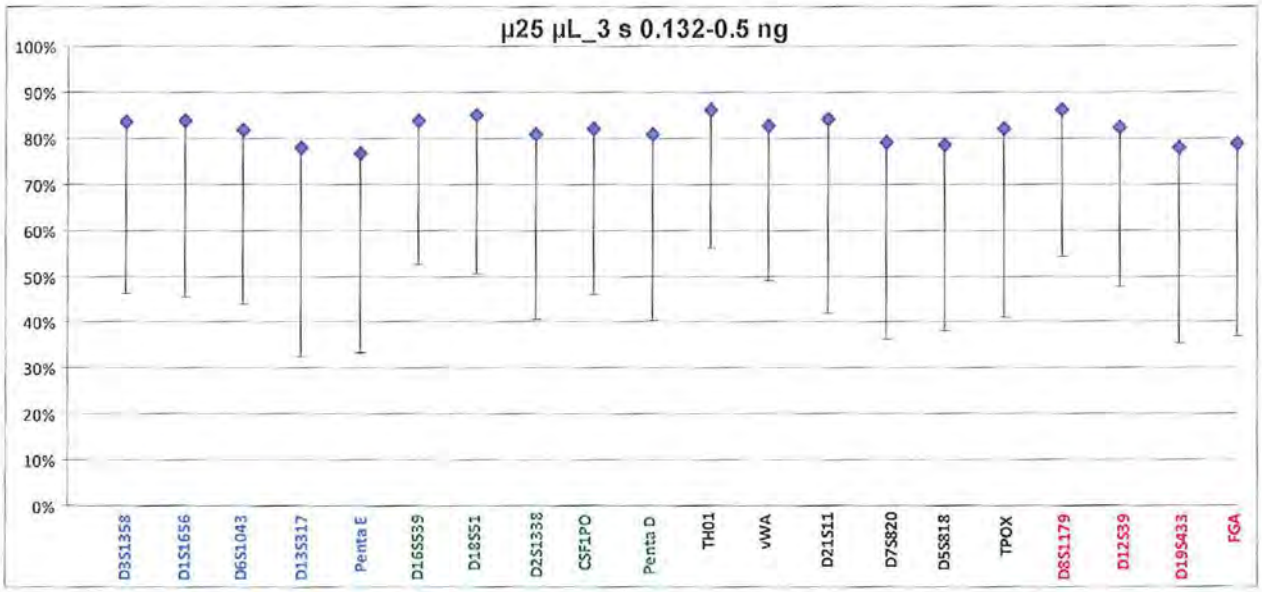


Figure 14 – 25 µL total PCR volume 3 s injection time - µPHR per Loci. Error bars show minus 3 standard deviations.

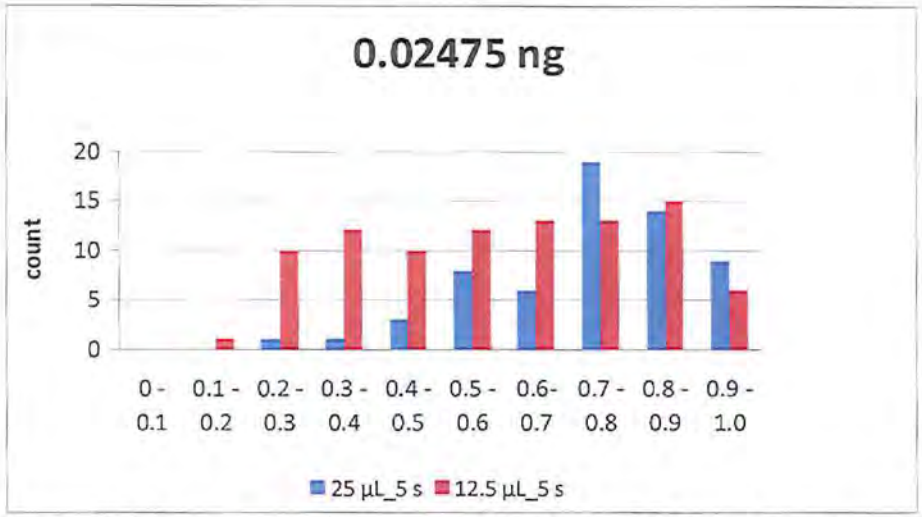


Figure 15 - The n of allele pairs per 0.1 PHR bin for 0.02475 ng 5 s inj.

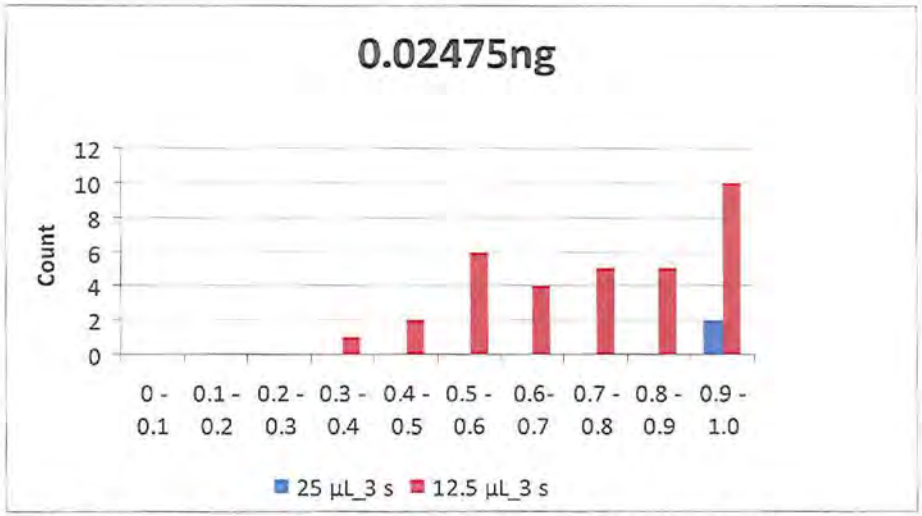


Figure 16 - The n of allele pairs per 0.1 PHR bin for 0.02475ng 3 s inj.

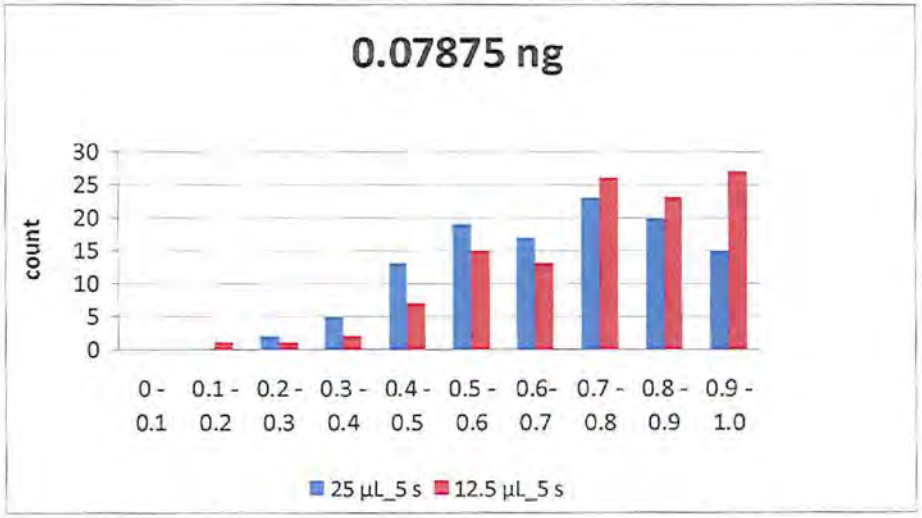


Figure 17 -The n of allele pairs per 0.1 PHR bin for 0.07875 ng 5 s inj.

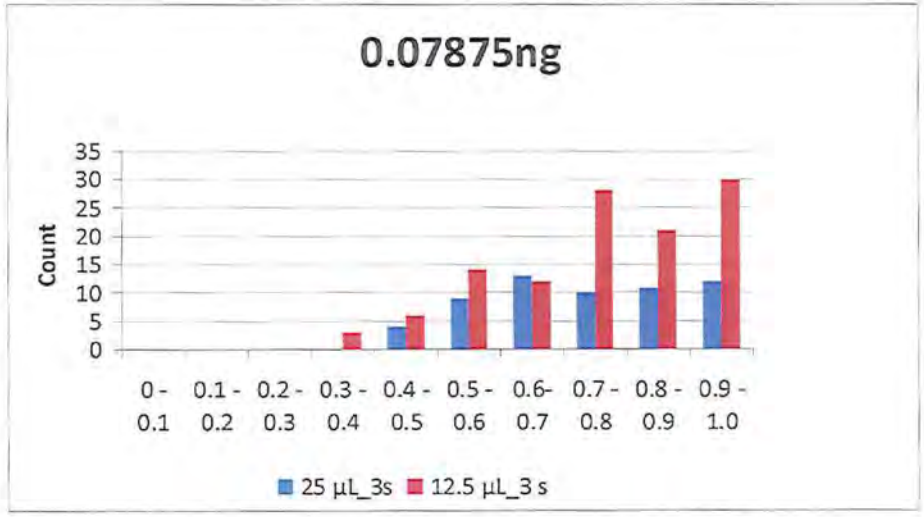


Figure 18 -The n of allele pairs per 0.1 PHR bin for 0.07875 ng 3 s inj.

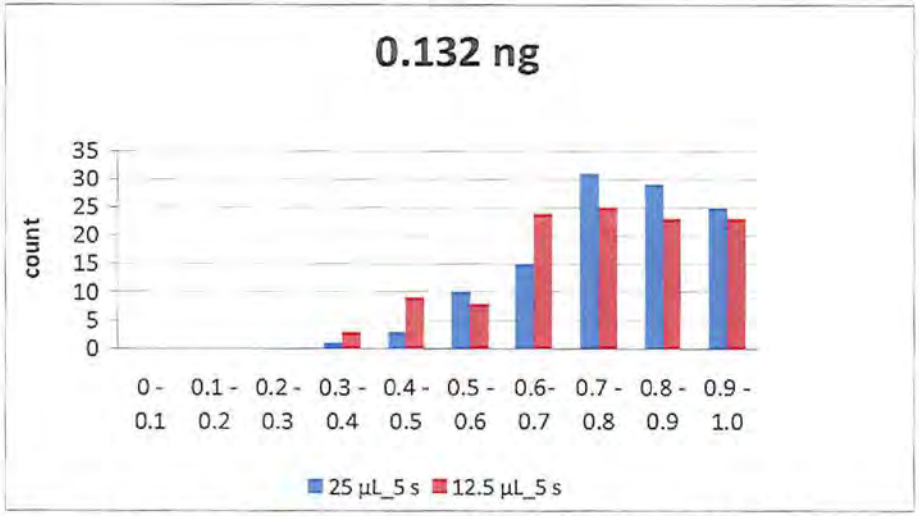


Figure 19 - The n of allele pairs per 0.1 PHR bin for 0.132 ng 5 s inj.

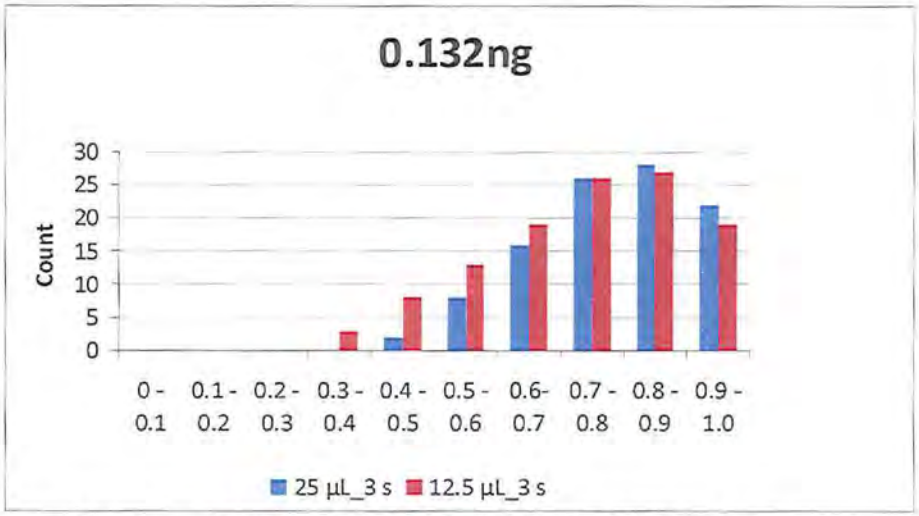


Figure 20 - The n of allele pairs per 0.1 PHR bin for 0.132 ng 3 s inj.

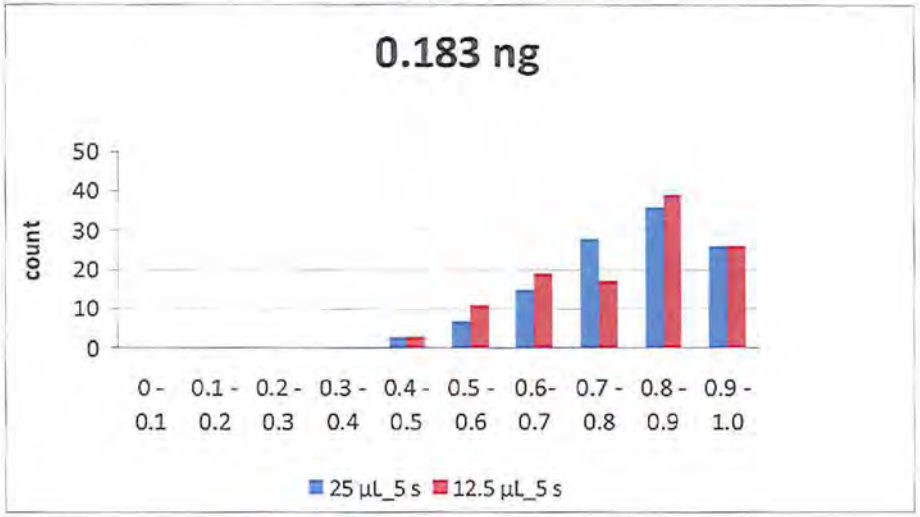


Figure 21 - The n of allele pairs per 0.1 PHR bin for 0.183 ng 5 s inj.

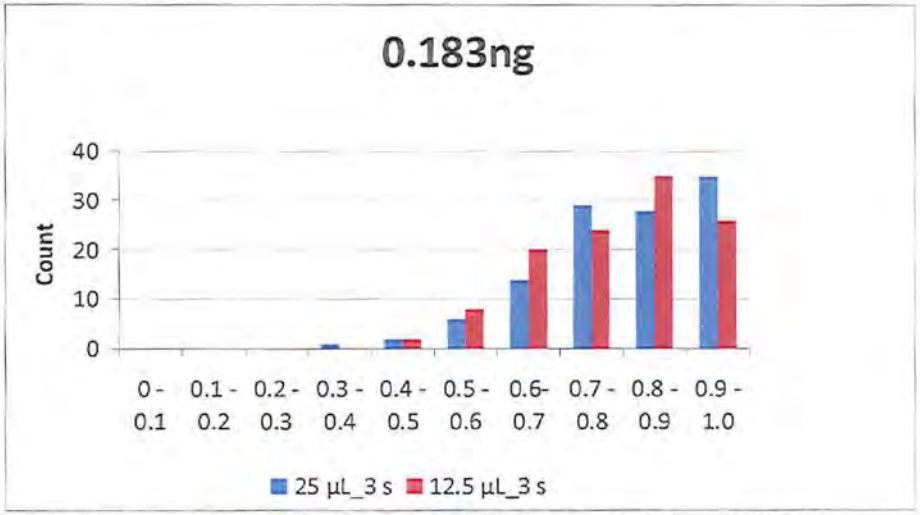


Figure 22 - The n of allele pairs per 0.1 PHR bin for 0.183 ng 3 s inj.

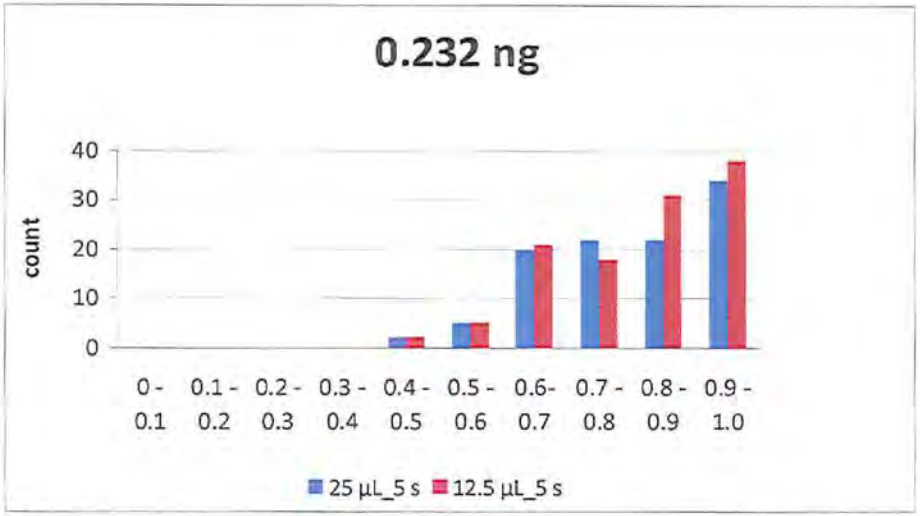


Figure 23 - The n of allele pairs per 0.1 PHR bin for 0.2.32 ng 5 s inj.

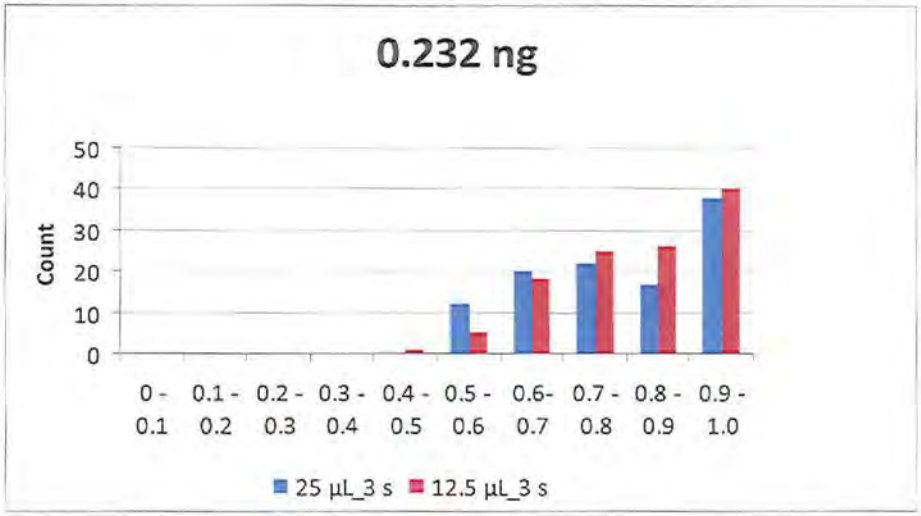


Figure 24 - The n of allele pairs per 0.1 PHR bin for 0.232 ng 3 s inj.

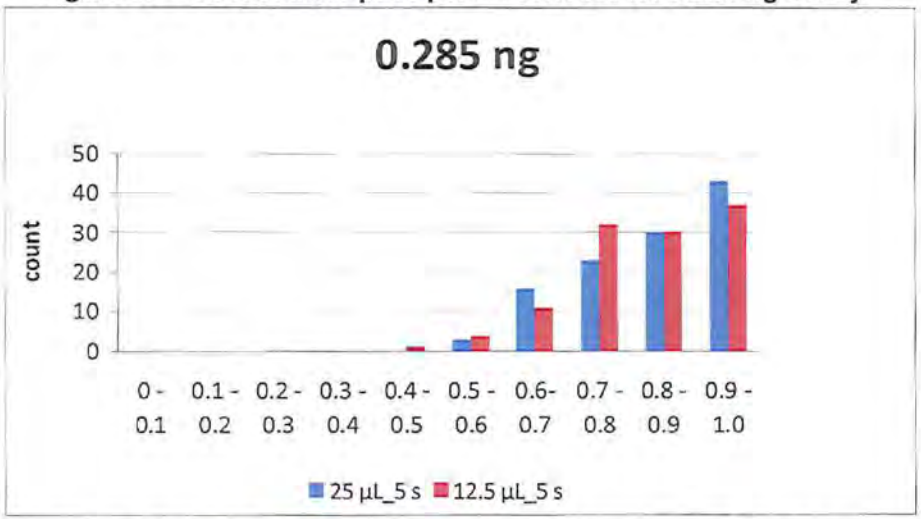


Figure 25 - The n of allele pairs per 0.1 PHR bin for 0.2.85 ng 5 s inj.

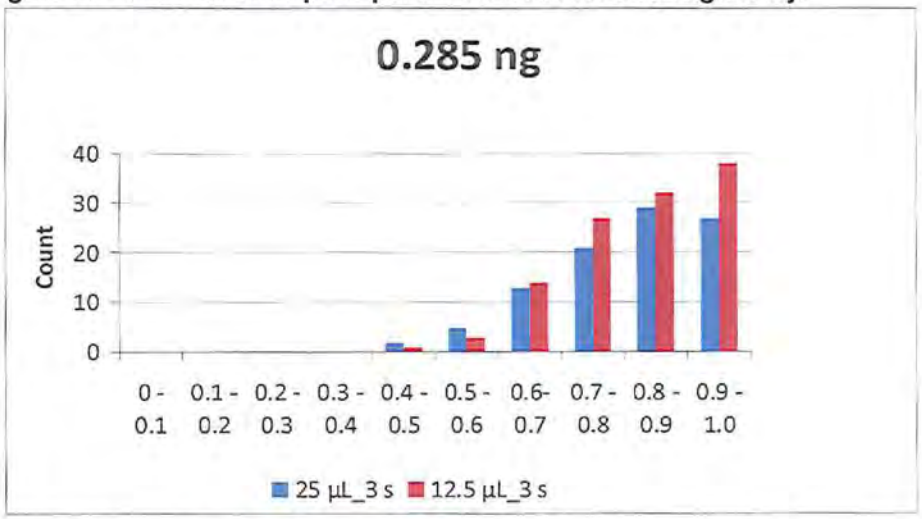


Figure 26 - The n of allele pairs per 0.1 PHR bin for 0.285 ng 3 s inj

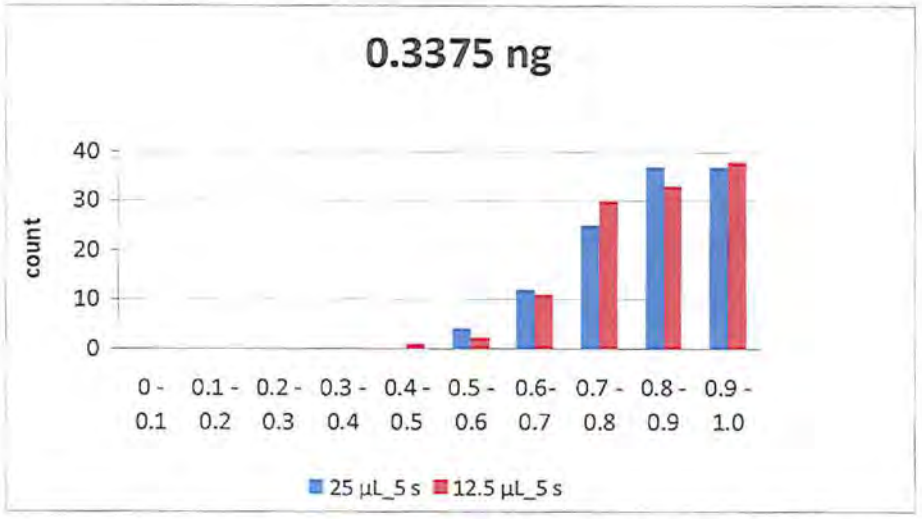


Figure 27 - The n of allele pairs per 0.1 PHR bin for 0.3375 ng 5 s inj.

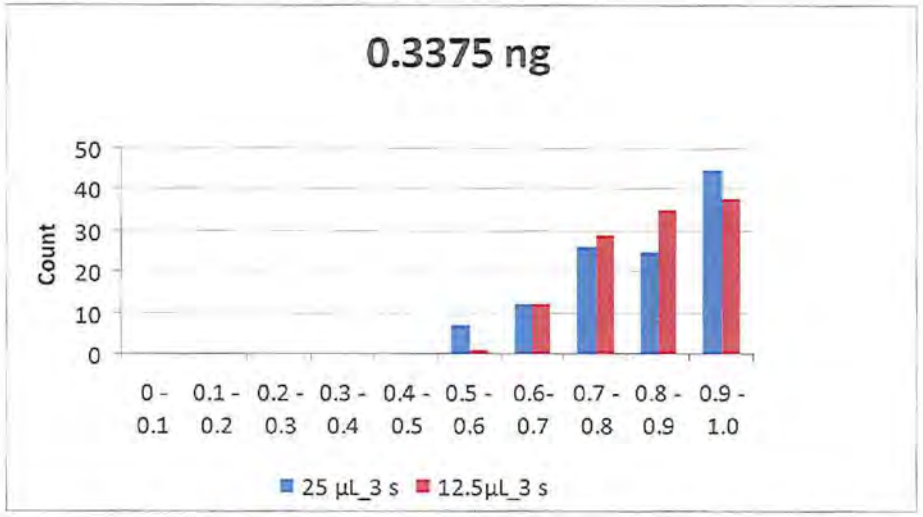


Figure 28 - The n of allele pairs per 0.1 PHR bin for 0.3375 ng 3 s inj.

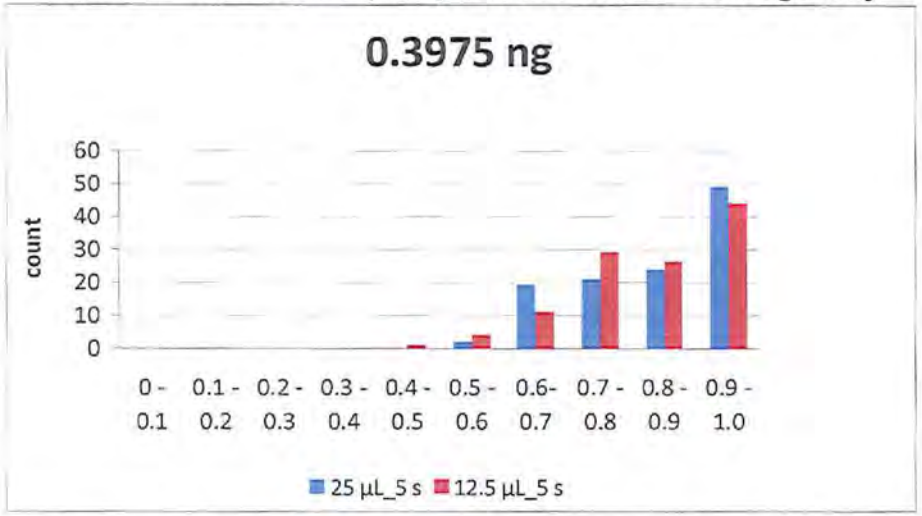


Figure 29 - The n of allele pairs per 0.1 PHR bin for 0.3975 ng 5 s inj.

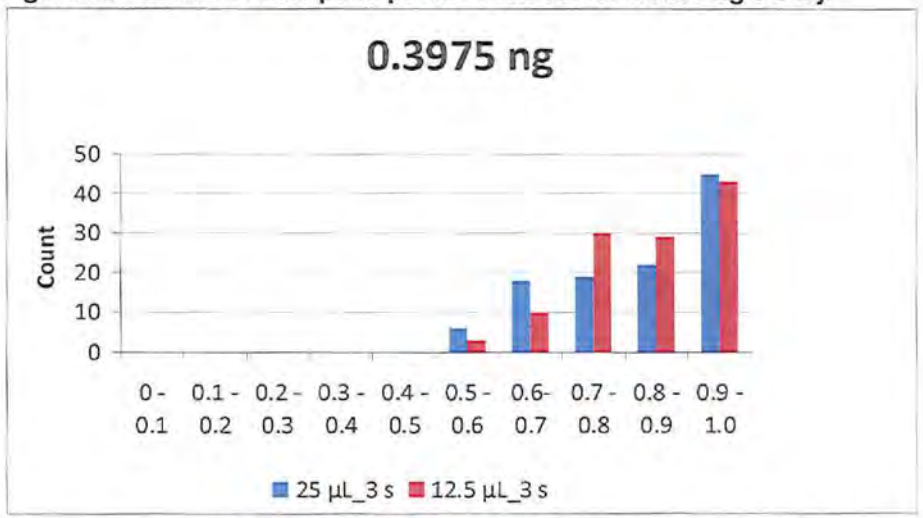


Figure 30 - The n of allele pairs per 0.1 PHR bin for 0.3975 ng 3 s inj.

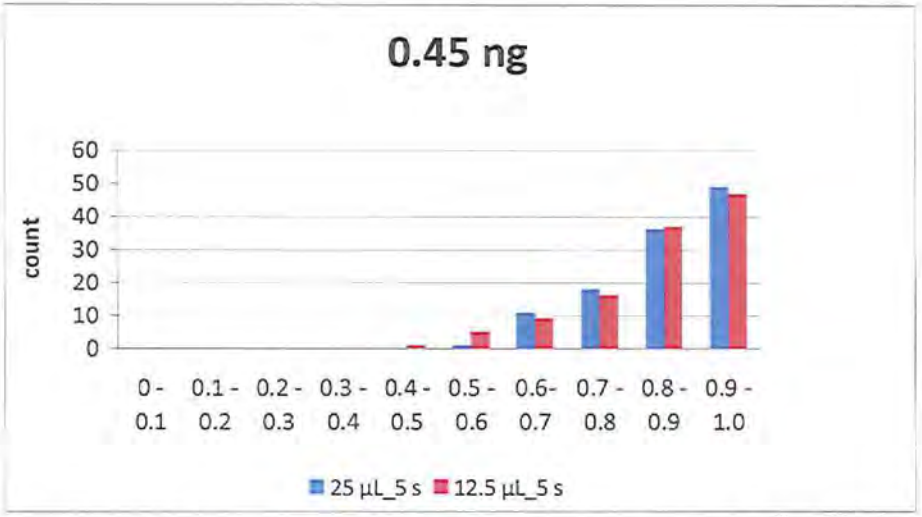


Figure 31- The n of allele pairs per 0.1 PHR bin for 0.45 ng 5 s inj.

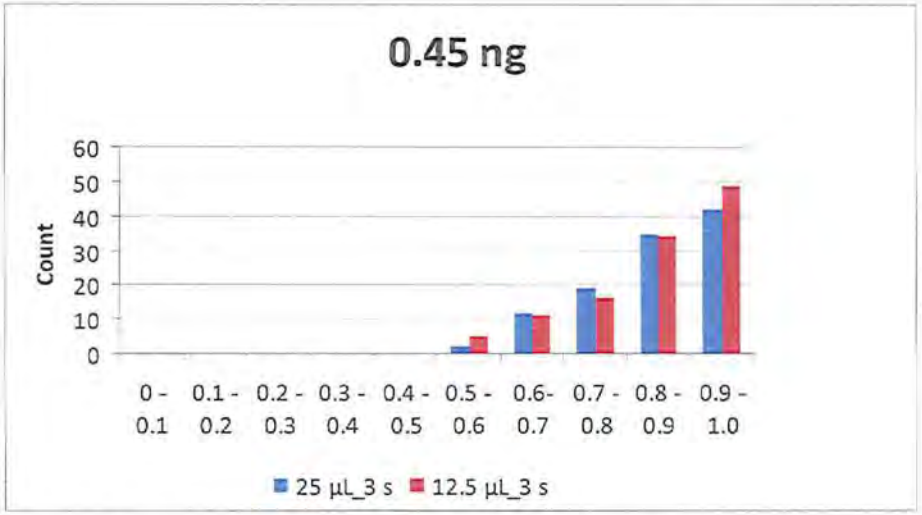


Figure 32 -The n of allele pairs per 0.1 PHR bin for 0.45 ng 3 s inj.

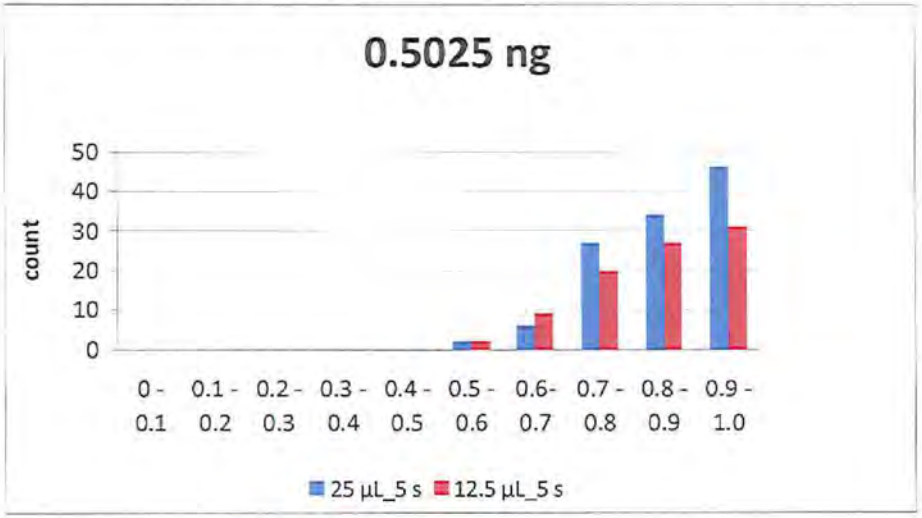


Figure 33- The n of allele pairs per 0.1 PHR bin for 0.5025 ng 5 s inj.

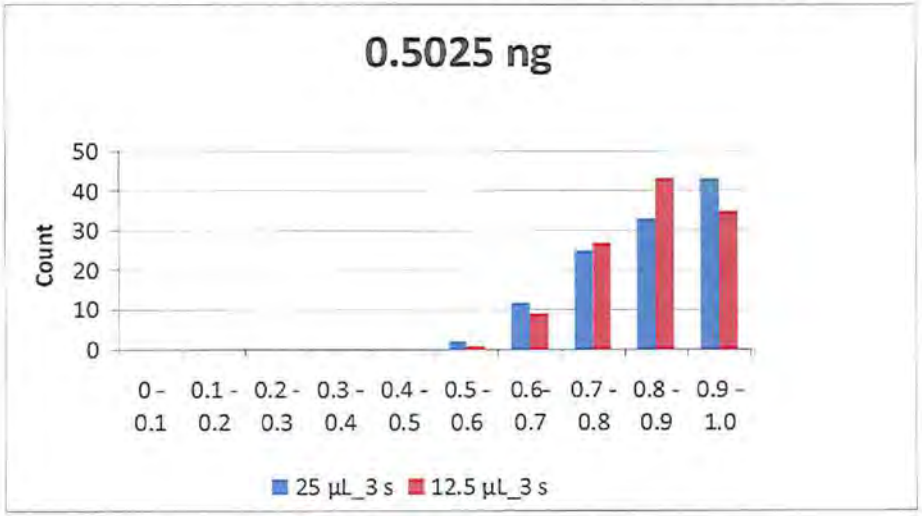


Figure 34 - The n of allele pairs per 0.1 PHR bin for 0.5025 ng 3 s inj.

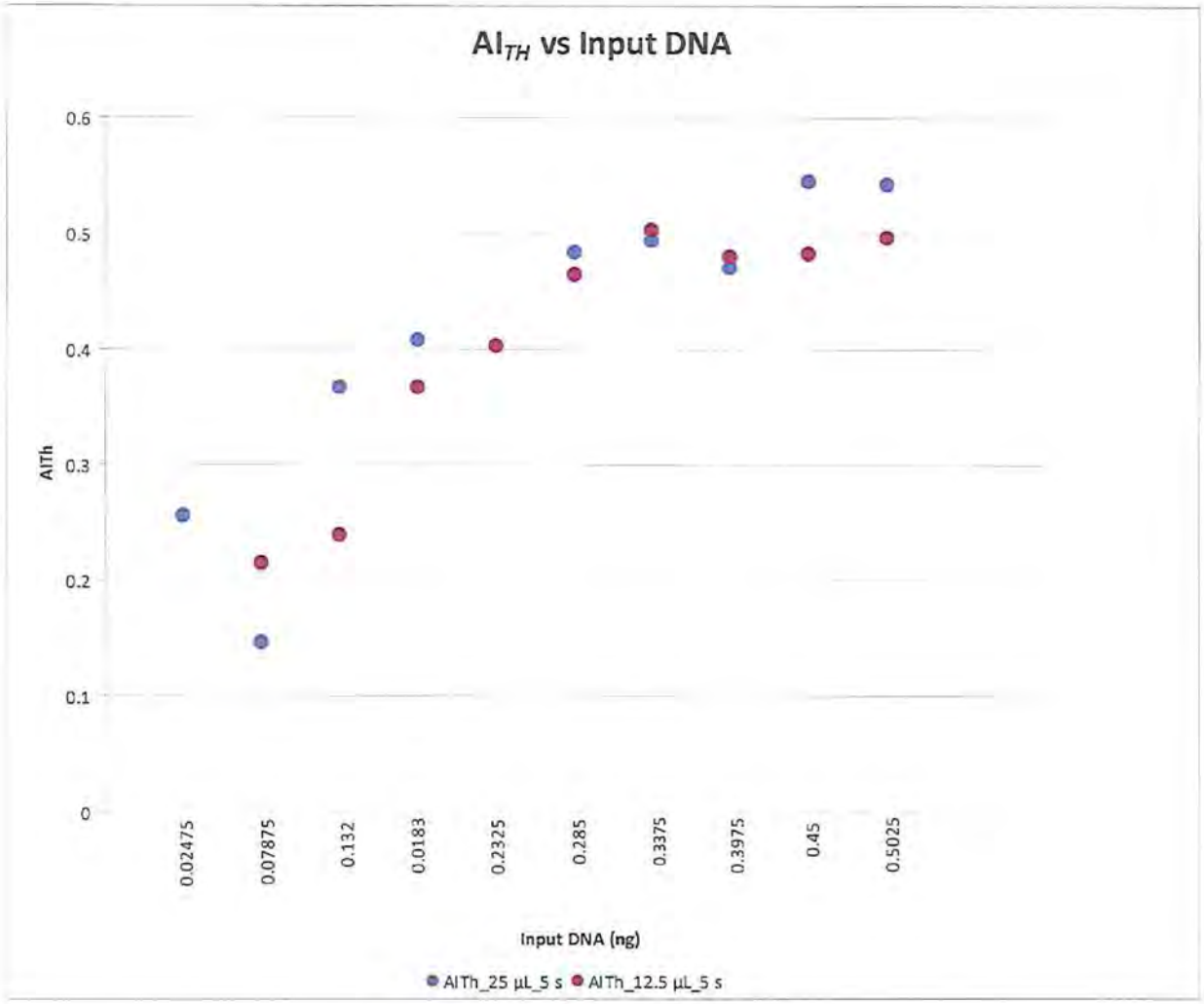


Figure 35 - Calculated AI$_{TH}$ vs DNA template 5 s inj.

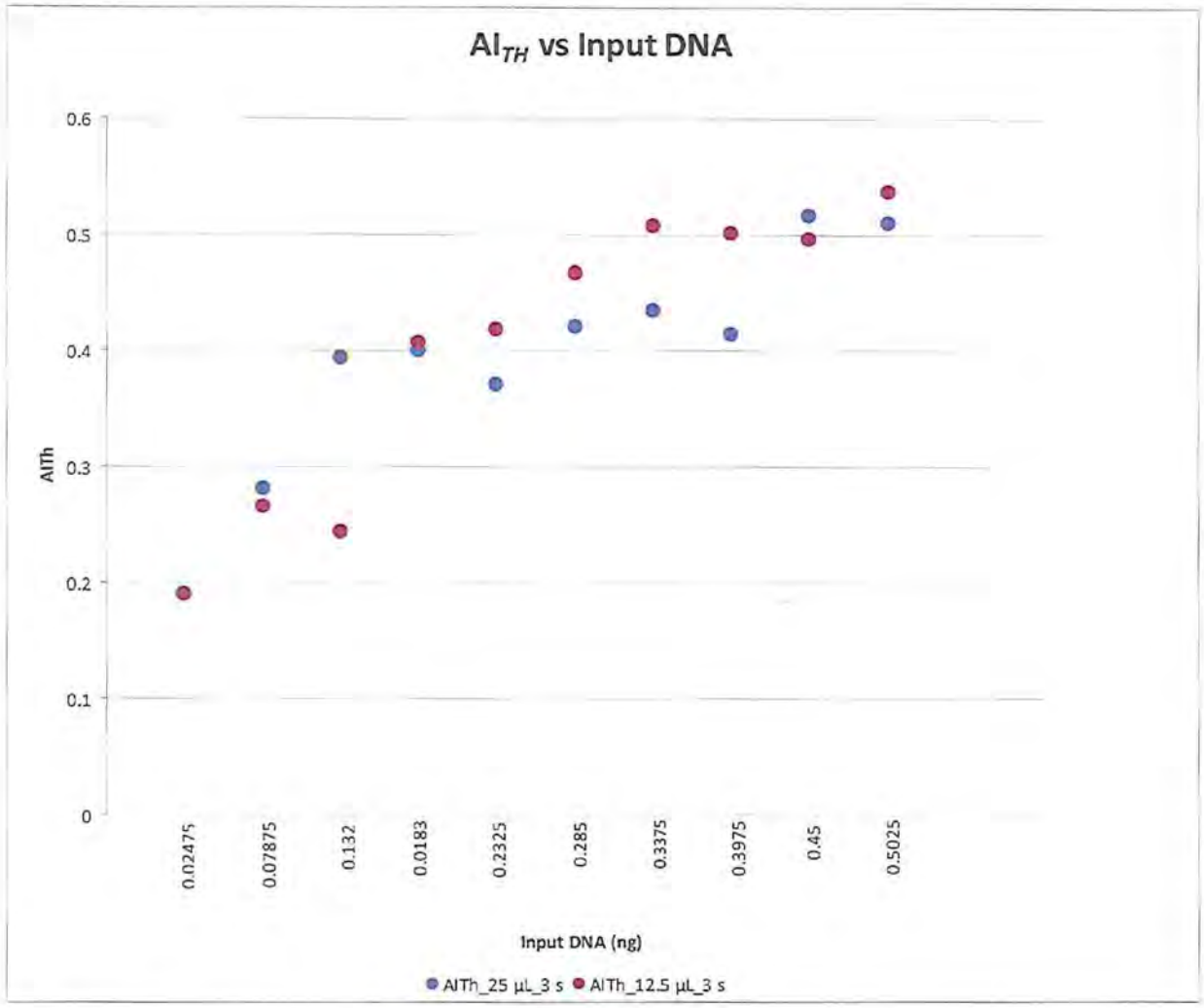


Figure 36 - Calculated AITH vs DNA template 3 s inj

6.7.2 Homozygote thresholds

The homozygote threshold is the threshold above which you can be confident that a heterozygote locus will not be incorrectly called as a homozygote locus.

Setting the homozygous threshold too high will result in excessive reworking of samples as a partial DNA profile would be called. Conversely, setting the threshold too low could result in false exclusions [1, 11, 23].

The method for determining the homozygote threshold varies in the literature. Traditionally, it had been arbitrarily designated at a particular level above the LOR. As already mentioned the risk of Type 1 and Type 2 errors should be balanced. Literature describes the setting of Th_{Hom} with respect to casework samples [21, 51, 52].

Previously in DNA Analysis, the Th_{Hom} was calculated as described in section 5.8.2 Equation 9. Using this method a result of 176 RFU for 25 µL(5 s inj), 193 RFU for 12.5 µL (5 s inj), 187 RFU for 25 µL(3 s inj), 186 RFU for 12.5 µL (3 s inj) was calculated. These thresholds have been calculated excluding data below 0.132 ng DNA template.

Another method of determining the Th_{Hom} is described in the Promega Internal Validation of STR systems reference manual[15]. This plots the peak height ratio for heterozygous loci against the lower RFU peak. The threshold is defined as the point at which peak height ratio drops off significantly. Figures 37 - 40 display the data, the average AI_{TH} calculated for the range 0.132 ng-0.5 ng in section 6.7.1 for 25 µL (5 s inj), 12.5 µL (5 s inj), 25 µL (3 s inj), 12.5 µL (3 s inj) respectively. An RFU that encompasses the majority of the data that falls below the average AI_{TH} calculated.

Unlike data reported in other publications[21, 53] there is not a rapid drop off of peak height ratios observed in the PowerPlex® 21 system, most likely due to the exclusion of the lower template data that exhibits extreme allelic imbalance. We have observed that the PowerPlex® 21 system loci tend to completely drop out completely compared to partially dropping out.

As both methods used give similar results, it is recommended the homozygote threshold be set at 200 RFU for 25 µL(both 5 s and 3 s inj) and 250 RFU for 12.5 µL(both 5 s and 3 s inj).

These methods are subjective but when considered with the observed drop out data in Figures 37 - 41, Th_{Hom} of 200RFU would result in no type 2 errors. Additionally the threshold is more than three times the LOR threshold so Type 1 errors would also be addressed.

The homozygote threshold calculated in this validation will be used for extracted reference samples as case work samples do not require a homozygote threshold for STRmix™ analysis.

To ensure all of the thresholds set for this validation are appropriate a post implementation review of the thresholds will be performed. If the

thresholds are found to be too conservative and have resulted in additional processing the review will provide an opportunity to re-adjust the thresholds based on empirical data.

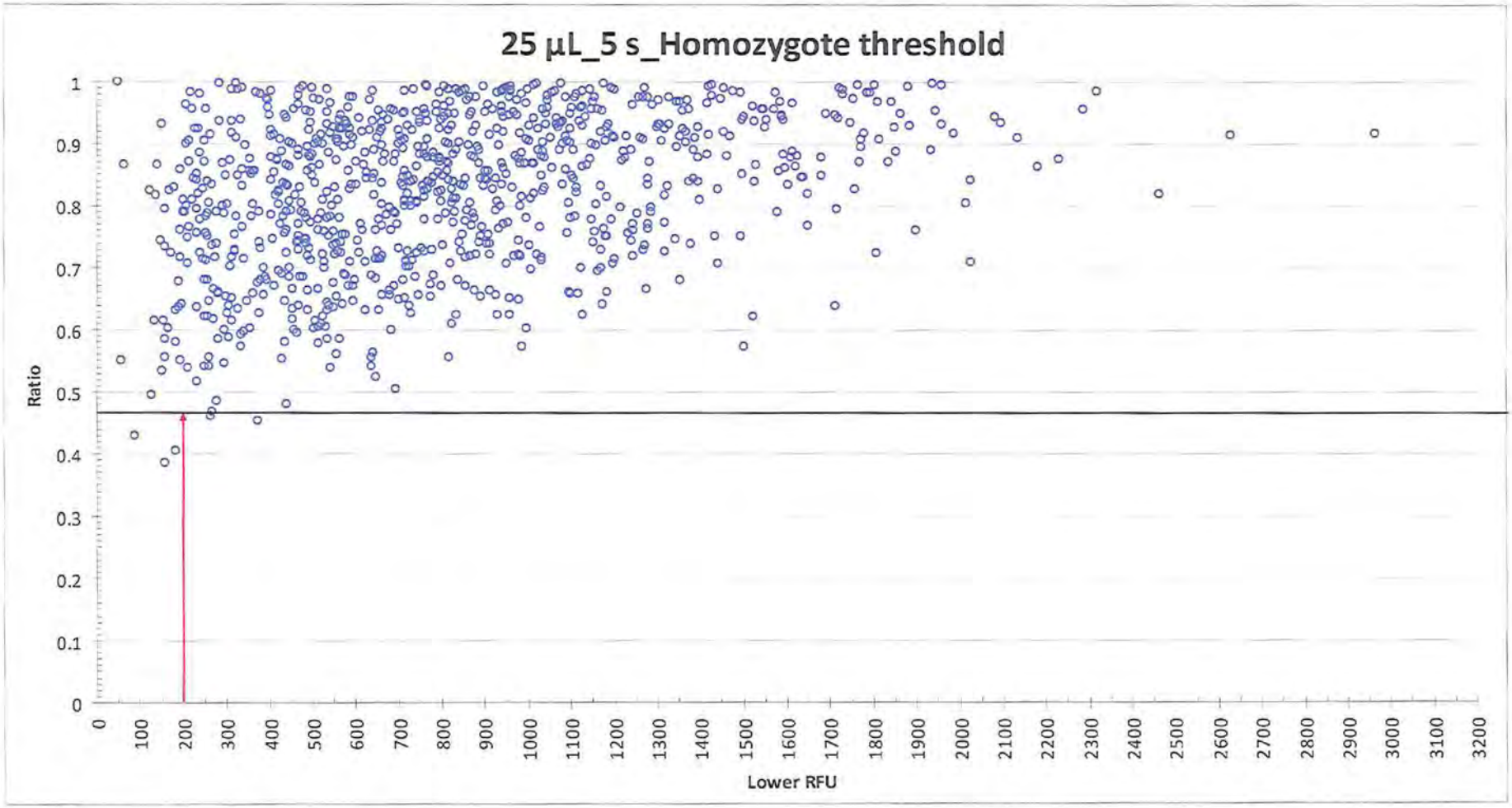


Figure 37 - Plot of the peak height ratio vs RFU of lower peak for 25 µL. The black horizontal line is the AI_{TH}. The red vertical line is set to approximately encompass the majority of points that fall below the AI_{TH}.

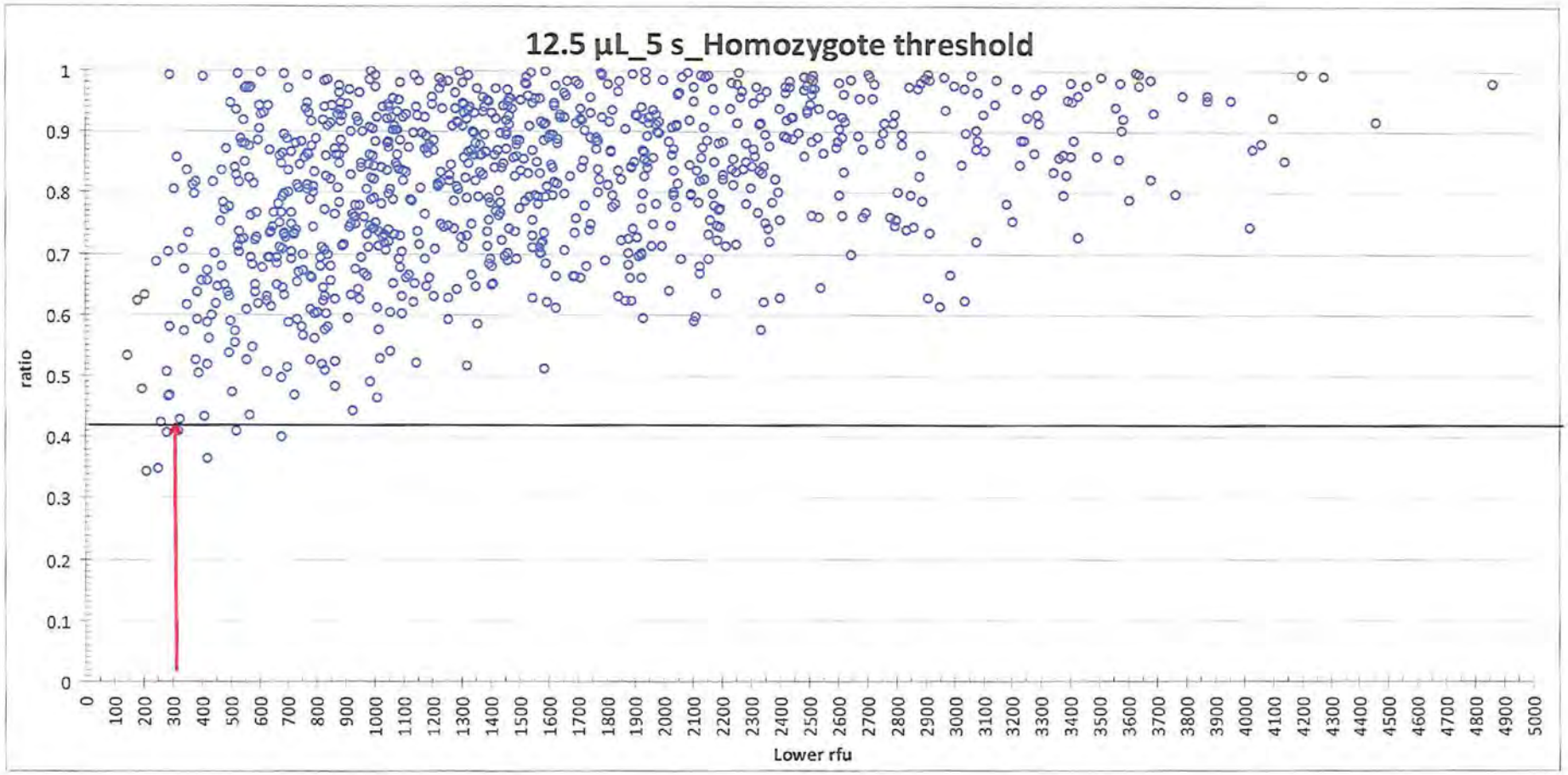


Figure 38 - Plot of the peak height ratio vs RFU of lower peak for 12.5 µL. The black horizontal line is the AITH. The red vertical line is set to approximately encompass the majority of points that fall below the AITH

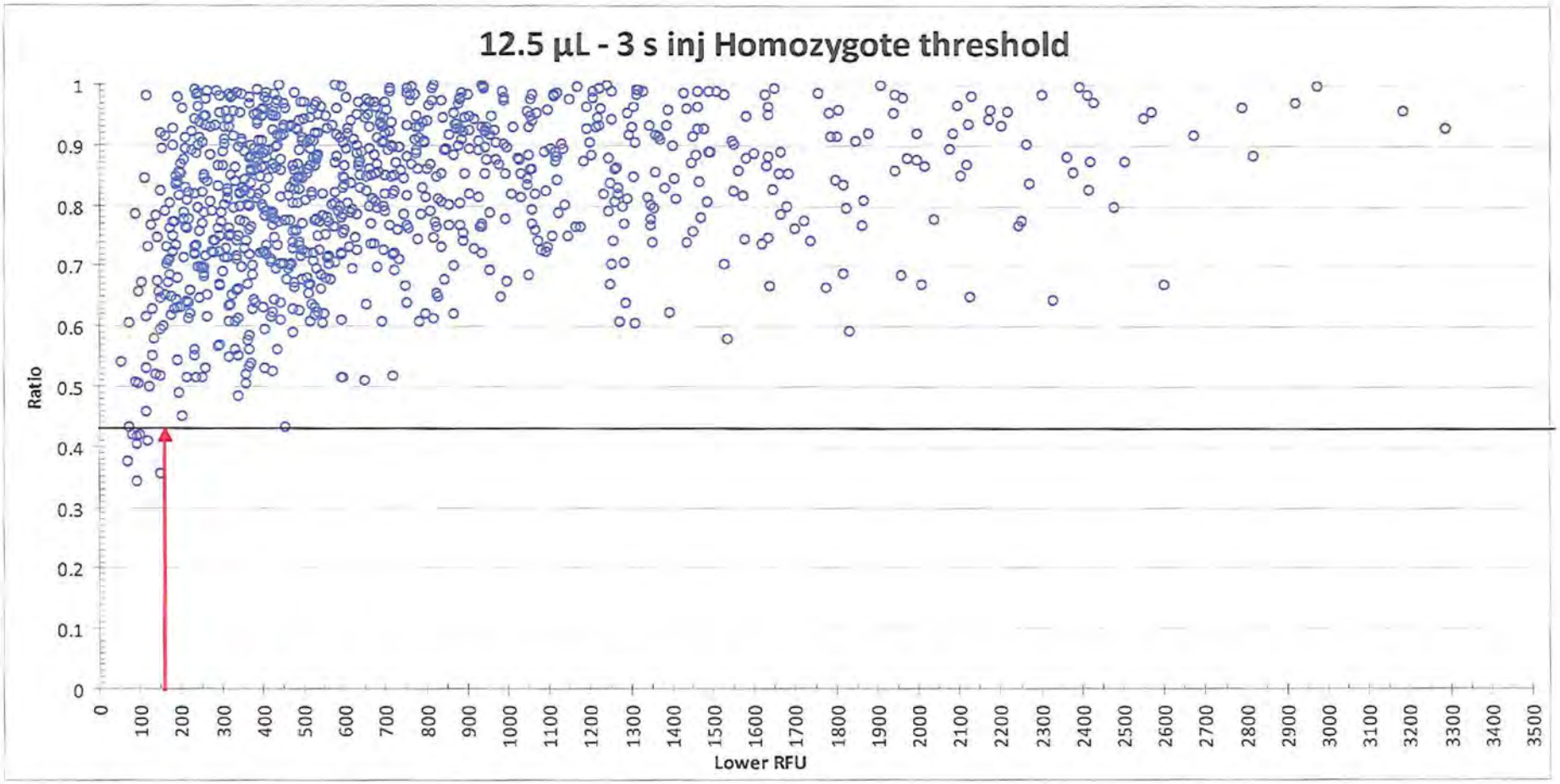


Figure 39 - Plot of the peak height ratio vs RFU of lower peak for 12.5 µL 3 s injection time. The black horizontal line is the AI_{TH}. The red vertical line is set to approximately encompass the majority of points that fall below the AI_{TH}

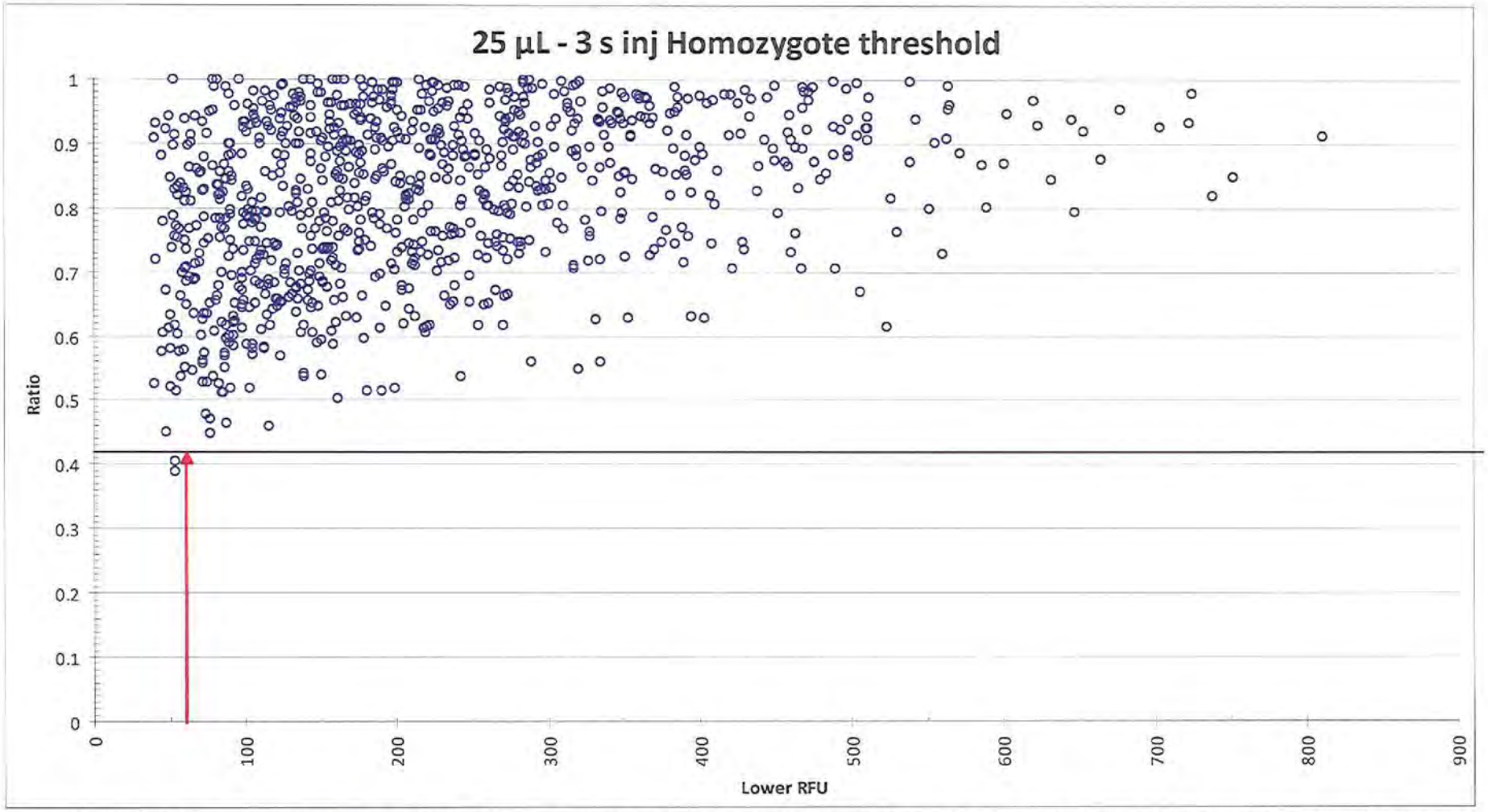


Figure 40 - Plot of the peak height ratio vs RFU of lower peak for 25 µL 3 s injection time. The black horizontal line is the AI_{TH}. The red vertical line is set to approximately encompass the majority of points that fall below the AI_{TH}

6.8 Dropout Experiments

Allelic dropout is when one allele of a heterozygous pair has not appeared or has a very low peak height[54]. One cause of dropout is one allele of a heterozygous pair is preferentially amplified thus giving the false impression of a homozygous allele at a particular locus[35].

This experiment used sensitivity 1 data of the two donors from 1 ng to 1 pg the 4 ng and 2 ng data was excluded due to the excess nature of the profiles. The heat maps shown in Figures 41 - 44 summarise the data to quickly compare the drop out events observed.

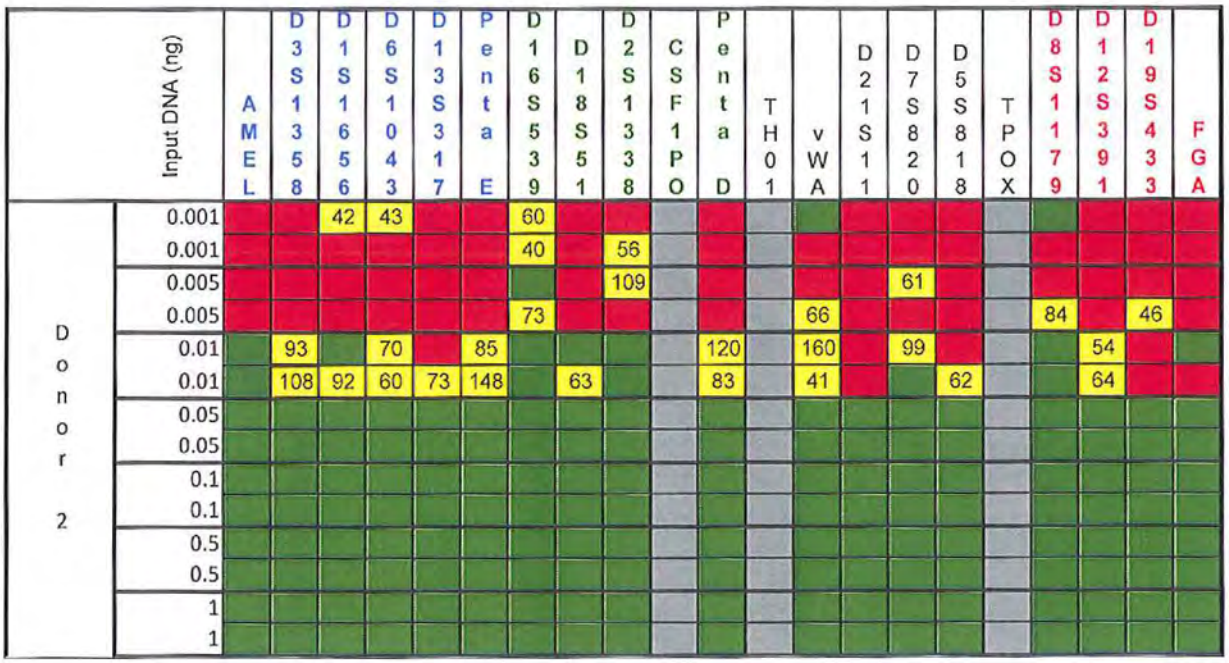
The data for the 25 µL amplification shows 62 drop out events occurred across both donors from dilutions 0.001 ng to 0.05 ng. Figures 41 and 42 show the highest peak height (RFU) where a heterozygous pair dropped out was at 160 RFU for the 0.01 ng dilution for donor 2 amplified at 25 µL total PCR volume.

The data for the 12.5 µL amplification shows 70 drop out events occurred across both donors from dilutions 0.001 ng to 0.05 ng. Figures 43 and 44 show the highest peak height (RFU) where a heterozygous pair dropped out was at 399 RFU for the 0.01 ng dilution for donor 2.

Locus dropout
Allele dropout (surviving allele RFU)
Complete heterozygous locus
Homozygous locus

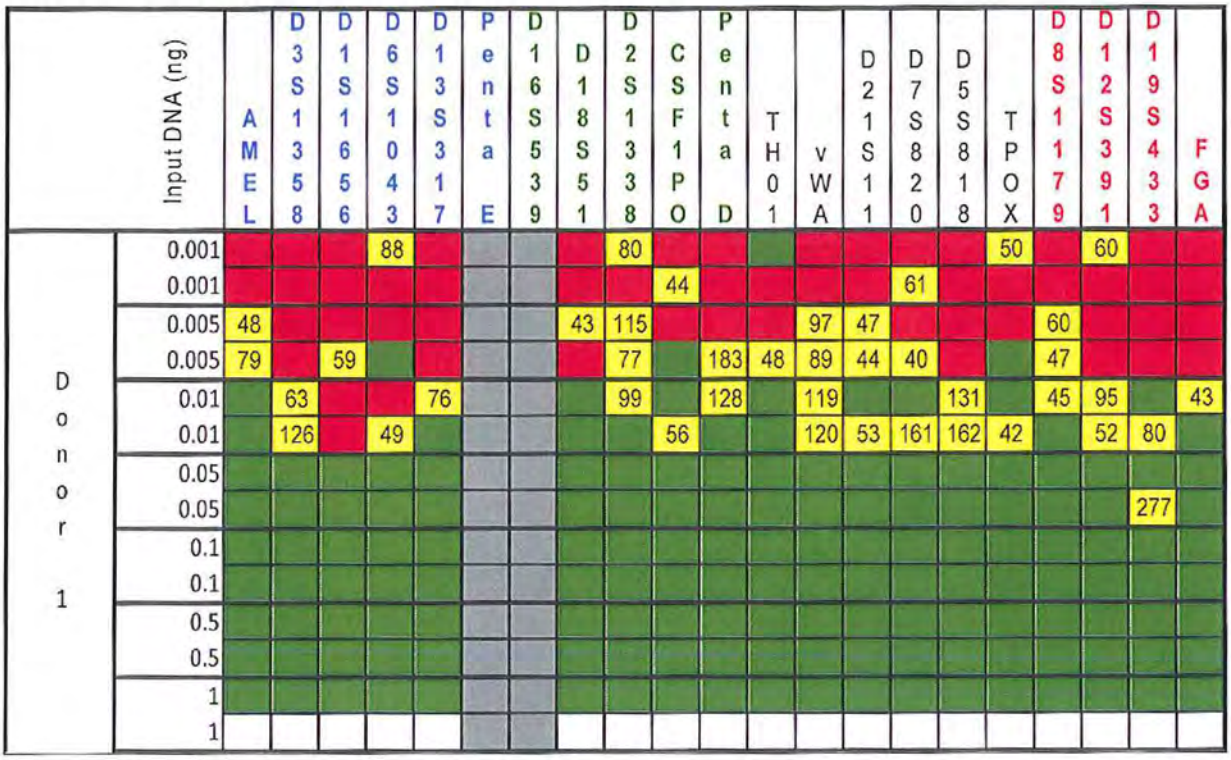
	Input DNA (ng)	AMEL	D3S1358	D1S1656	D6S1043	D13S317	Penta E	D16S539	D18S51	D2S1338	CSF1PO	Penta D	TH01	vWA	D21S11	D7S820	D5S818	TPOX	D8S1179	D12S391	D19S433	FGA
Donor 1	0.001										54											
	0.001								43													
	0.005	83												50		96					69	
	0.005	41		46		61								46				54	70			
	0.01	100	76	73						58	67	49		65	51		90	103	140			
	0.01	89								47			120		41	87	42		50	40	88	63
	0.05																131					
	0.05																					
	0.1																					
	0.1																					
	0.5																					
	0.5																					
	1																					
	1																					

Figure 41 - Heat map - Donor 1 – 25 µL total PCR volume



Donor 2	Input DNA (ng)	AMEL	D3S1358	D1S1656	D6S1043	D13S317	Penta E	D16S539	D18S51	D2S1338	CSF1PO	Penta D	TH01	vWA	D21S11	D7S820	D5S818	TPOX	D8S1179	D12S391	D19S433	FGA
	0.001			42	43			60														
	0.001							40		56												
	0.005									109						61						
	0.005							73						66					84		46	
	0.01		93		70		85					120		160		99				54		
	0.01		108	92	60	73	148		63			83		41			62			64		
	0.05																					
	0.05																					
	0.1																					
	0.1																					
	0.5																					
	0.5																					
	1																					
	1																					

Figure 42 - Heat map - Donor 2 – 25 µL total PCR volume



Donor 1	Input DNA (ng)	AMEL	D3S1358	D1S1656	D6S1043	D13S317	Penta E	D16S539	D18S51	D2S1338	CSF1PO	Penta D	TH01	vWA	D21S11	D7S820	D5S818	TPOX	D8S1179	D12S391	D19S433	FGA
	0.001				88					80								50		60		
	0.001										44					61						
	0.005	48							43	115				97	47				60			
	0.005	79		59						77		183	48	89	44	40			47			
	0.01		63			76				99		128		119			131		45	95		43
	0.01		126		49						56			120	53	161	162	42		52	80	
	0.05																					
	0.05																				277	
	0.1																					
	0.1																					
	0.5																					
	0.5																					
	1																					
	1																					

Figure 43 - Heat map - Donor 1 - 12.5 µL total PCR volume

	Input DNA (ng)	AMEL	D3S1358	D16S539	D6S1043	D13S317	Penta E	D18S51	D2S1338	CSF1PO	Penta D	TH01	vWA	D21S11	D7S820	D5S818	TPOX	D8S1179	D12S391	D19S433	FGA
Donor 2	0.001																				
	0.001																				
	0.005	97			64						62		53						47		
	0.005		74	53		42			103						77			53		47	
	0.01			74				89	124		399			43					92	46	
	0.01	230		60				154	298		101			42	202				54	44	
	0.05																				
	0.05																				
	0.1																				
	0.1																				
	0.5																				
	0.5																				
	1																				
	1																				

Figure 44 - Heat Map – Donor 2 - 12.5 µL total PCR volume

6.8.1 Drop out 2

Analysis for drop out 2 used the data obtain from the Aboriginal dataset and both sensitivity experiments for 25 µL total PCR volume (5 s inj), baseline experiment (3 s inj) for 25 µL total PCR volume (3 s inj), the baseline experiment, both sensitivity experiments for 12.5µL total PCR volume (5 s inj) and concordance for 12.5 µL (3 s inj). The dropout 2 results are displayed in figures 45 -48. Figure 45 shows the dropout events for all samples amplified at 25 µL total PCR volume (5 s inj). Figure 46 shows the dropout events for all samples amplified at 25 µL total PCR volume (3 s inj).

Figure 47 shows the dropout events for all samples amplified at 12.5 µL total PCR volume (5s inj). Figure 48 shows the dropout events for all samples amplified at 12.5 µL total PCR volume (3 s inj).

For both 25 µL and 12.5 µL total PCR volume amplifications and both injection times, there were more drop out events of whole loci compared with a single allele drop out events.

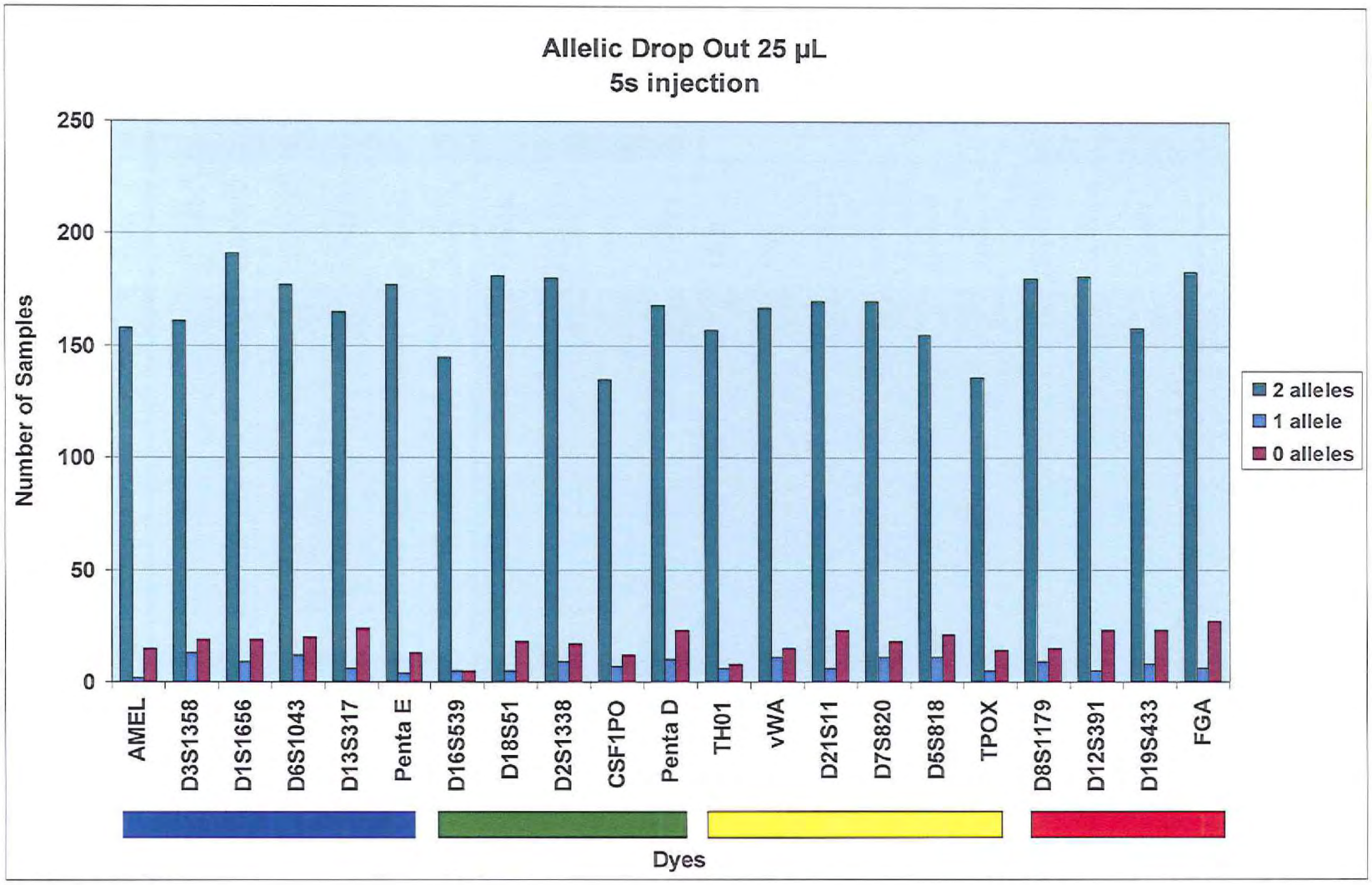


Figure 45 - Dropout events for samples amplified at 25 µL 5 s injection time.

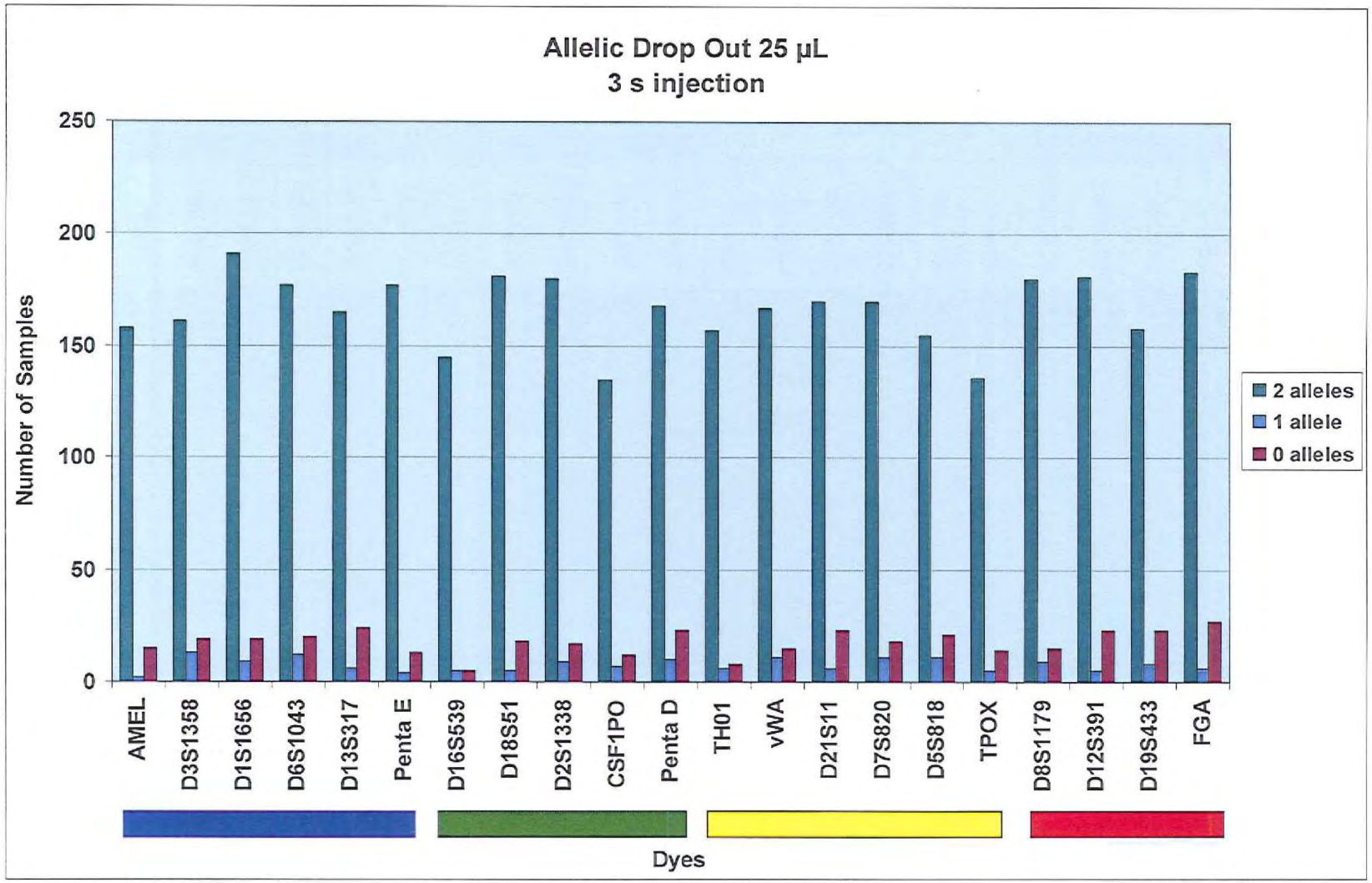


Figure 46 - Dropout events for samples amplified at 25 µL 3 s injection time.

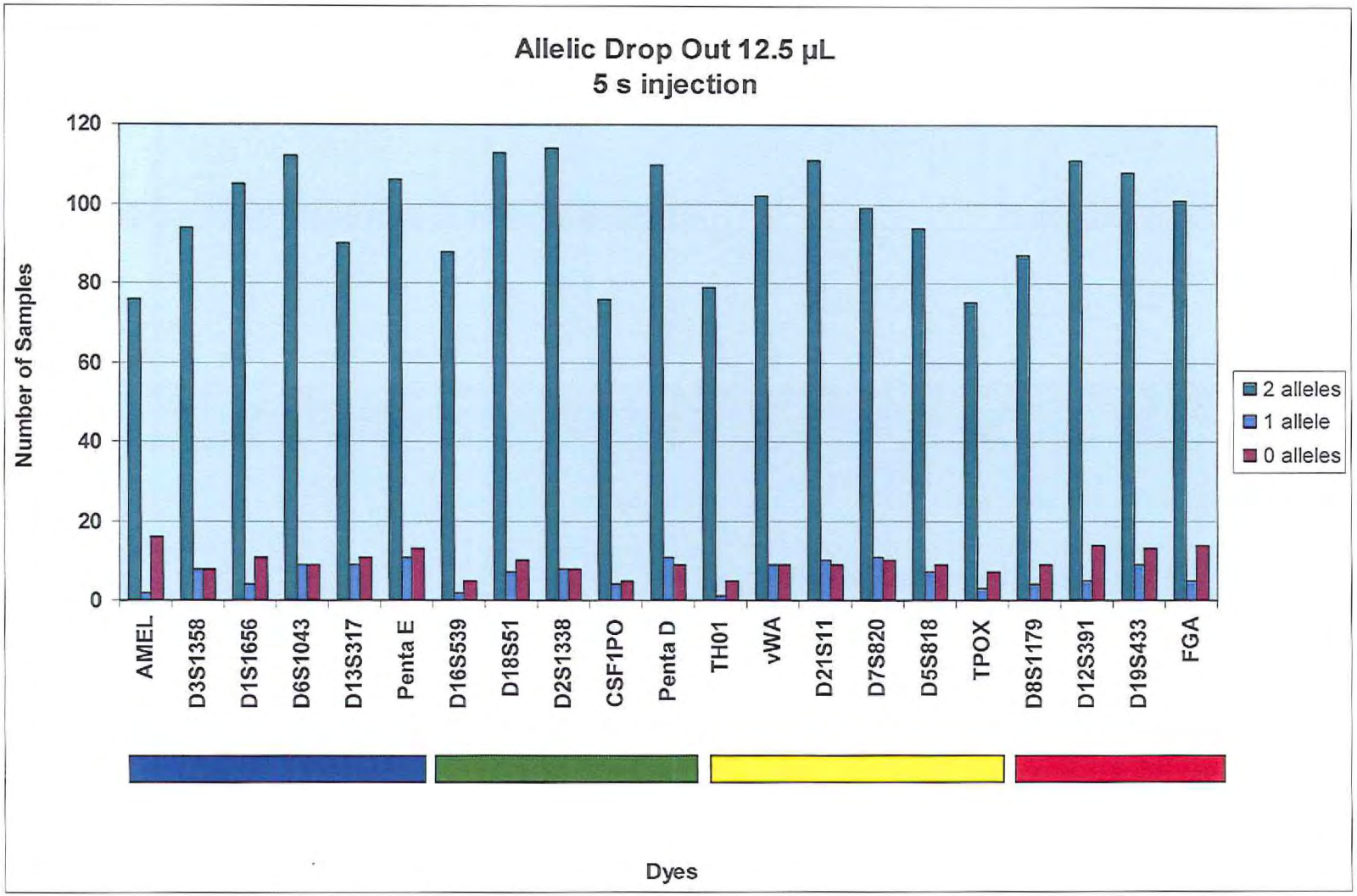


Figure 47 - Dropout events for samples amplified at 12.5 µL 5 s injection time.

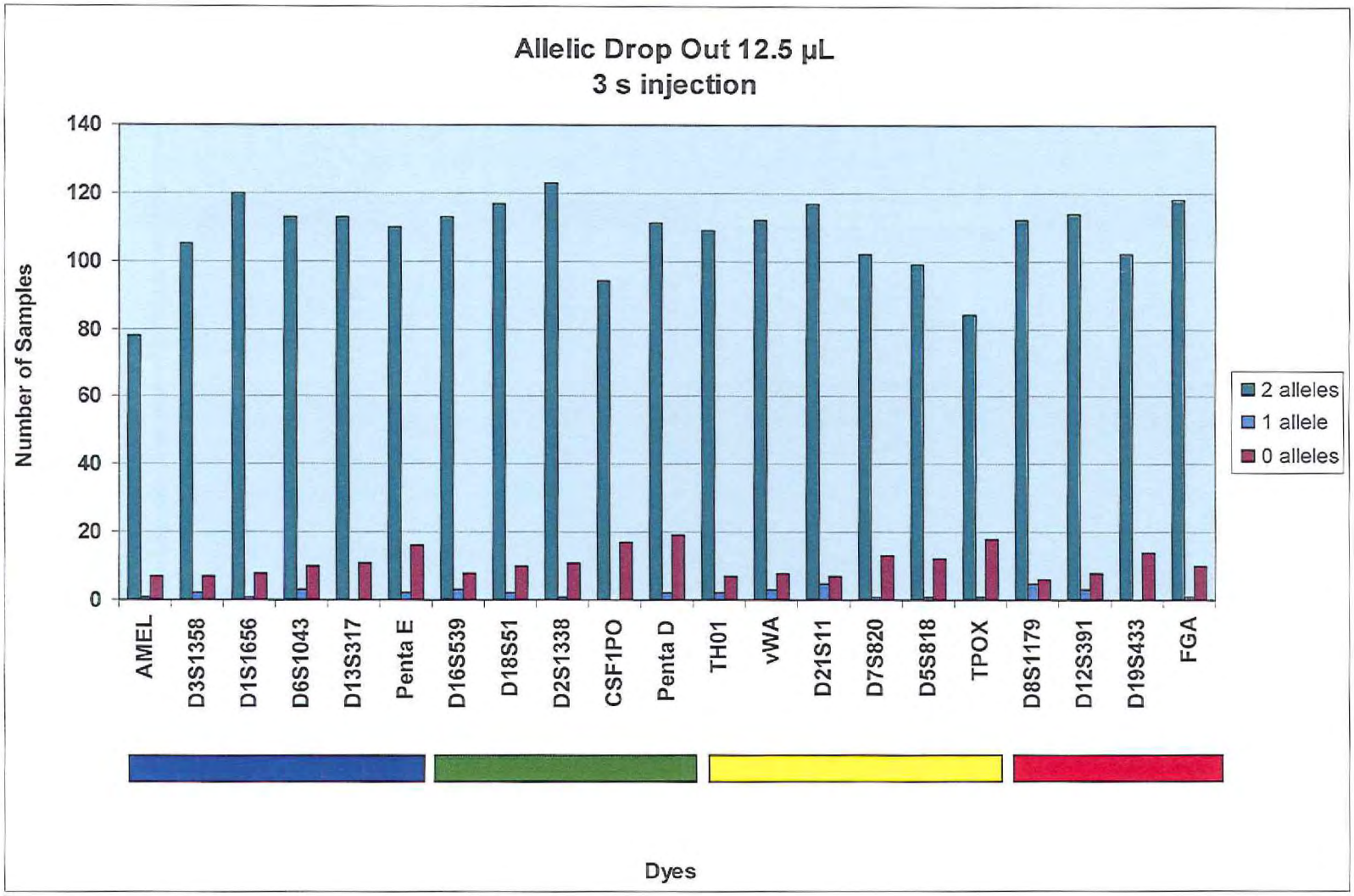


Figure 48- Dropout events for samples amplified at 12.5 µL 3 s injection time.

6.8.2 Drop out 3

Analysis for drop out 3 used the data from the baseline samples (10 x 10) and both sensitivity experiments at both 25 µL and 12.5 µL total PCR volume. There were 205 drop out events observed for the 25 µL total PCR volume compared to198 drop out events observed at 12.5 µL total PCR volume. Figure 49 shows the number of drop out events for a range of peak heights. This shows the majority of drop out events occur below 150 RFU for 25 µL total PCR volume and below 180 RFU for 12.5 µL total PCR volume.

Figures 50 - 52 show the peak heights where one of the heterozygote pairs has dropout at each DNA template. Figure 50 shows one dropout event occurred at 226 RFU for the 12.5 µL total PCR volume at a DNA template of 0.131 ng whereas no dropout events occurred at 25 µL total PCR volume at the same DNA template. The highest drop out seen for 12.5 µL total PCR volume was at 234 RFU at a DNA template of 0.025 ng and for 25 µL total PCR volume was at 193 RFU. The total number of dropout events seen for the baseline samples at 25 µL total PCR volume was 59 and 30 at 12.5 µL total PCR volume.

Figure 51 (Sensitivity 1) shows the highest drop out for 12.5 µL total PCR volume was seen at 399 RFU at a DNA template of 0.01 ng and 160 RFU at DNA template 0.01 ng for the 25 µL total PCR volume. The total number of dropout events seen for the sensitivity 1 experiment at 25 µL total PCR volume was 58 and 66 at 12.5µL total PCR volume.

Figure 52 (Sensitivity 2) shows the highest drop out for 12.5 µL total PCR volume was seen at 246 RFU at a DNA template of 0.0094 ng and 249 RFU at a DNA template of 0.0375 ng for the 25 µL total PCR volume. The total number of dropout events seen for the sensitivity 2 experiment at 25 µL total PCR volume was 89 and 102 at 12.5 µL total PCR volume.

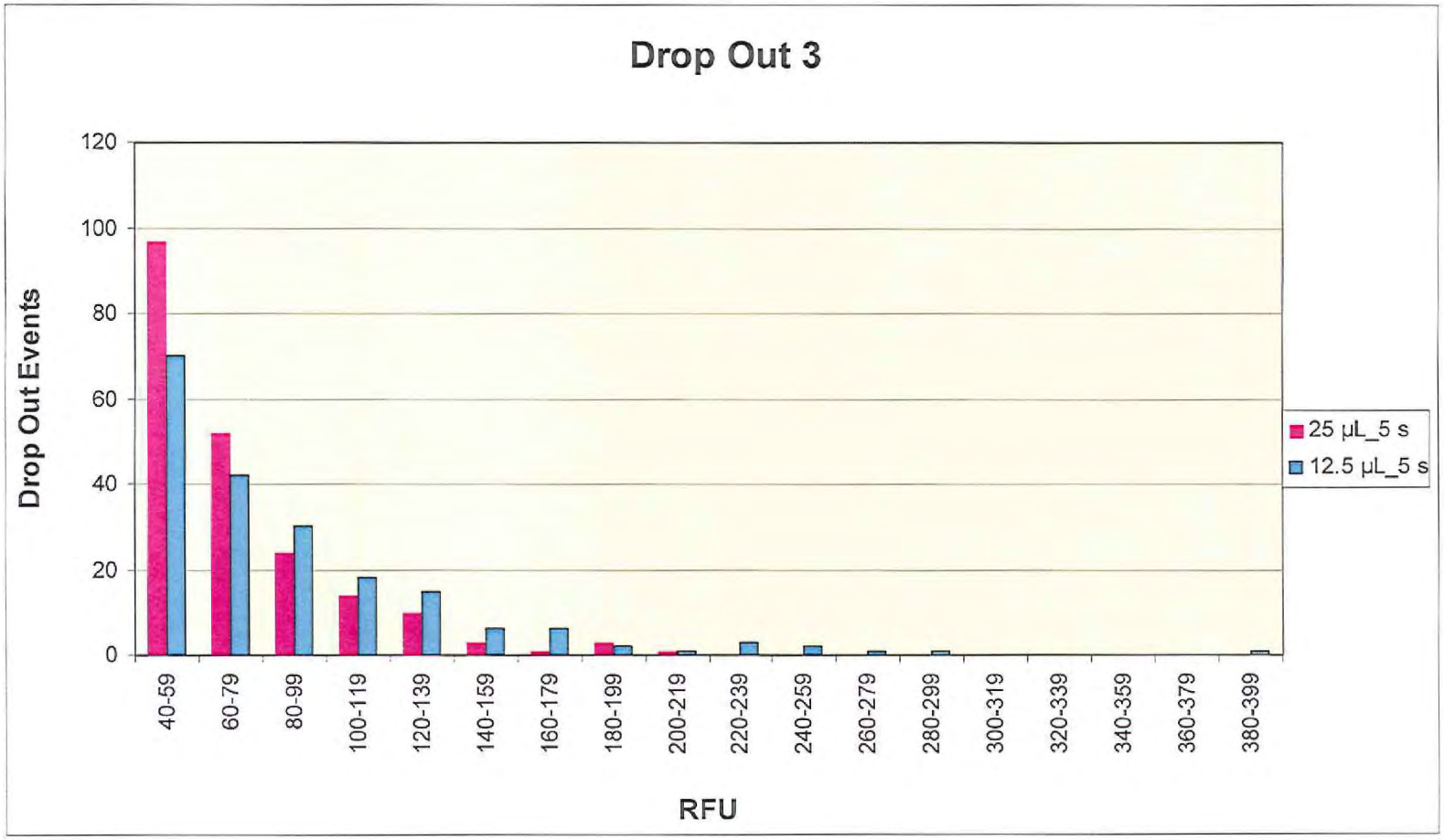


Figure 49 - Number of drop out events seen within peak height ranges at 25 µL and 12.5 µL amplifications (5 s inj)

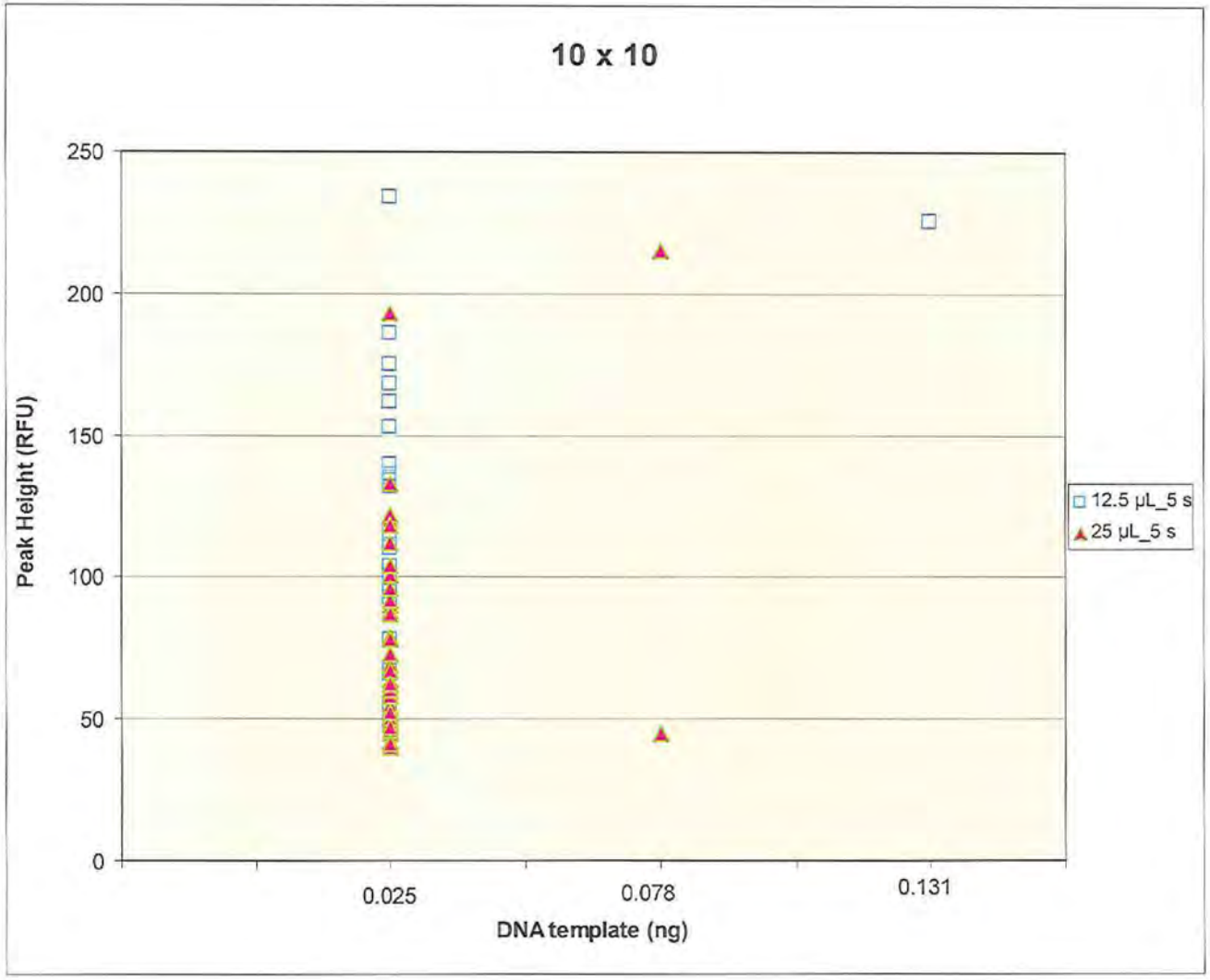


Figure 50 - Peak heights where the heterozygote pair has dropped out at different DNA templates for 12.5 µL and 25 µL using the baseline data (10 x10)

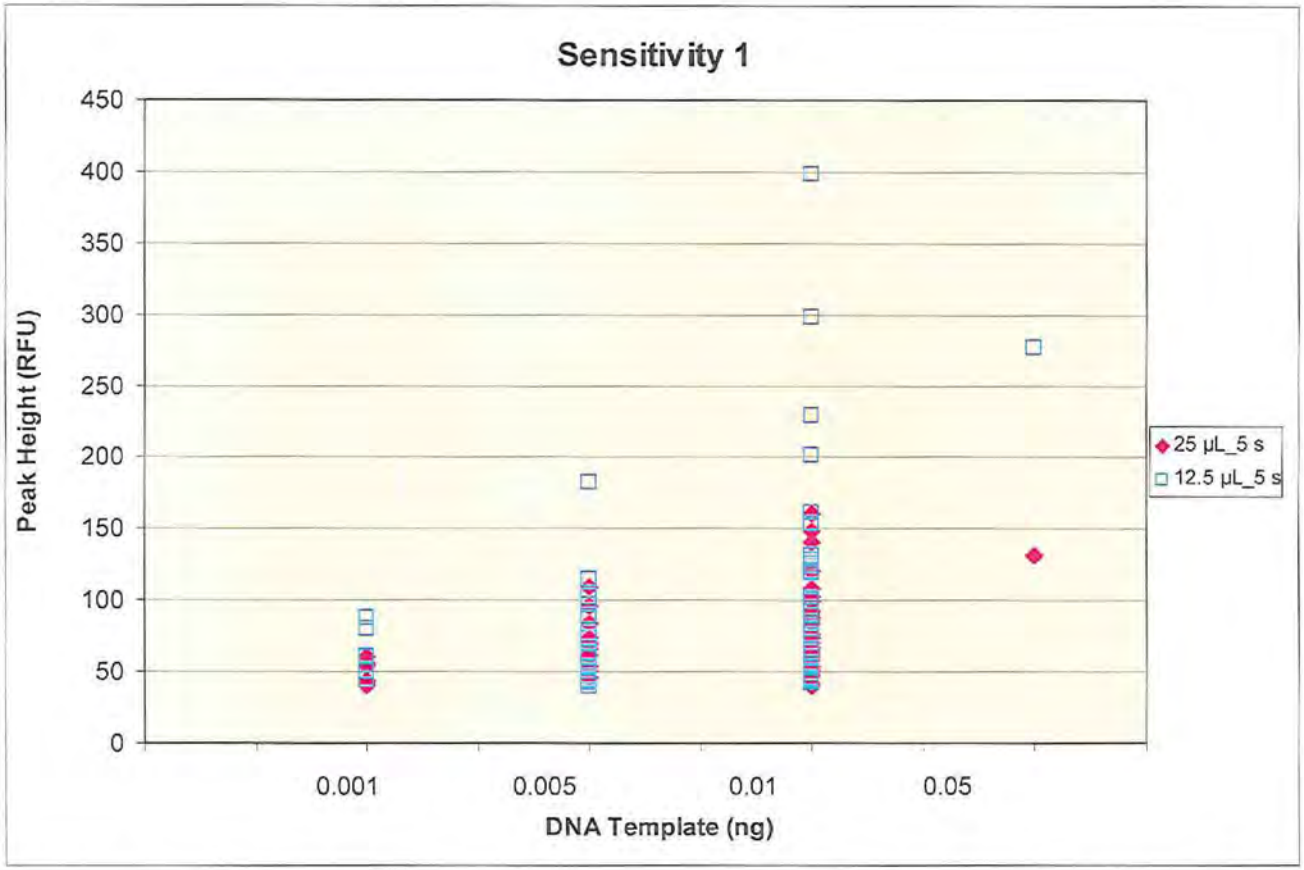


Figure 51 - Peak heights where the heterozygote pair has dropped out at different DNA templates for 12.5 µL and 25 µL using sensitivity 1 data

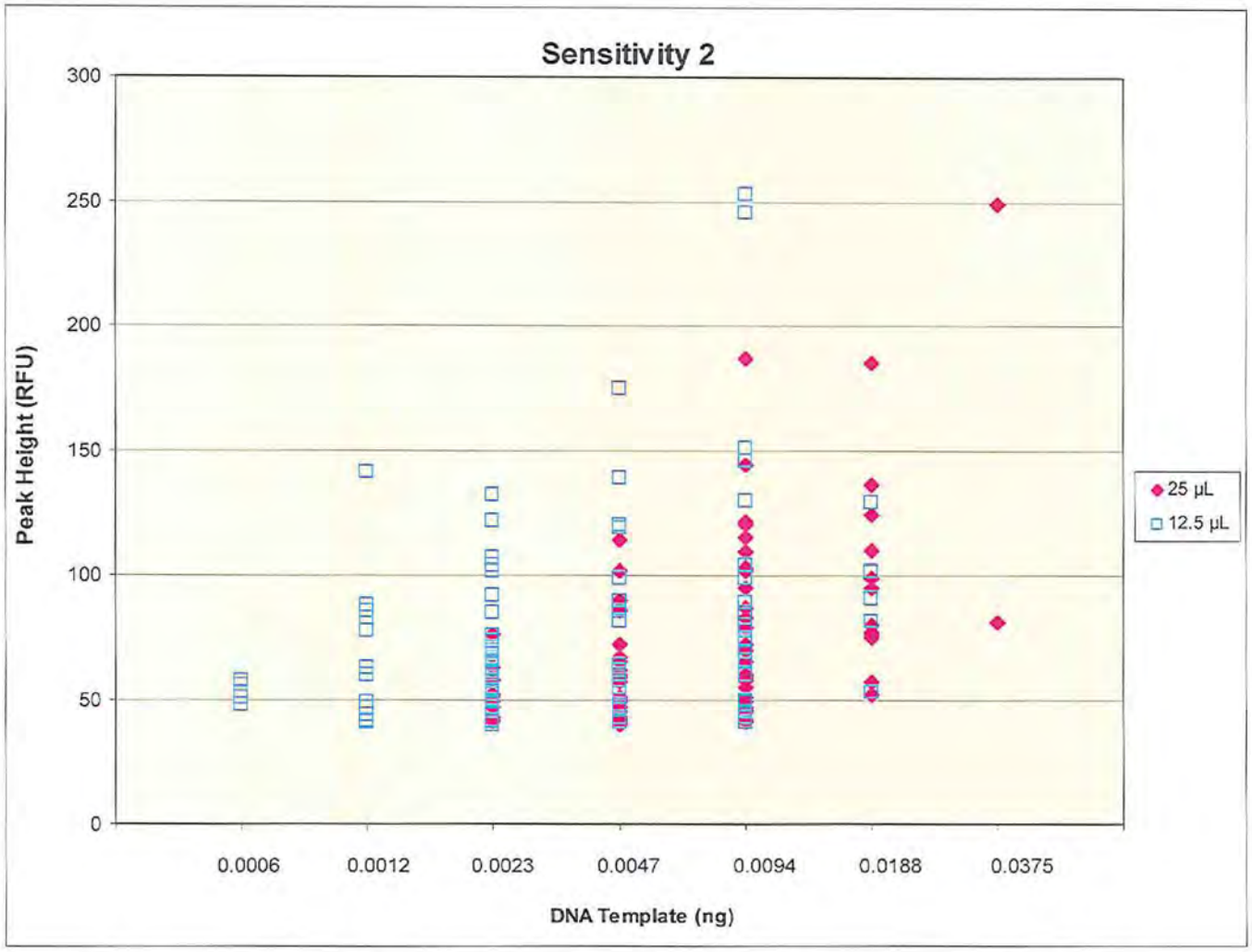


Figure 52 - Peak heights where the heterozygote pair has dropped out at different DNA templates for 12.5 µL and 25 µL using sensitivity 2 data

6.9 Mixture Studies

At a total input template of 0.5 ng, for both 25 µL and 12.5 µL, all alleles were detected for the mixtures with ratios of 1:1, 2:1 and 5:1. Any allelic imbalance was observed at a level of greater than 40%.

When the template was decreased to 0.125 ng for 5:1 mixtures, drop-out of the lower level contributor was observed for both 25 µL and 12.5 µL volumes. At this template level, allelic imbalance of down to 35% was observed for the lower level contributor at both 25 µL and 12.5 µL volumes, however, one of these peaks fell into the stutter position of the larger contributor.

When the template was decreased to 0.06 ng for 2:1 mixtures, drop-out of the lower level contributor was observed for both 25 µL and 12.5 µL volume with the partner allele being as high as 562 RFU. At this template level, allelic imbalance of down to 20% was observed for the lower level contributor and 23% for the higher level contributor.

For the remaining mixtures with ratios of 10:1, 20:1, 30:1 and 50:1 of varying template levels (maximum 0.5 ng), the lower contributors exhibited, sometimes quite marked, stochastic variation. This included drop-out with peaks up to 392 RFU and allelic imbalance as low as 20%.

The data in Table 21 and Table 22 show the approximate mixture ratio of the profile compared with the mixture ratio of the sample. For the 2 person mixtures this was averaged over all loci where there was no allele sharing between the two contributors and where the alleles did not fall into a stutter position. For the 3 person mixtures, the ratio was averaged over all loci where there was no allele sharing between the three contributors, however it was not possible to exclude loci where the alleles fell into stutter positions as there were no loci fulfilling this criteria. It was not possible to accurately calculate mixture ratios for the four person mixtures.

The data shows that the mixture ratio after DNA amplification is approximately equal to the mixture ratio of the initial sample for both 25 µL and 12.5 µL volumes at all ratios. The mixture ratio deviates more as the ratio increases most likely due to the stochastic effects of the lower contributor. The mixture ratios for the 25 µL volume amp appear to be slightly lower than for the12.5 µL volume amp.

Although mixture ratios have not been calculated for the four person mixtures, the alleles obtained are consistent with expected profiles.

Table 21 - 12.5 µL total PCR volume mixture studies

Mixture Ratio of Sample	Total Input Template (ng)	Approximate Mixture Ratio of Profile
2 Person Mixtures		
1:1	0.500	1.2:1
2:1	0.500	2.2:1
	0.060	2.9:1
5:1	0.500	6.1:1
	0.125	6.1:1
10:1	0.500	12:1
	0.125	11:1
20:1	0.500	24:1
	0.250	16:1
	0.125	19:1
30:1	0.500	21:1
50:1	0.500	35:1
	0.250	49:1
	0.125	Unable to calculate
3 Person Mixtures		
5:2:1	0.500	4.2:1.3:1
	0.125	Unable to calculate
10:5:1	0.500	13:9.1:1
20:10:1	0.500	10:5.7:1
	0.125	Unable to calculate
4 Person Mixtures		
5:3:2:1	0.500	Unable to calculate
	0.125	Unable to calculate

Table 22 – 25 µL total PCR mixture studies

Mixture Ratio of Sample	Total Input Template (ng)	Approximate Mixture Ratio of Profile
2 Person Mixtures		
1:1	0.500	1.2:1
2:1	0.500	1.8:1
	0.060	1.7:1
5:1	0.500	4.1:1
	0.125	4.8:1
10:1	0.500	8.5:1
	0.125	6.3:1
20:1	0.500	22:1
	0.250	17:1
	0.125	10:1
30:1	0.500	15:1
50:1	0.500	26:1
	0.250	9.2:1
	0.125	6.7:1
3 Person Mixtures		
5:2:1	0.500	2.9:1.5:1
	0.125	2.7:1.1:1
10:5:1	0.500	7.4:5.4:1
20:10:1	0.500	10:6.4:1
	0.125	10:4.7:1
4 Person Mixtures		
5:3:2:1	0.500	Unable to calculate
	0.125	Unable to calculate

7 Conclusion

The results from this validation support that Promega's PowerPlex®21 System is suitable for analysis of STRs.

Despite slight differences observed between the two 3130xl analysers, the use of single LOD and LOR of 16 RFU and 40 RFU is more practical for use in DNA Analysis.

The PowerPlex21® System displays full concordance with all alleles observed in testing being concordant.

The three national population datasets (Caucasian, Aboriginal and SE Asian) created collaboratively within Australia, have been externally validated and will be implemented in conjunction with STRmix™ for statistical interpretation.

12.5 µL total PCR volumes gave higher peak heights than their 25 µL counterparts at the same DNA template.

The PowerPlex®21 system is a very sensitive amplification kit when used at either the standard amplification volume (25 µL) or reduced volume amplification (12.5 µL); however the increased sensitivity does not necessarily result in more reliable information.

The two sensitivity experiments explored the range on DNA template inputs from very large inputs (4 ng) to very small inputs (0.00059 ng). Within this validation complete PowerPlex® 21 DNA profiles were obtained with as little as 0.01875 ng of template DNA. However, the PHR data indicate that as the amount of template DNA decreases the μ_{PHR} decreases and σ_{PHR} increases. The risk of type 2 errors is greatly increased from template DNA amounts of less than 0.132 ng for both 25 µL and 12.5 µL total PCR volumes, which is supported by the experimental drop out data.

The data presented within this report indicates that input templates less than 0.132 ng total DNA (concentrations 0.0176 ng/µL if using 12.5 µL total PCR volume or 0.0088 ng/µL for 25 µL total PCR volume) may result in increased stochastic effects.

As previously documented in DNA Analysis[55, 56], the Quantifiler™ Human DNA Quantification kit gives an estimate of the DNA concentration. Careful consideration of the DNA profile is required before reporting because the precision within a quantification method and between different quantification methods may vary.

For the range of DNA templates specified above, significant differences between 12.5 µL and 25 µL total PCR volumes was not observed. The use of 12.5 µL total amplification volume as the default protocol with DNA Analysis is indicated. The disadvantage of the 12.5 µL total PCR volume are the physical constraints of the process i.e. a maximum of 7.5 µL of sample can be used compared with 15 µL for the 25 µL total PCR volume. However, higher peak heights and the cost savings associated with

reduced volume amplifications even with additional processes to increase the sample concentration, mitigate the disadvantage.

The implementation of PowerPlex® 21 for amplification of DNA extracts will coincide with the implementation of STRmix™. The combination of the two processes will apply a continuous biological model rather than a binary model to DNA interpretation. STRmix™ models stutter, drop out, heterozygote balance and homozygote threshold for case work samples.

The rate of drop in events has been calculated for both total PCR volumes and will be implemented in conjunction with STRmix™.

At a total input template of 0.5 ng, for 25 µL and 12.5 µL total PCR volumes, all alleles were detected for the mixtures with ratios of 1:1, 2:1 and 5:1.

For the remaining mixtures with ratios of 10:1, 20:1, 30:1 and 50:1 of varying template levels (maximum 0.5 ng), the lower contributors exhibited, sometimes quite marked, stochastic variation.

Mixture interpretation is beyond the scope of this validation and will be dealt with in the STRmix™ validation report.

8 Recommendations

1. A common LOD/LOR (16 RFU/40 RFU) will be used for both 3130*xl* instruments as outline in section 6.4.
2. The default total PCR volume will be 12.5 µL. Samples can also be amplified at 25 µL total PCR volume.
3. Initially samples with concentrations below 0.01 ng/µL will not be routinely processed in the first instance. If necessary, these samples may undergo post extraction concentration via centrifugal filter concentration procedure to increase the concentration or re-amplify at 25 µL total PCR volume.
4. Initially samples with concentrations between 0.01 ng/µL and 0.0176 ng/µL will not be routinely amplified. These samples are considered as candidates for post extraction concentration via centrifugal filter concentration procedure to increase the concentration to the point that stochastic effects are minimized.
5. Initially samples with concentrations between 0.0176 ng/µL and 0.0244 ng/µL will be amplified and assessed for stochastic effects during case management to ensure the suitability of these DNA profiles for reporting.
6. Samples with concentrations above 0.0244 ng/µL will be routinely amplified.
7. AI_{TH} to be set at 40% and Hom_{TH} 250 RFU for extracted reference, environmental and quality control samples amplified at 12.5 µL total PCR volume.

8. AI_{TH} to be set at 45% and Hom_{TH} 200 RFU for extracted reference, environmental and quality control samples amplified at 25 µL total PCR volume.
9. Adoption of the national Caucasian, Asian and Aboriginal sub-population datasets that DNA Analysis contributed to as part of this validation for use within statistical calculations.
10. Adoption of the locus specific stutter filter as per results section.
11. Thresholds listed in 7 and 8 are to be used as a guidelines when assessing the number of contributors in a mixture.
12. A post implementation review must be performed to review the appropriateness of points 3 – 8. The review will at minimum examine the outcomes of samples amplified within 0.0176 ng/µL and 0.0244 ng/µL concentration range. Similarly, all of the extracted reference samples will be reviewed with regards to the AI_{TH} and homozygote threshold.
13. A default injection time of 5 s is to be used.

9 Notes on this version

The initial version of the validation published results that had been obtained from multiple capillary electrophoresis injection times (5 s or 3 s injection times). The amount of DNA injected into the capillary during capillary electrophoresis is affected by a number of factors including injection time [57]. A reduction in the injection time will decrease the amount of DNA injected (relative to a longer injection time) and therefore the peak height RFU will be decreased.

As the injection time was the only factor that varied, it is assumed that a reduction in peak height RFU is the only effect on the results.

Appendix A below is a summary of each experiment and the injection time used. A decision was made by the Forensic DNA Analysis Management Team not to re-analyse experiments where the peak height RFU were not significant or did not impact the final results. These experiments were:

1. Population Datasets (Experiment 5.1). The allele calls are not affected by the time of injection.
2. Concordance (Experiment 5.2). As with the Population datasets, the allele calls are not affected by the time of injection.
3. Stutter (Experiment 5.7). The amount of stutter product generated is proportional to the allele peak height.

The original data published for the experiments below was a mix of results obtained from 5 s and 3 s injection times. Re-analysis was required to separate these data. As the net effect of a reduced injection time is lower peak height RFU; combination of these data would be expected to skew results slightly for lower template inputs. This is because if the sample is

close to the limit of reporting when injected for 5 s, the sample is likely to partially or fully drop out when injected for 3 s. The experiments that were re-analysed were:

1. Drop out 2.
2. Drop out 3

The original data published for the experiments relating to Peak Balance was restricted to data obtained for 5 s injection times. Re-Analysis was performed on data already obtained at 3 s injection time but not previously analysed.

1. Peak Balance, additional results are published for 3 s injection times. (See section 6.7)

New experiments performed:

1. Baseline, additional baseline experiments on 3130xlB at 5 s injection time was performed and results are published in the summary report[25].

This version of the validation report also incorporates updated stutter thresholds to incorporate the -2 repeat thresholds.

Additional Reference

After this internal validation was initially published, a developmental validation for the PowerPlex 21 system kit was published [58]. This developmental validation covered a wider spectrum than was required of our internal validation including species specificity, polymerase titration, Mastermix concentration, magnesium concentration, primer concentration. The most relevant to our internal validation are discussed below.

Cycle number:

The authors of this study varied the cycle number. For extracted DNA they examined cycle numbers from 28 – 32 cycles. Higher cycle number with higher concentrations of sample may cause poor balance due to preferential amplification. The results we present here are consistent with these results.

While this validation did not examine the variation in results if the PCR cycle number was varied, the observation of poor balance and preferential amplification at high template amounts was observed in our validation.

Reaction volume:

Unlike our validation, which was designed to validate multiple reaction volumes; this developmental validation only amplified the same DNA concentration (e.g. 500 pg / 25 µL, 250 pg/ 12.5µL and 125 pg / 6.25µL). The article presents results consistent to our results; reduced volume amplification is possible with this kit but increased stochastic effects and inhibitor concentration should be considered.

Stutter:

The authors conducted stutter calculations from 568 CTS samples but only included stutter with peak heights greater than 200 RFU to prevent artificially inflating the stutter thresholds (Personal communication from author). The results they have published are similar to our results although some of our stutter thresholds are much higher presumably because of the limited data and inclusion on stutter peak heights less than 200 RFU. This will not greatly impact on our thresholds as the stutter file used in STRmix was made from all Australian Laboratories data. However, the -2 repeat and +1 repeat thresholds are also used for providing information regarding the number of contributors in a sample for STRmix and consideration of the limited data is essential.

Artefacts:

Author observed similar artefacts to what we have observed and is listed in the technical manual.

Sensitivity:

Within the developmental validation, templates from 50 pg to 500 pg were amplified in triplicate with more than 95% alleles called with the lowest template. They also confirmed that as the amount of template decreased the peak height ratios also decreased and the variation was greater.

We performed several sensitivity studies and had similar results.

Mixture Study:

The authors performed mixture studies at several ratios and found that up to a 1:5 mixture ratio 99% of unique alleles were called. We found similar results up to the same ratio, at the 1:5 ratio 100% of alleles were detected.

Concordance:

In this study they examined 32 382 alleles and found two discordant calls (one @D7S820 8,9.3 that should have been 8,11, and one @Amel Y,Y that should have been X,Y). We did not observe any discordant allele calls within our experiments although the total number of alleles compared was much lower (.4644 alleles in our study).

Final notes:

Although data was re-analysed for completeness and accuracy, the application of this data is for use in reference samples and determination of number of contributors to a mixture. Model maker is used to determine parameters for STRmix analysis.

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Appendix A - Index to Supplementary data

The summary of experiment is documented in: **PowerPlex 21 summary of experiments v2.0.xls**

Reference	Description	Project	Version 1	Version 2
5.1.1	Aboriginal & Torres Strait Islander dataset	101	Aboriginal-Torres Straits Results.xls	Project 107 - 5.1 v2.0.xls
5.1.2				
5.1.3	Caucasian dataset		Caucasian results.xls	
5.1.4	South East Asian dataset		PP21_SEAsian_Population data.xls	
5.2	Concordance	104	PowerPlex_21 to CTS manufacturer results comparison.xls	Project 107 - 5.2 v2.0.xls
			Powerplex21_Concordance_Allele Table_PowerPlex_21_IDX_v1.0.xls	
5.3	Baseline determination	102	Baseline_3130xlA-original.xlsx	Project 107 - 5.3 v2.0.xls
			Baseline_3130xlA.xlsx	
			Baseline 3130xl A_rerun.xls	
			Baseline_3130xlB - original.xlsx	
			Baseline_3130xlB.xlsx	
			Baseline 3130xl B_rerun.xls	
			Baseline 3130xl A Half.xls	
			Baseline 3130xl B Half.xls	
5.4	Sensitivity 1	100	DA for PowerPlex21_Exp1_Exp3_40RFUs	Project 107 - 5.4 v2.0.xls
5.5	Sensitivity 2		Low quant values.xls	Project 107 - 5.5 v2.0.xls
5.6	Drop in	105	Baseline_3130xlA-original.xlsx	Project 107 - 5.6 v2.0.xls
			Baseline_3130xlA.xlsx	
			Baseline 3130xl A_rerun.xls	
			Baseline_3130xlB - original.xlsx	
			Baseline_3130xlB.xlsx	
			Baseline 3130xl B_rerun.xls	
			Baseline 3130xl A Half.xls	
			Baseline 3130xl B Half.xls	
5.7	Stutter	102	10x10 CW data full volume - stutter data	Project 107 - 5.7 v2.0.xls
			12.5uL n-1_n+1 Summary	
5.8	Peak Balance	102	Alth_Homoth_summary.xls	Project 107 - 5.8 v2.0.xls

			Pk balance_both_final.xls	
			Alt_Homozygote_b_20130719.xls	
			PP21_10x10_half_B_20130722_Results Table_PowerPlex_21_IDX_v1.1.1.xlsx	
5.9.1	Drop out 1	102	Dropout1_heat maps.xls	Project 107 - 5.9 v2.0.xls
5.9.2	Drop out 2	102	Allelic drop out_full20130718.xls	
			Allelic drop out_half20130717.xls	
5.9.3	Drop out 3	102	Drop out20130718.xls	
5.10	Mixture studies	103	Mixtures_val_2012.xls	Project 107 - 5.10 v2.0.xls

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Procedure for Change Management in Forensic DNA Analysis

1 Purpose and Scope

This document describes the change management procedure that is to be used within Forensic DNA Analysis, to ensure that all process changes and projects occur in a controlled and timely manner. This procedure applies to all process changes or projects that:

- involve the validation/verification of equipment
- involve the validation/verification of technical procedures
- are projects with external funding
- are internal projects (minor or major) which impact on sample reporting/processing
- involve major LIMS function/configuration changes
- impact on multiple stakeholders
- require staff training to be implemented
- significantly alter workflow procedures

This procedure does not apply to:

- routine document updates/alterations
- minor technical changes which do not impact on sample reporting/processing (e.g. changes in specimen type, storage configuration changes)

As an appendix to this document - is a checklist that can be used to guide staff on how they might approach a new idea/observation. It will assist in establishing if it should be recorded as an emerging/novel practice, as a minor change, or as a full project/change management.

2 Definitions and Abbreviations

For a comprehensive list of abbreviations refer to QIS 23849 Common Forensic DNA Analysis Terms and Acronyms.

e-sign	Electronic signature
FR:	Forensic Register
FSS:	Forensic Scientific Services
IT:	Information Technology
LIMS:	Laboratory Information Management System used to record information and track exhibits/case files.
NATA:	National Association of Testing Authorities

3 Principle

Changes within Forensic DNA Analysis have the potential to impact on our clients, on stakeholders (internal/external to FSS) and may impact on compliance with NATA. As such changes which occur with Forensic DNA Analysis must be carefully considered and

documented. There are a number of types of changes that may occur within Forensic DNA Analysis; for the purpose of documentation - these are classified into five types: administrative change, IT/LIMS change, minor project, major project, and external projects.

Administrative changes: are restricted to changes in processes/workflows that impact on documentation or administration processes only. These changes will most likely occur within the Administrative team within Forensic DNA Analysis. It does not include any changes of a technical nature.

IT/LIMS change: An IT change would apply to the introduction of new software into Forensic DNA Analysis, in some instances for upgrades in software versions or the introduction of new hardware. This type of change would require collaboration with IT services. A LIMS project would include any alteration that required a change in the LIMS function, or major configuration changes. It would not include minor changes such as storage configurations, or minor changes to specimen types etc.

Minor Project: are generally defined as projects that have a duration of <6 weeks and a budget of <$5,000. These projects have a minor impact on sample processing/reporting. Any project which major impact on workflow or sample reporting should be considered under major projects.

Major Project: are generally defined as projects that have a duration of >6 weeks and/or a budget of >$5,000. Major projects require significant planning and detailed consideration of project impacts and implementation procedures.

External Projects: is to be used for all projects which have been externally funded. Where there are no documentation requirements for an externally funded project – standard change management document as described in this document apply. For RDAC projects, RDAC documentation requirements apply (QIS 33017) with the additional requirements of:

- A change management number will be assigned within Forensic DNA Analysis
- Management Team are to indicate that they have reviewed all RDAC proposals by adding their name to the Excel sheet included within the project folder

The change management procedure utilises a three step process:

- the initial request (Step 1)
- minor change (Step 2a) OR project plan (Step 2b)
- final report, approval/implementation (Step 3)

The utilisation of these steps is dependent on the type of change (administrative, IT/LIMS, minor, major and external) and on the progression of the change management process. Refer to Section 4 for details.

4 Actions

Prior to the preparation of any change management documentation it is recommended that ideas are discussed at the work unit level to determine the merit of each idea or proposal. If the process of change management is initiated it will need to follow the documentation requirements as listed in sections 4.1 to 4.8 and the workflow as shown in Appendix 1.

*An exception is made for projects that are a mandatory requirement for the laboratory e.g. validation/verification of a new process or equipment item. In these cases it is possible to proceed directly to a full project plan (section 4.3).

For large projects an overarching project number is allocated (by quality) to the work, and sub-projects may then be allocated "a letter" such that sections/parts of a project can be signed off separately. For example in validating an amplification kit a project number 1234

may be applied (for the overarching project), with sub-projects 1234a – referring the sensitivity testing, 1234b referring to concordance, 1234c referring to thresholds etc.

In cases where supplementary testing for a project is required (post-sign off), if the data is an extension of previous work - it may also be appropriate to allocate the supplementary work "a letter" ie. part b of the same work. If the supplementary work is substantially different in topic or content a new project number should be allocated.

All project documents are to e-signed and locked at completion. Refer to Appendix 5 for e-sign procedure.

Technical Review:
For major projects and for validations it is a requirement for the project to have a technical reviewer. The role of the technical reviewer is to 'peer view' critical technical aspects of the project (e.g. new instrument programs/settings, new analytical procedures) and/or to review data analysis with the project (e.g. Excel data transformations, formula's and calculations etc.). The technical reviewer/s are nominated by the team leader and/or management team at project proposal stage (section 4.3). The technical review is completed either during the project or at the completion of the laboratory work and data analysis - but prior to final report being presented to the management team. The technical review should provide to the Management Team as a written document that outlines the aspects of the project reviewed and general findings (Refer to Appendix 2 for template)

Communication:

- For large projects regular project updates should be given by the project leader (or delegate) to the management team. This will allow the management team to ensure that the project is meeting all requirements (NATA, internal needs etc), and that they have a full understanding of the project prior to final report preparation and sign off.
- When projects are complete - presentations should be made at team meetings so that all staff have an awareness of new processes and technology as it is released.
- Appropriate communications should be made at time of implementation (emails to applicable staff, additions to minor change registers, records to quality etc).

4.1 Initial Request (Stage 1)

Change requests can be initiated by any staff member within Forensic DNA Analysis, and are to be recorded on an **Initial Request Form** (QIS 31543). Submission of an initial request requires the following actions:

- Complete the **Initial Request Form** (QIS 31543). The initiator is required to complete the blue sections of the form only.
- Initiator is to email the Quality Team and Line manager (of the person initiating the request) with the network location of the document so it can progress.
- Quality will allocate the request a proposal number
- The Line Manager is to complete the red sections of the form, create a PDF of the request form and e-sign the document. Store/save the document to the appropriate project folder in I:\Change Management

The Line Manager will assess the initial request recommending either:

- **Abandon process at Initial Request** (Refer to section 4.7)
- **Proceed to Step 2:**
  - **Minor Change** (Refer to section 4.2)

    or

- **Project Proposal** (Refer to section 4.3)

If the line manager wants to recommend proceeding to a full project proposal – they will need to seek Management Team approval.

If the initial request is abandon - no further action or documentation will be required.

On completion of the initial request form (e-signed and locked), the line manager is to advise quality team

4.2 Minor Change (Stage 2a)

The minor change form is used to document the purpose, method and date of change. If the Line Manager recommends that the change management is to proceed as a minor change, the project initiator must complete the blue sections of the **Minor Change Form** (QIS 31548) and submit it to their line manager. In some circumstances a small amount of experimental data may be included within a minor change – where the data is used for decision making purposes.

The Line Manager must then complete the following actions:

- **E-sign** the minor process change document (QIS 31548). Store/save the document to the appropriate project folder in I:\Change Management\Minor Change Forms - completed
- Add the change to the **Minor Change and emerging or novel practices** register located in: I:\Change Management\Change Register - Minor Changes and emerging or novel practices.xls
- **Inform the quality team and all stakeholders of the change** e.g. team meetings or email
- Update SOPs etc. if required
- Inform the Quality & Projects Senior Scientist to complete the process

The Quality & Projects Senior Scientist must:

- **E-sign and lock** the minor process change document (QIS 31548)
- Ensure all above actions have been completed by the line manager.

4.3 Project Plan (Stage 2b)

If the Management Team recommends that a change management should proceed as a full proposal (administrative, IT/LIMS, major change or external project) the project leader is required to complete the following project documents:

1. **Project Risk Assessment Document** (QIS 22872): A risk assessment must be completed documenting the risks of the project for each team.

2. **Change Management Project Proposal (experimental design) Document**: This document should cover all aspects of what the project is proposing to do: It should include an introduction to the project (including literature review), purpose/background, methodology and experimental design (either laboratory experiments or data analysis as applicable) and a detailed materials and methods section.

   Refer to QIS 23402 for writing guidelines and template for the project proposal. These project proposals will essentially constitute the introduction and materials and methods section of the projects final project report

This document must be prepared and submitted to the Forensic DNA Analysis Management Team along with the Project Risk Assessment Form (QIS 22872).

3. **Consider ethics requirements**: QIS 33268 Police Services – Human Ethics Review Checklist, it may impact on the projects methodology, and ethics approval maybe required before the project can start.
4. **(Optional) Project Budget** (QIS 31052): A budget can be prepared and submitted to the Forensic DNA Analysis Management Team - with the project proposal. A budget template is provided in QIS 31052.

For a new piece of equipment, new chemical or new process a formal risk assessment (QIS 29106) will be needed in addition to the project risks that are outlined in QIS 22872 The formal risk assessment addresses workplace health and safety risks and the project risk assessment is in relation to business risks.

After all project documents have been prepared (as listed above); risk assessments (if applicable) and LIMS documentation completed (if applicable) email your Line Manager and Quality Team [redacted] and advise them of the location of the documents in I:\Change Management. The Line Manager/Project leader will submit the documentation to the Forensic DNA Analysis Management Team for consideration (Refer the section 4.4), with a due date for feedback.

4.4 Forensic DNA Analysis Management Team – Consideration of Project Proposal

The Forensic DNA Analysis Management team will consider the change management project proposal documents as outlined in section 4.3. It is not necessary for all Management Team members to read and approve every proposal; however a quorum of the Management team must approve the proposal. The quorum must include the Managing Scientist, Team Leaders, Quality and Projects Senior Scientist, Senior Scientist that has Line Management of the staff/project and Senior Scientist/s of areas significantly affected by the project. For major projects and validations a technical reviewer suggestion should also be provided to the management team for consideration (Refer to section 4).

Consideration of the proposal should include:

1. *A determination of the impact of the proposed change on all stakeholders*
2. *Cost/Benefit Analysis of the project*
3. *Risk Assessment (Workplace Health & Safety and Business Risks)*
4. *A communication plan for all project participants and stakeholders*

The Forensic DNA Analysis Management Team will then make a recommendation as follows:

- **Implement proposal.** If the proposal is approved, the project documentation will be e-signed by the Management Team. The project leader/appointed staff can initiate the project.
  - Project work must be conducted by a technically experienced and competent person (Refer QIS 10662)
  - For projects that are >3 months, the Senior Scientist Quality and Projects will meet with each project team ~ every 2 weeks to ensure project progression, and to provide advice and resources as required.
- **Implement proposal after change.** If the Management Team requires additions/edits to the project proposal, the Management team will return the document to the project leader/appointed staff with feedback. The project

documents will need to be edited and resubmitted (as per section 4.3.) before further consideration by the Management Team.
- **Abandon process.** Refer to Section 4.7 for details.

After the due date for feedback project leader/line manager should:
- Make edits (if required).
- Create a PDF of the project proposal and project risk assessment documents
- Store/save the document to relevant project folder in I:\Change Management

Management team must:
- Provide feedback on the proposal
- Complete the risk assessment

4.5 Implementation and Final Report (Step 3)

On completion of the change management project - a final report is required, this is usually written by the project leader (Refer to QIS 23402 for report preparation details). A Technical Review - if it is required (Appendix 2), and an Implementation Plan (Refer to Appendix 3) must also be prepared. The implementation plan will be a list of the steps required to be completed either before the change is implemented, or shortly after implementation. Although a proposal may not be implemented on completion, a basic implementation plan that can be refined closer to implementation should still be completed and submitted. On completion of the report, technical review and implementation plan, they are to be forwarded by email to your Line Manager. The Line Manager/project leader will submit the final report, technical review and implementation plan to the Forensic DNA Analysis Management Team for consideration/acceptance.

If the final report is accepted by the Forensic DNA Analysis Management Team it will be e-signed and the project/change management process closed. If the Management Team requires additions/edits to the final report, it will be returned to the project leader/appointed staff with feedback. The final report will need to be edited and resubmitted for consideration by the Management Team.

After the due date for feedback project leader/line manager should:
- Make edits (if required).
- Create a PDF of the project proposal and project risk assessment documents
- Ask the management team to e-sign the document.
- Store/save the document to relevant project folder in I:\Change Management

Management team must:
- Provide feedback on the final report
- E-sign the documents as/when requested by the project leader/line manager.

After acceptance of the final report the Forensic DNA Analysis Management team will recommend that the:

- **Change is implemented** into routine use (Refer to Appendix 3 for implementation plan for project leaders).
- **Change is accepted but will be implemented at a later date** (Refer to Appendix 3 for implementation plan for project leaders).
- **Change is abandoned** (Refer to Section 4.7 for details).

After completion of the project, all stakeholders must receive communications about the findings and outcomes of the project. This may include presentations at meetings, or the provision of final reports to stakeholders. For significant projects, a summary of the project is to be presented at team meetings.

On completion of the final e-signature by the Managing Scientist a communication is to be sent to the Quality team so that they can ensure all documents have been finalised. Quality team can then lock and store data files by loading them to the Forensic Register.

**Please note: in the event the work is to be published, please consider if the publication needs to reviewed by the FSS Ethics committee. Refer to QIS 32177 FSS Publication checklist.*

4.6 Responsibilities in Signing Documentation

When a project proposal or report is submitted for review, it is the responsibility of the reviewer to ensure that all feedback is provided by the due date. Any feedback provided after the due date may not be considered (based on the merit of the feedback).

It is acceptable for a reviewer from the Forensic DNA Analysis Management Team to seek advice from other members of staff where it is deemed appropriate (e.g. where another person may have more experience in the subject of the report). In this instance, it is the responsibility of the person seeking the advice to provide the feedback to the project officer and to do so by the due date.

4.7 Abandoned/Cancellation

Should a change proposal not be approved, or if at any time the change is no longer required, the change management process may be abandoned/cancelled. This shall be recorded on the change management documents (to be forwarded to the Quality Team). If the project is abandon mid-way through a process an electronic file note can be created to detail the date and reason for project cessation.

It is possible to re-start abandon change management processes at a later date, and there are relevant sections in the change management forms to record a restarted process.

4.8 Recording Feedback

Project feedback, including feedback on project proposal and reports, is to be tabulated and stored in the relevant change management folder (under the appropriate project number folder).

All email communications regarding the project are also to be stored in the relevant change management folder.

5 Records

- All change management documentation (plans, reports, data etc.) are to be stored electronically in a network drive (e.g. I:Drive)
- On completion of projects all records (plans, reports, excel files etc) are to be stored in Forensic Register. To store records in FR:
    - Create new FR case Job Type=Research
    - Subject/Complainant=Project number and short title
    - Offence Class=Miscellaneous
    - Location=Forensic DNA Analysis Quality
    - Project documents loaded as an examination summary

6 Associated Documentation

QIS: 10662 FSS Guidelines for Method Validation
QIS: 22872 Project Risk Assessment for Change Management in Forensic DNA Analysis
QIS: 23401 Forensic DNA Analysis Validation and Verification Guidelines
QIS: 23402 Writing Guidelines for Validation and Change Management Reports
QIS: 29100 Health & Safety Risk Assessment Form
QIS: 29106 Risk Management Guideline – conducting and evaluating Health and Safety risk assessments
QIS: 31052 Forensic DNA Analysis - Change Management Budget
QIS: 31543 Initial Request Form for Change Management in Forensic DNA Analysis
QIS: 31548 Minor Process Change Form for Change Management in Forensic DNA Analysis
QIS: 32177 Human Ethics Review Checklist - FSS Publications
QIS: 33017 FSS Research and Development short form
QIS: 33268 Human Ethics Review Checklist - Police Services
QIS: 33333 Participant Information and Consent Form (PICF) - Common Biological Samples
QIS: 33334 Participant Information and Consent Form (PICF) - Semen Samples
QIS: 33335 Participant Information and Consent Form (PICF) - Vaginal Samples

7 Amendment History

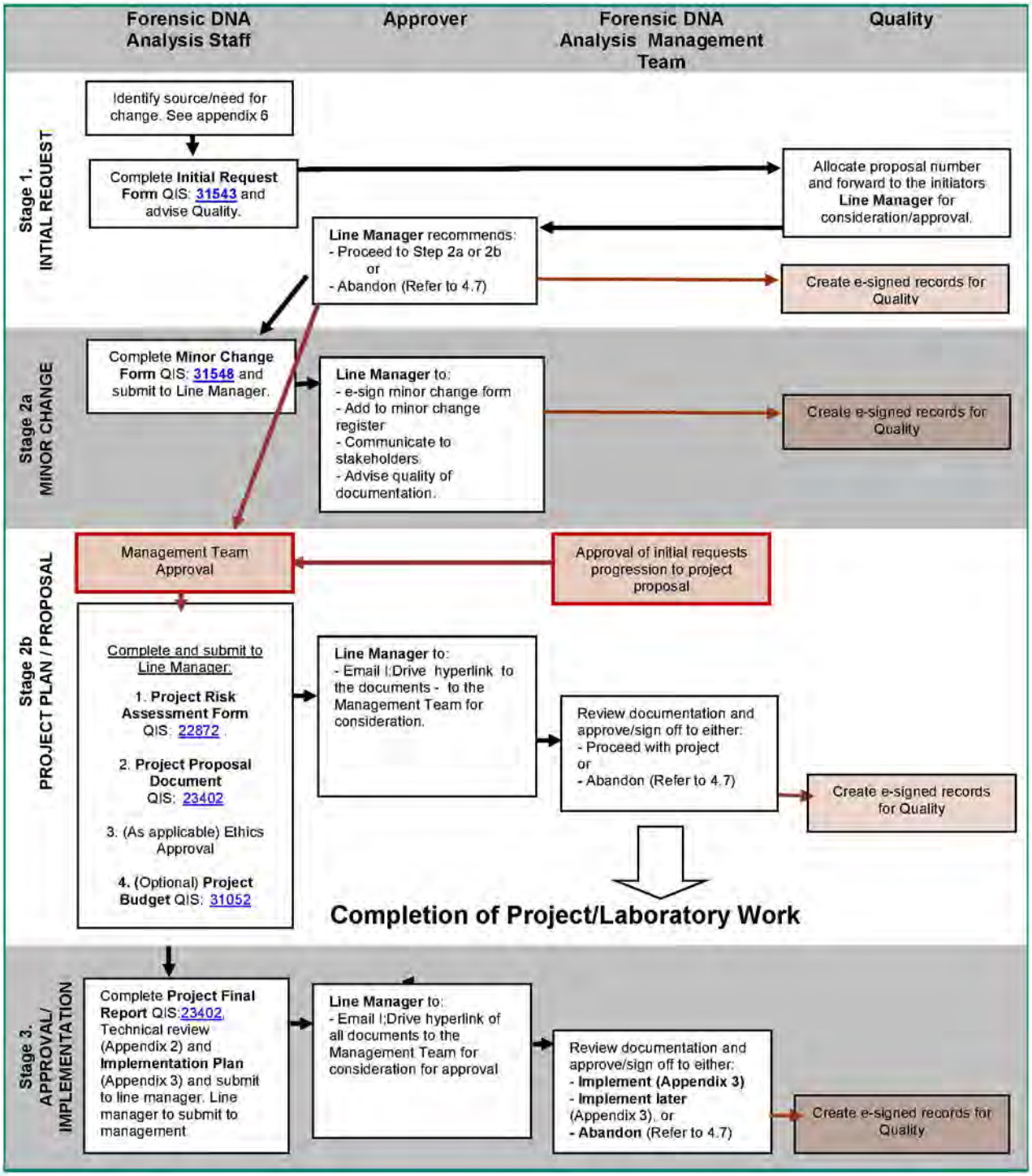
Version	Date	Author/s	Amendments
1	25 Aug 2005	Mary Gardam	First Issue
2	27 Feb 2007	J Olsson, M Gardam V Ientile	Format Changed to include Project Management.
2	April 2008	QIS2 Migration Project	Headers and Footers changed to new CaSS format. Amended Business references
3	25 Sept 2008	Robyn Smith Crystal Revera	Formatting, Changes made to reflect new Laboratory name & Contacts
4	14 May 2012	Shannon Thompson Kirsten Scott	Major revision/re-write as the change management process changed.
5	21 Jan 2013	Kirsten Scott	Update QIS numbers and headers. Add records, associated documents and minor edits.
6	26 Mar 2013	Kirsten Scott	Clarify point 3 in section 4.4. Update hyperlinks
7	6 June 2014	Kirsten Scott	Remove Assessment Phase. Change in actions required by line managers for approving initial plan and minor change documents.
8	19 June 2015	Kerry-Anne Lancaster	New template. Added milestone register and implementation plan. changed AUSLAB to LIMS, defined project proposal and responsibilities of the reviewer. Add QIS 33017
9	21 Oct 2015	Kirsten Scott	Inclusion of consent forms in associated documents. Option for mandatory projects to proceed directly to project plan. Inclusion of RDAC processes & Quality Checklist
10	25 Nov 2015	Kirsten Scott	Inclusion of a technical review for major projects and validations, and minor text update in other section as a result of technical review
11	20 Sept 2016	Kirsten Scott	Specify implementation plan as mandatory, Section 4.5 and 5 add a note on locking of data by quality. Section 3 clarify RDAC requirements

12	1 June 2018	Kirsten Scott	Remove milestone register (section 4.3, 4.8). Add comms and project numbering to section 4. Addition of FR instructions section 5. Add technical review template as appendix 2.
13	19 Nov 2019	Kirsten Scott	Add Human ethics checklist section 6. Additions to section 4.4: meetings with Quality Sen/Sci., and staff competency requirements. Header added to appendix 8.4
14	2 Oct 2020	Kirsten Scott	Edit document to reflect change from hardcopy records to electronic sign-off processes. Additions to appendix 4
15	14 July 2021	Abbie Ryan	Addition of Appendix 5 – e-sign procedure. 4.2 Addition of extra signature step to minor change procedure for Quality Senior Scientist. 4.3.1 Changed title of document 22872 to Project Risk assessment.
16	10 Dec 2021	Kirsten Scott	New header, remove optional Gantt chart for projects, add ethics QIS links and requirements and emerging/novel practices (Appendix 6)
17	30 Mar 2022	Abbie Ryan	Updated Appendix 3 – implementation plan tasks.

8 Appendices

- APPENDIX 1: Change Management Process
- APPENDIX 2: Technical Review Template
- APPENDIX 3: Implementation Plan for project leaders
- APPENDIX 4: Checklist of documents required for a Change Management Project
- APPENDIX 5: Procedure for e-signing documents
- APPENDIX 6: New and emerging novel practices checklist

8.1 APPENDIX 1: Change Management Process



8.2 APPENDIX 2: Technical Review Template

Technical review of Proposal #Project number
Project title

General project observations:

Experiment 1:

Program settings checked: Yes / No / Not Applicable. Comments:_____

Formulas checked: Yes / No / Not Applicable Comments:_____

Data transformations checked: Yes / No / Not Applicable Comments:_____

Calculations checked: Yes / No / Not Applicable Comments:_____

Experimental observations (design/results etc):

Experiment 2: (add additional experiments as required)

Program settings checked: Yes / No / Not Applicable. Comments:_____

Formulas checked: Yes / No / Not Applicable Comments:_____

Data transformations checked: Yes / No / Not Applicable Comments:_____

Calculations checked: Yes / No / Not Applicable Comments:_____

Experimental observations (design/results etc):

Technical Reviewer

Name	Position	Signature	Date

Project Manager

Name	Position	Signature	Date

8.3 APPENDIX 3: Implementation Plan for project leaders

Successful project implementation may require numerous tasks to be completed either prior to implementation, or shortly after the implementation date. Some of the considerations/tasks that may be required are listed below; however, this is not intended to be a comprehensive list of tasks as each project will have different implementation requirements. Project leaders must devise and submit a comprehensive implementation plan for management review prior to the final report being signed off. Ideally, this implementation plan should be provided at the same time as the draft final report.

Once complete, the checklist should be submitted to the quality team for filing with the signed project documents.

Project Title:_____ Project Number:_____

Task	Details	Responsible Line Manager/ Allocated to:	Date Completed
e.g. Create new procedures	New SOPs and training modules to be written and approved		
e.g. Update procedure/s	Existing SOPs and training modules to be revised and approved		
e.g. Staff training	Project members and relevant to staff to be issued with CTT statements as required		
	CTT staff to train relevant staff		
e.g. Software setup	Final version of software to be setup and reviewed on instrument		
	Check if Macro updates are required		
e.g. Equipment tasks	Add equipment to QIS		
	Add equipment to LIMS		
e.g. Consumable tasks	Add consumables to LIMS.		
	Addition of products to FAMMIS		
	Order new consumables		
e.g. Forensic Register development/requirements			
e.g. DNA interpretation/reporting	May include: Model Maker requirements and assessment, Statement of Witness appendix update		
e.g. Impacts/risks assessed	Any risks identified in risk assessment are addressed.		
e.g. Add to minor change register	Ensure that implementation has been added to the minor changes register		
e.g. Communication	Communicate to staff and other stakeholders – by meetings and emails.		

8.4 APPENDIX 4: Checklist of documents required for a Change Management Project

Project Number: _____

Minor Change:

☐ Initial Request Form (31543) (May not be required for mandatory projects)

☐ Minor Change Form (31548)

☐ Added to Minor Change Register and emerging or novel practices register

☐ Implementation (Comments added to SOPs (if required) and communication to staff)

Major Project:

☐ Initial Request Form (31543) (May not be required for mandatory projects)

☐ Project Risk Assessment Form (22872)

☐ Project Proposal Document

☐ (Optional) Project Budget (31052)

☐ Ethics checklist and/or approval - if applicable (33268)

☐ Risk Assessment (As applicable for new equipment and laboratory procedures 29100)

☐ Project Final Report

☐ Technical Review (for validations and major projects only)

☐ Implementation Plan

** Consent forms for staff collections should have been previously provided to quality if applicable.

RDAC project:

☐ RDAC Application Form (Copy only, original stored with Research Office)

☐ RDAC Final Report – if the project is funded (Copy only)

☐ Excel Sheet – with Names of Management Team for acknowledgment of project.

☐ **Quality team have loaded all key project documents to FR for storage**

Checklist completed by:_____ Date: _____

8.5 APPENDIX 5: Procedure for e-signing documents in Adobe

First time process to set up digital signature:

1. Scan an image of your personal signature and save to your desktop.
2. Open up a PDF document in Adobe
3. Click tools and Open - Certificate
4. Choose "Digitally Sign"
5. Drag the box to point in PDF document where you want to apply your digital signature.
6. Select Configure Digital ID
7. Select Create a new Digital ID – then continue
8. Select "Save to File" then continue
9. Ensure that you place all your credentials in the name section. (Do not use symbols)

Sample of how and areas to fill out:

Note: you can change the place where you save your credentials, the default saving file location is generally where the adobe program files are kept.

10. Enter a password of your choice. You will use this password every time that you apply it
11. Last step in the process is to attach a copy of your 'signature'. Click continue
12. Click on the create button
13. Select image then select "Browse" to import in your signature from the file location
14. Click save.
15. To now digitally sign the PDF document, enter password and click sign.

Note: – if you are the final approver, e.g. expenditure delegate, line manager approving the document, you must check the 'Lock document after signing' checkbox. This will lock the entire document down and cannot be edited once this has been done.

16. You will be asked to save the PDF file.
17. If the PDF document requires further electronic approvals, it can be forwarded to the next approval for their Digital ID. If the check box is checked 'lock document after signing', then the document can no longer be edited or signed.

For all future PDF documents, when you click Digitally sign, you will be asked to select the area to sign and then can select the Digital ID, enter your password and sign the document.

8.6 APPENDIX 6: New and emerging novel practices checklist

This checklist is provided as a template/processes by which staff can consider what to do - when they have seen something new, wish to do something new or are unsure how to proceed with a decide or idea. The emphasis is on the documentation and communication of decisions and thought processes - in line with best quality practices.

Step 1: Gather the facts and define the issue/problem.

Step 2: Make an assessment of your idea or what you have seen: taking into account:
- the case implications
- possible expenditure of resources (time and money)
- impact on clients
- health and safety etc. (refer to Section 4 above).

This will allow you to determine who is accountable for the decision, and how big the required and appropriate process will need to be.

Step 3: Action and documentation: For any issue that have a cost implication (resources or significant staff time), or implications for clients - the full change management process would apply (refer to this document above). For new observations and/or emerging novel practices that are smaller in nature - it maybe more appropriate to use following document to detail the issue, your thinking and the decision:

I:\Change Management\Change Register - Minor Changes and emerging or novel practices.xls

Step 4: Communicate to appropriate audience

Example: **Raised by:** John Smith **Date started:** 20/01/2022

Define your issue:
Apparent artefact at D18S51. Artefact shifts between labelling as a 17.1 or 17.2 variant allele. No stutter is observed for this artefact. Only observed in samples from peri-anal, rectal or penile areas.

Has it been seen before? Yes
Where? Case XXXXXXXxXX
Who can make the decision? Myself

Assessment
Adds contributor to otherwise single source assumed known contributor, height of artefact not consistent with another contribution dropping out. No expenditure of money, time or resources required.

Actions
- Removed artefact from FR GeneMapper table.
- Annotated epgs and re-loaded to Forensic Register
- Notations added to case in Forensic Register.
- Added to Change Register - Minor Changes and emerging or novel practices document

Communication

Who	When	How
All reporters via Microsoft Teams	02/02/2021	Posted
Line manager	01/02/2021	Email

CA-52

Queensland Health
Forensic and Scientific Services

Forensic DNA Analysis Validation and Verification Guidelines

1 Purpose and scope

Validation is the developmental process used to acquire the necessary information: to assess the ability of a procedure to obtain a reliable result, to determine the conditions under which such results can be obtained, and to determine the limitations of the procedure (National Association of Testing Authorities, 2020). Method validation and verification provides objective evidence that a method is fit for purpose, meaning that the particular requirement for a specific intended use are fulfilled (National Association of Testing Authorities, 2020). Verification studies are typically smaller than those that are required for validation. For full details refer to National Association of Testing Authorities, 2020 specific documents.

The Forensic DNA Analysis laboratory is certified by the National Association of Testing Authorities (NATA) and is obliged to meet these specifications. ENFSI (2010) states that for DNA based tests, validations/verifications must demonstrate that the profile/s obtained under the new regime will be of the same or better quality than those obtained under the previous regime.

The purpose of this procedure is to describe validation and verification guidelines for use within Forensic DNA Analysis. Test methods, equipment, computer/software systems and information management systems must be shown to be fit for purpose before they are used by the laboratory to generate results. Validations will be required in Forensic DNA Analyses for:

- all new methods developed "in-house";
- methods laboratory/commercial that have been modified;
- methods without validation data adopted from other laboratories or from literature;

Verifications will be required in Forensic DNA Analyses for:

- use of a previously published and validated method
- use of commercial kits

This procedure shall apply to all validation/verification projects conducted within Forensic DNA Analysis. The final decision regarding the extent and scope of the study shall be made by the Managing Scientist.

2 Definitions

Accuracy and Precision

Accuracy (trueness): is the closeness of agreement between the test result and the "true" or accepted value.

Precision: is a measure of closeness (degree of scatter) between independent test results under stipulated conditions (National Association of Testing Authorities, 2020). High precision does not necessarily imply high accuracy.

An example of accuracy and precision measures would be, a determination of the proportion of correct genotypic assignment of samples, and a review of the number of alleles correctly assigning to the expected 0.5bp window/bin.

Repeatability is a measure of the maximum acceptable difference between two test results obtained at the same time by the same analyst under identical conditions on the same material. ENFSI (2010) recommends repeatability studies contain a minimum of five replicates, while NATA (2020) specifies at least six degrees of freedom (e.g. 4 times in a series with 2 samples or 3 times in a series with 3 samples). A repeatability test might be: 12 samples on a plate 7 times with standards and/or controls in an amplification plate and processed by a single operator (suggest that the DNA extract of a defined concentration is prepared in a large volume, and aliquot out to PCR plate or CE plate etc. This will ensure pipetting error is minimised in the preparation of multiple samples to an equivalent concentration).

Reproducibility

- Within laboratory (in-house) reproducibility - A measure of the maximum acceptable difference between two test results obtained on the same material by different analysts at different times.
- Between-laboratory reproducibility - A measure of the maximum acceptable difference between two test results obtained on the same material by different laboratories. It is most conveniently determined in collaborative trials.

Reproducibility in Forensic DNA Analysis could be assessed by: several DNA samples being prepared on an amplification plate by one operator, and the same DNA samples prepared on an amplification plate by a second (different) operator.

Sensitivity is the rate of change of the measured response with change in the concentration of analyte National Association of Testing Authorities, 2020). For PCR-based assays, validation studies must consider the stochastic effects of PCR; particularly as it relates to DNA concentration. ENFSI (2010) recommends sensitivity tests have a minimum of 5 dilutions tested.

3 Principle

Validation provides objective evidence that the particular requirements for a specific intended use are met. There is no one method of validation that is universally agreed upon, however the validation guidelines below are consistent with NATA criteria (National Association of Testing Authorities, 2020), and are consistent with Scientific Working Group on DNA Analysis Methods (SWGDAM 2020) recommendations for the minimum criteria for the validation of DNA profiling processes (ENFSI, 2010).

4 Actions

The planning and implementation of a validation/verification project in Forensic DNA Analysis should occur as follows:

a. Determine if it is a verification or a validation that is required. For example - if a standard published method, with full validation data, and a commercially available kits is to be implemented within the laboratory - a verification not validation would be required (prior to its introduction). If a new methodology is developed - a validation would be necessary.

b. Using the 'Procedure for Change Management in DNA Analysis' standard operating procedure QIS 22871, a project proposal must be prepared. In the planning the work consider the following:

- Validation studies require an assessment of reproducibility, repeatability, sensitivity, accuracy and precision (ENFSI, 2010). Refer to definitions section 2 for details.
- Qualifying Test - For validation studies the use of known samples and where possible authentic case samples should be used. This may be accomplished through the use of proficiency test samples, or samples that the laboratory routinely analyses (e.g. controls). Where previous typing results are available concordance of genotypes should be assessed.
- Mixture Studies – Forensic casework laboratories must define and mimic the range of detectable mixture ratios. Studies should be conducted using samples that mimic those typically encountered in casework (e.g. postcoital vaginal swabs)
- The laboratory must ensure that the procedure/s minimise contamination that would compromise the integrity of the results (QIS 22857). The laboratory should employ appropriate controls and implement quality practices to assess contamination and demonstrate that its procedure minimises contamination.
- Manufacturer's information and previous published validation studies should be used to inform the laboratories validation process.
- Refer to all NATA and ENFSI documentation listed in the reference list section 6 for specific and detailed validation study requirements
- Refer to QIS 10662 for additional resources.
- The project proposal must then be submitted to the Forensic DNA Analysis Management Team for approval prior to the initiation of experiment work.
- On completion of the experimental component of the validation, a final report will need to be written using the final report template QIS 23402. The final report is to be submitted to the Forensic DNA Analysis Management Team for consideration

5 Records

Minimum records required for a validation are:

Project Risk Assessment for Change Management in Forensic DNA Analysis 22872.
Project Proposal document. (see Writing Guidelines for Validation and Change Management Reports QIS 22871 & 23402).
Implementation Plan (Refer QIS 22871)
Final Report (Refer QIS 22871 & 23402).

Additional requirements (as applicable):

Ethics approval (Refer QIS 32177)
Technical review (Refer QIS 22871)
Forensic DNA Analysis - Change Management Budget (Refer QIS 31052).

6 References

National Association of Testing Authorities. (2020). NATA – National Association of Testing Authorities, Australia. Available at: https://nata.com.au/nata/ [Accessed 27 Aug. 2020].

ENFSI (2010) Recommended Minimum Criteria for the Validation of Various Aspects of the DNA Profiling Process. ENFSI DNA Working QA/QC subgroup. Issue No 1.

ENFSI (2020) European Network of Forensic Science Institutes. Available at: http://enfsi.eu/ [Accessed 27 Aug. 2020].

Scientific Working Group on DNA Analysis Methods (SWGDAM). (2020). Available at https://www.swgdam.org/ [Accessed 27 Aug. 2020].

7 Associated documents

QIS: 10662 - FSS – Guidelines for Method Validation

QIS: 22871 - Procedure for Change Management in Forensic DNA Analysis

QIS: 22872 - Project Risk Assessment for Change Management in Forensic DNA Analysis

QIS: 23402 - Writing Guidelines for Validation and Change Management Reports

QIS: 31052 - Forensic DNA Analysis - Change Management Budget

8 Amendment history

Version	Date	Author/s	Amendments
0	06 Sep 2005	Mary Gardam	First Issue
1	April 2008	QIS2 Migration Project	Headers and Footers changed to new CaSS format. Amended Business references from QHSS to FSS, QHPSS to CaSS and QHPS to Pathology Queensland
2	25 July 2008	C Revera	New Title, Changed Forensic Biology to DNA Analysis, authorised by C Allen, Chief scientist to Managing scientist. Purpose and scope combined, hyperlinks updated, definition of verification included.
3	4 Dec 2012	K Scott	New header. Complete rewrite to fit with new change management procedures in DNA Analysis
4	18 June 2014	K Scott	Update organisational name, document names and hyperlinks
5	20 Nov 2015	K Scott	Update header/template, references and minor text updates
6	8 Aug 2017	K Scott	Update references
7	27 Aug 2020	K Scott	Minor updates all areas
8	15 March 2022	K Scott	Template update, document names and references updated

9 Appendices

1 Appendix A Additional terms used in validation studies

9.1

Appendix A

Additional terms used in validation studies

Functional Specification: Defines how it is expected to function - these functions are typically outlined by the manufacturer of equipment/software.

Installation Qualification: Verifies design specification, the physical components of the system have been designed/constructed/supplied/installed in compliance with the design specifications. This is usually completed by the company performing the installation.

Lower limit of detection (LOD) - The lowest concentration or amount of analyte that can be reliably distinguished from zero, but not necessarily quantified, by the test method.

Limit of reporting/quantitation (LOR) - The lowest concentration of analyte that can be determined with acceptable repeatability and accuracy by the test method.

Operational Qualification: Verifies the functional specification, that the system functions as intended throughout anticipated operating ranges.

Performance Qualification: Verifies that the system will consistently produce results meeting user requirement specifications and quality attributes under both normal and worst-case conditions.

Uncertainty - The spread of values within which the true value would be expected to lie, with the stated degree of confidence (usually 95%).

User Requirement Specification: Defines how the system is expected to perform - this is usually set out in the tender document requirements.

CA-53

Queensland Health
Forensic and Scientific Services

Initial Request

Stage 1

		Proposal #:	
Proposed by :		**Date:**	
		Due Date:	
Title of Proposal:			
Project type	☐ Administration ☐ IT/LIMS ☐ Laboratory ☐ Data mining/analysis ☐ External Project ☐ Other_____		
Brief Outline of Proposed Change			
Line Manager :		**Recommendation:**	
Signature:		☐ Proceed to minor change ☐ Proceed to full project plan ☐ Place on hold or abandon Reason:_____	

Proposal restarted by:		**Date:**	
Approved By: **Signature:** **Date:**		**Reason:**	

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Advise quality [redacted] when finalised.

Queensland Health

Forensic and Scientific Services

CA-54

Business Case Management at FSS

1 Purpose

The purpose of this procedure is to describe the preparation and procedure for the approval of business cases for asset purchases, change initiatives and project proposals at Queensland Health Forensic and Scientific Services.

2 Scope

This procedure shall apply to all FSS staff seeking funding approval capital items, from the minor capital approved budget, HTER budget or new capital items. In general, this will apply to requests over the $5,000 threshold.

Generally, business cases are required for:

- Purchase of additional assets (building, plant and scientific)
- Upgrades to assets
- Purchase of Information Technology (IT) services
- Commercial projects (revenue)
- Research projects
- Organisational change projects requiring funding

This procedure does not apply to:

- QIS: 32129 – Scientific Equipment Service Maintenance Agreement Request
- Briefing note for decision / noting with the Deputy Director General, Prevention Division.

3 Actions

Funding

For pre-approved capital budget funding requests **over $100,000** the staff member must complete the *FSS Business Case - Capital Request > $100,000* QIS 26375. Internal approval will be required from the Business Performance Officer for FSS, the Delegate with the appropriate Financial Delegation, either Managing Scientist or the Executive Director if above the Managing Scientists delegation.

3.1 For funding requests **under $100,000** from the pre-approved minor capital budget, the staff member must complete the *FSS Business Case - Minor Capital Request < $100,000* QIS 33921. Internal approval will be required from Business Performance Officer for FSS, the Delegate with the appropriate Financial Managing Scientist or the Executive Director if above the Managing Scientists delegation.

3.2 For **HTER** funding requests from the pre-approved HTER budget, the staff member must complete the *FSS Business Case – HTER Request* QIS 33922. Internal approval will be

required from the Business Performance Officer for FSS, Managing Scientist or the Executive Director if above the Managing Scientists delegation. Any amendments to the HTER program need to be approved by the Principal Advisor Infrastructure & Assets.

Development

3.3 The business case author is responsible for seeking quotes relevant to the procurement of goods / services and in line with DOH Financial and Procurement Delegations

3.4 The Principal Advisor Infrastructure Asset and the Business Performance Officer, Prevention Division, Finance can provide advice and support to cost centre managers on the development of the business cases.

FSS Financial / Procurement Delegations:

Position	Delegations
Executive Director	Financial delegation up to & including $500,000
Managing Scientists	Financial delegation up to & including $150,000
Chief Forensic Pathologist	Financial delegation up to & including $500,000

* Any requests above these delegations will require escalation to the General Manager, Pathology Queensland, or Deputy Director General, Prevention Division.

Submission & Approval

3.5 The author will submit the business case, completed Asset Acquisition Request Form, current quote/s and the Completed Procurement < $250,000 form to the relevant Line Manager for endorsement.

3.6 If endorsed by the Line Manager, he / she will progress the business case to the TBM team for registering. The TBM team will progress the endorsed business case to Business Performance Officer and then the Managing Scientist or the Executive Director whichever is appropriate to delegation.

3.7 If approved by the Managing Scientist or Executive Director, the Financial Delegate will return the signed business case to TBM for processing. The Author, Business Performance Officer Prevention Division Finance and Managing Scientist will be Cc'd into the email to the Principal Advisor Infrastructure Asset when requesting the asset number.

3.8 Capital requests > $100,000 the author will submit the business case, finalised request for quote (RFQ) paperwork, current quotes and Asset Acquisition Form to TBM the Asset and the Procurement teams for processing, and Business Performance Officer Prevention Division Finance and Managing Scientist and Author will be Cc'd.

4 Records

Completed business cases will be sent to the Records department as a hard copy.

5 Associated Documentation

QIS: 26375 - *Business Case - Capital Request > $100,000*

QIS: 33921 - *Business Case - Minor Capital Request < $100,000*

QIS: 33922 - *Business Case - HTER Request > $100,000*

QIS: 32129 – Scientific Equipment Service Maintenance Agreement Request.

Briefing note for decision / noting with the Deputy Director General.

6 Amendment History

Revision	Date	Author/s	Amendments
0	3 May 1998	Rob Langdon	First Issue
1	4 Jan 1999	Monica McCulloch	Body of text changed to allow a broader application of the document
2	May 1999	Rob Langdon	Annual review – *List Changes.*
QIS² Edition			
Version	**Date**	**Updated By**	**Amendments**
4	Mar 2009	F Stewart	Template Changes made
5	Nov 2009	P Keleti	BDG signed off on renaming Author/s column to Updated By.
6	Aug 2012	H Gregg	New template header and colours applied.
7	September 2012	F Stewart	Heading 3 updated to black
8	October 2013	F Stewart/A Hardman	1) Replaced the HSSA graphic in the header of the document. with the blank document size has decreased from 712 KB to 52KB which means it will open a lot faster in QIS. 2) Removed all tabs and changed the default tab length from ½ inch (1.27cm) to 1 cm. 3) Changed the Recommended Options found under Tools -> Options -> Compatibility from Microsoft Word 97 to Microsoft 2002
9	November 2013	C Gillen	Updated process in line with relevant approval requirements and delegations
10	August 2016	Vibhashika Sinha Mark Waterson	Added processes and links to new templates for business cases with requests for funding under $100,000; over $100,000 and HTER. Amended the submission and approval process to suit.

CA-55 Forensic and Scientific Services

Project Risk Assessment

Stage 2

		Project #:	
Name/s of Project Staff:		**Start Date:**	
		Due Date:	
Name Project Team Leader:		**Contact Phone Number:**	
Technical Reviewer/s			
Project Title:			

RISK ASSESSMENT:
If a risk is identified: Refer to QIS document 29100 and 29106 for further information on risk identification and management.

Team:	**Details of Risk/s Identified**	**Type of Risk/s:**
Evidence Recovery		**Signature Line Manager**
Analytical		**Signature Line Manager**
Intel		**Signature Line Manager**
Reporting 1		**Signature Line Manager**
Reporting 2		**Signature Line Manager**

Quality & Projects (includes CA's)		**Signature Line Manager**
Admin (if applicable)		**Signature Line Manager**
Team Leader ER & Quality		**Signature Line Manager**
Team Leader FRIT		**Signature Line Manager**

Project Proposal approved by:			
Signature Team Leader ER and Quality:		**Date:**	
Signature Team Leader FRIT:		**Date:**	
Signature Managing Scientist:		**Date:**	

Comments:

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Advise quality [redacted] when finalised.

Writing Guidelines for Validation and Change Management Reports.

1 Purpose

Change management and validation projects in Forensic DNA Analysis are planned using the procedure for change management QIS 22871 and the Forensic DNA Analysis validation guidelines QIS 23401. The purpose of this document is to provide Forensic DNA Analysis staff with guidelines for writing the final report - after completion of either a validation or change management project. This guide applies to all Forensic DNA Analysis staff.

2 Scope

This procedure applies to all validation and change management project reports within Forensic DNA Analysis.

3 Actions

Final reports within Forensic DNA Analysis are to be written using the template located at:

https://qheps.health.qld.gov.au/fss/staff/corporate-identity/templates

General guidelines on the content and style of each of these report subsections are provided below. The quality team is able to provide previous reports – to use as exemplars (on request).

- The suggested major headings to be included in the report are:
  - Abstract
  - Introduction
  - Materials (and/or Resources)
  - Methods
  - Experimental Design (suggested - for large projects)
  - Results
  - Discussion
  - Conclusion/Recommendations
  - Abbreviations (suggested - for large projects)
  - References.
- Authors – must be listed under the report title. All major contributors to the work should be listed as authors. As a minimum this must include: the Project Leader, Project Leader's Line Manager and the Managing Scientist Police Services Stream. The staff member that writes the report is usually listed as the first author, and the Managing

Scientist is usually listed as the last author in the list. Smaller contributions to a project (that are not sufficient for authorship) should be noted within the Acknowledgments section of the report.

Abstract

Abstracts are a single paragraph (200-300 words) written in past tense. The abstract is a summary of the paper and should briefly state:

- Why the project was undertaken (~1-2 sentences)
- What methodology was used (~2-3 sentences)
- What the key findings/trends/results were (~2-3 sentences)
- Implications of project including the interpretation and conclusion/s (~1-2 sentences)

Due to the required content of an abstract, most authors find that the abstract is most easily written last (after the remaining components of the report are complete).

Introduction

The introduction is usually several paragraphs written in present tense. The introduction should outline all relevant primary research literature, and detail how the literature relates to the issue/s under investigation in the project/study. It should clearly state the studies purpose and rationale.

Scope

A statement of the extent/limits of the project and to which area/s it applies.

Governance

A list of the project staff, the roles of the staff, and a statement about how the project decisions will be managed. Example as follows

The Management Team and the Senior Project Officer, are the decision making group for this project and may use the defined acceptance criteria in this project to cease part or all of the experimentation at any stage. The Decision Making Group may also make modifications to this Experimental Design as required, however this must be documented and retained with the original approved Experimental Design.

Materials and/or Resources

- Materials are listed with item (chemical, consumable or equipment), manufacturer and location. For example:
    - Promega PowerPlex®21 Allelic Ladder (Promega Corp., Madison, WI, US)
    - Promega WEN Internal Lane Standard (Promega Corp., Madison, WI, US)
    - Promega PowerPlex 5 Dye Matrix Standard (Promega Corp., Madison, WI, US)
    - 5804 Centrifuge (Eppendorf, Germany)
    - 2800M Control DNA, 10ng/µl (Promega Corp., Madison, WI, USA)
- International Standard (SI) Units are to be used (e.g. µL)

- A description of the organism/biological materials studied should be included (e.g. human, blood, cells)

Methods and/or Experimental Design

Methods are written in past tense (do not use first person). The use of sub-headings may be required in this section of the report. Methods should explain in detail the materials that were used, the experimental design and full methodology. It should be written with sufficient detail to enable an experienced scientist to replicate the work (i.e. temperatures, times, concentrations must be described). Ensure the following:

- Materials are adequately described
- International Standard (SI) Units are to be used (e.g. µL)
- For reporting: numbers less than ten are written in words and not numerals (e.g. two minutes). When writing numbers >10 use numerals, and do not write in words (e.g. 12 minutes).
- Experimental or sampling design is to be described (e.g. structure of the experiments, selection of samples, use of controls, sample numbers, sample duplicates etc.). Refer to Appendix A for guidelines.
- Detail how the procedure was carried out (e.g. DNA extractions details, amplification conditions).
- Explain how the data was analysed (e.g. statistical methodology). Refer to appendix A for recommendations.
- The acceptance criteria for the results is clearly defined.

For Materials and/or Resources and Methods and/or Experimental Design, it is acceptable for the Final Report not to reproduce the content from the Experimental Design, but to reference it and include any changes by exception.

Results

Results are written in past tense. The purpose of this section is to objectively present the key results without interpretation. It should always begin with text presenting the key findings (that address the questions being investigated), and statistical evaluation (Refer to Appendix A for recommendation). Tables and Figures can be included within this section to provide clarifying information.

Tables and Figures

Tables and Figures are included within the results section of a report. Table and Figure presentation guidelines are as follows:

- Tables and Figures are numbered consecutively. Table and Figures are assigned numbers separately e.g. Table 1, Table 2, Table 3 and Figure 1, Figure 2, Figure 3 etc.
- Legends are to be a brief description of the result/information being presented.
- Table legends go above the table and are left aligned.
- Figure legends go below the figure and are left aligned.
- In the text of the report, figures can be abbreviated to "Fig" (i.e. Fig 1). Table is never abbreviated.
- SI units should be specified in the column headings wherever required.

- Footnotes are used to clarify points in the table, denote statistical differences among groups or to convey repetitive information about entries.

Table exemplar:

Table 1 Student's t-testP-values for comparison of QS5-A and Qs5-B with 7500-A

Standard	Instruments compared	SAT	LAT	Y-Target
NIST A	QS5-A & 7500-A	0.70050	0.06813	0.42519
	QS5-B & 7500-A	0.44247	0.77529	0.19765
NIST C	QS5-A & 7500-A	0.23834	0.09180	0.39582
	QS5-B & 7500-A	0.52538	0.45386	0.32165

Note: P-values < 0.05 indicate a significant difference between results produced by the two instruments.

Figure exemplar:

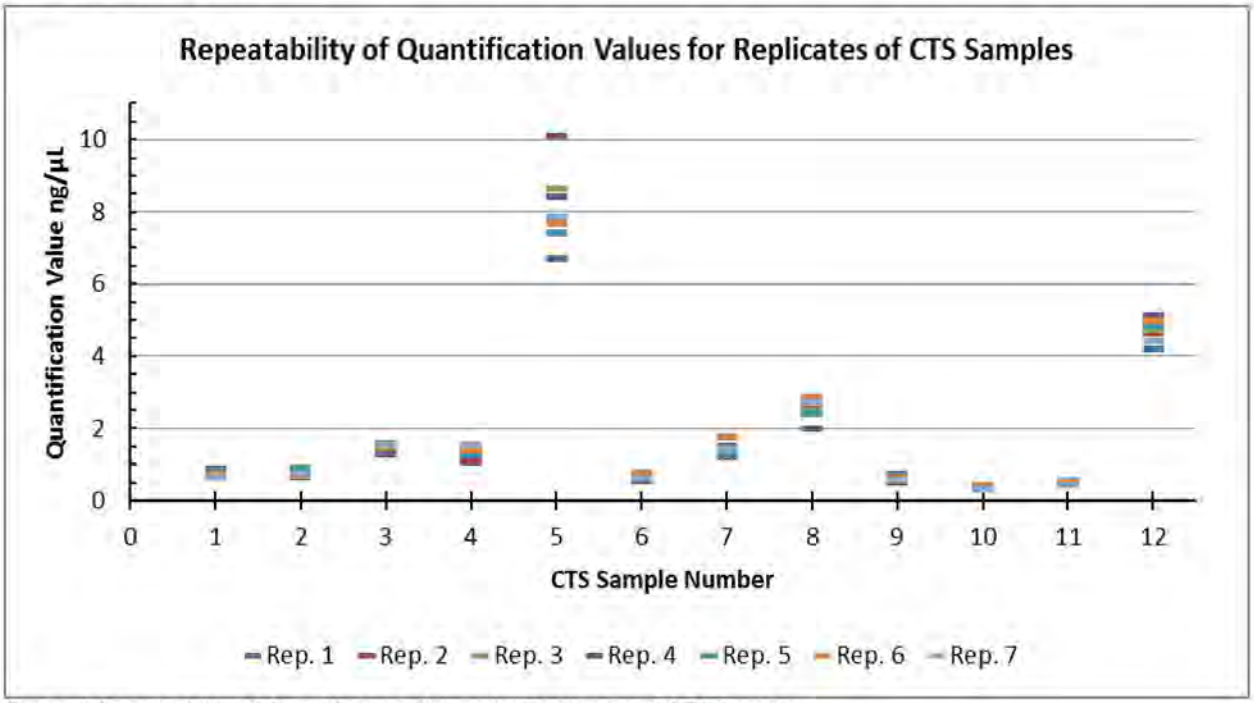

Figure 1 Repeatability of Quantification Values for Replicates of CTS Samples

Discussion

A discussion is written in past tense and will usually consist of multiple paragraphs. The purpose of the discussion is to explain/interpret the results with reference to the acceptance criteria and to relate the results back to current understandings in the field, and in the published literature. There should be links/connections of ideas/concepts between the introduction and the discussion; explaining how the project/validation has moved current understandings forward. Questions that should be considered when writing the discussion may include:

- Do the results support the projects hypotheses? If not, why not – try to provide reasons (if it is possible)?

- Do the findings agree with current literature/publications? If not, why not – try to provide reasons (if it is possible)?
- What are the implications of the findings to the laboratory, and to the scientific community?

Note: If appropriate, the results and discussion can be combined under one heading. If the project contains more than one experiment it may be necessary to have a combined result/discussion section for each experiment.

Conclusions/Recommendations

A conclusion and/or recommendation section can either be written as a separate section/s (each under its own heading), or it can be incorporated into the end of the discussion section without a separate heading.

A conclusion is usually one paragraph written in past tense. The conclusion should summarise the most significant finding, the implication of the finding/s, and may indicate what direction – additional projects should take.

Recommendations are usually written as several statements, or dot points that outline what actions are required. This may include recommendations on the implementation (or not) of a procedure, what type of further work that is required, and/or recommendations on how data should be utilised and interpreted.

Acknowledgements

The purpose of acknowledgements is to note the contributions from others (that are not listed authors). This may include acknowledgments of:

- Funding source/s
- Staff that completed laboratory work
- Reviewers/Collaborators.

References

Referencing should be used wherever a report refers to another's work. It is usual for there to be extensive referencing with the introduction section of the report, with referencing also commonly used within the methods and discussion sections of the report. References can be managed with programs such as EndNote.

Requirements for referencing:

- Place quotation marks on either side of text " " when quoting directly.
- A reference list is arranged alphabetically by author (If an item has no author, it is cited by title, and included in the alphabetical list using the first significant word of the title).
- If you have more than one item with the same author, list them in chronological order (starting with the earliest publication).

There are several acceptable methods of referencing including ACS, AGPS/AGIMO, AMA and the Harvard Style. In the Harvard Style referencing: within the text reference by author and date e.g. (Smith, 2012). Referencing format with the Harvard Style as below:

Harvard Style:

Referencing a book:

Smith, JB, Scott, KD & Jones, LM 2012, *Forensics: A molecular approach*, 2nd edn, McGraw Hill, London.

Referencing a chapter in a book:

Martin, F 2012, 'DNA Profiling', in Lee CW (ed.), *Forensics: A molecular approach*, 2nd edn, McGraw Hill, London, pp. 35-61.

Referencing a journal article:

Holden, LM 2011, 'Validation of Powerplex21', *International Forensics*, vol. 50, no. 2, pp. 49-52

Referencing an on-line journal article:

Holden, LM 2011, 'Validation of Powerplex21', *International Forensics*, vol. 50, no. 2, viewed 31 December 2012, <insert website address>.

Appendices

Appendices can be used if required and are numbered consecutively. The appendices contain information that supports the content of the report but is not essential within the body of the report.

4 Records

Nil

5 Associated documents

QIS 10662 FSS - Guidelines for Method Validation
QIS 22871 Procedure for Change Management in Forensic DNA Analysis
QIS 22872 Project Risk Assessment for Change Management in Forensic DNA Analysis
QIS 23401 Forensic DNA Analysis Validation Guidelines

6 References

Nil

7 Amendment history

Version	Date	Updated By	Amendments
1	13 March 2006	R Smith	First Issue
2	Sep 2008	T Nurthen	Minor update
3	07 Jan 2013	K Scott	Some content from this document transferred into QIS 23401. Complete re-write of remaining document – focusing on the reporting of validations and projects. Update header
4	17 July 2014	K Lancaster	Changed references to DNA Analysis to Forensic DNA Analysis. Included extra detail for experimental design. Updated titles for hyperlinked documents. Updated title of Managing Scientist.

			Updated report template hyperlink. Included a figure exemplar.
5	03 Feb 2016	K Scott	Template update, separate materials and methods, minor text edits and correction of amendment history table
6	09 Aug 2017	K Scott	Update names of kits used as exemplars
7	21 March 2019	K Lancaster	Updated hyperlink to report templates
8	08 May 2019	K Scott	Inclusion of Appendix A – recommendations for statistics. Minor updates throughout
9	14 Nov 2019	K Scott	Addition of sections on scope and governance. Addition of Appendix B – Resources for Statistics. Minor text edits
10	20/07/2021	A Ryan	Amended header to remove HSQ. Updated hyperlink to report templates. Amended document title for QIS 22872.Captioned table 1 and figure 1 correctly. Added how the acceptance criteria are mentioned and referred back to.

8 Appendices

1 Appendix A Recommendations for Statistics
2 Appendix B Resources for Statistics

8.1 Appendix A: Recommendations for Statistics

The following recommendations have been drawn from a review of literature, NATA guidelines, advice from senior quality staff at Forensic and Scientific Services and from National Forensic Statisticians.

For definitions of accuracy (trueness), precision, repeatability, reproducibility (within laboratory and between laboratory), blank. linearity, limit of detection (LOD), limit of (LOR), sensitivity, uncertainty and verification refer to QIS 10662 and QIS 23849, and NATA guidelines (https://nata.com.au/).

Please also refer to the FSS Guidelines for Method Validation QIS 10662.

Considerations in the design and approach to a validation study or research project:

Are statistics necessary given the experiment or analysis being considered:

- For strong statements "significant difference", "linear trend" etc. a statistic will be required to support the statement. For comparative statements it may not always be informative, or operationally appropriate to complete a statistic i.e. "differences were seen", or "appears to be a trend" statements do not require a statistic.
- Where a statistical test is not informative, and/or particularly where the difference between the experimental groups will not have an operational meaning - use of box plots are recommended. Box plots display the variation present in a system. Generally if the box plots overlap the difference between the groups is functionally non-significant.

Sample numbers:

When deciding how many samples are require for an individual experiment the following should be evaluated:

- Consider the amount of variation you are expecting to see. Where little variation is expected (e.g. number of alleles obtained from blood samples) small experimental sample numbers are needed. Where variation is higher (e.g. peak heights from low DNA quantification samples) sample numbers should be much higher. Where the amount of expected variation is unknown it is possible to run one set of samples, assess the results and then run additional samples if required.
- The experimental design is always aiming to include enough samples to model the expected variation in the relevant experiment (given the experimental factors under consideration). Thereby producing sufficient information (via sample numbers) for the development of methods/thresholds to cover "most situations". It is not possible for a study/validation to cover all possible situations.
- In cases were a project/validation is assessing locus amplification efficiency, and inter-locus peak height balance larger sample sizes may be required (suggest use of population samples ~200-250); this is particularly relevant for Y kits where a linear relationship may not be seen.

Which statistics might be most appropriate:

- ANOVA – to compare independent groups of samples
  Example: Dziak, R, Peneder, A, Buetter, A & Hageman, C. 2018 'Trace DNA Sampling Success from Evidence Items Commonly Encountered in Forensic Casework,' *J Forensic Sci*, vol 63, pp 835-841. doi:10.1111/1556-4029.13622

- Kruskal-Wallis – to compare independent groups of samples
  Example: Henry, J & Scandrett, L. 2019 'Assessment of the Yfiler® Plus PCR amplification kit for the detection of male DNA in semen-negative sexual assault cases,' *Science & Justice*, in press 2019.

- Paired T-test – to compare repeated samples i.e. same samples run through two different methods.
  Example: Tsai, L, Lee, C, Chen, C, Lee, J.C, Wang, S, Huang, N, Linacre, A. & Hsieh, H. 2016, 'The Influence of Selected Fingerprint Enhancement Techniques on Forensic DNA Typing of Epithelial Cells Deposited on Porous Surfaces.' *J Forensic Sci*, vol 61: S221-S225
- Chi-square test – may be applied to demonstrate the average peak heights between loci (or dye layer) may differ
  Example: Montpetit, S & O'Donnell, P, 2015, 'An optimized procedure for obtaining DNA from fired and unfired ammunition,' *Forensic Science International: Genetics*, vol 17, pp 70-74,

Tools for statistics:

- Excel – basic statistics
- R software program
- SPSS Software – commercially available software for statistics and graphing

Practical guidelines and suggestions:
It is not possible for a "procedure" to be written that will cover all possible approaches/analysis for studies that may be required within the Forensic DNA Analysis Laboratory. However, some key principles and guidelines are provided below that may assist with the development of an experimental design.

Instrument validations:

- For instruments that perform pipetting tasks, assessment of %inaccuracy and %CV are generally assessed on the Artel MVS instrument, and must meet laboratory guidelines +/- 5% (10% for volumes ≤10µL)
- Contamination checks can be important in many studies, particularly those that involve pipetting or liquid movement steps. This may include soccer-ball plates for 96-well formats.

Software validations

- Ensure the computer on which the software is installed meets the specifications of the software
- The software must have a version number (this must be referenced in the validation)
- Settings/configurations must be consistent with the software specifications, and only able to be accessed by authorised users
- Software should have pre-existing developmental validation (i.e. publication, or manufacturers validation). This validation should ensure that calculations and parameters meet requirements.

Sensitivity and Limit of Detection:

- Sensitivity studies will often be conducted prior to repeatability/reproducibility assessments.
- Concordance assessments may be incorporated with sensitivity studies. Concordance is usually an assessment of ~100 samples.

DNA Extraction

- Serial dilutions of cell suspensions (where a cell count has been done) are useful for DNA extraction sensitivity studies (Refer project #168 final report for further details)
- Dilutions should result in range of cell concentrations~10-500 cells (per extraction), such that the capacity of extraction technology is assessed at ranges suitable for forensic analysis.

DNA Quantification

- Serial dilutions of NIST standards are useful for LOD and sensitivity assessments where DNA quantifications methods are to be evaluated. Percentage change (inaccuracy) may be calculated from the expected and observed results.

- Dilutions should extend both below and above expected functional range as defined by the manufacturer. For example in validating Quant Studio 5 the dilutions utilised were: 0.0001, 0.001, 0.002, 0.003, 0.004, 0.005, 0.006, 0.007, 0.008, 0.009, 0.01, 0.03, 0.05, 0.07, 0.09, 0.1, 0.5, 1.0 and 5.0 ng/µL (Refer project #185 final report for further details)

DNA Amplification

- Optimal PCR cycle number to be evaluated by the laboratory: this should include 7-12 samples, plus controls over at least 3 different PCR cycle numbers.

Capillary Electrophoresis

- Baseline should utilise 20-100 samples, with samples analysed at 1RFU. Stutter, pull-up, carry-over and artefacts should be removed. Average peak height RFU (μ_{Pk}) for each dye channel calculated using the AVERAGE function (Arithmetic mean) in Excel. The standard deviation (σ_{Pk}) will be calculated using the STDEV function in Microsoft Excel (Refer project #196 for further details)
  - Limit of Detection (LOD)= $\mu_{Pk} + 3\ \sigma_{Pk}$
  - Limit of Reporting (LOR)= $\mu_{Pk} + 10\ \sigma_{Pk}$

Repeatability:

- Run a set of samples multiple times on a plate. Ideally each sample should be run at least 7 times.
  - On a standard PCR plate 12 samples can usually be run on a plate 7 times with standards and/or controls – this is considered statistically sound.
  - Scatter plots or box plots can be a way to display the data and evaluate the variability between replicates.

Reproducibility:

- Run a plate over multiple days (as many as is practicable e.g. over 3-5 days), with different operators.
- The "plate" of samples used for reproducibility may include the same samples used for repeatability. It is suggested that ~12 samples (min 7 samples), plus controls are included in the reproducibility plate.
- Scatter plots or box plots can be a way to display the data to evaluate reproducibility within the system.

Performance Study:

For some projects a performance study is worthwhile. This is generally a set of "Typical" samples received within the laboratory. Generally, a larger number of routine samples are processed.

Exemplar publications of forensic validation studies:

Coble, MD, Buckleton, J, Butler, JM, Egeland, T, Fimmers, R, Gill, P, Gusmão, L, Guttman, B, Krawczak, M, Morling, N, Parson, W, Pinto, N, Schneider, PM, Sherry, ST, Willuweit, S & Prinz, M 2016 'DNA Commission of the International Society for Forensic Genetics: Recommendations on the validation of software programs performing biostatistical calculations for forensic genetics applications,' *Forensic Science International: Genetics*, vol 25, pp 191-197

Hollard, C, Ausset, L, Chantrel, Y, Jullien, S, Clot, M, Faivre, M, Suzanne, E, Pène, L & Laurent, F-X. 2019, 'Automation and developmental validation of the ForenSeq™ DNA Signature Preparation kit for high-throughput analysis in forensic laboratories', *Forensic Science International: Genetics,* vol. 40, pp. 37-45

Meuwly, D, Ramos, D & Haraksim, R 2017, 'A guideline for the validation of likelihood ratio methods used for forensic evidence evaluation', *Forensic Science International*, vol. 276, pp. 142-15

8.2 Appendix B: Resources for Statistics

QFAB Biostats Sites Sheet

A list of useful online Biostatistics sites.

Introductory Theory

Discovering Statistics by Andy Field
https://www.discoveringstatistics.com/

Study Design

Phases of Clinical Trials by Australian Clinical Trials
https://www.australianclinicaltrials.gov.au/what-clinical-trial/phases-clinical-trials

Study Designs by The Centre for Evidence-Based Medicine
https://www.cebm.net/2014/04/study-designs/

Choosing the Right Statistical Test

Numerical Methods for Biosciences Students
https://web.anglia.ac.uk/numbers/biostatistics/biostatistics.html

Statistical Decision Tree
https://www.anzmtg.org/stats/

Sample Size and Power

Calculating an optimal samples size or identifying the power of a sample size
https://www.anzmtg.org/stats/Guides/PowerOfSampleSize

Sample Size and Power Calculators

G*Power, MedCalc, EpiTools, StatsToDo, StatsPages

Sample size estimates need to be inflated to take into account estimated drop outs and missing values. QFAB has developed a Study Length Calculator for this.

Randomisation

Directory of randomisation software and services
https://www-users.york.ac.uk/~mb55/guide/randsery.htm

Surveys & Questionnaires

Measurement Tools/Research Instruments
http://guides.lib.uw.edu/c.php?g=99174&p=641942

Prepared by the QFAB Biostatistics Team
https://qfab.org/biostatistics

QFAB recommends using REDcap, especially for longitudinal studies, and provides training in this. Please check if your employer supports this software.

Data Management

Good Data Guidelines
https://qfab.org/good-data-guidelines
Numerical conversion is not required is using the software R.

Online Calculators

MedCalc, Vassar Stats, EpiTools, StatSciCalc

Software

Software support
https://stats.idre.ucla.edu/#

We recommend against using Excel for data analysis. In increasing sophistication but decreasing ease of use: GraphPad Prism, SPSS, STATA, SAS, R. Each software has its own online help documentation. QFAB provides training in R, SPSS, and STATA.

Data Analysis

Choosing the right distribution
https://blog.cloudera.com/blog/2015/12/common-probability-distributions-the-data-scientists-crib-sheet/

Everything you need to complete your data analysis
https://statistics.laerd.com/features-overview.php

Statistical Help
https://www.statsdirect.com/help/default.htm

References

Handbook of Biological Statistics
http://www.biostathandbook.com/analysissteps.html

Biostatistics Resource for Medical, Health and Allied Research
http://www.medicalbiostatistics.com/

Statistics for Biologists
http://www.nature.com/collections/qghhqm/pointsofsignificance

Prepared by the QFAB Biostatistics Team
https://qfab.org/biostatistics

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HealthSupport Queensland
Forensic and Scientific Services

Police Services - Human Ethics Review Checklist

Part A – To be completed by the Principal Researcher

Submitted by:	***Date of submission:***

Project Title:

☐ Please attach Research and Development Application (QIS 27005 or 33017)

Proposed project commencement date:	***Estimated completion date:***

1. This project is being performed:

☐ As part of an FSS project ☐ In collaboration with an external organisation ☐ Other:

** An agreement may be required if the project involves or is funded by a third party. Please discuss with the FSS Research Office.*

2. Description of the proposed project:

☐ Research ☐ Development ☐ Analysis of existing data ☐ Case study ☐ Quality Assurance * e.g. method validation

☐ Other, please describe:

** Ethical review of quality assurance activities may be required if the activity uses data about or samples taken from people. Most quality assurance activities are focussed on process improvement and would therefore not require ethical consideration.*

3. This project will involve: ☐ Retrospective analysis # ☐ Prospective analysis

 # Data or samples already collected at the time of application or events that have already occurred.

4. This project will involve the following biological material and/or data:

☐ Buccal, hair, blood, fingernails ☐ Vaginal sample ☐ Semen sample ☐ No biological material

☐ Other, please describe: ☐ Data, specify:

5. How was the material or data originally collected: *

☐ Intel - Reference sample ☐ Evidence - reference sample ☐ Volunteer Limited Purpose – reference sample ☐ Staff sample

☐ Other: ☐ Data source, describe:

** Acknowledgement of the materials source shall be provided in the final publication*

6. Do you intend to seek consent from any participants in this project? ☐ Yes ☐ No

7. Will testing or data collection additional to routine process be required? ☐ Yes ☐ No

If 'yes', is the testing related to the purpose that the original sample was collected? * ☐ Yes ☐ No

** Refer to relevant legislation in your area.*

8. The primary/raw data or material used during the project will be: ☐ Individually Identifiable* ☐ Non-identifiable ☐ Re-identifiable (e.g. unique/uncommon characteristics, photograph)

** Ability to identify individuals from data varies according to the characteristics and will impact on the level of ethical review required.*

9. How will you disseminate the findings of the project?

☐ Presentation/poster at a conference ☐ Publication in Public Health Bulletin ☐ Paper in peer review journal

☐ Method Validation Report ☐ Other, please describe:

 # An electronic copy of all publications shall be provided to [redacted] for loading onto the QHFSS ePrints Server.

10. Will individuals be identifiable/re-identifiable in the final publication/presentation: ☐ Yes* ☐ No

**Where individuals have not consented to participate in the project, or a waiver of consent has not been granted by a HEC, potentially identifiable characteristics must be removed. The draft paper/presentation must also be submitted to the FSS-HEC for review prior to submission.*

11. Is approval to use the data/material for this project required? * ☐ Yes ☐ No

If yes, specify:

** Refer to relevant legislation for your work area.*

12. Will disclosing the data require legislative approval? * ☐ Yes ☐ No

If yes, specify:

** Refer to relevant legislation for your work area.*

13. Will your project involve an external student / collaborator? ☐ Yes ☐ No

If 'yes', will they be required to access identifiable information? ☐ Yes ☐ No

14. What is your assessment of the ethical risks associated with this project? *

** For further explanation refer to Section 2, National Statement on Ethical Conduct in Human Research 2007 (updated 2018).*

Type of Risk

Level of Risk	***Type of risk (examples)***	***Describe potential risks for your project***
Negligible Risk	**Inconvenience:** - *Filling in a form, participating in a street survey, time*	
Low Risk	**Discomfort** of body or mind: - *Minor-side effects of medication, measuring blood pressure, anxiety induced by an interview* *(Where a person's reactions exceed discomfort and becoming distress, they should be viewed as harms).*	
High Risk	**Harms:** - *Physical harms: injury, illness, pain* - *Psychological harms: feelings of worthlessness, distress, guilt, anger, fear e.g. related to disclosure of sensitive or embarrassing information, learning about a genetic possibility of developing an untreatable disease* - *Devaluation of personal worth: humiliation, manipulation, disrespectful or unjust treatment* - *Social harms: damage to social networks/relationships, discrimination in access to benefits/services/employment/insurance, social stigmatism, findings of previous unknown paternity status* - *Economic harms: direct or indirect costs* - *Legal harms: discovery and prosecution of criminal conduct*	

Likelihood - ☐ Not likely ☐ Likely ☐ Very likely

15. What are the potential benefits of this project?

16. Do the benefits of this project outweigh the potential risks?

17. Comments

Research Office use only

Part A – Human ethics recommendation		
Review: ☐ Further information is required. ☐ This project does not meet the definition of research and therefore does not require human ethics review (p.6 *National Statement).* ☐ This project has been assessed as negligible risk in accordance with section 5.1.22 of the National Statement and is exempt from full human ethics review. ☐ A waiver of consent is required in accordance with section 2.3.9 of the National Statement and must be referred to the HEC for review. ☐ This project requires the submission of a Low and Negligible Risk Application (LNR) to a registered human research ethics committee. ☐ This project requires the submission of a Human Research Ethics Application (HREA) to a registered human research ethics committee. ☐ Refer to the Chair of the FSS-HEC for recommendation.		
FSS-HEC Member / Delegate	Signature	Date of Assessment
Comments:		

Amendment history

Version	Date	Author/s	Amendments
1	May 2015	L Angus / K Scott	First Issue
2	November 2018	L Angus	Insertion of questions 14-17. Revision of Part A to reflect current assessment process and revised version of the National Statement.

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Funding Source (if applicable)		
Funding Source	Amount Requested	Approved
FSS Internal Fund		YES
Partner Contribution		YES
External Fund		YES
Total	0	

Expenditure Type	Monthly	For duration of project - Months:_____
Labour		
DNA Analysis Personnel (Salaries and on-costs - for this email Business Management Information (BMI) Team for a salary forecast).		
Other:		
Subtotal Labour:	0	0
Non- Labour		
Equipment		
Consumables		
Travel		
Publication Costs		
Other:		
Subtotal Non-labour:	0	0
Total:	0	0

Justification of Funding (Non-Labour Costs)

Justify in terms of need and cost, each budget item in previous table. Please attach quotes where necessary

Justification of Funding (Labour Costs)

If project includes an appointment to assist or backfill, please provide details in the table below and submit to the BMI teamfor a detailed quote.

Status	☐ Permanent
	☐ Part-Time
	☐ Temporary (<12mths)
	☐ Casual
Classification	☐ Administrative
	☐ Operational Officer
	☐ Health Practitioner
Time Period	
Position Title	
Qualification Required	
Budget Required - Salary:	
On-Costs:	
Total:	0
Cost Centre	

Any other information that you think maybe relevant please explain below:

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HealthSupport
Queensland
Forensic and Scientific Services

Risk Management Guideline – conducting and evaluating Health and Safety risk assessments

1 Purpose

The purpose of this document is to provide guidance for the completion of a workplace health and safety risk assessment, in line with:

- Work Health & Safety Act & Regulation 2011
- AS 2243 Safety in Laboratories (set)
- AS 4360 Risk Management

2 Scope

This procedure applies to Forensic & Scientific Services (FSS) and is intended for use by FSS staff when conducting and / or reviewing risk assessments.

3 Definition

Hazard: A source of potential harm to people or a situation with potential to cause injury or loss to plant, property or equipment.

Hazard control: Is the process of implementing measures to reduce the risk associated with a hazard.

Hazard identification: Is the process of identifying all situations or events that could give rise injury, illness or damage to plant or property.

HSRs Health and Safety Representatives. Nominated and voted by staff members in respective work units.

Hierarchy of Control: Is the established priority order for the types of measures to be used to control risks.
Risk: The likelihood that a harmful consequence (e.g. death, injury, illness) might result from exposure to a hazard. The degree of risk is affected by the likelihood of the event and the severity of the consequences.

Risk Assessment: A systematic approach to assessing hazards which provides an objective measure of the hazard and allows hazards to be prioritised and compared.

Risk Score: The measurement of risk using a common score so that risks can be compared and prioritised for control.

4 Responsibilities

FSS leadership team is accountable for:

- ensuring established policy and procedures are utilised, providing the necessary resources to enable the identification of hazards, the evaluation of risks, and the recommendation, implementation, monitoring and review of control measures.
- monitoring the outcomes and effectiveness of those policies and procedures

Team leaders and supervisors are responsible for:

- ensuring that hazards associated with work unit processes have been identified, risks assessed, and control measures implemented in accordance with hierarchy of control principles.
- ensuring risk assessments are undertaken in consultation with employees
- reviewing the risk assessments to ensure that they are conducted, evaluated, recommended controls have been agreed and an implementation of control measures is undertaken.
- monitoring the effectiveness of the control measures implemented.
- ensuring employees are trained in and follow safe work procedures.
- ensuring that personal protective equipment (PPE) and other equipment necessary to complete the task safely is available, maintained and used correctly.
- ensuring that work-caused incidents are reported, investigated and corrective actions implemented (viz. RiskMan).
- records of all risk assessments are available to all staff and regulatory bodies
- ensuring risk assessments are reviewed and updated on a regular basis (3 to 5 year periodic evaluations subject to hazards, risks and control measures).
- Risk assessments are to be re-evaluated and considered prior to changes in the work area (e.g. introduction of new instrumentation, a change of process, substitution of materials etc).

Employees are responsible for:

- evaluating tasks and procedures in light of hazards and perceived risks
- undertake risk assessment training and coaching so they can competently conduct a risk assessment as a participant on an assessment team.
- making themselves self-aware of the hazards, risks and control measures associated with their work area processes.
- following safe work procedures, including wearing of appropriate personal protective equipment (PPE) and understanding of implemented hierarchy of controls in respective work areas
- identifying and reporting any identified hazards (whether previously identified previously or not) which they encounter whilst carrying out of work area processes.
- reporting any incidents that occur in the workplace to the relevant Team Leader / supervisors, including recording in RiskMan.

Note:	Given the responsibilities outlined above, it is recommended that the team leader / supervisor is not a participant in the Assessment team. If it is necessary for the team leader / supervisor to be on the assessment team, then the risk assessment MUST be provided to the overarching manager (e.g. managing scientist, section manager). Risk assessments should clearly identify the *contact persons* (e.g. Subject matter experts) and disclose if the SME contact is on the assessment team. Where possible, a staff member should maintain a single role, to avoid conflicts of interest. For example: a Contact person is not on an Assessment team. A team leader / supervisor should consider not to be on the assessment team when they will be reviewing the risk assessment, otherwise the next manager above should be considered. It is recommended that consultation occurs with the Quality manager and / or Scientific Skills Development Unit (SSDU), in the event of staff having more than one role in a risk assessment.

5 Risk management guidelines

A risk assessment should be carried out:

- on all work area processes, tasks, activities where staff may potentially be exposed to hazards and associated risks
- when a new activity is being considered or introduced
- when changes are being made to an existing process
- at regular or scheduled intervals (consultation is necessary with organisational management, HSRs and HSQ Safety and Wellbeing)
- when using new or used equipment or using new or substituted materials and substances
- planning to improve productivity or reduce costs
- responding to workplace, work area, work unit incidents (even if they have caused no perceived injury)
- when legislative, compliance, standards requirements change
- when new information on a hazard or control measure becomes available
- within agreed timeframes (3 months to a maximum of 5 years) of the last assessment (refer to dot points above)
- if health surveillance or monitoring shows that control measures need to be reviewed

Note: annual risk assessments are required if the process involves a risk from exposure to lead.

5.1 Step 1: Define the context

It is important to consider the context in which the risk assessment process takes place before the next steps are undertaken. During this phase (and all other in the risk assessment process) it is essential to undertake extensive consultation with stakeholders (staff members, Team Leaders / Managers, H&S Representatives / OHS staff, and subject specialists). Defining the context involves consideration of:

- The activity / tasks / procedure:
  - What is the purpose of the activity?
  - What are the steps involved in carrying out the activity?
  - Do steps have to follow a particular sequence?
  - How long will it take?
  - What could change / impact on the activity?
- Methods / procedures:
  - Are there safe work procedures available?
  - Are the procedures applicable to this task in this situation?
  - Are the workers who will carry out the task trained in the correct procedures?
- Location / environment:
  - Where is the work / task to be carried out?
  - Are there particular hazards arising from the location / environment?
  - Will the location / environment affect how the task can be done?
  - Are there access and/or exit issues to be considered?
- People:
  - Who will be involved?
  - Are workers / others required to have different roles?
  - How are responsibilities allocated?
  - Have the workers / others been informed and trained in their roles and responsibilities?
  - What communication is needed?

- Equipment and materials:
  - What equipment and materials are required to perform the task?
  - What safety equipment / personal protective equipment is required?
  - Are there checks in place to ensure the equipment and materials are in good condition and fit for the task?
  - Have those using the equipment / materials been trained in their correct use and maintenance?
  - How will the equipment and materials be transported to the location of the task?

- Hazards and Risks
  - What could cause harm?
  - How could workers / others be exposed to the hazard, for how long, and how often?
  - What could go wrong?
  - How serious could the consequences be?
  - How can the risk be reduced?
  - What incidents have occurred in the past?

- Emergencies
  - What types of emergencies could arise? (e.g. fire, medical)
  - Is there an emergency plan?
  - How would the emergency be managed / communicated?
  - What assistance would be needed?
  - Are there First Aid Officers available?

- Relevant legislation, standards & guidelines

5.2 Step 2: Identify the hazards

Hazard identification is the process of identifying all sources, situations or events that could give rise to the potential of injury or illness. Hazards may be grouped as physical, chemical, ergonomic, biological, or psychological

Methods of identification include:

- Observation & analysis of tasks / processes / activities (and agents involved)
- Use of hazard identification checklists (such as Health & Safety Inspection Checklists)
- Reviewing Workplace Incident Report Forms / statistical analysis
- Reviewing workers' compensation records
- Audit / H&S Inspection findings
- Referring to authoritative sources of information (Legislation / Codes of Practice, Australian Standards, SDS, labels, manuals, industry information, reference material, literature reviews etc)
- Consultation with staff

5.3 Step 3: Assess the risks

Once a hazard has been identified, a risk assessment must be undertaken to determine the level of risk arising from the hazard / event. This process requires a systematic approach to assessing hazards and provides an objective measure of the hazard. Steps are as follows:

5.3.1 Consequence

This refers to the physical outcome of the hazard / event, and provides an indication of the severity of the risk in relation to harmful effects on humans, property, the environment and organisational productivity.

	Negligible	Minor	Moderate	Major	Extreme
Work Health and Safety	No injury. First aid treatment only. No time lost	Medical treatment injury. A full shift/workday has not been lost	Lost time injury or serious injury or illness without permanent impairment (as defined by *S36 Work Health & Safety Act (QLD) 2011)*	Serious injury or illness with permanent impairment (as defined by *S36 Work Health & Safety Act (QLD) 2011)*	Reportable fatality (as defined by *S35 Work Health & Safety Act (QLD) 2011)*

This measures the likelihood of the event and associated consequences.

Part 2 Likelihood table

The Likelihood shall be used to rate how likely/how often a risk is expected to occur. When assessing likelihood, use either description or probability.

Likelihood	Description	Probability
Almost Certain	The risk/event will likely occur in most circumstances.	>90%
Likely	The risk/event will probably occur at least once.	60-90%
Possible	The risk/event could be expected to occur at some time.	30-60%
Unlikely	The risk/event could occur at some time but is not expected.	5-30%
Rare	The risk/event may occur only in exceptional circumstances.	<5%

5.3.2 Risk rating

To provide a measure of the level of risk, the above consequence and likelihood descriptors are then combined in a risk matrix. The higher the level of risk score, the greater priority is required to control the hazard.

		Consequence				
		Negligible	Minor	Moderate	Major	Extreme
Likelihood	Almost Certain	Medium (7)	Medium (11)	High (17)	Very High (23)	Very High (25)
	Likely	Medium (6)	Medium (10)	High (16)	High (20)	Very High (24)
	Possible	Low (3)	Medium (9)	High (15)	High (18)	High (22)
	Unlikely	Low (2)	Medium (8)	Medium (12)	Medium (14)	High (21)
	Rare	Low (1)	Low (4)	Low (5)	Medium (13)	High (19)

5.3.3 Ranking & prioritising hazards

Following assessment, the risk score used to rank risks in order of priority. Extreme, very high and high risks must be dealt with immediately.

Part 4 Response to Risk

Risk Rating	*Response to the risk
Very High	• As soon as possible (and within 1 month) commence treatment planning for moderation • Monthly – review by risk owner until effectively moderated. This includes risk treatment status updates • Monthly – provide risk update as relevant to governing body or management team (e.g. Project Board, Divisional Leadership Team, Executive Committee or Executive Management Team) and risk stakeholders
High	• Within 1 month – commence treatment planning for moderation • Monthly – review by risk owner until risk is effectively moderated. This includes risk treatment status updates. • Monthly - provide risk update as relevant to governing body or management team and risk stakeholders
Medium	• Within 3 months – evaluate for treatment planning requirements based on cost/benefit and resource prioritisation • Quarterly – Review by risk owner. This includes risk treatment update (if applicable). • As required, provide risk update as relevant to governing body or management team and risk stakeholders
Low	• Maintain effectiveness of current controls and manage by routine procedures. • Monitoring and review schedule should be considered based on potential rapid escalation/volatility of the risk • As required, provide risk update as relevant to governing body or management team and risk stakeholders

*Note: See Risk Profile Process Map for further guidance on Executive Risk Profile Requirements

When determining control solutions, consultation is required between the risk assessment team, Managers, Team Leaders, Supervisors, employees, Health and Safety Representatives (HSRs), WH&S committee and the external stakeholders as required (e.g. HSQ Safety and Wellbeing, Quality manager etc).

5.4.1 Methods of Risk Control

When planning and evaluating how hazards can be controlled, and associated risks mitigated, the following Hierarchy of Control priorities should be considered.

Controls closer to the top of the hierarchy are preferable to those lower down the hierarchy.

In many situations at Forensic and Scientific Services (FSS), a number of control measures will invariably be necessary to be incorporated in risk mitigation.

Hierarchy of Control

Control	***Details***
Elimination	The preferred and most effective control measure, which involves removing the hazard from the workplace (e.g. introducing automation to eliminate manual handling / ergonomics hazards.
Substitution	Involves replacing a hazard with one that presents a lower and more manageable hazard (e.g. using a less toxic chemical)
Isolation	Use of barriers to separate or isolate a hazard. Examples include installing screens or barriers around hazardous areas or guarding around machinery.
Engineering / Redesign / Isolation	Designing and installing equipment to minimise hazards, for example exhaust systems to extract fumes / dusts etc. Use of barriers to separate or isolate a hazard. Examples include installing screens or barriers around hazardous areas or guarding around machinery
Administrative Controls	Involves minimising exposure to risk through a range of controls such as procedures, training, job rotation, signage, permit to work systems, exclusion, supervision.
Personal Protective Equipment (PPE)	This is the least preferred method and should be used in combination with higher order control measures. Included are items such as safety glasses, boots, gloves, masks, ear plugs.

Elimination is the preferred choice in controlling hazards. Where elimination of a hazard is not practicable then engineering / design / isolation controls should be next considered.

Administrative controls and protective equipment may provide interim solutions in a planned program to mitigate or reduce a particular risk, or they may be useful in addition to other control methods.

The lower range, of the above tabled control measures, are not a preferred control measure, particularly if they are the only mitigation controls considered to be available.

Review of the selected control measures must be undertaken by the Team leader and supervisors, in consultation, to ensure that control measures are adequate and practicable.

Note: The risk assessment should be reviewed by management, HSRs, work area staff and where appropriate other stakeholders, in advance of the implementation plan being agreed upon; particularly when only administrative controls and PPE were considered as the only available control measure.

If for instance, the risk assessment was based on processed with a purpose built, dedicated, laboratory (viz. physical containment laboratory), this too is to be considered as an engineering and / or isolation control. Other examples include Biosafety Cabinets (BSC II) and dedicated work space.

5.5 Step 5: Monitoring and review

The implemented control measures should be monitored to check that they are effective, adequate, being applied / used correctly, and have not introduced another hazard or issue.

Risk assessments should be reviewed and updated to ensure they reflect current practices and requirements:

- Timeframes: it is reasonable to consider 3 to 5 year re-evaluations of risk assessments. Comments can be included on the risk assessment for recommended and agreed shorter timeframes.
- when there is a change to the work area process, task, activities which may alter hazards and risks in the work unit / area.
- after an incident or near miss (which should have been recorded in RiskMan).
- when legislative, compliance requirements change
- when new information becomes available.

6 Consultation

Consultation with the relevant staff members and H&S Representatives should take place when identifying, assessing and controlling risks. See note in section 5.4.1.

7 Records

Each risk assessment must be comprehensively documented and referenced in relevant procedures and methods. The FSS Risk Assessment Form (QIS 29100) must be completed by the risk assessment team (minimum of two staff) and reviewed before being signed by the Team Leader / Manager (see note on page 2).

A record of the completed risk assessment shall then be added to QIS (Audit Module), under the audit type: **Risk Management**. OQIs *should* be raised when recommendations for control measures have been identified. OQIs assist in the tabling and progression of the implementation plan.

Each work area is required to keep a hardcopy of the risk assessment. It is recommended that scanned e-copy of the signed (by assessment team and team leaders / supervisor) is placed in an appropriate drive, e.g. G: drive and made available by request.

In line with AS2243.1 risk assessment documentation should be kept for a minimum of 7 years, or longer if specified in legislation, (e.g. 30 years, if there is a significant degree of risk to health).

Records of monitoring and health surveillance must also be kept with the Risk Assessment.

Risks that are rated as VERY HIGH or HIGH, after the introduction of control measures, are to be reported to the FSS Risk register and consultation MUST be conducted with HSRs and FSS Safety and Wellbeing.

8 Training and support

Information, instruction and training provide employees with the skills and knowledge to perform their work in a manner that is safe and with mitigated risk to health. All staff are required to undergo induction and ongoing training in the following areas:

- Workplace health and safety legislation;
- Responsibilities for health and safety
- Safe work procedures (including use of PPE)
- Risk assessment procedures and use of the H&S Risk Assessment Form (QIS 29100 refers).

Records of training provided must be kept and maintained. The record must include:

- the date of the training session (including coaching sessions when conducted)
- the details of the information presented in the session
- the name of the person who conducted the session
- the names of the workers who attended the session

9 Associated Documents

FSS Health and Safety Risk Assessment form (QIS 29100)

10 References

Work Health and Safety Act & Regulation 2011

Hazard identification and risk management procedure (Note: do not use templates and links sourced from this link but only refer to the procedure)

AS2243 Safety in Laboratories (Parts1-10)

AS4360 Risk Management

11 Amendment History

Version	Date	Updated by	Amendments
1-5	various	R. MacKenzie	Refer to QIS2 version history. It appears versions 4-5 did not exist prior to version 6 being published in October 2015.
6	15 Oct 2015	R. Gleeson	Updated format. Note edited version had V5 in the footer.

7	June 2020	P Clausen	Extensive review of responsibilities, including rewording of the guideline. Updated hyperlinks to associated documents and references, including the addition of the Hazard identification and risk management procedure (HSQ document not available in QIS2). Added details regarding consultation and the independence of roles in relation to a risk assessment.

Procedure for Verification and Maintenance of Equipment

1 PURPOSE AND SCOPE

The purpose of this document is to describe the procedure for the verification, storage, use, transport and maintenance of equipment and instruments within Forensic DNA Analysis. The procedure applies to all equipment and instruments within Forensic DNA Analysis requiring verification and maintenance.

2 PRINCIPLE

Critical items of equipment must operate correctly to ensure the quality of test results. To ensure correct operation of equipment, calibration and verification checks must be performed on equipment.

3 GENERAL EQUIPMENT REQUIREMENTS

- All pieces of equipment must be uniquely identified and the identifier must not be re-used (if the equipment is decommissioned).
- All equipment must be maintained in proper working order.
- The quality team is responsible for the maintenance of an equipment list located in Forensic Register (FR). Equipment within FR is under the FSS Forensic DNA Analysis Station/Establishment. The FR records details equipment service history, calibration records and descriptive details (Make, Model, Serial number etc).
- Copies of instruction manuals relating to equipment and/or software are stored to I:\Equipment\Equipment Manuals, and may also be stored in hardcopy in the Quality storage cupboard.
- Risk assessments to determine status of equipment i.e. critical or non-critical located in I:\Quality & Projects\Risk Assessments\Equipment Risk Assessments

4 NEW EQUIPMENT

- For all new equipment installations contact
  - BEMS: Building, Engineering and Maintenance Services - to discuss installation requirements
  - Warehouse to discuss labelling the asset with a barcode, receipting, logistics (storage/space), ETA, forklift access
- All new equipment and on-loan equipment entering the laboratory must undergo "Test and Tag" prior to use.

- All new equipment will need to be registered in FR by the Quality Team (Refer to **Appendix 1: Register new equipment in the FR**). Any calibration record (from manufacturer) must be loaded against the equipment – using the "issued" action on the service history tab.
- New equipment must not be used until it has been verified (if applicable) within Forensic DNA Analysis and/or by the manufacturer (Refer to **Appendix 2: Adding a calibration/verification or service record to equipment**).

5 VERIFICATION AND CALIBRATION OF EQUIPMENT

- Verification and calibration records are kept indefinitely; These are stored in network drive I:\Equipment\Maintenance and Calibration records, in addition to being stored in the FR against the equipment number.
- Equipment that requires calibration/verification is listed within Forensic Register (FR) under the FSS Forensic DNA Analysis Station/Establishment. The FR records details equipment service history, previous calibration/verification records and ongoing verification requirements. Addition of the verification/calibration record is to be added to the FR following the procedure in **Appendix 2: Adding a calibration/verification or service record to equipment**.
- For historical records it will also be possible to refer back to QIS2 or to source documents in the network drive I:\Equipment\Maintenance and Calibration records,
- Verification/calibrations records must uniquely identify each piece of equipment, record the method used to verify the equipment, record the equipment used to verify the equipment, record the verification data, and record the officer performing verification.
- The verification date and the verification due date must be labelled on equipment. Label type generic – may be a service company label, dymo label etc.
- Senior Scientist for Quality and Project Team must be notified if a piece of equipment does not pass verification requirements. The equipment must not be used until this has been investigated and corrective action implemented.
- To remove or edit an equipment record (e.g. service or calibration) please see quality. If quality is unable to edit/remove the record they will lodge a change request within FR.
- Equipment requiring service or if it is faulty must be removed from service and the equipment clearly marked as '**out of service**' until it is serviced/repaired and has been calibrated.
- Temperature records for all fridges and freezers are stored to network drives I:\Equipment\Maintenance and Calibration records\BMS and are kept indefinitely.
- The pH meter records are kept with the instrument initially, and are then kept within the quality cupboard, and stored to network drives I:\Equipment\Maintenance and Calibration records\pH Meter All records are to be kept indefinitely.
- Equipment that does not require verification must be marked as non – critical.

Table 1: Documents and forms for calibration/verification in Forensic DNA Analysis

QIS #	Document	Instrument
10666	Balance Verification and Assessment (FSS and PQ)	Balance
32418	BTS and FSS Balance Verification Spreadsheet	
33955	Procedure for thermometer checks using the Fluke 7103 Micro Bath	Digital Thermometers, Alcohol Thermometers
17238	Forensic DNA Analysis Fridge/Freezer Issues Log	
33954	FSS Thermometer Verification Spreadsheet	
31702	BMS monitoring and storage of refrigerator and freezer temperature data in Forensic DNA Analysis	Fridge/freezers
10672	HSQ - The Verification of Timing Devices	Electronic Timer
10671	Procedure for In-House Calibration and Verification of Piston Operated Volumetric Apparatus (POVA)	Pipettes and Multi-channel pipettes
26628	Calibration using the Artel MVS®	
31956	Calibrations using the PCS Pipette Calibration System	
34050	Operation and Maintenance of the Microlab STARlet and LabElite Integrated I.D.Capper	STARlet
23922	Procedure for the Use and Calibration of the pH Test 30 pH Meter	pH Meters

6 MAINTENANCE OF EQUIPMENT

- Maintenance records from all pieces of equipment are stored in network drive I:\Equipment\Maintenance and Calibration records and a hardcopy (as applicable) stored in the corporate equipment file with Quality Team. These records are to be stored indefinitely.
- MILLIQ IQ7000 User Manual to associated docs for maintenance procedures I:\Equipment\Equipment Manuals\Millipore\Milli-Q IQ7000
- S4HANA maintenance register for all scientific equipment work order requests located in G:\ForBiol\AAA Administration\Office Equipment and Consumables\Maintenance\Maintenance Register.xls. Refer to details is QIS 24138.
- SEMT service agreements are to be stored in G:\SCRATCH\Scientific Equipment Maintenance
- When equipment that requires calibration/verification it will be listed within Forensic Register (FR) under the FSS Forensic DNA Analysis Station/Establishment. The FR records details equipment service history. Addition of a service record is to be added to the FR following the procedure in **Appendix 2: Adding a calibration/verification or service record to equipment**
- For historical records it will also be possible to refer back to QIS2 or to source documents in the network drive I:\Equipment\Maintenance and Calibration records.
- Commonly used instrument and equipment such as fume hood, vortex, and microfuge requires routine cleaning using 0.5% v/v Bleach and 70% v/v alcohol before and after use. Centrifuges, heat blocks and other instrument that will corrode using bleach will be wiped instead with 5% v/v trigene and 70% v/v alcohol or refer to individual SOP for routine maintenance and cleaning.
- Faults with equipment are to be reported to the Senior Scientist Analytical, Evidence Recovery or Quality & Projects. The Senior Scientist will organise repair of the equipment if required.
- Equipment requiring service or equipment that is faulty is to be removed from service. The equipment is to be clearly marked as '**out of service**' until it is serviced/repaired and has been calibrated and checked appropriately.

- Six monthly and yearly maintenance on equipment (e.g. centrifuges, balances, biohazard hoods, fume hoods, thermal cyclers and BSD), may be provided externally by the manufacturer, by Biomedical Technology Services (BTS) or by another external service company. Refer to I:\Equipment\Maintenance and Calibration records for records of previous service suppliers.
-

Table 2: Maintenance procedures that apply to equipment within Forensic DNA Analysis

QIS#	Title
34050	Operation and Maintenance of the Microlab STARlet and LabElite Integrated I.D.Capper
34312	Operation and Maintenance of the Applied Biosystems 3500xL Genetic Analyzer
34035	Forensic Register FTA Processing
35692	BSD600 Ascent A2 Operator Manual
34042	Procedure for the use of STORstar unit for Automated Sequence Checking
35093	Operation and Maintenance of the Direct-Q® 3 UV-R system
25747	Use and routine care of compound optical and stereo microscopes

7 DISPOSAL OR EXCHANGE OF EQUIPMENT

If equipment has to be disposed of, or exchanged for another piece of equipment (due to recall) then the following procedure should be followed:

- Before being removed from the laboratory, the equipment will need to be decontaminated. This should be done using bleach and/or ethanol (or to the manufacturers requirements). If the equipment is to be returned to the company which supplied it - a decontamination form may need to be completed (refer to manufacture/supply company) or QIS 32602. If the equipment is for disposal no decontamination form is needed.
- Remove the Asset barcode from equipment and give it to Senior Scientist Quality and Projects
- Notify Asset Officer of disposal/exchange (for assets)
- Quality officer or asset owner must remove the piece of equipment from FR (if applicable) refer to **Appendix 4: Recording disposal of equipment in FR**

8 ASSOCIATED DOCUMENTS

QIS: 14475 - FSS Analytical Service Framework
QIS: 24753 - CMMS Equipment Transfer/Retirement/Disposal Form
QIS: 24138 - Ordering System Procedures - (Forensic DNA Analysis)
QIS: 35877 - FSS Procedure for work area organised contractors
QIS: 32602 - FSS Decontamination Certificate

9 REFERENCES

Nil

10 AMENDMENT HISTORY

Version	Date	Author/s	Comments
1	7 August 2015	K.Scott	First Issue (Created to replace QIS#17160 when FR is implemented)
2	2 Feb 2017	K.Scott	Remove MPII add STARlet, update all document numbers and hyperlinks
3	27 July 2018	K.Scott	Update all associated documents and hyperlinks. Add instructions to remove a service/calibration record
4	15 January 2020	C. Savage	Add POVAs and timers to section 5. Removed 25045 from table 2 (archived). Added SEMT agreement storage location.
5	17 August 2021	K Scott	General update including: QIS documents, removal old equipment list reference, removal 3130xl, instructions for editing equipment records
6	28 June 2022	C Savage	Remove mention of archived NATA document. Amend appendices to reflect the new version of the FR.

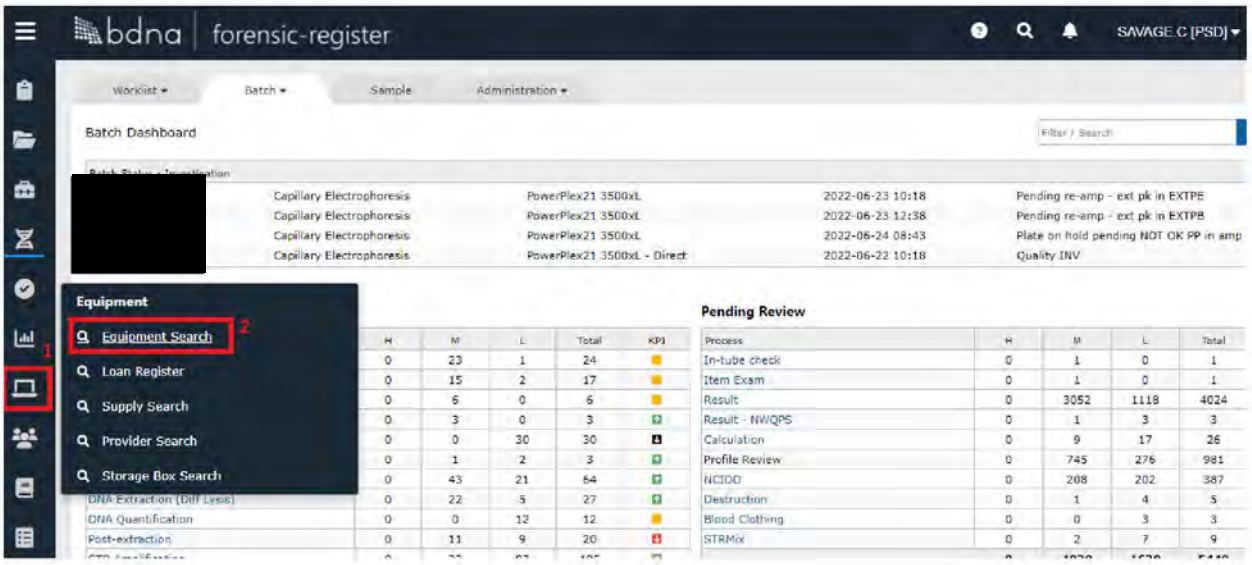
11 APPENDICES

Appendix 1 Register new equipment in the FR
Appendix 2 Adding equipment calibration record to the FR
Appendix 3 Notification of equipment requiring calibration
Appendix 4 Recording disposal of equipment in FR

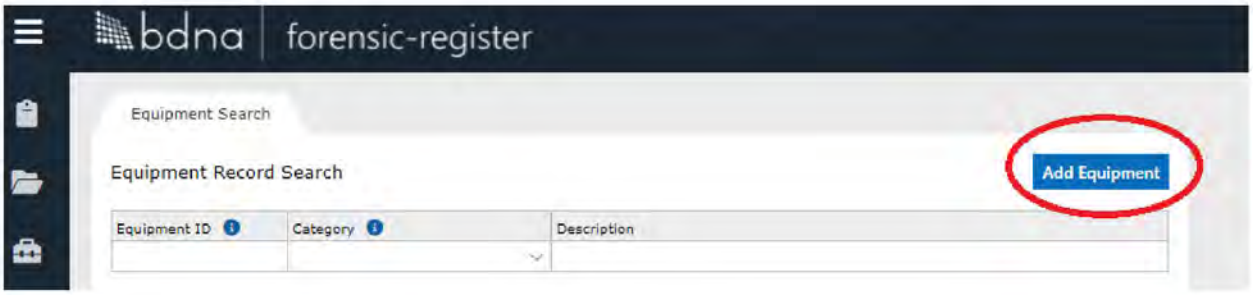
11.1 Appendix 1: Register new equipment in the FR

To register a new equipment item in the FR follow:

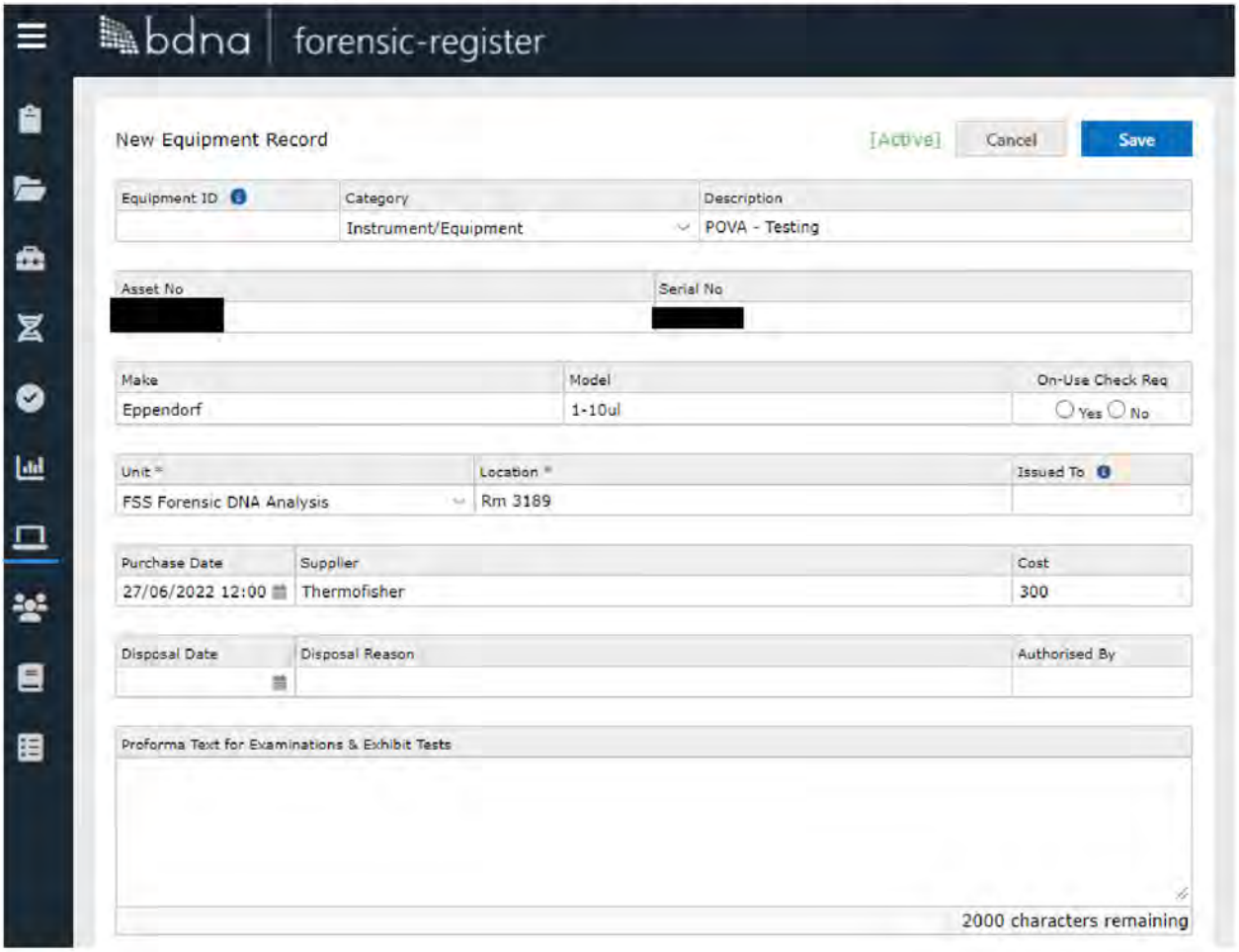
1. Select the 'Equipment' Icon and then click on 'Equipment Search'.



2. Click 'Add Equipment'



3. Enter relevant equipment information as displayed and then save

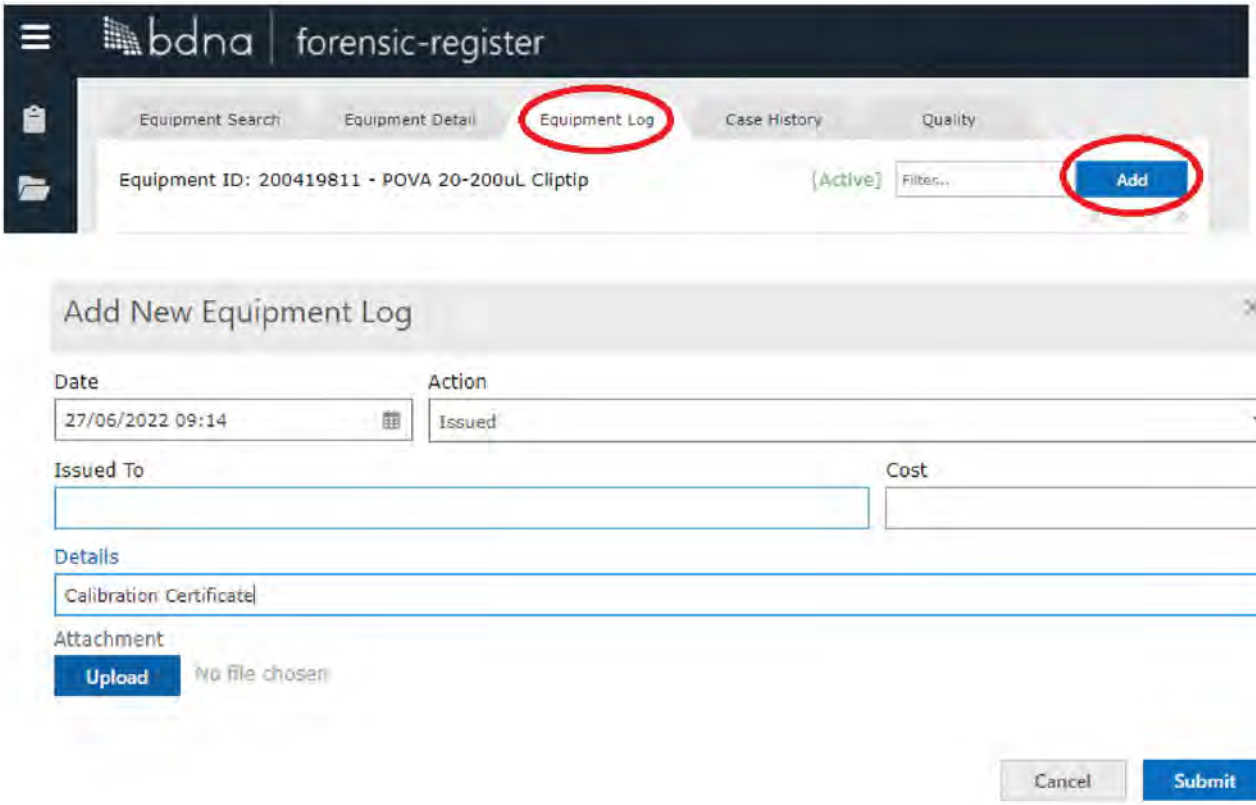


4. After the equipment has been registered, equipment compliance activities are to be set for the item of equipment. Refer to the SOP specific for the piece of equipment you have registered as specified in Table 1 to set appropriate equipment compliance activities and then save.

	Equipment Compliance Activities	Interval		Notification Lead Time		Responsible Unit
☐	Calibration	3	Months	1	Months	FSS Forensic DNA Analysis
☐						

Note: Once the compliance activity has been performed, the row is locked and can no longer be edited. If the compliance activity needs to be updated once locked, the existing activity should be deleted and replaced with a new one.

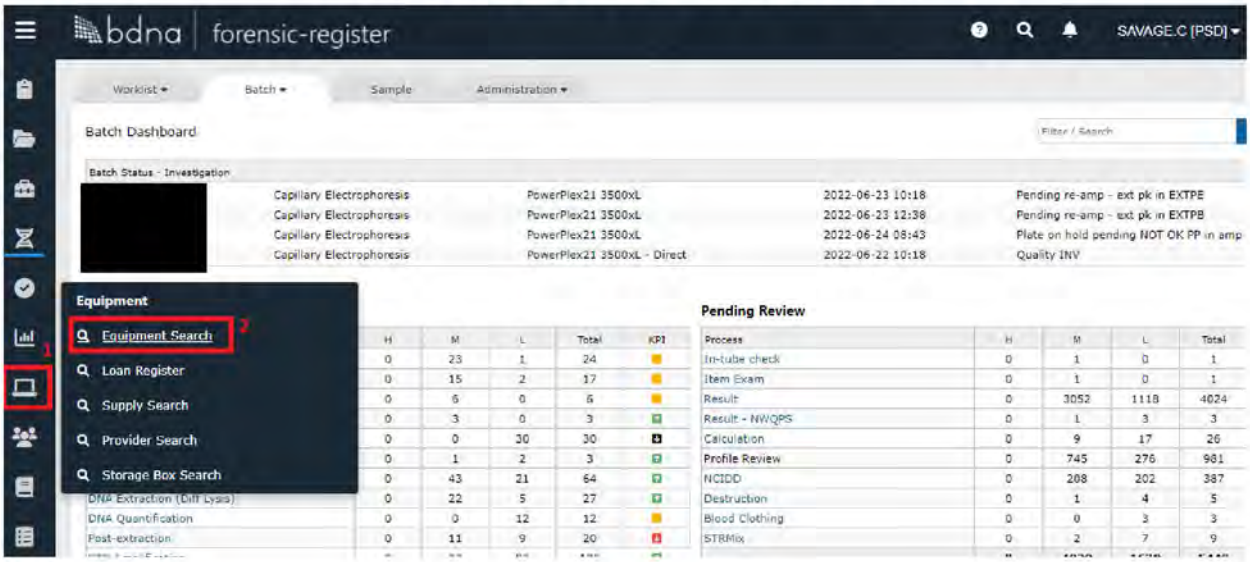
5. As applicable – load the manufacturers calibration certificate as a PDF to the equipment - from the service history tab as an attachment to an action of "Issued"



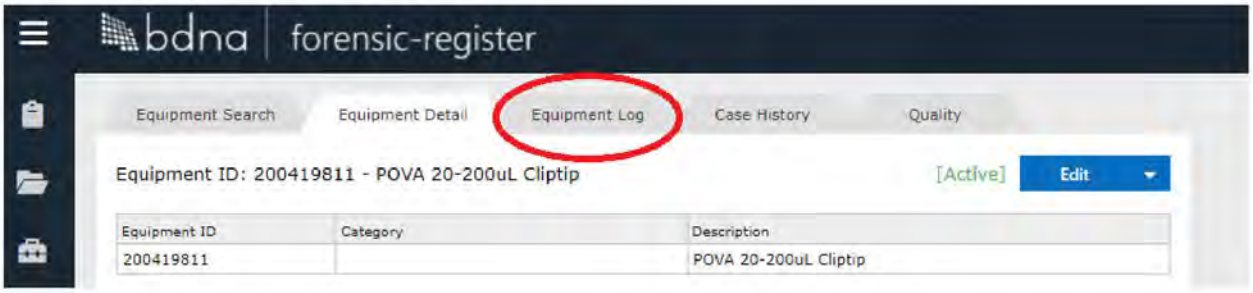
11.2 Appendix 2: Adding a calibration/verification or service record to equipment

To add a calibration/verification or service record to an item of equipment item in the FR:

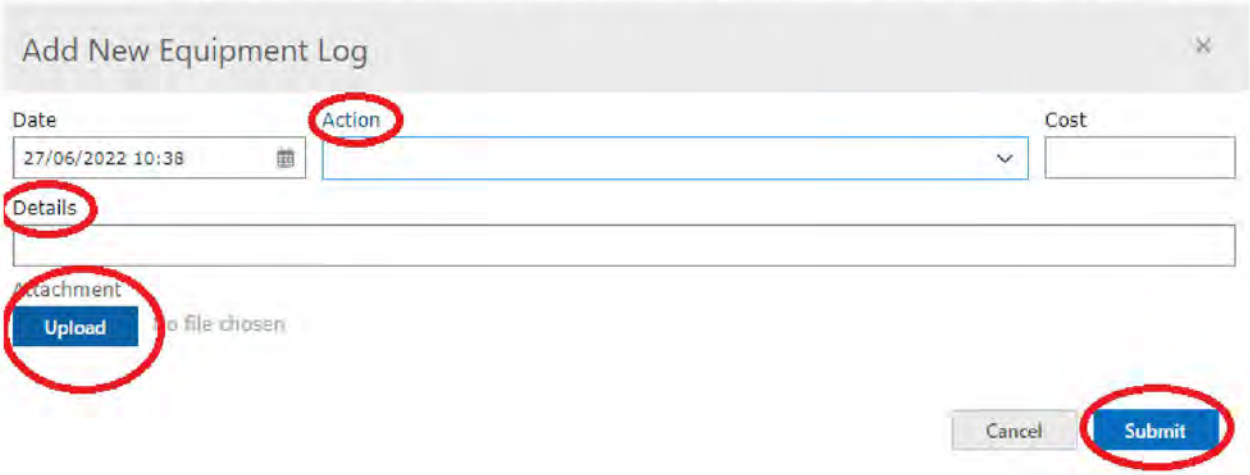
1. Select the 'Equipment' Icon and then click on 'Equipment Search'.



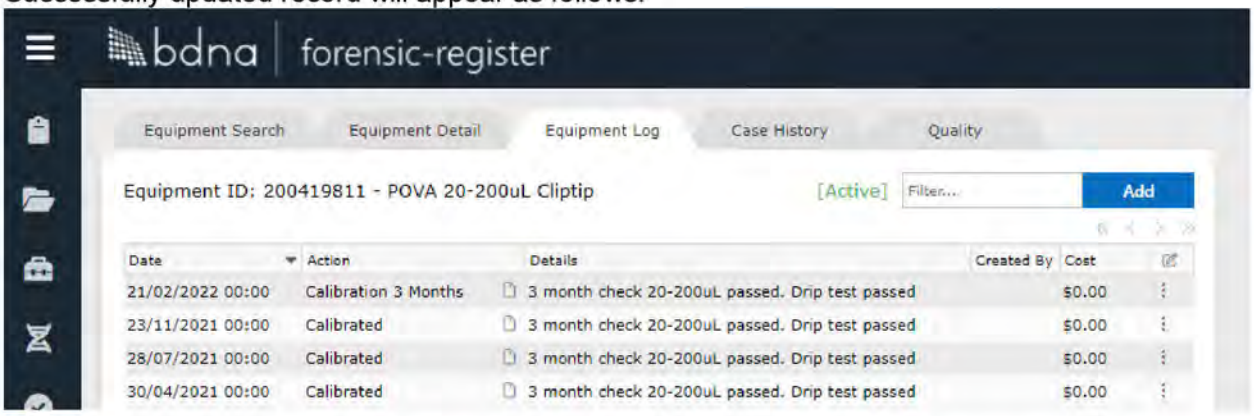
2. Enter the Asset barcode or Equipment number of the item and enter
3. Select the 'Equipment Log' tab



4. Click Add
5. Select appropriate action from the look up list, add description of item (with notes if required) in the details field, attach calibration/verification or service record and submit.



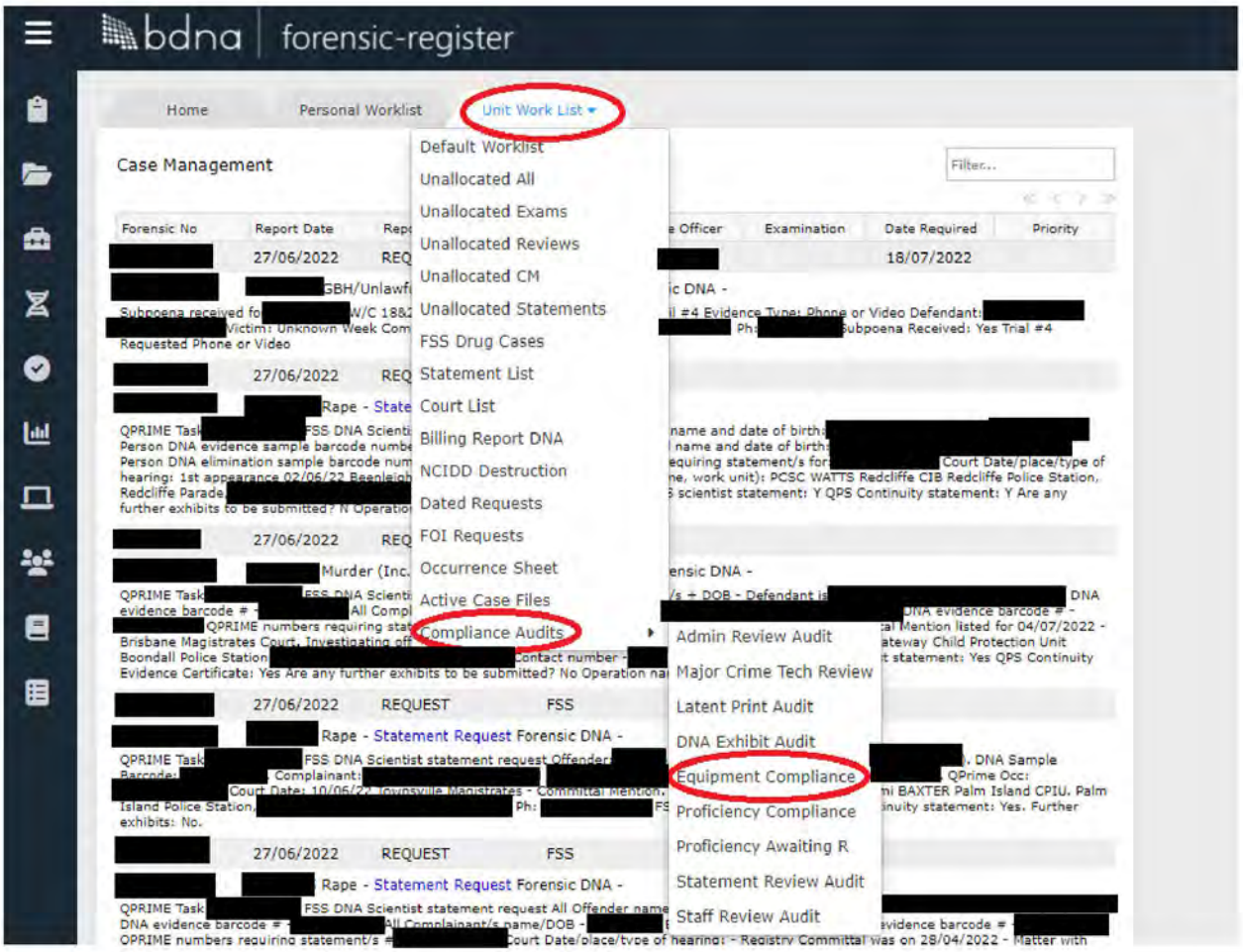
Successfully updated record will appear as follows:



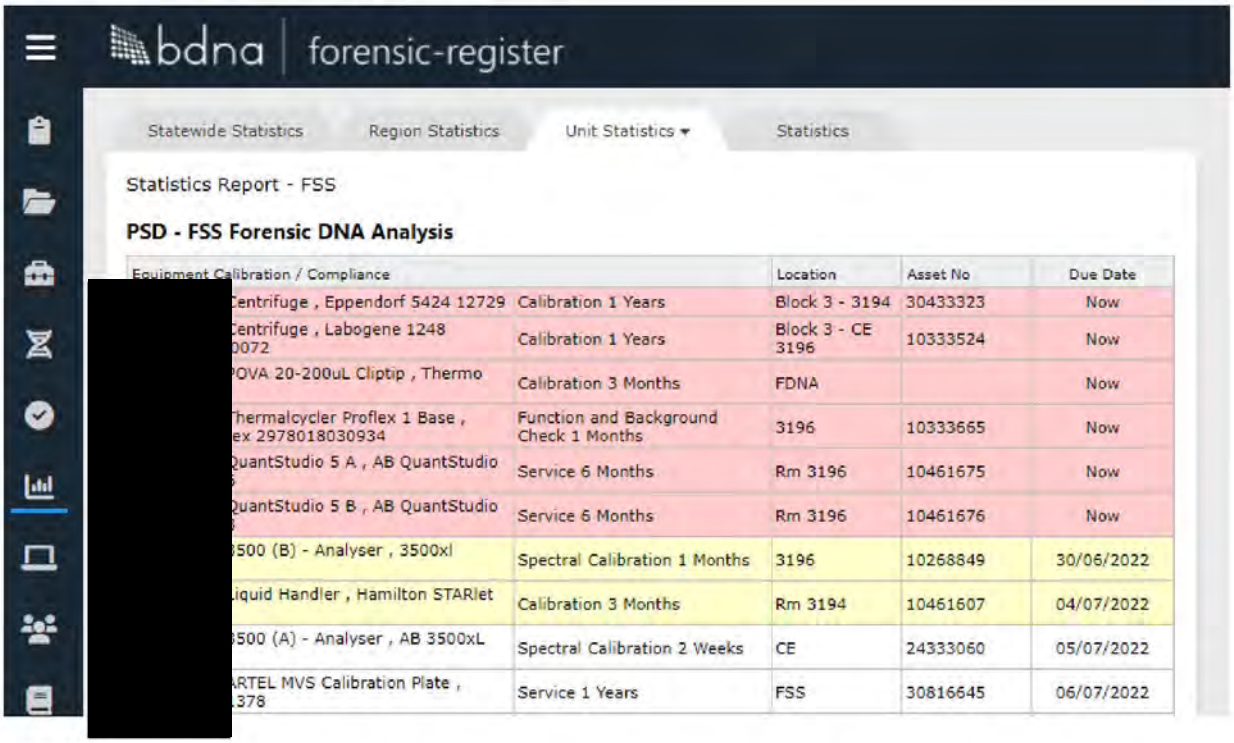
To edit an equipment record (e.g. Service or calibration), click on the three dots at the right side of the screen relevant for the record you wish to amend. Click 'edit' and make any necessary changes. If you wish to delete an equipment record, click on the three dots at the right side of the screen relevant for the record you wish to delete and select 'change request'. A window will pop up, this page must be completed with relevant specific details and saved.

11.3 Appendix 3: Notification of equipment requiring calibration

1. A list of equipment requiring calibration/verification can be located in the Unit worklist under Equipment Compliance



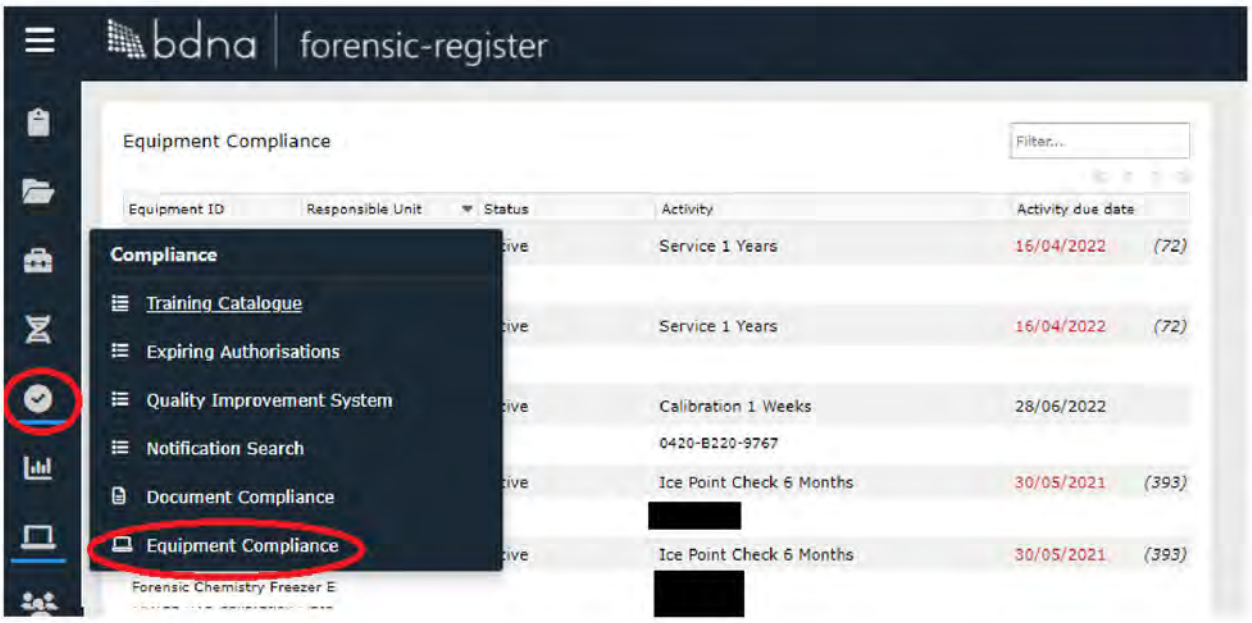
2. Due or overdue calibrations/verifications for the workunit will display in red, while equipment that is due soon will appear in yellow.



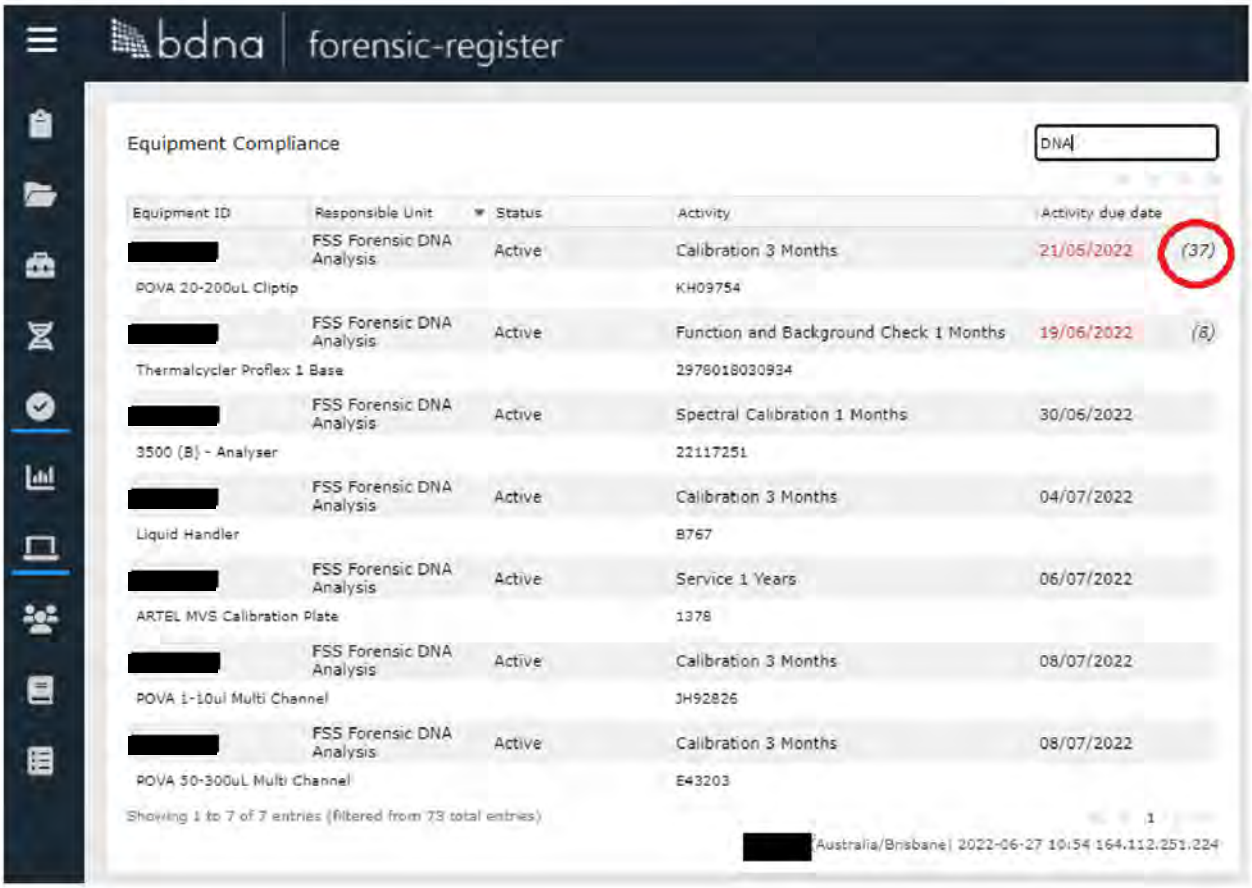
Equipment Calibration / Compliance		Location	Asset No	Due Date
[redacted] Centrifuge , Eppendorf 5424 12729	Calibration 1 Years	Block 3 - 3194	30433323	Now
[redacted] Centrifuge , Labogene 1248 0072	Calibration 1 Years	Block 3 - CE 3196	10333524	Now
[redacted] POVA 20-200uL Cliptip , Thermo	Calibration 3 Months	FDNA		Now
[redacted] Thermalcycler Proflex 1 Base , ex 2978018030934	Function and Background Check 1 Months	3196	10333665	Now
[redacted] QuantStudio 5 A , AB QuantStudio	Service 6 Months	Rm 3196	10461675	Now
[redacted] QuantStudio 5 B , AB QuantStudio	Service 6 Months	Rm 3196	10461676	Now
[redacted] 3500 (B) - Analyser , 3500xl	Spectral Calibration 1 Months	3196	10268849	30/06/2022
[redacted] Liquid Handler , Hamilton STARlet	Calibration 3 Months	Rm 3194	10461607	04/07/2022
[redacted] 3500 (A) - Analyser , AB 3500xL	Spectral Calibration 2 Weeks	CE	24333060	05/07/2022
[redacted] ARTEL MVS Calibration Plate , 1378	Service 1 Years	FSS	30816645	06/07/2022

3. When the calibrations/verifications record is added (as per **Appendix 2: Adding a calibration/verification or service record to equipment**) the record will update to white with the next scheduled date

Note: All equipment for Police Services Stream can be viewed by clicking on the 'Compliance' icon and then selecting 'Equipment Compliance'.



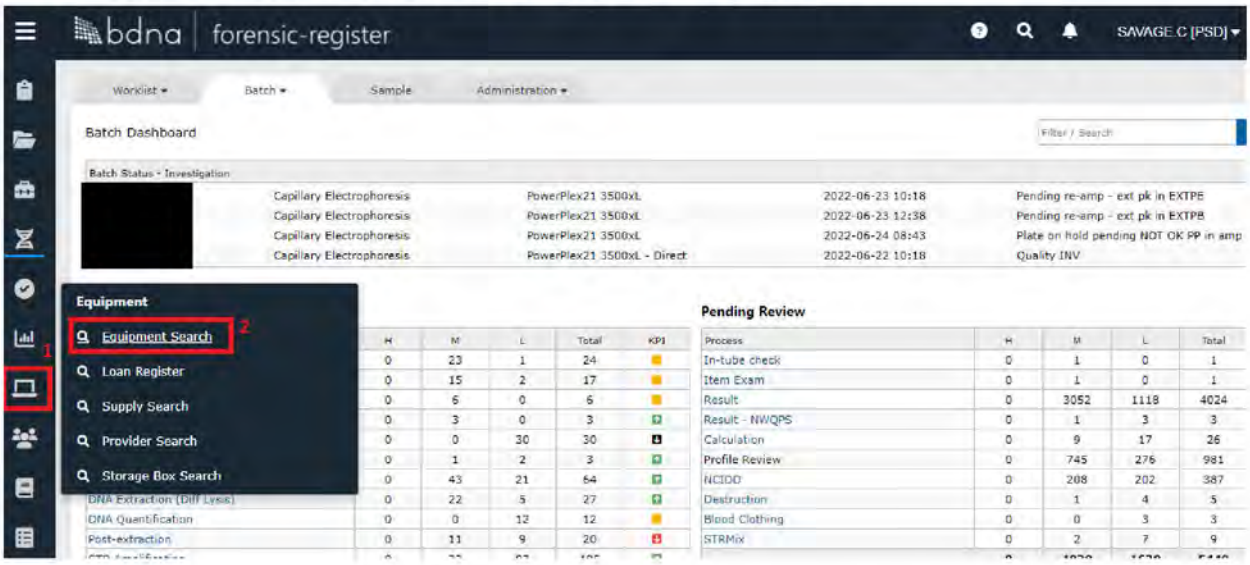
Equipment specific for Forensic DNA Analysis can be viewed by typing 'DNA' into the Filter field. This list will also show the number of days that an item is overdue.



11.4 Appendix 4: Recording disposal of equipment in FR

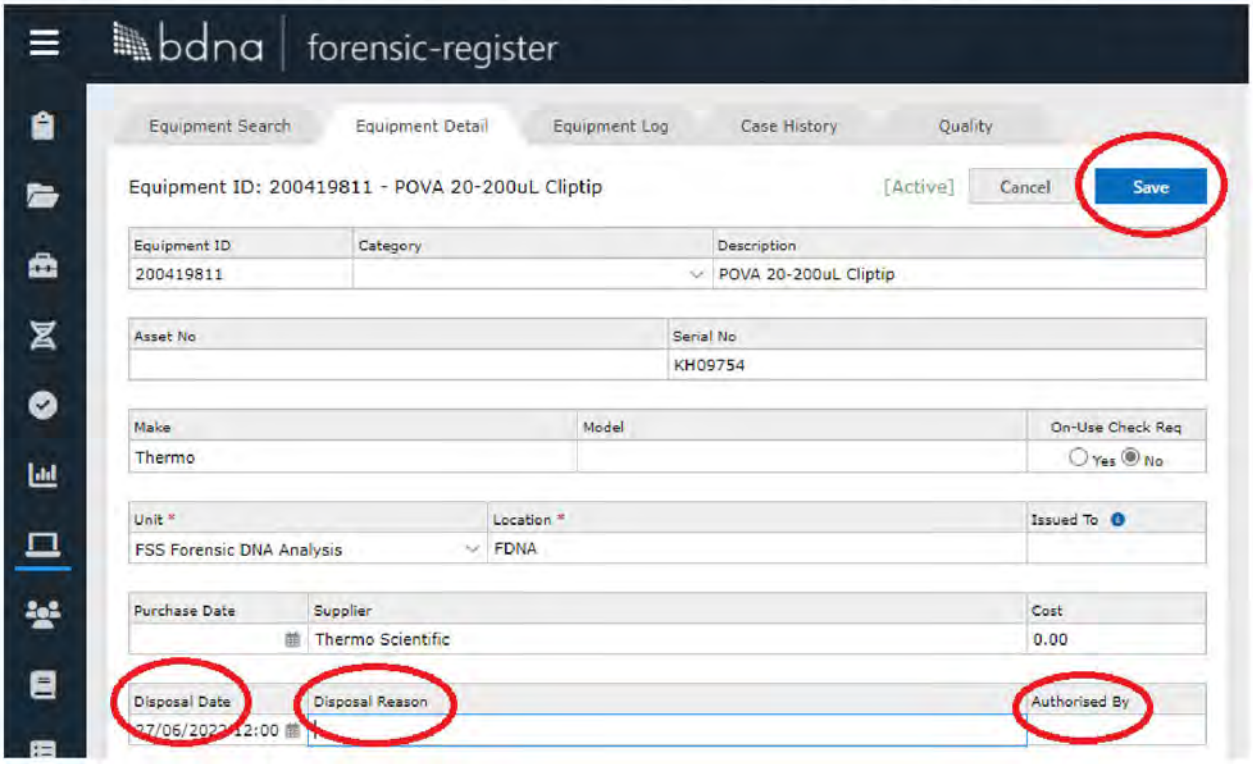
To record the disposal of an item of equipment item in the FR:

1. Select the 'Equipment' Icon and then click on 'Equipment Search'.



2. Enter the Asset barcode or Equipment number of the item and enter

3. Select edit, and add date of disposal, reason for disposal and your staff ID, then save



CA-61

Queensland Health
Forensic and Scientific Services

Procedure for Change Management in Forensic DNA Analysis

1 Purpose and Scope

This document describes the change management procedure that is to be used within Forensic DNA Analysis, to ensure that all process changes and projects occur in a controlled and timely manner. This procedure applies to all process changes or projects that:

- involve the validation/verification of equipment
- involve the validation/verification of technical procedures
- are projects with external funding
- are internal projects (minor or major) which impact on sample reporting/processing
- involve major LIMS function/configuration changes
- impact on multiple stakeholders
- require staff training to be implemented
- significantly alter workflow procedures

This procedure does not apply to:

- routine document updates/alterations
- minor technical changes which do not impact on sample reporting/processing (e.g. changes in specimen type, storage configuration changes)

As an appendix to this document - is a checklist that can be used to guide staff on how they might approach a new idea/observation. It will assist in establishing if it should be recorded as an emerging/novel practice, as a minor change, or as a full project/change management.

2 Definitions and Abbreviations

For a comprehensive list of abbreviations refer to QIS 23849 Common Forensic DNA Analysis Terms and Acronyms.

e-sign	Electronic signature
FR:	Forensic Register
FSS:	Forensic Scientific Services
IT:	Information Technology
LIMS:	Laboratory Information Management System used to record information and track exhibits/case files.
NATA:	National Association of Testing Authorities

3 Principle

Changes within Forensic DNA Analysis have the potential to impact on our clients, on stakeholders (internal/external to FSS) and may impact on compliance with NATA. As such changes which occur with Forensic DNA Analysis must be carefully considered and

documented. There are a number of types of changes that may occur within Forensic DNA Analysis; for the purpose of documentation - these are classified into five types: administrative change, IT/LIMS change, minor project, major project, and external projects.

Administrative changes: are restricted to changes in processes/workflows that impact on documentation or administration processes only. These changes will most likely occur within the Administrative team within Forensic DNA Analysis. It does not include any changes of a technical nature.

IT/LIMS change: An IT change would apply to the introduction of new software into Forensic DNA Analysis, in some instances for upgrades in software versions or the introduction of new hardware. This type of change would require collaboration with IT services. A LIMS project would include any alteration that required a change in the LIMS function, or major configuration changes. It would not include minor changes such as storage configurations, or minor changes to specimen types etc.

Minor Project: are generally defined as projects that have a duration of <6 weeks and a budget of <$5,000. These projects have a minor impact on sample processing/reporting. Any project which major impact on workflow or sample reporting should be considered under major projects.

Major Project: are generally defined as projects that have a duration of >6 weeks and/or a budget of >$5,000. Major projects require significant planning and detailed consideration of project impacts and implementation procedures.

External Projects: is to be used for all projects which have been externally funded. Where there are no documentation requirements for an externally funded project – standard change management document as described in this document apply. For RDAC projects, RDAC documentation requirements apply (QIS 33017) with the additional requirements of:

- A change management number will be assigned within Forensic DNA Analysis
- Management Team are to indicate that they have reviewed all RDAC proposals by adding their name to the Excel sheet included within the project folder

The change management procedure utilises a three step process:

- the initial request (Step 1)
- minor change (Step 2a) OR project plan (Step 2b)
- final report, approval/implementation (Step 3)

The utilisation of these steps is dependent on the type of change (administrative, IT/LIMS, minor, major and external) and on the progression of the change management process. Refer to Section 4 for details.

4 Actions

Prior to the preparation of any change management documentation it is recommended that ideas are discussed at the work unit level to determine the merit of each idea or proposal. If the process of change management is initiated it will need to follow the documentation requirements as listed in sections 4.1 to 4.8 and the workflow as shown in Appendix 1.

*An exception is made for projects that are a mandatory requirement for the laboratory e.g. validation/verification of a new process or equipment item. In these cases it is possible to proceed directly to a full project plan (section 4.3).

For large projects an overarching project number is allocated (by quality) to the work, and sub-projects may then be allocated "a letter" such that sections/parts of a project can be signed off separately. For example in validating an amplification kit a project number 1234

may be applied (for the overarching project), with sub-projects 1234a – referring the sensitivity testing, 1234b referring to concordance, 1234c referring to thresholds etc.

In cases where supplementary testing for a project is required (post-sign off), if the data is an extension of previous work - it may also be appropriate to allocate the supplementary work "a letter" ie. part b of the same work. If the supplementary work is substantially different in topic or content a new project number should be allocated.

All project documents are to e-signed and locked at completion. Refer to Appendix 5 for e-sign procedure.

Technical Review:
For major projects and for validations it is a requirement for the project to have a technical reviewer. The role of the technical reviewer is to 'peer view' critical technical aspects of the project (e.g. new instrument programs/settings, new analytical procedures) and/or to review data analysis with the project (e.g. Excel data transformations, formula's and calculations etc.). The technical reviewer/s are nominated by the team leader and/or management team at project proposal stage (section 4.3). The technical review is completed either during the project or at the completion of the laboratory work and data analysis - but prior to final report being presented to the management team. The technical review should provide to the Management Team as a written document that outlines the aspects of the project reviewed and general findings (Refer to Appendix 2 for template)

Communication:

- For large projects regular project updates should be given by the project leader (or delegate) to the management team. This will allow the management team to ensure that the project is meeting all requirements (NATA, internal needs etc), and that they have a full understanding of the project prior to final report preparation and sign off.
- When projects are complete - presentations should be made at team meetings so that all staff have an awareness of new processes and technology as it is released.
- Appropriate communications should be made at time of implementation (emails to applicable staff, additions to minor change registers, records to quality etc).

4.1 Initial Request (Stage 1)

Change requests can be initiated by any staff member within Forensic DNA Analysis, and are to be recorded on an **Initial Request Form** (QIS 31543). Submission of an initial request requires the following actions:

- Complete the **Initial Request Form** (QIS 31543). The initiator is required to complete the blue sections of the form only.
- Initiator is to email the Quality Team and Line manager (of the person initiating the request) with the network location of the document so it can progress.
- Quality will allocate the request a proposal number
- The Line Manager is to complete the red sections of the form, create a PDF of the request form and e-sign the document. Store/save the document to the appropriate project folder in I:\Change Management

The Line Manager will assess the initial request recommending either:

- **Abandon process at Initial Request** (Refer to section 4.7)
- **Proceed to Step 2:**
  - **Minor Change** (Refer to section 4.2)

    or

- **Project Proposal** (Refer to section 4.3)

If the line manager wants to recommend proceeding to a full project proposal – they will need to seek Management Team approval.

If the initial request is abandon - no further action or documentation will be required.

On completion of the initial request form (e-signed and locked), the line manager is to advise quality team

4.2 Minor Change (Stage 2a)

The minor change form is used to document the purpose, method and date of change. If the Line Manager recommends that the change management is to proceed as a minor change, the project initiator must complete the blue sections of the **Minor Change Form** (QIS 31548) and submit it to their line manager. In some circumstances a small amount of experimental data may be included within a minor change – where the data is used for decision making purposes.

The Line Manager must then complete the following actions:

- **E-sign** the minor process change document (QIS 31548). Store/save the document to the appropriate project folder in I:\Change Management\Minor Change Forms - completed
- Add the change to the **Minor Change and emerging or novel practices** register located in: I:\Change Management\Change Register - Minor Changes and emerging or novel practices.xls
- **Inform the quality team and all stakeholders of the change** e.g. team meetings or email
- Update SOPs etc. if required
- Inform the Quality & Projects Senior Scientist to complete the process

The Quality & Projects Senior Scientist must:

- **E-sign and lock** the minor process change document (QIS 31548)
- Ensure all above actions have been completed by the line manager.

4.3 Project Plan (Stage 2b)

If the Management Team recommends that a change management should proceed as a full proposal (administrative, IT/LIMS, major change or external project) the project leader is required to complete the following project documents:

1. **Project Risk Assessment Document** (QIS 22872): A risk assessment must be completed documenting the risks of the project for each team.

2. **Change Management Project Proposal (experimental design) Document**: This document should cover all aspects of what the project is proposing to do: It should include an introduction to the project (including literature review), purpose/background, methodology and experimental design (either laboratory experiments or data analysis as applicable) and a detailed materials and methods section.

   Refer to QIS 23402 for writing guidelines and template for the project proposal. These project proposals will essentially constitute the introduction and materials and methods section of the projects final project report

This document must be prepared and submitted to the Forensic DNA Analysis Management Team along with the Project Risk Assessment Form (QIS 22872).

3. **Consider ethics requirements**: QIS 33268 Police Services – Human Ethics Review Checklist, it may impact on the projects methodology, and ethics approval maybe required before the project can start.
4. **(Optional) Project Budget** (QIS 31052): A budget can be prepared and submitted to the Forensic DNA Analysis Management Team - with the project proposal. A budget template is provided in QIS 31052.

For a new piece of equipment, new chemical or new process a formal risk assessment (QIS 29106) will be needed in addition to the project risks that are outlined in QIS 22872 The formal risk assessment addresses workplace health and safety risks and the project risk assessment is in relation to business risks.

After all project documents have been prepared (as listed above); risk assessments (if applicable) and LIMS documentation completed (if applicable) email your Line Manager and Quality Team [redacted] and advise them of the location of the documents in I:\Change Management. The Line Manager/Project leader will submit the documentation to the Forensic DNA Analysis Management Team for consideration (Refer the section 4.4), with a due date for feedback.

4.4 Forensic DNA Analysis Management Team – Consideration of Project Proposal

The Forensic DNA Analysis Management team will consider the change management project proposal documents as outlined in section 4.3. It is not necessary for all Management Team members to read and approve every proposal; however a quorum of the Management team must approve the proposal. The quorum must include the Managing Scientist, Team Leaders, Quality and Projects Senior Scientist, Senior Scientist that has Line Management of the staff/project and Senior Scientist/s of areas significantly affected by the project. For major projects and validations a technical reviewer suggestion should also be provided to the management team for consideration (Refer to section 4).

Consideration of the proposal should include:

1. *A determination of the impact of the proposed change on all stakeholders*
2. *Cost/Benefit Analysis of the project*
3. *Risk Assessment (Workplace Health & Safety and Business Risks)*
4. *A communication plan for all project participants and stakeholders*

The Forensic DNA Analysis Management Team will then make a recommendation as follows:

- **Implement proposal.** If the proposal is approved, the project documentation will be e-signed by the Management Team. The project leader/appointed staff can initiate the project.
  - Project work must be conducted by a technically experienced and competent person (Refer QIS 10662)
  - For projects that are >3 months, the Senior Scientist Quality and Projects will meet with each project team ~ every 2 weeks to ensure project progression, and to provide advice and resources as required.
- **Implement proposal after change.** If the Management Team requires additions/edits to the project proposal, the Management team will return the document to the project leader/appointed staff with feedback. The project

documents will need to be edited and resubmitted (as per section 4.3.) before further consideration by the Management Team.
- **Abandon process.** Refer to Section 4.7 for details.

After the due date for feedback project leader/line manager should:
- Make edits (if required).
- Create a PDF of the project proposal and project risk assessment documents
- Store/save the document to relevant project folder in I:\Change Management

Management team must:
- Provide feedback on the proposal
- Complete the risk assessment

4.5 Implementation and Final Report (Step 3)

On completion of the change management project - a final report is required, this is usually written by the project leader (Refer to QIS 23402 for report preparation details). A Technical Review - if it is required (Appendix 2), and an Implementation Plan (Refer to Appendix 3) must also be prepared. The implementation plan will be a list of the steps required to be completed either before the change is implemented, or shortly after implementation. Although a proposal may not be implemented on completion, a basic implementation plan that can be refined closer to implementation should still be completed and submitted. On completion of the report, technical review and implementation plan, they are to be forwarded by email to your Line Manager. The Line Manager/project leader will submit the final report, technical review and implementation plan to the Forensic DNA Analysis Management Team for consideration/acceptance.

If the final report is accepted by the Forensic DNA Analysis Management Team it will be e-signed and the project/change management process closed. If the Management Team requires additions/edits to the final report, it will be returned to the project leader/appointed staff with feedback. The final report will need to be edited and resubmitted for consideration by the Management Team.

After the due date for feedback project leader/line manager should:
- Make edits (if required).
- Create a PDF of the project proposal and project risk assessment documents
- Ask the management team to e-sign the document.
- Store/save the document to relevant project folder in I:\Change Management

Management team must:
- Provide feedback on the final report
- E-sign the documents as/when requested by the project leader/line manager.

After acceptance of the final report the Forensic DNA Analysis Management team will recommend that the:

- **Change is implemented** into routine use (Refer to Appendix 3 for implementation plan for project leaders).
- **Change is accepted but will be implemented at a later date** (Refer to Appendix 3 for implementation plan for project leaders).
- **Change is abandoned** (Refer to Section 4.7 for details).

After completion of the project, all stakeholders must receive communications about the findings and outcomes of the project. This may include presentations at meetings, or the provision of final reports to stakeholders. For significant projects, a summary of the project is to be presented at team meetings.

On completion of the final e-signature by the Managing Scientist a communication is to be sent to the Quality team so that they can ensure all documents have been finalised. Quality team can then lock and store data files by loading them to the Forensic Register.

**Please note: in the event the work is to be published, please consider if the publication needs to reviewed by the FSS Ethics committee. Refer to QIS 32177 FSS Publication checklist.*

4.6 Responsibilities in Signing Documentation

When a project proposal or report is submitted for review, it is the responsibility of the reviewer to ensure that all feedback is provided by the due date. Any feedback provided after the due date may not be considered (based on the merit of the feedback).

It is acceptable for a reviewer from the Forensic DNA Analysis Management Team to seek advice from other members of staff where it is deemed appropriate (e.g. where another person may have more experience in the subject of the report). In this instance, it is the responsibility of the person seeking the advice to provide the feedback to the project officer and to do so by the due date.

4.7 Abandoned/Cancellation

Should a change proposal not be approved, or if at any time the change is no longer required, the change management process may be abandoned/cancelled. This shall be recorded on the change management documents (to be forwarded to the Quality Team). If the project is abandon mid-way through a process an electronic file note can be created to detail the date and reason for project cessation.

It is possible to re-start abandon change management processes at a later date, and there are relevant sections in the change management forms to record a restarted process.

4.8 Recording Feedback

Project feedback, including feedback on project proposal and reports, is to be tabulated and stored in the relevant change management folder (under the appropriate project number folder).

All email communications regarding the project are also to be stored in the relevant change management folder.

5 Records

- All change management documentation (plans, reports, data etc.) are to be stored electronically in a network drive (e.g. I:Drive)
- On completion of projects all records (plans, reports, excel files etc) are to be stored in Forensic Register. To store records in FR:
    - Create new FR case Job Type=Research
    - Subject/Complainant=Project number and short title
    - Offence Class=Miscellaneous
    - Location=Forensic DNA Analysis Quality
    - Project documents loaded as an examination summary

6 Associated Documentation

QIS: 10662 FSS Guidelines for Method Validation
QIS: 22872 Project Risk Assessment for Change Management in Forensic DNA Analysis
QIS: 23401 Forensic DNA Analysis Validation and Verification Guidelines
QIS: 23402 Writing Guidelines for Validation and Change Management Reports
QIS: 29100 Health & Safety Risk Assessment Form
QIS: 29106 Risk Management Guideline – conducting and evaluating Health and Safety risk assessments
QIS: 31052 Forensic DNA Analysis - Change Management Budget
QIS: 31543 Initial Request Form for Change Management in Forensic DNA Analysis
QIS: 31548 Minor Process Change Form for Change Management in Forensic DNA Analysis
QIS: 32177 Human Ethics Review Checklist - FSS Publications
QIS: 33017 FSS Research and Development short form
QIS: 33268 Human Ethics Review Checklist - Police Services
QIS: 33333 Participant Information and Consent Form (PICF) - Common Biological Samples
QIS: 33334 Participant Information and Consent Form (PICF) - Semen Samples
QIS: 33335 Participant Information and Consent Form (PICF) - Vaginal Samples

7 Amendment History

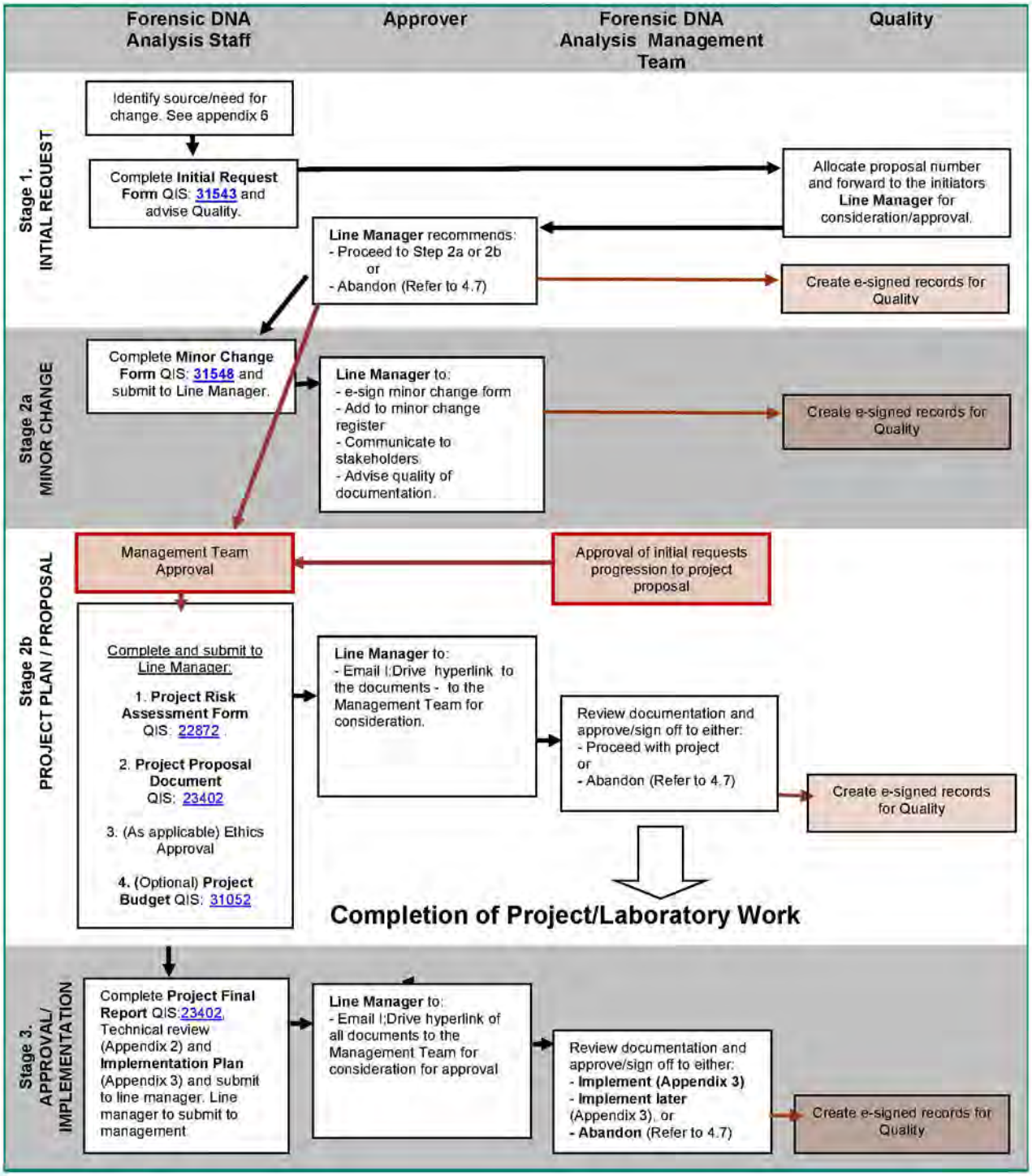
Version	Date	Author/s	Amendments
1	25 Aug 2005	Mary Gardam	First Issue
2	27 Feb 2007	J Olsson, M Gardam V Ientile	Format Changed to include Project Management.
2	April 2008	QIS2 Migration Project	Headers and Footers changed to new CaSS format. Amended Business references
3	25 Sept 2008	Robyn Smith Crystal Revera	Formatting, Changes made to reflect new Laboratory name & Contacts
4	14 May 2012	Shannon Thompson Kirsten Scott	Major revision/re-write as the change management process changed.
5	21 Jan 2013	Kirsten Scott	Update QIS numbers and headers. Add records, associated documents and minor edits.
6	26 Mar 2013	Kirsten Scott	Clarify point 3 in section 4.4. Update hyperlinks
7	6 June 2014	Kirsten Scott	Remove Assessment Phase. Change in actions required by line managers for approving initial plan and minor change documents.
8	19 June 2015	Kerry-Anne Lancaster	New template. Added milestone register and implementation plan. changed AUSLAB to LIMS, defined project proposal and responsibilities of the reviewer. Add QIS 33017
9	21 Oct 2015	Kirsten Scott	Inclusion of consent forms in associated documents. Option for mandatory projects to proceed directly to project plan. Inclusion of RDAC processes & Quality Checklist
10	25 Nov 2015	Kirsten Scott	Inclusion of a technical review for major projects and validations, and minor text update in other section as a result of technical review
11	20 Sept 2016	Kirsten Scott	Specify implementation plan as mandatory, Section 4.5 and 5 add a note on locking of data by quality. Section 3 clarify RDAC requirements

12	1 June 2018	Kirsten Scott	Remove milestone register (section 4.3, 4.8). Add comms and project numbering to section 4. Addition of FR instructions section 5. Add technical review template as appendix 2.
13	19 Nov 2019	Kirsten Scott	Add Human ethics checklist section 6. Additions to section 4.4: meetings with Quality Sen/Sci., and staff competency requirements. Header added to appendix 8.4
14	2 Oct 2020	Kirsten Scott	Edit document to reflect change from hardcopy records to electronic sign-off processes. Additions to appendix 4
15	14 July 2021	Abbie Ryan	Addition of Appendix 5 – e-sign procedure. 4.2 Addition of extra signature step to minor change procedure for Quality Senior Scientist. 4.3.1 Changed title of document 22872 to Project Risk assessment.
16	10 Dec 2021	Kirsten Scott	New header, remove optional Gantt chart for projects, add ethics QIS links and requirements and emerging/novel practices (Appendix 6)
17	30 Mar 2022	Abbie Ryan	Updated Appendix 3 – implementation plan tasks.

8 Appendices

- APPENDIX 1: Change Management Process
- APPENDIX 2: Technical Review Template
- APPENDIX 3: Implementation Plan for project leaders
- APPENDIX 4: Checklist of documents required for a Change Management Project
- APPENDIX 5: Procedure for e-signing documents
- APPENDIX 6: New and emerging novel practices checklist

8.1 APPENDIX 1: Change Management Process



8.2 APPENDIX 2: Technical Review Template

Technical review of Proposal #Project number
Project title

General project observations:

Experiment 1:

Program settings checked: Yes / No / Not Applicable. Comments:_____

Formulas checked: Yes / No / Not Applicable Comments:_____

Data transformations checked: Yes / No / Not Applicable Comments:_____

Calculations checked: Yes / No / Not Applicable Comments:_____

Experimental observations (design/results etc):

Experiment 2: (add additional experiments as required)

Program settings checked: Yes / No / Not Applicable. Comments:_____

Formulas checked: Yes / No / Not Applicable Comments:_____

Data transformations checked: Yes / No / Not Applicable Comments:_____

Calculations checked: Yes / No / Not Applicable Comments:_____

Experimental observations (design/results etc):

Technical Reviewer

Name	Position	Signature	Date

Project Manager

Name	Position	Signature	Date

8.3 APPENDIX 3: Implementation Plan for project leaders

Successful project implementation may require numerous tasks to be completed either prior to implementation, or shortly after the implementation date. Some of the considerations/tasks that may be required are listed below; however, this is not intended to be a comprehensive list of tasks as each project will have different implementation requirements. Project leaders must devise and submit a comprehensive implementation plan for management review prior to the final report being signed off. Ideally, this implementation plan should be provided at the same time as the draft final report.

Once complete, the checklist should be submitted to the quality team for filing with the signed project documents.

Project Title:_____ Project Number:_____

Task	Details	Responsible Line Manager/ Allocated to:	Date Completed
e.g. Create new procedures	New SOPs and training modules to be written and approved		
e.g. Update procedure/s	Existing SOPs and training modules to be revised and approved		
e.g. Staff training	Project members and relevant to staff to be issued with CTT statements as required		
	CTT staff to train relevant staff		
e.g. Software setup	Final version of software to be setup and reviewed on instrument		
	Check if Macro updates are required		
e.g. Equipment tasks	Add equipment to QIS		
	Add equipment to LIMS		
e.g. Consumable tasks	Add consumables to LIMS.		
	Addition of products to FAMMIS		
	Order new consumables		
e.g. Forensic Register development/requirements			
e.g. DNA interpretation/reporting	May include: Model Maker requirements and assessment, Statement of Witness appendix update		
e.g. Impacts/risks assessed	Any risks identified in risk assessment are addressed.		
e.g. Add to minor change register	Ensure that implementation has been added to the minor changes register		
e.g. Communication	Communicate to staff and other stakeholders – by meetings and emails.		

8.4 APPENDIX 4: Checklist of documents required for a Change Management Project

Project Number: _____

Minor Change:

☐ Initial Request Form (31543) (May not be required for mandatory projects)

☐ Minor Change Form (31548)

☐ Added to Minor Change Register and emerging or novel practices register

☐ Implementation (Comments added to SOPs (if required) and communication to staff)

Major Project:

☐ Initial Request Form (31543) (May not be required for mandatory projects)

☐ Project Risk Assessment Form (22872)

☐ Project Proposal Document

☐ (Optional) Project Budget (31052)

☐ Ethics checklist and/or approval - if applicable (33268)

☐ Risk Assessment (As applicable for new equipment and laboratory procedures 29100)

☐ Project Final Report

☐ Technical Review (for validations and major projects only)

☐ Implementation Plan

** Consent forms for staff collections should have been previously provided to quality if applicable.

RDAC project:

☐ RDAC Application Form (Copy only, original stored with Research Office)

☐ RDAC Final Report – if the project is funded (Copy only)

☐ Excel Sheet – with Names of Management Team for acknowledgment of project.

☐ **Quality team have loaded all key project documents to FR for storage**

Checklist completed by:_____ Date: _____

8.5 APPENDIX 5: Procedure for e-signing documents in Adobe

First time process to set up digital signature:

1. Scan an image of your personal signature and save to your desktop.
2. Open up a PDF document in Adobe
3. Click tools and Open - Certificate
4. Choose "Digitally Sign"
5. Drag the box to point in PDF document where you want to apply your digital signature.
6. Select Configure Digital ID
7. Select Create a new Digital ID – then continue
8. Select "Save to File" then continue
9. Ensure that you place all your credentials in the name section. (Do not use symbols)

Sample of how and areas to fill out:

Note: you can change the place where you save your credentials, the default saving file location is generally where the adobe program files are kept.

10. Enter a password of your choice. You will use this password every time that you apply it
11. Last step in the process is to attach a copy of your 'signature'. Click continue
12. Click on the create button
13. Select image then select "Browse" to import in your signature from the file location
14. Click save.
15. To now digitally sign the PDF document, enter password and click sign.

Note: – if you are the final approver, e.g. expenditure delegate, line manager approving the document, you must check the 'Lock document after signing' checkbox. This will lock the entire document down and cannot be edited once this has been done.

16. You will be asked to save the PDF file.
17. If the PDF document requires further electronic approvals, it can be forwarded to the next approval for their Digital ID. If the check box is checked 'lock document after signing', then the document can no longer be edited or signed.

For all future PDF documents, when you click Digitally sign, you will be asked to select the area to sign and then can select the Digital ID, enter your password and sign the document.

8.6 APPENDIX 6: New and emerging novel practices checklist

This checklist is provided as a template/processes by which staff can consider what to do - when they have seen something new, wish to do something new or are unsure how to proceed with a decide or idea. The emphasis is on the documentation and communication of decisions and thought processes - in line with best quality practices.

Step 1: Gather the facts and define the issue/problem.

Step 2: Make an assessment of your idea or what you have seen: taking into account:
- the case implications
- possible expenditure of resources (time and money)
- impact on clients
- health and safety etc. (refer to Section 4 above).

This will allow you to determine who is accountable for the decision, and how big the required and appropriate process will need to be.

Step 3: Action and documentation: For any issue that have a cost implication (resources or significant staff time), or implications for clients - the full change management process would apply (refer to this document above). For new observations and/or emerging novel practices that are smaller in nature - it maybe more appropriate to use following document to detail the issue, your thinking and the decision:

I:\Change Management\Change Register - Minor Changes and emerging or novel practices.xls

Step 4: Communicate to appropriate audience

Example: **Raised by:** John Smith **Date started:** 20/01/2022

Define your issue:
Apparent artefact at [redacted] Artefact shifts between labelling as a 17.1 or 17.2 variant allele. No stutter is observed for this artefact. Only observed in samples from peri-anal, rectal or penile areas.

Has it been seen before? Yes
Where? Case XXXXXXXxXX
Who can make the decision? Myself

Assessment
Adds contributor to otherwise single source assumed known contributor, height of artefact not consistent with another contribution dropping out. No expenditure of money, time or resources required.

Actions
- Removed artefact from FR GeneMapper table.
- Annotated epgs and re-loaded to Forensic Register
- Notations added to case in Forensic Register.
- Added to Change Register - Minor Changes and emerging or novel practices document

Communication

Who	When	How
All reporters via Microsoft Teams	02/02/2021	Posted
Line manager	01/02/2021	Email

Queensland Health
Forensic and Scientific Services

Forensic DNA Analysis Validation and Verification Guidelines

1 Purpose and scope

Validation is the developmental process used to acquire the necessary information: to assess the ability of a procedure to obtain a reliable result, to determine the conditions under which such results can be obtained, and to determine the limitations of the procedure (National Association of Testing Authorities, 2020). Method validation and verification provides objective evidence that a method is fit for purpose, meaning that the particular requirement for a specific intended use are fulfilled (National Association of Testing Authorities, 2020). Verification studies are typically smaller than those that are required for validation. For full details refer to National Association of Testing Authorities, 2020 specific documents.

The Forensic DNA Analysis laboratory is certified by the National Association of Testing Authorities (NATA) and is obliged to meet these specifications. ENFSI (2010) states that for DNA based tests, validations/verifications must demonstrate that the profile/s obtained under the new regime will be of the same or better quality than those obtained under the previous regime.

The purpose of this procedure is to describe validation and verification guidelines for use within Forensic DNA Analysis. Test methods, equipment, computer/software systems and information management systems must be shown to be fit for purpose before they are used by the laboratory to generate results. Validations will be required in Forensic DNA Analyses for:

- all new methods developed "in-house";
- methods laboratory/commercial that have been modified;
- methods without validation data adopted from other laboratories or from literature;

Verifications will be required in Forensic DNA Analyses for:

- use of a previously published and validated method
- use of commercial kits

This procedure shall apply to all validation/verification projects conducted within Forensic DNA Analysis. The final decision regarding the extent and scope of the study shall be made by the Managing Scientist.

2 Definitions

Accuracy and Precision

Accuracy (trueness): is the closeness of agreement between the test result and the "true" or accepted value.

Precision: is a measure of closeness (degree of scatter) between independent test results under stipulated conditions (National Association of Testing Authorities, 2020). High precision does not necessarily imply high accuracy.

An example of accuracy and precision measures would be, a determination of the proportion of correct genotypic assignment of samples, and a review of the number of alleles correctly assigning to the expected 0.5bp window/bin.

Repeatability is a measure of the maximum acceptable difference between two test results obtained at the same time by the same analyst under identical conditions on the same material. ENFSI (2010) recommends repeatability studies contain a minimum of five replicates, while NATA (2020) specifies at least six degrees of freedom (e.g. 4 times in a series with 2 samples or 3 times in a series with 3 samples). A repeatability test might be: 12 samples on a plate 7 times with standards and/or controls in an amplification plate and processed by a single operator (suggest that the DNA extract of a defined concentration is prepared in a large volume, and aliquot out to PCR plate or CE plate etc. This will ensure pipetting error is minimised in the preparation of multiple samples to an equivalent concentration).

Reproducibility

- Within laboratory (in-house) reproducibility - A measure of the maximum acceptable difference between two test results obtained on the same material by different analysts at different times.
- Between-laboratory reproducibility - A measure of the maximum acceptable difference between two test results obtained on the same material by different laboratories. It is most conveniently determined in collaborative trials.

Reproducibility in Forensic DNA Analysis could be assessed by: several DNA samples being prepared on an amplification plate by one operator, and the same DNA samples prepared on an amplification plate by a second (different) operator.

Sensitivity is the rate of change of the measured response with change in the concentration of analyte National Association of Testing Authorities, 2020). For PCR-based assays, validation studies must consider the stochastic effects of PCR; particularly as it relates to DNA concentration. ENFSI (2010) recommends sensitivity tests have a minimum of 5 dilutions tested.

3 Principle

Validation provides objective evidence that the particular requirements for a specific intended use are met. There is no one method of validation that is universally agreed upon, however the validation guidelines below are consistent with NATA criteria (National Association of Testing Authorities, 2020), and are consistent with Scientific Working Group on DNA Analysis Methods (SWGDAM 2020) recommendations for the minimum criteria for the validation of DNA profiling processes (ENFSI, 2010).

4 Actions

The planning and implementation of a validation/verification project in Forensic DNA Analysis should occur as follows:

a. Determine if it is a verification or a validation that is required. For example - if a standard published method, with full validation data, and a commercially available kits is to be implemented within the laboratory - a verification not validation would be required (prior to its introduction). If a new methodology is developed - a validation would be necessary.

b. Using the 'Procedure for Change Management in DNA Analysis' standard operating procedure QIS 22871, a project proposal must be prepared. In the planning the work consider the following:

- Validation studies require an assessment of reproducibility, repeatability, sensitivity, accuracy and precision (ENFSI, 2010). Refer to definitions section 2 for details.
- Qualifying Test - For validation studies the use of known samples and where possible authentic case samples should be used. This may be accomplished through the use of proficiency test samples, or samples that the laboratory routinely analyses (e.g. controls). Where previous typing results are available concordance of genotypes should be assessed.
- Mixture Studies – Forensic casework laboratories must define and mimic the range of detectable mixture ratios. Studies should be conducted using samples that mimic those typically encountered in casework (e.g. postcoital vaginal swabs)
- The laboratory must ensure that the procedure/s minimise contamination that would compromise the integrity of the results (QIS 22857). The laboratory should employ appropriate controls and implement quality practices to assess contamination and demonstrate that its procedure minimises contamination.
- Manufacturer's information and previous published validation studies should be used to inform the laboratories validation process.
- Refer to all NATA and ENFSI documentation listed in the reference list section 6 for specific and detailed validation study requirements
- Refer to QIS 10662 for additional resources.
- The project proposal must then be submitted to the Forensic DNA Analysis Management Team for approval prior to the initiation of experiment work.
- On completion of the experimental component of the validation, a final report will need to be written using the final report template QIS 23402. The final report is to be submitted to the Forensic DNA Analysis Management Team for consideration

5 Records

Minimum records required for a validation are:

Project Risk Assessment for Change Management in Forensic DNA Analysis 22872.
Project Proposal document. (see Writing Guidelines for Validation and Change Management Reports QIS 22871 & 23402).
Implementation Plan (Refer QIS 22871)
Final Report (Refer QIS 22871 & 23402).

Additional requirements (as applicable):

Ethics approval (Refer QIS 32177)
Technical review (Refer QIS 22871)
Forensic DNA Analysis - Change Management Budget (Refer QIS 31052).

6 References

National Association of Testing Authorities. (2020). NATA – National Association of Testing Authorities, Australia. Available at: https://nata.com.au/nata/ [Accessed 27 Aug. 2020].

ENFSI (2010) Recommended Minimum Criteria for the Validation of Various Aspects of the DNA Profiling Process. ENFSI DNA Working QA/QC subgroup. Issue No 1.

ENFSI (2020) European Network of Forensic Science Institutes. Available at: http://enfsi.eu/ [Accessed 27 Aug. 2020].

Scientific Working Group on DNA Analysis Methods (SWGDAM). (2020). Available at https://www.swgdam.org/ [Accessed 27 Aug. 2020].

7 Associated documents

QIS: 10662 - FSS – Guidelines for Method Validation

QIS: 22871 - Procedure for Change Management in Forensic DNA Analysis

QIS: 22872 - Project Risk Assessment for Change Management in Forensic DNA Analysis

QIS: 23402 - Writing Guidelines for Validation and Change Management Reports

QIS: 31052 - Forensic DNA Analysis - Change Management Budget

8 Amendment history

Version	Date	Author/s	Amendments
0	06 Sep 2005	Mary Gardam	First Issue
1	April 2008	QIS2 Migration Project	Headers and Footers changed to new CaSS format. Amended Business references from QHSS to FSS, QHPSS to CaSS and QHPS to Pathology Queensland
2	25 July 2008	C Revera	New Title, Changed Forensic Biology to DNA Analysis, authorised by C Allen, Chief scientist to Managing scientist. Purpose and scope combined, hyperlinks updated, definition of verification included.
3	4 Dec 2012	K Scott	New header. Complete rewrite to fit with new change management procedures in DNA Analysis
4	18 June 2014	K Scott	Update organisational name, document names and hyperlinks
5	20 Nov 2015	K Scott	Update header/template, references and minor text updates
6	8 Aug 2017	K Scott	Update references
7	27 Aug 2020	K Scott	Minor updates all areas
8	15 March 2022	K Scott	Template update, document names and references updated

9 Appendices

1 Appendix A Additional terms used in validation studies

9.1

Appendix A

Additional terms used in validation studies

Functional Specification: Defines how it is expected to function - these functions are typically outlined by the manufacturer of equipment/software.

Installation Qualification: Verifies design specification, the physical components of the system have been designed/constructed/supplied/installed in compliance with the design specifications. This is usually completed by the company performing the installation.

Lower limit of detection (LOD) - The lowest concentration or amount of analyte that can be reliably distinguished from zero, but not necessarily quantified, by the test method.

Limit of reporting/quantitation (LOR) - The lowest concentration of analyte that can be determined with acceptable repeatability and accuracy by the test method.

Operational Qualification: Verifies the functional specification, that the system functions as intended throughout anticipated operating ranges.

Performance Qualification: Verifies that the system will consistently produce results meeting user requirement specifications and quality attributes under both normal and worst-case conditions.

Uncertainty - The spread of values within which the true value would be expected to lie, with the stated degree of confidence (usually 95%).

User Requirement Specification: Defines how the system is expected to perform - this is usually set out in the tender document requirements.

Writing Guidelines for Validation and Change Management Reports.

1 Purpose

Change management and validation projects in Forensic DNA Analysis are planned using the procedure for change management QIS 22871 and the Forensic DNA Analysis validation guidelines QIS 23401. The purpose of this document is to provide Forensic DNA Analysis staff with guidelines for writing the final report - after completion of either a validation or change management project. This guide applies to all Forensic DNA Analysis staff.

2 Scope

This procedure applies to all validation and change management project reports within Forensic DNA Analysis.

3 Actions

Final reports within Forensic DNA Analysis are to be written using the template located at:

https://qheps.health.qld.gov.au/fss/staff/corporate-identity/templates

General guidelines on the content and style of each of these report subsections are provided below. The quality team is able to provide previous reports – to use as exemplars (on request).

- The suggested major headings to be included in the report are:
  - Abstract
  - Introduction
  - Materials (and/or Resources)
  - Methods
  - Experimental Design (suggested - for large projects)
  - Results
  - Discussion
  - Conclusion/Recommendations
  - Abbreviations (suggested - for large projects)
  - References.
- Authors – must be listed under the report title. All major contributors to the work should be listed as authors. As a minimum this must include: the Project Leader, Project Leader's Line Manager and the Managing Scientist Police Services Stream. The staff member that writes the report is usually listed as the first author, and the Managing

Scientist is usually listed as the last author in the list. Smaller contributions to a project (that are not sufficient for authorship) should be noted within the Acknowledgments section of the report.

Abstract

Abstracts are a single paragraph (200-300 words) written in past tense. The abstract is a summary of the paper and should briefly state:

- Why the project was undertaken (~1-2 sentences)
- What methodology was used (~2-3 sentences)
- What the key findings/trends/results were (~2-3 sentences)
- Implications of project including the interpretation and conclusion/s (~1-2 sentences)

Due to the required content of an abstract, most authors find that the abstract is most easily written last (after the remaining components of the report are complete).

Introduction

The introduction is usually several paragraphs written in present tense. The introduction should outline all relevant primary research literature, and detail how the literature relates to the issue/s under investigation in the project/study. It should clearly state the studies purpose and rationale.

Scope

A statement of the extent/limits of the project and to which area/s it applies.

Governance

A list of the project staff, the roles of the staff, and a statement about how the project decisions will be managed. Example as follows

The Management Team and the Senior Project Officer, are the decision making group for this project and may use the defined acceptance criteria in this project to cease part or all of the experimentation at any stage. The Decision Making Group may also make modifications to this Experimental Design as required, however this must be documented and retained with the original approved Experimental Design.

Materials and/or Resources

- Materials are listed with item (chemical, consumable or equipment), manufacturer and location. For example:
    - Promega PowerPlex®21 Allelic Ladder (Promega Corp., Madison, WI, US)
    - Promega WEN Internal Lane Standard (Promega Corp., Madison, WI, US)
    - Promega PowerPlex 5 Dye Matrix Standard (Promega Corp., Madison, WI, US)
    - 5804 Centrifuge (Eppendorf, Germany)
    - 2800M Control DNA, 10ng/µl (Promega Corp., Madison, WI, USA)
- International Standard (SI) Units are to be used (e.g. µL)

- A description of the organism/biological materials studied should be included (e.g. human, blood, cells)

Methods and/or Experimental Design

Methods are written in past tense (do not use first person). The use of sub-headings may be required in this section of the report. Methods should explain in detail the materials that were used, the experimental design and full methodology. It should be written with sufficient detail to enable an experienced scientist to replicate the work (i.e. temperatures, times, concentrations must be described). Ensure the following:

- Materials are adequately described
- International Standard (SI) Units are to be used (e.g. µL)
- For reporting: numbers less than ten are written in words and not numerals (e.g. two minutes). When writing numbers >10 use numerals, and do not write in words (e.g. 12 minutes).
- Experimental or sampling design is to be described (e.g. structure of the experiments, selection of samples, use of controls, sample numbers, sample duplicates etc.). Refer to Appendix A for guidelines.
- Detail how the procedure was carried out (e.g. DNA extractions details, amplification conditions).
- Explain how the data was analysed (e.g. statistical methodology). Refer to appendix A for recommendations.
- The acceptance criteria for the results is clearly defined.

For Materials and/or Resources and Methods and/or Experimental Design, it is acceptable for the Final Report not to reproduce the content from the Experimental Design, but to reference it and include any changes by exception.

Results

Results are written in past tense. The purpose of this section is to objectively present the key results without interpretation. It should always begin with text presenting the key findings (that address the questions being investigated), and statistical evaluation (Refer to Appendix A for recommendation). Tables and Figures can be included within this section to provide clarifying information.

Tables and Figures

Tables and Figures are included within the results section of a report. Table and Figure presentation guidelines are as follows:

- Tables and Figures are numbered consecutively. Table and Figures are assigned numbers separately e.g. Table 1, Table 2, Table 3 and Figure 1, Figure 2, Figure 3 etc.
- Legends are to be a brief description of the result/information being presented.
- Table legends go above the table and are left aligned.
- Figure legends go below the figure and are left aligned.
- In the text of the report, figures can be abbreviated to "Fig" (i.e. Fig 1). Table is never abbreviated.
- SI units should be specified in the column headings wherever required.

- Footnotes are used to clarify points in the table, denote statistical differences among groups or to convey repetitive information about entries.

Table exemplar:

Table 1 Student's t-testP-values for comparison of QS5-A and Qs5-B with 7500-A

Standard	Instruments compared	SAT	LAT	Y-Target
NIST A	QS5-A & 7500-A	0.70050	0.06813	0.42519
	QS5-B & 7500-A	0.44247	0.77529	0.19765
NIST C	QS5-A & 7500-A	0.23834	0.09180	0.39582
	QS5-B & 7500-A	0.52538	0.45386	0.32165

Note: P-values < 0.05 indicate a significant difference between results produced by the two instruments.

Figure exemplar:

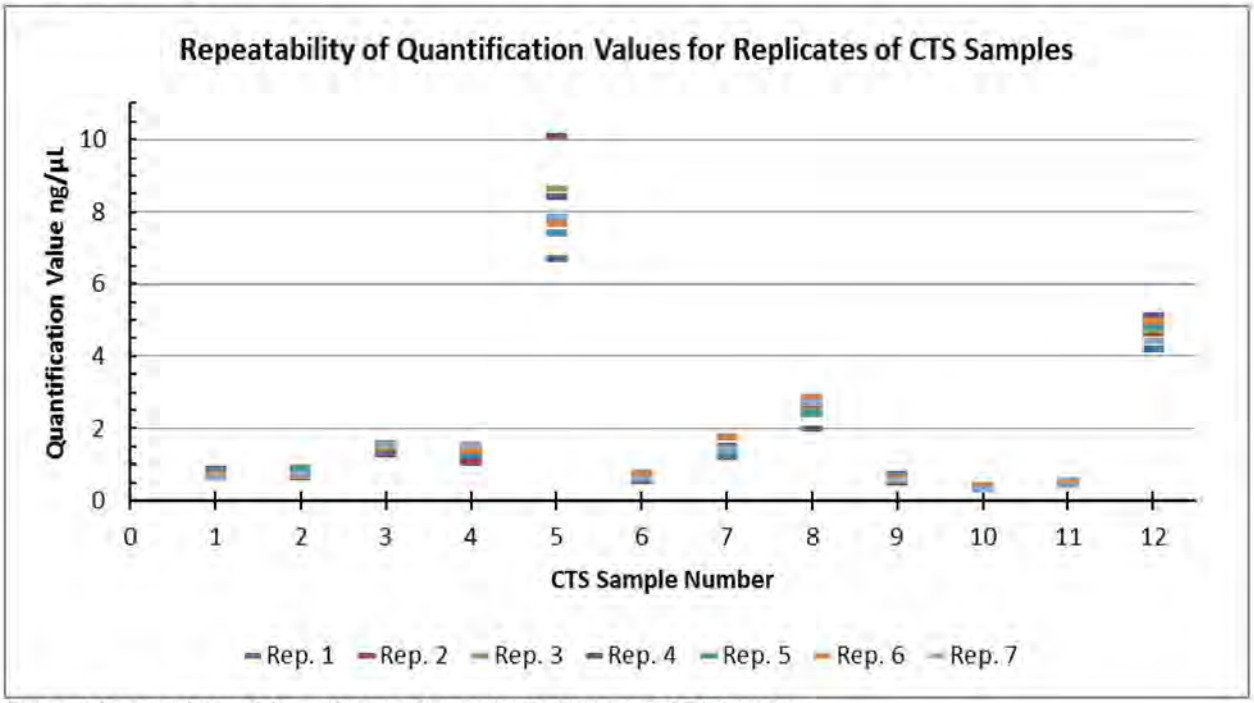


Figure 1 Repeatability of Quantification Values for Replicates of CTS Samples

Discussion

A discussion is written in past tense and will usually consist of multiple paragraphs. The purpose of the discussion is to explain/interpret the results with reference to the acceptance criteria and to relate the results back to current understandings in the field, and in the published literature. There should be links/connections of ideas/concepts between the introduction and the discussion; explaining how the project/validation has moved current understandings forward. Questions that should be considered when writing the discussion may include:

- Do the results support the projects hypotheses? If not, why not – try to provide reasons (if it is possible)?

- Do the findings agree with current literature/publications? If not, why not – try to provide reasons (if it is possible)?
- What are the implications of the findings to the laboratory, and to the scientific community?

Note: If appropriate, the results and discussion can be combined under one heading. If the project contains more than one experiment it may be necessary to have a combined result/discussion section for each experiment.

Conclusions/Recommendations

A conclusion and/or recommendation section can either be written as a separate section/s (each under its own heading), or it can be incorporated into the end of the discussion section without a separate heading.

A conclusion is usually one paragraph written in past tense. The conclusion should summarise the most significant finding, the implication of the finding/s, and may indicate what direction – additional projects should take.

Recommendations are usually written as several statements, or dot points that outline what actions are required. This may include recommendations on the implementation (or not) of a procedure, what type of further work that is required, and/or recommendations on how data should be utilised and interpreted.

Acknowledgements

The purpose of acknowledgements is to note the contributions from others (that are not listed authors). This may include acknowledgments of:

- Funding source/s
- Staff that completed laboratory work
- Reviewers/Collaborators.

References

Referencing should be used wherever a report refers to another's work. It is usual for there to be extensive referencing with the introduction section of the report, with referencing also commonly used within the methods and discussion sections of the report. References can be managed with programs such as EndNote.

Requirements for referencing:

- Place quotation marks on either side of text " " when quoting directly.
- A reference list is arranged alphabetically by author (If an item has no author, it is cited by title, and included in the alphabetical list using the first significant word of the title).
- If you have more than one item with the same author, list them in chronological order (starting with the earliest publication).

There are several acceptable methods of referencing including ACS, AGPS/AGIMO, AMA and the Harvard Style. In the Harvard Style referencing: within the text reference by author and date e.g. (Smith, 2012). Referencing format with the Harvard Style as below:

Harvard Style:

Referencing a book:

Smith, JB, Scott, KD & Jones, LM 2012, *Forensics: A molecular approach*, 2nd edn, McGraw Hill, London.

Referencing a chapter in a book:

Martin, F 2012, 'DNA Profiling', in Lee CW (ed.), *Forensics: A molecular approach*, 2nd edn, McGraw Hill, London, pp. 35-61.

Referencing a journal article:

Holden, LM 2011, 'Validation of Powerplex21', *International Forensics*, vol. 50, no. 2, pp. 49-52

Referencing an on-line journal article:

Holden, LM 2011, 'Validation of Powerplex21', *International Forensics*, vol. 50, no. 2, viewed 31 December 2012, <insert website address>.

Appendices

Appendices can be used if required and are numbered consecutively. The appendices contain information that supports the content of the report but is not essential within the body of the report.

4 Records

Nil

5 Associated documents

QIS 10662	FSS - Guidelines for Method Validation
QIS 22871	Procedure for Change Management in Forensic DNA Analysis
QIS 22872	Project Risk Assessment for Change Management in Forensic DNA Analysis
QIS 23401	Forensic DNA Analysis Validation Guidelines

6 References

Nil

7 Amendment history

Version	Date	Updated By	Amendments
1	13 March 2006	R Smith	First Issue
2	Sep 2008	T Nurthen	Minor update
3	07 Jan 2013	K Scott	Some content from this document transferred into QIS 23401. Complete re-write of remaining document – focusing on the reporting of validations and projects. Update header
4	17 July 2014	K Lancaster	Changed references to DNA Analysis to Forensic DNA Analysis. Included extra detail for experimental design. Updated titles for hyperlinked documents. Updated title of Managing Scientist.

			Updated report template hyperlink. Included a figure exemplar.
5	03 Feb 2016	K Scott	Template update, separate materials and methods, minor text edits and correction of amendment history table
6	09 Aug 2017	K Scott	Update names of kits used as exemplars
7	21 March 2019	K Lancaster	Updated hyperlink to report templates
8	08 May 2019	K Scott	Inclusion of Appendix A – recommendations for statistics. Minor updates throughout
9	14 Nov 2019	K Scott	Addition of sections on scope and governance. Addition of Appendix B – Resources for Statistics. Minor text edits
10	20/07/2021	A Ryan	Amended header to remove HSQ. Updated hyperlink to report templates. Amended document title for QIS 22872.Captioned table 1 and figure 1 correctly. Added how the acceptance criteria are mentioned and referred back to.

8 Appendices

1 Appendix A Recommendations for Statistics
2 Appendix B Resources for Statistics