Report for QIS OQI as of 28/06/2022 11:13:55 AM

Report for QIS OQI -

21718 No Title Provided

OQI Details

Status	Closed Approved
Subject	Refer to Audit 9175 (DNA IQ external audit) and report by Sloots & Whiley (14 November 2008). A summary of items for further consideration is listed below: 1. Develop a standard validation protocol based on Butler (Profiles in DNA, September 2006) and incorporate into a SOP. 2. Increase the number of negative controls to comprise at least 10% of the total number of samples in the batch. 3. Test a control plate once every 3-4 weeks on each of the MPII platforms (alternate between soccerball, checkerboard and zebra stripe). 4. Constant observation by the operator of all processes leading up to and including the addition of magnetic particle is necessary to ensure that resin is added correctly. 5. Workflow dynamics for future detection of LCN DNA must be carefully examined to minimise the risk or post-PCR carryover from amplification or post-amplification areas into pre-amplification areas.
Source of OQI	Audit
Date Identified	15/12/2008

OQI Creator Contact Details

Creator	Thomas NURTHEN
Organisational Unit/s	DNA Analysis
Service/s	Forensic and Scientific Service
Site Location/s	Coopers Plains

Investigator/Actioner Contact Details

Actioner	Kirsten SCOTT, Thomas NURTHEN, Chiron WEBER
Organisational Unit/s	Quality and Projects
Service/s	Forensic and Scientific Service
Site Location/s	Coopers Plains

Investigation Details

Investigation Completed	02/11/2009	**Root Cause Type**	Procedure/Method/Process
Investigation Details	Refer to Audit 9175 (DNA IQ external audit) and report by Sloots & Whiley (14 November 2008). A summary of items for further consideration is listed below: 1. Develop a standard validation protocol based on Butler (Profiles in DNA, September 2006) and incorporate into a SOP. 2. Increase the number of negative controls to comprise at least 10% of the total number of samples in the batch.		

3. Test a control plate once every 3-4 weeks on each of the MPII platforms (alternate between soccerball, checkerboard and zebra stripe).

4. Constant observation by the operator of all processes leading up to and including the addition of magnetic particle is necessary to ensure that resin is added correctly.

5. Workflow dynamics for future detection of LCN DNA must be carefully examined to minimise the risk or post-PCR carryover from amplification or post-amplification areas into pre-amplification areas.

Preformed By	Chiron WEBER

Investigation Completed	13/01/2009	**Root Cause Type**	Otherreassign to Chiron Weber.
Investigation Details		**Preformed By**	Quality Information System

Action Details

Action Complete	14/02/2014	**Action Fix Type**	Changed ProcessActions from Audit 9175
Title	(DNA IQ external audit)		
Action Description	1. Develop a standard validation protocol based on Butler (Profiles in DNA, September 2006) and incorporate into a SOP.		

2. Increase the number of negative controls to comprise at least 10% of the total number of samples in the batch.

3. Test a control plate once every 3-4 weeks on each of the MPII platforms (alternate between soccerball, checkerboard and zebra stripe).

4. Constant observation by the operator of all processes leading up to and including the addition of magnetic particle is necessary to ensure that resin is added correctly.

5. Workflow dynamics for future detection of LCN DNA must be carefully examined to minimise the risk or post-PCR carryover from amplification or post-amplification areas into pre-amplification areas.

Action Complete	13/01/2009	**Action Fix Type**	Changed Processreassign to
Title		**Action Description**	Chiron Weber.

Task Details

Title	Standardise validation		
Task Status	Completed	**Task Completed**	14/02/20141. Develop a
Task Fix Type	Documentation	**Task Assignee**	Thomas NURTHENstandard validation
Task Undertaken	protocol based on Butler (Profiles in DNA, September 2006) and incorporate into a SOP.		

Title	Increased negative controls in automated extraction batches		
Task Status	Completed	**Task Completed**	02/02/2010Increase the
Task Fix Type	Changed Process	**Task Assignee**	Thomas NURTHENnumber of negative
Task Undertaken	controls to comprise at least 10% of the total number of samples in the batch.		

As of the 02/02/2010 the number of controls on the extration plate is as follows:

2x Pos, 2x neg, 10 x blank

Title	Automated control plates
Task Status	Completed
Task Fix Type	Changed Process
Task Undertaken	on each of the MPII platforms (alternate between soccerball, checkerboard and zebra stripe).

Task Completed	14/02/2014 Test a control plate once every 3-4 weeks
Task Assignee	Thomas NURTHEN

Title	Observation of automated extraction procedure
Task Status	Completed
Task Fix Type	Changed Process
Task Undertaken	operator of all processes leading up to and including the addition of magnetic particle is necessary to ensure that resin is added correctly.

Task Completed	14/02/2014 Constant observation by the
Task Assignee	Thomas NURTHEN

Title	LCN lab processes
Task Status	Completed
Task Fix Type	Changed Process
Task Undertaken	LCN DNA must be carefully examined to minimise the risk or post-PCR carryover from amplification or post-amplification areas into pre-amplification areas.

Task Completed	14/02/2014 Workflow dynamics for future detection of
Task Assignee	Thomas NURTHEN

Follow-up And Approval

Follow-up Status	Accepted
Follow-up Status Comment	14/02/2014 10:20:00 AM Thomas NURTHEN: Accepted 13/03/2009 12:00:00 AM Iman MUHARAM: reassign to Chiron Weber.
Approver	Thomas NURTHEN
Approval/Rejection Date	14/02/2014
Approval/Rejection Comment	14/02/2014 10:20:41 AM Thomas NURTHEN: Accepted as per managment team as at 13/02/2014

Associations

Module	Audit
QIS Record	DNA IQ external audit
QIS Record Number	9175
Status	Closed
Association Description	

Associated Version	Migrated Data from QIS version 1
Current Version	

Records

No Records found