

Report for QIS OQI as of 28/06/2022 10:46:54 AM

Report for QIS OQI -**19477 No Title Provided****OQI Details**

Status	Closed Approved
Subject	A Negative extraction control sample [REDACTED] was extracted on CWIQLYS20080429_01/CWIQEXT20080430_01 had been profiled twice confirming a partial profile in the DNA extract.
Source of OQI	Internal Problems (QHPSS)
Date Identified	12/05/2008

OQI Creator Contact Details

Creator	Amy CHENG
Organisational Unit/ s	Analytical
Service/ s	
Site Location/ s	Coopers Plains

Investigator/ Actioner Contact Details

Actioner	Allan MCNEVIN
Organisational Unit/ s	Analytical
Service/ s	
Site Location/ s	Coopers Plains

Investigation Details

Investigation Completed	22/07/2008	Root Cause Type	Procedure/Method/Process
Investigation Details	<p>Negative extraction control [REDACTED] showed a single peak above 75RFU at Amelogenin after extraction. This was confirmed after re-amplification. The control was then concentrated via microcon and both the original results and the microcon results were analysed at 30RFU values. A full 9-loci profile was able to be elucidated from the concentrated sample. This was then searched against all profiles from the same extraction batch (CWIQEXT20080430_01). A match was found with samples [REDACTED] which are all from the same case. Further matches were found to a mixture 333810182 and a match was found to sample [REDACTED] after it had undergone a clean up procedure with the NucleoSpin Tissue Kit. Samples [REDACTED] (5.61ng/uL), (320124335 8.8ng/uL) & [REDACTED] (10.53ng/uL) had quite high quantification values and one or more were the most likely source(s) of the contamination. During the course of the investigation two further examples of potential well-to-well contamination have been identified and taken in conjunction with two previously documented events, these events build a picture of potential systematic problems. This other events have been documented as OQI's 19330, 19349, 19767, & 19768.</p>		
Performed By	Quality Information System		

Action Details

Action Complete Title	22/07/2008	Action Fix Type	Changed Process
	<p>Action Description audit (audit # 8227 ? DNA IQ) has been commissioned to thoroughly review all facets of the automated extraction process. This had been planned as a post implementation review but has been brought forward in view of events mentioned above. A investigation report has been written and stored in I:\AAA Analytical Section\Adverse event investigations\ An extra-ordinary meeting of the DNA Analysis management meeting was held 14/07/2008 and the following actions were agreed upon: i) Processing of Reference samples only on Extraction platform A (initial investigations indicated events were likely related to platform A) ii) Processing of Casework samples on Extraction platform B in a checkerboard pattern with extraction reagent blanks iii) Urgent progression of audit mentioned above and investigation into findings iv) A full information review of results from automated extractions with documented quality events and extractions without documented events to gain further information This OQI has been discussed in the Analytical team meeting. Staff have additionally been individually approached with questions re: concerns, possible solutions etc. by the audit team for audit #8227</p>		

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status	Accepted
Follow-up Status Comment	<u>8/08/2008 3:28:01 PM Amy CHENG:</u>
Approver	Cathie ALLEN
Approval/ Rejection Date	18/08/2008
Approval/ Rejection Comment	<u>18/08/2008 12:00:00 AM Catherine ALLEN:</u>
	Accepted as this OQI will be addressed in the Process Audit 8227 Part of a larger investigation and with Audit 8227.

Associations

No Associations found

Records

No Records found

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