

Report for QIS OQI as of 28/06/2022 10:50:23 AM

## Report for QIS OQI -

# 19768 No Title Provided

### OQI Details

<b>Status</b>	Closed Approved
<b>Subject</b>	During the uploading of results for genotyper batch GEN9CW20080513_02, it was noted by the scientist that sample [REDACTED] (which was the negative control for extraction batch CWIQLYS20080502_02 and CWIQEXT20080506_01), was found to have a partial profile result which instead should have resulted in 'NSD?' which is expected for any negative control. The folder was reviewed through Genescan (version 3.7.2) and Genotyper (version 3.7.1) software, and confirmed that there were peaks visible which were overseen during the initial genescanning of that sample.
<b>Source of OQI</b>	Internal Problems (QHPSS)
<b>Date Identified</b>	14/06/2008

### OQI Creator Contact Details

<b>Creator</b>	Maria AGUILERA
<b>Organisational Unit/ s</b>	Analytical
<b>Service/ s</b>	
<b>Site Location/ s</b>	Coopers Plains

### Investigator/ Actioner Contact Details

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

### Investigation Details

<b>Investigation Completed</b>	30/07/2008	<b>Root Cause Type</b>	Procedure/Method/Process
<b>Investigation Details</b>	Initially, negative extraction control sample [REDACTED] was extracted as outlined above on batches CWIQLYS20080502_02 and CWIQEXT20080506_01. The DNA extract was then quantified with a quant value 0.00544 ng/uL. This value is above the limit of detection (0.00426ng/uL) but below the limit of reporting (0.0128ng/uL). The DNA extract was then amplified at 20uL. The sample was analysed on CE batch CEPCW20080509_01 and Genotyper batch GEN9CW20080513_02. A single peak at the Amelogenin locus was observed above the peak detection threshold (75RFU) but below the reporting threshold (150RFU) for casework samples. The DNA extract was re-amplified at 20uL with no peaks visible above peak detection threshold, however potential peaks were visible below threshold. The DNA extract was then concentrated using the standard Microcon procedure. The DNA extract was reduced from approximately 50-60uL in volume to approximately 5uL in volume. This extract was then amplified and no DNA profile was observed. This was thought to be		

erroneous and the NUNC tube containing the DNA extract was visually reviewed. 3uL of DNA extract was shown to be remaining. This was most likely due to a failure of the MPII to pipette small volumes (see OQI 20113). The DNA extract was re-amplified and a partial DNA profile was observed. The partial DNA profiles obtained from the original amplification, the re-amplification and the repeat amplification of the concentrated extract were then re-analysed using a lowered peak detection threshold of 30RFU. A profile of 15 discernable alleles was then elucidated. This profile was then searched against all profiles obtained from samples on the same extraction batch (CWIQEXT20080506\_01). Matches were made to two different samples, [REDACTED] [REDACTED]. Further investigation was then carried out to determine at what processing step the contamination was likely to have occurred. The AUSLAB audit trails for negative extraction control 346796064 and samples [REDACTED] [REDACTED] were reviewed. The quantification and amplification batches samples [REDACTED] [REDACTED] were processed on after extraction were found to be different to the batches negative extraction control 346796064 was processed on. Thus the only stage the samples and the control were processed together was during the extraction process (off-deck lysis and automated extraction). The most likely cause of contamination was during the MPII processing of the extraction batch, however the off-deck lysis component cannot be excluded. The off-deck lysis component is least likely as this is a manual process, during which only one tube is opened at a time and samples are processed sequentially, as negative extraction control 346796064 was the first sample on the lysis batch (position 1) and samples [REDACTED] and [REDACTED] were in positions 31 & 32 respectively, a large number of samples were processed in between.

Performed By | Quality Information System

## Action Details

Action Complete Title	30/07/2008	Action Fix Type	Other
		<p><b>Action Description</b></p>	<p>This event has been discussed in an Analytical team meeting and will constitute part of the ongoing investigations and discussions around the automated extraction procedure. AUSLAB audit entries for extraction batch CWIQEXT20080506_01, and AUSLAB specimen notes, and notation in the comments section of the 9PLEX page to refer to specimen notes were made for all samples on this extraction batch. Additionally this OQI was also entered into the UR notes of all samples. A full process 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 was brought forward in view of this OQI and OQI's 19330, 19349, 19477, &amp; 19767. An extra-ordinary meeting of the DNA Analysis management team was held 14/07/2008 and the following actions were agreed upon: Processing of Reference samples only on Extraction platform A (initial investigations indicated events were likely related to platform A) Processing of Casework samples on Extraction platform B in a checkerboard pattern with extraction reagent blanks Urgent progression of audit mentioned above and investigation into findings A full information review of results from automated extractions with documented quality events and extractions without documented quality events to gain further information Initial findings from Audit # 8227 have highlighted some pipetting steps within the automated extraction process as being of particular concern. A second extra-ordinary meeting of the DNA Analysis management team was held on 28/07/2008 and a decision was made to cease processing of samples through the automated extraction process until problems identified could be rectified to the satisfaction of the management team.</p>

## Task Details

No Tasks found

## Follow-up And Approval

<b>Follow-up Status</b>	Accepted
<b>Follow-up Status Comment</b>	<u>31/07/2008 1:53:19 PM Maria AGUILERA:</u> Note: The full report can be found in I:\AAA Analytical Section\Adverse event investigations\2008 Events
<b>Approver</b>	Cathie ALLEN
<b>Approval/ Rejection Date</b>	18/08/2008
<b>Approval/ Rejection Comment</b>	<u>18/08/2008 12:00:00 AM Catherine ALLEN:</u> No comment was recorded

## Associations

No Associations found

## Records

No Records found

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