

Report for QIS OQI as of 28/06/2022 10:49:56 AM

Report for QIS OQI -**19767 No Title Provided****OQI Details**

Status	Closed Approved
Subject	During the genescan of batch CEPRF20080521_01 (to become GEN9REF20080526_01), it was noted that a mixture was found in a FTA sample (barcode ██████████). Initially FTA sample 184858899 was processed through routine FTA processing procedures: on batch FTA20080207_01 (to become GEN9REF20080225_03), and due to the initial `NSD?` profile obtained on this original process, the sample was re-punched and processed on FTARUN20080318_02 (to become GEN9REF20080423_04). The results after being re-punched resulted in a partial DNA profile of 12 alleles plus Amelogenin. This partial DNA profile necessitated an automated extraction of the FTA card. The FTA sample was again re-punched in batch FTAEXT20080515_01 and was extracted on batch FFIQEXT20080515_01 on the MPII extraction platform. After this extraction process, the sample progressed through to routine quantification and amplification processes. The DNA extract resulted in a quantitation value of 0.0558ng/?L, in which 20?L of the DNA extract was then amplified. The PCR product was then prepared and run through the Applied Biosystems 3130xl Prism Genetic Analyser and analysed using Genescan (version 3.7.2). It was at this stage that the mixture on this sample was noted.
Source of OQI	Internal Problems (QHPSS)
Date Identified	14/06/2008

OQI Creator Contact Details

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

Investigator/ Actioner Contact Details

Actioner	Allan MCNEVIN
Organisational Unit/ s	Analytical
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Investigation Details

Investigation Completed	22/07/2008	Root Cause Type	Procedure/Method/ProcessA
Investigation Details	mixture was located in reference sample 184858899 from extraction batch RFIQEXT20080515_01 during the genescan analysis of capillary electrophoresis batch CEPRF20080521_01. The sample was re-prepared and re-analysed and the mixture was still present. The sample was then re-amplified and the the mixture was still present. The mixture contained alleles in common with all alleles seen from a		

partial profile obtained when the same sample had been processed on FTA batch FTARUN20080318_02. Sample 184858899 was re-extracted under barcode [REDACTED], and this gave a full single source profile consistent with previously obtained partial profile. The mixture obtained from the original extraction of 184858899 was then separated into the true profile and the second mixture contributor. The mixture contributor was then searched against all profiles obtained from extraction batch RFIQEXT20080515_01 and a match was found with sample [REDACTED]. The presence of a reproducible DNA profile from within the extract and with both samples [REDACTED] being both processed alongside each other on initial quantification and amplification batches indicates that contamination has occurred at the point of the first Amplification set-up or earlier (e.g. quantification or extraction). During the course of investigation information has been gained that when viewed alongside other previous and subsequent quality events (namely OQI's # 19330, 19349, 19477, & 19768) a picture of potential systematic quality failure of the quality processes from the automated extraction processes is present. Further information is required to further elucidate and rectify if necessary any problems.

Performed By Quality Information System

Action Details

Action Complete	22/07/2008	Action Fix Type	Other
Title	<p>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 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>24/07/2008 1:51:03 PM Maria AGUILERA:</u> No comment was recorded
Approver	Cathie ALLEN
Approval/ Rejection Date	15/09/2008
Approval/ Rejection Comment	<u>15/09/2008 12:00:00 AM Catherine ALLEN:</u>

As this sample was processed with the other sample on extraction, quant and amp, it is difficult to pinpoint the possible root cause. The sample was also processed on the BSD machine with the other sample, so this is a possible source too. A large investigation is being undertaken into this and other OQIs and will be documented.

Associations

No Associations found

Records

No Records found

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