Report for QIS OQI as of 28/06/2022 10:03:18 AM

Report for QIS OQI -

20617 No Title Provided

OQI Details

Status	Closed Approved
Subject	A match was found between [redacted] (Pos. 47 - single 9L profile) and two other profiles; [redacted] (Pos. 55 - mixture)and [redacted] (Pos. 46 - mixture) on CWIQEXT20080614_02. After conditioning of these mixtures a match to [redacted] can be obtained. The initial match was found to the profile[redacted] whilst performing an extraction batch search (using autofilter elimination on the extraction batch excel file) on alleles observed on an UKM1 profile in mixture [redacted] Subsequent searching revealed the match with [redacted]
Source of OQI	Internal Problems (QHPSS)
Date Identified	05/09/2008

OQI Creator Contact Details

Creator	Rhys PARRY
Organisational Unit/s	Reporting 3
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	02/12/2008 **Root Cause Type** Procedure/Method/Process
Investigation Details	Samples [redacted] were all extracted on the same extraction batch CWIQEXT20080614_02. Samples [redacted] (from positions 55 & 46 respectively) contained mixed DNA profiles, and upon analysis of the results were deemed to have been contaminated by a profile matching that of sample [redacted] (from position 47) as outlined above. During the investigation, the stored lysate for all three samples were re-extracted as well as the stored substrate. Throughout the investigation, the results from the original extraction and subsequent re-extractions were analysed using GeneMapper-IDX software with a peak detection threshold of 20RFU to gain the most information. The re-extraction of the stored lysate (i.e. lysed material that was retained after removal from the para-magnetic resin during the automated DNA IQ extraction process) for each of the three samples gave results consistent with that obtained from the initial extaction process. From these results, it

	can be concluded that the contamination of samples [redacted] by sample [redacted] must have occured prior to or during the separation of the lysis solution and the para-magnetic resin. The re-extraction of the stored substrate (i.e. the material originally submitted for DNA extraction that had passed through the initial off-deck lyss step of the original extraction process) gave differing results for samples [redacted] Both of these samples only yielded single source profiles (compared to the mixed DNA profiles obtained from the original extraction). Sample [redacted] showed the same single source profile as originally obtained. These results show that the obsreved contamination has occured after the processing of the stored substrate (i.e. after the manual off-deck lysis procedure). The potential steps at which contamination may have occurred are: 1. During the transfer of the lystate obtained from manual lysis into the deep-well plate via the use of the STORstar. However this is unlikely as staff are trained to perform such pipetting steps with due diligence and care. 2. Seepage of sample from well 47 to adjacent wells 46 and 55 during cold storage of the lysed material in the deep-well plate. After the cessation of processing and the carrying out of investigations, it was noted in one instance that a heavily blood-stained lysate had condensed on the underside of the adhesive seal used to seal the stored plate. This had seeped accross into an adjacent well. This was possibly due to insufficient application of the adhesive seal to the interstitial barrier. 3. During the removal of the adhesive seal. It was noted during Audit 8227 that condensation on the underside of the adhsive seal was not removed after centrifugation. 4. Operator error during the manual addition of DNA IQ para-magnetic resin during the start of the automated extraction procedure (i.e. incorrect pipetting procedure), however this is unlikely as staff are trained to perform such pipetting steps with due diligence and care. 5. During the mixing of the deep-well plate (containing 1.5mL of buffers and resin within a 2.2mL well) on the extraction platform DPC shaker. This had not been observed, however has been proposed a possible mechanism for adjacent well contamination during close scrutiny of the automated procedure. 6. During the lysis removal from the para-magentic resin to the storage plate. This procedure occurs twice during the automated extraction protocol (fresh disposable tip for each step). If there was drippage of the lysate containing unbound DNA and this was to drip from well 47 to adjacent wells (either 46 or 55) this may account for the contamination event. The same mechanism may occur where a bubble forms at the end of the pipette tip and bursts whilst still in the vicinity of the adjacent wells.
Preformed By	Quality Information System

Action Details

Action Complete	02/12/2008 **Action Fix Type** Changed Process
Title	As a result of
Action Description	previous OQI's raised and concerns identified around the automated DNA IQ extraction process, the extraction of samples using the automated DNA IQ procedure was halted on the 28-7-2008. Prior to this, Audit 8227 had been commissioned and carried out. A number of areas for improvement were identified through the audit, and these have been implemented or are under investigation as outlined in OQI's 20367, 20368 and 20369. After the cessation of the automated DNA IQ extraction protocol, a review of all batches processed through this protocol was carried out by a specially commissioned team. A number of potential contamination events were identified and each is to be investigated on batch-by-batch basis. Additionally, careful review of results obtained from samples processed through the automated DNA IQ extraction procedure prior to reporting will be carried out. Every DNA result obtained from these samples will be interpreted with caution. Modifications have been made to the automated DNA IQ extraction procedure (including the use of an alternative to the

adhesive seal and an alternative resin mixing procedure). This modified procedure is undergoing extensive verification and approval from the DNA Analysis management team must be obtained prior to re-introduction. The contamination events and concerns and improvements etc. that surround the automated DNA IQ extraction procedure have been discussed at various departmental and team meetings.

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status	Accepted
Follow-up Status Comment	12/12/2008 12:45:37 PM Rhys PARRY: No comment was recorded
Approver	Paula BRISOTTO
Approval/Rejection Date	08/01/2009
Approval/Rejection Comment	8/01/2009 12:00:00 AM Paula TAYLOR: No comment was recorded

Associations

No Associations found

Records

No Records found

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