Report for QIS OQI as of 28/06/2022 10:17:17 AM

Report for QIS OQI -

21309 No Title Provided

OQI Details

Status	Closed Approved
Subject	When performing a quality check of batch CWIQEXT20080531_01 for case [redacted] (blue case), it was found that the 9 loci profile from sample [redacted] could not be excluded from contributing to the profile for sample [redacted] from unrelated case [redacted] and this profile was also found to be a below threshold match to the minor profile in sample [redacted] from a second unrelated volume case.
Source of OQI	Internal Problems (QHPSS)
Date Identified	06/11/2008

OQI Creator Contact Details

Creator	Thomas NURTHEN
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	04/12/2008 **Root Cause Type** Procedure/Method/Process
Investigation Details	Samples [redacted] both contain mixed DNA profiles from apparently unrelated cases, additionally the single source DNA profile obtained sample [redacted] could have contributed to the mixture in both samples. This sample is also from an apparently unrelated case. As part of the investigation, the stored lysate and the stored substrate for all three samples were re-extracted. Throughout the investigation, the results from the original extraction and subsequent re-extractions were analysed using GeneMapper ID-X 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 showed results consistent with that obtained from the initial extraction process. From these results, it can be concluded that the contamination of samples [redacted] by sample [redacted] must have occurred 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 lysis step of the

original extraction process) gave a differing results for samples [redacted] Both gave single source DNA profiles that were consistent with the alternate contributor of the initial mixed DNA profiles when conditioned against contaminating sample [redacted] Sample [redacted] yielded the same single source profile as obtained initially. This indicates that there was no contamination of the substrate during the manual processing on initial extraction (off-deck lysis procedure), and that contamination has occurred between this step in the procedure and the step noted above. 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 all staff are trained to perform such pipetting steps with due diligence and care. 2. Seepage of sample [redacted] (well 88) into adjacent wells 87 [redacted] and 96 [redacted] 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 across 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 adhesive 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 one well to another well 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 another well.

Preformed By Quality Information System

Action Details

Action Complete 04/12/2008 **Action Fix Type** Changed Process

Title

Action Description As sample [redacted] contained significantly higher levels of DNA (quantification values of 3.59ng/ul, 14.0ng/ul and 7.91ng/ul were obtained from the initial DNA extract, re-extraction of the lysate and re-extraction of the substrate respectively) when compared to the affected samples, only a small amount of lysate would have been required to have transferred to an adjacent well to have caused the contamination. Given the single source profiles obtained from samples [redacted] after re-extraction of the stored substrate, contamination has occurred. As a result of 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	5/11/2013 4:15:42 PM Thomas NURTHEN: Agree with actions taken
Approver	Paula BRISOTTO
Approval/Rejection Date	14/11/2013
Approval/Rejection Comment	14/11/2013 10:49:51 AM Paula BRISOTTO: Nil

Associations

No Associations found

Records

No Records found

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