Report for QIS OQI as of 28/06/2022 10:29:06 AM

Report for QIS OQI -

21589 No Title Provided

OQI Details

Status	Closed Approved
Subject	Sample [redacted] was a negative control on batch RFIQLYS20080627_01 and RFIQEXT20080630_01. These batches only contained project samples. During the Genemapper ID-X validation it was noted that this sample contained a below threshold profile. Additionally this sample did not contain a 9FTAR Processing Comment to indicate this sample was a negative extraction control.
Source of OQI	Internal Problems (QHPSS)
Date Identified	05/12/2008

OQI Creator Contact Details

Creator	Chiron WEBER
Organisational Unit/s	DNA Analysis
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	27/03/2009 **Root Cause Type** | Procedure/Method/Process
Investigation Details	Extraction batch RFIQEXT20080630_01 consisted of a positive and a negative extraction control and 15 samples. The 15 samples were samples used in the assessment of a new swab type (Copan 4N6 swab). Each sample consisted of 30ul of buccal suspension from the same volunteer (previously profiled staff member) spotted onto various swabs. There were three swab types under test and each was done five times (therefore 15 samples). After initial processing and profiling, all samples and controls yielded expected results and no further

action was taken.

At a later stage, during the validation of a new software package for the analysis of DNA profiles, GeneMapper-IDX, it was noted that the negative extraction control [redacted]) from extraction batch RFIQEXT20080630_01 contained a partial DNA profile that were not previously detected. This was due to the reduced peak detection threshold used in GeneMapper-IDX. The negative extraction control was concentrated using microcon filter centrifugation. All alleles obtained from initial processing and after concentration were consistent with the DNA profile obtained from all 15 samples. It is notable, however, that at the time of processing, there was an expectation of staff to observe potential peaks below peak detection threshold in negative extraction controls during sample analysis.

At the time of processing extraction batch RFIQEXT20080630_01, the process in use at the time was a two-stage automated extraction method using promega DNA IQ technology. This process involved a manual tube lysis of samples, storage of the lysed sample in a deep-well plate (that was potentially sealed and stored at 4oC prior to processing), then DNA extraction on the MPII liquid handling platform. During the automated extraction, the lysate containing the lysis buffers and any potentially un-bound DNA (i.e. DNA not bound to the para-magnetic resin) was removed and stored. This stored lysate was re-extracted for all samples and controls on the extraction batch. DNA profiles obtained from the stored lysates were all consistent with those obtained from initial processing.

Therefore, contamination of the negative extraction control had occurred prior to or during the removal of the lysate during the automated extraction process. As noted in audit 8227 and a number of OQi's prior to and subsequent to the audit, a number of steps within the automated extraction and associated processes were potentially the cause of the contamination event. These are:

1. During the processing of the manual in-tube lysis procedure or transfer of the lysate into the deep-well plate via the use of the Storstar. This however is considered unlikely as the lysate of the negative extraction control was processed at all stages prior to any samples and the nature of the processing whereby individual care is during the process to prevent contamination.
2. During the removal of the adhesive seal used to seal the deep-well plate containing stored lysates awaiting automated DNA IQ extraction. This is the most likely as it was noted during Audit 8227 that condensation on the seal that could not be removed by centrifugation was a contamination risk. Additionally, it was observed in one instance that seepage across the adhesive seal (from a positive to a negative control in adjacent wells) appeared to have occurred. The negative extraction control was in an adjacent well and diagonal from samples.
3. There may have been 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.
4. 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 as a possible mechanism during close scrutiny of the automated procedure.
5. During the 1st stage of removal of lysate from the para-magnetic resin to the storage plate. This procedure occurs twice during the automated extraction protocol (fresh disposable tips for each step). If there was dripping of the lysate containing unbound DNA and this was to drip from from a tip containing sample (or a bubble of liquid burst), this may account for the contamination event.

Preformed By Allan MCNEVIN

Action Details

Action Complete 27/03/2009 **Action Fix Type** Expenditure of Resources

Title	Improvements to automated DNA IQ protocol & implementation of GeneMapper-IDX
Action Description	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 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 investigated on a batch-by-batch basis. 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. This modified procedure is undergoing extensive verification and will require approval from the DNA Analysis management team 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. Lastly, with the introduction of GeneMapper-IDX software, a procedure whereby all extraction negative controls are checked with a peak detection threshold of 20RFU (compared with 50RFU for samples) is performed in order to locate any potential below threshold profiles.

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status	Accepted
Follow-up Status Comment	22/04/2009 7:45:01 AM Chiron WEBER: Investigation and findings OK.
Approver	Paula BRISOTTO
Approval/Rejection Date	05/05/2009
Approval/Rejection Comment	5/05/2009 8:27:11 AM Paula TAYLOR: Agreed

Associations

No Associations found

Records

No Records found

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