

Report for QIS OQI as of 28/06/2022 10:59:41 AM

Report for QIS OQI - 20231 No Title Provided

OQI Details

Status	Closed Approved
Subject	During review of extraction negative controls it was noted that the negative extraction control ██████████ contained peaks above threshold. The sample was extracted on batch CWIQEXT20080417_01 on the extraction platform B.
Source of OQI	Internal Problems (QHPSS)
Date Identified	24/07/2008

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	29/07/2008	Root Cause Type	Procedure/Method/Process
Investigation Details	The correct negative extraction control lab number is ██████████ (the wrong lab number has been added to description). In July 2008, concern was raised as the quality of the automated DNA IQ extraction process, with a number of contamination events having occurred leading to evidence of well to well contamination during the automated DNA IQ extraction (using the MPII platform) process. A review of all negative extraction controls from all batches performed through this process was conducted. It was noted that negative extraction control sample ██████████ showed the presence of a partial DNA profile in AUSLAB. The DNA extract from ██████████ was then concentrated by Microcon concentration. The concentrated DNA extract was re-quantified, amplified and analysed. Two peaks were present above peak detection threshold. Both the original amplification result and the microcon amplification result were analysed at reduced peak height detection threshold (30RFU) and a number of alleles were determined. A combined profile was then obtained and this was searched against profiles obtained from the same extraction batch. A match was found to ██████████, an environmental monitoring sample that was submitted as a blind positive control (consisted of a staff members buccal swab). Further analysis of the extraction batch was conducted at reduced peak detection threshold and environmental monitoring		

samples [REDACTED] were found to contain consistent alleles. After reviewing the quantification values for the samples it was determined that sample [REDACTED] was most likely the source of the contamination as this sample had the highest quantification value (1.62ng/uL). Negative extraction control [REDACTED] was quantified and amplified on separate batches to environmental sample [REDACTED] and the additional samples [REDACTED]. Therefore the contamination can be defined to have occurred during the extraction procedure (either during off-deck lysis, or during automated extraction). This would be consistent with the preliminary findings of Audit 8227 and previous OQI's raised (particularly 19330, 19349, 19477, 19767, and 19768).

Performed By Quality Information System

Action Details

Action Complete Title	08/08/2008	Action Fix Type	Other
			This OQI was raised as part of previously initiated actions relating to the investigation into the automated DNA IQ procedure (see Audits and OQI's listed in Investigation), A full investigation report surrounding this OQI can be located in I:\AAA Analytical Section\Adverse event investigations\2008 Events Appropriate specimen notes, UR notes and batch audit entries have been made in AUSLAB. This event will be discussed in the next available Analytical team meeting. Particular attention will additionally be placed on the initial acceptance of the Negative control (i.e. the control passing through the quality process). The need for due care when reviewing control results will be highlighted.

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status	Accepted
Follow-up Status Comment	<u>15/08/2008 7:17:05 AM Chiron WEBER:</u> No comment was recorded
Approver	Cathie ALLEN
Approval/ Rejection Date	18/08/2008
Approval/ Rejection Comment	<u>18/08/2008 12:00:00 AM Catherine ALLEN:</u> No comment was recorded

Associations

No Associations found

Records

No Records found

20231 No Title Provided
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