CaSS | Forensic and Scientific Services
A CLINICAL AND STATEWIDE SERVICE

AGENDA

Chairperson:	JAH	**Date and Time:**	14 July 2008 2pm – 3.45pm
Venue:	FSS Conference Room 102	**Contact:**	
Attendees:	VKI, JAH, AAP, AM, AJS, EJC, KDR, PT, PAC, RS, TEN, WH		
Apologies:	CJA		
Guests:	Ingrid Moeller, Julie Connell		

1.0 PREVIOUS MINUTES ENDORSED

No Previous meeting held

2.0 NEW BUSINESS

OQIs and actions around reporting and investigation OQI trends.

- OQIs 19768, 19477, and 19349 refer. Positive control profiles found in negative controls on two separate occasions. Case work profile appears to have contaminated 3 wells on another plate, including the negative control.

  Appears that well to well contamination has occurred during extraction.

- How are we going to report these cases affected? i.e "Quality Failure has been detected".

  Need to establish words for inclusion in statements.

  Need to be prepared to answer questions in court.

- Agreed to not report on all samples affected in the OQIs mentioned.

Where EXRSs have been released, need to send an Intell letter to FIRMU to explain the quality failure and the changes to results.

New EXR to be created to use for results not yet reported and appropriate wording to be developed for statements.

Agreed that DNA Analysis should be conservative; do not report on samples affected.

Full disclosure is a must. Reporting Scientist should be comfortable and confident in their reporting.

- For future cases of contamination – an EXR line (specific wording) will need to be created.

- Need to determine the source, to prevent reoccurrence. Amy, Iman and Peter Clausen are currently reviewing processes. Chiron is collating information on equipment / trends etc.

All but one of the issues appeared to be attributed to Platform A.

- An audit is currently being conducted on all processes. Appears that the contamination is sporadic.

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AGENDA

Chairperson:	VKI	**Date and Time:**	28 July 2008 11.00am – 12.30pm
Venue:	FSS Conference Room 611	**Contact:**	
Attendees:	VKI, JAH, AAP, AM, AJS, EJC, KDR, PAC, PT, TEN, WH		
Apologies:	CJA , RS		
Guests:			

Follow up meeting on preliminary DNA IQ audit report

- Audit report has been prepared – currently in draft. PAC agrees with comments made in the draft report. Audit report covers process from start to finish.

Summary found at -
I:\AAA Analytical Section\Adverse event investigations\IQ extraction evaluation July 2008\DNA IQ troubleshooting strategy 25-7-08.doc

Agreed with findings and actions. Steps to commence -

1. Troubleshooting – look at performance of pipettes and syringes
2. Review of methods, programs by PerkinElmer and other labs using multiprobe (not limited to those using platforms for forensic work). Look at enhancing existing program. Including review of deck positions.
3. Look at assessing current maintenance and ascertain whether additional maintenance steps are required.

All of the above actions can run concurrently.

- All extractions to stop on the platforms immediately. Return to chelex and nucleospin extraction* (*as required)

- Availability of bench space is an issue. Tom and Allan to manage extractions with current amount of staff and using current bench space.

- Currently approx 6 batches that have had off deck lysis completed will now have manual IQ performed. Notes must be included that detail what steps will be taken to do this.

- How & When to return to using platforms?
  Discuss regularly at Management Team meetings to identify a decision point.

Background

Following a request from the Director, Mr Greg Shaw, a review of procedures was conducted by Drs Sloots and Whiley (the reviewers) at the Forensic and Scientific Services laboratory, Clinical and State-wide Services, Coopers Plains, pertaining to the extraction of nucleic acids from samples submitted for analysis.

The reason for this review related to a previous episode in the laboratory which resulted in anomalous results and which appeared to be linked to the operation of robotic instrumentation utilised in the nucleic acid extraction process.

During their visit, the reviewers were made aware of the operations applied in the general laboratory from receipt of specimens to issuing of results, and then examined in detail the bench process relating to the pre-digestion of specimens and the extraction of nucleic acids using the Perkin Elmer MultiPROBE II PLUS HT EX with Gripper Integration Platform.

All aspects of these operations were scrutinised including staff input and instrument operation.

Findings

It was obvious to the reviewers that extensive measures were applied by all staff to prevent the misidentification or cross contamination of samples. There was appropriate use of personal protection equipment and other protective measures to prevent contamination of the work environment with extraneous nucleic acid.

The procedures currently in place for the Off-Deck Lysis and MPII extraction appeared to be adequate and specifically designed to prevent cross contamination of test samples.

We agree with the Forensic Services Management team that the previous issue of possible cross-contamination of samples most likely related to the use of adhesive film in sealing the deep-well plates used in the Off-Deck lysis procedure. The type of plate used, and the period of storage at reduced temperatures have in our experience caused similar problems in molecular diagnostics. The subsequent decision to change this procedure to the use of capped tubes has clearly solved this problem.

The use of robotic equipment for the extraction of nucleic acids has some considerable benefits for a busy laboratory, and prevents human error introduced as a result of repetitive actions. However, the efficient use of such instruments requires the proper maintenance and calibration be performed at the requisite time intervals. These appeared to be adequately performed at the time of review.

It may appear that the original issue concerning the cross-contamination of samples in the deep-well plates could have been prevented if this change in procedure had been fully validated against existing protocol when the new method was introduced. Although most