

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.



- Vanessa to communicate to DNA Analysis regarding OQI processes; what we are doing to identify the source.
- Agreed to commence from tomorrow (15 July 2008) to have –
 - 1 pos control
 - 1 neg control
 - 47 blank
 - 47 samples

per plate. Working in a diagonal design. Blanks will be amp'd to see if any problems.

Robyn to advise Operational Officers of the need to register all 47 blank spaces on the batch.

- Time required to manually extract - 4 hrs for 24 samples.
- During Audit Process - Platform A to be only used for Reference samples.
- Platform B to be used for casework.
- All Analytical OQIs are detailed on the Analytical Issues Log – adverse events log tab.
- Agreed that a discussion needs to be held at action/approval stage of OQIs.
- Robyn to flag these occurrences at management team meetings.

This is in addition to current email correspondence about OQI.

- Allan to update Minor Change Register regarding change in checkerboard pattern for extractions.

3.0 CLOSURE