Queensland Government
Queensland Health

MEMORANDUM

To: DNA Analysis

Copies to:

From: Vanessa Ientile, Managing Scientist **Contact No:** [redacted]
Fax No:

Subject: DNA IQ Extractions

File Ref: 140708

An extraordinary management team meeting was held on the 14th July to discuss what actions should be taken to address concerns within DNA Analysis in relation to reporting samples on extraction batches referred to in a number of OQIs. The purpose of this memo is to outline the agreed decisions and actions as a result of the meeting.

Concerns have been raised specifically in relation to OQIs # 19477, 19768 and 19349. Initial investigations appear to indicate some form of well to well cross contamination during the extraction process. The investigations undertaken to date have not been able to identify the cause of this contamination. The three events have occurred on or around the following dates:

OQI#19477 – 29/4/08
OQI#19768 – 2/5/08
OQI#19349 – 25/2/08

As each of these events was discovered a thorough investigation commenced to determine the possible causes. This process involves attempting to identifying the point at which the contamination may have occurred by repeating the samples (i.e. extraction, quantitation, amplification, 3130), determining where the contamination came from (well to well, automated or manual process, operator error etc) and working out whether additional controls or changes to procedures are required to prevent the event from reoccurring.

Automated DNA IQ extractions were introduced in October 2007, after an extensive validation process. The results of various tests undertaken during this validation phase demonstrated no well to well contamination or transfer. This process was approved and implementation was agreed to by the management team with the understanding that ongoing optimisation would continue as part of the normal continuous improvement process.

Given the issues cannot be easily identified or reproduced, the following actions were agreed to by the Management team:

Reporting the results from the affected extraction batches

All samples on the affected extraction batches will be reported as a "quality system failure" and therefore the profiles or matches will not be reported. It was agreed that full disclosure is required.
A new EXR line will be created to cover this.
Appropriate statement wording is being developed.
If any of these samples have been previously reported via EXRs, then an Intelligence type letter to FIRMU will be drafted explaining the changes to the results reported.

Further investigations

An audit of the entire automated extraction process is underway to attempt to identify any potential causes or areas of improvement. This audit is being conducted by Amy Cheng, Iman Muhuram and Pete Clausen.
Further testing may be required to rule out or confirm potential causes identified through this process.

The details of all the events are being reviewed to see if any common factors can be identified. For example at this early stage, it appears that all but one event has occurred on Platform A. No confirmed trends have yet been identified.

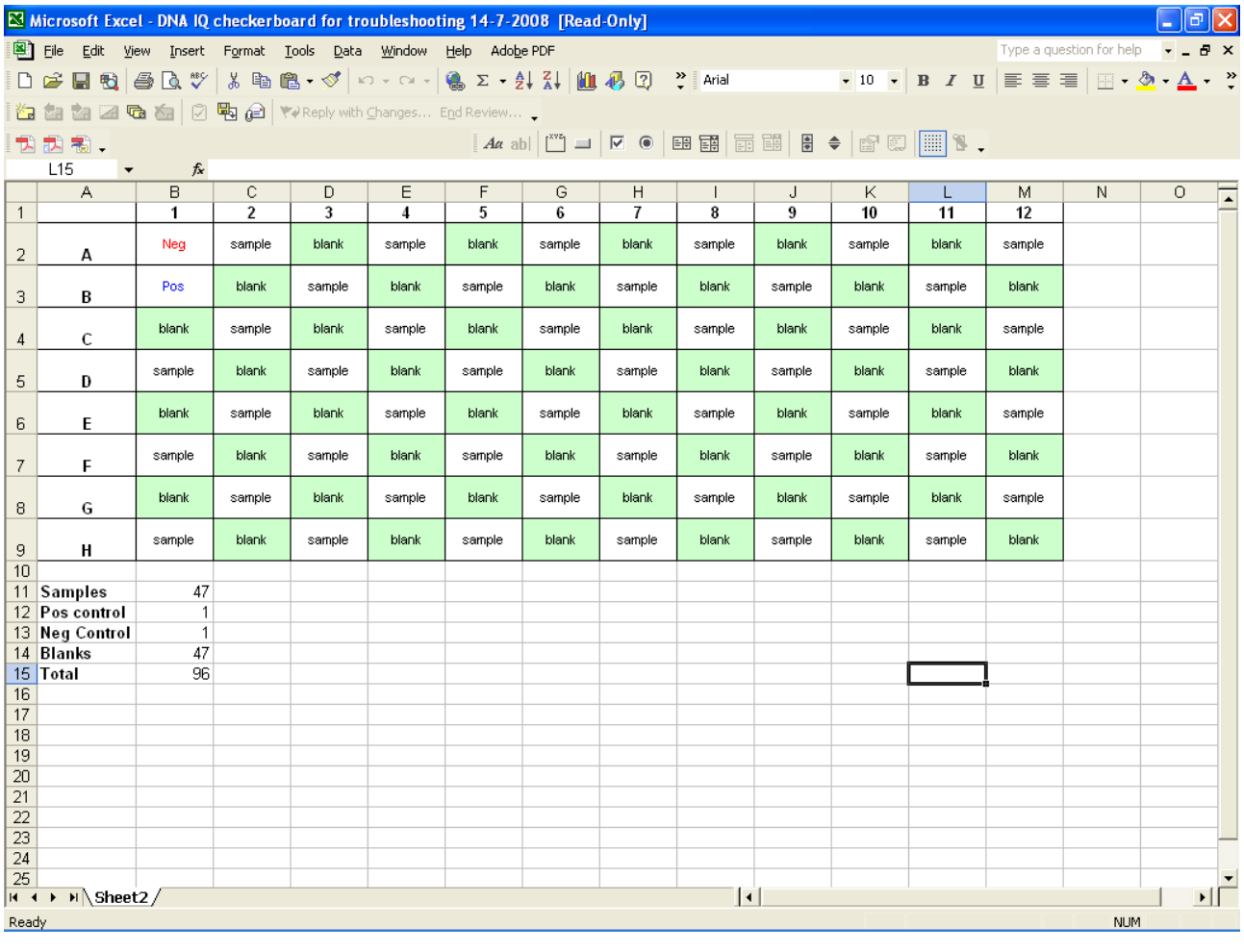
Interim changes to procedures

The decision has been made that processing will need to continue during the investigation phase. It is not feasible to stop all extractions. It is also not feasible at this stage to move to completely manual processing. The interim changes decided upon are designed to increase the number of controls used on each plate in an effort to identify any additional issues and minimise the chances of any further occurrences. As the findings from the audit become available, these interim changes will be reviewed as required.

From the 15th July 2008, the following changes will be implemented:

1. Platform A will not be used for casework extractions. It was agreed that reference samples could be extracted on platform A, as these can be repeated.
2. Case work extractions will continue on platform B with a new checkerboard sample arrangement (see example below). This will half the number of samples per batch but will allow us to easily identify through analysis of the blanks whether any additional well to well contamination has occurred.

These changes have been added to the Minor Change Register.



Microsoft Excel - DNA IQ checkerboard for troubleshooting 14-7-2008 [Read-Only]

File Edit View Insert Format Tools Data Window Help Adobe PDF

L15

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1		1	2	3	4	5	6	7	8	9	10	11	12		
2	A	Neg	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample		
3	B	Pos	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank		
4	C	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample		
5	D	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank		
6	E	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample		
7	F	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank		
8	G	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample		
9	H	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank	sample	blank		
10															
11	Samples	47													
12	Pos control	1													
13	Neg Control	1													
14	Blanks	47													
15	Total	96													
16															
17															
18															
19															
20															
21															
22															
23															
24															
25															

Sheet2

Ready NUM

Additional updates will be provided to all staff as the investigation progresses.

Vanessa Ientile
Managing Scientist
14/7/2008