DNAIQ

Question 47 – Explain what DNAIQ is. Explain the way or ways in which the DNA laboratory used DNAIQ, and/or DNAIQ system(s), as at the start of 2008.

262. The DNA IQ™ System (DNAIQ) was a commercial DNA extraction kit from Promega Corporation. I am not aware of whether the kit is still commercially available. DNAIQ was a magnetic bead DNA extraction kit. From memory, my recollection of how the kit works is as follows: Samples are immersed in special buffer to break open the cells to release the DNA (lysis). This liquid is referred to as a lysate, and it contains not only any DNA present, but contaminants from the sample itself, as well as proteins and other molecules from the resultant cell lysis. Added to the lysate are then special beads. These beads will bind any DNA present (up until the binding capacity of the beads is met). They also have a magnetic property. The beads can be held securely in a tube with a magnet or transferred from one tube to another. The beads can be "washed" with one or more buffers to remove any contaminants present, then they can be exposed to a buffer which changes the properties of the solution allowing the DNA to be released from the beads. This process is referred to as elution. In common terms, the DNA might be referred to as "purified" due to the theoretical concept that only DNA will be present in the final solution (eluent or DNA extract) due the binding properties of the magnetic beads and the intervening washing steps.

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263. According to the Minor Change register, the Forensic DNA Analysis laboratory introduced automated DNA IQ extractions using automated liquid handler platforms – the MultiPROBE® II PLUS HT EX platforms (MPII) - in October 2007. In March 2008, DNA IQ extraction using off-deck lysis was introduced. Off-deck lysis referred to the process whereby the initial steps of the DNA IQ extraction would be performed in a manual manner (the lysis step) followed by completion of the DNA extraction procedure (binding of DNA to the beads, washing and elution) on an MPII.

264. Please see exhibit **'ARM-104'** Copy of Change Register - Minor Changes and emerging or novel practices as at 20-09-2022.xls.

Question 48 – Explain what problems with DNAIQ were experienced in approximately 2008. Explain, to the best of your knowledge, how these problems were first detected.

265. From my recollection, there were some initial teething problems with the introduction of automated processing. Many of these were the result of human error. The kinds of errors included staff placing labware in incorrect orientations, making errors while using new equipment. As these initial problems arose, ongoing training and adjustments to processes took place.

266. One of the teething problems that arose was the formation of a gel like consistency in the reagents during the processing of the extraction. To resolve this SDS was replaced with Sarcosyl as one of the reagents.

267. Aside from the human error type problems that took place, some instances of cross-contamination were detected. These problems were related to the automated DNA IQ extraction procedure. At some point it became apparent that there was a systemic problem rather than isolated incidences. According to information supplied in Question 50 below, it would appear that it became apparent that it was systemic issue sometime around early July just prior to the extraordinary management team meeting noted below. I cannot identify a more specific date.

Question 49 – Identify each OQI and adverse event that relates to DNAIQ problems at around this time, or has since been linked to DNAIQ problems from around this time.

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268. I have conducted a search of QIS and from reading of the OQI investigations, I can gather that the following OQI numbers refer to problems identified with cross-contamination in the DNA IQ automated extraction process: 19330, 19349, 19477, 19767, 19768, 20231, 20351, 20367, 20368, 20369, 20422, 20437, 20617, 20690, 20925, 21222, 21309, 21589, 21715, 21718, and 22882. I have not listed OQIs that contain no investigation as these were duplicates of OQIs listed (i.e. the same event was raised in two separate OQIs, but only investigated under one entry).

269. OQIs 18893 and 19213 refer to human errors associated with automated DNA IQ processing.

270. OQI 21062 relates to problems identified with pipetting associated with liquid transforming to a gel-like substance (refer Question 48 above, replacing SDS with Sarcosyl).

Question 50 – What actions did the management committee and/or staff at the DNA laboratory take in response to the discovery of the problem? Provide a clear timeline which covers the problems identified, the decisions taken in response and by whom, and how those decisions were implemented.

271. I am not currently able to access all e-mail records from 2008, and given the passing of time, my memory of events from 2008 is not overly clear. The following is as much as I can ascertain from records I could locate.

272. Referring to documents titled "DNA-IQ Timeline Oct 2008" and "DNA IQ timeline 12-11-2008" I can see that troubleshooting of the automated DNA IQ extraction process began on 14/07/2008 and a Memo was sent to all DNA staff on 15/07/2008 outlining issues with DNA IQ.

273. Please see **Exhibit 'ARM-105'** DNA-IQ Timeline Oct 2008.pdf.

274. Please see **Exhibit 'ARM-106'** Copy of DNA IQ timeline 12-11-2008.xls

275. Please see **Exhibit 'ARM-107'** DNA IQ Investigation memo 150708.pdf.

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276. The first OQI raised (OQI 19330) has a date identified listed as 21/04/2008. The dates that subsequent OQIs were listed as date identified are as follows: 19349 – 23/04/2008; 19477 – 12/05/2008; 19767 – 14/06/2008 and 19768 – 14/06/2088. It would appear to me that these were the OQIs which were sufficient to determine that there was a systemic problem relating to multiple incidences of cross-contamination. The memo listed above only mentions OQIs 19349, 19477 and 19768. All other OQIs listed in Question 49 above were created subsequent to 14/07/2008.

277. According to the Actions for OQI 19768, an extraordinary management team meeting was held on 14/07/2008 with the following actions agreed on: Processing of Reference samples only on Extraction platform A (initial investigations indicated events were likely related to platform A); Processing of Casework samples on Extraction platform B in a checkerboard pattern with extraction reagent blanks; Urgent progression of Audit 8227 and investigation into findings; A full information review of results from automated extractions with documented quality events and extractions without documented quality events to gain further information. I have been unable to locate minutes for the meeting held 14/07/2008, it is possible that none were taken.

278. On 23-07-2008 I advised the Analytical Team and the Management Team that further investigations had uncovered events across both platforms. I provided further information to Justin Howes and the remainder of the management team via e-mail on 24-07-2008.

279. Please see **Exhibit 'ARM-108'** E-mail 2008-07-23 Use of Extraction platforms.pdf.

280. Please see **Exhibit 'ARM-109'** E-mail 2008-07-24 Re Plates.pdf.

281. An e-mail sent on 24-07-2008 from Paula Brisotto to the Management Team indicates that OQIs 19349, 19477 and 19768 were the first three that were identified as showing contamination from the automated DNA IQ process, and that subsequently OQIs 19330, 19767 and 20231 were identified as belonging to the same category.

282. Please see **Exhibit 'ARM-110'** E-mail 2008-07-24 OQI's.pdf.

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283. Action entries for OQI 19768 also indicate that a second extraordinary management team meeting was held on 28/07/2008, and at that point a decision was made to cease processing of samples through the automated extraction process until problems that had been identified could be rectified. This information was communicated to all of DNA analysis via e-mail on 28/07/2008. I have been unable to locate minutes for the meeting held 28/07/2008, it is possible that none were taken.

284. Please see **Exhibit 'ARM-111'** E-mail 2008-07-28 DNA IQ Extraction Update.pdf.

285. According to QIS records, Audit 8752 was conducted on 28/07/2008. This involved the use of a macro to identify contamination events by comparing DNA profiles between samples on the same batch.

286. Whilst I was heavily involved in the initial investigations into identifying the issues with automated DNA IQ extractions due to my role as manager of the Analytical Team, my role reduced as the investigation continued as work was conducted by Thomas Nurthen and his team (Quality and Projects team). I do recall remaining current with the investigations from discussions with Tom and the staff carrying out the investigations. I do not recall having much to do with the reporting of profiles as I would have had my hands full looking after the Analytical Team at that time.

287. An e-mail dated 12 August 2008 indicates that Desley Pitcher, a liquid handling specialist with PerkinElmer (maker of the MPII instruments) provided some enhancements to the protocols on the MPII instruments. I have also located a document "20081003 MPII DNA Extraction Modifications" it is unclear to me if Desley made two separate visits to improve our liquid handling protocols, or the document is merely a formalisation of the improvements stated in the e-mail.

288. Please see **Exhibit 'ARM-112'** E-mail 2008-08-12 MPII test changes.pdf.

289. Please see **Exhibit 'ARM-112a'** 20081003 MPII DNA Extraction Modifications.pdf.

290. On 23 October 2008, Cathie Allen sent an e-mail to all of DNA Analysis to advise that external auditors (Dr Theo Sloots and Dr David Whiley) would be auditing the

automated DNA IQ extraction processes. Note that in August 2008 Vanessa Ientile left the position of Managing Scientist and Cathie Allen had begun a period of acting in the role.

291. Please see **Exhibit 'ARM-113'** E-mail 2008-10-23 External Auditor.pdf.

Question 51 – Was the cause of the issues or problems relating to DNAIQ identified? If yes, what was it?

292. The Audit report for audit 8227 does not identify a specific cause of the cross-contamination, although it does identify potential areas of risk. These are outlined in the document "Audit 8227 DNA IQ FINAL".

293. Please see **Exhibit 'ARM-114'** Audit 8227 DNA IQ FINAL.pdf.

294. From my re-reading of the document and recollections, pipetting protocols on the liquid handling platforms, along with labware issues appeared to be the main areas that required further attention.

295. From my re-reading of the external review by Drs Sloots & Whiley, the seals used to seal off the individual reaction wells of plates appeared to have been identified as the cause of the cross-contamination.

296. Please see **Exhibit 'ARM-115'** 20081121 Sloots & Whiley external review.pdf.

Question 52 – What immediate action was taken after the cause of the issues or problems was identified?

297. The immediate actions taken once the issue was identified is covered in my response to Question 50. My recollection is that no single part of the process was immediately identified as the cause of the problems. Because of this, rectification involved making changes / improvements to the process and then carrying out tests to see if the improvements had been successful, thereby also providing information on what the likely cause of the problems were. Ultimately an improved process was implemented and these are outlined in my response to Question 56.

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Question 53 – Identify each staff member involved in detecting and responding to the problems with DNAIQ, and the nature of each person's involvement.

298. I cannot recall who specifically identified that there was a systemic problem with the automated DNA IQ protocol, however, in the early stages of this I was involved as the manager of the Analytical Team.

299. Audit 8227 was carried out by Amy Cheng, Iman Muharam and Peter Clausen.

300. It is my recollection that decisions made with respect to halting processing of automated DNA IQ extractions, and ultimately the re-introduction of automated DNA IQ extractions were made by the Managing Scientist – initially Vanessa Ientile then Cathie Allen. I recall that the whole management team was involved, but I cannot recall to what extent.

301. My recollections are that the process for re-designing and testing the improved automated DNA IQ process was undertaken by Thomas Nurthen and members of his team. I cannot recall exactly who those staff were, from memory they were Chiron Weber, Vojtech Hlinka, Iman Muharam and Generosa Lundie.

Question 54 – Identify whether any issue or problem with respect to DNAIQ was audited by an external agency? If yes, when did that occur and in respect of what particular issue or issues. Who decided that should occur? Provide:

a. instructions;

b. list of material; and

c. the report, including draft reports.

302. Based on the information within the document "20081121 Sloots & Whiley external review", the review was requested by Greg Shaw the Director of FSS at that time. I am unaware of what instructions were provided to Drs Sloots and Whiley regarding the review.

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303. Based on an e-mail sent by me on 11-11-2008, I provided Dr Sloots a copy of our draft SOP prior to their visit. I believe that they were auditing our improved protocol rather than the protocol that was in place when the cross-contamination occurred.

304. Please see **Exhibit 'ARM-116'** E-mail 2008-11-11 Fwd RE FSS DNA Analysis automated DNA IQ extraction SOP.pdf.

305. A copy of the final report is provided as document titled "20081121 Sloots & Whiley external review". I am not aware of any draft versions that were provided.

306. Please see **Exhibit 'ARM-115'** 20081121 Sloots & Whiley external review.pdf.

Question 55 – How were the results of the audit by the external agency communicated to the DNA laboratory?

307. I cannot recall and I have not been able to locate any documents to provide additional information.

Question 56 – What permanent changes, or amendments to SOPs, were made as a result of identifying the problems related to DNAIQ?

308. As the procedure for processing samples through automated DNA IQ extraction had changed, the corresponding SOP underwent an update – 24897 Automated DNA IQ Method of Extracting DNA from Reference and Casework samples. Attached are copies of the SOP before update and after update.

309. Please see **Exhibit 'ARM-117'** 24897 - V4.0 - Automated DNA IQ Method of Extracting DNA from Reference and Casework samples.pdf.

310. Please see **Exhibit 'ARM-118'** 24897 - V5.0 - Automated DNA IQ Method of Extracting DNA from Reference and Casework samples.

311. My recollection is that, upon resumption automated DNA IQ extractions, processing proceeded using extensive cross-contamination checking, including processing samples in a "soccerball" and "checkerboard" layout. A "soccerball" layout is one where each sample is completely surrounded by reagent blank / negative control

samples. A checkerboard layout is where each alternate well is a reagent blank / negative control sample. After a period of monitoring, the numbers of controls were reduced such that a batch consisted of 2 positive controls, 2 negative controls, 10 reagent blanks and up to 76 samples (76 samples was the limitation of the batch size for a quantification batch at the time due to the number of controls / standards required for that batch.

Question 57 – Explain what communications were made to external agencies, including the Queensland Police Service, the Office of the Director of Public Prosecutions, and the Queensland Courts, about the problems with DNAIQ and when the communications were made. Attach copies of any emails or letters sent to the external agencies.

312. I am not aware of what communications were made external to Forensic DNA Analysis regarding the problems with DNA IQ. Due to my role at the time of the event – supervising the Analytical Team – I did not tend to be involved with issues of external communication. My recollection is, at that time, these communications were usually sent by the Managing Scientist.

Question 58 – Did the DNAIQ problems lead to the retraction or amendment of results in these cases?

313. In my role as supervisor of the Analytical Team, I was not involved in the issuing or re-issuing of results at that time. My recollection is, at that time, that would have been managed by either the managers of the Reporting Team, the team leader of the Forensic Reporting and Intelligence team and/or the Managing Scientist. There may have been discussions held at the level of the management team. I cannot recall whether this was the case.

Question 59 – Has the DNA laboratory since returned to using DNAIQ processes, systems and/or products? Explain all further problems in detail, including what has been done in response to them. Attach any OQI, Adverse Entry Log or record of the problem being identified and investigated.

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314. According to the Minor Changes register, the manual method for DNA IQ extractions was re-introduced on 19/06/2009. On 20/08/2009 automated DNA IQ extraction recommenced on Extraction platform B (MPII instrument B).

315. On 22 August 2011, the Maxwell-16 MDX instrument was implemented for routine use. The Maxwell is a small automated platform that uses a cartridge system for DNA extraction. The kit that is used with the Maxwell-16 MDX instrument is a type of DNA IQ kit that is designed specifically for that instrument. The "16" refers to the capacity of the instrument – 16 samples can be processed in a single run. Practically, this represents 14 samples, 1 one positive control and 1 negative control. The Maxwell MDX instruments have been replaced with updated Maxwell FSC instruments that continue to use the DNA IQ kit for DNA extraction.

316. On 21 November 2016, the QIAsymphony instruments were introduced into routine use as a replacement to automated DNA IQ extractions on MPII instruments. The QIAsymphony instruments are manufactured by Qiagen and use the Qiagen DNA investigator kit which is a similar technology to DNA IQ (magnetic bead based DNA extraction). It is my understanding that most Forensic DNA facilities use a magnetic bead based DNA extraction technology.

317. Please see **Exhibit 'ARM-119'** Copy of Change Register - Minor Changes and emerging or novel practices as at 20-09-2022.xls.

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