## Commission of Inquiry to examine DNA Project 13 concerns

Brisbane Magistrates Court Court 40, 363 George Street, Brisbane

On Monday, 30 October 2023 at 10am

Before: The Hon Dr Annabelle Bennett AC SC, Commissioner

Counsel Assisting:

Mr Andrew Fox SC (Senior Counsel Assisting)

Ms Gabriella Rubagotti (Counsel Assisting)

 THE COMMISSIONER: Good morning, everybody. I will just get myself sorted. There have been a few issues just getting ourselves in and ready for this morning in here.

I want to make a brief opening to outline a couple of matters and then I will take appearances.

This Commission was established on 5 October 2023 to inquire into matters that have arisen following the conclusion of the Commission of Inquiry Into Forensic DNA Testing in Queensland in November 2022.

Those matters relate to the extraction of DNA from samples taken from crime scenes using the automated DNA IQ process. The DNA IQ process was implemented in Queensland's Forensic and Scientific Services in 2007. The Queensland Forensic and Scientific Services report on the verification of the DNA IQ process is Project 13.

Questions relating to the integrity of the work of forensic sciences in Queensland are clearly of importance, in particular insofar as is necessary for the results to be reliable and for people to have faith in the system. This Inquiry is being brought into being because of the nature of concerns that have been privately and publicly expressed.

The Inquiry is framed by terms of reference. Those terms of reference are:

That the Commissioner will undertake an open and independent Inquiry to:

- (a) review recent public statements and other documents including but not limited to documents that were provided by Queensland Health in relation to Project 13; and
- (b) consider whether recommendations in the report that is the Sofronoff report are sufficient to address the matters raised in the above materials; and
- (c) in undertaking (a) and (b), interview any or all experts who provided advice in the Commissions of Inquiry Order (No.3) 2022 in relation to Project 13 or related DNA extraction methods.

So it can be seen that the terms of reference are reasonably clear and are reasonably narrow in scope and, of

course, this Inquiry will be confined to those terms of reference.

But first, I appreciate the amount of work that has gone into the statements and responses to notices served. It is my intention to take careful regard of all material relevant to the terms of reference.

Specifically, I must examine public statements and other material about Project 13 and consider whether the recommendations of the Forensic DNA Testing Inquiry are sufficient to address concerns raised in those public statements and other materials.

The Inquiry is working within very strict time frames. It has requested and received a large amount of material under notice to produce from Queensland Health, the Department of Justice and Attorney-General's and other organisations and individuals. These documents, together with public statements and the evidence given at the hearings this week will inform my findings and report.

The Inquiry will undertake its work as transparently as possible. Hearings will be live streamed and transcripts, along with witness statements and exhibits, will be published on the Commission's website where possible.

The first focus of hearings will be the Project 13 report. This morning we will hear concurrent evidence from the scientific officers who were involved in the implementation and review of the DNA IQ process at Queensland Forensic and Scientific Services and who were the authors of the Project 13 report.

Tomorrow, the Inquiry will hear concurrent evidence from scientists who provided expert evidence to the Forensic DNA Testing Inquiry about matters relating to the DNA IQ process and Project 13.

There will then be further evidence, the exact nature of which will probably depend to some degree on what comes out of the first two days' evidence. But it will extend, of course, to looking at current practices as to the extraction and testing of DNA insofar as that relates to the matters within Project 13.

I'm aware of the significant media interest in these 1 2 proceedings and so I wish to take this opportunity to 3 remind members of the media of the media protocols, particularly in relation to recording, re-broadcasting or 4 5 publishing the live stream. The media protocols are 6 available on the Commission's website. 7 8 I will now take appearances. 9 If the Commission pleases, I appear with my 10 learned friends Ms Rubagotti, Ms Bembrick and Ms Constable 11 12 as counsel assisting. 13 I appear for Queensland Health with my MR G R RICE KC: 14 15 learned friends Mr L Dollar and Ms L Dawson, instructed by 16 Crown Law. 17 THE COMMISSIONER: Thank you. Are there any other people 18 19 who wish to announce appearances for the purposes of today's proceeding? 20 21 MS A C FREEMAN: 22 Yes, thank you, Commissioner. My name is 23 Freeman, initials AC, counsel instructed by MinterEllison, appearing with Ms Cooper, initials EJ, for the following 24 25 people: Ms Gallagher, Ms Iannuzzi, Ms Lundie, Mr McNevin, Mr Muharam and Mr Nurthen. 26 27 MR S C HOLT KC: May it please the Commission. 28 My name is Holt, initials SC, KC I appear with my learned friend 29 Ms Hughes of counsel. We appear for Ms Vanessa Ientile and 30 31 we're instructed by Holding Redlich, may it please the 32 Commission. 33 34 MR G W DIEHM KC: Commissioner, my name is Diehm, 35 D-I-E-H-M, initials GW. I appear with my learned friend 36 Ms Goldie, initials JM, instructed by Ashhurst, for Professor Linzi Wilson-Wilde. 37 38 39 MR A McLEAN-WILLIAMS: Commissioner, my name is 40 McLean Williams, initial A. I appear for Ms Amanda Reeves, instructed by Macpherson Kelley. 41 42 43 THE COMMISSIONER: All right. I think that means that we've now had the formalities dealt with. 44 We're now going to, I think, open up the evidence, after you make an 45

will go into evidence?

46 47 opening, Mr Fox, to outline some of the matters, then we

 MR FOX: Yes, thank you, Commissioner. There are just a couple of matters by way of introduction, if I may.

THE COMMISSIONER: Sure.

MR FOX: You have already indicated in respect of the terms of reference, which are important in the way in which they have been crafted. May I just say some observations in relation to the way in which this matter finds us here today.

Following the delivery of Mr Sofronoff's final report the Queensland Government indicated that it accepted all of the Commission's recommendations. As part of the implementation of all of those recommendations, a new administrative unit known as the Forensic Science Queensland or FSQ was established to focus solely on the delivery of forensic DNA and chemistry services within Queensland.

That new unit is headed up by Adjunct Professor Linzi Wilson-Wilde, who was appointed as the CEO to lead FSQ through the necessary reform process. To guide that implementation an advisory board was established, which has been chaired by the former Commissioner, Mr Sofronoff KC, and also former president of the Children's Court of Queensland, Ms Julie Dick SC.

The board consists also of senior experts from the criminal justice system, victim advocacy and forensic science agencies. All are expected to play a critical role in restoring the integrity and transparency of the delivery of Queensland's forensic service.

In September 2023, so just over a month or so ago, the advisory board reported to the Queensland Government that in the eight months since it had been established - that is, after the final report had been delivered - almost three-quarters of the Commission's 123 recommendations have been delivered or are currently being progressed.

If I can then make some observations about Project 13. It has been styled in those terms because of a report. The evidence that you will hear this morning from the various scientists who were associated with that task regarded it as an automation project - that is, the implementation of

automation within the lab.

So Project 13, we constantly refer to by those terms, but just so that people are aware, it didn't have some special name within the lab. There are a series of projects that had developed through the laboratory, each happened to be given a number, and you will hear later today they go up to 21, 22 and indeed into 70.

 Now, Project 13 concerns the introduction in October 2007 at the laboratory, then known as the Queensland Health Forensic and Scientific Services, or QHFSS, of a fully automated DNA testing system using a device known as the MultiPROBE II PLUS HT EX forensic work station platform, which I'll just call "the MultiPROBE device". The MultiPROBE device was, at that time, known to be suitable for use in automated testing.

Before October 2007, DNA testing was conducted manually by the staff in the laboratory using a chemistry set known as the DNA IQ protocol, which was manufactured by Promega Corporation in the US.

 The DNA IQ protocol had been investigated by a team of seven scientists at the laboratory, together with four other potential extraction kits made by other manufacturers. The team of scientists, which I'll call the Project 9 team, produced a report dated June 2007, known as the Project 9 report. That reported on their investigation of these five extraction kits and recommended that Promega's DNA IQ protocol be the one that be adopted for use in the laboratory.

So that it is clear, there is no suggestion that Promega's DNA IQ protocol was not fit for proper purpose whether for manual extraction or for potentially an automated system but, at that time, Project 9 was only looking at the DNA IQ protocol with respect to suitability for manual extraction.

 Now, as was addressed in the course of the first Inquiry, the laboratory was at that time under considerable pressure to reduce a significant backlog of specimens and material for DNA testing. That was addressed as part of the first Inquiry and it is also addressed in the final report, but an important background for present purposes is a 2005 report, dated October 2005, in fact, by the

Ministerial Taskforce, Forensic and Scientific Services, report titled "Report on the Role and Function of Forensic and Scientific Services in the Queensland Government".

At paragraph 6.4.5 of that report, is a subheading titled "Automation" and it indicates that money was being put aside for the very task of purchasing a robotic system that was to introduce automation of processes so as to assist in reducing this significant backlog that then existed. That particular section of the report also indicated that the process of validation of any automated system might well take up to 12 months to implement. So this is not something that was going to be a quick fix; it was always going to be something that needed to be looked at carefully within the laboratory and, over a period of time, introduced.

You have also indicated in your opening to the Commission this morning, Commissioner, that recommendation 105 is an important recommendation - that is, one where, at the conclusion of the Sofronoff report, the laboratory was tasked with the exercise of investigating, as far as it wished, the notion of retesting and samples that needed to be retested - how far might that go back, how might they engage in that exercise.

 Now, there will be evidence before the Commission in this hearing this week that indicates that a decision has been made by the laboratory to do further testing which goes right back to the origins that I've just been describing - that is, from the very time when the DNA IQ system commenced being used.

So that that can be made clear that there is not going to be a debate before you during the course of this week as to whether there is a particular point in time where the testing goes back to. The decision has been made that it will go back to the very beginning, so far as there is a capacity to do testing, and that will no doubt be explored during the course of this week.

 Two other matters then just to mention briefly by way of introduction. This is now particularly referable to the experts that we will hear from shortly. I have given an indication of the Project 9 team. Those people are all people that we find their names in the later documents that I will be coming to. So there was consistency in terms of

the personnel. After Project 9, was what was called Project 11, and then I will move to Project 13.

So the laboratory then investigated - in terms of the commencement of looking at automation, after having done Project 9 and picking the DNA IQ protocol for manual introduction, in manual use, they then start the automation process, at least in terms of investigating the next stages, in around the period June to October 2007.

That process starts with the Project 9 team producing a new report being a Project 11 report. But what this concerns is investigating and reporting on a modified method of the manufacture's process for the DNA IQ protocol. So what they concluded in the Project 11 report was that certain modifications could be made to the manufacturer's preferred - or settings, if you like, for the DNA IQ manual system, and they then looked at those particular modifications that they made and they say that in the end they concluded that by way of validation, they had satisfied themselves that the amendments or modifications they made were satisfactory.

Then from that point, we find the scientists moved to testing the full automation, which is Project 13, and here we have the introduction of the modified DNA IQ protocol, with the MultiPROBE device, and that's what we call the automated system. So those are the stages that work their way through.

I will be dealing with the experts briefly to get us to that particular point. But no doubt they have been listening and to the extent there is any difference of opinion, they will let us know.

Can I then just introduce each of the various experts who are going to appear today. Before I do so, can I indicate that we have circulated, and there is a hard copy for you, Commissioner, a tender list for today's purposes. I might just provide the Commission with a copy of that.

I will formally tender documents, Commissioner, whenever you would like me to do so, but at this stage I don't think - for the moment I will just walk you through what the document is.

The first row there you will see is what we styled as the first report of Dr Kirsty Wright, which is her assessment of the Project 13 report and the circumstances around it, based on her review of documentation that she had prior to receiving all of the expert statements in this proceeding. Then you will see at rows 2, 3, 4, 5 and 6 are the various annexures to that first report and, indeed, row 7 as well.

Then following, from row 8, are the various statements of the various scientists that are being relied upon for today's purposes. Then what we've done over the page, you will see separately it starts with item 23, the Project 13 report, then the Project 9 report, 11, 21, 22 and 70, which I briefly mentioned.

The other documents that are all there - you will see they have various TN references - those are coming from Mr Nurthen's statement. We just thought it was convenient to have them itemised individually so that if there was a need to bring them up on the screen we can get them quickly rather than being buried through pages of annexures. Strictly, those are all repeated from materials that are there.

The only other matter to indicate I think is item 52 relates to the MultiPROBE device and if we need to go there, I think it is one of the standard operating procedure documents. That's in terms of the tender list, but as I say, I won't formally tender anything unless you would wish me to do so.

THE COMMISSIONER: No, I think it might be handy to deal with, otherwise we will forget.

MR FOX: Certainly.

THE COMMISSIONER: It is probably convenient to admit into evidence before the Inquiry documents 1 to 52 with the document ID references probably the best ways to encapsulate the identification of each document.

DOCUMENTS 1 TO 52 ADMITTED INTO EVIDENCE BY REFERENCE TO THE DOCUMENT ID REFERENCES ALLOCATED TO THEM

MR FOX: So I can then indicate who is going to be in the expert conclave this morning. Firstly, we have Mr Nurthen.

His role was between September 2004 and June 2006. He was a scientist in forensic biology at Queensland Health, forensic services. Then between June 2006 and October 2008 - so we're then into that very territory of the acquisition of the DNA IQ protocol and the automation - he was a senior scientist in the automation implementation project. His evidence indicates that that was a temporary project position that he held at that time.

Then, after that - that's from October 2008 - he then, through to 2012, was a senior scientist in quality and projects in the DNA analysis. Since 2012, he continues to be employed by what is now known as Forensic Science Queensland, as a reporting scientist in the forensic biology division.

 Nextly, Mr McNevin. Mr McNevin was in the analytical team. There is a difference, as you, Commissioner, will appreciate from the evidence that you have read so far, as we have an automation team that deals with the automation implementation project, then there's an analytical team that act separately but, as you will hear, there is some degree of consultation between the two and dealings between the two, so an artificial boundary line that existed in the laboratory between them, separating them.

From September 2004 to June 2006 he was a scientist in the analytical team; from June 2006 to February 2014 he was a senior scientist in that same team; then from February 2014 to October 2021, he was a senior scientist in the evidence recovery team; and from 2021 he is a reporting scientist at QHFSS.

 Ms Ientile was the managing scientist at QHFSS from 2004 to July 2009. There was a period, though, where she left the organisation in about July 2008 and then it was Ms Allen, who then assumed the role of the managing scientist.

Mr Muharam, from September 2004 to January 2009, was a scientist in the forensic biology analytical team. Ther he left the organisation.

 Dr Hlinka, from May 2004 to May 2023, was a forensic scientist within QHFSS, and he was a project leader in 2004 to 2006 of the DNA processing improvement project, and from 2004 to 2008, but mainly he says in his evidence between

2006 and 2008, he was a scientist of forensic biology and a member of the automation project team.

And finally, Ms Gallagher, she was from March 2006 to the end of 2006, an operational officer, and from the end of 2006 to May 2008, a project scientist in the automation implementation project team.

Those are the only matters I wish to say by way of introduction. I think Mr Muharam is going to be appearing by videolink.

Dr Hlinka has not been well and he has kindly indicated - and I appreciate from the dealings that we have had with him that he has made a considerable effort to try to participate today due to his ill health, and we are endeavouring to have him by telephone. Just before you came on, Commissioner, we were able to indicate that he was ready to go and would participate for as long as the process would let him do so, in terms of his physical condition.

THE COMMISSIONER: I should just interpolate to say that if Mr Hlinka feels at any time, if he is online and can hear me, if he needs to take a break for any reason, we can always take a short adjournment to deal with that.

MR FOX: Thank you, Commissioner. That's all I want to say by way of opening.

THE COMMISSIONER: Thank you, Mr Fox. What I propose to do is to ask those people who are going to engage in the first hot tub, as we call them, to come into - over there, is that the witness box? I guess it must be. Over there.

The first thing we will do is to swear each of them in, and then I will explain - if someone can get them, they are not here; they are not in the room yet - to them the way in which the hot tub will be conducted. It may also assist counsel if I explain that as well. I gather they are now being got.

MR FOX: Now being gathered.

THE COMMISSIONER: Are there enough seats? Oh, there are, because two are remote. Yes. Thank you very much. I think if you can come and take seats over here, that

1 2 3 4 5 6 7 8	would be very helpful. Just take a seat and make yourselves comfortable. We're going to ask each of you to take the oath or affirmation, depending on whichever you choose, then I'm going to explain to you a little bit about how this is going to work. I will ask you each if you would just - do you want to call them formally, with their names, then we'll just swear them.
9 10 11	MR FOX: Ms Ientile, would you say your full name to the Commission, please.
12 13	MS IENTILE: Yes, Vanessa Kate Ientile, thank you.
14 15	MR FOX: And Mr Nurthen?
16 17	MR NURTHEN: Thomas Edmund Kersey Nurthen.
18	MR McNEVIN: Allan Russell McNevin.
19 20 21	THE COMMISSIONER: We will start with you, Ms Ientile. Do you wish to take an oath or an affirmation?
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	TALLAN ROOCLE HONEVIN, arrinmou. [10.24am]
28 29 30	THE COMMISSIONER: Thank you. We probably should then deal with the two who are remote. Did you say one was on video?
28 29 30 31 32	THE COMMISSIONER: Thank you. We probably should then deal
28 29 30 31 32 33 34	THE COMMISSIONER: Thank you. We probably should then deal with the two who are remote. Did you say one was on video?
28 29 30 31 32 33 34 35 36	THE COMMISSIONER: Thank you. We probably should then deal with the two who are remote. Did you say one was on video?  MR FOX: Yes.
28 29 30 31 32 33 34 35 36 37 38	THE COMMISSIONER: Thank you. We probably should then deal with the two who are remote. Did you say one was on video?  MR FOX: Yes.  THE COMMISSIONER: I can see him.
28 29 30 31 32 33 34 35 36 37 38 39 40 41 42	THE COMMISSIONER: Thank you. We probably should then deal with the two who are remote. Did you say one was on video?  MR FOX: Yes.  THE COMMISSIONER: I can see him.  MR FOX: Apparently we've got two now, I'm told.
28 29 30 31 32 33 34 35 36 37 38 39 40 41	THE COMMISSIONER: Thank you. We probably should then deal with the two who are remote. Did you say one was on video?  MR FOX: Yes.  THE COMMISSIONER: I can see him.  MR FOX: Apparently we've got two now, I'm told.  THE COMMISSIONER: On video?  MR FOX: Quite so. There are two on video and one by telephone, I think. That's Ms Breanna Gallagher.

MR FOX: Iman Muharam, are you there?

MR MUHARAM: I am here. Yes.

MR FOX: Can you please state your full name?

MR MUHARAM: Iman (indistinct) Muharam.

<IMAN MUHARAM, affirmed:</pre> [10.26am]

MR FOX: Finally, by telephone, we should have Mr Hlinka. Oh, he is by Zoom now. Apparently he is now on video, which is better. Dr Hlinka, can you hear us?

DR HLINKA: Yes. Can you hear me?

MR FOX: Yes, we can, thank you. Would you say your full name to the Commission

DR HLINKA: My full name is Vojtech Hlinka.

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MR FOX: Thank you.

<VOJTECH HLINKA, affirmed:</pre> [10.28am]

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THE COMMISSIONER: Thank you very much.

I'm now going to give a bit of an explanation on the way this is going to work hopefully. It is both formal and not formal, if I can put it that way.

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The idea is that you all had different jobs to do during the course of the matters that we're looking at, but we thought it best to put you all in together rather than have someone say, "That wasn't me", and we'd have to call So there will be some people backwards and forwards. questions asked of you and there might be a question directed specifically to one of you, but if anyone else wishes to add anything, if you just indicate, either with a physical hand up, and if we don't see you and if you are on screen, if you know how to work the electronic hand, you can always put that up. Probably after each set of questions I will ask whether anybody wishes to add anything.

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So you can add, you can qualify, and if you don't

remember, you don't remember, but we're trying to get the whole of the picture here to the extent that we can for what occurred in this time frame.

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> So you should understand that your statements have been read and they will be in evidence. So no-one's going to take you back through all of those matters in your There will be questions asked perhaps around it, and don't feel - if you want to repeat what is in your statement or draw attention to it. that's fine. but we're not going to read them all out now and do that.

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So there will be some questions asked. Each of you is able simply to - anyone who feels they can assist by responding to that, please do so, and if somebody says something and you wish to qualify, change, expand, or even if you don't agree with it, or if you have a different recollection of it, feel free to do that, because what we're trying to do is to get an understanding of what actually happened during the course of the validation procedure.

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Does anyone have any questions? Okay, if anyone feels a need, Mr Hlinka in particular - if anyone feels that they would like a five-minute break for any reason, please This is not meant to be personally as arduous indicate it. We're going to try to make it as sensible as we can, but the whole idea is we're in a short time and this is the most efficient way to get the information to us.

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What will happen is Mr Fox will start by asking some I may intervene and ask my own questions if I want to add anything. Don't worry, my questions don't necessarily have any greater import that anybody else's, it might just be something that I want to have clarified or to help me understand.

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Counsel will get a chance to ask any questions that they feel that they want to draw out from you while you are here. We may have to bring you back if there is something that comes up later but we will try and deal with everything to the extent, in relation to this subject matter, while you are here today.

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As far as counsel are concerned, if we change topics and move on, I might ask if you want to, if there is something desperate that you want to add in to something

because you think it's the right time, just, please, give me an indication.

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To the extent that there is going to be evidence -I mean, it can be either, of course, evidence that you wish to draw and if anyone wishes to cross-examine, of course, there will be an opportunity to do that as well. of the questions can be directed generally; the questions can be directed to individual witnesses and we'll just see Okay? If it gets unruly, I'll indicate that. But it's not meant to be a procedure at this stage, other than to try and understand what occurred. So Mr Fox?

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MR FOX: Could I just inquire of those who are handling the technology as to how we're going in being able to get the faces a bit bigger? We're working on it, okay, great.

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In the meantime, for those of you, just THE COMMISSIONER: so you understand, at this end, we have one slightly larger small picture and two microscopically small pictures of you That's because in the middle of the on the screen. But, of course, what happens if we screen - we can do it. have to put documents up, they are going to go up electronically so everybody can see them, including you, which means that your faces are smaller. So if that happens, you might have to wave frantically if you want to add something, if you feel that you - before I get to you. It's not that we're ignoring you; it's just that electronics are only what they are. 0kay?

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All right. Does that cover everything you think we need at this stage, Mr Fox? They can put an electronic hand up or they can call out.

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MR FOX: Yes, or just speak out and then we will hear them.

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THE COMMISSIONER: Or just speak out. Don't worry about speaking out. If I know that you want to say something, I will either take what you want to say immediately or I will just say, "Thank you, I note you were going to say I'll come to you in a moment." Okay? something.

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The only other introductory matter MR FOX: Thank you. I was going to add to it was if at any point during the course of answering questions you consider that you might want to descend into things that are a bit technical, feel free to just mark it and tell us "I can go into a lot more on the technical side of it, but I can also give you the English version", which will obviously help everybody to understand the general point that you are making and then we can descend from there into the science if we need to. Thank you.

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THE COMMISSIONER: I think you can take it though, that as far as I'm concerned and counsel are concerned, we do understand; having read your statements, we have got an appreciation of what's in those and the technology and terminology that you have used. 0kay?

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MR FOX: Now, I just wanted to start briefly Thank you. by just talking about Project 9 so that we are all on the same page as to that, then we can get ourselves into practicalities, which is really the first topic for some questions of you.

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I also appreciate that not all of you were employees through the whole of the chronology that we're dealing with today, and so I'm cognisant of that, if you feel it is important to draw that out at any point, please feel free. But at least all on board initially.

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Now, the Project 9 investigation concerned the selection of the DNA IQ protocol for a manual DNA That involved looking at five extraction process. off-the-shelf, so to speak, chemistry sets and then making a selection, which was the DNA IQ protocol. You'll all remember that? Just say "yes". Yes?

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Yes, all right. I appreciate I'm going to ask this question generally, and amongst yourselves, someone can be the person who wants to go first, and anybody else who wants to can then say anything after it, but is it the case that the DNA IQ protocol was the only one that had been, at least from the manufacturer's perspective, shown that it could be used in an automated environment?

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MR NURTHEN: My understanding or my recollection is that we could have validated any of those chemistries on the robots but it was the only one that we had a protocol that was already built by the manufacturers for that particular platform.

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MR FOX: Does anyone want to add anything to what

Mr Nurthen has just said on that topic? 1 2 3 MR McNEVIN: No. 4 MS IENTILE: 5 No. 6 7 MR FOX: Was there any awareness on your part, at that time, that the DNA IQ protocol was better, so to speak, 8 than the Chelex manual process which had been used to that 9 time in the lab? 10 11 MR NURTHEN: 12 The automated one or the manual? 13 MR FOX: The manual, just from a manual perspective. 14 15 16 MR NURTHEN: We certainly had that experience within the 17 validation to show that it was a better method, it got cleaner DNA. 18 19 THE COMMISSIONER: 20 Does anybody wish to cavil with what Mr Nurthen has just said on that front? 21 22 No. 23 MS IENTILE: 24 25 MR FOX: Thank you. 26 27 THE COMMISSIONER: Can you just clarify, when you say "cleaner DNA", you mean DNA more free of impurities? 28 29 MR NURTHEN: Yes, the Chelex method was renowned for not 30 31 purifying. You would get a lot of DNA that would often have inhibitors, impurities within it, which make it 32 33 difficult to get a DNA profile. The virtue of the DNA IQ 34 chemistry allowed for washing of the DNA, which meant we 35 got better quality DNA at the end. 36 THE COMMISSIONER: 37 Thank you. 38 39 Then move forward to Project 11. This is, as 40 I understand it, in the period of around June to October 2007 that Project 11 is conducted. This is what appears to 41 be the first in the series of steps towards automation. 42 43 And what this involved was a validation exercise concerning a modified form of the DNA IQ protocol, which had been 44 acquired from Promega; is that right? 45 46

Yes, that's correct.

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MR NURTHEN:

MR FOX: Everyone is in agreement with that?

MS IENTILE: Yes.

MR FOX: Sorry, Dr Hlinka or anyone on the - anyone wishing to add anything?

THE COMMISSIONER: Dr Hlinka, did you wish to add something to that?

DR HLINKA: No.

THE COMMISSIONER: Can we just make one thing - just to clarify one thing, I know there has been an issue raised in some of the statements, the difference between a verification and a validation, I think - I know that sometimes people use words reasonably loosely. I think in this case, it might be important for us to make clear, when we're talking about a verification and we're talking about a validation, just as a heads-up.

MR FOX: Now, Mr Nurthen, in your statement - this is your first statement, which is your principal statement - and if at any point you want me to take you to it, I will --

THE COMMISSIONER: It is not an exam, you can refer to it.

MR FOX: Exactly, it is not a test. You indicated, starting at paragraph 14 and you mentioned also at paragraphs 26 and 28, that this was validation work that was being conducted on the modified manual method, the manual DNA IQ method. What did you have in mind by that word "validation"?

MR NURTHEN: Well, verification would take an existing protocol that had already been optimised and then see how it works in-house. The validation, because we were modifying it, would require more work than what you would normally do for a verification.

MR FOX: When you say "more work", what did you have in mind by that?

 MR NURTHEN: I think more challenging to make sure that it is actually operational, that it is actually working. Coupled with Project 11 as well, we obviously challenged

the system as a whole through other experiments that may not have been done before, with respect to inhibitors, with respect to different substrates that we were extracting from, and if you are doing a verification you may not necessarily do all of that work.

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Does anyone have any comments they want to make on Mr Nurthen's response just then or is everyone in general agreement with that?

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MS IENTILE: Yes.

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MR FOX: Ms Ientile has just indicated yes but does anyone on the screen want to indicate yes or no or otherwise?

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MS GALLAGHER: Yes.

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Yes. DR HLINKA:

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MR MUHARAM: Yes.

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MR FOX: Can we turn to the topic of the Thank you. modifications that were actually made. Each of you have, where you have been able to, because you have some direct knowledge of it, given an indication about some of the modifications that were made.

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Now, Dr Hlinka, can I start with you on this particular topic?

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DR HLINKA: Yes.

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MR FOX: You indicate in your statement that there were, I think, four modifications that you identify. We're just going to work through each of those and it may be that some of your colleagues wish to have some comments to make about it, or they may want to clarify things that you might say. So let's just start with the first modification that you indicated, which was the inclusion of a lysis step using an extraction buffer in the presence of Proteinase K. That's before the incubation in the DNA IQ lysis buffer. Do you recall that?

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46 47 DR HLINKA: That derives from the Centre of Yes, I do. Forensic Sciences protocols, CFS in Toronto, Ontario. we used the TNE buffer that consisted of - well, the extraction buffer consisted of a TNE buffer, Proteinase K

and SDS to make a total volume of 300 microlitres. 1 2 3 MR FOX: Thank you. Now, the audio is reasonably good here but not perfect, so just to understand, I think you 4 indicated that this step, this modification, the inclusion 5 6 of the lysis step, followed the CFS automated protocol; 7 that's correct? 8 DR HLINKA: That's correct. 9 10 MR FOX: And so that was not following the Promega 11 12 automated protocol. That's your evidence; is that right? 13 DR HLINKA: No, that's - I don't know what you are 14 15 referring to regarding a Promega automated protocol. It's --16 17 MR FOX: So the Promega is the --18 19 20 DR HLINKA: The Promega protocol is a manual protocol usually for DNA IQ, yes, for case work samples. 21 22 23 MR FOX: So if you just look at your statement --24 25 DR HLINKA: Yes. 26 27 -- you will see on page 11, at point number 2 it may be that I have misunderstood what you're saying 28 29 Just to understand where you got your understanding of this, if you like, the appropriateness of making this 30 modification, is that it follows the CFS automated 31 32 protocol? 33 34 DR HLINKA: Yes. 35 36 MR FOX: But it is not one that you saw in the Promega 37 protocol; is that right? 38 39 DR HLINKA: Yes, the Promega DNA IQ has a different well, similar lysis buffer but it slightly varies in 40 concentration. That's correct. 41 42 43 MR NURTHEN: Commissioner, if I could just clarify, I think the confusion here is, when we're talking about 44 modifying, we have the Promega protocol, which is one 45 supplied by the manufacturer, and they hadn't supplied an 46 47 automated one but PerkinElmer did supply an automated one,

1 2	which is the CFS protocol.
3 4 5	THE COMMISSIONER: My understanding is that the CFS protocol - which came with the MultiPROBE, didn't it?
6 7	MR NURTHEN: Yes, it did.
8 9	THE COMMISSIONER: And it had been validated for use on the MultiPROBE?
10 11 12	MR NURTHEN: Yes.
13 14 15	THE COMMISSIONER: The CFS protocol had been validated for use on the MultiPROBE; is that correct?
16 17	MR NURTHEN: Yes.
18 19 20	THE COMMISSIONER: And the DNA IQ, the Promega one, was not identical to that?
21 22 23 24 25	MR NURTHEN: No, it was different, and the CFS protocol, whilst validated by them, already included that TNE step at the start. I think what Vojtech's referring to, at least, is the Promega protocol.
26 27	DR HLINKA: That's correct.
28 29 30 31	MR NURTHEN: So what I see the modification, we didn't modify the TNE part of the CFS, our step had the same part of that.
32 33	DR HLINKA: Yes.
34 35 36 37	MR NURTHEN: But it was different from the Promega. I think that's where Vojtech, when he answered that question, was referring to the Promega.
38 39 40 41	THE COMMISSIONER: Does it come down to the fact that when you started using the MultiPROBE, you started - you worked on the basis of the CFS protocol?
42 43	MR NURTHEN: Yes.
44 45	THE COMMISSIONER: And then adapted that to deal with your own manual?
46 47	MR NURTHEN: Yes.

1 2	THE COMMISSIONER: Your own manual method?
3 4	MR NURTHEN: Yes.
5 6	THE COMMISSIONER: Is that fair enough, Dr Hlinka?
7 8	DR HLINKA: Yes, that's right.
9	THE COMMISSIONER: Thank you.
11 12 13 14 15	MR FOX: Those who can contribute to this discussion agree that that's what was happening and that was the change that was made and why it was made?
16 17 18 19	MR NURTHEN: That wasn't a change. We started with the CFS protocol and then did some modifications to that. So when we're talking about modifications, I'm referring to modifications to the CFS protocol not the Promega protocol.
20 21	MR FOX: Right. Okay.
22 23 24 25 26 27 28	Then Dr Hlinka, the second modification you talked about in your statement is with respect to the conditions for lysis incubation that was lowered to 37 degrees Celsius, and in your evidence you say that that was to broaden the range of samples that could be used for testing. Do you recall that?
29 30	DR HLINKA: Yes, I do. Yes.
31 32 33 34	MR FOX: Was that bringing the temperature down from around 65 degrees down to 37 degrees Celsius; is that right?
35 36 37	DR HLINKA: Yes, yes, correct.
38 39 40	MR FOX: And again, that followed the CFS automated protocol?
41 42	MR NURTHEN: Correct.
43 44	DR HLINKA: That's right.
45	THE COMMISSIONER: Can I just clarify that so I really

understand that, because the temperature is an issue. My

understanding is that the temperature was reduced in

order - for some of the substrates that were being used, I think nylon was an example, that needed a lower temperature. Then you made the decision to use that same lowered temperature for all samples and you've given reasons for that, which include consistency of practice, which I understand. Did anyone do a double-check to check that that lowered temperature did or did not affect the extraction from other materials that were not nylon or whatever the other one was - nylon polyester.

MR NURTHEN: I guess it is worth noting that the 37 degrees was the temperature from the CFS protocol.

THE COMMISSIONER: They used it for everything?

MR NURTHEN: That's their protocol.

THE COMMISSIONER: Everything?

MR FOX: For their automated one, yes. So we based off that because it gives you that variety of samples. Gum particularly being an issue that at the higher temperature would go gooey and cause pipetting issues, is my understanding for that. So the 65 degrees, my understanding, is the Promega protocol and each Promega protocol has a separate protocol for the substrate you're working with.

THE COMMISSIONER: But as far as you were aware, the CFS protocol had validated the use of 37 degrees for all samples?

MR NURTHEN: Yes, it is called a mixed sample or mixed case work example. Because when you looked at the Promega one you had to run different protocols depending on (a) the material you were trying to extract from and (b) the fluid you were trying to extract from as well.

THE COMMISSIONER: Does that accord with your - do you want to add anything to that, Dr Hlinka?

DR HLINKA: Yes, that's basically the general gist of it. It was to encompass a whole range of different sample types to avoid problems with DNA being encased by dissolving samples which would have lowered the yield and so on as well.

THE COMMISSIONER: Sorry, do you want to say that again? Can you say that one other thing --

DR HLINKA: I will rephrase it. If the higher temperature had been used, then heat labile samples could have also encased DNA and lowered the yields, potentially. That's with regard to the 37 degrees Celsius which was present in the CFS protocol.

THE COMMISSIONER: Thank you. By the way, I'm not trying to stop Dr Muharam or Ms Gallagher from chiming in. If you wish to chime in, raise your hand or say something. That obviously applies to you, too, Ms Ientile and Mr McNevin. Thank you. Sorry Mr Fox, back to you.

 MR FOX: And just on that topic, some of my questions may seem very pointed. I may just have to be direct from time to time with you. But were any of you concerned by the -as a methodological approach, to adopt the CFS protocol in that way - that is, it is seen in that protocol that 37 degrees worked across a broad range of samples. But was adopting that, from your perspective, a sound course?

 MR NURTHEN: I think so, yes, because in addition to lowering the temperature, the introduction of the Proteinase K somewhat accounted for the decrease in temperature. That first step is about breaking open the cells and allowing the DNA to get out. So having a lower temperature and then coupling that with the Proteinase K, which actually would allow the cells to break, would counteract then having that 65 degree, which was what was in the Promega protocol.

THE COMMISSIONER: There are two questions arising out of that. First, just for my knowledge, this has nothing to do, then, with the need to denature the DNA? This is just a lysis step, temperature?

MR NURTHEN: Correct.

THE COMMISSIONER: Because you need to decrease the DNA to undo the helix; right?

MR NURTHEN: Yes.

THE COMMISSIONER: That's not that step?

1 2	MR NURTHEN: No.
3 4 5 6	THE COMMISSIONER: I have another question just following Mr Fox's. Why, then, did Promega have 65 degrees for different samples? Did anyone sort of think about that?
7 8 9 10 11 12 13 14 15	MR NURTHEN: I think they optimised that for the particular method that they did and I think there is a reference article Komonski et al, that explored taking that and then trying to automate it. I think, from recollection - I haven't looked at it recently - they found that by putting it in this additional buffer, you were going to get better results than just doing the 65 degree lysis and a wider range of temperatures - sorry, a wider range of substrates.
17 18 19 20 21	DR HLINKA: Might I add to that? 37 degrees Celsius is a perfectly standard and acceptable temperature to perform lysis at. It's not an unusual temperature for different sample types, because Proteinase K works at a broad range of temperatures, so it's not really a critical step.
23 24	THE COMMISSIONER: Proteinase K has optimal or completely satisfactory activity at that temperature?
25 26 27	DR HLINKA: Yes, that's correct.
28 29	MR FOX: That's your understanding too, Mr Nurthen?
30 31	MR NURTHEN: Yes.
32 33	MR FOX: And Ms Ientile?
34 35 36	MS IENTILE: I believe so. My role wasn't this detailed part, so I could not add anything to this.
37 38	MR FOX: Thank you. Mr McNevin so far nothing from you?
39 40 41	MR McNEVIN: No, that sort of thing I usually look up in a book. I wouldn't quote it off the top of my head, sorry.
42 43 44 45 46	MR FOX: Thank you. Can we then move to the third modification you, Dr Hlinka, that you refer to in your statement, Which is now the double elution step. Do you recall giving that evidence?

Yes, I do.

DR HLINKA:

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This is where the manual and automated DNA IQ methods both involved a double elution step of 50 microlitres, whereas the CFS automated DNA IQ protocol had a smaller elution volume towards the lower amount recommended in the Promega manual method - that was using Now, would you like to explain 25 to 100 microlitres. about the double elution step and why that was brought in?

Double elution step, we found we - I believe we found we got a higher yield with doing two sets of elutions rather than a single step elution. The volume amount which we ended up using was 100 microlitres to match basic protocol volumes that we had already used in the lab for other methods, and it was a sufficient amount for a workable amount in the lab.

And Mr Nurthen, you draw attention to this in MR FOX: your main statement about this double elution step, and if I may paraphrase that, you indicated that your recollection was that the experience of the lab was that DNA was still bound to the beads after a single elution step and a double elution step allowed recovery of additional DNA.

MR NURTHEN: That's correct. I think we even - we may have even tried three elutions as well, but there were diminishing returns and after the third you just diluted out your DNA too much.

THE COMMISSIONER: That raises the question, doesn't it? As I understand what I'm hearing, you do two elutions because that increases the extraction, the amount you can extract from the beads, but at the same time, you're diluting it, and you're not - let's not go into micro-concentrations but you're not taking any steps to concentrate it again. So wasn't there a concern that by increasing the volume of the elute that you were decreasing concentration of DNA?

I think that was looked into but I think the MR NURTHEN: pay-off was that we were seeing that much better quality in yields at the double elution than the single elution that meant whilst you would have had a lower yield, concentration - per concentration, it was better to go for Whilst, yes, you might have a slightly lower the double. concentration, with that higher yield, if there was DNA there that if you needed to do additional concentration

down the - through the process, you could do that as well.

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THE COMMISSIONER: Did you do that?

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MR NURTHEN: Additional concentrations? Yes, through the laboratory, microcon concentrations were used to concentrate DNA quite regularly.

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DR HLINKA: And also the advantage of the higher elution was that you could go back and retest the sample if that was required to be done at a later stage. So you have a higher amount to be able to work with for --

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MR NURTHEN: Microlitres of extracted DNA to amplify. If it eluted in 50 you would just get two amplifications, so having a higher elution volume actually gave you a little bit more to work with.

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THE COMMISSIONER: In the later stages?

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MR NURTHEN: In the later stages for amplification.

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THE COMMISSIONER: You needed to do replicates or go back and redo it?

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MR NURTHEN: Yes.

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46 47 THE COMMISSIONER: Can I just while we are at it, sorry to keep interrupting, just try and divide up my - help me with my thinking. There is the extraction stage, and there is the - after you have extracted it's then making sure you don't lose DNA during the automated process that takes it through to profiling, whatever else you are doing. a lot of what we're talking about here is the extraction stage, the concerns that come out of Project 13, aren't they? The question was not that you were losing DNA after you got it out of the lysis step and put it on to the machine; but somehow, there was an issue about how much extraction you were getting. And that's why I'm thinking about the volumes and things like that, whether or not the various - I think there's another - I'm just looking also at Dr Hlinka. I think this was not the only increase in volume in the procedure that was introduced. I'm not sure I haven't actually followed that through, but about that. I thought there was another increased volume somewhere as well, and that just put into my head the idea of whether or not, you know, you were diluting the DNA down too much.

I was just wondering (a) was that thought about and (b) how did you check for that?

MR NURTHEN: So broadly I guess answering your question, the way I see the automated procedure is you have the first step, which is the lysis, and that's getting the DNA out; the second step, which I think is far more critical is around the binding of the DNA to those beads and then the release from those beads.

THE COMMISSIONER: That will all really form part of the extraction process?

Yes, but we think that - well, I think from MR NURTHEN: the experiments that we've seen, that's the critical part, is that binding and the release. It works on an ionic strength, the way the beads and the way the DNA will bind So I don't think we had any issue getting to the beads. the DNA out of any of the cells. I think the 37 degrees and the TNE buffer worked fantastically. I think the issue we were having was having it bound to the beads and getting them back off the beads, hence the double elution being required because some of that DNA was stuck to the beads. Ideally, one elution should allow it to fully come off. But it wasn't coming off.

 MR FOX: Mr Nurthen, just earlier when you were giving an answer, I think it was in answer to the Commissioner's question about just in terms of the - she asked you about the processes that were engaged in, and you said you had looked into or I think you looked into that. When you use phrases like that, is that just part of the testing, if you like, of the process on a day-to-day basis as part of the validation or verification process?

 MR NURTHEN: Yes, I think it was part of developing that method, so we looked at - we must have seen the results and, at one elution, not been happy with it and gone back and looked at it with an additional elution.

 MR FOX: Everyone has heard, in terms of the experts, what has been said so far about this third modification. Is there anyone who wants to add anything further to what has been said, whether by way of agreement or otherwise?

MS IENTILE: No.

MR McNEVIN: No.

MR FOX: Thank you. Then we move to the final modification which is in relation to the specific consumable or plasticware, the hardware, that was used. Mr Nurthen, you drew attention to this and also Dr Hlinka, you drew attention to this hardware component. Perhaps Dr Hlinka, if you just indicate as to how significant that was, at all? It may not be that that was particularly a big issue but I'm curious to understand.

DR HLINKA: Are you talking about the Nunc tube addition?

MR FOX: That's right, yes.

DR HLINKA: That was what was being used standardly at the time for storage, at DNA IQ, and it made sense to put the plasticware that we used already in forensics for storage purposes - to put it on to the robot, just for convenience reasons. It wasn't really significant.

MR FOX: Thank you. This is, just to be clear for those witnesses who are here, present, it is the Nunc Bank-It tubes that are being described at this particular moment. Thank you. So are we in agreement that that wasn't necessarily a particularly major change? That was what Dr Hlinka just indicated then.

MR NURTHEN: No, I don't think for the Nuncs, but I think you were referring in my statement to the Slicprep device?

MR FOX: Yes, I think you identified in your statement, paragraphs 31 and 32, about the CFS protocol specifying particular consumables. Would you like to just elaborate on that then?

MR NURTHEN: Yes. So we wanted to incorporate the Slicprep device, which was a 96-well spin basket, if you will, rather than leave the substrates sitting in the deepwell plate. It was essentially a brand new product that this been available probably around about the time that we had started the validation. It was so new that there was no protocol or various other consumables already built for that particular device already.

MR FOX: Is this the part where you have described that you needed to cut the plate into a different shape or

 MR NURTHEN: The way the plate was designed, there are plastic struts all around the plate, and that meant it wouldn't sit on the heating block. So the heating block had to be modified to allow the plate to actually sit in the heating block. Otherwise, it wouldn't heat.

 MR FOX: Right. Before we move on to the next aspect of this, can I just ask, Mr McNevin, did you have any involvement at any point in time in discussing with your colleagues in the automation team about these types of modifications that were being made?

 MR McNEVIN: Yes, so I sat actually physically next to Tom and guys like, you know, Vojtech and Iman, we all sat in a very small desk area. So whilst my role was looking after the day-to-day running of the analytical team, there would - from time to time, we'd have some chats about things or maybe I'd overhear a conversation and have a bit of a chat.

I think most of my input into the extraction part of it might have been when we had discussions around the actual liquid handling settings on the instrument itself, because I had been involved in some earlier validation with the liquid handling instruments for (indistinct). So I had been trained by PerkinElmer along with Vojtech and Tom, and I can't remember who else, probably Iman, and so was aware of how to do the programming on the instrument, how to adjust those settings and that kind of thing, so - but I remember having some of those conversations. I don't remember a lot of detail.

The cutting of the heating tile was something that I had completely forgotten about until I read someone's statement and I went, "Oh, that's right. We did do that." So there were things there that I might have, you know, been involved in conversation about, but I was certainly not, you know, the decision-maker and that sort of thing. And it wasn't sort of my - really - it wasn't really my role to get involved and tell Tom and his team how to do their job either, you know, that was their role.

 MR FOX: Ms Ientile, in terms of your more management role at this time, having worked through each of these modifications that you've just heard about, is it the case

that you were consulted from time to time during the course of that work in whether it be informally or were you kept informed of these types of steps that were being taken by the team?

MS IENTILE: I don't have any direct recollection of being informed of detailed changes. I would have been given progress updates on where the - all the projects were up to, and perhaps in updates we had regular management team meetings, in which senior scientists and team leaders attended and there may have been updates which may have discussed in detail some of those aspects and why some of those things might have been adjusted at the time.

MR FOX: And that general description that Ms Ientile just provided, and Mr Nurthen, is that something you would agree with, with the way the lab was conducting between yourself on the tools, so to speak, and management?

 MR NURTHEN: Yes, we were given the discretion, if you will, to develop the method and that didn't necessarily mean reporting every change that we'd had made for every part of the - every step of the way, basically.

MR FOX: Dr Hlinka, you've heard the exchange that just happened then. Are you in agreement with what Mr Nurthen has just said in terms of the way in which the team members interacted with management at the time regarding these modifications?

DR HLINKA: Yes, except that those modifications are also listed in the final standard operating procedures, so that other people who would have read those procedures would have been aware of them as well. So although they weren't directly communicated to management, it was documented in the standard operating procedures.

 MR FOX: Thank you. Ms Gallagher, I appreciate you had a junior role at the time, but from what you have heard, do you have anything to contribute to the discussion, and I will ask the same question of Mr Muharam after Ms Gallagher has finished. You might want to seamlessly transition into giving your comments about that as well.

 MS GALLAGHER: The comments that have been made so far are within the best of my recollection and I'm in agreement with what has been said.

MR FOX: And Mr Muharam?

MR MUHARAM: Yes, I agree with that as well, that's as best as I can recollect.

MR FOX: Thank you. Now, can we just then turn, before we get ourselves into the activities around October 2007 --

THE COMMISSIONER: Can I just ask one more question, sorry? We've heard or we've read about a number of small or big changes that were made, you know, double elution, change the temperature, there are a few others that - I'm not going to get into the heating tile but, you know, there were other extraction volumes - there was another extraction volume somewhere, I've forgotten exactly where it was.

 Isn't it normal that when you do something, that, if you really want to validate it, you change one variable at a time and check for the consequences of that, and then you change a second variable and check for the consequences of that? Was that done here? Or did you then - because you were looking at what you thought was an okay method in another context, you know, that you had validated that in a different context, whether it was a manual one or something or you were looking at the CFS one, that you put it in, all the changes, in one go?

 MR NURTHEN: Sorry, can I just clarify that? From the changes from the CFS protocol, we increased the volume of buffer at the start, which the knock-on effect meant additional lysis buffer had to be added. The temperature remained the same and we changed the elution.

THE COMMISSIONER: So the big issue there was there were two different steps that introduced increased volume?

MR NURTHEN: Yes. But I don't think we did them concurrently. I think we would have done the first protocol with the single elution, with just the volume change made, and then, having assessed that, gone back and then done the double elution.

THE COMMISSIONER: Is that recorded anywhere?

MR NURTHEN: I don't think so.

37 degrees; right?

Yes.

MR NURTHEN:

THE COMMISSIONER:

THE COMMISSIONER: Yes. So what you did change, to bring in your manual method then, as you have just described, as I'm hearing it, is there were probably two different volume changes, one - they may have been consequential, where you had the double elution and then you had the other one that was a - and there was also something about covering the sample sufficiently in the well and you had to increase from 300 to 500 microlitres for that. I guess my question is: did you check for the consequences of each of those changes individually or did you take it that this was the method you were going to use and you put that method in with those modifications in one go to test it?

I mean, I understand the temperature, you were doing

a validated method from CFS, they had the temperature at

Because that is proper procedure, isn't

 MR NURTHEN: No, I think my recollection was that we started with just increasing the volumes and putting the Slicprep in - this is for the automated protocol - and then seeing the yields out the other side with the single elution not giving us what we expected, then going and doing the additional elution step. I don't think we would have coupled them.

THE COMMISSIONER: So the double elution step was done after you had used a single elution but with the other increased volume already in there?

MR NURTHEN: Yes. Yes.

THE COMMISSIONER: Thank you. That's helpful. Is that your recollection, Dr Hlinka?

DR HLINKA: I can't honestly recall.

THE COMMISSIONER: Okay, don't worry. That's fine. If you don't recall, that's fine. I just want to make sure that I'm getting everyone who can recall what happened, that I'm getting that input. Does anyone else want to make a comment about that, about the way that was staged?

DR HLINKA: I did want to comment that that - having that

double lysis volume was what was recommended by the Promega manual DNA IQ protocol. That was not --

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THE COMMISSIONER: Yes. I understand.

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DR HLINKA: It was not something that was made up.

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14 15 THE COMMISSIONER: So you didn't bring it from All right. the air, it was recommended from the manual protocol, but it was still a modification to the CFS protocol; you were matching two different protocols together, each of which had been validated to your satisfaction, but you were combining them, in effect, and which meant that there were - there was, let's say, more than one modification to the CFS protocol, by reason of your importing the manual protocol; is that fair?

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DR HLINKA: I believe so, yes.

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MR NURTHEN: Sorry, can --

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THE COMMISSIONER: Although I think, Mr Nurthen, you said no, it happened in two stages, because you tweaked the elution?

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MR NURTHEN: Yes, so from what I recall --

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30 31 THE COMMISSIONER: The concept is the same. You were taking a manual protocol that you had sufficiently validated, you had a validated CFS automated protocol and you wanted to put the validated manual protocol into the CFS protocol?

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MR NURTHEN: No, I recall us doing both the manual and the automated concurrently. We didn't do one project and finish that and then move on to the next one. I think thev were overlapping somewhat. The manual part was quite straightforward because we could just lift off that entire protocol, the CFS protocol, and then go ahead and do all those - all that other bit of work, and at the same time develop the automated one as well.

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So I think, with respect to the two volumes of lysis, that exists both within both protocols, the CFS protocol and the Promega protocol. Because we increased that buffer from 300 to 500, the amount, those two volumes obviously greatly increased as well. So it appears like it is a big

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deviation from the CFS protocol, when, in actual fact, it's just a scale-up of their protocol itself.

THE COMMISSIONER: Yes, but the scale-up increases the dilution factor, doesn't it?

MR NURTHEN: No, because at the end - because that's the first bit, getting bound on to the beads. Once the beads are on there and it gets washed, you then control how much is in the elution buffer.

THE COMMISSIONER: Right. So if I can clarify that, so while you increased the volume initially of the lysis step, your evidence is that that did not affect the concentration later of the DNA because that gets it on to the beads?

MR NURTHEN: Correct.

THE COMMISSIONER: That elution amount goes, that - the solvent, whatever you want to call it, goes - and you're then eluting off the beads, it is a fresh start in terms of volume --

MR NURTHEN: Correct, yes.

THE COMMISSIONER: -- you've got the DNA attached to the beads, and then you use a double elution step off the beads, and that's where you put in the double elution to get the increased DNA, as I'm trying to summarise what I have heard - you accept that that may have - obviously that itself would decrease the concentration of DNA in the sample, but your evidence earlier was, as I understand it, that you felt that the increased DNA you got off was worth it, even though you meant - even though you had to use an increased volume.

MR NURTHEN: Yes. So for want of a better word, if you had X amount of DNA but you could only get 50 per cent of that DNA off, as opposed - and have it at a higher concentration, as opposed to getting 100 per cent of the DNA off at a lower concentration --

THE COMMISSIONER: So it was a trade-off.

MR NURTHEN: It was a trade-off, yes.

THE COMMISSIONER: It was a trade-off that you evaluated

2 3 MR NURTHEN: As I recall, yes. 4 Dr Hlinka, or anybody else, does 5 THE COMMISSIONER: anybody want to add anything to that or agree or disagree? 6 7 I agree with it, yes. 8 DR HLINKA: 9 THE COMMISSIONER: All right. Thanks. Mr Fox. 10 11 12 MR FOX: This is still in the same territory that the Commissioner has been asking about. We're now in the 13 territory of validations, and I would like you to describe 14 15 what steps you took to satisfy yourselves that you were engaging in a rigorous validation process? 16 17 18 MR NURTHEN: So the manual part is really challenging the 19 chemistry itself, the kit itself, as to how well it's performing under a whole lot of different scenarios. 20 then the step up to the automated platform was then 21 22 assuming that it's performing well under all of those 23 conditions, when we move to the automated, we would 24 likewise get similar results, hence the comparison between 25 the automated and the manual. 26 27 MR FOX: And Dr Hlinka, do you have anything to add about 28 that? 29 30 DR HLINKA: No. 31 32 MR FOX: And focusing on steps towards properly validating 33 in a scientific way, what these changes were that were 34 being made? 35 36 DR HLINKA: I think that that was correct, what he said. 37 I don't have any additional --38 39 MR FOX: You don't have any further comments? 40 DR HLINKA: No. 41 42 MR FOX: 43 Ms Ientile, from your perspective, were you seeking to make sure that what changes were made were 44 validated in a scientific way? 45 46 47 MS IENTILE: I believed that the project team was working

at the time.

in that manner, yes.

MR FOX: When you say you "believed", what did you - in a position of management - do to satisfy yourself that that was so?

MS IENTILE: I would have had regular updates and I think regular updates with Tom that updated the steps that they were doing throughout the process, updates on what they had found at the time and then the next steps they were taking based on those decisions, is my recollection.

MR FOX: Mr Nurthen, is there data that's gathered in a systematic way that you were looking at and that was then guiding you when changes were made? Was that sort of process being adopted as well?

MR NURTHEN: My recollection is that we actually started to - well, we planned how we would validate or how we would actually test the system through consulting articles on - you know, that were available, but also talking to the other laboratories that already had experience.

So Western Australia and South Australia had had experience with both the same systems. We talked to both of them around their approach to validating their particular chemistry or their kit on the MultiPROBE, and I think after reviewing all of that, we had come up with a plan to say, "We will test this; we will test the ability for inhibitors to" - well, whether DNA IQ could actually remove inhibitors, we would test to see if the different size of the substrates would affect the outcome at the end. All of those steps were part of that initial plan, that rigorous testing to ensure that what we got out the other end was suitable.

MR FOX: Moving along the way there, did anyone want to add anything?

MS IENTILE: Yes, in preparation for this, reviewing documents that have been made available to me, it does appear that that automation whole project that you referred to before was all of these steps, and that was planned out, and they were part of a users group that had detailed discussions as to what each of those aspects meant.

Ms Gallagher, you have heard what has been said MR FOX: about the process of validation. I appreciate, again, your position, but is there anything you wanted to add from the perspective of a junior scientist so much as you can recall back then?

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MS GALLAGHER: I do recall participating in work that went ahead to create the samples that Tom was talking about in terms of different substrates, us having conversations about the types of materials that we were likely to receive within the laboratory at the time, and to create those sort of mock samples to be run through the automated method that was being created, and while I don't recall the specifics of conversations, I do recall us, as a team, reaching out to the other laboratories that had other automated platforms and having conversations with them about how they went about validating the procedures within their own laboratories.

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22 23 MR FOX: So you satisfied yourself, through what you have just described then, that what you were doing in the laboratory and what your colleagues were doing appeared to you to be best practice?

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MS GALLAGHER: Yes.

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28 29 MR FOX: Mr Muharam, do you want to add anything to what you have heard so far, obviously going back to your perspective in the lab as part of the automation team at that time?

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MR MUHARAM: Sure, I don't have anything significant to add, actually. I agree with everything that has been said. We did, as I think Mr Nurthen mentioned earlier, consult with the wider community, we investigated a lot of different papers, publications, we received - we were able to contact other labs that were, you know, using the chemistry and the technology at the time, and therefore formulated our own plan based on all of that.

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But also, the existing standards and guidelines that were applicable at the time, we made sure that, you know, we were, I guess, trying to do what we thought at the time But, of course, these things evolve was best practice. over time, but definitely I think in terms of what we were trying to achieve during that period, we did the best that we could and we believe that we've ticked all the boxes.

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Dr Hlinka, do you want to add anything to what you have heard your colleagues say in the last few minutes?

Yes, we also had support from PerkinElmer through Desley Pitcher and those colleagues regarding the setting up and doing things on the robots. So that was a great help when we were doing the validation as well.

That's the manufacturer of the device, is that right, the MultiPROBE device?

The manufacturer of the MultiPROBE device; DR HLINKA: They supplied us with the protocols and so that's correct. on, from CFS.

MR FOX: We'll come a little more to the Thank you. automation process in a second. You otherwise don't have anything else you wanted to add in relation to what you have heard?

DR HLINKA: No.

MR FOX: Thank you.

Can I just add a little bit? As I mentioned MR McNEVIN: earlier, I sat adjacent to these guys and so they would regularly have meetings where I could overhear them planning stuff out. I mean, I wasn't involved in the conversation direct but I can confirm that it wasn't just done, you know, ad hoc; that they were certainly like "Okay, we're going to do this next, you do this, you do that", I can't remember a lot of the detail but I remember those meetings occurring.

MR FOX: Those are conversations, I think you indicated you sat directly next to them and so --

MR McNEVIN: Yes, so I could hear that they were having those conversations but obviously I don't recall the details.

MR FOX: Can I then take you to a topic of the automation - that is, in October 2007. We have what I've described as the modified DNA IQ protocol and it's now being used in conjunction with the MultiPROBE device, otherwise known as the robot - I'm endeavouring to speed

Now, Mr Nurthen, you have started to talk matters up. about this notion of the automated DNA IQ protocols in your main statement, starting at around paragraph 57. Would you just like to explain in your own terms what you mean by that, in terms of that process - that is, the development of the automated DNA IQ protocol?

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MR NURTHEN: Like I said, we based it on the CFS protocol and the idea was to do a manual part of that to say, "Here is that protocol, but if we do it manually, yes, we get ', and also we good results, test it out really thoroughly" had a benefit being if the robots go down for any particular reason we had a back-up method, a manual method, to be able to extract from with DNA IQ, although not ideally.

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Then the second step should have been move it on to the platform, because when it was done manually, whilst we're trying to align temperatures, volumes, all that kind of stuff to be the same, the reality was the plasticware and the hardware was different in the manual method from the automated method, if that makes sense. So when we were talking about developing it, we were hoping to pick up that method and basically start to use it, but we needed to make changes to that method to incorporate the Slicprep device.

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28 29 MR FOX: Does anyone want to make any comment about what Mr Nurthen has just said then just by way of a general introduction? Everyone's comfortable with what he said there?

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MS GALLAGHER: Yes.

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MR MUHARAM: Yes.

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MR FOX: When the automated method started to Thank you. be used, you indicated in your statement, Mr Nurthen - this is at paragraph 89 - that you noticed that there were low yield results that were being achieved. I'd just like you to indicate, when you started to notice this, how it came about and what raised that as a matter of concern in your mind that it was something that needed to be looked at.

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46 47 MR NURTHEN: I think it was something that throughout the whole optimisation of that program we were obviously aware of the results as we stepped through them, and that was obviously in the forefront of our minds as to how do we

ensure the yields are the same as the manual? As I said, one of those bits would have been looking at the different volumes, I guess, involved.

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Part of when we talk about modifications - and this is where it tends to get a little bit more technical - on the actual robot itself, the way the robot pipettes is different to the way you would manually pipette. involves a number - like, quite a few number of steps that are programmed within the robot that would affect the outcome at the other side, and that's where a lot of that time was spent in optimising things like the dispense heights, how things were mixed, how it was shaken on the robot, and as we were doing that there was no, I guess - we were always cognisant of what was coming out the other end and trying to revise it and make it better, if you will.

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It wasn't that we got to the end and went, all of a sudden, "Oh, the yields were down", it was an ongoing As you do those experiments you become aware the yields aren't giving what you need. So what do we do? We try a different mixing technique because we talked to PerkinElmer and they said, well, perhaps the beads were settling out, so you needed to change the way that parameter worked.

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33 34 THE COMMISSIONER: Can you explain something to me, because I think I picked up something in Dr Hlinka's statement about potential for clumping. So I'm trying to work out where the pipettes are going in. I'm assuming we are talking automatic pipettes, even manually, you are not talking about pipetting by mouth, which is something that I think is long gone from my day. So when you get it off the beads - I mean, I think there's a reference to clumping that may have occurred.

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Now, I'm trying to understand, what was being pipetted off, out of what? So if it was a purely clear - if it had been taken off the beads completely clearly and dissolved, why would there be clumping? And I mean, I understand that a machine - picking up what you are saying, a machine just goes like that (indicating) whereas a person can see that there is something at the bottom and maybe tilt the tube before they take something out. So can you give me a bit of an understanding of what it looks like when it comes off the beads?

MR NURTHEN: Sure.

THE COMMISSIONER: Is it crystal clear?

MR NURTHEN: I'll just take you back a step. The clumping I think refers to the resin itself, so the paramagnetic beads come in a little bottle, quite densely packed, and you have to mix that with a certain amount of lysis buffer to bring it back into solution, and that was a very difficult thing to do, that once you put it on to the deck of the robot, they would tend to settle out back to the bottom of the container.

THE COMMISSIONER: So the beads - the beads were still there?

MR NURTHEN: This is before the beads have been added to the sample.

THE COMMISSIONER: Right.

MR NURTHEN: So you put it on the deck, it's sitting on the deck in a container. The robot then had to mix that first to get a homogeneous mixture.

THE COMMISSIONER: This is the lysate?

MR NURTHEN: No, the beads before it goes into the lysate. So if I step through the broad strokes for the extraction, lysis, extract - you know, basically, here's the substrate, put the lysis buffer on it, after a period of time, take the substrate out, spin it down, get all the lysate, so all you've got left is liquid. You then add the beads to that lysate, let the beads - let the DNA bind to the beads and then you add it to a magnet and then the magnet then pulls the beads to the side with a bound DNA. You then pipette out all the lysate, wash it and then elute from it.

THE COMMISSIONER: Elute from the beads?

 MR NURTHEN: Elute from the beads. So that step we're talking about, the clumping, would have been around the beads themselves being pipetted into that lysate. It is a very difficult thing to do for a robot, very easy for a person to do, because, like you said, you can sit there, vortex it so you get a homogeneous mixture in between every step, but when you are doing it with a robot it had to mix

it itself. 1 2 3 THE COMMISSIONER: But surely that would have been part of the design of the automated system itself, and the - that 4 would have been part of the validation of the fact that 5 that worked, the mixing was sufficient as part of the CFS 6 7 validation, wouldn't it? 8 It would be, but even though it's out of the 9 MR NURTHEN: box, it doesn't come out of the box perfect, if that makes 10 And that was our experience with the other 11 12 laboratories too, that when they tried out those methods, they had to make modifications themselves in order to get 13 it to work to the level that they were happy with. 14 15 THE COMMISSIONER: 16 Was their problem also at that mixing 17 stage? Did they also have problems at that mixing stage? 18 19 MR NURTHEN: I don't know, but I know that that's one that we had to talk to PerkinElmer about around the beads 20 21 settling out. 22 23 THE COMMISSIONER: Dr Hlinka, is that what you're talking 24 about with the clumping that you refer to? 25 26 DR HLINKA: That's partially it, but there might have also 27 been clumping in the samples when they were prepared and I'm not really certain about that. 28 29 THE COMMISSIONER: I'm sorry, I shouldn't be asking you 30 31 out of nowhere. In your statement at page 25, you refer to the fact that both manual and automated methods gave 32 33 sufficient quality DNA profiles although yield and 34 sensitivity appeared significantly lower for the automated 35 My interpretation is this could have been 36 potentially partly attributed to sample clumping during 37 preparation. So that's a different clumping? 38 39 MR NURTHEN: That's different. That's putting the cells on the substrate to start with. 40 41 DR HLINKA: Yes, that's correct. 42 43

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DR HLINKA: That's the sample preparation.

THE COMMISSIONER:

there, the cell stage?

So that's what you were referring to

THE COMMISSIONER: And is that also something that - where does the automated - the automation problem work there badly? I mean, we've got the other clumping because you say the machine didn't do it sufficiently with the beads, what was the problem of clumping in an automated system? At what stage was that a problem that you didn't get manually?

MR NURTHEN: So we're talking about the preparation of the samples?

THE COMMISSIONER: It says, "sample clumping during preparation and dilution".

MR NURTHEN: I think that was around the consistency of preparing the samples, that when you tried to take a buccal cell suspension and you tried to make dilutions and pipette them out, getting reliable, consistent dilutions across all of your substrates, all of those replicates, was difficult because of clumping of the cells. So if the cells were homogeneous --

THE COMMISSIONER: So manually you would spin it or do something to break it up into suspension, at least, but if you waited too long it settled out?

MR NURTHEN: The cells - if we're talking about the cells now, we're talking about when you initially collect the cells from inside of the cheek, the cells tended to clump to each other. So if you then pipetted that on to 10 different swabs, you know, five of them might have 10 nanograms of DNA and five of them might have 2 nanograms of DNA. That was around the inconsistency of knowing what you are providing is going to get back out the other end.

 THE COMMISSIONER: And what part of that was manual and what part of that was ultimately automated or during this Project 13 system, that dealt with that issue?

MR NURTHEN: It wasn't an issue to deal with; it was more around the samples that we were then challenging the robot with, about giving it adequate samples to go, "That's the same, that's the same, that's the same", so that then when you looked at the variants, you were seeing that the variation was due to the robot, not the sample preparation.

DR HLINKA: Yes. 1 2 3 MS IENTILE: Can I ask a question or clarify? I believe what Mr Nurthen is talking about is the preparation of the 4 mock samples to then test the processes on that - that's 5 6 what you're referring to? 7 MR NURTHEN: 8 That's correct, yes. 9 MR McNEVIN: Do I recall correctly, Tom, that we observed 10 that when we were doing some cell counting to try and 11 12 determine how many cells were going into the sample? 13 MR NURTHEN: Yes. 14 15 MR McNEVIN: 16 So we could observe then under the microscope the cells, you know, getting inconsistent counts because in 17 some samples there was - all the cells were clumped 18 19 together, and sometimes they weren't. So we knew that when we were then transferring that, when we make up our 20 samples, we knew we were not able to get necessarily very 21 22 consistent samples like you would, say, out of pipetting some blood or something like that. 23 24 25 I'm going to come to Dr Hlinka in a THE COMMISSIONER: second because he raised it - what steps does one take to 26 overcome that problem? 27 28 29 DR HLINKA: Are you asking me now? 30 31 THE COMMISSIONER: Yes. I'm asking you now. 32 33 DR HLINKA: We obviously tried to vortex the samples to 34 distribute them, we tried to vortex to try and homogenise 35 the sample as much as possible, so that means to get an 36 even concentration in your sample as much as possible, by 37 vortexing. 38 39 THE COMMISSIONER: So if you automate - what do you do if 40 you are going to automate that? 41 We didn't automate the sampling procedure of 42 DR HLINKA: 43 the mock samples I don't believe. 44

manually?

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46 47 THE COMMISSIONER:

So that was always done

I see.

That was always done manually. DR HLINKA:

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THE COMMISSIONER: Sorry, can I ask you to go to page 25 of your statement. I'm just trying to understand it.

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DR HLINKA: Mmm.

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THE COMMISSIONER: About halfway down, you say, and I just read it out before, you have got it there:

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Both manual and automated methods gave sufficient quality DNA profiles, although yield and sensitivity appeared significantly lower for the Automated ... method. My interpretation was that this could have been potentially partly attributed to sample "clumping" during preparation and dilutions of some of the samples as described in ... Project 13 ...

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So I'm trying to work out where that clumping, if it was always done manually with the sample - how that was something - oh, thank you. Thank you for that - how that changed in the automated system or how that could have been responsible for a decreased yield in Project 13, if, in fact, that was something you were always doing, and it was a manual procedure, and you just made sure you vortexed sufficiently to create a homogeneous suspension?

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MR NURTHEN: I think that is regards to going if we have made up 10 samples and five of them are used for the manual and five of them are used for the automated, that there was possibly discrepancies in those samples being made up, that they actually had different amounts of DNA on it, and that might be one of the reasons that we weren't getting the same results.

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> DR HLINKA: Yes

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42 43 MR NURTHEN: That's where I think that line comes in. That if you made up the sample and there are supposed to be 100 cells on every one of those samples but some of them have 150 and some of them only have 70, when you extracted them, you're going to get different quantities of DNA.

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THE COMMISSIONER: But that's a problem all the time.

1	MR NURTHEN: Yes.
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3	THE COMMISSIONER: That's not just in testing an automated
4	procedure, I mean, that's just random luck.
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6	MR NURTHEN: Yes.
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	DD III TNIZA. Vaa
8	DR HLINKA: Yes.
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10	MR NURTHEN: But I think we raised it as a potential
11	reason as to why we saw differences between the two.
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13	THE COMMISSIONER: Are you comfortable with that,
14	Dr Hlinka?
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	DD III TNIKA. Vaa that la tuura
16	DR HLINKA: Yes, that's true.
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18	THE COMMISSIONER: I'm good to keep going, happily, but
19	I just wondered if the witnesses wanted a 10-minute break?
20	Up to you.
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22	MR FOX: Can I just ask
23	THE TOX. Out I just usk
	THE COMMICCIONED. To average comfortable to know reign?
24	THE COMMISSIONER: Is everyone comfortable to keep going?
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26	MR NURTHEN: I'm fine.
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28	DR HLINKA: Yes.
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30	THE COMMISSIONER: Are you okay, Dr Hlinka?
31	THE COMPLEXITY THE YOU CRAY, DI HITHING.
	DR HLINKA: I'm okay but I don't know if Zoom has a time
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33	limit on it. Someone told me it's limited to 45 minutes.
34	
35	THE COMMISSIONER: Did the Commission send you a Zoom
36	invitation?
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38	DR HLINKA: Yes, indeed.
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40	THE COMMISSIONED. Con completely shock what has that in
	THE COMMISSIONER: Can somebody check whether that is
41	going to have a time expiry. No, there is no time limit,
42	I'm told. No. No. That's good, the Zoom hasn't got
43	a time limit. We can keep you here 24 hours, Dr Hlinka.
44	It's fine.
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46	MR FOX: I just want to ask one question before the break,
47	if I could. We will come back to this topic, but I think
• •	2 334.41 No Hill Some Back to tillo topio, but I tilling

Mr Nurthen, if it's convenient --

THE COMMISSIONER:

 MR FOX: No, I'm quite happy to stop and give the - I think the indication is that they would gratefully appreciate a 10-minute break. So, sorry to do this, but one further question. Just while we are on a roll I think it would be helpful rather than losing momentum. That description you described, probably about 10 minutes or so ago, you were going through the steps in the process of DNA extraction. When we hear the phrase "off-deck lysis" amongst the automation process, would you as a - I think it is good to do it now because we're going to come back to it as a topic. What does that mean in terms of the process that you have described, which bits?

I'm not trying to stop you.

MR NURTHEN: That refers to the first part of the process, that breaking open the cells, because in the first iteration of the automated method, we did as much as we could on the robot, which meant the lysis part sat in the Slicprep on the deck of the robot. Off-deck lysis was done not on the robot. So that lysis step was done in little tubes, separately, on a completely different instrumentation off the robot. So that --

THE COMMISSIONER: Was that manual or not manual?

MR NURTHEN: No, it's off-deck lysis, because the critical component, which is the binding of the DNA to the magnetic beads, occurred on the robot.

MR FOX: Was the use of this off-deck lysis approach, in other words, having manual exercise separately, was that because you had a greater - and I say "you" as a team had a greater confidence that that would be done better by humans than by the machine?

 MR NURTHEN: I don't recall that aspect but I know we certainly had to create a method for retaining supernatant. I think it can be safely said that being off the deck of the robot we would get better results because it's closer to the manual; that using individual tubes was always going to give you better results than using a larger deepwell plate on the deck of the instrument, you're going to get better thermal transfer with individual tubes than in a plate.

THE COMMISSIONER: So off-deck lysis was still automated but it was a single-tube preparation rather than 70 or whatever it is?

MR NURTHEN: Correct, and then you put that lysis in those tubes on the deck, which then would pipette it into a deepwell plate to then do the binding of the DNA to the resin. And the rest of it was automated.

MR McNEVIN: So that initial lysis step was done manually, then you take that lysate, put that on the instrument, then that becomes your automated method.

MR FOX: We will come back to this later.

THE COMMISSIONER: I thought that Mr Nurthen had said that was also automated. I thought it was manual but I thought you said it was also automated.

MR NURTHEN: Think of it part and part. So the overall method, the on-deck lysis, method, was fully automated. The off-deck lysis was part and part. The first step was done off the robot manually, the second step was done on the robot.

THE COMMISSIONER: Okay. Sorry, Mr Fox.

 MR FOX: No, it's about whether there was any reason for doing it in that way, that there was something that was recognised about the lysis step that it was preferable to do it manually before leading to the other automated steps. Anything around that, did you have any awareness of or concerns about, that led to this notion of having an off-deck lysis?

 MR NURTHEN: As I recall, the Slicprep device was incredibly difficult to use. In order to prepare it, we had to - because it's a 96-well plate, we had to get every substrate pushed down into it, and it was quite a laborious process that involved another instrument to sit there and with tweezers push it down into the deepwell plate, make sure you haven't contaminated on the outside, whereas if it was already in the tube, it was much easier and much quicker to process. So that's my recollection around the Slicprep device and the preparation of the Slicprep device, it was just too time consuming, it was too risky for

contamination, completely remove the Slicprep and do it manually, which wasn't what we wanted to do initially, we wanted to put everything on the robot, walk away and then come back, but that's not what worked, basically.

MR McNEVIN: I can recall my staff not being enthusiastic about the Slicprep device. It was too difficult, it was, you know, fiddly. I can't remember the exact details, it was quite some time ago, but I do remember them not liking using it and so I can't remember whether that was a major or a minor factor into us changing to off-deck lysis but I do remember that particularly, when Tom was talking about pushing the samples down, I sort of recall them finding that process difficult.

MR FOX: You're not disagreeing with what Mr Nurthen has said?

MR McNEVIN: No, no, I'm just saying a remember there being an element of it being difficult to use. I just don't know whether that was a major or a minor factor.

MR FOX: Has anyone anything else they want to contribute to that? Dr Hlinka?

DR HLINKA: No, that sounds correct.

THE COMMISSIONER: Ms Gallagher, Mr Muharam, anything to contribute so far? No? Thank you. Ms Ientile, you're the last one.

MS IENTILE: No, I agree with what was said, but also in reviewing the documents, I think the other - and it was mentioned that the other aspect was to retain a little bit of supernatant so that other presumptive tests could be done in another area of the lab.

MR FOX: Thank you. That's a convenient time?

 THE COMMISSIONER: Do I take it that people do want a 10-minute break? Okay. Now, just one procedural thing, if you can find a place that will do coffee in 10 minutes, please don't feel - you can bring it back and bring it with you. You don't have to find it and drink it. I'm very happy for anyone, including counsel, to have a cup of coffee on the table, if you want to have one, or a cup of tea or something, but in view of the timing, I would just

prefer to leave it about 10 minutes. That's all I'm saying. Is everyone comfortable with that? All right. We will adjourn.

## SHORT ADJOURNMENT

THE COMMISSIONER: Thank you, Mr Fox.

MR FOX: Commissioner, are we going to sit Supreme Court hours or Federal Court hours?

THE COMMISSIONER: I thought, seeing we have had a 10-minute break, that we would sit Supreme Court hours. What we can do is sit until 1 o'clock and then work out how we are going and decide whether we have an hour or an hour and a quarter for lunch. But of course I do plan, if we're close - I'm not going to break and have the witnesses all have to return tomorrow. If it gets to 4 o'clock, I'm quite happy to keep sitting until we finish.

MR FOX: Yes.

THE COMMISSIONER: Unless it's huge and it's going to be a really prolonged one, in which case we will make that decision. It doesn't mean we will necessarily stop on the dot of 4. I assume they are the same hours in Queensland as they are in New South Wales.

MR FOX: Yes. Mainly for the benefit of those witnesses today, just to have an understanding of where the goalposts are.

THE COMMISSIONER: My intention is that - it is now basically 12 o'clock so we will keep going until 1, we will probably take an hour's break, then we will come back, and go hopefully until it is finished. If we finish before, we finish after, we will just see how we go. I would very much prefer to finish it today.

MR FOX: I think we are tracking well at the moment.

THE COMMISSIONER: I don't know if I can have - does anyone so far envisage any lengthy evidence to be called from anybody else, from other counsel representing the witnesses so far? I'm not closing you down. I want to get an indication of whether you think you will have any questions, prolonged evidence questions you need to bring

in. 1 2 3 MR RICE: Not long, if any, Commissioner. . 4 5 THE COMMISSIONER: That's a good indication. You are not bound by it. 6 7 MR FOX: Professor Wilson-Wilde has given a statement in 8 this proceeding and I don't know whether you have had an 9 opportunity to read it but I just want to provide a comment 10 that she makes about automation in her report or statement, 11 12 and just to read it to you and to gauge your reaction to it: 13 14 15 In Project 13 the analysis compared the fully automated DNA IQ method to the manual 16 17 method verified in Project 11. 18 19 This is paragraphs 89 to 94, and it is not in the tender bundle, I'm afraid: 20 21 22 The change of a DNA extraction method from 23 manual to fully automated is significant. Most laboratories in Australia run a part 24 25 automated method, where the lysis step is conducted manually, and the DNA capture 26 27 washing and elution is completed on 28 a robotic platform; this was the case in 29 2007 when Project 13 was implemented. 30 31 In my experience, it may be expected that 32 there could be a reduction in the amount of 33 DNA recovered from samples using a robotic 34 platform, when compared to a manual 35 platform, although this reduction is highly 36 dependent on a particular method. 37 38 For instance, an automated process may have 39 difficulty in getting similar amounts of DNA when compared to a manual method, 40 because a human can perform functions such 41 as mix a sample longer, tip a tube so that 42 43 the tip can more easily reach the bottom of a tube to remove all of the sample, etc. 44 45 This is particularly the case during the

lysis step.

It can be difficult to automate the lysis step and obtain an equivalent DNA yield to the manual version of the method. because swabs or other bulky material are more difficult for robotic platforms to It follows that I expected deal with. there to be a reduction in yield where the lysis step was automated.

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So the proposition I want to get your response to is what she indicates about the difficulty of automating the lysis step and the consequence being that you inevitably, on her view, would get a lower DNA yield. Dr Hlinka, would you like to start by providing your response to what you have heard me read out, whether you agree with that proposition that is being put?

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DR HLINKA: I can see what concerns she would have in I don't really know - I'm sorry, I don't writing that. know how to respond.

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MR FOX: That's all right. We'll ask some of your colleagues while you have a chance to reflect on it, and I will come back and ask you in a minute.

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Mr Nurthen, would you like to start by providing your comments in response to those observations that the professor made?

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Yes, I think that's fair comment. MR NURTHEN: technically more difficult, when you are starting to work with different plasticware, the thermal dynamics with a plate compared to a sample are much different. the introduction of the Slicprep was supposed to somewhat address that, because we were going to have this substrate removed from the deepwell plate, whereas the original methods, if the substrate is sitting in the plate, you can get clump - well, not clumping, you can get clogging of the tip because the pipette would then get stuck on the So I can see how that would obviously then substrate. lower your potential yield.

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I think we tried to address that somewhat by putting in the Slicprep, where it was incubated and then you removed the substrate and then, hopefully, that thermal capacity of the plate is better than what it was before, if that makes sense. But you will not beat manual because of the - basically, the difference in plasticware.

MR FOX: In responding to the proposition, what you have done is to agree with it and then say, "Okay, there are some things that we did to kind of deal with that proposition."

Mr McNevin, did you want to make any comment about that, what Mr Nurthen has said?

MR McNEVIN: Yes. I think if you were to look at certain sample types, you know, maybe that you could work around with a single protocol that, you know, ameliorated some of the difficulties associated with using an automated platform, you know, you could potentially set up your platforms in such a way as to suit a very specific sample type. Hat's not what we were trying to do at the time. We were trying to use - get all our samples on rather than having, you know, "Oh, well, I'll go and do a bunch of these samples and a bunch of those samples" and have different protocols to suit all those.

So I think as a sort of general principle, yes, they're some of the difficulties you are going to be faced with when developing an automated - fully automated system.

MR FOX: Were they difficulties, in your mind, that were insurmountable? In other words, you were never really going to overcome them?

 MR NURTHEN: I didn't think so, because when we tendered for the instruments, we tendered for a walk-away method, as part of the tender, that you could put the samples on, walk away, come back, which meant we were trying to automate as much of that as possible. You know, in retrospect, I can see that is a really good idea, but in practice, just doesn't work as well, because of all of those things, with regard to plasticware and thermal and all of that stuff. So I think we approached the project as, "Everything's on-deck lysis", which is what that first iteration was, and then when it became procedurally difficult, with, like, the Slicprep, we then stepped back and went, "No, we're going to need to go to off-deck lysis, we have to actually give up something. We can't process the whole lot on the robot as well."

I think the idea that the Slicprep plate was MR McNEVIN: going to solve all those problems sounded good in theory, but I never actually hopped on the tools myself to see that in practice it wasn't quite so good. But, yes, the fact that we ended up with an off-deck lysis, I guess indicates that a fully automated system just wasn't the bees knees that we thought it would be.

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> MR FOX: That's a comment with the benefit of hindsight as opposed to what was being experienced at the time>.

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Definitely a comment with the benefit of MR McNEVIN: I can't remember what I was thinking 18 years hindsight. There was a lot - so many projects have been through that laboratory in the last, you know, X number of years. To be honest, a lot of my thoughts also meld into one about my memories of that specific time. So yes, that's me thinking about it today.

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22 23 MR NURTHEN: I think because Western Australia had managed to incorporate a protocol where it was done on the deck, that meant it could be done, and CFS had done it, which meant it could be done. We were now trying to get it to work for us, but with the Slicprep.

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Ms Ientile, I haven't addressed you just yet but I will in the moment but I want you to hear the next question because you may be able to wrap them all up. have heard the major questions and you can then feel free to respond globally. And the same goes for those of you who are listening online.

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What I want to put to you is this: the proposition that at the time you are looking at automation and there's a recognition that at least with the lysis step, that might be one that is better done manually, it's a safer outcome, that you had sufficient information about full automation that it was never going to work?

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I want to put that proposition to you, because there are suggestions that have been made - we're obviously here to respond to matters that have been put in the media, but there is a suggestion that is put that the laboratory that is, those who were working in the laboratory at the time on the automation project - must have been sufficiently cognisant of difficulties with automation as a whole that persisting with it was irresponsible.

you like to comment? I do wish for each of you to respond to that, because it is an important and a very serious allegation that has been put and I would like each of you to respond to it. Who would like to go first?

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I think we persisted with the robotics MR NURTHEN: because after investigating the amount of money that we had invested in the robots and the benefits from it, and we could see that it had been implemented in, you know, Western Australia, it could be done, we tried our best to try to get that protocol working, with as much on the deck as possible, and like I said, in retrospect and in hindsight, you can look and go, "Well, when you start carving away aspects of that protocol, it becomes more and more manual", we know the manual method was fantastic but it was also a very, very long method, something like four hours to do between 12 to 24 samples. And that just wasn't going to be practical. It was also quite labour intensive as well, there was lots of pipetting steps. So persisting with the robots was part of trying to get an efficient workflow that was useable.

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MS IENTILE: In answering, I would like to provide some context from the laboratory at the time. When this method was introduced, our extraction method was Chelex. wasn't DNA IQ manually. It was the Chelex method and the goal of the project was to automate as much of the analytical section as possible.

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We knew that Chelex was unable to clean up samples, so we knew that DNA IQ provided a cleaner extract, and that was information that was supported by the work that the automation project team had done.

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So from a laboratory perspective, we were looking to replace a Chelex method with an automated DNA IQ method. I think it appears when we review the documents that while we understood the manual version - and I agree with Dr Wilson-Wilde's comments about the supposition that maybe you would never get - you know, there are factors with automation that you would never see in a manual method, I think that the trade-off was to automate those processes and I think we looked at that in view with then it was recognised quite soon after it was implemented that the off-deck lysis was a requirement to make that change and that change was made and implemented.

MR McNEVIN: So I guess from my perspective at the time, the lab had a massive backlog of work and so if we had just continued down a fully manual method, we would have been irresponsible, because a lot of work wouldn't have just got done. So, you know, I see that it was necessary for us to implement technologies that would enable us to actually process the samples required. If we'd have just continued down doing low numbers of samples in a very laborious way, the laboratory wouldn't have needed any other liquid handling platforms because we wouldn't have had the volume of work to feed them from the extraction process. So in order for us to actually get on with the business of doing DNA profiling, we needed to automate.

So was it irresponsible to persist with validating an automated method? No, I think that was the remit we were given and it was what we set out to do. It seemed to me that that was a necessary - we needed to move the laboratory forward. We needed to implement technologies which enabled us to actually get through the volume of work that the laboratory was being supplied with.

MR FOX: Dr Hlinka, what do you wish to say in relation to what I have put?

DR HLINKA: I would say the same thing as well. The demands on manual work were getting to be fairly unrealistic to be able to continue manual work. A lot of people had problems with shoulder pain and things like that doing manual work, and it was very hard for the people to continue to keep on doing manual work, and it was not fair to the staff to actually continue everything manually. We needed help with the limited resources that we had, like with the robots, to be able to go through all the case work samples that we had at the time.

MR FOX: Mr Muharam, your response, please?

MR MUHARAM: I don't have anything really additional to add to the comments already. One minor comment is that, you know, we weren't - at the time, not doing really anything novel per se, you know, we were using technologies and chemistries available to many different labs and, you know, obviously a lot of labs had already successfully used the system. So we were trying to do our best to, you know, basically keep up and, you know, adopt new technology.

Ms Gallagher, would you wish to MR FOX: Thank you. provide your response to what I have said?

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MS GALLAGHER: Sure. Like those before me, I concur with the comments that were being made with regards to implementing technology to speed up the workflow within the laboratory at the time. As you referenced at the beginning, the - there had been previous inquiries and investigations into the backlog of the laboratory and, ultimately, everybody was working with a goal to try to achieve clearing that backlog and this was one aspect of trying to clear that backlog through the implementation of the automated platforms.

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16 17 MR FOX: Now, if you would all just cast your mind to around October 2007 - so this is on the eve of going live with the fully automated system

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I will just ask if it is possible to bring up paragraph 89 of Mr Nurthen's first statement, which is the one dated 25 October.

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This is at paragraph 89. Mr Nurthen, you recount what appears to be a conversation that you had with your manager, Ms Ientile, at this time on the eve of Project 13 You indicated that you were concerned for the aoina live. yields being too low at that time, and you attached two notes that are made, and Ms Ientile has had a chance to consider those in the last few days. I'm just going to ask firstly, because it's obviously a point of disagreement that has arisen between the two of you, and I do want to have some discussion about that, and that won't surprise We can't gloss over that. vou.

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Can I just ask firstly, Mr Nurthen, would you mind just expanding on, in terms of explaining, what was the concern that you held at that time, how you came to reach that concern, and then what you did about it - that is, you obviously had the conversation with Ms Ientile, but would you mind working through those steps so that we can properly understand what was going on in your mind on the eve of going live?

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Yes, so obviously leading up to the go-live MR NURTHEN: we were still working on the protocol, it wasn't finished. I think I had raised probably on that one on the 16th saying, you know, "The yields are still down." We

obviously knew the yields were down. I think the outcome of that was for Vojtech to be talking with Promega to see was there anything that we were doing wrong that was causing, you know, these yields to go down. PerkinElmer at this stage; we had already reached now out to Promega.

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I think there was the possibility of thinking that maybe there was alcohol left over from the washes that was interfering with the beads being eluted. Yes, I think I raised it, I think basically we would need more time to continue to develop that protocol.

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MR FOX: And were you, so far as you can remember - was your advice that it should not launch?

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I can't recall if I said it should not MR NURTHEN: I know the feeling was we weren't ready, but I can also appreciate that the laboratory itself had other priorities as well. So I can't recall using those words to Vanessa saying, you know, "I do not support this going live". Obviously I supported it going live, in terms of getting standard operating procedures written up and developed and implemented within the laboratory. I would have disagreed with - I don't think we were there yet because those yields weren't up.

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MR FOX: I'm just trying to get a sense of how vehement your view was, how strong your view, so that Ms Ientile can hear everything you have to say about this so that she can then respond to it. But is this a matter of - I don't expect it to be a casual conversation, but how formal was the discussion and how strident were you in expressing your views?

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MR NURTHEN: Well, it was a formal discussion in the sense that it was part of the weekly update that I had with Vanessa for the project, so it was part of that meeting that we would have every other week to discuss how the project was going, and it wasn't just that part of the project, there were other parts of the automation project that we'd also discuss as well. Like I said, I can't recall not wanting to go live, but I guess the context being that we had received the instruments in roughly 2006 and we were nearly at the end of 2007 and we still hadn't brought them online.

 MR FOX: Ms Ientile, would you like to now provide your response to this, and having read through those two notes that are attached to Mr Nurthen's statement?

MS IENTILE: Yes. I don't have any independent recollection of any conversations that we had at the time. I do acknowledge that we did have weekly meetings and they were my handwritten notes from those meetings.

Obviously my writing indicates that I was aware that we had discussed yields in terms of the automated method in comparison to the manual method, and that was referring to specifically the two DNA IQ methods.

It was our - as I mentioned before, it was our intention to replace a Chelex method with an automated method, so I - while I can't recall the details of the conversation, from my research in preparing for this and access to documents, it appears that we had had discussions around comparing the DNA IQ method automated with our Chelex yields, and they were - and our understanding was that was comparable.

It lists that there were actions and it has a note to say "Impact on going live", is what I have written in the status. I would indicate that that may have been an acknowledgment of the outcomes of the actions being taken. May need to consider - reconsider whether the go-live was going to happen on that particular date.

Then in the second note, from 16 October, yes, it indicates that we did have further discussion around the yield and the results using the automated process, and that the actions listed indicate that the project team was continuing to work on the issue, and I believe that the notes that I made there were an outcome of the discussion. But I did not at any stage write that we had made a decision to not proceed, and I don't - I don't have a recollection of that event.

MR FOX: Was it your responsibility, in the end - you were the person who had responsibility to decide whether it would go live?

MS IENTILE: It would have been my - ultimately, as managing scientist, but I believe it would have been made in consultation with the automation project team and taking

into consideration factors in the laboratory, the advice that they had given, potentially conversations with other staff as well, although I have no independent recollection whether those occurred.

MR FOX: And do you have any recollection of why, in the end, having that responsibility - and I appreciate you have indicated you had discussions with colleagues - but having that responsibility, do you have any recollection of why you were satisfied that you could approve this going live at that time?

MS IENTILE: I do not have any specific recollection.

MR FOX: Is there anything that you have read in terms of the documents that you have been provided with for the purpose of preparing your evidence - is there anything that has refreshed your memory that might help you to be able to answer that question? No-one is asking you to guess, but is there anything that you have read that would help refresh your memory as to what might have led to you being satisfied that you could have said "Yes"?

MS IENTILE: There was an email that I sent to all staff just announcing that a date had been set for the go-live, and in that email, it says that they will start using platforms for casework extraction on that date, and that the initial steps will be training of analytical staff, so there was a number of aspects to going live.

Going live did not - from reading this, my understanding was going live didn't mean that we stopped all manual extraction and every sample was done on the automated platform; it was a slow implementation that involved training, workflow processes, changes to the way the scientists who were examining exhibits and sampling would be doing that, and that involved a whole lot of training.

There was also the aspect of being able to provide detailed information sessions to all staff around the whole validation process, and discussions around that, and that's outlined in the email that I've sent. So from that, I can - I believe I can consider that those, all those aspects, were thought through.

The other aspect of that is that it outlines which

samples - and I'm just checking; I have a copy of that 1 2 email - which samples would be run on that, on that 3 platform at that time to provide that slow implementation. 4 5 And these emails you are referring to or looking at now, these are the attachments to an outline of evidence 6 7 that wasn't - it's not a sworn statement? 8 MS IENTILE: Yes. 9 10 MR FOX: But your solicitors provided it to the Commission 11 12 in response to having read this particular part of Mr Nurthen's statement? 13 14 15 MS IENTILE: That is correct, ves. 16 17 MR FOX: So we'll be able to know precisely where they are and they can be tendered in due course. 18 19 Sorry, did you wish to add anything further in terms 20 21 of your answer about the decision-making process? 22 23 MS IENTILE: No. 24 25 Mr Nurthen, did you not, then, express your MR FOX: views - that is, your concerns about the low yield and 26 27 concerns about the fully automated process going live - you didn't express those concerns to anybody above Ms Ientile 28 29 in management, did you? 30 31 MR NURTHEN: Above Vanessa? 32 33 MR FOX: So in other words, she has made the decision that 34 it's going to go live. You'd formed the view that you had 35 some concerns. Did you escalate those concerns anywhere 36 else within the laboratory or amongst management at all? 37 MR NURTHEN: 38 No. 39 40 MR FOX: And can you explain - and I'm not asking this in a critical way but just so that we understand - why you 41 considered that you didn't need to do that? 42 43 44 MR NURTHEN: I think because the project wasn't stopped. We were going to continue to develop it.

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"Here it is, this is done", walk away, "There you go"; it

was going to be continued to be developed.

So with the benefit of hindsight, do you look back at your decision to act the way you did - would you have done anything differently?

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MR NURTHEN: Oh, it's easy in hindsight to take a look back and go, "Well, maybe I should have raised it", maybe -I don't know. I can't answer that to know whether or not I would have raised it or wouldn't have raised it.

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MR FOX: What I'm testing with you is your level of Because there's a concern that you don't think it's good enough to go live, but you can see that after it goes live there may be further work to be done and you might become satisfied as that goes along, and there's a concern that is held that. "I have such a concern that if it goes live, I feel quite conflicted about this because I think it's the wrong thing to do." I'm just trying to test what the level of concern was that you had in your mind at that time?

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MR NURTHEN: I think if you will look at Chelex, what we were delivering was better than Chelex. We were going to get cleaner DNA without the need to do additional processing, hopefully, and we were going to, I guess, increase the capacity within the laboratory. So I would have to concede that that was one of the - probably one of the factors that, whilst we weren't getting as much of the DNA, we were still getting DNA profiles from them.

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What isn't, I guess, included within Project 13, that graph at the end that talks about the actual yields, is all of those - all of those samples were then subsequently DNA profiled and all down to the one in 100 dilutions were giving nearly full DNA profiles as well.

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42 43 THE COMMISSIONER: Sorry, I have just a couple of questions, if I can just interrupt for a second. We have talked about decreased yield, but it wasn't just a decreased yield, I mean, you know, it was a dramatic decrease, not for all samples but for some of the samples. It was - I mean, I think a figure has been put around of a 92 per cent decrease. That's not just a decrease. dramatic, isn't it?

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MR NURTHEN: That's comparative between the manual IQ and the automated IQ, but not a comparison between Chelex and

automated IQ. So we still could have obtained DNA profiles from some of those samples that maybe Chelex couldn't.

THE COMMISSIONER: Did you see a significant increase in the number of samples following the implementation of the automatic method where you got no DNA detected results?

MR NURTHEN: I can't answer that because at the time we weren't doing - we were amplifying everything at the time, from what I recall. Even if it had a zero quantitation value, I think they were still being - this was in 2007, we were amplifying everything.

MR McNEVIN: I think so. I think that might have been --

MR NURTHEN: There was no threshold to meet. Everything was going through, irrespective.

THE COMMISSIONER: The full procedure --

MR NURTHEN: Yes, yes.

THE COMMISSIONER: While I have interrupted, Mr Fox, I'm going to keep going. Could you just explain one thing to me. I'm taking some time and getting on top of everything. In paragraph 49 of your statement, you attach a number of SOPs, starting in October 2007 and going through to 2017. Can you just explain to me what that represents? Because you have talked about continuation of steps, so I just want to know, does that link at all in to what you then were doing afterwards?

MR NURTHEN: Yes. So the way I look at the SOPs, the SOPs are the instructions, the higher-level instructions. Obviously they contain individual steps as to how to prepare the samples and put them on the robot, but what the SOP doesn't, I guess, show you is the individual steps on the robot, so the actual robotic method and what changed between those robotic methods.

THE COMMISSIONER: So does this signify - all of these, were these variations to the method?

MR NURTHEN: Some of them were. Version 1 was a version - and I think this is outlined in my second statement in the table that I provided - where it aligned each SOP with an automated version protocol.

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THE COMMISSIONER: So was there - I mean, does that represent at all just routine minor adjustments or does that represent any action being taken to try and do something about this yield problem?

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Because I can't get inside those programs to MR NURTHEN: know, I don't know what actually changed within them, because it could be, like I said previously, around a mixing step or something to try to increase it, but I can't tell.

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THE COMMISSIONER: Can I just go back to the question a bit. I know you said you amplified up everything; irrespective of whether you got measurable DNA, as I understand it, you put it through the procedure for amplification. You didn't answer the question whether, at the end of the day, you ended up with more samples that didn't have a result?

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MR NURTHEN: The answer is I don't know because I wasn't a reporting scientist at the time, to know whether or not we were seeing less samples with DNA profiles, but it would be difficult to know whether it was the method or the sample that was supplied, as to the reason you didn't get a DNA profile.

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32 33 THE COMMISSIONER: Well, if you just introduced a new method and suddenly there was an increase in - if it were the case there was an increase in no results coming out of that method, it's not an illogical conclusion that at least you would test to see if it was the method that was the So I'm just wondering whether there was - who problem. would know that?

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MR NURTHEN: I guess the reporting scientists at the time. They were the ones who were actually looking at the DNA profiles and doing the interpretations.

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Can I add to that? So before it was MS IENTILE: mentioned that all of the samples were amplified, there wasn't a cut-off to stop a sample from progressing. was also, in the whole casework management process at the time, no restrictions on reworking or concentrating samples, and the case managers or the casework scientists who were the ones who examined the exhibits and selected the samples to go through the process of DNA profiling,

would review them on a case-by-case basis and take action based on that.

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In reviewing what was available to me, there was no indication that there was any - in terms of the go-live or following that, any indication that people had raised any concerns about that at the time.

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If I can also, in relation to your question about the versions of the SOP, to expand on what Tom was saying, there's the aspects that he was talking about, but in those versions, I think, version 1 was the first version, which was used to train the staff in the analytical section to use the protocol; version 2 was some adjustments in the writing of that protocol to make it clearer to people, which was feedback that was given; my understanding of version 3 is when the additional work that the project team was doing was when they introduced the off-deck lysis step.

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26 27 THE COMMISSIONER: Can I just go back to one other matter. You said that the comparison was between Chelex and not necessarily - I can understand that if that was an 8 per cent difference or a 10 per cent difference, you could say, "Well, you know, it's different methodology and we've increased - there's a decrease, but there was an increase in the ultimate result". But 92 per cent, the DNA IQ method was not a hundred per cent better than Chelex, was it? You see what I'm getting at and if --

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MR NURTHEN: I know, because it's not --

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THE COMMISSIONER: If you have 92 per cent of absolute DNA yield, it just doesn't - the mathematics don't seem to suggest that you would get increased DNA sufficient to overcome that deficiency.

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I think it's because it's about quality and MR NURTHEN: quantity, it's not both, and that's a very difficult thing to, I guess, measure with respect to the Chelex and going, "We know that Chelex gave us buckets of DNA", it always did, that method, but it also gave you the inhibitors, it would also co-extract bacterial DNA as part of the process Whereas DNA IQ was definitely giving you far more cleaner - so whether or not you could say, you know, DNA IQ at its worst was still better than Chelex, that's where I'm sort of saying in terms of going, "Well, we didn't actually directly compare, then, the Chelex method with the

automated IQ method to see how different they were going to 1 2 be." 3 You went back to Chelex at one stage, THE COMMISSIONER: 4 didn't you? 5 6 7 MR NURTHEN: After we had the contamination, we stopped 8 and then --9 THE COMMISSIONER: Is that what caused you to go back, the 10 contamination issue, not the yield? 11 12 MR NURTHEN: Yes, yes. 13 14 15 MS IENTILE: I would like to note also that in referring, Commissioner, to the 92 per cent, you are referring to 16 17 information that was in the Project 13 report, and I believe that all of us here have indicated that that was 18 19 a draft report of which there were multiple versions, so there was not a finalised report. 20 21 22 THE COMMISSIONER: No, but the graphs and the tables that 23 indicate that degree of reduction of DNA are not in the writing but in the results. 24 So even if it wasn't a final 25 report, surely those data were still the data? 26 27 MS IENTILE: Whether that was complete data, though, is 28 the question, I think. So whether - as it was incomplete, 29 whether there was additional testing done and not added to the draft report, I don't know. 30 31 32 MR NURTHEN: I think that's likely. I think that's raw 33 data which is - well, I was able to say for the DNA 34 profiling, for instance, that the DNA profiling showed that 35 even in that 1 in 100 dilution that looks, you know, 36 comparatively compared to the manual method, very low 37 yields, they were still giving us DNA profiles. 38 39 THE COMMISSIONER: Were you going to say something, Mr McNevin? 40 41 It was on the point earlier about the 42 MR McNEVIN: 43 collecting of data, I think. 44 THE COMMISSIONER: Sorry? 45 46 47 MR McNEVIN: I was just going to say I don't recall, and

over the years I did do various data mining exercises. I don't recall doing that at the time and I also don't recall anyone else raising it as something that would be a worthwhile study.

THE COMMISSIONER: By which you mean no-one said, "Hang on a second, we're suddenly getting --"

MR McNEVIN: That's right, and I don't recall any of the other sort of senior scientists at the time saying "Hey, should we be looking into this?" I don't recall any of that conversation happening.

THE COMMISSIONER: I'm going to turn to see if anyone on the screen wants to add anything to this discussion?

MS GALLAGHER: No.

MR MUHARAM: No.

DR HLINKA: No.

MR NURTHEN: Commissioner, could I just add, as well, that with the Chelex method, we had Chelex implemented for various substrate and sample types - so you could do semen, blood, cells, hair, tissue, and they were all done with different protocols. But with the IQ, with this validation, we were looking at just cells and blood, which represented a subset of our work. So cases, for instance, that would have been a sexual assault case, still would have been extracted with Chelex at the time. We didn't - that was outside of the remit of this first part of the project. We always intended to go further down the path and use DNA IQ for everything, but this first step was looking at cells and blood.

THE COMMISSIONER: Okay. Let me say two things on that. First, the question that has been nagging at me about the temperature is if 37 was a perfectly good way of doing it, why did people do it at 65?

MR NURTHEN: Because the --

THE COMMISSIONER: What's the advantage of doing it at 65?

MR NURTHEN: Because the lysis buffer that was supplied by Promega didn't have any Pro K in it. So heating it up with

their lysis buffer relied on the chemicals.

THE COMMISSIONER: By "Pro K" you mean Proteinase K?

MR NURTHEN: Yes. Which, like I said, was piggy-backed on that work by Komonski et al which looked at using this TNE buffer with the Pro K that would digest down those cells prior, then, to doing the extraction.

THE COMMISSIONER: I have one other question, I'm sorry, while I'm at it. Just talking about the samples that you were testing and the yield, I can understand conceptually that if you are doing a sample that has - you know, that you might have picked up from a glass or something, you know, that you don't get DNA, you say to yourself, "Okay, well, there wasn't enough DNA to be detectable". But blood seems to be in a different situation. Do you recall any instances where, during the automated protocol and using it this way, that you have a lot of blood and you have no DNA? It doesn't seem to be possible, does it, to extract no DNA from a blood sample?

 MR NURTHEN: I guess you would expect to get something out of a blood sample, but every blood sample, I guess, is quite unique, because at the time - if we're talking mock samples, at the time the blood was drawn, we're deriving the DNA from white blood cells, not from the red blood cells. So if someone had an infection at the time you would have far more white blood cells than you would normally. So between samples, between bleedings, you could get wildly different results between the same amount of blood, irrespective of the method that you do.

So is it possible that someone has no white blood cells? I guess it is, it's probably not particularly likely. I would normally expect that a blood sample would give - you would extract DNA. The volumes that we were working around was roughly 30 microlitres for a neat sample, which is a very --

THE COMMISSIONER: I understand it is a small sample, but if there is anything that is going to give you DNA, you would have thought it would be a blood sample.

MR NURTHEN: And for the neat ones we were getting a fair bit of DNA out of that. Like I said, they were all generating DNA profiles --

THE COMMISSIONER: Even with the automated approach?

MR NURTHEN: Yes, they were still generating profiles down to 1 in 100 dilution of that, and I'm not sure whether Chelex would have been able to necessarily perform the same way, but we didn't do the comparison to know.

THE COMMISSIONER: While we're talking 20:20 hindsight, Mr Fox has raised with you, looking back at the validation procedure encompassed by Projects 9, 11 and 13 (indistinct), looking back on it, do you have any observations to make about the quality of that validation process?

 MR NURTHEN: I think the documentation - we didn't document it nearly as well as we should have. hindsight, I think as we did each change, we should have written that into a report at the time, so it would have been very, very clear, it wouldn't have been a - we're relying on memory, you know, what did we do, what did we I think it should have been incremental and it should have been developmental - you get up to a certain point and then you are happy with that and then you go and do the rigorous testing after that. I think we took it quite naively that the method that we were supplied was going to work, and even with a minimal modification, which we thought substituting a bit of plastic ware shouldn't have changed the outcome, but it potentially did, or that method wasn't as good as what they said it was.

THE COMMISSIONER: Just while I'm on that question again, Mr Fox raised the report that came out in 2005, (indistinct) and I picked up one thing in that, that it said, in fact, it can take you over 12 months to validate, therefore, it is recommended that you use validations from other laboratories. Were you aware of that recommendation in that report?

MR NURTHEN: I think so. I mean, like I said, we'd contacted Western Australia, we had obtained their method and their validation, and I think we --

THE COMMISSIONER: Is it common to use validations from other laboratories?

MR NURTHEN: As the basis, yes. If they've done the hard

yards and they have tested it rigorously.

MR McNEVIN: I mean, to a certain extent, that's what you did by taking the CFS protocol, right? That was from the Toronto laboratory --

THE COMMISSIONER: That is the point, that you did take the CFS protocol.

MS IENTILE: But that is instead of developing your own protocol from scratch.

MR NURTHEN: Which, if we had gone for any other chemistry other than DNA IQ, we would have had to develop from scratch an automated protocol.

MR FOX: On that point, the modifications made, they were permissible in the sense that you have a validated system from another manufacturer, you can see another lab has used As I understand some of the evidence - it may not be entirely in this Inquiry but maybe in the previous Inquiry - it's not as though you can't change or modify that process to a point. Did you, just while we're on that topic - we've been through the various modifications that I'm asking this of Mr Nurthen firstly but were made. I will ask others in a moment - did you feel that the changes that you were making, those modifications we went through, other than the fourth one, the plastics, and I appreciate that was significant in itself (indistinct), were they within acceptable parameters of change in that you weren't then engaging in essentially the creative work that Ms Ientile was alluding to as coming up with a completely different system?

MR NURTHEN: I think all of the temperatures or any of those parts of that protocol were based on something that we had already observed, that we had already seen, either elsewhere. We didn't, for instance, go, "Well, 37 degrees, no-one has used 37, let's just try 37 degrees." There were reference points for everything that we did.

THE COMMISSIONER: Because a higher temperature normally gives you a better result, doesn't it?

 MR NURTHEN: It can, but I think what was noted in the Western Australian report, they even tried at 95 degrees lysis, but it resulted in not obtaining DNA profiles

3	THE COMMISSIONER: At 95?
4 5 6 7	MR NURTHEN: There is a point where you can, I guess, overdo it and damage the DNA that you are trying to extract.
8 9 10	THE COMMISSIONER: What temperature do you have to heat DNA to, to get it to denature?
11 12 13 14 15	MR NURTHEN: In amplification, yes, you can do that, but it is probably in conjunction with, like, the lysis chemicals and the temperature that then damaged the DNA, is what I expect.
16 17 18 19 20	MR FOX: Can I come back to the going live part and the questions I was posing before to you, Mr Nurthen, in terms of your
21 22 23	THE COMMISSIONER: I'm just turning to see if anyone here wants to comment.
24 25	MR FOX: Sorry, did anybody on the screen want to add anything to this particular point?
26 27 28	DR HLINKA: Yes, denaturation occurs at about 56 to 58 degrees, usually.
29 30 31	MR FOX: Would you mind just saying that again? You are just fading out there.
32 33 34	DR HLINKA: DNA starts to denature at about 56 to 58 degrees Celsius, depending on conditions.
35 36 37	THE COMMISSIONER: Okay, thank you, that's very helpful.
38 39 40 41	MR FOX: Thank you. When you were expressing your views about low yield to Ms Ientile, had you formed in your mind any views about what might be causing that?
42 43 44	MR NURTHEN: No, I think we were stumped. We were genuinely stumped. We had tried a few different things, we had contacted a few different people to try to work out why
45 46 47	we were getting those lower yields. I think the concern would have been that it was getting onto the beads, or it wasn't binding on the beads initially, and just being
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because they think it had damaged the DNA. So there's --

essentially washed away, or it was getting on the beads and they weren't being eluted.

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Mr McNevin I want to go back to the territory of where I asked Mr Nurthen about why he didn't escalate. We've heard that the two of you were sitting next to each I appreciate you were in a different team. are a scientist yourself, you have a scientific code, et cetera, that quides you. You were aware of Mr Nurthen's concerns?

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MR McNEVIN: To be honest, I really can't recall what level of understanding I had around those concerns and whether he directly expressed them to me, whether we had discussed them earlier in the project but not at the end or any of that kind of detail. I really don't remember. be honest, the whole implementation of the whole automated protocol is quite vague in my memory. As I said, so many changes went through that analytical laboratory when I was looking after it that they've all kind of melded together in my mind and I don't have any specific recollection of that. I'm sorry.

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26 27 THE COMMISSIONER: Mr Nurthen, you said you thought at the time, as an explanation for the yield drop, that it could have been something about it not getting onto the beads or not being eluted from the beads. Do you recall whether you took any steps to try to check either of those? (

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MR NURTHEN: Yes, I think we did. We saved the lysate. So that the normal protocol, the CFS protocol, basically binned the lysate, but I think from day 1 we introduced a step that we would save the lysate into a deepwell plate. I can recall, but I'm not sure whether or not this was pre-October 2007 or whether this was in 2008 when we were dealing with the contamination, there were experiments about re-extracting it from the lysates to see if that's where the DNA was going.

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46 47 THE COMMISSIONER: Because my first reaction when you said "We thought this was the problem" was, well, then, why didn't you do something about it, if you thought that was the yield issue. But why would you be doing that with the lysate to see where the DNA was going if it was only a decontamination question? You said, "I'm not sure whether it was for the yield" - you remember doing these experiments and you said you weren't sure whether it was

for the yield or for the contamination. Why would it work --

MR NURTHEN: Well, we went back to those lysis plates and re-extracted from them to work out what was going on with the contamination. So that was actually what helped us diagnose parts of the contamination, because we could go back to these lysate plates, re-extract and see, oh, the lysate wasn't contaminated, but the sample was contaminated.

THE COMMISSIONER: I see.

MR NURTHEN: But I am trying to recall whether or not we had done additional experiments on re-extracting from those lysates prior to going live, and I can't recall. I know we did at some stage do those experiments.

THE COMMISSIONER: When you did those experiments - sorry, you recall doing those experiments or the experiments with the retained lysate for the purposes of the contamination issue?

MR NURTHEN: Yes.

 THE COMMISSIONER: You can't recall one way or the other whether you did it for the purpose of re-examining the yield if the yield problem arose from the lysate to the beads and then coming off the beads, right? If you had done it for the purpose of yield levels, you would have had those results somewhere, wouldn't you?

MR NURTHEN: Yes, possibly, and we may even have raw data that has that somewhere in there. Like I said, I can recall - and this might have been in some of those automation meeting minutes where we were talking about the lower yields and whether or not any of those meeting minutes talk about the possibility if it not getting on the beads and being in the lysate. I honestly can't recall. Yeah.

 I think that would have been one of the logical solutions that, when you're trying to backtrack and work out at what point you weren't getting DNA, the binding is step one and the release is step 2. So I imagine that it would have been before, because we would have gone, "Well, we've got those lysates, let's go back to them, let's see

1	if we can get the DNA."
2 3 4	THE COMMISSIONER: Did it occur to you that it could have been a problem with the lysis step itself?
5 6 7	MR NURTHEN: I didn't ever think that the lysis was the problem.
8 9	THE COMMISSIONER: You didn't ever?
10 11 12 13 14 15 16	MR NURTHEN: No, I didn't. I didn't ever think that the lysis was - because that was an established protocol, using Proteinase K in a buffer and incubating for a period of time was like a standard protocol that was out and about within the forensic domain. So I wasn't concerned about getting enough DNA off the substrate to start with; it was always the binding and the release.
18 19 20 21 22 23	THE COMMISSIONER: One more thing just for ongoing purposes: looking at it now, if you wished to retest samples that which, for some reason or other did, not work, would you retest the lysate or would you go back and start all over again on those samples?
<ul><li>24</li><li>25</li><li>26</li></ul>	MR NURTHEN: I don't think we have the option to retest the lysate anymore. I think I would
27 28 29	THE COMMISSIONER: You would go back and re-extract?
30 31	MR NURTHEN: I think they were kept for many, many, wany years.
32 33 34 35	THE COMMISSIONER: You would have to go back to the samples themselves?
36 37	MR NURTHEN: I think now you would have to do that.
38 39 40 41 42	THE COMMISSIONER: It would not help to simply look at so you don't have any - you don't believe - not "any", but you don't believe that the system has stored the extracted DNA anyway?
43 44 45	MR NURTHEN: Sorry, we did - like I said, we did store all of those deepwell plates with the lysates in them for a number of years, but I think they have since been

discarded.

1 2	THE COMMISSIONER: That's what I mean, now; you don't necessarily have them now.
3 4	MR NURTHEN: Correct.
5 6 7	THE COMMISSIONER: You would have to go back and start from scratch with the original samples.
8 9 10 11	MR NURTHEN: Unless we had some substrate left over. Spin baskets - are they still kept?
12 13 14 15	THE COMMISSIONER: For more certainty, just in case it was a problem pre-lysis, the practice would be to go back to the original samples, wouldn't it?
16 17 18 19	MR NURTHEN: Yes, but if we had the spin baskets, that would also, I guess, indicate if that was a - the pre-lysis issue. So the spin baskets
20 21 22 23 24	THE COMMISSIONER: But if you looked at after the lysis step and you had lots of DNA there, you'd be okay, but if you didn't have a lot of DNA there you'd have to go back and start again from the samples?
25 26	MR NURTHEN: It would be ideal.
27 28	THE COMMISSIONER: Yes.
29 30	MR FOX: Mr McNevin, you wanted to say something?
31 32 33	MR McNEVIN: Yes. I think we did used to also split the samples back in the day.
34 35	THE COMMISSIONER: You used to what, sorry?
36 37 38 39	MR McNEVIN: Split the samples, so there may be an un-extracted portion remaining from some of those. I can remember the storage of the lysates and
40 41	THE COMMISSIONER: You mean the samples after lysis?
42 43	MR McNEVIN: Both. So both the
44 45 46	THE COMMISSIONER: You mean the original sample? When I'm talking about samples, contrast the lysate
47	MR McNEVIN: Yes.

THE COMMISSIONER: You used to take the original sample, split it, put one through and keep the rest, the other part?

Some of them, yes, I think.

process; with the scientists actually doing the

resolve quality issues and stuff like that.

on the screen in relation to this topic?

what they had previously been giving us.

you couldn't put certain sizes of samples through and that

was where Vanessa was talking about part of that education

examinations, we had to train them to take less sample than

the spin basket, which is the - after you've carried out

a coarse sieve to then retain some physical materials.

be a portion, some of them, left. I'm not sure that

much left when you finish doing the DNA extraction.

the lysis, you'd centrifuge the sample essentially through

part can then be retained and it is a question of how long

everything - some samples kind of are not - there's nothing

at some point. I think there may have even been an issue

with - I can't really remember, but I think it might have

of knocked over and - in the freezer or some sort of -

because we had a lot of storage issues with space. We

been an issue with storage where some of them were all sort

I think we did ultimately get rid of all those lysates

So, ves, I think there would be some

But based on the size because with DNA IQ,

And then there is also the - what we refer to as

Yes, and we have used them in the past to

You take samples off that and the other

So there would

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MR McNEVIN:

MR NURTHEN:

MR McNEVIN:

MR McNEVIN:

THE COMMISSIONER:

it has been retained for.

retained.

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46 47 MS GALLAGHER: No.

THE COMMISSIONER:

lacked a lot of space.

DR HLINKA: No.

MR MUHARAM: No.

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Is there anything anyone wants to add

MR FOX: I have one more question to clarify around the going live part, this is really - the decision having been made, Ms Ientile, to go live, and you're armed with Mr Nurthen's concerns, he has expressed those to you, you've indicated that at some point you must have satisfied yourself enough, did you - do you recall whether or not, having been armed with Mr Nurthen's concerns and this whole issue about low yield, whether that was something that you might need to express to a third party like the Queensland Police Service, that would be relying on results coming out of the lab?

MS IENTILE: I don't recall any specific conversations around that. I believe, based on the information that I've reviewed, that I was comfortable that it was comparable to our existing manual method so therefore that was --

 MR FOX: I just want to be clear, and I'm not asking you to guess, but do you have any recollection of escalating it, in that sense of informing, informing the Queensland Police Service, or indeed any other body that might rely on results coming out of the lab, that there might have been any concerns around using the automated process?

MS IENTILE: I don't have any recollection.

MR FOX: I think that's a convenient point because I'm going to move into the contamination issue that arose fairly shortly after --

THE COMMISSIONER: Your timing is pretty good. There are only four minutes to go.

 MR HOLT: Commissioner, given there are only four minutes to go, might I, in that time, for Ms Ientile just ask a couple of clarifying questions, that would only take a few minutes. I'd be very grateful. I'm going to ask those initially of Dr Nurthen, if that's okay.

 I just want to be clear about maths, if we can do this. There obviously has been a lot of talk in this process about the 92 per cent number and I just want to make sure that we are clear about what the 92 per cent is of, if I can put it that way. As I understand it, the 92 per cent is the difference between yield from the manual DNA IQ method and the automatic DNA IQ method. Is that your understanding?

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Am I right, though, that the manual Thank you. DNA IQ method was that one was being used as part of the

That's my understanding of when you actually

process of getting to the point of automation, not one that was actually ever in place in the lab; that wasn't what you were replacing?

compare the two or when you divide the two - that's what

MR NURTHEN: Correct, we weren't replacing that.

MR HOLT: I understand. So what was being replaced, in fact, was the Chelex manual system?

MR NURTHEN: Yes.

you get.

MR HOLT:

MR HOLT: And the 92 is not a comparison in terms of yield between Chelex, the system that was actually in place, and which r and everyone else would have been used to, and the automatic DNA IQ extraction method?

MR NURTHEN: Correct, there are no direct comparisons between the two.

MR HOLT: No, I understand that. In fact, we have seen some material, just in the form of emails and things which the Commission has, which suggest that, in fact, the Chelex DNA - the Chelex manual extraction method was comparable in terms of yield, maybe slightly better but not much, than the automatic DNA IQ method. Can you assist us with that? Do you have any memory of that comparison being done at a11?

MR NURTHEN: No, I don't, but, like I said, I know Chelex can give you very high yields but it is the quality that's the problem.

I guess what I'm interested in, in terms of the MR HOLT: significance of the change, is whether or not we're talking here about the 92 per cent being a difference from that which was then being - the yield that was then being got from DNA and that which was to then now be got from the automatic DNA IQ method.

MR NURTHEN: I guess without a comparative validation,

like I said, I'm not aware of there being any validation 1 2 done on Chelex at all within the laboratory, so there's no 3 reference point to actually directly compare the results that came out of automated IQ and Chelex, like sample per 4 5 sample. 6 I understand, thank you so much. We literally 7 MR HOLT: have one email, in the limited time that we have had, which 8 suggests that the yield extracted using Chelex and the 9 yield extracted using the automatic DNA IQ are, in fact, 10 similar. 11 12 MR NURTHEN: 13 Okay. 14 15 MR HOLT: I take it you have no independent recollection, I don't expect you to, given the time. 16 17 It's possible. MR NURTHEN: 18 19 20 THE COMMISSIONER: To look at the comparison, you're saying the comparison between Chelex and the automated 21 22 system? 23 MR HOLT: 24 Yes. 25 THE COMMISSIONER: 26 You say you have an email to suggest 27 that was similar? 28 29 MR HOLT: Yes, we have provided that to the Commission. 30 31 THE COMMISSIONER: I'm not on top of every email. 32 33 MR HOLT: I think it was provided not long after we 34 received it about 24 hours ago. Thank you, Commissioner. 35 36 I just want to see whether you have any recollection of that work being done at all. And again I acknowledge it 37 was a decade and a half ago. 38 39 MR NURTHEN: No, I don't. 40 41 Just finally, in terms of the significance of 42 MR HOLT: 43 go-live, and I'm sorry, Commissioner I've been slightly longer than --44 45 THE COMMISSIONER: No, that's all right. 46

MR HOLT: Thank you.

In terms of the significance of go-live - Ms Ientile I might ask you this - there was some reference to the fact that you took some handwritten notes - do you recall those?

Would it be possible to bring up Dr Nurthen's statement and page 606 of that, please, which has the second set of notes.

You will recall this was effectively "implement and optimise", that phrase that was used, Ms Ientile? Do you recall that?

MS IENTILE: Yes.

MR HOLT: I will ask you both, but what did you understand to be meant by "implement", and particularly "optimise", in that context?

 MS IENTILE: I believe my understanding was both twofold - one about yield and one also about the usability of the method, in terms of (indistinct) as a process that's used within the laboratory.

 MR HOLT: Thank you. Dr Nurthen, I know you know it because you helpfully provided it. Again from your perspective, "implementing" and "optimising", and I guess particularly off-deck lysis, those sorts of things which occurred, what was the process of ongoing optimisation that was to be done following go-live or were you just kind of leaving it to see what happened?

MR NURTHEN: No, I think I take that to mean that, yes, implement, but continue to work on the method to get those yields up. Continue to work on in the background.

MR HOLT: And again in terms of the significance of go-live, and, Dr Nurthen, you might recall this, but I think it's clear from the memorandum that Ms Ientile sent at the time to all staff, that initially it was only to be that the automated DNA IQ system was to be used for high-volume backlog cases, not everything across the board?

MR NURTHEN: That's my understanding.

MR HOLT: So in that sense, it wasn't like go-live

1	involved everything suddenly moving to automated DNA IQ?
2 3	MR NURTHEN: And like I said, not everything was validated
3 4	for IQ anyway. Anything outside of cells and blood wasn't
5	going to be put on the robot. So sexual assault cases,
6	tissue, hair - none of that was validated for it.
7	tissue, nati - none of that was varidated for it.
8	THE COMMISSIONER: So none of that was validated for it;
9	it wasn't
	IL Wasii L
10	MR NURTHEN: We hadn't even - sorry?
11	TR NORTHEN. WE HAUTE C EVEIL - SOLLY!
12	THE COMMISSIONED: Sorry can you just I know we're
13	THE COMMISSIONER: Sorry, can you just - I know we're
14	taking time, just to clarify that, are you saying that the
15	automated method was not to be used other than for backlogs
16	at that time, when it went live?
17	MD NUDTUEN. Ween't to be used for
18	MR NURTHEN: Wasn't to be used for
19	THE COMMISSIONED. Now acces
20	THE COMMISSIONER: New cases.
21	MD NUDTUEN: somen or heir or ticque because we hadn't
22	MR NURTHEN: semen or hair or tissue, because we hadn't
23	even developed that part of the protocol.
<ul><li>24</li><li>25</li></ul>	THE COMMISSIONER: What was it to be used for?
26	THE CONTISSIONER. WHAT WAS IT to be used for:
27	MR NURTHEN: For blood and cells, and I think initially -
28	and you have seen within that email, or within that
29	memorandum, it says "for volume crime samples".
30	memorandum, re says for vorume of the sampres.
31	THE COMMISSIONER: I don't know if I understand what's
32	encompassed
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34	MR NURTHEN: Crimes against, like, vehicles, break and
35	enters, rather than the major crimes, crimes against
36	a person.
37	a por con.
38	MR HOLT: In other words, go-live involved a relatively
39	small part of the workload, probably not by numbers, but
40	lower-volume crime, not dealing with that major crime
41	material, and there was to be a process of optimisation
42	that you were to lead in that respect?
43	ind you not a contract toopood.
44	MR NURTHEN: Possible. I don't - I didn't recall the
45	volume crime being the only samples, I just assumed that
46	all the - all of major and volume were going on there,
47	I don't actually have a recollection of that.

 THE COMMISSIONER: It is still pretty well 1 o'clock, so

Thank you, Commissioner. I'm very grateful for

I'm not going to extend it. I think that if we can come back at 2 o'clock; is that convenient for everybody?

So for the break, those on the screen, thank you very much. You can just put yourselves on - take your cameras off, if you like, and leave the Zoom on. We know it's an open-ended Zoom, so it's probably better to do that, because if you go off, you will probably find you won't be able to reconnect and that will be a problem, so I suggest you just come back and turn your cameras on at about 2 o'clock, if that works. Okay, we will adjourn.

## **LUNCHEON ADJOURNMENT**

MR HOLT:

that time.

MR FOX: Two matters before we start. It was just indicated to me before you came back on that people in the back of the gallery are finding it sometimes difficult to hear you, whether the microphone could come up or otherwise. Just so that you are cognisant of that.

The other thing is Mr Diehm indicated that he would like to ask a few questions as well, so now is the time for him to do that.

THE COMMISSIONER: Okay.

MR DIEHM: It's on that topic we were on just before lunch, and before counsel assisting moves on to the next topic.

Mr Nurthen, in the first instance I might direct my questions to you, but of course, in keeping with the Commission's process here, allowing for any of the other witnesses to answer them to the extent that they think they have something to add or to offer. I wanted to ask you about, firstly, the process that preceded the rollout of this automated method. That was one where, if I've understood your evidence correctly, the team was engaged in, in effect, a series of experiments, trialling the process to see what results they could get; is that so?

MR NURTHEN: I believe so.

MR DIEHM: And when results were less than what was hoped for or to be expected, then you would make some changes to the process that was being engaged in?

MR NURTHEN: That's as I understand, we started with the same method for both manual and automated and then obviously made incremental changes.

 MR DIEHM: Now, some of those changes might have been with respect to subtle things and some of them were with respect to more substantial matters; would that be fair to describe it that way?

MR NURTHEN: What do you mean by "substantial"?

MR DIEHM: So to put it into a commonly understood concept, some might be the question of tweaking of a dial but others might be making a change to the process mechanically as to what was being done?

MR NURTHEN: I think that was the intention, to try to obviously increase the yields.

MR DIEHM: Yes. Now, after the rollout took place, the commencement of the Project 13 automation method in October of 2007, was it the case that that experimentation continued?

MR NURTHEN: I believe so, and that's what led to the off-deck lysis, so projects 21 and 22.

MR DIEHM: As those steps were being taken with the modifications that were being made, both before the commencement of Project 13 and after it, again, is it right to understand your evidence as being to say, "We didn't document all of the different things we were doing"?

MR NURTHEN: For projects 21 and 22?

MR DIEHM: No, within Project 13, as you were preparing - in advance of the rollout, the commencement in October 2007, those tweaks that you were making to the process, you weren't documenting all of those as you went along?

MR NURTHEN: I think they might have been documented but not easily to get back out of. So I'd imagine the

1	worksheets, that if something had changed, it may have been
2	written on the worksheet, but not easily extractible in the
3	sense of it had been noted down in a Word document, for
4	instance.
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6	MR DIEHM: Or put into a report?
7	in seem of partition of topol of
8	MR NURTHEN: Put into a report to be able to say we did
9	this, this, this and this.
10	cirro, cirro, cirro ana cirro.
11	MR DIEHM: So now you're unable to go back and find what
	, and the second se
12	those changes were from time to time?
13	MD MUDTUEN V II C (I ) 13
14	MR NURTHEN: Yes, and because some of them are actually
15	within the program of the robot itself, of which we're
16	unable to read the actual program to know what changed on
17	the robot.
18	
19	MR DIEHM: Now, leaving aside the change to the off-deck
20	lysis in, I think it was March 2008 - that's about the
21	right time?
22	ŭ
23	MR NURTHEN: Somewhere about that time, yes.
24	, , ,
25	MR DIEHM: Leaving aside that change, again, the tweaks
26	that were being done post the commencement of the
27	Project 13 rollout in October 2007, again, weren't being
28	documented in a now readily retrievable way?
	documented in a now readily retrievable way:
29	MD NUDTUEN. Voc. they were within prejects 21 and 22 wee
30	MR NURTHEN: Yes, they were within projects 21 and 22, was
31	the documentation of the new process, I guess.
32	MD BIEIM
33	MR DIEHM: And that was from immediately after the
34	commencement in October 2007.
35	
36	MR NURTHEN: Or thereabouts, yes.
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38	MR DIEHM: Or thereabouts. So, now, in projects 21 and
39	22, there was data that was collected?
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41	MR NURTHEN: Yes.
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43	MR DIEHM: And some representation of that, at least, was
44	made in project reports that were prepared in that regard?
45	mado in project reports that were prepared in that regard:
46	MR NURTHEN: Yes.
46	III NUNIILN. 165.
+1	

Can I ask if this document can be put up on the 1 2 screen, it's from Mr Nurthen's primary statement, and I can give a page reference from the Commission's indexation if 3 that's convenient. It's LAY.010.011.0454, if that helps. 4 5 Is this Mr Nurthen's current statement? THE COMMISSIONER: 6 7 MR DIEHM: Yes, it is. 8 9 10 THE COMMISSIONER: What page was it? 11 12 MR DIEHM: It is, to use the computer indexation, LAY.010.011.0454. 13 14 15 THE COMMISSIONER: Is it a page of his statement? 16 MR DIEHM: 17 It's an annexure to it. 18 19 THE COMMISSIONER: Which one? 20 21 454, I'm sorry, Commissioner. MR DIEHM: 22 23 So Mr Nurthen, there we can see a table for manual versus automated blood sensitivity on rayon swabs, figure 24 9 - I should have said "figure", rather than "table". And 25 then on to the next page, if I may, we have figures 10 and 26 27 11, for blood sensitivity on cotton swabs and cell 28 sensitivity on rayon swabs, and then to the next page, 456, 29 figure 12, for cell sensitivity on cotton swabs. I wanted 30 to ask you, firstly, were you the person who put this data 31 into this report? 32 33 MR NURTHEN: I can't recall. I may have, but I honestly 34 can't recall. 35 36 MR DIEHM: I should have said to you, in fairness, to orientate you to this, the document I have you looking at 37 at the moment is the last of the documents that have been 38 39 saved to the system, and figures of this kind appear in the 40 last couple or the last few, but not in earlier versions. So you can't recall whether you were the person who 41 inserted this data into the report? 42

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MR NURTHEN: Correct.

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MR DIEHM: Draft as it was?

1	MR NURTHEN: Yes.
2 3	MR DIEHM: Do you know when the data was collected?
4 5 6 7	MR NURTHEN: I assume it was at the time that we were doing both the manual and the automated, so in - prior to October 2007, I'm assuming.
8 9 10 11	MR DIEHM: Do you remember how long before October 2007 it was that that was being done?
12 13	MR NURTHEN: No.
14 15 16 17 18	MR DIEHM: Are you able to say by reference to the various tweaks that were being done to the system in preparation for rollout or in advance of rollout in October 2007, what mode of operation the system was using at the time this data was collected?
19 20 21	MR NURTHEN: I can't tell from that graph, no.
22 23	MR DIEHM: And you have no recollection of it?
24 25	MR NURTHEN: No.
26 27 28 29	MR DIEHM: Can I ask whether any of the other witnesses can say whether or not they were the person who inserted this data into the draft report? Firstly, those present in the courtroom?
30 31	MS IENTILE: I wasn't.
32 33	MR McNEVIN: It wouldn't have been me.
34 35 36	MR DIEHM: And those attending virtually?
37 38	DR HLINKA: I can't recall.
39 40	MR MUHARAM: I do not recall.
41	MS GALLAGHER: No.
42 43 44 45 46 47	MR DIEHM: And may I ask if any of the other witnesses are able to say anything about the time point at which the data refers and the method of operation of the system that it is based upon?

2 MR DIEHM: I'm taking that to be a "no", Commissioner. 3 MR MUHARAM: 4 No. 5 DR HLINKA: 6 No. 7 MR McNEVIN: I'm not sure what you mean by "method of the 8 9 system". 10 MR DIEHM: So I go back to the questions that I've been 11 12 asking about, of how whilst there was this project for the automation of the system, there were tweaks being made to 13 the way in which the system operated as experiments were 14 15 being conducted to try to get the best results. 16 I'm asking is, if you accept that that was what happened, 17 if you know, whether you're able to say the mode of operation within those realms that was in place at the time 18 19 this data was collected? 20 MR McNEVIN: Oh, so which of the many steps were made? 21 22 23 MR DIEHM: Yes. 24 25 MR McNEVIN: Oh, no, I don't --26 27 MR DIEHM: Thank you. Does that clarification help any of 28 the other witnesses in terms of being able to offer some 29 evidence about this? 30 MR MUHARAM: 31 No. 32 MS GALLAGHER: 33 No. 34 35 DR HLINKA: No. 36 MR DIEHM: 37 Thank you, Commissioner. 38 39 MR RICE: Commissioner, if I may, I have perhaps two or 40 three questions on the same matters that Mr Holt raised before lunch, it may be convenient to --41 42 43 THE COMMISSIONER: Okay. 44 Perhaps I could ask you this, Mr Nurthen, 45 Mr Holt asked you to confirm what that figure of 46 47 92 per cent published in the draft Project 13 report

MS GALLAGHER:

No.

represented. You told us it was a comparison between yield sensitivity as between manual and automated DNA IQ processes. Did I understand you correctly to say that even from low yield DNA IQ automated process, it was nonetheless possible to still develop useable profiles?

MR NURTHEN: Yes.

 MR RICE: Does it follow, then, that to assess the true significance of the difference between the yield from the automated and manual processes, one would need to compare the extent to which that difference impacted on the obtainability, if that's a word, of useable profiles?

MR NURTHEN: Yes, I think you'd need to take in the full context in the quality, quantity and whether you could get a DNA profile, because if you get a lot of DNA but you still couldn't generate a DNA profile, then it wasn't much use.

 MR RICE: Is it right to say that a 92 per cent difference between pure yield from manual to automated processes does not mean that there is a 92 per cent reduction in the obtainability of a useable profile?

MR NURTHEN: Correct.

MR RICE: Thank you.

THE COMMISSIONER: I think I understand that question and answer. Mr Fox.

MR FOX: Thank you. I was waiting to see if anybody else wanted to jump up.

May I just take you back to the question that was posed by Mr Holt before lunch to Mr Nurthen, and this was in relation to the use of the automated system with respect to only particular types of samples, and it was - I think the answer that was given was it was not being used for major crime cases.

MR NURTHEN: I hadn't recalled that was the case. I don't recall the memo. But if that's what it was, I accept that's what it was. I assumed it was everything.

MR FOX: Right. If --

THE COMMISSIONER: Sorry, when you say you assumed it was everything, you assumed that the automated method was being applied to all samples, once it was --

MR NURTHEN: Cells and blood but, no, not restricted to any particular case type.

THE COMMISSIONER: I understand.

MS IENTILE: May I add to that, please?

MR FOX: Yes.

MS IENTILE: According to the email that I sent to all staff announcing what was happening, it was written that initially, as training in both analytical and the other areas is happening, the samples will mainly be some of the backlog samples, and there was a reference to the fact that in other areas, the scientists still needed to be trained. So it may mean that some other cases were implemented but I'm not sure of the time frame.

THE COMMISSIONER: Just to clarify that, I know your memory is probably not as precise as that --

MS IENTILE: Yes.

THE COMMISSIONER: -- but when you say "mainly to other samples".

MS IENTILE: I'm reading what I wrote.

THE COMMISSIONER: That's right, but that's not exclusory.

MS IENTILE: I'm just reading, yes.

THE COMMISSIONER: What that seems to say is "We'll start off that way", but it doesn't say when a transition - if a transition does occur to all samples, when and if that will happen; it simply allows for some training to take place before further development - before further application is put in place.

MS IENTILE: Yes, I do write - the next sentence in my email says:

1 2 3	I would expect also that we would not reach full capacity on these platforms until the new year.
4 5 6 7	THE COMMISSIONER: "The new year" being in the beginning of 2008?
8 9	MS IENTILE: Yes.
10 11 12 13	THE COMMISSIONER: Yes, so the fact that it wasn't being applied to all samples or a greater type of samples was a short-term matter to enable further training to occur?
14 15	MS IENTILE: That's my understanding, yes.
16 17 18	THE COMMISSIONER: Thank you very much. That's very helpful.
19 20 21 22 23	MR FOX: I think that was the area that I was going to ask about. So that means that, to the best of your understanding, it would have been anticipated that by the beginning of 2008, it would then be applied across the full suite?
24 25 26 27 28	MS IENTILE: I guess so at the stage that I wrote that email but I don't have any records to indicate what happened.
29 30 31 32 33 34	THE COMMISSIONER: Is there any reason why, looking at that time, if you had got it up and running to satisfactory levels, it would not be applied across all samples? Is there any particular kind of sample that does not lend itself to the automatic
35 36	MR NURTHEN: For the cell type or
37 38	THE COMMISSIONER: Cell type or substrates?
39 40 41 42 43 44	MR NURTHEN: Yes, because we'd only validated for cells and blood, we knew we had to do additional work on it, for instance, for hairs and for semen and for tissue, because we knew they'd be modifications of the automated protocol, because that automated protocol didn't cover those particular biological sample types.
45 46 47	THE COMMISSIONER: But would you have had - is there any record of having done that further testing that would have

meant that that application was extended? 1 2 3 MR NURTHEN: There's records of projects that we were going to start but we never started them, with respect to 4 5 semen and - yes. 6 7 THE COMMISSIONER: Thank you. Did you want to add something? 8 9 MR McNEVIN: Yes, there was an element of - we talked a 10 little bit earlier about the sample size. 11 12 THE COMMISSIONER: Yes. 13 14 15 MR McNEVIN: So I seem to recall reading an email in preparation for today that the volume crime team had 16 already been sampling to a smaller sample size in 17 preparation for automation, but that the major crime team 18 19 had not, so that would have been another reason why we wouldn't have just gone to everything. 20 So samples that hadn't been sampled to a proportion that was amenable to 21 22 the automated extraction would have continued through the 23 older process until the newer samples had come through, or 24 we would have had to have done some sort of resampling 25 prior to carrying out the extraction. 26 27 THE COMMISSIONER: Thank you. 28 29 MR FOX: Now, could I take --30 31 THE COMMISSIONER: Just looking to the other side, no-one 32 is waving a hand, so I'm assuming there is no further comment from those on screen. 33 34 35 MS GALLAGHER: No. 36 MR MUHARAM: 37 No. 38 No. 39 DR HLINKA: 40 Can I then take you to the events of February 41 2008, so this is when contamination starts to be 42 43 discovered, and the first contamination event is

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11 February 2008, which is recorded in the OQI 19330 part

of the analytical issues log. Then there are further

instances of contamination in April and May.

Mr Nurthen, you indicated in paragraph 95 of your main declaration or statement that it was sample cross-contamination that you believed was what was the cause of the problems in early 2008. So in terms of - what steps were then taken to resolve that contamination problem?

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So initially it was trying to work out how we MR NURTHEN: thought it had occurred, as to what had actually occurred, which I think - it took a number of different OQIs before we could link them all. With the initial one we didn't suspect that it was definitely contamination. I think there were re-extractions of the samples to see whether the samples had been contaminated initially, at what step.

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MR McNEVIN: Yes, I can't recall super clearly but we had a process of just trying to work out what step that contamination had occurred. We must have at some point decided that it was the extraction, and then - I seem to recall that I was involved in doing some of the early investigations, of trying to work out exactly where - how that contamination had occurred, where it occurred in the And then I think at some point we realised that it was a much bigger problem and I needed to keep working on keeping the lab running, and that was - the contamination investigation was handed over, back to sort of Tom and the automation team to deal with.

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So I can't remember the exact steps we took, but certainly that was always our sort of process to doing contamination investigations, was trying to work out at what step in the process did it occur and, again, what was the source, what were the contaminated things, you know, where did it come from, where did it go to, and then sort of backtrack from there to try to work out what mechanism that might have been.

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MR NURTHEN: I think because initially there could be multiple places where contamination can occur - it can occur at extraction, it could have occurred at amplification, when it was being amplified, that's another spot that contamination can occur, or within the capillary electrophoresis, which is the separation of the DNA.

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So the standard protocol is to do a series of steps to see if you can rule out any of those steps. The first one would have been - and I think you probably agree with me,

it would have been re-CE-ing to make sure that that
particular source of - because that's where you have got
very concentrated DNA, that's probably the riskiest part of
the whole process, so you would reinject that into the CE
to see if that was possibly where the contamination
occurred and then work your way backwards.

MR McNEVIN: Yes, generally speaking the process was to work backwards from capillary electrophoresis all the way back to extraction, when you're looking thorough for your potential source of contamination.

MR FOX: That's July 2008 when the decisions are made to stop using the automated system.

MR NURTHEN: Mmm.

 MR FOX: Can you inform the Commissioner about, during that period from February to July, why the automated system didn't cease earlier? (Indistinct). If you were looking for the cause, you know there is a problem, why isn't there a swifter cessation of the use of the automated system?

 MR NURTHEN: I think, from memory, and I could be wrong, that the first lot of contamination occurred on a reference batch. Reference batches, reference sample processing, where you would expect to only see a single-source profile, but when you're dealing with casework, you could be dealing with mixtures of - and it's harder to detect contamination in a casework batch because you can get mixtures as part of your extracting of DNA, so it's easy to detect in a reference batch, because you wouldn't get a mixture.

 So I remember thinking at the time that it was difficult to work out at what point this was happening, when initially it was a reference one. But I think after we started to make - and be really concerned that there was contamination, that meant stepping back through all those batches previously and re-looking at things that had been passed off as not being caused by the robots but then later determining that yes, it was actually the robot that caused that, and that was also, I think, re-extracting that lysate then to confirm that it was the robot where that contamination occurred.

MR FOX: Ms Ientile, you recall a memorandum that you have dated I think 14 July, and this is a memorandum that you

sent to DNA analysis, which I assume is a group of --1 2 It's the entire section. 3 MS IENTILE: 4 MR FOX: The entire team. You have that memorandum near 5 you, I trust, because that was the subject of your outline 6 7 of additional evidence, and you indicate in the second paragraph - this is on the list. 8 9 MS IENTILE: I'm not sure I have a copy. 10 11 12 MR FOX: They will bring it up on the screen now. the list that was handed up earlier. Number 30, I'm told. 13 [FSS.0001.0024.0802] Thank you. 14 15 16 You refer to an extraordinary management team meeting 17 on 14 July discussing what action should be taken, and in the second paragraph you refer to concerns by reference to 18 19 three OQIs, the issue of cross-contamination in the second sentence, and then the third sentence: 20 21 22 The investigations undertaken to date have 23 not been able to identify the cause of this 24 contamination. 25 26 Then you summarise at the bottom automated DNA IQ 27 extractions were introduced in October 2007, after an 28 extensive validation process. 29 30 The results of various tests undertaken 31 during this validation phase demonstrated 32 no well to well contamination or transfer. 33 This process was approved and 34 implementation was agreed to by the 35 management team with the understanding that 36 the ongoing optimisation would continue as 37 part of the normal continuous improvement 38 process. 39 That last sentence, we have had that discussion earlier 40 about ongoing optimisation. 41 43 MS IENTILE: Mmm-hmm.

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Would you just explain to Commissioner in terms of how this decision came about, it's obviously been escalated to you, to then report and have this particular extraordinary management team meeting, as to - to the best you can remember, having re-looked at these documents now and reminding yourself, what were the steps that were taken in you forming the view that this is the decision that needed to be made, to cease the automation?

MS IENTILE: I don't have an independent recollection of any of these events. My reconstruction is based on reviewing what documents were available to me and also I think documents that were available in the - from statements that people made last year. My understanding is this - is that would have been discussed and decided in the management team meeting. It wouldn't have been a decision solely based - made by me; it would have been a decision that was based on the input of many scientists in the management team.

MR FOX: Mr Nurthen, in response to questions that were posed just shortly after lunch by Mr Diehm, you made reference to Projects 21 and 22, and the documents are on the schedule, but we're bringing them up as is necessary. This is rows 26 and 27. We'll just come to them if we need to in terms of bringing particular pages up, but the date of the Project 22 is February 2008. We might just get the cover page for that document. Is it the case that that report was actually prepared in February 2008? There are other documents we have seen where the date of preparation may not necessarily - may not state the date of preparation.

MR NURTHEN: I can't recall because around about that period I was off on leave midway through February for the birth of my second child so I wasn't actually in the lab at the time. I can only assume that that is the case, that that was a final - it appears to be a final document that had been distributed.

MR FOX: The Project 21 just has a date of 2008, but as I understood you when answering questions from Mr Diehm, you made reference to both of these projects. Were these projects live, in the sense that they were happening, in terms of the investigative work, in around, you know, early 2008? In other words, before the decision is made to cease automation in July 2008?

MR NURTHEN: Yes, yes.

THE COMMISSIONER: And why were projects - I should just be clear about Project 21 [FSS.0001.0084.1422]. titled "A Modified DNA IQ Method Consisting of Off-Deck Lysis", so now we've got back to that discussion we had about before off-deck lysis. That's 21. And then Project 22 [FSS.0001.0084.1436] has essentially the same heading, "A modified DNA IQ method of Off-Deck Lysis Prior to Performing Automated DNA Extraction". So we're contemplating the notion of off-deck lysis here in both of these reports. Why was that being investigated at that time?

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MR NURTHEN: As in the off-deck lysis component? as I said before, the issues with the Slicprep, in getting them prepared for the robot, was technically very So off-deck lysis was a way of manually getting those samples ready to put on the robot without all the hassle of having to do it through the Slicprep.

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MR FOX: I suppose the point of confusion that I have in my mind, (indistinct), is if we've committed to full automation and we've discovered that there is contamination going on, we're investigating that, the decision made in July 2008 to actually stop full automation, why at the same time have we got an ongoing project which is looking at the off-deck lysis, which is essentially a manual/automated process?

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MR NURTHEN: Because I think that had already been done prior to contamination being detected. I think the first event, the first instance of contamination was only Even though it had occurred earlier, it detected in May. wasn't linked to the robots until later, is my So this had already been implemented and recollection. then later, then we started to detect the contamination.

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MR FOX: Again I put this to you as a proposition. there any foundation to any suggestion that the reason why off-deck lysis is being looked at is because, even by early 2008, put to one side when contamination rears its head, there was some belief within the laboratory that a fully automated system just was not feasible?

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I think with that feedback, with respect to MR NURTHEN: the Slicprep, it made it pretty obvious that we weren't going to be able to automate that entirely, and the only solution was to take part of that offline.

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MR NURTHEN:

Yes.

The other alternative would have been to go back to the CFS protocol, which was leaving the substrates in the deepwell and run the risk of clogging of the tips, which I don't think we accepted as being an acceptable solution.

MR McNEVIN: Could I add to that? I think it was also the fact that because the Slicprep was so difficult to use, and this is just me trying to recall events now, it could have been just that the Slicprep was so difficult to use that you actually weren't getting that throughput benefit of the automated protocol that you were trying to achieve. an element of it, I think. I think it was so laborious and time consuming and it just really wasn't making that automated method what the idea, the theoretical idea, was, that it was going to ramp up the throughput of the I don't really recall it that well, but I just laboratory. remember something like that.

THE COMMISSIONER: Can I just interrupt, then, to ask a couple of questions about this decision. If you go, Mr Nurthen - sorry to take you back - to your first statement [LAY.010.013.0001] at paragraphs 88 and 89, it raises another issue, which is the number of drafts that Project 13 went through, and I think you point out there that the draft recommendation to proceed first appeared in version 3 of the draft, which was last dated on 12 August 2008, after it went live. So that's an area that I will leave it to Mr Fox, if he wants to, to ask you some questions about, because that seems to me to be an interesting chronology, but we'll come back to that.

But then just going back to this yield question - I'm sorry, and it does fit in with what the alternatives would be of stopping the automation, in a way - you then say that your view was that:

... we were not ready to go live because the yields from the automated DNA IQ Protocol were too low ...

and your concern was that the yields would not be as sensitive to extract low amounts of DNA. Now, the alternative to the automated process was really to go back

to Chelex, wasn't it?

98 PROJECT 13 SCIENTISTS CONCLAVE

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THE COMMISSIONER: And yet you said earlier in your evidence that even the lower amounts of extracted DNA in the DNA IQ method, even if it was less than Chelex, was better quality, and therefore it was still worth proceeding So I'm trying to fit that concept in with the idea that the yields were too low to proceed with. the tension that I'm referring to? Can you explain that?

MR NURTHEN: Yes so I think as technology was increasing, the aim was to be able to extract the smallest amount of DNA possible. And certain Chelex, being a fairly non-specific method, it wasn't super, super sensitive to those low amounts of cells.

THE COMMISSIONER: Yes, but if you didn't go ahead with the automated method, then there was no alternative but to go back to Chelex.

MR NURTHEN: Yes, or to implement the manual version of the DNA IQ.

THE COMMISSIONER: Which you validated.

MR NURTHEN: Yes.

THE COMMISSIONER: So what you say in 89, which is when you're looking back, of course, when you say that you weren't ready to go live because the yields were too low do you recall whether what was in your mind as the alternative was going back to Chelex or doing a manual DNA IQ extraction?

MR NURTHEN: Well, at this stage it wasn't going back to Chelex, because we hadn't implemented it, so we were still doing Chelex. It was about replacing Chelex with that particular method, so --

But if you hadn't proceeded, if you THE COMMISSIONER: hadn't got - I mean, you didn't recommend proceeding or you had concerns about proceeding, that you expressed and reflected in those two documents with Ms Ientile, but then - and then we've got the recommendation going in in 2008, or live in 2007, but I guess I'm trying to understand if you said - if you had at the time said, "Let's not go ahead with this, it's not working, because the yield's too low", on one hand, you are saying, "Well, even an automated

1 2 3 4	yield is better than a Chelex yield because it might be low but it's still better quality and we are getting results", or what would - otherwise, what was the alternative?
5 6 7	MR NURTHEN: Was the status quo, which is that we don't implement any of the - or any DNA IQ and you can
7 8 9	THE COMMISSIONER: And go back to Chelex.
10 11	MR NURTHEN: No, we stay with Chelex, because we weren't we hadn't ceased Chelex, but we don't get the
12 13 14	THE COMMISSIONER: That was the alternative?
15 16	MR NURTHEN: But we don't get the benefits of the
17 18 19	THE COMMISSIONER: Isn't there a tension between that and the view you expressed that a bad result from the automated system was still better than Chelex?
20 21 22 23	MR NURTHEN: I think that was my opinion because of the quality coming out of DNA IQ, yes.
24 25 26 27 28	THE COMMISSIONER: There's a tension between saying, "I formed the view that even a low yield was better than Chelex", and saying, "Don't proceed", which means don't automate and stay with Chelex. There's a tension between those two conclusions, isn't there?
29 30 31 32 33	MR NURTHEN: I think I would have like to have ridden the project out to get it all the way back up to so it was the same or as - you know
34 35	THE COMMISSIONER: Before implementing?
36 37 38 39 40 41	MR NURTHEN: Before implementing. But if having to implement, there is still the notion where it is still giving good quality DNA, with respect to Chelex, with being, you know, dirty and needing to be cleaned up as well.
42 43 44	THE COMMISSIONER: I think I understand. So your view was, it wasn't ditch it completely, but wait till you optimise it further before you transition to it?
45 46 47	MR NURTHEN: There is a trade-off and the trade-off is that if you are going to implement the automated one, even

with the lower yields, you were going to get some benefit out of it, with respect to not implementing it and staying with fully manual method and Chelex.

THE COMMISSIONER: But then you recommended not proceeding with the automated one.

MR NURTHEN: Yes, because I would have preferred to have got that method up first.

THE COMMISSIONER: Okay, thank you.

MR FOX: Now, the contamination issue, as you know, was dealt with by the Sofronoff Inquiry, so we're not going to relive that saga, but can I just ask you this: by the time the contamination issue is believed to be resolved - that's through independent audit and all the rest of it - what had happened with the yield issue? Did anybody sort of turn their mind to whether the cross-contamination point solved everything, because you are on notice before the contamination point arises in early 2008 that there's a yield problem, but what was then in the mind of the scientists in the lab at the time, knowing that there had been previously a yield problem?

MR NURTHEN: I can't speak as to the scientists who did that particular work. I know the idea was that whole - in correcting the contamination, that basically meant that whole method had to be pulled apart and rearranged and redone entirely, and I think as part of doing that, this efficiency plate went through to show that what we were getting - what we were putting in was coming back out the other end, if that makes sense.

MR FOX: Yes. I appreciate we're starting to get ourselves into territory, once we get ourselves beyond the middle of 2008 and into 2009, people then start - of the seven members - either leave the organisation or splinter off, can I just turn to those who are appearing virtually, is there anything that you would like to indicate to those - it is said that you were still around at the time - as to once the contamination issue was resolved, why was the yield, the previous yield issues, why was there a belief that either they were resolved implicitly or what steps were taken to resolve them?

Dr Hlinka, would you like to start?

DR HLINKA: I remember that Desley Pitcher from PerkinElmer came in at one time just to help with certain issues around bubble formation and optimisation of pipetting. I believe that occurred in October 2009, I'm not quite certain. Maybe someone else can say when that happened, I'm not absolutely sure. But there was a period of time when we were just having possible problems with bubble formation and just resolving any possible things with pipetting and so on, just to get the program a bit more streamlined.

MR FOX: Is there anything anybody else wants to contribute on that? It was mentioned about bubbles being formed, he has referred to that in his evidence about what that is about. I appreciate we're going to come to the April 2009 report, it's just really - we'll to get into the detail of that in due course, but it really is just why there is a believe that resolving contaminations means that, okay, we had the problem before with yield, we've kind of put that to one side for the moment, and then we'll deal with contamination, but we've still got the elephant in the corner of the room, so to speak, on yield.

 MR NURTHEN: I think it was part of that process of ensuring that there wasn't contamination, that they looked at every step of that process and looked to optimise it, which was - from what I understand, that mixing is the critical component, the mixing of the resin is critical, and after we saw the reimplementation, we had basically carved off another of the automated parts of the process off the robot to a manual component as well.

MR FOX: Now, October 2008 is when you finish your role in the automation team.

MR NURTHEN: Yes.

MR FOX: You then move to the senior scientist quality and projects DNA analysis, so did you finish all association with automation at that point or did you continue to be involved or --

 MR NURTHEN: No, I think it was a loose association, that if they needed me I would help them, and obviously I had an interest in it anyway. But that wasn't my primary role anymore, so someone else took after me, I think it was Iman

took on that senior scientist role after me. So I would assume I was still involved, but I wasn't the primary person involved.

MR FOX: And Mr Muharam, would you like to just indicate - you have listened to a bit of dialogue between your various colleagues over the last few minutes. Would you like to indicate whether you have got anything to say on this topic of why, with contamination being resolved, it doesn't necessarily mean that the yield problem identified earlier had been resolved?

MR MUHARAM: I actually don't have a lot of recollection of that period of time in the chronology of events that followed, so I'm not sure if I can provide an answer here.

MR FOX: All right. We certainly won't ask you to speculate.

I'm going to move to a new topic, which is the Project 13 report, if that's convenient and no-one else has any questions.

So we turn to the report. I think it's collectively agreed that it's a draft, it certainly has its gaps and question marks and red highlighting and the rest of it. But Mr Nurthen, you have managed to uncover - you've referred to this at paragraph 76 of your main declaration - 10 different versions of that. And then Ms Gallagher, you've managed to produce four different versions of the standard operating procedures, so we have - we have talked previously, before, about the SOPs and their role.

Can I just ask this, is it, in terms of the explanation that is given that - Mr Nurthen, you have ventured into this territory to try and explain why there is the disconnect between the abstract and the conclusion that is expressed there and the data that is in the body of the document. Would you just mind explaining how you work through that process? I think you look at version number 1 and say that it's a historical carry-on.

 MR NURTHEN: Yes, so when I looked at that version number 1 and I was looking at the author list and going, "Well, why would we change the order of the author list if that's what we thought it was", and then when you start reading through the body and get further down through version 1 of

that project, there starts to be phrases in there that don't relate to automated extraction at all and that refer to automated quantitation set-up.

So I did the next thing, which was look for that particular report, which was report 1, and then make a comparison between the two - between version 1 of Project 13 and report 1, and it would appear that that was the template used for the first draft of that document.

MR FOX: One can engage in speculation as to why version 1 would have a conclusion like that stated, and then testing occurs and processes occur thereafter and drafts are produced, which take the document in a different - potentially down a different path, but do you have any - other than drawing attention to the fact that it was there at the very beginning in the version 1, any understanding as to why that would have been said, that is, stated at all, in such an early document?

 MR NURTHEN: Because that's what came out of report 1. It was copied as a template and that wording hadn't been changed when that document draft started. It's word for word come out of report 1.

THE COMMISSIONER: Just to make it clear, you are talking about the abstract.

 MR NURTHEN: Yes. It's come out of - so report 1, if you look at the abstract for report 1, which is the validation for automated quantitation, that wording is the wording used within that document.

THE COMMISSIONER: Except for the last sentence, I think.

MR NURTHEN: Yes, I think there are slight substitutions, but --

THE COMMISSIONER: The last sentence is the recommendation of the use of the MultiPROBE that ultimately ended up, that wasn't in report 1.

 MR NURTHEN: Probably not, but like I said it was a draft that had been started, just been copied word for word, or that whole document, and then started to be substituted, there's different colours in there indicating that was going to be the template of which we were working

what I would imagine. 2 3 No-one is asking you to speculate. 4 MR FOX: 5 that answer, you have endeavoured to try and explain the different versions that you have read; is that right? 6 7 MR NURTHEN: Yes. 8 9 MR FOX: And put what you believe is the most likely 10 reason for it being in that form? 11 12 MR NURTHEN: Yes. 13 14 15 MR FOX: Do any of you who have - these are the named authors now, and I appreciate some people regard themselves 16 as named in spirit more than in writing - but does anybody 17 have a version of events that is different to that that has 18 19 been uttered by Mr Nurthen as his explanation as to how this came about? 20 21 DR HLINKA: 22 No. 23 MS GALLAGHER: 24 No. 25 MR MUHARAM: 26 No. 27 28 THE COMMISSIONER: Can I clarify a couple of matters. 29 see there are some "no"s. There are a couple of matters with that. As I understand it, there were numerous 30 31 versions of this Project 13 draft report; right? 32 MR NURTHEN: 33 Yes 34 35 THE COMMISSIONER: And I also understand from the evidence 36 that the abstract was not in version 1. Or was it? Was 37 the abstract always there? 38 39 MR NURTHEN: Yes, it was. There was an abstract in there. 40 THE COMMISSIONER: An abstract? 41 42 43 MR NURTHEN: Yes. 44 THE COMMISSIONER: So the abstract was always there? 45 46 47 MR NURTHEN: An abstract, yes.

off, and then the data was going to be put in there, is

you - I think you were not part of the drafting of this. I think you said you were in Germany and asked to look at

I'm having real troubles, I definitely read

DR HLINKA: I'm sure of it, yes. But I'm not sure (indistinct) --

THE COMMISSIONER: But I also think - sorry.

DR HLINKA: Sorry, I --

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I also think you said in your evidence THE COMMISSIONER: that when you read the abstract, you read the sentence that said data indicate the results from the automatic procedure are comparable to those in the manual procedure - you read that as referring to profiles. I think that was your evidence, was it? You didn't see the inconsistency between

1	that and the yield data?
2 3 4 5 6	DR HLINKA: No, that's correct. I think the profiles themselves were okay. Maybe it was later, the profiling, I'm not sure, but that's correct. I think it was based on primarily the profiling data.
7 8 9 10 11	THE COMMISSIONER: Thank you. Yet Mr Nurthen, I think you said when you read it, you realised it was totally inapplicable?
12 13 14 15 16 17	MR NURTHEN: Yes, I think once I saw "Report 1" and saw that it was, you know, verbatim, that section on comparable, I think that's when I went, "Oh, okay, that wasn't referring to anything within the automated, it was referring to the QuantiFiler report", but it hadn't been updated with respect to the automated DNA IQ.
19 20 21 22	THE COMMISSIONER: When you look at the Project 13 paper today and you see that sentence in the abstract, is that a valid conclusion as to the content of the paper?
23 24 25	MR NURTHEN: No, because I think it's contradicted by the results further down in that body of the actual work.
26 27 28	THE COMMISSIONER: Does anyone else want to comment on that? No? Okay.
29 30 31 32 33 34 35	MR FOX: So the question posed collectively to those present and those virtually - and I just ask people to indicate by saying no or yes, in the sequence that we have done, we will deal with the people live first and then those who are virtually - but nobody has any recollection of who actually wrote the abstract; is that right?
36 37	MR NURTHEN: Which version of the abstract?
38 39 40	MR FOX: The version in the Project 13 document that is the one that is causing the issue - I call it the
41 42	THE COMMISSIONER: That sentence.
43 44	MR FOX: That sentence.
45 46 47	MR NURTHEN: I think that is fully derived from report 1. It seems to be copied directly and not applicable to that project at all.

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So your answer is you don't know who actually wrote the sentence?

MR NURTHEN:

If it has come from report 1, it has come from the author of report 1 but doesn't apply to Project 13.

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> MR FOX: And that's the best you can say?

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Yes. MR NURTHEN: 11

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THE COMMISSIONER: Does anyone disagree that they have somebody has some knowledge as to who, other than what Mr Nurthen has indicated?

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MR McNEVIN: I have no recollection.

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MS IENTILE: No knowledge.

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MR MUHARAM: No knowledge.

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MS GALLAGHER: No knowledge, sorry.

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MR FOX: And is anyone aware whether the report was ever finalised?

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MR NURTHEN: I'm not aware of it being finalised.

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DR HLINKA: I think it was, actually, one last, but there was a period when Tom had a meeting, two meetings, and we were looking for the final copy. We couldn't that's what I think I recall, and we couldn't actually find the final copy, and he was rushing to go off to another meeting, so we - the choice made by Tom was take one of the draft copies that were present for the presentation that was being made at the time. If --

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> MR FOX: When you say - you go.

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DR HLINKA: If it had been finalised, it would have had proper referencing and everything. The document presented to me by the Inquiry is not a final document. It's just missing proper references, it has got flags that I've put in there, like after (indistinct), the question marks that indicate that a reference must be obtained. There's also another inconsistency, and there's another flag I put in

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29	indicating that it's a completely draft document, what the Inquiry has, and I do believe
	THE COMMISSIONER: Can I ask a question.
	DR HLINKA: I do believer have there was a final document; it's just that it somehow vanished.
	THE COMMISSIONER: Let me try and ask a question. You are the first named author. Who wrote the paper? Who wrote the report?
	MR NURTHEN: I don't think anyone wrote one - like, the whole of the report. I think it was someone might have put out one section, someone might have put in another section.
	THE COMMISSIONER: I think Dr Hlinka says he recognises that he wrote - Dr Hlinka, you wrote some of the material for that report, as I understand you saying?
	DR HLINKA: Yes, that's correct. But the reference style at the back, the one reference that is given, that's in my particular template.
	THE COMMISSIONER: Right. So you were responsible at least for some of the data and the writing up of that data and I assume in the results and discussion section, and maybe the methodology section? Who wrote the - for example, does anyone recollect who wrote the introduction?
30 31 32	DR HLINKA: No.
32 33 34 35 36 37 38	MR NURTHEN: Like I said, part of that introduction had been taken from the other report, from report 1
	THE COMMISSIONER: No, this is actually - the introduction says it was - it's about the MultPROBE.
39 40	MR NURTHEN: Sorry, the introduction.
41 42 43 44 45	THE COMMISSIONER: Not the abstract, sorry. I'm just trying to break it down a little bit. I think Dr Hlinka, as I understand it, says that he wrote at least parts of the methodology and the results, I'm assuming, as the - is that correct?
46 47	DR HLINKA: I'm not sure who wrote the results actually

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3	THE COMMISSIONER: Well, do you recall providing some of
4	these data?
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6	DR HLINKA: No. I don't actually. Sorry.
7	
8	THE COMMISSIONER: No worries. Back to Mr Nurthen. Do
9	you have any - I mean, if you don't have a recollection,
10	you don't have a recollection, but do you have
11	a recollection, for example, as to whether you wrote the
12	introduction, not the abstract but the introduction?
13	
14	MR NURTHEN: No, I don't, but I think it's unlikely that
15	I wouldn't have authored something within that document.
16	
17	MR FOX: Does anyone have a similar recollection to
18	Mr Nurthen's - that is, they don't think they can point to
19	the part that they would have written, but they would have
20	written part of it?
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22	Dr Hlinka? I think you indicated before you've
23	contributed to some of it?
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25	DR HLINKA: I think I have already said everything.
26	THE COMMISSIONED. I think he said that
27	THE COMMISSIONER: I think he said that.
28 29	MR FOX: Yes. Mr Muharam, do you have any recollection of
30	writing any part? If you can't point to
31	withing any part: If you can't point to
32	MR MUHARAM: No, actually, I don't recall - I don't have
33	the recollection of writing particular parts. I can
34	comment that some of the content is in a format that I'm
35	not familiar with, as in the sort of format where I would
36	have, you know, done it in that way.
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38	MR FOX: Ms Gallagher?
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40	MS GALLAGHER: I don't recall participating in writing
41	anything for the report. I had left by May of 2008, so
42	depending upon when this report was started, I may not have
43	even been still with the laboratory at the time.
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45	MR FOX: Thank you. Now, the document is dated August
46	2008. Is the only explanation to that the fact that it is
47	in a sequence of different versions and each one has

but the data had to come from somewhere.

a subsequent date - is that the only logical reason why it 1 2 would bear that date, Mr Nurthen, 3 4 MR NURTHEN: Why it bears August 2008? 5 MR FOX: Yes. 6 7 THE COMMISSIONER: And not earlier. 8 9 MR NURTHEN: I just think it was being added to constantly 10 and that might have been the date at which that draft 11 12 because I think that's in several of those drafts. go back, August 2008 is somewhere in amongst that, and that 13 might have been the particular date that the document was 14 15 picked up and added to. 16 17 MR FOX: Dr Hlinka, earlier on you indicated that you thought that the report might have been finalised. 18 19 DR HLINKA: Yes. 20 21 22 MR FOX: And you recall - you said that there had been 23 a couple of meetings that you'd had with Mr Nurthen about Do you have any recollection of what that date - you 24 25 go --26 27 DR HLINKA: No, it was the date that yield issues were being presented to either the team scientists - I think 28 29 actually it was the day that Iman was giving a talk, to either the team scientists or the automation team, 30 31 I believe. 32 33 MR FOX: So you can't give us any indication of what date 34 or around approximately what date that might have been? 35 36 DR HLINKA: I can't recall what that date was, no. 37 would have to look at the records for that time period to 38 be certain. 39 40 MR FOX: Thank you. 41 Mr Nurthen, I appreciate you have only heard that for 42 43 the first time, but do you have any observations or comments to make in relation to what Dr Hlinka has said 44 about he thinks that the report might have been finalised 45

46 47 and he referred to conversations with you?

MR NURTHEN: Yes, I don't recall it ever being finalised because other reports that we had finalised at the time had been printed and bound, and I think if you look at the copies of some of those ones you received for 21 and 22, you can see the bindings on the side. I think when we looked - again looked to try to find a final copy, we couldn't locate a printed version of it. And then again, looking at the actual body of the document, it would appear to be midway through sentences, it's been stopped. So I can't imagine it being finalised.

DR HLINKA: It's not a polished final copy.

MR FOX: No.

DR HLINKA: It's (indistinct - simultaneous speakers) --

MR FOX: Thank you, Dr Hlinka.

Mr Muharam you, have heard a moment ago that your name was mentioned. Would you like to respond at all to what was said?

MR MUHARAM: I believe you are referring to Dr Hlinka's comment earlier?

MR FOX: That's right.

MR MUHARAM: I actually don't recall that in the events, actually, so yes, I probably can't contribute information to that one. But as I think - as per the comments of others, I think we're all on the same page that the document that we have been presented with is - you know, it really does look like it's a draft copy and not the final copy, and fact that we haven't been able to locate a final one, I'm not sure exactly what that means, but at least the document that we have looks like it's incomplete.

So in terms of the conclusions I guess we can make from that document, you know, that - yeah, that's what we're discussing today. But I think we all agree that it is a draft.

 MR FOX: Thank you. While you're answering questions, do you recall, even though it was a draft document, do you recall it being distributed in any way, whether within the laboratory or to any external organisations?

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MR MUHARAM: To the best of my recollection, I don't recall, you know, I guess, myself distributing the report, or it being distributed to anybody. But having said that, I mean, a lot - all the documents were on the lab's server, right, so anyone in the lab could have access to it, for example. But whether it was distributed in an official capacity I cannot recall, I don't remember.

MR FOX: Thank you.

Ms Gallagher, I appreciate you left after at least the August date that's referred to here, but just in terms of any prior drafts of the Project 13 report, you don't recall distributing it yourself or anybody that you worked with, whether within the lab or to an external organisation?

MS GALLAGHER: I believe I stated in my statement earlier that I don't even recall seeing a draft of Project 13, as it's being discussed, in my time within the lab. So no, I wouldn't have distributed it to anybody internally or externally.

MR FOX: Thank you.

Dr Hlinka, do you have any recollection of either yourself or any of your colleagues distributing it outside - within the lab or to an external organisation?

DR HLINKA: I think it was done early and kept on the internal hard drive so that anybody from DNA analysis or any team scientist or any management staff member could actually go into that folder and locate it if they needed to. I do not remember actually any physical distribution of a document as per se. Most likely - no, I shouldn't really speculate. I won't speculate.

MR FOX: No, we won't ask you to speculate.

Then the three who are present here, obviously the same question. Does anyone have any recollection of either themselves distributing it within the lab or to an external organisation? Ms Ientile?

MS IENTILE: I have no recollection of ever seeing it until this event.

MR FOX: Thank you.

MR NURTHEN: No, I don't recall distributing it because it wasn't finished. I don't think even if it - well, being it wasn't finished, I can't imagine I would have circulated it. I have no recollection of circulating it.

MR FOX: Mr McNevin, just for the sake of completeness?

MR McNEVIN: No, no. I don't think we got in the habit of distributing project reports until much later anyway.

THE COMMISSIONER: I have one question about it, though, still. Just one thing. I understand that the abstract was probably a placeholder, as your evidence is, most likely, because it was the same as the abstract in report 1. But bearing in mind that you and Ms Ientile had a conversation about whether or not you would go ahead, this version of Project 13 does have a sentence added to the abstract that is peculiar to this - to the work of the MultiPROBE rather than report 1, because it says:

We recommend the use of the MultiPROBE to perform automated DNA extraction using the DNA IQ system.

And at the back under the summary of recommendations, it recommends the use of it for reference samples, for automatic extraction of casework samples, and consistently with the conversation that is noted in that note, "ongoing development of the automated extraction program to increase the efficiency of extraction".

So this version of Project 13 obviously took account of the various work that you have done and so much specifically in relation to this and the recommendation is recorded in there.

MR NURTHEN: I can only assume, because looking at the dates at which those versions were recorded, the only version that we've got that is prior to going live is that version point 1, and the subsequent versions after that are in 2008, well and truly --

THE COMMISSIONER: Which is after it went live.

MR NURTHEN: Yes. So I can only assume that that was

after the fact.

THE COMMISSIONER: Okay.

MR NURTHEN: Based on that information.

THE COMMISSIONER: Thank you.

MR FOX: I don't have any further questions about this particular document because everybody is in heated agreement that no-one really understands where it has come from and - other than what we have heard in terms of the explanation.

THE COMMISSIONER: It's an orphan.

MR FOX: Never finalised, never distributed. I don't know whether any of the other legal parties wish to ask any questions about it.

THE COMMISSIONER: After having all of those questions, unless any of the witnesses wish to volunteer anything extra in relation to the Project 13 document or Project 13? No.

MR FOX: If we can then move to the next topic, and this is the last, I think, of the major topics and the other topics are shorter. This is in terms of the reintroduction of the automated DNA extraction system using the MultiPROBE device. Now, can we start with this, and that is just in terms of people's general recollections of the circumstances in which the automated DNA system came to be reintroduced. Now, I appreciate that there was the April 2009 reimplementation report, but I just want to put that to one side for the moment.

Perhaps I will just put it this way. Anybody wishes to start off the discussion, I appreciate, Ms Ientile, you had the fortunate position of being able to say "I wasn't there" and you will adopt that position, but just looking to understand what people do recall about the reintroduction of the automated system itself - that is, it's been offline because of the contamination issue, but there then needed to be a level of satisfaction that it could be brought back online. So just with that topic, I just wanted to explore with you what people's recollections were about it.

MR NURTHEN: I can recall that part of that reimplementation obviously goes back into diagnosis of what the original contamination problem was, and that wasn't an easy thing to do, and that required a fair bit of testing to come to some sort of confident solution as to what was causing it, which meant then working out how to fix it. I can recall that being a fair focus of leading up to the reimplementation, and then having possibly identified that, rebuilding the whole protocol so as to deal with the contamination and then checking what that efficiency was before it was reimplemented, to give confidence to all of the scientists, which I know were very concerned of - due to the contamination in the first place, very concerned with reimplementing automated DNA IQ, and when it was reimplemented it wasn't a - it was a stage-wise reimplementation where samples were surrounded by blank samples initially, what we call a Soccerball format, to ensure that we best captured if there was contamination by having blanks all around it, so it was a very measured approach to reimplementing, knowing that we weren't going to get all those benefits of throughput, but it was a way 

in the implementation.

MR FOX: Mr Muharam, your name is on that 2009 reimplementation report, so perhaps it's presumptuous of me to say that you must have some knowledge, but your name is on the report. Is there anything you can contribute further to what Mr Nurthen has said just by way of introduction to this topic?

of ensuring that we could reimplement and have confidence

MR MUHARAM: I can't, actually. Even though my name might appear on the report, I mean, I cannot independently recall the details, however, I did also depart the lab, I ceased employment at the lab, you know, around January of 2009, and I believe the reimplementation came after that. So in terms of, you know, finalising the work or the report, you know, I was probably not there at the time.

MR FOX: Right. But do you recall in your work prior to January 2009, because the reimplementation presumably was something that was considered over a period of time, it wasn't an instantaneous decision made to do it, but do you recall being involved in what I'll call the preparatory work for reimplementation of the automated system?

MR MUHARAM: Mr Nurthen mentioned just now the Soccerball format, for example, so I have recollection of pieces of information like that. Like, it was an --

MR FOX: What's your --

MR MUHARAM: -- approach, there were some considerations. I do recall there were concerns from members of the lab, obviously, in terms of the reimplementation itself, but I cannot recall the detail.

MR FOX: Thank you. Now, if we could just go to the reimplementation report, this is annexure TM32, and it's item 29 in the tender bundle list. Now, can I start with just on page 2 of that document, it's 611 of 639 of Mr Nurthen's statement, and in the fifth paragraph, which starts with:

The automated DNA IQ protocol was reviewed ..

It says it was reviewed internally and also externally by the PerkinElmer National Liquid Handling Specialist, and the necessary changes made:

Some of the changes included modifications to dispense heights; optimisation of scan, aspirate, dispense and retract speeds; insertion of post-dispense transport air gaps to remove bubbles; and the removal of flush protocols. A report of the observations was made available to DNA Analysis (Pitcher, 3 October 2008).

 I will direct this question firstly to Mr Nurthen because it is relatively minor, you may be able to resolve it swiftly. Where in the second line of that paragraph it refers to "the PerkinElmer National Liquid Handling Specialist" is that Desley Pitcher who is referred to in the last line?

MR NURTHEN: Yes.

MR FOX: So you recall Desley Pitcher attending upon the lab to assist in making some modifications to the device; is that right?

Not modifications per se. MR NURTHEN: This is where we move into the actual programming of the robot and those changes that I was saying that we can't look into the So where we had difficulty, and I think Al actual program. would be able to explain this as well, that when we first got the robots, even for the amplification and quantification, things like the aspirate and dispense speeds are something that you need to optimise in-house, so I know we've been in touch with Desley before. I recall is there was a whole lot of work that had been done by Kieran with respect to looking at contamination and preventing the contamination. We then asked Desley to come and look at what we had done. She recommended some changes, of which we made, and then there was more testing done and more changes made, and then she did some more review, is what I recall.

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MR FOX: And the person you just referred to there as Kieran, surname?

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MR NURTHEN: Webber.

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MR FOX: Thank you. Do you recall when that - when that sort of modification or adjustment work was being done, with any precision?

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MR NURTHEN: No.

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MR McNEVIN: I think those October and November dates are fairly indicative of when we were doing a lot of that work.

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MR FOX: Right. Now --

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THE COMMISSIONER: Can I just ask some questions about the background of this and then go straight to a couple of others that I have, before you hit the deck, Mr Fox.

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46 47 The abstract, of course, talks about the adverse events identified in the laboratory, et cetera, and then at the last bit it talks about improvements to the extraction procedures, so that's what this was really about. As I read page 2, it's a bit historical as to what has happened to some degree, because you've got validation of the manual DNA IQ method commenced in April 2007. You talk about Project 9, Project 11, not in those terms, but by words, some of the validations that you said you did. Then you talk about the contamination issues that arose, and

then, you know, you deal with the automatic protocol was reviewed internally.

But the purpose of this, it seems to me, was then to move on to what you then deal with, further enhancement and changes to the protocol were made to increase efficiency and further the well-to-well cross-contamination events. So you have raised efficiency fairly and squarely here, because that was still a problem?

 MR NURTHEN: I think it was assumed that what we had done wouldn't necessarily fix everything. It may have, but I think this was the opportunity that when they were looking at how to prevent the contamination, you would have to assess the efficiency coming back out the other side as well.

THE COMMISSIONER: You also say, if you go over to page 4, just after figure 2:

These changes were tested in order to determine the sensitivity and the efficiency of recovery of the new protocol.

So am I right in saying that was directed to the recovery of DNA?

MR NURTHEN: Yes, because the protocol had changed, which is when it changed significantly from that first version, and this was about assessing what impact that had on the final recovery.

THE COMMISSIONER: If I can understand what was tested here and how you did it, this seems, if I can read this correctly - and please forgive me, please correct me if I'm wrong - when you get to 6.2, you talk about the fact that you used male human genomic DNA and then you assessed the recovery of that through the process and you got a hundred per cent, basically. That really functions, doesn't it, as a positive control, in effect? If you take a known amount of DNA, you put it through the system, and then you end up with - you test your result against that known control.

MR NURTHEN: It really is an efficiency positive control, because when you do something like blood or cells, without any sort of confidence you can't say what you would expect to get back out.

extracting DNA from the sample, but it does deal with the fact that you then take the lysate and you put it on the

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MR NURTHEN: Yes.

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THE COMMISSIONER: The eluted lysate --

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MR NURTHEN: What I think is --

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THE COMMISSIONER: -- sorry, the dissolved, and spun-down lysate, and you put that on the beads. This tests for the efficiency of on and off the beads?

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MR NURTHEN: Yes, which I think is the critical step

1 within the process. 2 3 THE COMMISSIONER: But if you had a problem in the lysis procedure, this doesn't go to that? 4 5 Correct. MR NURTHEN: But I didn't think there was 6 7 a problem with the lysis procedure. 8 No, I understand that. I'm just trying 9 THE COMMISSIONER: to work out what this validated. 10 11 12 MR NURTHEN: Yes. Because if you had put on some blood and not knowing the exact number of cells that you are 13 putting in, even if you do a cell count, you can't really 14 know what the exact efficiency is. 15 16 Not unless you have five different 17 THE COMMISSIONER: methodologies testing that blood to try to equate them to 18 19 see if you have got some sort of picture out of that. 20 21 But even out of that it's a theoretical MR NURTHEN: yield, and if I can refer you to Project 11, there's 22 23 a table within that where we get yields of 284 per cent, because what we thought we were putting in, we were 24 25 obviously putting in more, because you shouldn't be getting 284 per cent out. So what I recall is that this was a way 26 27 to assess that bind and release with the knowledge of 28 knowing you are putting on X amount and you're getting X 29 back off. 30 31 THE COMMISSIONER: So I think you used the expression 32 earlier sort of a positive efficiency control. 33 34 MR NURTHEN: Yes. 35 36 THE COMMISSIONER: Okay, I think I understand that now. 37 Thanks. 38 39 MR FOX: That was the main point of --40 THE COMMISSIONER: But you then reintroduced this 41 Did you have a degree of confidence then in 42 methodology. 43 reintroducing it? 44 45 MR NURTHEN: Yes. 46 47 THE COMMISSIONER: Have you had problems with DNA recovery

3 4	MR NURTHEN: Well, it was reintroduced in 2009 and ceased
5	in 2016.
	THE COMMISSIONER: Is that when you went to the Maxwell?
8 9  0	MR NURTHEN: The Maxwells got implemented in 2010 or 2011.
	MR McNEVIN: Something like that.
	MR NURTHEN: at least for some
15	THE COMMISSIONER: Was that when you ceased using - did you cease using the MultiPROBE then?
	MR NURTHEN: No, not then, not until 2016, there were
	THE COMMISSIONER: That's what I mean, sorry. So 2016 you ceased using the MultiPROBE?
	MR NURTHEN: Yes, that's what I understand.
	THE COMMISSIONER: So between this test and 2016 you were using the automated procedure on the MultiPROBE.
28 29	MR NURTHEN: To some capacity in the laboratory it would have been being used, yes.
30 31 32	THE COMMISSIONER: On-deck or off-deck lysis?
33 34 35 36 37	MR NURTHEN: Only off-deck lysis. That on-deck was never - and this reimplemented version, which is 6.5, 6.6, 6.7, would have only been in the laboratory since 2009. So I have confidence, so since 2009, based on these results, that it is efficient, that what we're presenting to the machine, it was binding and releasing that DNA.
11	THE COMMISSIONER: And have you had any evidence before you within the laboratory setting since this was reintroduced of problems with DNA recovery?
14 15	MR NURTHEN: I don't know how you would assess if there was a
16 17	THE COMMISSIONER: Systemic problems, I don't mean ad hoc

individual problems with one sample, but have you had any indication that there has been a systemic or systematic lack of recovery of DNA?

MR NURTHEN: I can only recall one time when there was what appeared to be a systemic problem and that was where the Queensland Police had changed the swab type. They had changed the swabs that they were using to collect the DNA and hadn't advised us, and I can recall that swabs that had been described as being blood positive weren't yielding any results at all, and that's the only time I can recall.

 And then there was some investigation looking into yields at that particular time, but other than that I can't recall any other time. It's a bit hard to assess to know whether or not, like I said, the sample you're getting, whether it's got sufficient DNA to when you get out the other side to go, "That definitely equates to that."

THE COMMISSIONER: Yes. But if that - I mean, you can get an individual case where there's a problem, but if the - I mean, I was asking whether, if you are using the same method over a number of samples and you keep getting bad results or not sufficient DNA, then you start thinking it's the system, not the sample --

MR NURTHEN: Yes, I --

THE COMMISSIONER: -- but have you had any such results that indicate that there is a systemic problem?

MR NURTHEN: I would have to say that the staff within analytical, who are looking - so part of the process would be that every batch would have an extraction positive control that would be analysed all the way through the system and when it got to the capillary electrophoresis, which is the separation stage, the profile would be assessed then.

MR McNEVIN: Mmm.

MR NURTHEN: But would the quantitation --

THE COMMISSIONER: Sorry, just to understand that, so what you are saying is that when you run it, you always run a positive control?

MR NURTHEN: Yes, with every extraction batch, and a negative.

THE COMMISSIONER: That would show if you were having - if the machine was not recovering DNA.

MR NURTHEN: If it hadn't been consistently recovering DNA, I would assume those positive controls to be consistently failing.

THE COMMISSIONER: Missing? Missing in action, yes.

 MR NURTHEN: And that that would have been raised within analytical, because any time anything didn't conform, there would be a batch note associated with the batch, to say, "We didn't get any DNA". I can recall seeing that comment for things like differential lysis controls where the semen within the Chelex method often didn't give a DNA profile that needed to be cleaned up afterwards. I can recall that being a common --

MR MCNEVIN: Yes

MR NURTHEN: -- comment against differential lysis ones, so I --

 THE COMMISSIONER: But I guess my question is, once this was reimplemented, is the understanding correct that whenever you ran a test through it, you ran a negative and a positive control?

MR NURTHEN: Yes.

THE COMMISSIONER: Thank you. Anyone else want to - I don't know if anyone else wants to comment on that? No? Okay, back to you, Mr Fox.

 MR FOX: Mr Nurthen, you may not have this recollection, but I'm just looking at part of - I appreciate this is in a report and you may not have seen, this is Professor Linzi Wilson-Wilde's report that she provided. She has a table at paragraph 36 which indicates that on 20 August 2009, "DNA IQ on MP II reimplemented", and then observations made "off-deck lysis". That doesn't suggest fully automated, but what is - assume that's correct, but do you have any recollection of it being off-deck lysis that was actually being reintroduced in August 2009?

MR NURTHEN: Yes, I think it actually describes the method. Within the actual body of this report, further down it will actually describe - sorry, within that reimplementation documentation should actually describe the method by which it was occurring, which would describe as an off-deck lysis procedure.

MR FOX: Right, thank you.

MR NURTHEN: But it also involved, as part of that procedure - and this is what I was saying, the mixing is really important and it's raised within this report that the mixing of the resin is no longer on the deck of the robot, it's physically removed, put on a separate instrument and mixed on a separate instrument before being put back on to the robot. So like here I said that it's been carved off again, it's less automated again.

MR FOX: Okay. When the Commissioner asked you some questions a minute ago about the process that had been reintroduced having no problems, et cetera, is that by reference to what you've just described then, off-deck lysis, or did it go to the full automation?

MR NURTHEN: No, we never reintroduced full automation again, it was always off-deck lysis and modifications to the off-deck lysis.

MR FOX: Thank you. I wanted to be clear about that. I don't have any further questions about that, given the nature of the evidence that has been given.

THE COMMISSIONER: I don't see anyone else jumping madly to their feet.

MR FOX: Not this time. Can I then move to a subtopic but we're now in post reintroduction world, and this is Project 70, which is in 2011. This document is at tab 28 or item 28 of the bundle.

Now, Mr McNevin, your name is on this document.

MR McNEVIN: Mmm-hmm.

MR FOX: Would you by way of introduction explain what the purpose of Project 70 was?

Project 70 and some subsequent projects Yes. were looking at verifying the Maxwell 16 MDx, I think it was, instrument, which is a DNA IQ chemistry but the Maxwell instrument is - in comparison to the MultiPROBEs, which are quite customisable, is a plug and play type You get your reagents, they're in a cartridge form, they are in an individual strip, and all of the pipetting steps and movement within the instrument is all locked down, you can't modify it. You perform similar sorry, I have trouble with that word. Like the other method, it has an off-deck lysis component, then you add that lysate to the individual strips and the Maxwell instrument goes along and does its business with those strips.

So it's called a 16 because it has 16 slots for 16 samples, which in practicality means 14, because you have 14 samples and a positive and negative control.

MR FOX: And this particular report, was it, in short, to endeavour to conduct a comparison between the DNA IQ protocol and the Maxwell system?

MR McNEVIN: Yes.

 MR FOX: Would you like to just explain what was actually being compared - that is, when one looks at the abstract to this document, it talks about the current - this is the first line - the current manual and automated liquid handling units DNA IQ method, so there are two that are being referred to there.

MR McNEVIN: Mmm-hmm.

MR FOX: Then about halfway down that paragraph, the Promega Maxwell 16 with a modified Promega procedure was comparable or outperformed the manual DNA IQ method in the sensitivity studies. Do you see that part?

MR McNEVIN: Yes.

MR FOX: So are we talking about, where it talks about the "manual DNA IQ method" in that fourth-last line, the actual manual, or is it a sort of hybrid automated and manual process?

1 2 3	MR McNEVIN: What it says on the box, so "manual DNA IQ method".
4 5	MR FOX: Only the manual.
6 7 8	MR NURTHEN: I think it's referring to the method that we had validated and implemented in the laboratory not the Promega manual method.
9  0  1  2	MR McNEVIN: The manual method that was part of our SOPs at the time.
12 13 14	THE COMMISSIONER: Sorry, I didn't understand. Can you say that again?
16 17	MR McNEVIN: So we discussed earlier that the manual method that we had validated as part of
18 19 20	MR NURTHEN: Project 11.
21 22 23	MR McNEVIN: Project 11, yes, that was different to the out-of-the-box Promega method, we discussed temperatures and that sort of thing.
24 25 26	THE COMMISSIONER: Yes.
27 28 29	MR McNEVIN: So the comparison is the manual DNA IQ method that was in place at the laboratory at the time, not the Promega manufacturer protocol.
31 32 33	MR FOX: I've been referring to it as the modified manual - the manual method of the DNA
34 35 36	MR McNEVIN: So the method that was in our SOP at the time.
37 38 39	MR FOX: That's the comparison, between that modified DNA IQ protocol now with the automated Maxwell system; correct?
11 12	MR McNEVIN: Yes, I think that it is mentioned a couple of times throughout the report - I think.
13 14 15	THE COMMISSIONER: So this is again off-deck lysis?
16 17	MR McNEVIN: No, no, it is the manual method - the manual method of - so it doesn't involve the use of the MultiPROBE

for extraction, this validation. 1 2 3 THE COMMISSIONER: I thought at some stage somebody said that that was never actually implemented, it was only used 4 5 as a test comparator. 6 7 Yes, it was a method that was - that we had MR McNEVIN: in the laboratory and I think we did from time to time 8 require to use it because of, you know, the MultiPROBE's9 not working or whatever, so it was used as a comparison 10 because we were looking at the Maxwell, and look, I can't 11 12 remember why we chose to compare it to the manual method. We've talked a bit about not speculating but I think my 13 quess is that it was so that we had an alternative to the 14 MultiPROBEs, so therefore, it would be replacing the manual 15 method as the alternative to the MultiPROBEs. 16 17 I seem to recall that it was about having 18 19 a small-batch method, we could, you know, do things like urgent samples on, rather than having to do a big massive 20 21 lot. 22 23 THE COMMISSIONER: Excuse me for this, probably - I mean, 24 obviously I'm just trying to understand how all this fits 25 This refers to a pre-lysis testing. 26 27 MR NURTHEN: This refers to an alternate DNA IQ system, 28 run on a completely different instrument to the MultiPROBE. 29 30 THE COMMISSIONER: Yes. But when it talks about - I'm 31 trying to work out if there is anything in common between 32 the pre-lysis procedure that is looked at here and any 33 pre-lysis procedure that was used for the purposes of the MultiPROBE. 34 36 MR McNEVIN: Yes, so to be honest, I can't quite remember, 37 but just reading that, is it the second sentence:

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Initially pre-lysis methods were tested to determine which method gave acceptable results and then would be used for the remainder of the verification.

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THE COMMISSIONER: It says the Promega recommended Now, that sounds like -procedure.

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MR McNEVIN: Sorry, which line are you looking at?

THE COMMISSIONER: The next line. It says that it was determined that the Promega recommended procedure with a few modifications was deemed to be the most suitable pre-lysis procedure. So I'm just trying to work out how that fits in with the MultiPROBE Promega methodologies.

 MR McNEVIN: Oh, okay. I don't recall. My guess is that we must have done some different pre-lysis methods and it may well have been that there was a pre-lysis method that was published by Promega for use with the Maxwell MDx instrument.

THE COMMISSIONER: I guess without speculation, from your recollection or knowledge, does that have steps in common with the procedure used for the purposes of the MultiPROBE?

MR McNEVIN: I would imagine that they're all very similar. There's probably just some variations on, you know, quantities, concentrations, that sort of thing. So these instruments came along subsequent to the MultiPROBEs, subsequent to the DNA IQ procedure that would have been available back when we validated the manual method some, you know, years previous, so it may well be that Promega might have even updated their protocols in the interim as well. So, look, I would have to go back and re-read the report with more detail, but there would be some different variations on a theme.

THE COMMISSIONER: The fact that if you had any problems with this pre-lysis procedure that you were referring to in this report, it doesn't necessarily tell us anything about the procedure that was used for the MultiPROBE?

MR McNEVIN: No. I can't recall which - what the various --

THE COMMISSIONER: You can't help one way or the other on that?

MR McNEVIN: No, not without maybe digging deeper into all of the records that we have.

THE COMMISSIONER: I understand, thank you.

Thanks, Mr Fox.

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MR McNEVIN:

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for example, the off-deck lysis approach that was

reintroduced in 2009 against the Maxwell?

PROJECT 13 SCIENTISTS CONCLAVE

So in your mind,

MR FOX:

MR FOX:

MR McNEVIN:

mind than --

If this was a comparison between the modified

If it was a comparison between that and the

So a little bit further, please, a little bit

If you just go down to "Methods", there's a

DNA IQ protocol, so the manual - I am just going to call

Maxwell automated system, why, when one looks at item 4, "Equipment and Materials", would it be necessary to list

"Materials and Methods" section, if we scroll through the

Amplification". So if you just stop there for a minute, so

5.2, there talks about the extraction procedure, and then

So that's why it wouldn't be listed in the equipment used,

And then, sorry, you added in also the

Sort of. It's a little bit fresher in my

No, it's the manual method, and I think, you

But reading through this, you say that you're

satisfied that where it refers to the idea of comparing the modified manual, DNA IQ protocol, with the Maxwell - the

automated Maxwell, is that it's not referring by the word

that is the off-deck lysis approach. We're not comparing,

"manual" to a hybrid - that is, a manual plus automated,

you have no doubt at all that - firstly, do you remember

further along in the report, please, yes, a little bit

you can see under "Quantification and Amplification":

performed using a MultiPROBE II PLUS HT EX

All quantification reaction setups were

because we used the MultiPROBE for setting up the

quantification and amplification reactions.

amplification, which one can see there.

further, when you get to "Quantification and

this the modified manual system --

Okay.

the MultiPROBE device there?

with Gripper ...

this report and this work?

MR McNEVIN:

MR McNEVIN:

MR FOX:

know, it's in more than one place throughout the report, it's referred to as "the manual method".

MR FOX: I understand that, but I just want to make sure my understanding - I understand what your recollection is of what this actually was as a test, that it wasn't, in fact, comparing the off-deck lysis approach against - that is, the reintroduced approach, against the Maxwell system.

MR McNEVIN: Mmm.

 MR FOX: Then can I just ask this question, then: why wasn't that the appropriate test to be doing a couple of years later - that is, to actually be testing the reintroduced or reimplemented off-deck lysis system against the Maxwell?

MR McNEVIN: Well, like I said, I can't really recall exactly why we chose the manual method. My only sort of thought is that that was because we were looking to have an alternative to the - alternative to the automated method. The previous alternative was to use the manual IQ method and so we were looking to replace the manual IQ method, so we were testing it against the method we were going to replace. We weren't replacing the off-deck lysis method.

To be honest, I'm not entirely sure why we chose to do that. I can imagine that we would have not tested it against both methods because that would have added an extra layer of testing that, you know, for all intents and purposes had been done on a previous - we said, "Test it against one method" and we chose the manual method. You know, it's a small-batch method, testing it against a small-batch method. But I can't remember the exact reasons, to be honest.

MR FOX: Can I just ask you to turn to page 7 of the document. This is the heading, just for those who are sliding through the electronic version, "Results and Discussion", item 7, 7.1 is "Suitability", there is a graph and then there is a table under that, "Summary of Suitability Results". And you will see there in the last four lines of page 7:

 The original validation of the manual DNA IQ chemistry gave an average yield of 307 Ng for blood swabs with a standard

deviation of 102.36.

Then the next sentence is:

The results of the manual DNA IQ in this verification showed a significantly lower yield with a lower standard deviation for the blood swabs and a much greater yield for the cell swabs with an increased standard deviation when compared to the original validation of the manual DNA IQ chemistry.

Now, just pausing there, when it says "the original validation of the manual DNA IQ chemistry", what do you understand that to be referring to?

MR McNEVIN: One of those earlier projects, 9 or 11, or one of those two.

MR FOX: Well, 9 was just simply doing a comparison between that and four other manufacturers.

MR McNEVIN: Yes.

MR FOX: Then 11 was a modification.

MR McNEVIN: It must have been 11, then.

 MR FOX: Mr Nurthen, do you have any insight? I appreciate you don't have your name on this document, but you have read this document and we're reading it now. What do you think that's referring there to, "the original validation"?

MR NURTHEN: I would think it would make sense to be referring to Project 11, if that's where that initial work had been done. It would make sense to me that that's where those figures were derived from. But what I'm unaware and I'm not intimately involved or intimately over this particular report, but I don't know how much blood was put on those swabs to know whether or not you can directly compare them, because they clearly weren't the same samples that were done in Project 11, which leads me back down that path of the efficiency as well to go, "Could you directly compare it?" I'm not sure that you could directly compare it.

MR FOX: Then just asking you, both Mr McNevin and then Mr Nurthen if you wish, just in relation to the sentence about "The results of the manual DNA IQ in this verification showed a significantly lower yield with a lower standard deviation", so this is a lower yield compared to either the original validation, which is what it seems to be suggesting, or it is a lower yield by comparison with the Maxwell.

MR NURTHEN: I think it would be referring to the original manual DNA IQ, but if we could go further up in the document to where they have actually prepared the samples, to give me any indication as to how much - so they have 60, 30, 15, 5, 2, 1 microlitre, 0.5, of blood. I think originally we did a 30 microlitre, and then a 1 in 10, 1 in 100, 1 in 1,000, but again, unless you are using exactly the same blood, being able to make extrapolations back to Project 11, I wouldn't think would be a good idea.

Comparatively doing it the same time with the same blood, that's okay. But we just don't know how many white cells were in this particular version of the blood compared to whoever's blood was used back in 2007.

MR FOX: Mr McNevin, did you want to make any comment about that?

 MR McNEVIN: Yes. So going back to that sentence, I think it's referring to the results for the manual DNA IQ when we did it in Project 70 comparing it to the results for manual DNA IQ from the validation - is that - can I go back and re-read that sentence?

MR FOX: Yes, that's the sentence I'm lingering on.

MR McNEVIN: Yes, is that --

MR FOX: So you are saying Project 70 is --

MR McNEVIN: Can I just read it again?

MR FOX: Yes, of course.

MR McNEVIN: Is that okay?

MR FOX: No, absolutely. Yes, so we have to scroll back

up. We're back to where we were before, please, just at --1 2 3 MR McNEVIN: 4 The results of the manual DNA IQ in this 5 verification showed a significantly lower 6 7 yield with a lower standard deviation. 8 Yes, so I'm talking about - I think here we're talking 9 about the results from manual DNA IQ in this experiment, in 10 this project, comparing them to the original validation 11 12 manual DNA IQ. I can't remember whether we were using the same donor or not. 13 14 15 MR NURTHEN: And I think this table is different because that other one indicated the sensitivity, so I'm not sure 16 17 where this - because this is only presenting if it is an absolute value. 18 19 MR McNEVIN: 20 Which experiment is this one? Have we got 21 the whole document to look through rather than just a page at a time? It's a little bit difficult. 22 23 THE COMMISSIONER: 24 Is there a spare hard copy? 25 MR FOX: I have one but it has handwritten notes all over 26 27 it. 28 29 THE COMMISSIONER: I'm sorry, I have written on this as well. 30 31 32 (Hard copy shown to Mr McNevin). 33 Thank you. So we're looking at results from 34 MR McNEVIN: 35 Project 70, "Suitability". Okay, so looking at that now, so that's the page 7, that's section 7.1, "Suitability", so 36 we're looking back at the "Experimental Design", "7.1, 37 Suitability", talking about buccal swabs, the report 38 39 actually doesn't point out exactly how much blood was on 40 those cells, so it's not very good. 41 THE COMMISSIONER: I'm just wondering, Mr Fox, do you have 42 43 much else to do with these witnesses? 44 45 MR FOX: We're pretty close to the end. 46 47 THE COMMISSIONER: I was just wondering whether it might

be fair to allow five minutes just - I don't mind if I sit here quietly, but I think it might be fair to let him just read through that slowly and get on top of it.

MR McNEVIN: It could be referring to - so 5.1.4 talks about 30 microlitres of blood, so it could be comparing - did we do 30 microlitres of blood in the original DNA IQ extraction?

MR NURTHEN: I believe so, yes.

MR McNEVIN: So it's probably comparing that 30 microlitre result with the 30 microlitre result from the previous experiment. I don't know whether we used the same donor or not. We keep our - for each validation, who the donor is, is anonymised, is made anonymous so that, you know, with the fullness of time I can't go back and tell you whether it's the same donor or not. If it was the same donor, you would expect the results to be similar, not necessarily bang on, but you would expect - you would sort of get similar levels of DNA out of someone's blood over a period of time.

MR FOX: I think we'll give you those few minutes, Mr McNevin, just to look at that document.

THE COMMISSIONER: Why don't we take five minutes so that you can actually sit down quietly without the pressure of everyone staring at you and have a read through that. The other is if you don't feel that you - you haven't had a chance to look through this and understand what it is, why don't we give you an opportunity of putting in something overnight.

MR FOX: Certainly. I might then just ask the question, which is: If you turn to page 14 of the document, this is item 7.3, "Sensitivity Testing and DNA Yield", you will see there the graph with respect to sensitivity, and the Maxwell automated system is giving better results from 2 microlitres up to 60 microlitres, that were significantly better in the range of 2 to 5, this is as against the manual method.

MR McNEVIN: Mmm.

MR FOX: I just wanted to ask you whether that result struck you as being rather impressive in terms of favouring

Maxwell against the manual system, which one would expect to perform well, ordinarily?

MR McNEVIN: To be honest, testing at that high level, where you're getting quite good quantitation values, it's probably a little bit of a moot point because you're probably (a) reaching the maximum binding capacity of the beads that you have in your method and you're also getting to the point where you're going to get plenty of DNA regardless of whether the yield is a bit up or a bit down, when you are talking about samples of a lot of DNA.

Where your interest really lies is when you've got So looking at, you know, 0.51 microlitre, that's your area of actual critical concern when you are talking about whether a method - you know, when you're getting more DNA than what you need to produce a DNA profile, does it really matter whether your yield is a bit up or down, when you have got plenty anyway, you know? If I've got enough paint to paint a wall, it doesn't matter whether I've got an extra five pots of paint or an extra 20 pots of paint, I've still got enough paint to paint the wall. So what you're really interested in is when you're getting further down the smaller end of the scale. The fact that the results for manual sort of seem to level out at around 100 nanograms total yield indicates that's probably what the maximum binding capacity of the method was, and maybe the Maxwell had a greater maximum binding capacity. really remember.

MR NURTHEN: I think, if I can help with that, that I would expect the Maxwells probably have a different binding capacity but I don't think they state in any of their literature what the binding capacity is for the Maxwells, but they do to for the Promega DNA IQ by itself. The binding capacity by itself is approximately 100 nanograms, so if the resin is different and there's a different amount of binding capacity, you're going to see better results for the Maxwell even if it isn't as efficient. I think it probably is more efficient, but you're not necessarily comparing apples and apples, if that makes sense.

 MR FOX: The only other topic - there is a matter before you rise today that I just want to raise, it comes out of the questions that we've just been dealing with on the last topic. The only other matter which I had was in relation

to going forward, that was whether there are any comments that any of the experts wish to make about lessons learnt, would they do things differently; what would they recommend, in terms of retesting, that general territory.

THE COMMISSIONER: Sure.

MR FOX: Just a few questions, then. You have had the benefit of reflecting on matters that are (indistinct) --

THE COMMISSIONER: Just with regard to that last document, if there is anything you wish to add in relation to that document, you can put it in writing, you know, just to help us with that.

MR FOX: I will deal with that issue then, now.

 MR FOX: So the legal representatives for the scientists, but particularly those representing Mr Nurthen and also Mr McNevin, were provided with some points that had been raised by Dr Wright in reviewing the evidence, and they were given that document.

THE COMMISSIONER: This one?

 MR FOX: Yes, thanks. In relation to the Project 70, but there were some other questions which have been dealt with in the course of this afternoon. And it was raised with me just before we commenced today that there may have been a disruption to this afternoon's events by reason of whether they had had sufficient time to digest the comments that had been made.

I gather that, by the fact that people haven't leapt up and tried to throttle me during the course of this examination-in-chief, things have gone reasonably satisfactorily, but what I would wish to indicate, so they can hear what I have to say - if they want to say anything further, now is the time to do it - that it seems to me that if both of those gentlemen would be given an opportunity, if they wished, to put something in writing in response to - further to what they have said, which is on the territory of these questions, that they be given that opportunity to do so.

MS FREEMAN: Thank you, Mr Fox. Yes, Commissioner, those issues were only raised with us this morning, and so

I haven't really had much of a chance to take full instructions from my clients about those points. So it may be that at the conclusion of today I just confer with particularly Mr McNevin and Mr Nurthen about that, and if there is something in particular they wish to directly respond to in writing, we will do so overnight, if that is suitable to the Commission.

THE COMMISSIONER: That makes sense to me. Thank you very much.

MS FREEMAN: Thank you.

MR FOX: I think their answers have dealt with the issues but I thought it would be better to extend that courtesy to them given that they had only received the material --

THE COMMISSIONER: Yes, Mr McNevin at the very least was doing it on the run, and I think I would be assisted by any reflections if they occur overnight. Thank you.

MR FOX: So in terms of the final topic, this is intended to be one of reflection, if anybody wishes, by reason of having gone back to matters some 15 years ago and the steps that have been taken, would we have done anything differently with the benefit of hindsight? It's not intended to offer an opportunity for anybody to fall on a sword, I don't expect that from the evidence that has been given today, but if there are any suggestions or reflections that you would like to make to the Commissioner at that point, now is your invitation to do so, and that can also include in terms of - I indicated, you know, when you were outside early this morning when the matter opened, that there had been a decision made to go and test right back to 2007, and whether you had any observations to make in relation to what might be there to be tested, et cetera. I think we've covered some of that already today.

 THE COMMISSIONER: I have one specific question about that before you go on to the general reflections. You went back to Chelex for a period of time, I think between July 2008 and some time in 2009, and that was when the automated procedure was reintroduced. When you make your comments, I wouldn't mind any comments you could make about the reliability of the testing that was done during that period, even if you assume that there was a problem with the extraction of DNA in any event, whatever was the

situation with the automated - when you went back to Chelex, if you could just give me an understanding of what you think about the retesting of those samples.

MR NURTHEN: I think if you look at it on a risk basis, I don't think there is a lot of risk associated with going back to the status quo which was the Chelex. There was no reason to suggest before we started the IQ that Chelex was unreliable, it is known to produce DNA and known to get DNA profiles. I think the problem was it just wasn't as clean.

THE COMMISSIONER: And the quality.

MR NURTHEN: The quality. So I don't have any concerns in that period where we retested with Chelex that any of those cases would need to be retested.

THE COMMISSIONER: Does anyone else have an observation to make about what I will call the closed Chelex period?

MR McNEVIN: No, I don't think so. I don't think the laboratory had any validation reports or anything from Chelex, on those, when it was very first implemented, so I don't think there would be anything much to go back to, to sort of check off on that.

THE COMMISSIONER: I don't know if anyone on screen has any comment to make about that, but otherwise, if not, I will go back to you, Mr Fox.

MR FOX: Thank you, this is just in terms of maybe training, reflections on that, it may be the validation processing, maybe report writing. You've had an opportunity to reflect no doubt on it, and this is just an opportunity if there are any positive sentiments that you would wish to express to the Commissioner and be given the chance for an opportunity to make some observations about what has occurred.

 MR NURTHEN: I think that I took the lessons that are learned from working on that particular project forward with all of the other projects I've worked on subsequently, with respect to documenting, with respect to, you know, writing everything up and trying to get everything planned first. I think in retrospect - and again, at the time, being very new to this process and not having undergone any formal validation training at the time - I now look back

and go, "We shouldn't have picked up any instruments. We shouldn't have started anything until there was a fully signed-off plan."

But at the time, that's not the way I guess we were working. Now I would say, "No, you don't start any experiments until you have a plan that has been written out in total, you've looked at what kind of statistical testing you want to do, everything is basically put out on the table and reviewed externally, hopefully, prior to even starting the experiments."

I'd say that's where, in retrospect, that would have greatly benefited us by actually having a full plan before going to something as large as this was. I think, naively moving into it, we thought we could just pick up a method and it would be plug and play, and it clearly wasn't that easy and that simple.

 MS IENTILE: I think building on what Tom has said about the reflections, at that period of time when these reports in 2007 or this work was done, prior to that, the validation reports hadn't included a summary report, they had just been the data that was collected. So we were moving in a process of continuous improvement in the laboratory as a whole towards what Tom is alluding to, a better planning situation and reporting. So I think the lessons learned from that, I support what Tom has said around the planning and around the documentation and the final report and where the sign-off occurs.

MR McNEVIN: Yes, and I think if you go to projects later, like 70 and 71, some of those subsequent ones, and so on and so forth, you'll see, you know, there's project reports, there's experimental designs with all members of the management team signing off on them, there's review processes and, you know, certainly the subject of the previous Inquiry, there was much discussion about, you know, feedback on reports and that sort of thing.

 So if there was a lot more - an expansion of that kind of thing where we had a final report that was signed off by all members of the management team prior to implementation of a procedure, that wouldn't have led us to this stage where we're having a conversation today about a draft report on a process that we had implemented that certainly, you know, wouldn't have - didn't happen later on because

we'd learned some of those lessons about finalisation of documentation; we had a much more stringent project management system in place that came along as a result of those subsequent validations that we did. We also got better at, like, naming conventions with files and things where, you know - and unfortunately, some staff still struggle to appreciate it but you need to, you know, have everything labelled so that when you go back to look at it some years later, you know what that spreadsheet - what all that data in that spreadsheet is, rather than it just being a whole bunch of values and numbers, you're kind of like, "Oh, what part of the experiment was that?" So we've learned a lot of - a lot of lessons learned from that and I certainly, you know, implemented a lot of those lessons in a lot of the projects that I was involved in subsequent to the automation project.

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MR FOX: Thank you.

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And, Dr Hlinka, would you like to indicate any thoughts or reflections, looking back now?

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DR HLINKA: I haven't been working at the lab since 2009, so I do not actually know what has been happening since then. I think there should be a level of protection on internal documents so that, you know, important documents like the Project 13 report do not disappear or get deleted accidentally. There should be some kind of quality management around that.

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MR FOX: Thank you. Ms Gallagher?

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46 47 MS GALLAGHER: Given my position at the time was fairly junior, it's hard to sort of recollect what I might have been able to do differently in terms of the project, but I certainly think in listening to conversations today, I guess things that I could have done better at the time would have been, you know, as I was going about doing my work sort of like what has been mentioned already is making better records of each iteration that we were going through in terms of creating the documentation and - sorry, in terms of creating the protocol that was put in place, and as we've been going back over different methods that were provided by the manufacturer, maybe having records of each protocol that we had at the time that could have been saved alongside these projects that could be referenced in those documents so that we could see what the original

manufacturer's protocol was at the time.

MR FOX: Thank you. Mr Muharam?

MR MUHARAM: Thank you, Mr Fox. Just I guess to make a minor comment, you know, again reflecting on my time of employment there, I do recall, you know, as the part of the - any validation work that was done, the lab actually tended to overvalidate, if I could say that, you know, fairly, meaning that, you know, the team went above and beyond to identify what's kind of like the minimum that needs to be done and then often a lot more was done on top of that.

For example, the efficiency study that was mentioned earlier, you know, with human male genomic DNA carrying that through, as far as I know personally, that's not a common experiment that a lot of labs do. So, you know, just to highlight that, you know, the lab at the time was to some extent trying to do the best that they could, and often actually employing best practices, but maybe to some extent overvalidating.

But in terms of reflecting on, you know, improvements that could have been made, I agree definitely with all the other experts here in terms of, you know, understanding the scope, scoping, scoping experiments beforehand, understanding the stakeholder expectations and having that approval matrix put into place, record-keeping has come up a couple of times, project tracking, and obviously nomenclature around identifying a draft document versus the finalised document, I think these could be, you know, future areas of improvement.

MR FOX: Thank you. Now it's really a matter of residual questions.

THE COMMISSIONER: I have a few residual questions. Thank you very much for those reflections. Everyone has described in a way, you know, expansion and contraction of the same concept of the systems that are in place. You said that things got better and that, you know, you have learnt things since then.

 I'm trying to put some time frames into this because one of the things that I have to consider is the period of time during which there may have been some uncertainty as to outcomes, for any of the reasons that we've discussed, including, you know, not every lack of record-keeping gives rise to a consequence, but some may, and some may introduce questions of uncertainty as to results. So what I'm just trying to look at are time frames when things got better and also times during which there was any uncertainty sufficient to - not to justify, to call for a retesting of the underlying samples. I guess that's - so when you said things got better and things have improved and we all acknowledge there were systems that were not working as they should in that time, and I think Mr Muharam put it - I mean, the fact is we're talking about a draft document that went through iterations and never seems to have been finalised for sure, yet it formed the basis for the implementation of a methodology, I mean, that's something.

So can you give me an idea of the time frames and any comments you want to make about the time periods in your experience that raised that potential for uncertainty?

MR NURTHEN: I think it's an iterative process of improvement.

THE COMMISSIONER: Let's go back to 2007, if I may, which is when this started, and give me - can you give me, since that time, a time when you would say that you would not be confident, for any of the reasons, whether it was because there were contamination issues or any recovery issues or things were not perfect - the times during which you feel there was sufficient uncertainty in the testing results, looking at it now? I'm not suggesting at the moment that you saw it then, because that's not relevant really for me now; it's looking at it now.

MR NURTHEN: Are you referring just to the extraction process now? I thought you were talking about validation.

THE COMMISSIONER: This is about Project 13, so it's the use of the MultiPROBE, the automated system with the MultiPROBE, in its various iterations. I mean, if you told me today - I'm not suggesting this is to be said - that we now reckon that the off-deck lysis was a disaster as well - I mean, what I'm saying is I just want your views on that time frame if I can have it, please.

MR NURTHEN: I think it would be prudent, where possible, and where indicated, that you would go back and retest, if

possible, because it just makes good scientific sense, if there is any uncertainty. It is no good me giving assurances saying, "We think it's okay". It would seem logical to me that if you have the opportunity as part of the case, why not retest it?

We actually get the added benefit, because back in 2007 we were using the Profiler Plus kit with a 3130 or a 3100 instrument, and we were using binary interpretation of DNA profiles. We now have a much bigger suite of testing that we can do that is more sensitive, the amplification kit we use is more sensitive, everything is more sensitive.

THE COMMISSIONER: I understand.

MR NURTHEN: So it indicates to me that whole period, why wouldn't you go back.

THE COMMISSIONER: Back to when? You reintroduced - TN32 brings in a period with the genomic DNA efficiency verification. Are we talking about from 2007 to 2009, from 2007 to 2016? What are we talking about?

MR NURTHEN: I don't think you can put a cap on it because we do, as a regular basis for cold cases, go back to samples in the mid '80s, in the '70s, even earlier, and retest them with the current technology and get results. So I don't see why you'd restrict yourself to any time period. I think if anything you might want to prioritise which cases in which period you might possibly look at. That would seem a sensible approach to me, rather than go, "Oh, I would only test" --

THE COMMISSIONER: I'm looking - because I mentioned at the beginning the terms of reference, so I'm not making a free for all here. I think at the moment, let's just start with one thing, which is the consequences of any uncertainty that may arise because of the methodology outlined in Project 13 as it was then carried out, implemented and subsequently to the extent that it subsequently was relevant in the laboratory testing procedure.

MR NURTHEN: I think to give the community confidence, we would have to test anything in that time period.

1 2	THE COMMISSIONER: But when did it stop?
3 4 5	MR NURTHEN: Well, if you want to give the community the best confidence, it would be all the way to the end of the MultiPROBE, which I -
6 7 8	THE COMMISSIONER: In 2016.
9 10 11	MR NURTHEN: 2016, which I understand was already on the cards for testing or retesting anyway.
12 13 14	THE COMMISSIONER: Does anyone else wish to make an observation about that?
15 16	MS IENTILE: No.
17 18 19	THE COMMISSIONER: Thank you very much. That's very helpful.
20 21	I don't have any other questions. Do you have any other questions?
22 23 24	MR FOX: No, I don't. I don't know whether anyone else does.
25 26 27 28 29	THE COMMISSIONER: Does anybody else have any questions arising, or not arising? It doesn't have to arise from my question, it can be any independent question that anyone wishes to put to any of these witnesses? No?
30 31 32 33	Look, I appreciate it has been a novel - possibly a novel procedure for you all. I appreciate you coming on and giving me the evidence that you have.
34 35 36 37 38	Thank you for making the system work, and I think it has worked, and I hope you feel that you have had the benefit of having each other present to deal with these matters.
39 40 41 42 43	In particular I would like to thank Dr Hlinka because I know that your medical condition is such that you didn't think you would be able to make it for the whole day, and yet you have.
44 45 46	DR HLINKA: Yes, thank you.
46 47	THE COMMISSIONER: So I'm very appreciative of that.

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DR HLINKA: Thank you very much.

THE COMMISSIONER: Thank you all.

Unless anyone has anything - are we going to get something in writing? It may well be that we will ask some of you - I can't say for sure; it's not up to me. At the moment I can't see it, but it may well be that some of you might be asked to come back for further evidence but we will give you appropriate notice with respect to that.

Can you notify us, please, one way or the other, whether you intend to put anything further in writing, so we know?

Of course, yes, Commissioner. MS FREEMAN:

THE COMMISSIONER: Thank you very much. Is there anything else, Mr Fox?

MR FOX: Yes, just in terms of the start time.

THE COMMISSIONER: Tomorrow morning, the start time.

MR FOX: Yes. I think at this stage, it will 9 o'clock, because we're dealing with Dr Budowle in the US.

THE COMMISSIONER: If not, we will notify people.

MR FOX: It won't be earlier than 9. Exactly.

THE COMMISSIONER: We did think of earlier than 9 but we decided to have some sympathy for others who may not be prepared to come that much earlier but we will start at 9 o'clock rather than 10 because of the time frame for We will be having another hot tub tomorrow. Dr Budowle.

Thank you. I will adjourn.

AT 4.07PM THE SPECIAL COMMISSION OF INQUIRY WAS ADJOURNED TO TUESDAY, 31 OCTOBER 2023 AT 9AM

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