October 13, 2000	munity on Hormone Receptor Testing
	THIS PAGE ONLY REVISED NOVEMBER 18, 2008
COMMISSION OF INQUIRY	LIST OF EXHIBITS
ON HORMONE RECEPTOR TESTING	EXHIBITS P-2939 THROUGH P-2944
	EXHIBITS P-2948 AND P-2949
BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER	EXHIBITS P-2951 THROUGH P-2957Pg. 347
	EXHIBIT P-2960 Pg. 347
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Appearances:	EXHIBITS P-2979 THROUGH P-2981
	EXHIBITS P-2983 THROUGH P-3003
Bernard Coffey, Q.C Commission Co-counsel	EXHIBITS P-3005 THROUGH P-3029Pg. 347
Sandra Chaytor, Q.C Commission Co-counsel	EXHIBITS P-3031 THROUGH P-3035Pg. 347
	EXHIBIT P-3037
Rolf Pritchard/Jackie Brazil, Q.C Her Majesty in Right of NL	EXHIBITS P-3040 AND P-3041
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Peter Browne, Q.C./Jane Hennebury Doctors Kara Laing et al	
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Daniel Simmons Eastern Regional Integrated	EXHIBITS P-3059 THROUGH P-3073
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Chesley Crosbie, Q.C Members of the Breast Cancer	
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Mark Pike, Q.C NL Medical Association	EXHIBITS P-3413 THROUGH P-3415 Pg. 348 EXHIBITS P-3417 THROUGH P-3418 Pg. 348 EXHIBITS P-3420 THROUGH P-3462 Pg. 348
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	2 Q. Please be seated. Mr. Browne.
MR. TERRY GULLIVER - RESUMES THE STAND	3 MR. TERRY GULLIVER - EXAMINATION BY PETER BROWNE, Q.C.: 4 BROWNE, Q.C.:
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Examination by Sandra Chaytor, Q.C	10 A. Good morning, Mr. Browne.
MS. HEATHER PREDHAM - SWORN	11 BROWNE, Q.C.:
	12 Q. I just want to clarify some of your answers to
Examination by Sandra Chaytor, Q.C Pgs. 345 - 376	
Ziminimion of Sundin Cington, Quelitritin 1 got one	your testimony, and unfortunately I have to go
Certificate	back to the first day, but we'll try to move
	16 forward very quickly.
	17 MR. GULLIVER:
	18 A. It seems forever ago.
	19 BROWNE, Q.C.:
	20 Q. We'll try to move as quickly as we can here.
	21 You had mentioned to Ms. Chaytor that the
	training - I guess, the schooling program for
	23 lab technology is a three year diploma program
	24 followed by national certification exam, and
	25 that applies across - uniformly across the
	25 that applies across - uniformly across the

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1 country, is that right?		needs to be done and the bio - is it the bio
2 MR. GULLIVER:	2	engineering, did you say?
3 A. The national exam does.	3 MR. GU	
4 BROWNE, Q.C.:	4 A.	Yeah.
5 Q. The national exam.	5 BROWN	NE, Q.C.:
6 MR. GULLIVER:		When they're contacted, or is it just set
7 A. Training programs may differ from province	-	times when they come in?
8 province, but you do have a national	8 MR. GU	
9 competency profile that each training progr		I think the protocol is to recalibrate once a
has to ensure the students follow that		year.
profile.	11 BROWN	
12 BROWNE, Q.C.:		And thermometers as well?
13 Q. Okay. Now looking at - if you wish you co	1	
call it up, and that's Ms. Wegrynowski's fir		And the thermometers is the - NIST is an
report, P-0047, but generally within that		instrument that verifies that your thermometer
review of the lab, she mentions a number		is working properly. So, you know, the case
things surrounding, I guess, the equipment		where Ms. Wegrynowski had mentioned that was
use of equipment by the technologists, and		in the - for example, the Ventana platform,
particular the pipette calibration and		the procedures taking place inside the
20 accuracy, the use of, I think it's an NIST		instrument at a certain temperature, and the
21 thermometer. Just dealing with those tw		instrument automatically sets itself in a
pieces of equipment, is that something that		program at that temperature, and she said what
you learn about in the program in terms of		Mount Sinai uses, they actually put a
of this equipment, and, I guess, accuracy o		thermometer inside the instrument and measure
the equipment and so on.		to make sure that the instrument is working
25 the equipment and 50 on.		
1 MD CHILINED	Page 6	Page 8
1 MR. GULLIVER:		properly and is really at that temperature.
2 A. The pipetters, you would learn how to use	<u> </u>	So if it's supposed to be at 37 celsius, they
3 pipetter in your training program.		put a thermometer to measure that. What the NIST is then it's another calibration to make
4 BROWNE, Q.C.:		
5 Q. Yes.		sure the thermometer you're using to measure
6 MR. GULLIVER:		the instrument is actually working properly.
7 A. But certainly the calibration of it or - and		NE, Q.C.:
8 it's not the calibration of it, it's to verify	-	So would these sorts of things - ULLIVER:
9 that the calibration set by the manufacturer		
is still at that setting, whether it's a year	<u> </u>	And that's not something that you learn in the
la provint of		general medical lab technology program.
12 BROWNE, Q.C.:	12 BROW	
13 Q. Right.		Okay, and that's what I was coming back to.
14 MR. GULLIVER:		These sorts of things are, like, I guess,
15 A. That's really something that's a function o	<u> </u>	we've heard the term troubleshooting. Is that
the biomedical engineering department.		- would that canvas that, sort of checking
17 BROWNE, Q.C.:		instrumentation and so on, would that be
18 Q. Okay.		troubleshooting?
19 MR. GULLIVER:	19 MR. G	
20 A. Within your organization that's now who	<u> </u>	That's not really troubleshooting. That's
21 that for us.		your preventative maintenance kind of
22 BROWNE, Q.C.:		schedules.
23 Q. But in terms of recognizing, I guess, when	- 23 BROW	NE, Q.C.:

25

Q. Okay. The notion of troubleshooting in the

lab, is that again something that is canvassed

24

25

is that already set? Does the technologist

have any involvement in recognizing when that

Page 9 1 in either the national certification 2 examination or in the training program, the 3 three year training program? 4 MR. GULLIVER: 5 A. Troubleshooting, yes, it is. It's covered 6 off, but troubleshooting in a general sense 7 within medical laboratory (technology, i.e. it 8 could be troubleshooting in a biochemistry 9 environment, a pathology environment, in microbiology environment, a pathology environment, in microbiology environment, in microbiology environment, and thoology environment, in microbiology environment, in mi	October 15, 2008 Mult	i-Page inquiry on Hormone Receptor Testing
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4 MR. GULLIVER: 5 A. Troubleshooting, yes, it is. It's covered 6 off, but troubleshooting in a general sense 7 within medical laboratory technology, i.e. it 8 could be troubleshooting in a biochemistry 9 environment, a pathology environment, 10 microbiology environment, but how to 11 troubleshoot specific instances within any 12 certain test, that really is learning on the 13 job. 14 BROWNE, Q.C.: 15 Q. But the theory, the notion that it's necessary 16 to- 17 MR. GULLIVER: 18 A. The theory behind it, yes. 19 BROWNE, Q.C.: 20 Q. Now in terms of going back to the 21 instrumentation, such as pipettes, 22 thermometers, and then, I guess, add to that 23 slides and pH meters, those sorts of pieces of 24 equipment, in your lab or in the lab at the 25 Health Sciences Complex, who would have been 26 quipment? 27 MR. GULLIVER: 28 A. Troubleshooting in a general sense 29 within medical laboratory technology, i.e. it 29 Q. Now in terms of going back to the 21 instrumentation, such as pipettes, 22 thermometers, and then, I guess, add to that 23 slides and pH meters, those sorts of pieces of 24 equipment, in your lab or in the lab at the 25 Health Sciences Complex, who would have been 26 Q. Yes, selection of a particular piece of 27 equipment? 28 MR. GULLIVER: 39 A. They're basic lab equipment. They'd be at the 10 division manager's level. 11 BROWNE, Q.C.: 40 MR. GULLIVER: 41 A. Tor ordering it? 50 Q. And you had mentioned in your - you became - I 51 DROWNE, Q.C.: 52 DROWNE, Q.C.: 53 DROWNE, Q.C.: 54 Contain test, that really is learning on the 55 DROWNE, Q.C.: 56 Q. Yes, selection of a particular piece of 66 Q. Yes, selection of a particular piece of 77 equipment? 88 CULIVER: 80 A. Troubleshooting in a biochemistry 81 MR. GULIVER: 91 A. No. 92 DROWNE, Q.C.: 93 Q. Now you had - when you became manager, was there any requirement upon you, or supervisor at that point, or assess -1 think we've heard 94 That M. Guetter the Mere we invented them. I certainly helped, and, you know, passed along any material that 1 Had. I did submi	2 examination or in the training program, the	2 MR. GULLIVER:
5 A. Troubleshooting, yes, it is. It's covered 6 off, but troubleshooting in a general sense 7 within medical laboratory technology, i.e. it 8 could be troubleshooting in a biochemistry 9 environment, a pathology environment, to microbiology environment, but how to to troubleshoot specific instances within any it the four it is the with some individuals in term your it specific instances	3 three year training program?	3 A. For about three or four years at that point.
6 evolutions of the IHC up to now the Ventana. 7 Were kits being used at the time you were 8 could be troubleshooting in a biochemistry 9 environment, a pathology environment, 10 microbiology environment, but how to 11 troubleshoot specific instances within any 12 certain test, that really is learning on the 13 job. 18 BROWNE, Q.C.: 15 Q. But the theory, the notion that it's necessary 16 to - 17 MR. GULLIVER: 18 A. The theory behind it, yes. 19 BROWNE, Q.C.: 19 BROWNE, Q.C.: 19 BROWNE, Q.C.: 10 Q. Now in terms of going back to the 21 instrumentation, such as pipettes, 22 thermometers, and then, I guess, add to that 23 slides and pH meters, those sorts of pieces of 24 equipment, in your lab or in the lab at the 25 Health Sciences Complex, who would have been Page 10 1 responsible for ordering that type of 2 equipment? 3 MR. GULLIVER: 4 A. For ordering it? 5 BROWNE, Q.C.: 5 BROWNE, Q.C.: 6 Q. Yes, selection of a particular piece of 7 equipment? 8 MR. GULLIVER: 9 A. They're basic lab equipment. They'd be at the 10 division manager's level. 11 BROWNE, Q.C.: 12 Q. And you had mentioned in your - you became - I 13 guess you went into management in 1987? 14 MR. GULLIVER: 15 A. No. 16 MR. GULLIVER: 17 BROWNE, Q.C.: 18 WR. GULLIVER: 19 A. No. 20 Now you had - when you became manager, was there any requirement upon you, or supervisor at that point, to assess - I think we've heard Page 10 1 that Ms. Butler and Ms. Welsh were trained to do HtC and brought in. Did you supervise and train both of these individuals in terms of their knowledge of - I guess, test their knowledge of HtC before they went on the bench? 7 MR. GULLIVER: 8 A. I don't think I would say that it was just myself who trained them. I certainly helped, and, you know, passed along any type of antigen retrieval? 10 A. No. 11 BROWNE, Q.C.: 12 Q. Now you had - when you became manager, was there any requirement upon you, or supervisor at that point, to assess - I think we've heard Page 10 1 that Mid Marcha and the proper of the bench? 7 MR. GULLIVER: 18 A.	4 MR. GULLIVER:	4 BROWNE, Q.C.:
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116 DROWNER O.C. 116 Administration Walked a tauth and builtimes of		
	16 BROWNE, Q.C.:	companies. We had a textbook by Sternberger
17 Q. You became the divisional manager at that 17 that we used at the bench, and again, you	_	
point? la know, Dr. Chittal was there and he also would	_	
19 MR. GULLIVER: 19 have been good assistance with Mary and Peggy.		
20 A. Pathology supervisor. 20 BROWNE, Q.C.:		
21 BROWNE, Q.C.: 21 Q. Uh-hm.		
22 Q. Pathology supervisor, and I was unclear, at 22 MR. GULLIVER:	1	
the point that you made that transition, there 23 A. And mostly on the troubleshooting side, you	_ *	
24 was some IHC being performed. I think you'd 24 know, that would read the slides.		know, that would read the slides.
25 mentioned Dr. Wang and Dr. Chittal were doing 25 BROWNE, Q.C.:	25 mentioned Dr. Wang and Dr. Chittal were doing	25 BROWNE, Q.C.:

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Page 13	Page 15
1 Q. You mentioned as well, I guess, that Mr.	1 BROWNE, Q.C.:
2 Hewlett who testified here, he had been at and	2 Q. So just going back, if the technologists noted
3 did some presentations?	that, would their line of communication be to
4 MR. GULLIVER:	4 the manager, though, in terms of getting
5 A. In 1986, we had - our professional	5 something rectified?
6 association, we had our national week long	6 MR. GULLIVER:
7 congress being hosted in St. John's, and a	7 A. It would, yes.
8 part of that - and it's a combination of	8 BROWNE, Q.C.:
9 workshops, lectures, to cover all disciplines	9 Q. Okay, and then presumably the manager would
in laboratories. It's a combination of a	then, if they could not resolve it directly
11 trade show with the new technology, like your	with pathologists, go to the site chief and/or
basic overall congress, and during that time	the clinical chief to get that resolved?
13 Mr. Hewlett did a one day workshop and we used	13 MR. GULLIVER:
	14 A. Yes.
	14 A. 168. 15 BROWNE, Q.C.:
15 BROWNE, Q.C.:	
16 Q. And were these in IHC?	Q. Was there ever any point prior to 2005 issues
17 MR. GULLIVER:	brought to your attention, either as the
18 A. It was just when IHC - again back in 1986, it	manager or the program director, from
would have been a one day workshop in basic	19 technologists surrounding fixation?
20 theory and principles in IHC, and then talking	20 MR. GULLIVER:
21 about your PAP procedure, policies procedure.	A. At the Health Sciences site, which is my home
22 BROWNE, Q.C.:	base, I don't remember any instances. At St.
Q. You mentioned in 2001 he was back again?	Clare's site, I certainly was made aware of
24 MR. GULLIVER:	some issues up at St. Clare's.
25 A. Again we had our national congress here again	25 BROWNE, Q.C.:
Page 14	Page 16
in 2001, and we're here again next year, 2009.	1 Q. And were those followed up?
2 BROWNE, Q.C.:	2 MR. GULLIVER:
3 Q. In terms of - we've heard a lot about issues	3 A. Yes.
4 surrounding fixation and so on. If	4 BROWNE, Q.C.:
5 technologists noted problems with fixation,	5 Q. How were they followed up?
6 would it be incumbent on them to report if	6 MR. GULLIVER:
7 they saw a regular problem with fixation	7 A. It was pretty well just in basic discussions
8 coming from specimens? Would it be incumbent	8 with the site chief at St. Clare's that there
9 upon them to bring that to the attention of	9 seems to be an issue at St. Clare's with
the manager and/or the program director at an	specimens that were not being fixed properly
point?	for either two reasons; that the specimen
12 MR. GULLIVER:	initially was not left in formalin long
13 A. They wouldn't bring it to the program	enough, or when it was grossed, the tissue was
director. I mean, it's operations within the	too thick to go into the cassette and -
pathology division.	because consequently, I was made aware - I was
16 BROWNE, Q.C.:	actually the division manager for pathology at
17 Q. Right, so presumably if there was a noticeable	Health Sciences/Janeway, and I worked fairly
problem, they would bring it to the manager	18 closely with John Murphy, the manager of
and the manager would, if felt -	pathology at the Grace/St. Clare's, and the
20 MR. GULLIVER:	issue was the amount of reprocessing that the
21 A. In pathology, would go to the site chief.	21 technologists at St. Clare's had to carry out
22 BROWNE, Q.C.:	primarily because the tissue was not fixed
23 Q. Site chief.	properly from the beginning at the gross
24 MR. GULLIVER:	24 bench.
25 A. Yeah.	25 THE COMMISSIONER:
23 A. I Can.	20 THE COMMISSIONER.

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Page 2	Page 23
1 A. It all depends what your definition of set up	1 I think it was Ms. Butler, about her
2 is.	2 reluctance towards computers and so on. Were
3 BROWNE, Q.C.:	the technicians given - the technologists,
4 Q. Well, I guess, in terms of lab structure,	4 excuse me, given any courses in introduction
5 management, and those sorts of things, the	to computers because, I guess, they both are
6 notion, say, for instance, of having a lead	6 required to use the computer for both the DAKO
7 technologist for IHC, for example?	system when it came in, and also the Meditech
8 MR. GULLIVER:	8 system?
9 A. Not - no, not that kind of detail, no.	9 MR. GULLIVER:
10 BROWNE, Q.C.:	10 A. Well, basic computer training is something
Q. What about in the area of quality control and	that's offered all the time through the Health
quality assurance, again were there any sort	12 Care Corporation of St. John's, even now with
of discussions surrounding how things were set	Eastern Health, so employees can avail of your
up internally or externally within these labs?	basic computer skills. To go back to '87 when
15 MR. GULLIVER:	15 Meditech came in, I mean, it was not just the
16 A. No. Most discussion would be more the big	technologists, it was myself as a manager who
picture for the profession across the country,	had to learn, you know, say, computer skills,
you know, more talking about accreditation and	in particular the Meditech system. So we did
those licensing - those kinds of issues.	have - I think we might have been six months
20 BROWNE, Q.C.:	20 or eight months where we had the test system
21 Q. What about in terms of advances in the	21 at the work bench with all the terminals for
profession, say, for histology, IHC, as it was	people to learn and use before we actually
expanding because this was a period where this	went to a live - to a live date.
24 was expanding quite - we've heard from a	24 BROWNE, Q.C.:
25 number of witnesses.	25 Q. Were, I guess, individuals such as
Page 2	
1 MR. GULLIVER:	technologists who were required to use both
2 A. Those kinds of things are what you would	2 Meditech and later on computer systems such as
probably see at our national congress or if	the DAKO, were they required as part of their
you went to an international conference.	job to take computer courses to expand their
5 BROWNE, Q.C.:	5 knowledge?
6 Q. But nothing -	6 MR. GULLIVER:
7 MR. GULLIVER:	7 A. Well, there is no computer course in Meditech
8 A. Not through the professional association work,	8 that there are - IM & T does have a training
9 no.	9 room and they do have staff who do provide
10 BROWNE, Q.C.:	basic computer training to all new staff.
11 Q. Now you had spent a bit of time, and Ms.	11 BROWNE, Q.C.:
12 Chaytor spent a bit of time exploring with you	12 Q. Okay.
the set up of the Meditech system, and I	13 MR. GULLIVER:
14 understand it was introduced initially in	14 A. To go through that process. The DAKO computer
15 1987?	that was a PCU, the person who came in and set
16 MR. GULLIVER:	up the initial instrument who was in St.
17 A. At the Health Sciences, yes.	John's, I don't know, might have been three,
18 BROWNE, Q.C.:	four, or five days, did the basic computer set
19 Q. And you stated I think the first day that the	_
	19 up with Mary and Peggy
l	19 up with Mary and Peggy.
20 technical staff were more inclined to use the	20 BROWNE, Q.C.:
20 technical staff were more inclined to use the 21 system as opposed to physicians?	20 BROWNE, Q.C.: 21 Q. And I presume would be available for any
20 technical staff were more inclined to use the 21 system as opposed to physicians? 22 MR. GULLIVER:	20 BROWNE, Q.C.: 21 Q. And I presume would be available for any 22 questions on a regular basis? Was there a
20 technical staff were more inclined to use the 21 system as opposed to physicians?	20 BROWNE, Q.C.: 21 Q. And I presume would be available for any

A. Yes, it was a toll free number.

Q. We had learned from one of the technologists,

O	ctober 15, 2008 Mu	ılti-P	age	Inquiry on Hormone Receptor Testing
	Page	25		Page 27
1	BROWNE, Q.C.:	1	0.	When Meditech was set up, and I gather it was
2				integrated in 1999, all the systems, did I
3		3		understand that correctly from you?
4	1 101 1 .11			GULLIVER:
5		5		Yes, when St. John's went to one -
6	D'11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			WNE, Q.C.:
7	1998 introduced synoptic reporting in	7		One system.
8				GULLIVER:
1	MR. GULLIVER:	9		- one database, pretty well one system.
10				WNE, Q.C.:
11		11		Right, because, I mean, I view that sort of,
12		12		that issue, broader than just ER/PR. Was
13		13		Meditech consulted as to sort of the best use
1	BROWNE, Q.C.:	14		and most efficient use of how items could be
15		15		searched within a pathology report?
16				GULLIVER:
17		17		I think by that time, the people who were
18		18		using the system, Meditech system, at all
19		19		sites had a fairly good knowledge in how to
20		20		search the Meditech system for pathology.
1	MR. GULLIVER:			WNE, Q.C.:
22		22		My question was more designed towards was
23	•	23		Meditech brought in to look at the current
24	· · · · · · · · · · · · · · · · · · ·	24		system, say in 1999, when all the systems were
25		25		beingbecause, I think, it was recognized
F				
١,	Page			Page 28
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	interpretation under the pathological interpretation. We had another one that was	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$		that different set ups existed at the various hospitals. For instance, there was different
$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$		$\frac{1}{3}$		dictionaries at St. Clare's than there was at
4		4		Health Sciences. Were they brought in and
Ι.	standard place on the report where you could			sort of said, "okay, now we're going to
5		$\begin{vmatrix} 5 \\ 6 \end{vmatrix}$		integrate. Can we look at a most efficient
6				
1	BROWNE, Q.C.: Q. In terms of searching for that information,	8		use in making sure that this does work uniformly?"
8				GULLIVER:
9				
10	and "PR" and get that information back? Was	10		No, they weren't brought in, but we weren't upgrading the Meditech system. I mean, the
11	•	11		Meditech system, it's pretty well how you
12	•	12		decide to operate the system and there's where
1	MR. GULLIVER: A. Yes, it is, but Meditech would come back and	13 14		your differences is come in in dictionaries.
14		15		When we did the consolidation of
15		16		Meditech, the consolidation wasn't really
16				•
17	1	17		taking Meditech from the Grace and St. Clare's
18 19	-	18		and Janeway and Health Sciences and making it one. It was taking the Health Sciences
1	_	19		_
20		20		current Meditech system and expanding that to include the Grace, St. Clare's and Janeway.
21	-	21		•
22	will I find it under tumour summary. So again	22		What we did within Lab Medicine, in all parts

23

24

25

of lab, not just pathology, we worked for

almost a year in looking at the standard operations of Meditech at each site and how

little bit more.

25 BROWNE, Q.C.:

it just makes the - it just complicates it a

23

$\mathbf{\Sigma}$	tiober 15, 2008 Mulu	1-1	age inquiry on normone Receptor Testing
	Page 29		Page 31
1	could we agree upon a standard set of	1	data input? It would not require their
2	dictionary or template for the city-wide	2	expertise to sort of -
3	computer system.	3	3 MR. GULLIVER:
4	For example, one of the things that we	4	4 A. Not, no.
5	did talk about was just the basic standard	5	5 BROWNE, Q.C.:
6	report format of how a pathology report would	6	Q. Registrar, P-1889, please? Mr. Gulliver, this
7	look when it went back to a physician, and we	7	exhibit was shown to you by Ms. Chaytor, and
8	didn't get agreement on that. That ended up	8	it's the letter, and I think you said you
9	St. Clare's wanted to have their own report	9	don't recall receiving this letter from Dr.
10	format and the Health Sciences continued to	10	Khalifa in 1997. I just want to go over a
11	use the one that was in existence for the ten	11	couple of comments that Dr. Khalifa made here
12	years prior. So there's the standard	12	and just ask you for your feedback. The third
13	operations that went on.	13	line here saysthis is, again, you're quite
14	BROWNE, Q.C.:	14	familiar with this letter. You've seen it
15	Q. So that happened internally? Meditech or	15	previously. It mentions, Dr. Khalifa mentions
16	their representatives weren't sort of brought	16	,
17	in to sort of consult with you as to the best	17	
18	way to approach this and to come up with a	18	1
19	solution that would work well for all sites?	19	, ,
20	Is that right? They weren't sort of consulted	20	1 ,
21	as to -	21	
22	MR. GULLIVER:	22	
23	A. No.	23	1
	BROWNE, Q.C.:	24	•
25	Q. Whose decision would that have been, to sort	25	system in combination with an old primary
	Page 30		Page 32
1	of bring them in, if that was viewed as a	1	antibody," and then two, his comment that "any
2	positive thing?	2	trial of a new technique need to be done in
3	MR. GULLIVER:	3	parallel with a well-established one before a
4	A. Well, it would have been a combination of IM &	4	switch could be safely made."
5	T, because the consolidation was taking place	5	Were you aware of the significance of
6	for Meditech. The lab information system was	6	what Dr. Khalifa was saying to you about using
7	one component of Meditech, so it would have	7	an old antibody with a new detection kit?
8	been an IM & T broader decision for the	8	3 MR. GULLIVER:
9		9	
10	•	10	
11	we weren't changing our Meditech system at	11	
12	all. It was for the different groups to come	12	ž
13	to a decision on how are you going to use and	13	Č
14	operate Meditech.	14	
15	BROWNE, Q.C.:		5 BROWNE, Q.C.:
16	Q. So from your -	16	6
	MR. GULLIVER:	17	£
18	A. Within existing mainframe, the existing that	18	
19	was already there. The dictionaries are all	19	• •
20	ž 1	20	e ·
21	there and how you want to use them that you	21	•
22	have to agree about.		2 MR. GULLIVER:
	BROWNE, Q.C.:	23	
24	Q. So what I understand is you're saying, from		BROWNE, Q.C.:
25	your perspective, all it would require is a	25	Q. Okay, and in fact, if we look at Ms.

attending those meetings?

with Dr. Khalifa.

Q. Yes, it was a negative. Now in 1997/1998,

there were a number of meetings where Dr.

making the switch over from biochemical assay

to immunohistochemistry reporting for IHC, and

there was a number of discussions surrounding,

I guess, how that would occur and reporting

and how it would be reported. Do you recall

A. I don't remember attending specific meetings.

Q. Right. There were a number of site chief

meetings and I can take you through them. I have one, two, three, four, five, between 1997

issue was discussed and including the 30

percent cut off. Do you recall anything from

those meetings about that discussion, how the

30 percent cut off was arrived at, the discussions between St. Clare's and the Health

and 1998 where you were in attendance and this

It might have been just things in discussion

Khalifa, I guess, introduced the notion of

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10 MR. GULLIVER:

14 BROWNE, O.C.:

Page 33 Wegrynowski's report, she talks about that 1 2 whole notion as well, the use of validating and optimizing and making sure that there's a 3

parallel testing. That's a critical value in 4

5 IHC. is it not?

6 MR. GULLIVER:

7

A. Well, Trish is talking about parallel testing.

If you're going to switch, say, from DAKO to 8

Ventana or you're going to switch antibodies 9

10 to do validation.

11 BROWNE, O.C.:

Q. Right. 12

13 MR. GULLIVER:

14 A. Dr. Khalifa is talking about moving from a biochemistry, biochemical assay to an IHC 15

16 assay. So it's a difference there.

17 BROWNE, Q.C.:

18 Q. Okay, so you view this as making a switch. I 19

read this as one kit to another kit using the

old antibody from an old kit with a new 20

detection system. You don't view it that way?

A. - before a switch can be safely made." By

this point in time, we have no established

method, except for the biochemical assay in

Q. Okay. But going back to the previous comment,

"new detection system in combination with an

old primary antibody." Ms. Wegrynowski talks

22 MR. GULLIVER:

1 BROWNE, Q.C.:

3 MR. GULLIVER:

8 BROWNE, O.C.:

Q. Um-hm.

chemistry.

21

5

6

7

9

10

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17

19

A. When he's talking about here, "any trial with 23

new technique needs to be done in parallel 24

with a well-established one -25

Page 34

A. I don't offhand right now, anything specific -

Sciences Centre?

2 BROWNE, Q.C.:

3 Q. But you -

25 MR. GULLIVER:

4 MR. GULLIVER:

A. - discussion there.

6 BROWNE, Q.C.:

7 Q. - you wouldn't have remembered that from when

8 this came up in 2005, being at those meetings,

9 the information that was disseminated among

the pathologists where you were there? 10

about the importance of making sure that the -12 13 MR. GULLIVER:

14 A. Yes, I have to agree with it, yes.

15 BROWNE, O.C.:

Q. Now another area I was unclear on, Mr. 16

Gulliver, is you had mentioned on several

occasion to Ms. Chaytor that your 18

understanding of the reporting of ER/PR was

that a negative result was zero, zero. That 20

was negative to you. Did I capture that 21

22 correctly?

23 MR. GULLIVER:

A. Zero, zero is negative. 24

25 BROWNE, Q.C.:

13 BROWNE, Q.C.:

12

11 MR. GULLIVER:

14 Q. Okay, sure. Well then, let's start with the

A. If you have to show me the minutes -

first and that's May 13, 1997, and that's P-15

2351. Oh, sorry, maybe--let me just see. No, 16

17 that can't be right. Let me try, sorry,

Registrar, 1856. Yes, okay. My apologies, 18

Mr. Gulliver. And you'll see, right there. 19

Now just to go back, those in attendance, 20

21 you'll see you're listed.

22 MR. GULLIVER:

23 A. Yeah, I see that, yeah.

24 BROWNE, O.C.:

25 Q. Okay, and that's May 13, 1997, and then you'll

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Page 40

October 15, 2008 Multi		Multi	i-Page TM		Inquiry on Hormone Receptor Testin	
	Pa	ge 37			Page 3	
	see there's an extensive minute there about		1	MR. G	ULLIVER:	
	2 Dr. Khalifa reporting to the committee about	t	2	A.	Sometimes, but I can't say all the time.	
	3 his correlation and then about how results are		3	BROW	NE, Q.C.:	
	4 reported and that there will be a consensus		4	Q.	Okay. This is now December 17th, sorry, 16th,	
	5 among pathologists. "Such a meeting will be	e	5		1997, and you'll see here again, I thought	
	6 held in June" and then it was agreed to, so		6		there was a reference here. Let me justI	
	7 that "individual pathologists reporting these		7		must have missed that, sorry. Item number	
	8 receptors and need for standardized criteria		8		three, yes, okay. Item number three here.	
	9 to determine what is positive and negative."		9		Sorry, it wasn't headed"steroid receptors	
	10 Again, does this -		10		assessment and paraffin sections. Dr. Khalifa	
	11 MR. GULLIVER:		11		discussed the issue further and suggested	
	12 A. I can'tI don't remember this -		12		pathologists start reporting their own cases.	
	13 BROWNE, Q.C.:		13	1	A suggestion was made that Dr. Khalifa write	
	14 Q. So you don't remember being at -		14		up a proposal with criteria cut off values	
	15 MR. GULLIVER:		15		distributed to various pathologists and ask	
	16 A discussion from ten years ago, no.		16		them for their feedback." Does this -	
	17 BROWNE, Q.C.:		17	MR. G	ULLIVER:	
	18 Q. And then P-1857, again, I think you're there		18	A.	I do remember it being, at some point, where	
	present. This is in June of 1997. You're		19		they were discussing, you know, where all the	
	listed as being present again, and there's		20		other pathologists now will start doing their	
	further discussion surrounding the reporting		21		own interpretation.	
	of ER/PR. Again, no recollection about the		22	BROW	VNE, Q.C.:	
	discussions at this meeting either, Mr.		23	Q.	Do you recalland we'll go to the next, I	
	24 Gulliver?		24		think it's 2416, which is the January meeting,	
	25 MR. GULLIVER:		25		and I understand fromI stand to be	
	Pa	ge 38			Page 4	
	1 A. No.		1		correctedI think you are present at this	
	2 BROWNE, Q.C.:		2		one. This meeting, this was a meeting Dr.	
	3 Q. Just take a moment, sorry, and I'll just -		3		Khalifa actually made a draft proposal and it	
	4 MR. GULLIVER:		4		was distributed at this meeting about the	
	5 A. I'm reading other -		5		reporting and how it would be reported and 30	
	6 BROWNE, Q.C.:		6		percent cut off was used. Do you recall that,	
	i				-	

Q. Yes, and I apologize. It's 3.4 there.

8 MR. GULLIVER:

A. - other parts of the minutes here to see if there's something else. 10

11 BROWNE, Q.C.:

12 Q. Yes, if anything around that would refresh.

13 MR. GULLIVER:

A. Yeah. 14

15 BROWNE, Q.C.:

Q. By all means then, use the mouse, if you wish, 16

17 to just -

18 MR. GULLIVER:

19 A. Again, this one here, I'm not in attendance?

20 Yes.

25

21 BROWNE, Q.C.:

Q. This is--okay, you're not there, okay. Then 22

let's, if we could, move to P-2413? Now would 23

24 you receive minutes nonetheless as being the

manager?

7 ever seeing that proposal or in fact, later on

8 the final version of that, at any of these

9 meetings?

10 MR. GULLIVER:

11 A. I don't remember seeing it at the meeting, no,

12 but I do remember, you know, at this time, you

13 know, Dr. Khalifa who had been doing pretty

14 well most of the ER/PR interpretations, that

you know, I guess we're getting to that 15

literature suggests 30 percent.

17 BROWNE, Q.C.:

Q. Right. 18

16

25

19 MR. GULLIVER:

20 A. I mean, that's Dr. Khalifa is the one that had

21 suggested that, yes.

22 BROWNE, Q.C.:

23 Q. Right. So you were--I guess that's what I'm

trying to understand here now. You were 24

familiar about that discussion around it

		Page

- being, the 30 percent being the cut off as
- being a correlation to negative in biochemical
- 3 assay?
- 4 MR. GULLIVER:
- 5 A. Yes.
- 6 BROWNE, Q.C.:
- 7 Q. So you do recall that being discussed around
- 8 that time?
- 9 MR. GULLIVER:
- 10 A. Yeah. Exactly which meeting, you know, or
- which time frame, I can't tell you exactly.
- 12 BROWNE, Q.C.:
- 13 Q. Sure, no, and I appreciate, there were a
- number--as I've taken you through here, and
- there are a number of others, but I guess my
- question goes back to your understanding of
- zero, zero being negative. This seems to be
- somewhat at odds with what was being discussed
- around this time among the pathologists with
- the 30 percent.
- 21 MR. GULLIVER:
- 22 A. The 30 percent was a cut off that they were
- talking about for that the oncologists would
- use. I mean, I'm going back to a zero, zero,
- a lab test. If there's no staining, it's
- Page 42
- negative. If there is staining, well, it's
 - positive. It's trying to decide what
- 3 percentage of tumour cells are positive.
- 4 BROWNE, Q.C.:

2

- 5 Q. Right, and you understood that that, that all
- 6 that sort of discussion that had occurred
- 7 previously, despite, I guess, what you had
- 8 learned in terms of the basic lab training of
- 9 zero means negative, you were familiar with
- what discussions had occurred in 1997/1998?
- 11 MR. GULLIVER:
- 12 A. I was familiar with Dr. Khalifa was talking
- about the 30 percent was a correlation to the
- 14 biochemical assay.
- 15 BROWNE, O.C.:
- Q. And there are others there as well where this
- is all discussed, but thank you, Mr. Gulliver,
- I think you've clarified that for me. Now Ms.
- 19 Chaytor asked you about the position of the
- 20 quality management manager position and I
- 21 think you had said you had raised this with
- Dr. Williams around 2001/2002. When the
- external reviewers were here, did this ever
- come up about the notion of having a quality
- position within the lab, either with Dr.

e 41

1

Banerjee or Dr. Wegrynowski or Ms.

Page 43

Page 44

- 2 Wegrynowski?
- 3 MR. GULLIVER:
- 4 A. A quality manager?
- 5 BROWNE, Q.C.:
- Q. Yes, or having someone in the lab responsible
- 7 for quality.
- 8 MR. GULLIVER:
- 9 A. Do you mean in the lab or in pathology lab?
- 10 BROWNE, Q.C.:
- 11 Q. Well, in the pathology lab or in the lab
- itself, either.
- 13 MR. GULLIVER:
- 14 A. Because our quality manager, you know, it's
- for the whole Laboratory Medicine program.
- 16 BROWNE, Q.C.:
- 17 Q. Right, right.
- 18 MR. GULLIVER:
- 19 A. It's not just for pathology.
- 20 BROWNE, Q.C.:
- 21 Q. Sure. Did that whole notion ever come up with
- either of the reviewers?
- 23 MR. GULLIVER:
- 24 A. Not as a dedicated quality manager, but we had
- 25 talked about a technologist being dedicated
- ige 42
 - 1 for quality in pathology.
 - 2 BROWNE, Q.C.:
 - 3 Q. And did you discuss with either of the
 - 4 reviewers about your sort of previous thoughts
 - 5 along that line in previous years to
 - 6 management?
 - 7 MR. GULLIVER:
 - 8 A. I don't--well, I didn't have a lot of
 - 9 discussions with them. I mean, they were in
 - for a very set time and they had--you know,
 - they had, I guess, a job to perform, to do
 - their review. So I mean, we didn't discuss
 - all aspects. It was -
 - 14 BROWNE, Q.C.:
 - 15 Q. Or did you point out to them, "look, I have
 - been trying to sort of get quality position
 - here in the lab for a number of years, but
 - iust haven't been successful"?
 - 19 MR. GULLIVER:
 - 20 A. I think with Trish, both myself and Mr. Dyer,
 - and we pointed out a significant number of
 - things that we would hope that she would
 - include in her final report.
 - 24 BROWNE, Q.C.:

22

25 Q. Did you specifically say "look, we have been

				inquiry on Hormone Receptor Testing
	Page 45			Page 47
1	trying to do this for years, but we weren't	1		that communicated out to the other labs in the
2	successful"?	2		province?
3	MR. GULLIVER:	3	MR. C	GULLIVER:
4	A. I may have. I may not have. I can't tell	4	A.	I don't know what he means by special slides.
5	you.	5		I know the IHC, at some point, I don't know
6	BROWNE, Q.C.:	6		which company, they came out with another
7	Q. We've heard as well, Mr. Gulliver, about, I	7		slide, I think it was called Histogrip. They
8	guess, from actually Mr. Green when he	8		were more expensive than your regular slides
9	testified, the different types of slides that	9		used every day. And what that did was create
10	were being used forat St. Clare's and the	10		a positive charge in your slide and it helped
11	Health Sciences and that he, as we understand	11		keep your tissue on the slide. I don't think
12	it, had been at St. Clare's, transferred over	12		it had anything to do with background
13	after Ms. Welsh had left over at the Health	13		staining. But then, most labs who were
14	Sciences, and he recognized when he was over	14		sending their blocks, they would send their
15	at the Health Sciences being trained in for -	15		blocks to the Health Sciences. The Health
1	MR. GULLIVER:	16		Sciences would actually cut the slides on
17	A. Ken was there with Ms. Welsh.	17		those slides. So if Corner Brook wanted an
		18		IHC test done, they just sent the paraffin
19	BROWNE, Q.C.: Q. Right.	19		block in and if there's 20 slides to be
1				created, the lab at the Health Sciences
1	MR. GULLIVER:	20		·
21	A. Les Simms moved over when Ms. Welsh left.	21		created the slides, and I'm kind of thinking,
	BROWNE, Q.C.:	22		again I can't be 100 percent sure, Mr. Browne,
23	Q. Right. That the Health Sciences were using	23		I know that at oneI think St. Clare's used
24	special slides for IHC where St. Clare's	24		to cutthe techs at St. Clare's used to cut
25	slides were, I guess, normal adalin slides	25		their own blocks and just send the unstained
	Page 46			Page 48
1	Page 46 were being used and that he recognized there	1		Page 48 slides to Health Sciences, and I think Mr.
1 2				_
	were being used and that he recognized there as a result that it could probably cause more background staining. Was therewho would	1		slides to Health Sciences, and I think Mr.
2	were being used and that he recognized there as a result that it could probably cause more	1 2		slides to Health Sciences, and I think Mr. Dyer stopped that practice when he became the
2 3	were being used and that he recognized there as a result that it could probably cause more background staining. Was therewho would	1 2 3		slides to Health Sciences, and I think Mr. Dyer stopped that practice when he became the manager for the city and just told St. Clare's
2 3 4	were being used and that he recognized there as a result that it could probably cause more background staining. Was therewho would have beenagain, to come back to my previous	1 2 3 4		slides to Health Sciences, and I think Mr. Dyer stopped that practice when he became the manager for the city and just told St. Clare's to send your blocks as anybody else, and let
2 3 4 5	were being used and that he recognized there as a result that it could probably cause more background staining. Was therewho would have beenagain, to come back to my previous question to you. Who would have been	1 2 3 4 5		slides to Health Sciences, and I think Mr. Dyer stopped that practice when he became the manager for the city and just told St. Clare's to send your blocks as anybody else, and let the Health Sciences Lab cut your blocks,
2 3 4 5 6 7	were being used and that he recognized there as a result that it could probably cause more background staining. Was therewho would have beenagain, to come back to my previous question to you. Who would have been responsible for ordering slides for, I guess,	1 2 3 4 5 6 7		slides to Health Sciences, and I think Mr. Dyer stopped that practice when he became the manager for the city and just told St. Clare's to send your blocks as anybody else, and let the Health Sciences Lab cut your blocks, because the slides were at the Health
2 3 4 5 6 7	were being used and that he recognized there as a result that it could probably cause more background staining. Was therewho would have beenagain, to come back to my previous question to you. Who would have been responsible for ordering slides for, I guess, at that point, the Health Care Corporation?	1 2 3 4 5 6 7	BROW	slides to Health Sciences, and I think Mr. Dyer stopped that practice when he became the manager for the city and just told St. Clare's to send your blocks as anybody else, and let the Health Sciences Lab cut your blocks, because the slides were at the Health Sciences.
2 3 4 5 6 7 8	were being used and that he recognized there as a result that it could probably cause more background staining. Was therewho would have beenagain, to come back to my previous question to you. Who would have been responsible for ordering slides for, I guess, at that point, the Health Care Corporation? MR. GULLIVER:	1 2 3 4 5 6 7 8	BROW Q.	slides to Health Sciences, and I think Mr. Dyer stopped that practice when he became the manager for the city and just told St. Clare's to send your blocks as anybody else, and let the Health Sciences Lab cut your blocks, because the slides were at the Health Sciences. WNE, Q.C.:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	were being used and that he recognized there as a result that it could probably cause more background staining. Was therewho would have beenagain, to come back to my previous question to you. Who would have been responsible for ordering slides for, I guess, at that point, the Health Care Corporation? MR. GULLIVER: A. No, at that point, it's St. Clare's has a separate manager. For most years, it was John Murphy. And again, I can't answer your question because, you know, I don't know about the bench level operations at St. Clare's pathology and St. Clare's pathology or the bench level operations of chemistry in Carbonear. That question needs to go to the technologists or, I guess, to the division manager. BROWNE, Q.C.: Q. Right, but I guess my question is more directed at the fact that Health Sciences Centre is the referral lab for IHC for the	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BROV Q. MR. C A. BROV Q. MR. C A. BROV A. BROV	slides to Health Sciences, and I think Mr. Dyer stopped that practice when he became the manager for the city and just told St. Clare's to send your blocks as anybody else, and let the Health Sciences Lab cut your blocks, because the slides were at the Health Sciences. WNE, Q.C.: Okay, and that would have occurred for all labs around the province? GULLIVER: Yes. WNE, Q.C.: The procedure would be that they would send in the blocks so they would be cut - GULLIVER: Yes. WNE, Q.C.: So the same uniform slide would be - GULLIVER: Slides would be used, yeah. WNE, Q.C.:

Page 49 Page 51 commercial use of formalin. Was there a A. I don't think we ever measured it, no, but the 1 1 2 particular--at least while you were a manager, 2 formula that was given you by the textbook was presumably this was occurring, it would be for 7.0 pH. 3 3 bulk formalin would be purchased and then 4 BROWNE, Q.C.: 4 5 mixed in house, and we heard from Mr. Hewlett 5 Q. Around 2003 as well, and you spoke to this on and Mr. Parks about sort of the steps that are a number of questions from Ms. Chaytor about 6 6 necessary to making your in-house preparation. the centralization of lab services, and this 7 7 8 Was there a procedure in place, a documented 8 had been--I think you indicated had been an 9 procedure in place for mixing in-house issue or at least on the table for discussion 9 10 formalin while you were the manager? 10 since 1998 and then when Mr. Dyer became manager in 2000, 2003, the issue was brought 11 MR. GULLIVER: 11 A. Yes, yeah. forth once again. 12 12 13 BROWNE, Q.C.: 13 MR. GULLIVER: Q. Was there--and we also heard about the 14 14 A. I'm assuming you mean centralization of importance of measuring the pH and so on. Was pathology services. 15 15 16 all this set out in some sort of policy or 16 BROWNE, Q.C.: protocol for -Q. Yes, yes, and that's one of the--one 17 17 clarification I want to--when you say 18 MR. GULLIVER: 18 19 A. For the making of your ten percent buffered 19 centralization of pathology services, as a layperson, am I understanding that that, you 20 formalin? 20 mean both the technology side and the 21 BROWNE, Q.C.: 21 22 o. Yes. 22 pathologist side being moved to one site or 23 are you just talking about the technology 23 MR. GULLIVER: A. There was a set procedure, you know. It's 24 24 pretty well a mixture of two different 25 25 MR. GULLIVER: Page 50 Page 52 A. The original '98 was to have one lab for the powders, a mixture of your concentrated 1 1 formaldehyde and then added to--basically to 2 city of St. John's. 2 3 BROWNE, Q.C.: 3 water. 4 BROWNE, O.C.: Q. Right, but pathologists would remain on both Q. What were the two powders that were used, do 5 sites. Is that -5 you know? 6 MR. GULLIVER: 6 7 MR. GULLIVER: A. No. A. Well, I haven't done it in 20 years. I'm 8 8 BROWNE, Q.C.: thinking sodium--sodium monobasic and sodium Q. No. 9 phosphate dibasic. And again, you know, what 10 MR. GULLIVER: 10 11 you have in your textbook is that your target 11 A. Originally in '98, the discussion was the is pretty well a pH around seven. So the text Grace Hospital was closing, the Janeway was 12 12 13 book would tell you to get a pH of seven using 13 closing. The Lab Medicine program had made a 20 litres of water, you had to add I think it 14 14 decision to have--to consolidate and have one was two litres of concentrated formaldehyde. microbiology lab for the City of St. John's, 15 15 You had to add then so many grams mixed in and again, there was a proposal put forward to 16 16 17 water, premixed in water, of one powder and 17 have one pathology lab for the City of St. the second one, you added all three together 18 John's. 18 19 and then that would give you your neutral ten 19 BROWNE, Q.C.: percent buffered formalin. Q. I guess both then and in 2003, where was it 20 20 envisioned that the pathologists would end up 21 BROWNE, O.C.: 21 Q. And then was that--was there sort of a set at the Health Sciences? I understand now that 22 22 process in place to measure the pH of the they still can't move because of--even though 23 23

24

25

that's desirable, they still can't move

because of space issues. How was that sort of

24

formalin?

25 MR. GULLIVER:

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	Page 53	Page 55
1 envisaged?	1	MR. GULLIVER:
2 MR. GULLIVER:	2	A. Well that was more of a risk management
3 A. Well, the Grace had not closed. The Jane	eway 3	assessment.
4 had not closed. There were plans ongoin	•	BROWNE, Q.C.:
5 renovate the space at the Health Sciences,	_	Q. Right.
6 it would have been pretty well an issue wl		MR. GULLIVER:
7 you may have moved one service out of		A. To ensure that that would not be an issue.
8 Clare's and moved something out of the F	Health 8	BROWNE, Q.C.:
9 Sciences to go to St. Clare's in order to		Q. Did Dr. Cook also raise issues about sort of
accommodate like a pathology consolidati		how surgery would interface with pathology,
11 BROWNE, Q.C.:	11	given that there was a large degree of surgery
12 Q. Was there sort of a set plan as to how al	1 12	still occurring at St. Clare's if that were to
that would occur?	13	occur as well?
14 MR. GULLIVER:	14	MR. GULLIVER:
15 A. Back in 1998?	15	A. Well obviously, I mean, as I testified at some
16 BROWNE, Q.C.:	16	point, myself and Dr. Cook met with George
17 Q. Or in 2003 even.	17	Tilley, the CEO; Dr. Bob Williams, and these
18 MR. GULLIVER:	18	are some of the concerns Dr. Cook was putting
19 A. In 2003/2004 when it was being discuss		forward of why we should not move services
well, we had not gotten to the planning sta		from St. Clare's and obviously to allay some
with Facilities Management because we d	-	of those concerns, we had engaged both risk
have agreement to even go that far.	22	management, like Heather Predham and we had
23 BROWNE, Q.C.:	23	engaged management engineering to do sort of
Q. Okay, and just dealing with that point, do		an operations review and again, you know, one
recall some of theyou mentioned one of	-	of Dr. Cook's concerns was the transport of
i i	Page 54	Page 56
from your perspective, there was, you felt	·	specimens across the city of St. John's. And
2 Cook, there was a cultural concern about		another issue was about having on-site
would happen to St. Clare's and there w		pathologists with surgeons.
4 rumours around that time that St. Clare		BROWNE, Q.C.:
5 would movesorry, would close. Was t		Q. And that was the importance of having frozen
6 anydo you recall any discussions with		sections and doing frozen sections and so on,
7 Cook about concerns over having qual		in consult in terms of -
8 assurance issues about transportation of		MR. GULLIVER:
9 specimens?	9	A. I don't know about the frozen sections, but
10 MR. GULLIVER:	10	again, you know, across the country there are
11 A. I think that was one of Dr. Cook's issue		multiple, multiple organizations who have
where if we did move parts of patholo		moved to one pathology lab for the city and
services, it would require specimens from		pathologists would then, on an out-call basis,
14 Clare's having to be transported across the		go back to a certain site to do an on-site
15 city.	15	frozen section. And, you know, I have to say
16 BROWNE, Q.C.:	16	that while, you know, Dr. Cook did have his
17 Q. Right.	17	concerns about, you know, transporting
18 MR. GULLIVER:	18	specimens across the city, however, you know,
19 A. To be processed, embedded, cut and stain		he put a process in place where we transport
the Health Sciences and then slides return		specimens to Dynacare in Ottawa every day. So
21 over there for interpretation.	21	on one side he was against sending specimens
22 BROWNE, Q.C.:	22	from St. Clare's to Health Sciences and then
23 Q. And in fact, did Dr. Cook ask for and rece		on the other side, you know, we're sending
a quality initiatives review of that whole		specimens on an average of 500 a month to
scheme to make sure that that was what -	25	Dynacare in Ottawa for pathologist

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	Page 57		Page 59
1	interpretation.	1	
2	BROWNE, Q.C.:	2	
3	Q. No, but coming back to Dr. Cook's concerns,	3	
4	once he had those reviews done, did he not	4	
5	agree with the proposal once those reviews	5	
6	were conducted? And in fact, we saw	6	
7	documentationthe Commission has seen	7	
8	documentation where he in fact went to the MAC	8	8 MR. GULLIVER:
9	and -	9	9 A. I think he copiedhe addressed it to a number
10	MR. GULLIVER:	10	_
11	A. That was like in 2005. Once the reviews were	11	
12	done, we met with George Tilley and Dr.	12	2 Q. Right, pathologists and technical staff and
13	Williams and there was no decision from	13	
14	executive to go ahead and do a consolidation	14	4 MR. GULLIVER:
15	of pathology. I think that might be May '04	15	5 A and I think he cc'd the technologists and
16	and at some point after that, we do move the	16	6 Mr. Dyer, yes.
17	technical component from pathology to the	17	7 BROWNE, Q.C.:
18	Health Sciences and consolidate that	18	8 Q. So in terms of your order of command, Mr. Dyer
19	component.	19	9 would have had the responsibility to bring
20	BROWNE, Q.C.:	20	that to your attention.
21	Q. As I understand, there's still not available	21	21 MR. GULLIVER:
22	there's no space available to bring	22	A. Or Dr. Cook as the clinical chief on the
23	pathologists over to the -	23	leadership team with him.
24	MR. GULLIVER:	24	24 BROWNE, Q.C.:
25	A. We now have detailed plans in place, as you	25	Q. But in terms of direct, in terms of the sort
	Page 58		Page 60
1	are probably well aware, with facilities	1	of set up, Mr. Dyer would have been -
2	management now to do the physical construction	2	2 MR. GULLIVER:
3	to accommodate that move. But again, I mean,	3	3 A. Reported directly to me, yes.
4	and I've said this to Ms. Chaytor, you know, I	4	4 BROWNE, Q.C.:
5	know Dr. Cook for a long time was against the	5	5 Q. And again, I don't necessarily wishif you
6	pathology consolidation, but I really believe	6	6 wish, you can bring up the memo, but in the
7	that, you know, Dr. Cook was concerned about	7	June 19th, 2003 memo, Ms. Chaytor went through
8	St. Clare'sSt. Clare's hospital, as were	8	8 that extensively with you. I got the sense
9	many physicians at St. Clare's in that, you	9	9 that Dr. Ejeckam was also suggesting that or
10	know, you pull out pathology, what's going to	10	o recommending that technologists be given time
11	go next, you know, then goes DI, then goes	11	and resources to learn more. Did you get that
12	<u>c</u>	12	sense from reading that June 19th, 2003 memo?
13	Clare's as a, you know, as a physical building	13	3 MR. GULLIVER:

17 BROWNE, Q.C.:

was.

14

15

16

Q. And that was where I think he testified that 18 19 he wanted a strategic plan overall in terms of 20 what was going to happen, do you recollect -21 MR. GULLIVER:

or as a full hospital operation and that's

really where I believe his biggest concern

22 A. I think he wanted a plan for, you know, health care services for the city of St. John's, not 23 24 just labs. 25 BROWNE, Q.C.:

20 MR. GULLIVER:

15 BROWNE, Q.C.:

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21 A. He wanted to free up some of their duties, 22 even though we didn't have the workload to 23 support three fulltime techs in IHC. What he 24 was saying was that he wanted them to have 25 time to be able to spend fulltime in IHC and

A. No, I got the sense from him talking directly.

Q. Either way, it was clear from Dr. Ejeckam's

point of view that technology should be given

time and resources to learn more about IHC and

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Page	Page 63
give them the opportunity if they wanted to	1 IHC. He didn't talk about the technologists
2 learn more. And I think Dr. Ejeckam wanted to	getting more basic training in IHC theory. He
3 teach them more and I think what he wanted to	3 talked about him wanting to have time to spend
4 teach them was to start reading things in a	4 with the technologists.
5 microscope and start reading control slides,	5 BROWNE, Q.C.:
6 so that they would be able to troubleshoot	6 Q. But putting aside Dr. Ejeckam's own
7 anything at that end, as opposed to on the	7 initiatives, what about from your end in terms
8 pathologist end.	8 of either you or Mr. Dyer looking at this and
9 BROWNE, Q.C.:	9 saying, okay, well what can we do to sort of
10 Q. And in terms of that, just sort of from the	escalate the knowledge of our technologists,
11 technologist's point of view, after receiving	either with protected time, with journals,
this letter from your discussions with Dr.	like a journal club, interactions with
13 Ejeckam, did you give thought to sort of	colleagues and we saw from Ms. Wegrynowski's
we've heard, the Commissioner has heard the	report the ability to interact with their
notion of protected time and so on, of giving	peers in other institutions to learn -
the technologists protected time and access to	16 MR. GULLIVER:
journals and subscriptions to journals, to	17 A. That would have to be outside Newfoundland
learn more about IHC and the theory of IHC as	because they're the only ones in Newfoundland
19 a result of what Dr. Ejeckam suggested in	doing the testing.
20 2003?	20 BROWNE, Q.C.:
21 MR. GULLIVER:	21 Q. Sure, I appreciate that, but that whole notion
22 A. Well Dr. Ejeckam never ever came back with any	is taking upon yourselves to sort of look at
kind of outline or plan of this is the kinds	organizing a plan, independent of what Dr.
of things he would like the technologists to	Ejeckam was saying, for technologists?
25 learn.	25 MR. GULLIVER:
Page	62 Page 64
1 BROWNE, Q.C.:	1 A. No, I mean, if Dr. Ejeckam would have done an

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Q. Could you not have done that on your own without talking to and in terms of saying, 3 well Dr. Ejeckam -4

5 MR. GULLIVER:

A. Again, I'm not the manager over there, I mean, 6 7 I'm the director.

8 BROWNE, O.C.:

9 Q. Okay, so that would have been the manager's responsibility to go to him and say, okay, can 10 11 you show me what journals, can you show me where they can -12

13 MR. GULLIVER:

A. Yes. 14

15 BROWNE, Q.C.:

Q. Was there any discussion about sort of going 16 17 to Dr. Ejeckam and sitting down with him and organizing that type of plan? 18

19 MR. GULLIVER: A. Dr. Ejeckam sat in my office with myself and 20 Mr. Dyer and we talked about the whole memo 21 22 and Dr. Ejeckam pretty--his thing was, he wanted the technologists to have more time in 23 24 the IHC lab so he could spend time with them 25 and he could actually teach them new skills in

A. No, I mean, if Dr. Ejeckam would have done an 1 2 assessment, he'd be able to bring something forward, it certainly would have been 3 supported by myself and Mr. Dyer. 4

6

5 BROWNE, Q.C.: O. We saw as well around this time, the letter that was sent to Ms. Butler and Mr. Dyer from the DAKO representative and if you wish, you can refer to it, it's Exhibit P-2155. Was there any thought, again on the technologist side because we've heard from Mr. Hewlett and Mr. Parks about this, the notion that communicating that information in a similar memo to lab directors around the island--from the technology side, putting aside what Dr. Ejeckam is doing, because I understood from Mr. Parks and Mr. Hewlett as well independent of the pathologist's role in fixation that technologists also have a role in sort of recognizing and looking at blocks and looking at slides and communication back to the pathologist. Was there any thought sort of communicating that information, where you're again, the referral centre, to other labs

around the island, that information piece?

	-1 age inquiry on from one Receptor Testing
Page 65	Page 67
1 MR. GULLIVER:	1 technologists was going to do anything
2 A. You mean this letter from DAKO?	2 different.
3 BROWNE, Q.C.:	3 BROWNE, Q.C.:
4 Q. And, well also saying the notion of, I think	4 Q. You were shown a memo that you wrote to Dr.
5 he talks about here in terms of to get some	5 Williams in 2004 following the accreditation
6 guidelines from other hospitals, going out and	6 that occurred, I think it's P-3113 and I just-
7 getting information from them. Do you see	7 -yes, the second sentence here, "We also
8 that there?	8 voluntarily participated in multiple
9 MR. GULLIVER:	9 proficiency testing programs from outside
10 A. I know, they're suggesting that we, as in the	agencies that assess our accuracy and quality
Health Sciences, as in the IHC lab -	of testing." What multiple proficiency
12 BROWNE, Q.C.:	testing programs are you referring to there,
13 Q. Uh-hm.	13 Mr. Gulliver?
14 MR. GULLIVER:	14 MR. GULLIVER:
15 A should provide guidelines to the other	15 A. Again, this is writing from me, as director of
hospitals.	16 Laboratory Medicine -
17 BROWNE, Q.C.:	17 BROWNE, Q.C.:
18 Q. Right.	18 Q. Yes.
19 MR. GULLIVER:	19 MR. GULLIVER:
l	
	20 A. At this point in time, we are enrolled in
	21 external proficiency testing, as we are now
22 BROWNE, Q.C.:	for IHC in particular, that was taking place
Q. Okay, but what about in terms of communhe	23 in, for example, tissue transplantation, flow
sent it to pathologists, but what about that	24 cytometry, biochemical genetics, most parts of
sort of closing the loop from your side as the	25 biochemistry, hematology, coagulation, even in
Page 66	Page 68
technical arm of this whole process, to your	pathology at that time we were enrolled in CAP
2 colleagues around the island, again	2 and ASAP, but it was more from a pathologist
3 emphasizing that information?	3 side.
4 MR. GULLIVER:	4 BROWNE, Q.C.:
5 A. Well I guess Dr. Ejeckam didn't even give me a	5 Q. Right.
6 copy as a director sitting in the lab with	6 MR. GULLIVER:
7 him, so you're saying to me I should have sent	7 A. As you know now, we're enrolled in external
8 this memo then to other administrative	8 proficiency testing that assesses both the
9 directors in the province?	9 technical and the clinical side of IHC
10 BROWNE, Q.C.:	
10 BROWNE, Q.C	testing. At this point in time, lab medicine
11 Q. No, no, what I'm saying is the information	
	testing. At this point in time, lab medicine
11 Q. No, no, what I'm saying is the information	testing. At this point in time, lab medicine had enrolled in external proficiency testing
11 Q. No, no, what I'm saying is the information 12 Mr. Dyer got Dr. Ejeckam's two memos. Mr.	testing. At this point in time, lab medicine had enrolled in external proficiency testing for years.
11 Q. No, no, what I'm saying is the information 12 Mr. Dyer got Dr. Ejeckam's two memos. Mr. 13 Dyer also got this information from DAKO. Was	10 testing. At this point in time, lab medicine 11 had enrolled in external proficiency testing 12 for years. 13 BROWNE, Q.C.:
11 Q. No, no, what I'm saying is the information 12 Mr. Dyer got Dr. Ejeckam's two memos. Mr. 13 Dyer also got this information from DAKO. Was 14 there any thought given to sort of	testing. At this point in time, lab medicine had enrolled in external proficiency testing for years. BROWNE, Q.C.: Q. But I guess, in terms of this statement, it's
11 Q. No, no, what I'm saying is the information 12 Mr. Dyer got Dr. Ejeckam's two memos. Mr. 13 Dyer also got this information from DAKO. Was 14 there any thought given to sort of 15 communicating again or reinforcing what Dr. 16 Ejeckam had said in his memos from the	testing. At this point in time, lab medicine had enrolled in external proficiency testing for years. BROWNE, Q.C.: Q. But I guess, in terms of this statement, it's a general statement, there's no limitations on it when you're writing this to Dr. Williams.
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11 Q. No, no, what I'm saying is the information 12 Mr. Dyer got Dr. Ejeckam's two memos. Mr. 13 Dyer also got this information from DAKO. Was 14 there any thought given to sort of 15 communicating again or reinforcing what Dr. 16 Ejeckam had said in his memos from the 17 technical side, where you're - 18 MR. GULLIVER: 19 A. Well I think when I seen Dr. Ejeckam's second 20 memo, I mean, he sent it to all pathologists, 21 you know, and it was an excellent memo and he 22 outlines the importance of fixation and gives	testing. At this point in time, lab medicine had enrolled in external proficiency testing for years. BROWNE, Q.C.: Q. But I guess, in terms of this statement, it's a general statement, there's no limitations on it when you're writing this to Dr. Williams. Should that have, again, recognizing it's hindsight, should you have not indicated with the exception of the technology side of the Lab Medicine Program? MR. GULLIVER:

meeting and why she voiced her opinion was

that there was a discussion around that time or during that meeting about what information

should go in a draft press release and she was

sensitivity--of the Ventana machine being more

sensitive than the DAKO machine and so on and

the implications that that may mean to the

public. Do you recall any discussion around

A. I think I can remember something like that, I

don't know if she challenged on it. I think I

information about the Ventana, you know,

when the Ventana system was implemented, that

it was more sensitive than using the old DAKO

Q. Okay. And that would have been your sort of

input to, I guess, that whole discussion.

A. It would have been a part of my input, yes.

system and that was one of the things that

was being asked at the time for basic

that and her challenging on that?

concerned about your use of the term

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11 MR. GULLIVER:

20 BROWNE, Q.C.:

23 MR. GULLIVER:

25 BROWNE, Q.C.:

- Q. I'm sorry, for IHC, that limitation should 1
- 2 have been, because it wasn't occurring at that
- point in time. 3
- 4 MR. GULLIVER:
- 5 A. Well at this point in time we don't have
- external proficiency testing in the renal lab 6
 - or IHC--I mean, there's other parts of the
- 8 program that we don't have external
- proficiency testing in.
- 10 BROWNE, Q.C.:

7

- Q. Okay, so there's no indication here as to what 11
- 12 ones you are in and what ones you are not in,
- what programs are in -13
- 14 MR. GULLIVER:
- A. In this memo here, no. There isn't a detailed 15
- 16 list of here's what we participated in or here
- is what we don't participate in. 17
- 18 BROWNE, Q.C.:
- Q. And then finally, Mr. Gulliver -
- 20 MR. GULLIVER:
- 21 A. And most is from CAP.
- 22 BROWNE, O.C.:
- Q. Right. You were asked about the meeting of 23
- August 1st, 2005 and the discussion that 24
- occurred between yourself and Mr. Dyer and Dr. 25
 - Page 70
 - Q. Mr. Gulliver, thank you very much.

autostainer.

- 2 MR. GULLIVER:
- 3 A. You're welcome.
- 4 THE COMMISSIONER:
- 5 Q. Thank you, Mr. Browne.
- 6 BROWNE, Q.C.:
- 7 Q. Thank you, Commissioner.
- 8 THE COMMISSIONER:
- 9 Q. Ms. Newbury? I'm assuming you're still of the
- 10 same position?
- 11 MR. PRITCHETT:
 - 12 Q. I am Commissioner.
 - 13 THE COMMISSIONER:
 - 14 Q. All right, thank you.
 - 15 MR. TERRY GULLIVER, EXAMINATION BY MS. JENNIFER NEWBURY
 - 16 MS. NEWBURY:
 - 17 Q. Good morning, Mr. Gulliver.
 - 18 MR. GULLIVER:
 - 19 A. Good morning.
- 20 MS. NEWBURY:

- 21 Q. Jennifer Newbury for the Canadian Cancer
 - Society, Newfoundland and Labrador division.
- 23 Mr. Gulliver, yesterday you were asked if you
- 24 were aware in July or August of 2005 when you 25
 - were gathering together information for

- Carter. 1
- 2 MR. GULLIVER:
- A. Well Mr. Dyer didn't really speak at all.
- 4 BROWNE, O.C.:
- Q. Okay. At that meeting, was there a 5
- representative--I think Ms. Bonnell who was 6
- the communications officer for Eastern Health 7
- 8 at that time, was she present at that meeting?
- Do you recall her being there?
- 10 MR. GULLIVER:
- 11 A. I would assume so, I can't tell you for sure.
- 12 BROWNE, Q.C.:
- Q. Do you recall--I guess my question more 13
- specifically in terms of do you recall at that 14
- meeting was there any discussion about--and 15
- the Commissioner has seen draft press releases 16
- 17 and so on, do you recall any discussion about
- the wording of a draft press release? 18
- 19 MR. GULLIVER:
- A. At that particular meeting? No, I don't. I'm 20
- not saying that we didn't, but you know, 21
- there's so many meetings in that time frame. 22
- 23 BROWNE, Q.C.:
- 24 Q. Dr. Carter has testified that one of the
- things that sort of concerned her at the 25

Oc	ctober 15, 2008 Mu	lti-P	age	e TM	Inquiry on Hormone Receptor Testing
	Page 7	3			Page 75
1	retesting, if anyone is going to try and		l MS	S. NEWBU	JRY:
2	figure out what happened and that's with	2	2	Q. You	were never asked by anyone to do that
3	respect to the ER/PR test results, and you	3	3	spec	ifically or generally, if not said it to
4	responded that you would assume at some point	4	1	some	eone, to at the very least make sure that
5	that would be a focus that you would need to	5	5		don't discard any relative documentation
6	work on, but at that point in time, which is	6	5	or to	•
7	July and August, 2005, all you were focused on	7	7 MR	R. GULLI	VER:
8	was trying to identify patients who could be	8	3 .	A. But	you're asking me by an Eastern Health
9	retested and who could be offered hormone	9)	perso	on.
10	therapy. Can you recall any time between July	10) MS	S. NEWBU	JRY:
11	or August, 2005 and up until the spring of	11	1	Q. By a	nyone within Eastern Health and how about
12	2007 when the Inquiry was called, were you	12	2	outsi	de Eastern Health?
13	asked by anyone within Eastern Health to	13	3 MR	R. GULLI	VER:
14	retain or collect all documentation regarding	14	1 .	A. Well	we were asked that by -
15	ER/PR, whether it's e-mails or letters or	15	5 MS	S. NEWBU	JRY:
16	policies or articles or educational documents,	16	5	Q. For t	the Class Action.
17	manuals, et cetera, for the purposes of any	17	7 MR	R. GULLI	VER:
18	such investigation or review or whatever that	18	3 .	A. Yes.	
19	you had contemplated might very well happen?	19	MS MS	S. NEWBU	JRY:
20	MR. GULLIVER:	20)	Q. And	on your own initiative did you ever, say
21	A. And you're saying up until July '07?	21	1		in July or August of 2005, when you had
22	MS. NEWBURY:	22	2	it in	your mind that at some point, you know,
23	Q. Any time between the summer of 2005 when, at	23	3	this	is something that we will probably focus
24	that point in time you were focusing on	24	1	on, c	lid you take your own initiative to speak
25	collecting results for testing.	25	5	to p	eople who you are responsible for
	Page 7	4			Page 76
1	MR. GULLIVER:	1	1	supe	rvising to make sure that as soon as you
2	A. I don't remember ever being asked to	2	2	have	an e-mail or an article or anything here
3	specifically, you know, collect every piece of	3	3	that	relates to ER/PR, please don't discard
4	document that you have to go to this group who	4	1	it? I	Oid you take that initiative yourself?
5	are going to start assessing to try to	5	5 MR	R. GULLI	VER:
6	determine, you know, what went wrong or why	6	5 .		n't remember specifically telling people
7	the results changed.	7			t throw anything away, no.
8	MS. NEWBURY:	8		S. NEWBU	
9	Q. Okay.	9)		y. And you're in a transition here between
10	MR. GULLIVER:	10)		ern Health and developing new policies,
11	A. I mean, certainly, being involved in meetings	11	l		arding, I guess, or replacing Health Care
12	after meetings after meetings, after meetings,	12		_	poration policies with Eastern Health
13	I mean, certainly there was discussion about,	13		_	eies, so that wasn't a concern of yours.
14	well, what could have went wrong, what could			R. GULLI	VER:
15	have happened? Why would results change like	15		A. No.	
16	this and I mean, you've heard through all this			S. NEWBU	
17	inquiry the multiple scenarios that could be a	17			is there any reason why you didn't think
18	possibility in, you know, leading to a changed	18			that might be something more of looking
19	result.	19)	ınto,	just for the purposes of your Laboratory

20 MS. NEWBURY:

21 Q. Right, and I guess the focus of my question 22 was the mechanics of trying to answer those

questions and whether -23

24 MR. GULLIVER:

A. And I was never asked that, no.

22 A. When it comes to the policies?

23 MS. NEWBURY:

21 MR. GULLIVER:

20

Q. Anything that relates to the ER/PR. You know 24 you've got an issue here, you know, that right 25

Medicine Program that you're the director of?

Page 77 Page 79 now, July, August, 2005, you're focusing on 1 MS. NEWBURY: 1 2 retesting, but at some point we might want to Q. And what opinion is that? try and put our heads together and figure out 3 3 MR. GULLIVER: what's going on. I'm just wondering whether A. That, you know, they told us that if patients 4 you focused on that, I guess, somewhat of an were positive, then you can make the 5 5 administrative task assumption that those patients were either 6 6 7 MR. GULLIVER: offered hormone therapy or on hormone therapy. 7 8 A. At that point in time, no, not at that point 8 MS. NEWBURY: in time. Q. Okay, but in terms of whether or not the 10 MS. NEWBURY: 10 positive test result is a correct result for Q. Mr. Gulliver, yesterday you had indicated when that patient -11 11 asked about the changed test results between 12 MR. GULLIVER: 12 1997 and 2005, and in particular your response 13 A. Well that's a different matter, I mean, I know 13 to or your contribution to an article by 14 14 where -Carolyn Stokes in October of 2005 and you 15 15 MS. NEWBURY: 16 indicated that it's your belief today that in Q. But I guess what you said yesterday and I 16 the eight-year time frame that almost 3000 guess the general concept that was covered off 17 17 patients were originally tested and assessed by you in your contribution to the article 18 18 for treatment for hormone therapy and that written by Carolyn Stokes is that 3000 19 19 three years later, after going through patients were tested over that eight-year time 20 20 thousands of hours of work to identify review frame and 90 percent of those patients were 21 21 22 patients, have patients retested that could be 22 done correctly right from the beginning. So affected, we now know that approximately 300 it's a positive assertion that those 2000 23 23 patient's results have changed and a lessor patients results that were never retested are 24 24 number than that had to require a treatment correct and I'm just wondering what basis do 25 25 Page 78 Page 80 So based on your original you have to say that they were correct? change. 1 1 2 approximately 3000 patients, 90 percent of the 2 MR. GULLIVER: 3 patients were done correctly right from the 3 A. Well I think we've seen enough submissions beginning. Now, of those 3000 test results, through the inquiry and enough evidence since 4 4 5 how many were actually retested? 5 then that, you know, the issue with this test 6 MR. GULLIVER: is the false negatives. You know, certainly 6 there's documentation that there could be 7 A. I think you've seen documentation, there's 7 about a little over a thousand, about one 8 anywhere from, you know, up to three percent 8 false positives. I think through all this third. 9 review there's been a documented, you know, a 10 MS. NEWBURY: 10 11 Q. So the other approximately 2000 were not 11 handful of patients who were originally called retested? positive who are now being treated as a 12 12 13 MR. GULLIVER: negative, you know. It's been five or six or 13 A. And as you know, they weren't retested because seven, so and listen to the oncologists that, 14 14 they were deemed to be positive, therefore, 15 you know, patients who were originally 15 they would have been a candidate for hormone positive were either offered or on hormone 16 16 17 therapy. 17 therapy, I think the issue is the false negatives, not the false positives. 18 MS. NEWBURY: 18 Q. Okay, but in terms of saying that those, all 19 MS. NEWBURY: 19 3000 tests or 90 percent of the 3000 were done Q. So that's your understanding and nothing over 20 20 correctly right from the beginning, how can the last three years has changed your mind 21 21 you be confident that those other 2000 were that there is no issue with those 2000 test 22 22 done correctly from the beginning? results that were not redone? 23 23 24 MR. GULLIVER: 24 MR. GULLIVER: A. Well I trust the opinion of the oncologist. A. And I think Eastern Health has made that

25

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determination also.	1	
2 MS. NEWBURY:	2	
3 Q. Okay, and have you been involved in meetings	3	THE COMMISSIONER:
4 where that's been determined?	4	
5 MR. GULLIVER:	5	
6 A. I was at meetings with, you know, Eastern	6	
7 Health officials and oncologists and	7	MR. GULLIVER:
8 pathologists and executive, you know, in	8	A. And there has been some of those, yes.
9 talking about should we go back and retest all	9	THE COMMISSIONER:
the positives.	10	Q. And there were some people who one might,
11 MS. NEWBURY:	11	
12 Q. And who generally was at those meetings?	12	
13 MR. GULLIVER:	13	
14 A. At some of those meetings was Kara Laing, Joy	14	-
McCarthy from the oncologist side; Dr. Denic,	15	•
Dr. Cook, Pat Pilgrim, Dr. Howell, you know,	16	
myself and Heather Predham, you know, it's	17	
18 been -	18	
19 MS. NEWBURY:	19	
20 Q. Those are the main players.	20	
21 MR. GULLIVER:		MR. GULLIVER:
22 A. The main players we'll say, yes.	22	
23 MS. NEWBURY:	23	
24 Q. And you've indicated that in the last three	24	
years thousands of hours of work were actually	25	
<u> </u>	,	Page 84
Page 82 1 spent reviewing the results of ER and I assume		MS. NEWBURY:
the positive test results, but was there any	2	
portion of time spent reviewing theor sorry,	3	
the ER negative results, but was a portion of	4	Table 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
that thousand of hours of work actually spent		MR. GULLIVER:
6 reviewing the ER positive test results?	6	
7 MR. GULLIVER:	7	
8 A. No, a portion of time was reviewing the actual		MS. NEWBURY:
9 pathology reports where a patient was reported	9	
as positive and to ensure that, you know, if	10	
they're deemed positive, that they are	11	
positive. There was not a lot of time in	12	
ensuring the patients who were called positive	13	·
are still positive, with the exception of	14	
doing some retesting to confirm that a patient	15	
who was positive was still retested positive.	16	
17 MS. NEWBURY:		-
18 Q. So essentially once the report was identified	17	
to be a positive test result for ER, then that	18 19	
	20	
was put aside and that was the end of the inquiry for those particular results?		· · · · · · · · · · · · · · · · · · ·
22 MR. GULLIVER:	21	
22 MIN. UULLIVEK.	22	were assessed by paniology and it was found

24

25

that the original interpretation was accurate.

She was one of the four patients that we

classified as retro converters; in other

A. For individual patients, yes, but as a

positive group, there were some samples

retested and confirmed positive that they were

23

24

Oc	etober 15, 2008 Multi	-F
	Page 85	
1	words, she originally stained positive but now]
2	was coming back negative, the opposite of our	2
3	concern." Now are these the patients that you	3
4	were just mentioning had been tested in the	_
5	summer of 2005 for whatever reason?	5
6	MR. GULLIVER:	۱,
7	A. No, I don't think so.	7
8	MS. NEWBURY:	{
9	Q. Okay, so there was another group of patients	٥
10	retested then?	10
11	MR. GULLIVER:	11
12	A. I think Dr. Carter had selected some positive	12
13	patients, I think mostly from the Ventana	13
14	system and had them retested just to be	14
15	confirmed positive because there was some	15
16	discussion in the summer of '05 about are we	16
17	getting too many positives off the Ventana	17
18	system? Is it too sensitive?	18
	MS. NEWBURY:	
		19
20	Q. And where were they retested? MR. GULLIVER:	20
22	A. I think she sent them to the Mount Sinai and	22
23	they were done as like consults.	23
	MS. NEWBURY:	24
25	Q. Okay, and what was your understanding as to	25
	Page 86	
1	the results of those?	
2	MR. GULLIVER:	2
3	A. That they were confirmed positive.	3
	MS. NEWBURY:	4
5	Q. Okay. If I could bring up Exhibit P-0125,	-
6	page 42 please? This is a document that was	(
7	prepared by Eastern Health for the Department	7
8	of Health and Community Services in November	8
9	of 2006, November 23rd. And this has, it's	٥
10	called "ER/PR case analysis" and has a	10
11	breakdown of some numbers and are you familiar	11
12	generally with the information in this	12
13	particular document?	13
14	MR. GULLIVER:	14
15	A. I wasn't involved in that and I didn't see the	15
16	document.	16
17	MS. NEWBURY:	17
18	Q. Okay, but are you familiar with the content of	18
19	it, the numbers, the general types of -	19
20	MR. GULLIVER:	20
21	A. I guess in general, yes.	21
	MS. NEWBURY:	22
23	Q. And if you note there under the first group,	23
	Coup,	٦,

Page 87 numbering 12" and down below, "originally had 1 a degree of ER positivity, but on retesting 2 was negative", that's down under the change in 3 results section. And those are the only 4 references there to positive test results that 5 are specifically broken down, so that would be 6 four, plus the 12 is 16. So 12 were confirmed 7 positive. Now do you know if Dr. Carter's 8 information would likely have been included in 9 this? 0 1 MR. GULLIVER: A. I don't think it is, Ms. Newbury. I think 2 these are--this is an assessment of the 3 4 patients that were sent off in the retesting. I think what Dr. Carter had done was just to 5 have some positive cases from Ventana system 6 confirmed positive by Mount Sinai. 7 8 MS. NEWBURY: Q. So you think that that would have been excluded from -20 21 MR. GULLIVER: A. And they would not have been part of the retesting--they would be excluded from this, 3 yes. 5 MS. NEWBURY: Page 88 Q. And if any of the preliminary results retested 1 under the guidance of Dr. Carter had resulted 2 in changes, would that be included in this 3 breakdown of numbers generally speaking? 4 5 MR. GULLIVER: A. You're saying if those positive Ventanas had 6 to come back as negative? 7 8 MS. NEWBURY: Q. If any results came back, because Dr. Carter wasn't only sending up positives, she was 0 sending up a selection of results and this was 1 before sort of the mass retesting. 2 3 MR. GULLIVER: A. Right. 4 5 MS. NEWBURY: Q. I'm just wondering if any of those other 7 results would be reflected in these numbers? 8 MR. GULLIVER: A. I would think the ones that she sent off in 2002 would be in these numbers. 20 1 MS. NEWBURY: Q. In 2002? 23 MR. GULLIVER: A. Like Dr. Carter had organized about 60 cases 24

from 2002 that were sent off, those numbers,

24

25

the third bullet, there is a statement that

"there are confirmed positive results

October 15, 2000 White	i-i age inquiry on from one Receptor resumg
Page 89	Page 91
1 I'm assuming would be reflected in this total	1 Q. The NLCHI database?
2 number.	2 MR. GULLIVER:
3 MS. NEWBURY:	3 A. The NLCHI database.
4 Q. So you think there's a separate group of	4 MS. NEWBURY:
5 numbers -	5 Q. But prior to that, prior to NLCHI's
6 MR. GULLIVER:	6 involvement, would you have had access, as the
7 A. That were Ventana positive and then confirmed	7 director of the Laboratory Medicine Program to
8 as positive.	8 these results? If you wanted to look at those
9 MS. NEWBURY:	9 for any reason to do your own analysis or what
10 Q. And Mr. Gulliver -	10 have you?
11 MR. GULLIVER:	11 MR. GULLIVER:
12 A. And there were, you know, another dozen cases	12 A. If I wanted to get them, I would be able to
13 I think we sent out to Montreal to try and	get them, yes.
14 correlate and confirming, I mean, those	14 MS. NEWBURY:
numbers would not be here in this retest.	15 Q. Okay, you're permitted access to that, is my
16 MS. NEWBURY:	16 question.
17 Q. And why is that?	17 MR. GULLIVER:
18 MR. GULLIVER:	18 A. Yes.
19 A. Because they were not being done to retest the	19 MS. NEWBURY:
patient, they were being done to compare	20 Q. And you can physically, from a practical
21 systems.	sense, you can log into a system and get it or
22 MS. NEWBURY:	make a request to get access to that
23 Q. Sort of quality assurance with the systems?	information. Mr. Gulliver, do you today have
24 MR. GULLIVER:	your own idea as to the number of retro
25 A. Pretty well, yeah.	conversions and that's the term that was used
Page 90	
· · · ·	
Page 90	Page 92
Page 90 1 MS. NEWBURY:	Page 92 1 in the e-mail from Heather Predham, do you
Page 90 1 MS. NEWBURY: 2 Q. And are there records available of that?	Page 92 in the e-mail from Heather Predham, do you know today how many retro conversions, whether
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	Page 93
Q. Okay, and have you ever comp	oiled a list of all

- 2 retro conversions?
- 3 MR. GULLIVER:

- 4 A. I have not, no.
- 5 MS. NEWBURY:
- 6 Q. Okay, and has anyone in the lab, such as Mr
- 7 Dyer compiled such a list?
- 8 MR. GULLIVER:
- 9 A. Not to my knowledge, Barry hasn't no. I don't
- know if the pathologists have.
- 11 MS. NEWBURY:
- 12 Q. Okay.
- 13 MR. GULLIVER:
- 14 A. Dr. Denic would be the best one to answer
- that.
- 16 MS. NEWBURY:
- 17 Q. Okay, now Dr. Denic does not appear to have
- done so. Do you know if anyone else in
- Eastern Health has prepared such a list?
- 20 MR. GULLIVER:
- 21 A. My best guess would be Ms. Predham.
- 22 MS. NEWBURY:
- 23 Q. Your guess, so that means you have no idea of
- 24 whether she has or hasn't, is that correct?
- 25 MR. GULLIVER:

1

A. I think that Dr. Denic would ask Barry Dyer

Page 95

Page 96

- 2 something like that, to help him organize and
- pull blocks of slides and do those basic
- 4 things.
- 5 MS. NEWBURY:
- 6 Q. And are you aware of whether Dr. Denic has
- asked Barry Dyer to assist in that regard?
- 8 MR. GULLIVER:
- 9 A. I know that Dr. Denic has reviewed some retro
- 10 converters.
- 11 MS. NEWBURY:
- 12 Q. But in terms of actually compiling a list of
- all of the retro converters?
- 14 MR. GULLIVER:
- 15 A. I can't tell you for sure if he has or has
- 16 not.

19

2

5

- 17 MS. NEWBURY:
- 18 Q. And if Dr. Denic had taken it upon himself to
 - compile such a list of retro converters, would
- you anticipate receiving a copy of that list?
- 21 MR. GULLIVER:
- 22 A. I would think that he would keep me informed,
- yes.
- 24 MS. NEWBURY:
- 25 Q. Okay, and would that be of any value or

Page 94

- A. I can't tell you for sure, but I think she
- 2 would be the best person to ask.
- 3 MS. NEWBURY:

- 4 Q. Okay. So she hasn't come to you for any
- 5 information or any input on how to go about
- 6 doing this? You don't have any reason to
- 7 believe that she's done it?
- 8 MR. GULLIVER:
- 9 A. No.
- 10 MS. NEWBURY:
- 11 Q. And why have you not compared or compiled such
- a list of retro converters?
- 13 MR. GULLIVER:
- 14 A. I think that, I mean, that's more of a
- clinical issue, you know, someone like Dr.
- Denic, our clinical chief, would be something
- 17 he would want to undertake and, you know, and
- review the original slides and compare them to
- 19 the retest slides.
- 20 MS. NEWBURY:
- 21 Q. And you don't see that, as a director of the
- 22 Laboratory Medicine Program, that you would
- have any role in helping to gather together
- 24 the information?
- 25 MR. GULLIVER:

- benefit to you as the director, either you or
 - perhaps Mr. Dyer?
- 3 MR. GULLIVER:
- 4 A. Well I think the benefit would be, number one,
 - how many do you have, so you know, if you--I
- 6 mean, we know we have documented less than ten
- 7 out of, you know, so we're talking out of 2000
- 8 patients approximately, that you know, the
- 9 2000 patients who were deemed to be positive
- and have not been retested, so within that
- group, you know, for whatever reason, we've
- identified that there may be ten or less than
- 13 ten who have converted from a positive,
- whether it was a misinterpretation, whether it
- was a technical false positive and now they're
- retested negative. So you're talking about
- less than one percent of that total. If, so
- if Dr. Denic compiled a list, you know, and
- that list, Ms. Newbury, was like 200. I think
- 20 then, you know, yes, that's something that you
- 21 really want to be interested in if the numbers
- were something like that.
- 23 MS. NEWBURY:
- 24 Q. Okay, and is that because if you take 200 and
- 25 divide that by 2000, which are the approximate

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1 total of -	the expected false positive rate would be
2 MR. GULLIVER:	2 anywhere from 1 to 3 percent.
3 A. It's 10 percent.	3 MS. NEWBURY:
4 MS. NEWBURY:	4 Q. Very rare, I think, was your evidence
5 Q. Ten percent, and ten percent for you would be	5 yesterday, that experts said it would be very
6 a concern, would it?	6 rare to get a false positive, but my question
7 MR. GULLIVER:	is here you have only retested, according to
8 A. It would be, yes.	8 this particular document, a total of sixteen
9 MS. NEWBURY:	9 positive test results, you haven't retested
10 Q. Okay. Now you're assuming that the 2000 tes	t the approximately 2000 others that didn't get
results that haven't been retested are all	into part of this retesting program. You've
12 accurate?	only retested sixteen in total. Four of those
13 MR. GULLIVER:	have converted. That's not a particularly
14 A. I have to say yes.	good success rate if you compare it with what
15 MS. NEWBURY:	the experts expected, which is one to three or
16 Q. Okay.	very rare, and I'm just wondering whether that
17 MR. GULLIVER:	has caused you to delve into that issue any
18 A. As many other people are, yes.	18 further than that?
19 MS. NEWBURY:	19 MR. GULLIVER:
20 Q. Okay. Now the document right here shows so	me 20 A. It has not, no.
21 results. Now unfortunately it appears from	21 MS. NEWBURY:
your understanding that Dr. Carter's	22 Q. Okay, so it doesn't concern you that the
23 information is not there, but based on this	expectations of the experts has not been borne
information, you have four out of sixteen	out by what's being shown here?
positive test results that converted upon	25 MR. GULLIVER:
	Page 98 Page 100
1 retesting. That's 25 percent.	1 A. I think I'd be more concerned if our
2 MR. GULLIVER:	2 oncologists were concerned.
3 A. I know when I see this, it's reviewing 76	_
4 cases.	4 Q. Okay. Now you haven't compiled a list of the
5 MS. NEWBURY:	5 actual retro conversions, so you can't say
6 Q. Right.	6 today here's a list, here are the exact
7 MR. GULLIVER:	7 number, your understanding is that it's fewer
8 A. And within that 763 cases, four of them h	•
9 been confirmed as a retro converter.	9 MR. GULLIVER:
10 MS. NEWBURY:	10 A. Yes.
11 Q. Yeah, but 763, those are - you know, the l	arge 11 MS. NEWBURY:
bulk of that would be negative results. So	a 2 Q. And is it your understanding that that's the
negative test result for ER doesn't tell you	same information that the oncologists would
anything about a PR test or a positive test	have that they're relying upon to decide
result for ER. So wouldn't you have to loo	ok 15 whether or not we should be concerned about
at the actual total number of positive test	this?
results to see how are we doing here, how	are 17 MR. GULLIVER:
we doing with conversions of positive to	st 18 A. No. Even before retesting started, you know,
results?	the oncologists had no concern about the
20 MR. GULLIVER:	patients who were already called positive.
21 A. Of false positives?	21 MS. NEWBURY:
22 MS. NEWBURY:	22 Q. And in that case, the retesting program
23 Q. Exactly.	started because of an ER negative test result
24 MR. GULLIVER:	24 that converted?
25 A. I know, and you've heard experts testify t	nat 25 MR. GULLIVER:

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1	A. Yes.	1	
2	MS. NEWBURY:	2	
3	Q. But once it was discovered that we're actually	3	3 MR. GULLIVER:
4	getting more positive test results that are	4	4 A. I'm just thinking in general within the lab
5	converting to negative than would be expected,	5	
6	based on what the experts say, did that cause	6	6 not something that you see.
7	you to say, well, we should gather together	7	7 MS. NEWBURY:
8	all of the information, all of the data on	8	8 Q. That you're not supposed to see?
9	these conversions, to make sure that the	9	9 MR. GULLIVER:
10	oncologists are aware of that before they	10	0 A. It's very rare.
11	decide, listen, we shouldn't be worried about	11	1 MS. NEWBURY:
12	this? I'm just wondering whether you've	12	2 Q. Okay.
13	actually gathered together the data for that?	13	3 MR. GULLIVER:
14	MR. GULLIVER:	14	4 A. Very rare.
15	A. I have not personally, no.	15	5 MS. NEWBURY:
16	MS. NEWBURY:	16	6 Q. And if it turns out that there are more
17	Q. Or thought about doing it?	17	7 instances of that, of retro conversions, which
18	MR. GULLIVER:	18	8 contradicts what's expected by the literature
19	A. No.	19	and by the experts, would that cause you a
20	MS. NEWBURY:	20	concern?
21	Q. And you don't know that anyone else has?	21	1 MR. GULLIVER:
22	MR. GULLIVER:	22	A. Certainly would. As I mentioned earlier - I
23	A. I think you should ask Ms. Predham.	23	think what you need to be concerned with is
24	MS. NEWBURY:	24	what is the reason for a false positive, why
25	Q. And I will do that, I'm sure, but I'm just	25	was something called positive originally and
	Page 102		Page 104
1	wondering about your particular role there as	1	now why is it retesting and there's no
2	the director of the laboratory medicine	2	2 staining.
3	program. On that issue of what the experts	3	3 MS. NEWBURY:
4	have told you to expect, 1 to 3 percent, what	4	4 Q. And what are the things that you would look
5	experts specifically are you talking about?	5	for to try to ascertain what the reasons are
6	MR. GULLIVER:	6	for false positives?
7	A. Well, I think we've seen through literature,	7	7 MR. GULLIVER:
8	through literature researches -	8	Ç •
9	MS. NEWBURY:	9	
10	Q. I'm just wondering what your understanding at	10	•
11	the time. I know there's a lot of information	11	
12	from the literature, but prior to, say, the	12	giving an awful lot of background staining

15

17

18

19

20

22

23

25

14 MS. NEWBURY:

16 MR. GULLIVER:

21 MS. NEWBURY:

24 MR. GULLIVER:

Q. Okay.

positive.

that could be misread.

A. Or is it simply that the pathologist who read

the original slide misinterpreted plasmic

staining for nuclear staining and called it

Q. Are you aware of any other possible causes,

A. I would think that's the two main - the two

such as over antigen retrieval?

13 inquiry and all of the evidence that came out

14 there, what was your understanding from 2005,

15 2006, early 2007, as to what experts - which

16 experts would have expected very rare or 1 to

17 3 percent?

18 MR. GULLIVER:

A. I spoke to an expert who's involved with the 19

class action, so I can't really disclose

21 anything there.

22 MS. NEWBURY:

20

Q. Okay, I don't want to go there. Is there 23

24 anyone else that you spoke to, any other - the 25

reviewers that were here, or anyone that you

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A. No. 2 3 MS. NEWBURY: Q. Okay, so you don't recognize anything about that particular group, not the e-mail itself 5 because I know that you weren't a recipient of 6 7 that?

8 MR. GULLIVER: 9

A. Not that group as a group. You know, individually, if these patients were - if 10

11 Heather came across these patients, you know, she may ask me to do some further 12

13 documentation to ensure the Meditech system,

that what the original results were and those 14

15 kinds of things, but I've not been involved in

this small list of patients here, Ms. Newbury. 16

17 MS. NEWBURY:

1 MR. GULLIVER:

Q. Okay, and there's a larger list which contains 18 19 this information and some additional information at Exhibit P-2642, and this was 20 21 from Heather Predham to Dr. Denic, and Dr. 22 Laing was familiar with this as well, and

attached - I wonder if we can reverse the 23

24 orientation. There we go. Are you familiar

with the information in this? 25

A. I don't - and I even hate the term "retro 1

2 converter".

3 MS. NEWBURY:

o. Okay.

5 MR. GULLIVER:

A. Whoever invented that term internally -

7 MS. NEWBURY:

8 O. I think someone at Eastern Health can take

credit for that.

10 MR. GULLIVER:

11 A. I know they did - as a retro converter, you

know, a patient converted. 12

13 MS. NEWBURY:

14 Q. Right.

15 MR. GULLIVER:

A. Whether it was from positive to negative or 16

17 negative to positive.

18 MS. NEWBURY:

Q. And I think the purpose was to try to 19

distinguish. 20

21 MR. GULLIVER:

22

A. To try to distinguish that these are patients

who originally -23

24 MS. NEWBURY:

25 Q. For simplicity sake.

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1 MR. GULLIVER:	1 Q. But you don't know for sure how that number
2 A. Yeah.	was derived by the person using the figure,
3 MS. NEWBURY:	whether they included the deceased patients or
4 Q. I guess you can call it false positives as	4 not?
5 well.	5 MR. GULLIVER:
6 MR. GULLIVER:	6 A. When I first heard the four, I heard it from
7 A. Yeah.	7 somebody on the class action side of it, so I,
8 MS. NEWBURY:	8 you know -
9 Q. Do you know of that collection of four or	9 MS. NEWBURY:
whatever number it is less than ten now that	10 Q. Okay.
it might be, would that include the results of	11 MR. GULLIVER:
a specimen for a deceased patient whose	12 A. But after that number is when we sent off the
results changed?	deceased patients for retesting.
14 MR. GULLIVER:	14 MS. NEWBURY:
15 A. I'm assuming it would because we've had all	15 Q. So if the official number now is still four,
the deceased patients now retested.	do you know if that would include the results
17 MS. NEWBURY:	of deceased patients or not?
18 Q. Okay, but in terms of the -	18 MR. GULLIVER:
19 MR. GULLIVER:	19 A. I don't know if the official number - what the
20 A. But the original four, by that time we had not	official number is.
retested the deceased patients because the	21 MS. NEWBURY:
original four I knew by, I would say, sometime	Q. And would the figure for the number of retro
in '07, and I think those four were documented	conversions of a test result include a
before the deceased patients were sent off for	situation where there was a change from a
25 retesting.	positive result to a negative result, but
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1 MS. NEWBURY:	there was no recommended treatment change by a
2 Q. It was Ms. Pilgrim's evidence just in the last	2 physician or the review panel?
3 couple of weeks, I think, late September,	3 MR. GULLIVER:
4 early October, that she's now aware of four	4
5 material appropriations Amaryon recorded that ha	4 A. I wouldn't know that.
5 retro converters. Are you - would that be	4 A. I Wouldn't know that. 5 MS. NEWBURY:
6 something that's consistent with your	
	5 MS. NEWBURY:
6 something that's consistent with your	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion
something that's consistent with your understanding or not, based perhaps on new	 5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER
something that's consistent with your understanding or not, based perhaps on new information about the results -	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon
6 something that's consistent with your 7 understanding or not, based perhaps on new 8 information about the results - 9 MR. GULLIVER:	 5 MS. NEWBURY: Q. Okay, and do you know if a retro conversion would include a situation where you have an ER negative/PR positive test result, but upon retesting it was determined to be ER and PR
6 something that's consistent with your 7 understanding or not, based perhaps on new 8 information about the results - 9 MR. GULLIVER: 10 A. I knew some time in '07, again through the	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process.	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters?
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process. MS. NEWBURY:	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER:
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process. MS. NEWBURY: Q. Yeah. This has nothing to do with what you	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER: 13 A. I don't think so.
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process. MS. NEWBURY: Q. Yeah. This has nothing to do with what you were doing on a day to day basis?	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER: 13 A. I don't think so. 14 MS. NEWBURY: 15 Q. And why is that? 16 MR. GULLIVER:
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process. MS. NEWBURY: Q. Yeah. This has nothing to do with what you were doing on a day to day basis? MR. GULLIVER: A. Right. MS. NEWBURY:	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER: 13 A. I don't think so. 14 MS. NEWBURY: 15 Q. And why is that? 16 MR. GULLIVER: 17 A. Because I think the focus was more on the ER.
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process. MS. NEWBURY: Q. Yeah. This has nothing to do with what you were doing on a day to day basis? MR. GULLIVER: A. Right. MS. NEWBURY: Q. Coming up with these figures.	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER: 13 A. I don't think so. 14 MS. NEWBURY: 15 Q. And why is that? 16 MR. GULLIVER: 17 A. Because I think the focus was more on the ER. 18 MS. NEWBURY:
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process. MS. NEWBURY: Q. Yeah. This has nothing to do with what you were doing on a day to day basis? MR. GULLIVER: A. Right. MS. NEWBURY: Q. Coming up with these figures.	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER: 13 A. I don't think so. 14 MS. NEWBURY: 15 Q. And why is that? 16 MR. GULLIVER: 17 A. Because I think the focus was more on the ER. 18 MS. NEWBURY: 19 Q. Okay. From your perspective, and keeping in
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process. MS. NEWBURY: Q. Yeah. This has nothing to do with what you were doing on a day to day basis? MR. GULLIVER: A. Right. MS. NEWBURY: Q. Coming up with these figures. MR. GULLIVER: A. Right.	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER: 13 A. I don't think so. 14 MS. NEWBURY: 15 Q. And why is that? 16 MR. GULLIVER: 17 A. Because I think the focus was more on the ER. 18 MS. NEWBURY: 19 Q. Okay. From your perspective, and keeping in 20 mind that the oncologists involved are
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process. MS. NEWBURY: Q. Yeah. This has nothing to do with what you were doing on a day to day basis? MR. GULLIVER: A. Right. MS. NEWBURY: Q. Coming up with these figures. MR. GULLIVER: A. Right. MR. GULLIVER: A. Right.	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER: 13 A. I don't think so. 14 MS. NEWBURY: 15 Q. And why is that? 16 MR. GULLIVER: 17 A. Because I think the focus was more on the ER. 18 MS. NEWBURY: 19 Q. Okay. From your perspective, and keeping in 20 mind that the oncologists involved are 21 probably focused on trying to find out whether
something that's consistent with your understanding or not, based perhaps on new information about the results - 9 MR. GULLIVER: 10 A. I knew some time in '07, again through the other process. 12 MS. NEWBURY: 13 Q. Yeah. This has nothing to do with what you were doing on a day to day basis? 15 MR. GULLIVER: 16 A. Right. 17 MS. NEWBURY: 18 Q. Coming up with these figures. 19 MR. GULLIVER: 20 A. Right. 21 MS. NEWBURY: 22 Q. So you heard the number from someone?	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER: 13 A. I don't think so. 14 MS. NEWBURY: 15 Q. And why is that? 16 MR. GULLIVER: 17 A. Because I think the focus was more on the ER. 18 MS. NEWBURY: 19 Q. Okay. From your perspective, and keeping in 20 mind that the oncologists involved are 21 probably focused on trying to find out whether 22 or not there should be a change of treatment
something that's consistent with your understanding or not, based perhaps on new information about the results - MR. GULLIVER: A. I knew some time in '07, again through the other process. MS. NEWBURY: Q. Yeah. This has nothing to do with what you were doing on a day to day basis? MR. GULLIVER: A. Right. MS. NEWBURY: Q. Coming up with these figures. MR. GULLIVER: A. Right. MR. GULLIVER: A. Right.	5 MS. NEWBURY: 6 Q. Okay, and do you know if a retro conversion 7 would include a situation where you have an ER 8 negative/PR positive test result, but upon 9 retesting it was determined to be ER and PR 10 negative, would that be included in the group 11 of retro converters? 12 MR. GULLIVER: 13 A. I don't think so. 14 MS. NEWBURY: 15 Q. And why is that? 16 MR. GULLIVER: 17 A. Because I think the focus was more on the ER. 18 MS. NEWBURY: 19 Q. Okay. From your perspective, and keeping in 20 mind that the oncologists involved are 21 probably focused on trying to find out whether

director of the laboratory medicine program,

25 MS. NEWBURY:

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1 you're dealing with the day to day events	1 MS. NEWBURY:
2 happening in the lab -	2 Q. Okay.
3 MR. GULLIVER:	3 MR. GULLIVER:
4 A. You mean during '05?	4 A. Anybody involved in this.
5 MS. NEWBURY:	5 MS. NEWBURY:
6 Q. Any time, 2005, 2006, 2007, today?	6 Q. And if a test result was originally ER
7 MR. GULLIVER:	7 negative and PR positive, but that converts to
8 A. My perspective is different how?	8 0/0, is that of interest to you as the
9 MS. NEWBURY:	9 director of the laboratory medicine program?
10 Q. Your focus is broader, I would assume, than on	10 MR. GULLIVER:
just whether or not a living patient needs a	11 A. Again anybody who's involved in this, those
12 change of treatment?	would be of interest to us, yes.
13 MR. GULLIVER:	13 MS. NEWBURY:
14 A. I don't get what you want to ask me.	14 Q. And your particular interest would be to do
15 MS. NEWBURY:	what? How is that of interest to you?
	16 MR. GULLIVER:
Q. Let me ask the question another way. Would it be of interest to you that a specimen for a	
· · · · · · · · · · · · · · · · · · ·	17 A. Well, I think it's - through all this here, I
deceased patient changed from a positive	think it's also an interest in to look at
result to a negative result?	19 individual cases.
20 MR. GULLIVER:	20 MS. NEWBURY:
21 A. It certainly would be of interest to me, but I	21 Q. But in terms of assessing potential problem
think it would be more important to the	areas or quality areas in the laboratory
23 oncologist.	23 medicine program, would it be of interest to
24 MS. NEWBURY:	you to gather up and add up the numbers into
25 Q. And why is it more important to the	25 those categories?
	-
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Page 114 1 oncologist?	Page 116 1 MR. GULLIVER:
1 oncologist?	1 MR. GULLIVER:
1 oncologist? 2 MR. GULLIVER: 3 A. Well, I think the oncologist would like to	1 MR. GULLIVER: 2 A. It would give us statistics, add up those
1 oncologist? 2 MR. GULLIVER: 3 A. Well, I think the oncologist would like to	1 MR. GULLIVER: 2 A. It would give us statistics, add up those 3 categories, and compare them to what you would
1 oncologist? 2 MR. GULLIVER: 3 A. Well, I think the oncologist would like to 4 know that if they had a patient that they were 5 treating for a various number of years, and	1 MR. GULLIVER: 2 A. It would give us statistics, add up those 3 categories, and compare them to what you would 4 expect in the literature or expect in the
1 oncologist? 2 MR. GULLIVER: 3 A. Well, I think the oncologist would like to 4 know that if they had a patient that they were 5 treating for a various number of years, and 6 now they discover that patient retested	1 MR. GULLIVER: 2 A. It would give us statistics, add up those 3 categories, and compare them to what you would 4 expect in the literature or expect in the 5 world now. 6 MS. NEWBURY:
1 oncologist? 2 MR. GULLIVER: 3 A. Well, I think the oncologist would like to 4 know that if they had a patient that they were 5 treating for a various number of years, and 6 now they discover that patient retested 7 negative, you know, and that patient probably	1 MR. GULLIVER: 2 A. It would give us statistics, add up those 3 categories, and compare them to what you would 4 expect in the literature or expect in the 5 world now. 6 MS. NEWBURY: 7 Q. Okay, and you've had no reason to date to
1 oncologist? 2 MR. GULLIVER: 3 A. Well, I think the oncologist would like to 4 know that if they had a patient that they were 5 treating for a various number of years, and 6 now they discover that patient retested	1 MR. GULLIVER: 2 A. It would give us statistics, add up those 3 categories, and compare them to what you would 4 expect in the literature or expect in the 5 world now. 6 MS. NEWBURY: 7 Q. Okay, and you've had no reason to date to 8 compile such a list that would include retro
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October 15, 2006	Mulu-r ag	e inquiry on normone keceptor resun
P	age 117	Page 11
and 2642, and the information is contained	lin 1	A. Was it a specimen that originated in St.
2 a document P-0720. This is an e-mail. Ag	gain 2	Clare's, Health Sciences, Corner Brook. I
you did not - you're not named here as	a 3	would have interest in the total numbers that
4 recipient of the e-mail, and it is informatio	n 4	were sent off from the nine different
5 that was provided to Mark Quinn following	ng a 5	pathology labs in the province. I would have
6 request for information, access to informat	ion 6	interest in, you know, pathologists or groups
7 request, and it contains several - quite a	7	of pathologists -
8 number of pages of information by colum	mns 8 M	S. NEWBURY:
9 indicating the original ER, the original PR,	9	Q. Right.
the Mount Sinai ER, and the Mount Sinai	PR. 10 M	R. GULLIVER:
11 Are you generally familiar with the layout	of 11	A. Who may be interpreting them.
this, the data contained -	12 M	S. NEWBURY:
13 MR. GULLIVER:	13	Q. And year by year analysis, would that be of
14 A. Not really, no, no.	14	interest to you?
15 MS. NEWBURY:	15 M	R. GULLIVER:
16 Q. Did you ever do a similar analysis of	16	A. Yes, it would be.
comparing the original test results, whether		S. NEWBURY:
they were positive, negative, with the Mou	unt 18	Q. Yeah.
19 Sinai test results?	19 M	R. GULLIVER:
20 MR. GULLIVER:	20	A. But that's certainly something that by July
21 A. In -	21	'07, you know, we just did not have the time
22 MS. NEWBURY:	22	or the resources to be able to start doing
Q. In an organized fashion like this prior to the		that, and, you know, when NLCHI then was
24 NLCHI involvement?	24	seconded and we knew that would be a piece of
25 MR. GULLIVER:	25	the outcome from NLCHI.
P	Page 118	Page 12
1 A. Prior to NLCHI, no.	1 M	S. NEWBURY:
2 MS. NEWBURY:	2	Q. Did you ever express that view to anyone else
3 Q. And why is that?	3	that this will be a worthwhile exercise?
4 MR. GULLIVER:		R. GULLIVER:
5 A. I just didn't have time.		A. I certainly have, yes.
6 MS. NEWBURY:		S. NEWBURY:
7 Q. Did you think it was important and didn't have		Q. And to whom did you express that?
8 time?		R. GULLIVER:
9 MR. GULLIVER:	, 9	A. I think in general to again the same people that you've heard over and over who were
10 A. I knew that, you know, NLCHI was coming in, i started in July '07.	t 10 11	actively involved in this here. Again they're
11 started in July '07. 12 MS. NEWBURY:	11 12	all in the same boat that I was in, you know,
13 Q. But prior to that, you had no knowledge that	13	you're doing this - this file along with the
14 NLCHI would be involved until, I think,	13	rest of your job. I think that it's something
somewhere around June or July of 2007.	15	that Eastern Health had talked about, you
16 MR. GULLIVER:	16	know, talking about engaging, like, even
17 A. Certainly prior to that time, I had interest	17	researchers to do some kind of analysis and
in things like, well, of the totals that were	18	summary of all this here.
retested, you know, how many - how many ca		S. NEWBURY:
20 back with a changed result. I would have	20	Q. But even something less sophisticated than
21 interest in the origin of the original	21	having perhaps statisticians or
	1	~ ^

23

24

25

epidemiologists involved, just for your own

review - you don't think you had any time just to add to your tables. You already had

tables, I think, by year that you and Mr. Dyer

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22

specimen.

23 MS. NEWBURY:

25 MR. GULLIVER:

Q. Uh-hm.

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- prepared, just to add in the results for the 1
- 2 Mount Sinai ER and PR?
- 3 MR. GULLIVER:
- A. I know, but that would have meant reviewing
- another thousand patients and then reviewing 5
- them and putting them into specific 6
- categories. So it's a patient from Western 7
- Memorial, Gander, Grand Falls, Carbonear, 8
- Clarenville, Health Sciences, Grace, St. 9
- 10 Clare's, St. Anthony. There would have been
- another table then which pathologist did the 11
- original interpretation, you know, the time 12
- frame that the testing was done, broken down 13
- 14 by year, so it's -
- 15 MS. NEWBURY:
- Q. Now a couple of those categories -16
- 17 MR. GULLIVER:
- A. It's a significant amount of work.
- 19 MS. NEWBURY:
- Q. Yes, no doubt it will be, but a couple of 20
- those tables already existed by year and by 21
- 22 region, isn't that correct?
- 23 MR. GULLIVER:
- A. Not only in numbers, but not broken down by 24
- 25 patient results.

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- Q. Okay, so you didn't have separate tables -
- 3 MR. GULLIVER:

1 MS. NEWBURY:

- A. No.
- 5 MS. NEWBURY:
- Q. For sending off for retesting purposes? I had 6
- understood that that was -7
- 8 MR. GULLIVER:
- A. No, no, we had for the regions, yes.
- 10 MS. NEWBURY:
- Q. Yes, for the regions. 11
- 12 MR. GULLIVER:
- A. Yes. 13
- 14 MS. NEWBURY:
- 15 Q. Okay, and how about St. John's, would you have
- 16
- 17 MR. GULLIVER:
- A. And for St. John's, they were for St. John's 18
- 19 patients.
- 20 MS. NEWBURY:
- 21 Q. Okay, and that wasn't broken down by year, was
- 22
- 23 MR. GULLIVER:
- 24 A. It was broken down by year, and then you could
- go to the spreadsheet to see what the original 25

- site, like, where the patient had their
- 2 primary surgery.
- 3 MS. NEWBURY:
 - Q. Okay, but at the very least you did have some

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- tables, not as organized or sophisticated -5
- 6 MR. GULLIVER:
- A. Yes. 7
- 8 MS. NEWBURY:
- Q. As having pathologists or sites in St. John's
- 10 even, but you did have some tables there?
- 11 MR. GULLIVER:
- A. Some. 12
- 13 MS. NEWBURY:
- Q. Now, Mr. Gulliver, there's some information 14
- here on Exhibit 720 which is something that 15
 - you're not familiar with, but I wanted to
- bring to your attention some results here, and 17
- line 20 has two entries, which I assume would 18
- be for the same patient, although I'm really 19
- not sure, and one of the results was a 20
- negative ER, 75 PR, and retesting it went to 2 21
- 22 and 0, and I couldn't locate that on either P-
- 23
- 2642 or 1373, which were the lists that Dr.
 - Laing was aware of.
- 25 MR. GULLIVER:
- A. Okay.

24

- 2 MS. NEWBURY:
- Q. And would you have any explanation for why 3
- that would not be on her lists? 4
- 5 MR. GULLIVER:
- A. No. 6
- 7 MS. NEWBURY:
- Q. Were you even aware of this type of a result, 8
- this particular did anyone ever bring to 9
- your attention, gee, this is unusual, we have 10
- 11 a result that was negative for ER, 75 for PR,
- and then it converted to 2 and 0? 12
- 13 MR. GULLIVER:
- A. No. 14
- 15 MS. NEWBURY:
- Q. No one ever brought that to your attention?
- 17 MR. GULLIVER:
- A. No. 18
- 19 MS. NEWBURY:
- Q. Line 61, we have a result again there are
- several entries there, but the third line for 21
- 61 -22
- 23 MR. GULLIVER:
- A. And I'm thinking this must be the same 24 25
 - patient retested more than once or more than

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one block, I'm assuming.	1 positive?
2 MS. NEWBURY:	2 MS. NEWBURY:
3 Q. Yeah, unfortunately there's not - this was	3 Q. Yes.
done for Mr. Quinn, so it's not as elaborate	4 MR. GULLIVER:
5 as having surgical numbers.	5 A. I don't know if that was - I think you heard
6 MR. GULLIVER:	6 individual oncologists apply that differently.
7 A. Yeah.	7 MS. NEWBURY:
8 MS. NEWBURY:	8 Q. I think the evidence of Dr. McCarthy, that was
9 Q. Those types of information. So this is - or	9 a prevalent practice, and she's been here,
10 even whether this was done over several.	that she was aware of anyway. So certainly
11 Unfortunately, that information is not there,	some did, if not all. And that was never ever
but the third line for 61, we've got a 0 ER,	brought to your attention at any time
13 50/60 PR, 0 and 0, and I couldn't locate that	throughout this process or is thatdid you
on the table that Dr. Laing was working with.	just hear that for the first time after the
15 MR. GULLIVER:	15 Inquiry started?
16 A. And again I wouldn't know.	16 MR. GULLIVER:
17 MS. NEWBURY:	17 A. Hear what? That something was a zero ER and
18 Q. And no one ever brought that to your	18 positive PR -
19 attention?	19 MS. NEWBURY:
20 MR. GULLIVER:	20 Q. Yes.
21 A. No.	21 MR. GULLIVER:
22 MS. NEWBURY:	22 A and then was a zero, zero?
23 Q. Would that have been of interest to you?	23 MS. NEWBURY:
24 MR. GULLIVER:	Q. And then a patient who's a zero ER but a
25 A. This particular case, or do you mean in	positive PR might be treated with hormone
Page 126	Page 128
1 general?	1 therapy?
2 MS. NEWBURY:	2 MR. GULLIVER:
3 Q. Just the very fact that you've got that	3 A. Oh no, I heard that before the Inquiry
4 conversion. I mean, you've indicated that it	4 started.
5 was your understanding that a conversion from	5 MS. NEWBURY:
6 a positive result to a negative result would	6 Q. Oh, okay. So you were aware of that.
7 be very rare. Was there ever any	7 MR. GULLIVER:
8 understanding that it would be different for	8 A. At some meeting where we were there with the
9 PR?	9 oncologists.
10 MR. GULLIVER:	10 MS. NEWBURY:
11 A. Well, and again I think, you know, we were	11 Q. Okay, I had misunderstood when you said that.
told by the oncologists that the ER was the	12 MR. GULLIVER:
more critical one to focus on.	13 A. I even heardI heard Dr. Kwan say that people
14 MS. NEWBURY:	who were zero, zero, he treated them with
15 Q. Do you know whether or not they would have	15 hormone therapy. He looked at the clinical
treated a patient who was -	the age of the woman, the clinical history.
17 MR. GULLIVER:	So he stated that early on.
18 A. I don't know that. I mean -	18 MS. NEWBURY:
19 MS. NEWBURY:	19 Q. Right, but did he make any comment about how
20 Q. And just in terms of the - and again there is	20 common it was for oncologists to treat -
some evidence that they did, in fact, treat	21 MR. GULLIVER:
these patients as positive. That was a	22 A. He did not say that, no.
general practice.	23 MS. NEWBURY:
24 MR. GULLIVER:	Q. Okay. Would it concern you that you've got
125 A Vou man if they were EB negative DB	25 conversions? Like today if you went into

conversions? Like today, if you went into

A. You mean if they were ER negative, PR

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page here with the oncologists, are you? 23 24 MR. GULLIVER:

Q. So there's no sort of--you're not on the same

A. No.

21 MS. NEWBURY:

25

22

Q. And there are a number of others, I'm not

21

23

25

Q. Okay.

A. Pretty well.

22 MR. GULLIVER:

24 MS. NEWBURY:

Page 133 Page 135 that's a 20 for ER, zero for PR and then zero, 1 MS. NEWBURY: 1 Q. In terms of what would be considered a retro 2 zero upon retesting at Mount Sinai, and then back at the beginning of the document, line 3 converter? 3 68, we have a 20 ER, zero PR and that converts 4 MR. GULLIVER: 4 A. No. 5 to zero, zero upon retesting at Mount Sinai. 5 These numbers that I've just shown you, 6 MS. NEWBURY: 6 Q. And no one has ever brought to your attention on the longer of the two exhibits that I 7 that there's a potential issue here with PRs 8 8 showed to you this morning that Dr. Laing was that are converting to zeros? familiar with, there was one instance of a 9 10 MR. GULLIVER: 10 ten, ten converting to zero, zero. There was A. No. only one instance of that, whereas in this 11 11 document here, there are a total of four, and 12 THE COMMISSIONER: 12 Q. Ms. Newbury, it's around the time for the the other conversions that I just showed you, 13 morning break (inaudible). the 40, zero to five, zero, 10-20, 40-50 to 14 14 15 MS. NEWBURY: zero, zero, 20 zero to zero, zero, two 15 Q. Okay. Well, this is probably a good place to instances of those, they were not on the list 16 16 that Dr. Laing had been shown and was familiar break. 17 17 18 THE COMMISSIONER: 18 with. 19 Q. All right. We'll take the morning break. 19 So there appears to be here, in addition to the PR retro conversions, a number of other 20 (BREAK) 20 ER retro conversions. That would be, you 21 THE COMMISSIONER: 21 22 Q. Please be seated. Ms. Newbury. 22 know, what you might glean from the numbers there, and are you familiar with all of these 23 23 MS. NEWBURY: different instances of apparent retro Q. Mr. Gulliver, I just showed you a few entries 24 24 in the data that was given to Mark Quinn at Pconversions? 25 25 Page 136 Page 134 0720, please, and you indicated that those 1 MR. GULLIVER: 1 were--you noted that those were PR A. Not individually, but I think first of all, 2 conversions. They weren't ER conversions, and you have to ask what were the oncologists and 3 3 perhaps that may have been a reason why it Ms. Predham's definition of a retro converter, 4 4 5 wasn't brought to your attention. Is that -5 and to my knowledge, they categorize people as a retro converter as people who had a 6 MR. GULLIVER: 6 A. Quite possible, yes. 7 treatment change in reverse. 7 8 MS. NEWBURY: 8 MS. NEWBURY: Q. Okay. There are some other retro conversions Q. Right, so they had been given hormone therapy 9 that are not on either of Dr. Laing's lists and perhaps they ought not to have -10 10 11 that she was familiar with, the two that I 11 MR. GULLIVER: showed you just before the break. If we go to A. Based upon the original test results, and what 12 12 line 132 of Exhibit P-0720? We have an entry, 13 13 line 132, original ER and PR ten and ten and 14 14 MS. NEWBURY: 15 Mount Sinai zero and zero, and there are Q. Now before the break-sorry, before the break, 15 several other similar entries. 239, we've got you weren't aware of that. I had asked you 16 16 17 a ten ten and zero zero, and the same thing at 17 that question. Is that something that you line 413. Actually, there is a ten, ten and learned in between or -18 18 19 less than one and zero, upon retesting. And 19 MR. GULLIVER: line 804, we have ten ten going to zero zero, A. You asked me what--sorry? 20 line 804. Also, line 778, there's a 10 to 20 21 21 MS. NEWBURY: 22 for ER and 40 to 50 for PR and that converts Q. I had asked you if you understood what their definition was of retro conversion. to zero, zero. And line 520, there is a 23 23 24 result 40 for ER, zero for PR and that 24 MR. GULLIVER: converts to five and zero. And line 615, A. I don't remember you asking me that question. 25

Multi-Page TM October 15, 2008 Page 137 Page 139 you to get to the root of that problem, to 1 MS. NEWBURY: Q. Okay. So is that something that just came to 2 find out why are there conversions from ten to your mind then, that that's what they would zero? Whether it's a zero ten to a zero, zero 3 3 have included as a retro conversion? 4 4 or a ten, ten to zero, zero. 5 MR. GULLIVER: 5 MR. GULLIVER: A. To my knowledge, that's what they were--the A. Well, again, I think you've heard it could be 6 6 retro conversions were based upon treatment, multiple factors that could be involved in a 7 7 8 but all what you showed--what we're not seeing 8 reason for a change like that. here though in this table, Ms. Newbury, is the 9 MS. NEWBURY: 9 10 ones that you're highlighting certainly on 10 Q. Yes, and I'm wondering if you're interested in paper could look like it was ten and ten and 11 finding out what those multiple factors are in 11 came back zero and zero, and why was not that these particular instances. 12 12 considered a retro converter. What we're 13 MR. GULLIVER: 13 missing here is the time frame of the original 14 14 A. I'll have to say yes. test. I'm assuming that most, as you've shown 15 MS. NEWBURY: 15 16 me, ten, ten, zero, zero, were probably done 16 Q. Okay, and given that Ms. Predham might have in the '97 to 2000 time frame where the been focused on the actual treatment, in terms 17 17 treatment side was--it was less than 30 they of her role there, do you see that your 18 18 considered as negative and didn't offer interest might be a little broader than that? 19 19 treatment. But on a retesting, it came back Your interest might be more on what does this 20 20 ten, ten, zero, zero, so it probably didn't tell us mechanically about what's happening or 21 21 technically in the lab from a day-to-day 22 effect a treatment change. 22 23 basis? 23 MS. NEWBURY: Q. So that's a possible explanation, but do you 24 24 MR. GULLIVER: actually know that that's the case? 25 25 A. Well, I think both technically and from a Page 138 Page 140 pathologist's perspective also. I mean, the 1 MR. GULLIVER: 1 A. I can't tell you 100 percent, no, but I mean, 2 lab is just not the pathologists or just the that's from--you're asking me my opinion and technologists. I mean, it's a group effort. 3 3 that's the best opinion I can give you. 4 MS. NEWBURY: 4 5 MS. NEWBURY: 5 Q. Okay, and in light of these various numbers Q. Okay, and it is your understanding that the that I've shown you and regardless of whether 6 6 7 treatment--whether or not there was a change 7 there's a change of treatment, from your perspective, would you still say that there 8 of treatment is what would determine who would 8 be placed on the list of retro conversions? 9 are only four or fewer than ten retro 10 MR. GULLIVER: conversions? Do you have any--has this cast 10 11 A. To the best of my knowledge, yes. 11 any doubt on your conclusion about that? 12 MS. NEWBURY: 12 MR. GULLIVER: Q. Okay. 13 A. I don't think so. I think that, again, the 13 best of my knowledge that there's been a few 14 MR. GULLIVER: 14 A. Again, you know, Ms. Predham, who is up after number of patients who were on hormone 15 15 me, would be probably the best person to ask therapy. On retesting they had to come off 16 16 17 that question. 17 hormone therapy. 18 MS. NEWBURY: 18 MS. NEWBURY: Q. From your own perspective, considering that Q. Okay. So in your mind, not just in Ms. 19 19 you're the director of Laboratory Medicine, Predham's mind, but in your mind, if a person 20 20 and recognizing that the standards have was not initially treated with hormone

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therapy, whether it was 1998 or 2002, even if

their results ended up, upon retesting, being

a zero, zero result, you do not consider that

a retro conversion?

changed over the years, that a ten now is

typically treated as positive--that's evidence

that we've heard from any oncologist, in fact

sometimes less than that--is it of interest to

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Page 14	Page 143
1 MR. GULLIVER:	1 MS. NEWBURY:
2 A. So originally, what was the original result?	2 Q. Okay. But would you consider at ten, ten
3 MS. NEWBURY:	3 converting to zero, zero, if it happened in
4 Q. Well, I've shown you a number. You've got a	4 2004, as an example, after the change of cut
5 negative ER, 40-50 PR.	off, would you consider that to be retro
6 MR. GULLIVER:	6 conversion?
7 A. And that patient -	7 MR. GULLIVER:
8 MS. NEWBURY:	8 A. I would consider it to be a false positive.
9 Q. Going to zero, zero.	9 MS. NEWBURY:
10 MR. GULLIVER:	10 Q. A false positive, okay.
11 A. And the patient was not treated, based upon	11 MR. GULLIVER:
12 that?	12 A. Whether it affected a patient treatment, I
13 MS. NEWBURY:	13 wouldn't know.
Q. Well, I have no idea. I'm just wondering,	14 MS. NEWBURY:
from your perspective, would you consider that	15 Q. Okay. So that'sthose are two separate
to be a retro conversion or would you need to	issues?
know whether that person was initially treated	17 MR. GULLIVER:
18 or not?	18 A. Yeah.
19 MR. GULLIVER:	19 MS. NEWBURY:
20 A. I think you'd need to know what the treatment	20 Q. So, and you've mentioned earlier that you
21 was also.	don't like the term retro conversion. Let me
22 MS. NEWBURY:	22 ask this question. If all of those numbers
Q. And say if you have a 40 ER and a zero PR	would you consider those to be all false
converting to five and zero.	positives, the ones that I showed you? I
25 MR. GULLIVER:	mean, just looking at the numbers. Perhaps
Page 14	2 Page 144
1 A. I would call that a retro converter, in my	there's a typographical error there, but if
2 lingo. But then you'd need to know how the	those numbers are accurate, would you consider
patient was affected by it.	those to be false positives?
4 MS. NEWBURY:	4 MR. GULLIVER:
5 Q. Okay, and say a patient was determined to be	5 A. So you're saying the one that, for example,
6 ten ER and ten PR in 2004, which is well after	6 that you see number 70 or something, it was
7 the change in cut off, would you consider that	ten, ten and was zero, zero?
8 to be a retro conversion or would you need to	8 MS. NEWBURY:
9 know whether or not there's been a change of	9 Q. Ten, ten, zero, zero or -
10 treatment?	10 MR. GULLIVER:
11 MR. GULLIVER:	11 A. Would I consider it to be a false positive?
12 A. In 2004, the patient was originally tested	12 MS. NEWBURY:
ten, ten and then retested zero, zero?	13 Q. Yes.
14 MS. NEWBURY:	14 MR. GULLIVER:
Q. Converts to zero, zero, and I don't have any	15 A. I would have to say yes.
idea because I don't have information about	16 MS. NEWBURY:
when these were done, but say that happened.	17 Q. Okay.
18 MR. GULLIVER:	18 MR. GULLIVER:
19 A. And I can'tI can't say at all because I	19 A. But then, you'd need to know why was it -
don't have it either.	20 MS. NEWBURY:
21 MS. NEWBURY:	21 Q. I understand. I'm focusing, I guess, on your
22 Q. No, and you haven't compiled your own list of	22 perspective. Whether or not it impacted a
23 that?	patient's treatment, that would be another
24 MR. GULLIVER:	24 issue.
25 A. No, no.	25 MR. GULLIVER:

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1 A. Right.	1 MS. NEWBURY:
2 MS. NEWBURY:	2 Q. Okay. So looking at the two lists that Dr.
3 Q. But I'm focusing on your role, running a lab,	3 Laing was familiar with, as well as the
4 the director of lab -	4 information that I read out to you this
5 MR. GULLIVER:	5 morning, there would appear to be a number of
6 A. From a lab perspective, I would have to	false positives there, and a greater number
7 consider that to be a false positive.	7 than for retro conversions.
8 MS. NEWBURY:	8 MR. GULLIVER:
9 Q. Okay, and how about negative 75 and converting	9 A. I would have to say yes.
to two, zero? Would you consider that to be a	10 MS. NEWBURY:
11 false positive?	11 Q. Okay, and is that of any concern to you?
12 MR. GULLIVER:	12 MR. GULLIVER:
13 A. Negative and 75 for PR?	13 A. I think it onlyit becomes a concern when you
14 MS. NEWBURY:	know how is the patient affected or how is the
15 Q. Yes.	treatment, based upon that.
16 MR. GULLIVER:	16 MS. NEWBURY:
17 A. And on retesting it's two percent?	17 Q. Is it a concern that you're having such a high
18 MS. NEWBURY:	frequency of these false positives, from a
19 Q. And zero.	19 technical perspective?
20 MR. GULLIVER:	20 MR. GULLIVER:
21 A. And zero percent?	21 A. Again, I have not yet seen a full review of
22 MS. NEWBURY:	all the testing to be able to tell us this was
23 Q. Yes.	the number of cases that tested false
24 MR. GULLIVER:	24 positive.
25 A. That would beagain, that's one of those grey	25 MS. NEWBURY:
Page 146	Page 148
Page 146	1 Q. Okay. So you can't rule out whether or not
1 ones. 2 MS. NEWBURY:	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is
1 ones.2 MS. NEWBURY:3 Q. Okay, and is that because the two is not zero?	1 Q. Okay. So you can't rule out whether or not
 ones. MS. NEWBURY: Q. Okay, and is that because the two is not zero? MR. GULLIVER: 	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER:
 ones. MS. NEWBURY: Q. Okay, and is that because the two is not zero? MR. GULLIVER: A. I don't know. 	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say
 ones. MS. NEWBURY: Q. Okay, and is that because the two is not zero? MR. GULLIVER: A. I don't know. MS. NEWBURY: 	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one.
 ones. MS. NEWBURY: Q. Okay, and is that because the two is not zero? MR. GULLIVER: A. I don't know. MS. NEWBURY: Q. Okay. 	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY:
 ones. MS. NEWBURY: Q. Okay, and is that because the two is not zero? MR. GULLIVER: A. I don't know. MS. NEWBURY: Q. Okay. MR. GULLIVER: 	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't
 ones. MS. NEWBURY: Q. Okay, and is that because the two is not zero? MR. GULLIVER: A. I don't know. MS. NEWBURY: Q. Okay. MR. GULLIVER: A. You know, two percent. 	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false
 ones. MS. NEWBURY: Q. Okay, and is that because the two is not zero? MR. GULLIVER: A. I don't know. MS. NEWBURY: Q. Okay. MR. GULLIVER: A. You know, two percent. MS. NEWBURY: 	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives?
1 ones. 2 MS. NEWBURY: 3 Q. Okay, and is that because the two is not zero? 4 MR. GULLIVER: 5 A. I don't know. 6 MS. NEWBURY: 7 Q. Okay. 8 MR. GULLIVER: 9 A. You know, two percent. 10 MS. NEWBURY: 11 Q. Okay. So zero ER and 50 to 60 PR converting	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives? 11 MR. GULLIVER:
1 ones. 2 MS. NEWBURY: 3 Q. Okay, and is that because the two is not zero? 4 MR. GULLIVER: 5 A. I don't know. 6 MS. NEWBURY: 7 Q. Okay. 8 MR. GULLIVER: 9 A. You know, two percent. 10 MS. NEWBURY: 11 Q. Okay. So zero ER and 50 to 60 PR converting to zero, zero?	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives? 11 MR. GULLIVER: 12 A. Right.
1 ones. 2 MS. NEWBURY: 3 Q. Okay, and is that because the two is not zero? 4 MR. GULLIVER: 5 A. I don't know. 6 MS. NEWBURY: 7 Q. Okay. 8 MR. GULLIVER: 9 A. You know, two percent. 10 MS. NEWBURY: 11 Q. Okay. So zero ER and 50 to 60 PR converting 12 to zero, zero? 13 MR. GULLIVER:	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives? 11 MR. GULLIVER: 12 A. Right. 13 MS. NEWBURY:
1 ones. 2 MS. NEWBURY: 3 Q. Okay, and is that because the two is not zero? 4 MR. GULLIVER: 5 A. I don't know. 6 MS. NEWBURY: 7 Q. Okay. 8 MR. GULLIVER: 9 A. You know, two percent. 10 MS. NEWBURY: 11 Q. Okay. So zero ER and 50 to 60 PR converting 12 to zero, zero? 13 MR. GULLIVER: 14 A. I would have to say it's a false positive.	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives? 11 MR. GULLIVER: 12 A. Right. 13 MS. NEWBURY: 14 Q. Do you know if Dr. Denic would be aware of the
1 ones. 2 MS. NEWBURY: 3 Q. Okay, and is that because the two is not zero? 4 MR. GULLIVER: 5 A. I don't know. 6 MS. NEWBURY: 7 Q. Okay. 8 MR. GULLIVER: 9 A. You know, two percent. 10 MS. NEWBURY: 11 Q. Okay. So zero ER and 50 to 60 PR converting 12 to zero, zero? 13 MR. GULLIVER: 14 A. I would have to say it's a false positive. 15 MS. NEWBURY:	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives? 11 MR. GULLIVER: 12 A. Right. 13 MS. NEWBURY: 14 Q. Do you know if Dr. Denic would be aware of the 15 number of false positives?
1 ones. 2 MS. NEWBURY: 3 Q. Okay, and is that because the two is not zero? 4 MR. GULLIVER: 5 A. I don't know. 6 MS. NEWBURY: 7 Q. Okay. 8 MR. GULLIVER: 9 A. You know, two percent. 10 MS. NEWBURY: 11 Q. Okay. So zero ER and 50 to 60 PR converting 12 to zero, zero? 13 MR. GULLIVER: 14 A. I would have to say it's a false positive. 15 MS. NEWBURY: 16 Q. False positive, okay. So perhaps there's a	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives? 11 MR. GULLIVER: 12 A. Right. 13 MS. NEWBURY: 14 Q. Do you know if Dr. Denic would be aware of the 15 number of false positives? 16 MR. GULLIVER:
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1 ones. 2 MS. NEWBURY: 3 Q. Okay, and is that because the two is not zero? 4 MR. GULLIVER: 5 A. I don't know. 6 MS. NEWBURY: 7 Q. Okay. 8 MR. GULLIVER: 9 A. You know, two percent. 10 MS. NEWBURY: 11 Q. Okay. So zero ER and 50 to 60 PR converting 12 to zero, zero? 13 MR. GULLIVER: 14 A. I would have to say it's a false positive. 15 MS. NEWBURY: 16 Q. False positive, okay. So perhaps there's a 17 difference in terminology between what Ms. 18 Predham is using and others are using. 19 MR. GULLIVER: 20 A. It could be, yeah. 21 MS. NEWBURY:	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives? 11 MR. GULLIVER: 12 A. Right. 13 MS. NEWBURY: 14 Q. Do you know if Dr. Denic would be aware of the 15 number of false positives? 16 MR. GULLIVER: 17 A. I don't know. 18 MS. NEWBURY: 19 Q. And his evidence was that he had reviewed four 20 slides that were from the retro converters and 21 perhaps he was using the term in the same way
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1 ones. 2 MS. NEWBURY: 3 Q. Okay, and is that because the two is not zero? 4 MR. GULLIVER: 5 A. I don't know. 6 MS. NEWBURY: 7 Q. Okay. 8 MR. GULLIVER: 9 A. You know, two percent. 10 MS. NEWBURY: 11 Q. Okay. So zero ER and 50 to 60 PR converting 12 to zero, zero? 13 MR. GULLIVER: 14 A. I would have to say it's a false positive. 15 MS. NEWBURY: 16 Q. False positive, okay. So perhaps there's a 17 difference in terminology between what Ms. 18 Predham is using and others are using. 19 MR. GULLIVER: 20 A. It could be, yeah. 21 MS. NEWBURY: 22 Q. Refer to retro conversion, you prefer the term 23 false positive?	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives? 11 MR. GULLIVER: 12 A. Right. 13 MS. NEWBURY: 14 Q. Do you know if Dr. Denic would be aware of the 15 number of false positives? 16 MR. GULLIVER: 17 A. I don't know. 18 MS. NEWBURY: 19 Q. And his evidence was that he had reviewed four 20 slides that were from the retro converters and 21 perhaps he was using the term in the same way 22 that you were. Were you aware of Dr. Denic 23 conducting a review of any other of these
1 ones. 2 MS. NEWBURY: 3 Q. Okay, and is that because the two is not zero? 4 MR. GULLIVER: 5 A. I don't know. 6 MS. NEWBURY: 7 Q. Okay. 8 MR. GULLIVER: 9 A. You know, two percent. 10 MS. NEWBURY: 11 Q. Okay. So zero ER and 50 to 60 PR converting 12 to zero, zero? 13 MR. GULLIVER: 14 A. I would have to say it's a false positive. 15 MS. NEWBURY: 16 Q. False positive, okay. So perhaps there's a 17 difference in terminology between what Ms. 18 Predham is using and others are using. 19 MR. GULLIVER: 20 A. It could be, yeah. 21 MS. NEWBURY: 22 Q. Refer to retro conversion, you prefer the term	1 Q. Okay. So you can't rule out whether or not 2 there is a concern, but you can't say there is 3 one? 4 MR. GULLIVER: 5 A. I can't say that there is one or I can't say 6 there is not one. 7 MS. NEWBURY: 8 Q. And that's primarily because you haven't 9 actually seen the full list of false 10 positives? 11 MR. GULLIVER: 12 A. Right. 13 MS. NEWBURY: 14 Q. Do you know if Dr. Denic would be aware of the 15 number of false positives? 16 MR. GULLIVER: 17 A. I don't know. 18 MS. NEWBURY: 19 Q. And his evidence was that he had reviewed four 20 slides that were from the retro converters and 21 perhaps he was using the term in the same way 22 that you were. Were you aware of Dr. Denic

	Page 149		Page 151
1	MR. GULLIVER:	1	MR. GULLIVER:
2	A. No, I'm not.	2	A. Yes.
3	MS. NEWBURY:	3	MS. NEWBURY:
4	Q. Okay. If Dr. Laing was not actually aware of	4	Q. Okay.
5	the frequency of the false positives here, and	5	MR. GULLIVER:
6	if she were focusing, for example, on retro	6	A. And to date, as far as I know, again I'll tell
7	conversions or false positives that had an	7	you that to verify that, you know, those
8	impact upon patient treatment, for example, of	8	numbers have been very, very small.
9	patients who were living as opposed to any	9	MS. NEWBURY:
10	deceased patients, would it be of concern to	10	Q. Right, but you don't know though how many
11	you that you're relying upon oncologists to	11	numbers of false positives there are in total
12	say "oh, there's no concern with the positive	12	and how many of them have been reviewed by the
13	test results"? That perhaps she didn't have a	13	oncologists? I mean, Dr. Laing, I've showed
14	full picture of what was going on in the lab?	14	you -
15	MR. GULLIVER:	15	MR. GULLIVER:
16		16	A. I don't know the full total number, no.
17	picture is or isn't.	17	MS. NEWBURY:
18	MS. NEWBURY:	18	Q. Right, and I've showed you a number of bits of
19		19	data that Dr. Laing wasn't familiar with. She
20	understanding was?	20	was familiar with two lists of retro
21	MR. GULLIVER:	21	converters and she had some recollection of
22	A. No.	22	having some of those panelled, but she wasn't
23	MS. NEWBURY:	23	able to explain a number of these other
24		24	entries from Exhibit P-0720.
25	don't know what information Dr. Laing had?	25	MR. GULLIVER:
	Page 150		Page 152
1	You're relying upon her to say whether there	1	A. And I can't explain them either.
2	is or is not a concern, but you don't know	2	MS. NEWBURY:
3	what -	3	Q. Mr. Gulliver, in your e-mail to Reza on July
4	MR. GULLIVER:	4	24th, 2007, in which you summarize the
5	3 3 2 1	5	guidelines and the process used to select
6	MS. NEWBURY:	6	patients for retesting, you stated at the end
7		7	of the documentI could bring this up for
8	MR. GULLIVER:	8	your information, P-2129 please? Okay, this
9	, , , , , , , , , , , , , , , , , , ,	9	is the document. I think you were shown this
10	, ,	10	yesterday. It's July 24th, 2007, and I wanted
11		11	to refer you to the end of the document here,
12	· · · · · · · · · · · · · · · · · · ·	12	item ten, and then the last paragraph. It
13		13	states that "once results started to come
14		14	back, they were reviewed by our pathologists
15	1	15	and then the new results from Mount Sinai were
1	MS. NEWBURY:	16	added to the patient's original report in our
17	Q. Right, but when they did come across false	17	LIS Meditech system, and a new report
18	1	18	generated with both the original and new
19	•	19	results. Barry and I had very little
20	•	20	involvement after results came back. The
21	•	21	pathologists, oncologists, QI department,
22		22 23	communications department, handles this phase of the process."
23		23	Mr. Gulliver, was that division of duties
24		24 25	
25	were to occur:	23	and I guess your lack of involvement after the

- results came back, was that something that 1
- 2 was, you know, by design? Was there a meeting
- to discuss the allocation of who does what 3
- when the results come back? 4
- 5 MR. GULLIVER:
- A. I don't think there was a--there was no
- meeting. I think it just evolved. 7
- 8 MS. NEWBURY:
- Q. Okay.
- 10 MR. GULLIVER:
- A. Again, what I'm indicating there, once the 11
- 12 results came back and were verified, the
- laboratory's responsibility, particularly mine 13
- and Mr. Dyer's and the staff, was to ensure 14
- that the new results were put into the 15
- 16 computer system so it's documented and
- recorded. The last piece here for Reza is 17
- talking about then the implications of those 18
- 19 new results. That was dealt with by those
- people, either the oncologists in speaking to 20
- patients or assessing treatment or the QI 21
- 22 department, communications in the patient
- disclosure, contacting patients and that whole 23
- 24 piece of it.
- 25 MS. NEWBURY:

- Page 154
- Q. And so in terms of the mechanics of you, of 1
- entering the results into the LIS Meditech 2
- 3 system, who did that? Who sat down at the
- 4 system and -
- 5 MR. GULLIVER:
- A. Most often, early on, mostly it was Dr. Cook's 6
- 7 secretary.
- 8 MS. NEWBURY:
- Q. Okay.
- 10 MR. GULLIVER:
- 11 A. Who would input information. I know Mr. Dyer
- 12 did some. I know Mary Butler, the senior
- tech, that was part of her role to ensure that 13
- 14 new results would go into the computer system,
- 15 that a new number was created to document
- receiving back from Mount Sinai and that 16
- 17 reports were printed off by the secretary and
- then, you know, distributed. 18
- 19 MS. NEWBURY:
- 20 Q. So there's a combination of people involved
- 21 with that?
- 22 MR. GULLIVER:
- 23 A. A combination, yes.
- 24 MS. NEWBURY:
- 25 Q. Was there any thought given to asking that

- Page 153
- person to also, aside from entering it into

Page 155

Page 156

- 2 the Meditech system, adding it to the tables
- that you and Mr. Dyer had? 3
- 4 MR. GULLIVER:
- A. No. 5
- 6 MS. NEWBURY:
- Q. And why not?
- 8 MR. GULLIVER:
- A. Well, what would enter in the table would be
- 10 the actual results.
- 11 MS. NEWBURY:
- Q. Yes. 12
- 13 MR. GULLIVER:
- 14 A. New results.
- 15 MS. NEWBURY:
- Q. Yes. 16
- 17 MR. GULLIVER:
- 18 A. Dr. Cook was doing that piece of it. He was
- 19 adding the results to -
- 20 MS. NEWBURY:
- 21 Q. To the Meditech?
- 22 MR. GULLIVER:

- A. No, he was adding results to the spreadsheets, 23
 - so he would know here are the results of the
- 25 patients and he was tracking that there in
- - conjunction with Heather Predham. 1
 - 2 MS. NEWBURY:
 - Q. Okay, and was that side by side with the 3
 - original results? 4
 - 5 MR. GULLIVER:
 - A. In most cases, as far as I know, yes. 6
 - 7 MS. NEWBURY:
 - Q. Okay, and have you seen those results?
 - 9 MR. GULLIVER:
 - A. I have not seen a full list of them, no.
 - 11 MS. NEWBURY:
 - Q. Okay, and is there any reason why you haven't? 12
 - 13 MR. GULLIVER:
 - 14 A. Nothing in particular.
 - 15 MS. NEWBURY:
 - O. Okay, and -
 - 17 MR. GULLIVER:
 - A. That's been--was handled by the clinical side.
 - 19 MS. NEWBURY:
 - 20 Q. And what format was Dr. Cook using for those
 - 21 tables?
 - 22 MR. GULLIVER:
 - A. The spreadsheets which I've shown that I've 23
 - 24 created.
 - 25 MS. NEWBURY:

Multi-Page TM October 15, 2008 **Inquiry on Hormone Receptor Testing** Page 157 Page 159 Q. Okay, that you provided to him. 1 MS. NEWBURY: 2 MR. GULLIVER: Q. And you never thought to ask Dr. Cook to have access to at least the incomplete documents A. They were copied and he had a copy of those, 3 3 and there was a place on those spreadsheets that he had, just for some--to see if you can 4 4 left for the results from Mount Sinai to be glean anything from that, for your 5 5 entered in there. perspective? 6 7 MS. NEWBURY: 7 MR. GULLIVER: 8 Q. Okay, and it's your understanding that those A. No. were all completed, were they? 9 MS. NEWBURY: 10 MR. GULLIVER: Q. Now Mr. Gulliver, as a program director for 10 A. To the best of my knowledge. the laboratory medicine program, was there an 11 11 opportunity for you to have input into 12 MS. NEWBURY: 12 Q. Okay, and so earlier today, I was trying to decisions by Eastern Health about the 13 find out if there had been a comparison done retesting plan for the ER and PR issues, 14 14 of the original and the Mount Sinai test particularly as they might relate to the 15 15 16 results, and you thought it would be 16 laboratory medicine program? interesting to do, to have some information to 17 MR. GULLIVER: 17 look for trends perhaps in the years or the 18 A. I would say yes. 19 pathologists. 19 MS. NEWBURY: Q. Okay. Were there ever any limits placed upon 20 MR. GULLIVER: 20 your participation or your input? 21 A. But those spreadsheets doesn't have complete 21 22 information. 22 MR. GULLIVER: 23 A. I don't think I've seen a list of things that 23 MS. NEWBURY: I can't do. I think we all accepted here's Q. No, what does it have? 24 25 MR. GULLIVER: the piece of it that, you know, that I can 25 Page 158 Page 160 A. Again, you've seen them. It has the basis help with or that I can do. 1 1 patient demographic. It has the original 2 MS. NEWBURY: 2 result and that's all I had. Q. And so no one ever said, well, this is going 3 3 to be your role and only your role and don't 4 MS. NEWBURY: 4 Q. Okay. So it's not broken down by year? stray from that? You could have, if you 5 6 MR. GULLIVER: wanted to, for example, suggest looking at PR 6 A. No. 7 retro conversions or doing an analysis of the 8 MS. NEWBURY: results to compare, you know, what happened by 8 Q. And you had some other sheets broken down by pathologists or breaking down by pathologists 9 year and by region. or regions? 10 10 11 MR. GULLIVER: 11 MR. GULLIVER: A. No, no, the spreadsheets are broken down by A. But I think we're only at that point now that 12 12 we can do that. 13 13 year. 14 MS. NEWBURY: 14 MS. NEWBURY: Q. Okay, and is that something that you'd ever 15 Q. Okay. 15 suggested before? 16 MR. GULLIVER: 16 17 A. But then on those spreadsheets, there is not 17 MR. GULLIVER: documentation, complete documentation of what 18 A. Again, as I said to you earlier, that before 18

block was originally tested, what block was 19 NLCHI got involved, those are some of the 19 retested. You know, so it's not a complete-basic things that we did talk about and some 20 20 it's not complete enough to do a full set of of the things that we could look back and 21 21 22 data analysis of them. I think we're at that review, and you know, who would we get to do 22 point now with, you know, NLCHI being this kind of analysis and kind of review and 23 23 involved, that those are the kinds of things before, I think, there was any kind of 24 24 decision made, you know, NLCHI then got that we can now perform. 25 25

involved and we all felt that once that 1

- 2 exercise was completed, that Eastern Health
- would now be in a position to do some data 3
- analysis. 4
- 5 MS. NEWBURY:
- Q. Okay, and is it your understanding that 6
- Eastern Health would intend to look at the 7
- 8 retro conversions, whether they're PR retro
- conversions or retro conversions for deceased 9
- 10 patients?
- 11 MR. GULLIVER:
- A. I just think that they would look at retro 12
- conversions. 13
- 14 MS. NEWBURY:
- Q. But retro conversions by Ms. Predham's 15
- 16 definition or retro conversions or false
- positives? 17
- 18 MR. GULLIVER:
- 19 A. I don't know. I think that we would have to
- do both. In my opinion -20
- 21 MS. NEWBURY:
- 22 Q. That's your opinion.
- 23 MR. GULLIVER:
- A. I think if the retro converters are being 24
- classified as that because they had a 25
 - Page 162
- treatment change, that that's one piece, and I 1
- 2 think I would be more interested in looking at
- a false positive rate. 3
- 4 MS. NEWBURY:
- Q. Have you ever expressed that opinion to anyone 5
- before, within Eastern Health? 6
- 7 MR. GULLIVER:
- A. I would say yes, yeah.
- 9 MS. NEWBURY:
- Q. And do you know who and when?
- 11 MR. GULLIVER:
- A. I don't know when. I think some of these 12
- 13 things are, you know, we discuss on a regular
- basis. On a weekly basis, we have, you know, 14
- what we call our ER/PR meeting. Those kinds 15
- of things would come up. 16
- 17 MS. NEWBURY:

25

- Q. Okay. Just a couple of documents I wanted to 18 ask you to explain, if you can. P-3107,
- 19
- please? Okay, this is a document sent by you 20
- to Ms. Predham, January 28th, 2008, so earlier 21
- 22 this year, and it attaches some ER/PR
- statistics, and in the top two headings there, 23
- you've got a heading for DAKO and a heading 24
 - for Ventana. So would it be correct to assume

that the information in this table here would

Page 163

- 2 be the rates prior to any retesting at Mount
- Sinai? 3
- 4 MR. GULLIVER:
- A. Oh yes. 5
- 6 MS. NEWBURY:
- Q. Okay, these haven't been readjusted?
- 8 MR. GULLIVER:
- A. No.
- 10 MS. NEWBURY:
- Q. Okay. 11
- 12 MR. GULLIVER:
- A. This is an exercise that confirmed with Reza
- through NLCHI in all parts of this whole ER/PR 14
- testing to kind of finalize those numbers. 15
- 16 MS. NEWBURY:
- Q. Okay, and has tried to make sure that the data 17
- is accurate essentially? 18
- 19 MR. GULLIVER:
- A. Yeah. 20
- 21 MS. NEWBURY:
- 22 Q. Okay, and does this include only the non--does
- this include any non-breast primaries? 23
- - A. I can't say 100 percent, but it's pretty well
 - Page 164 part of our exercise was to make sure we
 - removed any of those non-breast primaries.
- 3 MS. NEWBURY:

1

- Q. Okay. So the intention was not to include non-
- 5 breast primaries in this table?
- 6 MR. GULLIVER:
- A. Exactly, yeah.
- 8 MS. NEWBURY:
- Q. And in this table, there's references to
- positive negative rates and got several 10
- 11 categories here on the left-hand side, the
- left-hand column. When you're talking about 12
- positive here, are you referring to ER only? 13
- So would that include ER positive, PR 14
- positive, ER negative, PR--or ER positive, PR 15
- negative? 16
- 17 MR. GULLIVER:
- A. If it--say it again.
- 19 MS. NEWBURY:
- Q. Let's put it this way, if you had an ER 20
- negative, PR positive test -21
- 22 MR. GULLIVER:
- A. I would call that a weak positive. 23
- 24 MS. NEWBURY:
- 25 Q. That would be called a weak positive.

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Pa	ge 165	Page 167
1 MR. GULLIVER:	1	Q. And looking at the results there for 2004, you
2 A. In that category, yes.	2	have a positivity rate of 89 percent and then
3 MS. NEWBURY:	3	that's for the DAKO machine, so -
4 Q. So that would all be -	4	MR. GULLIVER:
5 MR. GULLIVER:	5	A. Again, but that's justthat's for three
6 A. The ones where you see strong positive, all	1 6	months.
7 those would be a positive result for both ER	7	MS. NEWBURY:
8 and PR. The weak positives may have had, y	you 8	Q. Right.
9 know, a low positive for ER and it could be	9	MR. GULLIVER:
five percent ER, 90 percent PR. I would call	10	A. January, February, March.
that a weak positive.	11	MS. NEWBURY:
12 MS. NEWBURY:	12	Q. So it's a small sample size.
Q. Say you had, and I'll refer to a couple of the	13	MR. GULLIVER:
examples that I showed you earlier, a negati	ive 14	A. Very small sample size.
ER and a 40-50 PR or a negative ER and a 60-		MS. NEWBURY:
16 PR?	16	Q. And then you have the Ventana, you have 86 for
17 MR. GULLIVER:	17	all three or for two of those periods of time.
18 A. That would be weak positive.	18	So April 4th to March 5th, 2005.
19 MS. NEWBURY:	19	MR. GULLIVER:
Q. Okay. So even if the PR is quite high, if the	20	A. That's for like a year and three or four
21 ER is negative, you call it a weak -	21	months under Ventana.
22 MR. GULLIVER:	22	MS. NEWBURY:
23 A. Right.	23	Q. Okay. So it's 86 percent for those two years?
24 MS. NEWBURY:	24	MR. GULLIVER:
25 Q. Okay, thank you.	25	A. And again, it's still notstill, I mean,
Pa	ge 166	Page 168
1 MR. GULLIVER:	1	that's one of the things too that we had
2 A. Again, and this is just for an overview and	2	talked about with doing all this exercise is
assessment from a lab perspective that, you		that, you know, when you have such a small
4 know, what percentage of cases had some do		sample size, you know, five or six or seven or
5 of positivity reported on them.	5	eight patients one way or the other, it could
6 MS. NEWBURY:	6	make a big difference in your percentages.
7 Q. Okay, and when you talk generally about yo	our 7	MS. NEWBURY:
8 positivity rates, you've mentioned that you		Q. Sure. Do you have any idea how many would be
9 were interested in finding out what the	9	in say that period, April '04 to March '05?
positivity rates are for year to year, so that	10	MR. GULLIVER:
positivity rate would include ER negatives, P	PR 11	A. April, it tells you right here.
positives?		MS. NEWBURY:
13 MR. GULLIVER:	13	Q. It's 119 atokay, 119. So you consider that
14 A. Yes.	14	too small -
15 MS. NEWBURY:	15	MR. GULLIVER:
16 Q. Because you had categorized them as we		A. There's 139 with results. So the percentages
positives?	17	you see below are based upon the ones we have
18 MR. GULLIVER:	18	documented results that we know we can
19 A. Right.	19	categorize them as positive or negative, weak
20 MS. NEWBURY:	20	positive. So the sample size there was 139.
21 Q. Okay. Have you ever prepared a similar tab		MS. NEWBURY:
that has the adjusted positivity rates?	22	Q. Oh yes, I see, it's a third.
23 MR GILLIVER:		MP CHILIVED

A. The total Ventana is 198.

23 MR. GULLIVER:

25 MS. NEWBURY:

23 MR. GULLIVER:

A. No.

25 MS. NEWBURY:

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o. Okav.

2 MR. GULLIVER:

- A. So when you see a positivity rate of 3 percent on 198, again, you change five or six 4
- patients and it could drop down to 80 percent. 5
- 6 MS. NEWBURY:
- Q. Now 189 is a bit of a larger sample size 7
- 8 though than some of the others, like the 42
- for 2004 on DAKO is pretty small.
- 10 MR. GULLIVER:
- A. And that's for the first three--the last three 11
- months of DAKO. 12
- 13 MS. NEWBURY:
- Q. Until the Ventana was put in. 14
- 15 MR. GULLIVER:
- A. First three months of the year, yes. But even 16
- if you see anything in any kind of like 17
- surveys, you know, really a sample size less 18
- than 400 is something that really could have a 19
- significant plus or minus. 20
- 21 MS. NEWBURY:
- 22 Q. So looking here though at the total test
- performed for each of those years, they're all 23
- less than 400. 24

staining and 23 percent that were reported

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- 2 with negative staining.
- 3 MS. NEWBURY:
 - Q. But do you think there's any value in looking
- at this year by year? I guess the question is 5
- if you found a particularly high or a 6
 - particularly low rate for positivity in any
- given year, you had a small sample size in any 8
- given year -9
- 10 MR. GULLIVER:
- A. Well, I can--I mentioned this the other day. 11
- If you look at this table and the two years 12
- that really would look at--well, accepting it 13
- at face value, the two years that you would 14
- look in here would be 2000 and 2002. 15
- 16 MS. NEWBURY:
- Q. And that's because there are 68 and 70 -17
- 18 MR. GULLIVER:
- 19 A. And you look at there, that's the highest
- years that we have the highest percentage of 20
- negatives, of zero, zeros. 21
- 22 MS. NEWBURY:
- Q. Right, but do you still see value in looking 23
 - at that on a year-by-year basis,
- notwithstanding your small sample size? 25

Page 170

1 MR. GULLIVER:

24

5

- A. I think so, yes.
- 3 MS. NEWBURY:
 - Q. Okay, and looking at the Ventana results, and
 - even the result for 2004, even though it's a
- small sample size, would that have to be 6
- 7 adjusted to take into account your Mount Sinai
- 8 retest results?
- 9 MR. GULLIVER:
- A. Well, there's no retest results added in here.
- 11 MS. NEWBURY:
- Q. No, I know, but if you were to look at--now to 12
- look back on what was your real positivity 13
- rate, would you not have to adjust it to take 14
- into account what happened at Mount Sinai? 15
- 16 MR. GULLIVER:
- 17 A. That has not been done.
- 18 MS. NEWBURY:
- Q. Okay.
- 20 MR. GULLIVER:

22

- 21 A. But however, I mean, if you're asking so for
 - example, if you're talking about the first
- three months of 2004? 23
- 24 MS. NEWBURY:
- 25 Q. Yes, just looking at the Ventana years, for

1 MR. GULLIVER:

- A. With results.
- 3 MS. NEWBURY:
- Q. With results. So are you saying that there's
- no information -5
- 6 MR. GULLIVER:
- A. With results, I mean, I don't know the numbers 7
- of positives and weak positive negatives that 8
- were interpreted outside St. John's. These 9
- are strictly for St. John's numbers. 10
- 11 MS. NEWBURY:
- Q. Right, so the only information you have is 12
- about what happened in St. John's? 13
- 14 MR. GULLIVER:
- A. Right. 15
- 16 MS. NEWBURY:
- 17 Q. But are you concerned though that they're all under 400, in terms of sample size?
- 18
- 19 MR. GULLIVER:
- A. Well I think then that's why on the bottom you 20
- do sort of a total test with results that you 21
- look at, you know, the whole big picture. 22
- There are 1,529 St. John's patients with 23
- results documented and of that total, there 24 were 77 percent reported with positive 25

Multi-Page TM October 15, 2008 **Inquiry on Hormone Receptor Testing** Page 173 Page 175 example, you've got--that's a fairly large 1 1 MR. GULLIVER: 2 sample size. A. Right, to my knowledge, from what I've seen -3 MR. GULLIVER: 3 MS. NEWBURY: A. Okay, and again, I mean, for the years under Q. - there was not one single conversion? Ventana, you know, and the ones that were 5 5 MR. GULLIVER: retested were all the negatives, as you're A. - we haven't seen one conversion from the 6 well aware. 7 Ventana. 7 8 MS. NEWBURY: 8 MS. NEWBURY: Q. Right. Q. Okay. So you wouldn't then have to adjust 10 MR. GULLIVER: 10 your positivity rate then? A. So here, for the total for Ventana, during 11 11 MR. GULLIVER: that time frame, there are 28 samples that 12 A. No. 12 were tested as negative, negative and I don't 13 13 MS. NEWBURY: think any of them were converted. Q. There's no data that would suggest that? 14 14 15 MS. NEWBURY: 15 MR. GULLIVER: Q. But the information here would be with regard A. No. 16 to all of the results that were done for that 17 MS. NEWBURY: 17 18 particular year? Q. Okay, and -19 MR. GULLIVER: 19 MR. GULLIVER: A. For the year. So for Ventana, the statistic A. And if it went back to '97, you know, the 20 20 wouldn't change because there are--we didn't numbers of negatives that were retested that 21 21 22 have any confirmed conversions of a negative, 22 converted to--you know, came back as a negative Ventana and restained positive at positive, again, it was a very low number, so 23 23 it wouldn't--the positivity rate may go up Mount Sinai. 24 24 three or four percent in '97. 25 MS. NEWBURY: 25 Page 176 Page 174 Q. There were no conversions? 1 MS. NEWBURY:

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2 MR. GULLIVER:
   A. No.
4 MS. NEWBURY:
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- Q. Okay, and is that the same for 2005? 6 MR. GULLIVER:
- A. Well, the Ventana is all 2005, for all of 7
- Ventana. 8
- 9 MS. NEWBURY:
- Q. You've got two different periods of time here, 10 11 sorry.
- 12 MR. GULLIVER:
- A. From April '04, because see, when I first did 13 this here, it was the fiscal year up to April 14
- '04 to March '05 when we stopped--stopped 15
- DAKO, I did a full year of Ventana, get a full 16
- year statistics. Then I added on April, March 17
- (sic), June, July when we stopped testing. 18
- 19 MS. NEWBURY:
- 20 Q. Okay.
- 21 MR. GULLIVER:
- A. But for the Ventana period -
- 23 MS. NEWBURY:
- Q. The entire period, from April 2004 to July 24
- 31st 2005, there was not -25

- Q. One more document, just if you can briefly
- explain what it is, P-3215, please? I'm not 3
- sure if you're familiar with this particular 4
- document. You're not a recipient here of the 5
- document. It was sent from Deborah Gregory to 6
- Paula Dillon and copied to Pat Pilgrim, is one 7
- of the people, what she received. And this is 8
- a draft document for internal review purposes 9
- only, and I believe this was prepared by 10
- 11 NLCHI, and given that you were having some
- interaction with NLCHI in terms of getting the 12
- data together, would you be able to comment on 13
- what this particular table is about? Is this 14
- something that you're familiar with? 15
- 16 MR. GULLIVER:
- 17 A. Well, I mean, again, I mean I can't give you--
- I think NLCHI people are going to come and 18
 - testify.
- 20 MS. NEWBURY:

19

- 21 Q. Okay, so you don't have any--you can't speak
 - to this at all?
- 23 MR. GULLIVER:
- 24 A. Well, I mean, because this is just one table.
- 25 There's multiple tables.

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1 MS. NEWBURY:		frozen - frozen tissue, and creating an
2 Q. Sure, okay.	2	emulsion out of it and using equipment, I
3 MR. GULLIVER:	3	won't try to describe because I don't
4 A. And again, when you go through them, they're	4	understand, to get a count on the presence of
5 doing analysis based upon if something was one	5	positive staining in this emulsion, is that
6 percent staining positive, if that was	6	roughly true as well?
7 considered a positive, or ten percent or		MR. GULLIVER:
8 higher or 30 percent or higher.	8	A. I think, or the amount of estrogen in the
9 MS. NEWBURY:	9	emulsion.
10 Q. Okay. Thank you, Mr. Gulliver. Those are all		CROSBIE, Q.C.:
11 the questions.	11	Q. Uh-hm.
12 MR. GULLIVER:		MR. GULLIVER:
13 A. You're welcome.	13	A. It's not a staining then, it's a measurement.
14 THE COMMISSIONER:		CROSBIE, Q.C.:
15 Q. Mr. Crosbie.	15	Q. Okay. Now again this was conducted in - this
16 MR. TERRY GULLIVER, EXAMINATION BY CHESLEY CROSBIE		was a biochemical procedure and it wasn't done
17 CROSBIE, Q.C.:	17	in histology?
18 Q. One moment, Commissioner, figure out a way to		MR. GULLIVER:
re-rig so that I can see my notes better. It	19	A. Correct.
20 may work for Ms. Chaytor very well, but not		CROSBIE, Q.C.:
21 for me.	20 21	Q. It was done in biochemistry, whereas in
22 THE COMMISSIONER:	22	histology there was at that time, 1997, and
23 Q. I learned long ago not to comment on Ms.	23	had been for a number of years going back to
	23	the 80s, I believe, tumours were being
24 Chaytor's size, Mr. Coffey. It's a very dangerous thing to do.	25	assessed or tested for staining purposes, and
dangerous uning to do.		
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1 CROSBIE, Q.C.:	1	the results of that were being used by
2 Q. Well, it seems to work for Mr. Coffey as	s well, 2	pathologists to refine their diagnoses, and
3 but not for me.	3	these tumours might be lung, they might be
4 THE COMMISSIONER:	4	brain, they might be other things. That's
5 Q. Okay.	5	roughly correct again?
6 CROSBIE, Q.C.:		MR. GULLIVER:
7 Q. Thanks, Mr. Gulliver. We've met before		A. For the IHC testing at that time?
8 as you know, I'm the class counsel for n	I	CROSBIE, Q.C.:
9 of the Breast Cancer Testing Class Action		Q. IHC testing was done -
we have standing here. I'd like to take	e a 10	MR. GULLIVER:
step back, a step back to 1997, and just l	look 11	A. Yes.
at the overall setting at that time when t	the 12	CROSBIE, Q.C.:
decision was being taken to establish E	ER/PR 13	Q. In histology for a number of years.
testing in a different section of the lab th	nan 14	MR. GULLIVER:
it had been done before, and what I	I'm 15	A. Yes.
referring to there, I guess, is the fact that	t 16	CROSBIE, Q.C.:
there was a technique called enzyme in	mmuno 17	Q. This again being in 1997. So that if we
assay or EIA which was conducted in	the 18	contrast it to the - as I understand it now,
19 biochemistry section of the lab for th	ne 19	the pathologists had nothing to do with the
20 detection of positive ER and PR status	in 20	enzyme immuno assay testing performed over in
cancer patients. Am I correct so far?	21	the chemistry section, they weren't involved
22 MR. GULLIVER:	22	in signing out reports or interpreting the
23 A. Yes, that's correct.	23	results of that testing at all, is that
24 CROSBIE, Q.C.:	24	correct?
25 O And this tachnique involved taking for	maah as	MD CHILINED

25 MR. GULLIVER:

Q. And this technique involved taking fresh

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1 A. They didn't interpret the result, but	ıt again, I	being used for - it wasn't being relied on by
2 mean, that patient who would have	e had a sample 2	oncologists for therapeutic purposes.
of a tumour submitted to biocher	nistry, then 3 MR.	GULLIVER:
4 would have had their primary br	east surgery 4 A.	You mean, IHC overall, or ER/PR testing, in
5 done and the pathologist would ha		particular?
6 the patient's tissue after the biod	chemical 6 CRO	SBIE, Q.C.:
7 assay was performed, but they		No, we're talking about a time before ER/PR.
8 involved in interpreting the as	say in 8 MR.	GULLIVER:
9 biochemistry.	9 A.	Okay, so before ER/PR -
10 CROSBIE, Q.C.:		SBIE, Q.C.:
11 Q. Right, but they did do, of course,	their usual 11 Q.	Yes.
histological diagnosis?		GULLIVER:
13 MR. GULLIVER:	13 A.	The pathologist would order based upon their
14 A. Yes.	14	type of case, type of tumour, type of tissue,
15 CROSBIE, Q.C.:	15	they would request the technologists to
16 Q. However, in terms of the assay, t	-	perform a certain number of IHC antibodies
involved in the interpretation of re	eporting of 17	and, you know, they were using that strictly
that?	18	in their own aid in interpretation of the
19 MR. GULLIVER:	19	patient case.
20 A. Not to my knowledge, no.	<u> </u>	SBIE, Q.C.:
21 CROSBIE, Q.C.:	21 Q.	That's what I understand.
22 Q. Yeah, they had nothing to do with	-	GULLIVER:
That was done for the benefit, we	•	Yes.
patient, but for the oncologist	who is 24 CRO	SBIE, Q.C.:
25 managing the case and treating?	25 Q.	However it was not being relied on for
	Page 182	Page 184
1 MR. GULLIVER:	1	therapeutic purposes by the oncologist?
2 A. To the best of my knowledge.		GULLIVER:
3 CROSBIE, Q.C.:	3 A.	To the best of my knowledge, also that's
4 Q. The assay was done -	4	correct.
5 MR. GULLIVER:		SBIE, Q.C.:
6 A. Yes.	6 Q.	Which, of course, is something dramatically
7 CROSBIE, Q.C.:	7	different about ER/PR testing?
8 Q. That was for the oncologist?	8 MR.	GULLIVER:
9 MR. GULLIVER:	9 A.	Yes.
10 A. Yeah.	10 CRO	SBIE, Q.C.:
11 CROSBIE, Q.C.:	11 Q.	So just to get that picture, up until '97 when
12 Q. Whereas tumour antigens in II-	IC done in 12	ER/PR was commenced as a test or as a stain
histology at this time were done	for the 13	done in histology, what histology was doing
pathologist?	14	with stains was being done for the diagnosis
15 MR. GULLIVER:	15	or diagnostic purposes of the pathologist, not
16 A. Well, the pathologists interprete	d it, but	for the therapeutic purposes of the
still being performed for the final	benefit of 17	oncologist?
the oncologist.	18 MR.	GULLIVER:
19 CROSBIE, Q.C.:	19 A.	To the best of my knowledge, yes.
20 Q. Well, my information is that it w		SBIE, Q.C.:
21 the pathologist for diagnostic pu	rposes to 21 Q.	That's what I understand. So that when ER/PR
loo	. 1 .	1 7770 1

23

24

25

testing was moved over as an IHC procedure to

histology, that's something that made that

task unique, the fact that it was being done not just for diagnosis but also for therapy?

assist them in refining their diagnosis, but

that the IHC testing being done in 1997 in

histology was not - was not basically being

used for treatment of patients, it wasn't

22

23

24

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1 MR. GULLIVER:	1 Q. And you also testified that you had the utmos	t
2 A. Correct.	2 confidence in both of those techs?	
3 CROSBIE, Q.C.:	3 MR. GULLIVER:	
4 Q. And, of course, if you got the test wrong,	4 A. I thought they were both two good very	
5 then the risk was the patient could be	5 technologists.	
6 deprived or hormone therapy?	6 CROSBIE, Q.C.:	
7 MR. GULLIVER:	7 Q. Can you explain, sir, what were your	
8 A. It all depends on what your definition is of	8 responsibilities as the supervisor of	
getting the test wrong. You mean if the test	9 anatomical pathology in relation to IHC	
was performed incorrectly or do you mean it		
11 was not interpreted correctly or -	11 MR. GULLIVER:	
12 CROSBIE, Q.C.:	12 A. Overall for IHC testing? I guess, my primary	
Q. If it yielded an incorrect result for whatever	role was to ensure that obviously we had the	
reason, it could have therapeutic	financial resources to maintain that section	
implications?	of our pathology laboratory. You know, if	
16 MR. GULLIVER:	there were new antibodies that were being	
17 A. Yes.	added to the list of antibodies, to ensure	
18 CROSBIE, Q.C.:	that those things got - that we had the money	
19 Q. One of which is that a patient might not get	for those. I was also responsible, I guess,	
20 hormone therapy?	responsible for the staff who were performing	ŗ
21 MR. GULLIVER:	21 the testing, responsible for the	
22 A. Yes.	22 administrative functions for the lab, you	
23 CROSBIE, Q.C.:	know, general - what you would expect the	
Q. So in 1997 we have, I think, Dr. Haegert was	supervisor to be responsible for.	
25 the clinical chief; Dr. Khalifa was the site	25 CROSBIE, Q.C.:	
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chief; Vern Whelan was the program director		, 100
2 am I right?	quality of the output of the lab?	
3 MR. GULLIVER:	3 MR. GULLIVER:	
4 A. Uh-hm.	4 A. I really can't agree with that statement.	
5 CROSBIE, Q.C.:	5 CROSBIE, Q.C.:	
6 Q. And you, sir, was the supervisor or manager of		
7 histology, the histology lab, with its - can	7 MR. GULLIVER:	
8 we call it a subsection, IHC section?	8 A. Because I think the way, you know, laborator	V
9 MR. GULLIVER:	9 medicine - the practice of laboratory	,
10 A. Yes.	medicine, in particular in pathology, it	
11 CROSBIE, Q.C.:	really is a - it's a combined effort between	
12 Q. Okay, and you explained earlier in your	the technical side and clinical side. I think	
testimony that at this time in 1997, you'd	that the overall quality for the laboratory	
been off the bench in histology for about ten	would be a joint responsibility for	
years or more even, is that right?	administrative side and the clinical side,	
16 MR. GULLIVER:	however, the assessment of the quality is	
17 A. Yeah.	really - was the primary function of the	
18 CROSBIE, Q.C.:	pathologists, and, you know, the technologists	S
19 Q. And you had to rely on Mary Butler and Peg	y 19 relied upon that feedback from the	
20 Welsh to perform procedures, including the II	C 20 pathologists to assess the outcome or output	
procedures, in an adequate fashion?	from all the slides. Whether it was an H & E	
22 MR. GULLIVER:	slide or an IHC slide, they still relied upon	
23 A. And they had been doing them for a number	of 23 the pathologist's feedback.	
years by this time.	24 CROSBIE, Q.C.:	
25 CROSBIE, Q.C.:	25 Q. The clinical side would have to rely on the	

	1 7 1 1 1 1 1 1 1 1 1 1
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1 manager of the lab to ensure that the	1 Q. Registrar, could we bring up Document P-1889,
2 technical things that were required to be done	2 please. My up and down control doesn't seem
in order to get a quality output were done and	to be working here. We'll probably see the
4 were done right, though?	4 full letter on the screen. Thank you. So this
5 MR. GULLIVER:	5 was sent - it appears sent to you in March,
6 A. That's correct.	6 1997, but you've told us - or February. I
7 CROSBIE, Q.C.:	7 think there was a March date on it as well.
8 Q. And what you're explaining is that there had	8 Yes, March 12th. In any event, that's the
9 to be an interaction between the clinical side	9 time period, and I think you've explained to
and the technical side to ensure that that	the Commissioner that as far as you can
objective of good quality product was	ascertain you did not receive this?
continuously being met?	12 MR. GULLIVER:
13 MR. GULLIVER:	13 A. I couldn't say that I could or I could not.
14 A. Yes.	When I was shown this, you know, in
15 CROSBIE, Q.C.:	preparation for the Commission of Inquiry, you
16 Q. And you're saying that it was a shared	know, my opinion was I was reading it for the
responsibility?	first time, but I really can't say that I did
18 MR. GULLIVER:	not get that ten years ago or did I get it ten
19 A. I mean, certainly - I mean, ti can't be all	19 years ago.
left to the clinical side nor the	20 CROSBIE, Q.C.:
21 administrative side, I mean, it has to be a	Q. You don't have a recollection of it, though?
shared dual responsibility.	22 MR. GULLIVER:
23 CROSBIE, Q.C.:	23 A. No.
24 Q. And, I guess, we could say that as director of	24 CROSBIE, Q.C.:
25 the - manager of the histology lab, you would	25 Q. And I think it's not in your own personal file
Page 190	Page 192
Page 190 1 be responsible for development of new	
1 be responsible for development of new	1 011
1 be responsible for development of new	1 or the files that - 2 MR. GULLIVER:
 be responsible for development of new procedures and the deletion of old ones? MR. GULLIVER: 	or the files that - MR. GULLIVER: A. We couldn't find it, no.
 be responsible for development of new procedures and the deletion of old ones? MR. GULLIVER: A. Not necessarily, no. 	or the files that - MR. GULLIVER: A. We couldn't find it, no. CROSBIE, Q.C.:
1 be responsible for development of new 2 procedures and the deletion of old ones? 3 MR. GULLIVER: 4 A. Not necessarily, no. 5 CROSBIE, Q.C.:	1 or the files that - 2 MR. GULLIVER: 3 A. We couldn't find it, no. 4 CROSBIE, Q.C.:
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4

13

- test, its clinical consequences, and the 1
- 2 overall emotional charge in the public
- regarding this very sensitive procedure". 3
- Whether you received this or not, or recall 4
- receiving this or not, did Dr. Khalifa and you 5
- have a conversation along those lines about 6
- any concern that he harboured that you didn't 7
- 8 appreciate the delicacy of the test?
- 9 MR. GULLIVER:
- A. Again, not to my knowledge. 10
- 11 CROSBIE, Q.C.:
- 12 Q. Is that something that you think you would
- remember? 13
- 14 MR. GULLIVER:

16

2

- 15 A. And again that's what I had said when I read
 - this, that, you know, when I'm reading this
- here you know, Dr. Khalifa and I had a 17
- fantastic relationship, and I was thinking, 18
- well, you know, if Dr. Khalifa said this and 19
- sent it to me, it's something that I would 20
- have remembered, but I can't say that I did. 21
- 22 CROSBIE, Q.C.:
- 23 Q. Doesn't stand out?
- 24 MR. GULLIVER:
- 25 A. It doesn't stand out, no.
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2

- 1 CROSBIE, Q.C.:
 - Q. Do you agree or disagree with me when he says,
- "I do not think you fully appreciate the 3
- delicacy of the test". 4
- 5 MR. GULLIVER:
- A. I think I testified that I certainly think at 6
- 7 that time when this test was being implemented
- by Dr. Khalifa, and he was working with Dr. 8
- Prabhakaran in biochemistry, that my knowledge 9
- of the test at that time, certainly this would 10
- 11 be - that would be accurate.
- 12 CROSBIE, O.C.:
- Q. So you had a learning curve ahead of you? 13
- 14 MR. GULLIVER:
- A. And I think as many of our pathologists did 15
- also. I mean, this is a new test coming into 16
- it's not just a new procedure, it's a whole 17
- new test coming into the laboratory. 18
- 19 CROSBIE, Q.C.:
- Q. Can you say approximately when you became 20
- aware Dr. Khalifa was planning this, this new 21
- 22 test?
- 23 MR. GULLIVER:
- 24 A. I would - I can't tell you the exact time
- frame, Mr. Crosbie. I know there was 25

discussions between himself and, I guess, Dr.

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- 2 Haegert, and the biochemistry people, and I
- think that was going on for a few months 3
 - before we even the staff even started
- testing anything. So I would say maybe late 5
- '96, you know, like, to this time frame, '97. 6
- 7 CROSBIE, O.C.:
- 8 Q. And you and Dr. Khalifa were present in
- various committee meetings where discussion of 9
- 10 this took place during 1997/1998?
- 11 MR. GULLIVER:
- A. Well well, whether it's the implementation 12
 - or whether now it's been implemented and Dr.
- Khalifa is giving updates on it, I think. 14
- 15 CROSBIE, O.C.:
- Q. How close would you say you were to Dr. 16
- Khalifa during the process of developing the 17
- 18 test?
- 19 MR. GULLIVER:
- A. You mean, was I involved was I actively 20
- involved in developing the test? 21
- 22 CROSBIE, Q.C.:
- Q. However you wish to describe it. 23
- A. I wasn't involved at all in the actual
- Page 196 development of the test. I mean, he worked 1
 - specifically with the biochemistry people and,
 - in particular in the pathology lab, he 3
 - worked with the pathologists, but in 4
 - 5 particular he worked with Mary and Peggy, the
 - two technologists. 6
 - 7 CROSBIE, Q.C.:
 - 8 Q. Did Dr. Khalifa give you any what you describe
 - as education in the new test? 9
 - 10 MR. GULLIVER:
 - 11 A. I don't remember Dr. Khalifa sitting me down
 - and giving me a lecture. I just know in 12
 - general discussions over a period of time, you 13
 - know, that we knew this test was being used 14
 - for hormone therapy. 15
 - 16 CROSBIE, O.C.:
 - 17 Q. Something I left out of the overall picture
 - that perhaps help pull it together. We 18
 - 19 mentioned that when the ER/PR procedure or
 - test was being performed by biochemistry by 20
 - the EIA, or the enzyme immuno assay, this was 21
 - being done on frozen sections and did not 22
 - involve paraffinized blocks of tissue? 23
 - 24 MR. GULLIVER:
 - 25 A. It was done on fresh tissue, and then it was

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snap frozen, I think.	1	his assessment of reviewing the quality of the
2 CROSBIE, Q.C.:	2	slides being produced by Mary and Peggy, and,
3 Q. Yeah, so I guess a big part of the rationale	3	you know, if he decided to use this antibody
4 for moving the location within the laborator	ry 4	dilution or those kinds of variables - my role
5 structure of the ER/PR test to histochemistry	•	would have been to ensure, you know, that we
is the fact that it was now to be done on	6	have resources on hand to buy the reagents and
7 paraffinized blocks of tissue?	7	buy kits. I had discussions with - you know,
8 MR. GULLIVER:	8	at the time Vern Whelan was our program
9 A. Right, and, therefore, then you had a	9	director. We did - I mean, the most expensive
permanent block and permanent slide.	10	piece of doing this testing was do you have
11 CROSBIE, Q.C.:	11	the equipment and staff in place. It's adding
12 Q. Yeah, superior in many ways to the previous	ous 12	two new antibodies to the current list of
method of emulsifying?	13	antibodies you already perform in your
14 MR. GULLIVER:	14	laboratory, and I know I spoke to Dr. Haegert
15 A. Yes.	15	and to Vern Whelan to say that while in my
16 CROSBIE, Q.C.:	16	estimate adding these two antibodies to the
Q. But it's in histology where they dealt with	17	IHC part of the laboratory, and the additional
tissue in paraffinized blocks?	18	work involved, would probably have cost - I
19 MR. GULLIVER:	19	think it was, like, 10 or 20,000 dollars per
20 A. Yes.	20	year, and, you know, I had asked Mr. Whelan
21 CROSBIE, Q.C.:	21	then, he should transfer - if biochemistry is
22 Q. And were already doing the tumour marker	s that 22	going to stop performing the testing, you
we spoke of before. You mentioned that I		know, whatever money they had in their
24 Khalifa worked with the techs?	24	operations budget should be transferred over
25 MR. GULLIVER:	25	to the pathology budget to cover off our extra
Pa	age 198	Page 200
1 A. Yes.	1	expense for the operations side of the
2 CROSBIE, Q.C.:	2	testing. I mean, that would have been more my
3 Q. Can you describe to what extent or what th		involvement with Dr. Khalifa as opposed to
4 involved, are you able to tell us?	4	being on the bench overseeing the staff.
5 MR. GULLIVER:		SBIE, Q.C.:
6 A. I really can't tell you to the extent. I		. And the assumption you made as manager is that
7 mean, I just know that he worked really we	1	no other financial resources were going to be
8 with the technologists. I know Mary and Pe		required in order to do this test to an
9 had the utmost respect for Dr. Khalifa. I	9	appropriate standard than the transfer of the
think they appreciated any advice or	10	20,000 or so from the chemistry side?
involvement he had with them, but, you kno		GULLIVER:
can't give you a detailed outline.		. Biochemistry.
13 CROSBIE, Q.C.:		SBIE, Q.C.:
14 Q. You can't give a detailed description?		. That was your assumption?
15 MR. GULLIVER:	1	GULLIVER:
16 A. No, no.		. Well, it's my assumption, and it was in
17 CROSBIE, Q.C.:	17	talking to Dr. Khalifa and looking at, you
18 Q. Okay. Sir, you said that you had no active		know, what would be the cost of the reagents
role in setting up or supervising these tests	19	to start up, how many tests do you expect to
for the ER/PR, in particular. Therefore, we	20	perform on a yearly basis, and then multiply
21 must infer that it was Dr. Khalifa who set u		it by the number of patients that we're going
22 and supervised the test.	$\begin{vmatrix} 21 \\ 22 \end{vmatrix}$	to be testing. We already had two
23 MR. GULLIVER:	23	technologists in the laboratory that were
24 A. Dr. Khalifa set up and supervised the actual		doing IHC testing for a number of years, so
25 performance of it and then you know it w		those same two staff you know would perform

those same two staff, you know, would perform

performance of it, and then, you know, it was

10

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- the testing. You know, we had Dr. Khalifa on 1
- 2 staff who was going to do the clinical side,
- so I didn't see other parts of the resources 3
- required to start this test up. 4
- 5 CROSBIE, Q.C.:
- Q. It wasn't assumed, for example, that any of 6 the techs would need to be sent out for 7
- 8 training to another institution?
- 9 MR. GULLIVER:
- A. Dr. Khalifa never assessed that, and never 10 asked for that, and I think you've heard him 11
- testify that when he came to St. John's, he 12
- was fairly impressed with the amount of IHC 13
- testing taking place and the quality of the 14
- work and the technologists. If Dr. Khalifa 15 16 had suggested it or asked for it, I'm sure
- funding would have been found for it. 17
- 18 CROSBIE, O.C.:
- 19 Q. We've talked about your responsibility for
- quality of output and that it's an interaction 20
- with the clinical side to achieve that, right, 21
- 22 but as manager, you would be responsible as
- well for documenting the processes followed in 23
- the lab, is that right, for the documentation 24
- 25 of it?

2

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- 1 MR. GULLIVER: A. No, I mean the staff, you know, had to
- document, you know, what they were doing and 3
- it all depends what documentation that you are 4
- 5 referring to. If it's documenting the fact
- that we have a patient and here's a test 6
- 7 performed and here's the results on the
- patient, those things are documented, you 8
- know, that's a part of the lab function. 9
- 10 CROSBIE, O.C.:
- 11 Q. Yes, but if you're the supervisor, then it
- falls to you, the responsibility falls to you 12
- to ensure that the techs are actually doing 13
- that, right? 14
- 15 MR. GULLIVER:
- A. I guess ultimately, yes.
- 17 CROSBIE, Q.C.:
- Q. Well that's your job as manager. 18
- 19 MR. GULLIVER:
- A. A part of my role, yes.
- 21 CROSBIE, Q.C.:
- Q. You're responsible for those techs doing their 22
- jobs right which includes documenting they're 23
- doing their jobs right. 24
- 25 MR. GULLIVER:

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A. I think people have to take responsibility for 2 their own job also.

- 3 CROSBIE, O.C.:
 - Q. Yet there's a manager responsible to ensure
- that they are doing so. And in histology, 5
- that was you. 6
- 7 MR. GULLIVER:
- 8 A. Yes, I was the manager but I don't think I can
- be, you know, watching over the shoulder of 25 9
 - or 30 staff every day, I mean staff worked
- different schedules, you know. You also have 11
- to assume that staff are going to accept their 12
- responsibility and perform their role as what 13
- they're supposed to do. 14
- 15 CROSBIE, O.C.:
- Q. Ultimately as manager the bucks stops with 16
- you; you're the manager. 17
- 18 MR. GULLIVER:
- 19 A. I guess if you apply that line of thinking,
- ultimately I guess it rests with the CEO, I 20
- mean because the manager responds--is 21
- 22 responsible to somebody else, then that person
- is responsible to somebody else. I mean, 23
- that's how a organization works. 24
- 25 CROSBIE, Q.C.:

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- Q. Sir, I thought I was attempting to establish a 1
 - 2 fairly uncontroversial proposition, which is
 - that the manager is responsible for the 3
 - quality of the work of the people who work 4
 - 5 under him., the manager of histology lab

 - responsible for the techs in this case? 6
 - 7 MR. GULLIVER:
 - A. I know and the pathology lab structure had 8
 - both an administrative and clinical structure, 9
 - so it would be a joint responsibility and 10
 - 11 accountability for the quality of the work
 - produced in the laboratory. 12
 - 13 CROSBIE, Q.C.:

16

- Q. I wonder if I gave the Registrar this 14
- reference here, I'm looking for the October 15
 - 9th, 2008 testimony of Dr. Torlakovic and I
- may or may not have given you that, Registrar, 17
- sorry, I missed that one. It takes a little 18
- longer if you don't put them on alert that 19
- you're looking for a transcript, you see, page 20
- 181 is what I'm looking for. Thanks. So you 21
- can see in the lead up to these questions on 22
- page 181, we--there's information provided, we 23
- assume that there's about 14,000 24
 - immunohistochemical tests performed per year

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1 by your institution?	I .	CROSBIE, Q.C.:
2 MR. GULLIVER:	2	Q. Sorry, I meant 181, I apologize.
3 A. I think there'sslides.	3	THE COMMISSIONER:
4 CROSBIE, Q.C.:	4	Q. Okay.
5 Q. Slides.	5	CROSBIE, Q.C.:
6 MR. GULLIVER:	6	Q. Line 5, she's saying "The pathologist would
7 A. That would be total slides, that would inclu	ide 7	have to closely interact on a daily basis with
8 patient slides, control slides, the whole	8	an expert technologist who is in charge of
9 total.	9	immunohistochemistry." So the first part of
10 CROSBIE, Q.C.:	10	that, do you agree that there should be close
11 Q. Uh-hm, and about 350 ER/PR.	11	interaction on a daily basis with a
12 MR. GULLIVER:	12	pathologist?
13 A. I think that's correct, yes.	13	MR. GULLIVER:
14 CROSBIE, Q.C.:	14	A. Yes.
15 Q. Yes. So then she wanted to know what t	he 15	CROSBIE, Q.C.:
volumes were because I was asking this doc	ctor 16	Q. And do you agree there should be an expert
from Saskatchewan, this pathologist, for he	er 17	technologistin charge of
feelings as to what the duties of a	18	immunohistochemistry?
pathologist whoshould there be a patholog	gist 19	MR. GULLIVER:
20 responsible to assist in ER/PR IHC testing and	d 20	A. I think there needs to a technologist, that's
that sort of thing, and she gives an answer	21	their primary function, I mean, it all depends
here starting at line 20, I think you can see	22	on what your definition of an expert
it there. You can move that up and down	to 23	technologist is.
suit yourself as well, sir, I think you have a	. 24	CROSBIE, Q.C.:
25 mouse. And the first one is, she feels that	25	Q. Well just going from that idea, somebody who
Pa	age 206	Page 208
where there is volume enough, you should have	_	
2 a designated specialist to dedicate part of	2	
3 his or her time for immunohistochemistry	3	
4 laboratory work alone. You would agree with	4	MR. GULLIVER:
5 that, I guess?	5	A. I would have to say that both Peggy Welsh and
6 MR. GULLIVER:	6	Mary Butler have been performing these
7 A. She's talking about a pathologist there, I	7	procedures for ten years and I would say that
8 think.	8	Peggy was probably more knowledgeable for IHC
9 CROSBIE, Q.C.:	9	testing and she was more the lead person for
10 Q. She is, yes.	10	IHC.
11 MR. GULLIVER:	11	CROSBIE, Q.C.:
12 A. Yes.	12	Q. And when Dr. Khalifa was present, which was up
13 CROSBIE, Q.C.:	13	until I believedo you know the month in
14 Q. You agree with that?	14	1999? Was it summer or fall -
15 MR. GULLIVER:	15	MR. GULLIVER:
16 A. Sure.	16	A. I think it might have been June, June of '99
17 CROSBIE, Q.C.:	17	when he left.
18 Q. And down on page 181, you can move it down		CROSBIE, Q.C.:
19 you wish, around line 5.	19	•
20 THE COMMISSIONER:	20	
21 Q. 181, line 5?	21	Welsh or anyone else?
22 CROSBIE, Q.C.:		MR. GULLIVER:
23 Q. Yes.	23	A. I don't know on a daily basis. I would have
24 THE COMMISSIONER:	24	
25 Q. Thank you.	25	CROSBIE, Q.C.:

	i-i age inquiry on from one Receptor Testing
Page 209	Page 211
1 Q. And if you could then go to page 183, which is	1 Q. Along with the control slides.
2 back up and around line 10, Dr. Torlakovic is	2 MR. GULLIVER:
3 saying "The pathologist would be in charge of	3 A. Yes.
4 making sure that daily quality control systems	4 CROSBIE, Q.C.:
5 are functioning correctly and there is	5 Q. That was the quality control.
6 participation in standard quality assurance	6 MR. GULLIVER:
7 programs and would be touching base with other	7 A. For that particular procedure.
8 pathologists to make sure that unusual results	8 CROSBIE, Q.C.:
9 are being reported or communicated." Now,	9 Q. Uh-hm. Now, participation I think we know in
first of all to take the first of that, in the	standard quality assurance programs that was a
period of Dr. Khalifa in respect to ER/PR	little bit of an issue because there wasn't
testing, what were the quality control	any, was there?
13 systems?	13 MR. GULLIVER:
14 MR. GULLIVER:	14 A. In what kind of quality assurance programs?
15 A. Well the quality control system was the	You mean external proficiency testing programs
technologist, as you've heard, would run a	16 or -
known positive control with, you know, with	17 CROSBIE, Q.C.:
the ER and the PR, so a positive ER, a	18 Q. Well to take that as an example, yes.
positive PR, those controls would be read by	19 MR. GULLIVER:
Dr. Khalifa to verify the quality of the	20 A. Well at that point in time in pathology, the
controls and to make sure the quality of the	21 pathologists were enrolled in external
staining and then any feedback back to the	proficiency in getting samples in to do
23 laboratory.	interpretations and get assessment on it.
24 CROSBIE, Q.C.:	There was no external proficiency testing in
25 Q. That was the quality control system. The	particular for the IHC part of the pathology
25 Q. That was the quality control system. The	particular for the part of the pathology
	, , , , , , , , , , , , , , , , , , , ,
Page 210	Page 212
Page 210 1 positive external control?	Page 212
Page 210 1 positive external control? 2 MR. GULLIVER:	Page 212 1 lab. 2 CROSBIE, Q.C.:
Page 210 positive external control? MR. GULLIVER: A. Well some of the daily quality control system,	Page 212 1 lab. 2 CROSBIE, Q.C.: 3 Q. Do you mean it wasn't available or you just
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Page 213	Page 215
Dr. Ejeckam who came with us in 2003, it	1 MR. GULLIVER:
wasn't until 2005 that he suggests that we	2 A. For the IHC.
3 should enrole in UK NEQAS, so I don't know	3 CROSBIE, Q.C.:
4 when that program was -	4 Q. For IHC.
5 CROSBIE, Q.C.:	5 MR. GULLIVER:
6 Q. You don't know, so that's the answer.	6 A. Yes.
7 MR. GULLIVER:	7 CROSBIE, Q.C.:
8 A. No.	8 Q. That's what she's calling the medical section
9 CROSBIE, Q.C.:	9 head. Is that a position which is being
10 Q. As the lab manager, did you have	created or recognized at this point in time?
responsibility for training of techs?	11 MR. GULLIVER:
12 MR. GULLIVER:	12 A. Well it's Dr. Ford Elms.
13 A. Not training directly, no.	13 CROSBIE, Q.C.:
14 CROSBIE, Q.C.:	14 Q. So he's doing that function?
15 Q. Did you have responsibility to ensure that	15 MR. GULLIVER:
they were adequately trained to the tasks they	16 A. Yes, but I think he's officially called the
17 were doing?	director of IHC lab.
18 MR. GULLIVER:	18 CROSBIE, Q.C.:
19 A. Pretty well yes, I mean it all depends, you	19 Q. Director.
know, as you realize pathology is a process,	20 MR. GULLIVER:
you're talking about technologists performing	21 A. I don't think it's called medical section
the functions in the pre-analytical part of	22 head.
pathology, they do the embedding of blocks,	23 CROSBIE, Q.C.:
the cutting of blocks, the routine staining,	Q. Okay, same thing though, you would think.
25 the histochemical staining,	25 MR. GULLIVER:
Page 214	Page 216
Page 214 immunohistochemical stainings, so what you	1 A. Yes.
Page 214 immunohistochemical stainings, so what you pretty well rely upon is that you have your	1 A. Yes. 2 CROSBIE, Q.C.:
Page 214 immunohistochemical stainings, so what you pretty well rely upon is that you have your other technologists and senior technologists	 A. Yes. CROSBIE, Q.C.: Q. And so that, although there is no title or
Page 214 immunohistochemical stainings, so what you pretty well rely upon is that you have your other technologists and senior technologists to assist and train new staff into those	1 A. Yes. 2 CROSBIE, Q.C.: 3 Q. And so that, although there is no title or 4 described function of director or medical
Page 214 immunohistochemical stainings, so what you pretty well rely upon is that you have your other technologists and senior technologists to assist and train new staff into those functions.	 A. Yes. CROSBIE, Q.C.: Q. And so that, although there is no title or described function of director or medical section head, Dr. Khalifa effectively
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Page 214 immunohistochemical stainings, so what you pretty well rely upon is that you have your other technologists and senior technologists to assist and train new staff into those functions. CROSBIE, Q.C.: And you had responsibility for budgeting, for	1 A. Yes. 2 CROSBIE, Q.C.: 3 Q. And so that, although there is no title or 4 described function of director or medical 5 section head, Dr. Khalifa effectively 6 functioned in that role, that's more or less 7 what you've told us.
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1 MR. GULLIVER:	1 A. Dr. Chittal retired maybemight be two years
2 A. No.	2 now.
3 CROSBIE, Q.C.:	3 CROSBIE, Q.C.:
4 Q. So really we go from Dr. Khalifa at the end of	4 Q. So are you saying to the Commission here that
5 June '99 to Dr. Parai and he takes over	5 Dr. Chittal filled the role of giving daily
6 whatever the function was that Dr. Khalifa was	6 interaction and guidance to laboratory staff?
7 performing.	7 MR. GULLIVER:
8 MR. GULLIVER:	8 A. He certainly didn't fill the role Dr. Khalifa
9 A. As site chief.	9 left, but in the absence of Dr. Khalifa, I
10 CROSBIE, Q.C.:	think that's the pathologistand Dr. Chittal
11 Q. As site chief. However, we've heard, I think	was at the Health Sciences maybe since
as well, that Dr. Parai didn't have an	12 1981/'82 and I think that's the clinical
interest or, well an interest in IHC testing	person who Mary and Peggy probably went to
and that his role was pretty much limited to	looking for any questions or guidance or
reading the control slides, is that about	because they already had an established
16 right?	relationship working together as technologist,
17 MR. GULLIVER:	pathologist since the early '80's.
18 A. That's for a time period, yes.	18 CROSBIE, Q.C.:
19 CROSBIE, Q.C.:	19 Q. Dr. Khalifa had a formal position of site
20 Q. Well, he would be the site chief up to March	20 chief.
21 2005 is what I have here.	21 MR. GULLIVER:
22 MR. GULLIVER:	22 A. Yes.
23 A. No, I mean a time period where it was Dr.	23 CROSBIE, Q.C.:
Parai who was then reading the control slides	Q. Dr. Parai had the formal position of site
from the IHC lab and then at some point, that	25 chief.
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1 changed and the individual pathologist at the 2 Health Sciences were then, they were all	1 MR. GULLIVER: 2 A. Yes.
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Page 221 Page 223 director or medical section head during that 1 CROSBIE, O.C.: 1 2 period in relation to the IHC lab? Q. Four and a half years and then Mr. Dyer took over. So Dr. Ejeckam, we've heard, came on 3 MR. GULLIVER: 3 A. Well there was no position as such during that the scene and he became the resource person 4 time frame regardless. for people who had questions or issues in the 5 5 6 CROSBIE, Q.C.: lab, but he didn't come on the scene until, 6 Q. Correct. So you're saying that informally what is it, September 2000? 7 7 this gentleman gave some assistance to the 8 8 MR. GULLIVER: techs on a periodic basis? A. No, I think he comes in late 2002, I think. 10 MR. GULLIVER: 10 CROSBIE, Q.C.: A. Pretty well, yes. Q. Perhaps Ms. Chaytor knows. Okay, so late 2002 11 11 it is, Dr. Ejeckam comes on the scene. 12 CROSBIE, Q.C.: 12 Q. Something which Dr. Parai, as site chief, 13 MR. GULLIVER: 14 didn't do? 14 A. Uh-hm. 15 MR. GULLIVER: 15 CROSBIE, O.C.: A. I don't think so, no. Q. So what I'm getting from this is that from the 16 time Dr. Khalifa leaves in June '99 to the 17 17 CROSBIE, Q.C.: time Dr. Ejeckam comes on the scene in 18 Q. Now you were the lab manager until, right from 18 September, 2002, with the exception of the 19 the beginning of '97 to October, 2001. 19 gentleman you mentioned who hasn't appeared o 20 MR. GULLIVER: 20 the record here all that much, no one was 21 A. 2001. 21 22 CROSBIE, Q.C.: 22 doing the job of daily interacting with the techs to help them with any problems they were Q. And then Mr. Dyer took over from you. 23 having in performing their ER/PR IHC 24 MR. GULLIVER: 24 procedure? 25 A. A few months afterwards, yes. 25 Page 222 Page 224 1 CROSBIE, Q.C.: 1 MR. GULLIVER: Q. The majority of the period then, from 1997 to A. Well I think and your answer is right and I 2 2 2005, you were the lab manager? think that, you know, if there was a problem 3 3 encountered by the technologists, they would 4 MR. GULLIVER: 4 A. It was about half, I guess. informally go to Dr. Chittal. 5 6 THE COMMISSIONER: 6 CROSBIE, Q.C.: Q. A bit more than half. Q. Mr. Crosbie, when there's a convenient spot, 7 8 MR. GULLIVER: we'll break for the luncheon break. 8 A. To 2005? 9 CROSBIE, Q.C.: Q. Thanks for the reminder. As you've noticed 10 CROSBIE, Q.C.: 10 11 Q. October 2001, we're talking about '97, '98, 11 with lawyers before, they tend to forget what time it is. '99, 2000. 12 12 13 MR. GULLIVER: 13 THE COMMISSIONER: A. From '97 to '01, I was the only manager. 14 Q. Uh-hm. 15 CROSBIE, Q.C.: 15 CROSBIE, Q.C.: o. Pardon? Q. Thank you. Well I have some other things to 17 MR. GULLIVER: 17 ask about and we'll do that after lunch at A. From '97 to October, 2001, all that time frame what time, Commissioner? 18 18 I was the pathology manager. 19 THE COMMISSIONER: 19 20 CROSBIE, O.C.: 20 o. At 2:15. Q. Exactly, so that's four and almost five years. 21 21 (ADJOURNED FOR LUNCH) Almost five years from '97 to October -22 THE COMMISSIONER: 22 23 MR. GULLIVER: Q. Please be seated. Mr. Crosbie? 23

24 CROSBIE, O.C.:

25

Q. Thank you, Commissioner. I'd like to talk,

A. Well it was March '97 to October '01, so it's

four years and a bit, whatever, maybe, yes.

24

i	inquiry on Hormone Receptor Testing
Page 225	Page 227
1 Mr. Gulliver, about antigen retrieval and in	1 A. I think it can, yes.
2 simple terms what we are trying to accomplish	2 CROSBIE, Q.C.:
3 here is to useif we have a method for	3 Q. So a couple of timesmore than a couple of
4 uncovering the cross linkages that obscure the	4 times, numerous times you've made reference to
5 antigen sites to which we want our antibodies	5 boiling on a hot plate, for example, I've made
6 to bind and then be visible under the	a note here "manually take your slides and put
7 microscope as brown dots, simplistic, but	7 them on a hot plate and boil them." And you
8 that's about the right idea?	8 said that a couple of times.
9 MR. GULLIVER:	9 MR. GULLIVER:
10 A. Correct.	10 A. And what I'm meaning there is that you
11 CROSBIE, Q.C.:	actually take the substrate buffer that you're
12 Q. And so to achieve antigen retrieval or to	using, that you're boiling to a certain
reveal these antigen sites or these receptor	temperature, which is in like a pyrex dish,
sites, the method that we've been talking	then your slides go in that dish which is on
about most of the time here is heat, the use	15 the hot plate.
of heat.	16 CROSBIE, Q.C.:
17 MR. GULLIVER:	Q. So it's not like a pot with the slides in it
18 A. A part of it is using heat.	on a hot plate, it's something like a coplin
19 CROSBIE, Q.C.:	jar in the solution in the pot on a hot plate,
20 Q. There are other methods though and Trypsin	is that what you mean?
21 would be an example?	21 MR. GULLIVER:
22 MR. GULLIVER:	22 A. Yes.
23 A. Trypsin is used also at the front end of IHC	23 CROSBIE, Q.C.:
testing, but not as a part of antigen	Q. Can I have brought up document P-0565 please?
25 retrieval for the ER/PR.	25 And there, probably in the third paragraph
Page 226	Page 228
Page 226	
1 CROSBIE, Q.C.:	there, at the time you're talking about '97,
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October 15, 2008	Multi-Page TM	Inquiry on Hormone Receptor Testing
·	ge 229	Page 231
then you canpeople do use pressure cooked and people do use microwave ovens to heat substrate solution. We always use the hot plate and then at some point, I think DAKO came out then with like a waterbath that you could use to heat up your substrate solution. 8 CROSBIE, Q.C.: 9 Q. Did you adopt the waterbath technique at so point? 11 MR. GULLIVER: 12 A. Well it's not a technique, it's just replacing the hot plate. 14 CROSBIE, Q.C.: 15 Q. But did you? 16 MR. GULLIVER: 17 A. Yes, we did. 18 CROSBIE, Q.C.: 19 Q. Can I have document P-3050? You'll see on top left there, "Source is Eastern Health, source, Terry Gulliver. It's a protocol sheet for high temperature epitope unmasking." It you recognize this document?	the 1 a h rs 2 place the 3 kitce 4 effects 5 follows 1 6 MR. GULL 7 A. To a 8 they me 9 you 10 CROSBIE, 11 Q. Uh-12 MR. GULL 13 A. Year 14 CROSBIE, 15 Q. Who 16 to the 17 MR. GULL 18 A. Year 19 CROSBIE, 20 Q. Oka 21 said 20 pressure 20 year 21 said 22 year 22 ye	ot water bath, 95 to 99 degrees C by cing water into a large vessel, such as a hen pot on a hot plate." Is that ectively the protocol that your lab was owing? IVER: the best of my knowledge, yes. And I think y used to use, like, you know, a Corning, know, the plain glass Corning dish. Q.C.: hm, rather than the kitchen pot, you mean? IVER: th. Q.C.: en it's put that way, it sounds a bit crude the layperson, you would agree? IVER: th. Q.C.: ay. Hot plates and kitchen pots. But you at at some point you switched to, I guess at they describe on the first page, the sesure cooker?
24 MR. GULLIVER: 25 A. Well I gather the document is from the	24 MR. GULL 25 A. No,	we never ever switched to pressure cooker.
	ge 230 1 CROSBIE,	Page 232
 Q. You're named as the source. 4 MR. GULLIVER: A. I gathered them from the pathology lab an provided all documents for ER/PR to the inquiry. 8 CROSBIE, Q.C.: Q. Do you know what this designation, volume page 188 is over there in the top right? 	4 MR. GULL 5 A. Yes 6 in o 7 was 8 did 14, 9 use 10 CROSBIE,	s, when they were first doing this testing, order to heat the substrate solution, it is boiled on a hot plate. At some point DAKO come out with like a waterbath you could in place of that. Q.C.:
11 MR. SIMMONS: 12 Q. Commissioner, the same question about that 13 Gulliver wouldn't know the answer, that's ju 14 the indexing method used by us as we product 15 the documents to the Commission, so that ju 16 indicates the volume of production and page 17 numbering of the production. 18 CROSBIE, Q.C.:	Mr. 12 MR. GULL 13 A. But 14 met 15 CROSBIE, 16 Q. I m	we never ever used a pressure cooker hod or a microwave oven method. Q.C.: ight be able to help you if we go to hibit P-2888? And we go along to page 3 of

20

21

22

23

24

25 MR. GULLIVER:

19 Q. Well there's the answer. You can--or I can, go over to the second page. There's your 20

21 pressure cooker mentioned there, item A,

22

autoclave. There seems to be a microwave oven

23 method and then they have here at C, hot water 24 bath method and there under hot water bath on

25 page 2 of the exhibit, DAKO is saying "set up

Page 229 - Page 232

document I was looking for, actually, Mr. Gulliver. What I thought I had there was and

somewhere, is the acquisition of a waterbath

by the lab was acquired on October 27, 1999,

I believe it's here in the documents

would that seem about right?

October 15, 2000	muni-rage inquiry on from mone receptor resumg
Pag	ge 233 Page 235
1 A. That got to be, yeah, I think so.	1 my paper copy. Under day two, it says -
2 CROSBIE, Q.C.:	there's the word "trypsin" again, which you
3 Q. And in fact, it seems that you were given the	
4 waterbath by DAKO, after all, I guess, you	did you - first of all, these interrogatories
5 were spending a lot of money with DAKO.	5 were addressed to Ms. Predham, as you
6 MR. GULLIVER:	6 remember, but she obviously required the
7 A. Probably, yeah.	7 assistance of other people and on this
8 CROSBIE, Q.C.:	8 occasion, you, to answer the interrogatories
9 Q. So they sort of threw that in and do you think	
then that from around that period, late '99	10 MR. GULLIVER:
11 you started using a waterbath method?	11 A. Yes.
12 MR. GULLIVER:	12 CROSBIE, Q.C.:
13 A. Yes.	13 Q. So the question that this was meant to answer
14 CROSBIE, Q.C.:	14 was, "Attach a copy of the bench manual for
15 Q. As opposed to the cruder sounding hot plate.	
16 MR. GULLIVER:	
	methodology on antigen retrieval controls, negative and positive, etc". My question is
18 CROSBIE, Q.C.:	why did you give us the immunoperoxidase step
19 Q. Kitchen pot, yes, okay. Can we now go to	
Document 1853, and I'm interested in page t	
21 please. As you can see, sir, these are	21 A. Is there anything else attached to this?
answers to interrogatories, and the question	22 CROSBIE, Q.C.:
three appears there, "Please attach a copy of	Q. Yes, feel free to have a look. There's a fe
the bench manual for the DAKO system,	24 more pages in the attachment.
specifically written methodology on antiger	1 25 MR. GULLIVER:
1 1	
	ge 234 Page 236
Pag 1 retrieval controls, negative and positive,	Page 234 1 A. Well, I guess this is the procedure that was
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Multi-Page TM **Inquiry on Hormone Receptor Testing** Page 237 Page 239 but, you know, if you want to get into more 1 CROSBIE, O.C.: 1 2 technical detail, you'll have to speak to the Q. So your evidence is you were using trypsin, as technologists who are actually performing the described in the step by step procedure at 3 3 page six, and the recommended waterbath? 4 test. 4 5 CROSBIE, Q.C.: 5 MR. GULLIVER: Q. So, in fact, you can't tell us whether trypsin A. But trypsin is not used - trypsin is not used 6 6 is still in use, or in use up to when the as an antigen retrieval for ER/PR antibodies. 7 7 Trypsin is used for - is applied to most 8 testing was being performed? 8 antibodies for IHC testing. 9 MR. GULLIVER: A. Trypsin is used still for some antibodies, 10 CROSBIE, O.C.: 10 even in the Ventana system. Q. One final thing before we leave page nine - by 11 11 all means, have a look, but if you -12 Q. But you can't tell us whether it was being 13 MR. GULLIVER: 13 used for ER/PR testing? A. I'm still scrolling - do you want me to scroll 14 14 15 MR. GULLIVER: back? 15 A. I can't tell you definitively right now, no. 16 CROSBIE, Q.C.: 16 So what you have here, the first couple of Q. Page nine, when you're ready. Just one more 17 17 pages, Mr. Crosbie, is the actual step by step thing, a few lines into that paragraph that 18 18 procedure for doing IHC antibodies. The ER/PR you have marked off, it says, "Heat waterbath 19 19 antigen retrieval is applied before the slides to 95/99 centigrade. Do not boil". Any 20 20 get to this part of the procedure. What particular significance to that advice? 21 21 you're seeing here next is the - it's just 22 22 MR. GULLIVER: documentation from the manufacturer that this 23 A. Well, I mean, they always told the staff that 23 you don't allow your retrieval solution to is the DAKO retrieval solution that's used for 24 24 boil, which is a much higher temperature than 25 antigen retrieval. 25 Page 238 Page 240 1 CROSBIE, Q.C.: that. 1 Q. And also you've got isolated there with your 2 CROSBIE, O.C.: 2 own markings, DAKO antigen retrieval, step by 3 Q. Well, some of us may be struck by the fact 3 that you repeatedly referred to boiling. step? 4 4 5 MR. GULLIVER: 5 MR. GULLIVER: A. And this is the procedure for the antigen A. Oh, I think you're just taking things too 6 6 retrieval piece, yes. 7 literally. What is meant is that instead of 7 8 CROSBIE, O.C.: putting your solution on a hot plate and then 8 Q. And it mentions waterbath specifically? you turn it up and let it boil and bubble, and 9 then wait for it to cool down to 95/99, you 10 MR. GULLIVER: 10 11 A. Uh-hm. 11 actually apply a more even heat until the solution reaches up to 95/99 degree 12 CROSBIE, Q.C.: 12 Q. So I would have guessed that after you were 13 temperature. 13 given the waterbath in late 1999, you adopted 14 14 CROSBIE, Q.C.: 15 what's set out there, recommended procedure, Q. When the - well, it's called kitchen pot and 15 hot plate method was being used, did you - you waterbath? 16 16 17 MR. GULLIVER: 17 were ten years off the bench at that point in time in '97. Did you work with the techs to A. But this procedure is still the same whether 18 18 you're using a waterbath or using a hot plate 19 see how they were performing that part of the

19 or a kitchen pot. It's still the same 20 procedure. You still have to use our pH 21 22 solution, you still have to dewax your slides and rehydrate your tissue sections, you still 23 24 got to immerse them into the retrieval solution. 25

21 MR. GULLIVER: A. I didn't work with the techs to see it, but, I 22 mean, I was in the lab enough to see the times 23 when they were doing the procedure, yes. 24 25 CROSBIE, Q.C.:

procedure?

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2 temperature to make sure -

3 MR. GULLIVER:

1

A. With a thermometer.

5 CROSBIE, Q.C.:

Q. The slides were not in a solution which 6

Q. Do you know how they controlled for the

boiled? 7

8 MR. GULLIVER:

A. They had a thermometer in it, like, a 9

thermometer. 10

11 CROSBIE, O.C.:

Q. In which? 12

13 MR. GULLIVER:

A. Into the solution. 14

15 CROSBIE, O.C.:

Q. In the solution in which the slides were 16

placed? 17

18 MR. GULLIVER:

A. Exactly. To make sure it's at 95/99 degrees, 19

there was a thermometer placed into it so they 20

know when it reached up to that range. 21

22 CROSBIE, Q.C.:

Q. And they'd keep it at that range for how long?

24 MR. GULLIVER:

25 A. Well, the time was 20 minutes that they used

Page 242

to incubate for. 1

2 CROSBIE, Q.C.:

3

Q. And you know this, though, not from having

watched them do it, or taken them through the 4

5 process of doing it, you know that from what's

set out here? 6

7 MR. GULLIVER:

A. No, I know that from speaking to the 8

technologists and I know that enough times 9

over the years that just by chance I might 10

11 have been out in the lab when they were doing

their procedure to verify that. 12

13 CROSBIE, Q.C.:

Q. How was the twenty minutes timed for? 14

15 MR. GULLIVER:

A. How was it timed?

17 CROSBIE, Q.C.:

O. Uh-hm. 18

19 MR. GULLIVER:

22

25

A. It was - in all parts of pathology, there's 20

multiple different stains that are performed 21

and different timings for different solutions,

whether it's an IHC test, histochemical test, 23

24 or an H & E stain, and they use multiple

timers. So you have a lab timer clock that

you set your time for twenty minutes, and then

Page 243

2 when the time is up, the buzzer goes off, you

take your things out, and do the next - enter 3

the next step. 4

5 CROSBIE, Q.C.:

Q. I guess in lay terms, an alarm clock? 6

7 MR. GULLIVER:

8 A. Pretty well, yeah.

9 CROSBIE, Q.C.:

Q. A timer that would make an audible noise and 10

you'd know your time was up? 11

12 MR. GULLIVER:

A. Yes.

14 CROSBIE, Q.C.:

Q. And you saw that, did you? 15

16 MR. GULLIVER:

A. Hundreds of times. 17

18 CROSBIE, O.C.:

Q. Was it always used?

20 MR. GULLIVER:

A. To my knowledge, yes. 21

22 CROSBIE, Q.C.:

24

2

8

Q. Of course, you didn't see this procedure done 23

every time it was done?

25 MR. GULLIVER:

Page 244 A. Obviously not, no, but my experience with the 1

technologists is they had a procedure to

follow and that's the procedure they followed. 3

Again whether it's an ER/PR or an H & E stain, 4

that's the procedure that you follow. 5

6 CROSBIE, Q.C.:

7 Q. Document 1889, please. We looked at this

before. That's the Dr. Khalifa letter which

you don't recall receiving, and, of course, we 9

looked at the part where it says, "I do not 10

11 think you appreciate the delicacy of this

test", and I think you told us that at the 12

13 outset you may not have, but you learned, is

that true? 14

15 MR. GULLIVER:

A. I think we all learned, yes. This was a new 16

17 test that was being introduced, and Dr.

Khalifa was pretty well the only - even the 18

only pathologist that had knowledge about this

20 test.

19

22

21 CROSBIE, O.C.:

Q. Was it a delicate test?

23 MR. GULLIVER:

A. I think you have to say yes. 24

25 CROSBIE, Q.C.:

Page 245

Q. Did Dr. Khalifa know you were using trypsin as 1

2 part of your technique?

3 MR. GULLIVER:

A. Yes. I can't tell you if trypsin was used for

ER/PR. Again I know some antibodies, you use 5

trypsin digestion, other ones you don't. 6

7 CROSBIE, O.C.:

8 Q. So you're not sure whether trypsin was used

for ER/PR?

10 MR. GULLIVER:

A. I can't tell you that. I mean, I didn't do 11

the procedure. I certainly can find out and 12

provide information to the Commission. 13

14 CROSBIE, Q.C.:

Q. So, Mr. Gulliver, your evidence is that you've 15

16 learned, as everyone does, and I guess by the

end of the period to 2005, you knew an awful 17

lot more about the delicacy of this procedure 18

19 than you did at the outset?

20 MR. GULLIVER:

21 A. Sure.

22 CROSBIE, O.C.:

Q. You had a good understanding of the procedure 23

24 by 2005?

25 MR. GULLIVER:

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A. Yes. 1

2 CROSBIE, O.C.:

Q. That, however, does not seem to be the opinion 3

of Dr. Carter, does it? Dr. Carter was a 4

5 pathologist with special expertise in breast

cancer. 6

7 MR. GULLIVER:

A. And that's her opinion, yes.

9 CROSBIE, Q.C.:

11

25

Q. And she thought you did not have a good 10

understanding of ER/PR testing, as we see at

the letter at 0079, and here in the second 12

13 paragraph she says that, "Mr. Terry Gulliver

and Mr. Barry Dyer do not have a good 14

15 understanding of the limitations of automated

immunohistochemistry, etc". 16

17 MR. GULLIVER:

A. But she's talking about the Ventana system 18

here now. She's not talking about ER/PR 19

testing in general. Dr. Carter was not in 20

favour of the Ventana system of automation. 21

22 CROSBIE, O.C.:

Q. Okay, in the first paragraph she talks about 23

organizational role in the investigation of 24

the problems with ER/PR testing from '97 to

Page 247

2004, and the planning of solutions to the 1 2 current issues discovered with the Ventana

3 automated system. She seems to be looking at

both things.

5 MR. GULLIVER:

4

6

7

10

24

1

2

A. No, specifically here she's talking about she

believed that automation had limitations, and

8 that's exactly what she's saying there, that

she doesn't think that we have a good 9

understanding of the limitations of automated

immunohistochemistry. 11

12 CROSBIE, Q.C.:

Q. Okay, so you would limit that statement to an 13

understanding of the Ventana automated system, 14

not the ER/PR testing generally? 15

16 MR. GULLIVER:

A. Exact - well, she doesn't say there "ER/PR 17

18 testing".

19 CROSBIE, Q.C.:

Q. She goes on to say, "Rigorous clinical and 20

technical validation of antibodies against ER 21

22 and PR and establishment of reliable and

23 reproducible means of providing ER/PR results

to our patients using the substantial

published peer review" and then continuous 25

Page 248

monitoring of immunohistochemical testing

protocol. All that's not limited just to the

Ventana machine surely? 3

4 MR. GULLIVER:

5 A. No, but what she's referring there, by August

1st, '05, since the Ventana system had been 6

7 in, Dr. Ejeckam is the director of IHC lab,

Dr. Ejeckam is the one that validated the 8

antibodies for ER/PR that we were using, so 9

that was all done under Dr. Ejeckam's 10

guidance. 11

12 CROSBIE, O.C.:

13 Q. So, sir, your evidence is that her intent here

was to say that you didn't have a good

understanding of the Ventana automated system? 15

16 MR. GULLIVER:

17 A. Yes.

14

20

22

23

25

18 CROSBIE, Q.C.:

Q. I'd like to go to Document 2095, page 13. I 19

guess this was advice to Mr. Tilley from Dr.

Williams, who in turn would be relying on 21

people in pathology and in the lab, and

presumably yourself, for the statement at the

bottom of the page, "It has been determined 24

that positive controls were conducted every

October 15, 2000	inquiry on from one Receptor Testing
Page 2	Page 251
day as part of the quality assurance process	1 Q. Because you can't run moreor rather one per
within the lab". Were you the source of that	2 batch as you might be able to do with a
3 information?	3 positive control, can you? With negative
4 MR. GULLIVER:	4 controls, you have to run one per patient
5 A. I could be.	5 sample.
6 CROSBIE, Q.C.:	6 MR. GULLIVER:
7 Q. And that's what you believe today?	7 A. I think that would be the ideal scenario.
8 MR. GULLIVER:	8 CROSBIE, Q.C.:
9 A. I believe what today?	9 Q. Is it more than the ideal scenario? Isn't the
10 CROSBIE, Q.C.:	point that it's the patient's own tissue?
11 Q. Positive controls were conducted every day?	11 MR. GULLIVER:
12 MR. GULLIVER:	12 A. That's a part of the negative control, yes.
13 A. Yes.	13 Again, you're asking me questions that really
14 CROSBIE, Q.C.:	need to be answered by a pathologist.
15 Q. And these were controls that weren't run	15 CROSBIE, Q.C.:
necessarily with each patient slide. They	16 Q. Well, I think we're interested, sir, in
were run with a batch, right?	knowing just how much you did understand about
18 MR. GULLIVER:	this procedure. So with the negative control,
19 A. They were runthere were known positive	19 how is that treated differently than the
20 controls run every single time the ER	20 patient's specimen which it is intended to be
21 procedure was performed. Sometimes there ma	ay 21 read for ER/PR status? What's different about
be four patient cases in the run with a PR	the negative?
control, ER control. Other times, there were,	23 MR. GULLIVER:
depending on the pathologist who was	24 A. The negative control, when you are applying
interpreting, other times there might have	25 the particular antibody that you're trying to
Page 2	250 Page 252
been four patient cases in the batch and four	1 uncover, investigate, like ER, at that stage
2 ER controls and four PR controls. It depended	2 of the procedure, you don't apply any
on how many pathologists were doing the	antibody. It's almost like applying a
4 interpretation afterwards. But controls were	4 placebo, we'd say. But you still treat the
5 run every single time.	5 negative slide in all the same other steps of
6 CROSBIE, Q.C.:	6 the procedure.
7 Q. I thought that you explained earlier in your	7 CROSBIE, Q.C.:
8 testimony that there might only be one control	8 Q. Same in all other respects, except it doesn't
9 per batch, even if there were -	9 get the antibody?
10 MR. GULLIVER:	10 MR. GULLIVER:
11 A. There were times like that, yes.	11 A. Correct.
12 CROSBIE, Q.C.:	12 CROSBIE, Q.C.:
13 Q. Yes.	13 Q. And it's to control for what?
14 MR. GULLIVER:	14 MR. GULLIVER:
15 A. Yeah, but there was a control run every time.	15 A. I think it's mostly used to control when
16 CROSBIE, Q.C.:	you're looking atif you have a positive
Q. Okay. That's the positive external control?	external control, you have the patient's own
18 MR. GULLIVER:	tissue and the negative control that the
19 A. Yes.	negative control would assist in identifying
20 CROSBIE, Q.C.:	background staining or excessive background
21 Q. And did your lab run negative controls every	21 staining.
22 day?	22 CROSBIE, Q.C.:
23 MR. GULLIVER:	Q. So the theory of it, I guess, is that it would
24 A. No, we did not.	24 prevent false positives?
124 A. 140, we did not.	prevent talse positives.

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1 A. I don't know if it would prevent false	1 controls in order to save money?
2 positives. I think that it would help reduce	2 MR. GULLIVER:
false positives.	3 A. Not to my knowledge, no.
4 CROSBIE, Q.C.:	4 CROSBIE, Q.C.:
5 Q. Ideally prevent them, but certainly reduce	5 Q. Could we go to document 3114, please, page 29?
6 them?	6 This is a DAKO handbook you provided over the
7 MR. GULLIVER:	7 weekend. Not this weekend, but the one
8 A. Yeah.	8 before. You see that title there, controls?
9 CROSBIE, Q.C.:	9 MR. GULLIVER:
10 Q. Can you explain why negative controls were not	10 A. Positive and negative controls, yes.
run on a regular basis?	11 CROSBIE, Q.C.:
12 MR. GULLIVER:	12 Q. Can you do us the service of reading the first
13 A. The decision to usewhat controls were run,	sentence?
it was made by a pathologist. Whether it's	14 MR. GULLIVER:
made by the site chief, whether it's made by	15 A. "Positive and negative controls must be
the director of that part of the lab, you	processed alongside with the unknown to assure
know, it's not a technologist's decision.	the accuracy of the results in any stain
18 It's not an administrative decision. Nobody	technique," and this is 1983.
had requested to run negative controls with	19 CROSBIE, Q.C.:
20 every antibody.	20 Q. Yes. In fact, if we go to page four, that's a
21 CROSBIE, Q.C.:	21 long way back, we'll go there.
22 Q. So your evidence to the Commission then is	22 THE COMMISSIONER:
that this was not a technology decision, not a	23 Q. Do you want four? The Registrar could get
lab manager decision? It was done under	24 that.
direction of the pathologists and that the	25 CROSBIE, Q.C.:
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decision not to run negative controls, you're	1 Q. Yes, that's going to be faster than if I turn
2 not responsible for that decision?	2 to it. Down at the foot.
3 MR. GULLIVER: 4 A. No.	3 THE COMMISSIONER:
	4 Q. The foot of the page, thank you.
5 CROSBIE, Q.C.:	5 CROSBIE, Q.C.:
6 Q. You agree, your evidence is that you were not	6 Q. We see copyright 1983 by DAKO Corporation,
7 responsible for that decision?	7 suggesting that this direction or knowledge
8 MR. GULLIVER:	8 about the importance of negative controls goes
9 A. Right, that was not my decision to make.	9 back quite a ways.
10 CROSBIE, Q.C.:	10 MR. GULLIVER:
Q. Did you know there was an issue about negative controls or even that it's a decision had to	11 A. Um-hm. Again, you know, negative controls are 12 used to help assess background staining. Over
1	
13 be made? 14 MR. GULLIVER:	
l	-
15 A. I don't think there was ever really much discussion over negative controls.	reduced background staining in patient slides. So the requirement for negative controls, if
17 CROSBIE, Q.C.: 18 Q. Was there any?	
18 Q. Was there any? 19 MR. GULLIVER:	labs don't run negative controls, as this has
	19 advanced. If you actually go read this 20 manual, back when we first started doing this
20 A. During this time frame, Mr. Crosbie, I don't remember any specific discussion about, you	20 manual, back when we first started doing this 21 procedure, I used to apply glue to glass
22 know, running negative controls with ER/PR or	22 slides to try to keep the tissue on, and that
23 any other IHC antibodies.	23 glue would produce a lot of background
24 CROSBIE, Q.C.:	24 staining. So back in the early 80s, it was
25 Q. Was this a case of not running negative	25 more important to run negative controls just
2. Thus this a case of not fullting negative	25 more important to run negative controls just

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4

7

16

17

18

21

- for the background staining. 1
- 2 When I first started doing this procedure
- with Dr. Wang, I used to run negative controls 3
- for the first antibodies. What I would have 4
- to do, I would actually have to go and collect 5
- blood samples from volunteers in the lab and
- 6
- centrifuge that blood and take the person's 7
- 8 serum, separate it out and add that serum to a
- phosphate buffered saline and that was my 9
- 10 placebo that I used to run a negative control
- with Dr. Wang. But we did that only for a 11
- short period of time, and -12
- 13 CROSBIE, Q.C.:
- Q. Can I just extract a point here? Are you 14
- saying that it was more important in an 15
- 16 earlier period, in the '80s, to be running
- negative controls and it became less important 17
- 18 later?
- 19 MR. GULLIVER:
- A. No, it became more important when you're 20
- running prognostic markers like ER/PR, but for 21
- 22 general IHC staining, the negative control is
- used to look at the amount of background 23
- staining that may be present in that 24
- particular slide. 25

1 CROSBIE, Q.C.:

4 MR. GULLIVER:

2

3

5

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- Q. Now did you just say that most labs don't use
 - A. It looks like to me it's either Mary Butler--I 3
- A. To my knowledge, a lot of labs do not use--
- don't run negative controls with all their IHC 6
- 7 testing.
- 8 CROSBIE, Q.C.:
- Q. What about ER/PR?

negative controls?

- 10 MR. GULLIVER:
- 11 A. I can't tell you specifically what every lab
- is doing for ER/PR, if they're running both 12
- positive and negative controls, and have 13
- always been running positive and negative 14
- controls. 15
- 16 CROSBIE, O.C.:
- 17 Q. You think there are some credible labs that
- don't use negative controls, today, for ER/PR? 18
- 19 MR. GULLIVER:
- A. I would submit that you'll probably find that, 20
- 21 yes.

25

- 22 CROSBIE, Q.C.:
- Q. Can we go to the Predham answer to 23
- interrogatories 1852, please? This is a 24
 - different answer. This is a different

interrogatory and a different answer from the

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Page 260

- 2 one we just looked at, and specifically page
- six, please? Question 17 on page six. And so 3
 - question 17 asked "please provide a copy of
- the bench procedure for antigen retrieval 5
- during the use of the DAKO system" and if we 6
 - could then go to page nine, thank you,
- Registrar, we see there a spec sheet. 8
- 9 MR. GULLIVER:
- 10 A. That looks like it's the ER spec sheet, the
- clone. 11
- 12 CROSBIE, Q.C.:
- Q. I just have to find my marked up copy. Give 13
- me a moment, please. Down at the bottom of 14
- page nine, I'm going to read a sentence there. 15
 - It's like three from the bottom. It says
 - "there are no obvious signs to indicate
 - instability of this product. Therefore,
- positive and negative controls should be run 19
- simultaneously with patient specimens," and 20
 - I'm going to guess that's your writing at the
- 22 top of the page.
- 23 MR. GULLIVER:
- A. That's not my writing, no.
- 25 CROSBIE, Q.C.:
- Q. Do you know whose writing it is?
 - 2 MR. GULLIVER:

 - think Mary Butler. 4
 - 5 CROSBIE, Q.C.:
 - Q. And did you assist Ms. Predham in giving the 6
 - 7 answer to this question, "please provide a
 - copy of the bench procedure for antigen 8
 - retrieval during the use of the DAKO system"? 9

 - 10 MR. GULLIVER:
 - 11 A. I think I supplied a--I gave as much
 - information to Ms. Bussey. 12
 - 13 CROSBIE, Q.C.:
 - Q. And the answer is "please see the bench 14
 - procedures for certain clones," and then as 15
 - part of the appendix to all that, we have the 16
 - spec sheet from DAKO and the statement 17
 - "positive and negative controls should be run 18
 - 19 simultaneously with patient specimens."
 - That's not really an equivocal statement, is 20
 - 21 it?
 - 22 MR. GULLIVER:
 - A. That's their recommendation. 23
 - 24 CROSBIE, O.C.:
 - 25 Q. It is their recommendation, isn't it?

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Page 261

1 MR. GULLIVER:

- A. Yeah, and I will submit to you that if the
- pathologists want negative controls, they 3
- would have been run. But no pathologist ever 4
- asked to start running negative controls for 5
- IHC testing until recently we're now doing 6
- negative controls. 7
- 8 CROSBIE, Q.C.:
- Q. Whose files were these documents in that are 9 10 appended here? Were they in any pathologists'
- files? 11
- 12 MR. GULLIVER:
- A. These were -
- 14 CROSBIE, Q.C.:
- Q. Or were they in your files? 15
- 16 MR. GULLIVER:
- A. They weren't in my files, no. I retrieved 17
- them. I asked the pathology staff to please 18
- gather any documentation. If I got requests 19
- either from, you know, our lawyer's office, I 20
- gathered them up and sent them down to Ms. 21
- 22 Bussey.
- 23 CROSBIE, Q.C.:
- Q. Is this spec sheet intended for the 24
- pathologist or for the technologist and lab 25

Page 262

- manager? 1 2 MR. GULLIVER:
- A. It's certainly intended for both. There's
- information here that applies to both clinical 4
- and technical. 5
- 6 CROSBIE, Q.C.:
- Q. Does it imply that negative controls were 7
- 8 mandatory?
- 9 MR. GULLIVER:
- A. It says that they're recommended.
- 11 CROSBIE, Q.C.:
- Q. If the purpose of negative controls was to 12
- eliminate or reduce the presence of false 13
- positive readings -14
- 15 MR. GULLIVER:
- A. Which is the background staining, yes.
- 17 CROSBIE, Q.C.:
- Q. Yes. Does that absence of negative controls 18
- increase the risk of having false positives? 19
- 20 MR. GULLIVER:
- 21 A. Again, I think you got to ask the pathologists
- that question. 22
- 23 CROSBIE, Q.C.:
- 24 Q. Could we go to document 3108, page two? This
- document was prepared by you, sir. It's a 25

- spreadsheet prepared by you?
- 2 MR. GULLIVER:
- A. Mostly along the way, yes. 3
- 4 CROSBIE, Q.C.:
- Q. And it's entitled "ER/PR technical positive 5
- negative rate for St. John's specimens." What 6
 - do you mean by technical?
- 8 MR. GULLIVER:

7

16

- A. Technical means if there's something reported 9 10 as being positive. So it's not zero, zero.
- Someone says it's two percent, five percent, 11
- 90 percent, 100 percent, that there is 12
- positive staining detected within the tissue. 13
- 14 CROSBIE, Q.C.:
- Q. So what does this table assist us in arriving 15
 - at by way of the positivity rate for the total
- DAKO period? What do you say it is? 17
- 18 MR. GULLIVER:
- 19 A. From a lab perspective, we're saying there
- there was 74 percent of the total cases that 20
- were reported as positive staining and 26 21
- 22 percent were reported with zero, zero
- 23 staining.
- 24 CROSBIE, Q.C.:
 - Q. Okay, and now you qualify that by saying "from
- a lab perspective." Just explain that. 1
 - 2 MR. GULLIVER:

3

- A. Well, if you have, you know, a slide that
- comes from the pathology lab and the 4
- 5 pathologist reads the slide and they assign
- the case out and says that the tumour cells 6
- 7 are five percent positive for ER/PR or 25
- percent positive or 75 percent or 100 percent, 8
- they are saying that there's a portion of that 9
- slide is positive. 10
- 11 CROSBIE, Q.C.:
- Q. So in arriving at that 74 percent positivity 12
- 13 rate, you're excluding all the clinically
- negative slides? 14
- 15 MR. GULLIVER:
- A. Yes.
- 17 CROSBIE, Q.C.:
- Q. And you think that's the proper way to arrive 18
- at the positivity rate? 19
- 20 MR. GULLIVER:

- A. I don't think that there's any proper way and 21
 - I think if you search the world, you're
- probably not going to find any agreement on 23
- what you should categorize as a positive lab 24 25
 - result or a negative lab result.

October 13, 2000	TVIUIU-1 (rage inquiry on Hormone Receptor Testing
	Page 265	Page 267
1 CROSBIE, Q.C.:	1	1 CROSBIE, Q.C.:
2 Q. Well, sir, it sure does produce	e a different 2	2 Q. "I read each hard copy of reports and then
3 result, I suggest to you, when	n you include 3	logged them the same as we did two years ago."
4 thewhen you exclude, rather	r, the clinically 4	Then you say "positive, weak positive and
5 negative and if you go to that	t column, total 5	5 negative, no staining, the positive negative
6 DAKO, over toward the right, 1	rather, you count 6	6 rate overall is excellent," and if we look
7 down three lines, you got 53	percent, and I 7	down to the table, which is page two, we see a
8 suggest to you that that's the	true positivity 8	8 78.3 percent positivity rate, which in fact is
9 rate for the total DAKO period	. 9	9 excellent, isn't it?
10 MR. GULLIVER:	10	10 MR. GULLIVER:
11 A. That's 53 percent of what w	ve call strong	11 A. Um-hm.
positive.	-	12 CROSBIE, Q.C.:
13 CROSBIE, Q.C.:	13	
14 Q. And that's the most appropria		14 MR. GULLIVER:
the calculation is your evidence		15 A. I never met with him. I was in a room where
you feel is most appropriate		
that arrives at 74 percent, tha		17 MR. SIMMONS:
18 appropriate way?	18	
19 MR. GULLIVER:	19	
20 A. No, that's why I have three di		
21 here. When this was being do	•	
within Eastern Health, there	-	22 THE COMMISSIONER:
23 agreement upon between the		
24 oncologists side of what really		•
	-	1
125 DOSHIVE OF A HEGALIVE WE HE		
positive or a negative. We he		
	Page 266	Page 268
1 that anything above one per	Page 266 recent should be 1	Page 268 classified as solicitor-client privilege, I
that anything above one per considered positive. So that	Page 266 cent should be 1 2 2	Page 268 classified as solicitor-client privilege, I don't think.
that anything above one per considered positive. So that three separate categories, so	Page 266 recent should be 1 results why I made 2 we could make 3	Page 268 1 classified as solicitor-client privilege, I 2 don't think. 3 MR. SIMMONS:
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Paş	Page 271
calculating the positivity rate for	the question, Mr. Crosbie.
2 Clarenville than you did for St. John's?	2 CROSBIE, Q.C.:
3 MR. GULLIVER:	3 Q. I'm suggesting to the witness that this
4 A. How is there a different method? I got	4 positivity result for Clarenville is a
5 positives, the weak positives and then the	5 reasonable control for what was being done in
6 zero, the negative no staining.	6 St. John's at the same point in time.
7 CROSBIE, Q.C.:	7 MR. GULLIVER:
8 Q. All right, let's put it this way, if we follow	8 A. I don't understand.
9 the same method you followed at Exhibit 31	9 THE COMMISSIONER:
for Clarenville, who we know was sending	g 10 Q. Control or comparable?
theirpast a certain point, their material	11 CROSBIE, Q.C.:
out to Mount Sinai, we get 78.3 percent	12 Q. Pardon me?
positivity. That's obvious. If we follow the	13 THE COMMISSIONER:
same methodology for St. John's, we get	53 14 Q. I mean, in theI think it's the use of the
percent positivity, the same methodology.	word "control" that I'm having trouble with.
16 MR. GULLIVER:	16 CROSBIE, Q.C.:
17 A. Again, this is a total of 112 specimens. The	17 Q. Well -
numbers here is a total of 143 cases that wer	e 18 THE COMMISSIONER:
19 reviewed for Peninsulas.	19 Q. Are you suggesting they should have had the
20 CROSBIE, Q.C.:	20 same -
21 Q. Yes. So that's not big enough to have arur	1 21 CROSBIE, Q.C.:
22 a valid estimate of positivity rates?	22 Q. For the same reason that you keep tabs on your
23 MR. GULLIVER:	positivity rate, it's a metric that tells you
24 A. I don't know that, but I didn't do this to	whether you're conforming to established
determine the positive, negative rates for	expectations in your outcomes. So sir, I'm
	ge 270 Page 272
1 Clarenville. That's not why this was done.	simply suggesting that this is an interesting
2 CROSBIE, Q.C.:	2 and valid control against what was going on at
3 Q. Okay. Well, we just take the same methodo	
which yields 78.3 percent and we do it with	••
5 St. John's and it yields 53 percent. We're	5 A. Well, you haven't even asked me why I even did
6 agreed on that?	6 this.
7 MR. GULLIVER:	
	7 CROSBIE, Q.C.:
8 A. The strong positives, yes.	8 Q. Can you answer the question, please?
9 CROSBIE, Q.C.:	9 MR. GULLIVER:
Q. Yet 53 percent doesn't find its way into Dr.	
Gown's affidavit. It's 74 percent.	assumingI think you're trying to infer that
12 MR. GULLIVER:	this was done to compare the St. John's
13 A. Again, I did not give him anything directly.	testing to a pool of results that we could
14 CROSBIE, Q.C.:	14 access in Clarenville that were done at Mount
15 Q. Never met with him?	Sinai and compare the two from St. John's to
16 MR. GULLIVER:	16 Clarenville.
17 A. I was in a room where he was in attendance.	
never met with him individually, separately	
19 no.	19 MR. GULLIVER:
20 CROSBIE, Q.C.:	20 A. This was done just quite recently, the
21 O Suggest to you that the Clarenville positivity	Claranyilla ones I ong after all of our

ently, the 21 Clarenville ones. Long after all of our 22 retesting was completed. 23 CROSBIE, Q.C.: 24 Q. Would you go back to page one there? What 25 you're saying there is these were tested at Page 269 - Page 272

in St. John's, done at Mount Sinai.

Q. Suggest to you that the Clarenville positivity

Q. I'm sorry, the question, I didn't understand

rates are a reasonable control for positivity

21

22

23

25

24 THE COMMISSIONER:

Oc	etober 15, 2008	Multi-	Pa	age TM	Inquiry on Hormone Receptor Testing
	Pa	age 273			Page 275
1	Mount Sinai from 1999 to 2005.		1		thought in Clarenville.
2	MR. GULLIVER:		2	MR. G	ULLIVER:
3	A. Right, but I did this in October of 2007, lor	ng	3	A.	And plus, they were paying for this.
4	after our retesting was pretty well complete	_	4		BIE, Q.C.:
5	at Mount Sinai. This was not done to comp		5		That's what they thought in Clarenville.
6	St. John's results to somehow Mount Sir		6		ULLIVER:
7	results.		7	A.	And I think that was during a time after Dr.
8			8		Khalifa stopped all the interpretations.
9	Q. No, it doesn't matter why you did it. I'm	L	9		There were control slides that were run and
10	saying there's the data. When we compare	I .	10		the control slide was being read and verified
11	two, for the samemore or less the same	I .	11		pathologists in St. John's and then cases
12	periods, your calculations yield, done by th	I	12		then the slides werethe patient slides were
13	same methodology, 53 percent positivity in	I	13		sent out to around the region. That went on
14	John's, and yet in Clarenville, sending their	I	14		for a small time frame before control slides
15	specimens to Mount Sinai, they got 78 perc		15		were done for every pathologist that were
1	MR. GULLIVER:	I	16		outside St. John's interpreting.
17	A. On 143 samples over almost six years. But	I		CROSI	BIE, Q.C.:
18	main reason why we did this here was th	I	18		I put it to you that this suggests that
19	every patient with a test performed in		19		positive controls were not being conducted
20	Newfoundland had the review done to see		20		every day.
21	they should be retested at Mount Sinai, an	I		MR. G	ULLIVER:
22	the assumption was made that the patients	I	22		Well, I'm telling you that's not correct.
23	resided on the Clarenville domain and had				BIE, Q.C.:
24	tested at Mount Sinai from '99 up until thi		24		Thank you. Now could we have the testimony of
25	point in time, that the assumption was tha		25		Dr. O'Malley? It's June 23, 2008, page 179.
		age 274			Page 276
1	any negative patients there could not retest		1	REGIS	STRAR:
$\frac{1}{2}$	positive and should those patients be give		2		June 23rd?
3	the same review as all the other patients in				BIE, Q.C.:
4	Newfoundland. It had nothing to do with	I .	4		That's what my note says, June 23rd. And page
5	trying to compare positive rates to what wa	I	5	Q.	179. Let's see if we are where I think we
6	found in St. John's.	45	6		are. Yes. Could you just read that passage,
1	CROSBIE, Q.C.:		7		roughly lines one to 17 at the top of page
8	Q. That may be so. Could the reason for the	_	8		179? Just read it to yourself.
	difference in performance on this metric			MR C	GULLIVER:
10	positivity rates, be poor quality tissue		10		On the right-hand side?
11	preparation and lack of controls?				BIE, Q.C.:
1	MR. GULLIVER:		12		On the right-hand side, that's page 179. Just
13	A. Lack of controls at St. John's? I don't think		13	ζ.	read it to yourself. Whenever you're ready,
14	so. Controls were run every time in St.		14		sir.
15	John's, but it certainly could be due to-			MR G	GULLIVER:
16			16		Go ahead.
17	that's obviously one of the factors that coul	I .			BIE, Q.C.:
18	affect the outcome.	I	18		So the first point I'd extract out of that is
1	CROSBIE, Q.C.:		19	Q.	"a good control should catch problems in the
20	Q. Could we go to 2141, please? And I rea		20		preparation of specimens." Nothing
21	there, March 6th, 2006. Now this is a note		21		controversial about that.
22	Dr. Cook but he's speaking to Dr. Naghibi	-		MR C	GULLIVER:
23	, ,	-	23		And I don't know if he means the internal or
1		Ι.			

25 CROSBIE, Q.C.:

external control.

24

replied "it was due to poor quality and to lack of external controls." That's what they

October 13, 2000		-1 a	• <u>5</u> -	inquiry on Hormone Receptor Test	-
	Page 277			Page 2	279
_	nt is that "the effectiveness of	1	Α.	I was the manager then, yes.	
_	ds on having a senior,	2	CROSE	BIE, Q.C.:	
*	chnologist or pathologist to	3		And you were responsible to ensure that these	
4 oversee the tec	hnical steps." Anything	4		people were doing - were performing that	
5 controversial ab	out that?	5		critical function?	
6 MR. GULLIVER:		6		ULLIVER:	
7 A. No.		7	Α.	And to the best of my knowledge, they	
8 CROSBIE, Q.C.:		8		performed that function.	
1	scribing, it's she, is	9	CROSE	BIE, Q.C.:	
_	ical function in ensuring a	10	Q.	Your answer then is "yes"?	
11 quality test, so	enior supervision and	11	MR. GU	JLLIVER:	
oversight.		12	A.	The technologists?	
13 MR. GULLIVER:		13	CROSE	BIE, Q.C.:	
14 A. Yeah.		14	Q.	No, no, I asked you, you were responsible as	
15 CROSBIE, Q.C.:		15		manager?	
16 Q. And on the tech	nical side, you said that the	16	MR. GU	ULLIVER:	
17 persons perform	ing that critical function in	17	A.	well, at that time I'm managing pathology,	
the period from	1997 to 2005 were who again?	18		blood collection, immunology. I probably got	
19 MR. GULLIVER:		19	,	75 staff, and I said to you earlier I cannot	
20 A. Well, from 1987	7 up until -	20		be behind staff shoulders 24 hours a day, 7	
21 CROSBIE, Q.C.:	_	21		days a week. There's a point where you have	
22 Q. '97.		22		trained staff where you expect that they will	
23 MR. GULLIVER:		23		perform their job as they're supposed to.	
24 A. But from '87, M	Iary Butler and Peggy Welsh are	24	CROSE	BIE, Q.C.:	
25 doing IHC testing	g. Then they're the two ten	25	Q.	So is the answer then that no one was	
25 doing nie testing					
doing me testing	Page 278			Page 2	280
	Page 278	1		Page 2	280
1 years later who st	art doing the ER/PR testing	1 2		exercising managerial oversight over their	280
years later who st with Dr. Khalifa.	art doing the ER/PR testing They continue that up until	2		exercising managerial oversight over their fulfilment of those responsibilities?	280
years later who st with Dr. Khalifa. Mr. Ken Green, w	art doing the ER/PR testing They continue that up until who was 25 years in pathology	2 3	MR. GU	exercising managerial oversight over their fulfilment of those responsibilities? JLLIVER:	280
years later who st with Dr. Khalifa. Mr. Ken Green, w at St. Clare's.	art doing the ER/PR testing They continue that up until who was 25 years in pathology He moves in as a third	2 3 4	MR. GU	exercising managerial oversight over their fulfilment of those responsibilities? JLLIVER: No, that's not the answer.	280
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19

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- Q. And if they had a problem and didn't know it, 1
- then I guess they wouldn't go and seek 2
- guidance? 3
- 4 MR. GULLIVER:
- A. Well, if they had a problem and didn't know 5
- it, that problem should show up in the end 6
 - product, which is the slide, and then the
- pathologist would still read every single 8
- slide and sign it out and verify it, so they 9
- 10 would pick up a problem.
- 11 CROSBIE, O.C.:

7

- Q. Looking at line 15 on page 181, "So if it 12
- turns out that an institution was not getting 13
- reliable reading of the patient's tissue 14
- sample, it stands to reason we should look for 15
- 16 problems with the controls", and she says,
- "Definitely, yes". Do you agree, disagree? 17
- 18 MR. GULLIVER:
- 19 A. I never heard her testimony, or don't know how
- this is all framed here, but certainly with 20
- that simple statement, I would have to say 21
- 22 yes. I'm thinking she's wanting to talk about
- the internal patient's control. She's talking 23
- about reading the patient's tissue sample. 24
- 25 CROSBIE, Q.C.:

1

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- Q. Could we go to the testimony of Dr. Cook, July
- 2 7th, 2008, page 218. What I'm asking Dr. Cook
- about right there in that paragraph starting 3
- around line six -4
- 5 MR. GULLIVER:
- A. Over on page 218? 6
- 7 CROSBIE, Q.C.:
- Q. Right. There was testimony from a Dr. Mullen 8
- from Mount Sinai earlier, and he looked at his 9
- data and he depending on what values you use 10
- 11 for clinically positive/clinically negative,
- then his positivity rate for the material he 12
- had processed on behalf of Eastern Health here 13
- would vary between 46.3 and 53.7 percent 14
- positivity rate, and I was putting that to Dr. 15
- Cook, and Dr. Cook, you might see at 219, page 16
- 219, "No, it's more it's in the range of 70 17
- to 67 percent 67 to 70 percent positivity, 18
- 19 30 to 33 percent negative". He's disagreeing,
- in other words, and I'm suggesting it would 20
- look like he's getting that information from 21
- 22 you?
- 23 MR. GULLIVER:
- 24 A. I have never said directly to Dr. Cook - again you've seen multiple times where that 25

- Page 283 spreadsheet was updated. You've seen the 1
 - template, and I mean, Dr. Cook would have a 2
 - copy of it and he could use it as he and 3
 - that's his opinion. 4
 - 5 CROSBIE, Q.C.:
 - Q. Do you have a view, Mr. Gulliver, on who's 6
 - correct, Dr. Mullen or Dr. Cook? Was it more
 - in the area of 50 percent or 30 percent? 8
 - 9 MR. GULLIVER:
 - A. About positive cases? 10
 - 11 CROSBIE, Q.C.:
 - 12 Q. Well, 30 percent would refer to the negative
 - 13
 - 14 MR. GULLIVER:
 - A. I think that our negative rate is closer to 15 16 the 30 percent.
 - 17 CROSBIE, Q.C.:
 - Q. So what is the you're program director now. 18
 - What is the laboratory's position on the
 - positivity rate for the period of the DAKO 20
 - machine, what is your position? 21
 - 22 MR. GULLIVER:
 - 23 A. I don't think Eastern Health has a position on
 - 25 CROSBIE, Q.C.:

Q. All this time later?

- 2 MR. GULLIVER:
- A. Are you asking my opinion or are you asking 3
- what's Eastern Health's position on the 4
- 5 overall positivity rate?
- 6 CROSBIE, Q.C.:
- 7 A. Well, both. If your opinion is different from
 - something you know to be the official view of
- Eastern Health, you can let us know about it, 9
- but let's come back to your answer, you're not 10
- 11 sure that Eastern Health has a position on
- what its positivity rate was during the 12
- 13 relevant period?
- 14 MR. GULLIVER:
- A. I don't think Eastern Health has done an 15
- official release of data to say here was the 16
- official positivity rate. Again you're going 17
- back to a debate that's been going on for a 18
- long time, not just in Eastern Health, across 19
- a lot of labs, in what really is the 20
- definition of a positive, what's a positive, 21
 - what's a negative.
- 23 CROSBIE, Q.C.:

22

- Q. And so you can't give us the position of 24
- Eastern Health on that question? 25

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P	age 285	Page 287
1 MR. GULLIVER:		it to me, and that's why - and there's been
2 A. I can't, no.	2	some dispute over did I even ask him to do
3 CROSBIE, Q.C.:	3	that, and, you know, my point is I'm the only
4 Q. Thank you. I'd like to go back to these	4	one who gets addressed this one. He doesn't
5 Ejeckam memos, 113, page 5. I'm just loo	king 5	send the memo shutting down testing, he
for my paper copy because I have it mark	-	doesn't send me the memo putting testing back
7 Yes, it's page 5 of 113. So just to pick a	7	in place, but he - I'm the only one who he's
8 few things out of there we can note - nov	, 8	addressed this to, and he copies the clinical
9 first of all, this is the third memorandum,	9	chief, and I think Dr. Robb, but he addressed
June 19th, 2003. The earlier one, which y	ou 10	this one specifically to me because I asked
can look at if you want to, but you've	11	him any else with the lab, put it in writing,
probably seen it lots of times, it's at page	12	and then we sat down and we talked about it.
one, and it's April of 2003. That's the first	13 CROS	BIE, Q.C.:
one and it was addressed to pathologists a	nd 14 Q.	Could it be because you had budgetary
Barry Dyer, and all technical staff on	15	responsibility?
immunohistochemistry.	16 MR. G	GULLIVER:
17 MR. GULLIVER:	17 A.	I think that's a part of my role, yes.
18 A. It's addressed to pathologists across the	18 CROS	BIE, Q.C.:
province, and it's cc'd to	19 Q.	Well, let's look at what he's saying here.
20 CROSBIE, Q.C.:	20	Paragraph one, he's talking about physical
21 Q. CC'd, yeah.	21	location. Paragraph three, he's talking about
22 MR. GULLIVER:	22	the need for a dedicated staff. Over on page
23 A. To Barry and the technical staff in the IHC	23	two down toward the bottom of the paragraph,
24 lab.	24	he's talking about to do less would become a
25 CROSBIE, Q.C.:	25	gamble where you may win or lose?
P	age 286	Page 288
1 Q. So your evidence would be that this was	n't 1 MR. G	GULLIVER:
2 sent to you and it didn't find its way into	2 A.	Uh-hm.
3 your hands?	3 CROS	BIE, Q.C.:
4 MR. GULLIVER:	4 Q.	And talks about spelling disaster, and bottom
5 A. I found out from Mr. Dyer after the fact,	5	of page - paragraph four, he talks about an
6 after testing had been stopped.	6	activity being identified as special and
7 CROSBIE, Q.C.:	7	unique and requiring financing and staffing.
8 Q. So then if we go to the next one, we see M	-	At paragraph six -
9 2nd, 2003. This one is to pathologists -		GULLIVER:
10 MR. GULLIVER:		The next paragraph he compliments our existing
11 A. It's the same group as the other one, and		staff.
think it's CC'd to Mr. Dyer and technical		BIE, Q.C.:
13 staff.		Yes, he does, and in paragraph six, he speaks
14 CROSBIE, Q.C.:	. 14	of diagnosis and so on, jeopardizing patient
15 Q. Yes, same as before. So that's why I'm go	-	care, and at the bottom he says, "Therefore,
to ask you why the difference when we ge		advise you kindly take a hard look and then
17 June? That's addressed to you.	17	commit the necessary resources, human and
18 MR. GULLIVER:	18	financial, to this special all important and
19 A. Again I've said in my testimony with M		only service", and you described for us
20 Chaytor that - and this takes place - it's	20	earlier how your responsibility had to do with
seven weeks after he puts testing back in		budgeting and making sure that what was being
place. I had met Dr. Ejeckam over in the l		done was adequately budgeted for?
corridor and I had said to him that if there'	s 23 MR. G	SULLIVER:

25

A. That's a part of my overall responsibility as

the program director.

anything else that he views in the IHC part of

our lab, you know, put it in writing and send

24

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	,	_	4. 7.
	Page 289		Page 29
1	OSBIE, Q.C.:	1	estimated time. I still have a fair amount of
2 (Q. Sir, we know that this didn't find its way to	2	material here.
3	Dr. Williams, did it?	3	THE COMMISSIONER:
	. GULLIVER:	4	Q. Do you want to take the afternoon break?
	A. Not to my knowledge, no.	5	CROSBIE, Q.C.:
1	OSBIE, Q.C.:	6	Q. Probably a good place.
1	Q. Until much later.	7	(BREAK)
	GULLIVER:		THE COMMISSIONER:
1	A. Yeah.	9	Q. Please be seated. Mr. Crosbie.
	OSBIE, Q.C.:		CROSBIE, Q.C.:
1	Q. If human and financial resources had to be	11	Q. Thanks. Registrar, could we have Dr. Cook's
12	committed, that by itself would mean that this	12	testimony, July 2nd, 2008, page 262. What I'm
13	would have to go to Dr. Williams?	13	asking Dr. Cook about there is the follow-up
	GULLIVER:	14	to the Ejeckam memorandum, and as we've just
	A. If we had to find - if we had to ask for new	15	seen, the memorandum in June addressed to you
16	resources or additional resources.	16	had recommendations for various forms of
1	OSBIE, Q.C.:	17	action, Mr. Gulliver, including mention of
1	Q. When I read this, it sure looks to me like Dr.	18	resources that should be committed, and so I'm
19	Ejeckam thinks that necessary human and	19	just going to ask you to have a look at Dr.
20	financial resources be committed, meaning new	20	Cook's account. You can take your mouse there
21	ones. You had a different view?	21	if you would, and go from page 262 to 265.
	. GULLIVER:	22	Read that to yourself, and when you're through
1	A. No, I sat down with Dr. Ejeckam and we	23	I'm going to ask you if his account squares
24	discussed all parts of this here, and I've	24	with your recollection of how this transpired.
25	testified, as you probably read or heard, what	25	I might have said I asked the questions, but
	Page 290		Page 292
1	we did in response to this here for Dr.	1	it's obviously Mr. Coffey.
2	Ejeckam. It was physically moving the staff	2	MR. GULLIVER:
3	and the lab into its own dedicated space,	3	A. You want me to go to the end of 265?
4	which did not require new additional	4	CROSBIE, Q.C.:
5	resources. We took the current staff that	5	Q. Well, 265 is probably - that tells the story.
6	were working in the IHC lab with Dr. Ejeckam.	6	MR. GULLIVER:
7	He wanted them to be full time in the lab to	7	A. Okay.
8	spend more time with him for training and	8	CROSBIE, Q.C.:
9	read, as he says - as he outlines there. I	9	Q. And you notice at line 11, 265, Dr. Cook -
10	think Mr. Dyer took one of the technologists	10	well, he was asked just before that why he
11	from St. Clare's, moved them over to Health	11	wouldn't have spoken to Dr. Ejeckam about it.
12	Sciences to train them in to do the small	12	He said, "Because I felt an agreement or
13	grossing to replace part of the work these	13	understanding had been made with Mr. Gulliver
14	people were doing, and then the advancement in	14	to address his concerns". First of all, can
15	the new technology, new equipment to help with	15	you tell the Commissioner whether this seems
16	workload and productivity and volumes, I've	16	like a fair account of what transpired in
17	already testified we had enough money in our	17	relation to whatever meeting you had about Dr.
18	operating budget to be able to go out and	18	Cook and the question of following up on Dr.
19	acquire the Ventana system within existing	19	Ejeckam's concerns?
20	resources. So I didn't need to go to Dr.	20	MR. GULLIVER:
21	Williams to look for new resources for this	21	A. I think that's a fair account, that after Dr.
22	here.	22	Ejeckam and I and Barry had met in my office
23 CR	OSBIE, Q.C.:	23	and talked about, you know, June 19th memo,
24 (Q. Commissioner, I'll no longer be critical of	24	and the things that we could do, the time
25	Ms. Chaytor for going longer than her	25	frame that it would take, I think Dr. Cook and
1			

Multi-Page TM October 15, 2008 **Inquiry on Hormone Receptor Testing** Page 293 Page 295 I just spoke about it, and I let Dr. Cook know Q. There's no actual appraisal of what would be 1 2 what we had talked about, and I think this is 2 acted on and what would not be acted on? a fairly accurate account of what transpired. 3 3 MR. GULLIVER: A. In relation to what we could do? 4 CROSBIE, Q.C.: 5 Q. So what I get out of that is that the follow-5 CROSBIE, O.C.: up was informal in the sense there's nothing Q. In relation to what Dr. Ejeckam set out as 6 in writing? being his concerns. 7 7 8 MR. GULLIVER: 8 MR. GULLIVER: A. Yes. A. Well the concerns were the space, the staffing 10 CROSBIE, O.C.: 10 being dedicated and then to address the workload volumes and productivity. 11 O. Was there further oral communication between 11 12 you and Dr. Cook on the response to Dr. 12 CROSBIE, Q.C.: Eieckam's concerns? Q. There was no budget drawn up because you 13 13 didn't see those issues or any other issues 14 MR. GULLIVER: 14 A. Not specifically. I just think that over a raised by Ejeckam as requiring a commitment of 15 15 16 time period, I think that both Dr. Cook and I 16 fresh resources. saw that, you know, the laboratory itself was 17 MR. GULLIVER: 17 moving into its own space, knew that Mr. Dyer 18 A. It didn't seem to be at the time, no. had start putting a process in place to 19 19 CROSBIE, O.C.: retrain other techs in pathology to take over Q. And overall, you and Dr. Cook regarded the 20 20 the grossing function that the IHC techs were issues raised by Dr. Ejeckam as among a host 21 21 22 taking, thereby freeing them up to have more 22 of other issues of similar importance facing time down in the IHC lab, and I think that Dr. 23 23 the lab, the lab program? Cook knew - and this happened in late June. 24 MR. GULLIVER: 24 Again it's during the summer period with 25 A. I would say yes. Page 294 Page 296 vacations and things, and then I think in 1 CROSBIE, Q.C.: 1 September Mr. Dyer starts writing the tender Q. And the Ejeckam issues deserved no special 2 to go out to the marketplace looking for a new attention and no documentation of a special 3 3 nature and no special reporting? system. 4 4 5 CROSBIE, Q.C.: 5 MR. GULLIVER: Q. But there's no oral communication about the A. I think they required the attention that we 6 6 7 progress of this between you and Cook, is 7 gave them in talking to Dr. Ejeckam. Dr. Ejeckam seen the physical things that were 8 there? 8 taking place and, you know, what we committed 9 MR. GULLIVER: 9 to, it actually all took place. A. I don't think we had a separate meeting about 10 10 it, just thinking in just talking -11 CROSBIE, Q.C.: 11 Q. In your opinion, did Dr. Cook provide 12 CROSBIE, Q.C.: 12 appropriate leadership on the Ejeckam issues? Q. Oral communication. 13 13

14 MR. GULLIVER:

A. In speaking to Dr. Cook, yes.

16 CROSBIE, Q.C.:

17 Q. You did speak to him about the progress of these matters? 18

19 MR. GULLIVER:

A. To my knowledge, yes.

21 CROSBIE, Q.C.:

Q. Okay, nothing in writing, though, is there?

23 MR. GULLIVER:

A. No. 24

25 CROSBIE, Q.C.:

14 MR. GULLIVER:

A. I really don't think I could answer that. I 15 think that from my perspective, what was in my 16

17 realm of responsibility, talking about the

space, staff and equipment, that I think I 18

responded appropriately, along with Mr. Dyer 19

in conjunction with Dr. Ejeckam and Dr. Cook 20

was well aware of the things that were taking 21 place. 22

23 CROSBIE, Q.C.:

24 Q. I'd like to turn now to the question of some 25 statistics and I mentioned earlier about the

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Page 297 Page 299 O. So that was left for NLCHI to do. Gown affidavit and that's found at P-0375, 1 2 page 2 if the Registrar can take us there, 2 MR. GULLIVER: please? And page 2, paragraph 6, and that's 3 A. And I guess it looks like to me if you're 3 the reference there, "In reviewing the generic using the clinical guidelines as to what's a 4 4 data presented to me, it appeared that the ER negative and positive for this table, on the 5 5 bottom it says "30 percent cut off and 10 positivity rate was in the range of 65 to 75 6 6 percent for breast cancers analyzed at the percent". 7 7 laboratory during the time the DAKO instrument 8 8 CROSBIE, Q.C.: was employed. I have been advised that the 9 Q. Yes. Clinically negative. I want to come 9 10 seven year average was 74 percent ER 10 back to--so just to get that clear now, positivity." And that information would seem Eastern Health as far as you're aware doesn't 11 11 to be in sync with what you developed in your have a calculation or an official position on 12 12 spreadsheets? what a false negative rate was. 13 13 14 MR. GULLIVER: 14 MR. GULLIVER: A. Probably, yes. A. No, I think that NLCHI is doing some of that 15 15 16 CROSBIE, Q.C.: 16 analyses in the database and I think they're Q. Could we now bring up Exhibit P-1841? This is doing it, Mr. Crosbie, based upon a one 17 17 explained in the footnotes, Mr. Gulliver. It percent positivity, which would be, you know, 18 18 a positive result, but at one percent, ten was prepared by Dr. Hutton and it's based on 19 19 percent, 30 percent, looking at different cut information contained in those 20 20 interrogatories, the documents which we looked 21 21 offs. 22 at a little earlier. And it's simply a matter 22 CROSBIE, O.C.: of taking numbers and doing a little math on 23 23 O. Well I'm sure that will be revealed to us all them and arriving at percentages, and you'll in good time. I want to come to your--when 24 24 see in that top table there where Dr. Hutton you were talking to Ms. Chaytor and it was in 25 25 Page 298 Page 300 simply takes total test, total positives and relation to this NTV story from October 13th, 1 1 any of us could take the same information from 2 2 2005, you know the one that talked about new 3 the Predham answers to interrogatories and do technology with more accurate results and 90 3 the same calculations. We come up with a to 95 percent of patients won't be affected 4 4 5 calculation of a false negative rate and 5 and all testing would be complete in a month, percentage terms, and for the period in the that one? 6 6 7 top table, the period when the DAKO 7 MR. GULLIVER: autostainer was in use, the statistical 8 A. Yeah. 9 performance shows a 44 percent false negative 9 CROSBIE, Q.C.: rate. Are you in any position to dispute Q. You adopted the approach of talking about 3000 10 10 11 that? 11 patients, meaning, I guess, 3000 patients who 12 MR. GULLIVER: had been, on whom this test had been run in 12 the period '97 through 2005. 13 A. I'm really in no position to either agree or 13 disagree. This is the first time I've seen 14 14 MR. GULLIVER: 15 this kind of analysis. A. Well I think at that time, but that time, I 15 16 CROSBIE, O.C.: think that's October '05, I think that the day 16 17 Q. Have you calculated the false negative rate? 17 that we had available at that time was that I had seen through the computer searches that we 18 MR. GULLIVER: 18 A. No, I have not. 19 searched for ER/PR tests and there were approximately 3000 tests that were performed. 20 CROSBIE, O.C.: 20 Q. Nobody asked you to do that? 21 CROSBIE, O.C.: 22 MR. GULLIVER: 22 Q. Uh-hm. How does that relate to what we looked at in Exhibit P-3107 this morning at page 2 A. I think that's a part of what NLCHI has been 23 23 working on and doing some analyses. where the number 2700 and 26 appears? 24 24 25 CROSBIE, Q.C.:

25 MR. GULLIVER:

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1	A. Again, this here has been refined many times,	1	who were tested during this period were
2	this is dated January of '08, I think, over	2	affected, that's how you put it.
3	three years later. And by this time we've	3	MR. GULLIVER:
4	gone back through all the reports and verified	4	A. That would be affected by this whole retest
5	and patients who had ER/PR tests performed	5	process.
6	that weren't on the primary breast cancers	6	CROSBIE, Q.C.:
7	were removed from thefrom numbers.	7	Q. Uh-hm. Yet the patient group who stood to be
8	CROSBIE, Q.C.:	8	most affected would be the ones who tested
9	Q. Uh-hm, so you know, are we talking about	9	negative during the period, wouldn't they?
10	twenty seven hundred and something patients?	10	MR. GULLIVER:
11	MR. GULLIVER:	11	A. They would be, yes.
12	A. Who have ER/PR for primary breast cancer. But	12	CROSBIE, Q.C.:
13	in October '05, at that point in time, we	13	Q. There's something I don't understand here, so
14	wouldn't be at this with that final number, it	14	I'm going to ask you to try and enlighten me.
15	was an approximate number of 3000 patients who	15	I'm not sure if I picked up that there are
16	had an ER/PR test performed.	16	patients you discovered going through your
17	CROSBIE, Q.C.:	17	through Meditech and through the pathology
18	Q. All right.	18	reports, there were patients for whom ER/PR
19	THE COMMISSIONER:	19	had not been requisitioned, do I understand
20	Q. For whatever reason.	20	that to be the case?
21	MR. GULLIVER:	21	MR. GULLIVER:
22	A. For whatever reason, yes.	22	A. They were not ordered in the Meditech system,
23	CROSBIE, Q.C.:	23	yes.
24	Q. And do I get that there may be another hundred	24	CROSBIE, Q.C.:
25	who had the test for tumours of unknown	25	Q. They were not ordered.
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1	primary origin?	1	MR. GULLIVER:
2	MR. GULLIVER:	2	A. Yeah.
3	A. Could be more than that, a bit more than that,	3	CROSBIE, Q.C.:
4	yes.	4	Q. And therefore not done?
5	CROSBIE, Q.C.:	5	MR. GULLIVER:
6	Q. How many?	6	A. Oh they were done. So what would happen, Mr.
7	MR. GULLIVER:	7	Crosbie, the pathologists who were in the
8	A. I can't tell you an exact number, but I mean,	8	reporting room most of times doing their
9	it's somewhere between this number and 3000.	9	readings, they would fill out a manual IHC
10	It could be 150, it could be 175.	10	requisition form and then that form would go
11	CROSBIE, Q.C.:	11	to the technologist to perform the testing,
12	Q. Okay. And do you know what the current	12	but then the technologist would do the data
13	estimate of the number of patients tested	13	entry and put their request in the computer
14	false positive is now?	14	system on behalf of the pathologist to say Dr.
15	MR. GULLIVER:	15	So and So wants an ER/PR on this patient. And
16	A. No, I don't.	16	they would go and physically order the test in
ı			
17	CROSBIE, Q.C.:	17	the computer system and then when the slides
17 18	CROSBIE, Q.C.: Q. That we get from NLCHI, does 386 mean anything		
l		17	were completed, they would go back and say and
18 19	Q. That we get from NLCHI, does 386 mean anything	17 18	were completed, they would go back and say and they're now complete and done and bring them back. We came across, you know, there were a
18 19	Q. That we get from NLCHI, does 386 mean anything to you?	17 18 19	were completed, they would go back and say and they're now complete and done and bring them
18 19 20 21	Q. That we get from NLCHI, does 386 mean anything to you?MR. GULLIVER: A. No.CROSBIE, Q.C.:	17 18 19 20	were completed, they would go back and say and they're now complete and done and bring them back. We came across, you know, there were a handful of situations where that function was not completed by the technologist and again,
18 19 20 21	 Q. That we get from NLCHI, does 386 mean anything to you? MR. GULLIVER: A. No. CROSBIE, Q.C.: Q. It doesn't. So from your experience, though, 	17 18 19 20 21	were completed, they would go back and say and they're now complete and done and bring them back. We came across, you know, there were a handful of situations where that function was not completed by the technologist and again, over the almost 3000 total ER/PR tests done, I
18 19 20 21 22 23 24	 Q. That we get from NLCHI, does 386 mean anything to you? MR. GULLIVER: A. No. CROSBIE, Q.C.: Q. It doesn't. So from your experience, though, you told Ms. Chaytor that you thought that 	17 18 19 20 21 22 23 24	were completed, they would go back and say and they're now complete and done and bring them back. We came across, you know, there were a handful of situations where that function was not completed by the technologist and again, over the almost 3000 total ER/PR tests done, I think we came across eight or nine or ten
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·	i-rage inquiry on from one receptor resung
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transcribed into the computer record.	1 CROSBIE, Q.C.:
2 CROSBIE, Q.C.:	2 Q. Well it wouldn't be a retest because you
3 Q. Uh-hm. But you could discover a result	3 couldn't figure out if it had been tested
4 because the testing was done.	4 already.
5 MR. GULLIVER:	5 MR. GULLIVER:
6 A. The testing was done and the pathologist had	6 A. I think when we went through them, there were
7 put the result into the computer systemin	7 original slides, but there was no result
8 the patient's report.	8 documented into the computer system.
9 CROSBIE, Q.C.:	9 CROSBIE, Q.C.:
10 Q. So there was a result there to be looked at?	10 Q. So did someone read the slide before the block
11 MR. GULLIVER:	or whatever was sent to Mount Sinai?
12 A. Yes.	12 MR. GULLIVER:
13 CROSBIE, Q.C.:	13 A. I don't know what Dr. Cook or Dr. Fontaine did
14 Q. Okay, so that actually didn't result in any	14 with the -
distortion of anything, it was just a matter	15 CROSBIE, Q.C.:
of maybe, well it's just a matter of finding	16 Q. Yeah, this may be a small effect, but I'm
out what the result as entered by the	guessing that the two or three people for whom
pathologist was?	no result could be found, either not reported
19 MR. GULLIVER:	or because the test was not done, well they
20 A. Right.	20 can't show up in the false negative rate
21 CROSBIE, Q.C.:	21 because there's no -
Q. Then was there a category of patients for whom	22 MR. GULLIVER:
ER/PR was requisitioned but there was no test	23 A. I know and that was so small that really it's
or no report andor have I got that wrong.	not going to change significantly anything on
25 Is that the same thing you just described to	25 these spreadsheets here.
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Page 306	
	1 CROSBIE, Q.C.:
1 me? 2 MR. GULLIVER:	1 CROSBIE, Q.C.: 2 Q. However, I suppose they could have been
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	Page 3
1	if you had any suggestion as to why that would
2	be?
3 N	MR. GULLIVER:
4	A. It reallyI really can't comment on that.

- 5 CROSBIE, Q.C.:
- Q. Okay. Now if I could ask you about standard 6 operating procedure manuals, you know who I 7
- mean by Dr. Dabbs? 8
- 9 MR. GULLIVER:
- A. I know he was here, I didn't hear his 10 testimony but I know he was here. 11
- 12 CROSBIE, Q.C.:
- Q. Eminent authority in lab medicine, pathology, 13
- IHC testing and so forth. Anyway, you've 14
- heard of him, right? 15
- 16 MR. GULLIVER:
- A. I've heard of him, yes. 17
- 18 CROSBIE, Q.C.:
- Q. And you know he testified here.
- 20 MR. GULLIVER:
- 21 A. Yes.
- 22 CROSBIE, O.C.:
- Q. So, sir, when you were lab manager, there was 23 no SOP in the sense that the witnesses we've
- 24
- heard here have described it. there's no SOP 25

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for ER/PR testing, was there? 1

- 2 MR. GULLIVER:
- A. Well, you've seen what we submitted is that we 3
- had a procedure and multiple procedures, but 4
- 5 they certainly were not to the level of what
- Trish would have expected to see and that's 6
- 7 well documented now.
- 8 CROSBIE, O.C.:
- Q. They were manufacturer specs and procedures 9
- marked up by you in your handwriting, and 10
- 11 maybe others?
- 12 MR. GULLIVER:
- A. Well they were marked up by me after the fact 13
- in submitting them to the Inquiry. 14
- 15 CROSBIE, Q.C.:
- Q. Okay. So you didn't see a need for an SOP?
- 17 MR. GULLIVER:
- A. No, I've never said that.
- 19 CROSBIE, Q.C.:
- O. You didn't have one.
- 21 MR. GULLIVER:

25

- A. Well we did have an operating procedure and 22
- protocols, we didn't have them in a format and 23
- a template as I've testified that Trish would 24
 - expect in Mount Sinai, that one would expect

if you were going through an accreditation

Page 311

- 1 2 process like the QMPLS process in Ontario and
- we didn't have them in formats like the 3
- Clinical Lab Standard Institute from the 4
- 5 United States, as what Trish had recommended.
- And when you're able to have those in those 6
- templates, you know, you're able to have them 7
- signed off by the signing authorities, you 8
- have to put a date there when they must be 9 10
 - reviewed over a certain period of time -
- 11 CROSBIE, O.C.:
- Q. This is what we've heard. 12
- 13 MR. GULLIVER:
- 14 A. And those are things that we did not do. I
- mean, that's well--we've acknowledged that. 15
- 16 CROSBIE, Q.C.:
- Q. At the time you thought what you had was 17
- 18 enough?
- 19 MR. GULLIVER:
- A. At the time I thought what we had was enough 20
- for the staff to perform the procedure 21
- correctly. We were following the protocols 22
- and again, we relied heavily upon the 23
- pathologists' feedback and their 24
- interpretation. 25

Page 312

- 1 CROSBIE, Q.C.: Q. Dr. Dabbs told the Inquiry that the absence of
- an SOP in the sense we're talking about, is a 3
- recipe for disaster. In retrospect, do you 4
- agree?
- 6 MR. GULLIVER:
- 7 A. I think in retrospect there's a lot of things
- 8 we had absent.
- 9 CROSBIE, Q.C.:
- Q. That you rather you'd have. 10
- 11 MR. GULLIVER:
- A. Yes. 12
- 13 CROSBIE, Q.C.:
- Q. That might have made for a better quality 14
- test. 15
- 16 MR. GULLIVER:
- 17 A. I think that would have made for minimizing
- the risk or chance of reducing our false 18
- negatives because you're going to have false 19
- negatives. We obviously had more false 20
- negatives than you would see in most other 21
- major teaching labs. 22
- 23 CROSBIE, Q.C.:
- Q. And NLCHI will tell us exactly how many that 24 was. Madam Registrar, could I ask you to go 25

			use	inquity on Hormone Receptor Testing
	Page 313			Page 315
1	to Dr. Cook's transcript again, page 232?	1		But at the time, Mr. Crosbie, '97, you know,
2	Here, Dr. Cook is being asked by Mr. Coffey,	2		we looked at what resources were required to
3	it's between pages 232 and 236, about cost	3		actually perform the testing. There was no
4	benefit analysis. Because we remember that	4		thought given to well let's now, because we're
5	you and Dr. Cook signed, as co-authors, a	5		doing ER/PR testing, let's now hire pathology
6	proposal in October, 2005 and you were taken	6		assistants, let's now put in this or this. I
7	through that in the last few days.	7		mean, it wasn't thought of back then.
8	MR. GULLIVER:	8		BIE, Q.C.:
9	A. Yes.	9		Well with the luxury of hindsight, it might
10	CROSBIE, Q.C.:	10		seem to some people that the question should
11	Q. Which came up with a budget and you defined a	11		have been asked what resources, human and
12	goal and the goal was to provide an equivalent	12		financial, were going to be required to do
13	ER/PR and immunohistochemical testing service,	13		this testing service in the new manner, moving
14	equivalent to that of the reference lab in	14		it from biochemistry over to histology, to an
15	Mount Sinai, that was your goal?	15		acceptable standard. And if the answer was
1	MR. GULLIVER:	16		that the authorities in the organization were
17	A. And that submission was more to do with the	17		not prepared to fund those resources, then it
18	resources required to work towards that goal.	18		shouldn't have been done.
1	CROSBIE, Q.C.:			GULLIVER:
20	Q. Right. There's a budget in there too,	20		Well I'm saying to you what was done, the
21	\$282,000 is what you estimated at the time and	21	11.	authorities in the organization were not asked
22	I think you said it's actually turned out to	22		for additional resources. Dr. Khalifa worked
23	cost more.	23		with Dr. Prabhakaran in biochemistry. It was
1	MR. GULLIVER:	24		moving a testing methodology from biochemistry
25	A. I think we spent more than that, yes.	25		to pathology to another part of the
23		23		
	Page 314			Page 316
1	Page 314 CROSBIE, Q.C.:	1		Page 316 laboratory, and we already had two
1 2	Page 314 CROSBIE, Q.C.: Q. So your initial thought that reallocating	1 2		Page 316 laboratory, and we already had two technologists who were skilled in doing IHC
1 2 3	Page 314 CROSBIE, Q.C.: Q. So your initial thought that reallocating \$20,000 or thereabouts from the biochemical	1 2 3		Page 316 laboratory, and we already had two technologists who were skilled in doing IHC testing. The biggest obstacle would have been
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1 2 3 4 4 5 6 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Page 314 CROSBIE, Q.C.: Q. So your initial thought that reallocating \$20,000 or thereabouts from the biochemical laboratory in 1997, that turned out not to be a correct assumption. MR. GULLIVER: A. At the time it was the right assumption, that's how much money was required to start performing the ER/PR procedure in that IHC lab under the guidance of Dr. Khalifa. CROSBIE, Q.C.: Q. To what standard? MR. GULLIVER: A. Well what you see in 2005 is really a report that addresses the pathology laboratory overall, where a new resources where we now have approval to create pathologist assistants, i.e. we take technologists and train them up to do the grossing, that was a large chunk of the new resources required for that report. We also asked for, I think a fulltime med lab assistant and those things	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	CROSS Q. MR. G A.	Page 316 laboratory, and we already had two technologists who were skilled in doing IHC testing. The biggest obstacle would have been having a pathologist with the expertise to interpret the testing. And we had that, we now had that pathologist on site in St. John's, Dr. Khalifa and the resources required was the actual operation's money to order the supplies and reagents in order to add that to the existing pool of antibodies that was taking place in the pathology lab. BIE, Q.C.: So a lot of the difference, by the time you got to 2005, October, and signed that joint proposal with a budget with Dr. Cook, is that you knew a lot more about what was required to do this right, than you did in 1997? GULLIVER: I think we realized in 2005 that a large segment of an issue, as we've talked about the possibility of specimens being not fixed properly or grossed properly and if the

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			Page 317
1		core team of people to do all the surgical	
2		grossing, and that would require the	
3		additional hire of four new staff and training	
4		of those four staff. I mean, what else we've	
5		learned since 2005 is obviously we	
6		wholeheartedly agree with all the	
7		recommendations from Ms. Wegrynowski ar	nd from
8		Dr. Banerjee, you know, is the documentation	on
9		of all the work processes in pathology,	
10		including technical and clinical. We've also	
11		learned that we started this test with Dr.	
12		Khalifa, who in my opinion was an expert i	n
13		breast pathology in this field, and we now	
14		have gone back to that process where we have	e a
15		dedicated team of pathologists ensuring that	-
16		they are reading all of those slides.	
17	CROS	BIE, Q.C.:	
18	Q.	There is no defined objective back in 1997,	
19		was there, nothing set down in writing?	
20	MR. G	ULLIVER:	
21	A.	To my knowledge, I don't remember Dr. Kh	alifa
22		doing anything in writing as an objective. I	
23		just think it was something that he worked	
24		with, the biochemistry staff and our clinical	
25		chief at the time and the program director an	d
			Page 318

1 MR. GULLIVER:

- A. Well, the budget piece was done, that I had submitted an official request to Mr. Whelan to 3 say that in our estimation it will cost 4
- \$20,000.00 additional to perform this testing 5

came forward and said that there was a new way to do this test, it would mean that there would be a permanent record kept, where it was done in pathology on a paraffin block and a glass slide. It also meant the patients didn't have to go through a lumpectomy to get a sample for chemistry, it could be done using a biopsy, so it was much more less

10 CROSBIE, O.C.: Q. And I think we understand the reasons why this was considered to be a good shift, but what

I'm saying is there is no defined objective,

in terms of quality or standard for this 14

15 testing to meet, no institution was

referenced, like Mount Sinai and there is no 16

17 budget drawn up for the resources needed to

achieve that objective. And I think the 18

answer to that is quite obviously, yes, there

was no such thing. 20

intervention.

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in pathology, and my recommendation would -1

2 was that resources that were currently used in

chemistry to perform the test, to switch those 3

resources to the pathology budget. The other 4

5 piece of it, Mr. Crosbie, to my knowledge, was not done, but I think that Dr. Khalifa should

6 7 be asked that question.

8 CROSBIE, O.C.:

9 Q. Indeed, and the \$20,000.00 was estimated and sought at the time when your understanding of 10 11 the test was much more in its beginning stages than it became? 12

13 MR. GULLIVER:

14 A. No, at that time I knew how much it was going to cost because Dr. Khalifa - we had gotten 15 the cost from DAKO to purchase reagents and 16 17 Dr. Khalifa had given an estimate of how many patients we expect to do a year, and we 18 19 estimated it was going to cost on average about \$100.00 per patient, and he figured it 20 would be about 200 cases done a year, times 21 22 100 was \$20,000.00.

23 CROSBIE, Q.C.:

Q. Could we bring up Dr. Cook, page 303 to 304. 24 25 REGISTRAR:

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October 15, 2008 Mul	lti-Page [™] Inquiry on Hormone Receptor Testing
Page 32	0 Page 322
1 Q. I think you're looking for July 7th.	division and other divisions may take
2 CROSBIE, Q.C.:	2 exception to that assessment that they're a
3 Q. Yeah, it's not the right date. Thank you, by	3 community lab and not a university teaching
4 the way for straightening this out. I think	4 lab.
5 the Registrar was concerned it was about to	5 CROSBIE, Q.C.:
6 topple over.	6 Q. Sir, let me put something to you. In ER/PR
7 THE COMMISSIONER:	7 testing, the lab could have performed to the
8 Q. We're very conscious of quality control, Mr.	8 standard of Mount Sinai if the service had
9 Crosbie.	9 been established on sound principles and
10 CROSBIE, Q.C.:	adequately resourced from the start. Do you
11 Q. And health and life safety. So is this what	11 agree?
we're looking for? Okay, so right about line	12 MR. GULLIVER:
13 11, page 303 and then just over to 304.	13 A. I think from the start it was sound principles
14 MR. GULLIVER:	because I think that we had the luxury of
15 A. Start reading page 303?	having Dr. Khalifa here to put that testing in
16 CROSBIE, Q.C.:	place, we had the luxury of him reviewing the
Q. Yes. You see there that Dr. Cook is saying	control slides, and we had the luxury of him
that we were in reality nothing more than a	pretty well doing almost all the
glorified community lab. As a lab man, could	interpretations, and we had the resources at
we have your comment on that?	20 the time to perform the testing. We didn't
21 MR. GULLIVER:	have the resources at the time to have a level
22 A. Well, I think Dr. Cook is actually stating	of documentation of what we see today.
that, I think, in retrospect, and I think Dr.	23 CROSBIE, Q.C.:
Cook is probably talking about, in particular,	24 Q. That's your comment?
25 the pathology department. I don't think that	25 MR. GULLIVER:
Page 32	1 Page 323
1 he's talking about the lab medicine program.	1 A. I think that's - well, you've asked for my
2 I think he's talking about pathology, in	2 opinion and that's how I feel.
particular, and I guess by the time Don gives	3 CROSBIE, Q.C.:
his testimony this summer, you know, we've	4 Q. If the service could not be established with
seen that as a university teaching hospital,	5 adequate resources, it should have been
6 when it came to our pathology department, and	6 referred out.
you look at our practises - for example,	7 MR. GULLIVER:
8 pathologist assistants, you know, most major	8 A. And I submit to you that when the service was
9 tertiary care hospitals, teaching hospitals in	9 started with Dr. Khalifa, we had adequate
the country, had long ago had pathologist	resources to perform the testing and do the
assistants that would assist the pathologists	interpretations.
and do - standardize the fixation, grossing,	12 CROSBIE, Q.C.:
and those practices. Most university teaching	13 Q. Including the human resources in the form of
hospitals in this country would have had	expertise on the bench?

A. Well, the two technologists had been - had ten

15 MR. GULLIVER:

16

17 years experience in IHC testing, and you've 18 heard Dr. Khalifa who came in from Sunnybrook and testified. He said when he first came to 19 St. John's and he had come from Washington, 20 21 DC, and other large centres, he said that he 22 was impressed with the level and quality of service from the technologists in the IHC lab. 23 24 CROSBIE, Q.C.: 25 Q. And he must have been of the view that your

Page 320 - Page 323

dedicated technologists and managers that

Q. These things were missing back in the period?

A. Well, they're missing up until just recently,

and I think that's - what Dr. Cook is

referring to, I certainly - when you look at

other parts of our laboratory medicine

program, I think, you know, our biochemistry

oversaw quality management for laboratory

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services.

18 CROSBIE, Q.C.:

20 MR. GULLIVER:

Page 324 Page 326 staff in the lab adequately understood the 1 1 CROSBIE, O.C.: Q. My question is what, if any, personal 2 delicacy of the test? responsibility do you take for the women who 3 MR. GULLIVER: 3 A. Again you'll have to ask Dr. Khalifa that. feel that they should have had therapy earlier 4 than they have. He can answer or not. 5 CROSBIE, Q.C.: 5 Q. Lastly, Rosalind Jardine testified here in 6 THE COMMISSIONER: April. She was one of the patients who 7 O. Are you saying he can answer or not? You're testified initially. I spoke to her myself 8 8 giving the witness an opportunity to answer last week, I met with her, and she continues the question if he wishes, is that the idea? 9 10 well, you may be pleased to know, 10 CROSBIE, Q.C.: Commissioner, although she - and she knew at Q. Yes, I can hardly - I'm not going to beat him 11 11 12 that time that she'd had a recurrence. She's 12 around the head if he doesn't want to answer in her 50s, and she believes that she should that. 13 13 have been on Tamoxifen several years before it 14 14 MR. SIMMONS: was offered. In relation to ER/PR testing Q. Well, Commissioner, even doing that is putting 15 15 16 problems, what if any personal responsibility 16 the weight on Mr. Gulliver to decide whether do you take for that? he feels the pressure to address a question 17 17 like that. Personal responsibility is not 18 MR. SIMMONS: 18 19 O. Commissioner, I don't think that's a fair 19 within the mandate of really of what the question for Mr. Gulliver. It's not grounded Commission is all about. It's getting -20 20 in any particular evidence (inaudible). The 21 21 THE COMMISSIONER: 22 analysis is just an open ended question. I 22 Q. It is true that I'm not to determine any personal liability in respect of any 23 don't think it's fair that now Mr. Gulliver 23 particular person, as Mr. Crosbie knows all 24 has to respond to -24 too well. The question of liability is -25 CROSBIE, Q.C.: 25 Page 325 Page 327 Q. I'm attempting to give the question of 1 CROSBIE, Q.C.: 1 2 responsibility a human face, Commissioner, and Q. Well, strike the word "personal". 3 that's somebody who testified here back six 3 THE COMMISSIONER: months ago. My suggestion is that the patient Q. Is to be determined elsewhere, but what you 4 4 5 population whose lives are involved in this 5 are - if you are giving this witness an would like to hear from the responsible opportunity to comment on a personal level 6 6 7 persons in Eastern Health whether and to what 7 about the circumstances of the patients, then 8 extent they accept responsibility for what I'm prepared to let him comment if he wishes 8 to do so. He does not have, however, to -9 these patients have had to endure. 9 he's not obliged to do so. So do you 10 11 Q. Commissioner, there's been many witnesses from 11 understand what's happened? 12 Eastern Health that Mr. Crosbie has had the 12 MR. GULLIVER: 13 opportunity to ask such questions to, if he 13 A. I do, and I think my answer would be that my closing statement will probably answer that. 14 wanted to depose them, the proper position 14 15 THE COMMISSIONER: 15 would have been to depose them to someone like Q. Okay. So it appears, Mr. Crosbie, that there 16 the CEO or people in authority to speak up now 16 17 within the organization. He hasn't chosen to 17 will be an answer. Mr. Simmons. 18 address other witnesses from Eastern Health in 18 MR. SIMMONS: 19 Q. Thank you, Commissioner. this way. And I don't think he should now be 20 put in a position - Mr. Gulliver shouldn't be 20 THE COMMISSIONER: 21 put in a position to have to take that kind of 21 Q. Mr. Simmons, do you want that left as it is? 22 burden and responsibility upon himself to Are you prepared to enter into this dangerous 22 ground? 23 answer that question. 23 24 MR. SIMMONS: 24 THE COMMISSIONER: 25 Q. I think the quality assurance manager has 25 Q. Your question again was?

23

25

24 MR. GULLIVER:

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		Pag	e 328	
1		addressed it satisfactorily. I won't be long,		1
2		Commissioner. Mr. Gulliver, you'll be happy		2
3		to know I won't be very long either.		3
4	MR. TI	ERRY GULLIVER - EXAMINATION BY MR. DAN SIMMO	NS	4
5	MR. SI	IMMONS:		5
6	Q.	I just had actually one very specific thing to		6
7		ask you about. I'd like to have Exhibit P-		7
8		1373 again, please. This is one that Ms.		8
9		Newbury showed you, and it's an e-mail message	,	9
10		from Heather Predham to a number of people,		10
11		not to you, on May 18th, 2006, and there was a		11
12		table attached to it here. You'd said you		12
13		weren't familiar with the particular message.		13
14		In the text of it, Ms. Predham says that		14
15		"Kara", and that would be Dr. Laing, the		15
16		oncologist, "and I reviewed the retrolist and		16
17		here is the final list that will need to be		17
18		reviewed", and attached to it there is a table		18
19		which has, I think, eight separate lines there		19
20		for separate entries. I'm going to ask you		20
21		just to presume that the four that were		21
22		ultimately identified as the retro converters		22

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24

11

1 MR. SIMMONS: Q. And you'll see that there's an original ER 2 result, an original PR, a Mount Sinai ER, and 3 a Mount Sinai PR, and if we look at the first 4 5 entry across, the name and the specimen numbers and the RS numbers are all blocked 6 7 out. I'm going to ask you to assume that the 8 first line there has a specimen number for 1999. 9 10 MR. GULLIVER: 11 A. I was just going to ask that question, what year are these from?

are included on these listed here.

A. I think they are, yes.

12 13 MR. SIMMONS: 14 Q. Assume the first one is from 1999. original ER of 25 to 30, would that specimen 15 have met the criteria for retesting of 16 negatives? 17 18 MR. GULLIVER: A. Yes. 19

20 MR. SIMMONS: 21 Q. Okay, and -22 MR. GULLIVER:

A. Again I had testified that anything we seen 23 24 close to even the 25 to 30, even, say, 25 to 35, that those patients were all put on the 25

spreadsheet to be reviewed for retesting.

MR. SIMMONS:

Q. Right, and the second entry there, assume as well that the second entry is from the period prior to the year 2000.

MR. GULLIVER:

A. So that would be retested, yes.

MR. SIMMONS:

Q. That one has an original ER of 30. So that would be considered a clinical negative and selected for retesting? MR. GULLIVER:

A. Yes.

MR. SIMMONS:

Q. And the remaining entries there are either

negative 10 or WP, and do you know what WP

would indicate?

MR. GULLIVER:

A. Well, that means it would have said a weak positive would have been the interpretation in

the patient's report.

22 MR. SIMMONS:

23 Q. So all of these entries here, would these all

have met the criteria for selection for

25 retesting at Mount Sinai?

1 MR. GULLIVER:

A. Yes.

3 MR. SIMMONS:

Q. And would any of them have been considered

positives, which would have been excluded from 5

the retesting? 6

7 MR. GULLIVER:

A. No, no.

9 MR. SIMMONS:

Q. Okay. So - and in these particular cases, 10

these tests then were reported by Mount Sinai 12

as having an ER and PR of zero or very low

13 numbers?

14 MR. GULLIVER:

A. Uh-hm.

16 MR. SIMMONS:

17 Q. Now aside from any cases where there is no

order entered for a test, can we safely say 18

that all cases like these where the original 19

ER fell within the testing criteria were 20

selected for retesting and have been retested? 21

22 MR. GULLIVER:

A. Yes, every one. 23

24 MR. SIMMONS:

25 Q. So there would be no other similar cases that

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Page 332	Page 334
we're aware of that we could locate?	1 MR. GULLIVER:
2 MR. GULLIVER:	2 A. Thank you. It's a short statement. Over
3 A. No.	3 these past few days, and months, the
4 MR. SIMMONS:	4 Commission has heard from various witnesses,
5 Q. That need to be retested, okay. Now another	5 including myself, regarding the years of cost
6 example here, if we look at the third line,	6 cutting and downsizing that impacted
7 there's one there from Carbonear which had an	7 laboratory medicine. The laboratory, in my
8 original ER negative and an original PR of 50	8 opinion, has for years been viewed as a call
9 to 60, and that original PR, 50 to 60, would	9 centre within the health care system, and in
be above the - if the cutoff were being	difficult financial times, the laboratory was
applied to it, that would be considered a	required to reduce expenditures. This inquiry
positive result, correct?	has put the laboratory and the health care
13 MR. GULLIVER:	system in general under the microscope. The
14 A. For PR.	laboratory, I feel, is now viewed as a value
15 MR. SIMMONS:	centre and not a call centre, as we are now
16 Q. For PR.	recognized for the critical role we play in
17 MR. GULLIVER:	patient care. Eastern Health laboratories,
18 A. Yes.	with its 500 staff, produce over 10 million
19 MR. SIMMONS:	19 results every year that physicians and
20 Q. And but since the ER is negative, then that	20 patients rely upon for diagnosis, prognosis,
21 was -	treatment, and preventive care. Even though
22 MR. GULLIVER:	the laboratory and health care in general
23 A. Was an automatic retest.	23 underwent many years of downsizing and reduced
24 MR. SIMMONS:	24 budgets, I feel that every technologist,
25 Q. Selected for retesting.	25 pathologist, manager, oncologist,
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1 MR. GULLIVER:	administrator, came to work every day and did
2 A. Yeah.	their best to serve our patients. However, at
3 MR. SIMMONS:	3 times our best was not good enough for some of
4 Q. Okay. So among all the tests that were	4 our patients, and when I say patients, that
5 identified and reviewed for retesting, are	5 includes my family, your families, co-workers
6 there any cases where there was a negative ER	6 and my friends. The list of approximately
7 and a PR that was 30 or higher which were	7 1000 patients that I helped organize for
8 excluded from retesting?	8 retesting was not just a list of names. The
9 MR. GULLIVER:	9 list included friends of mine and staff.
10 A. No, none.	During this review process, I lost a very dear
11 MR. SIMMONS:	friend of mine, she was 40 years old, due to
12 Q. No. So every case that falls into that	breast cancer. In the summer of 2005 when the
category has been retested, and if any of	decision was made to review and retest all
14 those were to have changed to	patients that tested negative, I was in full
negative/negative on retesting, we would be	support because as a laboratory professional,
aware of them?	is support occurse as a laboratory professionar,
	16 I felt a duty to do anything I possibly could
17 MR. GULLIVER:	
17 MR. GULLIVER: 18 A. Yes.	I felt a duty to do anything I possibly could to help serve our patients. However, at that time I never realized the full magnitude of
	I felt a duty to do anything I possibly could to help serve our patients. However, at that
18 A. Yes.	I felt a duty to do anything I possibly could to help serve our patients. However, at that time I never realized the full magnitude of
18 A. Yes. 19 MR. SIMMONS:	I felt a duty to do anything I possibly could to help serve our patients. However, at that time I never realized the full magnitude of the issue and the enormous amount of time it
 18 A. Yes. 19 MR. SIMMONS: 20 Q. Okay. Now Mr. Gulliver, I understand you do 	I felt a duty to do anything I possibly could to help serve our patients. However, at that time I never realized the full magnitude of the issue and the enormous amount of time it was going to take. Myself, my manager,
 18 A. Yes. 19 MR. SIMMONS: 20 Q. Okay. Now Mr. Gulliver, I understand you do 21 have a statement that you would like to make. 	I felt a duty to do anything I possibly could to help serve our patients. However, at that time I never realized the full magnitude of the issue and the enormous amount of time it was going to take. Myself, my manager, technologists, and pathologists were focused
 18 A. Yes. 19 MR. SIMMONS: 20 Q. Okay. Now Mr. Gulliver, I understand you do 21 have a statement that you would like to make. 22 MR. GULLIVER: 	I felt a duty to do anything I possibly could to help serve our patients. However, at that time I never realized the full magnitude of the issue and the enormous amount of time it was going to take. Myself, my manager, technologists, and pathologists were focused on reviewing, identifying, and getting samples

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7

- retesting, and after thousands of additional hours of work by our laboratory staff and others, the work still continues. You have
- 4 heard through this inquiry that much good as
- 5 come from this. You have heard that our
- laboratory today has improved tissue fixationand tissue preparation.
- and dissue preparation.
- 8 MR. GULLIVER:

1

- A. ... You have heard that our laboratory has 9 improved its testing and the documentation of 10 the testing. You have heard that our 11 12 laboratory has improved its reporting and interpretation of this testing and you have 13 14 also heard that our oncologists have improved the clinical treatment based upon this 15 16 testing.
- All of the above would not be possible
 without the support of Government, Eastern
 Health and the new resources that have been
 added to the laboratory and other parts of the
 health care system, and this support must
 continue.
- 23 We, in the laboratory, and all parts of

- 1 other questions, Commissioner.
- 2 THE COMMISSIONER:
- 3 Q. Do you have anything arising, Ms. Chaytor?
- 4 MR. TERRY GULLIVER, EXAMINATION BY SANDRA CHAYTOR, Q.C.
- 5 CHAYTOR, Q.C.:
- 6 Q. Just one. I don't know if you can see me or
 - not, but hopefully you can hear me. This
- 8 arose out of a question, Mr. Gulliver, that
- 9 Mr. Crosbie asked you, and Registrar, if we
- 10 could have, please, P-1852? In asking about
- 11 the standard operating procedures at the time,
- 12 I think it's at page nine of this exhibit, and
- you were brought to this exhibit which was
- 14 filed as part of the appendix to the answers
- 15 to interrogatories at the time, and I believe
- you are indicating that this would be the standard operating procedures that the staff
- standard operating procedures that the staff, the technologists, would have been using in
- 19 performing the ER/PR tests throughout the
- period that the DAKO machine was used?
- 21 MR. GULLIVER:
- 22 A. Yes.
- 23 CHAYTOR, Q.C.:
- 24 Q. Okay, and I understood you to say to Mr.
- 25 Crosbie that you did have a procedure and this

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1 ...

- is your procedure, but not to the level -
 - 2 MR. GULLIVER:
 - 3 A. This is the antibody specification sheet
 - 4 you're showing here.
 - 5 CHAYTOR, Q.C.:
 - 6 Q. Yes, on this page. I think page six,
 - 7 Registrar, it begins? Unfortunately, my
 - 8 mouse--oh, here it is, okay. Maybe it's page-
 - 9 -here we go. Well, we saw it in one of the
 - 10 exhibits.
 - 11 MR. GULLIVER:
 - 12 A. Yes.
 - 13 CHAYTOR, Q.C.:
 - 14 Q. It was the -
 - 15 MR. GULLIVER:
 - 16 A. The actual step-by-step procedure.
 - 17 CHAYTOR, Q.C.:

25

- 18 Q. Yes, the step by step, and then it was the 19 specification sheet, and I just understood you
- to say that you had a procedure in place,
- while it might not have been to the standard
- that Trish Wegrynowski would have expected,
- 23 that you did have a procedure in place, and I
- think you said it may not have been to the
 - level she expected or the format that she was

- the health care system that are involved in
- breast cancer testing and treatment, havegained a huge amount of knowledge through this
- 4 whole process. When I started my testimony
- 5 here, it was Canadian Patient Safety Week and
- 6 this year's theme is knowledge is the best
- 7 medicine. My hope and my vision is that the
- 8 knowledge gained through the past three years,
- and in particular, the knowledge gained from this Commission of Inquiry, is truly used to
- ensure that Eastern Health's laboratory will
- be recognized as a leader within Canada. I
- hope that our laboratory will be given the resources to do so and I feel that we have
- dedicated and qualified technologists and
- pathologists and support staff to help us
- achieve that goal.
- In closing, I would like to thank you,
- Madam Justice Cameron and her counsel for the opportunity to speak at this Inquiry and more
- 21 importantly, for the very professional manner
- in which you have treated all laboratory staff
- who have been called to testify. Thank you. 24 MR. SIMMONS:
- 25 Q. Thank you, Mr. Gulliver. I don't have any

expecting?

2 MR. GULLIVER:

1

- A. That's correct.
- 4 CHAYTOR, Q.C.:
- Q. And my question is, Mr. Gulliver, are you 5
- telling the Commissioner that there was a 6
- standardized and consistent procedure in place 7
- 8 for the testing of ER/PR throughout the entire
- time period that was followed by the 9
- 10 technologists consistently, rigidly throughout
- the entire period? 11
- 12 MR. GULLIVER:
- A. Yes, and that's my firm belief.
- 14 CHAYTOR, Q.C.:
- Q. And do you know whether or not all of the 15
- technologists utilized the same antibody 16
- dilution? 17
- 18 MR. GULLIVER:
- A. That I can't verify, I mean -
- 20 CHAYTOR, Q.C.:
- Q. Wouldn't that be part of your standard 21
- 22 operating procedure?
- 23 MR. GULLIVER:
- A. That would be part of the protocol.
- 25 CHAYTOR, Q.C.:

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Q. Yes. 1

2 MR. GULLIVER:

- A. And the validation process of what antibody
- dilution to use, and I would be aware that at 4
- 5 different times, you could use different
- antibody dilutions if the lot number changed 6
- or those kinds of things, and that's 7
- something, as you're well aware, you do during 8
- the validation or revalidation.
- 10 CHAYTOR, O.C.:
- 11 Q. But would you expect that the--whichever
- technologist was doing the procedure would use 12
- the same dilution of antibody? 13
- 14 MR. GULLIVER:
- A. Oh, I'm sorry, so if the recommended dilution 15
- was, say, one of 50? 16
- 17 CHAYTOR, Q.C.:
- Q. Yes, that whether it's Peggy Welsh doing the 18
- test or Mary Butler doing the test -19
- 20 MR. GULLIVER:
- 21 A. Irregardless, it would be done one of 50 every
- time. 22
- 23 CHAYTOR, Q.C.:
- Q. Right. Do you know whether or not that was 24
- the case, that your technologists were all 25

- using the same antibody dilution at whatever
- that was for any particular time period?
- 3 MR. GULLIVER:
- A. I can't guarantee you 100 percent, but to the
- best of my knowledge, the answer would be yes. 5
- 6 CHAYTOR, Q.C.:
 - Q. Do you know whether or not they were all
- utilizing the same incubation periods? 8
- 9 MR. GULLIVER:
- A. To the best of my knowledge, yes.
- 11 CHAYTOR, Q.C.:
- 12 Q. Okay, and if they were to have told the
- Commissioner otherwise, you'd be unaware of 13
- that? If Mary was using -14
- 15 MR. GULLIVER:
- A. Yes.
- 17 CHAYTOR, Q.C.:
- Q. a different dilution at a particular period
- 19 in time than -
- 20 MR. GULLIVER:
- A. And I'd be unaware and surprised.
- 22 CHAYTOR, Q.C.:
- Q. You'd be surprised. And are you aware of any 23
 - documentation--for example, this is written
- here, July 14th, 2003, one out of 20. Are you 25

24

1

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Page 343 aware of, if we pick another date, we could

- say July 2nd 2002, which I believe is the date
- that Peggy Deane's test was carried out, is 3
- there any documentation that would tell us 4
- 5 what your standard operating procedure was on
- that date? 6
- 7 MR. GULLIVER:
- A. Well, it would be the same procedure as what
- we submitted to you. 9
- 10 CHAYTOR, Q.C.:
- 11 Q. And what would the dilution of the antibody be
- 12
- 13 MR. GULLIVER:
- A. I can't tell you what the dilution would be. 14
- 15 CHAYTOR, Q.C.:
- Q. or what the incubation period that the
- 17 technologists were using?
- 18 MR. GULLIVER:
- A. But generally, the technologists would write 19
- the dilution on the sheets and on the actual 20
- bottle that they were using. 21
- 22 CHAYTOR, Q.C.:
- Q. And what about the incubation period? 23
- 24 MR. GULLIVER:
- 25 A. And that's set out in the procedure.

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1 CHAYTOR, Q.C.:	1 CHAYTOR, Q.C.:
2 Q. Well, it gives an optimal period in the	2 Q. Good afternoon, Ms. Predham.
3 procedure, in the spec sheet. Is that what	3 MS. PREDHAM:
4 you're referring to?	4 A. Good afternoon.
5 MR. GULLIVER:	5 CHAYTOR, Q.C.:
6 A. Yes.	6 Q. And thank you for your patience.
7 CHAYTOR, Q.C.:	7 MS. PREDHAM:
8 Q. But whether or not -	8 A. No problem.
9 MR. GULLIVER:	9 CHAYTOR, Q.C.:
10 A. I think they always used 30 minutes, but I	10 Q. We have a number of new exhibits that I would
can't be 100 percent sure.	ask, please, to have entered this afternoon,
12 CHAYTOR, Q.C.:	12 Commissioner, and it's actually quite a
13 Q. Thank you, that's it, Commissioner.	number, so that might eat up all of our time.
14 THE COMMISSIONER:	I hope not. Okay, so we have P-2939 through
15 Q. Thank you. Thank you, Mr. Gulliver. I'm sure	to P-2944 inclusive, P-2948, P-2949, P- 2951
it's been a long few days.	through to P-2957 inclusive, P-2960, P- 2965
17 MR. GULLIVER:	through to P-2973 inclusive, P-2979 through to
18 A. It has, yes.	P-2981 inclusive, P-2983 through to P- 3003
19 THE COMMISSIONER:	inclusive, P-3005 through to P-3029 inclusive,
20 Q. Spread out over weeks. I do appreciate your	20 P-3031 through to P-3035 inclusive, P-3037, P-
21 contribution. Thank you very much.	21 3040, P-3041, P-3043 through to P- 3048
22 MR. GULLIVER:	inclusive, P-3049no, I'm sorry, not P-3049.
23 A. Thank you so much.	P-3052 through to P-3054 inclusive, P-3056, P-
24 THE COMMISSIONER:	24 3059 through to P-3073 inclusive, P-3075, P-
25 Q. Ms. Chaytor, it's late in the day, but is the	25 3078, P-3370 through to P-3380 inclusive, P-
Page 345	Page 347
1 next witness here?	1 3382 through P-3385 inclusive, P-3387 through
1 next witness here? 2 CHAYTOR, Q.C.:	1 3382 through P-3385 inclusive, P-3387 through 2 to P-3410, P-3413 through P-3415 inclusive, P-
1 next witness here?	1 3382 through P-3385 inclusive, P-3387 through 2 to P-3410, P-3413 through P-3415 inclusive, P- 3 3417, P-3418, P-3420 through to P-3462
1 next witness here? 2 CHAYTOR, Q.C.: 3 Q. I believe she is. 4 THE COMMISSIONER:	1 3382 through P-3385 inclusive, P-3387 through 2 to P-3410, P-3413 through P-3415 inclusive, P- 3 3417, P-3418, P-3420 through to P-3462 4 inclusive and then we have four C exhibits, C-
 next witness here? CHAYTOR, Q.C.: Q. I believe she is. THE COMMISSIONER: Q. Let'smy suggestion is that we carry on until 	1 3382 through P-3385 inclusive, P-3387 through 2 to P-3410, P-3413 through P-3415 inclusive, P- 3 3417, P-3418, P-3420 through to P-3462 4 inclusive and then we have four C exhibits, C- 5 0264, C-0265, C-0273 and C-0274. Is that it,
 next witness here? CHAYTOR, Q.C.: Q. I believe she is. THE COMMISSIONER: Q. Let'smy suggestion is that we carry on until five and let's get over the introduction and 	1 3382 through P-3385 inclusive, P-3387 through 2 to P-3410, P-3413 through P-3415 inclusive, P- 3 3417, P-3418, P-3420 through to P-3462 4 inclusive and then we have four C exhibits, C- 5 0264, C-0265, C-0273 and C-0274. Is that it, 6 Registrar?
1 next witness here? 2 CHAYTOR, Q.C.: 3 Q. I believe she is. 4 THE COMMISSIONER: 5 Q. Let'smy suggestion is that we carry on until 6 five and let's get over the introduction and 7 let her get sworn in and have thewe'll	1 3382 through P-3385 inclusive, P-3387 through 2 to P-3410, P-3413 through P-3415 inclusive, P- 3 3417, P-3418, P-3420 through to P-3462 4 inclusive and then we have four C exhibits, C- 5 0264, C-0265, C-0273 and C-0274. Is that it, 6 Registrar? 7 REGISTRAR:
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1 next witness here? 2 CHAYTOR, Q.C.: 3 Q. I believe she is. 4 THE COMMISSIONER: 5 Q. Let'smy suggestion is that we carry on until 6 five and let's get over the introduction and 7 let her get sworn in and have thewe'll 8 return that to the comfort level for Ms. 9 Chaytor. Thank you very much, gentlemen. 10 CHAYTOR, Q.C.: 11 Q. Thank you. 12 THE COMMISSIONER: 13 Q. Now Ms. Chaytor. 14 CHAYTOR, Q.C.:	1 3382 through P-3385 inclusive, P-3387 through 2 to P-3410, P-3413 through P-3415 inclusive, P- 3 3417, P-3418, P-3420 through to P-3462 4 inclusive and then we have four C exhibits, C- 5 0264, C-0265, C-0273 and C-0274. Is that it, 6 Registrar? 7 REGISTRAR: 8 Q. Yes. 9 CHAYTOR, Q.C.: 10 Q. Thank you. 11 THE COMMISSIONER: 12 Q. Entered. 13 EXHIBITS ENTERED AND MARKED P-2939 THROUGH P- 2944 14 EXHIBITS ENTERED AND MARKED P-2948 AND P-2949
1 next witness here? 2 CHAYTOR, Q.C.: 3 Q. I believe she is. 4 THE COMMISSIONER: 5 Q. Let'smy suggestion is that we carry on until 6 five and let's get over the introduction and 7 let her get sworn in and have thewe'll 8 return that to the comfort level for Ms. 9 Chaytor. Thank you very much, gentlemen. 10 CHAYTOR, Q.C.: 11 Q. Thank you. 12 THE COMMISSIONER: 13 Q. Now Ms. Chaytor. 14 CHAYTOR, Q.C.: 15 Q. Commissioner, the next witness is Heather	1 3382 through P-3385 inclusive, P-3387 through 2 to P-3410, P-3413 through P-3415 inclusive, P- 3 3417, P-3418, P-3420 through to P-3462 4 inclusive and then we have four C exhibits, C- 5 0264, C-0265, C-0273 and C-0274. Is that it, 6 Registrar? 7 REGISTRAR: 8 Q. Yes. 9 CHAYTOR, Q.C.: 10 Q. Thank you. 11 THE COMMISSIONER: 12 Q. Entered. 13 EXHIBITS ENTERED AND MARKED P-2939 THROUGH P- 2944 14 EXHIBITS ENTERED AND MARKED P-2948 AND P-2949 15 EXHIBITS ENTERED AND MARKED P-2951 THROUGH P- 2957
1 next witness here? 2 CHAYTOR, Q.C.: 3 Q. I believe she is. 4 THE COMMISSIONER: 5 Q. Let'smy suggestion is that we carry on until 6 five and let's get over the introduction and 7 let her get sworn in and have thewe'll 8 return that to the comfort level for Ms. 9 Chaytor. Thank you very much, gentlemen. 10 CHAYTOR, Q.C.: 11 Q. Thank you. 12 THE COMMISSIONER: 13 Q. Now Ms. Chaytor. 14 CHAYTOR, Q.C.: 15 Q. Commissioner, the next witness is Heather 16 Predham.	1 3382 through P-3385 inclusive, P-3387 through 2 to P-3410, P-3413 through P-3415 inclusive, P- 3 3417, P-3418, P-3420 through to P-3462 4 inclusive and then we have four C exhibits, C- 5 0264, C-0265, C-0273 and C-0274. Is that it, 6 Registrar? 7 REGISTRAR: 8 Q. Yes. 9 CHAYTOR, Q.C.: 10 Q. Thank you. 11 THE COMMISSIONER: 12 Q. Entered. 13 EXHIBITS ENTERED AND MARKED P-2939 THROUGH P- 2944 14 EXHIBITS ENTERED AND MARKED P-2948 AND P-2949 15 EXHIBITS ENTERED AND MARKED P-2951 THROUGH P- 2957 16 EXHIBIT ENTERED AND MARKED P-2960
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Page 348	Page 350
1 EXHIBIT ENTERED AND MARKED P-3056	point? Did you get to know Mr. Dawe?
2 EXHIBITS ENTERED AND MARKED P-3059 THROUGH P-3073	2 MS. PREDHAM:
3 EXHIBIT ENTERED AND MARKED P-3075	3 A. Yes, for a period of time he was a social
4 EXHIBIT ENTERED AND MARKED P-3078	4 service worker, I believe, and he worked on
5 EXHIBITS ENTERED AND MARKED P-3370 THROUGH P-3380	5 the unit that I worked on at that time.
6 EXHIBITS ENTERED AND MARKED P-3382 THROUGH P-3385	6 CHAYTOR, Q.C.:
7 EXHIBITS ENTERED AND MARKED P-3387 THROUGH P-3410	7 Q. Okay, and then while you're still at the
8 EXHIBITS ENTERED AND MARKED P-3413 THROUGH P-3415	8 Waterford, from 1993 to 1994, what was your
9 EXHIBITS ENTERED AND MARKED P-3417 THROUGH P-3418	9 position at that period?
10 EXHIBITS ENTERED AND MARKED P-3420 THROUGH P-3462	10 MS. PREDHAM:
11 EXHIBITS ENTERED AND MARKED C-0264 AND C-0265	11 A. In 1993, I was a medical resource person and
12 EXHIBITS ENTERED AND MARKED C-0273 AND C-0274	that's a title theyI was almost an
13 CHAYTOR, Q.C.:	administrative support person with the
14 Q. Thank you, Commissioner. Ms. Predham, perhaps	physicians. I helped develop audits,
you can begin by telling us about yourself,	developed policies, write their policy and
your educational and professional background.	procedure manual, that type of administrative
17 MS. PREDHAM:	support, and I did that for just over a year.
18 A. I graduated from Memorial University in 1986	18 CHAYTOR, Q.C.:
with a Bachelor of Nursing. I then was	19 Q. And other than your BN, do you have any other
20 employed as a psychiatric nurse at the	educational or continuing education courses?
21 Waterford Hospital untilas a front-line	21 MS. PREDHAM:
psychiatric nurse until 1993. At that time, I	22 A. In '93 or '94 actually I think it was, I did
worked with the medical department in quality,	the Canadian Hospital Association year-long
in that area, until 1994, and then I had the	program in quality management, and I did some
position as quality care coordinator at the	graduate courses in nursing and then in 2004,
	
Page 349	Page 351
Page 349 Waterford Hospital and I had that position	
1 Waterford Hospital, and I had that position	1 I started my Masters in Community Health. So
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	Page 352		Page 354
1	consumer feedback, a comprehensive course in	1	also learn about risk management, how to
2	quality management.	2	investigate an incident, how to utilize
3 СНА	YTOR, Q.C.:	3	1 &
4 Q	. Okay, so basically the fundamentals of quality	4	
5	management?	5	Since then, of course, there are other
6 MS.	PREDHAM:	6	tools that have been taken from engineering,
7 A	. Exactly.	7	such as root cause analysis and a failure mode
8 CHA	YTOR, Q.C.:	8	effects analysis. So I've done courses in
9 Q	. Okay, and what types of things, for example,	9	those as well.
10	would youwhat would you learn through that?	10	CHAYTOR, Q.C.:
11	Like what does it mean for us lay people, what	11	Q. In root cause analysis and failure mode
12	is quality management basically?	12	analysis as well?
13 MS.	PREDHAM:	13	MS. PREDHAM:
14 A	. Do you want to know what is quality management	14	A. Failure mode effects analysis.
15	-	15	CHAYTOR, Q.C.:
16 CHA	YTOR, Q.C.:	16	Q. Effects analysis, okay. And is quality
17 Q	. Yes.	17	management then different in the health care
18 MS.	PREDHAM:	18	setting than it would be in, for example, as
19 A	or what I learned?	19	you've given the engineering setting? Is
20 CHA	YTOR, Q.C.:	20	there any difference in quality management?
21 Q	. It's different, is it? Okay. Well tell us	21	MS. PREDHAM:
22	then, what are the fundamentals of quality	22	A. There iswell, it's a slight difference.
23	management?	23	_
24 MS.	PREDHAM:	24	difference, but in quality management, there
25 1	. I guess the history of it, how it started off	25	
25 A	. I guess the history of it, now it started off	43	is a difference because it simorein more
23 A		+	
	Page 353		Page 355
1	Page 353 with quality assurance, basic quality	1	Page 355 industries, it's more structured and it's the
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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	with quality assurance, basic quality assurance, would be auditing and just the auditing functions that are in a hospital, and of course, the focus of it all was hospital based and the other premises are taken from a lot of work by Edward Demmings, who was an engineer in the automobile industry. So he developed TQM, which is total quality management or CQI, which is continuous quality improvement. So the concept there was that you take your audits, you build on the quality assurance activities, but you go into this continuous quality improvement of plan, do, check, act cycle. So you would go into thatit's a continuous quality improvement, I guess, is what I'm trying to say, and that you would plan what you were doing. You would measure, you wouldand you'd keep going. You keep evaluating there. So that's the basic premises that you would learn. Then they would teach you the different tools. So you'd learn how to do a process	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Page 355 industries, it's more structured and it's the same every day or you have that more regulated environment. In hospitals, you tend to have a lot of activity and a lot of fluctuating activity, I guess, is a term that I'd like to use. It is never the same twice. So you may do something one day, but something subtle will change to that. So there's nuances that make it different than another type of industry. If you're in a more manufacturing type industry, it's more stagnant. It's the same type of thing day in and day out. CHAYTOR, Q.C.: Q. Okay, and I'll come back probably, leave that for now and come back because I would like to explore a little bit more with you as to, you know, what root cause analysis is and the other things. MS. PREDHAM: A. Sure. CHAYTOR, Q.C.: Q. So right now, I'd just like to explore your background. So you have a BN and you've done this one-year correspondence course in quality

Page 356	Page 358
1 MS. PREDHAM: 1 CHAYTOR, Q.C.:	
2 A. Yes. 2 Q. And were you res	ponsible for the laboratory
3 CHAYTOR, Q.C.: 3 medicine program	? Was that one of the
4 Q. And you've done other courses you've said 4 programs you were	e responsible for?
5 along the way which included courses that 5 MS. PREDHAM:	
6 taught you about root cause analysis. Your 6 A. Yes, I think, in the	e beginning, I think in
background then in moving to Eastern Health in 7 1996 I was linked	to that.
8 1994 or moving to the - 8 CHAYTOR, Q.C.:	
9 MS. PREDHAM: 9 Q. Okay, and for how	long? From 1996 until when?
10 A. Health Care Corporation. 10 MS. PREDHAM:	
11 CHAYTOR, Q.C.: 11 A. I think I was only	linked with that program
12 Q Health Care Corporation at that time, in 12 for about a year.	
13 1994, and your position at that time was 13 CHAYTOR, Q.C.:	
quality facilitator? Is that correct? 14 Q. So, perhaps up unt	il 1997?
15 MS. PREDHAM: 15 MS. PREDHAM:	
16 A. Yes. 16 A. Sometime in 1997	
17 CHAYTOR, Q.C.: 17 CHAYTOR, Q.C.:	
18 Q. And what did that involve, to be a quality 18 Q. Sometime in 1997	, okay. And do you know then
facilitator at Health Care Corp? 19 who took over aft	erso there are different
20 MS. PREDHAM: 20 quality facilitators.	, I take it, assigned to
21 A. The quality facilitator role was a support 21 different programs	
role to the programs. We hadwhen Health 22 MS. PREDHAM:	
Care Corporation was set up, they went into 23 A. Yes.	
program management. So each of the quality 24 CHAYTOR, Q.C.:	
facilitators were linked to a series of 25 Q. And do you know	who took over then in 1997?
Page 357	Page 359
programs, a group of programs, and supported 1 MS. PREDHAM:	
them in developing their goals, their 2 A. I'm not sure. I	know later in 1998 after
objectives, their indicators, and we were all 3 Nancy Parsons	started, she had the lab
4 just moving into this process. So one of the 4 program. I can r	emember that.
5 big things we spent a lot of time on were 5 CHAYTOR, Q.C.:	
6 developing indicators in which they could 6 Q. Yes and I believe	e she's told us about that.
7 monitor, not the routine things that 7 MS. PREDHAM:	
8 traditionally areas have monitored, but things 8 A. Yes, but I can't r	remember, and it may be that
9 that we can focus in on to improve. So you 9 I had it until she	started in '98.
know, you'd sit down and you'd look at 10 CHAYTOR, Q.C.:	
	re I move then into your period
types of things, trying to get the information 12 of time as risk m	anager and then onto acting
for them. 13 director, you edu	cationyou said that you're
14 CHAYTOR, Q.C.: 14 still working on	your Masters degree.
Q. Would you be involved in any education of the 15 MS. PREDHAM:	
frontline staff as to what it means to have 16 A. Yes.	
quality control and quality assurance in 17 CHAYTOR, Q.C.:	
	y is it that you'rewhat is it
20 A. Yes, we did. We had a day-long session on 20 Masters, I take it	y is it that you'rewhat is it g your Mastersit's a nursing
quality and quality improvement and that was 21 MS. PREDHAM:	g your Mastersit's a nursing
121 quanty and quanty improvement and that was 121 ms. 1 REDITAM.	g your Mastersit's a nursing
	g your Mastersit's a nursing
	your Mastersit's a nursing?
broken out into six sessions, I think, on what 22 A. No, it's in Comn	y your Mastersit's a nursing? nunity Health actually.

A. Yes.

- 2 CHAYTOR, O.C.:
- Q. And is that at all involved in risk management 3
- or quality management?
- 5 MS. PREDHAM:
- A. No, but it's much linked to it because you're 6
- learning about qualitative research. You're 7
- 8 doing epidemiology and biostats. So, it has a
- lot of--I found it to be a better fit for what 9
- 10 I was actually working at than when I started
- doing the nursing degree. 11
- 12 CHAYTOR, Q.C.:
- Q. Okay. And does it involve patient safety at 13
- 14 all?
- 15 MS. PREDHAM:
- A. Well, that's a focus of what my thesis is 16
- going to be because that's my focus of things. 17
- So, projects that I've done as I've went 18
- through that, I've used that as my focus. 19
- 20 CHAYTOR, Q.C.:
- 21 Q. And so it is something that fits with what
- 22 you're doing in your day-to-day work.
- 23 MS. PREDHAM:
- A. Yes.
- 25 CHAYTOR, Q.C.:

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- Q. And so then after--well, the quality 1
- 2 initiatives portfolio that you had and again
- remind me, that's 1994 -3
- 4 MS. PREDHAM:
- A. 1996.
- 6 CHAYTOR, Q.C.:
- Q. '96 through to -
- 8 MS. PREDHAM:
- A. '98 I became Risk Manager.
- 10 CHAYTOR, Q.C.:
- 11 Q. '98, okay. And what does it mean then, what's
- the difference in moving then into Risk 12
- Manager itself? What were your duties and 13
- responsibilities in 1998 when you took that 14
- on? 15
- 16 MS. PREDHAM:
- 17 A. Well, as a quality facilitator, you're linked
- with the program, so you're involved. You 18
- screen the occurrence reporting and you're 19
- involved with investigation of incidences, but 20
- when you move into the risk manager position, 21
- 22 you're responsible for occurrence reporting.
- So, you're responsible to make sure staff are 23 educated and that the program works, that the 24
- 25 form needs to be updated or whatever. So,

you're responsible for co-ordinating that

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Page 363

- 1 2 entire program, getting the reports back to
- the program. You're also responsible for 3
 - investigating the complaint, liaisoning with
- insurer, with legal counsel. 5
- 6 CHAYTOR, Q.C.:

4

- Q. And that's as the risk manager.
- 8 MS. PREDHAM:
- A. As the risk manager.
- 10 CHAYTOR, Q.C.:
- Q. Okay. 11
- 12 MS. PREDHAM:
- A. As a quality facilitator you could also end up
- linking with the legal counsel, but usually 14
- the contact goes through the risk manager. 15
- 16 CHAYTOR, Q.C.:
- Q. Okay. So, you do do investigations of 17
- occurrences or incidences? 18
- 19 MS. PREDHAM:
- A. Yes. 20
- 21 CHAYTOR, Q.C.:
- 22 Q. And you say you make sure that staff are
- educated and when you say the staff, do you 23
- mean the staff within the quality initiatives 24
- department or the staff actually out in the 25

programs doing the frontline work? 1

- 2 MS. PREDHAM:
- A. Oh no, we do--I've done education sessions on 3
- occurrence reporting to--I don't know how many 4
 - staff, but also on different consent policies,
- you know, where you go around doing in-6
- services on consent. And those types of 7
- issues that are higher risk, I guess, types of 8
- procedures then, that's what you would educate 9
- staff on. 10

5

- 11 CHAYTOR, Q.C.:
- Q. Okay. So, staff would include anyone who 12
- 13 worked within -
- 14 MS. PREDHAM:
- A. Frontline staff.
- 16 CHAYTOR, O.C.:
- 17 Q. - any frontline. Would it also include the
- physicians? 18
- 19 MS. PREDHAM:

22

23

25

- A. At times, depending on the issue. It usually 20
- would be a special session for physicians or 21
 - we'd work in something, probably with a VP
 - medical or with clinical chief. We'd work
- 24 around some way to get that information to
 - them.

Page 364 Page 366 message out there. 1 CHAYTOR, O.C.: Q. Okay. And in this time period, in the late 2 CHAYTOR, Q.C.: 1990's, how well informed were the staff in Q. So, I guess in getting the report, not only 3 3 terms of quality initiatives? would you investigate that particular incident 4 4 and look for whatever may have contributed to 5 MS. PREDHAM: 5 A. From '96 to '98 we did a lot of education for the incident, would you then keep track and 6 6 staff because although there was a quality keep that in some sort of database or 7 7 8 person in each of the legacy boards up to that 8 otherwise keep it so that you could follow any point, their roles were quite different. At trends of similar instances that may arise? 9 10 the Waterford my role, majority of my role was 10 MS. PREDHAM: responding to patient complaints. A. Yes, and that was a big challenge when we 11 11 although I was following up on occurrence first started. We were doing it manually when 12 12 13 reports and that type of thing, that was the we first started. So, tallying up to, I think 13 primary focus of my role. So, if frontline it was--we were probably getting 3 to 4000 14 14 occurrence reports a year. So, internally, staff in the mental health program saw me, 15 15 16 that's what they would think first and the 16 our IT department was able to do a front end same with the different legacy organizations. reporting mechanism. So, the quality 17 17 So, we had to do a lot of education on what facilitators would take the occurrence 18 18 19 type of thing that quality initiatives would 19 reports, we'd code them and then enter it all do. But the other thing that's very important into this database. But then we had to 20 20 for frontline staff to know what we're doing download the information into Excel and format 21 21 22 is because we can't be everywhere. We have to 22 it into a report to quarterly get back to the programs to say these are the types of things 23 rely on them to tell us what's happening out 23 there. that you're reporting. So beyond the 24 24 individual follow up for occurrences, we had 25 CHAYTOR, Q.C.: 25 Page 365 Page 367

to do this trending as well. 1

2 MS. PREDHAM:

A. Exactly.

4 CHAYTOR, O.C.:

Q. Feel comfortable in reporting an incident or 5 something they see as being dangerous or less 6 7 than optimal.

Q. And to feel comfortable in telling you.

8 MS. PREDHAM:

24

25

- A. Exactly. And when we came together as the 9 Health Care Corporation, we--two of the 10 11 previous sites had very punitive form of occurrence reporting. So, that was another 12 challenge that we had to deal with. So, we 13 14 15 reporting is non punitive, but we also had to, I guess, walk the walk, for the better way of 16 17 putting it. We had to go through that process 18
- had to get that message across that occurrence and say that, you know, you are not getting in 19 trouble because you filled these out. So, we had to get examples and show them how this is 20 so beneficial to us. These are the things 21 22 that we've learned from occurrence reporting. If nobody reported this, we wouldn't know 23

about it; we wouldn't be able to deal with it.

So, it was really important to get that

- 2 CHAYTOR, Q.C.:
- Q. Okay, and then you'd give feedback on a 3 quarterly basis to the various programs. 4
- 5 MS. PREDHAM:
- A. Yes. 6
- 7 CHAYTOR, Q.C.:
- 8 Q. For anything that you were seeing in terms of trends or types of incidences that were being 9
- 10

11 MS. PREDHAM:

- A. Well they give a summary of all their 12 13 occurrences, so they would say over this quarter you had these many medication 14 15 occurrences, these many files, this many property loss, you know, that type of thing. 16 And then annually we would do that as well. 17
- 18 CHAYTOR, Q.C.:
- 19 Q. And if there is anything that you saw or that caused you concern that there was a trend, 20 21 well whose attention would you then bring that 22 to?
- 23 MS. PREDHAM:
- 24 A. Well it would depend on the type of 25 occurrence. If it was anything--we had one

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- trend that we picked up fairly quickly with a 1 2 certain type of suction machine that we had
- 3 and we had to get a large group of people,
- because that was throughout the organization, 4
- 5 but it was because we were trending the
- occurrences that we picked up that we had an 6
- issue, because we had an issue in DI, 7
- 8 diagnostic imaging, we had an issue on a
- 9 surgery floor, we had an issue on the medicine
- 10 floor and we had an issue in critical care.
- So they were very similar and because they 11
- 12 were similar, we picked up that trend and then
- it was a very broad base group that had to get 13
- together to deal with that. 14
- 15 CHAYTOR, O.C.:
- 16 Q. And then you were able to track it back to the
- 17
- 18 MS. PREDHAM:
- 19 A. It was the--fundamentally it was a new suction
- device that we were using and the way that it 20
- had a backflow valve in it. The way we were 21
- 22 using it was causing this problem and an
- interruption in the suction, so we actually 23
- had to cancel the tender with this one and go 24
- back to another version that we were using 25
 - Page 369
 - because to change practice, it would have been
 - too difficult to ensure that that machine
- 3 could keep working.
- 4 CHAYTOR, O.C.:

1 2

8

- Q. And so that's a good concrete example of how 5
- somebody filling out the occurrence report and 6
- 7 having it come to a centralized location and
 - having the trends followed, could then pick up
- 9 on the issues and enhance patient care and
- safety. 10
- 11 MS. PREDHAM:
- A. Exactly. 12 13 CHAYTOR, Q.C.:
- 14 Q. First of all I should ask you, where were you
- 15 when you first came over to Health Care
- Corporation in 1996, where were you physically 16
- 17 located?
- 18 MS. PREDHAM:
- A. At that time our department centrally had an 19
- office at St. Clare's, but each of the quality 20
- facilitators had two offices, so I had an 21
- 22 office at the Waterford and an office at St.
- Clare's because I was--we had a transition 23
- 24 period going in through the Health Care
- Corporation where the programs had not been 25

- established yet, but the quality initiatives
- 2 department had, so when we originally started,
- we were linked to sites. So I was linked to 3
- 4 the St. Clare's site and the Waterford site.
- 5 Another quality facilitator was linked to the
- Health Sciences site and the Grace and another 6
- 7 one was the Janeway and somewhere else--I
- 8 can't think of where else it was. But we had
- a central office then at St. Clare's.
- 10 CHAYTOR, O.C.:
- 11 Q. Okay, and when you became risk manager, where
- were you physically then located? 12
- 13 MS. PREDHAM:
- 14 A. Well coincidentally, just when I became risk
- 15 manager, we moved our entire office at the
- 16 Waterford, so I was at the Waterford site.
- 17 CHAYTOR, Q.C.:
- 18 Q. Okay, and you remained then in the risk
- 19 management position from 1998 until 2004, is
- 20 that correct.
- 21 MS. PREDHAM:
- 22 A. 2004.

24

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5

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- 23 CHAYTOR, Q.C.:
 - Q. And then you became acting director--what was
 - the name of your title?

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- 1 MS. PREDHAM:
 - A. Well again, coincidentally, our department
- changed just before I became acting director 3
- and we merged with the Management and 4
 - Engineering Department. In Quality
- Initiatives, besides the quality facilitator, 6
- 7 utilization manager and the director, we also
 - had an infection control division reported to
- us, so when we became Quality and Systems 9
- Improvement, we had three divisions, so our 10
- 11 department changed slightly and became--we had
- a management engineering division, the quality 12
- 13 and risk management division and infection
- control division. 14
- 15 CHAYTOR, Q.C.:
- O. And that was as of 2004?
- 17 MS. PREDHAM:
- 18 A. 2004.
- 19 CHAYTOR, Q.C.:
- O. And that continued until when? 20
- 21 MS. PREDHAM:

22

25

- A. That continued until, I think in the summer of
- 2005, management engineering reported to 23
- 24 planning and research with the formation of
 - Eastern Health, they moved over there.

·	inquiry on from one receptor resting
Page 372	Page 374
1 Infection control has just now become a	1 CHAYTOR, Q.C.:
2 division of their own with their own director.	2 Q. So when you became the manager of quality and
3 CHAYTOR, Q.C.:	3 risk in the fall of 2005, was that in essence
4 Q. And so then you remained in your acting	4 the same position that you held as risk
5 director capacity until when?	5 manager?
6 MS. PREDHAM:	6 MS. PREDHAM:
7 A. October of 2005.	7 A. Other than the quality facilitators reported
8 CHAYTOR, Q.C.:	8 to me, it was.
9 Q. October of 2005. And then in October, 2005,	9 CHAYTOR, Q.C.:
10 you became -	Q. So you had all the same duties in terms of
11 MS. PREDHAM:	making sure the staff were educated, making
12 A. I went back to the manager of quality and	sure that incidents were being reported,
risk, which wasit was the risk manager	liaisoning with the insurer or lawyers and
position, I guess, but because we changed at	investigating incidents, all of those same
that time to the three division format of our	duties, plus then you had the quality
department, it was the manager of quality and	16 facilitators reporting to you? 17 MS. PREDHAM:
17 risk, so the quality facilitators reported to	
the previous position of a risk manager. 19 CHAYTOR, Q.C.:	18 A. Yes. 19 CHAYTOR, Q.C.:
20 Q. So in 1998 when you were risk manager, the	20 Q. And that's the position that you still hold?
21 quality facilitators were reporting -	21 MS. PREDHAM:
22 MS. PREDHAM:	22 A. No. Sorry.
23 A. No, they were reporting to the director.	23 CHAYTOR, Q.C.:
24 CHAYTOR, Q.C.:	24 Q. Do you have a C.V.?
25 Q. They were reporting to the director, not to	25 MS. PREDHAM:
Page 373	Page 375
1 you.	1 A. Yes, I do.
2 MS. PREDHAM:	2 CHAYTOR, Q.C.:
3 A. No.	3 Q. We have a C.V. okay.
4 CHAYTOR, Q.C.:	4 MS. PREDHAM:
5 Q. And when you became the manager of quality and	5 A. In June of 2006 because one we were becoming
	5 A. In June of 2006, because see, we were becoming
6 risk in the fall of 2005, then the quality	
6 risk in the fall of 2005, then the quality 7 facilitators were reporting to you?	
· ·	6 Eastern HealthI was acting director until
7 facilitators were reporting to you?	6 Eastern HealthI was acting director until 7 Pam Elliott started as director of quality and
7 facilitators were reporting to you? 8 MS. PREDHAM:	Eastern HealthI was acting director until Pam Elliott started as director of quality and risk management.
7 facilitators were reporting to you? 8 MS. PREDHAM: 9 A. Yes.	6 Eastern HealthI was acting director until 7 Pam Elliott started as director of quality and 8 risk management. 9 CHAYTOR, Q.C.:
7 facilitators were reporting to you? 8 MS. PREDHAM: 9 A. Yes. 10 THE COMMISSIONER:	6 Eastern HealthI was acting director until 7 Pam Elliott started as director of quality and 8 risk management. 9 CHAYTOR, Q.C.: 10 Q. Yes.
7 facilitators were reporting to you? 8 MS. PREDHAM: 9 A. Yes. 10 THE COMMISSIONER: 11 Q. Wait now, what was your title in 2004? I	6 Eastern HealthI was acting director until 7 Pam Elliott started as director of quality and 8 risk management. 9 CHAYTOR, Q.C.: 10 Q. Yes. 11 MS. PREDHAM: 12 A. And that was October 31st, 2005. So after 13 that, we didn't have a structure for a
7 facilitators were reporting to you? 8 MS. PREDHAM: 9 A. Yes. 10 THE COMMISSIONER: 11 Q. Wait now, what was your title in 2004? I 12 thought you became acting director of quality	Eastern HealthI was acting director until Pam Elliott started as director of quality and risk management. CHAYTOR, Q.C.: Q. Yes. MS. PREDHAM: A. And that was October 31st, 2005. So after that, we didn't have a structure for a department, so I had to go back to my old
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Page 376 1 could tell us about how the department changed 2 when Ms. Elliott came along into the position. 3 THE COMMISSIONER: 4 Q. All right. I'm sorry we were so late getting 5 on with you, but I felt it was worthwhile 6 using this half hour to try and straighten out 7 your history. Thank you. 9:30 in the 8 morning.	
Page 377 CERTIFICATE I, Judy Moss, hereby certify that the foregoing is	
a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 15th day of October, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus. Dated at St. John's, Newfoundland and Labrador	
this 15th day of October, A.D., 2008 Judy Moss	

Inquiry on Hormone Receptor Testing

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