

<p style="text-align: center;">COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING</p> <p style="text-align: center;">BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER</p> <p style="text-align: center;">October 9, 2008</p> <p>Appearances:</p> <p>Bernard Coffey, Q.C. . . . . Commission Co-counsel Sandra Chaytor, Q.C. . . . . Commission Co-counsel</p> <p>Rolf Pritchard, Jackie Brazil, Q.C. . Her Majesty in Right of NL</p> <p>Peter Browne, Q.C./Jane Hennebury . . . Doctors Kara Laing et al</p> <p>Daniel Simmons . . . . . Eastern Regional Integrated . . . . . Health Authority</p> <p>Chesley Crosbie, Q.C.. . . . . Members of the Breast Cancer . . . . . Testing Class Action</p> <p>Mark Pike, Q.C. . . . . NL Medical Association Jennifer Newbury . . . . . Canadian Cancer Society (NL Division) Blair Pritchett. . . . . Central, Western and Labrador-Grenfell Regional Integrated Health Authorities</p>	<p style="text-align: center;">LIST OF EXHIBITS</p> <p>EXHIBITS P-3360 THROUGH P-3362, INCLUSIVE . . . . 4 . . . Pg.</p> <p>EXHIBIT P-3365 . . . . . Pg. 234</p> <p>EXHIBIT P-3036 . . . . . Pg. 296</p> <p>EXHIBIT P-3038 . . . . . Pg. 296</p>
<p style="text-align: center;">TABLE OF CONTENTS</p> <p>DR. EMINA TORLAKOVIC - SWORN</p> <p>Examination by Bernard Coffey, Q.C. . . . . Pgs. 4 - 179</p> <p>Examination by Chesley Crosbie, Q.C. . . . . Pgs. 179 - 190</p> <p>Examination by Daniel Simmons . . . . . Pgs. 190 - 231</p> <p>Examination by Peter Browne, Q.C. . . . . Pgs. 231 - 252</p> <p>Examination by Jennifer Newbury . . . . . Pgs. 252 - 283</p> <p>Re-examination by Bernard Coffey, Q.C. . . . . Pgs. 283 - 296</p> <p>MR. TERRY GULLIVER - RESUMES THE STAND</p> <p>Examination by Sandra Chaytor, Q.C. - Cont'd . . Pgs. 296 - 397</p> <p>Certificate</p>	<p style="text-align: right;">Page 4</p> <p>1 THE COMMISSIONER:</p> <p>2 Q. Mr. Coffey.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Commissioner, the next witness is Dr. Emina</p> <p>5 Torlakovic.</p> <p>6 DR. EMINA TORLAKOVIC, SWORN, EXAMINATION BY BERNARD</p> <p>7 COFFEY, Q.C.</p> <p>8 REGISTRAR:</p> <p>9 Q. Would you please state and spell your complete</p> <p>10 name for the Commission?</p> <p>11 DR. TORLAKOVIC:</p> <p>12 A. Emina Torlakovic, E-M-I-N-A, T, as in Tom, O-</p> <p>13 R-L-A-K-O-V-I-C.</p> <p>14 REGISTRAR:</p> <p>15 Q. Thank you.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Thank you, Doctor. Commissioner, there are</p> <p>18 three new exhibits, please, they are Exhibits</p> <p>19 3360, 3361 and 3362.</p> <p>20 THE COMMISSIONER:</p> <p>21 Q. Entered.</p> <p>22 EXHIBITS ENTERED AND MARKED P-3360 THROUGH P-3362,</p> <p>23 INCLUSIVE.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Thank you. Registrar, when you're ready,</p>

Page 5

1 please, Exhibit P-3360? Doctor, is this your  
 2 curriculum vitae?  
 3 DR. TORLAKOVIC:  
 4 A. Yes, it is.  
 5 COFFEY, Q.C.:  
 6 Q. And, Doctor, as well, I understand that you  
 7 have prepared a PowerPoint presentation to  
 8 assist, well, in effect, assist me in leading  
 9 you through your testimony here today. So I'm  
 10 going to ask, please, Registrar, if you could  
 11 bring up Exhibit P-3361?  
 12 REGISTRAR:  
 13 Q. Actually, Mr. Coffey, I'm going to bring up  
 14 the PowerPoint presentation itself.  
 15 COFFEY, Q.C.:  
 16 Q. Okay, yeah, thank you. I appreciate that.  
 17 And that's the presentation, Doctor, itself?  
 18 DR. TORLAKOVIC:  
 19 A. Yes, it is.  
 20 COFFEY, Q.C.:  
 21 Q. Okay. And if we could go to the page, the  
 22 second page, please, Registrar? Doctor, I  
 23 take it that this is really an outline here on  
 24 this page of your academic and your  
 25 professional background?

Page 6

1 DR. TORLAKOVIC:  
 2 A. Yes, it's a summary. It basically shows my  
 3 training, education and training in the  
 4 special skill of pathology and my credentials.  
 5 COFFEY, Q.C.:  
 6 Q. Take us through, please then, your academic  
 7 and your professional background, go ahead?  
 8 DR. TORLAKOVIC:  
 9 A. I have attended and graduated medical school  
 10 in Croatia, actually, that was former  
 11 Yugoslavia at the time, in Zagreb Medical  
 12 School and I graduated in 1986. And so  
 13 afterwards I moved to United States to  
 14 continue my education. I have spent two years  
 15 in New York City at Columbia University  
 16 affiliated hospital, St. Luke's/Roosevelt,  
 17 actually, it's two hospitals together, where I  
 18 have spent one year in anatomic pathology and  
 19 one year in clinical pathology; after which we  
 20 moved to University of Minnesota where I  
 21 continued my education in pathology as a  
 22 resident for next two years also doing  
 23 anatomic and clinical pathology; and after  
 24 which, I mean, the reason for moving there was  
 25 my interest in the program that they had

Page 7

1 because they had excellent fellowship programs  
 2 in surgical pathology and hematopathology,  
 3 somewhat the best in the country. And I have  
 4 continued after my residency there fellowship  
 5 in hematopathology and two years of fellowship  
 6 in surgical pathology where I did a lot of  
 7 training in molecular biology and in addition  
 8 to that cytology. And after which I actually  
 9 moved to Oslo, to Norway, where I was  
 10 recruited as a pathologist with adequate  
 11 background to help establish a modern  
 12 immunohistochemistry laboratory for their  
 13 national cancer institute equivalent, which  
 14 was Norwegian Radium Hospital at the time, and  
 15 that was the name, the Det Norske Radium  
 16 Hospital. So when I moved in 1997, I have  
 17 spent there seven years working, my main task,  
 18 my main job was to work in  
 19 immunohistochemistry laboratory where I also  
 20 started some national and international  
 21 project in quality control and so on. So I  
 22 think that, I don't know if it's the time to  
 23 mention these details or not, but I would like  
 24 to mention it because I think it's pertinent  
 25 to this testimony overall. So after I moved

Page 8

1 to Norway and started to work in that  
 2 particular lab that I had a large number of  
 3 cancer patients, so that immunohistochemistry  
 4 is a critical tool for the pathologist to  
 5 properly classify the diseases and also to  
 6 identify prognostic and predictive markers for  
 7 these cancers. I noticed that as a  
 8 consultation specimens that you were getting  
 9 from local hospitals that there was great  
 10 variability -  
 11 COFFEY, Q.C.:  
 12 Q. Doctor -  
 13 DR. TORLAKOVIC:  
 14 A. - in their outcomes.  
 15 COFFEY, Q.C.:  
 16 Q. If I could?  
 17 DR. TORLAKOVIC:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. I just ask you just to slow down? You speak  
 21 even--here in Newfoundland we speak very  
 22 quickly and you speak as fast or even faster,  
 23 okay.  
 24 DR. TORLAKOVIC:  
 25 A. All right.

Page 9

1 COFFEY, Q.C.:

2 Q. So if you could just because I'm following you

3 and I appreciate -

4 DR. TORLAKOVIC:

5 A. A little bit slower.

6 COFFEY, Q.C.:

7 Q. If you would, please?

8 DR. TORLAKOVIC:

9 A. Okay, fine.

10 COFFEY, Q.C.:

11 Q. Thanks.

12 DR. TORLAKOVIC:

13 A. I will.

14 COFFEY, Q.C.:

15 Q. So you were saying, Doctor, you had noticed in

16 the course of your practice there that you

17 were seeing samples from regional hospitals in

18 the area who were coming in?

19 DR. TORLAKOVIC:

20 A. Yes.

21 COFFEY, Q.C.:

22 Q. Could you--okay, I'm sorry, Doctor, go ahead?

23 DR. TORLAKOVIC:

24 A. With very variable results. And I just wanted

25 why is this happening and why there is no

Page 10

1 program that would help laboratories achieve

2 better results. So therefore I started an

3 initial--I attempted to start the national

4 Norwegian program that would help improve

5 quality. Norway as most--I shouldn't say

6 most, because I actually don't know the

7 number, but I know that many countries in the

8 Europe have laboratories that do not need to

9 be accredited and there is no need for

10 certification of specialized, many specialized

11 tests and therefore immunohistochemistry was

12 not regulated as laboratory technique at all.

13 COFFEY, Q.C.:

14 Q. And, Doctor, what year would this have been?

15 What years would this be, around 19?

16 DR. TORLAKOVIC:

17 A. This was 1997, '98.

18 COFFEY, Q.C.:

19 Q. Okay. Go ahead, Doctor, I'm sorry.

20 DR. TORLAKOVIC:

21 A. And so at that time my initial pilot study,

22 some of the results I'm going to show later in

23 this presentation, showed that there was very

24 high difference between the laboratories.

Page 11

1 Some achieved excellent results and some

2 achieved very poor results, but all of the

3 participants believed that their results were

4 actually good. So there was a component that

5 I noticed, an educational component that was

6 missing in the insight to what results are

7 supposed to look like, what are the expected

8 outcomes. It's very difficult to improve on

9 any technique or any results if the achieved

10 goal is not fully understood or known. And

11 Norway was actually too small of a country to

12 have a strong program, because there are just

13 a small number of laboratories that are

14 present. And at the same time there was an

15 initiative from a company that is making--that

16 is producing reagents for

17 immunohistochemistry, the branch of them, it's

18 DAKO Nordic was that they thought they wanted

19 to do something that would be of interest to

20 improve the qualities. Many of the reagent

21 producing companies try to do and even more so

22 today they pay attention to quality issues a

23 lot. And so when they become aware, as they

24 are continuously aware, I think that this is

25 the area that needs more standardization and

Page 12

1 improvement, they do try to collaborate with

2 professionals in the certain areas. And this

3 was the case they have actually provided funds

4 for representatives from Scandinavian

5 countries to get together and to discuss this

6 issue. And this was just in the very

7 beginning of that initiative that actually

8 ended up creating a Scandinavian quality

9 control program that is called NordiQC. I was

10 the Norwegian representative and was there

11 from the first types of its inception until I

12 left Europe and moved to Canada, which was in

13 December, 2003.

14 I think it's important I shall emphasize

15 here for the benefit of NordiQC and many other

16 programs that are supported occasionally with

17 funds from the industry that NordiQC was, even

18 though it was, even though the company paid

19 for the travel cost and hotel accommodation

20 costs, there was, it was all the time from the

21 very beginning a profession dissociation from

22 the company, from the reagents they supply or

23 any preference to their products. It is true

24 that at the time our lab was using products

25 from DAKO company, but we have chosen to do so

Page 13

1 before this initiative because we thought that  
 2 the products that they were using were good  
 3 for us. It doesn't mean that there aren't  
 4 other companies that are producing excellent  
 5 if not better products, makes no difference at  
 6 all, but at the moment we were using--and I do  
 7 want to emphasize again that this organization  
 8 is totally independent and currently is  
 9 actually supported by several different  
 10 companies also that are posted on their home  
 11 website clearly as supporters.

12 So the point about NordiQC is that just  
 13 that together these four countries now. So it  
 14 was Denmark, Norway, Sweden and Finland, they  
 15 were big enough with large enough, large  
 16 number of laboratories that this program  
 17 actually could make sense and also provided  
 18 enough of highly qualified specialists to be  
 19 able to do what we call in quality assurance  
 20 program assessments.

21 Assessments are a critical part of a  
 22 quality assurance programs because experts are  
 23 evaluating the results of laboratories and  
 24 making a judgment of how good the results are  
 25 and also at the same time they could and often

Page 14

1 make the conclusions and recommendations what  
 2 can be changed that the results should be  
 3 improved. This is not a part of practice of  
 4 every external quality assurance program, but  
 5 when that part is missing, then the feedback  
 6 that laboratory is getting is of very limited  
 7 value. So I personally believe that NordiQC  
 8 has become what it has become as external  
 9 quality assurance program so important and  
 10 useful to laboratories in Scandinavia because  
 11 it does provide this feedback and helped  
 12 laboratories to change and improve these  
 13 results.

14 I do want to mention that there are other  
 15 organizations that with even longer history,  
 16 of course, and probably the most famous one is  
 17 UK NEQAS that was originally created to  
 18 support external quality assurance and have  
 19 accreditation of laboratories in United  
 20 Kingdom. In '80, '84 I believe they started  
 21 their module on immunocytochemistry, they call  
 22 it, but it's basically immunohistochemistry.  
 23 And since then large number of laboratories  
 24 from outside of UK, that means European and  
 25 globally have decided to participate in their

Page 15

1 program and use their expertise to improve  
 2 what they do. However, it is interesting that  
 3 their own results show that from run to run  
 4 results do improve for UK laboratories which  
 5 accreditation depends on the results they  
 6 produce in this program. But they did not  
 7 improve according or not to that degree in  
 8 those other laboratories that are  
 9 international laboratories that are  
 10 participating because most of this--well, not  
 11 to say most, I don't know the number, but I  
 12 know that in many of these laboratories this  
 13 is not follow--this is not a requirement for  
 14 accreditation and therefore there is not  
 15 follow up with the requirement for  
 16 accreditation, the success is much less. They  
 17 continue to repeat the same sub-optimal  
 18 practice from one run to another.

19 And that's why am I mentioning this at  
 20 all, I'm mentioning because I want to point  
 21 out that external laboratory assurance  
 22 programs are not sufficient if they're not  
 23 linked to appropriate accreditation. But on  
 24 the other hand, I also want to credit NordiQC  
 25 which still today functions with most of the

Page 16

1 labs, this is not a requirement for  
 2 accreditation, their participation, but they  
 3 have seen great improvements from one run to  
 4 another assuring that direct feedback and  
 5 close communication with laboratories and  
 6 emphasis on education and posting the results  
 7 on the internet really available that all of  
 8 that in itself, even without requirements for  
 9 accreditation can change the practice how  
 10 laboratories function.

11 COFFEY, Q.C.:

12 Q. Okay, so, Doctor, what I'd like to do is, if I  
 13 could, ask, please, if perhaps we could go to  
 14 the next--let me see there. The next slide,  
 15 I'll take you through this, your own personal  
 16 background first so the Commissioner gets--and  
 17 I appreciate you've given us an overview. The  
 18 Commissioner get some actual sense of what you  
 19 have been involved in in a more detailed way.  
 20 You've pointed out to the Commissioner already  
 21 that the beginning of 1997, you'll see here on  
 22 the screen, you were the director of the  
 23 immunohistochemistry from '97 through 2003 at  
 24 the department of pathology, the Norwegian  
 25 Radium Hospital in Oslo, Norway. Doctor, at

Page 17

1 the time director of immunohistochemistry,  
 2 what did that actually mean during those six  
 3 years, in a practical way, what did that  
 4 involve?  
 5 DR. TORLAKOVIC:  
 6 A. For my own practice it involved actually not  
 7 only administratively overseeing what  
 8 laboratory is doing, but actually because we  
 9 were trying to develop the centre for  
 10 excellence in immunohistochemistry, at the  
 11 time, actually, when new techniques have been  
 12 just introduced to diagnostic  
 13 immunohistochemistry, meaning normal  
 14 antibodies were just put--were made available  
 15 for paraffin embedded tissues, meaning that  
 16 highly sensitive methods were just starting to  
 17 be available commercially, like polymer based  
 18 methods, and suddenly we were faced that we  
 19 are looking at the results of  
 20 immunohistochemistry that has totally  
 21 different outlook than it had just a few years  
 22 ago. So this meant for me, as a laboratory  
 23 director, that I had to learn everything about  
 24 what we were producing. That means suddenly  
 25 we have seen, for example, there is this new

Page 18

1 antibody CD14; CD14 was traditionally used  
 2 with flowcytometry only and now I'm faced with  
 3 looking at tissue sections and there is no  
 4 literature published on that, how it should  
 5 look like, not pathology literature. So I had  
 6 to go resources like basic science literature  
 7 and try to find all kinds of different  
 8 resources in the--whatever source I could get  
 9 my hands on to try to figure out whether the  
 10 results we are getting are truthful, whether  
 11 they're okay, whether they're acceptable, is  
 12 this antibody cross-reactive or not or is it--  
 13 so whether that is something we can use for  
 14 patient care.  
 15 COFFEY, Q.C.:  
 16 Q. This was back in '97, '98, that time?  
 17 DR. TORLAKOVIC:  
 18 A. Yes, yes.  
 19 COFFEY, Q.C.:  
 20 Q. Doctor, and -  
 21 DR. TORLAKOVIC:  
 22 A. But I want to say on more thing, also, that  
 23 that was like in addition, that was not  
 24 routine, that is not part of the job that is  
 25 routinely thought up as being for director of

Page 19

1 immunohistochemistry. Much more routine thing  
 2 is to make sure that laboratory is using  
 3 adequate positive controls, adequate negative  
 4 controls, that I also evaluated every slide  
 5 that came out, from the--every run in that  
 6 laboratory to be sure that what we are seeing  
 7 in the controls and in the tissues make sense  
 8 and so on. But this was little bit more, I  
 9 think, that would belong to a usual  
 10 description to that, but -  
 11 COFFEY, Q.C.:  
 12 Q. To actually get into like for the CD14, for  
 13 example, to actually have to research it all  
 14 yourself?  
 15 DR. TORLAKOVIC:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. Okay. Doctor, I want to backup a bit because,  
 19 well, first of all, before you took the  
 20 position in Oslo.  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. As the director, in your own career had you  
 25 had exposure to immunohistochemistry?

Page 20

1 DR. TORLAKOVIC:  
 2 A. I had, as a resident, actually, two ways how I  
 3 had exposure to immunohistochemistry. It's  
 4 one through the training program. And at the  
 5 training program has been established, has  
 6 been--well, the immunohistochemistry part, I  
 7 should say, the immunohistochemistry I think  
 8 at that--at the University of Minnisota was  
 9 established by Markwick and Paul Swason, those  
 10 are really internationally, the United States  
 11 pathologists, but they're internationally  
 12 known experts in immunohistochemistry. At the  
 13 time I was a resident they just left couple of  
 14 years before me, right. But there was the  
 15 setup with the algorithms, there was, the  
 16 technology was there, the understanding how  
 17 things should be done was there. And that, I  
 18 think I that I had this privileged position of  
 19 having the exposure to excellence, at the  
 20 time. And at the same time my research  
 21 interest involved my personal exposure in the  
 22 laboratory where I performed  
 23 immunohistochemistry on my own, but also  
 24 actually went a step further and combined  
 25 immunohistochemistry with in situ

Page 21

1 hybridization which was, this is known as  
 2 fiction. It's not because it is fiction  
 3 itself, but it is abbreviation that kind of  
 4 units florescence in situ hybridization with  
 5 immunohistochemistry. And that's a very  
 6 challenging technique and at the time I used  
 7 the technique to show for the first time  
 8 evidence of unmanipulated cells that the pH  
 9 chromosome, which is a hallmark of chronic  
 10 myeloleukemia is also present in benign  
 11 circulating T and B cells of patients with  
 12 this disease in chronic phase. And that has  
 13 been published in high impact journal. And  
 14 while doing that, I mean, this just didn't  
 15 happen, there were no simple protocols to  
 16 follow, I had to be inventive and figure out  
 17 on my own how to produce technically this  
 18 part. So I went through lost of methods and  
 19 lots of hands-on experience and that made me  
 20 quite aware of what are the components of  
 21 immunohistochemistry, what can go wrong and  
 22 how things can be improved or not.  
 23 COFFEY, Q.C.:  
 24 Q. Okay. And this would be in the mid 1990s  
 25 going thorough -

Page 22

1 DR. TORLAKOVIC:  
 2 A. Yes, yes.  
 3 COFFEY, Q.C.:  
 4 Q. Looking at your time in Minnisota?  
 5 DR. TORLAKOVIC:  
 6 A. Right.  
 7 COFFEY, Q.C.:  
 8 Q. Kind of, and, I'm sorry, yes, in Minnapolis.  
 9 You were there, you know, really beginning in  
 10 '91 to '93, then '93, '94, '94 to '96?  
 11 DR. TORLAKOVIC:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. Different positions, but you were there  
 15 throughout that time?  
 16 DR. TORLAKOVIC:  
 17 A. Right.  
 18 COFFEY, Q.C.:  
 19 Q. So you then in 1997 ended up in Oslo. Were  
 20 you recruited as the director of  
 21 immunohistochemistry, were you recruited or  
 22 asked to--when you first came to that  
 23 hospital, that was your position?  
 24 DR. TORLAKOVIC:  
 25 A. Yeah, I was asked to do that specific task. I

Page 23

1 was also asked if I could prepare a handout  
 2 that would help pathologists better use  
 3 immunohistochemistry, not with the sense of to  
 4 save the money because that's often on minds  
 5 of many, but with the sense of like because so  
 6 much literature that is being published in the  
 7 field then, and even more now, it is difficult  
 8 for practising pathologists, even for  
 9 specialized pathologists in certain field, to  
 10 absolutely follow every published record and  
 11 focus on the immunohistochemical aspects of  
 12 their practice. So I actually got as a part  
 13 of my job to prepare that handout, which I  
 14 did.  
 15 COFFEY, Q.C.:  
 16 Q. Okay, and was there a director of  
 17 immunohistochemistry at that hospital before  
 18 you arrived?  
 19 DR. TORLAKOVIC:  
 20 A. No, there was not.  
 21 COFFEY, Q.C.:  
 22 Q. So this was a new initiative?  
 23 DR. TORLAKOVIC:  
 24 A. Right.  
 25 COFFEY, Q.C.:

Page 24

1 Q. And did you have any understanding as to why  
 2 someone in the hospital had already arrived at  
 3 the idea of obtaining a director, appointing a  
 4 director of immunohistochemistry? In terms of  
 5 at the time you arrived -  
 6 DR. TORLAKOVIC:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. What was your understanding about why they  
 10 wanted a director of immunohistochemistry?  
 11 DR. TORLAKOVIC:  
 12 A. Oh, but it was clear. I think I mentioned  
 13 this that this was--Norwegian Radium Hospital  
 14 is a major cancer hospital and referral centre  
 15 for Norway. So they diagnose and treat cancer  
 16 patients. So the emphasis was--it was clear  
 17 to them that--clear to Dr. Nesland who was the  
 18 chief of the department that they must have a  
 19 specialist in this area because this is the  
 20 area that is critical for diagnosis and  
 21 establishing appropriate prognostic and  
 22 predictive markers.  
 23 COFFEY, Q.C.:  
 24 Q. Okay, and you're the person who arrived there  
 25 to set it up. He asked you to come and

Page 25

1       oversee it?

2 DR. TORLAKOVIC:

3     A. Yes, I was just out of training, but the thing

4       is at the time there was very--in Europe, I

5       don't think there was any place where you

6       could actually obtain official training and

7       certification in this area. I was not

8       certified to practice immunohistochemistry or

9       anything like that, but he--my name was

10       probably recommended to him by some people who

11       knew me.

12 COFFEY, Q.C.:

13     Q. Okay. Doctor, then as you've indicated

14       already to the Commissioner, after you got

15       established there, got your office set up and

16       started to work, you realized that or noticed

17       that there was--you said particularly from

18       hospitals, because it was a regional centre -

19 DR. TORLAKOVIC:

20     A. Yes.

21 COFFEY, Q.C.:

22     Q. This particular hospital, you noticed that

23       variability in the quality of the material

24       that was being sent to you, or variable

25       results? What was it that caused you then to

Page 26

1       think, well, I have to organize something here

2       so that we're all kind of dealing with the

3       same or approaching this in the same way?

4       What was it about what you saw at the time?

5 DR. TORLAKOVIC:

6     A. Often when patients would arrive to the

7       hospital, their diagnostic material would

8       follow them from different hospitals, and that

9       included sending slides and blocks. So what

10       we do usually, and I think it's done all over

11       Canada and United States, and it's part of

12       routine practice, and you have to actually

13       evaluate this material and confirm the

14       diagnosis that was made in another centre

15       before the patient receives the treatment in

16       that hospital--in your hospital. So we had

17       this paraffin blocks and we did immunostaining

18       on our own with panels that we maybe had and

19       they didn't, but also with things that they

20       did, and it often would show that our results

21       were better. So there was a great discrepancy

22       and some of diagnosis were actually missed--

23       not missed, but maybe not completely correct

24       because some of the results with

25       immunohistochemistry were wrong.

Page 27

1 COFFEY, Q.C.:

2     Q. Okay.

3 DR. TORLAKOVIC:

4     A. And that for me--that was something that after

5       repeated several times, for me that was a red

6       light that we can do something before patients

7       are sent to us. Maybe we can help them

8       improve.

9 COFFEY, Q.C.:

10    Q. Doctor, you've indicated to the Commissioner

11       that you then set about organizing, at least

12       from the Norwegian perspective, an approach to

13       this, and you've indicated as well that DAKO

14       Nordic -

15 DR. TORLAKOVIC:

16    A. Yes.

17 COFFEY, Q.C.:

18    Q. As it turned out, who was providing these

19       products at times, the various type of

20       products in use in Norway, did provide some

21       funding to assist this, and you described

22       that. Doctor, what about the other three

23       countries that ended up in NordiQC, I mean,

24       how did you go about not only within Norway,

25       but like across an international border,

Page 28

1       organizing other pathologists to become part

2       of this, how did that work? How did you get

3       the Fins involved and the Swedes? I mean, how

4       did that come about?

5 DR. TORLAKOVIC:

6     A. I actually have no direct knowledge who has

7       selected who to invite from each country, but

8       obviously that company has made some choices

9       on their own for who are the leaders in each

10       country. So they picked out representatives

11       of major laboratories from different

12       countries, and it started as, like, nine

13       laboratories and then it shrink to the core

14       group of four with one representative from

15       each country.

16 COFFEY, Q.C.:

17    Q. So the actual organization initially was done

18       by whom?

19 DR. TORLAKOVIC:

20    A. Actual invitations were done by DAKO Nordic.

21 COFFEY, Q.C.:

22    Q. By DAKO itself?

23 DR. TORLAKOVIC:

24    A. I believe, yes.

25 COFFEY, Q.C.:

Page 29

1 Q. Okay, and your recollection is they original  
 2 started with nine reps from nine labs?  
 3 DR. TORLAKOVIC:  
 4 A. Right.  
 5 COFFEY, Q.C.:  
 6 Q. And then over time it went down to four core  
 7 labs, I take it, one in each country?  
 8 DR. TORLAKOVIC:  
 9 A. Right.  
 10 COFFEY, Q.C.:  
 11 Q. Okay.  
 12 DR. TORLAKOVIC:  
 13 A. But that core was actually kind of--that was  
 14 not what the company did. That core remained  
 15 there after. Of those nine representatives,  
 16 things filtered out and we figured ourselves,  
 17 like, these are the people who are going to  
 18 take it further.  
 19 COFFEY, Q.C.:  
 20 Q. Okay.  
 21 DR. TORLAKOVIC:  
 22 A. And since then, I mean, that core group has  
 23 remained with one representative from each  
 24 country and it's still like that.  
 25 COFFEY, Q.C.:

Page 30

1 Q. So, Doctor, I take it--do I understand you to  
 2 be saying, look, DAKO had a hand in organizing  
 3 this to start, inviting people?  
 4 DR. TORLAKOVIC:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. And providing some kind of funding for travel  
 8 and stuff -  
 9 DR. TORLAKOVIC:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. So people could come to this initial meeting?  
 13 DR. TORLAKOVIC:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. And then when the representatives from the  
 17 nine labs--nine of 11, sorry?  
 18 DR. TORLAKOVIC:  
 19 A. Nine laboratories.  
 20 COFFEY, Q.C.:  
 21 Q. Nine laboratories, showed up, we then took it  
 22 upon ourselves and from then on -  
 23 DR. TORLAKOVIC:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

Page 31

1 Q. It evolved as time went on and it ended up as  
 2 four of us?  
 3 DR. TORLAKOVIC:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. Over time.  
 7 DR. TORLAKOVIC:  
 8 A. And at the time also it switched from any  
 9 sponsorship from DAKO to participation fees.  
 10 So the laboratories that participate, they pay  
 11 for each run they participate in, and that  
 12 totally supports the function--all functions  
 13 of NordiQC.  
 14 COFFEY, Q.C.:  
 15 Q. So, Doctor, here looking at this, it indicates  
 16 in the second bullet here, "NordiQC, a core  
 17 group, you were the Norwegian representative  
 18 from 1999 through 2004?  
 19 DR. TORLAKOVIC:  
 20 A. That's right.  
 21 COFFEY, Q.C.:  
 22 Q. And from 2004 to the present, you're indicated  
 23 to be an external contributor?  
 24 DR. TORLAKOVIC:  
 25 A. Yes.

Page 32

1 COFFEY, Q.C.:  
 2 Q. You review articles?  
 3 DR. TORLAKOVIC:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. What does that involve?  
 7 DR. TORLAKOVIC:  
 8 A. That involves that I review certain topics of  
 9 interest, certain epitopes like CD23, and I  
 10 look at the literature, current literature,  
 11 and I write a summary, like, where the--what  
 12 are the expected results in benign tissue  
 13 tumours, and I provide images that I think are  
 14 most useful, most informative, and that part  
 15 of NordiQC is very valuable because it has an  
 16 educational role.  
 17 COFFEY, Q.C.:  
 18 Q. Yes.  
 19 DR. TORLAKOVIC:  
 20 A. And I think that that part was commented on to  
 21 me personally from several people who go to  
 22 NordiQC site. If they want to quickly review  
 23 what's important about certain epitopes, they  
 24 go there and then they see the summary, and  
 25 they also see referenced literature which is



Page 33

1 also helpful.

2 COFFEY, Q.C.:

3 Q. Doctor, in relation to that then, I was going

4 to have you, if you would, outline for the

5 Commissioner what it is that NordiQC does,

6 what services do they provide to the four

7 country participants? What services do they

8 provide?

9 DR. TORLAKOVIC:

10 A. They provide--well, they are external quality

11 assurance program.

12 COFFEY, Q.C.:

13 Q. Now what does that mean in practice?

14 DR. TORLAKOVIC:

15 A. And that means that they provide tissue

16 samples that are carefully selected for

17 testing. They send unstained slides to

18 laboratories.

19 COFFEY, Q.C.:

20 Q. I'm sorry, they send?

21 DR. TORLAKOVIC:

22 A. They send unstained slides to laboratories

23 that stain them with certain antibodies. They

24 send it back. A group of assessors or experts

25 are reviewing the results and scoring them,

Page 34

1 and then telling participants how they can

2 improve their results.

3 COFFEY, Q.C.:

4 Q. The staining process, I take it?

5 DR. TORLAKOVIC:

6 A. The staining process and the interpretation,

7 if necessary, and also for each of the runs

8 for the epitopes that are being tested, so for

9 the molecules that we are evaluating, these

10 short reviews from experts are also provided

11 as additional education in the area.

12 COFFEY, Q.C.:

13 Q. Okay.

14 DR. TORLAKOVIC:

15 A. So what it really provides, we can summarize

16 it, it provides them means to calibrate their

17 internal quality assurance program in a sense

18 to make sure that it's calibrated properly,

19 and also it provides education that is

20 necessary to run certain tests in their

21 laboratories.

22 COFFEY, Q.C.:

23 Q. For example--so the NordiQC group -

24 DR. TORLAKOVIC:

25 A. I should mention--I'm sorry to interrupt, but

Page 35

1 I should mention that they also organize

2 seminars and courses and workshops, which are

3 held typically in a different country at a

4 different site where technologists can come

5 and have direct interaction with expert

6 technologists and pathologists and discuss

7 issues, problems, and anything that they find

8 that they want to do. There is a lecture

9 format where it's presentations and topics are

10 evaluated by experts, but also there is bench

11 type of format, actually technologists being

12 able to interact directly with experts is also

13 an important part of that.

14 COFFEY, Q.C.:

15 Q. So NordiQC then provides unstained slides that

16 presumably the people who are doing the

17 providing know what's on the slide?

18 DR. TORLAKOVIC:

19 A. Yes, they do.

20 COFFEY, Q.C.:

21 Q. They know exactly what's on the slide, the

22 type of tissue that's there?

23 DR. TORLAKOVIC:

24 A. They know exactly, yes.

25 COFFEY, Q.C.:

Page 36

1 Q. And they know the characteristics that it

2 should show?

3 DR. TORLAKOVIC:

4 A. Absolutely.

5 COFFEY, Q.C.:

6 Q. Or should exhibit if appropriately stained, if

7 the staining process is appropriate?

8 DR. TORLAKOVIC:

9 A. Correct.

10 COFFEY, Q.C.:

11 Q. And so they send those out to the

12 participating labs, and are they told to stain

13 for particular--do the participating labs

14 understand that they're supposed to stain for

15 particular antibodies?

16 DR. TORLAKOVIC:

17 A. Absolutely. Each run has a list for tests

18 that they apply for. They select themselves

19 which test they want to apply for, and,

20 therefore, they get appropriate material for

21 that.

22 COFFEY, Q.C.:

23 Q. And then the participating lab, wherever it

24 is, stains the slides -

25 DR. TORLAKOVIC:

Page 37

1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. For that antibody, and do they also have their  
 4 own pathologists, like, in the participating  
 5 labs, do they give an interpretation of what  
 6 they see on the slide?  
 7 DR. TORLAKOVIC:  
 8 A. That depends on the test.  
 9 COFFEY, Q.C.:  
 10 Q. Okay.  
 11 DR. TORLAKOVIC:  
 12 A. It is not required for the test--for the usual  
 13 tests or what we call Class I test, but it is  
 14 required for Class II test like HER2 test.  
 15 COFFEY, Q.C.:  
 16 Q. So the Class II tests, the pathologists get  
 17 involved?  
 18 DR. TORLAKOVIC:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. At participating institutions and give their  
 22 interpretations as well  
 23 DR. TORLAKOVIC:  
 24 A. Exactly.  
 25 COFFEY, Q.C.:

Page 38

1 Q. Which accompany the slides back to the core  
 2 group?  
 3 DR. TORLAKOVIC:  
 4 A. Exactly.  
 5 COFFEY, Q.C.:  
 6 Q. And for the Class I slides, they're examined  
 7 in the way you've described for their quality?  
 8 DR. TORLAKOVIC:  
 9 A. Exactly.  
 10 COFFEY, Q.C.:  
 11 Q. And they're given feedback, the participating  
 12 labs get feedback?  
 13 DR. TORLAKOVIC:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. And the Class II slides, they're examined for  
 17 quality by the core group?  
 18 DR. TORLAKOVIC:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. And as well, there's a commentary upon the  
 22 interpretation?  
 23 DR. TORLAKOVIC:  
 24 A. Exactly.  
 25 COFFEY, Q.C.:

Page 39

1 Q. By the participating pathologists?  
 2 DR. TORLAKOVIC:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. And indicated that as well NordiQC provides in  
 6 respect of particular antibodies, educational  
 7 seminars and, in fact, some of it, I take it,  
 8 would be electronic, would be online?  
 9 DR. TORLAKOVIC:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. Where the participants are able to avail of  
 13 it, and there are seminars held by time to  
 14 time, courses, seminars?  
 15 DR. TORLAKOVIC:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. Those courses or seminars are for  
 19 technologists you've indicated that already to  
 20 the Commissioner, the technologists do go to  
 21 them?  
 22 DR. TORLAKOVIC:  
 23 A. Also for pathologists.  
 24 COFFEY, Q.C.:  
 25 Q. And for pathologists too.

Page 40

1 DR. TORLAKOVIC:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. Okay. Is participation in NordiQC mandatory  
 5 for the labs in the Scandinavian countries?  
 6 DR. TORLAKOVIC:  
 7 A. No.  
 8 COFFEY, Q.C.:  
 9 Q. It's not.  
 10 DR. TORLAKOVIC:  
 11 A. They have in Finland separate program that is  
 12 their national program, which is obligatory,  
 13 it's regulated, but that--to my best  
 14 knowledge, that is the only country that has  
 15 obligatory participation, but participation in  
 16 NordiQC is not obligatory. Still many  
 17 laboratories choose to participate.  
 18 COFFEY, Q.C.:  
 19 Q. That was my next question, if it's not  
 20 obligatory, at least up to the time that you  
 21 left in 2004, what was your sense of how many  
 22 clinical laboratories--what proportion of  
 23 clinical laboratories do participate in  
 24 NordiQC? Would there be a high percentage of  
 25 participation?

Page 41

1 DR. TORLAKOVIC:  
 2 A. High percentage, I think, yes. I know in the  
 3 beginning there was obviously smaller number,  
 4 started with nine, but very soon it went to  
 5 the numbers of 56, and now I think it's range  
 6 of hundreds.  
 7 COFFEY, Q.C.:  
 8 Q. And, Doctor, what I'd like to do now is I'm  
 9 going to come back to where you're coming to  
 10 Canada and your experience here, I'm going to  
 11 return to that, okay, but what I'd like to do  
 12 now is--I'll return to that slide in a little  
 13 while. In relation to--and you've spoken  
 14 about here on this slide, the NordiQC program.  
 15 DR. TORLAKOVIC:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. You made a note to speak to the Commissioner  
 19 about, from your perspective, the history of  
 20 quality control in IHC in the United States  
 21 because, of course, you had a time there,  
 22 quite a number of years as a resident doing  
 23 different residencies in Indianapolis. What  
 24 has been your experience in relation to  
 25 quality control in the United States for IHC,

Page 42

1 what's the situation there?  
 2 DR. TORLAKOVIC:  
 3 A. My personal experience?  
 4 COFFEY, Q.C.:  
 5 Q. Yes, and in terms of your observations as a  
 6 participant in NordiQC -  
 7 DR. TORLAKOVIC:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. Is there any central body in the US that  
 11 handles quality control for IHC; if so, what  
 12 is it?  
 13 DR. TORLAKOVIC:  
 14 A. Yes, there is actually. Of course, there is  
 15 College of American Pathologists that have a  
 16 special module also for immunohistochemistry  
 17 and it's requirement for accreditation--  
 18 participation in their program is requirement  
 19 for accreditation of the labs, and I also know  
 20 that many of the Canadian laboratories  
 21 participate in that program.  
 22 COFFEY, Q.C.:  
 23 Q. In the CAP program?  
 24 DR. TORLAKOVIC:  
 25 A. Yes, in the CAP program. If you want me to

Page 43

1 comment on differences -  
 2 COFFEY, Q.C.:  
 3 Q. Yes, between the CAP program and the -  
 4 DR. TORLAKOVIC:  
 5 A. I don't know if I can move the slide.  
 6 COFFEY, Q.C.:  
 7 Q. Yes, you certainly can.  
 8 DR. TORLAKOVIC:  
 9 A. Like, here -  
 10 COFFEY, Q.C.:  
 11 Q. Exploratory--sorry, external laboratory  
 12 quality assurance, EQA, and you have -  
 13 DR. TORLAKOVIC:  
 14 A. So you see I have mentioned there is UK NEQAS  
 15 and CAP program from United States. NordiQC,  
 16 it's actually the youngest of them, except for  
 17 the one that we just started--tried to develop  
 18 in Canada, which is Canadian  
 19 Immunohistochemistry Quality Control. So there  
 20 are other programs, of course. This is not  
 21 total list of all programs around the world,  
 22 and some of them are smaller, some of them are  
 23 larger, but these are the ones that will come  
 24 up for anybody who's practising in Canada,  
 25 people will see these names, and they have

Page 44

1 contacts with one or the other or all of them.  
 2 CAP program is structured differently than  
 3 NordiQC, and it's different than UK NEQAS.  
 4 What UK NEQAS and NordiQC have in common that  
 5 they have this assessors component. So there  
 6 is a group of experts. They don't have to be  
 7 pathologists necessarily, but group of trained  
 8 experts who understand how the results should  
 9 look like, to sit down to score the slides,  
 10 and it's just not one who would see that.  
 11 Assessments are typically organized by four  
 12 people sitting at the microscope, and there is  
 13 no magic number, whether it should be one,  
 14 two, three, four or whatever the number may  
 15 be. The number has been selected as--during  
 16 these assessments, there is always some kind  
 17 of discussion that is arising, and as  
 18 technology is progressing, we are faced with  
 19 results that we have not seen before, and  
 20 that's certainly the case even now, not only  
 21 in '97 when I started to run the laboratory in  
 22 Norway, but I see still that with new  
 23 developments we can see different results now.  
 24 Now that has to be interpreted and discussed  
 25 between the experts so that we do not make a

Page 45

1 wrong ruling on the success of the staining.  
 2 We don't want to proclaim something being  
 3 false positive if indeed it's positive more  
 4 than previously known because of better  
 5 technology. So we have to have people with  
 6 enough background and different type of  
 7 background and knowledge to be able to assess  
 8 the complexity of this results. So these  
 9 assessments are not simple, they cannot be  
 10 automatized, they cannot be done by machines,  
 11 they have to be done by experts in various  
 12 fields actually at the same time.  
 13 COFFEY, Q.C.:  
 14 Q. So UK NEQAS and NordiQC both use assessor--  
 15 expert assessor panels?  
 16 DR. TORLAKOVIC:  
 17 A. Yes, and CAP does not have that component, so  
 18 this -  
 19 COFFEY, Q.C.:  
 20 Q. How does CAP go?  
 21 DR. TORLAKOVIC:  
 22 A. The difference is that there is a self-  
 23 assessment. So when you receive unstained  
 24 slides from them -  
 25 COFFEY, Q.C.:

Page 46

1 Q. From CAP?  
 2 DR. TORLAKOVIC:  
 3 A. You sent the slides from CAP and you score the  
 4 slides yourself, and scoring the slides  
 5 yourself, it's done to the best possible  
 6 knowledge, and it's only one person who is  
 7 doing it and it doesn't even have to be  
 8 director of immunohistochemistry because not  
 9 every laboratory has director of  
 10 immunohistochemistry, so it's the pathologist  
 11 at hand, let's say, sometimes. So that when  
 12 these results are received by CAP, they are  
 13 plotted on graphs that show where do you  
 14 belong in the overall picture, how many other  
 15 laboratories have received the same results as  
 16 your are based on your own judgment what your  
 17 results are.  
 18 COFFEY, Q.C.:  
 19 Q. So CAP sends out the unstained slides. They  
 20 are slide--I'm sorry, they are stained?  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. And interpreted locally?  
 25 DR. TORLAKOVIC:

Page 47

1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. Wherever the hospital is, the lab is, and then  
 4 that interpretation is sent back to CAP?  
 5 DR. TORLAKOVIC:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. And CAP just plots that result on a graph with  
 9 all other reported results?  
 10 DR. TORLAKOVIC:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. And then the hospital that did the staining  
 14 and interpretation can see where they stand in  
 15 relation to everybody else?  
 16 DR. TORLAKOVIC:  
 17 A. Exactly.  
 18 COFFEY, Q.C.:  
 19 Q. Yes.  
 20 DR. TORLAKOVIC:  
 21 A. And that means--that usually means if we agree  
 22 with the most, that's okay, and if we don't  
 23 agree, if we are on one or other side of the  
 24 curve, you're probably not good, but it really  
 25 doesn't mean that.

Page 48

1 COFFEY, Q.C.:  
 2 Q. Okay. What is, from your perspective, what is  
 3 the weakness with that or potential problems  
 4 with that, that assumption that if I'm in with  
 5 the group, I'm fine?  
 6 DR. TORLAKOVIC:  
 7 A. I mean, everybody can be wrong, too.  
 8 COFFEY, Q.C.:  
 9 Q. Yes.  
 10 DR. TORLAKOVIC:  
 11 A. If something that is common and very frequent  
 12 results, it's not necessarily correct result.  
 13 So there has to be expert evaluation and  
 14 decision whether the results are really  
 15 appropriate or not.  
 16 COFFEY, Q.C.:  
 17 Q. So from your perspective, I take it, when you  
 18 compare that aspect of CAP to the expert  
 19 assessment group and UK NEQAS and NordiQC  
 20 offer, it's your view that UK NEQAS and  
 21 NordiQC have a stronger program in that  
 22 regard?  
 23 DR. TORLAKOVIC:  
 24 A. In that regard, I would say that I think  
 25 personally and professionally I would always

Page 49

1 opt to participate in a program that has  
 2 assessors as a step.  
 3 COFFEY, Q.C.:  
 4 Q. Expert assessment?  
 5 DR. TORLAKOVIC:  
 6 A. Right.  
 7 COFFEY, Q.C.:  
 8 Q. Now Doctor, does CAP offer any other service  
 9 related to immunohistochemistry that you're  
 10 aware of anyway?  
 11 DR. TORLAKOVIC:  
 12 A. We are not using anything else. Actually, our  
 13 laboratory in Canada where I work now, we are  
 14 participating in the program and this is all  
 15 we do with CAP.  
 16 COFFEY, Q.C.:  
 17 Q. And now in relation to--I'll ask you now about  
 18 NordiQC. You've described the process that  
 19 was arrived at for immunohistochemistry. Do  
 20 they offer any other service in  
 21 immunohistochemistry?  
 22 DR. TORLAKOVIC:  
 23 A. NordiQC?  
 24 COFFEY, Q.C.:  
 25 Q. Yes.

Page 50

1 DR. TORLAKOVIC:  
 2 A. Well, they do in a sense because if you fail  
 3 the results, you can request additional slides  
 4 to be retested to see whether you can improve.  
 5 You have an option of personal communication,  
 6 not in the sense to complain, I don't like  
 7 your readings, but you can actually request  
 8 advice and there is also this educational  
 9 component that is available on the web all the  
 10 time, showing what results should look like  
 11 and so on.  
 12 COFFEY, Q.C.:  
 13 Q. And in relation to UK NEQAS, okay, what sorts  
 14 of services are you aware that they offer for  
 15 IHC? What does UK NEQAS do?  
 16 DR. TORLAKOVIC:  
 17 A. Well, they test. Also, they assess the  
 18 results. They send the scores back and their  
 19 detailed score sheet shows how--what each  
 20 separate assessor meant, not--like NordiQC  
 21 gives a common score between the agreed  
 22 assessor score. UK NEQAS gives each  
 23 individual and then I think it's average that  
 24 they go by at the end. They have some other  
 25 comments talking about--they will comment on

Page 51

1 background staining and details if they know  
 2 it is something that is immediately relevant,  
 3 but they will not go into the details of your  
 4 procedure at NordiQC to identify whether a  
 5 specific buffer, in their opinion, was wrong  
 6 and whether the dilution of the antibody  
 7 perhaps was wrong. But they will give some  
 8 educational component with this assessor's  
 9 score sheet.  
 10 COFFEY, Q.C.:  
 11 Q. And UK NEQAS then, NordiQC -  
 12 DR. TORLAKOVIC:  
 13 A. They also publish their results. They do,  
 14 there is a publication and in that  
 15 publication, there are many good instructive  
 16 images of the staining. It's similar--that's  
 17 similar between NordiQC and UK NEQAS, but I  
 18 think the major difference being that NordiQC  
 19 is totally internet based, while UK NEQAS is  
 20 not.  
 21 COFFEY, Q.C.:  
 22 Q. Nordi, I'm sorry, is totally -  
 23 DR. TORLAKOVIC:  
 24 A. Is internet based.  
 25 COFFEY, Q.C.:

Page 52

1 Q. Internet based?  
 2 DR. TORLAKOVIC:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. And UK NEQAS is not?  
 6 DR. TORLAKOVIC:  
 7 A. Right.  
 8 COFFEY, Q.C.:  
 9 Q. As of yet anyway, it's not.  
 10 DR. TORLAKOVIC:  
 11 A. Right.  
 12 COFFEY, Q.C.:  
 13 Q. Doctor, could you tell the Commissioner,  
 14 please, from your perspective, what the  
 15 potential ramifications are of not having  
 16 appropriate quality control for IHC? What's  
 17 the down side to not having appropriate  
 18 quality control?  
 19 DR. TORLAKOVIC:  
 20 A. If I'm--maybe I'm free to move to some sites?  
 21 COFFEY, Q.C.:  
 22 Q. Sure, go ahead.  
 23 DR. TORLAKOVIC:  
 24 A. Well, that's also now, we're going back to the  
 25 classification of tests because then we have

Page 53

1 to go kind of from the beginning, because it's  
 2 hard to say -  
 3 COFFEY, Q.C.:  
 4 Q. Well, that's what we'll do then. We'll go  
 5 back to the (unintelligible) mostly then take  
 6 you through because you had at the time--go  
 7 back perhaps to the history, just go back even  
 8 further, Doctor, right there. Perhaps you  
 9 could just take up the narrative then and,  
 10 because this is done in a chronological  
 11 organized fashion by subject, and take the  
 12 Commissioner then through this.  
 13 DR. TORLAKOVIC:  
 14 A. I think the main point about reviewing the  
 15 history is to show that it was not before 1989  
 16 that these issues about quality control in  
 17 immunohistochemistry were taken really as  
 18 something of critical importance that needs  
 19 regulation. So 1989, that's now about 20  
 20 years ago, immunohistochemistry has been in  
 21 use much longer than that and has been  
 22 historically considered as an art rather than  
 23 science, because of so many components that  
 24 are present in this technique, three major  
 25 areas. I'm sure this has been mentioned by

Page 54

1 many by now that there is pre-analytical,  
 2 analytical and post-analytical components and  
 3 none of the components of these components can  
 4 be ignored when it comes to what outcome or  
 5 the result of the testing will be. However,  
 6 there were no means previously technically  
 7 that these procedures could be standardized or  
 8 regulated. So when they become available  
 9 technically and when the knowledge,  
 10 accumulating knowledge on the techniques has  
 11 been--has reached this point, it has been  
 12 decided that some regulation is possible in  
 13 the area, and therefore this first workshop  
 14 from NH in 1989 started this movement and that  
 15 developed further through various ways,  
 16 meetings, publications, which--all with the  
 17 same aim to see how much regulation we can do  
 18 without harming the procedure, because we do  
 19 want to avoid over regulation in this area.  
 20 COFFEY, Q.C.:  
 21 Q. And why is that?  
 22 DR. TORLAKOVIC:  
 23 A. Over regulation would mean, I think, by  
 24 definition, too much of a burden for  
 25 laboratories to do things that have no

Page 55

1 clinical relevance or to tie down a laboratory  
 2 with numerous tests that would be LAR  
 3 (phonetic) meaning that they are done on their  
 4 own without any practical use, clinical use  
 5 for pathologists, patients, clinicians and so  
 6 on. So we don't want--and actually, we don't  
 7 want to over regulate also in the sense that  
 8 we expect what is not possible, because some  
 9 of the things are just not possible, even  
 10 today, even though technology has progressed  
 11 and some aspects can be regulated.  
 12 COFFEY, Q.C.:  
 13 Q. Okay, so, I'm sorry, Doctor, go ahead. The  
 14 narrative then was taken out, I believe, in  
 15 1991 with the--go back, there was a biological  
 16 stain commission?  
 17 DR. TORLAKOVIC:  
 18 A. Yeah, I was--obviously I was not involved  
 19 personally in any of these steps. This is the  
 20 review that I gained from reviewing the  
 21 literature, reviewing different sites and  
 22 discussions on this topic and this use and  
 23 events seem to, in my professional opinion, is  
 24 worthwhile listing here because they, at the  
 25 time, made some kind of impact on clinical

Page 56

1 practice. So if I would have to point out  
 2 some of them here, what they really meant--  
 3 actually, let us move further.  
 4 COFFEY, Q.C.:  
 5 Q. Sure.  
 6 DR. TORLAKOVIC:  
 7 A. I think the one that was, in my personal  
 8 opinion, the most important one is this  
 9 classification of IHC devices and this is  
 10 where Class I and Class II tests and class  
 11 three tests, for that matter, have been  
 12 mentioned in the document, and that is a  
 13 critical point about understanding different  
 14 impact of different immunohistochemical tests.  
 15 COFFEY, Q.C.:  
 16 Q. And that's in 1994, this FDA panel meeting to  
 17 recommendation a classification of IHC  
 18 devices?  
 19 DR. TORLAKOVIC:  
 20 A. Right.  
 21 COFFEY, Q.C.:  
 22 Q. Okay.  
 23 DR. TORLAKOVIC:  
 24 A. That, I think, was--and that is still carried  
 25 out today, and I'm going to talk a little bit

Page 57

1 more about it, how is this important and how  
 2 this should be taken, you know, into practice  
 3 through QC programs and so on, because that  
 4 determines actually everything for the  
 5 practice of laboratories. I don't think we  
 6 need to mention specifically more about  
 7 immunohistochemistry and the definition of it,  
 8 but I think we need to talk about Class I and  
 9 Class II tests.

10 COFFEY, Q.C.:  
 11 Q. Okay.

12 DR. TORLAKOVIC:  
 13 A. So that FDA ruled at the time that -

14 COFFEY, Q.C.:  
 15 Q. This is back in the mid '90s?

16 DR. TORLAKOVIC:  
 17 A. Yes, mid '90s, that there are tests clinically  
 18 that have different clinical impact, and there  
 19 are tests that are used in conjunction with  
 20 morphology in conjunction with clinical  
 21 information and they're interpreted usually in  
 22 panels, looking at results of other  
 23 immunohistochemical tests too, and all of this  
 24 together meant that pathologists are using  
 25 this, trying to understand the differentiation

Page 58

1 of the tissue to gain additional information  
 2 about biological aspects of the disease they  
 3 are looking at, but they are not used alone.  
 4 They are interpreted in conjunction with this  
 5 other available information and they are never  
 6 reported alone as such. So there is, at no  
 7 time, clinicians will get a diagnosis that  
 8 says this is 45 positive tumour period or  
 9 something like that, and that would not--that,  
 10 in itself, would not carry any clinical  
 11 information for them. So Class I tests  
 12 therefore do not stand alone.

13 Class II tests, we call them, they stand  
 14 alone and they are reported independently and  
 15 the best example of that is the example of  
 16 breast cancer markers. Estrogen receptor,  
 17 progesterone receptor, HER2, they--we already  
 18 have the diagnosis, so we already know that  
 19 the patient has breast cancer. Now we have to  
 20 give additional information and describe the  
 21 characteristic of biological (unintelligible)  
 22 of this disease to tell the clinician whether  
 23 the tumour actually shows expression of these  
 24 receptors or HER2 and to what degree. So we  
 25 have to say something about these molecules.

Page 59

1 We have to tell about their presence and  
 2 quantitate them. So, and it's all--they can  
 3 be reported actually not only as a stand-alone  
 4 conceptually result, but also separate reports  
 5 are frequently generated just to report on  
 6 that fact in addition to, as an adjunct report  
 7 to previously reported diagnosis of breast  
 8 cancer, or they can be incorporated in the  
 9 original diagnostic report.

10 So therefore, the stand-alone tests,  
 11 prognostic and predictive tests, they can be  
 12 both at the same time. For example, estrogen  
 13 receptor is both prognostic and predictive,  
 14 but it's predictive value to predict the  
 15 outcomes of the therapy is far more critical  
 16 for the patient than its prognostic value.

17 COFFEY, Q.C.:  
 18 Q. So generally, tests fall into Class I or Class  
 19 II and I take it the bulk of tests, in terms  
 20 of sheer numbers, would be Class I?

21 DR. TORLAKOVIC:  
 22 A. Yes. We have only very few Class II tests and  
 23 these Class II tests, they can be qualitative  
 24 or quantitative or both at the same time, and  
 25 that's--I'm showing this slide to point out

Page 60

1 that there is further classification of  
 2 immunohistochemical tests. It's not spelled  
 3 out as such, but many of the Class II tests  
 4 actually test drug combos or combinations,  
 5 when you have a result of the test that is  
 6 ultimately linked to specific therapy and that  
 7 test drug combination, for example, it's not  
 8 only breast cancer markers. It could be in  
 9 lymphomas, CD20 and Rituxan therapy because  
 10 that special drug is designed to target CD20  
 11 molecule, so that's why I call it test drug  
 12 combination.

13 COFFEY, Q.C.:  
 14 Q. So you have here a classification of IHC tests  
 15 into Class I, Class II, and in fact, class  
 16 three.

17 DR. TORLAKOVIC:  
 18 A. In fact, class three too, yes.

19 COFFEY, Q.C.:  
 20 Q. Is there a class--could you just tell the  
 21 Commissioner about what a class--I take it  
 22 that ER and PR and HER2/neu would fall into  
 23 the Class II category?

24 DR. TORLAKOVIC:  
 25 A. This is changing because I think the major

Page 61

1 difference between Class II and class three is  
 2 whether there is sufficient scientific  
 3 evidence to validate their use as prognostic  
 4 and predictive tests. So therefore, the  
 5 category of ER/PR and HER2, they were all, at  
 6 some time, would belong to class three without  
 7 enough evidence and as the evidence is  
 8 accumulated, they move to Class II.  
 9 COFFEY, Q.C.:  
 10 Q. Okay, move, okay.  
 11 DR. TORLAKOVIC:  
 12 A. So at this time, for sure, ER/PR, and to tell  
 13 you the truth, I haven't look it up at last  
 14 time, but they are conceptually Class II tests  
 15 for us because this is how we use them.  
 16 Whether FDA would define them either as Class  
 17 II and class three, it's for this purpose  
 18 irrelevant because what we are talking about  
 19 are stand-alone tests and are reported  
 20 separately with this impact on patient care.  
 21 COFFEY, Q.C.:  
 22 Q. And certainly the ER/PR and HER2/neu fall into  
 23 that category?  
 24 DR. TORLAKOVIC:  
 25 A. Yes, absolutely, but there are also a couple

Page 62

1 other tests that have similar impact. I just  
 2 mentioned CD20, but it hasn't been classified  
 3 as such, basically because entities that are  
 4 treated with Rituxan are biologically known to  
 5 express CD20 and it is rarely that we have to  
 6 report separately CD20, though more and more  
 7 now, there is a clinical pressure to do so.  
 8 So I think that we have to move CD20 also in  
 9 the category of Class II test now, and CD117  
 10 in gist, it's basically used to define biology  
 11 of the--to use diagnostically so that you  
 12 arrive to the appropriate diagnosis of  
 13 gastrointestinal stomal tumour, but because of  
 14 the relevance for the therapy, the targets  
 15 actually, imagine if the targets this protein  
 16 kind is separate, therefore, it is also Class  
 17 II test. So in Canada, one of the things that  
 18 we are working on right now, in the National  
 19 Standards Committee that I'm chairing, is to  
 20 find the Canadian consensus, like which tests  
 21 we are going to put in Class II test and  
 22 request adequate external quality assurance  
 23 program to follow them.  
 24 COFFEY, Q.C.:  
 25 Q. Okay, and I'll be coming to that. So in the

Page 63

1 regulatory regime in the United States, under  
 2 the FDA, there are--you can kind of go onto  
 3 their site, I take it, and find out whether a  
 4 particular marker is a Class I, they consider  
 5 a Class I, or whether they consider a Class II  
 6 or class three, I take it? Because there's a  
 7 definition. They have a definition of what is  
 8 Class I, Class II and class three?  
 9 DR. TORLAKOVIC:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. Characteristics. And I take it in terms of  
 13 just sheer numbers, there are relatively few  
 14 Class II markers compared to the number of  
 15 Class I markers?  
 16 DR. TORLAKOVIC:  
 17 A. Absolutely, very few.  
 18 COFFEY, Q.C.:  
 19 Q. Very few, and I'll come to that in a bit, in  
 20 the Canadian context, in particular. And  
 21 here, you've noted here, panels,  
 22 undifferentiated tumour panel (unintelligible)  
 23 panel, in which non-specific tests when used  
 24 together are considered highly specific versus  
 25 a single specific test used in the appropriate

Page 64

1 context, having high specificity.  
 2 DR. TORLAKOVIC:  
 3 A. Specificity.  
 4 COFFEY, Q.C.:  
 5 Q. Yes, I have a problem pronouncing that. And  
 6 you've given as examples, ALK1 and CD117. So  
 7 CD117, would that be a Class I or Class II, in  
 8 this context?  
 9 DR. TORLAKOVIC:  
 10 A. In this context, it is Class I.  
 11 COFFEY, Q.C.:  
 12 Q. Class I, and if we could then, Doctor, go  
 13 ahead. You were speaking about the--telling  
 14 the Commissioner the difference between Class  
 15 I and Class II. I believe here, you have some  
 16 examples, a paraffin section immuno  
 17 phenotyping of particular types of  
 18 malignancies. Would you take the Commissioner  
 19 just through this?  
 20 DR. TORLAKOVIC:  
 21 A. Yeah. I have two examples actually for Class  
 22 I tests, how they work, and these are both  
 23 taken from this document that is posted by Dr.  
 24 Markwick on his website and he made it  
 25 available to anybody for free access and use,



Page 65

1 so I felt free that I can copy this here and  
 2 show you. It is not exactly how it has to be  
 3 used. This is not a guideline, but it's an  
 4 algorithm that can be used, and now you can  
 5 see that we already have the idea that we are  
 6 working with hematoporietic malignancy, but we  
 7 have to arrive to specific diagnosis. So then  
 8 what do we do? All of the boxes that are  
 9 presented here are different antibodies.

10 COFFEY, Q.C.:  
 11 Q. That's the box, the black box with the white  
 12 writing?  
 13 DR. TORLAKOVIC:  
 14 A. Right. It says vimentin, lyasyme,  
 15 myloperoxidase, CD34, CD20, other B cell  
 16 markers, CD45RO, CD45, and therefore, we apply  
 17 a panel of antibodies and then follow known  
 18 rules about their distribution in different  
 19 tumours, but we don't make the judgment based  
 20 on positivity or negativity of just one of  
 21 them. So it looks rather complex here and it  
 22 is a complex process, but generally, it's not  
 23 that complicated, in a sense, when you work  
 24 with it. Immunohistochemical diagnosis of  
 25 small cell tumours, now we already have

Page 66

1 morphological entity. We know it's a small  
 2 cell tumour. There is just certain number--  
 3 there is a list of diseases that can be in  
 4 differential--that is in differential  
 5 diagnosis of this diagnostic category and then  
 6 you apply some of the markers, like  
 7 cytokeratin, leucocyte common antigen, EMA,  
 8 vimentin, S100 and then based on their  
 9 positivity or negativity and interpretation of  
 10 that, one makes the final diagnosis.

11 However, for Class II tests, there are no  
 12 complicated schemes like that. You just have  
 13 single test and you have to give a score on  
 14 it, if there is a score in that guideline or  
 15 just say it's positive or negative, and the  
 16 reports are generally very simple when  
 17 generated on Class II tests, and the  
 18 simplicity of the reports is actually what  
 19 masks, I think, the true biological and  
 20 technical complexity of the testing, because  
 21 they are far more complex to regulate and  
 22 technically optimize than Class I tests, which  
 23 as you could see from this presentation, Class  
 24 I tests may appear to have--to be very complex  
 25 for daily use and interpretation, but it is

Page 67

1 Class II tests that we actually have the most  
 2 trouble with, despite the superficial  
 3 simplicity of the reports.

4 COFFEY, Q.C.:  
 5 Q. Could you go on to the next slide, Doctor,  
 6 yes.  
 7 DR. TORLAKOVIC:  
 8 A. It's very little that we speak about  
 9 sensitivity and specificity of these tests.  
 10 And it is something that in my personal  
 11 opinion, it is not of lacking, especially the  
 12 sensitivity of the test, that is lacking from  
 13 our reports. This reports are generated today  
 14 and for decades since they started to be used,  
 15 you never have in the clinical report a  
 16 statement on the sensitivity of the test.  
 17 None of the laboratories, to the best of my  
 18 knowledge, report we have 94 percent  
 19 sensitivity in detecting estrogen receptors.  
 20 That does not exist. And there are reasons  
 21 why that does not exist, but I think as a  
 22 clinical test that these should be followed  
 23 and that clinicians who are using that  
 24 information should have that information. And  
 25 why is that? We know when we do quality

Page 68

1 assurance testing, if we use large enough of  
 2 samples to do so, I can tell you for CAP  
 3 survey now, they use 40 samples for HER 2  
 4 tests. 40 samples is a large enough number  
 5 that one can actually calculate sensitivity of  
 6 the test in relation to the reference value or  
 7 one can calculate Kappa-value with reference  
 8 value or one can calculate the concordance and  
 9 recommended concordance is 95 percent. So any  
 10 of these are somehow reflecting the  
 11 sensitivity of the laboratory, so you know  
 12 that acceptable pass rate today for Class 2  
 13 test, like HER2 is 95 percent concordance by  
 14 ASCO guideline and that was adopted also by  
 15 Canadian panel on HER2. So that means that  
 16 it's not a hundred percent and I think that  
 17 needs to be clear when this values are  
 18 reported to the clinicians. It may be that  
 19 it's even much lower than that from the log  
 20 that is reporting results. Maybe it's 80  
 21 percent concordance, maybe it's not 95  
 22 percent, but who knows and since clinicians  
 23 don't know, they take our reports as for  
 24 granted a hundred percent sensitivity, which  
 25 we do not often have. Therefore, I personally

Page 69

1 think that that's a component that is missing  
 2 from the reports. Once it's there, it allows  
 3 clinician to think more rightly about their  
 4 political options and to also take into  
 5 account other things that most of them usually  
 6 do, but sometimes they don't. So it enables,  
 7 gives additional power to oncologist to make  
 8 decision on the treatments and say, all right,  
 9 it's 95 percent, it's not one hundred percent,  
 10 maybe I should treat this patient anyway  
 11 because there is this other evidence that this  
 12 type of treatment may be helpful. They don't  
 13 necessarily need this value, but I think it is  
 14 a clinical test and such information can be  
 15 produced and I think it's of value, so it's my  
 16 personal take on the sensitivity and  
 17 specificity of this test.  
 18 COFFEY, Q.C.:  
 19 Q. To your knowledge no pathology laboratories,  
 20 at least to date, actually do report on that?  
 21 DR. TORLAKOVIC:  
 22 A. No.  
 23 COFFEY, Q.C.:  
 24 Q. Of course, if they were to do so, to  
 25 clinicians, the clinicians would have to

Page 70

1 understand actually the significance of it?  
 2 DR. TORLAKOVIC:  
 3 A. Right, but that would also mean that they have  
 4 to participate to such programs that enable  
 5 them to determine the sensitivity of their  
 6 tests.  
 7 COFFEY, Q.C.:  
 8 Q. And would the lab have to do that--the  
 9 particular lab would have to do that at the  
 10 beginning.  
 11 DR. TORLAKOVIC:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. And the clinicians would have to understand,  
 15 in fact, what it is the reports mean?  
 16 DR. TORLAKOVIC:  
 17 A. Exactly.  
 18 COFFEY, Q.C.:  
 19 Q. Okay. Doctor, this is entitled "Standards and  
 20 Optimization", would you just take the  
 21 Commissioner through this?  
 22 DR. TORLAKOVIC:  
 23 A. I think that the term standards has been over  
 24 used greatly in this area. Since it is such a  
 25 critical issue today in immunohistochemistry

Page 71

1 that we produce accurate results, there is a  
 2 lot of use of the term standardization.  
 3 Standardization should be used when we can  
 4 actually standardize all the components of the  
 5 procedure. Since we cannot standardize at  
 6 current time, pre-analytical component, it's  
 7 just simply not possible, we can go towards  
 8 that goal of standardizing it, but since we  
 9 cannot standardize tissue processing, we  
 10 cannot truly standardize the test. So  
 11 therefore -  
 12 COFFEY, Q.C.:  
 13 Q. When you say you cannot standardize, I take it  
 14 you cannot perfectly standardize it in the  
 15 sense of -  
 16 DR. TORLAKOVIC:  
 17 A. You can standardize components but you cannot  
 18 standardize the entire test.  
 19 COFFEY, Q.C.:  
 20 Q. Pre-analytic.  
 21 DR. TORLAKOVIC:  
 22 A. Pre-analytic without standardization of pre-  
 23 analytical component, all of this other  
 24 things, if you standardize, will not result  
 25 with ultimately standard all test.

Page 72

1 COFFEY, Q.C.:  
 2 Q. Sure.  
 3 DR. TORLAKOVIC:  
 4 A. And that's why I have problem with that and an  
 5 additional problem is that, first I think what  
 6 we want to do is optimization. In the current  
 7 state of knowledge, technology and what we  
 8 have available, we can optimize the test  
 9 definitely, but I don't think we can  
 10 standardize. And standardization actually  
 11 also depends on the ability of a lab to have  
 12 standardized controls. Even for the  
 13 analytical component, we cannot standardize  
 14 fully. We can make it the same every time,  
 15 that doesn't mean it's standardized.  
 16 Something if it's the same, it's not--  
 17 standards means that we have a point of  
 18 reference that we use to which we adjust all  
 19 the protocols and procedures to such product  
 20 and what is our point of reference?  
 21 Immunohistochemistry, that's positive  
 22 controls, so the standardization process  
 23 should start and it's not complete, but should  
 24 start with standardization of positive  
 25 controls and that is the greatest challenge

Page 73

1 right now at this point, historically at this  
 2 point of time is to standardize positive  
 3 controls.  
 4 COFFEY, Q.C.:  
 5 Q. And why is that, Doctor. Why is there a  
 6 challenge -  
 7 DR. TORLAKOVIC:  
 8 A. The challenges, one is that--there are several  
 9 challenges, actually, it's rather complex  
 10 procedure to standardize the controls, one of  
 11 them is this tissue processing which we can  
 12 try to make as uniform as possible. We can  
 13 try to involve surgery departments in that,  
 14 but you cannot control, for example why this  
 15 cannot be fully standardized, let me tell you,  
 16 because you cannot tell the surgeon how long  
 17 the surgical procedure will last, you cannot  
 18 tell them since you claim (phonetic) this  
 19 vessel and the tissue ischemia is changing our  
 20 epitopes, did you record that time so that we  
 21 know exactly when you did that and you know,  
 22 you shouldn't be doing that for too long  
 23 because the tissue will become, you know,  
 24 would alter it and then our  
 25 immunohistochemistry is not going to work. I

Page 74

1 mean, that's nonsense, that's not going to  
 2 work, so the tissue degradation starts with  
 3 the point of when these vessels have been cut  
 4 or tied and that interoperative part we  
 5 certainly cannot control at all. And after  
 6 that, we can try optimizing from the point of  
 7 tissue procurement to the laboratory and what  
 8 happens from there on, but it's a rather  
 9 complex process. I know that in many of the  
 10 laboratories or hospitals this is being done,  
 11 they are optimizing every step in the tissue  
 12 processing now, looking at the best ways how  
 13 this antigen preservation will be uniform and  
 14 the best, how antigens are going to be best  
 15 preserved in the given circumstances of  
 16 realities of operating room and how pathology  
 17 departments work with their specimen receiving  
 18 system and so on. But what are the other  
 19 challenges? Tissue process is one. The other  
 20 one is you have to have expert consensus on  
 21 what are the outcomes and for positive  
 22 controls, unfortunately still many  
 23 laboratories what they're using as a reference  
 24 point is just anything that gives positive  
 25 reaction and it's rather simple to find that.

Page 75

1 It's simple to find, for example, a tumour of  
 2 benign tissue that shows high cytokeratin  
 3 expression or high chromagram (phonetic)  
 4 expression, yes. But that is not what should  
 5 be used for positive control and the practice,  
 6 if it hasn't changed in some of the labs, it  
 7 has to be changed. And the guidelines should  
 8 be there that there always has to be composite  
 9 tissue that has, tissue that presents  
 10 expression, various expression levels of  
 11 epitope, including and the most critical one  
 12 that has very low levels of expression of the  
 13 protein that we are looking for. That is  
 14 critical for the calibration of daily QC  
 15 process. Without it, we don't really know how  
 16 our procedures are set up, to what level, how  
 17 they are calibrated and there is no definite  
 18 and final document that would tell to  
 19 pathologists or to technologists how to  
 20 collect those controls. There are some  
 21 general guidelines I can tell you right away,  
 22 I like to use these because it's so simple to  
 23 explain that for some of the epitopes, it's  
 24 very easy, like CD-23, if you use a tonsil,  
 25 which most people actually use because it's a

Page 76

1 lymphoid tissue and this is a lymphoid  
 2 antigen, then you're looking at cells that  
 3 have very strong expression of CD-23 and those  
 4 are fully chondrogenic cells and at the same  
 5 time, the follicle is surrounded with a mantle  
 6 that has lymphocytes that has a very weak  
 7 expression. So in the same tissue it's benign  
 8 and it's predictable, you have this various  
 9 levels of antigen expression. However, do we  
 10 have this spelled out for every epitope that  
 11 we are looking for and there are over hundreds  
 12 of tests that are used in many of the  
 13 laboratories, this Class 1 test, you don't.  
 14 And we don't even have definite guidelines how  
 15 to create positive controls for Class 2 tests  
 16 and that's another very important topic is  
 17 where are the guidelines, how do you prepare  
 18 actually positive controls for ER/PR and HER2?  
 19 Any test that has a quantitative component has  
 20 to have its own quantitative positive  
 21 controls. So there are some suggestions and,  
 22 of course, there is industry behind it too  
 23 that are creating tissue culture controls with  
 24 given amount of epitope we are looking at, but  
 25 that's not perfect solution either because

Page 77

1 tissue cuts just do not fully represent what's  
 2 going on in the tissues. And I just want to,  
 3 I hope, yeah, perfect, that's the slide we  
 4 want. This is the last NordiQC round of tests  
 5 on HER2 and this table is taken directly from  
 6 their site. You can see these are the results  
 7 of the cell lines and these are the results of  
 8 tissues, so their score is either optimal,  
 9 good, borderline or poor. Now you can see  
 10 that for some of the samples, here is three,  
 11 in three labs that was a borderline result  
 12 with cell lines, but optimal with tissue or a  
 13 good--so there was no perfect correlation and  
 14 cell lines did not do better than tissues and  
 15 some explanations that NordiQC has for this is  
 16 that this happened because of the impaired  
 17 morphology of the cell lines and this is  
 18 possible because of excessive retrieval. But  
 19 more testing, I don't think this is the final  
 20 ruling, but I think this is the first evidence  
 21 that has been shown that cell lines are not  
 22 necessarily superior to tissue controls and  
 23 actually the conclusion from NordiQC was, I  
 24 don't know if it's going to stand the test of  
 25 time and for the studies, but it is believed

Page 78

1 now by NordiQC that tissue controls actually  
 2 are better, but there is a value also of the  
 3 controls from tissue cell lines.  
 4 COFFEY, Q.C.:  
 5 Q. So the idea of using -  
 6 DR. TORLAKOVIC:  
 7 A. Kind of both show these.  
 8 COFFEY, Q.C.:  
 9 Q. - both cell cultures is there, it's out  
 10 there, it's being looked at and it's still,  
 11 from your perspective, there's still no  
 12 conclusion -  
 13 DR. TORLAKOVIC:  
 14 A. No, that's not a perfect solution and also  
 15 there is a very high cost of such positive  
 16 controls and if one is to use such positive  
 17 controls on every slide that we prefer to use  
 18 in our current practice, we prefer to use  
 19 positive controls on every slide that we test.  
 20 That would be prohibitively expensive. I  
 21 think it's \$40.00 per one slide or so. I don't  
 22 know the exact value, but I know it's high  
 23 enough that it's not something that--and since  
 24 there is no proof that they're better, I don't  
 25 think they should be recommended at this point

Page 79

1 as an ultimate controls for Class 2 tests.  
 2 But having said that, I have been involved in  
 3 trying to create so called perfect tissue  
 4 controls, so we tried, in collaboration with  
 5 Jewish General Hospital with Dr. Pilavdzic,  
 6 she provided numerous samples from tumours  
 7 with various expression levels of one of the  
 8 Class 2, with HER2 basically, for HER2  
 9 positive controls and we collect--looked at 50  
 10 samples and made cores for tissue microarrays  
 11 and tested the first to see what are their  
 12 expression levels and also official results  
 13 were available. So the idea was if you have  
 14 this information, maybe you can still get,  
 15 maybe you can sample tissue cores from those  
 16 tumours that you have well characterized as  
 17 your positive controls and create, perhaps,  
 18 small tissue microarrays with the perfect  
 19 combination of from zero to three plus, so it  
 20 would be four cores or maybe even 8 just so--  
 21 because to allow for some tissue  
 22 hydrogenating, and it works, but it does not  
 23 work as we predicted because of this tissue  
 24 hydrogenating, you don't get exactly the same  
 25 value in each core from the same tumour. You

Page 80

1 do make--you are able to make very good  
 2 positive controls like that, but each of them  
 3 have to be again validated, each of them has  
 4 to be, it's a unique, actually, positive  
 5 control, has to be photographed at the  
 6 beginning as a reference value, so that they  
 7 can be interpreted after each run, in  
 8 comparison of what their perfect results  
 9 should look like. So it's a rather complex  
 10 process and I don't know, we never looked at  
 11 how many laboratories actually trying to do  
 12 what other laboratories are doing with  
 13 positive controls, but I know it's not  
 14 standardized yet, even for Class 2 tests, not  
 15 to speak about Class 1 at all.  
 16 COFFEY, Q.C.:  
 17 Q. So, Doctor, my way of bringing you around to  
 18 your arrival in Canada, okay, you arrived in  
 19 Canada, I believe, in 2004, 2005?  
 20 DR. TORLAKOVIC:  
 21 A. No, actually in December of 2003.  
 22 COFFEY, Q.C.:  
 23 Q. '03, I'm sorry, and you came here to work  
 24 where?  
 25 DR. TORLAKOVIC:

Page 81

1 A. At the Royal University Hospital College of  
 2 Medicine at the University of Saskatchewan.  
 3 COFFEY, Q.C.:  
 4 Q. And what's your position there?  
 5 DR. TORLAKOVIC:  
 6 A. I'm academically appointed pathologist. I'm  
 7 currently an associate professor in the  
 8 Department of Pathology and Laboratory  
 9 Medicine.  
 10 COFFEY, Q.C.:  
 11 Q. And, Doctor, when you arrived in Canada and  
 12 started a practice, what did you find in  
 13 relation to the situation here in terms of  
 14 quality control or quality assurance and in  
 15 particular for IHC testing?  
 16 DR. TORLAKOVIC:  
 17 A. Well, the first--my first experience was, of  
 18 course, with the laboratory in Saskatoon.  
 19 COFFEY, Q.C.:  
 20 Q. Yes.  
 21 DR. TORLAKOVIC:  
 22 A. So I have looked at, like, what is their  
 23 practice in daily QC and what's their practice  
 24 in EQA, their participation in different  
 25 programs, and despite participation in

Page 82

1 different programs, I found that at the time  
 2 there were many things about the practice that  
 3 could have benefited and be improved with some  
 4 simple measures, but that also showed me that  
 5 participation in EQA program itself was not  
 6 sufficient to do this changes for the lab.  
 7 COFFEY, Q.C.:  
 8 Q. I'm going to ask you about this. So the  
 9 laboratories in Saskatoon Hospital there where  
 10 you were working -  
 11 DR. TORLAKOVIC:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. Did at the time you arrived, prior to your  
 15 arrival, participated in EQA?  
 16 DR. TORLAKOVIC:  
 17 A. Yes, they participated in CAP.  
 18 COFFEY, Q.C.:  
 19 Q. But based upon what you were seeing, and some  
 20 observations, and I take it you would be  
 21 comparing that really to your experience in  
 22 Europe in the main?  
 23 DR. TORLAKOVIC:  
 24 A. Right.  
 25 COFFEY, Q.C.:

Page 83

1 Q. That there were some relatively simple things  
 2 from your perspective could be changed to  
 3 improve?  
 4 DR. TORLAKOVIC:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. Matters--yet they hadn't occurred despite the  
 8 participation in CAP?  
 9 DR. TORLAKOVIC:  
 10 A. Exactly.  
 11 COFFEY, Q.C.:  
 12 Q. Would you go ahead then, Doctor, what then  
 13 happened? You say you made this observation.  
 14 What did you do?  
 15 DR. TORLAKOVIC:  
 16 A. So I made this observations and it gave me a  
 17 lot of thought about what kind of EQA is  
 18 necessary for us in Saskatoon, what we would  
 19 like to have. So, of course, I suggested  
 20 let's go and participate in NordiQC, but it's  
 21 an overseas program and Canada is not really--  
 22 I mean, it takes many days for the specimens  
 23 to travel from one side of the ocean to  
 24 another. So it just wasn't a good enough  
 25 idea. I noticed that actually Canada did not

Page 84

1 have a national program. I heard that  
 2 somebody is doing something in BC and there is  
 3 an Ontario program, but there was no program  
 4 for Canada which I found surprising because  
 5 Canada is large enough country that--I found  
 6 it unusual that it's totally dependent on CAP  
 7 program, and at the same time some provinces  
 8 have their own, like, they are separate  
 9 country or something, and it's just--it was  
 10 unusual that there is such big border between  
 11 the provinces. I didn't really quite  
 12 understand how big these borders  
 13 administrative are until I actually tried to  
 14 approach some people to see whether we can  
 15 start developing a national program.  
 16 COFFEY, Q.C.:  
 17 Q. Okay, so you arrived, you made your  
 18 observations within your own lab?  
 19 DR. TORLAKOVIC:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. Thought about NordiQC, but there is just  
 23 simply the geographic distance, and shipping  
 24 times, I take it, and so on?  
 25 DR. TORLAKOVIC:

Page 85

1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. And what then happened? You noticed British  
 4 Columbia has some kind of a program involving  
 5 laboratories. You understood Ontario does?  
 6 DR. TORLAKOVIC:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. What then happened?  
 10 DR. TORLAKOVIC:  
 11 A. Since I didn't know at the time many  
 12 pathologists in Canada, I did ask my  
 13 colleagues who would be logical, you know,  
 14 colleagues to contact to try to set up such a  
 15 program, and it was very difficult to find  
 16 people who would be willing or find that  
 17 interesting enough to try to create, or it was  
 18 just some of them were very pessimistic about  
 19 the possibility of a national program in the  
 20 view of provincial borders.  
 21 COFFEY, Q.C.:  
 22 Q. Yes.  
 23 DR. TORLAKOVIC:  
 24 A. But I did find Dr. Blake Gilks from BC who was  
 25 the--Dr. Blake Gilks from Vancouver General

Page 86

1 Hospital. He was rather enthusiastic because  
 2 they were in the middle of developing their  
 3 own provincial program and he thought that  
 4 provincial program is not a solution, that we  
 5 do need a national program. So we got  
 6 together. I actually travelled with my own  
 7 funds to Vancouver and we discussed this in  
 8 detail, and made a plan how are we going to  
 9 start this. I approached the Dean of Medicine  
 10 at the University of Saskatchewan at the  
 11 College of Medicine and asking him for his  
 12 help. I told him I think this is necessary, I  
 13 think I need help because we need a web page,  
 14 we need IT support for this, would you be  
 15 willing to support us, and he said yes. So  
 16 the College of Medicine provided IT support  
 17 and the web page was set up, and it was set up  
 18 in such a nice way that it's very easy to do  
 19 changes, upgrades. So with administrative  
 20 powers that I have, I can go easily and since  
 21 I work with computers, I can do a lot of that  
 22 on my own, not demanding too much from IT  
 23 people or from the College of Medicine. The  
 24 idea was to create a program that is going to  
 25 have both--provide testing that are adequate

Page 87

1 for immunohistochemistry, quality assurance,  
 2 but also to provide education, and what we  
 3 wanted the most, actually, Dr. Blake Gilks and  
 4 I, is to create a program that will have  
 5 transparency.  
 6 COFFEY, Q.C.:  
 7 Q. Yes.  
 8 DR. TORLAKOVIC:  
 9 A. Because as you can see, and I don't know if  
 10 anybody try to go into certain programs,  
 11 pages, and to see the results, you may see  
 12 some results, you may see some of the good  
 13 examples of the staining and stuff like that  
 14 that is presented there, but you actually  
 15 cannot compare directly the results of your  
 16 lab with results of other laboratories. You  
 17 always get some kind of intermediate between  
 18 this to interpretation from--you either get  
 19 scores from assessor panels, overall picture,  
 20 but not direct insight, and we wanted to  
 21 create program that will give pathologists the  
 22 ability and technologists to go in and to  
 23 compare side by side their results with  
 24 someone else's results and see also a link to  
 25 that--those results, the protocols that

Page 88

1 produced them. So they can immediately change  
 2 if they want their protocols and adjust them  
 3 to improve their results if they need to be  
 4 improved.  
 5 COFFEY, Q.C.:  
 6 Q. So if we could, Doctor, on that, just to  
 7 explore that a bit with you, so there are EQA  
 8 programs that do exist and are accessible via  
 9 the web?  
 10 DR. TORLAKOVIC:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. Nordic would be an example of it?  
 14 DR. TORLAKOVIC:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. And one can go in as a pathologist,  
 18 particularly if you're a member, you can go in  
 19 and log in, click, put in your password, and  
 20 up comes, for example, your own results on the  
 21 screen, presumably. If you participate, you'd  
 22 be able to look at your own or you could have  
 23 them there -  
 24 DR. TORLAKOVIC:  
 25 A. Actually not. In Nordic, you can't see your

Page 89

1 own.  
 2 COFFEY, Q.C.:  
 3 Q. Okay, you can't even see your own?  
 4 DR. TORLAKOVIC:  
 5 A. No, no, no.  
 6 COFFEY, Q.C.:  
 7 Q. But you can see your own in front of you?  
 8 DR. TORLAKOVIC:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. In a microscope, you know on a microscope?  
 12 DR. TORLAKOVIC:  
 13 A. Actually, you send it back, so you don't see  
 14 it ever after.  
 15 COFFEY, Q.C.:  
 16 Q. So, Doctor, in terms of being able to compare  
 17 your results, what you're getting for any  
 18 particular stain, whatever it is -  
 19 DR. TORLAKOVIC:  
 20 A. Right.  
 21 COFFEY, Q.C.:  
 22 Q. To anyone else's stains, are you able actually  
 23 to do that?  
 24 DR. TORLAKOVIC:  
 25 A. Now we are. In CAPs, I mean, let me just show

Page 90

1 you what we have made on this. This is not  
 2 moving.  
 3 COFFEY, Q.C.:  
 4 Q. There it is.  
 5 DR. TORLAKOVIC:  
 6 A. There are some stains here that I would like  
 7 to go back. I just want to skip now to this  
 8 program in Canada. This is what we call  
 9 multi-viewer. I have--we have asked IT  
 10 specialist to design this program for us  
 11 specifically with this idea, to make four  
 12 windows for virtual microscopy, so that we  
 13 design--the test material that is used by  
 14 Canadian immunohistochemistry quality control,  
 15 that's what CIQC stands for, are tissue  
 16 microarrays. So they're multiple tumours or  
 17 other tissue samples, so that one can go and  
 18 zoom in and even under higher power than here,  
 19 it will be even high close up, and compare.  
 20 Select the test you want to compare with  
 21 another lab and see how they do, and then  
 22 there are the protocols here. They are all  
 23 coded. The participation is anonymous, so you  
 24 can link certain result with certain protocol.  
 25 COFFEY, Q.C.:

Page 91

1 Q. So the protocol for a particular lab, the lab  
 2 is not identified?  
 3 DR. TORLAKOVIC:  
 4 A. No.  
 5 COFFEY, Q.C.:  
 6 Q. It's given a code number?  
 7 DR. TORLAKOVIC:  
 8 A. Right.  
 9 COFFEY, Q.C.:  
 10 Q. But the actual protocol used to produce that  
 11 particular slide -  
 12 DR. TORLAKOVIC:  
 13 A. Exactly.  
 14 COFFEY, Q.C.:  
 15 Q. Is there.  
 16 DR. TORLAKOVIC:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. It's laid out for themselves and anyone else  
 20 who participates to look at, and if they look  
 21 at a particular slide, you can look at the  
 22 corresponding protocol that the lab that  
 23 produced the slide used?  
 24 DR. TORLAKOVIC:  
 25 A. Yes.

Page 92

1 COFFEY, Q.C.:  
 2 Q. And then, presumably, compare it to your own  
 3 or another labs as you go?  
 4 DR. TORLAKOVIC:  
 5 A. Yes, and in addition to that, we also provide  
 6 summary pages, and this is very interesting  
 7 one where this is a quick--this hasn't been  
 8 done yet in External Quality Assurance  
 9 programs, a quick orientation where you are at  
 10 with your concordance rate is spelled out here  
 11 in this row, and each of the column here is  
 12 one laboratory that participated in the  
 13 testing, and you see the positive results are  
 14 coloured as red, negative are white, and  
 15 samples that were not possible to evaluate for  
 16 several technical reasons, they are yellow.  
 17 So they are taken out of the calculations. So  
 18 one can quickly see how laboratories compared  
 19 to each other in regards to positivity and  
 20 negativity, and also there is a concordance  
 21 rate that they get right away and this is the  
 22 value they need if one is to follow ASCO  
 23 guidelines for Class II tests.  
 24 COFFEY, Q.C.:  
 25 Q. I'll be coming back to this, but when you set

Page 93

1 out to do this back in the middle of 2000  
 2 after you arrived in Canada -  
 3 DR. TORLAKOVIC:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. I take it, that there was--from your  
 7 perspective, there was no such EQA available  
 8 that you were aware of anywhere that your lab  
 9 could participate?  
 10 DR. TORLAKOVIC:  
 11 A. No, but I--maybe I should go to this slide now  
 12 when we talk about this in Canada. No, there  
 13 was nothing like that, and still, I mean, when  
 14 you look at what--there is a good program, of  
 15 course, in Ontario, and the program that is  
 16 now in some other provinces is also very good.  
 17 So one cannot say that there is no good  
 18 external quality assurance programs in Canada.  
 19 I think it's critical to say that there are.  
 20 COFFEY, Q.C.:  
 21 Q. Yes.  
 22 DR. TORLAKOVIC:  
 23 A. But there is no national program, so not  
 24 everybody is in Ontario, not every is--so it  
 25 has to be also one of--also their programs,

Page 94

1 they don't do this educational component,  
 2 which I think is critical, and I think that it  
 3 has to be developed in many ways to enable  
 4 technologists, not only pathologists, to have  
 5 very close interactions with experts. Just  
 6 yesterday we were discussing like we should  
 7 create something like a hotline question and  
 8 answer pages where people can quickly answer  
 9 with their critical questions during the day  
 10 because you do need -- you need technical  
 11 support for instrumentation, you also need  
 12 expert support for all kinds of problems that  
 13 arise in daily practice of the lab that cannot  
 14 be sometimes solved by the pathologist who is  
 15 responsible or by expert technologist they  
 16 have there. There are some issues we can  
 17 benefit from interacting with each other and  
 18 they are actually not rare, if you let people  
 19 ask. I mean, I have been approached--  
 20 bombarded with number of e-mails at a time  
 21 with all kinds of questions, like, why is  
 22 this, why is that, how to use this, how to use  
 23 that. So there are so many things that people  
 24 need help with, and that is because the  
 25 technology is developing rapidly, that is

Page 95

1 because the publications are--numerous  
 2 publications in this field are out almost  
 3 daily and all of this has to be incorporated  
 4 into practice in the best way possible without  
 5 significant lag between the current state of  
 6 the art practises and the real picture in the  
 7 laboratory.  
 8 COFFEY, Q.C.:  
 9 Q. Doctor, if we could, you found--you noted  
 10 here, "No national standards for diagnostic  
 11 immunohistochemistry". You've pointed out  
 12 that there's no national accreditation body  
 13 certainly for immunohistochemical labs. For  
 14 clinical laboratories, you pointed out there  
 15 is a program in Ontario. When you arrived,  
 16 you learned that British Columbia was in the  
 17 process of setting one up. You prevailed upon  
 18 your Dean to give you at least a certain basic  
 19 resource, and talked to Dr. Gilks, met with  
 20 him?  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. I'm going to ask, Registrar, if you would,  
 25 please, bring up Exhibit P-0412. If we could

Page 96

1 go to page 26, please. Doctor, this is a  
 2 document that we obtained--the Commission  
 3 obtained from Eastern Health in the course of  
 4 preparing for the hearings, and this is  
 5 entitled, "Proposal for establishment of a  
 6 Canadian national external laboratory quality  
 7 control in diagnostic immunohistochemistry".  
 8 DR. TORLAKOVIC:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. And it's--it has your name there, yours and  
 12 Dr. Gilks, and it's dated 11th July, 2006.  
 13 This is a two page document. I'll just show  
 14 you, that's the second page, and if we go back  
 15 to page 20 of the exhibit--it's the first page  
 16 of the document here. It's proposal for  
 17 establishment of a national external quality  
 18 assurance program for clinical/diagnostic  
 19 immunohistochemistry, and then this particular  
 20 document goes on for six pages and the contact  
 21 person is indicated to be yourself?  
 22 DR. TORLAKOVIC:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. Now, Doctor, could you tell us, please--I take



Page 97

1 it, this shorter one, the two page, page and a  
 2 half here at page 26 of the exhibit, is really  
 3 just an executive summary of the first six  
 4 pages?  
 5 DR. TORLAKOVIC:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. Doctor, this is dated the 11th of July, 2006.  
 9 What had happened prior to this? I mean, how  
 10 far had you gotten or advanced with this  
 11 effort before July of '06, between the time  
 12 you first approached your Dean now and  
 13 produced this?  
 14 DR. TORLAKOVIC:  
 15 A. To tell you the truth, I don't know exact date  
 16 how this happened, I just have to say, because  
 17 I think at the time we already have  
 18 established web page.  
 19 COFFEY, Q.C.:  
 20 Q. Okay, you had probably the web page up?  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. Who was this proposal addressed to? It's a  
 25 proposal. Who is your target audience here?

Page 98

1 DR. TORLAKOVIC:  
 2 A. This was sent to--I believe, to Canadian  
 3 Association of Pathologists because for us,  
 4 that was a logical contact in the first place.  
 5 So we sent it there to the Executive Committee  
 6 of the CAP to consider this and help us out in  
 7 creating such a program.  
 8 COFFEY, Q.C.:  
 9 Q. And if I could, please, Exhibit P-1143.  
 10 Doctor, this is a couple of e-mails, but look  
 11 down at the bottom of the page here, the first  
 12 page. I believe it's an e-mail from Dr.  
 13 Laurette Geldenhuys, I believe a Nova Scotian,  
 14 Wednesday, July 12th, 2006. It's addressed to  
 15 Dr. Banerjee and Dr. Cook and it says--the  
 16 subject is QC for Immunoperoxidase. She  
 17 says, "Diponkar and Don, I received these  
 18 documents from Emina Torlakovic. Since we  
 19 discussed the issue at an executive meeting  
 20 recently, I thought you might find these  
 21 interesting. I attach". Do you know Dr.  
 22 Geldenhuys?  
 23 DR. TORLAKOVIC:  
 24 A. Yes, I know she--I think she was -  
 25 COFFEY, Q.C.:

Page 99

1 Q. She's at Dalhousie University, I take it?  
 2 DR. TORLAKOVIC:  
 3 A. Dalhousie, but she was--she's very active in  
 4 CAP. She's on the executive committee and she  
 5 also was in charge of, I think, continuing  
 6 medical education programs with CAP.  
 7 COFFEY, Q.C.:  
 8 Q. And here apparently in that e-mail, she had  
 9 sent on to Dr. Banerjee and Dr. Cook a copy  
 10 of, in fact, what is your proposal for the  
 11 establishment of a national external quality  
 12 assurance program for clinical/diagnostic  
 13 immunohistochemistry, that document, as well  
 14 as your executive summary. See that? So you  
 15 had submitted this to CAP?  
 16 DR. TORLAKOVIC:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. And apparently this was being circulated  
 20 within CAP itself, the executive there. If we  
 21 could look, please, at Exhibit P-2273. This  
 22 is another exhibit that we obtained. I  
 23 believe this is from Dr. Cook or Eastern  
 24 Health, one or other, or both, and this is Dr.  
 25 Cook's handwriting, "Executive meeting, July

Page 100

1 15th, 2006". Under paragraph five, in  
 2 particular, items for discussion, paragraph  
 3 5.4, it says, "National standards for  
 4 laboratory/immunohistochemistry testing, Dr.  
 5 Banerjee noted that a handout was circulated  
 6 regarding a proposal for the establishment of  
 7 a national external quality assurance program  
 8 for clinical/diagnostic immunohistochemistry.  
 9 This proposal was prepared by Dr. Torlakovic  
 10 and Gilks. A quick review of their proposal  
 11 brought forth a few areas of concern. In  
 12 particular, the last paragraph on page four  
 13 regarding Class II tests in HER2. The members  
 14 were asked to carefully read over the proposal  
 15 and forward their comments by e-mail to Dr.  
 16 Banerjee", and then, "they need to develop a  
 17 working group with medical and radiation  
 18 oncologists, Cancer Societies, CAP, and CCQLM  
 19 is in progress". Now, Doctor, if we could  
 20 then go back to Exhibit P-1143. This is one  
 21 of the copies of a proposal you made. You  
 22 sent your proposal to CAP. What happened?  
 23 DR. TORLAKOVIC:  
 24 A. In the beginning, nothing happened, actually.  
 25 COFFEY, Q.C.:

Page 101

1 Q. Okay.  
 2 DR. TORLAKOVIC:  
 3 A. I did not get any comments. I just  
 4 unofficially heard that this was found as an  
 5 interesting document and that it was decided  
 6 that CAP needs to--Canadian Association of  
 7 Pathologists needs to do something in this  
 8 area, and then later on I submitted a proposal  
 9 for a workshop that also takes in diagnostic  
 10 immunohistochemistry for Canadian Association  
 11 of Pathologists annual meeting. This was  
 12 accepted and this year--well, second year and  
 13 next year will be possibly the last year this  
 14 workshop is given, but it's one additional  
 15 thing that I did, but what then happened is  
 16 that last year Canadian Association of  
 17 Pathologists decided to form a committee which  
 18 they decided to call National Standards  
 19 Committee/immunohistochemistry. As I  
 20 understand, this would hope that there will be  
 21 other branches/something else in various  
 22 fields of pathology. So for this committee  
 23 try for national standards in  
 24 immunohistochemistry, they invited several  
 25 people or interested parties as members, and

Page 102

1 then they invited me, if I could chair this  
 2 committee, and I accepted that. So that was,  
 3 I think, in March last year that it happened,  
 4 and then I started to work with the committee  
 5 with an idea that we are going to try to  
 6 identify areas all in an effort to ultimately  
 7 improve practice of diagnostic  
 8 immunohistochemistry. Whether we call it  
 9 standards or not, as I said, I don't prefer to  
 10 use the word "standards" but I understand that  
 11 it has to be used sometimes.  
 12 COFFEY, Q.C.:  
 13 Q. Now, Doctor, you say you were invited to do  
 14 this last March. Would that be March of 2008  
 15 or 2007, March?  
 16 DR. TORLAKOVIC:  
 17 A. 2007.  
 18 COFFEY, Q.C.:  
 19 Q. 2007, okay. So it's been now about a year and  
 20 a half?  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. Okay. Doctor, if we could look just at this,  
 25 your original proposal--this is page, yes,

Page 103

1 eight, just looking at that, it's page eight  
 2 of the exhibit of P-1143, well, it states in  
 3 the beginning, I suppose, well, it was  
 4 certainly obvious to you that "Canada does not  
 5 have a national external laboratory QC program  
 6 in diagnostic immunohistochemistry. Other  
 7 countries, including the USA, United Kingdom  
 8 and Scandinavian countries have established  
 9 such programs adapted for their own national  
 10 needs and arena." You write, "Quality  
 11 assurance in laboratory medicine includes, (a)  
 12 constant checking of test reliability by  
 13 internal quality control, ICQ; external  
 14 quality assessment, EQA, by an independent  
 15 agency to check performance of a number of  
 16 laboratories at intervals in order to obtain a  
 17 retrospective indication of their performance;  
 18 and (c) proficiency control by supervision of  
 19 pretest and post-test phases of laboratory  
 20 work, from specimen collection to delivery of  
 21 report to the clinician. Currently diagnostic  
 22 IHC has in excess of 100 tests on the menu and  
 23 none are currently uniformly assessed since  
 24 there is no national Canadian external  
 25 laboratory"--I'm sorry, "laboratory" I'm

Page 104

1 sorry, "independent agency to check their  
 2 performance." And then you go on to speak  
 3 about the United States, College of American  
 4 Pathologists and UK NEQAS. And you note  
 5 toward the bottom, you say, "Therefore, so far  
 6 only NordiQC from Scandinavia provides  
 7 directly applicable information for each  
 8 participating laboratory as well as direct  
 9 communication and personal approach in problem  
 10 solving. However, with the number of experts  
 11 in pathology and clinical immunohistochemistry  
 12 there is no reason for Canada not to have its  
 13 own external laboratory testing in clinical  
 14 immunohistochemistry. We would like to invite  
 15 Canadian Association of Pathology to support  
 16 our intention to develop such a program to  
 17 serve pathology community in Canada and hope  
 18 that despite the differences in individual  
 19 practices the common goal and future benefits  
 20 of such an organization would unite all  
 21 interested parties to participate"--I'm sorry,  
 22 "to contribute in the development of this  
 23 service. Enclosed is a more detailed proposal  
 24 with additional pertinent information." So,  
 25 Doctor, that's what you first sent to the

Page 105

1 Canadian Association of Pathologists. And  
 2 this, in fact, I'm going to suggest, is a  
 3 proposal by both yourself and Dr. Gilks? I'm  
 4 correct on that?  
 5 DR. TORLAKOVIC:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. In fact, it covers everything from the  
 9 proposed name, which is CIQC for Canadian  
 10 Immunohistochemical Quality Control, the  
 11 proposed program; the mechanisms that would be  
 12 use?  
 13 DR. TORLAKOVIC:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. In a sense of arranging three to four external  
 17 challenges per year for assessing the  
 18 performance of participating clinical labs in  
 19 support of their internal quality control  
 20 programs. There's a commentary about the  
 21 American situation, CAP Laboratory  
 22 Accreditation Program, UK NEQAS and NordiQC.  
 23 And then you have a paragraph entitled  
 24 "Background" which I take it, in effect,  
 25 describes the then current situation in

Page 106

1 immunohistochemistry. Then you talk about  
 2 Class I tests and Class II tests, explaining  
 3 what they are. And class three tests, as  
 4 well. Doctor, here at the bottom of page 4 of  
 5 your proposal itself.  
 6 DR. TORLAKOVIC:  
 7 A. Um-hm.  
 8 COFFEY, Q.C.:  
 9 Q. This, you say here in the second-last  
 10 paragraph, "No national surveys are available  
 11 to answer these and many other basic questions  
 12 relevant to laboratory performance in clinical  
 13 immunohistochemistry." And the questions  
 14 you've posed above or suggested above that are  
 15 "We do not know and are not able to predict  
 16 what the degree of the problem, if any, on a  
 17 national level we may have in clinical  
 18 immunohistochemistry. We do not know if most  
 19 or all laboratories are using currently  
 20 available technically advanced methods which  
 21 provide excellent sensitivity and specificity  
 22 of the tests. And if these methods are  
 23 implemented, what is the level of internal and  
 24 external quality control the laboratories use  
 25 in daily practice? Are appropriate positive

Page 107

1 and negative controls used? Who is creating  
 2 optimized positive controls? Are quantitative  
 3 tests supplied by quantitative positive  
 4 controls, etcetera?" Suggesting, I'm going to  
 5 suggest to you, Doctor, really there's almost  
 6 nothing known nationally about what's going on  
 7 in the country?  
 8 DR. TORLAKOVIC:  
 9 A. Exactly.  
 10 COFFEY, Q.C.:  
 11 Q. At that time?  
 12 DR. TORLAKOVIC:  
 13 A. Actually, it hasn't changed much since then.  
 14 COFFEY, Q.C.:  
 15 Q. Yes. I was going to ask you that. I'm going  
 16 to come back to that. Then you go on at the  
 17 bottom of this page to say,  
 18 "Immunohistochemical tests are basically  
 19 either qualitative or quantitative. Both  
 20 could be of diagnostic or prognostic  
 21 significance. While quantitative tests are  
 22 currently used for scoring of results and  
 23 determination of hormone receptors or HER2/neu  
 24 in breast carcinoma which are Class II tests,  
 25 since Class II tests are very few but require

Page 108

1 particular expertise in both technical aspects  
 2 and interpretation of the results, it appears  
 3 most appropriate that additional specialized  
 4 organization provides a means for their  
 5 standardization and quality control. These  
 6 tests would not be the subject of CIQC, which  
 7 would try to focus on the remaining more than  
 8 100 Class I tests."  
 9 DR. TORLAKOVIC:  
 10 A. Yeah, I can explain that.  
 11 COFFEY, Q.C.:  
 12 Q. I appreciate that, because that's what I was  
 13 going to ask you about in terms of that.  
 14 Because anybody who is reading this, and of  
 15 course, it's readily available now publicly  
 16 because it's up, certainly, on the  
 17 Commission's website.  
 18 DR. TORLAKOVIC:  
 19 A. Right.  
 20 COFFEY, Q.C.:  
 21 Q. Anybody who has been following this closely.  
 22 And in any case, I wanted to ask you about  
 23 your original approach and then how it's  
 24 evolved.  
 25 DR. TORLAKOVIC:

Page 109

1 A. It has changed.  
 2 COFFEY, Q.C.:  
 3 Q. Well, for the Commissioner to understand your  
 4 initial approach, of course, I wanted to  
 5 canvass it with you. Why initially, Doctor,  
 6 was it your view that CIQC would initially get  
 7 involved in the Class I tests?  
 8 DR. TORLAKOVIC:  
 9 A. Because I heard that there is a Canadian panel  
 10 on HER2 and my assumption was that that panel  
 11 is also going to deal with all the aspects of  
 12 Class II tests, meaning also that it will also  
 13 organize appropriate national program for EQA  
 14 -  
 15 COFFEY, Q.C.:  
 16 Q. For -  
 17 DR. TORLAKOVIC:  
 18 A. And then I thought--for HER2, and that means I  
 19 hope because these all breast cancer  
 20 specialists, that they are going to provide,  
 21 organize such program for breast cancer  
 22 testing, and so -  
 23 COFFEY, Q.C.:  
 24 Q. Which would include?  
 25 DR. TORLAKOVIC:

Page 110

1 A. Which would include the ER/PR and HER2.  
 2 COFFEY, Q.C.:  
 3 Q. Okay.  
 4 DR. TORLAKOVIC:  
 5 A. That was my assumption and it was wrong  
 6 because that did not happen. What that panel  
 7 did, they looked at the ASCO CP guidelines for  
 8 HER2 and then they adopted or slightly changed  
 9 that for Canadian pathology practice. So they  
 10 issued Canadian guidelines for that, but they  
 11 did not -  
 12 COFFEY, Q.C.:  
 13 Q. For HER2?  
 14 DR. TORLAKOVIC:  
 15 A. For HER2. But they did not even decide to  
 16 address EQA. There are some things that are  
 17 in the guidelines that address EQA, external  
 18 quality assurance, saying that this 95 percent  
 19 of concordance is necessary, that optimization  
 20 or development of the test in the lab, how it  
 21 has to be done, what number of samples has to  
 22 be used, that reference laboratory wise--  
 23 reference laboratory should be used to, you  
 24 know, to calibrate the test in the beginning,  
 25 but there is nothing about the program. So

Page 111

1 since that did not happen -  
 2 COFFEY, Q.C.:  
 3 Q. Okay, so if I could, Doctor, just to give it  
 4 the context. So originally in the summer of  
 5 2006, which is when this proposal was made?  
 6 DR. TORLAKOVIC:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. July of '06, at the time you understood, look,  
 10 there's some other group that's dealing with  
 11 HER2/neu, and your assumption, as it turns  
 12 out, it was not well founded. Your assumption  
 13 at the time was is they will also deal with,  
 14 in the course of doing HER2/neu will do other  
 15 breast markers?  
 16 DR. TORLAKOVIC:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. In particular, ER and PR?  
 20 DR. TORLAKOVIC:  
 21 A. Yes.  
 22 COFFEY, Q.C.:  
 23 Q. And EQA for those Class II tests?  
 24 DR. TORLAKOVIC:  
 25 A. Right.

Page 112

1 COFFEY, Q.C.:  
 2 Q. As it turns out, ER/PR wasn't dealt with at  
 3 all?  
 4 DR. TORLAKOVIC:  
 5 A. True.  
 6 COFFEY, Q.C.:  
 7 Q. Those two stains. And EQA has not been dealt  
 8 with?  
 9 DR. TORLAKOVIC:  
 10 A. No, it hasn't.  
 11 COFFEY, Q.C.:  
 12 Q. At all either for the Class II tests by that  
 13 group. They focused on guidelines for HER2?  
 14 DR. TORLAKOVIC:  
 15 A. Right.  
 16 COFFEY, Q.C.:  
 17 Q. For Canada?  
 18 DR. TORLAKOVIC:  
 19 A. Right.  
 20 COFFEY, Q.C.:  
 21 Q. And they published those. And in the  
 22 meantime, with that in mind, because that was  
 23 your original mind set while they're off doing  
 24 that for Class II tests?  
 25 DR. TORLAKOVIC:

Page 113

1 A. Right.  
 2 COFFEY, Q.C.:  
 3 Q. You were going to initially focus on Class I?  
 4 DR. TORLAKOVIC:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. Why is that, what did you propose to do about  
 8 it at the time and why, why Class I?  
 9 DR. TORLAKOVIC:  
 10 A. Well, Class I tests, actually, large number of  
 11 tests. And depending on the lab and their  
 12 particular area of practice they may vary  
 13 anywhere probably between 10 or hundreds of  
 14 tests that are done. And -  
 15 COFFEY, Q.C.:  
 16 Q. Of Class I tests?  
 17 DR. TORLAKOVIC:  
 18 A. Of Class I tests, different tests.  
 19 COFFEY, Q.C.:  
 20 Q. Different, yeah.  
 21 DR. TORLAKOVIC:  
 22 A. And what is important about Class I test is  
 23 even though we have external quality assurance  
 24 that is addressing some Class I tests, only  
 25 those that are most frequently used and only

Page 114

1 very few are being tested. So if you look at  
 2 even in an ambitious external quality  
 3 assurance program only about 10 to 12 tests  
 4 are tested per year.  
 5 COFFEY, Q.C.:  
 6 Q. Ten to twelve antibodies?  
 7 DR. TORLAKOVIC:  
 8 A. Yes. Of all possible existing Class I tests,  
 9 which are almost 100 that are in clinical use.  
 10 So that was, in my mind, I know it's a lot of  
 11 work but it's a huge discrepancy that large  
 12 number of these tests is never tested, will  
 13 never be tested or addressed, and then nobody  
 14 will ever tell you how to calibrate this test  
 15 or help out.  
 16 COFFEY, Q.C.:  
 17 Q. They're never subjected to EQA?  
 18 DR. TORLAKOVIC:  
 19 A. Never.  
 20 COFFEY, Q.C.:  
 21 Q. Process?  
 22 DR. TORLAKOVIC:  
 23 A. Never.  
 24 COFFEY, Q.C.:  
 25 Q. So there are 100 plus, easily more than 100

Page 115

1 Class I tests available -  
 2 DR. TORLAKOVIC:  
 3 A. Absolutely.  
 4 COFFEY, Q.C.:  
 5 Q. - and in usage?  
 6 DR. TORLAKOVIC:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. But out of that 100 some are far more used  
 10 than others, more commonly used?  
 11 DR. TORLAKOVIC:  
 12 A. Exactly.  
 13 COFFEY, Q.C.:  
 14 Q. And it's the more common ones that are  
 15 routinely tested in the EQA processes that  
 16 exist?  
 17 DR. TORLAKOVIC:  
 18 A. Right.  
 19 COFFEY, Q.C.:  
 20 Q. And therefore you were thinking, well, wait  
 21 now, what about the other 60 or 70 that are--  
 22 or 50 or 60 or however many it is that are  
 23 almost never tested by EQA, that was your  
 24 concern?  
 25 DR. TORLAKOVIC:

Page 116

1 A. Right. Am I free now to elaborate a little  
 2 bit more on that?  
 3 COFFEY, Q.C.:  
 4 Q. Yes.  
 5 DR. TORLAKOVIC:  
 6 A. I have some cites prepared just because if we  
 7 can go back -  
 8 COFFEY, Q.C.:  
 9 Q. If we could go back to the PowerPoint, please?  
 10 Yes, Doctor, go ahead.  
 11 DR. TORLAKOVIC:  
 12 A. I think we go here, start here. This will do,  
 13 as well. These are images that illustrate the  
 14 use of Class I tests in detection of lymphoma,  
 15 basil lymphoma, which is a malignancy of  
 16 lymphocytes, that's cancer of the lymphocytes  
 17 in the bone marrow. Every patient when they  
 18 get this type of diagnosis has to have bone  
 19 marrow biopsy which is used for staging to  
 20 detect how far the disease has spread, whether  
 21 it's present in the bone marrow or not. So if  
 22 you bear in mind that I said previously that  
 23 Class I tests are interpreted in conjunction  
 24 with morphology, clinical data, other test  
 25 results. I will show you now that Class I

Page 117

1 tests are not always interpreted in the  
 2 conjunction of morphology, and actually, that  
 3 they are critically important for appropriate  
 4 diagnosis and their significance is no less  
 5 than any Class II test in that way and cannot  
 6 be controlled by other parameters. Like, we  
 7 hope that it should be--that applies  
 8 biologically to all Class I tests, but it  
 9 doesn't, and it does not apply in many  
 10 clinical situations. On the left is the  
 11 images illustrate black or dark brown staining  
 12 of the B lymphocytes in the bone marrow. This  
 13 is evidence of follicular lymphoma. This is  
 14 minimal evidence of involvement, but  
 15 nevertheless, for clinical purposes, this is  
 16 stage four follicular lymphoma for that  
 17 patient and is important. It's a huge clinical  
 18 difference between stage one and stage four  
 19 disease. And that, I'm not going to talk  
 20 specifically about follicular lymphoma but in  
 21 general, there are many instances when  
 22 involvement of the bone marrow is so minimal  
 23 that only by immunohistochemistry we can  
 24 detect the disease, not by morphology alone,  
 25 and so this combination of--these are two

Page 118

1 different patients, so we can see this is not  
 2 a rare--it wasn't very hard to find examples  
 3 like this where there is only  
 4 immunohistochemical evidence. So that means  
 5 that was the only means by which we have  
 6 diagnosed this disease.  
 7 COFFEY, Q.C.:  
 8 Q. And classify it between one and four, for  
 9 example?  
 10 DR. TORLAKOVIC:  
 11 A. Well, it's stage appropriate.  
 12 COFFEY, Q.C.:  
 13 Q. Stage -  
 14 DR. TORLAKOVIC:  
 15 A. Appropriate staging of the patient, and here,  
 16 it's even for diagnosis. If you see these two  
 17 images, these are two on the right, from the  
 18 same--different patient, but from one patient  
 19 CD20 that also we interpret in correlation  
 20 with results of other Class I tests and here  
 21 it shows that it's not always the case. CD20  
 22 is a B cell marker. Pax-5 is also B cell  
 23 marker. Now we are looking at here very few  
 24 positive cells and then you are looking at  
 25 here with Pax-5, it lights up like a Christmas

Page 119

1 tree. So this shows that there is lots of  
 2 lymphoma that stained with this marker and  
 3 here, we don't see that lymphoma at all, and  
 4 it was also something that has not been  
 5 detected morphologically, and I must say, I  
 6 have--this is the case I've seen myself. I  
 7 have been practising hemapathology for many,  
 8 many years and I don't think that I am a  
 9 beginner that would not recognize this because  
 10 of the lack of experience. It just happens  
 11 that some of the things are difficult to  
 12 recognize morphologically and  
 13 immunohistochemistry is frequently being used  
 14 to enable us to see more than with just H & E  
 15 staining. So in these two examples, you can  
 16 see that the interpretation of  
 17 immunohistochemistry, the use of the it and  
 18 the result, are critical for the diagnosis.  
 19 COFFEY, Q.C.:  
 20 Q. And these are Class I tests?  
 21 DR. TORLAKOVIC:  
 22 A. These are Class I tests. There is another  
 23 one, even more radical example. This is  
 24 detecting leukemic cells or blast cells what  
 25 we call in the bone marrow. Many times, we

Page 120

1 don't have optimal material to detect blast  
 2 otherwise, but we have to look at the core  
 3 biopsy. So to detect blast in the core  
 4 biopsy, we have to use CD34 staining, which  
 5 detects these immature cells, and this shows  
 6 actually you can quantitate very carefully  
 7 four percent, 11 percent of positive cells and  
 8 21 percent, 20 percent being a cut off point  
 9 to diagnose acute leukemia.  
 10 So in this, between--it was not possible  
 11 morphologically to make this distinction, but  
 12 here we use Class I test to make a critical  
 13 diagnosis of acute leukemia, yes, or acute  
 14 leukemia, no, and it has to be quantitated  
 15 very carefully. So at the same time, it's a  
 16 quantitative test and it's critically  
 17 important for therapy decision making. So it  
 18 doesn't mean that Class I tests are not less  
 19 worthy, let's say, and there are more than  
 20 hundreds of them and we don't--and they don't  
 21 undergo careful testing by external programs  
 22 and calibration as actually now we are trying  
 23 to do with Class II tests.  
 24 Another example is breast cancer. Of  
 25 course ER and PR are important, but even more

Page 121

1 important for this patient was just the  
 2 detection that there is a metastatic tumour in  
 3 the bone marrow. That would be like Class I  
 4 test, and then to determine that it's coming  
 5 from the breast, it's AP-15, again Class I  
 6 test, and then ER/PR at the end as an adjunct  
 7 to fully characterize the disease. So I  
 8 should say that Class I tests have not been  
 9 appropriately considered in external quality  
 10 assurance programs, but it's not because  
 11 people are negligent or they don't want to do  
 12 it. I just don't know, I have personally no  
 13 idea how to design a program, external quality  
 14 assurance program for over hundreds of tests  
 15 frequent enough so that it's giving the  
 16 information we need, and at the same time that  
 17 it's not going to be overburden for the  
 18 laboratories, pathologists, external quality  
 19 assurance programs, all of that. I just  
 20 personally have no vision how to do that.  
 21 COFFEY, Q.C.:  
 22 Q. As of yet anyway.  
 23 DR. TORLAKOVIC:  
 24 A. As of yet, yes.  
 25 COFFEY, Q.C.:

Page 122

1 Q. Doctor, here, just if we could, just the slide  
 2 that's there on the screen, the slide in the  
 3 top left-hand side is a H & E?  
 4 DR. TORLAKOVIC:  
 5 A. This one, yes.  
 6 COFFEY, Q.C.:  
 7 Q. Yes, and this is of a metastatic breast  
 8 carcinoma?  
 9 DR. TORLAKOVIC:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. And this is located in, I'm sorry, in?  
 13 DR. TORLAKOVIC:  
 14 A. The bone marrow.  
 15 COFFEY, Q.C.:  
 16 Q. The bone, as it turns out.  
 17 DR. TORLAKOVIC:  
 18 A. Right.  
 19 COFFEY, Q.C.:  
 20 Q. So breast cancer that was understood to have  
 21 metastasized to the bone. The purpose then of  
 22 using CK8 and AP-15 are both Class I tests?  
 23 DR. TORLAKOVIC:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

Page 123

1 Q. What is the C--what was the purpose of using  
 2 the CK8 there?  
 3 DR. TORLAKOVIC:  
 4 A. CK8 is a type, low molecular rate cytokeratin  
 5 that detects adenocarcinomas. So it qualifies  
 6 this disease as adenocarcinoma. So we know  
 7 now this is adenocarcinoma in the bone marrow  
 8 and that's not normal. That means it's  
 9 metastatic lesion.  
 10 COFFEY, Q.C.:  
 11 Q. Okay, and I take it in doing--in utilizing  
 12 this here, in looking at it, in order to make  
 13 that determination -  
 14 DR. TORLAKOVIC:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. - of adenocarcinoma, you would have to be--the  
 18 pathologist in question would have to be  
 19 relying upon the CK8 slide making process  
 20 being accurate?  
 21 DR. TORLAKOVIC:  
 22 A. Absolutely. If we are going to use this as to  
 23 be sure that we are dealing with  
 24 adenocarcinoma, I think we want--should today,  
 25 in current level of standards of practice, we

Page 124

1 use it frequently immunohistochemistry as  
 2 evidence of what we may believe that exists  
 3 anyways. Like I could look at the slide on  
 4 the left, H & E, and say there is a lesion  
 5 there and I think it may be metastatic  
 6 adenocarcinoma, but then often, we would like  
 7 to confirm that, so it's for medically-based  
 8 evidence to practice like that. You need the  
 9 confirmation, and that is what cytokeratin 8  
 10 is going here. It's confirming indeed that  
 11 this is a metastatic adenocarcinoma.  
 12 COFFEY, Q.C.:  
 13 Q. And I take it then, as a pathologist then, you  
 14 wanted to be somewhat assured that the CK 8  
 15 process is actually working?  
 16 DR. TORLAKOVIC:  
 17 A. Absolutely.  
 18 COFFEY, Q.C.:  
 19 Q. If it's not working, if it's giving you an  
 20 improper result then -  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. - you're led down the wrong path.  
 25 DR. TORLAKOVIC:

Page 125

1 A. Then you are misled thinking that this is  
 2 something else.  
 3 COFFEY, Q.C.:  
 4 Q. I'll go to the next slide here, the AP-15  
 5 slide. I'm sorry, it's--you were telling the  
 6 Commissioner it's used for?  
 7 DR. TORLAKOVIC:  
 8 A. It's a mark too that is highly specific, not  
 9 100 percent, but it's highly specific for  
 10 breast carcinoma. So it identifies this as  
 11 organ of origin is breast.  
 12 COFFEY, Q.C.:  
 13 Q. And again, I take it again, for the same  
 14 purpose, I take it to see that this metastatic  
 15 carcinoma is originated in the breast, that's  
 16 the point of using the AP-15?  
 17 DR. TORLAKOVIC:  
 18 A. Yes, it is.  
 19 COFFEY, Q.C.:  
 20 Q. And again, in arriving at that determination,  
 21 you'd be relying upon the AP-15 being  
 22 accurate?  
 23 DR. TORLAKOVIC:  
 24 A. Yes, absolutely.  
 25 THE COMMISSIONER:

Page 126

1 Q. Mr. Coffey, we're well past the break.  
 2 COFFEY, Q.C.:  
 3 Q. If I could, just one more moment,  
 4 Commissioner, please? Thank you. And then  
 5 finally then, in this process here, Doctor,  
 6 with this particular patient, the purpose then  
 7 of doing an ER and PR on that would be what?  
 8 DR. TORLAKOVIC:  
 9 A. To provide additional information that is used  
 10 to stratify the patient for appropriate  
 11 therapies.  
 12 COFFEY, Q.C.:  
 13 Q. Therapy?  
 14 DR. TORLAKOVIC:  
 15 A. Yes, as a predictive markers regarding the use  
 16 of hormonal therapy or not, Tamoxifen or not.  
 17 COFFEY, Q.C.:  
 18 Q. And again that's, I take it, it's important,  
 19 even at that stage, to know that because it  
 20 may be of some significance to the oncologist  
 21 -  
 22 DR. TORLAKOVIC:  
 23 A. Oh, absolutely.  
 24 COFFEY, Q.C.:  
 25 Q. - as to how to approach the patient?

Page 127

1 DR. TORLAKOVIC:  
 2 A. Yes, yes.  
 3 COFFEY, Q.C.:  
 4 Q. And that would have to be accurate too?  
 5 DR. TORLAKOVIC:  
 6 A. Absolutely, yes.  
 7 COFFEY, Q.C.:  
 8 Q. Okay. Thank you, Commissioner.  
 9 THE COMMISSIONER:  
 10 Q. We'll take 15 minutes.  
 11 (BREAK)  
 12 THE COMMISSIONER:  
 13 Q. Please be seated.  
 14 COFFEY, Q.C.:  
 15 Q. Thank you, Commissioner. If we could bring up  
 16 Exhibit P-0113, please? Doctor, this is a  
 17 memo, the Commissioner has seen this  
 18 innumerable times now. It's dated April 4th,  
 19 2003. It was from a pathologist who practised  
 20 in St. John's at the time, Dr. Gersham  
 21 Ejeckam, and I'm not going to ask you to  
 22 comment upon the memo itself, but there's a  
 23 certain part of it here. There's certain  
 24 antibodies identified here, following  
 25 antibodies. They're, in effect, CK34, I think

Page 128

1 is the short name for it. Am I correct in  
 2 that?  
 3 DR. TORLAKOVIC:  
 4 A. No.  
 5 COFFEY, Q.C.:  
 6 Q. Okay.  
 7 DR. TORLAKOVIC:  
 8 A. Let's just call it, for this purpose, high  
 9 molecular rate cytokeratin.  
 10 COFFEY, Q.C.:  
 11 Q. Okay.  
 12 DR. TORLAKOVIC:  
 13 A. So it's a special type of cytokeratin which is  
 14 often used to recognize whether in prostate  
 15 biopsy there is prostate carcinoma or not.  
 16 COFFEY, Q.C.:  
 17 Q. Or not, okay, number one. CD3 used for?  
 18 DR. TORLAKOVIC:  
 19 A. T cell antigen, to identify T cells both  
 20 benign and malignant.  
 21 COFFEY, Q.C.:  
 22 Q. CD5?  
 23 DR. TORLAKOVIC:  
 24 A. It's another lymphoid marker. It's expressed  
 25 by old T cells frequently lost in T cell



Page 129

1 lymphoma. So the absence of which we use  
 2 diagnostically, but it's also typically  
 3 present in some B cell lymphomas in some  
 4 carcinomas. So we use it for different  
 5 purposes.  
 6 COFFEY, Q.C.:  
 7 Q. Depending upon the circumstances?  
 8 DR. TORLAKOVIC:  
 9 A. Depending on the circumstance, yes.  
 10 COFFEY, Q.C.:  
 11 Q. CD20?  
 12 DR. TORLAKOVIC:  
 13 A. This is called a universal pan or pan B cell  
 14 marker. It identifies B lymphocytes.  
 15 COFFEY, Q.C.:  
 16 Q. CD79a?  
 17 DR. TORLAKOVIC:  
 18 A. It's a similar--it's more widely expressed in  
 19 various stages of development of B cell,  
 20 normal B cells in various B cell lymphomas and  
 21 then in some T cell malignancies and even in  
 22 some cancerous, rarely.  
 23 COFFEY, Q.C.:  
 24 Q. CEA would be?  
 25 DR. TORLAKOVIC:

Page 130

1 A. CEA, it's a marker of--it's a kind of  
 2 oncogene. It's fetal antigen that is re-  
 3 expressed with embryonic antigen, it's re-  
 4 expressed in some carcinomas and it's  
 5 typically expressed, for example, in colon  
 6 cancer and it's typically absent in renal cell  
 7 carcinoma. So it's useful often in evaluating  
 8 what type of malignancy we are looking at.  
 9 COFFEY, Q.C.:  
 10 Q. So the six of these then I just looked at here  
 11 are Class I tests?  
 12 DR. TORLAKOVIC:  
 13 A. Exactly.  
 14 COFFEY, Q.C.:  
 15 Q. Now Doctor, as a pathologist, if you were to  
 16 be told that those six tests were, for an  
 17 unknown period of time, unreliable, erratic  
 18 and unhelpful for diagnostic purposes,  
 19 unbeknownst to you that had been so, okay, but  
 20 you are now being told that -  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. - you know, for an unknown period of time,  
 25 this is not specified, that those six Class I

Page 131

1 tests have been unreliable and erratic and  
 2 unhelpful for diagnostic purposes and you had  
 3 been utilizing one or more of those six Class  
 4 I tests dealing with your patients, okay?  
 5 DR. TORLAKOVIC:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. Would that cause you any concern about the  
 9 accuracy of the diagnosis that you'd been  
 10 given, based upon those tests? Would it cause  
 11 you to question them?  
 12 DR. TORLAKOVIC:  
 13 A. This is rather complex question and I'll tell  
 14 you why, because in practice, this has never  
 15 happened to me.  
 16 COFFEY, Q.C.:  
 17 Q. I appreciate that.  
 18 DR. TORLAKOVIC:  
 19 A. And this has never happened because I cannot  
 20 be told that this is not--retrospectively,  
 21 these tests have not been working because  
 22 wherever I work, we monitor very closely what  
 23 happens every day. So I have never been in a  
 24 situation like that, that somebody tells me  
 25 your test is not--these tests are not working

Page 132

1 for this period of time. But if that would  
 2 happen that I would come somewhere and where I  
 3 was not able to use the quality control and  
 4 quality assurance measures to make sure that I  
 5 know daily whether they're working or not--I'm  
 6 not saying that in our lab, all of these  
 7 antibodies are working all the time, but we'd  
 8 recognize when they are not and then do  
 9 something about it right away.  
 10 So in that hypothetical situation, if I  
 11 would have to practice without being able to  
 12 control their performance, I would be  
 13 definitely in a state of panic because, as I  
 14 have mentioned before, Class I tests are  
 15 extremely important for our diagnostic  
 16 practice. I just illustrated that you cannot  
 17 see often without CD20 the presence of B cell  
 18 lymphoma in the bone marrow. If CD20 was  
 19 false positive, maybe I have diagnosed B cell  
 20 lymphoma, something that wasn't and it was  
 21 otherwise poorly differentiated carcinoma and  
 22 if I haven't had working high molecular rate  
 23 cytokeratin in prostate biopsies, that's a  
 24 particularly bad one to say to have not  
 25 working because when it's negative, it tells

Page 133

1 us that it's cancer. So maybe I have made  
 2 some false positive diagnosis based on  
 3 evaluation of that. Even though we never use  
 4 just one single evidence, but when you have  
 5 small glands in a prostate biopsy and you  
 6 order this test, you ordered it with an idea  
 7 that it's going to be and it's not going to be  
 8 there. So you were suspicious enough for  
 9 cancer since you ordered the test, and then  
 10 you see the stain is not there, this supports  
 11 the diagnosis of cancer. So yeah, I would be  
 12 quite concerned that I have possibly made the  
 13 wrong diagnosis.  
 14 COFFEY, Q.C.:  
 15 Q. And you would, I take it then, at least in a  
 16 theoretical--if you were find, theoretically  
 17 to find yourself in that position, you'd want  
 18 to go back to check, well, where did I use  
 19 them? What period are we talking about?  
 20 DR. TORLAKOVIC:  
 21 A. Again, this is all hypothetical.  
 22 COFFEY, Q.C.:  
 23 Q. Yes.  
 24 DR. TORLAKOVIC:  
 25 A. But what I would do if this would ever happen,

Page 134

1 since it's never happened, what I would do, I  
 2 would probably go back. I think I would go  
 3 back. Yes, I would want to know, for my own  
 4 self, right away to check the things, to make  
 5 sure even though it's unlikely that the single  
 6 wrong judgment will be made, but still I would  
 7 go back to make sure that it hasn't happened.  
 8 COFFEY, Q.C.:  
 9 Q. Doctor, we were talking about Class I tests,  
 10 just before the break, and the reason for that  
 11 being your initial focus in July of 2006 as to  
 12 where you thought CIQC would, you know, would  
 13 initially go.  
 14 DR. TORLAKOVIC:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. And you've indicated why that was so, in terms  
 18 of Class I tests. What then happened? You  
 19 made your proposal. Initially you didn't hear  
 20 anything immediately back from the Canadian  
 21 Association of Pathologists you said.  
 22 DR. TORLAKOVIC:  
 23 A. Right.  
 24 COFFEY, Q.C.:  
 25 Q. And what then happened? You found out, I take

Page 135

1 it, that the HER2 group were in fact not going  
 2 to be doing EQA for Class II tests, and then  
 3 how did this evolve? Perhaps you could take  
 4 the Commissioner then through how you ended up  
 5 where you are today, between July of '06 and  
 6 now?  
 7 DR. TORLAKOVIC:  
 8 A. If we can go back to the presentation.  
 9 COFFEY, Q.C.:  
 10 Q. Sure, go back to the -  
 11 DR. TORLAKOVIC:  
 12 A. I have a couple of slides that I can use to -  
 13 COFFEY, Q.C.:  
 14 Q. Sure.  
 15 DR. TORLAKOVIC:  
 16 A. As we can see, we started with run 1. We just  
 17 started. We didn't have an answer yet, but  
 18 then we created anyways the testing material  
 19 and invited several laboratories throughout  
 20 Canada if they want to participate just on a  
 21 voluntary basis free of charge, just if they  
 22 want to -  
 23 COFFEY, Q.C.:  
 24 Q. Okay, so just so we're clear on that. So you  
 25 have made your proposal to the Canadian

Page 136

1 Association of Pathologists?  
 2 DR. TORLAKOVIC:  
 3 A. Right.  
 4 COFFEY, Q.C.:  
 5 Q. In the summer of '06?  
 6 DR. TORLAKOVIC:  
 7 A. Um-hm.  
 8 COFFEY, Q.C.:  
 9 Q. Initially, you hadn't heard anything back.  
 10 You had your website up?  
 11 DR. TORLAKOVIC:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. You create Run 1, which is referred to here?  
 15 DR. TORLAKOVIC:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. And undifferentiated tumour panel. Who's we?  
 19 You say "we created".  
 20 DR. TORLAKOVIC:  
 21 A. It is basically between Dr. Gilks and myself.  
 22 We created this tissue microarray block with  
 23 72 samples, tissue samples, and asked  
 24 laboratories if they would volunteer and stain  
 25 them with different markers that are used very

Page 137

1 often in an undifferentiated tumour panel.  
 2 This is a critical tumour panel to decide on  
 3 when we have morphologically non-descript  
 4 entity, so we morphologically don't know what  
 5 it is, to figure out whether it's--in which  
 6 group it belongs. Is it carcinoma? Is it  
 7 lymphoma? Is it sarcoma or what?  
 8 COFFEY, Q.C.:  
 9 Q. So you create a microarray.  
 10 DR. TORLAKOVIC:  
 11 A. So that is Class I. That's why we started  
 12 with Class I.  
 13 COFFEY, Q.C.:  
 14 Q. Microarray set of slides.  
 15 DR. TORLAKOVIC:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. And in effect, contacted other labs in Canada?  
 19 DR. TORLAKOVIC:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. And said "look, would you like to  
 23 participate?"  
 24 DR. TORLAKOVIC:  
 25 A. Um-hm.

Page 138

1 COFFEY, Q.C.:  
 2 Q. "We'll send you the slides."  
 3 DR. TORLAKOVIC:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. So what happened initially? How many -  
 7 DR. TORLAKOVIC:  
 8 A. 12 laboratories altogether participated in  
 9 this run and so we got some really interesting  
 10 results. I'm not sure--did I--okay, so I  
 11 don't have detailed results from Run 1 but I  
 12 can summarize it, that because we used a large  
 13 number of tissue samples, we were able,  
 14 despite the small number of labs, to actually  
 15 calculate their performance, in the sense of  
 16 false positive, false negative, and overall  
 17 success rate and so on. So it was quite  
 18 surprising for us to see that there was some  
 19 tests in which you had as many as 30 percent  
 20 of false positives, a range of 30 percent or  
 21 so false negative in these tests. So it was -  
 22 COFFEY, Q.C.:  
 23 Q. And these were all Class I tests?  
 24 DR. TORLAKOVIC:  
 25 A. Class I tests, and these are very frequently

Page 139

1 used. These are not some bizarre, rare tests.  
 2 These are tests that are used daily.  
 3 Virtually every lab that has  
 4 immunohistochemistry will use these tests, all  
 5 of them.  
 6 COFFEY, Q.C.:  
 7 Q. Okay. So you got the--what then happened?  
 8 DR. TORLAKOVIC:  
 9 A. After that, the focus shifted on Class II or  
 10 breast cancer markers.  
 11 COFFEY, Q.C.:  
 12 Q. Before I go on to that, if I could, Doctor, so  
 13 initially you got the slides back.  
 14 DR. TORLAKOVIC:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. And they were looked at, and so if I could,  
 18 perhaps I'd just like to explore that a bit.  
 19 You sent out the slides, they were stained?  
 20 DR. TORLAKOVIC:  
 21 A. Yes.  
 22 COFFEY, Q.C.:  
 23 Q. By these labs?  
 24 DR. TORLAKOVIC:  
 25 A. Um-hm.

Page 140

1 COFFEY, Q.C.:  
 2 Q. They sent back the stained slides?  
 3 DR. TORLAKOVIC:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. And they were looked at by?  
 7 DR. TORLAKOVIC:  
 8 A. Both of us.  
 9 COFFEY, Q.C.:  
 10 Q. By yourself and Dr. Gilks?  
 11 DR. TORLAKOVIC:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. And based upon what you were seeing, you were  
 15 saying, well, you know, you anticipated that a  
 16 particular part of the microarray should stain  
 17 in a particular manner?  
 18 DR. TORLAKOVIC:  
 19 A. Absolutely.  
 20 COFFEY, Q.C.:  
 21 Q. Absolutely?  
 22 DR. TORLAKOVIC:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. And you were seeing, at times, some positives

Page 141

1 that shouldn't be positive, which were -  
 2 DR. TORLAKOVIC:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. - classed false positives?  
 6 DR. TORLAKOVIC:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. And some that were negatives, visually  
 10 negative to yourselves, but should have been  
 11 positive?  
 12 DR. TORLAKOVIC:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. Or false negatives, and the rate overall, when  
 16 you did the calculations is about 30 percent  
 17 for some stains?  
 18 DR. TORLAKOVIC:  
 19 A. It varied greatly. Actually, the results  
 20 were, in summarized format, presented at the--  
 21 in Toronto, at the annual meeting of CAP. We  
 22 had a poster presentation on those results,  
 23 and they're also--I mean, they're widely  
 24 available. They're available on our web page  
 25 for each individual test, and they are

Page 142

1 illustrated in detail.  
 2 COFFEY, Q.C.:  
 3 Q. If we could, please, Exhibit P-3362? Doctor,  
 4 there's a summary at P-0276? Is that the -  
 5 DR. TORLAKOVIC:  
 6 A. Yeah, that's a poster. That's in an abstract  
 7 format. That was in poster format, this is  
 8 much larger obviously. The big poster was  
 9 created with images and more detailed methods  
 10 and more detailed results.  
 11 COFFEY, Q.C.:  
 12 Q. Here, Doctor, this was presented at Canadian  
 13 Laboratory Medicine Congress 2007.  
 14 DR. TORLAKOVIC:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. And is this the results of that first run?  
 18 DR. TORLAKOVIC:  
 19 A. Yes, it is.  
 20 COFFEY, Q.C.:  
 21 Q. That you were referring to, and this, I take  
 22 it, summarizes then, in a textual manner -  
 23 DR. TORLAKOVIC:  
 24 A. It does.  
 25 COFFEY, Q.C.:

Page 143

1 Q. - what yourself and Dr. Gilks' observations  
 2 were?  
 3 DR. TORLAKOVIC:  
 4 A. Um-hm.  
 5 COFFEY, Q.C.:  
 6 Q. Then I notice yourself and Dr. Gilks' name.  
 7 There is a Klassen and -  
 8 DR. TORLAKOVIC:  
 9 A. That's a resident that was--we tried to--since  
 10 we have residency program, we try to include  
 11 residents more in some scientific project. So  
 12 we included this resident in this project.  
 13 COFFEY, Q.C.:  
 14 Q. And just looking down through this, Doctor -  
 15 DR. TORLAKOVIC:  
 16 A. And Klassen is our--Shannon Klassen, she's our  
 17 expert technologist in immunohistochemistry  
 18 lab.  
 19 COFFEY, Q.C.:  
 20 Q. Okay.  
 21 DR. TORLAKOVIC:  
 22 A. And we do include them as co-authors any time  
 23 they do extra work that is not specified by  
 24 their work description, job description.  
 25 COFFEY, Q.C.:

Page 144

1 Q. Here, Doctor, just to summarize this, in the  
 2 middle of it, it begins "15 Canadian clinical  
 3 immunohistochemistry laboratories were invited  
 4 to stain tissue microarray slides that contain  
 5 76 tissue cores to represent lesions with  
 6 various expressions of tested epitopes.  
 7 Selected were tests that are in daily use for  
 8 evaluation of undifferentiated tumours," and  
 9 you name them, and then it goes on "in  
 10 appropriate setting, these markers enable  
 11 distinction between carcinoma, melanoma and  
 12 sarcoma. Stains were scored on a scale of  
 13 zero to three plus with separate scores for  
 14 pathological or predominant cell population as  
 15 appropriate and background non-specific  
 16 staining. Pan cytokeratin," I don't know what  
 17 you -  
 18 DR. TORLAKOVIC:  
 19 A. Pan cytokeratin.  
 20 COFFEY, Q.C.:  
 21 Q. Yes, "staining produced from zero to 30  
 22 percent false negative rate with similarly  
 23 significant differences between the  
 24 laboratories also for LMWCQ, vimentin and  
 25 S100. While most laboratories enjoyed

Page 145

1 similar"--sorry, "employed similar detection  
 2 methods, the differences appear to be  
 3 secondary to variations in antigen retrieval  
 4 procedures or dilution of the primary  
 5 antibodies. The results are a more detailed  
 6 poster for viewing and visual microscopy at  
 7 the CIQC website. We conclude that Canadian  
 8 clinical immunohistochemistry laboratories  
 9 produce variable results, even with the most  
 10 commonly used tests and that external QC  
 11 programs would probably help to achieve  
 12 standardization in QC programs"--I'm sorry,  
 13 "standardization in immunohistochemistry," and  
 14 you've--there's--here, it refers to false  
 15 negative, but there's--somebody has  
 16 handwritten here also, false positive, and you  
 17 did indicate to the Commissioner -  
 18 DR. TORLAKOVIC:  
 19 A. Yes, that was in the poster itself presented  
 20 that -  
 21 COFFEY, Q.C.:  
 22 Q. There were both false positive rates and -  
 23 DR. TORLAKOVIC:  
 24 A. Right, there were false positives.  
 25 COFFEY, Q.C.:

Page 146

1 Q. Doctor, so, I'm sorry, I interrupted you. You  
 2 did the first run, Class I tests, and then  
 3 what happened, in terms, if we could go back,  
 4 please, to the exhibit we were looking at?  
 5 You were about to tell the Commissioner the  
 6 focus then shifted.  
 7 DR. TORLAKOVIC:  
 8 A. It shifted because then we actually, at that  
 9 time, actually learned about what's happening  
 10 about false negative results with ER in  
 11 Newfoundland.  
 12 COFFEY, Q.C.:  
 13 Q. Yes.  
 14 DR. TORLAKOVIC:  
 15 A. So, and there was lots of now focus on how  
 16 ER/PR tests were done, and since nobody else  
 17 was really doing it for Canada, we decided we  
 18 are going to create tissue microarrays with a  
 19 particular purpose to study now Class II tests  
 20 for breast cancer markers. So Run 2, Run 3  
 21 and now we are preparing Run 4 as we speak.  
 22 They are all focused on breast cancer markers.  
 23 COFFEY, Q.C.:  
 24 Q. Now here, in the fourth bullet, there's a note  
 25 "18 labs participated in run 2," which is

Page 147

1 ER/PR and HER2/neu?  
 2 DR. TORLAKOVIC:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. And then 23 labs participated in run 3, which  
 6 was ER/PR. Do you recall when runs 2 and 3  
 7 were done, approximately when they were done?  
 8 DR. TORLAKOVIC:  
 9 A. No.  
 10 COFFEY, Q.C.:  
 11 Q. Okay.  
 12 DR. TORLAKOVIC:  
 13 A. I'm sorry, not -  
 14 COFFEY, Q.C.:  
 15 Q. Sometime since the first, since run 1?  
 16 DR. TORLAKOVIC:  
 17 A. Well, let me say that run 3 probably was  
 18 completed three months ago or something like  
 19 that, and the one before that, five to six  
 20 months.  
 21 COFFEY, Q.C.:  
 22 Q. Prior to that?  
 23 DR. TORLAKOVIC:  
 24 A. Yes, prior to that. I'm not sure about exact  
 25 dates.

Page 148

1 COFFEY, Q.C.:  
 2 Q. Doctor, what were the results, in general, in  
 3 terms of looking at the results in runs 2 and  
 4 3?  
 5 DR. TORLAKOVIC:  
 6 A. It's quite surprising, and I did want to show  
 7 you this.  
 8 COFFEY, Q.C.:  
 9 Q. So this is this -  
 10 DR. TORLAKOVIC:  
 11 A. This is run 3.  
 12 COFFEY, Q.C.:  
 13 Q. This is run 3, go ahead.  
 14 DR. TORLAKOVIC:  
 15 A. I think it is.  
 16 COFFEY, Q.C.:  
 17 Q. If you could blow that up just a tiny bit,  
 18 please, if it's possible? See it there, in  
 19 the top left-hand side, it's run 3.  
 20 DR. TORLAKOVIC:  
 21 A. Yeah, it's run 3. Yes, it's run 3. I'm sure  
 22 it's run 3. So this is in the summarized form  
 23 as to what happened with this, the number of  
 24 labs, but run 2 was even better. When I say  
 25 even better, that means that even these

Page 149

1 results are good. Run 2 and Run 3 were  
 2 designed differently, even though both  
 3 consists of tumour samples with variable  
 4 expression of estrogen and progesterone  
 5 receptors. Run 2 also ran HER2, and the  
 6 reference values were from FISH, or  
 7 Fluorescent In Situ Hybridization, and for  
 8 ER/PR, a most common or consensus why you  
 9 would use those reference values, but I wanted  
 10 to tell you that we were very surprised to see  
 11 in Run 2 that we got extremely good results.  
 12 We expected much worse results, not because  
 13 ER/PR themselves are challenging technically,  
 14 it's just because of historical evidence that  
 15 there is much more variability than what we  
 16 achieve. So we wondered why was that, you  
 17 know, and I think it's because people started  
 18 to pay attention because that Run 2 was run  
 19 after people learned about what happened in  
 20 Newfoundland, and I think that just the fact  
 21 that this happened and everybody is paying  
 22 attention now has improved greatly clinical  
 23 practice in diagnostic immunohistochemistry in  
 24 Canada. Just as an upshot of this, I think we  
 25 already have much better practice without any

Page 150

1 additional intervention. So we actually  
 2 prepared those results to be published and  
 3 submitted it for publishing in scientific  
 4 literature and it's currently under review.  
 5 COFFEY, Q.C.:  
 6 Q. And that's the results of Run 2--Run 2 or Run  
 7 3 or both?  
 8 DR. TORLAKOVIC:  
 9 A. Run 2 only. Run 3 was designed a little bit  
 10 differently. Run 3 was designed with tumours  
 11 that were selected with low expression mainly.  
 12 So large number of low expressors, which is  
 13 not the case in clinical practice because most  
 14 tumours, when they show expression of estrogen  
 15 receptors, they vary, but it is rare that  
 16 there is a big expression that we detect,  
 17 compared to strong expression is much less  
 18 frequent. So this Run 3 was designed with an  
 19 idea now if we design it like that because the  
 20 results were so good, maybe we can still see  
 21 if there are any fine tuning differences that  
 22 can be detected and the internal quality  
 23 controls can be further fine tuned not to miss  
 24 this low expressors. So we did that, and we  
 25 got also very good results. It was a little

Page 151

1 bit less successful because this is extremely  
 2 challenging material, and this is usually not  
 3 the material that you would usually use in  
 4 ordinary external quality assurance program.  
 5 So, therefore, it's providing a special type  
 6 of information to us. I don't think that  
 7 otherwise they would have an opportunity to  
 8 discover how exactly, you know, where even the  
 9 minor problems now should come up after these  
 10 tests, and it can be fixed.  
 11 COFFEY, Q.C.:  
 12 Q. And have the laboratories that participated in  
 13 Runs 1, 2, and 3, were they given feedback on  
 14 their results?  
 15 DR. TORLAKOVIC:  
 16 A. Yes. I mean, what they--they can go also on  
 17 that web page themselves. They can look at--  
 18 compare their own laboratory with others, all  
 19 of this. I mean, the major feedback is that  
 20 you look at the protocols and look at the  
 21 results, and look at the assessment of what  
 22 values and look at your concordance rate, and  
 23 this is what matters. So they have all the  
 24 information they need to have for their  
 25 quality assurance purposes.

Page 152

1 COFFEY, Q.C.:  
 2 Q. And you had shown the Commissioner earlier,  
 3 for example, the lab identified with a number,  
 4 like, lab 102, for example?  
 5 DR. TORLAKOVIC:  
 6 A. Right.  
 7 COFFEY, Q.C.:  
 8 Q. You can go elsewhere on the website and  
 9 actually look at the protocol used by detail?  
 10 DR. TORLAKOVIC:  
 11 A. Right.  
 12 COFFEY, Q.C.:  
 13 Q. By that lab, lab 102, for their ER?  
 14 DR. TORLAKOVIC:  
 15 A. Right.  
 16 COFFEY, Q.C.:  
 17 Q. And for their PR. You just actually watch it  
 18 and I suppose then compare it--if you were lab  
 19 105, you can compare what you've done in the  
 20 process to -  
 21 DR. TORLAKOVIC:  
 22 A. Right. It doesn't mean it gives you all the  
 23 solutions and it doesn't mean that those that  
 24 participated did excellent and use these  
 25 protocols, these are the only protocols that

Page 153

1 will work, or the only reagent that will work.  
 2 This just means this is what this particular  
 3 lab was doing and was very successful or not,  
 4 and if not, I mean, we can identify the  
 5 problem right away. I can tell you there was  
 6 one of the labs in Run 2 that was less  
 7 successful than others in ER. It had, I  
 8 think, 92 percent concordance rate, which is  
 9 still good, it's not bad, but it wasn't over  
 10 95 percent, and the only difference was it was  
 11 clear in the protocol that they were using six  
 12 times higher dilution of the primary  
 13 antibodies than others, even though they used  
 14 identical clonal antibody, identical  
 15 protection system, identical instrumentation.  
 16 So the point was that was quickly changed. The  
 17 dilution was re-titrated and the lab was  
 18 retested and the results were perfect. So  
 19 that was one of the illustrations how things  
 20 could be done quickly.  
 21 COFFEY, Q.C.:  
 22 Q. Doctor, go back to the slide then that--let's  
 23 see. Just a moment, please, Commissioner.  
 24 You've indicated you're currently preparing  
 25 Run 4?

Page 154

1 DR. TORLAKOVIC:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. And Run 4 will involve what types of -  
 5 DR. TORLAKOVIC:  
 6 A. We thought about two arms of Run 4, it all  
 7 starts to go back to Class I test also, but to  
 8 continue to run breast cancer markers because  
 9 it's so important. So for Run 4, we will have  
 10 about 50 tissue cores on the block for ER/PR  
 11 and HER2, and then we will have also tissue  
 12 microarray for a set of lymphoid markers now  
 13 for Class I tests.  
 14 COFFEY, Q.C.:  
 15 Q. Doctor, here on this particular slide, a  
 16 couple of things I wanted to ask you about  
 17 beyond what we've already touched on. One of  
 18 them is the program offered by CIQC provides  
 19 testing material adequate for sensible  
 20 statistical analysis currently recommended in  
 21 new guidelines for Class II test, i.e. for  
 22 HER2, okay. I take it this has to do with the  
 23 sheer number of samples in a microarray?  
 24 DR. TORLAKOVIC:  
 25 A. Absolutely.

Page 155

1 COFFEY, Q.C.:  
 2 Q. Okay, can you tell--elaborate on that for the  
 3 Commissioner a bit as to why compared to, for  
 4 example, some other programs that don't use  
 5 microarrays, and the advantage of using a  
 6 microarray.  
 7 DR. TORLAKOVIC:  
 8 A. One has to be aware that it's only recently  
 9 that ASCO or CAP guidelines or even our  
 10 national Canadian guidelines for HER2 point  
 11 out the level of concordance that is necessary  
 12 with reference labs. It's spelled out to be  
 13 more than 95 percent, and that means that  
 14 there should be material provided by EQA  
 15 program that is created--designed as such to  
 16 enable a meaningful statistical analysis and a  
 17 meaningful calculation of concordance, or for  
 18 that matter, otherwise. So to do so, that has  
 19 to be based on actually proper analysis,  
 20 taking into consideration the type of  
 21 statistical analysis or other calculations  
 22 that need to be done and the type of the  
 23 material that we are using. So when that  
 24 comes to that, that means that you cannot  
 25 really use material from any external quality

Page 156

1 assurance program to fulfil this requirement.  
 2 For example, NordiQC is right now not  
 3 providing large enough samples in their  
 4 material for testing for HER2. I think they  
 5 are below 10 still, and you cannot calculate  
 6 95 percent concordance with 10 samples. I  
 7 think CAP is providing 40 samples, which is  
 8 probably sufficient, but my problem with that  
 9 is they provide it only once a year. So we  
 10 have to have external quality assurance  
 11 program that is providing this sensible  
 12 testing material, but often enough also so  
 13 that laboratories can -  
 14 COFFEY, Q.C.:  
 15 Q. Enough at a time, enough samples at a time?  
 16 DR. TORLAKOVIC:  
 17 A. Enough samples at a time -  
 18 COFFEY, Q.C.:  
 19 Q. To provide statistically significant results?  
 20 DR. TORLAKOVIC:  
 21 A. Right.  
 22 COFFEY, Q.C.:  
 23 Q. As well as often enough throughout the year -  
 24 DR. TORLAKOVIC:  
 25 A. Right.

1 COFFEY, Q.C.:

2 Q. To achieve quality control goals--quality

3 assurance goals?

4 DR. TORLAKOVIC:

5 A. Yes.

6 COFFEY, Q.C.:

7 Q. And once a year perhaps is not enough?

8 DR. TORLAKOVIC:

9 A. No.

10 COFFEY, Q.C.:

11 Q. Because it's another 12 months before it gets

12 done again?

13 DR. TORLAKOVIC:

14 A. Exactly. So there is--I think in the United

15 States they go by twice a year as a minimum,

16 and what we want to suggest is three times a

17 year as a minimum for Canada, because I think

18 that would be more like ISO standards or just

19 our own feeling that how--large gap, we want

20 to have for these sensitive and very important

21 sensitive tests to be able to not miss a large

22 number of patients in between.

23 COFFEY, Q.C.:

24 Q. If it's twice a year, it's six months before

25 you get around to it again?

1 DR. TORLAKOVIC:

2 A. Right.

3 COFFEY, Q.C.:

4 Q. And in the meantime, you process six months

5 worth of patients?

6 DR. TORLAKOVIC:

7 A. Right.

8 COFFEY, Q.C.:

9 Q. And potentially if you have had a problem, I

10 take it, for up to six months undetected by

11 outside -

12 DR. TORLAKOVIC:

13 A. Except that if this program is used as

14 external quality assurance program should be

15 used to actually calibrate your own lab, so

16 your own positive controls should be

17 constructed like that, and you should notice

18 if there is a problem or not, and you should

19 often demonstrate also that you don't have a

20 problem. So that external quality assurance

21 is not going to be used only so that

22 laboratories can adopt their quality assurance

23 programs and calibrate, but also to have for

24 accreditation purposes as evidence for

25 certification.

1 COFFEY, Q.C.:

2 Q. And here, Doctor, in the third last bullet,

3 "Provides extensive feedback to participating

4 laboratories. Can use this information to

5 improve results immediately", and you gave us

6 the one example of the lab that was -

7 DR. TORLAKOVIC:

8 A. Yes.

9 COFFEY, Q.C.:

10 Q. One particular lab earlier involved in Run 2,

11 but here as well at one of the middle bullets

12 here it says, "No funding so far". Now I was

13 going to ask you about how is all this being

14 paid for, CIQC, or is it being paid for at

15 all, and if so, how, and what else is needed

16 from your perspective?

17 DR. TORLAKOVIC:

18 A. We had to pay to construct that multiviewer

19 that enables comparison side by side. I think

20 the price was about \$6,000.00 or so. So we

21 asked some companies that sell us antibodies

22 and immunohistochemical material if they would

23 want to have their logos displayed on our home

24 page, so we got money from two companies that

25 covered just exactly for that program, two and

1 a half thousand from each company, and then

2 otherwise we basically donate totally our time

3 and our work. Why we didn't come up with

4 participation fees; I mean, we are not really

5 well established program, we have no program

6 manager, we have no way how to actually

7 determine what the real cost is, we don't know

8 how large this program may be in the future.

9 So larger the program, smaller the fees would

10 be because you have the same structure to

11 support your small laboratory, so the only

12 additional cost if the lab grows eventually.

13 When it's established, it's just like for

14 mailing of the slides, which is minimal. So I

15 don't really know in that official sense.

16 Like, we have put some calculations together

17 approximately how much it would cost because,

18 as I said, assessment of the results is

19 critical, and I think that face to face

20 meetings--or even maybe not face to face with

21 the current technology. As we scan all the

22 slides, maybe we can do it over

23 teleconference, but it is important that in

24 real time assessors look at the same specimen

25 and discuss the results of the labs and try to



Page 161

1 figure out what the recommendations would be  
 2 for each individual lab result. So that costs  
 3 money and it will cost--if we actually travel,  
 4 it will cost to travel, it will cost for  
 5 accommodations, for food, and currently if you  
 6 want to have four assessors as most  
 7 assessments, that's how they're performed  
 8 today, that means cost for four people, and if  
 9 it's three times a year at least. So we have  
 10 come up with some kind of sum of money that we  
 11 need. If we would charge participation fees  
 12 about 20/30 labs, that would be extremely  
 13 expensive. So we cannot do that, and somehow  
 14 we do not feel that laboratories kind of  
 15 should pay for this service, because it's  
 16 really hard to put a price. You have to have  
 17 service like this. I think it's--if you  
 18 mandate participation in such a program, you  
 19 have to provide such a program available to  
 20 labs, and I see that--the Class II test, there  
 21 may be more of them coming up in the future,  
 22 so there will be even more demands on the labs  
 23 to participate. Additional fees, I mean, it's  
 24 just going to crash budget of laboratories  
 25 because unfortunately pathologists are not--

Page 162

1 labs are not paid fee for service like they  
 2 are in the United States. They have their  
 3 budget, and you don't want to crash that  
 4 budget just because now you mandate something  
 5 that is expensive.  
 6 COFFEY, Q.C.:  
 7 Q. For example, participation in something like  
 8 CIQC if it was -  
 9 DR. TORLAKOVIC:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. If it had to be funded by the participants and  
 13 it was an expensive program, and it, in  
 14 effect, would--ultimately if the labs don't  
 15 have the money in their budgets, they'd have to  
 16 find it somewhere within their own budget?  
 17 DR. TORLAKOVIC:  
 18 A. Right.  
 19 COFFEY, Q.C.:  
 20 Q. Which would negatively affect, presumably,  
 21 potentially what they're doing otherwise.  
 22 Doctor, can you tell the Commissioner have any  
 23 other funding sources been canvassed or  
 24 sought, governmental sources, for example?  
 25 DR. TORLAKOVIC:

Page 163

1 A. I cannot list for you now agencies, but  
 2 National Standards Committee for  
 3 immunohistochemistry from CAP have various  
 4 committee members and some of them have better  
 5 understanding of potential sources of funding  
 6 than myself, and so some of the agencies were  
 7 shortlisted for the members to consider and  
 8 contact, and we will try to find some sources,  
 9 but so far no definite source has been  
 10 promised or identified. So we cannot say now  
 11 that this program may be funded by whatever  
 12 particular agency or source.  
 13 COFFEY, Q.C.:  
 14 Q. Doctor, it's October 9th, 2008 as we sit here  
 15 today. As of today you do refer here to, in  
 16 the second-last bullet, to "This program is  
 17 adequate to fulfil the criteria for mandatory  
 18 certification."  
 19 DR. TORLAKOVIC:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. We've also, of course, heard references to  
 23 laboratory accreditation?  
 24 DR. TORLAKOVIC:  
 25 A. Yes.

Page 164

1 COFFEY, Q.C.:  
 2 Q. In a wider sense, labs, clinical lab  
 3 accreditation. Doctor, to your knowledge,  
 4 where in Canada to date is there laboratory  
 5 accreditation for clinical labs? I understand  
 6 Ontario has it, there's mandatory accrediting  
 7 by QMPLS?  
 8 DR. TORLAKOVIC:  
 9 A. I think that laboratory--not think. I think I  
 10 know the answer to this question. There are  
 11 five provinces that have laboratory  
 12 accreditation in place, and those five  
 13 provinces are from, it's BC, it's Alberta,  
 14 it's Saskatchewan, it's Manitoba and it's  
 15 Ontario. And they have obligatory  
 16 participation for immunohistochemistry labs in  
 17 quality, in external quality assurance  
 18 programs. And since recently, actually, some  
 19 of them--and that varies now from one  
 20 accreditation program to another, when they  
 21 started to actually mandate these for breast  
 22 cancer markers, and each of them has their own  
 23 history and where they are at. And I can tell  
 24 you for Saskatchewan we are right now in the  
 25 middle of creating such requirement that it's

Page 165

1 mandatory with Saskatchewan. We have  
 2 participation for breast cancer markers for a  
 3 very long time. It hasn't been mandated and  
 4 it's going to be changed now to being  
 5 mandatory. But, national standards committee  
 6 for immunohistochemistry from CAP, one of the  
 7 immediate tasks that we have on our program is  
 8 to call for mandatory certification or uniform  
 9 mandatory certification requirements for all  
 10 laboratories that practice in diagnostic  
 11 immunohistochemistry everywhere, even where  
 12 there are no accreditation programs. It also  
 13 means -  
 14 COFFEY, Q.C.:  
 15 Q. Such as, for example, this province?  
 16 DR. TORLAKOVIC:  
 17 A. Right.  
 18 COFFEY, Q.C.:  
 19 Q. I'm sorry, Doctor, you were saying, it also  
 20 means?  
 21 DR. TORLAKOVIC:  
 22 A. It also means that if there is no  
 23 accreditation program, I think that it has to  
 24 be built quickly. And if--for immediate use I  
 25 think one could use a good external quality

Page 166

1 assurance program and just good practices.  
 2 And even without accreditation we know that  
 3 results can be, results can be improved and  
 4 the quality can rise. We saw that from  
 5 NordiQC. In Scandinavia many laboratories  
 6 don't have accreditation but they still kind  
 7 of certified their tests by participating. So  
 8 there is a difference between test  
 9 certification and accreditation programs.  
 10 COFFEY, Q.C.:  
 11 Q. Yeah.  
 12 DR. TORLAKOVIC:  
 13 A. So in this case we can go and certify the test  
 14 even without the accreditation program for the  
 15 time being.  
 16 COFFEY, Q.C.:  
 17 Q. And -  
 18 DR. TORLAKOVIC:  
 19 A. So what would it mean to certify the test? I  
 20 think it would mean to participate three times  
 21 a year and with a success rate in the testing  
 22 in EAQ program for that particular test. That  
 23 would mean that, say, for ER, three times a  
 24 year, stain the slide for ER and show that you  
 25 have more than 95 percent concordance with

Page 167

1 reference wise and that would be certified,  
 2 that would then certify the lab--the test  
 3 itself.  
 4 COFFEY, Q.C.:  
 5 Q. Yes. Is CIQC affiliated with the Canadian  
 6 Association of Pathologists? Are you a part  
 7 of that group?  
 8 DR. TORLAKOVIC:  
 9 A. Not formally, no.  
 10 COFFEY, Q.C.:  
 11 Q. Yes, and I was going to ask you about the  
 12 relationship between CIQC and the Canadian  
 13 Association of Pathologists.  
 14 DR. TORLAKOVIC:  
 15 A. There is, I mean, I am co-founder of CIQC.  
 16 COFFEY, Q.C.:  
 17 Q. Yes.  
 18 DR. TORLAKOVIC:  
 19 A. And I am chairing the committee in CAP and I  
 20 am now executive committee of CAP, but other  
 21 than that there is no connection, there is no  
 22 official connection. They support the program  
 23 because they think that the program has valid  
 24 scientific and--all of the principles that we  
 25 have demonstrated so far show that this

Page 168

1 program is well structured and provides  
 2 information that is sufficient for laboratory-  
 3 -or that tests can be certified by using this  
 4 program. It has all the components of -  
 5 COFFEY, Q.C.:  
 6 Q. If we could look, please--just come down a  
 7 little bit here, yeah. This is a slide, it's  
 8 one of the last slides of the presentation.  
 9 It's the CAP Five-Point Plan?  
 10 DR. TORLAKOVIC:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. Could you take us through that, please,  
 14 Doctor?  
 15 DR. TORLAKOVIC:  
 16 A. I wanted to say that the committee had a task  
 17 to create a document for this last summer to--  
 18 in Ottawa at the annual meeting CAP committee  
 19 was to present a draft document that contains  
 20 suggestions like where we should go in regards  
 21 to standardization in diagnostic  
 22 immunohistochemistry. So -  
 23 COFFEY, Q.C.:  
 24 Q. This is a CAP committee?  
 25 DR. TORLAKOVIC:

Page 169

1 A. CAP committee, yes.  
 2 COFFEY, Q.C.:  
 3 Q. Yes, go ahead.  
 4 DR. TORLAKOVIC:  
 5 A. So that draft document was submitted to  
 6 executive committee. And out of that draft  
 7 document some of--most of the points that are  
 8 listed here as one, two, three, four and five,  
 9 we had our five points, it's was slightly  
 10 modified, it's a final CAP document and five-  
 11 point plan that you see here. So, first of  
 12 all, we are as a committee or the CAP,  
 13 actually, is calling for mandatory  
 14 certification for each prognostic and  
 15 predictive test performed by a medical  
 16 laboratory. That means those are breast  
 17 cancer markers that, that EG4 (phonetic) the  
 18 CD117 and the CD20 to be included. External  
 19 validation system where test results from one  
 20 laboratory would be verified by another  
 21 independent external laboratory or the  
 22 participation in EQA is obligatory.  
 23 Dissemination and use of the Canadian National  
 24 Checklist for diagnostic IHC. This point  
 25 actually is extremely important because

Page 170

1 national standards committee is not there to  
 2 create standards all over, because there are  
 3 many standards that are published already. So  
 4 our role was not in creating yet another  
 5 duplicate document and overlap with major  
 6 documents that are created for this area. But  
 7 we found that our role would be in trying to  
 8 provide standards for implementation of  
 9 guidelines into the laboratories, because of  
 10 the only existing guidelines and standards  
 11 that are published, they are not uniformly  
 12 transformed or translated into the practice,  
 13 so we found that as a missing link. And we  
 14 think that creating checklists would be the  
 15 way that would help laboratories implement  
 16 existing guidelines into their practice, and  
 17 therefore we created two working groups or  
 18 subcommittees, if you will, in the national  
 19 standards committee that will work on creating  
 20 a checklist for Class I and another checklists  
 21 for Class II tests, that should help in more  
 22 uniform translation of published guidelines  
 23 and standards in the practice.  
 24 COFFEY, Q.C.:  
 25 Q. Into actually laboratory processes?

Page 171

1 DR. TORLAKOVIC:  
 2 A. Yes, right. And then point four, "Creation of  
 3 national body separate from government to  
 4 accredit all medical laboratories in Canada  
 5 and ensure they need quality and critical"--  
 6 "meet" sorry, that "quality and critical mass  
 7 standards." This is because right now some  
 8 provinces when we listed out that have  
 9 accreditation, laboratory accreditation, but  
 10 some of them don't. And it would be logical,  
 11 I think, that we should have a national  
 12 accreditation body that would use the same  
 13 standards for all labs. How accreditation  
 14 processes differ from one province to another,  
 15 I don't know in detail exactly because I'm not  
 16 involved directly in laboratory accreditation,  
 17 but I know that there are differences and  
 18 there are different levels of sophistication  
 19 that are used for this process. On the other  
 20 hand, there is no reason why provinces should  
 21 have different standards for accreditation.  
 22 And then the point five, "Immediate and  
 23 ongoing support from federal, provincial and  
 24 territorial governments to address the  
 25 critical workforce and resource shortages

Page 172

1 undermining laboratory medicine." As we all  
 2 know, I mean, the shortage of pathologists as  
 3 well a shortage of expert technologists that  
 4 are working in the labs is something that we  
 5 cannot easily solve. And that is creating a  
 6 lot of problems because quality assurance and  
 7 quality control, they need expertise but they  
 8 also need time. And I can say my own time, my  
 9 time and my ability to do what I want to do is  
 10 actually limited. I am not even able for my  
 11 own lab to do everything that I would want to  
 12 do because I just don't have enough time for  
 13 that. So we do need more resources to be able  
 14 to actually do this job the way we currently  
 15 think we can and we know how.  
 16 COFFEY, Q.C.:  
 17 Q. And in terms of before I come back to the idea  
 18 of like a national effort here, in number four  
 19 here there's a reference to critical mass  
 20 standards. What is that, Doctor, equality and  
 21 critical mass standards, what is that? Took  
 22 care of all and ensured that the issue--  
 23 pointed out, the need should be meet. They  
 24 meet quality, quality standards, I think is  
 25 pretty self-evident. Critical mass standards

Page 173

1 would be what?  
 2 DR. TORLAKOVIC:  
 3 A. For standards, I mean, again, I think that  
 4 term is overused.  
 5 COFFEY, Q.C.:  
 6 Q. Yes.  
 7 DR. TORLAKOVIC:  
 8 A. We need the critical mass of evidence.  
 9 Critical mass, that's why we need a national  
 10 body, because some of the places is just  
 11 simply too small to provide--to create and to  
 12 have one of their own quality assurance  
 13 systems. They need to be part of the larger  
 14 mass, quality mass because at some point, I  
 15 don't know if it's--I should mention this,  
 16 quantity at some point becomes quality, and  
 17 that's the critical mass. You cannot run  
 18 really good quality assurance programs between  
 19 two labs in Saskatchewan. There is no quality  
 20 assurance program that is necessary for--  
 21 makes, doesn't make sense for two labs. But  
 22 when you put all the laboratories in Canada  
 23 together, you get a mass, critical mass that  
 24 is necessary for such a program to function.  
 25 COFFEY, Q.C.:

Page 174

1 Q. And just in terms of the, illustrating for the  
 2 Commissioner the current state of affairs, if  
 3 I could, just while it's come up here,  
 4 Commissioner, here this slide is QC, QA and  
 5 IHC in Canada. And this is--you pointed out  
 6 there there's no national list of diagnostic  
 7 laboratories that perform the IHC testing for  
 8 patients' care. So I take it to your  
 9 knowledge there is no actual complete list -  
 10 DR. TORLAKOVIC:  
 11 A. There's no national list, no, no, there is no  
 12 complete list. And that is the greatest  
 13 frustration we deal with because even--when  
 14 you think about it, how do you know what's  
 15 going on? How do you know what's happening on  
 16 the ground when you don't even know who  
 17 people--where are the labs. Who -  
 18 COFFEY, Q.C.:  
 19 Q. Who's doing the test?  
 20 DR. TORLAKOVIC:  
 21 A. - are the constants (phonetic)? Who is doing  
 22 what? So at the committee, CAP committee that  
 23 I am chairing we try to do a survey to see  
 24 where we are and who is doing what, how many  
 25 tests on their menus to identify how big the

Page 175

1 problem is that we deal with, how are we going  
 2 to plan for the future, you know, where we are  
 3 going and so on. There's absolutely no  
 4 information that we can get because--also,  
 5 when we were creating CIQC, we wanted to  
 6 invite as large numbers as possible of  
 7 laboratories to participate. But just to gain  
 8 the information who these people are, I mean,  
 9 and you know that people move from one place  
 10 to another. What's published in one directory  
 11 is not necessarily accurate for the current  
 12 state--for what's currently on the ground. So  
 13 it took us a lot of time and contacts and  
 14 phone calling until we get, like, this 12  
 15 laps for the first run just to organize that  
 16 to contact them, to have accurate address,  
 17 where to send the slides and who's going to  
 18 take care of them who's going to--that was a  
 19 huge problem and that still is. So we don't--  
 20 we have to find a way how to get a list of the  
 21 labs and then we have to do the survey and  
 22 then we have to see--to get an insight how big  
 23 is the problem and then we have to take--plan  
 24 other steps because before that I don't think  
 25 we can plan anything.

Page 176

1 COFFEY, Q.C.:  
 2 Q. Without knowing who might even be involved or  
 3 how many?  
 4 DR. TORLAKOVIC:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. And where they are?  
 8 DR. TORLAKOVIC:  
 9 A. We have no idea.  
 10 COFFEY, Q.C.:  
 11 Q. Doctor, I'm going to end on that note,  
 12 Commissioner. They're the questions I have.  
 13 THE COMMISSIONER:  
 14 Q. All right, then. Thank you. Mr. Pritchard?  
 15 MR. PRITCHARD:  
 16 Q. I don't have any questions for this witness.  
 17 Thank you -  
 18 THE COMMISSIONER:  
 19 Q. Mr. Simmons?  
 20 MR. SIMMONS:  
 21 Q. Thank you, Commissioner. I do have a few  
 22 questions. I wonder if we might be able to  
 23 canvas the room and see if Dr. Torlakovic is  
 24 coming back this afternoon anyway and if she  
 25 is, I might benefit from an early break so I

Page 177

1 can organize my thoughts a little bit. It's  
 2 been, you know, obviously, a very interesting  
 3 and complex (inaudible) testimony so far this  
 4 morning. But if we could finish Ms.  
 5 Torlakovic by lunch break, I'll go ahead.  
 6 THE COMMISSIONER:  
 7 Q. All right. Well, why don't we do that. Mr.  
 8 Browne, do you have any questions?  
 9 MR. BROWNE:  
 10 Q. At this point I just have a couple of--there  
 11 is one area, actually, I wanted to explore  
 12 with Dr. Torlakovic and I may also benefit  
 13 from a short adjournment.  
 14 THE COMMISSIONER:  
 15 Q. Ms. Newbury?  
 16 MS. NEWBURY:  
 17 Q. I'll probably be ten minutes.  
 18 THE COMMISSIONER:  
 19 Q. All right. Mr. Crosbie?  
 20 CROSBIE, Q.C.:  
 21 Q. Five minutes.  
 22 PIKE, Q.C.:  
 23 Q. No questions for me.  
 24 MR. SIMMONS:  
 25 Q. It's your call, Commissioner.

Page 178

1 THE COMMISSIONER:  
 2 Q. It's my call, obviously. Clearly you feel  
 3 that you'd benefit from being able to put your  
 4 thoughts together. Why don't we just take the  
 5 luncheon break a little early and come back at  
 6 ten to two, instead of the normal time. How  
 7 is that?  
 8 MR. SIMMONS:  
 9 Q. Thank you, Commissioner. It's a valuable  
 10 opportunity and I wouldn't want to miss the  
 11 opportunity -  
 12 THE COMMISSIONER:  
 13 Q. Well, indeed, and I appreciate that. But when  
 14 we have somebody of the knowledge of this  
 15 witness, we want to take advantage of it. So  
 16 we'll take the luncheon break and come back at  
 17 ten to two. Thank you.  
 18 (LUNCH BREAK)  
 19 THE COMMISSIONER:  
 20 Q. Please be seated. Mr. Simmons?  
 21 MR. SIMMONS:  
 22 Q. I have a request from Mr. Crosbie, he has an  
 23 appointment to (inaudible), so I -  
 24 THE COMMISSIONER:  
 25 Q. All right, then. Mr. Crosbie.

Page 179

1 DR. EMINA TORLAKOVIC, EXAMINATION BY CHESLEY CROSBIE,  
 2 Q.C.  
 3 CROSBIE, Q.C:  
 4 Q. Thank you. Doctor, this may be a little off  
 5 the overall topic that you'd been addressing  
 6 before the Commission today. But we've heard  
 7 evidence that in the lab here at Eastern  
 8 Health there was a period of time, maybe three  
 9 and a half years, after Dr. Khalifa in the  
 10 fall of 1999, when the amount of clinical or  
 11 pathology supervision or input that was  
 12 available to the IHC lab consisted mainly in  
 13 the reading of slides and there seemed to be  
 14 no real resource person with expertise in IHC  
 15 testing available to the technical people.  
 16 I'm just wondering if you can say a few words  
 17 on what you think should be the relationship  
 18 between the chief technical person in charge  
 19 of the lab and the clinical side, how should  
 20 that be structured, set up and what's the  
 21 division of responsibilities?  
 22 DR. TORLAKOVIC:  
 23 A. It would also depend a little bit on the size  
 24 of the laboratory I should start with saying,  
 25 because if one particular lab is performing

Page 180

1 very limited spectro (phonetic) in small  
 2 number from your histochemical test, it would  
 3 be difficult to imagine that you would have a  
 4 special person, special pathologist dedicated  
 5 to the function of being a director of  
 6 immunohistochemistry for such limited volumes.  
 7 Therefore, there wouldn't be a special person  
 8 designated with expertise and responsibility  
 9 for this area.  
 10 CROSBIE, Q.C.:  
 11 Q. Do you know what the volumes were in the lab  
 12 here in the period we're talking about?  
 13 DR. TORLAKOVIC:  
 14 A. No, I have no idea.  
 15 CROSBIE, Q.C:  
 16 Q. Is it just over 300, have I got that about  
 17 right?  
 18 COFFEY, Q.C:  
 19 Q. I'm sorry, you're looking for?  
 20 CROSBIE, Q.C:  
 21 Q. The volume of ER/PR tests in the lab a year?  
 22 COFFEY, Q.C:  
 23 Q. About 350 a year.  
 24 CROSBIE, Q.C:  
 25 Q. 350 a year.

Page 181

1 DR. TORLAKOVIC:  
 2 A. All immunohistochemical tests together?  
 3 COFFEY, Q.C.:  
 4 Q. No, 14,000.  
 5 DR. TORLAKOVIC:  
 6 A. 14,000.  
 7 COFFEY, Q.C.:  
 8 Q. Mr. Simmons will correct me if I'm wrong,  
 9 14,000.  
 10 MR. SIMMONS:  
 11 Q. I'm not sure.  
 12 DR. TORLAKOVIC:  
 13 A. So that -  
 14 COFFEY, Q.C.:  
 15 Q. That's the figure we've heard.  
 16 CROSBIE, Q.C.:  
 17 Q. 350 ER/PR.  
 18 DR. TORLAKOVIC:  
 19 A. All right, so that means probably what you  
 20 said is correct about thousands. So that is  
 21 volume enough to have a designated specialist  
 22 to dedicate part of his or her time for  
 23 immunohistochemistry laboratory alone. And  
 24 that -  
 25 CROSBIE, Q.C.:

Page 182

1 Q. Sorry, are you talking on the pathology side  
 2 now?  
 3 DR. TORLAKOVIC:  
 4 A. Pathology, pathology side. And that  
 5 pathologist would have to closely interaction  
 6 on daily basis with expert technologist who is  
 7 in charge of immunohistochemistry too. And  
 8 there should be one person, and preferably,  
 9 depending on how much volume is--what's the  
 10 level of automation and so on. But whoever is  
 11 there, there should be a permanent technology  
 12 setup of technologists who are the same  
 13 people, not rotating too much to doing other  
 14 things because this area is so sophisticated  
 15 and demanding a special knowledge from the  
 16 technologist that they cannot, they cannot  
 17 simply be imported from other areas on  
 18 temporary basis without clear supervision from  
 19 other expert pathologists. So you would think  
 20 that there should be at least one or two, for  
 21 such number of tests it would be optimally two  
 22 full time technologists for  
 23 immunohistochemistry with additional person  
 24 helping with more simple tasks. And you would  
 25 have part-time pathologists involved who would

Page 183

1 be daily in contact with the top technologist  
 2 or whoever is mainly responsible for that.  
 3 CROSBIE, Q.C.:  
 4 Q. What would the responsibilities of the  
 5 pathologist be?  
 6 DR. TORLAKOVIC:  
 7 A. Ideally, we can speak only ideally, because  
 8 this varies greatly from one lab to another,  
 9 from one country to another. But as I see it  
 10 ideally, such pathologist would be in charge  
 11 of making sure that daily quality control  
 12 systems are functioning correctly and that  
 13 there is participation in standard quality  
 14 assurance programs and that even touch base  
 15 with other pathologists in making sure there  
 16 is communication that unusual results can be  
 17 reported to him or her so that any  
 18 intervention that needs to be done is being  
 19 done in time.  
 20 CROSBIE, Q.C.:  
 21 Q. I get the sense, listening to various people  
 22 talking about this, that pathologists  
 23 themselves have varying degrees of skill and  
 24 experience with actually how things are done  
 25 in the lab. In other words, I guess you could

Page 184

1 call it lab or bench experience available to  
 2 them. Is that correct?  
 3 DR. TORLAKOVIC:  
 4 A. It's varied. The background of various  
 5 pathologists in their training level in these  
 6 areas is extremely variable, extremely  
 7 heterogenous and the expertise they have, it's  
 8 usually devised from their personal exposure  
 9 and experience in their practice, rather than  
 10 structured education in this area. As I am  
 11 aware, even today education with residents is  
 12 lacking in this area, in particular when it  
 13 comes to quality control and quality assurance  
 14 issues. I don't think we are educating even  
 15 the newest generation of pathologists enough  
 16 on these issues.  
 17 CROSBIE, Q.C.:  
 18 Q. Well, perhaps I could ask this: Would it be a  
 19 prudent quality assurance measure to actually  
 20 describe the characteristics or  
 21 qualifications, which may not be formal ones,  
 22 they may be based on experience, the sorts of  
 23 things that the pathology resource person  
 24 available to a lab with the volume that you've  
 25 heard about we have here, should be able to

Page 185

1 exhibit and make available to the technology  
 2 staff in the lab itself? In other words, to  
 3 describe that formally?  
 4 DR. TORLAKOVIC:  
 5 A. Again -  
 6 CROSBIE, Q.C:  
 7 Q. In writing, and when I say "formally", a  
 8 written description?  
 9 DR. TORLAKOVIC:  
 10 A. I mean, ideally a pathologist should be a  
 11 resource for selection of controls,  
 12 appropriate controls for all the tests that  
 13 are run in the lab and ideally should be going  
 14 over the entire communication of the lab on a  
 15 periodic basis, at minimum once a year, making  
 16 sure that all laboratory protocols and  
 17 procedures are updated appropriately. And  
 18 minimally he should be available as a resource  
 19 any time because technologists are usually  
 20 very diligent to bond this, whatever they  
 21 produce they review, they look at it and they  
 22 make a judgment. If they notice any potential  
 23 problems, pathologist should be a first  
 24 resource for them for discussion and potential  
 25 intervention.

Page 186

1 CROSBIE, Q.C:  
 2 Q. And again, would it be useful to have that  
 3 sort of, those sort of qualifications that you  
 4 just described reduced to writing for a lab?  
 5 DR. TORLAKOVIC:  
 6 A. In writing? I'm not sure that I understand  
 7 your question.  
 8 CROSBIE, Q.C:  
 9 Q. Well, you just described for the Commissioner  
 10 a list of attributes and functions that the  
 11 clinical side ought to make available to the  
 12 lab?  
 13 DR. TORLAKOVIC:  
 14 A. Yes.  
 15 CROSBIE, Q.C:  
 16 Q. Would it not be a good idea, would it be a  
 17 good idea to have that in writing?  
 18 THE COMMISSIONER:  
 19 Q. A job description, you would -  
 20 CROSBIE, Q.C:  
 21 Q. Yes, indeed, yeah.  
 22 DR. TORLAKOVIC:  
 23 A. Oh, yes, well, why not. I think that would be  
 24 actually helpful, since I'm not sure that  
 25 anybody described ever in such--in a very

Page 187

1 detailed manner like what is the job  
 2 description of an immunohistochemistry  
 3 director, you know, of a pathologist who is in  
 4 charge. I don't think there is an exact and  
 5 uniform description of what that job should  
 6 be. But I just told you like from my own  
 7 experience and practice -  
 8 CROSBIE, Q.C:  
 9 Q. But that may vary from one lab to another?  
 10 DR. TORLAKOVIC:  
 11 A. And may vary.  
 12 CROSBIE, Q.C:  
 13 Q. But at least it helps to reduce the scope for  
 14 any confusion -  
 15 DR. TORLAKOVIC:  
 16 A. Absolutely.  
 17 CROSBIE, Q.C:  
 18 Q. - or lack of clarity about who's responsible  
 19 for what?  
 20 DR. TORLAKOVIC:  
 21 A. Yes.  
 22 CROSBIE, Q.C:  
 23 Q. Another thing I wanted to ask you briefly is,  
 24 there may be others, but I have this sort of  
 25 model in my head of IHC testing and I guess

Page 188

1 the testing that you described as Class I and  
 2 Class II as being done in larger typically  
 3 university affiliated labs that are part of a  
 4 health sciences complex with medical schools  
 5 and the like affiliated with them. You know,  
 6 we've obviously heard a lot here about Mount  
 7 Sinai and heard from people from Mount Sinai  
 8 and whatnot. Are these Class I tests, for  
 9 example, are they being done in smaller  
 10 regional labs or outside that kind of  
 11 environment that I just described?  
 12 DR. TORLAKOVIC:  
 13 A. Class I is typically done by any lab that is  
 14 doing diagnostic immunohistochemistry. It's  
 15 Class II tests that are not often performed by  
 16 smaller labs because of the level of  
 17 sophistication that is necessary to do them.  
 18 But Class I, they are all Class I tests except  
 19 for ER/PR and HER2, you know, everything else  
 20 in immunohistochemistry is Class I.  
 21 CROSBIE, Q.C:  
 22 Q. Yes. So, you know, in a regional centre you  
 23 might have only two pathologists, let's say,  
 24 because it's doing surgery and you have to  
 25 have pathology staff into place in order to do

Page 189

1 surgery. Are we talking--are they doing  
 2 immunohistochemistry in that kind of a small,  
 3 small lab?  
 4 DR. TORLAKOVIC:  
 5 A. That I don't know.  
 6 CROSBIE, Q.C:  
 7 Q. You don't know the answer?  
 8 DR. TORLAKOVIC:  
 9 A. I know, I heard of very small laboratories  
 10 that do like four or five different stains and  
 11 those would be the Class I tests.  
 12 CROSBIE, Q.C:  
 13 Q. Yes.  
 14 DR. TORLAKOVIC:  
 15 A. Some small labs will do that, but that's very  
 16 unusual. It's usually larger labs that  
 17 perform diagnostic immunohistochemistry. It  
 18 is rare that--my belief is to the best of my  
 19 knowledge it is not common to have very small  
 20 immunohistochemistry labs.  
 21 CROSBIE, Q.C:  
 22 Q. But it's hard to be definitive about it  
 23 because you don't have accurate data?  
 24 DR. TORLAKOVIC:  
 25 A. No, I don't have.

Page 190

1 CROSBIE, Q.C:  
 2 Q. Yes. Thank you.  
 3 THE COMMISSIONER:  
 4 Q. Thank you, Mr. Crosbie. Mr. Simmons?  
 5 DR. EMINA TORLAKOVIC, EXAMINATION BY MR. DANIEL SIMMONS  
 6 MR. SIMMONS:  
 7 Q. Dr. Torlakovic, I'm Dan Simmons. I'm here for  
 8 Eastern Health, which is the authority that's  
 9 operated the IHC lab here. I had a question  
 10 for you first coming out of the comments that  
 11 you made about residency training and yours,  
 12 in particular. Mr. Crosbie has just touched  
 13 on it, as well. Did I gather that you  
 14 described yourself as having been privileged  
 15 in your residency to be able to work with some  
 16 people who were experts in the field of  
 17 immunohistochemistry or you regarded them as  
 18 such? Did I hear that correctly?  
 19 DR. TORLAKOVIC:  
 20 A. Almost correctly, because what I said is I was  
 21 privileged to work in a centre that with  
 22 diagnostic immunohistochemistry that was  
 23 established by experts who, at the time, when  
 24 I was a resident, were actually gone from the  
 25 place.

Page 191

1 MR. SIMMONS:  
 2 Q. I see.  
 3 DR. TORLAKOVIC:  
 4 A. But good practices were in place already.  
 5 MR. SIMMONS:  
 6 Q. Yes, okay. Would you be able -  
 7 DR. TORLAKOVIC:  
 8 A. But also not to say that people who I worked  
 9 with then were not experts also in  
 10 interpretation and usage and technological  
 11 aspects. But I just mentioned two names  
 12 specifically because these are very well  
 13 internationally regarded specialists in  
 14 diagnostic immunohistochemistry.  
 15 MR. SIMMONS:  
 16 Q. Are you in a position to make any comment for  
 17 us on how your exposure in your residency to  
 18 immunohistochemical testing would compare to  
 19 what you would expect of other anatomical  
 20 pathology residents in other situations?  
 21 Would you have been more or less exposed, do  
 22 you think, than others?  
 23 DR. TORLAKOVIC:  
 24 A. I think that I was more exposed than others,  
 25 definitely.

Page 192

1 MR. SIMMONS:  
 2 Q. Yes, okay. When you were talking about  
 3 beginning your work in Norway, which I think  
 4 you began at Oslo in 1997, one of the comments  
 5 you made in response to some questions from  
 6 Mr. Coffey was that by that time  
 7 immunohistochemistry had changed somewhat from  
 8 years, from a number of years before?  
 9 DR. TORLAKOVIC:  
 10 A. Yes.  
 11 MR. SIMMONS:  
 12 Q. And did I gather from that that the changes  
 13 that had taken place may have included the  
 14 introduction of more and newer antibodies than  
 15 had been in use previously?  
 16 DR. TORLAKOVIC:  
 17 A. Absolutely. And more and newer detection  
 18 methods which enhanced the sensitivity of the  
 19 test to that degree that the results were--  
 20 have become radically different than in the  
 21 past in the sense that we needed new skills  
 22 for interpretation of these new results.  
 23 MR. SIMMONS:  
 24 Q. Okay. So the progress in the technology  
 25 behind the performance of immunohistochemical



Page 193

1 staining was requiring pathologists to have  
 2 greater skills and knowledge when it came to  
 3 the interpretation of those stains, as well?  
 4 DR. TORLAKOVIC:  
 5 A. Right. And that knowledge actually was not  
 6 widely available or published because what was  
 7 published in the literature was based on those  
 8 previously used methods. So now the whole  
 9 thing have to be rewritten than normal  
 10 (phonetic) and it took about a decade, I would  
 11 say, or so, until things settled down and we  
 12 think we know approximately or with greater  
 13 confidence where are we at with the  
 14 distribution of certain antigens in certain  
 15 tissues.  
 16 MR. SIMMONS:  
 17 Q. Um-hm. Now, when would you say that decade  
 18 transition began and ended?  
 19 DR. TORLAKOVIC:  
 20 A. Just about at that time. I think it started  
 21 about '97 because that's about the time when  
 22 these more sensitive detection systems have  
 23 been made available.  
 24 MR. SIMMONS:  
 25 Q. Yes.

Page 194

1 DR. TORLAKOVIC:  
 2 A. And that's just about the time when I had at  
 3 least personally noticed the kind of explosion  
 4 in new antibody that performed well in  
 5 formalin fixed paraffin embedded tissues.  
 6 MR. SIMMONS:  
 7 Q. Um-hm.  
 8 DR. TORLAKOVIC:  
 9 A. Otherwise numerous antibodies that were  
 10 available before the time were used in frozen  
 11 sections and were not applicable for daily  
 12 practice.  
 13 MR. SIMMONS:  
 14 Q. Well, ten years, a decade from 1997 would  
 15 bring us up to 2007 -  
 16 DR. TORLAKOVIC:  
 17 A. Right, right.  
 18 MR. SIMMONS:  
 19 Q. - which is just last year.  
 20 DR. TORLAKOVIC:  
 21 A. Yes.  
 22 MR. SIMMONS:  
 23 Q. So from that can we take it that throughout  
 24 that decade there has been a continuous period  
 25 of change and increase in the knowledge

Page 195

1 available to pathologists about how to use and  
 2 interpret these tests?  
 3 DR. TORLAKOVIC:  
 4 A. Yes. And it still continues to develop, as it  
 5 does. There's more and more methods that are  
 6 being developed. And most recently in our run  
 7 three in Canadian immunohistochemical quality  
 8 control we had one lab with far more positive  
 9 results than any other laboratory for estrogen  
 10 receptor and progesterone receptor. And when  
 11 we look at that, they used hypersensitive  
 12 method. The problem with that -  
 13 MR. SIMMONS:  
 14 Q. They used?  
 15 DR. TORLAKOVIC:  
 16 A. Hypersensitive detection methods for -  
 17 MR. SIMMONS:  
 18 Q. Hypersensitivity?  
 19 DR. TORLAKOVIC:  
 20 A. Hypersensitive I call them because they are  
 21 much more sensitive detection systems than  
 22 those that are routinely used or those that  
 23 are used for to produce the results that are  
 24 published in the literature. So we don't  
 25 really know what is the clinical relevance of

Page 196

1 such results, even though I believe that they  
 2 have not produced false positive results,  
 3 those are true positive results, we have no  
 4 idea what these results mean clinically. So  
 5 we took them out kind of competition because  
 6 they are not to be compared, really, for  
 7 concordance and similar because we don't know  
 8 what it means yet. I think it yet has to be  
 9 discovered whether these systems are wisely  
 10 used in clinical practice or not.  
 11 MR. SIMMONS:  
 12 Q. Now when you speak of a detection system -  
 13 DR. TORLAKOVIC:  
 14 A. Yes.  
 15 MR. SIMMONS:  
 16 Q. - is that a commercially available product or  
 17 set of products -  
 18 DR. TORLAKOVIC:  
 19 A. Yes, it is.  
 20 MR. SIMMONS:  
 21 Q. - that a lab can acquire to use in their  
 22 testing process?  
 23 DR. TORLAKOVIC:  
 24 A. Yes, it is. It's a system--it's one part of  
 25 the immunohistochemistry is when you are

Page 197

1 actually using the antibody that is  
 2 specifically designed to detect the protein of  
 3 interest. But then, there is an amplification  
 4 system that is put on the top of that, so it  
 5 makes a visual signal and that amplification  
 6 system can be of different sensitivity. It  
 7 can amplify the type of protein one time, ten  
 8 times, 200 times, 2,000 times and so on. So  
 9 depending on the level of amplification, we  
 10 were read different intensity of staining and  
 11 then for more sensitive the system is, the  
 12 stronger the staining, and as I said, with  
 13 this ultra sensitive systems today, when they  
 14 can amplify one molecule of one protein in the  
 15 tissue, we still don't know what that means  
 16 possibly for clinical use, what's the  
 17 relevance of that, and therefore that always  
 18 has to be taken into account when as methods  
 19 develop whether they have been widely tested  
 20 for clinical practice or not.

21 MR. SIMMONS:  
 22 Q. So that example you give us though of the one  
 23 lab whose results you took out of the mix -  
 24 DR. TORLAKOVIC:  
 25 A. Yes.

Page 198

1 MR. SIMMONS:  
 2 Q. - because they were using the newer detection  
 3 system, would that be an example though of a  
 4 change in progression in technology which  
 5 resulted in a lab finding more positive  
 6 results for this test than they may have found  
 7 had they used the previous detection system?  
 8 DR. TORLAKOVIC:  
 9 A. Absolutely, and I would say that I know that  
 10 still not all the labs in Canada are using  
 11 normal sensitive, I mean, sensitive methods  
 12 which are polymer based methods, which give  
 13 very good, what we call immunohistochemistry  
 14 signal to noise ratio, so you want to see  
 15 specifically to find what you are looking for  
 16 and not to detect background. There are still  
 17 laboratories that are not using these systems  
 18 and when they transfer to these new systems,  
 19 they may yet see that the sensitivity of their  
 20 tests will increase, and it wouldn't be  
 21 strange at all if the material from one  
 22 hospital is being tested in another and you  
 23 see the huge difference, and that may be  
 24 because of the detection, different detection  
 25 system that it's using.

Page 199

1 MR. SIMMONS:  
 2 Q. Over the last ten years, have there been other  
 3 examples of changes in the technology  
 4 available for this testing that may have had  
 5 similar results of allowing laboratories to  
 6 test samples and find that they are getting  
 7 more positive results than they had before the  
 8 change, aside from this one you've spoken of,  
 9 of the detection system?  
 10 DR. TORLAKOVIC:  
 11 A. Yes, they have. Another good example is  
 12 development of antigen retrieval methods. So  
 13 it has been said that some of the epitopes of  
 14 interest do not need antigen retrieval at all,  
 15 which may be generally true, but antigen  
 16 retrieval methods do change results and the  
 17 sensitivity with which we detect molecules of  
 18 interest in the tissue, and we have learned,  
 19 during the last decade or so, that pH of those  
 20 antigen retrieval buffers matters. It matters  
 21 whether you are using a pressure cooker or  
 22 microwave or some other instrument for that  
 23 purpose. It really makes a difference how  
 24 this process is done because that is the one  
 25 that critically alters the structure of the

Page 200

1 tissue, and therefore, I think that only  
 2 illustrates even more that external quality  
 3 assurance program is absolutely necessary  
 4 because these are the programs that will  
 5 enable people to calibrate their own quality  
 6 assurance to the level that is clinically  
 7 applicable, relevant and valid, and this is  
 8 what we should aim for.  
 9 So we don't aim for ultimate sensitivity  
 10 for sensitivity alone, because we want to have  
 11 sensitive tests. We want to have tests that  
 12 is titrated appropriately for clinical use,  
 13 and therefore, I don't think that laboratories  
 14 should be left alone to decide what cut off  
 15 point or calibration is. I think they need to  
 16 have expert base to have them out to do so.  
 17 MR. SIMMONS:  
 18 Q. So to just take you back for a second to the  
 19 antigen retrieval example which you just gave  
 20 us, do I understand that knowledge about the  
 21 importance of the pH of the solution used in  
 22 the antigen retrieval process is something  
 23 that was acquired during the last ten years?  
 24 That this is something that was learned or  
 25 became better understood during that time

Page 201

1 period? Is that correct?  
 2 DR. TORLAKOVIC:  
 3 A. Of course, and I was personally involved in  
 4 teaching on that topic. I have personally  
 5 done no such studies myself, but I used  
 6 studies from others that illustrated that pH  
 7 may be critical in highlighting or destroying  
 8 epitopes of interest and that there are other  
 9 components of buffers that are important and  
 10 today, there are many different commercial  
 11 also antigen retrieval solutions for which we  
 12 don't even know complete composition, but we  
 13 know when we use one or the other that some of  
 14 the epitopes will be better demonstrated. So  
 15 it's a critical part for--and it's definitely  
 16 something you learn. It's definitely  
 17 something you learn also through EQA programs  
 18 because they show the comparisons, what are  
 19 results between different laboratories using  
 20 different antigen retrieval methods too.  
 21 MR. SIMMONS:  
 22 Q. So then the science behind IHC testing and ER  
 23 and PR in particular has been progressing, up  
 24 to the present time. Are we there yet? Have  
 25 we reached the point where it is--the science

Page 202

1 has optimized the test, or in your view, are  
 2 there still things to learn and more to be  
 3 done?  
 4 DR. TORLAKOVIC:  
 5 A. I think that the level of sensitivity of  
 6 detection methods will continue to rise and  
 7 this just last example that I gave and will  
 8 mention again the lab that had far more  
 9 positive results for estrogen and progesterone  
 10 receptors taken out of competition because  
 11 they are using now another detection system  
 12 that is not comparable to others and it's not  
 13 comparable to what's published in the  
 14 literature too. So it will continue to  
 15 develop, but in what sense and how exactly,  
 16 that is difficult to say, but it's something  
 17 that we will all watch and see how it evolves  
 18 and then use expert judgments like what of  
 19 that development needs to be translated into  
 20 clinical practice, what is relevant and what  
 21 is not.  
 22 MR. SIMMONS:  
 23 Q. Okay. Now when you're speaking of  
 24 sensitivity, it's a term that's well  
 25 understood by people who work in your field.

Page 203

1 Those of us who come from other backgrounds  
 2 don't always understand it with the same  
 3 precision that you do. Am I correct in  
 4 understanding that sensitivity is a measure of  
 5 how likely a test is to actually detect the  
 6 target antigen that you're looking for?  
 7 DR. TORLAKOVIC:  
 8 A. Right, true positive results.  
 9 MR. SIMMONS:  
 10 Q. The true positive results.  
 11 DR. TORLAKOVIC:  
 12 A. Yes.  
 13 MR. SIMMONS:  
 14 Q. And you measure sensitivity in percentages, I  
 15 understand, do you?  
 16 DR. TORLAKOVIC:  
 17 A. Yes, in percentages, but sensitivity itself,  
 18 as a test sensitivity, is not necessarily the  
 19 measure we need to use or it hasn't been  
 20 traditionally used in this area.  
 21 MR. SIMMONS:  
 22 Q. Yes.  
 23 DR. TORLAKOVIC:  
 24 A. And if you look at careful language that they  
 25 are using in ASCO and CAP guidelines and the

Page 204

1 same language can be translated into Canadian  
 2 guidelines for HER2. That would be our best  
 3 example where this is commented on  
 4 specifically is that 95 percent concordance  
 5 and it says concordance with both positive and  
 6 negative values. It does not speak of  
 7 sensitivity of the test, but sensitivity also  
 8 can be calculated if you have large sample  
 9 enough and then compare the test results from  
 10 one laboratory to reference values, yes, it  
 11 can be.  
 12 MR. SIMMONS:  
 13 Q. Okay, because you--I understood you to tell  
 14 us, in relation to the reporting of ER/PR  
 15 testing, and I may have gotten this wrong, I  
 16 understood you to say that in your view,  
 17 sensitivity is something that should be  
 18 reported to the clinicians who use the test?  
 19 DR. TORLAKOVIC:  
 20 A. Right, that's in my opinion.  
 21 MR. SIMMONS:  
 22 Q. And is that a practice that you're aware of is  
 23 actually in place anywhere now? Is there  
 24 anywhere you're aware of where the reporting  
 25 of ER and PR testing includes some statement

Page 205

1 about the sensitivity of that test?  
 2 DR. TORLAKOVIC:  
 3 A. No, no, no.  
 4 MR. SIMMONS:  
 5 Q. How -  
 6 DR. TORLAKOVIC:  
 7 A. It was taken for granted by clinicians, as I  
 8 understand it. If you tell them it's positive  
 9 or negative, they take it as granted.  
 10 MR. SIMMONS:  
 11 Q. Would the sensitivity vary from lab to lab?  
 12 DR. TORLAKOVIC:  
 13 A. It does. We saw in round, Run 2 testing in  
 14 Canadian immunohistochemistry quality control,  
 15 that it actually didn't vary much from one lab  
 16 to another, but we all know that now everybody  
 17 is paying attention.  
 18 MR. SIMMONS:  
 19 Q. Yes.  
 20 DR. TORLAKOVIC:  
 21 A. But it still varied and still there were labs  
 22 that were below 95 percent concordance, let's  
 23 say, for that value and there were some that  
 24 were--we also calculate sensitivities that  
 25 were below 95 percent sensitivity.

Page 206

1 MR. SIMMONS:  
 2 Q. Right, so how is it that you would like to see  
 3 the sensitivity reported? How would that be  
 4 done?  
 5 DR. TORLAKOVIC:  
 6 A. I think that because it's derived from EQA  
 7 testing, we don't really know what the  
 8 sensitivity of the test would be on the lab's  
 9 own material, because there is no other  
 10 reference to go by. So it should be reported  
 11 in the framework of the standing with EQA,  
 12 last EQA test.  
 13 MR. SIMMONS:  
 14 Q. I see, yes. So in other words, if a  
 15 particular lab had a 95 percent concordance on  
 16 their last EQA test -  
 17 DR. TORLAKOVIC:  
 18 A. Right.  
 19 MR. SIMMONS:  
 20 Q. - then you would suggest that that would be  
 21 something to be included in the pathology  
 22 report?  
 23 DR. TORLAKOVIC:  
 24 A. Yes.  
 25 MR. SIMMONS:

Page 207

1 Q. We have an ER/PR of this percent, PR of X  
 2 percent.  
 3 DR. TORLAKOVIC:  
 4 A. Yes.  
 5 MR. SIMMONS:  
 6 Q. Our last EQA test done on such and such a date  
 7 -  
 8 DR. TORLAKOVIC:  
 9 A. Right.  
 10 MR. SIMMONS:  
 11 Q. - gave us a concordance of 95 percent.  
 12 DR. TORLAKOVIC:  
 13 A. Right.  
 14 MR. SIMMONS:  
 15 Q. So it would give the clinician some measure of  
 16 how likely this ER/PR result is to reflect the  
 17 actual positivity?  
 18 DR. TORLAKOVIC:  
 19 A. Exactly, right.  
 20 MR. SIMMONS:  
 21 Q. Okay. Now why 95 percent as a target?  
 22 Because I gather that's a target concordance  
 23 that you're hoping to see labs achieve.  
 24 DR. TORLAKOVIC:  
 25 A. Yes.

Page 208

1 MR. SIMMONS:  
 2 Q. Why not 100 percent?  
 3 DR. TORLAKOVIC:  
 4 A. To tell you the truth, I don't know how ASCO,  
 5 because I was not involved in their expert  
 6 panel and I don't know all the details how  
 7 they arrived with 95 percent concordance, but  
 8 I know from our own, from the experience with  
 9 NordiQC, there is a small number of test  
 10 results that fail and you don't know why. We  
 11 have no explanation. It's unexplained  
 12 category. For most of the tests that failed,  
 13 we could always find--it's either wrong  
 14 antigen retrieval or it's dilution or it's  
 15 whatever. You find something. But for very  
 16 small number of tests that are generated, you  
 17 just don't find the reason why the test  
 18 failed, but it did. So it's not possible in  
 19 biological system to have 100 percent, I  
 20 believe.  
 21 MR. SIMMONS:  
 22 Q. So for those small number of tests that fail  
 23 where you cannot find the reason for failure -  
 24 DR. TORLAKOVIC:  
 25 A. Right.

Page 209

1 MR. SIMMONS:  
 2 Q. - would it be fair to say that that small  
 3 proportion of tests are unavoidable? That the  
 4 lab will not be able to avoid having a certain  
 5 number of say false negatives from the test?  
 6 DR. TORLAKOVIC:  
 7 A. That sounds like a reasonable conclusion.  
 8 Since we don't know what is causing it, I  
 9 don't think we can avoid that.  
 10 MR. SIMMONS:  
 11 Q. Is there any consensus on what percentage of  
 12 ER and PR testing falls into that unavoidable  
 13 false negative category?  
 14 DR. TORLAKOVIC:  
 15 A. I'm not aware of exact.  
 16 MR. SIMMONS:  
 17 Q. Since we know that 95 percent is the  
 18 concordance that's been adopted, would it be  
 19 reasonable to say that five percent is in the  
 20 range of what would be an unavoidable false  
 21 negative rate?  
 22 DR. TORLAKOVIC:  
 23 A. I think that might be the case.  
 24 MR. SIMMONS:  
 25 Q. Okay. But has there been any real study done

Page 210

1 or any materials in the literature that have  
 2 really addressed that issue and established a  
 3 percentage of what would be expected to be the  
 4 unavoidable false negative rate in ER and PR  
 5 testing, anything you are aware of?  
 6 DR. TORLAKOVIC:  
 7 A. I never paid attention to that specific point,  
 8 so perhaps this was addressed but I'm not  
 9 aware of it.  
 10 MR. SIMMONS:  
 11 Q. Okay.  
 12 DR. TORLAKOVIC:  
 13 A. I remember reading through large number of  
 14 studies with large number of tumours tested  
 15 and I don't remember that anybody of them, any  
 16 of these larger studies were designed as such  
 17 to address this. We don't--we do know there  
 18 is correlation with biochemical assays, but  
 19 then again, we don't have a gold standard.  
 20 Biochemical assays are not a gold standard and  
 21 immunohistochemistry tests are again not a  
 22 gold standard. So while they're approach  
 23 closely, each of them, to something that is  
 24 gold standard, we know that in biochemical  
 25 tests, the nature of the sampling of the

Page 211

1 tissue prevent us from being sure that we are  
 2 dealing with 100 percent cancer cell  
 3 population and therefore, the value that we  
 4 provide is not necessarily the value that is  
 5 attached to each tumour cell separately or in  
 6 aggregate, and on the same time, for  
 7 immunohistochemistry not having a gold  
 8 standard, again, how do you then adjust your  
 9 values to something. You know, it's always--  
 10 our solution to that in CIQC, our reference  
 11 values were those that were derived from most  
 12 commonly achieved result, which may be totally  
 13 wrong in relationship to what ideally this  
 14 should look like, but we have no means by  
 15 knowing what the results should actually look  
 16 like.  
 17 MR. SIMMONS:  
 18 Q. So it sounds like there still remains some  
 19 inherent uncertainty -  
 20 DR. TORLAKOVIC:  
 21 A. There is.  
 22 MR. SIMMONS:  
 23 Q. - in ER/PR testing which no one yet knows how  
 24 to resolve or avoid?  
 25 DR. TORLAKOVIC:

Page 212

1 A. To the best of my knowledge, there is no given  
 2 gold standard for ER/PR tests.  
 3 MR. SIMMONS:  
 4 Q. Okay. You told us about the work that you  
 5 started with NordiQC starting around 1997, and  
 6 that that was spurred, I guess, by your  
 7 observations of variability in testing from  
 8 lab to lab and also by some initiatives  
 9 undertaken by DAKO, the commercial supplier of  
 10 antibodies and materials.  
 11 DR. TORLAKOVIC:  
 12 A. Yes.  
 13 MR. SIMMONS:  
 14 Q. Had there been any kind of formal study done  
 15 in Scandinavia of interlab variability or was  
 16 this just observations that were made by  
 17 yourself and others or was there any kind of  
 18 structured study in advance of the NordiQC  
 19 work to look at interlab variability?  
 20 DR. TORLAKOVIC:  
 21 A. In advance, I just started a small pilot study  
 22 for which actually I have slides here to show,  
 23 if there is a chance maybe we can go to that,  
 24 my presentation.  
 25 MR. SIMMONS:

Page 213

1 Q. Yes.  
 2 DR. TORLAKOVIC:  
 3 A. I have a couple of slides from that Norwegian  
 4 project.  
 5 MR. SIMMONS:  
 6 Q. Sure, okay, if you could find it, that would  
 7 be very helpful.  
 8 DR. TORLAKOVIC:  
 9 A. Here it is. There aren't that many  
 10 laboratories in Norway, so we started with six  
 11 and did the very common antigens and one of  
 12 the Class I test is vimentin. It's widely  
 13 spread in many tissues, and here, it shows the  
 14 staining results between the six laboratories  
 15 in Norway, and you can see from results that  
 16 are like in the middle part, panel B, it shows  
 17 you that there is a very strong staining, very  
 18 clear signal and there is no background. So  
 19 that's an optimal result, and then you see our  
 20 intermediate result in some others, and then  
 21 you see totally negative results in one  
 22 laboratory, and we speak about vimentin being  
 23 one of the most commonly used tests at that  
 24 time, and all of these laboratories that  
 25 perform this testing were under impression

Page 214

1 that they were doing a good job.  
 2 Another epitope, S100, it does look more  
 3 or less comparable. If you get--I mean, some  
 4 of the laboratories use red detection system  
 5 so--red colour so that is equivalent to brown  
 6 for the signal and you can see that most of  
 7 these laboratories have rather convincing  
 8 positivity. But when you look at the tumour  
 9 sample that was in the benign tissue, you can  
 10 see again that in this laboratory and partly  
 11 in this laboratory, and in this one, so three  
 12 out of six, you have sub-optimal or negative  
 13 results totally when it comes to tumours. So  
 14 the system is not--wasn't titrated properly  
 15 and the result on benign tissue was  
 16 misleading.  
 17 HMB45, it's a marker of melanoma, and  
 18 there you see also in benign tissues even some  
 19 of the laboratories were not able to produced  
 20 expected results and then similarly, in  
 21 tumours again, one lab totally negative and  
 22 some producing results that are below the  
 23 threshold for calling the case positive.  
 24 And so finally, not all the labs were  
 25 using this antibody, melanae (phonetic),

Page 215

1 another melanocyte marker and you can see the  
 2 huge difference in this and how that relates  
 3 clinically. What is the point clinically?  
 4 This was the purpose of the pilot study. This  
 5 pilot was chosen for ability of the lab to  
 6 diagnose metastatic melanoma. So it's a  
 7 metastatic tumour of melanocytes and that's a  
 8 relatively common problem, because in Nordic  
 9 countries, people with fair complexion get  
 10 melanoma and metastatic melanoma is not an  
 11 unusual clinical scenario.  
 12 So we looked at it and we actually see  
 13 that there are two laboratories that totally  
 14 failed clinically in the use of this. They  
 15 would not be able to diagnose malignant  
 16 metastatic melanoma because they can be  
 17 morphologically non-descript in the sense that  
 18 when you see the lesion, you cannot say  
 19 whether it has any origin--any melanocyte  
 20 differentiation or not and therefore you  
 21 absolutely depend on the results of this test  
 22 and you can see that two of the labs would not  
 23 be able to make clinical use of their immuno  
 24 results and you had one laboratory that had  
 25 full clinical profile that was perfect and

Page 216

1 then some others that could improve. That PI  
 2 means improvement and PC meaning just minor  
 3 comment, how they can be modified to be even  
 4 better, but they were good.  
 5 So out of six labs, you had two labs  
 6 fail. I know this is not a large enough  
 7 sample to make statistical conclusions, but  
 8 that was quite surprising that it wasn't--when  
 9 you put it in the clinical context like that,  
 10 that it really gives you a larger picture than  
 11 just when you look at each individual test  
 12 separately.  
 13 MR. SIMMONS:  
 14 Q. Right, and were these small community hospital  
 15 laboratories or were these tertiary care  
 16 hospital laboratories?  
 17 DR. TORLAKOVIC:  
 18 A. It's a mixture.  
 19 MR. SIMMONS:  
 20 Q. Or a mixture?  
 21 DR. TORLAKOVIC:  
 22 A. A mixture.  
 23 MR. SIMMONS:  
 24 Q. It was a mixture, okay. Now when the NordiQC  
 25 program was initiated, did you--I presume

Page 217

1 there was monitoring to see if these results  
 2 improved over time, once the program came into  
 3 effect, and would I be correct in assuming  
 4 that you then saw an improvement in the  
 5 performance of laboratories?  
 6 DR. TORLAKOVIC:  
 7 A. Yes, there was, but to tell you the truth, in  
 8 most laboratories, even with any epitope we  
 9 test, we still get very variable results, and  
 10 that's true for--that's true for Canadian  
 11 immunohistochemistry quality control. Our  
 12 initial runs show that with the run 1. It's  
 13 true for any program, and you can see here, on  
 14 this diagram, this is taken from NordiQC page  
 15 from run five to run ten, what happened with  
 16 altogether 23 different epitopes, and we can  
 17 see an average. There is about 20 to 30  
 18 percent of the results are inadequate. They  
 19 are either red or yellow. That means totally  
 20 poor or sub-optimal for clinical use. So 30  
 21 percent is a huge number for any given test.  
 22 Were there any improvements further? Yes, and  
 23 you can see here, these are unexplained  
 24 category that we were talking about.  
 25 MR. SIMMONS:

Page 218

1 Q. Yes.  
 2 DR. TORLAKOVIC:  
 3 A. False negative, it's six percent. So it's  
 4 very close to five percent number that we were  
 5 talking about that we don't know when the test  
 6 failed, and furthermore, to show like we did  
 7 recent testing in European Bone Marrow Working  
 8 Group, which I am a member, to see very  
 9 commonly used tests from the major  
 10 laboratories. The members of that group, we  
 11 track, you know, major labs in European  
 12 countries and you can see, again, that sub-  
 13 optimal poor results are anywhere from even 50  
 14 percent for CD117, which is huge, and then  
 15 like 40 percent for CD61. Very--these are  
 16 basic, commonly used markers, and what's  
 17 surprising about this, that overall, there is  
 18 about 35 percent of sub-optimal and poor  
 19 results in these laboratories throughout  
 20 Europe.  
 21 MR. SIMMONS.:  
 22 Q. Now, this 35 percent figure here, that is a  
 23 figure reflecting results how long after the  
 24 NordiQC program had been in effect? How long  
 25 had the program been in effect?

Page 219

1 DR. TORLAKOVIC:  
 2 A. This is new. I mean, this is totally new, and  
 3 this is not from NordiQC, which was a separate  
 4 study I did as a member of the European Bone  
 5 Marrow Working Group, and many of these  
 6 laboratories do participate--some of them  
 7 actually definitely do participate in NordiQC.  
 8 MR. SIMMONS.:  
 9 Q. Uh-hm.  
 10 DR. TORLAKOVIC:  
 11 A. And some of them don't, but the point being is  
 12 that this value, about 30 percent, poor  
 13 results when the EQA test--EQA testing just  
 14 start, it's something to be expected.  
 15 MR. SIMMONS.:  
 16 Q. Yes.  
 17 DR. TORLAKOVIC:  
 18 A. And it's something that you're going to see  
 19 for a very long time until you see the  
 20 improvement because it takes time, but is  
 21 there improvement; yes, there was involvement.  
 22 I think NordiQC website, if you go there, you  
 23 will see how much improvement was from one run  
 24 to another in some specific tests. What I  
 25 want to show with this slide, you can see--I

Page 220

1 also did a survey at the time as a member of  
 2 European Bone Marrow Working Group, and there  
 3 is this discrepancy between what people  
 4 believed that they are doing and what they  
 5 actually achieve in the real life. So we saw  
 6 that 95 percent believed that they have  
 7 excellent or good results over time, but  
 8 actually only 65 achieved that. So that lack  
 9 of appreciation that they have a problem is  
 10 something that education needs to deal with.  
 11 MR. SIMMONS.:  
 12 Q. Uh-hm.  
 13 DR. TORLAKOVIC:  
 14 A. So it shows the lack of education in this  
 15 particular area.  
 16 MR. SIMMONS.:  
 17 Q. Uh-hm. In the establishment of NordiQC, you  
 18 told--you described that for us, and I didn't  
 19 hear anything about the role of government or  
 20 any government agencies in establishment of  
 21 NordiQC.  
 22 DR. TORLAKOVIC:  
 23 A. There is no role of government.  
 24 MR. SIMMONS.:  
 25 Q. Okay. I didn't hear anything about the role

Page 221

1 of any professional organizations, physicians,  
 2 or pathologists, or laboratory technologists?  
 3 DR. TORLAKOVIC:  
 4 A. That actually had nothing to do with any  
 5 pathologist association.  
 6 MR. SIMMONS.:  
 7 Q. Okay. We've heard of the UK NEQAS program.  
 8 Are you familiar with some of the work done, I  
 9 think, by Dr. Rhodes in the UK where he did  
 10 some studies concerning interlaboratory  
 11 variability in the UK?  
 12 DR. TORLAKOVIC:  
 13 A. Yes, yes, I am. Not probably on everything,  
 14 but I'm quite aware of his work, yes.  
 15 MR. SIMMONS.:  
 16 Q. Is it fair to say that this work showed very  
 17 similar results for interlaboratory  
 18 variability in the studies that he did in the  
 19 UK to those that you've described in  
 20 Scandinavia?  
 21 DR. TORLAKOVIC:  
 22 A. I think they are very, very comparable.  
 23 MR. SIMMONS.:  
 24 Q. The UK NEQAS program is the proficiency  
 25 testing program is available to laboratories

Page 222

1 outside the UK, as you told us, and the  
 2 laboratory here now participates in it. Do  
 3 you know how widely used the UK NEQAS external  
 4 proficiency testing is in Canada among  
 5 Canadian laboratories?  
 6 DR. TORLAKOVIC:  
 7 A. How widely used it is?  
 8 MR. SIMMONS.:  
 9 Q. How widely used? Is it a commonly used  
 10 proficiency program for Canadian laboratories?  
 11 DR. TORLAKOVIC:  
 12 A. If I remember correctly, maybe there's nine  
 13 Canadian laboratories that participate in UK  
 14 NEQAS.  
 15 MR. SIMMONS.:  
 16 Q. Okay. In Ontario, we understand the QMPLS has  
 17 their own proficiency testing program?  
 18 DR. TORLAKOVIC:  
 19 A. Right.  
 20 MR. SIMMONS.:  
 21 Q. Is that widely utilized outside of Ontario, do  
 22 you know, or do you know if other labs are  
 23 able to use that that aren't Ontario  
 24 laboratories?  
 25 DR. TORLAKOVIC:

Page 223

1 A. I'm not actually--to tell you the truth, I'm  
 2 not aware that anybody else can participate in  
 3 their program. I don't think it's an open  
 4 program. I heard something that perhaps they  
 5 may be opening up, but I'm not sure about  
 6 that.  
 7 MR. SIMMONS.:  
 8 Q. So then for most laboratories in Canada,  
 9 outside of Ontario, the proficiency testing  
 10 that has been available to them has primarily  
 11 been the CAP, College of American  
 12 Pathologists, proficiency testing?  
 13 DR. TORLAKOVIC:  
 14 A. Exactly.  
 15 MR. SIMMONS.:  
 16 Q. Prior to your program?  
 17 DR. TORLAKOVIC:  
 18 A. Yes.  
 19 MR. SIMMONS.:  
 20 Q. You've told us about the first three runs in  
 21 your CIQC program. That the first run was  
 22 Class I stains, and that you did find a large  
 23 variability between laboratories?  
 24 DR. TORLAKOVIC:  
 25 A. Yes.

Page 224

1 MR. SIMMONS.:  
 2 Q. In performance. Was the variability that you  
 3 found what you expected to find, or was it in  
 4 any way unexpected, given your past  
 5 experience?  
 6 DR. TORLAKOVIC:  
 7 A. It was expected, actually.  
 8 MR. SIMMONS.:  
 9 Q. Uh-hm.  
 10 DR. TORLAKOVIC:  
 11 A. But the only thing that surprised me was the  
 12 level of false positive results. It's usually  
 13 false negative results that are much more  
 14 common, and false positive results, even  
 15 though they occur in many laboratories, my  
 16 previous experience the frequency of false  
 17 positive was something that I was surprised  
 18 with.  
 19 MR. SIMMONS.:  
 20 Q. And this was in the Class I stains in Run 1?  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 MR. SIMMONS.:  
 24 Q. Now in Run 2, you've told us what the result  
 25 was, that there wasn't as much interlaboratory



Page 225

1 variability as you had anticipated, and I'm  
 2 wondering what did you expect to see with the  
 3 ER/PR tests in Run 2?  
 4 DR. TORLAKOVIC:  
 5 A. I thought that about 30 percent will be sub-  
 6 optimal or poor, and nobody was poor, and -  
 7 MR. SIMMONS.:  
 8 Q. Why did you expect that many of those tests  
 9 would be sub-optimal or poor?  
 10 DR. TORLAKOVIC:  
 11 A. Because that's published in the literature and  
 12 that was previous experience that we had in  
 13 NordiQC, that almost any test you look at,  
 14 this is what you get when you start EQA  
 15 program.  
 16 MR. SIMMONS.:  
 17 Q. Right. So if 30 percent of the tests for  
 18 ER/PR were sub-optimal or poor, can we then  
 19 conclude that across all the laboratories  
 20 being surveyed, there would be a significant  
 21 number of tests that were being reported  
 22 incorrectly?  
 23 DR. TORLAKOVIC:  
 24 A. If indeed the case is that there are so many,  
 25 some of them will be reported incorrectly,

Page 226

1 yes.  
 2 MR. SIMMONS.:  
 3 Q. Yeah, okay. Now in other cases elsewhere in  
 4 the world where these studies have been  
 5 carried out, and there's been findings that as  
 6 many 30 percent of these tests have been sub-  
 7 optimal or poor -  
 8 DR. TORLAKOVIC:  
 9 A. Yes.  
 10 MR. SIMMONS.:  
 11 Q. Are you ever aware anywhere of there being any  
 12 steps taken to review past tests in an effort  
 13 to find those that may have been incorrectly  
 14 reported?  
 15 DR. TORLAKOVIC:  
 16 A. No.  
 17 MR. SIMMONS.:  
 18 Q. In the Run 2 tests that you did for CIQC, I  
 19 understand that the process used was to send  
 20 out the slides with the microarray of 72  
 21 different -  
 22 DR. TORLAKOVIC:  
 23 A. Yes.  
 24 MR. SIMMONS.:  
 25 Q. Very tiny tissue pieces?

Page 227

1 DR. TORLAKOVIC:  
 2 A. No, 70 something was Run 1. Run 2 had smaller  
 3 number, about 40.  
 4 MR. SIMMONS.:  
 5 Q. About 40 -  
 6 DR. TORLAKOVIC:  
 7 A. Yes.  
 8 MR. SIMMONS.:  
 9 Q. Separate tissue samples, and the participating  
 10 lab employees had to stain those slides using  
 11 their own standard protocol that -  
 12 DR. TORLAKOVIC:  
 13 A. Yes.  
 14 MR. SIMMONS.:  
 15 Q. They had adopted, and presumably optimized for  
 16 their own testing?  
 17 DR. TORLAKOVIC:  
 18 A. Yes.  
 19 MR. SIMMONS.:  
 20 Q. Were those slides then interpreted by the  
 21 pathologists at those institutions and the  
 22 results of those interpretations reported back  
 23 to you?  
 24 DR. TORLAKOVIC:  
 25 A. Yes.

Page 228

1 MR. SIMMONS.:  
 2 Q. They were as well, as well as the slides  
 3 returned to you?  
 4 DR. TORLAKOVIC:  
 5 A. Yes.  
 6 MR. SIMMONS.:  
 7 Q. So you had an opportunity to evaluate both the  
 8 staining on the slides and the interpretations  
 9 of the pathologists?  
 10 DR. TORLAKOVIC:  
 11 A. Yes.  
 12 MR. SIMMONS.:  
 13 Q. Okay. On that run, were there any particular  
 14 conclusions you were able to draw about the  
 15 quality of interpretation versus the quality  
 16 of staining, were there any particular issues  
 17 one way or the other?  
 18 DR. TORLAKOVIC:  
 19 A. Actually, the quality of interpretation was  
 20 very good, and that maybe reflects another  
 21 fact that when interpret this small pieces of  
 22 tissue in tissue microarrays, what you use as  
 23 your cutoff point for positivity is just any  
 24 tumour positive cell.  
 25 MR. SIMMONS.:

Page 229

1 Q. Yes.  
 2 DR. TORLAKOVIC:  
 3 A. And it's a small piece of tissue. It does not  
 4 show entire tumour where you have to make a  
 5 decision where to look, how long you are going  
 6 to look and so on. So it's just--focusing on  
 7 such small pieces of tissue makes  
 8 interpretation really easy.  
 9 MR. SIMMONS.:  
 10 Q. I see.  
 11 DR. TORLAKOVIC:  
 12 A. And that may not reflect the true  
 13 interpretative skills and practices in real  
 14 world, and, therefore, we did not make large  
 15 emphasis on interpretive part of the test,  
 16 although we did see some that we considered  
 17 discrepancies between how it was interpreted  
 18 and how it was interpreted at the assessment.  
 19 So there was some difference.  
 20 MR. SIMMONS.:  
 21 Q. So in the clinical setting then where there  
 22 are larger pieces of tissue being examined by  
 23 a pathologist, and the pathologist has to  
 24 identify the appropriate place on that tissue  
 25 in which -

Page 230

1 DR. TORLAKOVIC:  
 2 A. Right.  
 3 MR. SIMMONS.:  
 4 Q. To count the cells and come up with an  
 5 interpretation, there might, in fact, be  
 6 larger variability in interpretation than  
 7 would show up in your testing?  
 8 DR. TORLAKOVIC:  
 9 A. Right. So our testing was not designed to  
 10 test post-analytical component in detail how  
 11 it should be done, if that was the focus.  
 12 MR. SIMMONS.:  
 13 Q. Okay. So in promoting national external  
 14 quality assurance as an important goal, would  
 15 I be correct in thinking that one of the big  
 16 advantages of that approach is the ability to  
 17 pool resources and expertise around the  
 18 quality of IHC testing as opposed to leaving  
 19 individual labs on their own to try and  
 20 develop their own quality assurance measures?  
 21 DR. TORLAKOVIC:  
 22 A. Absolutely. I mean, this is the area of high  
 23 complexity.  
 24 MR. SIMMONS.:  
 25 Q. Uh-hm.

Page 231

1 DR. TORLAKOVIC:  
 2 A. And it is not realistic to expect each  
 3 individual lab should be able to develop such  
 4 level of expertise without additional  
 5 guidance.  
 6 MR. SIMMONS.:  
 7 Q. Yes, okay. Thank you very much. I don't have  
 8 any other questions.  
 9 THE COMMISSIONER:  
 10 Q. Thank you, Mr. Simmons. Mr. Browne.  
 11 MR. BROWNE:  
 12 Q. Thank you, Commissioner.  
 13 DR. EMINA TORLAKOVIC, EXAMINATION BY PETER BROWNE, Q.C.  
 14 BROWNE, Q.C.:  
 15 Q. Good afternoon, Dr. Torlakovic. We met  
 16 earlier. My name is Peter Browne. I  
 17 represent a number of the individual  
 18 pathologists and oncologists who have been  
 19 asked to testify before the inquiry. I just  
 20 want to go back and touch on a couple of areas  
 21 now. First of all, your comment to Mr.  
 22 Simmons about, I guess, the changes over the  
 23 past decade in immunohistochemistry and the  
 24 advances in, I guess, the--I took the  
 25 impression, the immense volume of information

Page 232

1 and changes in antibodies and in detection  
 2 kits, and I guess also the literature in terms  
 3 of dealing with all the issues surrounding  
 4 IHC. Is that a fair description of what has  
 5 occurred in the past decade?  
 6 DR. TORLAKOVIC:  
 7 A. It is. I mean, it has been developing before,  
 8 but since this technical advances in the last  
 9 ten years are so remarkable, the upshot of  
 10 that is that we are today using very powerful  
 11 technique with different results than before.  
 12 BROWNE, Q.C.:  
 13 Q. And Mr. Crosbie asked you about in terms of  
 14 selecting a medical director for an IHC lab  
 15 and so on. In terms of getting a person to do  
 16 that, would it not be important to have a  
 17 couple of things in place; one, someone who  
 18 has had basic training in IHC, first of all,  
 19 and you talked about the fact that there is  
 20 that sort of gap within the residence program  
 21 here in Canada.  
 22 DR. TORLAKOVIC:  
 23 A. Yes.  
 24 BROWNE, Q.C.:  
 25 Q. Secondly, I guess, if there's a problem with

Page 233

1 recruitment and retention, you need to try to  
 2 recruit someone who has that skillset, and  
 3 then providing them with resources to be able  
 4 to keep on top of all this information that  
 5 has occurred over the past ten years?  
 6 DR. TORLAKOVIC:  
 7 A. Absolutely, but since there is a lack in  
 8 education, there is a lack in perception,  
 9 like, what's going on and what's necessary,  
 10 there is going to be, of course, lack in  
 11 providing means to get to the point where we  
 12 should be.  
 13 BROWNE, Q.C.:  
 14 Q. Okay.  
 15 DR. TORLAKOVIC:  
 16 A. But it's necessary, yes.  
 17 BROWNE, Q.C.:  
 18 Q. Now you mentioned interestingly, and,  
 19 Registrar, if we could enter P-3365.  
 20 EXHIBIT ENTERED AND MARKED P-3365  
 21 THE COMMISSIONER:  
 22 Q. So entered.  
 23 BROWNE, Q.C.:  
 24 Q. Doctor, this is actually--I had spoken to you  
 25 over the lunch break about this article, and I

Page 234

1 mentioned I may enter it. This is the results  
 2 of the Royal College of Pathologists quality  
 3 assurance program, I think an audit that was  
 4 performed between 2004 and 2006 of their labs  
 5 and sort of the results were published.  
 6 DR. TORLAKOVIC:  
 7 A. Yes.  
 8 BROWNE, Q.C.:  
 9 Q. Have you--are you familiar with this  
 10 particular article?  
 11 DR. TORLAKOVIC:  
 12 A. Yes, I'm familiar. I think it's very  
 13 interesting article that shows when audits are  
 14 done a larger scale, what they can possibly  
 15 find.  
 16 BROWNE, Q.C.:  
 17 Q. Right.  
 18 DR. TORLAKOVIC:  
 19 A. And I read it with great interest. Especially  
 20 there is a table. I don't know if we can move  
 21 down there -  
 22 BROWNE, Q.C.:  
 23 Q. Yes. If I could walk you through because  
 24 there are a number of comments you made, and I  
 25 just want to point out, first of all, a couple

Page 235

1 of points. Mr. Simmons asked you about the  
 2 fact about these changes that have been noted  
 3 and so on, has there ever been a look back as  
 4 a result of it. Given--and this is now in  
 5 relation to estrogen progesterone receptors,  
 6 particularly.  
 7 DR. TORLAKOVIC:  
 8 A. Yes.  
 9 BROWNE, Q.C.:  
 10 Q. And in the conclusions section here, I just  
 11 want to point out it says, "A number of  
 12 individual laboratories do not meet the target  
 13 values", and we'll talk about that. As a  
 14 matter of fact, I'll show you, I think in a  
 15 paragraph just below here, they as well found  
 16 30 percent variability, poor results, which is  
 17 I guess similar to the experience you had in  
 18 the Nordic program, but more importantly, "A  
 19 number of individual laboratories did not meet  
 20 the target values and variation results, which  
 21 would impact on patient treatment decisions".  
 22 So they recognized that this problem would  
 23 have an impact on treatment decisions?  
 24 DR. TORLAKOVIC:  
 25 A. Right, and I'm not aware that they went back

Page 236

1 and they actually did anything with that.  
 2 BROWNE, Q.C.:  
 3 Q. Okay. As well, I was noticing in reviewing  
 4 this over the lunch hour, they started, the  
 5 specimens just note right there, "The  
 6 specimens consist of routine formalin fixed  
 7 paraffin embedded material that has been  
 8 supplied to the QAP by participants". Sorry,  
 9 just above here, "The original material was a  
 10 composite block, but this has been changed to  
 11 tissue microarray construct for the past two  
 12 years". So they started using as part of this  
 13 -  
 14 DR. TORLAKOVIC:  
 15 A. Yes.  
 16 BROWNE, Q.C.:  
 17 Q. Tissue microarray construct as well.  
 18 DR. TORLAKOVIC:  
 19 A. Yes, I think that is now prevailing practice  
 20 for this province when it comes to Class II  
 21 tests, and in general, it is recommended. I  
 22 think it was Dr. Gilks who first published  
 23 actually on use of tissue microarrays for  
 24 quality control/quality assurance purposes,  
 25 and logically this was quickly implemented in

Page 237

1 many ways because it's a very powerful  
 2 approach for QA.  
 3 BROWNE, Q.C.:  
 4 Q. I think the table you were looking for, we'll  
 5 just find here now, those are the results, but  
 6 there may be further on--here, is that the  
 7 table you're looking at?  
 8 DR. TORLAKOVIC:  
 9 A. That's the table.  
 10 BROWNE, Q.C.:  
 11 Q. Yes. Now it's quite--I'll let you--if you  
 12 want to sort of refer to anything in  
 13 particular there.  
 14 DR. TORLAKOVIC:  
 15 A. When you look at positivity for ER, the  
 16 variability, and if I can correctly remember  
 17 some numbers here--I think it's in the middle  
 18 of the column or so. There are few--here it  
 19 is, laboratory 49, 30 percent, and then you  
 20 have laboratory 24, 90 percent, and then for  
 21 PR, below 30 percent for some labs, and then  
 22 over 80 percent, and even 96 percent by other  
 23 labs. So this extreme variation in the  
 24 results, you can see obviously that something  
 25 is wrong. I mean, there are laboratories who

Page 238

1 are producing large number of false negative  
 2 results.  
 3 BROWNE, Q.C.:  
 4 Q. If we can just go back for a minute as well--  
 5 I'm going to go back to your observation about  
 6 changes over the past ten years because there  
 7 is a note here as well by the authors.  
 8 DR. TORLAKOVIC:  
 9 A. While you're looking for that, I just would  
 10 like to comment on overall percent, like there  
 11 is a variation between 30 or 90 percent in ER  
 12 results, but overall 75 percent, which if you  
 13 would take them overall, you would come  
 14 probably to the number that is expected for  
 15 breast cancer in general.  
 16 BROWNE, Q.C.:  
 17 Q. Right, we've heard that, so -  
 18 DR. TORLAKOVIC:  
 19 A. So overall picture doesn't give you exact  
 20 information what's going on in each individual  
 21 laboratory.  
 22 BROWNE, Q.C.:  
 23 Q. And that's why the importance is participating  
 24 in the process so you can get this feedback  
 25 from the -

Page 239

1 DR. TORLAKOVIC:  
 2 A. Exactly.  
 3 BROWNE, Q.C.:  
 4 Q. - Quality Assurance Program. This comment  
 5 right here in the conclusion section, it says,  
 6 "Over the last decade IHC has moved from"--and  
 7 this is a 2007 article -  
 8 DR. TORLAKOVIC:  
 9 A. Yes.  
 10 BROWNE, Q.C.:  
 11 Q. --"moved from a qualitative test brown or not  
 12 brown to a quantitative test that determines  
 13 selection of patient therapy and treatment  
 14 outcomes with a development of new targeted  
 15 therapy imperative to identify predictive  
 16 tests will increase. IHC may be able to  
 17 fulfil this role, but the data from this and  
 18 other studies indicate it is fraught with  
 19 difficulties. The difficulties with  
 20 predicting response to epidemial growth factor  
 21 receptor by tyrosine kinase inhibitors and  
 22 monoclonal antibodies based on IHC graphically  
 23 illustrates this point." So does that sort of  
 24 summarize what you are saying, we start out  
 25 with this notion of brown--is it brown or not

Page 240

1 brown to this more, as you are now talking  
 2 about, the notion of probably putting into  
 3 your reports the sensitivity as a  
 4 communication tool to clinicians?  
 5 DR. TORLAKOVIC:  
 6 A. But I can warn you that my view may not be  
 7 shared by everyone because even today you have  
 8 articles published in which experts in  
 9 immunohistochemistry say that they do not  
 10 believe in quantitation, in formalin fixed  
 11 paraffin embedded tissues and they published,  
 12 particularly an article by Dr. Nadji.  
 13 BROWNE, Q.C.:  
 14 Q. Nadji, we've seen that article, the  
 15 Commissioner has seen that article.  
 16 DR. TORLAKOVIC:  
 17 A. And there is another review article very  
 18 recent from the same author who says again  
 19 that the quantitation is not reliable in  
 20 paraffin embedded tissues. I object to that  
 21 scientifically and object to that they might  
 22 publish research in which I--as I was  
 23 interested in B cell lymphoma and  
 24 transcription factors and their target genes,  
 25 I wanted to see whether we can quantitate in

Page 241

1 tissue defects some of the transcription  
 2 factors so in my studies for my PhD one of the  
 3 things that I did, I wanted to see how--  
 4 whether there is any correlation between P1,  
 5 which is a transcription factor that regulates  
 6 expression of some other genes, so I picked up  
 7 those that we know that these transcription  
 8 factors should regulate, that's proven, those  
 9 that are hypothetical possible targets for  
 10 this transcription factor, those that the  
 11 factor knew that this transcription factor  
 12 does not regulate at all. And my results  
 13 clearly showed that there is perfect  
 14 correlation between those genes that regulate  
 15 it, so it's a winner. I also constructed  
 16 tissue microarrays with different lymphomas  
 17 and this was particularly useful for, you can  
 18 call it dosage of the gene, so more staining  
 19 you see, then you think there is more of the  
 20 product, so we think quantitative in that  
 21 sense. So we measure the intensity, so we  
 22 measure the intensity of the transcription  
 23 factor and then we measure the intensity of  
 24 the staining of these target genes and we  
 25 notice more transcription factor, more target

Page 242

1 gene expression. That means we have  
 2 biological proof that we indeed can quantitate  
 3 when using histochemistry for quantitating  
 4 analogies and we also showed that, when that  
 5 P1 was up, that genes that are not regulated  
 6 by this, by this transcription factor, that  
 7 were not up in those, in know, in those  
 8 lesions. So I believe that, strongly believe  
 9 that the techniques that we are using today  
 10 enable us to quantitate very, very precisely,  
 11 so not in this way. It's always semi  
 12 quantitating, we are not talking about  
 13 picamoles or actual measurements in that  
 14 sense, but can we distinguish between weakly,  
 15 weak expression of tumour and strong  
 16 expression of tumours. I believe we can.  
 17 BROWNE, Q.C.:  
 18 Q. Okay, and we've heard from Dr. Dabbs, Dr.  
 19 David Dabbs from the United States on this  
 20 point, the notion of--are you referring now to  
 21 the use of a H score, that type of approach to  
 22 reporting?  
 23 DR. TORLAKOVIC:  
 24 A. Yes, H one was exactly the score I used in my  
 25 studies and I used this for specific reason.

Page 243

1 This is not the score that is used perhaps for  
 2 a measurement of ante--we know Allred score is  
 3 more frequently used in Northern America for  
 4 measuring, for scoring estrogen progesterone  
 5 receptors and in my personal opinion H score  
 6 is better because it gives you more  
 7 information, it does not artificially make--it  
 8 does not categorize artificially as Allred  
 9 score does in a way. So with H score what you  
 10 do is, actually you're looking at the percent  
 11 of positive cells for each intensity and then  
 12 you multiply and derive the score from zero to  
 13 300 and that is the score that was originally  
 14 published was that McCarthy, I believe was the  
 15 author, where biochemical tests for ER and PR  
 16 were related to, correlated with the results  
 17 in the tissue sections and it was proven that  
 18 you can actually do excellent job with  
 19 immunohistochemistry in identifying ER/PR. So  
 20 my personal opinion, there is no need for yet  
 21 another type of scoring, I would use the one  
 22 that actually showed this perfect correlation  
 23 with biochemical ones if it were up to me, and  
 24 I know that there will be different approaches  
 25 as to which score to use and I'm not here, an

Page 244

1 expert to say, to make a judgement about that,  
 2 but it is just my personal opinion that my  
 3 preference would be to use H score.  
 4 BROWNE, Q.C.:  
 5 Q. And that's the Harvey article, I think, is it,  
 6 Dr. Harvey's work in that area, is the H score  
 7 Dr. Harvey or -  
 8 DR. TORLAKOVIC:  
 9 A. McCarthy I think is the original from 80's, so  
 10 when it was first time published that one  
 11 could use immunohistochemistry as means of  
 12 determining the quantity of ER in tissue  
 13 sections.  
 14 BROWNE, Q.C.:  
 15 Q. But I take it from your answer, though, Doctor  
 16 that this is a subject of great debate still,  
 17 today?  
 18 DR. TORLAKOVIC:  
 19 A. It is still debateable and still there is no  
 20 definite rule on this and there will be  
 21 laboratories that are using one score system  
 22 over the other because it's in guidelines,  
 23 this is not something that really a standard.  
 24 In standard you have to perform it all the  
 25 way, all the time the same way. When using

Page 245

1 guidelines, one has a freedom to modify some  
 2 parameters in the guidelines.  
 3 BROWNE, Q.C.:  
 4 Q. Now just one last area I wanted to cover with  
 5 you and this was covered somewhat by Mr.  
 6 Simmons and that is sort of looking forward  
 7 and the Commissioner has to look at making  
 8 sort of recommendations. The Australia, I  
 9 guess in terms of its legal structure has a  
 10 Federal and Provincial arrangement. Would you  
 11 see your work in the CIQC as being sort of  
 12 ideally, now let's look at ideals here for a  
 13 minute, in an ideal world, something which is  
 14 funded by governments or certain bodies,  
 15 regulatory bodies, to allow that work, as you  
 16 talk about getting that critical mass to both  
 17 disseminate information and then to evaluate  
 18 material forwarded?  
 19 DR. TORLAKOVIC:  
 20 A. Absolutely because as I said, I believe that  
 21 this type of testing should be free and this  
 22 type of expert knowledge or hotline should be  
 23 also provided. It is not realistic, as I  
 24 said, to expect each individual laboratory to  
 25 be able to gain that type of expertise in

Page 246

1 daily routine work.  
 2 BROWNE, Q.C.:  
 3 Q. Do you know whether the UK NEQAS Program that  
 4 was under discussion here a few moments ago,  
 5 is that government funded or -  
 6 DR. TORLAKOVIC:  
 7 A. I think it's government funded, I think it's  
 8 government funded for UK, but then  
 9 participation is paid by other countries,  
 10 other labs from other countries who want to  
 11 participate.  
 12 BROWNE, Q.C.:  
 13 Q. But for United Kingdom itself, it's -  
 14 DR. TORLAKOVIC:  
 15 A. I think it's government.  
 16 BROWNE, Q.C.:  
 17 Q. And I think you mention as well that in  
 18 relation to the UK NEQAS experience,  
 19 literature has sort of shown a sort of  
 20 discrepancy in terms of improvements. The  
 21 volunteer participants have not improved as  
 22 well as the UK labs, is that my understanding?  
 23 DR. TORLAKOVIC:  
 24 A. That's correct, that's their result--that's  
 25 their own, you know, published evidence.

Page 247

1 BROWNE, Q.C.:  
 2 Q. Are you able to indicate to the Commissioner  
 3 any, at least your observations or your  
 4 knowledge as to why that may be so?  
 5 DR. TORLAKOVIC:  
 6 A. Well, obviously, I mean one of the reasons why  
 7 this may be so, I don't know exactly why is  
 8 that so, but I would guess that a success in  
 9 this test in the UK is kind of mandatory  
 10 because accreditation of the lab depends on  
 11 it, so they will--they will be given some time  
 12 to make corrections and to improve, but they  
 13 will have to pass this test to actually  
 14 continue to be accredited. How exactly this  
 15 is used in their accreditation process, I  
 16 cannot tell you the details, but I know that  
 17 they are expected to correct and they do  
 18 correct and they become better. But that is  
 19 because of the accreditation. Additional role  
 20 that they also have is educational role and  
 21 that is more obvious for UK labs than for  
 22 other labs that participate in UK. How much  
 23 and exactly what they do, I don't know, but I  
 24 am certain that the education component must  
 25 play a role.

Page 248

1 BROWNE, Q.C.:  
 2 Q. Lastly, Doctor, just in terms of the  
 3 experience, the findings of programs such as  
 4 UK NEQAS and NordiQC and I guess the  
 5 Australian RCPA Program, were there any  
 6 particular areas that were identified to  
 7 explain the interlab variability of results,  
 8 do you know, in terms of the whole analytical  
 9 process? Were there studies to indicate  
 10 where, if there were any problems where those  
 11 problems lay? For instance, antigen  
 12 retrieval, antibody concentration, is there  
 13 any literature -  
 14 DR. TORLAKOVIC:  
 15 A. No, I am not aware of, other than to show you  
 16 again, like from, if I am free to go to my  
 17 presentation -  
 18 BROWNE, Q.C.:  
 19 Q. Sure.  
 20 DR. TORLAKOVIC:  
 21 A. Of some of the things that are very obvious,  
 22 for example, this is how it's done at least in  
 23 NordiQC. This was a run where this particular  
 24 anti-smooth muscle antigen, CD15 EMA estrogen  
 25 receptor and progesterone receptor, this

Page 249

1 illustrates several things, this type of  
 2 presentation here that I am showing you. It  
 3 shows that ER was good and PR was poor and it  
 4 shows that if you do good, well with one test,  
 5 there's no guarantee you're going to do well  
 6 with another test. And it also tells you now  
 7 that this one was considered false negative,  
 8 first it says it could be false positive or  
 9 false negative if it's poor, so this one was  
 10 false negative, but it tells you suggestions  
 11 for improvement that come from this judgment  
 12 was to optimize antigen retrieval, use  
 13 different pH because they look--the look was  
 14 different to low pH and possibly increase  
 15 primary antibody concentration and this is the  
 16 result that this is how it looked before and  
 17 this is how it looked after this improvements  
 18 were done. And they solved really the  
 19 problem, so that shows you how in most  
 20 efficient way external quality assurance can  
 21 help. To give exact precise instructions for  
 22 what can be done, I think that's done, the  
 23 success is obtained. Now in the summaries  
 24 format, I also have one slide to show you what  
 25 was the results of false negative and false

Page 250

1 positive test and you can see here that there  
 2 are different reasons for false negative tests  
 3 and different reasons for false positive and  
 4 different percentages were given to that. So  
 5 very often it's through diluted primary  
 6 antibody and so one third of cases that the  
 7 reason for failing, having false negative  
 8 result. Inappropriate primary antibodies,  
 9 you're using, selecting the one clone that  
 10 will not do as good job, but you didn't know  
 11 before you participated that that's not a good  
 12 clone, it's a reason for additional 13 percent  
 13 of false negative test. Insufficient antigen  
 14 retrieval, so what happens to the tissue  
 15 before it goes to the test, it's one forth of  
 16 the cases, so that's a large number too and  
 17 then inappropriate epitope retrieval, so using  
 18 not only insufficient, so not long enough or  
 19 not even a high temperature but just using  
 20 wrong, for example, enzyme digestion instead  
 21 of cooking in the EDTA buffer and that would  
 22 be the example, or just the lack of epitope  
 23 (unintelligible) for additional 14 percent and  
 24 then unexplained, this is about that magical  
 25 five or six percent value, we don't know why.

Page 251

1 So those are the false--and false positives  
 2 again, there are some reasons but they were  
 3 not that common. So then you kind of  
 4 summarize, you see, it's the experience of  
 5 NordiQC for those three runs, those eight to  
 6 ten, eight, nine and then, but were there any  
 7 larger studies done in that sense? I'm sure  
 8 that UK NEQAS looked at that and so on, but I  
 9 don't know their numbers at hand, but they  
 10 should not be too different from these.  
 11 BROWNE, Q.C.:  
 12 Q. So if I--to take away any sort of particular  
 13 message on the quality assurance or quality,  
 14 CIQC that you're looking at right now, there's  
 15 both sort of a national, global sort of  
 16 information sharing that labs across the  
 17 country will know particular global issues,  
 18 but also on the local level, feedback from,  
 19 for their particular lab -  
 20 DR. TORLAKOVIC:  
 21 A. Yes.  
 22 BROWNE, Q.C.:  
 23 Q. Would that be the sort of the two, the two-  
 24 tier focus of that type of program?  
 25 DR. TORLAKOVIC:

Page 252

1 A. Yes, you could say that.  
 2 BROWNE, Q.C.:  
 3 Q. Thank you.  
 4 THE COMMISSIONER:  
 5 Q. Thank you, Mr. Browne. Ms. Newbury? Mr.  
 6 Pritchett, I don't think you were here this  
 7 morning when we did the rounds of the room, so  
 8 I skipped over you just then, did you have any  
 9 questions for this witness?  
 10 MR. PRITCHETT:  
 11 Q. No, we don't have any questions, thank you,  
 12 Commissioner.  
 13 THE COMMISSIONER:  
 14 Q. Thank you.  
 15 DR. EMINA TORLAKOVIC, EXAMINATION BY MS. JENNIFER NEWBURY  
 16 MS. NEWBURY:  
 17 Q. Good afternoon, Dr. Torlakovic, Jennifer  
 18 Newbury, we met earlier. I represent the  
 19 Newfoundland and Labrador division of the  
 20 Canadian Cancer Society. I wanted to ask you  
 21 first of all about a comment in the Exhibit P-  
 22 1143 please? This is the proposal from July  
 23 2006 for quality assurance and you were shown  
 24 that earlier today, so this is the proposal  
 25 for the establishment of a national EQA

Page 253

1 program. And on that very first page, item  
 2 No. C is the one I'm interested in, so quality  
 3 assurance in laboratory medicine includes, and  
 4 then down to item C, "Proficiency control by  
 5 supervision of pre-test and post test phases  
 6 of laboratory work from specimen collection to  
 7 delivery of report to the clinician." And I  
 8 wonder if you can elaborate a bit on that  
 9 particular point?  
 10 DR. TORLAKOVIC:  
 11 A. I could, I mean it's not something that I am  
 12 intimately involved in all the phases of pre-  
 13 test, post-test phases, but we--we cannot over  
 14 emphasize the significance of tissue  
 15 processing and reporting of the results and  
 16 this is also, I mean, it's one thing that EQA  
 17 can deal with directly is exactly the test  
 18 itself and then looking at the slides, but  
 19 also cannot be forgotten there are pre-  
 20 analytical and post-analytical components and  
 21 they have to be somehow incorporated and  
 22 regulated in any clinical laboratory and that  
 23 is what it refers to. It refers to--and we  
 24 know that it's a novel thing, actually, it's  
 25 from 2007, first time that officially

Page 254

1 guidelines address pre-analytical component.  
 2 This has never been done before and it's huge  
 3 news for our practice, so it introduces  
 4 totally different components that we, as  
 5 pathologists, have to now deal with. It  
 6 introduces, it actually incorporates surgery  
 7 department now in the whole process of testing  
 8 and it will--it requires their co-operation  
 9 and several changes in the laboratory and  
 10 tissue or specimen receiving that enable  
 11 careful tracking of tissue through all these  
 12 steps before it comes for the testing.  
 13 MS. NEWBURY:  
 14 Q. And sorry, who did you say introduced that in  
 15 2005?  
 16 DR. TORLAKOVIC:  
 17 A. No, it's 2007, actually first time, ASCO CAP  
 18 guidelines on HER2 testing, it's first time  
 19 that this was put from an expert panel that it  
 20 was officially address--when for many years,  
 21 of course, you could read in the literature  
 22 and many distinguished immunohistochemistry  
 23 experts around the world would write about the  
 24 significance of tissue processing. But that  
 25 has never been put into guidelines before, so

Page 255

1 that directly would have to be addressed by  
 2 laboratories and hospitals, as they should be  
 3 now.  
 4 MS. NEWBURY:  
 5 Q. Okay, and in talking about the CIQC program  
 6 and the fact that it doesn't focus on the  
 7 interpretation by pathologists, although it  
 8 can pick up some problems, but it's not--  
 9 because of the sample size of the tissue on a  
 10 microarray -  
 11 DR. TORLAKOVIC:  
 12 A. Right.  
 13 MS. NEWBURY:  
 14 Q. It's certainly not going to be the target, I  
 15 guess, of the CIQC program, do I understand  
 16 that correctly?  
 17 DR. TORLAKOVIC:  
 18 A. Not necessarily because we are just starting  
 19 and these I call like baby steps at this  
 20 point, it's a very modest approach. I think  
 21 that it is also necessary for CIQC to address  
 22 the post-analytical component and to enable,  
 23 to actually put on the ramp of scan slides  
 24 that it was the idea that what I would like to  
 25 see in next year or next two years, developing

Page 256

1 in this year to put, to scan the slides with  
 2 variable results and to have expert scores on  
 3 one side and then to have people log in and  
 4 they can test by virtual microscopy the steps  
 5 on line and the large number of specimens and  
 6 see their own average score and they can  
 7 improve if they--so it would enable them self  
 8 evaluation and training also, that material  
 9 should be available for resident training too,  
 10 because if it's on line and if it's already  
 11 scored and if it's already prepared for this  
 12 particular purpose, it would enable a large  
 13 number of people to use it if some specimens  
 14 that may not be so easy to prepare for every  
 15 centre or every residency program separately.  
 16 MS. NEWBURY:  
 17 Q. So it's both a quality assurance type tool as  
 18 well as an educational -  
 19 DR. TORLAKOVIC:  
 20 A. Yes, yes.  
 21 MS. NEWBURY:  
 22 Q. So, while that hasn't been done yet, that is  
 23 something that you're -  
 24 DR. TORLAKOVIC:  
 25 A. We have the idea that we would like to put



Page 257

1 that in -  
 2 MS. NEWBURY:  
 3 Q. And would you anticipate perhaps varying the  
 4 types of specimens that are posted from year  
 5 to year or expanding upon the type of a  
 6 program just to get a the post-analytical or  
 7 the interpretation aspect?  
 8 DR. TORLAKOVIC:  
 9 A. I mean, definitely, one would focus on those  
 10 specimens that post-analytical component is  
 11 critical and that means scoring again prog--  
 12 predictive Class II test. That would be the  
 13 first focus. And secondly, also, it should  
 14 not be forgotten that the interpretation of  
 15 Class I tests may be very difficult. And it's  
 16 difficult to learn if somebody is not  
 17 constantly exposed to large number of such  
 18 specimens. One of the reasons, one of--my  
 19 main motivation for example for the book that  
 20 I recently prepared and it will be out early,  
 21 I think, 2009, Bone Marrow  
 22 Immunohistochemistry, is knowing that in  
 23 general practice, it's very difficult to train  
 24 residents who come and rotate for two, three  
 25 months without exposing them to some kind of

Page 258

1 reference point and what good result is or  
 2 what you expect in different types of  
 3 specimens. That type of image collection was  
 4 never available and it was my motivation to  
 5 put that book out, to show that, of the  
 6 spectrum of possible results, what people can--  
 7 and this is what I think is the idea, is to  
 8 produce such source, whether it's total  
 9 internet based or not, but to produce such  
 10 sources easily available to anybody who wants  
 11 to learn, see quickly. We don't need to have  
 12 pathologists learning two decades about  
 13 something that can be presented and taught,  
 14 you know, in matter of hours.  
 15 MS. NEWBURY:  
 16 Q. Okay. And in addition to guidelines that may  
 17 be available about the pre-analytic phases of  
 18 testing, particularly as it relates to ER and  
 19 PR testing, are there any techniques or tools  
 20 that CIQC is going to explore as to how you  
 21 could have some sort of quality assurance  
 22 program to focus on that or is that something  
 23 that you think is possible or -  
 24 DR. TORLAKOVIC:  
 25 A. No, but I am aware that as part of

Page 259

1 accreditation of the laboratory, those that  
 2 have accreditation, that some of the things  
 3 that they look at is actually tissue  
 4 processing and when the inspections are  
 5 coming, they look at how the tissue was  
 6 processed, how the recording was done and so.  
 7 How uniformed that is applied in different  
 8 provinces and to what extent, I cannot comment  
 9 on.  
 10 MS. NEWBURY:  
 11 Q. Okay. And are you referring then to having  
 12 standard operating procedures in place that  
 13 are -  
 14 DR. TORLAKOVIC:  
 15 A. Absolutely.  
 16 MS. NEWBURY:  
 17 Q. - known to produce good results.  
 18 DR. TORLAKOVIC:  
 19 A. Yes, absolutely.  
 20 MS. NEWBURY:  
 21 Q. And there are no programs available, that  
 22 you're aware of, that someone could work up a  
 23 slide through the tissue processing stage to  
 24 compare it with other laboratories to see how  
 25 it compares?

Page 260

1 DR. TORLAKOVIC:  
 2 A. I'm not aware of that. That doesn't mean it  
 3 does not--it hasn't been done, but I'm not  
 4 aware of it.  
 5 MS. NEWBURY:  
 6 Q. And in terms of--there are a variety of  
 7 programs that you've spoken about earlier  
 8 today, the NordiQC, the UK NEQAS CAP, your new  
 9 CIQC program and there was some reference to  
 10 QMPLS which is the Ontario program.  
 11 DR. TORLAKOVIC:  
 12 A. Yes.  
 13 MS. NEWBURY:  
 14 Q. Do you know much about the QMPLS?  
 15 DR. TORLAKOVIC:  
 16 A. No, and I kind of feel embarrassed because  
 17 it's Canadian, you know, and I know so little  
 18 about it. The thing is also, as I said, like  
 19 our time limitations, how much time we can  
 20 invest into learning about--and it's not  
 21 something that is easy to figure out. I can  
 22 tell you that just most recently I learned  
 23 more about what's happening in Alberta. We  
 24 are working on something in Saskatchewan and  
 25 who else knows about it? Nobody knows about

Page 261

1 it. It's just--not even pathologists in  
 2 Saskatchewan all know exactly what we are  
 3 working on. So, it's not a type of  
 4 information that is widely posted and  
 5 available.  
 6 MS. NEWBURY:  
 7 Q. Right. So there's no sort of clearing house -  
 8 DR. TORLAKOVIC:  
 9 A. No, no.  
 10 MS. NEWBURY:  
 11 Q. - as to all of the types of programs that are  
 12 available.  
 13 DR. TORLAKOVIC:  
 14 A. No.  
 15 MS. NEWBURY:  
 16 Q. Would you think that there are any advantages  
 17 to a laboratory perhaps enrolling in several  
 18 programs just to take advantage, I guess, of  
 19 the benefits that one might have over another  
 20 particular program or is that something that  
 21 you think might already be done by some  
 22 laboratories?  
 23 DR. TORLAKOVIC:  
 24 A. I think that laboratories participate in more  
 25 than one program for several reasons. One of

Page 262

1 them is that these programs are not identical  
 2 and they offer different type of information  
 3 for the laboratories. I already pointed out  
 4 some differences between CAP program and UK  
 5 NEQAS program and then other differences with  
 6 NordiQC and with CIQC again, we provide  
 7 different type of information and education  
 8 and insight than others. So I don't think  
 9 that these are necessarily competition to each  
 10 other or that even when you look at just  
 11 Canada, CIQC is right now small addition to  
 12 other programs and I think that all of them  
 13 are valuable and all of them should be  
 14 supported and I don't think that any of the  
 15 programs should be extinguished or closed at  
 16 this time, just in the contrary.  
 17 MS. NEWBURY:  
 18 Q. You think that they perhaps complement one  
 19 another?  
 20 DR. TORLAKOVIC:  
 21 A. Absolutely.  
 22 MS. NEWBURY:  
 23 Q. Okay, and in light of the fact that at this  
 24 time, the CIQC doesn't have any particular  
 25 focus on the interpretation issue or the post-

Page 263

1 analytic testing, is there a program there  
 2 that you think that might be particularly  
 3 beneficial for that particular aspect of  
 4 testing?  
 5 DR. TORLAKOVIC:  
 6 A. NordiQC I think looks at that, at the  
 7 interpretation too, and I think it's also UK  
 8 NEQAS that looks at interpretation. I think  
 9 that in Ontario, QMPLS, I don't think that  
 10 they look at interpretation.  
 11 MS. NEWBURY:  
 12 Q. Okay.  
 13 DR. TORLAKOVIC:  
 14 A. And CIQC, as I said, we have the data, but the  
 15 time itself prevents drawing of larger  
 16 conclusions out of that, but we will go into  
 17 that direction. I don't think there is a  
 18 perfect program to address that because a  
 19 perfect program would have to have not only  
 20 testing abilities, to see the performance of  
 21 the pathologists, but also this training  
 22 component, as I said, and also what people try  
 23 to emphasize in this post-analytical component  
 24 is that not everybody should be interpreting  
 25 the results, for example, of ER/PR if they're

Page 264

1 not sufficiently exposed to it in their  
 2 practice to a certain number of tests that  
 3 would make them proficient, but having that  
 4 said, I think if you made available online  
 5 large number of tests and if the pathologist  
 6 can prove that they are competent, they should  
 7 not be prohibited from doing this practice.  
 8 That's my opinion.  
 9 MS. NEWBURY:  
 10 Q. Thank you. You were just shown or you  
 11 actually pointed to a slide, and I wanted to  
 12 bring that up again just for some  
 13 clarification. It's Exhibit 3361, please, and  
 14 I believe it's page 31 of the presentation?  
 15 And this is the NordiQC run, three particular  
 16 runs. Could you just clarify what those runs  
 17 related to? What was the scope of the testing  
 18 in that case?  
 19 DR. TORLAKOVIC:  
 20 A. I don't remember what were exact epitopes, but  
 21 if one wants to know, they are all the time  
 22 available online. I don't know if we have  
 23 online capability in this computer to go to  
 24 NordiQC site and maybe open that.  
 25 MS. NEWBURY:

Page 265

1 Q. Okay. I don't know if we -  
 2 DR. TORLAKOVIC:  
 3 A. Can we do that?  
 4 MS. NEWBURY:  
 5 Q. Actually, I just wondered if that related to  
 6 ER and PR testing?  
 7 REGISTRAR:  
 8 Q. What's the web site reference?  
 9 DR. TORLAKOVIC:  
 10 A. It's NordiQC, N-O-R-D-I-Q-C.org and then go to  
 11 assessments.  
 12 MS. NEWBURY:  
 13 Q. Assessments?  
 14 DR. TORLAKOVIC:  
 15 A. Yeah, I can do that actually, and you were  
 16 interested whether that estrogen -  
 17 MS. NEWBURY:  
 18 Q. I think they were 8, 9 and 10, I believe, were  
 19 the numbers. The ones are numbers 8, 9 and  
 20 10.  
 21 DR. TORLAKOVIC:  
 22 A. And you were specifically interested in  
 23 estrogen receptor, correct?  
 24 MS. NEWBURY:  
 25 Q. I was wondering if it included ER and PR

Page 266

1 testing, those results?  
 2 DR. TORLAKOVIC:  
 3 A. No, that was called 1B5, so no, it didn't.  
 4 MS. NEWBURY:  
 5 Q. Okay.  
 6 DR. TORLAKOVIC:  
 7 A. I don't think it did. Maybe we can also read  
 8 through this. No.  
 9 MS. NEWBURY:  
 10 Q. Okay, and how about PR, would that -  
 11 DR. TORLAKOVIC:  
 12 A. No.  
 13 MS. NEWBURY:  
 14 Q. Okay, so it's something other than ER and PR  
 15 testing?  
 16 DR. TORLAKOVIC:  
 17 A. Yes.  
 18 MS. NEWBURY:  
 19 Q. Okay. Could you indicate what factors, if  
 20 any, could negatively impact on the  
 21 specificity of testing for ER and PR?  
 22 DR. TORLAKOVIC:  
 23 A. What factors specifically?  
 24 MS. NEWBURY:  
 25 Q. What types of factors? And just again

Page 267

1 referring back to that slide, there are some  
 2 references there, and I don't know if they  
 3 would equally apply to ER and PR testing. If  
 4 you've got--I understand that if there's a  
 5 problem or a lack of specificity with testing,  
 6 then that might lead to false positives.  
 7 DR. TORLAKOVIC:  
 8 A. Yes.  
 9 MS. NEWBURY:  
 10 Q. And here, there are a list of factors that  
 11 could possibly contribute to false positives,  
 12 and I'm wondering if they would equally apply  
 13 to a problem with false positives in ER and PR  
 14 testing?  
 15 DR. TORLAKOVIC:  
 16 A. Yes, you can say generally speaking. I do not  
 17 have a reference to support this what I am  
 18 saying, but generally speaking, these are the  
 19 factors that are widely applicable as a cause  
 20 of false positive results.  
 21 MS. NEWBURY:  
 22 Q. Okay. So in terms of whatever the test that  
 23 was being run here with runs 8, 9 and 10, you  
 24 did have, I think, about ten percent of all of  
 25 the insufficient staining were related to

Page 268

1 false positive results, as opposed to false  
 2 negatives?  
 3 DR. TORLAKOVIC:  
 4 A. But the false positive result, specifically  
 5 when you think about it, also as they are  
 6 being reported, that's a different thing than  
 7 actually when you have a slide and you have--  
 8 you see that, that the nuclei are really  
 9 positive and they should not be positive.  
 10 That's a different thing. False positive  
 11 results sometimes are reported because of the  
 12 interpretive component.  
 13 MS. NEWBURY:  
 14 Q. Okay. So if you have excessive background  
 15 staining, as an example?  
 16 DR. TORLAKOVIC:  
 17 A. Excessive background staining or, you know,  
 18 inappropriately interpreted staining might end  
 19 up as false positive in patient's report, yes.  
 20 MS. NEWBURY:  
 21 Q. Okay, and so it might be a positive result for  
 22 a particular test. It's not valid for that  
 23 particular specimen and it's due to  
 24 interpretation?  
 25 DR. TORLAKOVIC:

Page 269

1 A. Yes.  
 2 MS. NEWBURY:  
 3 Q. Or a combination of interpretation and perhaps  
 4 background staining?  
 5 DR. TORLAKOVIC:  
 6 A. Right, right.  
 7 MS. NEWBURY:  
 8 Q. Okay. If you have absent negative controls  
 9 during a test, would that be a factor that  
 10 might contribute to having a wrong result or  
 11 an inappropriate result for an ER or PR test?  
 12 DR. TORLAKOVIC:  
 13 A. Yes. I mean, and there are different types of  
 14 negative controls that should be taken into  
 15 account. Generally speaking, there is a rule  
 16 that should be followed that from the block  
 17 that is being tested piece of the tissue,  
 18 there should be one negative control for each  
 19 type of tissue processing. For example, if I  
 20 do three different tests and they all have  
 21 different antigen retrieval, I'd say for one,  
 22 the best one would be process digestion.  
 23 Another one would be buffer and another one  
 24 would be nothing. I need negative controls  
 25 for all of them, so I would need three

Page 270

1 negative controls. But there is also internal  
 2 negative control that has to be interpreted  
 3 with knowledge and skill of the pathologist  
 4 that are looking at this, at the tissue. You  
 5 know what to expect. It should be negative  
 6 and when it comes to the critical test, the  
 7 tissue sections that enable you to identify  
 8 internal negative controls are designed as  
 9 such, are selected for the testing, if  
 10 possible at all. So once you take into  
 11 account two types of controls, negative  
 12 controls that are used for interpretation, and  
 13 certainly I thank you actually for pointing--  
 14 for asking me about them because it's  
 15 frequently thought that we are overusing or  
 16 that negative controls are not an important  
 17 part of the testing because we are wasting  
 18 money because to test one negative control,  
 19 it's expensive thing. You have additional  
 20 slides and as I said, even for just one, this  
 21 particular patient, you need three negative  
 22 controls that some people think that that's  
 23 not reasonable to do in clinical practice.  
 24 But I think, in my personal opinion, it is  
 25 critical that one follows such rules.

Page 271

1 MS. NEWBURY:  
 2 Q. Okay, and that would help to detect, by using  
 3 a negative control, whether there's any  
 4 inappropriate staining of the slide that might  
 5 lead to a false positive result?  
 6 DR. TORLAKOVIC:  
 7 A. Yes, but there is no perfect system.  
 8 MS. NEWBURY:  
 9 Q. Sure.  
 10 DR. TORLAKOVIC:  
 11 A. There is no perfect system, but it does help,  
 12 it definitely helps.  
 13 MS. NEWBURY:  
 14 Q. Okay, and just back to what you were saying  
 15 there a minute ago, that background staining,  
 16 I think your evidence is that that wouldn't  
 17 necessarily be a true false positive result  
 18 and would a true false positive result be when  
 19 you have nuclear staining that should not have  
 20 occurred?  
 21 DR. TORLAKOVIC:  
 22 A. Right, if your expected result is true false  
 23 positive is the one that when your evidence  
 24 that you have on the slide looks like a  
 25 specific staining but it is not.

Page 272

1 MS. NEWBURY:  
 2 Q. Okay.  
 3 DR. TORLAKOVIC:  
 4 A. I'll give you one example of that, that is a  
 5 nuclear staining. There was a viral epitope  
 6 that sometimes people are interested in  
 7 looking at medical practice. I don't want to  
 8 say any specifics about it, but I can tell you  
 9 that the clone that was available on the  
 10 market for a while was the one that actually  
 11 cross reacted with histones in the nucleus,  
 12 human histones, but not histones for on which  
 13 epitope it was designed originally. So when  
 14 it was used in renal transfer and pathology,  
 15 you would get like positivity in the nuclei  
 16 and it really looked like a true specific  
 17 result, and it was true false positive because  
 18 it just looked like it should look like, very  
 19 specific, just some nuclei stained and it was  
 20 only nuclear. There was no cytoplasmic and it  
 21 looked like there is perfect signal to know  
 22 its ratio, but it was the result of cross  
 23 reactivity with human histones in the nuclei.  
 24 So that is the thing that reflects true

Page 273

1 false positive result, but when it comes to ER  
 2 and PR, it can happen, but I think it's  
 3 extremely rare.  
 4 MS. NEWBURY:  
 5 Q. Okay, and are there certain types of  
 6 procedures that might be more apt to cause  
 7 false nuclear staining? And there's been some  
 8 reference to -  
 9 DR. TORLAKOVIC:  
 10 A. Yes, when there is too much antigen retrieval,  
 11 that can happen.  
 12 MS. NEWBURY:  
 13 Q. Too much antigen, okay.  
 14 DR. TORLAKOVIC:  
 15 A. Yes.  
 16 MS. NEWBURY:  
 17 Q. And that's also referred to as over antigen  
 18 retrieval, is it?  
 19 DR. TORLAKOVIC:  
 20 A. Yes.  
 21 MS. NEWBURY:  
 22 Q. Okay, and is that more common with one  
 23 technique over another?  
 24 DR. TORLAKOVIC:  
 25 A. How do you mean?

Page 274

1 MS. NEWBURY:  
 2 Q. The avidin biotin method versus the PAP method  
 3 or some other type of antigen retrieval.  
 4 DR. TORLAKOVIC:  
 5 A. Well, I don't--I'm not aware of a systematic  
 6 study to look at that. Perhaps there was, but  
 7 I just don't remember anything, but I can only  
 8 tell you that some--when you think about  
 9 antigen--avidin biotin systems, of course,  
 10 they are generally prone to endogenous biotin  
 11 and false positive type of results, but that  
 12 would not apply to ER/PR because these are  
 13 nuclear antigens, so endogenous biotin  
 14 activity would not cause false positive ER  
 15 test.  
 16 MS. NEWBURY:  
 17 Q. Okay, and are you aware--you just mentioned a  
 18 clone that caused a particular problem, just  
 19 because of the--I guess the studies that  
 20 didn't translate as well from animals to  
 21 humans. Are you aware of any of those types  
 22 of clones that might be used for ER/PR  
 23 testing?  
 24 DR. TORLAKOVIC:  
 25 A. No.

Page 275

1 MS. NEWBURY:  
 2 Q. Okay. Are you aware if there might be any  
 3 possible problems with a false positive test  
 4 or inappropriate positive test if there's  
 5 inadequate fixation of tissue followed by  
 6 exposure to alcohol, either through tissue  
 7 processing or tissue reprocessing? Is that  
 8 something that you have ever encountered?  
 9 DR. TORLAKOVIC:  
 10 A. No, I cannot comment on that. I don't know  
 11 that.  
 12 MS. NEWBURY:  
 13 Q. If you discovered, I guess, in participating  
 14 in a quality assurance review that there had  
 15 been instances of excessive background  
 16 staining and that this background staining was  
 17 inappropriately interpreted to be a positive  
 18 test result, what recommendations would you  
 19 make to the laboratory that was involved in  
 20 providing those results?  
 21 DR. TORLAKOVIC:  
 22 A. Well, generally they are made all the time,  
 23 from NordiQC when such specimens come.  
 24 Background staining is something that is  
 25 looked at carefully. It's immediately

Page 276

1 commented on and recommendations are given  
 2 based on what is thought to produce that  
 3 background staining. It's very difficult. If  
 4 we see that it's endogenous biotin staining,  
 5 clearly we'll say switch to another detection  
 6 system that is not based on avidin biotin, you  
 7 know, interactions, but otherwise, there will  
 8 be different sources of background staining.  
 9 Sometimes it's obvious that some lab is using  
 10 too high primary antibody concentration, so we  
 11 would say well, dilute the antibody further.  
 12 MS. NEWBURY:  
 13 Q. And that's one of the factors listed here on  
 14 this NordiQC.  
 15 DR. TORLAKOVIC:  
 16 A. Right.  
 17 MS. NEWBURY:  
 18 Q. Run 8, 9, 10, the too high primary antibody  
 19 concentration. It's the first item there  
 20 under false positives, and that would be, I  
 21 guess, a technique that would have to be  
 22 adjusted in the laboratory by the technologist  
 23 or whoever is involved in optimizing the  
 24 particular techniques. Is that correct?  
 25 DR. TORLAKOVIC:

Page 277

1 A. Right, correct.  
 2 MS. NEWBURY:  
 3 Q. Okay, but in terms of the combination of  
 4 having the background staining and then having  
 5 a pathologist interpret that as a positive  
 6 result, would there be any additional steps to  
 7 rectify that part of the problem? I assume  
 8 that sometimes there might be background  
 9 staining, but the pathologist doesn't  
 10 interpret it as a positive result. They still  
 11 interpret it as a negative result.  
 12 DR. TORLAKOVIC:  
 13 A. Right.  
 14 MS. NEWBURY:  
 15 Q. What happens if you have the background  
 16 staining and in addition to that, the  
 17 pathologist interpreted that to be a positive  
 18 result?  
 19 DR. TORLAKOVIC:  
 20 A. Then you have it reported as false positive  
 21 test obviously. I don't know what else to  
 22 say.  
 23 MS. NEWBURY:  
 24 Q. Okay. No, I'm just wondering in terms of  
 25 corrective actions.

Page 278

1 DR. TORLAKOVIC:  
 2 A. Of correcting, I mean, you would have to have  
 3 somebody first notice that that has happened  
 4 in the first place, and if pathologists didn't  
 5 notice that, then it's hard to imagine--to me,  
 6 it's hard to figure out how, except for the  
 7 wide audit, who would go back and review those  
 8 specimens again, I don't know.  
 9 MS. NEWBURY:  
 10 Q. Okay. So really, it would just have to be a  
 11 review just to make sure that that's not a  
 12 common problem?  
 13 DR. TORLAKOVIC:  
 14 A. I know that in some instances, where the  
 15 breast pathologist--it's responsibility of  
 16 certain pathologists in the department if  
 17 there is breast cancer expert. Those are the  
 18 people that will frequently review such--you  
 19 know, go back and review what other people in  
 20 the department are doing and take, you know,  
 21 actions when necessary.  
 22 MS. NEWBURY:  
 23 Q. Okay, and are those types of quality reviews--  
 24 those would be in addition to a program such  
 25 as CIQC or -

Page 279

1 DR. TORLAKOVIC:  
 2 A. Right, definitely, yes.  
 3 MS. NEWBURY:  
 4 Q. Okay, or UK NEQAS?  
 5 DR. TORLAKOVIC:  
 6 A. Yes.  
 7 MS. NEWBURY:  
 8 Q. And what types of programs, are there any sort  
 9 of informal programs or guidelines as to how  
 10 that would be done, you know, within a  
 11 particular institution?  
 12 DR. TORLAKOVIC:  
 13 A. See when you have breast carcinoma experts  
 14 working with this, you know, with breast  
 15 cancer in the department, they will take into  
 16 account all available guidelines and knowledge  
 17 that is there published, and they will be sure  
 18 to monitor that well differentiated carcinomas  
 19 are positive, do they expect that all  
 20 papillary carcinomas will be positive for ER,  
 21 that all medullary carcinomas will be  
 22 negative, and will look for things like that,  
 23 there is evidence, accumulative evidence. For  
 24 example, in Saskatoon, we have breast  
 25 pathologist, Dr. Rees. She's following for

Page 280

1 many years now in an extensive database  
 2 exactly what is the histologic type and what's  
 3 the percent of positivity just to see that,  
 4 yes, we are on the line with published  
 5 evidence and that is what is expected in that,  
 6 and she goes back and retests, reviews, and  
 7 re-scores a certain number of specimens  
 8 throughout the year and so on to make sure  
 9 that we don't get--that you notice trends if  
 10 they are developing at the time.  
 11 MS. NEWBURY:  
 12 Q. Okay. So your monitor trends -  
 13 DR. TORLAKOVIC:  
 14 A. Yes.  
 15 MS. NEWBURY:  
 16 Q. As to what will be statistically expected?  
 17 DR. TORLAKOVIC:  
 18 A. Right.  
 19 MS. NEWBURY:  
 20 Q. I guess, based on a certain type of cancer.  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 MS. NEWBURY:  
 24 Q. And you would also have reviews by other  
 25 pathologists just to verify?

Page 281

1 DR. TORLAKOVIC:  
 2 A. She organizes occasional throughout the year  
 3 meetings with other pathologists and  
 4 circulates the material for them to score and  
 5 so on, so that we have an idea that the whole  
 6 group is--how the whole group is performing  
 7 the scoring and everything, and understanding  
 8 of the topic and so on. So it is something  
 9 that that particular pathologist has a  
 10 responsibility for, and can I do that, in  
 11 theory, I could, but it's not really my job.  
 12 I'm not doing it, you know.  
 13 MS. NEWBURY:  
 14 Q. Okay.  
 15 DR. TORLAKOVIC:  
 16 A. So this is a kind of ideally how it should be,  
 17 that in the department there are certain  
 18 responsibilities for certain areas that we  
 19 take care of. Even though I oversee  
 20 immunohistochemistry, she still makes sure  
 21 that results fall into the trends. She's the  
 22 one to monitor the trends. I'm not doing it.  
 23 MS. NEWBURY:  
 24 Q. Based on tumour site?  
 25 DR. TORLAKOVIC:

Page 282

1 A. Based on the tumour--yes.  
 2 MS. NEWBURY:  
 3 Q. And if the expertise were not available at a  
 4 particular institution, if there was no one  
 5 there at that particular time who had that  
 6 wealth of knowledge, I guess, in breast  
 7 carcinoma, are there any other sort of  
 8 informal or formal programs that are available  
 9 for that type of review of interpretation  
 10 results?  
 11 DR. TORLAKOVIC:  
 12 A. I'm not aware of that, no. There is  
 13 literature available, but I don't think there  
 14 are any set programs.  
 15 MS. NEWBURY:  
 16 Q. Thank you, Dr. Torlakovic, those are all my  
 17 questions.  
 18 THE COMMISSIONER:  
 19 Q. Thank you, Ms. Newbury. Anything arising, Mr.  
 20 Coffey?  
 21 MR. COFFEY:  
 22 Q. Yes, just a couple of questions for Dr.  
 23 Torlakovic.  
 24 DR. EMINA TORLAKOVIC - RE-EXAMINATION BY BERNARD COFFEY,  
 25 Q.C.

Page 283

1 COFFEY, Q.C.:  
 2 Q. If we could bring up, please, Exhibit P-3365.  
 3 Doctor, this is this article that Mr. Browne  
 4 referred you to. I just note that it is  
 5 published online, January 26th, 2007, and you  
 6 recall Mr. Browne asked you about Dr. Rhodes  
 7 publications, and just in terms of time  
 8 frames, Doctor, here foot reference #2, the  
 9 Rhodes publication is there in 2000, another  
 10 one published in 2000, footnote #3, footnote  
 11 #5 is a publication in--another publication in  
 12 2000 by Dr. Rhodes, and footnote #19 is  
 13 another publication, again by Dr. Rhodes in  
 14 2000, and these are all, I believe, in the  
 15 Journal of Clinical Pathology. Just look down  
 16 through them. Doctor, I'm going to ask you,  
 17 in terms of the findings that Dr. Rhodes made  
 18 in relation to his study in the UK and he  
 19 published them in the main in 2000, I think  
 20 one or two of them in 2001, that Journal of  
 21 Clinical Pathology, is that widely known in  
 22 your world? Is it a journal that's widely  
 23 available?  
 24 DR. TORLAKOVIC:  
 25 A. It's widely available--well, it's widely

Page 284

1 available, of course. I mean, it's accessible  
 2 on internet, that's not a problem, but it's  
 3 widely read in Europe, it's not widely read in  
 4 North America, to the best of my knowledge.  
 5 COFFEY, Q.C.:  
 6 Q. And the next question, the second one is  
 7 there's a reference to Layfield in this  
 8 article, buried in the actual journal  
 9 publication itself out of Australia, and here  
 10 footnote 18 is by Dr. Layfield, I believe, and  
 11 we've seen the actual--the Commissioner has  
 12 been shown the actual article itself. This is  
 13 Breast Journal 2003. His article dates from  
 14 that time, dealing--Dr. Layfield, dealing with  
 15 a study in the UK and the US in terms of ER  
 16 and PR. Finally then in relation to this,  
 17 doctor, I wanted to ask you about this. Here  
 18 in the last paragraph actually the publication  
 19 or article says, and to put it in context, in  
 20 the paragraph before they point out for HER2  
 21 there's always, if necessary, FISH testing  
 22 available as confirmatory testing. Then they  
 23 conclude, "However, for ER and PR, no  
 24 alternative methodology to IHC is available.  
 25 Therefore, it is essential that the clinician

Page 285

1 and laboratory are at all times aware of the  
 2 potential impact reporting of IHC has on  
 3 patient treatment and outcome. Internal  
 4 audits should be performed in the laboratories  
 5 to ensure results are as accurate as possible  
 6 and referral laboratory should be considered  
 7 for laboratories performing small numbers of  
 8 cases".  
 9 DR. TORLAKOVIC:  
 10 A. Yes, I agree with that.  
 11 COFFEY, Q.C.:  
 12 Q. This is the beginning of 2000 in Australia,  
 13 this particular article is published out of  
 14 Australia in 2000--2007, I apologize.  
 15 DR. TORLAKOVIC:  
 16 A. 2007, yes.  
 17 COFFEY, Q.C.:  
 18 Q. As a European at the time, like, going back to  
 19 the time of Rhodes publication or publications  
 20 in 2000, in the European context, what's  
 21 stated here in this paragraph, anybody who  
 22 followed the journal that Dr. Rhodes published  
 23 in, would they have been aware of this, in the  
 24 sense of this sentiment, the idea of the  
 25 necessity for being careful with ER/PR?

Page 286

1 DR. TORLAKOVIC:  
 2 A. I can tell you that I was present at his  
 3 original presentation in Europe when he first  
 4 time was at a meeting talking about his  
 5 results, and everybody was kind of shocked,  
 6 but everybody said we knew this, you know, but  
 7 they were shocked that this information was  
 8 actually publicly displayed and scientifically  
 9 supported now and it's going to be published.  
 10 So it was like a bomb really, even though  
 11 despite the knowledge that something is wrong  
 12 and that not everybody is getting good results  
 13 with ER and PR, people just didn't pay  
 14 attention to it. They didn't--I don't know  
 15 what is this inertia, why is that happening,  
 16 but it seems like that an intervention in  
 17 immunohistochemistry is not something that is  
 18 easily done. So people somehow don't know  
 19 where to start, and that is what we are seeing  
 20 now. Now it's clear that we now are  
 21 crystallizing the role of internal quality  
 22 assurance, external quality assurance,  
 23 accreditation. We have come to the point  
 24 where things are understood, we know how to do  
 25 it, and we're going to do it, and we are doing

Page 287

1 it, but some years ago this was not clear at  
 2 all.  
 3 COFFEY, Q.C.:  
 4 Q. Doctor, in relation to a question Mr. Simmons  
 5 asked you about concordance and he referred to  
 6 95 percent is -  
 7 DR. TORLAKOVIC:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. The minimum acceptable.  
 11 DR. TORLAKOVIC:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. In relation to that, Doctor, is there such a  
 15 thing as having a higher concordance than 95?  
 16 Like, can you have a 98 percent concordance or  
 17 a 100 percent concordance?  
 18 DR. TORLAKOVIC:  
 19 A. Oh, yes, we have 100 percent, and 98, in some  
 20 of the laboratories with reference value, yes.  
 21 COFFEY, Q.C.:  
 22 Q. So I take it, the higher the better?  
 23 DR. TORLAKOVIC:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

Page 288

1 Q. And 95 being kind of an accepted minimum, but  
 2 if you're up to 99 or 100, better still?  
 3 DR. TORLAKOVIC:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. Okay, and finally if I could, both Mr. Simmons  
 7 and Mr. Brown asked you questions about the  
 8 development of, in particular, ER/PR, IHC and  
 9 ER/PR in particular over the past ten years.  
 10 If we could go to the PowerPoint presentation  
 11 please. If we could go to--let me see, it's  
 12 page--blow it up, thank you. Doctor, this is  
 13 this Run 3 you referred to, and I appreciate  
 14 that things have changed over the years, but  
 15 at the time this Run 3 was done which was, in  
 16 effect, I take it, within the past six months  
 17 or so?  
 18 DR. TORLAKOVIC:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. By CIQC. Just looking down through the  
 22 headings here, the lab numbers are obviously  
 23 different. Antigen retrieval being used is  
 24 "yes" all the way down, so that's fine,  
 25 they're all using--instruments, the type of



Page 289

1 instrument being used in these various  
 2 laboratories.  
 3 DR. TORLAKOVIC:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. And I believe I counted up--let me see, 23  
 7 labs are listed here, I think is what it is.  
 8 There are a number of different types of  
 9 instruments that are utilized?  
 10 DR. TORLAKOVIC:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. Different types of instruments. There are a  
 14 number of different temperatures used?  
 15 DR. TORLAKOVIC:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. For antigen retrieval. There are certainly a  
 19 number of different antigen retrieval times  
 20 used.  
 21 DR. TORLAKOVIC:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. It varies all over when you look down through  
 25 it. There are certainly quite a number of

Page 290

1 different types of buffers used?  
 2 DR. TORLAKOVIC:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. There are quite a number of different types of  
 6 primary antibody clones used? I shouldn't say  
 7 quite a number. There are relatively few  
 8 here.  
 9 DR. TORLAKOVIC:  
 10 A. Relatively few in this particular case, but if  
 11 it were even large number of clones, that  
 12 would be still okay.  
 13 COFFEY, Q.C.:  
 14 Q. Suppliers, of course, will vary. The  
 15 dilutions of the primary antibodies vary  
 16 somewhat in terms of the dilution ratios. You  
 17 can see that throughout?  
 18 DR. TORLAKOVIC:  
 19 A. Right.  
 20 COFFEY, Q.C.:  
 21 Q. And some are premixed--are prediluted, I'm  
 22 sorry. The dilutant types vary somewhat. The  
 23 incubation times vary. In fact, at times  
 24 somewhat considerably depending upon which one  
 25 you look at. Detection systems vary, a number

Page 291

1 of different types of detection systems?  
 2 DR. TORLAKOVIC:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. And from different--using different names. The  
 6 incubation time for the detection systems vary  
 7 somewhat, if you'll look down through that,  
 8 would you agree?  
 9 DR. TORLAKOVIC:  
 10 A. Uh-hm.  
 11 COFFEY, Q.C.:  
 12 Q. And what I want--what I wanted to ask you then  
 13 is this, having drawn yours and the  
 14 Commissioner's attention to that, is--and I  
 15 appreciate this is Run 3.  
 16 DR. TORLAKOVIC:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. Was there a similar table done for Run 2?  
 20 Would there be a similar table existing?  
 21 DR. TORLAKOVIC:  
 22 A. Yes, yes, of course.  
 23 COFFEY, Q.C.:  
 24 Q. Okay, and there would be similar sort of  
 25 variability at the time?

Page 292

1 DR. TORLAKOVIC:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. And yet in Run 2, you said that all the labs  
 5 that participated, the dozen or so who  
 6 participated at the time, all got -  
 7 DR. TORLAKOVIC:  
 8 A. Very good results. It was -  
 9 COFFEY, Q.C.:  
 10 Q. Very good results.  
 11 DR. TORLAKOVIC:  
 12 A. Excellent, yes.  
 13 COFFEY, Q.C.:  
 14 Q. Right across the board?  
 15 DR. TORLAKOVIC:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. And despite all that variability?  
 19 DR. TORLAKOVIC:  
 20 A. Right.  
 21 COFFEY, Q.C.:  
 22 Q. Recorded as to protocols and so on and so  
 23 forth.  
 24 DR. TORLAKOVIC:  
 25 A. Do you want me to comment on that?

Page 293

1 COFFEY, Q.C.:

2 Q. Yes.

3 DR. TORLAKOVIC:

4 A. I will do that. It's not actually difficult

5 to explain because that illustrates that more

6 than one method can lead to optimized result

7 as long as you know what is your target, what

8 is your goal, and this is the start point for

9 any standardization. You have to know the

10 goals before you try to standardize the

11 procedures. So even if you used all the same

12 procedures, maybe select one best procedure

13 that we think is best, and make it the

14 standard, the outcome may not be standard for

15 each of the labs. So my point would be that

16 my preference for standardization is

17 standardization of the results and expected

18 outcomes of the methods, not methods

19 themselves. By the way, in this process, we

20 end up doing less and less different methods,

21 and they appear to be more and more similar.

22 That is all right, or not, I really don't

23 think that emphasis should be put on methods

24 so much as it should be on the results.

25 COFFEY, Q.C.:

Page 294

1 Q. And getting the correct result?

2 DR. TORLAKOVIC:

3 A. Getting the correct result.

4 COFFEY, Q.C.:

5 Q. As often as possible.

6 DR. TORLAKOVIC:

7 A. Yes.

8 COFFEY, Q.C.:

9 Q. And, Doctor, one final point, if I might be

10 allowed just a little bit of latitude,

11 Commissioner, you did differentiate between

12 Run 2 and 3.

13 DR. TORLAKOVIC:

14 A. Yes.

15 COFFEY, Q.C.:

16 Q. And this is Run 3--well, the actually protocol

17 that was used at the time, and you do refer to

18 the fact that in Run 3, though, the results

19 were more--were not as -

20 DR. TORLAKOVIC:

21 A. Not as good.

22 COFFEY, Q.C.:

23 Q. And that you attributed to this low--you

24 utilized in Run 3, low expressors.

25 DR. TORLAKOVIC:

Page 295

1 A. Exactly. There was -

2 COFFEY, Q.C.:

3 Q. Which makes it more difficult?

4 DR. TORLAKOVIC:

5 A. This was designed to be very challenging. It

6 was not designed to reflect daily practice.

7 It was designed with the purpose to detect

8 deficiencies of the staining, even define

9 deficiencies of the staining systems.

10 COFFEY, Q.C.:

11 Q. And so assuming that generally the same

12 protocols were being utilized, you know,

13 generally, and I appreciate there were more

14 people involved in -

15 DR. TORLAKOVIC:

16 A. Yes, some people changed the protocols perhaps

17 little bit. But again, the same protocols

18 could have been used and then you would, yes,

19 you end up with more differences between the

20 labs.

21 COFFEY, Q.C.:

22 Q. Thank you, Commissioner. I appreciate it.

23 THE COMMISSIONER:

24 Q. Thank you very much, Doctor, for having come

25 and assisted us today. I'm sure everyone in

Page 296

1 the room joins me in saying how very much we

2 appreciate your contribution. People suggest

3 we take the afternoon break and then we'll

4 continue.

5 (BREAK)

6 MR. TERRY GULLIVER, EXAMINATION BY SANDRA CHAYTOR, Q.C.

7 (CONTINUED)

8 CHAYTOR, Q.C.:

9 Q. Good afternoon, Mr. Gulliver. Commissioner,

10 there's two new exhibits this afternoon that

11 I'd ask, please, to have entered. P-3038 and

12 P-3036?

13 THE COMMISSIONER:

14 Q. Entered.

15 EXHIBIT ENTERED AND MARKED P-3036.

16 EXHIBIT ENTERED AND MARKED P-3038.

17 CHAYTOR, Q.C.:

18 Q. And if we could bring up, please, Registrar,

19 P-0080? And this is again is a note from Dr.

20 Williams' notes, and it's dated August 20th,

21 2005. And at this point the key notes, key

22 points that he notes are that Mount Sinai is

23 to do all new cases. And secondly he says,

24 "Waiting for Ventana technical expert for

25 Canada to phone Terry Gulliver to arrange an

Page 297

1 early site visit." And thirdly, "Heather  
 2 Predham to start QI review process in the  
 3 a.m." And he goes on with the fourth point  
 4 being some results, it appears, from retests  
 5 that were done. Mr. Gulliver, the technical  
 6 expert from Ventana coming in, you were  
 7 involved, obviously, in arranging that. And  
 8 what was the purpose for that visit?  
 9 MR. GULLIVER:  
 10 A. The main purpose, Ms. Chaytor, was obviously  
 11 at this time when all of the discussions were,  
 12 you know, surrounding the ER/PR, there was  
 13 some concern expressed that we had been using  
 14 the Ventana system by this time, you know, for  
 15 almost a year and a half and there was some  
 16 question about are we getting more positives,  
 17 higher staining than we should expect. So we  
 18 felt it was important that we have the Ventana  
 19 technical expert come in to St. John's and do  
 20 a complete review of the Ventana system to  
 21 make sure it is operating as per the  
 22 specifications provided by the vendor.  
 23 CHAYTOR, Q.C.:  
 24 Q. And the third note here, "Heather Predham to  
 25 start QI review process in the a.m." what did

Page 298

1 you understand Ms. Predham was to do?  
 2 MR. GULLIVER:  
 3 A. I think Dr. Williams had asked Heather to, you  
 4 know, to go into the pathology laboratory, in  
 5 particular, IHC lab--I mean, from Heather's  
 6 portfolio and her role in the organization I  
 7 guess there's been many events in other parts  
 8 of the organization where she had done what  
 9 they call, I think, roots cause analysis and  
 10 those kinds of things. I think he asked Ms.  
 11 Predham to go to the lab and see if we could  
 12 start that kind of process.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay. And you ultimately, I take it, arranged  
 15 to have the Ventana expert come in. And what  
 16 was the result of that?  
 17 MR. GULLIVER:  
 18 A. Well, I made contact with Ventana. And in  
 19 Canada the person we dealt with who set the  
 20 instrumentation up originally, her name is  
 21 Carole, I think it's Quevillon out of, she's  
 22 based out of Quebec, and she came in and she  
 23 came in to, you know, review the whole Ventana  
 24 system.  
 25 CHAYTOR, Q.C.:

Page 299

1 Q. Okay, and if we could look, then, please, at  
 2 P-0552? And this is Ms. Quevillon's report to  
 3 you dated August 5th, 2005. And she writes,  
 4 "As per your request, I checked the Ventana  
 5 benchmark instruments, the procedure and  
 6 protocols used for the ER and PGR stains, the  
 7 knowledge and the capacity of the technicians  
 8 to troubleshoot and run the instrument." And  
 9 so in contacting her what was it--what did you  
 10 explain to her and what did--the issue to be  
 11 and what did you ask her to do?  
 12 MR. GULLIVER:  
 13 A. I didn't ask her to do anything specifically.  
 14 We just asked her to do a complete review of  
 15 the Ventana system to ensure everything is  
 16 operating properly.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. And she concludes that she feels  
 19 confident that the technicians knew what they  
 20 were doing. "They know how to use the  
 21 instruments and that the benchmark instruments  
 22 are staining as they should be." She did find  
 23 that the recommended maintenance procedures,  
 24 monthly and quarterly, were never done on the  
 25 instruments. And "We did it monthly and

Page 300

1 quarterly on one benchmark yesterday and they  
 2 are doing the second one today." So there was  
 3 an issue in terms of the recommended  
 4 maintenance being carried out, but otherwise -  
 5 MR. GULLIVER:  
 6 A. Yes.  
 7 CHAYTOR, Q.C.:  
 8 Q. - the system was in place?  
 9 MR. GULLIVER:  
 10 A. Yeah.  
 11 CHAYTOR, Q.C.:  
 12 Q. And upon receipt, then, of her report what did  
 13 you do?  
 14 MR. GULLIVER:  
 15 A. Well, I brought the report Dr. Williams. And  
 16 I think that Dr. Williams met with Carole  
 17 before she left.  
 18 CHAYTOR, Q.C.:  
 19 Q. Yes. And did you attend that meeting, as  
 20 well?  
 21 MR. GULLIVER:  
 22 A. Yes, I did.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. And was there anything different  
 25 discussed in the meeting than what we see in

Page 301

1 her report?

2 MR. GULLIVER:

3 A. I don't think so. I think she, you know,

4 verified in person to Dr. Williams that, you

5 know, the Ventana system that we had been

6 using since April, '04, it was operating as it

7 should. She validated some of the antibodies

8 on it, she looked at some of the slides, and

9 she said to Dr. Williams that our staff are

10 well trained. And I remember she made a point

11 saying that Mr. Dyer was one of the best

12 troubleshooters on the system she had

13 encountered. Because during the system being

14 set up originally, Ken Green, who was our sort

15 of lead tech in IHC and Barry Dyer had went to

16 Phoenix, Arizona for a week of sort of in-

17 depth training on the instrumentation and that

18 kind of stuff.

19 CHAYTOR, Q.C.:

20 Q. Yes. And so other than you and Dr. Williams,

21 did anyone else meet with her?

22 MR. GULLIVER:

23 A. Well, she obviously spent time with our

24 technologists. I mean, she was in the lab

25 with them physically doing the reviews and

Page 302

1 checks with them.

2 CHAYTOR, Q.C.:

3 Q. And did Dr. Cook attend the meeting with her?

4 MR. GULLIVER:

5 A. I think he did, Ms. Chaytor.

6 CHAYTOR, Q.C.:

7 Q. And did you communicate the results of her

8 review to anyone else?

9 MR. GULLIVER:

10 A. You mean other than Dr. Williams and Dr. Cook?

11 CHAYTOR, Q.C.:

12 Q. Yes.

13 MR. GULLIVER:

14 A. Well, I mean, obviously the pathology manager

15 and the technologists.

16 CHAYTOR, Q.C.:

17 Q. Yes. So, for example, the issue regarding the

18 recommendation for maintenance procedures to

19 be carried out, you communicated that to Mr.

20 Dyer, I would take it?

21 MR. GULLIVER:

22 A. Yes.

23 CHAYTOR, Q.C.:

24 Q. Okay. And that was attended to, was it?

25 MR. GULLIVER:

Page 303

1 A. To the best of my knowledge, yes, yeah.

2 CHAYTOR, Q.C.:

3 Q. If we could have, please, 0542? Mr. Gulliver,

4 did you inquire of Mr. Dyer as to why that

5 wasn't happening in any event, why they had

6 not been carrying out the recommended

7 maintenance schedules?

8 MR. GULLIVER:

9 A. I don't know if I asked Barry that directly.

10 I mean, I know I've been over in that part of

11 our laboratory in pathology, because I

12 remember seeing they have by the

13 instrumentation on the wall, there is a big

14 chart there where they tick off the

15 maintenance and those kinds of things. But,

16 no, I don't know if I asked Barry or not.

17 CHAYTOR, Q.C.:

18 Q. So you didn't ask, you didn't follow up with

19 that to find out -

20 MR. GULLIVER:

21 A. I don't remember if I did or not. I could

22 have and I could not have.

23 CHAYTOR, Q.C.:

24 Q. Then we have 0542 is a memo of Dr. Cook to all

25 pathologists and to yourself and Mr. Dyer

Page 304

1 dated August 2nd, 2005. And it indicates that

2 "Dr. Ejeckam is currently our resource person

3 for immunohistochemistry. All inquiries

4 regarding immunohistochemistry should be

5 referred to Dr. Ejeckam and in the event that

6 he's not available, then Dr. Fontaine." Mr.

7 Gulliver, was this discussed with you before

8 this memo was sent out?

9 MR. GULLIVER:

10 A. Yes, I do believe myself and Dr. Cook and Dr.

11 Ejeckam met in my office. It was just

12 basically Dr. Cook, you know, asking Dr.

13 Ejeckam, he had--by this time he had been in

14 our lab for two years and while he had been

15 performing in the role of our lead pathologist

16 for IHC part of our lab, it was never really

17 formalized.

18 CHAYTOR, Q.C.:

19 Q. So this was formalizing what, in fact, was -

20 MR. GULLIVER:

21 A. Pretty well, yes.

22 CHAYTOR, Q.C.:

23 Q. - the situation?

24 MR. GULLIVER:

25 A. Yeah.

Page 305

1 CHAYTOR, Q.C.:

2 Q. And telling it to all the pathologists in a

3 formal manner, I take it?

4 MR. GULLIVER:

5 A. Yes.

6 CHAYTOR, Q.C.:

7 Q. And in terms of the communications issues that

8 we spoke briefly on about in early on in your

9 evidence about technologists receiving

10 different advice from different individuals,

11 once this was done and the memo was sent out,

12 did that seem to make any improvement in the

13 communications issues that the technologists

14 were experiencing?

15 MR. GULLIVER:

16 A. I certainly think it made, I guess it made

17 improvements in several areas. It certainly

18 made improvement in from a technologist's

19 perspective. They were quite clear now that

20 Dr. Ejeckam has been officially appointed in

21 that role and that's who the technologists

22 would consult for advice or any issues. And

23 then the pathology manager, Mr. Dyer, would

24 know now Dr. Ejeckam is the lead pathologist.

25 I think the staff seen some overall

Page 306

1 improvement. I don't know if they seen, you

2 know, a full improvement in still the numbers

3 of pathologists that would make direct phone

4 calls to the lab and say I'd like this done

5 this way or a pathologist going into that part

6 of the lab, you know, physically and asking to

7 have something done this way or that way.

8 CHAYTOR, Q.C.:

9 Q. And is that something -

10 MR. GULLIVER:

11 A. But this was the beginnings of really

12 implementing that sort of direct line

13 communication.

14 CHAYTOR, Q.C.:

15 Q. So over time it's further improved, I take it?

16 MR. GULLIVER:

17 A. Yes.

18 CHAYTOR, Q.C.:

19 Q. And to the point now where Dr. Elms is in the

20 position and those lines of communication are

21 clear, everybody understands that any

22 questions about immunohistochemistry are

23 directed through Dr. Elms?

24 MR. GULLIVER:

25 A. Today?

Page 307

1 CHAYTOR, Q.C.:

2 Q. Yes.

3 MR. GULLIVER:

4 A. Yes.

5 CHAYTOR, Q.C.:

6 Q. If we could have, please, 0940? And this is

7 an e-mail from Heather Predham to Doctors Cook

8 and Williams and it's August 4th, 2005. And

9 it says, "Hi, just wanted to let you know that

10 I met the technical expert from Ventana this

11 a.m. with Terry and Barry. We went over the

12 issues and what we needed from her." So I

13 take it there was a meeting with Carole

14 Quevillon and yourself -

15 MR. GULLIVER:

16 A. I think I remember that Heather was in the

17 lab, actually. I think Heather had to be

18 there doing her thing that Dr. Williams asked

19 her to do, to do like a quality review.

20 CHAYTOR, Q.C.:

21 Q. Okay. And in terms of going over the issues

22 and what we needed from her, do you recall

23 what was discussed?

24 MR. GULLIVER:

25 A. Other than just the basic do a complete review

Page 308

1 of the system.

2 CHAYTOR, Q.C.:

3 Q. And it says, "Terry told her we would be

4 meeting with her tomorrow to hear her

5 assessment of our system. During our

6 conversation with her Terry questioned whether

7 the 58 cases that we retested were all

8 negatives or did they include weak positives,

9 as well. He had a feeling that Dr. Carter may

10 have included weak positives in this group

11 when the slides were pulled. If that is the

12 case, then we haven't had 41 out of 58 convert

13 and that was the reason we began questioning

14 the Ventana system. Barry is going to recheck

15 these cases to see if they were all negative.

16 He should know this by this afternoon."

17 What's that about, Mr. Gulliver?

18 MR. GULLIVER:

19 A. Oh, this is not discussion with the Ventana

20 person. This is Heather's e-mail, I guess,

21 telling Dr. Williams here's some of our

22 discussion yesterday afternoon. There was

23 some question about the original, the 2002

24 cases that were first identified, you knew the

25 index case from 2002, and there were three or

Page 309

1 four other patients that the oncologists  
 2 specifically asked Dr. Carter to review and  
 3 retest and then Dr. Carter did a broader  
 4 retest of the 2002 negatives. There was some  
 5 confusion over at that point in time were  
 6 those 58 cases all sort of like zero, zero  
 7 negatives or in that 58 cases were some of  
 8 those reported earlier as ten percent, 15  
 9 percent positive and were they retested.  
 10 CHAYTOR, Q.C.:  
 11 Q. And why did you--what difference would that  
 12 have made, why were you querying that?  
 13 MR. GULLIVER:  
 14 A. Oh, because, well, you see there they were  
 15 saying of the 58, 41 converted.  
 16 CHAYTOR, Q.C.:  
 17 Q. Um-hm.  
 18 MR. GULLIVER:  
 19 A. There was no assessment done to see of those  
 20 41 did they convert from zero, zero to  
 21 positive or did they convert from 15 percent  
 22 to 25 percent.  
 23 CHAYTOR, Q.C.:  
 24 Q. Now, were you of the understanding that the  
 25 PRs were also being looked at when you say

Page 310

1 zero, zero as opposed to -  
 2 MR. GULLIVER:  
 3 A. To my understanding, yes. But obviously the  
 4 ER was the main focus.  
 5 CHAYTOR, Q.C.:  
 6 Q. So your understanding at that point in time,  
 7 at least, was that the 58 cases were, you were  
 8 thinking they were zero, zero, zero ER and  
 9 zero PR?  
 10 MR. GULLIVER:  
 11 A. Yes.  
 12 CHAYTOR, Q.C.:  
 13 Q. And did you come to learn anything different  
 14 from that or was that, in fact, the case?  
 15 MR. GULLIVER:  
 16 A. I think it was later on that we learned, Ms.  
 17 Chaytor, that some of those 58, they weren't  
 18 all zero, zeros, like the true negatives.  
 19 CHAYTOR, Q.C.:  
 20 Q. And were they all zero ERs?  
 21 MR. GULLIVER:  
 22 A. I don't think so. And again, I can't swear to  
 23 you 100 percent, but I don't think so.  
 24 CHAYTOR, Q.C.:  
 25 Q. And it says, "As well, Barry will pull the

Page 311

1 cases tested between June 29th and November  
 2 1st to confirm that all results in that period  
 3 of time were negative." Now, is that the six-  
 4 month or thereabouts time period that you were  
 5 referring to that came up in the issue with  
 6 Dr. Carter on August 1st?  
 7 MR. GULLIVER:  
 8 A. I'm not sure exactly if that's the time frame.  
 9 I don't know if she means Barry will pull or  
 10 if we had already pulled.  
 11 CHAYTOR, Q.C.:  
 12 Q. Because this is now August 4th and I believe  
 13 you indicated that you did that immediately  
 14 the evening of August 1st?  
 15 MR. GULLIVER:  
 16 A. It was done--yeah. Well, I'd say within that  
 17 few-day period.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay.  
 20 MR. GULLIVER:  
 21 A. I couldn't tell you the exact day, time.  
 22 CHAYTOR, Q.C.:  
 23 Q. So this might be, in fact, that. Do you  
 24 recall any other period then for which Barry  
 25 would have checked a time period to see if

Page 312

1 they were -  
 2 MR. GULLIVER:  
 3 A. No.  
 4 CHAYTOR, Q.C.:  
 5 Q. - negative?  
 6 MR. GULLIVER:  
 7 A. No.  
 8 CHAYTOR, Q.C.:  
 9 Q. So this must be in reference to the issue  
 10 raised by Dr. Carter?  
 11 MR. GULLIVER:  
 12 A. In all likelihood. But what we did pull was  
 13 the whole year.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. "I'm at a meeting at St. Clare's this  
 16 afternoon. If you need me, page me. I had a  
 17 long chat with Barry and Terry after we got  
 18 the Ventana lady settled away .... Heather."  
 19 And what do you recall about that, having a  
 20 long chat with Barry and Terry, do you recall  
 21 what that would have been about?  
 22 MR. GULLIVER:  
 23 A. I don't remember anything in particular, no.  
 24 CHAYTOR, Q.C.:  
 25 Q. So this is August -

Page 313

1 MR. GULLIVER:  
 2 A. We spoke to Heather like almost every day,  
 3 sometimes three or four times a day. I can't  
 4 tell you -  
 5 CHAYTOR, Q.C.:  
 6 Q. This is August 4th and this is shortly after  
 7 the issue arose with Dr. Carter and she  
 8 resigned her position on August 2nd. Does  
 9 that help in any way indicate what it was that  
 10 you may have spoken with with Ms. Predham?  
 11 MR. GULLIVER:  
 12 A. I really don't believe I would speak to  
 13 Heather about, you know, what had just  
 14 transpired, you know, the couple of days  
 15 before with Dr. Carter.  
 16 CHAYTOR, Q.C.:  
 17 Q. Do you think it had anything then to do with  
 18 quality initiatives in the laboratory because  
 19 that certainly would be within her -  
 20 MR. GULLIVER:  
 21 A. I'm thinking that's more likely what the  
 22 conversation would be. I can't verify that  
 23 100 percent, but I know Dr. Williams had asked  
 24 her to do some kind of quality review. And I  
 25 think Heather does some kind of review and

Page 314

1 report. I think really what Heather tells Dr.  
 2 Williams is that, you know, this is so  
 3 technical that really it's out of her  
 4 experience level, type of thing. Understand,  
 5 I mean, you know, this is still within a few  
 6 weeks of all this issue starting, you know,  
 7 and people like Heather who now have been at  
 8 this for a long time were just really starting  
 9 to understand just laboratory in general.  
 10 CHAYTOR, Q.C.:  
 11 Q. If we could have, please, P-0941? This is  
 12 another e-mail from Ms. Predham, August 8th,  
 13 2005. And you're included in this. It's to  
 14 Doctors Williams, Cook, yourself and Ms.  
 15 Pilgrim. "Overall Database." She writes,  
 16 "I've got the lab database and NCRTF database  
 17 combined, but I still have issues to clarify.  
 18 There are data quality issues such as people  
 19 with the same name and address, different  
 20 MCPs" and she goes on from there. "Also,  
 21 there are a lot of individuals with incomplete  
 22 MCPs" and she's going to work on that. What  
 23 would the lab database be that she's referring  
 24 to here?  
 25 MR. GULLIVER:

Page 315

1 A. There was no database. It's, I think what  
 2 she's referring to is, you know, by this time  
 3 myself and Mr. Dyer, we have all the surgical  
 4 pathology reports that we had searched  
 5 Meditech for where we were going through then  
 6 a process of reviewing patients, making those  
 7 spreadsheets, what you refer to now as the  
 8 spreadsheets that actually Dr. Carter is the  
 9 one who created the spreadsheet. You know,  
 10 that's what we used when we took over doing  
 11 this project. And I think that's more to what  
 12 Heather is talking about.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay, so it would be the spreadsheets that -  
 15 MR. GULLIVER:  
 16 A. That's by this -  
 17 CHAYTOR, Q.C.:  
 18 Q. - Dr. Carter had started?  
 19 MR. GULLIVER:  
 20 A. - this is what we had done by this--well, Dr.  
 21 Carter didn't really start them. By this time  
 22 myself and Barry are doing them.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay, so that's what this would be referring  
 25 to?

Page 316

1 MR. GULLIVER:  
 2 A. I'm pretty sure, yeah.  
 3 CHAYTOR, Q.C.:  
 4 Q. The spreadsheet that you worked from in then  
 5 identifying the patients?  
 6 MR. GULLIVER:  
 7 A. Yeah.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. And she goes on to say, "There are a  
 10 couple of issues that have come to light"--  
 11 "that came to light, though, during this  
 12 process." And she says, "Rough numbers from  
 13 the combined database now show 4510 people  
 14 overall." Do you know where that number would  
 15 have come from?  
 16 MR. GULLIVER:  
 17 A. No idea.  
 18 CHAYTOR, Q.C.:  
 19 Q. How many people did you identify?  
 20 MR. GULLIVER:  
 21 A. Well -  
 22 CHAYTOR, Q.C.:  
 23 Q. Or approximately?  
 24 MR. GULLIVER:  
 25 A. Yeah. My search identified from 1997 up

Page 317

1 until, well, until we stopped testing in the  
 2 end of July of '05, it was like 2860, it was  
 3 roughly around that number that our lab  
 4 Meditech system had identified of the number  
 5 of specimens that were--had ER/PR testing  
 6 done.  
 7 CHAYTOR, Q.C.:  
 8 Q. So your number of about 2800 would have  
 9 included -  
 10 MR. GULLIVER:  
 11 A. All ER/PR tests that had tested -  
 12 CHAYTOR, Q.C.:  
 13 Q. - all ER/PR tests done -  
 14 MR. GULLIVER:  
 15 A. Breast primaries and non-breast primary.  
 16 CHAYTOR, Q.C.:  
 17 Q. Right, for whatever reason, all ER/PR tests  
 18 completed that you could pull off Meditech and  
 19 what you could pull off Meditech would include  
 20 which centres, which institutions?  
 21 MR. GULLIVER:  
 22 A. Those numbers included the specimens refer--as  
 23 you know, the Health Sciences was the only lab  
 24 in the province doing the testing, so we would  
 25 have received blocks, i.e. specimens that were

Page 318

1 already fixed and grossed and processed in  
 2 other labs, and sent them to the Health  
 3 Sciences for the ER/PR test, and there were  
 4 nine--at various times, there were as many as  
 5 nine pathology labs in the province. But when  
 6 the specimen came in to the pathology lab at  
 7 the Health Sciences, there would be a record  
 8 into our Meditech system that we received a  
 9 block on patient so and so from Gander or  
 10 Grand Falls or Corner Brook. We did an ER/PR  
 11 test and it was sent back then for  
 12 interpretation. But we had that level of  
 13 documentation. So my numbers would have  
 14 included any patient from around the province  
 15 that had an ER/PR test ordered in our system.  
 16 CHAYTOR, Q.C.:  
 17 Q. From 1997 up through to 2005?  
 18 MR. GULLIVER:  
 19 A. Yeah.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. So you're not able to say what the  
 22 4500--we'll have to ask, I guess, Ms. Predham  
 23 about that. "The Cancer Registry does not  
 24 identify almost 2100 of individuals who had  
 25 ER/PR testing. Current status, living or

Page 319

1 deceased, is only identified in 1245 of those  
 2 people. ER/PR status is indicated in 1230  
 3 people with an overall ER positivity rate of  
 4 55 percent" and -  
 5 MR. GULLIVER:  
 6 A. And all those numbers, Ms. Chaytor, are not  
 7 from the lab data.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay.  
 10 MR. GULLIVER:  
 11 A. This is the information she's getting at this  
 12 time, information getting back from the Cancer  
 13 Registry.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. So then these numbers that we see here,  
 16 because you were working of course on  
 17 positivity rates yourself -  
 18 MR. GULLIVER:  
 19 A. Yes.  
 20 CHAYTOR, Q.C.:  
 21 Q. - overall ER positivity by year, and she says  
 22 "and remember, this is rough" and she gives  
 23 "2003, 61 percent. 2002, 48. 2001, 46. The  
 24 Cancer Registry only indicates P and negative  
 25 or positive and negative, not percentage." So

Page 320

1 you're saying that's not your figures.  
 2 MR. GULLIVER:  
 3 A. No.  
 4 CHAYTOR, Q.C.:  
 5 Q. That must be coming from the Cancer Registry.  
 6 MR. GULLIVER:  
 7 A. I had nothing to do with that.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay, and at the time then that you received  
 10 the e-mail, did it catch your attention, the  
 11 difference in those figures as compared to  
 12 what your data was indicating?  
 13 MR. GULLIVER:  
 14 A. Oh, I was certainly well aware, and that's  
 15 why--read the next sentence, where Heather  
 16 says now she's "going to pick up from Terry  
 17 the spreadsheets that he and Barry worked on  
 18 over the weekend and incorporate this  
 19 information as well."  
 20 CHAYTOR, Q.C.:  
 21 Q. Yes. So then, did you discuss this issue with  
 22 her and the discrepancy in the positivity  
 23 rate?  
 24 MR. GULLIVER:  
 25 A. I don't remember specifically. I'm sure we



Page 321

1 had just basic general conversation about it,  
 2 and I know that Heather would have--was saying  
 3 to us that, you know, information she's able  
 4 to gather from the Cancer Registry side, you  
 5 know, wasn't complete information. Again, she  
 6 identified there that they had 4,500 people  
 7 and 2,100 didn't have ER/PR testing. I think  
 8 the Registry just registered patients who had  
 9 like a breast specimen done and not  
 10 specifically patients who were positive for  
 11 cancer and had ER/PR testing done. There was  
 12 a big debate over that also.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay, and if we could look, please, at P-2375?  
 15 And this, Mr. Gulliver, I believe to be a copy  
 16 of one of the spreadsheets. Is that right?  
 17 MR. GULLIVER:  
 18 A. Yeah.  
 19 CHAYTOR, Q.C.:  
 20 Q. And this is indicated to be in 2002. So this  
 21 is the type--this is the spreadsheet that you  
 22 and Mr. Dyer used in going through the  
 23 pathology reports?  
 24 MR. GULLIVER:  
 25 A. Yeah, and Dr. Carter actually had--this was

Page 322

1 her original intent when she was going to do  
 2 the review of the patients, and we just took  
 3 it from her.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay, and so she's the one who came up with  
 6 the headings, I take it, surgical number and  
 7 MCP number, hospital of origin?  
 8 MR. GULLIVER:  
 9 A. Yeah.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, and the printing on this, is this your  
 12 writing?  
 13 MR. GULLIVER:  
 14 A. That's actually not my writing. That's Mr.  
 15 Dyer's.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay. We see over, and then up on top, the  
 18 total tested, those numbers, is that your  
 19 writing?  
 20 MR. GULLIVER:  
 21 A. That's my writing, yeah.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay. So you've got 2002, total tested 189;  
 24 negative, negative, 48; and is this weak  
 25 positive?

Page 323

1 MR. GULLIVER:  
 2 A. Yeah.  
 3 CHAYTOR, Q.C.:  
 4 Q. Less or greater than ten percent ER, what does  
 5 this say? What does this tell us?  
 6 MR. GULLIVER:  
 7 A. 30.  
 8 CHAYTOR, Q.C.:  
 9 Q. So weak positive, you're calling what?  
 10 MR. GULLIVER:  
 11 A. The ones that are positive but didn't meet the  
 12 clinical threshold.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay. So weak positive, and what does it mean  
 15 that you've got in brackets, greater than ten  
 16 percent ER, and then the number?  
 17 MR. GULLIVER:  
 18 A. That probably should be just a written--that  
 19 should be less than probably.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay, and there were 30 of those cases you're  
 22 saying?  
 23 MR. GULLIVER:  
 24 A. Yeah.  
 25 CHAYTOR, Q.C.:

Page 324

1 Q. And 48 negative, negative?  
 2 MR. GULLIVER:  
 3 A. Zero, zeroes.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay, and those are the ones to be repeated,  
 6 you're indicating?  
 7 MR. GULLIVER:  
 8 A. Retested, yeah.  
 9 CHAYTOR, Q.C.:  
 10 Q. Out of the entire -  
 11 MR. GULLIVER:  
 12 A. Of the 189 though, Ms. Chaytor -  
 13 CHAYTOR, Q.C.:  
 14 Q. 189 would include the positives too, I take  
 15 it, is that right?  
 16 MR. GULLIVER:  
 17 A. Yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. Yes.  
 20 MR. GULLIVER:  
 21 A. And these are--understand now that in our  
 22 Meditech system, in reading all the  
 23 pathologists reports and identifying patients  
 24 and putting them on the spreadsheets, we could  
 25 only spreadsheet patients that were tested and

Page 325

1 interpreted in St. John's.  
 2 CHAYTOR, Q.C.:  
 3 Q. Right.  
 4 MR. GULLIVER:  
 5 A. While we did have a list, another list  
 6 generated of out-of-town specimens with no  
 7 interpretation. So the numbers you see on  
 8 top, that 189, would be--reflect the sort of  
 9 St. John's Health Care Corporation patients.  
 10 CHAYTOR, Q.C.:  
 11 Q. So this 189 is just St. John's?  
 12 MR. GULLIVER:  
 13 A. Right. We're doing our St. John's -  
 14 CHAYTOR, Q.C.:  
 15 Q. St. John's area hospitals.  
 16 MR. GULLIVER:  
 17 A. - we're doing the St. John's patients and St.  
 18 John's sheets during this time.  
 19 CHAYTOR, Q.C.:  
 20 Q. So the ones you have results on?  
 21 MR. GULLIVER:  
 22 A. Yeah.  
 23 CHAYTOR, Q.C.:  
 24 Q. And even though you would have had a stack of  
 25 pathology reports or not--a stack of Meditech

Page 326

1 records -  
 2 MR. GULLIVER:  
 3 A. What we call out of town.  
 4 CHAYTOR, Q.C.:  
 5 Q. Yes, which included the out-of-towns, but you  
 6 wouldn't have had the results for those?  
 7 MR. GULLIVER:  
 8 A. No.  
 9 CHAYTOR, Q.C.:  
 10 Q. I guess except for the period of time when Dr.  
 11 Khalifa was doing the reporting?  
 12 MR. GULLIVER:  
 13 A. Well, '97 would be a bit different, because in  
 14 '97, where Dr. Khalifa was doing pretty well  
 15 most of the reporting or all reporting for the  
 16 province, in our Meditech system, we did have  
 17 both the test documentation and we had the  
 18 patients interpretation as provided by Dr.  
 19 Khalifa.  
 20 CHAYTOR, Q.C.:  
 21 Q. What did you call negative, negative? What  
 22 did you define as being -  
 23 MR. GULLIVER:  
 24 A. Zero, zero. What you see here, see the  
 25 negative, negative?

Page 327

1 CHAYTOR, Q.C.:  
 2 Q. Yes.  
 3 MR. GULLIVER:  
 4 A. What we logged in here, see ER/PR?  
 5 CHAYTOR, Q.C.:  
 6 Q. Yes.  
 7 MR. GULLIVER:  
 8 A. Whatever the original report said is what we  
 9 put in there. So that stroke minus, minus, is  
 10 like zero, zero, negative, negative.  
 11 CHAYTOR, Q.C.:  
 12 Q. Yes.  
 13 MR. GULLIVER:  
 14 A. But they would be all zero, zero.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, and so then you call weak positives  
 17 anything, and this you're saying should be  
 18 less than ten percent?  
 19 MR. GULLIVER:  
 20 A. Right, and actually, when we did all these  
 21 here, we kind of erred on the side of caution  
 22 that any patient that we thought could even be  
 23 on the borderline, we put them on--this is--  
 24 you probably got all the sheets for '02?  
 25 CHAYTOR, Q.C.:

Page 328

1 Q. Okay, yes, the next page then.  
 2 MR. GULLIVER:  
 3 A. If you continue on.  
 4 CHAYTOR, Q.C.:  
 5 Q. We have the next page, and again -  
 6 MR. GULLIVER:  
 7 A. Right, and you see what's--and you see this  
 8 next line, controls and original?  
 9 CHAYTOR, Q.C.:  
 10 Q. Yes.  
 11 MR. GULLIVER:  
 12 A. This is if we actually read in the  
 13 pathologists interpretation that they said in  
 14 their report positive controls were viewed.  
 15 We made a notation of the times that was  
 16 documented in the pathologist's report. But  
 17 these are all the zero zeros, the negative,  
 18 negatives.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. Then the next page then, so page three.  
 21 MR. GULLIVER:  
 22 A. Again, all negative negatives.  
 23 CHAYTOR, Q.C.:  
 24 Q. And page four is all negative negatives?  
 25 MR. GULLIVER:

Page 329

1 A. Yeah.  
 2 CHAYTOR, Q.C.:  
 3 Q. And page five?  
 4 MR. GULLIVER:  
 5 A. And then that would be the end of the negative  
 6 negatives for '02.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay.  
 9 MR. GULLIVER:  
 10 A. Then we started new sheets where anybody  
 11 reading reports that we thought could be  
 12 debatable, to have them reviewed then after,  
 13 once the sheets were done. So you see that  
 14 first patient there, it was zero for ER, 20-25  
 15 for PR.  
 16 CHAYTOR, Q.C.:  
 17 Q. Right, okay.  
 18 MR. GULLIVER:  
 19 A. And even though we had, you know, some  
 20 oncologists had said well--some had said we  
 21 would still treat somebody if they had a 40 or  
 22 50 percent PR but negative ER, that still  
 23 wasn't sure and it wasn't standard. So we  
 24 just put anybody that could be possibly  
 25 reviewed on those next set of sheets. All the

Page 330

1 zero, zeros were a guarantee retest.  
 2 CHAYTOR, Q.C.:  
 3 Q. And did you understand that it was standard  
 4 and it was firm that if somebody was -  
 5 MR. GULLIVER:  
 6 A. Zero for ER -  
 7 CHAYTOR, Q.C.:  
 8 Q. - over ten percent ER, after January 1st, 2001  
 9 -  
 10 MR. GULLIVER:  
 11 A. 2001.  
 12 CHAYTOR, Q.C.:  
 13 Q. - that they would have been treated?  
 14 MR. GULLIVER:  
 15 A. That's what we were told, but you will see  
 16 lots of cases where even after the 2001, if  
 17 the report said even like 10 to 15 percent, we  
 18 put them on the list to be reviewed.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, and what about beyond 15 percent? What  
 21 about the patient who was, say, 20 percent in  
 22 March of 2002, did she end up on your  
 23 spreadsheet?  
 24 MR. GULLIVER:  
 25 A. If it was 20 percent ER, no. No, they didn't.

Page 331

1 CHAYTOR, Q.C.:  
 2 Q. So you used a bit of discretion and said 10 to  
 3 15 percent?  
 4 MR. GULLIVER:  
 5 A. Yeah.  
 6 CHAYTOR, Q.C.:  
 7 Q. And that was just on your initiative, as  
 8 opposed to anything told to you by the  
 9 physicians?  
 10 MR. GULLIVER:  
 11 A. No, I--no, myself and Dr. Cook had talked  
 12 about it.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay.  
 15 MR. GULLIVER:  
 16 A. And we just both decided, "look, anything--  
 17 anything even close to the cut offs, put them  
 18 on the list so we can review them."  
 19 CHAYTOR, Q.C.:  
 20 Q. And close to the cut off, you interpreted as  
 21 being about a five percent difference?  
 22 MR. GULLIVER:  
 23 A. Around five to ten. Sometimes it said 10 to  
 24 20 percent, and we would put them on the list.  
 25 CHAYTOR, Q.C.:

Page 332

1 Q. Well then that's what I was wondering. What  
 2 about the woman who was 20 percent ER?  
 3 MR. GULLIVER:  
 4 A. But if someone said just 20 percent, there was  
 5 no ten percent, you know what I mean?  
 6 MR. SIMMONS:  
 7 Q. I think there's probably a bit of confusion  
 8 here. I think Mr. Gulliver is referring to -  
 9 THE COMMISSIONER:  
 10 Q. It's clear between the difference between a  
 11 number and a range.  
 12 MR. SIMMONS:  
 13 Q. - a pathology report. I think Mr. Gulliver is  
 14 referring to a pathology report when the  
 15 report is 10 to 15 percent on this one report.  
 16 CHAYTOR, Q.C.:  
 17 Q. Yes.  
 18 THE COMMISSIONER:  
 19 Q. Yes. I don't think there's any confusion.  
 20 MR. SIMMONS:  
 21 Q. Sorry.  
 22 CHAYTOR, Q.C.:  
 23 Q. I didn't think I was confused.  
 24 MR. GULLIVER:  
 25 A. I don't know.

Page 333

1 THE COMMISSIONER:  
 2 Q. Mr. Gulliver is indicating that if it  
 3 specifically said 20, he treated it as 20, and  
 4 that wasn't in a--that wasn't doubtful.  
 5 MR. GULLIVER:  
 6 A. It wasn't from a range, yes.  
 7 CHAYTOR, Q.C.:  
 8 Q. Right.  
 9 THE COMMISSIONER:  
 10 Q. But if you put in 10 to 15, he didn't know  
 11 whether it was on the 10 end or -  
 12 MR. GULLIVER:  
 13 A. Or 10 to 20, yes.  
 14 THE COMMISSIONER:  
 15 Q. - on the 15 end, so that was doubtful.  
 16 CHAYTOR, Q.C.:  
 17 Q. Right.  
 18 MR. GULLIVER:  
 19 A. You see one here, Ms. Chaytor, it says 15 and  
 20 20 percent.  
 21 CHAYTOR, Q.C.:  
 22 Q. Yes, that's right. So 15 to 20 percent, you  
 23 considered that 15 and so you included it?  
 24 MR. GULLIVER:  
 25 A. Right.

Page 334

1 CHAYTOR, Q.C.:  
 2 Q. Right, yes, okay, all right. We're all good.  
 3 MR. GULLIVER:  
 4 A. And you can see that one is crossed off.  
 5 BROWNE, Q.C.:  
 6 Q. Commissioner is (inaudible).  
 7 THE COMMISSIONER:  
 8 Q. Pardon?  
 9 BROWNE, Q.C.:  
 10 Q. (Inaudible).  
 11 THE COMMISSIONER:  
 12 Q. Is that what it is? No, I just might be  
 13 months of being back there, Mr. Browne.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. So one moment, please.  
 16 THE COMMISSIONER:  
 17 Q. Mr. Gulliver, I'm taking these things  
 18 literally, because the little dash you're  
 19 saying is zero, but I'm assuming that if it's-  
 20 -either it said zero or said negative only on  
 21 your report?  
 22 MR. GULLIVER:  
 23 A. Yes, you're correct.  
 24 THE COMMISSIONER:  
 25 Q. And if there was a percentage at all, you put

Page 335

1 that percentage in?  
 2 MR. GULLIVER:  
 3 A. Yes.  
 4 THE COMMISSIONER:  
 5 Q. Okay.  
 6 MR. GULLIVER:  
 7 A. And sometimes, Judge Cameron, the report might  
 8 have said WP for weak positive. If it said  
 9 WP, we wrote WP on the sheet.  
 10 THE COMMISSIONER:  
 11 Q. Okay, all right.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay, so for an example, the one here that  
 14 we're looking--that you just pointed to, Mr.  
 15 Gulliver, where it was 15 to 20, and then it's  
 16 crossed off. Why was that person crossed off?  
 17 MR. GULLIVER:  
 18 A. All the ones you see--once we got to the stage  
 19 where the spreadsheets were done for each year  
 20 and any patients that were questionable, I  
 21 brought them to Dr. Cook's attention. So he  
 22 would speak to the oncologists. I think what  
 23 they did, Ms. Chaytor, is just verified if  
 24 that person--like that 15 to 20 percent  
 25 person, did that person receive therapy back

Page 336

1 in 2002? If they did receive therapy, then  
 2 they weren't sent for retesting.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay.  
 5 MR. GULLIVER:  
 6 A. So that's the kind of verification went  
 7 through, but the ones--when we got ready to  
 8 send them all off in these batches, Heather  
 9 Predham was working with the Cancer Centre and  
 10 she provided to us the list of patients who  
 11 had already passed away, and our first focus  
 12 was the patients who were still living, and  
 13 all the ones you see with a cross marked going  
 14 through and see deceased written over on the  
 15 end?  
 16 CHAYTOR, Q.C.:  
 17 Q. Yes, so this patient was crossed off because  
 18 you had determined -  
 19 MR. GULLIVER:  
 20 A. They were crossed off -  
 21 CHAYTOR, Q.C.:  
 22 Q. - she was deceased?  
 23 MR. GULLIVER:  
 24 A. - at that time, yes, at that time.  
 25 CHAYTOR, Q.C.:

Page 337

1 Q. Based on the list that Ms. Predham gave you?

2 MR. GULLIVER:

3 A. Right, and as you know, all the deceased

4 patients went together as one batch later on,

5 after all the living patients in town and out

6 of town were retested.

7 CHAYTOR, Q.C.:

8 Q. So you, for your purposes, you put everyone on

9 there and you understood anyone who was ten

10 percent or greater -

11 MR. GULLIVER:

12 A. And 30 percent or less up to 2001.

13 CHAYTOR, Q.C.:

14 Q. Right, up to 2001, and then after 2001, ten

15 percent or greater, and you put in a little

16 bit of a buffer, in terms of after your

17 discussions with Dr. Cook, that well, let's

18 have some leeway, anyone close to the cut off.

19 MR. GULLIVER:

20 A. Yeah.

21 CHAYTOR, Q.C.:

22 Q. So if you saw 15 to 20 percent, you put that

23 person in. But someone who was just 20

24 percent ER, that person wouldn't have gone on

25 your spreadsheet?

Page 338

1 MR. GULLIVER:

2 A. I don't--I don't think so. If it was 20

3 percent ER and negative PR, I might have put

4 it on the sheet just to make sure.

5 CHAYTOR, Q.C.:

6 Q. Okay. So you used some discretion yourself in

7 terms of coming up with who should go on your

8 spreadsheet, and then you understood there was

9 going to be a further vetting after you passed

10 in your spreadsheet and that people who had

11 already been treated, that would be

12 determined, and those people would also not be

13 sent for retesting?

14 MR. GULLIVER:

15 A. Well, Dr. Cook then reviewed those particular

16 patients and reports.

17 CHAYTOR, Q.C.:

18 Q. And so you understood they wouldn't be sent?

19 Or the intent was not to send them if they'd

20 already been -

21 MR. GULLIVER:

22 A. If they already had received treatment, yes.

23 CHAYTOR, Q.C.:

24 Q. Okay, and did you ever learn anything

25 different from that?

Page 339

1 MR. GULLIVER:

2 A. No, not to my knowledge, no.

3 CHAYTOR, Q.C.:

4 Q. Okay. So the fact that people who had

5 received treatment were in fact sent for

6 retesting, you weren't aware of that?

7 MR. GULLIVER:

8 A. No.

9 CHAYTOR, Q.C.:

10 Q. Okay, and -

11 MR. GULLIVER:

12 A. Now again, you know, the other labs outside of

13 St. John's who were doing, I guess, a similar

14 kind of review, you know, I don't know if they

15 were doing the exact same thing that myself

16 and Barry were doing. Again, if they had a

17 questionable patient, I'm assuming they

18 contacted the oncologist or the pathologist,

19 spoke to the oncologist and made a

20 determination at that point in time.

21 CHAYTOR, Q.C.:

22 Q. Okay, and Mr. Gulliver, who gave you the

23 criteria by which you were to search? Whose

24 decision, I guess, was it to say ten percent

25 from January 1st, 2001 and 30 percent before

Page 340

1 that? Who gave you that criteria?

2 MR. GULLIVER:

3 A. At one of these meetings, you know, we've

4 seen. You've seen lots of them.

5 CHAYTOR, Q.C.:

6 Q. Yes.

7 MR. GULLIVER:

8 A. At one of the meetings where it was a meeting

9 with the oncologists were there, you know,

10 Kara Laing was there, Joy McCarthy was there,

11 and I think that one too, I think Dr. Kwan was

12 at that one, and I guess to go back to the

13 beginning, there actually originally, there is

14 debate about who should identify the patients

15 over this time frame that required retesting.

16 That was the first decision, of who should

17 actually do all this process and all this

18 work. You know, I had indicated to the

19 oncologists, pathologists, Dr. Williams, that

20 you know, originally when the decision was

21 made to retest patients, you know, I had told

22 them that, you know, lab practice is that we

23 keep patients blocks and slides for 20 years.

24 So that we actually do have the capability to

25 go back and retest. Of course, the next step

Page 341

1 is then who are you going to retest? And that  
 2 was a debate and a decision that was made at  
 3 one of those meetings.  
 4 It was my viewpoint originally that the  
 5 oncologists were working--by this time, were  
 6 working with Dr. Carter and Dr. Cook. The  
 7 oncologists were pretty well reviewing  
 8 patients and picking out key patients and  
 9 giving them to Dr. Carter and Dr. Cook and  
 10 they were being done as a consult, as a  
 11 retest, and that was my first opinion, well,  
 12 the oncologist should go and review all their  
 13 patients, whether it meant reviewing clinical  
 14 charts or I had no idea what computer records  
 15 the Cancer Clinic kept, and I thought that  
 16 would be the best method to--for them to  
 17 review their own patients and then give us a  
 18 list by year of who they felt should be  
 19 retested.  
 20 But Dr. Kara Laing said that, you know,  
 21 the computer systems at the Cancer Clinic, you  
 22 know, they weren't up to date. There were  
 23 oncologists who had come and gone. You'd have  
 24 to go and read every single patient's clinical  
 25 chart, and this was--time was of the essence,

Page 342

1 type of thing, and you know, I had--and they  
 2 asked, "well, how would the lab do it?" and I  
 3 said that well, the lab does keep a computer  
 4 record on Meditech of every patient that comes  
 5 in for an ER/PR test. So everyone pretty well  
 6 agreed that that was probably the most  
 7 complete way and probably the quickest way to  
 8 be able to identify patients who had an ER/PR  
 9 test done, and in that discussion, the  
 10 guidelines that were given to me by the  
 11 oncologists and everyone in the room was  
 12 there, was that, you know, the 30 percent cut  
 13 off and the ten percent cut off time line.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay, and so the oncologists set those  
 16 parameters?  
 17 MR. GULLIVER:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. Was there any oncologists in attendance who  
 21 disagreed with the parameters or said that his  
 22 or her practice was different than that?  
 23 MR. GULLIVER:  
 24 A. I know, and that's why I remember Dr. Kwan was  
 25 there, because Dr. Kwan had made a statement.

Page 343

1 He said that he has treated people with--who  
 2 were zero, zeros, depending on the age of the  
 3 woman, the clinical history and other factors,  
 4 and yes, that was stated at that meeting.  
 5 CHAYTOR, Q.C.:  
 6 Q. And was there anything--was Dr. Alidina there  
 7 or did he have any opinion?  
 8 MR. GULLIVER:  
 9 A. Who?  
 10 CHAYTOR, Q.C.:  
 11 Q. Is it Alidina? No? Okay.  
 12 MR. GULLIVER:  
 13 A. No.  
 14 CHAYTOR, Q.C.:  
 15 Q. So Dr. Kwan indicated he had treated people  
 16 zero, zero?  
 17 MR. GULLIVER:  
 18 A. That's why I remember him being there, because  
 19 he actually made that statement.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay.  
 22 MR. GULLIVER:  
 23 A. And there was also some discussion, you know,  
 24 other oncologists said that if it was a  
 25 negative ER but a high positive PR, they

Page 344

1 looked at the hormone receptor in total.  
 2 Others, I think, said that we're practising at  
 3 strictly with the cut offs. So that's how the  
 4 decision was made to, well, we should apply  
 5 the 30 percent, 10 percent rule.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and so in terms of how far then to go  
 8 back, and to start at 1997, who decided that?  
 9 Whose decision was that?  
 10 MR. GULLIVER:  
 11 A. I don't think that was decided first, Ms.  
 12 Chaytor. In that discussion, this is 2005, I  
 13 think it was Dr. Laing, you know, who pretty  
 14 well, I mean, she's the oncologist expert.  
 15 She was the one that said that, you know,  
 16 literature shows and clinical trials show that  
 17 women who had not had hormonal therapy, even  
 18 if it's four or five years that's gone by,  
 19 they can still be helped by giving them  
 20 hormonal therapy. So the original thing was  
 21 looking over a five-year period and it was  
 22 just pretty well decided--I said well--and  
 23 they actually asked a combination of when did  
 24 we start doing ER/PR testing by IHC method,  
 25 and then they asked would we have blocks even

Page 345

1 back to the testing even began. Of course,  
 2 the answer was yes, because we keep them for  
 3 20 years, patient records. And the decision  
 4 was to do--start with the current year, you  
 5 know, in trying to assess who should we do  
 6 first. It was start with the most current  
 7 patients and work back. So that's why you  
 8 might see some of my stats didn't include '97,  
 9 '98 and '99.

10 CHAYTOR, Q.C.:  
 11 Q. Yes, you add to that as time went on.

12 MR. GULLIVER:  
 13 A. We did 2000 and 2004. So we got current, that  
 14 five-year group of patients done first.

15 CHAYTOR, Q.C.:  
 16 Q. Uh-hm.

17 MR. GULLIVER:  
 18 A. And then went back and started the patients  
 19 from '97,'98, and '99.

20 CHAYTOR, Q.C.:  
 21 Q. And you could have gone back, I guess, even  
 22 beyond that, but the decision, I take it, was  
 23 made to start with IHC testing?

24 MR. GULLIVER:  
 25 A. Well, we couldn't go back beyond that.

Page 346

1 CHAYTOR, Q.C.:  
 2 Q. You had blocks beyond that. So if you wanted  
 3 to test, for example, people who had had their  
 4 test done by way of the biochemical method,  
 5 there were blocks available that you could  
 6 have done that?

7 MR. GULLIVER:  
 8 A. Not really, no.

9 CHAYTOR, Q.C.:  
 10 Q. Why not?

11 MR. GULLIVER:  
 12 A. Well, when the biochemical method was being  
 13 performed in biochemistry--again it's not my  
 14 area of expertise, but I do know a little bit  
 15 about it, that that methodology meant that--at  
 16 that time, if you--if a woman found--if there  
 17 was a lump in a woman's breast, in the old  
 18 methodology, the surgeon had to do an invasive  
 19 procedure and remove part of that lump, which  
 20 hopefully included the tumour. That tumour  
 21 then was submitted to the biochemistry lab.  
 22 That tissue was snap frozen in liquid nitrogen  
 23 and it was stored for a period of days and  
 24 weeks, and then it was unthawed and you put it  
 25 into a bowl, like a crucible, you added

Page 347

1 solutions to it and you mashed it all up.

2 CHAYTOR, Q.C.:  
 3 Q. Yes.

4 MR. GULLIVER:  
 5 A. And then you try to measure how much  
 6 supernatant came out of the tissue. When that  
 7 was done, the tumour tissue then is gone.

8 CHAYTOR, Q.C.:  
 9 Q. Right, so you didn't have -

10 MR. GULLIVER:  
 11 A. And this methodology, it was more--now you can  
 12 do an non-invasive procedure and do a biopsy  
 13 of the lump and send it for IHC. So it was a  
 14 different--whole different.

15 CHAYTOR, Q.C.:  
 16 Q. So unless you had other -

17 MR. GULLIVER:  
 18 A. Unless you had other tumours and stuff there.

19 CHAYTOR, Q.C.:  
 20 Q. If all of the tumour was used -

21 MR. GULLIVER:  
 22 A. Yes.

23 CHAYTOR, Q.C.:  
 24 Q. If all the tumour was used up in that process,  
 25 you wouldn't have it?

Page 348

1 MR. GULLIVER:  
 2 A. Right.

3 CHAYTOR, Q.C.:  
 4 Q. So it would only be for any patient that there  
 5 was additional tumour and tissue available,  
 6 for example, if the patient had a mastectomy  
 7 and only part of their tumour had been used?

8 MR. GULLIVER:  
 9 A. Right.

10 CHAYTOR, Q.C.:  
 11 Q. Okay. So the decision was made to go back to  
 12 1997 and that's when the IHC method had begun?

13 MR. GULLIVER:  
 14 A. Right.

15 CHAYTOR, Q.C.:  
 16 Q. Okay. Then if we just continue on here with  
 17 your 2002 records--I think that might actually  
 18 be your--no, it's another page. Then on page  
 19 eight of this exhibit, P-2375, we'll see  
 20 there's some here where you write in again 10  
 21 to 20. Those are, I think, Dr. Cooks records  
 22 of the same. So if we go back then -

23 MR. GULLIVER:  
 24 A. Well, I guess once these sheets were finalized  
 25 and any patients that were in question that we

Page 349

1 spoke to Dr. Cook about, the next step was the  
 2 time consuming process then to go and retrieve  
 3 all these original blocks and slides from the  
 4 filing cabinets.  
 5 CHAYTOR, Q.C.:  
 6 Q. Yes, and I'm going to ask you about that.  
 7 First of all, though, before we leave the  
 8 exhibit, this "reviewed May '07", is that your  
 9 handwriting?  
 10 MR. GULLIVER:  
 11 A. That's my writing, yes.  
 12 CHAYTOR, Q.C.:  
 13 Q. And why--what does that indicate, what  
 14 happened in May of 2007?  
 15 MR. GULLIVER:  
 16 A. I think I reviewed those, Ms. Chaytor, just to  
 17 verify the exact numbers. I think there were  
 18 some questions coming from Heather and Susan  
 19 Bonnell about what was the exact number of  
 20 patients that were sent for retesting and  
 21 those kinds of things, and I think these are  
 22 reviewed again another time through the NLCHI  
 23 process.  
 24 CHAYTOR, Q.C.:  
 25 Q. Yes. So in May of '07, it was Ms. Predham and

Page 350

1 Ms. Bonnell who asked you about exact numbers.  
 2 So your review at that time was just to count  
 3 up what you put on your spreadsheets, is that  
 4 what happened?  
 5 MR. GULLIVER:  
 6 A. Yes. Oh, yeah, it wasn't recheck patients, if  
 7 they were sent or not sent.  
 8 CHAYTOR, Q.C.:  
 9 Q. So you weren't checking names -  
 10 MR. GULLIVER:  
 11 A. Right.  
 12 CHAYTOR, Q.C.:  
 13 Q. To see if there was a patient on your list  
 14 that--was or wasn't on your list?  
 15 MR. GULLIVER:  
 16 A. It wasn't a cross-reference. It was verifying  
 17 the numbers because people were worried about  
 18 the numbers, the numbers.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, all right. Well, then tell the  
 21 Commissioner about how you went about then,  
 22 first of all, identifying all the  
 23 approximately 2800 people who had had ER/PR  
 24 tests, and then you've told us how then you  
 25 reviewed to try and figure out who would end

Page 351

1 up on your spreadsheet. So what did you have  
 2 to do? After finding out there was 2800  
 3 approximately people who had the test--you  
 4 wouldn't have had, obviously, pathology  
 5 reports on all those people?  
 6 MR. GULLIVER:  
 7 A. No.  
 8 CHAYTOR, Q.C.:  
 9 Q. Because you wouldn't have the out of town  
 10 people. So what did you next have to do in  
 11 order to end up with people to put on your  
 12 spreadsheet?  
 13 MR. GULLIVER:  
 14 A. Well, I guess, I mean, what I did, in the  
 15 Meditech hospital system there is a separate  
 16 laboratory information system, and within  
 17 that, there is a separate anatomical pathology  
 18 module, and the pathology module actually has  
 19 a fair bit--has more search capabilities than  
 20 all the other lab modules in the system. So  
 21 what I did, I went in by year and did a search  
 22 on Meditech and I asked the computer system  
 23 could you please identify every patient who  
 24 had an ER or PR procedure performed. From  
 25 that, I would get the total numbers. Then I

Page 352

1 printed off hard copies of every single  
 2 patient report, and then by year would read  
 3 the reports and I would separate them into key  
 4 piles. So, obviously, you can see here all the  
 5 negatives, the 0/0 were in a pile, all the  
 6 ones that were questionable, like, what we  
 7 called the weak positives were in a pile, all  
 8 the strong positives were in a pile. We made  
 9 a pile then for the non-breast specimens, and  
 10 then we made a pile for the ones that were  
 11 sent out of town that we had no results or  
 12 idea if they were positive, negative, weak  
 13 positive, and--that was just documentation  
 14 that test was performed.  
 15 CHAYTOR, Q.C.:  
 16 Q. What did you define as strong positive? Who  
 17 went in that pile?  
 18 MR. GULLIVER:  
 19 A. Well, again, I mean, anybody you don't see  
 20 here, anybody who had 70/70, 90/90, 50/90, all  
 21 those ones, yes.  
 22 CHAYTOR, Q.C.:  
 23 Q. Anyone above 10 percent or the range that you  
 24 used?  
 25 MR. GULLIVER:



Page 353

1 A. The range was--yes.  
 2 CHAYTOR, Q.C.:  
 3 Q. The 10 to 15 kind of thing?  
 4 MR. GULLIVER:  
 5 A. Yeah.  
 6 CHAYTOR, Q.C.:  
 7 Q. So they were--the strong positives got put to  
 8 one side and didn't end up on your  
 9 spreadsheet?  
 10 MR. GULLIVER:  
 11 A. Right.  
 12 CHAYTOR, Q.C.:  
 13 Q. And the out of town people, did you then at  
 14 least make a list of their names and whatever  
 15 centre they were from?  
 16 MR. GULLIVER:  
 17 A. I had the computer print off that came off the  
 18 pathology module that would say--it would  
 19 indicate the patient's name and demographic  
 20 information. The surgical number and the  
 21 specimen that was assigned in the referral  
 22 hospital, and then the surgical number that  
 23 was assigned when it arrived in our lab for  
 24 the procedure to be performed, and then  
 25 generally most of them just had a specimen

Page 354

1 comment that said, "return back to Gander for  
 2 interpretation" or "return back to Corner  
 3 Brook", and even at times return back to St.  
 4 Clare's, or the Grace when they were open.  
 5 CHAYTOR, Q.C.:  
 6 Q. Yes, and did you make a list of them, though,  
 7 of those people?  
 8 MR. GULLIVER:  
 9 A. No, they weren't on no spreadsheets. They  
 10 were just--they were put together sort of in a  
 11 group as "other, out of town".  
 12 CHAYTOR, Q.C.:  
 13 Q. And was that grouping then ever used at any  
 14 point in time afterwards? For example, when  
 15 samples were coming in from other regions -  
 16 MR. GULLIVER:  
 17 A. No, no, it wasn't.  
 18 CHAYTOR, Q.C.:  
 19 Q. Was there any cross checking to make sure your  
 20 stack--they had everyone that was in your  
 21 stack?  
 22 MR. GULLIVER:  
 23 A. No, because I would have no idea -  
 24 CHAYTOR, Q.C.:  
 25 Q. Yes.

Page 355

1 MR. GULLIVER:  
 2 A. Because I--I had no results, so I would have  
 3 no idea. If I had 50 -  
 4 CHAYTOR, Q.C.:  
 5 Q. You didn't know if they were positives or  
 6 negatives?  
 7 MR. GULLIVER:  
 8 A. Exactly.  
 9 CHAYTOR, Q.C.:  
 10 Q. Fair enough.  
 11 MR. GULLIVER:  
 12 A. So if I had 50 patients that were, say, in the  
 13 year 2002 that were, say, from Western  
 14 Memorial, and from their region, could be  
 15 Stephenville or Corner Brook, but their  
 16 responsibility, if I had a list of 50 patients  
 17 and Corner Brook sent me in 35 for retesting,  
 18 which came in like maybe September/October -  
 19 CHAYTOR, Q.C.:  
 20 Q. Yes.  
 21 MR. GULLIVER:  
 22 A. I would have no idea if the 35 they sent -  
 23 CHAYTOR, Q.C.:  
 24 Q. Right, who was what?  
 25 MR. GULLIVER:

Page 356

1 A. Who was what on the list.  
 2 CHAYTOR, Q.C.:  
 3 Q. And you didn't provide them with the complete  
 4 list?  
 5 MR. GULLIVER:  
 6 A. I know, and I've actually said that to my--  
 7 well, not just to myself. I've actually said  
 8 that many times since that, you know, when we  
 9 were doing this here, I mean, understand we  
 10 were doing this night and day up until  
 11 midnight most nights, weekends, for weeks. It  
 12 was such a time consuming process that--I  
 13 really wish that--I don't know why I never  
 14 thought about it, that the list that I printed  
 15 off of us having a record of a test performed  
 16 from the regions, that I could have just sent  
 17 that list out to the regions.  
 18 CHAYTOR, Q.C.:  
 19 Q. Yes.  
 20 MR. GULLIVER:  
 21 A. And another strange thing is, and I did have  
 22 some contact with the regions, and no one in  
 23 the region ever asked, you know, do you have a  
 24 list in your records of who was sent in from  
 25 Corner Brook, Gander, or Grand Falls.

1 CHAYTOR, Q.C.:  
 2 Q. Mr. Gulliver, does that list still exist that  
 3 you had of all the -  
 4 MR. GULLIVER:  
 5 A. They're still in my original files, yes.  
 6 CHAYTOR, Q.C.:  
 7 Q. You still have that?  
 8 MR. GULLIVER:  
 9 A. I think you've got copies of all that.  
 10 CHAYTOR, Q.C.:  
 11 Q. Copies of all that?  
 12 MR. GULLIVER:  
 13 A. Yeah.  
 14 CHAYTOR, Q.C.:  
 15 Q. Including -  
 16 MR. GULLIVER:  
 17 A. All those repots that were copied, they're in  
 18 there under "other category" or they might say  
 19 "out of town".  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay, I see what you mean, yes.  
 22 MR. GULLIVER:  
 23 A. Yeah.  
 24 CHAYTOR, Q.C.:  
 25 Q. Why were you keeping track of

1 MR. GULLIVER:  
 2 A. This is earlier.  
 3 CHAYTOR, Q.C.:  
 4 Q. I'm just wondering, though, when you were then  
 5 figuring out who to put in these categories -  
 6 MR. GULLIVER:  
 7 A. Well, just go to 2002.  
 8 CHAYTOR, Q.C.:  
 9 Q. Yes.  
 10 MR. GULLIVER:  
 11 A. Which we just seen.  
 12 CHAYTOR, Q.C.:  
 13 Q. Yes.  
 14 MR. GULLIVER:  
 15 A. So you would see there that we had 344 tests  
 16 that were found in our system.  
 17 CHAYTOR, Q.C.:  
 18 Q. Right.  
 19 MR. GULLIVER:  
 20 A. Of those, 155 were sent in from -  
 21 CHAYTOR, Q.C.:  
 22 Q. Were from out of town.  
 23 MR. GULLIVER:  
 24 A. From all the regions outside St. John's.  
 25 There were 189 St. John's tests that we had

1 negative/negatives. Was that of any  
 2 significance to you?  
 3 MR. GULLIVER:  
 4 A. Well, the significance is we're also looking  
 5 at these spreadsheets, looking at how many  
 6 patients were--the whole positive/negative  
 7 issue too was ongoing. So the  
 8 negative/negative, true 0/0, to me that's true  
 9 lab--that's a negative test.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay.  
 12 MR. GULLIVER:  
 13 A. There was no staining whatsoever.  
 14 CHAYTOR, Q.C.:  
 15 Q. So if we could just go to P-0514 for a moment,  
 16 please, and this is a document I showed you  
 17 yesterday, Mr. Gulliver, and this is the  
 18 first, I think, of these sheets that you came  
 19 up with on stats for positivity rates, July  
 20 20th, 2005 document.  
 21 MR. GULLIVER:  
 22 A. And the spreadsheets aren't done by this  
 23 point.  
 24 CHAYTOR, Q.C.:  
 25 Q. Right, okay.

1 results on.  
 2 CHAYTOR, Q.C.:  
 3 Q. Yes.  
 4 MR. GULLIVER:  
 5 A. And then of those, 95 were positive, which  
 6 means they were clearly positive.  
 7 CHAYTOR, Q.C.:  
 8 Q. Uh-hm.  
 9 MR. GULLIVER:  
 10 A. There were 33 cases that we called weak  
 11 positive, i.e. that list you see, the second  
 12 list.  
 13 CHAYTOR, Q.C.:  
 14 Q. Uh-hm.  
 15 MR. GULLIVER:  
 16 A. It could have been 1 percent ER, 80 percent  
 17 PR.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay.  
 20 MR. GULLIVER:  
 21 A. We called them a positive under the weak  
 22 positive category.  
 23 CHAYTOR, Q.C.:  
 24 Q. So these are the under 10s?  
 25 MR. GULLIVER:

Page 361

1 A. Right.  
 2 CHAYTOR, Q.C.:  
 3 Q. For 2002.  
 4 MR. GULLIVER:  
 5 A. And then there was 32--sorry, 61 of them that  
 6 were clearly no staining, zero, zero.  
 7 CHAYTOR, Q.C.:  
 8 Q. So you were looking at zero, zero?  
 9 MR. GULLIVER:  
 10 A. Yes.  
 11 CHAYTOR, Q.C.:  
 12 Q. But what about if 0/40?  
 13 MR. GULLIVER:  
 14 A. That would be in our weak positives.  
 15 CHAYTOR, Q.C.:  
 16 Q. So they're under weak positives?  
 17 MR. GULLIVER:  
 18 A. Yeah, the hormone receptor test had a certain  
 19 degree of positivity reported.  
 20 CHAYTOR, Q.C.:  
 21 Q. So regardless--so it's not just ER negativity  
 22 we're talking about here.  
 23 MR. GULLIVER:  
 24 A. Yes.  
 25 CHAYTOR, Q.C.:

Page 362

1 Q. We're talking--in order to be come classified  
 2 as negative here -  
 3 MR. GULLIVER:  
 4 A. It was zero, zero.  
 5 CHAYTOR, Q.C.:  
 6 Q. It had to be both estrogen and progesterone  
 7 negative?  
 8 MR. GULLIVER:  
 9 A. They were both negative, yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. And under here under this 33 is where I would  
 12 find my--what might be classified ER negative,  
 13 but PR positive, and I would also find in here  
 14 the people who were 10 percent or under for ER  
 15 positivity?  
 16 MR. GULLIVER:  
 17 A. Right, yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay.  
 20 MR. GULLIVER:  
 21 A. And when you--then you see the bottom, I just  
 22 added up and said "overall, we can see the  
 23 strong positives, the weak positives", and  
 24 again you can call the weak positives the low  
 25 expressors, if you like, and then the true

Page 363

1 zero, zero, and we're saying for that year  
 2 there were--when I did this at this point--now  
 3 this may change 1 percent after it's been  
 4 refined several times, but we're saying  
 5 overall for that year, 68 percent of the cases  
 6 that we had results on that we could document  
 7 from St. John's, 68 percent were reported with  
 8 some degree of positivity.  
 9 CHAYTOR, Q.C.:  
 10 Q. In either -  
 11 MR. GULLIVER:  
 12 A. Either/or -  
 13 CHAYTOR, Q.C.:  
 14 Q. ER or PR.  
 15 MR. GULLIVER:  
 16 A. Strong or weak, and 32 percent of all cases  
 17 were zero, zero.  
 18 CHAYTOR, Q.C.:  
 19 Q. Were zero, zero?  
 20 MR. GULLIVER:  
 21 A. Yeah, and again you're highlighting 2002.  
 22 CHAYTOR, Q.C.:  
 23 Q. Right.  
 24 MR. GULLIVER:  
 25 A. And if you look at the--all the years, you

Page 364

1 know, three years later, you've circled--and  
 2 2000, you're pretty well looking at -  
 3 CHAYTOR, Q.C.:  
 4 Q. This came to us. We didn't do the circling.  
 5 MR. GULLIVER:  
 6 A. I know, and that might have been mine who did  
 7 this.  
 8 CHAYTOR, Q.C.:  
 9 Q. Yes.  
 10 MR. GULLIVER:  
 11 A. I mean, you're looking at the two years that  
 12 had the highest numbers of specimens that were  
 13 zero, zero.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay, and then for 2000, under your weak  
 16 positives, you would have been using the 30  
 17 percent cutoff?  
 18 MR. GULLIVER:  
 19 A. Exact same--same criteria, except for the 30  
 20 percent.  
 21 CHAYTOR, Q.C.:  
 22 Q. 30 percent cutoff.  
 23 MR. GULLIVER:  
 24 A. Well, no, not really.  
 25 CHAYTOR, Q.C.:

Page 365

1 Q. No?

2 MR. GULLIVER:

3 A. It would still be--if there was a percent of

4 positivity, you know, 5 percent, 10 percent--

5 yes, you're right, less than 30 percent.

6 CHAYTOR, Q.C.:

7 Q. Okay. Are you sure?

8 MR. GULLIVER:

9 A. Yeah, yeah.

10 CHAYTOR, Q.C.:

11 Q. Okay. Just have a look at--there was a new

12 exhibit. I think this might be an updated

13 version of what you had done. Let's try 3036,

14 please. This is then into January--January

15 28th, 2008, and it's an e-mail from yourself

16 to Ms. Predham, and you call it an update, and

17 you'll see here--I don't know if you can read

18 that, Mr. Gulliver, the print is a bit small,

19 but it's positive/negative rates for St.

20 John's and your numbers when I looked at--

21 well, we were just looking at 2000, 2001,

22 2002, onwards, and when we look at those, they

23 appear to be the same as what I was showing

24 you on your original. If we could go 514

25 again, please, Registrar.

Page 366

1 MR. GULLIVER:

2 A. This was--I think I did this, Ms. Chaytor,

3 after--during the NLCHI exercise.

4 CHAYTOR, Q.C.:

5 Q. Okay.

6 MR. GULLIVER:

7 A. One of the questions was these original

8 tables, you know, and I had said to them that

9 these tables change and updated.

10 CHAYTOR, Q.C.:

11 Q. Yes.

12 MR. GULLIVER:

13 A. Myself and Reza, who was assigned that task,

14 we went back and reread every single report

15 just to make sure. Again it was a numbers

16 game, it wasn't reviewing patients who might

17 have been missed for retesting.

18 CHAYTOR, Q.C.:

19 Q. Right, okay. No, that's--okay, that's what I

20 understood the exercise to be, it's a

21 positivity rate.

22 MR. GULLIVER:

23 A. Yeah.

24 CHAYTOR, Q.C.:

25 Q. If we could just go back, Registrar, to 3036,

Page 367

1 and again so your numbers seem to be, I

2 believe, consistent through this time period.

3 So there was no--even though this is an

4 update, your numbers didn't change. Your

5 numbers appear to have been accurate back in

6 July of 2005.

7 MR. GULLIVER:

8 A. I think 2000 the numbers might have changed a

9 bit.

10 CHAYTOR, Q.C.:

11 Q. Okay.

12 MR. GULLIVER:

13 A. During this here.

14 CHAYTOR, Q.C.:

15 Q. Okay, and -

16 MR. GULLIVER:

17 A. We came across some cases that we had included

18 in our positive category.

19 CHAYTOR, Q.C.:

20 Q. Yes.

21 MR. GULLIVER:

22 A. For statistic purposes, and they were

23 positive, but they weren't necessarily a

24 breast primary, so we kind of took those away

25 from our stats.

Page 368

1 CHAYTOR, Q.C.:

2 Q. And then the number of tests, strong positive,

3 those are the ones that didn't end up on your

4 spreadsheet, as you say?

5 MR. GULLIVER:

6 A. Right.

7 CHAYTOR, Q.C.:

8 Q. All right, and then we see the breakdown

9 number of tests, weak positive, and then

10 that's defined. Number of tests,

11 negative/negative, and that's straightforward.

12 Number of tests reported with positive

13 staining, strong, plus weak, what was that

14 referring to?

15 MR. GULLIVER:

16 A. That's the two--see strong positive and a weak

17 positive, that's just adding them together.

18 CHAYTOR, Q.C.:

19 Q. Oh, that's adding them together, sorry, yes.

20 MR. GULLIVER:

21 A. Right.

22 CHAYTOR, Q.C.:

23 Q. Yes, okay. Number of tests reported negative,

24 no staining, percentage.

25 MR. GULLIVER:

Page 369

1 A. Right.  
 2 CHAYTOR, Q.C.:  
 3 Q. And your total tests than are 2,726?  
 4 MR. GULLIVER:  
 5 A. For the breast primary specimens.  
 6 CHAYTOR, Q.C.:  
 7 Q. And that's just for -  
 8 MR. GULLIVER:  
 9 A. That's DAKO and Ventana for the whole time  
 10 period up to August--July 31st, '05.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay, just for St. John's?  
 13 MR. GULLIVER:  
 14 A. No, no, no, the total tests for the province.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, so this up here where it says  
 17 positive/negative rates for St. John's, that  
 18 includes the tests carried out in St. John's,  
 19 I take it?  
 20 MR. GULLIVER:  
 21 A. Right.  
 22 CHAYTOR, Q.C.:  
 23 Q. But it's for the entire province?  
 24 MR. GULLIVER:  
 25 A. See the total--with results?

Page 370

1 CHAYTOR, Q.C.:  
 2 Q. Yes.  
 3 MR. GULLIVER:  
 4 A. Those would be the total St. John's patients,  
 5 1529, that we had documented results in  
 6 reports that we could do statistics on.  
 7 CHAYTOR, Q.C.:  
 8 Q. Right.  
 9 MR. GULLIVER:  
 10 A. Our total positives reported for those totals  
 11 for St. John's, 77 percent were reported as  
 12 some positivity, and 23 percent were reported  
 13 as zero/zeros.  
 14 CHAYTOR, Q.C.:  
 15 Q. So that's just for your St. John's -  
 16 MR. GULLIVER:  
 17 A. Yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. Because those are the only ones that -  
 20 MR. GULLIVER:  
 21 A. That we have documented information on.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay. Now where you would have had--right,  
 24 okay. So that's all you would have had at  
 25 that point, but certainly in January, 2008,

Page 371

1 you would have had somewhere within your  
 2 system the records for everyone else, but  
 3 that's not included in what you've done here  
 4 it's just St. John's?  
 5 MR. GULLIVER:  
 6 A. Right, and I still--I still don't have any  
 7 records of the positive/negative rates for  
 8 outside St. John's. I have not been privy to  
 9 those results.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, Dr. Cook would have them, but you  
 12 wouldn't, on his spreadsheets?  
 13 MR. GULLIVER:  
 14 A. No, Dr. Cook only has results of the ones that  
 15 were retested. This is all the patients who  
 16 were retested or not retested in this file.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. The -  
 19 MR. GULLIVER:  
 20 A. And again, we were still doing, you know, some  
 21 comparisons, Ms. Chaytor.  
 22 CHAYTOR, Q.C.:  
 23 Q. Uh-hm.  
 24 MR. GULLIVER:  
 25 A. Looking at, you know, the total DAKO specimens

Page 372

1 that were done and the total rates by year,  
 2 positive, negative and then the overall  
 3 average of 75.8 and 24.2 and then comparing to  
 4 the year and a few months of the specimens on  
 5 a Ventana that we had results on, we seen that  
 6 the overall rate there was an 86.14 percent.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay, and you got one person from James Paton  
 9 added on, why was that person included in your  
 10 numbers?  
 11 MR. GULLIVER:  
 12 A. I think--this is now 2008.  
 13 CHAYTOR, Q.C.:  
 14 Q. Yes.  
 15 MR. GULLIVER:  
 16 A. You know, I think by this time there was  
 17 patient who wasn't originally on the list or  
 18 retested who was added to that list, so we  
 19 added one number to 97.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay, were you keeping a list--you said you  
 22 kept a list of the out-of-town patients and  
 23 how about the list of what you determined to  
 24 be strong positives? Was a list of those -  
 25 MR. GULLIVER:

Page 373

1 A. They were all kept too, yes.  
 2 CHAYTOR, Q.C.:  
 3 Q. That's all kept.  
 4 MR. GULLIVER:  
 5 A. Yeah, that's all in your, in everything  
 6 provided.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay.  
 9 MR. GULLIVER:  
 10 A. And they're separated by yellow sheets, all  
 11 the different years and by the sheets in  
 12 front.  
 13 CHAYTOR, Q.C.:  
 14 Q. And if we could just go back, please, to I  
 15 think it's P-2375, that's your 2002 stats.  
 16 THE COMMISSIONER:  
 17 Q. Mr. Gulliver, when the out-of-town information  
 18 came in, did you take it just as it was and  
 19 send on or was there any kind of assessment  
 20 done of those lists that you received from,  
 21 say Grand Falls?  
 22 MR. GULLIVER:  
 23 A. No, you mean like a clinical assessment?  
 24 THE COMMISSIONER:  
 25 Q. Well, no, in the sense of--well I am making an

Page 374

1 assumption now, I should back up. My  
 2 understanding is that in Grand Falls, for  
 3 example, they would have pulled a particular  
 4 number of blocks, sent them to you -  
 5 MR. GULLIVER:  
 6 A. Correct.  
 7 THE COMMISSIONER:  
 8 Q. And then they went on through some method to  
 9 Mount Sinai?  
 10 MR. GULLIVER:  
 11 A. Right.  
 12 THE COMMISSIONER:  
 13 Q. Would you just have transmitted to them  
 14 directly to the Mount Sinai or would you have  
 15 for any reason excluded a number of them?  
 16 MR. GULLIVER:  
 17 A. We didn't exclude any, but we did--myself and  
 18 Mr. Dyer and some of the technologists who  
 19 were doing this, we actually then made a list  
 20 for ourselves of what we received from, for  
 21 example, Grand Falls and documented what was  
 22 sent and then we packed it up and sent them in  
 23 the same manner as all the St. John's  
 24 patients. But there was no secondary review  
 25 process by us to either add or exclude -

Page 375

1 THE COMMISSIONER:  
 2 Q. Yes, for example if in that group of, not  
 3 slides, blocks which had been sent to you thee  
 4 were a number of people who were deceased, you  
 5 would not have -  
 6 MR. GULLIVER:  
 7 A. We had no idea.  
 8 THE COMMISSIONER:  
 9 Q. You would not have culled those out because  
 10 you were keeping deceased until later -  
 11 MR. GULLIVER:  
 12 A. No.  
 13 THE COMMISSIONER:  
 14 Q. You would have sent it on then.  
 15 MR. GULLIVER:  
 16 A. No.  
 17 CHAYTOR, Q.C.:  
 18 Q. And if there were also people who were 30  
 19 percent throughout the whole time, if someone  
 20 used the 30 percent cut-off throughout -  
 21 MR. GULLIVER:  
 22 A. They were sent.  
 23 CHAYTOR, Q.C.:  
 24 Q. - and sent them in, you sent it all on?  
 25 MR. GULLIVER:

Page 376

1 A. Yeah.  
 2 CHAYTOR, Q.C.:  
 3 Q. You didn't do any further vetting?  
 4 MR. GULLIVER:  
 5 A. No. As you know, Dr. Cook sent out some  
 6 criteria to the other laboratories and  
 7 pathologists of what they should do to review  
 8 their patients.  
 9 CHAYTOR, Q.C.:  
 10 Q. Yes, and whether or not they stuck with that  
 11 or decided to do something different, there  
 12 was no further or secondary check, as you say  
 13 -  
 14 MR. GULLIVER:  
 15 A. No.  
 16 CHAYTOR, Q.C.:  
 17 Q. - done in St. John's.  
 18 MR. GULLIVER:  
 19 A. I know during the timeframe that--I know  
 20 Corner Brook called me, you know, the lab  
 21 director in Corner Brook and generally just  
 22 talked about to make sure, what are you doing  
 23 in St. John's, what should we do out here?  
 24 And pretty well walk through over the phone,  
 25 you know, to make sure they are clear what

Page 377

1 they're doing and I think--I don't know if it  
 2 was Gander or Grand Falls, someone else called  
 3 too just to be clear on what they're supposed  
 4 to be doing type of thing.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay. And I just want to be clear too again  
 7 on lists because I know what we've received in  
 8 terms of receiving pathology reports and  
 9 having it broken down into categories. But  
 10 did you actually compile lists of the peoples'  
 11 names who would be in those categories?  
 12 MR. GULLIVER:  
 13 A. No.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. That's where I'm -  
 16 MR. GULLIVER:  
 17 A. No, the only people you see in a list or  
 18 spreadsheet are the ones we identified that  
 19 could possibly be retested.  
 20 CHAYTOR, Q.C.:  
 21 Q. And those are what we are looking at here on  
 22 the screen.  
 23 MR. GULLIVER:  
 24 A. And that's what you're seeing there, yes.  
 25 CHAYTOR, Q.C.:

Page 378

1 Q. So, there's no actual list of the names of the  
 2 people deemed to be strongly positive, lists  
 3 of the people from out of town, that list  
 4 doesn't exist.  
 5 MR. GULLIVER:  
 6 A. No, and when we started the NLCHI exercise,  
 7 you know, in July of '07, that was actually my  
 8 recommendation, that if we're going to do a  
 9 database, we should do every single patient  
 10 who was ever tested for ER/PR, but again time  
 11 was of essence and it was decided to do the  
 12 patients who were retested and put those in  
 13 the database.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. So, you were wanting to put all the  
 16 positives in the database for example, as  
 17 well.  
 18 MR. GULLIVER:  
 19 A. Correct.  
 20 CHAYTOR, Q.C.:  
 21 Q. Put everyone in, okay. Did you, at any point  
 22 too, Mr. Gulliver, suggest that everyone  
 23 should be retested?  
 24 MR. GULLIVER:  
 25 A. No, I didn't, no. Again, as you know, that

Page 379

1 was discussed with various experts and we've  
 2 seen lots of literature where false positives  
 3 are very rare and there was no concern  
 4 expressed from the oncologists. So, it just  
 5 wasn't never decided to do.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay. Were you of the opinion that the  
 8 original slides should have been re-read along  
 9 with the test being--the blocks being turned  
 10 into new slides and re-tested?  
 11 MR. GULLIVER:  
 12 A. I think shortly after Dr. Banerjee had come in  
 13 to do his first review, you know, I had the  
 14 privilege to spend an afternoon with him,  
 15 myself and Mr. Dyer, and it was--so, after he  
 16 left, that's one thing that struck me, that we  
 17 should engage someone like him to actually re-  
 18 read every single original slide. We were in  
 19 the process of sending out original blocks to  
 20 get re-tested and get re-interpreted somewhere  
 21 else, but I thought--I suggested that. That  
 22 we should have -  
 23 CHAYTOR, Q.C.:  
 24 Q. And who did you suggest that to?  
 25 MR. GULLIVER:

Page 380

1 A. To Dr. Cook and Dr. Williams.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay. And was that ever done, apart from, of  
 4 course, Dr. Mullen has done it through this  
 5 process here.  
 6 MR. GULLIVER:  
 7 A. No.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. And why not? Was anyone opposed to  
 10 having that done?  
 11 MR. GULLIVER:  
 12 A. Well, they weren't in favour, so it didn't get  
 13 done.  
 14 CHAYTOR, Q.C.:  
 15 Q. And who wasn't in favour of it?  
 16 MR. GULLIVER:  
 17 A. I don't know if it was both of them or either  
 18 one of them, but it just--it was something I  
 19 suggested and it just didn't go anywhere.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. And did they say why? Were you told  
 22 why they didn't think that would be a  
 23 worthwhile exercise?  
 24 MR. GULLIVER:  
 25 A. I don't know if they said it wouldn't be

Page 381

1 worthwhile. I think we're in the crux of all  
 2 this here, we're spending thousands of hours  
 3 between all of us, identifying patients,  
 4 packing up blocks, pulling blocks, pulling  
 5 slides, re-reading the original H&Es that are  
 6 being sent off. I think again it was just  
 7 something else that would have been very time  
 8 consuming to organize, at that point in time.  
 9 CHAYTOR, Q.C.:  
 10 Q. So, was that the reason given to you for not  
 11 having the slides reviewed?  
 12 MR. GULLIVER:  
 13 A. That was my understanding, yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. That's what you were told at the time, yes.  
 16 MR. GULLIVER:  
 17 A. Yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay. And why did you want it done? What  
 20 benefit did you think that would have been, to  
 21 have the slides re-read?  
 22 MR. GULLIVER:  
 23 A. Well, again, you know, this is--we're talking  
 24 about August/September '05, while we're  
 25 heavily in the retesting process of

Page 382

1 identifying patients and trying to get  
 2 patients sent away as quickly as possible,  
 3 we're not performing the tests currently in  
 4 the lab. We had stopped the Ventana system  
 5 until we thought we'd get Ventana in to review  
 6 it. We knew that we had two outside reviewers  
 7 coming in to the laboratory. I felt it would  
 8 be important information to--we have the  
 9 original slides, why not have an outside  
 10 pathologist come in and sit down and review  
 11 the original slides. I think that person  
 12 could have given us a lot of insight and they  
 13 could have said, well, you know, in this  
 14 particular year, I reviewed your slides, the  
 15 staining quality seems to be fine, there  
 16 doesn't seem to be something at issue with  
 17 this or this. Or they might have said, as you  
 18 know, Dr. Banerjee had looked at stuff, you  
 19 know, internal controls weren't staining, but  
 20 yet, reported. I just felt that we could have  
 21 got a lot of useful information from that  
 22 exercise.  
 23 CHAYTOR, Q.C.:  
 24 Q. And were you aware that up to, by August 1st,  
 25 2005, Dr. Carter had reviewed the original

Page 383

1 slides of approximately 80 or 90 patients?  
 2 MR. GULLIVER:  
 3 A. I was aware that she was reviewing 2002 cases.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay. So, and including the slides, were you  
 6 aware that she had already started a process  
 7 which included reviewing original slides?  
 8 MR. GULLIVER:  
 9 A. I think from 2002.  
 10 CHAYTOR, Q.C.:  
 11 Q. Yes, okay. In going through, perhaps we could  
 12 just bring up--and I'm not going to take you  
 13 through all of your spreadsheets because time  
 14 is of the essence.  
 15 MR. GULLIVER:  
 16 A. Yes, I know, but I can assure you that the  
 17 same process was done every single year.  
 18 CHAYTOR, Q.C.:  
 19 Q. Was done for each year. And so there's  
 20 nothing in particular that you want to point  
 21 on any of the years?  
 22 MR. GULLIVER:  
 23 A. I don't think so, no. And I did these  
 24 searches originally, Ms. Chaytor, and when  
 25 Barry came back to work, you know, I kind of

Page 384

1 said to Barry, you go in and do searches now  
 2 and see if we can get similar numbers for each  
 3 year, which he did, just to kind of cross-  
 4 reference that my searching was similar to  
 5 him.  
 6 CHAYTOR, Q.C.:  
 7 Q. So, he went back over what you had already  
 8 done?  
 9 MR. GULLIVER:  
 10 A. Yes.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay. And in doing that--well, let's look at  
 13 2373, I think, or 74, might be the year  
 14 before, 2001, or let's try--no, sorry, let's  
 15 try 73, 2373. So, this is just another, your  
 16 spreadsheet this time is 2000. And the reason  
 17 I look at 2000 is because in this time period  
 18 then you'd be at the 30 or below mark, right?  
 19 And so then on your first page here, and then  
 20 this is your writing, I take it, is it?  
 21 MR. GULLIVER:  
 22 A. No, that's Barry's -  
 23 CHAYTOR, Q.C.:  
 24 Q. Oh, sorry, Barry's, right. And this is your  
 25 writing up in the corners.



Page 385

1 MR. GULLIVER:  
 2 A. Yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay. And similar then, he's got the  
 5 negative/negatives.  
 6 MR. GULLIVER:  
 7 A. And then the next group would be the ones that  
 8 had a positive, certain positivity, and even  
 9 see one there--go back.  
 10 CHAYTOR, Q.C.:  
 11 Q. Sorry.  
 12 MR. GULLIVER:  
 13 A. And if the report said positive, weak  
 14 positive, that we see here.  
 15 CHAYTOR, Q.C.:  
 16 Q. So, if you just said positive -  
 17 MR. GULLIVER:  
 18 A. We just wrote down positive and we--that's  
 19 exactly what was written in the report.  
 20 CHAYTOR, Q.C.:  
 21 Q. And I took Mr. Dyer through some of this in  
 22 some detail. This person here is crossed off  
 23 and DCIS is written there, what were you told  
 24 to do in terms of DCIS patients?  
 25 MR. GULLIVER:

Page 386

1 A. They weren't sent for retesting. And again,  
 2 this will be somebody who Dr. Cook will say to  
 3 us on review, this was a confirmed DCIS, so we  
 4 haven't got to send that person for retesting.  
 5 CHAYTOR, Q.C.:  
 6 Q. And who told you to also limit the test review  
 7 to primary breast patients?  
 8 MR. GULLIVER:  
 9 A. Oh, that was right from the beginning with the  
 10 oncologists, who would review? And they said,  
 11 well, it's primary breast patients who would  
 12 be getting the hormone therapy, so that's the  
 13 ones we're trying to identify.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. So, when you went in and found ER/PR  
 16 tests run for -  
 17 MR. GULLIVER:  
 18 A. Metastatic, for example. If we see an ER/PR  
 19 result that it said, and it was a liver  
 20 specimen -  
 21 CHAYTOR, Q.C.:  
 22 Q. Yes.  
 23 MR. GULLIVER:  
 24 A. - and the question mark was, but is it  
 25 metastatic from breast cancer, and those ones

Page 387

1 were still--that's the other categories you'll  
 2 see in the files.  
 3 CHAYTOR, Q.C.:  
 4 Q. Yes. So, you actually--in order to be able to  
 5 determine that, you had to actually print off  
 6 the pathology reports.  
 7 MR. GULLIVER:  
 8 A. Oh, I had to read every one of them, thousands  
 9 and thousands -  
 10 CHAYTOR, Q.C.:  
 11 Q. And you had to read through them?  
 12 MR. GULLIVER:  
 13 A. - and thousands and thousands and thousands of  
 14 pages.  
 15 CHAYTOR, Q.C.:  
 16 Q. So it was more than 2800. 2800 comes down to  
 17 primary breast?  
 18 MR. GULLIVER:  
 19 A. Right.  
 20 CHAYTOR, Q.C.:  
 21 Q. Right. And then you -  
 22 MR. GULLIVER:  
 23 A. There might have been over 3000 in--  
 24 understand, each year there might be 10, 15,  
 25 20 ER/PRs done per year that are done looking

Page 388

1 for metastatic disease to another organ.  
 2 CHAYTOR, Q.C.:  
 3 Q. Right.  
 4 MR. GULLIVER:  
 5 A. That primary cancer was the breast.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay. And so and so you would have reviewed  
 8 pathology reports where they were looking at  
 9 liver, lung -  
 10 MR. GULLIVER:  
 11 A. Lung, brain.  
 12 CHAYTOR, Q.C.:  
 13 Q. - brain. And -  
 14 MR. GULLIVER:  
 15 A. Mostly lung, brain, liver for most of them.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay. And do you know about how many of those  
 18 tests then got put to one side and -  
 19 MR. GULLIVER:  
 20 A. All of them, all of them went to -  
 21 CHAYTOR, Q.C.:  
 22 Q. They all got put to one side?  
 23 MR. GULLIVER:  
 24 A. They weren't sent for retesting.  
 25 CHAYTOR, Q.C.:

Page 389

1 Q. But do you know how many there would be, would  
 2 it be over 100, over 1000.  
 3 MR. GULLIVER:  
 4 A. Oh, no, not 1000. I would think on average  
 5 like 10 to 15 reports per year, so there might  
 6 be 100 in total.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay.  
 9 MR. GULLIVER:  
 10 A. And I think remember I said to you earlier I  
 11 thought the total number was like 2860 in  
 12 total and it came down to like 27 something  
 13 for primary breasts.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. So that the number comes down to about  
 16 2700, so it's about 160 or so?  
 17 MR. GULLIVER:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. And those are just St. John's, I take it,  
 21 though?  
 22 MR. GULLIVER:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. Are they? Because that's all you would have

Page 390

1 pathology reports for?  
 2 MR. GULLIVER:  
 3 A. Yes. And out of town would have less. We  
 4 went through this here with NLCHI. There'd be  
 5 less non-breast specimens coming in from out  
 6 of town just because of the kinds of patients.  
 7 Those patients would have been in St. John's  
 8 for their tertiary care.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay.  
 11 THE COMMISSIONER:  
 12 Q. Ms. Chaytor, it's five so wherever you can  
 13 find a convenient spot we'll break for the  
 14 day.  
 15 MR. GULLIVER:  
 16 A. I was going to--before you leave the  
 17 spreadsheets.  
 18 CHAYTOR, Q.C.:  
 19 Q. Yes.  
 20 MR. GULLIVER:  
 21 A. I was going to ask could you pull up 1997?  
 22 CHAYTOR, Q.C.:  
 23 Q. Sure.  
 24 MR. GULLIVER:  
 25 A. Because you asked me just then is there

Page 391

1 something else I'd like to -  
 2 CHAYTOR, Q.C.:  
 3 Q. 2370, I think.  
 4 MR. GULLIVER:  
 5 A. - point out before you move on.  
 6 CHAYTOR, Q.C.:  
 7 Q. Yes, 2370, I believe.  
 8 MR. GULLIVER:  
 9 A. Now, 1997 -  
 10 CHAYTOR, Q.C.:  
 11 Q. Now, this might--yeah, this is yours, is it?  
 12 MR. GULLIVER:  
 13 A. So I mean, and I did these here kind of  
 14 working backwards, you know. And by this time  
 15 I'm weeks, you know, reading reports and  
 16 documenting, writing up sheets and stuff. And  
 17 I guess I just want to show you this sheet for  
 18 '97. When you look what's filled in here  
 19 reading the pathology reports, to read there  
 20 the controls on original. That means if the  
 21 pathologist documented in their written report  
 22 I read the positive external control was in  
 23 there. And go to the far left if I had seen  
 24 any other comments where it says there  
 25 "positive internal control."

Page 392

1 CHAYTOR, Q.C.:  
 2 Q. Yes.  
 3 MR. GULLIVER:  
 4 A. And if we went to the next page and next page.  
 5 CHAYTOR, Q.C.:  
 6 Q. Yes, you can't see there. Yeah, here we go.  
 7 MR. GULLIVER:  
 8 A. And again -  
 9 CHAYTOR, Q.C.:  
 10 Q. This is when Dr. Khalifa is -  
 11 MR. GULLIVER:  
 12 A. This is to show you this is what Dr. Khalifa  
 13 did.  
 14 CHAYTOR, Q.C.:  
 15 Q. Yes.  
 16 MR. GULLIVER:  
 17 A. So most of the time he documented he read the  
 18 positive external control and/or the patient's  
 19 internal control.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay.  
 22 MR. GULLIVER:  
 23 A. Because I was struck by it after doing, like,  
 24 2004, 2003, 2002, 2001, 2000, '99, '98 and  
 25 then -

Page 393

1 CHAYTOR, Q.C.:

2 Q. You went back and -

3 MR. GULLIVER:

4 A. - '97 we had more complete information to put

5 on the sheets.

6 CHAYTOR, Q.C.:

7 Q. Right, okay. Yeah, that is an interesting

8 observation. And so then also in that--so if

9 we look, for example, then in this 2372, for

10 example. And I think that'll be 1999. So the

11 controls on original there's nothing filled

12 in?

13 MR. GULLIVER:

14 A. It's not very often you see it documented in

15 the report.

16 CHAYTOR, Q.C.:

17 Q. Right.

18 MR. GULLIVER:

19 A. Some of them, you can see some of them there.

20 CHAYTOR, Q.C.:

21 Q. Some here in '99. And a couple there, okay.

22 And no mention of any internal controls in the

23 report for -

24 MR. GULLIVER:

25 A. If it was there, I would have written it over

Page 394

1 to the side.

2 CHAYTOR, Q.C.:

3 Q. You would have filled it in?

4 MR. GULLIVER:

5 A. Yeah.

6 CHAYTOR, Q.C.:

7 Q. Okay.

8 MR. GULLIVER:

9 A. Of a patient had HER2/neu done, I would write

10 that to the far comment side.

11 CHAYTOR, Q.C.:

12 Q. Mr. Gulliver, in looking through these, for

13 example, this is now 1999, and if we look

14 through, we see a lot of, starting page one is

15 your negative, negatives?

16 MR. GULLIVER:

17 A. That's where I start all of them at.

18 CHAYTOR, Q.C.:

19 Q. And again, yes, yeah, that seems to be how you

20 would start out. And then we come down

21 estrogen receptor. They're all very low

22 numbers, one, five -

23 MR. GULLIVER:

24 A. On the weak, the weak positives -

25 CHAYTOR, Q.C.:

Page 395

1 Q. - ten -

2 MR. GULLIVER:

3 A. - yes.

4 CHAYTOR, Q.C.:

5 Q. Okay.

6 MR. GULLIVER:

7 A. Again, what's missing is -

8 CHAYTOR, Q.C.:

9 Q. I'm seeing a 20 here.

10 MR. GULLIVER:

11 A. Right.

12 CHAYTOR, Q.C.:

13 Q. I'm seeing a 20. But you would have been

14 checking for anything 30 -

15 MR. GULLIVER:

16 A. Anything.

17 CHAYTOR, Q.C.:

18 Q. - 30 or below?

19 MR. GULLIVER:

20 A. Yeah.

21 CHAYTOR, Q.C.:

22 Q. Okay. The number 30 just didn't come up very

23 often, I guess, it was either -

24 MR. GULLIVER:

25 A. And again you can see here '99, there's one at

Page 396

1 ten percent for PR and 70 to 80 for PR.

2 CHAYTOR, Q.C.:

3 Q. Yes.

4 MR. GULLIVER:

5 A. Again, it was put on this sheet to ensure that

6 we rather err on the side of caution than, you

7 know, than not.

8 CHAYTOR, Q.C.:

9 Q. Okay, perhaps we could take it up again

10 another day, thank you, Commissioner.

11 THE COMMISSIONER:

12 Q. All right, then, we'll break until the morning

13 and commence again at 9:30. For those in the

14 room, I want to plan for their next week. I

15 remind you that Tuesday is voting day, as a

16 result we will have to adjourn at 4:30 to

17 enable our staff to have the required amount

18 of time in which to vote. I'm therefore

19 suggesting we start at 9:00, so that we will

20 have the same full day that we would normally

21 have. So, that will be commencing at 9

22 instead of 9:30 on Tuesday morning, next week.

23 Thank you all, 9:30 tomorrow morning.

24 Upon conclusion at 5:05 p.m.

CERTIFICATE

1  
2 I, Judy Moss, hereby certify that the foregoing is  
3 a true and correct transcript in the matter of the  
4 Commission of Inquiry on Hormone Receptor Testing,  
5 heard on the 9th day of October, A.D., 2008 before  
6 the Honourable Justice Margaret A. Cameron,  
7 Commissioner, at the Commission of Inquiry, St.  
8 John's, Newfoundland and Labrador and was  
9 transcribed by me to the best of my ability by  
10 means of a sound apparatus.  
11 Dated at St. John's, Newfoundland and Labrador  
12 this 9th day of October, A.D., 2008  
13 Judy Moss

Inquiry on Hormone Receptor Testing

<p><b>-#-</b></p> <p>#19 [1] 283:12 #2 [1] 283:8 #3 [1] 283:10 #5 [1] 283:11</p>	<p>353:3 362:14 365:4 387:24 389:5</p> <p><b>100</b> [17] 103:22 108:8 114:9,25,25 115:9 125:9 208:2,19 211:2 287:17 287:19 288:2 310:23 313:23 389:2,6</p> <p><b>1000</b> [2] 389:2,4</p>	<p><b>2,100</b> [1] 321:7</p> <p><b>2,726</b> [1] 369:3</p> <p><b>20</b> [25] 53:19 96:15 120:8 217:17 330:21,25 331:24 332:2,4 333:3,3,13,20 333:22 335:15,24 337:22 337:23 338:2 340:23 345:3 348:21 387:25 395:9,13</p>	<p><b>2800</b> [5] 317:8 350:23 351:2 387:16,16</p> <p><b>283</b> [2] 2:7,8</p> <p><b>2860</b> [2] 317:2 389:11</p> <p><b>28th</b> [1] 365:15</p> <p><b>296</b> [4] 2:8,10 3:4,5</p> <p><b>29th</b> [1] 311:1</p> <p><b>2nd</b> [2] 304:1 313:8</p>	<p>218:13 329:22 355:3,12 355:16</p> <p><b>50/90</b> [1] 352:20</p> <p><b>514</b> [1] 365:24</p> <p><b>55</b> [1] 319:4</p> <p><b>56</b> [1] 41:5</p> <p><b>58</b> [7] 308:7,12 309:6,7 309:15 310:7,17</p> <p><b>5:05</b> [1] 396:24</p> <p><b>5th</b> [1] 299:3</p>
<p><b>-\$-</b></p> <p><b>\$40.00</b> [1] 78:21</p> <p><b>\$6,000.00</b> [1] 159:20</p>	<p><b>102</b> [2] 152:4,13</p> <p><b>105</b> [1] 152:19</p> <p><b>10s</b> [1] 360:24</p>	<p><b>20-25</b> [1] 329:14</p> <p><b>20/30</b> [1] 161:12</p> <p><b>200</b> [1] 197:8</p>	<p><b>-3-</b></p>	<p><b>-6-</b></p>
<p><b>-&amp;-</b></p> <p><b>&amp;</b> [3] 119:14 122:3 124:4</p>	<p><b>11</b> [2] 30:17 120:7</p> <p><b>1143</b> [1] 252:22</p> <p><b>11th</b> [2] 96:12 97:8</p> <p><b>12</b> [4] 114:3 138:8 157:11 175:14</p>	<p><b>2000</b> [17] 93:1 283:9,10 283:12,14,19 285:12,14 285:20 345:13 364:2,15 365:21 367:8 384:16,17 392:24</p> <p><b>2001</b> [12] 283:20 319:23 330:8,11,16 337:12,14 337:14 339:25 365:21 384:14 392:24</p>	<p><b>3</b> [24] 146:20 147:5,6,17 148:4,11,13,19,21,21,22 149:1 150:7,9,10,18 151:13 288:13,15 291:15 294:12,16,18,24</p>	<p><b>60</b> [2] 115:21,22</p> <p><b>61</b> [2] 319:23 361:5</p> <p><b>65</b> [1] 220:8</p> <p><b>68</b> [2] 363:5,7</p>
<p><b>-'-</b></p> <p><b>'02</b> [2] 327:24 329:6</p> <p><b>'03</b> [1] 80:23</p> <p><b>'04</b> [1] 301:6</p>	<p><b>1230</b> [1] 319:2</p> <p><b>1245</b> [1] 319:1</p> <p><b>12th</b> [1] 98:14</p> <p><b>13</b> [1] 250:12</p> <p><b>14</b> [1] 250:23</p>	<p><b>2002</b> [18] 308:23,25 309:4 319:23 321:20 322:23 330:22 336:1 348:17 355:13 359:7 361:3 363:21 365:22 373:15 383:3,9 392:24</p> <p><b>2003</b> [7] 12:13 16:23 80:21 127:19 284:13 319:23 392:24</p>	<p><b>30</b> [30] 138:19,20 141:16 144:21 217:17,20 219:12 225:5,17 226:6 235:16 237:19,21 238:11 323:7 323:21 337:12 339:25 342:12 344:5 364:16,19 364:22 365:5 375:18,20 384:18 395:14,18,22</p>	<p><b>70</b> [3] 115:21 227:2 396:1</p> <p><b>70/70</b> [1] 352:20</p> <p><b>72</b> [2] 136:23 226:20</p> <p><b>73</b> [1] 384:15</p> <p><b>74</b> [1] 384:13</p> <p><b>75</b> [1] 238:12</p> <p><b>75.8</b> [1] 372:3</p> <p><b>76</b> [1] 144:5</p> <p><b>77</b> [1] 370:11</p>
<p><b>'05</b> [3] 317:2 369:10 381:24</p> <p><b>'06</b> [4] 97:11 111:9 135:5 136:5</p> <p><b>'07</b> [3] 349:8,25 378:7</p>	<p><b>14,000</b> [3] 181:4,6,9</p> <p><b>15</b> [19] 127:10 144:2 309:8,21 330:17,20 331:3 332:15 333:10,15,19,22 333:23 335:15,24 337:22 353:3 387:24 389:5</p> <p><b>1529</b> [1] 370:5</p>	<p><b>2004</b> [7] 31:18,22 40:21 80:19 234:4 345:13 392:24</p> <p><b>2005</b> [12] 80:19 254:15 296:21 299:3 304:1 307:8 314:13 318:17 344:12 358:20 367:6 382:25</p>	<p><b>300</b> [2] 180:16 243:13</p> <p><b>3000</b> [1] 387:23</p> <p><b>3036</b> [2] 365:13 366:25</p> <p><b>31</b> [1] 264:14</p> <p><b>31st</b> [1] 369:10</p>	<p><b>-7-</b></p>
<p><b>'08</b> [1] 14:20</p> <p><b>'84</b> [1] 14:20</p> <p><b>'90s</b> [2] 57:15,17</p>	<p><b>155</b> [1] 359:20</p> <p><b>15th</b> [1] 100:1</p> <p><b>160</b> [1] 389:16</p> <p><b>179</b> [2] 2:3,4</p> <p><b>18</b> [2] 146:25 284:10</p>	<p><b>2006</b> [8] 96:12 97:8 98:14 100:1 111:5 134:11 234:4 252:23</p> <p><b>2007</b> [12] 102:15,17,19 142:13 194:15 239:7 253:25 254:17 283:5 285:14,16 349:14</p>	<p><b>31st</b> [1] 369:10</p> <p><b>32</b> [2] 361:5 363:16</p> <p><b>33</b> [2] 360:10 362:11</p> <p><b>3360</b> [1] 4:19</p> <p><b>3361</b> [2] 4:19 264:13</p> <p><b>3362</b> [1] 4:19</p> <p><b>344</b> [1] 359:15</p>	<p><b>78</b> [6] 79:20 124:9 265:18 265:19 267:23 276:18</p> <p><b>80</b> [5] 68:20 237:22 360:16 383:1 396:1</p> <p><b>80's</b> [1] 244:9</p> <p><b>86.14</b> [1] 372:6</p> <p><b>8th</b> [1] 314:12</p>
<p><b>'84</b> [1] 14:20</p> <p><b>'90s</b> [2] 57:15,17</p> <p><b>'91</b> [1] 22:10</p>	<p><b>189</b> [6] 322:23 324:12,14 325:8,11 359:25</p> <p><b>19</b> [1] 10:15</p> <p><b>190</b> [2] 2:4,5</p> <p><b>1986</b> [1] 6:12</p> <p><b>1989</b> [3] 53:15,19 54:14</p>	<p><b>2008</b> [8] 1:4 102:14 163:14 365:15 370:25 372:12 397:5,12</p> <p><b>20th</b> [2] 296:20 358:20</p> <p><b>21</b> [1] 120:8</p> <p><b>2100</b> [1] 318:24</p>	<p><b>35</b> [4] 218:18,22 355:17 355:22</p> <p><b>350</b> [3] 180:23,25 181:17</p> <p><b>397</b> [1] 2:10</p>	<p><b>-8-</b></p>
<p><b>'93</b> [2] 22:10,10</p> <p><b>'94</b> [2] 22:10,10</p> <p><b>'96</b> [1] 22:10</p>	<p><b>1990s</b> [1] 21:24</p> <p><b>1991</b> [1] 55:15</p> <p><b>1994</b> [1] 56:16</p> <p><b>1997</b> [13] 7:16 10:17 16:21 22:19 192:4 194:14 212:5 316:25 318:17 344:8 348:12 390:21 391:9</p>	<p><b>2009</b> [4] 31:18 179:10 393:10 394:13</p> <p><b>1B5</b> [1] 266:3</p> <p><b>1st</b> [6] 311:2,6,14 330:8 339:25 382:24</p>	<p><b>-4-</b></p> <p><b>4</b> [8] 2:3 3:2 106:4 146:21 153:25 154:4,6,9</p> <p><b>4,500</b> [1] 321:6</p> <p><b>40</b> [7] 68:3,4 156:7 218:15 227:3,5 329:21</p> <p><b>41</b> [3] 308:12 309:15,20</p> <p><b>45</b> [1] 58:8</p> <p><b>4500</b> [1] 318:22</p> <p><b>4510</b> [1] 316:13</p> <p><b>46</b> [1] 319:23</p> <p><b>48</b> [3] 319:23 322:24 324:1</p> <p><b>49</b> [1] 237:19</p> <p><b>4:30</b> [1] 396:16</p> <p><b>4th</b> [4] 127:18 307:8 311:12 313:6</p>	<p><b>-9-</b></p> <p><b>9</b> [7] 1:4 257:21 265:18 265:19 267:23 276:18 396:21</p> <p><b>90</b> [3] 237:20 238:11 383:1</p> <p><b>90/90</b> [1] 352:20</p> <p><b>92</b> [1] 153:8</p> <p><b>94</b> [1] 67:18</p> <p><b>95</b> [22] 68:9,13,21 69:9 110:18 153:10 155:13 156:6 166:25 204:4 205:22,25 206:15 207:11 207:21 208:7 209:17 220:6 287:6,15 288:1 360:5</p> <p><b>96</b> [1] 237:22</p> <p><b>97</b> [1] 372:19</p> <p><b>98</b> [2] 287:16,19</p> <p><b>99</b> [1] 288:2</p> <p><b>9:00</b> [1] 396:19</p> <p><b>9:30</b> [3] 396:13,22,23</p> <p><b>9th</b> [3] 163:14 397:5,12</p>
<p><b>'97</b> [10] 16:23 18:16 44:21 193:21 326:13,14 345:8 345:19 391:18 393:4</p> <p><b>'98</b> [5] 10:17 18:16 345:9 345:19 392:24</p> <p><b>'99</b> [5] 345:9,19 392:24 393:21 395:25</p>	<p><b>2</b> [29] 68:12 76:15 79:1,8 80:14 146:20,25 147:6 148:3,24 149:1,5,11,18 150:6,6,9 151:13 153:6 159:10 205:13 224:24 225:3 226:18 227:2 257:21 291:19 292:4 294:12</p> <p><b>2,000</b> [1] 197:8</p>	<p><b>23</b> [4] 147:5 217:16 289:6 370:12</p> <p><b>231</b> [2] 2:5,6</p> <p><b>234</b> [1] 3:3</p> <p><b>2370</b> [2] 391:3,7</p> <p><b>2372</b> [1] 393:9</p> <p><b>2373</b> [2] 384:13,15</p> <p><b>24</b> [1] 237:20</p> <p><b>24.2</b> [1] 372:3</p> <p><b>25</b> [1] 309:22</p> <p><b>252</b> [2] 2:6,7</p> <p><b>26</b> [2] 96:1 97:2</p> <p><b>26th</b> [1] 283:5</p> <p><b>27</b> [1] 389:12</p> <p><b>2700</b> [1] 389:16</p>	<p><b>-5-</b></p> <p><b>5</b> [1] 365:4</p> <p><b>5.4</b> [1] 100:3</p> <p><b>50</b> [8] 79:9 115:22 154:10</p>	<p><b>0</b> [2] 257:21,21</p> <p><b>0/0</b> [2] 352:5 358:8</p> <p><b>0/40</b> [1] 361:12</p> <p><b>0542</b> [2] 303:3,24</p> <p><b>0940</b> [1] 307:6</p>
<p><b>---</b></p> <p><b>-and</b> [1] 258:7</p> <p><b>-either</b> [1] 334:20</p> <p><b>-or</b> [1] 168:3</p>	<p><b>-2-</b></p>	<p><b>-3-</b></p>	<p><b>-4-</b></p>	<p><b>-5-</b></p>
<p><b>-0-</b></p>	<p><b>-1-</b></p>	<p><b>-2-</b></p>	<p><b>-3-</b></p>	<p><b>-4-</b></p>
<p><b>0</b> [2] 257:21,21</p> <p><b>0/0</b> [2] 352:5 358:8</p> <p><b>0/40</b> [1] 361:12</p> <p><b>0542</b> [2] 303:3,24</p> <p><b>0940</b> [1] 307:6</p>	<p><b>1</b> [12] 76:13 80:15 135:16 136:14 138:11 147:15 151:13 217:12 224:20 227:2 360:16 363:3</p> <p><b>10</b> [23] 113:13 114:3 156:5,6 265:18,20 267:23 276:18 330:17 331:2,23 332:15 333:10,11,13 344:5 348:20 352:23</p>	<p><b>2008</b> [8] 1:4 102:14 163:14 365:15 370:25 372:12 397:5,12</p> <p><b>20th</b> [2] 296:20 358:20</p> <p><b>21</b> [1] 120:8</p> <p><b>2100</b> [1] 318:24</p> <p><b>23</b> [4] 147:5 217:16 289:6 370:12</p> <p><b>231</b> [2] 2:5,6</p> <p><b>234</b> [1] 3:3</p> <p><b>2370</b> [2] 391:3,7</p> <p><b>2372</b> [1] 393:9</p> <p><b>2373</b> [2] 384:13,15</p> <p><b>24</b> [1] 237:20</p> <p><b>24.2</b> [1] 372:3</p> <p><b>25</b> [1] 309:22</p> <p><b>252</b> [2] 2:6,7</p> <p><b>26</b> [2] 96:1 97:2</p> <p><b>26th</b> [1] 283:5</p> <p><b>27</b> [1] 389:12</p> <p><b>2700</b> [1] 389:16</p>	<p><b>4</b> [8] 2:3 3:2 106:4 146:21 153:25 154:4,6,9</p> <p><b>4,500</b> [1] 321:6</p> <p><b>40</b> [7] 68:3,4 156:7 218:15 227:3,5 329:21</p> <p><b>41</b> [3] 308:12 309:15,20</p> <p><b>45</b> [1] 58:8</p> <p><b>4500</b> [1] 318:22</p> <p><b>4510</b> [1] 316:13</p> <p><b>46</b> [1] 319:23</p> <p><b>48</b> [3] 319:23 322:24 324:1</p> <p><b>49</b> [1] 237:19</p> <p><b>4:30</b> [1] 396:16</p> <p><b>4th</b> [4] 127:18 307:8 311:12 313:6</p>	<p><b>9</b> [7] 1:4 257:21 265:18 265:19 267:23 276:18 396:21</p> <p><b>90</b> [3] 237:20 238:11 383:1</p> <p><b>90/90</b> [1] 352:20</p> <p><b>92</b> [1] 153:8</p> <p><b>94</b> [1] 67:18</p> <p><b>95</b> [22] 68:9,13,21 69:9 110:18 153:10 155:13 156:6 166:25 204:4 205:22,25 206:15 207:11 207:21 208:7 209:17 220:6 287:6,15 288:1 360:5</p> <p><b>96</b> [1] 237:22</p> <p><b>97</b> [1] 372:19</p> <p><b>98</b> [2] 287:16,19</p> <p><b>99</b> [1] 288:2</p> <p><b>9:00</b> [1] 396:19</p> <p><b>9:30</b> [3] 396:13,22,23</p> <p><b>9th</b> [3] 163:14 397:5,12</p>

Inquiry on Hormone Receptor Testing

<p><b>-A-</b></p> <p><b>A.D</b> [2] 397:5,12</p> <p><b>a.m</b> [3] 297:3,25 307:11</p> <p><b>abbreviation</b> [1] 21:3</p> <p><b>abilities</b> [1] 263:20</p> <p><b>ability</b> [6] 72:11 87:22 172:9 215:5 230:16 397:9</p> <p><b>able</b> [35] 13:19 35:12 39:12 45:7 80:1 88:22 89:16,22 106:15 132:3 132:11 138:13 157:21 172:10,13 176:22 178:3 184:25 190:15 191:6 209:4 214:19 215:15,23 222:23 228:14 231:3 233:3 239:16 245:25 247:2 318:21 321:3 342:8 387:4</p> <p><b>above</b> [4] 106:14,14 236:9 352:23</p> <p><b>absence</b> [1] 129:1</p> <p><b>absent</b> [2] 130:6 269:8</p> <p><b>absolutely</b> [26] 23:10 36:4,17 61:25 63:17 115:3 123:22 124:17 125:24 126:23 127:6 140:19,21 154:25 175:3 187:16 192:17 198:9 200:3 215:21 230:22 233:7 245:20 259:15,19 262:21</p> <p><b>abstract</b> [1] 142:6</p> <p><b>academic</b> [2] 5:24 6:6</p> <p><b>academically</b> [1] 81:6</p> <p><b>acceptable</b> [3] 18:11 68:12 287:10</p> <p><b>accepted</b> [3] 101:12 102:2 288:1</p> <p><b>access</b> [1] 64:25</p> <p><b>accessible</b> [2] 88:8 284:1</p> <p><b>accommodation</b> [1] 12:19</p> <p><b>accommodations</b> [1] 161:5</p> <p><b>accompany</b> [1] 38:1</p> <p><b>according</b> [1] 15:7</p> <p><b>account</b> [5] 69:5 197:18 269:15 270:11 279:16</p> <p><b>accredit</b> [1] 171:4</p> <p><b>accreditation</b> [35] 14:19 15:5,14,16,23 16:2,9 42:17,19 95:12 105:22 158:24 163:23 164:3,5 164:12,20 165:12,23 166:2,6,9,14 171:9,9,12 171:13,16,21 247:10,15 247:19 259:1,2 286:23</p> <p><b>accredited</b> [2] 10:9 247:14</p> <p><b>accrediting</b> [1] 164:6</p> <p><b>accumulated</b> [1] 61:8</p> <p><b>accumulating</b> [1] 54:10</p> <p><b>accumulative</b> [1] 279:23</p>	<p><b>accuracy</b> [1] 131:9</p> <p><b>accurate</b> [9] 71:1 123:20 125:22 127:4 175:11,16 189:23 285:5 367:5</p> <p><b>achieve</b> [6] 10:1 145:11 149:16 157:2 207:23 220:5</p> <p><b>achieved</b> [5] 11:1,2,9 211:12 220:8</p> <p><b>acquire</b> [1] 196:21</p> <p><b>acquired</b> [1] 200:23</p> <p><b>Action</b> [1] 1:13</p> <p><b>actions</b> [2] 277:25 278:21</p> <p><b>active</b> [1] 99:3</p> <p><b>activity</b> [1] 274:14</p> <p><b>actual</b> [11] 16:18 28:17 28:20 91:10 174:9 207:17 242:13 284:8,11,12 378:1</p> <p><b>acute</b> [3] 120:9,13,13</p> <p><b>adapted</b> [1] 103:9</p> <p><b>add</b> [2] 345:11 374:25</p> <p><b>added</b> [5] 346:25 362:22 372:9,18,19</p> <p><b>adding</b> [2] 368:17,19</p> <p><b>addition</b> [8] 7:7 18:23 59:6 92:5 258:16 262:11 277:16 278:24</p> <p><b>additional</b> [21] 34:11 50:3 58:1,20 69:7 72:5 101:14 104:24 108:3 126:9 150:1 160:12 161:23 182:23 231:4 247:19 250:12,23 270:19 277:6 348:5</p> <p><b>address</b> [10] 110:16,17 171:24 175:16 210:17 254:1,20 255:21 263:18 314:19</p> <p><b>addressed</b> [6] 97:24 98:14 114:13 210:2,8 255:1</p> <p><b>addressing</b> [2] 113:24 179:5</p> <p><b>adenocarcinoma</b> [6] 123:6,7,17,24 124:6,11</p> <p><b>adenocarcinomas</b> [1] 123:5</p> <p><b>adequate</b> [7] 7:10 19:3 19:3 62:22 86:25 154:19 163:17</p> <p><b>adjourn</b> [1] 396:16</p> <p><b>adjournment</b> [1] 177:13</p> <p><b>adjunct</b> [2] 59:6 121:6</p> <p><b>adjust</b> [3] 72:18 88:2 211:8</p> <p><b>adjusted</b> [1] 276:22</p> <p><b>administrative</b> [2] 84:13 86:19</p> <p><b>administratively</b> [1] 17:7</p> <p><b>adopt</b> [1] 158:22</p> <p><b>adopted</b> [4] 68:14 110:8 209:18 227:15</p> <p><b>advance</b> [2] 212:18,21</p>	<p><b>advanced</b> [2] 97:10 106:20</p> <p><b>advances</b> [2] 231:24 232:8</p> <p><b>advantage</b> [3] 155:5 178:15 261:18</p> <p><b>advantages</b> [2] 230:16 261:16</p> <p><b>advice</b> [3] 50:8 305:10 305:22</p> <p><b>affairs</b> [1] 174:2</p> <p><b>affect</b> [1] 162:20</p> <p><b>affiliated</b> [4] 6:16 167:5 188:3,5</p> <p><b>afternoon</b> [10] 176:24 231:15 252:17 296:3,9 296:10 308:16,22 312:16 379:14</p> <p><b>afterwards</b> [2] 6:13 354:14</p> <p><b>again</b> [60] 13:7 80:3 121:5 125:13,13,20 126:18 133:21 157:12,25 173:3 185:5 186:2 202:8 210:19,21 211:8 214:10 214:21 218:12 240:18 248:16 251:2 257:11 262:6 264:12 266:25 278:8 283:13 295:17 296:19 310:22 321:5 328:5,22 339:12,16 346:13 348:20 349:22 352:19 362:24 363:21 365:25 366:15 367:1 371:20 377:6 378:10,25 381:6,23 386:1 392:8 394:19 395:7,25 396:5,9 396:13</p> <p><b>age</b> [1] 343:2</p> <p><b>agencies</b> [3] 163:1,6 220:20</p> <p><b>agency</b> [3] 103:15 104:1 163:12</p> <p><b>aggregate</b> [1] 211:6</p> <p><b>ago</b> [6] 17:22 53:20 147:18 246:4 271:15 287:1</p> <p><b>agree</b> [4] 47:21,23 285:10 291:8</p> <p><b>agreed</b> [2] 50:21 342:6</p> <p><b>ahead</b> [11] 6:7 9:22 10:19 52:22 55:13 64:13 83:12 116:10 148:13 169:3 177:5</p> <p><b>aim</b> [3] 54:17 200:8,9</p> <p><b>al</b> [1] 1:9</p> <p><b>Alberta</b> [2] 164:13 260:23</p> <p><b>alcohol</b> [1] 275:6</p> <p><b>algorithm</b> [1] 65:4</p> <p><b>algorithms</b> [1] 20:15</p> <p><b>Alidina</b> [2] 343:6,11</p> <p><b>ALK1</b> [1] 64:6</p> <p><b>allow</b> [2] 79:21 245:15</p> <p><b>allowed</b> [1] 294:10</p> <p><b>allowing</b> [1] 199:5</p>	<p><b>allows</b> [1] 69:2</p> <p><b>Allred</b> [2] 243:2,8</p> <p><b>almost</b> [9] 95:2 107:5 114:9 115:23 190:20 225:13 297:15 313:2 318:24</p> <p><b>alone</b> [8] 58:3,6,12,14 117:24 181:23 200:10,14</p> <p><b>along</b> [1] 379:8</p> <p><b>alter</b> [1] 73:24</p> <p><b>alternative</b> [1] 284:24</p> <p><b>alters</b> [1] 199:25</p> <p><b>altogether</b> [2] 138:8 217:16</p> <p><b>always</b> [12] 44:16 48:25 75:8 87:17 117:1 118:21 197:17 203:2 208:13 211:9 242:11 284:21</p> <p><b>ambitious</b> [1] 114:2</p> <p><b>America</b> [2] 243:3 284:4</p> <p><b>American</b> [4] 42:15 104:3 105:21 223:11</p> <p><b>among</b> [1] 222:4</p> <p><b>amount</b> [3] 76:24 179:10 396:17</p> <p><b>amplification</b> [3] 197:3 197:5,9</p> <p><b>amplify</b> [2] 197:7,14</p> <p><b>analogies</b> [1] 242:4</p> <p><b>analysis</b> [5] 154:20 155:16,19,21 298:9</p> <p><b>analytic</b> [1] 263:1</p> <p><b>analytical</b> [5] 54:2 71:23 72:13 248:8 253:20</p> <p><b>anatomic</b> [2] 6:18,23</p> <p><b>anatomical</b> [2] 191:19 351:17</p> <p><b>animals</b> [1] 274:20</p> <p><b>annual</b> [3] 101:11 141:21 168:18</p> <p><b>anonymous</b> [1] 90:23</p> <p><b>answer</b> [8] 94:8,8 106:11 135:17 164:10 189:7 244:15 345:2</p> <p><b>ante</b> [1] 243:2</p> <p><b>anti-smooth</b> [1] 248:24</p> <p><b>antibodies</b> [21] 17:14 33:23 36:15 39:6 65:9 65:17 114:6 127:24,25 132:7 145:5 153:13 159:21 192:14 194:9 212:10 232:1 239:22 250:8 290:15 301:7</p> <p><b>antibody</b> [15] 18:1,12 37:3 51:6 153:14 194:4 197:1 214:25 248:12 249:15 250:6 276:10,11 276:18 290:6</p> <p><b>anticipate</b> [1] 257:3</p> <p><b>anticipated</b> [2] 140:15 225:1</p> <p><b>antigen</b> [31] 66:7 74:13 76:2,9 128:19 130:2,3 145:3 199:12,14,15,20 200:19,22 201:11,20</p>	<p>203:6 208:14 248:11,24 249:12 250:13 269:21 273:10,13,17 274:3,9 288:23 289:18,19</p> <p><b>antigens</b> [4] 74:14 193:14 213:11 274:13</p> <p><b>anyway</b> [5] 49:10 52:9 69:10 121:22 176:24</p> <p><b>anyways</b> [2] 124:3 135:18</p> <p><b>AP-15</b> [5] 121:5 122:22 125:4,16,21</p> <p><b>apart</b> [1] 380:3</p> <p><b>apologize</b> [1] 285:14</p> <p><b>apparatus</b> [1] 397:10</p> <p><b>appear</b> [5] 66:24 145:2 293:21 365:23 367:5</p> <p><b>Appearances</b> [1] 1:5</p> <p><b>applicable</b> [4] 104:7 194:11 200:7 267:19</p> <p><b>applied</b> [1] 259:7</p> <p><b>applies</b> [1] 117:7</p> <p><b>apply</b> [9] 36:18,19 65:16 66:6 117:9 267:3,12 274:12 344:4</p> <p><b>appointed</b> [2] 81:6 305:20</p> <p><b>appointing</b> [1] 24:3</p> <p><b>appointment</b> [1] 178:23</p> <p><b>appreciate</b> [11] 5:16 9:3 16:17 108:12 131:17 178:13 288:13 291:15 295:13,22 296:2</p> <p><b>appreciation</b> [1] 220:9</p> <p><b>approach</b> [11] 27:12 84:14 104:9 108:23 109:4 126:25 210:22 230:16 237:2 242:21 255:20</p> <p><b>approached</b> [3] 86:9 94:19 97:12</p> <p><b>approaches</b> [1] 243:24</p> <p><b>approaching</b> [1] 26:3</p> <p><b>appropriate</b> [20] 15:23 24:21 36:7,20 48:15 52:16,17 62:12 63:25 106:25 108:3 109:13 117:3 118:11,15 126:10 144:10,15 185:12 229:24</p> <p><b>appropriately</b> [4] 36:6 121:9 185:17 200:12</p> <p><b>April</b> [2] 127:18 301:6</p> <p><b>apt</b> [1] 273:6</p> <p><b>area</b> [24] 9:18 11:25 24:19,20 25:7 34:11 54:13,19 70:24 101:8 113:12 170:6 177:11 180:9 182:14 184:10,12 203:20 220:15 230:22 244:6 245:4 325:15 346:14</p> <p><b>areas</b> [10] 12:2 53:25 100:11 102:6 182:17 184:6 231:20 248:6 281:18 305:17</p> <p><b>arena</b> [1] 103:10</p>
--	---	---	---	--

<p><b>arise</b> [1] 94:13  <b>arising</b> [2] 44:17 282:19  <b>Arizona</b> [1] 301:16  <b>arms</b> [1] 154:6  <b>arose</b> [1] 313:7  <b>arrange</b> [1] 296:25  <b>arranged</b> [1] 298:14  <b>arrangement</b> [1] 245:10  <b>arranging</b> [2] 105:16 297:7  <b>arrival</b> [2] 80:18 82:15  <b>arrive</b> [3] 26:6 62:12 65:7  <b>arrived</b> [13] 23:18 24:2 24:5,24 49:19 80:18 81:11 82:14 84:17 93:2 95:15 208:7 353:23  <b>arriving</b> [1] 125:20  <b>art</b> [2] 53:22 95:6  <b>article</b> [15] 233:25 234:10,13 239:7 240:12 240:14,15,17 244:5 283:3 284:8,12,13,19 285:13  <b>articles</b> [2] 32:2 240:8  <b>artificially</b> [2] 243:7,8  <b>ASCO</b> [7] 68:14 92:22 110:7 155:9 203:25 208:4 254:17  <b>aside</b> [1] 199:8  <b>aspect</b> [3] 48:18 257:7 263:3  <b>aspects</b> [6] 23:11 55:11 58:2 108:1 109:11 191:11  <b>assays</b> [2] 210:18,20  <b>assess</b> [3] 45:7 50:17 345:5  <b>assessed</b> [1] 103:23  <b>assessing</b> [1] 105:17  <b>assessment</b> [11] 45:23 48:19 49:4 103:14 151:21 160:18 229:18 308:5 309:19 373:19,23  <b>assessments</b> [8] 13:20 13:21 44:11,16 45:9 161:7 265:11,13  <b>assessor</b> [5] 45:14,15 50:20,22 87:19  <b>assessor's</b> [1] 51:8  <b>assessors</b> [5] 33:24 44:5 49:2 160:24 161:6  <b>assigned</b> [3] 353:21,23 366:13  <b>assist</b> [3] 5:8,8 27:21  <b>assisted</b> [1] 295:25  <b>associate</b> [1] 81:7  <b>association</b> [12] 1:14 98:3 101:6,10,16 104:15 105:1 134:21 136:1 167:6 167:13 221:5  <b>assume</b> [1] 277:7  <b>assuming</b> [4] 217:3 295:11 334:19 339:17  <b>assumption</b> [6] 48:4 109:10 110:5 111:11,12</p>	<p>374:1  <b>assurance</b> [59] 13:19,22 14:4,9,18 15:21 33:11 34:17 43:12 62:22 68:1 81:14 87:1 92:8 93:18 96:18 99:12 100:7 103:11 110:18 113:23 114:3 121:10,14,19 132:4 151:4 151:25 156:1,10 157:3 158:14,20,22 164:17 166:1 172:6 173:12,18 173:20 183:14 184:13,19 200:3,6 230:14,20 234:3 236:24 239:4 249:20 251:13 252:23 253:3 256:17 258:21 275:14 286:22,22  <b>assure</b> [1] 383:16  <b>assured</b> [1] 124:14  <b>assuring</b> [1] 16:4  <b>attach</b> [1] 98:21  <b>attached</b> [1] 211:5  <b>attempted</b> [1] 10:3  <b>attend</b> [2] 300:19 302:3  <b>attendance</b> [1] 342:20  <b>attended</b> [2] 6:9 302:24  <b>attention</b> [9] 11:22 149:18,22 205:17 210:7 286:14 291:14 320:10 335:21  <b>attributed</b> [1] 294:23  <b>attributes</b> [1] 186:10  <b>audience</b> [1] 97:25  <b>audit</b> [2] 234:3 278:7  <b>audits</b> [2] 234:13 285:4  <b>August</b> [13] 296:20 299:3 304:1 307:8 311:6,12,14 312:25 313:6,8 314:12 369:10 382:24  <b>August/September</b> [1] 381:24  <b>Australia</b> [4] 245:8 284:9 285:12,14  <b>Australian</b> [1] 248:5  <b>author</b> [2] 240:18 243:15  <b>Authorities</b> [1] 1:17  <b>authority</b> [2] 1:11 190:8  <b>authors</b> [1] 238:7  <b>automation</b> [1] 182:10  <b>automatized</b> [1] 45:10  <b>avail</b> [1] 39:12  <b>available</b> [54] 16:7 17:14 17:17 50:9 54:8 58:5 64:25 72:8 79:13 93:7 106:10,20 108:15 115:1 141:24,24 161:19 179:12 179:15 184:1,24 185:1 185:18 186:11 193:6,23 194:10 195:1 196:16 199:4 221:25 223:10 256:9 258:4,10,17 259:21 261:5,12 264:4,22 272:9 279:16 282:3,8,13 283:23 283:25 284:1,22,24 304:6 346:5 348:5  <b>average</b> [5] 50:23 217:17</p>	<p>256:6 372:3 389:4  <b>avidin</b> [3] 274:2,9 276:6  <b>avoid</b> [4] 54:19 209:4,9 211:24  <b>aware</b> [34] 11:23,24 21:20 49:10 50:14 93:8 155:8 184:11 204:22,24 209:15 210:5,9 221:14 223:2 226:11 235:25 248:15 258:25 259:22 260:2,4 274:5,17,21 275:2 282:12 285:1,23 320:14 339:6 382:24 383:3,6  <b>away</b> [10] 75:21 92:21 132:9 134:4 153:5 251:12 312:18 336:11 367:24 382:2</p> <hr/> <p style="text-align: center;"><b>-B-</b></p> <hr/> <p><b>b</b> [17] 20:22 21:11 65:15 117:12 118:22,22 129:3 129:13,14,19,20,20 132:17,19 213:16 240:23 257:21  <b>baby</b> [1] 255:19  <b>background</b> [24] 5:25 6:7 7:11 16:16 45:6,7 51:1 105:24 144:15 184:4 198:16 213:18 268:14,17 269:4 271:15 275:15,16 275:24 276:3,8 277:4,8 277:15  <b>backgrounds</b> [1] 203:1  <b>backup</b> [1] 19:18  <b>backwards</b> [1] 391:14  <b>bad</b> [2] 132:24 153:9  <b>Banerjee</b> [6] 98:15 99:9 100:5,16 379:12 382:18  <b>Barry</b> [15] 301:15 303:9 303:16 307:11 308:14 310:25 311:9,24 312:17 312:20 315:22 320:17 339:16 383:25 384:1  <b>Barry's</b> [2] 384:22,24  <b>base</b> [2] 183:14 200:16  <b>based</b> [24] 17:17 46:16 51:19,24 52:1 65:19 66:8 82:19 131:10 133:2 140:14 155:19 184:22 193:7 198:12 239:22 258:9 276:2,6 280:20 281:24 282:1 298:22 337:1  <b>basic</b> [7] 18:6 95:18 106:11 218:16 232:18 307:25 321:1  <b>basil</b> [1] 116:15  <b>basis</b> [4] 135:21 182:6 182:18 185:15  <b>batch</b> [1] 337:4  <b>batches</b> [1] 336:8  <b>BC</b> [3] 84:2 85:24 164:13  <b>bear</b> [1] 116:22  <b>became</b> [1] 200:25  <b>become</b> [8] 11:23 14:8,8</p>	<p>28:1 54:8 73:23 192:20 247:18  <b>becomes</b> [1] 173:16  <b>began</b> [4] 192:4 193:18 308:13 345:1  <b>beginner</b> [1] 119:9  <b>beginning</b> [15] 12:7,21 16:21 22:9 41:3 53:1 70:10 80:6 100:24 103:3 110:24 192:3 285:12 340:13 386:9  <b>beginnings</b> [1] 306:11  <b>begins</b> [1] 144:2  <b>begun</b> [1] 348:12  <b>behind</b> [3] 76:22 192:25 201:22  <b>belief</b> [1] 189:18  <b>belong</b> [3] 19:9 46:14 61:6  <b>belongs</b> [1] 137:6  <b>below</b> [8] 156:5 205:22 205:25 214:22 235:15 237:21 384:18 395:18  <b>bench</b> [2] 35:10 184:1  <b>benchmark</b> [3] 299:5 299:21 300:1  <b>beneficial</b> [1] 263:3  <b>benefit</b> [6] 12:15 94:17 176:25 177:12 178:3 381:20  <b>benefited</b> [1] 82:3  <b>benefits</b> [2] 104:19 261:19  <b>benign</b> [8] 21:10 32:12 75:2 76:7 128:20 214:9 214:15,18  <b>Bernard</b> [5] 1:6 2:3,8 4:6 282:24  <b>best</b> [20] 7:3 40:13 46:5 58:15 67:17 74:12,14,14 95:4 189:18 204:2 212:1 269:22 284:4 293:12,13 301:11 303:1 341:16 397:9  <b>better</b> [19] 10:2 13:5 23:2 26:21 45:4 77:14 78:2 78:24 148:24,25 149:25 163:4 200:25 201:14 216:4 243:6 247:18 287:22 288:2  <b>between</b> [41] 10:24 43:3 44:25 50:21 51:17 61:1 64:14 84:10 87:17 95:5 97:11 113:13 117:18 118:8 120:10 135:5 136:21 144:11,23 157:22 166:8 167:12 173:18 179:18 201:19 213:14 220:3 223:23 229:17 234:4 238:11 241:4,14 242:14 262:4 294:11 295:19 311:1 332:10,10 381:3  <b>beyond</b> [5] 154:17 330:20 345:22,25 346:2  <b>big</b> [10] 13:15 84:10,12 142:8 150:16 174:25</p>	<p>175:22 230:15 303:13 321:12  <b>biochemical</b> [7] 210:18 210:20,24 243:15,23 346:4,12  <b>biochemistry</b> [2] 346:13 346:21  <b>biological</b> [6] 55:15 58:2 58:21 66:19 208:19 242:2  <b>biologically</b> [2] 62:4 117:8  <b>biology</b> [2] 7:7 62:10  <b>biopsies</b> [1] 132:23  <b>biopsy</b> [6] 116:19 120:3 120:4 128:15 133:5 347:12  <b>biotin</b> [6] 274:2,9,10,13 276:4,6  <b>bit</b> [26] 9:5 19:8,18 56:25 63:19 88:7 116:2 139:18 148:17 150:9 151:1 155:3 168:7 177:1 179:23 253:8 294:10 295:17 326:13 331:2 332:7 337:16 346:14 351:19 365:18 367:9  <b>bizarre</b> [1] 139:1  <b>black</b> [2] 65:11 117:11  <b>Blair</b> [1] 1:16  <b>Blake</b> [3] 85:24,25 87:3  <b>blast</b> [3] 119:24 120:1,3  <b>block</b> [5] 136:22 154:10 236:10 269:16 318:9  <b>blocks</b> [14] 26:9,17 317:25 340:23 344:25 346:2,5 349:3 374:4 375:3 379:9,19 381:4,4  <b>blow</b> [2] 148:17 288:12 4:6 282:24  <b>board</b> [1] 292:14  <b>bodies</b> [2] 245:14,15  <b>body</b> [5] 42:10 95:12 171:3,12 173:10  <b>bomb</b> [1] 286:10  <b>bombarded</b> [1] 94:20  <b>bond</b> [1] 185:20  <b>bone</b> [15] 116:17,18,21 117:12,22 119:25 121:3 122:14,16,21 123:7 132:18 218:7 219:4 220:2  <b>Bonnell</b> [2] 349:19 350:1  <b>book</b> [2] 257:19 258:5  <b>border</b> [2] 27:25 84:10  <b>borderline</b> [3] 77:9,11 327:23  <b>borders</b> [2] 84:12 85:20  <b>bottom</b> [5] 98:11 104:5 106:4 107:17 362:21  <b>bowl</b> [1] 346:25  <b>box</b> [2] 65:11,11  <b>boxes</b> [1] 65:8  <b>brackets</b> [1] 323:15  <b>brain</b> [3] 388:11,13,15  <b>branch</b> [1] 11:17</p>
---	--	---	--	--

<p><b>branches/something</b> [1] 101:21  <b>Brazil</b> [1] 1:8  <b>break</b> [13] 126:1 127:11 134:10 176:25 177:5 178:5,16,18 233:25 296:3 296:5 390:13 396:12  <b>breakdown</b> [1] 368:8  <b>breast</b> [41] 1:12 58:16 58:19 59:7 60:8 107:24 109:19,21 111:15 120:24 121:5 122:7,20 125:10 125:11,15 139:10 146:20 146:22 154:8 164:21 165:2 169:16 238:15 278:15,17 279:13,14,24 282:6 284:13 317:15 321:9 346:17 367:24 369:5 386:7,11,25 387:17 388:5  <b>breasts</b> [1] 389:13  <b>briefly</b> [2] 187:23 305:8  <b>bring</b> [9] 5:11,13 95:25 127:15 194:15 264:12 283:2 296:18 383:12  <b>bringing</b> [1] 80:17  <b>British</b> [2] 85:3 95:16  <b>broader</b> [1] 309:3  <b>broken</b> [1] 377:9  <b>Brook</b> [7] 318:10 354:3 355:15,17 356:25 376:20 376:21  <b>brought</b> [3] 100:11 300:15 335:21  <b>brown</b> [8] 117:11 214:5 239:11,12,25,25 240:1 288:7  <b>Browne</b> [47] 1:9 2:6 177:8,9 231:10,11,13,14 231:16 232:12,24 233:13 233:17,23 234:8,16,22 235:9 236:2,16 237:3,10 238:3,16,22 239:3,10 240:13 242:17 244:4,14 245:3 246:2,12,16 247:1 248:1,18 251:11,22 252:2 252:5 283:3,6 334:5,9 334:13  <b>budget</b> [4] 161:24 162:3 162:4,16  <b>budgets</b> [1] 162:15  <b>buffer</b> [4] 51:5 250:21 269:23 337:16  <b>buffers</b> [3] 199:20 201:9 290:1  <b>built</b> [1] 165:24  <b>bulk</b> [1] 59:19  <b>bullet</b> [4] 31:16 146:24 159:2 163:16  <b>bullets</b> [1] 159:11  <b>burden</b> [1] 54:24  <b>buried</b> [1] 284:8</p> <hr/> <p style="text-align: center;"><b>-C-</b></p> <p><b>c</b> [8] 11:16 103:18 119:12 119:12 123:1 182:22</p>	<p>253:2,4  <b>cabinets</b> [1] 349:4  <b>calculate</b> [6] 68:5,7,8 138:15 156:5 205:24  <b>calculated</b> [1] 204:8  <b>calculation</b> [1] 155:17  <b>calculations</b> [4] 92:17 141:16 155:21 160:16  <b>calibrate</b> [6] 34:16 110:24 114:14 158:15,23 200:5  <b>calibrated</b> [2] 34:18 75:17  <b>calibration</b> [3] 75:14 120:22 200:15  <b>calls</b> [1] 306:4  <b>Cameron</b> [3] 1:3 335:7 397:6  <b>Canada</b> [39] 12:12 26:11 41:10 43:18,24 49:13 62:17 80:18,19 81:11 83:21,25 84:4,5 85:12 90:8 93:2,12,18 103:4 104:12,17 112:17 135:20 137:18 146:17 149:24 157:17 164:4 171:4 173:22 174:5 198:10 222:4 223:8 232:21 262:11 296:25 298:19  <b>Canadian</b> [37] 1:15 42:20 43:18 62:20 63:20 68:15 90:14 96:6 98:2 101:6,10,16 103:24 104:15 105:1,9 109:9 110:9,10 134:20 135:25 142:12 144:2 145:7 155:10 167:5,12 169:23 195:7 204:1 205:14 217:10 222:5,10,13 252:20 260:17  <b>cancer</b> [44] 1:12,15 7:13 8:3 24:14,15 58:16,19 59:8 60:8 100:18 109:19 109:21 116:16 120:24 122:20 130:6 133:1,9,11 139:10 146:20,22 154:8 164:22 165:2 169:17 211:2 238:15 252:20 278:17 279:15 280:20 318:23 319:12,24 320:5 321:4,11 336:9 341:15 341:21 386:25 388:5  <b>cancerous</b> [1] 129:22  <b>cancers</b> [1] 8:7  <b>cannot</b> [36] 45:9,10 71:5 71:9,10,13,14,17 72:13 73:14,15,16,17 74:5 87:15 93:17 94:13 117:5 131:19 132:16 155:24 156:5 161:13 163:1,10 172:5 173:17 182:16,16 208:23 215:18 247:16 253:13,19 259:8 275:10  <b>canvas</b> [1] 176:23  <b>canvass</b> [1] 109:5  <b>canvassed</b> [1] 162:23  <b>CAP</b> [48] 42:23,25 43:3 43:15 44:2 45:17,20 46:1</p>	<p>46:3,12,19 47:4,8 48:18 49:8,15 68:2 82:17 83:8 84:6 98:6 99:4,6,15,20 100:18,22 101:6 105:21 141:21 155:9 156:7 163:3 165:6 167:19,20 168:9 168:18,24 169:1,10,12 174:22 203:25 223:11 254:17 260:8 262:4  <b>capabilities</b> [1] 351:19  <b>capability</b> [2] 264:23 340:24  <b>capacity</b> [1] 299:7  <b>CAPs</b> [1] 89:25  <b>carcinoma</b> [11] 107:24 122:8 125:10,15 128:15 130:7 132:21 137:6 144:11 279:13 282:7  <b>carcinomas</b> [5] 129:4 130:4 279:18,20,21  <b>care</b> [9] 18:14 61:20 172:22 174:8 175:18 216:15 281:19 325:9 390:8  <b>career</b> [1] 19:24  <b>careful</b> [4] 120:21 203:24 254:11 285:25  <b>carefully</b> [5] 33:16 100:14 120:6,15 275:25  <b>Carole</b> [3] 298:21 300:16 307:13  <b>carried</b> [5] 56:24 226:5 300:4 302:19 369:18  <b>carry</b> [1] 58:10  <b>carrying</b> [1] 303:6  <b>Carter</b> [14] 308:9 309:2 309:3 311:6 312:10 313:7 313:15 315:8,18,21 321:25 341:6,9 382:25  <b>case</b> [15] 12:3 44:20 108:22 118:21 119:6 150:13 166:13 209:23 214:23 225:24 264:18 290:10 308:12,25 310:14  <b>cases</b> [19] 226:3 250:6,16 285:8 296:23 308:7,15 308:24 309:6,7 310:7 311:1 323:21 330:16 360:10 363:5,16 367:17 383:3  <b>catch</b> [1] 320:10  <b>categories</b> [4] 359:5 377:9,11 387:1  <b>categorize</b> [1] 243:8  <b>category</b> [11] 60:23 61:5 61:23 62:9 66:5 208:12 209:13 217:24 357:18 360:22 367:18  <b>caused</b> [2] 25:25 274:18  <b>causing</b> [1] 209:8  <b>caution</b> [2] 327:21 396:6  <b>CCQLM</b> [1] 100:18  <b>CD-23</b> [2] 75:24 76:3  <b>CD117</b> [5] 62:9 64:6,7 169:18 218:14  <b>CD14</b> [3] 18:1,1 19:12</p>	<p><b>CD15</b> [1] 248:24  <b>CD20</b> [13] 60:9,10 62:2 62:5,6,8 65:15 118:19 118:21 129:11 132:17,18 169:18  <b>CD23</b> [1] 32:9  <b>CD3</b> [1] 128:17  <b>CD34</b> [2] 65:15 120:4  <b>CD45</b> [1] 65:16  <b>CD45RO</b> [1] 65:16  <b>CD5</b> [1] 128:22  <b>CD61</b> [1] 218:15  <b>CD79a</b> [1] 129:16  <b>CEA</b> [2] 129:24 130:1  <b>cell</b> [27] 65:15,25 66:2 77:7,12,14,17,21 78:3,9 118:22,22 128:19,25 129:3,13,19,20,21 130:6 132:17,19 144:14 211:2 211:5 228:24 240:23  <b>cells</b> [14] 21:8,11 76:2,4 118:24 119:24,24 120:5 120:7 128:19,25 129:20 230:4 243:11  <b>central</b> [2] 1:16 42:10  <b>centre</b> [9] 17:9 24:14 25:18 26:14 188:22 190:21 256:15 336:9 353:15  <b>centres</b> [1] 317:20  <b>certain</b> [28] 12:2 23:9 32:8,9,23 33:23 34:20 66:2 87:10 90:24,24 95:18 127:23,23 193:14 193:14 209:4 245:14 247:24 264:2 273:5 278:16 280:7,20 281:17 281:18 361:18 385:8  <b>certainly</b> [16] 43:7 44:20 61:22 74:5 95:13 103:4 108:16 255:14 270:13 289:18,25 305:16,17 313:19 320:14 370:25  <b>Certificate</b> [2] 2:11 397:1  <b>certification</b> [8] 10:10 25:7 158:25 163:18 165:8 165:9 166:9 169:14  <b>certified</b> [4] 25:8 166:7 167:1 168:3  <b>certify</b> [4] 166:13,19 167:2 397:2  <b>chair</b> [1] 102:1  <b>chairing</b> [3] 62:19 167:19 174:23  <b>challenge</b> [2] 72:25 73:6  <b>challenges</b> [4] 73:8,9 74:19 105:17  <b>challenging</b> [4] 21:6 149:13 151:2 295:5  <b>chance</b> [1] 212:23  <b>change</b> [10] 14:12 16:9 88:1 194:25 198:4 199:8 199:16 363:3 366:9 367:4  <b>changed</b> [14] 14:2 75:6 75:7 83:2 107:13 109:1</p>	<p>110:8 153:16 165:4 192:7 236:10 288:14 295:16 367:8  <b>changes</b> [9] 82:6 86:19 192:12 199:3 231:22 232:1 235:2 238:6 254:9  <b>changing</b> [2] 60:25 73:19  <b>characteristic</b> [1] 58:21  <b>characteristics</b> [3] 36:1 63:12 184:20  <b>characterize</b> [1] 121:7  <b>characterized</b> [1] 79:16  <b>charge</b> [7] 99:5 135:21 161:11 179:18 182:7 183:10 187:4  <b>chart</b> [2] 303:14 341:25  <b>charts</b> [1] 341:14  <b>chat</b> [2] 312:17,20  <b>Chaytor</b> [333] 1:7 2:10 296:6,8,17 297:10,23 298:13,25 299:17 300:7 300:11,18,23 301:19 302:2,5,6,11,16,23 303:2 303:17,23 304:18,22 305:1,6 306:8,14,18 307:1,5,20 308:2 309:10 309:16,23 310:5,12,17 310:19,24 311:11,18,22 312:4,8,14,24 313:5,16 314:10 315:13,17,23 316:3,8,18,22 317:7,12 317:16 318:16,20 319:6 319:8,14,20 320:4,8,20 321:13,19 322:4,10,16 322:22 323:3,8,13,20,25 324:4,9,12,13,18 325:2 325:10,14,19,23 326:4,9 326:20 327:1,5,11,15,25 328:4,9,19,23 329:2,7 329:16 330:2,7,12,19 331:1,6,13,19,25 332:16 332:22 333:7,16,19,21 334:1,14 335:12,23 336:3 336:16,21,25 337:7,13 337:21 338:5,17,23 339:3 339:9,21 340:5 342:14 342:19 343:5,10,14,20 344:6,12 345:10,15,20 346:1,9 347:2,8,15,19 347:23 348:3,10,15 349:5 349:12,16,24 350:8,12 350:19 351:8 352:15,22 353:2,6,12 354:5,12,18 354:24 355:4,9,19,23 356:2,18 357:1,6,10,14 357:20,24 358:10,14,24 359:3,8,12,17,21 360:2 360:7,13,18,23 361:2,7 361:11,15,20,25 362:5 362:10,18 363:9,13,18 363:22 364:3,8,14,21,25 365:6,10 366:2,4,10,18 366:24 367:10,14,19 368:1,7,18,22 369:2,6 369:11,15,22 370:1,7,14 370:18,22 371:10,17,21 371:22 372:7,13,20 373:2 373:7,13 375:17,23 376:2 376:9,16 377:5,14,20,25</p>
---	--	---	--	--



<p>378:14,20 379:6,23 380:2 380:8,14,20 381:9,14,18 382:23 383:4,10,18,24 384:6,11,23 385:3,10,15 385:20 386:5,14,21 387:3 387:10,15,20 388:2,6,12 388:16,21,25 389:7,14 389:19,24 390:9,12,18 390:22 391:2,6,10 392:1 392:5,9,14,20 393:1,6 393:16,20 394:2,6,11,18 394:25 395:4,8,12,17,21 396:2,8</p> <p><b>check</b> [5] 103:15 104:1 133:18 134:4 376:12</p> <p><b>checked</b> [2] 299:4 311:25</p> <p><b>checking</b> [4] 103:12 350:9 354:19 395:14</p> <p><b>checklist</b> [2] 169:24 170:20</p> <p><b>checklists</b> [2] 170:14,20</p> <p><b>checks</b> [1] 302:1</p> <p><b>Chesley</b> [3] 1:12 2:4 179:1</p> <p><b>chief</b> [2] 24:18 179:18</p> <p><b>choices</b> [1] 28:8</p> <p><b>chondrogenic</b> [1] 76:4</p> <p><b>choose</b> [1] 40:17</p> <p><b>chosen</b> [2] 12:25 215:5</p> <p><b>Christmas</b> [1] 118:25</p> <p><b>chromagram</b> [1] 75:3</p> <p><b>chromosome</b> [1] 21:9</p> <p><b>chronic</b> [2] 21:9,12</p> <p><b>chronological</b> [1] 53:10</p> <p><b>CIQC</b> [29] 90:15 105:9 108:6 109:6 134:12 145:7 154:18 159:14 162:8 167:5,12,15 175:5 211:10 223:21 226:18 245:11 251:14 255:5,15,21 258:20 260:9 262:6,11 262:24 263:14 278:25 288:21</p> <p><b>circled</b> [1] 364:1</p> <p><b>circling</b> [1] 364:4</p> <p><b>circulated</b> [2] 99:19 100:5</p> <p><b>circulates</b> [1] 281:4</p> <p><b>circulating</b> [1] 21:11</p> <p><b>circumstance</b> [1] 129:9</p> <p><b>circumstances</b> [2] 74:15 129:7</p> <p><b>cites</b> [1] 116:6</p> <p><b>City</b> [1] 6:15</p> <p><b>CK34</b> [1] 127:25</p> <p><b>CK8</b> [5] 122:22 123:2,4 123:19 124:14</p> <p><b>claim</b> [1] 73:18</p> <p><b>Clare's</b> [2] 312:15 354:4</p> <p><b>clarification</b> [1] 264:13</p> <p><b>clarify</b> [2] 264:16 314:17</p> <p><b>clarity</b> [1] 187:18</p> <p><b>class</b> [136] 1:13 37:13,14 37:16 38:6,16 56:10,10</p>	<p>56:10 57:8,9 58:11,13 59:18,18,20,22,23 60:3 60:15,15,15,18,20,21,23 61:1,1,6,8,14,16,17 62:9 62:16,21 63:4,5,5,6,8,8 63:8,14,15 64:7,7,10,12 64:14,15,21 66:11,17,22 66:23 67:1 68:12 76:13 76:15 79:1,8 80:14,15 92:23 100:13 106:2,2,3 107:24,25 108:8 109:7 109:12 111:23 112:12,24 113:3,8,10,16,18,22,24 114:8 115:1 116:14,23 116:25 117:5,8 118:20 119:20,22 120:12,18,23 121:3,5,8 122:22 130:11 130:25 131:3 132:14 134:9,18 135:2 137:11 137:12 138:23,25 139:9 146:2,19 154:7,13,21 161:20 170:20,21 188:1 188:2,8,13,15,18,18,20 189:11 213:12 223:22 224:20 236:20 257:12,15</p> <p><b>classed</b> [1] 141:5</p> <p><b>classification</b> [5] 52:25 56:9,17 60:1,14</p> <p><b>classified</b> [3] 62:2 362:1 362:12</p> <p><b>classify</b> [2] 8:5 118:8</p> <p><b>clear</b> [16] 24:12,16,17 68:17 135:24 153:11 182:18 213:18 286:20 287:1 305:19 306:21 332:10 376:25 377:3,6</p> <p><b>clearing</b> [1] 261:7</p> <p><b>clearly</b> [6] 13:11 178:2 241:13 276:5 360:6 361:6</p> <p><b>click</b> [1] 88:19</p> <p><b>Clinic</b> [2] 341:15,21</p> <p><b>clinical</b> [56] 6:19,23 40:22,23 55:1,4,25 57:18 57:20 58:10 62:7 67:15 67:22 69:14 95:14 104:11 104:13 105:18 106:12,17 114:9 116:24 117:10,15 117:17 144:2 145:8 149:22 150:13 164:2,5 179:10,19 186:11 195:25 196:10 197:16,20 200:12 202:20 215:11,23,25 216:9 217:20 229:21 253:22 270:23 283:15,21 323:12 341:13,24 343:3 344:16 373:23</p> <p><b>clinical/diagnostic</b> [3] 96:18 99:12 100:8</p> <p><b>clinically</b> [6] 57:17 196:4 200:6 215:3,3,14</p> <p><b>clinician</b> [6] 58:22 69:3 103:21 207:15 253:7 284:25</p> <p><b>clinicians</b> [11] 55:5 58:7 67:23 68:18,22 69:25,25 70:14 204:18 205:7 240:4</p> <p><b>clonal</b> [1] 153:14</p> <p><b>clone</b> [4] 250:9,12 272:9 274:18</p>	<p><b>clones</b> [3] 274:22 290:6 290:11</p> <p><b>close</b> [7] 16:5 90:19 94:5 218:4 331:17,20 337:18</p> <p><b>closed</b> [1] 262:15</p> <p><b>closely</b> [4] 108:21 131:22 182:5 210:23</p> <p><b>co-authors</b> [1] 143:22</p> <p><b>Co-counsel</b> [2] 1:6,7</p> <p><b>co-founder</b> [1] 167:15</p> <p><b>co-operation</b> [1] 254:8</p> <p><b>code</b> [1] 91:6</p> <p><b>coded</b> [1] 90:23</p> <p><b>Coffey</b> [423] 1:6 2:3,8 4:2,3,7,16,24 5:5,13,15 5:20 6:5 8:11,15,19 9:1 9:6,10,14,21 10:13,18 16:11 18:15,19 19:11,17 19:23 21:23 22:3,7,13 22:18 23:15,21,25 24:8 24:23 25:12,21 27:1,9 27:17 28:16,21,25 29:5 29:10,19,25 30:6,11,15 30:20,25 31:5,14,21 32:1 32:5,17 33:2,12,19 34:3 34:12,22 35:14,20,25 36:5,10,22 37:2,9,15,20 37:25 38:5,10,15,20,25 39:4,11,17,24 40:3,8,18 41:7,17 42:4,9,22 43:2,6 43:10 45:13,19,25 46:18 46:23 47:2,7,12,18 48:1 48:8,16 49:3,7,16,24 50:12 51:10,21,25 52:4 52:8,12,21 53:3 54:20 55:12 56:4,15,21 57:10 57:14 59:17 60:13,19 61:9,21 62:24 63:11,18 64:4,11 65:10 67:4 69:18 69:23 70:7,13,18 71:12 71:19 72:1 73:4 78:4,8 80:16,22 81:3,10,19 82:7 82:13,18,25 83:6,11 84:16,21 85:2,8,21 87:6 88:5,12,16 89:2,6,10,15 89:21 90:3,25 91:5,9,14 91:18 92:1,24 93:5,20 95:8,23 96:10,24 97:7 97:19,23 98:8,25 99:7 99:18 100:25 102:12,18 102:23 105:7,15 106:8 107:10,14 108:11,20 109:2,15,23 110:2,12 111:2,8,18,22 112:1,6 112:11,16,20 113:2,6,15 113:19 114:5,16,20,24 115:4,8,13,19 116:3,8 118:7,12 119:19 121:21 121:25 122:6,11,15,19 122:25 123:10,16 124:12 124:18,23 125:3,12,19 126:1,2,12,17,24 127:3 127:7,14 128:5,10,16,21 129:6,10,15,23 130:9,14 130:23 131:7,16 133:14 133:22 134:8,16,24 135:9 135:13,23 136:4,8,13,17 137:8,13,17,21 138:1,5 138:22 139:6,11,16,22 140:1,5,9,13,20,24 141:4</p>	<p>141:8,14 142:2,11,16,20 142:25 143:5,13,19,25 144:20 145:21,25 146:12 146:23 147:4,10,14,21 148:1,8,12,16 150:5 151:11 152:1,7,12,16 153:21 154:3,14 155:1 156:14,18,22 157:1,6,10 157:23 158:3,8 159:1,9 162:6,11,19 163:13,21 164:1 165:14,18 166:10 166:16 167:4,10,16 168:5 168:12,23 169:2 170:24 172:16 173:5,25 174:18 176:1,6,10 180:18,22 181:3,7,14 192:6 282:20 282:21,24 283:1 284:5 285:11,17 287:3,9,13,21 287:25 288:5,20 289:5 289:12,17,23 290:4,13 290:20 291:4,11,18,23 292:3,9,13,17,21 293:1 293:25 294:4,8,15,22 295:2,10,21</p> <p><b>collaborate</b> [1] 12:1</p> <p><b>collaboration</b> [1] 79:4</p> <p><b>colleagues</b> [2] 85:13,14</p> <p><b>collect</b> [2] 75:20 79:9</p> <p><b>collection</b> [3] 103:20 253:6 258:3</p> <p><b>College</b> [8] 42:15 81:1 86:11,16,23 104:3 223:11 234:2</p> <p><b>colon</b> [1] 130:5</p> <p><b>colour</b> [1] 214:5</p> <p><b>coloured</b> [1] 92:14</p> <p><b>Columbia</b> [3] 6:15 85:4 95:16</p> <p><b>column</b> [2] 92:11 237:18</p> <p><b>combination</b> [7] 60:7 60:12 79:19 117:25 269:3 277:3 344:23</p> <p><b>combinations</b> [1] 60:4</p> <p><b>combined</b> [3] 20:24 314:17 316:13</p> <p><b>combos</b> [1] 60:4</p> <p><b>coming</b> [16] 9:18 41:9 62:25 92:25 121:4 161:21 176:24 190:10 259:5 297:6 320:5 338:7 349:18 354:15 382:7 390:5</p> <p><b>commence</b> [1] 396:13</p> <p><b>commencing</b> [1] 396:21</p> <p><b>comment</b> [14] 43:1 50:25 127:22 191:16 216:3 231:21 238:10 239:4 252:21 259:8 275:10 292:25 354:1 394:10</p> <p><b>commentary</b> [2] 38:21 105:20</p> <p><b>commented</b> [3] 32:20 204:3 276:1</p> <p><b>comments</b> [7] 50:25 100:15 101:3 190:10 192:4 234:24 391:24</p> <p><b>commercial</b> [2] 201:10 212:9</p>	<p><b>commercially</b> [2] 17:17 196:16</p> <p><b>commission</b> [9] 1:1,6,7 4:10 55:16 96:2 179:6 397:4,7</p> <p><b>Commission's</b> [1] 108:17</p> <p><b>Commissioner</b> [93] 1:3 4:1,4,17,20 16:16,18,20 25:14 27:10 33:5 39:20 41:18 52:13 53:12 60:21 64:14,18 70:21 109:3 125:6,25 126:4 127:8,9 127:12,15,17 135:4 145:17 146:5 152:2 153:23 155:3 162:22 174:2,4 176:12,13,18,21 177:6,14,18,25 178:1,9 178:12,19,24 186:9,18 190:3 231:9,12 233:21 240:15 245:7 247:2 252:4 252:12,13 282:18 284:11 294:11 295:22,23 296:9 296:13 332:9,18 333:1,9 333:14 334:6,7,11,16,24 335:4,10 350:21 373:16 373:24 374:7,12 375:1,8 375:13 390:11 396:10,11 397:7</p> <p><b>Commissioner's</b> [1] 291:14</p> <p><b>committee</b> [22] 62:19 98:5 99:4 101:17,22 102:2,4 163:2,4 165:5 167:19,20 168:16,18,24 169:1,6,12 170:1,19 174:22,22</p> <p><b>Committee/immunohistochemistry</b> [1] 101:19</p> <p><b>common</b> [14] 44:4 48:11 50:21 66:7 104:19 115:14 149:8 189:19 213:11 215:8 224:14 251:3 273:22 278:12</p> <p><b>commonly</b> [7] 115:10 145:10 211:12 213:23 218:9,16 222:9</p> <p><b>communicate</b> [1] 302:7</p> <p><b>communicated</b> [1] 302:19</p> <p><b>communication</b> [8] 16:5 50:5 104:9 183:16 185:14 240:4 306:13,20</p> <p><b>communications</b> [2] 305:7,13</p> <p><b>community</b> [2] 104:17 216:14</p> <p><b>companies</b> [5] 11:21 13:4,10 159:21,24</p> <p><b>company</b> [7] 11:15 12:18,22,25 28:8 29:14 160:1</p> <p><b>comparable</b> [4] 202:12 202:13 214:3 221:22</p> <p><b>compare</b> [13] 48:18 87:15,23 89:16 90:19,20 92:2 151:18 152:18,19 191:18 204:9 259:24</p>
---	--	---	---	--

<p><b>compared</b> [6] 63:14 92:18 150:17 155:3 196:6 320:11</p> <p><b>compares</b> [1] 259:25</p> <p><b>comparing</b> [2] 82:21 372:3</p> <p><b>comparison</b> [2] 80:8 159:19</p> <p><b>comparisons</b> [2] 201:18 371:21</p> <p><b>competent</b> [1] 264:6</p> <p><b>competition</b> [3] 196:5 202:10 262:9</p> <p><b>compile</b> [1] 377:10</p> <p><b>complain</b> [1] 50:6</p> <p><b>complement</b> [1] 262:18</p> <p><b>complete</b> [12] 4:9 27:23 174:9,12 201:12 292:20 299:14 307:25 321:5 342:7 356:3 393:4</p> <p><b>completed</b> [2] 147:18 317:18</p> <p><b>completely</b> [1] 26:23</p> <p><b>complex</b> [10] 65:21,22 66:21,24 73:9 74:9 80:9 131:13 177:3 188:4</p> <p><b>complexion</b> [1] 215:9</p> <p><b>complexity</b> [3] 45:8 66:20 230:23</p> <p><b>complicated</b> [2] 65:23 66:12</p> <p><b>component</b> [20] 11:4,5 44:5 45:17 50:9 51:8 69:1 71:6,23 72:13 76:19 94:1 230:10 247:24 254:1 255:22 257:10 263:22,23 268:12</p> <p><b>components</b> [11] 21:20 53:23 54:2,3,3 71:4,17 168:4 201:9 253:20 254:4</p> <p><b>composite</b> [2] 75:8 236:10</p> <p><b>composition</b> [1] 201:12</p> <p><b>computer</b> [6] 264:23 341:14,21 342:3 351:22 353:17</p> <p><b>computers</b> [1] 86:21</p> <p><b>concentration</b> [4] 248:12 249:15 276:10,19</p> <p><b>conceptually</b> [2] 59:4 61:14</p> <p><b>concern</b> [5] 100:11 115:24 131:8 297:13 379:3</p> <p><b>concerned</b> [1] 133:12</p> <p><b>concerning</b> [1] 221:10</p> <p><b>conclude</b> [3] 145:7 225:19 284:23</p> <p><b>concludes</b> [1] 299:18</p> <p><b>conclusion</b> [5] 77:23 78:12 209:7 239:5 396:24</p> <p><b>conclusions</b> [5] 14:1 216:7 228:14 235:10 263:16</p> <p><b>concordance</b> [26] 68:8</p>	<p>68:9,13,21 92:10,20 110:19 151:22 153:8 155:11,17 156:6 166:25 196:7 204:4,5 205:22 206:15 207:11,22 208:7 209:18 287:5,15,16,17</p> <p><b>confidence</b> [1] 193:13</p> <p><b>confident</b> [1] 299:19</p> <p><b>confirm</b> [3] 26:13 124:7 311:2</p> <p><b>confirmation</b> [1] 124:9</p> <p><b>confirmatory</b> [1] 284:22</p> <p><b>confirmed</b> [1] 386:3</p> <p><b>confirming</b> [1] 124:10</p> <p><b>confused</b> [1] 332:23</p> <p><b>confusion</b> [4] 187:14 309:5 332:7,19</p> <p><b>Congress</b> [1] 142:13</p> <p><b>conjunction</b> [5] 57:19 57:20 58:4 116:23 117:2</p> <p><b>connection</b> [2] 167:21 167:22</p> <p><b>consensus</b> [4] 62:20 74:20 149:8 209:11</p> <p><b>consider</b> [4] 63:4,5 98:6 163:7</p> <p><b>considerably</b> [1] 290:24</p> <p><b>consideration</b> [1] 155:20</p> <p><b>considered</b> [7] 53:22 63:24 121:9 229:16 249:7 285:6 333:23</p> <p><b>consist</b> [1] 236:6</p> <p><b>consisted</b> [1] 179:12</p> <p><b>consistent</b> [1] 367:2</p> <p><b>consists</b> [1] 149:3</p> <p><b>constant</b> [1] 103:12</p> <p><b>constantly</b> [1] 257:17</p> <p><b>constants</b> [1] 174:21</p> <p><b>construct</b> [3] 159:18 236:11,17</p> <p><b>constructed</b> [2] 158:17 241:15</p> <p><b>consult</b> [2] 305:22 341:10</p> <p><b>consultation</b> [1] 8:8</p> <p><b>consuming</b> [3] 349:2 356:12 381:8</p> <p><b>Cont'd</b> [1] 2:10</p> <p><b>contact</b> [8] 85:14 96:20 98:4 163:8 175:16 183:1 298:18 356:22</p> <p><b>contacted</b> [2] 137:18 339:18</p> <p><b>contacting</b> [1] 299:9</p> <p><b>contacts</b> [2] 44:1 175:13</p> <p><b>contain</b> [1] 144:4</p> <p><b>contains</b> [1] 168:19</p> <p><b>CONTENTS</b> [1] 2:1</p> <p><b>context</b> [8] 63:20 64:1,8 64:10 111:4 216:9 284:19 285:20</p>	<p><b>continue</b> [9] 6:14 15:17 154:8 202:6,14 247:14 296:4 328:3 348:16</p> <p><b>continued</b> [3] 6:21 7:4 296:7</p> <p><b>continues</b> [1] 195:4</p> <p><b>continuing</b> [1] 99:5</p> <p><b>continuous</b> [1] 194:24</p> <p><b>continuously</b> [1] 11:24</p> <p><b>contrary</b> [1] 262:16</p> <p><b>contribute</b> [3] 104:22 267:11 269:10</p> <p><b>contribution</b> [1] 296:2</p> <p><b>contributor</b> [1] 31:23</p> <p><b>control</b> [40] 7:21 12:9 41:20,25 42:11 43:19 52:16,18 53:16 73:14 74:5 75:5 80:5 81:14 90:14 96:7 103:13,18 105:10,19 106:24 108:5 132:3,12 157:2 172:7 183:11 184:13 195:8 205:14 217:11 253:4 269:18 270:2,18 271:3 391:22,25 392:18,19</p> <p><b>control/quality</b> [1] 236:24</p> <p><b>controlled</b> [1] 117:6</p> <p><b>controls</b> [48] 19:3,4,7 72:12,22,25 73:3,10 74:22 75:20 76:15,18,21 76:23 77:22 78:1,3,16 78:17,19 79:1,4,9,17 80:2,13 107:1,2,4 150:23 158:16 185:11,12 269:8 269:14,24 270:1,8,11,12 270:16,22 328:8,14 382:19 391:20 393:11,22</p> <p><b>convenient</b> [1] 390:13</p> <p><b>conversation</b> [3] 308:6 313:22 321:1</p> <p><b>convert</b> [3] 308:12 309:20,21</p> <p><b>converted</b> [1] 309:15</p> <p><b>convincing</b> [1] 214:7</p> <p><b>Cook</b> [21] 98:15 99:9,23 302:3,10 303:24 304:10 304:12 307:7 314:14 331:11 337:17 338:15 341:6,9 349:1 371:11,14 376:5 380:1 386:2</p> <p><b>Cook's</b> [2] 99:25 335:21</p> <p><b>cooker</b> [1] 199:21</p> <p><b>cooking</b> [1] 250:21</p> <p><b>Cooks</b> [1] 348:21</p> <p><b>copied</b> [1] 357:17</p> <p><b>copies</b> [4] 100:21 352:1 357:9,11</p> <p><b>copy</b> [3] 65:1 99:9 321:15</p> <p><b>core</b> [11] 28:13 29:6,13 29:14,22 31:16 38:1,17 79:25 120:2,3</p> <p><b>cores</b> [5] 79:10,15,20 144:5 154:10</p> <p><b>Corner</b> [7] 318:10 354:2 355:15,17 356:25 376:20</p>	<p>376:21</p> <p><b>corners</b> [1] 384:25</p> <p><b>Corporation</b> [1] 325:9</p> <p><b>correct</b> [24] 26:23 36:9 48:12 105:4 128:1 181:8 181:20 184:2 201:1 203:3 217:3 230:15 246:24 247:17,18 265:23 276:24 277:1 294:1,3 334:23 374:6 378:19 397:3</p> <p><b>correcting</b> [1] 278:2</p> <p><b>corrections</b> [1] 247:12</p> <p><b>corrective</b> [1] 277:25</p> <p><b>correctly</b> [6] 183:12 190:18,20 222:12 237:16 255:16</p> <p><b>correlated</b> [1] 243:16</p> <p><b>correlation</b> [6] 77:13 118:19 210:18 241:4,14 243:22</p> <p><b>corresponding</b> [1] 91:22</p> <p><b>cost</b> [9] 12:19 78:15 160:7 160:12,17 161:3,4,4,8</p> <p><b>costs</b> [2] 12:20 161:2</p> <p><b>count</b> [2] 230:4 350:2</p> <p><b>counted</b> [1] 289:6</p> <p><b>countries</b> [12] 10:7 12:5 13:13 27:23 28:12 40:5 103:7,8 215:9 218:12 246:9,10</p> <p><b>country</b> [15] 7:3 11:11 28:7,10,15 29:7,24 33:7 35:3 40:14 84:5,9 107:7 183:9 251:17</p> <p><b>couple</b> [14] 20:13 61:25 98:10 135:12 154:16 177:10 213:3 231:20 232:17 234:25 282:22 313:14 316:10 393:21</p> <p><b>course</b> [27] 9:16 14:16 41:21 42:14 43:20 69:24 76:22 81:18 83:19 93:15 96:3 108:15 109:4 111:14 120:25 163:22 201:3 233:10 254:21 274:9 284:1 290:14 291:22 319:16 340:25 345:1 380:4</p> <p><b>courses</b> [3] 35:2 39:14 39:18</p> <p><b>cover</b> [1] 245:4</p> <p><b>covered</b> [2] 159:25 245:5</p> <p><b>covers</b> [1] 105:8</p> <p><b>CP</b> [1] 110:7</p> <p><b>crash</b> [2] 161:24 162:3</p> <p><b>create</b> [14] 76:15 79:3,17 85:17 86:24 87:4,21 94:7 136:14 137:9 146:18 168:17 170:2 173:11</p> <p><b>created</b> [9] 14:17 135:18 136:19,22 142:9 155:15 170:6,17 315:9</p> <p><b>creating</b> [10] 12:8 76:23 98:7 107:1 164:25 170:4 170:14,19 172:5 175:5</p>	<p><b>Creation</b> [1] 171:2</p> <p><b>credentials</b> [1] 6:4</p> <p><b>credit</b> [1] 15:24</p> <p><b>criteria</b> [5] 163:17 339:23 340:1 364:19 376:6</p> <p><b>critical</b> [32] 8:4 13:21 24:20 53:18 56:13 59:15 70:25 75:11,14 93:19 94:2,9 119:18 120:12 137:2 160:19 171:5,6,25 172:19,21,25 173:8,9,17 173:23 201:7,15 245:16 257:11 270:6,25</p> <p><b>critically</b> [3] 117:3 120:16 199:25</p> <p><b>Croatia</b> [1] 6:10</p> <p><b>Crosbie</b> [34] 1:12 2:4 177:19,20 178:22,25 179:1,3 180:10,15,20,24 181:16,25 183:3,20 184:17 185:6 186:1,8,15 186:20 187:8,12,17,22 188:21 189:6,12,21 190:1 190:4,12 232:13</p> <p><b>cross</b> [5] 272:11,22 336:13 354:19 384:3</p> <p><b>cross-reactive</b> [1] 18:12</p> <p><b>cross-reference</b> [1] 350:16</p> <p><b>crossed</b> [6] 334:4 335:16 335:16 336:17,20 385:22</p> <p><b>crucible</b> [1] 346:25</p> <p><b>crux</b> [1] 381:1</p> <p><b>crystallizing</b> [1] 286:21</p> <p><b>culled</b> [1] 375:9</p> <p><b>culture</b> [1] 76:23</p> <p><b>cultures</b> [1] 78:9</p> <p><b>current</b> [14] 32:10 71:6 72:6 78:18 95:5 105:25 123:25 160:21 174:2 175:11 318:25 345:4,6 345:13</p> <p><b>curriculum</b> [1] 5:2</p> <p><b>curve</b> [1] 47:24</p> <p><b>cut</b> [9] 74:3 120:8 200:14 331:17,20 337:18 342:12 342:13 344:3</p> <p><b>cut-off</b> [1] 375:20</p> <p><b>cutoff</b> [3] 228:23 364:17 364:22</p> <p><b>cuts</b> [1] 77:1</p> <p><b>cytokeratin</b> [9] 66:7 75:2 123:4 124:9 128:9 128:13 132:23 144:16,19</p> <p><b>cytology</b> [1] 7:8</p> <p><b>cytoplasmic</b> [1] 272:20</p> <hr/> <p style="text-align: center;"><b>-D-</b></p> <p><b>d</b> [3] 11:16 20:22 119:12</p> <p><b>Dabbs</b> [2] 242:18,19</p> <p><b>daily</b> [15] 66:25 75:14 81:23 94:13 95:3 106:25 132:5 139:2 144:7 182:6 183:1,11 194:11 246:1</p>
---	---	---	--	---

<p>295:6 <b>DAKO</b> [10] 11:18 12:25 27:13 28:20,22 30:2 31:9 212:9 369:9 371:25 <b>Dalhousie</b> [2] 99:1,3 <b>Dan</b> [1] 190:7 <b>Daniel</b> [3] 1:10 2:5 190:5 <b>dark</b> [1] 117:11 <b>dash</b> [1] 334:18 <b>data</b> [7] 116:24 189:23 239:17 263:14 314:18 319:7 320:12 <b>database</b> [10] 280:1 314:15,16,16,23 315:1 316:13 378:9,13,16 <b>date</b> [5] 69:20 97:15 164:4 207:6 341:22 <b>dated</b> [7] 96:12 97:8 127:18 296:20 299:3 304:1 397:11 <b>dates</b> [2] 147:25 284:13 <b>David</b> [1] 242:19 <b>days</b> [3] 83:22 313:14 346:23 <b>DCIS</b> [3] 385:23,24 386:3 <b>deal</b> [7] 109:11 111:13 174:13 175:1 220:10 253:17 254:5 <b>dealing</b> [8] 26:2 111:10 123:23 131:4 211:2 232:3 284:14,14 <b>dealt</b> [3] 112:2,7 298:19 <b>Dean</b> [3] 86:9 95:18 97:12 <b>debatable</b> [1] 329:12 <b>debate</b> [4] 244:16 321:12 340:14 341:2 <b>debateable</b> [1] 244:19 <b>decade</b> [8] 193:10,17 194:14,24 199:19 231:23 232:5 239:6 <b>decades</b> [2] 67:14 258:12 <b>deceased</b> [6] 319:1 336:14,22 337:3 375:4 375:10 <b>December</b> [2] 12:13 80:21 <b>decide</b> [3] 110:15 137:2 200:14 <b>decided</b> [13] 14:25 54:12 101:5,17,18 146:17 331:16 344:8,11,22 376:11 378:11 379:5 <b>decision</b> [13] 48:14 69:8 120:17 229:5 339:24 340:16,20 341:2 344:4,9 345:3,22 348:11 <b>decisions</b> [2] 235:21,23 <b>dedicate</b> [1] 181:22 <b>dedicated</b> [1] 180:4 <b>deemed</b> [1] 378:2 <b>defects</b> [1] 241:1 <b>deficiencies</b> [2] 295:8,9</p>	<p><b>define</b> [5] 61:16 62:10 295:8 326:22 352:16 <b>defined</b> [1] 368:10 <b>definite</b> [4] 75:17 76:14 163:9 244:20 <b>definitely</b> [9] 72:9 132:13 191:25 201:15,16 219:7 257:9 271:12 279:2 <b>definition</b> [4] 54:24 57:7 63:7,7 <b>definitive</b> [1] 189:22 <b>degradation</b> [1] 74:2 <b>degree</b> [6] 15:7 58:24 106:16 192:19 361:19 363:8 <b>degrees</b> [1] 183:23 <b>delivery</b> [2] 103:20 253:7 <b>demanding</b> [2] 86:22 182:15 <b>demands</b> [1] 161:22 <b>demographic</b> [1] 353:19 <b>demonstrate</b> [1] 158:19 <b>demonstrated</b> [2] 167:25 201:14 <b>Denmark</b> [1] 13:14 <b>department</b> [8] 16:24 24:18 81:8 254:7 278:16 278:20 279:15 281:17 <b>departments</b> [2] 73:13 74:17 <b>depend</b> [2] 179:23 215:21 <b>dependent</b> [1] 84:6 <b>depending</b> [7] 113:11 129:7,9 182:9 197:9 290:24 343:2 <b>depth</b> [1] 301:17 <b>derive</b> [1] 243:12 <b>derived</b> [2] 206:6 211:11 <b>describe</b> [3] 58:20 184:20 185:3 <b>described</b> [11] 27:21 38:7 49:18 186:4,9,25 188:1,11 190:14 220:18 221:19 <b>describes</b> [1] 105:25 <b>description</b> [8] 19:10 143:24,24 185:8 186:19 187:2,5 232:4 <b>design</b> [4] 90:10,13 121:13 150:19 <b>designated</b> [2] 180:8 181:21 <b>designed</b> [14] 60:10 149:2 150:9,10,18 155:15 197:2 210:16 230:9 270:8 272:13 295:5,6,7 <b>despite</b> [7] 67:2 81:25 83:7 104:18 138:14 286:11 292:18 <b>destroying</b> [1] 201:7 <b>Det</b> [1] 7:15 <b>detail</b> [6] 86:8 142:1 152:9 171:15 230:10</p>	<p>385:22 <b>detailed</b> [8] 16:19 50:19 104:23 138:11 142:9,10 145:5 187:1 <b>details</b> [5] 7:23 51:1,3 208:6 247:16 <b>detect</b> [11] 116:20 117:24 120:1,3 150:16 197:2 198:16 199:17 203:5 271:2 295:7 <b>detected</b> [2] 119:5 150:22 <b>detecting</b> [2] 67:19 119:24 <b>detection</b> [21] 116:14 121:2 145:1 192:17 193:22 195:16,21 196:12 198:2,7,24,24 199:9 202:6,11 214:4 232:1 276:5 290:25 291:1,6 <b>detects</b> [2] 120:5 123:5 <b>determination</b> [4] 107:23 123:13 125:20 339:20 <b>determine</b> [4] 70:5 121:4 160:7 387:5 <b>determined</b> [3] 336:18 338:12 372:23 <b>determines</b> [2] 57:4 239:12 <b>determining</b> [1] 244:12 <b>develop</b> [9] 17:9 43:17 100:16 104:16 195:4 197:19 202:15 230:20 231:3 <b>developed</b> [3] 54:15 94:3 195:6 <b>developing</b> [6] 84:15 86:2 94:25 232:7 255:25 280:10 <b>development</b> [7] 104:22 110:20 129:19 199:12 202:19 239:14 288:8 <b>developments</b> [1] 44:23 <b>devices</b> [2] 56:9,18 <b>devised</b> [1] 184:8 <b>diagnose</b> [4] 24:15 120:9 215:6,15 <b>diagnosed</b> [2] 118:6 132:19 <b>diagnosis</b> [20] 24:20 26:14,22 58:7,18 59:7 62:12 65:7,24 66:5,10 116:18 117:4 118:16 119:18 120:13 131:9 133:2,11,13 <b>diagnostic</b> [23] 17:12 26:7 59:9 66:5 95:10 96:7 101:9 102:7 103:6 103:21 107:20 130:18 131:2 132:15 149:23 165:10 168:21 169:24 174:6 188:14 189:17 190:22 191:14 <b>diagnostically</b> [2] 62:11 129:2 <b>diagram</b> [1] 217:14</p>	<p><b>differ</b> [1] 171:14 <b>difference</b> [17] 10:24 13:5 45:22 51:18 61:1 64:14 117:18 153:10 166:8 198:23 199:23 215:2 229:19 309:11 320:11 331:21 332:10 <b>differences</b> [9] 43:1 104:18 144:23 145:2 150:21 171:17 262:4,5 295:19 <b>different</b> [81] 13:9 17:21 18:7 22:14 26:8 28:11 35:3,4 41:23 44:3,23 45:6 55:21 56:13,14 57:18 65:9,18 81:24 82:1 113:18,20 118:1,18 129:4 136:25 171:18,21 189:10 192:20 197:6,10 198:24 201:10,19,20 217:16 226:21 232:11 241:16 243:24 249:13,14 250:2 250:3,4 251:10 254:4 258:2 259:7 262:2,7 268:6,10 269:13,20,21 276:8 288:23 289:8,13 289:14,19 290:1,5 291:1 291:5,5 293:20 300:24 305:10,10 310:13 314:19 326:13 338:25 342:22 347:14,14 373:11 376:11 <b>differential</b> [2] 66:4,4 <b>differentiate</b> [1] 294:11 <b>differentiated</b> [2] 132:21 279:18 <b>differentiation</b> [2] 57:25 215:20 <b>differently</b> [3] 44:2 149:2 150:10 <b>difficult</b> [12] 11:8 23:7 85:15 119:11 180:3 202:16 257:15,16,23 276:3 293:4 295:3 <b>difficulties</b> [2] 239:19 239:19 <b>digestion</b> [2] 250:20 269:22 <b>diligent</b> [1] 185:20 <b>dilutant</b> [1] 290:22 <b>dilute</b> [1] 276:11 <b>diluted</b> [1] 250:5 <b>dilution</b> [6] 51:6 145:4 153:12,17 208:14 290:16 <b>dilutions</b> [1] 290:15 <b>Diponkar</b> [1] 98:17 <b>direct</b> [7] 16:4 28:6 35:5 87:20 104:8 306:3,12 <b>directed</b> [1] 306:23 <b>direction</b> [1] 263:17 <b>directly</b> [9] 35:12 77:5 87:15 104:7 171:16 253:17 255:1 303:9 374:14 <b>director</b> [16] 16:22 17:1 17:23 18:25 19:24 22:20 23:16 24:3,4,10 46:8,9 180:5 187:3 232:14</p>	<p>376:21 <b>directory</b> [1] 175:10 <b>disagreed</b> [1] 342:21 <b>discover</b> [1] 151:8 <b>discovered</b> [2] 196:9 275:13 <b>discrepancies</b> [1] 229:17 <b>discrepancy</b> [5] 26:21 114:11 220:3 246:20 320:22 <b>discretion</b> [2] 331:2 338:6 <b>discuss</b> [4] 12:5 35:6 160:25 320:21 <b>discussed</b> [7] 44:24 86:7 98:19 300:25 304:7 307:23 379:1 <b>discussing</b> [1] 94:6 <b>discussion</b> [9] 44:17 100:2 185:24 246:4 308:19,22 342:9 343:23 344:12 <b>discussions</b> [3] 55:22 297:11 337:17 <b>disease</b> [10] 21:12 58:2 58:22 116:20 117:19,24 118:6 121:7 123:6 388:1 <b>diseases</b> [2] 8:5 66:3 <b>displayed</b> [2] 159:23 286:8 <b>disseminate</b> [1] 245:17 <b>Dissemination</b> [1] 169:23 <b>dissociation</b> [1] 12:21 <b>distance</b> [1] 84:23 <b>distinction</b> [2] 120:11 144:11 <b>distinguish</b> [1] 242:14 <b>distinguished</b> [1] 254:22 <b>distribution</b> [2] 65:18 193:14 <b>division</b> [3] 1:15 179:21 252:19 <b>doctor</b> [83] 4:17 5:1,6,17 5:22 8:12 9:15,22 10:14 10:19 16:12,25 18:20 19:18 25:13 27:10,22 30:1 31:15 33:3 41:8 49:8 52:13 53:8 55:13 64:12 67:5 70:19 73:5 80:17 81:11 83:12 88:6 89:16 95:9 96:1,25 97:8 98:10 100:19 102:13,24 104:25 106:4 107:5 109:5 111:3 116:10 122:1 126:5 127:16 130:15 134:9 139:12 142:3,12 143:14 144:1 146:1 148:2 153:22 154:15 159:2 162:22 163:14 164:3 165:19 168:14 172:20 176:11 179:4 233:24 244:15 248:2 283:3,8,16 284:17 287:4,14 288:12 294:9 295:24</p>
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Inquiry on Hormone Receptor Testing

<p><b>Doctors</b> [3] 1:9 307:7 314:14</p> <p><b>document</b> [18] 56:12 64:23 75:18 96:2,13,16 96:20 99:13 101:5 168:17 168:19 169:5,7,10 170:5 358:16,20 363:6</p> <p><b>documentation</b> [3] 318:13 326:17 352:13</p> <p><b>documented</b> [7] 328:16 370:5,21 374:21 391:21 392:17 393:14</p> <p><b>documenting</b> [1] 391:16</p> <p><b>documents</b> [2] 98:18 170:6</p> <p><b>doesn't</b> [16] 13:3 46:7 47:25 72:15 117:9 120:18 152:22,23 173:21 238:19 255:6 260:2 262:24 277:9 378:4 382:16</p> <p><b>Don</b> [1] 98:17</p> <p><b>donate</b> [1] 160:2</p> <p><b>done</b> [88] 20:17 26:10 28:17,20 45:10,11 46:5 53:10 55:3 74:10 92:8 110:21 113:14 146:16 147:7,7 152:19 153:20 155:22 157:12 183:18,19 183:24 188:2,9,13 199:24 201:5 202:3 206:4 207:6 209:25 212:14 221:8 230:11 234:14 248:22 249:18,22,22 251:7 254:2 256:22 259:6 260:3 261:21 279:10 286:18 288:15 291:19 297:5 298:8 299:24 305:11 306:4,7 309:19 311:16 315:20 317:6,13 321:9 321:11 329:13 335:19 341:10 342:9 345:14 346:4,6 347:7 358:22 365:13 371:3 372:1 373:20 376:17 380:3,4 380:10,13 381:19 383:17 383:19 384:8 387:25,25 394:9</p> <p><b>dosage</b> [1] 241:18</p> <p><b>doubtful</b> [2] 333:4,15</p> <p><b>down</b> [24] 8:20 29:6 44:9 52:17 55:1 98:11 124:24 143:14 168:6 193:11 234:21 253:4 283:15 288:21,24 289:24 291:7 377:9 382:10 385:18 387:16 389:12,15 394:20</p> <p><b>dozen</b> [1] 292:5</p> <p><b>Dr</b> [740] 2:2 4:4,6,11 5:3 5:18 6:1,8 8:13,17,24 9:4 9:8,12,19,23 10:16,20 17:5 18:17,21 19:15,21 20:1 22:1,5,11,16,24 23:19,23 24:6,11,17 25:2 25:19 26:5 27:3,15 28:5 28:19,23 29:3,8,12,21 30:4,9,13,18,23 31:3,7 31:19,24 32:3,7,19 33:9 33:14,21 34:5,14,24 35:18,23 36:3,8,16,25</p>	<p>37:7,11,18,23 38:3,8,13 38:18,23 39:2,9,15,22 40:1,6,10 41:1,15 42:2,7 42:13,24 43:4,8,13 45:16 45:21 46:2,21,25 47:5 47:10,16,20 48:6,10,23 49:5,11,22 50:1,16 51:12 51:23 52:2,6,10,19,23 53:13 54:22 55:17 56:6 56:19,23 57:12,16 59:21 60:17,24 61:11,24 63:9 63:16 64:2,9,20,23 65:13 67:7 69:21 70:2,11,16 70:22 71:16,21 72:3 73:7 78:6,13 79:5 80:20,25 81:5,16,21 82:11,16,23 83:4,9,15 84:19,25 85:6 85:10,23,24,25 87:3,8 88:10,14,24 89:4,8,12 89:19,24 90:5 91:3,7,12 91:16,24 92:4 93:3,10 93:22 95:19,21 96:8,12 96:22 97:5,14,21 98:1 98:12,15,15,21,23 99:2 99:9,9,16,23,24 100:4,9 100:15,23 101:2 102:16 102:21 105:3,5,13 106:6 107:8,12 108:9,18,25 109:8,17,25 110:4,14 111:6,16,20,24 112:4,9 112:14,18,25 113:4,9,17 113:21 114:7,18,22 115:2 115:6,11,17,25 116:5,11 118:10,14 119:21 121:23 122:4,9,13,17,23 123:3 123:14,21 124:16,21,25 125:7,17,23 126:8,14,22 127:1,5,20 128:3,7,12 128:18,23 129:8,12,17 129:25 130:12,21 131:5 131:12,18 133:20,24 134:14,22 135:7,11,15 136:2,6,11,15,20,21 137:10,15,19,24 138:3,7 138:24 139:8,14,20,24 140:3,7,10,11,18,22 141:2,6,12,18 142:5,14 142:18,23 143:1,3,6,8 143:15,21 144:18 145:18 145:23 146:7,14 147:2,8 147:12,16,23 148:5,10 148:14,20 150:8 151:15 152:5,10,14,21 154:1,5 154:24 155:7 156:16,20 156:24 157:4,8,13 158:1 158:6,12 159:7,17 162:9 162:17,25 163:19,24 164:8 165:16,21 166:12 166:18 167:8,14,18 168:10,15,25 169:4 171:1 173:2,7 174:10,20 176:4 176:8,23 177:12 179:1,9 179:22 180:13 181:1,5 181:12,18 182:3 183:6 184:3 185:4,9 186:5,13 186:22 187:10,15,20 188:12 189:4,8,14,24 190:5,7,19 191:3,7,23 192:9,16 193:4,19 194:1 194:8,16,20 195:3,15,19 196:13,18,23 197:24 198:8 199:10 201:2 202:4 203:7,11,16,23 204:19</p>	<p>205:2,6,12,20 206:5,17 206:23 207:3,8,12,18,24 208:3,24 209:6,14,22 210:6,12 211:20,25 212:11,20 213:2,8 216:17 216:21 217:6 218:2 219:1 219:10,17 220:13,22 221:3,9,12,21 222:6,11 222:18,25 223:13,17,24 224:6,10,21 225:4,10,23 226:8,15,22 227:1,6,12 227:17,24 228:4,10,18 229:2,11 230:1,8,21 231:1,13,15 232:6,22 233:6,15 234:6,11,18 235:7,24 236:14,18,22 237:8,14 238:8,18 239:1 239:8 240:5,12,16 242:18 242:18,23 244:6,7,8,18 245:19 246:6,14,23 247:5 248:14,20 251:20,25 252:15,17 253:10 254:16 255:11,17 256:19,24 257:8 258:24 259:14,18 260:1,11,15 261:8,13,23 262:20 263:5,13 264:19 265:2,9,14,21 266:2,6 266:11,16,22 267:7,15 268:3,16,25 269:5,12 271:6,10,21 272:3 273:9 273:14,19,24 274:4,24 275:9,21 276:15,25 277:12,19 278:1,13 279:1 279:5,12,25 280:13,17 280:21 281:1,15,25 282:11,16,22,24 283:6 283:12,13,17,24 284:10 284:14 285:9,15,22 286:1 287:7,11,18,23 288:3,18 289:3,10,15,21 290:2,9 290:18 291:2,9,16,21 292:1,7,11,15,19,24 293:3 294:2,6,13,20,25 295:4,15 296:19 298:3 300:15,16 301:4,9,20 302:3,10,10 303:24 304:2 304:5,6,10,10,12,12 305:20,24 306:19,23 307:18 308:9,21 309:2,3 311:6 312:10 313:7,15 313:23 314:1 315:8,18 315:20 321:25 326:10,14 326:18 331:11 335:21 337:17 338:15 340:11,19 341:6,6,9,9,20 342:24 342:25 343:6,15 344:13 348:21 349:1 371:11,14 376:5 379:12 380:1,1,4 382:18,25 386:2 392:10 392:12</p> <p><b>draft</b> [3] 168:19 169:5,6</p> <p><b>draw</b> [1] 228:14</p> <p><b>drawing</b> [1] 263:15</p> <p><b>drawn</b> [1] 291:13</p> <p><b>drug</b> [4] 60:4,7,10,11</p> <p><b>due</b> [1] 268:23</p> <p><b>duplicate</b> [1] 170:5</p> <p><b>during</b> [14] 17:2 44:15 94:9 199:19 200:23,25 269:9 301:13 308:5 316:11 325:18 366:3</p>	<p>367:13 376:19</p> <p><b>Dyer</b> [11] 301:11,15 302:20 303:4,25 305:23 315:3 321:22 374:18 379:15 385:21</p> <p><b>Dyer's</b> [1] 322:15</p> <hr/> <p style="text-align: center;"><b>-E-</b></p> <hr/> <p><b>e</b> [14] 11:16,16 20:22,22 20:22,22 119:12,12,14 122:3 124:4 182:22,22 257:21</p> <p><b>E-M-I-N-A</b> [1] 4:12</p> <p><b>e-mail</b> [8] 98:12 99:8 100:15 307:7 308:20 314:12 320:10 365:15</p> <p><b>e-mails</b> [2] 94:20 98:10</p> <p><b>EAQ</b> [1] 166:22</p> <p><b>early</b> [5] 176:25 178:5 257:20 297:1 305:8</p> <p><b>easily</b> [5] 86:20 114:25 172:5 258:10 286:18</p> <p><b>Eastern</b> [5] 1:10 96:3 99:23 179:7 190:8</p> <p><b>easy</b> [5] 75:24 86:18 229:8 256:14 260:21</p> <p><b>EDTA</b> [1] 250:21</p> <p><b>educating</b> [1] 184:14</p> <p><b>education</b> [15] 6:3,14 6:21 16:6 34:11,19 87:2 99:6 184:10,11 220:10 220:14 233:8 247:24 262:7</p> <p><b>educational</b> [8] 11:5 32:16 39:6 50:8 51:8 94:1 247:20 256:18</p> <p><b>effect</b> [9] 5:8 105:24 127:25 137:18 162:14 217:3 218:24,25 288:16</p> <p><b>efficient</b> [1] 249:20</p> <p><b>effort</b> [4] 97:11 102:6 172:18 226:12</p> <p><b>EG4</b> [1] 169:17</p> <p><b>eight</b> [5] 103:1,1 251:5,6 348:19</p> <p><b>either</b> [13] 61:16 76:25 77:8 87:18 107:19 112:12 208:13 217:19 275:6 363:10 374:25 380:17 395:23</p> <p><b>Either/or</b> [1] 363:12</p> <p><b>Ejckam</b> [7] 127:21 304:2,5,11,13 305:20,24</p> <p><b>elaborate</b> [3] 116:1 155:2 253:8</p> <p><b>electronic</b> [1] 39:8</p> <p><b>Elms</b> [2] 306:19,23</p> <p><b>elsewhere</b> [2] 152:8 226:3</p> <p><b>EMA</b> [2] 66:7 248:24</p> <p><b>embarrassed</b> [1] 260:16</p> <p><b>embedded</b> [5] 17:15 194:5 236:7 240:11,20</p> <p><b>embryonic</b> [1] 130:3</p>	<p><b>Emina</b> [10] 2:2 4:4,6,12 98:18 179:1 190:5 231:13 252:15 282:24</p> <p><b>emphasis</b> [4] 16:6 24:16 229:15 293:23</p> <p><b>emphasize</b> [4] 12:14 13:7 253:14 263:23</p> <p><b>employed</b> [1] 145:1</p> <p><b>employees</b> [1] 227:10</p> <p><b>enable</b> [13] 70:4 94:3 119:14 144:10 155:16 200:5 242:10 254:10 255:22 256:7,12 270:7 396:17</p> <p><b>enables</b> [2] 69:6 159:19</p> <p><b>Enclosed</b> [1] 104:23</p> <p><b>encountered</b> [2] 275:8 301:13</p> <p><b>end</b> [16] 50:24 121:6 176:11 268:18 293:20 295:19 317:2 329:5 330:22 333:11,15 336:15 350:25 351:11 353:8 368:3</p> <p><b>ended</b> [6] 12:8 22:19 27:23 31:1 135:4 193:18</p> <p><b>endogenous</b> [3] 274:10 274:13 276:4</p> <p><b>engage</b> [1] 379:17</p> <p><b>enhanced</b> [1] 192:18</p> <p><b>enjoyed</b> [1] 144:25</p> <p><b>enroling</b> [1] 261:17</p> <p><b>ensure</b> [4] 171:5 285:5 299:15 396:5</p> <p><b>ensured</b> [1] 172:22</p> <p><b>enter</b> [2] 233:19 234:1</p> <p><b>entered</b> [8] 4:21,22 233:20,22 296:11,14,15 296:16</p> <p><b>enthusiastic</b> [1] 86:1</p> <p><b>entire</b> [5] 71:18 185:14 229:4 324:10 369:23</p> <p><b>entities</b> [1] 62:3</p> <p><b>entitled</b> [3] 70:19 96:5 105:23</p> <p><b>entity</b> [2] 66:1 137:4</p> <p><b>environment</b> [1] 188:11</p> <p><b>enzyme</b> [1] 250:20</p> <p><b>epidemiol</b> [1] 239:20</p> <p><b>epitope</b> [9] 75:11 76:10 76:24 214:2 217:8 250:17 250:22 272:5,13</p> <p><b>epitopes</b> [11] 32:9,23 34:8 73:20 75:23 144:6 199:13 201:8,14 217:16 264:20</p> <p><b>EQA</b> [30] 43:12 81:24 82:5,15 83:17 88:7 93:7 103:14 109:13 110:16,17 111:23 112:7 114:17 115:15,23 135:2 155:14 169:22 201:17 206:6,11 206:12,16 207:6 219:13 219:13 225:14 252:25 253:16</p>
---	---	--	--	---

<p><b>equality</b> [1] 172:20  <b>equally</b> [2] 267:3,12  <b>equivalent</b> [2] 7:13 214:5  <b>ER</b> [54] 60:22 111:19 120:25 126:7 146:10 152:13 153:7 166:23,24 201:22 204:25 209:12 210:4 237:15 238:11 243:15 244:12 249:3 258:18 265:6,25 266:14 266:21 267:3,13 269:11 273:1 274:14 279:20 284:15,23 286:13 299:6 310:4,8 319:3,21 323:4 323:16 329:14,22 330:6 330:8,25 332:2 337:24 338:3 343:25 351:24 360:16 361:21 362:12,14 363:14  <b>ER/PR</b> [50] 61:5,12,22 76:18 110:1 112:2 121:6 146:16 147:1,6 149:8,13 154:10 180:21 181:17 188:19 204:14 207:1,16 211:23 212:2 225:3,18 243:19 263:25 274:12,22 285:25 288:8,9 297:12 317:5,11,13,17 318:3,10 318:15,25 319:2 321:7 321:11 327:4 342:5,8 344:24 350:23 378:10 386:15,18  <b>ER/PRs</b> [1] 387:25  <b>err</b> [1] 396:6  <b>erratic</b> [2] 130:17 131:1  <b>erred</b> [1] 327:21  <b>ERs</b> [1] 310:20  <b>especially</b> [2] 67:11 234:19  <b>essence</b> [3] 341:25 378:11 383:14  <b>essential</b> [1] 284:25  <b>establish</b> [1] 7:11  <b>established</b> [9] 20:5,9 25:15 97:18 103:8 160:5 160:13 190:23 210:2  <b>establishing</b> [1] 24:21  <b>establishment</b> [7] 96:5 96:17 99:11 100:6 220:17 220:20 252:25  <b>estrogen</b> [14] 58:16 59:12 67:19 149:4 150:14 195:9 202:9 235:5 243:4 248:24 265:16,23 362:6 394:21  <b>et</b> [1] 1:9  <b>etcetera</b> [1] 107:4  <b>Europe</b> [7] 10:8 12:12 25:4 82:22 218:20 284:3 286:3  <b>European</b> [7] 14:24 218:7,11 219:4 220:2 285:18,20  <b>evaluate</b> [4] 26:13 92:15 228:7 245:17  <b>evaluated</b> [2] 19:4 35:10</p>	<p><b>evaluating</b> [3] 13:23 34:9 130:7  <b>evaluation</b> [4] 48:13 133:3 144:8 256:8  <b>evening</b> [1] 311:14  <b>event</b> [2] 303:5 304:5  <b>events</b> [2] 55:23 298:7  <b>eventually</b> [1] 160:12  <b>everybody</b> [10] 47:15 48:7 93:24 149:21 205:16 263:24 286:5,6,12 306:21  <b>everywhere</b> [1] 165:11  <b>evidence</b> [23] 21:8 61:3 61:7,7 69:11 77:20 117:13,14 118:4 124:2,8 133:4 149:14 158:24 173:8 179:7 246:25 271:16,23 279:23,23 280:5 305:9  <b>evolve</b> [1] 135:3  <b>evolved</b> [2] 31:1 108:24  <b>evolves</b> [1] 202:17  <b>exact</b> [14] 78:22 97:15 147:24 187:4 209:15 238:19 249:21 264:20 311:21 339:15 349:17,19 350:1 364:19  <b>exactly</b> [35] 35:21,24 37:24 38:4,9,24 47:17 65:2 70:17 73:21 79:24 83:10 91:13 107:9 115:12 130:13 151:8 157:14 159:25 171:15 202:15 207:19 223:14 239:2 242:24 247:7,14,23 253:17 261:2 280:2 295:1 311:8 355:8 385:19  <b>Examination</b> [12] 2:3,4 2:5,6,7,10 4:6 179:1 190:5 231:13 252:15 296:6  <b>examined</b> [3] 38:6,16 229:22  <b>example</b> [52] 17:25 19:13 34:23 58:15,15 59:12 60:7 73:14 75:1 88:13,20 118:9 119:23 120:24 130:5 152:3,4 155:4 156:2 159:6 162:7 162:24 165:15 188:9 197:22 198:3 199:11 200:19 202:7 204:3 248:22 250:20,22 257:19 263:25 268:15 269:19 272:4 279:24 302:17 335:13 346:3 348:6 354:14 374:3,21 375:2 378:16 386:18 393:9,10 394:13  <b>examples</b> [7] 64:6,16,21 87:13 118:2 119:15 199:3  <b>excellence</b> [2] 17:10 20:19  <b>excellent</b> [8] 7:1 11:1 13:4 106:21 152:24 220:7 243:18 292:12  <b>except</b> [6] 43:16 158:13 188:18 278:6 326:10</p>	<p>364:19  <b>excess</b> [1] 103:22  <b>excessive</b> [4] 77:18 268:14,17 275:15  <b>exclude</b> [2] 374:17,25  <b>excluded</b> [1] 374:15  <b>executive</b> [9] 97:3 98:5 98:19 99:4,14,20,25 167:20 169:6  <b>exercise</b> [5] 366:3,20 378:6 380:23 382:22  <b>exhibit</b> [27] 3:3,4,5 5:1 5:11 36:6 95:25 96:15 97:2 98:9 99:21,22 100:20 103:2 127:16 142:3 146:4 185:1 233:20 252:21 264:13 283:2 296:15,16 348:19 349:8 365:12  <b>exhibits</b> [6] 3:1,2 4:18 4:18,22 296:10  <b>exist</b> [6] 67:20,21 88:8 115:16 357:2 378:4  <b>existing</b> [4] 114:8 170:10 170:16 291:20  <b>exists</b> [1] 124:2  <b>expanding</b> [1] 257:5  <b>expect</b> [10] 55:8 191:19 225:2,8 231:2 245:24 258:2 270:5 279:19 297:17  <b>expected</b> [14] 11:7 32:12 149:12 210:3 214:20 219:14 224:3,7 238:14 247:17 271:22 280:5,16 293:17  <b>expensive</b> [5] 78:20 161:13 162:5,13 270:19  <b>experience</b> [21] 21:19 41:10,24 42:3 81:17 82:21 119:10 183:24 184:1,9,22 187:7 208:8 224:5,16 225:12 235:17 246:18 248:3 251:4 314:4  <b>experiencing</b> [1] 305:14  <b>expert</b> [26] 35:5 45:15 48:13,18 49:4 74:20 94:12,15 143:17 172:3 182:6,19 200:16 202:18 208:5 244:1 245:22 254:19 256:2 278:17 296:24 297:6,19 298:15 307:10 344:14  <b>expertise</b> [11] 15:1 108:1 172:7 179:14 180:8 184:7 230:17 231:4 245:25 282:3 346:14  <b>experts</b> [19] 13:22 20:12 33:24 34:10 35:10,12 44:6,8,25 45:11 94:5 104:10 190:16,23 191:9 240:8 254:23 279:13 379:1  <b>explain</b> [5] 75:23 108:10 248:7 293:5 299:10  <b>explaining</b> [1] 106:2  <b>explanation</b> [1] 208:11</p>	<p><b>explanations</b> [1] 77:15  <b>Exploratory</b> [1] 43:11  <b>explore</b> [4] 88:7 139:18 177:11 258:20  <b>explosion</b> [1] 194:3  <b>exposed</b> [4] 191:21,24 257:17 264:1  <b>exposing</b> [1] 257:25  <b>exposure</b> [7] 19:25 20:3 20:19,21 184:8 191:17 275:6  <b>express</b> [1] 62:5  <b>expressed</b> [7] 128:24 129:18 130:3,4,5 297:13 379:4  <b>expression</b> [20] 58:23 75:3,4,10,10,12 76:3,7,9 79:7,12 149:4 150:11,14 150:16,17 241:6 242:1 242:15,16  <b>expressions</b> [1] 144:6  <b>expressors</b> [4] 150:12 150:24 294:24 362:25  <b>extensive</b> [2] 159:3 280:1  <b>extent</b> [1] 259:8  <b>external</b> [44] 14:4,8,18 15:21 31:23 33:10 43:11 62:22 92:8 93:18 96:6 96:17 99:11 100:7 103:5 103:13,24 104:13 105:16 106:24 110:17 113:23 114:2 120:21 121:9,13 121:18 145:10 151:4 155:25 156:10 158:14,20 164:17 165:25 169:18,21 200:2 222:3 230:13 249:20 286:22 391:22 392:18  <b>extinguished</b> [1] 262:15  <b>extra</b> [1] 143:23  <b>extreme</b> [1] 237:23  <b>extremely</b> [8] 132:15 149:11 151:1 161:12 169:25 184:6,6 273:3</p> <hr/> <p style="text-align: center;"><b>-F-</b></p> <p><b>f</b> [4] 11:16 20:22 182:22 182:22  <b>face</b> [4] 160:19,19,20,20  <b>faced</b> [3] 17:18 18:2 44:18  <b>fact</b> [24] 39:7 59:6 60:15 60:18 70:15 99:10 105:2 105:8 135:1 149:20 228:21 230:5 232:19 235:2,14 255:6 262:23 290:23 294:18 304:19 310:14 311:23 339:4,5  <b>factor</b> [9] 239:20 241:5 241:10,11,11,23,25 242:6 269:9  <b>factors</b> [10] 240:24 241:2 241:8 266:19,23,25 267:10,19 276:13 343:3  <b>fail</b> [4] 50:2 208:10,22</p>	<p>216:6  <b>failed</b> [4] 208:12,18 215:14 218:6  <b>failing</b> [1] 250:7  <b>failure</b> [1] 208:23  <b>fair</b> [6] 209:2 215:9 221:16 232:4 351:19 355:10  <b>fall</b> [5] 59:18 60:22 61:22 179:10 281:21  <b>falls</b> [7] 209:12 318:10 356:25 373:21 374:2,21 377:2  <b>false</b> [60] 45:3 132:19 133:2 138:16,16,20,21 141:5,15 144:22 145:14 145:16,22,24 146:10 196:2 209:5,13,20 210:4 218:3 224:12,13,14,16 238:1 249:7,8,9,10,25 249:25 250:2,3,7,13 251:1,1 267:6,11,13,20 268:1,1,4,10,19 271:5 271:17,18,22 272:17 273:1,7 274:11,14 275:3 276:20 277:20 379:2  <b>familiar</b> [3] 221:8 234:9 234:12  <b>famous</b> [1] 14:16  <b>far</b> [15] 59:15 66:21 97:10 104:5 115:9 116:20 159:12 163:9 167:25 177:3 195:8 202:8 344:7 391:23 394:10  <b>fashion</b> [1] 53:11  <b>fast</b> [1] 8:22  <b>faster</b> [1] 8:22  <b>favour</b> [2] 380:12,15  <b>FDA</b> [4] 56:16 57:13 61:16 63:2  <b>federal</b> [2] 171:23 245:10  <b>fee</b> [1] 162:1  <b>feedback</b> [10] 14:5,11 16:4 38:11,12 151:13,19 159:3 238:24 251:18  <b>feeling</b> [2] 157:19 308:9  <b>feels</b> [1] 299:18  <b>fees</b> [5] 31:9 160:4,9 161:11,23  <b>fellowship</b> [3] 7:1,4,5  <b>felt</b> [5] 65:1 297:18 341:18 382:7,20  <b>fetal</b> [1] 130:2  <b>few</b> [17] 17:21 59:22 63:13,17,19 100:11 107:25 114:1 118:23 176:21 179:16 237:18 246:4 290:7,10 314:5 372:4  <b>few-day</b> [1] 311:17  <b>fiction</b> [2] 21:2,2  <b>field</b> [5] 23:7,9 95:2 190:16 202:25  <b>fields</b> [2] 45:12 101:22  <b>figure</b> [10] 18:9 21:16</p>
---	--	---	---	--

<p>137:5 161:1 181:15 218:22,23 260:21 278:6 350:25</p> <p><b>figured</b> [1] 29:16</p> <p><b>figures</b> [2] 320:1,11</p> <p><b>figuring</b> [1] 359:5</p> <p><b>file</b> [1] 371:16</p> <p><b>files</b> [2] 357:5 387:2</p> <p><b>filing</b> [1] 349:4</p> <p><b>filled</b> [3] 391:18 393:11 394:3</p> <p><b>filtered</b> [1] 29:16</p> <p><b>final</b> [5] 66:10 75:18 77:19 169:10 294:9</p> <p><b>finalized</b> [1] 348:24</p> <p><b>finally</b> [4] 126:5 214:24 284:16 288:6</p> <p><b>finding</b> [2] 198:5 351:2</p> <p><b>findings</b> [3] 226:5 248:3 283:17</p> <p><b>fine</b> [6] 9:9 48:5 150:21 150:23 288:24 382:15</p> <p><b>finish</b> [1] 177:4</p> <p><b>Finland</b> [2] 13:14 40:11</p> <p><b>Fins</b> [1] 28:3</p> <p><b>firm</b> [1] 330:4</p> <p><b>first</b> [55] 12:11 16:16 19:19 21:7 22:22 54:13 72:5 77:20 79:11 81:17 81:17 96:15 97:3,12 98:4 98:11 104:25 142:17 146:2 147:15 169:11 175:15 185:23 190:10 223:20,21 231:21 232:18 234:25 236:22 244:10 249:8 252:21 253:1,25 254:17,18 257:13 276:19 278:3,4 286:3 308:24 329:14 336:11 340:16 341:11 344:11 345:6,14 349:7 350:22 358:18 379:13 384:19</p> <p><b>FISH</b> [2] 149:6 284:21</p> <p><b>five</b> [20] 100:1 147:19 164:11,12 169:8,9,10 171:22 177:21 189:10 209:19 217:15 218:4 250:25 329:3 331:21,23 344:18 390:12 394:22</p> <p><b>Five-Point</b> [1] 168:9</p> <p><b>five-year</b> [2] 344:21 345:14</p> <p><b>fixation</b> [1] 275:5</p> <p><b>fixed</b> [5] 151:10 194:5 236:6 240:10 318:1</p> <p><b>florescence</b> [1] 21:4</p> <p><b>flowcytometry</b> [1] 18:2</p> <p><b>Fluorescent</b> [1] 149:7</p> <p><b>focus</b> [16] 23:11 108:7 113:3 134:11 139:9 146:6 146:15 230:11 251:24 255:6 257:9,13 258:22 262:25 310:4 336:11</p> <p><b>focused</b> [2] 112:13 146:22</p>	<p><b>focusing</b> [1] 229:6</p> <p><b>follicle</b> [1] 76:5</p> <p><b>follicular</b> [3] 117:13,16 117:20</p> <p><b>follow</b> [9] 15:13,15 21:16 23:10 26:8 62:23 65:17 92:22 303:18</p> <p><b>followed</b> [4] 67:22 269:16 275:5 285:22</p> <p><b>following</b> [4] 9:2 108:21 127:24 279:25</p> <p><b>follows</b> [1] 270:25</p> <p><b>Fontaine</b> [1] 304:6</p> <p><b>food</b> [1] 161:5</p> <p><b>foot</b> [1] 283:8</p> <p><b>footnote</b> [4] 283:10,10 283:12 284:10</p> <p><b>foregoing</b> [1] 397:2</p> <p><b>forgotten</b> [2] 253:19 257:14</p> <p><b>form</b> [2] 101:17 148:22</p> <p><b>formal</b> [4] 184:21 212:14 282:8 305:3</p> <p><b>formalin</b> [3] 194:5 236:6 240:10</p> <p><b>formalized</b> [1] 304:17</p> <p><b>formalizing</b> [1] 304:19</p> <p><b>formally</b> [3] 167:9 185:3 185:7</p> <p><b>format</b> [6] 35:9,11 141:20 142:7,7 249:24</p> <p><b>former</b> [1] 6:10</p> <p><b>forth</b> [3] 100:11 250:15 292:23</p> <p><b>forward</b> [2] 100:15 245:6</p> <p><b>forwarded</b> [1] 245:18</p> <p><b>found</b> [14] 82:1 84:4,5 95:9 101:4 134:25 170:7 170:13 198:6 224:3 235:15 346:16 359:16 386:15</p> <p><b>founded</b> [1] 111:12</p> <p><b>four</b> [25] 13:13 28:14 29:6 31:2 33:6 44:11,14 79:20 90:11 100:12 105:16 117:16,18 118:8 120:7 161:6,8 169:8 171:2 172:18 189:10 309:1 313:3 328:24 344:18</p> <p><b>fourth</b> [2] 146:24 297:3</p> <p><b>frame</b> [2] 311:8 340:15</p> <p><b>frames</b> [1] 283:8</p> <p><b>framework</b> [1] 206:11</p> <p><b>fraught</b> [1] 239:18</p> <p><b>free</b> [7] 52:20 64:25 65:1 116:1 135:21 245:21 248:16</p> <p><b>freedom</b> [1] 245:1</p> <p><b>frequency</b> [1] 224:16</p> <p><b>frequent</b> [3] 48:11 121:15 150:18</p> <p><b>frequently</b> [9] 59:5</p>	<p>113:25 119:13 124:1 128:25 138:25 243:3 270:15 278:18</p> <p><b>front</b> [2] 89:7 373:12</p> <p><b>frozen</b> [2] 194:10 346:22</p> <p><b>frustration</b> [1] 174:13</p> <p><b>fulfil</b> [3] 156:1 163:17 239:17</p> <p><b>full</b> [3] 215:25 306:2 396:20</p> <p><b>fully</b> [6] 11:10 72:14 73:15 76:4 77:1 121:7</p> <p><b>function</b> [4] 16:10 31:12 173:24 180:5</p> <p><b>functioning</b> [1] 183:12</p> <p><b>functions</b> [3] 15:25 31:12 186:10</p> <p><b>funded</b> [6] 162:12 163:11 245:14 246:5,7,8</p> <p><b>funding</b> [5] 27:21 30:7 159:12 162:23 163:5</p> <p><b>funds</b> [3] 12:3,17 86:7</p> <p><b>furthermore</b> [1] 218:6</p> <p><b>future</b> [4] 104:19 160:8 161:21 175:2</p> <hr/> <p style="text-align: center;"><b>-G-</b></p> <hr/> <p><b>g</b> [5] 11:16,16 119:12,12 182:22</p> <p><b>gain</b> [3] 58:1 175:7 245:25</p> <p><b>gained</b> [1] 55:20</p> <p><b>game</b> [1] 366:16</p> <p><b>Gander</b> [4] 318:9 354:1 356:25 377:2</p> <p><b>gap</b> [2] 157:19 232:20</p> <p><b>gastrointestinal</b> [1] 62:13</p> <p><b>gather</b> [4] 190:13 192:12 207:22 321:4</p> <p><b>Geldenhuis</b> [2] 98:13 98:22</p> <p><b>gene</b> [2] 241:18 242:1</p> <p><b>general</b> [10] 75:21 79:5 85:25 117:21 148:2 236:21 238:15 257:23 314:9 321:1</p> <p><b>generally</b> [13] 59:18 65:22 66:16 199:15 267:16,18 269:15 274:10 275:22 295:11,13 353:25 376:21</p> <p><b>generated</b> [5] 59:5 66:17 67:13 208:16 325:6</p> <p><b>generation</b> [1] 184:15</p> <p><b>genes</b> [5] 240:24 241:6 241:14,24 242:5</p> <p><b>geographic</b> [1] 84:23</p> <p><b>Gersham</b> [1] 127:20</p> <p><b>Gilks</b> [10] 85:24,25 87:3 95:19 96:12 100:10 105:3 136:21 140:10 236:22</p> <p><b>Gilks'</b> [2] 143:1,6</p> <p><b>gist</b> [1] 62:10</p>	<p><b>given</b> [19] 16:17 38:11 64:6 74:15 76:24 91:6 101:14 131:10 151:13 212:1 217:21 224:4 235:4 247:11 250:4 276:1 342:10 381:10 382:12</p> <p><b>giving</b> [4] 121:15 124:19 341:9 344:19</p> <p><b>glands</b> [1] 133:5</p> <p><b>global</b> [2] 251:15,17</p> <p><b>globally</b> [1] 14:25</p> <p><b>goal</b> [5] 11:10 71:8 104:19 230:14 293:8</p> <p><b>goals</b> [3] 157:2,3 293:10</p> <p><b>goes</b> [7] 96:20 144:9 250:15 280:6 297:3 314:20 316:9</p> <p><b>gold</b> [6] 210:19,20,22,24 211:7 212:2</p> <p><b>gone</b> [6] 190:24 337:24 341:23 344:18 345:21 347:7</p> <p><b>good</b> [44] 11:4 13:2,24 47:24 51:15 77:9,13 80:1 83:24 87:12 93:14,16,17 149:1,11 150:20,25 153:9 165:25 166:1 173:18 186:16,17 191:4 198:13 199:11 214:1 216:4 220:7 228:20 231:15 249:3,4 250:10,11 252:17 258:1 259:17 286:12 292:8,10 294:21 296:9 334:2</p> <p><b>government</b> [8] 171:3 220:19,20,23 246:5,7,8 246:15</p> <p><b>governmental</b> [1] 162:24</p> <p><b>governments</b> [2] 171:24 245:14</p> <p><b>Grace</b> [1] 354:4</p> <p><b>graduated</b> [2] 6:9,12</p> <p><b>Grand</b> [6] 318:10 356:25 373:21 374:2,21 377:2</p> <p><b>granted</b> [3] 68:24 205:7 205:9</p> <p><b>graph</b> [1] 47:8</p> <p><b>graphically</b> [1] 239:22</p> <p><b>graphs</b> [1] 46:13</p> <p><b>great</b> [5] 8:9 16:3 26:21 234:19 244:16</p> <p><b>greater</b> [6] 193:2,12 323:4,15 337:10,15</p> <p><b>greatest</b> [2] 72:25 174:12</p> <p><b>greatly</b> [4] 70:24 141:19 149:22 183:8</p> <p><b>Green</b> [1] 301:14</p> <p><b>grossed</b> [1] 318:1</p> <p><b>ground</b> [2] 174:16 175:12</p> <p><b>group</b> [28] 28:14 29:22 31:17 33:24 34:23 38:2 38:17 44:6,7 48:5,19 100:17 111:10 112:13 135:1 137:6 167:7 218:8 218:10 219:5 220:2 281:6</p>	<p>281:6 308:10 345:14 354:11 375:2 385:7</p> <p><b>grouping</b> [1] 354:13</p> <p><b>groups</b> [1] 170:17</p> <p><b>grows</b> [1] 160:12</p> <p><b>growth</b> [1] 239:20</p> <p><b>guarantee</b> [2] 249:5 330:1</p> <p><b>guess</b> [31] 183:25 187:25 212:6 231:22,24 232:2 232:25 235:17 245:9 247:8 248:4 255:15 261:18 274:19 275:13 276:21 280:20 282:6 298:7 305:16 308:20 318:22 326:10 339:13,24 340:12 345:21 348:24 351:14 391:17 395:23</p> <p><b>guidance</b> [1] 231:5</p> <p><b>guideline</b> [3] 65:3 66:14 68:14</p> <p><b>guidelines</b> [28] 75:7,21 76:14,17 92:23 110:7,10 110:17 112:13 154:21 155:9,10 170:9,10,16,22 203:25 204:2 244:22 245:1,2 254:1,18,25 258:16 279:9,16 342:10</p> <p><b>Gulliver</b> [344] 2:9 296:6 296:9,25 297:5,9 298:2 298:17 299:12 300:5,9 300:14,21 301:2,22 302:4 302:9,13,21,25 303:3,8 303:20 304:7,9,20,24 305:4,15 306:10,16,24 307:3,15,24 308:17,18 309:13,18 310:2,10,15 310:21 311:7,15,20 312:2 312:6,11,22 313:1,11,20 314:25 315:15,19 316:1 316:6,16,20,24 317:10 317:14,21 318:18 319:5 319:10,18 320:2,6,13,24 321:15,17,24 322:8,13 322:20 323:1,6,10,17,23 324:2,7,11,16,20 325:4 325:12,16,21 326:2,7,12 326:23 327:3,7,13,19 328:2,6,11,21,25 329:4 329:9,18 330:5,10,14,24 331:4,10,15,22 332:3,8 332:13,24 333:2,5,12,18 333:24 334:3,17,22 335:2 335:6,15,17 336:5,19,23 337:2,11,19 338:1,14,21 339:1,7,11,22 340:2,7 342:17,23 343:8,12,17 343:22 344:10 345:12,17 345:24 346:7,11 347:4 347:10,17,21 348:1,8,13 348:23 349:10,15 350:5 350:10,15 351:6,13 352:18,25 353:4,10,16 354:8,16,22 355:1,7,11 355:21,25 356:5,20 357:2 357:4,8,12,16,22 358:3 358:12,17,21 359:1,6,10 359:14,19,23 360:4,9,15 360:20,25 361:4,9,13,17 361:23 362:3,8,16,20</p>
---	---	--	---	--

<p>363:11,15,20,24 364:5 364:10,18,23 365:2,8,18 366:1,6,12,22 367:7,12 367:16,21 368:5,15,20 368:25 369:4,8,13,20,24 370:3,9,16,20 371:5,13 371:19,24 372:11,15,25 373:4,9,17,22 374:5,10 374:16 375:6,11,15,21 375:25 376:4,14,18 377:12,16,23 378:5,18 378:22,24 379:11,25 380:6,11,16,24 381:12 381:16,22 383:2,8,15,22 384:9,21 385:1,6,12,17 385:25 386:8,17,23 387:7 387:12,18,22 388:4,10 388:14,19,23 389:3,9,17 389:22 390:2,15,20,24 391:4,8,12 392:3,7,11 392:16,22 393:3,13,18 393:24 394:4,8,12,16,23 395:2,6,10,15,19,24 396:4</p>	<p><b>Heather</b> [17] 297:1,24 298:3 307:7,16,17 312:18 313:2,13,25 314:1,7 315:12 320:15 321:2 336:8 349:18 <b>Heather's</b> [2] 298:5 308:20 <b>heavily</b> [1] 381:25 <b>held</b> [2] 35:3 39:13 <b>help</b> [17] 7:11 10:1,4 23:2 27:7 86:12,13 94:24 98:6 114:15 145:11 170:15,21 249:21 271:2,11 313:9 <b>helped</b> [2] 14:11 344:19 <b>helpful</b> [4] 33:1 69:12 186:24 213:7 <b>helping</b> [1] 182:24 <b>helps</b> [2] 187:13 271:12 <b>hemapathology</b> [1] 119:7 <b>hematopathology</b> [2] 7:2,5 <b>hematoporietic</b> [1] 65:6 <b>Hennebury</b> [1] 1:9 <b>HER2</b> [29] 37:14 58:17 58:24 61:5 68:3,13,15 76:18 77:5 79:8,8 100:13 109:10,18 110:1,8,13,15 112:13 135:1 149:5 154:11,22 155:10 156:4 188:19 204:2 254:18 284:20 <b>HER2/neu</b> [7] 60:22 61:22 107:23 111:11,14 147:1 394:9 <b>hereby</b> [1] 397:2 <b>heterogenous</b> [1] 184:7 <b>Hi</b> [1] 307:9 <b>high</b> [17] 10:24 21:13 40:24 41:2 64:1 75:2,3 78:15,22 90:19 128:8 132:22 230:22 250:19 276:10,18 343:25 <b>higher</b> [5] 90:18 153:12 287:15,22 297:17 <b>highest</b> [1] 364:12 <b>highlighting</b> [2] 201:7 363:21 <b>highly</b> [5] 13:18 17:16 63:24 125:8,9 <b>histochemical</b> [1] 180:2 <b>histochemistry</b> [1] 242:3 <b>histologic</b> [1] 280:2 <b>histones</b> [4] 272:11,12 272:12,23 <b>historical</b> [1] 149:14 <b>historically</b> [2] 53:22 73:1 <b>history</b> [6] 14:15 41:19 53:7,15 164:23 343:3 <b>HMB45</b> [1] 214:17 <b>home</b> [2] 13:10 159:23 <b>Honourable</b> [2] 1:3 397:6</p>	<p><b>hope</b> [5] 77:3 101:20 104:17 109:19 117:7 <b>hopefully</b> [1] 346:20 <b>hoping</b> [1] 207:23 <b>hormonal</b> [3] 126:16 344:17,20 <b>hormone</b> [6] 1:2 107:23 344:1 361:18 386:12 397:4 <b>hospital</b> [25] 6:16 7:14 7:16 16:25 22:23 23:17 24:2,13,14 25:22 26:7 26:16,16 47:3,13 79:5 81:1 82:9 86:1 198:22 216:14,16 322:7 351:15 353:22 <b>hospitals</b> [8] 6:17 8:9 9:17 25:18 26:8 74:10 255:2 325:15 <b>hotel</b> [1] 12:19 <b>hotline</b> [2] 94:7 245:22 <b>hour</b> [1] 236:4 <b>hours</b> [2] 258:14 381:2 <b>house</b> [1] 261:7 <b>huge</b> [8] 114:11 117:17 175:19 198:23 215:2 217:21 218:14 254:2 <b>human</b> [2] 272:12,23 <b>humans</b> [1] 274:21 <b>hundred</b> [3] 68:16,24 69:9 <b>hundreds</b> [5] 41:6 76:11 113:13 120:20 121:14 <b>hybridization</b> [3] 21:1 21:4 149:7 <b>hydrogenating</b> [2] 79:22,24 <b>hypersensitive</b> [3] 195:11,16,20 <b>Hypersensitivity</b> [1] 195:18 <b>hypothetical</b> [3] 132:10 133:21 241:9</p>	<p>127:24 152:3 163:10 248:6 308:24 316:25 317:4 319:1 321:6 377:18 <b>identifies</b> [2] 125:10 129:14 <b>identify</b> [15] 8:6 51:4 102:6 128:19 153:4 174:25 229:24 239:15 270:7 316:19 318:24 340:14 342:8 351:23 386:13 <b>identifying</b> [6] 243:19 316:5 324:23 350:22 381:3 382:1 <b>ignored</b> [1] 54:4 <b>IHC</b> [35] 41:20,25 42:11 50:15 52:16 56:9,17 60:14 81:15 103:22 169:24 174:5,7 179:12 179:14 187:25 190:9 201:22 230:18 232:4,14 232:18 239:6,16,22 284:24 285:2 288:8 298:5 301:15 304:16 344:24 345:23 347:13 348:12 <b>II</b> [48] 37:14,16 38:16 56:10 57:9 58:13 59:19 59:22,23 60:3,15,23 61:1 61:8,14,17 62:9,17,21 63:5,8,14 64:7,15 66:11 66:17 67:1 92:23 100:13 106:2 107:24,25 109:12 111:23 112:12,24 117:5 120:23 135:2 139:9 146:19 154:21 161:20 170:21 188:2,15 236:20 257:12 <b>illustrate</b> [2] 116:13 117:11 <b>illustrated</b> [3] 132:16 142:1 201:6 <b>illustrates</b> [4] 200:2 239:23 249:1 293:5 <b>illustrating</b> [1] 174:1 <b>illustrations</b> [1] 153:19 <b>image</b> [1] 258:3 <b>images</b> [6] 32:13 51:16 116:13 117:11 118:17 142:9 <b>imagine</b> [3] 62:15 180:3 278:5 <b>immature</b> [1] 120:5 <b>immediate</b> [3] 165:7,24 171:22 <b>immediately</b> [6] 51:2 88:1 134:20 159:5 275:25 311:13 <b>immense</b> [1] 231:25 <b>immuno</b> [2] 64:16 215:23 <b>immunocytochemistry</b> [1] 14:21 <b>immunohistochemical</b> [14] 23:11 56:14 57:23 60:2 65:24 95:13 105:10 107:18 118:4 159:22 181:2 191:18 192:25 195:7</p>	<p><b>immunohistochemistry</b> [103] 7:12,19 8:3 10:11 11:17 14:22 16:23 17:1 17:10,13,20 19:1,25 20:3 20:6,7,12,23,25 21:5,21 22:21 23:3,17 24:4,10 25:8 26:25 42:16 43:19 46:8,10 49:9,19,21 53:17 53:20 57:7 70:25 72:21 73:25 87:1 90:14 95:11 96:7,19 99:13 100:8 101:10,24 102:8 103:6 104:11,14 106:1,13,18 117:23 119:13,17 124:1 139:4 143:17 144:3 145:8 145:13 149:23 163:3 164:16 165:6,11 168:22 180:6 181:23 182:7,23 187:2 188:14,20 189:2 189:17,20 190:17,22 191:14 192:7 196:25 198:13 205:14 210:21 211:7 217:11 231:23 240:9 243:19 244:11 254:22 257:22 281:20 286:17 304:3,4 306:22 <b>Immunoperoxidase</b> [1] 98:16 <b>immunostaining</b> [1] 26:17 <b>impact</b> [10] 21:13 55:25 56:14 57:18 61:20 62:1 235:21,23 266:20 285:2 <b>impaired</b> [1] 77:16 <b>imperative</b> [1] 239:15 <b>implement</b> [1] 170:15 <b>implementation</b> [1] 170:8 <b>implemented</b> [2] 106:23 236:25 <b>implementing</b> [1] 306:12 <b>importance</b> [3] 53:18 200:21 238:23 <b>important</b> [25] 12:14 14:9 32:23 35:13 56:8 57:1 76:16 113:22 117:3 117:17 120:17,25 121:1 126:18 132:15 154:9 157:20 160:23 169:25 201:9 230:14 232:16 270:16 297:18 382:8 <b>importantly</b> [1] 235:18 <b>imported</b> [1] 182:17 <b>impression</b> [2] 213:25 231:25 <b>improper</b> [1] 124:20 <b>improve</b> [17] 10:4 11:8 11:20 14:12 15:1,4,7 27:8 34:2 50:4 83:3 88:3 102:7 159:5 216:1 247:12 256:7 <b>improved</b> [9] 14:3 21:22 82:3 88:4 149:22 166:3 217:2 246:21 306:15 <b>improvement</b> [11] 12:1 216:2 217:4 219:20,21 219:23 249:11 305:12,18</p>
<p><b>-H-</b></p>		<p><b>-I-</b></p>		
<p><b>h</b> [13] 20:22 119:12,14 122:3 124:4 182:22 242:21,24 243:5,9 244:3 244:6 257:21 <b>H&amp;Es</b> [1] 381:5 <b>half</b> [5] 97:2 102:20 160:1 179:9 297:15 <b>hallmark</b> [1] 21:9 <b>hand</b> [5] 15:24 30:2 46:11 171:20 251:9 <b>handles</b> [1] 42:11 <b>handout</b> [3] 23:1,13 100:5 <b>hands</b> [1] 18:9 <b>hands-on</b> [1] 21:19 <b>handwriting</b> [2] 99:25 349:9 <b>handwritten</b> [1] 145:16 <b>happening</b> [6] 9:25 146:9 174:15 260:23 286:15 303:5 <b>hard</b> [7] 53:2 118:2 161:16 189:22 278:5,6 352:1 <b>harming</b> [1] 54:18 <b>Harvey</b> [2] 244:5,7 <b>Harvey's</b> [1] 244:6 <b>head</b> [1] 187:25 <b>headings</b> [2] 288:22 322:6 <b>health</b> [11] 1:11,17 96:3 99:24 179:8 188:4 190:8 317:23 318:2,7 325:9 <b>hear</b> [5] 134:19 190:18 220:19,25 308:4 <b>heard</b> [16] 84:1 101:4 109:9 136:9 163:22 179:6 181:15 184:25 188:6,7 189:9 221:7 223:4 238:17 242:18 397:5 <b>hearings</b> [1] 96:4</p>	<p><b>HER2</b> [29] 37:14 58:17 58:24 61:5 68:3,13,15 76:18 77:5 79:8,8 100:13 109:10,18 110:1,8,13,15 112:13 135:1 149:5 154:11,22 155:10 156:4 188:19 204:2 254:18 284:20 <b>HER2/neu</b> [7] 60:22 61:22 107:23 111:11,14 147:1 394:9 <b>hereby</b> [1] 397:2 <b>heterogenous</b> [1] 184:7 <b>Hi</b> [1] 307:9 <b>high</b> [17] 10:24 21:13 40:24 41:2 64:1 75:2,3 78:15,22 90:19 128:8 132:22 230:22 250:19 276:10,18 343:25 <b>higher</b> [5] 90:18 153:12 287:15,22 297:17 <b>highest</b> [1] 364:12 <b>highlighting</b> [2] 201:7 363:21 <b>highly</b> [5] 13:18 17:16 63:24 125:8,9 <b>histochemical</b> [1] 180:2 <b>histochemistry</b> [1] 242:3 <b>histologic</b> [1] 280:2 <b>histones</b> [4] 272:11,12 272:12,23 <b>historical</b> [1] 149:14 <b>historically</b> [2] 53:22 73:1 <b>history</b> [6] 14:15 41:19 53:7,15 164:23 343:3 <b>HMB45</b> [1] 214:17 <b>home</b> [2] 13:10 159:23 <b>Honourable</b> [2] 1:3 397:6</p>	<p><b>idea</b> [29] 24:3 65:5 78:5 79:13 83:25 86:24 90:11 102:5 121:13 133:6 150:19 172:17 176:9 180:14 186:16,17 196:4 255:24 256:25 258:7 281:5 285:24 316:17 341:14 352:12 354:23 355:3,22 375:7 <b>ideal</b> [1] 245:13 <b>ideally</b> [8] 183:7,7,10 185:10,13 211:13 245:12 281:16 <b>ideals</b> [1] 245:12 <b>identical</b> [4] 153:14,14 153:15 262:1 <b>identified</b> [11] 91:2</p>	<p><b>illustrate</b> [2] 116:13 117:11 <b>illustrated</b> [3] 132:16 142:1 201:6 <b>illustrates</b> [4] 200:2 239:23 249:1 293:5 <b>illustrating</b> [1] 174:1 <b>illustrations</b> [1] 153:19 <b>image</b> [1] 258:3 <b>images</b> [6] 32:13 51:16 116:13 117:11 118:17 142:9 <b>imagine</b> [3] 62:15 180:3 278:5 <b>immature</b> [1] 120:5 <b>immediate</b> [3] 165:7,24 171:22 <b>immediately</b> [6] 51:2 88:1 134:20 159:5 275:25 311:13 <b>immense</b> [1] 231:25 <b>immuno</b> [2] 64:16 215:23 <b>immunocytochemistry</b> [1] 14:21 <b>immunohistochemical</b> [14] 23:11 56:14 57:23 60:2 65:24 95:13 105:10 107:18 118:4 159:22 181:2 191:18 192:25 195:7</p>	<p><b>immunohistochemistry</b> [103] 7:12,19 8:3 10:11 11:17 14:22 16:23 17:1 17:10,13,20 19:1,25 20:3 20:6,7,12,23,25 21:5,21 22:21 23:3,17 24:4,10 25:8 26:25 42:16 43:19 46:8,10 49:9,19,21 53:17 53:20 57:7 70:25 72:21 73:25 87:1 90:14 95:11 96:7,19 99:13 100:8 101:10,24 102:8 103:6 104:11,14 106:1,13,18 117:23 119:13,17 124:1 139:4 143:17 144:3 145:8 145:13 149:23 163:3 164:16 165:6,11 168:22 180:6 181:23 182:7,23 187:2 188:14,20 189:2 189:17,20 190:17,22 191:14 192:7 196:25 198:13 205:14 210:21 211:7 217:11 231:23 240:9 243:19 244:11 254:22 257:22 281:20 286:17 304:3,4 306:22 <b>Immunoperoxidase</b> [1] 98:16 <b>immunostaining</b> [1] 26:17 <b>impact</b> [10] 21:13 55:25 56:14 57:18 61:20 62:1 235:21,23 266:20 285:2 <b>impaired</b> [1] 77:16 <b>imperative</b> [1] 239:15 <b>implement</b> [1] 170:15 <b>implementation</b> [1] 170:8 <b>implemented</b> [2] 106:23 236:25 <b>implementing</b> [1] 306:12 <b>importance</b> [3] 53:18 200:21 238:23 <b>important</b> [25] 12:14 14:9 32:23 35:13 56:8 57:1 76:16 113:22 117:3 117:17 120:17,25 121:1 126:18 132:15 154:9 157:20 160:23 169:25 201:9 230:14 232:16 270:16 297:18 382:8 <b>importantly</b> [1] 235:18 <b>imported</b> [1] 182:17 <b>impression</b> [2] 213:25 231:25 <b>improper</b> [1] 124:20 <b>improve</b> [17] 10:4 11:8 11:20 14:12 15:1,4,7 27:8 34:2 50:4 83:3 88:3 102:7 159:5 216:1 247:12 256:7 <b>improved</b> [9] 14:3 21:22 82:3 88:4 149:22 166:3 217:2 246:21 306:15 <b>improvement</b> [11] 12:1 216:2 217:4 219:20,21 219:23 249:11 305:12,18</p>

<p>306:1,2 <b>improvements</b> [5] 16:3 217:22 246:20 249:17 305:17 <b>inadequate</b> [2] 217:18 275:5 <b>inappropriate</b> [5] 250:8 250:17 269:11 271:4 275:4 <b>inappropriately</b> [2] 268:18 275:17 <b>inaudible</b> [4] 177:3 178:23 334:6,10 <b>inception</b> [1] 12:11 <b>include</b> [8] 109:24 110:1 143:10,22 308:8 317:19 324:14 345:8 <b>included</b> [18] 26:9 143:12 169:18 192:13 206:21 265:25 308:10 314:13 317:9,22 318:14 326:5 333:23 346:20 367:17 371:3 372:9 383:7 <b>includes</b> [4] 103:11 204:25 253:3 369:18 <b>including</b> [4] 75:11 103:7 357:15 383:5 <b>INCLUSIVE</b> [2] 3:2 4:23 <b>incomplete</b> [1] 314:21 <b>incorporate</b> [1] 320:18 <b>incorporated</b> [3] 59:8 95:3 253:21 <b>incorporates</b> [1] 254:6 <b>incorrectly</b> [3] 225:22 225:25 226:13 <b>increase</b> [4] 194:25 198:20 239:16 249:14 <b>incubation</b> [2] 290:23 291:6 <b>indeed</b> [6] 45:3 124:10 178:13 186:21 225:24 242:2 <b>independent</b> [4] 13:8 103:14 104:1 169:21 <b>independently</b> [1] 58:14 <b>index</b> [1] 308:25 <b>Indianapolis</b> [1] 41:23 <b>indicate</b> [8] 145:17 239:18 247:2 248:9 266:19 313:9 349:13 353:19 <b>indicated</b> [14] 25:13 27:10,13 31:22 39:5,19 96:21 134:17 153:24 311:13 319:2 321:20 340:18 343:15 <b>indicates</b> [3] 31:15 304:1 319:24 <b>indicating</b> [3] 320:12 324:6 333:2 <b>indication</b> [1] 103:17 <b>individual</b> [12] 50:23 104:18 141:25 161:2 216:11 230:19 231:3,17 235:12,19 238:20 245:24</p>	<p><b>individuals</b> [3] 305:10 314:21 318:24 <b>industry</b> [2] 12:17 76:22 <b>inertia</b> [1] 286:15 <b>informal</b> [2] 279:9 282:8 <b>information</b> [41] 57:21 58:1,5,11,20 67:24,24 69:14 79:14 104:7,24 121:16 126:9 151:6,24 159:4 168:2 175:4,8 231:25 233:4 238:20 243:7 245:17 251:16 261:4 262:2,7 286:7 319:11,12 320:19 321:3 321:5 351:16 353:20 370:21 373:17 382:8,21 393:4 <b>informative</b> [1] 32:14 <b>inherent</b> [1] 211:19 <b>inhibitors</b> [1] 239:21 <b>initial</b> [6] 10:3,21 30:12 109:4 134:11 217:12 <b>initiated</b> [1] 216:25 <b>initiative</b> [5] 11:15 12:7 13:1 23:22 331:7 <b>initiatives</b> [2] 212:8 313:18 <b>innumerable</b> [1] 127:18 <b>input</b> [1] 179:11 <b>inquire</b> [1] 303:4 <b>inquiries</b> [1] 304:3 <b>inquiry</b> [4] 1:1 231:19 397:4,7 <b>insight</b> [5] 11:6 87:20 175:22 262:8 382:12 <b>inspections</b> [1] 259:4 <b>instance</b> [1] 248:11 <b>instances</b> [3] 117:21 275:15 278:14 <b>instead</b> [3] 178:6 250:20 396:22 <b>institute</b> [1] 7:13 <b>institution</b> [2] 279:11 282:4 <b>institutions</b> [3] 37:21 227:21 317:20 <b>instructions</b> [1] 249:21 <b>instructive</b> [1] 51:15 <b>instrument</b> [3] 199:22 289:1 299:8 <b>instrumentation</b> [5] 94:11 153:15 298:20 301:17 303:13 <b>instruments</b> [7] 288:25 289:9,13 299:5,21,21,25 <b>insufficient</b> [3] 250:13 250:18 267:25 <b>Integrated</b> [2] 1:10,17 <b>intensity</b> [5] 197:10 241:21,22,23 243:11 <b>intent</b> [2] 322:1 338:19 <b>intention</b> [1] 104:16 <b>interact</b> [1] 35:12 <b>interacting</b> [1] 94:17</p>	<p><b>interaction</b> [2] 35:5 182:5 <b>interactions</b> [2] 94:5 276:7 <b>interest</b> [9] 6:25 11:19 20:21 32:9 197:3 199:14 199:18 201:8 234:19 <b>interested</b> [7] 101:25 104:21 240:23 253:2 265:16,22 272:6 <b>interesting</b> [9] 15:2 85:17 92:6 98:21 101:5 138:9 177:2 234:13 393:7 <b>interestingly</b> [1] 233:18 <b>interlab</b> [3] 212:15,19 248:7 <b>interlaboratory</b> [3] 221:10,17 224:25 <b>intermediate</b> [2] 87:17 213:20 <b>internal</b> [13] 34:17 103:13 105:19 106:23 150:22 270:1,8 285:3 286:21 382:19 391:25 392:19 393:22 <b>international</b> [3] 7:20 15:9 27:25 <b>internationally</b> [3] 20:10,11 191:13 <b>internet</b> [6] 16:7 51:19 51:24 52:1 258:9 284:2 <b>interoperative</b> [1] 74:4 <b>interpret</b> [6] 118:19 195:2 228:21 277:5,10 277:11 <b>interpretation</b> [34] 34:6 37:5 38:22 47:4,14 66:9 66:25 87:18 108:2 119:16 191:10 192:22 193:3 228:15,19 229:8 230:5,6 255:7 257:7,14 262:25 263:7,8,10 268:24 269:3 270:12 282:9 318:12 325:7 326:18 328:13 354:2 <b>interpretations</b> [3] 37:22 227:22 228:8 <b>interpretative</b> [1] 229:13 <b>interpreted</b> [16] 44:24 46:24 57:21 58:4 80:7 116:23 117:1 227:20 229:17,18 268:18 270:2 275:17 277:17 325:1 331:20 <b>interpreting</b> [1] 263:24 <b>interpretive</b> [2] 229:15 268:12 <b>interrupt</b> [1] 34:25 <b>interrupted</b> [1] 146:1 <b>intervals</b> [1] 103:16 <b>intervention</b> [4] 150:1 183:18 185:25 286:16 <b>intimately</b> [1] 253:12 <b>introduced</b> [2] 17:12 254:14</p>	<p><b>introduces</b> [2] 254:3,6 <b>introduction</b> [1] 192:14 <b>invasive</b> [1] 346:18 <b>inventive</b> [1] 21:16 <b>invest</b> [1] 260:20 <b>invitations</b> [1] 28:20 <b>invite</b> [3] 28:7 104:14 175:6 <b>invited</b> [5] 101:24 102:1 102:13 135:19 144:3 <b>inviting</b> [1] 30:3 <b>involve</b> [4] 17:4 32:6 73:13 154:4 <b>involved</b> [19] 16:19 17:6 20:21 28:3 37:17 55:18 79:2 109:7 159:10 171:16 176:2 182:25 201:3 208:5 253:12 275:19 276:23 295:14 297:7 <b>involvement</b> [3] 117:14 117:22 219:21 <b>involves</b> [1] 32:8 <b>involving</b> [1] 85:4 <b>irrelevant</b> [1] 61:18 <b>ischemia</b> [1] 73:19 <b>ISO</b> [1] 157:18 <b>issue</b> [16] 12:6 70:25 98:19 172:22 210:2 262:25 299:10 300:3 302:17 311:5 312:9 313:7 314:6 320:21 358:7 382:16 <b>issued</b> [1] 110:10 <b>issues</b> [17] 11:22 35:7 53:16 94:16 184:14,16 228:16 232:3 251:17 305:7,13,22 307:12,21 314:17,18 316:10 <b>item</b> [3] 253:1,4 276:19 <b>items</b> [1] 100:2 <b>itself</b> [19] 5:14,17 16:8 21:3 28:22 58:10 82:5 99:20 106:5 127:22 145:19 167:3 185:2 203:17 246:13 253:18 263:15 284:9,12</p>	<p>376:17,23 389:20 390:7 397:8,11 <b>joins</b> [1] 296:1 <b>journal</b> [7] 21:13 283:15 283:20,22 284:8,13 285:22 <b>Joy</b> [1] 340:10 <b>Judge</b> [1] 335:7 <b>judgement</b> [1] 244:1 <b>judgment</b> [6] 13:24 46:16 65:19 134:6 185:22 249:11 <b>judgments</b> [1] 202:18 <b>Judy</b> [2] 397:2,13 <b>July</b> [14] 96:12 97:8,11 98:14 99:25 111:9 134:11 135:5 252:22 317:2 358:19 367:6 369:10 378:7 <b>June</b> [1] 311:1 <b>Justice</b> [2] 1:3 397:6</p> <hr/> <p style="text-align: center;"><b>-K-</b></p> <p><b>k</b> [1] 257:21 <b>Kappa-value</b> [1] 68:7 <b>Kara</b> [3] 1:9 340:10 341:20 <b>keep</b> [4] 233:4 340:23 342:3 345:2 <b>keeping</b> [3] 357:25 372:21 375:10 <b>Ken</b> [1] 301:14 <b>kept</b> [4] 341:15 372:22 373:1,3 <b>key</b> [4] 296:21,21 341:8 352:3 <b>Khalifa</b> [6] 179:9 326:11 326:14,19 392:10,12 <b>kinase</b> [1] 239:21 <b>kind</b> [44] 21:3 22:8 26:2 29:13 30:7 44:16 53:1 55:25 62:16 63:2 78:7 83:17 85:4 87:17 130:1 161:10,14 166:6 188:10 189:2 194:3 196:5 212:14 212:17 247:9 251:3 257:25 260:16 281:16 286:5 288:1 298:12 301:18 313:24,25 327:21 336:6 339:14 353:3 367:24 373:19 383:25 384:3 391:13 <b>kinds</b> [7] 18:7 94:12,21 298:10 303:15 349:21 390:6 <b>Kingdom</b> [3] 14:20 103:7 246:13 <b>kits</b> [1] 232:2 <b>Klassen</b> [3] 143:7,16,16 <b>knew</b> [6] 25:11 241:11 286:6 299:19 308:24 382:6 <b>knowing</b> [3] 176:2 211:15 257:22 <b>knowledge</b> [29] 28:6</p>
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Inquiry on Hormone Receptor Testing

<p>40:14 45:7 46:6 54:9,10 67:18 69:19 72:7 164:3 174:9 178:14 182:15 189:19 193:2,5 194:25 200:20 212:1 245:22 247:4 270:3 279:16 282:6 284:4 286:11 299:7 303:1 339:2 <b>known</b> [9] 11:10 20:12 21:1 45:4 62:4 65:17 107:6 259:17 283:21 <b>knows</b> [4] 68:22 211:23 260:25,25 <b>Kwan</b> [4] 340:11 342:24 342:25 343:15</p>	<p>255:2 259:24 261:22,24 262:3 285:4,7 287:20 289:2 376:6 <b>laboratory</b> [78] 7:12,19 10:12 14:6 15:21 17:8 17:22 19:2,6 43:11 44:21 46:9 49:13 55:1 68:11 74:7 81:8,18 92:12 95:7 96:6 103:5,11,19,25,25 104:8,13 105:21 106:12 110:22,23 142:13 151:18 160:11 163:23 164:4,9 164:11 168:2 169:16,20 169:21 170:25 171:9,16 172:1 179:24 181:23 185:16 195:9 204:10 213:22 214:10,11 215:24 221:2 222:2 237:19,20 238:21 245:24 253:3,6 253:22 254:9 259:1 261:17 275:19 276:22 285:1,6 298:4 303:11 313:18 314:9 351:16 382:7 <b>laboratory/immunohistochemistry</b> [1] 100:4 <b>Labrador</b> [3] 252:19 397:8,11 <b>Labrador-Grenfell</b> [1] 1:16 <b>labs</b> [69] 16:1 29:2,7 30:17 36:12,13 37:5 38:12 40:5 42:19 75:6 77:11 92:3 95:13 105:18 137:18 138:14 139:23 146:25 147:5 148:24 153:6 155:12 160:25 161:12,20,22 162:1,14 164:2,5,16 171:13 172:4 173:19,21 174:17 175:21 188:3,10,16 189:15,16 189:20 198:10 205:21 207:23 214:24 215:22 216:5,5 218:11 222:22 230:19 234:4 237:21,23 246:10,22 247:21,22 251:16 289:7 292:4 293:15 295:20 318:2,5 339:12 <b>lack</b> [9] 119:10 187:18 220:8,14 233:7,8,10 250:22 267:5 <b>lacking</b> [3] 67:11,12 184:12 <b>lady</b> [1] 312:18 <b>lag</b> [1] 95:5 <b>laid</b> [1] 91:19 <b>Laing</b> [4] 1:9 340:10 341:20 344:13 <b>language</b> [2] 203:24 204:1 <b>laps</b> [1] 175:15 <b>LAR</b> [1] 55:2 <b>large</b> [29] 8:2 13:15,15 14:23 68:1,4 84:5 113:10 114:11 138:12 150:12 156:3 157:19,21 160:8 175:6 204:8 210:13,14 216:6 223:22 229:14</p>	<p>238:1 250:16 256:5,12 257:17 264:5 290:11 <b>larger</b> [13] 43:23 142:8 160:9 173:13 188:2 189:16 210:16 216:10 229:22 230:6 234:14 251:7 263:15 <b>last</b> [23] 61:13 73:17 77:4 100:12 101:13,16 102:3 102:14 159:2 168:8,17 194:19 199:2,19 200:23 202:7 206:12,16 207:6 232:8 239:6 245:4 284:18 <b>Lastly</b> [1] 248:2 <b>latitude</b> [1] 294:10 <b>Laurette</b> [1] 98:13 <b>lay</b> [1] 248:11 <b>Layfield</b> [3] 284:7,10,14 <b>lead</b> [6] 267:6 271:5 293:6 301:15 304:15 305:24 <b>leaders</b> [1] 28:9 <b>leading</b> [1] 5:8 <b>learn</b> [8] 17:23 201:16 201:17 202:2 257:16 258:11 310:13 338:24 <b>learned</b> [7] 95:16 146:9 149:19 199:18 200:24 260:22 310:16 <b>learning</b> [2] 258:12 260:20 <b>least</b> [13] 27:11 40:20 69:20 95:18 133:15 161:9 182:20 187:13 194:3 247:3 248:22 310:7 353:14 <b>leave</b> [2] 349:7 390:16 <b>leaving</b> [1] 230:18 <b>lecture</b> [1] 35:8 <b>led</b> [1] 124:24 <b>leeway</b> [1] 337:18 <b>left</b> [9] 12:12 20:13 40:21 117:10 124:4 200:14 300:17 379:16 391:23 <b>left-hand</b> [2] 122:3 148:19 <b>legal</b> [1] 245:9 <b>lesion</b> [3] 123:9 124:4 215:18 <b>lesions</b> [2] 144:5 242:8 <b>less</b> [17] 15:16 117:4 120:18 150:17 151:1 153:6 191:21 214:3 293:20,20 323:4,19 327:18 337:12 365:5 390:3,5 <b>leucocyte</b> [1] 66:7 <b>leukemia</b> [3] 120:9,13 120:14 <b>leukemic</b> [1] 119:24 <b>level</b> [16] 75:16 106:17 106:23 123:25 155:11 182:10 184:5 188:16 197:9 200:6 202:5 224:12 231:4 251:18 314:4 318:12</p>	<p><b>levels</b> [6] 75:10,12 76:9 79:7,12 171:18 <b>life</b> [1] 220:5 <b>light</b> [4] 27:6 262:23 316:10,11 <b>lights</b> [1] 118:25 <b>likelihood</b> [1] 312:12 <b>likely</b> [3] 203:5 207:16 313:21 <b>limit</b> [1] 386:6 <b>limitations</b> [1] 260:19 <b>limited</b> [4] 14:6 172:10 180:1,6 <b>line</b> [6] 256:5,10 280:4 306:12 328:8 342:13 <b>lines</b> [7] 77:7,12,14,17 77:21 78:3 306:20 <b>link</b> [3] 87:24 90:24 170:13 <b>linked</b> [2] 15:23 60:6 <b>liquid</b> [1] 346:22 <b>list</b> [43] 3:1 36:17 43:21 66:3 163:1 174:6,9,11 174:12 175:20 186:10 267:10 325:5,5 330:18 331:18,24 336:10 337:1 341:18 350:13,14 353:14 354:6 355:16 356:1,4,14 356:17,24 357:2 360:11 360:12 372:17,18,21,22 372:23,24 374:19 377:17 378:1,3 <b>listed</b> [4] 169:8 171:8 276:13 289:7 <b>listening</b> [1] 183:21 <b>listing</b> [1] 55:24 <b>lists</b> [4] 373:20 377:7,10 378:2 <b>literally</b> [1] 334:18 <b>literature</b> [21] 18:4,5,6 23:6 32:10,10,25 55:21 150:4 193:7 195:24 202:14 210:1 225:11 232:2 246:19 248:13 254:21 282:13 344:16 379:2 <b>liver</b> [3] 386:19 388:9,15 <b>living</b> [3] 318:25 336:12 337:5 <b>LMWCQ</b> [1] 144:24 <b>local</b> [2] 8:9 251:18 <b>locally</b> [1] 46:24 <b>located</b> [1] 122:12 <b>log</b> [3] 68:19 88:19 256:3 <b>logged</b> [1] 327:4 <b>logical</b> [3] 85:13 98:4 171:10 <b>logically</b> [1] 236:25 <b>logos</b> [1] 159:23 <b>longer</b> [2] 14:15 53:21 <b>look</b> [69] 11:7 18:5 30:2 32:10 44:9 50:10 61:13 80:9 88:22 91:20,20,21 93:14 98:10 99:21 102:24 111:9 114:1 120:2 124:3</p>	<p>137:22 151:17,20,20,21 151:22 152:9 160:24 168:6 185:21 195:11 203:24 211:14,15 212:19 214:2,8 216:11 225:13 229:5,6 235:3 237:15 245:7,12 249:13,13 259:3 259:5 262:10 263:10 272:18 274:6 279:22 283:15 289:24 290:25 291:7 299:1 321:14 331:16 363:25 365:11,22 384:12,17 391:18 393:9 394:13 <b>looked</b> [21] 78:10 79:9 80:10 81:22 110:7 130:10 139:17 140:6 215:12 249:16,17 251:8 272:16 272:18,21 275:25 301:8 309:25 344:1 365:20 382:18 <b>looking</b> [45] 17:19 18:3 22:4 31:15 57:22 58:3 74:12 75:13 76:2,11,24 103:1 118:23,24 123:12 130:8 143:14 146:4 148:3 180:19 198:15 203:6 237:4,7 238:9 243:10 245:6 251:14 253:18 270:4 272:7 288:21 335:14 344:21 358:4,5 361:8 364:2,11 365:21 371:25 377:21 387:25 388:8 394:12 <b>looks</b> [4] 65:21 263:6,8 271:24 <b>lost</b> [2] 21:18 128:25 <b>lots</b> [6] 21:19 119:1 146:15 330:16 340:4 379:2 <b>low</b> [10] 75:12 123:4 150:11,12,24 249:14 294:23,24 362:24 394:21 <b>lower</b> [1] 68:19 <b>Luke's/Roosevelt</b> [1] 6:16 <b>lump</b> [3] 346:17,19 347:13 <b>lunch</b> [4] 177:5 178:18 233:25 236:4 <b>luncheon</b> [2] 178:5,16 <b>lung</b> [3] 388:9,11,15 <b>lyasyme</b> [1] 65:14 <b>lymphocytes</b> [5] 76:6 116:16,16 117:12 129:14 <b>lymphoid</b> [4] 76:1,1 128:24 154:12 <b>lymphoma</b> [12] 116:14 116:15 117:13,16,20 119:2,3 129:1 132:18,20 137:7 240:23 <b>lymphomas</b> [4] 60:9 129:3,20 241:16</p>
<b>-L-</b>				
<p><b>I</b> [7] 20:22 119:12,12,12 182:22,22,22 <b>lab</b> [99] 8:2 12:24 36:23 47:3 70:8,9 72:11 82:6 84:18 87:16 90:21 91:1 91:1,22 93:8 94:13 110:20 113:11 132:6 139:3 143:18 152:3,4,13 152:13,18 153:3,17 158:15 159:6,10 160:12 161:2 164:2 167:2 172:11 179:7,12,19,25 180:11 180:21 183:8,25 184:1 184:24 185:2,13,14 186:4 186:12 187:9 188:13 189:3 190:9 195:8 196:21 197:23 198:5 202:8 205:11,11,15 206:15 209:4 212:8,8 214:21 215:5 227:10 231:3 232:14 247:10 251:19 276:9 288:22 298:5,11 301:24 304:14,16 306:4 306:6 307:17 314:16,23 317:3,23 318:6 319:7 340:22 342:2,3 346:21 351:20 353:23 358:9 376:20 382:4 <b>lab's</b> [1] 206:8 <b>laboratories</b> [110] 10:1 10:8,24 11:13 13:16,23 14:10,12,19,23 15:4,8,9 15:12 16:5,10 28:11,13 30:19,21 31:10 33:18,22 34:21 40:17,22,23 42:20 46:15 54:25 57:5 67:17 69:19 74:10,23 76:13 80:11,12 82:9 85:5 87:16 92:18 95:14 103:16 106:19,24 121:18 135:19 136:24 138:8 144:3,24 144:25 145:8 151:12 156:13 158:22 159:4 161:14,24 165:10 166:5 170:9,15 171:4 173:22 174:7 175:7 189:9 198:17 199:5 200:13 201:19 213:10,14,24 214:4,7,19 215:13 216:15,16 217:5 217:8 218:10,19 219:6 221:25 222:5,10,13,24 223:8,23 224:15 225:19 235:12,19 237:25 244:21</p>	<p><b>laboratory/immunohistochemistry</b> [1] 100:4 <b>Labrador</b> [3] 252:19 397:8,11 <b>Labrador-Grenfell</b> [1] 1:16 <b>labs</b> [69] 16:1 29:2,7 30:17 36:12,13 37:5 38:12 40:5 42:19 75:6 77:11 92:3 95:13 105:18 137:18 138:14 139:23 146:25 147:5 148:24 153:6 155:12 160:25 161:12,20,22 162:1,14 164:2,5,16 171:13 172:4 173:19,21 174:17 175:21 188:3,10,16 189:15,16 189:20 198:10 205:21 207:23 214:24 215:22 216:5,5 218:11 222:22 230:19 234:4 237:21,23 246:10,22 247:21,22 251:16 289:7 292:4 293:15 295:20 318:2,5 339:12 <b>lack</b> [9] 119:10 187:18 220:8,14 233:7,8,10 250:22 267:5 <b>lacking</b> [3] 67:11,12 184:12 <b>lady</b> [1] 312:18 <b>lag</b> [1] 95:5 <b>laid</b> [1] 91:19 <b>Laing</b> [4] 1:9 340:10 341:20 344:13 <b>language</b> [2] 203:24 204:1 <b>laps</b> [1] 175:15 <b>LAR</b> [1] 55:2 <b>large</b> [29] 8:2 13:15,15 14:23 68:1,4 84:5 113:10 114:11 138:12 150:12 156:3 157:19,21 160:8 175:6 204:8 210:13,14 216:6 223:22 229:14</p>	<p>238:1 250:16 256:5,12 257:17 264:5 290:11 <b>larger</b> [13] 43:23 142:8 160:9 173:13 188:2 189:16 210:16 216:10 229:22 230:6 234:14 251:7 263:15 <b>last</b> [23] 61:13 73:17 77:4 100:12 101:13,16 102:3 102:14 159:2 168:8,17 194:19 199:2,19 200:23 202:7 206:12,16 207:6 232:8 239:6 245:4 284:18 <b>Lastly</b> [1] 248:2 <b>latitude</b> [1] 294:10 <b>Laurette</b> [1] 98:13 <b>lay</b> [1] 248:11 <b>Layfield</b> [3] 284:7,10,14 <b>lead</b> [6] 267:6 271:5 293:6 301:15 304:15 305:24 <b>leaders</b> [1] 28:9 <b>leading</b> [1] 5:8 <b>learn</b> [8] 17:23 201:16 201:17 202:2 257:16 258:11 310:13 338:24 <b>learned</b> [7] 95:16 146:9 149:19 199:18 200:24 260:22 310:16 <b>learning</b> [2] 258:12 260:20 <b>least</b> [13] 27:11 40:20 69:20 95:18 133:15 161:9 182:20 187:13 194:3 247:3 248:22 310:7 353:14 <b>leave</b> [2] 349:7 390:16 <b>leaving</b> [1] 230:18 <b>lecture</b> [1] 35:8 <b>led</b> [1] 124:24 <b>leeway</b> [1] 337:18 <b>left</b> [9] 12:12 20:13 40:21 117:10 124:4 200:14 300:17 379:16 391:23 <b>left-hand</b> [2] 122:3 148:19 <b>legal</b> [1] 245:9 <b>lesion</b> [3] 123:9 124:4 215:18 <b>lesions</b> [2] 144:5 242:8 <b>less</b> [17] 15:16 117:4 120:18 150:17 151:1 153:6 191:21 214:3 293:20,20 323:4,19 327:18 337:12 365:5 390:3,5 <b>leucocyte</b> [1] 66:7 <b>leukemia</b> [3] 120:9,13 120:14 <b>leukemic</b> [1] 119:24 <b>level</b> [16] 75:16 106:17 106:23 123:25 155:11 182:10 184:5 188:16 197:9 200:6 202:5 224:12 231:4 251:18 314:4 318:12</p>	<p><b>levels</b> [6] 75:10,12 76:9 79:7,12 171:18 <b>life</b> [1] 220:5 <b>light</b> [4] 27:6 262:23 316:10,11 <b>lights</b> [1] 118:25 <b>likelihood</b> [1] 312:12 <b>likely</b> [3] 203:5 207:16 313:21 <b>limit</b> [1] 386:6 <b>limitations</b> [1] 260:19 <b>limited</b> [4] 14:6 172:10 180:1,6 <b>line</b> [6] 256:5,10 280:4 306:12 328:8 342:13 <b>lines</b> [7] 77:7,12,14,17 77:21 78:3 306:20 <b>link</b> [3] 87:24 90:24 170:13 <b>linked</b> [2] 15:23 60:6 <b>liquid</b> [1] 346:22 <b>list</b> [43] 3:1 36:17 43:21 66:3 163:1 174:6,9,11 174:12 175:20 186:10 267:10 325:5,5 330:18 331:18,24 336:10 337:1 341:18 350:13,14 353:14 354:6 355:16 356:1,4,14 356:17,24 357:2 360:11 360:12 372:17,18,21,22 372:23,24 374:19 377:17 378:1,3 <b>listed</b> [4] 169:8 171:8 276:13 289:7 <b>listening</b> [1] 183:21 <b>listing</b> [1] 55:24 <b>lists</b> [4] 373:20 377:7,10 378:2 <b>literally</b> [1] 334:18 <b>literature</b> [21] 18:4,5,6 23:6 32:10,10,25 55:21 150:4 193:7 195:24 202:14 210:1 225:11 232:2 246:19 248:13 254:21 282:13 344:16 379:2 <b>liver</b> [3] 386:19 388:9,15 <b>living</b> [3] 318:25 336:12 337:5 <b>LMWCQ</b> [1] 144:24 <b>local</b> [2] 8:9 251:18 <b>locally</b> [1] 46:24 <b>located</b> [1] 122:12 <b>log</b> [3] 68:19 88:19 256:3 <b>logged</b> [1] 327:4 <b>logical</b> [3] 85:13 98:4 171:10 <b>logically</b> [1] 236:25 <b>logos</b> [1] 159:23 <b>longer</b> [2] 14:15 53:21 <b>look</b> [69] 11:7 18:5 30:2 32:10 44:9 50:10 61:13 80:9 88:22 91:20,20,21 93:14 98:10 99:21 102:24 111:9 114:1 120:2 124:3</p>	<p>137:22 151:17,20,20,21 151:22 152:9 160:24 168:6 185:21 195:11 203:24 211:14,15 212:19 214:2,8 216:11 225:13 229:5,6 235:3 237:15 245:7,12 249:13,13 259:3 259:5 262:10 263:10 272:18 274:6 279:22 283:15 289:24 290:25 291:7 299:1 321:14 331:16 363:25 365:11,22 384:12,17 391:18 393:9 394:13 <b>looked</b> [21] 78:10 79:9 80:10 81:22 110:7 130:10 139:17 140:6 215:12 249:16,17 251:8 272:16 272:18,21 275:25 301:8 309:25 344:1 365:20 382:18 <b>looking</b> [45] 17:19 18:3 22:4 31:15 57:22 58:3 74:12 75:13 76:2,11,24 103:1 118:23,24 123:12 130:8 143:14 146:4 148:3 180:19 198:15 203:6 237:4,7 238:9 243:10 245:6 251:14 253:18 270:4 272:7 288:21 335:14 344:21 358:4,5 361:8 364:2,11 365:21 371:25 377:21 387:25 388:8 394:12 <b>looks</b> [4] 65:21 263:6,8 271:24 <b>lost</b> [2] 21:18 128:25 <b>lots</b> [6] 21:19 119:1 146:15 330:16 340:4 379:2 <b>low</b> [10] 75:12 123:4 150:11,12,24 249:14 294:23,24 362:24 394:21 <b>lower</b> [1] 68:19 <b>Luke's/Roosevelt</b> [1] 6:16 <b>lump</b> [3] 346:17,19 347:13 <b>lunch</b> [4] 177:5 178:18 233:25 236:4 <b>luncheon</b> [2] 178:5,16 <b>lung</b> [3] 388:9,11,15 <b>lyasyme</b> [1] 65:14 <b>lymphocytes</b> [5] 76:6 116:16,16 117:12 129:14 <b>lymphoid</b> [4] 76:1,1 128:24 154:12 <b>lymphoma</b> [12] 116:14 116:15 117:13,16,20 119:2,3 129:1 132:18,20 137:7 240:23 <b>lymphomas</b> [4] 60:9 129:3,20 241:16</p>
<b>-M-</b>				
<p><b>m</b> [4] 20:22 119:12 182:22 257:21</p>				

<p><b>machines</b> [1] 45:10  <b>magic</b> [1] 44:13  <b>magical</b> [1] 250:24  <b>mailing</b> [1] 160:14  <b>main</b> [8] 7:17,18 53:14  82:22 257:19 283:19  297:10 310:4  <b>maintenance</b> [5] 299:23  300:4 302:18 303:7,15  <b>Majesty</b> [1] 1:8  <b>major</b> [9] 24:14 28:11  51:18 53:24 60:25 151:19  170:5 218:9,11  <b>makes</b> [8] 13:5 66:10  173:21 197:5 199:23  229:7 281:20 295:3  <b>malignancies</b> [2] 64:18  129:21  <b>malignancy</b> [3] 65:6  116:15 130:8  <b>malignant</b> [2] 128:20  215:15  <b>manager</b> [3] 160:6  302:14 305:23  <b>mandate</b> [3] 161:18  162:4 164:21  <b>mandated</b> [1] 165:3  <b>mandatory</b> [9] 40:4  163:17 164:6 165:1,5,8  165:9 169:13 247:9  <b>Manitoba</b> [1] 164:14  <b>manner</b> [5] 140:17  142:22 187:1 305:3  374:23  <b>mantle</b> [1] 76:5  <b>March</b> [5] 102:3,14,14  102:15 330:22  <b>Margaret</b> [1] 397:6  <b>mark</b> [4] 1:14 125:8  384:18 386:24  <b>marked</b> [5] 4:22 233:20  296:15,16 336:13  <b>marker</b> [9] 63:4 118:22  118:23 119:2 128:24  129:14 130:1 214:17  215:1  <b>markers</b> [21] 8:6 24:22  58:16 60:8 63:14,15  65:16 66:6 111:15 126:15  136:25 139:10 144:10  146:20,22 154:8,12  164:22 165:2 169:17  218:16  <b>market</b> [1] 272:10  <b>Markwick</b> [2] 20:9  64:24  <b>marrow</b> [13] 116:17,19  116:21 117:12,22 119:25  121:3 122:14 123:7  132:18 218:7 219:5 220:2  <b>mashed</b> [1] 347:1  <b>masks</b> [1] 66:19  <b>mass</b> [12] 171:6 172:19  172:21,25 173:8,9,14,14  173:17,23,23 245:16</p>	<p><b>mastectomy</b> [1] 348:6  <b>material</b> [23] 25:23 26:7  26:13 36:20 90:13 120:1  135:18 151:2,3 154:19  155:14,23,25 156:4,12  159:22 198:21 206:9  236:7,9 245:18 256:8  281:4  <b>materials</b> [2] 210:1  212:10  <b>matter</b> [5] 56:11 155:18  235:14 258:14 397:3  <b>matters</b> [4] 83:7 151:23  199:20,20  <b>may</b> [49] 44:14 66:24  68:18 69:12 87:11,12  106:17 113:12 124:2,5  126:20 160:8 161:21  163:11 177:12 179:4  184:21,22 187:9,11,24  192:13 198:6,19,23 199:4  199:15 201:7 204:15  211:12 223:5 226:13  229:12 234:1 237:6  239:16 240:6 247:4,7  256:14 257:15 258:16  293:14 308:9 313:10  349:8,14,25 363:3  <b>McCarthy</b> [3] 243:14  244:9 340:10  <b>MCP</b> [1] 322:7  <b>MCPs</b> [2] 314:20,22  <b>mean</b> [69] 6:24 13:3 17:2  21:14 27:23 28:3 29:22  33:13 47:25 48:7 54:23  70:3,15 72:15 74:1 83:22  89:25 93:13 94:19 97:9  120:18 141:23 151:16,19  152:22,23 153:4 160:4  161:23 166:19,20,23  167:15 172:2 173:3 175:8  185:10 196:4 198:11  214:3 219:2 230:22 232:7  237:25 247:6 253:11,16  257:9 260:2 269:13  273:25 278:2 284:1 298:5  301:24 302:10,14 303:10  314:5 323:14 332:5  344:14 351:14 352:19  356:9 357:21 364:11  373:23 391:13  <b>meaning</b> [5] 17:13,15  55:3 109:12 216:2  <b>meaningful</b> [2] 155:16  155:17  <b>means</b> [37] 14:24 17:24  33:15 34:16 47:21,21  54:6 68:15 72:17 108:4  109:18 118:4,5 123:8  148:25 153:2 155:13,24  161:8 165:13,20,22  169:16 181:19 196:8  197:15 211:14 216:2  217:19 233:11 242:1  244:11 257:11 311:9  360:6 391:20 397:10  <b>meant</b> [6] 17:22 50:20  56:2 57:24 341:13 346:15  <b>meantime</b> [2] 112:22</p>	<p>158:4  <b>measure</b> [9] 184:19  203:4,14,19 207:15  241:21,22,23 347:5  <b>measurement</b> [1] 243:2  <b>measurements</b> [1]  242:13  <b>measures</b> [3] 82:4 132:4  230:20  <b>measuring</b> [1] 243:4  <b>mechanisms</b> [1] 105:11  <b>medical</b> [10] 1:14 6:9,11  99:6 100:17 169:15 171:4  188:4 232:14 272:7  <b>medically-based</b> [1]  124:7  <b>medicine</b> [10] 81:2,9  86:9,11,16,23 103:11  142:13 172:1 253:3  <b>Meditech</b> [11] 315:5  317:4,18,19 318:8 324:22  325:25 326:16 342:4  351:15,22  <b>medullary</b> [1] 279:21  <b>meet</b> [7] 171:6 172:23,24  235:12,19 301:21 323:11  <b>meeting</b> [16] 30:12 56:16  98:19 99:25 101:11  141:21 168:18 286:4  300:19,25 302:3 307:13  308:4 312:15 340:8 343:4  <b>meetings</b> [6] 54:16  160:20 281:3 340:3,8  341:3  <b>melanae</b> [1] 214:25  <b>melanocyte</b> [2] 215:1  215:19  <b>melanocytes</b> [1] 215:7  <b>melanoma</b> [6] 144:11  214:17 215:6,10,10,16  <b>member</b> [4] 88:18 218:8  219:4 220:1  <b>members</b> [6] 1:12  100:13 101:25 163:4,7  218:10  <b>memo</b> [5] 127:17,22  303:24 304:8 305:11  <b>Memorial</b> [1] 355:14  <b>mention</b> [10] 7:23,24  14:14 34:25 35:1 57:6  173:15 202:8 246:17  393:22  <b>mentioned</b> [10] 24:12  43:14 53:25 56:12 62:2  132:14 191:11 233:18  234:1 274:17  <b>mentioning</b> [2] 15:19  15:20  <b>menu</b> [1] 103:22  <b>menus</b> [1] 174:25  <b>message</b> [1] 251:13  <b>met</b> [6] 95:19 231:15  252:18 300:16 304:11  307:10  <b>metastasized</b> [1] 122:21</p>	<p><b>metastatic</b> [13] 121:2  122:7 123:9 124:5,11  125:14 215:6,7,10,16  386:18,25 388:1  <b>method</b> [10] 195:12  274:2,2 293:6 341:16  344:24 346:4,12 348:12  374:8  <b>methodology</b> [4] 284:24  346:15,18 347:11  <b>methods</b> [22] 17:16,18  21:18 106:20,22 142:9  145:2 192:18 193:8 195:5  195:16 197:18 198:11,12  199:12,16 201:20 202:6  293:18,18,20,23  <b>microarray</b> [12] 136:22  137:9,14 140:16 144:4  154:12,23 155:6 226:20  236:11,17 255:10  <b>microarrays</b> [8] 79:10  79:18 90:16 146:18 155:5  228:22 236:23 241:16  <b>microscope</b> [3] 44:12  89:11,11  <b>microscopy</b> [3] 90:12  145:6 256:4  <b>microwave</b> [1] 199:22  <b>mid</b> [3] 21:24 57:15,17  <b>middle</b> [7] 86:2 93:1  144:2 159:11 164:25  213:16 237:17  <b>midnight</b> [1] 356:11  <b>might</b> [39] 98:20 176:2  176:22,25 188:23 209:23  230:5 240:21 261:19,21  263:2 267:6 268:18,21  269:10 271:4 273:6  274:22 275:2 277:8 294:9  311:23 334:12 335:7  338:3 345:8 348:17  357:18 362:12 364:6  365:12 366:16 367:8  382:17 384:13 387:23,24  389:5 391:11  <b>mind</b> [4] 112:22,23  114:10 116:22  <b>minds</b> [1] 23:4  <b>mine</b> [1] 364:6  <b>minimal</b> [3] 117:14,22  160:14  <b>minimally</b> [1] 185:18  <b>minimum</b> [5] 157:15,17  185:15 287:10 288:1  <b>Minnapolis</b> [1] 22:8  <b>Minnesota</b> [3] 6:20 20:8  22:4  <b>minor</b> [2] 151:9 216:2  <b>minus</b> [2] 327:9,9  <b>minute</b> [3] 238:4 245:13  271:15  <b>minutes</b> [3] 127:10  177:17,21  <b>misleading</b> [1] 214:16  <b>misled</b> [1] 125:1  <b>miss</b> [3] 150:23 157:21</p>	<p>178:10  <b>missed</b> [3] 26:22,23  366:17  <b>missing</b> [5] 11:6 14:5  69:1 170:13 395:7  <b>mix</b> [1] 197:23  <b>mixture</b> [4] 216:18,20  216:22,24  <b>model</b> [1] 187:25  <b>modern</b> [1] 7:11  <b>modest</b> [1] 255:20  <b>modified</b> [2] 169:10  216:3  <b>modify</b> [1] 245:1  <b>module</b> [5] 14:21 42:16  351:18,18 353:18  <b>modules</b> [1] 351:20  <b>molecular</b> [4] 7:7 123:4  128:9 132:22  <b>molecule</b> [2] 60:11  197:14  <b>molecules</b> [3] 34:9 58:25  199:17  <b>moment</b> [5] 13:6 126:3  153:23 334:15 358:15  <b>moments</b> [1] 246:4  <b>money</b> [6] 23:4 159:24  161:3,10 162:15 270:18  <b>monitor</b> [4] 131:22  279:18 280:12 281:22  <b>monitoring</b> [1] 217:1  <b>monoclonal</b> [1] 239:22  <b>month</b> [1] 311:4  <b>monthly</b> [2] 299:24,25  <b>months</b> [10] 147:18,20  157:11,24 158:4,10  257:25 288:16 334:13  372:4  <b>morning</b> [5] 177:4 252:7  396:12,22,23  <b>morphological</b> [1] 66:1  <b>morphologically</b> [5]  119:5 120:11 137:3,4  215:17  <b>morphology</b> [5] 57:20  77:17 116:24 117:2,24  <b>Moss</b> [2] 397:2,13  <b>most</b> [40] 10:5,6 14:16  15:10,11,25 32:14,14  47:22 56:8 67:1 69:5  75:11,25 87:3 106:18  108:3 113:25 144:25  145:9 149:8 150:13 161:6  169:7 195:6 208:12  211:11 213:23 214:6  217:8 223:8 249:19  260:22 326:15 342:6  345:6 353:25 356:11  388:15 392:17  <b>mostly</b> [2] 53:5 388:15  <b>motivation</b> [2] 257:19  258:4  <b>Mount</b> [5] 188:6,7  296:22 374:9,14  <b>move</b> [9] 43:5 52:20 56:3</p>
---	--	--	---	---

<p>61:8,10 62:8 175:9 234:20 391:5 <b>moved</b> [8] 6:13,20 7:9 7:16,25 12:12 239:6,11 <b>movement</b> [1] 54:14 <b>moving</b> [2] 6:24 90:2 <b>Ms</b> [95] 177:4,15,16 252:5 252:15,16 254:13 255:4 255:13 256:16,21 257:2 258:15 259:10,16,20 260:5,13 261:6,10,15 262:17,22 263:11 264:9 264:25 265:4,12,17,24 266:4,9,13,18,24 267:9 267:21 268:13,20 269:2 269:7 271:1,8,13 272:1 273:4,12,16,21 274:1,16 275:1,12 276:12,17 277:2 277:14,23 278:9,22 279:3 279:7 280:11,15,19,23 281:13,23 282:2,15,19 297:10 298:1,10 299:2 302:5 310:16 313:10 314:12,14 318:22 319:6 324:12 333:19 335:23 337:1 344:11 349:16,25 350:1 365:16 366:2 371:21 383:24 390:12</p>	<p><b>nature</b> [1] 210:25 <b>NCRTF</b> [1] 314:16 <b>necessarily</b> [11] 44:7 48:12 69:13 77:22 175:11 203:18 211:4 255:18 262:9 271:17 367:23 <b>necessary</b> [15] 34:7,20 83:18 86:12 110:19 155:11 173:20,24 188:17 200:3 233:9,16 255:21 278:21 284:21 <b>necessity</b> [1] 285:25 <b>need</b> [39] 10:8,9 57:6,8 69:13 86:5,13,13,14 88:3 92:22 94:10,10,11,24 100:16 121:16 124:8 151:24 155:22 161:11 171:5 172:7,8,13,23 173:8,9,13 199:14 200:15 203:19 233:1 243:20 258:11 269:24,25 270:21 312:16 <b>needed</b> [4] 159:15 192:21 307:12,22 <b>needs</b> [9] 11:25 53:18 68:17 101:6,7 103:10 183:18 202:19 220:10 <b>negative</b> [76] 19:3 66:15 92:14 107:1 132:25 138:16,21 141:10 144:22 145:15 146:10 204:6 205:9 209:13,21 210:4 213:21 214:12,21 218:3 224:13 238:1 249:7,9,10 249:25 250:2,7,13 269:8 269:14,18,24 270:1,2,5 270:8,11,16,18,21 271:3 277:11 279:22 308:15 311:3 312:5 319:24,25 322:24,24 324:1,1 326:21 326:21,25,25 327:10,10 328:17,22,24 329:5,22 334:20 338:3 343:25 352:12 358:9 362:2,7,9 362:12 368:23 372:2 394:15 <b>negative/negative</b> [2] 358:8 368:11 <b>negative/negatives</b> [2] 358:1 385:5 <b>negatively</b> [2] 162:20 266:20 <b>negatives</b> [15] 141:9,15 209:5 268:2 308:8 309:4 309:7 310:18 328:18,22 328:24 329:6 352:5 355:6 394:15 <b>negativity</b> [4] 65:20 66:9 92:20 361:21 <b>negligent</b> [1] 121:11 <b>NEQAS</b> [28] 14:17 43:14 44:3,4 45:14 48:19,20 50:13,15,22 51:11,17,19 52:5 104:4 105:22 221:7 221:24 222:3,14 246:3 246:18 248:4 251:8 260:8 262:5 263:8 279:4 <b>Nesland</b> [1] 24:17 <b>never</b> [22] 58:5 67:15</p>	<p>80:10 114:12,13,17,19 114:23 115:23 131:14,19 131:23 133:3 134:1 210:7 254:2,25 258:4 299:24 304:16 356:13 379:5 <b>nevertheless</b> [1] 117:15 <b>new</b> [20] 4:18 6:15 17:11 17:25 23:22 44:22 154:21 192:21,22 194:4 198:18 219:2,2 239:14 260:8 296:10,23 329:10 365:11 379:10 <b>Newbury</b> [73] 1:15 2:7 177:15,16 252:5,15,16 252:18 254:13 255:4,13 256:16,21 257:2 258:15 259:10,16,20 260:5,13 261:6,10,15 262:17,22 263:11 264:9,25 265:4 265:12,17,24 266:4,9,13 266:18,24 267:9,21 268:13,20 269:2,7 271:1 271:8,13 272:1 273:4,12 273:16,21 274:1,16 275:1 275:12 276:12,17 277:2 277:14,23 278:9,22 279:3 279:7 280:11,15,19,23 281:13,23 282:2,15,19 <b>newer</b> [3] 192:14,17 198:2 <b>newest</b> [1] 184:15 <b>Newfoundland</b> [6] 8:21 146:11 149:20 252:19 397:8,11 <b>news</b> [1] 254:3 <b>next</b> [25] 4:4 6:22 16:14 16:14 40:19 67:5 101:13 125:4 255:25,25 284:6 320:15 328:1,5,8,20 329:25 340:25 349:1 351:10 385:7 392:4,4 396:14,22 <b>NH</b> [1] 54:14 <b>nice</b> [1] 86:18 <b>night</b> [1] 356:10 <b>nights</b> [1] 356:11 <b>nine</b> [13] 28:12 29:2,2,15 30:17,17,19,21 41:4 222:12 251:6 318:4,5 <b>nitrogen</b> [1] 346:22 <b>NL</b> [3] 1:8,14,15 <b>NLCHI</b> [4] 349:22 366:3 378:6 390:4 <b>nobody</b> [4] 114:13 146:16 225:6 260:25 <b>noise</b> [1] 198:14 <b>non-breast</b> [3] 317:15 352:9 390:5 <b>non-descript</b> [2] 137:3 215:17 <b>non-invasive</b> [1] 347:12 <b>non-specific</b> [2] 63:23 144:15 <b>none</b> [3] 54:3 67:17 103:23 <b>nonsense</b> [1] 74:1 <b>Nordi</b> [1] 51:22</p>	<p><b>Nordic</b> [7] 11:18 27:14 28:20 88:13,25 215:8 235:18 <b>NordiQC</b> [66] 12:9,15 12:17 13:12 14:7 15:24 27:23 31:13,16 32:15,22 33:5 34:23 35:15 39:5 40:4,16,24 41:14 42:6 43:15 44:3,4 45:14 48:19 48:21 49:18,23 50:20 51:4,11,17,18 77:4,15 77:23 78:1 83:20 84:22 104:6 105:22 156:2 166:5 208:9 212:5,18 216:24 217:14 218:24 219:3,7 219:22 220:17,21 225:13 248:4,23 251:5 260:8 262:6 263:6 264:15,24 265:10 275:23 276:14 <b>normal</b> [6] 17:13 123:8 129:20 178:6 193:9 198:11 <b>normally</b> [1] 396:20 <b>Norske</b> [1] 7:15 <b>North</b> [1] 284:4 <b>Northern</b> [1] 243:3 <b>Norway</b> [13] 7:9 8:1 10:5 11:11 13:14 16:25 24:15 27:20,24 44:22 192:3 213:10,15 <b>Norwegian</b> [8] 7:14 10:4 12:10 16:24 24:13 27:12 31:17 213:3 <b>notation</b> [1] 328:15 <b>note</b> [9] 41:18 104:4 146:24 176:11 236:5 238:7 283:4 296:19 297:24 <b>noted</b> [4] 63:21 95:9 100:5 235:2 <b>notes</b> [3] 296:20,21,22 <b>nothing</b> [9] 93:13 100:24 107:6 110:25 221:4 269:24 320:7 383:20 393:11 <b>notice</b> [7] 143:6 158:17 185:22 241:25 278:3,5 280:9 <b>noticed</b> [8] 8:7 9:15 11:5 25:16,22 83:25 85:3 194:3 <b>noticing</b> [1] 236:3 <b>notion</b> [3] 239:25 240:2 242:20 <b>Nova</b> [1] 98:13 <b>novel</b> [1] 253:24 <b>November</b> [1] 311:1 <b>now</b> [123] 13:13 18:2 23:7 33:13 41:5,8,12 44:20 44:23,24 49:8,13,17,17 52:24 53:19 54:1 58:19 62:7,9,18 65:4,25 68:3 73:1 74:12 77:9 78:1 89:25 90:7 93:11,16 96:25 97:12 100:19 102:13,19 108:15 115:21 116:1,25 118:23 120:22 123:7 127:18 130:15,20</p>	<p>135:6 146:15,19,21,24 149:22 150:19 151:9 154:12 156:2 159:12 162:4 163:1,10 164:19 164:24 165:4 167:20 171:7 182:2 193:8,17 196:12 202:11,23 204:23 205:16 207:21 216:24 218:22 222:2 224:24 226:3 231:21 233:18 235:4 236:19 237:5,11 240:1 242:20 245:4,12 249:6,23 251:14 254:5,7 255:3 262:11 280:1 286:9 286:20,20,20 305:19,24 306:19 309:24 311:3,12 314:7 315:7 316:13 320:16 324:21 339:12 347:11 363:2 370:23 372:12 374:1 384:1 391:9 391:11 394:13 <b>nuclear</b> [5] 271:19 272:5 272:20 273:7 274:13 <b>nuclei</b> [4] 268:8 272:15 272:19,23 <b>nucleus</b> [1] 272:11 <b>number</b> [87] 8:2 10:7 11:13 13:16 14:23 15:11 41:3,22 44:13,14,15 63:14 66:2 68:4 91:6 94:20 103:15 104:10 110:21 113:10 114:12 128:17 138:13,14 148:23 150:12 152:3 154:23 157:22 172:18 180:2 182:21 192:8 208:9,16 208:22 209:5 210:13,14 217:21 218:4 225:21 227:3 231:17 234:24 235:11,19 238:1,14 250:16 256:5,13 257:17 264:2,5 280:7 289:8,14 289:19,25 290:5,7,11,25 316:14 317:3,4,8 322:6 322:7 323:16 332:11 349:19 353:20,22 368:2 368:9,10,12,23 372:19 374:4,15 375:4 389:11 389:15 395:22 <b>numbers</b> [34] 41:5 59:20 63:13 175:6 237:17 251:9 265:19,19 285:7 288:22 306:2 316:12 317:22 318:13 319:6,15 322:18 325:7 349:17 350:1,17 350:18,18 351:25 364:12 365:20 366:15 367:1,4,5 367:8 372:10 384:2 394:22 <b>numerous</b> [4] 55:2 79:6 95:1 194:9</p>	
<p style="text-align: center;"><b>-N-</b></p> <p><b>n</b> [7] 11:16,16 119:12,12 182:22 257:21,21 <b>N-O-R-D-I-Q-C.org</b> [1] 265:10 <b>Nadji</b> [2] 240:12,14 <b>name</b> [12] 4:10 7:15 25:9 96:11 105:9 128:1 143:6 144:9 231:16 298:20 314:19 353:19 <b>names</b> [7] 43:25 191:11 291:5 350:9 353:14 377:11 378:1 <b>narrative</b> [2] 53:9 55:14 <b>national</b> [40] 7:13,20 10:3 40:12 62:18 84:1 84:15 85:19 86:5 93:23 95:10,12 96:6,17 99:11 100:3,7 101:18,23 103:5 103:9,24 106:10,17 109:13 155:10 163:2 165:5 169:23 170:1,18 171:3,11 172:18 173:9 174:6,11 230:13 251:15 252:25 <b>nationally</b> [1] 107:6</p>		<p><b>new</b> [20] 4:18 6:15 17:11 17:25 23:22 44:22 154:21 192:21,22 194:4 198:18 219:2,2 239:14 260:8 296:10,23 329:10 365:11 379:10 <b>Newbury</b> [73] 1:15 2:7 177:15,16 252:5,15,16 252:18 254:13 255:4,13 256:16,21 257:2 258:15 259:10,16,20 260:5,13 261:6,10,15 262:17,22 263:11 264:9,25 265:4 265:12,17,24 266:4,9,13 266:18,24 267:9,21 268:13,20 269:2,7 271:1 271:8,13 272:1 273:4,12 273:16,21 274:1,16 275:1 275:12 276:12,17 277:2 277:14,23 278:9,22 279:3 279:7 280:11,15,19,23 281:13,23 282:2,15,19 <b>newer</b> [3] 192:14,17 198:2 <b>newest</b> [1] 184:15 <b>Newfoundland</b> [6] 8:21 146:11 149:20 252:19 397:8,11 <b>news</b> [1] 254:3 <b>next</b> [25] 4:4 6:22 16:14 16:14 40:19 67:5 101:13 125:4 255:25,25 284:6 320:15 328:1,5,8,20 329:25 340:25 349:1 351:10 385:7 392:4,4 396:14,22 <b>NH</b> [1] 54:14 <b>nice</b> [1] 86:18 <b>night</b> [1] 356:10 <b>nights</b> [1] 356:11 <b>nine</b> [13] 28:12 29:2,2,15 30:17,17,19,21 41:4 222:12 251:6 318:4,5 <b>nitrogen</b> [1] 346:22 <b>NL</b> [3] 1:8,14,15 <b>NLCHI</b> [4] 349:22 366:3 378:6 390:4 <b>nobody</b> [4] 114:13 146:16 225:6 260:25 <b>noise</b> [1] 198:14 <b>non-breast</b> [3] 317:15 352:9 390:5 <b>non-descript</b> [2] 137:3 215:17 <b>non-invasive</b> [1] 347:12 <b>non-specific</b> [2] 63:23 144:15 <b>none</b> [3] 54:3 67:17 103:23 <b>nonsense</b> [1] 74:1 <b>Nordi</b> [1] 51:22</p>	<p><b>Nordic</b> [7] 11:18 27:14 28:20 88:13,25 215:8 235:18 <b>NordiQC</b> [66] 12:9,15 12:17 13:12 14:7 15:24 27:23 31:13,16 32:15,22 33:5 34:23 35:15 39:5 40:4,16,24 41:14 42:6 43:15 44:3,4 45:14 48:19 48:21 49:18,23 50:20 51:4,11,17,18 77:4,15 77:23 78:1 83:20 84:22 104:6 105:22 156:2 166:5 208:9 212:5,18 216:24 217:14 218:24 219:3,7 219:22 220:17,21 225:13 248:4,23 251:5 260:8 262:6 263:6 264:15,24 265:10 275:23 276:14 <b>normal</b> [6] 17:13 123:8 129:20 178:6 193:9 198:11 <b>normally</b> [1] 396:20 <b>Norske</b> [1] 7:15 <b>North</b> [1] 284:4 <b>Northern</b> [1] 243:3 <b>Norway</b> [13] 7:9 8:1 10:5 11:11 13:14 16:25 24:15 27:20,24 44:22 192:3 213:10,15 <b>Norwegian</b> [8] 7:14 10:4 12:10 16:24 24:13 27:12 31:17 213:3 <b>notation</b> [1] 328:15 <b>note</b> [9] 41:18 104:4 146:24 176:11 236:5 238:7 283:4 296:19 297:24 <b>noted</b> [4] 63:21 95:9 100:5 235:2 <b>notes</b> [3] 296:20,21,22 <b>nothing</b> [9] 93:13 100:24 107:6 110:25 221:4 269:24 320:7 383:20 393:11 <b>notice</b> [7] 143:6 158:17 185:22 241:25 278:3,5 280:9 <b>noticed</b> [8] 8:7 9:15 11:5 25:16,22 83:25 85:3 194:3 <b>noticing</b> [1] 236:3 <b>notion</b> [3] 239:25 240:2 242:20 <b>Nova</b> [1] 98:13 <b>novel</b> [1] 253:24 <b>November</b> [1] 311:1 <b>now</b> [123] 13:13 18:2 23:7 33:13 41:5,8,12 44:20 44:23,24 49:8,13,17,17 52:24 53:19 54:1 58:19 62:7,9,18 65:4,25 68:3 73:1 74:12 77:9 78:1 89:25 90:7 93:11,16 96:25 97:12 100:19 102:13,19 108:15 115:21 116:1,25 118:23 120:22 123:7 127:18 130:15,20</p>	<p>135:6 146:15,19,21,24 149:22 150:19 151:9 154:12 156:2 159:12 162:4 163:1,10 164:19 164:24 165:4 167:20 171:7 182:2 193:8,17 196:12 202:11,23 204:23 205:16 207:21 216:24 218:22 222:2 224:24 226:3 231:21 233:18 235:4 236:19 237:5,11 240:1 242:20 245:4,12 249:6,23 251:14 254:5,7 255:3 262:11 280:1 286:9 286:20,20,20 305:19,24 306:19 309:24 311:3,12 314:7 315:7 316:13 320:16 324:21 339:12 347:11 363:2 370:23 372:12 374:1 384:1 391:9 391:11 394:13 <b>nuclear</b> [5] 271:19 272:5 272:20 273:7 274:13 <b>nuclei</b> [4] 268:8 272:15 272:19,23 <b>nucleus</b> [1] 272:11 <b>number</b> [87] 8:2 10:7 11:13 13:16 14:23 15:11 41:3,22 44:13,14,15 63:14 66:2 68:4 91:6 94:20 103:15 104:10 110:21 113:10 114:12 128:17 138:13,14 148:23 150:12 152:3 154:23 157:22 172:18 180:2 182:21 192:8 208:9,16 208:22 209:5 210:13,14 217:21 218:4 225:21 227:3 231:17 234:24 235:11,19 238:1,14 250:16 256:5,13 257:17 264:2,5 280:7 289:8,14 289:19,25 290:5,7,11,25 316:14 317:3,4,8 322:6 322:7 323:16 332:11 349:19 353:20,22 368:2 368:9,10,12,23 372:19 374:4,15 375:4 389:11 389:15 395:22 <b>numbers</b> [34] 41:5 59:20 63:13 175:6 237:17 251:9 265:19,19 285:7 288:22 306:2 316:12 317:22 318:13 319:6,15 322:18 325:7 349:17 350:1,17 350:18,18 351:25 364:12 365:20 366:15 367:1,4,5 367:8 372:10 384:2 394:22 <b>numerous</b> [4] 55:2 79:6 95:1 194:9</p>	<p style="text-align: center;"><b>-O-</b></p> <p><b>O</b> [15] 4:12 11:16,16 20:22 20:22,22 119:12,12,12 119:12 182:22,22,22 257:21,21 <b>object</b> [2] 240:20,21 <b>obligatory</b> [6] 40:12,15 40:16,20 164:15 169:22</p>

<p><b>observation</b> [3] 83:13 238:5 393:8</p> <p><b>observations</b> [8] 42:5 82:20 83:16 84:18 143:1 212:7,16 247:3</p> <p><b>obtain</b> [2] 25:6 103:16</p> <p><b>obtained</b> [4] 96:2,3 99:22 249:23</p> <p><b>obtaining</b> [1] 24:3</p> <p><b>obvious</b> [4] 103:4 247:21 248:21 276:9</p> <p><b>obviously</b> [18] 28:8 41:3 55:18 142:8 177:2 178:2 188:6 237:24 247:6 277:21 288:22 297:7,10 301:23 302:14 310:3 351:4 352:4</p> <p><b>occasional</b> [1] 281:2</p> <p><b>occasionally</b> [1] 12:16</p> <p><b>occur</b> [1] 224:15</p> <p><b>occurred</b> [4] 83:7 232:5 233:5 271:20</p> <p><b>ocean</b> [1] 83:23</p> <p><b>October</b> [4] 1:4 163:14 397:5,12</p> <p><b>off</b> [24] 112:23 120:8 179:4 200:14 303:14 317:18,19 331:20 334:4 335:16,16 336:8,17,20 337:18 342:13,13 352:1 353:17,17 356:15 381:6 385:22 387:5</p> <p><b>offer</b> [5] 48:20 49:8,20 50:14 262:2</p> <p><b>offered</b> [1] 154:18</p> <p><b>office</b> [2] 25:15 304:11</p> <p><b>official</b> [4] 25:6 79:12 160:15 167:22</p> <p><b>officially</b> [3] 253:25 254:20 305:20</p> <p><b>offs</b> [2] 331:17 344:3</p> <p><b>often</b> [18] 13:25 23:4 26:6 26:20 68:25 124:6 128:14 130:7 132:17 137:1 156:12,23 158:19 188:15 250:5 294:5 393:14 395:23</p> <p><b>old</b> [2] 128:25 346:17</p> <p><b>once</b> [10] 69:2 156:9 157:7 185:15 217:2 270:10 305:11 329:13 335:18 348:24</p> <p><b>oncogene</b> [1] 130:2</p> <p><b>oncologist</b> [6] 69:7 126:20 339:18,19 341:12 344:14</p> <p><b>oncologists</b> [16] 100:18 231:18 309:1 329:20 335:22 340:9,19 341:5,7 341:23 342:11,15,20 343:24 379:4 386:10</p> <p><b>one</b> [185] 6:18,19 14:16 15:18 16:3 20:4 28:14 29:7,23 43:17 44:1,10 44:13 46:6 47:23 56:7,8 62:17 65:20 66:10 68:5</p>	<p>68:7,8 69:9 73:8,10 74:19,20 75:11 78:16,21 79:7 83:23 88:17 90:17 92:7,12,18,22 93:17,25 95:17 97:1 99:24 100:20 101:14 117:18 118:8,18 119:23 122:5 126:3 128:17 131:3 132:24 133:4 147:19 153:6,19 154:17 155:8 159:6,10 159:11 164:19 165:6,25 168:8 169:8,19 171:14 173:12 175:9,10 177:11 179:25 182:8,20 183:8,9 187:9 192:4 195:8 196:24 197:7,14,14,22 198:21 199:8,24 201:13 204:10 205:15 211:23 213:11,21 213:23 214:11,21 215:24 219:23 228:17 230:15 232:17 241:2 242:24 243:21 244:10,21 245:1 245:4 247:6 249:4,7,9 249:24 250:6,9,15 253:2 253:16 256:3 257:9,18 257:18 261:19,25,25 262:18 264:21 269:18,21 269:22,23,23 270:18,20 270:25 271:23 272:4,10 273:22 276:13 281:22 282:4 283:10,20 284:6 290:24 293:6,12 294:9 300:1,2 301:11 315:9 321:16 322:5 332:15 333:19 334:4,15 335:13 337:4 340:3,8,11,12 341:3 344:15 353:8 356:22 366:7 372:8,19 379:16 380:18 385:9 387:8 388:18,22 394:14 394:22 395:25</p> <p><b>ones</b> [21] 43:23 115:14 184:21 243:23 265:19 323:11 324:5 325:20 335:18 336:7,13 352:6 352:10,21 368:3 370:19 371:14 377:18 385:7 386:13,25</p> <p><b>ongoing</b> [2] 171:23 358:7</p> <p><b>online</b> [5] 39:8 264:4,22 264:23 283:5</p> <p><b>Ontario</b> [13] 84:3 85:5 93:15,24 95:15 164:6,15 222:16,21,23 223:9 260:10 263:9</p> <p><b>onto</b> [1] 63:2</p> <p><b>onwards</b> [1] 365:22</p> <p><b>open</b> [3] 223:3 264:24 354:4</p> <p><b>opening</b> [1] 223:5</p> <p><b>operated</b> [1] 190:9</p> <p><b>operating</b> [5] 74:16 259:12 297:21 299:16 301:6</p> <p><b>opinion</b> [13] 51:5 55:23 56:8 67:11 204:20 243:5 243:20 244:2 264:8 270:24 341:11 343:7 379:7</p> <p><b>opportunity</b> [4] 151:7</p>	<p>178:10,11 228:7</p> <p><b>opposed</b> [5] 230:18 268:1 310:1 331:8 380:9</p> <p><b>opt</b> [1] 49:1</p> <p><b>optimal</b> [7] 77:8,12 120:1 213:19 218:13 225:6 226:7</p> <p><b>optimally</b> [1] 182:21</p> <p><b>optimization</b> [3] 70:20 72:6 110:19</p> <p><b>optimize</b> [3] 66:22 72:8 249:12</p> <p><b>optimized</b> [4] 107:2 202:1 227:15 293:6</p> <p><b>optimizing</b> [3] 74:6,11 276:23</p> <p><b>option</b> [1] 50:5</p> <p><b>options</b> [1] 69:4</p> <p><b>order</b> [7] 103:16 123:12 133:6 188:25 351:11 362:1 387:4</p> <p><b>ordered</b> [3] 133:6,9 318:15</p> <p><b>ordinary</b> [1] 151:4</p> <p><b>organ</b> [2] 125:11 388:1</p> <p><b>organization</b> [6] 13:7 28:17 104:20 108:4 298:6 298:8</p> <p><b>organizations</b> [2] 14:15 221:1</p> <p><b>organize</b> [7] 26:1 35:1 109:13,21 175:15 177:1 381:8</p> <p><b>organized</b> [2] 44:11 53:11</p> <p><b>organizes</b> [1] 281:2</p> <p><b>organizing</b> [3] 27:11 28:1 30:2</p> <p><b>orientation</b> [1] 92:9</p> <p><b>origin</b> [3] 125:11 215:19 322:7</p> <p><b>original</b> [27] 29:1 59:9 102:25 108:23 112:23 236:9 244:9 286:3 308:23 322:1 327:8 328:8 344:20 349:3 357:5 365:24 366:7 379:8,18,19 381:5 382:9 382:11,25 383:7 391:20 393:11</p> <p><b>originally</b> [11] 14:17 111:4 243:13 272:13 298:20 301:14 340:13,20 341:4 372:17 383:24</p> <p><b>originated</b> [1] 125:15</p> <p><b>Oslo</b> [5] 7:9 16:25 19:20 22:19 192:4</p> <p><b>otherwise</b> [9] 120:2 132:21 151:7 155:18 160:2 162:21 194:9 276:7 300:4</p> <p><b>Ottawa</b> [1] 168:18</p> <p><b>ought</b> [1] 186:11</p> <p><b>ourselves</b> [3] 29:16 30:22 374:20</p> <p><b>out-of-town</b> [3] 325:6</p>	<p>372:22 373:17</p> <p><b>out-of-towns</b> [1] 326:5</p> <p><b>outcome</b> [3] 54:4 285:3 293:14</p> <p><b>outcomes</b> [6] 8:14 11:8 59:15 74:21 239:14 293:18</p> <p><b>outline</b> [2] 5:23 33:4</p> <p><b>outlook</b> [1] 17:21</p> <p><b>outside</b> [11] 14:24 158:11 188:10 222:1,21 223:9 339:12 359:24 371:8 382:6,9</p> <p><b>overall</b> [20] 7:25 46:14 87:19 138:16 141:15 179:5 218:17 238:10,12 238:13,19 305:25 314:15 316:14 319:3,21 362:22 363:5 372:2,6</p> <p><b>overburden</b> [1] 121:17</p> <p><b>overlap</b> [1] 170:5</p> <p><b>overseas</b> [1] 83:21</p> <p><b>oversee</b> [2] 25:1 281:19</p> <p><b>overseeing</b> [1] 17:7</p> <p><b>overused</b> [1] 173:4</p> <p><b>overusing</b> [1] 270:15</p> <p><b>overview</b> [1] 16:17</p> <p><b>own</b> [47] 15:3 16:15 17:6 19:24 20:23 21:17 26:18 28:9 37:4 46:16 55:4 76:20 84:8,18 86:3,6,22 88:20,22 89:1,3,7 92:2 103:9 104:13 134:3 151:18 157:19 158:15,16 162:16 164:22 172:8,11 173:12 187:6 200:5 206:9 208:8 222:17 227:11,16 230:19,20 246:25 256:6 341:17</p>	<p>233:20 283:2</p> <p><b>p.m</b> [1] 396:24</p> <p><b>P1</b> [2] 241:4 242:5</p> <p><b>packed</b> [1] 374:22</p> <p><b>packing</b> [1] 381:4</p> <p><b>page</b> [42] 5:21,22,24 86:13,17 96:1,13,14,15 96:15 97:1,1,2,18,20 98:11,12 100:12 102:25 103:1 106:4 107:17 141:24 151:17 159:24 217:14 253:1 264:14 288:12 312:16 328:1,5 328:20,20,24 329:3 348:18,18 384:19 392:4 392:4 394:14</p> <p><b>pages</b> [6] 87:11 92:6 94:8 96:20 97:4 387:14</p> <p><b>paid</b> [6] 12:18 159:14,14 162:1 210:7 246:9</p> <p><b>pan</b> [4] 129:13,13 144:16 144:19</p> <p><b>panel</b> [14] 56:16 63:22 63:23 65:17 68:15 109:9 109:10 110:6 136:18 137:1,2 208:6 213:16 254:19</p> <p><b>panels</b> [5] 26:18 45:15 57:22 63:21 87:19</p> <p><b>panic</b> [1] 132:13</p> <p><b>PAP</b> [1] 274:2</p> <p><b>papillary</b> [1] 279:20</p> <p><b>paraffin</b> [7] 17:15 26:17 64:16 194:5 236:7 240:11 240:20</p> <p><b>paragraph</b> [9] 100:1,2 100:12 105:23 106:10 235:15 284:18,20 285:21</p> <p><b>parameters</b> [4] 117:6 245:2 342:16,21</p> <p><b>Pardon</b> [1] 334:8</p> <p><b>part</b> [32] 13:21 14:3,5 18:24 20:6 21:18 23:12 26:11 28:1 32:14,20 35:13 74:4 127:23 140:16 167:6 173:13 181:22 188:3 196:24 201:15 213:16 229:15 236:12 258:25 270:17 277:7 303:10 304:16 306:5 346:19 348:7</p> <p><b>part-time</b> [1] 182:25</p> <p><b>participant</b> [1] 42:6</p> <p><b>participants</b> [7] 11:3 33:7 34:1 39:12 162:12 236:8 246:21</p> <p><b>participate</b> [24] 14:25 31:10,11 40:17,23 42:21 49:1 70:4 83:20 88:21 93:9 104:21 135:20 137:23 161:23 166:20 175:7 219:6,7 222:13 223:2 246:11 247:22 261:24</p> <p><b>participated</b> [11] 82:15 82:17 92:12 138:8 146:25 147:5 151:12 152:24</p>
--	--	--	---	--

**-P-**

<p>250:11 292:5,6 <b>participates</b> [2] 91:20 222:2 <b>participating</b> [16] 15:10 36:12,13,23 37:4,21 38:11 39:1 49:14 104:8 105:18 159:3 166:7 227:9 238:23 275:13 <b>participation</b> [21] 16:2 31:9 40:4,15,15,25 42:18 81:24,25 82:5 83:8 90:23 160:4 161:11,18 162:7 164:16 165:2 169:22 183:13 246:9 <b>particular</b> [69] 8:2 25:22 36:13,15 39:6 63:4,20 64:17 70:9 81:15 89:18 91:1,11,21 96:19 100:2 100:12 108:1 111:19 113:12 126:6 140:16,17 146:19 153:2 154:15 159:10 163:12 166:22 179:25 184:12 190:12 201:23 206:15 220:15 228:13,16 234:10 237:13 248:6,23 251:12,17,19 253:9 256:12 261:20 262:24 263:3 264:15 268:22,23 270:21 274:18 276:24 279:11 281:9 282:4,5 285:13 288:8,9 290:10 298:5 312:23 338:15 374:3 382:14 383:20 <b>particularly</b> [8] 25:17 88:18 132:24 235:6 240:12 241:17 258:18 263:2 <b>parties</b> [2] 101:25 104:21 <b>partly</b> [1] 214:10 <b>parts</b> [1] 298:7 <b>pass</b> [2] 68:12 247:13 <b>passed</b> [2] 336:11 338:9 <b>password</b> [1] 88:19 <b>past</b> [11] 126:1 192:21 224:4 226:12 231:23 232:5 233:5 236:11 238:6 288:9,16 <b>path</b> [1] 124:24 <b>pathological</b> [1] 144:14 <b>pathologist</b> [34] 7:10 8:4 46:10 81:6 88:17 94:14 123:18 124:13 127:19 130:15 180:4 182:5 183:5 183:10 185:10,23 187:3 221:5 229:23,23 264:5 270:3 277:5,9,17 278:15 279:25 281:9 304:15 305:24 306:5 339:18 382:10 391:21 <b>pathologist's</b> [1] 328:16 <b>pathologists</b> [63] 20:11 23:2,8,9 28:1 35:6 37:4 37:16 39:1,23,25 42:15 44:7 55:5 57:24 75:19 85:12 87:21 94:4 98:3 101:7,11,17 104:4 105:1 121:18 134:21 136:1 161:25 167:6,13 172:2</p>	<p>182:19,25 183:15,22 184:5,15 188:23 193:1 195:1 221:2 223:12 227:21 228:9 231:18 234:2 254:5 255:7 258:12 261:1 263:21 278:4,16 280:25 281:3 303:25 305:2 306:3 324:23 328:13 340:19 376:7 <b>pathology</b> [48] 6:4,18 6:19,21,23 7:2,6 16:24 18:5 69:19 74:16 81:8 101:22 104:11,15,17 110:9 179:11 182:1,4,4 184:23 188:25 191:20 206:21 272:14 283:15,21 298:4 302:14 303:11 305:23 315:4 318:5,6 321:23 325:25 332:13,14 351:4,17,18 353:18 377:8 387:6 388:8 390:1 391:19 <b>patient</b> [36] 18:14 26:15 58:19 59:16 61:20 69:10 116:17 117:17 118:15,18 118:18 121:1 126:6,10 126:25 235:21 239:13 270:21 285:3 318:9,14 327:22 329:14 330:21 336:17 339:17 342:4 345:3 348:4,6 350:13 351:23 352:2 372:17 378:9 394:9 <b>patient's</b> [4] 268:19 341:24 353:19 392:18 <b>patients</b> [60] 8:3 21:11 24:16 26:6 27:6 55:5 118:1 131:4 157:22 158:5 309:1 315:6 316:5 321:8 321:10 322:2 324:23,25 325:9,17 326:18 335:20 336:10,12 337:4,5 338:16 340:14,21,23 341:8,8,13 341:17 342:8 345:7,14 345:18 348:25 349:20 350:6 355:12,16 358:6 366:16 370:4 371:15 372:22 374:24 376:8 378:12 381:3 382:1,2 383:1 385:24 386:7,11 390:6,7 <b>patients'</b> [1] 174:8 <b>Paton</b> [1] 372:8 <b>Paul</b> [1] 20:9 <b>Pax-5</b> [2] 118:22,25 <b>pay</b> [6] 11:22 31:10 149:18 159:18 161:15 286:13 <b>paying</b> [2] 149:21 205:17 <b>PC</b> [1] 216:2 <b>people</b> [74] 25:10 29:17 30:3,12 32:21 35:16 43:25 44:12 45:5 75:25 84:14 85:16 86:23 94:8 94:18,23 101:25 121:11 149:17,19 161:8 174:17 175:8,9 179:15 182:13 183:21 188:7 190:16 191:8 200:5 202:25 215:9 220:3 256:3,13 258:6 263:22 270:22 272:6</p>	<p>278:18,19 286:13,18 295:14,16 296:2 314:7 314:18 316:13,19 319:2 319:3 321:6 338:10,12 339:4 343:1,15 346:3 350:17,23 351:3,5,10,11 353:13 354:7 362:14 375:4,18 377:17 378:2,3 <b>peoples'</b> [1] 377:10 <b>per</b> [7] 78:21 105:17 114:4 297:21 299:4 387:25 389:5 <b>percent</b> [130] 67:18 68:9 68:13,16,21,22,24 69:9 69:9 110:18 120:7,7,8,8 125:9 138:19,20 141:16 144:22 153:8,10 155:13 156:6 166:25 204:4 205:22,25 206:15 207:1 207:2,11,21 208:2,7,19 209:17,19 211:2 217:18 217:21 218:3,4,14,15,18 218:22 219:12 220:6 225:5,17 226:6 235:16 237:19,20,21,22,22 238:10,11,12 243:10 250:12,23,25 267:24 280:3 287:6,16,17,19 309:8,9,21,22 310:23 313:23 319:4,23 323:4 323:16 327:18 329:22 330:8,17,20,21,25 331:3 331:21,24 332:2,4,5,15 333:20,22 335:24 337:10 337:12,15,22,24 338:3 339:24,25 342:12,13 344:5,5 352:23 360:16 360:16 362:14 363:3,5,7 363:16 364:17,20,22 365:3,4,4,5 370:11,12 372:6 375:19,20 396:1 <b>percentage</b> [8] 40:24 41:2 209:11 210:3 319:25 334:25 335:1 368:24 <b>percentages</b> [3] 203:14 203:17 250:4 <b>perception</b> [1] 233:8 <b>perfect</b> [16] 76:25 77:3 77:13 78:14 79:3,18 80:8 153:18 215:25 241:13 243:22 263:18,19 271:7 271:11 272:21 <b>perfectly</b> [1] 71:14 <b>perform</b> [4] 174:7 189:17 213:25 244:24 <b>performance</b> [11] 103:15,17 104:2 105:18 106:12 132:12 138:15 192:25 217:5 224:2 263:20 <b>performed</b> [11] 161:7 169:15 188:15 194:4 234:4 285:4 346:13 351:24 352:14 353:24 356:15 <b>performing</b> [5] 179:25 281:6 285:7 304:15 382:3 <b>perhaps</b> [20] 16:13 51:7 53:7,8 79:17 135:3 139:18 157:7 184:18</p>	<p>210:8 223:4 243:1 257:3 261:17 262:18 269:3 274:6 295:16 383:11 396:9 <b>period</b> [20] 58:8 130:17 130:24 132:1 133:19 179:8 180:12 194:24 201:1 311:2,4,17,24,25 326:10 344:21 346:23 367:2 369:10 384:17 <b>periodic</b> [1] 185:15 <b>permanent</b> [1] 182:11 <b>person</b> [26] 24:24 46:6 96:21 179:14,18 180:4,7 182:8,23 184:23 232:15 298:19 301:4 304:2 308:20 335:16,24,25,25 337:23,24 372:8,9 382:11 385:22 386:4 <b>personal</b> [13] 16:15 20:21 42:3 50:5 56:7 67:10 69:16 104:9 184:8 243:5,20 244:2 270:24 <b>personally</b> [10] 14:7 32:21 48:25 55:19 68:25 121:12,20 194:3 201:3,4 <b>perspective</b> [10] 27:12 41:19 48:2,17 52:14 78:11 83:2 93:7 159:16 305:19 <b>pertinent</b> [2] 7:24 104:24 <b>pessimistic</b> [1] 85:18 <b>Peter</b> [4] 1:9 2:6 231:13 231:16 <b>Pg</b> [4] 3:2,3,4,5 <b>PGR</b> [1] 299:6 <b>Pgs</b> [7] 2:3,4,5,6,7,8,10 <b>pH</b> [6] 21:8 199:19 200:21 201:6 249:13,14 <b>phase</b> [1] 21:12 <b>phases</b> [5] 103:19 253:5 253:12,13 258:17 <b>PhD</b> [1] 241:2 <b>phenotyping</b> [1] 64:17 <b>Phoenix</b> [1] 301:16 <b>phone</b> [4] 175:14 296:25 306:3 376:24 <b>phonetic</b> [8] 55:3 73:18 75:3 169:17 174:21 180:1 193:10 214:25 <b>photographed</b> [1] 80:5 <b>physically</b> [2] 301:25 306:6 <b>physicians</b> [2] 221:1 331:9 <b>PI</b> [1] 216:1 <b>picamoles</b> [1] 242:13 <b>pick</b> [2] 255:8 320:16 <b>picked</b> [2] 28:10 241:6 <b>picking</b> [1] 341:8 <b>picture</b> [5] 46:14 87:19 95:6 216:10 238:19 <b>piece</b> [2] 229:3 269:17 <b>pieces</b> [4] 226:25 228:21</p>	<p>229:7,22 <b>Pike</b> [2] 1:14 177:22 <b>Pilavdzic</b> [1] 79:5 <b>pile</b> [6] 352:5,7,8,9,10,17 <b>piles</b> [1] 352:4 <b>Pilgrim</b> [1] 314:15 <b>pilot</b> [4] 10:21 212:21 215:4,5 <b>place</b> [14] 25:5 98:4 164:12 175:9 188:25 190:25 191:4 192:13 204:23 229:24 232:17 259:12 278:4 300:8 <b>places</b> [1] 173:10 <b>plan</b> [7] 86:8 168:9 169:11 175:2,23,25 396:14 <b>play</b> [1] 247:25 <b>plots</b> [1] 47:8 <b>plotted</b> [1] 46:13 <b>plus</b> [4] 79:19 114:25 144:13 368:13 <b>point</b> [60] 13:12 15:20 53:14 54:11 56:1,13 59:25 72:17,20 73:1,2 74:3,6,24 78:25 120:8 125:16 153:16 155:10 169:11,24 171:2,22 173:14,16 177:10 200:15 201:25 210:7 215:3 219:11 228:23 233:11 234:25 235:11 239:23 242:20 253:9 255:20 258:1 284:20 286:23 293:8,15 294:9 296:21 297:3 301:10 306:19 309:5 310:6 339:20 354:14 358:23 363:2 370:25 378:21 381:8 383:20 391:5 <b>pointed</b> [8] 16:20 95:11 95:14 172:23 174:5 262:3 264:11 335:14 <b>pointing</b> [1] 270:13 <b>points</b> [4] 169:7,9 235:1 296:22 <b>political</b> [1] 69:4 <b>polymer</b> [2] 17:17 198:12 <b>pool</b> [1] 230:17 <b>poor</b> [14] 11:2 77:9 217:20 218:13,18 219:12 225:6,6,9,18 226:7 235:16 249:3,9 <b>poorly</b> [1] 132:21 <b>population</b> [2] 144:14 211:3 <b>portfolio</b> [1] 298:6 <b>posed</b> [1] 106:14 <b>position</b> [8] 19:20 20:18 22:23 81:4 133:17 191:16 306:20 313:8 <b>positions</b> [1] 22:14 <b>positive</b> [117] 19:3 45:3 45:3 58:8 66:15 72:21 72:24 73:2 74:21,24 75:5</p>
--	--	---	---	---

<p>76:15,18,20 78:15,16,19 79:9,17 80:2,4,13 92:13 106:25 107:2,3 118:24 120:7 132:19 133:2 138:16 141:1,11 145:16 145:22 158:16 195:8 196:2,3 198:5 199:7 202:9 203:8,10 204:5 205:8 214:23 224:12,14 224:17 228:24 243:11 249:8 250:1,3 267:20 268:1,4,9,10,19,21 271:5,17,18,23 272:17 273:1 274:11,14 275:3,4 275:17 277:5,10,17,20 279:19,20 309:9,21 319:25 321:10 322:25 323:9,11,14 328:14 335:8 343:25 352:12,13,16 360:5,6,11,21,22 362:13 367:18,23 368:2,9,12,16 368:17 372:2 378:2 385:8 385:13,14,16,18 391:22 391:25 392:18</p> <p><b>positive/negative</b> [4] 358:6 365:19 369:17 371:7</p> <p><b>positives</b> [29] 138:20 140:25 141:5 145:24 251:1 267:6,11,13 276:20 297:16 308:8,10 324:14 327:16 352:7,8 353:7 355:5 361:14,16 362:23 362:23,24 364:16 370:10 372:24 378:16 379:2 394:24</p> <p><b>positivity</b> [21] 65:20 66:9 92:19 207:17 214:8 228:23 237:15 272:15 280:3 319:3,17,21 320:22 358:19 361:19 362:15 363:8 365:4 366:21 370:12 385:8</p> <p><b>possibility</b> [1] 85:19</p> <p><b>possible</b> [22] 46:5 54:12 55:8,9 71:7 73:12 77:18 92:15 95:4 114:8 120:10 148:18 175:6 208:18 241:9 258:6,23 270:10 275:3 285:5 294:5 382:2</p> <p><b>possibly</b> [8] 101:13 133:12 197:16 234:14 249:14 267:11 329:24 377:19</p> <p><b>post</b> [2] 253:5 262:25</p> <p><b>post-analytical</b> [7] 54:2 230:10 253:20 255:22 257:6,10 263:23</p> <p><b>post-test</b> [2] 103:19 253:13</p> <p><b>posted</b> [4] 13:10 64:23 257:4 261:4</p> <p><b>poster</b> [6] 141:22 142:6 142:7,8 145:6,19</p> <p><b>posting</b> [1] 16:6</p> <p><b>potential</b> [6] 48:3 52:15 163:5 185:22,24 285:2</p> <p><b>potentially</b> [2] 158:9 162:21</p>	<p><b>power</b> [2] 69:7 90:18</p> <p><b>powerful</b> [2] 232:10 237:1</p> <p><b>PowerPoint</b> [4] 5:7,14 116:9 288:10</p> <p><b>powers</b> [1] 86:20</p> <p><b>PR</b> [37] 60:22 111:19 120:25 126:7 152:17 201:23 204:25 207:1 209:12 210:4 237:21 243:15 249:3 258:19 265:6,25 266:10,14,21 267:3,13 269:11 273:2 284:16,23 286:13 310:9 329:15,22 338:3 343:25 351:24 360:17 362:13 363:14 396:1,1</p> <p><b>practical</b> [2] 17:3 55:4</p> <p><b>practice</b> [53] 9:16 14:3 15:18 16:9 17:6 23:12 25:8 26:12 33:13 56:1 57:2,5 75:5 78:18 81:12 81:23,23 82:2 94:13 95:4 102:7 106:25 110:9 113:12 123:25 124:8 131:14 132:11,16 149:23 149:25 150:13 165:10 170:12,16,23 184:9 187:7 194:12 196:10 197:20 202:20 204:22 236:19 254:3 257:23 264:2,7 270:23 272:7 295:6 340:22 342:22</p> <p><b>practices</b> [4] 104:19 166:1 191:4 229:13</p> <p><b>practised</b> [1] 127:19</p> <p><b>practises</b> [1] 95:6</p> <p><b>practising</b> [4] 23:8 43:24 119:7 344:2</p> <p><b>pre</b> [3] 71:22 253:12,19</p> <p><b>pre-analytic</b> [3] 71:20 71:22 258:17</p> <p><b>pre-analytical</b> [3] 54:1 71:6 254:1</p> <p><b>pre-test</b> [1] 253:5</p> <p><b>precise</b> [1] 249:21</p> <p><b>precisely</b> [1] 242:10</p> <p><b>precision</b> [1] 203:3</p> <p><b>Predham</b> [12] 297:2,24 298:1,11 307:7 313:10 314:12 318:22 336:9 337:1 349:25 365:16</p> <p><b>predict</b> [2] 59:14 106:15</p> <p><b>predictable</b> [1] 76:8</p> <p><b>predicted</b> [1] 79:23</p> <p><b>predicting</b> [1] 239:20</p> <p><b>predictive</b> [10] 8:6 24:22 59:11,13,14 61:4 126:15 169:15 239:15 257:12</p> <p><b>prediluted</b> [1] 290:21</p> <p><b>predominant</b> [1] 144:14</p> <p><b>prefer</b> [3] 78:17,18 102:9</p> <p><b>preferably</b> [1] 182:8</p> <p><b>preference</b> [3] 12:23 244:3 293:16</p> <p><b>premixed</b> [1] 290:21</p>	<p><b>prepare</b> [4] 23:1,13 76:17 256:14</p> <p><b>prepared</b> [6] 5:7 100:9 116:6 150:2 256:11 257:20</p> <p><b>preparing</b> [3] 96:4 146:21 153:24</p> <p><b>presence</b> [2] 59:1 132:17</p> <p><b>present</b> [9] 11:14 21:10 31:22 53:24 116:21 129:3 168:19 201:24 286:2</p> <p><b>presentation</b> [14] 5:7 5:14,17 10:23 66:23 135:8 141:22 168:8 212:24 248:17 249:2 264:14 286:3 288:10</p> <p><b>presentations</b> [1] 35:9</p> <p><b>presented</b> [6] 65:9 87:14 141:20 142:12 145:19 258:13</p> <p><b>presents</b> [1] 75:9</p> <p><b>preservation</b> [1] 74:13</p> <p><b>preserved</b> [1] 74:15</p> <p><b>pressure</b> [2] 62:7 199:21</p> <p><b>presumably</b> [5] 35:16 88:21 92:2 162:20 227:15</p> <p><b>presume</b> [1] 216:25</p> <p><b>pretest</b> [1] 103:19</p> <p><b>pretty</b> [10] 172:25 304:21 316:2 326:14 341:7 342:5 344:13,22 364:2 376:24</p> <p><b>prevailed</b> [1] 95:17</p> <p><b>prevailing</b> [1] 236:19</p> <p><b>prevent</b> [1] 211:1</p> <p><b>prevents</b> [1] 263:15</p> <p><b>previous</b> [3] 198:7 224:16 225:12</p> <p><b>previously</b> [6] 45:4 54:6 59:7 116:22 192:15 193:8</p> <p><b>price</b> [2] 159:20 161:16</p> <p><b>primaries</b> [1] 317:15</p> <p><b>primarily</b> [1] 223:10</p> <p><b>primary</b> [17] 145:4 153:12 249:15 250:5,8 276:10,18 290:6,15 317:15 367:24 369:5 386:7,11 387:17 388:5 389:13</p> <p><b>principles</b> [1] 167:24</p> <p><b>print</b> [3] 353:17 365:18 387:5</p> <p><b>printed</b> [2] 352:1 356:14</p> <p><b>printing</b> [1] 322:11</p> <p><b>Pritchard</b> [3] 1:8 176:14 176:15</p> <p><b>Pritchett</b> [3] 1:16 252:6 252:10</p> <p><b>privilege</b> [1] 379:14</p> <p><b>privileged</b> [3] 20:18 190:14,21</p> <p><b>privy</b> [1] 371:8</p> <p><b>problem</b> [25] 64:5 72:4 72:5 104:9 106:16 153:5 156:8 158:9,18,20 175:1</p>	<p>175:19,23 195:12 215:8 220:9 232:25 235:22 249:19 267:5,13 274:18 277:7 278:12 284:2</p> <p><b>problems</b> [10] 35:7 48:3 94:12 151:9 172:6 185:23 248:10,11 255:8 275:3</p> <p><b>procedure</b> [11] 51:4 54:18 71:5 73:10,17 293:12 299:5 346:19 347:12 351:24 353:24</p> <p><b>procedures</b> [11] 54:7 72:19 75:16 145:4 185:17 259:12 273:6 293:11,12 299:23 302:18</p> <p><b>process</b> [44] 34:4,6 36:7 49:18 65:22 72:22 74:9 74:19 75:15 80:10 95:17 114:21 123:19 124:15 126:5 152:20 158:4 171:19 196:22 199:24 200:22 226:19 238:24 247:15 248:9 254:7 269:22 293:19 297:2,25 298:12 315:6 316:12 340:17 347:24 349:2,23 356:12 374:25 379:19 380:5 381:25 383:6,17</p> <p><b>processed</b> [2] 259:6 318:1</p> <p><b>processes</b> [3] 115:15 170:25 171:14</p> <p><b>processing</b> [9] 71:9 73:11 74:12 253:15 254:24 259:4,23 269:19 275:7</p> <p><b>proclaim</b> [1] 45:2</p> <p><b>procurement</b> [1] 74:7</p> <p><b>produce</b> [11] 15:6 21:17 71:1 91:10 145:9 185:21 195:23 258:8,9 259:17 276:2</p> <p><b>produced</b> [7] 69:15 88:1 91:23 97:13 144:21 196:2 214:19</p> <p><b>producing</b> [5] 11:21 13:4 17:24 214:22 238:1</p> <p><b>product</b> [3] 72:19 196:16 241:20</p> <p><b>products</b> [7] 12:23,24 13:2,5 27:19,20 196:17</p> <p><b>profession</b> [1] 12:21</p> <p><b>professional</b> [4] 5:25 6:7 55:23 221:1</p> <p><b>professionally</b> [1] 48:25</p> <p><b>professionals</b> [1] 12:2</p> <p><b>professor</b> [1] 81:7</p> <p><b>proficiency</b> [8] 103:18 221:24 222:4,10,17 223:9 223:12 253:4</p> <p><b>proficient</b> [1] 264:3</p> <p><b>profile</b> [1] 215:25</p> <p><b>prog</b> [1] 257:11</p> <p><b>progesterone</b> [8] 58:17 149:4 195:10 202:9 235:5 243:4 248:25 362:6</p> <p><b>prognostic</b> [8] 8:6 24:21</p>	<p>59:11,13,16 61:3 107:20 169:14</p> <p><b>program</b> [134] 6:25 10:1 10:4 11:12 12:9 13:16 13:20 14:4,9 15:1,6 20:4 20:5 33:11 34:17 40:11 40:12 41:14 42:18,21,23 42:25 43:3,15 44:2 48:21 49:1,14 62:23 82:5 83:21 84:1,3,3,7,15 85:4,15,19 86:3,4,5,24 87:4,21 90:8 90:10 93:14,15,23 95:15 96:18 98:7 99:12 100:7 103:5 104:16 105:11,22 109:13,21 110:25 114:3 121:13,14 143:10 151:4 154:18 155:15 156:1,11 158:13,14 159:25 160:5 160:5,8,9 161:18,19 162:13 163:11,16 164:20 165:7,23 166:1,14,22 167:22,23 168:1,4 173:20 173:24 200:3 216:25 217:2,13 218:24,25 221:7 221:24,25 222:10,17 223:3,4,16,21 225:15 232:20 234:3 235:18 239:4 246:3 248:5 251:24 253:1 255:5,15 256:15 257:6 258:22 260:9,10 261:20,25 262:4,5 263:1 263:18,19 278:24</p> <p><b>programs</b> [44] 7:1 12:16 13:22 15:22 43:20,21 57:3 70:4 81:25 82:1 87:10 88:8 92:9 93:18 93:25 99:6 103:9 105:20 120:21 121:10,19 145:11 145:12 155:4 158:23 164:18 165:12 166:9 173:18 183:14 200:4 201:17 248:3 259:21 260:7 261:11,18 262:1 262:12,15 279:8,9 282:8 282:14</p> <p><b>progress</b> [2] 100:19 192:24</p> <p><b>progressed</b> [1] 55:10</p> <p><b>progressing</b> [2] 44:18 201:23</p> <p><b>progression</b> [1] 198:4</p> <p><b>prohibited</b> [1] 264:7</p> <p><b>prohibitively</b> [1] 78:20</p> <p><b>project</b> [5] 7:21 143:11 143:12 213:4 315:11</p> <p><b>promised</b> [1] 163:10</p> <p><b>promoting</b> [1] 230:13</p> <p><b>prone</b> [1] 274:10</p> <p><b>pronouncing</b> [1] 64:5</p> <p><b>proof</b> [2] 78:24 242:2</p> <p><b>proper</b> [1] 155:19</p> <p><b>properly</b> [4] 8:5 34:18 214:14 299:16</p> <p><b>proportion</b> [2] 40:22 209:3</p> <p><b>proposal</b> [21] 96:5,16 97:24,25 99:10 100:6,9 100:10,14,21,22 101:8</p>
---	--	---	--	--

<p>102:25 104:23 105:3 106:5 111:5 134:19 135:25 252:22,24 <b>propose</b> [1] 113:7 <b>proposed</b> [2] 105:9,11 <b>prostate</b> [4] 128:14,15 132:23 133:5 <b>protection</b> [1] 153:15 <b>protein</b> [5] 62:15 75:13 197:2,7,14 <b>protocol</b> [8] 90:24 91:1 91:10,22 152:9 153:11 227:11 294:16 <b>protocols</b> [14] 21:15 72:19 87:25 88:2 90:22 151:20 152:25,25 185:16 292:22 295:12,16,17 299:6 <b>prove</b> [1] 264:6 <b>proven</b> [2] 241:8 243:17 <b>provide</b> [21] 14:11 27:20 32:13 33:6,8,10,15 86:25 87:2 92:5 106:21 109:20 126:9 156:9,19 161:19 170:8 173:11 211:4 262:6 356:3 <b>provided</b> [11] 12:3 13:17 34:10 79:6 86:16 155:14 245:23 297:22 326:18 336:10 373:6 <b>provides</b> [10] 34:15,16 34:19 35:15 39:5 104:6 108:4 154:18 159:3 168:1 <b>providing</b> [10] 27:18 30:7 35:17 151:5 156:3 156:7,11 233:3,11 275:20 <b>province</b> [9] 165:15 171:14 236:20 317:24 318:5,14 326:16 369:14 369:23 <b>provinces</b> [8] 84:7,11 93:16 164:11,13 171:8 171:20 259:8 <b>provincial</b> [5] 85:20 86:3,4 171:23 245:10 <b>PRs</b> [1] 309:25 <b>prudent</b> [1] 184:19 <b>publication</b> [9] 51:14 51:15 283:9,11,11,13 284:9,18 285:19 <b>publications</b> [5] 54:16 95:1,2 283:7 285:19 <b>publicly</b> [2] 108:15 286:8 <b>publish</b> [2] 51:13 240:22 <b>published</b> [30] 18:4 21:13 23:6,10 112:21 150:2 170:3,11,22 175:10 193:6,7 195:24 202:13 225:11 234:5 236:22 240:8,11 243:14 244:10 246:25 279:17 280:4 283:5,10,19 285:13,22 286:9 <b>publishing</b> [1] 150:3 <b>pull</b> [6] 310:25 311:9 312:12 317:18,19 390:21</p>	<p><b>pulled</b> [3] 308:11 311:10 374:3 <b>pulling</b> [2] 381:4,4 <b>purpose</b> [13] 61:17 122:21 123:1 125:14 126:6 128:8 146:19 199:23 215:4 256:12 295:7 297:8,10 <b>purposes</b> [9] 117:15 129:5 130:18 131:2 151:25 158:24 236:24 337:8 367:22 <b>put</b> [42] 17:14 62:21 88:19 160:16 161:16 173:22 178:3 197:4 216:9 254:19,25 255:23 256:1 256:25 258:5 284:19 293:23 327:9,23 329:24 330:18 331:17,24 333:10 334:25 337:8,15,22 338:3 346:24 350:3 351:11 353:7 354:10 359:5 378:12,15,21 388:18,22 393:4 396:5 <b>putting</b> [2] 240:2 324:24</p> <hr/> <p style="text-align: center;"><b>-Q-</b></p> <hr/> <p><b>Q.C</b> [805] 1:6,7,8,12,14 2:3,4,6,8,10 4:3,7,16,24 5:5,15,20 6:5 8:11,15,19 9:1,6,10,14,21 10:13,18 16:11 18:15,19 19:11,17 19:23 21:23 22:3,7,13 22:18 23:15,21,25 24:8 24:23 25:12,21 27:1,9 27:17 28:16,21,25 29:5 29:10,19,25 30:6,11,15 30:20,25 31:5,14,21 32:1 32:5,17 33:2,12,19 34:3 34:12,22 35:14,20,25 36:5,10,22 37:2,9,15,20 37:25 38:5,10,15,20,25 39:4,11,17,24 40:3,8,18 41:7,17 42:4,9,22 43:2,6 43:10 45:13,19,25 46:18 46:23 47:2,7,12,18 48:1 48:8,16 49:3,7,16,24 50:12 51:10,21,25 52:4 52:8,12,21 53:3 54:20 55:12 56:4,15,21 57:10 57:14 59:17 60:13,19 61:9,21 62:24 63:11,18 64:4,11 65:10 67:4 69:18 69:23 70:7,13,18 71:12 71:19 72:1 73:4 78:4,8 80:16,22 81:3,10,19 82:7 82:13,18,25 83:6,11 84:16,21 85:2,8,21 87:6 88:5,12,16 89:2,6,10,15 89:21 90:3,25 91:5,9,14 91:18 92:1,24 93:5,20 95:8,23 96:10,24 97:7 97:19,23 98:8,25 99:7 99:18 100:25 102:12,18 102:23 105:7,15 106:8 107:10,14 108:11,20 109:2,15,23 110:2,12 111:2,8,18,22 112:1,6 112:11,16,20 113:2,6,15 113:19 114:5,16,20,24 115:4,8,13,19 116:3,8</p>	<p>118:7,12 119:19 121:21 121:25 122:6,11,15,19 122:25 123:10,16 124:12 124:18,23 125:3,12,19 126:2,12,17,24 127:3,7 127:14 128:5,10,16,21 129:6,10,15,23 130:9,14 130:23 131:7,16 133:14 133:22 134:8,16,24 135:9 135:13,23 136:4,8,13,17 137:8,13,17,21 138:1,5 138:22 139:6,11,16,22 140:1,5,9,13,20,24 141:4 141:8,14 142:2,11,16,20 142:25 143:5,13,19,25 144:20 145:21,25 146:12 146:23 147:4,10,14,21 148:1,8,12,16 150:5 151:11 152:1,7,12,16 153:21 154:3,14 155:1 156:14,18,22 157:1,6,10 157:23 158:3,8 159:1,9 162:6,11,19 163:13,21 164:1 165:14,18 166:10 166:16 167:4,10,16 168:5 168:12,23 169:2 170:24 172:16 173:5,25 174:18 176:1,6,10 177:20,22 179:2,3 180:10,15,18,20 180:22,24 181:3,7,14,16 181:25 183:3,20 184:17 185:6 186:1,8,15,20 187:8,12,17,22 188:21 189:6,12,21 190:1 231:13 231:14 232:12,24 233:13 233:17,23 234:8,16,22 235:9 236:2,16 237:3,10 238:3,16,22 239:3,10 240:13 242:17 244:4,14 245:3 246:2,12,16 247:1 248:1,18 251:11,22 252:2 282:25 283:1 284:5 285:11,17 287:3,9,13,21 287:25 288:5,20 289:5 289:12,17,23 290:4,13 290:20 291:4,11,18,23 292:3,9,13,17,21 293:1 293:25 294:4,8,15,22 295:2,10,21 296:6,8,17 297:23 298:13,25 299:17 300:7,11,18,23 301:19 302:2,6,11,16,23 303:2 303:17,23 304:18,22 305:1,6 306:8,14,18 307:1,5,20 308:2 309:10 309:16,23 310:5,12,19 310:24 311:11,18,22 312:4,8,14,24 313:5,16 314:10 315:13,17,23 316:3,8,18,22 317:7,12 317:16 318:16,20 319:8 319:14,20 320:4,8,20 321:13,19 322:4,10,16 322:22 323:3,8,13,20,25 324:4,9,13,18 325:2,10 325:14,19,23 326:4,9,20 327:1,5,11,15,25 328:4 328:9,19,23 329:2,7,16 330:2,7,12,19 331:1,6 331:13,19,25 332:16,22 333:7,16,21 334:1,5,9 334:14 335:12 336:3,16 336:21,25 337:7,13,21</p>	<p>338:5,17,23 339:3,9,21 340:5 342:14,19 343:5 343:10,14,20 344:6 345:10,15,20 346:1,9 347:2,8,15,19,23 348:3 348:10,15 349:5,12,24 350:8,12,19 351:8 352:15 352:22 353:2,6,12 354:5 354:12,18,24 355:4,9,19 355:23 356:2,18 357:1,6 357:10,14,20,24 358:10 358:14,24 359:3,8,12,17 359:21 360:2,7,13,18,23 361:2,7,11,15,20,25 362:5,10,18 363:9,13,18 363:22 364:3,8,14,21,25 365:6,10 366:4,10,18,24 367:10,14,19 368:1,7,18 368:22 369:2,6,11,15,22 370:1,7,14,18,22 371:10 371:17,22 372:7,13,20 373:2,7,13 375:17,23 376:2,9,16 377:5,14,20 377:25 378:14,20 379:6 379:23 380:2,8,14,20 381:9,14,18 382:23 383:4 383:10,18 384:6,11,23 385:3,10,15,20 386:5,14 386:21 387:3,10,15,20 388:2,6,12,16,21,25 389:7,14,19,24 390:9,18 390:22 391:2,6,10 392:1 392:5,9,14,20 393:1,6 393:16,20 394:2,6,11,18 394:25 395:4,8,12,17,21 396:2,8 <b>Q.C./Jane</b> [1] 1:9 <b>QA</b> [2] 174:4 237:2 <b>QAP</b> [1] 236:8 <b>QC</b> [8] 57:3 75:14 81:23 98:16 103:5 145:10,12 174:4 <b>QI</b> [2] 297:2,25 <b>QMPLS</b> [5] 164:7 222:16 260:10,14 263:9 <b>qualifications</b> [2] 184:21 186:3 <b>qualified</b> [1] 13:18 <b>qualifies</b> [1] 123:5 <b>qualitative</b> [3] 59:23 107:19 239:11 <b>qualities</b> [1] 11:20 <b>quality</b> [109] 7:21 10:5 11:22 12:8 13:19,22 14:4 14:9,18 25:23 33:10 34:17 38:7,17 41:20,25 42:11 43:12,19 52:16,18 53:16 62:22 67:25 81:14 81:14 87:1 90:14 92:8 93:18 96:6,17 99:11 100:7 103:10,13,14 105:10,19 106:24 108:5 110:18 113:23 114:2 121:9,13,18 132:3,4 150:22 151:4,25 155:25 156:10 157:2,2 158:14 158:20,22 164:17,17 165:25 166:4 171:5,6 172:6,7,24,24 173:12,14 173:16,18,19 183:11,13</p>	<p>184:13,13,19 195:7 200:2 200:5 205:14 217:11 228:15,15,19 230:14,18 230:20 234:2 236:24 239:4 249:20 251:13,13 252:23 253:2 256:17 258:21 275:14 278:23 286:21,22 307:19 313:18 313:24 314:18 382:15 <b>quantitate</b> [5] 59:2 120:6 240:25 242:2,10 <b>quantitated</b> [1] 120:14 <b>quantitating</b> [2] 242:3 242:12 <b>quantitation</b> [2] 240:10 240:19 <b>quantitative</b> [10] 59:24 76:19,20 107:2,3,19,21 120:16 239:12 241:20 <b>quantity</b> [2] 173:16 244:12 <b>quarterly</b> [2] 299:24 300:1 <b>Quebec</b> [1] 298:22 <b>querying</b> [1] 309:12 <b>questionable</b> [3] 335:20 339:17 352:6 <b>questioned</b> [1] 308:6 <b>questioning</b> [1] 308:13 <b>questions</b> [19] 94:9,21 106:11,13 176:12,16,22 177:8,23 192:5 231:8 252:9,11 282:17,22 288:7 306:22 349:18 366:7 <b>Quevillon</b> [2] 298:21 307:14 <b>Quevillon's</b> [1] 299:2 <b>quick</b> [3] 92:7,9 100:10 <b>quickest</b> [1] 342:7 <b>quickly</b> [10] 8:22 32:22 92:18 94:8 153:16,20 165:24 236:25 258:11 382:2 <b>quite</b> [13] 21:20 41:22 84:11 133:12 138:17 148:6 216:8 221:14 237:11 289:25 290:5,7 305:19</p> <hr/> <p style="text-align: center;"><b>-R-</b></p> <hr/> <p><b>r</b> [13] 11:16,16,16 20:22 20:22,22,22,22 119:12 119:12 182:22 257:21,21 <b>R-L-A-K-O-V-I-C</b> [1] 4:13 <b>radiation</b> [1] 100:17 <b>radical</b> [1] 119:23 <b>radically</b> [1] 192:20 <b>Radium</b> [4] 7:14,15 16:25 24:13 <b>raised</b> [1] 312:10 <b>ramifications</b> [1] 52:15 <b>ramp</b> [1] 255:23 <b>ran</b> [1] 149:5 <b>range</b> [7] 41:5 138:20</p>
---	---	--	--	---

<p>209:20 332:11 333:6 352:23 353:1 <b>rapidly</b> [1] 94:25 <b>rare</b> [7] 94:18 118:2 139:1 150:15 189:18 273:3 379:3 <b>rarely</b> [2] 62:5 129:22 <b>rate</b> [18] 68:12 92:10,21 123:4 128:9 132:22 138:17 141:15 144:22 151:22 153:8 166:21 209:21 210:4 319:3 320:23 366:21 372:6 <b>rates</b> [7] 145:22 319:17 358:19 365:19 369:17 371:7 372:1 <b>rather</b> [11] 53:22 65:21 73:9 74:8,25 80:9 86:1 131:13 184:9 214:7 396:6 <b>ratio</b> [2] 198:14 272:22 <b>ratios</b> [1] 290:16 <b>RCPA</b> [1] 248:5 <b>re</b> [3] 130:2,3 379:17 <b>Re-examination</b> [2] 2:8 282:24 <b>re-interpreted</b> [1] 379:20 <b>re-read</b> [2] 379:8 381:21 <b>re-reading</b> [1] 381:5 <b>re-scores</b> [1] 280:7 <b>re-tested</b> [2] 379:10,20 <b>re-titrated</b> [1] 153:17 <b>reached</b> [2] 54:11 201:25 <b>reacted</b> [1] 272:11 <b>reaction</b> [1] 74:25 <b>reactivity</b> [1] 272:23 <b>read</b> [18] 100:14 197:10 234:19 254:21 266:7 284:3,3 320:15 328:12 341:24 352:2 365:17 379:18 387:8,11 391:19 391:22 392:17 <b>readily</b> [1] 108:15 <b>reading</b> [7] 108:14 179:13 210:13 324:22 329:11 391:15,19 <b>readings</b> [1] 50:7 <b>ready</b> [2] 4:25 336:7 <b>reagent</b> [2] 11:20 153:1 <b>reagents</b> [1] 12:22 <b>real</b> [7] 95:6 160:7,24 179:14 209:25 220:5 229:13 <b>realistic</b> [2] 231:2 245:23 <b>realities</b> [1] 74:16 <b>realized</b> [1] 25:16 <b>really</b> [47] 5:23 16:7 20:10 22:9 34:15 47:24 48:14 53:17 56:2 75:15 82:21 83:21 84:11 97:2 107:5 138:9 146:17 155:25 160:4,15 161:16 173:18 195:25 196:6 199:23 206:7 210:2 216:10 229:8 244:23</p>	<p>249:18 268:8 272:16 278:10 281:11 286:10 293:22 304:16 306:11 313:12 314:1,3,8 315:21 346:8 356:13 364:24 <b>reason</b> [14] 6:24 104:12 134:10 171:20 208:17,23 242:25 250:7,12 308:13 317:17 374:15 381:10 384:16 <b>reasonable</b> [3] 209:7,19 270:23 <b>reasons</b> [8] 67:20 92:16 247:6 250:2,3 251:2 257:18 261:25 <b>receipt</b> [1] 300:12 <b>receive</b> [3] 45:23 335:25 336:1 <b>received</b> [11] 46:12,15 98:17 317:25 318:8 320:9 338:22 339:5 373:20 374:20 377:7 <b>receives</b> [1] 26:15 <b>receiving</b> [4] 74:17 254:10 305:9 377:8 <b>recent</b> [2] 218:7 240:18 <b>recently</b> [6] 98:20 155:8 164:18 195:6 257:20 260:22 <b>receptor</b> [14] 1:2 58:16 58:17 59:13 195:10,10 239:21 248:25,25 265:23 344:1 361:18 394:21 397:4 <b>receptors</b> [8] 58:24 67:19 107:23 149:5 150:15 202:10 235:5 243:5 <b>recheck</b> [2] 308:14 350:6 <b>recognize</b> [3] 119:9 128:14 132:8 <b>recognized</b> [1] 235:22 <b>recollection</b> [1] 29:1 <b>recommendation</b> [3] 56:17 302:18 378:8 <b>recommendations</b> [5] 14:1 161:1 245:8 275:18 276:1 <b>recommended</b> [8] 25:10 68:9 78:25 154:20 236:21 299:23 300:3 303:6 <b>record</b> [5] 23:10 73:20 318:7 342:4 356:15 <b>Recorded</b> [1] 292:22 <b>recording</b> [1] 259:6 <b>records</b> [8] 326:1 341:14 345:3 348:17,21 356:24 371:2,7 <b>recruit</b> [1] 233:2 <b>recruited</b> [3] 7:10 22:20 22:21 <b>recruitment</b> [1] 233:1 <b>rectify</b> [1] 277:7 <b>red</b> [5] 27:5 92:14 214:4 214:5 217:19 <b>reduce</b> [1] 187:13</p>	<p><b>reduced</b> [1] 186:4 <b>Rees</b> [1] 279:25 <b>refer</b> [5] 163:15 237:12 294:17 315:7 317:22 <b>reference</b> [26] 68:6,7 72:18,20 74:23 80:6 110:22,23 149:6,9 155:12 167:1 172:19 204:10 206:10 211:10 258:1 260:9 265:8 267:17 273:8 283:8 284:7 287:20 312:9 384:4 <b>referenced</b> [1] 32:25 <b>references</b> [2] 163:22 267:2 <b>referral</b> [3] 24:14 285:6 353:21 <b>referred</b> [6] 136:14 273:17 283:4 287:5 288:13 304:5 <b>referring</b> [11] 142:21 242:20 259:11 267:1 311:5 314:23 315:2,24 332:8,14 368:14 <b>refers</b> [3] 145:14 253:23 253:23 <b>refined</b> [1] 363:4 <b>reflect</b> [4] 207:16 229:12 295:6 325:8 <b>reflecting</b> [2] 68:10 218:23 <b>reflects</b> [2] 228:20 272:24 <b>regard</b> [2] 48:22,24 <b>regarded</b> [2] 190:17 191:13 <b>regarding</b> [5] 100:6,13 126:15 302:17 304:4 <b>regardless</b> [1] 361:21 <b>regards</b> [2] 92:19 168:20 <b>regime</b> [1] 63:1 <b>region</b> [2] 355:14 356:23 <b>regional</b> [6] 1:10,17 9:17 25:18 188:10,22 <b>regions</b> [5] 354:15 356:16,17,22 359:24 <b>registered</b> [1] 321:8 <b>Registrar</b> [12] 4:8,14,25 5:10,12,22 95:24 233:19 265:7 296:18 365:25 366:25 <b>Registry</b> [6] 318:23 319:13,24 320:5 321:4,8 <b>regulate</b> [5] 55:7 66:21 241:8,12,14 <b>regulated</b> [6] 10:12 40:13 54:8 55:11 242:5 253:22 <b>regulates</b> [1] 241:5 <b>regulation</b> [5] 53:19 54:12,17,19,23 <b>regulatory</b> [2] 63:1 245:15 <b>related</b> [5] 49:9 243:16 264:17 265:5 267:25</p>	<p><b>relates</b> [2] 215:2 258:18 <b>relation</b> [15] 33:3 41:13 41:24 47:15 49:17 50:13 68:6 81:13 204:14 235:5 246:18 283:18 284:16 287:4,14 <b>relationship</b> [3] 167:12 179:17 211:13 <b>relatively</b> [5] 63:13 83:1 215:8 290:7,10 <b>relevance</b> [4] 55:1 62:14 195:25 197:17 <b>relevant</b> [4] 51:2 106:12 200:7 202:20 <b>reliability</b> [1] 103:12 <b>reliable</b> [1] 240:19 <b>relying</b> [2] 123:19 125:21 <b>remained</b> [2] 29:14,23 <b>remaining</b> [1] 108:7 <b>remains</b> [1] 211:18 <b>remarkable</b> [1] 232:9 <b>remember</b> [16] 210:13 210:15 222:12 237:16 264:20 274:7 301:10 303:12,21 307:16 312:23 319:22 320:25 342:24 343:18 389:10 <b>remind</b> [1] 396:15 <b>remove</b> [1] 346:19 <b>renal</b> [2] 130:6 272:14 <b>repeat</b> [1] 15:17 <b>repeated</b> [2] 27:5 324:5 <b>report</b> [33] 59:5,6,9 62:6 67:15,18 69:20 103:21 206:22 253:7 268:19 299:2 300:12,15 301:1 314:1 327:8 328:14,16 330:17 332:13,14,15,15 334:21 335:7 352:2 366:14 385:13,19 391:21 393:15,23 <b>reported</b> [27] 47:9 58:6 58:14 59:3,7 61:19 68:18 183:17 204:18 206:3,10 225:21,25 226:14 227:22 268:6,11 277:20 309:8 361:19 363:7 368:12,23 370:10,11,12 382:20 <b>reporting</b> [9] 68:20 204:14,24 242:22 253:15 285:2 326:11,15,15 <b>reports</b> [26] 59:4 66:16 66:18 67:3,13,13 68:23 69:2 70:15 240:3 315:4 321:23 324:23 325:25 329:11 338:16 351:5 352:3 370:6 377:8 387:6 388:8 389:5 390:1 391:15 391:19 <b>repots</b> [1] 357:17 <b>represent</b> [4] 77:1 144:5 231:17 252:18 <b>representative</b> [4] 12:10 28:14 29:23 31:17 <b>representatives</b> [4] 12:4 28:10 29:15 30:16</p>	<p><b>reprocessing</b> [1] 275:7 <b>reps</b> [1] 29:2 <b>request</b> [5] 50:3,7 62:22 178:22 299:4 <b>require</b> [1] 107:25 <b>required</b> [4] 37:12,14 340:15 396:17 <b>requirement</b> [7] 15:13 15:15 16:1 42:17,18 156:1 164:25 <b>requirements</b> [2] 16:8 165:9 <b>requires</b> [1] 254:8 <b>requiring</b> [1] 193:1 <b>re-read</b> [1] 366:14 <b>research</b> [3] 19:13 20:20 240:22 <b>residence</b> [1] 232:20 <b>residencies</b> [1] 41:23 <b>residency</b> [6] 7:4 143:10 190:11,15 191:17 256:15 <b>resident</b> [8] 6:22 20:2 20:13 41:22 143:9,12 190:24 256:9 <b>residents</b> [4] 143:11 184:11 191:20 257:24 <b>resigned</b> [1] 313:8 <b>resolve</b> [1] 211:24 <b>resource</b> [8] 95:19 171:25 179:14 184:23 185:11,18,24 304:2 <b>resources</b> [5] 18:6,8 172:13 230:17 233:3 <b>respect</b> [1] 39:6 <b>response</b> [2] 192:5 239:20 <b>responsibilities</b> [3] 179:21 183:4 281:18 <b>responsibility</b> [4] 180:8 278:15 281:10 355:16 <b>responsible</b> [3] 94:15 183:2 187:18 <b>result</b> [44] 47:8 48:12 54:5 59:4 60:5 71:24 77:11 90:24 119:18 124:20 161:2 207:16 211:12 213:19,20 214:15 224:24 235:4 246:24 249:16 250:8 258:1 268:4 268:21 269:10,11 271:5 271:17,18,22 272:17,22 273:1 275:18 277:6,10 277:11,18 293:6 294:1,3 298:16 386:19 396:16 <b>resulted</b> [1] 198:5 <b>results</b> [178] 9:24 10:2 10:22 11:1,2,3,6,9 13:23 13:24 14:2,13 15:3,4,5 16:6 17:19 18:10 25:25 26:20,24 32:12 33:25 34:2 44:8,19,23 45:8 46:12,15,17 47:9 48:12 48:14 50:3,10,18 51:13 57:22 68:20 71:1 77:6,7 79:12 80:8 87:11,12,15 87:16,23,24,25 88:3,20</p>
---	--	--	---	--



<p>89:17 92:13 107:22 108:2 116:25 118:20 138:10,11 141:19,22 142:10,17 145:5,9 146:10 148:2,3 149:1,11,12 150:2,6,20 150:25 151:14,21 153:18 156:19 159:5 160:18,25 166:3,3 169:19 183:16 192:19,22 195:9,23 196:1 196:2,3,4 197:23 198:6 199:5,7,16 201:19 202:9 203:8,10 204:9 208:10 211:15 213:14,15,21 214:13,20,22 215:21,24 217:1,9,18 218:13,19,23 219:13 220:7 221:17 224:12,13,14 227:22 232:11 234:1,5 235:16 235:20 237:5,24 238:2 238:12 241:12 243:16 248:7 249:25 253:15 256:2 258:6 259:17 263:25 266:1 267:20 268:1,11 274:11 275:20 281:21 282:10 285:5 286:5,12 292:8,10 293:17 293:24 294:18 297:4 302:7 311:2 325:20 326:6 352:11 355:2 360:1 363:6 369:25 370:5 371:9,14 372:5</p> <p><b>RESUMES</b> [1] 2:9</p> <p><b>retention</b> [1] 233:1</p> <p><b>retest</b> [7] 309:3,4 330:1 340:21,25 341:1,11</p> <p><b>retested</b> [14] 50:4 153:18 308:7 309:9 324:8 337:6 341:19 371:15,16,16 372:18 377:19 378:12,23</p> <p><b>retesting</b> [11] 336:2 338:13 339:6 340:15 349:20 355:17 366:17 381:25 386:1,4 388:24</p> <p><b>retests</b> [2] 280:6 297:4</p> <p><b>retrieval</b> [22] 77:18 145:3 199:12,14,16,20 200:19,22 201:11,20 208:14 248:12 249:12 250:14,17 269:21 273:10 273:18 274:3 288:23 289:18,19</p> <p><b>retrieve</b> [1] 349:2</p> <p><b>retrospective</b> [1] 103:17</p> <p><b>retrospectively</b> [1] 131:20</p> <p><b>return</b> [5] 41:11,12 354:1 354:2,3</p> <p><b>returned</b> [1] 228:3</p> <p><b>review</b> [40] 32:2,8,22 55:20 100:10 150:4 185:21 226:12 240:17 275:14 278:7,11,18,19 282:9 297:2,20,25 298:23 299:14 302:8 307:19,25 309:2 313:24,25 322:2 331:18 339:14 341:12,17 350:2 374:24 376:7 379:13 382:5,10 386:3,6 386:10</p>	<p><b>reviewed</b> [12] 329:12,25 330:18 338:15 349:8,16 349:22 350:25 381:11 382:14,25 388:7</p> <p><b>reviewers</b> [1] 382:6</p> <p><b>reviewing</b> [11] 33:25 53:14 55:20,21 236:3 315:6 341:7,13 366:16 383:3,7</p> <p><b>reviews</b> [5] 34:10 278:23 280:6,24 301:25</p> <p><b>rewritten</b> [1] 193:9</p> <p><b>Reza</b> [1] 366:13</p> <p><b>Rhodes</b> [8] 221:9 283:6 283:9,12,13,17 285:19 285:22</p> <p><b>right</b> [147] 1:8 8:25 20:14 22:6,17 23:24 29:4,9 31:20 49:6 52:7,11 53:8 56:20 62:18 65:14 69:8 70:3 73:1 75:21 82:24 89:20 91:8 92:21 108:19 111:25 112:15,19 113:1 115:18 116:1 118:17 122:18 132:9 134:4,23 136:3 145:24 152:6,11 152:15,22 153:5 156:2 156:21,25 158:2,7 162:18 164:24 165:17 171:2,7 176:14 177:7,19 178:25 180:17 181:19 193:5 194:17,17 203:8 204:20 206:2,18 207:9,13,19 208:25 216:14 222:19 225:17 230:2,9 234:17 235:25 236:5 238:17 239:5 251:14 255:12 261:7 262:11 269:6,6 271:22 276:16 277:1,13 279:2 280:18 290:19 292:14,20 293:22 317:17 321:16 324:15 325:3,13 327:20 328:7 329:17 333:8,17,22,25 334:2,2 335:11 337:3,14 347:9 348:2,9,14 350:11,20 353:11 355:24 358:25 359:18 361:1 362:17 363:23 365:5 366:19 368:6,8,21 369:1,21 370:8,23 371:6 374:11 384:18,24 386:9 387:19 387:21 388:3 393:7,17 395:11 396:12</p> <p><b>rightly</b> [1] 69:3</p> <p><b>rise</b> [2] 166:4 202:6</p> <p><b>Rituxan</b> [2] 60:9 62:4</p> <p><b>role</b> [14] 32:16 170:4,7 220:19,23,25 239:17 247:19,20,25 286:21 298:6 304:15 305:21</p> <p><b>Rolf</b> [1] 1:8</p> <p><b>room</b> [6] 74:16 176:23 252:7 296:1 342:11 396:14</p> <p><b>roots</b> [1] 298:9</p> <p><b>rotate</b> [1] 257:24</p> <p><b>rotating</b> [1] 182:13</p> <p><b>rough</b> [2] 316:12 319:22</p>	<p><b>roughly</b> [1] 317:3</p> <p><b>round</b> [2] 77:4 205:13</p> <p><b>rounds</b> [1] 252:7</p> <p><b>routine</b> [5] 18:24 19:1 26:12 236:6 246:1</p> <p><b>routinely</b> [3] 18:25 115:15 195:22</p> <p><b>row</b> [1] 92:11</p> <p><b>Royal</b> [2] 81:1 234:2</p> <p><b>rule</b> [3] 244:20 269:15 344:5</p> <p><b>ruled</b> [1] 57:13</p> <p><b>rules</b> [2] 65:18 270:25</p> <p><b>ruling</b> [2] 45:1 77:20</p> <p><b>run</b> [82] 15:3,3,18 16:3 19:5 31:11 34:20 36:17 44:21 80:7 135:16 136:14 138:9,11 142:17 146:2 146:20,20,21,25 147:5 147:15,17 148:11,13,19 148:21,21,22,24 149:1,1 149:5,11,18,18 150:6,6 150:6,9,9,10,18 153:6 153:25 154:4,6,8,9 159:10 173:17 175:15 185:13 195:6 205:13 217:12,15,15 219:23 223:21 224:20,24 225:3 226:18 227:2,2 228:13 248:23 264:15 267:23 276:18 288:13,15 291:15 291:19 292:4 294:12,16 294:18,24 299:8 386:16</p> <p><b>runs</b> [10] 34:7 147:6 148:3 151:13 217:12 223:20 251:5 264:16,16 267:23</p> <hr/> <p style="text-align: center;"><b>-S-</b></p> <hr/> <p><b>s</b> [4] 11:16,16 182:22,22</p> <p><b>S100</b> [3] 66:8 144:25 214:2</p> <p><b>sample</b> [5] 79:15 204:8 214:9 216:7 255:9</p> <p><b>samples</b> [24] 9:17 33:16 68:2,3,4 77:10 79:6,10 90:17 92:15 110:21 136:23,23 138:13 149:3 154:23 156:3,6,7,15,17 199:6 227:9 354:15</p> <p><b>sampling</b> [1] 210:25</p> <p><b>Sandra</b> [3] 1:7 2:10 296:6</p> <p><b>sarcoma</b> [2] 137:7 144:12</p> <p><b>Saskatchewan</b> [8] 81:2 86:10 164:14,24 165:1 173:19 260:24 261:2</p> <p><b>Saskatoon</b> [4] 81:18 82:9 83:18 279:24</p> <p><b>save</b> [1] 23:4</p> <p><b>saw</b> [6] 26:4 166:4 205:13 217:4 220:5 337:22</p> <p><b>says</b> [22] 58:8 65:14 98:15,17 100:3 159:12 204:5 235:11 239:5</p>	<p>240:18 249:8 284:19 296:23 307:9 308:3 310:25 316:12 319:21 320:16 333:19 369:16 391:24</p> <p><b>scale</b> [2] 144:12 234:14</p> <p><b>scan</b> [3] 160:21 255:23 256:1</p> <p><b>Scandinavia</b> [5] 14:10 104:6 166:5 212:15 221:20</p> <p><b>Scandinavian</b> [4] 12:4 12:8 40:5 103:8</p> <p><b>scenario</b> [1] 215:11</p> <p><b>schedules</b> [1] 303:7</p> <p><b>schemes</b> [1] 66:12</p> <p><b>school</b> [2] 6:9,12</p> <p><b>schools</b> [1] 188:4</p> <p><b>science</b> [4] 18:6 53:23 201:22,25</p> <p><b>sciences</b> [4] 188:4 317:23 318:3,7</p> <p><b>scientific</b> [4] 61:2 143:11 150:3 167:24</p> <p><b>scientifically</b> [2] 240:21 286:8</p> <p><b>scope</b> [2] 187:13 264:17</p> <p><b>score</b> [24] 44:9 46:3 50:19,21,22 51:9 66:13 66:14 77:8 242:21,24 243:1,2,5,9,9,12,13,25 244:3,6,21 256:6 281:4</p> <p><b>scored</b> [2] 144:12 256:11</p> <p><b>scores</b> [4] 50:18 87:19 144:13 256:2</p> <p><b>scoring</b> [7] 33:25 46:4 107:22 243:4,21 257:11 281:7</p> <p><b>Scotian</b> [1] 98:13</p> <p><b>screen</b> [4] 16:22 88:21 122:2 377:22</p> <p><b>search</b> [4] 316:25 339:23 351:19,21</p> <p><b>searched</b> [1] 315:4</p> <p><b>searches</b> [2] 383:24 384:1</p> <p><b>searching</b> [1] 384:4</p> <p><b>seated</b> [2] 127:13 178:20</p> <p><b>second</b> [8] 5:22 31:16 96:14 101:12 200:18 284:6 300:2 360:11</p> <p><b>second-last</b> [2] 106:9 163:16</p> <p><b>secondary</b> [3] 145:3 374:24 376:12</p> <p><b>secondly</b> [3] 232:25 257:13 296:23</p> <p><b>section</b> [3] 64:16 235:10 239:5</p> <p><b>sections</b> [5] 18:3 194:11 243:17 244:13 270:7</p> <p><b>see</b> [148] 16:14,21 32:24 32:25 37:6 43:14,25 44:10,22,23 47:14 50:4 54:17 65:5 66:23 77:6,9</p>	<p>79:11 84:14 87:9,11,11 87:12,24 88:25 89:3,7 89:13 90:21 92:13,18 99:14 118:1,16 119:3,14 119:16 125:14 132:17 133:10 135:16 138:18 148:18 149:10 150:20 153:23 161:20 169:11 174:23 175:22 176:23 183:9 191:2 198:14,19 198:23 202:17 206:2,14 207:23 213:15,19,21 214:6,10,18 215:1,12,18 215:22 217:1,13,17,23 218:8,12 219:18,19,23 219:25 225:2 229:10,16 237:24 240:25 241:3,19 245:11 250:1 251:4 255:25 256:6 258:11 259:24 263:20 268:8 276:4 279:13 280:3 288:11 289:6 290:17 298:11 300:25 308:15 309:14,19 311:25 319:15 322:17 325:7 326:24,24 327:4 328:7,7 329:13 330:15 333:19 334:4 335:18 336:13,14 345:8 348:19 350:13 352:4,19 357:21 359:15 360:11 362:21,22 365:17 368:8 368:16 369:25 377:17 384:2 385:9,14 386:18 387:2 392:6 393:14,19 394:14 395:25</p> <p><b>seeing</b> [10] 9:17 19:6 82:19 140:14,25 286:19 303:12 377:24 395:9,13</p> <p><b>seem</b> [4] 55:23 305:12 367:1 382:16</p> <p><b>select</b> [3] 36:18 90:20 293:12</p> <p><b>selected</b> [6] 28:7 33:16 44:15 144:7 150:11 270:9</p> <p><b>selecting</b> [2] 232:14 250:9</p> <p><b>selection</b> [2] 185:11 239:13</p> <p><b>self</b> [3] 45:22 134:4 256:7</p> <p><b>self-evident</b> [1] 172:25</p> <p><b>sell</b> [1] 159:21</p> <p><b>semi</b> [1] 242:11</p> <p><b>seminars</b> [5] 35:2 39:7 39:13,14,18</p> <p><b>send</b> [15] 33:17,20,22,24 36:11 50:18 89:13 138:2 175:17 226:19 336:8 338:19 347:13 373:19 386:4</p> <p><b>sending</b> [2] 26:9 379:19</p> <p><b>sends</b> [1] 46:19</p> <p><b>sense</b> [26] 13:17 16:18 19:7 23:3,5 34:17 40:21 50:2,6 55:7 65:23 71:15 105:16 138:15 160:15 164:2 173:21 183:21 192:21 202:15 215:17 241:21 242:14 251:7 285:24 373:25</p>
---	---	---	---	--

<p><b>sensible</b> [2] 154:19 156:11 <b>sensitive</b> [10] 17:16 157:20,21 193:22 195:21 197:11,13 198:11,11 200:11 <b>sensitivities</b> [1] 205:24 <b>sensitivity</b> [31] 67:9,12 67:16,19 68:5,11,24 69:16 70:5 106:21 192:18 197:6 198:19 199:17 200:9,10 202:5,24 203:4 203:14,17,18 204:7,7,17 205:1,11,25 206:3,8 240:3 <b>sent</b> [41] 25:24 27:7 46:3 47:4 98:2,5 99:9 100:22 104:25 139:19 140:2 304:8 305:11 318:2,11 336:2 338:13,18 339:5 349:20 350:7,7 352:11 355:17,22 356:16,24 359:20 374:4,22,22 375:3 375:14,22,24,24 376:5 381:6 382:2 386:1 388:24 <b>sentence</b> [1] 320:15 <b>sentiment</b> [1] 285:24 <b>separate</b> [12] 40:11 50:20 59:4 62:16 84:8 144:13 171:3 219:3 227:9 351:15,17 352:3 <b>separated</b> [1] 373:10 <b>separately</b> [5] 61:20 62:6 211:5 216:12 256:15 <b>September/October</b> [1] 355:18 <b>serve</b> [1] 104:17 <b>service</b> [6] 49:8,20 104:23 161:15,17 162:1 <b>services</b> [3] 33:6,7 50:14 <b>set</b> [18] 24:25 25:15 27:11 75:16 85:14 86:17,17 92:25 112:23 137:14 154:12 179:20 196:17 282:14 298:19 301:14 329:25 342:15 <b>setting</b> [3] 95:17 144:10 229:21 <b>settled</b> [2] 193:11 312:18 <b>setup</b> [2] 20:15 182:12 <b>seven</b> [1] 7:17 <b>several</b> [13] 13:9 27:5 32:21 73:8 92:16 101:24 135:19 249:1 254:9 261:17,25 305:17 363:4 <b>shall</b> [1] 12:14 <b>Shannon</b> [1] 143:16 <b>shared</b> [1] 240:7 <b>sharing</b> [1] 251:16 <b>sheer</b> [3] 59:20 63:13 154:23 <b>sheet</b> [6] 50:19 51:9 335:9 338:4 391:17 396:5 <b>sheets</b> [11] 325:18 327:24 329:10,13,25 348:24 358:18 373:10,11 391:16</p>	<p>393:5 <b>shifted</b> [3] 139:9 146:6,8 <b>shipping</b> [1] 84:23 <b>shocked</b> [2] 286:5,7 <b>short</b> [3] 34:10 128:1 177:13 <b>shortage</b> [2] 172:2,3 <b>shortages</b> [1] 171:25 <b>shorter</b> [1] 97:1 <b>shortlisted</b> [1] 163:7 <b>shortly</b> [2] 313:6 379:12 <b>show</b> [31] 10:22 15:3 21:7 26:20 36:2 46:13 53:15 65:2 78:7 89:25 96:13 116:25 148:6 150:14 166:24 167:25 201:18 212:22 217:12 218:6 219:25 229:4 230:7 235:14 248:15 249:24 258:5 316:13 344:16 391:17 392:12 <b>showed</b> [8] 10:23 30:21 82:4 221:16 241:13 242:4 243:22 358:16 <b>showing</b> [4] 50:10 59:25 249:2 365:23 <b>shown</b> [6] 77:21 152:2 246:19 252:23 264:10 284:12 <b>shows</b> [15] 6:2 50:19 58:23 75:2 118:21 119:1 120:5 213:13,16 220:14 234:13 249:3,4,19 344:16 <b>shrink</b> [1] 28:13 <b>side</b> [22] 47:23 52:17 83:23 87:23,23 122:3 148:19 159:19,19 179:19 182:1,4 186:11 256:3 321:4 327:21 353:8 388:18,22 394:1,10 396:6 <b>signal</b> [5] 197:5 198:14 213:18 214:6 272:21 <b>significance</b> [8] 70:1 107:21 117:4 126:20 253:14 254:24 358:2,4 <b>significant</b> [4] 95:5 144:23 156:19 225:20 <b>similar</b> [18] 51:16,17 62:1 129:18 145:1,1 196:7 199:5 221:17 235:17 291:19,20,24 293:21 339:13 384:2,4 385:4 <b>similarly</b> [2] 144:22 214:20 <b>Simmons</b> [118] 1:10 2:5 176:19,20 177:24 178:8 178:20,21 181:8,10 190:4 190:5,6,7 191:1,5,15 192:1,11,23 193:16,24 194:6,13,18,22 195:13 195:17 196:11,15,20 197:21 198:1 199:1 200:17 201:21 202:22 203:9,13,21 204:12,21 205:4,10,18 206:1,13,19 206:25 207:5,10,14,20</p>	<p>208:1,21 209:1,10,16,24 210:10 211:17,22 212:3 212:13,25 213:5 216:13 216:19,23 217:25 218:21 219:8,15 220:11,16,24 221:6,15,23 222:8,15,20 223:7,15,19 224:1,8,19 224:23 225:7,16 226:2 226:10,17,24 227:4,8,14 227:19 228:1,6,12,25 229:9,20 230:3,12,24 231:6,10,22 235:1 245:6 287:4 288:6 332:6,12,20 <b>simple</b> [9] 21:15 45:9 66:16 74:25 75:1,22 82:4 83:1 182:24 <b>simplicity</b> [2] 66:18 67:3 <b>simply</b> [4] 71:7 84:23 173:11 182:17 <b>Sinai</b> [5] 188:7,7 296:22 374:9,14 <b>single</b> [10] 63:25 66:13 133:4 134:5 341:24 352:1 366:14 378:9 379:18 383:17 <b>sit</b> [3] 44:9 163:14 382:10 <b>site</b> [8] 32:22 35:4 63:3 77:6 264:24 265:8 281:24 297:1 <b>sites</b> [2] 52:20 55:21 <b>sitting</b> [1] 44:12 <b>situ</b> [3] 20:25 21:4 149:7 <b>situation</b> [7] 42:1 81:13 105:21,25 131:24 132:10 304:23 <b>situations</b> [2] 117:10 191:20 <b>six</b> [20] 17:2 96:20 97:3 130:10,16,25 131:3 147:19 153:11 157:24 158:4,10 213:10,14 214:12 216:5 218:3 250:25 288:16 311:3 <b>size</b> [2] 179:23 255:9 <b>skill</b> [3] 6:4 183:23 270:3 <b>skills</b> [3] 192:21 193:2 229:13 <b>skillset</b> [1] 233:2 <b>skip</b> [1] 90:7 <b>skipped</b> [1] 252:8 <b>slide</b> [39] 16:14 19:4 35:17,21 37:6 41:12,14 43:5 46:20 59:25 67:5 77:3 78:17,19,21 91:11 91:21,23 93:11 122:1,2 123:19 124:3 125:4,5 153:22 154:15 166:24 168:7 174:4 219:25 249:24 259:23 264:11 267:1 268:7 271:4,24 379:18 <b>slides</b> [54] 26:9 33:17,22 35:15 36:24 38:1,6,16 44:9 45:24 46:3,4,4,19 50:3 135:12 137:14 138:2 139:13,19 140:2 144:4 160:14,22 168:8 175:17 179:13 212:22 213:3</p>	<p>226:20 227:10,20 228:2 228:8 253:18 255:23 256:1 270:20 301:8 308:11 340:23 349:3 375:3 379:8,10 381:5,11 381:21 382:9,11,14 383:1 383:5,7 <b>slightly</b> [2] 110:8 169:9 <b>slow</b> [1] 8:20 <b>slower</b> [1] 9:5 <b>small</b> [27] 11:11,13 65:25 66:1 79:18 133:5 138:14 160:11 173:11 180:1 189:2,3,9,15,19 208:9 208:16,22 209:2 212:21 216:14 228:21 229:3,7 262:11 285:7 365:18 <b>smaller</b> [6] 41:3 43:22 160:9 188:9,16 227:2 <b>snap</b> [1] 346:22 <b>Societies</b> [1] 100:18 <b>Society</b> [2] 1:15 252:20 <b>solution</b> [5] 76:25 78:14 86:4 200:21 211:10 <b>solutions</b> [3] 152:23 201:11 347:1 <b>solve</b> [1] 172:5 <b>solved</b> [2] 94:14 249:18 <b>solving</b> [1] 104:10 <b>someone</b> [10] 24:2 87:24 232:17 233:2 259:22 332:4 337:23 375:19 377:2 379:17 <b>Sometime</b> [1] 147:15 <b>sometimes</b> [11] 46:11 69:6 94:14 102:11 268:11 272:6 276:9 277:8 313:3 331:23 335:7 <b>somewhat</b> [8] 7:3 124:14 192:7 245:5 290:16,22 290:24 291:7 <b>somewhere</b> [4] 132:2 162:16 371:1 379:20 <b>soon</b> [1] 41:4 <b>sophisticated</b> [1] 182:14 <b>sophistication</b> [2] 171:18 188:17 <b>sorry</b> [33] 9:22 10:19 22:8 30:17 33:20 34:25 43:11 46:20 51:22 55:13 80:23 103:25 104:1,21 122:12 125:5 145:1,12 146:1 147:13 165:19 171:6 180:19 182:1 236:8 254:14 290:22 332:21 361:5 368:19 384:14,24 385:11 <b>sort</b> [27] 186:3,3 187:24 232:20 234:5 237:12 239:23 245:6,8,11 246:19 246:19 251:12,15,15,23 258:21 261:7 279:8 282:7 291:24 301:14,16 306:12 309:6 325:8 354:10 <b>sorts</b> [2] 50:13 184:22 <b>sought</b> [1] 162:24</p>	<p><b>sound</b> [1] 397:10 <b>sounds</b> [2] 209:7 211:18 <b>source</b> [4] 18:8 163:9,12 258:8 <b>sources</b> [6] 162:23,24 163:5,8 258:10 276:8 <b>speak</b> [14] 8:20,21,22 41:18 67:8 80:15 104:2 146:21 183:7 196:12 204:6 213:22 313:12 335:22 <b>speaking</b> [5] 64:13 202:23 267:16,18 269:15 <b>special</b> [9] 6:4 42:16 60:10 128:13 151:5 180:4 180:4,7 182:15 <b>specialist</b> [3] 24:19 90:10 181:21 <b>specialists</b> [3] 13:18 109:20 191:13 <b>specialized</b> [4] 10:10,10 23:9 108:3 <b>specific</b> [14] 22:25 51:5 60:6 63:24,25 65:7 125:8 125:9 210:7 219:24 242:25 271:25 272:16,19 <b>specifically</b> [15] 57:6 90:11 117:20 191:12 197:2 198:15 204:4 265:22 266:23 268:4 299:13 309:2 320:25 321:10 333:3 <b>specifications</b> [1] 297:22 <b>specificity</b> [7] 64:1,3 67:9 69:17 106:21 266:21 267:5 <b>specifics</b> [1] 272:8 <b>specified</b> [2] 130:25 143:23 <b>specimen</b> [11] 74:17 103:20 160:24 253:6 254:10 268:23 318:6 321:9 353:21,25 386:20 <b>specimens</b> [23] 8:8 83:22 236:5,6 256:5,13 257:4 257:10,18 258:3 275:23 278:8 280:7 317:5,22,25 325:6 352:9 364:12 369:5 371:25 372:4 390:5 <b>spectro</b> [1] 180:1 <b>spectrum</b> [1] 258:6 <b>spell</b> [1] 4:9 <b>spelled</b> [4] 60:2 76:10 92:10 155:12 <b>spend</b> [1] 379:14 <b>spending</b> [1] 381:2 <b>spent</b> [4] 6:14,18 7:17 301:23 <b>spoke</b> [4] 305:8 313:2 339:19 349:1 <b>spoken</b> [5] 41:13 199:8 233:24 260:7 313:10 <b>sponsorship</b> [1] 31:9 <b>spot</b> [1] 390:13 <b>spread</b> [2] 116:20 213:13</p>
--	--	---	---	---

<p><b>spreadsheet</b> [14] 315:9 316:4 321:21 324:25 330:23 337:25 338:8,10 351:1,12 353:9 368:4 377:18 384:16</p> <p><b>spreadsheets</b> [14] 315:7 315:8,14 320:17 321:16 324:24 335:19 350:3 354:9 358:5,22 371:12 383:13 390:17</p> <p><b>spurred</b> [1] 212:6</p> <p><b>St</b> [32] 6:16 127:20 297:19 312:15 325:1,9,11,13,15 325:17,17 339:13 354:3 359:24,25 363:7 365:19 369:12,17,18 370:4,11 370:15 371:4,8 374:23 376:17,23 389:20 390:7 397:7,11</p> <p><b>stack</b> [4] 325:24,25 354:20,21</p> <p><b>staff</b> [5] 185:2 188:25 301:9 305:25 396:17</p> <p><b>stage</b> [8] 117:16,18,18 118:11,13 126:19 259:23 335:18</p> <p><b>stages</b> [1] 129:19</p> <p><b>staging</b> [2] 116:19 118:15</p> <p><b>stain</b> [11] 33:23 36:12,14 55:16 89:18 133:10 136:24 140:16 144:4 166:24 227:10</p> <p><b>stained</b> [6] 36:6 46:20 119:2 139:19 140:2 272:19</p> <p><b>staining</b> [52] 34:4,6 36:7 45:1 47:13 51:1,16 87:13 117:11 119:15 120:4 144:16,21 193:1 197:10 197:12 213:14,17 228:8 228:16 241:18,24 267:25 268:15,17,18 269:4 271:4 271:15,19,25 272:5 273:7 275:16,16,24 276:3,4,8 277:4,9,16 295:8,9 297:17 299:22 358:13 361:6 368:13,24 382:15 382:19</p> <p><b>stains</b> [11] 36:24 89:22 90:6 112:7 141:17 144:12 189:10 193:3 223:22 224:20 299:6</p> <p><b>stand</b> [5] 2:9 47:14 58:12 58:13 77:24</p> <p><b>stand-alone</b> [3] 59:3,10 61:19</p> <p><b>standard</b> [16] 71:25 183:13 210:19,20,22,24 211:8 212:2 227:11 244:23,24 259:12 293:14 293:14 329:23 330:3</p> <p><b>standardization</b> [14] 11:25 71:2,3,22 72:10 72:22,24 108:5 145:12 145:13 168:21 293:9,16 293:17</p> <p><b>standardize</b> [14] 71:4,5 71:9,10,13,14,17,18,24</p>	<p>72:10,13 73:2,10 293:10</p> <p><b>standardized</b> [5] 54:7 72:12,15 73:15 80:14</p> <p><b>standardizing</b> [1] 71:8</p> <p><b>standards</b> [29] 62:19 70:19,23 72:17 95:10 100:3 101:18,23 102:9 102:10 123:25 157:18 163:2 165:5 170:1,2,3,8 170:10,19,23 171:7,13 171:21 172:20,21,24,25 173:3</p> <p><b>standing</b> [1] 206:11</p> <p><b>stands</b> [1] 90:15</p> <p><b>start</b> [25] 10:3 30:3 72:23 72:24 84:15 86:9 116:12 179:24 219:14 225:14 239:24 286:19 293:8 297:2,25 298:12 315:21 344:8,24 345:4,6,23 394:17,20 396:19</p> <p><b>started</b> [30] 7:20 8:1 10:2 14:20 25:16 28:12 29:2 41:4 43:17 44:21 54:14 67:14 81:12 102:4 135:16 135:17 137:11 149:17 164:21 193:20 212:5,21 213:10 236:4,12 315:18 329:10 345:18 378:6 383:6</p> <p><b>starting</b> [6] 17:16 212:5 255:18 314:6,8 394:14</p> <p><b>starts</b> [2] 74:2 154:7</p> <p><b>state</b> [6] 4:9 72:7 95:5 132:13 174:2 175:12</p> <p><b>statement</b> [4] 67:16 204:25 342:25 343:19</p> <p><b>states</b> [12] 6:13 20:10 26:11 41:20,25 43:15 63:1 103:2 104:3 157:15 162:2 242:19</p> <p><b>statistic</b> [1] 367:22</p> <p><b>statistical</b> [4] 154:20 155:16,21 216:7</p> <p><b>statistically</b> [2] 156:19 280:16</p> <p><b>statistics</b> [1] 370:6</p> <p><b>stats</b> [4] 345:8 358:19 367:25 373:15</p> <p><b>status</b> [2] 318:25 319:2</p> <p><b>step</b> [5] 20:24 49:2 74:11 340:25 349:1</p> <p><b>Stephenville</b> [1] 355:15</p> <p><b>steps</b> [7] 55:19 175:24 226:12 254:12 255:19 256:4 277:6</p> <p><b>still</b> [47] 15:25 29:24 40:16 44:22 56:24 74:22 78:10,11 79:14 93:13 134:6 150:20 153:9 156:5 166:6 175:19 195:4 197:15 198:10,16 202:2 205:21,21 211:18 217:9 244:16,19,19 277:10 281:20 288:2 290:12 306:2 314:5,17 329:21 329:22 336:12 344:19</p>	<p>357:2,5,7 365:3 371:6,6 371:20 387:1</p> <p><b>stomal</b> [1] 62:13</p> <p><b>stopped</b> [2] 317:1 382:4</p> <p><b>stored</b> [1] 346:23</p> <p><b>straightforward</b> [1] 368:11</p> <p><b>strange</b> [2] 198:21 356:21</p> <p><b>stratify</b> [1] 126:10</p> <p><b>strictly</b> [1] 344:3</p> <p><b>stroke</b> [1] 327:9</p> <p><b>strong</b> [14] 11:12 76:3 150:17 213:17 242:15 352:8,16 353:7 362:23 363:16 368:2,13,16 372:24</p> <p><b>stronger</b> [2] 48:21 197:12</p> <p><b>strongly</b> [2] 242:8 378:2</p> <p><b>struck</b> [2] 379:16 392:23</p> <p><b>structure</b> [3] 160:10 199:25 245:9</p> <p><b>structured</b> [5] 44:2 168:1 179:20 184:10 212:18</p> <p><b>stuck</b> [1] 376:10</p> <p><b>studies</b> [14] 77:25 201:5 201:6 210:14,16 221:10 221:18 226:4 239:18 241:2 242:25 248:9 251:7 274:19</p> <p><b>study</b> [11] 10:21 146:19 209:25 212:14,18,21 215:4 219:4 274:6 283:18 284:15</p> <p><b>stuff</b> [6] 30:8 87:13 301:18 347:18 382:18 391:16</p> <p><b>sub</b> [3] 218:12 225:5 226:6</p> <p><b>sub-optimal</b> [6] 15:17 214:12 217:20 218:18 225:9,18</p> <p><b>subcommittees</b> [1] 170:18</p> <p><b>subject</b> [4] 53:11 98:16 108:6 244:16</p> <p><b>subjected</b> [1] 114:17</p> <p><b>submitted</b> [5] 99:15 101:8 150:3 169:5 346:21</p> <p><b>success</b> [6] 15:16 45:1 138:17 166:21 247:8 249:23</p> <p><b>successful</b> [3] 151:1 153:3,7</p> <p><b>such</b> [48] 58:6 60:3 62:3 69:14 70:4,24 72:19 78:15,16 84:10 85:14 86:18 93:7 98:7 103:9 104:16,20 109:21 155:15 161:18,19 164:25 165:15 173:24 180:6 182:21 183:10 186:25 190:18 196:1 201:5 207:6,6 210:16 229:7 231:3 248:3</p>	<p>257:17 258:8,9 270:9,25 275:23 278:18,24 287:14 314:18 356:12</p> <p><b>suddenly</b> [2] 17:18,24</p> <p><b>sufficient</b> [5] 15:22 61:2 82:6 156:8 168:2</p> <p><b>sufficiently</b> [1] 264:1</p> <p><b>suggest</b> [7] 105:2 107:5 157:16 206:20 296:2 378:22 379:24</p> <p><b>suggested</b> [4] 83:19 106:14 379:21 380:19</p> <p><b>suggesting</b> [2] 107:4 396:19</p> <p><b>suggestions</b> [3] 76:21 168:20 249:10</p> <p><b>sum</b> [1] 161:10</p> <p><b>summaries</b> [1] 249:23</p> <p><b>summarize</b> [5] 34:15 138:12 144:1 239:24 251:4</p> <p><b>summarized</b> [2] 141:20 148:22</p> <p><b>summarizes</b> [1] 142:22</p> <p><b>summary</b> [7] 6:2 32:11 32:24 92:6 97:3 99:14 142:4</p> <p><b>summer</b> [3] 111:4 136:5 168:17</p> <p><b>superficial</b> [1] 67:2</p> <p><b>superior</b> [1] 77:22</p> <p><b>supernatant</b> [1] 347:6</p> <p><b>supervision</b> [4] 103:18 179:11 182:18 253:5</p> <p><b>supplied</b> [2] 107:3 236:8</p> <p><b>supplier</b> [1] 212:9</p> <p><b>Suppliers</b> [1] 290:14</p> <p><b>supply</b> [1] 12:22</p> <p><b>support</b> [12] 14:18 86:14 86:15,16 94:11,12 104:15 105:19 160:11 167:22 171:23 267:17</p> <p><b>supported</b> [4] 12:16 13:9 262:14 286:9</p> <p><b>supporters</b> [1] 13:11</p> <p><b>supports</b> [2] 31:12 133:10</p> <p><b>suppose</b> [2] 103:3 152:18</p> <p><b>supposed</b> [3] 11:7 36:14 377:3</p> <p><b>surgeon</b> [2] 73:16 346:18</p> <p><b>surgery</b> [4] 73:13 188:24 189:1 254:6</p> <p><b>surgical</b> [7] 7:2,6 73:17 315:3 322:6 353:20,22</p> <p><b>surprised</b> [3] 149:10 224:11,17</p> <p><b>surprising</b> [5] 84:4 138:18 148:6 216:8 218:17</p> <p><b>surrounded</b> [1] 76:5</p> <p><b>surrounding</b> [2] 232:3 297:12</p> <p><b>survey</b> [4] 68:3 174:23</p>	<p>175:21 220:1</p> <p><b>surveyed</b> [1] 225:20</p> <p><b>surveys</b> [1] 106:10</p> <p><b>Susan</b> [1] 349:18</p> <p><b>suspicious</b> [1] 133:8</p> <p><b>Swason</b> [1] 20:9</p> <p><b>swear</b> [1] 310:22</p> <p><b>Sweden</b> [1] 13:14</p> <p><b>Swedes</b> [1] 28:3</p> <p><b>switch</b> [1] 276:5</p> <p><b>switched</b> [1] 31:8</p> <p><b>SWORN</b> [2] 2:2 4:6</p> <p><b>system</b> [43] 74:18 153:15 169:19 196:12,24 197:4 197:6,11 198:3,7,25 199:9 202:11 208:19 214:4,14 244:21 271:7 271:11 276:6 297:14,20 298:24 299:15 300:8 301:5,12,13 308:1,5,14 317:4 318:8,15 324:22 326:16 351:15,16,20,22 359:16 371:2 382:4</p> <p><b>systematic</b> [1] 274:5</p> <p><b>systems</b> [14] 173:13 183:12 193:22 195:21 196:9 197:13 198:17,18 274:9 290:25 291:1,6 295:9 341:21</p> <hr/> <p style="text-align: center;"><b>-T-</b></p> <hr/> <p><b>t</b> [14] 4:12 11:16 20:22 21:11 128:19,19,25,25 129:21 162:15 182:22,22 182:22 257:21</p> <p><b>table</b> [8] 2:1 77:5 234:20 237:4,7,9 291:19,20</p> <p><b>tables</b> [2] 366:8,9</p> <p><b>takes</b> [3] 83:22 101:9 219:20</p> <p><b>taking</b> [2] 155:20 334:17</p> <p><b>Tamoxifen</b> [1] 126:16</p> <p><b>target</b> [12] 60:10 97:25 203:6 207:21,22 235:12 235:20 240:24 241:24,25 255:14 293:7</p> <p><b>targeted</b> [1] 239:14</p> <p><b>targets</b> [3] 62:14,15 241:9</p> <p><b>task</b> [4] 7:17 22:25 168:16 366:13</p> <p><b>tasks</b> [2] 165:7 182:24</p> <p><b>taught</b> [1] 258:13</p> <p><b>teaching</b> [1] 201:4</p> <p><b>tech</b> [1] 301:15</p> <p><b>technical</b> [12] 66:20 92:16 94:10 108:1 179:15 179:18 232:8 296:24 297:5,19 307:10 314:3</p> <p><b>technically</b> [6] 21:17 54:6,9 66:22 106:20 149:13</p> <p><b>technicians</b> [2] 299:7 299:19</p>
---	---	--	--	---

<p><b>technique</b> [8] 10:12 11:9 21:6,7 53:24 232:11 273:23 276:21</p> <p><b>techniques</b> [5] 17:11 54:10 242:9 258:19 276:24</p> <p><b>technological</b> [1] 191:10</p> <p><b>technologist</b> [6] 94:15 143:17 182:6,16 183:1 276:22</p> <p><b>technologist's</b> [1] 305:18</p> <p><b>technologists</b> [18] 35:4 35:6,11 39:19,20 75:19 87:22 94:4 172:3 182:12 185:19 221:2 301:24 302:15 305:9,13,21 374:18</p> <p><b>technology</b> [12] 20:16 44:18 45:5 55:10 72:7 94:25 160:21 182:11 185:1 192:24 198:4 199:3</p> <p><b>teleconference</b> [1] 160:23</p> <p><b>telling</b> [5] 34:1 64:13 125:5 305:2 308:21</p> <p><b>tells</b> [5] 131:24 132:25 249:6,10 314:1</p> <p><b>temperature</b> [1] 250:19</p> <p><b>temperatures</b> [1] 289:14</p> <p><b>temporary</b> [1] 182:18</p> <p><b>ten</b> [28] 114:6 177:17 178:6,17 194:14 197:7 199:2 200:23 217:15 232:9 233:5 238:6 251:6 267:24 288:9 309:8 323:4 323:15 327:18 330:8 331:23 332:5 337:9,14 339:24 342:13 395:1 396:1</p> <p><b>term</b> [4] 70:23 71:2 173:4 202:24</p> <p><b>terms</b> [35] 24:4 42:5 59:19 63:12 81:13 89:16 108:13 134:17 146:3 148:3 172:17 174:1 232:2 232:13,15 245:9 246:20 248:2,8 260:6 267:22 277:3,24 283:7,17 284:15 290:16 300:3 305:7 307:21 337:16 338:7 344:7 377:8 385:24</p> <p><b>territorial</b> [1] 171:24</p> <p><b>Terry</b> [9] 2:9 296:6,25 307:11 308:3,6 312:17 312:20 320:16</p> <p><b>tertiary</b> [2] 216:15 390:8</p> <p><b>test</b> [127] 36:19 37:8,12 37:13,14,14 50:17 60:4 60:5,7,11 62:9,17,21 63:25 66:13 67:12,16,22 68:6,13 69:14,17 71:10 71:18,25 72:8 76:13,19 77:24 78:19 90:13,20 103:12 110:20,24 113:22 114:14 116:24 117:5 120:12,16 121:4,6 131:25</p>	<p>133:6,9 141:25 154:7,21 161:20 166:8,13,19,22 167:2 169:15,19 174:19 180:2 192:19 198:6 199:6 202:1 203:5,18 204:7,9 204:18 205:1 206:8,12 206:16 207:6 208:9,17 209:5 213:12 215:21 216:11 217:9,21 218:5 219:13 225:13 229:15 230:10 239:11,12 247:9 247:13 249:4,6 250:1,13 250:15 253:5,13,17 256:4 257:12 267:22 268:22 269:9,11 270:6,18 274:15 275:3,4,18 277:21 318:3 318:11,15 326:17 342:5 342:9 346:3,4 351:3 352:14 356:15 358:9 361:18 379:9 386:6</p> <p><b>tested</b> [19] 34:8 79:11 114:1,4,12,13 115:15,23 144:6 197:19 198:22 210:14 269:17 311:1 317:11 322:18,23 324:25 378:10</p> <p><b>testify</b> [1] 231:19</p> <p><b>testimony</b> [3] 5:9 7:25 177:3</p> <p><b>testing</b> [79] 1:2,13 33:17 54:5 66:20 68:1 77:19 81:15 86:25 92:13 100:4 104:13 109:22 120:21 135:18 154:19 156:4,12 166:21 174:7 179:15 187:25 188:1 191:18 196:22 199:4 201:22 204:15,25 205:13 206:7 209:12 210:5 211:23 212:7 213:25 218:7 219:13 221:25 222:4,17 223:9,12 227:16 230:7,9 230:18 245:21 254:7,12 254:18 258:18,19 263:1 263:4,20 264:17 265:6 266:1,15,21 267:3,5,14 270:9,17 274:23 284:21 284:22 317:1,5,24 318:25 321:7,11 344:24 345:1 345:23 397:4</p> <p><b>tests</b> [171] 10:11 34:20 36:17 37:13,16 52:25 55:2 56:10,11,14 57:9 57:17,19,23 58:11,13 59:10,11,18,19,22,23 60:2,3,14 61:4,14,19 62:1,20 63:23 64:22 66:11,17,22,24 67:1,9 68:4 70:6 76:12,15 77:4 79:1 80:14 92:23 100:13 103:22 106:2,2,3,22 107:3,18,21,24,25 108:6 108:8 109:7,12 111:23 112:12,24 113:10,11,14 113:16,18,18,24 114:3,8 114:12 115:1 116:14,23 117:1,8 118:20 119:20 119:22 120:18,23 121:8 121:14 122:22 130:11,16 131:1,4,10,21,25 132:14 134:9,18 135:2 138:19 138:21,23,25 139:1,2,4</p>	<p>144:7 145:10 146:2,16 146:19 151:10 154:13 157:21 166:7 168:3 170:21 174:25 180:21 181:2 182:21 185:12 188:8,15,18 189:11 195:2 198:20 200:11,11 208:12 208:16,22 209:3 210:21 210:25 212:2 213:23 218:9 219:24 225:3,8,17 225:21 226:6,12,18 236:21 239:16 243:15 250:2 257:15 264:2,5 269:20 317:11,13,17 350:24 359:15,25 368:2 368:9,10,12,23 369:3,14 369:18 382:3 386:16 388:18</p> <p><b>textual</b> [1] 142:22</p> <p><b>thank</b> [31] 4:15,17,25 5:16 126:4 127:8,15 176:14,17,21 178:9,17 179:4 190:2,4 231:7,10 231:12 252:3,5,11,14 264:10 270:13 282:16,19 288:12 295:22,24 396:10 396:23</p> <p><b>Thanks</b> [1] 9:11</p> <p><b>that'll</b> [1] 393:10</p> <p><b>thee</b> [1] 375:3</p> <p><b>themselves</b> [6] 36:18 91:19 149:13 151:17 183:23 293:19</p> <p><b>theoretical</b> [1] 133:16</p> <p><b>theoretically</b> [1] 133:16</p> <p><b>theory</b> [1] 281:11</p> <p><b>therapies</b> [1] 126:11</p> <p><b>therapy</b> [14] 59:15 60:6 60:9 62:14 120:17 126:13 126:16 239:13,15 335:25 336:1 344:17,20 386:12</p> <p><b>There'd</b> [1] 390:4</p> <p><b>thereabouts</b> [1] 311:4</p> <p><b>therefore</b> [25] 10:2,11 15:14 36:20 54:13 58:12 59:10 61:4 62:16 65:16 68:25 71:11 104:5 115:20 151:5 170:17 180:7 197:17 200:1,13 211:3 215:20 229:14 284:25 396:18</p> <p><b>thinking</b> [5] 115:20 125:1 230:15 310:8 313:21</p> <p><b>third</b> [3] 159:2 250:6 297:24</p> <p><b>thirdly</b> [1] 297:1</p> <p><b>thorough</b> [1] 21:25</p> <p><b>thought</b> [20] 11:18 13:1 18:25 83:17 84:22 86:3 98:20 109:18 134:12 154:6 225:5 270:15 276:2 327:22 329:11 341:15 356:14 379:21 382:5 389:11</p> <p><b>thoughts</b> [2] 177:1 178:4</p> <p><b>thousand</b> [1] 160:1</p>	<p><b>thousands</b> [7] 181:20 381:2 387:8,9,13,13,13</p> <p><b>three</b> [38] 4:18 27:22 44:14 53:24 56:11 60:16 60:18 61:1,6,17 63:6,8 77:10,11 79:19 105:16 106:3 144:13 147:18 157:16 161:9 166:20,23 169:8 179:8 195:7 214:11 223:20 251:5 257:24 264:15 269:20,25 270:21 308:25 313:3 328:20 364:1</p> <p><b>threshold</b> [2] 214:23 323:12</p> <p><b>through</b> [48] 3:2 4:22 5:9 6:6 16:15,23 20:4 21:18 31:18 53:6,12 54:15 57:3 64:19 70:21 135:4 143:14 168:13 201:17 210:13 234:23 250:5 254:11 259:23 266:8 275:6 283:16 288:21 289:24 291:7 306:23 315:5 318:17 321:22 336:7,14 349:22 367:2 374:8 376:24 380:4 383:11,13 385:21 387:11 390:4 394:12,14</p> <p><b>throughout</b> [10] 22:15 135:19 156:23 194:23 218:19 280:8 281:2 290:17 375:19,20</p> <p><b>tick</b> [1] 303:14</p> <p><b>tie</b> [1] 55:1</p> <p><b>tied</b> [1] 74:4</p> <p><b>tier</b> [1] 251:24</p> <p><b>timeframe</b> [1] 376:19</p> <p><b>times</b> [24] 27:5,19 84:24 119:25 127:18 140:25 153:12 157:16 161:9 166:20,23 197:8,8,8 285:1 289:19 290:23,23 313:3 318:4 328:15 354:3 356:8 363:4</p> <p><b>tiny</b> [2] 148:17 226:25</p> <p><b>tissue</b> [81] 18:3 32:12 33:15 35:22 58:1 71:9 73:11,19,23 74:2,7,11 74:19 75:2,9,9 76:1,7,23 77:1,12,22 78:1,3 79:3 79:10,15,18,21,23 90:15 90:17 136:22,23 138:13 144:4,5 146:18 154:10 154:11 197:15 199:18 200:1 211:1 214:9,15 226:25 227:9 228:22,22 229:3,7,22,24 236:11,17 236:23 241:1,16 243:17 244:12 250:14 253:14 254:10,11,24 255:9 259:3 259:5,23 269:17,19 270:4 270:7 275:5,6,7 346:22 347:6,7 348:5</p> <p><b>tissues</b> [11] 17:15 19:7 77:2,8,14 193:15 194:5 213:13 214:18 240:11,20</p> <p><b>titrated</b> [2] 200:12 214:14</p>	<p><b>today</b> [26] 5:9 11:22 15:25 55:10 56:25 67:13 68:12 70:25 123:24 135:5 161:8 163:15,15 179:6 184:11 197:13 201:10 232:10 240:7 242:9 244:17 252:24 260:8 295:25 300:2 306:25</p> <p><b>together</b> [14] 6:17 12:5 13:13 57:24 63:24 86:6 160:16 173:23 178:4 181:2 337:4 354:10 368:17,19</p> <p><b>Tom</b> [1] 4:12</p> <p><b>tomorrow</b> [2] 308:4 396:23</p> <p><b>tonsil</b> [1] 75:24</p> <p><b>too</b> [31] 11:11 39:25 48:7 54:24 57:23 60:18 73:22 76:22 86:22 125:8 127:4 173:11 182:7,13 201:20 202:14 250:16 251:10 256:9 263:7 273:10,13 276:10,18 324:14 340:11 358:7 373:1 377:3,6 378:22</p> <p><b>took</b> [12] 19:19 30:21 172:21 175:13 193:10 196:5 197:23 231:24 315:10 322:2 367:24 385:21</p> <p><b>tool</b> [3] 8:4 240:4 256:17</p> <p><b>tools</b> [1] 258:19</p> <p><b>top</b> [7] 122:3 148:19 183:1 197:4 233:4 322:17 325:8</p> <p><b>topic</b> [5] 55:22 76:16 179:5 201:4 281:8</p> <p><b>topics</b> [2] 32:8 35:9</p> <p><b>Torlakovic</b> [633] 2:2 4:5 4:6,11,12 5:3,18 6:1,8 8:13,17,24 9:4,8,12,19 9:23 10:16,20 17:5 18:17 18:21 19:15,21 20:1 22:1 22:5,11,16,24 23:19,23 24:6,11 25:2,19 26:5 27:3,15 28:5,19,23 29:3 29:8,12,21 30:4,9,13,18 30:23 31:3,7,19,24 32:3 32:7,19 33:9,14,21 34:5 34:14,24 35:18,23 36:3 36:8,16,25 37:7,11,18 37:23 38:3,8,13,18,23 39:2,9,15,22 40:1,6,10 41:1,15 42:2,7,13,24 43:4,8,13 45:16,21 46:2 46:21,25 47:5,10,16,20 48:6,10,23 49:5,11,22 50:1,16 51:12,23 52:2,6 52:10,19,23 53:13 54:22 55:17 56:6,19,23 57:12 57:16 59:21 60:17,24 61:11,24 63:9,16 64:2,9 64:20 65:13 67:7 69:21 70:2,11,16,22 71:16,21 72:3 73:7 78:6,13 80:20 80:25 81:5,16,21 82:11 82:16,23 83:4,9,15 84:19 84:25 85:6,10,23 87:8 88:10,14,24 89:4,8,12</p>
---	---	--	---	---

<p>89:19,24 90:5 91:3,7,12 91:16,24 92:4 93:3,10 93:22 95:21 96:8,22 97:5 97:14,21 98:1,18,23 99:2 99:16 100:9,23 101:2 102:16,21 105:5,13 106:6 107:8,12 108:9,18,25 109:8,17,25 110:4,14 111:6,16,20,24 112:4,9 112:14,18,25 113:4,9,17 113:21 114:7,18,22 115:2 115:6,11,17,25 116:5,11 118:10,14 119:21 121:23 122:4,9,13,17,23 123:3 123:14,21 124:16,21,25 125:7,17,23 126:8,14,22 127:1,5 128:3,7,12,18 128:23 129:8,12,17,25 130:12,21 131:5,12,18 133:20,24 134:14,22 135:7,11,15 136:2,6,11 136:15,20 137:10,15,19 137:24 138:3,7,24 139:8 139:14,20,24 140:3,7,11 140:18,22 141:2,6,12,18 142:5,14,18,23 143:3,8 143:15,21 144:18 145:18 145:23 146:7,14 147:2,8 147:12,16,23 148:5,10 148:14,20 150:8 151:15 152:5,10,14,21 154:1,5 154:24 155:7 156:16,20 156:24 157:4,8,13 158:1 158:6,12 159:7,17 162:9 162:17,25 163:19,24 164:8 165:16,21 166:12 166:18 167:8,14,18 168:10,15,25 169:4 171:1 173:2,7 174:10,20 176:4 176:8,23 177:5,12 179:1 179:22 180:13 181:1,5 181:12,18 182:3 183:6 184:3 185:4,9 186:5,13 186:22 187:10,15,20 188:12 189:4,8,14,24 190:5,7,19 191:3,7,23 192:9,16 193:4,19 194:1 194:8,16,20 195:3,15,19 196:13,18,23 197:24 198:8 199:10 201:2 202:4 203:7,11,16,23 204:19 205:2,6,12,20 206:5,17 206:23 207:3,8,12,18,24 208:3,24 209:6,14,22 210:6,12 211:20,25 212:11,20 213:2,8 216:17 216:21 217:6 218:2 219:1 219:10,17 220:13,22 221:3,12,21 222:6,11,18 222:25 223:13,17,24 224:6,10,21 225:4,10,23 226:8,15,22 227:1,6,12 227:17,24 228:4,10,18 229:2,11 230:1,8,21 231:1,13,15 232:6,22 233:6,15 234:6,11,18 235:7,24 236:14,18 237:8 237:14 238:8,18 239:1,8 240:5,16 242:23 244:8 244:18 245:19 246:6,14 246:23 247:5 248:14,20 251:20,25 252:15,17 253:10 254:16 255:11,17</p>	<p>256:19,24 257:8 258:24 259:14,18 260:1,11,15 261:8,13,23 262:20 263:5 263:13 264:19 265:2,9 265:14,21 266:2,6,11,16 266:22 267:7,15 268:3 268:16,25 269:5,12 271:6 271:10,21 272:3 273:9 273:14,19,24 274:4,24 275:9,21 276:15,25 277:12,19 278:1,13 279:1 279:5,12 280:13,17,21 281:1,15,25 282:11,16 282:23,24 283:24 285:9 285:15 286:1 287:7,11 287:18,23 288:3,18 289:3 289:10,15,21 290:2,9,18 291:2,9,16,21 292:1,7 292:11,15,19,24 293:3 294:2,6,13,20,25 295:4 295:15</p> <p><b>Toronto</b> [1] 141:21</p> <p><b>total</b> [16] 43:21 258:8 322:18,23 344:1 351:25 369:3,14,25 370:4,10 371:25 372:1 389:6,11 389:12</p> <p><b>totally</b> [15] 13:8 17:20 31:12 51:19,22 84:6 160:2 211:12 213:21 214:13,21 215:13 217:19 219:2 254:4</p> <p><b>totals</b> [1] 370:10</p> <p><b>touch</b> [2] 183:14 231:20</p> <p><b>touched</b> [2] 154:17 190:12</p> <p><b>toward</b> [1] 104:5</p> <p><b>towards</b> [1] 71:7</p> <p><b>town</b> [12] 326:3 337:5,6 351:9 352:11 353:13 354:11 357:19 359:22 378:3 390:3,6</p> <p><b>track</b> [2] 218:11 357:25</p> <p><b>tracking</b> [1] 254:11</p> <p><b>traditionally</b> [2] 18:1 203:20</p> <p><b>train</b> [1] 257:23</p> <p><b>trained</b> [2] 44:7 301:10</p> <p><b>training</b> [14] 6:3,3 7:7 20:4,5 25:3,6 184:5 190:11 232:18 256:8,9 263:21 301:17</p> <p><b>transcribed</b> [1] 397:9</p> <p><b>transcript</b> [1] 397:3</p> <p><b>transcription</b> [9] 240:24 241:1,5,7,10,11,22,25 242:6</p> <p><b>transfer</b> [2] 198:18 272:14</p> <p><b>transformed</b> [1] 170:12</p> <p><b>transition</b> [1] 193:18</p> <p><b>translate</b> [1] 274:20</p> <p><b>translated</b> [3] 170:12 202:19 204:1</p> <p><b>translation</b> [1] 170:22</p> <p><b>transmitted</b> [1] 374:13</p>	<p><b>transparency</b> [1] 87:5</p> <p><b>transpired</b> [1] 313:14</p> <p><b>travel</b> [5] 12:19 30:7 83:23 161:3,4</p> <p><b>travelled</b> [1] 86:6</p> <p><b>treat</b> [3] 24:15 69:10 329:21</p> <p><b>treated</b> [6] 62:4 330:13 333:3 338:11 343:1,15</p> <p><b>treatment</b> [8] 26:15 69:12 235:21,23 239:13 285:3 338:22 339:5</p> <p><b>treatments</b> [1] 69:8</p> <p><b>tree</b> [1] 119:1</p> <p><b>trends</b> [4] 280:9,12 281:21,22</p> <p><b>trials</b> [1] 344:16</p> <p><b>tried</b> [4] 43:17 79:4 84:13 143:9</p> <p><b>trouble</b> [1] 67:2</p> <p><b>troubleshoot</b> [1] 299:8</p> <p><b>troubleshooters</b> [1] 301:12</p> <p><b>true</b> [22] 12:23 66:19 112:5 196:3 199:15 203:8 203:10 217:10,10,13 229:12 271:17,18,22 272:16,17,24 310:18 358:8,8 362:25 397:3</p> <p><b>truly</b> [1] 71:10</p> <p><b>truth</b> [5] 61:13 97:15 208:4 217:7 223:1</p> <p><b>truthful</b> [1] 18:10</p> <p><b>try</b> [26] 11:21 12:1 18:7,9 73:12,13 74:6 85:14,17 87:10 101:23 102:5 108:7 143:10 160:25 163:8 174:23 230:19 233:1 263:22 293:10 347:5 350:25 365:13 384:14,15</p> <p><b>trying</b> [9] 17:9 57:25 79:3 80:11 120:22 170:7 345:5 382:1 386:13</p> <p><b>Tuesday</b> [2] 396:15,22</p> <p><b>tumour</b> [27] 58:8,23 62:13 63:22 66:2 75:1 79:25 121:2 136:18 137:1 137:2 149:3 211:5 214:8 215:7 228:24 229:4 242:15 281:24 282:1 346:20,20 347:7,20,24 348:5,7</p> <p><b>tumours</b> [14] 32:13 65:19,25 79:6,16 90:16 144:8 150:10,14 210:14 214:13,21 242:16 347:18</p> <p><b>tuned</b> [1] 150:23</p> <p><b>tuning</b> [1] 150:21</p> <p><b>turned</b> [2] 27:18 379:9</p> <p><b>turns</b> [3] 111:11 112:2 122:16</p> <p><b>twelve</b> [1] 114:6</p> <p><b>twice</b> [2] 157:15,24</p> <p><b>two</b> [43] 6:14,17,22 7:5 20:2 44:14 64:21 96:13</p>	<p>97:1 112:7 117:25 118:16 118:17 119:15 154:6 159:24,25 169:8 170:17 173:19,21 178:6,17 182:20,21 188:23 191:11 215:13,22 216:5 236:11 251:23,23 255:25 257:24 258:12 270:11 283:20 296:10 304:14 364:11 368:16 382:6</p> <p><b>type</b> [37] 27:19 35:11,22 45:6 69:12 116:18 123:4 128:13 130:8 151:5 155:20,22 197:7 242:21 243:21 245:21,22,25 249:1 251:24 256:17 257:5 258:3 261:3 262:2 262:7 269:19 274:3,11 280:2,20 282:9 288:25 314:4 321:21 342:1 377:4</p> <p><b>types</b> [19] 12:11 64:17 154:4 257:4 258:2 261:11 266:25 269:13 270:11 273:5 274:21 278:23 279:8 289:8,13 290:1,5 290:22 291:1</p> <p><b>typically</b> [7] 35:3 44:11 129:2 130:5,6 188:2,13</p> <p><b>tyrosine</b> [1] 239:21</p> <hr/> <p><b>-U-</b></p> <p><b>u</b> [2] 11:16 182:22</p> <p><b>Uh-hm</b> [10] 219:9 220:12 220:17 224:9 230:25 291:10 345:16 360:8,14 371:23</p> <p><b>UK</b> [41] 14:17,24 15:4 43:14 44:3,4 45:14 48:19 48:20 50:13,15,22 51:11 51:17,19 52:5 104:4 105:22 221:7,9,11,19,24 222:1,3,13 246:3,8,18 246:22 247:9,21,22 248:4 251:8 260:8 262:4 263:7 279:4 283:18 284:15</p> <p><b>ultimate</b> [2] 79:1 200:9</p> <p><b>ultimately</b> [5] 60:6 71:25 102:6 162:14 298:14</p> <p><b>ultra</b> [1] 197:13</p> <p><b>Um-hm</b> [8] 106:7 136:7 137:25 139:25 143:4 193:17 194:7 309:17</p> <p><b>unavoidable</b> [4] 209:3 209:12,20 210:4</p> <p><b>unbeknownst</b> [1] 130:19</p> <p><b>uncertainty</b> [1] 211:19</p> <p><b>under</b> [15] 63:1 90:18 100:1 150:4 213:25 246:4 276:20 357:18 360:21,24 361:16 362:11,11,14 364:15</p> <p><b>undergo</b> [1] 120:21</p> <p><b>undermining</b> [1] 172:1</p> <p><b>understand</b> [28] 5:6 30:1 36:14 44:8 57:25 70:1,14 84:12 101:20</p>	<p>102:10 109:3 164:5 186:6 200:20 202:2,15 205:8 222:16 226:19 255:15 267:4 298:1 314:4,9 324:21 330:3 356:9 387:24</p> <p><b>understands</b> [1] 306:21</p> <p><b>understood</b> [13] 11:10 85:5 111:9 122:20 200:25 202:25 204:13,16 286:24 337:9 338:8,18 366:20</p> <p><b>undertaken</b> [1] 212:9</p> <p><b>undetected</b> [1] 158:10</p> <p><b>undifferentiated</b> [4] 63:22 136:18 137:1 144:8</p> <p><b>unexpected</b> [1] 224:4</p> <p><b>unexplained</b> [3] 208:11 217:23 250:24</p> <p><b>unfortunately</b> [2] 74:22 161:25</p> <p><b>unhelpful</b> [2] 130:18 131:2</p> <p><b>uniform</b> [5] 73:12 74:13 165:8 170:22 187:5</p> <p><b>uniformed</b> [1] 259:7</p> <p><b>uniformly</b> [2] 103:23 170:11</p> <p><b>unintelligible</b> [4] 53:5 58:21 63:22 250:23</p> <p><b>unique</b> [1] 80:4</p> <p><b>unite</b> [1] 104:20</p> <p><b>United</b> [14] 6:13 14:19 20:10 26:11 41:20,25 43:15 63:1 103:7 104:3 157:14 162:2 242:19 246:13</p> <p><b>units</b> [1] 21:4</p> <p><b>universal</b> [1] 129:13</p> <p><b>university</b> [8] 6:15,20 20:8 81:1,2 86:10 99:1 188:3</p> <p><b>unknown</b> [2] 130:17,24</p> <p><b>unless</b> [2] 347:16,18</p> <p><b>unlikely</b> [1] 134:5</p> <p><b>unmanipulated</b> [1] 21:8</p> <p><b>unofficially</b> [1] 101:4</p> <p><b>unreliable</b> [2] 130:17 131:1</p> <p><b>unstained</b> [5] 33:17,22 35:15 45:23 46:19</p> <p><b>unthawed</b> [1] 346:24</p> <p><b>unusual</b> [5] 84:6,10 183:16 189:16 215:11</p> <p><b>up</b> [93] 5:11,13 12:8 15:15 18:25 22:19 24:25 25:15 27:23 30:21 31:1 40:20 43:24 53:9 61:13 75:16 85:14 86:17,17 88:20 90:19 95:17,25 97:20 108:16 118:25 127:15 135:4 136:10 148:17 151:9 158:10 160:3 161:10,21 174:3 179:20 194:15 201:23 223:5 230:4,7 241:6 242:5,7</p>
---	--	--	--	--

<p>243:23 255:8 259:22 264:12 268:19 283:2 288:2,12 289:6 293:20 295:19 296:18 298:20 301:14 303:18 311:5 316:25 318:17 320:16 322:5,17 330:22 337:12 337:14 338:7 341:22 347:1,24 350:3 351:1,11 353:8 356:10 358:19 362:22 368:3 369:10,16 374:1,22 381:4 382:24 383:12 384:25 390:21 391:16 395:22 396:9</p> <p><b>update</b> [2] 365:16 367:4 <b>updated</b> [3] 185:17 365:12 366:9 <b>upgrades</b> [1] 86:19 <b>upshot</b> [2] 149:24 232:9 <b>USA</b> [1] 103:7 <b>usage</b> [2] 115:5 191:10 <b>used</b> [89] 18:1 21:6 57:19 58:3 62:10 63:23,25 65:3 65:4 67:14 70:24 71:3 75:5 76:12 90:13 91:10 91:23 102:11 107:1,22 110:22,23 113:25 115:9 115:10 116:19 119:13 125:6 126:9 128:14,17 136:25 138:12 139:1,2 145:10 152:9 153:13 158:13,15,21 171:19 193:8 194:10 195:11,14 195:22,23 196:10 198:7 200:21 201:5 203:20 213:23 218:9,16 222:3,7 222:9,9 226:19 242:24 242:25 243:1,3 247:15 270:12 272:14 274:22 288:23 289:1,14,20 290:1 290:6 293:11 294:17 295:18 299:6 315:10 321:22 331:2 338:6 347:20,24 348:7 352:24 354:13 375:20</p> <p><b>useful</b> [6] 14:10 32:14 130:7 186:2 241:17 382:21 <b>using</b> [44] 12:24 13:2,6 19:2 49:12 57:24 67:23 74:23 78:5 106:19 122:22 123:1 125:16 153:11 155:5,23 168:3 197:1 198:2,10,17,25 199:21 201:19 202:11 203:25 214:25 227:10 232:10 236:12 242:3,9 244:21 244:25 250:9,17,19 271:2 276:9 288:25 291:5 297:13 301:6 364:16</p> <p><b>usual</b> [2] 19:9 37:12 <b>usually</b> [10] 26:10 47:21 57:21 69:5 151:2,3 184:8 185:19 189:16 224:12 <b>utilized</b> [4] 222:21 289:9 294:24 295:12 <b>utilizing</b> [2] 123:11 131:3</p>	<p style="text-align: center;"><b>-V-</b></p> <p><b>valid</b> [3] 167:23 200:7 268:22 <b>validate</b> [1] 61:3 <b>validated</b> [2] 80:3 301:7 <b>validation</b> [1] 169:19 <b>valuable</b> [3] 32:15 178:9 262:13 <b>value</b> [18] 14:7 59:14,16 68:6,8 69:13,15 78:2,22 79:25 80:6 92:22 205:23 211:3,4 219:12 250:25 287:20 <b>values</b> [10] 68:17 149:6 149:9 151:22 204:6,10 211:9,11 235:13,20 <b>Vancouver</b> [2] 85:25 86:7 <b>variability</b> [17] 8:10 25:23 149:15 212:7,15 212:19 221:11,18 223:23 224:2 225:1 230:6 235:16 237:16 248:7 291:25 292:18 <b>variable</b> [7] 9:24 25:24 145:9 149:3 184:6 217:9 256:2 <b>variation</b> [3] 235:20 237:23 238:11 <b>variations</b> [1] 145:3 <b>varied</b> [3] 141:19 184:4 205:21 <b>varies</b> [3] 164:19 183:8 289:24 <b>variety</b> [1] 260:6 <b>various</b> [16] 27:19 45:11 54:15 75:10 76:8 79:7 101:21 129:19,20 144:6 163:3 183:21 184:4 289:1 318:4 379:1 <b>vary</b> [12] 113:12 150:15 187:9,11 205:11,15 290:14,15,22,23,25 291:6 <b>varying</b> [2] 183:23 257:3 <b>vendor</b> [1] 297:22 <b>Ventana</b> [19] 296:24 297:6,14,18,20 298:15 298:18,23 299:4,15 301:5 307:10 308:14,19 312:18 369:9 372:5 382:4,5 <b>verification</b> [1] 336:6 <b>verified</b> [3] 169:20 301:4 335:23 <b>verify</b> [3] 280:25 313:22 349:17 <b>verifying</b> [1] 350:16 <b>version</b> [1] 365:13 <b>versus</b> [3] 63:24 228:15 274:2 <b>vessel</b> [1] 73:19 <b>vessels</b> [1] 74:3 <b>vetting</b> [2] 338:9 376:3 <b>via</b> [1] 88:8 <b>view</b> [6] 48:20 85:20</p>	<p>109:6 202:1 204:16 240:6 <b>viewed</b> [1] 328:14 <b>viewing</b> [1] 145:6 <b>viewpoint</b> [1] 341:4 <b>vimentin</b> [5] 65:14 66:8 144:24 213:12,22 <b>viral</b> [1] 272:5 <b>virtual</b> [2] 90:12 256:4 <b>Virtually</b> [1] 139:3 <b>vision</b> [1] 121:20 <b>visit</b> [2] 297:1,8 <b>visual</b> [2] 145:6 197:5 <b>visually</b> [1] 141:9 <b>vitae</b> [1] 5:2 <b>volume</b> [5] 180:21 181:21 182:9 184:24 231:25 <b>volumes</b> [2] 180:6,11 <b>voluntary</b> [1] 135:21 <b>volunteer</b> [2] 136:24 246:21 <b>vote</b> [1] 396:18 <b>voting</b> [1] 396:15</p> <p style="text-align: center;"><b>-W-</b></p> <p><b>w</b> [2] 20:22 257:21 <b>wait</b> [1] 115:20 <b>Waiting</b> [1] 296:24 <b>walk</b> [2] 234:23 376:24 <b>wall</b> [1] 303:13 <b>wanting</b> [1] 378:15 <b>wants</b> [2] 258:10 264:21 <b>warn</b> [1] 240:6 <b>wasting</b> [1] 270:17 <b>watch</b> [2] 152:17 202:17 <b>ways</b> [5] 20:2 54:15 74:12 94:3 237:1 <b>weak</b> [25] 76:6 242:15 308:8,10 322:24 323:9 323:14 327:16 335:8 352:7,12 360:10,21 361:14,16 362:23,24 363:16 364:15 368:9,13 368:16 385:13 394:24,24 <b>weakly</b> [1] 242:14 <b>weakness</b> [1] 48:3 <b>wealth</b> [1] 282:6 <b>web</b> [9] 50:9 86:13,17 88:9 97:18,20 141:24 151:17 265:8 <b>website</b> [7] 13:11 64:24 108:17 136:10 145:7 152:8 219:22 <b>Wednesday</b> [1] 98:14 <b>week</b> [3] 301:16 396:14 396:22 <b>weekend</b> [1] 320:18 <b>weekends</b> [1] 356:11 <b>weeks</b> [4] 314:6 346:24 356:11 391:15 <b>Western</b> [2] 1:16 355:13 <b>whatnot</b> [1] 188:8</p>	<p><b>whatsoever</b> [1] 358:13 <b>wherever</b> [4] 36:23 47:3 131:22 390:12 <b>white</b> [2] 65:11 92:14 <b>whole</b> [11] 193:8 248:8 254:7 281:5,6 298:23 312:13 347:14 358:6 369:9 375:19 <b>wide</b> [1] 278:7 <b>widely</b> [17] 129:18 141:23 193:6 197:19 213:12 222:3,7,9,21 261:4 267:19 283:21,22 283:25,25 284:3,3 <b>wider</b> [1] 164:2 <b>Williams</b> [15] 298:3 300:15,16 301:4,9,20 302:10 307:8,18 308:21 313:23 314:2,14 340:19 380:1 <b>Williams'</b> [1] 296:20 <b>willing</b> [2] 85:16 86:15 <b>windows</b> [1] 90:12 <b>winner</b> [1] 241:15 <b>wise</b> [2] 110:22 167:1 <b>wisely</b> [1] 196:9 <b>wish</b> [1] 356:13 <b>within</b> [12] 27:24 84:18 99:20 162:16 232:20 279:10 288:16 311:16 313:19 314:5 351:16 371:1 <b>without</b> [16] 16:8 54:18 55:4 61:6 71:22 75:15 95:4 132:11,17 149:25 166:2,14 176:2 182:18 231:4 257:25 <b>witness</b> [4] 4:4 176:16 178:15 252:9 <b>woman</b> [3] 332:2 343:3 346:16 <b>woman's</b> [1] 346:17 <b>women</b> [1] 344:17 <b>wonder</b> [2] 176:22 253:8 <b>wondered</b> [2] 149:16 265:5 <b>wondering</b> [7] 179:16 225:2 265:25 267:12 277:24 332:1 359:4 <b>word</b> [1] 102:10 <b>words</b> [4] 179:16 183:25 185:2 206:14 <b>worked</b> [3] 191:8 316:4 320:17 <b>workforce</b> [1] 171:25 <b>works</b> [1] 79:22 <b>workshop</b> [3] 54:13 101:9,14 <b>workshops</b> [1] 35:2 <b>world</b> [6] 43:21 226:4 229:14 245:13 254:23 283:22 <b>worried</b> [1] 350:17 <b>worse</b> [1] 149:12</p>	<p><b>worth</b> [1] 158:5 <b>worthwhile</b> [3] 55:24 380:23 381:1 <b>worthy</b> [1] 120:19 <b>WP</b> [3] 335:8,9,9 <b>write</b> [5] 32:11 103:10 254:23 348:20 394:9 <b>writes</b> [2] 299:3 314:15 <b>writing</b> [13] 65:12 185:7 186:4,6,17 322:12,14,19 322:21 349:11 384:20,25 391:16 <b>written</b> [7] 185:8 323:18 336:14 385:19,23 391:21 393:25 <b>wrong</b> [18] 21:21 26:25 45:1 48:7 51:5,7 110:5 124:24 133:13 134:6 181:8 204:15 208:13 211:13 237:25 250:20 269:10 286:11 <b>wrote</b> [2] 335:9 385:18</p> <p style="text-align: center;"><b>-X-</b></p> <p><b>X</b> [1] 207:1</p> <p style="text-align: center;"><b>-Y-</b></p> <p><b>y</b> [2] 20:22 119:12 <b>year</b> [53] 6:18,19 10:14 101:12,12,13,13,16 102:3 102:19 105:17 114:4 156:9,23 157:7,15,17,24 161:9 166:21,24 180:21 180:23,25 185:15 194:19 255:25 256:1 257:4,5 280:8 281:2 297:15 312:13 319:21 335:19 341:18 345:4 351:21 352:2 355:13 363:1,5 372:1,4 382:14 383:17 383:19 384:3,13 387:24 387:25 389:5 <b>years</b> [36] 6:14,22 7:5,17 10:15 17:3,21 20:14 41:22 53:20 119:8 179:9 192:8,8 194:14 199:2 200:23 232:9 233:5 236:12 238:6 254:20 255:25 280:1 287:1 288:9 288:14 304:14 340:23 344:18 345:3 363:25 364:1,11 373:11 383:21 <b>yellow</b> [3] 92:16 217:19 373:10 <b>yesterday</b> [4] 94:6 300:1 308:22 358:17 <b>yet</b> [17] 52:9 80:14 83:7 92:8 121:22,24 135:17 170:4 196:8,8 198:19 201:24 211:23 243:20 256:22 292:4 382:20 <b>York</b> [1] 6:15 <b>youngest</b> [1] 43:16 <b>yourself</b> [17] 19:14 46:4 46:5 96:21 105:3 133:17 140:10 143:1,6 190:14 212:17 303:25 307:14</p>
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<p>314:14 319:17 338:6 365:15 <b>yourselves</b> [1] 141:10 <b>Yugoslavia</b> [1] 6:11</p> <hr/> <p><b>-Z-</b></p> <hr/> <p><b>Z</b> [1] 119:12 <b>Zagreb</b> [1] 6:11 <b>zero</b> [46] 79:19 144:13 144:21 243:12 309:6,6 309:20,20 310:1,1,8,8,8 310:9,18,20 324:3 326:24 326:24 327:10,10,14,14 328:17 329:14 330:1,6 334:19,20 343:2,16,16 361:6,6,8,8 362:4,4 363:1,1,17,17,19,19 364:13,13 <b>zero/zeros</b> [1] 370:13 <b>zeroes</b> [1] 324:3 <b>zeros</b> [4] 310:18 328:17 330:1 343:2 <b>zoom</b> [1] 90:18</p>				
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