

2006 01T 2966 CP

IN THE SUPREME COURT OF NEWFOUNDLAND AND LABRADOR
TRIAL DIVISION

BETWEEN:

VERNA DOUCETTE

PLAINTIFF

AND:

EASTERN REGIONAL INTEGRATED
HEALTH AUTHORITY

DEFENDANT

BROUGHT UNDER THE *CLASS ACTIONS ACT*
BEFORE THE HONOURABLE MR. JUSTICE THOMPSON,
CASE MANAGEMENT JUDGE

INTERROGATORIES

TO: DR. ALLEN M. GOWN
c/o Stewart McKelvey Stirling Scales
Solicitors for the Defendant
Suite 1100, 100 New Gower Street
PO Box 5038
St. John's, NL A1C 5V3

It is hereby required that the following interrogatories be answered by you, and that the answers be served upon the Plaintiff within ten (10) days from the time these interrogatories are served on you. Provided herewith as reference materials are the following documents, bound and titled "Documents Provided with Interrogatories to Dr. Gown":

- (a) Affidavit of Heather Predham dated February 9, 2007;
- (b) Affidavit of Dr. Allen Gown dated February 12, 2007;
- (c) Answers to Interrogatories, Ms. Predham, dated May 10, 2007;

- (d) Letter of Undertakings, Dr. Hutton, dated May 16, 2007;
 - (e) Eastern Health Annual Performance Report 2005-2006;
 - (f) Predham Interrogatories – New Data, analysis by Dr. Hutton;
 - (g) Internal Memoranda and Minutes, including Dr. Ejeckam memo of June 19, 2003;
 - (h) Undertakings from Cross-examination of Affidavit of Dr. Hutton, April 23, 2007: list of publications.
1. Are you qualified to express opinion on the performance of an ER/PR testing facility, and whether its performance is or was within standard of care?
 2. As to paragraph 5 of your Affidavit dated February 12, 2007, were you aware of the contents of paragraphs 14 and 15 of the Affidavit of Heather Predham filed in the Supreme Court on February 9, 2001, which stated that in June and July of 2005 Eastern Health laboratories tested 58 cases of ER/PR negative cases from 2002 and found that 38 cases were false negative (65%)?
 3. Were you aware that the following generic data was supplied to the Plaintiff by Ms. Predham's Answers to Interrogatories dated May 10, 2007, paragraph 3, for the year 2000?

Total Tests January 12th, 2000 – December 31st

Total Tests	344
Total Positives	197 - 58%
Total Negatives	147 - 42%

4. If you were aware of the above performance in 2000, and had authority with respect to the Eastern Health laboratory, would you recommend discontinuing ER-PR testing until you got the percentage of positivity up to the range of 75%? Would you retest all 147 negatives? Explain.

5. Would you notify treating oncologists of the possibility of false negatives? Would you characterize 42% negativity as having a high possibility of false negatives? Explain.

6. Please read the Ejeckam memorandum of April 4, 2003, the minutes of inaugural meeting of the Surgical Pathology Review Committee April 15, 2003, and the minutes of the same Committee dated September 23, 2003.
 - (a) Were you aware of the activities of this Committee?

 - (b) Was the Committee still functioning during your visit in February 2006?

 - (c) During your investigation of the performance of ER-PR testing by the laboratory, were you aware of any other oversight committee or individual responsible for the activities and quality of performance of the Immunohistochemical laboratory prior to the formation of the Surgical Pathology Review Committee in April 2003?

 - (d) Would you agree with Dr. Ejeckam on the need for dedicated and knowledgeable technicians as well as a special site for IHC procedures? What other comments would you offer as to the significance of this memorandum?

7. As to paragraph 6 of your Affidavit, you stated that in reviewing the generic data presented, it appeared that the ER positivity rate was in the 65-75% for breast cancers analyzed at the laboratory during the time the Dako instrument was employed, and that you had been advised that the seven year average was 74% ER positivity. Did you review the generic data supplied by Ms. Predham, paragraph 3 of her Answers to Interrogatories, which was to the following effect (totals and total positives added):

<u>Dako system</u>	<u>Total Tests</u>	<u>Total Neg.(%)</u>	<u>Total Pos. (%)</u>
May 1997 to December 31	137	57 (42%)	80 (58%)
January 1, 1998 to December 31	147	76 (52%)	71 (48%)
January 1, 1999 to December 31	360	126 (32%)	134 (68%)
January 1, 2000 to December 31	370	170 (46%)	200 (54%)
January 1, 2001 to December 31	374	143 (40%)	231 (60%)
January 1, 2002 to December 31	344	147 (42%)	197 (58%)
January 1, 2003 to December 31	373	89 (24%)	284 (76%)
January 1, 2004 to December 31	109	16 (15.6%)	93 (84.4%)
Totals	2214	824 (37.2%)	1390 (62.8%)

8. The generic data of Ms. Predham is summarized in “Predham Interrogatories – New Data”, which is an analysis by Dr. Hutton. This includes the overall performance of ER-PR testing at the laboratory from May 1997 to August 2005 with a breakdown of various time periods. Do you agree that the positivity rate for the seven years while the Dako system was employed is actually 48% to 84.4% and the average was 62.8%? How do you explain these differences?
9. If you focus on the timeframe May 1997 to December 2002 (5 years and 8 months), do you agree that the following statistics result?

Total Tests	1732	
Positives	1013	58.5%
Negatives	719	41.5%

10. How would you rate the performance standard during this time? Was it within standard for an institution of this standing? Do you have an opinion on how this situation occurred, and what is your opinion?
11. If these results came to your attention, would you advise discontinuing the service? Would you advise retesting? Explain your answer.

12. In your laboratory do you look at your statistical performance daily, weekly, monthly, yearly? How often?
13. Which staff are responsible for keeping these statistics, and if statistics indicate a problem, are they responsible for making corrective measures?
14. In paragraphs 8, 9 and 10 of your Affidavit, you discuss the importance of preservation and fixation of the pre-analytical factors. Further in paragraph 10 you state that this is especially a potential problem in a setting like Newfoundland and Labrador. Would you agree that if a referred-in specimen or even an in-house specimen is improperly handled, there is a potential for degradation of the hormone receptors?
15. If the hormone receptors have been degraded in-house or referred-in, would they be more likely to be negative for hormone receptors when tested in-house or in a reference lab?
16. Would you agree that any false negatives attributed to faulty pre-analytical factors would end up in the confirmed negatives by Mount Sinai?
17. Would you agree that the confirmed negatives by Mount Sinai do in fact contain some false negatives which can be attributed to pre-analytical factors?
18. Do you have any experience or studies estimating the percentage of false negatives attributable to the pre-analytical factors? Please identify such studies, if any. What would you estimate the percentage to be?

19. Would you agree that the false negatives uncovered by Mount Sinai are not caused by pre-analytical factors, that is, the receptors were present and not detected by the laboratory but detected by Mount Sinai? Would you agree there is a low sensitivity in the IHC procedure being performed by the laboratory while the Dako autostainer was in use?
20. As to paragraphs 17, 18, 19, 20 and 21 of your Affidavit you discuss cut off points used by different pathologists across North America and in particular, the cut off points used by pathologists at the laboratory in St. John's. Do you know or were you informed if all the pathologists at the laboratory and St. Clare's used the same cut off point?
21. Do you know what cut off points were used by other pathologists referring in cases?
22. Before swearing your Affidavit, did you know that of the 330 false negatives of the 763 cases retested by Mount Sinai, only 13 or 4% were considered positive on the basis that the standard interpretation of what constitutes an ER positive result (cut off point) had changed between the original testing and the Tumor Board review?
23. At paragraph 24 of your Affidavit you state that based on your experience with breast cancer ER-PR testing, you would say that with respect to the ER-PR IHC performed at St. John's Regional Hospital from 1997 to the current time (February 2006), the quality of the pathologists, the quality of the technical support, and the overall quality of the immunostains employed are all within the range of what would be found in the vast majority of comparable laboratories in North America today. Having regard to the Eastern Health Annual Performance Report and other publicly available information:
 - (a) As to your referring to the General Hospital as the St. John's Regional Hospital, were you aware that besides this function it is also the referral hospital for 10 regional hospitals and other health care facilities totaling 2651 beds and servicing over half the population of Newfoundland?

- (b) Were you aware that the General Hospital is the main referral centre for Newfoundland and Labrador in acute and critical care in neurosurgery, cardiovascular surgery, high risk pregnancies, cancer treatment and children's diseases (Janeway Children's Hospital)?
- (c) Were you aware that the laboratory at the General Hospital does the bulk of the diagnostic tests for these institutions and health care facilities?
- (d) Were you aware that the General Hospital is a teaching centre with affiliation with Memorial University's Medical School, School of Nursing and School of Pharmacy?
- (e) Were you aware that as a teaching hospital that Royal College Fellowship training courses are offered in many medical and surgical specialties, including clinical and anatomical pathology?
- (f) Would you agree that the St. John's Regional Hospital is an academic teaching hospital?
- (g) Would you expect a high standard from an academic teaching hospital's support services, including the laboratory?
- (h) Do you consider the standard of sensitivity of the IHC procedure for the assay of ER-PR status to be 75% ER positivity?

- (i) The overall performance of the laboratory with ER-PR testing from inspection in May 1997 to discontinuance in August 2005 was:

Total Tests	2709	
Positives	1825	67.7%
Negatives	884	32.3%

Would you rate this overall performance as up to standard for a laboratory servicing an academic teaching hospital? Explain.

- (j) The overall performance of the Ventana system from April 2004 to July 2005 was:

Total Tests	495	
Positives	435	87.9%
Negatives	60	12.1%
False Negatives	3	5%

Would you rate this overall performance as up to standard for a hospital laboratory servicing an academic teaching hospital?

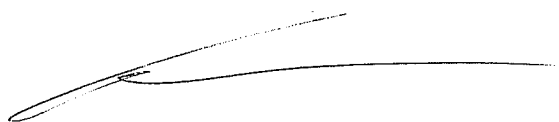
- (k) With reference to “Predham Interrogatories – New Data”, para. F, do you agree that the overall performance while the Dako stainer was in use from May 1997 to April 2004 was:

Total Tests	2214	
Positives	1390	62.8%
Negatives	824	37.2%
False Negatives	366	44.4%

- (l) Would you rate this overall performance as up to standard for a hospital laboratory servicing an academic teaching centre? Explain.

- (m) What standard of estrogen positivity do you set in your own laboratory? Explain.
24. Would you consider Mount Sinai in Toronto to be a peer laboratory to the General Hospital? Explain your answer, comparing and contrasting.

DATED at St. John's, in the Province of Newfoundland and Labrador, this 14th day of June, 2007.



CHES CROSBIE BARRISTERS
Solicitors for the Plaintiff
Whose address for service is:
169 Water Street, 4th Floor
St. John's, NL A1C 1B1
Attention: Chesley F. Crosbie, Q.C.