

**Question and Answer Briefing Note
Department of Health and Community Services**

Title: ER/PR Testing, Eastern Health

Issue: CBC has reported both provincially and nationally on May 15th that court documents show that Eastern Health got many more ER/PR test results wrong than it reported months ago.

Anticipated Questions:

- ♦ In December, Eastern Health reported that 117 of 939 breast cancer patients had to have treatment changes because of the ER/PR retesting. Why are court documents obtained by CBC showing that almost three times as many tests were wrong?
- It took more than a year for Eastern Health to go public and release the results of the ER/PR testing review. Are they hiding the real numbers?
- Why has Eastern Health not released the test results for 176 patients who have died since the original tests?
- Now that testing has resumed in St. John's, what has Government done to ensure the reliability and accuracy of the ER/PR testing at the St. John's hospitals?
- Are pathologists or laboratory staff to blame for the incorrect ER/PR test results?

Key Messages:

- Eastern Health has been accountable to the public. A technical briefing was held on December 11, 2006 at which time information on the number of patients retested at Mount Sinai and those requiring treatment changes was released to the media.
- Eastern Health sent 939 original ER/PR test results to Mount Sinai for retesting. The retesting results were reviewed by an expert panel of oncologists, pathologists, and surgeons in St. John's. At this time, 117 patients are identified as requiring treatment changes.
- The expert panel recommended that the focus of the retesting should be on patients who are alive. Eastern Health has been working with families of deceased patients on an individual basis.
- Providing quality health services to the people of this province is a priority for our Government. We regret that the past two years (since May 2005) has been a stressful period for some patients and their families and this news further adds to the anxiety that these patients as well as newly diagnosed patients are experiencing.
- Eastern Health resumed ER/PR testing in St. John's on February 1, 2007. We are confident that Eastern Health has implemented the appropriate new measures to ensure the highest standard of care for breast cancer patients.
- There were multiple factors involved in the ER/PR testing. There has been no blame assigned within Eastern Health. Since legal proceedings have been initiated, Government will have to allow the legal process to determine if in fact error has occurred.

Other Suggested Response(s):

- When the ER/PR testing problem was discovered in May 2005, arrangements were put in place quickly for an independent laboratory to review the test results and complete ongoing work. Eastern Health took the time it felt was necessary to review the test results from Mount Sinai and conduct an extensive quality review of the laboratory prior to releasing the outcomes to the public in December 2006.
- Eastern Health has put a number of measures in place to provide a high standard of ER/PR testing for new breast cancer patients. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training.
- Newly diagnosed patients should be assured that these high standards are in place and staff have the necessary training to ensure accurate results are obtained.
- Eastern Health has implemented the recommendations from two external reviews and a dedicated laboratory has been established to perform the ER/PR testing with 3 designated technologists, a lab medical director, and a dedicated cutter. A centre of excellence for breast cancer cases has been established at Eastern Health so that examination and reporting will be directed to a dedicated group of pathologists.

Background:

- Prior to April 2004, the Dako testing technique was used at Eastern Health's laboratories which required the manual boiling of tissue samples and the measurement of minute mixtures of immunoperoxidase staining.
- In April 2004, Eastern Health installed the Ventana system for conducting ER/PR testing. This new system automated the process, thereby removing much of the human manipulation of samples.
- In May 2005, a patient who was diagnosed in 2002 with breast cancer and had been determined to be negative using the Dako system, converted to positive after further ER/PR testing using the Ventana system.
- In June – July 2005, Eastern Health conducted a case review of negative ER/PR tests it obtained in 2002. Of 57 cases retested, 37 converted from negative to positive.
- In early July 2005, Eastern Health decided to retest all negative ER/PR tests performed between May 1997 and August 8, 2005. In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratories. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients tested for breast cancer. All new cases were sent to Mount Sinai for ER/PR testing. The chronology of the ER/PR retesting is attached as Annex I.
- The details on the test results are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	No. of Tests sent to Mount Sinai	939
	- Live Patients	763
	- Deceased Patients	176

- Live Patients Whose Samples were Retested	763
- Patients with no change in ER/PR results and no change in treatment recommended	433
- Patients with no change in ER/PR results but a change in treatment recommended by expert panel	13
- Patients where ER/PR test results were different following retesting	<u>317</u>
	763
- Patients who required a change in treatment	104
- Deceased Patients Whose Original ER/PR Test Results were Negative	176
- Patient samples that were retested and results received	101
- Patient samples that have been retested on request	2
- Patient samples that will not be retested unless requested by the families	<u>73</u>
	176

- The May 15th CBC story is reporting that of the 763 live patients, upwards of 42% of the test results were wrong (317 of 763 alive patients). The story is also focused on why Eastern Health has not released the test results for 176 deceased patients. The story quotes a US pathologist, a leading expert on hormone receptor tests in North America, as saying laboratories across the US are having the same problems with these tests.
- In the December press release, Eastern Health stated that 117 of the 939 patients required treatment changes. This appears to be a 12% error rate. In the court affidavit filed by Eastern Health, the 117 patients include 104 patients who required a treatment change due to a change in ER/PR test results and a further 13 patients who saw no change in their ER/PR test results but a change in treatment was recommended. The US pathologist also states that the average error rate in the US is probably as high as 20%. Eastern Health advises that it is very difficult to confirm an actual error rate as ER/PR testing is a complicated procedure that involves more than 40 steps.
- Eastern Health did not initially advise patients of the retesting (despite the Department's suggestion that it should consider doing so) and many learned of it from the media. Eastern waited for the actual results before disclosing information to the patients as Eastern didn't know what this would mean for individuals without the results. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.
- Last Spring (2006), the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which

would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.

- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. There are approximately 40 plaintiffs.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has filed an affidavit in court on December 15, 2006. The lawyers for the plaintiff and the defendant have filed documents for certification and case law with the court on February 9, 2007. A hearing of the certification application is scheduled for May 23-25, 2007.

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ANNEX I – CHRONOLOGY OF ER/PR RETESTING

- April 2004 – The former HCCSJ installed a new VENTANA system for the immunohistochemistry lab to replace the DAKO system.
- May 2005 – An oncologist noted that a patient, diagnosed in 2002 with breast cancer who tested negative* on the DAKO system, converted to positive in 2005 on the new VENTANA system. Oncologists decided further retest 25 negative patients from 2002. Of the 25 retested, 12 converted to positive. An additional 32 negative tests were retested and 25 of the 32 converted to positive on the VENTANA system.
- June 2005 – decision made to retest all patients who were ER/PR negative for the year 2002.
- Early July 2005 – decision made to retest all patients who were ER/PR negative between May 1997 and August 8, 2005.
- Late July 2005 – decision made to arrange for an independent laboratory to complete retesting (Mount Sinai) and all new patients. All testing of ER/PR at the Health Sciences laboratory was stopped.
- August 2005 - process of collecting, packaging and shipping negative test results to Mount Sinai Hospital in Toronto began.
- October 2005 – Tumor board, consisting of two oncologists, two surgeons, two pathologists, one representative from quality department and one support person, was established to review the results as they arrived back from Mount Sinai and made treatment recommendations for each patient. Patients were contacted about specimens being sent away for retesting. This Board met weekly from October 2005 to May 2006 to review individual patient files, assess the impacts and make treatment recommendations.
- Mid October 2005 – Media interviews conducted and advertising purchased to inform the public of specimens sent for retesting.
- December 2005 – Mt. Sinai Hospital contacted by Eastern Health to express concerns on the slow pace of having the testing completed and the reports sent back (manpower issues reported by Mt. Sinai).
- December 7, 2005 – A statement of claim was filed in the Supreme Court of NL Trial Division on behalf of Michelle B. Hanlon.
- February 2006 – the last test results were received from Mount Sinai.
- February to May 2006 – Tumor board reviewed test results, wrote recommendations and disclosed information individually to each patient.
- May 11, 2006 A Statement of Defence is filed with the Supreme Court of NL on behalf of Michelle B. Hanlon.
- June to November 2006 – the new chief pathologist and new VP – Medical Services established a centre of excellence for breast cancer pathology, assigned a head pathologist for immunohistochemistry and prepared to resume ER/PR testing in St. John's and in September the accreditation process for the lab was initiated.
- Late November 2006 – Eastern Health completes its quality review.

- December 11, 2006 – Eastern Health releases outcomes of laboratory review to the public. A technical briefing was also provided to the media and since that time, one client issue was identified. The individual had not been seen by a doctor to obtain her test results despite a number of attempts by Eastern Health to establish contact. She has since received follow up by the physician.
- February 2007 - An affidavit was filed in the Supreme Court of NL between Verna Doucette (plaintiff) and Eastern Health (Defendant)
- February 2007 – lawyers for the plaintiff and the defendant have filed documents for certification and case law.

**The definition of "negative" has changed within this 7 year period. Oncologists previously believed that tumours with less than 30% positivity for ER/PR should be considered negative. With advancing understanding of cancer and treatment, the negative rate has dropped down to 10% and now to 1%. Today, oncologists believe that any positive result is worthy of hormonal therapy.*