

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

Title: ER/PR Testing, Eastern Health

Issue: Ongoing concerns regarding ER/PR testing at Eastern Health.

Anticipated Questions:

- Was there an attempt by the Department and/or Eastern Health to “cover up” the findings of the test results?
- Has Eastern Health now notified all affected patients of the results of retesting and why wasn’t this done sooner?
- At what time did former Ministers of Health become aware of this issue and why didn’t they disclose the magnitude of the problem?
- Why was Government and Eastern Health more concerned with the risk of litigation than patient care?
- Can women’s groups be consulted on how the judicial inquiry will be carried out?

Key Messages:

- Absolutely not. There was full disclosure with patients and their families once test results became available. Eastern Health contacted each patient who was affected by the ER/PR test review or their family physician to make sure they received all the information and support they required. They were told either one of three things:
 - That their tissue had been retested and there was no change in the original results;
 - That their tissue had been retested and that Eastern Health was recommending a change in their treatment; or
 - That although there was a change from their original test result, no change in treatment was recommended.
- This issue has also been in the public domain since late 2005. Eastern Health placed an ad in local papers in October 2005 to provide further details and a number where those with questions could call. The accusation that there was a “cover-up” is unfounded.
- The inquiry will address these questions. However, I must reiterate that all patients who were affected by the ER/PR test review were contacted, media interviews were conducted in late 2005 and early 2006, and an ad was placed in the paper in late 2005. There was no attempt to “cover up” this issue. The focus was on the patients who were impacted.
- The context in which I stated that was with respect to why Eastern Health did not release the number of changed test results during a media briefing in December. As Minister, do I feel the number should have been released at that time? Yes, I do. Eastern Health and Government’s primary concern is always that of the patient. The action taken by Eastern Health (retesting, quality assurance program, establishing an expert panel and expert reviews) and full disclosure to patients demonstrates that the patient and the families are the primary concern.

- The Commissioner will determine who he/she will need to hear from during the inquiry. Individuals or groups can apply to the commission to participate in the inquiry.

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
	(763 live; 176 deceased)	
• 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		317
• 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		73

Eastern Health had independent external reviews conducted by the Chief Pathologist at the BC Cancer Institute and the Chief Technologist and Mount Sinai Hospital in Toronto, and has implemented the recommendations from these reviews. In addition, 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.

- 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 live 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.
- In December 2005, 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.

- On Friday, May 18th, Eastern Health provided a media briefing in which CEO George Tilley publicly apologized for any confusion created as a result of not disclosing the total number of changed test results (317).
- Government held a news conference on Tuesday, May 22, to announce that it will undertake a Judicial Commission of Inquiry, with further details to be provided in the coming days.
- There are now calls for women's groups to be consulted on how the judicial inquiry into the faulty breast cancer will be carried out.

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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. If 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.
- On May 23-25, a hearing of the certification application is scheduled in Supreme Court.

**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.*