New Conference –
May 18, 2007

Media Statement

Introduce Panel

We want today to clarify some of the misinformation about estrogen and progesterone testing that has been in the public this week and to ensure the public that Eastern Health is taking this issue very seriously.

Let me say first of all that this issue is not about breast cancer screening. This is about a test that is taken once a breast cancer diagnosis has been made. It is used to determine if a breast cancer patient might benefit from hormonal therapy. At no time has there been any question of the accuracy of mammograms or biopsy results to diagnosis Breast Cancer.

Next let me say that as the President and Chief Executive Officer of Eastern Health, I am sorry for the confusion that has ensued over this issue. I take full responsibility for the organizations actions in talking about this issue and we are steadfast in our attempt to clarify the situation to ensure there is no more confusion about who is affected and what it all means.

At no time did Eastern Health withhold any personal information from any of the patients impacted by our decision to retest for estrogen and progesterone receptors, or ER/PR.

It is important for everyone to know that we contacted each and every patient who was affected by the ER/PR test review, making sure they received all the information and support they required.

Furthermore, once we became aware of the potential issues with the ER/PR test, we immediately suspended our own testing and began using an out-of-province testing facility. (JULY 2005)

In 2005 when we discovered that there were inconsistencies in a small number of ER/PR tests we made a decision, as an organization, to go back and review all the ER/PR tests we had conducted since 1997.

We did this because we know that hormonal therapy may still be of benefit to a breast cancer patient who was diagnosed that long ago.

We felt that if there was even the **possibility** that one patient may benefit from retesting, we had an **obligation** to retest all patients, regardless of the consequences.

It took us about a year to complete all the retesting and to conduct external and internal reviews in our laboratory. This is longer than any one of us would have liked, and we shared the distress of our patients resulting from this long delay.

However, as you know we had to rely on another facility in another province to conduct our retesting which took longer than at first anticipated.
Additionally, as test results came back to us it was necessary to assess all the results that had any change in them to see if we would recommend a treatment change for those patients.

These assessments were conducted by a panel of experts in cancer care, using the best knowledge available to us today on cancer treatment.

Before we talked about our results with the public we felt that had an obligation to contact each and every patient who was involved in the retesting to tell them either:

- that their tissue had been retested and there was no change in the original results;
- that there tissue had been tested and that we were 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 process was never a research project.
Nor was it quality review exercise.
It was about this organization redoing a test to provide every treatment opportunity possible for our patients.

In December when we issued an assessment of the review to the media, we did so because we felt that the public at large deserved to know as much as we could tell them about the results.

Let me explain the numbers:

- There were 939 patient with ER negative reports
- Of the 763 patients that we reviewed, 317 patients had a change in result
- 104 of those patients had a resulting change in treatment
- An additional 13 patients are added to these 104 because although their test results didn't change the definition of negative changed, meaning that hormonal therapy was possible for these individuals.

At that time, we focused on the 117 individuals whose treatment plans changed.

I acknowledge that we did not identify at that time the additional patients who had a change in test result but no change in treatment plan.

We believed at the time that the decision to focus on the 117 was the right one because this was, in our estimation, the critical piece of information. That being said, given the reaction that has come from not releasing the second number, I regret that decision and apologize for any confusion this has caused.

The total group of 317 patients who tests results changed appears to be the source of much confusion.

I need to stress that this is not a new group of patients and in fact includes the 117 individuals that we have already publicly indicated required a treatment change.

I also appreciate that this issue must be causing incredible anxiety for the families of the women who have passed away. We sincerely regret that.

Unfortunately we simply do not know how many of these patients may have benefited from hormonal therapy.

We are committed to being responsive to all our patients and their families and if a systematic review of these tissue samples would help to alleviate any concerns, than I am committed to ensure that this is completed and that all patient's families are contacted for follow-up.

This has been a learning experience for this organization, but I must reiterate that Eastern Health has acted and will continue to act in the best interests of our patients.

They are our first priority, and patient safety is important to us.

Our staff and physicians have been and will continue to be available to all the patients and their families impacted by this review. And I certainly encourage any patient or their family members with questions or concerns to bring them to us through our client services officers, physicians and other care providers.

I will now take your questions.

STATEMENT OF STATISTICS

Eastern Health

(AS FILED IN COURT AFFIDAVITS DATED FEBRUARY AND MARCH 2007)

Eastern Health reviewed 2709 ER/PR tests conducted between 1997 and August 2005. Of those cases reviewed, 939 of the tests were originally reported as ER-negative. The negative test samples were sent to Mount Sinai Hospital to be retested. Results were obtained and reviewed for 763 patients.

Of the 763 patients whose samples were retested and results obtained, 433 patients saw no change in their ER/PR results and therefore no change in treatment was recommended. Specifically,

- 341 patients were confirmed negative by Mount Sinai;
- 28 patients were confirmed negative by the Tumor Board;
- 12 patients were confirmed positive; and
- 52 patients were determined to have ductal carcinoma in situ, and therefore no form of treatment would have been recommended.

A further 13 patients saw no change in their ER/PR test results but a change in treatment was recommended as the standard for interpretation of what constituted an ER-positive test result had changed between the time of original testing and the Tumor Board's review.

The ER/PR test results were different for 317 patients following retesting.

Of the 317 patients, 104 patients required a change in treatment.

- 96 of these patients were recommended for treatment with Tamoxifen or another aromatase inhibitor;
- 4 of these patients saw a change in their original diagnosis; and
- 4 of these patients originally had a degree of ER positivity but were negative on retesting.

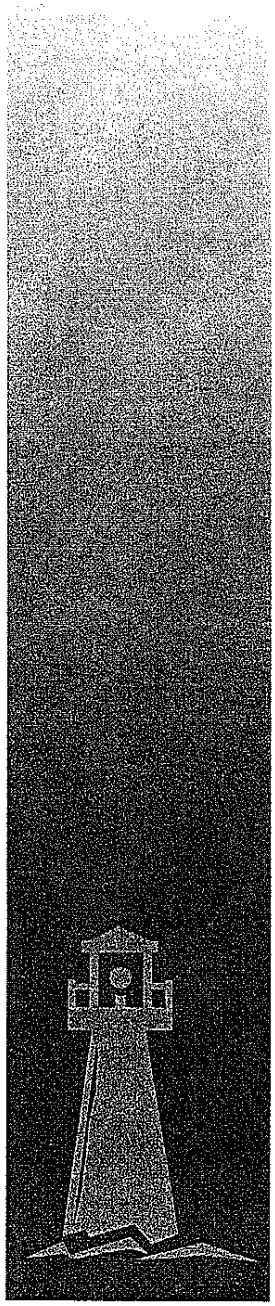
The remaining 213 patients whose ER/PR tests results were different on retesting did not require a change in the treatment that had been originally recommended for them because:

- 60 of these patients had a very low risk of recurrence;
- 148 of these patients had previously been treated with Tamoxifen or another aromatase inhibitor either at their request or their oncologist's recommendation following a review of the test results and their particular medical and family histories; (13 of these patients were not placed on Tamoxifen for their original disease but for subsequent metatstatic disease);
- 5 of these patients received no treatment as they required assessment prior to any recommendation being made.

176 of the patients whose ER/PR tests were originally reported as negative are deceased. Of these 176 patients:

- 105 patient's samples were retested and results have been received;
- Of those 105, 68 saw no change in their results, 1 originally clinically positive result retested as clinically negative, and 36 patient's test results changed from clinically negative to clinically positive.

2214 of the ER/PR breast tissue tests were conducted in the Dako system from 1997 to April 2004. 495 tests were conducted in the Ventana system from April 1, 2004 to August 1, 2005.



ER/PR RETESTING CHRONOLOGY

MAY 18, 2007

Eastern Health

April 2004: Eastern Health (then the Health Care Corporation of St. John's) installed a new Ventana system for use in our immunohistochemistry laboratory. This more extensively automated system replaced the Dako System, a complicated, manual and multi-phase procedure with more than 40 steps. The Dako system was an advance from biochemical assay, used prior to 1997.

May 2005: One of our oncologists was treating an individual whose ER/PR was originally tested in 2002 (using the Dako system) and shown to be negative. Given the nature of this woman's cancer, her age and other factors, the oncologist requested that the test be repeated. The second test was conducted on the new Ventana system, and converted to a positive result.

Representatives from the Laboratory Program met with oncologists to discuss this new result and a decision was made to retest five more negative patients, who all converted to positive.

June 2005: It was decided to retest all negative results from 2002 to determine if these were isolated cases or symptomatic of a bigger issue. The chief of pathology wrote to all Laboratory directors in the province to return all negative ER/PR specimens for the year 2002 for retesting on the new, more sensitive Ventana system.

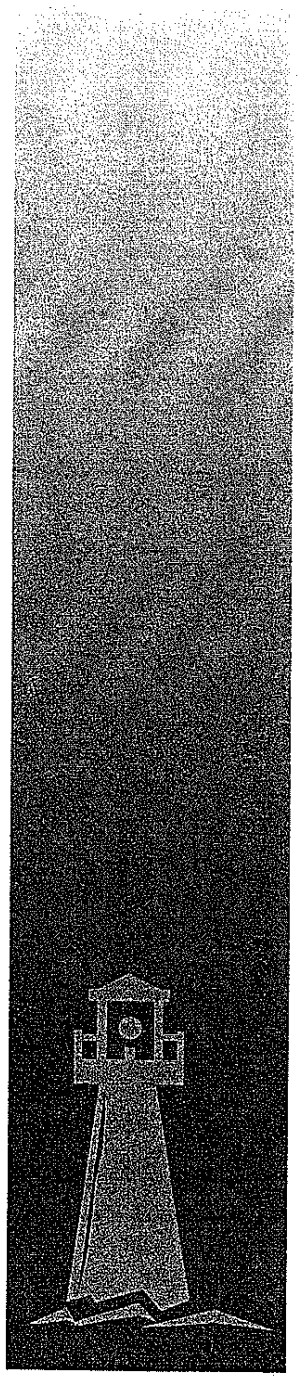
Early July 2005: A meeting was scheduled and the decision was made that all patients who were ER/PR negative from 1997-2004 would be retested internally on the Ventana System with testing to take place over the next number of weeks.

Late July 2005: The decision was made to stop reporting ER/PR in our laboratory and to arrange for an independent and external laboratory to complete our retesting as well as ongoing work.

August 2005: Mt. Sinai Hospital, considered to be a "gold standard" laboratory internationally, agreed to take on the project. Our laboratory began the process of collecting, packaging and shipping all negative* test results from 1997-2005 to Toronto.

** The definition of "negative" has changed within the seven year period in question. Originally, oncologists believed that tumors with less than 30% positivity for ER/PR should be considered negative. With advancing understanding of cancer and treatment, the negative rate has dropped, first to 10% and now to 1%. Today, oncologists believe that any positivity may be worth treating with hormonal therapy.*

Early October 2005: The first set of results arrived from Mt. Sinai.



Mid October 2005: The organization established a Tumor Board comprised of two (2) oncologists, two (2) surgeons, two (2) pathologists, one (1) representative from the Quality Department and one (1) support person. The Tumor Board was tasked with reviewing the results as they arrived, reviewing charts, and making treatment recommendations for each patient. The Tumor Board met once a week from October 2005 to May 2006 reviewing individual cases and making recommendations.

Mid October 2005: The organization conducted the first of numerous media interviews, and provided whatever background information was available at that time. Advertising was also purchased informing the general public of the retesting.

October 2005: Patient Relations representatives from Eastern Health telephoned all individuals whose specimens were being sent away for retesting. The laboratory conducted the first of a number of external review processes. During this period, the laboratory also attempted to gain insight from other laboratories across Canada regarding their experiences with ER/PR testing.

November/ December 2005: The organization expressed concerns to Mt. Sinai about the slow pace of reports. However, they were experiencing unexpected manpower issues and were unable to move the tests through the system any faster.

Late January 2006: The last batch of samples arrived at Eastern Health from the other provincial health authorities. They were forwarded to Mt. Sinai for review.

February 2006: The last test results were received from Mt. Sinai.

February - May 2006: Concentrated effort of the Tumor Board to review test results, write recommendations and conduct disclosures. A six month period *(May to October)* follows to ensure that the organization has completed all the disclosures possible and that every patient has had every opportunity to contact their physicians.

June – November 2006: The new Chief Pathologist and the new Vice-President, Medical Services worked on the results of the quality review process; established a centre of excellence for breast cancer pathology; assigned a head pathologist for immunohistochemistry; and generally prepared for the continuation of ER/PR testing in our laboratory.

September 2006: A statistical review was initiated to examine the numbers and arrive at conclusions. This information will form the basis of the quality review. Analysis is continuing.

Late November 2006: The organization completes its quality review.

December 2006: Public release of results and media briefing.

February 1, 2007: Testing begins again in our laboratory.

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