

To: Dr. R. Williams
V.P., Quality, Diagnostic and Medical Services

From: Heather Predham
Manager, Quality and Risk

Date: February 22, 2006

Re: Update on Estrogen and Progesterone Receptor Testing

A total of 851 patients have had their results returned from Mount Sinai.

- There are results on 23 patients recently received from St. Anthony. These are included in the total above, but are not included in the breakdown.
- Results have not been returned on 74 patients whose samples were sent but were later determined to be deceased.
- Results have not been returned on approximately 14 patients. The Laboratory program is reconciling the sent with returned samples and the final number has not been finalized.

Based on this information, the total number of patients that were sent for retesting was 939.

Patients whose results have been reported by Mount Sinai but require review

Total completed to date: 247

Total remaining to be done: 154

Category	Number	Comments
Patient status has changed but there are no treatment recommendations	142	This category includes: <ul style="list-style-type: none"> • Patients who are deemed to be at a low risk for recurrence or previously could not tolerate Tamoxifen (40) • People who have been previously treated with Tamoxifen or another aromatase inhibitor (102) <ul style="list-style-type: none"> ◦ This group of patients include those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13)
Patient status has changed and there are treatment recommendations	76	These patients are recommended to be placed on Tamoxifen or another Aromitase inhibitor. This group includes: <ul style="list-style-type: none"> • Patients who have been impacted by the delay in receiving Tamoxifen (9) • Patients whose results have not changed significantly, but the definition of positive and negative has changed since diagnosis. (13)
Confirmed negative	13	These patients' original results were considered to be negative by the treating clinician and treated appropriately. Review by the panel confirmed this interpretation. No action other than notification is required.
Confirmed positive	4	These patients' original results were considered to be positive by the treating clinician and treated appropriately. Review by the panel confirmed this interpretation. No action other than notification is required.

Category	Number	Comments
Confirmed DCIS	2	These patients were not retested at Mount Sinai as they were diagnosed as DCIS. Review of the original pathology report confirmed this; no action other than notification is required. It was an earlier practice to test these patients with this diagnosis for ER/PR however as it has no impact in treatment, ER/PR testing is no longer done.
Deceased	6	Upon review of the chart it was determined that the patient had died. These charts have been deferred.
Requires assessment prior to recommendation	4	The panel could not make a recommendation for these patients without seeing the patient. The combination of the time since diagnosis and the original presentation of the disease places the patient near the borderline between treatment and not.
Total	247	
Deferred	19	Panel could not make a recommendation with information and is waiting until additional information is available
To be paneled	154	These patients are scheduled to be reviewed
Total	420	

Confirmed negative

These are patients who were retested and the original results were verified by the Mount Sinai retesting

Region	Number	Comment
St. John's	150	Notified by Eastern Health staff or physicians. Currently trying to locate 5 patients.
Corner Brook	71	Notified by Western Health staff. Currently trying to locate 7 patients.
Carbonear	14	Notified by Eastern Health staff
Clareville	3	Notified by Eastern Health staff
St. Anthony	3	Notified by Eastern Health staff
Gander	19	Currently being notified by Central Health staff
Grand Falls	40	Currently being notified by Central Health staff
Total	300	

Patients from St. Pierre (Total - 9)

Dr. Malluret has been written to convey the following information:

- 4 patients were confirmed negative. Dr. Malluret has agreed to coordinate informing these patients
- 2 patients were paneled and recommended to start Tamoxifen (one for metastatic disease)
- 2 are deceased
- 1 results are not back

(please note that the 2 that are paneled are included in the numbers above)

Patients who are deceased (Total – 175)

These patients have been determined to have died since this retesting effort began. A list of confirmed deceased was sent to Mount Sinai and there were 74 patients who were not retested. However, there were 101 that were retested and results received. These will be dealt with as we progress and of course that number will change as we proceed with communication.

Patients whose samples were not retested at Mount Sinai

These 55 patients had slides that Mount Sinai determined were either Ductal carcinoma In Situ (DCIS) or had no tumor cells present. The Laboratory program is currently reviewing these slides to determine the action that needs to be taken. This number has been included in the number to be paneled as the outcome and implications will have to be discussed.