

Interpretation of Statistical Tables from Estrogen Receptor Database  
DRAFT: February 7, 2008

1. Introduction

This note provides a summary interpretation of the statistical tables from the NLCHI ER/PR Database. The tables address clinical issues only. Communications data will be forthcoming.

Throughout this report, references are made to original data from Eastern Health. It is important to bear in mind, however, that the data represents patients from all regions of the province and that not all of the steps in ER/PR testing take place in the Eastern Health laboratory. For example, tissue extraction and fixation occur at many sites throughout the province before transport to the laboratory, and post-laboratory interpretation and reporting by pathologists occur at many sites as well. Eastern Health collected and reported data on the retesting process for all patients starting in 2005, and therefore the data against which the NLCHI database can be compared belongs to Eastern Health.

2. Total Cases

Eastern Health reported to the public on December 11, 2006 that there were 939 patients retested at Mount Sinai. This number was also reported to the Minister of Health and Community Services on November 23, 2006, to the court in affidavits, and to the media and public throughout the period in 2007 leading up to the appointment of the Commission of Inquiry.

The 939 total was explained by Eastern Health as containing all patients who had an ER/PR negative test result performed at Eastern Health between 1997 and August 2005 and subsequently sent to Mount Sinai for retesting. It was acknowledged as well that the total contained some original positives which doctors had specifically asked to be retested.

Using the same definitions, NLCHI found 1016 cases, or 77 greater than the number reported by Eastern Health. It is not possible to explain completely the difference between the original 939 total and the new 1016 total because, as part of the tracking and data management process within Eastern Health, the spreadsheet which originally contained the 939 count was overwritten with updates many times. Therefore, it cannot be known with certainty how many cases, or which cases, were present or absent from the older Eastern Health spreadsheets. However, the general explanations for the new, higher total are:

- Some cases were identified by Eastern Health or self-identified by patients after the initial reporting of 939;
- Some cases of deceased individuals were not initially forwarded for testing because of a perception in some RHAs that only living patients need be identified;
- The challenges faced by Eastern Health (e.g., multiple information systems from which to identify original ER/PR tests and original test scores; multiple channels for

submitting retests to Mount Sinai; lack of an overarching information system to integrate records for all unique patients) made it difficult to identify every case.

Within the 1016 cases, there are 19 original positives that were sent to Mount Sinai for retesting. While the original purpose of retesting was focused on negatives, some physicians asked for certain positive results to be retested. If these are removed for analytical purposes, the total group of original negatives that were sent to Mount Sinai was 997.

3. Comparison of Eastern Health's November 23, 2006 Briefing for the Minister with New Database Results.

The briefing for the Minister on November 23, 2006 included a table with 11 categories of results, with total cases adding to 939. Eastern Health's briefing was primarily focused on the re-test outcomes for the 763 patients identified as living. All deceased patients were assigned to a 12<sup>th</sup> category entitled "deceased", whether or not re-test results on these cases had been received by that date. Eastern Health reported at that time that 176 people were deceased.<sup>1</sup>

As the new database contains a larger "total cases" than the data reported by Eastern Health, it is not surprising that some of the components have also changed. For example, if Eastern had captured all of the cases that are in the new database, and had it been linked to the Provincial Mortality Database (through NLCHI), 295 people would have been identified as deceased at that time instead of 176.<sup>2</sup> This variance means that some of the 763 cases which were reported as living on November 23, 2006 were in fact deceased at that time.<sup>3</sup>

The key comparisons between the Eastern Health table (November 23, 2006) and the new database are as follows:

- Eastern reported 433 living patients as having no change in result and thus no change in treatment. The new database shows 354 living patients and 187 deceased in this category;<sup>4</sup>
- Eastern reported 213 living patients who had test results that converted from negative to positive but for various reasons had no change in treatment recommendation. The new database contains 201 living patients and 16 deceased patients with this outcome.
- Eastern reported that 104 living patients had a change in test results and required treatment change.<sup>5</sup> The new database found 101 living patients and 1 deceased patient in this category.

<sup>1</sup> The Eastern Health data is contained in the first data column of Table 2 in Appendix 3.

<sup>2</sup> A year later, in late 2007, the number of deceased grew to 323 people.

<sup>3</sup> This finding gives rise to the question of how Eastern Health could have reported this result if they had been in contact with all patients who were retested. This question will be explored further when the database results on communications are known.

<sup>4</sup> The definition of "negative" between 1997 and 2000 uses a cut-off score of 30%, and after 2000 it uses a cutoff score of 10%. This approach is consistent with the letter (September 6, 2005) from Dr. Cook to lab directors and Medical Directors throughout the province in which instructions were given for the selection of samples for retesting at Mount Sinai. It is also consistent with Dr. Khalifa's proposed cutoff as communicated in his letter to pathologists on February 16, 1998.

~~Other than the identification of the number of the higher number of deceased, it cannot be concluded that the Eastern Health table contained errors. The original Eastern Health data cannot be fully verified because the spreadsheets no longer exist to determine which cases were in each of the categories of the table on November 23, 2006. The absence of an auditable trail of records and spreadsheets is a shortcoming of the data management process.~~

#### 4. Time frame for Retesting

The date that samples were sent to Mount Sinai can be determined for most of the cases. There are 52 cases where the date of testing cannot be determined from existing records. Out of the remaining cases, 85% were sent in 2005, 4% were sent in 2006 and 11% were sent in 2007.

The reason why there was an increase in cases in 2007 was the identification of some deceased that had been originally omitted due to uncertainty over "inclusion criteria", the inclusion of cases between January and May 1997 over which it was initially unclear whether they were supposed to be retested, and the identification of additional cases that should have been sent in 2005.

#### 5. Number of Cases by Year of Original Test

Table A in Appendix 1 displays the number of original ER negative cases by year which were subsequently retested at Mount Sinai Hospital. Out of the total 997 patients, the volumes were highest for patients tested between 1998 and 2002, peaking at 182 patients in 2000. The volume of negative cases declined substantially in 2004 and 2005 as the more sensitive Ventana testing system was utilized.

#### 6. Positivity Rates

The positivity rate is a readily accessible measure of whether a laboratory is producing results within expected ranges. In its initial internal assessment (July 2005) Eastern Health said that the normal range for positivity was 50-85%. Later, in a media briefing on December 11, 2006, Eastern said that the literature suggests that about 75% of breast cancers are estrogen-receptor – positive..... In June of 2007, Eastern reported its positivity rate as "65% from 1997-2005.....". In an affidavit by Dr. Allen Gown, he stated that he had been advised that the seven year average was 74% ER-positivity. Upon review of the data given to him by Eastern Health it appeared that the ER positivity rate was in the range of 65-75% for breast cancers analyzed during the time the DAKO instrument was used.

Positivity rates by year are presented in Table B in Appendix 1. To identify which tests were positive and which tests were negative, the clinical cutoffs of 30% for 1997-2000 and 10% for 2001-2005 are used in this table, reflecting the clinical cutoffs used by Eastern Health to identify

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<sup>5</sup> Eastern Health actually identified 117 patients who required treatment change. This total consists of the 104 patients noted above, plus 13 patients whose results did not change but who needed a treatment change because the definition of positive had changed in 2001.

samples for retesting at Mount Sinai.. This approach also enables a comparison with the data provided by Eastern Health to the court in an affidavit in May 2007 (see Table B.1).

The following are some methodological points about the data in Table B.

- First, these calculations refer to tests rather than patients because the positivity rate measures the quality of a group of tests, not the characteristics of a group of patients. The number of original negative tests (the numerator – column 1) was gathered by NLCHI using criteria for inclusion, plus measures to ensure the exclusion of ER/PR tests performed for a reason other than breast cancer, duplicate records and data entry mistakes.
- Second, the total number of ER/PR tests performed by Eastern (which is used as the denominator in the positivity rate – column 2) was provided by the Eastern Health. This number excludes the “non-breast” ER/PR tests in St. John’s, but data was not available to identify and exclude the non-breast cases from outside St. John’s. It is estimated that this factor has a small impact on the overall positivity rate, making it slightly higher than it should be. (It is possible that the total number of ER/PR tests for 1998 is under-estimated, given that the positivity rate is unusually low for that year.)
- Third, some of the retest samples were not the same paraffin blocks that were used to produce the original slides. The number of instances where this happened is believed to be about 10%, and it is uncertain whether the impact would be an increase, decrease or no change in the positivity rate.
- Fourth, between 1997 and 2005 there were 49 negative cases (54 tests) which were subsequently identified as DCIS. For purposes of calculating the positivity rate, these samples have been excluded from both the original tests and the Mount Sinai results because DCIS patients are not normally recommended for tamoxifen in Canada and consequently are not normally sent for ER/PR testing. It remains uncertain whether there are additional DCIS cases within the approximately 2000 positive tests that should be removed if they could be identified.
- Fifth, there are a number of tests (37 in Table B) which could not be interpreted for inclusion. The exclusion of these tests, and the exclusion of DCIS noted above, from both the number of original negatives and the number of total tests, slightly increase the positivity rate.

A comparison of the positivity rates during this period with those from the literature is necessary to evaluate the data. One of the difficulties in doing a comparison is that most studies use a consistent 10% cutoff rate for assessing positivity. As clinical guidelines, Eastern Health used the 10% cutoff after 2001, but the cutoff was 30% before 2001. NLCHI produced tables to eliminate this factor and allow for a more technical evaluation of the test. Table C (in Appendix 1) summarizes the positivity rates at the 1% and 10% cutoff levels.

The original purpose of the retesting process was patient care, not controlled research. Nonetheless, the retest group represents the complete set of negative ER cases between 1997 and 2005 and therefore is unbiased for Newfoundland and Labrador. The characteristics of the Newfoundland and Labrador population could vary from the characteristics of study groups in the literature, but this issue has not been verified one way or another.

## 7. Changes in ER Scores after Retesting

Eastern Health had a panel of physicians and quality officials examine most of the retests which had a changed result from Mount Sinai. This process allowed for an expert opinion to be rendered regarding each case, and a valid conclusion drawn on whether a change (i.e., from clinically negative to clinically positive and vice versa), had actually occurred. However, given that not all changed results were examined by the panel, another method was needed to calculate the total rate of changed results between Eastern Health tests and Mount Sinai tests.

Given that the results of the pathology reports are normally reported as a quantitative score between 1 and 100, it is possible to calculate the rate of change from negative to positive for the whole retest group, notwithstanding the determinations of the tumour panel. This approach is a mathematical approach, not a clinical one, and is not to be regarded as a substitute for the work of the tumour panel. In particular, the change rate in the test results is not an indicator of the proportion of patients who should have received alternate treatment. It is important to bear in mind that only 117 of the 317 changed results as reported by Eastern Health to the Minister on November 23, 2006 needed a change in treatment. Although the NLCHI database includes different numbers than Eastern Health's report, the general principle would remain the same.

The results are presented in Table D in Appendix 1, using a cutoff point of 30% between 1997 and 2000 and 10% between 2001 and 2005, reflecting the clinical cutoff used by Eastern Health to identify samples for retesting at Mount Sinai. It also enables a comparison with the data provided by Eastern Health to the court in an affidavit in August 2007 (see Table D.1).

Another approach to classification is to use the same cutoff for the whole period – i.e., either 1% or 10%. By using a standardized approach, the goal is not to reach a clinical conclusion, but rather to reach a conclusion about the technical aspects of the test. The results are presented in Table E.

## 8. Change Rate by Region

Using the clinical cutoff points, the change rates for patients in the province and the four regions are included in Table F in Appendix 1. On average for the whole period, the regions are not substantially different from the provincial average of 43%, except for Labrador/Grenfell at 50%, although it is not clear whether this may be a statistical anomaly due solely to low volumes from that region.

## 9. Changes by Site

Table G in Appendix 1 shows that the average percentage of changes by site was 43 percent. In other words, over 4 out of every 10 original negative results changed to positive. Most sites were close to or below this average. The two sites with the highest change rate were Clarenville (54%) and Labrador/Grenfell (51%).



Appendix 1: Results Tables (based on NLCHI Database results in Appendix 3)

Table A: Number and Percentage of Original Negative ER Tests and Cases by year.				
Year	Number of Tests with Negative ER	Percentage	Number of Cases	Percentage
1997	63	5.8	61	6.1
1998	159	14.6	140	14.0
1999	167	15.3	150	15.0
2000	195	17.9	182	18.3
2001	151	13.8	141	14.1
2002	157	14.4	147	14.7
2003	110	10.1	98	9.8
2004	61	5.6	54	5.4
2005	28	2.6	24	2.4
Total	1091	100.0	997	100.0
<ol style="list-style-type: none"> <li>1. Some patients had more than one ER/PR test. Some tests for a single patient may have occurred in different years, but the patient appears only in a single year.</li> <li>2. Between 1997 and 2000 ER negative is <math>\leq 30\%</math> and between 2001 and 2005 ER negative is <math>\leq 10\%</math>. This definition is based on a clinical guideline and was used to determine which tests would be retested at Mount Sinai Hospital.</li> </ol>				

Table B: Positivity Rate for ER Testing by Year					
Cutoff Point in Use	Testing System	Year	# of Original Negative Tests	# of ER Tests done by ERHA	ER Positivity Rate
>30%	DAKO	1997	56	130	56.9
		1998	142	201	29.4
		1999	158	351	55.0
		2000	180	317	43.2
>10%		2001	136	327	58.4
		2002	149	312	52.2
		2003	97	306	68.3
	DAKO to 31/03; Ventana after 31/03	2004	59	326	81.9
	Ventana	2005	23	191	88.0
		97-05	1000	2461	59.4

1. ERHA – Eastern Regional Health Authority. Total ER/PR tests were counted by the Laboratory Division, Eastern Health, in coordination with NLCHI. The total was 2552 and has been adjusted in this table to remove DCIS (54) and non-interpretable results (37).
2. Negative tests for this table are “total negative tests” (1091) less DCIS (54) and non-interpretable results (37).
3. Between 1997 and 2000 ER negative is  $\leq 30\%$  and between 2001 and 2005 ER negative is  $\leq 10\%$ . This definition is based on a clinical guideline and was used to determine which tests would be retested at Mount Sinai Hospital.

Source: Calculated from data provided in NLCHI Patient Listing and Communication Events- ER/PR Retesting Report (2007)

**Table B.1: Data Source Comparisons for Total Tests, ER/PR Negative Tests, and Positivity Rates Calculated by Dr. Hutton.**

	Year	Total ER/PR Tests at Eastern Health laboratory			# Tests ER/PR Negative (using 30/10 clinical cutoff point)		May 16, 2007 calculations by Dr. Hutton on May 10-07 data		Recalculation of Dr. Hutton's Rates on May 10-07 data	
		10-May-07	Jan-08	Feb-08	10-May-07	NLCHI	Pos%	Neg%	Pos%	Neg%
DAKO System	1997	137	137	137	57	56	58	42	58	42
	1998	147	218	218	76	142	48	52	48	52
	1999	360	360	360	126	158	68	32	65	35
	2000	370	370	332	170	180	54	46	54	46
	2001	374	374	342	143	136	60	40	62	38
	2002	344	344	320	147	149	58	42	57	43
	2003	373	373	319	89	97	76	24	76	24
	2004	109	109	82	16		85	15	85	15
	Subtotal	2214	2285	2110	824		63	37	63	37
Ventana System	2004	381	381	328	41	59	90	10	89	11
	2005	114	114	114	19	23	84	16	83	17
	Subtotal	495	495	442	60		87	13	88	12
	Total	2709	2780	2552	884	1000			67	33
	Source	ERHA	ERHA	ERHA	ERHA	NLCHI	C.A.	C.A.	n/a	n/a

Note: Eastern Health used the clinical cutoff approach when presenting Total Test and ER/PR negative statistics to the court in May 2007. This data was used by the Class Action consultant to calculate annual positivity rates. The use of this data to calculate positivity rates was not commented on by Eastern Health in any submission to the court. Using this approach, the NLCHI data has been used (in Table B above) to calculate positivity rates that can be compared to the consultant's original calculations (which have been revised above as they appeared to contain errors in the submission to the court).



Table B.2: Positivity Rate and Change rate, In and Outside St. John's, Using 1% Cutoff Point

	1997	1998	1999	2000	2001	2002	2003	2004	2005	97-05
<b>Negative Tests (Less DCIS and Other)</b>										
St. John's	28	48	48	81	69	75	39	27	11	426
Outside St. John's	19	59	55	47	38	45	31	23	9	326
Total	47	107	103	128	107	120	70	50	20	752
<b>Changed Negative to Positive</b>										
St. John's	6	17	27	35	35	42	18	4	1	185
Outside St. John's	7	32	35	23	19	28	8	6	1	159
Total	13	49	62	58	54	70	26	10	2	344
<b>Change Rates</b>										
St. John's	21.4	35.4	56.3	43.2	50.7	56.0	46.2	14.8	9.1	43.4
Outside St. John's	36.8	54.2	63.6	48.9	50.0	62.2	25.8	26.1	11.1	48.8
Total	27.7	45.8	60.2	45.3	50.5	58.3	37.1	20.0	10.0	45.7
<b>Total Tests (less DCIS and Other) (Source: Eastern Health)</b>										
St. John's	n/a	139	155	170	181	160	143	144	92	1184
Outside St. John's	n/a	63	197	150	150	153	165	180	103	1161
Total	132	202	352	320	331	313	308	324	195	2477
<b>Positivity</b>										
St. John's	n/a	65.5	69.0	52.4	61.9	53.1	72.7	81.3	88.0	64.0
Outside St. John's	n/a	6.3	72.1	68.7	74.7	70.6	81.2	87.2	91.3	71.9
Total	64.4	47.0	70.7	60.0	67.7	61.7	77.3	84.6	89.7	69.6

Table B.3: Positivity Rate and Change Rate, In and Outside St. John's, Using 10% Cutoff Point

	1997	1998	1999	2000	2001	2002	2003	2004	2005	97-05
<b>Negative Tests (Less DCIS and Other)</b>										
St. John's	32	57	59	92	81	84	46	27	12	490
Outside St. John's	24	71	79	71	55	64	51	32	11	458
Total	56	128	138	163	136	148	97	59	23	948
<b>Changed Negative to Positive</b>										
St. John's	9	21	30	35	44	43	20	2	0	204
Outside St. John's	12	35	48	34	26	33	15	8	0	211
Total	21	56	78	69	70	76	35	10	0	415
<b>Change Rates</b>										
St. John's	28.1	36.8	50.8	38.0	54.3	51.2	43.5	7.4	0.0	41.6
Outside St. John's	50.0	49.3	60.8	47.9	47.3	51.6	29.4	25.0	0.0	46.1
Total	37.5	43.8	56.5	42.3	51.5	51.4	36.1	16.9	0.0	43.8
<b>Total Tests (less DCIS and Other)</b>										
St. John's	n/a	139	152	168	179	160	143	144	92	1177
Outside St. John's	n/a	62	196	147	148	152	163	179	102	1149
Total	130	201	348	315	327	312	306	323	194	2456
<b>Positivity</b>										
St. John's	n/a	59.0	61.2	45.2	54.7	47.5	67.8	81.3	87.0	58.4
Outside St. John's	n/a	-14.5	59.7	51.7	62.8	57.9	68.7	82.1	89.2	60.1
Total	56.9	36.3	60.3	48.3	58.4	52.6	68.3	81.7	88.1	61.4

**Table C: Positivity Rate for Original ER Testing, by Cutoff Point, by Year**

Year	Cutoff Point		
	1%	10%	30%
1997	64.4	56.9	56.9
1998	47.0	36.3	29.4
1999	70.7	60.3	55.0
2000	60.0	48.3	43.2
2001	67.7	58.4	n/a
2002	61.7	52.6	n/a
2003	77.3	68.3	n/a
2004	84.7	81.9	n/a
2005	89.6	88.0	n/a
97-05	69.6	61.4	n/a
N=	752	948	
<ol style="list-style-type: none"> <li>1. The shaded areas highlight the results that are consistent with the clinical cutoff points used to determine which tests would be retested at Mount Sinai Hospital.</li> <li>2. Tests were not retested between 2001 and 2005 if ER scores were above 10%. Therefore, this period is not applicable (n/a) for the 30% column.</li> <li>3. The 1% and 10% columns exclude DCIS (54) and non-interpretable tests (21 for 1% cutoff and 42 for 10% cutoff)</li> </ol>			

Table D: Change Rates of Original Negative ER Tests as Compared to Mount Sinai Results, by Year						
Cutoff Point in Use	Testing System	Year	Confirmed Negatives	Changed Negative to Positive	Change as % of Negatives	
>30%	DAKO	1997	39	17	30.4	
		1998	87	55	38.7	
		1999	91	67	42.4	
		2000	114	66	36.7	
>10%		2001	66	70	51.5	
		2002	72	77	51.7	
		2003	62	35	36.1	
		DAKO to 31/04; Ventana after 31/04	2004	49	10	16.9
		Ventana	2005	23	0	0
			97-05	603	397	39.7

1.

Change Rate is defined as the proportion of total original negative ER samples that, upon retesting, had a positive score using the clinical guideline applicable for the original test.

2.

Between 1997 and 2000 ER negative is ≤30% and between 2001 and 2005 ER negative is ≤10%. This definition is based on a clinical guideline that was used to determine which tests would be retested at Mount Sinai Hospital.

**Table D.1: Number of False Negatives by Source**

Year	November 23, 2006 Media Release from Eastern Health (Patients)	August 3, 2007 Affidavit of Eastern Health (Tests)	NLCHI Data (Tests)
1997		16	17
1998		51	55
1999		71	67
2000		49	66
2001		61	70
2002		71	77
2003		39	35
2004		12	10
2005		2	0
Total	317	372	397

Note: Eastern Health used the clinical cutoff approach when presenting the false negatives to the court in an affidavit. Using this approach, the NLCHI data has been used (in Table D above) to calculate change rates. Change rates have also been calculated in Table E using a technical cutoff rather than a clinical cutoff.

**Table E: Change Rates of Original Negative ER Tests as Compared to Mount Sinai Results, by Cutoff Point and by Year**

Year	Cutoff Point		
	>1%	>10%	>30%
1997	27.7	37.5	30.4
1998	45.8	43.8	38.7
1999	60.2	56.5	42.0
2000	45.3	42.3	36.7
2001	50.5	51.5	n/a
2002	58.3	51.4	n/a
2003	37.1	36.1	n/a
2004	20.0	16.9	n/a
2005	10.0	0.0	n/a
97-05	45.7	43.8	n/a
N=	752	948	
<ol style="list-style-type: none"> <li>1. The shaded areas highlight the results that are consistent with the clinical cutoff points used to determine which tests would be retested at Mount Sinai Hospital.</li> <li>2. Tests were not retested between 2001 and 2005 if ER scores were above 10%. Therefore, this period is not applicable (n/a) for the 30% column.</li> </ol>			



**Table F: Retest Results and Change Rate of ER Negative Patients  
by Time Period by Region**

Time Period of Original Test	[1] Confirmed Negatives	DCIS	[2] Changed to Positive due to change in definition	[3] Changed to Positive	Other	Total	Change Rate (3)/ (1+3)
Eastern	298	22	27	227	9	583	43.2
Central	97	10	11	71	7	196	42.3
Western	80	16	15	59	8	178	42.4
Labrador	18	1	2	18	1	40	50.0
Total	493	49	55	375	25	997	43.2

1. Change Rate for this table is defined as the proportion of patients with original negative ER tests that, upon retesting, had a positive score using the clinical guideline applicable for the original test, excluding DCIS (49) and non-interpretable results (25).
2. Between 1997 and 2000 ER negative is  $\leq 30\%$  and between 2001 and 2005 ER negative is  $\leq 10\%$ . This definition is based on a clinical guideline that was used to determine which tests would be retested at Mount Sinai Hospital.

Table G: Change Rate of ER Negative Patients by Site of Original Test

Site		Number of Changes	Total Patients	%
St. John's	HSC	54	132	40.9
	St. Clare's	128	288	44.4
	Grace	28	74	37.8
	Unknown	0	4	0
Carbonear		36	70	51.4
Clareville		8	15	53.3
Grand Falls		54	122	44.3
Gander		28	74	37.8
Western		74	178	41.6
Lab/Grenfell		20	40	50.0
Total		430	997	43.1

1. Change Rate for this table is defined as the proportion of patients with original negative ER tests that, upon retesting, had a positive score using the clinical guideline applicable for the original test.
2. Between 1997 and 2000 ER negative is  $\leq 30\%$  and between 2001 and 2005 ER negative is  $\leq 10\%$ . This definition is based on a clinical guideline that was used to determine which tests would be retested at Mount Sinai Hospital.

## Appendix B: NLCHI Database - Source Tables

Table 1: Database Contents

Total Cases	1210
Total Patient Cases	1045
Less: Cases with original results before January 1997	---
Less: Cases with original results that were positive, and not known/included in Eastern Health spreadsheet August 1, 2006 (e.g., were retested after December 2006)	15
Less: Cases without original tests at Eastern Health.	14
Other???	---
Total A -- Retested Cases consistent with December 2006 EH Report	1016
Less Original Positives up to December 2006***	19
Total B -- Retested Cases with Original Negatives	997

Note: Total A includes:

- Any original positives that were identified in the August 1 Excel file
- Only those with original scores
- Cases with an original test done between January 1997 and August 2005

Total B includes

- Only those with original *negative* scores
- Cases with an original test done between January 1997 and August 2005

Table 2: Comparison of EH Results and Database (Using Total A)						
(Note: It is understood that NLCHI may not be able to determine if treatment changed for some of the converted cases. NLCHI will define appropriate categories to display this data.)						
Category	Sub-Category	Sub-sub-category	Nov 23 2006	NLCHI Database		
				Alive	Deceased <sup>1</sup>	Total
Results Obtained and Reviewed	No Change in Results and Subsequently No Change in Treatment	Confirmed Negative	341	301	177	478
		Confirmed Negative from Panel	28	5 (panel)	1 (panel)	6 (panel)
		Confirmed Negative from Panel, letter unsigned		1	0	1
		Confirmed Positive	12	5	3	8
		Confirmed Positive from Panel	n/a	1 (panel)	0 (panel)	1 (panel)
		DCIS	52	40	6	46
		DCIS from Panel	n/a	1 (panel)	0 (panel)	1 (panel)
		Sub-total	433	354	187	541
	No change in results; requires change in treatment as definition of negative has changed		13	No Data	No Data	No Data
	Change in results but does not require treatment change	No recommendation because they are low risk	60	51 (panel)	0 (panel)	51 (panel)
		No recommendation because they are previously treated with Tamoxifen or other aromatase inhibitor	148	132 (panel)	14 (panel)	146 (panel)
		New panel: No recommendation-previously treated	n/a	3 (panel)	0 (panel)	3 (panel)
		No treatment because they required assessment prior to recommendations	5	4 (panel)	0 (panel)	4 (panel)
		[No recommendation – other]	n/a	11 (panel)	2 (panel)	13 (panel)
		Sub-total	213	201	16	217
	Change in results and requires treatment change	Recommended for treatment with Tamoxifen or aromatase inhibitor	96	94 (panel)	0 (panel)	94 (panel)
		Recommended for treatment from panel, letter unsigned	n/a	1	0	1
		New panel: Recommend treatment	n/a	2 (panel)	0 (panel)	2 (panel)
		Original diagnosis revised	4	N/D	N/D	N/D
		Originally had a degree of ER positivity but on retesting was negative	4	4 (panel)	0 (panel)	4 (panel)
		Recommended to stop Tamoxifen	n/a	0 (panel)	1 (panel)	1 (panel)
		Sub-total	104	101	1	102
	Treatment changed-Not paneled		n/a	13	0	13
	No treatment changed-Not paneled		n/a	16	0	16
	Unknown treatment change-Not paneled		n/a	36	91	127
Deceased			176			
Total Retested			939	721	295	1016

<sup>1</sup> Deceased status as of November 23, 2006

<sup>2</sup> "No Recommendation-Other" includes information from panel letter that states the patient refused treatment, self-terminated, or could not tolerate treatment.

<sup>3</sup> In the above analysis, if a patient was paneled, that recommendation took precedence over any other categorization, i.e. if a patient was confirmed negative or positive in the database, *and* paneled, they would be counted only in the appropriate panel category.

<sup>4</sup> The difference in numbers presented November 23, 2006 (Eastern Health) and those provided by the Centre for Health Information cannot be resolved given the database used by Eastern Health in the 2006 news release no longer exists.

Table 3: Deceased (Using Total A)	
EH Reported as Deceased November 23, 2006	176
EH Reported as Deceased August 1, 2007	195
NLCHI Confirmed Deceased as of October 2005	239
NLCHI Confirmed Deceased as of November 23, 2006	295
NLCHI Confirmed Deceased August 1, 2007	316
NLCHI Confirmed Deceased November 26, 2007	323

Note: The vital status of any individuals from St. Pierre, or have since moved from the province are not captured.



Table 4: Number of Retests by Time Period and by Region (n=1091, Total B=997)					
Month Sent to MS	Number of Retests Sent to (or Reported from) Mount Sinai				
	Eastern	Central	Western	L/G	Total
2005	523 (477)	204 (183)	163 (143)	4 (4)	894 (807)
2006	17 (14)	-- (--)	-- (--)	22 (21)	39 (35)
2007	87 (86)	4 (4)	10 (10)	3 (3)	104 (103)
Not Available	6 (6)	9 (9)	27 (25)	12 (12)	54 (52)
Total	633 (583)	217 (196)	200 (178)	41 (40)	1091 (997)

## Note:

For n=1091, both those with no original testing and those with positive original scores were removed.

All other records kept; therefore analysis is based on number of original negative tests, not unique patients.

For Total B analysis is based on unique patients.

Time Period of Original Test	Table 5: Number of Cases and Tests by Time Period of Original Test	
	Database (Total B)	Database (Total Original negative tests)
	# Cases sent for Retests*	# Tests sent for Retests*
1997	61	63
1998	140	159
1999	150	167
2000	182	195
2001	141	151
2002	147	157
2003	98	110
2004	54	61
2005 (August)	24	28
Total	997	1091

\*Note: Excludes positives; negative defined as:  $\leq 30$  from 1997-2000, and  $\leq 10$  from 2001-2005.  
Includes tests with unclear original scores (i.e. weak positive, equivocal, etc.)

Table 6: Database Retest Results (from original negatives only) by Time Period (Total B)						
Time Period of Original Test	Province					
	Confirmed Negatives	DCIS	Conversion <sup>1</sup> due to change in definition	Converted Negative to Positive	Other <sup>2</sup>	Total B
1997	35	3	3	17	3	61
1998	65	10	10	53	2	140
1999	57	7	23	62	1	150
2000	86	9	19	63	5	182
2001	64	8	n/a	65	4	141
2002	64	5	n/a	76	2	147
2003	57	6	n/a	30	5	98
2004	44	---	n/a	9	1	54
2005	21	1	n/a	---	2	24
Total B	493	49	55	375	25	997

<sup>1</sup>Conversion is measured by original ER score  $\leq 30$  for 1997-2000 or  $\leq 10$  for 2001-2005 and Mount Sinai ER score  $\leq 10$ .

<sup>2</sup>Other includes: unclear original results, those which MS reported as NT, EPAP, etc.

Table 7: Database Retest Results (from original negatives only) by Time Period (Total B)						
Time Period of Original Test	Eastern					
	Confirmed Negatives	DCIS	Conversion due to change in definition <sup>1</sup>	Converted Negative to Positive	Other <sup>2</sup>	Total B
1997	24	2	1	9	1	37
1998	41	4	6	27	---	78
1999	31	4	10	35	1	81
2000	59	2	10	35	2	108
2001	38	4	n/a	47	3	92
2002	39	3	n/a	52	1	95
2003	31	2	n/a	20	1	54
2004	23	---	n/a	2	---	25
2005	12	1	n/a	---	---	13
Total B	298	22	27	227	9	583

<sup>1</sup>Conversion is measured by original ER score  $\leq 30$  for 1997-2000 or  $\leq 10$  for 2001-2005 and Mount Sinai ER score  $\leq 10$ .

<sup>2</sup>Other includes: unclear original results, those which MS reported as NT, EPAP, etc.

Table 8: Database Retest Results (from original negatives only) by Time Period (Total B)						
Time Period of Original Test	Central					Total B
	Confirmed Negatives	DCIS	Conversion due to change in definition <sup>1</sup>	Converted Negative to Positive	Other <sup>2</sup>	
1997	5	---	1	1	2	9
1998	13	3	---	17	---	33
1999	15	1	6	9	---	31
2000	17	3	4	15	1	40
2001	13	---	n/a	7	---	20
2002	12	---	n/a	11	1	24
2003	12	3	n/a	5	1	21
2004	8	---	n/a	6	1	15
2005	2	---	n/a	---	1	3
Total B	97	10	11	71	7	196

<sup>1</sup>Conversion is measured by original ER score  $\leq 30$  for 1997-2000 or  $\leq 10$  for 2001-2005 and Mount Sinai ER score  $\leq 10$ .

<sup>2</sup>Other includes: unclear original results, those which MS reported as NT, EPAP, etc.

Table 9: Database Retest Results (from original negatives only) by Time Period (Total B)						
Time Period of Original Test	Western					Total B
	Confirmed Negatives	DCIS	Conversion due to change in definition <sup>1</sup>	Converted Negative to Positive	Other <sup>2</sup>	
1997	5	1	1	7	---	14
1998	9	3	4	7	2	25
1999	8	1	7	15	---	31
2000	9	4	3	8	2	26
2001	10	4	n/a	9	1	24
2002	9	2	n/a	9	---	20
2003	13	1	n/a	3	3	20
2004	10	---	n/a	1	---	11
2005	7	---	n/a	---	---	7
Total B	80	16	15	59	8	178

<sup>1</sup>Conversion is measured by original ER score  $\leq 30$  for 1997-2000 or  $\leq 10$  for 2001-2005 and Mount Sinai ER score  $\leq 10$ .

<sup>2</sup>Other includes: unclear original results, those which MS reported as NT, EPAP, etc.



Table 10: Database Retest Results (from original negatives only) by Time Period (Total B)						
Time Period of Original Test	Labrador-Grenfell					
	Confirmed Negatives	DCIS	Conversion due to change in definition <sup>1</sup>	Converted Negative to Positive	Other <sup>2</sup>	Total B
1997	1	---	---	---	---	1
1998	2	---	---	2	---	4
1999	3	1	---	3	---	7
2000	1	---	2	5	---	8
2001	3	---	---	2	---	5
2002	4	---	---	4	---	8
2003	1	---	---	2	---	3
2004	3	---	---	---	---	3
2005	---	---	---	---	1	1
Total B	18	1	2	18	1	40

<sup>1</sup>Conversion is measured by original ER score  $\leq 30$  for 1997-2000 or  $\leq 10$  for 2001-2005 and Mount Sinai ER score  $\leq 10$ .

<sup>2</sup>Other includes: unclear original results, those which MS reported as NT, EPAP, etc.

**Table 11: Database Retest Results, Living and Deceased, positives excluded**

Table 11: Database Retest Results, Living and Deceased				
		Total B	Currently Living	Currently Deceased <sup>1</sup>
Confirmed Negative		493	315	178
Conversions	w/change treatment	105	102	3
	w/out change treatment	193	176	17
	d/k if change treatment	132	25	107
	Total Conversions	430	303	127
Other Results <sup>2</sup>	w/change treatment	1	1	0
	w/out change treatment	13	10	3
	d/k if change treatment	60	49	11
	Total Others	74	60	14
Total B		997	678	319

<sup>1</sup>Deceased status as of November 2007<sup>2</sup>Other includes: unclear original, NT, DCIS

**Table 12: Database Retest Results, Number of Conversions by Site, positives excluded.**

Table 12: Database Retest Results; Number of Conversions by Site (Total B)				
Site		Number of Conversions	Total Unique Retests	%
St. John's	HSC	54	132	40.9
	St. Clare's	128	288	44.4
	Grace	28	74	37.8
	Unknown	0	4	0
Carbonear		36	70	51.4
Clareville		8	15	53.3
Grand Falls		54	122	44.3
Gander		28	74	37.8
Western		74	178	41.6
Lab/Grenfell		20	40	50.0
Total		430	997	43.1