Quality and Risk Management Department
12th Floor, Southcott Hall
L.A. Miller Centre Site
100 Forest Road
St. John's, NL A1A 1E5
Telephone: (709) 777-6352 Fax: (709) 777-8033

June 7, 2006

Mr. Mark Quinn
Canadian Broadcasting Corporation
P.O. Box 12010, Station A
St. John's, NL
A1B 3T8

Dear Mr. Quinn:

Re: Your request to access to information under Part II of the *Access to Information and Protection of Privacy Act*

This is to confirm that, on March 16, 2006, Eastern Health received your request for access to the following records/information dated March 10, 2006:

- All reports, memos, letters, briefing notes and e-mails at the Eastern Regional Health Authority between May 1, 2005 and the present – regarding hormone receptor tests for people with breast cancer.

As described in my correspondence dated April 25, 2006, your request for access to these records has been granted in part. As a result of our follow-up telephone discussion, your request for access has been changed to limit the copies of the same correspondence and to exclude all associated medical literature.

We acknowledge receipt of payment for the cost of release in full and have enclosed documentation from the following:

- Mr. George Tilley, President and CEO
- Dr. Robert Williams, V.P., Quality, Diagnostics and Medical Services
- Ms. Pat Pilgrim, COO, Cancer, Child and Women's Health, Rehabilitation
- Dr. Donald Cook, past Clinical Chief, Laboratory Program
- Mr. Terry Gulliver, Program Director, Laboratory Program
- Corporate Communications Department

We have also included, at no cost, medical literature obtained during our review of the literature.

If you have any further questions, please feel free to contact the undersigned by telephone at (709) 777-6629 or by e-mail at deanne.emberley@hccsj.nl.ca.

Sincerely,

_____
Deanne Emberley
Access and Privacy Coordinator

Encls.

Documentation from
Dr. Donald Cook

CONFIDENTIAL

May 24, 2005

Dr Gardiner
informed
May 25, 2005
updated Joy McCarthy
on June 6, 2005

Dr. Robert Williams
Acting CEO & Vice-President,
Medical Services
General Hospital Site
Health Care Corporation of St. John's
St. John's, Newfoundland, A1B 3V6

Dear Dr. Williams:

Re: False Negative Results for Estrogen and Progesterone Receptors (ER & PR)

On May 11, 2005, I received a phone call from Dr. Joy McCarthy, a Medical Oncologist, informing me of an ER & PR reported negative in a patient with infiltrating lobular carcinoma of the breast diagnosed in 2002. When retested in May, 2005, the ER & PR were reported as strongly positive. Dr. McCarthy also expressed concern over what appears to be a high rate of infiltrating lobular carcinomas that were reported as ER & PR negative. She stated that usually 95% of lobular carcinomas are ER & PR positive, while 5% are negative. Dr. McCarthy requested that two other patients with infiltrating lobular carcinoma who were reported as ER & PR negative in 2002 also be retested. I also expressed concern over this and suggested that we meet to discuss this further.

On May 17, 2005, a meeting was held which included myself, Dr. Bev Carter, our resource person for breast pathology, Mr. Barry Dyer, Divisional Manager for Anatomical Pathology, and Drs. Joy McCarthy and Kara Laing, Medical Oncologists. During that meeting, I brought forth that a second patient originally reported as ER & PR negative in 2002 were now strongly positive for breast receptors on retesting. Much of this discussion at this meeting centered on the impact of estrogen receptors on breast cancer treatment. It is estimated that approximately 50 to 85% of all breast cancers (particularly infiltrating ductal and lobular carcinomas) exhibit estrogen receptors and that such tumours are commonly found in post-menopausal women. A high percentage of tumour with estrogen receptors may regress after hormonal manipulation whereas only a small number (approximately 5%) of those that are negative respond. The highest response rates are in patients with tumours exhibiting both ER & PR receptors. Breast cancer patients with high level hormone receptors have a slightly better prognosis than those without receptors.

Dr Gardiner - further
update on Jun 8, 2005
Discussion with pathologist
at Bonnel Site June 7, 2005
regarding whether are not
people were aware of the

Receptor status will influence at what stage chemotherapy will be given to a patient. Those patients that are ER & PR negative would be given chemotherapy with its side effects much earlier in the course of treatment. It is possible that the patient who is ER & PR positive and responds favourably to hormone manipulation may not require the full chemotherapeutic regime.

Prior to March / April, 2004, all ER & PR receptors in this Province were tested using a Dako manual system for immunoperoxidase staining on paraffin-embedded tissue. The staining procedure took place at the Histology Lab at the General Hospital Site. Interpretation of these stains were made by those pathologists who were assigned the cases. These stains were also circulated to pathologists across the province according to which lab the cases originated from.

Around March / April, 2004, the Dako manual system was replaced with a new Ventana automated system. This system provided more sensitivity and standardization than the old manual technique. The cases that were previously reported as ER & PR negative are now retested using the new automated procedure. It is my understanding that all previously reported ER negative patients under the old manual technique had positive controls.

Immunoperoxidase staining couples a peroxidase label to a primary antibody which then binds to a specific antigen in a cancerous lesion. One of the vital steps is to expose or unmask as many of these antigens as possible in order to increase the sensitivity of the procedure. This involves digestion with a variety of protolytic enzymes and treatment with microwaves or the combined action of heat and pressure to expose these antigens. Immunoperoxidase technique is widely used in many Histology labs across North America with more diagnostic weight being placed on these stains than our conventional histochemical stains. However, like any other technique, the immunoperoxidase stains have potential pitfalls. Many of these pitfalls can be avoided by scrupulous quality control, periodic checking of antibody activity and proper use of negative and positive controls.

In early 2003, Dr. Gershon Ejeckam, our point man for immunoperoxidase testing at the General Hospital Site, discontinued testing of the ER & PR receptors with the manual method for a six week period. A memo was circulated to all pathologists across the province stating this. The technique was temporarily halted because of erratic staining which required readjustments of titration and staining times. Once Dr. Ejeckam felt confident of the reliability of staining, the test was reintroduced.

At the conclusion of the May 17th. meeting, it was decided to retest all negative ER's & PR's for the year 2002 and possibly, 2001. I have no idea at this point in time in knowing whether these are a few isolated cases or whether we are dealing with a much bigger issue. For now, we have agreed that if there is a receptor conversion, that the oncologist would inform the patient that we have retested the ER & PR receptors under our newer more sensitive technique. However, if it is identified that we have a much more significant conversion factor problem involving many patients, we would need to seek advice and guidance from QI on how best to disclose this information, as this involves breast cancer patients across the province.

In closing, I would like to make the following recommendations for immunoperoxidase testing:

1) The immediate establishment of an external proficiency testing and monitoring program for immunoperoxidase testing.

2) The establishment of a separate immunoperoxidase service with at least three technologists solely dedicated to immunoperoxidase testing with separate testing facilities.

3) The training of immunoperoxidase technologists in a major immuno – referral lab that has a well established quality control and trouble shooting program.

4) Appropriate CME funding for these immunotechnologists.

These preliminary recommendations will no doubt require additional manpower and funding levels than currently exist. I will keep you updated as more information becomes available.

Respectfully submitted,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
Health Care Corporation of St. John's

CONFIDENTIAL

June 14, 2005

Dr. Robert Williams
Vice-President,
Quality, Diagnostic and Medical Services
Eastern Health
General Hospital Site
St. John's, Newfoundland
A1B 3V6

Dear Dr. Williams:

RE: Preliminary Update on False Negative Results for Estrogen and Progesterone Receptors

Further to my letter of May 24, 2005, we reviewed reports of the estrogen and progesterone receptors in 160 breast cancer patients that originated from the Division of Anatomical Pathology, Laboratory Medicine Program, at the Health Care Corporation of St. John's. These 160 cases are also confined to patients and attending surgeons within the Health Care Corporation of St. John's. Of the 160 cases that have estrogen and progesterone receptors, 50% of these are reported as ER/PR negative. This is following a preliminary review of the pathology reports. It also seems that most of the negative ER/PR results started some time around June 24, 2002. We are in the process of retesting all negative ER/PR cases with our newer more sensitive Ventana Benchmark immunoperoxidase method for the year 2002. We also need to retest cases that are outside of the confines of the Health Care Corporation of St. John's, and I have recently sent a memo to all Lab Directors across the Province asking them to refer ER/PR negative 2002 cases back to the division for retesting.

On the surface, a negative rate of 50%, though not the greatest, is not too bad when you compare a 60% positive and 40% negative rate according to figures provided by Dr. Joy McCarthy. We also need to correlate these figures more with our population. There may very well be a large number of women who have high grade lesions who would normally be negative for estrogen and progesterone receptors. We also have cases that are ER/PR negative for 1999 and 2000 and have converted following testing with the new Ventana system. These are specific cases that are identified and are requested for retesting by the oncologist. If the receptors have converted on retesting, the referring oncologist is notified and an addendum report is issued.

In regards to the large number of cases for the year 2002, a list of patients who have converted with the newer methodology are forwarded to Dr. Joy McCarthy. I had informed Dr. Gardiner of the situation on May 25, 2005, and updated him on June 8, 2005. There is also significant communication between ourselves and the oncologists regarding this issue. I will keep you updated as more information becomes available.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health

HealthCare
Corporation of St. John's
MEMO

TO: All Laboratory Directors
(Dr. D. Fontaine, HSC
Dr. G. Baker, Carbonear
Dr. S. Anwar, GB Cross Memorial
Dr. F. Gallagher, James Paton Memorial,
Dr. M. Dalton, Central NL Hospital
Dr. P. Neil, Western Memorial
Dr. Dankwa, St. Anthony)

FROM: Dr. Donald M. Cook
Clinical Chief, Laboratory Medicine Program

DATE: June 14, 2005

RE: **Estrogen and Progesterone Receptors**

We are aware of a number of negative estrogen and progesterone receptors that have converted on repeat testing with our new Ventana Benchmark immunoperoxidase testing. This new Ventana system is fully automated and is much more sensitive than the immunoperoxidase technique under the previous DAKO method. Most of these false negatives have occurred during the year 2002. Presently, we are in the process of retesting all negative ER and PR's for that particular year. I am requesting that you forward all negative ER and PR cases for the year 2002 to Mr. Barry Dyer at the General Hospital Site. I would ask that you submit the reports, original ER and PR slides including controls as well as H & E slides and paraffin blocks of the tumour. We will repeat all ER and PR receptors with the Ventana system and forward the results to you. I will keep you updated regarding additional information.

If you have any concerns or questions regarding this, please feel free to contact myself at 777-5482 or Dr. Bev Carter at 777-5530.

Sincerely yours,

Donald M Cook

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health

It will be necessary to have a computerized database for this project. This database should include the patient's name, MCP number, surgical number, hospital of origin (please remember that these patients were treated in all hospitals in Newfoundland), results of original estrogen receptor / progesterone receptor testing, presence of control tissues, results of new testing, and any comments about the case. Also included in these computerized report should be the histologic type of cancer as well as the grade of cancer.

As we have discussed in my opinion, the above suggestion should be carried out as quickly as possible.

Yours sincerely,

Beverley A. Carter, MD, FRCPC
Breast Pathologist
Phone 709-777-5530 / 709-777-5493
Fax 709-777-5178

c.c. Dr. Bob Williams

Discussed with Dr. Cook July 14, 2005

HealthCare
Corporation of St. John's

July 14, 2005

Dr. Donald M. Cook
Clinical Chief
Laboratory Medicine
Health Care Corporation of St. John's
St. John's, NL A1B 3V6

Dear Dr. Cook:

As per our many recent discussions, I agree with you that our estrogen receptor status reports prior to 2003 require immediate investigation. Our recent examples of sixteen patients converting from estrogen receptor negative for estrogen receptor positive status is quite concerning. Factors identified on those slides clearly show problems with the technique of estrogen receptor testing and the interpretation of same. I have been unable to review paperwork from 1997 – 2003 with regards to protocols, quality practice, and controls. I am therefore eager to review the estrogen receptor status of all patients seen in our laboratory from May, 1997, when immunohistochemical staining for estrogen receptor status first became available up until March, 2004, when analysis and readjustment of the estrogen receptor status protocol was carried out by Dr. G. Ejeckam. I think that it is vital that we expediently review these cases and let patients know as quickly as possible of any change in their estrogen receptor status.

As quickly as possible, I would like to know the estrogen receptor status of every patient tested in our laboratory between 1997 and 2004. From that information, I would also like an estimate of the total of positive cases given out per year. I would need all of the reports pulled from the computer for review. Patient demographics, including name, age, and MCP number, should be collated along with their surgical number, their histologic type of carcinoma and the histologic grade. All of the slides from the cases including the estrogen receptor slides need to be pulled and organized. All slides then need to be reviewed by me, both estrogen receptor negative and estrogen receptor positive patients. Estrogen receptor negative patients should be given priority. Blocks will be pulled from those cases and estrogen receptor / progesterone receptor status reordered. This test should be carried out as quickly as possible. 10% of cases should be randomly selected for outside quality assurance consultation. Dr. Frances O'Malley at Mount Sinai Hospital has agreed to act in this capacity. Problematic cases, as defined by a multiplicity of reasons, should also be sent for outside testing.

Meeting Notes

July 14, 2005

Laboratory Medicine

Present: Ms. Heather Predham
Dr. Don Cook
Dr. Bob Williams
Mr. Terry Gulliver

Issue Discussed: ER/PR Receptor Results

Priorities:

1. Identify all people who had ER and PR receptors.
2. Ones who are negative for ER and PR receptors – recheck receptors with new methodology.
3. Meet with surgeons and oncologists.
4. Assess current testing standards - cross referencing with another laboratory.
5. Advise the public.
6. Assess the quality of the service at the laboratory level once we have information on the magnitude of the problem and relevant timeframes. This will involve external technical consultation.

NL

2.5 FTE

- ? find lab to handle of all these cases very quickly
- phone all lab directors to send all neg cases to HSC.
- Cancer Registry has list of every breast cancer
- Find out how quickly we can pull out the names

July 14, 2005 - met with Drs Kurz, Felix, Cook, Williams, McCarthy, Laing, Gardner, Heather Predham, ~~[illegible]~~ Susan Bonnell.

July 19, 2005

Dr. Bev Carter
Division of Anatomic Pathology
Laboratory Medicine Program
St. John's Hospitals, Eastern Health
St. Clare's Site
St. John's, NL A1C 5B8

Dear Dr. Carter:

This is to acknowledge receipt of your letter dated July 14, 2005. I certainly accept what's been stated in your letter and will ensure that you obtain the necessary resources to carry out your suggestions.

Sincerely yours,

_____
Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health

c.c. Dr. Bob Williams

To: Mr. George Tilley

From: Dr. R. Williams

Re: Update on ER/PR receptor testing

The following activity has taken place since the memo of Dr. D. Cook to Dr. R. Williams dated May 24, 2005 (attached):

- Samples collected from 25 women, initially tested as negative in 2002, were retested. 16 of these came back positive. Testing is currently being done on 33 more patients. Approximately 12 of these patients have been informed by their oncologists.

- June 13, 2005, Dr. Cook wrote to all Laboratory directors in the province to submit all negative ER and PR cases for the year 2002 for retesting with the new, more sensitive Ventana system. So far, no samples have been received, so Dr. Cook will contact all Laboratory Directors again requesting samples from 1997 to 2004.

- The Dako test was implemented in 1997 to replace an a bioassey method for ER/PR receptors. All samples which initially tested as negative from 1997 until the implementation of the Ventana system in April 2004 will be retested. As the test results can affect future treatment, patients that are still living will have the testing done first, before it is done on those that are deceased.
  Extra resources have been identified within the HCCSJ lab to undertake identification and retesting. The list of patients will be double-checked with the names on the Cancer Registry to ensure none have been missed.
  Timelines required to do the retesting internally will be determined as soon as possible. If it is determined to be too time-consuming, options to utilize external laboratories will be explored.

- It has been determined that positive controls were conducted everyday, as part of the quality assurance process within the lab. The results were read and documented daily by a pathologist. Also the processes used by HCCSJ technicians were those outlined in the Dako procedure manual.

- The current testing standards (Ventana system) are being assessed by cross-referencing our results with another laboratory.

- The public will have to be informed. Corporate Communications have been involved and, as at least five patients are aware of this information already, disclosure has to be made quickly. After meeting with the surgeons and oncologists, it was decided to wait until we were able to get more information regarding retesting, the anticipated timelines and a support line established. This support line for patients will be coordinated through QSI. Legal counsel will review the proposed media release before it is distributed.

- Once the magnitude of the problem and the relevant time frames has been determined, an external technical consultation will need to be undertaken to assess standards and quality of service.

- HIROC will be contacted to determine if they are aware of any other issues with the Dako testing system.

HealthCare
Corporation of St. John's

MEMO

Copies sent July 26/05.

TO: All Pathologists, Mr. Terry Gulliver, Mr. Barry
Dr. R. Williams, Vice-President, Quality, Diagnostic & Medical Services
St. John's Hospitals Eastern Health

FROM: Dr. Don Cook
Clinical Chief

DATE: July 26, 2005

RE: **Reporting of Estrogen and Progesterone Receptors**

When reporting the ER and PR receptors, please use the following canned text. This will be issued as an Addendum Report.

For negative ER/PR (Meditech Canned Text **ERPRNEG**):

Using the Ventana benchmark system
(_____) Receptor immunohistochemical staining is negative.
Internal controls are (___). External controls are (___).
(Block "__")

For positive ER/PR (Meditech Canned Text **ERPRPOS**):

Using the Ventana benchmark system
(_____) Receptor immunohistochemical testing shows (___) nuclear staining in (__) % of cells.
Internal controls are (___). External controls are (___)
(Block "__")

The reporting of ER and PR receptors should include information on whether the nuclear staining is weak, moderate, or strong and an estimation of the percentage of invasive neoplastic cells show staining which can include a range. Controls should be described as adequate or absent.

For example, a positive report for ER could read as follows:

Using the Ventana benchmark system,
Estrogen Receptor immunohistochemical testing shows moderate nuclear staining in 70% of cells.
Internal control is absent. External control is adequate.
(Block "2D").

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

met with minister July 21, 2005

Eastern
HEALTH

BRIEFING NOTE – ER/PR RECEPTORS

Background:

May 11, 2005: Dr. Joy McCarthy, Oncologist, contacted Dr. Don Cook, Chief of Laboratory Medicine, to retest a patient who previously tested negative for Estrogen (ER) and Progesterone Receptors (PR) in 2002. Using new technology for immunoperoxidase staining installed at the General Hospital Histology Lab in April of 2004, this woman's sample was retested and discovered to be positive for ER and PR.

Until April of 2004, the Dako testing technique was used in the laboratories. This technique required the manual boiling of tissue and measuring of minute mixtures of immunioperoxidase staining. The Dako test was implemented in 1997 to replace a bioassay method for ER/PR receptors.

The Ventana method (installed in April 2004) automates this process removing as much manipulation as possible. In addition, all re-agents used on the Ventana system are quality controlled by the company and arrive in the laboratory as "ready for use."

The Health Care Corporation of St. John's was one of the earliest laboratories to obtain the Ventana system and switch to an automated system.

6. When a breast cancer tumor is removed from the body, tests are used to determine if the cancer cells have estrogen or progesterone receptors. The more estrogen receptors present on those cells, the more likely that anti-estrogen therapy such as tamoxifen will work against a particular cancer. Breast cancer patients with high level hormone receptors have a slightly better prognosis than those without receptors.

Literature suggests about 50 – 85 per cent of breast cancers are estrogen–receptor–positive (or "ER-positive"), "positive" meaning that a significant number of cancer cells have receptors present. When a cancer shows few if any estrogen receptors (when it is "ER-negative"), anti-estrogen therapy is not as effective. But anti-estrogen therapy may also be useful in cases where progesterone receptors are present ("PR-positive"). Women whose cancers are PR-positive but ER-negative may still respond to anti-estrogen therapy. A high percentage of tumours with estrogen receptors may regress after hormonal manipulation whereas only a small number (about 5 per cent) of those that are negative respond.

May 17, 2005: Representatives from the Laboratory Program met with Drs. McCarthy and Kara Laing to discuss this new result and a decision was made to retest five more negative patients, who all retested positive. These patients were selected by the oncologists. It was decided to retest all negative results from 2002 to determine if these were isolated cases or symptomatic of a bigger issue. Specimens collected from 25 women, initially tested as negative in 2002, were retested. 16 of these came back positive. Testing on 33 more patients found 25 converted to positive. Twelve of these patients have been informed by their oncologists.

Eastern HEALTH

June 13, 2005: Dr. Cook wrote to all Laboratory directors in the province to return all negative ER and PR specimens for the year 2002 for retesting on the new, more sensitive Ventana system.

July 14, 2005: The decision was made that all patients who were ER and PR negative from 1997-2004 would be retested, beginning with the 2002 patients, with testing to take place over the next number of weeks.

July 15, 2005: Dr. Cook spoke to four of the six provincial laboratory directors (two others were unreachable due to holidays) regarding sending specimens into St. John's for retesting. They said they will comply with the request as soon as possible.

July 18, 2005: Laboratory managers in St. John's began reviewing the statistical data for 2000-2004 to see if there are any inconsistencies in the findings of positive conversions or if this could just be a matter of the sensitivity of the Ventana system being more accurate with its findings.

July 20, 2005: Upon review of the statistical data is has been concluded that the positivity rates are, while on the low end of the scale, within acceptable range. Total positivity numbers for 2000 are 62 per cent; 2001 - 77 per cent; 2002 - 68 per cent; 2003 - 83 per cent and 2004/05 (after a full year with the Ventana system) - 90 per cent.

Eastern
HEALTH

Actions:

Considering the 50-85 per cent acceptable range in standard text books and Mount Sinai's standard of around 70-80 per cent, this also reconfirms that our numbers are legitimate. Regardless, the laboratory is still going ahead with retesting the specimens and officials will meet with the oncologists to see how they would like to proceed with informing patients of their conversion and possible change in treatment.

Extra resources have been identified within the HCCSJ lab to undertake identification and retesting. The list of patients will be double-checked with the names on the Cancer Registry to ensure none have been missed.

We do expect improved accuracy on retesting due to the sensitivity of the newer equipment.

As a precautionary measure and to back-up the validity of the new technology, the current testing standards (Ventana system) are being assessed by cross-referencing our results with another laboratory. (Mount Sinai)

A technology consultant from Mount Sinai will be reviewing our laboratory to assess the immunoperoxidase system. At that time we will ask the consultant his/her opinion of the past several years' results under the Dako methodology and for advice on the future direction of the immuno service.

HIROC have been contacted to determine if they are aware of any other issues with the Dako testing system and other hospitals are being contacted to see if there had been any inconsistencies reported with the DAKO system.

It is important to note that processes used by HCCSJ technicians were outlined in the Dako procedure manual. Also, as part of the protocol for testing, positive controls were conducted on the Dako system everyday, as part of the quality assurance process within the lab. The results were read and documented daily by a pathologist.

Dr. Williams has also asked if we could repeat any of the negative tested specimens again on the "old" Dako system to confirm that it was indeed the system and not a lab error. Terry Gulliver, HCCSJ Laboratory Program Director says it is unlikely we would be able to obtain such a system at this time to retest on that method.

July 27, 2005

Dr. K. Watters
Acting Chief and Chair
McGill University
Department of Pathology
Montreal General Hospital
1650 Cedar Avenue
Montreal, Quebec
H3G 1A4

Dear Dr. Watters:

As discussed, we are in the process of evaluating our ER and PR immunoperoxidase stains. We will be forwarding two unstained labelled slides to your lab. These slides will be stained for estrogen and progesterone receptors via immunoperoxidase technique. Once the slides are stained, they can be forwarded to my office. I anticipate that we may be evaluating anywhere from 40 to 50 cases. Of course, we will be reimbursing you for this service.

I certainly appreciate your help in this difficult situation.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
St. Clare's Site
Phone 709-777-5482
FAX 709-777-5178

c.c. Dr. Robert Williams
Mr. Terry Gulliver

HealthCare
Corporation of St. John's

July 29, 2005

Dr. Donald Cook
Clinical Chief, Laboratory Medicine Program
c/o Lab, St. Clare's

Dear Dr. Cook:

RE: ER/PR Receptors

The following suggestions are made for Dr. Carter's and your best advice on how to proceed from here:

1. **New Testing Results**
   - Send out ER/PR for staining at an outside lab for the next few months.
   - Process the same slides here.
   - Have both sets of slides read by the same Pathologist.
   - Check comparability between stains; and when we are satisfied, revert to processing here.

2. **Re-testing**
   - Have the negative results reviewed by pathology type and in consultation with Oncologists to see which cases should be restained and reviewed.
   - These cases should follow the same procedure as outlined for #1 above.

3. Ask Vantana to send out one of their technical experts very soon to look at our staining technique.

Yours sincerely,

R.J. WILLIAMS, M.D., M.P.H.
Vice President, Quality, Diagnostic and Medical Services

/dd

HealthCare
Corporation of St. John's

MEMO

TO: All Pathologists, Division of Anatomical Pathology
Mr. Terry Gulliver, Mr. Barry Dyer

FROM: Dr. Don Cook
Clinical Chief, Lab Medicine

DATE: August 2, 2005

RE: **Resource Individual for Immunohistochemistry**

Dr. Gershon Ejeckam is currently our resource person for Immunohistochemistry. All inquiries regarding Immunohistochemistry should be referred to Dr. Ejeckam. In the event that Dr. Ejeckam is not available, all inquiries will be referred to the Site Chief, General Hospital Site, who is currently Dr. Dan Fontaine.

Sincerely yours,

Donald M. Cook

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

Eastern Health

Faxed
Aug 2, 2005
1:25 PM

August 2, 2005

Dr. Kenneth Pritzker
Lab Director of Pathology and Laboratory Medicine
Pathologist in Chief
Mount Sinai Hospital
600 University Hospital
Toronto, Ontario
M56 1X5

Dear Dr. Pritzker:

As discussed in our telephone conversation, I am currently putting a hold on the reporting of all Estrogen and Progesterone Receptors from our Laboratory Medicine Program, St. John's Hospitals, Eastern Health. For all urgent and newly diagnosed patients with breast cancer, I certainly appreciate your laboratory's assistance in performing immuno-histochemical staining along with interpretative results on these cases. I anticipate that we may be dealing with anywhere from 30 to 40 cases per month, possibly over a three month period.

We will correlate Mount Sinai's results with our own to further help us validate our Ventana automated system. I will be in contact with Maria Mandes at your laboratory regarding this.

We will, of course, reimburse Mount Sinai for all costs incurred. Thank you for your help at this difficult time.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178
Donald.Cook@hccsj.nl.ca

Review of ER/PR Stats from 1997 – 2004/05

	DAKO/Semi-Manual Boiling								Ventana
	1997	1998	1999	2000	2001	2002	2003	Jan-Mar 04	Apr/04-Mar/05
Total Tests	135	147	360	370	374	344	373	109	386
Out of Town			202	159	150	155	171	42	189
Total HCCSJ Tests	136	147	158	208	224	189	202	67	187
# of Positive	80	71	96	108	126	95	152	55	165
% Positive	59%	49%	61%	52%	56%	51%	75%	82%	88%
# of Weak Positive	19	39	24	20	47	33	16	4	2
% Weak Positive	14%	26%	15%	10%	21%	17%	8%	6%	1%
# of Negative	37	37	38	80	51	61	34	8	20
% Negative	27%	25%	24%	38%	23%	32%	17%	12%	11%
Total Positivity	99	110	120	128	173	128	168	59	177
Total % Positivity	73%	75%	76%	62%	77%	68%	83%	88%	89%
Total Negative	37	37	38	80	51	61	34	8	20
Total % Negative	27%	25%	24%	38%	23%	32%	17%	12%	11%

1997 – Mar/04
7 Year Total Tests HCCSJ 1331 Reported
7 Year Total Positives HCCSJ 985
7 Year Total Negatives HCCSJ 346

7 Year Average Positive 1997-2004 DAKO 74%
7 Year Average Negative 1997-2004 DAKO 26%

VENTANA

August 5, 2005

Mr. Terry Gulliver
Health Care Corporation of St-John's

Sir,

As per your request, I checked the Ventana Benchmark instruments, the procedure and protocols used for the ER and PGR stains, the knowledge and the capacity of the technicians to troubleshoot and run the instruments.

- I performed a Level One on both instruments (Level One: Check instrument level, slide volumes, rinsing volumes, bar code reader alignment,): Both instruments are within specifications.
- I ran a Full coverage Vimentin run on both instruments to validate the staining of the instruments: both gave good results.
- I checked the protocols that you are using for the ER and PGR antibodies: CC1 standard and 32 min primary incubation: these protocols are used in many accounts in Canada and recommended by Ventana Medical Systems, Inc
- I checked the pH of the solutions: pH within specifications
- I asked questions to the different technicians using the instruments: they are properly trained and able to troubleshoot if a problem occurs
- I found out that the recommended maintenance procedures (monthly and quarterly) were never done on the instruments: we did it (monthly and quarterly) on one Benchmark yesterday and they are doing the second one today. A monthly and quarterly maintenance will be put in place.

As a conclusion, I feel confident that the technicians know what they are doing, they know how to use the instruments and that the Benchmark instruments are staining as they should be.

Thank you,

Carole Quevillon

Carole Quevillon
Ventana Medical Systems, Inc
Technical Marketing Representative – Canada
Cell: (514) 891-4745
cquevillon@ventanamed.com

VENTANA

Ventana Medical Systems
1910 Innovation Park Drive
Tucson, Arizona 85737
Toll Free: 1-800-227-2155

Benchmark® Level One

Service Rep:	Carole Quevillon
Customer:	Health Care CORP of St. John's
I.D. Number:	[redacted]
Service Request Number:	[redacted] CQ 8/4/05
Instrument Serial Number:	[redacted]
Computer Serial Number:	[redacted]

Test Equipment Information		
Description	I.D. #	Cal. Due
Digital Scale	A11932	12/27/05
Pressure Gauge	A12565	11/17/05
Flow Meter	A12378	08/05/05
Mixer Height Gauge	A11354	07/21/06

√	Description
☑	Clean bottle filter inserts and inspect associated o-rings
☑	Verify reagent homing alignment
☑	Jog reagent tray to verify position to position alignment
☑	Verify slide homing alignment
☑	Jog slide tray to verify position to position alignment
☑	Clean bar code reader mirror
☑	Verify slide bar code read alignment
☑	Verify reagent bar code read alignment
☑	Verify dispense cylinder actuation
☑	Verify operation of bar code blowoff
☑	Verify instrument level
☑	Test and record vortex mixer flow rates — Min-Max: Outer 210-330 ml/min, Inner 300-450 ml/min

Station	Trial	Station	Trial	Station	Trial	Station	Trial
20 (outer)	296	20 (inner)	365	14 (inner)	382	9 (inner)	382
19 (outer)	296	19 (inner)	365	13 (inner)	365	8 (inner)	382

☑	Record Average of inner mixers 374	Avg: Inner 325-425 ml/min
☑	Verify mixer height alignment and performance	
☑	Test and record PRV pressure: 24.9	Min-Max: 24.8 - 25.2 psi
☑	Record system air pressure: 12.94	Min-Max: 12.90 - 13.10 psi
☑	Record vacuum: -4.48	Min-Max: -4.40 - -4.60 psi

☑	Test and record IHC slide volumes	Test-Slide Volume IHC	Min-Max: .240-.300 grams, Avg: .255-.285 grams						
	Trial 1: 0.256	Trial 2: 0.278	Trial 3: 0.282	Trial 4: 0.275	Trial 5: 0.283	Avg: 0.275			
☑	Test and record rinse volumes	Test-Rinsing (Reac. Buffer)	Min-Max: 5.65 - 7.50 grams, Avg: 5.85 - 7.40						
	Trial 1: 6.78	Trial 2: 6.76	Trial 3: 6.81	Trial 4: 6.74	Trial 5: 6.57	Avg: 6.73			
☐ *	Test and record ISH slide volumes	Test-Slide Volume ISH (SSC)	Min-Max: .090-.130 grams						
	Trial 1: N/A	Trial 2: N/A	Trial 3: N/A	Trial 4: N/A	Trial 5: N/A				
☐ *	Test and record 2x SSC volumes	Test-Rinse Mix 2x SSC	Avg: .250-.320 grams						
	Trial 1: N/A	Trial 2: N/A	Trial 3: N/A	Trial 4: N/A	Trial 5: N/A	Avg: N/A			
☑	Test and record heater oil volumes	Test-Heater Oiler	Min-Max: .060-.100 grams						
	Trial 1: 0.063	Trial 2: 0.065	Trial 3: 0.069	Trial 4: 0.066	Trial 5: 0.068				
☑	Test and record EZ Prep volumes	Test-Volume Adjust [(Depar) Disco]	Avg: .530 - .630 grams						
	Trial 1: 0.525	Trial 2: 0.531	Trial 3: 0.536	Trial 4: 0.529	Trial 5: 0.534	Avg: 0.531			
☑	Test and record coverslip volumes	Test Coverslip +	Min-Max: .80 - 1.08 grams, Range ≤.10						
	Trial 1: 1.07	Trial 2: 1.08	Trial 3: 1.06	Trial 4: 1.07	Trial 5: 1.00	Range: 0.08			
☐	Test and record CC1 volumes	Test-Cell Conditioner #1	Avg.: .350 - .475 grams						
	Trial 1: 0.407	Trial 2: 0.423	Trial 3: 0.415	Trial 4: 0.419	Trial 5: 0.409	Avg: 0.415			
☐ *	Test and record CC2 volumes	Test-Cell Conditioner #2	Avg.: .300 - .400 grams						
	Trial 1: N/A	Trial 2: N/A	Trial 3: N/A	Trial 4: N/A	Trial 5: N/A	Avg: N/A			
☑	Verify instrument level								

Comments:

* N/A : Dist. H_2O in bottles

Service Rep Signature: C. Quevillon

Date: Aug 4/05

Ventana Medical Systems
1910 Innovation Park Drive
Tucson, Arizona 85737
Toll Free: 1-800-227-2155

VENTANA

Benchmark® Level One

Service Rep:	Carole Quevillon
Customer:	Health Care Corp. of St-John's
I.D. Number:	[redacted]
Service Request Number:	8275 CQ 8/4/05
Instrument Serial Number:	[redacted]
Computer Serial Number:	[redacted]

Test Equipment Information		
Description	I.D. #	Cal. Due
Digital Scale	A11932	12/27/05
Pressure Gauge	A12565	11/17/05
Flow Meter	A12378	08/05/05
Mixer Height Gauge	A11354	07/21/06

√	Description
☑	Clean bottle filter inserts and inspect associated o-rings
☑	Verify reagent homing alignment
☑	Jog reagent tray to verify position to position alignment
☑	Verify slide homing alignment
☑	Jog slide tray to verify position to position alignment
☑	Clean bar code reader mirror
☑	Verify slide bar code read alignment
☑	Verify reagent bar code read alignment
☑	Verify dispense cylinder actuation
☑	Verify operation of bar code blowoff
☑	Verify instrument level
☑	Test and record vortex mixer flow rates — Min-Max: Outer 210-330 ml/min, Inner 300-450 ml/min

Station	Trial	Station	Trial	Station	Trial	Station	Trial
20 (outer)	296	20 (inner)	443	14 (inner)	405 CQ 08/4/05	9 (inner)	400
19 (outer)	296	19 (inner)	443	13 (inner)	443	8 (inner)	417

☑	Record Average of inner mixers 424	Avg: Inner 325-425 ml/min
☑	Verify mixer height alignment and performance	
☑	Test and record PRV pressure: 25.0	Min-Max: 24.8 - 25.2 psi
☑	Record system air pressure: 12.94	Min-Max: 12.90 - 13.10 psi
☑	Record vacuum: ~~4.58~~ CQ 8/4/05	Min-Max: -4.40 - -4.60 psi
☑	Test and record IHC slide volumes — Test-Slide Volume IHC — Min-Max: .240-.300 grams, Avg: .255 - .285 grams	
	Trial 1: 0.268 Trial 2: 0.267 Trial 3: 0.276 Trial 4: 0.253 Trial 5: 0.269 Avg: 0.267	
☑	Test and record rinse volumes — Test-Rinsing (Reac. Buffer) — Min-Max: 5.65 - 7.50 grams, Avg: 5.85 - 7.40	
	Trial 1: 6.57 Trial 2: 6.62 Trial 3: 6.79 Trial 4: 6.69 Trial 5: 6.73 Avg: 6.68	
☐ *	Test and record ISH slide volumes — Test-Slide Volume ISH (SSC) — Min-Max: .090-.130 grams	
	Trial 1: N/A Trial 2: N/A Trial 3: N/A Trial 4: N/A Trial 5: N/A	
☐ *	Test and record 2x SSC volumes — Test-Rinse Mix 2x SSC — Avg: .250-.320 grams	
	Trial 1: N/A Trial 2: N/A Trial 3: N/A Trial 4: N/A Trial 5: N/A Avg: N/A	
☑	Test and record heater oil volumes — Test-Heater Oiler — Min-Max: .060-.100 grams	
	Trial 1: 0.068 Trial 2: 0.077 Trial 3: 0.068 Trial 4: 0.086 Trial 5: 0.080	
☑	Test and record EZ Prep volumes — Test-Volume Adjust [(Depar) Disco] — Avg: .530 - .630 grams	
	Trial 1: 0.624 Trial 2: 0.593 Trial 3: 0.585 Trial 4: 0.610 Trial 5: 0.596 Avg: 0.602	
☑	Test and record coverslip volumes — Test Coverslip + — Min-Max: .80 - 1.08 grams, Range ≤ .10	
	Trial 1: 0.84 Trial 2: 0.84 Trial 3: 0.83 Trial 4: 0.84 Trial 5: 0.84 Range: 0.01	
☑	Test and record CC1 volumes — Test-Cell Conditioner #1 — Avg.: .350 - .475 grams	
	Trial 1: 0.423 Trial 2: 0.418 Trial 3: 0.433 Trial 4: 0.419 Trial 5: 0.425 Avg: 0.424	
☐ *	Test and record CC2 volumes — Test-Cell Conditioner #2 — Avg.: .300 - .400 grams	
	Trial 1: N/A Trial 2: N/A Trial 3: N/A Trial 4: N/A Trial 5: N/A Avg: N/A	
☑	Verify instrument level	

Comments:

* N/A: dist. H_2O in bottles

Service Rep Signature:	Date
C. Quevillon	Aug 4/05

Aug 8, 2005

Dr. R Williams
Dr D. Cook

Dear Drs. Williams and Cook:

The following are, to the best of my current knowledge, the figures I have compiled with respect to Estrogen Receptor and Progesterone Receptor testing for cases seen at HCCSJ in 2002:

#patients identified as ER negative, using a 10% cut-off point or other surrogate markers such as male gender and/or favourable histologic subtype with a low positivity- 87 (based on reading selected pathology reports given to me by Barry Dyer)

Patients undergoing ER testing at HCCSJ- 189 (Based on figure give by Terry Gulliver re "in-town cases- please see his memo) 87/189= 46% negative rate

Of the 87 cases- 18 have not been retested. Of the 69 retested 43 have converted (read by Dr Carter and Dr Cook) using the Ventana machine. 43/69=62% conversion rate

Assuming a 62% conversion rate of all 87 negatives- 54 positives and 33 true negatives; 33/189=17.5% true negative rate using the Ventana.

From these very preliminary and very raw numbers I believe that the idea that the DAKO system- both it's performance and interpretation- greatly underestimated the number of women who would benefit from Hormonal manipulation of their breast cancer and should be investigated. From these numbers it would also appear that the Ventana system is overestimating the number of patients who are ER positive. Couple this finding with the recent 60% disagreement with Mount Sinai Hospital on crude progesterone status (positive vs. negative and not percentile staining) and it appears that we have another system that needs investigating.

MEMO

TO: All Pathologists, Division of Anatomical Pathology
St. John's Hospitals, Eastern Health
Mr. Barry Dyer, Mr. Terry Gulliver, Dr. Robert Williams

FROM: Dr. Don Cook
Clinical Chief, Lab Medicine

DATE: August 8, 2005

RE: **Estrogen Receptors (ER) and Progesterone Receptors (PR) on Current Cases**

1. There will be a hold on the reporting on ER and PR'S by all pathologists in the Division of Anatomical Pathology, St. John's Hospitals, Eastern Health.

2. All ER and PR'S will be forwarded to Mount Sinai Hospital for immunohistochemical processing and reporting. These reports will be returned to Dr. Carter and released into the hospital information system. Hard copies of these reports will be forwarded to the appropriate physician.

3. All pathologists will continue to order ER and PR's on their respective cases, fill out the immunohistochemical request form and forward this to the technologist.

4. The ER/PR immunohistochemical stain will simultaneously be processed by our technologist and sent back to the ordering pathologist.

5. Once these stains are received the ordering pathologist will give an interpretation using the enclosed form and forward this to Dr. Beverley Carter.

6. **This report is not to be released within the hospital information system.**

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

HealthCare
Corporation of St. John's

MEMO

TO: Mr. Terry Gulliver, Mr. Barry Dyer, Ms. Mary Butler, Mr. Ken Green, and Mr. Les Simms

FROM: Dr. Don Cook
Clinical Chief, Laboratory Medicine Program

DATE: August 8, 2005

RE: **Estrogen Receptors and Progesterone Receptors**

---

1. There will be a hold on reporting of all ER and PR'S by all pathologists.
2. The immunohistochemical form will continue to be filled by our pathologists.
3. Upon receipt of the immunohistochemical form, fax a copy to Dr. Carter at St. Clare's.
4. You will continue to proceed with requests and return stained ER and PR slides using the Ventana System to the ordering pathologist.
5. Following this, the same paraffin block will be forwarded to Dr. Carter at St. Clare's.
6. Dr. Carter will forward the paraffin blocks to Mount Sinai with a standardized request.
7. The Mount Sinai report with the slides and paraffin block will be returned to the St. Clare's Site.

Donald M. Cook

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

MEMO

TO: All Pathologists, Division of Anatomical Pathology
St. John's Hospitals, Eastern Health
Dr. Robert Williams, Mr. Barry Dyer, Mr. Terry Gulliver

FROM: Dr. Don Cook
Clinical Chief, Lab Medicine

DATE: **August 8, 2005**

RE: **ER and PR on Cases from May 1997 to August 9, 2005**

1. Cases from May 1997 to March 31, 2004 that are ER negative (except those from patients who are deceased) will be referred to Mount Sinai.

2. The paraffin block that the ER and PR was originally performed on will be forwarded to Mount Sinai for repeat testing.

3. Once the Mount Sinai report has been received at the St. Clare's Site, an addendum will be issued by Dr. Cook or Dr. Carter in the hospital information system.

4. This applies to all cases that are ER negative on the primary breast lesion independent of PR status. ER negative being defined as 10% or less.

5. All ER and PR's performed on the Ventana System from April 1, 2004 to August 9, 2005 will be referred to Mount Sinai as above.

2001 → 10%
2005 Cut off < 30%
1999
↓
1997

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

Spoke to Dr Long Aug 10, 2005 Regarding the

Jan 2001 onward, oncology decision to use 10% as cut off

Patient treated by radiation oncologist in 1999 - 2000 area

Review of ER/PR Service to date (Aug 10/05)

1997 Installed new Dako semi-automated/manual system for Immunopathology service (one of the first Labs in Canada)

1997 Switched ER/PR testing from Biochemical assay which involved freezing tumor tissue/mashing tissue then assay for ER/PR

At the time, the Immunohistochemistry method gave better results than the old Biochemistry assay. The new method involved a manual procedure to boil slides in a solution on a hot plate to unmask as best possible antigen sites in the patient's tissue. There was no standard methodology across Canada; our Lab followed the Dako procedure of boiling slides and other Labs used microwave ovens to boil slides.

Even though it was recognized that ER/PR testing by Immunohistochemistry would be more sensitive, previous samples performed in Biochemistry were not retested because of the change in technology/methodology.

2004 In January, new Ventana system which is fully automated with onboard antigen retrieval was installed in Laboratory. From January to March, staff were trained in Arizona on the new system in addition to on site training at The General Hospital. Hundreds of controls and patients were run on the system to correlate with the old methodology.

2004 In April, we started reporting results on the new system for those antibodies that had been correlated.

In general, the Pathologists' feedback on the new system was very positive. The new system produced crisper staining with little or no background staining.

2005 In May, a patient was retested on the new system and the results were positive on Ventana and were negative on the old boiling technique. Several other suspicious patients were retested by Dr. Carter at the request of the Oncologist. Those patients also tested positive on the new system.

In early July, I searched for all ER/PR tests performed by the Lab from January, 1999 – July, 2005.

I sorted the approximate 2500 reports by date, ER/PR status, and patients from HCCSJ versus out of town patients. This provided a snapshot by year of the number of tests performed and our positive versus negative rate.

At the same time, Dr. Carter had reviewed and requested 60 patients from 2002 to be retested on the new system. I have not seen the results, however, there seems to be some confusion on how many of those patients converted from negative/negative to positive.

Dr. Cook, Heather Predham, Barry Dyer, and myself have also contacted many other Labs to inquire about their positive/negative rates. It was clear that no Lab was able to give us this information. The Labs that have switched to the new automated system verified the same results as we have seen here, i.e. better staining quality, standardization, and reproducibility.

Barry Dyer and myself have double checked all reports from my original search and have created spread sheets by year indicating patients' results for ER/PR. We have also created a separate spread sheet for logging in blocks and slides being reviewed and consequently sent to Mount Sinai for retesting. The list for retesting has not been finalized.

Provided to Dr. Williams a log sheet of the 60 patients' original results that Dr. Carter retested from 2002. Of those, 34 were originally reported as negative/negative and 26 were reported as weak positives of varying degrees. As stated, I have not seen the repeat results.

Provided to Dr. Williams a log sheet of 2002 ER/PR tests by month. This showed that every month there were negatives and positives as it had been suggested that the Laboratory did not report a positive result from mid-June, 2002 to November, 2002.

The next step in this process is to finalize the list of patients to be retested and have those sent to Mount Sinai.

Currently, all new patients are being sent to Mount Sinai for testing and reporting and our Lab will also test on our new system and report for correlation.

July, 2005 Ventana sent in their technical expert for Canada and performed a complete review of our instruments, protocols, reagents, etc. A written report was submitted to Dr. Williams outlining that the system is working as it should be and that our Lab and technologists are as good as any in Canada. The only recommendation was to perform monthly and quarterly routine maintenance on the instruments.

Received Aug 11, 2005
2:20PM

Centre universitaire de santé McGill
McGill University Health Centre

Faxed to Dyer Aug 11, 2005 3:30PM

INVOICE

Invoice Date: Wednesday, August 10, 2005

Invoice To: Dr. Donald M. Cook
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
St. Clare's Mercy Hospital
154 LeMarchant Road
St. John's, NL
Canada A1C 5B8

Sale of Service: Charges related to ER/PR stained slides
No. of Cases: 7 (2 slides per case)

Fee: $15.00 per slide

AMOUNT: $210.00
Terms: Net 30 days

Please pay to the order of: MUHC Department of Pathology

Remit payment to: Montreal General Hospital
Department of Pathology, Room D3-245
1650 Cedar Avenue
Montreal, Quebec
H3G 1A4
Attention: Dr. Kevin Watters

Thanking you in advance.

N Impala

MUHC Department of Pathology
Nancy Impala
Administrative Secretary

(514) 934-1934 ext. 43838
(514) 934-8296

Amount: $15.00 per slide

Aug 18, 2005
Prostate
approx 115 block

Aug 19, 2005
HSC 99, 2000, 2001
SCH 2000, 2001

HealthCare
Corporation of St. John's

Memo

TO: Ms. Maria Mandes
Pathology, Room 6-404
Mount Sinai Hospital
600 University ~~Hospital~~ Avenue
Toronto, Ontario, M5G 1XB

FROM: Dr. Donald M. Cook
Clinical Chief, Laboratory Medicine
St Clare's Site
St. John's Hospitals, Eastern Health
154 LeMarchant Road
St. John's, NL A1C 5B8
Phone – 709-777-5482 / 777-5493
FAX – 709-777-5178

DATE: August 17, 2005

RE: **Repeat ER and PR Receptors**

As discussed, I am requesting the performance and interpretation of estrogen and progesterone receptor immunohistochemical stains using the LSAB procedure on the enclosed blocks. Each block is submitted in a plastic bag with demographic information and pathological interpretation. It would appreciated that the paraffin blocks and the stained ER and PR slides be returned to my office at St. Clare's Site. It would also be appreciated if the spreadsheet containing the ER and PR interpretation could be faxed to my office upon completion.

If you have any questions, please give me a call at 709-777-5482, or e-mail me at Donald.Cook@hccsj.nl.ca.

Sincerely yours,

Donald M. Cook

Donald M. Cook, MD, FRCPC, FCAP

MEMO

TO: Maria Tracey, Program Director, Surgical Program
Dr. Dan Fontaine, Site Chief, Lab Medicine, General Hospital Site

FROM: Dr. Don Cook
Clinical Chief
Laboratory Medicine Program
St. John's Hospital, Eastern Health
St. Clare's Site

DATE: August 23, 2005

RE: **Mastectomy Specimens**

I am requesting that all mastectomy specimens be placed in a large container and completely immersed in 10% formalin. Specimens should be immediately forwarded to the Pathology Lab where the breast tumour is appropriately sectioned to allow for even permeation and fixation by formalin.

Cases should not be left overnight or over the weekend unsectioned as this may interfere with proper fixation of tissue. For cases that occur after normal working hours, the pathologist on call should be notified,

Please make every attempt to ensure that these cases are done early in the day and submitted to the laboratory before 4:00 p.m.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

MEMO

TO: Dr. Robert Williams
Vice-President,
Quality, Diagnostic and Medical Services
St. John's Hospitals, Eastern Health
General Hospital Site
St. John's, Newfoundland
A1B 3V6

FROM: Dr. Don Cook
Clinical Chief
Laboratory Medicine Program
St. John's Hospital, Eastern Health
St. Clare's Site
A1C 5B8

DATE: August 24, 2005

RE: **Estrogen and Progesterone Receptors**

---

1) Cases from May, 1997, to March 31, 2004, that are ER negative (except those from patients who are deceased) are being referred to Mount Sinai Hospital for retesting.

2) This applies to all cases that are ER negative on the primary breast lesion independent of PR status. ER negative is defined as 10% or less on all cases from January 1, 2001, onward. Prior to December 31, 2000, ER negative has been defined as 30% or less.

3) All ER's and PR's performed on the Ventana system from April 1, 2004, to August 9, 2005, will be referred to Mount Sinai for repeat testing. We also plan to send approximately 30 to 40 cases from the Ventana system ranging from negative to intermediate to strongly positive cases to Montreal General for retesting and correlation with their Ventana System.

4) All current cases from August 9, 2005, will be referred to Mount Sinai for testing. There is a hold on reporting of current ER's and PR's by all pathologists in the Division of Anatomic Pathology, St. John's Hospitals, Eastern Health.

5) Mount Sinai reports on currently requested ER's and PR's will be returned to Dr. Bev Carter and released into the hospital information system. Hard copies of these reports will be forwarded to the appropriate physician.

6) All pathologists will continue to order ER's and PR's on their respective cases, fill out the immunohistochemical request form, and forward this to the technologist.

7) The ER and PR immunohistochemical stain will be simultaneously processed by our technologists and sent back to the ordering pathologist.

8) Once these stains are received, the ordering pathologist will give an interpretation using the standard form and forward this to Dr. Beverley Carter.

9) This report will not be released within the hospital information system. This will be used to correlate the results from the current Ventana System with those from Mount Sinai and Montreal General. This information, along with information from our technical and medical consultants, will help determine when the Ventana System can be returned to operational status.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

MEMO

TO: All Laboratory Directors:
Dr. D. Fontaine, HSC
Dr. G. Baker, Carbonear
Dr. S. Anwar, GB Cross Memorial
Dr. Maurice Dalton, Central NL Hospital
Dr. Barry Gallagher, James Paton Memorial Hospital
Dr. Paul Neil, Western Memorial Hospital
Dr. Dankwa, Charles S. Curtis,
Dr. R. Williams, Eastern Health

FROM: Dr. Don Cook
Clinical Chief
Laboratory Medicine Program
St. John's Hospital, Eastern Health
St. Clare's Site
St. John's, NL A1C 5B8

DATE: August 24, 2005

RE: **Estrogen and Progesterone Receptors (ER'S and PR'S)**

I wish to advise you that we are doing a review of our estrogen and progesterone receptors as a precautionary measure at this time. Once all data is compiled, we will have a better idea of the scope of this issue. I expect to have more information within the next few weeks, and will keep you updated. Please note the following points:

1) There is currently a hold on the reporting of Estrogen Receptors and Progesterone Receptors by all pathologists in the Division of Anatomical Pathology, Laboratory Medicine Program, St. John's Hospitals, Eastern Health.

2) All current requests for Estrogen and Progesterone Receptors are forwarded to Mount Sinai Hospital for immunohistochemical processing, interpretation, and reporting. You may elect to directly refer your Estrogen and Progesterone Receptors to Mount Sinai or to a laboratory of your choice.

3) Further to my memo dated June 13, 2005, I am requesting that you forward all ER negative cases on primary breast lesions, independent of PR status, from May, 1997, to March 31, 2004, to Mr. Barry Dyer at the General Hospital Site. From January 1, 2001, ER negative is defined as 10% or less. From May, 1997 to December 31,

2000, ER negative is defined as 30% or less. I would ask that you submit the pathology report, original ER and PR slides, including any control, as well as the H & E slide and paraffin block of the tumour. We will forward these ER negative cases to Mount Sinai for retesting. All ER's and PR's performed on the Ventana system from April 1, 2004, to August 9, 2005, will also be referred to Mount Sinai for retesting. You can also forward these cases to Mr. Barry Dyer. I would like to emphasize at this particular point in time, that you concentrate on the 1999 to 2004 years, followed by the 1997 to 1998 years, and then the April 1, 2004, to August 9, 2005 year. We will return all blocks and slides as soon as possible.

4) In regards to the operational status of the Ventana System, this will not be determined until we review correlations of ER and PR results from Mount Sinai and Montreal General Labs. We will also be awaiting reports of medical and technical consultants before it is decided to operationalize the Ventana System

5) If you have any questions, please feel free to call me at 709-777-5482.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

TO: Anthony Wing
Department of Laboratories
c/o Immunopathology, Room 6-304
Mount Sinai Hospital
600 University Avenue
Toronto, Ontario, M56 1X5

PHONE – 416-586-4800, EXT. 4457

FROM: Dr. Beverley Carter
Department of Pathology
St Clare's Site
St. John's Hospitals, Eastern Health
154 LeMarchant Road
St. John's, NL A1C 5B8
Phone – 709-777-5493 / 5530 / 5480
FAX – 709-777-5178

DATE:

RE: Estrogen and Progesterone Receptors

I am requesting the performance and interpretation of estrogen and progesterone receptor immunohistochemical status on the enclosed block.

I would appreciate your report being faxed to me when completed, as well as the return of the paraffin block and slides.

Yours sincerely,

Beverley A. Carter, MD, FRCPC
Pathologist

Pleas fax
to barry
Baker,
945-5158
faxed to
Gary Baker
Aug 24/05

MEMO

TO: Mr. Barry Dyer
Mr. Terry Gulliver
Dr. Robert Williams

FROM: Dr. Donald M. Cook
Clinical Chief, Laboratory Medicine Program

DATE: October 13, 2005

RE: **ER's and PR's**

As originally stated in my memo (dated September 6, 2005), to the Laboratory Directors throughout the province, it was our intent to retest all cases involving the Ventana System from April 1, 2004, to August 9, 2005. Considering the issues that Mount Sinai is having concerning capacity and turnaround times of ER and PR reports, I believe that we should concentrate our efforts on all negative ER's performed by the Ventana System for the time being. In speaking with Dr. Kara Laing, one of our medical oncologists, she agrees with this assessment.

For now, we will forward only negative ER cases from the 2004 and 2005 Ventana years. In regards to the remaining cases, we will send these at a later date when capacity levels at Mount Sinai permit.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health

October 13, 2005

Dr. Gershon Ejeckam
Staff Pathologist
Division of Anatomic Pathologist
General Hospital Site
St. John's Hospitals
Eastern Health

Dear Dr. Ejeckam:

As discussed, I appreciate your continuing role in overseeing the immunoperoxidase service. As you know, we are in the process of developing a specialized service with technologists solely dedicated in immunohistochemical technique. As agreed, you will oversee all aspects of the immunoperoxidase operation and have direct supervision over the technologists involved in the service. You will also provide direction to all pathologists involved in immunoperoxidase interpretation. In areas where we hope to develop subspecialized service, there will obviously be consultation between you and the appropriate pathologist on immunoperoxidase staining.

If you feel that there is any deviation from this, you should report this immediately to both the Clinical Chief of the Laboratory Medicine Program and the Vice-President of Quality, Diagnostic and Medical Services at Eastern Health. Once again, I thank you for your important contribution, guidance, and expertise to our organization in this area.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

c.c. Dr. Dan Fontaine
Mr. Terry Gulliver
Dr. Robert Williams

October 24, 2005

Dr. D. Banerjee
President, Canadian Association of Pathologists
Department of Pathology
BC Cancer Agency
600 West 10th. Avenue
Vancouver, BC Canada V5Z 4E6

Dear Dr. Banerjee:

RE: National Standards for Immunohistochemistry Testing

I have been asked by the President / Chief Executive Officer and the Vice-President of Quality Diagnostic and Medical Services, Eastern Health, as to whether the issue of Immunohistochemistry Testing could be brought forward to the Canadian Association of Pathologists. I think the whole issue of National Standards for Laboratories across Canada could be spearheaded by the Canadian Association of Pathologists and brought forward to the Federal Minister of Health. I wonder if we could put this on the agenda for our next face to face meeting of the Executive in late November.

I look forward to your reply.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

c.c. Dr. Bob Williams

CANADIAN ASSOCIATION OF PATHOLOGISTS
ASSOCIATION CANADIENNE DES PATHOLOGISTES
774 promenade Echo Drive, Ottawa, Canada K1S 5N8
Tel.: (613) 730-6230 Fax: (613) 730-0260
E-mail: cap@rcpsc.edu

November 2, 2005

Dr. D. M. Cook
St. Clare's Mercy Hospital
154 LeMarchant Road
St. John's, NL A1C 5B8

Dear Dr. Cook:

RE: National Standards for Immunohistochemistry Testing

Thank you for your letter of October 24, 2005. I have asked that this topic be added to the agenda for our November meeting of the CAP Executive.

Sincerely,

D Banerjee

Diponkar Banerjee MBChB, PhD, FRCPC
President

cc. Dr. Bob Williams, Eastern Health

Please note our fax number is: 613-730-1116

UK NEQAS *for Immunocytochemistry*
Room 3/02
Hamilton House
Mabledon Place
London WC1H 9BB
United Kingdom
Tel: 020 7554 8679 (Overseas + 44)
Fax: 020 7554 8685 (Overseas +44)
e-mail: rmkdalr@ucl.ac.uk
Web site: WWW.ukneqasicc.ucl.ac.uk

Date: 29th November 2005

Dr Gershon C Ejeckam
37 Musgrave Street
St. John's NL
A1A 5E7
Canada

Dear Dr Ejeckam

Thank you for the application to join UK NEQAS Scheme for Immunocytochemistry.

I have entered your details on our database so that you will be included on future assessments and confirm that your centre has now joined the scheme. Your laboratory code, which you should refer to in all correspondence and which ensures your laboratories anonymity,

The 2nd Run for **1st April 2005 – 31st March 2006** will despatch sometime in December 2005.

Lastly if there is any aspect that you would like to discuss further, please do not hesitate to contact me at the above address.

Yours sincerely

Ailin Rhodes
Office Manager

MEMO

TO: Dr. P. Neil, Pathology, Western Memorial Hospital
Dr. M. Dalton, Pathology, Central Newfoundland Hospital
Dr. S. Somers, Pathology, James Paton Memorial Hospital
Dr. S. Mustasa Khan, Pathology, G.B. Cross Memorial Hospital
Dr. G. Baker, Pathology, Carbonear Hospital
Dr. E. Dankwa, Pathology, Curtis Memorial Hospital
Dr. D. Fontaine, Pathology, General Hospital Site, Eastern Health
Dr. B. Williams, Medical Services, Eastern Health

FROM: Dr. Don Cook
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health

DATE: February 1, 2006

RE: **ER/PR Reports from Mount Sinai**

We have received most of the results from Mount Sinai regarding the ER/PR review process. The results from Mount Sinai were issued on Exel Spreadsheets. I will be issuing individual reports on patients and submitting these to you at your respective sites. When you receive these reports, please ensure that they are incorporated into your hospital information or laboratory information systems. I expect that you will be receiving the first of these reports within the next two weeks.

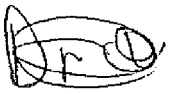
If you have any questions, please feel free to call me at 709-777-5482.

Sincerely yours,

✓

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health
Phone 709-777-5482
FAX 709-777-5178

Spoke to Gary Baker Feb 9.
and Brad Wed Feb 10 ensuring they got my memo.
Spoke to Dr Summers Feb 17, 5:15 PM To ensure they got My Memo



Mayo Clinic

Dr Cheville 507-284-3867

Darwin Heal

Logan

July 15, 2005 - meet with Dr Wilkins, Terry Sullivan to discuss future directions and timelines with respect to what resources needed to be allocated etc

July 27, 2005 - Drs Cox, Williams
10:30AM Met with Dr Carter
to ascertain her
perception on what
happened in Lab

July 21, 2005 - Informed manager
9:00AM and staff of
Education

July 22, 2005 -
9:00Am

Dr Cook, Dr Carter
Mr Sullivan met
to discuss what
Resources and Information Needs
And to Agree on.
timelines on which all
work to be completed
Dr Carter provided Sullivan
with list of Information required
It was agreed. all work
should be Completed by
Aug 30. 2005

Faxed to
Dr W. Williams
July 22/05
11:55Am

July 25, 2005

Spoke to Barry Duryea.

- Barry admits documentation is bad
- Numerous documents may have been destroyed during the Lab flood in Nov 2004.

also, advised him to order ASCP checkpoint for immunoperoxidase stains

- Ventana - arrived Dec 03, Operational April 04
  3-4 month evaluation and training period
  Tech were sent for company training in Arizona during this time

Aug 29. 2005

Spoke to Dan Fontaine to begin
Negative controls for ER and PR

~~604-877-6235 - Ass~~

Call July 25, 2005

1) Dr Banjerjee - out of town until Aug 2 - Vancouver

Erik Larsen

- Calgary Laboratory Services (403) 209-3763

(403) 770-3763

2) Tony Malignani (~~Medical~~ Pathology Director of Tom Baker Cancer) Centre

~~403-944-4854~~

403-521-3073

Calgary Martin Trotter 403-770-3500 - Until Aug 5, 2005

3) Carol Bourgeois

Hafford 4) Lauretta Geldenhuys

902-473-7334

~~292-2339~~

Grand Falls - 292-2500

5) Sandip 613-549-6666

Aug 12, 2005

Master list finally completed

Terry and Barry

with spent weekend

~~ED~~ Recovering slides and

block for Mount Sinai

Week of Aug 14, 2005 - Dr Cook

& Dr Fontaine with

identify blocks with

tumour for refund

to Mount Sinai

Eleven urgent ER & PR

Cases submitted

to Mount Sinai Aug 1, 2005

Observations cases 2001-2002 Aug 18, 2005

Fixation is a major problem in at least 15 to 20% of cases

A lot of high grade lesions

Aug 19, 2005 10:45 Am

Spoke to Dr Barry Gallagher - advised on own hold on ER & PR Reporting
- stated that Mount Sinai will be the issued Report, continues to refer ER & PR tests St. John's. Copy of Mount Sinai report will be faxed back to you for entry into hospital information system
- General discussion followed on Immunoperoxidase Techniques in General

Aug 10, 2005 11:50 Am (Clarenville)
- advise Dr Annan to send all cases in prior to 1999 as ER-ve, if Report as ER-ve 30% or less

Tom Costello Clinic 709-282-6297 Presented NLMA

Lab city

Tried to reach at the Number Aug 23, 2005 4:05 PM
couldn't reach

Hospital # 709-944-2632

Spoke to Tom Aug 23, 2005 4:25 PM.

- gave background on the problem.
- spoke about the index case.
- stated we are retesting cases from my 1997 up to Aug 2005
- explained briefly what immunoperoxidase testing was and the critical step of boiling slides for antigen retrieval, different pH, ~~ad~~ antibodies, dilution and titrations
- spoke to him about the human element and variability in the Dako system. and the standardization and reproducibility of the Ventanna System. Talked about the sensitivity of Ventana and high conversion rates.
- ~~stated~~ talk about the role of ER and PR and how other types of information (ie grade of tumour, lymph node involvement) affected treatment.
- stated ~~o~~ we are using Mount Sinai as a reference lab. Talked about failure to identify trends and the need for subspecialists and core pathology group to read ER & PR etc.
- talk about lack of standardization across North America
- spoke to him about having medical and technological consultant coming in and review our operation
- still don't have a good idea of the scope of the problem until we get results back from Mount Sinai, may take another 2-4 weeks
- we have resisted going public at this time until we get more information. and decide how we ~~o~~ are going to tell pt, set up appointment times etc, we may find that we may not as hard a serious impact than initially thought
- gave Tom my Number and agreed to keep in touch and communicate

Did not want to create un-→ due anxiety and stress

Tom agreed

Spoke to Terry Gulliver Aug 23, 2005 10:15 AM, on the Number of cases referred in from Outside St John's

From April 2004

- Gander . 1997 → 2004 < 10% Master Log 64 cases

- Carbonear 14 cases. 1998-3

Carbonear 14 cases

99-4
00-2
01-3
03-2
04-0

- Master log will be sent out on these cases. Hopefully case will be sent out on Aug 24, 2005

Call

- Grand Falls
- Corner Brook
- St. Anthony

Send - Paraffin blocks
- Pathology blocks
- ER & PR.

- ~~Conc~~ Concentrate on the 1999 to March 2004 years

- Spoke to Paul Neal Aug 23, 2005 10:30 AM
  Concentrate on the 1999 to 2004 years
  - current cases, refer directly to Mount Sinai, sent ~~copy~~ Name of contact individual at Mount Sinai

- Spoke to Maria Mandes Aug 23, 2005 10:55 AM
  - may not get result until 2 weeks down the road, as blocks may have to be reprocessed, technical issue with the blocks. Has received about 200 blocks

= Tried to Reach Maurice Dalton Aug 23, 2005 12:10 AM, currently on Holidays, will speak to him when he gets back on Monday Aug 29, 2005

- Spoke to Ken Green Aug 23, 2005 12:15 AM - send all ~~contacts~~ contacts and Her 2-New to be read by Bev Carter at St Clare

- Pat Pilgrim Aug 23, 2005 12:45 lathed about Herapla, and impact on the lab with Her 2-New testing

- Spoke to [illegible]

Sept 2, 2005 - spoke to Maria Mandes
- gave her list of pathology directors from NFLD as she was getting a number of inquiries
- tried to have first reports out by Sept 9, 2005, but no guarantees

Sept 7, 2005 10:00 AM - spoke to Dr Dan Kuer from St Anthony
- updated him on situation and gave background information before my memo went out

Sept 7, 2005 2:10 PM - spoke to Nancy Good at Mount Sinai
- still cutting blocks
- hope to start staining tomorrow

Sept 7, 2005 2:40 PM - spoke to Maria Mandes
- may not get first results until Tuesday or Wednesday on the week of the Sept 12, 2005. Currently doing this on an overtime evening basis

retro < Aug 9, 2005
good forward beyond Aug 9, 2005

Sept 13, 2005 12:35 PM - Possibly looking at selling results by this Friday.
Spoke to Mount Sinai
Spoke to Nancy Good Sept 13 2005 12:35 PM

Sept 14, 2005 - ER6PR issue brought to MAC

Sept 19, 2005 - update EP6PR at Clinical Chief Meeting

Sept 21, 2005 - Dr Cook, Dr Cate - Interviewed Trust

Sept 21, 2005 - ER6PR issue brought forward to Eastern Health Board by Dr Williams

Sept 23, 2005 -

Aug 26, 2005 @ 4:10 PM
416 586 4800, 3334

Judy: Email

M Mendes @ MT Sinai. ON. Ca.

Current Case

-

- ~~to~~ repl retrospective → straight to Marie Marks
exo spread sheet

spread sheet

Rems, next week
247 blocks

NO block #

highlight the places
when

S+Clan 1999 2001, 2002,
2003, 2004

excell spread

? block

Hope to have some results by Sept 10, 2005

Spoke to Barry Baker Aug 24, 2005 10:30 AM
advised him to send current ER and PR
cases directly to Mount Sinai or
to Summerside when time to
performed as opposed to sending
them into St. John's

Spoke to Barry Baker Aug 24, 2005 11:05 AM
- advised him to send current ER and PR's
directly to Mount Sinai as
opposed to sending cases to St. John's
- sent copy of contact individuals at Mt Sinai

Tried to reach Dr Darken Aug 24, 2005 11:10 AM

Spoke to Maura Dalton Sept 1, 2005 3:45 PM
at great length with background information
- wanted him to know the before I sent out
mine

Oct 1, 2005 - spoke to Dr Dankua at NAP meeting to send in pathology report on St Anthony case
Oct 1, 2005 - updated NAP members of ER and PR situation
Oct 3, 2005 - meeting with Surgeons, oncologist, Dr Ed Hunt to discuss media handling
Oct 4, 2005 - conference call of CEO's and Medical Directors on issues surrounding ER and ~~report~~ issuing of addendum report
- letter to be drafted by Cancer Clinic.

Oct 4, 2005 - Spoke to Alan Kwan regarding ~~draft~~ format of draft report

Oct 3 2005 - Spoke to Maura Dalton re regards receipt of Grand Falls case and 17 cases submitted to John's in June 2005

Sept 26, 2005 10:30 AM - Spoke to Nancy Good. Slated in final stages of reading slides. Should have reports by Tommorrow Sept 27, 2005

Sept 28, 2005 9:20 AM - Spoke to Dr Paul Neal working hard to collect cases. Should get first lot of case sent to St John's hopefully this week. The lab is working hard on this

Sept 28, 2005 9:30 AM - Voice mail left for Dr Dalton
- Hopefully ~~Next~~ next week, cases Tuesday or Wednesday
- final check -

Sept 28, 2005 1:00 PM - Maurice Dalton called
- hope to have paraffin blocks at bend by Tommorrow.

Sept 29, 2005 4:30 PM - Received call from Maurice Dalton 82 blocks are on the way in should arrive tommorrow
- I passed on message to Barry Duyer

Sept 28, 2005 3:00 PM - Correlate cases with tamoxifen Rx with Dr Kara Lang at her office. Dr Williams later visited Dr Lang received copy of watchdog

Sept 30, 2005 4:05 PM - received confirmation call from Rob Ritter

Sept 30, 2005 3:50 PM - Notified Dr. Tom Costello president NLMA

Sept 30, 2005 4:00 PM - Dr Pritchard away till Oct 14, 2005

Oct 11, 2005 - Spoke to Paul Neal
- sending in all blocks
from Corner Brook Wednesday or Thursday
- working during weekend

Oct 7, 2005 - Spoke to Dr Summers in Gander
- She is sending in additional cases
- reports that some ER and PR Negative patient have received Tamoxin

Oct 12, 2005 - Spoke to Nancy Good
- machines are giving trouble in immuno
- hopefully will be back up in a day or ~~to~~ two. This is
- the reason for delay

Oct 13, 2005 - Spoke to Tres Wegnoski.
Regarding immuno machines
- she said machines should be up and running soon
- No delays in consultation, expect some delays in retro cases.

Oct 27, 2005 - Called Dr Pritzkin, out of town, back on Oct 31, 2005
- ~~Left~~ Left phone message for Dr Miller to call back

Oct 28, 2005 1:30 AM - Spoke to [illegible] antibodies were used with the Dako system

Oct 28, 2005 4:10 PM - Spoke at great length to Dr Dalton in Grand Falls to gage his emotional state
- stated that I had nothing to report from Mount Sinai
- stated that I would generate reports to be sent to Lab Directors as no formal report on the review cases will be generated. Spoke to him on our review process with Tumour Board Rounds.

Oct 31, 2005 10:45 AM - Spoke to Terry Gulliver about logging sent off blocks in the review process into the HIS. We agree that Judy Q can do this
Left Voice mail for Barry Dwyer to give Judy Q computer access to HIS

Terry called back Oct 31, 2005 12:30 - Tiss with entire blocks into system. Barry has been trying to get computer status for Judy Q for the last 3-4 weeks from HIS

Oct 31, 2005 11:30 AM - Spoke to Barry Baker, will send out addendum reports from MSH. to Dr Baker - Dr Baker will have to enter into his own system and follow up with administration on how to handle this
gave him Kara Lang Nancy Heather Pridham, and Bob Williams

Oct 31, 2005 11:36 AM Spoke to Barry Gallagher - will be sending addendum reports to Dr Gallagher - He needs to enter them into his HIS and notify administration on this. on how to access the impact on patients. May want to consider Tumour Board. I told him he has about 60 patients waiting to be accessed. 10 have been accessed so far.

Oct 31, 2005 12:00 PM - Follow up with Heather Pridham to talk to Lab Directors regarding Tumour Board. Heather will also liase with Dr Williams

Eastern Health

Don / Terry / Barry / need ASAP.

1) All ER/PR results since 1996
- ~~[illegible]~~

2) Total cases per year of ER testing
% positive ER, can we find out next week, pre and post variation 75% true

3) All reports pulled

4) all slides pulled & organized

5) ~~[illegible]~~ Blocks pulled as ordered

6) ER/PR testing done ASAP

7) 10% selected using random selection for outside consult

8) ~~[illegible]~~ Problem cases for outside testing

- Person dedicated for this. July [illegible]
Carol Mealey

- move as quickly as possible
- ~~to~~ resources dedicated ~~for~~ to this

Message

Donald Cook

From: Donald Cook
Sent: Thursday, January 19, 2006 2:35 PM
To: Dr. Robert Williams
Subject: FW: Update on ER's/PR's

From: Mullen, Dr. Brendan [mailto:BMullen@mtsinai.on.ca]
Sent: Thursday, January 19, 2006 12:45 PM
To: Donald Cook; Pritzker, Dr. Kenneth
Cc: Robert Williams
Subject: RE: Update on ER's/PR's

We are currently reviewing and entering the technical repeats. The completed spread sheet will be sent to you on Monday.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, ON, Canada M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

-----Original Message-----
From: Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: January 19, 2006 11:12 AM
To: kpritzker@mtsinai.on.ca
Cc: Robert Williams; BMullen@mtsinai.on.ca
Subject: Update on ER's/PR's

Hi Ken,
Dr Williams has to give a report to our Board of Directors at Eastern Health early next week as to the status of the ER's and PR's.We know that these cases will be completed by the end of January 2006, however Dr. Williams would like an updated report as to the progress of staining and interpretation etc.This information would be greatly appreciated.
Thanks,
Don Cook

Donald Cook

From: Donald Cook
Sent: Monday, January 09, 2006 5:28 PM
To: 'BMullen@mtsinai.on.ca'
Cc: Robert Williams
Subject: RE-Institution date for ER/PR/HER2

Hi Brendan
In regards to the start up date for resumption of testing on our current cases ,We are looking at around March,31 2006 .We will of course will try for an earlier start up date depending on the implementation on the various recommendations.
Regards,
Don Cook

Message

Donald Cook

From: Donald Cook
Sent: Friday, January 13, 2006 4:17 PM
To: Dr. Robert Williams
Subject: FW: Update on ER's/PR's

From: Mullen, Dr. Brendan [mailto:BMullen@mtsinai.on.ca]
Sent: Monday, January 09, 2006 4:30 PM
To: Donald Cook
Cc: Robert Williams; Pritzker, Dr. Kenneth
Subject: RE: Update on ER's/PR's

Yes they will all be reported by the end of January. When do you plan to re-institute the ER/PR/HER2 assessment for the current cases?

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, ON, Canada M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

-----Original Message-----
From: Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: January 9, 2006 2:55 PM
To: BMullen@mtsinai.on.ca
Cc: Robert Williams
Subject: Update on ER's/PR's

Hi Brendan,
Dr Williams ,our vice president of Medical Services is wondering when we can expect to receive further results on the review/retro cases.It is our impression that all of these will be completed at the end of January 2006.I am assuming this target is still in place ?
Regards
Don Cook

Donald Cook

From: Donald Cook
Sent: Wednesday, January 04, 2006 4:35 PM
To: 'kpritzker@mtsinai.on.ca'
Cc: Robert Williams
Subject: Update on ER/PR's

Hi Ken,
Dr Williams is asking for an update on the ER's and PR's in regard to the progress in staining and how soon we can expect to receive further results in the review process. Looking forward in hearing from you.
All the best for the New Year.
Don Cook

Donald Cook

From: Donald Cook
Sent: Wednesday, December 21, 2005 8:39 AM
To: Dr. Robert Williams
Subject: FW: Update on ER/R's

From: Pritzker, Dr. Kenneth [mailto:kpritzker@mtsinai.on.ca]
Sent: Tuesday, December 20, 2005 5:00 PM
To: Donald Cook
Cc: Robert Williams; Mendes, Maria; Mullen, Dr. Brendan
Subject: RE: Update on ER/R's

Don ,
As of today, everything is tracking towards successful completion at end of January,2006.

All the best for the Holidays and the New year,

Ken

586 8589

E-mail: kpritzker@mtsinai.on.ca

-----Original Message-----
From: Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: December 19, 2005 8:28 AM
To: kpritzker@mtsinai.on.ca
Cc: Dr. Robert Williams
Subject: Update on ER/R's

Hi Ken
Dr. Williams has asked me to follow up with you on the status of the ER's and PR's in the review process. I understand there will be a push on this after Christmas with a view to completion at the end of January 2006.I am assuming this target is still in place? I would appreciate your comments.
Regards,
Don

Dr. Donald Cook

From: Mendes, Maria [mmendes@mtsinai.on.ca]
Sent: Sunday, December 04, 2005 5:55 PM
To: Dr. Donald Cook
Subject: RE: Last Batch of ER\PR cases

Hi Dr. Cook,

I received three packages on Friday I believe it is what you are referring to in the email below.

Maria

-----Original Message-----
From: Dr. Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: Friday, December 02, 2005 1:15 PM
To: MMendes@mtsinai.on.ca
Subject: Last Batch of ER\PR cases

Hi Maria ,
We are sending off what appears to be the last batch of cases for the ER\PR review.These are cases that are from hospitals outside of St.John's.This batch contain's approximately 130 to 140 blocks.You should receive these cases sometime early next week. I appreciate the work you folks have done to date.
Regards,
Dr.Cook

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Friday, December 02, 2005 2:45 PM
To: 'MMendes@mtsinai.on.ca'
Subject: Last Batch of ER\PR cases

Hi Maria ,
We are sending off what appears to be the last batch of cases for the ER\PR review.These are cases that are from hospitals outside of St.John's.This batch contain's approximately 130 to 140 blocks.You should receive these cases sometime early next week. I appreciate the work you folks have done to date.
Regards,
Dr.Cook

Spoke to Ken Pritchett Dec 2, 2005 5:15 PM
- should have cases cleared up by end of January
- spoke to him about The Tek Express
- Says mount looking at Dako automated system sometime in the New Year.

Denise Dunn

From: Dr. Donald Cook
Sent: Tuesday, November 29, 2005 8:55 AM
To: Dr. Robert Williams
Subject: FW: Cases from Newfoundland

C.htm (3 KB)

-----Original Message-----
From: Kevin Watters [mailto:kevin.watters@muhc.mcgill.ca]
Sent: Monday, November 28, 2005 11:49 AM
To: Dr. Donald Cook
Subject: Re: Cases from Newfoundland

Sorry Don, I approached Marie Laure Brisson at the Jewish General Hospital for you and unfortunately she is unable as well to accommodate out of province material at this point in time.

.... Kevin

"Dr. Donald Cook" <Donald.Cook@hccsj.nl.ca> on 11/24/2005 07:13:48 AM

To: <kevin.watters@muhc.mcgill.ca>
cc: "Dr. Robert Williams" <Robert.Williams@hccsj.nl.ca>
Subject: Cases from Newfoundland

(See attached file: C.htm)

Donald Cook

From: Dr. Donald Cook
Sent: Thursday, November 24, 2005 2:44 PM
To: Dr. Robert Williams
Subject: FW: ER\PR update

From: Pritzker, Dr. Kenneth [mailto:kpritzker@mtsinai.on.ca]
Sent: Thursday, November 24, 2005 1:25 PM
To: Dr. Donald Cook; Pritzker, Dr. Kenneth
Cc: Dr. Robert Williams
Subject: RE: ER\PR update

Don,
We are now completing validation studies with the batch autostainer equipment.
If there is no hitch, then we start in production mode for ER/PR for Newfoundland on Monday.

Ken

-----Original Message-----
From: Dr. Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: November 24, 2005 8:35 AM
To: kpritzker@mtsinai.on.ca
Cc: Dr. Robert Williams
Subject: ER\PR update

Hi Ken,
Dr.Bob Williams our VP for Quality,Diagnostic and Medical Services has asked me if I could contact you for an update on the operational status of your new batch stainer and the reporting of our ER\PR cases.He has asked for this information as he is giving a report to the Board of Directors at Eastern Health.
Regards,
Don Cook

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Thursday, November 24, 2005 10:05 AM
To: 'kpritzker@mtsinai.on.ca'
Cc: Dr. Robert Williams
Subject: ER\PR update

Hi Ken,
Dr.Bob Williams our VP for Quality,Diagnostic and Medical Services has asked me if I could contact you for an update on the operational status of your new batch stainer and the reporting of our ER\PR cases.He has asked for this information as he is giving a report to the Board of Directors at Eastern Health.
Regards,
Don Cook

Received directive from Tumor Board Rounds on Nov 17, 2005
- Not to order ER and PR's in DCIS or LCIS cases

Dr. Donald Cook

From: Pritzker, Dr. Kenneth [kpritzker@mtsinai.on.ca]
Sent: Wednesday, November 16, 2005 6:54 PM
To: Dr. Donald Cook
Cc: Mendes, Maria; Mulien, Dr. Brendan
Subject: RE: ER/PR'S

Don,

We have done 200 with 500 to go.

As we were at capacity, we have just received a batch stainer which I'm told can go live next week.
Then the pressures will be on us for interpretation.
We'll try to get this stuff out as soon as we can.

Had a good chat with Bev earlier in the afternoon.

Cheers,

Ken

-----Original Message-----
From: Dr. Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: November 16, 2005 3:32 PM
To: kpritzker@mtsinai.on.ca
Subject: ER/PR'S

Hi Ken,
I would like to thank you and your department for your ongoing efforts in helping us deal with this very difficult situation.We are getting a lot of pressure for faster reporting of the retro cases . In speaking 'to the powers that be' I repeated to them that Mount Sinai is operating at full capacity and that resources are limited. This appears to be the general state of Laboratory Medicine today in Canada and that there very little flexibility in the system,especially when it comes to our Pathology Manpower situation and the shortages we are experiencing.If there is any way Mount Sinai can speed up the reporting ,I would certainly appreciate it.
In the meantime ,the issue of "National Standards for Immunohistochemistry Testing" will be on the agenda for our next executive meeting of the Canadian Association of Pathologists in late November.There may be a good opportunity to make this a national issue to bring to the Federal Minister of Health along with the need for additional human and financial resources for our Labs , issues surrounding patient safety and national standards for all aspects of Laboratory Medicine. I will kept you posted on any developments.
Many Thanks .
Don Cook

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Tuesday, November 15, 2005 2:03 PM
To: 'NGood@mtsinai.on.ca'
Subject: ER and PR Stained Slides

Hi Nancy,
As far as I am aware ,the stained ER/PR slides will stay at Mount Sinai to be read and interpreted by Mount Sinai Pathologists.
Regards,
Dr.Cook

Follow up with phone call to Nancy at Nov 15/ 2:30PM
stated to her to send ER&PR slides back
to us once entire review is completed and
all interpretations were done

Spoke to George Tilley Nov 15/ 9:20AM.
- both of us concerned about slow pace
of Mount Sinai reports. George
considering to speak to Mount Sinai
CEO to see what can be done
to speed up the reporting.

Message

Dr. Donald Cook

From: Good, Nancy [NGood@mtsinai.on.ca]
Sent: Tuesday, November 15, 2005 11:47 AM
To: Dr. Donald Cook
Cc: Mendes, Maria
Subject: stained slides

Hi Dr. Cook,

Will we be sending you the ER PR stained slides once everything is done?

thanks,
Nancy

Nancy Good, M.L.T.
Medical Laboratory Technologist
Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, Ontario, Canada M5G 1X5

Phone: 416-586-4671
Fax: 416-586-8628

email: ngood@mtsinai.on.ca

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Thursday, November 10, 2005 2:29 PM
To: 'MMendes@mtsinai.on.ca'
Subject: ER/PR update

Hi Maria
I wonder if you can update me on whether you have more slides stained since my last e-mail and when we can expect some more results.
Regards
Dr. Cook

Donald Cook

From: Dr. Donald Cook
Sent: Thursday, November 10, 2005 2:16 PM
To: Terry Gulliver
Subject: FW: FW: Immunoperoxidase Technologist

-----Original Message-----
From: edepestr@pat.jgh.mcgill.ca [mailto:edepestr@pat.jgh.mcgill.ca]
Sent: Thursday, November 10, 2005 2:13 PM
To: Dr. Donald Cook
Cc: Barry Dyer
Subject: Re: FW: Immunoperoxidase Technologist

Dear Dr. Cook,
Dear Mr. Dyer,
We certainly can receive your technologist in January, preferably starting January 16, 2006.
We will need a letter confirming the date of his arrival also confirming his assurance coverage during his stay in our laboratories.
Sincerely yours,
Edouard Depestre

"Dr. Donald Cook" <Donald.Cook@hccsj.nl.ca>
11/08/2005 03:25 PM

To: <edepestr@pat.jgh.mcgill.ca>
cc:
Subject: FW: Immunoperoxidase Technologist

From: Dr. Donald Cook
Sent: Tuesday, November 08, 2005 4:52 PM
To: 'edpestr@pat.jgh.mcgill.ca'
Subject: Immunoperoxidase Technologist

Dear Mr.Depestre.
Thank you for your e-mail dated Nov.07,2005.What you have stated in the e-mail is acceptable to us.Unfortunately we are unable to send our technologist to Montreal in November of this year.Our employee will be available the week of Jan 7th,2006.Would this be acceptable?.You can also communicate with Mr.Barry Dyer our Divisional Manager at barry.dyer @ hccsj.nl.ca.I look forward to hearing from you.
Regards,
Dr .Cook

Donald Cook

From: Dr. Donald Cook
Sent: Wednesday, November 02, 2005 4:25 PM
To: Dr. Robert Williams
Subject: List of ER"s and PR's from Maria Mandes

Hi Bob,
The list from Maria is the same one from Nancy Good that I received on Monday .There are no new numbers.Hopefully Dr.Mullen will start reporting over the next few days.I will see you on Monday.
Regards,
Don Cook

Message

Donald Cook

From: Dr. Donald Cook
Sent: Wednesday, November 02, 2005 4:12 PM
To: Heather Predham
Subject: FW: updated list of ER PR
Attachments: Dr. Mullen.xls

From: Mendes, Maria [mailto:mmendes@mtsinai.on.ca]
Sent: Tuesday, November 01, 2005 9:09 PM
To: Dr. Donald Cook
Cc: Good, Nancy; Mullen, Dr. Brendan; Pritzker, Dr. Kenneth; D'Mello, Vince
Subject: FW: updated list of ER PR

Hi Dr. Cook,

Hopefully this is the information you required please let me know if you need other information. We have done some more staining today and will continue with the staining and sending the slides to Dr. Mullen for reporting.

Maria
-----Original Message-----
From: Good, Nancy
Sent: November 1, 2005 10:28 AM
To: 'Donald.Cook@hccsj.nl.ca'
Cc: Mendes, Maria
Subject: updated list of ER PR

Hi Dr. Cook,

This is the updated list of all the specimens we have received so far (including the few received yesterday). The list also includes which blocks have been reported, which have been stained and which have been cut so far. The specimens [redacted] will be stained today [redacted]

thanks,
Nancy

Donald Cook

From: Dr. Donald Cook
Sent: Wednesday, November 02, 2005 4:13 PM
To: Dr. Robert Williams
Subject: FW: Alternate for ER'S and PR's

From: Mullen, Dr. Brendan [mailto:BMullen@mtsinai.on.ca]
Sent: Wednesday, November 02, 2005 9:24 AM
To: Dr. Donald Cook
Subject: RE: Alternate for ER'S and PR's

Will do with a cc to you.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, ON, Canada M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

-----Original Message-----
From: Dr. Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: November 2, 2005 7:20 AM
To: BMullen@mtsinai.on.ca
Subject: Alternate for ER'S and PR's

Hi Brendan
I will be out of town for the next four days.If you have any results you can also forward them to Heather Predham at Heather.Predham @ hccsj.nl.ca.
Thanks,
Don Cook

Donald Cook

From: Dr. Donald Cook

Sent: Tuesday, November 01, 2005 3:23 PM

To: Dr. Robert Williams

Subject: ER and PR figures

Hi Bob,
These are rough figures based on what I have just received from Mount Sinai.
169 cases reported
559 cases left to report of which 219 blocks are cut and 26 cases are stained.
These are approximate figures.
It looks like it is going to take some time before all these cases are reported
Regards
Don

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Monday, October 31, 2005 4:38 PM
To: 'MMendes@mtsinai.on.ca'
Subject: Update on ER and Pr Receptors.

Hi Maria ,
As discussed , I would appreciate any additional results that can be forwarded to me as well any information on the number of blocks cut and slides stained etc.
Regards
Dr.Cook

Oct 31, 2005 - 4:35 Pm — Spoke to Maria Regarding the urgency of getting results from Mount Sinai

Nov 1, 2005 - 9:15 Am — spoke to Dr Paul Ward Regarding the issuing of written report from Mount Sinai by me and how this will be directed to the Lab Director

Donald Cook

From: Dr. Donald Cook
Sent: Thursday, October 27, 2005 7:10 PM
To: Dr. Robert Williams
Subject: FW: ER/PR results

Attachments: Results9.xls

Results9.xls (17 KB)

-----Original Message-----
From: Mullen, Dr. Brendan [mailto:BMullen@mtsinai.on.ca]
Sent: Thursday, October 27, 2005 2:59 PM
To: Dr. Donald Cook
Cc: Mendes, Maria; Good, Nancy
Subject: ER/PR results

This is the next set of results. I am waiting for the blocks which have been cut to be stained. I will read them as soon as they are available. The only other material I have to review are the previous negatives (0 or <1% with no internal control, an internal control that did not stain or stained
weakly) which were repeated to ensure that we did not miss any positives.
They should be available early next week.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine Mount Sinai Hospital 600 University Avenue
Toronto, ON, Canada M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

eye brows.

As a member of the Board of the Canadian Patient Safety Institute I want to ensure that, if there are learning's for others from our experience, we will share it. Having said that, I understand that Ontario already has a comprehensive accreditation program in place for its labs.

Our Laboratory Clinical Chief will be contacting the Canadian Association of Pathologists and others that we may subsequently identify. It appears that there is a gap in terms of a national entity who can take the lead with this issue, so we will likely have to take a shot gun approach to the follow up and hope that there is someone who can keep it moving.

George

George Tilley

President/Chief Executive Officer

Eastern Health

c/o Corporate Office

Waterford Bridge Rd.

A1E 4J8

Tel: 709-777-1330

Fax: 709-777-1302

Donald Cook

From: Dr. Donald Cook
Sent: Thursday, October 27, 2005 8:51 AM
To: Dr. Robert Williams
Subject: FW: ER/PR Testing

From: Pritzker, Dr. Kenneth [mailto:kpritzker@mtsinai.on.ca]
Sent: Wednesday, October 26, 2005 9:43 PM
To: Mullen, Dr. Brendan; Dr. Donald Cook
Subject: FW: ER/PR Testing

Brendan and Don,

There may be an opportunity here. Pathologist advocacy in Patient safety initiatives, may assist finding resources for Pathology labs.. even restoring the autopsy to prominence.
Worth thinking about..

KP

Kenneth P. H. Pritzker M.D. FRCPC
Pathologist-in-Chief
Director, Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, Canada, M5G 1X5

Phone (1)(416) 586 4453
Fax (1) (416) 586 8589

E-mail: kpritzker@mtsinai.on.ca

-----Original Message-----
From: George Tilley [mailto:George.Tilley@hccsj.nl.ca]
Sent: Thursday, October 20, 2005 2:40 PM
To: kpritzker@mtsinai.on.ca
Cc: robert.williams@easternhealth.ca
Subject: ER/PR Testing

Hi Ken;

Just wanted to thank you again for talking with me this morning. I appreciated the opportunity to talk through this difficult issue with you and get your advice.

There appears to be growing body of evidence and opinion that there are many questions inherent with this ER/PR test. Even for me as a non clinician, it raises

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Tuesday, October 25, 2005 10:13 AM
To: Dr. Robert Williams
Subject: FW: Status of ER and PR review

From: Dr. Donald Cook
Sent: Tuesday, October 25, 2005 10:12 AM
To: 'BMullen@mtsinai.on.ca'
Subject: Status of ER and PR review

Hi Brendan,
I am wondering how it is going with the review and when we can expect some more results. I can appreciate that Mount Sinai is probably at capacity levels.Could you update me .
Regards,
Don Cook

Also E-mail sent from Mr George Tilley to CEO of Mount Sinai and Lab Director of Mount Sinai around. Oct 19 → Oct 21, 2005

Message

Dr. Donald Cook

From: Banerjee, Diponkar [dbanerje@bccancer.bc.ca]
Sent: Monday, October 24, 2005 3:25 PM
To: Dr. Donald Cook
Cc: dsaintonge@rcpsc.edu
Subject: RE: Possible Agenda Item For CAP Meeting In Nov.

I agree this is an important topic that needs discussion. We should add it to the agenda, along with the National Standards of Practice topic.
-----Original Message-----
From: Dr. Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: Sunday, October 23, 2005 8:07 AM
To: Banerjee, Diponkar
Subject: Possible Agenda Item For CAP Meeting In Nov.

Hi Diponkar,
Mr. George Tilley CEO of Eastern Health and Dr Bob Williams,VP Quality,Diagnostic and Medical Services have ask me if we could discuss the issue of national standards for Immunohistochemistry at the Canadian Ass of Pathologists.Maybe we could put it on the agenda for the Nov meeting as an item we can bring to the Federal Minister of Health.This could be a part of a much larger issue such as National Standards of Practice For Laboratory Medicine in Canada.I would appreciate your thoughts,
Regards
Don

FW 5178

10:05

Dr. Williams

Dr. Robert Williams

13167

From: George Tilley
Sent: Thursday, October 20, 2005 9:29 AM
To: Alice Collins (alicec@mun.ca); Barb Roebotham (brosboth@rr... Fitzpatrick (cfitzptrck@hotmail.com); David Duffett (Business Fax); David Hiscock (davidh@personainternet.com); Ed Drover (Ed.Drover@freedom55financial.com); Ed Walsh (epwalsh@nf.sympatico.ca); Frank Davis (fdavis@nfld.net); Hubert McGrath (h-r.mcgrath@nf.sympatico.ca); Joan Dawe (jddawe@nf.sympatico.ca); Lewis Cole (pearl.lew@nf.sympatico.ca); Majorie Gibbons (marjorie.gibbons@nf.sympatico.ca); Paul Colbert (pcolbert63@hotmail.com); Primose Bishop (primrose.bishop@nf.sympatico.ca); Regina Bailey (r.bailey@superweb.ca); Rowena Bryans (rbryans@persons.ca); William Boyd (wboyd@wob.nf.ca)
Subject: FW: On CBC Website - and this aired on The National last night - Unreliable test gives lessons to all labs - Oct. 19

Trustees;

I am attaching a transcript of the item on the CBC National newscast last night pertaining to our laboratory situation. Aside from what we are doing locally, there is a growing awareness that this is a national issue which is referenced in this story. I do not know who Dr. Hewlitt is, who was interviewed.

We did talk to the Canadian Patient Safety Institute yesterday to discuss who could appropriately take the lead to ensure that standards are developed in this area. They wanted some time to reflect on it. We consulted with Health Canada but unless it is associated with an equipment failure they don't get involved. I also talked to one of my CEO colleagues in Toronto, who is an oncologist, and his opinion is that this is a very "grey test". He has given us the names of a couple of breast cancer specialists in the country to get there opinion as to how this can be followed up on. We will also be writing the Canadian Association of Pathologists to suggest their involvement.

In the meantime, since we are having limited success in getting all of our key messages covered by the media, this weekend we will be taking our newsprint ads to review where we are with this. As well, today, we will start calling all patients who are being retested to advise them of when their results can be expected. We are hoping we can conclude that next week. I have talked to the CEO of Mount Siani Hospital, which is doing the retesting for us, to see if there is any possible way they can move the retests any faster.

George

Bryan Hewlett
- Nfld Lym MacMath Health
- Implant Consultant
- Consultant to Docs - Vng Prostate & Docs
- Scient PhD Lipids

George Tilley
President/Chief Executive Officer
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Waterford Bridge Rd.
A1E 4J8
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Fax: 709-777-1302

Consultant Ph

Bryan Hewlett
Docs
Newfoundland Consultant

10/20/2005

Donald Cook

From: Dr. Donald Cook
Sent: Tuesday, October 18, 2005 10:04 AM
To: Dr. Robert Williams
Subject: FW: Status of ER/Pr reports

From: Mullen, Dr. Brendan [mailto:BMullen@mtsinai.on.ca]
Sent: Monday, October 17, 2005 8:52 PM
To: Dr. Donald Cook
Cc: Mendes, Maria
Subject: RE: Status of ER/Pr reports

I am out of the city except for a brief stop tomorrow until Saturday. I will do what is available on Sunday.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine
Mount Sinai Hospital
600-600 University Avenue
Toronto, ON M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

> -----Original Message-----
> **From:** Dr. Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
> **Sent:** Monday, October 17, 2005 7:40 AM
> **To:** BMullen@mtsinai.on.ca
> **Subject:** RE: Status of ER/Pr reports
>
> Hi Dr.Mullen
> I wonder if you could advise me of the status of our repeat ER's and PR's and when we can expect additional reports.We certainly appreciate all your efforts in this situation.Many Thanks.
> Regards
> Dr.Cook

Donald Cook

From: Dr. Donald Cook
Sent: Wednesday, October 12, 2005 3:24 PM
To: 'NGood@mtsinai.on.ca'
Subject: RE:ER'S/PR's

Hi Nancy
We are sending up another batch of blocks for repeat ER and PR testing .These should be sent up tomorrow and are for the years 1997 and 1998.These originate from St.John's .I would appreciate if on the spreadsheet that these are identified as St. John's cases.
Regards,
Dr.Cook

Donald Cook

From: Dr. Donald Cook
Sent: Wednesday, October 05, 2005 5:27 PM
To: 'NGood@mtsinai.on.ca'
Subject: RE ER'sandPR's

Hi Nancy,
Could you verify that the antibodies used in our review and reported in the spread sheets are 6F11 for the ER and PgR1294 for the PR.
Thanks,
Dr.Cook

Message

Dr. Donald Cook

From: Good, Nancy [NGood@mtsinai.on.ca]
Sent: Wednesday, October 05, 2005 5:24 PM
To: Dr. Donald Cook
Subject: ER PR antibodies

Hi Dr. Cook,

I checked with our immuno department and the antibodies are the same as what you thought - for ER it is 6F11 (by Vector) and for PR it is PgR 1294 (by Dako).

bye for now,
Nancy

Donald Cook

From: Dr. Donald Cook
Sent: Tuesday, October 04, 2005 5:56 PM
To: 'NGood@mtsinai.on.ca'
Subject: ER's and PR's

Hi Nancy,
I have received your updated list of blocks.We are in the process of sending you another 192 to 198 blocks within the next 2 to 3 days .Some of these are blocks from outside the St.John's region.I will keep you updated.
Many thanks
Dr.Cook

Message

Dr. Donald Cook

From: Mullen, Dr. Brendan [BMullen@mtsinai.on.ca]
Sent: Friday, September 30, 2005 10:54 PM
To: Dr. Donald Cook
Subject: RE: ER's/PR's
Attachments: Results5.xls

Sorry I missed your call today. I was a biotech symposium outside the hospital. We will expedite the cases as much as our capacity permits. I have attached the results for two cases that I was missing the demographics for.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine
Mount Sinai Hospital
600-600 University Avenue
Toronto, ON M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

-----Original Message-----
From: Dr. Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: Friday, September 30, 2005 2:55 PM
To: BMullen@mtsinai.on.ca
Subject: RE:ER's/PR's

Dr.Mullen,
I have received the results the second batch and the note regarding the DCIS's and the block without the tumour.We will be sending up more cases next week.I would appreciate if these cases could be handled as quickly as possible as this story is breaking in the news and patients will be asking questions on their ER and PR status.
Regards,
Dr.Cook

Donald Cook

From: Dr. Donald Cook
Sent: Thursday, September 29, 2005 6:16 PM
To: Dr. Robert Williams
Subject: FW: ER/PR Results

Attachments: Results3.xls; ER-PRCode.doc

Results3.xls (118 KB)

ER-PRCode.doc (24 KB)

-----Original Message-----
From: Mullen, Dr. Brendan [mailto:BMullen@mtsinai.on.ca]
Sent: Wednesday, September 28, 2005 7:18 PM
To: Dr. Donald Cook
Subject: ER/PR Results

One half of the next batch.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine Mount Sinai Hospital 600 University Avenue
Toronto, ON, Canada M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

Dr. Donald Cook

From: Mullen, Dr. Brendan [BMullen@mtsinai.on.ca]
Sent: Wednesday, September 28, 2005 1:19 PM
To: Dr. Donald Cook
Subject: RE: ER's/PR's

The slides are stained on the weekends and I try to read them the following week. I have a second similar sized batch that I will read tomorrow.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, ON, Canada M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

-----Original Message-----
From: Dr. Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: September 28, 2005 11:47 AM
To: BMullen@mtsinai.on.ca
Subject: ER's/PR's

Hi Dr.Mullen,
I received the results of the first batch of ER's and PR's.Could you let me know how quickly we can receive the results of the remaining cases.We would appreciate these results as soon as possible. Thanks for all your help.
Regards
Dr.Cook

Donald Cook

From: Dr. Donald Cook
Sent: Tuesday, September 27, 2005 10:23 AM
To: Dr. Robert Williams
Subject: FW: ER/PR Results

Attachments: Results1.xls; ER-PRCode.doc

Results1.xls (30 KB)

ER-PRCode.doc (24 KB)

-----Original Message-----
From: Mullen, Dr. Brendan [mailto:BMullen@mtsinai.on.ca]
Sent: Monday, September 26, 2005 6:09 PM
To: Dr. Donald Cook
Cc: Good, Nancy; Mendes, Maria
Subject: ER/PR Results

If you have any questions, please do not hesitate to call me.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine Mount Sinai Hospital 600 University Avenue
Toronto, ON, Canada M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

Donald Cook

From: Dr. Donald Cook
Sent: Thursday, September 22, 2005 8:51 AM
To: Dr. Robert Williams
Subject: FW: ER-PR reports

From: Good, Nancy [mailto:NGood@mtsinai.on.ca]
Sent: Wednesday, September 21, 2005 5:13 PM
To: Dr. Donald Cook
Subject: ER-PR reports

Hi Dr. Cook,

I spoke to Dr. Mullen and he will read the slides on the weekend and have reports for you early next week.

bye for now,
Nancy

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Wednesday, September 21, 2005 9:32 AM
To: 'NGood@mtsinai.on.ca'
Subject: ER-PR cases

Hi.Nancy
Could you advise me on the status of the ER and PR slides,and when we can expect some reports.
Regards,
Dr Cook

Message

Dr. Donald Cook

From: Good, Nancy [NGood@mtsinai.on.ca]
Sent: Tuesday, September 13, 2005 4:48 PM
To: Dr. Donald Cook
Subject: ER-PR slides

Hi Dr. Cook,

Here is the list of all the blocks we have received so far. The ones that are highlighted have been stained.

bye for now,
Nancy

Nancy Good, M.L.T.
Medical Laboratory Technologist
Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, Ontario, Canada M5G 1X5

Phone: 416-586-4671
Fax: 416-586-8628

email: ngood@mtsinai.on.ca

? attachment

Dr. Donald Cook

From: Good, Nancy [NGood@mtsinai.on.ca]
Sent: Friday, September 09, 2005 4:54 PM
To: Dr. Donald Cook
Subject: ER-PR staining

Hi Dr. Cook,
I just wanted to let you know that we have started cutting the blocks and staining will begin next week. The machine can handle 48 samples (16 complete cases - ER, PR and negative control) and will be run after hours. We'll keep you posted on the progress.

thanks,
Nancy

Nancy Good, M.L.T.
Medical Laboratory Technologist
Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, Ontario, Canada M5G 1X5

Phone: 416-586-4671
Fax: 416-586-8628

email: ngood@mtsinai.on.ca

Dr. Donald Cook

From: Dr. Donald Cook

Sent: Wednesday, September 07, 2005 3:04 PM

To: 'MMendes@mtsinai.on.ca'

Subject: ER and PR list

Hi Maria
The spread sheets look good.There are a number of names that are not on the list which I presume are still in the unopened envelopes.As mentioned the retro cases will originate from the St Clare's site,these will be cases from May 1997 to August 9,2005.More of these retros will come once we have received them from other hospitals across the province ,we will also be sending more retro cases from the years 1997 and 1998 from the St.Clare's site as these are taking longer to collect.You can proceed the the cutting ,staining and reporting of those cases on the sheets that you have forwarded to me .
Regards,
Dr.Cook

Donald Cook

From: Susan Bonnell
Sent: Friday, August 26, 2005 3:53 PM
To: George Tilley; Dr. Donald Cook; Dr. Robert Williams
Subject: As per your request...

I wish to advise you that we are doing a review of our estrogen and progesterone receptors. I expect to have more information within the next few weeks, and will keep you updated. Please note the following points:

- Further to my memo dated June 13, 2005, I am requesting that you forward all ER negative cases on primary breast lesions, independent of PR status, from May, 1997, to March 31, 2004, to Mr. Barry Dyer at the General Hospital Site.
- From January 1, 2001, ER negative is defined as 10% or less. From May, 1997 to December 31, 2000, ER negative is defined as 30% or less.
- I would ask that you submit the pathology report, original ER and PR slides, including any control, as well as the H & E slide and paraffin block of the tumour. We will forward these ER negative cases to Mount Sinai for retesting.
- All ER's and PR's performed on the Ventana System from April 1, 2004, to August 9, 2005, will also be referred to Mount Sinai for retesting. You can also forward these cases to Mr. Barry Dyer.
- I would like to emphasize at this particular point in time that you concentrate on the 1999 to 2004 years, followed by the 1997 to 1998 years, and then the April 1, 2004, to August 9, 005 year.
- We will return all blocks and slides as soon as possible.

The Laboratory Medicine Program for St. John's Hospitals is currently undergoing a quality review process. Consequently, please note the following changes:

- There is currently a hold on the reporting of Estrogen Receptors and Progesterone Receptors by all pathologists in the Division of Anatomical Pathology.

- All current requests for Estrogen and Progesterone Receptors are being forwarded to Mount Sinai Hospital for immunohistochemical processing, interpretation, and reporting. You may elect to directly refer your Estrogen and Progesterone Receptors to Mount Sinai or to a laboratory of your choice.

- The status of the Ventana System will be determined when we review correlations of the ER and PR results from Mount Sinai and Montreal General Labs. As a precautionary measure, we are awaiting reports from medical and technical consultants before we operationalize the Ventana System.

If you have any questions, please feel free to call me at (709)777-5482.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program

St. John's Hospitals, Eastern Health
Phone: (709)777-5482
Fax: (709)777-5178

Susan Bonnell
Director,
Corporate Communications
Eastern Health
709-777-1426 (1338)

Eastern Health

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Friday, August 19, 2005 11:55 AM
To: 'kevin.watters@muhc.mcgill.ca'
Subject: ER and PR's

Hi Kevin,
I received the slides,however these were stained with the semi-automated system as opposed to the Ventanna automated which we are using in St.John's.We note that there appears to be fairly good correlation with your semi-auto system and our Dako system on these small number of cases.I will get back to you on the phone .
Regards,
Don

Left Voice mail Rem:
Aug 19, 2005.

514-934-1934
ext 43840

Dr. Donald Cook

From: Kevin Watters [kevin.watters@muhc.mcgill.ca]
Sent: Friday, August 19, 2005 10:00 AM
To: Dr. Donald Cook
Subject: Re: ER and PR receptors - Follow-up

Attachments: pic21979.pcx; C.htm

pic21979.pcx (8 KB)

C.htm (2 KB)

Don .....

Did you receive the slides all right ?
Any problems?
Was there an answer to your question?

..... Kevin

---------- Forwarded by Kevin Watters/CUSM/Reg06/SSSS on 08/19/2005 08:26 AM ---------- (Embedded image moved to file: pic21979.pcx) Kevin Watters
07/26/2005 05:54:56 AM

From: Kevin Watters on 07/26/2005 05:54 AM

To: "Dr. Donald Cook" <Donald.Cook@hccsj.nl.ca>
cc:
Subject: Re: ER and PR receptors (Document link: Kevin Watters)

DC .....

Sorry about the delay in responding. I was off yesterday at a family funeral in Ottawa.
I will check this out for you with our Immuno Lab (when they come in!) and get back to you today.

..... AKW

"Dr. Donald Cook" <Donald.Cook@hccsj.nl.ca> on 07/25/2005 11:10:36 AM

To: <kevin.watters@muhc.mcgill.ca>
cc: "Dr. Robert Williams" <Robert.Williams@hccsj.nl.ca>
Subject: ER and PR receptors

(See attached file: C.htm)

Confidentialité : Ce message contient une information privilégiée, confidentielle et ne

For: COOK,DONALD M. DR. From: TERRY J. GULLIVER
Mon Aug 15, 2005 11:46 am Taken by: TERRY J. GULLIVER (777 6373)
Subject: FINAL NUMBERS FOR REPEAT TESTING BY MT. SINAI

FINAL LIST FOR REPEAT ER/P[R BY MT. SINAI

YEAR	NEG/NEG	WEAK POSITIVE	TOTAL
2004	6	0	6
2003	26	17	43
2002	48	30	78
2001	34	35	69
2000	47	28	75
1999	25	29	54
TOTALS	186	141	327

SENT TO: TERRY J. GULLIVER, DR. DONALD M. COOK, BOB DR.(CT) WILLIAMS, BARRY DYER

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Thursday, August 11, 2005 9:39 AM
To: 'kpritzker@mtsinai.on.ca'
Cc: Dr. Robert Williams
Subject: ER AND PR consultations

Hi Ken,
In regards to billing,your suggestion is good,you can bill for active consultation and bill me directly for the services employed in the review of the negative ER's.
I am hoping to send our reviews for the years 2003 and 2002 as soon as we can compile these cases, hopefully by the end of next week . We will submit the other years following these. I will contact Maria when we are ready to send these cases to your lab.
Once again,thanks for all your help,
Don,

Meeting with Minister Aug 15, 2005

Aug 15 2005 10:00 AM

Minister, Dr Laing, Dr Cook, Dr Flemming, George Tilley, ~~Maurice~~ Maria Maurice (ADM)

Carolyn – Communications director

- Public obligation for disclosure
- Need about 2 months for complete information
- Will hold of letter until all information received

Aug 16, 2005 11:45 AM

- Spoke to Maria Mandes about 100 blocks being sent up on Thursday or Friday
- She will get back to me regarding when these can be processed
- results will come out on spread sheet as opposed consultation form.
- I asked her (Mary) to sent down a copy of the spread sheet for review and to run by our executive

Dr Mandes

Aug 16, 2005 12:08 AM

Spoke to Pam King, Jesse about issuing Sinai reports from spread sheet into our HIS and issuing [illegible]

Dr. Donald Cook

From: Pritzker, Dr. Kenneth [kpritzker@mtsinai.on.ca]
Sent: Wednesday, August 10, 2005 4:12 PM
To: Dr. Donald Cook
Cc: Vaccaro, Anna
Subject: ER and PR consultation, immunohistochemistry

Don,

This is to ask your advice about billing for our services.
As I understand it, for usual services, our group bills OHIP which then recovers money from Newfoundland.

You may be very happy with this arrangement, particularly if you never see the $$ or the budget.
However, this arrangement is not specific to pathology services nor was it designed for "look backs" such as the studies to be performed on ER or PR negative tissues.
The alternative is for MSH to bill you directly.

One suggestion is to bill in usual way for active consultations and to bill you directly for the services associated with review of the negatives.

Please advise.
Thanks,

Ken

Kenneth P. H. Pritzker M.D. FRCPC
Pathologist-in-Chief
Director, Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, Canada, M5G 1X5

Phone (1)(416) 586 4453
Fax (1) (416) 586 8589

E-mail: kpritzker@mtsinai.on.ca

For: COOK,DONALD M. DR. From: TERRY J. GULLIVER
Wed Jul 27, 2005 11:18 am Taken by: TERRY J. GULLIVER
Subject: Re: UPDATED STATS THAT INCLUDE 1999

75.6% over 5 year

%%

Sun Jul 24, 2005 12:53 pm From:

REVIEW OF ER/PR STATS FROM 1999-2004/5

	1999	2000	2001	2002	2003	2004/5
TOTAL TESTS	360	370	374	344	373	386
OUT OF TOWN	202	159	150	155	171	189
TOTAL HCCSJ TESTS	158	211	224	189	202	197
NUMBER POSITIVE	96	108	126	95	152	175
%POSITVE	61%	52%	56%	51%	75%	89%
NUMBER WEAK POS.	24	20	47	33	16	2
%WEAK POS.	15%	10%	21%	17%	8%	1%
NUMBER NEGATIVE	38	80	51	61	34	20
%NEGATIVE	24%	38%	23%	32%	17%	10%
TOTAL POSITIVEITY	120	128	173	128	168	177
TOTAL % POSITIVITY	76%	62%	77%	68%	83%	90%
TOTAL % NEGATIVE	24%	38%	23%	32%	17%	10%

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5 YEAR TOTAL TESTS 981
5 YEAR TOTAL POSITIVES 717
5 YEAR TOTAL NEGATIVES 264

5 YEAR AVERAGE POSITIVE 1999-2003 OLD METHODALOGY = 73%

5 YEAR AVERAGE NEGATIVE 1999-2003 OLD METHODOLGY = 27%

%%

SENT TO: DR. DONALD M. COOK, BOB DR.(CT) WILLIAMS, HEATHER E-QI PREDHAM

SENT TO: DR. DONALD M. COOK, HEATHER E-QI PREDHAM, BOB DR.(CT) WILLIAMS

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Total # of pts

Dr. Donald Cook

From: Dr. Donald Cook
Sent: Monday, July 25, 2005 3:11 PM
To: 'kevin.watters@muhc.mcgill.ca'
Cc: Dr. Robert Williams
Subject: ER and PR receptors

Dear Kevin,
Both myself and Terry Gulliver want to talk to you about retesting some of our ER and PR receptors for the 2003 and 2004-5 years.We may want to retest 40 to 50 samples as a rough figure.Can you give me a call at 709-777-5482 as soon as possible.
Regards,
Don Cook

Left a message on phone as well.

Donald Cook

From: Heather Predham
Sent: Monday, July 18, 2005 12:29 PM
To: Dr. Robert Williams
Cc: Denise Dunn; Dr. Donald Cook; Terry Gulliver
Subject: ER/PR receptor letter

Attachments: Update on ERpr.doc

Hi Dr. Williams,

I've heard back form Dr. Cook and Terry Gulliver re: the letter and the changes have been made. Both agree that it should come from you.

I was speaking to Deborah Thomas today and the Department of Health has been notified and is now involved. They would like a letter sent to each woman outlining the problem and the steps we are taking to address it. That draft letter will have to be seen by our lawyer first of course.

I guess we'll have to decide tomorrow or the next day re: advising the public?

Heather

Update on ERpr.doc (28 KB)

Donald Cook

From: Donald Cook
Sent: Friday, January 20, 2006 11:01 AM
To: Robert Williams
Subject: ER\PR cases from St.Anthony

Hi Bob,
This is to let you know that we have received an additional 25 cases from St.Anthony intended for review at Mount Sinai.This time delay is completely unacceptable.I will have to contact Mount Sinai to see if they can handle these cases after I indicated that we sent up all cases,
Don

Donald Cook

From: Mullen, Dr. Brendan [BMullen@mtsinai.on.ca]
Sent: Monday, January 23, 2006 10:53 AM
To: Donald Cook
Subject: RE [redacted]

This was a restain because of absent internal controls. The repeat was stronger so I reported the second stronger in the final spreadsheet.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, ON, Canada M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

-----Original Message-----
From: Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: January 23, 2006 9:09 AM
To: BMullen@mtsinai.on.ca
Subject: [redacted]

Hi Brendan,
Could you recheck [redacted] e spreadsheet I received in early October reported an ER of 5%,the spreadsheet received on Jan 20 reports an ER of 65% on the same Block.
Thanks ,
Don Cook

Donald Cook

From: Mullen, Dr. Brendan [BMullen@mtsinai.on.ca]
Sent: Monday, February 20, 2006 9:55 AM
To: Donald Cook
Subject: [redacted]

Yes to the best of my recollection. The slides were sent to St. John's on January 30th so I am not able to recheck. Hope that helps.

Dr. Brendan Mullen
Department of Pathology and Laboratory Medicine
Mount Sinai Hospital
600 University Avenue
Toronto, ON, Canada M5G 1X5
t:416-586-4553 f:416-586-8589 e:bmullen@mtsinai.on.ca

-----Original Message-----
From: Donald Cook [mailto:Donald.Cook@hccsj.nl.ca]
Sent: February 20, 2006 7:54 AM
To: Mullen, Dr. Brendan
Subject: [redacted]

Brendan,
Our Tumor Board Committee reviewing the ER\PR cases wishes you to reconfirm that the ER result initially reported in Oct 2005 [redacted] is revised to ER -65% on the same block.The committee wants to know if the second result is the one to go by.
Regards,
Don Cook