

Note #1

July 8, 2005

- Met earlier in the day with Dr. Cook and Mr. Gulliver.
- On review of the situation the problem appears not to be confined to a few negatives that have converted to positives in one batch but a larger problem.
- Have been advised that all runs of test had control/controls which should be documented.
- Spoke to Mr. Tilley and advised him of concerns and larger problem and consideration of public rather than case by case follow-up on test results.

Note #2

July 12, 2005

**Attendees: Dr. Cook
Ms. Predham
Mr. Gulliver
Dr. Williams**

- Follow-up on status of I.P. Testing for ER/PR Receptors.
- Prior to 2004 semi-automated/semi-manual (Dako) testing procedure for testing for ER/PR Receptors (complicated procedure to unmask the antigens in the test which include boiling of tissue).
- There was a system of positive controls.
- October 2003. The Laboratory Medicine Program visited Ventana System at the Montreal Jewish Hospital.
- January 2004. Ventana System purchased training commenced late March/early April and new system fully operational here – fully automated (company says ten times more sensitive).
- We have pulled all the cases in September 2001 to review findings and re-test.
- There was an issue of erratic staining in early 2003 and testing pulled for ~~six weeks~~ titration times and staining times were adjusted – tests sent out for six weeks to other labs.
- *For breast tissue samples should be in formalin for 48 to 72 hours controls are in formalin for optimal time.
- I.P. Testing in place since late 1990s before this it was done in biochemistry.
- We can go back and re-test because we have the samples.
- We first alerted when patient was seen in USA and Oncologist there felt patient testing should have been positive for ER/PR. On re-testing here it was.
- Ventana System takes the human factor out of the equation.

Decision

1. Test all samples of living patients.
2. What are our positive rates for infiltrating lobular and ductule cancer.
3. Look at our rate of positivity by year.
4. Check out procedure versus Dako standards.
5. Set up process to inform Oncologists in the Cancer Care Program.
6. Check with Dr. Ejeckam re: process in 2003.
7. Implement recommendations of May 24, 2005 correspondence and identify.

Note #4

July 14, 2005 @ 5:00 p.m.

**Attendees: Dr. Joy McCarthy
Dr. Karen Laing
Dr. Al Felix
Dr. Don Cook
Dr. Paul Gardner
Dr. Alan Kwan
Ms. Heather Predham
Ms. Susan Bonnell
Ms. Thomas
Dr. Bob Williams**

- General background – Dr. Williams.
- Specific overview – Dr. Cook.
 - Issue of results specifically in 2002;
 - Change in 1997 to I.P. Testing – semi-automated.
 - Switched to Ventana late March/early April 2004. Started January/2004 training etc.
- Dr. Laing:
 - New information – Lobular CAs should all be ER/PR positive.
 - At Sloan Kettering went from 75% to 100% positive.
 - Dr. Laing requested re-testing and strongly positive results.
 - As a result asked to re-test some patients.
 - Followed-up on a lot of patients from 2002.
 - 16/25 on re-testing are positive.
 - Doing another 38 patients in process.
 - Farm out testing outside the Province.
- Dr. Cook to get info on who to follow-up.

NOTE #5

July 15, 2005

**Attendees: Terry Gulliver
Dr. Don Cook
Dr. Bob Williams**

- Reviewed meeting of July 14, 2005 re: identifying all patients in getting tests done as soon as possible.
- Plan pull one to two people to start process and assign for Mary to be assigned to cutting and testing only.
- Dr. Cook to contact Pathologists in other centres to get cases submitted.
- Terry advises that each patient slide was processed along side a control slide and the control slides were read and no reporting done until control read as positive.
- Dr. Carter to check with Mount Sinai to see if change in sensitivity over time with testing they used.
- Heather Predham advised Terry Malone of Cancer Registry NCTRF he will have a list of all patients that are currently alive and deceased.
- Dr. Cook to see if Dr. Laing can provide article from Sloan Kettering on research in change of ER/PR Receptor Testing.

NOTE #6

July 19, 2005

**Attendees: Heather Predham
Terry Gulliver
Dan Boone
Don Cook
Bob Williams
Susan Bonnell
Deborah Thomas**

- Background – Dr. Cook, Mr. Gulliver. 650 patients 1997 – 2004 – ER/PR negative.
- Total tests about 380 per year. 32 of 2003 reviewed 24 are positive.
- 2002 – results.
- 2003 – [???].
- 2001 – May.

July 20, 2005

**Attendees: Mr. T
Dr. W
Mr. Gulliver
Dr. Cook
Ms. Predham
Ms. Thomas**

- Data from 2000 to 2004/2005 reviewed.
- Cut off rate decreased from 30% to 10% 1997 to 2002/2003.
- Many factors go into treatment other than ER/PR- e.g. metastasis, size of lesion, etc.
- Now introducing issue of Herceptin.
- No national standards on ER/PR Receptors. Mount Sinai – 75%; Pathology text – 52 – 85%.
- Our organization gave reports as they were not just negative or positive.
- Technical Consultant from Mount Sinai coming in on September 12, 2005.
- No issues brought up at Tumour Board rounds.

Note #7

July 21, 2005 at 10:30 a.m.

**Attendees: Dr. Bev Carter
Dr. Don Cook
Dr. Bob Williams**

- In past didn't seem to be a clear picture.
- Sentinal case – reviewed old slides; program would not always run a control.
- Clear test didn't work.
- Dr. Carter feels there was a problem in 2002.
- Some runs on retrospect were not normal.
- Inconsistency from one batch to another.
- Current Ventana test is picking up too much. Have sent out a _____ results and sent to Mount Sinai.
- Dr. Carter also doing some work on quality control and use them as controls.
- Important for Dr. Carter to have all reports for ER/PR for each year.
- Techs may need to be retrained in immunoperoxidase and need controlled access to the room.
- Training of Techs in immunohistochemistry.
- Need separate service, need Q.A. and proficiency testing.
- Need to have an external consultant to come to the lab and do Q.A.

Note #8

July 21, 2005 at 3:30 p.m.

**Attendees: Mr. Gulliver
Dr. Cook
Dr. Williams**

1. Agree to get Dr. Carter information she needs.
2. Dr. Carter to do only this service.
3. Mary Butler to report and take direction from Dr. Carter.
4. Judy Quinlan to report to Dr. Carter.
5. Will arrange someone from Q.A. to be assigned.
6. We have proficiency testing in micro, hematology and biochemistry. Need to have proficiency testing and Q.A. Program for immunopathology.
7. Immunohistochemistry in separate space while awaiting final space.
8. Dedicated techs to immunohistochemistry don't have enough work for three Techs, but need three people for holidays, sick leave, etc.
9. When Barry Dyer and Dr. Ejeckam return they will work with Dr. Cook and Mr. Gulliver to develop Q.A. and proficiency testing program.

Note #9

July 24, 2005

ER/PR Receptors

Attendees: Mr. George Tilley
 Dr. Paul Gardener
 Dr. Karen Laing
 Dr. Don Cook
 Mr. T. Gulliver
 Ms. Susan Bonnell
 Dr. Alan Kwan
 Ms. Heather Predham
 Ms. Deborah Thomas
 Mr. Dan Boone
 [Dr. Bob Williams]

- Update on current status and what we know from other centres.
- Testing patients for 2002. 16/24; 25/32; 22 or 23 to come.
- There may be a problem with methodology or with the lab.
- Dr. Laing not worried about weekly positives.
- Dr. Laing wants to be sure new system is accurate and not overly sensitive.
- Working with Mount Sinai on quality control.
- Should we not test the repeats against the Ventana System.
- Dr. Laing need database to capture different kinds of breast cancers with ER/PR results.
- Need to wait until we know that our results are valid.
- Controls are run every day on ER/PR.
- Pathologist reporting is an issue.
- Dr. Kwan will need more info. He feels happier at this meeting that a large percentage due to technological change. Duplicate positive conversions before we report. Get data base of patients re: our testing.
- Need to check new Ventana System out.
- Take out some of our conversions and send to Montreal General to confirm our results.
- Need more information – systematic information.

Note #10

July 27, 2005 - Conference Call – 5:00 p.m.

Attendees: Dr. Don Cook
 Mr. Terry Gulliver
 Mr. Dan Boone
 Ms. Deborah Thomas
 Ms. Susan Bonnell
 Ms. Heather Predham
 Dr. Karen Laing (by phone)
 Dr. Joy McCarthy (by phone)
 Dr. Alan Kwan
 Mr. George Tilley (his name was crossed out)
 Dr. Paul Gardener
 [Dr. Bob Williams]

- Overview of our data – average 73%.
- Dr. Cook gave results of discussion with Dr. Walters in Montreal.
 - They will stain but send back here for interpretation.
 - Halifax. No info on tests of ER/PR.
 - Sloan Kettering – No information.
 - Mayo Clinic – Don't know their rates; No goal standard; Worried re: this issue.

Decision

- Share new information as soon as possible when it becomes available.
- Meet on a regular basis.

Note #11

August 1, 2005

- Dr. Cook:
 - 11 cases sent to Mount Sinai – negative and variable positives.
 - Some areas of disagreement.
 - One case 10% positive came back negative.
 - Some minor variations.
- Dr. McCarthy:
 - Positive is positive.
 - Some disagreements with the PR's.
 - As long as one ER or PR is positive this is okay.
- Dr. Cook:
 - Now have 11 cases we can use as controls.
 - Will do future correlation with Mount Sinai for next two or three months. Mount Sinai is accredited by AAP and participates in outside review.
- Dr. McCarthy. Very comfortable with future plan and Mount Sinai.
- Dr. Carter:
 - There has been known variability in the results over the years.
 - Tumour Board discussion. Talked about issue which has been found.
 - The memory of this case back when a patient was lobular CA tested negative.
 - June – November 2002. Follow-up that year and no positive reports.
 - 16/25 conversions have been reported.
 - 1. Dr. Kwan notified.
 - 1. Dr. Boone notified.
 - 10 have been notified by NCTR.
 - 4 already on appropriate treatment.
- Consensus:
 - Test and re-confirm 10 cases which tested positive.
 - Develop a process to identify negative testing patients and re-test as soon as possible.
 - Oncologist to notify Dr. Carter of urgent cases.

Note #12

August 2, 2005

Key Points

1. Mount Sinai to do all new cases – all reports to go to St. Clare's. We will do all the new cases. We will correlate our results with Mount Sinai to correlate technical capability and Pathologists capability.
2. Waiting for Ventana Technical Expert for Canada to phone back Terry Gulliver to arrange an early site visit.
3. Heather Predham to start Q.I. Review processing the a.m.
4. 2002 – All retested – recently 16 conversions out of 25 to be retested.
2004 – January/February/March – all done (six).
2003 – 1/3 – 1/2 done.

First Batch: 1. 16/25 – 2 handled by surgeons; 4 already treated; 10 were told they had converted. We are testing these now.

2. 25/32.

3. Three batched stained.

Note #13

August 3, 2005

Notes on PR/ER Issues:

- Met with Dr. Don Cook and Ms. Heather Predham x 2.
- Q.I. follow-up and interviews were held with Techs involved in the immunohistochemistry in the a.m.
- Heather Predham gave me a debriefing on the issue and the lack of communication between Techs and Pathologists.
- Heather Predham gave Dr. Cook and General Site Chief Dr. Dan Fontaine a briefing on her interview in the p.m.
- Met with Dr. Cook afterwards and discussed issue and need for Techs to have a Pathologist who they can go to for advice and communication.
- Dr. Cook and I will follow-up with Mr. Gulliver and on broad and specific communication issues identified.
- Dr. Cook waiting to hear back from Mount Sinai re: completing all negative ER/PR testing on a very expeditious basis.

Note #14

August 5, 2005

**Attendees: Dr. Karen Laing
Ms. Pat Pilgrim
Ms. Heather Predham
Dr. Paul Gardener
Dr. Don Cook
Dr. Bob Williams**

- All patients seen in the clinic since April 2003 that are negative are being retested (Patients with Metastatic Disease and with Lobular Cancer).
- All negatives at 10% or less since March 31, 2003 to be retested, plus infiltrating lobular and tubular breast cancers.
- Heather Predham will identify all patients and blocks will be pulled to send out.
- Having consultants coming in mid-September to review system.
- All tests – new and re-testing to Mount Sinai – blocks being pulled.
- 10 – 11 patients who have converted have been told.
- Dr. Laing said re-test on line patients – can confirm with Cancer Registry.
- People's reaction has been good to date.
- They have been told there was a problem with the testing and we don't know why yet.

Note #15

August 8, 2005

**Attendees: Dr. Cook
Dr. Williams
Mr. Gulliver**

- All cases for 1999 onwards.
- Cases with negative ER will be sent out.
- Working to get cases from 1997 to 1999.
- Also will re-check all Ventana reports.
- Dr. Cook will speak to Dr. Laing re: how cases were treated based upon degree of positivity.
- Check lists to see who is alive.
- All blocks will be pulled and then Dr. Cook and Dr. Fontaine will review blocks and then send in one big package.
- Will be next week before blocks sent off.
- Three to four weeks for re-testing.
- Dr. Cook stressed the need to plan carefully make sure sent from one site and sent in bulk.
- All future cases to be sent to Mount Sinai slides will be cut for ourselves and will do our own testing here.
- May be 1 ½ to 2 months to get all the reports done.
- Ask Mr. Gulliver to get out the trends for positive and negative reports over the years.
- 88 negative 2002; 20 not evaluate; 40 conversions of 68 (some of these 40 patients were reported as varying degrees of positivity/weakly).

Note #16

No date

- Dr. Cook and myself talked with Dr. Laing.
 - Prior to 2000 – ER/PR negative post menopausal women got Tamoxifen anyway. This practice changed in 2002.
 - Of women who test positive most are ER positive and PR positive. Less are ER positive and PR negative.
 - 5 – 10% are ER negative plus PR positive (it was felt this number is now less than 5 – 10%).
- Spoke with Mr. Tilley and Ms. Predham.
- Will arrange briefing session on Wednesday, a.m.
- Sent out 11 cases to Mount Sinai. Received July 29 from Mount Sinai – 3/11 converted one of which was treated as positive.
- First list June 29, 2004:
 - 16/25 converted on Ventana;
 - 10/16 were told;
 - of the six remaining some dead and some already treated.
- Second list July 18, 2005:
 - 25/32 Oncologists wishes to have repeats from Mount Sinai.

Note #17

August 10, 2005

Meeting on ER/PR Receptors

**Attendees: Dr. Laing
Mr. Tilley
Ms. Pilgrim
Dr. Cook
Dr. Williams**

- Dr. Cook's update:
 - Referred to his memos putting hold on all ER/PR testing.
 - A batch of cases who need ER/PR testing have been sent to Mount Sinai for re-testing.
 - Master list being compiled to send blocks to Mount Sinai. Need to ensure which paraffin blocks contain the tumour. Then compare Mount Sinai Dako to our Dako.
 - Two weeks to get blocks to Mount Sinai.
 - Four to six weeks for Mount Sinai to report these specimens.
 - All available resources are being applied (still doing a heavy workload ongoing).
 - Three distinct groups: new cases; urgent cases pulled out; previous cases to a current date.
- Heather Predham's update:
 - Combining Cancer Registry with lab data (4300 in lab data).
 - 1200 in Cancer Registry only.
 - Has a list of all people who need to be retested.
 - First page shows people who are on Tamoxifen.
- Dr. Laing's update:
 - All people who are ER negative need to be retested.
 - Treatment has varied a lot over the years.
 - ER positive and PR negative cases may be suitable for aromatase inhibitors.
 - Need to know what their true ER/PR status is.
 - All patients will need an individual reassessment.
 - Find out who is alive and who is dead.
 - Dr. Laing has a problem with sending out letters until we know how much of a problem we have.
- Mr. Tilley:
 - Advised of status of meetings with the Government and need to get out a letter.
- Dr. Laing:

- Feels this happened over eight years. Should be approached in a systematic way.
 - We can't fix overnight.
 - She doesn't feel we are trying to cover things up.
 - What is appropriate for patient care, testing of ER negative patients and when results come back then tell patients individually and not create panic in patients at this point in time. Can't tell them.
 - It is too soon to tell the patients.
 - Dr. Laing not worried about is doing the right thing given our current knowledge. She feels sending out information now until we can give them the answers.
 - Leave clinical management to Oncologists.
 - Dr. Laing feels we are creating unnecessary anxiety to a lot of patients. Need the information on hand before we go to these women.
 - Need to strike a balance between waiting and giving good information we are giving now and causing anxiety unduly.
- Dr. Cook:
 - There were deficiencies in our system making communication, proficiency tests, and quality assurance. Need Q.I. program for the lab.
 - Test all ER negative less than 30% about 400 cases to be tested.
1. Mr. Tilley requested that we not wait until we get all one batch. Can we make three to four large batches.
 2. What are key messages we should be saying.
 3. Decide on how we will address deceased people in terms of testing.

Note #18

August 12, 2005

Note to File

ER/PR Receptors

1. Spoke with Barry Dyer. All blocks should be pulled by Sunday and the Pathologist can review on Monday to assess which blocks have tumour samples to send to Mount Sinai. Dr. Cook/Dr. Fontaine will process.
2. Meeting Minister of Health and Community Services on Monday with Mr. Tilley, Dr. Laing and Dr. Cook.
3. Seven cases sent to Montreal all been assessed.
 - 5/7 were negative here.
 - 2/7 were weekly positive here.
 - All seven cases were assessed by Montreal's Ventana System and gave similar results to our Dako.
 - Our Ventana System called three of the seven positive but this not confirmed by Montreal's Ventana.
 - It is only seven cases but in the case that our Dako results were compared to Montreal's Ventana (there were all 2002 cases).
4. This week has been productive. We should know if we have a major problem once slides we will send out next week are reviewed at Mount Sinai.
5. Dr. Laing advises that ten patients were told to date re results.

Note #19

August 15, 2005

ER/PR Receptor Issues

**Attendees: Minister
Dr. Fleming
Ms. Hennessey
Mr. Tilley
Dr. Cook
Dr. Laing
Dr. Williams**

- Background
- Issue of writing 400 patients who were testing negative. Also reviewed that we would get Mount Sinai to re-test these samples.
- There are issues in regards to test standardization.
- Mount Sinai needs six to eight weeks to test, given this issues arose when consulted with Dr. Laing and her colleagues – consensus re: concerns with what to say at this time.
- Dr. Laing gave overview of ER/PR testing, how things work in 2005 and how it has changed over the years. On re-testing, a certain percentage will convert, how it impacts on therapy is an individual patient issue.
- Dr. Laing says first samples for re-testing biased and also retested on Ventana System therefore our problem, although undefined at present, may not be as bad as thought. Can't really have a value discussion until information available. Will notify everyone who is retested. Doesn't feel now is the time to write the letter. Better to wait until we have more information.
- Minister – if people advised as soon as possible then patients can do what he/she wishes to deal with the issues.
- Dr. Cook – there is a problem with immunoperoxidase testing.
- Dr. Laing advised that Dr. McCarthy, Dr. Ganguly agree with waiting to send something out until we have more information.
- Minister – will accept best advice for now. Wishes to meet again within the next two weeks.
- Will develop what should go in a letter in the meantime.

Note #20

August 17, 2005

**Attendees: Mr. Terry Gulliver
Dr. Bob Williams**

- All blocks pulled and reviewed at General site by Dr. Dan Fontaine. Now waiting to send off for 1999 to first three months of 2004.
- All blocks given to Dr. Cook yesterday for St. Clare's and Grace site. 1999 to first three months of 2004.
- Dr. Cook has contacted Mount Sinai and advised that the blocks will be sent this week. They will do as soon as possible.
- Dr. Cook says 2002, 2003, 2004 should be ready to go today.
- Note that Montreal's Ventana testing was done on semi-automated system and compares very very closely to our Dako results in the same seven patients. The reports provide excellent correlation of the Dako and Ventana semi-automated systems, Mr. Tilley and Dr. Fleming advise.

Note #21

August 18, 2005

- Advised by Terry Gulliver the 115 2002, 2003, 2004 ER/PR sent yesterday. 120-130 1999, 2000, 2001 should be sent today.

Note #22

August 23, 2005

Attendees: Mr. Terry Gulliver – phone discussion

- 1997 onwards to 2004 – Carbonear 14 cases; Gander 64 cases.
- These will be sent off today or tomorrow.
- Haven't heard from Corner Brook.
- Had 2002 from Grand Falls and they were sent off.
- Will ask Dr. Don Cook to follow-up with Grand Falls and Corner Brook.

Note #23

August 24, 2005

**Attendees: Mr. Terry Gulliver
Dr. Don Cook
Dr. Bob Williams**

- In addition to Dr. Cook's memo of August 24, 2005 we will adjust our Ventana System based on our new controls. When this is done we will re-test on the adjusted Ventana System same time we will send all samples to Mount Sinai for re-testing. We will then have one year of testing on our adjusted Ventana System to compare the results from Mount Sinai for 2004 – 2005.
- Dr. Cook will be sending out a number of memos in this and other issues.
- Blocks for 2004 – 2005 being pulled, hope to start in house testing on all specimens then pack blocks to send to Mount Sinai so that they will be processed as soon as current workload there completed.

August 26, 2005

- Met with Mr. Gulliver and Mr. Dyer.
- A lot of work and efforts gone into ER and PR controls for Ventana System.
- Dr. Cook reviews to confirm results.
- Testing to be done as soon as controls verified.

Note #24

October 3, 2005

(Note in corner of document: How to reports. Send letter to everyone. Medical Director of Cancer Clinic)

1. Overview of Decision;
2. Results to Date;
3. Status of future results;
4. Long term;
5. Individual information; public information; living/dead

Attendees: Dr. Kwan
Dr. Felix
Dr. Hunt
Dr. Laing
Mr. Tilley
Dr. Cook
Ms. Bonnell
Ms. Predham
Ms. Parsons
Ms. Pilgrim
Dr. Williams

- Regional Lab Directors to get the reports.
- Dead individuals follow-up when all living done.

Decision

1. Issue Addendum here to include previous reports.
 - Dr. Cook to follow-up with Regional Lab Directors.
2. Cancer Clinic draft letter to physicians. Dr. Pilgrim and Dr. Laing.
3. Set up clearing house for information and patient contact. Counselling available. Heather Predham and Chris Parsons.

Note #25

October 4, 2005

This refers to a conference call with other regional boards.

**Central: Dave Diamond
Dr. Larry Alteen
Stephanie Power**

**Western: Dr. Ken Jenkins
Susan (illegible)
Heidi Stoben-Simmons**

Labrador: Dr. Michael Jong

Carbonear: Dr. Gary Baker

**St. John's: George Tilley
Susan Bonnell**

Health Board's Association: Jeannie House

**General Site: Nancy Parsons
Heather Predham
Pat Pilgrim
Dr. Don Cook
Dr. Bob Williams**

- Full overview of background – RW
- Specific issues review – DC
- Questions of whether we should notify all patients who are being retested.

Note #26

October 17, 2006

**Attendees: Dr. Kara Laing
Nancy Parsons
Heather Predham
Chris Power
Susan Bonnell
Pat Pilgrim
Don Cook
Bob Williams**

1. Do information for the public – Susan.
2. Letter to patients – Heather.
3. Notify patients with results back a negative.
4. Chris Power – to get listing of all patients notified.

Note #27

October 18, 2006

**Attendees: Dr. Karen Laing
George Tilley
Heather Predham
Susan Bonnell
Don Cook
Bob Williams
Pat Pilgrim**

1. Dr. Laing – minutes of meeting of panel meetings are fine. Only a few suggestions to format.
2. Review media releases and patient letter and suggestions made.
3. (a) Suggestions is that we would call all people to be retested.
(b) Call all patients who have not converted. Converters will be dealt with by the physicians.

Decision

1. Get out information to media in print.
2. Phone patients who are retested.
3. Phone patients who have been retested and are not converters.
4. Patient panelled by Tumour Board to be contacted by physician.
5. Western and Central to phone their patients.

Note #27

[THIS IS RELATED TO AN INDIVIDUAL PATIENT AND FAMILY AND I WOULD NOT WISH THAT THEY BE DISCLOSED WITHOUT THE PERMISSION OF THE PATIENT. - Dr. Williams]

October 17, 2005 @ 4:00 p.m.

- Received call from Dr. Joy McCarthy and asked her to phone [REDACTED] at [REDACTED] re: ER/PR receptor issue. Returned call at 4:50 p.m.

October 4, 2005

**Attendees: Dr. Williams
Dr. Zulfiquor**

- ER/PR – on Tamoxifen.
- Re sister [REDACTED] – diagnosed 2000/2001 – Dr. [REDACTED] Died December 2003.

Note #28

[THIS IS RELATED TO AN INDIVIDUAL PATIENT AND FAMILY AND I WOULD NOT WISH THAT THEY BE DISCLOSED WITHOUT THE PERMISSION OF THE PATIENT. - Dr. Williams]

August 25th

- Ms. Pilgrim, Dr. Zulfiquor and Dr. Williams met with [REDACTED] re her ER/PR results for 2004 and her sister [REDACTED] results of 2001. Ms. [REDACTED] ER/PR results were positive and her sister's were negative. She requested hers and her sister's results both be retested. We advised her we would arrange for this to be done. Dr. Zulfiquor explained the background of ER/PR and its relevance to her and her sister.

September 1st

- Spoke to [REDACTED] re the fact that specimen sent to Mount Sinai and should get/hope to get results in a few weeks time. She was satisfied with progress and contact.

September 27, 2005

- Advised Ms. [REDACTED] re her test results after ensuring Dr. Zulfiquor had results.
- No change in results.

September 30, 2005

- Disclosed results of death of [REDACTED] to Ms. [REDACTED] and her niece. Ms. Predham and Pat Pilgrim present.

Note #29

Meeting with Ventana representative. It probably occurred on August 4 or August 5, 2005 but there is no date on the document, but it was attached in Ventana representative's report.

- All instruments retested
 - All within specs
 - Everything working as it should
- ER/PR protocols – same as in other labs across the country.
- 1. Trying two different protocols using our controls.
- 2. Doing validation of instruments.
- Results of one and two today.
- Went over with the Techs the maintenance of instruments. Done monthly and quarterly.
- Did one instrument yesterday and the second today.
- Instruments were giving good results.
- Assessment of four staff
 - They are within the competencies of other Techs throughout the country.
 - Knowledge and training adequate without any...(illegible) any problems.

Benefits (I presume that is of the Ventana System, automated system)

- Consistencies.
- Reproducibility.
- Remove a lot of human steps and the possible human error.
- In semi-automated system there are a lot of variability's and problems that can be removed (even temperature and humidity can _____).
- Stains are crisper and more intense.
- Antibody clone could be an issue (PR).
- At the end of the line the Pathologist has to make the call.