Ventana system

Date

October 2003

Jewish General - one of the 1st in Canada

January 2004

Purchased - staff trained

March 2004 / April 2004 fully

opted for Ventana Dako
Ventana Dako

Ventana system

- print barcoded label
- everything is barcoded correlated - 10 slides
- totally automated
- heats slide underneath 10x greater sensitivity

went back - pulled all cases October 2001 - recut and retested.

- as well as particular

Page

Is policy manual

They followed the manual
Terry has looked this up

① Datko's recommendations
- compared to what we did

② Data's of those that are different
- Pattern for rate
year to year
- rate of tve-ty by year.

③ Individual lab tve rate c̄ Datko testing
Lab
- depending on diagnosis
rates for infiltrating lobular and ductal ca are tve.

Lab
④ Test all samples for living patients

⑤ Need a mechanism to inform oncologists in Ca Clinic program

⑥ ✓ c̄ Dr Ejeckam
- memo

Dr a
Dec. Terry
Re.

Date

June 19, 2003 Memo

Dr Eyeckmans spoke ē Terry and Bunny

- a senior tech left in April

- isn't enough work to have 3 people dedicated to immuno stains

#3
- before the memo they were doing routine work as well.
- volumes have been going up.

- after memo they were limited to gross stains and OSNS +ve.

Senior tech left in April.
- senior tech came over from St. Clare's for 6 weeks to be orientated

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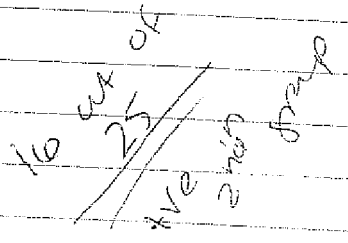
- Proficiency testing in pathology
- Can we be 100% sure that the Ventana works
- no.

PD = infiltrating lobular carcinoma
very unusual to be -ve
Oncologist

50-80% should be +ve
2002 - 30% +ve

* Sunnybrook is 75% +ve

May 1997
- 90% the Dako system
-



Date

① Identify the affected people
- assign resources to them
- find all the breast cases for a year
- testing of all -ve
- testing of live pts

② Meet ē surgeons and oncologists

③ Tell the public.
- 2-300 people.

④ Assess current testing
- cross-referencing ē another lab

⑤ Assess our standards and quality of service

external consultant to be brought in.

Radio Noon
- interview
- interview

(*) - News Release.

Meeting.
Paul Gardiner
Alan Kinsella
Al Felix
Kara Lavers
Jay McCarthy
Susan Burnell
Deborah Thomas
Dr Williams
Dee

* 1997 - March 2004.

They just released where lobular cancer and got 100%

to confirm that it would be

Published in Pathology journal

Date

40-50 +ve

-ve but were now strongly +ve

fecal fluid - there was a problem with the system but it was fixed

- Met on May 17th → Dr. McCready Kane Library

- Took 25 patients next from 2002. Breast Ca - who were

- he cut of 25. in the process of going through 33 more - sampling 2002 (2001/2002)

(1) About at least 12.

- premenopausal -

post menopausal

metastatic → got chemo 3yrs vs hormonal therapy

became metastatic →

Page

Treatment would have been very different

*** Controls are ~~being~~ what supposed to be done every day - and documented. - were they done.

(Controls on a separate slide vs. the ~~re~~

Who is responsible for the patient?
- oncologist
- surgeons.

If they shll have

Date

Pkup
- Hallway
- Results

Guideline to how we deal
w the treatment

to Kara Lacey
Jay McCarthy

Pharm at

*** June 13 → send them in and
get them retested.

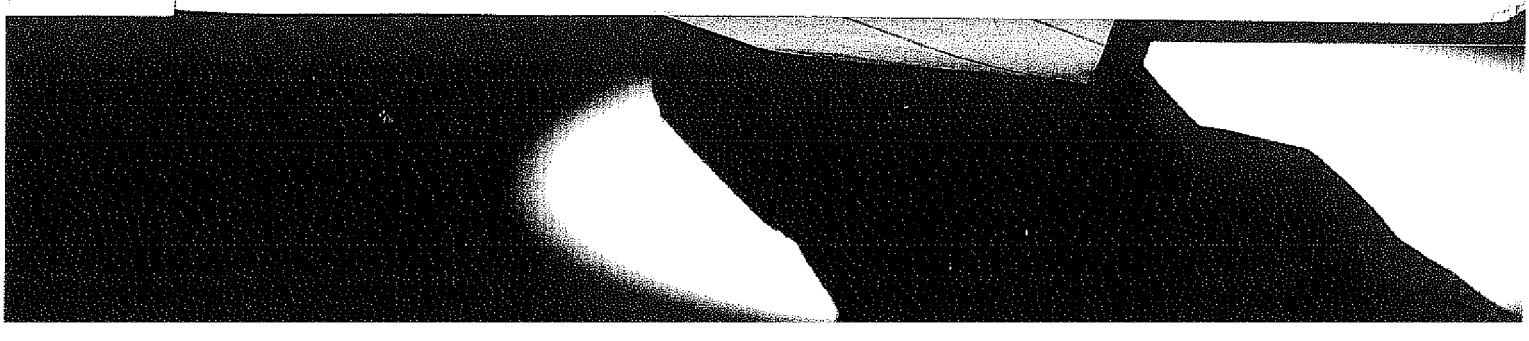
Reasons:
- SW
Nursing → PPL

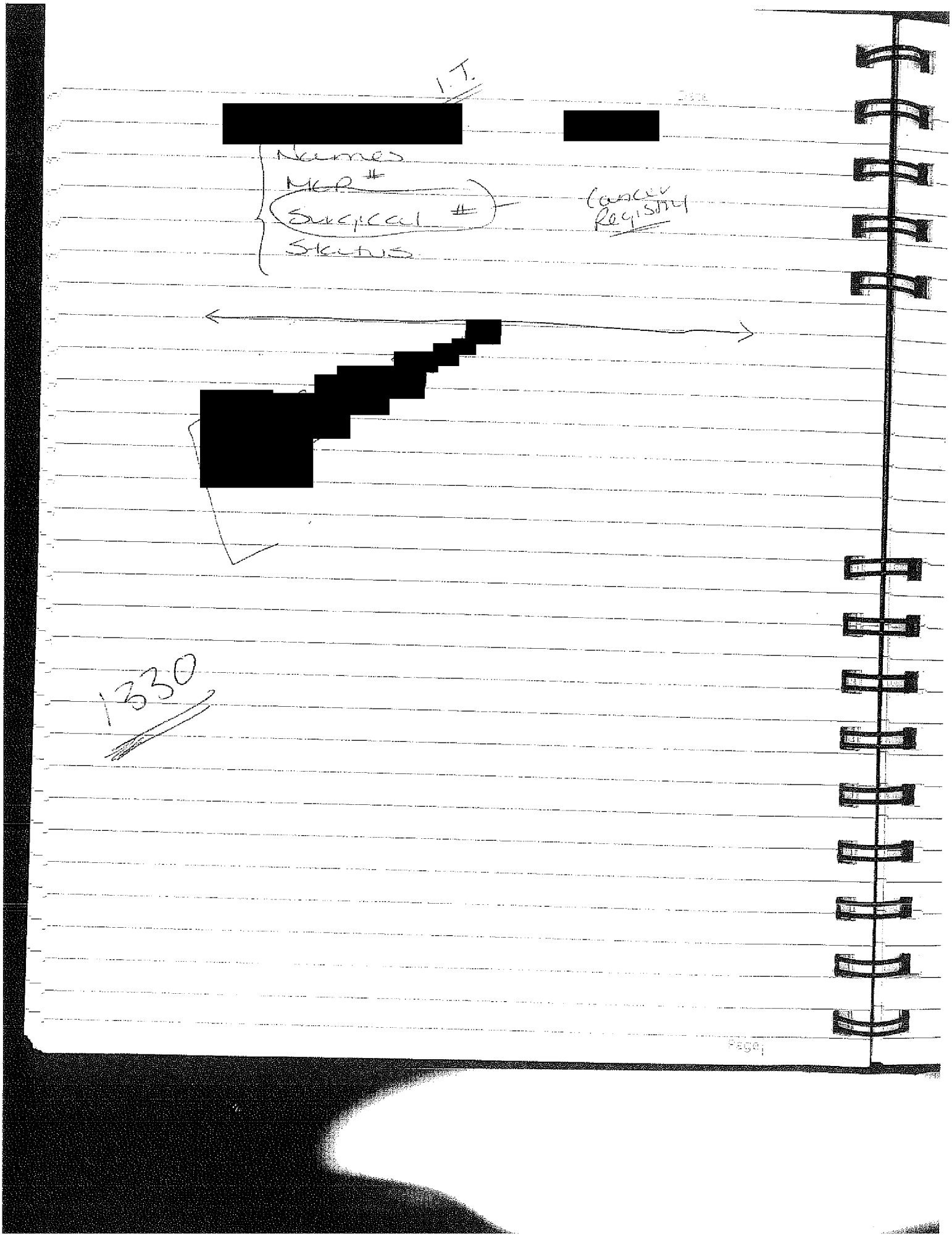
[redacted]

[redacted]

Cancer Registry
1997 -
List of live pts.

Page




I.T.
[redacted]
[redacted]
Names
MCP #
Surgical #
Status
Cancer Registry
[redacted]
1330

Date

① Dan - identify nine patients.
1½ kms.
Terry will find out what we timelines.

② Dan to fax colleagues re: why they have

3 Contacts were done every day and documents

4 Dan look
- was there a change in sensitivity that affect results.
- are our findings consistent with their findings.
* changes over time

QSL 5 HOT Line coordinator

6. Media Release. (Susan)

7. ~~me~~ HROC & other sites.

Page

July 20

Dr Williams
- Sunday afternoon
* - Dunn - media release.
*

Q1 - notifying patients
-

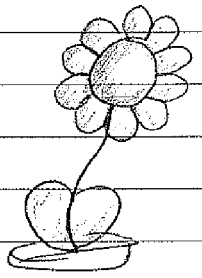
If there is a problem i
what we did

by making an exposure
will we create a
- can't expect HIROC
to pay for it.

- Someone else
is going all

Date

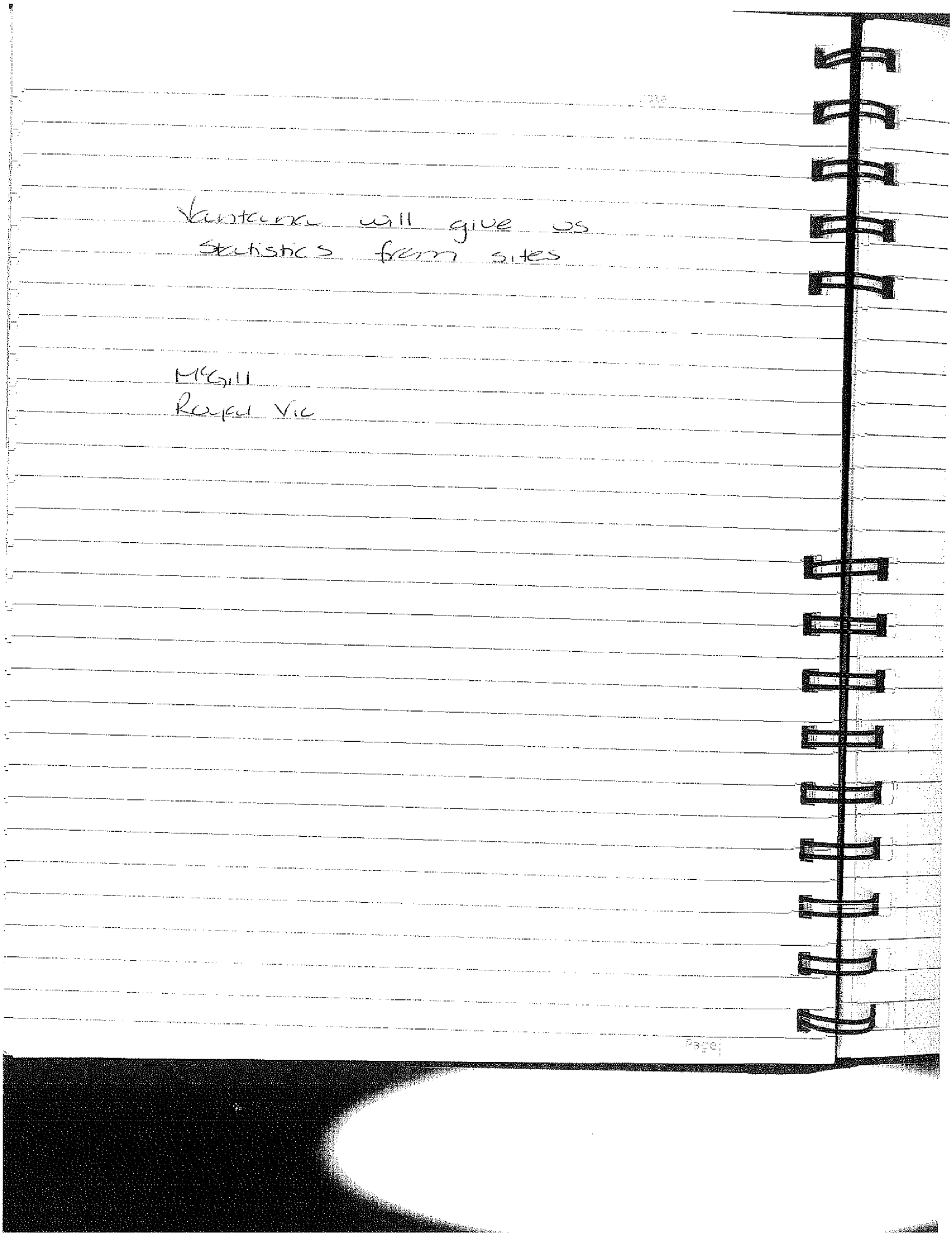
2:30 Dr Williams
-Dan.



[redacted]

Kara Laing.
@ 9 am.

Page


Kantarex will give us
statistics from sites

McGill
Royal Vic

Date

Susan B
Kara Lains.
Dr W
George T.
Don C.
Alan K.
Paul Gardiner
Terry Gulliver
Debrata Thomas
Me
Dan.

- Different kits are defining +vity differently
  Bridge (U.S) 1%

	2000	2001	2002	2003	Ventana
US	62%	77	68	83	90

- Mt Sinai 68-80 (Bev Carter)
  75 average

- Bev Carter
  - reviewing all -ve's.
  - 41 out of 57
  remaining 21 or 23 done next week.

- High conversion rate is the issue
- There seems to be acceptability with the level of tivity with the ckl system

Oncologists have been treating above 10% as positive.
- all those that they have pulled already have been on tamoxifen

200 cases have been sent to Mt. Sinai to confirm results

- How much of the true negative are converting to +ve

Date

- Sian Kerkins lab
25c - consider lobular is 100%
+ve
- Pauper

* feedback from Mt Sinai before we tell anyone else.

	Previous		current	
ductal/lobular	ER	PR	ER	PR.

pooling differentiated HER2
- now it's telling us that they are ER/PR +ve.

They are now saying ER -ve PR +ve

Page

Date

1. Add more centers
   - rate
   - conversion rate

2. Is this an elusive problem?
   - have others dealt with it
   - Or have they ignored it?

3. Accuracy of the new test.

Page

Date

① Send samples at of 2002
-ve that have converted
-using Ventana

② Info from Ventana

③ # converted from 2002
from current year
(-ve : +ve)
banded.

} c Ventana

Page

(1)

Capital Health
~~Community~~ Health Lab Services

(2)
Joy Howell
Mgr, Lab

ER/PR done - have Ventana since 2000

Dako prior to 2000

Do not look at positivity rates
Do not audit
Do not retest

They do current testing
- when they bring in new equipment they run them side/side few weeks to see if issues

Date

(2) Calgary Lab Services
Tracy Lenek
Mgr

ER/PR done
currently Ventana for
3 yrs
- used Biogenix Optimax

Pathologists look at tricky
route
- does not know of
any issues but if
there were she would
have

- they do not go back
and retest

- when new one came
on they retested - but
no issues

(Pathologist on A/c until Aug 8th)

(3)

Capital Health
Edmonton
Dept Lab Med (Pathology)
Cross Cancer Institute
(all Alberta)

Interviewed Mr. Laith Dabbagah

Cancer Research Uses ER - Ventana
PR - Dako

(more cost effective)
resulting is the same

1995

- eyeball tivity rates.
- bar read

before 1995 - manually.

Retesting
- they did have a pt that came back
- "fairly common i the type of cancer that the have changes"

Page 1

Date

Benchmark XT
- very sensitive
- very controlled
} much higher so you can get more positivity rate.

CPT
- had ↑ positives - so they went back and did retesting - through review.

- McGill - Unive.
- London lab Scr
  Cathy Crutenley.
- Vancover Hesp
- Kingston
- Regina
  Dr Alpert
- HSC Winnepeg
  Mgr felt that talk to pathologist (new)

Dr W Susan Me
Dr K Deborah
Dr C Dawn
Dr G Terry

- review of data from '99
- to 2004
  - 73% average.

Since Sunday
- Montreal General
- will stain cases.
  - turnaround should be quick if they only stain the slides (2 - 2½ wks)
- Montreal doesn't monitor their results or concordance

Halifax
- no info

Sloan - Kettering
no info on twenty rates

Date

Mayo
- Director [illegible]
- Mayo in the process of reviewing and they have no info on tretry or conversion rates.
Dako building
Considering Dako automated system.
Warned as they don't have a good handle on this.

- Various labs use different methodologies, use different titrations etc. (sleeping giant!).

What's next
① re: slides testing.
② Mt. Sinai

St. Jerome / Halifax / Moncton
- no idea re tretry vs conversion
- are getting better turnaround rates.

Page

Jan - to end of July
84% +ve) no weak
16% -ve) +ves

As soon as we get new
info we'll meet again.

2005

(8) Avalon) sending in
unknown # Grand Falls) samples

[redacted]

Date Aug 2, 2005

Dr W.
Dr C.
Terry
Me.

Dr W. spoke to Dr. [redacted] Kwan
- do critical pts first
- get Ventavis asap.
-
- technical expert will be bringing company controls
- reviewing all p/p
- releasing blocks back from Mt Sinai

- get [illegible] circles

Date

Chart Review
ER/PR

1. Maintenance - done since Venetoclax

2. who will provide data?
For the annual
- documentation

NCLS guidelines

Page

ER/PR

- 20 pts 73/327
- Pathologist knew about a conversion in 2000

73 → 99 - 2000 - 2001

Tamoxifen
- Lit review.
- efficacy
} 5 yrs

Andre Picard article
→

Sue/Judy

Plan - letters to oncologist/surgeon
- public notice.

EFIPP

142 results out of 327
35 conversions

- 7-8% tests have changed
Mainly
04 tests excl

- St. Anthony
- Grand Falls
- Gander
- Carbonear

have sent in blocks
- will be sent in

Results to date
327 (HCCSS)
142 { 35 - conversion (25%)

22% soft conversions

Date

We sent off all EP -ve

* 1997 - 1999
- those were pre-menopausal
& they wouldn't have
gotten Tamoxifen at that
time - wasn't part of
the protocol at the time

1 hr weights

(1) Determine the actual
Surgeon / oncologist

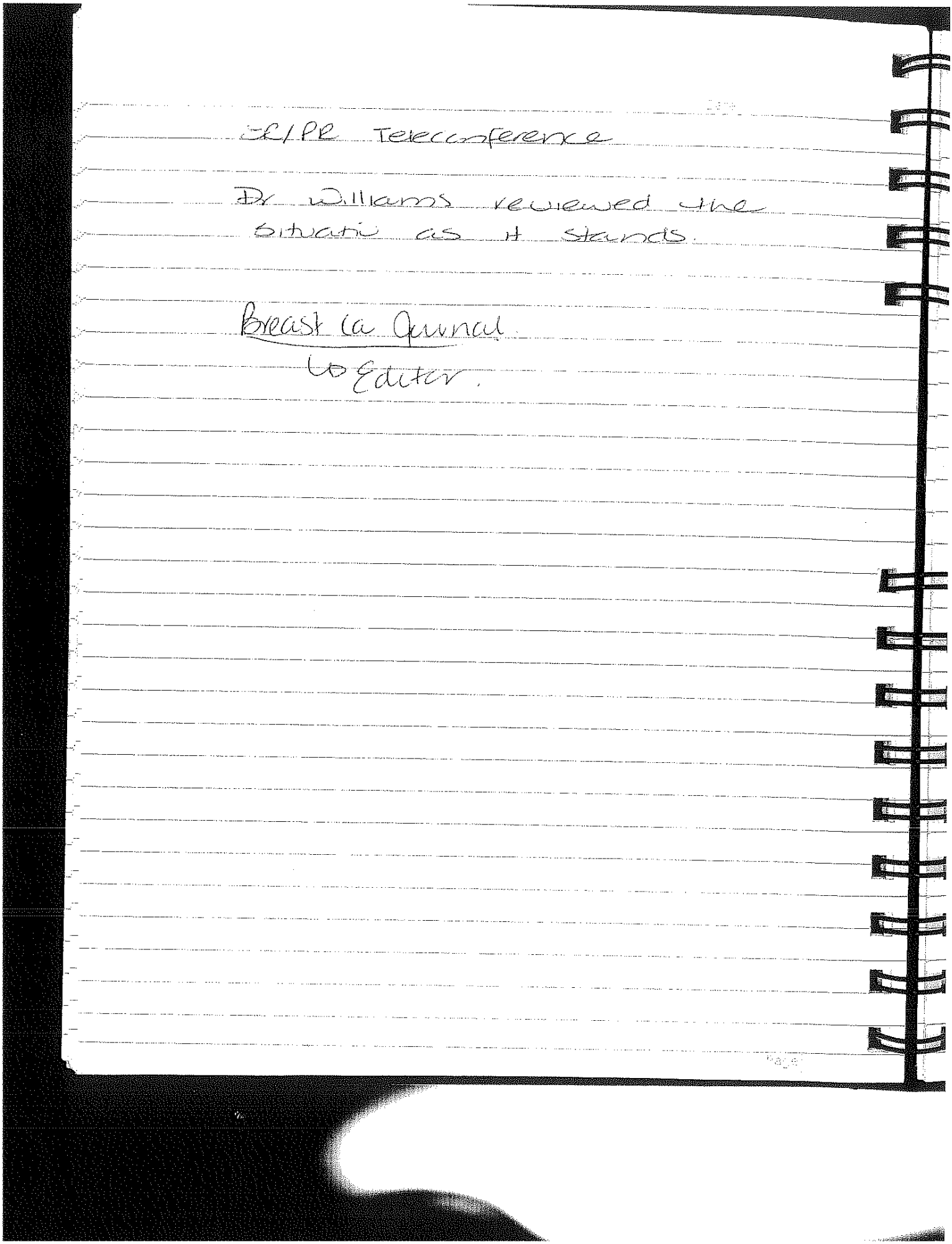
(2) Send to pharmacy

(3) Notify Quality people
Sue
Judy
Sherry
Emma
Jan
Glenys.

Database.

(1) Databrix

Page


ER/PR Teleconference
Dr Williams reviewed the
situation as it stands.
Breast Ca Journal
to Editor.

Date Oct 1 2005

Dave [illegible]
Lisa [illegible] (Western contact)
Dr Williams
Pat Pepin
George Tilley
Me

(Michelle [illegible] Lab [illegible])

Pat gave overview [illegible] as it [illegible]
[illegible].

Currently there are 210 results
c 12 conversions - 22 of
these belong to one oncologist
surgeon

[*] Contact every couple of days
- every Friday

Dr Paul Neil just called and lady in charge of the Cancer Registry to ask for all the names of patients from 1997-1999 as they (western) has no records

Quality Review
Date

ER/PR Panel.

- Goal is to act as a tumor board.
  - HCCSJ chart
  - NCRTF chart.
  - Lab results

Recommendations:
- will eventually go to chart person.

Each person will be officially typed...
- #1 - record.
- #2 - to identify the physician

Any patient we consider a conversion that the MRP has received the report.

T of R.

① - what we think should be done with the patient

② EH has to get info to the MRP.

③ Who's ~~responsible~~ responsible to order the Tamoxifen

" the med

Covering letter with a preamble that if they are not comfortable an option is that the person ~~other~~ could be referred.

(wording on letter).

If

42 out of 327.

Dear (MRP) ← to be determined

[detailed information

[generic paragraph
" if not contraindi

* because there is no N.A. research this is what it is based on.

Kara to draft

1 sheet for each patient:
- Name
- MCP #
- G.P.
- Surgeon
- Oncologist

Page 1

Date

Lasker - ~~take~~ at ER/PR
- add

Plan ~~1~~ Telephones call.

① all patients ~~[illegible]~~ retested ~ no results back

② all patients retested - neg / neg

③ all patients converted - notified by physician

~~scrpt~~
- who can call
- where

Nancy
Me
Deanne
Janet

Page

Date

Kuehler H.

2487 tests — Retest 750 (850)

retests 327 — 170 back, 158 relocate.

58% - St. John's
52% will be from here.

41 - 21 treatment impacts.

6.4%

162 people impacted.

Aug 2, 2005

Dr W. spoke ē Dr Kwan
- do critical patients first
- get Ventana up and running asap.
  - technical expert will be
    bring company controls
  - reviewing all policies and
    procedures
  - retesting blocks back from
    Mt Sinai
- use the large numbers when
  citing
- monitor results continually with
  outside lab
- check ē other sites re: how labs
  report (mentioning

- need to consult ē all pathologists
  re: feedback on reporting
  (Dr has already done
  this - asking them about
  how they felt about it and
  to refer at anything they
  feel unconf
- Send out info to Patients whose
  test results change
- Schedule extra clinics for oncolgy
  and compensate.

11 cases cut

10/11 1 ER -ve that was +ve

PR is more of an issue

There is an issue i our overstaining

- The slides must go to Montreal for r re staining and interpretation.
  - also in-house pathologists will be asked to review slides for QA.

- All Mt Sinai reports to come back to St Clare's - so results can be correlated
  - all the demographic results have to go through the slides
  - the Mt Sinai info re: test results will have to be put in Meditech as an addendum

2002

Dako Ventana Mt Sinai

1st batch
16/25

2nd batch
25/32.

Mt Sinai
- doing the new cases

- retesting

Ventana
- someone coming here.

[redacted]

missing. Specimens come in
Signed off.
Brought to grossing
Described
Put in ( ) - 300/night
takes 11 hrs
Getting over
300 + Queen
and St. Clare's.

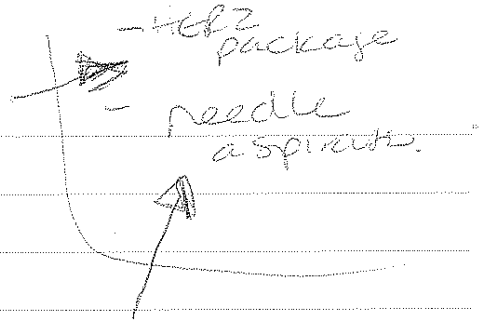
(4) New Machine
Tissue-Tek Xpress
- can do 4 runs in
20 minutes.

TNM follow up

August 2, 2005

Ken
Les
Mary Butler

Dako
1:25
1:50



- Met in the Pathology Lab.
- Process was reviewed from receipt of samples in lab
  - samples are in formalin
    * (kept for 24 hrs - not standard)
  - samples are grossed and put on processor.
    * 300/night - volume is currently more - these slides have increased to over 400/day and are left
    * new processor is in place that will run slides quickly this will change the work practices of the entire lab
      - is there any QA re: machine set-up?
- samples are blocked and cut
- H & E staining are done
  - staining is automated.
  - pathologists are the QA process
    * inconsistencies on if they have issues.
      - what happens if one has an issue?
      - concerns come forward if there is difficulty reading

- when feedback is sought they discuss issue & other pathologists.

Immunohistochemistry.

Staffing

- 3 senior techs
- when manager is off - senior tech is responsible for lab payroll etc.
- have to fill in in other areas

pathologists

- no proactive contact

QA

pathologists resp for controls however techs have to select and ask re: controls.

- only positive
- use book as guide
- no consistent feedback

- what happens when 1 employee and rest don't.

- Need a voice

Dr Gardiner
Dr Williams
Dr Cook
Dr Lewis

[redacted] [redacted]

August 5

① Ventana terminal expert in

② Mt Sinai
- all Ventana's 2004 - 2005 ~~March 31st 2005~~
- all negatives

all patients being seen in the clinic that are negative
(all pts ± metastatic disease and all those ± bladder cancer)

May 1997 until now
~~March 31, 2005~~ and ~~March~~ before
- Retest all negatives (below 10%)
- Retest all tubulars
mucinous
infiltrating lobular.

} to be done by Mt Sinai

Dr Bennett -
Chief Tech, Mt. Sinai } Mid September review.

11 tests

Notified by their physician following them for their cancer - appointment made to discuss the results

Reports will have to come to a central area. Determine.

① Cancer centre pts

② if not - who is following them.

↓

orphaned patients.

Mary Butler

Original 16 - 2 → Dr Kwan
→ Dr Boone
10 → informed

Dr D. Cook
- sent off 11 cases
- Mt Sinai results show areas of minor and major discrepancies
Ex
1 case weak positive back as negative

most were ER +ve
PR
5 major discrepancies
2 cases 55% +ve came back as negative
60% +ve came back as 5%.

(1)
(*) Hold on ER/PR reporting
- we know can use when as verified
controls.

Mt. Sinai
- Council of American Pathologists
- Involved in UK program

(2) calibrate the system
Blocks back by Tuesday.
Results should be done by Sunday.

Results from Mt. Sinai
one was negative in 2002
released determined to be +ve
was not notified
Mt Sinai confirmed they are negative.

- We won't be reporting anything from our lab.
  - correlating ? Mt Sinai
- Mt. Sinai reports will be released only
- We can correlate our results
- When this is European Rec

Public Release
- 70-80%
  - only one parameter

2003 Returns
- 110 tested
- 4 converted

Machine
- Set ups ?

parallel
testing

June 29 2002 - not a +ve report

30 pathologists

10 oncologists

Nov

Tumor Board ——— Minutes ??

Turnaround Time.

① Reset 10 form signal

② Develop plan to retest

③ Identify urgent

④ Reports will not be released until verification.

⑤ [redacted]

- Ventana documentation
  - verified by pathologists

- Knowledge of pathologists
  - were they aware they were verifying?

- other sites doing QC on lab
  items verify controls work

- Paperwork
  Pathology Techs)

  inconsistency in grossing.
  in QC activities

Cases that were selected.

original	2	2	-
1st batch	25	16	converted.
2nd batch	33	25	converted.
	60	41	

2002. col negative

- Is there any way we can get data by cancer type?

-

25. mixture of requests by oncologists

3700 - 02	1L	-ve	
73885 - 02	1L	-ve	
99	1DL	-ve	
5473	1DL	-ve	-ve.
-		-ve	
SU8300-02		-ve	

1999	10	5	true	-ve's	converted.	1st batch
	9	4	"	"	"	
2000	1	1	"	"	"	

(1) Start at 2004 and go back.

Determine serum procedure >
- must test ER/PR.
- pathologist(?).

get rid of exams.

2) is control determination within the scope of practice of lab dermatologists.

Clarenville → no longer using us??
why?

inter - 1 hr
auto - optimal fixation.