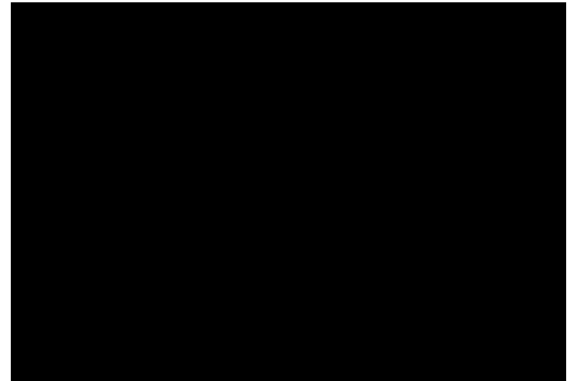
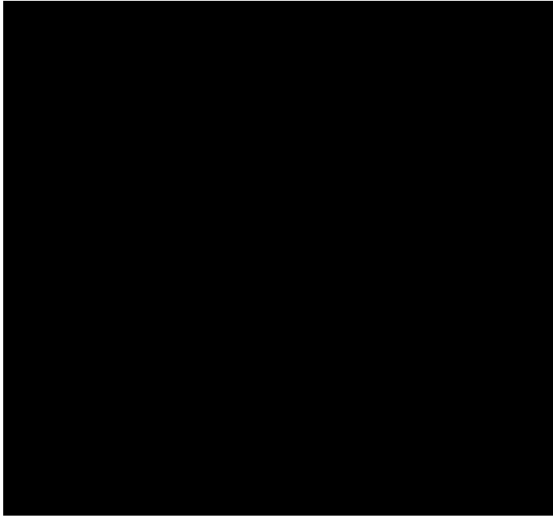


Results already known but not on list



Duplicates.



Grandee / St. Johns

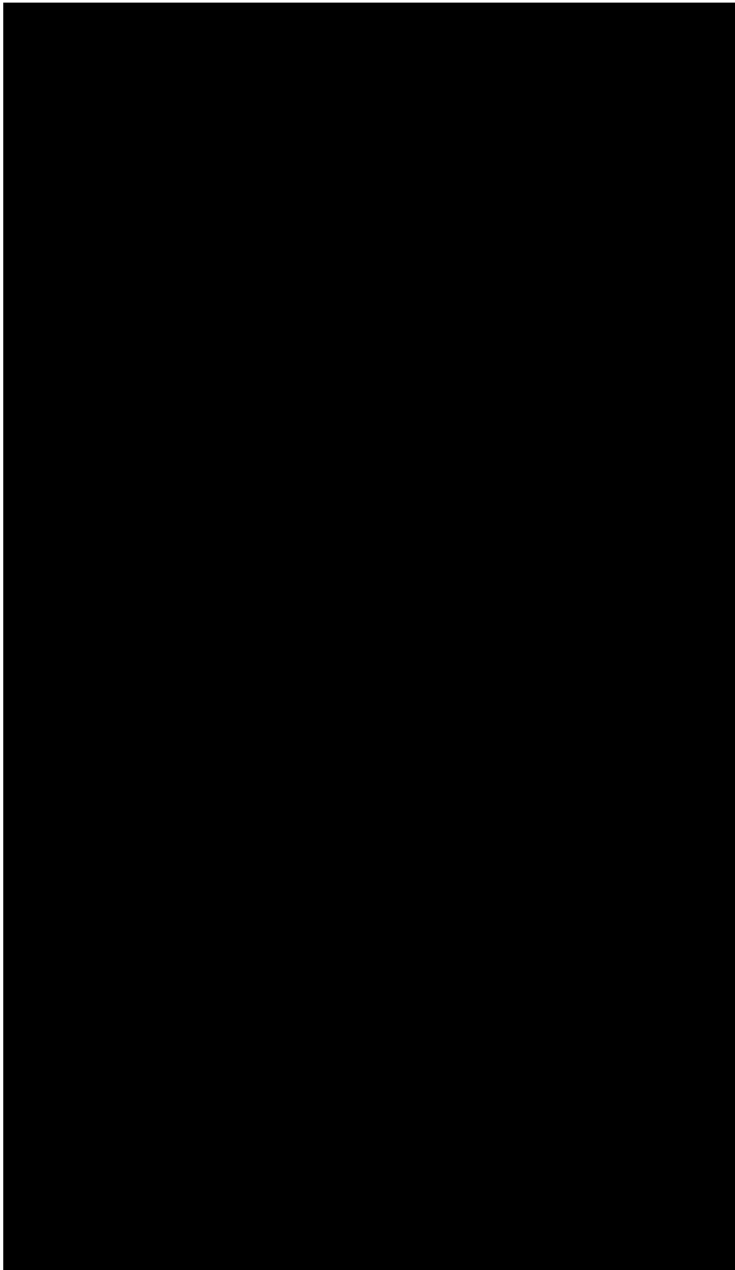
Grand Falls / St. Johns

Carbuncle / G. B. Cross.

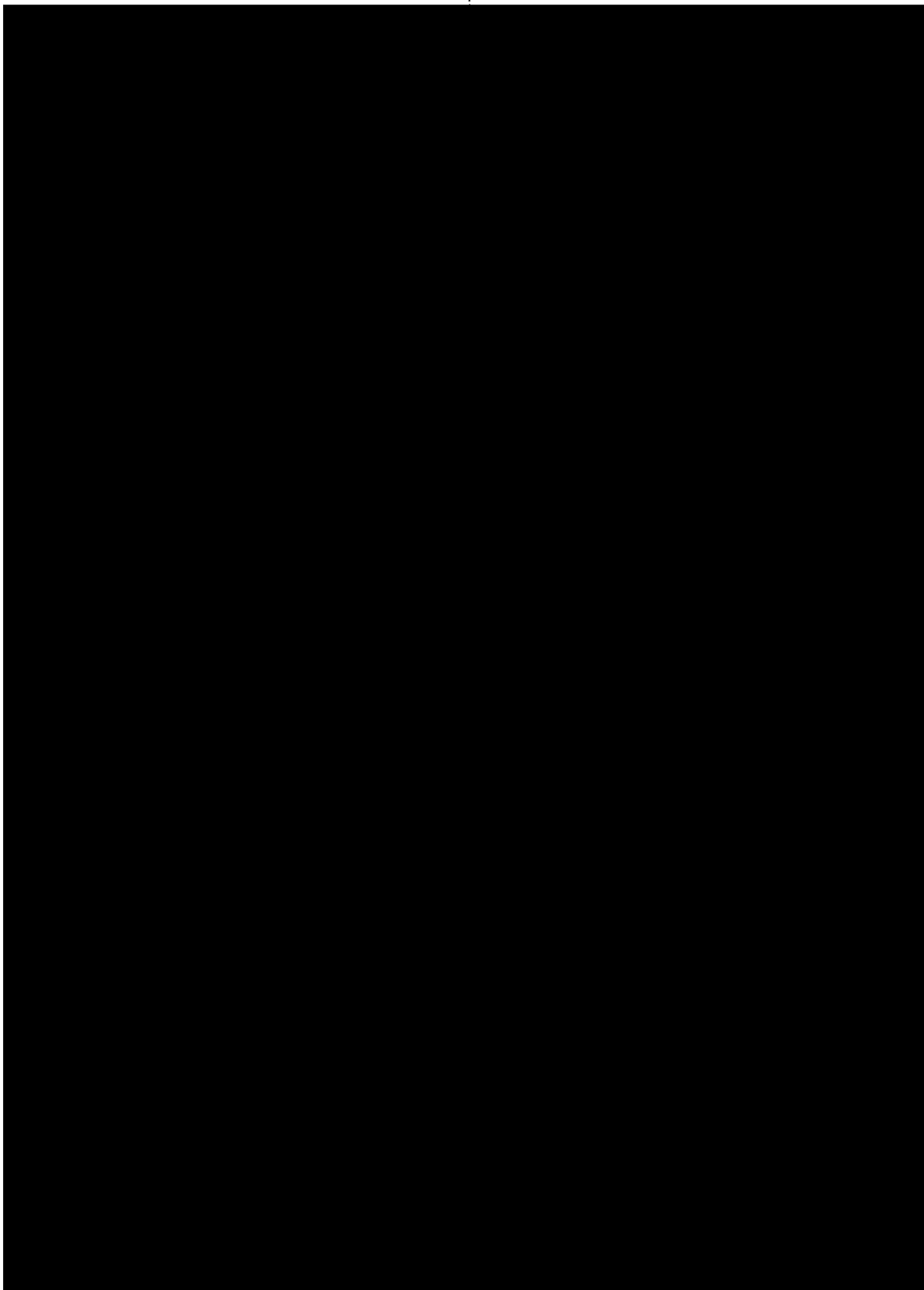
Missing

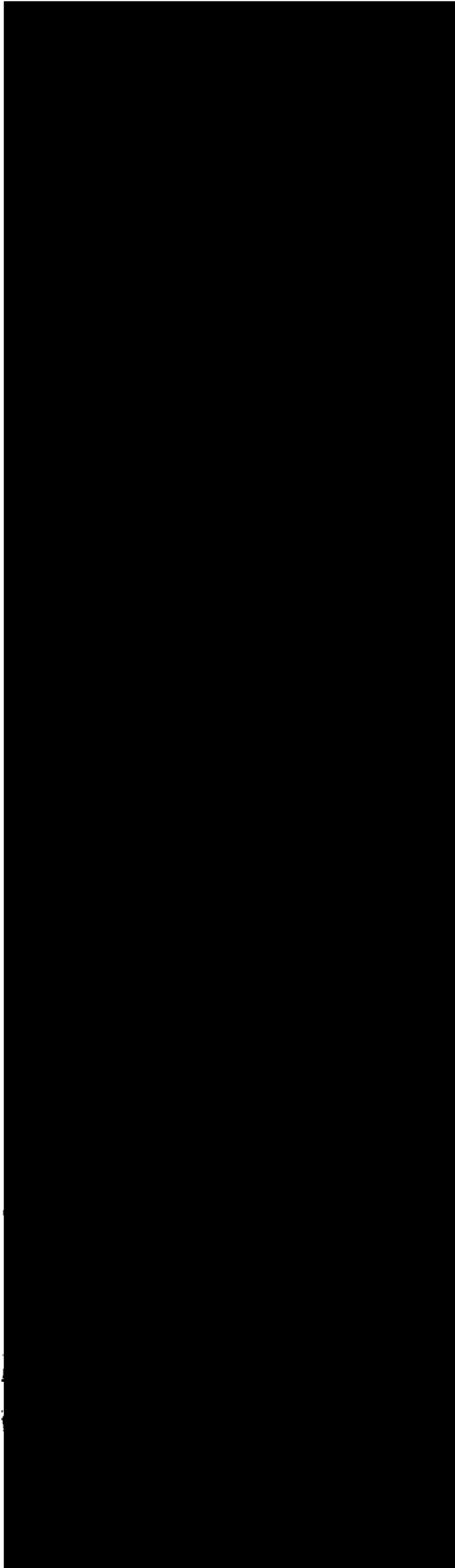


Revised 12/00 DCIS/NT
Lab VAD26341



Deceased results not returned





05/08/09

*Exhibit
copy*

Definition of positivity: Either ER or PR are positive with a value of 10% or greater.

	Number	Number confirmed by Mt. Sinai
Dako positive	19	1 confirmed as positive
Ventana Positive		
Dako negative	39	3 confirmed Ventana results as positive 2 confirmed Dako results as negative
Ventana Positive		
Dako Negative	34	5 confirmed as negative
Ventana negative		
Dako positive	1	
Ventana negative		
Dako positive	1	
Other positive		
Total	94	11 retested

Total Overall
4510

Patent Status Alive
NCRTF Database.

Total	2441	
Status identified		1245
not		1196

ER negative 552. ER -ve / PR -ve 378

ER -ve / PR -ve 378

ER -ve / FR +ve 174

el positive 678

EL+ve / FR -ve 115

EL+ve / PR +ve 563

ER only ER +ve 2

PR only PR -ve 2

PR +ve !!

<u>Date.</u>	Prior to 97	ER status		PR	
		+	-	+	-

	EE		PR	
	+ve	-ve	+ve	-ve
Prick to	1		11	1
97				
97				

	97			
Jan	P2 N3			
Feb	P2			
Mar	P-1			
Apr	P-5			
May	P-8 N-2			
June	P-3 N-1			
July	P-3 N-2			
Aug	P-4 N-3			
Sept	P-8 N-5			
Oct	P-4 N-12			
Nov				
Dec				

January

ER/PR RETESTING = RESULTS RECEIVED	
<i>For October 24/25/26, 2005</i>	
Total patients	14
Notified To date	12
To be notified	2

All patients on the results received have been called except for 2. Have tried them several times.

ER/PR RETESTING = RESULTS NOT RECEIVED			
Total patients per page	45		
<i>For Letters F to H</i>	<i>Oct 24</i>	<i>Oct 25</i>	<i>Oct 26</i>
Deceased	1	---	---
Called Nancy already	2	---	---
Notified To-date	13	7	4
To be notified (Including all regions)	29	22	18
<i>Patient Areas</i>			
Central Patients	(10)		
Western Patients	(1)		
LAMC Patient	1		
New Brunswick Patient	1		
Labrador Patient	3		
St Pierre Patient	1		
Eastern Patient	28		
Total	42		

10

all total
P's names
called 2-3x. 3 days
in past
January

ER/PR RETESTING = RESULTS NOT RECEIVED		
Total patients per page	38	
<i>For Letters O to R</i>	<i>Oct 25</i>	<i>Oct 26</i>
Deceased	1	---
Called Nancy already/notified	4	---
Notified To-date	7	5
To be notified (Including all regions)	26	21
<i>Patient Areas</i>		
Central Patients	7	
Western Patients	1	
Labrador Patient	2	
Eastern Patient	23	
Total	33	

Wed. Oct. 26 -

45 names total

23 contacted

11 outside region

5 shaded

3 dead

2 no need to call

one ~~10~~ left for me to call back

Nancy's report

Gemma

List from 24-10-05

Contacted 20

Shared Area 6

Central Region 8

Western Region 1

Moved to Nsg Home 1

Moved out of province 1 - possibly 2 (called number listed but not living there, name not in tel book)

Called Nancy already 1

Deceased 2

Left to Contact 2

List from 25-10-05

Contacted 14

Shaded Area Ø

Central Region 7

Western Region 2

Labourer 1

Moved to Nsg Home 2

Moved out of Province Ø

Called Nancy already 1

Deceased ? 1 (98 y/o lady in PCI with last clinic visit in 2000)

Left to Contact 8

05/08/09

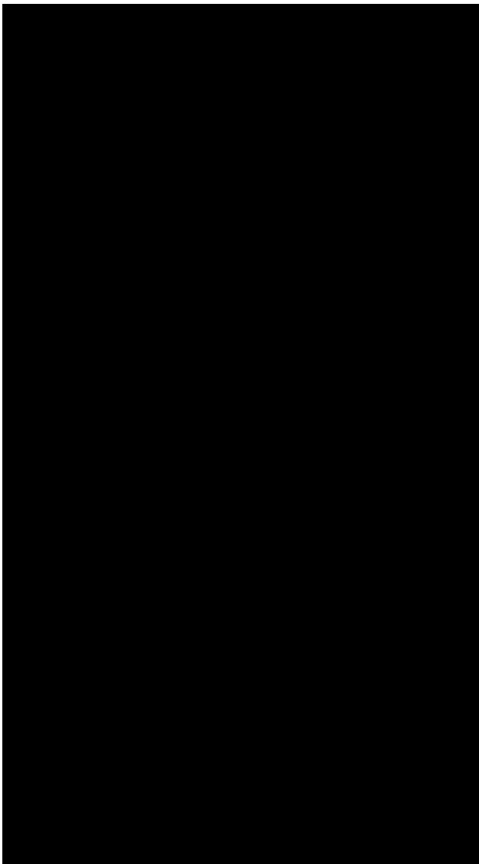
Definition of positivity: Either ER or PR are positive with a value of 10% or greater.

	Number	Number confirmed by Mt. Sinai
Dako positive	19	1 confirmed as positive
Ventana Positive		
Dako negative	39	3 confirmed Ventana results as positive 2 confirmed Dako results as negative
Ventana Positive		
Dako Negative	34	5 confirmed as negative
Ventana negative		
Dako positive	1	
Ventana negative		
Dako positive	1	
Other positive		
Total	94	11 retested

Age - check with
Tanner, first

Journal of Management Studies, 19(1), 67-80.

[illegible]



2000	10/10	10/10	(2)
2000	11/10	11/10	(2)
2000	12/10	12/10	(2)
2001	1/11	1/11	(2)
2001	2/11	2/11	(2)
2001	3/11	3/11	(2)
2001	4/11	4/11	(2)
2001	5/11	5/11	(2)
2001	6/11	6/11	(2)
2001	7/11	7/11	(2)
2001	8/11	8/11	(2)
2001	9/11	9/11	(2)
2001	10/11	10/11	(2)
2001	11/11	11/11	(2)
2001	12/11	12/11	(2)
2002	1/12	1/12	(2)
2002	2/12	2/12	(2)
2002	3/12	3/12	(2)
2002	4/12	4/12	(2)
2002	5/12	5/12	(2)
2002	6/12	6/12	(2)
2002	7/12	7/12	(2)
2002	8/12	8/12	(2)
2002	9/12	9/12	(2)
2002	10/12	10/12	(2)
2002	11/12	11/12	(2)
2002	12/12	12/12	(2)

[REDACTED]

2017-2018

2017-2018

2017-2018

[illegible]

1) $\{f, g\}$
2) $\{f, g\}$
3) $\{f, g\}$

161

778-6307.

June 28

Total patients retested 997

Total paneled: 509

228: status changed \bar{c} no rec.

110: status changed \bar{c} treatment rec

Confirmed negative: 312

Deceased: 176

Outstanding

25: already paneled but require
further review

Ethical review has taken place
re: handling results of pts who
have died

St. John's		negative to total						already panelled	to be panelled	negative to total	negative to total	same result as DLIS no results	deceased	panelled 1st test confirming negative
Total														
1	52	10	12	9	13	3	5							
2	55	16	10	6	11	3	9							
3	52	9	12	14	11	2	4							
4	52	7	10	10	12	6	7							
5	50	8	10	7	11	3	11							
6	53	8	15	5	11	3	8							
7	54	12	16	5	12	4	5							
8	29	5	8	7	6	2	6							
Total 397		75	93	60	90	24	55	123 to be confirmed						
all	13	1	9		3	2	?							
HLN	5		1	1	3	2	?							
car	39	35	18		14	2	?							
✓	71	3	27		19	2	20							
DLs	124	3	49		40	10	22							
acc	173	2	81		71	17	4							
822		85	280	60	242	55	101 156	74 deceased with no results						

potential duplicates = 3

Results not received	Nancy		Deanne		Janet		Heather	Total	Confirmed -ve	Overall
Sheet Total	45	45	42	42	44	38	36	292	Sheet Total	41
Contacted	14	23	20	14	24	12	19	126	Contacted	35
No answer	10	1	2	8	1	11	2	35	No answer	3
deceased	2	3	2	1	1	1	2	12		
moved	1		2	2	2	0	1	8	Other province	2
Not on terry's list	2	5	6	6	2	0	3	24		
Other region	15	11	9	10	12	10	8	75	Other region	1
Already contacted	1	2	1	1	2	4	1	12		
	45	45	42	42	44	38	36	292		41

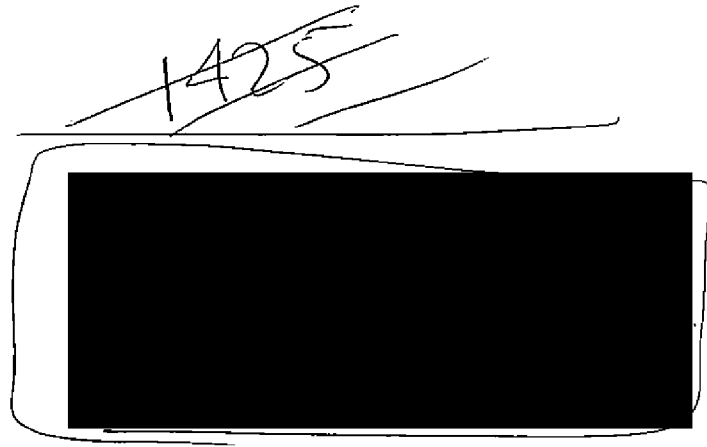
- called - 12th

called us - 4th

contacted 8th

difficult - 1st

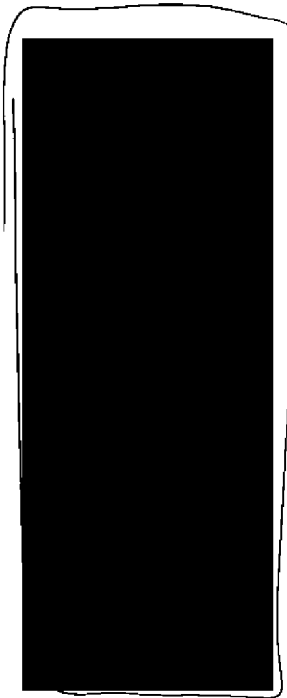
Total
333
161
38
10
76
333



	24-Oct-05	04-Nov-05	17-Nov-05	24-Nov-05	22-Feb-06
# patients known at time	424	432	835	835	851
Results recieved	104	147	172	173	728
Converted	63	59	83	83	420
Letters written	18	59	62	78	247
to be panelled	45		21	5	173
confirmed negative	41	88	89	90	300
contacted by EH	33	84	85	86	170
to be called	6	3	3	3	5
another region	1	1	1	1	130
to be clarified	1	0	0	0	
Results not received	320	285	484	482	
contacted	68	171	178	176	
to be called	147	22	73	73	
no contact information	4	6	6	6	
another region	82	86	227	227	
to be clarified	19				
St. Pierre			8	8	9
In Care			13	13	
Deceased			158	159	175

are
the dead
in here??

no?



1425

Nov-05	24-Nov-05	22-Feb-06
835	835	851
172	473	726
83	83	420
62	78	247
21	5	173
89	90	300
85	86	170
3	3	5
1	1	130
0	0	
484	482	
178	176	
73	73	
6	6	
227	227	
8	8	9
13	13	
158	159	175

200

are page??
the name??

Year	St. Anthony		Central East		Central West		Western		Carbonear		Clarenville		Total clinically negative by year
	# samples submitted	# samples clinically negative	# samples submitted	# samples clinically negative	# samples submitted	# samples clinically negative	# samples submitted	# samples clinically negative	# samples submitted	# samples clinically negative	# samples submitted	# samples clinically negative	
1997			1	1	3	3	11	11	1	1	7	7	23
1998			10	10	18	17	28	27	10	10	7	7	71
1999			17	17	14	14	28	28	5	5			64
2000			13	13	21	21	28	28	6	6			68
2001			7	7	13	12	26	23	3	3			45
2002	6	6	9	9	13	10	22	21	11	11			57
2003			10	10	12	11	19	17	4	4			42
2004 (Dako)			3	3	3	2	2	2					7
2004 (Ventana)			4	4	5	5	9	9	1	1			19
2005 (Ventana)			1	0	2	2	7	7	1	1			10
Total	6	6	75	74	104	97	180	173	42	42	14	14	406

[illegible]

	<u>CASES SENT TO DATE</u>					<u>CASES NOW REVIEWED, LOGGED AND READY</u>
	HCCSS	CARBONELL	GANDER	GIFALIS	CORNER BROOK	
1997	31	—	—	— 4	—	34
1998	60	3	6	13 7	—	7
1999	54	5	12	10 6	—	6
2000	75	4	12	23 6	27	33
2001	69	4	8	15 3	26	29
2002	78	8	9	18	22	22
2003	39	2	10	22	22	22
JAN/MARCH 2004	9	0	6	3	—	—
2004/ 2005 VENTNIA	31	0	0	8 8	—	39
	415 (31)	26	63	110 (34)	(97)	(162)

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

	<u>DAKO/Semi-Manual Boiling</u>							<u>Jan-Mar</u>	<u>Ventana</u>
	1997	1998	1999	2000	2001	2002	2003	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%

ER/PR Cases for Retest – Oct 4/05

	<u>HCCSJ</u>	<u>Carbonear</u>	<u>Gander</u>	<u>Grand Falls</u>	<u>Corner Brook</u>
1997	33	0	0	0	30 Immunohistochemistry
1998	62	3	6	13	72 Immunohistochemistry
1999	54	5	12	9	57
2000	75	4	12	14	45
2001	69	4	8	8	57
2002	78	8	9	17	70
2003	39	2	10	13	79
Jan-Mar/04	9	0	6	2	65
<hr/>					
Total for Retest	419	26	63	76	373*
# Sent to Date	324	14	54	0	No Answer on # of retests
# To be Sent	95	12 (4)*	9 (2)**	76***	

* 4 Cases from Carbonear waiting on more information before we can send

** 2 Cases from Gander waiting on more information before we can send

*** 76 Cases to be reviewed by Dr. Cook, then can be sent

We expect that all cases identified should be sent to Mt. Sinai by early next week (Oct 10/05)

For: PREDHAM, HEATHER E-QI

From: TERRY J. GULLIVER

Sun Jul 24, 2005 12:53 pm

Taken by: TERRY J. GULLIVER (777 6373)

Subject: Re: UPDTAED STATS THAT INCLUDE 1999

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

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
%POSITIVE	61%	52%	56%	51%	75%	89%
NUMBER WEAK POS.	24	20	47	33	16	2
%WEAK POS.	15%	10%	21%	17%	8%	1%
	(70)	(62)	(74)	(64)	(43)	(42)
NUMBER NEGATIVE	38	80	51	61	34	20
%NEGATIVE	24%	38%	23%	32%	17%	10%
TOTAL POSITIVITY	120	128	173	128	168	177
TOTAL % POSITIVITY	76%	62%	77%	68%	83%	90%
TOTAL % NEGATIVE	24%	38%	23%	32%	17%	10%

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

77 - negative
3 - weak positive

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

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

[illegible]

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

? what is the conversion rate of ~~negative~~ ^{negative} ~~protein~~ to ~~positive~~ ^{positive}.
(higher)
Onalogous (unfertilized) result
but new system is not working right
the conversion rate is too high.

* End of the week
we will have the
+ve rates for every
year.

2003 - 32
+ -ve
4-8 week +ve

May 1997 to present
use ER/PR -ve 500 still alive
To: Mr. George Tilley

From: Dr. R. Williams

Re: Update on ER/PR receptor testing

total
tested { 373 - 2003
371 - 2001
382 - 2002

35
10
41
all of
58

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 bioassay 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.

2002
25 of
the 33
are new
ER/PR +ve

(May 1997)

← control
sample
which the
pathologist
has already
identified
as positive

- 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.

12 have
been sent
to Mt. Sinai

2002 → 380 cases.

→ 80 -ve cases.

→ of these -ve cases 58 have been
tested and 41 are now +ve.

Dr. Blair Altheim
- Main on-line Network

Heather Predham

From: Heather Predham
Sent: Wednesday, October 26, 2005 8:41 PM
To: Dr. Robert Williams; Patricia Pilgrim
Cc: Denise Dunn; Dianne Smith
Subject: Current Tally for ER/PR

Hi,

Here are the latest numbers from the ER/PR contacting. I just wanted to note that Nancy Parsons, Janet Laidley and Deanne Emberley have done a tremendous job with this task. It is extremely draining and they have done all this notification, in the day and in the evenings, with the utmost of compassion and professionalism.

Confirmed negative: Total 41 patients

Contacted: 35
No answer (after many tries): 5
Other region: 1

Confirmed - ve
 25 - Physicians.

Results not received: Total 292 patients

Contacted: 126
No answer: 35
Deceased: 12 (despite all our efforts, these were discovered after we called the family)
Moved: 8 (we are exploring ways to contact them)
Already called us: 12
Other regions: 75
Not on Terry's list: 24 (these appear to be other region, or people we already tested over the summer; so right now it look like we won't need to call them)

So, overall we have spoken to 173 patients and have 40 left to get in touch with. We have 8 that we have to figure out how to get in touch.

Sharon Dominic is speaking with Dr. Mallure re: the St. Pierre patients (8), and we have to set something up for those in nursing homes (12).

The numbers for those who have converted have not changed from my last update:

There have been letters written on 18 patients, the letters have been sent over to Kara for signing. There are 45 patients left to be reviewed. 25 have been selected for this Thursdays meeting

I still haven't been able to make contact with Western. I reviewed Larry Alteen's data and provided feedback, but have not heard from him regarding who's going to contact his patients. Almost all of the 76 patients noted above from the Central region were on his list.

If you have any questions, don't hesitate to call me

Heather

04/05 - 31

Total Re + C stat. - 446

Sent 415

31 to be resent. (Oct 27/05).

Heather Predham

From: Allison, Dr. David [DavidAllison@hcssjr.nf.ca]
Sent: Wednesday, October 19, 2005 12:22 PM
To: Rosemary Barrington; Heather Predham; Miller, Wayne; Lorraine Miller-Hamlyn
Subject: FW: Pandemic Influenza Readiness

> -----Original Message-----

> From: Allison, Dr. David
> Sent: Friday, October 14, 2005 4:41 PM
> To: Donovan, Catherine (EHCSB_HOLYROOD); Morgan, Calvin
> (EHCSB_HOLYROOD); Cahill, Mary; Basha, Mary; Bussey, Trudy; Manning, Ann;
> Jim Hutchinson (E-mail); Marion Yetman (E-mail); Thomas, Deborah; Moody,
> Natalie (EHCSB_CVILLE); June Pollett (E-mail)
> Cc: Clarke, Beverley; Matthews, Fay (EHCSB_CVILLE);
> 'pat.coishsnow@easternhealth.ca'; Stephen Dodge (E-mail); George Butt
> (E-mail) (E-mail); Alice Kennedy (E-mail)
> Subject: Pandemic Influenza Readiness

> I've been asked by George Tilley to assemble some information from various
> parts of our regional organization with respect to 1. readiness to meet
> the demands pandemic influenza might make and 2. specific resource
> requirements we might need to face the pandemic, in order to respond to a
> query from government.

> It has been some time since Pandemic Plans were reviewed and many of the
> key players have now changed.

> Please try to organize your thoughts in relation to the key areas of
> potential activity. You may or may not have something to say about any of
> these:

> Emergency planning and Response (eg. established committees, linkages with
> municipalities, businesses etc)
> Surveillance
> Vaccines and Antivirals (eg. capacity to immunize, numbers in priority
> groups, occupational health programs,etc)
> Health Services (fit testing; availability of beds regular and ICU; care
> in the community,infection control readiness)
> Communications (eg. current activities for annual flu; contacts etc)
> Business Continuity Plans (internal and external)

> Any other points you'd like to make, please pass along; also, if I've
> missed some input from a key person in the organization, please pass this
> along and/or let me know. In particular I'm not sure who the appropriate
> contacts are in the institutional sector.

> Thans for your help.

> I'd appreciate responses as quickly as possible in order to compile them
> to return to Senior Management

> David J. Allison MD, FRCPC
> Medical Officer of Health
> Eastern Health
> 20 Cordage Place
> St. John's, NL
> A1B 4A4
> Tel : 709-752-4192
> Fax: 709-752-4989

Internal Analysis – Major Issues as Identified by Directors of Quality

Financial

There are significant financial pressures in the health sector. Sixty-five per cent of Eastern Health's 2005-06 budget is for salaries. New technologies, drugs (particularly cancer care) and investment requirements in facilities and infrastructure are straining the financial pie. Difficult choices often have to be made regarding resource allocation. Vigilance and accountability are key to ensuring appropriate stewardship of financial resources.

Human Resources

Human resource issues such as attendance management, professional development and workplace safety have received much focus over the past few years. These issues, and others such as recruitment, retention, labour relations, employee health and wellness and succession planning, will continue to require much attention. Shortages of certain occupation groups (i.e. physicians, pharmacy, allied health professionals) have created a number of challenges in the recruitment and retention area. Some of these challenges – recruitment, retention, professional development--are exacerbated in the rural areas.

Workloads and job satisfaction will be particularly sensitive during a merger when much uncertainty exists.

Patient/Resident/Staff Safety

The Canadian Adverse Events Study (May 2004) estimated that 7.5 per cent of patients admitted to acute care hospitals in Canada in the fiscal year 2000 experienced one or more adverse events, and that 36.9 per cent of those patients were judged to have highly preventable adverse events.

The safety of patients/residents has become a strong focus of the health sector within the past decade. This emphasis on safety will continue and will have an impact on many resources, including finances, infrastructure and education.

Safety of staff, particularly for those who visit clients in their homes (i.e. social workers, community health nurses, etc.) is extremely important.

Infrastructure & Equipment

There are many challenges related to maintaining our infrastructure. Facilities are aging and require maintenance, upgrading or replacement. The equipment used to deliver care and services is also aging and requires a replacement strategy. Foundations and auxiliaries word very hard to provide funding for health-related equipment but the needs are great.

Technology

Technology plays a significant role clinically and administratively.

Advances in technology can result in improvements in diagnosing and treating illnesses and requires significant resources. An electronic health record is important to provide optimum patient/resident care.

Technology is a necessary tool to help unify individuals in a merger. Developing a common network can enhance communications and help to integrate business approaches such as policies and payroll.

Information Management

Information technology and information management are critical to building an organization with enhancing continuity and quality of care.

The management of information plays a critical role to improve the scope, timeliness and quality of data as well as to develop and implement clinical tools to support evidenced-based decision-making. The successful provision, implementation and interpretation of timely and accurate health information is highly dependent on complex internal and external partnerships. In addition, there is an increasing focus on privacy and confidentiality that will require significant attention. The geography and size of Eastern Health makes information management extremely important.

Information management has a role to play in the utilization of data, ensuring availability of data on a timely basis

Clients

Consumer expectations of the health system are rising. Increasing numbers of health consumers are better informed and want more control and choice in their health care. These factors impact on perceptions and relationships between consumers and health professionals. People want to have a greater say in service planning.

Health boards have a major economic impact on rural areas of the region and changes will be subject to immense scrutiny by key external stakeholders. Employees and community leaders are concerned about impact on jobs and the resulting impact on communities. Community engagement at all levels will be integral to the success of the health system.

Oct. 4, 2005

763

433 - negatives

330 - conversions

13 - changes because
def'n changed.

317

4 - diagnosis
changed

313

4 - retroconverters

309

5 - need to be
seen

304 → 96 tx recommendation
148 no tx rec.
60 low risk

Treatment recommendations.

1997	1
1998	8
1999	14
2000	22
2001	20 19
2002	21
2003	7
2004	<u>1</u>
	96

Sept 5A.

CW risk

1997	7 13	1
1998	13	
1999	8	
2000	10	
2001	7	
2002	7	
2003	2	
2004		

54

60

Already on Tamoxifen.

Jan 2

March 04

3
1111

Dako

Vent.

①

1997

3

1998

22

1999

24

2000

14

2001

27

2002

33

2003

14

2004

6

2005

1

2006

~~2006~~

148

Draft

To:

Re: Update on Estrogen and Progesterone Receptor Testing

Based on this information, the total number of patients that were sent for retesting was 939. The numbers below include 9 patients from St. Pierre.

Confirmed negative

These are patients who were retested and the original results were verified by the Mount Sinai retesting. These patients did not require review by the panel and there was no change in the patient's treatment plan.

Region	Number
St. John's	186
Corner Brook	71
Carbonear	14
Clareville	3
St. Anthony	3
Gander	19
Grand Falls	40
St. Pierre	5
Total	341

Patients that required review by the panel.

This panel consists of representatives from medical oncology, pathology, surgery and quality.

Category	Number	Comments
Patient ER/PR status has changed from negative to positive but there are no other changes	208	This category includes: <ul style="list-style-type: none"> Patients who are deemed to be at a low risk for recurrence or previously could not tolerate or did not want Tamoxifen (60) People who have been previously treated with another aromatase inhibitor (148) <ul style="list-style-type: none"> de those not their original treatment metastatic
ER neg PR +V	343	10
247	247	31
146	146	246
147	147	239
	240	250
	273	
		be placed on itor. This group
		ed by the delay disease has
		changed finition of positive ice the time of
		e considered to ian and treated change in the patient's ER/PR status was confirmed by the panel confirmed the ER/PR status as still being negative. No action other than notification was required.

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Patient ER/PR status has changed from negative to positive and there are treatment recommendations	109	<p>These patients are recommended to be placed on Tamoxifen or another Aromitase inhibitor. This group includes:</p> <ul style="list-style-type: none"> Patients who have been impacted by the delay in receiving Tamoxifen: i.e. their disease has progressed (9) Patients whose results have not changed significantly, but the clinical definition of positive and negative has changed since the time of diagnosis. (13)
Confirmed negative	28	<p>These patients' original results were considered to be negative by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel confirmed the ER/PR status as still being negative. No action other than notification was required.</p>

Draft

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DCIS	56	Confirmed DCIS (39) Outstanding (14) Follow-up required (3) For further information see note below
Required assessment prior to recommendation	5	The panel could not make a recommendation for these patients without seeing the patient. The combination of the time since diagnosis and the original presentation of the disease places the patient near the borderline between treatment and not. This information was communicated to the patient through the most responsible physician with the offer of follow-up through the Cancer care program of Eastern Health.
Retro Convertors	4	See note below
Total	422	

Patients who are deceased (176):

176 patients are identified as being deceased either through chart review or direct contact with a family member.

Of these 176, 101 that were retested and results received. In June, an ethics review was conducted regarding notification to the families of the deceased. The recommendation was that upon conclusion of the ER/PR review, a public statement be made stating that if the next of kin of a deceased patient would like the results, that they contact Eastern Health.

Ductal Carcinoma In Situ (DCIS):

DCIS is a diagnosis made by the pathologist when the cancer cells grow inside the ducts of the breast. DCIS means that there is no, or only a very limited amount of, invasive component of the disease and this diagnosis would form the basis of the plan of treatment. As I understand it, from our specialists, Tamoxifen is not recommended for DCIS. There is, therefore, no reason to test the ER/PR status.

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If the panel could not do this initial step, then two pathologists reviewed the original blocks and slides. This has led to the identification of other "confirmed DCIS". In total, there have been 39 confirmed DCIS.

Draft

However, our review has also revealed patients who were incorrectly diagnosed in their original pathology report, which may have led them to being treated with Tamoxifen or chemotherapy. At this time, there are three women who fall in this category:

- One patient was diagnosed with invasive carcinoma when review indicates that it was DCIS
- Two patients were diagnosed with DCIS with a large amount of invasive component. Upon review the invasive component is much less.

Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care have disclosed this information to those affected.

There are **14** more DCIS patients throughout Newfoundland and Labrador that require further review by pathology.

Retro Convertors

All patients who were negative for ER were included in the retesting process. As the clinical definition of negative changed over the years, all patients with an ER of 30% or less were retested.

That means that in the group retested there are women who, although their ER level met this definition of negative, were considered positive at the time and received hormonal treatment. However, in **4** cases, retesting by Mount Sinai identified that women in this category now have an ER/PR status of 0% that has been confirmed by subsequent retesting at Mount Sinai.

Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care will meet with them in the near future to disclose this information.

Pam...I'm not sure about these two sections as we still don't know how Ches Crosbie found out his information.....also, DOH has already released our briefing notes in that ATIPP request last time.....what do you think?

Concerns

- Of the patients who were originally ER/PR negative but are now ER/PR positive, there is greatest concern for those patients who:
 - Were originally ER/PR negative and were not prescribed Tamoxifen at that time but are now receiving Tamoxifen because of metastatic disease.
 - Were originally ER/PR negative and were not prescribed Tamoxifen at that time but were at high risk for metastatic disease. Now that they have converted they are started on Tamoxifen.
- Patients who were originally ER/PR positive but are now ER/PR negative and they have received Tamoxifen for a period of time (retro convertors). Tamoxifen is linked with an increased risk of uterine cancer and stroke.
- Patients who it was discovered during this intensive chart review had a previously unknown adverse event. This is unrelated to the ER/PR review.

Factors contributing to review timeline

- Identification of an appropriate referral hospital to conduct retesting.
- Identification of patients requiring retesting. This includes verification with the cancer registry, HCCSJ Meditech laboratory module and the other region lab records.

take out

Draft

- Collection and coordination of the lab slides and blocks for retesting. This includes communicating with the other regions to receive their specimens and slides.
- Creating a database of the patients being retested and their results upon return
- Developing and implementing the process of informing patients directly within Eastern Health that their samples were to be retested and coordinating this communication process with the other regions.
- Developing and implementing the appropriate handling of the returned results.
- Developing and implementing the process of informing patients directly within Eastern Health that their results were returned and indicated that they were either confirmed negative or confirmed positive and coordinating this communication process within the other regions.
- Developing the review panel process, including scheduling of meetings and obtaining pertinent clinical records.
- Pathology review of select cases to verify results.

Draft

Prepared by: Heather Predham
Assistant Director, Quality and Risk

Re: Update on Estrogen and Progesterone Receptor Testing

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mhennessy@gov.nl.ca

Patients that

This panel consists of patients whose quality.

Category

Patient ER/PR status changed from negative to positive but no treatment recommendation

		<p>o This group of patients also includes those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13)</p>
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687
9915
Moira
729
3127

88

Draft

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It has been noted in the literature that false positive laboratory tests can occur.

Total patients retested. 997

Panelled. 503.

- left to be panelled: ~~509~~ 6

224 status changed no treatment changes

109 status changed and treatment rec.

36 (retro/DCIS) require further review

Confirmed negative: 312

Deceased: 176.



Total 939

Panelled: 574. + ~~1~~ + 6

confirmed Negative. (300) + 8

Deceased (results returned
not retested.

102
74.

581
308
174

53
+ 1

54
6.

Panelled 496 (minus 72).

509.
312

821
176

Deceased 175
C.N 300
Panelled 574.

DCIS 997

DCIS - to be reviewed
DCIS - handled - 30
Retro to be reviewed

26
10.

36

Total 997
dead 176
C.N. 312
panelled 503.
out.

997
36

961
176 - dead

785
312 - C.N.

473 - panelled.
473 - out (already panelled)

Total patients retested: 997

Total paneled: 509.

228 - status changed no rec.

140 - status changed with treatment rec.

Confirmed negative: 312

Deceased: 176

Outstanding

~~6 to be paneled~~

36 require further review

25 (have already been paneled)

503
312
103
36

6
950

For: GULLIVER, TERRY J.

From: TERRY J. GULLIVER

Wed Jul 20, 2005 11:53 am

Taken by: TERRY J. GULLIVER (777 6373)

Subject: REVIEW OF ER/PR STATS FROM 2000-2004/5

REVIEW OF ER/PR STATS FROM 2000-2004/5

*we reported weak +ve in 1997**April 2004
April 2005*

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

*only on
out of town**only
100%
considered**we started buying
we had to buy the
our pre-made sol'n
in late 2002 - early
2003**positive - more than 30% of calls were
positive**Very individual way to handle these cases**1997 to 2002 - the cut off for positivity
changed from 30% to 10% (globally)**Mount Sinai - 15%**Rate for all 50-80%**Sept 12th - Mt. Sinai*

Results not received	Nancy		Deanne		Janet		Heather	Total	Confirmed -ve	Overall
Sheet Total	45	45	42	42	44	38	36	292	Sheet Total	41
Contacted	14	23	20	14	24	12	19	126	Contacted	35
No answer	10	1	2	8	1	11	2	35	No answer	3
deceased	2	3	2	1	1	1	2	12		
moved	1		2	2	2	0	1	8	Other province	2
Not on terry's list	2	5	6	6	2	0	3	24		
Other region	15	11	9	10	12	10	8	75	Other region	1
Already contacted	1	2	1	1	2	4	1	12		
	45	45	42	42	44	38	36	292		41

Total
333
161
38
10
76
333

D. Williams

- # patients } 1997-2005
 - # tests } 2489

results / tests
 # patients

- decided by region
 - how many back

patients

Panel Summary

Outcome	February 9, 2006	February 16, 2006		February 18, 2006		February 23, 2006		February 25, 2006	
	YTD	Paneled at session	Total YTD	Paneled at session	Total YTD	Paneled at session	Total YTD	Paneled at session	Total YTD
Multiple results	1		1		1				
Deceased	5		5	1	6				
Confirmed negative	7	2	9	4	13				
Confirmed positive				4	4				
Confirmed DCIS				2	2				
No recommendation: reason	22	3	25	15	40	How many left to come back.			
No recommendation: on Tamoxifen	56	21	77	25	102				
Recommended for Tamoxifen	52	6	58	17	75	# impacted			
To be seen at Cancer Clinic prior	3	1	4		4	adjusted			
Other**		2	2		2	rec'd			
Total Completed	146	35	181	68	249				
Outstanding									
No chart	7	-1*	6	-3*	3				
Chart at external clinic	2	-2*	0						
Need more information	1	1	2	12	14				
Total	156	36	189	80	266				

*This means that a patient from this group identified at an earlier meeting was paneled and their results are included in the outcomes for that meeting (this number is included elsewhere and should not be added in the column total)

** These individuals were initially identified as positive, but on retesting are now 0/0.

Total cases reviewed 1997-August 2005: 2760 cases

Total retested: 939.

Results obtained and reviewed: 763

No change in results and subsequently no change in treatment: 433

Confirmed negative: 341

Confirmed negative from panel: 28

Confirmed positive: 12

DCIS: 52

No change in results; requires change in treatment as definition of negative has changed: 13

Change in results but does not require treatment change: 213

No recommendation because they are low risk: 60

No recommendation because they are previously treated with Tamoxifen or another aromatase inhibitor: 148

This group includes a group identified as being potentially impacted: those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13)

No treatment because they required assessment prior to recommendation: 5

Change in results and requires treatment change: 104

Recommended for treatment with Tamoxifen or aromatase inhibitor: 96

Originally diagnosis revised: 4

Originally had a degree of ER positivity but on retesting was negative: 4

Patients who are deceased (176):

101 were retested and results received.

There have been 2 retested upon request. The remaining 73 will not be retested unless the families approach us.

No treatment recommendations

208

includes - 60 - low risk / couldn't take it
148 - already on it (13 metastases)

Treatment recommendations

109

- 13 subtract clinical def'n neg

96

5 required assessment

Panel Summary

Outcome	February 9, 2006	February 16, 2006		February 18, 2006		February 23, 2006		February 25, 2006	
	YTD	Paneled at session	Total YTD	Paneled at session	Total YTD	Paneled at session	Total YTD	Paneled at session	Total YTD
Multiple results	1		1		1				
Deceased	5		5	1	6				
Confirmed negative	7	2	9	4	13				
Confirmed positive				4	4				
Confirmed DCIS				2	2				
No recommendation; reason	22	3	25	15	40				
No recommendation; on Tamoxifen	56	21	77	25	102				
Recommended for Tamoxifen	52	6	58	17	75				
To be seen at Cancer Clinic prior	3	1	4		4				
Other**		2	2		2				
Total Completed	146	35	181	68	249				
Outstanding									
No chart	7	-1*	6	-3*	3				
Chart at external clinic	2	-2*	0						
Need more information	1	1	2	12	14				
Total	156	36	189	80	266				

*This means that a patient from this group identified at an earlier meeting was paneled and their results are included in the outcomes for that meeting (**this number is included elsewhere and should not be added in the column total**)

** These individuals were initially identified as positive, but on retesting are now 0/0.

For: PREDHAM, HEATHER E-QI

From: TERRY J. GULLIVER

Sun Jul 24, 2005 12:53 pm

Taken by: TERRY J. GULLIVER (777 6373)

Subject: Re: UPDTAED STATS THAT INCLUDE 1999

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
%POSITIVE	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 POSITIVITY	120	128	173	128	168	177
TOTAL % POSITIVITY	76%	62%	77%	68%	83%	90%
TOTAL % NEGATIVE	24%	38%	23%	32%	17%	10%

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

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

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

[illegible]

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

Region	Total	Paneled	To be paneled	Confirmed Negative and Informed	Confirmed negative (to be told)	No results (identified as DCIS or No Tumor by Mount Sinai)	Deceased
St. John's	397	75	93	60	90	24	55
Clareville	13	1	9		4	-	?
St. Anthony	5	0	1		4	-	?
Carbonear	39	3	20		14	2	?
Gander	71	3	27		19	2	20
Grand Falls	124	3	49		40	10	22
Corner Brook	173	0	81		71	17	4
TOTAL	822	85	280	60	242	55	101

Please Note....

- these numbers are a bit different that I've given you before....and here are some reasons:
- the number to be paneled are high. The group decided that any change in ER/PR status would require review to confirm that appropriate treatment was given
- there are 74 people that are deceased that are not on the list
- there are three people (at least) that appear on the lists of more than one region
- the people with no results are samples that Mount Sinai have determined are DCIS or have no tumor. Obviously we didn't agree originally and these require follow up
- there are at least 17 people who have been informed of their status but do not appear on the list of results
- there are several people that are missing off this list...I will have numbers later today

Meanwhile:

- we are informing the confirmed negative starting this am.
- I suggest we send the regional lists back to the regions this am with the note that we will panel the patients on their lists that are cancer clinic patients and if they would like a patient paneled to contact us to arrange clinical information to be shared.

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

From: Heather Predham
Manager, Quality and Risk

Date: February 22, 2006

Re: Update on Estrogen and Progesterone Receptor Testing

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

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

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

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

Total completed to date: 247

Total remaining to be done: 154

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

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

Confirmed negative

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

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

Patients from St. Pierre (Total – 9)

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

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

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

Patients who are deceased (Total - 175)

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

Patients whose samples were not retested at Mount Sinai

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

Total retested: 939.**Confirmed negative: 341**

These were the ones that had no change in the values and could be determined as negative without further review. There were others determined through the paneling process (see below)

Patients paneled: 422

Converted with no treatment recommendations: 208

- No recommendation: low risk: 60
- No recommendation: previously treated with Tamoxifen or another aromatase inhibitor (148)
 - **This group includes a group identified as being potentially impacted:** those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13)

Converted with treatment recommendations: 109

- This group includes patients whose results have not changed significantly, but the clinical definition of positive and negative has changed since the time of diagnosis. (13)
- **This group includes a group identified as being potentially impacted:** those impacted by the delay in receiving Tamoxifen: i.e. their disease has progressed (9)

Confirmed negative: 28

- As noted above, these patients' original results were considered to be negative by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel confirmed the ER/PR status as still being negative. No action other than notification was required.

Confirmed positive: 12

- These patients' original results were considered to be positive by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel confirmed the ER/PR status as still being positive. No action other than notification is required.

DCIS

- Confirmed DCIS: 52
- Follow-up required: 4

Required assessment prior to recommendation: 5

- The panel could not make a recommendation for these patients without seeing the patient.

Retro Convertors: 4

Patients who are deceased (176):

- 101 were retested and results received.
- There have been 2 retested upon request. The remaining 63 will not be retested unless the families approach us.

763 pts

+33

- no change

catia neg

"

pos

SZ OUIS

330-13

→ no change defin)

317

317

- 4

dx change

4

retros

309

104 → recommended for
T/AI

60

→ no re low visL

148

→ no rel already

13

→ already ch.

5

→ needs assess

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