

*Tabled by Minister of Health and Community Services  
2008. 04. 23.  
JMK*

## PATHOLOGY EXTERNAL QUALITY ASSURANCE SURVEYS 2008

### College of American Pathologists Survey (CAP)

#### 1. HQIP – Histologic Quality Improvement Program

- Frequency - Twice each year the laboratory submits slides
- Evaluation - Fixation, tissue processing and embedding, microtomy, staining, and coverslipping.
- Description - The survey is designed as an educational program to improve the quality of histologic slides. provides participant evaluation, educational critique, peer comparison data, and benchmarking data. It also provides reading material and on-line learning assessments.

#### 2. MK - Immunohistochemistry Predictive Markers

- Frequency - Twice each year the laboratory receives slides
- Evaluation - Staining of a number of markers and pathologist' interpretation
- Description – Designed primarily as an educational program for IHC laboratories providing markers for diagnostic support. The CAP Immunohistochemistry committee no longer grades this program.

#### 3. PM – Immunohistochemistry Predictive Markers

- Frequency - Twice each year for ER and CD20 (One marker at each survey)
- Evaluation – Staining and pathologist interpretation
- Description – This survey is designed for laboratories performing immunohistochemistry procedures for predictive markers.

#### 4. PIP – Performance Improvement Program in Surgical Pathology

- Frequency – Four times per year; 10 cases each shipment
- Evaluation – Designed for educational purposes only
- Description - Designed as an education and performance assessment tool for pathologists to compare their performance with that of their peers.

#### 5. NP- Neuropathology Quality Improvement

- Frequency – Twice per year; 8 cases per shipment
- Evaluation – Designed as educational program
- Description – education program for pathologists to assess and improve their diagnostic skills and to learn of new developments in neuropathology



## American Society for Clinical Pathology

- Frequency – Four times per year; 5 cases each shipment
- Evaluation – Designed for educational purposes only
- Description - Designed as an education and performance assessment tool for pathologists to compare their performance with that of their peers.

## UK National External Quality Assessment Scheme (UK NEQAS)

### 1. Breast Pathology Hormonal Receptors ER and PR

- Frequency – Four times per year; one receptor per survey, alternating between ER and PR.
- Evaluation – Staining and pathologist interpretation of survey slide and in-house control
- Description – IHC laboratories stain slides provided and also submit in-house control slide for evaluation. The aim is to identify poor-performing laboratories as soon as possible (reporting UK labs only). Due to the direct impact of ER/PR results on patient management, stringent performance monitoring mechanisms have been proposed. Scores are determined by a panel of four assessors awarding a mark out of 5, which are then totaled to give a score out of 20. The ratings are as follows:

Acceptable	$\geq 13 / 20$
Borderline	$< 13 / 20$
Unacceptable	$< 10 / 20$

### 2. Breast pathology Hormonal Receptors HER-2

- Frequency – Four times per year
- Evaluation - Staining and pathologist interpretation of survey slide and in-house control
- Description – IHC laboratories stain slides containing 4 breast carcinoma cell lines provided and also submit in-house control slide for evaluation. Scoring will be determined following review by four expert assessors and is as follows:
  - Acceptable – All four cell lines show expected staining and intensity
  - Acceptable but some disagreement between assessors – Two of the 4 assessors have scored the cell lines as having acceptable stain.
  - Unacceptable – Three of four assessors have assessed the cell lines as unacceptable, indicating inappropriate staining.

Eastern Health IHC laboratory participates in the HER2 proficiency testing but is currently validating the protocol in its laboratory and is not performing patient testing.



### 3. Alimentary Tract Pathology CD117 – Pilot Module

- Frequency – Twice per year
- Evaluation - Staining and pathologist interpretation
- Description – Specialist antibody for gastrointestinal stromal cell tumours (GIST). Scoring will be as follows:

Acceptable	> 12 / 20
Borderline	10 – 12 / 20
Unacceptable	< 10 / 20

### 3. Lymphoid Pathology

- Frequency – Four Times per year
- Evaluation – Staining and pathologist interpretation of NEQAS and in-house slides.
- Description – Four assessments per year with two antigens at each run. The gold standard for 2008 will be Cyclin D1 (Mantle Cell Lymphoma) Four different antibodies will be assessed along with the gold standard. Scoring is as follows:

Acceptable	> 12 / 20
Borderline	10 – 12 / 20
Unacceptable	< 10 / 20



**1. College of American Pathologists (CAP) Proficiency Surveys and Anatomic Pathology Education Programs**

The College of American Pathologists offers proficiency and education program to promote laboratory performance improvement through an educational peer-comparison program..”

	HQIP Fixation, Microtomy, Staining	Predictive Marker (PM) CD20	Predictive Marker (PM) ER	MK Survey PR
2006	Average to excellent results	GOOD		GOOD
2007	Average to excellent results	GOOD	GOOD	*

\* The IHC laboratory participates in the CAP MK survey which is for educational purposes. The following antibodies are among those tested at Eastern Health IHC laboratory as part of the CAP proficiency MK Survey program and received a grade of GOOD in 2006:

- CD3
- CD5
- CD20
- 34BE12

The CAP no longer provides a grade for the markers in the MK program. The IHC laboratory continues to participate in the MK survey with good correlation for the technical IHC laboratory and pathologists' interpretations.

Comment: On its survey report to the laboratory, the College of American Pathologists "recommends that the result of this inter-laboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory"





**2. United Kingdom National External Quality Assessment Scheme (UK NEQAS)**

**Scores for ER and PR**

Acceptable scores for ER and PR will be greater than or equal to 13 / 20

	2005	2006 #1	2006 #2	2007 #1
<b>ER</b>	16	16	20	18
<b>PR</b>		16	14	16

**3. Additional Quality Assurance- Breast Pathology**

In addition to the proficiency testing programs of CAP and UK NEQAS, the Eastern Health Pathology laboratory conducts the following for breast cases:

- Dr. B Carter has indicated that Dr D. Cook and Dr. B. Carter send breast cases to Mt. Sinai for review, with excellent concordance to date
- In a memo to Dr. N. Denic, Dr. B. Carter indicates that in 2007, as of November 20, 147 estrogen receptor tests were performed at Eastern Health IHC laboratory. Of these cases, "35 were ER negative, a 24% negative rate." A total of 24 of the cases were sent to Mt Sinai for quality assurance "with excellent concordance."

Daily Laboratory Quality Control is performed with every Immunohistochemistry run. External proficiency testing must not be a sole measure of laboratory performance and must be considered in conjunction with intra-laboratory quality control and clinical correlation.

All proficiency testing records are available on request.

