HealthCare Corporation of St. John's MEMO

27 681

 TO: Provincial Laboratory Directors Program Director, Laboratory Medicine Program Divisional Managers, Division of Anatomic Pathology
FROM: Dr. D. Cook Acting Clinical Chief - Laboratory Medicine Program
DATE: April 27, 2000
RE: HER 2/neu Expression

Effective April 1, 2000, pathologists at the Health Care Corporation of St. John's have begun reporting on HER 2/neu overexpression. HER 2/neu overexpression will only be reported following a request from Oncology. We are using the DAKO Kit which has been approved by FDA and Health Canada. We are using the grading system as our standardized way of reporting. This grading system was also recommended by the Dako Corporation, as per our meeting with DAKO representatives on October 15, 1999. We will be remodelling our standardized report based on the Mayo Clinic report. Reporting of HER 2/neu protein overexpression is given as negative, weakly positive or strongly positive. This is followed by the score. This information is submitted on top of the report. An explanation of the scoring system is given underneath and is also submitted as part of the report. Attached is a form outlining the scoring system.

We will be able to perform HER 2/neu Immunoperoxidase stains on paraffin blocks on cases referred in. Once the stains are completed, both the paraffin blocks and the slides will be referred back to your hospital. At this point in time, reporting of HER 2/neu overexpression will be the responsibility of the pathologist who ordered the stain. It is also recommended that for evaluation of breast biopsies for HER 2/neu overexpression, the biopsies should be fixed overnight for at least 18 hours.

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

Sincerely yours,

Sonald M Cook

Donald M. Cook, MD, FRCPC, FCAP

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CIHRT Exhibit P-1870 Page 2

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Æ: 06/0 ME: 1131		LABORATORY NPR - HCC **LIVE** PTH CANNED TEXT DICTIONARY	антанан түрэгээ түрэгээ түрэгээ түрээ т м	PAGE 1
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HER2 Y	HER2/NEU IMMUNOPEROXIDASE	N 92		
	TEXT			
	The HCCSJ uses the interpret the FDA and CSA approved to follows:	etation guidelines as recommended by the sting method for Her2/neu overexpression	ne DAKO Herceptest. which is on. The guidelines are as	
· · · · · ·	STAINING INTENSITY SCORE	STAINING PATTERN	HER2 OVEREXPRESSION ASSESSMENT	
	0	No staining is present or partial membrane staining is present in less than 10% of maligant cells.	Negative	
	1+	Weak/barely perceptible membrane staining is present in greater than 10% of malignant cells. but the cells are only	Negative	-
	2+	Weak to moderate complete memebrane staining is present in greater than 10% of malignant cells.	Weakly Positive	
*	3+	Strong complete membrane staining is present in greater than 10% of malignant cells.	Strongly Positive	

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