

Scheme 2006, Assessment Run B1

Aalborg, 21 April 2006

Dear participant

Please find enclosed a pair of unstained sections for HER-2 and estrogen receptor α . Please note your three digit participant number (NQC...) shown on the address label and slides. This number must be indicated on all new slide labels and used for any communication with NordiQC.

Stain the sections according to your immunohistochemical protocol, and return for each marker one stained slide. Together with the HER-2 stain send the scoring slip also marked with your participant number to NordiQC at the above mentioned address not later than **7 May**. Keep the remaining NordiQC slide as your control.

Alternatively, if FISH/CISH is performed in your laboratory, you may hybridise the slide that you keep, and write the amplification score at the scoring slip. Do **not** send a FISH/CISH stained slide to NordiQC.

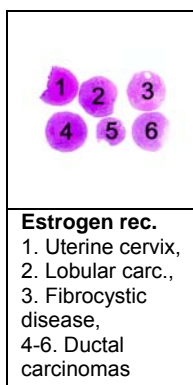
All stained slides submitted before deadline will be assessed, and the general results communicated on the website about 1 July. Examples of optimal as well as insufficient stains will be illustrated (anonymously) and the corresponding methods described. The origin of recommended protocols giving optimal results is published, encouraging technicians and pathologists to communicate directly.

About 7 July each laboratory will receive an e-mail with their individual assessment scores and possibly comments to the stains and suggestions for protocol improvement.

For the assessment of HER2 a multitissue block is composed containing 4 cell lines - BT474, JIMT-1 MCF-7 and MDA-453 - and 4 breast carcinomas (all fixed in 10 % neutral buffered formalin and paraffin-embedded) with different HER2 gene expressions (verified by FISH and CISH analyses) and immunohistochemical staining results (using the FDA approved HercepTest and the mAb clone CB11).

Since both IHC staining and its concordant interpretation are important for correct classification of HER-2 status, we have constructed a website containing reference HER-2 IHC-stains presented with a web-based virtual microscopy technique. The material consists of eight routinely formalin-fixed paraffin-embedded breast tumours stained with HercepTest kit. If you haven't tried already, we encourage you to visit the website, which can only be accessed via the protocol form (click on [HER-2 WebMicroscope](#) in the top menu bar) and score the slides using the 0/1+/2+/3+ scoring scheme. The scores are entered in the website. Once you have entered your IHC score of a tumour, you can review the gene amplification status by viewing the CISH hybridisation done on an adjacent slide. EQA using virtual microscopy is a new promising technique, and we would like to have your feedback of it.

Monographs describing HER-2 and ER are available on the website. Submitted sections are stored in the NordiQC file for future documentation. The laboratories can request their stained sections for review in case their control set is lost.




Content of the multitissue sections for ER

Top row closest to the glass label

continued ...

Content of the multitissue sections for HER-2

Top row closest to the glass label (1-4. Cell cultures, 5-8. Breast ductal carcinomas).

		IHC: HER-2 Score (0, 1+, 2+, 3+)*	ISH: Amplification (yes, no, not done)	Comments
	1. Cell line			
	2. Cell line			
	3. cell line			
	4. Cell line			
	5. Breast ductal carcinoma			
	6. Breast ductal carcinoma			
	7. Breast ductal carcinoma			
	8. Breast ductal carcinoma			

*) Guidelines how to score/interpret the HER2-result:

Score 0	No staining is observed or cell membrane staining is observed in less than 10% of the tumour cells.
Score 1+	A faint perceptible membrane staining can be detected in more than 10% of the tumour cells. The cells are only stained in part of their membrane.
Score 2+	A weak to moderate complete membrane staining is observed in more than 10% of the tumour cells.
Score 3+	A strong complete membrane staining is observed in more than 10% of the tumour cells.


If another scoring system is used (i.e. positive, negative) this should be noted on the slip returned to NordiQC with the stained slides.

Best regards,

NordiQC

Mogens Vyberg
Scheme manager

Participant No. NQC _____

		IHC: HER-2 Score (0, 1+, 2+, 3+)	ISH: Amplification** (yes, no, not done)	Comments
	1. Cell line			
	2. Cell line			
	3. Cell line			
	4. Cell line			
	5. Breast ductal carcinoma			
	6. Breast ductal carcinoma			
	7. Breast ductal carcinoma			
	8. Breast ductal carcinoma			

**Method: _____

Please return this slip with the slides