December 2023

Dear colleagues

Please take notice of the following important information. Immediate action may be required.

For all pathologists and laboratories not using standardized reporting (SR) level IV or higher yet, the use of these templates (in Dutch and French) hereafter is 'mandatory' (= strongly recommended) for the reporting of the results of estrogen receptors (ER), progesterone receptors (PR) and HER2 for breast cancer from January 1st, 2024.

The use of these templates will subsequently be monitored by the Belgian Cancer Registry (BCR) through our reports transmitted on regular basis as we are used to.

When ER, PR, HER2 as *companion diagnostic immuno (CDi)* are not reported according to these recommendations, this may lead to reimbursement denial of these tests at a higher tariff anymore. Standardized reporting of our CDi's is also a prerequisite for future flexible use of 588976-588980 (= nomenclature number that may be used for ER, PR, HER2, ALK, ROS1, TRK, PD-L1), i.e. for other biomarkers in the pipeline.

Note that the use of specific words (e.g. equivocal), spaces and some specific characters such as ':', '-' and '(' is important since our reports will be automatically scanned for these words and characters by AI-software (NLP) of the Belgian Cancer Registry (BCR) and the captured results stored for quality monitoring purposes. Therefore, please use this exact template in your reports or software used for reporting (e.g. by copy/paste if possible). The layout (**bold**, *italic* and underlined) is not of importance since the text transferred to the BCR is plain, unformatted text.

Labs already using standardized reporting level IV or higher do not have to comply to this recommendation but are recommended to take contact with the BCR in order to find the most appropriate way to get their results to the BCR.

These templates can be used as a (part of a) report as such, or as an addendum or as a complementary report.

Please share this communication with your colleagues and residents/trainees since it applies to everyone (French-speaking and Flemish) and the measures (rewarding or non-reimbursement at higher tariff) may be taken on lab and/or national level.

Important to keep in mind: the data collected from our reports by the BCR will be shared with the BSP and the Commission on AP in order to monitor the quality and get more insight into possible causes of variability in quality, as we did past years. These data may also be relevant for the BSP for scientific purposes.

Recommended template in Dutch

Resultaat ER (*3): *1
Resultaat PR (*3): *1
Resultaat HER2-IHC (*3): *2

Opmerkingen: optioneel
Interpretatie ER/PR volgens ASCO/CAP guidelines 2020 voor borstkanker.
Interpretatie HER2 volgens ASCO/CAP guidelines 2018 voor borstkanker.

Recommended template in French

Résultat RO (*3): *1
Résultat RP (*3): *1
Résultat HER2-IHC (*3): *2
Remarques: optionnel
Interprétation RO/RP selon les ASCO/CAP guidelines 2020 pour le cancer du sein.
Interprétation HER2 selon les ASCO/CAP guidelines 2018 pour le cancer du sein.

Explanation

*1 Limited possibilities in order to standardize the output of ER and PR analyses

DUTCH	FRENCH
• Positief (>10%). 11-20% kleurt zwak aan. 21-30% matig 31-40% sterk 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%	• Positif (>10%). 11-20% d'intensité faible. 21-30% intermédiaire. 31-40% forte. 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
• Gering positief (1-10%).	• Faiblement positif (1-10%).
• Negatief (minder dan 1% nucleaire positiviteit).	• Négatif (positivité nucléaire inférieure à 1%).

*2 Limited possibilities in order to standardize the output of HER2 analysis

DUTCH	FRENCH
• HER2 negatief (score 0).	• HER2 négatif (score 0).
• HER2 negatief (score 1+).	• HER2 négatif (score 1+).
• HER2 equivocal (score 2+).	• HER2 équivoque (score 2+).
• HER2 positief (score 3+).	• HER2 positif (score 3+).

Important notes

1. It's allowed to add free text after these standard texts, e.g. "Reflex FISH will follow." or "FISH has already been done."
2. It's not recommended to use "HER2-low" and "HER2-ultra low" in your pathology reports.

*3 It is useful to know whether the CDi is mostly done on CNB or on the resection specimens.

DUTCH	FRENCH
• CNB	• Biopsie
• Operatiespecimen	• Pièce opératoire
• Andere: bv. cytologie, metastase...	• Autre: p.ex. cytologie, metastase...

Free text is allowed after these sentences.

Examples in Dutch and French

Resultaat ER (CNB): Positief (>10%). 91-100% kleurt sterk aan.
Resultaat PR (CNB): Negatief (minder dan 1% nucleaire positiviteit).
Resultaat HER2-IHC (CNB): HER2 negatief (score 0).

Opmerkingen: zwakke,
partiële membranaire aankleuring voor HER2 in ±5% van de tumorcellen.
Interpretatie ER/PR volgens ASCO/CAP guidelines 2020 voor borstkanker.
Interpretatie HER2 volgens ASCO/CAP guidelines 2018 voor borstkanker.

Résultat RO (pièce opératoire): Positif (>10%). 11-20% d'intensité faible.
Résultat RP (pièce opératoire): Négatif (positivité nucléaire inférieure à 1%).
Résultat HER2-IHC (pièce opératoire): HER2 positif (score 2+). Test ISH réflexe désigné.
Interprétation RO/RP selon les ASCO/CAP guidelines 2020 pour le cancer du sein.
Interprétation HER selon les ASCO/CAP guidelines 2018 pour le cancer du sein.