Mid October 2024

Dear colleagues

Please take notice of this update on the guidelines of standardized reporting (SR) of the results of estrogen receptors (ER), progesterone receptors (PR) and HER2 for breast cancer. Immediate action may be required since this update takes place from January 1st, 2025. All updates on the former version are marked in yellow.

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

The use of these templates will 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 immunohistochemistry(CDi)* are not reported according to these recommendations, this could potentially result in a refusal of the reimbursement at a higher tariff (i.e. the so-called pharmacodiagnostic test). Standardized reporting of these CDi is also a prerequisite for future flexible use of 588976-588980 (i.e. the nomenclature number that may be used for ER, PR, HER2, ALK, ROS1, TRK, PD-L1), and potentially for other biomarkers in the pipeline.

These recommendations do not apply to these immunohistochemistry markers when not used as CDi, but when used as diagnostic markers.

Notice that the use of specific words (e.g. equivocal), spaces and punctation marks such as ':', '-' and '(' are important since our reports will be automatically scanned for these words (including all spaces and punctation marks) by AI-software (Natural Language Processing or NLP) of the Belgian Cancer Registry (BCR). The captured results will be 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 contact 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 Dutch-speaking) and the subsequent measures (potential cessation of reimbursement as pharmacodiagnostic test) 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 of the reports. This will allow us to get more insight into possible causes of variability in quality, as we monitored during the past years. These data may also be relevant for the BSP for scientific purposes.

Kind regards,

Romaric Croes, on behalf of the Commission on Anatomic Pathology and The Breast Pathology Working Group of the Belgian Society of Pathology (BSP)

§ Error has been corrected on 20241109: The deletion and marking in yellow were removed by RC on advice of the BWGBP.

Recommended template in Dutch

Resultaat ER (*5): *1
Resultaat PR (*5): *1
Resultaat HER2-IHC (*5): *2
Besluit HER2-ISH (*5): *3
Resultaat HER2-status (IHC en ISH) (*5): *4
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 (*5): *1
Résultat RP (*5): *1
Résultat HER2-IHC (*5): *2
Conclusion HER2-ISH (*5): *3
Résultat statut HER2 (ISH et IHC) (*5): *4
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%).	•	Positif (>10%).
11-20%	kleurt zwak aan.	11-20%	d'intensité faible.
21-30%	matig	21-30%	intermédiaire.
31-40%	sterk	31-40%	forte.
41-50%		41-50%	
51-60%		51-60%	
61-70%		61-70%	
71-80%		71-80%	
81-90%		81-90%	
91-100%		91-100%	
•	Gering positief (1-10%).	•	Faiblement positif (1-10%).
•	Negatief (minder dan 1% nucleaire positiviteit).	•	Négatif (positivité nucléaire inférieure à 1%).

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Important note

1. It is at the lab's discretion to report ER and PR as a continuous variable (instead of using decentiles), e.g. 22% kleurt matig aan.

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

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

DUTCH	FRENCH
• Geamplificeerd.	• Amplifié.
• Niet-geamplificeerd.	• Non-amplifié.
• Equivocal (CAP groep 2, 3 of 4).	• Equivoque (CAP groupe 2, 3 of 4).
• Niet interpreteerbaar.	• Non interprétable.
• Niet uitgevoerd.	• Pas effectué.

Important note

1. It's allowed to add free text after these standard texts.

***4** Limited possibilities to standardize the output of HER2 status (IHC and ISH combined):

DUTCH	FRENCH
• Positief.	• Positif.
• Negatief.	• Négatif.

Important notes

1. It's allowed to add free text after these standard texts.
2. It's not recommended to use "HER2-low" and "HER2-ultra low" in your pathology reports.

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

DUTCH	FRENCH

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- CNB
- Operatiespecimen
- Andere: bv. cytologie, metastase...

- Biopsie
- Pièce opératoire
- Autre: p.ex. cytologie, métastase…

Free text is allowed after these sentences.

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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).
Besluit HER2-ISH (CNB): Niet-geamplificeerd.
Resultaat HER2-status (IHC en ISH) (CNB): Negatief.

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.
Conclusion HER2-ISH (pièce opératoire): Non-amplifié.
Résultat statut HER2 (ISH et IHC) (pièce opératoire): Négatif.

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.

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