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HER2 reporting in **breast cancer**

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Have you updated your reporting **practice on HER2 expression?**

Check whether your lab's report format enables you to record comprehensive details of the parameters assessed for HER2 to ensure that HER2 status is more accurately captured. This will bring clarity to oncologists when considering the optimum treatment options for their patients[1-3].

Recent updates to country-specific guidelines recommend that specimens scored as IHC 1+ or IHC 2+/ISH- can now be categorised as HER2-low. HER2-low classification utilises existing ASCO/CAP parameters for IHC assessment[3-6].

	IHC 0 No staining OR faint, incomplete staining in <10% of cells	**IHC 1+** Faint incomplete or weak complete membrane staining in ≤10% of cells	**IHC 2+** Weak-moderate or strong-moderate staining in ≤10% of cells		**IHC 3+** Intense complete staining in >10% of cells
Current binary paradigm†	**HER2 - negative**		**ISH-**	**ISH+**	**HER2-positive**
Paradigm inclusive of HER2-low	**HER2-null**	**HER2-low** IHC 1+ or IHC 2+/ISH-			**HER2-positive**

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HER2 expression **pathology report checklist**

Consider including the following in the pathology report:

Specify the HER2 IHC assay used [2,4,7-10]

Assay selection can be an important factor when determining low levels of HER2 expression, as assays were historically optimised to detect high levels of HER2 expression. Ensure the HER2 IHC assay has been validated to detect HER2-low

Report the HER2 IHC score as 0, 1+, 2+ or 3+[1-3,5-7]

Complement with information on the guidelines followed by the lab

Report the HER2 ISH result (if completed) as negative or positive, as well as the HER2 and CEP17 copy number and ratio[1,2,5,6]

Reflex ISH is performed on samples scored as HER2 IHC 2+ or indeterminate to assess final HER2 status

Report the complete HER2 status, including IHC score[2-6]

- HER2-null (IHC 0)
- HER2-low (IHC 1+ or IHC 2+/ISH-)
- HER2-positive (IHC 2+/ISH+ or IHC 3+)

Include the estimated percentage of tumour cells stained‡ and staining intensity[§1,2,5,6]

Documenting this level of detail for IHC staining is important in differentiating between IHC 0 and IHC 1+, and therefore HER2-null or HER2-low status

Conclude the report with the final HER2 interpretation and estimated percentage staining[1-3,5-7]

Specify any notable specimen, pre-analytical, and IHC/ISH scoring factors that influenced the interpretation

† IHC 0: no staining observed or incomplete and faint/barely perceptible in ≤10% tumour cells; IHC 1+: incomplete membrane staining that is faint/barely perceptible in >10% of tumour cells; IHC 2+: weak to moderate complete membrane staining observed in >10% of tumour cells; IHC 3+: circumferential membrane staining observed in >10% of tumour cells

‡ Range (1–10% or >10%) and actual percentage of staining. § Partial, weak, moderate or strong staining.

1. Royal College of Pathologists. Pathology reporting of breast disease in surgical excision specimens incorporating the dataset for histological reporting of breast cancer. https://www.rcpath.org/resourceLibrary/ g148-breastdataset-hires-jun16-pdf.html. Accessed March 2024. 2. College of American Pathologists. Template for reporting results of biomarker testing of specimens from patients with carcinoma of the breast. March 2023. (Accessed March 2024). 3. Rakha EA, et al. J Clin Pathol. 2023;76(4):217–227. 4. Modi S, et al. New Engl J Med. 2022;387(1): 9–20. 5. Wolff AC, et al. J Clin Oncol. 2018;36:2105–2122. 6. Franchet C, et al. Ann Pathol. 2021;41(6):507–520.7 . Viale G, et al. Presented at ASCO Virtual Congress 2022. 4–8 June. Poster 465 HER2-15. 8. Scott M, et al. Presented at ASCO Virtual Congress 2021. 4–8 June. Abstract 1021. 9. Rüschoff J, et al. Virchows Archiv. 2022; 481:685–694. 10.Roche Diagnostics. https://diagnostics.roche.com/global/en/news-listing/2022/roche-receives-fda-approval-for-first-companion-diagnostic to-id.html. Accessed March 2024.