

HER2 in breast cancer and scoring guidance

HER2Know.com can be accessed via this QR code



Guidance on evaluating HER2 expression by IHC¹⁻⁴

Membrane staining	Visual estimate	Staining pattern and intensity	Magnification rule	Score
None	0 tumor cells	Membrane staining not present	No staining visible at any magnification, 4X(5X)* to 40X	IHC 0/absent membrane staining
Incomplete	≤10% tumor cells	Faint/barely perceptible	Staining barely perceptible at 4X(5X)* and 10X, visible at 20X and confirmed at 40X	IHC 0+/with membrane staining
	>10% tumor cells	Faint/barely perceptible	Staining barely perceptible at 4X(5X)* and 10X, visible at 20X and confirmed at 40X	IHC 1+
	>10% tumor cells	Moderate to strong	Staining visible at 4X(5X)*, confirmed at 10–20X	IHC 2+
Complete	>10% tumor cells	Weak to moderate	Staining visible at 4X(5X)*, confirmed at 10–20X	IHC 2+
	≤10% tumor cells	Strong	Staining visible at 4X(5X)*, confirmed at 10–20X	IHC 2+
	>10% tumor cells	Strong/intense	Readily visible 'chicken wire' pattern at 4X(5X)*	IHC 3+

When close to the cut-off point, it may be necessary to perform actual cell counts. Three representative fields at 40X or greater magnification should be chosen, and 100 cancer cells per field counted.⁴

*Depending on the type of objectives available, pathologists will use 4X or 5X.

Optimal tissue handling and sectioning requirements³

- The time from tissue acquisition to fixation should be as short as possible
- Tissue samples should be sectioned at 5–10 mm intervals
- Tissue samples should be fixed in 10% neutral buffered formalin for 6–72 hours
- Cut sections of tissue samples should be processed within 6 weeks

HER2 evaluation by IHC^{1,3,5,6}

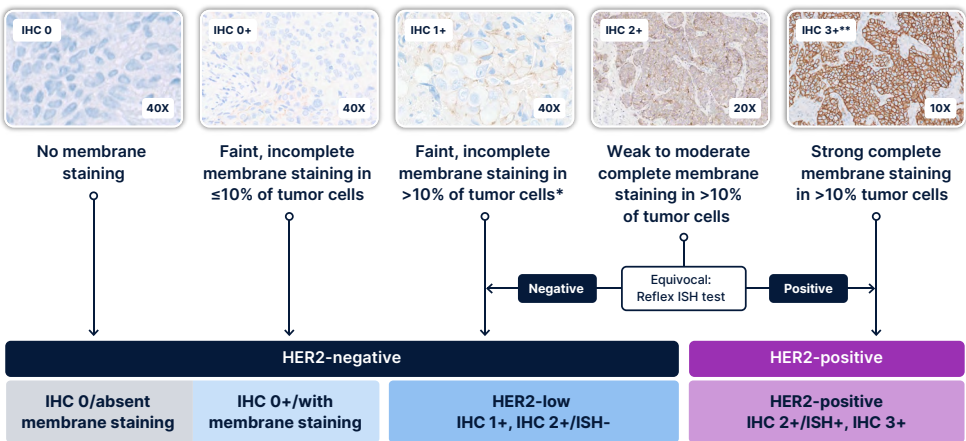


Figure adapted from CAP. Reporting Template for Reporting Results of Biomarker Testing of Specimens from Patients with Carcinoma of the Breast. Version: 1.6.1.0. Wolff AC, et al. 2023, Tarantino P, et al. 2020, Roy AM, et al. 2023.^{1,3,5,6} Images supplied by HER2Know⁷

Method for consensus scoring

Select breast cancer cases within the HER2Know IHC image gallery were independently reviewed and scored by expert breast pathologists to establish consensus. HER2 IHC interpretation was based on recommendations from the 2023 ASCO-CAP guideline updates,³ and expert alignment on analyzing staining patterns and intensity.

*This definition does not cover unusual staining patterns that are considered HER2 IHC 2+, such as moderate to intense but incomplete membrane staining and circumferential membrane staining that is intense but in ≤10% of tumor cells.³ **The image shown is the positive control.

ASCO, American Society of Clinical Oncology; CAP, College of American Pathologists; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, *in situ* hybridization.

1. CAP. Reporting Template for Reporting Results of Biomarker Testing of Specimens from Patients with Carcinoma of the Breast. Version: 1.6.1.0. 2. Tozbikian G, et al. Histopathology 2024;85(3):489–502. 3. Wolff AC, et al. Arch Pathol Lab Med 2023;147(9):993–1000. 4. PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody Interpretation Guide for Breast Cancer, 14991US Rev A 2025-01-28. 5. Tarantino P et al. J Clin Oncol 2020;38(17):1951–1962. 6. Roy AM, et al. Cancer 2023;129(18):2773–2788. 7. HER2Know.com. Daiichi Sankyo Inc. and AstraZeneca. Accessed August 5th, 2025.

This resource is intended for use by US healthcare professionals only.

©2025 Daiichi Sankyo, Inc. and AstraZeneca. PP-US-8201a-2212 09/25 US-104093