

DATE:	19 January 2026
TO:	Breast Cancer Care Teams (Alberta)
FROM:	Edmonton Zone Immunohistochemistry Laboratory, Alberta Precision Laboratories (APL)
RE:	Updated Reporting of HER2 Breast Biomarker Assay (Immunohistochemistry)

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message

- To accommodate the new HER2 ultralow designation, the HER2 Negative (Score 0) category in the breast biomarker report (immunohistochemistry) is now updated to *either*
 - **Negative (Score 0 / Absent membrane staining)** for the **HER2 null subset** or
 - **Negative (Score 0+ / WITH membrane staining)** for the **HER2 ultralow subset**.

Background

- Breast cancers with HER2 IHC scores of 0+, 1+, or 2+ (ISH negative) may be eligible for treatment targeting non-amplified levels of HER2 expression in the metastatic setting. Specifically, in the DESTINY-Breast 04 and 06 trials, “HER2 low” was considered IHC Score 1+ or 2+ / ISH negative, and “HER2 ultralow” was HER2 IHC Score of 0 (pattern 0+) with membrane staining that is incomplete and faint / barely perceptible in less than or equal to 10% of tumor cells. Breast cancers with these staining patterns may be eligible for treatment with trastuzumab-deruxtecan in the metastatic setting (but those with no staining, IHC 0, are currently excluded).
- **The HER2 Score 0 reporting change reflects recommendations from the current College of American Pathologists (CAP) Breast Biomarker reporting guideline (v1.6.1.0, June 2025).**

How this will impact you

- The language used in the HER2 Score 0 result in breast biomarker reports is updated to reflect the new HER2 ultralow group.
- Definitions of HER2 ultralow (and HER2 low) are now provided in the comment section of the report.

Action Required

- **No action required and no change to test request process.**
- This bulletin is circulated for awareness only.

Effective **January 12, 2026 (Edmonton Zone). Calgary Zone implementation has already occurred.**

Questions/Concerns

- *Edmonton:* Dr. Gilbert Bigras Gilbert.Bigras@albertaprecisionlabs.ca
- *Calgary:* Dr. Chad Luedtke Chad.Luedtke@albertaprecisionlabs.ca

Approved by

- Dr. Michael Mengel, North Sector Medical Director, APL
- Dr. Kate O'Connor, South Sector Medical Director, APL