

High Sensitivity-HER2

Yale Pathology Labs is pleased to offer High Sensitivity (HS)-HER2 testing through Yale's CLIA lab to stratify the lower ranges of HER2 expression for treatment decisions. Our assay uses more antibody than traditional legacy assays and increases the resolution to stratify HER2 expression to provide a quantitative measurement in attomole/ mm^2 .

Patients with lower levels of HER2 protein need more specific results. This is increasingly important as new treatment options, such as the antibody drug conjugate Trastuzumab deruxtecan (T-DXd), have become available for patients with breast cancer and low HER2.

Why HS-HER2?

- About 70% of breast cancer patient cases are defined as having low HER2.
- The current, FDA-approved HER2 assay for T-DXd is not sensitive enough to measure low levels of HER2 accurately.
- Many cases that are called HER2=0 have detectable amounts of HER2.
- The quantitative assay developed by Yale Pathology Labs is available as a reflex test for HER2=0 cases to detect patients with Low HER2 expression in an automated, non-subjective manner.
- Although the assay is a lab developed test and has been validated to CAP/CLIA requirements, it is not yet FDA-approved.

Superior Customer Service

- Timely and accurate results
- Access to results using the RELAY web portal
- Customized patient reports
- Dedicated Physician Liaison assigned to your account

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