

TRICORE IMPLEMENTS NEW DIAGNOSTIC GUIDELINES TO IMPROVE *HER2* FISH ANALYSIS

The Cytogenetics Laboratory at TriCore Reference Laboratories has long partnered with clients and sponsor institutions to provide the highest quality analysis for *HER2* amplification in breast cancer – a critical determination for selecting effective targeted therapy.

Updated guidelines from the American Society of Clinical Oncology (ASCO) and the College of American Pathologists (CAP) recommend several important changes in the laboratory workup for *HER2* analysis by fluorescence in situ hybridization (FISH). In particular, the new guidelines call for the concomitant review of both the FISH hybridization pattern and the *HER2* immunohistochemistry (IHC) slide “**in the same institution** to ensure parallel interpretation” (emphasis added). Thus, TriCore’s new *HER2* algorithm described below, includes two ways to ensure that the *HER2* IHC slide is available to guide the FISH analysis, as required by the guidelines.

The major practice advantages you will see with this new approach are:

- Fewer equivocal *HER2* results: by incorporating the IHC slide into the interpretive criteria, the new guidelines eliminate categories that were considered “equivocal” for *HER2* amplification under the older system. Patients and clinicians will benefit from clear and unambiguous results for *HER2* status.
- TriCore’s team of cytogeneticists and anatomic pathologists will provide expert guidance in applying the new criteria, including the proper workup and treatment options for the newly described Group 2, Group 3, and Group 4.

NEW *HER2* FISH TESTING REQUIREMENTS

Clients are encouraged to choose one of the following two options to ensure a quick turnaround time for *HER2* FISH testing.

1. Send both the paraffin block* and *HER2* IHC slide with the strongest staining areas circled to guide the FISH reading. Please submit the pathology report as well. No charge will be generated for review of the provided *HER2* IHC slide. Both the block and IHC slide will be returned expeditiously after the testing is completed.
2. If the client sends the paraffin block* without an accompanying *HER2* IHC slide, *HER2* IHC will be performed in selected cases as indicated below at TriCore, with an additional technical charge:
 - i. If the initial FISH data is scored as either positive or negative, no *HER2* IHC will be performed (no charge will be generated).
 - ii. If initial FISH results fall into any other category (see guideline, groups 2-4), *HER2* IHC will be performed (with additional charge) to guide further FISH scoring as dictated by the guideline.

We look forward to working with our clients and sponsor institutions to improve patient care by implementing these rigorous new interpretive criteria.

* Four unstained sections may be sent instead of the paraffin block.

Reference

Wolff AC, Hammond MEH, Allison KH, et al.: Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. J Clin Oncol doi:10.1200/JCO.2018.77.8738