**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:
   - If the initial FISH data is scored as either positive or negative, no HER2 IHC will be performed (no charge will be generated).
   - 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**