

NEW TEST ANNOUNCEMENT

NOTIFICATION DATE: January 14, 2011 **EFFECTIVE DATE:** January 19, 2011

HER2 Amplification Associated with Gastroesophageal Cancer, FISH, Tissue #60620

USEFUL FOR:

- To guide therapy for patients with gastroesophageal cancer, as patients with *HER2* amplification may be candidates for Herceptin therapy.
- To confirm the presence of *HER2* amplification in cases with 2+ (low-level) or 3+ (high-level) HER2 protein overexpression by immunohistochemistry

METHODOLOGY: Fluorescence in situ hybridization (FISH)

REFERENCE VALUES: An interpretative report is provided.

SPECIMEN REQUIREMENTS: Formalin-fixed, paraffin-embedded gastroesophageal cancer tissue block

NOTE: Please provide a pathology report with each tissue specimen. The pathology report must include type of fixation used (ie, >6 hours and <48 hours). The laboratory will not reject a specimen that arrives without this information but will hold analysis of the specimen until a pathology report is received.

CAUTIONS:

- This test is only for primary or metastatic gastroesophageal tumors. For breast tumors, order #81954 "*HER2* Amplification Associated with Breast Cancer, FISH, Tissue," for other tumor types, order #60655 "*HER2* Amplification, Miscellaneous Tumor, FISH, Tissue."
- This indication for the *HER2* FISH test is not approved by the FDA and should be used as an adjunct to existing clinical and pathologic information.
- The assay has been optimized for formalin-fixed, paraffin-embedded tissue specimens. Optimum fixation should be between 6 and 48 hours in 10% neutral buffered formalin. Other types of fixatives should not be used.
- The prognostic information provided by the *HER2* status of a patient's tumor should not be interpreted in isolation because other prognostic features (eg, lymph node status, tumor size) may be of equal or greater importance in determining the patient's prognosis.

LIST FEE: \$695.60 ANALYTIC TIME: 8 days

CPT CODE:

88271 x 2-Molecular cytogenetics (eg, FISH), each probe 88274-Interphase in situ hybridization 88291-Cytogenetics and molecular cytogenetics, interpretation and report **DAY(S) SET-UP:** Monday through Friday; 6 a.m.-9 p.m.,

Saturday, Sunday; 6 a.m.-4 p.m.