



INTERPHASE FLUORESCENCE IN SITU HYBRIDIZATION TEST FOR BREAST CANCER TISSUES, GASTRIC/GASTRO-OESOPHAGEAL JUNCTION CARCINOMAS (GEJ) USING HER2 (ERBB2) DNA PROBE

Synonym(s): FISH HER2

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Lab Section Category	Cytogenetics - Cancer/Cancer FISH Click here to find out more about the write-up (/clinical-departments-centers/pathology/pathology-handbook/lab-discipline-special-instructions/pages/cytogenetics.aspx).
Indications	FISH test using HER2 (ERBB2) DNA-probe is used in the detection of amplification of the HER2 (ERBB2) gene that plays a key role in the regulation of cell growth. This gene is amplified in some patients with human breast and gastric cancer. These patients respond well to trastuzumab (Herceptin®) treatment.
Specimen Required	Newly-cut fresh breast cancer sections is ideal.
Storage and Transport	The FISH test is optimal with fresh tissue samples. Tissue sections should preferably be between 4 - 6mm in thickness on coated/positively-charged slides. The optimal fixation time in formalin should be between 6 - 72 hours. An accompanying Hematoxylin and Eosin (H&E) stained slide with the invasive tumour region marked out by a pathologist should be submitted together with at least 3 unstained sections.
Test Result	Findings are reported in accordance to the International System for Human Cytogenomic Nomenclature (ISCN, 2016).

Reference Interval/Value	<p>ASCO/CAP guidelines - Reference ranges for ERBB2 amplification:</p> <ol style="list-style-type: none"> 1. Positive - Ratio greater or equal to 2.0. 2. Positive - Ratio less than 2.0 with average ERBB2 copy numbers greater or equal to 6.0 signals/cell. 3. Equivocal - Ratio less than 2.0 with average ERBB2 copy numbers greater or equal to 4.0 and less than 6.0 signals/cell. 4. Negative - Ratio less than 2.0 with average ERBB2 copy numbers less than 4.0 signals/cell. <p>For gastric/GEJ carcinomas, results are positive if the ratio is ≥ 2.0</p>
Turnaround Time	3 ~ 10 days
Day(s) Test Set up	Monday – Saturday (office hours)

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Change History Notes

- 02 Feb 2015 12:31 PM**
 Revised Turnaround Time to within 9 days.

- 07 Dec 2015 04:40 PM**
 - Updated Turnaround Time: 3 ~ 10 days

- 06 Jul 2017 11:08 AM**
 - Updated the test result for ISCN, 2013 to ISCN, 2016

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