

**Overview****Useful For**

Determining overexpression of HER2 protein of gastric and esophageal adenocarcinoma in formalin-fixed, paraffin-embedded tissue sections (no reflex to FISH testing)

**Method Name**

Ventana Pathway Immunoperoxidase Stain with Manual Semi-Quantitative Immunohistochemistry

**NY State Available**

Yes

**Specimen****Specimen Type**

Special

**Ordering Guidance**

**If ordering for diagnostic purposes:** order PATHC / Pathology Consultation and then request the stains.

For specimens such as intestine, liver, colon, which do not contain metastatic adenocarcinoma from the stomach or esophagus, order H2BR / HER2 Amplification, Miscellaneous Tumor, FISH, Tissue.

For breast cancer specimens, order HERBA / HER2, Breast, Quantitative Immunohistochemistry, Automated with HER2 FISH Reflex or HERBN / HER2, Breast, Quantitative Immunohistochemistry, Automated, No Reflex.

**Shipping Instructions**

Attach the green pathology address label included in the kit to the outside of the transport container.

Ship ambient.

**Necessary Information**

**Include accompanying pathology report stating the final diagnosis.** If not available, a preliminary diagnosis is acceptable **only** if it refers to invasive or metastatic gastric or esophageal adenocarcinoma.

**Specimen Required**

**Only formalin-fixed, paraffin-embedded (FFPE) gastric or esophageal adenocarcinoma specimens will be accepted.** Fixation in 10% neutral-buffered formalin is preferred. The performance and quality of immunohistochemical stains in 10% neutral-buffered FFPE tissue depends on proper fixation. It is recommended (not required) for surgical specimens to be fixed between 18 and 24 hours and biopsy specimens between 6 and 8 hours.

**If being ordered for prognostic purposes:****Specimen Type:** Gastric or esophageal adenocarcinoma**Supplies:** Pathology Packaging Kit (T554)**Preferred:** Paraffin-embedded tissue block containing invasive gastric or esophageal adenocarcinoma tissue**Additional Information:** Paraffin blocks will be returned with final report.**Acceptable:** Slides**Specimen Volume:** 5**Collection Instructions:** 5 Unstained sections, containing gastric or esophageal adenocarcinoma, on charged slides cut at 4 microns less than 1 month ago.**Forms**If not ordering electronically, complete, print, and send an [Immunohistochemical \(IHC\)/In Situ Hybridization \(ISH\) Stains Request](#) (T763)**Reject Due To**

No specimen should be rejected.

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Special	Ambient (preferred)		
	Refrigerated		

**Clinical & Interpretive****Clinical Information**

The *HER2* (official gene name *ERBB2*) proto-oncogene encodes a membrane receptor with tyrosine kinase activity and homology to the epidermal growth factor receptor.

Amplification and overexpression of the *HER2* gene have been associated with a shorter disease-free survival and shorter overall survival in gastric and gastroesophageal junction cancers, as well as breast, endometrial, and ovarian cancer.(1,2)

**Reference Values**

Reported as negative (0, 1+), equivocal (2+), and positive (3+)

**Interpretation**

Results are reported as positive (3+ HER2 protein expression), equivocal (2+), or negative (0 or 1+)

**Cautions**

No significant cautionary statements

**Clinical Reference**

1. Pergam M, Slamon D: Biological rationale for *HER2/neu* (*c-erbB2*) as a target for monoclonal therapy. *Semin Oncol* 2000;27(5):13-19
2. Gravalos C, Jimeno A: HER2 in gastric cancer: a new prognostic factor and a novel therapeutic target. *Ann Oncol* 2008 Sep;19(9):1523-1529
3. Meza-Junco J, Au HJ, Sawyer MB: Transtuzumab for gastric cancer. *Expert Opin Biol Ther* 1009;9(12):1543-1551

**Performance****Method Description**

Testing is performed on formalin-fixed paraffin-embedded tissue sections using Ventana Pathway Immunoperoxidase HER2 (4B5) rabbit monoclonal primary antibody and a proprietary detection system. No expression (HER2 score of 0), low expression (HER2 score of 1+) and high expression (HER2 score of 3+) controls are used. (Package insert: PATHWAY anti-HER-2/neu [4B5] Rabbit Monoclonal Primary Antibody; Ventana Medical Systems Inc 3/16/2012)

**Scoring:**

Scoring is performed for surgical and biopsy specimens according to the following article: Ruschoff J, Dietel M, Baretton G, et al: HER2 diagnostics in gastric cancer-guideline validation and development of standardized immunohistochemical testing. *Virchows Arch* 2010 Sep;457(3):299-307

**Surgical Specimen:**

Score of 0 is no reactivity or membranous reactivity (staining) in <10% of invasive tumor cells. Score of 1+ is faint/barely perceptible membranous reactivity (staining) in > or =10% of invasive tumor cells; cells are reactive (stained) only in part of their membrane. Score of 2+ is weak to moderate complete, basolateral, or lateral membranous reactivity (staining) in > or =10% of invasive tumor cells. Score of 3+ is strong complete, basolateral, or lateral membranous reactivity (staining) in > or =10% of invasive tumor cells.

**Biopsy Specimen:**

Score of 0 is no reactivity or no membranous reactivity (staining) in any invasive tumor cells. Score of 1+ is tumor cell cluster with a faint/barely perceptible membranous reactivity (staining) irrespective of percentage of invasive tumor cells stained. Score of 2+ is tumor cell cluster with a weak to moderate complete, basolateral, or lateral membranous reactivity (staining) irrespective of percentage of invasive tumor cells stained. Score of 3+ is tumor cell cluster with a strong complete, basolateral, or lateral membranous reactivity (staining) irrespective of percentage of invasive tumor cells stained.

\*Tumor cells cluster is defined as a cluster of 5 or more tumor cells by Ruschoff and colleagues (2010). There is no percentage cutoff in biopsy specimens for upper GI tract HER2 scoring.

**PDF Report**

No

**Day(s) Performed**

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Monday through Friday

**Report Available**

4 to 6 days

**Specimen Retention Time**

Until 1 week after results are reported. Materials made at Mayo Clinic may be retained at Mayo Clinic indefinitely.

**Performing Laboratory Location**

Mayo Clinic Laboratories - Rochester Main Campus

**Fees & Codes****Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

**CPT Code Information**

88360

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
HERGN	HER Gastric/Esoph IHC NO Reflex	Obsolete

Result ID	Test Result Name	Result LOINC® Value
MA021	Tumor classification	21918-8
70990	Interpretation	50595-8
70991	Participated in the Interpretation	No LOINC Needed
70992	Report electronically signed by	19139-5
70994	Material Received	81178-6
71626	Disclaimer	62364-5
71840	Case Number	80398-1