

## Overview

### Useful For

Qualitative detection of HER2 protein overexpression in a diagnostic setting in formalin-fixed paraffin-embedded tissue sections

### Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
IHTOI	IHC Initial, Tech Only	No	No
IHTOA	IHC Additional, Tech Only	No	No

### Testing Algorithm

For the initial technical component only immunohistochemical (IHC) stain performed, the appropriate bill-only test ID will be reflexed and charged (IHTOI). For each additional technical component only IHC stain performed, an additional bill-only test ID will be reflexed and charged (IHTOA).

### Method Name

Immunohistochemistry (IHC)

### NY State Available

Yes

## Specimen

### Specimen Type

TECHONLY

### Ordering Guidance

This test includes only technical performance of the stain (no pathologist interpretation is performed).

For immunostain detection of HER2 in invasive or metastatic breast primary specimens with interpretation and reflex fluorescence in situ hybridization (FISH) testing, order HERMB / HER2, Breast, Semi-Quantitative Immunohistochemistry, Manual with HER2 FISH Reflex.

For immunostain detection of HER2 in invasive or metastatic gastroesophageal adenocarcinoma primary specimens with interpretation and reflex FISH testing, order HERGM / HER2, Gastric/Esophageal, Semi-Quantitative Immunohistochemistry, Manual.

For immunostain detection of HER2 in invasive or metastatic gastroesophageal adenocarcinoma primary with

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interpretation but without reflex FISH testing, order HERGN / HER2, Gastric/Esophageal, Semi-Quantitative Immunohistochemistry, Manual, No Reflex.

For FISH HER2 testing in invasive or metastatic breast primary specimens with interpretation, order H2BR / *HER2* Amplification Associated with Breast Cancer, FISH, Tissue.

For FISH HER2 testing in invasive or metastatic primary gastroesophageal specimens with interpretation, order H2GE / *HER2* Amplification Associated with Gastroesophageal Cancer, FISH, Tissue.

For FISH HER2 testing in primary or metastatic tumor specimens which are not breast or gastroesophageal primary, order H2MT / *HER2* Amplification, Miscellaneous Tumor, FISH, Tissue.

For interpretation and diagnosis of submitted pathology specimens with appropriate additional stains and other ancillary testing, order PATHC / Pathology Consultation.

Additional material may be needed if alternative testing is requested. See the specific specimen requirements for the alternative requested testing.

### **Shipping Instructions**

Attach the green "Attention Pathology" address label (T498) and the pink Immunostain Technical Only label included in the kit to the outside of the transport container.

### **Specimen Required**

**Specimen Type:** Tissue

**Supplies:** Immunostain Technical Only Envelope (T693)

**Container/Tube:** Immunostain Technical Only Envelope

**Submit:**

-Formalin-fixed, paraffin-embedded tissue block

OR

-2 Unstained, positively charged glass slides (25- x 75- x 1-mm) per test ordered; sections 4-microns thick

### **Digital Image Access**

1. Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can be accessed through this website: <https://news.mayocliniclabs.com/pathology/digital-imaging/>

2. Clients ordering stains using a manual requisition form will not have access to digital images.

3. Clients wishing to access digital images must place the order for IHC stains electronically. Information regarding digital imaging can be accessed through this website: <https://news.mayocliniclabs.com/pathology/digital-imaging/#section3>

### **Forms**

If not ordering electronically, complete, print, and send a [Immunohistochemical \(IHC\)/In Situ Hybridization \(ISH\) Stains Request](#) (T763) with the specimen.

### **Reject Due To**

Wet/frozen	Reject
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tissue	
Cytology smears	Reject
Nonformalin fixed tissue	Reject
Nonparaffin embedded tissue	Reject
Noncharged slides	Reject
ProbeOn slides	Reject
Snowcoat slides	Reject

### Specimen Stability Information

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

### Clinical & Interpretive

#### Clinical Information

The human *HER2* gene (also known as *ERBB2* or *NEU*) encodes a protein often referred to as HER2 protein or P185(HER2). The HER2 protein is a membrane receptor tyrosine kinase with homology to the epidermal growth factor receptor (EGFR or HER1). The HER2 protein is a normal component expressed by a variety of epithelial cell types.

#### Interpretation

This test does not include pathologist interpretation, only technical performance of the stain.

The positive and negative controls are verified as showing appropriate immunoreactivity and documentation is retained at Mayo Clinic Rochester.

Interpretation of this test should be performed in the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

#### Cautions

Age of a cut paraffin section can affect immunoreactivity. Stability thresholds vary widely among published literature and are antigen dependent. Best practice is for paraffin sections to be cut within 6 weeks.

The charge of glass slides can be affected by environmental factors and subsequently may alter slide staining. Sending unsuitable glass slides can result in inconsistent staining due to poor slide surface chemistry.

Best practices for storage of positively charged slides:

- Minimize time slides are stored after being unpackaged
- Limit exposure to high humidity and heat
- Minimize exposure to plastics

### **Clinical Reference**

1. Calhoun BC, Collins LC. Predictive markers in breast cancer: an update on ER and HER2 testing and reporting. *Semin Diagn Pathol.* 2015;32(5):362-369. doi:10.1053/j.semdp.2015.02.011
2. Bahreini F, Soltanian AR, Mehdipour P. A meta-analysis on concordance between immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH) to detect HER2 gene overexpression in breast cancer. *Breast Cancer.* 2015;22(6):615-625. doi:10.1007/s12282-014-0528-0
3. Wolff AC, Hammond EH, Hicks DG, et al. Recommendations for human epidermal growth factor receptor 2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists clinical practice guideline update. *J Clin Oncol.* 2013;31(31):3997-4013. doi:10.1200/JCO.2013.50.9984

### **Performance**

#### **Method Description**

Immunohistochemistry on sections of paraffin-embedded tissue.(Unpublished Mayo method)

#### **PDF Report**

No

#### **Day(s) Performed**

Monday through Friday

#### **Report Available**

1 to 3 days

#### **Specimen Retention Time**

Until staining is complete.

#### **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.

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- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

88342-TC, Primary

88341-TC, If additional IHC

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
HER2I	HER2 IHC, Tech Only	Order only;no result

Result ID	Test Result Name	Result LOINC® Value
70770	HER2 IHC, Tech Only	Bill only; no result