MAYO CLINIC LABORATORIES

Test Definition: HERDM

HER2, Breast, DCIS, Quantitative Immunohistochemistry, Manual with HER2 FISH Reflex

Overview

Useful For

Determining overexpression of HER2 protein on formalin-fixed, paraffin-embedded tissue sections in ductal carcinoma in situ or solid/intracystic papillary carcinoma breast tissue with a reflex to FISH testing if the specimen is equivocal (2+)

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
CULFB	Fibroblast Culture for Genetic Test	Yes	No
CULAF	Amniotic Fluid Culture/Genetic Test	Yes	No
HERBN	HER Breast IHC Automated NO Reflex	Yes	No
H2BR	HER2, Breast Tumor, FISH, Tissue	Yes	No
_STR1	Comp Analysis using STR (Bill only)	No, (Bill only)	No
_STR2	Add'l comp analysis w/STR (Bill Only)	No, (Bill only)	No

Testing Algorithm

Cases that are equivocal (2+) by immunohistochemical stain will reflex to *HER2* amplification by FISH at an additional charge.

Method Name

Ventana Pathway Immunoperoxidase Stain with Manual Quantitative Immunohistochemistry

NY State Available

Yes

Specimen

Specimen Type

Special

Ordering Guidance

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This test is only for ductal carcinoma in situ or solid/intracystic papillary carcinoma breast tissue. For gastroesophageal cancer, order HERGM / HER2, Gastric/Esophageal, Semi-Quantitative Immunohistochemistry, Manual or HERGN / HER2, Gastric/Esophageal, Semi-Quantitative Immunohistochemistry, Manual, No Reflex.

Shipping Instructions

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

Necessary Information

Include accompanying pathology report stating the final diagnosis.

Specimen Required

Supplies: Pathology Packaging Kit (T554)

Specimen Type:

Preferred: A paraffin-embedded tissue block containing breast cancer tissue that has been fixed in 10% neutral buffered formalin within 1 hour from surgical collection time and for a total of 6 to 72 hours and shipped at ambient temperature

Acceptable: 5 Unstained sections containing breast carcinoma on charged slides cut at 4 microns less than 1 month ago and shipped at ambient temperature. Tissue on the slides should have been fixed in 10% neutral buffered formalin within 1 hour from surgical collection time and for a total of 6 to 72 hours.

Collection Instructions:

1. Submit paraffin-embedded ductal carcinoma in situ or solid intracystic papillary carcinoma breast carcinoma tissue.
2. Paraffin blocks will be returned with final report.

Forms

If not ordering electronically, complete, print, and send an Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763)

Specimen Minimum Volume

Entire specimen

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 in human breast, endometrial, ovarian, and other epithelial cancers have been associated with a shorter disease-free interval and shorter overall survival. Overexpression of HER2 protein is an indication for Herceptin therapy in patients with breast cancer.

Reference Values

Reported as negative (0, 1+), equivocal (2+), and strongly positive (3+) according to the interpretation guidelines for the FDA-approved Ventana Pathway HER2 (4B5) antibody.

Interpretation

Results are reported as negative (0, 1+), equivocal (2+), and strongly positive (3+) according to the interpretation guidelines for the FDA-approved Ventana Pathway HER2 (4B5) antibody.

Cautions

The performance and quality of immunohistochemical stains in formalin-fixed, paraffin-embedded tissue depends critically on proper fixation.

Clinical Reference

1. Riber-Hansen R, Vainer B, Steiniche T: Digital image analysis: a review of reproducibility, stability and basic requirements for optimal results. Apmis 2012 April;120(4):276-289
2. Gavrielides MA, Gallas BD, Lenz P, et al: Observer variability in the interpretation of HER2/neu immunohistochemical expression with unaided and computer-aided digital microscopy. Arch Pathol Lab Med Feb;135(2):233-242
3. Cuadros M, Villegas R: Systematic review of HER2 breast cancer testing. Appl Immunohistochem Mol Morphol Jan 2009;17(1):1-7
4. Nassar A, Cohen C, Agersborg SS, et al: Trainable immunohistochemical HER2/neu image analysis: a multisite performance study using 260 breast tissue specimens. Arch Pathol Lab Med 2011 July;135(7):896-902

Performance

Method Description

Testing is performed using FDA-approved Ventana Pathway HER2 (4B5) rabbit monoclonal primary antibody and a proprietary detection system.(Package insert: PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody)

Scoring is performed according to ASCO/CAP guidelines as follows:
-Score of 3+ is defined as circumferential membrane staining that is complete, intense and in greater than 10% of invasive tumor cells
-Score of 2+ is defined as weak to moderate complete membrane staining observed and in greater than 10% of the invasive tumor cells; or circumferential membrane staining that is complete, intense and in less than or equal to 10% of invasive tumor cells
-Score of 1+ is defined as incomplete membrane staining that is faint or barely perceptible and in greater than 10% of the invasive tumor cells; or weak to moderate complete membrane staining observed and less than 10% of the invasive

tumor cells
-Score of 0 is defined as no staining observed or membrane staining that is incomplete and is faint or barely perceptible and in less than or equal to 10% of the invasive tumor cells.(Wolff AC, Hammond ME, Hicks DG, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. [published online ahead of print May 30, 2018]. J Clin Oncol. doi: 10.1200/JCO.2018.77.8738.)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
4 to 14 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
HERDM	HER BreastDCIS IHC Manual + Reflex	Obsolete

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Result ID	Test Result Name	Result LOINC® Value
MA017	Tumor classification	21918-8
70980	Interpretation	50595-8
70981	Participated in the Interpretation	No LOINC Needed
70984	Material Received	81178-6
70982	Report electronically signed by	19139-5
71623	Disclaimer	62364-5
71837	Case Number	80398-1