



Reporting Title: HER2, Breast Tumor, FISH, Tissue

Performing Location: Rochester

Ordering Guidance:

This test is only performed on specimens from patients with primary or metastatic breast tumors.

This test is not appropriate if the specimen is derived from primary or metastatic gastroesophageal carcinoma. See H2GE / HER2 Amplification Associated with Gastroesophageal Cancer, FISH, Tissue. If this test is ordered and the laboratory is informed that the specimen is a primary or metastatic gastroesophageal carcinoma, it will be canceled and automatically reordered by the laboratory as H2GE.

For all other tumor types, order H2MT / HER2 Amplification, Miscellaneous Tumor, FISH, Tissue. If this test is ordered and the laboratory is informed that the specimen is a primary or metastatic colorectal adenocarcinoma, endometrial serous carcinoma, urothelial carcinoma, or any other non-breast, non-gastroesophageal it will be canceled and automatically reordered by the laboratory as H2MT.

This test does not include a pathology consult. If a pathology consultation is requested, order PATHC / Pathology Consultation, and the appropriate testing will be added at the discretion of the pathologist and performed at an additional charge.

Shipping Instructions:

Advise Express Mail or equivalent if not on courier service.

Necessary Information:

1. A pathology report is required for testing to be performed. If not provided, appropriate testing and/or interpretation may be compromised or delayed. Acceptable pathology reports include working drafts, preliminary pathology, or surgical pathology reports.
2. The following information must be included in the report provided:
 - Patient name
 - Block number - must be on all blocks, slides, and paperwork
 - Date of collection
 - Tissue source
 - Fixation used AND time in Fixation (recommended: >6 hours and <72 hours).
3. A reason for testing must be provided. If this information is not provided, an appropriate indication for testing may be entered by Mayo Clinic Laboratories.

Specimen Requirements:

Note: In accordance with College of American Pathologists guidelines, place specimens for HER2 (ERBB2) testing in fixative within one hour of biopsy or resection (cold ischemia time). Specimens should remain in 10% neutral buffered formalin for a minimum of 6 hours to a maximum of 72 hours (formalin fixation time). Do not use decalcification solutions with strong acids.(CAP Accreditation Program. CYG.48932 Fixation - HER2 (ERBB2) Breast Predictive Marker Testing. Cytogenetics Checklist. College of American Pathologists. 08/2023)

Submit only 1 of the following specimens:



Preferred

Specimen Type: Tissue block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded tumor tissue block. Blocks prepared with alternative fixation methods may be acceptable; provide fixation method used.

Acceptable

Specimen Type: Tissue slides

Slides: 1 Hematoxylin and eosin stained and 4 unstained

Collection Instructions: Submit 1 slide stained with hematoxylin and eosin and 4 consecutive, unstained, positively charged, unbaked slides with 5-micron-thick sections of the tumor tissue. Slides cut from blocks prepared with alternative fixation methods may be acceptable; provide fixation method used.

Specimen Minimum Volume:

Slides: 1 Hematoxylin and eosin stained and 2 unstained

Forms:

If not ordering electronically, complete, print, and send a Oncology Test Request (T729) with the specimen.

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

Ask at Order Entry (AOE) Questions:

Test ID	Question ID	Description	Type	Reportable
H2BR	GC028	Reason for Referral	Plain Text	Yes
HERBN	MA007	Fixed in 10% NB formalin w/in 1 hr: <ul style="list-style-type: none">• Yes• No• Unknown	Answer List	No
HERBN	MA008	Fixed in 10% NB formalin 6-72 hrs: <ul style="list-style-type: none">• Yes• No• Unknown	Answer List	No
HERBN	MA009	Tumor type: <ul style="list-style-type: none">• Primary invasive breast carcinoma• Metastatic breast carcinoma	Answer List	No

Test ID	Question ID	Description	Type	Reportable
HERBN	MA010	Tumor classification: • Invasive breast carcinoma • Metastatic breast carcinoma • Micro-invasive breast carcinoma	Answer List	No
HERBN	MA045	Tissue was decalcified: • Yes • No • Unknown	Answer List	No

Result Codes:

Result ID	Reporting Name	Type	Unit	LOINC®
603074	Result Summary	Alphanumeric		50397-9
603075	Interpretation	Alphanumeric		69965-2
603076	Result	Alphanumeric		62356-1
GC028	Reason for Referral	Alphanumeric		42349-1
603077	Specimen	Alphanumeric		31208-2
603078	Source	Alphanumeric		85303-6
603079	Tissue ID	Alphanumeric		80398-1
603080	Fixative	Alphanumeric		8100-0
603081	Method	Alphanumeric		85069-3
603082	Additional Information	Alphanumeric		48767-8
603083	Disclaimer	Alphanumeric		62364-5
603084	Released By	Alphanumeric		18771-6

LOINC and CPT codes are provided by the performing laboratory.

Supplemental Report:

No

CPT Code Information:

88377

**Reflex Tests:**

Test ID	Reporting Name	CPT Units	CPT Code	Always Performed	Orderable Separately
HERBN	HER Breast IHC Automated NO Reflex			No	Yes
HERBM	HER Breast Semi Quant IHC Manual			No	No

Result Codes for Reflex Tests:

Test ID	Result ID	Reporting Name	Type	Unit	LOINC®
HERBN	70975	Interpretation	Alphanumeric		50595-8
HERBN	70976	Participated in the Interpretation	Alphanumeric		No LOINC Needed
HERBN	70977	Report electronically signed by	Alphanumeric		19139-5
HERBN	70979	Material Received	Alphanumeric		81178-6
HERBN	MA012	Fixed in 10% NB formalin w/in 1 hr	Alphanumeric		8100-0
HERBN	MA013	Fixed in 10% NB formalin 6-72 hrs	Alphanumeric		8100-0
HERBN	MA014	Tumor type	Alphanumeric		44638-5
HERBN	MA015	Tumor classification	Alphanumeric		21918-8
HERBN	MA047	Tissue was decalcified	Alphanumeric		8100-0
HERBN	71622	Disclaimer	Alphanumeric		62364-5
HERBN	71836	Case Number	Alphanumeric		80398-1
HERBM	71059	Interpretation	Alphanumeric		50595-8
HERBM	71148	Participated in the Interpretation	Alphanumeric		No LOINC Needed
HERBM	71153	Report electronically signed by	Alphanumeric		19139-5
HERBM	71156	Material Received	Alphanumeric		81178-6
HERBM	MA029	Fixed in 10% NB formalin w/in 1 hr	Alphanumeric		8100-0
HERBM	MA030	Fixed in 10% NB formalin 6-72 hrs	Alphanumeric		8100-0
HERBM	MA031	Tumor type	Alphanumeric		44638-5
HERBM	MA032	Tumor classification	Alphanumeric		21918-8
HERBM	MA046	Tissue was decalcified	Alphanumeric		8100-0
HERBM	71401	Disclaimer	Alphanumeric		62364-5

Test ID	Result ID	Reporting Name	Type	Unit	LOINC®
HERBM	71843	Case Number	Alphanumeric		80398-1

Reference Values:

An interpretive report will be provided.