



Reporting Title: HER Breast SemiQuant IHC + Reflex

Performing Location: Rochester

Ordering Guidance:

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 "Attention Pathology" address label (T498) to the outside of the transport container before putting into the courier mailer.

Necessary Information:

1. An accompanying pathology report stating the final diagnosis is required. If not available, a preliminary diagnosis is acceptable only if it refers to invasive or metastatic breast carcinoma.
2. Information regarding fixative used, time to fixation, and duration of fixation as well as tumor type and classification is required.

The following questions, as stated on the Pathology/Cytology Information (T707) form or presented electronically, must be answered:

- a. "Was specimen fixed in 10% neutral buffered formalin within 1 hour from surgical collection time? Yes, No, or Unknown."
- b. "Has specimen been fixed in 10% neutral buffered formalin for 6 to 72 hours? Yes, No, or Unknown."
- c. "Was tissue decalcified? Yes, No or Unknown."
- d. "Tumor type? Primary invasive breast carcinoma or metastatic breast carcinoma."
- e. "Tumor classification? Invasive breast carcinoma, metastatic breast carcinoma, or micro-invasive breast carcinoma."

Specimen Requirements:

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.

Acceptable: 5 Unstained sections containing breast carcinoma on charged slides cut at 4 microns less than 1 month ago. 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.

Container/Tube: Pathology Packaging Kit

Collection Instructions: Submit paraffin-embedded invasive or metastatic breast carcinoma tissue.

Additional Information:

1. According to the American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines, HER2 protein immunohistochemical test results are only valid for nondecalcified, paraffin-embedded specimens fixed in 10% neutral buffered formalin within 1 hour from surgical collection time and for a total time of 6 to 72 hours. Delay to fixation, or under- or over-fixation may affect these results.(1)
2. HER2 immunohistochemistry testing on intracystic papillary carcinoma and solid papillary carcinoma, without clearly stating invasive carcinoma, is not appropriate and will be reported as indeterminate.
3. Paraffin blocks will be returned with final report.



Forms:

If not ordering electronically, complete, print, and send with the specimen:

1. Pathology/Cytology Information (T707) is required if not ordering electronically.
2. Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763)

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

Ask at Order Entry (AOE) Questions:

Test ID	Question ID	Description	Type	Reportable
HERMB	MA058	Fixed in 10% NB formalin w/in 1 hr: <ul style="list-style-type: none">• Yes• No• Unknown	Answer List	Yes
HERMB	MA059	Fixed in 10% NB formalin 6-72 hrs: <ul style="list-style-type: none">• Yes• No• Unknown	Answer List	Yes
HERMB	MA060	Tumor type: <ul style="list-style-type: none">• Primary invasive breast carcinoma• Metastatic breast carcinoma	Answer List	Yes
HERMB	MA061	Tumor classification: <ul style="list-style-type: none">• Invasive breast carcinoma• Metastatic breast carcinoma• Micro-invasive breast carcinoma	Answer List	Yes
HERMB	MA062	Tissue was decalcified: <ul style="list-style-type: none">• Yes• No• Unknown	Answer List	Yes
H2BR	GC028	Reason for Referral	Plain Text	No



Result Codes:

Result ID	Reporting Name	Type	Unit	LOINC®
620801	Interpretation	Alphanumeric		50595-8
620802	Participated in the Interpretation	Alphanumeric		No LOINC Needed
620803	Report electronically signed by	Alphanumeric		19139-5
620804	Material Received	Alphanumeric		81178-6
MA058	Fixed in 10% NB formalin w/in 1 hr	Alphanumeric		8100-0
MA059	Fixed in 10% NB formalin 6-72 hrs	Alphanumeric		8100-0
MA060	Tumor type	Alphanumeric		44638-5
MA061	Tumor classification	Alphanumeric		21918-8
MA062	Tissue was decalcified	Alphanumeric		8100-0
620805	Disclaimer	Alphanumeric		62364-5
620806	Case Number	Alphanumeric		80398-1

LOINC and CPT codes are provided by the performing laboratory.

Supplemental Report:

No

CPT Code Information:

88360

Reflex Tests:

Test ID	Reporting Name	CPT Units	CPT Code	Always Performed	Orderable Separately
H2BR	HER2, Breast Tumor, FISH, Tissue			No	Yes
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®
H2BR	603074	Result Summary	Alphanumeric		50397-9
H2BR	603075	Interpretation	Alphanumeric		69965-2
H2BR	603076	Result	Alphanumeric		62356-1
H2BR	GC028	Reason for Referral	Alphanumeric		42349-1
H2BR	603077	Specimen	Alphanumeric		31208-2
H2BR	603078	Source	Alphanumeric		85303-6
H2BR	603079	Tissue ID	Alphanumeric		80398-1
H2BR	603080	Fixative	Alphanumeric		8100-0
H2BR	603081	Method	Alphanumeric		85069-3
H2BR	603082	Additional Information	Alphanumeric		48767-8
H2BR	603083	Disclaimer	Alphanumeric		62364-5
H2BR	603084	Released By	Alphanumeric		18771-6
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

Reference Values:

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