
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 |

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 | Available Separately |
|---------|------------------------------------|-----------|----------|------------------|----------------------|
| HERBN | HER Breast IHC Automated NO Reflex | 1 | 88361 | No | Yes |
| H2BR | HER2, Breast Tumor, FISH, Tissue | 1 | 88377 | No | Yes |

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 |

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.