

## **Test Definition: H2BR**

HER2 Amplification Associated with Breast Cancer, FISH, Tissue

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



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**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.

#### 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         | Туре       | Reportable |
|---------|-------------|---------------------|------------|------------|
| H2BR    | GC028       | Reason for Referral | Plain Text | Yes        |

## **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



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## **CPT Code Information:**

88377

## **Reflex Tests:**

| Test Id | t Id Reporting Name                |   | CPT Code | Always Performed | Available Separately |
|---------|------------------------------------|---|----------|------------------|----------------------|
| HERBM   | HER Breast Semi Quant IHC Manual   | 1 | 88360    | No               | No                   |
| HERBN   | HER Breast IHC Automated NO Reflex | 1 | 88361    | No               | Yes                  |

## **Result Codes for Reflex Tests:**

| Test ID | Result ID | Reporting Name                     | Туре         | Unit | LOINC®          |
|---------|-----------|------------------------------------|--------------|------|-----------------|
| 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   | 70975     | Interpretation                     | Alphanumeric |      | 50595-8         |
| HERBN   | 70976     | Participated in the Interpretation | Alphanumeric |      | No LOINC Needed |
| HERBN   | 70979     | Material Received                  | Alphanumeric |      | 81178-6         |
| HERBN   | 70977     | Report electronically signed by    | Alphanumeric |      | 19139-5         |
| HERBN   | 71622     | Disclaimer                         | Alphanumeric |      | 62364-5         |
| HERBN   | 71836     | Case Number                        | Alphanumeric |      | 80398-1         |
| HERBN   | MA047     | Tissue was decalcified             | Alphanumeric |      | 8100-0          |

## **Reference Values:**

An interpretive report will be provided.