

Specimen Requirements and Preparation for HERmark Assays

This document describes the requirements and preparation of slides and paraffin-embedded tissue blocks prior to analysis using the HERmark™ Breast Cancer Assay. The HERmark Breast Cancer Assay is a CLIA-validated quantitative assay, based on VeraTag™ technology, that measures HER2 Total protein and HER2 homodimer levels.

Specimen Identification

Proper identification of specimens (slides or blocks) is extremely important. Please confirm that all specimens are labeled with bar code labels from the Test Requisition Form for each patient. Bar codes are unique and specific only to each individual patient.

Specimen Preparation (Slides or Blocks)

- The HERmark Breast Cancer Assay requires formalin-fixed, paraffin-embedded (FFPE) tissue.
 - Invasive adenocarcinoma of breast specimens is required; DCIS and LCIS only cases are not acceptable.
 - Excisional biopsy specimens are preferred; large core biopsies are also acceptable.

- Please send either:

Unstained Slides

- 5 µm sections on positively charged glass slides, 1 section per slide. A total of 5 unstained slides per patient is required. The minimum tumor size should be 10 mm² of invasive breast cancer.
- Freshly cut sections, stored at 4°C, should be sent to Monogram Biosciences within 1 week.

OR

1 Paraffin-embedded Tissue Block

- Select the tissue block with the highest amount of viable, invasive tumor. If multiple blocks are available—only submit one block.

Shipment Preparation (Slides or Blocks)

1. Remove and complete all fields of the HERmark Test Request Form.
2. Confirm that the Cold Pack has been placed in a –20°C or below freezer for at least 12 hours. Ensure that the Cold Pack is fully frozen prior to shipment.
3. Sample Preparation
 - Slides:
 - After labeling each slide, place the slides into the plastic cassette provided in the Shipping Kit
 - Place slide cassette securely into cut-out in the foam cushion
 - Place cushion with slides into sealed Biohazard Bag
 - Blocks:
 - Place block into plastic bag provided in the Shipping Kit
 - Place block securely into cut-out in the foam cushion
 - Place cushion with block into sealed Biohazard Bag
4. Insert Biohazard Bag containing specimen samples and Cold Pack into foil envelope. Place foil envelope inside the Shipping Kit.
5. Place completed Test Request Form and the completed Pathology Preorder Form (if used) on top of the foil envelope. Secure the kit by closing the flaps.
6. Complete “1. From” section of the FedEx Expanded Billable Stamp. Peel off completed label and adhere to top of the Shipping Kit. Retain copy of label receipt.
7. Place the package in the designated FedEx pickup location at your site. If your site does not have standard FedEx pickup, please call (800) GO FEDEX (800-463-3339) to arrange for a pickup.

FOR ALL SHIPMENTS
Please notify Monogram Biosciences of all packages, including the Airbill number.
Please e-mail Receiving@monogrambio.com
For any questions or to reorder additional kits, call 1-800 777-0177