HERmark® BREAST CANCER ASSAY

Monogram BIOSCIENCES
LabCorp Specialty Testing Group

TEST REQUEST FORM

Monogram Biosciences, Inc., 345 Oyster Point Blvd, South San Francisco, CA 94080
Samuel H. Pepkowitz, MD, Medical Director. Telephone: (800) 777-0177 Fax: (650) 615-0177 **www.hermarkassay.com**

1) PATIENT INFORMATION:

Patient Name: _____ DOB: _____
Last First MI

Address: _____
Street City State ZIP

Telephone: _____ SEX: ☐ M ☐ F

Patient ID or
Medical Record #: _____

Reference/Order/Case #: _____

2) BILLING INFORMATION:

Check one box for billing type and fill out all accompanying information. Attach a copy of the front and back of insurance card(s).

Primary Diagnosis:

_____

Diagnosis/Signs/Symptoms in ICD-CM format in effect at Date of Service (Highest Specificity Required)

_____

☐ **Private Insurance**

Relationship to Insured: ☐ Self ☐ Spouse ☐ Dependent ☐ Legal Partner

Primary Health Plan Name: _____

Primary Insured ID #: _____

Primary Insurance Telephone: _____

Secondary Health Plan Name: _____

Secondary Insured ID #: _____

☐ **Medicare** > Patient Medicare #: _____

☐ **Medicaid** > Patient Medicaid #: _____

☐ **Client**

☐ **Patient Self-Pay** (Check, money order, or credit card)

Name on Credit Card: _____

Credit Card #: _____

Exp. Date: _____ Security Code: _____

3) ORDERING ONCOLOGIST INFORMATION:

Oncologist / Physician Name: _____

Facility Name: _____

Address: _____
Street City State ZIP

Telephone: _____ Fax: _____

E-mail Address: _____

ID/License #: _____ NPI #: _____

The HERmark® Breast Cancer Assay provides an accurate and quantitative measurement of HER2 protein expression. In my judgment, the HERmark Breast Cancer Assay is medically necessary for this patient.

X _____ Date: _____
Signature of Ordering Physician

_____
Print Name

4) PATHOLOGY AND SUBMITTING INFORMATION:

Please complete all fields.

Pathologist Name: _____

Address: _____
Street City State ZIP

Telephone: _____ Fax: _____

E-mail Address: _____

Additional Physician to Receive Report: _____

Address: _____
Street City State ZIP

Telephone: _____ Fax: _____

E-mail Address: _____

Specimen Tissue ID#: _____

Date of Surgery: _____ Date Block Pulled From Archive: _____

Return Block to: ☐ Submitting Pathologist ☐ Additional Physician/Pathologist

If Different From the Submitting Pathologist, Send to: _____

_____

Please Attach Pathology Report.
Is Report Attached? ☐ Yes ☐ No

INTERNAL USE ONLY: **DATE / TIME STAMP:**

Received: # Slides _____ # Blocks _____

Initials/Date _____

Verified by: Initials/Date _____

Rev. 8/2015 PS#88779

HERmark® BREAST CANCER ASSAY

Monogram BIOSCIENCES
LabCorp Specialty Testing Group

TEST REQUEST FORM

Monogram Biosciences, Inc., 345 Oyster Point Blvd, South San Francisco, CA 94080
Samuel H. Pepkowitz, MD, Medical Director. Telephone: (800) 777-0177 Fax: (650) 615-0177 **www.hermarkassay.com**

1) PATIENT INFORMATION:

Patient Name: _____ DOB: _____
Last First MI

Address: _____
Street City State ZIP

Telephone: _____ SEX: ☐ M ☐ F

Patient ID or
Medical Record #: _____

Reference/Order/Case #: _____

2) BILLING INFORMATION:

Check one box for billing type and fill out all accompanying information. Attach a copy of the front and back of insurance card(s).

Primary Diagnosis:

_____

Diagnosis/Signs/Symptoms in ICD-CM format in effect at Date of Service (Highest Specificity Required)

_____

☐ **Private Insurance**

Relationship to Insured: ☐ Self ☐ Spouse ☐ Dependent ☐ Legal Partner

Primary Health Plan Name: _____

Primary Insured ID #: _____

Primary Insurance Telephone: _____

Secondary Health Plan Name: _____

Secondary Insured ID #: _____

☐ **Medicare** > Patient Medicare #: _____

☐ **Medicaid** > Patient Medicaid #: _____

☐ **Client**

☐ **Patient Self-Pay** (Check, money order, or credit card)

Name on Credit Card: _____

Credit Card #: _____

Exp. Date: _____ Security Code: _____

3) ORDERING ONCOLOGIST INFORMATION:

Oncologist / Physician Name: _____

Facility Name: _____

Address: _____
Street City State ZIP

Telephone: _____ Fax: _____

E-mail Address: _____

ID/License #: _____ NPI #: _____

The HERmark® Breast Cancer Assay provides an accurate and quantitative measurement of HER2 protein expression. In my judgment, the HERmark Breast Cancer Assay is medically necessary for this patient.

X _____ Date: _____
Signature of Ordering Physician

_____
Print Name

4) PATHOLOGY AND SUBMITTING INFORMATION:

Please complete all fields.

Pathologist Name: _____

Address: _____
Street City State ZIP

Telephone: _____ Fax: _____

E-mail Address: _____

Additional Physician to Receive Report: _____

Address: _____
Street City State ZIP

Telephone: _____ Fax: _____

E-mail Address: _____

Specimen Tissue ID#: _____

Date of Surgery: _____ Date Block Pulled From Archive: _____

Return Block to: ☐ Submitting Pathologist ☐ Additional Physician/Pathologist

If Different From the Submitting Pathologist, Send to: _____

_____

Please Attach Pathology Report.
Is Report Attached? ☐ Yes ☐ No

INTERNAL USE ONLY: **DATE / TIME STAMP:**

Received: # Slides _____ # Blocks _____

Initials/Date _____

Verified by: Initials/Date _____

Rev. 8/2015 PS#88779

TEST REQUEST FORM INSTRUCTIONS

Section 1: Patient Information

This Test Request Form is required for all sample submissions.

- Complete all lines. Some lines require more than one piece of information.
- Enter the Patient ID or Medical Record #.
- Enter the Reference/Order/Case #.

Section 2: Billing Information

- If the Primary Diagnosis is other than breast cancer, please print that diagnosis.
- Enter the Diagnosis/Signs/Symptoms in ICD-CM format in effect at Date of Service (Highest Specificity Required).
- Indicate the party responsible for payment of the HERmark® Breast Cancer Assay.
  - If **Private Insurance/Medicare/Medicaid:**
    1. **Include a copy of the front and back of the primary and secondary (if applicable) of the patient insurance card.**
       - Please indicate which insurance is primary and secondary.
    2. If this is included, no further billing information is required.
    3. If the copy of the insurance card(s) is not available, please complete all lines in this section.
  - If **Client** is responsible for payment, please notify Monogram Biosciences if you are NOT currently a contracted account.
  - If **Patient Self-Pays,** payment is required for processing. Payment forms include credit card (name on card, card number, expiration date, security code), money order, certified funds, or check (United States only). No further billing information is required.
  - Patient is responsible for all co-pays and/or deductible amounts and the full cost of the test in event of denial of insurance coverage, following appeal, or a false insurance claim.

Section 3: Ordering Information

- Print the name of the facility, address, phone number, fax number, e-mail address, ID/License #, and NPI #.
- Sign and date the Test Request Form and print your name. The signature must be that of an ordering physician (treating physician or pathologist) or an authorized representative.

Section 4: Pathology and Submitting Information

- Complete all lines. Some lines require more than one piece of information.
- If there is another physician/pathologist who has requested a copy of the report and who is responsible for the care of this patient, enter the applicable information in the lines provided.
- Enter the Specimen Tissue ID # as it appears on the submitted specimen.
- Enter the Date of Surgery.
- If submitting a block, please enter the Date Block Pulled From Archive.
- If a sample block should be returned to an address other than the Submitting Pathologist's, please complete the return block name and address lines.
- Please attach the Pathology Report and check the "yes" box.

B-1A

SPECIMEN REQUIREMENTS

Proper identification of specimens is extremely important. Please confirm that all specimens are labeled with at least two unique patient identifiers.

- HERmark® Breast Cancer Assay requires formalin-fixed, paraffin-embedded (FFPE) tissue.
- Invasive adenocarcinoma of breast 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 are required.
  - 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.**

STAINED SLIDES ARE NOT ACCEPTABLE

Please contact Monogram Biosciences toll free with any questions at 1-800-777-0177.

SHIPPING INSTRUCTIONS

1. Remove and complete all fields of the HERmark® Test Request Form.
2. Confirm the Cold Pack has been placed in a –20°C or below freezer for at least 12 hours. Make sure Cold Pack is fully frozen prior to shipment.
3. Sample Preparation

   Slides:
   - Place the slides into the plastic slide cassette provided in the Shipping Kit.
   - Place slide cassette securely into cut-out in the foam cushion.
   - Place cushion with slides into zipped Biohazard Bag.

   Block:
   - Place block into small ziplocked bag provided in the Shipping Kit.
   - Place ziplocked bag containing block securely into cut-out in the foam cushion.
   - Place cushion with block into zipped 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 Pathology Preorder Form (if available) on top of the foil envelope. Prior to shipping, secure the kit by removing the protective cover on the adhesive strip and by closing the flaps. Press firmly to secure closure.
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.
8. Notify Monogram at MGBReceiving@LabCorp.com of incoming shipment. Monogram will track your package to help ensure timely delivery.

Monogram BIOSCIENCES
LabCorp Specialty Testing Group

FOR ALL SHIPMENTS

Please notify Monogram of all packages, including the Airbill number. Please e-mail MGBReceiving@LabCorp.com.

For any questions or to reorder additional kits, call 1-800-777-0177.