Breast Cancer Index® (BCI™) Test Requisition Form

Biotheranostics, Inc.
A Hologic Company

Available for Lymph Node-Negative (LN-, N0) and Lymph Node-Positive (LN+: N1, up to 3 Positive Nodes)
Please see page 2 for BCI patient eligibility criteria and Medicare coverage criteria under the Medicare Local Coverage Determination.

1 **Complete all fields below.** Ordering Provider MUST sign and date this form to authorize the order. For assistance, contact Client Services at (877) 886-6739.

2 **Attach all required documents.**

Office Notes / Encounters / History & Physical
- Discussions pertaining to the need for BCI Testing
- Discussion of how results will manage treatment
- A medical list of any endocrine therapy prescribed

Pathology Reports
- All breast-associated reports including biopsy and excision
- For LN+ patients treated with neoadjuvant therapy, attach documentation establishing pre-treatment tumor size

Patient Face Sheet
- Patient demographics

Patient Insurance Card(s)
- Copy of front and back

3 **Submit completed requisition.** Ship with specimen to Biotheranostics **OR** fax this form to 800-266-9607 and Biotheranostics will request the specimen from Pathology.

Biotheranostics, Inc., A Hologic Company
6333 Sequence Dr., San Diego, CA 92121

Breast Cancer Index® Test Requested *Select one*

Postmenopausal

☐ **Full 0-10 Year Report -** Risk of overall (0-10 year) distant recurrence to inform primary adjuvant endocrine therapy plus risk of late (5-10 year) distant recurrence and prediction of benefit from extended endocrine therapy.*

☐ **5-10 Year Report -** Risk of late (5-10 year) distant recurrence and prediction of benefit from extended endocrine therapy.*

Premenopausal

☐ **Full 0-10 Year Report -** Risk of overall (0-10 year) distant recurrence to inform addition of OFS† to primary adjuvant endocrine therapy plus risk of late (5-10 year) distant recurrence and prediction of benefit from extended endocrine therapy.*

☐ **5-10 Year Report -** Risk of late (5-10 year) distant recurrence and prediction of benefit from extended endocrine therapy.*

**Predictive results for extended endocrine therapy benefit valid upon patient remaining distant recurrence-free following completion of primary adjuvant endocrine therapy. †Ovarian function suppression.*

Ordering Provider

Name | NPI | Email

Practice / Facility | Phone | Fax

Address

City | State | Zip Code

Patient Information *Note: Based on clinical validation, only specimens from biologically female patients are acceptable for testing.*

Name ☐ Female | DOB | Phone

Address | City | State | Zip Code

Specimen & Clinical Information *If testing multiple biopsies, complete a Requisition Form for each specimen.*

Specimen ID | Date of Collection | Breast Specimen Site ☐ Left ☐ Right | Special Instructions

ICD-10 Codes *Select all additional codes that may apply. See reverse for descriptions; please provide code with the greatest specificity.*

☐ C50.011 ☐ C50.111 ☐ C50.211 ☐ C50.311 ☐ C50.411 ☐ C50.511 ☐ C50.611 ☐ C50.811 ☐ Z17.0 (ER+)
☐ C50.012 ☐ C50.112 ☐ C50.212 ☐ C50.312 ☐ C50.412 ☐ C50.512 ☐ C50.612 ☐ C50.812 ☐ Other (*Diagnosis not covered by Medicare*)

Pathology Facility *Facility that will release specimen for BCI Testing.*

Pathologist Name | NPI | Fax

Practice / Facility | Phone | State

Address | City | Zip Code

Block Return Address *(If different from above)*

Billing Information

Bill To ☐ HMO ☐ IPA ☐ Medicare *(Complete next section)*
☐ Hospital / Facility ☐ PPO
☐ Medicare Advantage ☐ Patient

Prior Authorization Required? ☐ No ☐ Yes, prior authorization # _____

Required for Medicare

Medicare Status *(Check box for patient's hospital status when sample was obtained)*

☐ Hospital Inpatient ☐ Hospital Outpatient
Date of Discharge ☐ Non-Hospital Patient

Date Specimen Pulled from Archive

Ordering Provider Certification

I certify the following: I hereby request and authorize Biotheranostics to utilize the above information to process the tumor specimen for the indicated patient; the information is accurate; I am authorized by law to order the test indicated above which is reasonable and medically necessary for the patient; the test results will be used in determining treatment management of the patient for chemotherapy and/or endocrine therapy; and I have obtained any patient consent legally required for a) performing the test and b) disclosing test results to me, to the pathologist(s) providing the testing specimen and to any third party if required for payment. I agree to provide the necessary information and medical records needed to support billing or reimbursement. I have read the reverse side for additional details.

Signature | **Printed Name** | **Date**

Specimen Collection & Handling Procedures

Please note: Laboratory test result quality is highly dependent upon proper specimen collection and handling procedures.The specimen requirements and handling procedures are listed below. All samples must be clearly labeled with a unique block ID or specimen ID. We are unable to accept samples that are not labeled, or samples labeled with identifiers that do not match those listed on the documents submitted. All available breast associated pathology reports and completed Test Requisition Form must be submitted with the specimen.

Specimen Type

Testing is performed on untreated primary invasive breast cancer (in order of preference: surgical specimen or core biopsy).

Cases With Any of the Following Are Not Acceptable for Testing:

- ER- and PR-
- ≥4 positive-nodes
- Unknown nodal status
- Microinvasive carcinoma
- Fine Needle Aspirations (FNA) or fresh/frozen tissue
- Metaplastic breast cancer, Carcinosarcoma, Sarcoma, Neuroendocrine carcinoma, Adenoid cystic carcinoma, and Phyllodes tumor
- Male
- T4 tumor
- Metastatic breast cancer
- No evidence of invasive breast cancer
- Biopsy site: Chest wall, Lymph node, Skin
- Any post-treatment (adjuvant or neoadjuvant) specimen

Fixation Method

Formalin-Fixed Paraffin-Embedded (FFPE) tissue is recommended for all testing services. Optimum fixation should be between 6-72 hrs in 10% neutral buffered formalin, other types of fixatives should not be used.

Specimen Requirements

- An area of invasive tumor that is ≥2mm
- Specimen options: FFPE block (preferred) OR
- 3-4 unstained 7 micron sections on glass slides and 1 H&E slide

Specimen Selection

- If multiple acceptable specimen types are available, select the specimen containing tumor of the highest grade
- Multicentric and synchronous tumors: Prioritize specimen selection as follows 1) highest grade 2) largest size
- Select a specimen obtained prior to treatment (adjuvant or neoadjuvant therapy)
- Locally recurrent tumors: Select specimen from original excision or biopsy
- Do not submit multiple blocks from different biopsies or specimen sites; select the best block

Storage

Store specimen at room temperature (15-30°C).

Transportation

Ambient kit. Use pre-cooled cold pack for transport. Do not place cold pack in direct contact with specimen during transport. Place FFPE blocks in a plastic bag and slides in a plastic case or slide-mailer. Place the specimens, completed Test Requisition, completed Specimen Request Form, pathology report and supporting documents in a Biotheranostics Specimen Shipping Kit. Send specimens via FedEx service. A pickup may be scheduled online at www.fedex.com or by calling (800) 463-3339. To obtain specimen shipping kits and Biotheranostics FedEx account information, call Client Services at (877) 886-6739.

Billing Information

It is the sole responsibility of the patient who may be enrolled in an FSA/HSA or other medical spending account with an employer or insurance carrier, that the provision on coordination of benefits for any coverage policy may result in an automatic deduction of out-of-pocket costs directly from that fund by the insurance carrier or employer. Biotheranostics is in no way responsible or liable for that deduction, and does not have the ability to reverse it, refund it, or otherwise reimburse patients for those amounts. It is the patient's responsibility to contact any insurance carrier or employer in advance of services regarding coordination of benefits issues that may impact such accounts.

All patients will have an eligibility check. When the insurance provided is invalid, a representative will contact the ordering physician's office to validate patient information. Biotheranostics may contact the ordering physician's office for a statement of medical necessity to expedite appeals.

Medicare LCD Coverage Criteria

When ordering the Breast Cancer Index Test, please keep in mind that under the local coverage determination (LCD), the BCI Test is covered by Medicare for postmenopausal women with invasive breast cancer when the following criteria are met:

- Pathology reveals invasive carcinoma of the breast that is estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+) and Human Epidermal Growth Factor Receptor 2 negative (HER2-); and
- Patient has early-stage disease {Tumor, Node, Metastasis (TNM) stage T1-3, pN0-N1, M0} and
- Patient has no evidence of distant breast cancer metastasis (i.e., non-relapsed); and
- Test results will be used in determining treatment management of the patient for chemotherapy and/or endocrine therapy.

ICD-10 Code Reference

For the Breast Cancer Index Test, below is a list of covered diagnosis codes from the Medicare MolDX Local Coverage Determination policy. The codes are provided as a guide to help you determine if the test is covered by Medicare based on medical necessity.

Description	ICD-10 Code	
	Right Breast	Left Breast
Malignant neoplasm of nipple and areola of female breast	C50.011	C50.012
Malignant neoplasm of central portion of female breast	C50.111	C50.112
Malignant neoplasm of upper-inner quadrant of female breast	C50.211	C50.212
Malignant neoplasm of lower-inner quadrant of female breast	C50.311	C50.312
Malignant neoplasm of upper-outer quadrant of female breast	C50.411	C50.412
Malignant neoplasm of lower-outer quadrant of female breast	C50.511	C50.512
Malignant neoplasm of axillary tail of female breast	C50.611	C50.612
Malignant neoplasm of overlapping sites of female breast	C50.811	C50.812
Estrogen receptor positive status [ER+]	Z17.0	

Notice

In all cases, it is the treating physician's responsibility to determine how the test result should be used in determining a treatment plan for that patient. Biotheranostics will perform the test and report a result unless it determines that a) the test has been cancelled by the physician or patient; b) the specimen does not have adequate cancer tissue; or c) the forms submitted did not provide sufficient information to perform the test and report a result.

Intended Use and Limitations

The Breast Cancer Index (BCI) test is a polymerase chain reaction (PCR) based gene expression test which analyses two gene expression signatures from formalin-fixed, paraffin-embedded (FFPE) tissue block or unstained sections on glass slides via macrodissection. The gene expression signatures include the Molecular Grade Index (MGI), a five-gene signature, and the HOXB13/IL17BR (H/I), a two-gene ratio signature. The test is indicated for use in women diagnosed with early-stage hormone receptor-positive (HR+), lymph node-negative (N0) or lymph node-positive (N1; 1-3 positive nodes) invasive breast cancer. The BCI test provides a quantitative estimate of overall (years 0-10) and late (years 5-10) distant recurrence risk and informs the likelihood of endocrine therapy benefit for women who are distant recurrence-free.

BCI results are adjunctive to the ordering physician's workup; treatment decisions require correlation with all other clinical findings. This test was developed, and its performance characteristics determined by Biotheranostics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for clinical purposes and should not be regarded as experimental or investigational. How this information is used to guide patient care is the responsibility of the treating provider. Biotheranostics is certified under the Clinical Laboratory Improvement Amendments of 1988 to perform high complexity clinical laboratory testing.

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Web: BreastCancerIndex.com

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CA#CDF00334843