breast cancer index
NOT ANOTHER MINUTE™

TEST REQUISITION FORM

I. TEST REQUESTED

☐ **Breast Cancer Index™ (BCI)**
Available for Lymph Node-Negative (N0) and Lymph Node-Positive (N1; 1-3 positive nodes)

ORDERING INSTRUCTIONS

1. Complete ALL fields below (missing information will result in delay of testing); fields indicated with tabs labeled "R" or "Required" below MUST be completed by the ordering physician's office prior to testing
2. Attach patient face sheet and copy (front and back) of insurance card(s) and pathology report for the specimen requested in Section V
3. Ship with specimen to Biotheranostics' laboratory **OR** fax this form to 800-266-9607 and Biotheranostics will request the specimen from Pathology

INFORMATION ON THIS FORM MUST BE ACCURATE TO OBTAIN RELIABLE BCI TEST RESULTS

Prior to testing, Biotheranostics Patient Advocate Team will reach out to the patient listed below to explain the billing process and to discuss our Patient Assistance Program. Please ensure your patient is expecting our phone call, and promptly returns the call. If we are unable to reach your patient after 3 attempts, we will proceed with BCI testing and billing.

II. ORDERING PHYSICIAN/PRACTITIONER

SPECIALTY: ☐ Oncologist ☐ Surgeon ☐ Pathologist ☐ Other:_____

R

NAME	NPI	EMAIL
PRACTICE/FACILITY	PHONE	FAX
ADDRESS	CITY	STATE ZIP CODE

III. PATIENT INFORMATION

Please include a copy of the patient face sheet and a copy (front and back) of patient insurance card(s)

R

NAME	**DOB**	PHONE
SEX ☐ Female Note: Based on clinical validation, only specimens from biologically female patients are acceptable for testing	**POST-MENOPAUSAL?** (For billing purposes; Check one only) ☐ Yes ☐ No	R
ADDRESS	CITY	STATE ZIP CODE

IV. SPECIMEN & CLINICAL INFORMATION

All information below is required to proceed with testing & billing.
Please also include a copy of the corresponding pathology report.

Required

SPECIMEN ID / DATE OF COLLECTION	**HORMONE RECEPTOR STATUS:** ☐ ER+ (ICD-10: Z17.0) ☐ PR+ ☐ Other (specimen will not be accepted for testing) — R
R **SPECIMEN SITE** (if testing multiple biopsies, complete a Requisition for each specimen): Breast: ☐ Left ☐ Right	**DISEASE STATE:** ☐ Non-metastatic (M0), invasive breast carcinoma (ductal, lobular, or mixed ductal/lobular) ☐ Other (specimen will not be accepted for testing)
NODAL STATUS (Check one) ☐ Lymph Node-Negative (N0) ☐ Lymph Node Status Unknown (NX)* ☐ Lymph Nodes Contain Isolated Tumor Cells Only [N0(i+)]* *Test will be analyzed and reported as Lymph Node-Negative ☐ Lymph Node-Positive (N1 or N1mi; 1-3 positive nodes)	**HER2 STATUS:** ☐ HER2- ☐ HER2+
NODE POSITIVE Tumor Size: ____ . ____ cm Tumor Grade (Nottingham or Elston) - Check one; If mixed grade, select higher grade for classification ☐ 1 ☐ 2 ☐ 3	**STAGE:** ☐ T1-3 ☐ Other (specimen will not be accepted for testing)
	ICD-10 CODES - Select all additional codes that may apply (See reverse for descriptions; please provide the code with the greatest specificity) ☐ C50.011 ☐ C50.111 ☐ C50.211 ☐ C50.311 ☐ C50.411 ☐ C50.511 ☐ C50.611 ☐ C50.811 ☐ C50.911 ☐ C50.012 ☐ C50.112 ☐ C50.212 ☐ C50.312 ☐ C50.412 ☐ C50.512 ☐ C50.612 ☐ C50.812 ☐ C50.912 ☐ Other (diagnosis not covered by Medicare**): _____

Required

V. PATHOLOGY FACILITY

(Facility that will release the specimen for BCI testing)

PATHOLOGIST NAME	NPI	
PRACTICE/FACILITY NAME	PHONE	FAX
ADDRESS	CITY	STATE ZIP CODE
BLOCK RETURN ADDRESS (if different from above)		

VI. BILLING INFORMATION

Please include a copy (front and back) of patient insurance card(s)

BILL TO: ☐ Patient ☐ HMO ☐ IPA ☐ PPO ☐ Hospital/Facility ☐ Medicare Advantage ☐ Medicare** (complete section VII)

PRIOR AUTHORIZATION REQUIRED? ☐ Yes - Prior Authorization #_____ ☐ No

VII. REQUIRED FOR MEDICARE**

MEDICARE STATUS Check box for patient's hospital status when sample was obtained

Date specimen pulled from archive _____

☐ Hospital Inpatient: Date of Discharge _____

☐ Hospital Outpatient ! ☐ Non-Hospital Patient

****See reverse for details of Medicare LCD coverage criteria**

R

Required

VIII. PHYSICIAN/PRACTITIONER 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 extension of 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, and patient name or date of birth. 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. The corresponding pathology report and completed Specimen Request Form must be submitted with the specimen.

SPECIMEN TYPE
Testing is performed on breast primary invasive tumor. The following are acceptable specimen types in order of preference:

1) Surgical Resection/Excisional Biopsy
2) Core Needle Biopsy

CASES WITH ANY OF THE FOLLOWING ARE NOT ACCEPTABLE FOR TESTING:

- ER- and PR-
- ≥4 positive nodes
- 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 (ductal, lobular or mixed ductal lobular) carcinoma
- Biopsy site: Chest wall, Axilla or 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 tumor that contains ≥40% neoplastic cells
Specimen options: FFPE block (preferred) OR
3-4 unstained 10 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
- Multifocal 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.

If Patient/Medicare is selected, all patients will have an eligibility check and may be contacted during the process. If Patient is selected, where provided Insurance is invalid, a representative will contact the ordering physician's office to validate payment information. Biotheranostics may contact the ordering physician's office for a statement of medical necessity to expedite appeals.

MEDICARE LCD COVERAGE CRITERIA
When ordering Breast Cancer Index (BCI), please keep in mind that under the local coverage determination (LCD), BCI 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 Breast Cancer Index, 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
Malignant neoplasm of breast (female) unspecified site	C50.911	C50.912
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 Uses and Limitations
The Breast Cancer Index (BCI) Risk of Recurrence & Extended Endocrine Benefit Test is indicated for use in women diagnosed with hormone receptor-positive (HR+), lymph node-negative (LN-) or lymph node positive (LN+; with 1-3 positive nodes) early-stage, invasive breast cancer, who are distant recurrence-free. The BCI test provides: 1) a quantitative estimate of the risk for both late (post-5 years from diagnosis) distant recurrence and of the cumulative distant recurrence risk over 10 years (0-10y) in patients treated with adjuvant endocrine therapy (LN- patients) or adjuvant chemoendocrine therapy (LN+ patients), and 2) prediction of the likelihood of benefit from extended (>5 year) endocrine therapy. 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. It should not be regarded as investigational or for research. How this information is used to guide patient care is the responsibility of the physician. Biotheranostics is certified under the Clinical Laboratory Improvement Amendments of 1988 to perform high complexity clinical laboratory testing.

Biotheranostics, Inc. | 9640 Towne Centre Drive | Suite 200 | San Diego, CA 92121 | Biotheranostics.com
Client Services (877) 886-6739 | Fax (800) 266-9607 | Email: ClientServices@Biotheranostics.com

