Breast Cancer INDEX℠

Test Requisition Form

BIO THERANOSTICS

I. TEST REQUESTED	ORDERING INSTRUCTIONS
☐ **Breast Cancer Index℠ (BCI)** Available for Lymph Node-Negative (N0) and Lymph Node-Positive (N1; 1-3 positive nodes)	1. Complete ALL fields below (missing information will result in delay of testing) 2. Attach patient face sheet and copy (front and back) of insurance card(s) and pathology report for the specimen requested in Section IV 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

Specialty: ☐ Oncologist ☐ Surgeon ☐ Pathologist ☐ Other:_____

Name	NPI	Email	
Practice/Facility Name	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)

Name	DOB	Phone	
Sex ☐ Female — Note: Based on clinical validation, only specimens from female patients will be accepted for testing			
Address	City	State	Zip Code

IV. SPECIMEN & CLINICAL INFORMATION

All information below is required to proceed with testing

Specimen ID / **Date of Collection**	**Specimen Site** Breast: ☐ Right ☐ Left
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)	**ICD-10 Codes - List all codes that may apply** (See reverse for reference guide; please provide code with the greatest specificity, unless the anatomical site is properly designated with a general, unspecified code)
Node Positive Tumor Size: ____ . ____ cm Tumor Grade (Nottingham or Elston) - Circle One: 1 2 3 If mixed grade, select higher grade for classification	**Disease State** (Check one) ☐ ER+ primary, infiltrating breast carcinoma (ductal, lobular, or mixed ductal/lobular) ☐ ER-, PR+ primary, infiltrating breast carcinoma (ductal, lobular, or mixed ductal/lobular)
	Check if Applicable: ☐ Received neoadjuvant chemo, endocrine, or radiation therapy (Request specimen obtained prior to initiation of therapy)

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**

VIII. PHYSICIAN/PRACTITIONER CERTIFICATION

I hereby request and authorize Biotheranostics to utilize the above information to process the tumor specimen for the indicated patient. I certify the following: I am authorized by law to order the test(s); the tests ordered above are medically necessary; the results will be used in the management of the patient; and I have obtained any required patient consent for performing the test(s) and disclosure of test results to me as the ordering physician and to the pathologist(s) providing the testing specimen. I agree to provide the necessary information and records needed for billing or reimbursement of the test(s). I have read the reverse side for additional details.

Signature _____ Printed Name _____ Date _____

BTX USE ONLY	

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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 CRITERIA WILL NOT BE ACCEPTED 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, 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

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

- Multifocal tumors: Prioritize specimen selection as follows 1) highest grade 2) largest size
- Locally recurrent tumors: Select specimen from original excision
- Neoadjuvant, chemo, endocrine or radiation therapy: Select specimen obtained prior to initiation of therapy
- 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.

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 reimbursable by Medicare based on the patient's medical condition. Biotheranostics does not recommend diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff.

Description	ICD-10 Code		
	Right Breast	Left Breast	Unspecified
Malignant neoplasm of nipple and areola of female breast	C50.011	C50.012	C50.019
Malignant neoplasm of central portion of female breast	C50.111	C50.112	C50.119
Malignant neoplasm of upper-inner quadrant of female breast	C50.211	C50.212	C50.219
Malignant neoplasm of lower-inner quadrant of female breast	C50.311	C50.312	C50.319
Malignant neoplasm of upper-outer quadrant of female breast	C50.411	C50.412	C50.419
Malignant neoplasm of lower-outer quadrant of female breast	C50.511	C50.512	C50.519
Malignant neoplasm of axillary tail of female breast	C50.611	C50.612	C50.619
Malignant neoplasm of overlapping sites of female breast	C50.811	C50.812	C50.819
Malignant neoplasm of breast (female) unspecified site	C50.911	C50.912	C50.919
Estrogen receptor positive status [ER+]	Z17.0		

MEDICARE LCD COVERAGE CRITERIA

When ordering Breast Cancer Index (BCI), please keep in mind Medicare's position that the following criteria must be met for Medicare coverage:

- Post-menopausal female with non-relapsed, ER+ breast cancer, and was lymph node negative (LN-), and
- Is completing five (5) years of tamoxifen therapy, and
- Patient must be eligible for consideration of extended endocrine therapy based on published clinical trial data or practice guidelines, and
- Physician or patient is concerned about continuing anti-hormonal therapy because of documented meaningful toxicity or possible significant patient-specific side effects, and
- The test results will be discussed with the patient (including the limitations of the testing method, the risks and benefits of either continuing or stopping the therapy based on the test, and current cancer management guidelines).

ATTESTATION

The signature also constitutes a certification of the following: (1) If the ordering physician is not the treating physician (or his/her authorized representative), the ordering physician confirms that the treating physician has ordered the test for this purpose; (2) The treating physician has obtained the patient's consent for Biotheranostics to send the patient's test results to the patient's third party payer, if necessary for payment; (3) In all cases, it is the treating physician's responsibility to determine whether and how the test result should be used in determining a treatment plan for that patient. Biotheranostics will run 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 intended for use in patients diagnosed with estrogen receptor-positive (ER+), lymph node-negative (LN-) or lymph node positive (LN+; with 1-3 positive nodes) early-stage, invasive breast cancer, who are distant recurrence-free. BCI provides: 1) a quantitative assessment of the likelihood of both late (post-5 years) and overall (0-10 year) distant recurrence following an initial 5 years of endocrine therapy (LN- patients) or 5 years of endocrine therapy plus adjuvant chemotherapy (LN+ patients), and 2) prediction of 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.

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