Breast Cancer INDEX℠

Test Requisition Form

BIO THERANOSTICS

Biotheranostics • 9640 Towne Centre Dr., Suite 200 • San Diego, CA 92121, USA
Toll Free: (877) 886-6739 • Fax: (800) 266-9607 • www.Biotheranostics.com

ORDERING INSTRUCTIONS	SPECIMEN RETRIEVAL OPTION
1.Complete all fields below 2.Please include the completed Test Requisition Form, pathology report, & patient insurance card(s) along with the specimen 3. Ship to Biotheranostics via FedEx Priority Overnight	☐ I want Biotheranostics to request the specimen from Pathology (Please complete and fax this form to 800-266-9607)

ORDERING PHYSICIAN

Name ☐ Please check if you are the ordering physician		NPI
Practice/Facility Name		Address
City	State	Zip
Email	Phone	Fax

PATHOLOGIST

Name ☐ Please check if you are the ordering physician		NPI
Practice/Facility Name		Address
City	State	Zip
Email	Phone	Fax

SPECIMEN INFORMATION

Block ID Number	Biopsy Site	Date of Collection
Clinical Diagnosis	**ICD-10 Codes** (Required) **- List all codes that may apply** (See reverse for reference guide)	

PATIENT INFORMATION Please include a copy of the patient face sheet

Name	DOB	Phone
Social Security Number	Sex ☐ Male ☐ Female	**Medical Record #**
Address		
City	State	Zip

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

Bill to: ☐ Insurance ☐ Medicare - Part B* ☐ Patient ☐ Hospital/Facility ***For details of Medicare LCD coverage criteria, see reverse**

Primary Insurance Carrier Name	Group #	Policy #
Insurance Address		Phone
Secondary Insurance Carrier Name	Group #	Policy #
Insurance Address		Phone

Medicare Status (Required) Check box for patient's hospital status when sample was sent: ☐ Hospital Inpatient ☐ Non-Hospital Patient ☐ Hospital Outpatient Date of Discharge _____

REQUIRED

REQUIRED CLINICAL INFORMATION

 # Positive Nodes* (Circle One): 0 1 - 3 Note: Only accepting samples for patients with 0-3 positive nodes

Node-Positive

Tumor Size (cm): ____ . ____ cm

Tumor Grade (Nottingham or Elston) - Circle One: 1 2 3
If mixed grade, select higher grade for classification

TEST REQUESTED (Required)

☐ Breast Cancer Index℠ (BCI)

PHYSICIAN/PRACTITIONER CERTIFICATION (Required)

I hereby request and authorize Biotheranostics to utilize the above information to process the tumor specimen for the indicated patient. I certify that the BCI test is medically necessary and the results will be used in the management of the patient. I certify that I have obtained appropriate patient consent for the test, I am authorized by law to request the test and I agree to provide the necessary information and records needed for billing or reimbursement of the test. Please read the reverse side for full details.

Signature _____ Printed Name _____ Date _____

Block Return Location (if different from a location listed above) _____

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Specimen Collection and Handling Procedures

PLEASE NOTE: Laboratory test result quality is highly dependent upon proper specimen collection and handling procedures. The specimen requirements and handling procedures for tests processed in the Biotheranostics laboratory are listed below. All samples must be labeled with the patient name and date of collection. Unlabeled specimens will not be accepted for testing.

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 TYPE	Testing is performed on primary invasive tumor (not DCIS). The following are acceptable specimen types: • Surgical Resections • Core Needle Biopsies • Excisional Biopsies NOTE: Specimen must be from biopsy obtained prior to chemotherapy
SPECIMEN REQUIREMENTS	**Specimen options:** • FFPE block (preferred) **OR** 3-4 unstained 10 micron sections on glass slides (50% tumor content) and 1 H&E slide.
STORAGE CONDITIONS	Store specimen at room temperature (15-30°C).
QUESTIONS	Medical and scientific staff are available to answer questions about specimen and sample viability prior to sending blocks or slides for testing - call Toll Free (877) 886-6739 between 7am and 4pm Pacific Time.
PATHOLOGY REPORT	Please enclose a copy of the pathology report with the specimen.

Please label sample blocks or slides with identifiers that are also written on or affixed to the Test Requisition, such as patient name, case number, and/or sample number. We regret that we cannot accept samples for testing if the identifiers used on the blocks or slides do not match those listed on the Test Requisition submitted with the samples. We are unable to accept sample blocks or slides that are not labeled. Blocks will be returned immediately following test completion.

TRANSPORTATION: Place specimen blocks or slides in a plastic slide cassette. Place the cassette and the completed Test Requisition in a Biotheranostics Specimen Shipping Kit. Use cold pack for transport. Do not place cold pack in direct contact with specimen during transport. Send specimens via FedEx "Priority Overnight" service. A pickup may be scheduled online at www.fedex.com or by calling (800) 463-3339.

NOTE: To obtain FREE specimen shipping kits, and Biotheranostics FedEx account information call Client Services at (877) 886-6739. You may also use your own packaging to ship specimen.

ICD-10 CODE REFERENCE: For Breast Cancer Index, below is a list of covered diagnosis codes from the Palmetto (Medicare) 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 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).

Billing Note: 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.

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 a) that the specimen does not have adequate cancer tissue; or b) It determines that the Test Requisition Form provides insufficient information to perform and report a result.

***Node Status:** Enter the node status for the patient in the designated area. The node status is required to determine the risk of recurrence information included in the report for your patient. Additionally, the node status may be required for payor coverage determinations. If the node status is not specified, Biotheranostics may use the pathology report, if provided, to determine the node status for reimbursement purposes.

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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