Biotheranostics, Inc.
A Hologic Company

The **Breast Cancer Index**® Test Patient Eligibility Criteria

The Breast Cancer Index Test is the leading endocrine therapy biomarker to help set clear expectations for patients with early-stage, HR+ breast cancer from the start.

Please refer to the table below to ensure your patient is eligible for testing.

Criteria	Accepted
Sex	• Biologically female
Hormone Receptor Status	• ER+ / PR+ • ER+ / PR- • ER- / PR+
Breast Cancer Type	• Breast primary invasive tumor • Invasive ductal carcinoma including most unusual subtypes such as mucinous, tubular, medullary, micropapillary, papillary, cribriform • Invasive Lobular Carcinoma • Multifocal tumor (same specimen) • Bilateral Breast Cancer (BBC) • Contralateral new primary • Local recurrence has occurred *(submit original tumor or biopsy)*
Biopsy Site	• Breast
Nodal Status	• Node-negative (pN0) • Isolated tumor cell clusters (ITC) (pN0(i+)) • Micrometastases in 1-3 lymph nodes (pN1mi) • Node positive with 1-3 positive lymph nodes (pN1) • No lymph node dissection (pNx)
Tumor Size	• T1, T2, T3
Tumor Grade	• 1, 2, 3
HER2 Status	• HER2- • HER2+
Menopausal Status	• Pre-Menopausal • Post-Menopausal • Peri-Menopausal

See reverse for commonly ineligible patients

Please see below for what types of patients commonly ARE NOT eligible for testing.

Criteria	Not Accepted
Sex	• Biologically male
Hormone Receptor Status	• ER- and PR-
Breast Cancer Type	• Metastatic breast cancer • No evidence of invasive (ductal, lobular or mixed ductal lobular) carcinoma • Metaplastic breast cancer • Carcinosarcoma • Sarcoma • Neuroendocrine carcinoma • Phyllodes tumor • Adenoid cystic carcinoma
Biopsy Site	• Chest wall • Lymph node • Skin
Nodal Status	• ≥4 positive nodes • Unknown nodal status
Tumor Size	• Tis (DCIS) • Tis (LCIS) • Microinvasive carcinoma T1mi • T4

Please contact us if you have any questions.

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NOTE: This document is intended to educate physicians on eligibility criteria for Breast Cancer Index Testing. For Medicare coverage criteria under the Local Coverage Determination and the full Intended Use and Limitations, please visit **BreastCancerIndex.com**.