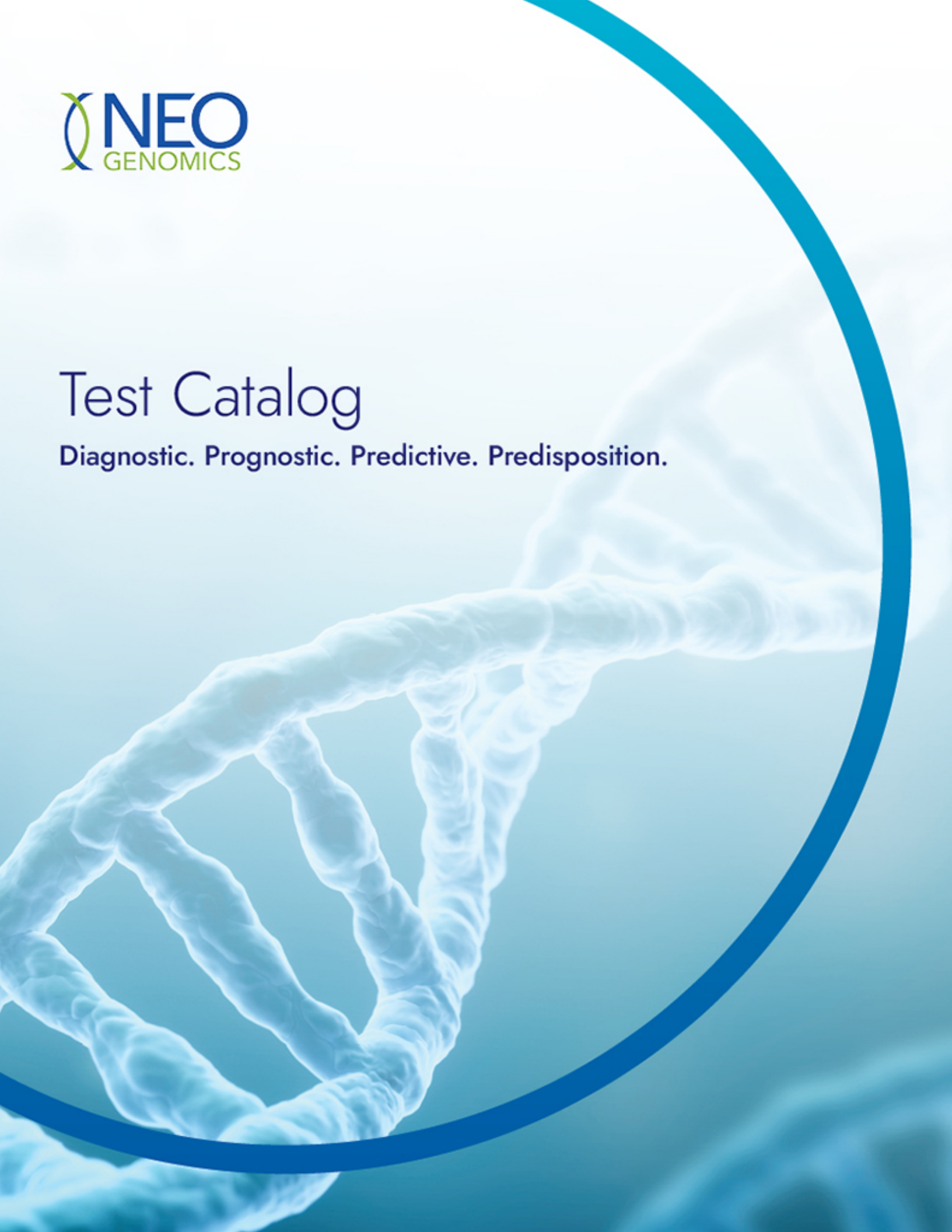
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



Breast Cancer Index® (BCI)

Methodology
Molecular

Test Description
Breast Cancer Index (BCI) is an RT-PCR assay performed on FFPE breast tumor tissue that integrates two gene expression-based biomarkers: 1) the HOXB13:IL17BR ratio (H/I), which is associated with tumor responsiveness to endocrine therapy; and 2) Molecular Grade Index (MGI), which consists of the average expression of five cell cycle-associated genes (BUB1B, CENPA, NEK2, RACGAP1 and RRM2) and provides quantitative and objective molecular assessment of tumor proliferative status.

Clinical Significance
BCI Risk of Recurrence & Extended Endocrine Benefit is a molecular tool to help with the extended endocrine decision after primary adjuvant therapy in HR+ early-stage (TNM stage T1-3, N0-1) breast cancer patients. Breast Cancer Index provides information regarding a patient's individualized risk for distant recurrence and prediction of likelihood of benefit from extended (>5 years) endocrine therapy.

The test is intended 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. BCI provides two results based on unique gene signatures:

- **BCI Prognostic**: a quantitative assessment of the likelihood of 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). Results are presented as percentage risk and categorized as high or low risk.
  **0-10 year results apply if BCI is ordered at the time of diagnosis.*

- **BCI Predictive**: prediction of likelihood of benefit from extended (>5 year) endocrine therapy. Results are presented as a high or low likelihood of benefit.

BCI results are adjunctive to the ordering physician's workup; treatment decisions require correlation with all other clinical findings. Testing is approved for specimens from the state of New York.

Breast Cancer Index is performed, reported, and billed separately by Biotheranostics, Inc., A Hologic Company. For comprehensive details about Breast Cancer Index including sample reports, clinical studies, intended use and limitations, and Medicare Local Coverage Determination (LCD) criteria, visit www.breastcancerindex.com

Specimen Requirements
Testing is performed on breast primary invasive tumor.

- **FFPE tissue**: Paraffin block is preferred. Alternatively, send 3-4 unstained, 10 micron thick sections on glass slides (an area of tumor that contains ?40% neoplastic cells) and one H&E-stained slide.
- **Note**: Cases with the following clinical or specimen characteristics are not acceptable: post-treatment (adjuvant or neoadjuvant) specimens, fine needle aspirations (FNA), fresh or frozen tissue, both ER- and PR-, ?4 positive nodes, microinvasive carcinoma, metaplastic or metastatic breast cancer, carcinosarcoma, sarcoma, neuroendocrine carcinoma, adenoid cystic carcinoma, phyllodes tumor, male gender, T4 tumor, no evidence of invasive (ductal, lobular

or mixed ductal lobular) carcinoma, biopsy site of chest wall, skin, axilla or lymph node.

Storage & Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

Please contact Biotheranostics, Inc. at 877-886-6739.

New York Approved

Yes

Level of Service

Global

Turnaround Time

10 days

References

1. Zhang Y, et al. *J Clin Oncol.* 2016; 34 (suppl abstr 541).
2. Sanft T, et al. *Breast Cancer Res Treat.* 2015;154(3):533-41.
3. Sgroi DC, et al. *Lancet Oncol.* 2013;14:1067 – 76.
4. Zhang Y, et al. *Clin Cancer Res.* 2013;19:4196-4205.
5. Sgroi DC, et al. *J Natl Cancer Inst.* 2013;105:1036-1042.
6. Ma X-J, et al. *Clin Cancer Res.* 2008;14:2601-2608.

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Please direct any questions regarding coding to the payor being billed.

NeoGenomics Laboratories is a specialized oncology reference laboratory providing the latest technologies, testing partnership opportunities, and interactive education to the oncology and pathology communities. We offer the complete spectrum of diagnostic services in molecular testing, FISH, cytogenetics, flow cytometry, and immunohistochemistry through our nation-wide network of CAP-accredited, CLIA-certified laboratories.

Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.

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