1.8% Risk of Late Recurrence (years 5-10)

LOW RISK CATEGORY*

1.8% RISK† (95% CI: 0.0% - 3.5%)
OF DISTANT RECURRENCE FOR ER+, LYMPH NODE-NEGATIVE PATIENTS AFTER YEAR 5†

† Risk of Recurrence estimate is based on analysis of BCI Prognostic in the Stockholm clinical study† and provides residual risk of distant recurrence beyond year 5 in patients treated with a maximum of 5 years of adjuvant endocrine therapy only (no adjuvant chemotherapy or extended endocrine therapy). Risk of recurrence applies only to LN- patients.

BCI Predictive was validated in a cohort that included both LN- and LN+ (1-3 nodes) patients; however, the study was not designed or powered to assess LN+ and LN- groups separately.

Patients with Low Likelihood of Benefit result had NO SIGNIFICANT RISK REDUCTION (p=0.35) when treated with extended endocrine therapy in the MA.17 validation study°

TREATMENT BENEFIT BASED ON INDEPENDENT VALIDATION DATA OF BCI PREDICTIVE IN MA.17°
ADDITIONAL RESULTS APPLICABLE IF BCI ORDERED AT TIME OF DIAGNOSIS

**BCI Prognostic - Node Negative**

**LOW RISK CATEGORY**

3.1% Risk of Overall Recurrence (years 0-10)

**BCI Predictive**

**LOW LIKELIHOOD OF BENEFIT FROM EXTENDED ENDOCRINE THERAPY**

BCI Predictive was validated in a cohort that included both LN- and LN+ (1-3 nodes) patients; however, the study was not designed or powered to assess LN+ and LN- groups separately.

Test Description and Clinical Evidence

BCI is a multi-gene quantitative RT-PCR assay that provides two outputs based on unique gene expression signatures: BCI Prognostic and BCI Predictive.

**BCI Predictive** provides a prediction of likelihood of benefit from extended (>5 years) endocrine therapy (EET). Patient results for this test are categorized as either High or Low Likelihood of Benefit. BCI Predictive was validated in the NCIC-CTG MA.17 trial. BCI Prognostic provides an individualized estimate for a patient's risk for distant recurrence in the late (5-10 years post-diagnosis) and overall (0-10 years post-diagnosis) time frames. For each time frame, a risk category is provided based on pre-specified cutpoints. BCI Prognostic has been validated in 3 independent cohorts. Independent validation data of BCI Prognostic in TransATAC

Risk of recurrence for lymph node-negative patients from years 5-10 by BCI risk groups in TransATAC

- Low Risk (BCI Score <5.0825): 3.5%
- Intermediate Risk (5.0825 ≤ BCI Score ≤ 6.5025): 18.3%
- High Risk (BCI Score ≥ 6.5025): 29.0%

Risk of recurrence for lymph node-negative patients from years 0-10 by BCI risk groups in TransATAC

- Low Risk (BCI Score <5.0825): 3.1%
- Intermediate Risk (5.0825 ≤ BCI Score ≤ 6.5025): 18.3%
- High Risk (BCI Score ≥ 6.5025): 29.0%

Further Information

For additional information including test description, methodology, clinical report and interpretation, please see: www.breastcancerindex.com/ordering

References


Laboratory Director: Sue Beruti, M.D. CLIA #: 05-D1065727 CLF334843 Electronically Signed By:

Intended use and Limitations

The Breast Cancer Index (BCI) Risk of Recurrence & Extended Endocrine Benefit Test is indicated 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.

Biotheranostics, Inc. 9640 Towne Center Drive, Suite 200 • San Diego, CA 92121 Tel: 877.886.6739

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