**Risk Of Distant Recurrence & Extended Endocrine Benefit (Report Page 1 of 2)**

**Physician Information**
Treating Physician
Pathologist

**Patient & Order Information**
Order ID

**BCI Prognostic - Node Negative**

12.3% Risk of Late Recurrence
(years 5-10)

**HIGH RISK CATEGORY**

12.3% RISK† (95% CI: 2.6% - 21.1%)
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**

HIGH LIKELIHOOD OF BENEFIT FROM EXTENDED ENDOCRINE THERAPY³

High Likelihood of Benefit

Low Likelihood of Benefit

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.

**Treatment Benefit Based on Independent Validation Data of BCI Predictive in MA.17³**

Patients with High Likelihood of Benefit result had 67% RELATIVE RISK REDUCTION (p=0.007) when treated with extended endocrine therapy in the MA.17 validation study³

**Additional Comments:**

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**CLIA #: 05-D1065727 CLIF334843**

**Electronically Signed By:**
**ADDITIONAL RESULTS APPLICABLE IF BCI ORDERED AT TIME OF DIAGNOSIS**

**BCI Prognostic - Node Negative**

**HIGH RISK CATEGORY**

22.7% Risk of Overall Recurrence (years 0-10)

**HIGH RISK CATEGORY** (95% CI: 10.1% - 33.5%)

**OF DISTANT RECURRENT FOR ER+, LYMPH NODE - NEGATIVE PATIENTS FROM YEARS 0-10**

† Risk of Recurrence estimate is based on analysis of BCI Prognostic in the Stockholm clinical study and provides risk of recurrence from years 0-10 post-diagnosis 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**

**HIGH 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.

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**Further Information**

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

**References**


**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.