1.2% Risk of Late Recurrence (years 5-10)

**LOW RISK CATEGORY**

1.2% RISK† (95% CI: 0.0% - 3.4%)

OF DISTANT RECURRENCE FOR ER+, LYMHP NODE-POSITIVE PATIENTS AFTER YEAR 5

† Risk of Recurrence estimate is based on analysis of BCI Prognostic in an independent validation cohort of patients with 1-3 positive lymph nodes and provides residual risk of distant recurrence from years 5-10 post-diagnosis in patients treated with adjuvant chemotherapy and 5 years of adjuvant endocrine therapy (no extended endocrine therapy). See page 2 for additional details.

**BCI Predictive**

LOW LIKELIHOOD OF BENEFIT FROM EXTENDED ENDOCRINE THERAPY

Your Result
Low BCI Predictive

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

Without Extended Endocrine Therapy

With Extended Endocrine Therapy

13

9

No significant benefit

Risk of Recurrence (%)
## Risk Of Distant Recurrence & Extended Endocrine Benefit (Report Page 2 of 2)

### Physician Information

Treating Physician

### Patient & Order Information

### ADDITIONAL RESULTS APPLICABLE IF BCI ORDERED AT TIME OF DIAGNOSIS

<table>
<thead>
<tr>
<th>BCI Prognostic - Node Positive (1-3)</th>
<th>BCI Predictive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LOW RISK CATEGORY</strong></td>
<td><strong>LOW LIKELIHOOD OF BENEFIT</strong></td>
</tr>
<tr>
<td>0.5% Risk of Overall Recurrence</td>
<td>FROM EXTENDED ENDOCRINE THERAPY²</td>
</tr>
<tr>
<td>(years 0-10)</td>
<td></td>
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</tbody>
</table>

† Risk of Recurrence estimate is based on analysis of BCI Prognostic in an independent validation cohort of patients with 1-3 positive nodes and provides risk of distant recurrence from years 0-10 post-diagnosis in patients treated with adjuvant chemotherapy and 5 years of adjuvant endocrine therapy (no extended endocrine therapy). See below for additional details.

### Test Description and Clinical Evidence

BCI provides two outputs based on unique gene expression (quantitative RT-PCR) signatures: BCI Prognostic and BCI Predictive.

**BCI Predictive** provides a prediction of likelihood of benefit from extended (>5 years) endocrine therapy (EET).² Patient results for this test are categorized as either High or Low Likelihood of Benefit. BCI Predictive is based on the ratio of H/I (HOXB13:IL17BR) and was validated in the NCIC-CTG MA.17 trial.²,³

**BCI Prognostic** for LN+ (1-3 positive nodes) 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.¹ For each time frame, a risk category is provided based on pre-specified cut points.¹ BCI Prognostic for LN+ patients (1-3 positive nodes) is based on the algorithmic combination of the BCI gene expression signature with tumor size and tumor grade. BCI prognostic for LN+ patients was validated in blinded study of patients with 1-3 positive nodes who were treated with adjuvant endocrine and chemotherapy.¹

### Further Information

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

### References


### Laboratory Director:

CLIA #: 05-D1065727 CLF334843 Electronically Signed By:

### Intended Use & 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.