

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

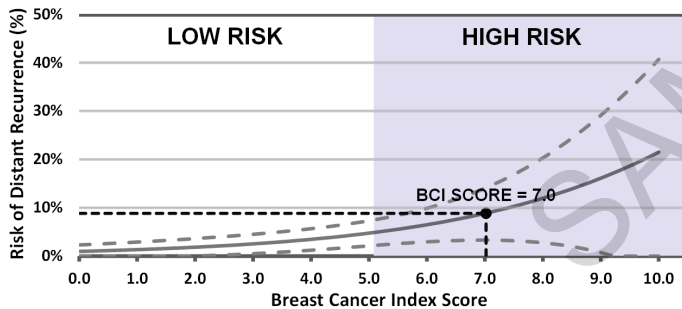
**8.8% Risk of Late Recurrence
(years 5-10)**

HIGH RISK CATEGORY*

8.8% RISK[†] (95% CI: 3.3% - 14.0%)
OF LATE DISTANT RECURRENCE FOR ER+,
LYMPH NODE-NEGATIVE PATIENTS¹

Based on the following clinical information for this patient:

Nodal Status: Lymph Node-Negative (N0)



[†] Risk of Recurrence estimate is based on analysis of BCI Prognostic in the Stockholm clinical study¹ 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

**LOW
Likelihood of Benefit**

**LOW LIKELIHOOD OF BENEFIT
FROM EXTENDED ENDOCRINE THERAPY³**



Your Result
Low BCI Predictive

High Likelihood
of Benefit

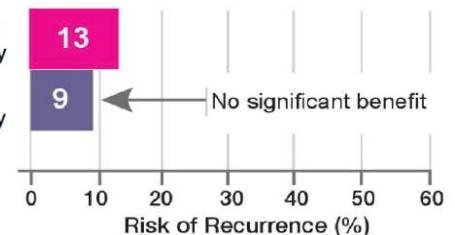
BCI Predictive was validated in a cohort that included both LN- and LN+ (1-3 nodes) patients; however, the study was not designed or powered to assess LN+ and LN- groups separately.

**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 study³**

TREATMENT BENEFIT BASED ON INDEPENDENT
VALIDATION DATA OF BCI PREDICTIVE IN MA.17³

Without Extended
Endocrine Therapy

With Extended
Endocrine Therapy



Additional Comments:

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

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ADDITIONAL RESULTS APPLICABLE IF BCI ORDERED AT TIME OF DIAGNOSIS

BCI Prognostic - Node Negative

16.2% Risk of Overall Recurrence (years 0-10)

HIGH RISK CATEGORY*

16.2% RISK[†] (95% CI: 9.2% - 22.7%)
OF DISTANT RECURRENCE FOR ER+, LYMPH NODE -
NEGATIVE PATIENTS FROM YEARS 0-10¹

Based on patient's clinical information listed on page 1

[†] Risk of Recurrence estimate is based on analysis of BCI Prognostic in the Stockholm clinical study¹ 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

LOW Likelihood of Benefit

LOW LIKELIHOOD OF BENEFIT

FROM EXTENDED ENDOCRINE THERAPY³

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

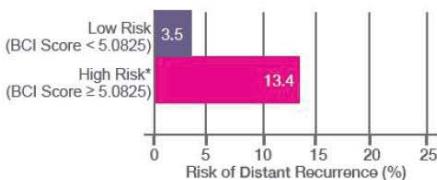
BCI is a multi-gene quantitative RT-PCR assay that provides two outputs based on unique gene expression signatures: BCI Prognostic and BCI Predictive.

BCI Predictive provides a prediction of likelihood of benefit from extended (>5 years) endocrine therapy (EET).³ 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.^{3,4}

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.^{1,2} For each time frame, a risk category is provided based on pre-specified cut points. BCI Prognostic has been validated in 3 independent cohorts.^{1,2}

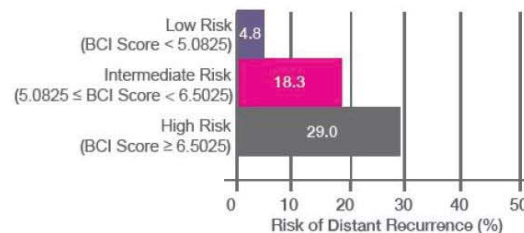
Independent validation data of BCI Prognostic in TransATAC²

Risk of recurrence for lymph node-negative patients from years 5-10 by BCI risk groups in TransATAC²



*In clinical studies, the BCI Intermediate risk group had a statistically similar risk of late (5-10 year) recurrence as the BCI High risk group;^{1,2} thus risk categories are reported as Low or High risk only.

Risk of recurrence for lymph node-negative patients from years 0-10 by BCI risk groups in TransATAC²



Further Information

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

References

- Zhang Y, et al. *Clin Cancer Res*. 2013;19:4196205.
- Sgroi D, et al. *Lancet Oncol*. 2013; 14:1067-76.
- Sgroi D, et al. *J Natl Cancer Inst*. 2013; 105:1036-42.
- Goss PE, et al. *N Engl J Med* 2003; 349:1793-802.

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CLIA# 05D1065725 CA# CLF00334843

Electronically Signed By: Miriam J. Bloch, M.D.

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.