BIO THERANOSTICS

Breast Cancer INDEX®

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

Physician Information

Treating Physician

Patient & Order Information

Order ID

ADDITIONAL RESULTS APPLICABLE IF BCI ORDERED AT TIME OF DIAGNOSIS

BCI Prognostic - Node Negative

[illegible]% Risk of Overall Recurrence [illegible] (years 0-10)

LOW RISK CATEGORY*

[illegible]% RISK† (95% [illegible] [illegible]

OF DISTANT RECURRENCE FOR ER+, LYMPH NODE - NEGATIVE PATIENTS FROM YEARS 0-10[1]

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 study[1] 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 THERAPY[3]

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

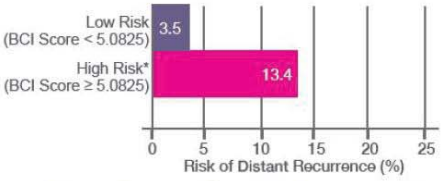
BCI is a multi-gene quantitative RT-PCR assay that provides two outputs based on unique gene expression signatures: BCI Prognostic and BCI Predictive.

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]

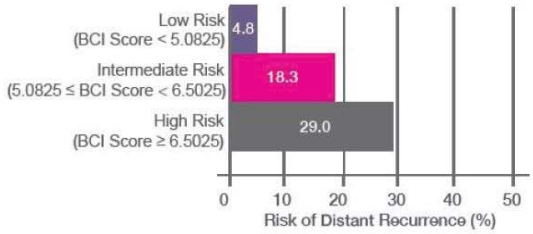
Independent validation data of BCI Prognostic in TransATAC[2]

Risk of recurrence for lymph node-negative patients from years 5-10 by BCI risk groups in TransATAC[2]



*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 TransATAC[2]



Further Information

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

References

1. Zhang Y, et al. *Clin Cancer Res*. 2013;19:4196205. 2. Sgroi D, et al. *Lancet Oncol*. 2013; 14:1067-76. 3. Sgroi D, et al. *J Natl Cancer Inst*. 2013; 105:1036-42. 4. Goss PE, et al. *N Engl J Med* 2003; 349:1793-802.

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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.

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