A PROVIDER GUIDE TO

EndoPredict®

Prognostic Precision Providing Results You Can Trust

FOR ER+, HER2–, EARLY-STAGE BREAST CANCER
Long-term prognosis is particularly important in ER-positive breast cancer.\(^1\)

Of patients with ER+ breast cancer who experience recurrent disease, more than 50% occur after 5 years.\(^{1,2}\)
EndoPredict was trained on a set of 964 ER+, HER2– breast tumors from women who were treated with adjuvant Tamoxifen only.

Gene selection process for 12-gene molecular score

Unbiased analysis of entire genome

Selected genes with reliable expression

Significantly associated with 10-year Distant Recurrence

Pathology friendly (FFPE tissue)

Correlation of Gene Expression with Early and Late Distant Recurrence

3 PROLIFERATION-RELATED GENES

• UBE2C
• BIRC5
• DHCR7

3 NORMALIZATION GENES

• CALM2
• OA1
• RPL37A

5 HORMONE RECEPTOR-RELATED GENES

• STC2
• AZGP1
• MGP
• IL6ST

1 CONTROL GENE

• RBBP8

EPclin Risk Score Algorithm:

Molecular Score + Tumor size + Nodal Status = EPclin Risk Score
EndoPredict offers powerful prognostic information for both N0 and N1 patients.\textsuperscript{3,4,6,7}

EndoPredict is a 2\textsuperscript{nd} generation test validated in over 3,500 patients with ER+, HER2–, N0 and N1 disease and provides robust 10-year prognostic results.\textsuperscript{3,4,6,8}

<table>
<thead>
<tr>
<th>Name of trial</th>
<th>N</th>
<th>Nodal status in cohort</th>
<th>Low-risk group average 10-year likelihood of distant recurrence</th>
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</thead>
<tbody>
<tr>
<td>Training</td>
<td>Multicenter 964</td>
<td>65% 35%</td>
<td>7%</td>
</tr>
<tr>
<td>Validation I</td>
<td>ABCSG-6 378</td>
<td>60% 40%</td>
<td>4%</td>
</tr>
<tr>
<td>Validation II</td>
<td>ABCSG-8 1324</td>
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<tr>
<td>Validation III</td>
<td>TransATAC 928</td>
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Utilized in clinical practice in over 25,000 patients worldwide.

\textbf{ACCORDING TO SIMON, HAYES AND PAIK:}

Studies using archived tissue from prospective studies MEET LEVEL 1 EVIDENCE when “the results are validated in at least one or more similarly designed studies using the same assay technique.”\textsuperscript{14}
EndoPredict is a second-generation assay trained and validated on 10-year distant recurrence data.

Filipits et al reported the independent validation of the EndoPredict molecular analysis and comprehensive EPclin score using data from two phase 3 studies, ABCSG-6 and ABCSG-8. Women in these studies received 5 years of endocrine therapy alone. Those in ABCSG-6 received either 5 years of tamoxifen or 2 years of tamoxifen and aminoglutethimide followed by 3 years of tamoxifen. Those in ABCSG-8 received either 5 years of tamoxifen or 2 years of tamoxifen followed by 3 years of anastrozole.\(^3\)
EndoPredict demonstrates superior prognostic performance in node-positive disease.\textsuperscript{6,7}

Analysis of node-positive ER+, HER2- patients from TransATAC Study\textsuperscript{7}

89.1\% of node positive patients are classified as NON-HIGH risk by Oncotype DX.

Sestak et al: Kaplan-Meier analysis of distant recurrence in 183 node-positive postmenopausal women in TransATAC using the EndoPredict EPclin score and the Oncotype DX RS. Participants received only 5 years of endocrine therapy (either tamoxifen or anastrozole).\textsuperscript{7}

“Combined genomic and clinical models showed enhanced prognostic performance particularly for patients with 1 to 3 positive lymph nodes.”

~ Sestak et al. JAMA Oncol 2018
Why EndoPredict?
EndoPredict is proven to have prognostic power to provide you with results you can trust.

- Individualized binary result with chemotherapy benefit
- Lower cost vs other breast cancer recurrence tests
- Fast 7-day turnaround
- Inclusion of proliferation- and hormone receptor–related genes contributes to accurate assessment of early and late recurrence risk
- Better identifies a large percentage of low-risk patients (average of 6% recurrence)
  - More than 70% of N0 patients
  - Up to 30% of N+ patients
For information on ordering EndoPredict visit endopredict.com

References:
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EARLY recurrence (0-5 years)

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- BIRC5
- DHCR7

- CALM2
- OAZ1
- RPL37A

- STC2
- AZGP1
- MGP
- IL6ST

LATE recurrence (5-10 years)

1 CONTROL GENE

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- Individualized binary result with chemotherapy benefit
- Lower cost vs other breast cancer recurrence tests
- Fast 7-day turnaround
- Inclusion of proliferation- and hormone receptor–related genes contributes to accurate assessment of early and late recurrence risk\(^4\,^5\)
- Better identifies a large percentage of low-risk patients (average of 6% recurrence)\(^3\,^6\,^8\)
- More than 70% of N0 patients\(^7\,^8\)
- Up to 30% of N+ patients\(^7\,^8\)

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**Analysis of node-positive ER+, HER2- patients from TransATAC Study\(^9\)**

\[\text{EndoPredict} \quad \text{EPclin} \quad (n=183)\]

- Hazard ratio: 1.69 (95% CI, 1.29-2.22)
- 23.5% low risk
- 5.6%

\[\text{Oncotype DX} \quad \text{RS} \quad (n=183)\]

- Hazard ratio: 1.39 (95% CI, 1.05-1.85)
- 57.4% low risk
- 19.4%

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References:

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