

# Oncotype DX tools<sup>®</sup> User Guide

**This guide provides an overview of the data and quick access to the Oncotype DX tools**

**Oncotype DX tools offers two quantitative calculator tools that may be used together with the Recurrence Score<sup>®</sup> result to enhance the understanding of the score in the assessment of distant recurrence risk.**

▶ **Recurrence Score & Hormonal Treatment Calculator**

▶ **RSPC (Recurrence Score-Pathology-Clinical) Calculator**

For newly diagnosed patients with lymph node-negative, ER-positive invasive breast cancer



**Oncotype DX tools offers two quantitative calculator tools that may be used together with the Recurrence Score result to enhance the understanding of the score in the assessment of distant recurrence risk.**

Oncotype DX tools is an educational website that offers two calculator tools:

**Recurrence Score & Hormonal Treatment Calculator**

- Allows the user to input an Oncotype DX® Breast Cancer Assay Recurrence Score result and view estimates of the risk of distant recurrence depending on which adjuvant hormonal therapy is planned (tamoxifen or an aromatase inhibitor)

**RSPC (Recurrence Score-Pathology-Clinical) Calculator**

- May help physicians understand how integrating clinical and pathological factors with the Oncotype DX Breast Cancer Recurrence Score result can enhance the understanding of the score

The two calculators are based on clinical experience in newly diagnosed female patients with lymph node–negative, ER-positive invasive breast cancer. The applicability of these calculator tools to patients with different characteristics (lymph node–positive, ER-negative, male, or not newly diagnosed) is not known.

The information and calculators included in the Oncotype DX tools site are for educational purposes only, and are not intended to render medical advice or to facilitate the diagnosis or treatment of patients with breast cancer. The information derived from the calculators presented on the Oncotype DX tools site has not been validated under the Clinical Laboratory Improvement Amendments (CLIA) for use in determining the prognosis of patients with breast cancer or the magnitude of benefit that may be predicted from treatments for breast cancer. The information derived from the calculators presented on this educational site is not intended to replace or substitute or be considered an add-on or separate diagnostic test from the Oncotype DX Breast Cancer Assay for the management of patients with breast cancer.

- The Calculation Tools tab allows you to enter the Oncotype DX tools site
- As you enter the site, there is a helpful video that explains Oncotype DX tools
- The Launch button opens the Oncotype DX tools microsite



- The introduction page describes the development and use of the Oncotype DX calculator tools



- Additional resources provide helpful links to publications, frequently asked questions, and educational videos



**Overview**

This calculator allows the user to input an Oncotype DX Breast Cancer Assay Recurrence Score result and view estimates of the risk of distant recurrence for node-negative, ER-positive invasive disease depending on which adjuvant hormonal therapy is planned (tamoxifen or an aromatase inhibitor). The adjustments to distant recurrence risk when aromatase inhibitor therapy is planned are based on a published meta-analysis comparing tamoxifen with aromatase inhibitors in 9,856 newly diagnosed, node-negative, ER-positive, postmenopausal women.<sup>1,3</sup>

The Recurrence Score & Hormonal Treatment Calculator has not been validated under CLIA for use in determining the prognosis of patients with invasive breast cancer for whom treatment with an aromatase inhibitor is planned or the magnitude of treatment benefit that may be predicted. The information derived from this calculator tool is not intended to replace or substitute or be considered an add-on or separate diagnostic test from the Oncotype DX Breast Cancer Assay for the management of patients with breast cancer.

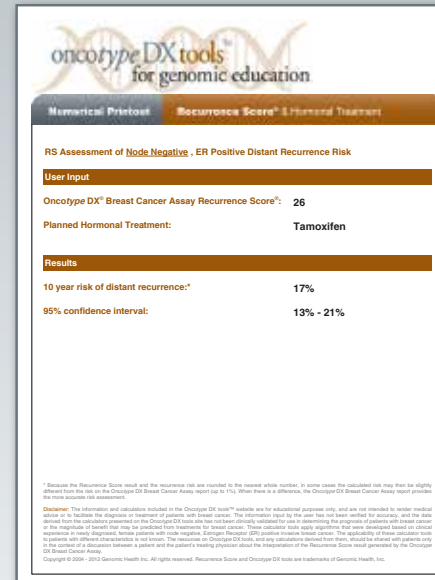
**Using the Calculator**

- To use the Recurrence Score & Hormonal Treatment calculator, enter the Recurrence Score result obtained from the Oncotype DX Breast Cancer Assay report
- Select the hormonal treatment you plan for this patient
- Once the Calculate button is selected, an estimate of the 10-year risk of distant recurrence and a 95% confidence interval will be displayed

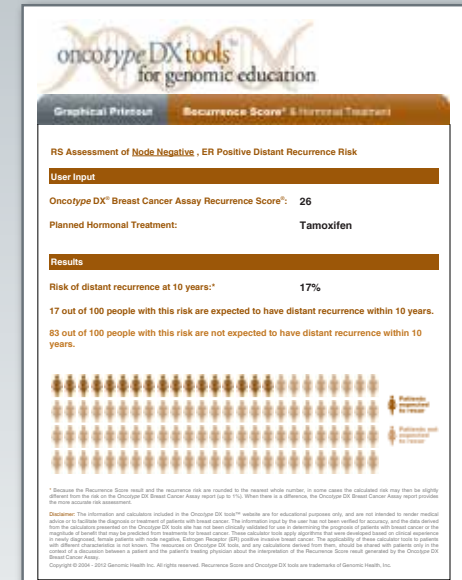


Because the Recurrence Score result and the recurrence risk are rounded to the nearest whole number, in some cases the calculated risk may be slightly different from the risk on the Oncotype DX Breast Cancer Assay report (up to 1%). When there is a difference, the Oncotype DX Breast Cancer Assay report provides the more accurate risk assessment.

The results are displayed as either a **numerical or graphical** printout in a PDF format.



Numerical printout



Graphical printout

**Disclaimer:**

*The resources on the Oncotype DX tools site, and any calculations derived from them, should be shared with patients only in the context of a discussion between the patient and the patient's treating physician about the interpretation of the Recurrence Score result generated by the Oncotype DX Breast Cancer Assay.*



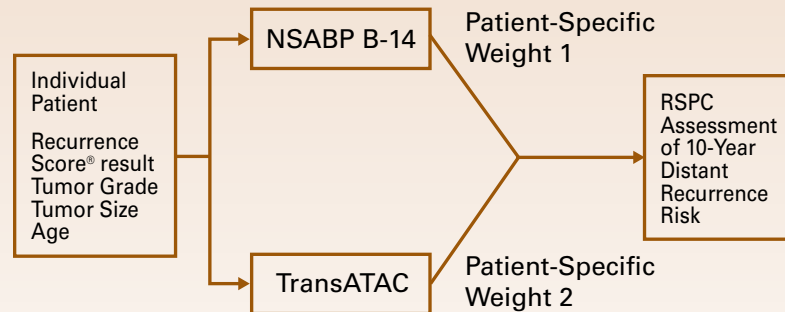
**Overview**

This calculator allows the user to input an Oncotype DX Breast Cancer Assay Recurrence Score result along with the traditional clinical and pathological factors: patient age, tumor size, and tumor grade, as well as the planned hormonal therapy (either tamoxifen or aromatase inhibitors), to enhance the understanding of the result in the context of node-negative, ER-positive invasive disease.

The RSPC tool has not been validated under CLIA for use in determining the prognosis of patients with invasive breast cancer for whom hormonal treatment is planned or the magnitude of treatment benefit that may be predicted. The information derived from this calculator tool is not intended to replace or substitute or be considered an add-on or separate diagnostic test from the Oncotype DX Breast Cancer Assay for the management of patients with breast cancer.

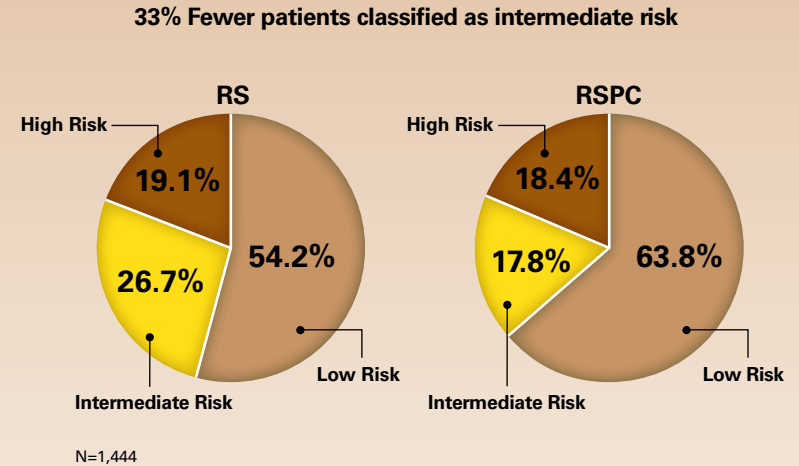
The RSPC tool was developed by combining the risk information from two trials (NSABP B-14 and TransATAC) in a patient-specific meta-analysis to enhance the understanding of the Recurrence Score result.<sup>2</sup>

**Calculation of Recurrence Score-Pathology-Clinical (RSPC)<sup>2</sup>**



**Clinical Data**

In a meta-analysis of the node-negative patients from two large studies (NSABP B-14 and TransATAC) that integrated clinical and pathological factors with the Recurrence Score result, RSPC classified approximately 33% fewer patients as intermediate risk compared to Recurrence Score result alone.<sup>2</sup>



In the meta-analysis of 1,735 patients\* from NSABP B-14 and TransATAC, the prognostic value of the RSPC model showed a statistically significant improvement relative to the Recurrence Score result alone ( $p < 0.001$ ) or to a model that combines the pathological and clinical factors of tumor size, tumor grade, and age ( $p < 0.001$ ).<sup>2</sup> However, only the Recurrence Score result has been clinically validated to assess the risk of recurrence in early-stage, node-negative, hormone receptor-positive invasive breast cancer patients in whom treatment with tamoxifen is planned. The RSPC tool has not been clinically validated.

Comparison	p-value
RSPC vs RS alone	<0.001
RSPC vs tumor size, grade, age	<0.001

\*The full meta-analysis included 1,735 node-negative and node-positive patients, adjusting for nodal status.

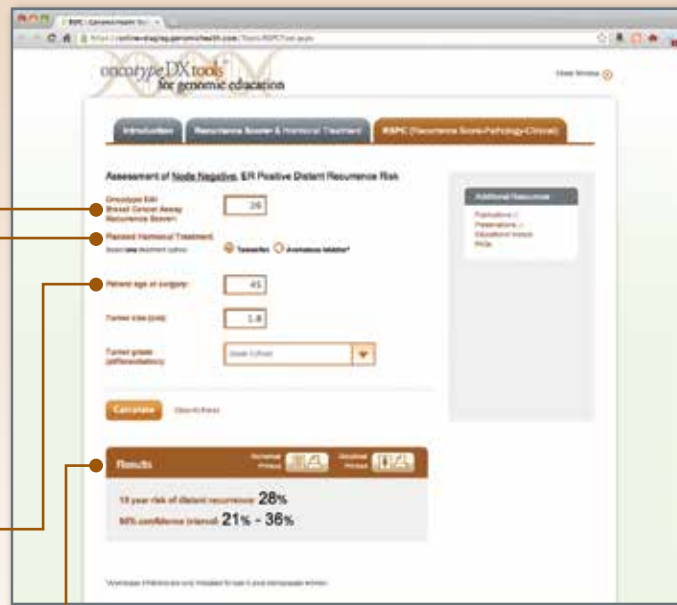
► **RSPC (Recurrence Score®-Pathology-Clinical) Calculator**

The addition of pathological and clinical factors to the Recurrence Score result did not improve the ability of the Recurrence Score result to predict chemotherapy benefit. This outcome is not unexpected, since pathological and clinical factors do not predict relative chemotherapy benefit.<sup>2</sup>

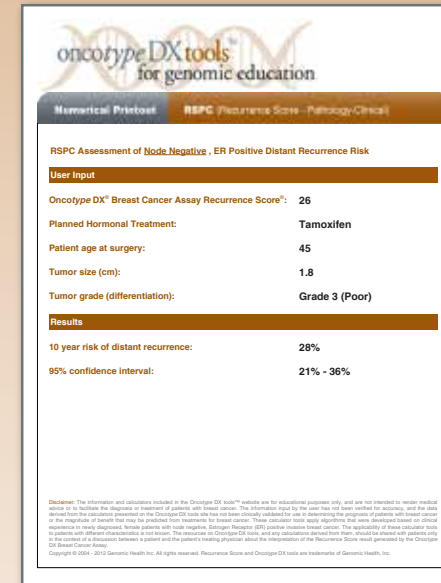
Variables	Hazard Ratio (95% CI)	p-value
RS x Treatment	0.66 (0.44 – 0.97)	0.037
RSPC x Treatment	0.65 (0.39 – 1.09)	0.10

**Using the Calculator**

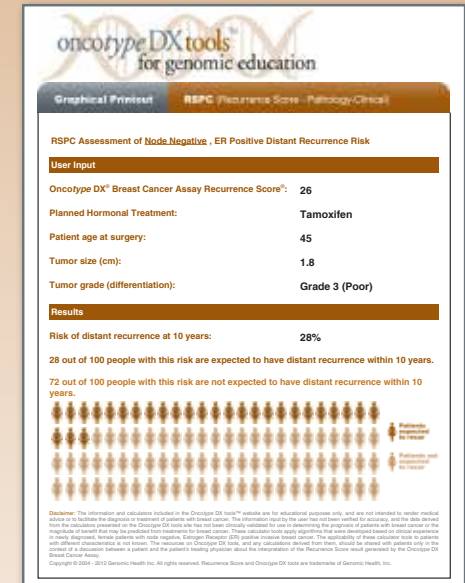
- To use the RSPC (Recurrence Score-Pathology-Clinical) calculator, enter the Recurrence Score result obtained from the *Oncotype DX* Breast Cancer Assay report
- Select the hormonal treatment you plan for this patient
- Enter patient age, tumor size, and tumor grade
- Once the Calculate button is selected, an estimate of the 10-year risk of distant recurrence and a 95% confidence interval will be displayed



The results are displayed as either a **numerical or graphical** printout in a PDF format.



Numerical printout



Graphical printout

**Disclaimer:**

*The resources on the Oncotype DX tools site, and any calculations derived from them, should be shared with patients only in the context of a discussion between the patient and the patient's treating physician about the interpretation of the Recurrence Score result generated by the Oncotype DX Breast Cancer Assay.*



Oncotype DX tools can be accessed via the Genomic Health Customer Portal (where Oncotype DX Assays can be ordered and patient results are accessed online): <https://online.genomichealth.com>

1. Call Customer Service at 886-ONCOTYPE to open an account
2. Log in to the Customer Portal at <https://online.genomichealth.com>
  - a. Enter your username and password
  - b. Select the new “Calculation Tools” tab to access the Oncotype DX tools landing page



**Oncotype DX tools offers two quantitative calculator tools that may be used together with the Recurrence Score result to enhance the understanding of the score in the assessment of distant recurrence risk.**

The Recurrence Score result gives a 10-year distant recurrence risk assessment when 5-year adjuvant tamoxifen therapy is planned

► **Recurrence Score & Hormonal Treatment Calculator**

is intended to enhance the understanding of the score in patients for whom adjuvant hormonal therapy with an aromatase inhibitor is planned

► **RSPC (Recurrence Score-Pathology-Clinical) Calculator**

provides an estimate of recurrence risk (prognosis) that integrates traditional prognostic characteristics with the Recurrence Score result

For further information, visit our Additional Resources section on the Oncotype DX tools website or contact Customer Service.

**References:**

1. Crager M, Tang G, Shak S. Using the 21-gene Recurrence Score (RS) and the recently developed Recurrence Score-Pathology-Clinical (RSPC) to assess recurrence risk in node-negative, ER-positive early stage breast cancer patients receiving aromatase inhibitor treatment alone. *J Clin Oncol.* 2011;29. Abstract 592.
2. Tang G, Cuzick J, Costantino J, et al. Risk of recurrence and chemotherapy benefit for patients with node-negative, estrogen receptor-positive breast cancer: recurrence score alone and integrated with pathologic and clinical factors. *J Clin Oncol.* 2011;29:4365-4372.
3. Dowsett M, Cuzick J, Ingle J, et al. Meta-analysis of breast cancer outcomes in adjuvant trials of aromatase inhibitors versus tamoxifen. *J Clin Oncol.* 2010;28:509-518.

## For customer service, please contact

---

### *U.S.A. Customer Service*

customerservice@genomichealth.com

866-ONCOTYPE (866-662-6897)

### *Outside of U.S.A.*

international@genomichealth.com

+ 650 569-2080

+ 866 662-6897 (Canada)

For additional toll-free access visit

[www.oncotypedx.com/contact](http://www.oncotypedx.com/contact)

Genomic Health is a global health company that provides actionable genomic information to personalize genomic health decisions.

### ***Disclaimer:***

*The Oncotype DX tools are a set of clinical educational tools intended to assist the physician with interpretation of the Recurrence Score result by providing the physician a convenient way to combine the Recurrence Score result with age, tumor grade, tumor size, and planned hormonal therapy. Unlike the Oncotype DX Breast Cancer Assay and the Recurrence Score result, the Oncotype DX tools are not clinical laboratory tests and, therefore, the outputs from the tools have not been validated under the Clinical Laboratory Improvement Amendments (CLIA). As the Oncotype DX tools are for educational purposes only, Genomic Health makes no intended use claims about the tools and leaves solely to the discretion of the treating physician when and how to apply the tools to help with the interpretation of the Recurrence Score result.*