



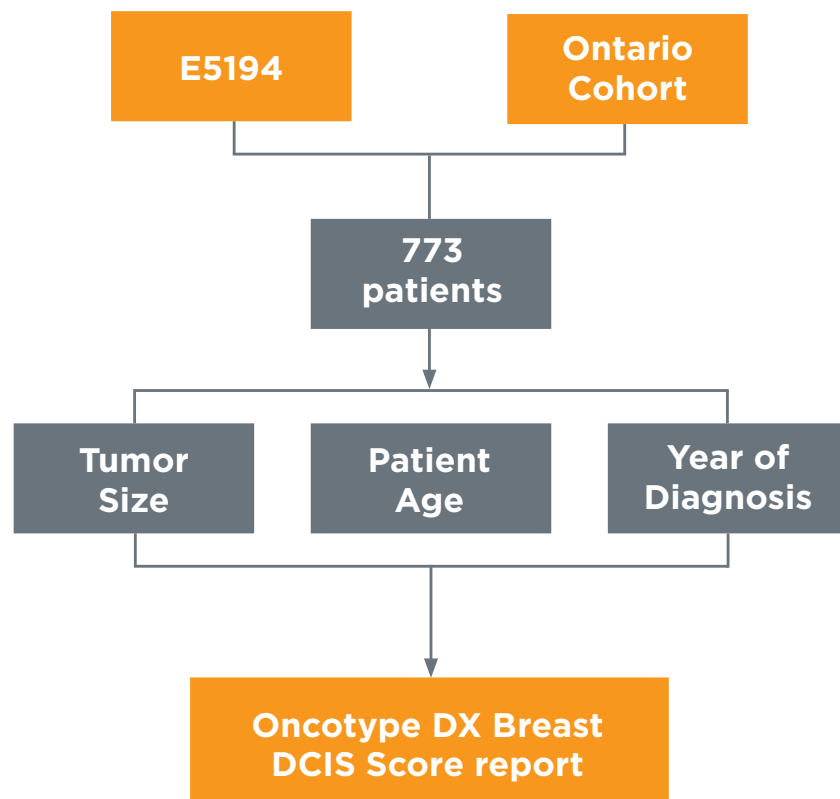
# Oncotype DX<sup>®</sup> Breast DCIS Score<sup>™</sup> Test: Confirmed by validation studies, refined by meta-analysis



The DCIS Score<sup>™</sup> report incorporates tumor size and patient age, providing refined 10-year risk of local recurrence.

A meta-analysis of the two validation studies, ECOG-ACRIN E5194 and the Ontario Cohort, reveals that DCIS Score result and certain clinicopathologic features (tumor size, age at diagnosis, and year of diagnosis) contribute significantly to the prognostic value of the 10-year risk of local recurrence.<sup>1</sup>

## DCIS Score Meta-Analysis



The report provides greater clarity regarding individual risk of local recurrence allowing you to better optimize treatment planning.

# The Breast DCIS Score™ report: Clear and clinically meaningful results

## Page 1 of report

### Breast DCIS Score Report

**PATIENT, SAMPLE**  
 Date of Birth: 01-Jan-1950    Gender: Female    Report Number: OR000123456-01    Report Date: 01-Aug-2017  
 Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

**Breast DCIS Score™ Result**

10

**What does a Breast DCIS Score of 10 mean?**  
 Based on your patient's age, tumor size, and Breast DCIS Score result of 10, your patient's risk of any local recurrence within 10 years is **6%**, if treated with breast-conserving surgery alone.

**10-Year Risk of Local Recurrence (PROGNOSIS)**    E5194 & Ontario Cohort Meta-analysis  
Age Category ≥ 50 years old, Tumor Size ≤ 1.0 cm

The Breast DCIS Score validation was derived from two studies, E5194 with 327 patients and the Ontario DCIS Cohort Study with 571 patients. The studies consisted of diverse DCIS patient populations treated with breast-conserving surgery alone. The results below reflect a meta-analysis with 773 patients of the two studies incorporating patient age and tumor size with the Breast DCIS Score result to estimate 10-year risk. The meta-analysis excluded patients whose tumors were multifocal and/or had positive margins.<sup>1-3</sup>

**Risk of Any Local Recurrence (DCIS or Invasive)**

6%    95% CI: 4% - 10%

**Risk of Invasive Local Recurrence**

4%    95% CI: 3% - 7%

Information on the Breast DCIS Score and clinical experience is available upon request  
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- **Visual representation** of DCIS Score result and overview of risk estimate
- Patient's 10-year risk of local recurrence, based on **patient's age, tumor size, and DCIS Score result**
- **Refined risk of recurrence** - any local recurrence (DCIS or invasive) and invasive local recurrence

# The Breast DCIS Score report: Quantitative estrogen and progesterone receptor scores

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### Breast DCIS Score Report

**PATIENT, SAMPLE**  
 Date of Birth: 01-Jan-1950    Gender: Female    Report Number: OR000123456-01    Report Date: 17-Aug-2017  
 Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01    Specimen Source/ID: Breast/SP-16\_0123456  
 Date of Collection: 02-Aug-2017    Client: Community Medical Center  
 Specimen Received: 04-Aug-2017  
 Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name  
 Pathologist: Dr. First-Name I. Pathologist-Last-Name

**Quantitative Single-Gene Scores**  
 The Oncotype DX® test uses RT-PCR to determine the RNA expression of the genes below. These results may differ from ER or PR results reported using other methods or reported by other laboratories.

**ER Score: 9.4 Positive**

9.4

**PR Score: 7.9 Positive**

7.9

References:  
 1. Solin et al. *J Natl Cancer Inst.* 2014; 2. Rakovitch et al. *Breast Cancer Res Treat.* 2015; 3. Rakovitch et al. *ASCO.* 2017.

**Laboratory Director(s): S. Shak, MD; F. Baehner, MD; H. Bailey, MD & P. Joseph, MD**

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

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 CLIA Number 05D1018272

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- Delivers quantitative single-gene scores for **informed hormone therapy decision-making**


Note: There are no data on the relationship between the ER or PR Scores and ER or PR by immunohistochemistry in DCIS

The Breast DCIS Score report provides refined 10-year risk of local recurrence by adding tumor size and patient age to the DCIS Score results.

# The Breast DCIS Score™ report: Streamlined for patient discussions

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### Breast DCIS Score Report



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**PATIENT, SAMPLE**

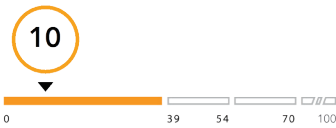
Date of Birth: **01-Jan-1950**    Gender: **Female**    Report Number: **OR000123456-01**    Report Date: **01-Aug-2017**

Ordering Physician: **Dr. First-Name I. Ordering-Physician-Last-Name**

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**Patient Educational Summary**

What does your result mean?

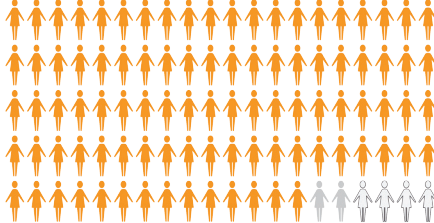


By measuring the activity of certain genes in your breast tumor tissue, the Oncotype DX™ test predicts the risk of disease returning in the same breast, as either DCIS or invasive cancer - a key factor in deciding your treatment following DCIS surgery.

Your Breast DCIS Score result of 10, combined with information about your age and tumor size, indicates a **6%** risk of your tumor returning as DCIS or invasive cancer in the same breast within 10 years, if treated only with breast-conserving surgery.

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What are the chances of your breast cancer returning?




If 100 women with a Breast DCIS Score result of **10** are treated with only breast-conserving surgery:

**94 women** will **not** have their disease return in the same breast as either DCIS or invasive cancer within 10 years.

**6 women** will have their disease return in the same breast as either DCIS or invasive cancer within 10 years. 4 women will have their disease return in the same breast as invasive cancer within 10 years.

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What are your treatment options? (For doctor/patient discussion)

 SURGERY  


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 RADIATION  



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 ENDOCRINE THERAPY  


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 MONITORING  


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Join other DCIS patients to learn about genomics and help transform patient care: [MyOncotype.com](http://MyOncotype.com)

This Patient Educational Summary is a brief explanation of your Oncotype DX test results. It is being provided by your doctor for discussion purposes. More information at [www.OncotypeIQ.com](http://www.OncotypeIQ.com) or [www.MyBreastCancerTreatment.org](http://www.MyBreastCancerTreatment.org).

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- Patient-friendly language to help explain the results to patients

- Visual representation of patient's personalized risk of local recurrence

- Notes section to facilitate patient discussions and treatment decisions

Order **Oncotype DX® Breast DCIS Score** to help you more accurately assess local recurrence risk and individualize treatment decisions for your patients.<sup>1-3</sup>

**References:** 1. Rakovitch et al. ASCO 2017. 2. Solin et al. *J Natl Cancer Inst.* 2013. 3. Rakovitch et al. *Breast Cancer Res Treat.* 2015. Genomic Health, Oncotype DX, Oncotype IQ, Oncotype DX Breast DCIS Score, and DCIS Score are trademarks or registered trademarks of Genomic Health, Inc.

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Breast DCIS Score