



NAVIGATING THE COMPLEX WATERS OF DCIS MANAGEMENT

The Oncotype DX® Breast Cancer Assay for DCIS:

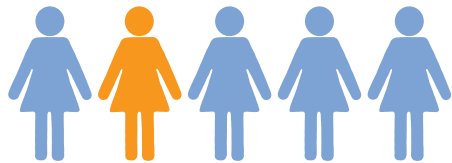
A genomic assay that increases clarity in
recurrence risk assessment and confidence in
your patient's personalized treatment plan

A BREAKTHROUGH
IN DCIS MANAGEMENT

oncotype DX®
Breast Cancer Assay
DCIS



DCIS INCIDENCE ON THE RISE



APPROXIMATELY
20%
of all new breast cancers in
the United States are DCIS¹

It is estimated that by 2020,
MORE THAN **ONE
MILLION
WOMEN**
in the United States will
be living with a DCIS
diagnosis, up from
500,000 in 2005¹

Traditional methods for assessing
risk of local recurrence do not
provide an individualized
estimate of risk¹

- DCIS is heterogeneous: no two patients
and no two tumors are the same—
despite similar clinical and pathologic
features at a given time
- Clinical and pathologic factors alone,
when combined in nomograms or
other models, use parameters that
are population-based estimates of
average risk and may have uncertainties
that impact result accuracy
- There is a need for clinical assays to
provide an individualized risk estimate
based on the underlying tumor biology
of each patient

“...THERE IS A PRESSING NEED TO IDENTIFY BIOMARKERS
THAT PREDICT LOCAL RECURRENCE AND PROGRESSION
TO INVASIVE BREAST CANCER INDEPENDENT OF
STANDARD PROGNOSTIC MARKERS SUCH AS GRADE
AND MARGIN STATUS.”

—Allegre et al. *J Natl Cancer Inst.* 2010¹

How do you determine a patient’s individual risk of
local recurrence (either invasive or DCIS) to inform
your treatment recommendation?



TWO VALIDATION STUDIES CONFIRM THAT THE
DCIS SCORE™ RESULT DETERMINES THE 10-YEAR
RISK OF LOCAL RECURRENCE^{2,3}

ONTARIO DCIS COHORT

A second study confirmed the results from the ECOG E5194
study and the ability of the DCIS Score result to risk stratify in
a community-based, real-world cohort of 571 DCIS patients
who had breast-conserving surgery and negative margins*

- **CONFIRMED THE DCIS SCORE
RESULT** reveals the 10-year risk
of local recurrence in patients
with DCIS who underwent breast-
conserving surgery ($P < .001$)
- **RESULTS BASED ON A LARGE
(N = 571), DIVERSE PATIENT
POPULATION** from a community-
based setting that resembles
real-world clinical practice

- **CONFIRMED THAT THE
DCIS SCORE RESULT** is strongly
associated with **RISK OF
AN INVASIVE LOCAL
RECURRENCE** ($P = .03$)
- **VALIDATED THAT THE DCIS
SCORE RESULT** is significantly
associated with **RISK OF A DCIS
LOCAL RECURRENCE** ($P = .002$)



“THIS LANDMARK STUDY RECONFIRMED ONCOTYPE DX AS AN OBJECTIVE
BIOMARKER...WHICH CAN BE SEEN AS THE **BIGGEST ADVANCEMENT IN**
THE MANAGEMENT OF DCIS IN MORE THAN A DECADE”

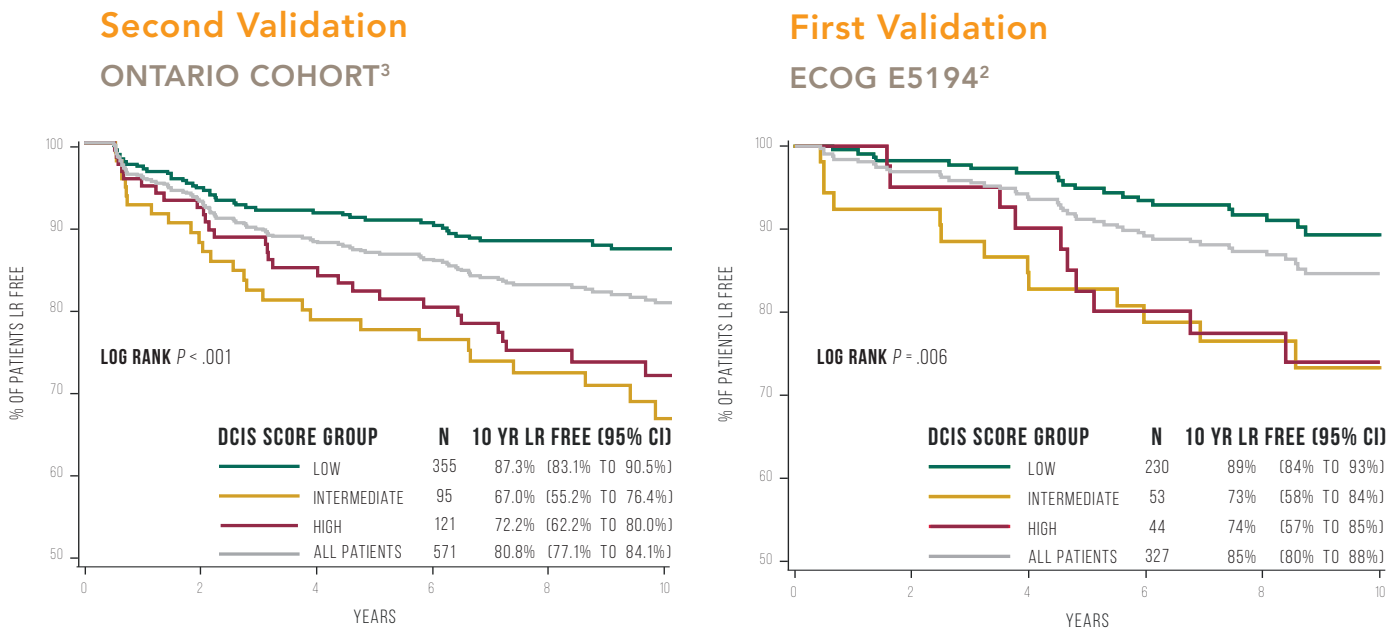
—DCIS Expert Panel, 2014⁴

*Defined as no tumor on ink.

THE DCIS SCORE™ RESULT
CONFIRMED IN TWO VALIDATION STUDIES TO ASSESS 10-YEAR
RISK OF LOCAL RECURRENCE

10-YEAR
RISK OF
RECURRENCE

THE DCIS SCORE RESULT DETERMINES 10-YEAR RISK
OF LOCAL RECURRENCE BY RISK GROUP^{2,3}



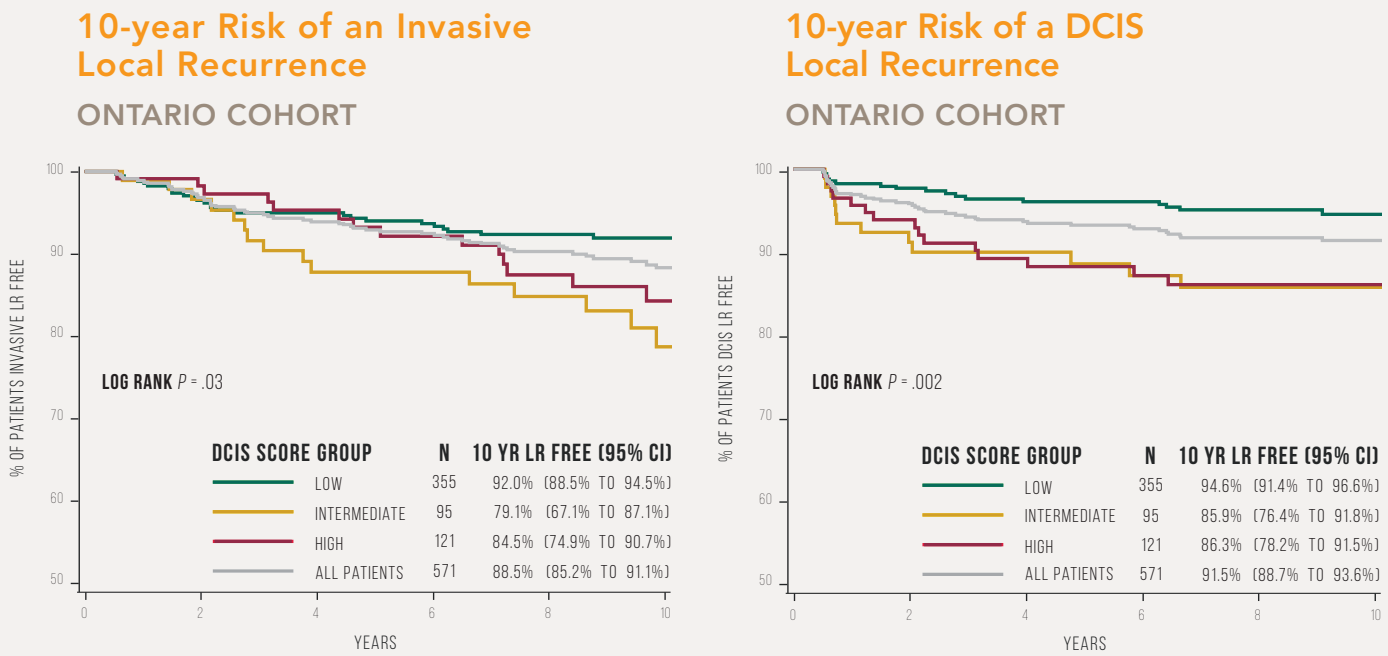
The second validation is a population-based study that confirmed the ability of the DCIS Score result to predict local recurrence, as demonstrated in ECOG E5194 ($P = .006$)³

Confirmed risk stratification based on underlying individual tumor biology that is not discernible in the risk of the entire patient population

THE DCIS SCORE™ RESULT
QUANTIFIES THE 10-YEAR RISK OF AN INVASIVE OR A DCIS LOCAL
RECURRENCE BY CLARIFYING THE COMPLEXITIES OF INDIVIDUAL
TUMOR BIOLOGY

INDIVIDUAL
TUMOR
BIOLOGY

GREATER INSIGHT INTO RISK STRATIFICATION
FOR AN **INVASIVE** OR A **DCIS** LOCAL RECURRENCE³



Confirms that the DCIS Score result stratifies patients for risk of an invasive local recurrence ($P = .006$)³

For the first time, you can now identify the risk of a DCIS local recurrence ($P = .002$)³

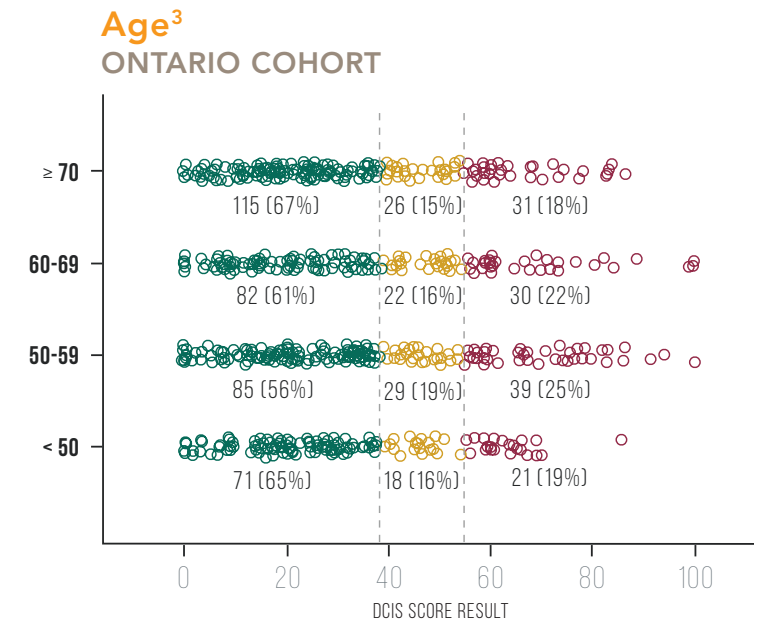
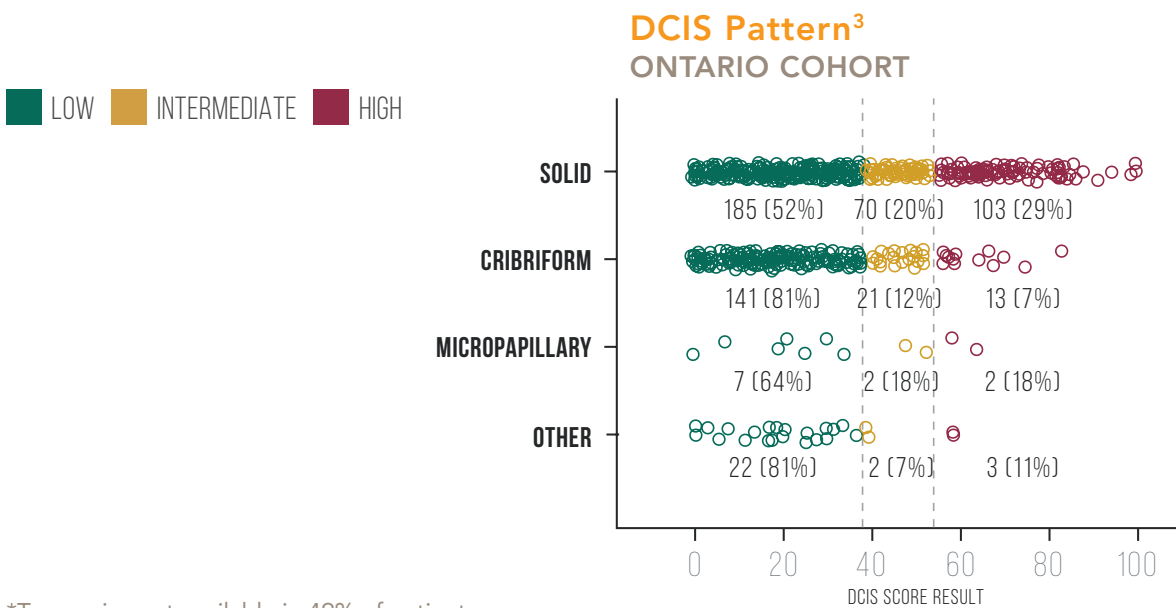
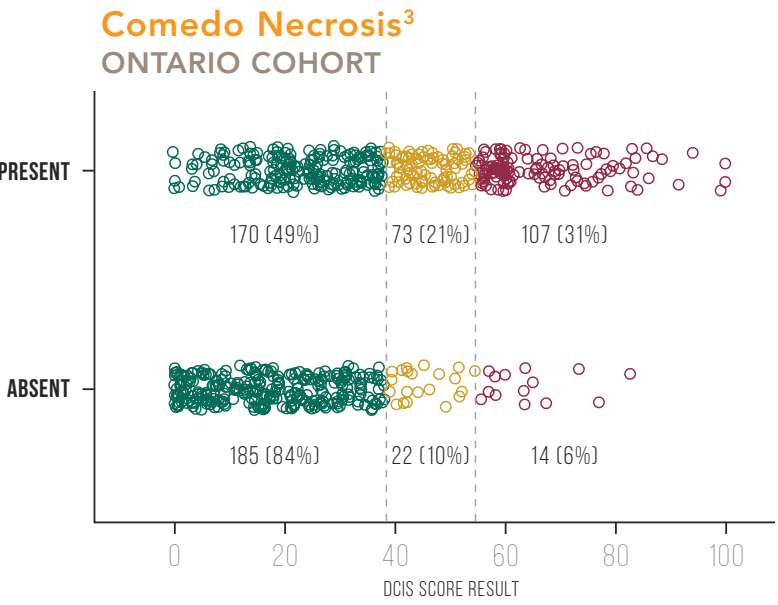
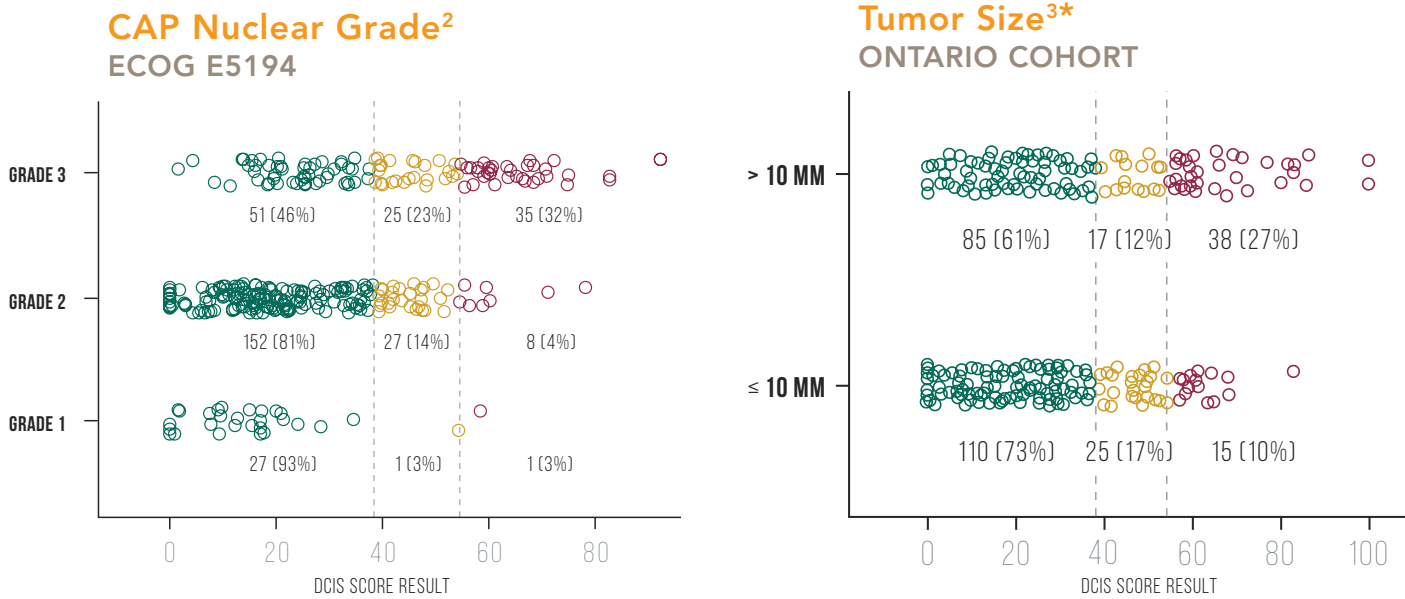
You can now identify each patient's risk for an invasive or a DCIS local recurrence to personalize treatment decisions



THE DCIS SCORE™ RESULT
PROVIDES GUIDANCE BEYOND CLINICAL
AND PATHOLOGIC FACTORS

There was a broad range of DCIS Score results and recurrence risks across clinical and pathologic factors^{2,3}

A substantial proportion of patients with high risk based on clinical and pathologic factors had low DCIS Score results



The DCIS Score result provides insight that is not apparent with clinical and pathologic factors alone

Greater clarity regarding individual risk of local recurrence allows you to better optimize treatment planning

*Tumor size not available in 49% of patients.

THE DCIS SCORE™ RESULT
PROVEN TO CONSISTENTLY RISK STRATIFY PATIENTS
ACROSS TWO VALIDATION STUDIES

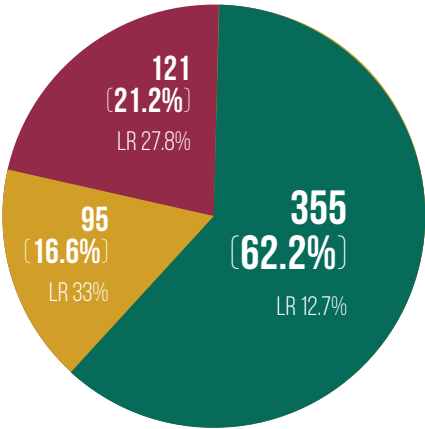


THE DCIS SCORE RESULT
has been validated in two studies involving
898 patients to more accurately risk stratify
patients than traditional methods alone^{2,3}

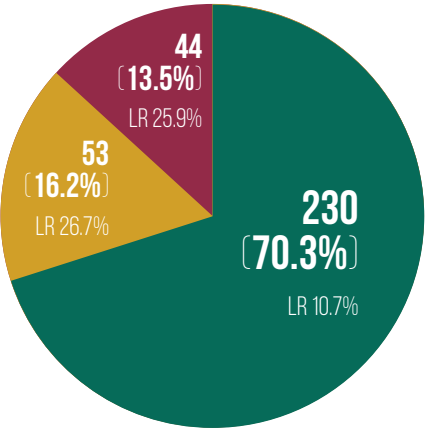
Consistent distribution of DCIS Score results in ECOG E5194
and the Ontario validation studies in two diverse patient populations

LOW INTERMEDIATE HIGH
LR = 10-YEAR RISK OF LOCAL RECURRENCE

Ontario Cohort³ (N = 571)



E5194² (N = 327)



The patients in the ECOG E5194 study were primarily selected for
low-risk features (margin, grade, and size), whereas the Ontario
study was a population-based registry that included patients
with a wide range of margin widths^{2,3}

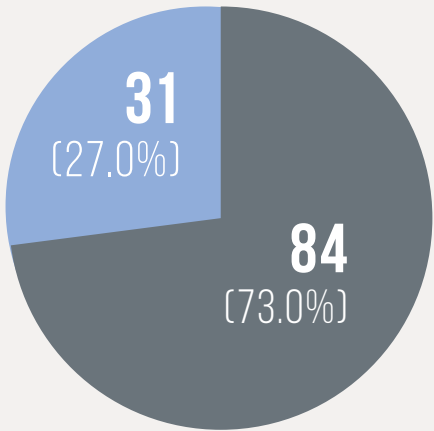
THE DCIS SCORE™ RESULT
CHANGES TREATMENT RECOMMENDATIONS



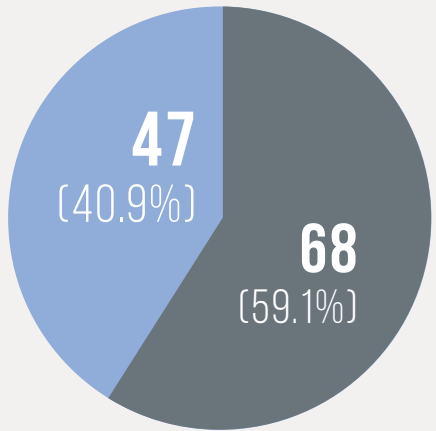
Results of a clinical utility study demonstrate that integration
of the DCIS Score result changed treatment recommendations
31% of the time⁵

XRT NO XRT

Pre-Assay N (%)



Post-Assay N (%)



Integration of the DCIS Score result led to a net change of 31%
in radiation therapy (XRT) recommendations⁵

The Oncotype DX® Breast Cancer Assay for DCIS is
an important advancement in DCIS management that
improves clarity and confidence in personalizing
treatment for patients with DCIS

THE ONCOTYPE DX® BREAST CANCER ASSAY FOR DCIS
USES THE POWER OF GENOMICS TO CLARIFY RECURRENCE RISK
AND PERSONALIZE YOUR PATIENT’S TREATMENT PLAN

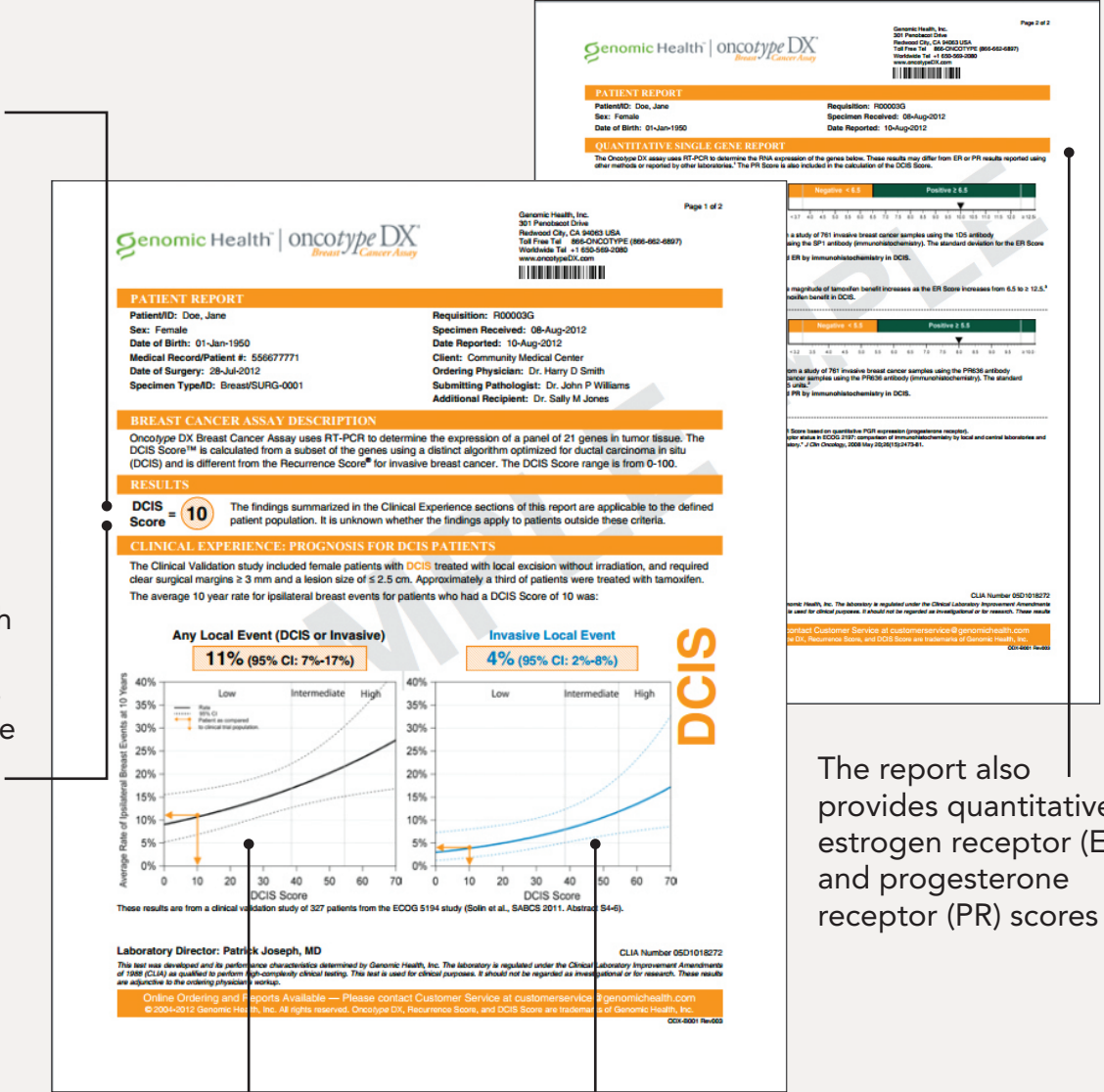
NO TWO PATIENTS—AND NO TWO TUMORS—ARE THE SAME

Even patients with similar clinical and pathologic features do not all have the same recurrence risk¹⁻³

EXAMPLE: Case Study Comparison—Clinical use of the DCIS Score™ result	
63-YEAR-OLD PATIENT	66-YEAR-OLD PATIENT
Menopausal Status: Postmenopausal Tumor Type: DCIS Tumor Size: 1.6 cm ER Status (IHC): Positive Nuclear Grade: 2 Comedo Necrosis: Absent Margin Width: 2 mm	Menopausal Status: Postmenopausal Tumor Type: DCIS Tumor Size: 1.0 cm ER Status (IHC): Positive Nuclear Grade: 2 Comedo Necrosis: Absent Margin Width: 2 mm
DCIS Score result: <div>3</div>	DCIS Score result: <div>57</div>
10% risk of any local recurrence (DCIS or invasive)	23% risk of any local recurrence (DCIS or invasive)
3% risk of an invasive local recurrence	13% risk of an invasive local recurrence
Cases submitted by Charles Leonard, MD, from Rocky Mountain Cancer Centers.	

REVIEW THE ONCOTYPE DX® BREAST CANCER ASSAY FOR DCIS
REPORT TO PERSONALIZE YOUR PATIENT’S TREATMENT PLAN

- The DCIS Score™ result on a 0–100 scale reflects tumor biology, helping refine each patient’s treatment plan
- Patients with a low risk of recurrence may be candidates for more conservative treatment
 - Patients with a high risk of recurrence may be candidates for more aggressive treatment



The report also provides quantitative estrogen receptor (ER) and progesterone receptor (PR) scores

The DCIS Score result quantifies the risk of any local recurrence

The DCIS Score result quantifies the risk of an invasive local recurrence



Knowing each woman’s unique tumor biology can clarify local recurrence risk and increase confidence in your patient’s personalized treatment

NAVIGATING THE COMPLEX WATERS OF DCIS MANAGEMENT

The DCIS Score™ result:

- CONFIRMED** in second validation study to determine 10-year risk of local recurrence
- QUANTIFIES** the 10-year risk of an invasive or a DCIS local recurrence
- VALIDATED** in two studies involving 898 patients
- CHANGED** treatment recommendations 31% of the time
- IMPROVES** multidisciplinary treatment discussions⁴
- INCREASES** clarity and confidence in your patient's personalized treatment plan

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Genomic Health is a CLIA-certified, CAP-accredited reference laboratory.

The Oncotype DX® Breast Cancer Assay for DCIS is a groundbreaking clinical tool from the company with a robust history in molecular diagnostic testing.

References

1. Allegra et al. *J Natl Cancer Inst.* 2010;102(3):161-69. 2. Solin et al. *J Natl Cancer Inst.* 2013;105(10):701-10. 3. Rakovitch et al. San Antonio Breast Cancer Symposium 2014. 4. Data on file. Genomic Health, 2014. 5. Alvarado et al. American Society of Clinical Oncology 2014.



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**THE SIDE OF
CANCER YOU'RE
NOT SEEING.**

With over half a million patients tested worldwide, the Oncotype DX® portfolio—assays for breast, colon, and prostate—is a world leader in applying genomic science to cancer treatment planning.

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