

oncotype dx[®]

Breast Recurrence Score

The Oncotype DX Breast Recurrence Score[®] test is for patients with breast cancer that is¹⁻⁷:

Invasive

Early-stage

HR+

HER2-

NO or N1

Not all patients benefit from chemotherapy⁸

The Oncotype DX Breast Recurrence Score[®] test reveals individual tumour biology by measuring the expression of 16 cancer genes and 5 reference genes.^{1,2}

21-Gene Panel

Proliferation	Invasion	HER2	Estrogen	Other
Ki-67 STK15 Survivin Cyclin B1 MYBL2	Stromelysin 3 Cathepsin L2	GRB7 HER2	ER PR BCL-2 SCUBE2	GSTM1 CD68 BAG1
Reference				
Beta-actin	GAPDH	RPLPO	GUS	TFRC

The only multigene assay validated for both prognosis and prediction^{1,2,4,5}

PREDICTIVE:

The ability to predict the response to a specific treatment (e.g., chemotherapy benefit).

PROGNOSTIC:

The ability to use biomarkers to inform about a likely clinical outcome.

It's never been as clear[™]

YES
CHEMOTHERAPY

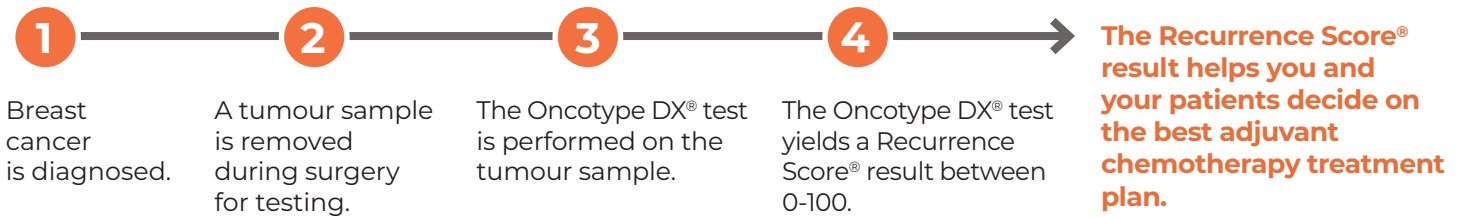
NO
CHEMOTHERAPY

HR+=hormone receptor positive;
HER2-=human epidermal growth factor receptor 2 negative;
NO=Node-negative;
N1=Node-positive (1-3 positive nodes)

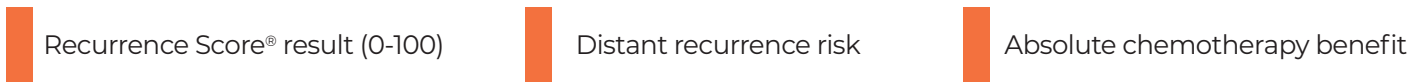
For your patients with HR+, HER2-, early-stage, invasive breast cancer

The only genomic test proven to predict chemotherapy benefit^{2,5}

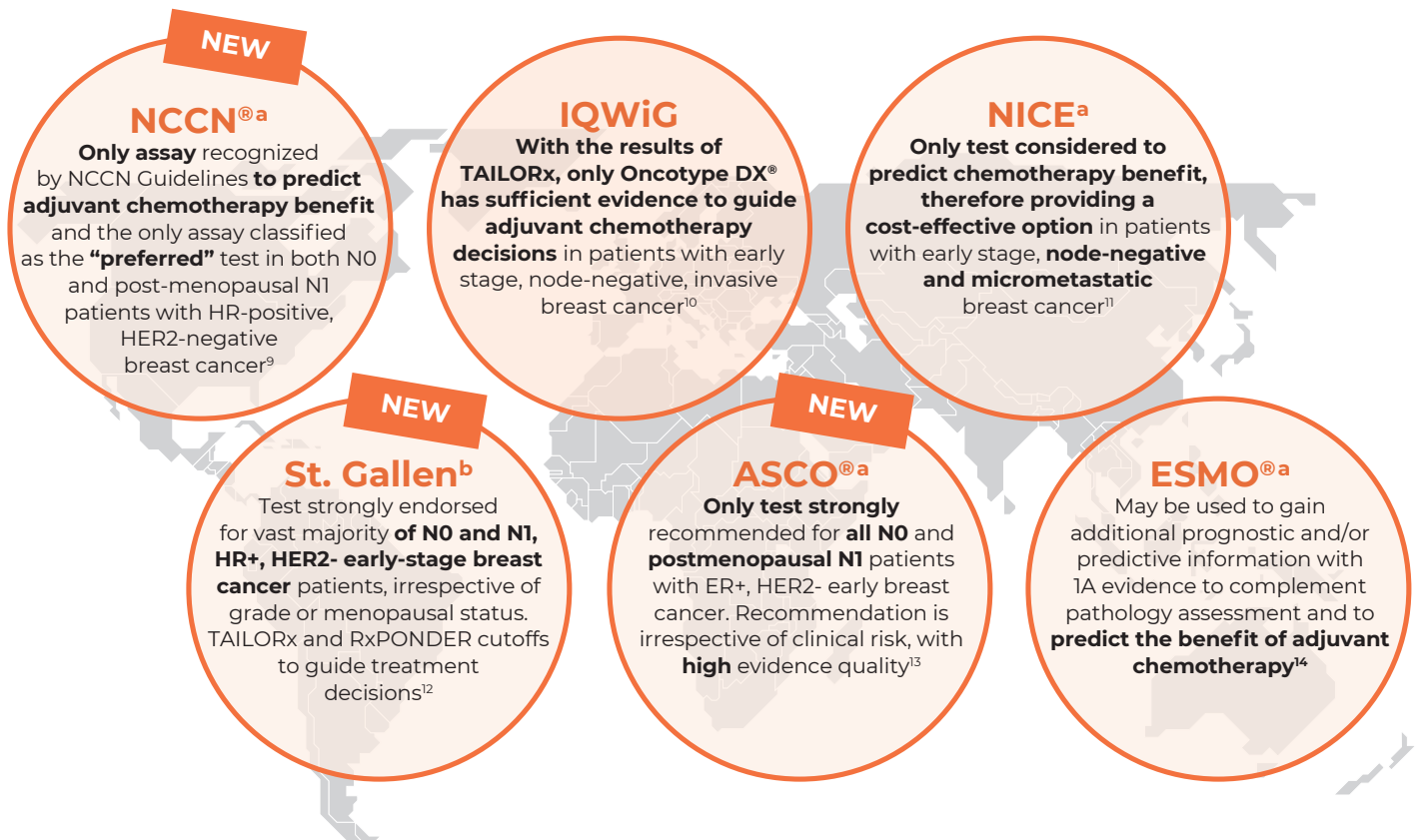
The Oncotype DX Breast Recurrence Score[®] test can be an important part of your patient's treatment journey



The Oncotype DX Breast Recurrence Score[®] test identifies your patient's^{2,3,5-7}:



Updated guidelines and HTA body recommendations position the Oncotype DX[®] test as the "preferred" assay



N0=Node-negative; N1=Node-positive (1-3 positive nodes); HR=hormone receptor; HER2-=human epidermal growth factor receptor 2; TAILORx=TriAL Assigning Individualized Options for Treatment (Rx); RxPONDER=a clinical trial Rx for POSitive NoDe, Endocrine Responsive breast cancer

^a National Comprehensive Cancer Network (NCCN) and NCCN are registered trademarks of NCCN. ASCO and ESMO are trademarks of the American Society of Clinical Oncology and European Society for Medical Oncology. NCCN, National Institute for Health and Care Excellence (NICE), St Gallen International Consensus Panel, ASCO and ESMO do not endorse any product or therapy.

^b As voted by a clear majority of the St Gallen International Expert Consensus panel.

Supported by an extensive body of evidence and major clinical practice guidelines

The Oncotype DX Breast Recurrence Score® test provides clarity for adjuvant treatment decisions, helping to reduce risks of over- and under-treatment

TAILORx trial results in node-negative patients showed that most patients do not benefit from chemotherapy and that clinicopathologic features alone – like age, tumour size, or tumour grade – are not sufficient to determine chemotherapy benefit³



A node-positive breast cancer diagnosis may not automatically mean chemotherapy

The RxPONDER trial showed that postmenopausal women with 1-3 positive nodes and Recurrence Score® results of 0-25 can forgo chemotherapy.⁵⁻⁷

		HR-POSITIVE, HER2-NEGATIVE, NODE-POSITIVE (N1) PATIENTS		
		RS® result 0-25	RS® result 26-100	
Postmenopausal ^{5,6}	No CT benefit	CT benefit		5-year outcomes
Premenopausal ⁷	2.4% CT benefit	CT benefit ^d		

CT benefit expressed in percentage points based on probability of distant recurrence with/without CT at 5 years. No CT benefit is considered for an absolute benefit <1%.

RxPONDER builds on data from SWOG-8814 that established prediction of chemotherapy benefit for patients with Recurrence Score® results 26-100.⁵⁻⁷

TAILORx=Trials Assigning Individualized Options for Treatment (Rx); RxPONDER=a clinical trial Rx for Positive Node, Endocrine Responsive breast cancer; RS=Recurrence Score®; CT=chemotherapy

^a High clinical risk: Grade 1, >3 cm; Grade 2, >2 cm; Grade 3, >1 cm.

^b Assuming that adjuvant treatment would have been determined by clinical risk alone.

^c Low clinical risk: Grade 1, ≤3 cm; Grade 2, ≤2 cm; Grade 3, ≤1 cm.

^d Benefit of chemotherapy for premenopausal N1 patients with Recurrence Score® results 26-100 has not been formally assessed in a randomised study. The benefit derived from chemotherapy was significant for Recurrence Score® results 0-13 and 14-25 in the RxPONDER study and it is inferred to be substantial for patients with Recurrence Score® results 26-100.

oncotype dx[®]

Breast Recurrence Score

For your patients with HR+, HER2-, early-stage, invasive breast cancer

Only the Oncotype DX Breast Recurrence Score[®] test is:

**STANDARD
OF CARE⁹⁻¹⁴**

With **prospective** outcomes in over 100,000 patients^{3,6,7,15-18}

PROVEN

To be predictive of chemotherapy benefit in patients with **node-negative** or **node-positive** disease^{2,5}

VALIDATED

In multiple studies with **consistent results** for 15+ years including Level 1 evidence for risk of distant recurrence and prediction of chemotherapy benefit^{2,3,6,7,9,19-21}

RECOMMENDED

In all major **international** guidelines^{9,11-14}

Order the Oncotype DX[®] test for your eligible node-negative and node-positive patients to determine which of your patients will and will not benefit from chemotherapy

HR+=hormone receptor positive;
HER2-=human epidermal growth factor receptor 2 negative

References: **1.** Paik et al. *N Engl J Med.* 2004. **2.** Paik et al. *J Clin Oncol.* 2006. **3.** Sparano et al. *N Eng J Med.* 2018. **4.** Dowsett et al. *J Clin Oncol.* 2010. **5.** Albain et al. *Lancet Oncol.* 2010. **6.** Kalinsky et al. *N Engl J Med.* 2021. **7.** Kalinsky et al. *SABCS 2021.* **8.** Peto et al. *Lancet.* 2012. **9.** Referenced with permission from the NCCN Guidelines[®] for Breast Cancer v4.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed August 8, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. **10.** IQWiG press release. Published September 9, 2018. **11.** NICE Guidelines. <https://www.nice.org.uk/guidance/dg34>. Published December 2018. **12.** Burstein et al. *Ann Oncol.* 2019. **13.** Andre et al. *J Clin Oncol.* 2022. **14.** Cardoso et al. *Ann Oncol.* 2019. **15.** Stemmer et al. *npj Breast Cancer.* 2017;3:32. **16.** Stemmer et al. *npj Breast Cancer.* 2017;3:33. **17.** Hortobagyi et al. *SABCS 2018.* **18.** Nitz et al. *Breast Cancer Res Treat.* 2017. **19.** Geyer et al. *npj Breast Cancer.* 2018. **20.** Sparano et al. *N Engl J Med.* 2015. **21.** Sparano et al. *ASCO 2018.*

National Comprehensive Cancer Network (NCCN) and NCCN are registered trademarks of NCCN. ASCO and ESMO are trademarks of the American Society of Clinical Oncology and European Society for Medical Oncology. NCCN, National Institute for Health and Care Excellence (NICE), St Gallen International Consensus Panel, ASCO and ESMO do not endorse any product or therapy.

Customer Service Europe

Tel: +41 22 715 29 00

europeansupport@exactsciences.com

Exact Sciences International GmbH

Lindenstrasse 2, 6340 Baar, Switzerland

www.exactsciences.com



For country-specific contact information,
please visit www.oncotypeiq.com

**EXACT
SCIENCES**

It's never been as clear, Oncotype DX Breast Recurrence Score, Oncotype DX, Recurrence Score and RS are trademarks or registered trademarks of Genomic Health, Inc. Exact Sciences is a registered trademark of Exact Sciences Corporation. All other trademarks are the properties of their respective owners.

© 2022 Genomic Health, Inc. All rights reserved. EXS13709_1222_EN_INT

