oncotype DX®

Breast Recurrence Score

The Oncotype DX Breast Recurrence Score® test is for patients with breast cancer that is[1-7]:

Invasive | Early-stage | HR+ | HER2– | N0 or N1

Not all patients benefit from chemotherapy[8]

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	Stromelysin 3	GRB7	ER	GSTM1
STK15	Cathepsin L2	HER2	PR	CD68
Survivin			BCL-2	BAG1
Cyclin B1			SCUBE2	
MYBL2				

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.

HR+=hormone receptor positive;
HER2–=human epidermal growth factor receptor 2 negative;
N0=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

1. Breast cancer is diagnosed.
2. A tumour sample is removed during surgery for testing.
3. The Oncotype DX® test is performed on the tumour sample.
4. The Oncotype DX® test yields a Recurrence Score® result between 0-100.

The Recurrence Score® result helps you and your patients decide on the best adjuvant chemotherapy treatment plan.

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

- Recurrence Score® result (0-100)
- Distant recurrence risk
- Absolute chemotherapy benefit

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

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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 benefit[3]

73% of patients with high clinical risk[a] had Recurrence Score® results 0-25 and may have been **overtreated** without the Recurrence Score® result[b]

43% of patients with Recurrence Score® results 26-100 had low clinical risk[c] and may have been **undertreated** without the Recurrence Score® result[b]

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**
Premenopausal[7]	**2.4% CT benefit**	**CT benefit**[d]

5-year outcomes

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=Trial 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.

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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 CARE[9-14]	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.

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