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 | | | | |

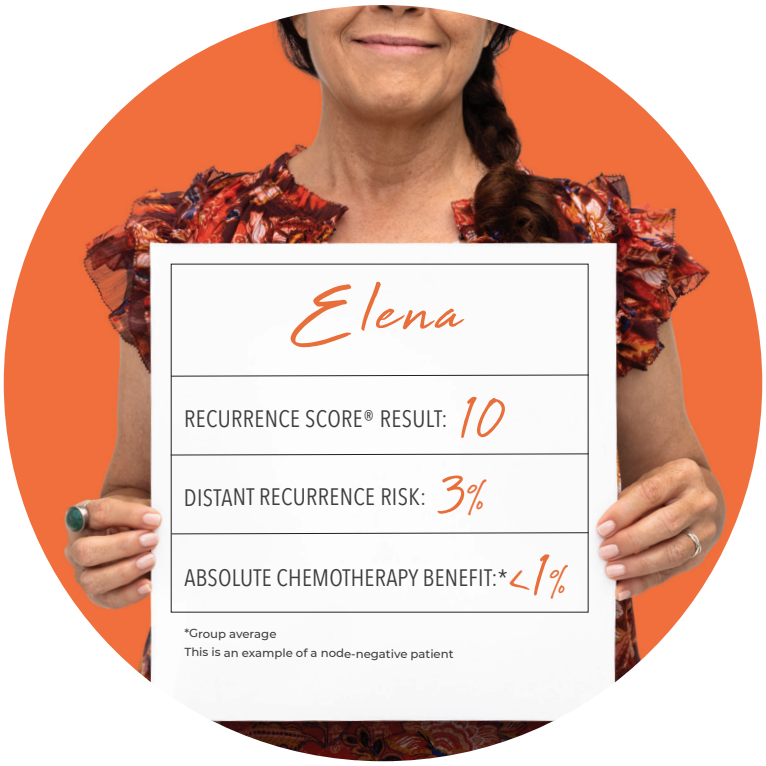
| Reference | | | | |
|---|---|---|---|---|
| Beta-actin | GAPDH | RPLPO | GUS | TFRC |

**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.



# 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

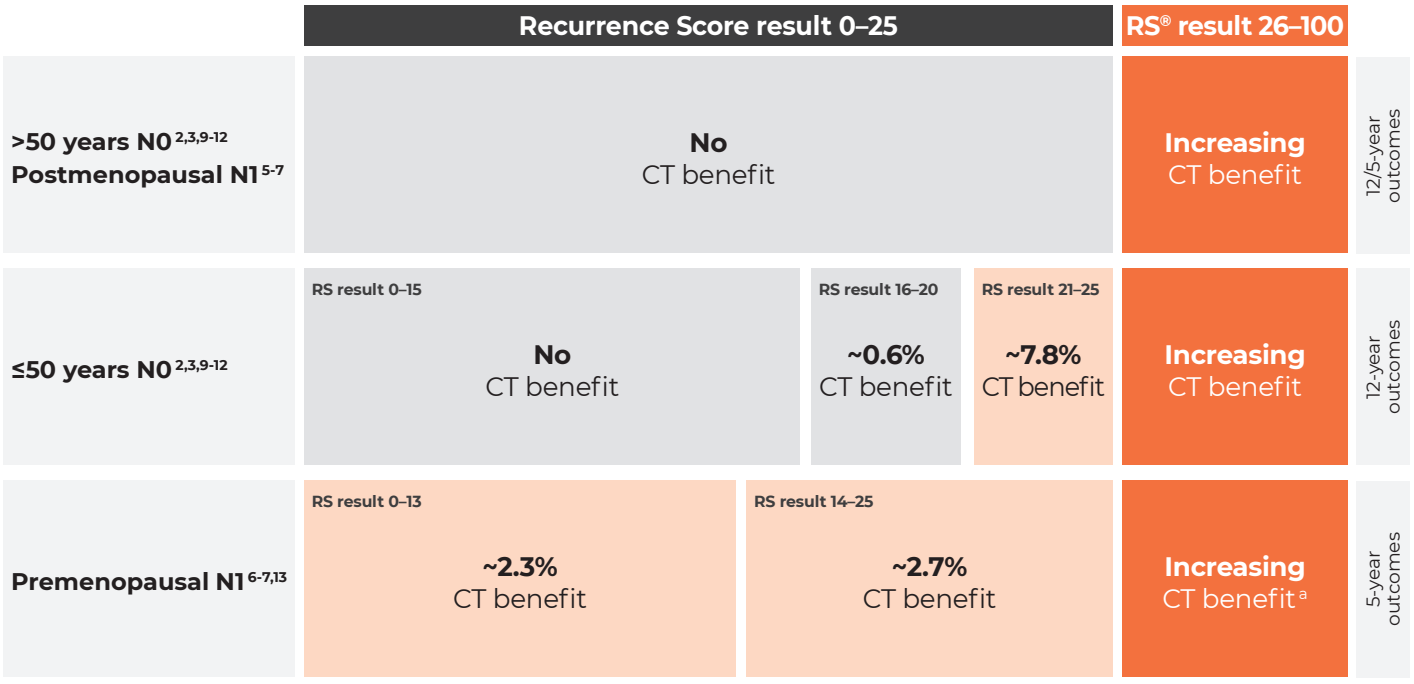
1. Breast cancer is diagnosed.
2. A tumour sample is removed during surgery for testing.
3. The Oncotype DX® test is performed on the tumour sample.
4. The Oncotype DX test yields a Recurrence Score result between 0-100.

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

## The Oncotype DX Breast Recurrence Score test identifies your patients': [2,3,5-7]

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

## The majority of HR+, HER2- early breast cancer patients can be spared chemotherapy when decisions are guided with the Oncotype DX test




CT benefit expressed in percentage points based on probability of distant recurrence (N0) or distant recurrence-free interval (N1) with / without CT
No CT benefit is considered for an absolute benefit <1%

**Node-negative (N0) patients:** TAILORx exploratory analyses by age suggested that patients ≤ 50 years derived some clinically meaningful benefit from CT at 9 years for RS results of 16-25; RS results 0-25 overall derived benefit from chemotherapy at 5 years.
**Node-positive (N1) patients:** Prespecified analysis of the RxPONDER data included analysis according to menopausal status and demonstrated that premenopausal patients with

**a** The benefit of chemotherapy for premenopausal N1 patients with RS results 26-100 has not been formally assessed in a randomised study. The benefit derived from chemotherapy was modest for RS results 0-13 and 14-25 in the RxPONDER study, and it is inferred to be substantial for patients with RS results 26-100.

# Supported by major clinical practice guidelines and HTA bodies

**NCCN®[a]**

**Only assay** recognized by NCCN guidelines **to predict adjuvant chemotherapy benefit** and the only assay classified as the **"preferred"** test in both N0 and post-menopausal N1 patients with HR-positive, HER2-negative breast cancer[14]

**ASCO®[a]**

**Only test strongly recommended** for **all N0** and **postmenopausal N1** patients with ER+, HER2- early breast cancer. Recommendation is irrespective of clinical risk, with **high** evidence quality[15]

**St Gallen[b]**

Test strongly endorsed for vast majority **of N0 and N1, HR+, HER2- early-stage breast cancer** patients, TAILORx and RxPONDER cutoffs to guide treatment decisions[16]

2023 update highlights the **need to test premenopausal patients** as not all require chemotherapy[17]

**ESMO®[a]**

May be used to gain additional prognostic and/or predictive information with 1A evidence to complement pathology assessment and to **predict the benefit of adjuvant chemotherapy**[18]

2024 update highlights that MGAs add value beyond pathology alone when defining patients for chemotherapy[19]

**NICE[a,c]**

**Only test considered likely to predict chemotherapy benefit, therefore providing a cost-effective option** in patients with early stage, **node-negative, micrometastatic and post-menopausal node-positive (N1)** breast cancer[20]

**IQWiG**

Only test with sufficient evidence to **guide adjuvant chemotherapy treatment decision for postmenopausal node-negative and node-positive patients** with early-stage invasive breast cancer[21,22]

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

**c** This summary of NICE diagnostics guidance 'Tumour profiling tests to guide adjuvant chemotherapy decisions in early breast cancer' (DG58) is promotional material. NICE has checked the accuracy of the content in this leaflet specifically relating to the NICE guidance. NICE is independent of any company or product advertised.

oncotype DX®

Breast Recurrence Score

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

# The Oncotype DX Breast Recurrence Score test – bringing clarity to treatment decisions

- Uniquely designed to help identify patients who need chemotherapy[1,2,9]
- The gold standard to avoid over- and undertreatment[3,7,14,15]
- High-quality testing in a centralised laboratory with a short time to result[13]

**Order the Oncotype DX test for your eligible node-negative and node-positive patients to determine which of your patients may or may not benefit from chemotherapy**

CT = chemotherapy
HR = hormone receptor
HR+ = hormone receptor positive
HER2– = human epidermal growth factor receptor 2 negative
N0 = Node-negative
N1 = Node-positive (1–3 positive nodes)
RxPONDER = a clinical trial Rx for POsitive NoDe, Endocrine Responsive breast cancer
RS result = Recurrence Score® result
TAILORx = Trial Assigning IndividuaLized Options for Treatment (Rx)

**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.** Sparano and Paik. *J Clin Oncol.* 2008. **10.** Geyer et al. *npj Breast Cancer.* 2018. **11.** Sparano et al. *N Engl J Med.* 2019. **12.** Sparano et al. *NEJM Evidence.* 2024. **13.** Exact Sciences. Data on file. **14.** NCCN Guidelines Breast Cancer, Version 06.2024. https://www.nccn.org **15.** Andre et al. *J Clin Oncol.* 2022. **16.** Burstein et al. *Ann Oncol.* 2019. **17.** Curigliano et al. *Ann Oncol.* 2023. **18.** Cardoso et al. *Ann Oncol.* 2019. **19.** Loibl et al. *Annals of Oncology* 2024. **20.** NICE DG58 https://www.nice.org.uk/guidance/dg58 **21.** IQWiG press release. Published September 9, 2018. **22.** Abschlussbericht D23-01A/B. 2024. 21.10.2024. https://doi.org/10.60584/D23-01B.

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