

Exact Sciences' Oncotype DX Breast Recurrence Score[®] Test Receives IVDR CE Certificate

As of October 31, 2023, the Oncotype DX Breast Recurrence Score[®] test is CE-marked under the new European In Vitro Diagnostic Regulation 2017/746 (IVDR).

The IVDR is the new regulatory standard set by the European Union, and compliance with it is progressively required for all in vitro diagnostic medical devices to continue being sold or made available in the European Union. The IVDR replaces the previous In Vitro Diagnostic Directive 98/79/EC (IVDD), under which the Oncotype DX[®] test has been CE-marked to date.

The IVDR sets a new standard for product performance evaluation and post-market surveillance and includes much stricter requirements than the IVDD. The Oncotype DX test received its IVDR certificate of conformity, permitting application of the CE mark, following a rigorous review demonstrating its quality, robust development process and performance.

The Oncotype DX CE mark was granted by BSI Group, The Netherlands B.V., an independent, EU-designated Notified Body entitled to carry out the relevant conformity assessment procedures.

The Oncotype DX Breast Recurrence Score test produces a semi-quantitative Recurrence Score[®] result based on the quantitative level of expression of 21 genes in RNA extracted from formalin-fixed, paraffin-embedded (FFPE) breast tumor tissue. The Recurrence Score result provides information regarding the risk of distant recurrence (prognosis) and the magnitude of chemotherapy benefit (prediction). The Recurrence Score result is intended to guide chemotherapy treatment decisions in patients with early-stage, hormone receptor-positive (HR+), and lymph node-negative or lymph node-positive breast cancer. It is the only predictive test used in early-stage breast cancer to understand whether a patient can derive benefit from chemotherapy.[1],[2],[3],[4] The Oncotype DX test was first made available in the United States in 2004, and over 1,5 million patients around the world have benefited from it.[5].

¹ Paik et al. *J Clin Oncol*. 2006.

² Sparano et al. *New Engl J Med*. 2018.

³ Geyer et al. *npj Breast Cancer*. 2018.

⁴ Albain et al. *Lancet Oncol*. 2010.

⁵ Exact Sciences, data on file.