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The National Institute for Health and Care Excellence (NICE) recommends use of Exact Sciences' Oncotype DX® test to help guide chemotherapy decisions for node-positive breast cancer patients

London, May 10 2024 – Exact Sciences, a leading provider of cancer screening and diagnostic tests, today announced that the UK's National Institute for Health and Care Excellence (NICE) has recommended the expanded use of the Oncotype DX Breast Recurrence Score® test to more effectively target chemotherapy treatment for women who have hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), early-stage breast cancer involving up to three positive nodes and who have been through the menopause. NICE confirmed that breast cancer patients who are male and trans, non-binary or intersex may benefit from the test depending on their hormonal profile. The recommendation has the potential to impact more than 3000 additional breast-cancer patients in England who will now have access to the test through the National Health Service (NHS).[1]

The new guidance expands upon earlier NICE recommendations for testing patients without lymph node involvement. Access to genomic testing for patients with lymph node-positive breast cancer addresses the issue of overtreatment with chemotherapy, helping many patients to avoid treatment side effects such as nausea, fatigue, hair loss and potentially secondary cancer. In addition, expanded reimbursement has the potential to free up resources and capacity within NHS breast cancer services.

Dr Caroline Archer, consultant medical oncologist Portsmouth Hospital NHS Trust said: "This is a practice-changing moment for node-positive patients and the NHS. There is an urgent need to target chemotherapy more precisely to those most likely to benefit from it, so that patients can avoid unnecessary side effects. The Oncotype DX Breast Recurrence Score result enables us to do this effectively by providing specific information about an individual's response to chemotherapy. This positive recommendation marks a significant step forward in supporting equitable access to the test across the country."

While the majority of patients with lymph node-positive early-stage breast cancer receive chemotherapy, research shows that only a minority benefit from the treatment. The Oncotype DX® test is the only test able to identify around 85% of postmenopausal patients whose cancer outcomes are not likely improved by chemotherapy, meaning they can avoid the risk of side effects.[2,3,4]

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[1] Tumour profiling tests to guide adjuvant chemotherapy decisions for lymph node-positive early breast cancer [DG58], NICE Resource impact tool, May 2024: https://www.nice.org.uk/guidance/dg58/resources/resource-impact-template-excel-13425543901
[2] Bello et al. Ann Surg Oncol. 2018.
[3] Zhang et al. Breast Can Res Treat. 2020.
[4] Stemmer et al. npj Breast Cancer. 2017.

A recent independent UK multi-centre trial led by Prof Holt involving 680 women with lymph node-positive early breast cancer confirmed that using the Oncotype DX test to help guide chemotherapy treatment decisions leads to a substantial reduction in unnecessary chemotherapy, as well as savings for the NHS.[5]

Prof Simon Holt, Health and Life Science, Swansea University & Peony Breast Care Unit, Prince Philip Hospital said:

"This decision to recommend the use of the Oncotype DX test to guide chemotherapy decisions in early node positive breast cancer will be of great benefit to our postmenopausal patients and to the NHS. The use of the test will reduce the suffering and inconvenience by sparing up to 85% of people unnecessary chemotherapy, which in turn, then reduces the care demands on Oncology services. It also reduces significantly the cost of treatment so that NHS resources can be redistributed to other medical priorities.

Also, our research has shown that the use of the Oncotype DX test means both clinicians and their patients will have much greater confidence in their chemotherapy decisions."

The test's efficacy is also supported by the landmark TAILORx[6] and RxPONDER[7] studies, which demonstrated that most patients with either node-negative or node-positive early-stage breast cancer do not benefit from chemotherapy and can be reliably identified using the Oncotype DX test.

Matt Bull, Head of Northern Europe (UK, Ireland and Nordics) at Exact Sciences, added: "We are delighted that more patients with node-positive breast cancer will now also benefit from knowing their Recurrence Score® result. We are proud of the potential impact the expanded use of the Oncotype DX test will have — better patient treatment, improved clinical confidence and less pressure on the health service."

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About the Oncotype DX Breast Recurrence Score test

The Oncotype DX Breast Recurrence Score test is designed to facilitate personalised clinical decisions by providing information about the biology of an individual breast cancer, with the potential to deliver financial benefits for healthcare systems. The test was first made available to patients in 2004, and over 1,5 million patients around the world have benefited from it. It is incorporated in major breast cancer treatment guidelines, including those of the European Society for Medical Oncology (ESMO) and the St. Gallen International Breast Cancer Conference, as well as the American Society of Clinical Oncology (ASCO®) and the National Comprehensive Cancer Network (NCCN®) in the U.S.

To learn more about the test, visit: https://www.oncotypeiq.com/en

About Exact Sciences

A leading provider of cancer screening and diagnostic tests, Exact Sciences gives patients and health care professionals the clarity needed to take life-changing action earlier. Building on the success of the Cologuard® and Oncotype® tests, Exact Sciences is investing in its pipeline

[5] Holt et al. British Journal of Cancer, 2024 pp. 1-8
[6] Sparano et al. N Engl J Med. 2018
[7] Kalinsky et al. New Engl J Med. 2021

to develop innovative solutions for use before, during, and after a cancer diagnosis. For more information, visit https://www.exactsciences.com, follow Exact Sciences on X (formerly known as Twitter) @ExactSciences, or find Exact Sciences on LinkedIn and Facebook.

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