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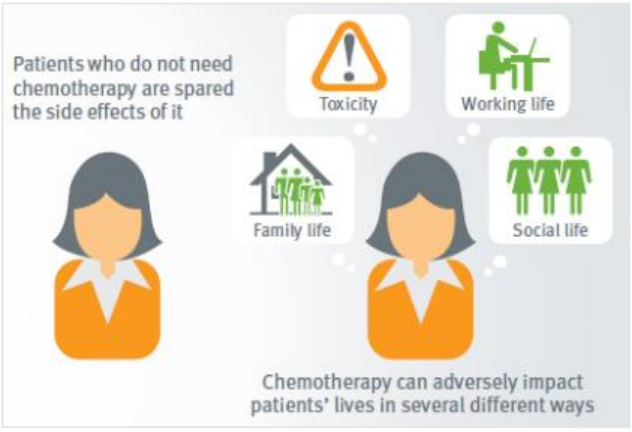
# Media Backgrounder:
# Genomics and the Oncotype DX® Test for Early-stage Breast Cancer

- Breast cancer is the most common cancer in women with an estimated incidence of 494,100 in Europe in 2012.[1]
- Most patients with early stage breast cancer are recommended chemotherapy after surgery as a cautionary measure to prevent cancer from returning. Chemotherapy comes at a price – it often brings side effects including nausea, hair loss, tiredness, an increased risk of developing infections and infertility.[2] These side effects, most of which can be managed, can be explained by the fact that chemotherapy targets rapidly developing cells – not just cancerous cells but also healthy ones like hair cells, gastrointestinal cells, blood cells and ovarian cells that are characterised by constantly regenerating themselves.




- Classic criteria used for making treatment decisions in clinical practice are based on factors such as the age and profile of the patient, or the size of the tumour. These are rough guides which are not predictive of benefit from chemotherapy and may result in substantial over- and undertreatment. Research shows that only a minority of patients with early-stage, node-negative breast cancer actually substantially benefit from chemotherapy and that the vast majority of patients can be spared this treatment and its related toxicities.[3,4] Therefore, being able to accurately identify patients most likely to benefit can help to enhance the efficiency of treatment decisions, improve patient outcomes and reduce costs for the healthcare system.

## What is Genomic Testing and Why Is It Important for Cancer Patients?

While genomics and genetics may sound similar, they focus on different information. Genetics is the study of how traits are passed from one generation to the next through specific genes and alterations that may give rise to particular health conditions. Genomics, meanwhile, looks at groups of genes expressed within specific tissue or location in the body, their functions and how they interact with one another. Genomics applied to tumour tissues from cancer patients is a powerful tool to better characterise the cancer and predict how a tumour is likely to grow and respond to treatment. Genomic testing is increasingly being used by physicians to help better understand patients' individual tumour biology and determine the most appropriate treatment approach.

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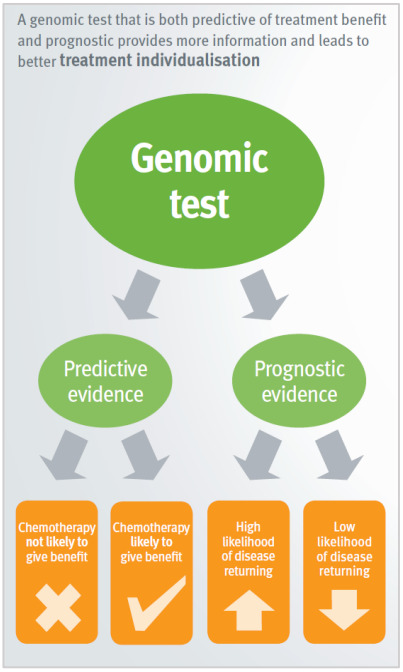
## What is the Oncotype DX test and Who Can Benefit?

The Oncotype DX Breast Recurrence Score® assay is a genomic test that looks at the expression of cancer-specific, carefully selected genes within a tumour sample and provides information about the biology of an individual's breast cancer. This information can help physicians tailor treatment for a specific patient with an unprecedented level of precision.



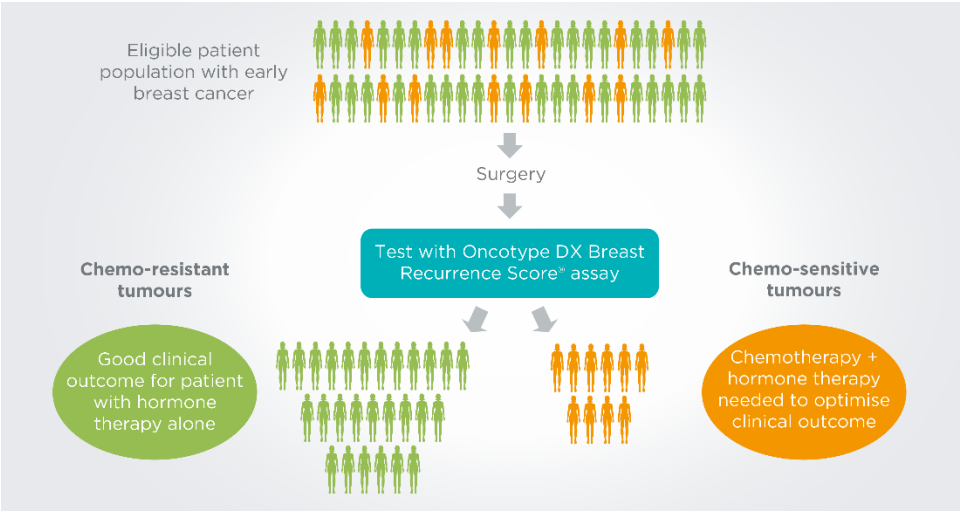

Chemotherapy specifically targets fast-growing tumour cells. The ability of tumour cells to proliferate more or less rapidly is intrinsically connected to their genes. The Oncotype DX test has been developed to identify with precision those patients whose tumour cells are chemo-sensitive, and those whose cells are not, based on its unique algorithm and selection of genes. Oncotype DX is the only test validated for its predictive ability in determining the likelihood of chemotherapy benefit in early breast cancer. The test has also been validated for its ability to predict the risk of cancer returning (recurrence) in individual patients.

The test is appropriate for early-stage breast cancer patients whose cancer is:

- Hormone-receptor positive (HR+). This means that the breast cancer cells have receptors for the hormones oestrogen and/or progesterone
- HER2-negative. This means that the cancer does not express high levels of the HER2 protein.

## How Does The Test Work?

The Oncotype DX test is performed on a small amount of tissue removed during surgery (biopsy). After the test has been performed, and the level of activity of cancer-related genes has been assessed, patients receive a Recurrence Score® result - a number between 0 and 100.




A Recurrence Score result in the range 0-25 means that cancer is less likely to come back if treated with hormonal therapy alone and that chemotherapy won't change the odds of the cancer's returning.

A Recurrence Score result in the range 26-100 suggests a greater risk that cancer will come back, and that chemotherapy is very likely to provide substantial benefit in reducing this risk in addition to hormone therapy.[5]

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## Is The Test Reimbursed?

Following assessment and recommendation by NICE, the Oncotype DX test is widely available to patients across the UK. Other European countries in which the test is reimbursed include Switzerland, Ireland, Greece and Spain. In France, the Oncotype DX test is available through a funding mechanism for innovative diagnostics. In other countries such as Germany the test is currently reimbursed by select payers and a general reimbursement review is underway.

## Are All Genomic Tests the Same?

The Oncotype DX test is supported by multiple rigorous clinical validation studies. Of the genomic tests available for breast cancer patients, it is the most extensively studied with prospective clinical trials and outcome data gathered from more than 70,000 patients.[5-10] This provides the highest level of evidence supporting the test's clinical utility. To date, the Oncotype DX test has been used in more than 850,000 patients worldwide[11] to guide their treatment decisions.

Not all genomic tests are the same. A recent study[12] analysed the same tumour sample with each of the different tests available on the market, including the Oncotype DX test. The results varied widely – the four tests all concurred on only 31% of tumours, reflecting the fact that tests measure different genes and that results are not interchangeable.

Results from the largest-ever adjuvant breast cancer trial – TAILORx – demonstrate that the Oncotype DX test definitively identifies the vast majority of women with early-stage breast cancer who receive no significant benefit from chemotherapy and the important minority of women for whom chemotherapy can be life-saving. The findings from this independent trial, which enrolled more than 10,000 women, were published in *The New England Journal of Medicine*.[5]

The Oncotype DX test is incorporated in all major clinical guidelines including St. Gallen, ESMO and NICE in Europe, and ASCO® and NCCN® in the U.S.

A meta-analysis of European decision impact studies[13] also showed that using the Oncotype DX test in clinical practice changed on average 32% of treatment decisions, resulting in an overall reduction in the recommended use of chemotherapy.

## Who Developed the Test?

Genomic Health is the world's leading provider of genomic-based diagnostic tests that help optimise cancer care. With its Oncotype IQ® Genomic Intelligence Platform, the company is applying its scientific and commercial expertise and infrastructure to translate significant amounts of genomic data into clinically actionable results for treatment planning throughout the cancer patient's journey, from diagnosis to treatment selection and monitoring. The company is based in Redwood City, California with European headquarters in Geneva, Switzerland. For more information, visit www.genomichealth.com. To learn more about Oncotype DX, visit: www.OncotypeIQ.com.

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