

oncotype DX[®]

Breast Cancer Assay

HAVE YOU RECENTLY BEEN DIAGNOSED WITH EARLY-STAGE BREAST CANCER? ARE YOU STRUGGLING TO MAKE TREATMENT DECISIONS?

You may be interested to know that not all women with early-stage breast cancer require chemotherapy. The Oncotype DX[®] test helps identify which women with early-stage, oestrogen receptor-positive (ER+) breast cancer are **more likely to benefit** from adding chemotherapy to their hormonal treatment.

This education piece is not designed to provide individual advice in connection with your diagnosis or treatment plan. Such matters should be discussed with your healthcare provider.



Planning Your Treatment

After a breast cancer diagnosis, doctors and patients work together to plan an appropriate course of treatment. The first step is usually surgery to remove the tumour. Following surgery, the next step is to determine how likely your cancer is to return, which may help you and your doctor make decisions about future treatment options, and whether to include chemotherapy.

Gathering Information to Help Make the Right Treatment Decision - for You

It can be overwhelming to receive a diagnosis of breast cancer, so it is important to gather as much information as possible to determine a treatment plan that is right for you. Your doctor may consider many factors in planning your treatment, including:

- your medical history
- your age
- the size and grade of your tumour
- whether your tumour has spread
- whether there are oestrogen receptors and HER2 receptors on the cells of your tumour
- the results of your Oncotype DX test
- your treatment preferences

Because every patient's breast cancer is unique, you and your doctor will need to understand the underlying biology of your tumour to individualise your treatment plan.

What Is the Oncotype DX Test?

The Oncotype DX test is a unique diagnostic test that measures a group of cancer genes in breast tumour tissue. The test gives you information regarding the:

- chance of your breast cancer returning
- likelihood that you may benefit from chemotherapy treatment (added to the standard hormonal treatment)

Why Should I Consider the Oncotype DX Test?

This is a unique test that provides information specific to your tumour, not available from traditional factors. Since the Oncotype DX test provides individualised information, it enables the treatment plan to be tailored specifically for you. Speak with your healthcare team to understand how the Oncotype DX results may impact your treatment planning.

Is the Oncotype DX Test Right for Me?

The test may be right for you if you are planning treatment after surgery, and you:

- are newly diagnosed with early-stage invasive breast cancer
- have tumour cells that are oestrogen receptor positive (ER+)
- have tumour cells that are human epidermal growth factor receptor negative (HER2-)
- are pre- or post-menopausal and lymph node negative or are post-menopausal and lymph node positive

How Will the Oncotype DX Test Help Me and My Doctor?

The test will tell you and your doctor the chances of your tumour coming back and your potential benefit from chemotherapy. Your doctor will receive a report with the results of your Oncotype DX test. The report contains your personal Recurrence Score[®] result, which is a number between 0 and 100.

- Women with lower Recurrence Score results have a lower risk that their cancer may return and are less likely to benefit from chemotherapy.
- Women with higher Recurrence Score results have a greater chance that their breast cancer may return and are more likely to benefit from chemotherapy.

(continued overleaf)

The *Oncotype DX* test results also provide additional information, such as the activity levels of the oestrogen and progesterone receptors in your tumour, which may help guide your treatment planning.

How Is the *Oncotype DX* Test Performed?

The test is performed on a small amount of your tumour tissue that was removed during your original surgery (lumpectomy, mastectomy, or core biopsy). This tissue is routinely saved and stored at the hospital where you had your surgery. **You will NOT have to go through any additional surgery or procedure to get the *Oncotype DX* test.**

When your doctor orders the *Oncotype DX* test, the hospital will send a sample of your tissue to the Genomic Health® laboratory in the USA, where the *Oncotype DX* test is performed.

Is the *Oncotype DX* Test Widely Recommended?

The *Oncotype DX* test is the only multigene breast cancer assay incorporated into five major internationally accepted clinical practice guidelines.

The National Comprehensive Cancer Network (NCCN)®, the American Society of Clinical Oncology (ASCO)®, St Gallen, and the European Society for Medical Oncology (ESMO)® have all incorporated the *Oncotype DX* test into their guidelines. In the UK, the National Institute for Health and Care Excellence (NICE) has recommended *Oncotype DX* as the only multi-gene breast cancer test for use in clinical practice to guide chemotherapy treatment decisions for some patients with early-stage, hormone-receptor-positive, invasive breast cancer.

The *Oncotype DX* test has been evaluated in multiple clinical studies in more than 6,000 patients. Since becoming available in 2004, more than 440,000 *Oncotype DX* tests have been requested by more than 19,000 physicians in over 70 countries.

When Should the *Oncotype DX* Test Be Done?

It is important that your doctor request the *Oncotype DX* test **before** you start any treatment, since the test is intended to help determine how likely your cancer is to return, which may guide treatment decisions.



*"The additional information provided by *Oncotype DX*® made a difficult decision much easier. I felt as if I had made the best possible decision for me, and I was able to concentrate all my energies into getting better."*

Sandy, mother and teacher

Diagnosed with early breast cancer in 2006

- Women with lower Recurrence Score results have a lower risk that their cancer may return and are less likely to benefit from chemotherapy.
- Women with higher Recurrence Score results have a greater chance that their breast cancer may return and are more likely to benefit from chemotherapy.
- For women with an intermediate Recurrence Score, other factors will need to be considered by their doctor to determine the degree of benefit from chemotherapy.

It is important to understand that although a lower Recurrence Score indicates a low probability of the cancer returning, it does not mean there is no chance that a woman's breast cancer will return.

Also, a higher Recurrence Score, while indicating a higher probability of the cancer returning, does not mean that a woman's cancer will definitely return.

How Do I Get the *Oncotype DX* Test?

The test can only be ordered by a licensed healthcare professional, such as your doctor. You may wish to share this brochure with your doctor and ask if the *Oncotype DX* test may be of benefit to you.

How Long Will It Take to Get the Results of the *Oncotype DX* Test?

Most results from the *Oncotype DX* test are available within 14 calendar days from the date the tumour sample is received by Genomic Health in the USA. Typically, this is around 3 weeks from when the test was requested.

The results are sent to your doctor so that he or she can discuss the results with you and answer your questions.

Understanding Your Recurrence Score Result

Your doctor will receive a report with the results of your *Oncotype DX* test. The report contains your Recurrence Score result, a number between 0 and 100.

To learn more about the *Oncotype DX* test, please talk to your healthcare team.

Further information can be found at:

www.mybreastcancertreatment.org

www.oncotypedx.com

www.genomichealth.com

www.specialisedtherapeutics.com.au

References: 1. Paik et al. J Clin Oncol. 2006. 2. NCCN Guidelines: Breast Cancer. V3.2014. 3. Harris et al. J Clin Oncol. 2007. 4. Goldhirsch A, et al. Ann Oncol. 2013; 00:1-18 5. Senkus E, et al. Ann Oncol. 2013. 6. NICE: Diagnostics guidance, DG10. Sept 2013 7. Paik et al. N Engl J Med. 2004. 8. Habel et al. Breast Cancer Res. 2006. 9. Dowsett et al. J Clin Oncol. 2010. 10. Albain et al. Lancet Oncol. 2010. 11. Senkus E, et al. Ann Oncol. 2013 12. Kim et al. J Clin Oncol. 2011. 13. Data on file. Genomic Health Inc. Redwood City, USA

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