Have you been

newly diagnosed with early-stage invasive breast cancer?

Do you need chemotherapy?

oncotype DX®
Breast Recurrence Score

Helping you with breast cancer treatment decision-making

An educational guide prepared by Genomic Health to assist healthcare professionals in explaining the Oncotype DX Breast Recurrence Score® test to their patients

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To learn more about this and other Oncotype DX® tests, visit :
www.oncotypedx.com
and talk to your healthcare team

Introduction

This pamphlet has been written to give you an introduction to the Oncotype DX Breast Recurrence Score® test

The Oncotype DX Breast Recurrence Score® test can help to make treatment decisions in early stage, oestrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-negative) invasive breast cancer.

Specifically, the test can help to establish how likely the addition of chemotherapy to hormone (endocrine) therapy will be beneficial to your treatment plan.

Treatment for breast cancer

All breast cancers are not the same. As the understanding of breast cancer has increased, **it has become possible to tailor a specific treatment plan to better suit each patient.**

Surgery is used to remove the initial (primary) cancer from the breast. All treatments following surgery are known as adjuvant treatments.

Adjuvant treatments, such as radiotherapy and drug treatments, can help to prevent cancer returning. Drug treatments also reduce the chance of the primary cancer returning in another part of the body (known as secondary or metastatic breast cancer).

- Anti-oestrogen (hormone) therapy is offered to all women with ER+ breast cancer.
- Chemotherapy treatment may be considered – this is for discussion between you and your healthcare professional.

The benefits of chemotherapy treatment are much less certain in women with ER+ and HER2-negative cancers.

In this case, there is a balance between the benefits of chemotherapy and its potential side effects. We need tests to identify those people who are more likely to benefit from treatment with chemotherapy and those who are less likely to benefit from chemotherapy. Genomic testing can help to do that.

Genomic testing

Research into the many factors that influence cancer cell growth has allowed the identification of important breast cancer genes that influence tumour growth and behaviour (activity).

Genomic tests allow us to measure the activity of genes in cancers. These tests can provide very useful additional information where there is uncertainty about the role of chemotherapy in helping to prevent breast cancer returning. **The most commonly used genomic test worldwide for invasive breast cancer, is the Oncotype DX Breast Recurrence Score® test.**

Genomics is different from genetics. Broadly speaking genetics can help to tell you your risk for getting cancer, while geomics can help to choose your treatment once a cancer is present. So, unlike a genetic test result, the Oncotype DX Breast Recurrence Score® test result will not have implications for any of your family members - the information it gives is only related to the cancer that has been tested

What is the Oncotype DX Breast Recurrence Score® test?

The Oncotype DX Breast Recurrence Score® is a diagnostic test that measures the activity of a group of cancer genes in a woman's breast cancer tissue. The test gives you information about:

The test takes place on cancer tissue removed at the time of surgery, **so no additional surgery is required.**

How can the Oncotype DX Breast Recurrence Score® test help me?

This test provides information specific to your cancer and so helps your healthcare professional(s) understand the underlying biology of your cancer, which will enable your treatment plan to be tailored specifically for you.

Am I eligible for the test?

Your healthcare professional will discuss this with you. The criteria for eligibility are that you:[2,3]

- ☑ are newly diagnosed with early stage invasive breast cancer
- ☑ have cancer cells that are ER+
- ☑ have cancer cells that are HER2 negative
- ☑ have either lymph node negative or 1-3 lymph nodes positive breast cancer.

It is important that you have the test before you start any treatment. The test would not be appropriate if you have already made a definite decision about whether or not to have chemotherapy.

What happens when my healthcare professional asks for the Oncotype DX Breast Recurrence Score® test

A small amount of breast cancer tissue that was removed during your original surgery is selected by the pathologist and sent to a central laboratory for testing. Testing in a central laboratory ensures the quality assurance of the test result. The activity of genes in the cancer cells is analysed. After the gene activity analysis is complete, a written report is prepared and sent electronically to your healthcare professional via a secure password-protected online account. The whole process takes about 2 weeks.

The test includes your Recurrence Score® result. This will help in discussions you will have with your healthcare professional about the need for chemotherapy treatment. It adds to the information from routine testing in the local hospital laboratory.

Understanding your Recurrence Score® result

The result of the Oncotype DX® test is called the Recurrence Score® result, which can be any number from 0 to 100. The lower the Recurrence Score® result is, the less likely you are to benefit from chemotherapy; the higher the Recurrence Score® result is, the more likely you are to benefit from chemotherapy.

It is important to understand that a lower Recurrence Score® result does not mean there is no chance that the cancer will return. Similarly, a higher result does not mean that chemotherapy will definitely prevent the cancer from returning.

The Oncotype DX Breast Recurrence Score® results also provide information such as the activity levels of the oestrogen and progesterone receptors in the cancer, which may also help to guide your treatment.

The Oncotype DX Breast Recurrence Score®: clinical trials and practice guidelines

The test has been validated in multiple clinical trials, and **over 750,000 people have used the test worldwide.**[1,4-11]

The test is incorporated in all major internationally accepted clinical practice guidelines for breast cancer treatment[12], ASCO®, NCCN® in the U.S., and St. Gallen, ESMO and NICE in Europe.

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List of terms

Adjuvant treatment: Treatment following surgery. Where there is a risk that the cancer could spread to another part of the body, adjuvant treatment is used. This may involve chemotherapy, radiotherapy, hormone therapy or targeted therapies such as anti-HER2 therapy.
Cell: The smallest unit of a tissue that makes up any living thing. Cells have a very specialised structure and function.
Chemotherapy: Treatment with drugs to destroy or slow the growth of cancer cells.
Clinical trial: A research study where patients help scientists evaluate ways to prevent, detect, diagnose or treat diseases.
Early stage breast cancer: The cancer has not spread beyond the breast or the nearby lymph nodes under the arm.
ER (oestrogen receptor): A protein that may be present on certain cells to which oestrogen molecules can attach. The term 'ER positive (ER+)' means a woman's cancer cells may be sensitive to, and respond to, hormone (endocrine) therapy.
Gene: The basic unit of heredity found in most cells of the body.
Genetics: The study of how characteristics (traits) are inherited from one generation to the next through the genes. These traits include physical characteristics (eg eye colour) and behavioural characteristics, including risk for disease/medical condition.
Genomic test: A test that looks at groups of genes and how active they are. This activity can influence how a cancer is likely to grow and respond to treatment.
Genomics: The study of complex sets of genes, their expression (level of activity) and their effects on biology.
HER2 (human epidermal growth factor receptor 2): A protein that appears on the cancer cells of some breast cancers. A woman whose tumour has greater than normal levels of HER2 is considered HER2 positive. A woman whose tumour has normal levels of HER2 is considered HER2 negative.
Hormone (endocrine) therapy: The use of specific drugs, such as tamoxifen or aromatase inhibitors, to reduce or regulate the production or effects of hormones in the body.
Invasive breast cancer: Cancer that has spread from where it started in the breast into surrounding, healthy tissue. This is the most common type of breast cancer.
Lymph nodes: Small bean-shaped organs (sometimes called lymph glands); part of the lymphatic system. Lymph nodes under the arm drain fluid from the chest and arm. During surgery, some underarm lymph nodes are removed to help determine the stage of breast cancer.
Lymph node-negative breast cancer: Breast cancer that has not spread to the lymph nodes.
Lymph node-positive breast cancer: Breast cancer that has spread to the lymph nodes.
Progesterone receptor: A protein that may be present on certain cells to which progesterone molecules can attach. These cells are generally sensitive to (respond to) hormone (endocrine) therapy.
Radiotherapy: The use of radiation to destroy cancer cells. Radiotherapy may be used before or after surgery and is sometimes used in combination with chemotherapy. Radiotherapy is used for local control of the cancer at the site of the cancer.
Secondary (metastatic) breast cancer: When cancer spreads to other parts of the body and forms a new cancer made up of breast cancer cells.
Tumour: A lump or growth. A tumour can be malignant (cancerous) or benign (non cancerous).

If you would like to learn more about the Oncotype DX® test for invasive breast cancer, please visit www.oncotypedx.com.
To learn more about the company, please visit www.genomichealth.com
You may also contact the Medilinks Inc. Customer Support Team.

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