oncotype DX®
Breast Recurrence Score

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The Oncotype DX Breast Recurrence Score® Test

A Guide for Patients

"The day I was told I had cancer, I knew that my daughter would not want to see my struggle through chemotherapy.

The Recurrence Score® result spared me and my family from this treatment."
Jane (UK)

"The diagnosis literally took my breath away. When I learned that I had a high Recurrence Score® result, I felt resigned but determined. I knew I would benefit from the treatment, and that made it less difficult to bear."
Anne-Marie (Ireland)

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EXACT SCIENCES

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The Oncotype DX® test - helps guide chemotherapy treatment decisions

Your healthcare team has offered you a genomic test known as the Oncotype DX test*. You have been offered this test because:

- you have early-stage breast cancer that is hormone (oestrogen) receptor positive (HR+) requiring hormone therapy
- your breast cancer is either lymph node negative or lymph node positive
- your doctor is not sure if chemotherapy is necessary

*Also known as the Oncotype DX Breast Recurrence Score® test

This guide is provided by Exact Sciences.

They cannot advise you about your diagnosis or treatment plan.

Please discuss these with your healthcare team.

Introduction

This guide has been written to explain more about the Oncotype DX Breast Recurrence Score test, a test that is done on a small sample of your breast cancer tissue.

Several different tests are performed on the breast cancer tumour after your core biopsy procedure or breast cancer operation. Surgery removes the tumour, and glands (lymph nodes) in your armpit may also be taken out.

Even after successful surgery a few cancer cells may remain in the body, so hormone treatment, radiotherapy and sometimes chemotherapy are given. These lessen the chance of breast cancer recurring (coming back).

Such treatments given after the breast cancer tumour has been removed are called adjuvant therapies. These therapies (treatments) are important because if the breast cancer recurs (comes back), this affects long term survival.

Did you know?
There are many different types of breast cancer. Some rely on hormones like oestrogen which help the cancer cells grow. Knowing information such as this helps guide treatment decisions.

Treatments

Not everyone needs the same breast cancer treatment. This depends on many factors including the type of tumour.

You might be offered hormone (endocrine/oestrogen) therapy if one test shows that the breast cancer is hormone receptor positive (HR+).

Chemotherapy is another treatment that can be useful for some breast cancers. However not everyone with HR+ breast cancer necessarily needs or has chemotherapy.

Research done on many thousands of patients with breast cancer shows that the results from the Oncotype DX test are useful when deciding if chemotherapy might have a role in treating your cancer.

Doctors consider several things such as your age, the size and type of breast tumour when deciding whether or not to recommend chemotherapy.

What is chemotherapy?

Chemotherapy is an anti-cancer treatment that kills cancer cells. It is usually given every 2 to 3 weeks for 4 to 5 months via an infusion into a vein. Preparing and giving the drugs this way can take most of the day.

Unfortunately chemotherapy does cause certain side effects as it destroys normal cells in the body as well as the cancer ones.

This is why doctors **only** want to give chemotherapy to those patients most likely to gain some value from it.

Some patients go through chemotherapy easily, but others find coping with the side effects such as nausea, hair loss and fatigue quite difficult. Chemotherapy can also have longer term side effects, for example tingling and/or numbness in the hands and feet. However, there are things your cancer treatment team can offer you to help with the side effects.

Remember that the point of any of these additional (adjuvant) treatments after surgery is to reduce the risk of the cancer returning.

For some patients it is unclear if chemotherapy will provide more benefit than hormone therapy alone, in which case your breast cancer team may consider the use of the Oncotype DX test.

What is the Oncotype DX test?

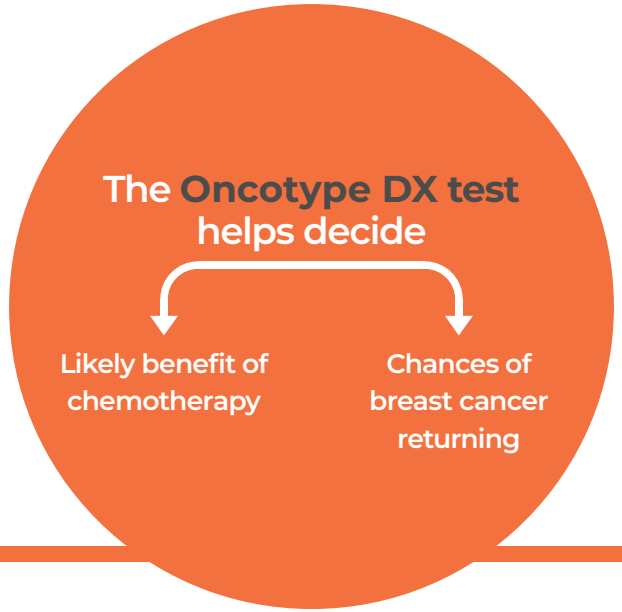
The Oncotype DX test is a genomic or gene expression profiling test performed at a specialised laboratory.

The test looks at the behaviour of 21 different genes inside the breast cancer cells.

These genes help determine the chances of the breast cancer coming back.

The test results provide additional information about your breast cancer including if chemotherapy should be part of your treatment plan.

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



What is the Recurrence Score® result?

Your doctor is sent a detailed report that contains your Recurrence Score result which can be a number between 0 to 100.

If the score is **below 25** you are less likely to benefit from chemotherapy in addition to hormone therapy, and there is a lower risk of the cancer returning.

If the score is **26 and above**, you are likely to benefit from having chemotherapy in addition to hormone treatment, and there is a greater chance of the cancer returning. Your healthcare team will consider recommending both treatments..

If your Recurrence Score result is 0 - 25 and you and your healthcare team have decided that you don't need chemotherapy this will mean that instead you will be treated with hormone therapy only.

This is an essential part of your treatment plan to help avoid the cancer returning.

It is very important that you take the hormone therapy for the duration indicated by your healthcare team.

Does age make a difference to your Recurrence Score result?

Some research suggests that your age or menopausal status might change the interpretation of your Recurrence Score result.

If you are postmenopausal and/or older than 50 years old with up to 3 lymph nodes positive, and have a Recurrence Score result of less than 25, you are not likely to benefit from chemotherapy.

If you are premenopausal and/or younger than 50 years old and have a Recurrence Score result of less than 25, your doctor is likely to have further discussions with you about your chemotherapy treatment plan.

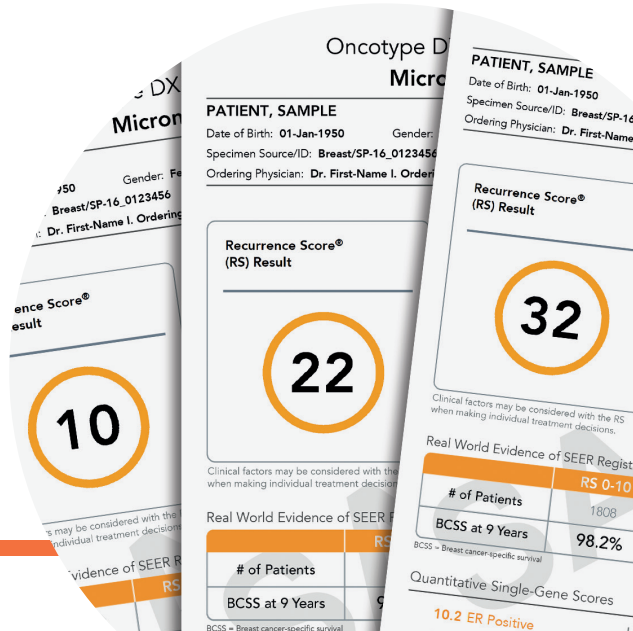
Remember to ask your doctor or nurse to explain any things that you find unclear.

Summary

You have been offered the Oncotype DX Breast Recurrence Score® test because:

- you have early-stage breast cancer that is hormone (oestrogen) receptor positive (HR+) requiring hormone therapy
- your breast cancer is either lymph node negative or lymph node positive
- your doctor is not sure if chemotherapy is necessary

The Oncotype DX® test provides additional information that is specific to your cancer and can help your doctor understand more about the biology of your tumour.



Glossary

Adjuvant treatment:
When there is a risk that the cancer could spread to another part of the body, adjuvant treatment is used following surgery. 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 certain drugs that destroy or slow the growth of cancer cells and prevent the cancer from spreading elsewhere in the body.

Core biopsy:
Under a local anaesthetic, a core biopsy uses a hollow needle to get a sample of the breast tissue to be looked at under a microscope.

Early-stage breast cancer:
A cancer that has not spread beyond the breast or the nearby lymph nodes under the arm.

Genomic test (also known as gene expression profiling 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.

HR/ER (hormone/ oestrogen receptor):
Proteins found in and on breast cells - that pick up hormone signals telling the cells to grow. The term HR or ER-positive (HR+/ER+) means a person's cancer cells may be sensitive to, and respond to, hormone (endocrine) therapy.

Hormone (endocrine) therapy:
A generic term to refer to drugs, such as tamoxifen or aromatase inhibitors, that reduce or regulate the production or effects of hormones in the body.

Hormone Receptor Status:
Shows whether a breast cancer needs hormones to grow. A hormone receptor-positive (estrogen and/or progesterone receptor-positive) cancer needs hormones to grow. A hormone receptor-negative (estrogen and/or progesterone receptor-negative) cancer does not need hormones to grow.

Glossary

Lymph nodes:
Small bean-shaped organs (sometimes called lymph glands) located in the underarms, groin, neck, chest, and abdomen which act as filters for the lymphatic system. Lymph nodes under the arm drain fluid from the chest and arm. During a biopsy or surgery, tissue from underarm lymph nodes might be 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. Additional information about the number of lymph nodes in which cancer has been found is usually provided as well as the size of the cancer in each node. Micrometastases are cancer cells larger than 0.2 mm but not bigger than 2 mm; macrometastases are cancer cells larger than 2 mm.

Menopause:
The time of life when a woman's ovaries stop producing hormones and menstrual periods stop.

Oestrogen:
Oestrogen is one of the main female sex hormones produced by the ovaries and adrenal glands. While both women and men produce oestrogen, it plays a bigger role in women's bodies. In the female body, oestrogen is needed for:

- **puberty**
- **the menstrual cycle**
- **pregnancy**
- **bone strength**
- **maintaining normal cholesterol levels**

Postmenopausal:
A woman is said to be postmenopausal when she has not had a period for 12 months.

Premenopausal:
This term is used for the years before the menopause.

Radiotherapy:
Radiotherapy is used to destroy cancer cells locally at the site of the cancer. Radiotherapy may be used before or after surgery and is sometimes used in combination with chemotherapy.

Tumour:
A lump or growth that can be malignant (cancerous) or benign (not cancerous).

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Further Information

If you would like to learn more about the Oncotype DX Breast Recurrence Score test please visit **www.oncotypeiq.com/en** or scan the QR Code.

You can also contact our Customer Support Team at:

europeansupport@exactsciences.com

This patient information booklet has been developed by Exact Sciences UK, Ltd. in collaboration with SHORE-C (Sussex Health Outcomes Research & Education in Cancer).

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