The Oncotype® DX Breast Recurrence Score

Oncotype® DX is a genomic laboratory test that helps guide treatment decisions for people with early-stage invasive breast cancers. Genomic tests look at the genes in tumors. This can tell us more about your risk of the cancer coming back. Genomic tests are not the same as genetic tests. Genetic tests look for a single-gene mutation in your body (like BRCA 1 and 2). Genomic tests look at the genes in the tumor.

Genomic tests are a way to look specifically at your tumor to help guide your treatment options. There are several genomic tests available. This article focuses on the Oncotype DX® breast recurrence score test. This test helps decide if having chemotherapy along with endocrine (hormone) therapy after surgery will lower your risk of the cancer coming back (recurring).

The Oncotype DX® test is endorsed by all major cancer organizations, including the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO). It can help you choose a treatment plan if you have early-stage breast cancer.

Who should get this test?

Oncotype DX® testing is used if you meet all of the following criteria:

- You are diagnosed with invasive breast cancer.
- The Oncotype® DX test is mainly used in women with breast cancer but is being studied in men with breast cancer.
- The stage of your cancer is I, II, or IIIA.
  - Your lymph nodes can be negative or you can have 1-3 positive nodes.
- The cancer is ER+(estrogen receptor-positive) and HER2 negative.
  - This information is found on your pathology report and means that the cancer is likely to respond to hormone therapy.

How does the test work?

After you have surgery (lumpectomy or mastectomy), pieces of the tumor are sent to Exact Sciences Laboratory where the test is done. It will take about 2 weeks for your provider to get the results.

Scientists look at the tumor samples. They measure the amount of 21 specific genes in the tumor tissue. Sixteen of the genes are cancer-related; the other 5 are used as "reference" genes. Based on the amount of each of these genes, a score is assigned. This is called the Recurrence Score (RS). This score is on a scale of 0-100. Higher scores mean there is a greater risk of recurrence (cancer coming back). A higher score also means you are likely to benefit from getting chemotherapy to reduce the risk of recurrence. Your recurrence score, in combination with your age and the size and grade of your tumor, will help pick the best treatment for you to prevent a recurrence.

What does the recurrence score mean?

How the score is used for treatment decisions depends on your menopausal status and if you had cancer in your lymph nodes.

A postmenopausal person with or without cancer in the lymph nodes (positive or negative nodes):

- A score of 0-25 indicates a low risk of recurrence. Adding chemotherapy to your treatment will not add any benefit. The risks of chemotherapy would outweigh the benefits of having chemotherapy.
- A score of 26-100 indicates a high risk of recurrence. The benefits of chemotherapy in preventing a future recurrence...
outweigh the risks.

A premenopausal person with no cancer found in the lymph nodes (node-negative):

- A score of 0-15 indicates a low risk of recurrence. Likely the risks of chemotherapy would outweigh the benefits of having chemotherapy.
- A score of 16-25 indicates a low to medium risk of recurrence. There may be a small benefit to adding chemotherapy to your treatment. You may get the same benefit by taking medicines to stop your ovaries from making estrogen along with hormone therapy. Your oncology team will talk about the risks and benefits with you.
- A score of 26-100 indicates a high risk of recurrence. The benefits of chemotherapy are greater than the risks of side effects.

A premenopausal person with cancer in the lymph nodes (positive nodes):

- If you have a score below 26, there is a benefit to adding chemotherapy to your treatment. You may be able to get the same benefit by taking medicines to stop your ovaries from making estrogen (called ovarian suppression) along with hormone therapy. Your oncology team will talk about the risks and benefits of chemotherapy or ovarian suppression with you.
- A score of 26-100 indicates a high risk of recurrence. The benefits of chemotherapy are greater than the risks of side effects.

**Is the test covered by my insurance?**

The test costs about $4,000 and is covered by Medicare and many private insurance companies. Exact Sciences will help patients and doctors’ offices with insurance claims. They also offer financial help to those who qualify for financial need. The test could determine the need for 6 or more months of chemotherapy treatments and all the related costs, making it beneficial for the patient and insurer.

**Resources for More Information**

**Oncotype IQ**

Information and resources for patients and caregivers from Exact Sciences.


**My Breast Cancer Treatment**

Information and resources for patients and caregivers from Genomic Health/Exact Sciences

https://www.mybreastcancertreatment.org/

**Breastcancer.org**

https://www.breastcancer.org/symptoms/testing/types/oncotype_dx

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