Have you been newly diagnosed with early-stage breast cancer?

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Author and anthropologist.
Diagnosed with invasive breast cancer in 2005.

Uncover the Unexpected™

An educational guide prepared by Genomic Health®

This guide is designed to educate women newly diagnosed with early-stage breast cancer about the Oncotype DX® test, a diagnostic test that may help you and your doctor make a more informed treatment decision based on your tumor’s biology.
Have you recently been diagnosed with early-stage invasive breast cancer? Are you struggling to make treatment decisions? If so, you may be interested to know that not all women with early-stage breast cancer benefit from chemotherapy. The Oncotype DX test helps identify which women with early-stage, estrogen receptor-positive (ER+) invasive breast cancer are more likely to benefit from adding chemotherapy to their hormonal treatment.1

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 tumor. 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.

“The additional information provided by the Oncotype DX test 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 on getting better.”

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

It is overwhelming to receive a diagnosis of breast cancer. 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 tumor
- whether your tumor has spread
- whether there are estrogen receptors and HER2 receptors on the cells of your tumor
- 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 tumor to individualize 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 a woman’s breast tumor tissue. The test gives you information regarding:

- the chances of your breast cancer returning
- the likelihood that you may benefit from chemotherapy treatment
Why Should I Consider the Oncotype DX Test?

This is a unique test that provides information specific to your tumor, not available from traditional factors. Since the Oncotype DX test provides individualized 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 tumor cells that are estrogen receptor positive (ER+)
- have tumor cells that are human epidermal growth factor receptor negative (HER2–)
- are pre- or post-menopausal and lymph node negative (N–) or are postmenopausal and lymph node positive (N+)

“I wanted to do everything I could to try and prevent the cancer from returning. So when I saw the Oncotype DX test results, I knew what I needed to do and felt more confident about my decisions regarding my treatment.”

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

The test will tell you and your doctor the chances of your tumor 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.

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

How Is the Oncotype DX Test Performed?

The test is performed on a small amount of your tumor 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.

“My Recurrence Score result was one more piece of information that helped us make that decision. You want to get as many facts together as you can.”

When your doctor orders the Oncotype DX test, the hospital will send a sample of your tissue to Genomic Health, the laboratory that performs the Oncotype DX test.

**Is the Oncotype DX Test Incorporated in Practice Guidelines?**

Yes, it is incorporated into major clinical guidelines. The American Society for Clinical Oncology® (ASCO®)* is an organization of cancer experts that publishes guidelines for how doctors treat cancer. The guidelines indicate that the Oncotype DX test may be used for treatment decision-making for patients with hormone (estrogen and progesterone) receptor-positive, lymph node-negative invasive breast cancer.2

Another leading group of cancer experts, the National Comprehensive Cancer Network® (NCCN®),* incorporated the Oncotype DX test in their breast cancer treatment guidelines.3

The Oncotype DX test has been studied and proven in multiple clinical trials with more than 4,000 women.1,4-9 Since the Oncotype DX breast cancer test became available in 2004, it has been used by thousands of doctors to help guide treatment for over 300,000 women.10

In addition, Genomic Health (the company that developed the Oncotype DX test) offers tests for DCIS (ductal carcinoma *in situ*) and colon cancer. To date, the Oncotype DX test (for all assays) has been ordered by over 10,000 doctors in 65 countries.

*American Society for Clinical Oncology and ASCO and National Comprehensive Cancer Network and NCCN are registered trademarks of ASCO and NCCN, respectively. ASCO and NCCN do not endorse any product or therapy.

“**The Oncotype DX test gave me a tangible way to view the benefits of chemotherapy.**”

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.

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 7 to 10 days from the date the tumor sample is received by the Genomic Health® laboratory. The results are sent to your doctor so that he or she can discuss the results with you and answer your questions.

“Before my Oncotype DX test, the people at Genomic Health called to tell me that they had taken care of the insurance paperwork for me so I wouldn’t have to worry about that. Three days later, I heard from Genomic Health that my insurance would cover the cost of the test, long before I ever heard back from the insurance company itself. It was quite a relief, given all of the other stress.”

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.

- 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.

It is important to understand that a lower Recurrence Score result does not mean that there is no chance that a woman’s breast cancer will return. Also, a higher Recurrence Score result does not mean that a woman’s breast cancer will definitely return.

Is the Oncotype DX Test Covered by Insurance?

Most insurance carriers, including Medicare, Aetna, Cigna, UnitedHealthcare, Kaiser Permanente, Anthem/WellPoint, Humana, Blue Cross Federal, and many others, cover the Oncotype DX test for eligible invasive breast cancer patients. Genomic Health has a comprehensive program to assist you throughout the entire reimbursement process.

Additionally, our Genomic Access Program (GAP) offers:

- Financial assistance for all patients who qualify (including un-insured and under-insured patients)
- Help determining whether your plan covers the test (for those with insurance)
- Prior authorization from your insurance company (if required)
- Processing of your claim when the test is complete (as required)
- Assistance throughout the appeal process (at your or your doctor’s request) if your claim is denied

Please note that in the rare event that attempts to gain insurance coverage are not successful, you may be financially responsible for some or all costs associated with the Oncotype DX test.

For specific insurance and financial-aid questions, please contact Genomic Health® Customer Service at 866-ONCOTYPE (866-662-6897) and we will be happy to assist you.

For additional resources and information, please visit www.mybreastcancertreatment.org or www.oncotypedx.com.
List of Terms

**Assay:** A laboratory test.

**Cancer:** A term for diseases in which abnormal cells divide without control or order. Cancer cells can invade nearby tissues and can spread through the bloodstream and lymph nodes to other parts of the body.

**Cell:** The smallest unit of a tissue that makes up any living thing. Cells have a very specialized 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.

**Core Biopsy:** A hollow needle is used to remove tissue samples from the lump in your breast. Several small samples are sent to the pathologist for further analysis.

**Early-Stage Breast Cancer:** Breast cancer is categorized by stage based on the size of the tumor and whether the cancer has spread. Stages I, IIA, IIB, and IIIA are considered “early-stage” and refer to cancers that may have spread to nearby lymph nodes but not to distant parts of the body.

**Estrogen Receptor (ER):** A protein that may be present on certain cells to which estrogen molecules can attach. The term “ER positive (ER+)” means a woman’s cancer cells may be sensitive to (respond to) hormonal therapy.

**Gene:** The basic unit of heredity found in most cells of the body.

**Genomics:** The study of complex sets of genes, their expression (level of activity), and their effects on biology.

**Hormonal 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.

**Human Epidermal Growth Factor Receptor 2 (HER2):** A protein that appears in the cancer cells of some women with breast cancer. A woman whose tumor has greater-than-normal levels of HER2 is considered HER2 positive. A woman whose tumor has normal levels of HER2 is considered HER2 negative.

**Lumpectomy:** A surgical procedure that removes a localized mass of tissue, including the breast cancer tumor and a small amount of tissue surrounding the tumor.

**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.

**Margin:** Healthy normal tissue that surrounds the edge of the tumor tissue that is removed during surgery. “Negative” or “clear” margin means the cancer was entirely removed; “positive” margin means some cancer cells still remain after surgery.

**Mastectomy:** A surgical procedure to remove all or part of the breast.

**Newly Diagnosed:** A term used to describe breast cancer that has recently been identified in a patient.

**Node-Negative (N–) Breast Cancer:** Breast cancer that has not spread to the lymph nodes.

**Node-Positive (N+) Breast Cancer:** Breast cancer that has spread to the lymph nodes.

**OncoType DX® Tests:** The OncoType DX tests are unique diagnostic tests that look at the genomic profile of a tumor.

**Progesterone Receptor (PR):** A protein that may be present on certain cells to which progesterone molecules can attach. The term “PR positive (PR+)” refers to tumor cells that contain the PR protein. These cells are generally sensitive to (respond to) hormonal therapy.

**Radiation:** The use of radiation to destroy cancer cells. Radiation therapy may be used before or after surgery, and is sometimes used in combination with chemotherapy. Radiation is used for local control of the cancer at the site of the tumor.

**Staging:** A classification system for breast cancers based on the size of the tumor, whether the cancer has spread to the lymph nodes, and whether the cancer has spread to other sites in the body (metastasis).

**Tumor:** Tissue growth in which the cells that make up the tissue have multiplied uncontrollably. A tumor can be benign (non-cancerous) or malignant (cancerous).

**Tumor Grade:** Characterization of a tumor based on how similar the cancer cells are to normal cells.

**Tumor Size:** How big the tumor is, usually reported in metric units (millimeters [mm] or centimeters [cm]).
To learn more about the Oncotype DX test, visit www.mybreastcancertreatment.org and talk to your healthcare team. For insurance, financial aid, or other questions about the Oncotype DX test, please call US (English) 866-ONCOTYPE (866-662-6897), US (Spanish) 877-444-9876, and international 001-650-569-2080.

For more information about this and other Oncotype DX tests, please visit www.genomichealth.com or www.oncotypedx.com.

The people shown in this booklet used the Oncotype DX Breast Cancer test in making their treatment decisions with their physicians.


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