

List of Terms

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 tissues that make up any living thing. Cells have a very specialized structure and function.

Chemotherapy: Treatment with drugs, given intravenously (in the vein), orally (by mouth), and by other routes of administration, to kill or slow the growth of cancer cells. These drugs are toxic to cancer cells and to normal cells. Due to the toxic nature of many of these drugs to all cells, chemotherapy can result in mild-to-severe side effects.

Clinical Trial: A research study where patients help scientists evaluate ways to prevent, detect, diagnose or treat diseases.

Early-Stage Breast Cancer: A term that can be used to describe stage I and II, lymph node-negative breast cancer.

Estrogen Receptor (ER): A protein that may be present on certain cells to which estrogen molecules can attach. The term "ER positive" means a woman's cancer cells may be sensitive to hormone 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 Treatment: 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.

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.

Node-Negative Breast Cancer: Breast cancer that has not spread to the lymph nodes.

Node-Positive Breast Cancer: Breast cancer that has spread to the lymph nodes.

Progesterone Receptor (PR): A protein that may be present on certain cells to which progesterone molecules can attach. The term "PR positive" refers to tumor cells that contain the progesterone receptor protein. These cells are generally sensitive to hormone therapy.

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 where the cells that make up the tissue have multiplied uncontrollably. A tumor can be benign (non-cancerous) or malignant (cancerous).

To learn more about Oncotype DX®, visit www.mytreatmentdecision.com and talk to your healthcare team.

For other questions about the Oncotype DX test, contact Healthscope Pathology
1868 Dandenong Road Clayton Vic 3168
Customer Service Centre: 1300 453 688
Call our Product Specialist: 0424 750 403
Email: Oncotype@healthscope.com.au
www.oncotypedx.com.



1868 Dandenong Road Clayton Vic 3168

References:

1. Paik S, Tang G, Shak S, et al. Gene expression and benefit of chemotherapy in women with node-negative, estrogen receptor-positive breast cancer. *J Clin Oncol*. 2006;24(23):3726-34.
2. Paik S, Shak S, Tang G, et al. A multigene assay to predict recurrence of tamoxifen-treated, node-negative breast cancer. *N Engl J Med*. 2004;351(27):2817-26.
3. Lo SS, Norton J, Mumby PB, et al. Prospective multi-center study of the impact of the 21-gene Recurrence Score (RS) assay on medical oncologist (MO) and patient (PT) adjuvant breast cancer (BC) treatment selection. Published Ahead of Print on January 11, 2010 as 10.1200/JCO.2008.20.2119. *J Clin Oncol* 28. © 2010 by American Society of Clinical Oncology
4. Harris L, Fritsche H, Menkel R, et al. American Society of Clinical Oncology 2007 update of recommendations for the use of tumor markers in breast cancer. *J Clin Oncol*. 2007;25(33):5287-312.
5. National Comprehensive Cancer Network 2010 Clinical Practice Guidelines in Oncology Breast Cancer. www.nccn.org

oncotype DX
Breast Cancer Assay

genomic
health

Genomic Health, Oncotype DX and Recurrence Score are registered trademarks of Genomic Health, Inc. ©2008 Genomic Health, Inc. All rights reserved. GH1201 Rev.3 08/08

Clinical Laboratories Pty Ltd ABN 62 006 823 089

HSGHBC0029 01/11

Have you been
newly diagnosed
with breast cancer?

Have you discussed
whether chemotherapy will be
part of your treatment plan?



oncotype DX
Breast Cancer Assay

This guide is designed to educate newly diagnosed women with early-stage breast cancer about Oncotype DX®, a diagnostic test that may help you and your doctor make a more informed treatment decision.

Have you recently been diagnosed with breast cancer? Are you struggling to make treatment choices? Then you may be interested to know that many women with early-stage breast cancer do not benefit from chemotherapy. For some women, chemotherapy may not add any significant medical advantage.

Oncotype DX® is a diagnostic test that helps identify which women with early-stage, estrogen receptor-positive breast cancer are **more likely to benefit** from adding chemotherapy to their hormonal treatment. This test also helps an individual woman understand the likelihood of having her breast cancer return. Oncotype DX provides important information that you and your doctor may use when making decisions about treatment.

"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 on getting better."

Sandy, mother and teacher
Diagnosed with breast cancer
in 2006

The Need for Treatment Planning

After a breast cancer diagnosis, doctors and patients work together to plan an appropriate treatment course following surgery. The goal is to keep breast cancer from coming back. One key step in treatment planning is to determine how beneficial certain types of treatment, such as chemotherapy, may be for an individual patient. Another step is to understand the individual likelihood of having her cancer return. Therefore, learning as much as you can about your breast cancer tumor **right now** can help you and your healthcare team develop a more informed treatment plan.

Gathering Information to Help Make the Right Treatment Decision for You

While it is upsetting 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**. Because every patient's breast cancer is unique, your doctor will analyze **your** cancer to design a plan based on the specific characteristics of **your** breast tumor. To help your doctor understand your tumor, many factors will be assessed. These factors include your age, the size of your invasive tumor, whether your tumor has spread and whether there are estrogen receptors and HER2 receptors on the cells of your tumor. In addition to these factors, the Oncotype DX® test provides more information about what is happening inside your tumor. The test measures the activity of 21 different genes, 16 of which relate to both benefit from chemotherapy and the chance of cancer coming back.

What is Oncotype DX®?

Oncotype DX is a unique diagnostic breast cancer test that looks at the activity of 21 different genes in a woman's breast tumor tissue. The test measures the chances of **your** breast cancer returning and the likelihood of **your** benefiting from chemotherapy treatment.^{1,2}

What Are the Benefits of Oncotype DX®?

Oncotype DX gives you and your doctor a better understanding of how your tumor behaves. This important information helps determine which treatment to use. Oncotype DX may increase confidence that the treatment plan is **tailored for you**.³ Speak with your healthcare team to understand how Oncotype DX results may impact your treatment planning.

Is the Oncotype DX® Test Right for Me?

The Oncotype DX test is appropriate for women who are newly diagnosed with early-stage estrogen receptor-positive breast cancer. You may wish to discuss with your doctor if the Oncotype DX test may be of benefit to you.

What Will I Learn from the Oncotype DX® Test?

Your doctor will receive a report with the results of your Oncotype DX test. The report contains the Recurrence Score® result, which is a number between 0 and 100. Women with lower Recurrence Scores have a lower risk that their cancer will return. These women also have a cancer that is less likely to respond to chemotherapy, so their doctors may recommend treatment with hormone therapy alone. Women with higher Recurrence Scores have a stronger chance that their breast cancer will return. While this can be distressing, the good news is that women with higher Recurrence Scores are more likely to gain a large benefit from chemotherapy. For these women, having chemotherapy now (in addition to hormonal therapy) may help reduce the chance that their cancer will come back in the future. 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 does not mean that a woman's breast cancer will definitely return. The Oncotype DX® test results also provide additional information, such as the activity levels of the estrogen and progesterone receptors in your tumor, to help guide your treatment.

Is the Oncotype DX® Test Recommended by Doctors?

Since Oncotype DX became available in the USA in 2004, it has been used by thousands of doctors to help guide treatment for over 175,000 women from more than 55 countries. Oncotype DX is the **only** test recommended in the ASCO and NCCN guidelines that predicts whether or not a woman with early-stage breast cancer is likely to benefit from chemotherapy. This information can help each woman and her doctor develop a more personalized treatment plan.

How is the Oncotype DX® Test Performed?

Oncotype DX 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. When your doctor orders the Oncotype DX test, the hospital will send a sample of your tissue to Genomic Health® (USA), the laboratory that performs the Oncotype DX® test. **This means that you will NOT have to go through any additional surgery or procedure to get the Oncotype DX test.**

Is the Oncotype DX® Test Reliable?

The Oncotype DX test has been studied in many different clinical trials with more than 4,000 women, demonstrating its accuracy and consistency. To learn more about these trials, please visit www.oncotypedx.com. In addition, to obtain a precise and accurate measure, the 21 genes in the Oncotype DX test are measured three separate times in each woman's tumor sample.

When Should the Oncotype DX® Test Be Done?

It is important for your doctor to request the Oncotype DX test **before** starting any treatment with chemotherapy, since the Oncotype DX test is intended to help determine whether or not you are likely to benefit from chemotherapy in addition to your hormonal treatment. If you do not know the stage of your breast tumor or the estrogen receptor or nodal status, please check with your doctor.

How Long Will it Take to Get the Results of the Oncotype DX® Test?

It will typically take 10 to 14 days from the date the tumor sample is received by Genomic Health® (USA), for the results to be available. The Oncotype DX test results are sent to your doctor so that he or she can discuss the results with you and answer your questions.

How Do I Get the Oncotype DX® Test?

The Oncotype DX 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 Oncotype DX may be of benefit to you.

Susan, art teacher and grandmother
Diagnosed with breast cancer in 2004

Linda, human resources manager
and active volunteer
Diagnosed with breast cancer in 2006