

To learn more about the *Oncotype DX* Colon Cancer Test, please visit www.oncotypedx.com and talk to your health care team. For insurance, financial aid or other questions about the *Oncotype DX* test, please contact Genomic Health Customer Service – U.S. (888-ONCOTYPE (888-662-6897) international +1-650-569-2080.

For more information about all *Oncotype DX* tests, please visit www.genomichealth.com or www.oncotypedx.com.

An interactive online resource for newly diagnosed colon cancer patients is available at www.mycoloncancercoach.org.

The people shown in this booklet used the *Oncotype DX* Colon Cancer Test in making their treatment decisions with their physicians.

References: 1. Gray RG, Quirke P, Handley K, et al. Validation study of a quantitative multigene reverse transcriptase—polymerase chain reaction assay for assessment of recurrence risk in patients with stage II colon cancer. *J Clin Oncol.* 2011;29(35):4611-4619. 2. Venook AP, Niedzwiecki D, Lopatin M, et al. Biologic determinants of tumor recurrence in stage II colon cancer: validation study of the 12-gene Recurrence Score in Cancer and Leukemia Group B (CALGB) 9581. *J Clin Oncol.* 2013;31(14):1775-1781. 3. Yothers G, O'Connell M, Lee M, et al. Validation of the 12-gene colon cancer Recurrence Score in NSABP C-07 as a predictor of recurrence in stage II and III colon cancer patients treated with 5-FU/LV and 5-FU/LV+ Oxaliplatin. *J Clin Oncol.* In press..

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Colon Cancer Assay

HAVE YOU BEEN RECENTLY DIAGNOSED with stage II or stage III colon cancer?



Dan C.
Father and police officer.
Diagnosed with colon cancer in 2010.

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Colon Cancer Assay

An educational guide prepared by Genomic Health
This guide is designed to educate people who have been newly diagnosed with stage II or stage III colon cancer, about the *Oncotype DX*® Colon Cancer test, a genomic diagnostic test that can help you and your doctor make a more informed treatment decision based on the unique biology of your tumor.



“My Recurrence Score® result was low, so I did not need to undergo further treatment and the possible side effects. I am grateful for the peace of mind that this test provided.”

David M.
Diagnosed with colon cancer in 2011

Take the time to learn about your cancer. Not all colon cancers are the same

Ask your doctor about the Oncotype DX Colon Cancer Assay

Are you struggling to make treatment decisions? If so, you may want more information about your level of risk.

This information can help you and your doctor make decisions about future treatment options.

Planning your treatment

After you have been diagnosed with colon cancer, 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 (recurrence risk), which helps you and your doctor make decisions about future treatment options. The *Oncotype DX* Colon Cancer Test is a first-of-its kind genomic test that provides a specific estimate of recurrence risk following surgery, for both stage II and stage III A/B colon cancers. It may help you with these questions.

- Should I consider chemotherapy following surgery? (Stage II patients)
- Should oxaliplatin be added to my treatment plan ? (Stage III patients)

This education piece is not designed to provide individual advice in connection with your diagnosis or treatment plan. Such matters should be discussed with your healthcare provider.



Gathering information to guide your treatment decision

A diagnosis of colon cancer can be frightening, but you can play an important role in planning your treatment. Since every colon cancer is unique, you should gather as much information as possible about your tumor to determine the best treatment approach for you. The following factors provide vital information that can help you and your doctor understand your cancer:

- Your medical history
- Your age
- Your treatment preferences
- T-stage – How deeply does your tumor invade the bowel wall?
- MMR status – How aggressive is your tumor?
- Lymph-node involvement – Are there cancer cells in your lymph nodes?
- Bowel perforation or obstruction – Is your tumor affecting the health and function of your bowels?
- Tumor grade* – How do your cancer cells look compared to normal cells?
- Lymphatic or vascular invasion – Are there cancer cells in your bloodstream or lymph system?
- Oncotype DX test results – What is the likelihood that your cancer will return?

*for stage III

“As an oncology nurse who personally went through a cancer diagnosis and had the Oncotype DX Breast Cancer Test, I know this is a challenging time.

The Oncotype DX Colon Cancer Test is available to anyone facing stage II or stage III A/B colon cancer.

Oncotype DX testing is part of the latest technology available to help patients to make the best decision for their treatment, with their physician”

Carol F., oncology nurse and grandmother.
Diagnosed with DCIS breast cancer in 2012.

What is the *Oncotype DX*® Test?

It is a unique diagnostic test that provides information specific to your tumor — information that is not available from other tests or procedures. It looks at the activity of 12 different genes in your colon cancer tumor to help identify the risk that your cancer will return following surgery. This information can be used to plan treatment that is most appropriate for you.

Why should I get this test?

If you have stage II or stage III A/B colon cancer, this test provides the Recurrence Score® result, which is not available from any other test. This result helps determine recurrence risk based on your tumor's biology.

Know your Recurrence Score result. Know your risk.

If you have been diagnosed with:

- Stage II colon cancer: Your Recurrence Score result can help your doctor decide whether or not you are at higher risk and are likely to have a greater absolute benefit from chemotherapy following surgery.
- Stage III A/B colon cancer: Your Recurrence Score result can help your doctor decide whether or not you are at lower risk, and may receive less absolute benefit from a drug called “oxaliplatin”. This may help your doctor decide not to recommend oxaliplatin following surgery.

Since the *Oncotype DX* Colon Cancer Test provides personalized information, it enables your treatment plan to be tailored just for you. Talk to your healthcare team to understand how the *Oncotype DX* Colon Cancer Test may affect your treatment decision.

Is this test right for me?

The test may be right for you if you are planning treatment after surgery, and you:

- Are newly diagnosed with either stage II or stage III A/B colon cancer
- Have not started treatment with chemotherapy

The science behind this test

The *Oncotype DX* Colon Cancer Test was created through an extensive research and development process — first to identify which tumor genes accurately predict the risk of colon cancer recurrence, then to evaluate the performance of the test in large clinical studies.

In three studies¹⁻³ involving thousands of colon cancer patients, the *Oncotype DX* Colon Cancer Test has been shown to provide valuable information about the recurrence risk for people with either stage II or stage III A/B colon cancer. The Recurrence Score result is not available from other tests or procedures and can help you and your doctor make a personalized treatment decision.

You can learn more about these clinical studies at www.oncotypedx.com.



How is the *Oncotype DX* Test performed?

The test is performed on a small amount of your tumor tissue that was removed during your surgery and stored at the hospital where you were treated. You will NOT have to go through any additional procedures to get the *Oncotype DX* Test.

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

When should this test be done?

It is important that your doctor request the *Oncotype DX* test before you start any chemotherapy. The Recurrence Score result is valuable when making decisions about whether or not to have chemotherapy (stage II colon cancer patients) or whether to add oxaliplatin to chemotherapy (stage III A/B cancer patients).

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 discuss whether or not you will benefit from *Oncotype DX* Colon Cancer Test.

Surgery to remove tumor

Doctor orders the *Oncotype DX* Test

Hospital sends sample of tumor to the Genomic Health® laboratory

The Genomic Health laboratory analyzes the 12 genes

Doctor receives the Recurrence Score® result

You and your doctor discuss the results and personalize treatment

“Being diagnosed with colon cancer was an absolute kick in the stomach. When my Recurrence Score result came back low, my doctor and I had the confidence to decide to forgo chemotherapy. My entire family was elated, and I was able to return to my life as a policeman, dad and husband. Having cancer gave me a new perspective on life and I’m ready to live it to the fullest”

Dan C.

How long will it take to get my test results?

Most results are available within 14 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 them with you, answer your questions, and help make your treatment decision.

What does my Recurrence Score result mean?

Your doctor will help you understand the result. Your doctor will receive a report with your personal Recurrence Score result (a number between 0 and 100). The report also gives an estimate of your risk of colon cancer recurrence.

- A lower Recurrence Score result indicates a lower risk that colon cancer may come back. It does not mean that there is no chance of the cancer returning.
- A higher Recurrence Score result indicates a higher risk that colon cancer may come back. It does not mean that the cancer will definitely return, but it means that you may want to consider additional therapies.

The results of your *Oncotype* DX Colon Cancer Test, combined with other key clinical risk factors such as T-stage and MMR (mismatch repair) status, can help you and your doctor make a more informed, personalized treatment decision — giving you greater confidence in your choice of care.

Is the *Oncotype* DX Colon Cancer Test covered by insurance?

Once you and your doctor agree the test is right for you, you will likely want to find out if it is covered by your insurance. Coverage varies by insurance plan for all medical services and benefits. Medicare covers this test for eligible patients with stage II colon cancer.

Genomic Health, the company that developed and performs the *Oncotype* DX Test, has a program called GAP (Genomic Access Program) to help you through the process.

GAP can help you find out if the test is covered and help process the claim once the test is complete. GAP can also help with the appeal process if your claim is denied. GAP offers financial assistance for patients who qualify (including uninsured and under-insured patients).

Please note that 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 in the U.S. at 888-ONCOTYPE (888-662-6897); outside the U.S., please call +1-650-569-2080.

For additional resources and information, please visit the following websites:

www.mycoloncancercoach.org
www.oncotypedx.com
www.coloncanceranswers.com



List of Terms

Assay: A laboratory test.

Adjuvant Therapy: Treatment performed in addition to surgery.

Biopsy: The removal of a small portion of tissue to see whether or not cancer is present.

Bowel obstruction: Blockage or clogging of the intestines.

Bowel perforation: A hole that develops in the intestinal wall.

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

Chemotherapy: Treatment with drugs to destroy or slow the growth of cancer cells. May be used in addition to surgery.

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

Colectomy: Surgery to remove all or part of the colon. Also called a resection.

Colon (bowel): The part of the large intestine that extends from the end of the small intestine to the rectum.

Diagnosis: Identification of a condition, such as colon cancer, by its signs and symptoms as well as the results of laboratory tests or other examinations.

Gene: The basic unit of inheritance that is passed from parents to children, found in most cells of the body. The genes found in normal colon tissue can change their expression, or level of activity, which can give rise to colon cancer.

Genomics: The study of complex sets of genes, their expression (level of activity), and the role they play in health and disease.

Lymph node involvement: The presence of cancer cells in the lymph nodes (small bean-shaped organs, sometimes called lymph glands) that are found throughout the body and produce and store cells that fight infection.

Lymphatic/vascular invasion (LVI): The presence of cancer cells in either the blood vessels or the lymphatic vessels, based on a pathologist's examination of a tumor sample. LVI is an indication of cancer that has developed the ability to spread.

MMR (Mismatch Repair): A system within the cell for correcting errors in DNA. MMR status can be helpful in treatment planning since patients with stage II and stage III colon cancer whose tumors are MMR-deficient have a lower risk of recurrence.

Newly diagnosed: A term used to describe colon cancer that has recently been identified in a patient.

Oncotype DX Colon Cancer Test: A unique diagnostic test that looks at the genomic profile of a surgically removed colon tumor to predict the likelihood that stage II or stage III colon cancer will recur, or return. This information is helpful in planning treatment for people recently diagnosed with stage II or stage III colon cancer.

Pathologist: A doctor who identifies diseases by studying cells and tissues under a microscope.

Pathology Report: A report that describes what was found in a sample of tissue (biopsy) removed from a patient.

Recurrence: The return of cancer after treatment.

Resection: Surgery to remove primary colon cancer.

Stage II colon cancer: Cancer that has spread outside the colon to nearby tissue, but has not gone into the lymph nodes. Also called Dukes B colon cancer.

Stage III colon cancer: Cancer that has spread beyond the outer layers of the colon to nearby lymph nodes, but not to other tissues or organs.

Tumor: An abnormal mass of tissue that can be non-cancerous (benign) or cancerous (malignant).

T-stage (Tumor-stage): A classification system based on how deeply the tumor has spread into the colon wall, and whether the cancer has spread to the lymph nodes or to other parts of the body. In colon cancer, tumor size is not as critical as T-stage, and whether or not there is lymph node involvement.

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