

PRECISELY
YOU



Not an actual patient.

BIOMARKER TESTING

and Its Role in Your Early Breast Cancer Journey

Overview

Biomarker Testing

Using Test Results

Genetic Testing for Inherited Mutations

Learn More

Introduction

If you are hearing about biomarkers for the first time, you may wonder how biomarkers affect your care and what to do next. Here is some background information to help you get started.

Why Are Biomarkers Important?

- Biomarkers provide clues about how your cancer works, including its strengths and weaknesses. Testing for biomarkers helps your doctors assess how your cancer may behave and understand how likely (or unlikely) it is that a specific treatment might work for you¹⁻⁴
- Recent scientific advances have increased the number of actionable biomarkers. This means doctors can now personalize your treatment plan in a new way⁵



No two breast cancers are the same. Biomarker testing helps your care team get key information to make treatment decisions *precisely for you*^{1,3,4,6,7}

ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor.

What Is a Biomarker?

- A **biomarker** is a substance that can be found in blood or tissues that signals a normal or abnormal process, or a condition or disease^{8,9}
- A biomarker can be a change in DNA (mutations), RNA, or protein⁹



To learn more about biomarkers, please go to **page 23**

Which Biomarkers Should I Be Tested for?

All patients with breast cancer should be tested for their hormone receptor (HR) status (determined by testing for ER and PR), and HER2 to determine subtype^{2,10-12}

Breast cancer subtypes:^{11,12}

HR-positive/HER2-negative	HR-positive/HER2-positive
Triple-negative (HR-negative/HER2-negative)	HR-negative/HER2-positive



Your doctor may recommend more biomarker testing based on your breast cancer subtype and stage^{2,10,13,14}



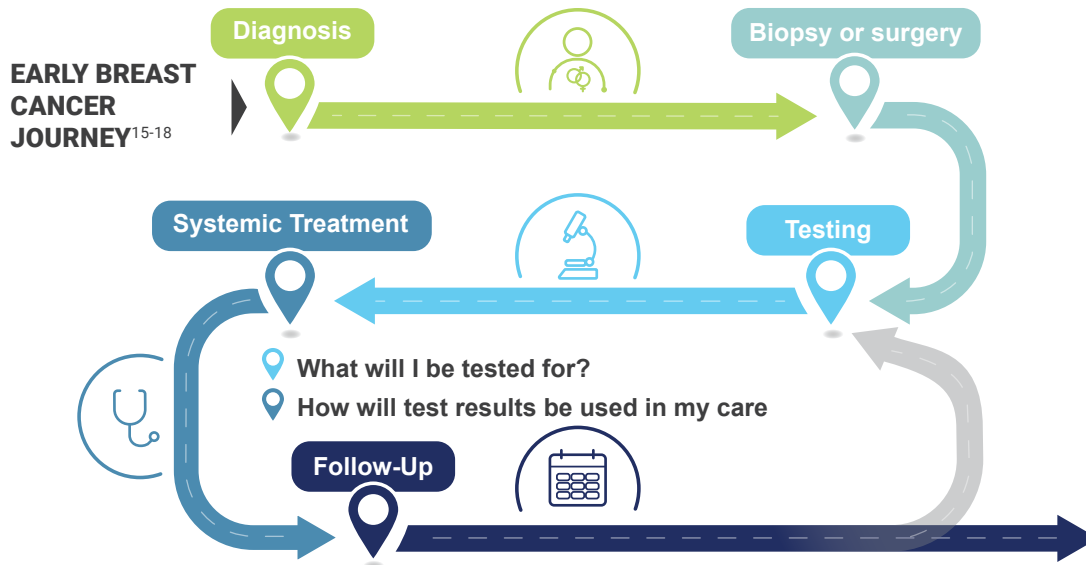
To learn more about additional biomarker testing, please go to **page 8**

When Will I Be Tested for Biomarkers?



All breast cancer journeys are unique, but most have similar steps. In early breast cancer, biomarker testing typically occurs before systemic treatment, or treatment with a therapy that goes throughout the body. It may also occur again at some point during systemic treatment^{2,3,13}

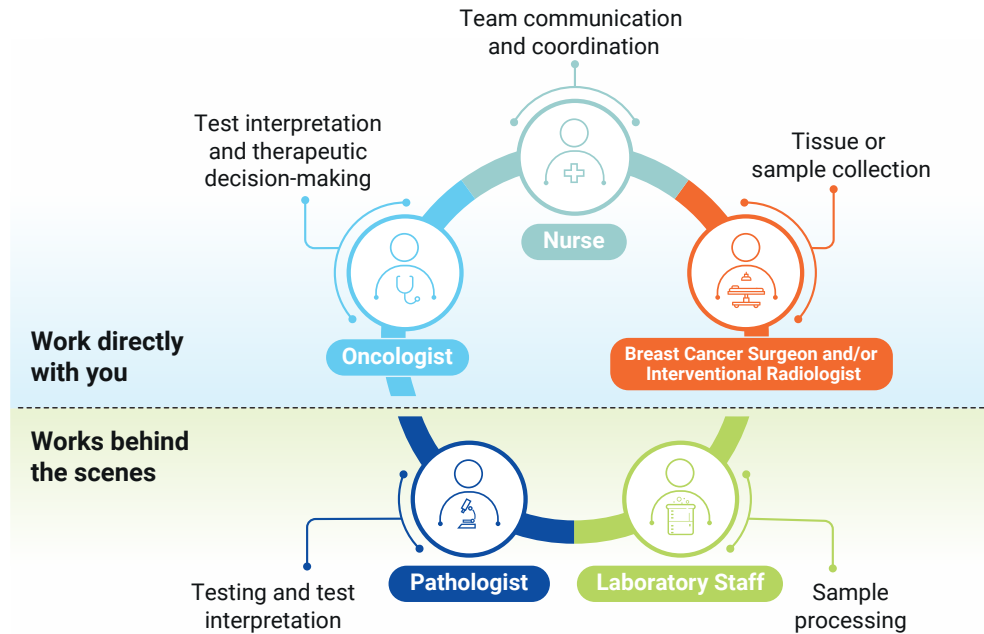
Different Types of Biomarkers Serve Different Purposes¹⁵



Who Is Involved in Biomarker Testing?

Biomarker testing requires input from different specialties, so your care team includes a multidisciplinary team made up of professionals who specialize in different areas. These experts work together to get you the best care, even if you never meet them all^{15,16,19}

Some Members of Your Care Team That Help You Get Biomarker Testing



Questions for Your Care Team

If I have questions about biomarker testing, whom should I ask?

Are there resources that can help support me, like financial assistance programs or financial counselors to help me understand my insurance coverage?

Biomarker Testing in Breast Cancer

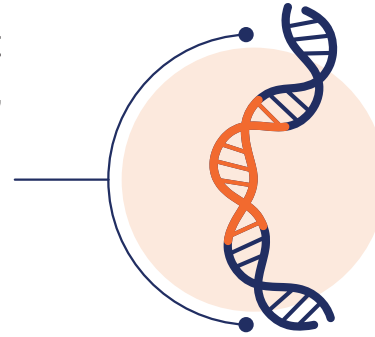
How Will Biomarker Tests Be Used in My Care?

- In early breast cancer, the goal is to cure breast cancer. The first step is a local therapy, like surgery or radiotherapy²⁰
- After the local therapy, some patients may have a systemic therapy to prevent your cancer from coming back, also called **recurrence**. You may have additional biomarker testing to determine if your cancer is likely to come back²⁰
- Additionally, some biomarkers are called **predictive biomarkers**. These biomarkers help your doctor understand how likely you are to respond or not respond to a particular therapy²¹



Guidelines recommend that all patients with breast cancer receive biomarker testing^{4-6,18}

- If your test shows that your breast cancer has a predictive biomarker, your doctor may recommend you get a particular therapy, such as hormone therapy, targeted therapy, immunotherapy, or chemotherapy^{2-4,10,13,22,23}



- Biomarker testing is key to understanding your personal risk of recurrence and to help your doctor determine if systemic therapy after surgery may be right for you^{13,24}



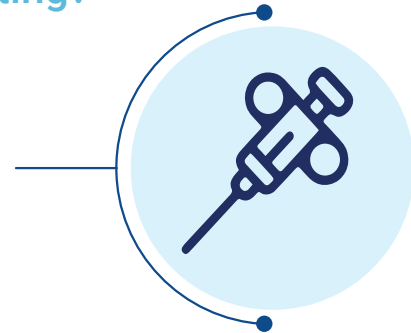
Biomarker testing helps your doctor decide if certain therapies are right for your treatment plan. Additional biomarker testing may unlock more treatment options specifically for you^{2-4,10,13,22,23}



To learn more about different types of therapy, please go to [page 12](#)

What Is the First Step in Biomarker Testing?

- Biomarker testing starts with a biopsy to remove tumor tissue or blood from your body²⁵
- In some situations, a biopsy procedure using the least invasive method possible will be used to remove tissue for biomarker testing²⁵
 - Most biopsy procedures for the initial diagnosis are core needle biopsies²⁵
- If surgery is part of your treatment plan, then biomarker testing may be conducted on the removed tumor tissue²⁵
 - In early breast cancer, surgery is usually a key part of the treatment plan²⁰
- In other situations, a separate biopsy procedure using the least invasive method possible will be used to remove tissue for biomarker testing¹¹
- Even if you received biomarker testing at initial diagnosis, you may receive a **rebiopsy** if your cancer recurs for additional biomarker testing⁶



It is important to remember that some biopsies do not involve surgery. Your care team will perform the recommended procedures and biomarker tests that are important for guiding your treatment plan^{2,4}

- Once your doctors have a sample of your tumor, they may test it to determine if your cancer is likely to come back, and, if so, what therapy may work best for you^{13,26}

Which Biomarkers Can Be Used to Tell If My Cancer Is Likely to Recur?

- Some biomarkers are called prognostic biomarkers. These help your doctors estimate how likely your cancer is to return²¹
 - In breast cancer, many gene expression profiles are prognostic, which can help your care team understand if your cancer is likely to return^{4,13,24}
 - Examples of these tests: **Oncotype Dx[®]**, **MammaPrint[®]**, **Prosigna[®]**, **Breast Cancer Index[®]**, and **EndoPredict^{®4,13}**



To learn more about gene expression to go **page 25**

Oncotype Dx is a registered trademark of Exact Sciences Corporation. *MammaPrint* is a registered trademark of Agendia. *Prosigna* is a registered trademark of Veracyte, Inc. *Breast Cancer Index* is a registered trademark of Hologic, Inc.

Biomarker Testing

- Your care team may also use a recurrence risk calculator to estimate your risk of recurrence^{28,29}
- Some gene expression profiling tests are also predictive biomarkers, which means that these tests can also help your care team understand which specific systemic treatment may be right for you^{13,23}



Gene expression profiling tests and recurrence risk calculators may be used to determine if you may benefit from systemic therapy after surgical removal of the tumor, or if less aggressive treatments can be used^{4,10,13,26,30}



Depending on your breast cancer subtype, additional biomarker testing for biomarkers may unlock more treatment options specifically for you^{13,30}

Questions for Your Care Team

How will I know what my risk of recurrence is?

What Gene Expression Profile will you use? When will I learn my results?

Are there any limitations of the testing I'm receiving? Are there other tools to further assess my risk of recurrence?

What can I do to reduce my risk of breast cancer coming back?

What Happens After Biomarker Testing?

Your care team will be there to support you



Your **oncologist** will discuss test results with you and use biomarker test results to help make treatment decisions¹⁶



Your **breast cancer surgeon** may meet with you for a postoperative checkup and may discuss the results from your surgery and the next steps of your treatment plan³¹



A **radiation oncologist** will administer radiation therapy if it is part of your treatment plan^{1,32}



Your **oncologist**, **advanced practice provider**, and **nurse** will oversee your overall treatment progress, help monitor symptoms and side effects, and adjust your treatment plan as needed¹⁶



A **pharmacist** will assist with providing prescription medications ordered by your oncologist³³

What Treatment Options Will Be Available to Me?

Your doctor will use your test results to determine if you are a good candidate for a particular therapy, such as hormone therapy, targeted therapy, immunotherapy, or conventional chemotherapy^{2-4,10,13,14}

How Do These Therapies Work?

Hormone Therapy

Hormone therapy, also known as endocrine therapy (ET), is used for the subtypes of breast cancers that are sensitive to hormones because they have high levels of the biomarkers:^{1,10}

Estrogen receptor (ER)

Progesterone receptor (PR)

There are several different types of hormone therapy. The most common types of hormone therapy work by blocking hormones from attaching to receptors on cancer cells or by decreasing your body's production of hormones^{1,34}



As mentioned on page 2, biomarkers for specific receptors determine your breast cancer subtype. This information helps your doctors pick the best treatment option for you.^{22,23} Additional biomarkers can also help guide your treatment^{22,23}

Targeted Therapy

- **Targeted therapy** is a type of treatment that is designed to “target” and attack cancer cells only and have less impact on normal cells¹

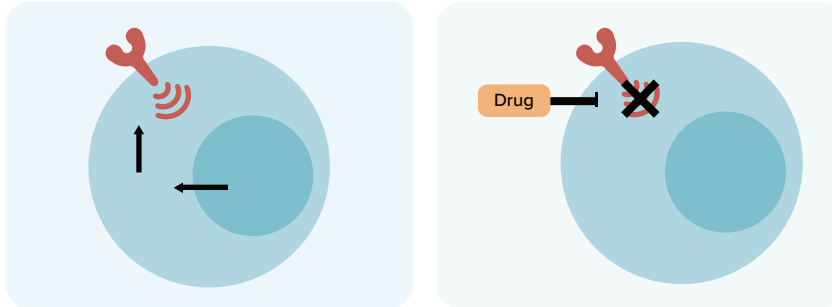


Image adapted with permission from Camidge DR et al. *Nat Rev Clin Oncol*. 2019;16(6):341-355.³⁵

- These drugs can either stop cancer cells from growing or carry chemicals to the cancer cells to kill them¹

- A biomarker that shows if you may be a good candidate for a targeted therapy is **HER2 expression**^{2,34}
- Other predictive biomarkers for targeted therapies, like Ki-67, show how quickly the cancer cells are dividing. This can help determine if you are eligible for a specific class of targeted therapy that stops cell division¹³
 - These biomarkers can be highly variable¹³



Targeted therapies are designed with a better understanding of how cancer works and behaves³⁵

Immunotherapy

- **Immunotherapy** is a treatment that uses your own immune system to recognize and destroy cancer cells^{1,34}
- Predictive biomarkers used to identify patients who may benefit from an immunotherapy are less consistent. These biomarkers include:¹⁴

PD-L1 expression

Microsatellite instability (MSI)

Tumor mutation burden (TMB)

- Depending on your subtype, additional biomarker testing may not be needed before starting an immunotherapy²⁷

Conventional Chemotherapy

- **Conventional chemotherapy** is a type of anticancer drug that kills all cells that divide quickly
 - This means that it kills cancer cells but can also kill normal cells, like hair cells or cells in your stomach¹
- Chemotherapy may be recommended to shrink a tumor prior to surgery to minimize the invasiveness of a surgery. It may also be used to kill any remaining cancer cells after surgical removal of a tumor to prevent new tumors from growing^{7,36}
- The need for chemotherapy in early breast cancer may be determined by gene expression profiling tests¹³

PD-L1, programmed death-ligand 1.



Based on your breast cancer subtype or other predictive biomarkers, you may be eligible for specific treatment options^{3,4,13,14}



It is important that you are tested for all predictive biomarkers for your breast cancer stage because knowing your biomarker status can help your health care team choose the best treatment option for you^{3,4,13,14}



Any decision to test for biomarkers, which tests to use, and choice of treatment should be made together by you and your care team⁸

Are There Any Additional Resources I Should Know About?

If you need help navigating patient resources, information, and programs, Susan G. Komen offers a free helpline you can find at: <https://www.komen.org/support-resources/breast-cancer-helpline/>

If you'd like to connect to other cancer patients who may have the same biomarker status as you, join a biomarker group at: <https://biomarkercollaborative.org/>

This list of resources is not exhaustive. The above websites are independently operated and not managed by Novartis Pharmaceuticals Corporation. Novartis assumes no responsibility for the content on the sites.

Questions for Your Care Team

What are my test results? What do these results mean?

	Biomarkers with an FDA-approved therapy for breast cancer or solid tumors	My Result
Biomarkers that determine breast cancer subtype ^{2,10-12}	ER	
	PR	
	HER2	
Current subtype ^{11,12}		
Gene expression profiling test ⁴	Test name:	
Additional biomarkers (testing based on subtype) ^{4,14}	Ki-67	
	gBRCA1	
	gBRCA2	
Immunotherapy biomarkers ¹⁴	PD-L1	
	TMB	
	MSI	

Using Test Results

How can I get a copy of my biomarker test results?

How will the biomarker test results affect my treatment plan? Are there any specific therapies that can be used to treat my breast cancer?

Will I need additional biomarker testing in the future? If so, when?

What next steps should I take?



NOTES

What Is an Inherited Mutation?

Some – but not all – breast cancers are more likely to occur in the same family. In this section, you will learn about breast cancers that run in some families and how doctors determine if your family members may be at greater risk for breast cancer. To understand if your family is at greater risk for developing breast cancer, we first need to understand how breast cancer occurs.

What Causes Cancer?

- Cancer is a genetic disease, which means it occurs because of a mutation, or change, in your DNA³⁷
- Mutations are normal and responsible for all of the diversity we see in the world. However, in cancer, some of these mutations cause the cell to grow and duplicate uncontrollably³⁷
- Some mutations that cause cancer are inherited while others are not^{37,38}
 - Inherited mutations are sometimes called germline mutations

Inherited Mutations^{37,38}

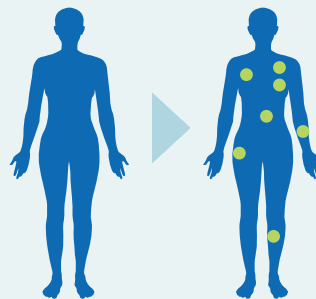
- Less common
- Exist in every cell in your body



Example of an inherited mutation:
BRCA1 mutations³⁷

Noninherited Mutations^{37,38}

- More common
- Only in some cells in your body



Example of a noninherited mutation:
PIK3CA mutations¹⁴



In **breast cancer**, 1 in 10 women are positive for an inherited mutation³⁹

If you have an inherited mutation, your family may be at a greater risk for developing breast cancer in their lifetime³⁹



Most people with breast cancer do not have an inherited mutation.³⁰ If your doctor identifies a mutation in your cancer that can be treated with a targeted therapy, it does not necessarily mean that your family is at greater risk for developing cancer^{14,39,40}

How Will I Know if I Have an Inherited Mutation That Causes Cancer?

You may be more likely to have an inherited mutation that causes cancer if⁴¹:

- You are under 50 years old when you are first diagnosed with breast cancer
- You have at least one close blood relative who:
 - Was first diagnosed with breast cancer before they turned 50
 - Had ovarian, pancreatic, or high-risk prostate cancer
 - Had male breast cancer
- You have at least 3 diagnoses of breast and/or prostate cancer on the same side of the family
- You have Ashkenazi Jewish ancestry

If you are more likely to have an inherited mutation that causes cancer, your doctor may recommend **genetic testing for an inherited mutation**⁴¹

- A genetic counselor will help you understand the results from this test. The genetic counselor will also work with you and your family to determine if your family wants to be tested⁴²

Questions for Your Care Team

Am I more likely to have an inherited mutation? Should I have genetic testing for an inherited mutation?

If I have genetic testing for an inherited mutation, when will I learn my results? How will they be communicated to me?

How much will these tests cost? Will insurance pay for these tests?

Biomarkers in Depth

Biomarkers and biomarker testing is complex. This section will help you understand some of the science behind the importance of identifying biomarkers and how your care team might conduct biomarker testing.

Biomarkers and Precision Medicine

- Major scientific breakthroughs over the last 2 decades led to the explosion of new biomarkers and biomarker testing. These new biomarkers are fundamental to precision or personalized medicine^{43,44}
 - Before precision medicine, cancer was treated with a “one-size-fits-all” approach. All patients with breast cancer received similar treatment plans⁴³
 - With precision medicine, treatment can be tailored for each individual patient with breast cancer⁴⁴
- There are different types of biomarkers that doctors use to understand your cancer, including your **diagnosis** (type of cancer), **prognosis** (how your cancer may behave over time), **predicting** how you may respond to specific therapies, and **monitoring** your response⁴⁴



Precision medicine uses biomarkers to aid in the diagnosis, prognosis, or treatment of breast cancer⁴⁴

Types of Biomarkers

Before diagnosis	Risk biomarkers	→	Identify patients at greater risk for certain diseases ²¹
	Diagnostic biomarkers	→	Help identify your disease and subtypes ²¹
Before treatment	Prognostic biomarkers	→	Provide information on expected clinical outcomes ²¹
	Predictive biomarkers	→	Provide information on expected treatment response ²¹
	Actionable predictive biomarkers	→	Have an associated FDA-approved therapy ⁴⁵
On therapy	Monitoring biomarkers	→	Are used to monitor disease recurrence, progression, and whether the treatment is working ²¹

Biomarkers Used in Breast Cancer

The biomarkers most commonly used to help guide treatment decisions and optimize your care are **prognostic biomarkers**, **predictive biomarkers**, and **risk or susceptibility biomarkers**^{21,45}



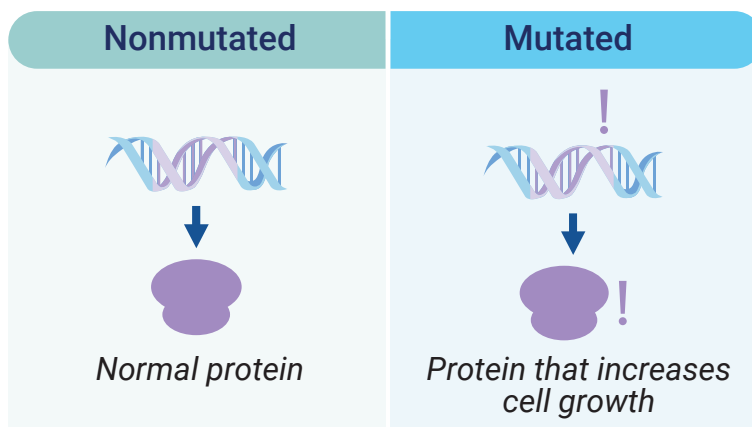
Importantly, some biomarkers can have multiple uses at once. A biomarker can be a risk, prognostic, and predictive biomarker at the same time⁴⁴

Key Scientific Discoveries That Led to the Explosion of New Biomarkers, New Therapies, and Precision Medicine

Scientists and doctors have spent decades trying to understand cancer. While there is still a lot to learn, our improved understanding of how cancers occur has impacted treatment for patients like you⁴³

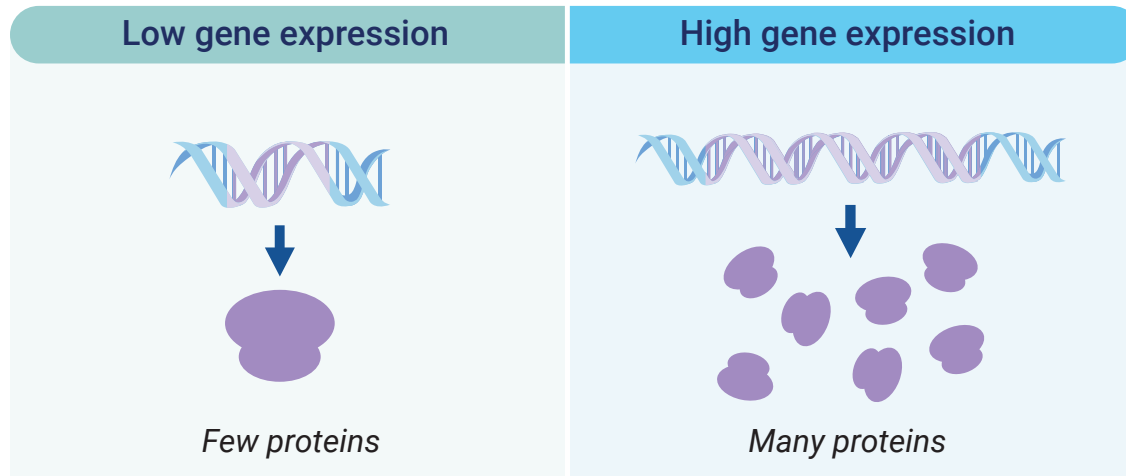
How Cancer Occurs

- Cancer is a genetic disease, which means it occurs because of a **mutation**, or change, in your DNA³⁷
- Most mutations do not result in disease. However, some mutations can cause cells to grow and divide uncontrollably, which can lead to cancer³⁷
- Some cancer-causing mutations are called **driver alterations**³⁵
 - Driver alterations are changes to your genes that may increase the growth or survival of cancer cells in your body³⁵



Some targeted therapies are specifically designed to stop the growth of cancer cells with a specific driver alteration³⁵

In addition to mutations, cancer is also impacted by changes in gene expression, or how much protein is made from 1 gene⁴⁶



Scientists and doctors have identified specific genes involved in the development of cancer and can measure the expression of these genes to understand how the cancer may behave⁴⁶



Gene expression profiling tests look at changes in the gene expression of specific genes to determine how likely your cancer is to come back²⁴

- If a tumor has high expression of genes involved in cancer, it is more likely to come back than a tumor with low expression of these genes²⁴

Summary

Understanding how cancer works and how it changes has created new and better treatment options for patients like you. As scientists and doctors continue to learn more about cancer, the number of biomarkers and treatment options may continue to grow^{10,13,14,43}

Ask your doctor about biomarker testing to see if the newest therapies may be appropriate for you.

Glossary

Biomarker: A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker can be a change in DNA (mutations), RNA, or protein. Biomarkers may be helpful for understanding the nature of a disease, predicting health outcomes, and planning treatments¹

Biomarker testing: One or more tests using various techniques to identify the presence or absence of biomarkers¹

Biopsy: A procedure to remove a piece of tissue or a sample of cells from your body so that it can be tested in a laboratory¹

Breast cancer stage: Refers to how advanced your breast cancer is based on the size of your tumor and whether it has spread to other locations (metastasized)^{1,13,14}

Chemotherapy: A type of treatment using drugs that kills cancer cells¹

Driver alterations: Changes to your genes that may promote the growth or survival of cancer cells in your body⁴⁷

Hormone therapy: A treatment for breast cancer that is sensitive to hormones¹

Genetic testing for an inherited mutation: A genetic test used to understand if your cancer is caused by an inherited mutation. Results from this test can be used to determine if members of your family should also be tested^{39,41}

Interventional radiologist: A medical doctor who is specially trained to use minimally invasive image-guided procedures to diagnose and treat diseases⁴⁸

Oncologist: A medical practitioner qualified to diagnose and treat cancer¹

Pathologist: A doctor who identifies diseases, and/or the presence of biomarkers, by studying cells and tissues under a microscope or with other equipment¹

Predictive biomarker: A biomarker that may provide information on expected treatment response²¹

Primary tumor: The original or first group of cancer cells in the body¹

Prognosis: The likely outcome or course of a disease; the chance of recovery or recurrence¹

Prognostic biomarker: A biomarker that may provide information on expected health outcomes²¹

Recurrence: The return of cancer after a period of it not being detectable¹

Risk biomarker: A biomarker used to identify patients at greater risk for developing cancer²¹

Targeted therapy: A type of treatment that uses drugs to attack specific types of cancer cells with less harm to normal cells. Some targeted therapies block the action of certain enzymes, proteins, or other molecules involved in the growth of cancer cells¹

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Summary



Comprehensive biomarker testing should be an ongoing part of your breast cancer journey and the treatment discussions with your health care team⁸



Knowing your breast cancer subtype and other additional biomarkers can help determine your eligibility for certain treatment options^{2-4,10,13,14}



Understanding the purpose of biomarker testing and knowing the right questions to ask may help you and your care team achieve the best possible health outcomes^{2-4,8}