



PRECISELY
YOU



Not an actual patient.



BIOMARKER TESTING

in Non-Small Cell Lung Cancer (NSCLC)

[Overview](#)

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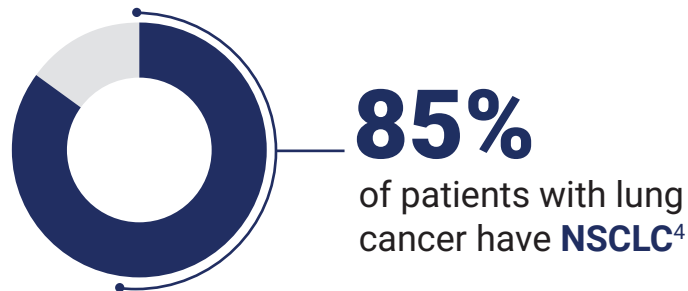
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Introduction

If you have recently been diagnosed with lung cancer and 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.

Lung Cancer Basics

- Lung cancer is the third most common cancer in the United States^{1,2}
- The two main types of lung cancer are non–small cell lung cancer (NSCLC) and small cell lung cancer (SCLC)^{3,4}



- While lung cancer causes the most cancer-related deaths, there is hope.¹ Recent scientific breakthroughs and new therapies have improved survival rates for patients with metastatic NSCLC⁵
 - Some of these new therapies require **biomarker testing** before they can be used^{5,6}

This booklet will focus on metastatic NSCLC.

What Are Biomarkers? Why Are They Important?



- **Biomarkers** are substances found in tissue or blood that signal a normal or abnormal process, a condition or disease^{7,8}
- A biomarker can be a change in DNA (mutations), RNA, or protein⁸
- In summary, biomarkers provide clues about how your cancer works, including its strengths and weaknesses. Testing for biomarkers helps your care team predict how your cancer may behave and understand how likely (or unlikely) it is that a specific treatment might work for you^{6,7,9}
- Recent scientific advances have led to the increased number of biomarkers. This means that doctors can now personalize your long-term treatment plan in a new way^{6,10}



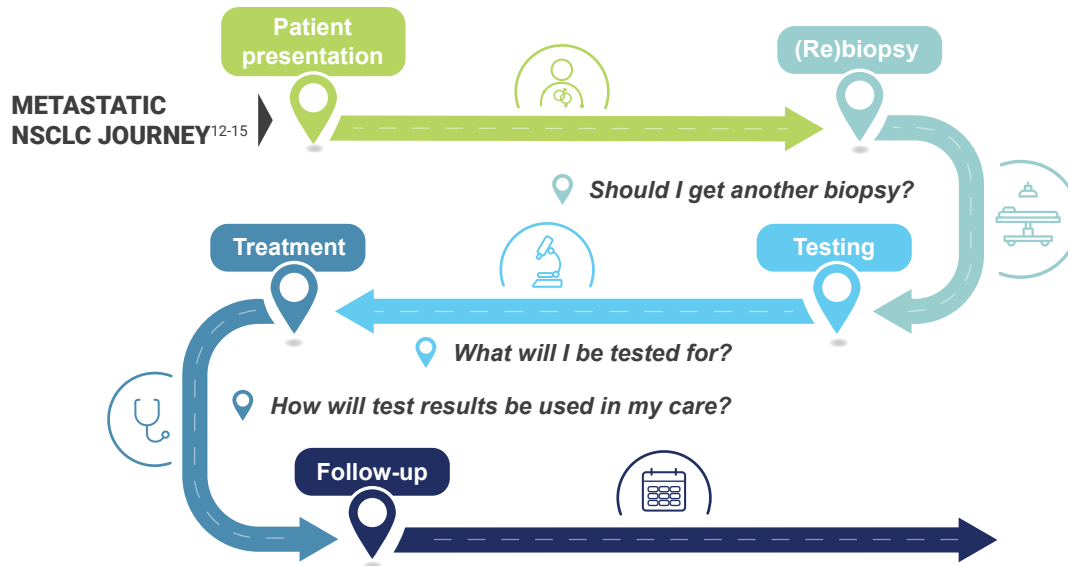
To learn more about biomarkers, please go to **page 25**



Each lung cancer is unique. Biomarker testing helps your care team get key information to make treatment decisions *precisely for you*¹¹

When Will I Be Tested for Biomarkers?

All metastatic NSCLC journeys are unique, but most have similar steps. Biomarker testing typically occurs before treatment initiation.¹¹

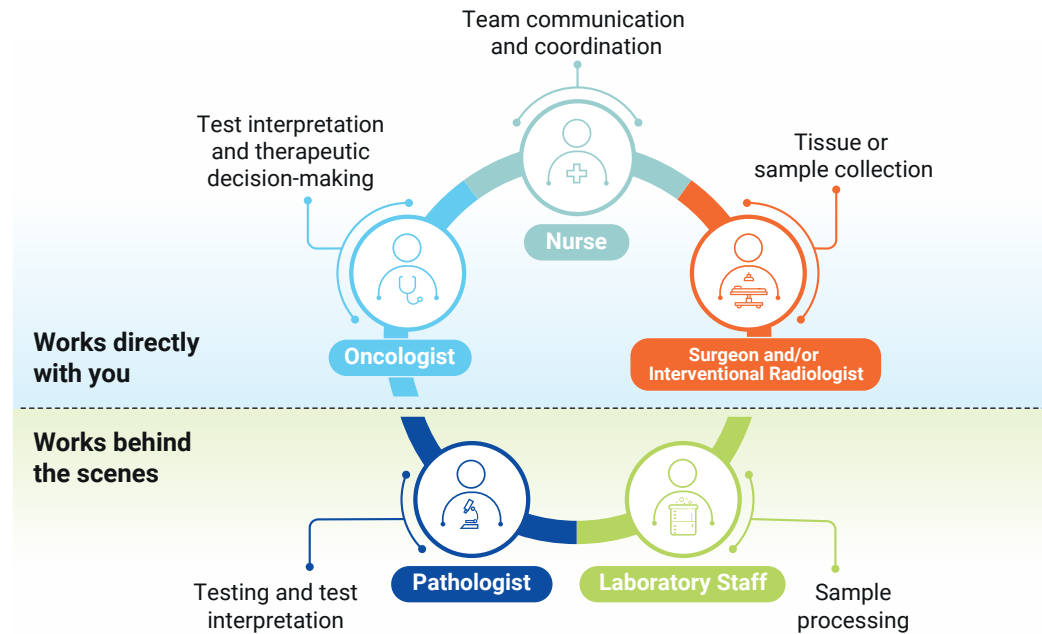


Who Is Involved in Biomarker Testing?

Biomarker testing requires input from different specialties, so your care team includes a multidisciplinary team made up of health care professionals who specialize in different areas. These specialists work together to get you the best care, even if you never meet them all.^{12,13,16}

- During your treatment journey, you will likely interact most closely with your **oncologist, nurse, or advanced practice provider** (eg, **nurse practitioner, physician assistant/physician associate**)^{12,13}
- You may also be assigned a **patient navigator** or **case manager** for additional support¹⁷

Some Members of Your Care Team That Help You Get Biomarker Testing^{12,13,16}



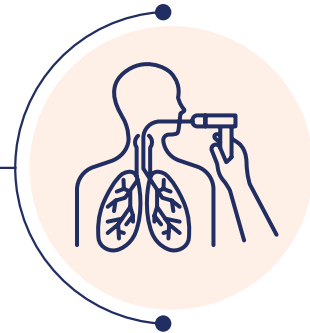
Questions for Your Care Team

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?

What Is the First Step in Biomarker Testing?

- Biomarker testing starts with a biopsy to remove tumor tissue or blood from your body¹¹
- In lung cancer, 2 common procedures used to get a tissue biopsy are **bronchoscopy** and **endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA)**¹¹
 - During a **bronchoscopy**, a thin, flexible tube called a bronchoscope is inserted into the nose or mouth and travels down the trachea to the lungs. Tiny tools are passed down through the bronchoscope to take tumor tissue samples¹¹
 - **EBUS-TBNA** is similar to a bronchoscopy. It uses a special bronchoscope that has an ultrasound device to take a sample of the lymph node with a needle, which will help your care team determine the stage of your cancer¹¹
- There are several other tissue biopsy procedures or techniques, including **transthoracic needle biopsy**, **fine-needle aspiration**, **thoracoscopy**, and **thoracentesis**¹¹
- Your **surgeon**, **interventional radiologist**, or **pulmonologist** who performs your tissue biopsy will consider the location of your cancer, your overall health, and other factors when deciding which procedure is best for you¹¹



What If I Can't Get a Tissue Biopsy?

- While a tissue biopsy is often preferred for biomarker testing, a **liquid biopsy** may be a better choice in some situations^{18,19}
 - A liquid biopsy involves taking a blood sample that is used to measure tumor cells and tumor DNA in the blood^{18,19}
 - Your doctor may recommend a liquid biopsy if:

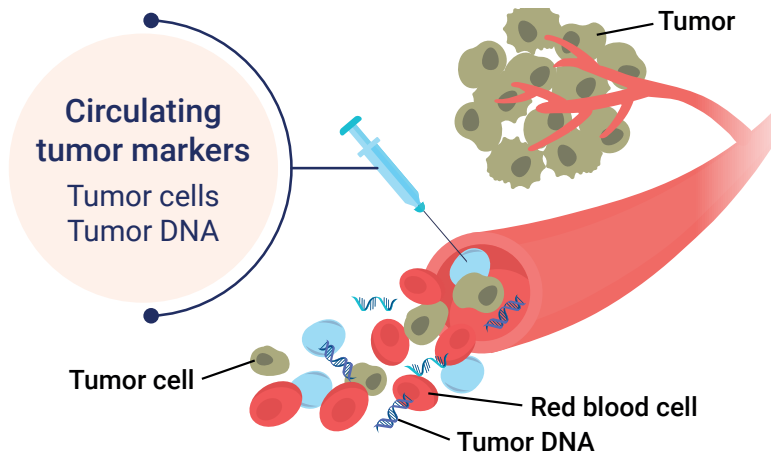


Image adapted with permission from Qi Z et al.
J Cancer. 2018;9(18):3417-3426.²⁰



To learn more about biopsies and biomarker testing, please go to [page 14](#)

- ▶ You are not a good candidate for a tissue biopsy^{18,19}
- ▶ You have progression or recurrence and to find out if your cancer changed^{18,19}
- ▶ Your doctor wants to test both liquid and tissue biopsies at the same time¹⁸

- Importantly, liquid biopsies can have a high false negative rate, which means they may not identify biomarkers in your cancer^{18,19}



If you get a negative result from a liquid biopsy, ask your doctor if tissue testing is right for you

What if I Already Had a Biopsy? Do I Need to Have Another One?

- Even if you previously had a biopsy and biomarker testing, it is important to have a second biopsy (or rebiopsy) if you have progressed on therapy at metastatic diagnosis, because¹¹
 - There are more biomarkers that are **actionable** or have an associated FDA-approved therapy for metastatic NSCLC compared with early-stage NSCLC¹¹
 - Cancers get new mutations over time, and some of these mutations may cause resistance to a particular therapy. There are new therapies that are designed specifically to target some of these mutations^{18,21}



To learn more about how cancer changes over time, please go to **page 30**



Rebiopsy and additional biomarker testing can help your care team know if your cancer has changed and may provide new information for treatment planning¹⁸



Any decision to get a biopsy should be made together by you and your care team. Don't be afraid to speak up and ask questions!⁷

Questions for Your Care Team

What type of biopsy will I get? Why?

How much will biomarker testing cost? Is there financial assistance if needed?



Notes

How Will Biomarker Tests Be Used in My Care?

- Some biomarkers are called **predictive biomarkers**. These biomarkers help your doctor understand how likely you are to respond or not respond to a particular therapy²²
- In metastatic NSCLC, predictive biomarkers can identify patients who may benefit from a **targeted therapy** or an **immunotherapy**⁹



To learn more about how these therapies work, please go to **page 19**

What Should I Know About Predictive Biomarkers for Targeted Therapies?

- Most predictive biomarkers for **targeted therapies** are **driver alterations**⁹
 - Driver alterations are changes to your genes that may increase growth or survival of cancer cells in your body⁹
- As of October 2023, there are at least **10 driver alterations that have an associated FDA-approved therapy** for metastatic NSCLC^{4,6,23}
 - More driver alterations have been identified but do not have an FDA-approved therapy yet²⁴⁻²⁶
 - Driver alterations are usually mutually exclusive, so it is unlikely you will test positive for more than one²⁴⁻²⁶

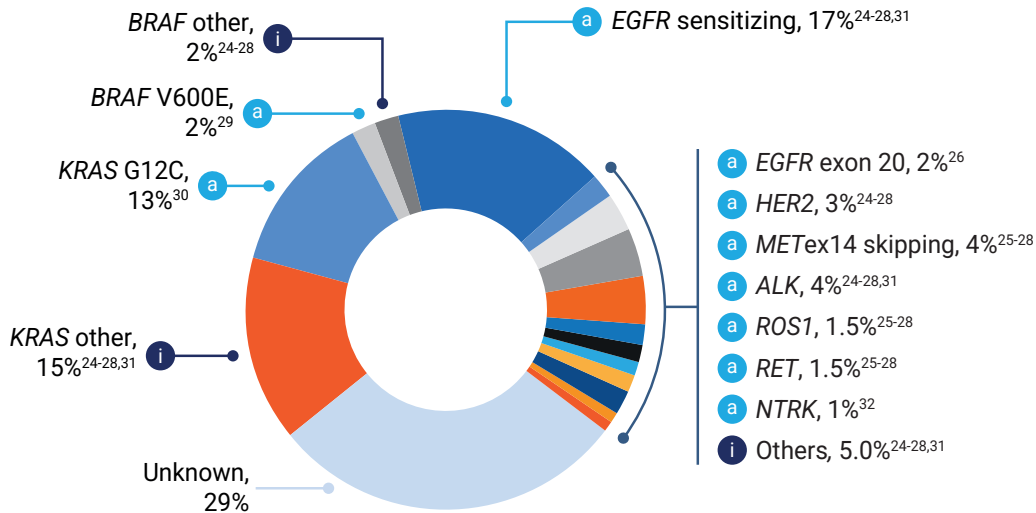


To learn more about driver alterations, please go to **page 26**

The Percentage of Patients With Metastatic NSCLC Who Have a Specific Driver Alteration

a Actionable
FDA-approved therapy

i Identified
No FDA-approved therapy



In Total...

 **≈50%** of patients with metastatic NSCLC have an actionable driver^{4,6,23-27,31}

 **≈20%** of patients with metastatic NSCLC harbor 1 of the 8 less common actionable alterations^{4,6,23-27,31}



Knowing if you have a driver alteration can help your doctors choose the best treatment for you^{6,7}

What Should I Know About Predictive Biomarkers for Immunotherapies?

- Most predictive biomarkers for immunotherapies are used for a specific type of immunotherapy, sometimes called immune checkpoint inhibitors, PD-1 inhibitors, or PD-L1 inhibitors³³
- Your care team may recommend testing for **PD-L1 expression** or **tumor mutational burden (TMB)**
 - If your tumor is positive for PD-L1 (PD-L1+), you may be a good candidate for this type of therapy^{6,34,35}



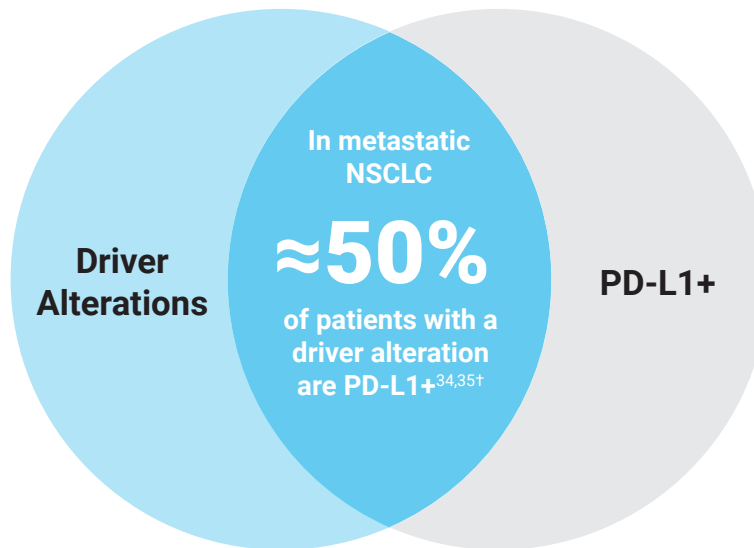
≈ **52%**

of all patients with metastatic **NSCLC**⁴ are PD-L1+³⁶

- TMB is the total number of mutations in your tumor, and high TMB is linked with a better response to this type of immunotherapy³⁷

It's possible that you could test positive for a driver alteration and an immunotherapy biomarker^{34,35}

- The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) recommend prioritizing driver alterations when choosing a treatment in patients who test positive for a driver alteration and PD-L1³⁸
- In these situations, the pros and cons of various treatments for which you are eligible should be carefully considered with your doctor



You may test positive for both a driver alteration and an immunotherapy biomarker. It is critical that you are tested for *all biomarkers with an FDA-approved therapy* before starting treatment^{34,35,38}

NCCN, National Comprehensive Cancer Network.

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

How Does Testing for Lung Cancer Biomarkers Work?

- The 2 main types of biomarker tests are **single-gene tests** and **multigene panels**³⁹

Single-gene tests³⁹

- Only test 1 biomarker at a time
- Can detect driver alterations and PD-L1 depending on the test^{6,40}
- More likely to lead to tissue exhaustion when testing for multiple biomarkers⁶

Multigene panels³⁹

- Test for multiple biomarkers at the same time
- Can detect driver alterations but not PD-L1^{6,40}
- More likely to test for all driver alterations without leading to **tissue exhaustion**⁶

- **Tissue exhaustion** is a situation where there is not enough tumor tissue to test for all biomarkers with an FDA-approved therapy³⁹

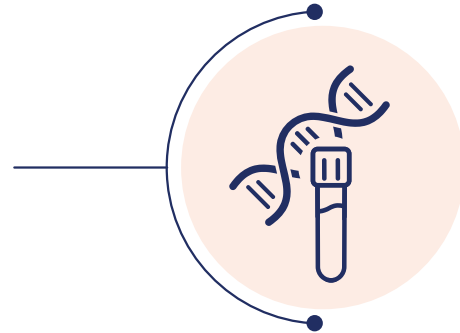


If there is not enough biopsy tissue for testing, you may need to have a second biopsy procedure or may not get tested for all biomarkers with an FDA-approved therapy³⁹



Multigene panel testing with 1 single-gene test for PD-L1 may be the best way to test for all predictive biomarkers in metastatic NSCLC without rebiopsy^{39,41}

- You may hear your doctors use other terms to describe a multigene panel, such as next-generation sequencing (NGS) or comprehensive genomic profiling (CGP)^{39,42}
- NGS and CGP are different types of multigene panels that test for tens or hundreds of genes simultaneously^{39,42}
- Some multigene panels may not be able to detect all driver alterations^{6,43}



Any decision to test for biomarkers and which tests to use should be made together by you and your health care team⁷

Biomarker testing decisions depend on several factors, including the type and stage of your cancer, availability of tissue, your current treatment plan, and your overall health⁷

Questions for Your Care Team

What biomarkers will you test for?

What type of test will you use to test for biomarkers? Single-gene tests? Multigene panels? NGS?

What are the limitations of the biomarker test I'm getting, if any?

How long will it take to get my biomarker test results?

What Happens After Biomarker Testing?

Your Care Team Will Be There to Support You



Your **medical oncologist** will discuss test results with you and use biomarker test results to make treatment decisions¹³



A **radiation oncologist** will administer radiation therapy if it is a part of your treatment plan^{37,44}



Your **oncologist**, your **nurse**, or your **advanced practice provider** will oversee your overall treatment progress, help monitor symptoms and side effects, and adjust the treatment plan as needed¹³



A **pharmacist** will assist with providing prescription medications ordered by your oncologist⁴⁵

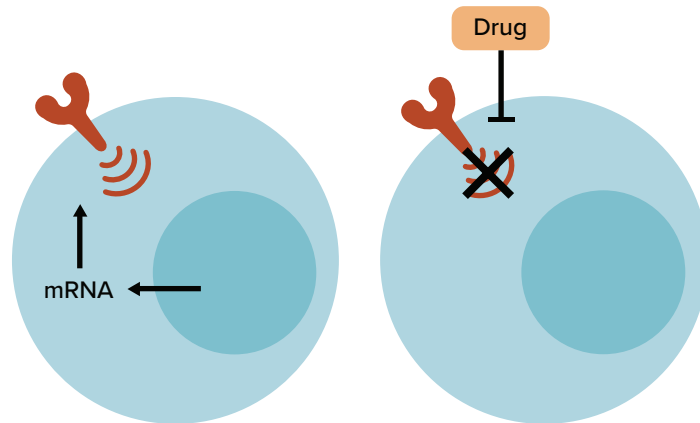
What Treatment Options Will Be Available to Me?

Your doctor will use your test results to determine if you are a good candidate for a particular therapy, like a targeted therapy, immunotherapy, or conventional chemotherapy.^{7,13}

How Do These Therapies Work?

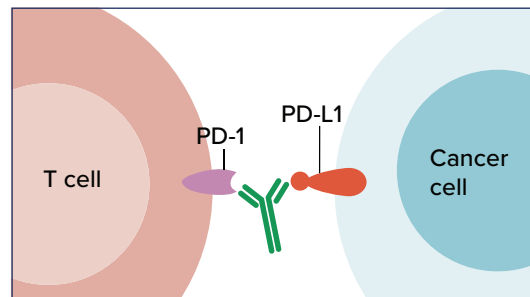
Targeted Therapy

- Many targeted therapies for NSCLC are specifically designed to stop the growth of cancer cells with a specific driver alteration⁹
- There are 10 biomarkers with an FDA-approved targeted therapy^{4,6,23}



Immunotherapy

- **Immunotherapy** is a treatment that uses your own immune system to recognize and destroy cancer cells³⁶
- PD-L1 inhibitors/PD-1 inhibitors are a type of immunotherapy used in NSCLC that helps your immune system find and fight cancer cells by preventing the binding of proteins called PD-1 and PD-L1³³



1 in 2 Patients With a Driver Alteration Are PD-L1+

- It is possible that you could test positive for a biomarker for a targeted therapy and one for an immunotherapy^{34,35}
 - In these situations, the pros and cons of various treatments for which you are eligible should be carefully considered with your doctor
 - NCCN Guidelines® recommend that driver alterations should be prioritized over PD-L1 status when choosing a therapy³⁸

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 stomach³⁷



Treatment decisions should be made together by you and your health care team. Don't be afraid to speak up and ask questions!⁷

Treatment decisions depend on several factors, including the type and stage of your cancer, your biomarker status, your overall health, and your treatment goals⁷

Are There Any Additional Resources I Should Know About?



There are multiple online resources for patients like you. Some resources are listed below.

If you need help managing emotions or navigating financial challenges for lung cancer, LUNGeivity offers a free helpline you can call: <https://www.lungevity.org/for-patients-caregivers/support-services/lung-cancer-helpline>

The American Cancer Society offers additional support, information, and resources for all patients with cancer: <https://www.cancer.org/about-us/what-we-do/providing-support.html>

To learn more about personalized medicine in cancer and other diseases, visit: <https://www.personalizedmedicinecoalition.org/personalized-medicine-101/>

If you'd like to connect with other patients with cancer 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?

Therapy type	Biomarker with an FDA-approved therapy ^{3,5,21}	My test result
Targeted therapy	<i>ALK</i>	
	<i>BRAF V600E</i>	
	<i>EGFR</i> exon 20	
	<i>EGFR</i> sensitizing	
	<i>HER2</i>	
	<i>KRAS G12C</i>	
	<i>MET</i> ex14 skipping	
	<i>NTRK</i>	
	<i>RET</i>	
	<i>ROS1</i>	
Immunotherapy	PD-L1	

Are there any situations where might I need additional biomarker testing?

How can I get a copy of the report with my biomarker testing results?

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

What next steps should I take?

Introduction

Biomarkers and biomarker testing are complex. This section will help you understand some of the science behind biomarkers and 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^{6,45}
 - Before precision medicine, cancer was treated with a “one-size-fits-all” approach. All patients with breast cancer received similar treatment plans⁴⁶
 - With precision medicine, treatment can be tailored to each individual patient with breast cancer⁶
- There are different types of biomarkers that doctors use to understand your cancer, including your diagnosis (type of cancer) and prognosis (how your cancer may behave over time), and to predict how you may respond to specific therapies and to monitor your response



Precision medicine uses biomarkers to aid in the diagnosis, prognosis, or treatment of breast cancer⁶

Types of Biomarkers

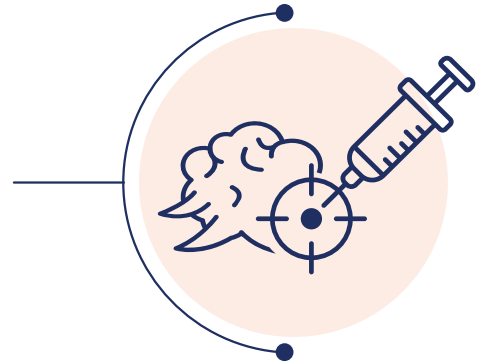
Before diagnosis	Risk biomarkers	→	Identify patients at greater risk for certain diseases ²²
	Diagnostic biomarkers	→	Help identify your disease and subtypes ²²
Before treatment	Prognostic biomarkers	→	Provide information on expected clinical outcomes ²²
	Predictive biomarkers	→	Provide information on expected treatment response ²²
	Actionable predictive biomarkers	→	Have an associated FDA-approved therapy ⁴⁷
On therapy	Monitoring biomarkers	→	Are used to monitor disease recurrence and progression and whether the treatment is working ²²



Importantly, a biomarker can have multiple uses at once. A biomarker can be a risk, prognostic, and predictive biomarker at the same time⁶

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 and how cancers change has impacted treatment for patients like you.⁴⁶

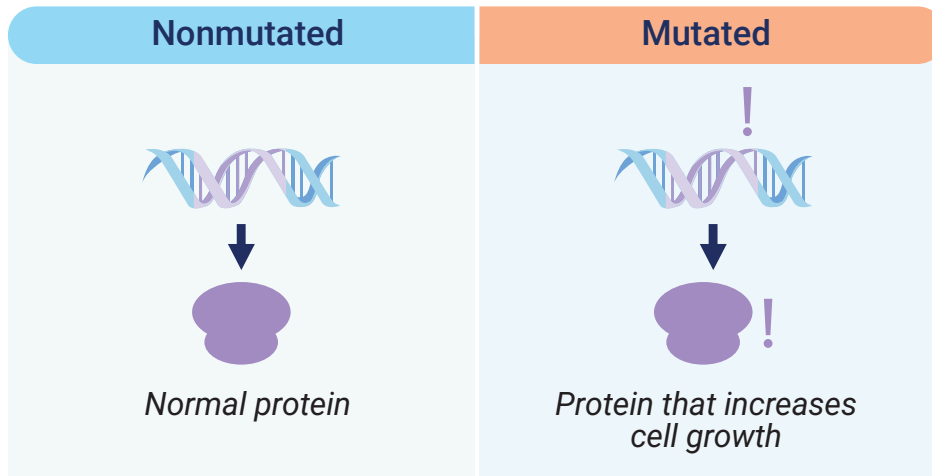


How Cancer Occurs

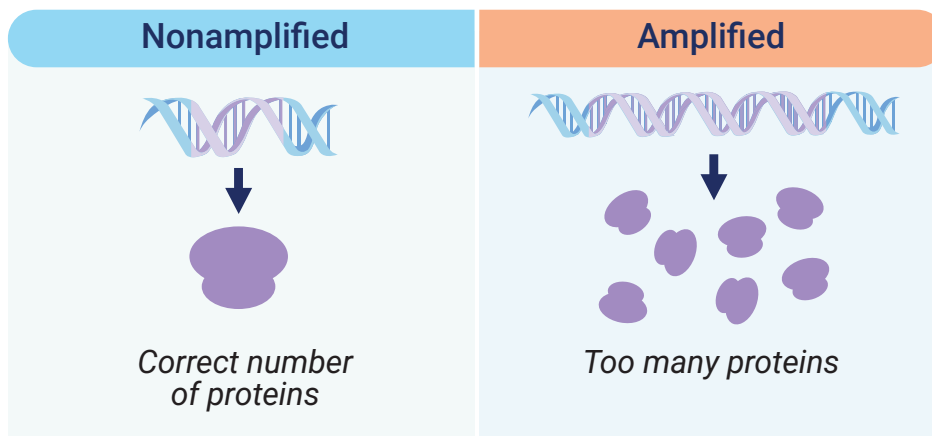
- Cancer is a genetic disease, which means it occurs because of a change in your DNA⁴⁸
- Genetic changes are normal and responsible for all of the diversity we see in the world
- However, in cancer, some of these changes cause the cell to grow, multiply, and survive uncontrollably. These types of changes are called driver alterations^{9,48}

There are many different types of driver alterations, including:

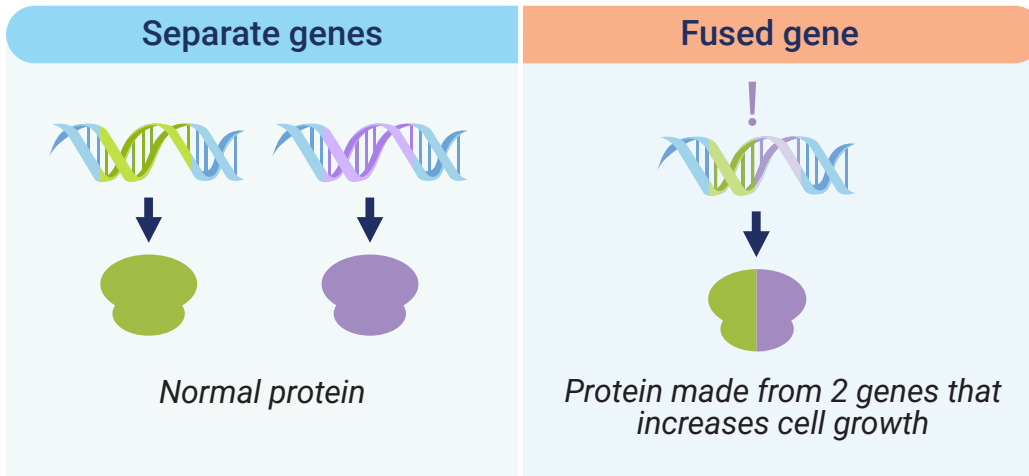
- **Gene mutations** or changes in the DNA sequence that change the way the protein works³



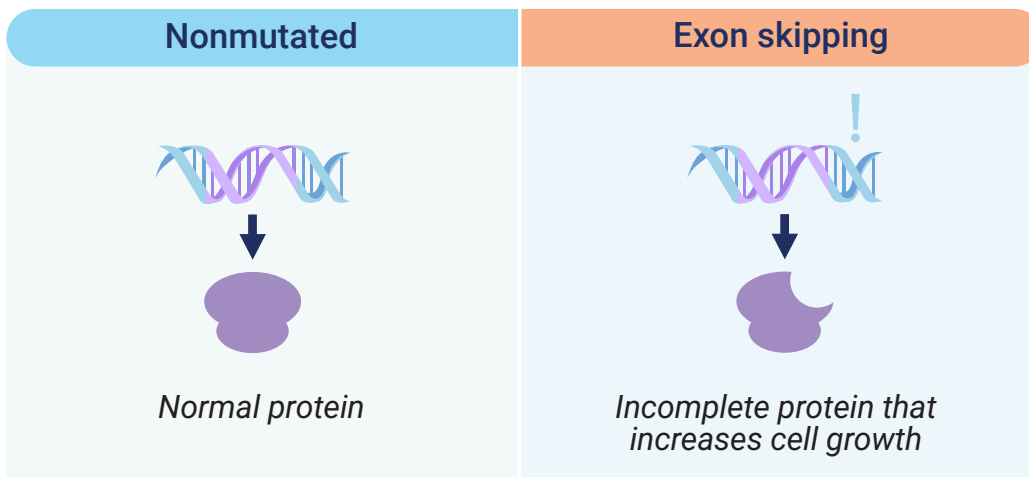
- **Gene amplifications** or increases in the number of copies of a gene, which lead to too many proteins³



- **Gene fusions** or the joining of parts from 2 separate genes³⁷



- **Exon skipping events** or mutations at the edge of a gene that result in incomplete proteins⁴⁹



Testing for Driver Alterations

- When scientists and doctors discovered different types of driver alterations, they realized that some are easier to find than others
 - Some driver alterations, like mutations, are easier to find and can be identified with many different types of biomarker tests^{6,40}
 - Other driver alterations, like fusions, are harder to find and can only be detected with a specific type of biomarker test^{6,40}



Because targeted therapies are designed to stop the growth of cancer cells with a specific driver alteration, it is important that:

- **You are tested for all driver alterations with an FDA-approved therapy⁶**
- **Your care team uses a biomarker test that can find all types of driver alterations^{6,40}**

How Cancer Changes

- Unlike other cells, cancer cells are genetically unstable. This means that they continue to get mutations over time^{18,21,50}

Time

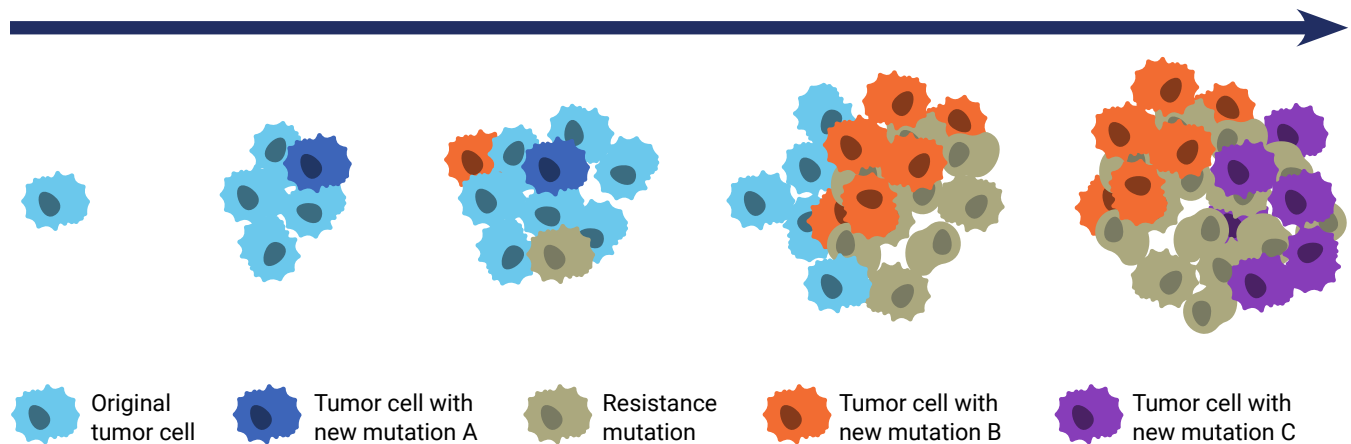


Image adapted with permission from Black JRM and McGranahan N. *Nat Rev Cancer*. 21(6):379-392. doi: 10.1038/s41568-021-00336-2⁵¹

- Some, but not all, of these mutations develop during your cancer treatment and cause your cancer to continue to grow and survive even though you are receiving treatment that kills cancer cells. These mutations are called resistance markers¹⁸



Recently, some targeted therapies have been developed that specifically target resistance markers. Testing for biomarkers after progression is important to determine if you are eligible for one of these new therapies¹⁸

- After your cancer metastasizes, or moves, to different parts of your body, it will continue to change and get more mutations. So, the mutations at one metastatic site may share some of the mutations at a different metastatic site. At the same time, it may have mutations that are unique to that tumor⁵⁰

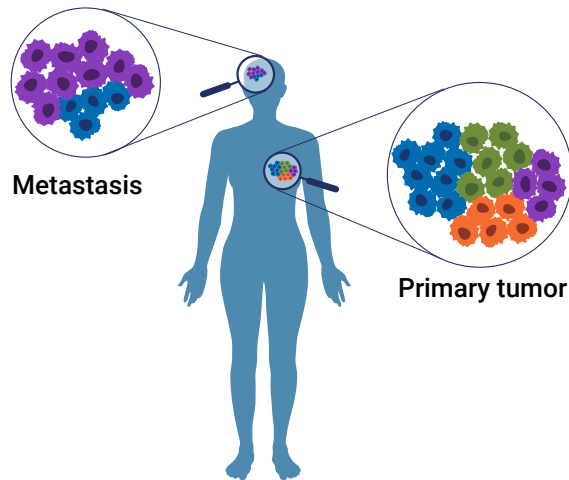


Image adapted with permission from Kashyap A et al. *Trends Biotechnol.* 2022;40(6):647-676. doi: 10.1016/j.tibtech.2021.11.006⁵²



Because tumor cells and tumor DNA from all metastatic sites appear in the blood, liquid biopsies can give your care team a better understanding of all mutations involved in your cancer^{18,19}

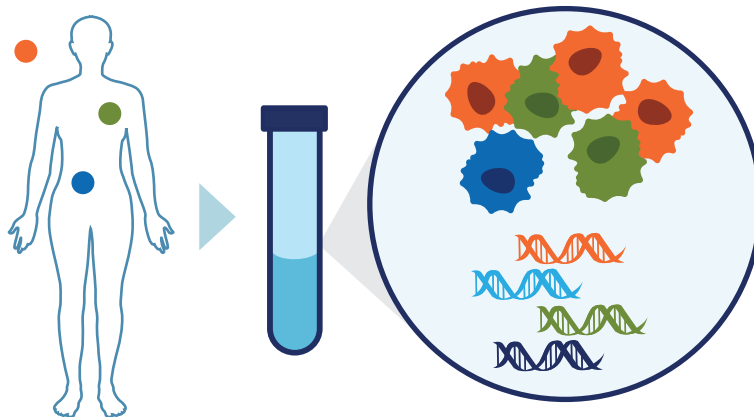


Image adapted with permission from Gilson P et al. *Cancers (Basel)*. 2022;14(6):1384. doi:10.3390.cancers14061384⁵³

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.^{6,46,54}

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

Glossary

Biomarker: A substance or process 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 disease, predicting health outcomes, and planning treatments³⁷

Biomarker testing: One or more tests using various techniques to identify the presence or absence of biomarkers³⁷

Chemotherapy: A type of treatment using drugs that kill cancer cells³⁷

Driver alteration: A change to your genes that may promote growth or survival of cancer cells in your body⁵⁴

Exon skipping: Refers to missing parts of a gene that may be important for tumor growth or treatment response⁴⁹

Gene amplifications: Increases in the number of copies of a gene, which may cause cancer cell growth or resistance to certain drugs³⁷

Gene fusion: The joining of parts of two separate genes that may lead to the development of certain types of cancer³⁷

Gene mutations: Changes in the DNA sequences of a cell, which may be inherited or caused by environmental factors³⁷

Histology: The study of tissues and cells under a microscope³⁷

Immunotherapy: A type of cancer therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases³⁷

Interventional radiologist: A medical doctor who is specially trained to use minimally invasive, image-guided procedures to diagnose and treat diseases⁵⁵

Liquid biopsies: Procedures that use blood, saliva, or urine to investigate the presence of tumor cells or DNA shed from the primary tumor³⁷

Malignancy: Tissue cells obtained from a biopsy sample that grow in an uncontrolled way (indicating cancer)³⁷

Metastatic cancer: Cancer cells that have spread from the original tumor location through the blood or lymph system to other locations in the body³⁷

Multigene panel: A biomarker test that examines multiple genetic biomarkers at the same time (may also be referred to as *comprehensive genomic profiling*, *comprehensive biomarker tests*, or *next-generation sequencing*)³⁷

Oncologist: A medical practitioner qualified to diagnose and treat cancer³⁷

Pathologist: A doctor who identifies diseases and/or the presence of biomarkers by studying cells and tissues under a microscope or with other equipment³⁷

Pathology report: The description of cells and tissues made by a pathologist based on what is seen under a microscope³⁷

Primary tumor: The original or first group of cancer cells in the body³⁷

Prognosis: The likely outcome or course of a disease; the chance of recovery or recurrence³⁷

Radiation therapy: The use of high-energy radiation from X-rays, gamma rays, neutrons, protons, and other sources to kill cancer cells and shrink tumors³⁷

Recurrent cancer: The return of cancer after a period of it not being detectable³⁷

Refractory cancer: Cancer that fails to respond to treatment³⁷

Remission: The signs and symptoms of cancer are partially or completely reduced³⁷

Single-gene test: A biomarker test that examines 1 specific genetic biomarker³⁹

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 cells³⁷

Tissue sufficiency: Having enough tissue from the biopsy to conduct needed tests accurately⁵⁶

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Summary



As we've seen, biomarker testing is a complex process that requires several steps and input from many different medical experts



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

To learn more about biomarkers associated with different cancer types, visit <https://www.mycancergenome.org/>

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

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