

PRECISELY
YOU



Not an actual patient.

BIOMARKER TESTING

and Its Role in Your Metastatic Cancer Journey

Overview

The First Step in Testing

Biomarker Testing

Using Test Results

Learn More

Introduction

If you have been recently diagnosed with metastatic 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.

What Is a Biomarker?

- A biomarker is a substance found in tissue or blood that signals a normal or abnormal process, a condition or disease^{1,2}
 - A biomarker can be a change in DNA (mutations), RNA, or protein²



To learn more about biomarkers, please go to **page 24**

Why Are Biomarkers Important?

- Biomarkers can 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^{2,3}

Recent scientific advances have led to an increased number of biomarkers. This means doctors can now personalize your long-term treatment plan in a new way.^{1,2,4,5}

How Will I Know if I Have a Biomarker?

Your health care team will find out if you have a biomarker with biomarker testing. Biomarker testing, also known as mutation, genomic, or molecular testing, is an essential part of your metastatic cancer journey to gather information about your unique metastatic cancer type.^{2,3}



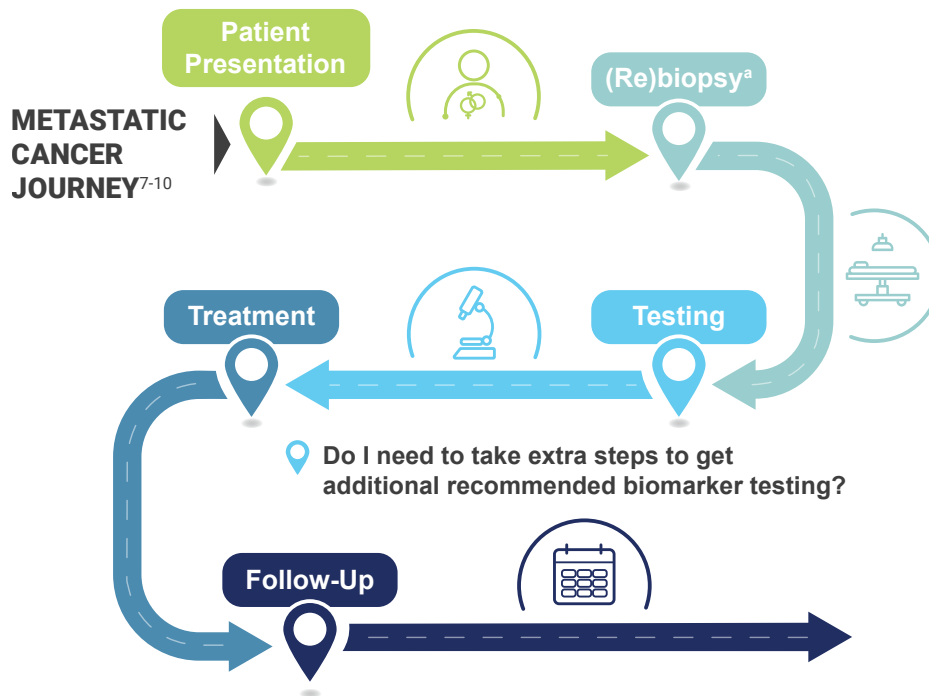
Biomarkers are important for your individual metastatic cancer journey because not all metastatic cancers are the same. Biomarker testing helps your care team get key information to make treatment decisions *precisely for you*^{2,3,6}

When Will I Be Tested for Biomarkers?

- Each metastatic journey is unique, but most have similar steps. Biomarker testing typically occurs before treatment initiation⁶
- Depending on your cancer type, testing for biomarkers at metastatic diagnosis may be important, even if you have had biomarker testing before⁶
 - There are often more biomarkers that are **actionable**, or have an associated US Food and Drug Administration (FDA)–approved therapy, for metastatic cancers⁶



Testing at metastatic diagnosis can provide important information when developing your treatment plan²



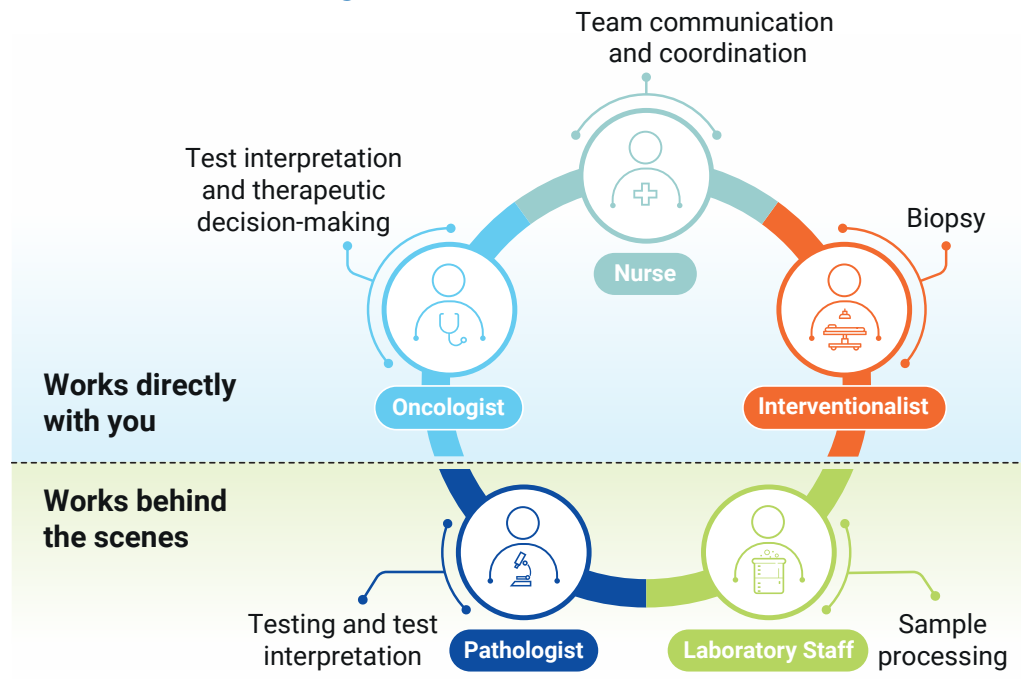
^aBiopsy may be a tissue sample or a liquid sample (eg, blood, saliva, urine).

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^{7,8}
 - 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**)^{7,8}

- You may also be assigned a patient navigator or case manager for additional support¹¹

Some Members of Your Care Team That Help You Get Biomarker Testing^{7,8}

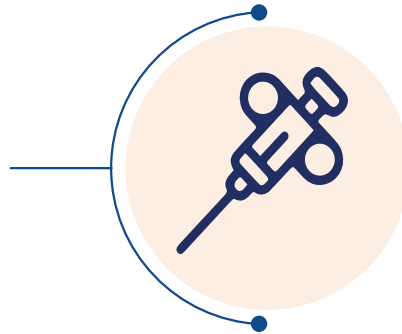


Questions for Your Care Team

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

What Is the First Step in Biomarker Testing?

- Biomarker testing starts with a biopsy to remove tumor tissue or blood from your body⁶
- If a **resection** (a surgical procedure to remove your tumor) is part of your treatment plan, then biomarker testing may be conducted on the removed tumor tissue⁶
- In other situations, a separate biopsy procedure using the least invasive method possible will be used to get tissue or blood for biomarker testing⁶
- Even if you received biomarker testing at initial diagnosis, you may receive a second biopsy (also called a **rebiopsy**) after your cancer has progressed for additional biomarker testing, which may provide new information for treatment planning⁶



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^{12,13}

- A liquid biopsy involves taking a blood sample that is used to measure tumor cells and tumor DNA in the blood^{12,13}

- Your doctor may recommend a liquid biopsy if:

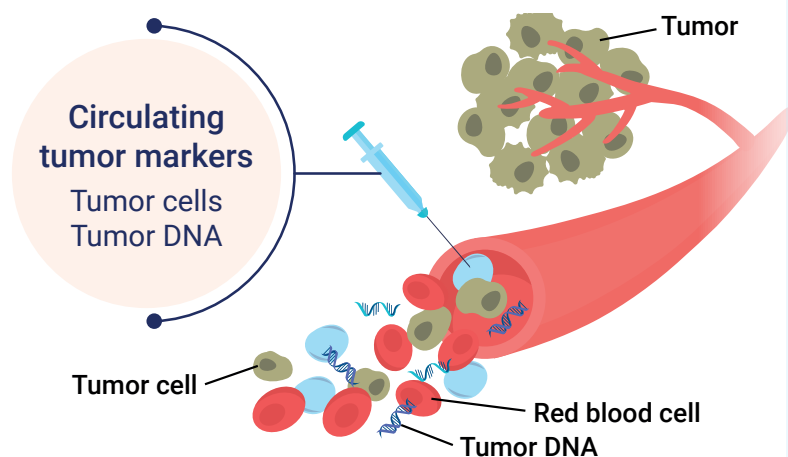


Image adapted with permission from Qi Z et al. *J Cancer*. 2018;9(18):3417-3426. doi:10.7150/jca.24591.¹⁴

- ▶ You are not a good candidate for a tissue biopsy^{12,13}
- ▶ You have progression or recurrence, to find out if your cancer changed^{12,13}
- ▶ Your doctor wants to test both liquid and tissue biopsies at the same time¹²

- Importantly, liquid biopsies can have a high false negative rate, which means they may not identify biomarkers in your cancer^{12,13}



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?

Previous biomarker testing and prior therapies may impact the speed at which you can start a second therapy if needed. You may need additional biopsies or biomarker testing if:

- You haven't received comprehensive biomarker testing before^{6,15}
- There is a chance a mutation occurred in response to your previous treatment^{2,16}
- Your cancer may have accumulated more mutations over the disease course^{6,17}
- The number of actionable biomarkers has increased since you were last tested²

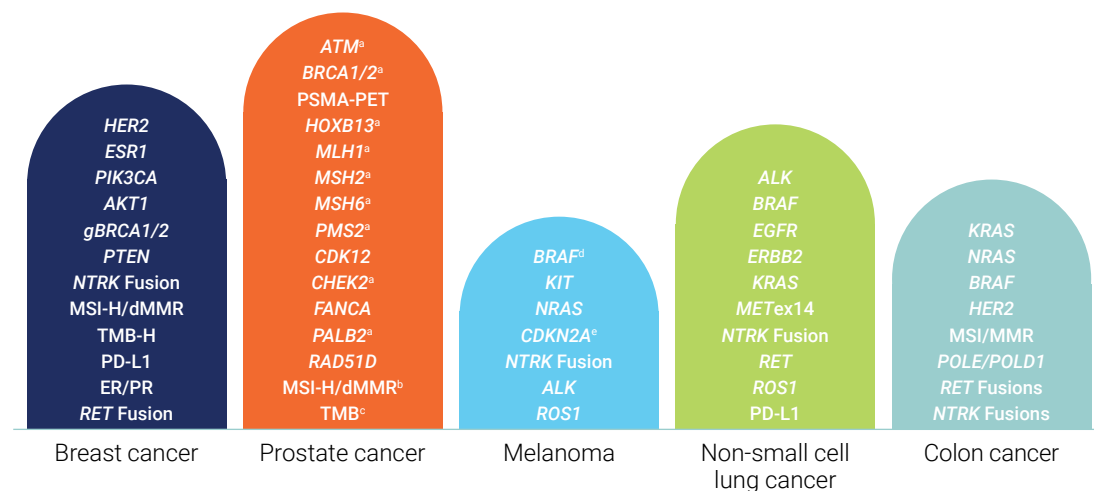


To learn more about how cancer changes over time, please go to **page 30**

- It's possible that you could test positive for multiple driver alterations and/or immunotherapy biomarkers^{18,19}
 - In these situations, the pros and cons of various treatments you are eligible for should be carefully considered with your doctor

What Biomarkers Should I Be Tested for?

In many cases, biomarker testing is specific to the stage and type of cancer. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) recommend testing for a number of different biomarkers for different metastatic cancer types to guide treatment decisions. Certain recommended biomarkers for the **five most common cancers** are below.¹⁸⁻²⁵



Ask your health care team if their biomarker tests cover all predictive biomarkers for your metastatic cancer type

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^aGermline testing should be considered in appropriate individuals where it is likely to impact the prostate cancer treatment and clinical trial options, management of risk of other cancers, and/or potential risk of cancer in family members.

^bTumor testing for MSI-H or dMMR is recommended in patients with mCRPC and may be considered in patients with regional or castration-sensitive metastatic prostate cancer.

^cTMB testing may be considered in patients with mCRPC.

^dBRAF mutation testing is recommended for patients with stage III disease at high risk for recurrence for whom future BRAF-directed therapy may be an option.

^eConsider genetic counseling referral for p16/CDKN2A mutation testing in the presence of 3 or more invasive cutaneous melanomas, or a mix of invasive melanoma, pancreatic cancer, and/or astrocytoma diagnoses in an individual or family. Multigene panel testing that includes CDKN2A is recommended for patients with invasive cutaneous melanoma who have a first-degree relative diagnosed with pancreatic cancer.

What If I Have a Less Common Cancer or My Cancer Type Doesn't Have Any Approved Biomarkers?

- While some biomarkers are relevant to only one cancer type, some biomarkers may be relevant across all cancer types. These biomarkers are called **pan-tumor biomarkers**²⁶
- The American Society of Clinical Oncology recommends testing for **pan-tumor biomarkers in patients who have a cancer without specifically approved biomarkers**²
- Additionally, studies have shown that patients with **less common cancers** may also benefit from pan-tumor biomarker testing^{2,5,27}
- Examples of pan-tumor biomarkers include ***NTRK* fusion**, ***BRAF V600E***, ***RET* fusion**, **TMB-H**, **MSI-H**, and ***HER2* overexpression**^{5,28}



To learn more about how pan-tumor biomarkers can be used in your treatment plan, please go to **page 16**



To learn more about fusions, overexpression, and how cancer occurs, please go to **page 24**



Pan-tumor biomarkers provide important information about your potential response to treatment, regardless of your cancer type²⁶



In some situations, your treatment plan may be better determined by your biomarker status than your cancer type^{2,26}

How Does Testing for Pan-Tumor Biomarkers Work?

There are different types of biomarker tests, including **single-gene tests** and **multigene panels**.

Single-gene tests²⁹:

- Only test 1 biomarker at a time
- Have quicker turnaround times
- Can be less cost-effective and time-efficient in the long run if multiple single-gene tests are required

HER2 overexpression may be tested with a single-gene test known as immunohistochemistry (IHC)^{20,28}

Multigene panels²⁹:

- Test for multiple biomarkers at the same time
- Require less tissue
- Have longer turnaround times compared with 1 single-gene test

Some pan-tumor biomarkers like **TMB** and **MSI** must be tested with multigene panels³⁰

Some pan-tumor biomarkers like **NTRK**, **BRAF**, and **RET** can be tested with single-gene tests or multigene panels.^{2,29}

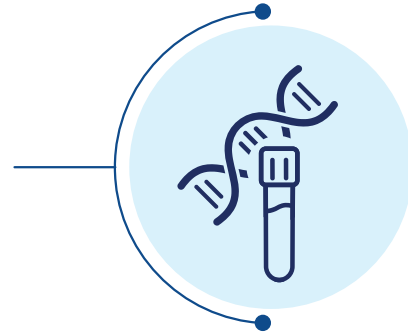


Some multigene panels can test for most pan-tumor biomarkers at once^{31,32}



To get tested for pan-tumor biomarkers, talk to your care team about both single-gene testing and multigene panels^{15,20,31,32}

- You may hear your health care providers use other terms to describe a multigene panel, such as **next-generation sequencing (NGS)** or **comprehensive genomic profiling (CGP)**^{29,33}
- NGS and CGP refer to multigene panels that test for alterations in a panel of tens or hundreds of prespecified genes simultaneously based on your cancer type^{29,33}
- Some cancer types have relatively few predictive biomarkers, so the added cost and time necessary for multigene panel testing may not be necessary²



Any decision to test for biomarkers, and which tests to use, should be made together by you and your health care team¹⁵



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 health¹⁵

Are You Ready for Your Biomarker Testing Appointment?

Things to Bring to Your Appointment

- Previous testing records
- Imaging tests
- Diagnostic referrals/reports
- Your insurance information
- List of questions to ask your doctor (see below)

Call the office ahead of time if you're not sure what to bring

Questions to Ask Your Care Team

Was I tested for any biomarkers when I was initially diagnosed?

Which biomarkers are you testing for? Why?

How will biomarker testing be conducted? Single-gene? NGS?
Other? What will be involved in these tests?

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

Do I need a new biopsy to get the test done? Can this be a blood draw-based test?

When will I learn my biomarker test results, and how will they be communicated to me?

Will my insurance pay for these tests?

Are there any cost assistance programs for these tests?

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 make treatment decisions⁸



A **radiation oncologist** will administer radiation therapy if part of your treatment plan^{3,34}



Your **oncologist**, your **nurse**, or your **advanced practice provider** will oversee your overall treatment progress, help monitor symptoms and side effects, and adjust your treatment plan as needed⁸



A **pharmacist** will assist with providing prescription medications ordered by your oncologist³⁵

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 or immunotherapy.^{15,36}



Treatment decisions should be made together by you and your care team. Don't be afraid to speak up and ask questions!¹⁵

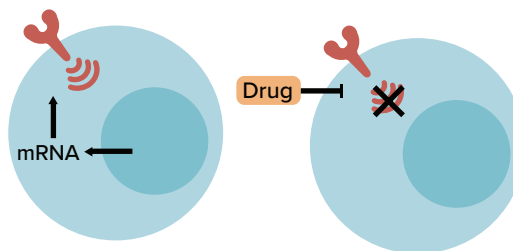


Treatment decisions depend on several factors, including the type and stage of your cancer, your biomarker status, your overall health, and your treatment goals¹⁵

How Do These Therapies Work?

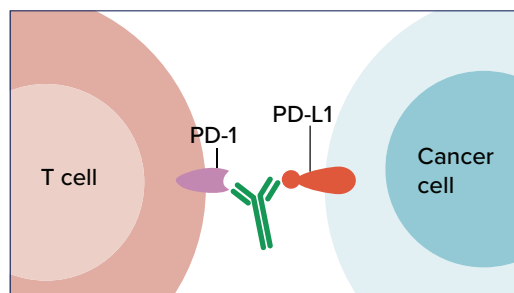
Targeted Therapy

- Many targeted therapies are specifically designed to stop the growth of cancer cells with a specific driver alteration³⁷
 - Some therapies can bring cytotoxic, cancer-killing agents to cancer cells based on specific biomarkers²⁸
- Pan-tumor biomarkers predictive of response to targeted therapy include **NTRK fusion**, **BRAF V600E**, **RET fusion**, and **HER2 overexpression**^{5,28,38}



Immunotherapy

- Immunotherapy is a treatment that uses your own immune system to recognize and destroy cancer cells³⁹
- PD-1 inhibitors/PD-L1 inhibitors are a type of immunotherapy that helps your immune system find and fight cancer cells by preventing the binding of proteins called PD-1 and PD-L1³⁹
 - If you have certain cancer types, you may be tested for PD-L1, which is a common biomarker, to see if immunotherapy is right for you⁴⁰
- Pan-tumor biomarkers predictive of response to immunotherapy, such as a PD-1 or PD-L1 inhibitor, include **TMB-H** and **MSI-H**^{5,40}



Traditional Treatment Strategy

Different treatments for different cancer types



Melanoma



Prostate cancer



Breast cancer



Lung cancer

The visual depictions on this page are hypothetical for illustrative purposes only.

Most treatments are evaluated and approved on groups of patients with cancer in a specific organ or tissue (for example, melanoma, prostate, breast, or lung).⁴¹

Pan-Tumor Treatment Strategy

Same treatment for different cancer types with the same pan-tumor biomarker



Shared biomarkers



The visual depictions on this page are hypothetical for illustrative purposes only.

Pan-tumor treatments are evaluated and approved on groups of patients with cancer who all have the same driver alteration or same biomarker, regardless of cancer type or the organ in which the cancer originated.⁴¹

- This means that any cancer patient with a pan-tumor biomarker may be eligible for an associated targeted therapy or immunotherapy

Questions to Ask Your Care Team

What are the results of my biomarker tests?

Checklist of pan-tumor biomarkers associated with approved therapy

Therapy type	Biomarkers with an FDA-approved therapy ^{5,28}	My test result
Targeted therapy	<i>NTRK</i> fusion	
	<i>BRAF</i> V600E	
	<i>RET</i> fusion	
	<i>HER2</i> overexpression	
Immunotherapy	TMB-H	
	MSI-H	

What do these test results mean for my cancer diagnosis?

How will these results affect my treatment plan, if at all?

Should I speak to a genetic counselor?

In what situations might I need additional biomarker testing later?

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

What steps should I take next?



Are There Any Additional Resources I Should Know About?

There are multiple online resources full of information and support for patients like you. Some resources are listed below.

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/>

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

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

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^{1,2}
 - Before precision medicine, cancer was treated with a “one-size-fits-all” approach. All patients with metastatic cancer received similar treatment plans²
 - With precision medicine, treatment can be tailored to each individual patient with metastatic cancer²
- 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), as well as **predicting** how you may respond to specific therapies, and **monitoring** your response



Precision medicine uses biomarkers to aid in the diagnosis, prognosis, or treatment of cancer²

Different Types of Biomarkers Serve Different Purposes⁹

Before diagnosis	Risk biomarkers	→	Identify patients at greater risk for certain diseases ³⁷
	Diagnostic biomarkers	→	Help identify your disease and subtypes ³⁷
Before treatment	Prognostic biomarkers	→	Provide information on expected clinical outcomes ³⁷
	Predictive biomarkers	→	Provide information on expected treatment response ³⁷
	Actionable predictive biomarkers	→	Have an associated FDA-approved therapy ³⁷
On therapy	Monitoring biomarkers	→	Monitor disease recurrence and progression and whether the treatment is working ⁴²



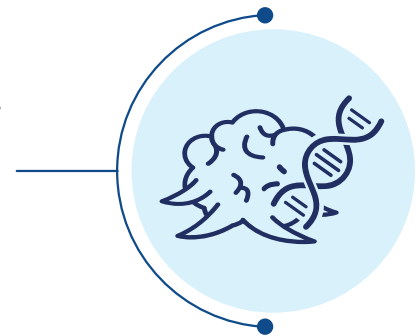
Importantly, a biomarker can have multiple uses at once. A biomarker can be a risk, prognostic, and predictive biomarker at the same time²

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.¹

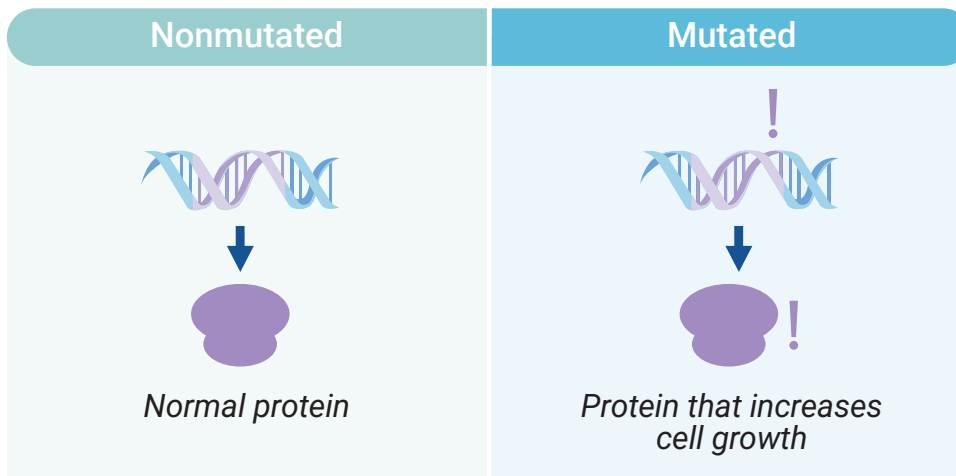
How Cancer Occurs

- Cancer is a genetic disease, which means it occurs because of a change in your DNA⁴³
- 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**^{37,43}
- In some cancers, these changes make the cancer cells more likely to get additional changes in DNA over time and at a faster rate. This process is known as **genomic instability**⁴⁴
 - This can lead to cancer growth and progression

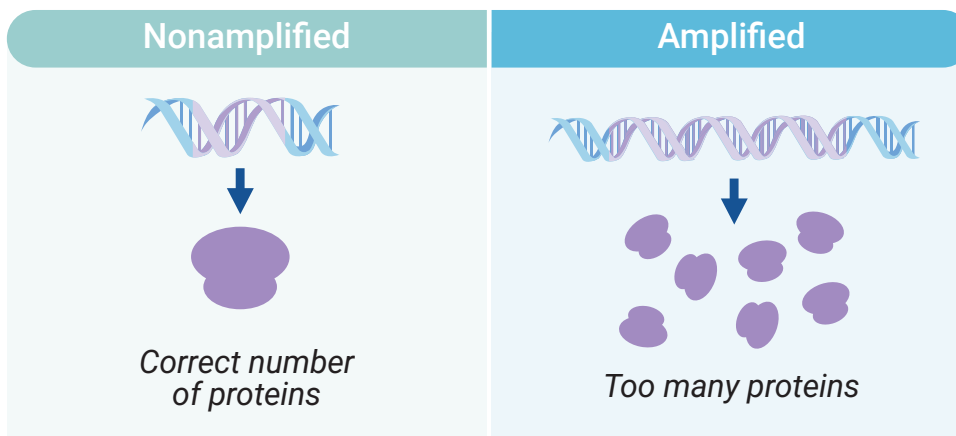


There are many types of driver alterations, including:

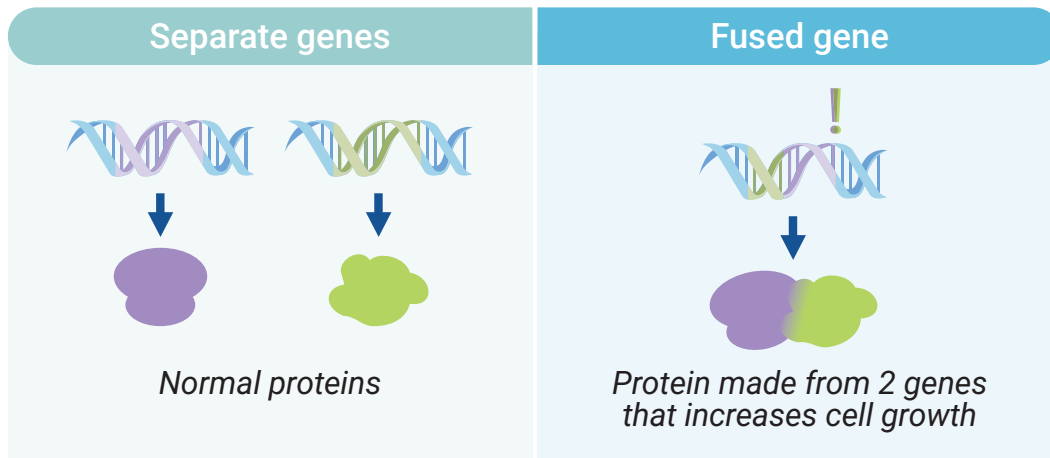
- **Gene mutations**, or changes in the DNA sequence that change the way the protein works³



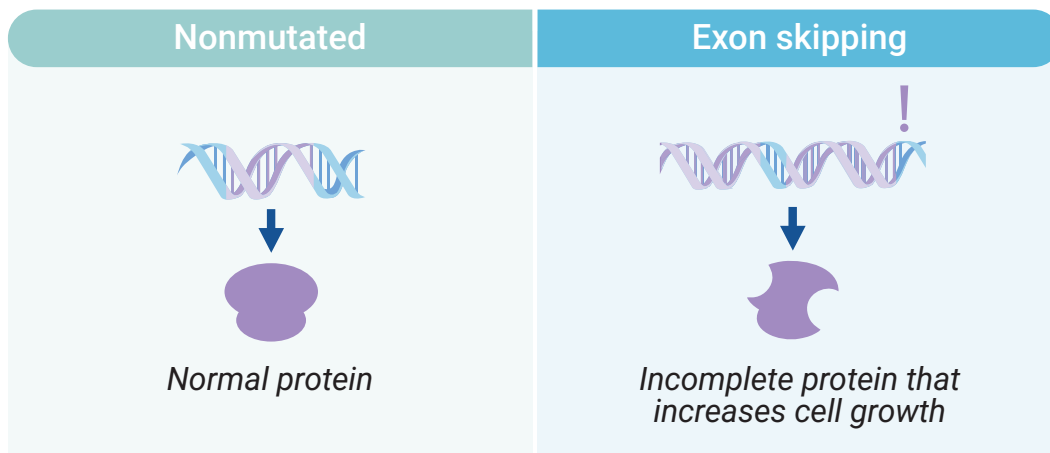
- **Gene amplifications**, or increases in the number of copies of a gene, which lead to too many proteins³



- **Gene fusions**, or the joining of parts from 2 separate genes³



- **Exon-skipping events**, or mutations at the edge of a gene that result in incomplete proteins⁴⁵



Testing for Driver Alterations and Genomic Instability

When scientists and doctors discovered different genetic causes of cancer, 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^{2,46}
- Other driver alterations, like fusions, are harder to find and can only be detected with a specific type of biomarker test^{2,46}
- Some driver alterations can only be detected by looking at a substance called a protein, which can be expressed at different levels²
- Genomic instability can be detected by looking at the number of mutations in the DNA of your cancer⁴⁴

Pan-Tumor Biomarkers Include Driver Alterations and Signs of Genomic Instability

Driver alterations ^{2,47}	Signs of genomic instability ⁴⁸
<i>BRAF</i> V600E, <i>NTRK</i> fusions, <i>RET</i> fusions, <i>HER2</i> overexpression	TMB, MSI



Because some therapies are designed to stop cancers that have a specific driver alteration or a lot of genomic instabilities, it is important that:

- You are tested for all driver alterations with an FDA-approved therapy^{2,5,28}
- Your care team uses biomarker tests that can find all types of driver alterations or genomic instabilities^{2,46}

How Cancer Changes

- Unlike other cells, cancer cells are genetically unstable. This means that they continue to get mutations over time^{12,49,50}

Time

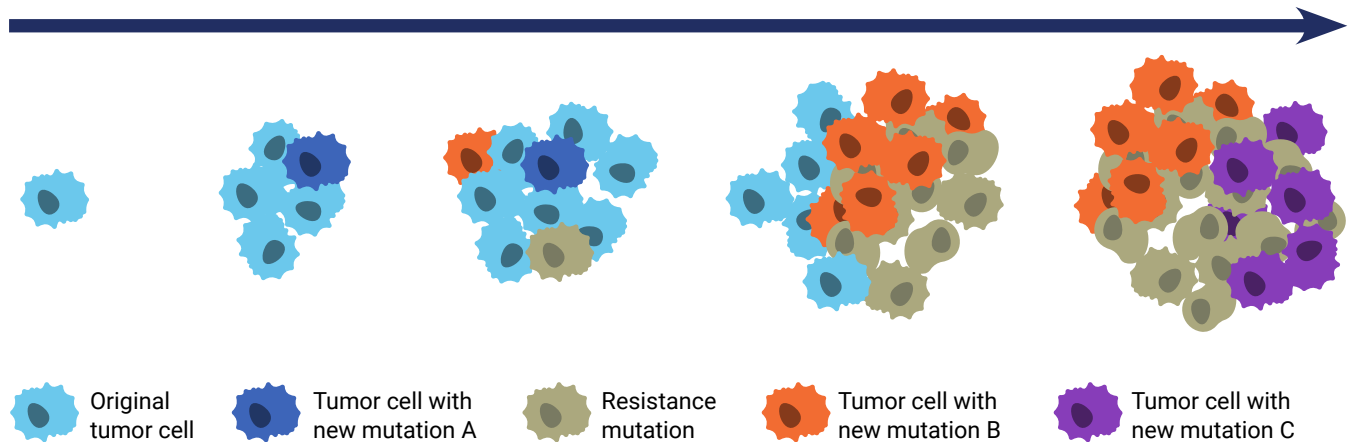


Image adapted with permission from Black JRM, McGranahan N. *Nat Rev Cancer*. 2021;21(6):379-392. doi:10.1038/s41568-021-00336-2.⁵¹

- 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 markers¹²



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 therapies¹²

- 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

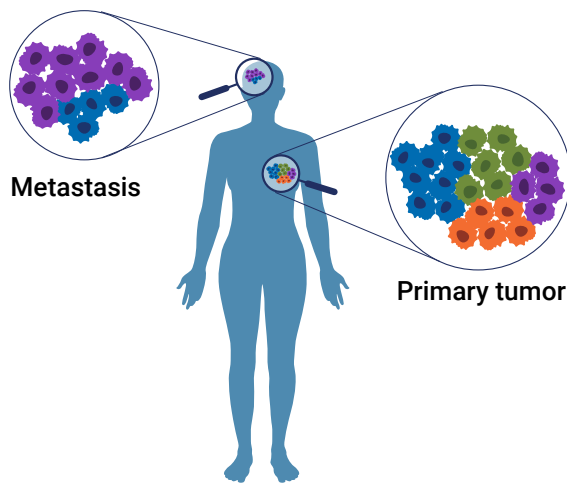


Image adapted with permission from Kashyap A et al. *Trends Biotechnol.* 2022;40(6):647-676. doi:10.1016/j.tibtech.2021.11.006.⁵²



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^{12,13}

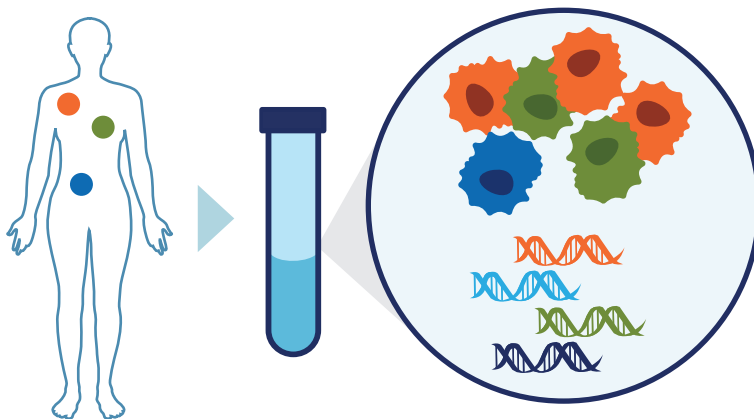


Image adapted with permission from Gilson P et al. *Cancers (Basel)*. 2022;14(6):1384. doi:10.3390.cancers14061384.⁵³

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.^{1,2,54}

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 treatments³

Biomarker testing: One or more tests using various techniques to identify the presence or absence of biomarkers³

Chemotherapy: A type of treatment using drugs that kills cancer cells³

Clinical stage: Refers to how advanced your cancer is based on the size of your tumor and whether it has spread to other locations (metastasized). Cancer staging will help your oncologist determine your chance of survival and the best course of treatment³

Clinical trial: A type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease³

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 response⁴⁵

Gene amplifications: Increases in the number of copies of a gene, which may cause cancer cell growth or resistance to certain drugs³

Gene fusion: The joining of parts of two separate genes that may lead to the development of certain types of cancer³

Gene mutations: Changes in the DNA sequences of a cell, which may be inherited or caused by environmental factors³

Genomic instability: The increased tendency for DNA mutations and other genetic changes to occur during cell division³

Histology: The study of tissues and cells under a microscope³

Imaging tests: Initial evaluations (eg, CT scans, MRIs, X-rays, mammography) to determine the presence of tumors³

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 diseases³

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 tumor³

Malignancy: Tissue cells obtained from biopsy that grow in an uncontrolled way (indicating cancer)³

Metastatic cancer: Cancer cells that have spread from the original tumor location through the blood or lymph system to other locations in the body³

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*)³

Oncologist: A medical practitioner qualified to diagnose and treat cancer³

Pathologist: A doctor who identifies diseases, and/or the presence of biomarkers, by studying cells and tissues under a microscope or with other equipment³

Pathology report: The description of cells and tissues made by a pathologist based on what is seen under a microscope³

Primary tumor: The original, or first, group of cancer cells in the body³

Prognosis: The likely outcome or course of a disease; the chance of recovery or recurrence³

Radiation therapy: The use of high-energy radiation from X-rays, gamma rays, neutrons, protons, and other sources to kill cancer cells and shrink tumors³

Recurrent cancer: The return of cancer after a period of it not being detectable³

Refractory cancer: Cancer that fails to respond to treatment³

Remission: The signs and symptoms of cancer are partially or completely reduced³

Resection: The removal of the entire tumor through surgery as part of the treatment plan³

Single-gene test: A biomarker test that examines 1 specific genetic biomarker³⁰

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 cells³

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

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