Understanding Biomarker Testing

A Guide for Patients With Cancer

What are biomarkers, and how can they affect your cancer treatment plan?
Learn the basics and feel confident about discussing biomarker testing with your care team.

Receiving a diagnosis of cancer is an overwhelming experience. You and your loved ones will have many questions about the disease, options for treatment, and what the future may hold. You may hear the term **biomarkers** as you sift through a lot of new information. In this guide, we hope to help you understand what biomarkers are and how you can use this information to talk with your health-care team.

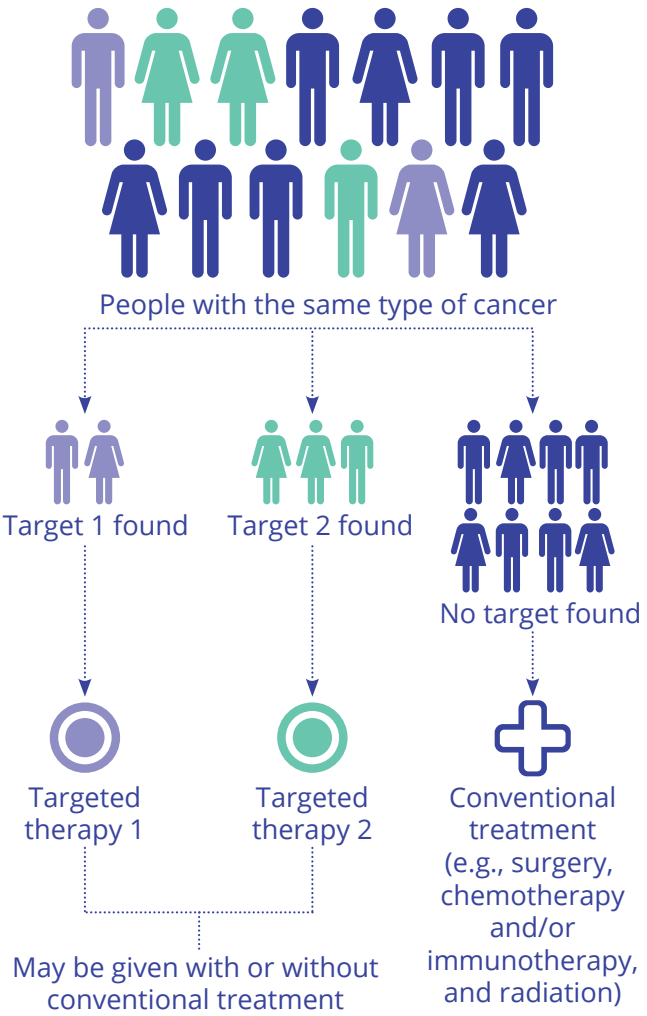
Biomarkers are molecular features, such as DNA mutations or proteins, that can be identified by testing a person's cancer tissue or their blood. These tests provide important information about the unique characteristics of a particular tumor, such as how quickly it's growing, how likely it is to spread to other parts of the body, and how high the risk for recurrence is.

Guiding Treatment Decisions

For many people with cancer, biomarker testing might provide useful information. Some biomarkers can help identify tumors that are likely to respond to a particular type of therapy. This means the health-care team can use **biomarker testing** results to tailor treatment plans to individual patients, rather than relying on a one-size-fits-all approach. Certain drugs work by binding with or blocking the tumor's mutation or protein (biomarkers) to stop it from growing and spreading. But these drugs will only work for people whose tumor has *that specific biomarker*. This concept is referred to as **targeted therapy**; this is different from **chemotherapy**, which works by killing existing cancer cells, but may also kill healthy cells as well.

Take a look at the illustration on the right. It shows how several people with cancer in the same part of the body may not have the same biomarkers in their tumor, so they may not get the same targeted treatment. People whose tumors have no biomarkers will not be good candidates for targeted therapy; they'll instead likely receive **conventional therapy**, which is generally some combination of surgery, chemotherapy and/or immunotherapy, and radiation.

In addition to guiding treatment decisions, biomarkers can also be used to monitor the progress of treatment. By re-testing biomarkers over time (they can change!), your care team can determine whether a treatment is working or if changes to the treatment plan need to be made. See the graphic at the bottom of the next page for some examples of the many ways biomarkers can be used.



Talking to Your Care Team

In this guide, you'll read the story of a patient living with lung cancer and how biomarker testing has helped guide her treatment plan over time. You'll also find definitions of key terms, a list of questions to ask your care team, and resources for finding more information. After reading this guide and watching the companion video "Biomarker Testing in Cancer: Empowering Patients for Important Discussions With the Care Team" found at **patiented.jadpro.com/biomarker**, we hope you'll feel confident having a discussion about this topic with your care team.

Ivy's Story

Meet Ivy Elkins, a lung cancer patient and advocate who lives with her husband, Ben, and dog, Missy, in Evanston, Illinois. Ivy is the proud mother of two sons who are both in college. She is a co-founder of EGFR Resisters, a lung cancer patient advocacy group. Through Ivy's story, you'll learn about the role biomarker testing has played in her cancer treatment journey.

Like many people with cancer, my diagnosis of lung cancer came completely out of the blue. It was 2013, and all was right in my world. I was considering going back to work part-time, as my two boys were tweens and becoming more self-sufficient. I was 47, in good health, and had been going to orthopedists and physical therapy for about 6 months with little relief for a problem with my elbow. After my orthopedist ordered an MRI to try to get to the root of the problem, a mass was seen in the joint area. Further testing showed that I had lung cancer, which had unfortunately traveled to the elbow joint and other areas in my bones. I also learned that I had eight tiny lesions in my brain. It was stage 4. I remember thinking, "How is this possible? My lungs feel fine. I have no symptoms and no risk factors." I didn't know then what I now know, which is that anyone with lungs can get lung cancer.

DEFINITIONS

Biomarker: A molecule produced by the body or a tumor in a person with cancer that can be associated with the growth of a tumor.

Biomarker testing: A way to look for molecules—often genes or proteins—that can provide information about a person's cancer.

Blood biopsy: The removal of a sample of blood to evaluate for the presence of cancer cells and/or genetic material; also called liquid biopsy.

Chemotherapy: Treatment with drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.

Conventional therapy: Cancer treatment that is widely accepted and used, such as surgery, chemotherapy and/or immunotherapy, and radiation.

Targeted therapy: A type of treatment that uses drugs or other substances to target specific molecules that cancer cells need to survive and spread.

Tissue biopsy: The removal of cells or tissues for examination by a pathologist.

Source: National Cancer Institute (cancer.gov)

Biomarker Testing and Treatment Decisions

Once we started to talk about treatment, I assumed I would get traditional intravenous chemotherapy. I knew the side effects of chemotherapy could be grueling, and I wasn't looking forward to that. But my care team explained that they sent material from a tissue biopsy of my elbow for testing to see whether it had some key genetic mutations, or biomarkers. I was told that this information would determine whether I'd be likely to respond to targeted therapy. At that time, I didn't know the difference between chemotherapy and targeted therapy. My providers explained that chemotherapy tries to kill the cancer cells (and often other healthy cells in the body), but targeted therapy

Uses of Cancer Biomarkers

RISK ASSESSMENT	SCREENING/ DETECTION	DIAGNOSIS	PROGNOSIS	PREDICTION	MONITORING
Identify factors to assess disease susceptibility	Indicate the presence of disease; early detection	Definitive diagnosis and general typing	Assess disease aggressiveness & likelihood of recurrence	Predict efficacy or response to different treatments	Monitor disease recurrence & response to therapy

attempts to stop the cancer's ability to grow by disrupting its molecular structure.

They tested for just three biomarkers: EGFR, ALK, and KRAS—the only lung cancer biomarkers that were generally tested for at that time. I learned that I had an *EGFR* mutation. This was good news: I was indeed a candidate for targeted therapy. In my case, I took an oral medication once a day in pill form. This worked to keep my cancer in check for 3 years, with relatively few side effects. But in 2016, the cancer figured out how to avoid the drug's mechanisms to stop its growth. The disease in my lungs had begun to grow. It was time for more biomarker testing to see if my cancer had developed any new mutations.

Further Testing and Medication Changes

The second time, I had comprehensive biomarker testing, which is testing for hundreds of biomarkers at once, rather than just the three that I was tested for in 2013. Biomarker testing had come a long way in a short time, and there were more treatment options too.

My biomarker results showed that I could take a new oral targeted medication (different than the first medicine I took) based on a new mutation the tumor had indeed developed, called *T790M*. I switched to that drug in November 2016 and still take it today. I also had a blood biopsy done at that time, which also underwent comprehensive biomarker testing. Interestingly, the blood testing did not pick up on this new mutation. I learned that blood biopsies may be easier and less costly than tissue biopsies, but they might miss things that will only show up on a tissue biopsy.

Next Steps

In early 2020, I had a PET scan that showed I had no identifiable cancer remaining in my body, other than the original mass in the upper right lobe of my lungs. This mass had shrunk with treatment, but never fully disappeared. As a result, my oncologist and I decided that surgery to remove my upper right lobe might be helpful. I had a lobectomy in February 2020 and recovered easily and fully. In my wildest dreams, I had never imagined that I would become eligible for surgery as a patient with stage 4 lung cancer! After this surgery, I had no evidence of disease for 2.5 years. I continued taking my targeted therapy medication throughout this period as maintenance.

QUESTIONS TO ASK YOUR CARE TEAM

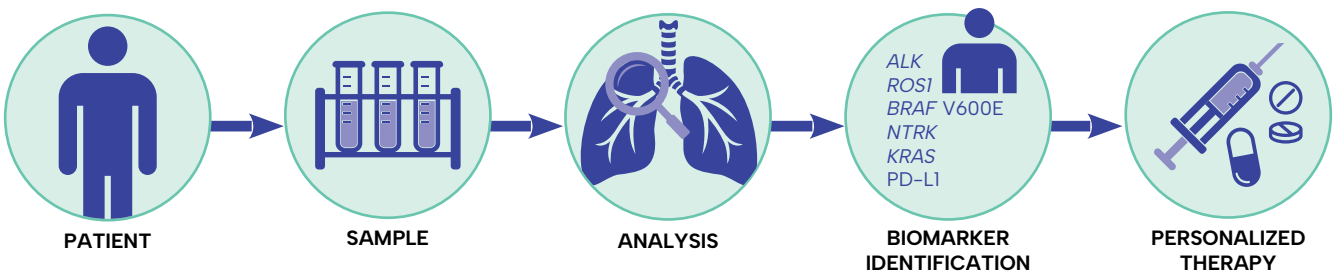
- **How will biomarker testing affect my treatment?**
- **Which biomarkers are generally associated with my cancer?**
- **Have I already had biomarker testing? If so, what are my results?**
- **How long will it take to get the test results?**
- **Can biomarker testing help identify clinical trials that might be a good fit for me?**
- **Can I start treatment before the test results are back?**
- **Should my family members be tested to see if they have these biomarkers too?**
- **How can I get assistance with costs related to these tests?**

Recently, my cancer grew again in my lungs, so I had biomarker testing done for a third time and found out that I had developed something called a BRAF fusion. Based on those results, my care team added a second new targeted therapy to the one I began in 2016. This combination of drugs has been working well for me, and the side effects are manageable.

Giving Back

As a result of my lung cancer experience, my priorities and my plans of going back to work shifted. I decided to become a lung cancer advocate. After learning more about the need for increased research in lung cancer, I felt I would be of most use through sharing my story and perspective as a patient. I learned what it meant to be a research advocate and started working with researchers in grant reviews and clinical trial development. In 2017, I co-founded EGFR Resisters, which has since grown to include more than 4,000 members from 90+ countries. We support and educate patients and caregivers, and direct patient-driven research to improve outcomes for those impacted by EGFR-positive lung cancer. To date, we have raised and funded over $1 million in research.

Key Steps in the Biomarker Testing Process



Resources for Patients

Information on Biomarkers in Cancer

American Cancer Society
Biomarker Tests and Cancer Treatment
cancer.org/treatment/understanding-your-diagnosis/tests/biomarker-tests.html

CancerCare
Understanding the Role of Biomarkers in Treating Cancer
cancercare.org/publications/413-understanding_the_role_of_biomarkers_in_treating_cancer

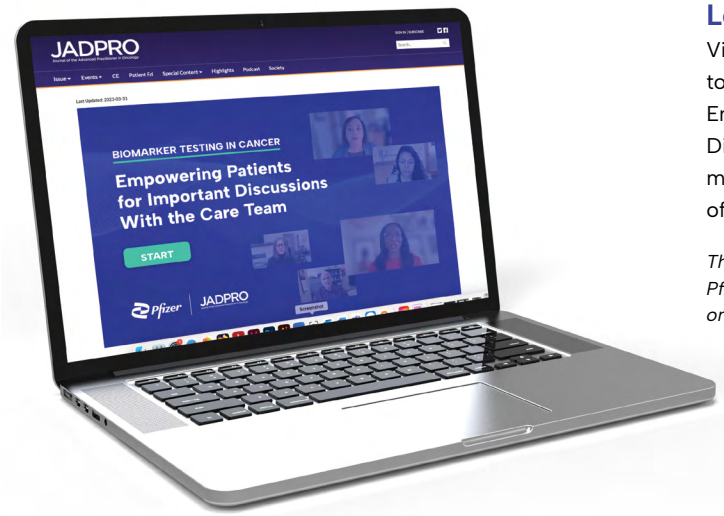
Cancer Support Community
Biomarker Testing for Cancer
cancersupportcommunity.org/biomarkers

National Cancer Institute
Biomarker Testing for Cancer Treatment
cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment

Find Connection and Support

CancerCare is a national organization providing free, professional support services and information to help people manage the emotional, practical, and financial challenges of cancer. cancercare.org

Colorectal Cancer Alliance raises awareness, provides support, and inspires the efforts that fund critical research to end colorectal cancer. ccalliance.org



TIPS FOR NAVIGATING MEDICAL APPOINTMENTS

- **Write down a list of questions to ask during your appointment (see page 3).**
- **Ask if you can record your appointment using your smartphone's audio recorder.**
- **Bring a friend or family member with you to your appointment, and ask them to take notes.**
- **Repeat back to your health-care professional what you heard during the appointment, and ask them to confirm or clarify.**

EGFR Resisters is a patient-driven community dedicated to improving outcomes for those with EGFR-positive lung cancer. egfrcancer.org

LUNGevity is the nation's largest lung cancer-focused nonprofit, changing outcomes for people with lung cancer through research, education, and support. lungevity.org

Susan G. Komen is an organization that addresses breast cancer on multiple fronts such as research, community health, global outreach, and public policy initiatives. komen.org

ZERO Prostate Cancer is the leading national nonprofit with the mission to end prostate cancer and help all who are impacted. zerocancer.org

Learn More About Biomarkers

Visit **patiented.jadpro.com/biomarker** to watch "Biomarker Testing in Cancer: Empowering Patients for Important Discussions With the Care Team" and learn more about the roles of different members of the cancer care team.

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