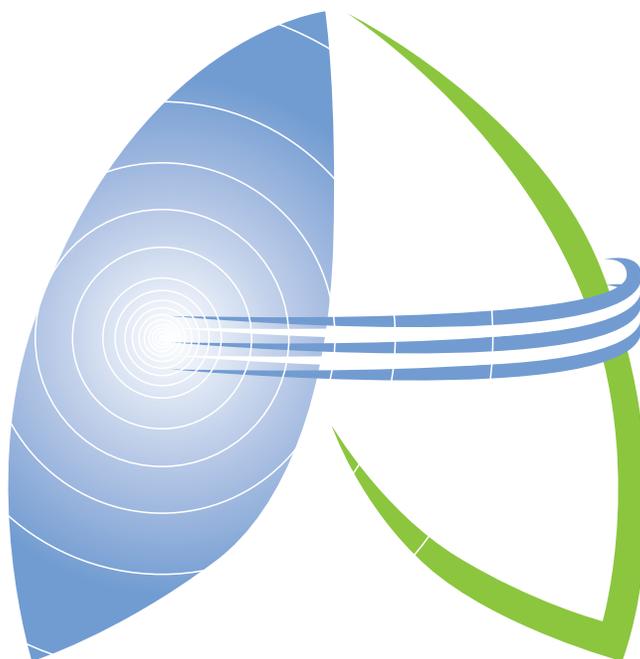




Individualizing Your Lung Cancer Care: Informing Decisions Through Biomarker Testing



These Are Hopeful Times for Lung Cancer Survivors

When people first learn they have cancer, they are often afraid. But these are hopeful times for lung **cancer survivors**—and by survivors we mean *everyone* diagnosed with lung cancer starting from the day of their diagnosis.

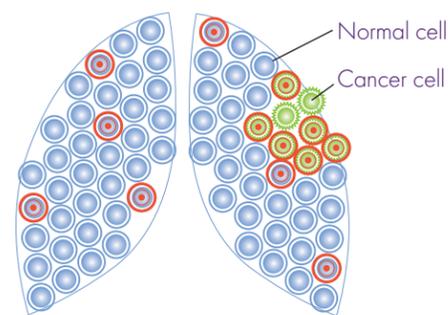
Treatment Options Are Advancing at a Rapid Pace

Treatment for the most common type of lung cancer, **non-small cell lung cancer (NSCLC)**, has changed a lot over the past 15 years.

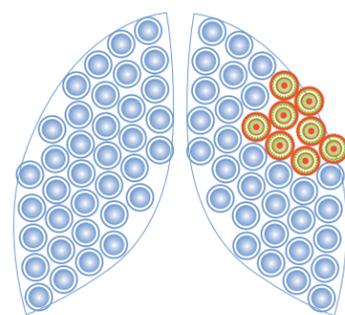
- Traditional **surgery, radiation,** and **chemotherapy** are **standard of care** and were once the only options
- **Targeted therapy**, which is designed to target abnormalities commonly seen in cancer cells, is now an option for some people (Figure 1)
- Combinations of targeted therapy and traditional treatments are also used

Standard of care: Treatment that experts agree is appropriate, accepted, and widely used.

Figure 1: Chemotherapy vs Targeted Therapy



Chemotherapy kills rapidly dividing cells, which means both normal and cancer cells can be affected.



Targeted Therapy is designed to target abnormalities commonly seen in cancer cells.

People with NSCLC should ask their doctor if they should undergo **biomarker testing** (also called **molecular testing** or **mutation testing**) to determine which therapy is most appropriate for them.

Individualized Therapy Is a New Focus

Biomarker testing is just one of the ways in which doctors are working to provide **individualized therapy** for people with NSCLC. Other things to consider when making treatment decisions are a person's goals, age, overall health, circumstances, and personal preferences. Individualizing therapy is part of a newer trend, known as personalized medicine, to make sure that the *right* treatment is given to the *right* patient at the *right* time.

Stay Current as New Options Become Available

People with NSCLC and their caregivers are encouraged to keep an open dialogue with their doctors to stay current on the latest treatment options. This may also include **clinical trials**. Resources that can help with this can be found on pages 10-11 of this booklet.

KEY POINTS

- With new approaches to diagnosis and treatment, now is a time of hope for those with lung cancer
- Biomarker testing is just one of the ways doctors are working to help inform treatment decisions for patients

Biomarker Testing Can Help You and Your Doctor

Decide Which Therapy Is Most Appropriate for You

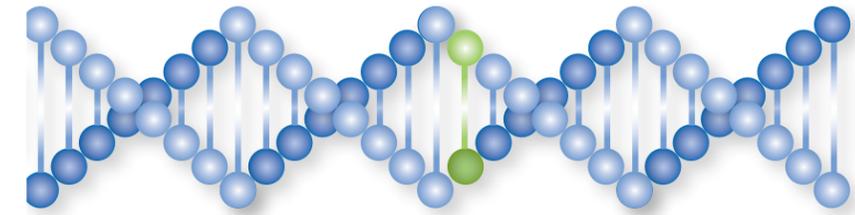
So, how do you know which therapy is right for you? The answer—at least in part—is **biomarker** testing.

Biomarker: A biological molecule that can be detected in a person’s blood or tissues. The presence or absence of a biomarker, also called *molecular marker*, can help predict whether a person is likely to respond to a specific targeted therapy. Biomarkers are measured by biomarker testing, also called *molecular marker* or *mutation testing*.

Lung Cancer Is Most Often Caused by Genetic Changes

Let’s take a step back and talk about how cancer develops. Normally, cells grow and divide *only* to replace other worn-out, damaged, or dying cells. With cancer, though, cells grow and divide out of control. This happens because of damage to pieces of **DNA** that make up the **genes** inside of cells (Figure 2).

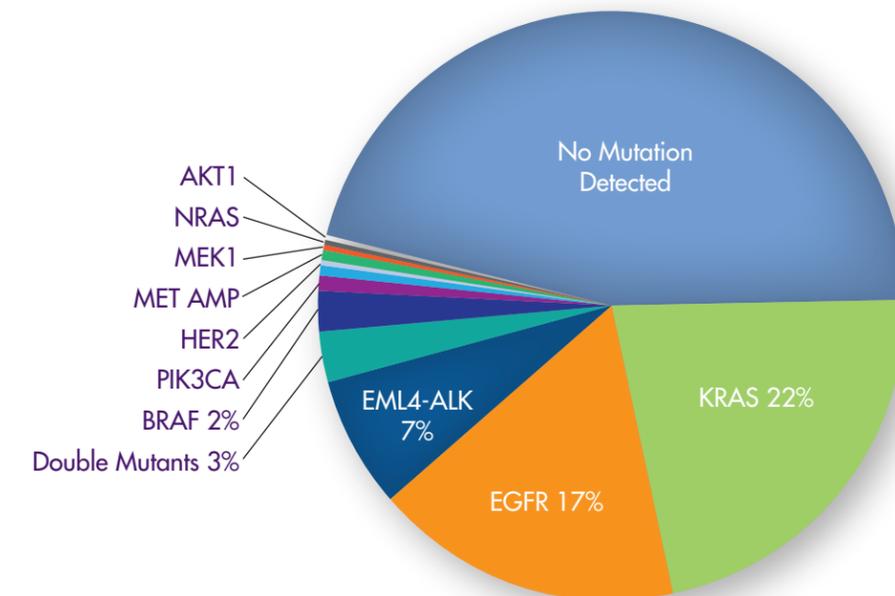
Figure 2: Damage to a Person’s Genes Can Lead to NSCLC



In NSCLC, **gene damage**—also called **molecular changes**, **genetic changes**, or **mutations**—is generally not something you inherit from your parents or pass on to your kids. Instead, gene damage is caused either by mistakes that happen when a normal cell divides or by exposure to something in the environment, such as cigarette smoke, radon gas, asbestos, certain other chemicals, or air pollutants.

There are many different kinds of genetic changes that can happen in people with NSCLC. Some of these changes result in the formation of biomarkers, also called *molecular markers*, which may be targets for therapy (Figure 3).

Figure 3: Genetic Changes (Mutations) Associated With NSCLC



A little more than half of lung cancer tumors tested to date by the Lung Cancer Mutational Consortium are associated with known genetic changes. Scientists are actively searching for other mutations in the “no mutation detected” category. Graph courtesy of Mark Kriss, MD, Memorial Sloan-Kettering Cancer Center.

Table 1: Biomarker Test Results and What They Can Mean

If Your Biomarker Testing Shows...	Then...
You have an EGFR or EML4-ALK mutation.	Targeted therapies are available by prescription that may be appropriate for you.
You have one of the other known mutations.	<p>A clinical trial may be an option. Clinical trials are research studies for which people can volunteer to receive new investigational therapies as they are being developed. (See pages 10-11 of this booklet for more information on locating and understanding clinical trials.)</p> <p>Also, new therapies and new combinations of therapies may become available for people with your molecular profile. (Resources that can help you keep up with such advances can also be found on pages 10-11 of this booklet.)</p>
You do not have a known mutation or biomarker.	Different combinations of treatments that are currently the standard of care may be the most appropriate treatment option for you. Also, scientists are investigating additional mutations or biomarkers, and investigational treatments associated with new biomarkers may become available in clinical trials. You may ask your doctor about clinical trials or search for them on EmergingMed.com (see Resources section).

Biomarker Testing Can Provide More Information About Your Cancer

A biomarker, or molecular marker, is a biological molecule that can be detected, for example, in a person’s blood or tissues. Today, doctors are testing for biomarkers for a wide range of uses. In an effort to learn more about your cancer, your doctor may use biomarker testing to obtain a **molecular profile** of your tumor. This profile may allow for a more detailed diagnosis of your cancer or even offer information that could guide treatment decisions. For example, biomarker testing can show a specific genetic change associated with your tumor. The information you get from biomarker testing may help you and your doctor decide what kind of treatment is most appropriate for you (Table 1).

KEY POINTS

- Lung cancer can happen because of changes to a person’s genes, also known as *molecular changes, genetic changes, or mutations*
- Biomarker testing can determine the molecular markers associated with your tumor
- Biomarker testing may help you and your doctor make the most appropriate treatment decision

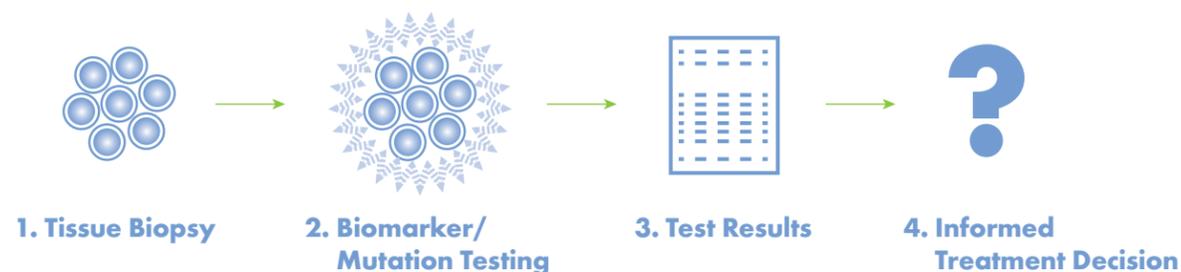
Taking Action: Getting Tested and Making Decisions

Now that you know what biomarker testing is and what it can tell you, let's talk about what actual testing involves.

There are 4 steps involved in biomarker testing (Figure 4):

1. **Provide a tissue sample**—A tissue sample from your tumor is needed for biomarker testing. If you have already had a **biopsy**, sometimes that tissue can be used. In some cases, such as when there is not enough tissue remaining from the original biopsy, a second biopsy may be needed.
2. **Have the test performed**—Tissue from your tumor is sent to a laboratory and analyzed.
3. **Receive the results**—A report will be sent back to your doctor showing what biomarker, if any, is associated with your tumor. In rare cases, more than 1 biomarker may be present.
4. **Make an informed treatment decision**—Whether you have a known biomarker or not, the information you get from biomarker testing may be useful in deciding what is most appropriate for your situation. (See Table 1 on page 6 for additional information on what the results of biomarker testing can mean.)

Figure 4: Four Steps to Biomarker Testing



Ask your doctor if biomarker testing has been done for your tumor, and, if not, is it appropriate to have it done.

Be Proactive—Ask Your Doctor About Biomarker Testing

As with so much of your cancer care, it is important that you be proactive and ask for the things you feel are right for you. We encourage you to talk with your doctor about biomarker testing. Has biomarker testing been ordered for you? If yes, what were the results? If no, can it be ordered and how long will it take to get the results?

Remember, you can get tested for biomarkers even after you have had other testing done and/or been treated with other therapies. It's never too late to discuss biomarker testing with your doctor. If your doctor doesn't recommend molecular testing, and you still have questions, consider getting a second opinion.

Once you receive the results of your biomarker test, you can work with your doctor to make the treatment decisions that are most appropriate for you. (See Table 1 on page 6 for additional guidance.)

Other Resources Can Also Help in Making Treatment Decisions

Ultimately, you and your doctor will make your treatment decisions, but don't forget there are many people who can help you find information and resources while you are deciding. These include:

- Healthcare and allied professionals/related groups, including social workers, patient navigators, etc
- Family and friends
- Clergy, counselors, and patient advocacy and support groups
- Regional and national resources, such as those listed on pages 10-11 of this booklet

KEY POINTS

- Biomarker testing involves 4 steps:
 - Providing a tissue sample
 - Having the test performed
 - Receiving the results
 - And making an informed treatment decision
- Be sure to ask your doctor about biomarker testing. Has it been done? If yes, what were the results? If no, can it be done and when will the results be known?

Resources

EmergingMed

Offers a clinical trials matching and referral service that includes options involving targeted therapies. Provides online and telephone guidance to help survivors find appropriate clinical trial options. Please visit www.emergingmed.com or the Lung Cancer Clinical Trial Call to Action website at www.LungCancerCTA.com or call 800-698-0931.

The following groups can also help you locate clinical trials and keep you up-to-date on treatment advances as well as provide other information on a variety of topics, helpful people to talk with about your situation, and many different forms of support.

Lung Cancer Action Network (LungCAN)

www.lungcan.org

A collaborative group of lung cancer advocacy organizations, LungCAN lists and provides links to a number of different organizations that connect those affected by lung cancer to educational and support resources, clinical trials, and individual advocacy groups. Links to organizations listed below can be found on this website.

American College of Chest Physicians

www.chestnet.org , www.onebreath.org

The American College of Chest Physicians (ACCP) promotes the prevention, diagnosis, and treatment of chest diseases through education, communication, and research. Working through its philanthropic arm, The CHEST Foundation, and the OneBreath® initiative, the ACCP inspires patients and their families to take care of their lungs and heart and never take their next breath for granted.

American Lung Association

www.lung.org

Provides education and support for those looking at their treatment options. Offers an interactive decision support tool, clinical trial matching service, and original publications.

The Beverly Fund

www.beverlyfund.org

Provides free radon test kits nationwide, raises awareness, and provides education, patient support, and clinical trials information.

Bonnie J. Addario Lung Cancer Foundation

www.lungcancerfoundation.org

This patient-founded, patient-focused, and patient-driven philanthropy provides funds for research through nationwide fundraising and awareness events. It also offers education and support, including the Lung Cancer Living Room™ series, which includes video talks on personalized medicine and treatment options.

CancerCare

www.cancercare.org

Provides free professional support services to anyone affected by cancer. Programs—including counseling and support groups, education, financial assistance, and practical help—are provided by oncology social workers, free of charge. Also offers free telephone workshops for people living with different types of cancer.

Caring Ambassadors Lung Cancer Program

www.lungcancercap.org

Through comprehensive, state-of-the-art information and weekly news updates, Lung Cancer CAP addresses the informational needs of lung cancer survivors, provides compassion and support, increases lung cancer awareness, and brings hope to families living with lung cancer.

Lung Cancer Alliance

www.lungcanceralliance.org

This national nonprofit organization, dedicated solely to providing patient support and advocacy for people living with or at risk for lung cancer, offers connections to educational, supportive, and practical resources.

LUNgevity Foundation

www.lungevity.org

Funds early detection and treatment research through nationwide fundraising events, provides an online support community for those affected by lung cancer, and supports the largest national grassroots lung cancer network.

National Lung Cancer Partnership

www.nationallungcancerpartnership.org

Works to save lives by funding lung cancer research, providing crucial information to patients and their loved ones, educating the public about lung cancer, and advocating for better diagnosis, treatment, and understanding of the disease.

Respiratory Health Association of Metropolitan Chicago

www.lungchicago.org

Provides information on clinical trials, offers connections to support groups, funds research, and supports education programs.

Uniting Against Lung Cancer

www.unitingagainstlungcancer.org

Dedicated to funding innovative research and raising awareness to find a cure for lung cancer.

Glossary

Biomarker: A biological molecule that can be detected, for example in a person's blood or tissues. The presence or absence of a biomarker, also called a *molecular marker*, can help predict whether a person is likely to respond to a targeted therapy.

Biomarker testing: Testing done to determine if a person has certain biomarkers, also called *molecular markers*. The presence or absence of a biomarker can help predict whether a person is likely to respond to a specific targeted therapy. Also called *molecular testing* or *mutation testing*.

Biopsy: The removal of cells or tissues for examination. Biomarker testing requires tissue from a biopsy.

Cancer survivor: Everyone diagnosed with cancer, starting from the day of their diagnosis.

Chemotherapy: A treatment that kills rapidly dividing cells and which is commonly used for people with cancer, including lung cancer.

Clinical trials: Research studies for which people can volunteer. Also called *clinical studies*.

DNA: The molecules inside cells that carry genetic information.

EGFR (epidermal growth factor receptor): A protein found on the surface of some cells. An abnormal *EGFR* gene is sometimes associated with lung cancer.

EML4-ALK: A fusion of 2 proteins caused by an abnormal gene mutation, which is sometimes associated with lung cancer.

Gene: A piece of DNA that directs the body to make specific biological molecules.

Gene damage: Any change in the DNA of a cell. In NSCLC, gene damage is generally not something you inherit from your parents or can pass on to your kids. Instead, it is caused by mistakes that happen when a normal cell divides, or by something in the environment. Gene damage may also be referred to as *molecular changes*, *genetic changes*, or *mutations*.

Genetic changes: See **Gene damage**.

Individualized therapy: Part of a bigger trend known as personalized medicine to make sure that the *right* treatment is given to the *right* patient at the *right* time.

Molecular changes: See **Gene damage**.

Molecular marker: See **Biomarker**.

Molecular profile: A profile consisting of known molecular markers associated with a tumor.

Molecular targets: Biological molecules in the body that may be targets for therapy.

Molecular testing: See **Biomarker testing**.

Mutations: See **Gene damage**.

Mutation testing: See **Biomarker testing**.

Non-small cell lung cancer (NSCLC): The most common type of lung cancer, found in about 85% of lung cancer patients.

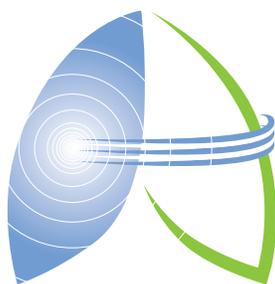
Radiation: A treatment commonly used for people with cancer, including lung cancer.

Standard of care: Treatment that experts agree is appropriate, accepted, and widely used. Also called *best practice*, *standard medical care*, or *standard therapy*.

Surgery: A treatment commonly used for people with cancer, including lung cancer. Generally, only NSCLC patients with stage I and II disease can be treated with surgery.

Targeted therapy: A type of treatment that selectively targets and attacks abnormalities commonly seen within cancer cells.

If you have non-small cell lung cancer (NSCLC), biomarker testing can help you and your doctor decide which therapy is most appropriate for you. Ask your doctor about biomarker testing today.



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