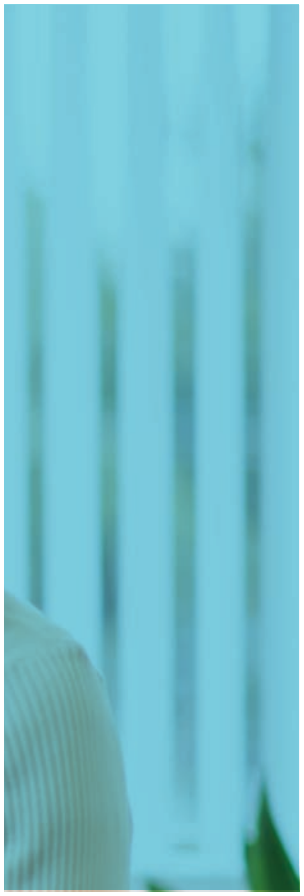
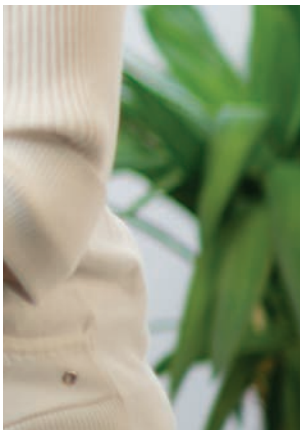
LUNG FORCE™

American Lung Association.

What You Need to Know About Lung Cancer Tumor Testing





Each lung cancer tumor is unique. Tumor testing looks at the makeup of the tumor to try and identify what is causing the tumor to grow.

What is lung cancer tumor testing?

Not all lung cancers are the same. When scientists look at tissue from a person's lung cancer tumor under a microscope they can tell what type (non-small cell, small cell or carcinoid) and subtype the lung cancer is. Now there is a way to get more detailed information about the makeup of the tumor. It involves testing tumor tissue for mutations (changes) in its DNA and levels of specific proteins. These tests are sometimes called biomarker, molecular or genomic testing. If doctors know exactly what causes the tumor to grow, a patient may be able to go on a "targeted" therapy that can slow tumor growth or shrink the tumor.

When should I talk to my doctor about tumor testing?

The best time to talk to your doctor about tumor testing is before a biopsy is done. This will help ensure that the doctor removes enough tissue during the biopsy to do molecular testing. It is also important to talk about additional molecular testing if your cancer continues to grow after you have been on a targeted therapy.

The best time to talk to your doctor about tumor testing is **before a biopsy is done.** Tell your doctor you want to discuss **comprehensive genomic testing.**

What type of testing should I ask for?

If you have non-small cell lung cancer (NSCLC), it is important to discuss comprehensive genomic testing. This looks for a large number of mutations and proteins in all the genes known to be associated with lung cancer. This gives doctors a full picture or "genomic profile" of your unique tumor. The results will show if you have a marker that can be treated with an FDA-approved targeted therapy. Testing results will also provide information about markers that are possibly being studied in clinical trials. This helps doctors make better-informed treatment recommendations to customize your treatment plan.

If your tumor wasn't tested before you started treatment, it might not be too late. Ask your doctor about testing leftover tissue or doing a liquid biopsy (blood draw).

If you decide to do biomarker testing, your tissue may be tested at the hospital or clinic where you are being treated, but it is most commonly sent to a certified company and laboratory. Your oncologist should order these tests and work with the pathology department in your hospital or clinic to arrange for your tissue to be sent to the right place. Results from this testing usually takes one to two weeks. Biomarker testing is not always covered under insurance. Your doctor, nurse navigator or financial support team may be able to help with understanding your insurance coverage. Still, it is important to ask about any out-of-pocket costs associated with tumor testing.

What if I have already had a biopsy and my tumor was not tested?

Sometimes treatment can cause a tumor makeup to change or the tumor to become resistant to targeted therapy. Ask your doctor about re-testing your tumor after your first treatment.

If the tumor tissue from your biopsy was not tested for molecular markers, you may want to ask your doctor if biomarker testing is right for you and if there is any leftover tissue that can be tested. Your doctor might also consider doing another biopsy or performing a blood test. The blood test is called a "liquid biopsy" (a simple blood draw). Liquid biopsies are not quite as accurate as tissue biopsies but can find several types of mutations. Lung cancer treatment can sometimes cause the makeup of a tumor to change, so some doctors may recommend another biopsy or liquid biopsy after you have already been on treatment and your tumor has become resistant to treatment. This allows doctors to get the most accurate and timely information available about your tumor.

What do the results of the testing show?

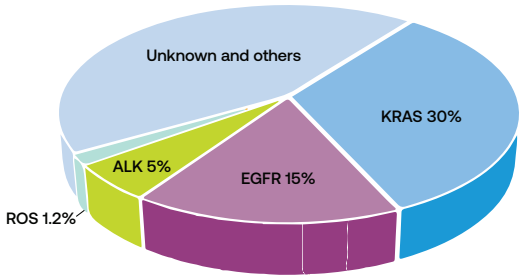
Biomarker testing is able to show if there are certain mutations in the DNA of the tumor and levels of specific proteins present in the tumor. The mutations found in the tumor are not inherited; they are changes that happen to your DNA over time. Mutations in lung cells can happen from exposure to environmental factors like cigarette smoke, radon, asbestos or other chemicals. Some gene changes in the cancer may also be random or have no known specific cause.

The results of the test may show biomarkers that can help determine what treatment options would be best for you. Not all doctors order testing for the same set of biomarkers. The most common markers tested are:

- Epidermal Growth Factor Receptor (EGFR) mutation
- Anaplastic Lymphoma Kinase (ALK) gene rearrangement
- ROS1 rearrangement

Your tumor may also be tested for other characteristics that are either being studied in clinical trials, have drugs approved for treatment in other types of cancer or provide information about how you might respond to a certain treatment.

Genetic Mutations in Adenocarcinoma



Source: Savas P. Hughes B. Solomon B. Targeted therapy in lung cancer: IPASS and beyond, keeping abreast of the explosion of targeted therapies for lung cancer. Journal of Thoracic Disease. 2013;5 (Suppl 5): S579-S592

Some examples include:

KRAS

KRAS mutations happen in about a quarter of patients with non-small cell lung cancer. If your tumor has a KRAS mutation, your doctor may recommend a clinical trial specifically designed for patients with this type of mutation. There are currently no FDA-approved targeted therapy drugs for KRAS mutations.

T790M

Patients who have been on a drug to treat the EGFR mutation might develop a new "resistance mutation" that can cause them to stop responding to treatment. The T790M mutation is the most common resistance mutation. New drugs have been developed that can target this resistance mutation and re-establish control of the tumor. Your doctor might want to do a tissue or liquid biopsy if you have been on treatment for EGFR and have become resistant to treatment in order to look for this type of mutation.

PD-L1

Your tumor may also be tested for PD-L1. This is a protein that may help determine your tumor's likelihood of responding well to certain immunotherapy drugs.

Talk to your doctor about receiving the most complete testing possible. The more information you have about the makeup of your tumor, the better informed you and your doctor will be to make treatment decisions.

If your tumor has an EGFR, ALK, ROS-1 or BRAF V600E mutation, you will likely be given a targeted therapy instead of traditional chemotherapy. If you have other mutations, a clinical trial might be right for you.

What treatment is available?

There are currently FDA-approved lung cancer treatments for tumors showing characteristics of mutations in EGFR, ALK, ROS-1 and BRAF V600E. These treatments are often called "targeted therapy," because they directly target what is causing the tumor to grow. There are also treatments available for patients with EGFR and ALK whose tumors have not responded to the first treatment given. If you do not test positive for these mutations, traditional chemotherapy may be recommended instead of a targeted therapy. Surgery or radiation may also be recommended. It may also be appropriate to enroll in a clinical trial looking at treatments for a number of other markers. There are also approved first- and second-line immunotherapy treatments. Some of these treatments require you to test positive for PD-L1.

Immunotherapy might be recommended for you as the first treatment you try or if your cancer continues to grow after you have already tried other treatment.

Who is most likely to benefit from tumor testing?

EGFR, ALK, ROS-1 and BRAF V600E are most common in patients with non-small cell lung cancer adenocarcinoma. While other types of lung cancer may occasionally have these mutations, tumor testing is generally not performed for squamous cell or small cell lung cancers unless the patient was a never smoker. If so, then tumor testing should be performed on these cell types. Not everyone with lung cancer will have mutations that can be treated with targeted therapies. While lung cancer tumor testing is a promising field, it does not guarantee a cure.

Mutations are most commonly found in non-small cell lung cancer.

If your doctor doesn't recommend tumor testing for you, you can ask why. Tumor testing may not be right for every person. If you have questions about whether or not your tumor should be tested, you may want to seek a second opinion. It is important to work closely with your doctor to discuss all of your treatment options at every step of your journey.