Understand your biomarker test results report

In this booklet, you’ll learn tips to read your report and find:

- Any biomarkers you have
- Available treatments based on your biomarker results

Lab companies report biomarker test results in different formats and may include different information in their reports.
Do I have any biomarkers?

Your report will show:
- Biomarkers your cancer has
- Biomarkers your cancer does not have

Your cancer may have been tested for one biomarker, or for all known lung cancer biomarkers at the same time (called comprehensive biomarker testing).

Visit [LUNGevity.org](http://LUNGevity.org) to learn more about the names of biomarkers and biopsies done for biomarker testing.

To find which biomarkers you do and don’t have:

1. Look for a section in your report with a heading that has any of these words:
   - Results summary
   - High impact results
   - Biomarker findings
   - Relevant findings
   - Results with therapy associations

2. Beside each biomarker you were tested for, look for these words, which describe the biomarkers your cancer has:
   - Positive
   - Detected
   - High expression or high levels

What does “unknown significance” mean?

Some reports may include biomarkers called “variants of unknown significance (VUS)”. A VUS is a biomarker that researchers currently don’t know if or how it affects cancer.
Below is an example of a results summary table.

<table>
<thead>
<tr>
<th>BIOMARKER</th>
<th>METHOD</th>
<th>ANALYTE</th>
<th>RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALK</td>
<td>NGS</td>
<td>RNA-Tumor</td>
<td>Fusion Detected</td>
</tr>
<tr>
<td></td>
<td>IHC</td>
<td>Protein</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>NGS</td>
<td>DNA-Tumor</td>
<td>Pathogenic Variant Exon 25</td>
</tr>
<tr>
<td>PD-L1</td>
<td>IHC</td>
<td>Protein</td>
<td>Positive, High Expression, TPS:50%</td>
</tr>
<tr>
<td>BRAF</td>
<td>NGS</td>
<td>DNA-Tumor Mutation</td>
<td>Not Detected</td>
</tr>
<tr>
<td>EGFR</td>
<td>NGS</td>
<td>DNA-Tumor Mutation</td>
<td>Negative</td>
</tr>
<tr>
<td>ROS1</td>
<td>NGS</td>
<td>RNA-Tumor Fusion</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>
What are the most common types of tests to check for biomarkers?

- **IHC (immunohistochemistry)** looks for levels of the protein PD-L1 and certain driver mutations, such as ALK and ROS1

- **FISH (fluorescence in situ hybridization)** looks for driver mutations in DNA, such as ALK, ROS1, and RET fusion (which means it joins with another gene)

- **NGS (next-generation sequencing)** looks for driver mutations in DNA and, or RNA

If your report doesn’t show any biomarkers with an available treatment, talk with your doctor. They may suggest more biomarker testing. Research is advancing quickly, so the treatments available for biomarkers may change over time.

What treatments are available based on my results?

If your test results show you have a biomarker, there are treatments that may work best, including:

- **Targeted therapy**, which treats cancer that has a driver mutation – it finds and attacks certain parts of cancer cells and the signals sent to cancer cells that cause them to grow uncontrolled

- **Immunotherapy**, which helps your immune system find and attack cancer cells with a certain level of the biomarker PD-L1

If your report shows more than one biomarker with an available treatment, talk with your doctor to decide on the best treatment plan.
To find treatments for cancers with your biomarkers:

1. Look for a section in your report with a heading that has any of these words:
   - Associated therapies
   - Therapy indications
   - Therapy implications
   - Therapeutic options

   This section will have a list of the available treatments. Some reports have this as a separate section and some list it in the results summary alongside the biomarker results.

2. For each available treatment, your report may tell you how well it works to treat cancer with your biomarkers. This may be called the “level of evidence”, “biomarker level”, or “evidence of benefit”. It is based on the results of research with the treatment.

   Look for these words to find treatments that have the most evidence that they work well for your biomarkers, based on research:
   - Benefit, beneficial, or increased benefit
   - Relevant
   - Evidence-based
   - Level 1 or Level 2, or Tier 1 or Tier 2

   Most doctors recommend level 1 treatments because research shows they may work best. Level 1 treatments are approved by the U.S. Food and Drug Administration (FDA).

   These words describe treatments that have less evidence for how well they work for your biomarkers, based on research:
   - Reduced benefit
   - Level 3 or Tier 3
Below is an example of a table showing available treatments:

The table shows examples of treatments available for biomarkers found in testing. It is not intended to show the most up-to-date treatment options.

<table>
<thead>
<tr>
<th>BIOMARKER</th>
<th>THERAPY ASSOCIATION</th>
<th>LEVEL OF EVIDENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALK</td>
<td>Therapy A</td>
<td>Level 1</td>
</tr>
<tr>
<td>PD-L1</td>
<td>Therapy B</td>
<td>Level 1</td>
</tr>
<tr>
<td></td>
<td>Therapy C</td>
<td>Level 2</td>
</tr>
<tr>
<td></td>
<td>Therapy D</td>
<td>Level 3A</td>
</tr>
</tbody>
</table>

**Therapy association**
Names of treatments that are available for cancer with the biomarker.

**Level of evidence**
How well the treatment will work for cancer with a certain biomarker. May also be called “biomarker level” or “evidence of benefit”.

**Level 1 & level 2**
Treatment that has the most evidence that it works well for a certain biomarker based on past research. May also be called “benefit”, “relevant”, or “evidence-based”.

**Level 3A**
Treatment has less evidence for how well it works for a certain biomarker. May also be called “reduced benefit”.
Are there clinical trials that I may be able to join?

Your report may include a section about clinical trials.

A clinical trial is a research study designed to learn how our bodies respond to medicines or other treatments. They help doctors find out if trial drugs are safe and if they can treat lung cancer.

You may want to consider a clinical trial if:

- There are no available, approved treatments for biomarkers you have
- There are approved treatments, but you could get a treatment that may work better in a clinical trial

Questions to ask your doctor

1. Has my cancer been tested for all biomarkers?
2. Did my test results show I have any biomarkers?
3. If my test results don’t show I have any biomarkers, what’s my next step?
4. How do we know if the results are accurate?
5. Is this testing the same as genetic testing for inherited cancer? Can I pass biomarkers on to my children?
6. Based on my results, how do we decide which treatment order is best for me?
7. If my results report shows I have a biomarker, how many drugs treat my type of cancer? Is one better than the other?
8. If my report does not list any available treatments, what are my next steps?
9. What will happen if the treatment stops working?
10. When should I be re-tested for biomarkers, because tumors change over time?
11 How can I get a copy of my results report?
12 Are there any clinical trials I could join?

Write the question numbers and their answers here

Created in partnership with:
Visit LUNGevity.org/educational-materials to learn more about biomarker testing in lung cancer and find other booklets in this series.

**Booklet 1**
Learn about biomarker testing and how it can help you get the best treatment for your specific lung cancer.

**Booklet 2**
Talk with your doctor about biomarker testing for lung cancer.

**Booklet 3**
How doctors test lung cancer for biomarkers: What to expect from a biopsy.

**Booklet 4**
Understand your treatment options.

Also available: comprehensive (more detailed) booklets:
- What you need to know about… biomarker testing
- What you need to know about… reading a biomarker test report

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Published March 2023