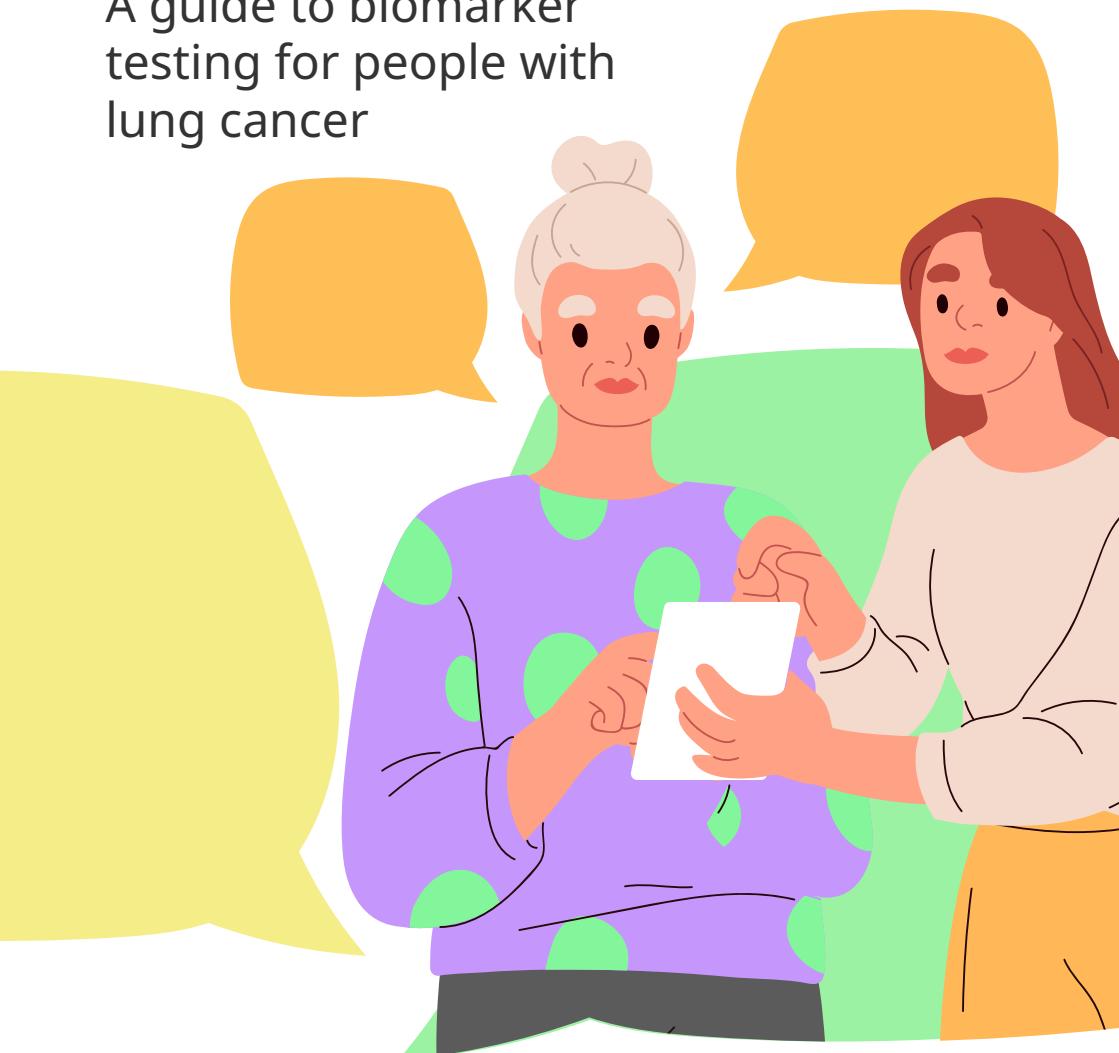


Talk Lung Cancer...

A guide to biomarker testing for people with lung cancer



Overview and aim

This brochure helps to summarise relevant information on biomarker testing and signposts additional resources should you wish to know more.

It is important for you and your doctor to have a complete picture of your lung cancer, so you can make informed decisions throughout your care – and that can start with biomarker testing for lung cancer. This brochure is intended to help you understand:



What biomarker testing is for lung cancer



What happens during the testing process and how long each stage takes



How biomarker testing might help you or your friends, family or loved ones

At the end of this brochure, you will find a **glossary** with definitions of key terms used in this brochure. Key terms have been highlighted in **green** at first mention. Please speak to your doctor if you are unsure about any of them.

You will also find a **notes** section at the end of the brochure. This is for you to record any important information or questions you would like to ask your doctor after reading the brochure.



Introducing biomarker testing

What is biomarker testing in lung cancer?

- **Biomarker testing** is an extra diagnostic test that analyses biomarkers in your lung cancer, to help you and your doctor understand more about your specific cancer.¹⁻³
- **Biomarkers** are characteristics of the body that can be measured.⁴ They can help your doctor identify a condition or disease. An example of a biomarker would be blood pressure, because this can be measured and tested for abnormalities.⁴ You can think of biomarkers like a target that can be 'aimed at' by certain medicines called **targeted treatments**.⁵

A note on terminology:

You may see biomarker testing referred to by other names, the most common being **genetic testing, genomic profiling/testing, molecular profiling/testing and tumour profiling/testing**. It is best to refer to this type of testing as 'biomarker testing' because it is most accurate.

Biomarker tests are different to tests that look for mutations you might have inherited from your family, such as **genetic testing for inherited mutations**, also called **germline mutations**.⁶ For a more comprehensive list of the different terms and their definitions, refer to the glossary on page 15.

If certain biomarkers are present (or absent), it might indicate if you will respond (or not respond) to certain treatments.⁷ In lung cancer, many biomarkers have been discovered and different patients will have different biomarkers.⁸

Examples of biomarkers include: BRAF, KRAS, HER2, PD-L1, RET, ALK, ROS1, MET, NTRK1 and EGFR.⁹⁻¹¹

What is the purpose of biomarker testing?

Whether you've just received a lung cancer diagnosis, or have had lung cancer for a while, biomarker testing could help you and your doctor:¹⁻³



Better understand your cancer

What is causing your lung cancer to occur.³

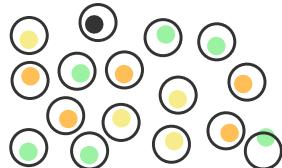
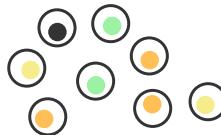


Better understand your treatment and care options

What treatment options are available to you and guide decisions about your care, including targeted treatments or selecting a **clinical trial** you may be able to join (see more information about this below).¹⁻³

What are the different types of tests to identify biomarkers?

There are three main tests, some detect a few biomarkers and others detect many biomarkers^{3,12-15}



Single biomarker tests can detect **one** target biomarker from one sample with one test.

Hotspot tests (also known as hotspot panels) can detect **some (≤ 50)** biomarkers from one sample with one test.

Comprehensive genomic profiling (CGP) can detect **many (> 50)** biomarkers from one sample with one test.

Different tests require different quantities of samples.¹⁶

What kind of biomarker testing is available to me?

If biomarker testing is appropriate for you, the type of test you have will depend on what's available in your local area. It's important to check with your doctor.

Why should I get tested?

Biomarker testing is a critical part of the treatment decision-making process and can help improve your lung cancer care.^{3,14,17-19} There are some benefits and considerations to bear in mind before you get tested:

Potential benefits	Potential considerations
<ul style="list-style-type: none">• A better understanding of your lung cancer, including what is making it spread and grow.³• Ability to predict how your cancer might respond to certain treatments.¹⁴• A more tailored care plan, which may be more effective (precision care).¹⁹• Opportunities to participate in clinical trials.²⁰• Opportunities to contribute to research for a better understanding of lung cancer and new or improved treatments.^{21*}	<ul style="list-style-type: none">• Waiting time for results.²²• Can require taking a tissue and/or blood sample.²³• May reveal inconclusive results.³

Specific tests or treatments may not be available in your area

**Note, it is up to you whether you choose to share your results or not*

If you are unsure, speak to your doctor about any considerations listed above.

The biomarker testing process

What takes place during biomarker testing?

1 Starting the conversation



Ordering a test

After you have received your lung cancer diagnosis, start the process by asking your doctor if biomarker testing would be helpful for you, and if so, if it is available to order.

2 Having a biomarker test



Collecting a sample

For your cancer to be tested, a small sample of **cancer cells** must be collected. This is called a **biopsy**.²³ You should have already had a biopsy to confirm your diagnosis. This sample can be used for biomarker testing but if there wasn't enough collected, your doctor may recommend an additional biopsy.^{16,24}

There are two types of samples that can be collected.¹⁶

- **Tissue** – a **tissue biopsy** involves taking a small piece of lung tissue or a piece of tissue from another cancerous site.^{23,25} There are a few ways to do this. The most common procedure is a **bronchoscopy**.²³ You may experience some pain or discomfort during this procedure, but you will be offered a sedative and given a local anaesthetic to avoid this. Then, your doctor will place a thin tube through your nose or mouth, down your throat and inside your airways, where small tools are used to remove a small sample of your lung cancer.²⁵ You may be offered alternative procedures called **needle biopsy**, **thoracoscopy** or **surgery**²⁵ – you can find out more about these tests in the glossary on page 15.

Liquid – a **liquid biopsy** involves taking a liquid sample which contains small pieces of genetic information from your cancer cells. The most common way to do this is by taking a sample of your blood through a simple blood draw.^{26,27}

Obtaining the results

2–4 weeks (tissue biopsy)^{22,28} 5–10 days (liquid biopsy)²⁸

You will likely need to travel to get a biopsy. Your doctor may be able to take the sample at the hospital or clinic you're visiting, or you may be referred to another hospital or clinic for the procedure.

Once agreeing on the most appropriate procedure, the doctor taking your sample should explain the procedure in more detail.



Laboratory analysis

Regardless of how the sample is collected, it will be sent to a laboratory for testing. Once the sample is received, a pathologist will prepare the sample. The genetic information will be extracted from the sample, then it will be tested to see if any biomarkers are present.^{12,20}

3

Receiving test results



Recording the results

The test results will be analysed and recorded in a report. The report might indicate if you have biomarkers or not.²⁹



Obtaining the results

The test results will then be sent to your doctor. It can take up to 2–4 weeks to receive results of a tissue biopsy and 5–10 days* for a liquid biopsy.²⁸ It is a good idea to ask your doctor for a copy of your report, if possible.



Discussing the results

You and your doctor can discuss the results and how they may help with your treatment plan. Discussions can also take place with a multidisciplinary team (MDT) of healthcare professionals that will work with you to develop an appropriate treatment plan.

4

Decision making using test results



Starting treatment (or other care options)

Depending on the results, you may be offered treatments already in clinical practice or a clinical trial. In some cases, results can be inconclusive.³ You should consider other options/possibilities with your doctor.

This process might be repeated if more sample is needed, or to monitor your lung cancer and make alterations to treatment if required.

**Note that the timeframes provided are in working days and are estimates only, so may change depending on your location.*

How can I get tested?

If you think you may be eligible for a biomarker test, speak to your doctor.

Your doctor will be the one to order the tests.



How long will the testing process take?

Overall, it can take 2–5 weeks from ordering a test to receiving results.^{22,28} However, it is important to note that these timings are estimates only and can vary greatly depending on where you live and other factors.

Additionally, there could be some delays in the testing process for different reasons, including:



Not enough sample – the sample taken during a biopsy is small so if there is an issue when testing it, there may not be enough sample left for further testing^{30,31}



Transporting samples – in some cases, samples may need to be sent to a different laboratory or hospital which can take time^{22,28}



Limited testing infrastructure and staff – some countries lack sufficient laboratory equipment or have shortages in laboratory staff which can cause delays^{31,32}



Insurance delays – if using health insurance, there can be delays when processing claims³¹

It is always best to discuss with your doctor about timings, so you understand what to expect.

Should I wait for the results of biomarker testing before starting treatment?

This is an important point to discuss with your doctor. It's a good idea to get as much biomarker information as possible before starting treatment, but your doctor may recommend chemotherapy or other ways to treat your cancer while you wait for your results.^{22,28}

After biomarker testing

When should I speak to my doctor?

Once results have been received by your doctor, you will be notified. An appointment may be made on your behalf, or you may have to arrange it yourself. It's important to discuss your results with your doctor. They can explain what the results mean for you and your treatment options, to allow you to determine the most appropriate care plan together.

For guidance on what questions to ask your doctor throughout the testing process, as well as how to get the most out of your consultation, see our brochure on [Frequently Asked Questions in Biomarker Testing](#).

Understanding your test results

What will my results look like?

If the biomarker tests have identified biomarkers from your sample of lung cancer, these will be listed on your report. The report may also list certain treatments that can target these biomarkers, but this isn't always the case.²⁰ Even if treatments are listed, they may not be suitable for you.

Additionally, in some cases, no biomarkers may be identified.³ So, it's best to discuss your treatment options with your doctor.

What do the results of my test mean for me?

For many people, results from biomarker testing can uncover more information about their lung cancer and help develop treatment plans that are specific to it.¹⁻³ Below are some care options that might open up to you based on your results.

Treatments



One or several targeted treatments may be available if your cancer has relevant biomarkers.⁸

About 7 in 10 people with non-small cell lung cancer (NSCLC) have at least one clinically-actionable biomarker¹⁸

Clinical trial



If no licensed treatments are available for the identified biomarkers, you may be eligible to join a clinical trial investigating specific treatments.²⁰

For people with NSCLC and no actionable biomarker, more than 86% are potentially eligible for a biomarker-associated clinical trial¹⁸

Why are targeted treatments important?



Targeted treatments can be beneficial for some people because they target biomarkers which can be found on cancer cells, but not on normal cells.³³ This means that they can be more effective and may have less side effects than traditional treatments, such as chemotherapy.^{17,34}



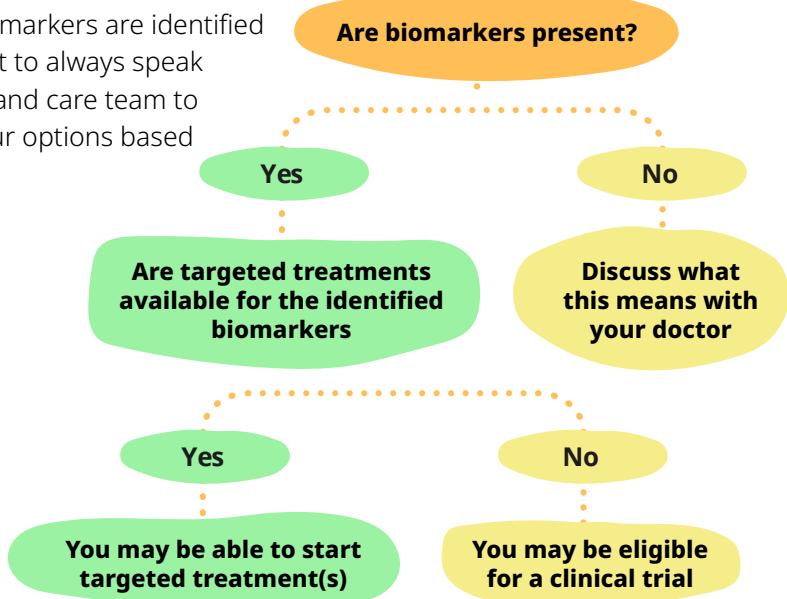
What happens if the results of my test are inconclusive?

In some cases, test results can be inconclusive. This means no biomarker has been identified, but other treatment options could be identified for you.³⁵

Scientists are working hard to discover new biomarkers, new treatments to target existing biomarkers or improving testing methods, to help more people with lung cancer receive the best possible treatment.³⁶ Getting tested regularly may help towards achieving this goal.⁴

Summary of potential next steps after receiving your test results

The next steps will depend on your lung cancer, your health status and what, if any, biomarkers are identified so it's important to always speak to your doctor and care team to understand your options based on your results.



What do the results mean for my family?

There is a common misconception that biomarker testing is the same as testing for mutations that may be inherited. This is called genetic testing for inherited mutations.⁶ Virtually all biomarkers that are helpful for making treatment decisions are not inherited.²⁰ This means it is very unlikely that the biomarkers identified can be passed down to family members.

Who can I speak to about my results?

Receiving so much information about your lung cancer can be overwhelming. Know that you are not alone. Speaking to your doctor can help you decipher and digest this information. Showing friends, family or loved ones this brochure can help them understand so they can better support you.

If you or your friends, family or loved ones require emotional support during this time, find more information on patient organisations offering support in your local area here: <https://www.lungcancereurope.eu/our-members>.

Glossary

Key term	Also known as...	Definition
Biopsy		<p>A procedure that removes a sample (tissue or cells) from the body for further examination. Biopsies are used to confirm a diagnosis of lung cancer and identify biomarkers.²³</p>
Biomarker	<ul style="list-style-type: none">• Molecular marker	<p>Characteristics of the body that can be measured.⁴ They help us to identify a condition or disease. An example of a biomarker would be blood pressure because this can be measured and tested for abnormalities.⁴ You can think of biomarkers like a target that can be 'aimed at' by certain medicines, called targeted treatments.⁵</p>
Biomarker testing	<ul style="list-style-type: none">• Genome sequencing• Genomic profiling• Genomic testing• Molecular profiling• Molecular testing• Next generation sequencing• Somatic testing• Tumour genetic testing• Tumour marker testing• Tumour subtyping• Tumour testing	<p>A laboratory test that looks for biomarkers from a tumour sample to determine what is causing the cancer to grow or spread.¹</p>
Bronchoscopy		<p>A procedure that allows a doctor to see the inside of your airways and remove a small sample of cells (biopsy).³⁷</p>

Key term	Also known as...	Definition
Cells		The basic structure of living things that makes up tissues in the body. ³⁸
Clinical trial	<ul style="list-style-type: none"> • Clinical study • Research study • Clinical research trial • Clinical research study 	A type of research study that tests how well new treatments or other medical approaches work in people. These studies test new methods of screening, prevention, diagnosis or treatment of a condition, like cancer. ³⁹
Comprehensive genomic profiling	<ul style="list-style-type: none"> • CGP 	A laboratory test that uses a single test to find multiple (>50) cancer biomarkers . ¹²
Genetic testing for inherited mutation	<ul style="list-style-type: none"> • Germline testing 	A laboratory test that looks for mutations that can be passed onto offspring (germline mutations) in a person who has been diagnosed with cancer. ⁶
Germline mutation	<ul style="list-style-type: none"> • Inherited mutation 	A change in a person's genetic information that can be passed down to offspring. ⁴⁰
Hotspot test	<ul style="list-style-type: none"> • Hotspot panel 	A laboratory test that uses a single test to find some (<50) cancer biomarkers . ⁴¹

Key term	Also known as...	Definition
Inhibitor		Any treatment that blocks the activity of certain molecules or processes, like biomarkers . ⁴²
Liquid biopsy		A procedure that takes a liquid sample, like blood, which contains small pieces of genetic information from lung cancer cells . ²⁶
Needle biopsy	<ul style="list-style-type: none"> • Transthoracic needle biopsy 	A procedure that involves inserting a small needle through the chest wall to obtain a small sample of cells or liquid. ⁴³
Precision care	<ul style="list-style-type: none"> • Personalised care 	An approach to cancer care that uses the genetic information of a person's cancer, to help diagnose, inform treatment or find out how well treatment is working. ⁴⁴
Single biomarker test		A laboratory test that can detect one target biomarker. ³
Somatic mutation	<ul style="list-style-type: none"> • Acquired mutation 	A change in a gene that can't be passed down to offspring. ⁴⁵

Key term	Also known as...	Definition
Surgery	<ul style="list-style-type: none"> Operation 	<p>A procedure to remove or repair a part of the body. This could be removing an entire tumour for biopsy.^{43,46}</p>
Targeted treatment	<ul style="list-style-type: none"> Targeted therapy 	<p>A type of treatment that uses drugs or other substances to identify and attack specific types of cancer cells, like biomarkers, with less harm to normal cells.⁴⁷</p>
Thoracoscopy	<ul style="list-style-type: none"> Video-assisted thoracoscopic surgery 	<p>A procedure in which a doctor makes a small cut in the skin of the chest wall and inserts a special instrument with a small video camera on the end to examine the lungs and inside of the chest, or take a sample of tissue (biopsy).⁴³</p>
Tissue		<p>A group of cells that work together to perform a special function.⁴⁸</p>
Tissue biopsy	<ul style="list-style-type: none"> Surgical biopsy 	<p>A procedure that takes a small amount of lung tissue so it can be analysed.²³</p>

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Notes/questions for your doctor

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Talk Lung Cancer has been developed by Janssen Pharmaceutica NV, with input from the following Patient Advocacy Groups and healthcare professionals.

