Talk Lung Cancer...



Overview

If you have lung cancer, it is important for you and your healthcare team to have a complete picture of your health so you can make informed decisions throughout your care – and that can start with biomarker testing.

This handbook aims to summarise relevant information on biomarker testing in lung cancer. It explains:

- · What biomarker testing for lung cancer is
- What happens during the testing process and how long it takes
- How biomarker testing might help you.

At the end of this handbook, you'll also find suggested questions you might like to ask your healthcare team, a notes section for you to record any helpful information, and a glossary of key terms.



Introducing biomarker testing

What are biomarkers?

Biomarkers, short for biological markers, are characteristics of the body that can be measured. They can be used to detect or monitor a feature of a disease, including cancer.¹

In lung cancer, biomarkers that might be measured are genetic changes to tumour cells – known as genetic mutations.^{2,3} Half of all non-small cell lung cancer patients are thought to have at least one such mutation in their tumour cells.²

What is biomarker testing in lung cancer?

Biomarker testing is an extra diagnostic test to identify if biomarkers are present in your lung cancer cells. This can give your healthcare team more information on what is causing your cancer to grow and spread.³

Examples of genetic mutation biomarkers that might be found in lung cancer cells include EGFR, ALK, MET, ROS1, BRAF, RET, NTRK1, KRAS, and HER2.³

A note on terminology...

You may see biomarker testing referred to by other names, the most common being genetic testing, genomic profiling/testing and tumour profiling/testing. See pages 9-11 for a full glossary.

What is the purpose of biomarker testing?3

Whether you've just received a lung cancer diagnosis, or have had lung cancer for a while, biomarker testing could help you and your healthcare team to:



Better understand what's causing your lung cancer to occur and grow.



Better understand your treatment and care options. For instance, if a genetic mutation is found in your lung cancer cells, your doctor may be able to prescribe a treatment that can specifically target it.

What does biomarker testing involve?

Typically, biomarker testing involves removing a sample of tissue from your lung cancer tumour through a biopsy, or taking a sample of blood, and testing it in a laboratory.³

What could biomarker testing mean for my family?^{5,6}

There is a common misconception that biomarker testing is the same as testing for inherited mutations.

But the most common biomarkers that are helpful for making treatment decisions about lung cancer are *not inherited* – which means it's very unlikely biomarkers identified can be passed down to your family.

There are also different ways this sample can be tested for biomarkers. Some tests are designed to detect one type of mutation in one gene, while more complex tests – such as next generation sequencing (NGS) – can detect several different mutations.⁴

What kind of biomarker testing is available to me?

Your oncologist will be able to explain what types of biomarker testing might be available to you. It is free on the NHS if you've been referred for it by a specialist.⁷

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.

Here are some benefits and considerations to bear in mind before you decide to get tested. If you're unsure, speak to your healthcare team about any considerations you might have.

Potential benefits	- Considerations
A better understanding of your lung cancer, including what is making it spread and grow. ³	It may take some time to get the results. ⁴
Ability to predict how your cancer might respond to certain treatments.8	It usually requires taking a tissue or blood sample.
A more tailored care plan that could include the use of targeted treatments. ³	There is no guarantee that biomarker testing will help your healthcare team to make decisions about your treatment.
Opportunities to participate in clinical trials. ³	
Opportunities to contribute to research that may help lung cancer patients in the future.	

The biomarker testing process

1 Starting the conversation

After you have received your lung cancer diagnosis – or even if you were diagnosed some time ago – start the process by asking your healthcare team if biomarker testing would be helpful for you, and if so, if it is available on the NHS.

2 Collecting your sample

If you're eligible and want to proceed, a sample will be taken either via a tissue biopsy or a liquid biopsy.

- A tissue biopsy is the most common method, and involves retrieving a sample of tissue from your lung, either via a bronchoscopy (where a small tube goes through your mouth or nose and down into your lungs) or a needle biopsy. 9,10
- A liquid biopsy is less invasive than a tissue biopsy and is becoming more common. It involves taking a sample of fluid from your body – usually blood from a vein using a needle.
 Because it requires high levels of circulating tumour DNA in the blood, not every lung cancer patient is suitable for a liquid biopsy.⁹





3 Laboratory analysis

Regardless of how the sample is collected, it will be sent to a laboratory for testing. Experts will extract genetic information from the sample, then it will be tested to see if any biomarkers are present.³

4 Waiting for results

Once analysis is complete, the laboratory staff will send a clinical report to your healthcare team, who will contact you once they've had time to digest the findings. The time this takes depends on the type of test, but it's usually three to four weeks.³

5 Discussing your results

You and your healthcare team will typically sit down and discuss the results and how they may help with your treatment plan. You can ask for a copy of the report sent from the laboratory if you wish.

6 Next steps

Depending on the results of your biomarker testing, you may be offered targeted treatments already approved for use, or informed about a clinical trial that could benefit you.

Remember...

There are no guarantees biomarker testing will provide information that can alter your treatment plan – so try to keep an open mind.

And, if you're finding it overwhelming receiving so much information, it may be helpful to show your loved ones this handbook, or ask your healthcare team for psychological support.

Questions to ask your healthcare team

Below are some suggested questions to ask your healthcare team to help you navigate the biomarker testing process. It's important to note that this is not an exhaustive list – feel free to choose the questions that are relevant to you or to ask questions that aren't included.

- Am I suitable for biomarker testing and if so, what tests are available to me?
- What specifically will you be testing me for?
- What happens during the biomarker testing process and how long will it take?
- Is the procedure invasive or painful?
- Will I need a general anaesthetic?
- Will it involve extensive travelling, or can I have it done at my usual hospital?
- Can I bring someone with me to the biomarker test?
- What is the recovery process after the test?
- Are there side effects to the testing process?
- How long do I have to wait for results?
- · How will I be informed of the results?
- Can I start treatment before my results are back?
- · What kind of information is the test result likely to give me?

Glossary

Key term	Also known as	Definition
Biomarker	Molecular marker Biological marker	Characteristics of the body that can be measured, which can be used to detect or monitor a feature of lung cancer. ¹
Biomarker testing	Genomic/genome/genetic profiling Genomic/genome/genetic testing Molecular testing Molecular profiling Somatic testing Tumour testing Tumour profiling	An extra diagnostic test to identify if biomarkers are present in your lung cancer cells.
Biopsy		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. 9,11
Bronchoscopy		A procedure where a small tube goes through your mouth or nose and down into your lungs, to allow a doctor to see the inside of your airways. It's often conducted to perform a biopsy. 10
Clinical trial	Clinical study Medical research	A type of research that involves testing medicines to evaluate their impact on human health, including how new treatments work, whether they have manageable side effects, and how they compare to existing treatment options. 12,13

Key term	Also known as	Definition
Genetic mutations	Genetic alterations Genetic variants	Specific changes that may happen to cells in your body, which can stop the cells working normally. ¹⁴
Hotspot test	Hotspot panel	A laboratory test that uses a single test to find multiple existing cancer biomarkers. ¹⁵
Inherited mutation	Germline mutation Hereditary mutation	A genetic mutation that can be passed down from parent to child. 14
Liquid biopsy		A process for taking a sample of fluid from the body, often blood, to extract and examine cells. ^{3,9}
Needle biopsy	Fine-needle aspiration biopsy Core needle biopsy	A procedure that uses a needle to take tissue samples from tumours that are below the surface of the skin. ¹⁶
Next generation sequencing (NGS)		A more complex biomarker testing method than hotspot testing, which looks at many more potential genetic alterations in up to several hundred genes. ¹⁵
Precision medicine	Precision care Personalised medicine	A healthcare approach that uses the genetic information of a person's cancer to help provide targeted treatments. 17
Single biomarker test		A laboratory test that can detect one target biomarker.

Key term	Also known as	Definition
Somatic mutation	Acquired mutation	A genetic mutation that happens in a person's lifetime, such as by chance, lifestyle or environment, that isn't inherited from family members. ¹⁴
Targeted treatment	Targeted therapy Precision therapy	A type of treatment that can identify a specific biomarker – such as a genetic mutation – and target it to help stop cancer cells growing. ³
Tissue biopsy	Surgical biopsy	A process for retrieving a sample of tissue to examine cancer cells, usually via a bronchoscopy or a needle biopsy. 9



Notes	
	•

References

- The Institute of Cancer Research. Biomarkers.
 Available at https://www.icr.ac.uk/our-research/about-our-research/research-themes/biomarkers. Last accessed November 2024
- Baumgart M. New Molecular Targets on the Horizon in Non-Small Cell Lung Cancer. Am J Hematol Oncol. 2015;11:10-13.
- Roy Castle Lung Cancer Foundation. Biomarker testing in lung cancer. Available at https://roycastle.org/app/uploads/2023/03/Biomarker-testing-in-lung-cancer-5-2022.pdf. Last accessed November 2024.
- Pennell NA, Arcila ME, Gandara DR, West H.
 Biomarker Testing for Patients With Advanced Non-Small Cell Lung Cancer: Real-World Issues and Tough Choices. Am Soc Clin Oncol Educ Book. 2019:39:531-542.
- Akita T, Ariyasu R, Kakuto S, Miyadera K, Kiritani A, Tsugitomi R, Amino Y, Uchibori K, Kitazono S, Yanagitani N, Tasaka S, Nishio M. Distinction of ALK fusion gene- and EGFR mutation-positive lung cancer with tumor markers. *Thorac Cancer*. 2024;15(10):788-796.
- All you Need is Lungs. Home. Available at https://www.allyouneedislungs.org.uk.
 Last accessed November 2024.
- NHS. Genetic and genomic testing. Available at https://www.nhs.uk/conditions/genetic-and-genomic-testing. Last accessed November 2024.
- The Institute of Cancer Research. Use of biomarkers in cancer research and treatment. Available at https://www.icr.ac.uk/about-us/policy-and-engagement/use-of-biomarkers-in-cancer-research-and-treatment. Last accessed November 2024.
- EGFR Positive. What is EGFR? Available at <u>https://www.egfrpositive.org.uk/about-egfr</u>. Last accessed November 2024.
- Cancer Research UK. Bronchoscopy. Available at https://www.cancerresearchuk.org/about-cancer/tests-and-scans/bronchoscopy. Last accessed November 2024.

- Modi P, Uppe A. Lung Biopsy Techniques and Clinical Significance. In: StatPearls. Treasure Island (FL): StatPearls Publishing; January 2024.
- World Health Organization (WHO). Clinical trials. Available at https://www.who.int/health-topics/clinical-trials. Last accessed November 2024.
- Cancer Research UK. What are clinical trials?
 Available at
 https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are.
 Last accessed November 2024.
- Macmillan Cancer Support. Acquired and inherited cancer gene variants. Available at https://www.macmillan.org.uk/cancer-information-and-support/worried-about-cancer/causes-and-risk-factors/genes-and-cancer. Last accessed November 2024.
- ASCO Connection. Hotspot Testing Versus Next-Generation Sequencing for NSCLC. Available at https://connection.asco.org/magazine/current-controversies-oncology/hotspot-testing-versus-next-generation-sequencing-nsclc.
 Last accessed November 2024.
- NHS. Biopsy: How it is performed. Available at https://www.nhs.uk/conditions/biopsy/what-happens. Last accessed November 2024.
- Manchester Cancer Research Centre.
 Experimental and Precision Cancer Medicine.
 Available at
 https://www.mcrc.manchester.ac.uk/research/research-themes/experimental-and-precision-cancer-medicine. Last accessed

 November 2024.

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















