

Understanding non-small cell lung cancer (NSCLC)

A patient's guide to comprehensive
biomarker testing

Advocacy Partners:

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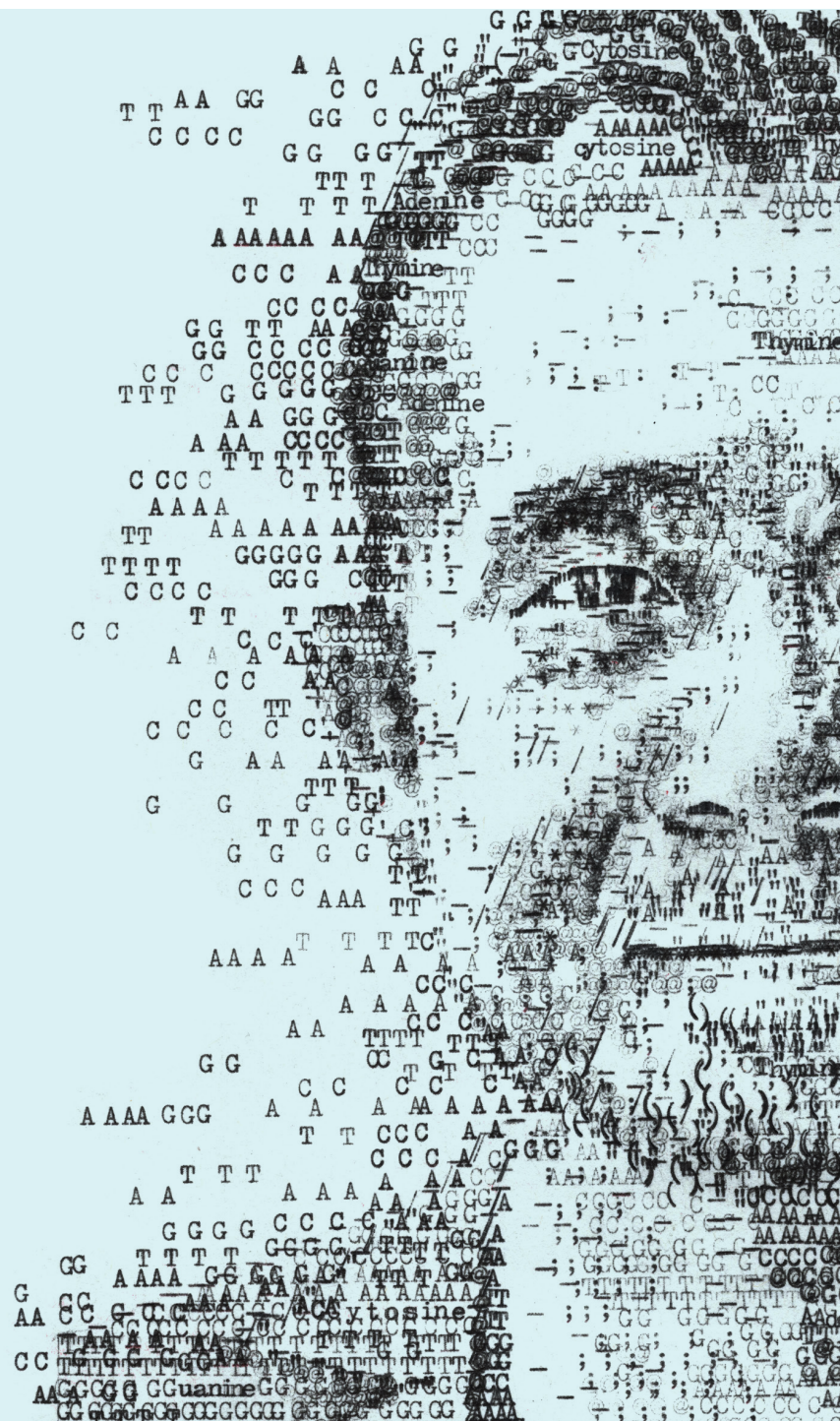
Lung Cancer Research Foundation

Contents

This booklet talks about why biomarker testing is important in non-small cell lung cancer (NSCLC) and how it is performed. Read this booklet to understand what biomarker testing means for your diagnosis and talk with your healthcare team.

Complete the Biomarker Information Sheet with your doctor to help you keep track of key information from your testing and what it means for your treatment plan.

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Glossary of common terms

Biomarker terms

BIOMARKER

A naturally occurring molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease, such as cancer.¹

DNA

The molecule inside cells that contains information about genes. DNA is made up of a double-stranded helix of nucleotide base pairs: adenine (A), thymine (T), guanine (G), and cytosine (C).¹

DRIVER MUTATION

A mutation that causes cancer growth. Cells with a driver mutation can be very sensitive to targeted therapy against that mutation.¹

GENE MUTATION

Changes that happen in genes that can affect how cells normally work; they can cause cells to grow out of control and become cancerous.¹

Biomarker testing

BIOPSY

A medical procedure where a small amount of tumor tissue or fluid is removed from your body and tested to find out about a disease.²

COMPREHENSIVE BIOMARKER TESTING

Testing for multiple tumor biomarkers in different cancer-related genes. Your doctor may also refer to this as 'broad molecular profiling' or 'broad-panel testing'.^{2,3}

NEXT GENERATION SEQUENCING (NGS)

A type of comprehensive biomarker testing that enables detection of cancer mutations using tumor tissue or blood.²

SINGLE-GENE TESTING

Testing for mutations in only one gene.⁴

Staging and treatments

CLINICAL TRIAL

A study to determine if a new treatment is safe and/or effective for patients.¹ Also called clinical study.¹

DISEASE STAGING

A test to see the size of the cancer in the body, and whether the cancer has spread to other parts of the body from where it first formed.¹

TREATMENTS:

CHEMOTHERAPY

Chemotherapy is a type of cancer treatment that uses drugs to kill or stop the growth of cancer cells.² Many different chemotherapy drugs are available and may be used alone or together with other treatments.¹

IMMUNOTHERAPY

A type of cancer treatment that stimulates your immune system to recognize and attack cancer cells.¹

TARGETED THERAPY

A type of cancer treatment that targets the gene mutations in cancer cells that help them grow, divide, and spread.¹

1. NCI. Dictionary of Cancer Terms. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms>. Accessed July 2022; 2. LUNGeVity. Biomarker Testing. Available at: www.lungevity.org/for-patients-caregivers/navigating-your-diagnosis/biomarker-testing. Accessed July 2022; 3. Breastcancer.org. Broad Molecular Profiling Tests. Available at: <https://www.breastcancer.org/screening-testing/molecular-profiling>. Accessed July 2022; 4. Centers for Disease Control and Prevention. Genetic Testing. Available at: https://www.cdc.gov/genomics/gtesting/genetic_testing.htm#:~:text=Single%20gene%20testing,dystrophy%20or%20sickle%20cell%20disease. Accessed July 2022.

A background on biomarkers

WHAT IS A BIOMARKER?



A biomarker is a molecule or gene mutation that can be measured in the tumor tissue or blood and gives information about your disease.¹ Key lung cancer biomarkers are shown in the figure below.²

WHAT ARE THE TESTS CALLED?



Biomarker testing can also be referred to as:^{3,4,5}

- Broad molecular profiling
- Comprehensive biomarker testing
- Molecular testing
- Next-generation sequencing

WHAT SAMPLES ARE USED FOR TESTING?



Tumor tissue sample

A sample of the tumor tissue is collected for testing, this is known as a tissue biopsy.³

Blood sample

A sample of blood is drawn and tested using a liquid biopsy.³

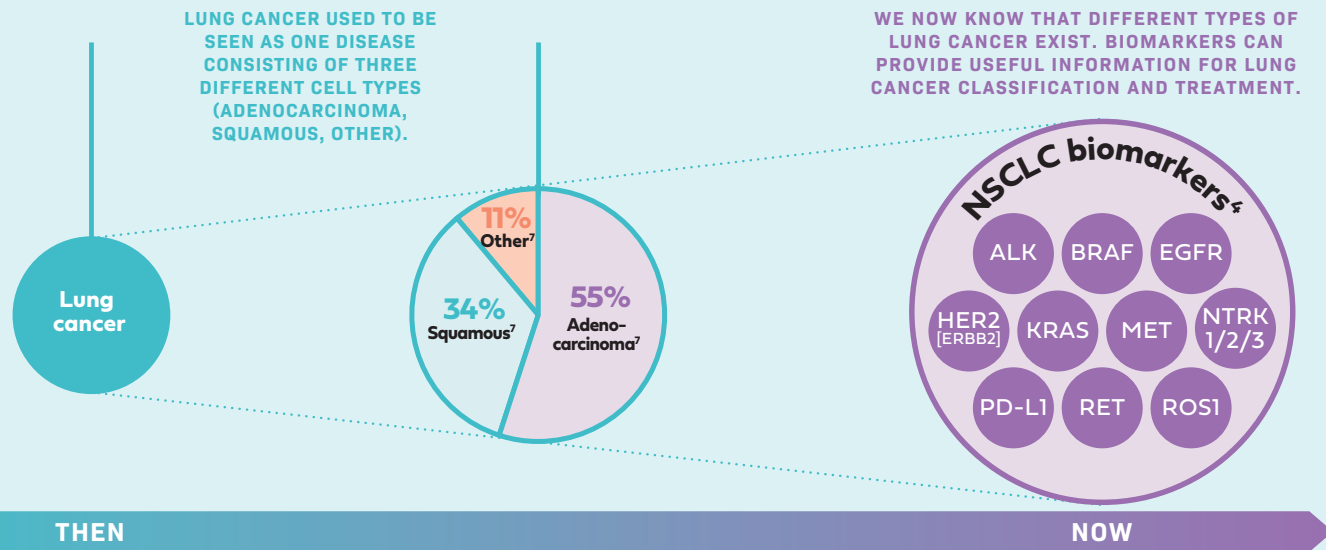
WHAT CAN TESTING SHOW?



Testing for biomarkers can help your doctor provide a treatment that may be right for you. Biomarker test results may take up to 4 weeks depending on which test is ordered.⁶ Sometimes, it is important to wait for biomarker testing results before treatment is started.⁶

Key biomarkers in NSCLC

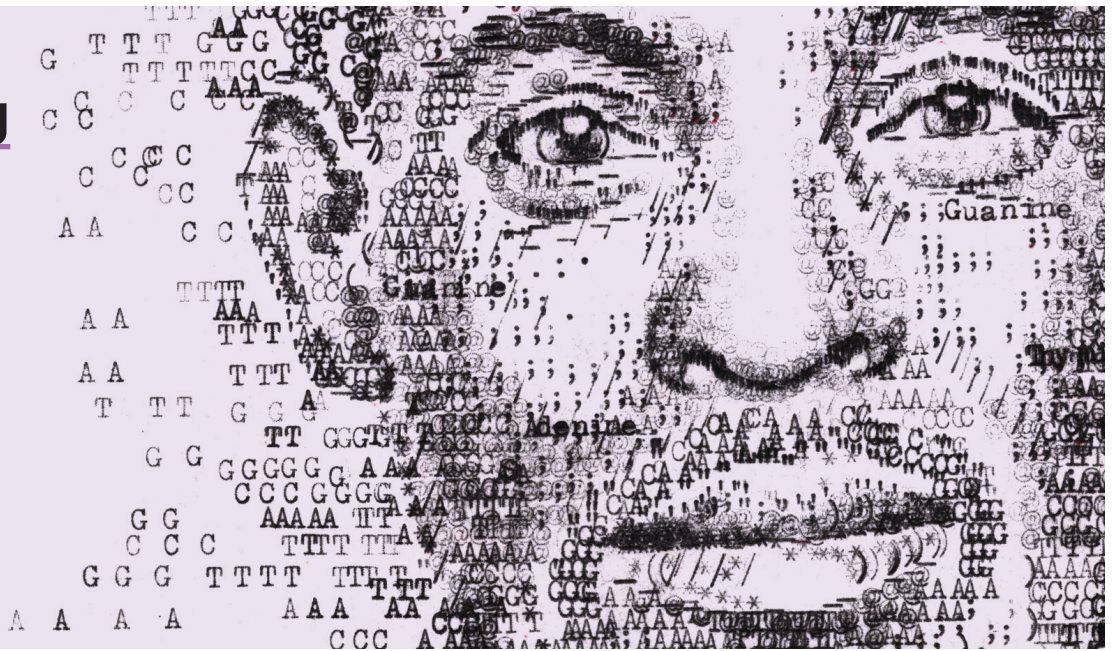
Our understanding of lung cancer has increased significantly over the past 2 decades.⁷



ALK: Anaplastic lymphoma kinase; BRAF: B-Raf proto-oncogene; EGFR: epidermal growth factor receptor; ERBB2: Erb-B2 receptor tyrosine kinase 2; KRAS: Kirsten rat sarcoma virus; MET: MET proto-oncogene; NTRK: neurotrophic tyrosine receptor kinase; PD-L1: programmed death-ligand 1; RET: RET proto-oncogene; ROS1: ROS Proto-Oncogene.
 1. NCI Dictionary of Cancer Terms. www.cancer.gov/publications/dictionaries/cancer-terms/def/biomarker. Accessed: January 2022; 2. Skoulidis F and Heymach JV. Nat Rev Cancer. 2019;19(9):495–509. 3. LUNGevity. Biomarker Testing. Available at: www.lungevity.org/for-patients-caregivers/navigating-your-diagnosis/biomarker-testing. Accessed July 2022; 4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.3.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed June 6th, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way; 5. Smeltzer M et al. J Thorac Oncol 2020; 15(9): 1434–1448; 6. Cancer.Net. What to Know About Biomarker Testing for Lung Cancer: An Expert Q&A. Available at: <https://www.cancer.net/blog/2022-06/what-know-about-biomarker-testing-lung-cancer-expertqa#:~:text=However%2C%20even%20in%20this%20case%2C%20testing%20will%20still,the%20sample%20has%20been%20sent%20to%20another%20facility>. Accessed July 2022; 7. Li T et al. J Clin Oncol. 2013;31(8): 1039–49.

Why is biomarker testing so important?

There are different types of NSCLC. The type of biomarkers are one way that your tumor is described. Therefore, comprehensive biomarker testing is an important step for determining your specific type of lung cancer and what treatment you may be eligible to receive.



Your healthcare team may carry out the following steps when diagnosing and treating your lung cancer:



SYMPTOMS AND EVALUATION

You and your doctor should discuss and evaluate changes in your health. Procedures could include: talking about your health history, physical examination, labs or bloodwork, imaging (such as X-rays or CT scans), and biopsy.



DIAGNOSIS AND STAGING

Diagnosing lung cancer is typically done using tumor tissue.

Staging determines the size of cancer, if it has spread, and where.



BIOMARKER TESTING

Biomarker testing looks for specific biomarkers in the cancer to determine which type of NSCLC you have.

Biomarker testing is used to determine the optimal treatment for you.



TREATMENT

Depending on the information your doctor collects (including the results of biomarker testing), treatment for lung cancer may include surgery, radiation, targeted therapy, chemotherapy, immunotherapy, or more than one type of therapy.

Patients may receive a new treatment when participating in a clinical trial.



ONGOING MONITORING

Monitoring may include: symptom management; side-effect management; and watching to see if the cancer is under control, which may include biopsy, imaging or blood work.

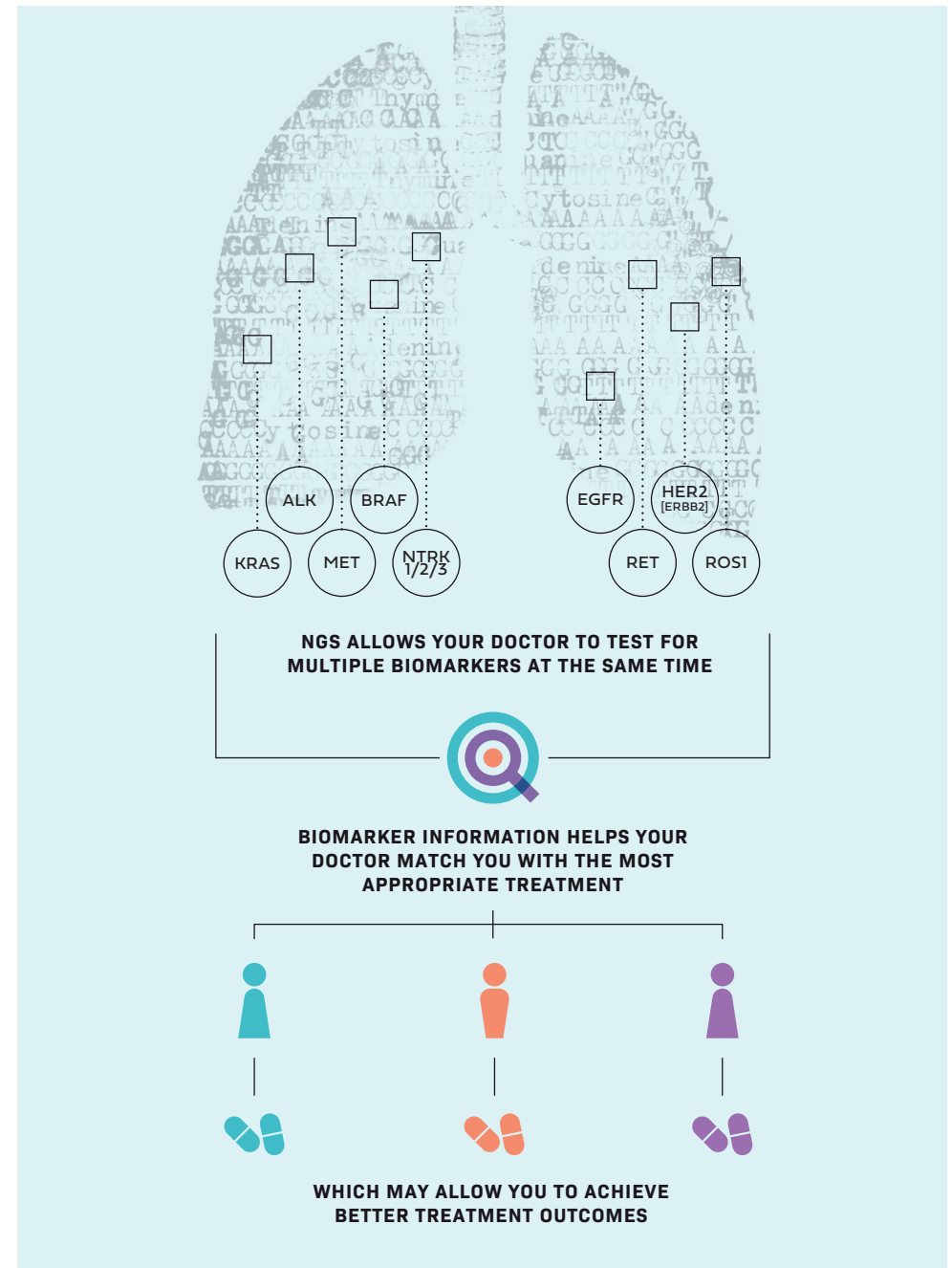
How can comprehensive biomarker testing guide my treatment?

Comprehensive biomarker testing is recommended by clinical guidelines. It allows your doctor to test for all biomarkers that can inform your treatment.

The type of biomarker test you receive matters, as it affects how much information you and your doctor can find out about lung cancer.² Given the number of targeted treatments available for lung cancer, it is important to know the biomarker test results before starting treatment.

Comprehensive biomarker testing can be done with Next-Generation Sequencing (NGS).¹ With NGS, multiple biomarkers can be tested at the same time, with the same tissue or blood sample.^{2,3} In addition, your doctor will likely order a different type of test* to detect PD-L1. The results of these biomarker tests will help your doctor determine the best treatment options for you.

Comprehensive biomarker testing, including NGS¹, provides you and your doctor with a more complete picture of your lung cancer to help find the treatment that may be right for you.

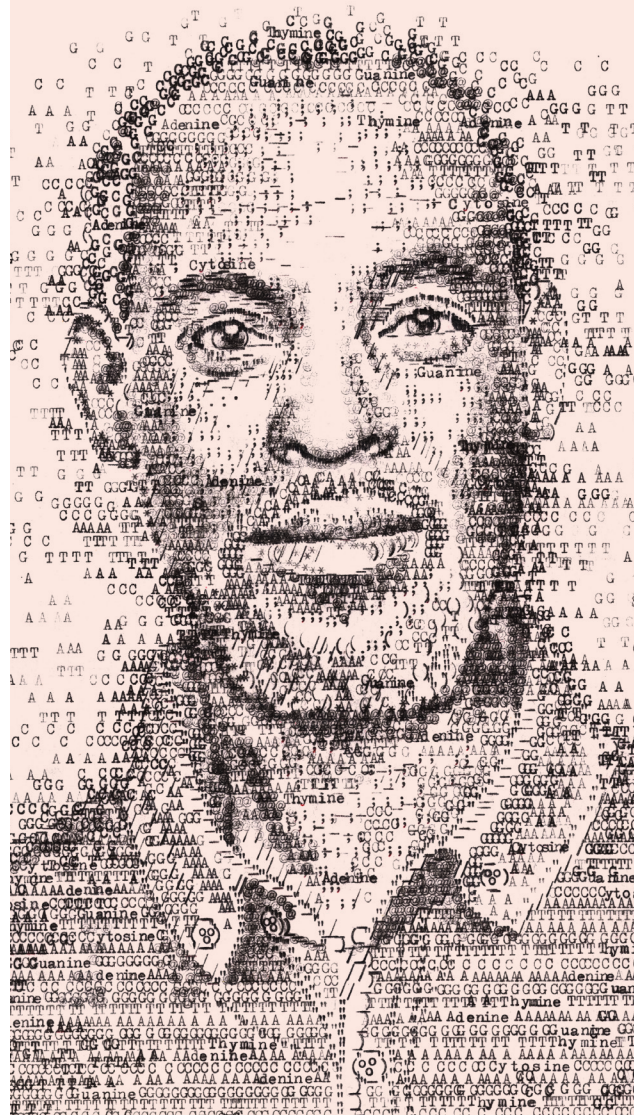


*PD-L1 expression level is determined by IHC, not NGS.

ALK: Anaplastic lymphoma kinase; BRAF: B-Raf proto-oncogene; EGFR: epidermal growth factor receptor; ERBB2: Erb-B2 receptor tyrosine kinase 2; KRAS: Kirsten rat sarcoma virus; MET: MET proto-oncogene; NGS: next generation sequencing; NSCLC: non-small cell lung cancer; NTRK: neurotrophic tyrosine receptor kinase PD-L1: programmed death-ligand 1; RET: RET proto-oncogene; ROS1: ROS Proto-Oncogene.

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.3.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed June 6th, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way; 2. LUNGeVity. Biomarker Testing. Available at: www.lungevity.org/for-patients-caregivers/navigating-your-diagnosis/biomarker-testing. Accessed July 2022; 3. Pennell NA, et al. JCO Precis Oncol. 2019;3:1-9.

Six questions to ask about biomarker testing



Keep these questions on hand to help guide your conversation with your doctor:

1. What type of biomarker testing will be performed? Check all that apply.

<input type="checkbox"/>	Comprehensive biomarker test (NGS)	<input type="checkbox"/>	Single-gene test
<input type="checkbox"/>	PD-L1 test		

2. What sample will be tested? Check all that apply.

<input type="checkbox"/>	Tumour tissue	<input type="checkbox"/>	Blood
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3. What biomarkers will be tested?

4. How long will it take to get the results?

5. What if no biomarkers are detected?

6. If biomarker testing is not done, can you tell me why? What will happen next?

Understanding your biomarker results

It is important to find out as much as you can about the results of your comprehensive biomarker tests, so you and your doctor can make decisions about your care together.



Biomarker test results are provided in a report that lists biomarkers that were tested for, and any that were found.¹



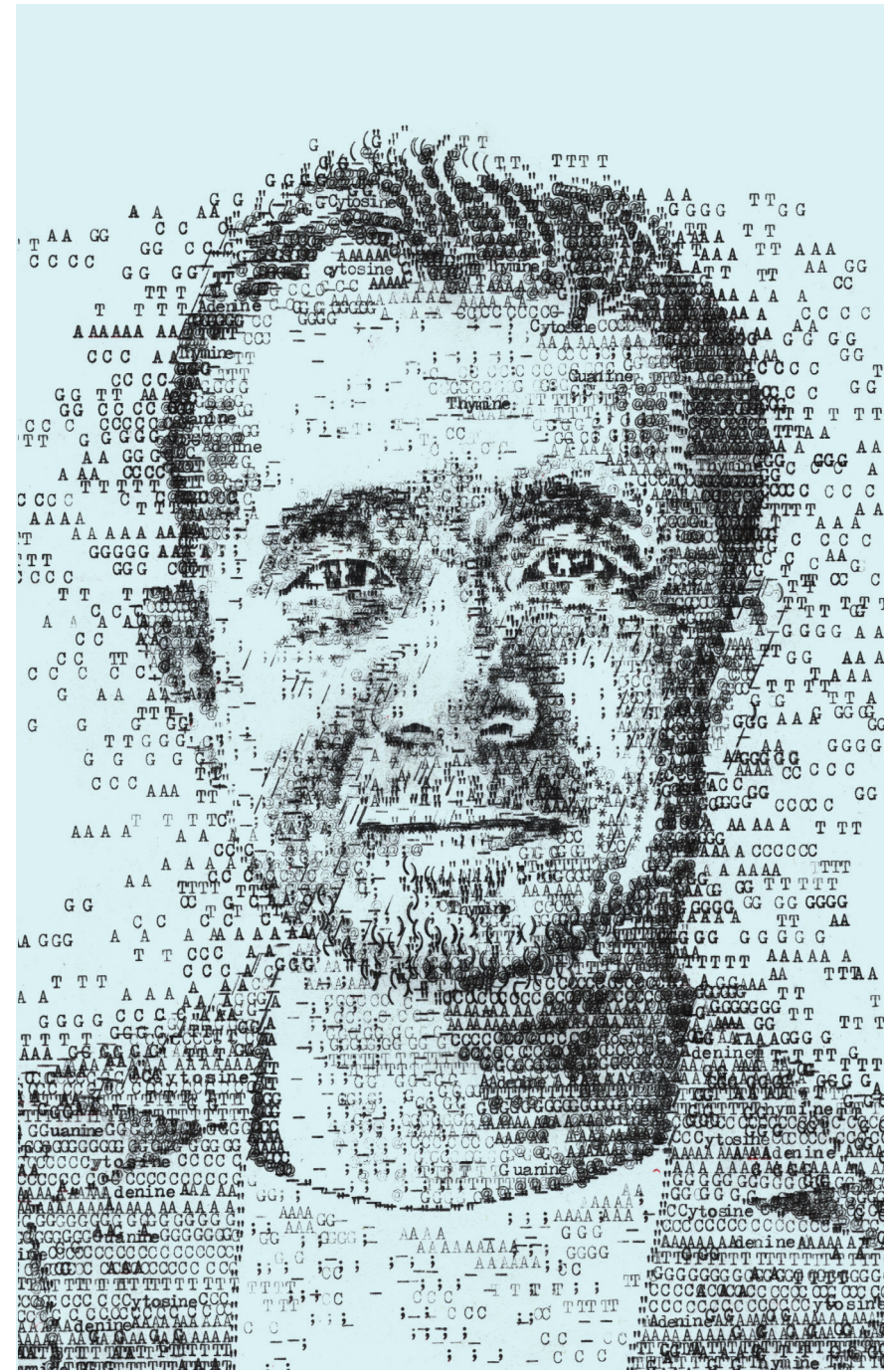
Reports may include recommendations for FDA-approved therapies that are associated with specific biomarkers.¹



Clinical trials for which you may be eligible could also be included in the report.¹ Discuss your treatment options and clinical trial participation with your doctor (see Page 9).

See page 7 for some questions to ask your doctor when discussing your treatment plan.

You and your doctor will decide the best approach for your treatment plan²
Ideally, biomarker testing is performed before a treatment is selected.^{2,3}
However, your doctor may recommend starting treatment before your biomarker test results are available.^{3,4}



NGS: next generation sequencing

1. Pennell NA, et al. Am Soc Clin Oncol Educ Book 2019;39:531–542; 2. LUNGEVITY: Biomarker testing can help you get the best treatment for your specific lung cancer. December 2021; 3. Cancer.Net. What to Know About Biomarker Testing for Lung Cancer: An Expert Q&A. Available at: <https://www.cancer.net/blog/2022-06/what-know-about-biomarker-testing-lung-cancer-expert-q-a#:~:text=However%2C%20even%20in%20this%20case%2C%20testing%20will%20still,the%20sample%20has%20been%20sent%20to%20another%20facility>. Accessed July 2022; 4. Mileham K et al. Cancer Med 2022; 11(2): 530–538.

My biomarker information sheet

Fill this in to help you keep track of key information about your biomarker test results and next steps.

MY DOCTORS' NAME AND CONTACT DETAILS

Primary care practitioner

.....

.....

Pulmonologist

.....

.....

Oncologist

.....

.....

What specific type of NSCLC do I have?

<input type="checkbox"/> Adenocarcinoma	<input type="checkbox"/> Squamous-cell carcinoma
<input type="checkbox"/> Large-cell carcinoma	<input type="checkbox"/> Other

What type of biomarker test was performed? Check all that apply.

<input type="checkbox"/> Comprehensive biomarker test (NGS)	<input type="checkbox"/> Single-gene test
<input type="checkbox"/> PD-L1 test	

KEY BIOMARKER RESULTS

Were any biomarkers identified?

<input type="checkbox"/> ALK	<input type="checkbox"/> BRAF	<input type="checkbox"/> EGFR	<input type="checkbox"/> HER2 (ERBB2)	<input type="checkbox"/> KRAS
<input type="checkbox"/> MET	<input type="checkbox"/> NTRK1/2/3	<input type="checkbox"/> PD-L1	<input type="checkbox"/> RET	<input type="checkbox"/> ROS1
<input type="checkbox"/> Other	Specify here:			

Do I need additional biomarker testing? Yes No

If yes why?

.....

HOW DO THE RESULTS AFFECT MY TREATMENT PLAN?

Are there any treatments that target my lung cancer? Yes No

If yes, which treatments?

.....

Do I qualify for any clinical trials? Yes No

If yes, which clinical trials?

.....

Useful support resources



AMERICAN CANCER SOCIETY

A nationwide, community-based voluntary health organization dedicated to eliminating cancer as a major health problem.

cancer.org
800-227-2345



CANCERcare®

Over 75 Years of Help and Hope

CANCERCARE

The leading national organization providing free, professional support services and information to help people manage the emotional, practical and financial challenges of lung cancer.

cancer.org/diagnosis/lung_cancer
Hopeline 800-813-HOPE (4673)



GO2 FOUNDATION FOR LUNG CANCER

Founded by patients and survivors, GO2 Foundation for Lung Cancer, transforms survivorship as the world's leading organization dedicated to saving, extending, and improving the lives of those vulnerable, at risk and diagnosed with lung cancer. GO2 Foundation offers many free services and provides referrals to help you and your family on your cancer journey.

To learn more, visit **support@go2foundation.org** or call our HelpLine at **800-298-2436**



LUNGEVITY

Changing outcomes for people affected by lung cancer through research, education and support.

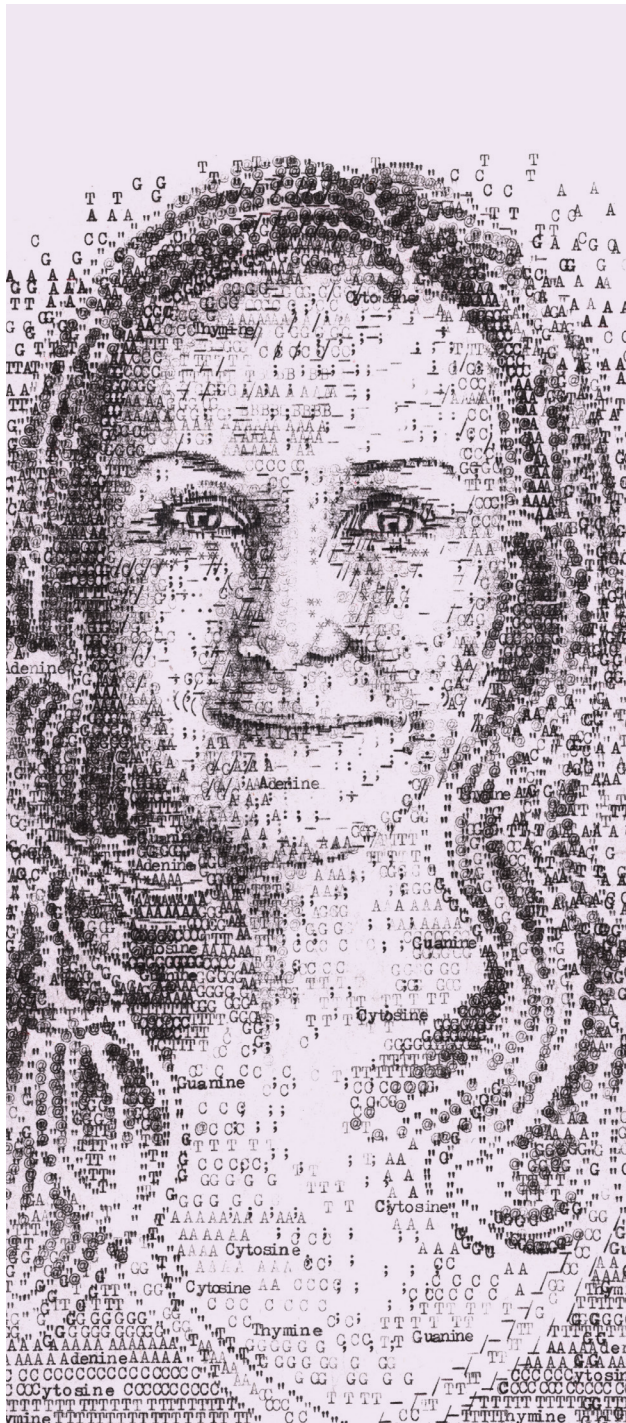
lungevity.org
Lung Cancer HELPLine
844-360-5864



LUNG CANCER RESEARCH FOUNDATION

An organization that aims to improve lung cancer outcomes by funding research.

lungcancerresearchfoundation.org
844-835-4325



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