DELFI Diagnostics

Next-Generation Liquid Biopsy Platform, Early Experience Program

DELFI is developing a new class of liquid biopsy tests to aid early detection and monitoring based on altered genome-wide fragmentation profiles, also known as "fragmentomes," representing aberrant packaging of DNA in cancer cells. By applying advanced machine learning algorithms, DELFI can detect these fragment patterns at a very low sequencing cost.

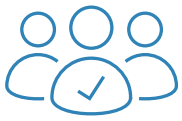
DELFI's first product is designed to enhance lung cancer screening.
We are working with health systems to make this innovative test available to patients.
See next page for more information.

DELFI

Lung Cancer Screening

Lung cancer screening represents a significant unmet need[1]

Lung cancer is the **#1** cause of cancer death among men and women in the United States[2]



15.1 million people eligible for screening[3]

Fewer than 5% get screened[4]

Early stage detection can lead to potentially curative options[5]

Lung cancer screening has been shown to reduce lung cancer deaths and all-cause mortality[6]

National Lung Cancer Screening Trial

Randomized trial results

Lung cancer mortality benefit of **20%**

All-cause mortality reduction of **6.7%**

Increased Access, Durable Advantages

Compared to legacy liquid biopsy technologies, DELFI's platform is:

- **More accessible across socioeconomic groups**
- **Easier to execute and distribute across geographies**
- **Covers entire genome to comprehensively identify cancer and its origin**
- **Achieving high sensitivity for early stage disease[7]**

Fragmentomics Spurred by Robust Science

DELFI is collaborating with Johns Hopkins School of Medicine on novel liquid biopsy tests that demonstrate high performance for the early detection of cancer.

While legacy approaches look for alterations of DNA sequence, focal methylation patterns, or protein levels in narrow regions of the genome, DELFI uses whole genome sequencing, and is not affected by confounding conditions such as CHIP, medications, or inflammatory conditions.

1.NLST Research Team. Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. N Engl J Med 2011; 365:395-409. 2.NIH National Cancer Institute. Cancer Stat Facts: Common Cancer Sites. 3.Meza R, Jeon J, Toumazis I, et al. Evaluation of the benefits and harms of lung cancer screening with low-dose computed tomography: modeling study for the US Preventive Services Task Force. JAMA. 2021;325(10):988-997. doi:10.1001/jama.2021.1077 4.NIH National Cancer Institute. Cancer Stat Facts: Common Cancer Sites. 5.US Preventive Services Task Force. Screening for Lung Cancer: US Preventive Services Task Force Recommendation Statement. JAMA. 2021;325(10):962–970. 6.NLST Research Team. Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. N Engl J Med. 2011;365:395-409. 7. Mazzone, P.J., Bach, P.B., Carey, J., et al. *Cancer Discovery*. 10.1158 – 2159-8290. CD-24-0519. (2024).

To learn more, visit
DELFIDiagnostics.com

FirstLook
By DELFI Diagnostics

Introducing DELFI's FirstLook Blood Test

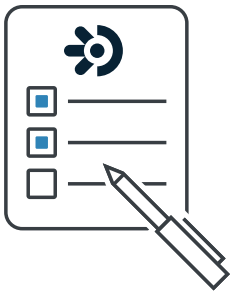
Now Available for Health Systems and Partners

The new FirstLook blood test offers a convenient, accessible, and personalized approach to enhance lung cancer screening. FirstLook helps determine the likelihood of detecting lung cancer through low-dose CT (LDCT).

Indications for Use

FirstLook Lung is based on a next generation assay of plasma cell-free DNA that analyzes the distribution of DNA fragment sizes in blood to indicate the possible presence of lung cancer.

It is intended to be an adjunct, qualitative aid in individuals deemed to have an elevated risk by USPSTF.*



A New Area in Lung Health

FirstLook provides easy-to-interpret results. It helps determine your patient's likelihood of having lung cancer and informs future screening decisions.

FirstLook Provides Two Different Results

An **Elevated result** suggests an **increased chance** that lung cancer will be detected by low-dose CT (LDCT).

A **Not Elevated result** suggests a **lower chance** that lung cancer will be detected by LDCT.

*The United States Preventive Services Task Force (USPSTF) recommends annual low-dose CT screening for lung cancer in adults aged 50-80 years who have a ≥20 pack-year smoking history who currently smoke or who have quit within the past 15 years.

To learn more, visit
FirstLooktest.com

Clinically Impactful Performance

FirstLook Lung was validated in a prospective, case-control, observational study.

The Key is High NPV

In individuals with a **Not Elevated** result 998 out of 1000 will not have lung cancer detected on low-dose CT.[1]

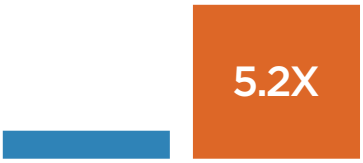
99.8%
Negative Predictive Value

Reduces the Number Needed to Screen

The NNS for an **Elevated** FirstLook lung result is **79**. While the NNS for the USPSTF population is **143**. Thus, improving the efficiency of a lung cancer screening program.[1]

Improves the Risk/Benefit Ratio of Lung Cancer Screening

The likelihood a lung cancer is found by LDCT for individuals with an **Elevated** result is **5.2 times higher** than it is for those with a **Not Elevated** result.[1]



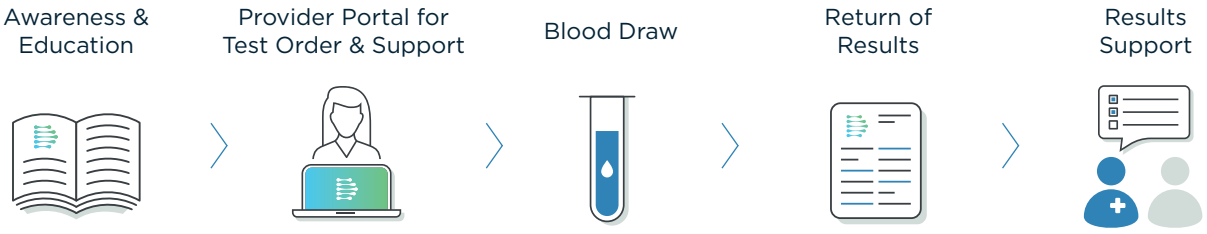
NPV: Negative Predictive Value **NNS:** Number Needed to Screen

An Investment in Health Systems and the Communities They Serve

DELFI developed the FirstLook Lung test to make low-dose CT scans more efficient for health systems and more effective for patients. FirstLook aligns with the CDC/HHS Healthy People 2030 Objectives, which highlight the importance of raising lung cancer screening rates among eligible adults and reducing lung cancer deaths.[2]

CDC: Centers for Disease Control and Prevention **HHS:** U.S. Department of Health and Human Services

FirstLook Seamlessly Integrates into Health System Workflows



FirstLook
By DELFI Diagnostics

Visit us online to learn more about the FirstLook Lung test. **FirstLooktest.com**

Laboratory Information
The FirstLook Lung test is a laboratory-developed test. It was developed and its performance characteristics determined by DELFI Diagnostics. It has not been cleared or approved by the FDA. The laboratory is regulated under the Clinical Laboratory Improvement Act (CLIA) as qualified to perform high complexity clinical tests. This test is used for clinical purposes. It should not be regarded as investigational or for research.

1. Unpublished data on file.
2. Cancer - Healthy People 2030 | health.gov. https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer.

Validating Milestones

2019 DELFI Diagnostics Founded

2019 Groundbreaking study published in *Nature*[1]

2019 Licensed DELFI technology from Johns Hopkins School of Medicine

2020 FDA grants Breakthrough Device Designation

2020 **$100** million Series A financing

2021 First patient enrolled in prospective lung trial

AUG 2022 Two issued patents on core technology

2022 **$225** million raised in Series B financing

2023 **CLIA/CAP** Accredited

2023 **Commercially Available** FirstLook Lung test (LDT)

2024 Monitoring Assay Available DELFI-Tumor Fraction assay (RUO)

Publications

Genome-wide cell-free DNA fragmentation in patients with cancer.
1. Cristiano S, Leal A, Phallen J, et al. Nature. 2019;570(7761):385-389.

Detection and characterization of lung cancer using cell-free DNA fragmentomes.
2. Mathios, D., Johansen, J.S., Cristiano, S. et al. Nat Commun. 12, 5060 (2021).

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DELFI

Accessibility — **Non-invasive and convenient blood test** for evaluation of those screen eligible who have not undergone LDCT for lung cancer screening and for those not adherent with follow-up screening. Easy to incorporate into routine practice.

Scalability — **Low-cost next-gen fragmentomics approach** using low-coverage whole genome sequencing, providing a comprehensive evaluation of cancer signals.

Performance — **High sensitivity** including for the earliest curable stages of cancer, reduces the number of LDCTs needed to screen to detect lung cancer and the LDCT false positive to true positive rate.[3,4,5]

Client Services:
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800.589.2182

To Learn More Visit:
DELFIDiagnostics.com

3.Cristiano S, et al. Nature. 2019;570(7761):385-389.
4.Mathios D, et al. Nature Commun. 2021;12(1):5060.
5.Bach P, et al. ISPOR 2023 (poster).