Circulogene

Ready to enhance *lung cancer detection and diagnosis?*

CONTACT US *Today*

to learn more about integrating
LungLifeAI into your screening program.

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CLIA Clinical Laboratory Improvement Amendments

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute

Circulogene + LungLifeAI™

Ensuring No Cancer is Missed

MOLECULAR BIOMARKERS FOR RISK ASSESSMENT OF PULMONARY NODULES

Know which nodules to take to biopsy sooner!
High Performance in small nodules!

Learn how LungLifeAI can support your lung cancer program

Because it Matters

THE PROBLEM

Whether or not to Biopsy - Being on the fence about next steps in the diagnostic journey can create anxiety and fear in you and your patient, potentially stalling next steps.

And for many pulmonary nodules you're not sure a biopsy is the right next step; the uncertainty in those cases can be just as challenging—stalling decisions and putting both you and your patient in a holding pattern.

Lung Cancer Statistics:

- Up to 13% of surgical lung resections from lung cancer screening programs are benign.
  https://pmc.ncbi.nlm.nih.gov/articles/PMC10730375/
- Early detection improves survival rates significantly.
  https://shorturl.at/CywEU
- CTB and RAB are revolutionizing the diagnosis of lung cancer, providing diagnostic yields above 80-90%.
  https://pmc.ncbi.nlm.nih.gov/articles/PMC10888048/

THE SOLUTION – LungLifeAI

LungLifeAI: Clinical Utility - A more accurate assessment of pulmonary nodules.

Key Benefits:

- Non-invasive blood-based test
- Improves early lung cancer detection
- Enhances clinical decision-making
- Now included in the National Cancer Institute Early Detection Research Network as a CLIA-approved test.

Utilizing the *Power* of AI

To develop this classifier, the algorithm scanned thousands of cells, detecting abnormal chromosomal signal patterns, and applies predefined decision rules to classify CGACs with high precision. It minimizes human error and interobserver variability, making the test more reproducible and scalable for clinical use.

Clinical Validation of LungLifeAI

A pivotal study published in BMC Pulmonary Medicine evaluated the efficacy of LungLifeAI in predicting lung cancer among individuals with IPNs. The study enrolled 151 participants scheduled for biopsy across two renowned institutions: Mount Sinai Hospital and MD Anderson Cancer Center.

Key Benefits:

SENSITIVITY & SPECIFICITY

- Positive Predictive Value (PPV): **80%**
- Sensitivity: **77%**
- Specificity: **74%**

INDEPENDENCE FROM TRADITIONAL RISK FACTORS

LungLifeAI's performance was not influenced by conventional clinical and radiological factors such as smoking history, previous cancer diagnosis, lesion size, or nodule appearance, suggesting it provides unique and valuable information beyond standard assessment criteria.

COMPARISON WITH EXISTING MODELS

Notably, the Mayo Clinic Model achieved an AUC of only 0.52 within the same study cohort. Highlighting LungLifeAI's superior diagnostic accuracy in distinguishing benign and malignant nodules.

Implications for Clinical Practice:

COMPLEMENTARY TO EXISTING DIAGNOSTIC TOOLS

LungLifeAI excels in small nodules where the uncertainty is greater and PET performs poorly, and serves as an adjunct to imaging studies, providing additional molecular insights allowing for more informed decision making for diagnosis and management.

EARLY DETECTION OF MALIGNANCY

Enhanced sensitivity facilitates the prompt identification of malignant nodules, enabling earlier intervention and potentially improving prognosis.

REDUCTION OF UNECESSARY INTERVENTIONS

By accurately identifying malignant nodules with a Rule In test with high PPV, LungLifeAI may help accelerate time to diagnosis and reduce delays in cancer treatment, which can improve outcomes and reduce healthcare costs.

If you think it may be cancer, order a LungLifeAI test to *minimize uncertainty & delays* in diagnosis.

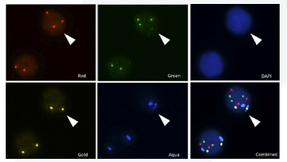
How LungLifeAI Works:

The *Science* Behind the Innovation

LungLifeAI is powered by AI and a FISH assay that identifies Circulating Genetically Abnormal Cells (CGACs) in a standard blood sample. These CGACs exhibit specific chromosomal abnormalities frequently found in lung cancer cells, allowing early detection of malignant transformation when imaging results are inconclusive.

CGAC IDENTIFICATION

- Illustrates the clear difference between normal and genetically abnormal cells under FISH imaging.
- Normal cells show two signals per probe, while CGACs show multiple or missing signals, indicating genomic instability.



Clinical *Highlights*

CASE STUDY 1

- Former Smoker (37.5 pack years)
- No history of cancer
- No underlying lung disease

Mayo Risk Score: 25%

- **November 2018**
  Initial Evaluation, CT scan shows solitary subsolid 1.3 cm nodule in upper left lobe
- **January 2020**
  Biopsy negative for lung cancer **LungLifeAI** test-**increased risk**
- **January 2021**
  Surgical resection of indeterminate nodule
  Stage 1 Adenocarcinoma

Days LungLifeAI May Have Saved: **365**

CASE STUDY 2

- Former Smoker (78 pack years)
- No history of cancer
- No underlying lung disease

Mayo Risk Score: 47%

- **October 2019**
  Initial Nodule Size 1.68cm in left upper lobe
- **February 2020**
  Slight increase of nodule size
- **March 2020**
  Biopsy found atypical-rare cells **LungLifeAI** test-**increased risk**
- **May 2020**
  Nodule negative for cancer (scar tissue)
  Lymph Nodes N2 & N3 **Small Cell Lung Cancer**

Days LungLifeAI May Have Saved: **60**