

CyPath[®] Lung

NONINVASIVE LUNG CANCER DETECTION

Increasing Survival

Noninvasive Early Detection of VA's Largest Cancer Killer

- At-home noninvasive sputum collection eliminates need to travel
- Personal coach, videos, instructional guides assist patients
- 3-day turnaround of results after sample reaches laboratory

Physicians and patients receive actionable results

- 92% Sensitivity¹
- 87% Specificity¹
- 99% Negative Predictive Value¹
- Earlier trial shows high sensitivity, specificity, NPV with pulmonary nodules ≤20mm

bioAffinity Technologies' exclusive flow cytometry test reveals the lung microenvironment with proprietary automated analysis of cell populations that indicate malignancy in the lung

1. [Lemieux ME, et al.](#)



Lowering Healthcare Costs

Significant healthcare savings

- Pulmonologists at South Texas VA Medical Center and Brooke Army Medical Center (San Antonio, TX) evaluated economic impact of the test added to Standard of Care
- Significant cost savings were projected for patients and America's healthcare system

\$2,733 per Medicare patient
for total annual savings of
~\$370 million to the healthcare
system

**\$6,460 per patient covered
by commercial insurance**
for total annual savings of
~\$895 million to the healthcare
system

CyPath[®] Lung is available at GSA/FSS

1. [Morris MJ, Habib SA, et al.](#)

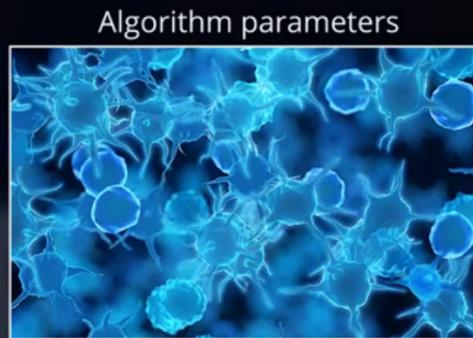
An Intelligent Model to Detect Cancer

Automated Analysis

- Identifies sputum cells of interest
- Excludes debris, dead cells, cell aggregates
- Identifies lung macrophages for quality control
- 3 cell populations plus age are analyzed for cancer

Detects changes to the lung microenvironment caused by cancer

Immune cell population



Apoptotic cell population



Cancer and cancer-associated cells population



Interpreting the CyPath[®] Lung Report

Scale reflects increasing probability of cancer

Reference Range:
>0.00 & <0.10 Very unlikely
≥0.10 & <0.50 Unlikely
≥0.50 & <0.90 Likely
≥0.90 & ≤1.00 Very likely

Precision Pathology Laboratory CyPath Lung

Patient: TEST, MARIA
DOB / Age / Sex: 6/28/1947, 77 Female
Accession Number:
Result ID: CY24-000324

Collection Date: 07/13/2024
Received Date: 07/16/2024
Report Date: 07/17/2024 05:40
ICD 10 Codes:
CPT Codes: 0406U X 1

Facility: Pulmonary Client Office
Client ID Number: CP00267
Ordering Physician: Pulmonologist, M.D.
Copies To:

Results Interpretation: LIKELY malignancy in the lung
Note: This test does not differentiate between primary or metastatic cancer in the lung.

0.01 0.25 0.5 0.70 1.0

Reference Range:
0.00 and <0.10 Very unlikely
0.10 and <0.50 Unlikely
0.50 and <0.90 Likely
0.90 and ≤1.00 Very likely

Sample Adequate: YES
Number of Alveolar Macrophages per 10,000: 12.54
Absolute Number of Cells for Analysis: 173006

Signed By: Pathologist, MD .06/28/2024 05:40

CyPath® Lung in Action: Patient Case Studies¹

- Detected Stage 1A adenocarcinoma when PET scan and serum markers failed. Led to biopsy and treatment. Early detection at Stage 1A offers a 92% 10-year survival rate² vs. 28% 5-year survival overall.³
- Identified Stage 1A neuroendocrine tumor missed by bronchoscopy and PET. These rare tumors are difficult to diagnose and on the rise. [4]
- Spared an 85-year-old from risky biopsy. Despite smoking and asbestos exposure, a negative result gave confidence to delay. Nodules resolved on follow-up. [1]
- Found second primary lung cancer in a patient previously treated for lung cancer. CyPath® Lung flagged “likely malignancy,” confirmed by biopsy. [1]
- Revealed hidden breast cancer recurrence. A small lung nodule on CT was flagged by CyPath® Lung. Led to a mammogram and biopsy confirming recurrence. Treatment was successful. [1]

**Matthew
McCumber**

VA Pulmonary Sales Executive
bioAffinity Technologies Inc.



 217-621-1187

 mm@bioaffinitytech.com

 www.cypathlung.com

Reach out to me with additional questions regarding orders.

1] CyPath® Lung, Patient Case Studies, https://www.cypathlung.com/wp-content/uploads/2025/05/CyPath%C2%AE-Lung-in-Practice_Cases-1-4_CPL-25018.pdf

[2] Survival of patients with stage I lung cancer detected on CT screening, NEJM, October 26, 2006, <https://www.nejm.org/doi/full/10.1056/NEJMoa060476>

[3] American Lung Association, State of Lung Cancer 2024, <https://www.lung.org/research/state-of-lung-cancer>.

[4] CyPath® Lung Detects Stage 1A Lung Cancer in High-Risk Patient with Inconclusive Imaging, <https://bioaffinitytech.com/case-study-cypath-lung-detects-stage-1a-lung-cancer-in-high-risk-patient-with-inconclusive-imaging/> OG