



## Noninvasive Accurate Lung Cancer Detection

Revolutionizing diagnostics with proprietary  
AI analysis of flow cytometry data



SPRING 2026 INVESTOR PRESENTATION

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# Lung Cancer Is A Global Problem and Large Market

Leading cause of cancer-related deaths



**2.48 Million**

New cases worldwide annually<sup>1</sup>

**1.8 Million**

Deaths annually<sup>1</sup>



## Major Screening Need in the United States

An estimated **19.3 million** Americans should have annual lung cancer screening according to the American Cancer Society<sup>2</sup>



## Large Population At Risk in the European Union

Up to **~34 million** people in the EU were at high risk for lung cancer in 2018<sup>3</sup>



## High Incidence in China

Reported **1,060,600** new cases of lung cancer in 2022<sup>4</sup>

## Diagnostic Market Growth

2034 Projected Market

**\$38 Billion**



2023 Estimated Market

**\$20 Billion**



Compound Annual Growth Rate (2025-2033)

**7.23% CAGR<sup>5</sup>**

1. The Cancer Atlas, Third Edition, American Cancer Society (ACS), World Health Organization (WHO) and The Union for International Cancer Control (UICC); <https://canceratlas.cancer.org/the-burden/lung-cancer/> and Global cancer statistics 2022: GLOBOCAN estimates. 2. NBC News. "Lung cancer screening guidelines." Accessed Nov. 2023. 3. Lung Cancer Burden in EU. European Union Joint Research Centre. Jan. 2021. 4. Cancer incidence and mortality in China, 2022, Journal of the National Cancer Center. 5. Research and Markets Lung Cancer Diagnostics Market Report.

# Early Detection of Lung Cancer Saves Lives

Improving survival rates through timely intervention and accurate diagnosis



## Current Survival Rates

In 2025, less than 30% of patients survived 5 years<sup>2</sup>



## Late-Stage Diagnosis

Most patients are diagnosed with late-stage cancer (Stages III-IV) when survival rates are significantly lower<sup>2</sup>



## Benefits of Accurate, Early Detection

Identifying cancer early leads to better patient outcomes:

- Curative treatment options
- Long-term survival
- Improving the positive predictive value of screening



1. 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>

2. American Lung Association, State of Lung Cancer 2025, State of Lung Cancer 2025

# CyPath<sup>®</sup> Lung Platform

Detecting Lung Cancer with Noninvasive Technology

**92%\***

Sensitivity<sup>1</sup>

**87%\***

Specificity<sup>1</sup>

**99%\***

NPV<sup>1</sup>

**88%\***

Accuracy<sup>1</sup>



## Proprietary AI Analysis

- ✓ AI-driven algorithm analyzes complex flow cytometric data from patient sputum samples.
- ✓ Profiles the lung microenvironment to differentiate between patients with or without lung cancer.



## Patient-Friendly & Physician-Focused

- ✓ At-home collection (no needles, no blood)
- ✓ Results 3 days after sample arrives at lab



## Growing Platform Technology

- ✓ Our commercial noninvasive lung cancer test is the first in a pipeline that includes development of companion diagnostics for:
  - Asthma
  - Chronic Obstructive Pulmonary Disease (COPD)

\*Test performance for patients with pulmonary nodules less than 20 mm. Also resulted in 95% Area Under the Curve, 95% Confidence Interval, 44% Positive Predictive Value. Nodules detected by low-dose computed tomography.

1. Lemieux ME, Detection of early-stage lung cancer in sputum using automated flow cytometry and machine learning. *Respir Res.* 2023;24(1):23. doi:10.1186/s12931-023-02327-3

# CyPath<sup>®</sup> Lung in Action: Patient Case Studies\*

Demonstrating Detection at Curative Stage 1A & Averting Risky Procedures



LIKELY MALIGNANCY

## "Gloria"

**Challenge:** PET scan and serum markers were non-diagnostic for this patient.

**CyPath<sup>®</sup> Result:**  
Returned a "likely" malignancy result.

### Outcome

Confirmed Stage 1A mucinous adenocarcinoma by biopsy. Patient is doing well after surgery.



LIKELY MALIGNANCY

## "Paula"

**Challenge:** Bronchoscopy and non-diagnostic PET scan missed the cancer. Rare neuro-endocrine tumors can be difficult to diagnose.

**CyPath<sup>®</sup> Result:**  
Returned a "likely" result.

### Outcome

Confirmed Stage 1A neuroendocrine tumor. Patient is doing well after surgery.



UNLIKELY MALIGNANCY

## "James"

**Challenge:** 85-year-old at high risk due to heavy tobacco use and asbestos exposure.

**CyPath<sup>®</sup> Result:**  
Returned an "unlikely" result.

### Outcome

Supported delaying invasive testing, sparing a high-risk biopsy. Pulmonary nodules resolved on follow-up.

# CyPath<sup>®</sup> Lung in Action: Patient Case Studies\*

Case Studies Demonstrate Cancer Detection In Surveillance Period;  
Earlier Detection of Malignant Ground Glass Nodule



LIKELY MALIGNANCY

"Joan"

**Challenge:** Surveillance in high-risk survivors is challenging.

**CyPath<sup>®</sup> Result:**

Returned a "likely" result during monitoring after initial lung cancer treatment.

Outcome

Follow-up PET scan led to diagnosis of a second primary cancer.



LIKELY MALIGNANCY

"Carol"

**Challenge:** New pulmonary nodule discovered post-treatment for breast and lung cancer.

**CyPath<sup>®</sup> Result:**

Returned a "likely" result for the new nodule.

Outcome

Led to mammogram, biopsy, and treatment for recurrent breast cancer metastatic to the lung.



LIKELY MALIGNANCY

"Helen"

**Challenge:** Incidentally detected ground glass nodules with no suspicious characteristics on imaging.

**CyPath<sup>®</sup> Result:**

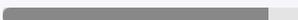
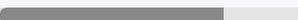
Returned a "likely" result.

Outcome

Early diagnosis and treatment, avoiding 3-5 years of "watchful waiting."

# Compares Favorably to Standards of Care

Proven Clinical Utility To Help Detect Lung Cancer Noninvasively

Lung Cancer Diagnostic Procedure or Test	Sensitivity	Specificity
★ CyPath® Lung <sup>1</sup>	92% 	87% 
Fine Needle Biopsy <sup>4</sup>	90% 	75% 
Core Needle Biopsy <sup>4</sup>	89% 	89% 
FDG PET imaging <sup>2</sup>	89% 	75% 
Bronchoscopy <sup>3</sup>	88% 	47% 

FDG = fluorodeoxyglucose; PET = positron emission tomography

1. M. Lemieux, et al., Detection of early-stage cancer in sputum using automated flow cytometry and machine learning, Respiratory Research, Jan 2023.

3. Silvestri et al. A Bronchial Genomic Classifier for the Diagnostic Evaluation of Lung Cancer, New England Journal of Medicine, 2015.

2. Deppen et al., Accuracy of FDG-PET to diagnose lung cancer in areas with infectious lung disease: A meta-analysis, JAMA, 2014.

4. Yao et al, Fine-needle aspiration biopsy versus core-needle biopsy in diagnosing lung cancer: a systemic review, Current Oncology, 2012

# Physician-Focused, Patient-Friendly, Reimbursed by Insurance



**@ Clinic**

Physician orders CyPath® Lung test to ship to patient or deliver in clinic.



**@ Home**

Patient videos, written instructions and personal coach assist with 3-day collection at home.



**@ Laboratory**

AI-driven automated analysis of flow cytometry data profiles the sample.



**@ Clinic**

Physician receives results within 3 days after lab receives sample.



**Actionable Results = Greater Confidence in Patient Care**

# Interpreting the Report

CyPath Lung



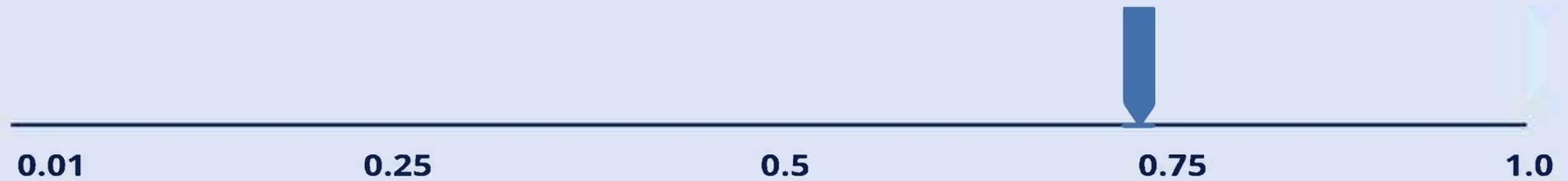
**Patient:** DOE, JANE  
**DOB / Age / Sex:** 01/06/1955 , 71 , Female  
**Accession Number:** 10460303  
**Result ID:** CY26-000035

**Collection Date:** 01/08/2026  
**Received Date:** 01/09/2026  
**Report Date:**  
**ICD 10 Codes:**  
**CPT Codes:**

**Facility:** Precision Pathology Laboratory Services - Nacogdoches  
**Client ID Number:** PPS  
**Ordering Physician:** Roby Joyce, MD  
**Copies To:**

## Results Interpretation: **LIKELY** malignancy in the lung

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



Patient Sample Result Value is 0.73

Reference Range:  
≥0.00 and ≤0.50 Unlikely  
>0.50 and ≤1.00 Likely

Sample Adequate: YES

Number of Alveolar Macrophages per 10,000: 88.18  
Absolute Number of Cells for Analysis: 97981

Scale reflects cancer probability

Reference Ranges  
>0.00 & <0.50 Unlikely  
≥0.50 & < 1.00 Likely

Signed by: Vibha Bhasin, MD

# Significant Healthcare Savings

## Economic Impact Analysis

 2024 study<sup>1</sup> authored by pulmonologists practicing at **Audie L. Murphy Memorial VA Hospital** and **Brooke Army Medical Center** evaluated CyPath<sup>®</sup> Lung's potential economic impact if added to the standard of care.



Medicare Patient

**\$2,733**

Savings per patient

**~\$370 Million**

Estimated Annual System Savings



Commercial Insurance

**\$6,460**

Savings per patient

**~\$895 Million**

Estimated Annual System Savings

**Conclusion:** Significant savings to individual patients and the overall healthcare system

VA=US Department of Veterans Affairs.

1. Morris, M., Habib, S., Do Valle, M., & Schneider, J.; Economic Evaluation of a Novel Lung Cancer Diagnostic in a Population of Patients with a Positive Low-Dose Computed Tomography Result (2024) (Accepted for Publication, Journal of Health Economics and Outcomes)

# How the Test Works



## Advanced Technology

Combining automated flow cytometry with proprietary AI to interrogate the lung microenvironment.



### Flow Cytometry Interrogates Lung Microenvironment

Sputum samples are processed into a single-cell suspension and labelled before data acquisition with antibodies, reagents, labeling agents and TCPP.



### Proprietary AI-Driven Platform Analysis

Automated analysis identifies cell populations of interest and eliminates debris, dead cells, and cell aggregates to distinguish between likely cancer and benign conditions.



### Quality Control Verification

Fluorescent antibody specifically identifies lung macrophages to ensure the sample comes from the lungs.



### Rapid AI-Driven Identification

Analysis developed by machine learning detects cell populations indicative of lung cancer in only minutes.

# Market Opportunity

The U.S. market for CyPath<sup>®</sup> Lung is poised for significant growth



Indeterminate Pulmonary Nodules

**2.9 MM**

2025



+62%

**4.7 MM**

2030

The total number of indeterminate pulmonary nodules (IPNs) detected by lung cancer screening and incidentally by imaging for other conditions is projected to increase significantly.

2030 Market Opportunity

**\$470 MM**



At 10% Market Share

\*Projection assumes 10% compound annual growth for the 2024-2030 period based on 1) utilization of LCS increasing from 18.1% in 2023 to close to 50% by 2030 due to growing adoption and awareness with improved access, and 2) improved ability to detect IPN in CT and X-ray through greater adherence to guideline recommendations and use of AI.

# Market Opportunity

## CyPath® Lung Use for Surveillance of Lung Cancer Recurrence



Lung Cancer Survivors

680,450

2025



+28%

871,580

2035

The total number of people living with lung cancer is projected to increase by 28% from 680,450 survivors in 2025 to 871,580 in 2035.<sup>1</sup>

2030 Market Opportunity

**\$87 MM**



At 10% Market Share

1. Wagle NS, Nogueira L, Devasia TP, et al. *Cancer treatment and survivorship statistics, 2025*. CA Cancer J Clin. 2025;75(4):308–340. doi:10.3322/caac.70011

# Revenue & Key Business Milestones Achieved in 2025

Jan '25

99%

Year-over-year **increase** in  
CyPath® Lung units sold

87%

Year-over-year **increase** in  
revenue

## A Solid Foundation for Growth



Published multiple **case studies** and physician testimonials



Entered major **VA medical centers** with lung nodule programs



Phased **market expansion** in Northeast and Southern US



Expanded indications for **surveillance** and metastatic cancer detection

Dec '25

VA = US of Veterans Affairs.

# Longitudinal Clinical Trial Launches in 2026

  
**2,000**  
Patients

  
**~20**  
Collection Sites

  
**Q1 2026**  
Enrollment Underway

-  Designed to assess CyPath® Lung performance for risk stratification, clinical decision-making, detection and survivor surveillance.
-  Collection sites include VA and military medical centers (qualified and ready) with funding and support from Murtha Cancer Center Research Program.
-  Supports inclusion of CyPath® Lung as part of the standard protocol for pulmonary nodules.

VA = US Department of Veterans Affairs



# Building on a Successful Diagnostic Platform

Next in Pipeline: Companion Diagnostics for Asthma and COPD

## Quantifying Lung Inflammation for Improved Therapy



**Precision Diagnostics** Match patients to effective treatments and monitor their effectiveness over time, ensuring optimal therapeutic outcomes.



**Inflammation 'Scorecard'** Companion diagnostic test panel offers a comprehensive quantitative assessment of the lung microenvironment.



**Targeted Therapy Matching** Test indication expanded to support identification of patients best suited for specific advanced therapies.



**23 M**

Adults in the U.S. with asthma<sup>1</sup>



**27 M**

People in the E.U. with asthma<sup>2</sup>



**14.2 M**

Adults in the U.S. with COPD<sup>3</sup>



**\$26 B**

Global Market for Asthma & COPD Therapeutics<sup>4</sup>

1. Asthma and Allergy Foundation of America; accessed 2.17.2025; <http://bit.ly/3X7edi1>

2. Eurostat, Weckler H. et al. World Allergy Organ. J. 2023, 16(8) PMID: 37564904CDC

3. CDC Morbidity and Mortality Weekly Report (MMWR) 2023, 72(46), 1250-1256

4. <https://www.grandviewresearch.com/industry-analysis/asthma-therapeutics-market>

# Management

Innovative, Experienced, Dedicated

## Executive Leadership



**Maria Zannes, JD**  
Founder, CEO & President

30+ years C-suite executive in medical and engineering fields building high-performing corporate teams who build shareholder value.



**Gordon Downie, MD, PhD**  
Chief Medical Officer

25+ years experience creating, building and managing CAP/CLIA labs and creating and commercializing LDTs; clinical cytogeneticist.



**Michael Edwards, MBA**  
Chief Financial Officer

30+ years in corporate finance including CFO at CytoBioscience and OncoVista Innovative Therapies.



**William Bauta, PhD**  
Chief Science Officer

30+ years directing R&D of multiple drugs and diagnostics for oncology, neuroscience, and immunology at big pharma including Ilex.



**Xavier Reveles, MS**  
Chief Operating Officer

30+ years in pulmonary medicine, clinical research, medical innovation, and interventional pulmonology; 30 peer-reviewed publications.

## Medical and Scientific Advisory Board

### David Ost, MD, MPH

Chief of Pulmonary, Critical Care, & Sleep Medicine, MD Anderson Cancer Center

### Daniel Sterman, MD

Chief of Pulmonary, Critical Care, & Sleep Medicine, NYU Langone Health

### David Hill, MD

Chairman, American Lung Association; Asst. Professor, Yale School of Medicine

### J. Scott Ferguson, MD

Director of Interventional Pulmonology, Univ. of Wisconsin School of Medicine

### Sheila Habib, MD

Director of Pulmonary Lung Nodule Clinic, South Texas VA

### Sandeep Bansal, MD

Medical Director, The Lung Center at Penn Highlands Healthcare

### Neil Alexis, PhD

Principal Investigator, UNC School of Medicine; Environmental Medicine

# Board of Directors

Decades of Successful Leadership from Start-Ups to Global Corporations

**Steve Girgenti**  
**Executive Chairman**



Founded leading global healthcare marketing firm Healthworld with 32 offices worldwide. Recognized as NASDAQ's 1999 "Entrepreneur of the Year."

**Jamie Platt, PhD**  
**Director**



20+ years of diagnostic expertise, led successful M&A exits for two diagnostic companies totaling \$1 Billion. Managing Director, CEO of Pictor Ltd.; Founder, CEO of BRIDGenomics.

**Peter Knight**  
**Director**



Founding Partner of Generation Investment Mgmt. with >\$18B AUM. Served as Campaign Manager for President Clinton's 1996 re-election campaign.

**John Oppenheimer, MD**  
**Director**



Clinical Professor of Medicine and Director of Clinical Research. Leading authority on asthma and COPD, participated in 180+ clinical trials, authored 260+ publications.

**Roby Joyce, MD**  
**Director**



Precision Pathology founder and Medical Director; board-certified in pathology and neurology. Former chief of staff at Methodist Healthcare System; Colonel, US Army, ret.

**Robert Anderson**  
**Director**



50+ years in healthcare executive positions at CIBA Pharmaceuticals, Becton Dickinson, Pfizer, Parke-Davis Division of Warner-Lambert, and Schering Plough.

**Maria Zannes, JD**  
**Director, CEO**



bioAffinity Technologies founder; former President of The Energy Recovery Council, The Zannes Firm, and Senior Executive at ECOS Corp.

**Roberto Rios, CPA**  
**Director**



40+ years of senior financial leadership in biotechnology and medical devices. Former CFO and board member for ILEX Oncology, BioMedical Enterprises.

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President & CEO



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