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NASDAQ: BIAF / BIAFW

Company Presentation

CyPath® Lung

Noninvasive, Accurate Lung Cancer Detection

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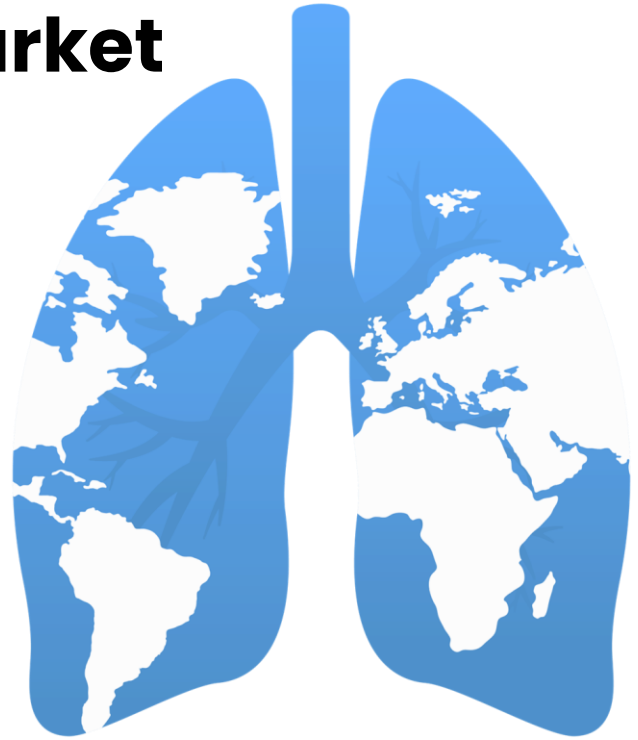
Lung Cancer Is A Global Problem and Large Market



Most common cancer and leading cause of cancer-related deaths

- 2.48 million new cases of lung cancer worldwide in 2022, with 1.8 million deaths annually[1]
  - An estimated **19.3 million Americans** should have annual lung cancer screening, according to the American Cancer Society[2]
  - Up to ~**34 million people in the European Union** were at high risk for lung cancer in 2018[3]
  - **China reported 1,060,600 new cases** of lung cancer in 2022[4]

Lung cancer diagnostic market is ever increasing

- Estimated at **$20 billion in 2023** and projected to reach **$38 billion by 2034**
  - CAGR of 7.23% over 2025-2033[5]

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 of incidence and mortality worldwide for 36 cancers in 185 countries https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21834 2. NBC News. "Lung cancer screening guidelines: Quit smoking, annual test." NBC News Health. Accessed Nov. 2023. https://nbcnews.to/3QmWv6w 3. Lung Cancer Burden in EU. European Union Joint Research Centre. Jan. 2021. https://bit.ly/EUStats and Estimation of the adult population at high risk of developing lung cancer in the European Union, Cancer Epidemiology, https://doi.org/10.1016/j.canep.2018.10.007
4. Cancer incidence and mortality in China, 2022, Journal of the National Cancer Center, https://doi.org/10.1016/j.jncc.2024.01.006 5. Research and Markets https://www.researchandmarkets.com/reports/5941158/lung-cancer-diagnostics-market-size-share

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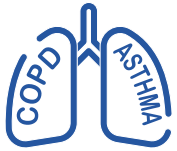
bioAffinity Technologies' Diagnostic Platform Starts with CyPath® Lung

We Tackled the Most Difficult Problem First : Lung Cancer

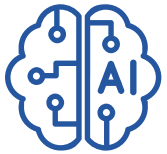


Growing Platform Technology

- Our commercial noninvasive lung cancer test is the first in a pipeline that includes development of companion diagnostics for asthma and chronic obstructive pulmonary disease (COPD)

92% Sensitivity[1] **87% Specificity[1]** **99% Negative Predictive Value[1]** **88% Accuracy[1]**

- CyPath® Lung shows high specificity and sensitivity in detecting lung cancer in people with small, indeterminate pulmonary nodules*



Proprietary Automated Data Analysis of Flow Cytometry Data

- Automated analysis of flow cytometric data uses machine learning resulting in high performance
- Profiles the lung microenvironment to differentiate between patients with or without lung cancer

Patient-friendly / Physician-focused

- At-home collection (no needles, no blood) with results 3 days after sample arrives at lab.

*Nodules detected by low-dose computed tomography. Test performance for patients with pulmonary nodules less than 20 mm also resulted in 88% accuracy, 95% Area Under the Curve; 95% Confidence Interval; 99% Negative Predictive Value, 44% Positive Predictive Value.

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

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Urgent Need for Early Detection of Lung Cancer

Only **28%** of patients with lung cancer survive 5 years[1]

- 63% of patients with Stages I-II lung cancer survive 5 years[1]
- Most patients are diagnosed with late-stage (Stages III-IV) lung cancer when survival is much lower[1]

92% of Stage I patients survive 10 years if treated within one month of diagnosis[2]

Accurate, early cancer detection can

- Increase long-term survival
- Reduce unnecessary invasive procedures
- Improve the positive predictive value of screening

1. American Lung Association, State of Lung Cancer 2024, https://www.lung.org/research/state-of-lung-cancer.
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

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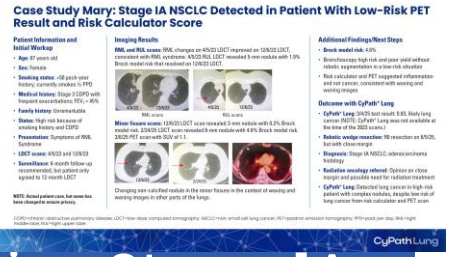
Real Patients, True Stories, Remarkable Outcomes


Case Study Mary: Stage IA NSCLC Detected in Patient With Low-Risk PET Result and Risk Calculator Score

Patient Case Studies Reveal CyPath® Lung Finds Cancer at Curative Stage 1A

- Detected Stage 1A adenocarcinoma in 67-year-old woman when risk models suggested a low probability of cancer and other diagnostics were contraindicated. CyPath® Lung **led to biopsy and curative treatment**.
- Stage 1A mucinous adenocarcinoma was detected by CyPath® Lung in a 62-year-old woman after insurance denied coverage for a 2nd PET scan and our **competitor's test resulted in an "indeterminant" finding.**
- Detected Stage 1A rare neuroendocrine tumor in an 80-year-old woman **after** other diagnostic tools – bronchoscopy, our competitor's test and radiological risk model score **– failed to identify** the malignancy.
- **Patient previously treated for lung cancer** had a small nodule in the opposing lung. **CyPath® Lung was positive**. A biopsy confirmed a second primary lung cancer for which the patient is being treated.
- CyPath® Lung identified a hidden recurrence of breast cancer after a routine CT detected a small pulmonary nodule. Other diagnostic approaches like a PET scan or serum markers could not be used.
- Imaging revealed nodules in an 85-year-old man, but invasive biopsy was averted when **CyPath® Lung was negative**, and three months later a new CT showed the nodules had disappeared.

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Savings to Individual and Overall Healthcare With CyPath® Lung

2024 study[1] authored by pulmonologists practicing at Audie L. Murphy Memorial VA Hospital and Brooke Army Medical Center evaluated CyPath® Lung's economic impact if added to the standard of care in 2022

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

$2,733 per Medicare patient
for total annual savings of
~$370 million to the
healthcare system[1]

$6,460 per patient covered by commercial insurance
for total annual savings of
~$895 million to the
healthcare system[1]

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)

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Physician-Focused, Patient-Friendly CyPath® Lung

@ Clinic	@ Home	@ Laboratory	@ Clinic

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

Patient videos, instructions, personal coach assist with 3-day collection **at home**

ships overnight

AI-driven automated data analysis of flow cytometry data

Physician receives results within **3 days** after lab receives sample

Actionable Results = Greater Confidence in Patient Care

AI=artificial intelligence.

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How the CyPath® Lung Test Works

Flow cytometry interrogates sputum cells after sample processing

- Test uses antibodies, reagents, labeling agents and TCPP, a synthetic porphyrin that labels cancer and cancer-related cells
- Sputum samples are processed into a single-cell suspension and labelled before data acquisition

Proprietary automated software ensures only cells of interest are interrogated

- Automated analysis identifies sputum cells of interest and eliminates debris, dead cells, and cell aggregates

Quality control assures the sample is from the lungs

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

Automated analysis takes only minutes to identify lung cancer in samples

- Analysis developed by machine learning detects cell populations indicative of lung cancer
  - Includes cancer and cancer-related cells, immune cells, and dying cells

TCPP=tetra (4-carboxylphenyl) porphyrin.

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CyPath® Lung Comparison vs Standard-of-Care Follow-Up

Lung Cancer Diagnostic Procedure or Test	Sensitivity	Specificity
CyPath® Lung[1] (individuals at high risk with nodules <20mm)	**92%**	**87%**
FDG PET imaging[2] (individuals with suspicious lung nodules)	89%	75%
Bronchoscopy[3] (individuals with suspicious lung nodules)	88%	47%
Fine Needle Biopsy[4] (individuals with suspicious lung nodules)	90%	75%
Core Needle Biopsy[4] (individuals with suspicious lung nodules)	89%	89%

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.
2. Deppen et al., Accuracy of FDG-PET to diagnose lung cancer in areas with infectious lung disease: A meta-analysis, JAMA, 2014. 3. Silvestri et al. A Bronchial Genomic Classifier for the Diagnostic Evaluation of Lung Cancer, New England Journal of Medicine, 2015. 4. Yao et al, Fine-needle aspiration biopsy versus core-needle biopsy in diagnosing lung cancer: a systemic review, Current Oncology, 2012

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Major Milestones Accomplished in 2024

2024 sales nearly 14X higher vs prior years

Sales & Marketing

- Medicare reimbursement code effective for use
- Medicare & private insurers begin reimbursing test
- Sales team expands to cover all major Texas markets
- Awarded right to sell to VA/government medical centers
- Completed beta market launch for CyPath® Lung in Texas

Jan '24 — Dec '24

Prospective Clinical Trial

- DoD supports military sites in pivotal clinical trial
- Col. Michael Morris,(Ret.), MD, accepts national PI role for pivotal trial
- Intense VA interest in participating in pivotal trial
- Qualification of VA clinical sites underway
- FDA meeting with agreement on improved trial design

DoD=Department of Defense; FDA=Food and Drug Administration; PI=Principal Investigator; VA=US Department of Veterans Affairs.

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Major Milestones to Achieve in 2025

Sales & Marketing

Prospective Clinical Trial

Product Pipeline

Begin continuous reporting of case studies highlighting The Human Side of CyPath® Lung

Increase market awareness with broader multi-media promotion

Expand sales team and marketing into strategic national markets

Enter major VA medical centers with lung nodule programs

Clinical Trial protocol approved by VA, military and private IRBs

Site selection complete, contracts executed with VA, active military, academic and private collection sites

Open collection sites; patient enrollment begins in prospective clinical trial

Jan '25 — Dec '25

Test panel designed / identification of cell populations indicating COPD/Asthma

Fluorescence antibody that labels therapeutic target confirmed in sputum

Continue to identify COPD/ Asthma therapeutic targets & expand diagnostic platform

IRB approves protocol for proof-of-concept asthma companion diagnostic study

FDA=Food and Drug Administration; VA=US Department of Veterans Affairs.

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Our Pipeline: Companion Diagnostics for $26 Billion Market

Asthma and COPD treatments work, but not for everyone . Our noninvasive tests aim to ensure patients receive the right treatment for their disease

Our pipeline of companion diagnostics targets a large global market estimated at $26 billion[1] for asthma and chronic obstructive pulmonary disease (COPD) therapeutics

Asthma

- An estimated **23 million adults** in the US[2] and **27 million people** in the European Union[3] have been diagnosed with asthma. China reported **45.7 million adults** had asthma in 2019[4]

COPD

- An estimated **14.2 million US adults** in the US have COPD[5]. An estimated **36.6 million people in Europe** have COPD, with more than 50 million expected by 2050[6]

COPD=chronic obstructive pulmonary disease.

1. https://www.grandviewresearch.com/industry-analysis/asthma-therapeutics-market; 2. Asthma and Allergy Foundation of America; accessed 2.17.2025; http://bit.ly/3X7edi1 3. Eurostat, Weckler H. et al. *World Allergy Organ. J.* 2023, 16(8) PMID: 37564904CDC 4. Huang, et al. Prevalence, risk factors, and management of asthma in China: a national cross-sectional study, *The Lancet* (2019). 5. CDC Morbidity and Mortality Weekly Report (MMWR) 2023, 72(46), 1250-1256. 6. Benjafield, A. et al. An estimate of the European prevalence of COPD in 2050. *Eur. Resp. J.* 2021.

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Management— Innovative, Experienced, Dedicated

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

Michael Edwards, MBA, CPA
CFO

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

Gordon Downie, MD, PhD
Chief Medical Officer

30+ years in pulmonary medicine, clinical research, medical innovation, and interventional pulmonology; 30 peer-reviewed publications, worked extensively in both academic medicine and private practice.

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 and Genzyme

Xavier Reveles, MS, CG(ASCP)^{CM}
Chief Operating Officer

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

Science & Medical Advisory Board

Sandeep Bansal, MD, FCCP
Medical Director,
The Lung Center and Interventional Pulmonology at Penn Highlands Healthcare

Sheila Habib, MD
Director of Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program, South Texas VA

David Hill, MD
Chairman of the Board, American Lung Association; Assistant Professor, Yale School of Medicine

Gerard Silvestri, MD, FCCP
Professor of Medicine & Lung Cancer Pulmonology, Medical University of South Carolina

Catherine Sears, MD
Assistant Professor, Indiana University School of Medicine

Neil Alexis, PhD
Principal Investigator, UNC School of Medicine; Environmental Medicine, Asthma & Lung Biology

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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; NASDAQ's 1999 "Entrepreneur of the Year"

Peter Knight, Director
Founding Partner of Generation Investment Mgmt. with >$18B AUM; Campaign Manager for President Clinton's '96 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, and contributed to numerous national clinical guidelines.

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

Roberto (Bobby) Rios, CPA, Director
40+ years of senior financial leadership in biotechnology, medical devices, and large-scale construction. Former CFO and board member for ILEX Oncology, BioMedical Enterprises, and Bartlett Cocke General Contractors,

Roby Joyce, MD, Director
Precision Pathology founder and Medical Director; board-certified in pathology, 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
BIAF founder; former President of The Energy Recovery Council, The Zannes Firm, Senior Executive at ECOS Corp.

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Perspective

"Exact Sciences was founded in 1995, although it took about 15 years to get the fecal DNA test off the ground. . .The company eventually went public with an initial offering on the NASDAQ in 2001. In the early years, there was much speculation that the company would be acquired by a competitor or exit the market; during this time the company's share price fell to less than one dollar."

For more information see: https://www.gastroendonews.com/In-the-News/Article/07-20/A-Closer-Look-at-Exact-Sciences-The-Company-Behind-Cologuard/59002?sub=46E34BC468AA42105FBFEB39A554DC4977EE2D415596C5B71CFB24B34418180 and https://en.wikipedia.org/wiki/Exact_Sciences_Corp.

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