

Clinical Utility of bioAffinity Technologies' CyPath® Lung Test Demonstrated in Real-World Case Study

Noninvasive CyPath® Lung test has shown 92% sensitivity, 87% specificity and 88% accuracy for detecting lung cancer in small nodules less than 2 centimeters

Case study highlights how CyPath® Lung reduces patient anxiety and supports physician confidence in assessment of benign pulmonary nodules

SAN ANTONIO, Texas--(BUSINESS WIRE)-- **[bioAffinity Technologies, Inc.](#)** (Nasdaq: **BIAF; BIAFW**), a biotechnology company advancing noninvasive diagnostics for lung cancer and other lung diseases, today announced a new clinical case study demonstrating how CyPath® Lung, its noninvasive diagnostic test for lung cancer, supported clinical decision-making in a high-risk patient with multiple pulmonary nodules.

The 59-year-old patient had a 30-year, three packs per day smoking history and underlying chronic obstructive pulmonary disease (COPD). Imaging revealed multiple scattered pulmonary nodules measuring between 3–7 mm and categorized as Lung-RADS 3 on the Lung Imaging Reporting and Data System (Lung-RADS), indicating a probably benign condition.

“Determining appropriate care for a patient with multiple nodules and a significant smoking history is often complicated by patient anxiety and concern about an ongoing risk of malignancy,” said Daya Nadarajah, MD, the patient’s pulmonologist. “Follow-up can be problematic without the additional diagnostic information provided by CyPath® Lung. A negative CyPath® Lung result helps reassure both physician and patient that an early cancer is unlikely to have been missed.”

Dr. Nadarajah ordered a CyPath® Lung test for his patient, which returned a negative result of “unlikely malignancy.” The CyPath® Lung score gave both physician and patient additional confidence to continue a serial six-month CT surveillance schedule, consistent with Lung-RADS 3 recommendations. In a follow-up CT scan, the sub-centimeter nodules remained stable.

“Patients with multiple small nodules and many years of tobacco use often face months of uncertainty and fear,” said Gordon Downie, MD, PhD, bioAffinity Technologies Chief Medical Officer. “CyPath® Lung provides physicians with additional, objective information that helps stratify risk and supports confident clinical decision-making while maintaining appropriate vigilance for patients at high risk for lung cancer.”

Supporting Confident, Noninvasive Management

This case illustrates the benefit of using CyPath® Lung as an adjunctive diagnostic tool for managing indeterminate pulmonary nodules – particularly in high-risk smokers – by:

- Supporting evidence-based surveillance decisions
- Reinforcing guideline-consistent follow-up intervals
- Potentially reducing invasive procedures on benign nodules
- Helping alleviate patient anxiety

About CyPath® Lung

CyPath® Lung by bioAffinity Technologies is a noninvasive test designed to improve the early detection of lung cancer in patients at high risk for the disease. CyPath® Lung uses advanced flow cytometry and proprietary artificial intelligence (AI) to identify cell populations in patient sputum that indicate malignancy. CyPath® Lung incorporates a fluorescent porphyrin that is preferentially taken up by cancer and cancer-related cells. [Clinical study results](#) demonstrated 92% sensitivity, 87% specificity and 88% accuracy in detecting lung cancer in patients at high risk for the disease who had small indeterminate lung nodules less than 20 millimeters.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and other diseases of the lung and broad-spectrum cancer treatments. The Company's first product, [CyPath® Lung](#), is a noninvasive test that has shown high sensitivity, specificity and accuracy for the detection of early-stage lung cancer. CyPath® Lung is marketed as a Laboratory Developed Test (LDT) by [Precision Pathology Laboratory Services](#), a subsidiary of bioAffinity Technologies. For more information, visit www.bioaffinitytech.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the federal securities laws. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "project," "plan," "intend" or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. These forward-looking statements are subject to various risks and uncertainties, many of which are difficult to predict, that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability of CyPath® Lung to indicate a high probability of lung cancer, CyPath® Lung providing confidence in a proposed course of action for high-risk patients when multiple pulmonary nodules are present, the ability of CyPath® Lung to determine if cancer is present or if the patient is cancer-free, and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, and its subsequent filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. Such forward-looking statements are based on facts and conditions as they exist at the time such statements are made and predictions as to future facts and conditions. While the Company believes these forward-looking statements are reasonable, readers of this press release are cautioned not to place undue reliance on any forward-looking statements. The information in this release is

provided only as of the date of this release, and the Company does not undertake any obligation to update any forward-looking statement relating to matters discussed in this press release, except as may be required by applicable securities laws.

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