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New Case Study: bioAffinity Technologies' CyPath® Lung Diagnostic Supports Physician's Assessment, Prompts Follow-Up Imaging and Defers Unnecessary Biopsy

Standard-of-care imaging and risk models indicated cancer after lung screening revealed 30-millimeter pulmonary nodule

CyPath® Lung test affirmed physician's assessment that the nodule could be inflammation, not cancer; nodule resolved upon follow-up scan

Noninvasive CyPath® Lung performed with 92% sensitivity, 87% specificity and 88% accuracy for detecting lung cancer in more difficult to diagnose small nodules in a clinical trial of patients at high risk for lung cancer

SAN ANTONIO--(BUSINESS WIRE)-- [bioAffinity Technologies, Inc.](#) (Nasdaq: BIAF; BIAFW), a biotechnology company advancing noninvasive diagnostics for lung cancer and other lung diseases, today released a new clinical case study illustrating how [CyPath® Lung](#), the Company's noninvasive sputum-based diagnostic test, helped determine next steps for a high-risk patient with a suspicious pulmonary nodule where imaging and risk models suggested a high likelihood of cancer, but the physician suspected possible inflammation.

The patient, a 70-year-old female with a 50 pack-year smoking history and smoking-related emphysema, presented with increased symptoms including cough, sputum production and shortness of breath. A low-dose CT scan identified a suspicious 30-millimeter (mm) lesion in the lower right lung with nearby enlarged lymph nodes, findings that can be associated with lung cancer. PET imaging suggested a high likelihood of malignancy. Lung cancer risk calculators estimated the probability of cancer as high on the Mayo and Herder models and intermediate on the Brock model.

"In this case, imaging findings and risk calculators suggested a very high probability of lung cancer, and we scheduled her for biopsy," said Daya Nadarajah, MD, the treating pulmonologist. "I routinely use CyPath® Lung in my practice and ordered the test for her. She received a negative result, 'Unlikely Malignancy,' which prompted another scan before we moved forward with the biopsy."

A follow-up CT scan showed that the concerning 30-mm nodule had completely resolved, confirming the physician's acumen that the abnormality was due to a reversible inflammatory

process rather than lung cancer.

“In patients with underlying lung disease, like emphysema, or other comorbidities like cardiovascular disease, biopsy can carry significant risks. Physicians must weigh the risks against the potential benefits,” said Gordon Downie, MD, PhD, Chief Medical Officer of bioAffinity Technologies. “Adding CyPath® Lung to the diagnostic pathway for indeterminate nodules provides additional objective data that can be very valuable when assessing patients with complicating health conditions. In this patient’s case, CyPath® Lung supported additional imaging before biopsy which resulted in saving the patient from a risky, costly and unnecessary procedure.”

This case highlights how CyPath® Lung can assist physicians with pulmonary nodule management by helping physicians confidently defer unnecessary – and often risky – invasive procedures. This case study is illustrative of a single patient experience and does not establish generalized clinical utility.

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. In a clinical trial of high-risk patients, CyPath® Lung 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. CyPath® Lung is not intended for use as a sole diagnostic tool and should be considered alongside other clinical findings.

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. LDTs are overseen under the Clinical Laboratory Improvement Amendments (CLIA), administered by the Centers for Medicare & Medicaid Services. 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 the probability of lung cancer, CyPath® Lung providing confidence in a proposed course of action for high-risk patients, 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, 2025, 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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