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bioAffinity Technologies Announces Precision Pathology Services' Validation of Novel Non-Invasive Early Lung Cancer Test

CyPath® Lung, an Innovative Lung Cancer Diagnostic, Fully Validated as a Laboratory Developed Test (LDT) by CAP/CLIA-Certified Laboratory

SAN ANTONIO--(BUSINESS WIRE)-- bioAffinity Technologies, a privately held biotech company advancing innovative cancer diagnostics, announced that Precision Pathology Services, a CAP/CLIA-certified anatomic and clinical pathology laboratory, has fully validated the clinical performance of CyPath® Lung, a non-invasive flow cytometric test for early-stage lung cancer. Precision Pathology licensed bioAffinity's intellectual property for development of CyPath® Lung as a laboratory developed test (LDT).

"We are confident that the validations we have completed and the systems we have implemented will enable high scalability of the CyPath® Lung flow cytometry test," said Roby Joyce, MD, President of Precision Pathology. "We will be adding this test to our menu of services in the coming months. This is a very exciting time for us. Lung cancer is the leading cancer killer. Our test for early detection of this dreaded disease can help many people live longer and healthier lives."

Validation of CyPath® Lung was conducted in accordance with College of American Pathologists (CAP) guidelines and Clinical Laboratory Improvement Amendments (CLIA) regulations. The CAP/CLIA validation establishes and validates the performance of CyPath® Lung, including accuracy, precision, reproducibility and analytical specificity, that are necessary for commercialization. After Precision Pathology adds CyPath® Lung to its menu of tests, physicians will be able to order the test for their patients at high risk for lung cancer who receive a positive screening result or are otherwise suspected of having the disease.

"Precision Pathology rightfully enjoys an excellent reputation for quick turnaround times while providing accurate pathology diagnoses. The company is known for its exceptionally responsive and helpful service to the physicians and patients it serves," bioAffinity President and CEO Maria Zannes said. "Dr. Joyce and his team will bring the same very high quality to the commercialization of CyPath® Lung. CyPath® Lung is in excellent hands."

CyPath® Lung is a flow cytometric test to aid in the diagnosis of lung cancer. Patients collect sputum samples non-invasively at home, a particular benefit during the COVID-19 pandemic. The sample is shipped overnight to the laboratory for processing. Sample data is acquired

by flow cytometry, a technique that can count, sort and profile individual cells with remarkable speed. Using an automated analysis with pre-set parameters, CyPath® Lung profiles the lung environment, including the presence of cancer-associated cells. Data acquisition and physician reports can be generated in minutes.

bioAffinity Technologies recently completed a test validation trial of CyPath® Lung evaluating sputum from people at high risk for lung cancer, including patients with the disease and others who were cancer-free. The trial resulted in 92% sensitivity and 87% specificity in high-risk patients who had nodules smaller than 20 mm.

The U.S. Preventive Services Task Force recommends that smokers and former smokers at high risk for lung cancer undergo annual screening by low dose computed tomography (LDCT). Screening by LDCT has been proven to detect lung cancer at earlier stages when it can be more successfully treated. The National Lung Cancer Screening Trial (NLCST) of more than 53,000 participants resulted in a 20% decrease in lung cancer-specific mortality when LDCT screening was performed in high-risk patients. However, screening by LDCT had a low 3.8% positive predictive value (PPV) which raises the risk of unnecessary, invasive and costly procedures for those who test positive. In the NLCST, for every 100 people who received a positive LDCT, less than four of those individuals actually had lung cancer.

"CyPath® Lung can assist physicians in determining next steps after a patient presents with a positive LDCT result, particularly in many cases where the lung nodule is considered indeterminate. In our test validation trial, bioAffinity successfully tested the automated analysis program used by CyPath® Lung and found it to be fast and very robust in predicting who has cancer and who was at high risk but did not have lung cancer," Zannes said. "Physician reports can be generated immediately after flow cytometry acquires sample data. Looking beyond lung cancer, we believe our automated platform can be successfully applied to cancer diagnostic tests for several other cancers, which will improve overall survival rates for patients through early diagnosis and treatment."

About Precision Pathology Services

The board-certified pathologists practicing at Precision Pathology Services and Village Oaks Pathology Services, PA, have provided anatomic and clinical pathology services for patients and their physicians since 1986. The Company is committed to bringing a spirit of excellence to all its services, remembering that every specimen has come from someone's loved one and requires precise diagnosis every time and as quickly as possible. Precision Pathology Services is known for exceptionally responsive and helpful service to the physicians and patients.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. is a privately held company addressing the significant unmet need for non-invasive, early-stage cancer diagnosis and treatment. The Company develops proprietary *in vitro* diagnostic tests and targeted cancer therapeutics using breakthrough technology that preferentially targets cancer cells. Research and optimization of its platform technology are conducted in bioAffinity Technologies' laboratories at the University of Texas San Antonio (UTSA). The Company's platform technology is being developed to diagnose,

monitor and treat many cancers.

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