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Smiths Medical and bioAffinity Technologies Partner to Advance Non-Invasive Testing for Early Lung Cancer

Partnership supports patient care and sample collection for automated test demonstrating high accuracy in finding lung cancer

SAN ANTONIO--(BUSINESS WIRE)-- [bioAffinity Technologies](#), a privately held biotech company, and [Smiths Medical](#), a leading global medical device manufacturer, today announced a partnership to improve patient care with at-home collection of sputum to be analyzed by CyPath® Lung, a non-invasive flow cytometry diagnostic test for lung cancer that is being developed as a Laboratory Developed Test (LDT) by [Precision Pathology Services](#).

"The partnership enables the use of the acapella® vibratory PEP therapy system made by Smiths Medical for at-home collection of samples that are analyzed by bioAffinity's CyPath® Lung, a patient-friendly test shown to have high sensitivity and specificity in detecting lung cancer in people at high risk for the disease," said bioAffinity Technologies President and CEO Maria Zannes. "One of the hallmarks of CyPath® Lung is the ease by which patients collect their sputum samples at home using the acapella® device."

"Innovation is a cornerstone of Smiths Medical. As a leader in airway management solutions, we are proud that our acapella® device can facilitate the use of this non-invasive breakthrough test that can detect lung cancer at its earliest stages when treatment can be most effective and lives can be saved," said JehanZeb Noor, Chief Executive Officer, Smiths Medical. "Smiths Medical and bioAffinity Technologies share a commitment to putting patients first and making quality healthcare accessible and affordable."

CyPath® Lung is a flow cytometric test to aid in the diagnosis of lung cancer. Patients collect sputum samples non-invasively at home using the acapella® device. 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 quickly. Using an automated analysis with pre-set parameters, CyPath® Lung profiles the lung micro-environment including the presence of cancer-associated cells. Test results can be provided to the physician in minutes.

A test validation trial conducted by bioAffinity Technologies comparing people at high risk for lung cancer to high-risk patients with the disease resulted in CyPath® Lung specificity of 88% and sensitivity of 82%, similar to far more invasive procedures currently used to diagnose lung cancer. CyPath® Lung performed even better, with 92% sensitivity and 87% specificity, in the group of cancer and cancer-free high-risk participants who had no nodules

or small nodules less than 2 cm in diameter. Results of the test validation trial have been submitted for presentation at the [International Association for the Study of Lung Cancer \(IASLC\) 2020 World Conference on Lung Cancer](#).

Precision Pathology Services has licensed and is developing CyPath® Lung as a Laboratory Developed Test (LDT) in accordance with the College of American Pathologists (CAP) and the Clinical Laboratory Improvement Amendment (CLIA) guidelines and regulations. Precision Pathology Services is an accredited CAP/CLIA laboratory in San Antonio, Texas. Following completion of development of CyPath® Lung as an LDT, physicians may order the test for their patients who are smokers and former smokers at high risk for lung cancer and who receive a positive screening result or otherwise are suspected of having the disease.

People who have smoked the equivalent of one pack of cigarettes a day for 30 years or more, have not quit smoking in the past 15 years and are 55-80 years of age are recommended for 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 successfully treated, but screening has a low Positive Predictive Value (PPV) that can lead to unnecessary and risky procedures.

About Smiths Medical

Smiths Medical is a leading supplier of specialized medical devices and equipment for global markets, focusing on the medication delivery, vital care and safety devices market segments. For more information, visit www.smiths-medical.com.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. (www.bioaffinitytech.com) 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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