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bioAffinity's CyPath® Lung Cancer Test Supported by Newly Published Flow Cytometry Guidelines

bioAffinity VP served on expert panel that published new guidance

SAN ANTONIO--(BUSINESS WIRE)-- bioAffinity Technologies' (Nasdaq: BIAF; BIAFW) Vice President of Diagnostics, Jennifer Rebeles, Ph.D., was part of a panel of worldwide experts that published the peer-reviewed paper, "Implementation of flow cytometry testing on rare matrix samples: Special considerations and best practices when the sample is unique or difficult to obtain," in the journal *Cytometry Part B: Clinical Cytometry*, the official journal of the International Clinical Cytometry Society.

"Our CyPath® Lung noninvasive test for the early detection of lung cancer is a novel test that uses sputum, a unique sample type that is not typically used in clinical flow cytometry assays," Rebeles said. Flow cytometry is a well-established technology used in both research and clinical practice because of its ability to rapidly measure physical and chemical properties of cells in biological samples.

The paper supplements the Clinical and Laboratory Standards Institute (CLSI) Guideline H62, the standard for validating assays performed by flow cytometry issued in 2021, by addressing challenges and considerations in validation with unique sample types.

"The new guidelines support the way we have validated the CyPath® Lung assay in our own laboratory, including customized protocols, specialized reagents, optimized cytometer settings and unique gating strategies," Rebeles added.

CyPath® Lung fulfills the need for a noninvasive test for the early detection of lung cancer and is especially useful for patients whose lung cancer screening or other scan reveals a pulmonary nodule. CyPath® Lung has shown 92% sensitivity and 87% specificity in detecting cancer in the lung for people who have pulmonary nodules 20 millimeters or less.

Rebeles was one of 12 subject matter experts from industry, government and healthcare professions who participated in CLSI's consensus process to provide best practices to expand the scope of the H62 guidelines beyond the use of flow cytometry to analyze common biological samples to include specialized samples like sputum.

The updated guidelines reflect the increasing use of specialized or unconventional samples in flow cytometry. The paper acknowledges some of the challenges bioAffinity scientists overcame when developing the CyPath® Lung test. The paper notes, "Factors such as high viscosity, presence of inhibitors, cellular debris or other artifacts, complex cellular mixtures,

or unique tissue and cellular morphology might necessitate adjustments to standard flow cytometry techniques to achieve accurate and reliable results."

"It is gratifying to see our workgroup's recommendations shared with the clinical cytometry community. The panel's work acknowledges and encourages the validation of rare matrices in flow cytometry for clinical use," Rebeles said.

About CyPath® Lung

CyPath® Lung uses proprietary advanced flow cytometry and artificial intelligence (AI) to identify cell populations in patient sputum that indicate malignancy. Automated data analysis helps determine if cancer is present or if the patient is cancer-free. CyPath® Lung incorporates a fluorescent porphyrin that is preferentially taken up by cancer and cancer-related cells. Clinical study results demonstrated that CyPath® Lung had 92% sensitivity, 87% specificity and 88% accuracy in detecting lung cancer in patients at high risk for the disease who had small lung nodules less than 20 millimeters. Diagnosing and treating early-stage lung cancer can improve outcomes and increase patient survival. For more information, visit www.cypathlung.com.

About bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW)

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 and follow us on LinkedIn, Facebook and X.

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 based upon current estimates and assumptions and include statements regarding the high viscosity, presence of inhibitors, cellular debris or other artifacts, complex cellular mixtures, or unique tissue and cellular morphology necessitating adjustments to standard flow cytometry techniques to achieve accurate and reliable results and acknowledging and encouraging the validation of rare matrices in flow cytometry for clinical use. 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 factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, 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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