UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 20, 2025**

bioAffinity Technologies, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41463**	**46-5211056**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

3300 Nacogdoches Road, Suite 216
San Antonio, Texas 78217
(Address of principal executive offices, including zip code)

(210) 698-5334
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e- 4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock, par value $0.007 per share	BIAF	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Warrants to purchase Common Stock	BIAFW	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On October 20, 2025, bioAffinity Technologies, Inc., a Delaware corporation, issued a press release announcing that it will present research at CHEST 2025, the annual meeting of the American College of Chest Physicians. Rossella Titone, PhD, the Company's project manager for product development, will present the poster *"The Effect of Sputum Storage and Shipping Temperature on Flow Cytometric Outcomes of Sputum-Based Diagnostic Tests"* on October 22, 2025, at 10:20 a.m. at poster board #4324.

Copies of the press release and poster are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by bioAffinity Technologies, Inc., dated October 20, 2025
99.2	Poster entitled "The Effect of Sputum Storage and Shipping Temperature on Flow Cytometric Outcomes of Sputum-Based Diagnostic Tests"
104	Cover Page Interactive Data File (embedded within the XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Current Report on Form 8-K to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 20, 2025

BIOAFFINITY TECHNOLOGIES, INC.

By: */s/ Maria Zannes*
Name: Maria Zannes
Title: President and Chief Executive Officer

Exhibit 99.1

News Release

bioAffinity Technologies Presents Research Supporting CyPath® Lung Processing Methods at CHEST 2025

Visit the CyPath® Lung team at Booth #2242 October 19-22

SAN ANTONIO, Texas – October 20, 2025 – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company advancing noninvasive diagnostics for lung cancer and other lung diseases, today announced it will present research at CHEST 2025, the annual meeting of the American College of Chest Physicians. The study supports the methods used to collect and transport patient samples for analysis by the Company's noninvasive CyPath® Lung test for detecting early-stage lung cancer.

*"*Our research reflects the scientific rigor applied to every step of the CyPath® Lung process that has been shown to result in clear, accurate and reliable answers when they matter most," said Maria Zannes, President and CEO of bioAffinity Technologies, Inc. "We are proud to present our work at CHEST, a premier pulmonary conference that brings the world's leading physicians together to discuss cutting-edge technology like our own CyPath® Lung."

Rossella Titone, PhD, project manager for product development at bioAffinity Technologies, will present the poster *"The Effect of Sputum Storage and Shipping Temperature on Flow Cytometric Outcomes of Sputum-Based Diagnostic Tests"* on October 22, 2025, at 10:20 a.m. at poster board #4324.

"This research supports the protocols we use for handling clinical samples collected at home by patients and returned to our laboratory for processing. Physicians usually receive results in two days," said Gordon Downie, MD, PhD, Chief Medical Officer of bioAffinity Technologies. "Our recent announcements of multiple case studies in which lung cancer was found at potentially curative Stage 1A illustrates the value of the kind of research Dr. Titone is presenting at CHEST. We look forward to speaking with physicians and other healthcare professionals at CHEST about how CyPath® Lung can result in better outcomes for patients."

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.

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 benefits to be derived from the research on collecting and transporting patient samples, the ability of CyPath® Lung to identify lung cancer 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.

Contact

bioAffinity Technologies
Julie Anne Overton
Director of Communications
jao@bioaffinitytech.com

THE EFFECT OF SPUTUM STORAGE AND SHIPPING TEMPERATURE ON FLOW CYTOMETRIC OUTCOMES OF SPUTUM-BASED DIAGNOSTIC TESTS

Rossella Titone[1], Lydia H. Bederka[1], David J. Elzi[1], William E. Bauta[1] and Jennifer Rebeles[1]

Introduction

- Sputum is a thick mixture of saliva and mucus, containing a diverse cellular population that includes both hematopoietic and non-hematopoietic elements.
- Sputum can be collected from patients for the diagnosis of lung diseases, but temperature excursions may have consequences on the test results.
- Controlled shipping and storage conditions of clinical specimens are crucial to preserve the integrity of the sample's cellular composition.
- This study investigated the impact of three storage temperatures on the flow cytometric analysis of sputum samples, utilizing markers specific to cell populations known to be well characterized in sputum.

Figure 1: Sputum Sample

Methods

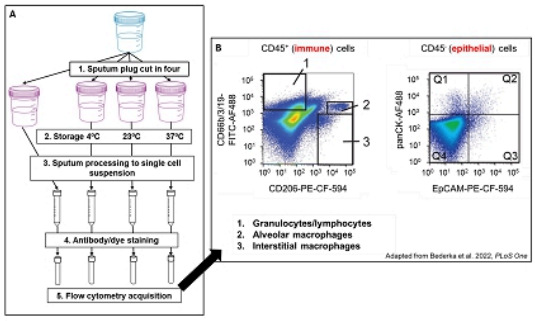


Figure 2: Sputum Sample Analysis Overview. (A) Experimental setup. **(B)** Flow cytometry of sputum samples showing immune cell markers (CD86b, CD3, CD19) vs. macrophage marker (CD206) fluorescence intensity (left plot). Epithelial markers (panCK vs. EpCAM) fluorescence intensity (right plot).

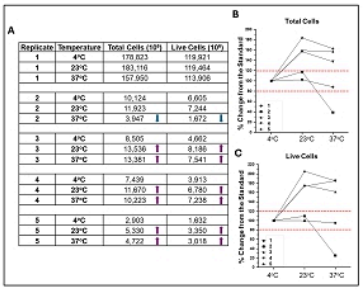
Sputum Processing, Staining and Analysis Method

- Sputum was collected for three days, stored at 4ºC, and shipped overnight on the third day (with cold pack) to the laboratory where it was cut into four similar weight pieces and processed or stored at 4, 23 or 37ºC, then processed as described in **Figure 2A**.
- Sputum was dissociated to a single cell suspension using 0.5% n-acetyl cysteine and 0.1% dithiothreitol, and cells were counted, with exclusion of dead cells by Trypan Blue staining.
- Single cell suspensions were labeled with a viability dye (FVS510) and fluorescently conjugated antibodies against immune and epithelial cell markers; they were subsequently analyzed by flow cytometry (**Figure 1B**).
- Variability differences were measured as the percentage difference between test condition measurements and standard storage temperature measurements; a ±20% difference was considered acceptable variability.

Results

Effect of Temperature on Sputum Viability

- Storage temperature above 4°C significantly affected cell number, causing over 20% variability in 60% of replicates stored at 23°C and 80% of replicates stored at 37°C (**Figure 3**).



Replicate	Temperature	Total Cells (10⁶)	Live Cells (10⁶)
1	4°C	179,823	119,821
1	23°C	183,116	119,464
1	37°C	157,950	113,906
2	4°C	10,124	6,605
2	23°C	11,923	7,244
2	37°C	3,947	1,672
3	4°C	8,505	4,662
3	23°C	13,536	8,186
3	37°C	13,381	7,541
4	4°C	7,499	3,913
4	23°C	11,870	6,780
4	37°C	10,223	7,238
5	4°C	2,003	1,832
5	23°C	5,330	3,350
5	37°C	4,722	3,018

Figure 3: Effect of storage temperature on cell number. (A) Table summarizing total and live cell counts data from replicates 1 to 5 and divided by storage temperature. Blue downward arrows (↓), indicate a ≥20% decrease in cell count compared to the standard 4°C storage. Pink upward arrows (↑), indicate a ≥20% increase in cell count compared to 4°C. Graphs of the total cell count **(B)** and live cells count **(C)** at the different temperatures show the percent change of the 23ºC and 37ºC storage compared to the standard 4°C storage. The red dotted lines indicate the acceptable variability range.

- Some of the replicates showed a population with smaller scatter and lower viability dye (FVS510) fluorescence. This population with lower FVS510 increased at higher temperatures, suggesting a rise in contamination (**Figure 4**).

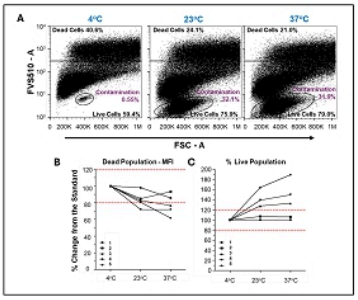


Figure 4: . Effect of storage temperature on cell viability. (A) Representative dot plots of FVS510 fluorescence intensity area (A) vs forward scatter-A (FSC-A) at 4º, 23º and 37ºC for one of the replicates. Live and dead cells were gated, while the black oval indicate contamination. Graphs of the total dead population mean fluorescence intensity (MFI) **(B)** and % of live cells **(C)** at the different temperatures show the % of change of the 23º and 37ºC storage compared to the standard 4°C storage. The red dashed lines indicate the acceptable variability range of 20% compared from the standard.

Effect of Temperature Sputum Cells on Immune and Non-immune cells

Storage temperature of 37°C significantly affected the MFI and the percentage of cells stained with granulocyte/lymphocyte, macrophage and epithelial cell markers for most of the replicates (**Figure 5**):

- The analysis of the MFI for granulocyte/lymphocyte and macrophage markers showed <20% variability in most of the samples stored at 23°C and >20% variability in 60% of samples stored at 37°C.
- Data on the percentages of granulocyte/lymphocyte and macrophage markers showed >20% variability in 60% of replicates at 23°C.
- The variability was >20% in 60% of replicates for the granulocyte/lymphocyte population and in 80% of the replicates for the macrophage population when stored at 37°C.
- The epithelial markers (panCK and EpCAM) showed similar variability patterns observed with immune cells.

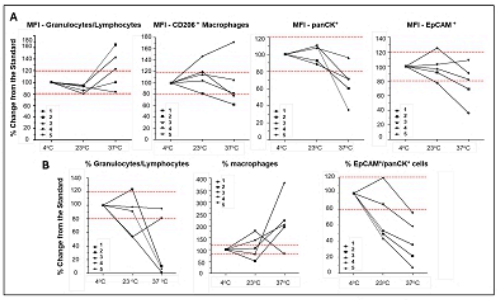


Figure 5: Effect of storage temperature on sputum cell populations. Graphs of the MFI **(A)** and percentage **(B)** of the granulocyte/lymphocyte, macrophage and epithelial cell (panCK, EpCAM) markers at the different temperatures show the percentage of change of the 23ºC and 37ºC storage compared to the standard 4°C storage. The red dashes indicate the acceptable variability range (20%).

Conclusion

- Our results demonstrate the importance of maintaining sputum samples at 4ºC for optimal results.
- We concluded that sputum samples should not be left out at temperatures above 4ºC to avoid contamination from bacterial and/or yeast growth that could affect the flow cytometric analysis.
- We recommend keeping sputum samples for use in flow cytometry-based diagnostic tests at 4ºC before processing.

COME SEE US AT BOOTH #2242

[1]bioAffinity Technologies, San Antonio, TX, USA