Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2306599	03/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Azimuth Dermatopathology Llc	1585 Mullet Ln, Naples, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA initial survey was conducted at AZIMUTH DERMATOPATHOLOGY LLC from 03/24/2025 to 03/28/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on lack of quality control records and Laboratory Director (LD) interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) for Hematoxylin & Eosin (H&E) stain for nine testing dates from 11/27/2024 to 01/17/2025 by the Testing Person (TP). Findings included: 1- Review of the Form CMS-209, Laboratory Personnel Report (CLIA); signed by the laboratory director on 03/21/2025 revealed that: The LD was also Clinical Consultant (CC), Technical Supervisor (TS), General Supervisor (GS) and Testing Person (TP). 2- Review of procedure manual signed by the LD on 04/20/2024 revealed that the laboratory does the Professional Component for Histopathology Testing. 3-Review of patient's final reports revealed that the laboratory did testing on the following dates: 11/27/2024, 12 /02/2024, 12/05/2024, 12/06/2024, 12/16/2024, 12/19/2024, 01/07/2025, 01/15/2025 and 01/17/2025 and the laboratory reported nine patients in that period. 4-The laboratory had no records of documentation of the approval of the Quality of H&E stain per testing date. 5-During an interview on 03/24/2025 at 12:25 PM the LD confirmed that she failed to document the acceptability of the Daily QC slide for H& E Stain for the days listed above.

D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on patient reports review and staff interview, the laboratory failed to ensure that the patient final reports listed the name and address of the laboratory that performed Technical Component for Histopathology testing for 11 out of 11 patient's reports reviewed. Findings include: Review of 11 final patient reports: P#1(dated 11/27 /2024), P#2 (dated 12/02/2024), P#3 (dated 12/05/2024), P#4 (dated 12/06/2024), P#5 (dated 12/16/2024, P#6 (dated 12/19/2024), P#7, P#8 and P#9 (dated 01/07/2025) P#10 (dated 01/15/2025) and P#11 (dated 01/17/2025), revealed that the reports failed to list the name and address of the laboratory that performed the Technical Component for the histopathology testing. During an interview on 03/24/2025 at 12: 00 PM, with the Laboratory Director, she confirmed that the final reports reviewed did not include the name and address of the laboratory that performed the Technical Component for the histopathology testing.