

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2132625	<b>(X3) Date Survey Completed</b>  01/09/2025
<b>Name of Provider or Supplier</b>  Academic Alliance In Dermatology Inc	<b>Street Address, City, State</b>  1258 West Bay Drive Unit G, Largo, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Academic Alliance in Dermatology on 01/06/2025 through 01/09/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy twice annually for (1) Hematoxylin and Eosin for one (2024) of two years (2023 and 2024) for Histopathology for one of one testing personnel (TP) and (2) potassium hydroxide and scabies for two of two years (2023 and 2024) for Mycology and Parasitology for two of two TP. Findings include: Review of the undated policy /procedure manual titled "KOH/Scabies/MOHS Proficiency Testing for Providers" showed twice a year three randomly selected cases would be chosen for each testing persons for Mycology, Parasitology and Histopathology. These samples would be analyzed and the results/findings would be compared to the testing persons findings. Review of the Laboratory Personnel Report dated 01/06/2025 revealed one TP (TP #A) for high complexity testing of Histology, and two TP (TP #A and TP #B) for moderate complexity testing of Mycology and Parasitology. Proficiency Testing Log Sheets for Histopathology showed the lab verified the accuracy only one time in 2024, on 11/13/2024. Proficiency Testing Log Sheets for Mycology and Parasitology showed the lab verified the accuracy for Mycology and Parasitology one time in 2024, 7/20/2024 for TP #A and TP #B, and no documentation of verification for accuracy</p>

was logged for 2023. The Lab Consultant confirmed the lab failed to verify the accuracy of the tests twice annually during an interview on 01/06/2025 at 10:45 am and 1:35 pm.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory systems quality assessment program failed to identify written policies and procedures for verifying the accuracy of analytes for two of two years (2023 and 2024) were not followed and failed to perform monthly quality assurance checklists for nine (04/2023 - 12/2023) out of twenty-one months (04/2023 - 12/2024) reviewed. Finding include: Review of Monthly Quality Assurance Checklists from 04/2023 through 12/2024 revealed: (1) There were no checklists completed for the months of 04/2023 through 12/2023. (2) The checklist dated 12/31/2024, signed by the Lab Director, was marked yes for all proficiency test results were evaluated and failures were investigated with remedial action taken. (See D5217) An interview with the Lab Consultant on 01/06/2025 at 1:10 pm verified the 12/31/2024 checklist did not identify the lab failed to verify the accuracy of the testing of analytes for 2023 and 2024, and no Quality Assurance Checklists were present for 04/2023 through 12/2023.