

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2031538	(X3) Date Survey Completed 07/22/2025
Name of Provider or Supplier Academic Alliance In Dermatology Inc	Street Address, City, State 2438 Bloomingdale Ave, Valrico, 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 recertification survey was conducted at Academic Alliance in Dermatology on 7/17/25-7/22/25. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to ensure protection from chemical hazards from 10/23/2023 to 7/17/2025. Findings included; 1. During a tour of the laboratory on 7/17/25 at 10:12 a.m., Clear-Rite 3, 100% Dehydrant, and Eosin-Y with Phloxine were observed stored in the safety cabinet. The primary container for the Clear-Rite 3, 100% Dehydrant, and Eosin-Y with Phloxine labels included the hazard sign for respiratory and stated Do not Breath dust/fume/gas/mist/vapors/spray and to use explosion proof ventilating. 2. The Histology technician confirmed on 7/17/25 at 10:12 a.m., the laboratory did not have a fume hood to mitigate exposure to harmful chemical fumes from the Clear-Rite 3, 100% Dehydrant, and Eosin-Y with Phloxine.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the

laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:

Based on record review and interview the Laboratory Director failed to develop a policy or provide evidence of the required onsite visits for one of one six month period reviewed (01/2025 - 07/2025). Findings included: 1. Review of records revealed no policy regarding the Laboratory Director being onsite every 6 months and no evidence of onsite visit for 01/2025 to 07/2025. 2. Interview with the Histology Tech on 7/17/25 at 11:10 a.m. confirmed the above. 3. The Laboratory Director confirmed via email on 7/21/25 at 10:37 a.m., the last time he was onsite in the laboratory was 4/27/2023.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services provided for 2024-2025. Findings included: 1. The laboratory CLIA Compliance Manual approved by the Laboratory Director on 6/4/2025, included the job description for Laboratory Director which stated the Director was responsible for compliance. 2. The Quality Assurance Quality Control procedure provided failed to indicate how the Laboratory Director was to document how the Quality Assessment Program was maintained. 3. Monthly Quality Assurance Checklists were provided for review including four pre-signed blank checklist forms with the Laboratory Director's signature. The Monthly Quality Assurance Checklists for 1/15/24, 9/16/24, and 3/3/25 all had identical signatures of the Laboratory Director. The Histology Technician stated on 7/17/25 at 10:50 a.m., the Histology Technicians completed the Monthly Quality Assurance Checklist and signed and dated the blank checklist forms which had the Laboratory Director's pre-signed signature. 4. The Laboratory Director stated via email on 7/21/25 at 10:37 a.m., the Mohs techs do the reviewing which is documented on the Quality Assurance checklist.