Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2056004	08/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Academic Alliance In Dermatology Inc	1201 S Myrtle Ave, Clearwater, 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 Inc. on 08/18/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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, review of reagent safety data sheets, and staff interview, the laboratory failed to ensure protection from chemical hazards from 06/2023 through 08 /2025. Findings included: 1. Observations were conducted during a tour on 08/18 /2025 beginning at 10:25 a.m. There was no fume hood over the staining work station. 2. Interview with the MOHs Supervisor/Histotech on 08/18/2025 at 10:50 a.m. confirmed the laboratory had no fume hood. 3. Manufacturer Safety Data Sheets (SDS) were reviewed for chemicals the laboratory utilized. a. The SDS for Xylene Mounting Media with a revision date of 03/16/2021 stated the following: Acute Inhalation Toxicity, harmful if inhaled, use only outdoors or in a well ventilated area, and move to fresh air in case of accidental inhalation of vapors. b. The SDS for Hematoxylin with a revision date of 06/04/2010 stated, ensure adequate ventilation, and do not breathe vapors or spray mist. c. The SDS for Eosin-Y Saturated with a revision date of 01/26/2015 stated if inhaled move to fresh air and ensure adequate ventilation, especially in confined areas. d. The SDS for Cytocool II with a revision date of 01/23/2015 stated if inhaled move to fresh air, avoid breathing fumes or vapors, and ensure adequate ventilation, especially in confined areas. e. The SDS for Clear-Rite 3 with a revision date of 03/01/2009 stated if inhaled remove to fresh air

	and avoid inhalation. f. The SDS for Bluing Reagent with a revision date of 10/31 /2024 stated Acute Inhalation Toxicity - Vapors and do not breath fumes, gas, or vapors. g. The SDS for 100% Dehydrant with a revision date of 01/26/2015 stated use outdoors or only in a well-ventilated area, do not breath fumes, gas or vapors, and the vapor is harmful. 4. Interview with the Laboratory Director on 08/18/2025 at 1:00 p. m. confirmed the laboratory did not have a fume hood to protect employees from chemical hazards.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of fungi and scabies testing twice annually for two testing personnel (TP) #A and #B of four TP (#A - #D) for two of two years (2023 and 2024) for TP who performed testing for the subspecialties of Mycology and Parasitology. Findings included: 1. Verification of Accuracy (VOA) documentation was reviewed for TP #A and #B. TP #A had no VOA for 2023 and one VOA in 2024 (07/22/2024) for fungi and scabies testing. TP #B had one VOA for 2023 and one for 2024 for fungi and scabies testing. 2. Interview with the Laboratory Director on 08/18/2025 at 1:00 p.m. confirmed the above.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observations, record review, and interview, the Laboratory Director failed to provide effective oversight and administration of the laboratory from 06/2023 through 08/2025. Findings included: 1. Observation, review of reagent safety data sheets, and staff interview, revealed the laboratory failed to ensure protection from chemical hazards from 06/2023 through 08/2025. (See D3011). 2. Record review and interview, revealed the laboratory failed to verify the accuracy of fungi and scabies testing twice annually for two testing personnel (TP) #A and #B of four TP (#A - #D) for two of two years (2023 and 2024) for TP who performed testing for the subspecialties of Mycology and Parasitology. (See D5217). 3. Record review and interview, revealed the Laboratory Director failed to develop a policy or procedure to document they were onsite at least once every 6 months for 2025. (See D6080). 4. Monthly Quality

	Assurance Checklist(s), signed and dated by the Laboratory Director each month, were reviewed for the months 01/2024 through 07/2025. No issues were identified. All documents reflected compliance. There was no documentation of safety concerns, failure to verify the accuracy twice a year for fungi and scabies testing, and failure to identify the lack of a policy and procedure to document onsite visits once every six months. 5. Interview with the Laboratory Director on 08/18/2025 at 1:00 p.m. confirmed the above.
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 procedure to document they were onsite at least once every 6 months for 2025. Findings included: 1. The policy and procedure manual, signed by the Laboratory Director 01/30/2025 failed to contain a policy regarding documenting Laboratory Director onsite visits at least once every 6 months. 2. Interview with the Laboratory Director on 08/18/2025 at 1:00 p.m. confirmed the above.