

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2215918	(X3) Date Survey Completed 09/04/2025
Name of Provider or Supplier Academic Alliance In Dermatology Inc	Street Address, City, State 6600 University Parkway Ste 302, Sarasota, 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 9/03/2025-9/4/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6076 493.1441-Condition: Laboratory Director High Complexity Testing
D5309	TEST REQUEST CFR(s): 493.1241(e) (e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on record review and interview, the manual test results for mycology (KOH) and parasitology (scabies) for two (Patient #2 and #3) of three patient results (Patient #1, #2, and #3) were not transcribed or entered accurately. Findings included: 1. The manual KOH & Scabies log documented Patient #2 had a KOH test performed on 5/22/25 with result documented as "+" (positive) and Patient #3 had a Scabies test performed on 5/16/25 with result documented as "+" (positive). The results for Patient #2 and #3 were reviewed by a second provider with documentation of agreement of results. 2. The electronic patient visit notes, which were the laboratory results for Patient #2, documented KOH as "no hyphae" which was not the same result as from the KOH & Scabies log. The electronic patient visit notes for Patient #3 documented results for Scabies as "no pathologic findings" which was not the same result as from the KOH & Scabies log. 3. On 9/3/25 at 12:05 p.m. Histology Tech #A confirmed the manual results documented on the KOH & Scabies log for Patients #2 and #3 were not accurately transcribed to the electronic patient visit notes. 4. The Laboratory Director responded via email on 9/4/25 at 4:44 p.m. and did not provide an answer as to why the manual results were not accurately transcribed or how the laboratory monitored to ensure transcription errors were identified and corrected.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have a Laboratory Director who provided overall management and direction from 09/2023 through 09/2025. The Laboratory Director failed to provide effective oversight and administration of the laboratory from 09/2023 through 09/2025 (See D 6079); the Laboratory Director failed to follow a policy to be onsite once every six months and document the onsite visits from 1/1/2025-9/3/2025 (See D 6080); the Laboratory Director failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services provided for 2023-2025 (See D6093); and the Laboratory Director failed to ensure that prior to testing patient specimens, all personnel had demonstrated that they could perform all testing operations reliably to provide and report accurate results for two of two newly hired Testing Personnel (TP#A and #B) who performed Histology (Hematoxylin and Eosin), Mycology (KOH), and Parasitology (Scabies) patient testing (D6102).
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 record review and interview, the Laboratory Director failed to provide effective oversight and administration of the laboratory from 09/2023 through 09/2025. Findings included: 1. The Laboratory Director failed to ensure the manual test results for mycology (KOH) and parasitology (scabies) for two (Patient #2 and #3) of three patient results (Patient #1, #2, and #3) were transcribed or entered accurately. (See D 5309) 2. The Laboratory Director failed to follow a policy to be onsite once every six months and document the onsite visits from 1/1/2025-9/3/2025. (See D 6080) 3. The Laboratory Director failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services provided for 2023-2025. (See D 6093) 4. The Laboratory Director failed to ensure that prior to testing patient specimens, all personnel had demonstrated that they could perform all testing operations reliably to provide and report accurate results for two of two newly hired Testing Personnel (TP#A and #B) who performed Histology (Hematoxylin and Eosin), Mycology (KOH), and Parasitology (Scabies) patient testing. (D 6102) 5. The

	Laboratory Director stated via email on 9/4/2025 at 4:44 p.m. he had not conducted laboratory duties for the last two years.
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 follow a policy to be onsite once every six months and document the onsite visits from 1/1/2025-9/3/2025 Findings included: 1. The laboratory's policies and procedures were reviewed and approved by the Laboratory Director on 7/10/23 which showed the manual would be reviewed biannually. There was a policy to reflect the Laboratory Director would be onsite at least once every six months and have detailed documented records of onsite visits. 2. Histology Tech #A confirmed on 9/3/25 at 12:05 p.m., there was no documentation of the Laboratory Director's 6 month visit and that the last time the Laboratory Director was onsite at the laboratory was 9/8/2023. The Laboratory Director stated via email on 9/4/2025 at 4:44 p.m. he had not conducted laboratory duties for the last two years.
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 the quality assessment program was maintained to assure the quality of laboratory services provided for 2023-2025. Findings included: 1. The laboratory CLIA Compliance Manual approved by the Laboratory Director on 7/10/2023, 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 for 6/25/24, 7/30/24, 8/28/24, 9/4/24, and 8/18/25 were provided for review. Each of the Monthly Quality Assurance Checklists indicated performed by Histology Technician #A with the Laboratory Director signature. There was no indication of any issues identified which needed to be corrected and that all personnel evaluations had been performed as necessary. Histology Technician #A stated on 9/3/2025 at 12:05 p.m., the Histology Technicians completed the Monthly Quality Assurance Checklist sent to the Laboratory Director for signature. 4. The Laboratory Director via email on 9/4/2025 at

4:44 PM did not answer how he had provided oversight of the laboratory when he had not been onsite since 9/8/2023 but did state he had not been conducting the laboratory duties for the last two years.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that prior to testing patient specimens, all personnel had demonstrated that they could perform all testing operations reliably to provide and report accurate results for two of two newly hired Testing Personnel (TP#A and #B) who performed Histology (Hematoxylin and Eosin), Mycology (KOH), and Parasitology (Scabies) patient testing. Findings included: 1. The CMS-209 Laboratory Personnel Report, signed by the Laboratory Director on 7/16/25, listed one Testing Personnel (TP#A) who performed High Complexity Histology Hematoxylin and Eosin (H & E) testing and (Testing Personnel (TP#B) who performed Moderate Complexity KOH and Scabies testing. The Histology Technician stated TP#A's date of hire was 5/2025 and TP #B was 11/2024. 2. The Laboratory policy manual approved by the Laboratory Director on 7/10/2023, included a Personnel Competency Assessment Policy which stated initial competency to be documented within the first 90 days. The policy did not indicate training and initial competency was to be documented prior to testing patient samples. 3. TP#A's personnel records included a 90 day competency signed and dated by the Laboratory Director on 6/2/2025 with documentation that the evaluator's observations were by "Direct Observation". There was no documentation of training at the laboratory for TP#A provided at the time of the survey. 4. TP#B's personnel records included a 90 day competency signed and dated by the Laboratory Director on 12/18/2024 and annual for 5/21/2025 with documentation that the evaluator's observations were by "Direct Observation". There was no documentation of training at the laboratory for TP#A provided at the time of the survey. 5. The Laboratory Director via email on 9/4/2025 at 4:44 p.m. did not answer how "Direct Observation" was accomplished by him for the competencies of TP#A and TP#B when he had not been onsite at the laboratory since 9/08/2023 (See D6080).