

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0985176	(X3) Date Survey Completed 05/09/2025
Name of Provider or Supplier Academic Alliance In Dermatology Inc	Street Address, City, State 5210 Webb Rd, Tampa, 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 validation survey was conducted at Academic Alliance in Dermatology Inc on 04/30/2025 - 05/09/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6076 493.1441 Condition: Laboratory Director D6168 493.1487 Condition: Laboratory Testing Personnel
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of competency assessments, educational records, quality assurance checklists, and staff interview, the Laboratory Director failed to ensure competency assessments were completed and ensure educational qualifications were met for Testing Personnel (See D6079) and failed to ensure Testing Personnel had the training, education, and failed to demonstrate they could perform high complexity histopathology testing operations reliably to provide accurate results prior to patient testing (See D6102).</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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</p>

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 review of competency assessments, educational records, and staff interview, the Laboratory Director failed to ensure competency assessments were completed for 4 (#B, C, D, and E) of 5 testing personnel (#A-E) for one of one year (2024) reviewed and failed to ensure the educational qualifications were met for 4 (#C, D, F, G) of 8 testing personnel (#A-H). Findings included: 1. Annual testing personnel (TP) competencies were reviewed for TP #B - E. The competencies were not filled out, but signed as reviewed by the Laboratory Director on 8/30/24. 2. Interview with TP #D (who also serves as the Laboratory Manager) on 05/09/2025 at 10:17 a.m. confirmed the competencies were signed by the Laboratory Director and not completed. 3. Educational records for TP #C and #D contained no documentation of their highest level of education. TP #F's educational record contained an unofficial college transcript, which had a total of 60 credit hours. This did not include 24 credit hours of science courses as required. TP #G's educational record did not contain a foreign equivalency evaluation of their foreign degree. 4. Interview with TP #D (who also serves as the Laboratory Manager) on 04/30/2025 at 3:25 p.m. and 05/09/2025 at 10:17 a.m. confirmed no additional educational records were present for TP #C, D, F and G.

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 review of quality assurance checklists and staff interview, the Laboratory Director failed to ensure testing personnel had the appropriate education, training, and demonstrated competency prior to testing patients' specimens for high complexity histopathology testing for two of two years reviewed (04/2023 - 03/2025). Findings included: 1. Monthly Quality Assurance Checklists, signed by the Laboratory Director, for 04/2023 through 03/2025 showed no problems were identified. The checklist included "Personnel evaluations were performed as necessary" and "All personnel who perform test have documented training for these tests." All boxes were checked "Y" for yes. 2. Interview with Testing Personnel #D (who also serves as the Laboratory Manager) on 4/30/2025 at 3:10 p.m. confirmed the Quality Assessment Checklists did not identify any problems. 3. See D6079.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.

1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory failed to verify four (#C, D, F, G) of eight (#A-H) testing personnel met the educational qualifications (See D6171).

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and interview, the lab failed to verify four (#C, D, F, G) of eight (#A-H) testing personnel met the educational requirements. Findings included: 1. Eight testing personnel (#A-H) records were reviewed. Testing personnel #C and #D's records contained no documentation of highest level of education. Testing personnel #F's record contained an unofficial college transcript which had a total of 60 credit hours. The 24 credit hours of science courses were not met. Testing personnel #G's record did not contain a foreign equivalency evaluation of their foreign degree. 2.

Interview with Testing Personnel #D (who also serves as the Laboratory Manager) on 04/30/2025 at 3:25 p.m. and 05/09/2025 at 10:17 a.m. confirmed all educational records the lab had were provided.