

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2126890	(X3) Date Survey Completed 03/30/2026
Name of Provider or Supplier Alliance Dermatology Physicians Pc	Street Address, City, State 11 Friends Lane, Suite 115, Newtown, PA	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 review of the laboratory's peer review records, and interview with the Practice Manager (PM), the laboratory failed to ensure that the verification of accuracy for MOHS microscopic slide examinations was performed at least twice annually, as required for tests not included in subpart I for 2 of 2 years (2024 and 2025). Findings Include: 1. On the day of the survey, 03/30/2026 at 09:47 am, the laboratory failed to provide documentation for the verification of accuracy of MOHS microscopic slide examinations stained using hematoxylin and eosin (H&E) performed at least twice annually for 2 of 2 years in 2024 and 2025. 2. The laboratory performed 406 microscopic slide examinations (histopathology) in 2025 (CMS-116, estimated annual volume, dated 3/23/2026). 3. The PM confirmed the findings above on 03/30/2026 at 10:15 am.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the Practice Manager (PM), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 Lecia DM1000 microscope and 1 of 1 Avantix QS12 cryostat used to perform histopathology microscopic slide examinations from 06/04/2024 to 03/30/2026. Findings include: 1. The manufacturer's operating environment specifications stated: "Lecia DM1000 microscope: 15-35 degrees Celsius (ambient temperature); maximum 80 % relative humidity." The Avantix Cryostat operating environment specifications stated: " 5-35 degrees Celsius (ambient temperature); maximum 60 % relative humidity." 2. On the day of the survey, 03/30/2026 at 09:45 am, the laboratory failed to provide documentation for the monitoring of room humidity to ensure operating conditions were met for the following instruments used to perform histopathology microscopic examinations from 06/04/24 to 03/30/2026: - 1 of 1 Lecia DM1000 microscope - 1 of 1 Avantix Cryostat 3. The laboratory performed 406 histopathology microscopic slide examinations in 2025 (CMS 116, estimated annual volume, dated 03/23/2026). 4. The PM confirmed the above findings on 03/30/2026 at 10:15 am.

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 review of laboratory procedure, lack of documentation and interview with the Practice Manager (PM), the Laboratory Director (LD) failed to follow and maintain the laboratory's established Quality Assessment (QA) program for 2 of 2 years from 06/04/2024 to 03/30/2026. Findings included: 1. The laboratory's Formal Policy Statement stated, " This procedure manual is reviewed by the Laboratory Director annually and at other times as required by major changes in procedure or other circumstances affecting laboratory performance of test." 2. On day of the survey, 03/30/2026 at 10:00 am, the laboratory failed to provide documentation of the annual review of the laboratory's procedure manual performed for 2 of 2 years from 06/04/2024 to 03/30/2026. 3. The PM confirmed the finding above on 03/30/2026 at 10:15 am.