

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1080362	(X3) Date Survey Completed 01/29/2026
Name of Provider or Supplier Advanced Dermatology Assoc Ltd	Street Address, City, State 236 Brodhead Rd, Suite #100, Bethlehem, 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
D0000	A recertification survey conducted by the Pennsylvania State Agency on 01/29/2026 found the Advanced Dermatology Associates LTD laboratory to be out of compliance with the following condition: 493.1250 Condition: Analytic systems.
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of temperature logs, lack of documentation and interview with Testing Personnel (TP) #13, the laboratory failed to monitor and document room temperature and humidity as required under 493.1252 to ensure reliable test system operation and test result reporting for instrumentation used to perform Potassium Hydroxide (KOH), ectoparasite (scabies) and dermatopathology (MOHS) microscopic examinations for 2 of 2 years from 01/29/2024 to 01/29/2026. Refer to D5413</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)</p>

Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of temperature logs, lack of documentation, and interview with Testing personnel (TP) #13, the laboratory failed to monitor and document room temperature and humidity to ensure reliable test system operation and test result reporting for instrumentation used to perform Potassium Hydroxide (KOH) , ectoparasite (scabies), and dermatopathology (MOHS) microscopic slide examinations for 2 of 2 years from 01/29/2024 to 01/29/2026. Findings include: 1. On the date of the survey, 01/29/2026 at 11:45 am, the laboratory could not provide documentation for monitoring room temperature (laboratory's acceptable range 20 to 25 degrees Celsius) and humidity (laboratory's acceptable range 30-50% RH) to ensure operating conditions were met for the following instrumentation used to perform KOH, scabies, and MOHS microscopic slide examinations for 2 of 2 years from 01/29/2024 to 01/29/2026: - 1 of 1 LaboMed CXL microscope (s/n 090631856) located in the clinical lab. (KOH, scabies) - 1 of 1 Leica DMLS microscope (s/n 202783) and 1 of 1 Nikon Ci microscope (s/n 500478) located in Consult Room A. (MOHS) 2. Review of the laboratory's test logs revealed the laboratory performed 258 KOH, 2 scabies, and 595 MOHS microscopic slide examinations from 01/29/2024 to 01/29/2026. 3. TP #13 (CMS 209 personnel #13, dated 01/27/2026) confirmed the findings above on 01/29/2026 at 12:10 pm. ** REPEAT DEFICIENCY

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of maintenance records and interview with Testing Personnel (TP) #13, the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 microscope used for specimen processing in the dermatopathology laboratory from 01/29/2024 to 01/29/2026. Findings Include: 1. The reference manual for the Reichert-Jung series 150 microscope stated, "Cleanliness of all optical components of the microscope is important for good optical performance. Optical surfaces should be cleaned with a lint-free, soft, linen cloth, lens paper or a Q tip just moistened with distilled water. Always promptly wipe the surface dry, using a circular motion, before allowing it to air dry." 2. On the day of the survey, 01/29/2026 at 11:45 am, the laboratory could not provide maintenance/function check records for the 1 of 1 Reichert-Jung Series 150 microscope (serial number 13678-8) used for specimen processing in the dermatopathology laboratory from 01/29/2024 to 01/29/2026. 3. During an interview on 01/29/2026 at 12:10 pm, TP #13 (CMS 209 personnel #13, dated 01/27/2026) confirmed the findings above and stated, "The microscope is only used by the histotechs to verify the edges of the specimen prior to submitting the slide to the pathologist for review".