

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0950417	<b>(X3) Date Survey Completed</b>  01/30/2025
<b>Name of Provider or Supplier</b>  Advanced Dermatology	<b>Street Address, City, State</b>  4904 Timber Ridge Dr Suite 101, Douglasville, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 30, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish and follow a policy and procedure to assess competency as required. Findings include: 1. An SOP review revealed there was no policy and procedure to assess competency available at the time of survey. 2. An interview with the MOHS technician, in the office by the lab, on 1/30/25 at 12:00 p.m. , confirmed the lack of a competency policy and procedure at the time of survey.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory maintenance records and interview with the MOHS</p>

technician, the laboratory failed to perform and document maintenance of the microscope used to perform the examination of biopsy or surgical specimen from January 2023 through January 2025. Findings include: 1. Review of laboratory records revealed there was no documentation of maintenance being performed on the microscope from January 2023 through January 30, 2025. 2. Microscopes used for testing and/or examination must be maintained and serviced by a professional as directed by the manufacturer. The laboratory must document all maintenance and professional service activities performed on the microscope. 3. Interview with the MOHS technician on 1/30/25 in the office by the lab at 12:30 PM confirmed, that no microscope maintenance records were available for the aforementioned time period.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of temperature records and staff interview, the lab failed to document corrective actions when temperatures exceeded acceptable limits during the time period of 2/1/23 to 1/29/25. Findings include: 1. Review of cryostat temperature logs revealed the cryostat temperature was outside acceptable limits (-25 to -30 c ) for 112 of 141 days. No corrective actions documented. 2. Review of the room temperature logs revealed the laboratory temperature was out of acceptable limits (64 to 69 F) for 141 of 141 days. No corrective actions documented. 3. Interview with the MOHS technician on 1/30/25 at 12:44 pm in the office outside the lab, confirmed the aforementioned findings.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP

review revealed the LD failed to specify, in writing, the duties and responsibilities for the Clinical Consultant, Technical Supervisor, General Supervisor, or the testing personnel. 2. An interview with the MOHS technician in a office by the lab on 1/30 /25 at 12:30 p.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure for the aforementioned personnel.