

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0686603	<b>(X3) Date Survey Completed</b>  09/25/2023
<b>Name of Provider or Supplier</b>  Dermatology Associates Of Georgia Llc	<b>Street Address, City, State</b>  1951 Clairmont Road, Decatur, 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 September 25, 2023. 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>D5293</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities on a monthly or quarterly basis that cover pre-analytic, analytic and post analytic phases of laboratory testing. The Findings include: 1. Review of the daily maintenance logs including: Room Temperature, Humidity, Refrigerator and Cryostat logs confirmed that incorrect normal ranges and logs with no location specific (Decatur) address on them. 2. A review of the maintenance logs confirmed the was no review or signature by the General Supervisor (GS) or Laboratory Director for years 2022 - 2023. 3. An interview with the office manager on 09/25/2023, at 2:30 PM, in the review room confirmed the lack of a QA checklist or standard quality over site of the laboratory by the General Supervisor (GS) or Laboratory Director for 2022 -2023.</p>
<b>D6022</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on documents review and interview with the office manager, the Lab Director (LD) failed to ensure that Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2022 - 2023 as required by the Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Standard Operating Procedures (SOP), QA and maintenance logs review revealed the Lab Director, who is also the Technical Supervisor (TS), did not review or sign Quality Assurance or maintenance logs in 2022 - 2023. 2. An interview with the laboratory's office manager, in the review room, on 09/25/2023, at approximately 2:40 PM, confirmed the LD failed to ensure proper oversight of the laboratory to solve problems as they occurred in 2022 - 2023.