

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>11D2232160</p>	<p>(X3) Date Survey Completed</p> <p>05/28/2025</p>
<p>Name of Provider or Supplier</p> <p>Ga Dermatology Specialists Of Coweta County, Llc</p>	<p>Street Address, City, State</p> <p>874 West Lanier Avenue, Suite 270, Fayetteville, GA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on May 28, 2025. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following standard level deficiencies were cited:</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) 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 service record review and staff interview , the lab failed to have annual maintenance performed on the 2 microscopes per the procedure manual. Findings include: 1. Review of the service records revealed the microscopes (serial numbers: 21790688 & 4F08558) were serviced 09/20/23 and 1/21/25. No record of service being performed in 2024. 2. Interview with the clinical supervisor on 05/28/25 in the break room at 12:13 PM, confirmed the lack of microscope maintenance for the year of 2024.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(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;</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on review of patient result log sheets, quality controls (QC) log sheets, and staff interview, the lab director failed to ensure the lab follows QC procedures and documents the parasitology and mycology QC each day of testing. The findings include: 1. Review of patient result log sheets and Mycology/Parasitology QC log sheets, revealed the lack of QC documentation. 3. Interview with the clinical supervisor, on 05/28/25 , at 11 am , in the laboratory, confirmed the laboratory director failed to ensure the lab documents QC in the subspecialties of parasitology and mycology.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>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 ensure that an approved procedure manual is available to all personnel. Findings include: 1. SOP review revealed the LD failed to approve/sign the SOP for the years of 2023, 2024, and 2025 to date. 2. An interview with the clinical supervisor in the break room on 05/28/25 at 11:15 a.m. confirmed the SOP was not sign by the LD for the aforementioned dates.</p>
<p>D6107</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>(e)(15) 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.</p> <p>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 of the LD, technical Supervisor (TS), General Supervisor (GS), and Clinical Consultant (CC). 2. An interview with the clinical supervisor in the break room on 05/28/25 at 11: 15 a.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure for the aforementioned required personnel.</p>