

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1059972	(X3) Date Survey Completed 03/04/2025
Name of Provider or Supplier Aqua Dermatology Of Georgia, Pc	Street Address, City, State 2045 Highway 34 East, Newnan, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 4, 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:
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:</p> <p>This STANDARD is not met as evidenced by: A review of 2023 - 2025 Maintenance Records, confirmed that Lab Staff failed to perform maintenance as required by the manufacturer. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Maintenance Records confirmed the following: a. The required daily maintenance was performed twice per year; b. The required weekly maintenance was performed twice per year; c. The required annual preventive maintenance was last performed in 2023. 2. An exit interview with the laboratory team, on March 4, 2025, at 12:00 pm confirmed the laboratory staff had not performed the required maintenance per manufacturer's requirements.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test</p>

results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Upon request of the 2023 - 2025 Quality Control (QC) records, confirmed that QC performance was not documented. THE FINDINGS INCLUDE: 1. A review of the QC Records confirmed that the laboratory performed QC but did not document. 2. There were no QC records available to review for 2023 - the date of survey, March 4, 2025. 3. An exit interview with the laboratory team, on March 4, 2025, at 12:00 pm confirmed laboratory staff had not documented QC performance for the inspection certificate survey period.