

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1086150	(X3) Date Survey Completed 01/03/2025
Name of Provider or Supplier Emory Integrated Genomics Core	Street Address, City, State 101 Woodruff Cir, Rms 7308 Memorial Bld, Atlanta, 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	<p>A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 3, 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:</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: A review of the 2023 - 2024 Maintenance, Temperature, and Humidity Records and an interview with the TS revealed failures in the performance of the required equipment maintenance as required by the manufacturers instructions. FINDINGS: 1. A review of the maintenance logs revealed that the required manufactures maintenance procedures were not completed as required for the SeqStudio 8 Flex Analyzer, Agilent 2100 Bioanalyzer, APPLIED BIOSYSTEMS Gene Amp PCR System 9700, ThermoFisher Scientific King Fisher Flex, TECAN INFINITE M200 PRO, and ThermoFisher Scientific NanoDrop One. 2. A tour of the laboratory revealed there was no room temperature or room humidity records available at the time of inspection. The aforementioned analyzers have required maintenance and/or</p>

humidity requirements per the manufacturers' specifications. 3. These findings were confirmed, with the TS, during review of the records and during the exit interview conducted on January 03, 2025 at 1:00pm.