Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D1028925	**(X3) Date Survey Completed** 08/20/2024
Name of Provider or Supplier Georgia Esoteric And Molecular Labs Llc	**Street Address, City, State** 1120 15th Street Building Bf 207, Augusta, 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 August 20, 2024. 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:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on the laboratory tour, maintenance documents and interviews with the technical supervisor, the laboratory did not document room temperature, humidity or heating block temperatures from January 2022 through day of survey August 20, 2024. Findings, 1.) During the lab tour and maintenance documents review, there were no room temperatures, heating block temperatures or humidity recorded for testing rooms 202, 206 and 207 from January 2022 through day of survey August 20, 2024. 2.) Interviews with the general supervisor and technical supervisor (TPs# 2 and 3 CMS 209) in the review conference room at approximately 12:15 PM on August 20, 2024 confirmed the above findings.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

	(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on personnel documents review and staff interview, the laboratory employed personnel who did not meet the qualifications as a high complexity Clinical Laboratory Improvement Amendments (CLIA) testing personnel (TP). Findings, 1.) Personnel document review revealed testing personnel (TP#4 CMS 209) failed to qualify as TP due to lack of educational documentation from an accredited institution or translation agency in the USA. 2.) Both the general supervisor and technical supervisor (TPs # 2 and 3 CMS 209) confirmed the findings in the conference review room on 08/20/2024 at approximately 12:25 PM.