

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0893924	(X3) Date Survey Completed 06/20/2025
Name of Provider or Supplier Emory Neuromuscular Pathology Laboratory	Street Address, City, State 101 Woodruff Circle, Wmrb, Rm 6310, 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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on June 20, 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:
D5429	<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 observation during the laboratory tour and staff interview, the laboratory failed to perform and document equipment maintenance checks as required in 2024 and 2025. Findings: 1. Observation during the laboratory tour on 06/20/2025 at approximately 10:15 a.m. revealed the GE refrigerator and Thermoscientific freezer forma 900 series had no evidence of annual pm maintenances in 2024 and 2025. 2. An interview with the laboratory coordinator (TP#5 CMS 209) during the laboratory tour at approximately 10:30 a.m confirmed the laboratory refrigerator and freezer had no annual maintenace done in 2024 through day of survey June 20, 2025.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p>

This STANDARD is not met as evidenced by:
Based on personnel and maintenance records review, the laboratory director failed to ensure that ALL pre analytic, analytic and post analytic quality assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2024 and 2025 as required by Clinical Laboratory Improvement Amendments (CLIA).
Findings: 1. Personnel documents review revealed the laboratory director, who is also the (TS), had no proof that annual competencies containing the CLIA six criteria, were performed on (TP#5 CMS 209) in 2024 and 2025. 2. Maintenance records review revealed the lab director missed the annual pm maintenance for the refrigerator and freezer, in the laboratory, for years in 2024- 2025. 3. An interview with the laboratory coordinator (TP#5 CMS 209) in the lab on 06/20/2025, at approximately 1: 15 PM, confirmed the lab director who is also the technical supervisor (TS) failed to ensure proper oversight of the laboratory from 2024 through June 2025.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:
Based on personnel records review and interview with laboratory staff, the laboratory director failed to ensure that annual competencies for testing personnel (TP) performing non grossing laboratory tasks were performed according to the CLIA six criteria in 2024 and 2025. Findings: 1. A review of competency assessment records revealed that TP # 5 (CMS-209) had no annual competency assessment records meeting the CLIA six criteria in 2024 and 2025. 2. An interview with the laboratory staff (TP# CMS 209) in the lab review area at approximately 1:10 PM, on 06/20/2025, confirmed there were no 2024 and 2025 annual competencies for TP # 5 (CMS -209) that met the current CLIA six criteria.