Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0893924	11/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Emory Neuromuscular Pathology Laboratory	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 November 13, 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:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. 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 in 2023 and 2024. Findings: 1. A review of competency assessment records revealed that TP # 6 (CMS-209 form) had no annual competency assessment records in 2023 thru 2024 available thru the date of survey, 11/13/2024. . 2. An interview with the laboratory staff, in the lab review room, at approximately 1:10 PM, on 11/13/2024, confirmed there were no 2023 or 2024 annual competencies for TP # 4 (CMS -209 form) documented and available on day of survey, 11/13/2024.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on SOP documents review and staff interviews, the laboratory director failed to enroll in a CMS approved Proficiency Testing (PT) program or a peer review program in 2023- 2024 in the specialty of Histopathology. Findings: 1. Review of laboratory SOP revealed the laboratory failed to follow its own procedure by not enrolling in a CMS approved PT testing program or peer review program, twice annually, in 2023 -2024. 2. Interviews with the lab tech (TP #4 CMS 209) , in the lab review room, at approximately 2:00 PM, on 11/13/2024, confirmed there was no PT enrollment, in a CMS approved PT program or peer review program in 2023 - 2024.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the Leica CM 1850 Cryostat maintenance logs including: freezer logs, humidity logs, annual PM maintenance sticker, expired eppendorf pipette maintenance stickers, water bath and dry oven maintenance logs, room temperature logs no microscope maintenance in 2023 and 2024, no employee competencies in 2023 and 2024, one(1) peer review in 2023 and none in 2024. The laboratory failed to monitor and evaluate the overall quality of the analytic systems to identify and correct any problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This is a CONDITION level citation. REFERENCE : D-5413 - Test Systems, Equipment, Instruments, Reagents 493.1252 (b), 5209,5217.
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 review and staff interviews, the laboratory did not document overall daily maintenances in the laboratory 2023 - 2024. Findings, 1.) The lab tour confirmed the laboratory did not document daily room temperatures, humidity, heating block, water bath temperatures or cryostat freezer temperatures. Annual eppendorf pipettes maintenance (1000 ul, 100 ul and 10ul) were not done in 2023 -2024, there were no maintenanance log for the thermoscientific stainer, no annual maintenance for the olympus BX40 microscope in 2023 -2024. The laboratory fire extinguisher was last checked in August of 2023. 2.)

	An Interview with the lab tech (TP4 CMS 209), in the lab review desk, at approximately 2:15 PM, on 11/13/ 2024, confirmed all the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document ALL quality assessment activities on a monthly basis, as stated in their QA policy manual from 2023 and 2024. Findings: 1. A review of the laboratory QA documents revealed the Laboratory Director, who is also the Technical Supervisor (TS), did not review and sign ALL monthly quality activities(QA) checklists, including neglecting Proficiency Testing (Peer reviews) in 2023 - 2024, in the Specialty of Histopathology. 2. Interview with the second lab tech (TP#4 CMS 209) in the lab review room, on 11/13/2024, at approximately 1:00 PM, confirmed no monthly (QA) checklist activities were monitored and signed off by the Lab Director from 2023 - 2024.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (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; This STANDARD is not met as evidenced by: Based on personnel and maintenance records review and interview with the laboratory staff, 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 2023 - 2024 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Personnel documents review revealed the Lab Director , who is also the (TS), had no proof that annual competencies were performed on the only testing personnel (TP # 4 CMS 209) in 2023 - 2024. 2. An interview with the laboratory tech in the lab review room, on 11/13 /2024, at approximately 2:15 PM, confirmed the Lab Director , who is also the technical supervisor (TS), failed to ensure proper oversight of the laboratory in 2023 - 2024.