

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0893924	<b>(X3) Date Survey Completed</b>  02/17/2020
<b>Name of Provider or Supplier</b>  Emory Neuromuscular Pathology Laboratory	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	On March 30, 2020, an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: A review of laboratory personnel records and interviews with the laboratory director and (TP # 3, CMS 209) revealed, the laboratory director failed to provide annual Competency Assessment for ALL its testing personnel in 2018 and 2019. Findings include: 1. A review of testing personnel records revealed there were no competency evaluations for testing personnel (TP#s 3 and 5 CMS 209) in 2018 and 2019. 2. An interview with the laboratory director and (TP # 3, CMS 209) on February 17, 2020 at 12:40 PM in the review room confirmed there were no annual competencies performed on testing personnel #s 3 and 5 (CMS 209) in 2018 and 2019.</p>
<b>D5293</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:  
Based on Quality Assurance (QA) document review and interview with the laboratory director, the laboratory failed to document all general laboratory systems QA activities as required. Findings include: 1. QA documents review revealed there was no QA documentation available at the time of survey for 2018 and 2019. 2. An interview with the laboratory director in the review room on 02/17/2020 at approximately 12:20 p.m. confirmed there were no QA documentation available for the aforementioned period, 2018 and 2019.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on laboratory tour, maintenance record review and an interview with the Laboratory director, it was determined that the laboratory failed to perform required equipment maintenance as written in the laboratory procedure manual in 2018 and 2019. Findings include: 1.) Laboratory tour and maintenance documents review revealed: last annual microscope (Olympus BX 40) maintenance was done in February of 2018 and last annual maintenance of the Eppendorf pipettes(4) were done on 3/1/2018. 2.) An interview with the Laboratory director and TP #3 (CMS 209) at approximately 12:15 pm on 02/17/2020 in the review room confirmed annual maintenance for the aforementioned equipments were not performed in 2018 and 2019.