Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652044	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Neuromuscular Clinical Lab	509 S Euclid Ave, Saint Louis, MO	

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
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 review of proficiency testing (PT) records and interview with the general supervisor, the laboratory failed to verify the accuracy of glycogen enzymatic pathways (GEP) test at least twice annually during 2018. Findings: 1. Review of PT records revealed the laboratory did not have documentation to show it verified the accuracy of the GEP test at least twice annually during 2018. 2. Interview with the general supervisor on September 25, 2019 at 12:15 PM confirmed the laboratory failed to verify the accuracy of GEP test at least twice annually during 2018.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

	(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the biochemistry protocols procedure manual in use 2018 and 2019 and interview with the general supervisor, the procedure manual failed to include written control procedures for three of three selected tests. Findings: 1. The biochemistry protocols procedure manual did not include written control procedures for the mitochondria, succinate dehydrogenase, and glycogen enzymatic pathways (GEP) tests. 2. Interview with the general supervisor on September 25, 2019 at 12:15 PM confirmed, the procedure manual did not include written control procedures for each test.