Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0969606	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Wesley Neuromuscular Laboratory	20 South Dudley Room 450, Memphis, TN	

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
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 observation of the laboratory, review of the laboratory quality assurance plan, laboratory records, and interview with the lead testing personnel, the laboratory failed to follow the quality assurance plan in 2019. The findings include: 1) Observation of the laboratory on January 14, 2020 at 12:30 p.m. revealed temperature dependent equipment/instruments in use for storage and preparation of reagents and tissue for histopathology testing. 2) Review of the laboratory's quality assurance plan revealed the following: The laboratory will identify problems and apply corrective actions; temperatures will be monitored daily. 3) Review of laboratory records revealed no temperatures were recorded for temperature dependent equipment from January 29, 2019 to current date (01.14.2020). The record had not been reviewed and no corrective action had been performed. 4) Interview with the lead testing personnel on January 14, 2020 at 2:20 p.m. confirmed the laboratory failed to follow the quality assurance plan when it did not monitor daily temperatures or perform corrective action for the lack of daily temperatures in 2019 and 2020.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case,

	prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel records, and interview with the lead testing personnel, the technical supervisor failed to perform competency assessment for testing personnel who perform patient testing in 2019 and 2020. The findings include: 1) Review of the Form CMS-209 revealed two testing personnel listed who perform grossing on patient specimens. 2) Review of personnel records revealed no competency assessments had been performed for 2019 or 2020. 3) Interview with the lead testing personnel on January 14, 2020 at 2:30 pm. confirmed the technical supervisor failed to perform annual competency assessment for testing personnel who perform tissue grossing in 2019 and 2020.