Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2049294	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gwinnett Neurology & Sleep Disorders Clinic	2331 Henry Clover Boulevard, Snellville, 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	Based on an initial CLIA certification survey performed on July 25, 2018, this facility was found not to be in complaince with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on validation document review and staff interview, the laboratory failed to obtain performance specifications comparable to the manufacturer as required. Findings include: 1. Validation document review revealed the laboratory failed to perform a carryover study for the Biolis 50i prior to reporting patient test results in 2017 and 2018 thus far. 2. An interview with the technical supervisor in an examination room on 7/25/18 at approximately 1:00 p.m. confirmed a crossover study had not been performed for the Biolis 50i prior to reporting patient test results in 2017 and 2018 thus far.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on competency document review and staff interview, the laboratory director (LD) failed to ensure that all laboratory personnel receive the appropriate training for the type and complexity of the services offered and have demonstrated they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. Technical supervisor (TS) document review revealed the LD failed to ensure an initial training competency, six-month competency, and annual competency were performed for Staff #2 (CMS 209) in 2017 and 2018 thus far. 2. An interview with Staff #2 (CMS 209) in an examination room on 7/25/2018 at approximately 1:00 p.m. confirmed initial, six-month, and annual competencies were not performed for the TS in 2017 and 2018 thus far.