Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2022435	03/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Neuro Spinal And Headache Center	2600 Parkwood Drive, Brunswick, 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	An Initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on March 26, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of 2016 and 2017 American Proficiency Institute(API) proficiency testing (PT) records and staff interview, the laboratory failed to have attestation statements signed by the testing personnel and laboratory director and failed to retain records showing each step of the testing process for events 1, 2 and 3 of 2016 and event 1 of 2017 Findings include: 1. Review of 2016 and 2017 API PT attestation statements revealed statements for events 1, 2 and 3 of 2016 and event 1 of 2017 were not signed by the testing personnel or the laboratory director as required. 2. Review of 2016 and 2017 API PT records for events 1, 2 and 3 of 2016 and event 1 of 2017 revealed instrument printouts, raw data and testing records are not available for review. 2. Interview with the testing personnel on March 26, 2018 at 1 pm in the

	laboratory confirmed signed attestation statements and testing records for the events listed above are not available .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2016 American Proficiency Institute (API) proficiency testing (PT) records and staff interview the laboratory director failed to document review of PT evaluations. Findings include: 1. Review of 2016 API PT records revealed no documentation that PT evaluations were reviewed by laboratory staff or laboratory director. 2. Interview with the testing personnel on March 26, 2018 at 1 pm in the laboratory confirmed there is no documentation of PT evaluation review in 2016.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records for toxicology testing performed on the Indiko Plus and staff interview, the laboratory failed to establish criteria for acceptability of the Thermo Fisher MAS DOA controls. Findings include: 1. Review of Levey Jennings charts, control assay sheet and results of control values obtained during testing of controls revealed the laboratory uses the assay values given by the manufacturer with a range of plus or minus 25% and has not adjusted their QC ranges to reflect the statistical parameters obtained by their laboratory. . 2. Interview with the testing personnel confirmed the laboratory uses the assay value supplied by the manufacturer with a range of plus or minus 25% as the criteria for accepting controls and has not adjusted their acceptable ranges to reflect the actual ranges obtained by their laboratory which are much tighter than 25% of the target value.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform

	test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel's competency assessment checklist as well as interview with the testing personnel and the office manager, the technical consultant failed to ensure the competency assessment policy and procedure for testing performed in the speciality of toxicology met the 6 required criteria and failed to perform the assessment on testing personnel.. Findings include: 1. Review of the laboratory competency assessment checklist for the present testing personnel which is the only checklist available, revealed it does not include all of the 6 required criteria and the competency is signed by the office manager instead of the technical consultant who is the only person qualified to assess competency. 2. No competency assessment is available for the two former testing personnel who are no longer employed. 3. Interview with the testing personnel and office manager on March 26, 2018 in the manager's office at 1:15 pm confirmed competency assessment is not performed by the technical consultant and it does not include the 6 required criteria for assessment.