Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2103500	09/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Phoenix Neurological Institute	2000 E Southern Ave Ste 106, Tempe, AZ	

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
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 lack of information for the control reference number used for one out of three patient test results reviewed for testing performed under the specialty of Hematology and interview with the laboratory director, the laboratory failed to include the control reference number used on three out of the four controls tested (2 for ACT and 1 for PT/INR). Findings include: 1. The correct manufacturer's assay sheets for the controls listed above could not be determined since the QC thermal paper records were taped to sheets of blank paper in such a way that information was not evident including the control reference sheet numbers that indicated the manufacturer's assayed ranges for each control level for ACT and PT/INR controls. 2. Some of the thermal paper records were not copied and it was evident that some of the thermal records were smudged or were beginning to fade. 3. The laboratory director acknowledged that the control number for the QC assay sheets were missing for the controls that were ran on 07/12/2018.

D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of refrigerator temperature logs for 2018 and interview with the laboratory director, the laboratory failed to provide any documented corrective actions for out of range temperatures for the refrigerator where testing reagents are store. Findings include: 1. The laboratory's established temperature range for the refrigerator is 2C to 8C or 39F to 46F. Only two of the recorded temperatures were within range of a total of 13 temperatures recorded from March of 2018 to the date of the survey. 2. Patient testing was also performed on February 13, 2018, but there were no temperatures recorded on that day including ambient and refrigerator. 3. No documented corrective actions were presented for review pertaining to the out of range temperatures and the temperatures that failed to be recorded. 4. Upon director observation of the refrigerator thermometer by the laboratory director and the surveyor it was evident that the thermometer was not functioning properly.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of i-Stat test records for ACT and PT/INR testing and interview with the facility personnel, the laboratory failed to identify the testing personnel who performed each test either by name or unique operator ID that is indicated on the i-Stat instrument printouts. Findings include: 1. Every i-Stat instrument print out presented for review for quality control records and patient test records indicated the Operator ID: 84014 even though there was more than one testing personnel. 2. The CMS-209 indicated two testing personnel, but there was no indication on the print out who performed the test either by individual name or unique Operator ID number. 3. The laboratory director acknowledged that the testing personnel were not identifiable on the test records.