Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0949974	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric And Neonatal Specialists	720 West Broadway Suite 201, Louisville, KY	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on staff interview and record review of proficiency testing records from the American Proficiency Institute, the Laboratory Director and testing personnel failed to sign Attestation Statements for two (2) of six (6) hematology testing events from July 19, 2016 through July 23, 2018. Findings include: Record review on 07/24/18, of proficiency testing records from the American Proficiency Institute, revealed there was no documented evidence the Laboratory Director and testing personnel signed Attestation Statements for two (2) of six (6) events from July 19, 2016 through July 23, 2018. Interview on 07/24/18 at 11:33 AM with staff, revealed there was no process in place to ensure the Laboratory Director and testing staff signed and retained all Attestation Statements.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview with the staff on 07/24/2018 the technical

	consultant failed to perform quality assurance from July 1, 2016 through December 31, 2016. Findings include: No quality assurance was performed from July1, 2016 thru December 31, 2016 The staff acknowledged in an interview on 07/24/2018 at 11: 33AM, that the they did not have a system in place to document Quality Assurance on a quarterly basis.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on staff interview and record review, the laboratory failed to monitor and document the humidity of the laboratory where the testing was performed. The laboratory humidity was not recorded from July 19, 2016 through July 23, 2018. Findings include: Review of the Manufacturer's Operations Manual for the ACT Diff CBC (Complete Blood Count) analyzer, listed the operating range for humidity for the analyzer to be between twenty percent (20%) and eighty-five percent (85%). Review of the Maintenance Log, on 07/24/18, revealed there was no documented evidence the laboratory humidity had been monitored from July 19, 2016 through July 23, 2018. Testing personnel acknowledged in an interview, on 07/24/18 at 11:33 AM, the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on staff interview and record review, the laboratory failed to test two (2) levels of quality control material each day Complete Blood Count (CBC) testing was performed on three (3) of six (6) days of chart review. Findings include: Review of the Policy and Procedure Manual on 07/24/18, revealed the laboratory's quality control plan was not followed. Review of Patient Test Reports, revealed there was no documented evidence quality control was performed from January 1, 2017 through

	February 2, 2017. In addition, there was no documented evidence quality control was performed for the dates of June 13, 2017 and December 13, 2017. Testing personnel acknowledged in an interview, on 07/24/18 at 11:33 AM, the laboratory failed to test at least two (2) levels of quality control material each day of patient testing.
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 staff interview and record review, the Technical Consultant failed to perform and document annual competency using the six (6) mandated competency assessment requirements for testing personal. Competency assessment was performed using zero (0) of six (6) methods of assessment for four (4) out of four (4) employees from July 19, 2016 through July 23, 2018 Findings include: Record review on 07/24 /18, revealed there was no documented evidence competency assessments were performed and documented between July 19, 2016 and July 23, 2018, for four (4) employees to include the following: direct observation of routine patient test performance; direct observation of performance of instrument maintenance function checks and calibration; monitoring the recording and reporting of test results; review of worksheets; review of quality control records; review of proficiency test results; review of maintenance records; assessment of testing external proficiency testing samples and problem solving skills. Interview with staff on 07/24/18 at 11:33 AM, revealed the facility failed to have a system in place to ensure competency was performed using all six (6) mandated competency assessment requirements from July 19, 2016 through July 23, 2018.