Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0121704	03/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Group Pa, The	281 Witherspoon Street, Princeton, NJ	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment for Hematology testing performed on the Beckman Coulter DxH-520 analyzer from May 2020 to the date of survey. The TP confirmed on 3/1/23 at 11:45 pm the assayed values of QC material were not verified before putting in use.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor review of Manufactures Package Inserts, observation of the Quality Control material, and interview with the Testing Personnel (TP), the laboratory failed to put open and expiration dates on Hematology control material run

	on the Beckman Coulter DxH-520 Analyzer on the date of survey. The TP confirmed on 3/1/23 at 12:00 pm the laboratory failed to put open and expiration dates on the control material.
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 surveyor review of Complete Blood Cell (CBC) and automated differential Performance Specification (PS) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all PS records were adequate for all analytes run on the Beckman Coulter DxH 520 Analyzer from May 2020 to the date of survey. The findings include: 1. There was no source cited for Normal Patient Range. 2. There was no documented evidence that Linearity was performed. 3. The TP confirmed on 3/1/23 at 11:30 am that the laboratory failed to ensure that all PS records were adequate.
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 surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Hematology tests performed on Beckman Coulter DxH-520 analyzer on the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The TP confirmed on 3/1/23 at 11:20 pm that the QC material was not verified before putting in use.
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 surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish written policies and procedures to monitor, assess and correct problem identified in the analytic system quality assessment from may 2020 to the date of survey. The findings include: 1. The laboratory did not have a corrective action procedure for Flagged patient results. 2. The TP confirmed on 3/1/23 at 11:10 am that they have no written policy for the above mentioned procedure.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to report Covid 19 testing accurately on the date of survey. The finding includes: 1. The laboratory performed non Food and Drug Administration (FDA) cleared tests and there was no statement stating "This test has not been FDA cleared or approved; The test has been authorized by FDA under an Emergency Use Authorization (EUA)". 2. The laboratory failed to ensure that the FR included the address of the laboratory where COVID-19 testing was performed. 3. The laboratory failed to ensure that the FR included a normal Patient range where COVID-19 testing was performed 4. The TP confirmed on 3/1/23 at 11:20 am that COVID 19 tests were not reported accurately. b) Based on surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to report Hematology testing accurately on the date of survey. The finding includes: 1. The laboratory failed to ensure that the FR included a normal Patient range where hematology testing was performed. 2. The TP confirmed on 3/1/23 at 11:20 am that hematology tests were not reported accurately.