Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0264038	04/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Primary Pediatrics Of Macon	5300 Bowman Road, Macon, 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	A recertification survey was performed on April 16, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. CONDITION LEVEL CITATIONS: D-5400 - Analytic Systems - 493.1250 D-6000 - Moderate Complexity Laboratory Director - 493.1403 NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation during the laboratory tour, review of documents, and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems for each specialty and subspecialty of testing performed. This is a CONDITION level citation. REFERENCE: D-5411 - Test Systems, Equipment, Instruments, Reagents - 493.1252(a) D-5415 - Test Systems, Equipment, Instruments, Reagents - 493.1252(c) D-5447 - Control Procedures - 493,1256(d)(3)(i)(g)

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Upon observation during the main laboratory tour, review of the manufacturer's instruction, and staff interview the laboratory failed to follow the manufacturer's requirements for performing the Erythrocyte Sedimentation Rate, Westergren (ESR). The testing rack was not properly stored in the laboratory. FINDINGS: 1. Observation during the lab tour revealed the testing rack was located next to a centrifuge. Vibration on the counter top was noted when the centrifuge was operational. 2. Review of the manufacturer's instructions, printed on the lid of the ESR tubes, stated that the testing rack and test unit must remain vertical in an area free from vibrations, drafts, and direct sunlight. 3. Interview with Testing Personnel #1 and #2 (CMS 209 form) in the main laboratory, on April 16, 2024, at approximately 11:30 am., confirmed the above aforementioned statements.
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: Observation during the tour of the different laboratories, and staff interview, revealed the laboratory failed to place an open date on the reagents and Quality Control (QC) vials that were currently in use. Findings: 1. Observation during the tour of the 5 testing areas in the practice revealed the laboratory failed to document open dates in 4 out of the 5 testing areas. There was no open date on the QC vials, or reagents currently in use. 2. Interview with Testing Personnel #1 and #2 (CMS 209 form) on April 16, 2024 at approximently 11:30 am to 11:45 am, during the lab tours, confirmed the above aforementioned statement.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Document review of the Quality Control (QC) and staff interview revealed the laboratory failed to provide any documentation that QC was being performed on the Erythrocyte Sedimentation Rate (ESR) test. Findings: 1. QC documents were requested for the ESR test. The laboratory could not provide any documentation that QC for the ESR test had been performed over current two year certificate period. 2. Interview with Testing Personnel #1 and #2 (CMS 209 form) on April 16, at 11:30 am, in the main laboratory, confirmed the above aforementioned statements.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: A review of the Quality Assessment (QA) and staff interview revealed the laboratory did not have a QA plan to review and confirm the manual entry data of patient results from the Abbott Cell-Dyn Emerald, Hematology Analyzer(Emerald). Findings: 1. A review of the QA documents confirmed that there were no records to support that the laboratory performed QA checks to verify that the results entered from the Emerald printout were entered in the Electronic Medical Record (EMR) accurately. 2. Interview with Testing Personnel #1 and #2 (CMS 209 form) on April 16, 2024 at approximately 4:15 pm, confirmed the above aforementioned statement.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The laboratory must have a director who provides overall management and direction in accordance with 493.1407. This is a CONDITION LEVEL CITATION: REFERENCE: D-6005-493.1407(C)