Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0264038	05/25/2022
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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on May 25, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. Condition level and standard deficiencies were cited:
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the Quality Assessment(QA) Policy and QA documents, and staff interview, the laboratory failed to follow their Policy for QA by not documenting monthly QA reviews and assessment activities between 9/2021 thru 5/2022. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems for each specialty and subspecialty of testing performed. Reference: D 5293
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The

	laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment(QA) Policy and QA documents, and staff interview, the laboratory failed to follow their Policy for QA by not documenting monthly QA reviews and assessment activities between 9/2021 thru 5/2022. Findings: 1. Review of the QA Policy and QA documents, the laboratory failed to document any QA reviews and assessment activities 9/2021 thru 5/2022. 2. Interview with staff #2 (CMS 209 form), on May 25, 2022, at approximately 1:50 pm, in the storage room, confirmed the above aforementioned statements.
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 review of the Calibration documents and Quality control (QC) documents for the Abbott Emerald Hematology Analyzer (Emerald), and staff interview the laboratory failed to document calibration every 6 months for Emerald SR#6729 and Emerald SR#7935 for the years 2019, 2020, 2021, and 2022. The laboratory failed to print the Levy Jennings (LJ) graphs for each lot number of QC material ran on the Emerald for years 2020- 2021, and January and February of 2022. The laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified for each specialty and subspecialty of testing performed. Reference: D 6046
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to

	identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Calibration documents for the Abbott Emerald Hematology Analyzer (Emerald), and staff interview the laboratory failed to document calibration every 6 months for Emerald SR#6729 ,and Emerald SR#7935 for the years 2019, 2020, 2021, and 2022. Findings: 1. Review of the calibration documents for the Emeralds SR#6729, and SR#7935 for the years 2019, 2020, 2021, and 2022, the following dates were documented as dates of calibrations: SR#6729 SR#7935 2/19 12 /19 6/20 16 months 6/20 3/21 9 months 3/21 9 months 5/21 9/21 3/22 10 months 3/22 2. Interview with staff #2 (CMS 209 form) on May 25 2022 at approximately 1:50 pm in the storage room, confirmed the above aforementioned statements.
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 review of the Quality Control (QC) documents for the Abbott Emerald Hematology Analyzer (Emerald) and staff interview the laboratory failed to monitor over time the test performance of the Emerald, by not printing the Levy Jennings(LJ) graphs for each lot number of QC material ran on the Emerald for the year 2020, 2021, and January and February of 2022. Findings: 1. Review of the QC documents showed that the laboratory had not printed the LJ graphs for the year 2020 or 2021, and January and February 2022. 2. Interview with staff #2 (CMS 209 form), on May 25 2022 at approximately 1:45 pm in the storage room confirmed the 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: Based on review of the competency documents for the testing personne(TP)l, and staff interview the Laboratory Director(LD) acting as the Technical Consultant (TC) failed

	to document competency assessment for 13 out of 24 testing personnel listed on the CMS form 209, for the year 2021.
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 competency documents for the testing personne(TP)l, and staff interview, the Laboratory Director(LD) acting as the Technical Consultant (TC) failed to document competency assessment for 13 out of 24 testing personnel listed on the CMS form 209, for the year 2021. Findings 1. Review of the competency documents, there were 24 names of testing personnel listed on the CMS form 209. There was no competency documentation for 13 out of the 24 names listed for the year 2021. 2. Interview with TP #2 (CMS form 209) on May 25, 2022 at approximately 2pm in the storage room, confirmed the above aforementioned statement.