

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0932951	(X3) Date Survey Completed 08/08/2019
Name of Provider or Supplier Youthcare Pediatrics Of Central Georgia Pc	Street Address, City, State 233 North Houston Road Suite 140 H, Warner Robins, 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 August 8, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Quality Control(QC) documents for the CellDyn Emerald (Emerald) Hematology analyzer, and staff interview, the laboratory failed to monitor the acceptability of the QC, before releasing patient results. Reference D5481</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the Quality Control(QC) documents for the CellDyn Emerald (Emerald) Hematology analyzer, and staff interview, the laboratory failed to monitor the acceptability of the QC, before releasing patient results. Findings: 1. Review of the QC documents for the Emerald confirmed during the months of May, October, and November 2018 the following findings: May 7, 2018, all three levels of controls were out of range for the analyte Red Blood Cell(RBC). and 10 patients were resultd May 8, 2018, all three levels of controls were out of range for the analyte RBC, and 17 patients were resultd May 14, 2018, all three levels of controls were out of range for the analyte RBC, and 13 patients were resultd October 19, 2018, all three levels of controls were out of range for the analyte RBC, and 1 patient was resultd November 2, 2018, two levels of controls were out of range for the analyte RBC, and 18 patients were resultd November 8, 2018, all three levels of controls were out of range for the analyte RBC, and 15 patients were resultd 2. Interview with staff #2 (CMS 209 form), on August 8, 2019, at approximately 4pm, in the office, confirmed that the QC was out of range for the aforementioned dates, and patients were resultd.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on review of the Quality Control(QC) documents for the CellDyn Emerald (Emerald) Hematology analyzer, and staff interview, the Laboratory Director (LD) failed to provide oversight for the accuracy and acceptability of the QC. Findings: 1. Review of the QC documents for the Emerald confirmed that during the months of May, October, and November 2018 the following findings: May 7, 2018, all three levels of controls were out of range for the analyte Red Blood Cell(RBC). and 10 patients were resultd May 8, 2018, all three levels of controls were out of range for the analyte RBC, and 17 patients were resultd May 14, 2018, all three levels of controls were out of range for the analyte RBC, and 13 patients were resultd October 19, 2018, all three levels of controls were out of range for the analyte RBC, and 1 patient was resultd November 2, 2018, two levels of controls were out of range for the analyte RBC, and 18 patients were resultd November 8, 2018, all three levels of controls were out of range for the analyte RBC, and 15 patients were resultd 2. Interview with staff #2 (CMS 209 form), on August 8, 2019, at approximately 4pm, in the office, confirmed that the QC was out of range for the aforementioned dates, and that patients were resultd.