

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1080883	(X3) Date Survey Completed 10/14/2020
Name of Provider or Supplier Primary Pediatrics Of Wr	Street Address, City, State 6082 Lakeview Road, 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	Based on a CLIA recertification survey performed on October 14, 2020, this facility was found to not be in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API), Proficiency Testing (PT) evaluation reports, for Erythrocyte Sedimentation Rate (ESR) and Bacteriology, Urine Colony Counts(UCC), and staff interview, the laboratory failed to verify the accuracy twice yearly for the ESR, and UCC for non-regulated analytes. Findings: 1. Review of the API, PT evaluation reports for Bacteriology, Urine Colony Counts, for the third event of 2019, and the second event of 2020, showed that the laboratory received scores of 50% for both events. 2. Review of the API, PT evaluation reports for Hematology, ESR, for the second and third event of 2019, and the first and second event of 2020, showed that the laboratory received scores of 50% for all four events. 2. Interview with the laboratory coordinator, on 10/14/2020, at approximately 1:10pm in the office, confirmed that the laboratory had unsuccessful events for the third event of 2019 and second event of 2020 in Bacteriology. The laboratory also confirmed unsuccessful events for the second and third event of 2019 as well as the first and second event of 2020 for the ESR.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

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 Abbott Emerald Hematology Analyzer (Emerald) calibration documents and staff interview the laboratory failed to provide documentation for bi-annual calibrations as required. Findings: 1. A review of the Emerald calibration documents confirmed that the laboratory failed to provide calibration documents for Bi-annual calibrations. Calibrations were as follows: 2/2019 NO DOCUMENTATION 8/2019 performed 2/2020 NO DOCUMENTATION 8/2020 NO DOCUMENTATION 10/2020 Performed 2. Interview with the Laboratory Coordinator, on 10/14/2020, at approximately 12/20/2020 in the office, confirmed the aforementioned document review.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents the laboratory failed to achieve satisfactory performance for Sedimentation Rate (ESR) for four consecutive events in 2019, and 2020, and for Bacteriology Urine Colony Counts for unsuccessful scores from 2019 and 2020. There was no written plan of correction for the unsatisfactory scores. The Laboratory Director had signed the acceptance of the results. Findings: 1. Based on review of the LD signed performance acceptance page, there was no corrective action for the unsatisfactory scores on the second and third event of 2019, and the first and second event of 2020 for ESR. 2. Based on review of the of the Bacteriology Urine Colony Count signed performance acceptance page, there was no corrective action for the unsatisfactory

scores on the third event of 2019, and the second event of 2020. 3. Interview with the Laboratory Coordinator, on October 14, 2029 at approximately 1pm in the office, confirmed that the LD had signed the performance reports but there was no corrective action for the unsatisfactory scores for ESR or Bacteriology Urine Colony Counts.