

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1011328	(X3) Date Survey Completed 01/09/2019
Name of Provider or Supplier Pediatric Specialty Care Of Macon Ga	Street Address, City, State 4035 Elnora Drive, 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 January 9, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Abbott Cell-Dyn 1700(CD1700) hematology Analyzer</p>

calibration records, Policy and Procedure for the CD1700, and staff interview, the laboratory failed to perform calibrations on the CD1700 at least every 6 months. Findings: 1. Review of the CD1700 calibration documents showed that calibration was performed: 1-2017 6-2017 - 5 months 12-2017 -6 months 11-2018 -11 months 2. Review of the Policy and Procedure for the CD1700 stated that calibration should be performed every 6 months on the CD1700. 3. Interview with staff # 2 (CMS 209 form), the Laboratory Director, and the Office Manager, at approximately 12:15 am, in the front office, confirmed that there was no documentation that the calibration for the CD1700 was performed between December 2017, and November 2018. A time period of 11 months.