

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0264027	(X3) Date Survey Completed 02/16/2018
Name of Provider or Supplier Pediatric Care Of Macon Llc	Street Address, City, State 3951 Ridge Ave Suite A, 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 February 16, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the calibration documentation for the Cell-Dyn Emerald hematology analyzer, and staff interview the laboratory failed to calibrate the Hematology analyzer at least every 6 months, as required by the manufacturer. The findings include: 1. Review of the Calibration documents for the Abbott Emerald hematology analyzer showed that the calibration was performed: February 2016 July 2016 February 2017 - 7 months July 2017 No calibration in January 2018 2. Cell-Dyn requirements for Calibration verification criteria include: When indicated by Quality Control data After major maintenance and service procedures At least every six</p>

months As directed by the regulatory agencies governing the laboratory 3. Interview with staff #5 on February 16, 2018 at 11am in the office, confirmed that the calibration was not performed at least every 6 months.