Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0925474	**(X3) Date Survey Completed** 05/08/2018
Name of Provider or Supplier Children's Medical Group Pc	**Street Address, City, State** 6918 Mcginnis Ferry Road, Suwanee, 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 8, 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:
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 hematology document review and staff interview the laboratory failed to

	perform instrument calibrations with the frequency required by Clinical Laboratory Improvement Amendments (CLIA).. Findings include: 1. Cell-Dyne Emerald calibration document review revealed the laboratory failed to supply documentation for calibration performed every six months in 2017. There was a gap in calibration documentation between 1/26/17 and 3/27/18. 2. An interview with Staff #2 (CMS 209) on 5/8/18 in a doctor's office at approximately 1:30 p.m. confirmed there was no calibration documentation for Cell-Dyne Emerald calibration for the period between 1 /26/17 and 3/27/18.