

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0685520	(X3) Date Survey Completed 02/14/2018
Name of Provider or Supplier Coliseum Pediatric & Adolescent Care	Street Address, City, State 145 N Crest Boulevard, 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 14, 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 in March 2016, and October 2017 (time span of 7 months), February 2017 (span of 4 months), May 2017 (span of 3 months). There were no calibration documents for November or December 2017. (Span of greater than 6 months). 2. Interview with staff #2, and #3 (CMS 209 form) on February 14, 2018 at 1:30 pm in the lab, confirmed that the calibration was not performed as required by the manufacturer.</p>