

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0255194	(X3) Date Survey Completed 02/02/2018
Name of Provider or Supplier East Cobb Pediatrics	Street Address, City, State 1121 Johnson Ferry Rd Ste 220, Marietta, 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) validation survey was completed on February 2, 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:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD did not sign the Hematology/Coagulation attestation statements for Events 1, 2, and 3 for 2016 and 2017. 2. An interview in a medical office with Staff #2 (CMS 209) at approximately 1:00 p.m. on 2/2/18 confirmed the LD did not sign the aforementioned PT attestation statements.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation and staff interview, the laboratory failed to performed required equipment calibration. Findings include: 1. Observation during the laboratory tour on 2/2/18 at approximately 12:00 p.m. revealed the Horizon miniB centrifuge was last calibrated on 10/28/11. 2. An interview with Staff #3 (CMS 209) on 2/2/18 in the laboratory at approximately 12:00 p.m. confirmed the Horizon miniB centrifuge was last calibrated on 10/28/11.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

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.

This STANDARD is not met as evidenced by:

Based on calibration document review and staff interview, the laboratory failed to perform instrument calibration with the required frequency. Findings include: 1. Cell-Dyn Emerald hematology analyzer document review revealed the laboratory failed to perform an instrument calibration between 3/7/2016 and 12/8/2016. 2. An interview in a medical office on 2/2/18 at approximately 1:00 p.m. with Staff #2 (CMS 209) revealed a required calibration was not performed between 3/7/2016 and 12/8/2016 for the Cell-Dyn Emerald hematology analyzer.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

;Based on testing personnel (TP) document review and staff interview, the Technical Consultant/Laboratory Director (TC/LD) failed to perform annual TP competencies as required. Findings include: 1. TP document review revealed the TC/LD failed to perform competencies on 3 of 3 TP in 2016 and 3 of 3 TP in 2017. 2. TP document review revealed the annual TP competencies for 2016 and 2017 were performed by unqualified TP. 3. TP 2016 annual competency document review revealed the following: Staff #2 (CMS 209) competency was performed by TP no longer employed; Staff #3 and Staff #4 (CMS 209) were performed by Staff #2 (CMS 209). 4. TP 2017 annual competency document review revealed the following: Staff #2 (CMS 209) competency was performed by Staff #3 (CMS 209); Staff #3 and Staff #4 (CMS 209) competencies were performed by Staff #2 (CMS 209). 2. An interview with Staff #2 (CMS 209) in a medical office on 2/2/18 at approximately 1 p.m. confirmed the TC/LD did not perform the annual TP competencies for the

aforementioned dates. During the same interview Staff #2 (CMS 209) confirmed the aforementioned competencies were performed by unqualified TP.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the laboratory failed to employ qualified individuals to perform laboratory testing as required.

Findings include: 1. TP document review revealed Staff #2 (CMS 209) was unqualified to perform laboratory testing due to lack of education documentation. 2. An interview with Staff #2 (CMS 209) in a medical office on 2/2/18 at approximately 1:00 p.m. confirmed Staff #2 (CMS 209) was unqualified to perform laboratory testing due to lack of education documentation.