

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0923455	(X3) Date Survey Completed 03/23/2021
Name of Provider or Supplier East Cobb Pediatrics	Street Address, City, State 6110 Pine Mountain Rod, #202, Kennesaw, 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 March 23, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to participate in CLIA required PT. Findings include: 1. American Proficiency Institute (API) PT document review revealed the laboratory failed to participate in the following Hematology PT events: 2019 -- Event Two; 2020 -- Event Two. 2. An interview with the Clinic Coordinator in Exam Room #2 on 3/23/2021 at approximately 4:00 p.m. confirmed the aforementioned failure to participate in PT events.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</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.

This STANDARD is not met as evidenced by:

Based on observation and staff interview, the laboratory failed to perform and document equipment maintenance with required frequency. Findings include: 1. Observation during the laboratory tour on 3/23/2021 at approximately 4:15 p.m. revealed the Path Group centrifuge was last calibrated on 9/27/2019. 2. An interview with the Clinic Coordinator in the laboratory on 3/23/2021 at approximately 4:15 p.m. confirmed the lack of required annual centrifuge calibration.

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 calibration document review and staff interview, the laboratory failed to perform instrument calibration every six months as required. Findings include: 1. Beckman Coulter AcT Diff calibration document review revealed a gap in the required six-month calibration intervals for the following time periods: 4/9/2019 to 11/27/2019 (seven months); 11/27/2019 to 7/22/2020 (8 months). 2. An interview with the Clinic Coordinator in Exam Room #2 on 3/23/2021 at approximately 3 p.m. confirmed the aforementioned gaps in calibration intervals.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the

laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) document review and staff interview, the laboratory failed to monitor over time the accuracy and precision of test performance as required. Findings include: 1. Beckman Coulter AcT Diff QC review revealed the lack of Levey-Jennings charts available at the time of survey for the following time periods: 2018 (November and December), 2019, 2020, and 2021 thus far. 2. An interview with the Clinic Coordinator on 3/23/2021 in Exam Room #2 at approximately 3:15 p.m. confirmed the lack of Levey-Jennings charts for the aforementioned time periods.