

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0923455	(X3) Date Survey Completed 04/02/2025
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 02, 2025. 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:
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) and maintenance documents review, the laboratory director failed to sign off on ALL quality assessment activities on a monthly basis as required by Clinical Laboratory Improvement Amendments (CLIA) from 2023 to day of survey 04/02/2025. Findings: 1. A review of the laboratory's (QA) activities revealed the technical consultant (TC), who is also the lab director, did not review and sign all monthly Quality Assessment(QA) activities including; daily maintenance and QC reviews for the Beckman Coulter DxH 500 Hematology analyzer, eye wash, humidity, refrigerator or room temperature logs from 2023 through day of survey 04/02/2025. 2. An interview with the office manager (TP#4 CMS 209) on 04/02/2025 at approximately 12:15 PM, in the review room confirmed all (QA) activities were not monitored or signed off by the lab director in 2023 through day of survey 04/02/2025.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual (SOP) and interview with the office manager, the laboratory director failed to updated the current procedure manual for Beckman Coulter DxH 500 (CBC) Hematology analyzer in 2024 - 2025 as required by CLIA Regulation 493.1251(b). Findings: 1.) A review of current SOP manual confirmed the absence of protocols for critical alert values for the Beckman Coulter DxH 500 CBC Hematology analyzer placed in use in November 2024. 2.) An SOP review revealed no written job descriptions specific to the laboratory director (LD), technical consultant(TC) or testing personnel(TP) CLIA positions. 3.) Interviews with the office manager(TP#4 CMS 209) in the review room on 04/02 /2025, at approximately 11:45 a.m, confirmed the above findings.