

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0930848	(X3) Date Survey Completed 10/14/2025
Name of Provider or Supplier Cobb Pediatrics	Street Address, City, State 3405 Dallas Highway Sw Bld 300, 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) recertification survey was completed on October 14, 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:
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, temperature log sheets, and staff interview, the lab failed to document corrective actions when QC and refrigerator temperatures exceeded acceptable limits. Findings include: 1. Review of QC records: 01/06/25 - 02/03/25 (normal lot#362516812 abnormal high lot# 372516813); 08/08/25 - 09/03/25 (normal lot #362517512) revealed one (1) or more analytes were out of range without corrective actions documented. 2. Review of Temperature log records of 8/1/25 - 08/29/25 revealed the refrigerator temperature (2-8 degrees celcius) was out of range 6 of 21 days without corrective actions documented. 3. Interview with the Technical onsultant (CMS 209 form) on 10/14/25 at 1:00 PM in the conference room, confirmed the corrective actions were not documented.</p>