

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0703348	<b>(X3) Date Survey Completed</b>  10/22/2025
<b>Name of Provider or Supplier</b>  Southern Crescent Pediatrics Pc	<b>Street Address, City, State</b>  150 Medical Blvd Suite B, Stockbridge, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 22, 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:
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the of the laboratory's American Association of Bioanalyst (AAB) proficiency testing (PT) records of 2024 - 2025 found the laboratory did not rotate the analysis of the PT samples among all Testing Personnel. Findings: 1. A review of the PT records revealed only 2 TP (#2 and #3) (CMS 209) were processing the PT samples for submission. 2. A review of the CMS 209 form revealed the laboratory has a total 6 clinical laboratory testing personnel. 3. Interview with TP #2 (CMS 209) on 10/22/25 at 12:24 PM in the break room confirmed the aforementioned findings.</p>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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:</p>

	<p>Based on review of Proficiency Testing (PT) records and staff interview, the laboratory Testing Personnel (TP) and Lab Director (LD) failed to attest that PT samples were analyzed in the same manner as patient specimens. Findings: 1. A review of the PT records for 2024 (events 1, 2, &amp;3) and 2025 (events 1 &amp; 2) revealed the attestation forms were not signed by the LD or TP. 2. An interview with TP #2 (CMS 209) on 10/22/25 at 12:24 PM in the break room confirmed the aforementioned findings.</p>
<p><b>D5403</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on (SOP) review and staff interview, the laboratory failed to include a procedure for the course of action required if a test system becomes inoperable. Findings include: 1. SOP review revealed the laboratory did not have a written procedure for the course of action if a test system becomes inoperable.. 2. An interview with testing personnel TP #2 (see CMS 209) on 10/22/25 at 12:20 p.m. confirmed the lack of the aforementioned procedure.</p>
<p><b>D6018</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and</p> <p>This STANDARD is not met as evidenced by: Based on review of AAB proficiency test (PT) records and staff interview, the laboratory director (LD) failed to review all PT results when received from the PT provider. Findings: 1. A review of the PT records for 2024 (events 1, 2, &amp;3) and 2025 (events 1 &amp; 2) revealed the 2025 event 2 was not reviewed/signed by the LD. 2. An interview with TP #2 (see CMS 209) on 10/22/25 at 12:22 PM in the break room confirmed the aforementioned finding.</p>

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing, the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. An SOP document review revealed the LD failed to specify, in writing, the duties and responsibilities of the Clinical Consultant (CC). 2. An interview with testing personnel #2 (CMS 209) in the break room on 10/22/25 at 12:20 p.m. confirmed the SOP did not contain the duties and responsibilities for the CC.