

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2044019	(X3) Date Survey Completed 10/07/2020
Name of Provider or Supplier Southeast Georgia Pediatrics, Llc	Street Address, City, State 1701 D Boulevard Square, Waycross, 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 7, 2020. 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:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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 proficiency testing (PT) records, review of the Laboratory Personnel Report Form (CMS 209), and staff interview, the laboratory failed to rotate performance of proficiency testing samples among all personnel who test patient samples. Findings include: 1. Review of PT attestation statements and PT testing records revealed all hematology PT samples in 2019 and 2020 were tested by staff # 3 (see CMS 209). All bacteriology PT samples in 2019 and 2020 were tested by staff # 3 and #4 (see CMS 209). 2. Review of the CMS 209 revealed 4 total employees listed as testing personnel. 3. Interview with staff #3 (see CMS 209) on October 7, 2020 at approximately 12:15 pm confirmed testing personnel # 3 performed testing on all PT samples in 2019 and 2020. **REPEAT DEFICIENCY**</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) records, review of the Laboratory Personnel Report Form (CMS 209), and staff interview, the laboratory failed to note corrective actions of missed proficiency testing samples. Findings include: 1. Review of PT result records revealed 2019 event #1 speciality of bacteriology (0005) received a score of 80% without corrective actions documented. 2. Review of the PT result records revealed 2019 event #1 speciality of hematology (0760) received a score of 96% due to subspecialty platelets (0815) receiving a score of 80% without corrective actions documented. 3. Interview with staff #3 (see CMS 209) on October 7, 2020 at approximately 12:00 pm confirmed corrective actions were not documented for the aforementioned PT scores.

D5463

CONTROL PROCEDURES
CFR(s): 493.1256(d)(7)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
Over time, rotate control material testing among all operators who perform the test.
(g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of quality control records, review of the Laboratory Personnel Report Form (CMS 209), and staff interview, the laboratory failed to rotate performance of quality control (QC) samples among all personnel who test patient samples. Findings include: 1. Review of QC records revealed all QC samples in 2018, 2019, and 2020 were tested by staff # 3 (see CMS 209). 2. Review of the CMS 209 revealed 4 total employees listed as testing personnel. 2. Interview with staff #3 (see CMS 209) on October 7, 2020 at 12:10 pm confirmed she had performed testing on all QC samples in 2018, 2019, and 2020. ****REPEAT DEFICIENCY****

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 review of testing personnel (TP) competency records and staff interview revealed the technical consultant (TC) failed to perform annual competency on all TP. Findings include: 1. Review of TP competency records revealed TP #3 (CMS 209 form) had competency records on 1/12/18, 1/2/19, but did not have competency documented for January 2020. 2. Interview with TP #1 (CMS 209 form) on October 7, 2020 in the breakroom at 11:00 am, confirmed TP #3 did not have competency performed to date for 2020.