Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2044019	07/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Georgia Pediatrics, Llc	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 July 31, 2018. 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 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 PT samples in 2017 and 2018 were tested by testing personnel # 1 (see CMS 209). 2. Review of the CMS 209 revealed 3 additional employees listed as testing personnel. 2. Interview with testing personnel #1 (see CMS 209) on July 31, 2018 at 11:30 am confirmed testing personnel # 1 performed testing on all PT samples in 2017 and 2018 and the other three testing personnel perform testing on patient samples...
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

	This STANDARD is not met as evidenced by: Based on observation by the surveyor during a tour of the facility and staff interview, the laboratory failed to have a biohazard sign and "no food or drink allowed" signage on the refrigerator located in the employee break room which is used to store biohazardous material. Findings include: 1. Observation by the surveyor during a tour of the facility revealed the refrigerator used to store laboratory supplies including biohazard material is located on top of a counter in the break room. No biohazard label or sign stating no food or drink should be placed inside the refrigerator is visible. 2. Interview with testing personnel # 1 (See CMS 209) on July 31, 2018 at 10:30 am in the break room confirmed the refrigerator contains biohazardous material and no warning notices are posted.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure for performing throat cultures for group A streptococcus, observation of culture plates in the incubator, observation of uninoculated media in the refrigerator, review of the laboratory's log of media shipments and interviews with the laboratory director and staff, the laboratory failed to follow its written policy for performing throat cultures for group A streptococcus. Findings include: 1. Review of the laboratory's procedure for performing throat cultures revealed Selective Streptococcus Agar (SSA) in conjunction with a bacitracin disk (A disk) is the only acceptable moderate complexity method for performing throat cultures to rule out group A streptococcus. 2. Observation by the surveyor of inoculated culture plates in the incubator and uninoculated media in the refrigerator revealed the laboratory is using trypticase soy agar (TSA) with 5 % sheep's blood instead of SSA as required. 3. Review of the laboratory's log of media shipments with dates & lot numbers revealed the laboratory is receiving TSA with 5% sheep's blood. There is no record of the laboratory receiving SSA. 3. Interviews with the laboratory director on July 31, 2018 at 10:45 am in the laboratory area and with the laboratory director and testing personnel # 1 (see CMS 209) at 1 pm in the break room confirmed the laboratory is using TSA with 5 % sheep's blood agar instead of SSA as required.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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's procedure for performing throat cultures and urine cultures, review of logs used to record quality control on media used for urine cultures and staff interview, the laboratory failed to have a procedure for performing quality control on media. Findings include: 1. Review of the laboratory's procedure manual revealed no written procedure for performing quality control on culture media used to perform throat cultures or urine cultures. 2. Review of logs used to record results of quality control (QC) performed on media used for urine cultures revealed the laboratory is recording "pass" or "positive" as the result for media QC. No instructions for interpretation or recording of results is available. 3. Interview with the laboratory director and testing personnel #1 (see CMS 209) on July 31, 2018 at 1 pm in the break room confirmed the laboratory does not have instructions for performing media QC.
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 records revealed all QC samples in 2017 and 2018 were tested by testing personnel # 1 (see CMS 209). 2. Review of the CMS 209 revealed 3 additional employees listed as testing personnel. 2. Interview with testing personnel #1 (see CMS 209) on July 31, 2018 at 11:30 am confirmed testing personnel # 1 performed testing on all QC samples in 2017 and 2018 and the other three testing personnel perform testing on patient samples...
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's microbiology quality control records, review of the laboratory's Individualized Quality Control Plan (IQCP) and staff interview, the laboratory failed to perform the required quality control (QC) on each lot number or shipment of media used to perform throat cultures. Findings include: 1. Review of the laboratory's IQCP revealed there is not a plan for media QC used to perform throat cultures for group A streptococcus, therefore; information necessary to support waiver of requirements for performing media QC is not available. 2. Review of the laboratory's microbiology QC records revealed no documentation of QC on the media used to perform throat cultures. 3. Interview with the laboratory director and testing personnel #1 (see CMS 209) at 1 pm in the break room confirm the IQCP is not adequate and the lab is not performing QC on media used for throat cultures.