Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0706472	09/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Partners Of Augusta Llc	1303 Dantignac Street Ste 2600, Augusta, 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 September 24, 2019. 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) and/or (TP) failed to attest to the routine integration of PT samples into the patient workload as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD failed to sign attestation statements for the following Microbiology PT events: 2018 -- Second event; 2019 -- First and Second event. 2. American Proficiency Institute (API) PT document review revealed the TP failed to sign attestation statements for the following Microbiology PT events: 2019 -- First and Second event. 3. An interview with the lead medical assistant in the breakroom on 9/24/2019 at approximately 12:15 p.m. confirmed the lack of LD and TP signatures on the aforementioned PT attestation statements.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to perform required corrective action for unsatisfactory PT scores. Findings include: 1. American Proficiency Institute (API) PT document review revealed the laboratory failed to perform corrective action for the 2018 Microbiology Third PT Event with a score of eighty percent. 2. An interview with the lead medical assistant in the breakroom on 9/24/2019 at approximately 12:15 pm. confirmed the aforementioned lack of PT corrective action.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on Bacteriology quality control (QC) document review and staff interview, the laboratory failed to perform required media QC. Findings include: For details refer to D5477
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 policy and procedure manual (SOP), the laboratory failed to follow established policies and procedures for quality assurance (QA) as required. Findings include: 1. SOP review revealed the laboratory failed to review (QA) checklists at least annually as required by the SOP.. 2. SOP review revealed the QA checklists were last reviewed on 7/24/2015. 3. An interview with the lead medical assistant in the breakroom on 9/24/2019 at approximately 12:00 p.m. confirmed the lack of QA checklist review.
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 policy and procedure manual (SOP) and staff interview, the laboratory failed to include required policies and procedures for specimen collection. Findings include: 1. SOP review revealed the laboratory did not establish a policy and procedure for specimen collection -- blood (venipuncture, capillary, and heelstick), throat culture (step by step), and urine (step by step). 2. An interview with the lead medical assistant in the laboratory at approximately 11:45 a.m. on 9/24/2019 confirmed the aforementioned lack of policies and procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on maintenance log review and staff interview, the laboratory failed to monitor and document laboratory room temperature (RT) as required. Findings include: 1. Review of temperature logs revealed laboratory RT was not monitored or documented for 2018 and 2019 thus far. 2. An interview with the lead medical assistant in the breakroom on 9/24/2019 at approximately 10:23 a.m. confirmed the lack of RT logs for the aforementioned time periods.
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 Bacteriology quality control (QC) document review and staff interview, the laboratory failed to perform required media QC. Findings include: 1. Review of CLED /EMB (Cystine-Lactose-Electrolyte-Deficient/Eosin Methylene Blue) QC documents revealed incubated sterility check of the media was not performed for 2018 and 2019 thus far. 2. An interview with the lead medical assistant at the nurses station at approximtely 12:00 p.m. on 9/24/2019 confirmed the lack of incubated sterility for the CLED/EMB media for 2018 and 2019 thus far. This is a REPEAT DEFICIENCY.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to perform required review of laboratory PT reports. Findings include: 1. American Proficiency Institute (API) document review revealed the LD failed to review PT reports for the following Microbiology events: 2018 -- Events One, Two, and Three; 2019 -- Events One and Two. 2. An interview with the lead medical assistant in the breakroom on 9/24/2019 at approximately 12:15 p.m. confirmed the lack of LD review of the aforementioned PT reports.