Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D2152298	**(X3) Date Survey Completed** 08/07/2019
Name of Provider or Supplier Pediatric Partners Of Augusta, Llc	**Street Address, City, State** 5135 Wrightsboro Road, Suite B, Grovetown, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on August 7, 2019. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory did not include required safety policies and procedures. Findings include: 1. SOP review revealed there was not a policy and procedure for the laboratory eyewash equipment. 2. An interview with the team leader in a medical office at approximately 12:45 p.m. on 8/7/2019 confirmed there was not an eyewash equipment policy and procedure in the SOP.
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 establish and document required policies and procedures in their SOP as required. Findings include: 1. SOP document review revealed there was not a policy and procedure for specimen collection for blood (venipuncture or capillary), urine, or throat specimens. 2. SOP document review revealed there was not a policy and procedure for specimen acceptability or rejection. 3. SOP document review revealed there was not a policy and procedure for specimen storage. 4. SOP document review revealed there was not a policy and procedure for quality control of bacteriology media (incubation of uninoculated media as part of sterility check). 5. SOP document review revealed there was not a policy and procedure for record retention. 5. An interview with the lead technologist on 8/7/2019 in a medical office at approximately 12:45 p.m. confirmed the lack of the required aforementioned policies and procedures in the laboratory SOP.
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 temperature and humidity log document review and staff interview, the laboratory failed to define the criteria for monitoring room temperature (RT) and failed to document RT and humidity as required. Findings include: 1. Temperature log document review revealed there were no acceptable RT ranges on the laboratory room temperature (RT) logs for 2018 (August through December) and 2019 thus far. 2. RT log document review revealed the RT was monitored and documented in January, 2019, for 4 of 20 days. 3. Humidity log document review revealed laboratory humidity was not monitored and documented in January, 2019. 4. An interview with the team leader in a medical office on 8/7/2019 at approximately 12:45 p.m confirmed there were no acceptable RT ranges listed on the RT logs. During the same interview, the team leader confirmed the lack of RT and humidity documentation for the aforementioned dates.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to perform and document equipment maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings include: 1. Observation during the laboratory tour on 8/7/2019 at approximately 11:30 a.m. revealed the eyewash equipment had not had a function check performed in 2018 (August through December) or 2019 thus far. 2. Observation during the laboratory tour on 8/7/2019 at approximately 11:30 a.m. revealed the Horizon centrifuge was last calibrated in 2013. 3. An interview with the team leader in the laboratory on 8/7/2019 at approximately 11:30 a.m. confirmed the lack of maintenance for the eyewash equipment and the Horizon centrifuge.
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 quality control (QC) document review and staff interview, the laboratory failed to check each batch of media for sterility as required. Findings include: 1. Bacteriology QC document review revealed the laboratory did not perform uninoculated sterility checks for the Strep Select and Uricult media 2018 (August through December) and 2019 thus far. 2. An interview with theteam leader in a medical office on 8/7/2019 at approximately 12:45 p.m. confirmed the lack of incubated sterility checks for Strep Select and Uricult media for the aforementioned dates.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director/technicall failed to ensure TP receive the appropriate documented training for the type and complexity of the laboratory test offered as required. Findings include: 1. TP competency document review revealed initial competencies were not performed at this facility in 2018 for the following TP listed on the CMS 209: Staff #3, Staff #4, Staff #5, Staff #6. 2. An interview with the team leader on 8/7/2019 in a medical office at approximately 12:45 p.m. confirmed the aforementioned TP did not have an initial competency performed at this facility in 2018.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document TP performance of moderate complexity laboratory tests at least semiannually during the first year the TP tests patient specimens as required. Findings include: 1. TP competency document review revealed a six-month competency was not performed for Staff #6 (CMS 209) in 2019. 2. An interview with the team leader in a medical office on 8/7/2019 at approximately 12:45 p.m. confirmed the aforementioned 6-month competency was not performed in 2019.