Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0706472	02/23/2022
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 February 23, 2022. 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:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on Proficiency Test(PT) document review and staff interview, the Laboratory Director(LD) and Testing Personnel(TP) failed to attest to the routine integration of the samples into the patient workload as required. The Findings include: 1. American Proficiency Institute (API) PT document review revealed that the LD and TP failed to sign the attestation statements for Microbiology for Events 2 and 3 of 2020. 2. API PT document review revealed that the LD and TP failed to sign the attestation statements for Microbiology for Microbiology for Events 2 and 3 of 2021. 3. During an interview with the Lead Medical Assistant and TP#3(CMS-209) on February 23, 2022 at approximately 12:40 PM, in the breakroom, confirmed that the attestation documents for PT was not signed by the LD and TP.

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 Testing(PT) document review and staff interview, the laboratory failed to evaluate and verify that all unsatisfactory scores were documented with a correction active. The Findings include: 1. American Proficiency Institute (API) PT document review revealed the corrective action for Microbiology for Event 2, Throat Culture Count in 2020(Score 50%) was not performed. 2. API PT document review revealed that there was no corrective action for Microbiology for Event 1 in 2021 (Score 80%) for the Urine Culture Count. 3. During an interview on February 23, 2022 at approximately 12:45 PM with the Certified Medical Assistant Lead and Testing Personnel #3(CMS 209), in the breakroom, confirmed that there was no corrective action performed or documented for the unsatisfactory scores.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the general laboratory standard operating procedure manual(SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The general laboratory procedure manual did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance) for staff to follow when sending specimens to reference laboratory(University Hospital, Quest, and LabCorp). 2. During an interview on February 23, 2022 at: 11:30 AM with the Lead Medical Assistant, in the breakroom, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to a reference laboratories and the main hospital.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 ensure all PT reports were received and reviewed by the

	appropriate staff to evaluate the laboratory's performance and to identify any problems that would require corrective action. The Findings include: 1. The LD failed to review and sign the attestation PT reports for Microbiology 2020(Events 2 and 3), and Microbiology 2021(Events 2 and 3). 2. During an interview on February 23, 2022 at approximately 12:40 PM with the Lead Medical Assistant and Testing Personnel#3 (CMS 209), in the breakroom, confirmed that the LD did not review the PT results and evaluate the performance to identify any problems that woukd require corrective action.