Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0967013	10/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Johns Creek Pc	4310 Johns Creek Parkway, Suite 150, Suwanee, 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 26, 2023. 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:
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 review of American Proficiency Institute (API) and interviews with staff and nurse manager, the laboratory failed to evaluate and perform corrective action on Proficiency Testing (PT) scores below 100% in 2022 as required. Findings: 1. (API) (PT) documents review revealed there was NO corrective action performed on Proficiency Testing results of less than 100% on (1st Event 2022 - 80% RBCs, 80% HCT, 80% MCH and 80% MCHC) and (2nd Event- 80% HCT, 80% MCHC, 60% MCV, 80% Platelet Count, 60% RDW, 80 WBC Diff, 80% Granulocytes and 60% Lymphocytes). 2. An interview with the office manager in the conference room at approximately 12:45 PM on 10/26/2023 confirmed the laboratory had no proof that corrective action was performed for the aforementioned unsatisfactory (PT) results in 2022.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on documents review and interview with the office manager, the Lab Director (LD) failed to ensure that Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2022 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Standard Operating Procedures (SOP), QA, (PT) and maintenance logs (Room Temperature, Refrigerator and QC) review revealed the Lab Director, who is also the Technical Consultant (TC), did not perform all Quality Assurance requirements in the laboratory. A review of PT performance or the initiation of corrective action for unsatisfactory (PT) results in Events #2 and #3 in 2022, were not performed. 2. An interview with the laboratory's office manager and staff, in the conference room, on 10/26/2023, at approximately 12: 30 PM, confirmed the LD failed to ensure proper oversight of the laboratory to solve problems as they occurred in 2022.