Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2060947	07/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Partners Of Gwinnett	4121 Steve Reynolds Boulevard Suite 101, Norcross, 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	On August 24, 2023 an off site follow-up review was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations.
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 observation during the laboratory tour and staff interview, the laboratory failed to implement and establish proper safety procedures to ensure protection from physical, biochemical and biohazardous materials in the laboratory area. Finding: 1. During the laboratory tour it was observed there was no flush eyewash equipment (for emergency use) in the laboratory testing and processing area. 2. The eyewash containers on the wall were completely empty with NO substance. 3. An interview with the lab lead (TP#5 CMS 209) during the lab tour, on 07/13/2023, at approximately 10:00 A.M, confirmed the absence of eyewash equipment on /0713 /2023.
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 document review and staff interview, the laboratory failed to perform corrective action for American Proficiency Institute (API) Proficiency Test (PT) results below 100% as required by Clinical Laboratory Improvement Amendments (CLIA). Finding: 1. (API) (PT) document review revealed the laboratory failed to perform corrective action for the following: a. Hematology/ Coagulation PT results: 2022 - 1st Event (Platelets and RBC score of 80%), b. 2022 - 3rd Event (Cell ID/ Flow Differential score of 80%) 2. An interview with staff # 5 (CMS 209) on 7/13 /2023 in the review room at approximately 12:45 PM confirmed no correction was done for the above (PT) scores below 100% in 2022.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of laboratory procedure manual (SOP) and staff interview, the laboratory director (LD) failed to approve, sign and date all current tests procedures in the (SOP) as of 07/13/2023. Finding: 1. (SOP) documents review revealed the lab director failed to approve, sign and date the validation and procedure for Complete Blood Count (CBC) on the Cell-dyn Emerald Hematology analyzer in October 2022. 2. An interview with staff #5 (CMS 209) in the review room on 07/13/2023 at approximately 12:30 PM, confirmed the lab director did not approve, sign and date the (SOP) and validation documents. Staff #5 also confirmed the validation was signed by the Technical representative of Cell-Dyn Emerald October 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 staff interview, the Lab Director(LD) failed to ensure that Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2022 and 2023 as required by Clinical Laboratory Improvement Amendments (CLIA). Finding: 1. Standard Operating Procedures (SOP) review, QA and maintenance logs (Room Temperature, Humidity, Refrigerator and eye wash) review revealed the lab director, who is also the Technical Supervisor (TS), did not review or sign ALL Quality Assurance or maitenance logs in 2022 and 2023. 2. An interview with the laboratory's lab lead (TP#5 CMS209) in the review room on 07/13 /2023, at approximately 12:50 PM, confirmed the LD failed to ensure the implementation of QA plan to discover and solve problems in the laboratory in 2022 and 2023.