Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2040982	03/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center For Wellness	1506 Klondike Road, Sw, Suite 205, Conyers, 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 March 29, 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:
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 the review of the Standard Operating Procedure(SOP) and staff interview, the laboratory failed to establish a safety procedure for an Eyewash. The Findings include: 1. SOP document review revealed that the laboratory failed to establish a safety procedure for the Eyewash in the laboratory. 2. During an interview with the Office Manager and the Administrative Lead, on March 29, 2023, in the breakroom, confirmed that the laboratory failed to establish a safety procedure for an Eyewash.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by:

	Based on the tour of laboratory and staff interview, the laboratory failed to ensure two identifier's were present on the urine specimens. Findings include: 1. During the laboratory tour, a urine specimen was observed with only one identifer, during the survey. 2. During an interview with the Office Manager and Administrative Lead on March 29, 2023 at 2:25 PM in the breakroom, confirmed the lack of two identifier's on the urine specimen.
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 the American Proficiency Institute (API) Proficiency Testing (PT) documents for 2022, Speciality- Hematology and staff interview, the laboratory failed to provide evaluation documentation. Findings: 1. A review of the API PT Hematology 2022 evaluation report for the 3rd event, the laboratory failed to provide corrective action documentation for the Erythrocyte count (80%). 2. During an interview with the Office Manager and Administrative Lead, on March 29, 2023, at 2: 45 pm in the breakroom, confirmed the findings.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist for 2021 (January 2021- December 2021) and 2022 (January-December 2022), and thus far 2023 (January-March 2023). 2. During an interview with the Office Administrator and Administrative Lead (CMS 209), on March 29, 2023 at 2:45 PM, in the breakroom, confirmed the lack of a QA checklist for 2021, 2022, and thus far 2023.
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 document review and staff interview, the laboratory director failed to review and evaluate Proficiency Testing results (PT) for corrective action. The Findings include: 1 American Proficiency Institute (API) PT document review revealed the laboratory director failed to review and evaluate PT for corrective action. 2. During an interview with the Office Manager and Administrative Lead on March 29, 2023 at 2: 45 PM, in the breakroom, confirmed the laboratory director failed to review and evaluate PT for corrective action.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory record review and staff interview, the laboratory director (LD) failed to ensure that quality assessment was maintained for the laboratory. Findings include: 1. Laboratory record review revealed the LD failed to provide a quality assessment checklist and corrective action for the overall laboratory. 2. During an interview with Office Manager and Administrative Lead, in the breakroom, on March 29, 2023, at approximately 2:40 PM, confirmed the LD failed to provide a quality assessment checklist for the laboratory.