Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2040982	05/25/2021
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 May 25, 2021. 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:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) document review and staff interview, the laboratory failed to enroll in a PT program for the speciality of Hematology (0760). Findings include: 1. Review of PT documents provided and CMS CASPER Report 0096D, the lab failed to enroll in PT program for 2020 and 2021 Event #1. Lab director ceased patient testing upon discovery (April 2021). 2. Interview with staff #1 (CMS 209 form) on 5/25/21 at 11:00 AM in the breakroom confirmed the lab was not enrolled in PT for 2020 and 2021 Event #1.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory quality assurance (QA) records and staff interview, the laboratory failed to follow the written policy for QA. Findings include: 1. Review of the laboratory's QA records reveals no documentation of preanalytic, analytic, or post analytic monitors being performed since 02/08/2019. 2. Interview with staff # 1 (CMS 209) on 05/25/21 at 12:30 pm in the breakroom, confirmed the laboratory has no documentation of QA review since 02/08/2019.
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/ Humidity record review and staff interview, the lab failed to document room temperaturer as required by the manufacturer. Findings include: 1. Review of Temperature/ Humidity records reveals the lack of monitoring /documenting the room temperature for January 2020 through May 25, 2021. 2. Interview with staff #1(CMS 209 form) on 05/25/21 in the breakroom at approximately 1230 PM, confirmed the lack of room temperature documentation.
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 Horiba Micros 60+ document review and staff interview, the lab failed to perform and document maintenance per the maufacturer's manual. Findings include: 1. Maintenance document review revealed the lab did not have documented maintenance available at the time of the survey for 2020 or 2021 to date. 2. Interview with staff #1(CMS 209 form) on 05/25/21 in the breakroom at approximately 1230 PM, confirmed the lack of maintenance documents.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures

	that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 lab failed to monitor over time the accuracy and precision of test performance. Findings include: 1. Review of QC records reveals the lab did not monitor QC overtime to detect shifts, trends, or any variance in the test system such as review of Levy-Jennings charts. 2. Interview with Staff #1 (CMS 209) in the breakroom on 05/25/21 at approximately 12: 30 p.m. confirmed the lab did not monitor QC over time for the accuracy and precision of test performance.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Quality Control (QC) record review and patient test report review, patient sample was processed on a day when QC was out of acceptable range. Findings include: 1. QC record review on 1/4/21 reveals low level lot # MX426 was out of range 6 runs without correcting and notation was documented by the lab director "No tests performed on 1/4/21". 2. Review of patient report Medical number # 13650 reveals the patient specimen was ran and reported at 12:29 PM. 3. Interview with staff #1 (CMS 209) on 5/25/21 at approximately 1:00 PM in the breakroom, confirmed the patient sample was ran without QC in acceptable limits.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on review of temperature/humidity records and staff interview, the lab failed to document corrective actions when humidity exceeded acceptable limits. Findings include: 1. Review of temperature/humidity records (January 2021-April 2021) revealed humidity was out of range 25 of 84 days without corrective actions documented. 2. Interview with staff #1 (CMS 209 form) on 05/25/21 at 1230 PM in the breakroom, confirmed the corrective actions were not documented.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and staff interview, the laboratory failed to enroll in a PT program for the speciality of Hematology (0760). Findings include: 1. Review of PT documents provided and CMS CASPER Report 0096D, the lab failed to enroll in PT program for 2020 and 2021 Event #1. 2. Interview with staff #1 (CMS 209 form) on 5/25/21 at 11:00 AM in the breakroom confirmed the lab was not enrolled in PT for 2020 and 2021 Event #1. a
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. An interview with Staff #1 (CMS 209) in the breakroom on 05/25/21 at approximately 12: 30 p.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure.
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 review of testing personnel(TP) documents and an interview with the lab director, the technical consultant (also the LD) failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of the TP competency records reveals staff #2 (CMS 209 form) did not have a 6 month competency performed upon due date of December 2020. 2. Interview with the LD on 05/25/21 in the breakroom at 11:10 AM, confirms the semiannual competency was not done on TP #2 (CMS 209) in December 2020.