Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0675960	09/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Llpc	111 Medical Drive, Palestine, TX	

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	An onsite survey conducted 09/26/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, review of patient records, review of the Center for Medicaid and Medicare Services (CMS) form 116, and confirmed in interview, the laboratory failed to include panic or alert values for complete blood counts (CBCs) in the laboratory's hematology policy since it was put into place in June 2021. The findings include: 1. Review of the laboratory policy titled "Critical

	Values" instated by the laboratory director on 6/18/2021 stated the following: "Critical values are test results that are either potentially life-threatening, requires immediate medical attention, or suggest that a change in current treatment may be necessary. These values must be forwarded to the ordering physician, attending nurse, or designated staff member in an expedient manner for immediate attention. THE FOLLOWING RESULTS ARE CONSIDERED TO BE CRITICAL VALUES:" With no additional documentation of said critical values in the policy. Surveyor queried testing person (TP) 2 on 9/26/2022 at 10:45 hours, at the laboratory desk, for a list of critical values and none was provided. 2. Through interview and review of patient records, the following patient was found that needed additional medical attention that could not be provided at the laboratory clinic location: Patient ID 10230, ran 5/2/2022 Test - Result - (Reference Range) - Units WBC - 1.2 - (4.5 - 13.5) - 10*3/uL RBC - 1.79 - (4.5 - 5.3) - 10*6/uL HGB - 5.1 - (13.0 - 17) - g/dL HCT - 15.4 - (35 - 49) - % PLT - 9 - (150 - 350) 10*3/uL Review of the CMS form 116, section VII "Non-Waived Testing" listed an annual test volume of 4,500 for the specialty of hematology. 3. In an interview on 9/26/2022 at 11:00 hours, in the breakroom, TP 2 and the practice manager confirmed that the laboratory policy did not have critical values. KEY: WBC: White blood cells RBC: Red blood cells HGB: Hemoglobin HCT: Hematocrit PLT: Platelet uL : microliter g/dL: grams per deciliter
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for use, patient final reports, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for the handling of complete blood count (CBCs) sample flags for ten of ten patients reviewed between 9/19/2022 and 9/23/2022 on the Sysmex XP-330. The findings include: 1. Review of the XP-300 Instructions for Use, chapter 8 "Display and Output of Analysis Results" had the following meanings of signs displayed on the left of the analysis data: "Sign Explanation [!] Value is out of the linearity limit [*] Result is unreliable" Flag: [WU] Probable sample cause: Incomplete lysing of red blood cells, presence of immature white blood cells, white blood cell aggregation, platelet satellite phenomenon, etc. Correction: 1) Centrifuge sample and replace the plasma with an equal volume of saline or CELLPACK and repeat analysis. 2) Check smear, etc. Flag: [F1], [F2], [F3] Probable sample cause: Presence of CML or other immature granulocytes, sample with high values for monocytes, eosinophils, and basophils, incomplete lysing of red blood cells, aged sample, etc. Correction: 1) Check smear, etc. 2) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37(degrees) Celsius for 30 minutes and repeat analysis, etc. Flag: [AG] Probable sample cause: Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction: 1) Check smear, etc 2. Review of patient results had the following ten patients reported with flags that were not corrected per manufacturer's instructions between 9/19/2022 and 9/23/2022: Patient ID:57516 , 9/19/2022 WBC: 5.6 - ,WU PLT: 234 - * LYM%: 79.5 - F1 LYM#: 4.5 - F1 Patient ID:57223, 9/19/2022 PLT: 407, AG* Patient ID: 56372, 9/19

	/2022 PLT: 320, AG* Patient ID: 23136, 9/20/2022 PLT: 246, AG* Patient ID: 56503, 9/20/2022 PLT: 123, AG* Patient ID: 57224, 9/21/2022 WBC: 7.7, WU LYM%: 35.8, F1 LYM#L 2.8, F1 Patient ID: 57605, 9/21/2022 PLT: 340, AG* Patient ID: 57236, 9/22/2022 WBC: 6.7, WU PLT: 276, * LYM%: 75.4, F1 LYM#: 5.1, F1 Patient ID: 56099, 9/22/2022 PLT: 295, AG* Patient ID: 56021, 9/23/2022 WBC: 8.8, WU PLT: 205, * LYM%: 74.9, F1 LYM#: 6.6, F1 3. In an interview on 9/26/2022 at 12:00 hours, in the breakroom, testing person (TP) 2 and the practice manager confirmed that the laboratory was not following the manufacturer's instructions for the handling of CBC flags. Key: WBC: White blood cells PLT: Platelet LYM%: Lymphocyte percent LYM#: Absolute lymphocyte count