Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0922350	04/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of West Tennessee, Pllc	1501 Brayton Ave, Dyersburg, TN	

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
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 observation of the laboratory, review of the Sysmex XP 300 operator's manual, review of patient data logs and final patient test reports, lack of procedure and staff interview, the laboratory procedure for Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) failed to include actions to take when CBC results were flagged, resulting in seven of seven patients reviewed from 2023 and 2024 that had flagged CBC results reported with no documented action taken. The findings include: 1. Observation of the laboratory on 04/04/24 at 8:20 am revealed the Sysmex XP 300 (Serial #B0249) used for patient testing for CBC w/diff.

	2. Review of the Sysmex XP 300 operator's manual revealed the following regarding instrument flags and possible causes: The manufacturer manual stated the following: "When the histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following: [WL]-Probable cause-Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. [RL]-Probable cause-Presence of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, etc. [PL]- Effects of cryoglobulins, fragmented red blood cells, or cellular fragments of white blood cells, etc. [WU] - Incomplete lysing of red blood cells, presence of immature white blood cells, white blood cell aggregation, platelet satellite phenomenon, etc. [RU]-Effects of cold agglutinin, inclusion of white blood cells, etc. [PU]-Increase of large platelets, inclusion of fragmented red blood cells, precipitation of cryoglobulins, etc. [DW] (RBC) Significant anisocytosis, etc. [DW] (PLT) Inclusion of fragmented red blood cells, non-uniformity in size of platelets, effects of cryoglobulins. [MP] (RBC) Effects of anemia treatment or blood transfusion causing the presence of cells of multiple sizes. [MP] (PLT) Platelet aggregation, sample with low values for platelets. [T1] Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, etc. [T2]- Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, aged sample, etc. [F1], [F2], [F3]- 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. [AG] Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Probable cause is platelet agglutination, which does not alter WBC count but may result in decreased platelet count. Suggested manufacturer actions included checking a smear, centrifuging the sample, performing saline replacement of plasma, warming the sample, and performing manual cell counts. 3. Review of patient data logs and final patient test reports revealed the following: Patient numbers one, two, and three were performed on 03/30/23 at 10:11, 12:51, and 14:52 respectively. All three patients had platelet results that were flagged with "*AG". Additionally, patient one had differential results that were flagged with T2. Patient number four, performed on 10/03/23 at 13:42 had platelet results flagged with "*AG." Patient numbers five, six, and seven were performed on 02/24/24 at 09:10, 09: 45, and 11:40 respectively. All three patients had platelet results flagged with "*AG", patient number seven had white blood cell, and differential results flagged as *WL". None of the seven patient CBCs were repeated. 4. The laboratory procedure manual did not include actions to take for results that were flagged by the instrument. 5. The technical consultant confirmed during interview on 04/04/24 at 10:30 am that the laboratory did not have a procedure to follow for results that were flagged by the CBC instrument. WORD KEY: CML=Chronic Myelogenous Leukemia RBC=Red Blood Cell PLT=Platelet WBC=White Blood Cell
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 observation of the laboratory, review of the Sysmex XP300 operator's manual, environmental monitoring records, and staff interview, the laboratory failed to monitor humidity using ranges that were consistent with the manufacturer's requirements in 2023 and 2024. 1. Observation of the laboratory on 04/04/24 at 8:20 am revealed the Sysmex XP300 (Serial #B0249) used for patient testing for CBC w /diff. 2. Review of the Sysmex XP300 operator's manual revealed an operating humidity range of 30-85 %. 3. Review of the laboratory environmental monitoring records from March 2023, October 2023, and February 2024 revealed the laboratory defined an acceptable humidity range as 10-80%. 4. The technical consultant confirmed during interview on 04/04/24 at 10:30 am that the laboratory failed to define humidity ranges that were consistent with the manufacturer's requirements in 2023 and 2024.