Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0994691	10/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
All Children's Pediatric Clinic P A	6900 N 10th Ste 8, Mcallen, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute's proficiency testing records from 2022 and 2023, and staff interview, the laboratory failed to ensure 2 of 5 testing personnel participated in proficiency testing. The finding included: 1. The laboratory's submitted Form CMS 209 identified 5 testing personnel. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2022 (events 1, 2 and 3) and 2023 (events 1 and 2) determined testing personnel number 3 and number 5 (as listed on Form CMS 209) did not participate in proficiency testing. 3. The technical consultant confirmed the findings in an interview on 10/19/2023 at 0845 hours in the office.
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 review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of the laboratory's procedures, review of patient results, and staff interview, the laboratory failed to have a policy to address flagged Complete Blood Count (CBC) results. The findings included: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Code No. AU553517. Date of Last Revision: May 2014) under the section titled "Analysis of histogram" stated: "Analysis of histogram allows use of the flagging system that suggests sample error or instrument error." The instructions then defined the following flags: WL - Relative frequency for LOWER discriminator (LD) exceeds the range. Probable cause is inclusion of numerous platelet agglutinations, large platelets, and etc. T1 - Lower TROUGH Discriminator, that distinguishes lymphocytes and mixed cells, cannot be not determined. T2 - Higher TROUGH Discriminator, that distinguishes mixed cells and neutrophils, cannot be not determined. F1 - Small cell histogram error. Relative frequency for T1 exceeds the range. F2 - Middle cell histogram error. Relative frequency for T1 or T2 exceeds the range. F3 - Large cell histogram error. Relative frequency for T2 exceeds the range. WU - Relative frequency for UPPER discriminator (UD) exceeds the range. Applicable case is that in which considerable leukocytes aggregation or numerous abnormal blood cells are present. AG - The particle count equal to or less than the LD exceeds a prescribed range. Probable cause is platelet agglutination, which does not alter WBC count but may result in decreased platelet count. Therefore, this flag is added to the PLT parameter. Manufacturer's instructions did not state how to resolve the identified flags. 2. A review of the laboratory's procedures showed the laboratory did not have a policy in place on how to resolve the identified flags. 3. A sampling of patient test results 09/01/2023 identified 3 patients whose CBC results had flags which were reported to the provider: a) ID: 1 Flag: WL b) ID: 5 Flag: WL c) ID: 8 Flag: WL 4. The technical consultant confirmed the findings in an interview conducted 10/19/2023 at 0916 hours in the office.
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 review of the laboratory's hematology quality control records from December 2022 to September 2023, and staff interview, the facility failed to have documentation of monitoring quality control over time to detect shifts and trends during the period of December 27, 2022 to March 17, 2023. The findings included: 1. A review of the laboratory's Eight Check 3 WP X-TRA quality control records from December 2022 to March 2023 identified the following two lots were used: Lot: 22780710 expiration: 1/11/2023 Lot: 23620710 expiration: 4/5/2023 2. Further review of the quality control records identified the laboratory failed to have documentation of monitoring quality control values over time from 12/22/2023 to 3/17/2023. 3. The technical consultant confirmed the findings in an interview on 03/19/2023 at 920 hours in the office.