Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1018588	09/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
All Childrens Pediatric Clinic	626 North Texas Blvd, Weslaco, 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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) shou1ld be notified immediately.
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 manufacturer's instructions, random review of final patient reports, and confirmed in interview of facility personnel, the laboratory's policy failed to instruct testing personnel on how to resolve flags on CBC (complete blood count) results according to the manufacturer's instructions prior to their release to the healthcare provider. The findings were: 1. Review of the laboratory's policy titled, "Policy For Abnormal Differentials" approved by the laboratory director on September 1, 2014, stated, " ...It will be the policy of this laboratory to send out abnormal differentials to the reference lab or send patient to the nearest hospital based on the Laboratory Directors decision. The laboratory Director will determine if a manual differential is required post evaluating CBC results and assessing the patient's clinical findings." 2. Review of the manufacturer's instructions for the Sysmex XP-300 (Code No. AU553517, Revision Date: May 2014) under, "8.3 Histogram flags" stated: Flag: WL Probable sample 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. Correction (reference): (1) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. (2) Check smear, etc. Flag: RL Probable sample cause: Presence of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, etc. Correction (reference): (1) Manual red blood cell count of sample. (2) Check smear, etc. Flag: PL Probable sample cause: Effects of cryoglobulins, fragmented red blood cells, or cellular fragments of white blood cells, etc. Correction (reference): (1) Warm sample at 37 degrees Celsius for 30 minutes and repeat analysis. (2) Check smear, etc. 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 (reference): (1) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. (2) Check smear, etc. Flag: RU Probable sample cause: Effects of cold agglutinin, inclusion of white blood cells, etc. Correction (reference): (1) Warm sample at 37 degrees Celsius for 30 minutes and repeat analysis. (2) Check smear, etc. Flag: PU Probable sample cause: Increase of large platelets, inclusion of fragmented red blood cells, precipitation of cryoglobulins, etc. Correction (reference): (1) Manual platelet count of sample. (2) Check smear, etc. Flag: DW (RBC) Probable sample cause: Significant anisocytosis, etc. Correction (reference): (1) Check smear, etc. Flag: DW (PLT) Probable sample cause: Inclusion of fragmented red blood cells, non-uniformity in size of platelets, effects of cryoglobulins. Correction (reference): (1) Check smear, etc. (2) Centrifuge sample and replace 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: MP (RBC) Probable sample cause: Effects of anemia treatment or blood transfusion causing the presence of cells of multiple sizes. Correction (reference): (1) Check smear, etc. Flag: MP (PLT) Probable sample cause: Platelet aggregation, sample with low values for platelets. Correction (reference): Check smear, etc. Flag: T1 Probable sample cause: Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, etc. Correction (reference): (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: T2 Probable sample cause: Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, aged sample, etc. Correction (reference): (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: F1, F2, F3 Probable sample cause: Presence of CMS or other immature granulocytes, incomplete lysing of red blood cells, aged sample, etc. Correction (reference): (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 (reference): Check smear, etc. 3. Random review of final patient reports from August and September 2018 revealed the following patient results that were released to the healthcare provider with flags (see patient alias list): Patient 1 Date: 08/23/2018 Flag: T2 Patient 2 Date: 08/23/2018 Flag: AG Patient 3 Date: 08 /24/2018 Flag: T2 Patient 4 Date: 09/03/018 Flag: AG, T2 Patient 5 Date: 09/03/2018 Flag: T2 Patient 6 Date: 09/03/2018 Flag: T2 Patient 7 Date: 09/04/2018 Flag: AG Patient 8 Date: 09/04/2018 Flag: AG Patient 9 Date: 09/04/2018 Flag: AG 4. The laboratory was asked to provide documentation of resolving the flags according to the manufacturer's instructions. No documentation was provided. 5. An interview with the technical consultant on 09/19/2018 at 13:40 hours in the patient room confirmed the findings. Key: CML - Chronic Myeloid Leukemia
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records for the Syxmex XP 300 hematology analyzer and staff interview, it was revealed the laboratory failed to ensure verification studies were complete prior to performing patient testing. The findings were: 1. Review of the laboratory's instrument verification records for the Sysmex XP 300 hematology analyzer revealed the laboratory director approved the instrument for patient testing on October 20, 2017. 2. Review of the laboratory's verification records for the Sysmex XP 300 hematology analyzer revealed the verification study failed to include a patient normal range study. 3. An interview with the technical consultant at 15:30 hours in the patient exam room confirmed the findings.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels

	of analytical performance for each test system; This STANDARD is not met as evidenced by: Based upon review of the laboratory's verification studies for the Sysmex 300 hematology analyzer, review of the manufacturer's instructions, and staff interview, it was revealed the laboratory director failed to provide a policy to address patient results when a result is out of the verified linearity range of the instrument. The findings were: 1. A review of the laboratory's verification records for the Sysmex hematology analyzer approved by the laboratory director on October 20, 2017, revealed the laboratory had established its linearity ranges as follows: WBC: 0 - 118.6 x 10^9/L RBC: 0.01 - 7.6 x 10^12/L HGB: 0 - 22.7 x g/dL PLT: 0 - 180 x 10^9/L 2. Review of the manufacturer's instructions for the Sysmex 300 hematology analyzer under "Technical Information" revealed the Reportable Ranges for the analyzer were as follows: WBC: 1.0 - 99.9 x 10^9/L RBC: 0.3 - 7.0 x 10^12/L HGB: .1 - 25.0 x g /dL PLT: 10 - 99 x 10^9/L 3. The laboratory director failed to implement a policy that instructed testing persons on how to report patient results outside of the laboratory established linearity range of the analyzer. 4. An interview with the technical consultant on September 29, 2018 at 1600 hours in the patient exam room confirmed the findings. Key: L - liter g - gram dL - deciliter WBC - white blood cell RBC - red blood cell HGB - hemoglobin PLT - platelet