

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1082475	(X3) Date Survey Completed 05/17/2018
Name of Provider or Supplier All Childrens Pediatric Clinic Pa	Street Address, City, State 4221 North Conway Suite D, Palmhurst, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory's policy for handling abnormal differentials failed to resolve flags identified on CBC (complete blood count) results. The findings were: 1. Review of the laboratory's policy titled, "Policy for Handling Flagged CBC Differentials" approved by the laboratory director on March 28, 2018 stated, "It will be the policy of this laboratory to return [SIC] flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials according the procedures in the unit's operator</p>

manual. See that the sample requirements are met, that the unit is in good working order, and that the testing procedure is correctly followed..." 2. Review of manufacturer's instructions for the Sysmex XP-300 hematology analyzer (code number AU553517), under "Description of the analysis screen results" stated: ! - value is outside the linearity limit +++.+ - value exceeds display range 3. Random review of final patient reports from May 15, 2018, revealed the following patient results that were resulted when the laboratory's procedure was not followed: Patient 1: Analyte Run 1: Run 2: Flag: WBC 10.0 0.2 ! RBC 5.03 3.71 HGB 9.3 0.2 HCT 43.1 31.9 MCV 85.7 86.0 MCH 18.5 0.5 MCHC 21.6 0.6 Patient 2: Analyte Run 1: Run 2: Flag: WBC 11.6 11.7 RBC 4.49 0.87 HGB 13.2 12.8 HCT 38.9 7.6 ! MCV 86.6 87.4 MCH 29.4 +++.+ MCHC 33.9 +++.+ 4. Interview with the technical consultant on 05 /16/2018 at 1430 hours in the office confirmed the findings. Key: WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean cell volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration