

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0101910	(X3) Date Survey Completed 09/19/2023
Name of Provider or Supplier Ridgefield Pediatric Associates	Street Address, City, State 38-B Grove St, Ridgefield, CT	
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 record review and staff interview, the laboratory failed to ensure the approved procedure for the Beckman DxH 520 Coulter contained the established and verified age-appropriate reference ranges for Complete Blood Counts (CBC) in the specialty of hematology. Findings include: 1. Record review on 9/19/2023 of the 'Hematology Laboratory Procedure Manual' revealed the following: a. Age -related reference ranges for the following age groups: Newborns, 7-14 days, 1 month, 3 months - 2 years, > 2yrs- 6years, > 6yrs - 12 years and > 12 years - 21 yrs. b. Analytes include White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (HGB),</p>

Hematocrit (HCT), Platelet (PLT), Neutrophils (NE), Lymphocytes (LY) and Monocytes (MO), MCV and MCH. 2. Record review on 9/19/2023 2 of 2 patient final test reports revealed the following: a. Patient #1 is a 17-year-old where reference ranges for the WBC, RBC, HGB, HCT, PLT, NE, LY, MO, MCV and MCH did not correspond with the procedure manual. b. Patient #2 is a 10-year-old where reference ranges for the WBC, RBC, HGB, HCT, PLT, NE, LY, MO, MCV and MCH did not correspond with the procedure manual. 3. Record review on 09/19/2023 of the Beckman Coulter DxH 520 Hematology Analyzer verification study revealed: a. Establishment and verification of age-related normal reference ranges with laboratory director approval effective 2019. b. Verification reference ranges did not coincide with the procedure manual. 4. Staff interview on 09/19/2023 at 10:00 AM with the office manager (OM) confirmed the above discrepancies. The OM commented he/she was unaware where the procedure values originated. 5. The laboratory performs 558 CBCs annually in the specialty of hematology.