

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0674569	(X3) Date Survey Completed 12/28/2023
Name of Provider or Supplier Pediatric Associates Inc Of Brockton	Street Address, City, State 6 Washington Street, Canton, MA	
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 include the reference ranges for complete blood count (CBC) in the procedure manual in the specialty of Hematology. Findings include: 1. Record review on 12/18/2023 of the 'Pediatric Associates of Brockton Emerald User Guide and Policy and Procedure for Obtaining Hemoglobin and CBC' compared to the CMS form 116 test list and a final patient test report, revealed, the procedure did not contain the reference ranges for the Complete Blood Count (CBC) test containing Hemoglobin, Hematocrit, Red Blood Count, White Blood Count, Mean Corpuscular Volume, Mean Corpuscular</p>

Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Red Cell Distribution Width, Mean Platelet Volume, Platelet Count, and Automated White Blood Cell differential. 2. Staff interview with clinical operations manager #1 and #2 on 12/18 /2023 at 12:30 PM confirmed the above findings. 3. Staff interview with the LD on 12 /28/2023 at 11:30 AM confirmed the above findings. The LD stated, "We will add the reference ranges to the procedure." 4. The laboratory performs 3,146 Hematology tests annually.