

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0664381	(X3) Date Survey Completed 08/20/2024
Name of Provider or Supplier Pediatric Health Care Associates Pc	Street Address, City, State 467 R Main Street, Melrose, 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
D0000	A CLIA recertification survey was conducted for the Pediatric Health Care Associates, PC laboratory on 08/20/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 all tests in the procedure manual in the specialty Hematology. Findings include: 1. Record review on 8/20/2024 of the procedure signed by the laboratory director revealed the procedure did not contain the reference (normal)</p>

ranges for Hemoglobin, Hematocrit, Red Cell Distribution Width, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Automated White Blood Cell differential. 2. Staff interview with the technical consultant (TC) on 8/20/2024 at 11:30 aM confirmed the above findings. The TC stated, "The normal values are in Lab Daq computer system." 3. The laboratory performs 8,568 Hematology tests annually.