

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0219053	<b>(X3) Date Survey Completed</b>  07/20/2022
<b>Name of Provider or Supplier</b>  Pediatric Center Llc,The	<b>Street Address, City, State</b>  5900 Waterloo Rd Suite 110, Columbia, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<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 the laboratory written procedures, the laboratory procedure did not include a description of how to positively identify a patient prior to collecting a specimen for laboratory testing. Findings: 1. Laboratory staff stated (the afternoon of survey) that the laboratory requires three identifiers for patient identification and this identification is performed at the time of collection; and 2. The procedure for collecting patient specimens did not describe how the patient is identified prior to obtaining a laboratory specimen.</p>

**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 record review, the laboratory validation for the hematology analyzer was incomplete. Findings: 1. In April 2021 a new hematology analyzer was installed; 2. The validation data did not include the data for the linearity studies and their approval by the laboratory director and did not identify the laboratory's upper and lower limits of detection for each hematology test, if required; and 3. The validation data did not include the analysis studies to check for accuracy and approval by the laboratory director (for appropriate analytes).