

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2139487	(X3) Date Survey Completed 12/11/2024
Name of Provider or Supplier Urgent Care - Jefferson City	Street Address, City, State 3527 W Truman Blvd Suite 100 A, Jefferson City, MO	
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 the laboratory's I-Stat procedure manual on December 11, 2024 and interview with technical consultant, the procedure manual failed to include reference intervals (normal values) for ten of ten analytes performed on the I-Stat analyzer. Findings: 1. The laboratory's I-Stat procedure manual did not include reference intervals (normal values) for the following analytes performed on the I-Stat analyzer: Troponin I, Sodium, Potassium, Chloride, Carbon Dioxide, Blood Urea Nitrogen, Creatinine, Ionized Calcium, Glucose and Hematocrit. The laboratory could</p>

not provide pertinent approved reference intervals (normal values) for analytes performed on the I-Stat analyzer. 2. Interview on December 11, 2024 at 11:55 AM, the technical consultant confirmed the laboratory's I-Stat procedure manual failed to include reference intervals (normal values) for ten analytes performed on the I-Stat analyzer.