

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2159851	<b>(X3) Date Survey Completed</b>  03/25/2025
<b>Name of Provider or Supplier</b>  Pediatric Urgent Care Of Rochester, Pllc	<b>Street Address, City, State</b>  6687 Pittsford Palmyra Rd - Ste 40, Fairport, NY	
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>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 Standard Operating Procedures (SOPs), lack of thermometer calibration records, as well as interviews with the Laboratory Manager (LM) and Clinical Administrator (CA), the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no calibration certificate documentation for the thermometers utilized for ambient, refrigerator, freezer temperatures and humidity monitoring in the laboratory where patient specimen processing occurred. 2. The current, approved SOPs did not include instructions for</p>

thermometer calibration and certificate retention. 3. The LM and CA confirmed the findings on March 25, 2025, at approximately 3:00 P.M.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observations, review of SOPs, as well as interviews with the LM and CA, the laboratory failed to remove from inventory expired patient testing materials in the area where patient specimen processing occurred. FINDINGS: 1. The surveyor's observations in the laboratory confirmed on March 25, 2025, at approximately 2:00 P. M., the following patient testing materials were not removed from inventory: a. OSOM Rapid Diagnostics Mono Test kit, lot: 241022, expiration: October 2024, stored on the laboratory Point of Care Testing (POC) testing cart. Approximately seventeen patients were processed utilizing the respective expired test kit. b. Consult Diagnostics McKesson Fecal Occult Blood Test kit, lot: 0120101-8, expiration: September 30, 2023. It was noted that no patient specimens were processed utilizing the respective expired test kit. 2. This is contrary to instructions included in the current, approved SOPs. 3. The LM and CA confirmed the findings on March 25, 2025, at approximately 3:00 P.M.

**D5781**

CORRECTIVE ACTIONS  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of refrigerator temperature log sheets, SOPs, manufacturer's package inserts, lack of corrective action records, as well as interviews with the LM and CA, the laboratory failed to perform and document corrective action for out-of-range refrigerator temperatures. FINDINGS: 1. Documented temperatures for the Emerson refrigerator, utilized for storage of patient specimen testing materials, deviated from the specified range of 36 - 46 F for multiple dates. 2. There was no documentation of corrective action performance for out-of-range refrigerator temperatures. 3. This is contrary to instructions included in the current, approved SOPs. 4. The LM and CA confirmed the findings on March 25, 2025, at approximately 3:00 P.M.