

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1101447	(X3) Date Survey Completed 02/03/2026
Name of Provider or Supplier Community Care Pediatrics - Saratoga	Street Address, City, State 5 Hemphill Place, Ballston Spa, NY	
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>(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 the laboratory's Standard Operating Procedures (SOPs) manual, lack of thermometer calibration records, as well as interview with the Laboratory Supervisor (LS), the laboratory failed to draft and approve calibration and calibration verification procedures. FINDINGS: 1. There was no documentation of calibration for the Doquas Digital Hygrometer Indoor Thermometer Humidity Meter used to monitor the ambient room temperature and humidity in the laboratory. 2. The current, approved SOP, "Policy Procedure of Lab Thermometer Replacement", did not include</p>

instructions for thermometer calibration and certificate retention. 3. The LS confirmed the findings on February 3, 2026, at approximately 12:20 P.M.