

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2042099	(X3) Date Survey Completed 03/25/2026
Name of Provider or Supplier Nephrology Associates Of Watertown, Pc	Street Address, City, State 19316 Us Route 11, Suite B, Watertown, 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 Quality Assurance (QA) and Procedure Manual, thermometer calibration records, as well as interview with Testing Person one (TP1), the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no documentation of calibration for the Acurite digital thermometer hygrometer utilized for monitoring ambient room temperature and humidity in the laboratory. 2. The VWR digital thermometer, SN: 130272718, utilized for monitoring the temperature of the Frigidaire freezer where patient specimens and</p>

calibration material were stored, featured a tag indicating recalibration due May 15, 2015. It was noted that the respective calibration thermometer certificate was retained. 3. The VWR digital thermometer, SN: 130272588, utilized for monitoring the temperature of the Frigidaire refrigerator where patient specimens, reagents, test kits, calibrator, and control materials were stored, featured a tag indicating recalibration due May 15, 2015. It was noted that the respective calibration thermometer certificate was retained. 4. The current, approved QA and Procedure Manual did not include instructions for thermometer calibration and certificate retention. 5. TP1 confirmed the findings on March 25, 2026, at approximately 5:00 P.M.