

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1054252	<b>(X3) Date Survey Completed</b>  02/12/2026
<b>Name of Provider or Supplier</b>  Knoxville Kidney Center, Pllc	<b>Street Address, City, State</b>  320 Park 40 North Blvd, Suite A, Knoxville, TN	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation of two laboratory rooms, a review of the laboratory's policy, a review of the manufacturer's cassette package, and staff interviews, the laboratory failed to follow its written policy for documenting "open vial" expiration dates for 14 i-STAT CHEM8+ test cartridges observed on the survey date (02.12.2026). This standard was previously cited from the survey on 05.14.2024, and it was determined that compliance was not maintained at the recertification survey on 02.12.2026. The findings include: 1. Observation of the two laboratory rooms on 02.12.2026 at 9:20 a. m. revealed one Abbott i-STAT instrument (serial number 21-434284) in laboratory room #1 and one Abbott i-STAT instrument (serial number 21-452071) in laboratory room #2 in use for patient testing for Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine and Hematocrit using the CHEM8+ test cartridge. Also observed were 10 CHEM8+ test cartridges (lot number H25327) stored at room temperature on the counter in laboratory room #1 and 4 CHEM8+ test cartridges (lot number H25327) stored at room temperature on the counter in laboratory room #2, not labeled with revised expiration dates. 2. A review of the laboratory's policy titled "Reagent Management" section "IV. Utilization" revealed the statement "Date all reagents, etc., when opened. Also documented the "open vial" expiration date on the container." 3. A review of the manufacturer's cassette package revealed that CHEM8+ cassettes can be stored for 14 days at room</p>

temperature (18C-30C). 4. Interviews with the Clinical Supervisor on 02.12.2026 at 9:25 a.m. and with the Practice Administrator on 02.12.2026 at 11:45 a.m. confirmed the above survey findings. Word Key: C = degrees Celsius