

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1054252	(X3) Date Survey Completed 05/14/2024
Name of Provider or Supplier Knoxville Kidney Center, Plc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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 an interview with the clinic manager, the laboratory failed to follow its written policy for documenting open and "open vial" expiration dates for 65 i-STAT CHEM8+ test cartridges observed on the survey date (05.14.2024). The findings include: 1. Observation of the two laboratory rooms on 05.14.2024 at 9:00 a.m. revealed two Abbott iSTAT instruments (serial numbers 434284 and 397786) in laboratory room #2 and one Abbott iSTAT instrument (serial number 416818) in laboratory room #3 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 31 CHEM8+ test cartridges (lot number H24068) stored at room temperature on the counter in laboratory room #2 and 34 CHEM8+ test cartridges (lot number H24068) stored at room temperature on the counter in laboratory room #3 not labeled with open or 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 temperature (18C-30C). 4. An interview with the clinic manager on 05.14.2024 at 9:03 a.m. confirmed the laboratory</p>

failed to follow its written policy for documenting open and "open vial" expiration dates for 65 i-STAT CHEM8+ test cartridges observed on the survey date (05.14.2024). Word Key: C = degrees Celsius