Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2284155	01/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Knoxville Kidney Center, Pllc	800 Oak Ridge Turnpike Ste 401-A, Oak Ridge, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and staff interview, the testing personnel and laboratory director/designee failed to sign three of six PT attestation statements from 2024 and 2025. The findings include: 1. A review of the laboratory's College of American Pathology (CAP) PT records revealed that the testing personnel and the laboratory director/designee failed to sign the attestation statement for 2024 Event One, and the laboratory director/designee failed to sign the attestation statements for 2024 Event Three and 2025 Event One. 2. An interview on 01.13.2026 at 12:45 p.m. with the clinic supervisor and practice manager confirmed the above survey findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and staff interviews, the laboratory failed to document the review and evaluation of the Critical Care Blood Gas PT results for six of six events reviewed from 2024 and 2025. The findings include 1. A review of the laboratory's College of American Pathology

	(CAP) PT records revealed no documented review and evaluation of the performance evaluations for 2024 Events One, Two, and Three, and 2025 Events One, Two, and Three for the Critical Care Blood Gas, iSTAT analytes on the date of the survey, 01.13.2026. 2. An interview on 01.13.2026 at 12:45 p.m. with the clinic supervisor and practice manager confirmed the above survey findings.
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 observation of the laboratory, review of laboratory policy, review of manufacturer instructions, review of laboratory refrigerator temperature logs, lack of records, and staff interviews, the laboratory failed to document corrective action for recorded refrigerator temperatures that exceeded the laboratory's established acceptable range for 91 out of 160 days reviewed from February 1, 2024, through December 31, 2025. The findings include: 1. Observation of the laboratory on 01.13.2026 at 9:30 a.m. revealed an Abbott iSTAT (Serial number 403629) in use for Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, and Hematocrit patient testing using the CHEM8+ cartridge. Also observed was a refrigerator used to store two boxes of Abbott iSTAT CHEM8+ cartridges (lot H25262A, expiration date: 03.18.2026). 2. A review of the laboratory's policy titled "Quality Assessment Guide" under the section "Environment, Instruments, Reagents, Materials, and Supplies" stated the following: "Each day of operation, the temperature will be read and recorded for all refrigerators. If any readings are not within acceptable limits, appropriate remedial action will be taken and documented. Refrigerator: Acceptable limits are 2C to 8C." 3. A review of the Abbott iSTAT CHEM8+ cartridge box revealed acceptable refrigerator storage temperature: 2C to 8C. 4. A review of the laboratory's refrigerator temperature logs revealed that recorded temperatures exceeded the laboratory's established acceptable range (2 - 8C) for 91 of 160 days reviewed from February 1, 2024, through December 31, 2025, as follows: February 2024: 14 of 16 days recorded March 2024: 7 of 13 days recorded April 2024: 8 of 10 days recorded May 2024: 4 of 7 days recorded June 2024: 3 of 6 days recorded July 2024: 4 of 8 days recorded August 2024: 5 of 9 days recorded September 2024: 8 of 8 days recorded October 2024: 2 of 6 days recorded November 2024: 3 of 5 days recorded December 2024: 4 of 5 days recorded January 2025: 2 of 3 days recorded March 2025: 1 of 4 days recorded July 2025: 6 of 9 days recorded August 2025: 9 of 9 days recorded September 2025: 6 of 6 days recorded October 2025: 3 of 7 days recorded November 2025: 2 of 8 days recorded 5. No corrective action documentation available for surveyor review on the survey date (01.13.2026) for the recorded temperatures that were outside the laboratory's

	established acceptable range (2 - 8C) in 2024 and 2025. 6. An interview on 01.13.2026 at 12:45 p.m. with the clinic supervisor and practice manager confirmed the above survey findings. Word Key: C = degrees Celsius