

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2284155	(X3) Date Survey Completed 01/25/2024
Name of Provider or Supplier Knoxville Kidney Center, Plc	Street Address, City, State 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of proficiency testing (PT) records, review of patient test records, interview with the practice manager, and follow-up email with the practice manager, the laboratory failed to enroll in PT for iSTAT CHEM8+ cartridge analytes in 2023 and 2024 with 277 patient results reported since testing began on 08.02.2023. The findings include: 1. Observation of the laboratory on 01.25.2024 at 9:45 a.m. revealed an Abbott iSTAT (serial number 403629) in use for patient testing for Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine and Hematocrit using the CHEM8+ cartridge. 2. Review of PT records revealed no PT records available. 3. Review of patient data logs revealed CHEM8+ cartridge patient testing began on 08.02.2023 (patient number 29921). 4. Interview with the practice manager on 01.25.2024 at 12: 15 p.m. confirmed the laboratory was not enrolled in PT for the hematology and chemistry regulated analytes (Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine and Hematocrit) included in the CHEM8+ cartridge since patient testing began on 08.02.2023. 5. Email</p>

communication with the practice manager on 01.29.2024 at approximately 4:00 p.m. confirmed the laboratory reported 277 patient CHEM8+ panels since testing began on 08.02.2023 through the date of the survey (01.25.2024).

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of patient data logs, review of manufacturer's operator's manual, lack of records and staff interview, the laboratory failed to ensure ambient temperature and relative humidity were monitored in the area where the Abbott iSTAT instrument was in use for chemistry and hematology patient testing from the time patient testing began (08.02.2023) until the date of the survey (01.25.2024). The findings include: 1. Observation of the laboratory on 01.25.2024 at 9:45 a.m. revealed the Abbott iSTAT (serial number 403629) in use for patient testing for Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine and Hematocrit using the CHEM8+ cartridge. 2. Review of patient data logs revealed the laboratory began patient testing on the Abbott iSTAT on 08.02.2023. 3. Review of the manufacturer's operator's manual revealed an operating temperature of 16-30 degrees Celsius and relative humidity of 90% (maximum). 4. There were no environmental records for monitoring of ambient temperature and relative humidity for surveyor review. 5. Interview with the practice manager on 01.25.2024 at 12:15 p.m. confirmed the laboratory failed to monitor ambient temperature and relative humidity in the area where the Abbott iSTAT instrument was in use for patient testing from the time patient testing began (08.02.2023) to the date of the survey (01.25.2024).