

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1054252	(X3) Date Survey Completed 04/12/2022
Name of Provider or Supplier Knoxville Kidney Center, Pllc	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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by:</p> <p>===== Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, the Centers for Medicare and Medicaid Services form 209 Laboratory Personnel Report (CMS-209) and interview with the laboratory practice administrator, the laboratory failed to test proficiency testing samples by routine testing personnel in 2020 and 2021. The finding include: 1. Review of the laboratory's PT records revealed that testing personnel number four performed four of four chemistry PT events (2020 event three; 2021 events one, two, and three). 2. Review of the CMS-209 revealed six personnel who perform patient testing. 3. Interview with the pactice administrator on April 12, 2022 at 12:30 pm confirmed that testing personnel number four performed four of four PT events for 2020 and 2021. The laboratory failed to test proficiency testing samples by the same personnel who perform patient testing in 2020 and 2021.</p> <p>=====</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 ===== Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, the Centers for Medicare and Medicaid Services form 209 Laboratory Personnel Report (CMS-209) and interview with the laboratory practice administrator, it was determined the testing personnel failed to sign the attestation sheets for chemistry PT for 2020, 2021, and 2022. The findings include: 1. Review of the laboratory's PT records revealed that attestation sheets were not signed by testing personnel for five of five chemistry PT events (2020 event three; 2021 events one, two, and three; 2022 event one). 2. Interview with the practice administrator on April 12, 2022 at 12:30 pm confirmed that attestation sheets were not signed by testing personnel for five of five chemistry PT events (2020 event three; 2021 events one, two, and three; 2022 event one).
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D5445

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
 (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 ===== Based on review of the quality control (QC) and patient records, lack of an Individualized Quality Control Plan (IQCP), and interview with the practice administrator, the laboratory failed to perform QC each day of patient testing or develop and implement an IQCP prior to March 12, 2020, for the iSTAT analyzers. The findings include: 1. Review of the QC and patient records revealed iSTAT QC performed when new lots of cartridges were started. 2. No IQCP was available for review at the time of survey on April 12, 2022. 3. Interview on April 12, 2022 at 12:30 p.m. with the practice administrator confirmed the laboratory does not perform QC daily with patient testing but follows the manufacturer's instructions for performance of QC frequency and does not have an IQCP in place for the iSTAT analyzer.
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