Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2234754	10/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Cardio-Kidney Vascular Care, Llc	3161 N Webb Rd Suite 220, Wichita, KS	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the lack of documentation for verification of performance specifications, lack of Individual Quality Control Plan (IQCP), lack of quality control values on patient testing dates and interview with technical consultant #1, the laboratory failed to have verified the performance specifications for accuracy, precision, analytical measurement range, and normal range (refer to D5421) and failed to perform QC on the day of patient testing with no established IQCP on the i-STAT for the test cartridges Chem 8+, Activated Clotting Time (ACT), and EG7+ (refer to D5445).
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on the lack of documentation of performance verifications, non-waived test list, and interview with TC #1, the laboratory failed to perform a validation/verification on Abbott's i-STAT analyzer performance specifications prior to reporting patient test results. Findings: 1. Request was made to review the performance verifications of one of one Abbott's i-STAT analyzer, serial number (S/N) 426351. The verification documentation of the manufacturer's performance characteristics for precision, reportable range, and normal values appropriate for the laboratory's patient population provided was performed by another laboratory. No accuracy studies were provided at the time of survey. 2. The non-waived test list contained the following analytes performed on the Abbott i-STAT analyzer: ACT (Kaolin), Sodium (Na), Potassium (K+), Chloride (Cl), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN), Total Carbon Dioxide (TCO2), Creatinine (Crea), Hematocrit (Hct), pH, Partial Pressure of Oxygen (PO2), Partial Pressure of Carbon Dioxide (PCO2), Oxygen Saturation (sO2), Hemoglobin (Hgb), Bicarbonate (HCO3), and Base Excess (BE). The TC#1 stated the laboratory began reporting patient test results on the analyzer as of 7/29/22. 3. Results were released for 7 patients for Na, K, Cl, iCa, Glu, BUN, TCO2, Crea and Hct for a total of 63 results from 7/29/22 to date of survey. 4. Interview with TC#1 on 10/24/22 at 3:20 p.m. confirmed, the laboratory failed to perform a verification study for Abbott's i-STAT analyzer performance specifications prior to reporting patient test results.
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 QC documentation for the Abbott's i-STAT Chem 8+ cartridge testing, lack of a valid IQCP plan, patient test results and interview with TC #1, the laboratory failed to perform QC at least once each day of patient testing. Findings: 1. Review of the QC documents for the i-STAT Chem 8+ cartridge revealed the laboratory only performed QC on three dates: 8/12/22, 9/30/22 and 10/7/22 since patient testing began on 7/29/22. 2. No acceptable Individualized Quality Control Plan (IQCP) for the Chem 8+ cartridge was provided at the time of survey. 3. Review of the patient test results revealed the laboratory failed to perform QC on six of seven days of patient testing for the Chem 8+ cartridge for six of seven patients from 7/29 /22 to date of survey for a total of 54 test results. 3. Interview with TC #1 on 10/24/22 at 3:20 p.m. confirmed the laboratory failed to perform QC at least once each day of patient testing.