Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0899006	12/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Kansas Surgery & Recovery Center, Llc	2770 N Webb Rd, 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
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 for performance verifications, non-waived test list, and interview with the laboratory director (LD), the laboratory failed to verify two of two Abbott iSTAT analyzer performance specifications prior to reporting patient test results. Findings: 1. Request was made to review the performance verifications of two of two Abbott iSTAT analyzers; serial numbers 414316 and 414355. No documentation for two of two instrument verifications were made available at the time of survey. The Director of Nursing (DON)stated the laboratory began reporting patient test results on two of two analyzers as of 4/19/21. 2. No documentation of verifications of the manufacturer's performance characteristics for accuracy, precision, reportable range, and normal values appropriate for the laboratory's patient population were available for 13 of 13 analytes performed on two of two analyzers at the time of survey. 3. Patient results were released for 11348 tests on 2863 patients from 4/19/21 to date of survey. 4. Interview with the LD on 12/14/21 at 2:10 p.m. confirmed, the laboratory failed to verify two of two Abbott iSTAT analyzer performance specifications prior to reporting patient test results.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, non-waived test list, QC records and patient result logs from 4/19/21 to the time of survey and interview with the LD, the laboratory failed to perform QC at least once each day of patient testing for quantitative procedures, to include two control materials of different concentrations. Findings: 1. The Abbott iSTAT System Manual and Instructions for Use (IFU) for Chem 8+, CG4+ and PT/INR under Quality Control state "Liquid materials that are used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question." 2. The laboratory's non waived test list consists of Abbott iSTAT system cartridges for the following analytes: a. CG4+ cartridge: pH, pCO2, pO2, and Lactate. b. Chem 8+ cartridge: Sodium (Na), Potassium (K), Chloride (Cl), total Carbon Dioxide (tCO2, ionized Calcium (iCa), Glucose, Hematocrit (Hct), Creatinine, and Blood Urea Nitrogen (BUN). c. PT/INR cartridge: prothrombin time 3. CG4+, Chem 8+, and PT/INR cartridges are categorized as moderate complexity tests and require quality control at least once a day of patient testing with two control materials of different concentrations per 493. 1256. 4. Chem 8+ QC was not performed for 7819 of 11263 patient test results for 1920 of 2825 patients from 4/19/21 to date of survey. 5. CG4+ QC was not performed for 12 of 12 patient test results for 2 of 2 patients from 4/19/21 to date of survey. 6. PT /INR QC was not performed for 68 of 73 patient test results for 34 of 36 patients from 4/19/21 to date of survey. 7. No Individualized Quality Control Plan (IQCP) had been performed to allow the laboratory to reduce the frequency of QC performance. 8. Interview with the LD on 12/14/21 at 2:30 p.m. confirmed, the laboratory failed to perform QC at least once each day of patient testing for quantitative procedures, to include two control materials of different concentrations.