Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2094447	01/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Overland Park Regional Med Center Er Of Olathe	13505 South Alden, Olathe, 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 of performance verifications, non-waived test list, and interview with technical consultant #2 (TC#2), the laboratory failed to verify two of two Siemen's epoc analyzer performance specifications prior to reporting patient test results. Findings: 1. Request was made to review the performance verifications of two of two Siemen's epoc analyzers; serial numbers (S/N) 27113 and 27122. No documentation of verification of the manufacturer's performance characteristics for accuracy, precision, reportable range, and normal values appropriate for the laboratory's patient population were made available for 10 of 10 analytes performed on two of two analyzers at the time of survey. 2. Non waived analytes performed were: pH, Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Lactate, Glucose, Creatinine, Blood Urea Nitrogen (BUN), and total Carbon Dioxide (tCO2). TC#2 stated the laboratory began reporting patient test results on two of two analyzers as of 3/2/21. 3. Patient results were released for 9078 tests on 1245 patients from 3/2/21 to date of survey. 4. Interview with the TC#2 on 1/24/22 at 1:10 p.m. confirmed, the laboratory failed to verify two of two Siemen's epoc 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, test complexity, quality control (QC) records from 3/2/21 to the time of survey, absence of Individualized Quality Control Plan (IQCP), and interview with TC#2, 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 epoc Blood Analysis System Manual requires at least 2 levels of fluid control for each lot in each shipment of cards. 2. The epoc Blood Analysis System cards for pH, Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Lactate, Glucose, Creatinine, Blood Urea Nitrogen (BUN), and total Carbon Dioxide (tCO2) 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. 3 QC was not performed for 297 of 309 patient testing days for 1197 of 1245 patients. 4. No IQCP had been performed to allow the laboratory to reduce the frequency of QC performance. 5. Interview with the TC#2 on 1/24/22 at 1:15 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.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of test lists, presence of two Siemens epoc analyzers, lack of comparison records and interview, the laboratory failed to evaluate and define the relationship between test results using two of two instruments for the same analytes. Findings: 1. Review of analytes pH, Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Lactate, Glucose, Creatinine, Blood Urea Nitrogen (BUN), and total Carbon Dioxide (tCO2) showed they are performed on the Siemens epoc. 2. Two epoc analyzers are used for testing: S/N 27113 and S/N 27122. 3. No epoc testing comparison records from 3/2/21 to 1/24/22 were made available at the time of survey. 4. Interview with TC#2 on 1/24/22 at 1:25 p..m. confirmed, the laboratory failed to evaluate and define the relationship between two of two Siemens epoc test results for pH, Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Lactate, Glucose, Creatinine, Blood Urea Nitrogen (BUN), and total Carbon Dioxide (tCO2).