Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2094447	08/31/2018
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
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: D5413 Based on review of the manufacturer's inserts and interview with the general supervisor, the laboratory failed to monitor and document the humidity of the laboratory for proper operation of the Sysmex XS 1000i. Findings: 1. Review of the manufacturer's product insert for performance specifications revealed, "to operate the analyzer in a relative humidity of 30-85 percent." 2. Review of the room temperature documentation showed the laboratory failed to monitor and document humidity. 3. Interview with the general supervisor on August 31, 2018 at 12:30 PM confirmed the laboratory failed to monitor and document the room humidity in the laboratory.
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: D5775 Based on review of 2017, 2018 instrument comparison documentation and interview with the general supervisor, the laboratory failed to perform the comparison study two times a year for the hematology analyzers. Findings: 1. Review of the instrument comparison documentation between the Sysmex XS 1000i (primary) and the Sysmex XP 300 (backup) hematology analyzers showed a lack of comparison studies two times a year for 2017. 2. Interview with the general supervisor on August 31, 2018 at 12:30 PM confirmed, the laboratory failed to perform instrument comparison studies two times a year for 2017.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: D5807 Based on review of approved reference ranges in the laboratory procedure manual and interview with the general supervisor, the laboratory failed to ensure the test report included pertinent normal ranges as determined by the laboratory. One of the nine complete blood cell count (CBC) parameters for female and male ranges and two of the six parameters for microscopic urinalysis listed on the laboratory information system(LIS) report differed from those in the approved procedure manual. Findings: 1. Review of the patient reports from the LIS system revealed one of the nine parameters for female and male ranges did not correctly match those reference ranges for the CBC test in the procedure manual and two of the six parameters for microscopic urinalysis exams on the LIS report did not match the procedure manual. LIS patient report Procedure manual WBC 5.0-10.0(male/female)) 4.1-11.1 Squamous cells no value Few Amorphous Crystals no value normal 2. Interview with the general supervisor on August 31, 2018 at 12:30 PM confirmed the laboratory failed to ensure correct reference ranges approved in the procedure manual were included on the LIS patient report.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: D6117 Based on review of 2017, 2018 quality control(QC) records and interview with the general supervisor, the technical supervisor failed to review QC for blood gas testing. Findings: 1. Review of the QC records for the ISTAT analyzer for pH, pCO2, pO2, for 2017 and to date 2018, showed the technical supervisor failed to review the

	records to verify instrument accuracy. 2. Interview with the general supervisor on August 31, 2018 at 12:30 PM confirmed the technical supervisor failed to review QC records.