Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2085338	09/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Overland Park Regional Med Center Ed Of Shawnee	10310 Shawnee Mission Parkway, Shawnee, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's 2019 College of American Pathology (CAP) proficiency testing (PT) documentation and interview, the laboratory failed to verify the accuracy of chemistry and microbiology analytes that were assigned a ungraded proficiency testing score. Findings: 1. Review of the laboratory's 2019 CAP PT documentation for chemistry and microbiology found the following ungraded results: Chemistry General Chemistry and Therapeutic Drug Monitoring, C-B 2019 : Received "Grade" of "Not Graded" Bilirubin: CHM-10 Calcium: CHM-06, CHM-09 Microbiology Gram Stain, D5-A 2019: Received "Grade" of "Not Graded" Educational Challenge Leukocytes D5-01,02,03,04,05 2. Review of the laboratory's PT original evaluation forms for C-B 2019 and D5-A 2019 failed to find any documentation demonstrating a self-assessment or self-grade of the "Not Graded" samples. 3. Technical Consultant (TC) #2 confirmed the laboratory failed to verify the accuracy of chemistry and microbiology analytes that were assigned a ungraded proficiency testing score. The interview occurred Septemmber 20, 2019 at 9:15 am.
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 review of performance verification documentation for the Abbott i-STAT analyzer, the Siemens Stratus analyzer and interview, the laboratory failed to verify the reference intervals (normal values) for the analytes: beta natriuretic peptide (BNP), lactic acid, troponin, and D-Dimer were appropriate for the laboratory's patient population. Findings: 1. Review of the verification documentation of the Abbott i-STAT analyzer for lactic acid and BNP testing showed no verification of normal values. 2. Review of the verification documentation of the Siemens Stratus analyzer for troponin and D-Dimer testing showed no verification of normal values. 3. Interview with the TC #2 on September 20, 2019 at 10:30 AM confirmed the laboratory failed to verify the reference intervals (normal values) for the analytes: beta natriuretic peptide (BNP), lactic acid, troponin, and D-Dimer were appropriate for the laboratory's patient population.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview, the laboratory failed to include the name and address of the laboratory location were the test was performed on the patient report. Findings: 1. Review of the selected patient test reports for i-Stat analytes and Siemens Stratus analytes showed a lack of the name and address of the laboratory location where the test was performed. 2. Interview with TC #2 on September 20, 2019 at 10:50 AM confirmed the laboratory failed to include name and address of the laboratory location were the test was performed on the patient report.