Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2140267	(X3) Date Survey Completed 09/28/2018
Name of Provider or Supplier Saint Luke's South - North Overland Park	**Street Address, City, State** 7246 W 75th Street, Overland Park, 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 review of performance specifications revealed and interview with the technical consultant on September 28, 2018 at 12:00PM confirmed, the laboratory failed to perform reference interval(normal values) verification for complete blood cell counts performed on the Sysmex XP-300 and for prothrombin time testing performed on the i-Stat analyzer.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory hours of operation, blood gas testing quality control (QC) documentation and interview with the technical consultant, the laboratory failed

	to perform QC every 8 hours. Findings: 1. Review of the laboratory's hours of operation showed the laboratory is open 24 hours/7 days a week. 2. Review of blood gas testing QC documentation to include pH, pO2, pCO2, showed the laboratory failed to run two levels of QC every 8 hours. 3. Interview with the technical consultant on September 28, 2018 at 12:00 PM confirmed the laboratory failed to run QC every 8 hours for blood gas testing.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory hours of operation, prothrombin time(PT) quality control(QC) documentation and interview with the technical consultant, the laboratory failed to perform QC every 8 hours. Findings: 1. Review of the laboratory's hours of operation showed the laboratory is open 24 hours/7 days a week. 2. Review of prothrombin time QC logs showed the laboratory failed to run two levels of QC every 8 hours. 3. Interview with the technical consultant on September 28, 2018 at 12:00 PM confirmed the laboratory failed to run QC every 8 hours for prothrombin time testing.