Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520720	08/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
St Luke's Jerome Laboratory	709 N Lincoln Ave, Jerome, ID	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to establish and document unscheduled maintenance activities for the analyzers in the laboratory since the last survey on September 22, 2016. Findings: 1. A review of instrument maintenance and trouble-shooting logs revealed the laboratory failed to have a system in place to document unscheduled maintenance and trouble-shooting activities for the Sysmex CA-600, Sysmex XN-1000, and the Ortho Vitros analyzer. 2. An interview on August 14, 2018 at 3:45 PM, with the laboratory supervisor, confirmed the laboratory failed to establish and document unscheduled maintenance activities in for the analyzers in the laboratory.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following

	occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to perform and document calibration verification procedures at least once every 6 months for the D-dimer test performed on the Sysmex CA-600 coagulation analyzer since the last survey on September 22, 2016. Findings: 1. A record review of calibration reports for the D-dimer revealed the laboratory failed to perform calibration verification at least once every 6 months since the last survey. 2. An interview on August 15, 2018, at 1:30 PM, with the laboratory supervisor, confirmed the laboratory failed to perform calibration verifications on the D-dimer test.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory testing personnel, the laboratory failed to perform and document quality control at least each week of use for gram stain tests since the last survey on September 22, 2016. Findings: 1. A record review of the gram stains performed revealed the laboratory failed to perform and document quality control at least once per week or to write an Individualized Quality Control Plan. 2. An interview with the testing personnel on August 14, 2018 at 3:15 PM, confirmed the laboratory failed to perform quality control for gram stains.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to perform and document alarm system inspections for the blood

	storage refrigerator since the last survey on September 22, 2016. Findings: 1. A record review of the laboratory procedure manual and worksheets in the laboratory revealed the laboratory failed to perform and document alarm system checks for the blood storage refrigerator. 2. An interview on August 14, 2018 at 3:15 PM with the laboratory supervisor, confirmed the laboratory failed to perform inspections of the alarm system where blood products are stored.
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory testing personnel, the technical supervisor failed to include the monitoring of reporting of test results in the competency evaluation for tests performed on the I-Stat Point-of -Care (POC) device since the last survey on September 22, 2016. Findings: 1. A review of the personnel competency evaluations for 2017 revealed the assessments failed to include monitoring of test results for 21 out of 21 POC testing personnel. 2. An interview on August 14, 2018 at 10:00 AM, with the laboratory testing personnel, confirmed the assessment forms failed to include the monitoring of test results.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory testing personnel, the technical supervisor failed to include the review of intermediate test results or worksheets, quality control, proficiency testing, and preventative maintenance records in the competency evaluation for tests performed on the I-Stat Point-of -Care (POC) device since the last survey on September 22, 2016. Findings: 1. A review of the personnel competency evaluations for 2017 revealed the assessments failed to include the review of intermediate test results or worksheets, quality control, proficiency testing, and preventative maintenance records for 21 out of 21 POC testing personnel. 2. An interview on August 14, 2018 at 10:00 AM, with the laboratory testing personnel, confirmed the assessment forms failed to include the review of intermediate test results or worksheets, quality control, proficiency testing, and preventative maintenance records.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

	This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory testing personnel, the technical supervisor failed to include the direct observation of performance of instrument maintenance in the competency evaluations for tests performed on the I-Stat Point-of -Care (POC) device since the last survey on September 22, 2016. Findings: 1. A review of the personnel competency evaluations for 2017 revealed the assessments failed to include the direct observation of performance of instrument maintenance for 21 out of 21 POC testing personnel. 2. An interview on August 14, 2018 at 10:00 AM, with the laboratory testing personnel, confirmed the assessment forms failed to include the direct observation of performance of instrument maintenance.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory testing personnel, the technical supervisor failed to include the test performance through blind testing or proficiency testing in the competency evaluations for tests performed on the I-Stat Point-of -Care (POC) device since the last survey on September 22, 2016. Findings: 1. A review of the personnel competency evaluations for 2017 revealed the assessments failed to include test performance through blind testing or proficiency testing for 21 out of 21 POC testing personnel. 2. An interview on August 14, 2018 at 10:00 AM, with the laboratory testing personnel, confirmed the assessment forms failed to include the test performance through blind testing or proficiency testing.