Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520606	04/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
St Luke's Anticoagulation Clinic Twin Falls	714 N College Rd, Twin Falls, 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
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 a review of patient test results, a document review, and an interview with the laboratory pharmacy supervisor, the laboratory failed to report patient International Normalized Ratio (INR) results within the established range of the i-STAT since the last validation in 2006. Findings: 1. A record review of the laboratory procedure manual for Protime/INR testing revealed the reportable range values of 0.9 to 8.0 and a reference footnote that stated the performance verification was not established for INR's greater than 6.0. 2. A record review of patient INR test result reported on April 17, 2019 revealed an INR reported at 7.12. 3. The laboratory performed approximately 9820 Protime/INR tests in 2018. 4. An interview on April 24, 2019 at 11:35 AM, with the laboratory pharmacy supervisor, confirmed the i-STAT was not validated to report INR results greater than 6.0 and that patient results were reported.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a record review, a policy review, and an interview with the laboratory Quality Coordinator, the laboratory director failed to specify in writing the delegation to sign attestation statements for proficiency testing (PT) through the College of American Pathologists (CAP) for 2018 and 2019. Findings: 1. A review of CAP proficiency testing records for Protimes revealed the laboratory director failed to sign attestations statements for all 3 events in 2018 and event 1 in 2019. 2. A review of the policy manual revealed the laboratory director failed to specify, in writing, the delegation to sign attestation statements to the Quality Coordinator. 3. An interview on April 24, 2019 at 10:15 AM, with the laboratory Quality Coordinator, confirmed the laboratory director failed to delegate in writing the responsibility to sign the attestation statements for the CAP PT program.