Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409236	06/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
St Lukes Hospital	702 1st St Sw, Crosby, ND	

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 record review, staff interview, and policy review, the laboratory failed to verify the precision for 3 of 3 new test methods (pO2 (partial pressure of oxygen), pCO2 (partial pressure of carbon dioxide), and pH (potential of hydrogen /measurement of acid-base balance)) on the epoc blood gas analyzer in June 2020 before reporting patient results. The laboratory performed approximately 54 patient pO2, pCO2, and pH tests on the epoc blood gas analyzer since implementation. Findings include: 1. Reviewed at 1:50 p.m. on 06/01/22, the laboratory's 2020 performance specification verification records for the epoc blood gas analyzer lacked evidence the laboratory verified the precision performance specifications for pO2, pCO2, and pH. Upon request the laboratory failed to provide evidence of precision verification for pO2, pCO2, and pH. 2. During interview at 2:15 p.m. on 06/01/22, the laboratory supervisor (#1) confirmed the laboratory began patient testing on the epoc blood gas analyzer for pO2, pCO2, and pH in January 2021, and the laboratory did not have evidence the laboratory director and/or technical consultant had verified the performance specifications for precision. 3. Reviewed at 2:30 p.m. on 06/01/22, the policy "Establishment and Verification of Performance Specifications," dated 09/26 /19, stated, "This Clinical Laboratory shall verify each new test, method, or instrument prior to reporting patient results. These verifications shall be documented. .

	. . Verification of Performance Specifications: Each laboratory that introduces an unmodified, FDA [Food and Drug Administration]-cleared or approved test system must do the following before reporting patient test results: Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: Accuracy Precision Reportable range of test results for the test system . . ."