

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0045928	(X3) Date Survey Completed 04/10/2019
Name of Provider or Supplier Saint Luke's North Hospital - Smikthville Campus	Street Address, City, State 601 South 169 Highway, Smithville, MO	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC), Individualized Quality Control Plan (IQCP) and interview with the laboratory director, the laboratory failed to include a risk assessment and an acceptable Quality Control Plan (QCP) with revised IQCP dated 10/23/18. Findings: 1. Review of IQCP for prothrombin time (PT) dated 10/23/18 showed a risk assessment that did not include identification and evaluation of potential failures and sources of errors in the testing system and a quality control plan that did not provide immediate detection of errors. 2. Review of IQCP for G3+ dated 10/23/18 showed a risk assessment that did not include identification and evaluation of potential failures and sources of errors in the testing system and a quality control plan that did not provide immediate detection of errors. 3. Review of IQCP for the G4+ cartridge dated 10/23/18 showed a risk assessment that did not include identification and evaluation of potential failures and sources of errors in the testing system and a quality control plan that did not provide immediate detection of errors. 4. Interview with the laboratory director on April 10, 2019 at 11:30 AM confirmed the laboratory failed to include an acceptable risk assessment and quality control plan for the PT, G3+ and G4+ IQCP's.</p>