Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0698063	01/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Baylor St Luke's Medical Group	310 Gaslight Boulevard, Lufkin, TX	

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	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's IQCP study for D-Dimer using the Quidel Triage MeterPro and confirmed in interview of laboratory personnel, the laboratory failed to have a complete IQCP study. The findings were: Note: An IQCP must include: - Risk Assessment (to include risks associated with specimen, test system, reagent, environment, and testing personnel) - Quality Control Plan - Quality Assessment (to include policies and procedures for the ongoing monitoring of the effectiveness of the IQCP) 1. Review of the laboratory's submitted IQCP for D-Dimer on the Quidel Triage MeterPro found no documentation of a complete risk assessment, quality control plan, or quality assessment. 2. The laboratory performed a 30 day quality control study, but failed to include a risk assessment, quality control plan, and quality assessment. 3. An interview with the primary testing person on January 25, 2022 at 10: 00 hours in the laboratory confirmed the findings. Key: IQCP - Individualized Quality Control Plan