Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450763	04/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
St Luke Hospital & Living Center	535 S Freeborn, Marion, KS	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, temperature monitoring records and interview, the laboratory failed to ensure that chemistry controls were stored at the required temperature. Findings: 1. A review of the manufacturer's instructions for Bio-Rad Liquichek Cardiac Markers Plus Control revealed that the proper unopened storage requirement was -20 degrees Celsius (C) to -70 degrees C. 2. A review of the temperature monitoring system records from 1/02/21 to 4/22/21 for the lab freezer showed temperatures recorded during this period failed to maintain consistent manufacturuer's required temperature. The period of daily temperatures reviewed for the freezer showed no dates when temperature was at the acceptable range to meet the manufacturer's requirements. Temperature log sheets listed an acceptable range of -14 C to -22 C. 3. Interview with General Supervisor (GS) 4/21/21 at 1 p.m. confirmed, the laboratory failed to ensure that chemistry controls were stored at the required temperature.