Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450763	03/29/2023
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
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and calibration records for Lactic Acid performed on the Siemens Dimension EXL chemistry analyzer from 1/15/23 to 1/16/23, lack of patient remediation documentation for Lactic patient results and interview with TC #1, the laboratory failed to evaluate patient test results since the last acceptable QC test run to determine if patient results had been adversely affected and may require corrective action. Findings: 1. Review of Lactic Acid QC records and Lactic Acid calibration records from the Siemens Dimension EXL revealed unacceptable QC values on 1/16/23. Repeat QC testing did not resolve the issue. The Lactic Acid assay required calibration in order to obtain acceptable QC values post calibration on 1/16/23 at 12:46 p.m. 3. Prior to the calibration listed in item #1, the last acceptable QC was obtained on 1/15/23 at 9:27 a.m. 4. No documentation to demonstrate Lactic Acid patient testing was not performed or results were evaluated for possible corrective action was provided at the time of survey. No corrective action documentation was present including notification to the provider and patients of results, and orientation/training for the performing test personnel was provided at the time of survey. 5. Review of patient test results revealed 2 Lactic Acid results were reported without evaluation for the unacceptable QC which required calibration to resolve. 6. Interview with TC #1 on 3/29/23 at 12:35 p.m. confirmed, the laboratory

	failed to evaluate Lactic Acid patient test results since the last acceptable test run to determine if patient results had been adversely affected and may require corrective action.