

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0648043	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier St Anthony Regional Hospital	Street Address, City, State 311 South Clark Street, Carroll, IA	
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	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 05/25/2022, the laboratory failed to take and document corrective action when Siemens Dimension chemistry QC fell outside the laboratory's established criteria for acceptability for 1 out of 31 days of patient testing (10/21/2021) in October 2021. The findings include: 1. The laboratory performs chemistry testing on two Siemens instruments identified as "DIMEXL 1234" and "DIMEXL 200". 2. Review of chemistry QC records revealed that the laboratory had out of control results without corrective action on 10/21/2021 for the following instruments and analytes: * DIMEXL 1234: Creatinine (level 1) * DIMEXL 1234: Aspartate aminotransferase (AST) (level 1) * DIMEXL 1234: Phosphorus (level 1) * DIMEXL 200: Magnesium (level 1) 3. At the time of the survey, personnel identifier #3 confirmed that the laboratory did not have documented corrective action for the out of control QC results listed above.</p>