Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648043	09/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
St Anthony Regional Hospital	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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of chemistry calibration verification records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 10:30 am on 09/10/2020, the laboratory failed to perform calibration verification every six months for one out of three time periods for the analytes: sodium, potassium and chloride from 1/1/2019 - 9/10/2020. The findings include: 1. On 4/26/2019 and 12/11/2019, the laboratory performed calibration verification for

	the analytes: sodium, potassium and chloride. 2. At the time of the survey, the laboratory did not have calibration verification records for the time period between 12 /12/2019 - 9/10/2020.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of arterial blood gas comparison records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:50 pm on 9/9/2020, the laboratory failed to perform arterial blood gas comparison activities twice annually between the two i-STAT instruments for two of three time periods from 1/1/2019 - 9/10/2020. The findings include: 1. The laboratory performed arterial blood gas testing using two different i-STAT instruments. 2. The laboratory perform comparison testing between the two instruments on 7/18/2019. 3. Laboratory personnel identifier #1 confirmed that is the only comparison testing performed between the two instruments from 1/1/2019 - 9/10 /2020.