Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648043	06/21/2018
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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of coagulation reagent verification records, observation of the CA1500 coagulation instrument, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 9:35 am on 06/21/2018, the laboratory fails to meet the hematology (coagulation) requirements for test system /equipment/reagent verification as specified in the standard D5411.
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 review of coagulation reagent verification records, observation of the CA1500 coagulation instrument, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 9:35 am on 06/21/2018, the laboratory failed to verify, for each thromboplastin lot number in use, the correct normal patient prothrombin time (PT) mean is being used for calculating the International Normalized Ratio (INR) value for one out of one lot number of

	thromboplastin reagent (lot number 539399, expiration 11/03/2019) in 2018. The findings include: 1. Reagent verification records from January and February 2018 indicated that the laboratory established a normal patient mean of 10.1 seconds for thromboplastin reagent lot number 539399, expiration 11/03/2019. 2. Observation of the coagulation analyzer's standard curve screen showed the normal patient mean programmed as 10.4 seconds. 3. Laboratory personnel identifier #3 confirmed that the laboratory began using thromboplastin reagent lot number 539399 on 02/17/2018 and that the actual normal patient mean was 10.1 seconds. 4. The laboratory did not have documentation verifying the correct normal patient PT mean was used for calculating the INR value for thromboplastin lot number 539399.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of performance specification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:40 am on 06/21/2018, the laboratory failed to verify the performance specifications of accuracy, precision, and reportable range for the Clinitek Advantus urinalysis test system prior to testing and reporting patient test results. The findings include: 1. The laboratory began using the Clinitek Advantus test system in September 2016. 2. At the time of the survey, the laboratory did not have performance specification records for this test system.
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 lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifiers #2 and #3 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 06/21/2018, the laboratory failed to perform two levels of QC each day of patient testing for the AVOXimeter 4000 test system. The findings include: 1. The laboratory performed optical filter QC with yellow and orange filters each day of patient testing. 2. The

	laboratory did not perform external liquid QC in addition to the optical filter QC. 3. Laboratory personnel identifiers #2 and #3 indicated that the laboratory intended to perform optical filter QC each day of patient testing. 3. At the time of the survey, the laboratory did not have an IQCP for the AVOXimeter 4000 test system.