Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648043	06/28/2024
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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 2:15 pm on 6/27 /2024, the laboratory failed to verify the accuracy of the non-graded PT analytes for three out of five events from 10/1/2022 - 6/28/2024. The findings include: 1. For 2023 event 1, the laboratory received non-graded PT results for the following analytes: alanine transaminase specimen CET -1; gentamicin specimen CET - 2; total iron binding capacity CET - 2; and antistreptolysin O specimens XS - 1, 2, 3, 4 & 5. 2. For 2023 event 2, the laboratory received non-graded PT results for the following analytes: high sensitivity C-reactive protein specimens IE - 6, 7, 8, 9 and 10; gamma-glutamyl transferase specimens CET - 6, 7, 8, 9 and 10; gentamicin specimens CET - 6, 7, 8, 9 and 10; cannabinoids specimen UD - 4; activated partial thromboplastin specimens CA - 6, 7, 8, 9 and 10; prothrombin time specimens CA - 6, 7, 8, 9 and 10; and antimicrobial susceptibility testing, rifampin specimen MC-14. 3. For 2023 event 3, the laboratory received non-graded PT results for the following analytes: activated partial thromboplastin specimens CA - 11, 12, 13, 14 and 15; fibrinogen specimens CA - 11, 12, 13, 14 and 15; and prothrombin time specimens CA - 11, 12, 13, 14 and 15. 4. At the time of the survey, the laboratory acknowledged the non-graded PT results but did not document verification of accuracy for the results.
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of quality controls records and review of the Testing for Blood Group Antigen procedure and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 10:06 am on 6/28/2024, the laboratory personnel failed to follow the blood group antigen control procedure for two out of two units of blood distributed on 6/13/2024. The findings include: 1. The Testing for Blood Group Antigen procedure stated, "Quality Control must be run once per day when blood group antigen typing is needed. Reagent red blood cells may be used directly from the vial. Positive Control - red blood cells known to possess the antigen. It should be heterozygous positive. Negative control - red blood cells known to lack the antigen." 2. On 6/13/2014, the laboratory performed antigen testing on units W037924148450 and W037924152068 of leukoreduced packed cells. 3. At the time of the survey, the laboratory did not have records of blood group antigen quality controls being performed on 6/13/2024 as outlined in the above procedure.
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 the laboratory analyzer test list and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 11:01 am on 6/28 /2024, the laboratory failed to perform comparison testing twice annually for the analytes SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus, and clostridium difficile for three out of three time periods from 1/1/2023 - 6/28/2024. The findings include: 1. The laboratory performed SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus, and clostridium difficile on the Cepheid analyzer. 2. The laboratory performed SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus, and clostridium difficile on the Biofire analyzer. 3. The laboratory performed clostridium difficile testing using the Techlab Toxin A/B Quick Check test kit. 4. At the time of the survey, the laboratory had not performed comparison testing for SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus performed between the Cepheid and Biofire analyzer. In addition, the laboratory had not performed comparison testing for clostridium difficile performed between the Cepheid, Biofire and Techlab Toxin A/B Quick Check test kit.