Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382531	09/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mary Greeley Medical Center	1111 Duff Avenue, Ames, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory test list, proficiency testing (PT) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 9/21/21, the laboratory failed to verify the accuracy twice annually for the analyte, Clostridium difficile (C. diff) - method Cepheid GeneXpert for two of of three time periods from 1/1/2020 - 9/21/2021. The findings include: 1. The laboratory test list indicated the laboratory performed C. diff testing using the Alere QuickChek Complete and the Cepheid GeneXpert. 2. Laboratory personnel identifier #2 indicated the laboratory used the Alere QuickChek Complete as the primary method for performing C. diff testing. 3. The laboratory enrolled in PT for the primary method of C. diff testing - Alere QuickChek Complete for 2020 and 2021. 4. The laboratory performed verification of accuracy for C. diff between the Alere QuickChek Complete and the Cepheid GeneXpert in November 2020. 5. At the time of the survey, the laboratory did not have any additional records verifying the accuracy of the analyte C. diff - method Cepheid GeneXpert.
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 studies, the STA Compact Max - PT Assay, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:15 pm on 9/21/2021, the laboratory failed to program the correct patient geometric mean into the Stago coagulation analyzer 6907 for one out of one lot number of coagulation reagent (lot number 256797, expiration date 1/31 /2022.) The findings include: 1. The laboratory had two Stago coagulation analyzers in use, analyzer 6096 and analyzer 6097. 2. The STA Compact Max - PT Assay procedure stated, "When PT-INR is reported, both the ISI and the geometric mean must be entered into the instrument for the INR calculation. With each new lot number of PT reagent (rollover), the geometric mean must be manually entered into the analyzer in order for the correct calculation of the INR." 3. The coagulation reagent studies for analyzer 6096 indicated the geometric mean as 13.5 for lot number 256797, expiration date 1/31/2022 of reagent. 4. The coagulation reagent studies for analyzer 6097 indicated the mean geometric mean as 13.4 for lot number 256797, expiration date 1/31/2022 of reagent. 5. At the time of the survey, the laboratory had the incorrect geometric mean of 13.5 programmed into analyzer 6097.