Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382978	(X3) Date Survey Completed 09/27/2022
Name of Provider or Supplier Story County Medical Center	**Street Address, City, State** 640 S 19th Street, Nevada, 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 records and observations of the coagulation analyzer and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 09/27/22, 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 studies, observations of the coagulation analzyer and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 9/27/22, the laboratory failed to establish a new normal patient mean and program the correct normal patient mean into the coagulation analyzer for lot number 564610, expiration date 01/20/2025 of prothrombin time reagent. The findings include: 1. The laboratory starting using lot

	number 564610, expiration date 1/20/2025 of prothrombin time reagent on 7/20/22. 2. At the time of the survey, the laboratory had a normal patient mean of 10.1 programmed into the coagulation analyzer. The laboratory had established a normal patient mean of 10.1 for a previous lot number of reagent (Lot 549788). 3. Laboratory personnel #1 confirmed that the laboratory had not established a normal patient mean for lot number 564610 of prothrombin time reagent.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of Ortho blood bank dispense maintenance records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 1:45 pm on 09/27/22, the laboratory failed to perform weekly Ortho blood bank dispenser checks weekly for ten out of 13 weeks from 4/1/2022 - 6/30 /2022. The findings include: 1. The Ortho blood bank dispenser maintenance log stated the laboratory must weekly clean the dispenser. 2. The laboratory performed the weekly dispenser cleaning on 4/5/2022, 5/3/2022, and 6/6/2022. 2. At the time of the survey, the laboratory did not have documentation of cleaning the dispenser for the week of 4/11/22, 4/18/22, 4/25/22, 5/9/22, 5/16/22, 5/23/22, 5/30/22, 6/13/22, 6/20/22 and 6/27/22.
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 chemistry records, the Laboratory Test List and Annual Volume report, and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 11:30 am on 09/27/2022, the laboratory failed to perform comparison evaluations for three out of three semiannual time periods from 1 /1/2021 - 9/27/2022 for the analytes: glucose, creatinine, blood urea nitrogen, sodium, potassium, and chloride. The findings include: 1. The laboratory performed the analytes: glucose, creatinine, blood urea nitrogen, sodium, potassium, and chloride on both the Dimension chemistry analyzer and the i-STAT analyzer. 2. At the time of the survey, the laboratory did not perform comparison evaluations between the Dimension chemistry analyzer and the i-STAT analyzer for the above listed analytes.