Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0387155	05/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Davis County Hospital	509 North Madison, Bloomfield, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 11:00 am on 05 /05/2021, the laboratory failed to enroll in an approved proficiency testing program for the analyte, rheumatoid factor for two out of two years. The laboratory did not enroll in an approved proficiency testing program in 2020 or 2021 for the analyte rheumatoid factor.
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, observations of the

	coagulation analyzer and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 5/5/2021, the laboratory fails to meet the hematology (coagulation) requirements for test system/equipment /reagent verification as specified in the standard D5411.
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 & Annual Volume report, proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 1:00 pm on 5/5/2021, the laboratory failed to verify the accuracy twice annually for the analyte, lactoferrin for 3 out of 3 time periods from 1/1/2020 - 5/5/2021. The findings include: 1. The Laboratory Test List & Annual Volume report indicated the laboratory performed lactoferrin testing. 2. At the time of the survey, the laboratory did not enroll in proficiency testing for the analyte lactoferrin. The laboratory did not have any additional records indicating the laboratory verified the accuracy twice annually for lactoferrin testing.
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, observations of the coagulation analyzer and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 5/5/2021, the laboratory failed to have the correct normal patient mean programmed into the ACL Elite coagulation analyzer for lot number N0998826, expiration date 09/2021 of prothrombin time reagent. The findings include: 1. The coagulations reagent verification records indicate the normal patient mean of 11.63 for lot number N0998826, expiration date 09/2021 of prothrombin time reagent. 2. At the time of the survey, the laboratory had the normal patient mean of 11.4 programmed into the ACL Elite coagulation analyzer.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of Clinical Laboratory Improvement Amendment (CLIA) application (Form CMS-116), patient test reports and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 12:30 pm on 05/05/2021, the laboratory failed to indicate the name and address of the testing facility for four out of 12 patient test reports from December 2020. The findings include: 1. Patient identifier A had mycoplasma testing performed on 12/15/20. 2. Patient identifier B had an erthrocyte sedimentation rate performed on 12/17/20. 3. Patient identifier C had a comprehensive chemistry panel performed on 12/17/20. 4. Patient identifier D had microalbumin testing performed on 12/18/20. 5. The CLIA application indicated the name and address of the facility as Davis County Hospital, 509 N Madison St, Bloomfield, IA, 52537. 6. The test report for the above four patients indicated the name and address of the testing facility as Davis County Medical Associates, 509 N Madison St, Suite 100, Bloomfield, IA, 52537.