Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0387155	01/16/2019
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 (PT) records, the Laboratory Test List & Volume form, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 01/16/2019, the laboratory failed to enroll in an approved proficiency testing program for one out of one year (2018) for the analytes: immunoglobulin A (IgA), immunoglobulin G (IgG), immunoglobulin M (IgM), rheumatoid factor (RF), complement C3, and complement C4. The findings include: 1. The Laboratory Test List & Annual Volume form included the analytes, IgA, IgG, IgM, RF, complement C3, and complement C4. 2. The laboratory installed and began using a new chemistry analyzer (Beckman Coulter AU480) in December 2017. 3. Personnel identifier #3 stated that the laboratory forgot to enroll in PT after the new install and did not perform PT for the analytes, IgA, IgG, IgM, RF, complement C3, and complement C4. 4. At the time of the survey, personnel identifier #3 confirmed that the laboratory did not enroll in PT testing in 2018 for the following analytes: IgA, IgG, IgM, RF, complement C3, and complement C4.
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) records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 11: 00 am on 01/16/2019, the laboratory failed to perform a self evaluation of ungraded PT scores for four out of six PT testing events in 2017 and 2018 (2017 events 1 and 2 and 2018 events 2 and 3). The findings include: 1. For 2017 testing event 1, the laboratory received ungraded PT test scores for the following: *2017 Chemistry Core 1st event- triglycerides (specimen CH-01) and free thyroxine (specimen CH-01) 2. For 2017 testing event 2, the laboratory received ungraded PT test scores for the following: *2017 Microbiology 2nd event- campylobacter (specimen CPL-03) 3. For 2018 testing event 2, the laboratory received ungraded PT test scores for the following: *2018 Hematology and Coagulation 2nd event- blood cell identification (specimen BCL-10) and partial thromboplastin time (specimen COA-07) *2018 Microbiology 2nd event- blood culture (specimen BL-01) and minimum inhibitory concentration testing/piperacillin/tazobactam (specimen UR-06) 4. For 2018 testing event 3, the laboratory received ungraded PT test scores for the following: *2018 Hematology and Coagulation 3rd event- partial thromboplastin time (specimen COA-12) 5. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores.
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 form, proficiency testing (PT) records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 01/16/2019, the laboratory failed to verify the accuracy of the analytes, thyroid peroxidase antibodies (TPO) and vitamin D, at least twice annually for two out of two time periods from December 2017- December 2018. The findings include: 1. The Laboratory Test List & Annual Volume form included the analytes, TPO and vitamin D. 2. The laboratory installed and began using a new chemistry analyzer (Beckman Coulter Access II) in December 2017. 3. Personnel identifier #3 stated that the laboratory forgot to enroll in PT after the new install and did not perform PT for the analytes, TPO and vitamin D, from December 2017- December 2018. 4. At the time of the survey, the laboratory did not have additional records indicating the verification of accuracy for the analytes, TPO and vitamin D.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

	All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 11: 00 am on 01/16/2019, the laboratory failed to take and document corrective action for 20 unacceptable PT scores from five out of six PT testing events (2017 events 1 and 3 and 2018 events 1, 2, and 3) in 2017-2018. The findings include: 1. For 2017 testing event 1, the laboratory received unacceptable PT test scores for the following: *2017 Chemistry Core 1st event- free triiodothyronine (specimen CH-05) *2017 Hematology and Coagulation 1st event- blood cell identification (specimen BCL-03); hemoglobin (specimen XE-04); and vaginal wet prep (specimen VA-01) *2017 Microbiology 1st event- gram stain morphology (specimen GS-03) and wound culture, anaerobic (specimen WO-01) 2. For 2017 testing event 3, the laboratory received unacceptable PT test scores for the following: *2017 Chemistry Core 3rd event- N-terminal pro B-type natriuretic peptide (specimen CM-11) *2017 Hematology and Coagulation 3rd event- blood cell identification (specimen BCL-18) *2017 Microbiology 3rd event- gram stain morphology (specimen GS-14); sputum culture (specimen SP-02); and minimum inhibitory concentration testing/amikacin (specimen UR-11) 3. For 2018 testing event 1, the laboratory received unacceptable PT scores for the following: *2018 Microbiology 1st event- gram stain (specimen GS-05) and throat culture (specimen TC-01) 4. For 2018 testing event 2, the laboratory received unacceptable PT test scores for the following: *2018 Chemistry Core 2nd event- partial pressure of oxygen (specimen IB-06) *2018 Microbiology 2nd event- gram stain (specimen GS-09); gram stain morphology (specimen GS-10); and sputum culture (specimen SP-01) 5. For 2018 testing event 3, the laboratory received unacceptable PT test scores for the following: *2018 Chemistry Core 3rd event- free triiodothyronine (specimen CH-13) and partial pressure of oxygen (specimen IB-12) *2018 Microbiology 3rd event- wound culture, aerobic (specimen WO-02) 5. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores.