Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0387155	01/26/2023
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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration records, lack of calibration verification records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 01/26/2023, the laboratory failed to perform and document calibration verification every 6 months for D-dimer testing for one out of two time periods from 03/21/2022- 01/26/2023. The findings include: 1. The laboratory calibrated and began using a new lot number of Innovance D-dimer reagent

	(lot 568816, expiration 06/20/2023) for patient testing on 03/21/2022. 2. At the time of the survey, the laboratory did not have additional calibration or calibration verification records for D-dimer reagent lot number 568816, expiration 06/20/2023.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of antimicrobial susceptibility testing (AST) quality control (QC) records, the laboratory's AST Individualized Quality Control Plan (IQCP), and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 12:15 pm on 01/26/2023, the laboratory failed to perform one out of five QC organisms for gram positive AST QC for one out of four weeks in July 2022. The findings include: 1. The laboratory's written IQCP stated that the following QC organisms would be performed weekly for gram positive panels: Staphylococcus aureus 29213, Enterococcus faecalis 29212, Escherichia coli 35218, Staphylococcus aureus BAA-977, and Staphylococcus aureus 43300. 2. The laboratory performed gram positive AST QC testing on 07/03/2022, 07/12/2022, 07/17/2022, and 07/24/2022. 3. On 07/12/2022, the laboratory had gram positive AST QC records for the organisms, Staphylococcus aureus 29213, Enterococcus faecalis 29212, Staphylococcus aureus BAA-977, and Staphylococcus aureus 43300. 4. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have AST QC records for the organism, Escherichia coli 35218, from 07/12/2022.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of MicroScan quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 12:15 pm on 01/26/2023, the laboratory failed to take and document corrective action when gram negative QC failed to meet the laboratory's established criteria for acceptability for two out of ten QC organisms and one out of one new lot of MicroScan gram negative panels (lot 2023-06-07). The findings include: 1. The

	laboratory used the following organisms to perform QC on lot 2023-06-07 of MicroScan gram negative panels: Pseudomonas aeruginosa 27853, Klebsiella pneumoniae 700603, Escherichia coli 25922, Escherichia coli 35218, Klebsiella oxytoca 49131, Proteus vulgaris 49132, Pseudomonas putida 49128, Shewanella haliotis 49138, Ralstonia insidiosa 49129, and Providencia stuartii 49809. 2. On 07/24 /2022, the laboratory had the following out of range biochemical QC result for organism Ralstonia insidiosa 49129: *Tobramycin (TO4): negative 2. On 07/24/2022, the laboratory had the following out of range biochemical QC result for organism Pseudomonas aeruginosa 27853: *Colistin (CL4): positive 4. At the time of the survey, the laboratory did not have documentation of corrective action for the out of range QC.