Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382810	04/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ellsworth Municipal Hospital	920 South Oak Street, Iowa Falls, 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 reagent studies, observations of the ACL Top 350 coagulation analyzer, and confirmed by interview with General Supervisor #1 (GS #1) at 2:48 pm on 04/24/2026, the laboratory failed to meet the hematology (coagulation) requirements for test system/equipment/reagent verification as specified in the standard D5411.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, personnel records, and confirmed by interview with General Supervisor #1 (GS #1) at 8:30 am on 04/24 /2026, the laboratory failed to follow written policies and procedures for assessing competency for 3 out of 13 testing personnel (TP #7, TP #12, and TP #13) in 2024 and 2025. The findings include: 1. The laboratory's Ancillary Testing policy stated that the laboratory director will document training, authorization and annual competency evaluation for all personnel performing ancillary testing. 2. Review of

	personnel records for TP #7, TP #12, and TP #13 did not include documentation of competency assessment performance for 2024 and 2025. 3. At the time of the survey, GS #1 confirmed the laboratory failed to assess and document annual competency for TP #7, TP #12, and TP #13 in 2024 and 2025.
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 American Proficiency Institute (API) proficiency testing (PT) records and confirmed by interview with General Supervisor #1 (GS #1) at 9:30 am on 04/24/2026, the laboratory failed to perform and document a self evaluation when the laboratory received 13 ungraded PT scores from three out of seven PT testing events from 01/01/2024- 04/24/2026. The findings include: 1. For 2025 testing event 2, the laboratory received ungraded PT test scores for the following: *2025 Chemistry Core- B-type natriuretic peptide (BNP) (specimen CM-07); total bilirubin (specimens CH-07, CH-09, and CH-10); and folate (specimens IA-07 and IA-09) *2025 Microbiology- mycoplasma pnemoniae (specimen MPM-04) 2. For 2025 testing event 3, the laboratory received ungraded PT test scores for the following: *2025 Chemistry Core- BNP (specimen CM-15) and total bilirubin (specimens CH-12 and CH-15) *2025 Hematology/Coagulation- blood cell identification (BCI-15) 3. For 2026 testing event 1, the laboratory received ungraded PT test scores for the following: *2026 Chemistry Core- total bilirubin (specimen CH-05) *2026 Microbiology- gram stain morphology (specimen GS-04) 4. At the time of the survey, GS #1 confirmed the laboratory failed to perform and document a self evaluation for the ungraded PT test scores listed above.
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 American Proficiency Institute (API) proficiency testing (PT) records and confirmed by interview with General Supervisor #1 (GS #1) at 9:30 am on 04/24/2026, the laboratory failed to take and document corrective action for 10 unacceptable PT scores from three out of seven PT testing events from 01/01/2024- 04 /24/2026. The findings include: 1. For 2024 testing event 3, the laboratory received unacceptable PT test scores for the following: *2024 Chemistry Core- phosphorus (specimen Ch-14) 2. For 2025 testing event 2, the laboratory received unacceptable PT test scores for the following: *2025 Chemistry Core- alcohol (specimen ALC-06) 3. For 2026 testing event 1, the laboratory received unacceptable PT test scores for the following: *2026 Chemistry Core- partial pressure of oxygen (PO2) (specimen BG-03); carbon dioxide (specimen CH-01); total iron (specimen CH-02); triglycerides (specimen CH-03); digoxin (specimen CH-05); and vancomycin (specimen CH-01)

	*2026 Microbiology- gram stain (GS-05) and urine culture susceptibility MIC testing for erythromycin (specimen UR-02) 4. At the time of the survey, GS #1 confirmed the laboratory did not take and document corrective action for the unacceptable PT test scores listed above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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, observations of the ACL Top 350 coagulation analyzer, and confirmed by interview with General Supervisor #1 (GS #1) at 2:48 pm on 04/24/2026, the laboratory failed to program the correct normal patient mean into the coagulation instrument for one out of one lot number of prothrombin time reagent (lot number N0653515, expiration 06/30/2027). The findings include: 1. The laboratory began using prothrombin time reagent lot number N0653515 (expiration 06/30/2027) for patient testing on 02/26/2026. 2. Review of the coagulation reagent verification records for prothrombin time reagent lot number N0653515 indicated that the laboratory established a normal patient mean of 11.9 seconds. 3. Observation of the coagulation instrument showed that the laboratory programmed a normal patient mean of 13.1 seconds in for prothrombin time reagent lot number N0653515. 4. At the time of the survey, GS #1 confirmed that the laboratory failed to program the correct normal patient mean into the coagulation instrument for prothrombin time reagent lot number N0653515 (expiration 06/30 /2027).
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 the laboratory's microbiology quality control policy, antimicrobial susceptibility testing (AST) Individualized Quality Control Plan (IQCP), AST quality control (QC) records, and confirmed by interview with General Supervisor #1 (GS #1) at 2:45 pm on 04/24/2026, the laboratory failed to perform weekly gram positive and streptococcus AST QC for one out of five weeks in December 2025. The findings include: 1. The laboratory performs AST testing on a BioMerieux Vitek instrument. 2. The laboratory's microbiology QC procedure and AST IQCP stated AST QC would be performed once weekly and with each new lot and/or shipment of gram positive

	and streptococcus susceptibility cards. 3. The laboratory performs weekly AST QC on Monday of each week and included 12/01/2025, 12/08/2025, 12/15/2025, 12/22/2025, and 12/29/2025 for the month of December 2025. 4. Review of weekly AST QC documentation revealed no QC records from 12/01/2025 for gram positive AST-GP67 susceptibility cards (Lot 1323316503, expiration 12/25/2026) or streptococcus AST-ST02 susceptibility cards (lot 5413260503, expiration 10/30/2026). 5. At the time of the survey, GS #1 confirmed that the laboratory failed to perform weekly gram positive and streptococcus AST QC on 12/01/2025. In addition, the laboratory did not perform weekly gram positive and streptococcus AST QC at any other time during the week of 12/01/2025.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's immunohematology policies, blood bank system alarm check records, and confirmed by interview with General Supervisor (GS) #1 at 1:30 pm on 04/24/2026, the laboratory failed to inspect, perform, and document quarterly blood bank refrigerator and plasma freezer alarm system checks for three out of nine time periods from 01/01/2024- 04/24/2026. The findings include: 1. The laboratory's Quarterly Temperature Alarms policy stated that the alarms for the blood bank refrigerator and plasma freezer would be checked quarterly. 2. The blood bank refrigerator and plasma freezer alarm check records showed no documentation of alarm checks performed during the 3rd quarter of 2024, the 3rd quarter of 2025, or the first quarter of 2026. 3. At the time of the survey, GS #1 confirmed the laboratory failed to perform quarterly blood bank refrigerator and plasma freezer alarm checks during the 3rd quarter of 2024, the 3rd quarter of 2025, and the first quarter of 2026.