Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382617	02/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Audubon County Memorial Hospital	515 Pacific Avenue, Audubon, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the hematology and blood gas instrument operator's manuals and confirmed by interview with General Supervisor #1 (GS #1) at 1:00 pm on 02/27 /2025, the laboratory director failed to approve, sign, and date all laboratory policies and procedures. The findings include: 1. The laboratory used the Sysmex XN-450 test system to perform hematology testing and the Opti CCA- TS2 test system to perform blood gas testing. 2. The laboratory intended to use the electronic operator's manuals as the procedure manual for both test systems. 3. At the time of the survey, GS #1 confirmed the laboratory director did not approve, sign, or date the Sysmex XN-450 or Opti CCA-TS2 operator's manuals.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the 2024 September maintenance checklist, the laboratory's blood

	bank policy and procedure manual, and confirmed by interview with General Supervisor #1 (GS #1) at 12:00 pm on 02/27/2025, the laboratory failed to document monthly blood bank dispenser volume checks for one out of three months reviewed from August 2024- October 2024. The findings include: 1. The laboratory used an Ortho MTS saline dispenser to perform immunohematology testing. 2. The 2024 September maintenance checklist indicated that blood bank dispenser volume checks would be performed monthly. 3. At the time of the survey, GS #1 confirmed the laboratory did not document monthly blood bank dispenser volume checks in September 2024. In addition, GS #1 confirmed the laboratory did not have a written policy/procedure for performing blood bank dispenser volume checks. This is a repeat deficiency previously cited on 03/22/2023.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports, PolyMedco Sedimat 15 instrument printouts, and confirmed by interview with general supervisor identifier #1 (GS #1) at 12:25 pm on 02/27/2025, the laboratory failed to have a system in place to ensure the accuracy and reliability of erythrocyte sedimentation rate (ESR) test results manually transcribed into the laboratory's electronic health record (EHR) for one out of one patient test report reviewed from February 2025. The findings include: 1. Patient A had ESR testing performed on 02/19/2025. 2. Patient A's EHR record recorded the test result as 8 mm/hr. 3. Review of patient A's PolyMedco Sedimat 15 instrument printout showed the result to be 5 mm/hr. 4. At the time of the survey, GS #1 confirmed patient A's EHR record did not include the correct test result. In addition, GS #1 confirmed the laboratory did not have a system in place to ensure the accurate and reliable transcription of manual test results into the EHR.