Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0647988	08/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Grundy County Memorial Hospital	201 East J Avenue, Grundy Center, 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
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 laboratory's blood bank logs and records and confirmed by Technical Supervisor #1 (TS #1) at 2:30 pm on 08/28/2025, the laboratory failed to perform and document volume checks on the Ortho MTS saline dispenser from 01/01 /2024- 08/28/2025. In addition, the laboratory did not have a policy/procedure for performing and documenting Ortho MTS saline dispenser volume checks that included the frequency with which they must be performed. The findings include: 1. The laboratory uses an Ortho MTS saline dispenser to perform immunohematology procedures. 3. At the time of the survey, TS #1 confirmed the laboratory did not document Ortho MTS saline dispenser checks from 01/01/2024- 08/28/2025. In addition, TS #1 confirmed the laboratory did not have a policy/procedure for performing and documenting Ortho MTS saline dispenser volume checks that included the frequency with which they must be performed
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless

	otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on the laboratory's Individualized Quality Control Plan (IQCP), observations made during the survey, lack of quality control (QC) records, and confirmed by interview with Technical Supervisor #1 (TS #1) at 1:30 pm on 08/28/2025, the laboratory failed to perform a positive and negative control in accordance with its IQCP for the C. Diff Quik Chek Complete test kit for one out of one lot number (lot 824035, expiration 07/01/2026). The findings include: 1. Review of the laboratory's IQCP indicated that the laboratory intended to perform QC with each new lot and shipment of C. Diff Quik Chek Complete test kits and monthly. 2. Observations made during the survey indicated the laboratory had in use one C. Diff Quik Chek Complete test kit (lot 824035, expiration 07/01/2026). The laboratory wrote on the outside of the box "Received 12/11/2024". The laboratory did not document the date on which it began using the kit. 3. At the time of the survey, TS #1 confirmed the laboratory did not know when it began using lot 824035 (expiration 07/01/2026) of the C. Diff Quik Chek Complete test kit it had in use nor did it document performance of QC according to its IQCP.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (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 policies and procedures, lack of plasma freezer alarm check records, and confirmed by interview with Technical Supervisor #1 (TS #1) at 2:30 pm on 08/28/2025, the laboratory failed to inspect, perform, and document alarm system checks for the plasma storage freezer from 01/01/2024- 08/28/2025. In addition, the laboratory did not have a policy/procedure for performing and documenting alarm system checks that included the frequency with which they must be performed. The findings include: 1. The laboratory stored fresh frozen plasma units in the laboratory's Helmer freezer. 2. At the time of the survey, TS #1 confirmed that the laboratory did not perform alarm checks on the plasma storage freezer from 01/01 /2024- 08/28/2025. In addition, TS #1 confirmed that the laboratory did not have a policy/procedure for performing and documenting alarm system checks that included the frequency with which they must be performed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test

	methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, personnel records, and confirmed by interview with Technical Supervisor #1 (TS #1) at 9:50 am on 08/28 /2025, the technical supervisor failed to assess and document the competency of individuals performing high complexity testing at least annually for nine out of nine testing personnel in 2023 and 2024. The findings include: 1. The CMS-209 Laboratory Personnel Report listed testing personnel (TP) #1- #9 as performing high complexity testing. 2. At the time of the survey, TS #1 confirmed TP #1- #9 did not have annual competency assessments performed and documented for high complexity testing in 2023 or 2024.