Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0701400	08/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Minidoka Memorial Hospital	1224 8th St, Rupert, ID	

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
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 a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, competency assessment records and an interview with the technical supervisor (TS) on 7/31/2024, the laboratory failed to follow written policies and procedures to assess testing personnel in 2023 and 2024. The findings include: 1. A review of the CMS 209 form identified 25 testing personnel and five (5) new since the previous inspection (7/29/2022). 2. A review of competency assessment records identified the laboratory failed to have documentation of annual competency for 10 testing personnel in 2023. 3. A review of competency assessment records identified the laboratory failed to have adequate documentation of six month competency assessments for three (3) testing personnel. 4. An interview with the TS on 7/31/2024 at 1:10 pm confirmed the above findings. 5. The laboratory reports performing 285,422 tests annually. 6. This is a repeat deficiency from a previous inspection completed on 3/30/2021.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the Quality Control (QC) records, patient logs and an interview with the technical supervisor (TS) on 7/31/2024 and general supervisor (GS) on 8/1 /2024, the laboratory failed to successfully perform two levels of QC each day of use on the Curion and the Sysmex CA-660. The findings include: 1. A review of QC documents and patient log from the Curion for Helicobacter pylori testing (HpSA) for 2024 identified that the laboratory failed to perform negative and positive QC on 8/10 /2024. The laboratory performed HpSA tests on two (2) patient samples on 8/10/2024. 2. A random review of QC documents and corresponding patient results for the Sysmex CA-600 for 2022, 2023 and 2024 identified that the laboratory failed to document QC results for level 3 for prothrombin time (PT) test / INR testing on 10/4 /2023. The laboratory performed four (4) patient PT/ INR tests on 10/4/2023. 3. An interview with the TS on 7/31/2024 at 11:40 am confirmed the HpSA findings and an interview with the GS on 8/1/2024 at 8:00 am confirmed the PT/ INR finding. 4. The laboratory reports performing 10 HpSA tests and 1,184 PT/ INR tests annually.
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. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of temperature logs and an interview with the laboratory manager on 8/1/2024, the laboratory failed to perform alarm checks on the immunohematology refrigerator and freezer in 2023 and 2024. The findings include: 1. A review of laboratory temperature logs identified that the laboratory failed to perform alarm checks on the immunohematology refrigerator and freezer temperature monitoring system (SmartSense) in 2023 and 2024. 2. An interview with the laboratory manager on 8/1/2024 at 1:20 pm confirmed the above finding. 3. The laboratory reports performing 102 immunohematology tests annually.