Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0701400	03/30/2021
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 training documentation, competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview on 3/29/2021 with the laboratory manager, the laboratory failed to establish and follow written policies and procedures to assess testing personnel in accordance with 42 C.F.R. 493.1451(b)(7)(8). The findings include: 1. A review of training and competency records identified that the laboratory failed to have documentation of initial training for the Nova Biomedical blood gas instrument for sixteen (16) of twenty-six (26) testing personnel listed on the CMS 209. 2. A review of training and competency records identified that the laboratory failed to have annual competency assessments for 2020 for one (1) of twenty-six (26) testing personnel listed on the CMS 209. 3. An interview with the laboratory manager on 3/29/2021 at 4:07 pm confirmed the above findings. 4. This is a repeat deficiency from the previous survey performed on 8/13/2018.
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 a record review of proficiency testing (PT) from College of American

	Pathologists (CAP) and American Association of Bioanalysts (AAB) and an interview with the laboratory manger on 3/30/2021, the laboratory failed to review PT and document corrective action taken for all unsatisfactory scores. The findings include: 1. A review of PT records from CAP for 2019 event one identified that the laboratory failed to evaluate results for Bacteria ID- Stool specimen D-04 with unacceptable scores. 2. A review of PT records from CAP for 2019 event two identified that the laboratory failed to evaluate results for Bacteria ID specimens D-08 and D-11 with unacceptable scores. 3. A review of PT records from CAP for 2019 event three identified that the laboratory failed to evaluate results for Creatine Kinase samples CHM-11, CHM-13, CHM-15 with unacceptable scores. 4. A review of PT records from CAP for 2020 event three identified that the laboratory failed to evaluate results for Carbon Dioxide (CO2) samples CHM-11, CHM-12, CHM-13,CHM-14 and CHM-15 with unacceptable scores. 5. A review of PT records from AAB for 2020 event three identified that the laboratory failed to evaluate results for Blood Cell Identification samples with unacceptable scores. 6. An interview with the laboratory manager on 3/30/2021 at 8:30 am confirmed the above findings. 7. The laboratory reports performing 251,512 tests annually. 8. This is a repeat deficiency from the previous survey performed on 8/13/2018.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a random review of the maintenance logs and interview with technical supervisors (TS) on 3/29/2021, the laboratory failed to perform and document maintenance with the frequency defined by the instrument manufacturers. The findings include: 1. A random review of the laboratory maintenance logs for the Beckman Coulter MicroScan WalkAway identified that the laboratory failed to perform and document maintenance as required by the instrument manufacturer. Daily maintenance was not documented 22 of 31 days in July 2020, 10 of 30 in November 2020 and 10 of 31 days in December 2020. Weekly maintenance was not documented 3 of 4 weeks in July 2020, 3 of 4 weeks in November 2020 and 2 of 4 weeks in December 2020. Monthly maintenance was not documented in July 2020 and November 2020. 2. A random review of the laboratory maintenance logs for the Horiba ABX Pentra XLR identified that the laboratory failed to perform and document maintenance as required by the instrument manufacturer. Daily maintenance was not documented 17 of 30 days in September 2019, 5 of 31 days in October 2020 and 12 of 30 days in November 2020. Weekly maintenance was not documented 1 week in October 2020 and 1 week in November 2020. 3. An interview with the microbiology TS on 3/29/2021 at 9:45 am confirmed that maintenance had not been documented for the Beckman Coulter MicroScan WalkAway for the above dates. An interview with the hematology TS on 3/29/2021 at 3:40 confirmed that maintenance had not been documented for the Horiba ABX Pentra XLR for the above days. 4. The laboratory performed 70 bacterial identification and antimicrobial susceptibility tests in July 2020, 42 in November 2020 and 43 in December 2020. The laboratory performed 267 complete blood counts on the Horiba ABX Pentra XLR in September 2019, 324 in October 2020 and 275 in November 2020.

D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random review of immunohematology quality control (QC) records and an interview with the laboratory manager on 3/30/2021, the laboratory failed to document control material results with graded or titered reactivity and include negative control material. The findings include: 1. A random record review of immunohematology QC for 2019 and 2020 identified that the laboratory failed to document QC with a graded or titered reactivity and a negative control. On 12/18/19, 2 /4/2020, 5/7/2020, 6/23/2020, 8/5/2020, 8/27/2020 and 8/30/2020, the laboratory failed to document positive QC (1-4+) and negative QC as required by regulation and the laboratory QC record form for buffered gel cards using Affirmagen red blood cell QC. 2. A random record review of immunohematology QC for 2019 and 2020 identified that the laboratory failed to document QC for all immunohematology reagents on 12/30/2019. 3. The laboratory performed an ABO Rh test for each of the following days: 12/30/2019 and 5/7/2020. One type and crossmatch was performed on the following days: 2/4/2020, 5/7/2020, 6/23/2020, 8/5/2020, 8/27/2020, and 8/30 /2020. 4. An interview with the laboratory manager on 3/30/2021 at 10:00 am confirmed that the laboratory failed to document immunohematology QC on the above dates. 5. The laboratory reports performing 179 immunohematology tests annually.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review of instrument verifications and an interview with the Technical Supervisor (TS) on 3/29/2021, the Laboratory Director (LD) failed to ensure that verification procedures that were used for verification of Heparin Anti-Xa were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method before beginning patient testing. The findings include: 1. A record review of the Heparin Anti-Xa verification performed on the Sysmex CA-600 in June 2020, identified that the Laboratory Director failed to approve verification of performance before implementation of patient testing. 2. An interview with the TS on 3/29/2021 at 2:30 pm confirmed that the LD failed to review and sign the verification before beginning patient testing.