Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0701400	08/13/2018
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 record review of personnel documents and an interview with the laboratory supervisor, the laboratory failed to follow their policy to assess to perform competency on the testing personnel during 2017. Findings: 1. A review of personnel competency assessment documents and the laboratory policy, revealed the laboratory supervisor or technical supervisor failed to perform and document competency assessments for 9 out of 9 personnel listed on the CMS-209 Personnel Report form. 2. An interview on August 13, 2018 at 8:45 AM, with the laboratory supervisor, confirmed the laboratory failed to perform and document competency assessments for the testing personnel and consultants for the laboratory.
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 record reviews and an interview with the laboratory supervisor, the laboratory failed to document the evaluations and corrective actions for proficiency testing (PT) through American Association of Bioanalysts (AAB) from the time reviewed between 2017 event 3 and 2018 event 2. Findings: 1. A PT record review from AAB revealed the laboratory failed to evaluate and correct problems for an

	unsatisfactory score for valproic acid during event 1 for 2018, and an unsatisfactory score for basophils for event 3 in 2017. 2. A PT record review from AAB revealed the laboratory failed to evaluate and correct problems for unacceptable responses for cerebral spinal fluid counts, parathyroid hormone, and minimum inhibitory concentration interpretation for event 1 of 2018. 3. An interview on August 13, 2018, at 9:15 AM, with the laboratory supervisor, confirmed reviews and corrective actions failed to be taken during evaluations of proficiency testing.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on an observation, a record review, and an interview with the laboratory supervisor, the laboratory failed to perform a positive and a negative control reaction for each substrate on the Microscan positive and negative identification system. Findings: 1. An observation of the laboratory on August 13, 2018 at 3:15 PM, revealed a Microscan system in use for gram-positive and gram-negative bacterial identification tests. 2. A quality control record review from Positive Combo 33 panels revealed the following biochemical reactions were missing a positive and negative reaction: ARA and OPT. 3. A quality control record review from Negative Combo 34 panels revealed the following biochemical reactions were missing a positive and negative reaction: CL4, H2S, NIT, OF/G, P4, TDA, and VP. 4. An interview on August 13, 2018, at 5:45 PM, with the laboratory supervisor, confirmed the control organisms failed to check each positive and negative reaction and the laboratory did not write an IQCP.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 an observation, record reviews, and an interview with the laboratory supervisor, the laboratory failed to perform compatibility testing to detect IgM

	antibodies using the Ortho Workstation since the last survey on October 5, 2016. Findings: 1. An observation on August 13, 2018 at 2:45 PM revealed the laboratory performed immunohematology tests on the Ortho Workstation. 2. A review of quality control records revealed the laboratory failed to perform an immediate spin crossmatch for the detection of IgM antibodies for ABO incompatibilities. 3. An interview on August 13, 2018, at 2:55 PM, with the laboratory supervisor, confirmed the laboratory failed to perform an immediate spin to demonstrate ABO incompatibilities.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a record review of personnel documents and an interview with the laboratory supervisor, the laboratory failed to perform competency assessments at least semiannually during the first year of employment for new testing personnel since the last survey on October 5, 2016. Findings: 1. A review of personnel competency assessment documents, revealed the laboratory supervisor or technical supervisor failed to perform and document semiannual competency assessments for 3 out of 9 personnel listed on the CMS-209 Personnel Report form. 2. An interview on August 13, 2018 at 8:45 AM, with the laboratory supervisor, confirmed the laboratory failed to perform and document semiannual competency assessments for the testing personnel.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)

	(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on personnel record review and an interview with the laboratory supervisor, the laboratory failed to ensure the high-complexity testing personnel were qualified to perform complete blood count (CBC) atypical cell identification since the last survey on October 5, 2016. Findings: 1. A record review of personnel diplomas, revealed 1 out 9 testing personnel failed to meet the qualifications for performing abnormal manual differential since the last survey. 2. An interview on August 13, 2018, at 8:45 AM, with the laboratory supervisor, confirmed that the 1 testing personnel failed to meet the personnel qualifications for performing high-complexity testing.