Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0522232	04/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Shoshone Medical Center	25 Jacobs Gulch Rd, Kellogg, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on an observation, a record review, and an interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions to calculate the mean normal patient Prothrombin time (MNPT) and enter the new international sensitivity index (ISI) for one new lot of Innovin in use since November 2018. Findings: 1. On April 2, 2019 at 10:10 AM, an observation of the laboratory revealed a Siemens CA-660 coagulation analyzer. 2. On April 2, 2019 at 10:10 AM, an observation of the analyzer settings revealed an Innovin lot number 549701 with an ISI of 1.03 and MNPT of 10.0. The lot of Innovin in use was 549709 with the manufacturer's stated ISI of 1.01. 3. A review of the laboratory's procedure for Prothrombin time (PT) revealed no instruction on how to perform the MNPT or change the ISI information in the analyzer as needed to calculate the international normalized ratio (INR). 4. The laboratory performed approximately 1040 PT tests in 2018. 5. An interview on April 2, 2019 at 10:20 AM, with the laboratory manager, confirmed the laboratory failed to update the CA-660 with the correct lot of Innovin, ISI value, and MNPT.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to perform and document calibration verification procedures for blood alcohol, chloride, and D-dimer analytes since the last survey on March 1, 2017. Findings: 1. A review of calibration documents revealed the laboratory failed to perform and document calibration verification procedures for blood alcohol and chloride performed on the Vitros 4600 chemistry analyzer and D-dimer performed on the Siemens CA-660 coagulation analyzer since the last survey. 2. The laboratory performed approximately 4600 chloride, 250 alcohol, and 230 D-dimer tests in 2018. 3. An interview on April 2, 2019 at 10:45 AM, with the laboratory manager, confirmed the laboratory failed to perform calibration verification procedures for the analytes.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on a record review and an interview with the laboratory manager, the laboratory failed to perform quality control each day of patient testing or establish an Individualized Quality Control Plan (IQCP) for the Meridian test kit for Clostrium difficile (C. difficile) and carboxyhemoglobin and methemoglobin performed on the A-Vox system. B. Based on a record review and an interview with the laboratory manager, the laboratory failed to establish a Quality Control Plan (QCP) and a Quality Assessment Plan (QAP) as part of the laboratory's Individualized Quality Control Plan

	(IQCP) for kit tests: human immunodeficiency virus (HIV), human chorionic gonadotropin (hCG), and infectious mononucleosis, as well as, creatine kinase MB (CK-MB), troponin, and proB-natriuretic peptide (BNP) performed on the Triage Alere and blood gases performed on the iStat since the last survey on March 1, 2017. Findings: 1. A record review of procedures revealed the laboratory failed to perform quality control at least once each day or write an IQCP for C. difficile and for carboxyhemoglobin and methemoglobin since the last survey. 2. A review of the IQCPs for hCG, HIV, mononucleosis, CK-MB, troponin, BNP, and blood gases revealed the procedures failed to include the QCP and the QAP as part of the IQCP for each test system. 3. The laboratory performed the CK-MB, BNP, and troponin as a backup test method to the Vitros 4600. 4. The laboratory performed approximately 30 HIV tests, 106 blood gases, 20 carboxyhemoglobin and methemoglobin, 80 Clostrium difficile, 12 infectious mononucleosis, and 170 hCG tests in 2018. 5. An interview on April 2, 2019 at 12:50 PM, with the laboratory manager, confirmed the laboratory failed to establish the IQCPs or include procedures for the QCP and QAP.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to establish a system that evaluated the relationship between complete blood counts (CBCs) performed on the Horiba ABX hematology analyzer and microscopic manual differentials at least twice a year since the last survey on March 1, 2017. Findings: 1. A record review revealed the laboratory failed to establish a system to evaluate the comparison of microscopic manual differentials and CBCs results from the Horiba analyzer since the last survey. 2. The laboratory performed approximately 429 CBCs and manual differentials in 2018. 3. An interview on April 2, 2019 at 10:20 AM, with the laboratory manager, confirmed the laboratory failed to evaluate the relationship between manual differentials and the CBC analyzer at least twice a year.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on reviews of policies and procedures and an interview with the laboratory manager, the laboratory failed to establish and/or follow the laboratory's Quality Assurance policy to identify and correct problems in quality controls and instrument function procedures since the last survey on March 1, 2017. Findings: 1. A review of

	the laboratory's Quality Assurance policy revealed a procedure that stated to update the manufacturer's quality control data into the laboratory information system (LIS) as necessary. 2. A review of quality control results for creatinine and human chorionic gonadotropin (hCG) from February 2019, revealed the laboratory failed to update the manufacturer's quality control reference range in the LIS. 3. The laboratory failed to establish a system to identify, correct, and monitor problems with the Siemens CA-660 coagulation specific instrument function necessary for patient prothrombin time test results. See D5411. 4. An interview on April 2, 2019 at 1:30 PM, with the laboratory manager, confirmed the Quality Assurance policy stated to update the control range information in the LIS, but was not done, as well as, failed to update the CA-660.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the laboratory manager, the laboratory failed to document training for 3 out of 3 testing personnel performing patient tests in chemistry and hematology since the last survey on March 1, 2017. Findings: 1. A record review of personnel documents revealed 3 out of 3 laboratory assistants failed to have documentation of training for the Horiba ABX hematology analyzer, Siemens CA-660 coagulation analyzer, and the Vitros 4600 chemistry analyzer prior to testing patients since the last survey. 2. An interview on April 2, 2019 at 8:30 AM, with the laboratory manager, confirmed the 3 laboratory assistants failed to have documented training for the test systems prior to testing patient samples.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory director failed to ensure all proficiency testing (PT) results received from the Wisconsin State Laboratory of Hygiene (WSLH) were reviewed by personnel to evaluate and identify problems that require corrective actions from events 1 through 3 of 2018. Findings: 1. A review of documents from the WSLH revealed the laboratory director failed to review, evaluate, and identify problems with the laboratory's PT performance for human chorionic gonadotropin (hCG) and lactate dehydrogenase (LDH). 2. A review of the results from WSLH PT revealed the laboratory failed to review the hCG scores that were assigned an artificial 100% for all 3 events in 2018, and the LDH PT scores that were assigned an artificial 100% for events 2 and 3 in 2018. 3. An interview on April 2, 2019 at 9:30 AM, with the laboratory manager, confirmed the laboratory director failed to evaluate PT results and identify problems that required corrective actions.

D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory director failed to specify in writing to the technical supervisor who is also the laboratory manager, the delegation to sign attestation statements from each proficiency testing provider since the last survey on March 1, 2017. Findings: 1. A review of policies and procedures revealed the laboratory director failed to specify in writing, the delegation to the laboratory manager, the responsibility for signing attestation statements for proficiency testing through Wisconsin State Laboratory of Hygiene, American Association of Bioanalysts, and the American Proficiency Institute for the specialties of chemistry, hematology, endocrinology, immunology, immunohematology, bacteriology, and toxicology since the last survey. 2. An interview on April 2, 2019 at 9:30 AM, with the laboratory manager, confirmed the laboratory director failed to delegate in writing the responsibility to sign the attestation statements for the PT programs.