Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	13D0522232	03/12/2025
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
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, laboratory procedures, training and competency assessment records and an interview with the laboratory manager on 3/11/2025, the laboratory failed to follow written procedures to assess testing personnel competency in 2024. The findings include: 1. The CMS 209 identified ten testing personnel (TP) performing moderate and high complexity testing. 2. A review of laboratory procedures identified that the laboratory established a procedure to assess TP initial training, semiannual and annual competency. 3. A review of training and competency assessment records identified that the laboratory failed to have annual competency assessments for one TP performing testing in 2024. 4. An interview with the laboratory manager on 3/11 /2025 at 8:27 am confirmed the above findings. 5. The laboratory reports performing 79,784 tests annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal

	values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the verification of performance specifications for the Alcor Scientific miniiSED ESR Analyzer and an interview with the laboratory manager on 3 /11/2025, the laboratory failed to ensure test performance specifications were established and verified before patient testing began in August 2023. The findings include: 1. A review of documentation for verification of performance specifications for erythrocyte sedimentation rate (ESR) testing on the miniiSED identified that the laboratory failed to verify precision and reportable range prior to performing patient testing in August 2023. 2. A review of documentation for verification of performance specifications for ESR testing identified that the laboratory failed to have the Laboratory Director review and approve the performance verification prior to performing patient testing. 3. An interview with the laboratory manager on 3/11/2025 at 3:20 pm confirmed the above findings. 4. The laboratory reports performing 472 ESR tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 review of calibration records, linearities, instrument documents for the Ortho Vitros 4600 and an interview with the laboratory manager on 3/12/2025, the laboratory failed to verify the reportable range at least once every six months for total iron-binding capacity (TIBC) and Hemoglobin A1c (HbA1c) in 2023 and 2024. The findings include: 1. A review of calibration records for the Vitros 4600 identified that TIBC had a two point calibration and HbA1c had a one point calibration. 2. A review of instrument documents and linearities for TIBC and HbA1c identified that the laboratory failed to perform verifications of the reportable range for TIBC and HbA1c at least every six months in 2023 and 2024. 3. An interview with the laboratory manager on 3/12/2025 at 8:44 am confirmed that the laboratory failed to verify the reportable range of TIBC and HbA1c at least once every six months in 2023 and 2024. 4. The laboratory reports performing 300 TIBC and 1,030 HbA1c tests annually.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on a review of Quality Control (QC) records, patient records and interviews with the laboratory manager on 3/11/2025 and 3/12/2025, the laboratory failed to successfully perform two levels of QC each day of patient testing for prothrombin time and total bilirubin in 2023 and 2024. The findings include: 1. A review of QC documents for the Sysmex CA660 for 2023 and 2024 identified that the laboratory failed to have at least two acceptable levels of QC for prothrombin time on 9/20/2024. A patient record review identified one patient (MRN 28902) with results reported on 9 /20/2024. 2. An interview with the laboratory manager on 3/11/2025 at 2:09 pm confirmed the prothrombin time finding. 3. A review of QC documents for the Vitros 4600 for 2023 and 2024 identified that the laboratory failed to have at least two acceptable levels of QC for total bilirubin on 4/14/2023. A patient record review identified 13 patients (MRNs 0056438, 0089124, 0061788, 0075336, 0085083, 0063409, 0053222, 0079992, 0088493, 0079122, 0069348, 0034045, 0036742) with total bilirubin results reported on 4/14/2023. 4. An interview with the laboratory manager on 3/12/2025 at 12:45 pm confirmed the total bilirubin finding. 5. The laboratory reports performing 324 prothrombin time and 2,662 total bilirubin tests annually.