Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0522232	03/22/2023
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
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 review of the bioMerieux Vidas 3 maintenance logs and an interview with the laboratory manager on 3/22/2023, the laboratory failed to perform instrument maintenance as required by the manufacturer. The findings include: 1. A review of maintenance records for the bioMerieux Vidas 3 identified that the laboratory failed to complete monthly maintenance which included cleaning the SPR block since the last inspection (5/10/2021). 2. A review of maintenance records for the bioMerieux Vidas 3 identified that the laboratory failed to complete six month maintenance which included cleaning the housing and front cover, cleaning vials, tubes and disposables rack, cleaning waste drawer, cleaning reagent strip sections and cleaning the touch screen since the last inspection. 3. An interview with the laboratory manager on 3/22 /2023 at 12:38 pm confirmed that the required monthly maintenance for the bioMerieux Vidas 3 was not performed. 4. The laboratory reports performing 77 procalcitonin tests on the bioMerieux Vidas 3 annually.
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 review of calibration records, instrument documents for the bioMerieux Vidas 3 and an interview with the laboratory manager on 3/22/2023, the laboratory failed to verify the reportable range at least once every six months for procalcitonin in 2021 and 2022. The findings include: 1. A review of calibration records and documents for the bioMerieux Vidas 3 identified that the laboratory failed to perform verifications of the reportable range for the analyte procalcitonin at least every six months in 2021 and 2022. 2. An interview with the laboratory manager on 3/22/2023 at 12:42 pm confirmed that the laboratory had not verified the reportable range of procalcitonin at least once every six months in 2021 and 2022. 3. The laboratory reports performing 77 procalcitonin tests annually.