Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0522334	02/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Benewah Community Hospital	229 S 7th St, Saint Maries, 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
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 verification documentation and an interview with the technical supervisor on 02/08/23 the laboratory failed to verify the reportable range for Hemoglobin A1C (HbA1C) and electrolytes (sodium, potassium, and chloride). The findings include: 1. A review of calibration verification documentation identified that the laboratory failed to perform calibration verifications on electrolytes and HbA1C in 2022. 2. An interview with the technical supervisor on 02/08/23 at 09:24

	confirmed the above findings. 3. The laboratory reports performing 83,900 chemistry tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random review of Quality Control (QC) documentation and an interview with the technical supervisor on 02/08/23, the laboratory failed to perform two (2) levels of QC each day of testing for creatinine and aspartate aminotransferase (AST). The findings include: 1. A random record review of QC from the Dimension EXL identified that the laboratory failed to have an acceptable level 3 control for creatinine (12 patients resulted) on 11/24/2021 and a level 1 control for AST (4 patients resulted) on 2/5/2022. 2. An interview with the technical supervisor on 02/08/23 at 09:58 am confirmed the above findings. 3. The laboratory reports performing 83,900 chemistry tests annually.