Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0522334	02/27/2025
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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 laboratory maintenance logs and an interview with the laboratory manager on 2/27/2025, the laboratory failed to perform maintenance as required by the Siemens Dimension EXL200 manufacturer in 2023, 2024 and 2025. The findings include: 1. A review of the laboratory maintenance logs identified that the laboratory failed to have documentation of weekly maintenance for the Dimension EXL200 as required by the manufacturer. The laboratory failed to document Cleaning HM Wash Probes and the R2 Reagent Probe weekly since February 2023. 2. A review of the laboratory maintenance logs identified that the laboratory failed to have documentation of monthly maintenance for the Dimension EXL200 as required by the manufacturer. The laboratory failed to document Cleaning the Clot Check Drain on the IMT Port, Replacing IMT Pump Tubing, Cleaning the IMT System, Replacing Instrument Air Filters, Styletting HM Wash Probes, Replacing HM Pump Heads on wash station, Cleaning the R1, R2 and R3 (if RMS equipped) Drains since February 2023. 3. An interview with the laboratory manager on 2/27/2025 at 11:36 am confirmed that the above findings. 4. The laboratory reports performing 86,400 tests on the Dimension EXL200 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 verification records, instrument documents for the Abbott i-STAT and an interview with the laboratory manager on 2/27/2025, the laboratory failed to verify the reportable range at least once every six months for blood gas analytes, troponin and prothrombin time (PT) in 2023 and 2024. The findings include: 1. A review of records for the Abbott i-STAT test system identified that the laboratory failed to perform verifications of the reportable range for the blood gas, troponin and PT analytes at least once every six months in 2023 and 2024. 2. An interview with the laboratory manager on 2/27/2025 at 12:52 pm confirmed the above finding. 3. The laboratory reports performing 1,125 i-STAT tests annually.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on a review of laboratory policies, temperature logs and an interview with the laboratory manager on 2/27/2025, the laboratory failed to perform alarm checks on the immunohematology refrigerator and freezer in 2023, 2024. The findings include: 1. The laboratory policies, "Alarm Check For Jewett Freezer" and "Alarm Check For Blood Bank refrigerator" state alarm checks will occur quarterly. 2. A review of laboratory temperature logs identified that the laboratory failed to perform alarm checks on the immunohematology refrigerator and freezer quarterly in 2023, 2024. 3. An interview with the laboratory manager on 2/27/2025 at 4:14 pm confirmed the above finding. 4. The laboratory reports performing 400 immunohematology tests annually.