Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521180	(X3) Date Survey Completed 02/07/2025
Name of Provider or Supplier Clearwater Valley Hospital	**Street Address, City, State** 301 Cedar St, Orofino, 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 technical supervisor (TS) on 2/6/2025, the laboratory failed to have a policy for performing competency assessments for TS and general supervisors (GS). The findings include: 1. A review of the submitted CMS-209 form identified one (1) TS and one (1) GS that were not the laboratory director. 2. A review of laboratory procedures identified that the laboratory failed to have a policy or procedure to assess TS and GS competency. 3. A review of laboratory competency assessments identified that the laboratory failed to have competency assessments performed for one (1) of one (1) TS and GS for their responsibilities as TS and GS by the laboratory director. 4. An interview with the TS on 2/6/2025 at 9:24 am confirmed that the laboratory director had not performed competency assessments for the TS and GS roles. 5. The laboratory reports performing 236,546 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 verification records, instrument documents for the Siemens epoc Blood Analysis System and the Quidel Triage and an interview with the technical supervisor (TS) on 2/6/2025, the laboratory failed to verify the reportable range at least once every six months for blood gas analytes, troponin and D-dimer in 2023 and 2024. The findings include: 1. A review of calibration verification records for the Siemens epoc Blood Analysis System identified that the laboratory failed to perform verifications of the reportable range for the blood gas analysis analytes in 2024. 2. A review of instrument documents for the Quidel Triage and a lack of calibration verification records for D-dimer and troponin identified that the laboratory failed to perform verifications of the reportable range for d-dimer and troponin at least every six months in 2023 and 2024. 3. An interview with the TS on 2/6/2025 at 1:55 pm confirmed the above findings. 4. The laboratory reports performing 2671 blood gas tests and 425 D-dimer tests annually.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) (d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; This STANDARD is not met as evidenced by: Based on a record review of immunohematology quality control (QC), patient test records and an interview with the technical supervisor (TS) on 2/6/2025, the laboratory failed to document control material results for immunohematology testing in 2025. The findings include: 1. A review of immunohematology QC for 2023, 2024 and 2025 identified that the laboratory failed to document QC on 1/2/2025 and 1/3 /2025 for ABO grouping, Rh typing, and unexpected antibody detection. 2. A review of patient test records identified ABO grouping, Rh typing, unexpected antibody detection and crossmatch was performed on one (1) patient on 1/2/2025. 3. A review of patient test records identified ABO grouping (front type) and Rh typing was performed on cord blood for one (1)patient on 1/3/2025. 4. An interview with the TS on 2/6/2025 at 3:34 pm confirmed the above findings. 5. The laboratory reports performing 713 immunohematology tests annually.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a)(2) Each week of use for Gram stains.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control (QC) records for microbiology and an interview with the technical supervisor (TS) on 2/6/2025, the laboratory failed to perform gram stain QC weekly in 2023, 2024 and 2025. The findings include: 1. A review of the laboratory's microbiology checklist identified that the laboratory failed to perform gram stain QC weekly since June 12, 2023. 2. An interview with the TS on 2/6/2025 at 2:46 pm confirmed that the laboratory failed to document gram stain QC weekly for 19 months in 2023, 2024 and 2025. 3. The laboratory reports performing 22 reported gram stains 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 technical supervisor (TS) on 2/6/2025, the laboratory failed to perform alarm checks on the immunohematology refrigerator in 2023, 2024 and 2025. The findings include: 1. The laboratory policy, "Blood Bank Temperature Monitoring" states alarm checks will occur monthly. 2. A review of laboratory temperature logs identified that the laboratory failed to perform alarm checks on the immunohematology refrigerator monthly in 2023, 2024 and 2025. 2. An interview with the laboratory manager on 2/6/2025 at 4:17 pm confirmed the above finding. 3. The laboratory reports performing 713 immunohematology tests annually.