Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520406	09/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Power County Hospital District	510 Roosevelt St, American Falls, 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 9/12/2024, the laboratory failed to follow written policies and procedures to assess testing personnel competency in 2023 and 2024. The findings include: 1. The CMS 209 identified 11 testing personnel (TP) performing moderate complexity and high testing of which six (6) were new since the last inspection on 10/18/2022. 2. A review of laboratory procedures identified that the laboratory established policies and procedures 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 six month competency assessments for three (3) TP performing i-STAT testing in 2023. 4. A review of training and competency assessment records identified that the laboratory failed to have annual competency assessments for three (3) TP performing i-STAT testing in 2024. 5. An interview with the laboratory manager on 9/12/2024 at 10:25 am confirmed the above findings. 6. The laboratory reports performing 24 i-STAT tests annually.
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 laboratory maintenance logs and an interview with the laboratory manager on 9/12/2024, the laboratory failed to perform maintenance as required by their instrument manufacturers in 2023 and 2024. The findings include: 1. A review of the laboratory maintenance logs identified that the laboratory failed to have documentation of daily maintenance for the Sysmex CA 600 and the Dimension EXL200 as required by the manufacturers. The laboratory failed to document Turning the Power OFF and on, Check/Replace Distilled Water, Check/Empty Waste Container, Check/Discard Pneumatic Trap Chamber Fluid, Check & Replenish Reaction Tubes, Empty/Clean Reaction Tube Trash Box, Load CA Clean II in Rinse Position, Run "Rinse Probe",Load Fresh CA Clean I in Rinse Position, Run "Rinse Probe",Wipe Sample Probe with Alcohol Swab and Check Temperatures daily on the Sysmex CA 600 daily in 2023 and 2024. The laboratory failed to document performing the daily system check on the Dimension EXL200 in 2023 and 2024 2. A review of the laboratory maintenance logs identified that the laboratory failed to have documentation of monthly maintenance for the bioMrieux Vidas 3 and the Dimension EXL200 as required by the manufacturers. The laboratory failed to clean the SPR block on the bioMrieux Vidas 3 in 2024. The laboratory failed to clean the R1 drain and clean the clot check drain on the IMT port on the Dimension EXL200 in 2023 and 2024. 3. A review of the laboratory maintenance logs identified that the laboratory failed to have documentation of semi annual maintenance for the bioMrieux Vidas 3 as required by the manufacturer. The laboratory failed to clean the housing, front cover, vials, tubes, disposables rack, reagent strip sections and touch screen in 2023 and 2024. 4. An interview with the laboratory manager on 9/12/2024 at 11:40 am confirmed that the above findings. 5. The laboratory reports performing 57,698 tests annually. 6. This is a repeat deficiency from the previous inspection on 3/10/2021.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of instrument manuals, a lack of maintenance logs and an interview with the laboratory manager on 9/12/2024, the laboratory failed to perform function checks as required by the Abbott i-STAT 1 manufacturer. The findings include: 1. A review of the Abbott i-STAT 1 user manual identified that the electronic stimulator is to be performed daily to verify the performance of the analyzer. 2. A lack of maintenance logs for the Abbott i-STAT 1 identified that the laboratory failed to perform the required performance verification using the electronic simulator in 2023 and 2024. 3. An interview with the laboratory manager on 9/12/2024 at 2:44 pm confirmed the above finding. 4. The laboratory reports performing 24 tests annually on the Abbott i-STAT 1.
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, linearities, instrument documents for the Biomerieux Vidas 3 and i-STAT 1 and an interview with the laboratory manager on 9 /12/2024, the laboratory failed to verify the reportable range at least once every six months for procalcitonin and blood gas analytes in 2023 and 2024. The findings include: 1. A review of calibration records, linearities 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 2023 and 2024. 2. A review of instrument documents and a lack of linearities for the i-STAT 1 identified that the laboratory failed to perform verifications of the reportable range for the blood gas analytes pH, PO2, PCO2, TCO2, HCO3, SO2 and lactate at least every six months in 2023 and 2024. 3. An interview with the laboratory manager on 9/12 /2024 at 3:10 pm confirmed that the laboratory had not verified the reportable range of procalcitonin and blood gas analytes at least once every six months in 2023 and 2024. 4. The laboratory reports performing 17 procalcitonin tests and 24 blood gas 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 lack of Quality Control (QC) records and an interview with the laboratory manager on 9/12/2024, the laboratory failed to successfully perform two levels of QC each day of use on the Abbot i-STAT 1. The findings include: 1. A lack of QC documents for the Abbot i-STAT 1 for 2023 and 2024 identified that the laboratory

	failed to perform at least two levels of QC for each analyte everyday of testing in 2023 and 2024. 2. An interview with the laboratory manager on 9/12/2024 at 2:44 pm confirmed the above finding. 3. The laboratory reports performing 24 i-STAT tests annually.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (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. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of temperature logs and an interview with the laboratory manager on 9/12/2024, the laboratory failed to perform alarm checks on the immunohematology refrigerator in 2024. The findings include: 1. A review of laboratory temperature logs identified that the laboratory failed to perform alarm checks on the immunohematology refrigerator used to store blood units for emergency release in 2024. 2. An interview with the laboratory manager on 9/12/2024 at 1:24 pm confirmed the above finding. 3. This a repeat deficiency from previous inspections on 10/22/2018 and 3/102021.