Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520406	10/22/2018
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record reviews and an interview with the laboratory manager, the laboratory director failed to sign the attestation statements from the American Association of Bioanalysts (AAB) for the specialty of Hematology, Chemistry, Immunology, Endocrinology, Toxicology, and Bacteriology since March 31, 2017. Findings: 1. An AAB PT record review from 2017 and 2018 revealed the laboratory director failed to sign the attestation statements for the specialty of Hematology, Chemistry, Immunology, Endocrinology, Toxicology, and Bacteriology. 2. An interview on October 22, 2018 at 9:40 AM, with the laboratory manager, confirmed the laboratory director failed to sign the attestation statements from AAB and failed to delegate the responsibility of signing the attestation forms to the technical supervisor.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a records review and an interview with the laboratory manager, the

	laboratory failed to retain instrument print-outs for patient test results, normal patient Prothrombin time mean and external quality control tests Sysmex CA-500 coagulation analyzer and the Beckman Coulter Act Diff 5 analyzer since the last survey on March 31, 2017. Findings: 1. A review of patient records and instrument data print-outs from the coagulation analyzer revealed the laboratory failed to retain instrument data print-outs for patient test results, normal patient Prothrombin time mean, and quality control test, as well as failed to retain quality control data for the hematology analyzer. 2. An interview on October 22, 2018 at 12:30 PM, with the laboratory manager, confirmed the laboratory failed to retain all patient and quality control data print-outs from the analyzers.
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 record review of personnel documents and the procedure manual, and an interview with the laboratory manager, the laboratory failed to follow the written policy to evaluate the competency of testing personnel performing tests on patient's specimens in the specialties of Hematology, Chemistry, Immunology, Endocrinology, Bacteriology, Toxicology, and microscopic examinations since the last survey on March 31, 2017. Findings: 1. A review of competency assessment documents for the testing personnel revealed the laboratory manager failed to have documented competency evaluations for testing performed on patient's specimen since the last survey. 2. An interview on October 22, 2018 at 9:30 AM, with the laboratory manager, confirmed the laboratory manager failed to follow written policy to assess the competency for the tests performed in the laboratory.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the laboratory manager, the laboratory failed to document the evaluation and review of unacceptable PT results for gram stains from the American Association of Bioanalysts (AAB) since the last survey on March 31, 2017. Findings: 1. A review of bacteriology PT results from AAB 2017 event 2 through 2018 event 2, revealed the laboratory failed to document the evaluation and corrective action for unacceptable gram stain results. 2. An interview on October 22, 2018 at 10:15 AM, with the laboratory manager, confirmed the laboratory failed to document the evaluation and corrective action for the unacceptable gram stain test results from AAB.
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 record review and an interview with the laboratory manager, the laboratory failed to perform and document calibration verification procedures at least once every 6 months for the Medience PathFast analyzer used to test cardiac markers since the last survey on March 31, 2017. Findings: 1. A record review of calibration verification reports for CK-MB, proBNP, and troponin performed on the Medience PathFast test system revealed the laboratory failed to perform and document calibration verifications at least once every 6 months. 2. An interview on October 22, 2018, at 11:30 AM, with the laboratory manager, confirmed the laboratory failed to perform and document calibration verifications.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a quality control records review and an interview with the laboratory manager, the laboratory failed to meet the quality control requirements for the Medience PathFast cardiac analyzer and the Sysmex CA-500 coagulation analyzer prior to reporting patient results during the dates reviewed in 2017 and 2018. Findings: 1. A review of quality control records for protimes and partial thromboplastin times from March through May 2017 and 2018 revealed 1 out of 2 levels of external quality controls failed to meet the manufacturer's acceptability range prior to reporting patient results. 2. A review of troponin quality control records from July through September 2018 revealed 1 out of 2 levels of external quality controls failed to meet the manufacturer's acceptability range prior to reporting patient results. 3. An interview on October 22, 2018 at 12:15 PM, with the laboratory manager,

	confirmed the laboratory failed to verify the results of quality control testing were within the manufacturer's expected range prior to reporting patient troponin, protime, and partial thromboplastin time results.
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 record review and an interview with the laboratory manager, the laboratory failed to perform and document the alarm system inspections for the blood storage refrigerator since the last survey on March 31, 2017. Findings: 1. A record review of the laboratory procedure manual and logs in the laboratory revealed the laboratory failed to perform and document alarm system checks for the blood storage refrigerator. 2. An interview on October 22, 2018 at 1:30 with the laboratory manager, confirmed the laboratory failed to follow the laboratory's policy for documenting monthly alarm check performance of the blood storage refrigerator.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to perform comparison activities between automated cell identification using the Beckman Coulter Act Diff 5 analyzer and manual differential identification using a microscope since the last survey on March 31, 2017. Findings: 1. A record review of proficiency testing and lab documents revealed the laboratory failed to perform and document the comparison activities between cell differentials performed on the hematology analyzer and manual microscopic examinations since the last survey. 2. An interview on October 22, 2018 at 1:40, with the laboratory manager, confirmed the laboratory failed to document comparison activities between cell differential methodologies.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The

	laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a procedure review and an interview with the laboratory manager, the laboratory failed to monitor and correct problems in the analytic test systems from the time period reviewed between March and May 2017 and 2018. Findings: 1. A review of the procedure manual revealed the laboratory failed to follow the policy for monthly quality assessment activities for the test systems to include the PathFast cardiac analyzer, Sysmex CA-500 coagulation analyzer, and the Beckman Coulter hematology analyzer. See D5439, D5481, D5555, and D5775. 2. An interview on October 22, 2018 at 1:50 with the laboratory manager, confirmed the laboratory failed to monitor, identify errors, and correct problems in the test systems.