Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520406	10/18/2022
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) proficiency testing (PT) data report (Report 155D), graded results from the American Proficiency Institute (API) and an interview with the laboratory manager on 10/18/2022, the laboratory failed to successfully participate and achieve an overall satisfactory score for two (2) of three (3) testing events in 2022 for the subspecialty of toxicology. See D2118
D2118	TOXICOLOGY CFR(s): 493.845(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) Proficiency Testing (PT) data report (Report 155D), graded PT results from the American Proficiency Institute (API) and an interview with the laboratory manager on 10/18 /2022, the laboratory failed to achieve satisfactory performance for two (2) consecutive PT events for the analyte phenytoin. The findings include: 1. A review of Report 155D and graded PT results from API identified that the laboratory failed to achieve satisfactory performance for events one (1) in 2022 and two (2) in 2022 for the subspecialty of toxicology for the analyte phenytoin. Analyte Year Event Score Phenytoin 2022 1 0% Phenytoin 2022 2 0% 2. An interview with the laboratory manager on 10/18/2022 at 3:40 pm confirmed the above findings. 3. The laboratory reports performing 4 phenytoin tests annually.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) 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 of Sysmex CA 620 coagulation quality control (QC) documentation, patient results, and an interview with the laboratory manager on 10/18 /2022, the laboratory failed to include two levels of QC material every eight hours of patient testing. The findings include: 1. A random record review of prothrombin time (PT) and partial thromboplastin time (PTT) QC identified that the laboratory failed to document two levels of QC every eight hours when patient testing occurred one day in January 2022, one day in March 2022 and one day in April 2022. 2. A review of the laboratory's patient results identified one patient PTT reported on 1/30/2022, four patient PT/INR's and one PTT reported on 3/7/2022 and one patient PT/INR reported on 4/16/2022 without two levels of QC. 3. An interview with the laboratory manager on 10/18/2022 at 12:03 pm confirmed the above findings. 4. The laboratory reports performing 120 PT/INR and 80 PTT tests annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on a record review of the Sysmex CA620 instrument verification, the Alcor miniiSED instrument verification and an interview with the laboratory manager on 10 /18/2022, the laboratory director failed to ensure that the instrument verifications were adequate before patient tests were reported. The findings include: 1. A record review of verifications for prothrombin time (PT) and partial thromboplastin time (PTT), performed on the Sysmex CA620, identified that the laboratory director failed to review and approve the verification results to ensure that they were adequate before beginning patient testing in June of 2021. 2. A record review of verifications for sedimentation rates, performed on the Alcor miniiSED, identified that the laboratory director failed to review and approve the verification results to ensure that they were adequate before beginning patient testing in June of 2022. 3. Interviews with the laboratory manager on 10/18/2022 at 12:16 pm and 1:56 pm confirmed the above findings. 4. The laboratory reports performing 120 PT, 80 PTT and 171 sedimentation rate tests annually.