Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2077535	01/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Bridger Valley Urgent Care	39901 Business Loop 80, Lyman, WY	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 1 of 11 testing events from January 2022 through December 2023. The findings were: 1. Review of the American Proficiency Institute (API) proficiency testing (PT) report failed to include documentation the laboratory had evaluated test scores of less than 100%. The following concerns were identified: a. Review of the 2022 API Hematology Event #3 PT results showed the laboratory scored an 80% on the platelet count. There was no documentation the laboratory had evaluated the proficiency testing results. 2. Interview with the laboratory director on 1/31/24 at 5:50 PM confirmed the laboratory had failed to evaluate the reason for the 80% score.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff

	interview, the laboratory failed to have a system in place for reviewing proficiency test results that received an artificial score of 100% due to lack of peer group data or due to a lack of consensus for 3 of 11 American Proficiency Institute (API) proficiency testing events reviewed from January 2022 through December 2023. The findings were: 1. Review of the 2022 API Microbiology Event #3 and the 2023 API Microbiology Event #1 proficiency testing results showed the laboratory scored an artificial score of 100% on the detection of Influenza A on the BioFire FilmArray analyzer due to a lack of peer group data. There was no documentation the laboratory had performed a self-evaluation. 2. Review of the 2023 API Hematology Event #1 proficiency testing results showed the laboratory scored an artificial score of 100% on the lymphocyte count performed on the Beckman Coulter DxH 520 analyzer due to a lack of consensus. There was no documentation the laboratory had performed a self-evaluation. 3. Interview with the laboratory director on 1/31/24 at 5:50 PM confirmed an evaluation of the proficiency testing results had not been completed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, and staff interview, the laboratory failed to ensure 2 of 5 (Henry Schein One-Step + Ultra Mono, Henry Schein One Step + H. pylori) waived testing kits were not used beyond their expiration date. The findings were: 1. Observation on 1/31/24 at 3:15 PM showed a Henry Schein One-Step + Ultra Mono kit had an expiration date of 11/30/23 and a Henry Schein One-Step + H. pylori kit had an expiration date of 5/31/23 and were available for patient testing. 2. Interview with the laboratory director on 1/31/24 at 3: 48 PM confirmed the test kits were expired. Further, the laboratory director revealed the H. pylori kit was used for patient testing on 1/27/24 and the Mono kit was used for patient testing on 12/23/23 and 1/9/24. 3. Review of the One Step + H. pylori Rapid Test Device manufacturer's instructions showed the kit was stable until the expiration date when stored as directed. 4. Review of the One Step + Ultra Mono Test Kit manufacturer's instructions showed "Do not use the Test Sticks or reagents after their expiration dates."
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials

	having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation, policy and procedure review, and staff interview, the laboratory failed to verify the statistical parameters of quality control material prior to use for 1 of 1 test system (Hematology) reviewed. The findings were: 1. There was no documentation the laboratory had verified new lot numbers of quality control material prior to being used on the Beckman Coulter DxH 520 hematology analyzer. 2. Review of the policy and procedure "Beckman DxH 520 Complete Blood Count with WBC Differential", effective 5/2022, showed "Assay values on a new lot of control should be confirmed before the new lot is put into routine use." 3. Interview with the laboratory director on 1/31/24 at 5:19 PM confirmed the statistical parameters of the quality control materials had not been verified before use.
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 review of quality assessment documentation and staff interview, the laboratory failed to have an ongoing system to monitor, assess, and correct problems in the analytic system which assesses the Individualized Quality Control Plan (IQCP) for 1 of 2 years (2023) reviewed. The findings were: 1. Review of an "Annual IQCP Quality Assessment" for the BioFire Film Array showed it was last completed by the laboratory director on 4/7/22. 2. Interview with the laboratory director on 1/31/24 at 6:23 PM confirmed there was no further documentation.