

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2077535	(X3) Date Survey Completed 04/11/2022
Name of Provider or Supplier Bridger Valley Urgent Care	Street Address, City, State 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and staff interview, the laboratory director and testing personnel failed to attest to the routine integration of proficiency tests into the patient workload using the laboratory's routine methods for 1 of 5 (American Proficiency Institute (API) microbiology event 1) proficiency testing events reviewed from December 2020 through April 2022). The findings were: 1. Review of the proficiency testing records failed to include the attestation statements signed by the laboratory director and the testing personnel for API 2022 microbiology event 1. 2. Interview with the laboratory director on 4/11/22 at 5:30 PM confirmed the attestation statements were not available.</p>
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Medonic hematology analyzer calibration records, review of the manufacturer's instructions, and staff interview, the laboratory failed to ensure the Medonic manufacturer's operator's manual was followed and calibrations were</p>

	<p>performed every 6 months for two survey cycles conducted on 11/9/20 and 4/11/22. Refer to D5411.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's operator's manual, review of calibration records, and staff interview, the laboratory failed to follow the Medonic complete blood count (CBC) instrument manufacturer's instructions to perform instrument calibration once every six months for 17 months of testing reviewed. The laboratory performed approximately 1400 CBCs annually. The findings were: 1. Review of the Medonic hematology calibration records showed the last calibration was performed on 5/15/21. There was no evidence a calibration had been performed in November 2021 or anytime thereafter. 2. Review of the Medonic operator's manual section 7 page 59 recommended calibration be performed every 6 months. The manufacturer's training manual instructions on page 18 stated calibration frequency was every 6 months or by local regulatory requirements. 3. Interview with the laboratory director on 4/11/22 at 3:55 PM confirmed the Medonic hematology analyzer had not been calibrated as required. THIS IS A REPEAT DEFICIENCY, last cited on 11/9/21.</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Medonic hematology analyzer manufacturer's instructions, review of the Medonic instrument calibration records, and staff interview, the laboratory director failed to ensure testing personnel followed the manufacturer's instructions to calibrate the instrument every 6 months. The laboratory performed approximately 1400 complete blood counts per year. Refer to D5411.</p>