Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2077535	11/09/2020
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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: . Based on lack of documentation, operator's manual review, and confirmation by staff, the laboratory failed to add 3 of 12 required elements to the manufacturer's operator's manuals for 2 of 2 moderately complex test systems reviewed, Medonic blood cell counter and Biofire Respiratory Panel 2.1, (include instructions for entering test results into the patient's test record, identificaton of the testing person performing the test, and what to do when the test system is inoperable). The laboratory performed 0-3 Complete Blood Counts (CBC) tests per day and 5 to 10 Biofire Respiratory panel tests per day. Findings include: 1. The laboratory used the Medonic operator's manual as the procedure manual for CBC testing and the Biofire Respiratory operator's manual for the laboratory procedure manuals. 2. The operator's manuals did not include the method for transcribing CBC tests into the patient's test record or saving the instrument printouts for the transcribed results. Biofire Respiratory Panel 2.1 operator's manual failed to include instructions for entering the instrument printouts into the patient's test record, identification of the test person performing the test, and what testing personnel are to do when the test systems are inoperable. 3. In an interview conducted on 11/09/2020 at approximately 3:50 P.M., staff confirmed the procedure manual lacked the laboratory specific information for CBC and Biofire Respiratory Panel 2.1 tests. .
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 lack of documentation, manufacturer's operator's manual review, and confirmation by staff, the laboratory failed to follow Medonic complete blood count instrument manufacturer's instructions to perform instrument calibrations once every six months for two of two years of testing reviewed, November 2018 to November 2020. The laboratory performed from 0 to 3 complete blood counts per day. Findings include: 1. The laboratory failed to record the dates and retain the calibration record for complete blood cell counts performed on the Medonic cell counting instrument from November 9, 2018 to November 9, 2020. 2. Operator's manual section 7 page 59 recommended calibration be performed every 6 months. Manufacturer's training manual instructions on page 18 stated calibration frequency was every 6 months or by local regulatory requirements. 3. In an interview conducted on 11/09/2020 at approximately 5:15 P.M., staff confirmed the calibration records for the Medonic cell counting instrument could not be located for testing performed from November 2018 to November 2020. .
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on complete blood count (CBC) test records review, lack of documentation, and interview with staff, the laboratory test records failed to include the identity of the personnel who performed CBC tests from 11/09/2018 to 11/09/20 for 8 of 11 tests reviewed. Findings include: 1. Patient CBC record review failed to include the identity of the person performing the CBC test for the following 8 of 11 tests reviewed: Patient 093097 collected on 02/15/2019; for patient 101497 collected on 09 /15/2019; patient 100394 collected on 08/27/2019; patient 02081961 collected on 09 /15/2020; patient 10041955 collected on 08/26/2020; patient 020770 collected on 07 /03/2020; patient 031653 collected on 03/13/2020; and patient 031008 collected on 02 /28/2020. 2. In an interview with staff on 11/09/2020 at approximately 4:30 P.M. staff confirmed when the laboratory began transcribing test results into the laboratory information system (LIS) the instrument printouts containing the initials of the person performing the CBC tests were not retained in a manner they could be retrieved. .
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be

	retained. This STANDARD is not met as evidenced by: . Based on patient test record review, lack of documentation, and interview with staff, the laboratory failed to retain Medonic instrument printouts for patient testing results that were transcribed into the patient's test record for 8 of 12 complete blood counts reviewed. The laboratory performed approximately 0 to 3 complete blood counts (CBC's) per day. Findings include: 1. Patient test records review failed to include instrument printouts for the transcribed complete blood count reports for: Patient 093097 collected on 02/15/2019 for which no mixed cell result was reported (Neutrophils were transcribed into the laboratory information system as 52.3 and Lymphocytes were transcribed as 40.0%, no mixed cell resullts were reported); patient 101497 collected on 09/15/2019; patient 100394 collected on 08/27/2019; patient 020861 collected on 09/15/2019; patient 100455 collected on 08/26/2020; patient 020770 collected on 07/03/2020; patient 031653 collected on 03/13/2020; and patient 031008 collected on 02/28/2020. 2. In an interview conducted with staff on 11 /09/2020 at approximately 4:45 P.M., staff confirmed the record system did not include the scanned instrument printouts for CBC's transcribed into the laboratory information system. .
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 Biofire Respiratory Panel 2.1 test verification documentation, lack of documentation, and interview with staff, the director failed to document test verification of accuracy precision, analytic specificity and analytic sensitivity met the laboratory's performance characteristics specified by the test's manufacturer. Findings include: 1. Biofire Respiratory Panel 2.1 test verification failed to include the director's signature and date of approval. 2. In an interview conducted on 11/09/2020 at approximately 4:00 P.M., staff confirmed the verification studies failed to include the date and signature of the director as approved.