Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0913810	02/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
B2 Urgent Care	1006 West Main Street, Bozeman, MT	

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 record review of American Proficiency Institute (API) proficiency testing scores and interview with the Testing Personnel (TP) #1, the laboratory failed to achieve satisfactory performance for two out of three testing events in chemistry for year 2021. (Refer to D2096)
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(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 review of 2021 Chemistry Core API proficiency testing scores and interview with the Testing Personnel (TP) #1, the laboratory failed to achieve a score of 80 percent for LDL Cholesterol (calculated) in 2 of 3 events (2021 Event 1, and 2021 Event 2), resulting in unsuccessful proficiency testing performance. Findings: 1. Review of American Proficiency Institute (API) proficiency testing scores for 2021 Chemistry Core revealed unsuccessful proficiency testing for LDL Cholesterol (calculated) with a 50% score for 2021 Event 1 and 50% score for 2021 Event 2. 2. Interview with the TP #1 on February 9, 2022 at 12:50 PM confirmed the laboratory failed to achieve satisfactory performance of LDL Cholesterol (calculated) for two out of three events in 2021.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on observation, record review and an interview with testing personnel (TP) #1, the laboratory failed to retain or be able to retrieve a copy of the patients test results report from their electronic medical record system, EPIC from January 1, 2020 to December 31, 2020. Findings: 1. Observed computer system in the laboratory with EPIC software used for the laboratory's electronic medical record system. 2. The laboratory failed to retrieve requested patient results reports from EPIC from January 1, 2020 to December 31, 2020. 3. Interview on February 9, 2022 at 12:45 PM with the TP #1, confirmed the laboratory was unable to retrieve data from EPIC for patients tested in 2020.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in

	the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of hematology, endocrinology, and urinalysis records, policy and procedures, and interview with testing personnel (TP) #1, the laboratory failed to include in their procedure manuals; reference intervals (normal values) for Complete Blood Counts (CBC) with differential, instructions for human chorionic gonadotropin (hCG) external quality control (QC) for serum specimens, step-by-step procedure including the intended staining characteristics for Kova stain for urine sediment slides, and an approved procedure for cobas Liat system for the detection of SARS-CoV-2. Findings: 1. No reference intervals (normal values) were available from the B2 Urgent Care lab's hematology procedure for CBC with differential. 2. Review of CBC Procedure -CLIA Moderately Complex Horiba Micros 60 Analyzer revealed, "The normal ranges in the Micros 60 are from the original installation in 2008. When the data is transmitted into EPIC, normal ranges are applied to fit the patient's gender and age according the BHDH Main Lab's values." 3. Review of Quidel QuickVue hCG Combo Test procedure failed to include instructions for serum hCG external QC. 4. Review of hCG Rapid Test Kit Procedure failed to include directions for serum specimens and testing of associated QC. 5. No step-by-step procedure for the preparation of microscopic slides using Kova stain for urine sediment and the intended staining characteristics were available for review. 6. Review of Miscellaneous QC Log lacked quality checks for Kova staining characteristics of urine sediment slides. 7. No approved procedure for the detection of SARS-CoV-2 using the Cobas Liat analyzer was available for review. 8. Interview on February 9, 2022 at 11:00 AM with the TP #1, confirmed the laboratory failed to include in their procedure manuals reference intervals (normal values) for CBC with differential, instruction for testing external hCG serum QC, step-by-step procedure including the intended staining characteristics for Kova stain for urine sediment slides, and an approved procedure for the detection of SARS-CoV-2 using the cobas Liat system.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and an interview with the testing personnel (TP) #1, the laboratory failed to ensure reagents, Kova stain for microscopic urinalysis and 10% potassium hydroxide (KOH) used for mycology microscopic examination were not used past their expiration date. Findings: 1. Observed a bottle of Kova stain for urine sediment labeled "Lot #K303694 Exp 2021-03" was present in the laboratory. 2. Observed a bottle of KOH 10% labeled "Lot9255 Exp 2-12-2021" was present in the laboratory. 3. No procedure or policy was available for reagent tracking. 4. Interview on February 9, 2022 at 9:00 AM with the TP #1, confirmed the laboratory failed to ensure reagents Kova stain for urine sediment and 10% KOH were not used past their expiration date.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the postanalytical laboratory systems from January 1, 2020 to February 9, 2022. Findings: 1. A record review of the electronic medical record system EPIC for year 2020 revealed no patient results reports were available for review. (Cross refer D3041) 2. Review of Quality Assurance Plan states " Post-Analytic - Bozeman Health Urgent Cares, Main Street laboratory will monitor, assess and correct problems identified in the following Post-Analytic areas: 1. Test Report." 3. No reports to periodically verify the accuracy of EPIC's calculated data, results sent to interfaced systems and patient specific data was available for review. 4. Interview on February 9, 2022 at 12:50 PM with the TP #1, confirmed the laboratory failed establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the postanalytical laboratory systems.