| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 53D2077535 | 02/07/2018 |
| **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 |
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| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing record review and confirmation by staff, the laboratory failed to document 3 of 5 American Proficiency Institute (API) proficiency testing events were reviewed for complete blood count, and 3 of 4 American Association of Bioanalysts (AAB) Thyroid Stimulating Hormone (TSH), Free Thyroxine, and Prostate Specific Antigen testing events were reviewed from July 2016 to January 2018. Findings include: 1. Proficiency tests review revealed the laboratory failed to document 3 of 5 American Proficiency Institute (API) proficiency testing events were reviewed for complete blood count, and 3 of 4 American Association of Bioanalysts (AAB) Thyroid Stimulating Hormone (TSH), Free Thyroxine, and Prostate Specific Antigen testing events were reviewed from July 2016 to January 2018. There was no documentation the test results had been reviewed by the personnel responsible for testing to ensure test results were evaluated for bias, accuracy, or if corrective actions were necessary. 2. In an interview conducted on 02/07/2018 at approximately 1:50 P. M. staff confirmed the proficiency test records failed to include documentation the results had been reviewed by staff to identify problems. |
| **D5405** | PROCEDURE MANUAL<br>CFR(s): 493.1251(c)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on FREND instrument procedures review, lack of documentation, and interview with staff, the laboratory failed to include in the steps testing personnel were to take when the FREND test system was inoperable and how to enter test results into the patient's test record in the procedures for 3 of 3 new tests performed, (Thyroid Stimulating Hormone [TSH], Free Thyroxine [FT4], and Prostate Specific Antigen [PSA]). Findings include: 1. The laboratory used the manufacturer's package instructions for test performance for TSH, FT4, and PSA test procedures. 2. The manufacturer's instructions failed to include the laboratory specific information for what testing personnel were to do when the test system was in operable (for example, quality control was out of range or the laboratory was out of test cartridges, or the test system did not provide a test result), or the process the laboratory testing personnel were to use to enter the test results into the patient's test record, (for example, the laboratory practice was to tape the instrument printout to paper and scan the results into the patient's chart record). 3. In an interview conducted on 02/07/2018 at approximately 2:00 P.M., staff confirmed the procedure did not include laboratory specific information. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on operator's manual review, lack of documentation, and interview with staff, the director failed to approve 3 of 3 new test procedures reviewed for Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4), and Prostate Specific Antigen (PSA) testing using the FREND test system. The laboratory performed approximately 4 TSH and 2 FT4 tests per month and 1 PSA test per 10 months. Findings include: 1. The laboratory used the operator's manual and manufacturer's instructions as the laboratory procedure. 2. The operator's manual and manufacturer's instructions failed to include the director's signature and date of test procedure approval prior to use for the FREND system for patient TSH, FT4, and PSA testing. 3. In an interview conducted on 02/07/2018 at approximately 2:00 P.M., staff stated the procedure did not include the signature and date the director approved the new FREND test system for TSH, FT4 and PSA testing. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of documentation, lack of an Individualized Quality Control Plan |

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| | (IQCP), patient test record review, and confirmation by staff, the laboratory failed to perform two levels of quality control each day of testing for six of six test days reviewed for Thyroid Stimulating Hormone (TSH) testing, two of two days of Free Thyroxine (FT4) testing and one of one day of Prostate Specific Antigen (PSA) testing reviewed as performed on the FREND test system. Findings include: 1. The laboratory quality control (QC) records reviewed failed to include documentation quality control performance for TSH, FT4 and PSA testing on the Frend test system since the laboratory performed test system verification March 9, 2017. 2. The laboratory failed to have an approved IQCP for TSH, FT4, and PSA testing for the FREND test system to qualify for a reduced QC test frequency. 3. Patient test records review included documentation patients were tested on 04/26/2017, 08/16/2017, 10/31 /2017, 11/11/2017, 11/18/2017, and 02/02/2018 for TSH tests; on 08/16/2017 and 10 /31/2017 for FT4; and 01/08/2018 for PSA testing. 4. The laboratory manager stated in an interview conducted on 02/07/2018 at approximately 1:50 P.M., that the laboratory did not perform two levels of quality control each day of testing and did not have an approved IQCP to qualify for reduced QC frequency. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>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).<br><br>This STANDARD is not met as evidenced by:<br>Based on FREND test records (log) review, patient test records review, and interview with staff, the laboratory failed to include the identity of the personnel performing testing for 5 of 7 Thyroid Stimulating Hormone (TSH) and 2 of 2 Free Thyroxine (FT4) test reports reviewed. The laboratory performed approximately 4 TSH and 2 FT4 tests per month. Findings include: 1. The laboratory failed to document the testing person's identification on the instrument printout or on the patient test log for patients tested on 04/26/2017, 08/16/2017, 10/31/2017, and 11/11/2017. 2. Patient test records reviewed failed to include the identity of the personnel who performed TSH and FT4 testing for tests performed on 04/26/2017, 08/16/2017, 10/31/2017, and 11/11 /2017. The laboratory scanned the instrument printout into the chart record as the test report. 3. In an interview conducted on 02/07/2018 at approximately 2:00 P.M., staff confirmed the laboratory record failed to include the identity of the personnel performing TSH and FT4 testing. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. |

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| | This STANDARD is not met as evidenced by:<br>Based on lack of documentation and interview with staff, the laboratory director failed to ensure the laboratory maintained a quality assessment program for pre-analytic and post analytic testing for complete blood cell counts and established a quality assessment program for Thyroid and Prostate Specific antigen testing. The laboratory tested approximately 40 Complete Blood Count tests and 50 Thyroid tests in 2017. Findings include: 1. The laboratory failed to document they reviewed test requests, specimen collection and specimen rejection for CBC, TSH, and FT4 testing for pre-analytic quality assessment monitoring. 2. The laboratory failed to document they reviewed quality control and patient test performance for TSH and FT4 testing for analytic quality assessment monitoring. 3. The laboratory failed to document they reviewed test reports for CBC, TSH, and FT4 testing for post-analytic quality assessment monitoring. 4. In an interview conducted on 02/07/2018 at approximately 2:00 P.M., staff confirmed they did not document quality assessment monitoring, evaluating or assessment for problems in the pre-anaytic, Thyroid analytic, or post analytic testing. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of documentation, test records review, personnel records review, and confirmation by staff, the director failed to ensure 6 of 7 testing personnel received the appropriate training for performing and reporting Free T4 (FT4) , Thyroid Stimulating Hormone (TSH), and Prostate Specific Antigen (PSA) prior to reporting patient test results. The number of patients tested by each test person could not be determined. Findings include: 1. Test record review for TSH, FT4 and PSA testing documented testing was performed beginning in April 2017 for patient 04261744982346 for TSH testing. 2. Personnel training records review failed to include FREND test system training for specimen acceptability, test performance and reporting for 6 of 7 staff testing personnel. 3. In an interview conducted on 02/07 /2018 at approximately 2:00 P.M., staff confirmed the laboratory failed to document testing personnel were trained for performing TSH, FT4 and PSA testing until 2/2 /2017 for 4 testing personnel and not documented for 2 testing personnel. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. |

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| | This STANDARD is not met as evidenced by:<br>Based on lack of documentation and confirmation by staff, the technical consultant failed to evaluate six of six testing personnel annually for 1 of 2 years of complete blood cell (CBC) testing reviewed (2017). Findings include: 1. The laboratory failed to document CBC competency evaluations were performed for testing personnel in 2017 for the six testing personnel performing CBC tests since mid 2016. 2. In an interview conducted on 02/07/2018 at approximately 2:00 P.M., staff confirmed the laboratory technical consultant failed to document CBC competency evaluations for testing personnel. |