| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 53D0666137 | 08/26/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Star Valley Medical Center | 901 Adams Street, Afton, 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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| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on American Proficiency Institute (API) proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to evaluate corrective actions taken to correct 2 consecutive proficiency testing failures for C-Reactive Protein (CRP) until the 2nd failure occurred. The laboratory performed approximately 90 CRP tests per year. Findings include: 1. API proficiency testing records review included reports the laboratory scored 0% the 2nd event of 2018 and 0% the 1st event of 2019. The laboratory continued testing patient samples after the 1st and 2nd failed events. 2. The laboratory lacked documentation for the assessment of corrective actions taken after the first 0% failure (2nd event of 2018) to prevent recurrence of the problem. The laboratory failed the 1st event of 2019. 2. In an interview conducted on 08/26/2020 at approximately 6:15 P.M., the laboratory technical supervisor confirmed the CRP corrective actions taken for the first failure did not correct the problem and prevent recurrence. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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 |

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| | determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on manufacturer's new lot number of Innovin (Thromboplastin) International Normalized Ration (INR) calculation instructions review, direct observation of the International Sensitivity Index (ISI) on 08/26/2020 at approximately 6:15 P.M., the laboratory failed to follow instructions to change the (ISI) in the instrument for 1 of 1 new lot number of thromboplastin, (549750) in use since 03/18/2020. The laboratory tested approximately 5 specimens per day. Findings include: 1. The manufacturer's instructions include entering the new lot number of Innovin reagent's ISI for INR calculations into the Sysmex CA600. The ISI for lot number 549750 is 1.07. 2. Direct observation of the ISI value currently displayed on the CA 600 instrument in use on 08 /26/2020 the surveyor observed the value of 1.03. 3. In an interview conducted on 08 /26/2020 at approximately 6:15 P.M., staff confirmed the previous lot number's ISI was not changed to the current lot number's ISI of 1.07. The ISI is the exponent value in the INR calculation. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of documentation and confirmation by staff, the laboratory failed to ensure they monitored water quality for use on the AU480 chemistry analyzer for 2 of 2 years of testing. The laboratory performed at least 75,000 tests per year on the AU480 instrument. Findings include: 1. The laboratory lacked documentation of routine daily function checks for the GWT water purification system from September 2018 to August 26, 2020. 2. In an interview with laboratory staff on 08/26/2020 at approximately 6:00 P.M., staff confirmed they did not have a maintenance record for the GWT water quality system. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation and confirmation by staff, the laboratory failed to ensure 1 of 4 microscan organism identification reagents was in use past its expiration date of 08/13/2020. The laboratory performed approximately 1-2 tests per day using the VP2 reagent. Finding include: 1. On 08/26/2020 at approximately 8:00 A.M., the VP2 |

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| | reagent was observed to be in use in the specimen processing safety cabinet. 2. In an interview with staff on 08/26/2020 at approximately 1:30 P.M., staff confirmed the reagent was in use past the expiration date. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of documentation and interview with staff, the laboratory failed to verify analytic sensitivity for SARS 2 CoVID 19 testing performed on the Biofire test platform prior to reporting patient test results. The laboratory performed approximately 1 to 3 tests per day since June 5, 2020. Findings include: 1. The laboratory lacked documentation they established the Biofire SARS 2 CoVID 19 test system's analytical sensitivity. 2. In an interview with staff on 08/26/2020 at approximately 7:30 P.M., the laboratory manager confirmed the laboratory did not verify analytic sensitivity, (True positive/True positive+False positive x 100) of SARS 2 CoVID 19 RNA the test could detect. The manager also confirmed the Biofire SARS 2 CoVID 19 test system is not FDA approved. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of documentation and confirmation by staff, the laboratory failed to follow Coulter Dix manufacturer's instructions to perform calibration verification at least once every 6 months for 3 of 4 six month calibration periods reviewed from September 1, 2018 to August 26, 2020. The laboratory performed approximately 20 to 30 complete blood count tests per day. Findings include: 1. The laboratory lacked calibration documentation for the second 6 months of 2018, the first 6 months of |

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| | 2019, and the first 6 months of 2020. 2. In an interview with staff on 08/26/2020 at approximately 6:45 P.M., laboratory staff confirmed the laboratory had not followed manufacturer's instructions to performed calibration every 6 months from September 2018 to August 26, 2020. |
| **D5507** | BACTERIOLOGY<br>CFR(s): 493.1261(b)(c)<br><br>(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control records review, lack of documentation, and interview with staff, the laboratory failed to perform susceptibility quality control testing each day of testing for 2 years of susceptibility testing reviewed. The laboratory performed approximately 200 susceptibility tests per year. Findings include: 1. Quality control records included weekly Quality Control (QC) performance for susceptibility testing. 2. Patient records review for urine culture for patient 18:M0001787S collected on 09 /01/2018 identified E.coli. An antibiotic susceptibility for E.Coli included that all antibiotics were susceptible; wound culture for patient 20M:0000265R collected on 02 /03/2020 susceptibility was performed on a Staphylococcus organism that was reported as Methicillin resistant; and a sputum specimen collected on 06/19/2020 for patient 20M0001174R susceptibility test for E.cloacae showed mixed antibiotic susceptible and resistant reactions. It was not determined if appropriate quality control was performed each day of susceptibility testing for these patient specimens. 3. In an interview with staff on 08/26/2020 at approximately 7:00 P.M., staff stated bacteriology QC was performed weekly rotating Gram's positive and negative organisms (i.e. Gram's negative QC was performed once every 2 weeks and Gram's positive susceptibility QC was performed once every two weeks.) |
| **D6128** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of documentation and confirmation by the laboratory technical supervisor, the technical supervisor failed to evaluate 6 of 6 of high complexity testing personnel at least annually for 1 of 2 years of competency evaluations reviewed (2019). Findings include: 1. The laboratory lacked documentation high complexity testing personnel (A-F) were evaluated annually after their first year for bacteriology, |

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| | virology, immunohematology, and hematology high complexity testing. 2. In an interview conducted on 08/26/2020 at approximately 7:30 P.M., the technical supervisor confirmed the laboratory did not document testing personnel competency for 2019. |