Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0666137	09/14/2022
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing records, review of the CMS (Center for Medicare and Medicaid Services) 209 Laboratory Personnel Report, and staff interview, the laboratory failed to include the respiratory therapists in the rotation of personnel performing blood gas (pH, partial pressure of oxygen, partial pressure of carbon dioxide) testing for 6 of 6 proficiency testing events reviewed from September 2021 through September 2022. The laboratory performed approximately 150 blood gases per year. The findings were: 1. Review of the CMS 209 Laboratory Personnel Report dated 9/8/22 showed 5 respiratory therapists were listed as testing personnel performing moderate complexity testing. 2. Review of 6 American Proficiency Institute Chemistry Core Proficiency testing events from September 2021 through September 2022 showed the blood gas section of the events was performed by laboratory personnel which did not include the respiratory therapists. 3. Interview with testing personnel #1 on 9/14/22 at 9 AM revealed blood gas testing was shared between the respiratory therapists and the laboratory staff. 4. Interview with the general supervisor on 9/14/22 at 11 AM confirmed the respiratory therapists had not participated in the proficiency testing events.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files, review of the CMS (Center for Medicare and Medicaid Services) 209 Laboratory Personnel Report, lack of documentation, review of policy and procedure, and staff interview, the general supervisor failed to complete competency assessments for 5 of 5 respiratory therapists (RT #1, RT #2, RT #3, RT #4, RT #5) as required for 2 of 2 years reviewed (2020, 2021). The findings were: 1. Review of the laboratory's personnel files showed the following concerns: a. Review of the personnel file for RT #1 showed he was hired in February of 2022. There was no evidence the general supervisor had completed an initial or 6 month competency assessment. b. Review of the personnel file for RT #2 showed she was hired in June of 2017. There was no evidence the general supervisor had completed the annual competency assessment in 2020 or 2021. c. Review of the personnel file for RT #3 showed he was hired in May of 2014. There was no evidence the general supervisor had completed the annual competency assessments in 2020 or 2021. d. Review of the personnel file for RT #4 showed she was hired in March of 2021. There was no evidence the general supervisor had completed the initial competency assessments or any required assessment thereafter. e. Review of the personnel file for RT #5 showed he was hired in February of 2020. There was no evidence the general supervisor had completed the initial competency assessments or any required assessment thereafter. 2. Interview with the general supervisor on 9/14/22 at 11:50 AM confirmed the competency assessments had not been completed. 3. Review of the policy and procedure titled "Clinical Laboratory Staff Training and Competency" dated 10/2021 showed "...Initial training is performed and documented for each staff member based on assigned duties. Competency is assessed and documented 6-months following initial training. Competency is assessed and documented annual (sic) thereafter." 4. Review of the policy and procedure titled "Laboratory Director Delegation of Responsibilities" dated 7/2022 showed the laboratory director had delegated the responsibility of performing the competency assessments to the general supervisor.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 6 of 37 proficiency testing events reviewed from September 2020 through August 2022. The findings were: 1. Review of the American Proficiency Institute (API) proficiency testing (PT) reports failed to include documentation the laboratory had evaluated test scores of less than 100%. The following concerns were identified: a. Review of the 2020 API Chemistry Core Event #3 showed the laboratory scored an 80% on sodium. There was no documentation the laboratory had evaluated the test results. b. Review of the 2021 API Chemistry Core Event #1 showed the laboratory scored an 80% on creatinine. There was no documentation the laboratory had evaluated the test results. c. Review of the 2021 Chemistry Core Event #2 showed the laboratory scored an 80% on triglyceride. There was no documentation the laboratory had evaluated the test results. d. Review of the 2021 Hematology Event #3 showed the laboratory scored an

	80% on eosinophils. There was no documentation the laboratory had evaluated the test results. e. Review of the 2021 Microbiology Event #1 showed the laboratory scored an 80% on the detection of Group A Streptococcus using the Quidel Solana test method. There was no documentation the laboratory had evaluated the test results. f. Review of the 2021 Microbiology Event #2 showed the laboratory scored an 80% on the detection of Mycoplasma pneumoniae using the BioFire test method. There was no documentation the laboratory had evaluated the test results. 2. Interview with the general supervisor on 9/14/22 at 11:50 AM confirmed the PT scores of less than 100% had not been investigated.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to have a system in place for reviewing proficiency test results that received an artificial score of 100% due to lack of peer group data for 5 of 6 College of American Pathologists (CAP) proficiency testing events reviewed from September 2020 to September 2021. The laboratory performed approximately 64 pancreatic amylase patient tests annually. The findings were: 1. Review of the CAP proficiency testing evaluation forms showed the laboratory received an artificial score of 100% on the analyte of pancreatic amylase on the third event of 2020, the second and third events of 2021, and the first and second events of 2022. There was no documentation the results of the proficiency testing events had been evaluated for accuracy. 2. Interview with the general supervisor on 9/13/22 at 9:36 AM confirmed an evaluation of the proficiency testing results had not been evaluated for accuracy.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's environmental records, review of manufacturer's instructions, and staff interview, the laboratory failed to monitor humidity in the testing and reagent storage areas. The laboratory performed approximately 190,000 patient tests annually. The findings were: 1. Review of the daily environmental log showed the humidity level in the laboratory was not monitored. 2. Review of the manufacturer's instructions for the Beckman Coulter DxH 690 and the DxH

	Slidemaker Stainer II hematology instruments showed the relative humidity must be maintained at less than 85% when the temperature of the laboratory was between 60 and 84 degrees Fahrenheit. The DxH Slidemaker Stainer II required the relative humidity to be maintained at less than 70% then the temperature of the laboratory was between 68 and 80 degrees Fahrenheit. 3. Review of the manufacturer's instructions for the Beckman Coulter AU 480 chemistry analyzer showed the relative humidity must be maintained between 15% and 90%. 4. Interview with the general supervisor on 9/14/22 at 11:50 AM confirmed the humidity of the laboratory had not been monitored.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to verify the statistical parameters of quality control material prior to use for 2 of 3 test systems reviewed (hematology, coagulation). The findings were: 1. There was no documentation the laboratory had verified new lot numbers of quality control material prior to being used on the hematology and coagulation analyzers. 2. Interview with the general supervisor on 9/14/22 at 9:57 AM confirmed the statistical parameters of the quality control materials had not been verified before use.