Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0666137	09/18/2024
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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicare 209 Laboratory Personnel Report, review of policy and procedures, lack of documentation, review of proficiency testing records, and staff interview, the laboratory failed to complete 6-month and annual competency assessments in a timely manner (D5209) and failed to ensure proficiency testing results with an artificial score of 100% were evaluated (D5215) for 2 survey cycles (2022, 2024).
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 Centers 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 6-month

	and annual 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 (2023, 2024). The findings were: 1. Review of the personnel file for RT #1, RT #2, RT #3, RT #4, and RT #5 showed an initial competency assessment had been completed in January of 2023. There was no evidence the laboratory had completed a 6-month competency assessment (due in July of 2023) or an annual competency assessment (due in January of 2024). The personnel files showed an annual assessment had been completed in September of 2024. 2. Interview with the general supervisor on 9/17/24 at 1:45 PM revealed the competency assessments had not been completed due to an oversight by the laboratory. 3. Review of the "Clinical Laboratory Staff Training and Competency" policy, effective 9/2022, 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 annually thereafter. 4. Review of the "Laboratory Director Delegation of Responsibilities" policy, last revised 10/2023, showed the laboratory director had delegated the responsibility of performing the competency assessments to the general supervisor. THIS IS A REPEAT DEFICIENCY, last cited on 9/14/22.
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 testing results that received an artificial score of 100% for 13 out of 34 American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing events reviewed from September 2022 through August 2024. The findings were: 1. Review of the 2022 API Immunology/Immunohematology Event #3 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on samples RUB-11, RUB-12, RUB-13, RUB-14, and RUB-15 (quantitative Rubella) due to a peer group of less than 10 participants. There was no documentation a self-evaluation of the results had been completed. 2. Review of the 2022 API Hematology/Coagulation Event #3 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on sample BCI-14 (blood cell identification) due to a lack of consensus. There was no documentation a self-evaluation of sample BCI-14 had been completed. 3. Review of the 2022 API Microbiology Event #3 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on sample ES-03 (beta-lactamase). There was no documentation a self-evaluation of sample ES-03 had been completed. 4. Review of the 2023 API Hematology/Coagulation Event #1 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on sample BFM-02 (body fluid microscopy) and GOB-02 (gastric pH) due to a lack of consensus. There was no documentation a self-evaluation of sample BFM-02 or GOB-02 had been completed. 5. Review of the 2023 API Hematology/Coagulation Event #3 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on sample VA-03 (vaginal wet-prep) due to a lack of consensus. There was no documentation a self-

	evaluation of sample VA-03 had been completed. 6. Review of the 2023 API Microbiology Event #1 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on sample UR-01 (antibiotic susceptibility testing for aztreonam and ceftazidime) due to a lack of consensus. There was no documentation a self-evaluation of sample UR-01 had been completed. 7. Review of the 2023 API Microbiology Event #2 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on sample UR-06 (antibiotic susceptibility testing for cefepime and cefotaxime) due to less than 5 participants. There was no documentation a self-evaluation of sample UR-06 had been completed. 8. Review of the 2023 API Immunology/Immunohematology Event #2 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on samples RUB-06, RUB-07, RUB-08, RUB-09, and RUB-10 (quantitative Rubella) due to a peer group of less than 10 participants. There was no documentation a self-evaluation of the results had been completed. 9. Review of the 2023 API Immunology/Immunohematology Event #3 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on samples RUB-11, RUB-12, RUB-13, RUB-14, and RUB-15 (quantitative Rubella) due to a peer group of less than 10 participants. In addition, sample SER-13 (compatibility testing) was not graded due to no consensus. There was no documentation a self-evaluation of the results had been completed. 10. Review of the 2024 API Hematology/Coagulation Event #1 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on sample COU-02 (nucleated red blood cells) and the laboratory was directed to review the data summary. There was no documentation the laboratory had reviewed the results. 11. Review of the 2024 API Microbiology Event #1 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on SF-01 (cerebrospinal fluid culture antibiotic susceptibility) and GS-02 (gram stain morphology) and the laboratory was directed to review the data summary. Other concerns identified included the BioFire Film Array molecular assay for detecting joint-wound resistant genes (7 total assays); RSP-01, RSP-02, RSP-03 (molecular respiratory virology); and UR-01 (urine culture susceptibility testing). There was no documentation the laboratory had reviewed the results. 12. Review of the 2024 Microbiology Event #2 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on GS-08 (gram stain) and UR-06 (urine culture antibiotic susceptibility) due to a lack of consensus. There was no documentation the laboratory had reviewed the results. 13. Review of the 2024 CAP Chemistry Event #1 proficiency testing evaluation showed the laboratory scored an artificial score of 100% on CHM-04 (quantitative serum pregnancy, free T3, digoxin, transferrin) and the laboratory was directed to review note 22 and note 30. There was no documentation the laboratory had reviewed the results. 14. Interview with the general supervisor on 9/17/24 at 1 PM confirmed a self-evaluation of the non-graded test results had not been conducted. 15. Review of the "Proficiency Testing for Non-Waived Testing" policy, last revised 8/2024, showed "...Evaluation of Ungraded Proficiency Testing...The General Supervisor shall routinely review the laboratory's proficiency testing results when a formal evaluation has not been provided by the testing agency under the following conditions: The PT program assigned an artificial score of 100% (i.e., results not evaluated or scored)..." THIS IS A REPEAT DEFICIENCY, last cited on 9/14/22.
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 review of patient test reports, the VITROS XT 7600 analyzer manufacturer's instructions for use, and staff interview, the laboratory failed to follow the manufacturer's instructions to include the prostate specific antigen (PSA) test assay method on 1 of 1 PSA patient test reports (patient #1) reviewed. The laboratory had performed approximately 490 patient PSA tests since the VITROS XT 7600 was approved for use in April of 2024. The findings were: 1. Review of the VITROS XT 7600 analyzer manufacturer's instructions stated "Different test methods cannot be used interchangeably. PSA results in a given patient sample determined with different tests and from different manufacturers can vary due to differences in test methods and reagent specificity. A change to a different method during serial monitoring of a patient should be accompanied by additional sequential testing to confirm baseline values. The results reported by the laboratory to the physician must include the identity of the PSA test used." Review of the VITROS XT 7600 new instrument verification study showed the study was approved by the laboratory director on 3/12 /24. The following concerns were identified: a. Review of the PSA test report for patient #1, dated 9/9/24, failed to include the test method used. 2. Interview with the general supervisor on 9/18/24 at 10:08 AM confirmed the PSA test method was not included on the patient test reports.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, patient testing logs, the laboratory's Individual Quality Control Plans (IQCP), policy and procedure review, and staff interview, the laboratory failed to perform a positive and negative control each day of patient testing from 4/5/24 through 9/15/24 for the SURE-VUE qualitative serum pregnancy test. This failure affected 60 patient samples. The findings were: 1. Review of the QC logsheet showed a positive and negative control were performed on 4/2/24, 5/7/24, 6/5/24, 7/2/24, 8/5/24, and 9/10/24. Review of the patient testing log showed 60 patient tests were performed on days in which QC was not performed. 2. Review of the "SURE-VUE Serum/Urine hCG Test" procedure, last revised 11/2022, showed "Quality Control...2. External Quality Control...a. Serum: Test external controls monthly, with each new lot, with each new shipment received..." 3. Review of the laboratory's IQCPs showed no evidence an IQCP had been developed for the SURE-VUE qualitative serum pregnancy test. 4. Interview with the general supervisor on 9 /18/24 at 9:40 AM confirmed an IQCP had not been developed for the qualitative serum pregnancy test and QC was not being performed as required.