Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0968118	09/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Star Valley Health - Alpine Clinic	37 Wintergreen Drive, Alpine, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing documentation, policy and procedure review, review of patient testing worksheets, and staff interview, the laboratory failed to enroll in an approved proficiency testing program for the regulated manual identification of blood cells. The laboratory performed approximately 217 complete blood counts from 7/2/24 to 9/18/24 of which a manual identification of blood cells was performed on 22 patient samples. The findings were: 1. Review of the 2024 American Proficiency Institute hematology/coagulation proficiency testing records showed the laboratory was enrolled in an automated complete blood count with a white blood cell differential program; however, had failed to enroll in a program to evaluate the manual method for identifying blood cells. 2. Review of the "Hematology-Manual Differential Procedure" and the "Hematology-Uniform Grading of Blood Smears" procedure showed an effective date of 8/2022 and were revised 9/2024. 3. Review of the patient testing worksheets from 7/2/24 to 9/18/14 showed a manual identification of blood cells was performed on 22 patients. 4. Interview with the technical consultant on 9/18/24 at 2:34 PM confirmed the laboratory had failed to enroll in a proficiency testing program for manually identifying blood cells.

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 2 of 6 American Proficiency Institute (API) proficiency testing events reviewed from September 2022 through August 2024. The findings were: 1. Review of the 2023 API Hematology /Coagulation Event #1 showed the laboratory was given an artificial score of 100% on DxH-04 (lymphocyte count) due to no consensus. There was no documentation a self-evaluation of the results had been completed. 2. Review of the 2023 API Hematology /Coagulation Event #3 showed the laboratory was given an artificial score of 100% on DxH-11 and DxH-14 (lymphocytes) due to no consensus. There was no documentation a self-evaluation of the results had been completed. 3. Interview with the technical consultant on 9/18/24 at 1:35 PM confirmed the non-graded samples had not been evaluated.