Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0968118	(X3) Date Survey Completed 09/15/2022
Name of Provider or Supplier Star Valley Health - Alpine Clinic	**Street Address, City, State** 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the individual testing the proficiency testing samples and the laboratory director failed to attest to the routine integration of the American Proficiency Institute (API) proficiency tests into the patient workload for 5 of 5 proficiency testing events reviewed from January 2021 to September 2022. The findings were: 1. Review of the proficiency testing records showed the following concerns related to the proficiency testing attestation statements: a. Review of the 2021 API Hematology Event #1 record showed the attestation statement had not been signed by the laboratory director until 9 /13/22. b. The laboratory was unable to locate the attestation statement for 2021 API Hematology Event #2. c. Review of the 2021 API Hematology Event #3 record showed no evidence of a signed attestation statement. d. Review of the 2022 API Hematology Event #1 record showed the attestation statement had not been signed by the laboratory director. e. Review of the 2022 API Hematology Event #2 record showed no evidence of a signed attestation statement. 2. Interview with technical consultant #1 on 9/15/22 at 10 AM confirmed no further documentation was available.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples.

	The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and staff interview, the laboratory failed to maintain a copy of each step in the testing and reporting of the API (American Proficiency Institute) proficiency samples for 5 of 5 proficiency testing events reviewed from January 2021 to September 2022. The findings were: 1. Review of the proficiency testing records showed no evidence of the following documentation: a. 2021 API Hematology Event #1 was missing the instrument printouts of the testing results, the attestation statement signed by the laboratory director, and the performance review form. b. 2021 API Hematology Event #2 was missing all of the required documentation. c. 2021 API Hematology Event #3 was missing the attestation statement, the instrument printouts of the testing results, and the submission forms. d. 2022 API Hematology Event #1 was missing the attestation statement signed by the laboratory director. e. 2022 API Hematology Event #2 was missing all of the required documentation. 2. Interview with technical consultant #1 on 9/15/22 at 10 AM confirmed no further documentation was available.
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 the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel records, policy and procedure review, and staff interview, the laboratory failed to ensure the technical consultants' (TC #1, TC #2, TC #3) competency assessments had been completed for 2 of 2 years reviewed (2020, 2021). The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed 3 laboratory personnel were listed as technical consultants. 2. Review of the personnel files for TC #1, TC #2, and TC #3 showed no evidence a competency assessment had been completed for the position of technical consultant as required. 3. Review of the policy and procedure provided by the laboratory showed it was a shared document from the laboratory's parent organization, was not unique to the laboratory, and had not been approved by the laboratory director. 4. Interview with TC #1 on 9/15/22 at 11:44 AM confirmed the laboratory did not have a policy and procedure related to competency assessments and the required competency assessments had not been completed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, review of the Beckman Coulter DxH 520 new instrument verification study, and staff interview, the laboratory director failed to approve 1 of 1 procedure manual (Beckman DxH 520 Complete Blood Count with WBC Differential) reviewed. The findings were: 1. Review of the Beckman Coulter DxH 520 new instrument verification study showed the laboratory director had approved the study on 2/9/22. 2. Review of the Beckman Coulter DxH 520 Complete Blood Count with WBC Differential policy and procedure, effective 9/2022, had not been signed and dated as approved by the laboratory director. 3. Interview with technical consultant #1 on 9/15/22 at 10:26 AM confirmed the procedure manual had not been signed by the laboratory director.
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 the Beckman Coulter DxH 520 manufacturer's instructions for use (IFU), review of patient testing records, and staff interview, the laboratory failed to follow the manufacturer's instructions and review and resolve any instrument flags prior to reporting patient results for 12 of 14 (#32658, #320591, #318643, #311164, #309970, #309968, #309033, #308245, #307781, #305914, #301970, #300089) patient tests reports with flagged analytes reviewed from 2/25/22 to 9/14/22. The findings were: 1. Review of the instrument printouts of patient testing showed the following concerns: a. Review of patient #326258, dated 9/14/22, showed a flag for platelet debris. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. b. Review of patient #320591, dated 8/5/22, showed a flag for suspect differential. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. c. Review of patient #318643, dated 7 /22/22, showed a flag for suspect differential. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. d. Review of patient #311164, dated 6/3/22, showed a flag for suspect differential. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. e. Review of patient #309970, dated 5/25/22, showed flags for abnormal differential, cellular interference, and suspect differential. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. f. Review of patient #309968, dated 5/25/22, showed flags for abnormal differential, suspect differential, and MO/NE (monocyte/neutrophil) overlap. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. g. Review of patient #309033, dated 5/15/22, showed a flag for platelet debris. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. h. Review of patient #308245, 5/11/22, showed a flag of platelet debris. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. i. Review of patient #307781, dated 5/8/22, showed a flag for platelet debris. There was

	no evidence the patient sample had been reviewed prior to the reporting of patient results. j. Review of patient #305914, dated 4/22/22, showed a flag for suspect differential. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. k. Review of patient #301970, dated 3/15/22, showed a flag for platelet debris. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. l. Review of patient #300089, dated 2/25/22, showed a flag for platelet debris. There was no evidence the patient sample had been reviewed prior to the reporting of patient results. 2. Interview with technical consultant #1 on 9/15/22 at 10:27 AM confirmed the flagged patient specimens had not been evaluated for accuracy prior to reporting the results. 3. Review of the Beckman Coulter DxH 520 manufacturer's IFU showed "Flags IMPORTANT Beckman Coulter recommends that you review all flags according to your laboratory's protocol before reporting any results." 4. Review of the Beckman DxH 520 Complete Blood Count with WBC differential showed "...Reporting Patient Results...Any patient results that are flagged by the analyzer must be reviewed and all flags need to be resolved prior to reporting patient results...If flags or other results (sic) issues cannot be resolved, specimens should be sent to the main lab for testing on primary hematology analyzer."
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 200 complete blood cell counts per year. The findings were: 1. Review of the daily environmental log showed the humidity level in the laboratory was not monitored. 2. Review of the Beckman Coulter DxH 520 manufacturer's instructions showed the analyzer met performance claims when operated at a maximum of 80% relative humidity (non-condensing) at 89.6 degrees Fahrenheit. 3. Interview with technical consultant #1 on 9/15/22 at 11:42 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 1 of 1 test system (hematology) reviewed. 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 Beckman Coulter DxH 520 hematology analyzer. 2. Interview with technical consultant #1 at 10:27 AM confirmed the statistical parameters of the quality control materials had not been verified before use.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of documentation, review of patient test records, and staff interview, the laboratory failed to have a written policy and procedure for identifying and correcting problems identified in the analytic phase of testing. The findings were: 1. Review of patient test records showed 12 patient test reports had been flagged for review by the Beckman Coulter DxH 520 hematology analyzer and reported to the provider prior to resolution of the flagged analytes. 2. There was no evidence the laboratory had developed a policy and procedure for ensuring the quality of patient test results during the analytic phase of testing. 3. Interview with technical consultant (TC) #1 and TC #2 on 9/15/22 at 11:49 AM revealed the final patient test results were reviewed from a remote location, however the instrument printouts had not been reviewed to ensure the results had not been flagged by the analyzer. In addition, the technical consultants confirmed a quality assessment policy and procedure had not been developed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on review of patient test reports and staff interview, the laboratory failed to ensure the patient test report included the name and address of the laboratory location where the test was performed. The laboratory performed approximately 200 complete blood cell counts per year. The findings were: 1. Review of the test report for patient #309968, dated 5/25/22, showed the location of the testing laboratory was incorrect. 2. Interview with technical consultant #1 on 9/15/22 at 11 AM confirmed the patient test report failed to include the correct name and address of the location the test was performed.