Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0968118	05/04/2021
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
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 lack of documentation, review of the manufacturer's operator's manual, and staff interview, the laboratory failed to follow the Beckman Coulter AC*T manufacturer's instructions to perform instrument calibrations once every 6 months for 2 of 2 years of testing reviewed (May 2019 to May 2021). In addition the laboratory failed to review flagged analytes on the analyzer printout for 5 of 15 (#18693, #193711, #198257, # 203832, #236484) hematology samples reviewed. The laboratory performed approximately 200 complete blood counts per year. The findings were: 1. Review of the laboratory's hematology records failed to include evidence the hematology analyzer had been calibrated from 5/1/19 through 5/4/21. The laboratory failed to record the date of the calibrations and retain the calibration records. 2. Review of the AC*T instrument for patient test #18693, #193711, #198257, # 203832, and #236484 showed results for platelets were flagged with an asterisk. There was no documentation the sample had been reviewed for accuracy. 3. Review of the Beckman Coulter AC*T operator's manual showed "Instrument calibration or calibration check should be done every 6 months and after major repairs". In addition the operator's manual showed on page A-15 a result value coded with an asterisk required review. 4. Interview with the technical consultant and general supervisor on 5/4/21 at 12:10 PM confirmed the calibration records could not be located. Further, they confirmed the manufacturer required patient's blood sample results be reviewed if the results were flagged with an asterisk, which had not been done, and a procedure should be implemented.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the lack of documentation, review of the Beckman Coulter AC*T operator's manual, and staff interview, the facility failed to follow the AC*T manufacturer's instructions to perform preventative maintenance as required. The laboratory tested approximately 200 hematology samples per year. The findings were: 1. Review of the Beckman Coulter AC*T operator's manual showed the instrument required the diluent filters and peristaltic pump tubing be replaced every 12,000 cycles. 2. Review of the laboratory's records failed to include pump and filter maintenance documentation for 2 years of records reviewed. 3. Interview with the technical consultant and general supervisor on 5/4/21 at 12:10 PM revealed the laboratory did not have a preventative maintenance contract with the manufacturer and provided the service internally. Further they confirmed the laboratory did not have documentation of when the maintenance was last performed.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on patient test record review, lack of documentation, and staff interview, the laboratory failed to retain the Beckman Coulter AC*T instrument printouts for patient testing that were transcribed into the patient's test record for 1 of 15 (#236484) complete blood counts (CBCs) reviewed. The laboratory performed approximately 200 CBCs per year. The findings were: 1. Review of patient test report #236484 showed a result of 231,000 platelets per microliter of blood and a monocyte result of 4.8 %. Further review showed these results were a corrected values from a previously reported result of 24,000 platelets per microliter of blood and a monocyte result of 10.4%. Review of the instrument's printout showed a result of 242,000 platelets per microliter and a monocyte result of 10.4%. 2. Interview with the technical consultant and general supervisor on 5/4/21 at 12:10 PM revealed the results of the CBC were manually entered into the computer system and the error was discovered during a quality assessment review. The instrument printout for the corrected values could not be located to verify the reported result of 231,000 platelets per microliter or the monocyte result of 4.8%.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if

	applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on patient test record review, lack of documentation, and staff interview, the laboratory failed to ensure the original copy of a corrected patient test report was maintained for 1 of 1 corrected test reports reviewed (#236484). The laboratory performed approximately 200 complete blood counts (CBCs) per year. The findings were: 1. Review of patient test report #236484 showed the original CBC test report dated 11/12/20 had been amended to include the corrected values for platelets and monocytes. There was no documentation of the original test report with the inaccurate test results. 2. Interview on 5/4/21 at 12:10 PM with the technical consultant and general supervisor confirmed the original test report was not available and understood the need to keep both the original and corrected versions of the test report.