

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0968118	(X3) Date Survey Completed 10/22/2018
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's specifications review, lack of documentation, and interview with staff, the laboratory failed to monitor and document the ambient temperature for performing complete blood counts (CBC) using the AcT 5 instrument to be consistent with the manufacturer's instructions. Findings include: 1. The manufacturer stated the operating temperature for performing CBC testing is from 16 to 34 degrees C (60-93 degrees F). 2. The laboratory failed to document they monitored the room temperature prior to reporting patient specimens for 1 of 1 patient (159299) tested on 10/19/2018. 3. In an interview with staff on 10/22/2018 at approximately 4:15 P.M. staff stated they did not monitor or record the room temperature where CBC testing was performed.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory</p>

director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on procedure manual review, lack of documentation, and interview with the laboratory manager, the director failed to ensure the laboratory established a quality assessment plan for general laboratory, pre-analytic, analytic, and post-analytic portions of complete blood cell count testing. The laboratory performs approximately 1 test per week. Findings include: 1. The laboratory procedure manual failed to include a quality assurance plan that includes the items the laboratory reviews, the frequency of review, and the method they use to document the review of general laboratory tasks (ex. proficiency testing review, testing personnel competency procedure performance, and complaint documentation and resolution); Pre-analytic quality assessment (ex. Specimen collection, patient identification verification, specimen labeling, storage, and transportation) performance; analytic quality assessment (ex. review of quality control, instrument preventive maintenance, reagent replacement and test record logs) performance; and post-analytic quality assessment, (ex. test report accuracy review) performance. 2. The laboratory lacked documentation of quality assessment plans or a method for documentation. 3. In an interview with the laboratory manager on 10/22/2018 at approximately 4:20 P.M. staff confirmed the laboratory did not have a written quality assessment plan for general laboratory, pre-analytic, analytic and post-analytic portions of the complete blood count testing process.