Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2111952	02/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Grand Ave Urgent Care	3236 E Grand Ave, Suite D, Laramie, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review and staff interview, the laboratory failed to ensure the procedure manuals contained all the required elements for 2 of 2 procedure manuals reviewed (Alere Triage Troponin I, Alere Triage D-dimer). The findings were: 1. Review of the Alere Triage Troponin I and the Alere Triage D-dimer procedure manuals failed to include the following: a. A procedure for performing biannual calibration verification. b. The reference ranges of the analytes. c. The

	laboratory's system for entering results in the patient record and reporting patient results. 2. Interview with the testing personnel #1 on 2/3/23 at 2:10 PM confirmed the laboratory's procedures were incomplete.
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 room temperature in the testing area. The laboratory estimated it would perform approximately 1500 patient tests annually. The findings were: 1. Review of the laboratory's daily environmental log showed the room temperature in the testing area of the facility was not monitored. 2. Review of the Alere Triage manufacturer's instructions showed testing should be performed between 68 degrees Fahrenheit and 75 degrees Fahrenheit to obtain optimal results. 3. Interview with testing personnel #1 on 2/2/23 at 3 PM confirmed the laboratory did not monitor the room temperature of the testing area.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (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 and patient testing logs, and staff interview, the laboratory failed to perform two levels of quality control each day of testing for the Alere Triage D-dimer and Alere Triage troponin I analytes for 3 months of testing reviewed (November 2022 through January 2023). This failure affected 26 patient D-dimer tests and 27 troponin I patient tests. The findings were: 1. Review of the QC records and patient testing logs for the Alere Triage D-dimer analyte showed the following concerns: a. Six patient tests were performed between 11/1/22 and 11/9 /22 with the last recorded QC being performed on 10/27/22. b. Eight patient tests were performed between 11/11/22 and 12/1/22 with the last recorded QC being performed on 11/10/22. c. Four patient tests were performed between 12/7/22 and 12/8/22 with the last recorded QC being performed on 12/2/22. d. Seven patient tests were performed between 12/13/22 and 1/5/23 with the last recorded QC being performed on 12/9/22. e. One patient test was performed on 1/10/23 with the last recorded QC being performed on 1/9/23. 2. Review of the QC records and patient testing logs for the Alere Triage troponin I analyte showed the following concerns: a. Seven patient

	tests were performed between 11/1/22 and 11/7/22 with the last recorded QC being performed on 10/14/22. b. Four patient tests were performed between 11/14/22 and 11/16/22 with the last recorded QC being performed on 11/10/22. c. Seven patient tests were performed between 11/21/22 and 12/8/22 with the last recorded QC being performed on 11/17/22. d. Nine patient tests were performed between 12/10/22 and 1/5/23 with the last recorded QC being performed on 12/9/22. 3. Review of the "Individual Quality Control Policy-Triage" procedure, revised on 6/6/22, showed "... 4.1 Analyze two levels of control after each change in reagent lot. Do not use QC material that was shipped with reagent being tested. 4.2 Analyze two levels of control at least monthly." There was no evidence the laboratory had developed an individualized quality control plan (IQCP) which included a risk assessment and a quality assessment. 4. Interview with testing personnel #1 on 2/2/23 at 2:10 PM confirmed the QC had not been performed each day of patient testing and the IQCP was incomplete.