Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2160566	(X3) Date Survey Completed 04/15/2021
Name of Provider or Supplier Vernal Urgent Care	**Street Address, City, State** 872 W Highway 40, Vernal, UT	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with the Clinical Consultant, positive identification of patients' specimen was not performed at the time of collection. Findings include: 1. Specimen collection SOP did not include instructions for verifying patient identification prior to specimen collection by asking the patient to repeat their name and date of birth. 2. During direct observation of patient specimen collection on 4/15/21 at approximately 2:20 pm, testing personnel (TP)3 did not ask the patient to confirm their identity prior to collection of the patients' specimen. 3. In an interview on 4/15/21 at approximately 2:40 pm, the Clinical Consultant confirmed that confirming patient identity was not included in the SOP for specimen collection or included in training of testing personnel.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	Based on record review and interview with the Clinical Consultant, a Quality Assessment (QA) plan is not in place for monitoring, assessing, or correcting problems. Findings include: 1. Document review did not include a policy or procedure for monitoring, assessing, or correcting problems identified in the laboratory. 2. In an interview on 4/15/21 at approximately 3:30 pm, the Clinical Consultant confirmed that a QA plan has not been written or established for the laboratory.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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 director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with the Clinical Consultant, personnel education requirements, training, and competency were not verified prior to testing patients' specimens. Findings include: 1. Personnel record review for testing personnel performing moderately complex testing did not include documentation of education. 2. Personnel record review for testing personnel performing moderately complex testing did not include record of training for 4 of 12 testing personnel. 3. Personnel record review for testing personnel performing moderately complex testing did not include evaluation of competency. 4. In an interview on 4/15/21 at approximately 1:30 pm, the Clinical Consultant confirmed that documentation of education was not requested from testing personnel, training records were incomplete, and evaluation and documentation of competency of testing personnel was not performed.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with the Clinical Consultant, initial competency for testing personnel was not evaluated or documented. Findings include: 1. Personnel record review did not include any documentation of evaluation of initial competency for 12 of 12 testing personnel. 2. In an interview on 4/15/21 at approximately 1:30 pm, the Clinical Consultant confirmed that initial competency evaluation of testing personnel was not performed or documented.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor

	of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview with the Clinical Consultant, documentation of education for 12 of 12 testing personnel (TP) performing moderately complex testing was not verified. Findings include: 1. Personnel record review of TP1 through TP12 did not contain education records. 2. In an interview on 4/15/21 at approximately 1:30 pm, the Clinical Consultant confirmed that they did not request documentation of education from their testing personnel.
D6067	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with the Clinical Consultant, training was not documented for 4 of 12 testing personnel (TP) performing moderately complex testing. Findings include: 1. Record review for TP4, TP5, TP6, and TP7 did not include documentation of training. 2. In an interview on 4/15/21 at approximately 1: 30 pm, the Clinical Consultant confirmed that TP4, TP5, TP6, and TP7 were performing moderately complex testing, but did not have documentation of initial training.