Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2257034	10/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Rocky Mountain Laboratories	12217 Lone Peak Pkwy, Ste 100, Draper, 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
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 record review of proficiency testing performance evaluations and interview with the technical supervisor (TS), the laboratory failed to attest that proficiency testing (PT) samples were tested in the same manner as patient specimens for proficiency samples in 2023 for College of American Pathology (CAP) PT testing events 1 and 2 for bacteriology and virology. Findings include 1. A review of the proficiency testing performance evaluations on 10/25/23 revealed that the laboratory director or designee and testing personnel performing testing failed to sign the attestation statements for the CAP 2023 Microbiology - 1st and 2nd events and the CAP 2023 Virology - 1st and 2nd events. 2. In an interview on 10/25/23 at 1:55 PM, the TS confirmed that the laboratory director or designee and testing personnel performing testing failed to sign the attestation statements.
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 a review of Proficiency Testing (PT) documentation and an interview with the Technical Supervisor (TS), the laboratory failed to maintain documentation of each step in in the testing and reporting of results for proficiency testing samples the CAP 2023 Microbiology - 1st and 2nd events and the CAP 2023 Virology - 1st and 2nd events. Findings include: 1. Record review of PT documentation of the CAP 2023 Microbiology - 1st and 2nd events and the CAP 2023 Virology - 1st and 2nd events on 10/25/23 failed to produce signed attestation statements, instrument printouts, PT program report forms, and documentation of who handled, prepared, processed, ran, and resulted each step of the PT submissions, instrument printouts, and PT forms. 2. In an interview on 10/25/23 at 2:00 PM, the TS confirmed that the laboratory did not retain required PT documentation for CAP Virology and Microbiology 2023 events.
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on patient test record review and interview with the QA Manager, the laboratory failed to retain test requisitions for at least 2 years for samples received by the laboratory for one of five patient records reviewed. The laboratory performed approximately 810,000 tests annually. Findings include: 1. Review of patient test records on 10/25/2023 failed to include requisitions for one of five samples that were received and analyzed by the laboratory. 2. The QA Manager confirmed during interview on 10/25/2023 at approximately 4:00 PM, that test requisitions are not always retained for at least 2 years.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on Record review and interview with the Technical Supervisor (TS), the laboratory failed to twice annually evaluate the accuracy of analytes of molecular panels that were not included in subpart I since the laboratory began operation in April 2022. The laboratory performed approximately 300,000 molecular tests annually. Findings include: 1. Record review on 10/25/2023, revealed a lack of documentation to verify twice annually the accuracy of analytes not included in subpart I of molecular respiratory pathogens panel, urinary tract infection panel, gastrointestinal pathogen panel, sexually transmitted infections panel, wound infections panel, nail, fungal panel, and women's health panel. 2. In an interview with

	the TS on 10/25/2023 at 2:20 PM, it was confirmed that the laboratory failed to twice annually evaluate the accuracy of analytes in molecular panels that were not included in subpart I.
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 a review of the laboratory procedure manual and interview with the technical supervisor (TS), the laboratory failed to include reference ranges in four of four standard operating procedures (SOPs) checked for molecular, chemistry, immunology, and hematology tests. The laboratory performed approximately 810,000 tests annually. Findings include: 1. Review of SOPs on 10/25/2023 showed that four of four SOPs failed to include reference ranges for all laboratory molecular, chemistry, immunology, and hematology testing performed by the laboratory. 2. Interview on 10/25/2023, at approximately 4:00 PM, the TS confirmed that the laboratory failed to include reference ranges in SOPs.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation of the laboratory and interview with the technical supervisor (TS), the laboratory failed to properly label two of two open bottles of Terrace Denatured Ethanol 95% with opened dates and expiration dates used with molecular Kingfisher Flex instrument. The laboratory performed approximately 300,000 molecular tests annually. Findings include: 1. Direct observation of the

	laboratory on 10/25/2023 at approximently 12:50 PM revealed two of two open bottles of Terrace Denatured Ethanol 95% used in molecular testing with the Kingfisher Flex instrument were not labeled with opened dates and expiration dates. 2. Interview with the TS on 10/25/2023 at approximately 12:55 PM confirmed the open bottles of Terrace Denatured Ethanol 95% were not labeled with opened dates and expiration dates.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a review of personnel competency documentation and interview with the technical supervisor (TS), the laboratory director (LD) failed to ensure competency for two of two technical supervisors (TS), and two of two general supervisors (GS). Findings include: 1. Review of 2022 and 2023 personnel competency documentation on 10/25/2023 revealed the laboratory failed to perform competency assessments for TS #1, TS #2, GS #1, and GS #2 for 2022 and 2023. 2. Interview with TS #1 on 10/25 /2023 at 10:45 PM confirmed the LD failed to ensure competency for two of two TS, and two of two GS for 2022 and 2023.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the technical supervisor, the laboratory failed to have documentation of academic credentials to qualify two of nine high complexity testing personnel (refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum,

include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) 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)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of personnel documentation and interview with the technical supervisor (TS), the laboratory failed to have the required documentation to qualify two of nine high complexity testing personnel (TP). Findings include: 1. Review of personnel documentation on 10/25/2023 revealed the laboratory failed to have academic credentials to qualify TP #7 and TP #8. 2. Interview with the TS on 10/25/2023 at 10:30 PM confirmed, the laboratory failed to have the required documentation to qualify the individuals serving as TP #7 and TP #8.