Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2257034	09/19/2025
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
D0000	The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: _ D5400 - 42 CFR 493.1250, Condition: Analytic systems D5800 - 42 CFR 493.1290, Condition: Postanalytic Systems _
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: _ Based on surveyor record review and staff interviews, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems by not including step by step instructions for manual integration of chromatogram peak area, pertinent literature references, and a description of the course of action to take if a test system becomes inoperable in its procedure (see D5403), by not properly establishing performance specifications for multiple assays (see D5423), by not determining calibration procedures based on establishment of performance specifications (see D5425), and by not retaining all validation run data of assay establishment studies for LC/MS/MS (see D5427) _
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test

	procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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's procedure manual and an interview with the technical supervisor, the laboratory failed to include step by step instructions for manual integration of chromatogram peak area, pertinent literature references, and a description of the course of action to take if a test system becomes inoperable in its written procedure for drug confirmation by LC/MS/MS testing. Findings Include: 1. On 09/09/2025, a review of the procedure manual for the LC/MS/MS drug confirmation test revealed it did not contain step by step instructions for the manual integration of chromatogram peak area for calibration, controls, and patient samples, pertinent literature references, and a course of action to take if the test system became inoperable. 2. The technical supervisor confirmed during an email interview on 09/19 /2025 at approximately 3:30 PM that manual integration was performed, there were pertinent literature references, and there was a course of action to take when the system was inoperable. All these components were not present in the laboratory's written procedure for LC/MS/MS drug confirmation. _
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: _ 1. Based on record review and interview with the Technical Supervisor, the laboratory failed to establish the performance specifications for interfering substances

	for Measles analyte testing on the QuantStuduio for the molecular Laboratory Developed Test (LDT). Finding Include: a. Review of "Validation Summary Testing: Influenza A, Influenza B, Measles" validation revealed lack of verification for interfering substances for the Measles analyte since testing began on 5/6/2025. b. Interview with Technical Supervisor on 9/3/2025 at approximately 2:15 p.m. confirmed the laboratory failed to document verification for interfering substances for the Measles analyte since testing began on 5/6/2025. _ 2. Based on a review of laboratory records, and interview with the technical supervisor, the laboratory failed to establish and document performance specifications for each test system by not including a complete list of mass transitions and which internal standards are used for each analyte and not evaluating analytical specificity to include interfering substances in its method validation for LC/MS/MS drug confirmation. Findings Include: a. A review of the laboratory's LC/MS/MS validation studies on 09/09/2025 revealed the laboratory failed to define the test system established by not including a list of the key instrument parameters of the mass transitions and which internal standard was used for each analyte. b. A review of the laboratory's LC/MS/MS validation studies on 09 /09/2025 revealed no documentation of analytical specificity studies of various urine samples that could cause interference. c. The laboratory's technical supervisor, in an email on 09/19/2025 at approximately 3:30 PM, confirmed that the laboratory failed to define the test system established by listing a complete list of mass transitions and which internal standards are used for each analyte and failed to evaluate analytical specificity of various urine samples that could cause interference. d. The laboratory performs approximately 1,115,810 toxicology test annually. _
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) (b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: _ Based on review of the laboratory procedure manual, method validation, and interview with the technical supervisor, the laboratory failed to ensure the test system's calibration procedures align with laboratory practice for the FCLong Urine Confirmation Method by LC/MS/MS. Findings Include: 1. A laboratory procedure entitled "FCLong Urine Confirmation Method SOP" was reviewed on 09/09/2025. This procedure included instructions for using historical calibration curves for the urine drug testing for LC/MS/MS confirmation test. 2. Review of validation documentation on 09/09/2025 failed to provide documentation that the use of historical calibration curves had been validated. 3. On 09/19/2025 at approximately 3: 30 PM, the technical supervisor was not able to identify a validation study that addressed the use of historical calibration curves. 4. The laboratory performs approximately 1,115,810 toxicology test annually. _
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section.

	This STANDARD is not met as evidenced by: _ Based on a review of laboratory records, and an interview with the technical supervisor, the laboratory failed to retain the records of validation studies for the laboratory-developed test (LDT) used for toxicology confirmation by LC/MS/MS. Findings Include: 1. On 09/09/2025, a review of the laboratory's validation records for the LC/MS/MS toxicology confirmation LDT failed to produce any run data. 2. The technical supervisor confirmed via email on 09/19/2025 at 3:30 PM that the laboratory did not maintain any run data for its validations by LC/MS/MS. _
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: _ Based on record review and interview with the Technical Supervisor, the laboratory failed to monitor and evaluate the overall quality of the postanalytical system resulting in failure to issue corrected results due to an analyzer cut-off error. (See D5821) _
D5821	TEST REPORT CFR(s): 493.1291(k) (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 record review and interview with Technical Supervisor, the laboratory failed to notify and issue amended reports for 64 of 64 patient reports due to an incorrect Amphetamine cut-off entered in the Beckman Coulter AU 480/680 analyzer since May 2025. Findings include: 1. Review of incident tracking form revealed an error for Amphetamine cut-off on 5/13/2025 resulting in 64 affected patients. 2. Interview with the Technical Supervisor on 9/3/2025 at approximately 11:30 a.m., confirmed the lab discovered a cut-off error on 5/13/2025 and as of 9/3/2025 no amended reports or corrected results have been issued. _
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: _ Based on personnel competency evaluations review, lack of documentation, and interview with the Technical Supervisor, the laboratory failed to reevaluate 8 of 8 testing personnel for addition of Measles analyte to Molecular assay since 5/6/2025. Findings include: 1. Competency and training records review revealed the laboratory failed to include documentation of performance reevaluation for 8 of 8 Testing Personnel for high complexity molecular testing since 5/6/2025. 2. In an interview conducted on 9/03/2025 at approximately 10:55 a.m., the Technical Supervisor confirmed the laboratory failed to include documentation of performance reevaluation for 8 of 8 Testing Personnel for high complexity molecular testing since 5/6/2025. _