Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2335453	10/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Rocky Mountain Laboratories	4150 Freidrich Lane, Ste J, Austin, TX	

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 Rocky Mountain Laboratory in Austin was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an initial survey on 10/13/2026 and certification is recommended. Standard level deficiencies were cited.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies and procedures, observation, interview, and pre-survey paperwork, the laboratory failed to provide a sink in the laboratory for handwashing after handling potentially hazardous material in the real-time reverse transcription polymerase chain reaction (RT-PCR) laboratory for the detection of nucleic acid from bacteria, viruses, fungi, and parasites for eight of eight months from February 2026 - October 2026. Findings follow. A. Review of the Thermo Scientific KingFisher Flex User Manual (revision 1.2, Cat no N07669), under Precautions and Limitations stated, "Wash your hands thoroughly after handling test fluids." B. 1. Review of the laboratory policy and procedure titled BioSafety Manual (version 3, approved 07/24/2026), under VII General Laboratory Practices and Techniques at H. Work practice Controls stated, "7. Handwashing a) Hands should be washed as soon as possible when they come into contact with potentially infectious materials. A rigorous handwashing with a mild soap for 20 full seconds is appropriate. b) Hands should also be washed as soon as feasible after gloves are removed and before exiting the laboratory." 2. Review of the laboratory's policy and procedure titled Real-Time PCR with Quant Studio (version 1.1, approved 06/06 /2026), under Safety stated, "1. Wear appropriate PPE when handling specimens,

	including gloves and a lab coat. 2. If aliquoting specimen or otherwise handling specimen in a way that increases the risk of splashing, use a bench splash shield or additional PPE such as a face shield, goggles, mask, etc. 3. Ethanol: 1. Hazard: Flammable liquid and vapor. Causes severe eye irritation. Causes respiratory tract irritation. This substance has caused adverse reproductive and fetal effects in humans. May cause central nervous system depression. May cause liver, kidney and heart damage. Causes moderate skin irritation. 2. Response: Flush exposed eyes and surfaces of the body with water. If ingested, drink milk or water. If inhaled, relocate to fresh air immediately." The policy and procedure titled Real-Time PCR with Quant Studio did not include handwashing. C. During a tour of the laboratory on October 13, 2026 at 1425 hours, the surveyor observed no sink for handwashing in the laboratory. D. Interview with the Technical Supervisor on October 13, 2026 at 1425 in the laboratory confirmed there was no sink in the laboratory. E. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed testing began 02/09/2026 (elapsed time 8 months 4 days). Review of the pre-survey paperwork titled CMS Form 116 showed an estimated test volume of 1,706,981 per year in the specialty of Microbiology.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies and procedures, observation, interview, and pre-survey paperwork, the laboratory director failed to provide a sink in the laboratory for handwashing after handling potentially hazardous material in the real-time reverse transcription polymerase chain reaction (RT-PCR) laboratory for the detection of nucleic acid from bacteria, viruses, fungi, and parasites for eight of eight months from February 2026 - October 2026 (see D3011).