Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0978424	01/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Virus Isolation And Serology Lab	Bldg 310, Floor 1, Ware Drive, Frederick, MD	

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	A Federal Surveyor from the Division of Clinical Laboratory Improvement and Quality (DCLIQ) Survey Branch conducted an announced CLIA recertification survey at the Virus Isolation and Serology Laboratory on January 14, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be out of compliance with standard level CLIA requirements. The following standard level deficiency was found.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation during a laboratory tour, review of laboratory room temperature records, review of instrument manufacturer's specification sheet and interview with the Technical Supervisor (TS), the laboratory failed to establish an acceptable room temperature range consistent with instrument manufacturer's operating room temperature requirements for 31 of 31 days in December 2025. Findings: 1. During a tour of the laboratory room 105 on 01/14/2026 at 11:45 AM, an illumina MiSeq System instrument, S/N: MO-7814, was observed used for specimen testing. 2. A review of the Rees Scientific automated room temperature monitoring system records revealed an acceptable room temperature range for room 105 as 59F to 77F (15C to 25C), which was established by the laboratory. 3. A review of the illumina MiSeq

	System specifications revealed the following room temperature requirement for operation of the instrument, 22C =/- 3C (66.2F to 77F). 4. In an interview on 01/14 /2026 at 12:00 PM, the TS confirmed the laboratory failed to establish an acceptable room temperature range consistent with the instrument manufacturer's operating requirements in room 105 for 31 of 31 days in December 2025.