Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0947274	01/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Clia Molecular Diagnostics Laboratory	8560 Progress Drive Atrf C3023, 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 CLIA Molecular Diagnostics Laboratory on January 16, 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 deficiencies were found.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory specimen handling and shipping policies and procedures and interview with the Laboratory Director, the laboratory failed to ensure patient specimen stability by not measuring and recording temperatures of blood specimen received for two of two years (2024 and 2025). Findings: 1. A review of the laboratory's Blood Collection for Pharmacogenomics Testing procedure, Doc. Number CMDL-SOP0605, v1.3, page 3, revealed blood samples are to be shipped on cold packs or wet ice and stored at 4C upon receipt at the laboratory. 2. A review of the NCI at Frederick, Shipping Requirements, Shipping Temperatures table revealed Blood samples are to be stored at 4C. 3. A review of the CLIA Specimen Submission, Handling, and Referral policy, Doc. Number CMDL-SP0107, v1.4, page 3 revealed the following blood storage statement, "stored at 2C to 8C immediately after venipuncture. Blood samples should be shipped to the laboratory as quickly as

	possible (on wet ice or cold packs) after collection ..." 4. In an interview on 01/16 /2025 at 11:20 PM, the Laboratory Director confirmed the following for two of two years: a. Specimen temperatures were not monitored during transit to the laboratory. b. Specimen temperatures were not measure and recorded upon receipt at the laboratory. c. Specimen received at the receiving dock were delivered to the respective laboratory rooms within 15 minutes of receipt and left on the floor at the doorway.
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 instrument operation manuals, review of room humidity records, and interview with the Laboratory Director, the laboratory failed to ensure room humidity was in acceptable ranges consistent with instrument manufacturer's requirements for operation for up to 112 of 112 days in laboratory rooms in 2025. Findings: 1. During a laboratory tour on 01/16 /2026 at approximately 10:00 AM, the following testing instruments were observed used for specimen testing in the following rooms. Room C002 ThermoFisher Scientific KingFisher Flex, S/N: 711-80339 Room C005 Agilent 4200 TapeStation System, S/N: DEDAC02117 ThermoFisher Scientific SeqStudio Flex Series Genetic Analyzer, S/N: 24433-050 Room C026 Hamilton Microlab Prep, S/N: PRPDB1950 2. A review of instrument operation manuals revealed the following room humidity requirements: Thermo Scientific KingFisher Flex, Rev. 1.2, page 22, stated, Room Humidity Requirement: 10% to 80% (non-condensing). Agilent 4200 TapeStation System Manual, page 30, stated, Room Humidity Requirement: 15% to 80% (non-condensing). ThermoFisher Scientific SeqStudio Flex Series Genetic Analzer, page 541, stated, Room Humidity Requirement: 20% to 80% (non-condensing). Hamilton Microlab Prep, page 55, stated, Room Humidty Requirement: 15% to 85% (non-condensing). 3. A review of laboratory room humidity records revealed the following dates where room humidity exceeded the instrument manufacturer's lower limits of acceptability for the corresponding rooms: Room C002 Number of days when room humidity reading was less than 10% = 31 Days. 01/05/2025, Humidity (H) = 7.35% 01 /06/2025, H = 8.36% 01/08/2025, H = 8.26% 01/09/2025, H = 5.33% 01/10/2025, H = 7.35% 01/14/2025, H = 8.54% 01/15/2025, H = 7.35% 01/16/2025, H = 7.46% 01/21 /2025, H = 4.00% 01/22/2025, H = 4.98% 01/23/2025, H= 3.58% 01/24/2025, H = 8.68% 01/25/2025, H = 8.96% 01/28/2025, H = 9.48% 02/02/2025, H = 9.45% 02/18 /2025, H = 4.49% 02/19/2025, H = 4.84% 02/20/2025, H = 5.95% 02/21/2025, H = 7.07% 02/22/2025, H = 8.75% 03/02/2025, H = 5.95% 03/03/2025, H = 8.05% 04/09 /2025, H = 9.17% 12/05/2025, H = 8.61% 12/09/2025, H = 6.79% 12/15/2025, H = 5.89% 12/16/2025, H = 7.70% 12/17/2025, H = 9.73% 12/22/2025, H = 9.03% 12/30 /2025, H = 9.31% 12/31/2025, H = 7.35% Room C005 Number of days when room humidity reading was less than 20% = 112 Days (January 2025 through April 2025

	and November 2025 through December 2025) Random sampling of humidity readings: 01/02/2025, H = 12.47% 01/23/2025, H = 2.67% 02/02/2025, H = 8.89% 02 /21/2025, H = 6.16% 03/03/2025, H = 6.72% 03/27/2025, H = 12.03% 04/09/2025, H = 9.03% 11/29/2025, H = 12.03% 12/31/2025, H = 8.33% Room C026 Number of days when room humidity reading was less than 15% = 62 Days (January 2025 through April 2025 and November 2025 through December 2025) Random sampling of humidity readings: 01/05/2025, H = 8.33% 02/18/2025, H = 5.26% 03/03/2025, H = 9.24% 04/09/2025, H = 10.77% 11/28/2025, H = 12.10% 12/30/2025, H = 9.8% 4. In an interview on 01/16/2026 at 10:55 AM, the Laboratory director confirmed the lower acceptable room humidity limits required by instrument manufacturers were exceeded up to 112 of 112 days in three laboratory rooms in 2025.