

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2097127	(X3) Date Survey Completed 01/13/2026
Name of Provider or Supplier Molecular Characterization Laboratory	Street Address, City, State 459 Miller Dr, 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 Molecular Characterization Laboratory on January 13, 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.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory personnel competency records review and interview with the Quality Assurance Manager II, the laboratory failed to establish and follow written policies and procedures to assess Clinical Consultant competency for two of two years (January 2024 to January 2026). Findings: 1. A request for competency assessment records for the Clinical Consultant for the years 2024 and 2025 resulted in no competency records available. 2. A request for policies and procedures for Clinical Consultant competency assessment resulted in no policy or procedure. 3. In an interview on 01/13/2026 at 10:15 AM, the Quality Assurance Manager II confirmed the laboratory failed to establish written policies and procedure for the Clinical Consultant role and no competency assessment had been completed for the Clinical Consultant from January 2024 to January 2026.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

(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:

I. Based on a laboratory tour observation (Room 147), review of room humidity records, review of instrument guide and an interview with the Quality Assurance Manager II, the laboratory failed to establish an acceptable room humidity range consistent with instrument manufacturer's requirements for operation for 31 of 31 days in December 2025. Findings: 1. During a laboratory tour on 01/13/2026 at 12:50 PM, the following instruments were observed, used for testing patient samples in room 147. C1000 Touch Thermal Cycler and CFX Real-Time PCR Detection Systems: C-1000-4, S/N: CT025147 C-1000-2, S/N: CT020480 C-1000-1, S/N: CT023967 C-1000-16, S/N: CT056847 C-1000-5, S/N: CT016487 2. A review of the REES automated room humidity record system (Room 147), randomly selected month of December 2025, revealed the laboratory established a maximum humidity alarm limit at 85%. 3. A review of the Bio-Rad C1000 Touch Thermal Cycler and CFX Real-Time PCR Detection Systems Instrument Guide, page 10, revealed the manufacturer's environmental requirements for room humidity as 0% to 80%, noncondensing. 4. In an interview on 01/13/2026 at 12:45 PM, the Quality Assurance Manager II confirmed the laboratory failed to establish an acceptable room humidity range consistent with the instrument manufacturer's requirement for room 147 for 31 of 31 days in December 2025. II. Based on a laboratory tour observation (Room 126), review of room humidity records, instrument user guide, and an interview with the Quality Assurance Manager II, the laboratory failed to establish an acceptable room humidity range consistent with instrument manufacturer's requirements for 12 of 12 month from January to December 2025. 1. During a laboratory tour on 01/13/2026 at 10:15 AM, the following instrument was observed, used for testing patient samples in room 126. ThermoFisher Scientific Genexus Integrated Sequencer MoCha ID-Gen-5, S/N: 2619122016585 (Theo) 2. A review of the REES automated room humidity record system (Room 126), randomly selected month of January 2025, revealed the laboratory established an acceptable room humidity range of 0% to 80% from 01/01/2025 to 12/31/2025. 3. A review of the ThermoFisher Scientific Genexus Integrated Sequencer User Guide, page 233, revealed the manufacturer's environmental requirements for humidity for operation as 20-70%, non-condensing. 4. In an interview on 01/13/2026 at 12:45 AM, the Quality Assurance Manager II confirmed the laboratory failed to establish an acceptable room humidity range consistent with the instrument manufacturer's requirements for room 126 for 12 of 12 months from January to December 2025. III. Based on a laboratory tour observation (Room 124), review of room temperature records, instrument user guide, and an interview with the Quality Assurance Manager II, the laboratory failed to establish an acceptable room temperature range consistent with instrument manufacturer's requirements for 31 of 31 days in December 2025. 1. During a laboratory tour on 01/13/2026 at 10:15 AM, the following instruments were observed, used for testing patient samples in room 124. Ion GeneStudio S5 Prime Systems: MoCha S5-MC6, S/N: 2272816080048 MoCha S5-MC5, S/N: 245734500464 MoCha S5-MC4, S/N: 245777100542 2. A review of the REES automated room temperature record system (Room 124), randomly selected

month of December 2025, revealed the laboratory established an acceptable room temperature range from 15C to 30C. 3. A review of the ThermoFisher Scientific Ion GeneStudio S5 Prime Instrument User Guide, page 38, revealed the manufacturer's environmental requirements for room temperature for operation was 20C to 30C. 4. In an interview on 01/13/2026 at 12:45 PM, the Quality Assurance Manager II confirmed the laboratory failed to establish an acceptable room temperature range consistent with the instrument manufacturer's requirement for room 124 for 31 of 31 days in December 2025.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
Based on a laboratory tour observation, and interview with the Quality Assurance Manager II, the laboratory failed to create a system to compare test results, twice a year, to evaluate instrument test results for two of two years (January 2024 to January 2026). Findings: 1. During a tour on 01/13/2026 at 9:50 AM, the following instruments were observed used for specimen testing: Room 124 ThermoFisher Scientific Genexus Integrated Sequencers: MoCha ID-Gen-3, S/N: 2619120100218 (Simon) MoCha ID-Gen-1, S/N: 2619120010100 (Alvin) MoCha ID-Gen-5, S/N: 2619122016585 (Theo) (Room 126) Ion GeneStudio S5 Prime Systems: MoCha S5-MC6, S/N: 2272816080048 MoCha S5-MC5, S/N: 245734500464 MoCha S5-MC4, S/N: 245777100542 Room 126 ViiA 7 Real-Time PCR Systems: ViiA7-1, S/N: 278881556 ViiA7-2, S/N: 278882559 2. A request for test result comparison studies for the years 2024 and 2025 resulted in no comparison records. 3. A request for policies and procedures for test result comparison studies resulted in no policies and procedures. 4. In an interview on 01/13/2026 at 11:40 AM, the Quality Assurance Manager II confirmed the laboratory did not have policy and procedure established for test result comparisons and no comparison studies have been completed for the instruments mentioned above in rooms 124 and 126 for the years 2024 and 2025.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

(e)(13) 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 laboratory personnel competency records review and interview with the Quality Assurance Manager II, the Laboratory Director failed to document competency assessments for the Clinical Consultant for two of two years, 2024 and 2025. (Refer to Dtag 5209 for findings)