Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2137521	04/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Molecular Characterization Laboratory	321 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 recertification survey was conducted April 23, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) Form 209, laboratory's written policies and procedures, and interview with the Quality Assurance (QA) Manager, the laboratory failed to establish written policies and procedures to assess consultant competencies for 4 of 4 consultants. Findings Included: 1) Review of the submitted CMS-209 Form revealed 2 Clinical Consultants (CCs), 1 Technical Supervisor (TS) and 1 General Supervisor (GS) listed. 2) Review of the laboratory's policy titled 'HIS-SOP0213 Competency and Proficiency Testing Program-MoCha Histology' did not contain procedures for assessing consultant competency. 3) In an interview on 4/23/2026 at 10:30 in the conference room, the QA Manager confirmed the laboratory policy contained procedures for technician (testing personnel) competency and not consultant competency.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, proficiency testing (PT) records, test volumes, and interview with the Quality Assurance (QA) Manager, the laboratory failed to verify the accuracy of testing histopathology tissue/slide biopsy specimens twice a year for 2 of 2 years (2024 and 2025). Findings Included: 1) Review of the laboratory's policy titled 'HIS-SOP0213 Competency and Proficiency Testing Program - MoCha Histology' stated the following on page 1 of 5, "Technician competency in gross trimming is currently assessed for the measurement and physical description of the clinical biopsy samples submitted for H&E slide preparation and subsequent sequencing HIS-SOP0200, Clinical Specimen Processing Workflow. Pathologist competency/lab proficiency will not be evaluated until the method performed by the pathologist(s) is deemed a test, as defined by CLIA regulations." 2) Review of the laboratory's PT records revealed one 'in-house' accuracy assessment event per year completed in conjunction with testing personnel (TP) annual competencies, rotating blind split samples among TPs in 2024 and 2025. 3) Review of the laboratory's annual patient test volumes revealed the following specimens: 2024: 1 (Specimen ID(s): HIS00042) 2025: 6 Patients (Specimen ID(s): HIS00043-HIS00048) 3) In an interview on 4/23/2026 at 11:00 AM in the conference room, the QA manager stated the laboratory verified accuracy once a year, at the same time as TP annual competencies, and did not perform the accuracy assessments twice a year.
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 direct observation, review of the manufacturer's instructions, laboratory Reese Monitoring temperature records, laboratory policies and procedures and interview with the QA manager, the laboratory failed to define room temperatures and humidity in accordance with manufacturer instructions for 6 of 6 Optik Hematoxylin and Eosin Staining Reagents. Findings Included: 1) During a laboratory tour on 4/23 /2026 at 11:52 AM, the following reagents were observed stored for use: a. 2 Optik Hematoxylin staining bottles, 500 mL, Lot Number 230902, Manufacturer storage temperature requirements 20 to 30 degrees Celsius b. 4 Optik Eosin staining bottles, 500 mL, Lot Number 246404, Manufacturer storage temperature requirements 20 to 30 degrees Celsius. 2) Review of the laboratory's Rees Scientific temperature monitoring records (Input 79 ROOM TEMP 321/107-0013A200425FBB19:1) revealed an acceptable room temperature range of 15 to 30 degrees Celsius, exceeding the manufacturer's lower threshold for acceptable storage temperature. 3) Review of the laboratory's Environmental Monitoring policy revealed the following on page 3 of 5: "General Operating Parameters: 8.2.1. Acceptable operating conditions for the MoCha laboratory areas and controlled temperature units are listed below. Operating

	range is based on the manufacturer's specifications for the unit type. Laboratory rooms and controlled temperature units have alarm set points defined within the Rees system depending on the type of unit and established operating range. The alarm set points listed below have been defined within the acceptable operating range of the corresponding unit in an attempt to prevent excursions and maintain integrity of the contents within the storage area. Unit: Room Temperature, Acceptable Range (Low to High) 15 to 30 degrees Celsius, Alarm Set Points 15.5 to 29.5 degrees Celsius ... 4) In an interview on 4/23/2026 at 12:00PM in the conference room, the QA manager confirmed the findings the laboratory policy and Rees Scientific temperature monitoring settings had a setpoint defined outside of the bounds of manufacturer requirements.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) Form 209, laboratory personnel records, and interview with the Quality Assurance (QA) Manager of the laboratory, the laboratory director (LD) failed to ensure the delegation of clinical consultant (CC) responsibilities for 1 of 2 CCs. Findings Included: 1) Review of the submitted CMS-209 Form revealed 2 individuals listed as CCs (CC#1 and CC#2) in 2025. 2) Review of the laboratory's personnel records revealed a lack of responsibility delegations for the CC role for CC#2, appointed the position in 2025. 3) In an interview on 4/23/2026 at 10:30 AM in the conference room, the QA Manager confirmed CC#2 was appointed the role in 2025 and did not have a delegation of responsibilities from the LD before beginning duties.