Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2187803	03/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Molecular Evolution Core Clia Laboratory	950 Atlantic Drive, Nw, Atlanta, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 18, 2026. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the Standard Operating Procedures (SOPs) and staff interviews, the laboratory director failed to to establish and make available a downtime procedure

	for testing personnel. Findings: 1. A review of the Standard Operating Procedures (SOPs) revealed that the laboratory director failed to establish and make available a downtime procedure for testing personnel. 2. An interview, with TP#2 (CMS-209), in the laboratory, on February 18, 2026, at 12:32 PM, confirmed that a downtime procedure was not available.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Standard Operating Procedures (SOPs) and staff interviews, the laboratory director failed to ensure that all SOPs were reviewed prior to initiating patient testing. Findings: 1. A review of the Standard Operating Procedures (SOPs) revealed that the laboratory director failed to review and sign the SOPs for the years 2024 and 2025. 2. An interview, with TP#2 (CMS-209), in the laboratory, on March 18, 2026, at 12:32 PM confirmed that the laboratory director failed review and sign the SOPs during the identified timeframes, prior to initiating patient testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of equipment maintenance records and staff interviews, the laboratory failed to ensure adherence to the manufacturer's calibration schedule for the traceable thermometer. Findings: 1. A review of the equipment maintenance logs revealed that the laboratory failed to adhere to the calibration schedule for the traceable thermometer for the years 2024 and 2025. The most recent calibration was performed in July 2021 and expired in July 2022. 2. An interview, with TP#2 (CMS-209), in the laboratory, on February 18, 2026, at 12:32 PM confirmed that the laboratory did not adhere to the manufacturer's calibration schedule.