Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1107626	04/22/2026
Name of Provider or Supplier	**Street Address, City, State**	
Emory/Children's Lab Innovative Assay Development	101 Woodruff Circle, Room 2339, 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 April 22, 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 and staff interviews, the

	laboratory director failed to establish and make availabile a downtime policy and procedure for testing personnel. Findings include: 1. A review of the Standard Operating Procedures revealed that the laboratory director failed to establish and make available a downtime policy and procedure for testing personnel. 2. An interview with the General Supervisor (CMS-209), in the laboratory, on April 22, 2026, at 12:30 PM confirmed that a downtime policy and procedure was not available on the day of survey.
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 and interviews with laboratory staff, the laboratory director failed to ensure that Standard Operating Procedures were reviewed, signed, dated, and approved prior to initiating patient testing. Findings include: 1. A review of the Standard Operating Procedures revealed that the laboratory director failed to ensure that Standard Operating Procedures were reviewed, signed, dated, and approved 2024 thru 2025. 2. An interview, with the General Supervisor (CMS-209) on April 22, 2026, at 12:30 PM in his office confirmed that the laboratory director failed to ensure that Standard Operating Procedures were reviewed, signed, dated, and approved for 2024 and 2025 prior to initiating patient testing.