Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2284164	05/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Aumc Mobile Laboratory Services	1120 15th Street, Ba1667, Augusta, 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 May 16, 2025. 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: A review of the current Laboratory Procedure Manual (SOP) confirmed that required procedures were missing for several Federal CLIA required laboratory practices. THE

	FINDINGS INCLUDE: 1. A review of the SOP, in use, revealed that the following procedures not available at the time of survey: a. Downtime Retrieval & Documents Retention SOP b. Personnel SOP c. Quality Assurance SOP d. Safety Practices SOP e. Reagent Handling & Storage SOP f. Specimen Handling & Storage SOP. 2. An interview with the Quality Assurance Team, during review of the SOP, confirmed that the procedures were not completed. 3. An exit interview with the Quality Assurance Team, on May 16, 2025, at 12:45pm, in the conference room, confirmed the statemnets above.
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: A review of the current Laboratory Procedure Manual (SOP) confirmed that procedures were placed into use without prior written approval. THE FINDINGS INCLUDE: 1. An interview with the Technical Consultant 1, (TC1) listed on Form 209: Laboratory Personnel Report, revealed the Quality Assurance Procedure was not approved, signed, and/ or dated by the Laboratory Director. 2. An exit interview, with the Quality Assurance Team, on May 16, 2025, at 12:45pm, in the conference room, confirmed that the statement above.
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: A review of 2023 - 2025 Maintenance Records revealed that laboratory personnel failed to monitor and document the humidity of the testing areas. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Maintenance Records confirmed the absence of documented humidity records. I-STAT 1 System has a manufacturer required operating relative humidity of 10 -90%. 2. An interview with the Technical Consultant 1 (TC1), as shown on Form 209: Laboratory Personnel Report, confirmed that humidity readings were not taken and documented. 3. An exit interview conducted with the Quality Assurance Team, on May 16, 2025, at 12:45pm confirmed that laboratory personnel failed to monitor and document the humidity of the testing areas as required by the manufacturer.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)

	(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: A review of the 2023 - 2025 Quality Control (QC) Records, 2023 - 2025 Maintenance Records, 2023 - 2025 Temperature Records, and 2023 - 2025 Patient Results Records confirmed that the Laboratory Director (LD) failed to ensure that the testing systems provided quality laboratory services. THE FINDINGS INCLUDE: 1. A review of laboratory documents confirmed that Quality Assurance procedures were not being perfomed consisently by the Labortory Director. 2. A review of the QC, Maintainance, Temperature, and Patient Report records revealed that record reviews were performed by Technical Consultant 1 (TC1), as listed on Form 209; Laboratory Personnel Report. 3. A review of the Procedure Manual confirmed that the LD had not delegated duties to TC1, in writing as required by Federal CLIA regulations. 4. An interview with TC1 revealed that test results were downloaded from the i-STAT analyzers directly into the hospital records of the patient. TC1 confirmed that the results delivery system was not audited to confirm the delivery of accurate results to the hospital records. 5. An exit interview, conducted with the Quality Assurance Team, on May 16, 2025, at 12:45pm confirmed that the Laboratory Director (LD) failed to ensure quality of all laboratory services.