Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2291040	09/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Macon Medical Group, Pc	309 Osigian Blvd, Warner Robins, 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 September 26, 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:
D3003	FACILITIES CFR(s): 493.1101(a)(2) (a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: A tour of the laboratory confirmed that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies was not minimized. THE FINDINGS INCLUDE: 1. A tour of the laboratory confirmed that the Eyewash Station was mounted onto the faucet of the dirty sink where specimens and reagent waste was discarded. 2. An exit interview, with the Technical Consultant and Testing Personne, on September 26, 2025 at 1:30pm, confirmed that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies was not minimized.
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 Temperature Records confirmed that the laboratory failed to store the testing reagents in the conditions as required by the manufacturer. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Temperature Records revealed that the temperature log sheet indicated a monitoring temperature range of -22C - -8C for Reagent Storage Freezer #1 (RSF1) and Reagent Storage Freezer #2 (RSF2). 2. A tour of the laboratory confirmed that RSF1 was used to store Beckman Coulter Liquid Assay Multiqual Controls which has a storage requirement of -70C - -20C and Beckman Coulter Immunoassay Plus Controls with a storage requirement of -70C - -20C. 3. A tour of the laboratory revealed that RSF2 was used to store Beckman Coulter Immunology Controls which has a storage requirement of -70C - -20C and Beckman Coulter Immunoassay Plus Controls with a storage requirement of -70C - -20C. 4. A review of the 2023 - 2025 Temperature Logs confirmed that RSF1 maintained the proper storage temperature for 97 of 410 days and RSF2 maintained the proper storage temperature 113 of 410 days for the reagents stored within. 5. A tour of the laboratory revealed that the room in use for room temperature storage reagents and reagents requiring humidity monitoring storage did not have monitors for room temperature or humidity in place. 6. A tour of the laboratory revealed that in the Reagent Storage Room contained the following reagents: " Medonics M-Series Lyse Reagent has a storage requirement of room temperature storage of 5C - 35C and a room humidity storage of 20% - 85%; " Beckman Coulter Mid Standard Solution, Beckman Coulter ISE Buffer, Beckman Coulter Reference Solution, and Beckman Coulter Wash Solution which have a requires storage temperature of 2C - 25C. " Grenier Bio One Vacuette Blood Collection Vacutainer and Collection Needles that have a storage temperature requirement of 4C - 25C. 7. An exit interview with the Technical Consultant and Testing Personnel, on September 26, 2025, at 1:30pm, confirmed that the laboratory failed to appropriately store or monitor testing reagents as required by the manufacturer.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A review of 2023 - 2025 Maintenance Records, confirmed that the laboratory failed to validate through verification of the performance specifications, accuracy, precision, reportable range, and reference intervals for all analyzers before reporting patient test results. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Maintenance Records revealed that the required validation was not performed for the Clinitek Advantus Urinalysis Analyzer. 2. An exit interview with the Technical Consultant and the Testing Personnel, on September 26, 2025, at 1:30pm, that the laboratory failed to

	validate the Clinitek Advantus Urinalysis Analyzer prior to conducting patient testing and reporting.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: A review of 2023 - 2025 Maintenance Records, 2023 - 2025 Quality Control Records, and 2023 - 2025 2023 - 2025 Personnel Records, confirmed that the Laboratory Director (LD) failed to perform the required quality assurance oversight as required. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Personnel Records revealed that the LD delegated the quality assurance oversight to the Technical Consultant (TC). 2. A review of 2023 - 2025 Maintenance Records, 2023 - 2025 Quality Control Records, and 2023 - 2025 Personnel Records confirmed that the quality assurance records review was performed by the TC, rather than the LD. 3. An exit interview, with the Technical Consultant (TC) and the Testing Personnel (TP), on September 26, 2025, at 1:30pm, confirmed that the LD failed to perform the required quality assurance oversight.