Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0975982	05/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Middle Georgia Chest & Medical Center, Llc	1209 N Columbia Dr, Milledgeville, 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 recertification survey was performed on .May 1, 2025. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Calibration Verification documents for the Horiba Micros60 (Horiba) Hematology analyzer and staff interview, the laboratory did not perform the Calibration on the Horiba as stated in the Manufacturer Manual that calibrations should be performed every six months. Findings: 1. Review of the Calibration documents for the Horiba confirmed the laboratory failed to perform a Calibraton

	between April 2023 and March 2024, a period of 11 months. 2. Staff interview with Testing Personnel (TP) 1, in the upstairs office, at approximately2 pm., confirmed the aforementioned statements
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Document review of the Quality Control (QC) documents for the Specialty Chemistry, Sub-specialty Blood Urea Nitrogen (BUN) and Creatinine(Creat), and staff interview, confirmed the laboratory failed to cease testing when QC results for both analytes and levels of QC were outside 3SD (Standard Deviations). Findings 1. Review of the QC documents for May 16 thru May 19, 2023 revealed that between May 17 and May 18, 2023, both levels of the BUN QC was outside of 3SD. Review of the test log, on May 17 revealed that 71 patients had BUN results reported when the QC was out of the acceptance range. 2. Review of the QC documents for May 16 thru 19, 2023 and March 6 thru March 8, 2024 revealed that the Creat QC was outside the acceptable range. Review of the test logs for May 16 thru 19, 2023 and March 6-8, 2024 confirmed that 168 patients had CREAT results reported when the QC was out of the acceptance range. 3. Interview with Testing Personnel(TP) #1 in the upstairs office on 5-1-25 at approximately 3pm confirmed the aforementioned statements
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the Patient's Requisition and staff interview the Laboratory Director (LD) failed to prevent patient test results from being reported when the system is not functioning properly. Findings: 1. Review of Quality Control documents and Patient's Requisition, the laboratory released patient results when the QC for BUN and CREAT during May 16 thru May 18, 2023 patient results were released when the QC values were outside acceptable range. On March 6 thru March 8, 2024 CREAT results were released when the QC values were outside acceptable range. 2. Interview with Testing Personnel (TP) 1, as listed on the Centers for Medicare and Medicaid (CMS) 209 Personnel form, on 5/1/2025, in the upstairs office, confirmed the aforementioned statement.