Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0975982	05/25/2021
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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on February 25, 2021. 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:
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) documents for the Horiba ABX Micro 60 (ABX60) hematology analyzer, the laboratory failed to document acceptable QC for three days in January, 2021, for the analyte Hemoglobin (Hgb), and Mean Corpuscular Hemoglobin. Patient results were reported on these three days Findings: 1. Review of the QC documents for January 2021, the laboratory failed to document acceptable Hgb and MCH, for January 11, 12, 13, 2021. Review of the patient logs showed that there was 54 patients which had a Complete Blood Cell Count (CBC) performed on January 11, 12, 13, 2021. The Hgb and MCH are part of the CBC panel. 2. QC documents showed that on January 11, and 12, Hgb was out of range for the Low, and Normal control. On January 13, Hgb was out of range for the Normal and

	High control. On January 12, for MCH, the Low, Normal, and High controls were all out of acceptable range. On January 13, and 14, the Normal and High controls for MCH were out of acceptable range. 3. Interview with the Laboratory Director (LD), on 05/25/2021, at approximately 1:45 pm in the laboratory, confirmed that the above aforementioned QC was out of range, and that 54 patient CBC results was released on those three days.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) procedure and QC documents for the Opti CCA TS Blood Gas Analyzer (Opti) for testing Arterial Blood Gasses (ABG's), and staff interview, the laboratory failed to document two controls of different concentrations at least once each day, patient specimens are assayed. Findings: 1. Review of the QC procedure and QC documents for the Opti, the laboratory did not document two controls of different concentrations each day of patient testing for ABG's. 2. Interview with the Laboratory Director (LD) on 05/25/2021 , at approximately 1:30 pm in the Laboratory , confirmed that the laboratory was not performing two levels of different concentrations at least once each day, patient specimens are assayed. It was also confirmed that an Individualized Quality Control Plan (IQCP) had not been performed.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) procedure and QC documents for the Opti CCA TS Blood Gas Analyzer (Opti) for testing Arterial Blood Gasses (ABG's), and staff interview, the Laboratory Director (LD) failed to verify that the laboratory documented two controls of different concentrations at least once each day, patient specimens are assayed. Findings: 1. Review of the QC procedure and QC documents for the Opti, the laboratory did not document two controls of different concentrations each day of patient testing for ABG's. 2. Interview with the Laboratory Director (LD) on 05/25/2021 , at approximately 1:30 pm in the Laboratory , confirmed that the laboratory was not performing two levels of different concentrations at least once each day, patient specimens are assayed. It was also confirmed that an Individualized Quality Control Plan (IQCP) had not been performed.

D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) procedure and QC documents for the Opti CCA TS Blood Gas Analyzer (Opti) for testing Arterial Blood Gasses (ABG's), and staff interview, the Technical Consultant failed to verify competency of the staff for performing Quality Control(QC). The testing personal failed to document two controls of different concentrations at least once each day, patient specimens are assayed. Findings: 1. Review of the QC procedure and QC documents for the Opti, the laboratory did not document two controls of different concentrations each day of patient testing for ABG's. 2. Interview with the Laboratory Director (LD) on 05/25 /2021 , at approximately 1:30 pm in the Laboratory , confirmed that the laboratory was not performing two levels of different concentrations at least once each day, patient specimens are assayed. It was also confirmed that an Individualized Quality Control Plan (IQCP) had not been performed.