Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0975982	01/17/2019
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 January 17, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluation reports for the 2017 3rd event, and staff interview, the laboratory failed to provide acceptable corrective action for an unsatisfactory score for Calcium. Findings: 1. Review of the API PT evaluation reports showed that on the 3rd event for 2017, the laboratory received a score of 20% on the regulated analyte Calcium. Review of the Corrective Action provided for the unsatisfactory 20% score for Calcium the lab did not identify or correct the problem. 2. Interview with the Laboratory Director and the Technical Consultant on January 17, 2019 at approximately 12:25 pm in exam room #9, confirmed that there was not enough follow-up documentation to determine the reason or provide a solution for the score of 20% for the analyte Calcium.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (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 Horiba Micros Hematology analyzer calibration documents for 2017 and 2018, Quality Assurance(QA) documents, and staff interview, the laboratory failed to perform calibrations at least once every 6 months. The fiindings include: 1. Review of the Horiba Micros Hematology analyzer calibration documents showed a calibration was performed in October 2017, and February 2018 (Field service), and December 2018. There was no calibration documentation for a calibration in August 2018 which would have been 6 months from Feburary 2018. 2. Review of the QA documents for August, September, October, and November 2018, stated that Calibration was performed February 2018 and was due August 2018. QA documents were signed as being reviewed by the Lab Tech and the Laboratory Director. 3. Interview with the Technical Consultant, and Laboratory Director on January 17 2019 at approximately 12:45pm in exam room 9, confirmed that the calibration was not performed in August of 2018. A period of 10 months from February to December.