Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0983961	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cynthia Chambless Md	6501 Peake Road Building 200, Macon, 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 27, 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:
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 calibration records of the Sysmex XP-300 Hematology

	analyzer from 2017 and 2018, and staff interview the laboratory was not calibrating the Hematology Analyzer every 6 months as required. Findings: 1. Review of the Sysmex XP-300 hematology analyzer calibration records from 2017 and 2018, showed that the laboratory had not calibrated the analyzer every 6 months as required. The records show that there was a calibration performed: 11-2016 3-2017 - 4 months 3-2018 - 12 months 10-2018 - 7 months 2. Interview with staff #2 (CMS-209 form) on 02/27/2019 at approximately 12:45 pm in the back office, confirmed that the calibration was performed as stated above.
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 Sysmex XP-300 (CBC analyzer) and staff interview the laboratory was not reviewing the Levey Jennings(LJ) Charts for the QC to detect immediate errors. Findings: 1. Based on review of the QC documents for the CBC analyzer, the laboratory was not documenting review of the LJ charts to detect shifts and trends of the QC results 2. Interview with staff #2, on 02/27/2019 at approximately 12:45 pm in the back office confirmed that the laboratory was not printing or reviewing the LJ charts for the QC on the CBC analyzer.