Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0945324	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Blood Gas Lab Of Evans Memorial Hospital, Inc	200 North River Street, Claxton, 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 May 15, 2019. 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:
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 ePOC Arterial Blood Gasses (ABG's) analyzer, and staff interview, the laboratory failed to document two controls of different concentrations at least once each day, patient specimens were assayed. Findings: 1. Review of the QC procedure and QC documents for the ePOC ABG analyzer, the laboratory did not document two controls of different concentrations each day of patient testing for ABG's. 2. Interview with staff #1 (CMS 209 form) on May 15, 2019, at approximately 1:30 pm in the Hospital Administrative Conference room, 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.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of temperature records and staff interview, the lab failed to document corrective actions when temperatures were outside acceptable limits. Findings include: 1. Review of the temperature charts revealed the refrigerator was out of the acceptable range from January 2018 to January 2019 , 234 out of 454 days. No corrective actions were documented. 2. Interview with testing personnel #1 (CMS 209 form), on May 15, 2019 at approximately 10:30 AM in the Hospital Conference Room, confirmed the corrective actions were not documented.