Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0978582	(X3) Date Survey Completed 03/19/2019
Name of Provider or Supplier Optim Medical Center - Tattnall	**Street Address, City, State** 247 South Main Street, Reidsville, 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 March 19, 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 Radiometer ABL 80 analyzer used for testing Arterial Blood Gases (ABG's) , review of QC records for D-dimer testing performed using the Alere Triage Meter and staff interview , the laboratory failed to perform two levels of controls with different concentrations at least once each day patient specimens were assayed. Findings: 1. Review of the QC procedure and QC documents for the ABL 80 ABG analyzer revealed the laboratory only performed external liquid control monthly or when a new lot number was placed into use and did not perform two external controls of different concentrations each day of patient testing. 2. Interview with the laboratory general supervisor and respiratory therapy supervisor (see CMS 209) on March 19, 2019 at 2 pm in the area where ABG testing is performed confirmed the laboratory was not performing two levels of different concentrations of external controls at least once each day patient specimens were assayed. They also confirmed an Individualized Quality Control Plan (IQCP) had not been performed. 3. Review of QC records for D-dimer testing performed on the Alere Triage meter revealed QC was only performed

	monthly and when a new kit or lot number was placed into use. 4. Interview with the laboratory general supervisor (see CMS 209) on March 19, 2019 at 2 pm in the area where D-dimer testing is performed confirmed the laboratory was not performing two levels of different concentrations of controls at least once each day patient specimens were assayed and also confirmed an Individualized Quality Control Plan (IQCP) had not been performed.