Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0933683	01/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kaiser Permanente - Gwinnett Medical Center	3650 Steve Reynolds Boulevard, Duluth, 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 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 deficiency was cited:
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to perform QC procedures for all laboratory testing as required. Findings include: 1. Hematology QC document review revealed no sperm count controls were performed for each day of patient testing for 2017, 2018, and 2019 thus far. 2. An interview with the General Supervisor in a medical office on 1/15/19 at approximately 2:30 p.m. confirmed sperm count controls were not performed for the aforementioned dates.