Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D1043842	01/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Women's Health Group, The	6363 W 120th Ave, Broomfield, CO	

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
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 a review of quality control (QC) records and staff interview, the laboratory failed to test a negative and a positive QC material each day patient specimens were assayed for the Chlamydia and Gonorrhea test since testing began on 8-28-17 and 73 patient specimens had been tested. Findings include: a. On 8-28-17, the laboratory began testing patient specimens for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) using the Cepheid Xpert CT/NG test system. b. Records showed the laboratory tested a positive and a negative QC material each day of patient testing for the first 30 days of patient testing. c. Records showed after 10-15-17, QC materials were tested once each month rather than each day of patient testing. d. Records showed from 10-16-17 through 1-26-18, QC materials had not been tested on 42 days of patient testing, and a total of 73 patients had been tested (OCT=15 patients across 10 days; NOV=25 patients across 12 days; DEC=18 patients across 8 days; JAN=15 patients across 12 days). e. Federal CLIA regulation requires external QC materials to be assayed either each day of patient testing or according to the frequency supported by the laboratory's Individualized Quality Control Plan (IQCP). f. The laboratory had not established an IQCP for the Cepheid Xpert CT/NG test system. g. Staff stated they were unaware of this regulatory requirement, and confirmed QC materials had not been assayed each day of patient testing as required by federal CLIA regulation.