Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0715273	07/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chesapeake Women's Care	2000 Medical Parkway Ste 306, Annapolis, MD	

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 quality control (QC) record review and interview with technical consultant (TC), the laboratory did not ensure that both a positive and a negative control were run each time external QC was run on the BD Affirm Microbial Identification System. Findings: 1. The laboratory uses a BD Affirm Microbial Identification System to test for Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis. A review of QC records from 2017 to 2018 showed that the laboratory was running a positive Candida albicans control on the BD Affirm but no negative external control. The laboratory did not run positive controls for Trichomonas vaginalis or Gardnerella vaginalis; 2. During an interview on 7/9/18 at 11:00 AM, the TC confirmed that a negative control and positive Trichomonas and Gardnerella controls were not being run, and stated that they were following the procedure manual from the company and were not aware that they needed to run the additional controls.