

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0876744	(X3) Date Survey Completed 09/10/2019
Name of Provider or Supplier Advanced Women's Care Of Pgh	Street Address, City, State 3928 Washington Rd, Suite 230, McMurray, PA	
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	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on quality control record review and interview with the GYN Nurse (Testing Person 7), and the Office Manager at the time of survey, the laboratory failed to perform the CMS required quality control for the Affirm VP III test, each day of patient testing. from June 2019 through the date of the survey. Findings include: 1. Affirm VP III quality control records reviewed, revealed the laboratory performed quality control using all 3 control organisms (Trichomonas vaginalis, Gardnerella vaginalis, and Candida albicans), each lot as per manufacturer instructions, for Affirm VP III test performed in 2019 from June 2019 through 09/10/2019. 2. CMS requires all 3 control organisms each day of patient testing, for Affirm VP III test . 3. The laboratory did not have an Individualized Quality Control Plan. 4. From the lab opening 05/24/2019 to the date of the survey, 105 patients were tested with the Affirm VP III test. 5. During the survey (14:30 09/10/2019), the Gyn Nurse (Testing Person 7), confirmed the above findings.</p>