

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0937879	(X3) Date Survey Completed 04/10/2018
Name of Provider or Supplier Upmc Speciality Care Ob/Gyn	Street Address, City, State 901 East Brady Street Suite 100, Butler, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: By personnel interview with the Office Manager and Testing Personnel#2, and review of the microbiology proficiency test records on the date of the survey (04/10/2018), all proficiency testing evaluation and verification activities were not documented. Findings: 1. The Director's review signature for proficiency test score reports were not found for 3 of 3 American Proficiency Institute micrology events in 2017. 2. The Laboratory did not document corrective action for a 60% parasitology score in the 2017 American Proficiency Institute micrology event 2. 3. During the survey, the Office Manager confirmed the above findings.</p>
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 Laboratory Testing Personnel #2 and the Office Manager at the time of survey (13:30 04/10/2018), the Laboratory failed to include a positive and negative control each day of patient testing for the Affirm vp III test. Findings include: 1. Records reviewed during survey</p>

revealed the Laboratory did not include a negative and positive control material at least once a day patients specimens were examined for the Affirm VP III test performed in 2017, from January through the date of the survey (04/10/2018). 2. The laboratory did not have an Individualized Quality Control Plan. 3. During the survey, the Office Manager, confirmed the above findings.