

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0714183	<b>(X3) Date Survey Completed</b> 07/24/2018
<b>Name of Provider or Supplier</b> Greater Binghamton Obstetrics & Gynecology, PLLC	<b>Street Address, City, State</b> 365 Harry L Drive, Suite 110, Johnson City, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of Medical Laboratory Evaluation (MLE) proficiency testing (PT) attestation statements for 2016 and 2017, and an interview with the practice manager, the laboratory failed to rotate PT samples among the two testing persons who have routinely performed bacteriology, mycology, and parasitology testing with the BD Affirm VPIII analyzer. Findings: The practice manager confirmed on July 24, 2018 at approximately 11:15 AM that the Affirm testing has been performed by the same testing person for the third event of 2016 and for all three events of 2017.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of PT records and confirmed in an interview with the</p>

practice manager, the laboratory director failed to ensure that bacteriology, mycology and parasitology samples tested with the Affirm VPIII analyzer were tested in the same manner as patient samples. Refer to D2007.