

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0714183	<b>(X3) Date Survey Completed</b> 03/27/2025
<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>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory systems Quality Assurance (QA) procedures, QA records, as well as interview with the Testing Person (TP), the laboratory failed to perform and document QA. FINDINGS: 1. There was no documentation of QA records for 2024. 2. This was contrary to instructions indicated in the current, approved QA Plan. 3. The TP confirmed the findings on March 27, 2025, at approximately 1:00 P.M.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria</p>

for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the Standard Operating Procedures (SOPs), lack of thermometer calibration records, as well as interview with the TP, the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no calibration certificate documentation for the thermometers utilized for ambient, refrigerator temperatures and humidity monitoring in the laboratory where patient specimen processing occurred. 2. The current, approved SOPs did not include instructions for thermometer calibration and certificate retention. 3. The TP confirmed the findings on March 27, 2025, at approximately 11:00 A.M.