

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0167925	<b>(X3) Date Survey Completed</b>  10/02/2019
<b>Name of Provider or Supplier</b>  Women's Ob/Gyn, Pc	<b>Street Address, City, State</b>  401 Main St, 1st Fl, 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 a surveyor's review of the laboratory's Quality Assurance (QA) policy and confirmed in an interview with the laboratory manager and testing person, the laboratory failed to follow their established written QA policy and perform an annual QA review, as required by the laboratory's QA policy, for the calendar year 2018.</p>
<b>D6021</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's QA policy and confirmed during the interview with the laboratory manager and testing person, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to: D5291</p>