

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D1092859	<b>(X3) Date Survey Completed</b> 11/19/2018
<b>Name of Provider or Supplier</b> Gastroenterology Consultants	<b>Street Address, City, State</b> 24-07 A Broadway, Fair Lawn, NJ	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Staff (OS) and on phone with the Laboratory Director, the laboratory failed to follow Section III, Subject: "Pathology laboratory Performance Improvement Plan" Title: 'Responsibility' procedure from 11/1/16 to the date of survey. The finding includes: 1. The PM stated 'A report received from another outside laboratory' but the laboratory did not receive any reports from another outside laboratory in the calendar year 2017 and 2018. 2. The OS confirmed on 11/19/18 at 10:15 am that the PM was not followed.</p>
<b>D6091</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Biannual Assessment (BA) records and interview with the Office Staff (OS) and on phone with the Laboratory Director (LD), the LD failed to ensure that results of Histopathology tests received from the reviewer were</p>

reviewed and evaluated for the calendar year 2017 and 2018. The OS confirmed on 11/19/18 at 10:00 am that the BA records were not reviewed and evaluated by LD.