

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1100095	(X3) Date Survey Completed 05/09/2019
Name of Provider or Supplier Gastroenterology Consultants	Street Address, City, State 693 Main Street, Amherst Commons, Lumberton, NJ	
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
D3027	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1)</p> <p>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Immunohistochemistry Stain (IHC) records and interview with the Laboratory Director (LD), the laboratory failed to retain Test Requisition (TR) for IHC stain from 6/1/17 to the date of survey. The LD confirmed on 5/9/19 at 11:00 am that the TR were not retained.</p>
D5401	<p>PROCEDURE MANUAL 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 Laboratory Director (LD), the laboratory failed to include all procedures needed to be in the PM from 6/1/17 to the date of survey. The findings include: 1. The laboratory did not have procedures for Microscope Maintenance, Records and Slides Retention and Biannual Assessment. 2. The LD confirmed on 5/9/19 at 11:15 pm that the laboratory did not have procedures mentioned above.</p>

D5601

HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to document reaction of Hematoxylin and Eosin (H&E) control slide from 6/1/19 to the date of the survey. The LD confirmed on /19 at 11:25 am that the laboratory did not document H&E QC stain reaction.