

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2075642	<b>(X3) Date Survey Completed</b>  04/29/2019
<b>Name of Provider or Supplier</b>  Gastroenterology Consultants Of Central Florida Pa	<b>Street Address, City, State</b>  10800 Dylan Loren Cir Ste 102, Orlando, FL	
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>D0000</b>	AMENDED 8/09/19 Initial Certification survey was conducted on 4/29/19. Gastroenterology Consultants of Central Florida PA was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5601</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(a)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a negative control slides for recording the negative reactivity for each for Immunohistochemical (IHC) stains . Findings: Only the microscopic examination of the slides is performed at the laboratory. Review of patient slides showed that there was no negative control slides for 2 (#2, 3) out of 3 (#1, 2, 3) patient slides reviewed. Patient #2 and #3 each had a CD3 (Cluster of Differentiation 3 lymphocyte IHC stain) and a Helicobacter pylori IHC stained slides. IHC stains at the laboratory include, CD3 and Helicobacter pylori. During an interview on 4/29/19 at 11:00 AM, the Office Manager confirmed she was unable to locate any negative control slides for IHC stains.</p>