Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2185384	10/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Consultants Of Boca Raton	951 Nw 13th St Suite 2e, Boca Raton, FL	

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
D0000	An initial survey conducted on 10/12/2020 found that the Gastroenterology Consultants of Boca Raton clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and staff interview, the laboratory failed to document the positive and negative control reactivity verification for the immunohistochemical (IHC) stain that the laboratory performed for 3 (BG20-022, BG20-119, BG20-198) out of 3 patients reviewed since 6/18/2020. The findings include: -The laboratory started testing since 6/18/2020. -Test menu for Immunohistochemical (IHC) stains revealed that the laboratory used 3 different IHC: Cluster Differentiation 3 (CD3), Helicobacter Pylori (HP) and Homeobox Protein CDX-2 (CDX-2). - Review of patient reports: BG20-022, BG20-119 and BG20-198, revealed that 3 out of 3 had immunohistochemical stains (CD3, CD-X3 or HP), no documentation of the evaluation of the reactivity of the positive and negative control was found in the laboratory logs or patient reports. The laboratory performed the interpretation of 127 cases using IHC from 6/18/2020 to 10/12/2020. During an Interview on 10/12/2020 at 11.30 am, the office manager confirmed that the laboratory failed to document the positive and negative control reactivity for the immunohistochemistry stains for the cases of reference.