Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0872089	09/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Boca Raton Gastroenterology Center Pa	1000 Nw 9th Ct Ste 204, 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**
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's procedure on proficiency testing was incomplete. Findings: Review of the procedure, "Proficiency testing and Verification of Accuracy" showed that the procedure failed to include what the laboratory would do if there was a difference in the diagnosis between initial pathologist and pathologist reviewing the proficiency testing, and what would be done if the patient's report needed to be amended. During an interview on 9/20/18 at 11:10

	AM, the Consultant acknowledged the procedure did not include the steps the laboratory would take if there was a difference between the pathologist's diagnosis, and what would be done if the patient's report needed to be amended.
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 interview, the laboratory failed to record the Immunohistochemical (IHC) stains for negative reactivity for each IHC stained slide that were examined from 6/14/16 to 9/19/18. Findings: Review of the log titled, "Stains Quality Control/Assurance" showed the laboratory failed to document a negative control slide for IHC stains. IHC stains performed at the laboratory include CDX2 (intestinal epithelium marker), CD3 (cluster of differentiation lymphocyte marker) and Helicobacter pylori (bacteria). During an interview on 9/20/18 at 10:13 AM, the Consultant confirmed that the negative reactivity for the IHC stains were not recorded.