Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0872089	12/11/2020
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
D0000	A recertification survey conducted on 12/11/2020 found that the Boca Raton Gastroenterology Center Pa clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document the initial and 6 months competency assessment for 1 out of 1 Testing Personnel (TP) that started on year 2020. Findings include: 1)Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 12/07/2020 revealed that: -That the laboratory had 1 TP (A) 2) Review of employee folders revealed that TP A started on 2/2020. There was no documentation of the initial and 6 months evaluation performed by the Technical Supervisor. During an interview on 12/11/2020 at 10:30 AM, with office consultant, she confirmed that the laboratory failed to document the initial and 6 months competency assessment for the TP A.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on record review and office consultant interview, the laboratory failed to ensure the twice a year accuracy verification for histopathology testing during 2020. Findings include: -Review of peer review documents revealed that the laboratory failed to document the peer review for 2020 -During an interview on 12/11/20 at 10:30 a.m., the office consultant confirmed that there was no documentation of peer review for histopathology during 2020.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and office consultant (OC) interview, the laboratory failed to follow their Quality Assurance (QA) policy for 2 out of 2 years (2019 and 2020). Findings include: -Review of QA policy revealed that the laboratory will perform monthly review of work. -There was no documentation of the QA reviews for 2019 and 2020. During an interview on 12/11/2020 at 2:00 PM, with OC , she confirmed that the laboratory failed to follow the QA policy.