Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2185384	05/11/2022
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	A recertification survey conducted on 05/11/2022 found the GASTROENTEROLOGY CONSULTANTS OF BOCA RATON clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish a Quality Assessment (QA) procedure for monitoring, assessing, and correcting identified problems from 11/01/2020 to 05/11/2022. Findings include: Review of laboratory procedure manual revealed that there was no procedure for QA to monitor, asses or correct problems with specimen accessioning, processing, complaint investigations, personnel competency and proficiency testing performance. During an interview on 05 /11/2022 at 12:30 PM, the office manager confirmed that the procedure manual did not include a QA policy.
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 observation, record review and interview, the laboratory's procedure manual failed to include instructions for making the 50, 70, 85, and 95 percent (%) reagent grade alcohol solutions used for the SAKURA TISSUE TEK Vacuum Infiltration Processor (VIP) and the 95 % reagent grade alcohol for the Hematoxylin and Eosin (H&E) staining process on the Leica Auto Stainer from 07/29/2021 to 05/11/2022. Findings include: During a tour on 05/11/2022 at 10:30 AM, the surveyor observed that there was only 100 % reagent grade alcohol in the cabinet containing flammable liquids. Review of the procedures titled: Specimen Processing, in section G and the Automated Hematoxylin and Eosin Staining, showed that the procedures failed to include instructions for making the 50, 70, 85 and 95 % reagent grade alcohol solutions used in the methods of reference. During an interview on 05/11/2022 at 11: 30 AM, the Officer Manager confirmed that the laboratory failed to include the alcohol solutions preparation instructions.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document room temperature requirement to ensure optimal operation for the SAKURA TISSUE TEK Vacuum Infiltration Processor (VIP) from 07/29/2021 to present. Findings include: Review of SAKURA TISSUE TEK VIP manual revealed a requirement for optimal operation a room temperature range between 10 to 40 Degrees Celsius (C). A review of temperature logs from 07/29/2021 to 05/11/2022 revealed that the laboratory failed to document the room temperature to ensure the instrument worked in the optimal range. During an interview on 05/11/2022, the Office Manager confirmed that the laboratory failed to document the room temperature requirement for the period of reference.

D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on procedure manual review and staff interview, the Laboratory Director (LD) failed to ensure that the laboratory had a Quality Assessment (QA) Policy. Findings Include: -Review of Procedure Manual revealed that the laboratory failed to have a QA policy. -Review of "Laboratory Director Responsibilities and Duties" in the Non-Delegated Responsibilities revealed that "Director must ensure that the documentation is complete for: -Procedure Manual, including annual Dating. -Signing Proficiency Testing Results. -Signing the Monthly QA/QC Monitors. During an interview on 05/11 /2022 at 12:15 PM, the Office Manager confirmed that the LD failed to ensure that there was a QA policy in the procedure manual and failed to ensure the laboratory documented the QA activity.