Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2185384	07/29/2026
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 announced CLIA recertification survey was conducted at Gastroenterology Consultants of Boca Raton on July 29, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the laboratory failed to store 100% Reagent Alcohol containers, Xylene, and Eosin Y Solution 1% weight to volume (w/v) in Alcohol and two reagent waste jug in a flammable cabinet. Findings Included: 1. On 7/29 /26 at 1:36 PM, 100% Reagent Alcohol containers, Xylene , and Eosin Y Solution 1% w/v in Alcohol containers were stored in a cabinet under the sink. Two reagent waste jugs were stored on the floor. 2. Review of Xylene sticker read, " Flammable liquid and vapor. Store locked up in a well-ventilated place." 3. Review of Eosin Y Solution ,1% w/v in Alcohol read, "Highly flammable liquid and vapor. Storage: Store locked up. Store in a well-ventilated place." 4. Review of 100% Reagent Alcohol sticker read "Highly Flammable liquid and vapor. Store in well-ventilated place. Use explosion-proof electrical/ventilating / light equipment" 5. Review of Quality Assurance Manual signed by the Laboratory Director on 6/20/2026 read, "All reagents shall be stored according to manufacturer's instructions." 6. On 7 /29/26 at 4:00 PM, the Administrator of Operations confirmed Reagent Alcohol containers, Xylene, and Eosin Y Solution 1% w/v in Alcohol containers and two reagent waste jug were not stored properly.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document open dates for reagents in use from 1/01/2025 to 7/29/2026. Findings Included: 1. Review of Manufactured Stains Reagents, Paraffin and Chemical Lot Log revealed no documented open dates for reagents in use listed from 1/01/2025 to 7/29/2026. 2. Review of the Quality Assurance manual signed by the Laboratory Director read, "All reagents will be marked with date opened." 3. On 7/29/26 at 4:00 PM, the Administrator of Operations confirmed no documented open dates for reagents from 1 /01/2025 to 7/29/2026.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to have a policy for onsite visits and documented two onsite visits for 2025. Findings Included: 1. Review of the Quality Assurance Manual signed by the Laboratory Director on 6/20 /2026 revealed a policy for onsite visits for Laboratory Director. 2. Review of Onsite Laboratory Director Visits revealed no documentation of two Laboratory Director onsite visits for 2025. 3. On 7/29/26 at 4:00 PM, the Administrator of Operations confirmed Laboratory Director did not have a policy for onsite visits and documentation of two onsite visits for 2025.