Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2049034	11/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Total Gastroenterology Pa	7441 Us Hwy 27 N, Sebring, 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 Total Gastroenterology PA on 11/14/24 to 11/21/24. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 observation, lack of documentation, and interview the laboratory failed to define, monitor, and document conditions for proper storage of reagents for Immunohistochemical CD3 testing from 5/30/2024 to 11/1/2024. Findings included: During a tour of the Immunohistochemical CD3 (IHC) testing area on 11/14/2024 at 11:20 am, the reagent refrigerator was observed to have one opened bottle and one unopened bottle of BioSB Immuno DNA reagent labeled to be stored at 20-25 degrees Celsius, one opened BioSB PolyDetector Perioxidase reagent, one opened and one unopened bottle of BioSB PolyDetector Plus reagent, and one opened bottle of AEC BioSB Buffer/Chelator reagent labeled to be stored at 2-8 degrees Celsius. On top of the IHC reagent refrigerator two bottles of Tris Buffered Saline labeled to be stored at 18-25 degrees Celsius were observed. No temperature monitoring device was observed in the IHC refrigerator or in the room, and no documentation of monitoring of the IHC reagents were available for review. The Pathology Manager confirmed on

	11/14/24 at 1:11 pm, the laboratory had not defined or monitored the storage of reagents used for IHC CD3 testing since the installation of the IHC CD3 testing instrument on 5/30/2024. Photographic evidence was obtained.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, interview, and record review the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 7/2024 to 11 /2024. Findings included: Review of the Quality Assurance (QA) procedure, approved by the Laboratory Director on 7/10/23, revealed the process was to monitor the pre-analytic, analytic, and post analytic phases monthly. Review of the Job Description for the Laboratory Director revealed responsibilities included ensuring that the physical and environmental conditions of the lab are appropriate for the testing performed. Review of the QA Event Calendar for 2024 revealed no documentation from 7/2024 to 11/2024 to show any QA monthly tasks had been performed following the laboratory's written procedure. There was no evidence the laboratory's QA procedure had identified the the failure to define, monitor and document conditions for proper storage of reagents for Immunohistochemical CD3 testing for 5/30/2024 to 11/1/2024 as cited at D5413.