Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2289804	08/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Gastrointestinal Health	950 Technology Way - Ste 130, Libertyville, IL	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of laboratory records, lack of documentation, laboratory standard operating procedures and an interview with the laboratory representative, the laboratory failed to monitor temperature for 20 of 20 days of patient testing in February 2026 affecting 192 patients. Findings include: 1. Review of laboratory quality control records revealed a document titled "Room temperature & humidity Log", with a temperature range of 72- 28 F (22-25 C). 2. Review of laboratory records revealed the laboratory failed to record temperature values for 20 of 20 days of patient testing in February 2026. Dates of missed temperature monitoring: 02-02-26 02-03-26 02-04-26 02-05-26 02-06-26 02-09-26 02-10-26 02-11-26 02-12-26 02-13-26 02-16-26 02-17-26 02-18-26 02-19-26 02-20-26 02-23-26 02-24-26 02-25-26 02-26-26 02-27-26 3. Review of laboratory standard operating procedures revealed a document titled "Materials and Equipment used" which stated, "Maintenance logs will be kept up to date for all equipment and daily temperature logs will be completed for temperature sensitive equipment ...." 4. Review of laboratory documentation titled "Slide Quality Control Checklist" revealed that case numbers CGH26-203 through CHG26-394 had been completed in February of 2026 resulting in the failure to monitor temperature affecting 192 patient cases. 5. On survey date 08-04-2026, at 01:

	47 pm, the laboratory representative confirmed the laboratory failed to monitor and document room temperature for 20 of 20 days of patient testing in February 2026, affecting 192 patients.