Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1033744	11/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gastro Care Llc	571 Central Avenue Suite 112, New Providence, NJ	

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) 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 surveyor review of the Leica DM750 Microscope User Manual (UM) and interview with the laboratory consultant (LC), the laboratory failed to document the room temperature and humidity daily per the UM requirements in the pathologist's office from 8/26/21 to the date of the survey. The findings include: 1. The surveyor observed requirements for the pathologist's office room temperature, 10-40C and humidity, 20-90%, in the microscope UM, but room temperature and humidity were not documented daily. 2. The LC confirmed on 11/21/23 at 1:00 pm that room temperature and humidity were not documented daily in the pathologist's office.