Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2165449	**(X3) Date Survey Completed** 07/01/2025
Name of Provider or Supplier Florida Digestive Specialists	**Street Address, City, State** 5651 49th Street N, Saint Petersburg, 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 Florida Digestive Specialists on 07/01/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
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 record review and staff interview, the laboratory failed to document temperature and humidity per the laboratory's policy for three of three months reviewed (12/2023, 06/2024, 06/2025). Findings included: The laboratory's Standard Operating Procedure Manual, originally signed by the Laboratory Director on 11/23 /2023, was reviewed. The policy titled Laboratory Cleaning and Maintenance GEN. 009, pg 2 directed; oven temperatures recorded on the Slide Oven Temperature Chart, reagent refrigerator temperatures recorded, and room temperature and humidity recorded each day. The Slide Oven Temperature Chart, Histology Lab form (used to document room temperature and percent humidity), and the Refrigerator Temperature Log were reviewed for 12/2023, 06/2024, and 06/2025. The temperatures and humidity were not documented. The Lab Director confirmed the above during an interview on 07/01/2025 at 1:00 p.m.