Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0220589	06/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Frederick Gastroenterology Assoc	7109 Guilford Drive #300, Frederick, MD	

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 record review and interview, the laboratory did not record humidity readings in the room that tissue processing occurred for histopathology, staining and tissue processing may be affected by humidity conditions. Findings: 1. The laboratory did not have humidity readings for 2024, to ensure that the humidity meet the manufacturers equipment and stain requirements for optimal staining of tissue. 2. This was confirmed with the general supervisor on 6/6/24 at 12;00 PM.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory quality control records for checking staining reactivity of immunohistochemical (IHC) stains did not specifically show that positive IHC control results were observed and interpreted as positive, Findings: 1. The laboratory quality control record for documenting stain quality control did not include a column or place to interpret the positive control check for the IHC stains the laboratory performs, specifically documenting that the positive control reacted as positive. 2. This was confirmed with the general supervisor on 6/6/24 at 12; 00 PM.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not issue a corrected report for a histopathology case reported 1/26/24. Findings: 1. The laboratory's first test report for Patient A was reported correctly, but the laboratory issued a second test report for the same procedure on the same day of service and the second report was inaccurate. 1, The laboratory deleted the second test report that was generated for Patient A, and that left the first correctly reported test report for Patient A in the patient A record for 1/26/24. 2. The laboratory did not issue a corrected report to the user, concerning the second test report. 2. This was confirmed with the general supervisor on 6/6/24 at 12;00 PM.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on interview with staff and observation of education records for testing staff, the laboratory director did not retain education records to show that two of three staff members met the educational requirements to perform tissue grossing for histopathology. See D6102 for findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate

	results. This STANDARD is not met as evidenced by: Based on interview with laboratory staff, the laboratory director did not ensure that testing staff performing tissue grossing for histopathology had the appropriate education to meet high complexity testing requirements. Findings: 1. The laboratory did not have transcripts for two of three staff performing tissue grossing so that they could be credentialed to perform high complexity testing (tissue grossing). The laboratory corrected this deficiency during the survey by not having the two staff members perform tissue grossing. 2. This was confirmed with the general supervisor on 6/6/24 at 12;00 PM.