Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0898621	06/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Specialists Of Frederick	85 Thomas Johnson Court Ste B, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the histopathology proficiency check was not performed as stated in the laboratorys written procedure. Findings: 1. The written procedure states that twice annually, proficiency checks will be performed by peer reviews. 2, The laboratory director did not complete the proficiency check peer review form for the second half of 2024. 3. This was confirmed during interview with the laboratory director on June 17, 2025 at 11:30 am.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review, observation and interview with the laboratory director, the laboratory did not follow written procedures for processing and labeling patient specimens for two of six cases reviewed. Findings: 1. The accession numbers on the slides for Case # 6 processed on December 18, 2023 and also for Case # 21 processed

	on December 27, 2023 did not agree with the accession numbers on their respective final reports. It was observed that the slides for Case # 6 were labeled CEC23-06, but the final report was identified as CEC24-06 and the slides for Case #21 were labeled CEC23-21, but the final report was identified as CEC24-21. 2. This was confirmed with the laboratory director during interview on June 17, 2025 at 11:30 am.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the written procedures and interview with the laboratory director, the laboratory did not have written procedures describing how histopathology special stains and immunohistochemistry stains are recorded. Findings: 1. The laboratory discontinued staining histology specimens in April 2024, and the technical component is now performed at an independent laboratory. 2. The laboratory director documents the stains performed on the shipping record that accompanies each group of slides mailed to the laboratory, and records the special and immunohistochemistry stain quality control result in the microscopic diagnosis on the final report, but this process was not described in the laboratorys written procedure. The written procedure referred to the use of special stain quality assurance logs to document PAS stains and immunohistochemistry stains. 3. This was confirmed during interview with the laboratory director on June 17, 2025 at 11:30 am.
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 interview with the laboratory director, the laboratory did not document temperature and humidity checks as required in the laboratory written procedures. Findings: 1. The laboratory did not document the room temperature and humidity readings on the 'Daily Room Temperature and Humidity' chart for the entire months of October and November 2023, this chart was reviewed and signed by the laboratory director. 2. The laboratory did not document the room temperature and humidity readings on the tissue block storage room log for the entire months of September 2023, October 2023 and November 2023. 3. The findings were confirmed during interview with the laboratory director on June 17, 2023 at 11:30 am.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory did not document solution changes on the tissue processing equipment as described by the written procedure to ensure that were not deteriorated. Findings: 1. The laboratory did not document the Tissue-TEK VIP solution changes on the schedule for the entire months of October 2023, November 2023, January 2024, February 2024 and March 2024. 2. This was confirmed during interview with the laboratory director on June 16, 2025 at 11:30 am.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory director did not ensure that quality control and quality assurance programs for histopathology were maintained. Findings: 1. The laboratory director did not complete monthly quality assurance summary reports from May 2024 to May 2025. The reports track quality assurance activities that include but are not limited to turn around time, condition of slides received for microscopic diagnosis (broken/bubbles), corrected reports. 2. The laboratory director did not document the hematoxylin and eosin stain quality control results from December 2023 to June 17, 2025. 3. This was confirmed during interview with the laboratory director on June 17, 2025 at 11:30 am.