Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0220589	10/24/2022
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 observation, review of the standard operating procedure manual (SOPM), and interview with the histotechnologist (HT), the laboratory's SOPM failed to include written instructions for using previously confirmed positive patient specimens for the quality control (QC) slides reviewed by the pathologist when interpreting patient test results. Findings 1. The surveyor observed multiple unstained slides in a rack that were only labeled with the name of a particular stain used in the laboratory. 2. When interviewed, the HT stated that they were the QC slides that are stained along with the patient specimens. The HT explained that the lab will use tissue from patients

	that have been reported as positive as the QC slide. The pathologist will identify the blocks that are over two years old and use the tissue for the QC slides. The QC records did not identify the source of the confirmed positive specimen along with the date put into use. 3. During the survey on 10/24/2022 at 12:15 PM, the HT confirmed that the SOPM did not include written instructions for obtaining and using previously confirmed positive patient specimens for the QC slides and how to maintain records showing the source of the confirmed positive specimens in use over the last two years.