Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2032600	09/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Digestive Disease, Pa	1520 Taylor Street, Suite 200, Columbia, SC	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, review of manufacturers user manual, and an interview with the laboratory director (LD) on September 17, 2024, the laboratory failed to perform and document maintenance and electrical function checks for the Histopathology microscope used for patient testing as provided by the manufacturer. The findings include: 1. The laboratory performs Histopathology slide reviews on the Lumon g540 microscope. The laboratory failed to follow the manufacturer's maintenance and electrical function checks instructions. a. The laboratory had failed to document the maintenance/cleaning for the years 2022, 2023, and 2024 as instructed by the manufacturer. The cleaning requirements for the optical lenses with optical cleaning solution are listed on page four (4), section 1.2 of the Lumon g540 microscope user manual. b. The laboratory failed to perform and document electrical function checks for the years 2022, 2023, and 2024 as listed in the manufacturer's user manual. On page two (2), the manufacturer's user manual lists the microscope's electrical power range to be maintained at 90-200 volts. 3. The LD confirmed by interview on 9/17 /2024, at 1:30 p.m., the lack of maintenance documentation and performing function checks for the Histopathology Lumon g540 microscope. 4. The laboratory reports performing 6000 Histopathology microscopic slide reviews annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on patient record review and interview with the laboratory director (LD) on September 17, 2024, the laboratory failed to include the name and address of the laboratory location where the test was performed on the patient's histopathology test reports. The findings include: 1. A review of six patient test reports revealed that the laboratory name and location were not included on six of the six patient test reports. Histopathology Record # Date Collected Date Reported DD22-5 01/03/2022 07/07 /2022 DD22-1342 06/08/2022 06/10/2022 DD23-877 04/07/2023 04/12/2023 DD23-2536 10/23/2023 10/25/2023 DD24-1113 05/16/2024 05/21/2024 DD24-1814 08/09 /2024 08/15/2024 2. The above test reports include the name and location of the laboratory where the Histopathology slides are prepared and retained. 3. The LD confirmed by interview on 9/17/2024, at 3:00 p.m., the name and address of the testing laboratory where the Histopathology slide review is performed and reported is not included on patient test reports 4. The laboratory CMS-116 record reports performing 6000 Histopathology patient slide reviews annually.