Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2144122	01/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Charlotte Gastroenterology & Hepatology, Pllc	2022 Vail Avenue, Charlotte, NC	

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 upon review of instrument manuals and review of 2022 and 2023 humidity logs, the laboratory failed to define an acceptable range for humidity that adhered to the manufacturer's requirements. Findings: Review of instrument operator manuals revealed the following: 1. The Tissue Tek TEC5 (Tissue and Embedding Console System) instrument requires operation in humidity ranging from 30-85%. 2. The Tissue Tek Coverslipper instrument requires operation in humidity ranging from 30-70%. Review of humidity logs revealed the following guidance for Testing Personnel: "Maximum relative humidity 80% for temperatures up to 15 degrees Celsius decreasing linearity to 50% relative humidity at 40 degrees Celsius."
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 upon review of the laboratory's policies and procedures, review of 2022 and 2023 maintenance logs and interview with TP#2 (Testing Personnel) and TP#3 on 1/30 /24, the laboratory failed to perform and document maintenance on the automated H&E (hematoxylin and eosin) stainer and the Tissue-Tek Coverslipper instrument as required by the manufacturer. Findings: Review of the laboratory's policies and procedures revealed the following: A. Review of the laboratory's "H&E Stainer Maintenance" policy revealed in Section "Policy": "1. Solvents (alcohol and xylene) used in the H&E staining process are changed bi-weekly or as needed." "2. Hematoxylin is then placed in a covered container changed monthly." "3. Place Eosin in a covered container changed monthly."..... "6. Staining containers are dismounted from stainers and washed once a week." B. Review of the laboratory's "Coverslipper Maintenance" policy revealed the following categories in Section "Policy": 1. Daily Maintenance 2. Weekly Maintenance 3. Monthly Maintenance 4. Yearly Maintenance Review of the laboratory's 2022 and 2023 maintenance logs revealed the following: 1. 2022 and 2023 Staining Maintenance Logs revealed documentation of daily maintenance activities. 2. 2022 and 2023 Coverslipper Maintenance Logs revealed documentation of daily maintenance activities. In interview at approximately 11:45 a. m.: 1. TP#3 reviewed the logs and stated that the Stainer Maintenance Logs and Coverslipper Maintenance Logs are constructed in a manner in which only the daily maintenance can be documented. 2. TP#2 and TP#3 stated they were unaware of the weekly and monthly maintenance requirements of the Tissue-Tek Coverslipper instrument. 3. TP#2 and TP#3 stated they are performing the maintenance activities reflected in their training and utilizing the logs they were provided.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based upon review of the laboratory's policies and procedures, review of 2023 laboratory records and interview with TP#3 (Testing Personnel) on 1/30/24, the laboratory does not perform the function check of testing its tapwater pH. Findings: Review of the laboratory's "Water pH Testing Procedure" revealed the following: 1. Section "Policy: Collection and Testing Procedure Tap Running Water" states "...3. Tap running water is checked daily using pH strips....7. The H&E (hematoxylin and eosin) stain may need to be adjusted if the quality has been affected." 2. Section "Method Performance Specifications" states "pH values are critical during the perfomance of routine H&E stains. Variables in water pH affect the quality of dye reaction and the general quality of the stain." Review of 2023 laboratory records revealed the absence of documentation that the laboratory tested the pH of its tapwater. In interview at approximately 12:15 p.m., TP#3 stated she was not trained to perform water pH testing in the laboratory.

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 upon review of laboratory policies and procedures, review of maintenance logs and interview with TP (Testing Personnel), the LD (Laboratory Director) failed to ensure that Testing Personnel received appropriate training for the services provided within the laboratory. Findings: The LD failed to ensure that TP received appropriate training to perform and document maintenance on the automated H&E (hematoxylin and eosin) stainer and the Tissue-Tek Coverslipper instrument as required by the manufacturer(see D5429). The LD failed to ensure that TP received appropriate training to perform and document the function check of testing its tapwater pH (see D5435).