Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2265937	01/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Associates, Llc	3495 Hacks Cross Rd Ste 103, Memphis, TN	

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 observation of the laboratory, review of the Leica Bond III manufacturer users manual, the laboratory's room temperature environmental records and interview with the general supervisor, the laboratory failed to define criteria for environmental conditions in the area where the Leica Bond III stainer was in use that was consistent with manufacturer requirements in 2022 and 2023. The findings include: 1. Observation of the laboratory on 01/11/23 at 9:30 am revealed the Leica Bond III stainer in use for performing H. pylori IHC staining of gastric tissues. 2. Review of the Leica Bond III manufacturer's user manual revealed the following environmental conditions: Minimum Operating Temperature: 5 degrees Celsius, Maximum Operating Temperature 35 degrees Celsius, Temperature Required to meet Staining Performance Requirements: 18-26 degrees Celsius and an Operating Humidity of 30 -80%. 3. Review of the laboratory's room temperature environmental monitoring log in use since September 2022 revealed the following: Temperature range of 15-25 degrees Celsius and a humidity range of 20-70%. Humidity levels that exceeded the manufacturer requirements were recorded 4 of 29 days in October 2022, 17 of 25 days in November 2022, 9 of 19 days in December 2022 and 4 of 7 days in January 2023. 4. Interview with the general supervisor on 01/11/23 at 2 pm confirmed the laboratory failed to define environmental conditions that were consistent with manufacturer

	requirements for the Leica Bond III stainer since beginning testing in September 2022 until the date of the survey on 01/11/23.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Helicobacter pylori (H. pylori) immunohistochemistry (IHC) stain manufacturer package insert, refrigerator temperature logs and interview with the general supervisor, the laboratory failed to ensure corrective action was performed when recorded refrigerator temperatures were outside the laboratory's stated requirements for 10 of 11 days in January 2023. The findings include: 1. Observation of the laboratory on 01/11/23 at 9:30 am revealed storage of the Leica Helicobacter pylori IHC stain in a monitored refrigerator using a minimum/maximum feature. 2. Review of the package insert for the H. pylori stain revealed a storage requirement of 2-8 degrees Celsius. 3. Review of the temperature log for the refrigerator where the stain was stored revealed the following: Minimum temperatures for January 2023 revealed recorded temperatures below the acceptable range for 10 of 11 days with no corrective action documented. 4. Interview with the general supervisor on 01/11/23 at 2 pm confirmed the laboratory failed to ensure the Helicobacter pylori stain was stored according to manufacturer's requirements with no corrective action performed for 10 of 11 days in January 2023.
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 review of final patient test reports, interview with the quality manager and phone interview with the laboratory director, three of three final patient test reports did not include the correct name and address of the laboratory in 2022 and 2023. The findings include: 1. Review of final patient tests reports revealed the following: The name and address where the grossing and staining was performed was incorrect. The name and address where the interpretation of the digitized pathology images were performed was not included as part of the reports. See patient report numbers below: Patient accessioning #TGW22-0240-0000003 reported on 09/14/22 Patient accessioning #TGW22-0240-0001877 reported on 12/22/22 Patient accessioning #TGW23-0240-0000003 reported on 01/05/23 2. Interview with the quality manager

	on 01/11/23 at 2 pm revealed the following: After the grossing and processing is performed the slides are digitized and read remotely by the laboratory director. The quality manager confirmed 3 of 3 final patient test reports did not reflect the correct name and address where testing was performed in 2022 and 2023 and did not contain the name and address where the digitized images were read in 2022 and 2023. 3. Phone interview with the laboratory director on 01/19/23 at 2 pm revealed the following: The grossing and slide preparation is performed at the 44D2265937 (Memphis) location. The slides are then digitized. The digitized images are then read by the pathologist remotely under a different CLIA number located in Wyoming. The lab director confirmed the survey findings..