Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2271971	08/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Associates Of The Piedmont	445 Pineview Drive Suite 200 B, Kernersville, 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) (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 review of manufacturer's instructions, review of 2024 and 2025 temperature and humidity logs, and interview with the laboratory supervisor 8/28/25, the laboratory failed to establish a humidity range that was consistent with the manufacturer's instructions for use of the Tissue-Tek DRS 2000 Automatic Slide Stainer. Findings: Review of manufacturer's instructions for the Tissue-Tek DRS 2000 Automatic Slide Stainer revealed "... INSTALLATION ... Environmental Factors ... Temperature and humidity should be held relatively constant to obtain the highest degree of operating stability. ... The ambient operating humidity range is between 30% to 85% relative humidity. ..." Review of 2024 and 2025 temperature logs revealed: 1. The January 2024 and February 2024 logs listed the acceptable range for room humidity as 5 degrees C - 40 degrees C. 2. The February 2025 log listed the acceptable range for room humidity as 20%-80%. During interview at approximately 12:15 p.m., the laboratory supervisor confirmed that the acceptable range for room humidity should be 30-80%.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and review of 2024 and 2025 temperature and humidity logs 8/28/25, the laboratory failed to document any corrective action for humidity readings outside the manufacturer's acceptable limits for operation of the Tissue-Tek DRS 2000 Automatic Slide Stainer. Findings: Review of manufacturer's instructions for the Tissue-Tek DRS 2000 Automatic Slide Stainer revealed an ambient operating humidity range of 30-85%. Review of 2024 and 2025 temperature and humidity logs revealed humidity readings below the manufacturer's specified low limit of 30% with no corrective action documented. Examples: 1. Humidity documented as 25% or below for 20 of 21 days in January 2024. 2. Humidity documented as 23% or below for 20 of 20 days in February 2024. 3. Humidity documented as 25% or below for 7 of 20 days in March 2024. 4. Humidity documented as 28% or below for 4 of 22 days in April 2024. 5. Humidity documented as 28% or below for 21 of 22 days in January 2025. 6. Humidity documented as 27% or below for 18 of 20 days in February 2025.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2025 laboratory records 8/28/25, the laboratory director failed to ensure that verification procedures used were adequate to verify the performance specifications of the new Ventana Benchmark ULTRA and Special Stainer prior to the initiation of patient testing. Findings: Review of the laboratory's "IMMUNOHISTOCHEMISTRY (IHC) POLICY & PROCEDURE VENTANA BENCHMARK ULTRA STAINING MODULE" revealed "... IV. ASSAY VALIDATION: ... B. If a new antibody is to be implemented, validation studies must be performed and documentation of acceptability by the pathologist must be recorded before procedure of the new antibody can be in effect. ... F. A sign-off sheet for the pathologist's signature is located with each stain that has been validated located in the validation books for IHC and Special Stains. ..." Review of laboratory records revealed the laboratory installed the Ventana Benchmark ULTRA and Special Stainer for performing automated immunohistochemical staining in March 2025. The laboratory had maintained the slides used to conduct the validation, but there was no documentation available to

	indicate how and when the validation was conducted, the performance specifications evaluated/established, and whether the instrument performance was determined to be acceptable by the laboratory director prior to the initiation of patient testing.