Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2271971	12/07/2023
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) 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 review of manufacturers' instructions, review of 2023 laboratory records, and interview with TP (testing personnel) #1 on 12/7/23, the laboratory failed to monitor and document humidity daily to ensure manufacturer's instructions were followed for accurate and reliable test system operation. Findings: Review of manufacturer's instructions for the Tissue-Tek DRS 2000 Automatic Slide Stainer revealed "Operating Conditions: ... Relative Humidity - 30% to 85% (noncondensing) ..." Review of manufacturer's instructions for the Tissue Embedding Center EC 350 revealed "Cryo Console ... Ambient conditions Max. humidity 80% (without condensation) ..." Review of manufacturer's instructions for the Leica CV5030 Robotic Coverslipper revealed "Instrument Components and Specifications ... Relative humidity: Maximum 85% (non-condensing) ..." Review of 2023 laboratory records revealed there was no documentation of humidity monitoring. During interview at approximately 1:00 p.m., TP #1 confirmed the laboratory had not monitored humidity.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, observation, and interview with the laboratory director and TP #1 on 12/7/23, the laboratory failed to discard supplies that exceeded their expiration dates. Findings: Review of the laboratory's policies and procedures revealed a "Reagent Expiration" policy. The policy stated "... A. All reagents in the pathology lab are required to have an expiration date. All reagents are used within the expiration date. If the reagent is not used within the expiration date, the reagent will be discarded according the lab practices within federal and local regulations. ..." During a tour of the laboratory at approximately 1:25 p.m., the surveyor observed the following items in the laboratory's refrigerator, available for use: 1. 1 small bottle of Silver Nitrate 1% for Warthin Starry Method lot #140476, expiration date 5/27/23; 2. 1 large bottle of Silver Nitrate 1% for Warthin Starry Method lot #152166, expiration date 9/30/23; 3. 1 small bottle of Gelatin 5% Solution lot #140474, expiration date 11/23/23. During the exit interview at approximately 2:30 p.m., the laboratory director and TP #1 stated they no longer perform Warthin Starry stains, so the supplies should have been discarded.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2023 laboratory records, and interview with the laboratory director 12/7/23, the laboratory failed to document stain quality for the H&E (Hematoxylin and Eosin) stain each day of use from 4/17/23 to 12/7/23. Findings: Review of the laboratory's "DAILY REVIEW OF SPECIMEN PROCESSING/STAINING/CONTROLS" policy revealed "... 1. The pathologist reading the slides each day will document processing, quality of staining and coverslipping as well as any floaters or mislabeled slides ect. On the histology QA form on the day of the occurrence. ..." Review of the "Pathology Quality Assurance" policy revealed "... A. Quality Assurance Forms are sent daily, with slides for interpretation, to the pathologist. The pathologist will document the overall quality of the slides on the Quality Assurance Form. ... D. The Quality Assurance Form will be used to document the quality of multiple histologic preparations, including H&E-stained slides, ..." Review of 2023 laboratory records revealed the laboratory failed to document H&E stain quality each day of use from 4 /17/23 to 12/7/23. During interview at approximately 12:45 p.m., the laboratory director stated they evaluated H&E stain quality each day of use, but the evaluations were not documented because they changed the QA form.