Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0680742	07/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Associates Napc	1022 First Street North Ste 220, Alabaster, AL	

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 reviews of the environmental logs, the Sakura Tissue-Tek Prisma Automated Slide Stainer and Sakura Tissue-Tek Vacuum Infiltration Processor (VIP) 6 Operating Manuals and an interview with the Consultant (DH), the laboratory failed to record the humidity in the room where the slide stainer and processor were operated. The surveyor noted there was no documentation of the humidity for approximately 25 months from June 2024 through July 2026. The findings include: 1. A review of the laboratory's environmental logs revealed no evidence of the laboratory's humidity documentation from June 7, 2024 - July 30, 2026. 2. Reviews of the Operating Manuals revealed the following manufacturer's requirement for the Sakura Tissue-Tek Prisma Automated Slide Stainer and Sakura Tissue-Tek VIP 6 manuals on Section 2, page 2.1, Environmental Factors "...The ambient operating humidity range is 30-85 percent..." 3. Consultant (DH) confirmed the above findings during the exit conference on 07-30-2026 at 1:00 PM.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and interviews with the Consultant (DH), the Laboratory Director (LD), who is also the Technical Supervisor (TS) failed to ensure Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report), performing high complexity testing had competency assessments which included all six CLIA minimal regulatory requirements. The surveyor noted two of the six requirements were missing from the semi-annual and annual competencies from 2024-2026. The findings include: 1. A review of the 2024-2026 personnel records for TP listed on the CMS-209 (Laboratory Personnel Report) revealed competency assessments in the Histopathology subspecialty were missing the following CLIA minimal regulatory requirements. (1) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (2) Assessment of problem-solving skills. 2. Consultant (DH) confirmed the above findings during the exit conference on 07-30-2026 at 1:00 PM.