Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1012006	06/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Consultants In Gastroenterology	11 Gateway Corners Park, Columbia, SC	

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
D0000	An onsite CLIA recertification survey was conducted at Consultants in Gastroenterology on June 12, 2025. The facility was found to be out of compliance with the Medicare Condition at 42 CFR 493 Laboratory Requirements. The following is a list of STANDARD LEVEL deficiencies cited as a result of June 12, 2025, recertification survey.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation and staff interview, the laboratory failed to monitor temperature and humidity for the room histology slides and paraffin blocks were kept as required for facilities 493.1101 for facilities to maintain and store under conditions that ensure proper preservation. Findings included: 1. During a tour of the laboratory on June 12, 2025, at 1:16 pm, the surveyor observed: a. In a room between the laboratory and the conference area, 81 storage boxes containing histology slides and paraffin blocks from 2014 thru 2025. b. No devices to monitor temperature and humidity in the room on day of survey. 2. Surveyor requested and laboratory failed to provide, documentation of temperature and humidity for the room storing slides and blocks processed by the histology laboratory. 3. In an interview on June 12, 2025, at 2:10 pm with testing personnel (TP1), Chief Executive Officer, and Nurse Manager in the conference room, the above findings were confirmed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the

	current laboratory director before use. This STANDARD is not met as evidenced by: Based on records reviewed and staff interview, the laboratory failed to ensure that the laboratory procedures and changes in procedures were approved, signed and dated by the laboratory director before use. Findings included: 1. Documentation of the laboratory director's approval for the use of the laboratory's standard operating procedures regarding all pre-analytic, analytic, and post-analytic phase of testing, quality assurance, quality control, and personnel activities were unavailable to review on the day of the survey. 2. TP1, Chief Executive Officer, and Nurse Manager in the conference room confirmed during an onsite interview on June 12, 2025, at 2:10 pm that the laboratory had failed to ensure the reviewed procedures were approved, signed and dated by the laboratory director.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 records reviewed and staff interview, the laboratory failed to ensure that the laboratory procedures and changes in procedures were approved, signed and dated by the laboratory director before use. Findings included: 1. Documentation of the laboratory director's approval for the use of the laboratory's standard operating procedures regarding all pre-analytic, analytic, and post-analytic phase of testing, quality assurance, quality control, and personnel activities were unavailable to review on the day of the survey. 2. TP1, Chief Executive Officer, and Nurse Manager in the conference room confirmed during an onsite interview on June 12, 2025, at 2:10 pm that the laboratory had failed to ensure the reviewed procedures were approved, signed and dated by the laboratory director.