Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0250504	06/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Charleston Gastroenterology Specialists	328 Midland Parkway, Summerville, 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 announced CLIA recertification survey was conducted at Charleston Gastroenterology on June 22, 2026, by the South Carolina Department of Public Health (SC DPH), Bureau of Nursing Homes and Medical Services. The facility was found to be out of compliance with the Medicare Condition 42 CFR Part 493, CLIA laboratory requirements. The following STANDARD LEVEL DEFICINCIES were found to be out of compliance as a result of the recertification survey on June 22, 2026:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review (Charleston Gastroenterology Specialist Quarterly QC Case Review), lack of documentation, and staff interview the laboratory director failed to verify the accuracy of the tests or procedure twice annually for Histopathology high complexity testing for 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. Review of CMS 116 application reveals the laboratory is performing the following high complexity testing: a. Histopathology 2. A review of the Quarterly QC Case Review reveals a lack of documentation verifying the accuracy of reading histopathology slides twice annually. The documentation lacks the following information: a. Who the evaluator that is that is reading the slide. No printed name or other identifying information of the evaluator. b. How is patient/case identified. c. What happens if results differ. 3. In an interview on June 22, 2026, at 11:45 am in the laboratory director's office with the laboratory director, the above findings were confirmed.
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 direct observation, lack of documentation, and staff interview, the laboratory failed to maintain the maintenance of the microscope equipment used to perform high complexity testing for 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. During an onsite visit on June 22, 2026, at 11:00 am, the surveyor directly observed in the laboratory director's office a Olympus BX41 microscope was present on the desk. 2. The Olympus BX41 microscope did not have a service label attached to it to document service activity. 3. In an interview on June 22, 2026, at 11:45 am in the laboratory director's office with the laboratory director, the above findings were confirmed.