Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0942418	06/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Palmetto Digestive Disease, Pa	2073 Charlie Hall Blvd, Charleston, 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	A Recertification Survey was initiated on 06/08/2023 and concluded on 06/08/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with one deficiency cited.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on interview and document review, it was determined the facility failed to ensure the name and address of the laboratory location where the test was performed was on the test report for 1 of 5 reports reviewed. Interviews revealed the specimens were sent to a pathologist at another laboratory for examination and that specimens may be sent to another laboratory if special stains were required. Review of the laboratory report revealed it did not reflect the actual name and address of the laboratory locations where these procedures were performed. Findings included: In an interview at 11:00 AM on 06/08/2023, Testing Personnel (TP) stated the slides she prepared were sent to a pathologist at another location to be read. If special stains were requested, the specimens were sent to another laboratory. In an interview with the Laboratory Director (LD) at 11:20 AM on 06/08/2023, he stated he performed the interpretation of the slides at another laboratory and if special stains were required, the specimens were sent to a second certified laboratory. Review of the laboratory report

	format revealed special stains for immunohistochemistry were not performed at the laboratory; however, they were indicated as being performed at the facility on the laboratory report. The report also included a statement that the technical component and the interpretation were performed at the laboratory. Only the technical component of the test was performed at the laboratory. However, the interpretation was performed at another location. In an interview with the TP and the Office Manager (OM) on 06/08/2023 at 12:10 PM, they were shown the sample report. They stated that the facility was listed as the testing location for all tests on all reports issued by the laboratory, even though other testing sites were utilized.