Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2145680	(X3) Date Survey Completed 08/04/2022
Name of Provider or Supplier Gastroenterology Institute Of Orlando Llc	**Street Address, City, State** 812 W Oak Street, Kissimmee, FL	
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 conducted on August 4, 2022. Gastroenterology Institute of Orlando clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review and interview, the laboratory failed to include name and address of the laboratory where the professional component was performed for five (#1, #2, #3, #4, #5) of six patients' gastrointestinal (GI) pathology reports, (#1, #2, #3, #4, #5, #6). Findings: Review of patients' "GI Histology Report" showed the name and address of the laboratory where the professional component was performed was not listed on five ((#1, #2, #3, #4, #5) of six patients' reports (#1, #2, #3, #4, #5, #6) reviewed. According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 08/04 /2022, the laboratory had an annual test volume of 810 tests. On 08/04/2022 at 12:00 PM, Laboratory Director confirmed that five of the reports did not have the name and address of the laboratory where the professional component was performed.