Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1045272	09/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Specialist Inc	3355 Burns Rd Ste 306, Palm Beach Gardens, 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	An announced recertification survey was conducted on 9/7/21 at Gastroenterology Specialist Inc., a clinical laboratory in Palm Beach Gardens, Florida. Gastroenterology Specialist Inc. is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the standard level deficiencies:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on histopathology twice annual verification of accuracy record review and interview with the histotechnologist , the Laboratory Director failed to ensure that corrective action was documented when the laboratory's histopathology twice annual verification of accuracy activity was unsuccessful for 2 (July through November 2019 and July through December 2020) out 4 (July through November 2019, January through June 2020, July through December 2020, and January through June 2021) verification activities. The findings included: Record review of the laboratory's policy revealed the procedure "Proficiency Testing" (revision date 01/28/19) which stated " Gastroenterology Specialists Inc. will collect 3 to 6 casts, based on the volume of specimens, every 6 months to be evaluated... Reports from this evaluation and corrective actions if any will be logged and kept for the laboratory for the time the lab is open." Record review of the histopathology twice annual verification of accuracy activities revealed 2 histopathology verification of accuracy activity (July through November 2019 and July through December 2020) out of 4 (July through November 2019, January through June 2020, July through December 2020, and January through June 2021) was unsuccessful because July through December 2019 the documentation showed the reviewing pathologist agreed and disagreed with 2 cases and July through December 2020 the reviewing pathologist did not agree with submitting pathologist's

	diagnosis from the histopathology slide review. Interview on 09/07/21 at 1:45 pm., the histotechnologist confirmed that she did not know that the laboratory must document corrective action for failed histopathology twice annual verification of accuracy.