Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0942775	04/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Gastrointestinal Associates	1 Cornerstone Drive Suite 300, Langhorne, PA	

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
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 peer review records and interview with the Laboratory Director (LD) and Laboratory Manager (LM), the laboratory failed to assess at least twice annually verification accuracy of histology slides read on site in 2017. Findings include: 1. Review of Quality Control & Performance Improvement Procedure, 2nd Opinion Peer Review Policy, Bullet number 5 states: "Peer review will be conducted a minimum of 2 times per year in each colander year. At the time, 2-3 cases will be reviewed for QA /QC purposes." 2. On the day of survey, 04/24/2018, the Clinical Gastroeneterology Quality Assurance check sheet used to document peer review lists: a. 2 cases reviewed in 2016 b. 1 case reviewed in 2017 c. 1 case reviewed so far for 2018. 3. The LD and LM confirmed that the laboratory failed to perform at least twice annually verification accuracy of histology slides read on site in 2017 on 04/24/2018 around 01:30 PM.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with the

	Laboratory Director (LD) and Laboratory Manager (LM) the laboratory failed to establish and follow written policies and procedures for ongoing mechanism to monitor and assess Laboratories Quality Assessment. Findings include: 1. On the day of survey, 04/24/2018, a review of the laboratory's manuals revealed that the laboratory failed to have a written policy to assess the quality of the laboratories, pre analytical, analytical and post analytical laboratory systems. 2. The LD and LM confirmed the findings above on 04/24/2018 around 02:00 PM.