Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0104129	06/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Group Of Northern Nj, Llc, The	140 Sylvan Avenue, Suite 101 C, Englewood Cliffs, NJ	

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 surveyor review of the Biannual Assessment (BA) records and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of Histopathology testing twice annually In the calendar years 2017 and 2018. The finding include: 1) The laboratory performed one BA in 2017. 4) The GS confirmed on 6/13/18 at 1:00 pm the laboratory did not perform BA twice annually.
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 surveyor review of the Procedure Manual (PM), Biannual Assessment (BA) records and interview with the General Supervisor (GS), the laboratory failed to have a written procedure for BA from 6/2/16 to the date of the survey. The GS confirmed on 6/26/18 at 10:30 am that the laboratory did have a written procedure for BA.
D5787	TEST RECORDS

	CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Logs (AL), Histopathology Slides (HS) and interview with the General Supervisor (GS), the laboratory failed to correctly date additional slide requested for histopathology cases ordered from 6/2/16 to the date of survey. The findings include. 1) Specimen GGNNJ17-00004 was processed 1/3/17 for Hematoxylin and Eosin. 2) Additional Immunostain CD3 was ordered and processed for specimen GGNNJ17-00004 on 1/5/17 but was labeled 1/3/17. 3) The GS confirmed on 6/26/18 at 10:00 am that the laboratory failed to correctly date additionally ordered slides.