Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D0860538	**(X3) Date Survey Completed** 05/20/2021
Name of Provider or Supplier Bucks County Gastroenterology Assoc	**Street Address, City, State** 301 Oxford Valley Rd #701, Yardley, 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**
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's Clinical Staff Competency procedure, annual competency assessment records, and interview with Office manager (OM) , the laboratory failed to establish a complete Competency assessment procedure that include the six points of competency assessment for 1 of 2 Testing Personnel (TP) who performed histopathology and Haemotoxylin and Eosin (H&E)slide examinations from 10/22/2018 to the date of survey. Findings include: 1. On the day of survey, 05/20/2021, the Clinical staff competency Assessment document for histopathology and H&E slide examinations did not include: - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing - Direct observations of performance of instrument maintenance and function checks 2. The OM confirmed the findings above on 05/20 /2021 around 11:00 a.m.
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 Quality Assessment (QA) records, review of QA procedure, and interview with the Office Manager (OM), the laboratory failed to follow their written QA and Performance improvement procedure for 1 of 12 months in 2019, 3 of 12 months in 2020, and 1 of 5 months in 2021. Findings include: 1. The quality assessment and performance improvement policy and procedure states:" The laboratory director will review each component of the quality measures and sign off on a monthly basis on the quality assessment document". 2. On the day of survey 5/20 /2021 at 10:35 a.m., the OM could not provide the documentation of QA performed for the following months: - November 2019 - January 2020 - February 2020 - March 2020 - March 2021. 3. The OM Confirmed the findings above on 05/20/2021 at 11:00 a.m.