

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2067596	(X3) Date Survey Completed 03/07/2024
Name of Provider or Supplier Pittsburgh Gastroenterology Associates, Ltd	Street Address, City, State 2589 Boyce Plaza Road, Pittsburgh, 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation and interview with the laboratory director (LD) and testing personnel #3 , the laboratory failed to follow a competency assessment procedure to assess the competency of 1 of 2 Clinical Consultant (CC) for their supervisory responsibilities in 2022 and 2023. Findings include: 1. On the day of the survey, 03/07/2024 at 10:15 am, the laboratory could not provide competency assessment documents for 1 of 2 CC (CMS 209 personnel #2) for their supervisory responsibilities in 2022 and 2023. 2. The LD and TP#3 confirmed the findings above on 03/07/2024 at 11:45 pm. *Repeated deficiency.</p>
D6125	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency assessment records, and interview with the Laboratory Director (LD) and Testing Personnel #3, the Technical Supervisor (TS) failed to assess the competency for 2 of 4 TP through external proficiency testing samples or internal blind testing samples for grossing examinations</p>

performed in histopathology in 2022 and 2023. Findings include: 1. On the day of survey, 03/07/2024 at 11:53 am, review of histopathology TP competency assessment records revealed annual competencies performed in 2022 and 2023 did not include the assessment of external proficiency testing samples or internal blind testing samples for 2 of 4 TP (CMS 209 TP #3 and #4) who performed grossing examinations in histopathology in 2022 and 2023. 2. The LD and TP#3 confirmed the findings above on 03/07/2024 at 12:00 pm.