

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2208926	(X3) Date Survey Completed 03/21/2023
Name of Provider or Supplier Greater Hazleton Gastroenterology	Street Address, City, State 10 Park Place, Hazleton, 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 review of the competency assessment records and interview with the laboratory director (LD), the laboratory failed to establish written policies and procedures to assess the competency of 2 of 3 clinical consultants (CC) and 2 of 2 general supervisors (GS) for their supervisory responsibilities from 07/01/2021 to the date of the survey. Findings Include: 1. On the day of the survey, 03/21/2023 at 01:14 pm, the laboratory could not provide a written procedure to assess the competency of 2 of 3 CC (CMS 209 personnel # 2, and #3) and 2 of 2 GS (CMS 209 personnel # 2, and #3) for their supervisory responsibilities from 07/01/2021 to 03/21/2023. 2. The laboratory could not provide competency assessment records for 2 of 3 CC and 2 of 2 GS for their supervisory responsibilities in 2021 and 2022. 3. The LD confirmed the findings above on 03/21/2023 around 02:30 pm.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory director (LD), the laboratory failed to ensure that the verification of accuracy for microscopic</p>

examinations for histopathology were performed at least twice annually in 2022. Findings Include: 1. On the day of the survey, 03/21/2023 at 01:45 pm, the laboratory could not provide documentation that the verification of accuracy for histopathology slide examinations stained using immunohistochemicals, special stains, and hematoxylin and eosin (H&E) were performed at least twice annually in 2022. 2. The laboratory performed 1977 histopathology examinations in 2022 (CMS 116 annual volume). 3. The LD confirmed the finding above on 03/21/2023 around 02:30 pm.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's competency assessment records and interview with the laboratory director (LD), the technical supervisor (TS) failed to evaluate the semiannual competency assessment during the first year for 2 of 3 TP who performed histopathology slide examinations from 07/01/2021 to the day of the survey. Findings include: 1. On the day of survey, 03/21/2023 at 01:40 pm, the laboratory could not provide semiannual competency assessment records for 2 of 3 TP (CMS 209 personnel #2, and #3) who performed histopathology slide examinations from 07/01/2021 to 03/21/2023. 2. The LD confirmed the findings above on 03/21/2023 around 02:30 pm.