

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D2033624	(X3) Date Survey Completed 04/28/2025
Name of Provider or Supplier Gi Associates Of Delaware	Street Address, City, State 742 South Governors Avenue, Suite 3, Dover, DE	
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
D0000	A Recertification Survey was conducted on April 28, 2025 at approximately 1:00 PM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
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 facility document review and interview, the laboratory failed to conduct twice-yearly accuracy verification for histopathology testing for each pathologist who performed testing. This was noted for 2 out of 2 years reviewed. Findings included: A CMS-209 "Laboratory Personnel Report (CLIA)" document, signed on 04/28/2025 by the Laboratory Director, revealed there were two pathologists employed as testing personnel. Undated "Peer Review Form" documents revealed peer reviews were conducted to verify the accuracy of the testing performed by testing personnel on the following dates: -Ten cases were diagnosed by Testing Personnel (TP) #6 on 06/26 /2023 and reviewed by TP #3 on 07/03/2023. -Ten cases were diagnosed by TP #3 on 12/19/2023 and reviewed by TP #6 on 02/13/2024. -Ten cases were diagnosed by TP #3 on 08/05/2024 and reviewed by TP #6 on 08/19/2024. During an interview on 04 /28/2025 at 1:55 PM, TP #3, who also served as the Laboratory Director, was asked if there were any other peer review events done to meet the requirement for twice yearly verification of accuracy. He stated the "Peer Review Form" documents provided showed the only peer review events performed. During a telephone interview on 04/28 /2025 at 2:15 PM, General Supervisor #7 confirmed peer reviews were not done twice a year for each pathologist.</p>