

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2150450	(X3) Date Survey Completed 12/11/2025
Name of Provider or Supplier Digestive Disease Specialists	Street Address, City, State 525 Valley View Dr, Moline, IL	
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	<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 review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with laboratory representative, the laboratory failed to perform bi-annual evaluations for one of one high complexity test system: histopathology testing in 2024. Findings Include: 1. Review of the laboratory's policy and procedure manual found the policy, "GE-PR-0070 Proficiency Testing Program", which stated, under "Purpose and Scope", "C. Proficiency testing is required for all tests listed in the "CAP Master Activity Menu with PT Options" D. If enrollment in a PT program is not required or is not available for a particular test, an alternative assessment method must be performed semiannually which may include:" 2. Review of laboratory records found no bi-annual method accuracy evaluations for histopathology testing in 2024. 3. Interview with the laboratory representative on 12-11-25 at 12:37 pm confirmed that no bi-annual method accuracy evaluation for histopathology in 2024 were available for review on the date of the survey.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with laboratory representative, the laboratory failed to follow policies and procedures regarding annual preventative maintenance service for the Olympus BX40 (Serial Number: 3E04062) microscope used for microscopic examination of slides in the subspecialty of histopathology in 2024 and 2025.

Findings include: 1. Review of laboratory policies and procedures revealed the policy, "AP-PR-0450 Microscope Calibration and Maintenance", which stated, under "Maintenance", "A qualified service representative lubricates the mechanical parts and cleans the optical system once a year." 2. Review of laboratory records revealed no documentation of annual preventative maintenance on the Olympus BX40 (Serial Number: 3E04062) microscope in 2024 and 2025. 3. Interview with laboratory representative on 12/11/2025, at 12:38 pm, confirmed the laboratory failed to follow policies and procedures regarding annual preventative maintenance service for the Olympus BX40 (Serial Number: 3E04062) microscope used for microscopic examination of histopathology slides.