

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0095981	(X3) Date Survey Completed 06/06/2025
Name of Provider or Supplier Digestive Disease Associates Llc	Street Address, City, State 687 Main St, 2nd Flr, Branford, CT	
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 record review and staff interview, the laboratory failed to establish competency assessment policy and procedures to assess competency for the regulatory responsibilities for the clinical consultant (CC) in the subspecialty of histopathology. Findings include: 1. Record review on 06/06/2025 of the personnel competency files revealed the lack of competency assessment documentation for the regulatory positions of CC. 2. Staff interview on 06/06/2025 at 10:00 AM with the laboratory director (LD) confirmed the above finding. The LD further commented that he/she was unaware that a CC competency assessment is a regulatory requirement. 3. The laboratory performs 4,689 tests annually in the subspecialty of histopathology.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on surveyor observation, record review and staff interview, the laboratory failed to define and provide evidence of monitoring and documenting ambient room temperature and humidity requirements in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 06/06/2025 at 10:30 AM of the laboratory's histopathology slide reading room revealed an 'Olympus CX41 Microscope' is in use. 2. Record review on 06/06/2025 of the laboratory's equipment maintenance records revealed the lack of documentation of ambient room temperature and humidity levels for the histopathology slide reading room. 3. Record review on 06/06/2025 of the 'Olympus CX41 Microscope' operators manual revealed the following operating environmental conditions: a. 'Ambient temperature: 0 to 40 degrees Celsius'. b. 'Maximum Relative Humidity: 80% for temperatures up 31 degrees Celsius, decreasing linearly through 70% at 34 degrees Celsius, 60% at 37 degrees Celsius, to 50% relative humidity at 40 degrees Celsius'. 4. Staff interview on 06/06/2025 at 10:45 AM with the laboratory director confirmed the above findings. 5. The laboratory performs 4,689 tests annually in the subspecialty of histopathology.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to follow their established policies and procedures and document daily stain quality in the subspecialty of histopathology. Findings include: 1. Record review on 06/06/2025 of the laboratory's 'In House Pathology SOP/Policy and Procedure Manual' revealed 'The pathologist will review the stain as he/she reads the slides and inform the reference laboratory as to inadequacy and problems. This is noted on the pathology log book and any problems are noted in the comment section of the worksheet with an explanation of what was done to correct the problem'. 2. Record review on 06/06/2025 of the laboratory's 'H/E, Special Stains, IHC Daily QC Log' revealed the lack of documentation of daily stain quality for the years 2023, 2024 and to-date 2025. 3. Staff interview on 06/06/2025 at 11:00 AM with the laboratory director confirmed the above findings. 4. The laboratory performs 4,689 tests annually in the subspecialty of histopathology.