

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2159522	(X3) Date Survey Completed 08/27/2025
Name of Provider or Supplier Digestive Disease Solutions Llc	Street Address, City, State 804 Toll House Avenue, Frederick, MD	
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not document that the first slide reviewed for each day of hematoxylin and Eosin (H & E) staining for histopathology testing met the intended reactivity characteristics for the stain (this would include documentation of unsatisfactory staining characteristics and corrective actions). Findings: 1. The laboratory performed microscopic analysis with the H & E stain. Beginning February 2025, the laboratory did not document that the first slide reviewed for each day of H & E staining met the intended staining reactivity. 2. This was confirmed, during interview, with the laboratory director on August 6, 2025 at 11:00 am.</p>