

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0960211	(X3) Date Survey Completed 03/19/2024
Name of Provider or Supplier Digestive Disease Center Histology Lab	Street Address, City, State 400 Westage Business Ctr Dr, Ste 104, Fishkill, NY	
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	An announced CLIA exempt-state validation survey was conducted at Digestive Disease Center - Histology on March 19, 2024, by the CMS New York CLIA Branch Location federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory is in compliance with condition-level CLIA requirements. The following standard-level deficiency was found during the CLIA exempt-state validation survey performed on March 19, 2024.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory humidity records, and interview with histology supervisor, the laboratory failed to document relative humidity conditions in the histology laboratory from 2022 to 2024. Finding Include: 1. The Agilent Technologies Dako PT Link's manufacture manual stated a an environmental requirement of 25 - 85% relative humidity. 2. The Tissue-Tek VIP 6 AI Tissue Processor manual stated an environmental requirement of 30 -85% relative humidity. 3. The Olympus BX41system microscope instructions, 8. operating environment states, maximum relative humidity 80%. 4. On the day of survey, March 19, 2024 the laboratory could not provide documentation of humidity conditions monitored in the histology</p>

laboratory from 2022 to 2024. 5. The histology supervisor and laboratory director confirmed relative humidity conditions was being monitored but not documented in the histology laboratory on March 19, 2024 at 12: 50 PM.