

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0898621	(X3) Date Survey Completed 01/06/2022
Name of Provider or Supplier Gastroenterology Specialists Of Frederick	Street Address, City, State 85 Thomas Johnson Court Ste B, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory did not document maintenance performed for the Quantum stainer. Findings: 1. The manufacturer instructions for the Quantum slide stainer requires cleaning of the module, chamber, wash stations and tube inspections. These activities were not documented in 2021; and 2. This was confirmed during interview with the histotechnologist on the afternoon of the day of the survey.</p>
D6121	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with laboratory staff, the laboratory director acting as technical supervisor did not perform competency checks for the histotechnician performing tissue grossing (inking tissue). Findings: 1. The Histotechnician performs tissue grossing that is high complexity testing; 2. The Technical supervisor did not perform competency checks in 2021 for the histotechnician; and 3. This was confirmed during interview on the afternoon of the</p>

day of survey when the histotechnician confirmed that competency check records were not available.