

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0220589	(X3) Date Survey Completed 08/28/2026
Name of Provider or Supplier Frederick Gastroenterology Assoc	Street Address, City, State 7109 Guilford Drive #300, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the laboratory used one of 31 lots of staining reagents beyond the documented expiration date. Findings: 1. The name, lot number, expiration date, and date in use for each staining reagent were documented on the "Reagent and Stain Lot to Lot Validation Form" (reagent log). 2. The quality control of each staining reagent used each day was documented on the "Daily Slide Quality Control" log (daily QC log). 3. Review of the reagent log showed that lot number 2425732 of Alcian Blue expired on 09/30/2025 and the next lot number, 2519714, was not put into use until 02/17/2026. 4. Review of the daily QC log showed that the Alcian Blue stain was used on patient slides for 21 days in 10/2025, 17 days in 11/2025, 13 days in 12/2025, 16 days in 01/2026, and 10 days in 02/2026 up until 02/17/2026 when the new lot was documented as put into use. 5. During the exit interview on 08/28/2026 at 2:45 PM, the LD confirmed that lot number 2425732 of the Alcian Blue stain reagent expired on 09/30/2025 and the next documented lot number, 2519714, was put into use 02/17/2026.