Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2162595	06/10/2026
Name of Provider or Supplier	**Street Address, City, State**	
Edmunds Gastroenterology, Pllc	4713 Papermill Dr Ste 100, Knoxville, TN	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Clinical Laboratory Improvement Amendement (CLIA) Application for Certification (FORM CMS-116) and Laboratory Personnel Report (CLIA) (FORM CMS-209), ASPEN 116 database, laboratory procedures and an interview with the Laboratory Operations Director, the laboratory failed to ensure that approved, signed, and dated procedures were in place by the current laboratory director (LD) before use, following the change in laboratory director on January 20, 2026. The findings include: 1. A review of the FORM CMS-116 and FORM CMS-209 revealed a new laboratory director since the last survey on October 8, 2024. 2. A review of the ASPEN 116 database revealed the current LD was qualified/changed on January 20, 2026. 3. A review of the laboratory's procedure manual revealed the current LD failed to approve, sign, and date 29 of 29 policies before use. 4. In an interview on June 10, 2026, at 8:15 a.m., the Laboratory Operations Manager confirmed that the current LD failed to approve, sign, and date the laboratory procedures when he became the LD on January 20, 2026.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory

	or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the Laboratory Operations Manager, the laboratory director failed to ensure that job descriptions, which outlined the duties and responsibilities of the laboratory director, clinical consultant, technical supervisor, and general supervisor, were in place on the survey date, June 10, 2026. The findings include: 1. Review of the laboratory procedure manual revealed that no job descriptions were present for the laboratory director, clinical consultant, technical supervisor, and general supervisor. 2. An interview on June 10, 2026, at 9:20 a.m. with the Laboratory Operations Manager confirmed the above survey findings.