Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2027269	11/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lake Gastroenterology Associates Llc	1858 Mayo Dr, Tavares, FL	

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 recertification survey was conducted at Lake Gastroenterology Associates LLC on November 13, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency was cited as follows:
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on interview, review of the procedure manual, and patient reports, the laboratory failed to document the acceptability of the Hematoxylin and Eosin (H&E) stain, Special Stains and Immunohistochemical (IHC) Stain Quality Control (QC) slides from 07/01/2025 to 11/13/2025. Findings Included: 1. Review of the Clinical Laboratory Improvement Amendments Application for Certification signed by the Laboratory Director on 11/04/25 listed the following stains were reported out from the laboratory: H&E, Alcian Blue (mucopolysaccharides and glycoproteins stain), PAS (Periodic Acid Schiff, polysaccharides stain), Giemsa (histological stain), Trichrome (connective tissues stain) and CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain). 2. Review of the procedure titled, QC Methods noted, "Pathologist will document on the report the acceptability of controls positive and negative when applicable." 3. During an interview on 11/13/2025 at 10:30 AM, the Laboratory Quality Assurance (QA) Coordinator/Compliance Officer stated the laboratory started reading and reporting patient's pathology reports in July 2025. 4. During an interview on 11/13/2025 at 11:35 AM, Testing Personnel B stated the acceptability of the controls was missing from the reports from when the laboratory switched to a new

	laboratory information systems (LIS). 5. During an interview on 11/13/2025 at 11:40 AM, the Laboratory Quality Assurance (QA) Coordinator/Compliance Officer confirmed the laboratory switched to a new LIS on 07/01/2025.