Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2159554	04/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Digestive Diseases Care For All Llc	508 East Garden Street, Lakeland, 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 Digestive Diseases Care for All LLC on 04/28/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain analytic records for one (11/2023) of three months (11/2023, 06/2024, 03/2025) selected for review. Findings included: Monthly analytic records were reviewed. The laboratory was unable to provide analytic records for November 2023. During an interview on 04 /28/2025 at 12:00 PM, the Laboratory Quality Assurance (QA) Coordinator /Compliance Officer confirmed the absence of analytic records for November 2023.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of

	slide interpretations for tissue stained with Hematoxylin and Eosin (H&E), Alcian Blue-Periodic Acid Shiff (ALB-PAS) and Giemsa for two of two years (2023, 2024). Findings included: The Pathology Quality Control Manual, unsigned by the Lab Director, signed by a Supervisor 04/2023, showed "Proficiency Testing is performed twice a year." Proficiency testing (peer review) for stained H&E, ALB-PAS, Giemsa slide interpretations were reviewed for 2023 and 2024. There was no evidence of peer review for 2023. The 2024 documentation included one "Peer Review Form" dated and signed by the Lab Director 10/10/2024. The Laboratory Quality Assurance (QA) Coordinator/Compliance Officer confirmed, on 04/28/2025 at 12:52 PM, the policy was to complete two peer reviews a year, and there was no documentation for 2023, and peer review was only performed one time in 2024.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory staff failed to follow the laboratory procedure to document a staining maintenance log for Alcien Blue PAS (Periodic Acid Shiff) and Giemsa for one (06/2024) of two months (06/2024, 03 /2025) available for review. Findings included: Monthly "Staining Maintenance Log (s)" for 06/2024 and 03/2025 were reviewed for Alcien Blue PAS and Giemsa stains. There were no logs for 06/2024 for either staining maintenance log. Interview with Testing Person B on 04/28/2025 at 12:50 PM confirmed the laboratory's protocol was to document a staining maintenance log and there were no logs present for 06/2024 for the above referenced stains.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to maintain a quality assessment program that identified, addressed, and effectively corrected failures in the laboratory. Findings include: Based on record review and interview, the laboratory failed to maintain analytic records for one (11/2023) of three months selected for review. See D3031. Based on record review and interview, the laboratory failed to verify the accuracy of slide interpretations for tissue stained with Hematoxylin and Eosin, Alcian Blue - Periodic Acid Shiff and Giemsa for two of two years (2023, 2024). See D5217. Based on record review and interview, the laboratory staff failed to follow their procedure to document a staining maintenance log for Alcian Blue PAS (Periodic Acid Shiff) and Giemsa for one (06/2024) of two months reviewed. See D5401. Histology Quarterly Quality Assurance Checklists for the months of April - August 2024, signed by the Lab Director on 09/07/2024 and for the

	months of September - December 2024, signed by the Lab Director on 01/02/2025 (1) failed to identify the lack of analytic records for 11/2023, (2) the failure to verify the accuracy of slide interpretation twice a year for 2023 and 2024, and (3) did not identify staff failure to follow the laboratory procedure to document staining maintenance logs. Quality Assessment Data prior to April 2024 were not available. Interview with the Laboratory Quality Assurance (QA) Coordinator/Compliance Officer on 4/28/2025 at 12:52 PM and 1:10 PM confirmed the above findings. The analytic data prior to April 2024 was unavailable and they did not know how to acquire it.