Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D0271936	**(X3) Date Survey Completed** 06/06/2023
Name of Provider or Supplier Digestive Disease Associates Of North Florida, Inc	**Street Address, City, State** 6400 W Newberry Rd Ste 302, Gainesville, 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	At the time of the announced, on-site recertification survey, Digestive Disease Associates of North Florida was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 histopathology testing twice annually for one (2022) of two years reviewed (2021 - 2022) for two of two Testing Personnel who read slides. Findings included: Record review of the Laboratory Personnel Report (Form CMS 209) completed and signed by the Laboratory Director on 5/31/23 showed that the Laboratory Director (Testing Person A) and one other Pathologist (Testing Person C) were responsible for reading Histopathology slides. Record review of twice annual verification of accuracy of histopathology testing showed the following: Testing Person A verification was performed in November 2022. Testing Person C verification was performed in May 2022. During the interview with Testing Person B on 6/6/23 at 11:00am, it was stated that Testing Person C only reads slides when Testing Person A is unavailable. She confirmed accuracy verification was performed only once for Testing Person A and once for Testing Person C in 2022.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 laboratory personnel, the laboratory used a reagent that had exceeded its expiration date in 2023. The findings include: The record review of the laboratory document titled "Alcian Blue PAS Stain Line QC Log" showed Alcian Blue with lot number 129373 expired on 2/23. The stain was documented as used from 2/1/23 until 4/7/23. The interview with Testing Person B on 6/6/23 at 11:00am confirmed the stain was expired and documented as used for 27 testing days.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain complete Histopathology quality control documentation for 2 of 2 years reviewed (2022 - 2023). Findings include: The record review of quality control documentation showed there was no record of lot numbers and expiration dates for the Hematoxylin and Eosin (H&E) stains that were used on patient histopathology slides during processing. The interview with Testing Person B on 6/6/23 at 11:00am confirmed that she does not keep any quality control logs that record the lot number and expiration dates for the H&E stains.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to perform a 6-month competency assessment for Testing Person B. Findings Include: The documentation provided by the laboratory for a 6 month competency assessment dated 5/2022 did not indicate if competency was met/not met and was not signed by the Technical Supervisor or Laboratory Director. During the interview with Testing Person B on 6/6 /22 at 11:00am, it was confirmed the documentation was incomplete. The facility policy titled "Clinical Laboratory Competency Assessment" revised May 2023 states "Laboratory personnel are required to be assessed on their competency of policies and procedures at 6 months of hire and annually thereafter." The policy later states "The evaluator will notate that competencies are or are not met, and date and sign the document."