Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2150450	08/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Digestive Disease Specialists	525 Valley View Dr, Moline, IL	

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
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. This STANDARD is not met as evidenced by: Based on review of quality control records, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to retain daily histopathology quality control test records for 23 of 24 months reviewed. Findings: 1. Review of the quality control documents, "Stains QC Review Log - DAILY", found documentation of stain quality acceptability records for August of 2023. 2. Further review of histopathology quality control records found the laboratory failed to retain histopathology daily stain quality acceptability records prior to August of 2023. The laboratory failed to have daily quality control acceptability records for 23 of 24 months reviewed from the past two years. 3. Interview with TS at 9:08am on 08/30 /2023 confirmed that the daily quality control logs are shredded after they are complete.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 review of laboratory procedures, lack of documentation, and interview with the technical supervisor (TS), the laboratory's procedure manual, "Policies & Procedures - Overall operation", for histopathology testing failed to include the digital slide reading process performed by the facility. 1. Review of laboratory procedure, "Policies & Procedures - Overall operation" revealed the lack of a procedure for the examination of digital histopathology slides. 2. Interview with the TS at 9:30am on 08/30/2023 confirmed that no procedures have been updated with the digital histopathology examination process.
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. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment policy, patient test reports, quality control records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to document the acceptability of reactivity for hematoxylin and eosin (H&E) stain, Warthin-Starry silver stain (WS), and Periodic Acid Shift-Alcian blue (PAS-AB) stain with each group of patient slides for four of five patient testing records reviewed. 1. Review of the laboratory policy, "Quality Assessment Program", stated on page two "Stains QC log, daily and monthly..Stains are reviewed daily for quality control and data is recorded daily and on a monthly basis" and on page three "QC review of slide quality and stains by the pathologist. - The pathologist performs gross and microscopic examination of slides and documents slide and stains quality. Any unacceptable slide quality including broken slides, issues with coverslips, suboptimal stains, or bad sections are documented in the QC form. Recutting and repeat preparation of the slide is requested using the PowerPath LIS electronically. Stain control slides are reviewed and documented for appropriate positive staining and negative background staining. Controls are accepted for appropriate pattern, quality, and intensity of staining." 2. Review of five histopathology testing reports found for four of five patient test reports reviewed the laboratory failed to document the acceptability of the differential (H&E) and special stains (Warthin-Starry silver stain, and Periodic Acid Shift-Alcian blue) on the daily quality control stain review log. See D3031. Chart Number Report Date Stain(s) 230466 11-19-2021 H&E, WS 223635 03-10-2022 H&E, WS, PAS-AB 601355 10-27-2022 H&E 602174 01-16-2023 H&E 3. Interview with TS at 9:08am on 08/30/2023 confirmed that the daily quality control logs are shredded after they are completed.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The

	laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to evaluate the differences between digital histopathology slides and glass slides at least bi-annually in 2022 through the date of survey (8-30-2023). Findings: 1. Review of laboratory records found no documented method comparisons for digital histopathology slides and glass slides in 2022 through the date of survey (8-30-2023). 2. Review of the procedure, "Policies & Procedures - Overall operation", stated "SLIDES DELIVERY OFR READING - Prepared glass slides or images are delivered to the pathologist for reading". 3. Interview with TS at 9:30am on 08/30/2023 confirmed that the laboratory failed to perform comparative evaluations between glass and digital slide reading.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on document review and interview with the technical supervisor (TS), the laboratory's histopathology test reports failed to contain the name and address of the grossing laboratory as well as the location where the professional component of the histopathology testing was performed for five of five patient testing records reviewed. 1. Review of five patient test reports for histopathology testing found for five of five patient test reports the laboratory failed to identify the name and address of the laboratory that performed the technical component (grossing) and identify the remote location where the professional component (reading of the slides) was performed. Chart Number Report Date 230466 11-19-2021 223635 03-10-2022 601355 10-27-2022 602174 01-16-2023 604599 08-15-2023 2. Interview with the TS at 9:24am on 08/30/2023 confirmed that the histopathology test reports failed to identify the name and address of the laboratory that performed the technical component and the remote location where the professional component was performed.