Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2150450	04/04/2019
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and an interview with laboratory director (LD); the laboratory failed to establish written policies and procedures for specimen handling, receiving, and referral, prior to receiving patient specimens for Histopathology. Findings include: 1. The laboratory procedures manual was reviewed. 2. The laboratory receives histology slides from tissue processing laboratories for interpretation. 3. The manual failed to include the following written policies and procedures: * The step-by-step procedure detailing how patients' slides are to be received and documented, which includes Specimen labeling (including patient name or unique patient identifier), date & time received, and, specimen source. * Specimen storage and preservation. * Specimen referral -the name, location and CLIA# of the processing or consulting laboratory. 4. On 04/04/2019 at 11:30 PM, the LD confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory director (LD), the laboratory's procedures manual failed to include all the applicable requirements specified in 493.1251(b)(1) - (14) for all tests, assays, and examinations performed by the laboratory in the specialty of Histopathology, prior to testing patients. Findings: 1. The laboratory procedures manual was reviewed. 2. The laboratory receives histology slides from tissue processing laboratories for interpretation. 3. The procedures manual failed to include the following written policies and procedures: * Requirements from the processing laboratories for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral. See D5311. * Procedures for the preparation of slides, stains, and other methods used to produced the slides submitted for interpretation/testing; * The twice annual slide interpretation verification procedures. * The Control procedures the laboratory will use to evaluate the quality of the various stained slides received from the processing laboratories. * Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. * Imminently life-threatening test results, or panic or alert values. * The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values; and * Description of the course of action to take if a test system becomes inoperable. 4. On 04/04/2019 at 11:30 PM, the LD confirmed the above findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 an interview with the laboratory director (LD); the LD failed to establish quality assurance (QA) programs for the laboratory providing Histopathology slide interpretations, prior to testing patients. Findings include: 1. The laboratory's procedures manual was reviewed. 2. The LD failed to establish an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions for the following phases of the testing process: *Preanalytic -

	assessing practices/issues related to test requests, specimen submission, handling and referral. *Analytic - assessing:practices/issues related to quality control and test verification procedures; comparison of test results, if applicable; corrective actions; and test records. *Post-analytic -assessing practices/issues related to test reports. 3. On 04/04/2019 at 11:30 PM, the LD confirmed the above findings.