Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383582	11/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Iowa Digestive Disease Center, Pc	1378 Nw 124th Street, Suite 200, Clive, IA	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 11/05/2021, the laboratory failed to establish written policies and procedures to assess the competency of the clinical consultant, technical supervisor, general supervisor, and testing personnel.
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 review of the laboratory's policies and procedures and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 11/05/2021, the laboratory failed to have the following written policies and procedures: specimen acceptability and rejection criteria and instructions for handling unacceptable specimens; microscopic examination including the detection of inadequately prepared slides; process for requesting recutting and/or restaining of inadequately prepared slides; control procedures including the type of control, identity, number, and frequency of testing controls and the criteria to determine acceptable control results; corrective action to take when control results fail to meet the laboratory's criteria for acceptability; and the laboratory's system for entering results into the patient record and reporting patient results.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 11/05/2021, the laboratory director failed to approve, sign, and date the laboratory's procedures. The findings include: 1. The laboratory had a binder with the following policies and procedures in it: Lab Specimens/Containers, Disposition of Tissue Specimens, Specimen Log, Specimens Not Requiring Pathological Examination, and Pathology Courier Check List/ SOP. 2. At the time of the survey, the laboratory director did not approve, sign, and date the procedures listed above.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test reports, quality control records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 11/05/2021, the laboratory failed to document Hematoxylin and Eosin (H & E) stain quality each day of use for two out of six days of patient testing reviewed from August- October 2021. The findings include: 1.

	Personnel identifier #1 stated that all biopsies collected for the Iowa Digestive Disease Center are shipped to another laboratory for specimen processing. Once processed, the processing laboratory sends the slides to personnel identifier #1 for interpretation and reporting. 2. Personnel identifier #1 also stated that the "Electronically Signed" and "Date Reported" fields on patient test reports indicated the date testing personnel interpreted and reported the slides. 3. Patients A and B had slides with H & E staining interpreted and reported on 10/27/2021. 4. Patient C had slides with H & E staining interpreted and reported on on 08/28/2021. 5. At the time of the survey, the laboratory did not have documentation of H & E stain quality for 10/27/2021 or 08/28/2021.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 11/05/2021, the laboratory director failed to meet responsibility requirements including: ensuring a quality assessment program is established and maintained as specified in D6094 and ensuring an approved procedure manual is available to all personnel as specified in D6106.
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 review of the laboratory's policies and procedures and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 11/05/2021, the laboratory director failed to ensure that the laboratory established and maintained a quality assessment program that included the four quality systems: general laboratory, pre analytical, analytical, and post analytical.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and confirmed by

	laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 11/05/2021, the laboratory director failed to ensure the laboratory had an approved procedure manual available. Refer to D5403 and D5407.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures, Hematoxylin and Eosin quality control records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 11/05/2021, the technical supervisor failed to establish a quality control program that maintained acceptable levels of analytic performance as specified in standard D6117.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, Hematoxylin and Eosin quality control records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 11/05/2021, the technical supervisor failed to establish a quality control program that ensured documentation of Hematoxylin and Eosin stain quality each day of patient testing for two out of six days reviewed from August- October 2021. Refer to D5473.