Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0340511	12/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Akron Digestive Disease Consultants, Inc	570 White Pond Drive, Suite 100, Akron, OH	

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 record review and an interview with the Practice Administrator (PA), the laboratory failed to establish and follow written policies and procedures to assess the competency of Testing Personnel (TP) #2 and TP#3 and of Clinical Consultant (CC) #2, CC#3, CC#4, CC#5, CC#6 and CC#7 and General Supervisor (GS) #2 based on the responsibilities of their positions. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 12/06 /2018, revealed three individuals listed as TP, seven individuals listed as CC's and two individuals listed as GS's, including the Laboratory Director. 2. Review of the laboratory's policy and procedure manuals titled "ADDC Pathologist Procedure Manual" and "ADDC Lab Manual", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to the start of patient testing on 09/04/2018, did not find any mention of a competency assessment policy and procedure for TP, CC's and GS's. 3. The Surveyor requested the laboratory's TP, CC, and GS competency assessment policies and procedures and the 2018 assessment documentation from 09/04/2018 to current from the PA. The PA confirmed that the laboratory did not establish and follow a competency assessment policy and procedure for the assessment of the TP, CC, and GS, did not assess the competency of TP#2 and TP#3 for the high complexity tissue biopsy grossing and interpretation procedures performed, did not assess the competency of CC#2, CC#3, CC#4, CC#5, CC#6, CC#7 and GS#2 based on the responsibilities of each of the positions and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2018 at 9:45 AM.

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 an interview with the Practice Administrator (PA), the laboratory failed to blindly verify the accuracy of the tissue biopsy grossing and slide interpretation procedures performed. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "ADDC Pathologist Procedure Manual" and "ADDC Lab Manual", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to the start of patient testing on 09 /04/2018, did not find any mention of a blind test accuracy verification (TAV) policy and procedure for the tissue biopsy grossing and slide interpretation procedures performed. 2. Review of the laboratory's "QA Random Review" log sheets for September and October 2018 revealed 10 cases each month were peer reviewed for diagnosis by the other professional component testing personnel. Documentation was indicated as "Agree". 3. The Surveyor requested the laboratory's policy and procedure for TAV activities for blind tissue biopsy grossing and slide interpretation procedures performed from the PA. The PA confirmed that the laboratory did not establish and follow a policy and procedure for blind TAV activities for the tissue biopsy grossing and slide interpretation procedures performed, the 10 case diagnostic peer review each month was not blind and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2018 at 11:50 AM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Administrator (PA), the laboratory failed to define criteria consistent with the manufacturer's instructions and document humidity conditions for reliable tissue biopsy procedures and test result reporting. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "ADDC Pathologist Procedure Manual" and "ADDC Lab Manual", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to the start of patient testing on 09/04/2018, did not find any instructions to monitor and document humidity conditions consistent with manufacturer's operating specifications. 2a. Review of the Microtome Thermo Scientific Microm HM355S manufacturer's operation manual revealed the following: "a max. rel. humidity of 60%" max; maximum rel; relative %; percent 2b. Review of the ClearVue manufacturer's operator guide revealed the following: "Relative Humidity Max. 80% RH up to 31C Decreasing linearly to 50% RH at 40C" RH;

	relative humidity C; degrees Celsius 3. The Surveyor requested the laboratory's policy and procedure for the humidity criteria consistent with the manufacturer's instructions and the humidity documentation from 09/04/2018 to current from the PA. The PA confirmed the laboratory did not establish a policy and procedure for the humidity criteria consistent with the manufacturer's instructions, did not monitor and document humidity from 09/04/2018 to current, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2018 at 12:15 PM.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Administrator (PA), the laboratory failed to establish, perform and document a maintenance protocol that ensured accurate and reliable microscope performance which was necessary for microscopic tissue biopsy grossing and slide interpretation test results and test result reporting. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "ADDC Pathologist Procedure Manual" and "ADDC Lab Manual", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to the start of patient testing on 09/04/2018, did not find any mention of a microscope maintenance policy and procedure. 2. Direct observation of the histopathology laboratory in Suite 300 for the tissue biopsy grossing and processing on 12/04/2018 at 3:20 PM found a microscope, serial number 0647120, which was utilized to assess the acceptability of slide preparations and the hematoxylin and eosin intended stain reactivity prior to sending the tissue biopsy slides to another laboratory location in Suite 100 to be interpreted and reported. 3. The Surveyor requested the laboratory's microscope maintenance policy and procedure and all microscope maintenance documentation from 09/04/2018 to current for Suite 300 and Suite 100 from the PA. The PA confirmed that the laboratory did not establish a policy and procedure, perform and document any microscope maintenance from 09/04/2018 to current and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2018 at 3:20 PM.
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 record review and an interview with the Practice Administrator (PA), the laboratory failed to ensure that the test report indicated the correct name and address of the laboratory location in which the professional component of tissue biopsy slide interpretation procedures were performed. Findings Include: 1. Review of nine out of nine of the laboratory's test records and test reports, on the date of the inspection, revealed the following footnote on 100% of the test reports reviewed: "Technical and Professional component performed at Digestive Health Diagnostics 570 White Pond Drive, Suite 300 Akron, OH 44320" 2. Direct observation of Suite 300 at the above mentioned street address on the date of the inspection at 3:20 PM, found this suite was utilized only for the technical component of tissue biopsy grossing and processing with no indications that professional component activities of the tissue biopsy slide interpretations were performed. 3. An interview with the PA, on 12/04/2018 at 1:53 PM, revealed that only the technical component of tissue biopsy grossing and processing was performed in Suite 300. Prepared tissue biopsy slides were then delivered to Suite 100 in which the professional component of tissue biopsy slide interpretation and reporting was performed. The PA also confirmed that the name and address of where the professional component of tissue biopsy slide interpretations were performed was incorrectly indicated on 100% of the final test reports from 09/04 /2018 to the date of the inspection.
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 record review and an interview with the Practice Administrator (PA), the Laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart for the tissue biopsy grossing and slide interpretation procedures performed. Findings Include: 1. The Laboratory Director failed to ensure that the hematoxylin and eosin (H&E) quality control (QC) program for the technical component laboratory was established and maintained to assure the quality of the routine histopathology H&E intended stain reactivity and to identify failures in quality as they occur. (Refer to D6093) 2. The Laboratory Director failed to ensure that the quality assessment programs were established and maintained to assure the quality of the high complexity tissue biopsy grossing and slide interpretation procedures performed and to identify failures in quality as they occur. (Refer to D6094) 3. The Laboratory Director failed to ensure that, prior to testing patients' specimens, Testing Personnel (TP) #2 and TP#3 had received the appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate results for the high complexity tissue biopsy grossing and slide interpretation procedures performed. (Refer to D6102) 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the tissue biopsy grossing and slide interpretation procedures performed. (Refer to D6106)

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 Practice Administrator (PA), the Laboratory Director failed to ensure that the hematoxylin and eosin (H&E) quality control (QC) program for the technical component laboratory was established and maintained to assure the quality of the routine histopathology H&E intended stain reactivity and to identify failures in quality as they occur. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "ADDC Pathologist Procedure Manual" and "ADDC Lab Manual", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to the start of patient testing on 09/04/2018, did not find any mention of a H&E stain and QC policy and procedure. 2. The Surveyor requested the laboratory's H&E stain and QC policy and procedure and the technical component H&E stain QC documentation from 09/04 /2018 to current from the PA. The PA confirmed the laboratory did not establish and follow a H&E stain and QC policy and procedure, the technical component laboratory did not document the H&E stain QC each day of testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12 /04/2018 at 12:35 PM.
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 Practice Administrator (PA), the Laboratory Director failed to ensure that the quality assessment programs were established and maintained to assure the quality of the high complexity tissue biopsy grossing and slide interpretation procedures performed and to identify failures in quality as they occur. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "ADDC Pathologist Procedure Manual" and "ADDC Lab Manual", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to the start of patient testing on 09/04/2018, found a policy and procedure titled "Pathology Lab Quality Assurance" but there was no mention of any ongoing mechanisms to assess, monitor and document all phases of the testing process proactively. 2. The Surveyor requested the laboratory's ongoing quality assessment policy and procedure and documentation of these activities from 09 /04/2018 to current for the high complexity tissue biopsy grossing and slide interpretation procedures performed from the PA. The PA confirmed the policy and procedure provided on the date of the inspection indicated the reactive process, the laboratory did not assess, monitor and document any quality assessment activities for

	all phases of the testing process and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2018 at 12:46 PM.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Administrator (PA), the Laboratory Director failed to ensure that, prior to testing patients' specimens, Testing Personnel (TP) #2 and TP#3 had received the appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate results for the high complexity tissue biopsy grossing and slide interpretation procedures performed. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "ADDC Pathologist Procedure Manual" and "ADDC Lab Manual", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to the start of patient testing on 09 /04/2018, did not find any mention of a training and competency assessment policy and procedure for TP. 2. The Surveyor requested the laboratory's TP training and competency assessment policy and procedure and the 2018 training and assessment documentation prior to testing patient tissue biopsies for TP#2 and TP#3 from the PA. The PA confirmed that the laboratory did not establish and follow a training and competency assessment policy and procedure for TP, did not train and assess the competency of TP#2 and TP#3 prior to the high complexity tissue biopsy grossing and slide interpretation procedures performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2018 at 9:56 AM.
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 record review and an interview with the Practice Administrator (PA), the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the tissue biopsy grossing and slide interpretation procedures performed. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "ADDC Pathologist Procedure Manual" and "ADDC Lab Manual", provided on the date of the inspection, unapproved by the Laboratory Director prior to beginning patient testing on 09/04/2018, did not find the following examples of policies and procedures: Training and Competency Assessment Test Accuracy Verification (TAV) Hematoxylin and Eosin (H&E) Staining H&E Quality Control (QC) Microscope Maintenance Humidity Monitoring 2. The Surveyor

	requested the laboratory's approved procedure manuals prior to beginning patient testing as well as the above mentioned policies and procedures, approved by the Laboratory Director, from the PA. The PA confirmed the Laboratory Director did not approve the procedure manuals prior to beginning patient testing, did not establish the above mentioned policies and procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2018 at 11:50 AM.