Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2162518	10/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Endoscopy Center Of The North Shore, Llc	1732 Central St, Evanston, 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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the regulatory affairs manager (RM), the laboratory failed to ensure 5 of 14 elements of procedure were documented in the "GOPATH Laboratories" procedure manual for histopathology slide interpretations from 10/05/2022 to 10/30/2024, affecting 7,591 tests (Refer to D5403). The laboratory failed to document quality control (QC) reviews for immunohistochemical stain Helicobactor pylori, special (Alcian blue /periodic acid-Schiff (PAS)) and differential staining Hematoxylin and Eosin (H & E) by the testing personnel (TP) performing histopathology slide interpretations for five of five patients from 10/05/2022 to 10/30/2024, affecting 7,591 patient tests (Refer to D5601).
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 laboratory records, lack of documentation and interview with the regulatory affairs manager (RM), the laboratory failed to ensure 5 of 14 elements of procedure were documented in the "GOPATH Laboratories" procedure manual for traveling testing personnel (TP) performing histopathology slide interpretations from 10/05/2022 to 10/30/2024, affecting 7,591 tests. Findings include: 1. Review of the "GOPATH Laboratories" procedure manual revealed no documentation of the following 5 of 14 elements of procedure utilized for traveling TP performing histopathology slide interpretations from 10/05/2022 to 10/30/2024, affecting 7,591 tests. a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. b. Microscopic examination, including the detection of inadequately prepared slides. c. Step-by-step performance of the procedure, including test calculations and interpretation of results. d. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. e. Control procedures. 2. On 10/31/2024, at 9:09 a.m., an interview with the RM confirmed the missing procedure elements in Finding 1 for histopathology slides delivered to the laboratory by traveling TP.
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: Repeat Deficiency Based on review of laboratory records, lack of documentation and interview with the regulatory affairs manager (RM), the laboratory failed to document quality control (QC) reviews for immunohistochemical stain Helicobactor pylori, special (Alcian blue/periodic acid-Schiff (PAS)) and differential staining Hematoxylin and Eosin (H & E) by the testing personnel (TP) performing histopathology slide interpretations for five of five patients from 10/05/2022 to 10/30/2024, affecting 7,591 patient tests. Findings include: 1. Repeat deficiency from 04/16/2021 survey. 2. Review of the "GoPath Laboratories Internal Quality Assessment and Performance Improvement Plan" revealed the following information: " ...V. Performance Aspects /Processes: ...e. Analytic variables ...viii. Review of stain and slide quality" 3. Review of five of five patient test dates revealed no documentation of QC stains reviewed by

	TP performing histopathology slide interpretations. a. DATE: 10/04/2022 STAIN(S) Reviewed: H & E, Alcian blue / PAS QC: Not documented b. DATE: 03/01/2023 STAIN(S) Reviewed: H & E, Alcian blue / PAS QC: Not documented c. DATE: 12/02 /2023 STAIN(S) Reviewed: H & E QC: Not documented d. DATE: 07/02/2024 STAIN(S) Reviewed: H & E, Alcian blue / PAS QC: Not documented e. DATE: 09/21 /2024 STAIN(S) Reviewed: H & E QC: Not documented 4. On 10/31/2024, at 11:15 a. m., an interview with the RM confirmed H & E, Alcian blue / PAS and Helicobactor pylori QC reviews are not documented by TP. 5. Review of laboratory records revealed 7,591 patient tests affected from 10/05/2022 to 10/30/2024. Number of stains reviewed: H & E: 4693 Alcian blue / PAS: 2053 Helicobactor pylori: 845
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 laboratory records, lack of documentation and interview with the regulatory affairs manager (RM), the laboratory director (LD) failed to ensure the quality control (QC) program was maintained for histopathology slide interpretations from 10/05/2022 to 10/30/2024, affecting 7,591 patient tests (Refer to D6093).
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 review of laboratory records, lack of documentation and interview with the regulatory affairs manager (RM), the laboratory director failed to ensure the quality control (QC) program was maintained for histopathology slide interpretations from 10 /05/2022 to 10/30/2024, affecting 7,591 patient tests. Findings include: 1. Review of the laboratory's "Lab Director Duties" policy revealed the following information: "5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur." 2. Review of the "GoPath Laboratories Internal Quality Assessment and Performance Improvement Plan" revealed the following information: " ...V. Performance Aspects/Processes: ...e. Analytic variables ...viii. Review of stain and slide quality" 3. The LD failed to ensure the QC program was maintained for histopathology testing (Refer to D5601).