Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2162518	04/16/2021
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
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 record review and an interview with the GoPath representative, the laboratory failed to document all control procedures performed, as specified in the specialty of Histopathology for 7 out 7 patients. Findings Include: 1. The laboratory's manual, Endoscopy Center of The North Shore patients' specimen submissions lists, and GoPath quality control (QC) log sheets were reviewed. 2. The procedures manual revealed the following: *The laboratory performed Histopathology slide interpretations only. *Patients' specimens were sent to GoPath laboratory for tissue processing and Histopathology slide production. 3. The 7 (seven) patients selected from the specimen lists and QC logs revealed the laboratory failed to document the following: *the QC of the Hematoxylin and eosin (H&E) stains for 6 out of 7 patients' slides; and *the QC from the special stains performed for 3 out of 3 patients' slides. 4. Further review of the QC log sheets showed it failed to provide space to include the recording of special stain quality controls. 5. The laboratory failed to document all tissue staining quality controls and failed to establish procedures which ensure the tissue stain quality of all processed tissue are assessed and documented from GoPath, prior to reading patients' Histopathology slides. 6. On a Recertification survey conducted on 04/16/2021 at 2:10 PM, the GoPath representative confirmed the above findings.

D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and an interview with the GoPath representative, the laboratory failed to meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. Findings Include: 1. The laboratory failed to meet the following inspection requirements: *To provide CMS agent with copies or exact duplicates of all records and data it requires. *To have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. *To provide, upon request, all information and data needed by CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. See D8103.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the GoPath representative, the laboratory failed to MEET the general requirements of the inspection process when it failed to *provide CMS agent with copies or exact duplicates of all records and data it requires. *have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. *provide, upon request, all information and data needed by CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. Findings Include: 1. The laboratory manual, Endoscopy Center of The North Shore patients' specimen submissions lists, GoPath quality control (QC) log sheets, and Clinical Laboratory Improvement Amendments (CLIA) survey packet were reviewed. 2. The procedures manual revealed the following: *The laboratory

	performed Histopathology slide interpretations only. *Patients' specimens were sent to GoPath laboratory for tissue processing and Histopathology slide production. *Patients' slide were stored at GoPath Laboratory (14D2037930), located on 1351 Barclay Blvd in Buffalo Grove, Illinois. 3. The surveyor selected 7 patients (PT1, PT2, PT3,....PT7) from the submissions' lists for requisition, slides, quality control (QC), and final report review. The laboratory failed to be able to print the requisitions and final reports; failed to present the selected patients' slides, and failed to provide the QC records for 7 out of 7 patients, during the survey. 4. The surveyor extended the submission of the requested documents listed in Findings #3 and the completion of CLIA forms (the "Disclosure of Ownership" & Laboratory Personnel Report (CMS 209) form) to 04/20/2021. The documents received on 04/21/2021 at 4:33 PM revealed the following: *The laboratory failed to provide the requisitions for 3 (PT2, PT4 & PT7) out of 7 patients; *The laboratory failed to provide the final reports for 2 (PT2 & PT4) out of 7 patients; *A photo of Hematoxylin and eosin (H&E) and special stains slides for all 7 patients were included, however the laboratory failed to include the QC records of these slides. *The laboratory failed to submit a completed "Disclosure of Ownership" and CMS 209 form. 5. On a Recertification survey conducted on 04/16/2021 at 2:10 PM, the GoPath representative confirmed the above findings.