Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2027406	12/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
North Coast Endoscopy	9500 Mentor Ave, Ste 340, Mentor, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to document all evaluations of test accuracy verification (TAV) activities for the tissue biopsy interpretations performed in the specialty of Histopathology. All patient tissue biopsy slide interpretation procedures performed from 05/03/2021 to 12/14/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policies and Procedures", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to new directorship and patient testing on 05/03/2021, did not find instructions to document the TAV re-interpretation of the microscopic tissue biopsy examination by the reviewing pathologist. 2. The Inspector requested the laboratory's TAV blind tissue biopsy interpretation activities for case numbers 21AL-0636, 21AL-0647, 21AL-0788, 21AL-0789, 21AL-0829 and 21AL-0842 from the GS. The GS stated the slide interpretations for TAV activities were not able to be located and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/14/2021 at 9:34 AM.
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 General Supervisor (GS), the Laboratory Director failed to ensure that, prior to testing patients' specimens, Testing Personnel (TP) #2 and TP#3 had demonstrated and documented that they could perform all testing operations reliably to provide and report accurate results for the high complexity tissue biopsy slide interpretation procedures performed in the specialty of Histopathology. All patient tissue biopsy slide interpretation procedures performed from 05/03/2021 to 12/14/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policies and Procedures", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to new directorship and patient testing beginning on 05/03/2021, did not find any mention of a training and competency assessment policy and procedure for the professional component of microscopic tissue biopsy examinations. 2. The inspector requested the laboratory's TP training and competency assessment policy and procedure and the 2021 training and assessment documentation prior to testing patient tissue biopsies for TP#2 and TP#3 from the GS. The GS confirmed that the laboratory did not follow their training and competency assessment policy and procedure for the professional component TP, did not train and assess the competency of TP#2 and TP#3 prior to the high complexity tissue biopsy slide interpretation procedures were performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/14/2021 at 8:42 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: Item 1 Based on record review and an interview with the General Supervisor (GS), 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 in the specialty of Histopathology. All patient tissue biopsy slide interpretation procedures performed from 05/03/2021 to 12/14 /2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policies and Procedures", provided on the date of the inspection, unapproved via signature and date by the Laboratory Director prior to new directorship and patient testing beginning on 05/03/2021, revealed that all procedures were unapproved via signature and date by the Laboratory Director upon new directorship and patient testing beginning on 05 /03/2021. 2. The Inspector requested the laboratory's approved policies and procedures upon the new directorship and prior to beginning patient tissue biopsy grossing and slide interpretation procedures from the GS. The GS confirmed the new Laboratory Director, as of 05/03/2021, did not approve the procedure manual prior to beginning patient tissue biopsy grossing and slide interpretation procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/14/2021 at 9:34 AM. Item 2 Based on record review and an interview with the General Supervisor (GS), the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any

	aspect of the microscopic tissue biopsy interpretation procedures performed in the specialty of Histopathology. All patient microscopic tissue biopsy interpretation procedures performed from 05/03/2021 to 12/14/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policies and Procedures", provided on the date of the inspection, revealed that all procedures were unapproved via signature and date by the Laboratory Director upon new directorship and patient testing beginning on 05/03 /2021 and did not find any policies and procedures for the professional component of microscopic tissue biopsy examinations. 2. The Inspector requested the laboratory's approved policies and procedures upon the new directorship and prior to beginning patient microscopic tissue biopsy interpretation procedures from the GS. The GS confirmed the new Laboratory Director, as of 05/03/2021, did not establish policies and procedures for the professional component of microscopic tissue biopsy procedures, did not approve the procedure manual and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12 /14/2021 at 9:34 AM.