Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0032533	06/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Uh Cleveland Medical Center	11100 Euclid Avenue, Cleveland, 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
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interviews with the Laboratory Director, the Anatomic Pathology Division Chief (APDC), the Anatomic Pathology Quality Director (APQD), the Surgical Anatomic Pathology Manager (SAPM), the Anatomic Pathology Technical Coordinator (APTC), the Clinical Pathology Director (CPD), the Quality and Regulatory Affairs Specialist (QRAS) and the Laboratory Technical Coordinator (LTC), the laboratory failed to meet the post analytic systems requirements in 493.1291 for patient tissue biopsy testing procedures in the subspecialty of Histopathology. This deficient practice affected one out of 157 patient tissue biopsy specimens received in the histopathology laboratory on 03/17/2025. Findings Include: 1. The laboratory failed to ensure patient tissue biopsy test results were entered in a timely manner to the final report in the subspecialty of Histopathology. (Refer to D5801) 2. The laboratory failed to notify the ordering provider of the delayed testing procedures when the established turn around times were not met for patient tissue biopsy testing procedures which adversely affected patient care in the subspecialty of Histopathology. (Refer to D5815) 3. The laboratory failed to follow procedures to monitor, assess and correct problems identified in their post analytic processes regarding unacceptable patient tissue biopsy specimens, timely

	notification of test results and when the laboratory's test result turn around time was not met for patient tissue biopsy testing procedures in the subspecialty of Histopathology. (Refer to D5891)
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director, the Anatomic Pathology Division Chief (APDC), the Anatomic Pathology Quality Director (APQD), the Surgical Anatomic Pathology Manager (SAPM), the Anatomic Pathology Technical Coordinator (APTC), the Clinical Pathology Director (CPD), the Quality and Regulatory Affairs Specialist (QRAS) and the Laboratory Technical Coordinator (LTC), the laboratory failed to ensure patient tissue biopsy test results were entered in a timely manner to the final test report in the subspecialty of Histopathology. This deficient practice affected one out of 157 patient tissue biopsy specimens received in the histopathology laboratory on 03/17/2025. Findings Include: 1. Review of the laboratory's Histopathology test menu, approved via signature and date by the Laboratory Director on 05/16/2025, revealed the laboratory conducted patient tissue biopsy testing procedures. 2. Review of the laboratory's "Gross Room 'Problem Bin' Escalation Job Aid", provided on the date of the complaint investigation revealed the laboratory receives the specimen on Day 1. On Day 2, the grossing person is to identify the presence of the specimen in the specimen container and if no specimen is found, is to immediately notify the surgical pathologist in accordance with "AP 3.12 Reporting and Handling of QNS Specimens in Surgical Pathology" policy and procedure. 3. Review of the laboratory's "AP 3.12 Reporting and Handling of QNS Specimens in Surgical Pathology" policy and procedure, approved via signature and date by the Laboratory Director on 02/12/2025 found the following statements: "1. Any specimen which is not found in the specimen container at gross will be held for the pathologist to view. The pathologist is responsible for the sign out of the case and must view the container prior to any measures being taken to try to retrieve tissue. 2. After viewing the container, the grossing person must follow the procedure outlined below and the phrase 'No material identified in the specimen container' must be placed in the Gross Description of the report. The resident/Surgical Pathology technician upon opening the specimen container does not visualize a specimen. The Surgical Pathologist assigned to the case is notified to inspect the container and the container lid. The below procedure should be followed if there is ANY question as to whether any tissue/specimen is present in the container. The resident/technician places several drops of eosin into the specimen container and pours the formalin through the filter paper. The resident or technician documents the 'Specimen Deficiency' in the lab computer system and dictates the deficiency in the gross description as 'No gross specimen was identified, and the specimen was filtered'. The filter paper is carefully folded and submitted in a labeled cassette. The Histology

information is entered in the lab computer system with a note 'no specimen seen grossly'. The Histology laboratory will carefully examine and scrape the histowrap paper at the embedding center and the paper will be re-embedded in the back of the cassette. Two representative slides will be cut and delivered to the assigned Pathologist. 3. Notify the ordering physician of this finding. This should be done by the Pathologist... Specimen Not Present After Processing 1. When a specimen has been processed, but is not present after processing; The technicians will carefully examine and scrape the histowrap paper at the embedding center and the paper will be re-embedded in the back of the cassette. Two representative slides will be cut and delivered to the assigned Pathologist. A QA report will be filed with the Surgical Pathology Supervisor. 2. The pathologist must enter the phrase 'No specimen present following processing.' in the Final Diagnosis field of the report. 3. The pathologist must notify the ordering physician and documentation of such must be entered in Epic Case Results. The documentation must include who was notified, on what date and by whom." 4. Review of the laboratory's "SurgPath.059 Surgical Pathology Services" policy and procedure, approved via signature and date by the Laboratory Director on 02/19/2025 found the following statements: "The ordering physician or charge nurse will be contacted to correct any problems with the specimen before it is processed. NOTE: Most surgical pathology specimens require overnight processing before a diagnosis is available. Please respond as soon as possible to correct problems." "Surgical Pathology Reports Surgical Pathology report status and final diagnosis is available in Epic, 24-hours a day." "Turn around time standards: Turn around times are based on the day that the specimen arrives in the department and the day that the final diagnosis is available on the computer system. Biopsy 3 days Routine 7 days" 5. Review of the laboratory's Information Technology Case Tracking tool for the affected patient tissue biopsy specimen revealed the following: 03/17/2025 Specimen accessioned, gross description entered, scanned for Surgical Pathology Consultation, Pathologist Assigned, Surgical Pathology Consultation Entered 03/18/2025 Specimen Tracked 03/19/2025 Specimen Embedded, Surgical Pathology Consultation Entered 03/27/2025 Specimen Microtomy 03/28/2025 Assigned Pathologist Removed, Assigned another Pathologist, Surgical Pathology Consultation Entered, Result Final Verified, Result Filed to Chart, Released to Patient Portal 04/08/2025 Communication Log Completed by reviewing Pathologist 6. Review of the laboratory's final test report for the affected patient tissue biopsy revealed, under the section titled, "Gross Description": "Received in formalin, labeled with patient's name and hospital number and 'bladder tumor', is a specimen consisting of formalin. Tissue is not seen. Eosin is added to the specimen container. Upon filtering of the formalin, tissue is not identified. The specimen has been reviewed. The Pathologist has been notified. The filtered material is submitted in formalin in one cassette." The Final Diagnosis read "Specimen designated as 'bladder tumor'. No specimen identified in the specimen container." with the newly assigned Pathologist's electronic signature on 03/28/2025 at 1350. The final test report also included a communication note by the reviewing Pathologist stating "The absence of specimen in the specimen container as well as the pathology department's 'empty container protocol' was discussed with the {ordering provider} on 04/07/2025 at 7:04 AM." 7. The Laboratory Director, the APDC, the APQD, the SAPM, the APTC, the CPD, the QRAS and the LTC confirmed via a round table interview on 05/13/2025 at 4:05 PM that the affected patient's tissue biopsy was received in the Histopathology laboratory on 03/17/2025, the final test report was electronically signed out by the reviewing Pathologist on 03/28/2025 and the Pathologist communicated with the ordering provider on 04/07/2025. They further confirmed that the laboratory identified extensive time delays with this particular case that exceeded the laboratory's final test result turn around time and lacked timely notification to the ordering provider regarding the lack of a tissue biopsy specimen.

D5815	TEST REPORT CFR(s): 493.1291(h) (h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director, the Anatomic Pathology Division Chief (APDC), the Anatomic Pathology Quality Director (APQD), the Surgical Anatomic Pathology Manager (SAPM), the Anatomic Pathology Technical Coordinator (APTC), the Clinical Pathology Director (CPD), the Quality and Regulatory Affairs Specialist (QRAS) and the Laboratory Technical Coordinator (LTC), the laboratory failed to notify the ordering provider of the delayed testing procedures when the established turn around times were not met for patient tissue biopsy testing procedures which adversely affected patient care in the subspecialty of Histopathology. This deficient practice affected one out of 157 patient tissue biopsy specimens received in the histopathology laboratory on 03/17/2025. Findings Include: 1. Review of the laboratory's Histopathology test menu, approved via signature and date by the Laboratory Director on 05/16/2025 revealed the laboratory conducted patient tissue biopsy testing procedures. 2. Review of the laboratory's "Gross Room 'Problem Bin' Escalation Job Aid", provided on the date of the complaint investigation revealed the laboratory receives the specimen on Day 1. On Day 2, the grossing person is to identify the presence of the specimen in the specimen container and if no specimen is found, is to immediately notify the surgical pathologist in accordance with "AP 3.12 Reporting and Handling of QNS Specimens in Surgical Pathology" policy and procedure. 3. Review of the laboratory's "AP 3.12 Reporting and Handling of QNS Specimens in Surgical Pathology" policy and procedure, approved via signature and date by the Laboratory Director on 02/12/2025 found the following statements: "1. Any specimen which is not found in the specimen container at gross will be held for the pathologist to view. The pathologist is responsible for the sign out of the case and must view the container prior to any measures being taken to try to retrieve tissue. 2. After viewing the container, the grossing person must follow the procedure outlined below and the phrase 'No material identified in the specimen container' must be placed in the Gross Description of the report. The resident/Surgical Pathology technician upon opening the specimen container does not visualize a specimen. The Surgical Pathologist assigned to the case is notified to inspect the container and the container lid. The below procedure should be followed if there is ANY question as to whether any tissue/specimen is present in the container. The resident/technician places several drops of eosin into the specimen container and pours the formalin through the filter paper. The resident or technician documents the 'Specimen Deficiency' in the lab computer system and dictates the deficiency in the gross description as 'No gross specimen was identified, and the specimen was filtered'. The filter paper is carefully folded and submitted in a labeled cassette. The Histology information is entered in the lab computer system with a note 'no specimen seen grossly'. The Histology laboratory will carefully examine and scrape the histowrap paper at the embedding center and the paper will be re-embedded in the back of the cassette. Two representative slides will be cut and delivered to the assigned Pathologist. 3. Notify the ordering physician of this finding. This should be done by the Pathologist... Specimen Not Present After Processing 1. When a specimen has been processed, but is not present after processing; The technicians will carefully examine and scrape the histowrap paper at the embedding center and the paper will be

	re-embedded in the back of the cassette. Two representative slides will be cut and delivered to the assigned Pathologist. A QA report will be filed with the Surgical Pathology Supervisor. 2. The pathologist must enter the phrase 'No specimen present following processing.' in the Final Diagnosis field of the report. 3. The pathologist must notify the ordering physician and documentation of such must be entered in Epic Case Results. The documentation must include who was notified, on what date and by whom." 4. Review of the laboratory's "SurgPath.059 Surgical Pathology Services" policy and procedure, approved via signature and date by the Laboratory Director on 02/19/2025 lacked instructions to notify the ordering provider when there was a delay in the laboratory's final result turn around time and found the following statements: "The ordering physician or charge nurse will be contacted to correct any problems with the specimen before it is processed. NOTE: Most surgical pathology specimens require overnight processing before a diagnosis is available. Please respond as soon as possible to correct problems." "Surgical Pathology Reports Surgical Pathology report status and final diagnosis is available in Epic, 24-hours a day." "Turn around time standards: Turn around times are based on the day that the specimen arrives in the department and the day that the final diagnosis is available on the computer system. Biopsy 3 days Routine 7 days" 5. Review of the laboratory's Information Technology Case Tracking tool for the affected patient tissue biopsy specimen revealed the following: 03/17/2025 Specimen accessioned, gross description entered, scanned for Surgical Pathology Consultation, Pathologist Assigned, Surgical Pathology Consultation Entered 03/18/2025 Specimen Tracked 03/19/2025 Specimen Embedded, Surgical Pathology Consultation Entered 03/27/2025 Specimen Microtomy 03/28/2025 Assigned Pathologist Removed, Assigned another Pathologist, Surgical Pathology Consultation Entered, Result Final Verified, Result Filed to Chart, Released to Patient Portal 04/08/2025 Communication Log Completed by reviewing Pathologist 6. Review of the laboratory's final test report for the affected patient tissue biopsy revealed, under the section titled, "Gross Description": "Received in formalin, labeled with patient's name and hospital number and 'bladder tumor', is a specimen consisting of formalin. Tissue is not seen. Eosin is added to the specimen container. Upon filtering of the formalin, tissue is not identified. The specimen has been reviewed. The Pathologist has been notified. The filtered material is submitted in formalin in one cassette." The Final Diagnosis read "Specimen designated as 'bladder tumor'. No specimen identified in the specimen container." with the newly assigned Pathologist's electronic signature on 03/28/2025 at 1350. The final test report also included a communication note by the reviewing Pathologist stating "The absence of specimen in the specimen container as well as the pathology department's 'empty container protocol' was discussed with the {ordering provider} on 04/07/2025 at 7:04 AM." 7. The Laboratory Director, the APDC, the APQD, the SAPM, the APTC, the CPD, the QRAS and the LTC confirmed via a round table interview on 05/13/2025 at 4:05 PM that the affected patient's tissue biopsy was received in the Histopathology laboratory on 03/17/2025, the final test report was electronically signed out by the reviewing Pathologist on 03/28/2025 and the Pathologist communicated with the ordering provider on 04/07/2025. They further confirmed that the laboratory identified extensive time delays with this particular case that exceeded the laboratory's final test result turn around time and lacked timely notification to the ordering provider.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review and interviews with the Laboratory Director, the Anatomic Pathology Division Chief (APDC), the Anatomic Pathology Quality Director (APQD), the Surgical Anatomic Pathology Manager (SAPM), the Anatomic Pathology Technical Coordinator (APTC), the Clinical Pathology Director (CPD), the Quality and Regulatory Affairs Specialist (QRAS) and the Laboratory Technical Coordinator (LTC), the laboratory failed to follow procedures to monitor, assess and correct problems identified in their post analytic processes regarding unacceptable patient tissue biopsy specimens, timely notification of test results and when the laboratory's test result turn around time was not met for patient tissue biopsy testing procedures in the subspecialty of Histopathology. This deficient practice affected one out of 157 patient tissue biopsy specimens received in the histopathology laboratory on 03/17/2025. Findings Include: 1. Review of the laboratory's Histopathology test menu, approved via signature and date by the Laboratory Director on 05/16/2025 revealed the laboratory conducted patient tissue biopsy testing procedures. 2. Review of the laboratory's "Reviewable Adverse Events, CP-11", policy and procedure, unapproved via signature and date by the Laboratory Director found the following statement: "3. Permanent harm: An event or condition that reaches the individual, resulting in any level of harm that permanently alters and/or permanently affects an individual's baseline health." 3. Review of the laboratory's "AP 3.12 Reporting and Handling of QNS Specimens in Surgical Pathology" policy and procedure, approved via signature and date by the Laboratory Director on 02/12/2025 found the following statements: "1. Any specimen which is not found in the specimen container at gross will be held for the pathologist to view. The pathologist is responsible for the sign out of the case and must view the container prior to any measures being taken to try to retrieve tissue. 2. After viewing the container, the grossing person must follow the procedure outlined below and the phrase 'No material identified in the specimen container' must be placed in the Gross Description of the report. The resident/Surgical Pathology technician upon opening the specimen container does not visualize a specimen. The Surgical Pathologist assigned to the case is notified to inspect the container and the container lid. The below procedure should be followed if there is ANY question as to whether any tissue/specimen is present in the container. The resident/technician places several drops of eosin into the specimen container and pours the formalin through the filter paper. The resident or technician documents the 'Specimen Deficiency' in the lab computer system and dictates the deficiency in the gross description as 'No gross specimen was identified, and the specimen was filtered'. The filter paper is carefully folded and submitted in a labeled cassette. The Histology information is entered in the lab computer system with a note 'no specimen seen grossly'. The Histology laboratory will carefully examine and scrape the histowrap paper at the embedding center and the paper will be re-embedded in the back of the cassette. Two representative slides will be cut and delivered to the assigned Pathologist. 3. Notify the ordering physician of this finding. This should be done by the Pathologist... Specimen Not Present After Processing 1. When a specimen has been processed, but is not present after processing; The technicians will carefully examine and scrape the histowrap paper at the embedding center and the paper will be re-embedded in the back of the cassette. Two representative slides will be cut and delivered to the assigned Pathologist. A QA report will be filed with the Surgical Pathology Supervisor. 2. The pathologist must enter the phrase 'No specimen present following processing.' in the Final Diagnosis field of the report. 3. The pathologist must notify the ordering physician and documentation of such must be entered in Epic Case Results. The documentation must include who was notified, on what date and by

whom." 4. Review of the laboratory's "SurgPath.059 Surgical Pathology Services" policy and procedure, approved via signature and date by the Laboratory Director on 02/19/2025 found the following statements: "The ordering physician or charge nurse will be contacted to correct any problems with the specimen before it is processed. NOTE: Most surgical pathology specimens require overnight processing before a diagnosis is available. Please respond as soon as possible to correct problems." "Surgical Pathology Reports Surgical Pathology report status and final diagnosis is available in Epic, 24-hours a day." "Turn around time standards: Turn around times are based on the day that the specimen arrives in the department and the day that the final diagnosis is available on the computer system. Biopsy 3 days Routine 7 days" 5. Review of the laboratory's Information Technology Case Tracking tool for the affected patient tissue biopsy specimen indicated the following: 03/17/2025 Specimen accessioned, gross description entered, scanned for Surgical Pathology Consultation, Pathologist Assigned, Surgical Pathology Consultation Entered 03/18/2025 Specimen Tracked 03/19/2025 Specimen Embedded, Surgical Pathology Consultation Entered 03 /27/2025 Specimen Microtomy 03/28/2025 Assigned Pathologist Removed, Assigned another Pathologist, Surgical Pathology Consultation Entered, Result Final Verified, Result Filed to Chart, Released to Patient Portal 04/08/2025 Communication Log Completed by reviewing Pathologist 6. Review of the laboratory's final test report for the affected patient tissue biopsy revealed, under the section titled, "Gross Description": "Received in formalin, labeled with patient's name and hospital number and 'bladder tumor', is a specimen consisting of formalin. Tissue is not seen. Eosin is added to the specimen container. Upon filtering of the formalin, tissue is not identified. The specimen has been reviewed. The Pathologist has been notified. The filtered material is submitted in formalin in one cassette." The Final Diagnosis read "Specimen designated as 'bladder tumor'. No specimen identified in the specimen container." with the newly assigned Pathologist's electronic signature on 03/28/2025 at 1350. The final test report also included a communication note by the reviewing Pathologist stating "The absence of specimen in the specimen container as well as the pathology department's 'empty container protocol' was discussed with the {ordering provider} on 04/07/2025 at 7:04 AM." 7. On 05/21/2025 at 2:08 PM, the CLIA surveyor, requested from the Laboratory Director, the APDC, the APQD, the SAPM, the APTC, the CPD, the QRAS and the LTC the laboratory's quality assessment investigation and Root Cause Analysis for the laboratory's lack of timely notification to the ordering provider regarding no specimen found and the laboratory's failure to meet a timely test result turn around time for patient tissue biopsy testing procedures. The QRAS provided the following notes from the Patient Advocacy Department: "Early Monday morning April 7th (0920am) the Advocate, after reviewing the medical records and gathering additional information, contacted 12:50pm appropriate leadership including pathology leadership. The Advocate received a reply within a couple of hours that a review was started on Pathology end and would update us." "4 /7 Lab leadership, Quality Grievance team notified requesting review and follow up. Lab leadership acknowledged email and started to investigate." "Per timelines provided...and in the summary from Patient Care Advocacy Department, when the sample container was discovered to be empty, Pathology process for handling an empty container was followed...the patient advocacy grievance process was followed. At the time of the above, this event did not trigger an RCA. On 5/16/25, an internal safety (PASS report) was filed from pathology. A Root Cause Learning From Defects review will be conducted and actions defined." 8. The Laboratory Director, the APDC, the APQD, the SAPM, the APTC, the CPD, the QRAS and the LTC confirmed via a round table interview on 05/13/2025 at 4:05 PM that the affected patient's tissue biopsy was received in the Histopathology laboratory on 03/17/2025, the final test report was electronically signed out by the reviewing Pathologist on 03

	/28/2025 and the Pathologist communicated with the ordering provider on 04/07 /2025. They further confirmed that the laboratory identified extensive time delays with this particular case that exceeded the laboratory's final test result turn around time and lacked timely notification to the ordering provider regarding the lack of a tissue biopsy specimen. It was also mentioned that the Histopathology laboratory had recent changes in management and until this concern was identified, a formal quality assessment investigation was not completed. RCA; Root Cause Analysis PASS; Patient Advocacy and Shared Stories