Name of Policy: Laboratory Downtime Procedure **Policy Number**: 3364-107-313 **Approving Officer**: Medical Director, Clinical Pathology **Responsible Agent**: Director, Clinical Pathology Administrative Director, Lab **Scope**: Pathology Laboratory University of Toledo Medical Center	UT UTOLEDO HEALTH **Effective date:** 01/04/2025 **Original effective date**: 05/01/2006

Key words: Computer outage, planned downtime, unplanned downtime, Epic read only, BCA computer.

☐	New policy proposal	☐	Minor/technical revision of existing policy
☐	Major revision of existing policy	☒	Reaffirmation of existing policy

A) Policy statement

Procedures for the operation of the laboratory during computer outages, either of the lab systems or other related systems, are available to all.

B) Purpose of policy

To assure that all personnel know how to keep the laboratory functioning during planned or unplanned computer outages.

C) Procedure

Procedures for operation of the lab when the laboratory computer systems are unavailable are established and maintained in the individual departments of the lab. These procedures are part of each area's policy manual. These policies are in effect when the lab system is unavailable, or when all network connectivity has been lost.

<u>Scheduled Downtime</u>

1. All scheduled downtimes will be coordinated by LIS/IT.
2. LIS/IT will provide notification of the date, time, and duration to the laboratory administration, as well as the managers and supervisors.
3. The managers and supervisors will assure that all specific downtime supplies, downtime logs/worksheets and other specific tasks are assigned to staff for completion prior to the downtime.

Unscheduled Downtime

An unscheduled downtime occurs when there is an unexpected event that renders the system unusable and unavailable.

1. If a laboratory staff member has reason to believe there has been a system failure, the charge person should contact the Help Deck (x383-2400).
    a. **NOTE:** Some indications of system failure might be error messages on screen, system is being logged out repeatedly, inability to use the system, or non-functioning devices.
2. LIS will make the appropriate contact to notify users of the downtime and its expected duration.
3. The charge person will coordinate downtime activities of the laboratory.
4. Laboratory management will be notified at the beginning of the code copper.
    a. **NOTE:** The Chief Information Office, Risk/Compliance Manager or others may be notified if deemed necessary by the Chief Pathologist and Administrative Director.
5. In an unscheduled downtime, each hospital floor is responsible for notifying the lab of any scheduled draws.

Prior to Downtime:

Tasks to be completed prior to downtime beginning:
1. Paper forms
    a. Each department is responsible for ensuring they have their red downtime binders stocked and forms available.
    b. Manual order requisitions.
    c. Manual accession logs.
2. Draw Lists
    a. Assure that the draw lists of orders have already been placed in Epic are available during the downtime.

        i. Draw lists can be located in the Epic RO (Read-Only Mode).
            1. Chart search → Patient List.
            2. Available Lists → Inpatient Draw Lists
            3. All Draws
            4. Right click → Print list
        ii. If there are any scheduled phlebotomy draws needed after the downtime has started, the floors are responsible for contacting the laboratory at 383-3470.
3. Downtime Specimen Creation
    a. Assure there is an adequate supply of downtime labels printed and available for use.
    b. Each downtime specimen ID should have 3 labels. (One label will be placed on the specimen, one label will be placed on the appropriate downtime log, and one label will be placed on the instrument printout or paper log in each department.)
4. Access to BCA: This device provides key clinical information during the downtime.
    a. Assure that the BCA devices are fully functional. The devices provide access to information that providers may request during downtime.
    b. Assure that a downtime staff member has access to proper training for the BCA device.
    c. The BCA location must be kept in an unlocked and accessible location.

  d. The BCA device mut be plugged into an emergency power outlet and be connected directly to a local printer.
5. Quality Control
  a. Each department should keep an updated reference page of each analyte's/assays acceptable range for each level of QC that is performed.
    i. If QC ranges can be viewed on the analyzer, it is not necessary to keep a reference page.
  b. The list should be stored in the downtime binder, near or on the analyzer, or in a designated area that is accessible to all users.
6. Auto verification
  a. Prior to the scheduled downtime beginning, or as soon as possible after notification of an unscheduled downtime, suspend auto verification in Beaker.
  b. To suspend auto verification: click the Actions icon ⊙ button in the upper right corner of the outstanding list screen → Select Auto verification Status → Select the instrument to be disabled using the "Downtime" as the reason.
    i. **NOTE:** During and unscheduled downtime, auto verification will be able to be suspended. Refer to the **Specimen Resulting** section under **Recovery.**
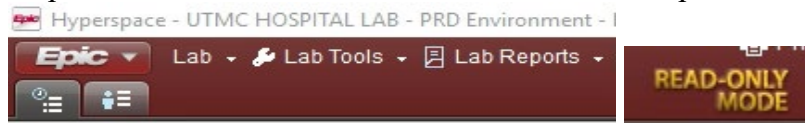
Downtime

Tasks to be completed during the downtime:

1. Before the start of downtime, communication will be announced overhead, or an email will be sent to alert all end users. At this time, all end users should switch to downtime procedures.
2. Access to Epic Data

  a. Read Only Access (RO Environment)
    i. Prior to Epic downtime, the user should logoff from the Epic Production (PRD) environment.
    ii. Using assigned network credentials, the user should logon to the Epic RO (Read-Only Mode) environment.
    iii. The RO environment will have a maroon heading and will only allow the user to view the Epic information until the downtime has been completed.
   1.
    iv. Information not accessible in the RO environment will be greyed out.

Instructions to Access RO (View/Read Only Environment):

1. RO will show a read-only view of Epic.
  a. The icon will appear like Production Epic but will be colored maroon. It will not allow any documentation; it will provide a view of what has been done on a patient.
  b. You will still use paper documentation during downtime.
    i. RO will be the tool to see what was documented on patients prior to downtime.

      ii.   If the RO environment is available, it will be used instead of the BCA PC.

2. Prior to a scheduled downtime, logoff Epic PRD.
3. Log into the RO environment:
   a. Open the Citrix Receiver (Start button → Citrix Receiver).
   b. At the top of the Citrix Receiver window, click Apps.
   c. Scroll down until the Epic RO icon is present and click that icon.
   d. Log into the RO environment using your UTAD credentials.
      i. For future use of the RO environment, you can add it to your favorites in the Citrix Receiver by clicking on the details button next to the RO icon, then click the Add to Favorites button.
4. Only use the RO environment in the event of a downtime.
5. Your workspace will have this header by the "Log Out" button:
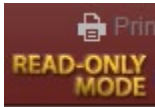
6. Available Lab Supervisor/Shift Lead will log into the BCA device.
   a. Use network credentials to login to the device.
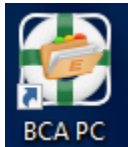
   b. Log into the BCA application
      i. Instructions to Print Reports via BCA PC:
         1. Log into the BCA PC.
         2. Select BCA Printing icon.
         3. Log into the BCA application.
         4. Choose Report.
         5. Double click to view the report and verify information has been pulled.
         6. For specimens to be sent out during a downtime, use the Manual Accession Log in place of the Epic packing list.
   c. Print desired reports
      i. UTMC Hospital Draws
      ii. UTMC Lab AP Outstanding List – Detail List
      iii. UTMC Lab Outstanding List – Detail List
      iv. UTMC Lab Follow-Up Tasks – Detail List
      v. UTMC Lab Follow-up Tasks – Summary
      vi. UTMC Lab Microbiology Outstanding List – Detail List
      vii. UTMC Lab Not Yet Received Specimens – Detail List
      viii. UTMC Lab Procedural and AP Expected List – Detail List
      ix. UTMC Lab Procedural and AP Expected List – Summary
      x. UTMC Lab Send outs – Detail List
7. Specimen Processing
   a. STAT specimens
      i. STAT specimens should be resulted by downtime procedures immediately.
      ii. When specimens arrive in the lab, there will be three downtime stickers for each specimen.

        iii. Place one sticker on the downtime log, and one on the specimen. The third label will go to the department section to be used on the instrument printout.

        iv. Run specimen as normal on the instrument.

b. Routine Specimens

        i. Process as per standard procedure.

        ii. During scheduled downtime, routine specimens are typically held for analysis until the system is back online.

        iii. During prolonged downtime (>2 hours), routine specimens will be processed as downtime specimens. See individual department downtime procedures.

c. Test results

        i. Each department should keep copies of a blank downtime report form in their downtime binder.

        ii. When test results are available on the instrument for a downtime specimen, print a copy of the test results from the analyzer.

        iii. Manually fill in the requested tests onto the blank downtime report form, and double check all manual entries.

        iv. Call the appropriate floor/clinic/office to notify of impending downtime test results being faxed to them. Record the name of the person notified, date and time of the call on the downtime report.

        v. Fax downtime report to appropriate floor/clinic/office with cover page included.

        vi. Set aside all faxed downtime reports for the downtime recovery.

d. Quality Control

        i. Scheduled downtime:

           1. If QC needs to be performed during a scheduled downtime, perform QC as per the standard operating procedure.

           2. Check the instrument QC results for QC values and flags and compare to the QC reference ranges on the analyzer, or on the QC reference page.

               a. The QC reference page should state the analyte/assay name, level, and 2SD range.

           3. If QC is out, follow troubleshooting steps.

           4. If QC is in, proceed to patient testing.

        ii. Unscheduled downtime:

           1. In the case of an unscheduled downtime, WC may expire and need to be performed multiple times without being verified in Beaker (i.e., downtime >8 hours or >24 hours).

           2. If QC has expired and needs to be performed, perform as per the SOP.

           3. Check the QC results in the instruments or on the QC reference page to verify results are in range and there are no flags.

           4. Print out QC results from the instrument, date, time, and initial, and set printout aside for future reference.

           5. Document any QC trouble shooting on the instrument printout.

           6. If QC is valid according to the instrument or QC reference page, proceed to patient testing.

Processing & Reporting Downtime Specimens and Quality Control

Prior to Downtime
1. Print downtime labels for appropriate department (3 labels per specimen).
   a. Epic → Downtime Specimen creation
   b. For microbiology and surgical pathology, refer to department specific procedures on labeling specimens during downtime.

During Downtime (First stage <2 hours)

Once a code copper is announced, the downtime procedure should be followed. The only specimens that will be forwarded to the testing departments are as follows:
1. All tests ordered as STAT
2. All timed specimens
3. All body fluids
4. All specimens delivered on ice (lactic acid, ammonia, etc.)
5. Stool for leukocytes
6. Sedimentation rate (ESR)
7. PTT, D-Dimer, or Fibrinogen (if not received frozen)
8. Other time or temperature sensitive analytes
   a. Refer to lab manual for time and temperature limitations.

All other specimens should be centrifuged and aliquoted if appropriate and held until further direction from laboratory management. Refer to lab manual for specimen storage requirements.

When it is determined that a test will be sent to a department for testing, the following actions will be taken.
1. Enter the patient information of the downtime log.
   a. Make certain to record the date and page number on the log.
2. Chose the next set of downtime labels.
   a. There are three labels for each specimen ID.
3. Completely fill in all sections of all three labels including the test(s) ordered.
4. Place one label in the log, the second label of that set on the specimen, and deliver the third label with the specimen and log to the testing department.
   a. The third label will be used on the report form by the tech performing the test.
5. Each department will follow their specific procedure for testing specimens during downtime. Refer to the department specific procedure for programming a specific analyzer.
   a. NOTE 1: Once a page is complete, make a copy (mark as copy) and deliver to testing department. The testing department will assure that all tests on the log have been performed, to make reconciliation easier once the system is available.
   b. NOTE 2: If a specimen is rejected for testing for any reason, document on the log that it was rejected and the reason for rejection. When the new specimen is received in the lab, it should be given a new downtime number and logged on the form as a new test.
6. When testing is complete in the department, the technologist will use the downtime report form and document the results in the appropriate place, noting the date, time, and initials on the report.

7. This downtime report will be delivered to the appropriate ordering location (fax, hand delivery, or calling). After delivery of the report is complete, documentation is written on the report form of where, when, and to whom the report was given.
8. A copy of the report should always be kept in the laboratory if the original copy is given to the ordering location.
9. Critical values will be communicated in accordance with the STAT Tests Critical Tests and Critical Limits Policy 3364-107-110. Documentation of the critical value call will be made directly on the downtime report form with the written notes of the test called and read back, who was notified (full name), date, time, and initials of the person completing the call.
10. All downtime reports will be sent back to the performing department, to keep all the logs and paperwork for the downtime recovery phase.

For an extended downtime period, it may be necessary to process specimens with the normal downtime process. The decision to process all specimens will be made by laboratory management and communicated to all network labs.

Processing/Verifying QC:

1. If QC is scheduled, or needs to be performed during a scheduled downtime, perform QC as per the SOP.
2. When the instrument is done processing the QC specimens, check the QC results on the instrument.
   a. QC results should be reviewed on the analyzer or compared with the QC reference range page.
3. In the event of an extended downtime where QC need to be performed multiple times without verifying in Epic, perform QC as per the SOP.

Post Downtime:

1. When the Epic system is restored, IT will send the communication that the system is available.
2. The laboratory at this time can resume the normal testing process for specimens.
3. Each department should immediately verify all analyzers are functioning properly in Beaker.
   a. NOTE: Some analyzers may need to be rest in Instrument Manager/Remisol.
4. **All downtime paperwork will be kept separate from all other reports and kept within the department for Downtime Recovery Phase.**

Downtime Recovery Phase

Staff will be designated by laboratory managers/supervisors, technical specialists, or department leaders for downtime recovery.

Tasks to be completed post-downtime:
1. When downtime is complete, end users may be notified that Epic PRD is ready for use via an overhead announcement, or an email.
2. Access to Epic Data

      a. Once the downtime is complete, log off from Epic RO and log back into Epic PRD to resume daily activities as normal.

3. Quality Control
   a. If QC was completed during the downtime, verify all levels of each analyte/assay performed interfaced into Beaker.
   b. If QC does not interface, proceed to the following steps:
      i. Resend the QC from the instrument.
      ii. Reset the instrument in Instrument Manager (Non-Beckman instruments).
      iii. Reset the instrument in Remisol (Beckman instruments).
      iv. Close out Remisol and restart RADV monitor (Beckman instruments).
      v. Reset the instruments Lantronix box.
   c. Enter QC trouble shooting documentation comments as needed and verify the QC.

4. Specimen Resulting
   a. All routine specimens collected and labeled with a Beaker label prior to downtime should be received and delivered to the appropriate department once Beaker is available.
   b. If a specimen was collected and labeled with a Beaker label, received prior to downtime, and tested, but not verified, the results should be available on the Outstanding List. Compare results with the analyzer printout and verify.
   c. For any specimen collected and received during the downtime:
      i. Inpatient/clinic orders will be placed into Epic by nursing/office staff.
      ii. Outpatient orders will be placed into Epic by lab staff.
      iii. Once orders are placed, use Specimen Linking (Chart search 🔍 → Specimen Linking), to link downtime specimens with the new order.
   d. Once all downtime specimens have been linked to a new order in Epic and verified, auto verification can be turned back on.
   e. **NOTE:** In the event of an unscheduled downtime, auto verification **NEEDS** to be suspended once Epic is available, and before specimen linking is performed.

5. Specimen Linking
   a. Chart search 🔍 → Specimen Linking activity.
   b. Scan the downtime label to search the test, this will highlight the specimen.
   c. On the right side of the screen in "Link to" 🔗 Link , scan the patient's new order label, verify all information is correct before linking specimens to ensure correct results are transferred.
   d. This will link the downtime specimen to the patient's order in Epic.
   e. Go to the Outstanding List and verify the samples linked are not on the list and have been resulted to the patient chart.

During Downtime Recovery the following should be performed:

1. Using the first downtime log, specimens received will be documented in Beaker using the Order Inquiry   function within Patient Station. **NOTE:** The correct visit encounter must be present before any test collecting and receiving can begin. Registration will create encounters, there will be a delay until the encounters are created.
   a. Priority is downtime.
   b. Update the collection date, time, and collector information.

2. Place the Beaker label on the downtime log in the column immediately right of the downtime label.
3. Continue to collect and receive all tests on the logs.
4. When all tests are complete, deliver the completed logs to the appropriate department.
5. Staff assigned to linking and reporting the specimens will ensure that the following are done:
    a. Verify all reports are with the completed logs.
    b. Suspend auto verification for the tests being linked if not already suspended.
    c. Like the specimens using the downtime logs, both labels and a scanner.
    d. Using the downtime report, go to the Outstanding List and verify the tests performed.
    e. Verify all patient testing filed correctly into patients' charts utilizing Chart Review.

*Before final verification, check the results in Beaker as compared to the downtime report to ensure all values are the same. *

6. For each specimen number being verified, use the edit key, and go to the comment box on the bottom of the result entry screen (white box) and enter "*Reported during Downtime to *** on *** at *** by ***.*"
7. Fill in the appropriate blanks for who the report was delivered to and date, time, and initials of tech.
8. If the test is not interfaced, use Result Entry to manually enter the result following the normal procedure and verify, making sure to enter "*Reported during Downtime to *** on *** at *** by ***.*"
9. Documentation of all critical values will be done in the communication log as per normal procedure using the following "*Critical Value called and read back during downtime to *** on *** at *** by ***.*"
10. Once all downtime specimens have been linked and verified, auto verification can be resumed, and testing continue in a normal manner.

Each department will review the Outstanding List and reports in their area to assure completion of all downtime testing.

All downtime documentation will be retained in the respective areas in accordance with regulatory requirements for document retention.

Recovery

*For specimens labeled with a Beaker label prior to downtime, skip to 7.

1. Click Patient Station.
2. Enter patient name or MRN to find patient.
3. Double click the encounter to open patient's chart. This will open Order Inquiry.
    a. Registration will create the encounters.
4. Highlight order(s) to be collected and click collect, then click receive.
    a. Multiple orders can be collected at once and allow container sharing to evaluate.
5. Print labels, update the collection information.

6. Suspend auto verification (if not already suspended) on the method before linking any specimens.
7. Open Specimen Linking (Epic → Specimen Linking).
8. The default view of "Lab Specimen Linking" displays a list of all downtime specimens that need to be linked. Scan the downtime barcode and highlight the downtime specimen to be linked on the left side of the screen.
9. Scan the new specimen barcode into the specimen field.
10. Click the link at the right of screen.
11. After linking, go to the appropriate Outstanding List and verify specimens. For each specimen number being verified, use the edit key and to the comment box on the bottom of the result entry screen (white box) and enter the documentation *"Reported during downtime to *** at *** by ***."*
12. Fill in the appropriate blanks for who the report was delivered to, and date, time, and initials of the tech. "*Reported during Downtime to *** on *** at *** by ***.*"
13. After verification, note on the log that the specimen has been completed.
14. Keep the log with downtime reports until verified be departmental technical specialist/team leader/Supervisor.
15. After downtime is completed and all results have been verified, all orders/results will be checked to assure there are no missed or incomplete orders.
16. After linking is complete for the method, resume auto verification.

Approved by: /s/ _____ Name: Amira Gohara, M.D. Title: Medical Director, Clinical Pathology 1/10/2025 _____ Date *Review/Revision Completed by:* *Joshua Otiso, Administrative Director, Lab*	**Policies Superseded by This Policy:** • *Q-13* Initial effective date: 05/01/2006 Review/Revision Date: 01/04/2025 Next review date: 01/04/2027