29-Laboratory Information System (LIS)

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ANNUAL REVIEW:

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SUPERSEDES: Procedure titled _____

Purpose:

This Standard Operating Procedure (SOP) provides comprehensive guidelines for the use of the Clinisys Laboratory Information Management System (LIMS). It includes detailed procedures for the following key processes

Scope:

This SOP applies to all employees, clients, and customers of MMCCCLs.

Definitions:

LIS-Laboratory Information System
ACCID – Accessioning ID – Unique Identifier for Laboratory Samples.
CLS – Clinisys Laboratory Solutions – Our LIMS

Policy:

A Laboratory Information System (LIS)/Clinisys is a critical tool for managing the entire laboratory workflow, from sample accessioning to result reporting. No one to have access to

Clinisys without being authorized and must be in compliance with HEPPA regulation and only do at the authorization being givin for the laboratory director/Manager/Supervisor

Procedure:

Sample Receiving

Sample Arrival: Samples are received at the laboratory intake desk in room 4010 they will have samples and requisition forms.

Accessioning: Sample details (patient information, test orders, collection date/time) are entered into software onsite in the facility and transferred digitally to Clinisys This creates a patient record and test requisition. The Requisition number is located at the top right of the requisition near the barcode. Prior to the start of accessioning ensure that there are enough 12mL and 5 mL tubes available for Lipid panel pour-offs and Send outs. Also be sure there is enough left on the label roll inside the barcode printer. Replace any missing working stock.

1. Pull all sample bags out of their secondary container and count the number of sample bags.
2. Lay the sample bags out neatly on the Accessioning Desk
3. Open Clinisys and navigate to High-Speed Login
4. In two additional tabs open the 'samples page' with login view, as well as the 'containers page'.
5. Open one specimen bag at a time by ripping along the perforated line at the top remove all sample tubes, and any paperwork. Visually inspect the bag for signs of contamination. If none is present, discard of the bag in the regular trash. If blood or other potentially infectious materials (OPIM) has leaked, or the bag is visually spoiled, discard the bag into the biohazard waste container. Ask for replacement
6. In High-Speed Login either enter the Req # or scan the barcode into the 'Chain' field.
7. When the patient and test info is loaded onto the screen check that the name and DOB match on the requisition and the tubes. If all information is correct proceed to step 8. If here are any issues here proceed to the Problems section of this SOP.
8. Look over the testing ordered to ensure sample containers are correct, check for expired containers, hemolytic, icteric, or lipemic serum samples. Be sure to note these in the sample receiving section in Clinisys.
9. Begin with Blood matrix:
    a. First, click 'edit tests' to view the testing orders
    b. It is preferable for the send out testing to have its own main sample ACCID, work on progress
        i. If any send out testing is present, highlight it and remove it by clicking the left facing arrow, and then click done.
    c. Ensure all container types that are required are present in the 'CONTAINERS' section.
    d. Ensure the collection date and time are correct.

10. Next move to Urine Matrix:
    a. Follow the same steps (a-d) for the blood matrix.
11. Once all of the information has been verified, click 'Login" at the bottom or top right of the page.
12. Labels will be printed automatically
    a. Label the paper requisition form with 1 label per ACCID.
    b. Labels print with testing at the bottom, be sure to put the correct labels on each tube. Use tubes with no testing along the bottom on the paper requisition form.
13. Once samples are labeled. Place them in a large white rack. 24 samples can usually be held in these racks. Once a rack is filled with 24 samples, place on the desk with Green tape labeled: 'Accessioned and Ready for Testing'
    a. If you need to add or reprint specific labels, navigate to the 'Containers page' choose the container label you need to print, and under 'Actions' click Print labels.
    b. To add a new Container click "New Container"
        i. Choose the Chain of Custody number which you want to add the container to.
        ii. Next, choose which ACCID to add this container under.
        iii. Next, choose the container ID- this is the ACCID with the addition of ' - #' at the end. Use the next number in numerical order (- 1, -2, -3 , etc.)
        iv. Next choose the container type.
        v. Next choose a preservative. If the tube does not contain any preservative, choose 'None'.
        vi. Click Save

Follow Up Login

1. Navigate to Follow-up Login through Main Menu>Samples>Follow-up Login
2. From the dropdown menu, click the sample ID that needs to be logged in.
3. Verify the name matches the paper requisition and click the blue "Save" button at the top of the screen.
    a. *Note: for samples that created 2 or more accessioning IDs there will be multiple Sample IDs showing up in the dropdown. Only one needs to be clicked and reviewed for the system to log in the entire sample.*

Data Entry and Verification

1. Data will transfer from the instruments automatically to CLS once results for all ordered tests are available.

2. Results appear first in the 'Data Upload' page.
3. Navigate to the "Data Upload" page and sort the samples by ACCID
4. Click the small arrow next to each entry to ensure results have crossed correctly.
    a. Review and Verify all results have crossed for each panel and that no tests are missing.
5. When you have confirmed the results, highlight the row and click 'Upload'

Result Reporting

Once results are uploaded, they are available for review in the 'Samples' Page.

1. For Samples Still "In Progress":
    a. Review the 'Tasks' page of the sample and check for pending sample tasks.
    b. If Send-out Results are missing, attach them in the following way) (refer to the full Quanum SOP for exact details of retrieving results from Quanum.
        i. Navigate to Quanum and search the results page for the patient name.
        ii. If a final report for that patient is ready:
            1. click 'print'
            2. Choose 'color'
            3. Choose 'simple'
        iii. This will generate the quest report in a new tab.
        iv. Save this file as a pdf locally in the Quest reports Folder
        v. Navigate back to CLS and while on the 'tasks' page take the following steps:
            1. Click the 'Actions' dropdown
            2. Documents
            3. Attach Sample Document
        vi. When the menu pops up, click "Choose File" and navigate to the folder where the quest report is saved (It should automatically load to that page)
        vii. Click on 'Document Settings"
        viii. Under the **[3] Report Type** dropdown menu choose: "Subcontract Results (s)"
        ix. Click Save
        x. Delete the associated Sendout Tasks in the 'tasks' page.
        xi. Click 'Save' at the top right.

   c. If any in house tests are missing, find results manually in the instruments and retransmit to CLS, or enter manually.
2. For 'Completed" Samples
   a. Navigate to the completed samples
   b. Click the accessioning ID to open the sample page
   c. Review results
   d. Navigate to the 'Run Report' page from the main menu
   e. Choose "Clinical Final MHR (CLINFINALMHR)"
      i. If a draft report is needed choose "Clinical Final MHR Draft (CLINDRAFTMHR)" and run the report.
   f. Choose the sample you would like to generate a report for or choose "ALL" to generate reports for all completed samples.
   g. Click the blue "Run" button

Once 'Run' is clicked, results will be sent directly to the client portal.

Result Archiving: Test results and patient information are archived according to retention 1policies life time of LIS and as per lab policy.

Checking the Pending List

Navigate to Samples > Backlog > General Laboratory > General Laboratory (GenLab). This pulls up all samples with pending tasks. Review the page in CLS or export to Excel for printing. Ensure all pending tasks are accounted for or finished prior to leaving for the day.

Issues with Clinisys

If issues are experienced with Clinisys, (i.e. errors, bugs, function requests) they should be reported via email to the lab manager or LIMS administrator. The Lab manager and LIMS administrator will work both independently and with Clinisys to maintain operability based on the SOPs, training, and guidance provided by Clinisys.

Key Roles and Responsibilities

1. Laboratory Assistants and Technologists: Receives samples, enters patient data, and labels samples.
2. Medical Technologists/Scientists: Process samples, perform tests, and enter results, verify results, review quality control, and resolve discrepancies.
3. Laboratory Supervisor/Manager: Oversees laboratory operations, ensures compliance with policies and regulations.
4. LIMS Administrator: Oversees the LIMS, adding new functions/reports/

Important Considerations

*Adherence to SOPs: All laboratory staff must follow established standard operating procedures.

* Quality Control: Regular quality control measures are essential to ensure accurate and reliable results.

* Data Integrity: Accurate and complete data entry is crucial for patient care and regulatory compliance.

* Security and Confidentiality: Patient information must be protected according to privacy regulations (e.g., HIPAA).

* Regulatory Compliance: The laboratory must comply with relevant accreditation and regulatory standards (e.g., CLIA, COLA).