LimitLIS®

User Guide - v4.0

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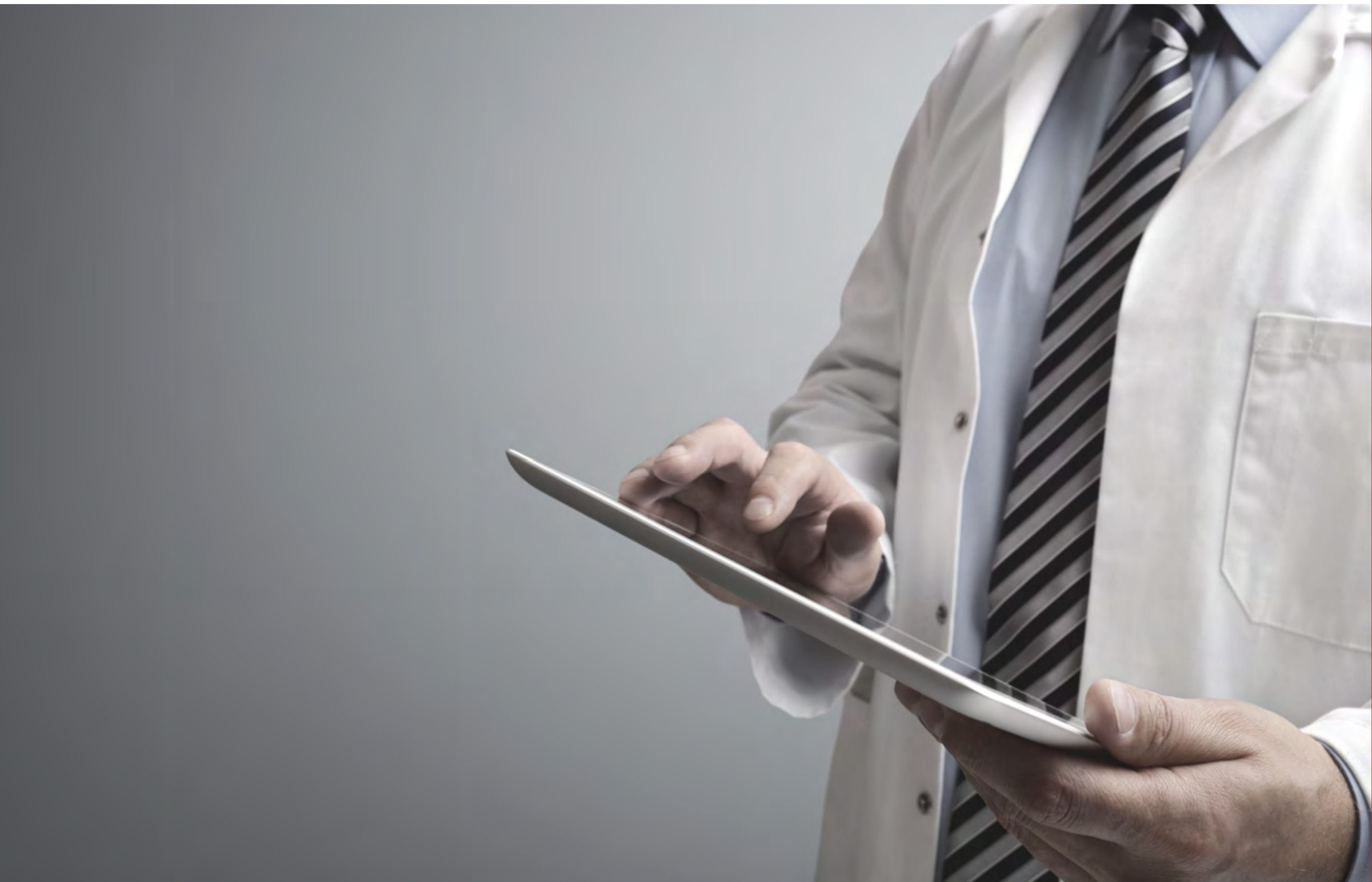


Table of Contents

Title: LimitLIS® User Manual

Doc. No. 4

Rev. 4.0

Revision Record

Revision No.	Date	Responsible Person	Description of Change
1.0	04/13/2016	Sasha Brocato	First full version released.
2.0	06/22/2017	Amanda Links	Updated for LimitLIS 3.0
3.0	03/01/2018	Nathan Mendoza	Updated for LimitLIS 3.1
3.2	06/20/2018	Alex Bodine	Updated for LimitLIS 3.2
4.0	10/26/2018	Alex Bodine	Updated for LimitLIS 4.0
4.0	11/19/2018	Sasha Brocato	Final version for LimitLIS 4.0

ABOUT THIS GUIDE

Purpose of this Guide

This guide introduces you to the features and functions of LimitLIS®. LimitLIS® is a web-based Laboratory Information System (LIS) that allows an individual to create, structure, and manage records for various laboratory and inventory management applications.

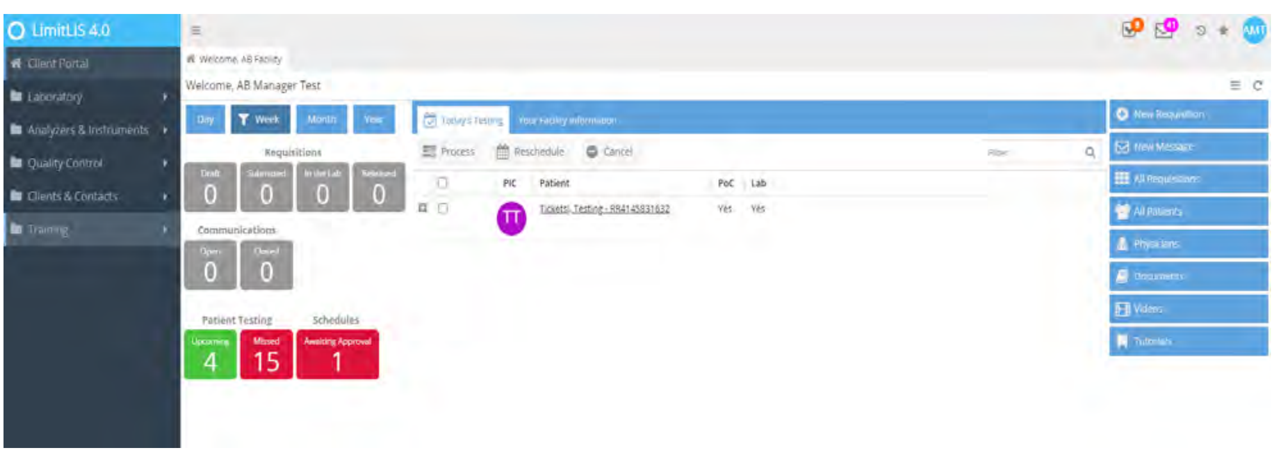
ACCESSING THE SYSTEM AS A CLIENT PORTAL USER

Navigating the Client Portal

The LimitLIS® software system requires login credentials for access. Client portal users are given access to LimitLIS® by laboratory managers. Upon being registered as a user within the system, the client will receive an email with their user name and a link to LimitLIS® where they will be prompted to create a password and then login.

After initial login, the client portal user is presented with the Terms of Use and can either decline – logging them out of the system – or click the "Accept Terms of Use" checkbox and accept, which will open the LimitLIS® **Dashboard** screen. Please note that several of the options discussed on the Dashboard are controlled by facility-specific settings determined by the laboratory and may not represent the Dashboard you see when logging in.

The left side of the Dashboard screen displays a summary of the various actions available within the system. The top tiles display the Requisition summaries, indicating how many requisitions have been created, submitted to the lab, received by the lab, and have had results released back to the client. The lower tiles display the number of communications between the client and the laboratory. All tiles not at zero can be selected and will display a list of the relevant items. The summary of these actions can be filtered by date range using the three buttons at the top of the section: Day, Week, and Month. If the patient scheduler is enabled for the facility of the logged in user, it will be shown in the center of the dashboard.



On the right side of the Dashboard screen are buttons for default links to **New Requisition**, **New Message, All Requisitions**, **All Patients**, **Documents**, **Videos**, and **Tutorials**.

The name of the user currently logged into the system and the logout option are under the **General Actions** menu located at the top right corner of the screen.

The General Actions icon can also be used to do the following:

- My Preferences - where the user is able to change their password, among other actions
- Viewers Bar - used to display records as new tabs in a tabbed bar
- About Limfinity – view version, BRICK, configuration date time stamp
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NOTE:

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Avoid using the **Back** and **Forward** functions of the web browser to navigate through the system. While using the system, it tracks your recent visited panels. The icon will allow the user to visit a recent panel without having to navigate the system.

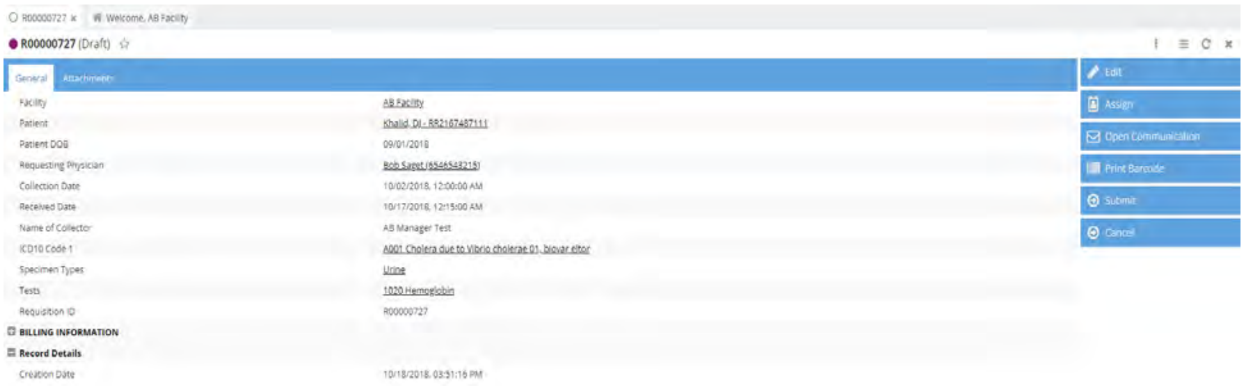
The inactivity time period can be changed in **Settings → Settings & Preferences → General Preferences.**

Creating and Submitting a New Requisition

Upon logging into the system, the client portal user can select the **New Requisition** button located on the right of the Dashboard screen. This will return a data entry form in which the client portal user can select—among other options—the patient and the requesting physician pre-registered within LimitLIS®, the specimen collection information, the ICD-10 (Diagnosis) codes, and the tests or panels being ordered.

There are a few optional fields that will only be shown if the required settings are enabled in System Settings, such as **Medical Necessity Statement, Patient Signature Authorization Statement, Patient Signature.** The **Provider Authorization Statement** and **Physician Signature** will be automatically appended to the printed requisition form if the corresponding settings are enabled in System Settings and signature and statement are present in LimitLIS.

Once the required data is completed, selecting "OK" will create the requisition in a draft state and open it in a new system tab. The requisition record displays a summary page of the entered data with a number of action buttons located on the right side. Client portal user is able to **Edit** the requisition information, **Open Communication** to users in the facility, **Submit** the requisition to the testing laboratory, or **Cancel** the requisition request.



If the requisition tab is closed, it can be accessed again through the "Draft" tile on the Dashboard. Once the user clicks **Submit**, LimitLIS® will display a confirmation dialog box with the Requisition ID for the submitted requisition and allows the client portal user to download a PDF of the requisition report to be printed and submitted with the samples. A PDF copy of the requisition report is also attached to the requisition as a downloadable link that the client portal user can access at any time. This requisition can now be viewed through the "Submitted" tile on the Dashboard.

Once a requisition is received at the laboratory, it can be viewed from the Dashboard under the "In The Lab" tile.

Accepting Test Results

Once a requisition has been released (sample accessioned and test results entered, finalized, and released) to the client portal user, it can be found by either clicking on the "Released" Dashboard tile or by searching for the Requisition ID from the **All Requisitions** button.

Initiating a New Communication

LimitLIS® supports the capability to initiate a secure conversation between the client and the testing laboratory. This module is a client-specific setting and will only be available if it has been enabled by the testing laboratory. To initiate a new communication, select the **New Message** button and an entry form will be displayed that allows the client portal user to reference a specific requisition and generate a message to the testing laboratory.

Registering and Managing Patients

In order to submit a requisition, the patient must first be registered in LimitLIS®. To view the list of all patients registered to the facility, select **All Patients** on the right of the Dashboard screen. The system will display the list of patients along with buttons on the right of the screen allowing the client portal user to **OPEN** an existing patient's record, **Add Patient** to the facility, or **Archive Patient** to prevent further requisitions from being submitted for that patient.

When **Add Patient** is selected, the system will present the client portal user with a form in which to enter the patient's information, including the MRN, first and last name, date of birth, and insurance information. If an MRN is not provided, LimitLIS® will automatically generate an MRN value for the patient. Once the data entry is complete, selecting "OK" will save the new patient to the system.

To manage a patient's information, select the patient from the list and click **OPEN** or double-click the record. The patient's record will be displayed in a new tab with a number of actions on the right side.

Edit	Displays the patient's current information in a dialog box for editing.
Upload Patient Photo	Allows the user to upload a photo for the patient if required by the facility.
Upload Insurance Card	Allows the user to upload a copy of the patient's insurance card (one file only).
Diagnoses & Medications	Portal users can assign specific medications and diagnoses in the event they influence test outcomes. If these fields are populated, these medications and diagnoses values will be auto-populated on all new requisitions for that patient.
Repeated Tests	Tracks test codes and test panels that are frequently ordered for the patient. If this field is populated, these test codes will be auto-populated on all new requisitions for that patient.

Print Patient Report	Prints a summary of the patient's medical record in LimitLIS®. The patient report file contains patient data such as billing, medical necessity, and demographic information as well as all requisitions and result reports on file for that patient.
New Requisition	Allows the user to submit a new Requisition with the current patient's data already populated
New Point of Care Test	Allows the portal user to submit a new point of care (POC) test result independent of a requisition.
Resend Demographic to Billing	Re-sends Patient info to Billing system
Archive Patient	Suspends the patient's portal account (if present) and prevents further requisitions from being submitted for the patient.

Managing Physicians

Physicians requesting requisitions must be registered within LimitLIS®. Note that the testing laboratory must enable the "Allow Physicians Management" setting on a client facility to in order for portal users to be able to view available physicians.

To view and manage the full list of physicians registered in the system, click **Physicians.**

The system will display the list of physicians along with buttons on the right of the screen allowing the to **OPEN** an existing physician's record, **Add Physician** to a facility, or **Archive Physician** to prevent further requisitions from being ordered by that physician.

When **Add Physician** is selected, the system will present the laboratory manager with a form in which to enter the physician's information, including the Physician ID, first and last name, and other information. If LimitLIS® has been enabled to support capture and storage of physical signatures, the laboratory manager is able to click in the "Physician Signature" field and have a physician sign with a mouse (computer) or finger (mobile device).

To edit a physician's information, select the physician from the list and click **OPEN** or double-click the record. The physician's record will be displayed in a new tab with options to **Edit** or **Archive Physician** record. The Edit option will display all of the physician's current information in a dialog box for editing. When a physician is archived using the "Archive Physician" button, they are no longer able to request requisitions.

Accessing Documents

Client portal users can view and download copies of documents uploaded by the testing laboratory. These are general forms, notices, user guides and other related documents.

To view a document: Click on the **Documents** button on the Dashboard. A list of all available documents provided by the testing laboratory will appear in a new tab. Click on the link within the "File" column to download a copy of the document.

NOTE: Documents uploaded to the system will be can be restricted to a specific facility or other user group.

Accessing Tutorials

Client portal users can watch tutorial videos that are deployed with the system. These are short instructional videos explaining how to execute various workflows within LimitLIS®.

To watch a tutorial video: Click on the **Tutorials** button on the Dashboard. The system will display the list of all available training videos in a new tab. Double click on the name of a tutorial to access a link to the video and start watching within the system. If you wish to maintain a record of completed tutorials, select the relevant tutorial and click **Complete Tutorial** on the right side of the page, then click "OK" in the dialog box.

NOTE: Tutorials uploaded to the system can be restricted to a specific facility or other user group.

Accessing Training Videos

Client portal users can watch training videos that are deployed with the system. These are short instructional videos explaining how to execute various workflows within LimitLIS®.

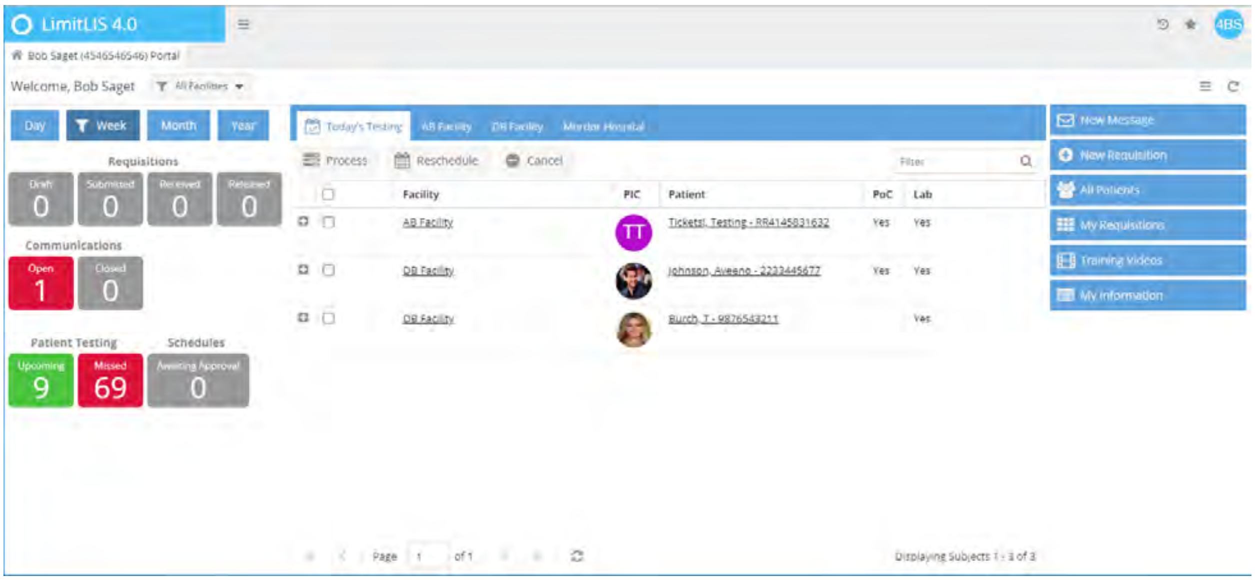
To watch a tutorial video: Click on the **Training Videos** button on the Dashboard. The system will display the list of all available training videos in a new tab. Select a video and click **Watch Video** to start watching within the system.

NOTE: Videos uploaded to the system can be restricted to a specific facility or other user group.

ACCESSING THE SYSTEM AS A PHYSICIAN PORTAL USER

Upon being registered as a user within the system, the physician will receive an email with their username and a link to LimitLIS® where they will be prompted to create a password and then login.

After the initial login, the physician is presented with the Terms of Use and can either decline – logging them out of the system – or click the "Accept Terms of Use" checkbox and accept, which will bring them to their LimitLIS® **Dashboard**. The left side of the Dashboard screen displays a summary of the various actions available within the system. The top tiles display the Requisition summaries, indicating the number of requisitions created, submitted to the lab, received by the lab, and have results released back to the physician. The lower tiles display the number of communications between the physician and the laboratory. All tiles not at zero can be selected and will display a list of the relevant items. The data can be filtered by date range using the three buttons at the top of the section: Day, Week, and Month and by **Facility** if the physician wishes to further filter the data by a specific facility. Each facility at which the physician is registered is displayed in a separate tab, and if the patient scheduler is enabled for any facilities at which the physician is registered, it will be displayed as the first tab in the center of the dashboard.



On the right side of the Dashboard screen are buttons for default links to **New Message, New Requisition**, **All Patients**, **My Requisitions, Training Videos**, and **My Information**.

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While using the system, it tracks your recent visited panels. The icon will allow the user to visit a recent panel without having to navigate the system.

The inactivity time period can be changed in **Settings** → **Settings & Preferences** → **General Preferences.**

Creating and Submitting a New Requisition

Physicians can create and submit requisitions by following the same steps as Client Portal Users, however the *Requesting Physician* field on requisition will be read-only and will contain the name of the currently logged in physician user. It is not possible for physician users to order a requisition for another physician. Please see Creating and Submitting a New Requisition for more information on this topic.

Accepting Test Results

Physicians can accept released test reports only for requisitions where they are listed as a *Requesting Physician*. The steps to accept a released requisition are identical to those described in Accepting Test Results for Client Portal Users.

Initiating a New Communication

Physicians can initiate and manage communications by following the same steps as Client Portal Users. Please see Initiating a New Communication for more information on this topic.

Registering and Managing Patients

To manage patients, physicians follow largely the same steps as Client Portal Users, however there are a few key differences:

- Physicians have access to patients from all the facilities they work at, while Client Portal Users are limited to patients in their facility.
- Physicians can create patients in any facility that they work at, while client portal users can only create patients in their facility.
- If the *Physician* field is populated on patient, then only that physician will be able to access the patient and the patient's data. No other physician (even from the same facility) will be able to access that patient or create requisitions for that patient.

Please see Registering and Managing Patients for more details on this topic.

Viewing Requisitions

Physicians can view all requisitions created by them by clicking on **My Requisitions.** Doing so will bring up a list of all requisitions in all states where the logged in physician is the "Requesting Physician" on the requisition. Each requisition can be opened one by one, and if the requisition has been released, the physician will be able to view the attached result report and **Mark** the requisition as **Accepted**.

Managing Physicians

Physician portal users are able to manage their own records only and cannot manage other physicians.

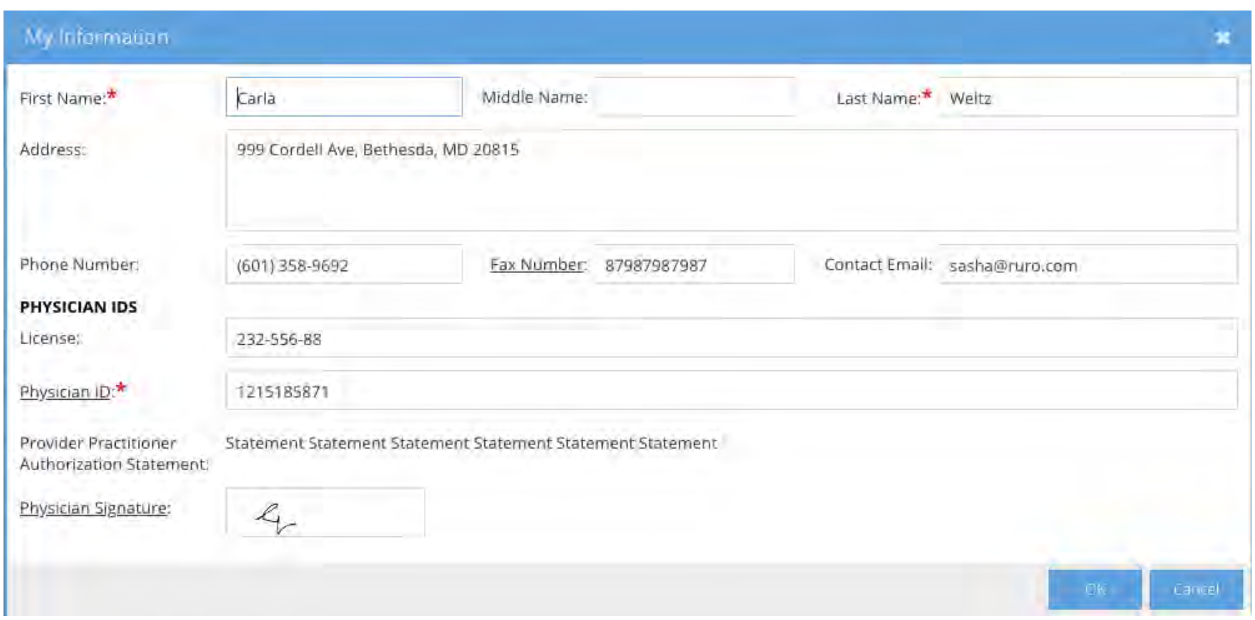
Accessing Training Videos, Documents and Tutorials

Physicians can access training materials in LimitLIS® by following the same steps as Client Portal Users. Please see the following sections for more information on this topic:

- Accessing Training Videos
- Accessing Documents
- Accessing Tutorials

Updating Physician's Personal Information

Physician portal users can update their personal information such as name, telephone number, license number, and signature by clicking on **My Information.**



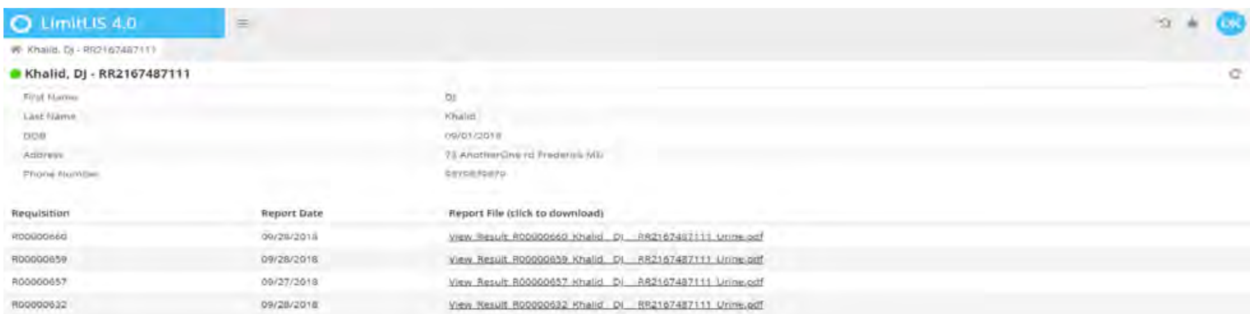
The *Physician ID* field can be used to enter the NPI Number of the physician or serve as another unique identifier that needs to be sent via DFT billing files in HL7 messages. If physician enters a signature, it will be saved and populated on every requisition that the physician requests in the future, eliminating the need to re-sign each electronic order.

ACCESSING THE SYSTEM AS A PATIENT PORTAL USER

Navigating the Patient Portal

Patient portal users are given access to LimitLIS® by the testing laboratory. Upon being registered as a user within the system, the patient will receive an email with their username and a link to LimitLIS® where they will be prompted to create a password and then login.

After the initial login, the patient portal user is presented with the Terms of Use and can either decline – logging them out of the system – or click the "Accept Terms of Use" checkbox and accept, which will open a screen displaying the patient's medical information and the last ten (10) released test results for download.



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While using the system, it tracks your recent visited views. The icon will allow the user to visit a recent view without having to navigate the system.

To close out a view, click the ✖ button located at the top of each view.

The inactivity time period can be changed in **Settings** → **Settings & Preferences** → **General Preferences.**

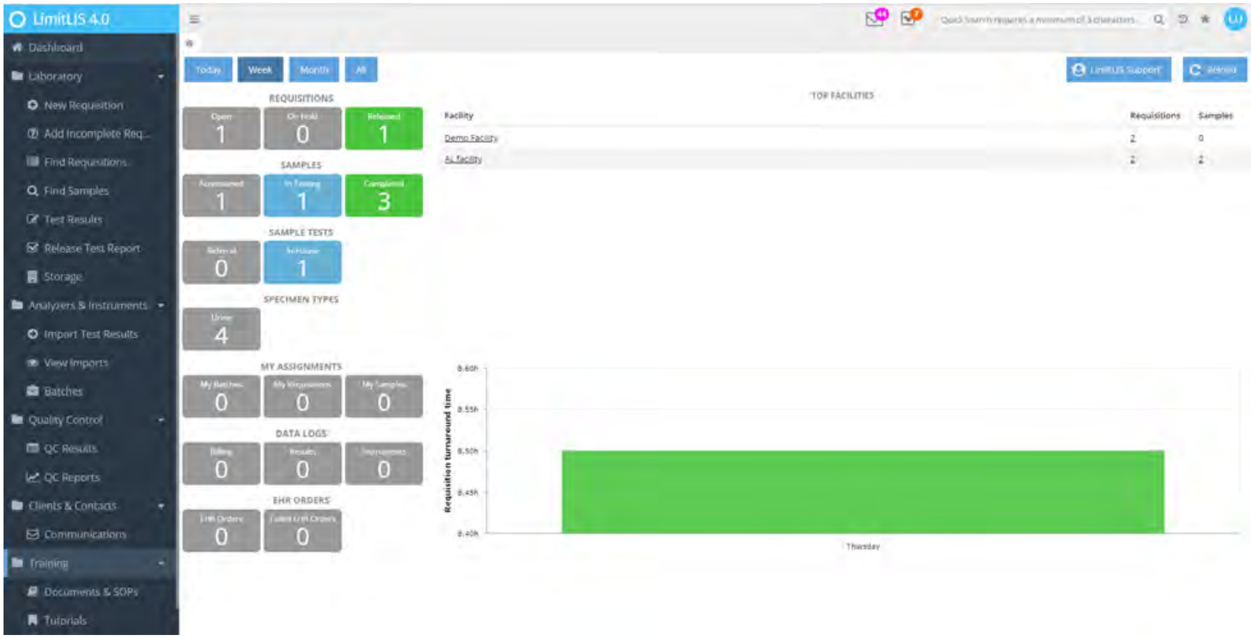
ACCESSING THE SYSTEM AS A LABORATORY USER

Navigating the LimitLIS® User Interface Features

The LimitLIS® system requires login credentials for access. The login credentials consist of a username and a password, both of which are case sensitive. Laboratory users are given access to LimitLIS® by laboratory administrators. Upon being registered within the system, the user will receive an email with their username and a link to LimitLIS® where they will be prompted to create a password and then login.

After the initial login, the laboratory user is presented with the Terms of Use and can either decline – logging them out of the system – or click the “Accept Terms of Use” checkbox and accept, which will open the LimitLIS® **Home** screen.

The left side of the Home screen consists of a panel with a **Quick Links** menu. In the center of the Home screen is the **Laboratory Dashboard**.



The name of the user currently logged into the system and the logout option are under the **General Actions** menu located at the top right corner of the screen. The General Actions menu can also be used to execute **My Preferences** where the laboratory user is able to change their password and time zone, among other actions.

The General Actions icon can also be used to do the following:

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The inactivity time period can be changed in **Settings → Settings & Preferences → General Preferences.**

Laboratory Dashboard

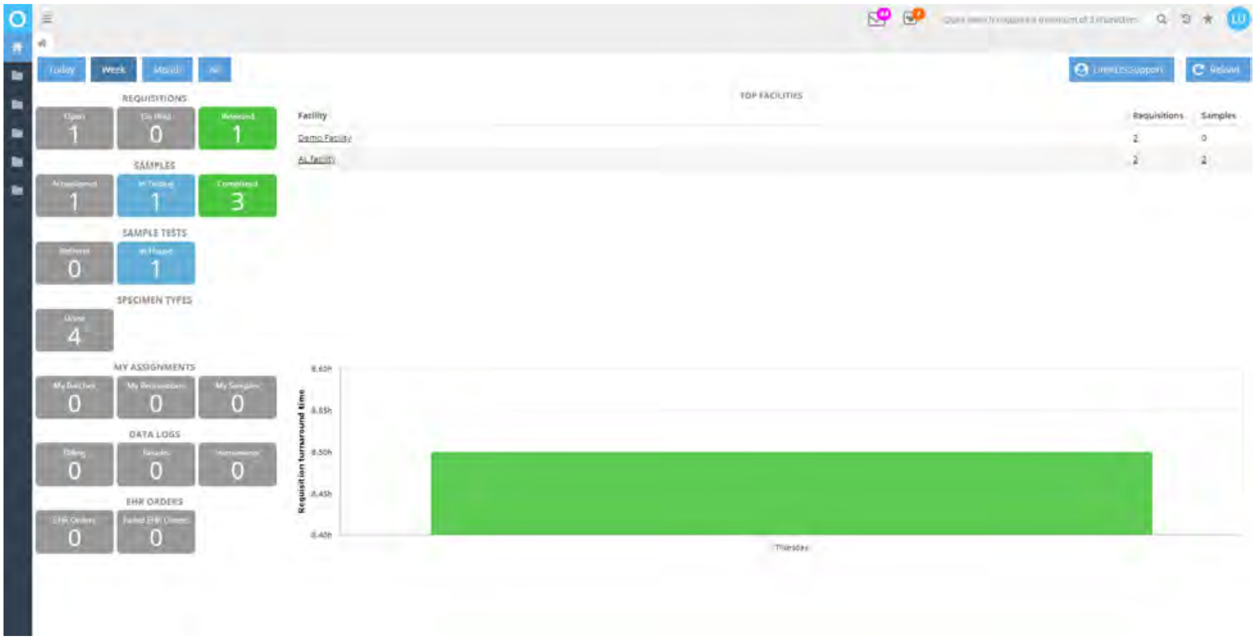
The Laboratory Dashboard contains a summary of various data captured by the system. To refresh the dashboard with real time data, click the reload button in the top right corner.

The left side of the Laboratory Dashboard screen contains tiles tracking various data in the system. The laboratory user is able to select the time period – today, week, month, all – in which the Dashboard should be filtered. All tiles not at zero can be clicked and will display a list of the relevant items. A breakdown of each type of tile is listed in the table below:

Requisitions	Counts of requisitions in the system for the duration selected that are open, on hold, and have results released back to the client.
Samples	Counts of the samples for the selected time period, indicating the number of samples that have been accessioned, are in testing, and have completed testing.
Sample Tests	Counts of samples that are in-testing by location (in-house vs. send-out samples done at an external lab).
Specimen Types	Counts of samples by specimen type.
My Assignments	Counts of batches, requisitions and samples assigned to the currently logged in user.
Data Logs	Counts of billing records, EMR Results and Instrument results received by LimitLIS®.
EHR Orders	Counts of received EHR orders that were imported without error and failed EHR orders that were imported with errors.

The bottom left section of the Laboratory Dashboard displays a chart showing the number of samples in the various states – accessioned in testing, released, on hold.

The top right section of the Laboratory Dashboard displays a table containing a list of the top 10 client facilities by sample count, with their requisitions and samples linked, for the time period selected. The bottom right section of the Dashboard displays a chart with the turnaround time for all requisitions by day, week, or month, depending on the selected Dashboard time filter.

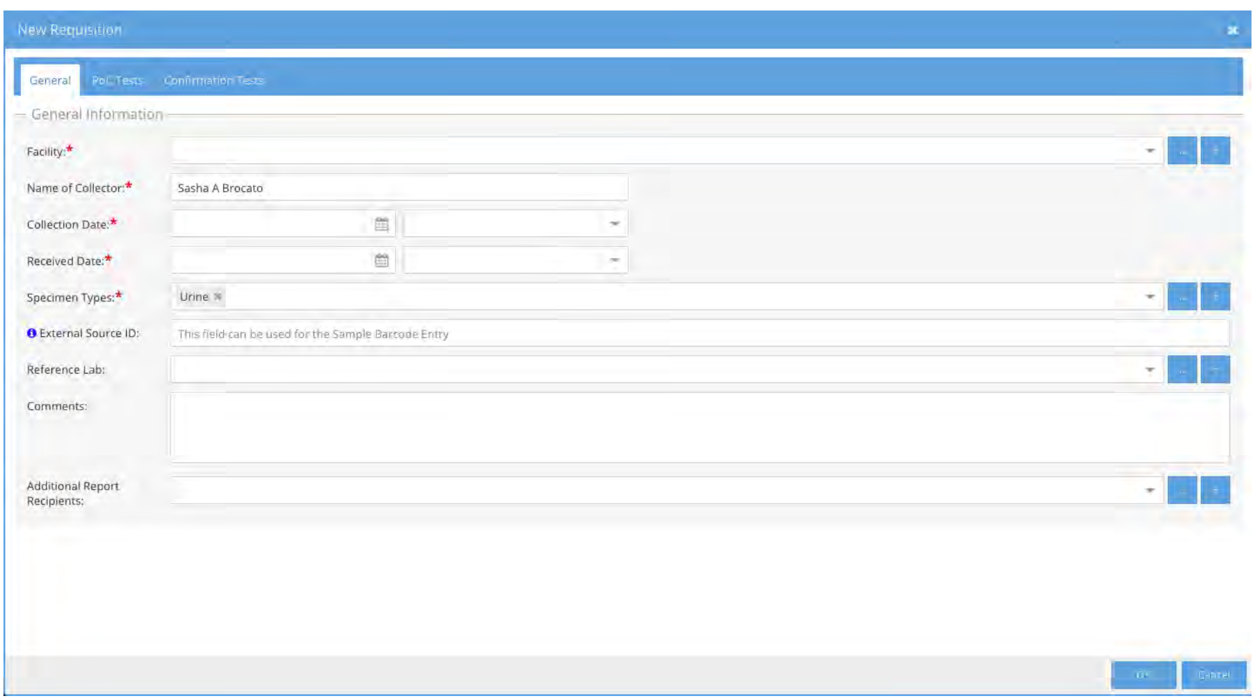


Adding Requisitions

LimitLIS® allows laboratory users to create new requisitions for samples that have not been registered in the client portal.

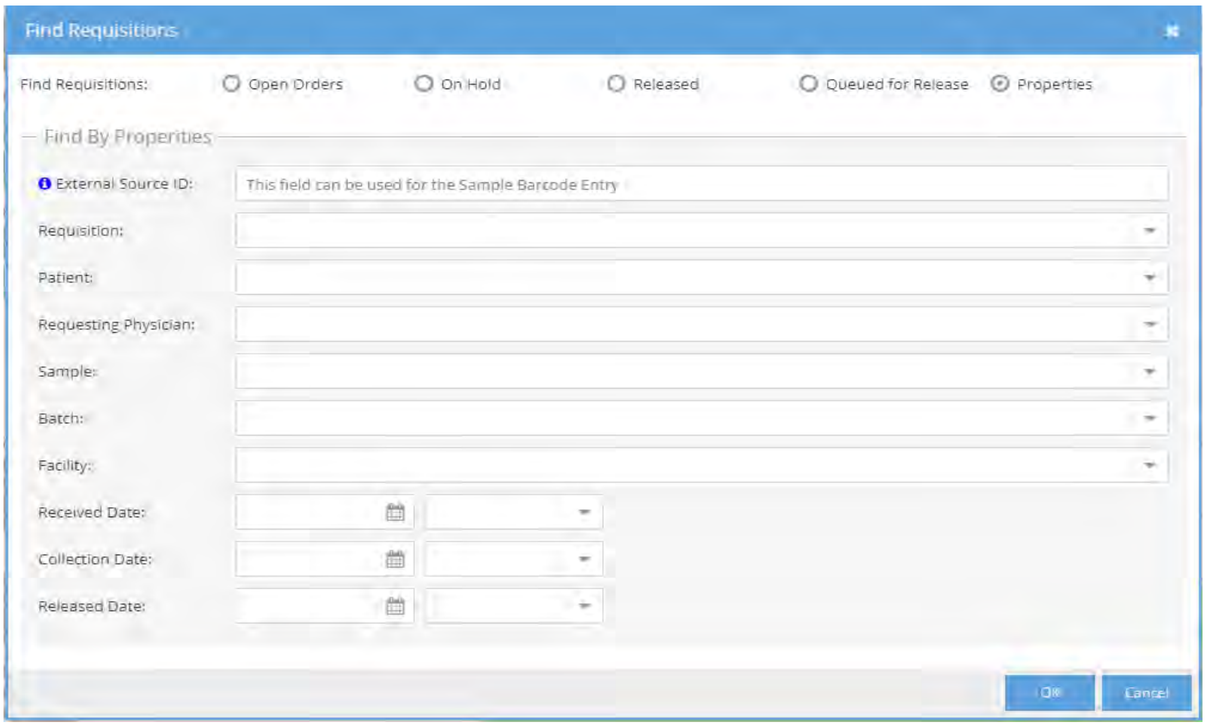
To create a new requisition:

1. Click on the **New Requisition** button in the Quick Links menu.
2. Enter information into the required fields.
3. Click **OK** to submit the requisition. Any requisitions entered by the testing laboratory will skip the "Draft" and "Submitted" states and be created in the "Received" state.



Searching for Requisitions

When a requisition arrives within the laboratory, laboratory users are able to use the **Find Requisitions** button located in the Quick Links menu to scan or type the requisition number and pull up the record within LimitLIS®. This button also allows the laboratory user to find groups of requisitions, such as all current orders, all requisitions on hold, all released requisitions, and all requisitions queued for release. The "Properties" option can be used to search for a requisition by a specific property, such as Patient, Requesting Physician, or Facility. Using this search will return a list of the requisitions matching the search criteria in a results grid.



If a group of requisitions is searched, a new tab will be returned with a list of the matching requisitions. Individual records can be opened by double-clicking.

NOTE: Requisition search can be turned on or off in System Settings by clicking **Features** and enabling/disabling the option to "Show Find Requisitions Quick Link".

Accessioning Requisitions

If a requisition in the "Submitted" state is opened, the requisition record will display in a new tab with the option to **Mark as Received**. When receiving, the laboratory user must enter the date and time the requisition was received as well as enter their credentials for verification. LimitLIS® will then update the requisition status to "Received" and display the following options for the record.

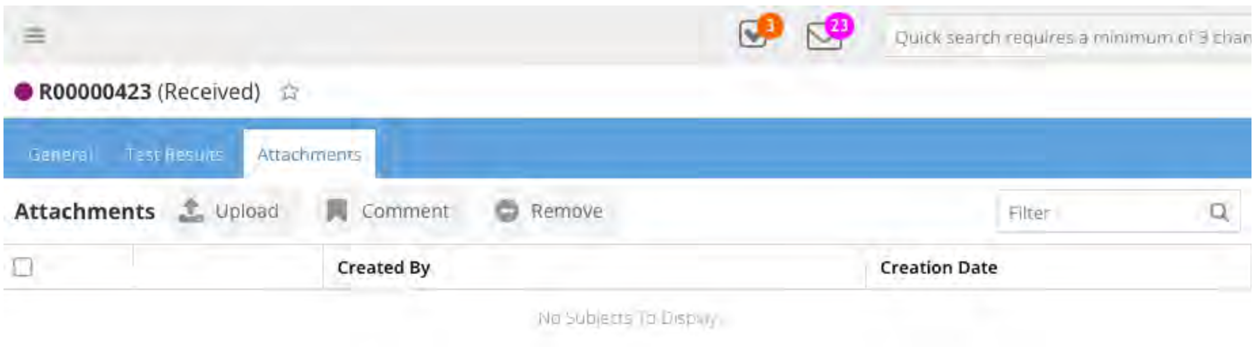
Pre-Registered Samples	If the client portal user pre-registered a sample before submitting the requisition, this button will be available to laboratory users. When selected, a list of all pre-registered samples will be displayed in a new tab. The laboratory user can then double-click to open a record and chose to **Receive Sample** – resulting in the sample being accessioned into the laboratory – or **Cancel** the sample.
Accession Sample	Creates individual sample records that can be associated with specific tests.
Edit	Allows users to edit the information about the requisition.
Assign	Assigns the requisition to a LimitLIS® user from a list of LimitLIS® users. The assignee can access their assigned requisitions from the lab dashboard.
Print Requisition Form	Generates a PDF of the requisition and displays a download link in a new dialog box. The PDF file is additionally saved to the requisition for future download and overwrites any previously generated requisition report.
Preview Report	Generates a preview of the preliminary result report
Regenerate Report	Allows the user to regenerate and view the preliminary report in the event there have been changes made to the data.
Put On Hold	Moves the requisition into a holding state and prevents users from making any changes or updates other than to release the hold(s).
Cancel	Moves the requisition into a cancelled state and prevents users from making any changes or updates or performing any actions on the requisition.

Users can view all attachments for a requisition clicking on the **Attachments** tab. Each file will be displayed as a thumbnail.

To upload an attachment: Click **Upload,** select desired files, then click **OK.** A minimizable progress dialog will be shown while attachments upload. Once attachments are finished uploading they will be viewable in the Attachments grid.

To delete an attachment: Select an an attachment, click **Remove,** then click **OK** to confirm.

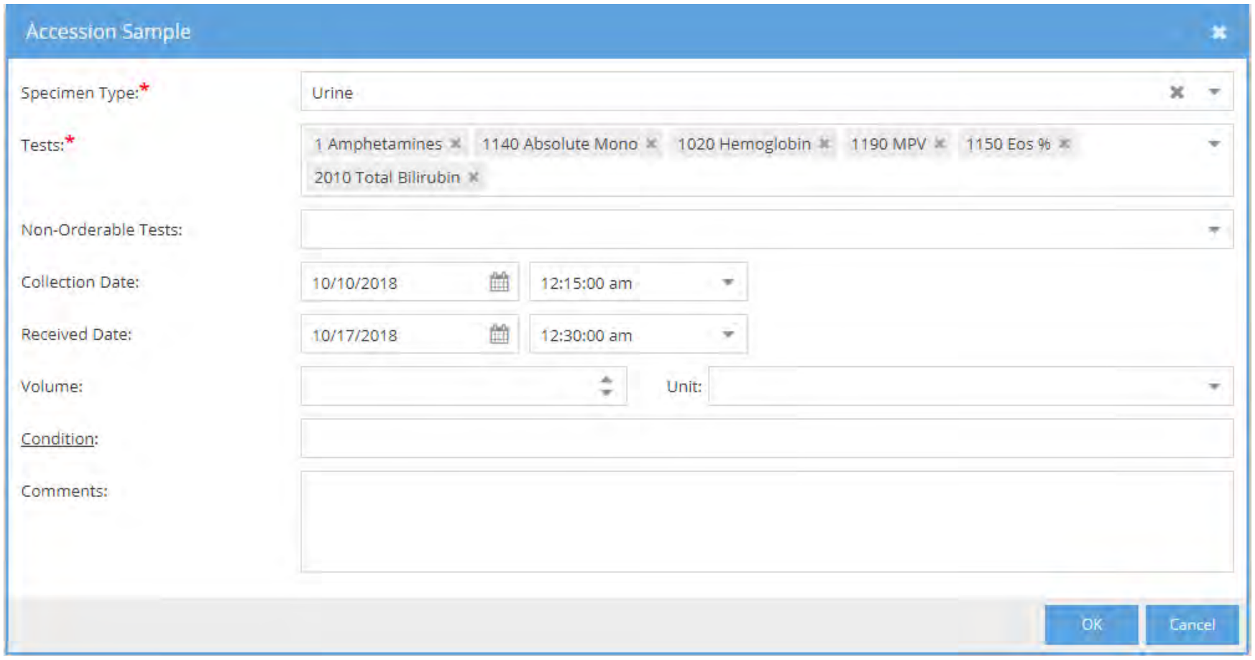
To comment on an attachment: Select an attachment in the "Attachments" grid, click **Comment** to enter a comment on the selected file. The comment will be displayed under the "Filename" field next to the file thumbnail.



Accessioning Samples

After receiving a requisition into the laboratory, a laboratory user can accession samples by selecting **Accession Sample** on the requisition record. A new dialog box will appear in which the ordered tests can be associated with a specific sample type and the volume and other sample information can be recorded.

NOTE: If the setting to "Auto-Accession Sample on Requisition Receipt" is enabled in System Settings, then the new sample will be created automatically as soon as the requisition is received at the lab eliminating the need for manual sample accessioning.



Once "OK" is selected, the sample record will be created and displayed in a new tab with additional actions.

Edit	Allows users to modify the sample information, including the volume and associated tests.
Print Barcode	Generates a barcode label using the selected template. If the template uses the Web Printing mode, the barcode label(s) will be displayed in a new browser window (popups must be enabled).
Assign	Assigns the sample to a LimitLIS® user from a list of LimitLIS® users.
Store	Only shown if Limfinity® StorageModule is enabled. Brings up a list of available boxes and allows the user to select the desired storage box and position to store the sample.
Approve For Testing	Creates a Test Result record for each analyte associated with the ordered tests on the sample and moves the sample into a Testing state.
Cancel	Moves the sample into a cancelled state and prevents users from making any changes or updates to the sample or performing any actions on the sample.

Entering Test Results

Receiving Test Result Data from Instruments

Once a sample has been successfully accessioned and approved for testing, Test Result records are created for each analyte within each ordered test on the sample. LimitLIS® supports bidirectional and unidirectional interface options with a number of laboratory instruments. If interfaced with a machine, the test results may be automatically imported into LimitLIS® upon test completion. The new instrument results can be accessed from the in-testing sample as well as the dashboard "Instrument" tile.

Uploading Test Result Data

Instrument import files from non-integrated analyzers can be imported and processed by LimitLIS®. The following import file formats are supported by LimitLIS®: CSV, XLSX, TXT, ODS.

The import file format maps the columns in the analyzer file to the fields in LimitLIS®. The import file can contain a mixture of control samples (QC Samples) and regular test results.

An example template is shown below along with a table explaining each of the columns within the file.

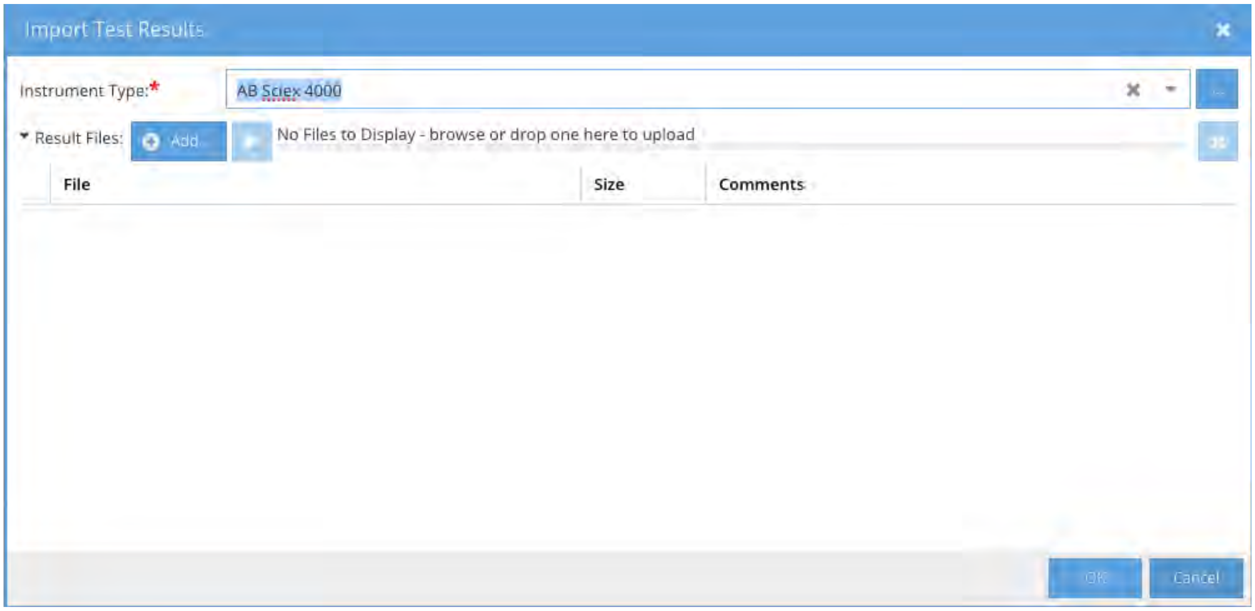
	A	B	C	D	E
1	Instrument SN	Acquisition Date			
2	V123456789	05/24/2016 8:13:38 AM			
3	Sample Name	Sample ID	Analyte Name	Calculated Concentration	
4	LC3	Positive Low	THC-COOH	20	
5	LC2	Positive Medium	THC-COOH	30	
6	LC2	Positive High 2	THC-COOH	73	
7	Sample013	9000561	Amphetamine	20	
8	Sample013	9000561	Methamphetamine	10	
9					

Instrument SN	The serial number of the instrument registered in LimitLIS®.
Acquisition Date	The date and time of the instrument run.
Sample Name	Control Type (QC samples) or sample name (requisition samples).
Sample ID	Sample name (QC samples) or sample barcode tag (requisition samples).
Analyte Name	Name of the analyte tested.
Calculated Concentration	Test result measurement for an analyte in a control sample or a requisition sample.

To import a test results file:

1. Select **Import Test Results** from the Quick Links menu.
2. A new dialog will be displayed with an option to select the originating instrument type and

upload files through the **Add** button at the top of the table. One or more files can be selected for import if they are the output of the same instrument type.
3. Click **OK** to start the import process.
4. The system will process the files and display a list of the imported files in a new system tab, detailing the number of records loaded and the number of errors encountered.
5. The system will automatically create a batch for each instrument import.



Entering Test Result Data Manually

To enter test results manually:

1. Select **Test Results** from the Quick Links menu.
2. A dialog box opens allowing the user to narrow down the search by specific properties. Select "OK" without filling in any data to view all unfinalized Test Results in the system.
3. A new tab will be displayed which lists all the tests awaiting results and finalization.
4. Select the entries to be updated and click **Enter Results** on the right.
5. A dialog box will appear containing the selected test result records in which the user can enter the Value for each selected test result as well as any result-specific Comments. Click "OK" to save.
6. The system will compare the entered Value to the range(s) associated with the analyte and will calculate a flag accordingly using the configured flag formulas.

Once test results have been completed, finalize the results by selecting the from the list and clicking **Finalize** on the right.

Auto-finalizing Test Results

LimitLIS® can automatically finalize test results that fit user-defined criteria. Auto-finalized test results will be finalized on import and will not require manual review and finalization.

To setup auto-finalization, lab managers or admins will need to enable the "Auto-finalize Test Results with Flags" setting in System Settings.

To enable auto-finalization:

1. Click on System Settings
2. Select **Features**
3. Select one or more flags to "Auto-finalize Test Results with flags" and outcomes for "outcomes"
4. Check the checkbox to "Auto-finalize QC Results"

All results with the selected flags and outcomes will be finalized. If any QC results are imported, they will be automatically finalized (the QC Test Result value does not matter in this case).

Releasing Test Reports

When all ordered tests for a requisition have been completed and finalized, the requisition becomes available through the **Release Test Report** button on the Quick Link menu and the preliminary test report is attached to the record as a PDF. All the completed requisitions ready for review and release are displayed in a new tab with multiple options.

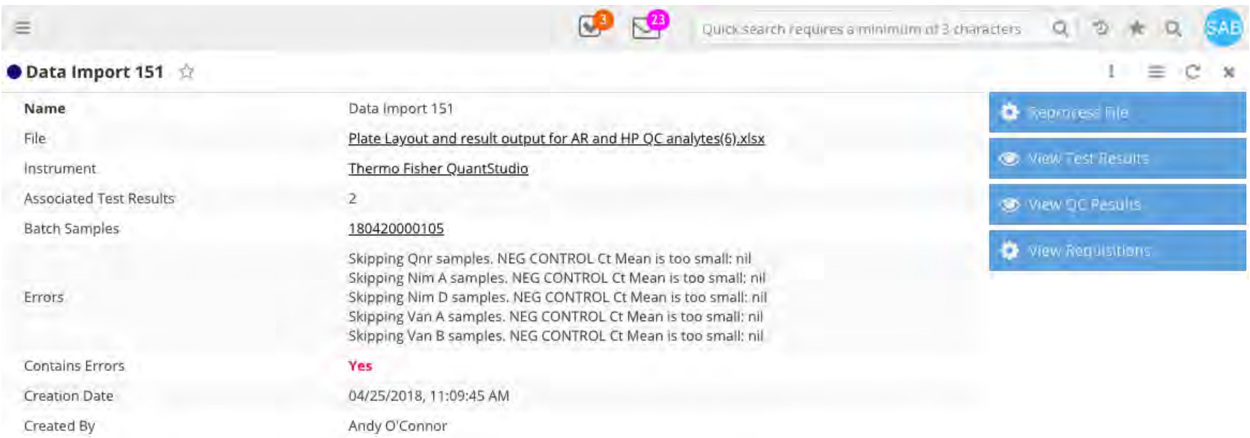
Open	Opens the selected requisition
Assign	Assigns the selected requisition(s) to a LimitLIS® user from a list of LimitLIS® users.
Preview Report	Displays the test report as a PDF in a new dialog box for review.
Regenerate Report	Regenerates the report in the event there have been changes made to the data.
Release	Requires the user to enter a release date and credentials for billing purposes. Once "OK" is selected, a dialog box will appear displaying the information submitted to the billing system if configured. Additionally, the requisition is marked as "Released" and is available for the client portal user to review.
Queue for Release	Multiple requisitions can be selected and placed in a queue for releasing at a later time. Releasing of these requisitions is managed by a Scheduled Script setup by system administrators and processed every ten (10) minutes.

Releasing Test Reports from Imported Batches

If file imports are the primary method of loading the instrument result data into LimitLIS®, laboratory users can make use of the Data Imports module in order to manage the import files and batches.

To view previously uploaded data:

1. Click **View Imports** under **Analyzers and Instruments** to open a new grid with all Data Import records.
2. Open an Import record by double-clicking a record in the results grid.
3. Click **View Test Results** to view and finalize all patient test results included in the Import.
4. Click **View QC Results** to view and finalize quality control results for the Import.
5. Click **View Requisitions** to view all requisitions linked to the test results in the Import and Release or Put on Hold.
6. Click **Reprocess File** to re-import the attached import data file and recalculate any flags or outcomes for each test results within the data file.

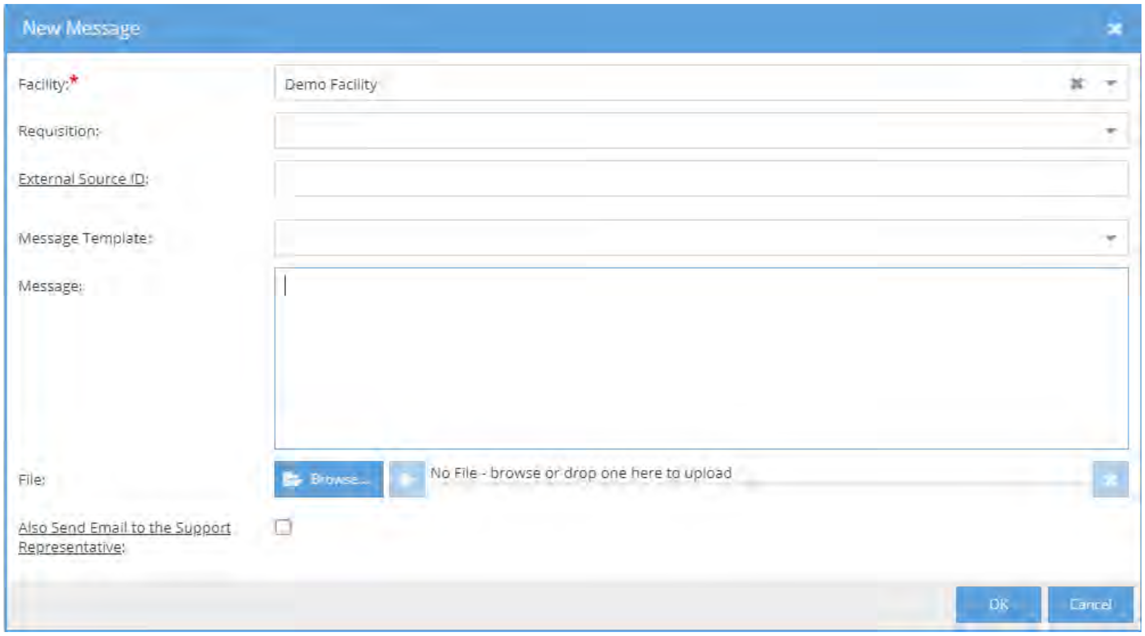


Managing Client Communications

Laboratory users can review and reply to client communications by selecting **Communications** from the Quick Links menu. When selected, a List View of all discussions are displayed with options to **Open**, create a **New Message**, and **Archive**.

To open an existing communication, select the discussion in the list and select "Open". The laboratory user can review the discussion as well as post a reply by selecting **Reply** from the right of the discussion record. The laboratory user is also able to **Archive** the discussion, which will prevent any further communication within the discussion thread.

To post a new message, the laboratory user can select **New Message** from the right of the List View. A dialog box will be displayed in which the laboratory user can enter the facility and associated requisition, fill out the body of the message, and upload a file attachment. When saved, an email will be sent to the contact email address for the client facility (optionally to the support representative of the facility in addition) informing them of a new discussion.



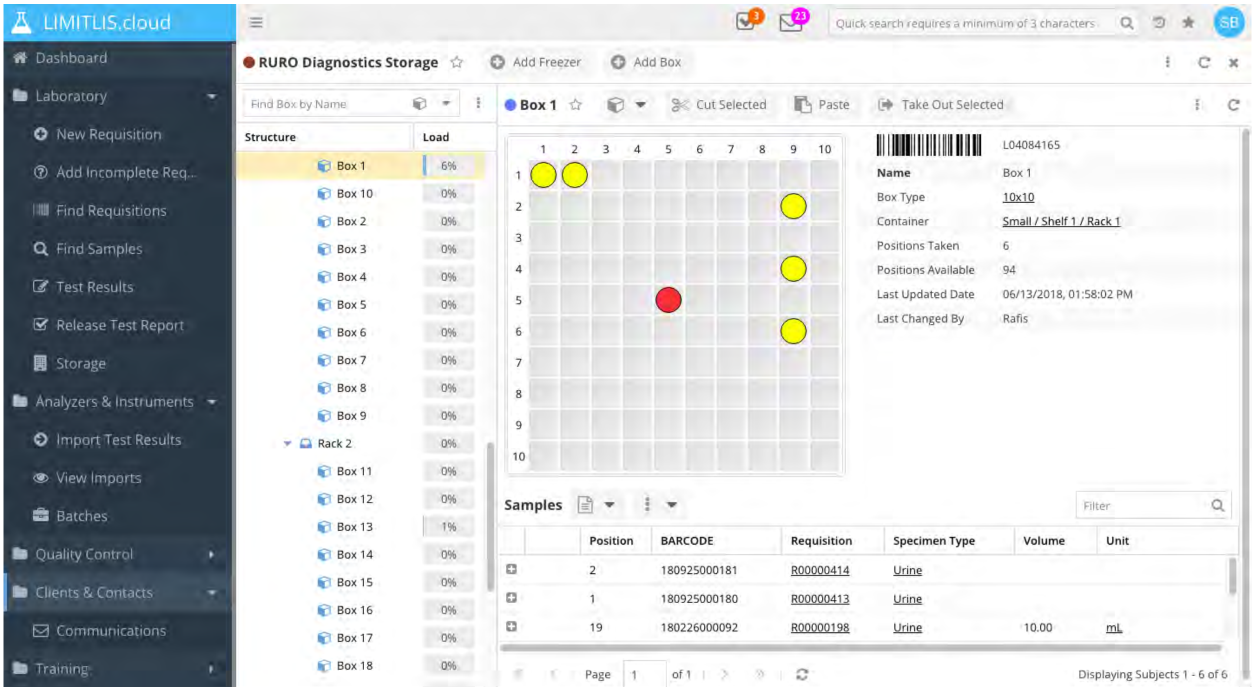
Archived discussions will be stored for reference, but no new replies will be available to be posted to the discussion.

Sample Storage & StorageModule

LimitLIS® can be deployed with an optional StorageModule addon that manages sample storage and tracks location of stored samples within freezers and boxes. A separate license key is required to activate the Storage Module.

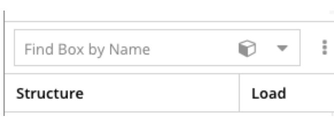
Laboratory users are able to access the storage module to create boxes, freezers, and other storage containers for their facility. Once samples are accessioned, laboratory users can place the samples in storage by selecting the desired box or bag within a freezer. Samples can be removed from storage once they have been placed into a box or bag. Both of these actions can be performed on one or more samples at a time.

Empty freezers can be populated with boxes, however unlike laboratory managers and admins, laboratory users cannot change the structure of the freezer or allowed subcontainers and box types.



To open storage and lookup a box by name or barcode:

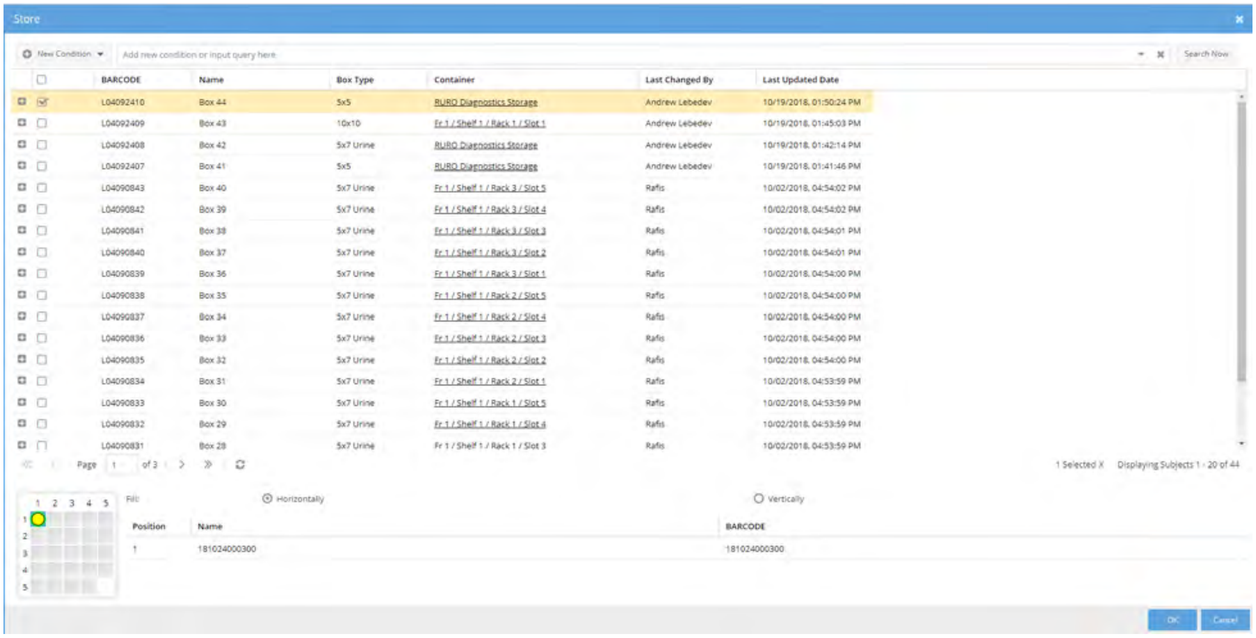
1. Click on **Laboratory,** then **Storage** in the left hand menu
2. The storage configured for currently logged in user's facility will open
3. Expand freezers and subcontainers by clicking on the arrow icon  next to each freezer or container.
4. Click on a box/container to bring up details about the box in the center pane.
5. To look up a box, paste the box identifier (name or barcode) into the search field at the top and hit 'Enter'

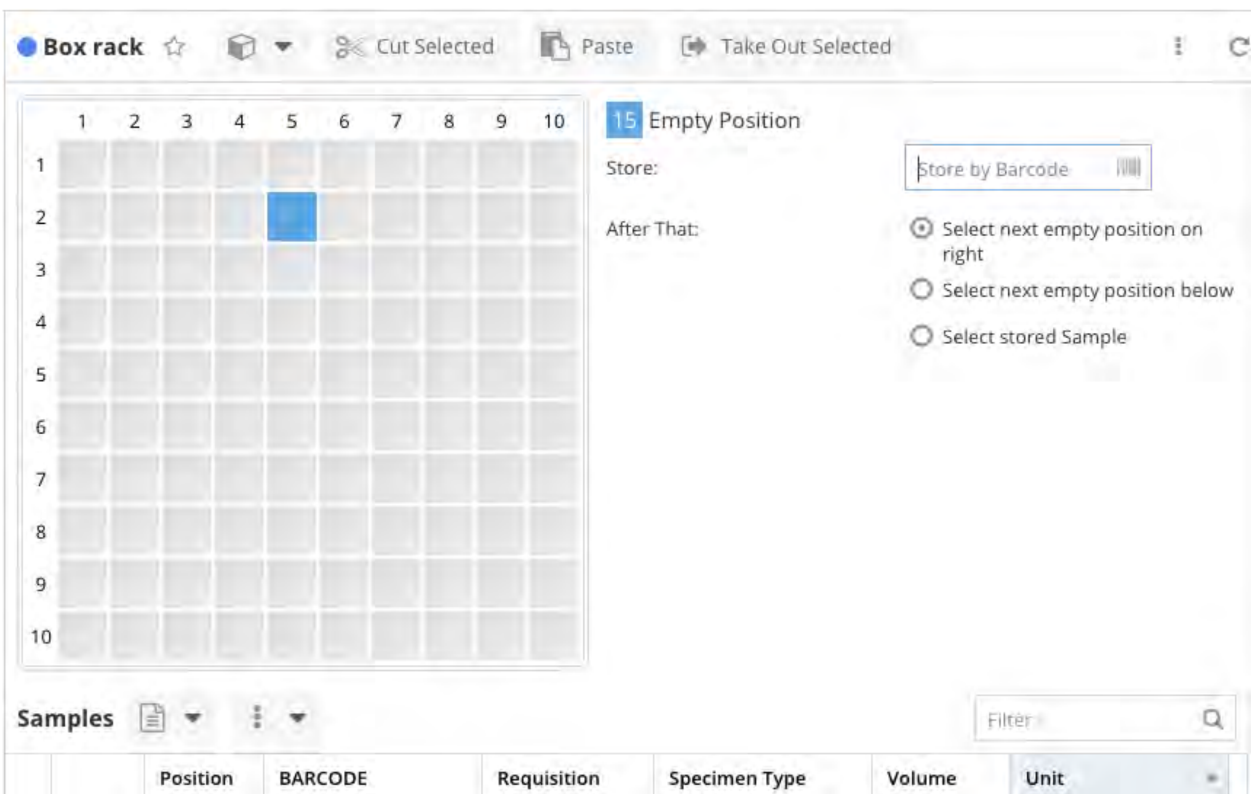
6. To switch the lookup field, click the arrow icon in the barcode scanner field.

To store samples:

1. Accessioned samples are available for storage by selecting **Find Samples** from the **Laboratory** menu.
2. A list of all samples available for storage will be displayed in a new tab within the system. These samples will be in one of the following states: Accessioned, In Testing, Released, or Stored.
3. Select the sample(s) to be stored and click **STORE**.
4. A dialog box will appear in which the user is able to select a box and enter the storage location for the sample(s).

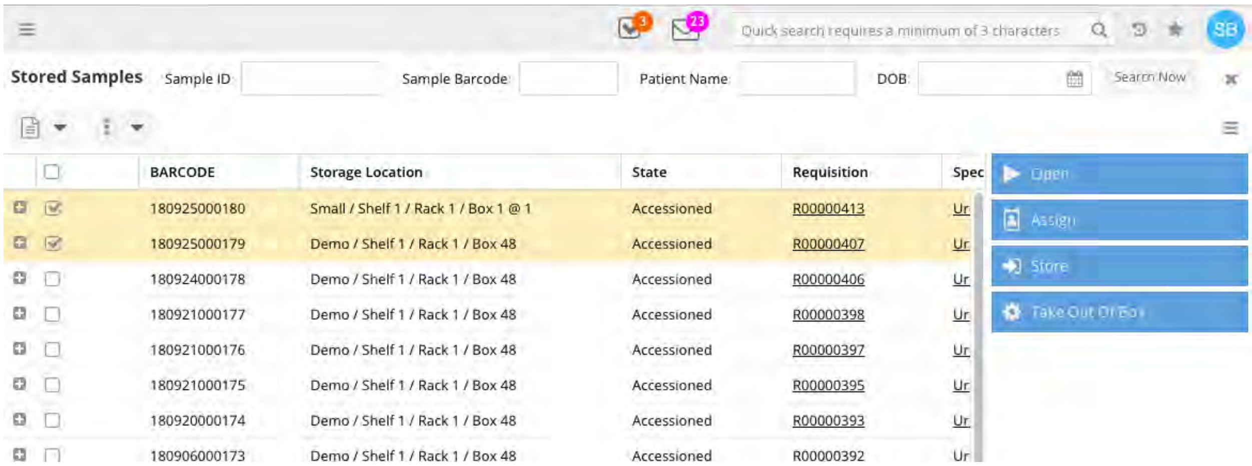


Samples can also be stored in a box by opening the desired box, then selecting a slot within that box. After scanning the sample's barcode, the sample will be placed into the selected slot. Users can choose the fill direction (vertical or horizontal) for subsequent samples, if scanning multiples.



To remove samples from storage:

1. Stored samples can be found by selecting **Find Samples** from the **Laboratory** menu then selecting *Stored* or by navigating to a sample that's currently in storage by scanning the sample's barcode.
2. Once selected, a list of all samples currently in storage will be displayed in a new tab within the system.
3. Select the samples to be removed from storage and click **Take Out of Box,** then click **OK**
4. The samples will be removed from storage and the storage location field will be blank on each sample



Managing Quality Control

Laboratory users can enter QC Results and view QC Reports by selecting the corresponding Quick Links. Selecting "QC Results" will give them the options to **Enter Results** and **Finalize** results, while "QC Reports" will give them the options to **Generate Report**, **Preview Report**, **Approve Report**, and **Discard Report**.

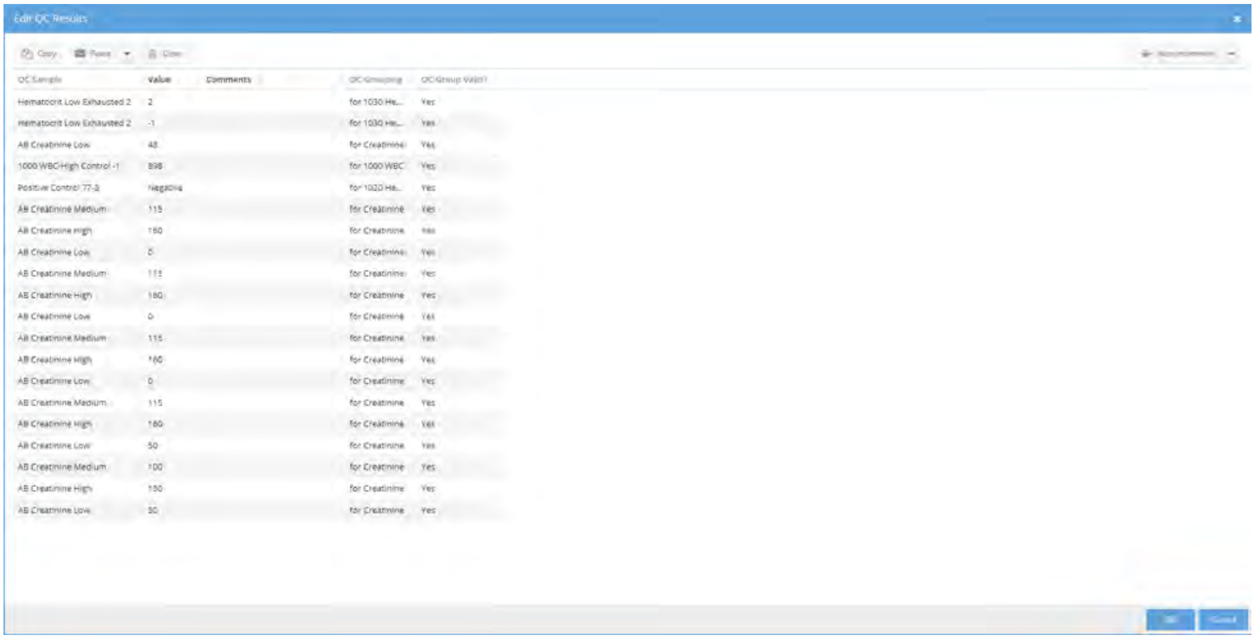
Entering QC Data

QC Result records are created only through the Import Test Results tool. They cannot be created manually.

Users can review and edit result values for each QC Sample by clicking on **QC Results** button located under the **Quality Control** menu. The QC Results view displays all non-finalized QC results created through a data import. All QC results will need to be finalized before they become available for Levey-Jennings charts.

To review QC Test Results:

1. Click **QC Results**.
2. Select one or more QC Test Results and click the **Edit QC Results** button.
3. A dialog containing the selected records will appear in which the laboratory user can enter a Value and Comment for each record displayed in the grid.
4. Click "OK" to save the values.



To view imported QC Test Results:

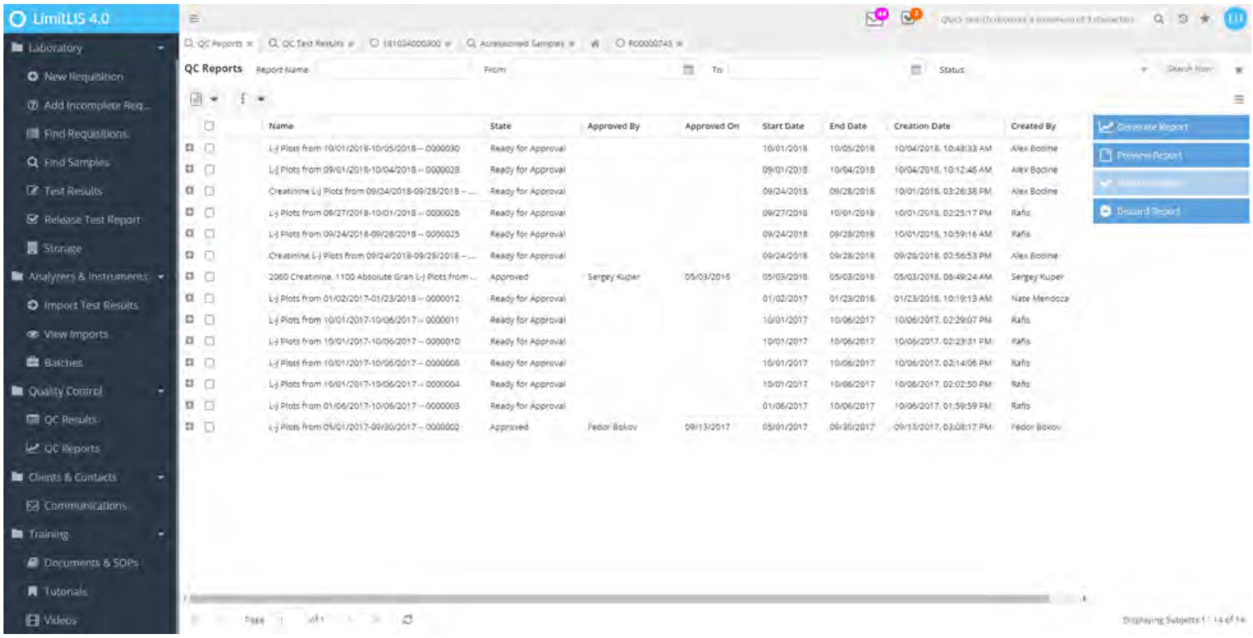
1. Click the **View Imports** button under the **Analyzers & Instruments** menu.
2. Open a Data Import record containing QC results and select **View QC Results** on the right of the screen. The list of QC test results imported for that batch will be displayed in a new tab within the system.
3. The QC results values can be manually overwritten via the **Edit QC Results** button on the right side of the screen.
4. QC Results can be finalized by clicking **Finalize** on the right side of the screen.

To finalize QC Test Results:

1. Select one or more QC Test Results from the **QC Results** view.
2. Click the **Finalize** button.
3. Once finalized, LimitLIS® will use the results when plotting Levey-Jennings charts.

Managing QC Reports and Levey-Jennings Charts

Laboratory users are able to generate and manage QC Reports and Levey-Jennings charts in LimitLIS® by selecting the **QC Reports** button under the Quick Links menu and clicking **Generate Report.**



Generate Report	Opens a dialog box allowing the laboratory user to enter parameters for plotting QC Results to a Levey-Jennings chart.
Preview Report	Allows the user to preview an already generated and selected report.
Approve Report	This option will be greyed out for laboratory users as it is only available for laboratory managers. When selected by laboratory managers, the system will save a copy of the report (HTML format) to the record and mark who approved the report.
Discard Report	Allows the user to delete a selected report.

NOTE: Only finalized QC Test Results will be plotted in Levey-Jennings charts. Ensure that all QC data is finalized after the measurements have been reviewed.

Printing QC Reports

Laboratory users can open generated QC reports in the browser and download them to a number of formats, including PDF.

To print a QC Report:

1. Double-click the QC Report record to open it in a new tab.
2. The "File" field will contain the report attachment in .html format
3. Click the .html file located in the "File" UDF to download and open in a browser window.
4. To print, either print the report directly from the browser or use the export button  located on the right of the chart to download one chart of the report to a PDF or other format file. Note:

this option will only download a single chart for the corresponding QC Sample, not for the entire batch as displayed in the browser.

Accessing Documents

Laboratory users can view and download copies of documents uploaded by their laboratory. These are general forms, notices, user guides, and other related documents curated by laboratory managers. Laboratory users are also able to upload documents.

To view a document: Click on the **Documents & SOPs** button located on the Quick Links menu. A list of all available documents will appear in a new tab. Click on the link under the "File" column to download a copy of the document.

NOTE: Documents uploaded to the system can be restricted to a specific user group.

Accessing Training Videos

Laboratory users can watch training videos that are deployed with the system. These are short instructional videos explaining how to execute various workflows within LimitLIS®.

To watch a training video: Click on the **Videos** button located under the Quick Links menu. The system will display a list of all available training videos in a new tab. Select a video and click **Watch Video** to start watching in a dialog within the system.

NOTE: Videos uploaded to the system can be restricted to a specific user group.

Accessing Tutorials

Client portal users can watch tutorial videos that are deployed with the system. These are short instructional videos explaining how to execute various workflows within LimitLIS®.

To watch a tutorial video: Click on the **Tutorials** button on the Dashboard. The system will display the list of all available training videos in a new tab. Double click on the name of a tutorial to access a link to the video and start watching within the system. If you wish to maintain a record of completed tutorials, select the relevant tutorial and click **Complete Tutorial** on the right side of the page, then click “OK” in the dialog box.

NOTE: Tutorials uploaded to the system can be restricted to a specific facility or other user group.

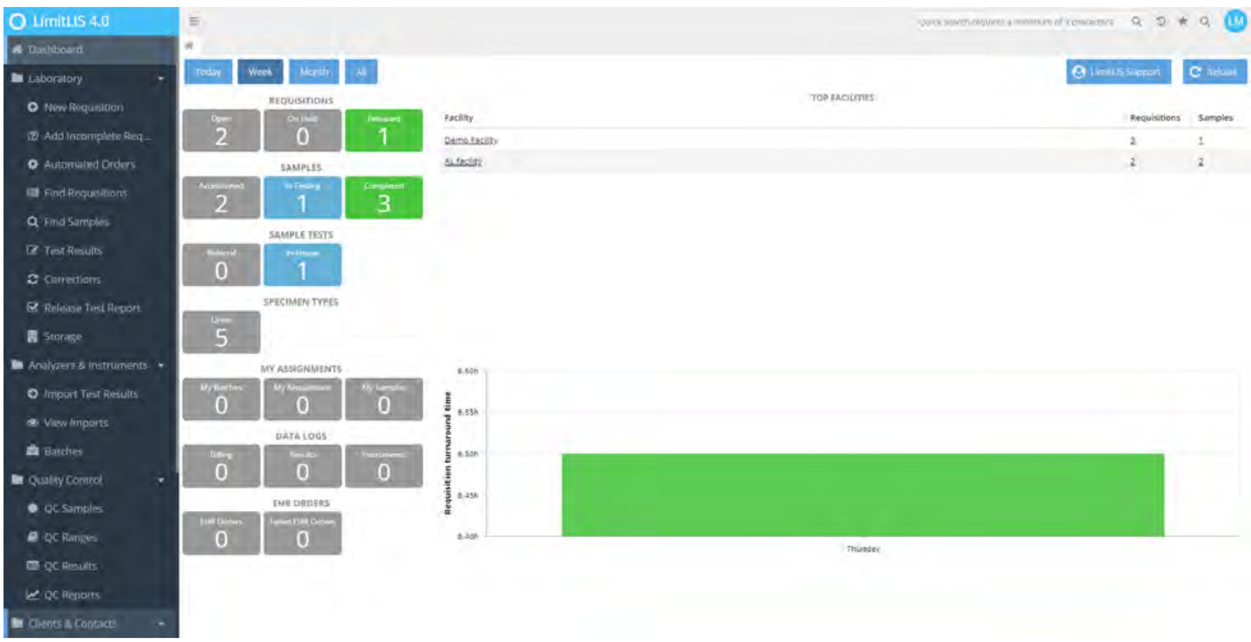
ACCESSING THE SYSTEM AS A LABORATORY MANAGER

Navigating the LimitLIS® User Interface Features

The LimitLIS® software system requires login credentials for access. The login credentials consist of a username and a password, both of which are case sensitive. Laboratory managers are given access to LimitLIS® by their laboratory administrators. Upon being registered within the system, the user will receive an email with their username and a link to LimitLIS® where they will be prompted to create a password and then login.

After initial login, the laboratory manager is presented with the Terms of Use and can either decline – logging them out of the system – or click the “Accept Terms of Use” checkbox and accept, which will open the LimitLIS® **Home** screen.

The left side of the Home screen consists of a Navigation panel with tabbed menus: **Quick Links**, **Explorer**, and **Search Queries**. In the center of the Home screen is the **Laboratory Dashboard**.



The **Quick Links** menu contains buttons that are used to initiate frequently executed workflows and processes within the system. The **Explorer** menu contains all records within the system and will open the records in a List View when selected. The **Search Queries** menu contains saved Advanced Searches for quick access.

The name of the user currently logged into the system and the logout option are under the **General Actions** menu 

located at the top right corner of the screen.


The General Actions icon can also be used to do the following:

- My Preferences - where the user is able to change their password, among other actions
- Viewers Bar - used to display records as new tabs in a tabbed bar
- About Limfinity – view version, BRICK, configuration date time stamp
- Logout – ends the current user session

NOTE:

The Menu/Navigation panel on the left side of the **Home** screen can be minimized or hidden.

To minimize the navigational panel, either click on this icon located at the top of the panel. In order to restore the panel back to the original configuration, simply click on the arrow.

Avoid using the **Back** and **Forward** functions of the web browser to navigate through the system.

While using the system, it tracks your recent visited views. The icon will allow the user to visit a recent view without having to navigate the system.

To close out a view, click the button located at the top of each view.

The inactivity time period can be changed in **Settings → Settings & Preferences → General Preferences.**

Managing Requisitions

The steps required to manage requisitions and samples are largely the same as those used by Laboratory Users. Please see the appropriate sections under *Accessing the System as a Laboratory User* for more information on the following processes:

- Adding Requisitions
- Searching for Requisitions
- Accessioning Requisitions
- Accessioning Samples
- Entering Test Results
- Auto-finalizing Test Results
- Releasing Test Reports
- Managing Client Communications
- Sample Storage

Cancelling Requisitions

Laboratory managers can cancel requisitions that are not yet released. A cancelled requisition will not proceed through the workflow and results for the requisition will not be released. A cancelled report will be sent out to the client with a note that the sample was cancelled.

To cancel a requisition:

1. Navigate to an open requisition that you wish to cancel.
2. Click the **Cancel** button and enter Cancellation Comments.
3. The requisition and sample(s) will be placed into the "Cancelled" state and a cancellation report will be provided to the client and saved as a PDF to the requisition record.

Placing Requisitions on Hold

In the event of an issue with a requisition, laboratory managers can place requisitions on hold to temporarily prevent them from going through the workflow until it has been released from the hold.

To place a requisition on hold:

1. Navigate to a requisition that you wish to place on hold.
2. Click the **Put On Hold** button and enter a reason or multiple reasons and a comment.

Any requisition that has been placed on hold can be taken off hold at any time by clicking the **Release Hold** button on the requisition. A laboratory manager can also initiate a new communication straight from the held requisition record by clicking on the **Open Communication** button.

Viewing EHR HL7 Orders

If bidirectional EHR integration is enabled, laboratory managers can view submitted HL7 orders (ORM messages) by clicking on the **View Automated Orders** button from the **Laboratory** menu. A grid containing received and processed EHR orders will open in a new tab. The EHR orders view contains the following columns:

Requisition	The requisition that was created in the system from the successful order.
Patient	The patient for whom the automated order was submitted.
External Source ID	External Source ID associated with the requisition
EHR Server Configuration	The system/provider that sent the automated order.
Comments	Any errors, warnings, or updates logged by the system during the processing of the order.
Creation Date	The date and timestamp when the order was processed.

NOTE: Laboratory managers and laboratory administrators can reprocess HL7 order files by selecting an existing automated order record and clicking the **Reprocess Order File** button on the right of the screen. During the reprocessing, LimitLIS® will re-run the automated order and attempt to create or update the requisition in the system based on the information contained in the HL7 file.

Submitting Requisition Corrections

Laboratory managers can correct released test reports through the **Corrections** button in the **Laboratory** menu in the event of incorrect data having been released to clients. Doing so will display a window where the user may select the Requisition, the correction date and the reason for correction. Once the requisition correction is created, the laboratory manager has several actions available to them.

Edit Test Results	Allows the laboratory manager to edit test results associated with the requisition. Flags will be recalculated using any updated values.
Correct Report	Regenerates the result report to pull all updated information. Test results do not need to be edited for the report to be updated if the patient demographics is the trigger. If the “Resend Test Report” option is checked, the system will resend the test report to the EHR provider.
Cancel	Terminates the corrections workflow without updating any files or clients.

Once the correction is finalized, a new test report PDF will be generated and attached to the requisition in the “Corrected Report File” field. The Requisition Correction record maintains PDF copies of both the original report file and the corrected report file.

NOTE: It is not necessary for the client portal manager to mark the requisition as Accepted once it has been corrected – the correction workflow does not trigger re-acceptance.

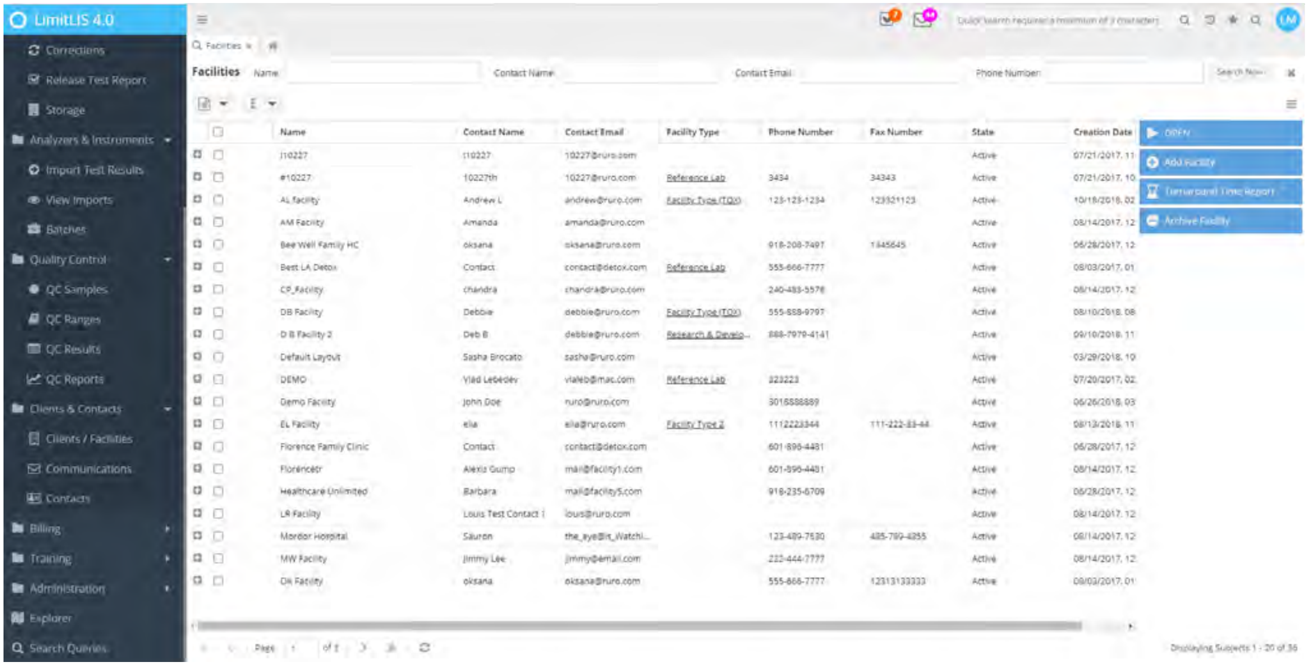
Resubmitting Requisition Results

After a requisition has been released and before it is accepted by the client portal user, the laboratory manager is able to resend the results to various locations as necessary. When the released requisition is selected and opened, the following options will be available on the right.

Resend Communications	Resends the notification that the test results are ready through the configured delivery option(s): fax, email, SMS.
Resend To Billing	Resends the HL7 billing file (DFT) to the revenue cycle management (RCM) system.
Resend EHR Results	Resends the test results to the integrated EHR system for the facility.
Assign	Assigns the requisition to a LimitLIS® user from a list of LimitLIS® users. The assignee can access their assigned requisitions from the lab dashboard.

Managing Client Facilities

Laboratory managers can review and add client facilities to LimitLIS® by selecting the **Clients / Facilities** button from the Quick Links menu. A List View of all existing client facilities will be displayed in a new tab with the options to **OPEN**, **Add Facility**, print a **Turnaround Time Report,** and **Archive Facility**.



To add a new facility to LimitLIS®, select **Add Facility** from the right of the List View. A dialog box will be presented in which the laboratory manager is able to enter the name and contact information for the new client facility.

To generate a turnaround time (TAT) report for a facility, select the facility in the results grid and click **Turnaround Time Report**. A new dialog with options to enter Specimen Type, Start Date, and End Date will open. Once confirmed, the system will return a CSV file containing a list of all the requisitions matching the entered parameters and the TAT statistics for each.

To open an existing client facility, highlight the facility and select **OPEN** or double-click the record. The laboratory manager can perform a number of actions on the opened facility record.

Edit	Allows the user to edit the contact information for the facility.
Settings & Options	Allows the user to manage the facility settings and configure the data that client portal users are able to see. Please see the Settings & Options table for more information.
Report Settings	Determines the report delivery method(s) that will be used to alert the contact(s) at the facility when a test report is released. These options include fax, email, and SMS (text) messaging. **Report Formats**: If the facility wishes to receive the report in a different format, this can be specified by selecting a report template from the "Test Report Types" dropdown. If left blank, the facility will

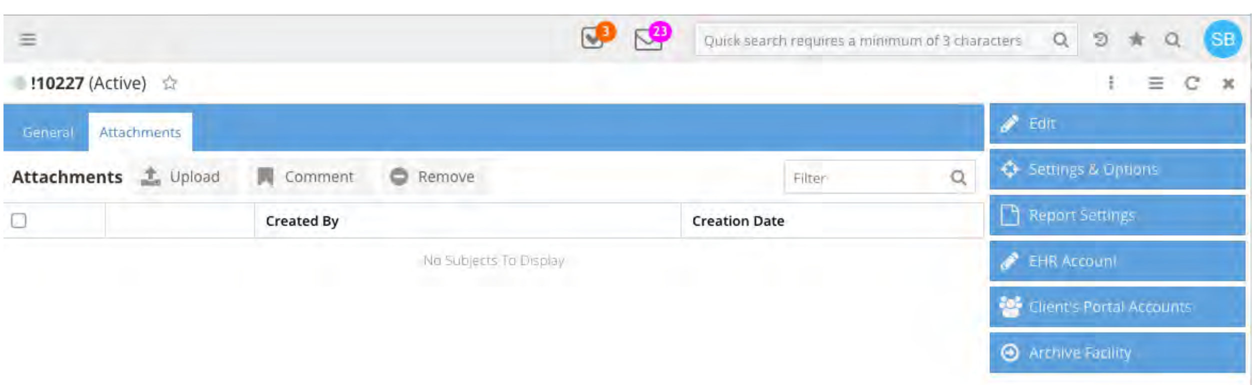
	receive their reports in the template specified on the Laboratory Report Settings.
EHR Account	Provides an entry field for the laboratory manager to select the configured EHR Server and to enter the account number for the facility as assigned by their EHR system.
Manage Client's Portal User Accounts	Allows the laboratory manager to create, edit, and archive client portal user accounts associated with the facility as well as reset passwords for the client portal user accounts.
Archive Facility	Suspends access to all associated client portal users and prevents new requisitions from being ordered from the facility. All existing requisitions and audit logs for the facility will be retained.

Users can view all attachments for a facility clicking on the **Attachments** tab. Each file will be displayed as a thumbnail.

To upload an attachment: Click **Upload,** select desired files, then click **OK.** A minimizable progress dialog will be shown while attachments upload. Once attachments are finished uploading they will be viewable in the Attachments grid.

To delete an attachment: Select an an attachment, click **Remove,** then click **OK** to confirm.

To comment on an attachment: Select an attachment in the **Attachments** tab, click **Comment** to enter a comment on the selected file. The comment will be displayed under the "Filename" field next to the file thumbnail.



Settings & Options

The following options can be configured for a client facility through the **Settings & Options** button available on a Facility record.

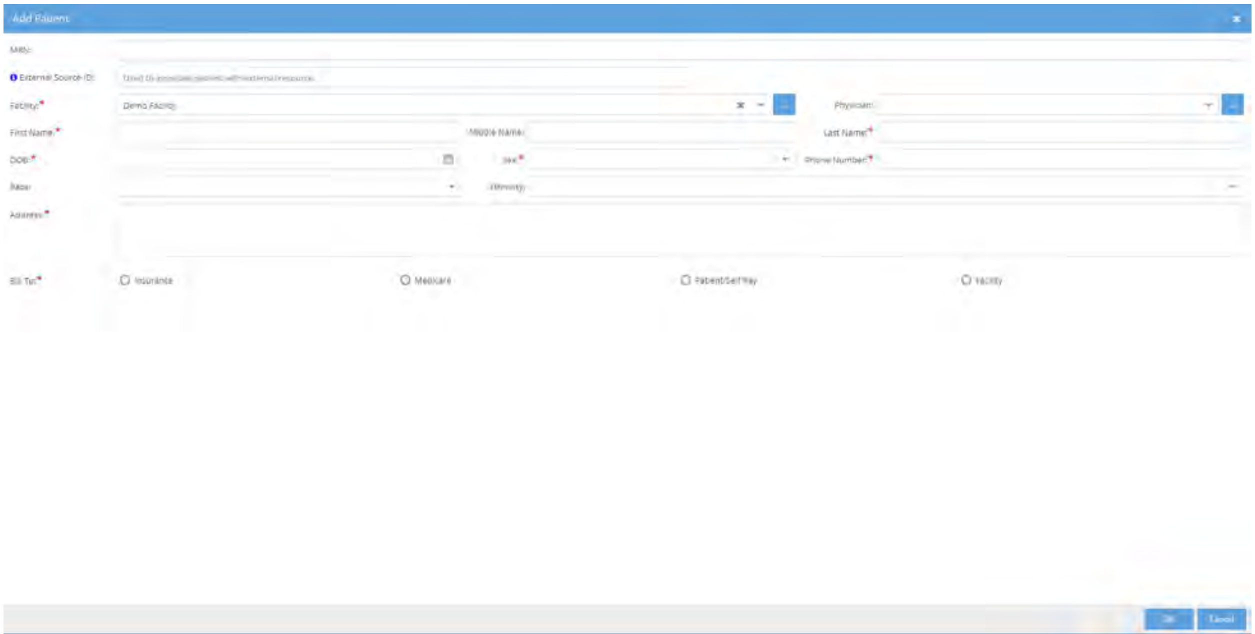
Account Manager	Assigns an Account Manager to the client facility. Pulls from the list of Contacts which can be edited through the Contacts Quick Link.
Support Representative	Assigns a Support Representative to the client facility from the list of Contacts (managed through the Contacts Quick Link). Support Representatives will receive an email if the "Also Send Email to the Support Representative" option is checked on a communication record.
Allow Physicians Management	If this option is enabled, the client portal users will be able to create and manage physicians for their facility from the client portal.
Schedules Require Physician Approval	If patient testing scheduler is enabled and this setting is enabled, all schedule records will require physician approval before they can be processed and turned into requisitions.
Online Communication Tools	Enables/Disables the Communication tools in client portal for the client portal users.
Client Portal Sample Accessioning	If this option is enabled, the client is able to pre-register samples from the portal.
Allow New Communication Emailing	If this option is enabled, emails will be sent to the facility contact(s) when a new Communication is opened or a Reply is posted.
Use Reflex Testing	If enabled, allows tests to be automatically added to requisitions from this facility based on reflex testing criteria.
Excluded Reflex POC Tests	If the "Use Reflex Testing" property is enabled but not all tests should be available for reflex criteria for the facility, this property allows specific tests to be excluded from the reflex rules.
Excluded Reflex Medications	If the "Use Reflex Testing" property is enabled but not all medications should be available for reflex criteria, this property allows medications to be excluded from the reflex rules.
Billing Identifier	Refers to the billing code for the facility used to calculate commissions. This value will be reported in the MSH.6 and FT1.33 segments in HL7 (DFT) files.

Remote File Path	The file path of the corresponding facility to place HL7 result (ORU) files on a remote server. If this file path is not configured, the client will either receive results on the Global File Path specified in LIS System settings (HL7 Server Configurations) or will not receive any EHR updates.
Use Patient Testing Scheduler	Enables the use of patient scheduling for this facility
Send EHR Cancelled Requisition	Sends an EHR when a requisition is canceled
Preliminary EHR Workflow Enabled	Enabling this setting will show a new section – EHR Results Workflow with the following options: • Preliminary EHR Report Test Types • Send to EHR Provider • Put requisition on hold after sending preliminary results • Preliminary EHR Report Template Here lab manager can selectively choose tests that will generate a preliminary report when finalized (meaning not all results for a requisition have to be finalized). The report does not have to be released by the lab to be automatically sent to an EHR provider if the "Send to EHR Provider" option is selected.

Managing Registered Patients

To submit a requisition for a patient, the patient must first be registered into LimitLIS®. To view the list of all patients registered in the system, select **Patients** from the **Administration** menu. The system will display the list of patients along with buttons on the right of the screen allowing the laboratory manager to **OPEN** an existing patient's record, **Add Patient** to the system, or **Archive Patient** to prevent further requisitions from being submitted for that patient.

When **Add Patient** is selected, the system will present the laboratory manager with a form in which to enter the patient's information, including a MRN, first and last name, date of birth, and insurance information. If the MRN is not provided, LimitLIS® will automatically generate a value for the patient.



To manage a patient’s information and control their access to the patient portal, select the patient from the list and click **OPEN** or double-click the record. The patient’s record will be displayed in a new tab with several actions on the right side.

Edit	Displays the patient’s current information in a dialog box for editing.
Upload Patient Photo	Allows the user to upload a photo for the patient if required by the facility.
Upload Insurance Card	Allows the user to upload a copy of the patient’s insurance card (single file only).
Diagnoses & Medications	Users can assign specific medications and diagnoses to the patient in the event they influence test outcomes. If these fields are populated, the medications and diagnoses values will be auto-populated on all new requisitions for the patient.
Repeated Tests	Tracks test codes and test panels that are frequently ordered for the patient. If these fields are populated, the test codes and test panels will be auto-populated on all new requisitions for the patient.
Testing Schedule	Allows the patient to have a schedule to give samples
Patient Portal Access	Enables the user to register the patient as a patient portal user by entering their email address.

Print Patient Report	Prints a summary of the patient's medical record in LimitLIS®. The patient report file contains patient data such as billing, medical necessity, and demographic information as well as all requisitions and result reports on file for that patient.
New Requisition	Allows for the creation of a new requisition for the patient
New Point of Care Test	Allows the user to submit new point of care test result(s) independent of a requisition.
Resend Demographic to Billing	Resends the demographic information of the patient as a HL7 (ADT) message to the billing provider.
Archive Patient	Suspends the patient's portal account (if present) and prevents further requisitions from being submitted for the patient.

Users can view all attachments for a patient by clicking on the **Attachments** tab. Each file will be displayed as a thumbnail.

To upload an attachment: Click **Upload,** select desired files, then click **OK.** A minimizable progress dialog will be shown while attachments upload. Once attachments are finished uploading they will be viewable in the Attachments grid.

To delete an attachment: Select an an attachment, click **Remove,** then click **OK** to confirm.

To comment on an attachment: Select an attachment in the "Attachments" grid, click **Comment** to enter a comment on the selected file. The comment will be displayed under the "Filename" field next to the file thumbnail.

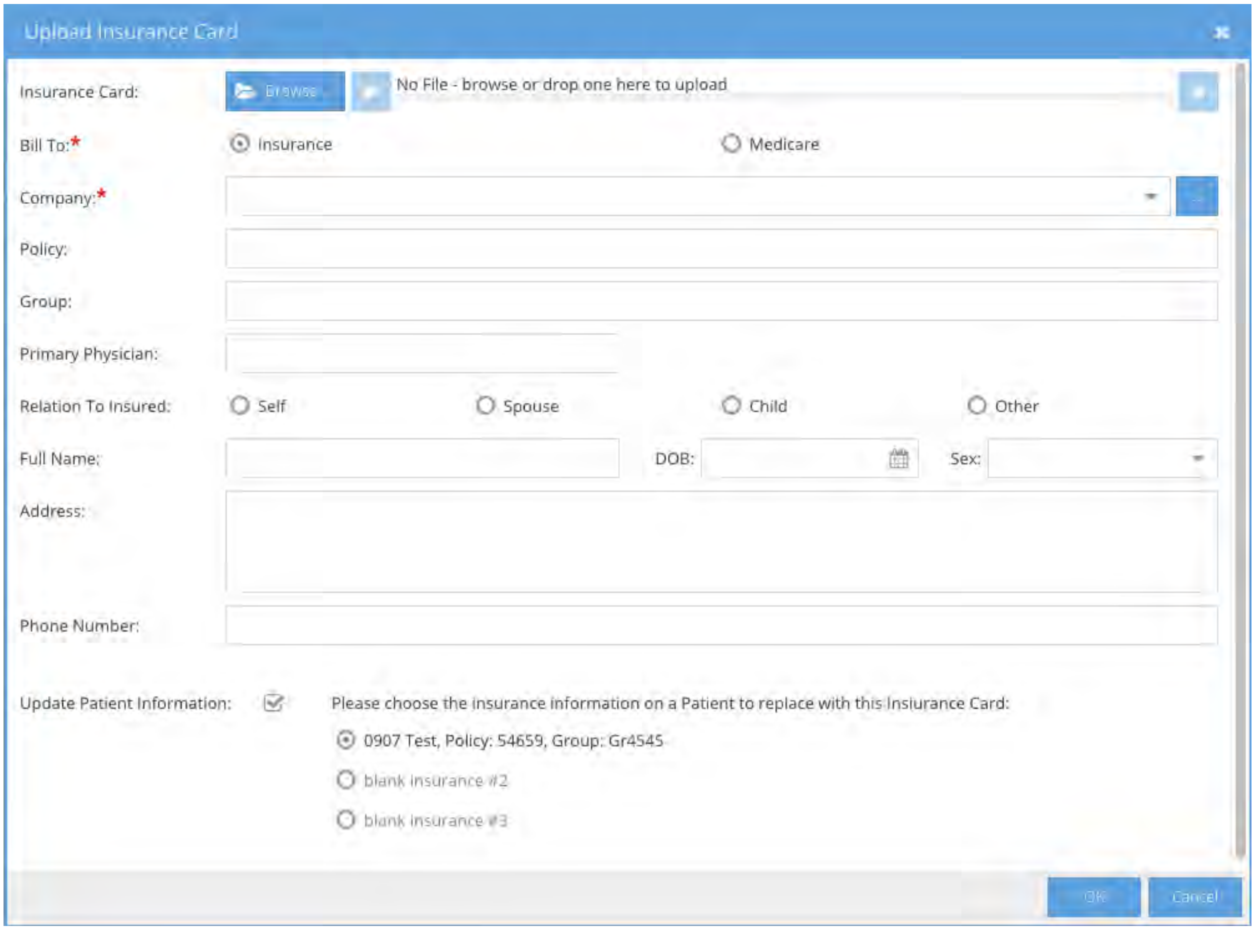
Uploading Patient Insurance Cards

Once a patient exists in LimitLIS®, one or more insurance cards can be attached to the patient record. Using this feature allows lab managers to capture insurance card information and the insurance card image in the .png format as well as quickly update insurance information.

To upload an insurance card:

1. Open a patient record
2. Click on **Upload Insurance Card**
3. Fill out the required fields in the dialog including Bill To and Insurance Company
4. If *Update Patient Information* is checked, the user will need to choose the current insurance on file that will be updated with the insurance information from the uploaded insurance card. The previous insurance information will be replaced with the new information on the card.
5. Click **OK**

Once insurance information has been updated on a patient, the patient and the patient's billing records can be re-sent to billing with the new insurance information.



Managing Registered Physicians

Physicians entering and submitting requisitions must be registered within LimitLIS®. To view and manage the full list of physicians registered in the system, select the **Physicians** button from the **Administration** menu. In a new tab, the system will display the list of physicians along with buttons on the right of the screen allowing the laboratory manager to **OPEN** an existing physician's record, **Add Physician** to a facility, or **Archive Physician** to prevent further requisitions from being ordered by that physician.

When **Add Physician** is selected, the system will present the laboratory manager with a form in which to enter the physician's information, including the Physician ID, first and last name, and other information. If LimitLIS® has been enabled to support capture and storage of physical signatures, the laboratory manager is able to click in the "Physician Signature" field and have a physician sign with a mouse (computer) or finger (mobile device).

To edit a physician's information, select the physician from the list and click **OPEN** or double-click the record. The physician's record will be displayed in a new view with the following actions:

Edit	Displays the physician's current information in a dialog box for editing.
Physician Portal Access	Grants the physician access to Physician Portal. To enable the Physician Portal, the laboratory manager must fill out the username, email, and the full name of the physician that's being signed up. A link inviting the physician user to access LimitLIS® will be emailed to the email address specified above.
Report Settings	**Report Formats**: If the physician wishes to receive the report in a different format, this can be specified by selecting a report template from the "Test Report Types" dropdown. If left blank, the physician will receive their reports in the template specified on the Laboratory Report Settings or Facility Report Settings.
Archive Physician	Archives the physician record. When a physician is archived, they are no longer able to request requisitions.

Managing Contacts

The **Contacts** button under the **Clients & Contacts** menu option contains a list of Contacts that can be associated with facilities and requisitions as additional contacts for communications and released report notifications. The laboratory manager can **OPEN** an individual contact, **Add Contact**, and **Archive Contact** to prevent further communications from being delivered to the individual. Opening a single Contact record allows the user to **Edit** the contact information, add **Comments** to the contact, and **Archive Contact**.

Managing Insurance Companies

The **Insurance Companies** button under the **Billing** menu option contains a list of all insurance companies available in the system which are used for billing on patient records and requisitions. Laboratory managers can **Open** an individual record, which will give them the option to **Edit** it, or **Add Insurance Company** from the list view page.

There are three types of billing in LimitLIS® 4.0 depending on configuration:

1. **Test Class billing** *(the option "Test Class Billing" is enabled in System Settings → General Settings → Features tab).*

    - Tests associated with a particular drug class will be grouped and billed as a class and not individually. Accordingly, the FT1 segment will be generated for each class, and the CPT code of the class will be sent in FT1.25.
    - CPT codes on individual tests will be ignored, as well as the absence of the CPT code on a test. For example:

- If on a test the CPT code is not specified, but the test is associated with a class, it is billed as the Test Class, and CPT code of the class will be sent to FT1;
- If the test is associated with the class, but the CPT code specified on the test is different than the CPT code specified on the class, it is still billed as the Test Class, and the CPT code of the class will be sent to FT1.

• If a test has the CPT code, but it is not associated with a class, or the test is marked as "Non-Reportable", it will be billed as an Individual Test. In this case, there will be separate FT1 segments per each CPT code specified on the test. The FT1 segment is generated only if the Individual Test has at least one CPT code on it.

2. <u>HCPCS G048x Codes billing</u> *(in addition to enabled option "Test Class Billing", the "HCPCS Code G048X Billing" option is enabled on an Insurance Company*).

• Tests associated with drug classes will be grouped by number of unique drug class values and billed as a G-Code depending on the number.
- G0480 – 1 - 7 drug class(es);
- G0481 – 8 - 14 drug classes;
- G0482 – 15 - 21 drug classes;
- G0483 – 22 or more drug classes.

• In this case, the FT1 segment will be generated for the corresponding group and display HCPCS G048x code in FT1.25.
• CPT codes on individual tests will be ignored, as well as absence of the CPT code on a test.
• If a test has a CPT code, but it is not associated with a class, or the test is marked as "Non-Reportable", it will be billed as an Individual Test. In this case, there will be separate FT1 segments per each CPT code specified on a test. The FT1 segment is generated only if the Individual Test has at least one CPT code on it.

3. <u>Individual Tests billing</u>.
• If a test is marked as "Non-Reportable" or unrelated to a class, it will be billed as an Individual Test.
• If the option "Test Class Billing" is disabled, all tests will be billed individually.
• There will be separate FT1 segments per each CPT code specified on the test.
• The FT1 segment is generated only if the Individual Test has at least one CPT code on it.

Managing Analytes

To view the list of registered analytes, navigate to the **Test Packages** Quick Link. Once open, select **Manage Analytes** to view and manage the list of registered analytes.

OPEN	Displays the selected analyte in a new tab within the system.
Add Analyte	Allows the user to create a new analyte with information including the name, type or value being returned, applicable ranges, and other settings.
Edit Analyte	Allows the user to edit the selected analyte.

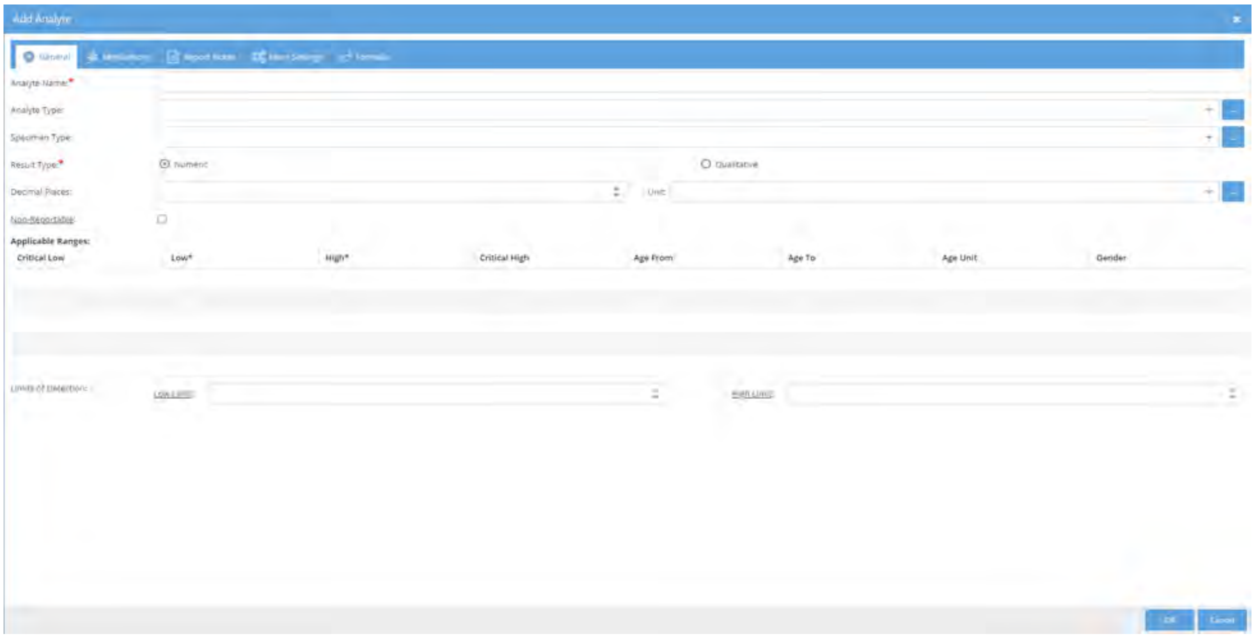
When adding and editing Analyte records, the dialog has multiple tabs that contain all the possible settings and options for the Analyte. These include an Applicable Ranges grid, medications that may influence the reported outcome, and whether the results are reported back to clients.

Adding a New Analyte

Each test panel consists of tests, which in turn consist of analytes. An analyte cannot be ordered individually and upon generation of the test result report, the system will display one result for each analyte. The following fields can be defined on an analyte:

Analyte Name	Unique name for the analyte in LimitLIS®.
Result Type	Numeric or qualitative. If qualitative is selected, the laboratory manager can enter possible result values separated by new line.
Specimen Type	The specimen type of the test where the analyte will be used.
Decimal Places	This setting controls the display of analyte results on the result report.
Unit	The unit in which the analyte is measured for this specimen type. This value will be displayed on the result report.
Non-Reportable	If chosen, this analyte or its results will not be shown on the result report.
Limits of Detection	Limits of detection or LOD represent the cutoff values for the analyte and control how the analyte's result will be displayed on the result report. They do not change the actual result value or control the flag of the result; the LOD is not the same as flags or reference ranges. Low Limit: Any value lower than this field will be reported as "< Low Limit" (< 2500) instead of the actual result for that analyte. High Limit: Any value higher than the value in this field will be reported as" > High Limit" (> 500) instead of the actual result for that analyte. LOD values are not required. If left blank, the result value will be reported as is.
Medications	This field contains a list of medications that influence outcome. If provided, the system can compute the INCONSISTENT/CONSISTENT value for each analyte (drug is present, but medication not listed and drug is not present, but medication is listed).
Trigger Normalization	If selected, other results for other analytes in the requisition will be normalized (divided by) the value

	of the result for this analyte.
Propagate Outcome To	If selected, the outcome (CONSISTENT/INCONSISTENT) value will be propagated to other chosen related analytes.



Example: Setting up a New Analyte

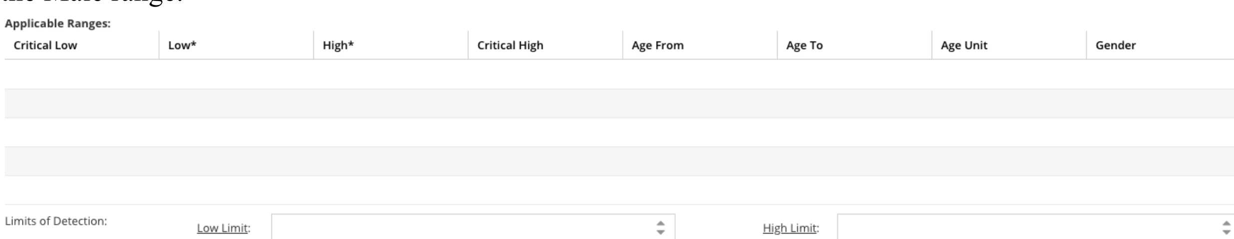
1. Enter a unique name. If you have the same analyte that's used in screens vs. confirmatory tests, you will need to differentiate them. For example: "Methamphetamine (Screen) vs. Methamphetamine.
2. Make sure **Limit of Detection** is entered appropriately –
    a. The values for the Limits of Detection indicate how the results will be displayed on the report. Any value lower than the Low Limit will be reported as "< Low Limit" (e.g., "< 16") and values higher than the High Limit will be reported as "> High Limit" (e.g. "> 4000").
3. Add **Medications**
    a. Linked Medications affect the system calculation of CONSISTENT/INCONSISTENT with prescribed Medications from the Patient/Requisition.
4. Add **Range** appropriately
    a. Each analyte can have one or more ranges. The reference ranges include high, low, critical low and critical high values and any conditions for the range such as age and gender. Upon result data entry (from instrument, data import, or manually), the system will attempt to match the result to the closest matching range and use that range to compute the resulting flag. Please see Adding a Range section below.
5. (Optional) Add **Instrument Codes**

    a. If the analyte is going to be sent by a directly integrated instrument you will need to add an instrument code. This value will help LimitLIS® understand which instrument is sending the analyte data in case the same analyte is analyzed on multiple machines. Please see Managing Instrument Codes section below.
6. Ensure that **Flags** are configured
    a. Flags can originate from an instrument or are set by LimitLIS® for each analyte once the result value has been entered for that result. Before LimitLIS® can set flags on results, the flags themselves must be defined in the system. Please see "Managing Flags" section below.
7. Ensure that "Propagate Result To" field is filled out with analytes if you wish to propagate the outcome of the chosen analytes to other analytes.

Adding a Range

Each analyte can have one or more reference ranges, QC ranges and instrument codes.

If the result for a new analyte will be numeric/quantitative, the laboratory manager is required to enter the range information for the analyte. This information includes the reference high and low values and any conditions for the ranges (age, gender, etc.). Analyte ranges can be added or updated on the Applicable Ranges grid when adding or editing an Analyte record. When matching the range to test results, the system will choose the range that most closely matches the tested patient – meaning if an analyte has two ranges: one for Female and one for Male, and the requisition is for a male patient, the range used will be the Male range.



The values for the Limits of Detection indicate how the results will be displayed on the report. Any value lower than the Low Limit will be reported as "<Low Limit" (e.g., "<16") and values higher than the High Limit will be reported as ">High Limit" (e.g. ">4000").

If no Age or Gender is specified for a range, the system will use the range as the default for patients of any age and gender.

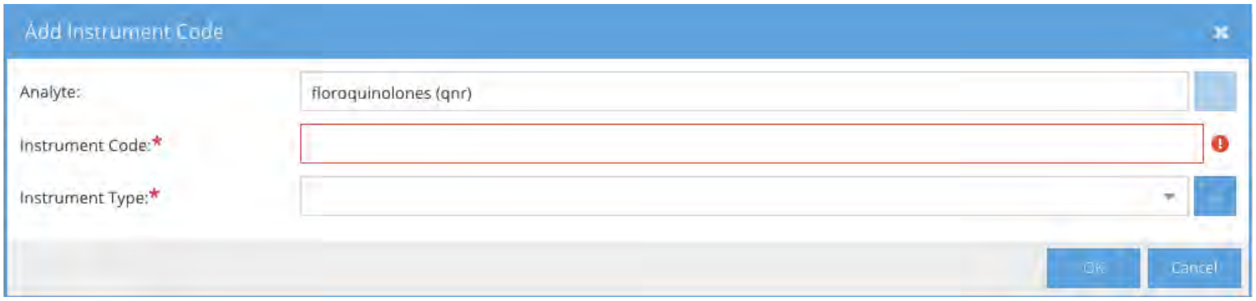
Managing Instrument Codes

An instrument code is a mapping from the instrument name for a given analyte to the actual analyte record within LimitLIS®. Because LimitLIS® can receive data from multiple instruments testing the same analyte, it is possible to have more than one instrument code for one single analyte.

To create an instrument code:

1. From an analyte, click **Add Instrument Code**
2. Enter an *Instrument Code*, then select an *Instrument Type*

3. Click **OK**



Managing Tests

Laboratory managers can manage test setup in LimitLIS® by selecting **Test Packages** from the **Aministration** menu. Once selected, a list view will be opened in a new tab with all the current tests registered in the system and a number of additional actions available on the right of the screen.

OPEN	Displays the selected test in a new tab within the system.
New Test	Allows the user to create a new test with CPT Code(s), specimen types, and associated analytes.
Archive Test	Archives the selected test which prevents it from being ordered on any new requisitions. All previous orders are kept.
Manage Analytes	Displays all the analytes available in the system and allows the laboratory manager to maintain the list.
Manage Test Panels	Displays all the test panels available in the system and allows the laboratory manager to maintain the list.
Manage Test Classes	Displays all the test classes available in the system and allows the laboratory manager to maintain the list.
Confirmation Tests	Displays all the confirmation tests available in the system. This button will only be visible if the system is configured by system administrators to capture confirmation test results at time of order.

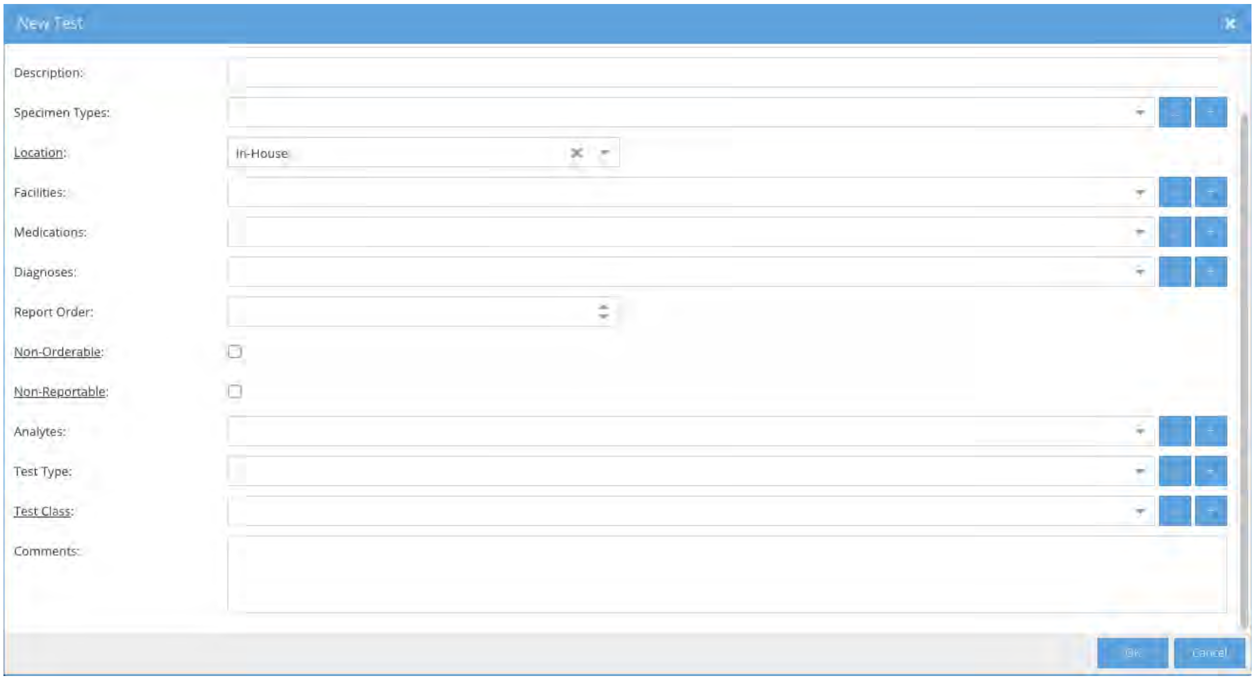
Manage POC Tests	Displays all the POC tests available in the system and allows the laboratory manager to maintain the list. This button will only be visible if the system is configured to capture Point of Care test results at time of order.
Manage Flags	Displays all flags available in the system and allows the laboratory manager to create, edit and delete flags.
Manage Reflex Rules	Displays all the reflex rules available in the system and allows the laboratory manager to maintain the list.

After opening a test record, the laboratory manager can **Edit** the test data, add or remove **Test Analytes**, or **Archive Test** to prevent new orders from being submitted for the test.

NOTE: If a test is marked as Non-Orderable, it will not be available for client selection in the “Tests” field in any new requisitions but will be available to the laboratory during sample accessioning. If the test is marked as Non-Reportable, it will be billed but the result will not be reported to clients.

Setting up new Tests

1. Click **New Test**
2. Enter a *Code* for the test. This will become the system name for the test
3. Enter a comma-delimited list of CPT codes if you wish for the test to be billed
4. Add one or more *Specimen Types*. If this field is populated, the system will validate the specimen type field in all new requisitions when this test is ordered.
5. Enter *Location* – Default is In-House.
6. Enter *Facilities* if you wish to restrict this test to one or more facility. If left blank, the test will be orderable by all facilities.
7. Select *Analytes* to be tested as part of this test.
8. If you wish to bill for this test as part of a group of other tests, assign a *Test Class.*



Managing Test Panels

Laboratory managers can create panels that group multiple test packages under one orderable item. The test panel names are not displayed on reports but are used to quickly select multiple packaged tests at time of ordering. Test panels are useful to create a standard, convenient grouping of tests for ordering purposes. Test panels, like tests, can be restricted to a single facility or multiple facilities. When a physician or facility orders a test panel, all associated tests are added to the requisition at once.

To view the list of all test panels in the system, navigate to **Test Packages** under **Administration** and select **Manage Test Panels** on the right.

Add Test Panel	Allows the laboratory manager to create a new test panel. These can be specific to client facilities and include any number of pre-registered tests. A test panel can include other test panels within it.
Edit Test Panel	Allow the laboratory manager to edit the selected test panel and add or remove associated Tests.
Archive Test Panels	Archives the selected test panel(s) and prevents new orders from being submitted for the test panel(s).

Example: Setting up a New Test

1. Once all analytes are in the system, add them by selecting them in the *Analytes* list.
2. (Optional) Group Tests together into a new Test Panel
   a. Test Panel's may be useful for creating a standard, convenient grouping of Tests for a

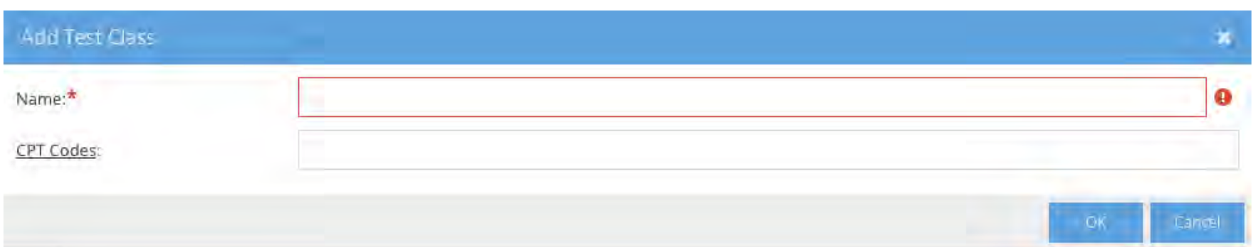
single client (e.g. Physician X's Test Panel)
    b. b. When a physician orders a Test Panel, all associated Tests are added to the Requisition at once
3. (Optional) Group tests together into Test Classes if they are billed together
    a. Test classes are used to group tests together for billing purposes. When there are multiple tests with the same CPT code being performed, the corresponding test class is used to avoid duplicate billing.
    b. Add appropriate CPT Code(s) and assign Tests to each Test Class

Managing Test Classes

Test classes are used to group tests together for billing purposes. When there are multiple tests with the same CPT code being performed, the corresponding test class is used to avoid duplicate billing. A test can be billed by an individual test CPT code, by the code of the corresponding test class, or by G-code if HCPCS billing is enabled on the insurance company. To view all test classes in the system, navigate to the **Test Packages** Quick Link and select **Manage Test Classes** from the right of the screen. From the list of test classes, the laboratory manager can **Add Test Class**, **Edit Test Class**, or **Archive Test Classes**.

To add a test class:

1. Specify a name
2. If all tests within the test class must be billed under a separate CPT code, enter CPT Codes corresponding to the test class
3. Click **OK**



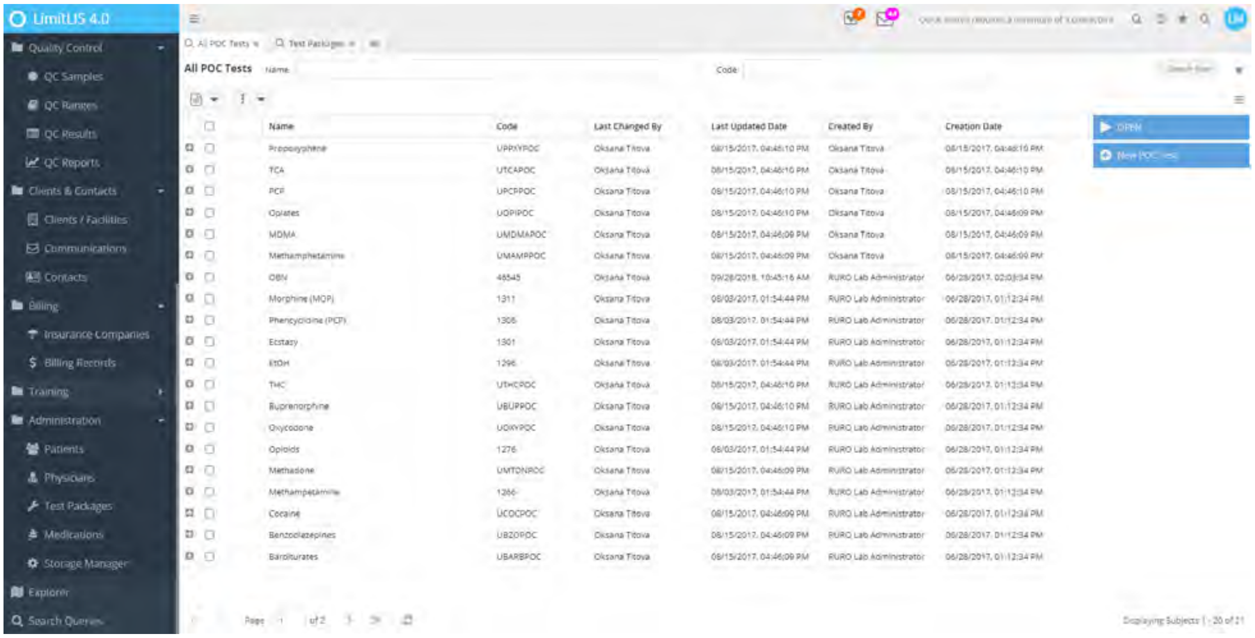
To use the new test class, laboratory managers will need to assign a test to a test class from the **Edit** test screen. Each test can only belong to one single test class.

Viewing Confirmation Tests

If the Confirmation test functionality has been enabled in LimitLIS® by system administrators, facilities are able to capture confirmation test results (reported as Positive, Negative, or Not Tested) and attach them to submitted requisition. To view all confirmation tests in the system, navigate to the **Test Packages** Quick Link and select **Confirmation Tests** from the right of the screen. No management options are currently available from this table.

Managing POC Tests

If the Point of Care (POC) test functionality has been enabled in LimitLIS® by system administrators, facilities are able to capture POC test results (reported as Positive, Negative, or Not Tested) and attach them to submitted requisitions. To view the list of all POC tests available in the system, navigate to the test packages list through the **Test Packages** Quick Link and select **Manage POC Tests** from the right of the screen.



From the POC Tests list, the laboratory manager can **Open** and create a **New POC Test** by entering a *Name* and *Code* for the new test. There is no need to specify reference ranges for POCT records – each POCT result can only be one of: positive, negative, or not tested.Managing Flags
Laboratory managers can define flags and specify how those flags get set on analyte results.

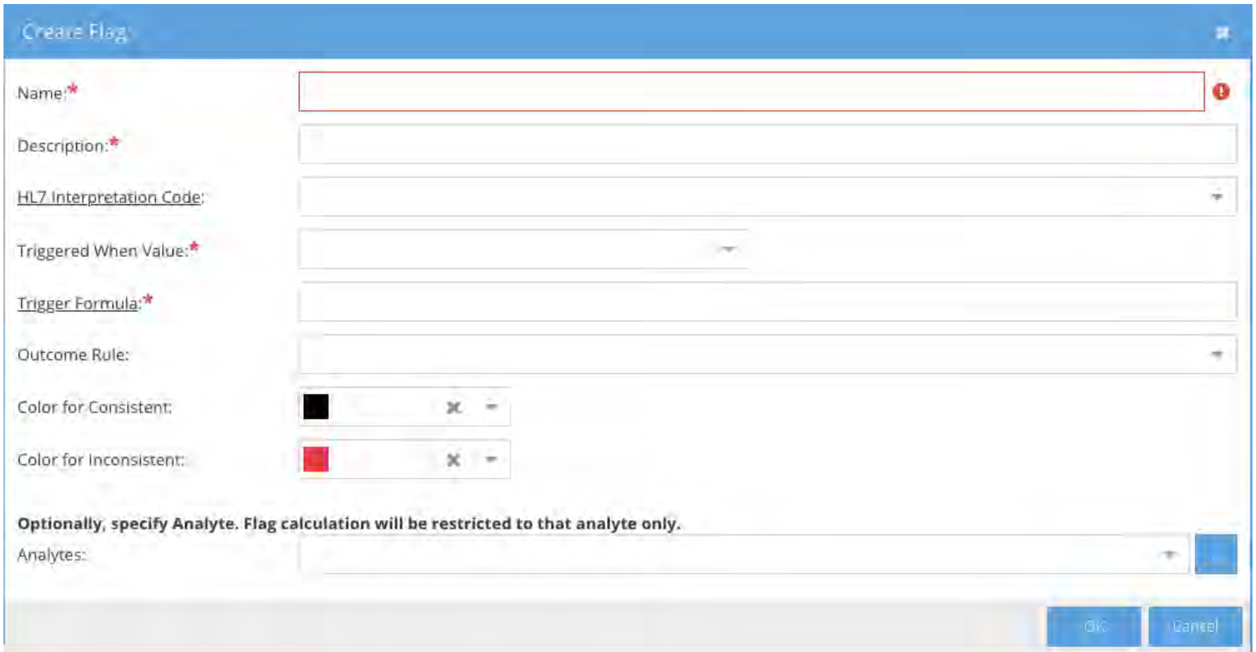
To manage the list of all flags configured in the system, navigate to **Test Packages** and select **Manage Flags** on the right of the screen. From the list of flags, the laboratory manager can **Create Flag**, **Edit Flag**, or **Delete Flag**.

To create a flag:

1. Click **Create Flag**
2. Fill out the required fields:
    a. *Name* – the short name or symbol for the flag, such as "ND"
    b. *Description* – the long name or description of the flag, such as "Not Detected"
    c. *Triggered when Value* – Condition that upon being met will set the flag on a test result for all affected analytes. Set this as "Other" if you wish to enter the trigger formula instead.
    d. *Trigger Formula* – Code expression describing the condition that upon being met will set the flag on a test result for all affected analytes, such as "{value} > {High} && {value} <= {Critical High}"
3. Fill out other fields as necessary:
    a. *Outcome Rule* – computes the CONSISTENT/INCONSISTENT outcome value on affected analyte result.
    b. *Color for Consistent* – if analyte result is consistent, this color will be used on the result report
    c. *Color for Inconsistent* – if analyte results is inconsistent, this color will be used on the

result report.

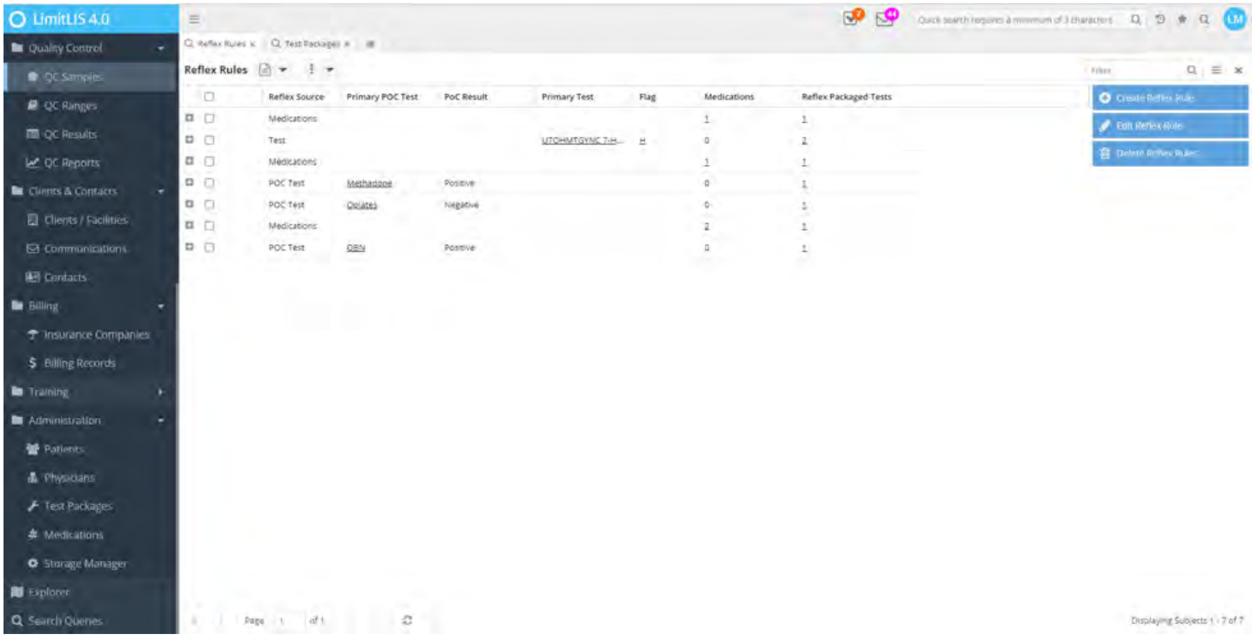
d. *Restricted to analytes* – if this is left blank, flag will apply to all analytes. If not blank, flag calculation will be restricted to specified analytes only.



Managing Reflex Rules

Laboratory managers can configure reflex rules to automatically add tests to an order based on various result outcomes or medications prescribed. Individual facilities can be configured to use reflex tests and exclude certain tests from being reflexed. Please see the Managing Client Facilities: Settings & Options section of this document for more information on configuring reflex rules for facilities.

To manage the list of all reflex rules configured in the system, navigate to **Test Packages** and select **Manage Reflex Rules** from the right of the screen.



From the Manage Reflex Rules screen, the laboratory manager has a number of actions available for managing Reflex Rules.

Create Reflex Rule	Opens a dialog in which the laboratory manager is able to set the parameters for the new Reflex Rule. Tests can be reflexed based on a POC result (triggered once a requisition is created), Test Result (triggered when the result is finalized), or Medication (triggered when a requisition is created). If a Reflex Rule is triggered, the specified packaged test or tests are automatically added to the requisition upon requisition creation (if source is Medication or when POC test results are entered) or result finalization (if source is Test)
Edit Reflex Rule	Allows the laboratory manager to edit the selected Reflex Rule.
Delete Reflex Rule	Allows the laboratory manager to delete existing Reflex Rules from the system.

Managing Quality Control

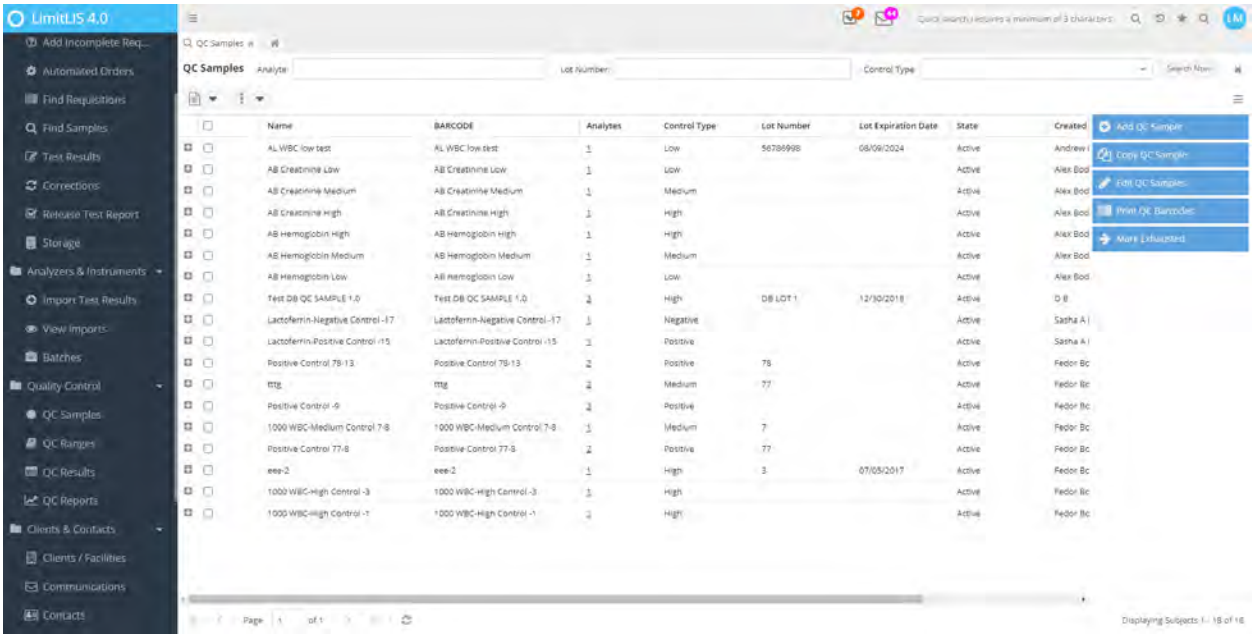
Laboratory managers have access to additional tools within the Quality Control module. Please see the appropriate sections under *Accessing the System as a Laboratory User* for more information on the following processes:

- Entering QC Data
- Managing and Printing QC Reports

Managing QC Samples

LimitLIS® allows laboratory managers to define QC Samples and Ranges that can be used to evaluate QC date for each instrument run.

Within the **QC Samples** grid accessible from the **Quality Control** menu, LimitLIS® offers several actions for setup.



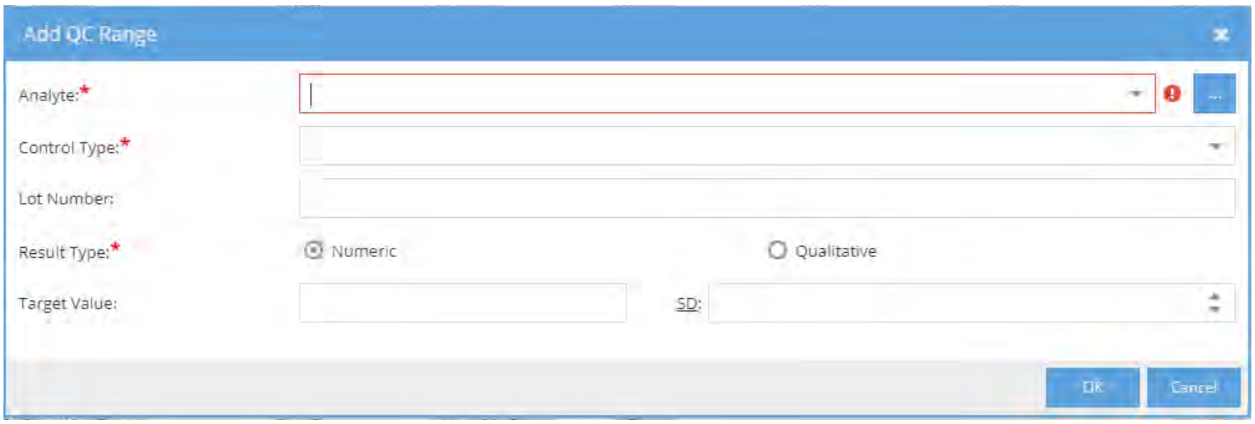
Add QC Sample	Allows users to define QC Samples for import by entering the Analyte(s), Control Type, Lot Number, and Lot Expiration Date.
Copy QC Sample	Allows users to duplicate an existing QC Sample with a new name, Lot Number, and Expiration Date. The Analyte(s) and Control Type values will be copied over from the original sample. This is often used to update expired lot numbers.
Edit QC Samples	Allows users to modify selected QC samples.
Mark Exhausted	Allows users to archive a QC Sample.
Print QC Barcodes	Allows users to print barcodes associated with QC Samples

Setting Up QC Ranges

The QC setup in LimitLIS® begins with establishing the QC Ranges. Laboratory managers can click on the **QC Ranges** button located in the **Quality Control** menu to manage the QC Ranges within the system. From the list, laboratory managers are able to **Add QC Range** and **Edit QC Range** that has been selected, as well as open an existing Range to **Edit** or **Archive**.

To setup a new QC Range:

1. Click on the **Add QC Range** button from the List View.
2. A dialog box will appear in which the laboratory manager is able to enter the applicable Analyte and Control type, as well as the Target Value and other relevant information. Note: if the SD field is filled out, the system will plot the entered SD value rather than calculating and plotting it based on imported data. QC results can be either Numeric or Qualitative. If Qualitative option is selected, the user will be prompted to enter *Result Choices* and *Valid Values.*



Edit a QC Range: to edit an existing QC Range, first open the record by selecting it and clicking Edit QC Range or double-click the record within the List View. Once opened, the information contained within the record can be updated by selecting the **Edit** button.

Archive a QC Range: to archive an existing QC Range, double-click the record within the List View and select the **Archive** button located on the right of the record view.

Uploading QC Runs

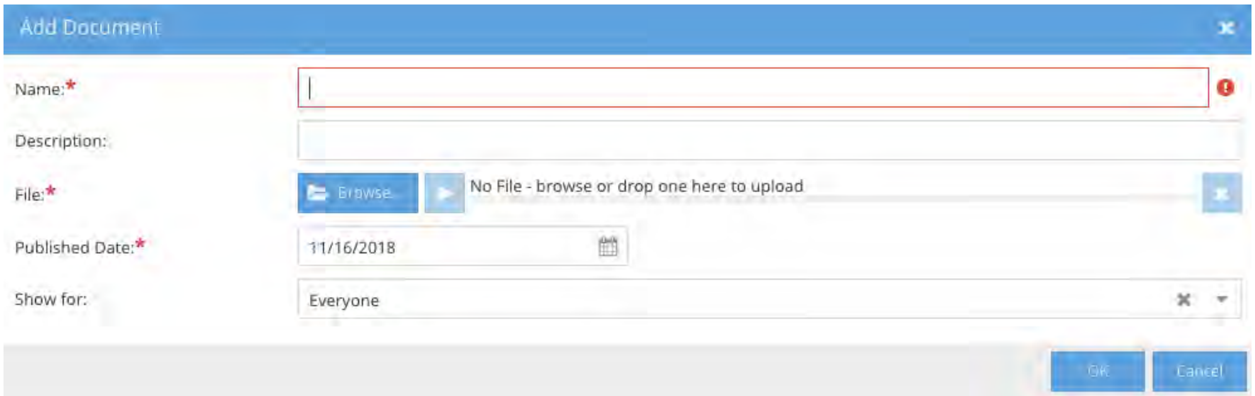
LimitLIS® is configured to accept QC Results through an imported file from an instrument, rather than accepting manual QC result creation. QC Runs will automatically be generated after successful import through the **Import Test Results** button in the **Analyzers & Instruments** menu. Please see the *Entering Test Results: Uploading Test Result Data* section of this document for more information on importing data files.

Managing and Reviewing Documents

Laboratory managers can add and update documents in LimitLIS® by selecting **Documents & SOPs** from the **Training** menu. If setup to be shown for everyone, these documents will be accessible to all system users and may include notices and schedules.

After clicking **Documents & SOPs**, the laboratory manager will be able to **Add Document, Approve Document** or **Archive** an existing document so that it is no longer accessible to system users.

NOTE: If "Show For" option is set to "Everyone", then the document will be global and accessible to all users. In order to show a document only to a particular user group, "Show For" must be set to the name of the desired user group.



Accessing Videos & Tutorials

Laboratory managers can watch training videos that are deployed with the system, and tutorials explaining important functions. These are short instructional videos or other content explaining how to execute various workflows within LimitLIS®.

To watch a training video: Click on the **Videos** button located under the Quick Links menu. The system will display a list of all available training videos in a new tab. Select a video and click **View Video** to start watching in a dialog within the system.

To access a tutorial: Click on the **Tutorials** button located under the Quick Links menu. Double click any tutorial in the list to access the link containing the tutorial. If you wish to keep a record of completed tutorials, select the tutorial and click the **Complete Tutorial** button on the right.

NOTE: Training Videos and Tutorials will be accessible to all users if the "Show For" field is set to "Everyone". In order to restrict specific videos or tutorials to a particular user group, it must be selected in the "Show For" dropdown.

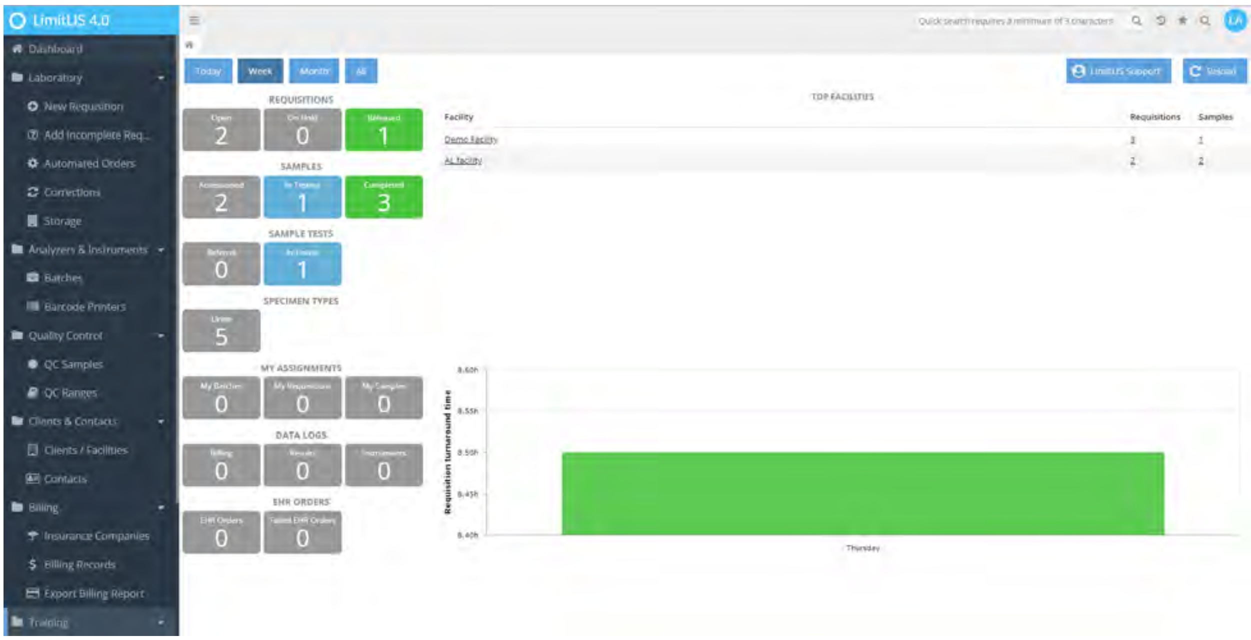
ACCESSING THE SYSTEM AS A LABORATORY ADMINISTRATOR

Navigating the LimitLIS® User Interface Features

The LimitLIS® software system requires login credentials for access. The login credentials consist of a username and a password, both of which are case sensitive. Laboratory administrators are given access to LimitLIS® by other laboratory administrators or system administrators. Upon being registered within the system, the user will receive an email with their user name and a link to LimitLIS® where they will be prompted to create a password and then login.

After the initial login, the laboratory administrator is presented with the Terms of Use and can either decline – logging them out of the system – or click the “Accept Terms of Use” checkbox and accept, which will open the LimitLIS® **Home** screen.

The left side of the Home screen consists of a Navigation panel with tabbed menus: **Quick Links**, **Explorer**, **Search Queries**, and **Settings And Preferences**. In the center of the Home screen is the **Laboratory Dashboard**.



The **Quick Links** menu contains buttons that are used to initiate frequently executed workflows and processes within the system. The **Explorer** menu contains all of the records within the system and will open the records in a List View when selected. The **Search Queries** menu contains saved Advanced Searches for easy access and execution. The **Settings And Preferences** menu allows the laboratory administrator to create and update Report Templates.

The name of the user currently logged into the system and the logout option are under the **General Actions** menu LA located at the top right corner of the screen.

The General Actions icon can also be used to do the following:

- My Preferences - where the user is able to change their password, among other actions
- Viewers Bar - used to display records as new tabs in a tabbed bar
- About Limfinity – view version, BRICK, configuration date time stamp
- Logout – ends the current user session

NOTE:

The Menu/Navigation panel on the left side of the **Home** screen can be minimized or hidden.

To minimize the navigational panel, either click on this icon ≡ located at the top of the panel. In order to restore the panel back to the original configuration, simply click on the arrow.

Avoid using the **Back** and **Forward** functions of the web browser to navigate through the system.

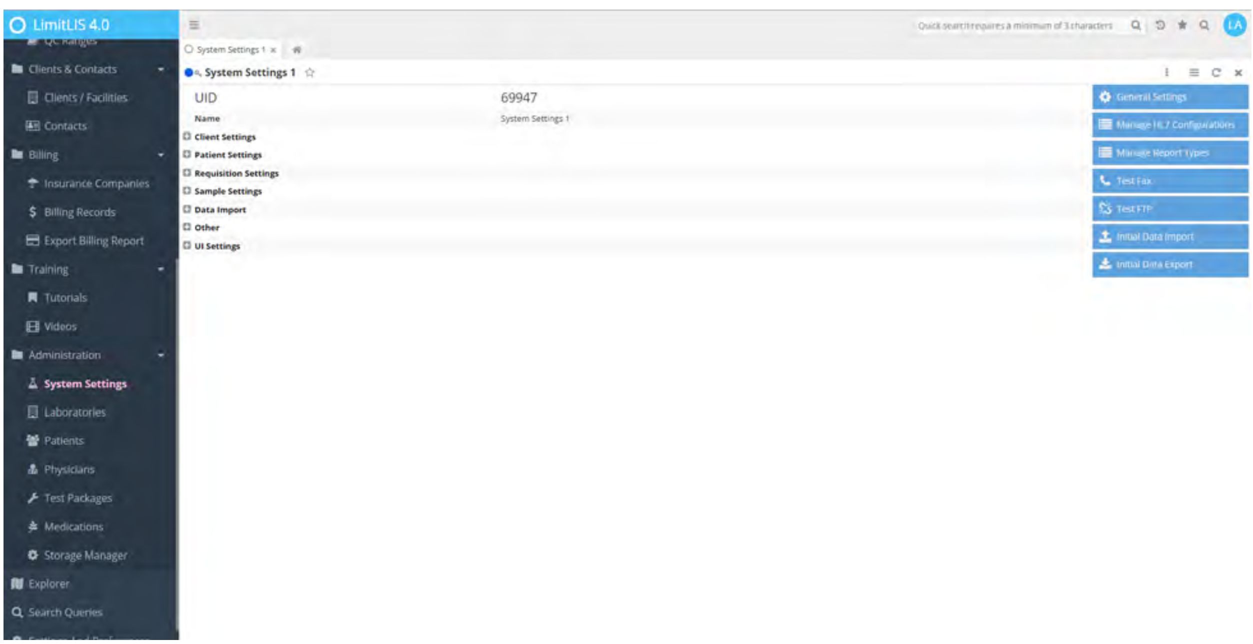
While using the system, it tracks your recent visited views. The icon will allow the user to visit a recent view without having to navigate the system.

To close out a view, click the ✖ button located at the top of each view.

The inactivity time period can be changed in **Settings → Settings & Preferences → General Preferences.**

Updating LimitLIS® System Settings

LimitLIS® allows laboratory administrators to view and update LimitLIS® system settings through the **System Settings** button in the Quick Links menu. The System Settings screen allows the laboratory administrator to update laboratory information, view currently configured system settings, or test fax submission if a faxing provider is configured.



Each of the tools within the system settings record allows the laboratory administrator to control the main global settings for the system.

General Settings	Allows the laboratory administrator to edit different options for Requisitions, Samples, Features, and integrations.

Manage HL7 Configurations	Opens a List View of the HL7 configurations for EHR and RCM integration for the laboratory administrator to manage.
Manage Report Types	Opens a list of current report types available in the system. A report type is a combination of specimen type and report template. Once a report type is defined, it can be selected at the lab level, facility level or physician level. After a report type is selected, all specimens of that type will use the selected report template.
Test Fax	If a faxing provider has been configured by a system administrator, the laboratory administrator is able to send a test fax to the number(s) entered in this dialog.
Test FTP	Allows the laboratory administrator to enter the information for a FTP server in order to send a test file and confirm receipt.
Initial Data Import	Allows the laboratory administrator to upload the configuration spreadsheet (template is available to download from this dialog as well as available upon request) in order to import data such as Medications, Physicians, POC Tests, Analytes, etc.
Initial Data Export	Allows the laboratory administrator to download the configuration spreadsheet in order to export data such as Medications, Physicians, POC Tests, Analytes, etc.

Managing Report Types

Report types connect report templates to specimen types that can be tested within LimitLIS®. At least one report type must be defined before the system can start generating result reports. A report type defines one or more specimen types and a report template format. By clicking on **Manage Report Types**, laboratory administrators are able to **Add, Edit** and **Delete** report types.

To add a Report Type:

1. Click on **Report Types** from **System Settings**
2. Click **Add**
3. Give your report type a name (e.g "Toxicology Normalization Report")
4. Select one or more Specimen Types that will use this report (e.g. "Urine")
5. Select a Report Template that will be used for the selected specimen types (e.g "Requisition Test Report")
6. Click **OK**

The report template must already exist in LimitLIS® and be defined in the system before it can be mapped to a specimen type. It is possible to map different specimen types to different report templates, such as Blood and Serum to Hematology and Nasal Swab to Molecular report templates. The report types added in **System Settings** can be selected by laboratory, facility, or physicians in their corresponding **Report Settings**.

Managing HL7 Configurations

LimitLIS® supports HL7 integration with a number of EHR and RCM systems and allows laboratory administrators to view and update the enabled HL7 configurations through the System Settings screen.

To access the list of all currently configured HL7 integrations, navigate to the **System Settings** Quick Link and click on **Manage HL7 Configurations** from the right of the record. From the HL7 Server Configuration list, the laboratory administrator can **Add**, **Edit**, **Archive**, or **Unarchive** specific configurations.

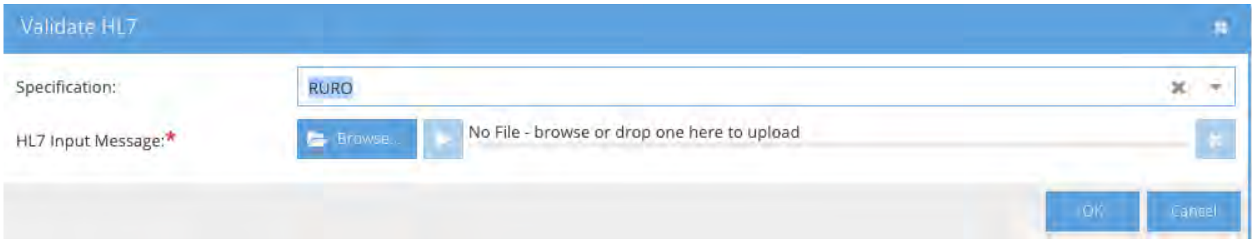
A new addition in LimitLIS® 4.0 is the **Validate HL7** button. This is a developer tool that can be used to troubleshoot HL7 messages and to quickly find out whether they conform to the RURO spec. The message types supported by the HL7 validator are: ORU, ORM & DFT. The tool analyzes segments and nature/format of the data each field contains according to the LimitLIS® v 4.0 HL7 Specification Requirements (available at https://ruro.com/support/hl7-specification-requirements or upon request), which is based on the HL7 International Standard for electronic data exchange in healthcare environments. Depending on the HL7 message type, the Validator applies the corresponding validation requirements and shows informative warning and/or error messages for segments, fields, and lines in the HL7 file.

Error messages show critical problems the application encountered during the HL7 file processing.

Warning messages are strictly informative and do not prevent processing the Hl7 file; nevertheless, they may provide important information regarding the HL7 message.

The absence of messages indicates compliance with the LimitLIS® v4.0 HL7 requirements.

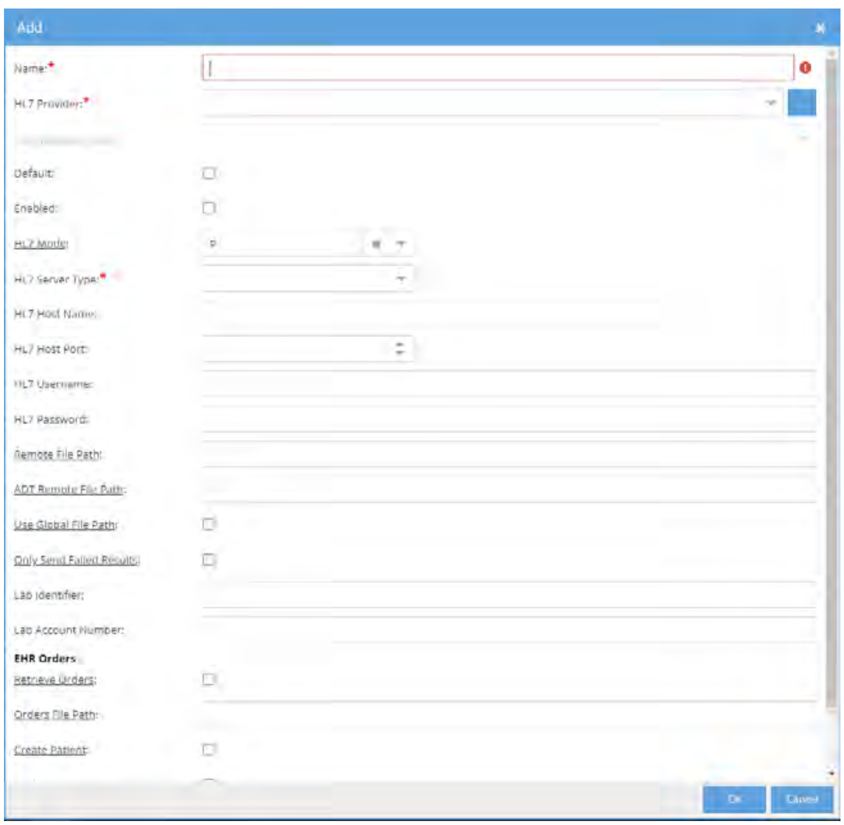
Unlike the Order (ORM_O01) Message Type, for Result (ORU_R01) and HL7 Billing (DFT_P03) the Validator analyzes only empty segments/fields in the LimitLIS® v4.0 HL7 Specification versus the uploaded file and vice versa, as well as format mismatches. This validation report should be used for farther parsing and correction of HL7 integration and usage issues within LimitLIS® based on negotiations with a Client/Vendor.



To use the HL7 validator:

1. Click on **Validate HL7**
2. The specification will be set to "RURO" by default
3. Click **Browse** to choose a valid HL7 file and click **OK**
4. Once a file is validated, a list of error messages and/or warnings will appear in a new dialog.

Within the **Add** dialog, the "HL7 Providers" field will display the list of all currently supported HL7 providers. If the required vendor is not in this list, please contact your RURO Account Manager or RURO support at support@ruro.com.



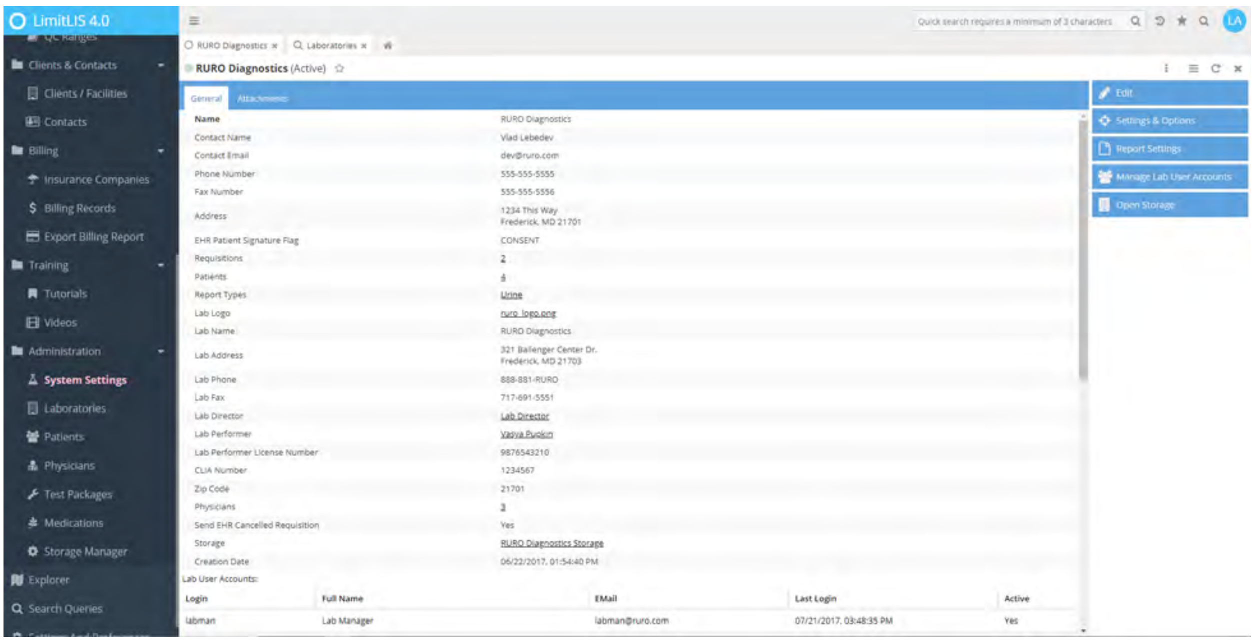
Once an HL7 configuration is added to the system, it will be available to laboratory administrators and laboratory managers for specific facilities. Please note that the "Enabled" box must be checked for the configuration to be active.

To enable EHR integration for Facilities:

1. Click the Clients / Facilities button from the Quick Links menu.
2. Double-click a Facility record to open it in a new tab.
3. Click **EHR Account** from the right of the screen, and in the dialog box that appears, select the appropriate HL7 Configuration from the list, then enter the account number for the Facility as assigned by the HL7 Provider.

Managing Laboratories

LimitLIS® allows laboratory administrators to view a list of all laboratory facilities through the **Laboratories** button in the Quick Links menu. Opening a laboratory facility allows the laboratory administrator to update laboratory information, view currently configured system settings, or manage the lab user accounts.



Each of the tools within the specific laboratory record allows the laboratory administrator to control the main settings for that lab facility.

Edit	Allows the laboratory administrator to set the contact information for the laboratory facility.

Settings & Options	Allows the laboratory administrator to define roles such as Account Manager and Support Representative. It allows the enabling/disabling of a range of functionalities within a facility such as Physician Management, Communication Tools, Client Portal Sample Accessioning, New Communication Emailing, Reflex Testing, and Patient Testing Scheduler. The tool also allows administrators to set excluded Reflex POC Tests and excluded Medications.
Report Settings	Allows the laboratory administrator to customize lab-specific different information on reports and to select report types. Usable Report Types are defined on System Settings and can be selected in the *Test Report Types* dropdown.
Manage Lab User Accounts	Allows the laboratory administrator to add new laboratory user accounts, edit user information, archive users and submit password reset emails.
Open Storage	Shown if StorageModule is enabled and a storage has been setup for the laboratory facility. Opens the storage associated with the laboratory facility where the lab admin can view freezers, boxes and work with samples placed into storage. *Note that this functionality is separate from StorageManager where lab managers and admins can setup freezer and box layouts.*

Users can view all attachments for a laboratory clicking on the **Attachments** tab. Each file will be displayed as a thumbnail.

To upload an attachment: Click **Upload,** select desired files, then click **OK.** A minimizable progress dialog will be shown while attachments upload. Once attachments are finished uploading they will be viewable in the Attachments grid.

To delete an attachment: Select an an attachment, click **Remove,** then click **OK** to confirm.

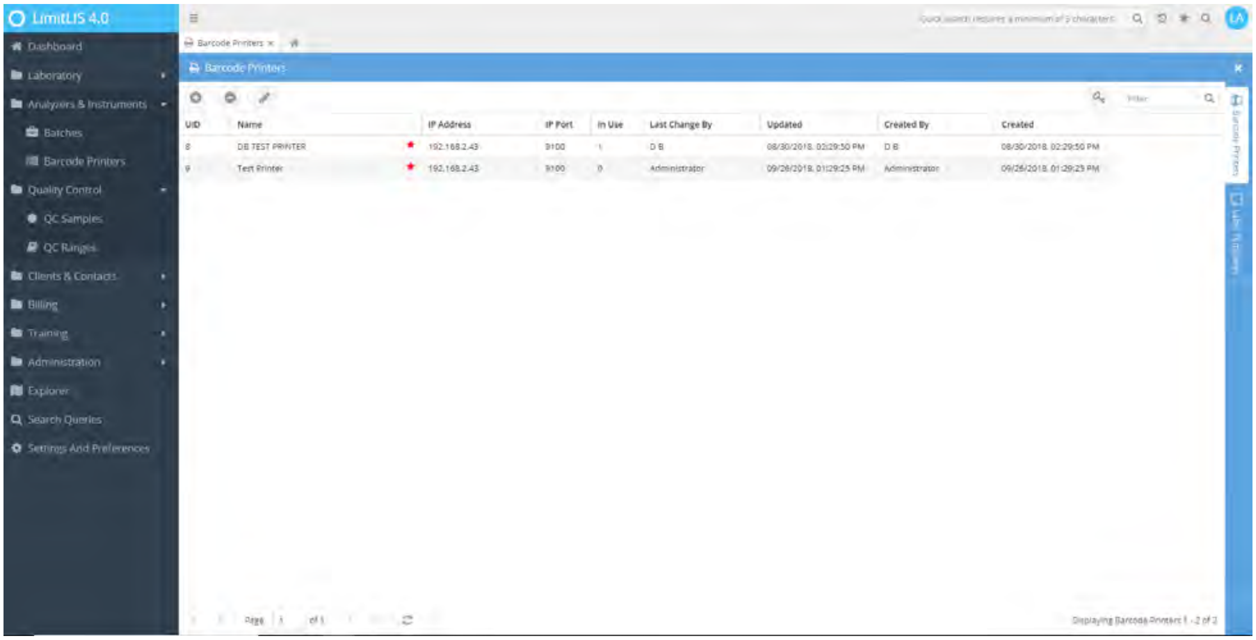
To comment on an attachment: Select an attachment in the **Attachments** tab, click **Comment** to enter a comment on the selected file. The comment will be displayed under the “Filename” field next to the file thumbnail.

NOTE: LimitLIS® does not currently support multi-site functionality for laboratories.

Managing Barcode Printers

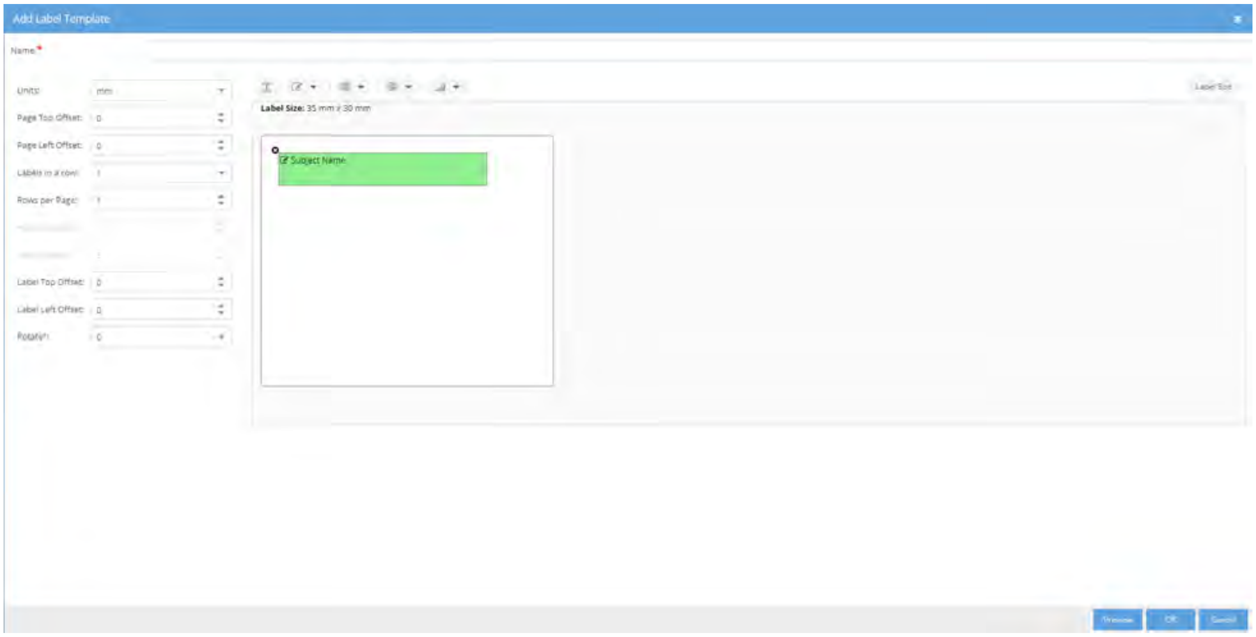
Before users can print barcode labels in LimitLIS®, barcode printers or label templates must be configured in the system. Note that LimitLIS® allows laboratory administrators to configure barcode labels to contain text, linear barcodes, 2D barcodes, and RFID Tags. It is no longer necessary to setup both a printer and a label template in order to use web printing. Barcode printers are needed only for local printing, and if the printing is done via the web, then only the label template needs to be created.

To manage the Barcode Printer Profiles, click the **Barcode Printers** link in the Quick Links menu under Analyzers & Instruments. Options to add, delete, and edit the profiles are available from the toolbar.



To add a Label Template:

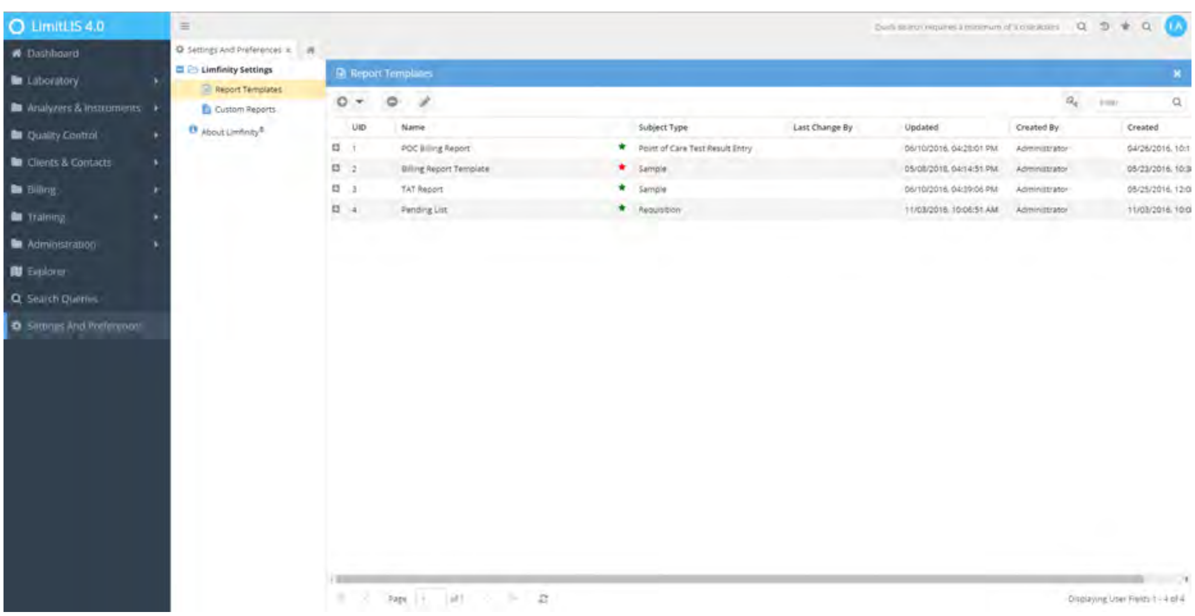
1. From the Manage Barcode Printers list view, click the "+" icon on the toolbar at the top of the tab.
2. A new dialog will be displayed in which the laboratory administrator is able to **Edit Label** to update the size, **Add Fields** to be displayed on the barcode label, and enter **Printer Preferences** to indicate whether the label design will be tied to a specific barcode printer or can be printed from the web browser.



If using web-printing, label templates can be selected from any **Print Barcode** button within the requisition and sample workflows.

Managing Report Templates

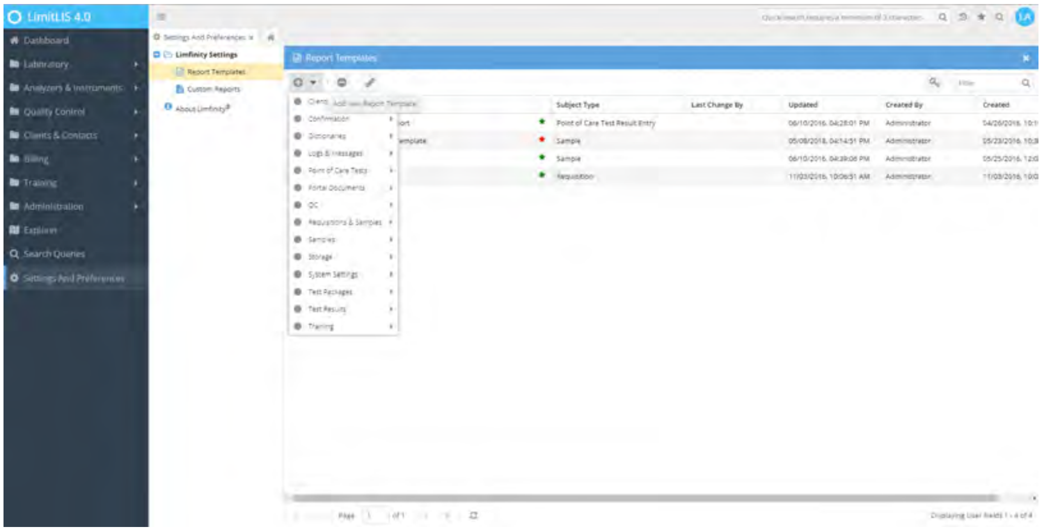
Report Templates allow users to specify a group of fields to export to a CSV file for any given list of Subjects. Laboratory administrators can create templates by clicking **Reports Templates** located under the “Settings and Preferences: Limfinity Settings” menu.



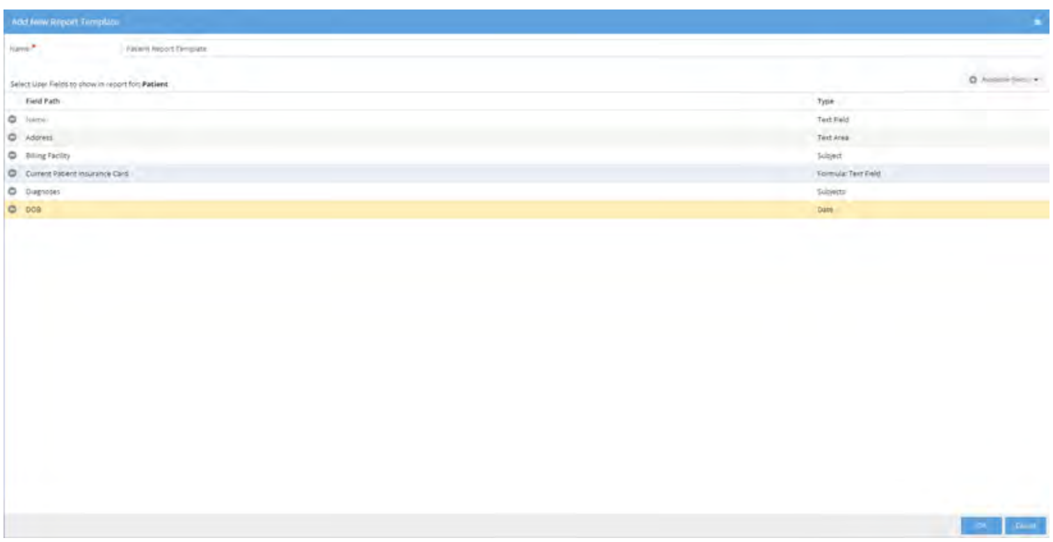
After opening the Report Templates list, the laboratory administrator will be able to **Create, Delete,** and **Edit** a Report Template using the icon buttons on the toolbar located at the top of the List View.

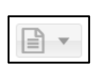
Configuring a Report Template

When creating a Report Template, first click the “add” button from the menu and select the appropriate **Subject Type** from the drop-down menu of options within LimitLIS® (e.g., Requisition).



A dialog window will be displayed in which the user can add any User-Defined Fields associated with the Subject Type by clicking on the “Available Fields” button located at the top right of the dialog.



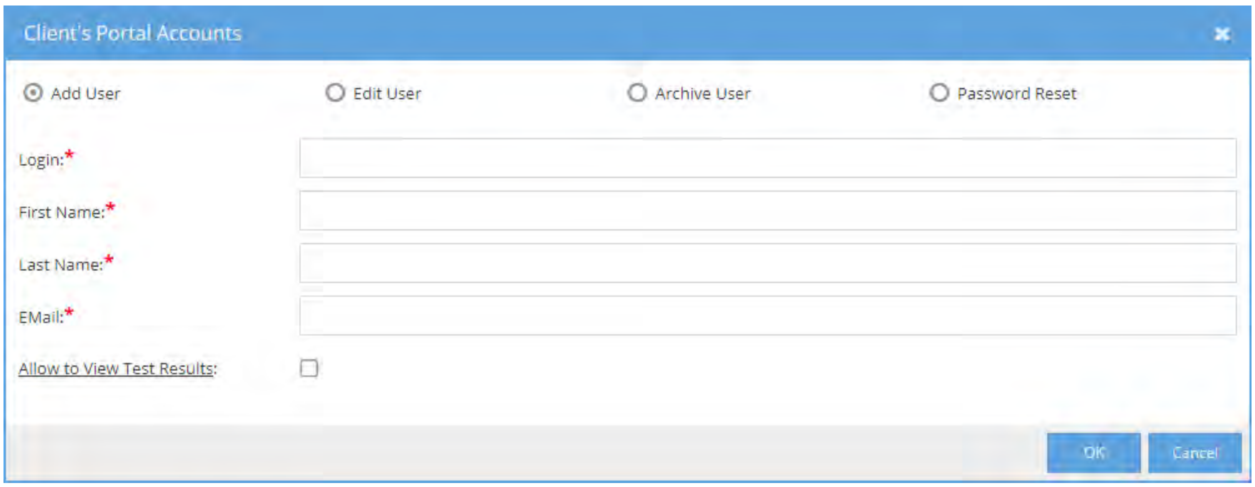
Once the Report Template is created, a report icon  will be displayed in the Explorer List View for that Subject Type. To access, navigate to the Explorer menu, open the Subject Type linked to the report, and select the records to run the report on.

MANAGING USER ACCOUNTS IN LIMITLIS®

Managing Client Portal Users

Laboratory managers and **laboratory administrators** can manage client portal user accounts in LimitLIS® from the Facility records. To navigate to a Facility record, click the **Clients / Facilities** button from the **Clients and Contacts** menu. A grid of all existing client facilities will be displayed in a new tab. The user is able to open a record either by double-clicking or by selecting “OPEN”.

From the individual Facility record, the user can click **Manage Client’s Portal User Accounts** to add, edit, and archive users linked to the facility as well as send a password reset link to the selected user. To create a new user, select “Add User” from the options at the top, fill in all the required fields and click OK. The newly created user will receive a welcome email with a link to create a password to log in.

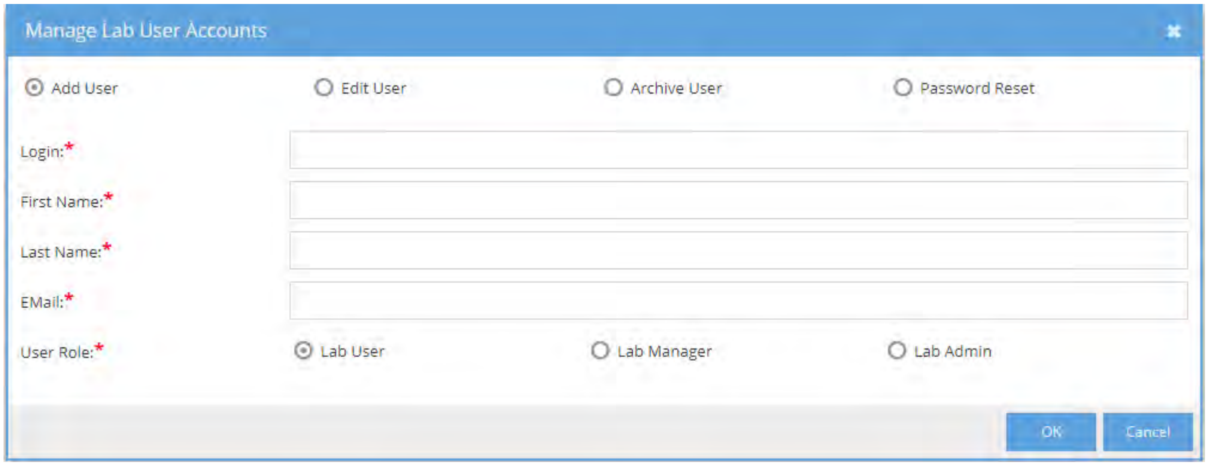


Archived user accounts will be disabled from the system and all access for the user will be suspended. All audit records for the user will remain within LimitLIS®.

Adding Laboratory User Accounts

Laboratory administrators can create new laboratory user accounts – laboratory user, laboratory manager, and laboratory administrator – by navigating to the **Laboratories** button under the Quick Link menu and opening the relevant testing laboratory.

From the individual Laboratory record, click the **Manage Lab User Accounts** button on the right. Within the resulting dialog, the laboratory administrator can Add, Edit, and Archive Users as well as request a Password Reset link be sent to the selected user.



When adding a new user, the laboratory administrator is able to select the User Role for the new account, which will set the access level for the created user. Once created, the user will receive a welcome email with instructions to access the system.

When a laboratory user account is archived using the **Archive Users** option, their access to LimitLIS® will be suspended. All audit records for the user will remain within LimitLIS®.

UNDERSTANDING LIMITLIS® FEATURES

Overview of LimitLIS® Main Components

Quick Links are links that can be used to direct a user to a particular **Workflow**, **Search Query**, or **Subject Type** or to perform a common function in the system.

Subject Type(s) is the main object of LimitLIS®.. A **Subject Type** is an object placeholder consisting of different User-Defined Fields.

User-Defined Fields are custom fields created by the user to describe characteristics of a **Subject Type**.

Explorer contains a list of all **Subject Types** currently in use by LimitLIS®.. All **Subject Types** are listed alphabetically and can be grouped into folders.

Search Queries contain saved **Advanced Searches**. A saved **Advanced Search** contains only the search parameters; the results are refreshed each time the query is run.

Audit Records are reports that contain the activities of all users. **Audit Records** can be viewed for certain time periods: All Audit Records, Today, Yesterday, Within this Week, and Within this Month, and Activity By User.

Settings and Preferences contains the configurable elements of the LimitLIS®.application including Users, User Groups, Roles, Limfinity Settings (User-Defined Fields, Subject Types, etc.), System Preferences, and About Limfinity.

LimitLIS® List View (Results Grid)

In all components of LimitLIS®., information and data are presented in a List View. The examples are, a List of All Subject Types in **Explorer**, List of Users in **Settings and Preferences**, List of **User-Defined Fields**, etc.

The List View panel in LimitLIS®.contains the following parameters:

List View presents all data in a table. The column names change based on the type of data that is presented. Up to 50 **User-Defined Fields** for a **Subject Type** can be displayed as columns in a List View. In Explorer list view, each column contains a down arrow, based on the the type of User-Define Fields that user may sort the data (in Ascending or Descending order) if configured for sorting and Columns option to select or deselect the columns to be displayed in the List View.

To select a row in the List View, check the square box located on the left side of the subject. Multiple subjects can be selected from a single page or from multiple pages. Double clicking on a subject in the List View opens a panel with the entire subject record.

For all List Views present in LimitLIS®., a **"Filter"** Filter function is available for the user. The **Filter** tool is located at the top right corner of the List View. This function allows a user to filter results viewed by the Name field. To filter a list, click within the "Filter" search box and type the Name or part of the Name, then press **Enter** on the keyboard or click once on the search icon. Note that the entry in the **Filter** box is not case-sensitive. In order to go back to the unfiltered list, click the icon within the filter box. **Filter** function will only be available if the "Name" column is present in the List View.

Depending on the permissions, List Views have a tool bar at the top with icons on the right and on the left to Add, Delete, Edit, Open Advanced Search, and Access Permission for the subjects in the List View.

Configuring User-Specific Preferences

Country Settings, Timezone, Date Format, Time Format, Page Size (Records per page), are configured in the **My Preferences** option, which is located in the **"General Actions."** A

ACCESSING INFORMATION USING LIMITLIS®

LimitLIS® offers several methods to access information contained in the application.

Accessing Subject Types

Click on **Explorer** tab Explorer and select a specific **Subject Type** to access all Subject records. Double clicking on any object displayed in the List View will open the Subject and display data associated with the record.

Searching for Data in LimitLIS®

A user can perform a Quick Search for data in LimitLIS® by entering at least 3 characters in the "**Quick Search**" field located at the top, right of the browser window. All records that contain the entered characters (in that order) will appear in a drop-down menu. Select a single Subject from the drop-down menu and click on it to see the additional details. Quick Search will not produce any results with partial entries for UIDs or Barcodes. When using **Quick Search** for UIDs or Barcodes**,** the full value must be entered.

The **Advanced Search** tool is accessible via the **"General Action"** icon located at the top right corner of the browser window. The **Advanced Search** tool allows a user to set specific parameters for a search. The parameters and the result of an **Advanced Search** can be saved as a **Search Query**.

The **Batch Search** tool is accessible via the **"General Action"** icon located at the top right corner of the browser window. The **Batch Search** tool allows a user to scan or copy/paste a list into a window to return all Subjects matching the list. Please note that only laboratory managers and laboratory administrators have access to this feature.

Accessing Search Queries

Click the **Search Queries** menu in the navigation panel and select an entry. Selecting an entry will open the saved **Search Query** in **Advanced Search** panel. User can edit the Advanced Search query fields to narrow down the saved search. In addition, clicking the search icon located under Search Queries and selecting the subject type from the drop-down menu will open a new Advanced Search query panel.

Please note that only laboratory managers and laboratory administrators have access to this feature.

NOTE:

- Saved **Search Queries** update each time they are run such that current entries meeting the search criteria are refreshed each time.
- Inside of the **Search Query** menu, user can only see the Queries that he/she has created. Select the Query and use the button to **Delete Query**, **Rename Query** or create a **New Folder.**
- A Subject Type must be enabled for Search types (Quick, Batch or Advanced) before using the search options. To enable/disable search types for any **Subject Types,** go to Settings and Preferences and click on **Subject Types**. Select a **Subject Type** from the list view, right click to open the selection menu and select checkboxes within "Searchable" to enable/disable the search options.

Accessing Audit Records

To Access **Audit Records**, click on the **General Actions** tool located at the top right corner of your home screen and select the desired option from **Audit Records**.. Please note that only laboratory managers and laboratory administrators have access to this feature. The following options are available under Audit Records:

- **All Audit Records**: Reports of all the audit records for the system.
- **Today**: Reports of all the audit records within today.
- **Yesterday**: Reports of all the audit records within yesterday.
- **Within this Week**: Reports of all the audit records within current week.
- **Within this Month**: Reports of all the audit records within current month.
- **Activity By User**: This will filter the audit records for a specific user in the system. The audit records will contain the user name, what kind of actions, what kind of objects used, the subject types, the subject workflows, the specific subjects, dates and time.

Audit Records can also be accessed from the following List View:

- Standard Subject View, an Admin user can right-click on a Subject Name and select Audit Records.
- From a Subject List View, select a subject, right click and select Audit Records.
- From a Users List View, select a User, right click and select Audit Records.

When working with the **Browse Audit Log** records, user has an option to select the **Choose Dates** option . This is a tool for narrowing down the list of displayed audit records by selecting a range of dates. User also has the option to generate a report in HTML or CSV format by using **Report** icon located at the top left corner.

NOTE:

It is recommended to use the **Refresh** icon following a new data entry. The **Refresh** icon is located at the top of the tabbed menu, as well as at the bottom of the content window. When numerous users simultaneously perform actions in the LimitLIS® application, frequent use of the **Refresh** icon will insure access to the most current information.

SEARCHING IN LIMITLIS®: QUICK, BATCH, AND ADVANCED SEARCH

With appropriate role rights, users have access to **Quick/Live Search**, **Batch Search,** and **Advanced Search** functions in the LimitLIS® Home screen and in all List Views.

Quick/Live Search

The Quick Search toolbar is located at the top right corner of the application window. **Quick Search** in LIMFINITY is a dynamic searching method that quickly finds matching **Subjects** based on the characters entered. A **Subject Type** must be enabled for Quick Search for records to be included in search results.

To perform a Quick/Live Search for Subjects:

1. In the Quick Search toolbar, enter at least three (3) characters associated with a Subject Name, Description, or any other User-Defined Fields marked for Quick Search and hit the Enter/Return key. All Subjects in the LimitLIS® database that match the characters entered will appear in a drop-down menu.
2. Click on a Subject entry in the search results to view Subject details.
3. To close the Quick/Live Search results, click elsewhere in LimitLIS®.

Advanced Search

To use **Advanced Search**, click on any Subject type. Once the subject type is selected, the **Advanced Search** will be available at the top of the panel. **Advanced Search** allows a user to search for Subjects matching one or more specified parameters. Please note that only laboratory managers and laboratory administrators have access to this feature.

To build the search query, use the "New Condition" icon New Condition located at the top left corner and select the search parameters. Select the "New Condition" icon New Condition again to add search conditions.

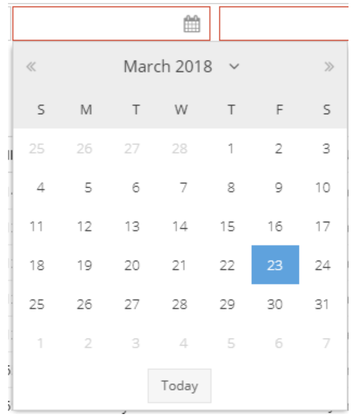
Search query options:

Lower, Upper, Length, No Function: If searching on **Subject** Name, click the down arrow next to the UDF Name to select **Lower**, **Upper**, **Length** or **No Function** options. These functions are applied to the search query characters to convert all letters to LOWER or UPPER case prior to searching to enable case-insensitive searches. **Length** specifies the number of characters in the value. **No Function** restores default conditions and the query is case-sensitive.

Operators: The comparison elements, such as: **Equals**, **Not Equals**, **Begins With**, **Contains**, **Does Not Contain**, **Ends With**, **Regular Expression**, **At Least One Of**, **Empty** and **Not Empty** can be selected in the search options field. A **Regular Expression** is a sequence of characters that define a search pattern, mainly used in pattern matching with strings. A search entry is entered following the comparison elements, while the **Search Now** button is used to perform the operation.

User can add one or more search conditions using the **New Condition** button or use the **Delete** icon to remove search parameters. Queries are re-run each time **Search Now** is clicked.

Date field values can be selected from a calendar.



Relative date options are also available: **Today, Yesterday, Tomorrow, Last week, 3 years ago,** and **In a month**.

A user can also use the query bar to manually enter or modify queries in SQL Query language. For example: (name LIKE 'CPR%' OR name LIKE 'ISR%') AND #state = ('Recorded Sample' OR 'Registered Sample'). The search results will contain all Samples with names that start with 'CPR' or 'ISR' and either in workflow state 'Recorded Sample' or 'Registered Sample'.

A user can save the parameters and results of an **Advanced Search** as a **Search Query.** The pull down on the right of the Advanced Search bar will show the **Save** icon 

. The **Save** icon opens a dialog window to prompt a **Search Query Name** entry.

Batch Search

A **Batch Search** allows a user to type, copy & paste, or scan Subject Name, Subject Barcode, Subject ID (UID), or any other User-defined Field marked for Batch Search into a dialog box to populate a search query. To access **Batch Search,** click the **General Action** icon  at top right corner of the home screen and specify the **Subject Type** within the drop-down menu of **Batch Search**. Batch Search entries must be separated by a new line.

Please note that only laboratory managers and laboratory administrators have access to this feature.

FREQUENTLY ASKED QUESTIONS (FAQS)

How are G-Codes and CPT Codes implemented in LimitLIS?

System Administrators can enable "Test Class Billing" on **System Settings** to group tests into classes during billing. CPT codes that are associated with a particular Drug/Test Class will be billed as a Class and not individually.

Insurance Companies can be configured for G-code billing through the "HCPCS Code G048X Billing" checkbox located on individual Insurance Company records.

The G-code value will be in accordance to the rules below:
- if ordered 1-7 drug class(es), code "G0480" will be billed.
- if ordered 8-14 drug class(es), code "G0481" will be billed.
- if ordered 15-21 drug class(es), code "G0482" will be billed.
- if ordered 22 or more drug class(es), code "G0483" will be billed.

NOTE: There are couple exceptions for both these types of billing. If the test is marked as Non-Reportable or unrelated to a Drug Class, it will be billed as an individual test.

How do I view open communications from the lab?

To view communications as a client portal user:

1. On the left side of the dashboard are tiles titled "Communications". The number in the "Open" tile indicates the number of open communications from the lab.
2. Clicking the number in the "Open" tile will display a list of all open communications from the lab in a new tab.
3. To reply to a communication, double-click the communication record to open it in a new tab and click "Reply".

To view communications as a laboratory user:

1. Under the **Clients and Contacts** menu, click the "Communications" button.
2. A grid of all open communications will be displayed in a new tab.
3. To reply to a communication, double-click the communication record to open it in a new tab and click "Reply".

How do I get my account unlocked?

The system will automatically lock your account after three (3) consecutive incorrect login attempts. To get your account unlocked, enter incorrect credentials and select the "Forgot Password" link in the resulting dialog box.

How do I unlock a locked LimitLIS® account?

To unlock a client portal user account:

1. Open the assigned facility.
2. Click on the **Manage Client's Portal User Accounts** button.
3. Click the Password Reset option and select the locked user from the list.
4. Click OK and instructions to login will be emailed to the user.

To unlock a laboratory user account:

1. Open the laboratory from the **Laboratories** Quick Link (laboratory administrators only).
2. Click on the **Manage Lab User Accounts** button.
3. Click the Password Reset option and select the locked user from the list.
4. Click OK and instructions to login will be emailed to the user.

How can I check that billing information has been transmitted after I released a requisition?

The system creates a record each time the billing information is sent to a billing provider. This record contains the link to the HL7 file that was sent, any error messages, the patient and requisition reference, and the created by/on values.

To find the billing record(s) for a requisition:

1. Open the requisition.
2. Click on the “Billing Records” link located on the record.
3. If more than one billing record is present for the requisition, all records will be displayed in a grid in a new tab. If only one is present, it will be opened in a new tab.

In the event of an error, please follow these steps:

1. Review the error message.
2. If the error is referencing a new required field or a change in the data model, this will need to be resolved with the billing provider and RURO. Please contact RURO support (support@ruro.com) with the error message specifics.
3. If the error is referencing server/connection issues, such as the SFTP/FTP being disabled, or a loss of connection with the remote host, this will need to be resolved with the billing provider.
4. Once the issue has been resolved, open the requisition billing and click **Resend to Billing** to resubmit the billing data.

How can I check that the instrument file has been transmitted?

Each time an instrument file is uploaded via integration or manually, the system makes a sample import record.

To view manual sample import records:

1. Click the **View Imports** button under the **Instruments and Analyzers** menu.
2. A list of sample import records will be displayed in a new tab.
3. Each sample import record will have a reference to the instrument, the instrument import file, associated tests results and/or QC Runs, error messages, and created by/on values.

To view automatic sample import records:

1. When an instrument file is imported into the system through a bidirectional or unidirectional integration, LimitLIS® maintains a log of the transmission. To review these transmissions, navigate to the Explorer menu and click “Results Entries” under the “Logs & Messages” folder.
2. If an error occurred during transmission or processing, the Result Entry record will have a link to Results Entry Messages.

Troubleshooting:

1. Find the sample import record following the steps above, and open the instrument file.
2. Refer to the error message in the sample import record or the Results Entry Messages records to troubleshoot the file.
3. If the system is not processing the instrument data correctly, please contact RURO support

(support@ruro.com), or manually adjust the file.

4. If the instrument files are not being registered by LimitLIS®, please verify that the files have been correctly deposited on the FTP server or contact RURO support (support@ruro.com).
5. If the file has been manually adjusted, the file can be re-imported by clicking the “Import Test Results” button under the Quick Links menu. A new file import record will be created.

GENERAL SOFTWARE INFORMATION

Regulatory Compliance

LimitLIS® is compliant with the following standards:

FDA 21 CFR Part 11

GLP/GMP (Good Laboratory Practice and Good Manufacturing Practice)

Supported Web Browsers

LimitLIS® supports all major web browsers including:

Internet Explorer

Firefox (PC, Mac, Linux)

Safari (PC, Mac)

Opera (PC, Mac)

Google Chrome (PC)

For the best LimitLIS® performance, consider using Apple Safari, Google Chrome, or Mozilla Firefox.

Backup/Restore Functionality

LimitLIS® includes:

Attachments backed up in the same package as the internal database

SMB/CIFS backup storage

Allows restoring attachments-only package

Supported Databases

LimitLIS® supports the following database back ends:

PostgreSQL, Oracle v11, and Oracle v12

Supported Languages

Limfinity® supports English, Chinese, and Russian languages.

TERMS AND CONDITIONS

Proprietary Statement

This manual contains proprietary information of RURO, Inc.

It is intended solely for the information and use of parties operating LimitLIS® software. Such proprietary information may not be used, reproduced, or disclosed to any other parties for any other purpose without the expressed written permission of RURO, Inc.

Product Improvements

Continuous improvement of the software product is a policy of RURO, Inc. All specifications and designs are subject to change without notice. As a result of these design changes, the content of this manual may change at any time without prior notice.

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