LABCORP DRUG DEVELOPMENT

LabLink+ Getting Started Guide

LABCORP CENTRAL LABORATORY SERVICES

THIS DOCUMENT IS A SUPPLEMENTAL TRAINING RESOURCE ON HOW TO PERFORM SPECIFIC TASKS IN LABLINK+. SEE THE ONLINE USER MANUAL IN LABLINK+ FOR MORE INFORMATION [LINKED HERE].

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General LabLink

Logging In

How to log into LabLink+

When your access is created, you will receive a Welcome Email containing your credentials and a link to the Password Manager.

Create New Password / Reset Password

- New Users can use the "Click here" link from your Welcome Email or go to Login Screen on the Labcorp CLS LabLink web page
- O Click on the "Need help signing in?" link
- Click on the "Password Manager" link
- Follow instructions to set or reset your password
- You will receive an email containing a link to reset your password.
 - Note! The link is only valid for 30 minutes once email is received.

To Log into Labcorp CLS LabLink:

- 1. **Launch** your web browser
- 2. In the address line, Type http://lablinkplus.labcorp.com and Press the Enter key
- 3. **Type** your email address and passcode in the appropriate fields and **Click** the Login button to display the LabLink+ Homepage

Note: When a default protocol is set, you can automatically bypass the Homepage and display a protocol when logging in.

Good Things to Know

- Labcorp CLS LabLink will timeout after 15 minutes of inactivity. You will need to reenter your email address and passcode to enter the system again
- Labcorp CLS LabLink will log you out after sixty minutes. Use your assigned email address and unique passcode to sign back in to Labcorp CLS LabLink
- o If you type in your email address and/or passcode incorrectly five times, your account will be locked and unavailable for use for 24 hours.
- Your LabLink Passcode will expire after 90 days

LabLink Training and Support

How to Get Assistance with LabLink+ Training and Support

This page provides you with information on how to get LabLink training and whom to contact when you have study questions, have technical difficulties, or need your password reset.

LabLink Training

The online user manual provides you with step-by-step instructions on how to use LabLink. Browse through the table of contents or use the index and search functionality to find what you are looking for.

- Click the Help icon (on any page to display the online user manual
- Customized LabLink+ training session can be set up by contacting your Labcorp CLS Global Study Manager or Regional Study Coordinator



Study Specific Questions or LabLink Access Requests

If emergency assistance is needed or if you have study specific or LabLink access-related questions, please contact your study lead or the Labcorp CLS Global Study Manager for your study.

Technical Difficulties / Logon Issues / Password Reset

If you are experiencing technical difficulties or problems logging into the LabLink application, please **Contact** our Help Desk [<u>Linked Here</u>]. They will troubleshoot your issue and escalate it to the appropriate specialist.

Specifically, for password resets, use the Password Manager [<u>Linked Here</u>]. You must update and maintain your password using the Password Manager. This tool allows you reset your own password anytime using security questions. If you have any issues accessing this tool please contact the Service Desk.

NOTE: Passwords expire in cycles of 90 days. Should you contact the Service Desk for a new password, you will receive a new temporary password which is valid for 60 days. It is imperative that the user login regularly to prevent password expiry or account deactivation.

Default Protocol

How to Bypass the Home Page

Typically, when you log on to LabLink, you see the Homepage. If needed, you can bypass the Homepage by choosing a default protocol and starting directly on a protocol's page.

To Set a Default Protocol Page:

- 1. **Select** a protocol to navigate to the Protocol page
- 2. Click the Set As Default Protocol button (near the Home button)

When you log on again, the protocol's page is automatically displayed instead of the Homepage.

To Remove the Default Protocol Page:

- 1. **Select** the default protocol to navigate to the Protocol page
- 2. Click the Clear Default Protocol button (near the Home button)

When you log on again, the Homepage is automatically displayed.

Online User Manual

How to Access the Online User Manual

LabLink provides access to the online user manual from every page.

To View the Online User Manual

• Click the Help icon (on any page to display the online user manual

Note: The manual will open to information relevant to the page or data module from which the manual was invoked.



Navigation

How to Navigate in LabLink+

Most navigation in LabLink is accomplished by clicking links, using the navigation bar, or using recent pages.

LabLink Navigation Bar

The navigation bar is at the top of most pages and can be used effectively for navigation.



Use These Buttons or Drop-Down Lists to Quickly Display the Particular Information You Need:

Home

Clicking Home button will take you to the LabLink+ Homepage.

Note: When you do not have a default protocol set, this is the page that is displayed after logging into LabLink+

The Home Page Displays:

- o a list of the three most recent protocols you have viewed
- a protocol list that displays all of the studies you have access to, as well as a high-level summary information
- a report list module that displays all reports that have been run manually or have been scheduled to run automatically

Protocol

Selecting a protocol from the drop-down list to displays that protocol's summary page.

The protocol page:

- allows you to set a Default Protocol
- displays a Protocol Summary
- displays the Visit Schedule
- displays Kit Type Definitions
- displays Test Group Definitions and Reference Ranges
- displays Complete Subject Listing for the study
- displays a Complete Kit Inventory Listing for the study
- displays a Protocol Visit Progress Graph
- o displays a Cancellations Graph
- displays the study's Investigator Listing
- o allow you to view and download Available Reports

Note: After navigating elsewhere, use the Protocol link (above the drop-down list) to quickly display the protocol's summary page again.



Investigator

Once a protocol is selected, the Investigator drop-down list is populated. **Selecting** an investigator from the drop- down list to displays that investigator's summary page.

The Investigator Page:

- o displays the Investigator Summary information
- displays Investigator Contact Information
- displays investigator's Subject List Module
- displays the investigator site's Kit Inventory

Note: After navigating elsewhere, use the Investigator link (above the drop-down list) to quickly display the investigator's summary page again.

Subject

Once an investigator is selected, the Subject drop-down list is populated. **Selecting** a subject from the drop-down list displays that subject's summary page.

The Subject Page:

- displays the Subject Summary information
- displays Subject Flags
- o displays which visits the subject has attended via the Subject Visit List

Note: After navigating elsewhere, use the Subject link (above the drop-down list) to quickly display the subject's summary page again.

Visit

Once a subject is selected, the Visit drop-down list is populated. **Selecting** a visit (Protocol Visit Code) from the drop-down list displays that visit's summary page.

The Visit Page:

- Displays the Visit Summary information
- Provides a link to view the visit's Containers
- Allow for the viewing of results, selectable by group or microbiology specimen from the Visit Activity List

Note: After navigating elsewhere, use the Visit link (above the drop-down list) to quickly display the visit's summary page again.

Reports

Clicking the Reports button from any page displays the Available Reports page.

The Reports Page

- Displays the report list module
- Allows for scheduling of reports



- Allows for generation of Standard Reports
- Allows for the creation, running, copying, and sharing of Ad-hoc queries

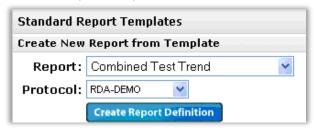
Report Options

How to Access LabLink's Report Features

LabLink provides you with 7 standard reports options, the ability to create your own custom reports via the Ad- hoc, the ability to save your report criteria selections, and the ability to run reports automatically. The Available Reports page contains all of LabLink's reporting features including: Report List, Scheduled Reports, Standard Report Templates, Ad-Hoc Reports, create a New Ad-Hoc Report Template, Copy Ad-Hoc Report Template, and the Import Ad-Hoc Report Template module.

Basic Steps to Run a Standard Report

- 1. From the Welcome Screen, Click Reports on the toolbar to display the Available Reports page
- 2. **Scroll** down to the *Standard Report Templates* module. Show me...



- 3. From the Report drop-down menu, Select a standard report
- 4. From the **Protocol** drop-down menu, **select** a protocol
- 5. Click the Greate Report Definition button to display the criteria selection page
- 6. **Define** the criteria selection
- 7. Schedule, Save, or Run the Report
- 8. **Download** and **View** the report from the Report List

Standard Reports

Combined Test Trend - Filterable by investigator site, visit, subject, and test criteria, this report displays the protocol's test results. It outputs in an Excel compatible *.csv (comma separated value) and a printer-friendly Adobe PDF format.

Kit Inventory - Displays a detailed listing of kits, with expiration dates, that have not been received by Labcorp CLS. A summary by kit type that shows how many kits have been shipped to the site, returned to Labcorp CLS, pending shipment, etc... is also available. It outputs in an Excel compatible *.csv (comma separated value) and a printer- friendly Adobe PDF format.

Subject Enrollment -Displays a timeline of each subject's visits in the visit schedule. Filterable by site, visit, tests, and output criteria selections, this report can also include a summary that is plays the total number of subject visits by site, by visit. It outputs in an Excel compatible *.csv (comma separated value) and a printer-friendly Adobe PDF format.



Simple Subject Listing- Displays a list of subjects and their visits. If desired, the report can also display the date resulting was completed for each visit. It outputs in an Excel compatible *.csv (comma separated value) and a printer-friendly Adobe PDF format.

Specimen Management Inventory - Provides a simple listing of each specimen, by container, in Labcorp CLS' inventory system. The report displays the current status of the sample and in cases when a specimen has been shipped, the location to where it was shipped to. It outputs in an Excel compatible *.csv (comma separated value) format.

Specimen Management Inventory Analysis - An Excel workbook that provides summary data relative to the study's subjects, visits, along with a detailed listing of specimens contained within Labcorp CLS' specimen management inventory system. The report is categorized into three tabs of information:

- Subject Summary: Provides counts of specimen by class for each subject. This section can also show the number of specimens collected by visit.
- Visit Details: Similar to the subject summary, this tab provides counts of specimens by class for each subject visit. This section can also display selected test results by subject visit.
- Specimen Details: displays a detailed listing of specimens and each one's current status. In the
 event a specimen has been shipped to an alternate location, this section also displays where the
 specimen was shipped along with the shipped date/time.

Visit Completeness - Allows you to stay up-to-date on visit progress by providing a detailed list of subject visits that are completed, have been cancelled, or are pending completion. It outputs in an Excel compatible *.csv (comma separated value) and a printer-friendly Adobe PDF format.

- Completed Shows all Visits where testing has been completed
- o Cancelled Shows all Visits where testing has been cancelled and the reason for cancellation
- Pending Shows all Visits where the kit has been received, but testing has not been completed

Basic Steps to Create a New Ad-Hoc Report Template

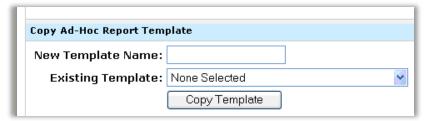
- 1. Type a descriptive name for the new query in the New Template Name Field
- 2. **Select** a protocol from the *Protocol* drop-down list
- 3. Click the Create Template button
- 4. Select the desired data items and add them to the right (Define order if necessary)
- 5. Click the Save and Close button
- 6. **Define** the sort order and add any conditions
- 7. **Click** on the *Run Report* button
- 8. **Download** and **View** the report from the *Report List*





Steps to Copy an Existing Ad-Hoc Report Template

- 1. **Type** a descriptive name for the copied report in the *New Template Name field*
- 2. **Select** the desired template from the *Existing Template* drop-down list
- 3. Click on the Copy Template button
- 4. Export/Schedule/Edit/Run the query as necessary from the Existing Query Templates module



Kit Inventory

How to View Kit Inventory Data by Investigator

This module displays relevant kit inventory data related to the selected investigator.

Navigate to The Investigator Kit Inventory Module

To view the Investigator Kit Inventory:

- 1. From the Homepage, select a protocol from the Protocol drop-down menu on the toolbar
- 2. Select an investigator from the Investigator drop-down menu on the toolbar
- 3. Scroll down to the Kit Inventory module



Note: The shipped Not Received & Received graphic displays the total number of that kit type that has been shipped to the site. The red bar indicates the number of individual kits still at the site. The blue bar represents the number of kits shipped back to Labcorp CLS.

The Module Includes This Data:

- Kit Type Labcorp CLS defined code that uniquely identifies the containers and testing for a particular type of kit
- Description Long description of the kit type
- Status Kits can be active, inactive, and on hold
- Pending Count of kits pending shipment
- Shipped Count of kits shipped



- Shipped Not Received & Received Graphical representation of the proportion of kits received to kits shipped
- Received Count of kits received
- Adjusted Sum of kits adjusted
- On Hand Quantity of kits on hand
- Last Shipment Quantity Number of kits in most recent shipment
- Last Shipment Date Date of most recent shipment

Complete Kit Inventory

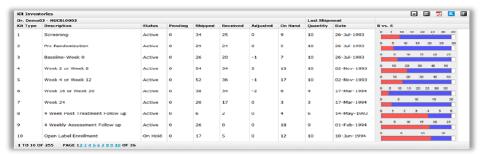
How to View Kit Inventory for All Investigator Sites

This module displays the study's complete kit inventory data by kit type.

Navigate to the Complete Kit Inventory Listing Module

To view the Complete Kit Inventory:

- 1. From the Homepage, Select a protocol from the Protocol drop-down menu on the toolbar
- 2. Click the View Complete Kit Inventory Listing button. and the Kit Inventories module will display



Tip: Because data modules only display 10 rows of data at a time, you might want to maximize the module to view more rows or export the entire module data set to Microsoft Excel.

Kit Inventory and Expiration Report

How to View Kit Expiration Dates

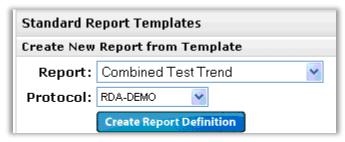
- O Q: What is the Kit Inventory and Expiration Report?
 - A: The Kit Inventory and Expiration Report displays a detailed listing of kits, with expiration dates, that have not been received by Labcorp CLS. A summary by kit type that shows how many kits have been shipped to the site, returned to Labcorp CLS, pending shipment, etc... is also available.

To Run the Report

Step 1: Navigate to Report from Welcome Screen

- 1. From the Welcome Screen, Click Reports on the toolbar to display the Available Reports page
- 2. **Scroll** down to the *Standard Report Templates* module





- 3. From the Report drop-down menu, Select Kit Inventory Report
- 4. From the *Protocol* drop-down menu, **Select** a protocol
- 5. Click the Greate Report Definition button to display the criteria selection page

Step 2: Investigator Criteria (Required)

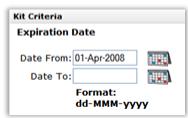
- 1. Select the options to add investigator sites to the report by either Country or by Investigator
 - a. (If choosing by countries) **Click** the **Select All Countries** button or **Select** a combination of countries from the list
 - b. (If choosing by investigators) **Click** the **Select All Investigators** button or select a combination of investigator sites from the list



Tip: Press and hold Ctrl button on keyboard while clicking with mouse to make multiple selections in a list

Step 3: Kit Criteria (Optional) Expiration Date

1. If desired, **Filter** the report by kit expiration date. See <u>specifying a date range [Linked Here]</u> for step-by-step instructions

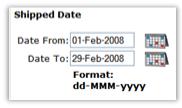


Note: Expiration Date will allow future dates

Shipped Date



2. If desired, **Filter** the report by shipped date (kits to sites). See <u>specifying a date range [Linked Here]</u> for step-by-step instructions



Note: Shipped Date will not allow future dates

Step 4: Output Options (Required)

- 1. **Select** one of the following output options
 - a. Detailed Report
 - b. Summary Only
 - c. Detailed Report and Summary

Step 5: Save, Save and Schedule, Reset, or Run Report

Choose one of the following:

- Save the Report
 - Allows to you to save criteria selection for manual report generation or future scheduling of the report from LabLink+'s Report page
 - Type an identifying name in the *Query Name*: text box and **Click** the button
- Save and Schedule
 - Allows you to schedule the report to run automatically based upon a user-defined recurrence patter and selected criteria.
 - Type an identifying name in the Query Name: text box and Click the
 Severand Schedule button
- Reset
 - o Allows you to quickly clear all selected criteria in this report.
 - Click the button
- Run Report
 - Allows you to run the report based upon the selected criteria, viewable from the Reports List module
 - Click the MunReport button

Labcorp CLS Kit / Sample Receipt

Sample Receipt Report

How to View Both Received and Missing Samples

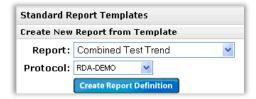
- O Q: What is the Sample Receipt Report?
 - A: The Report Sample Receipt module displays a list of containers/samples that have been received by Labcorp Central Laboratory Services. This report also gives you the option to view a listing of containers/samples that are missing from the received kit.



To Run the Report

Step 1: Navigate to Report from Welcome Screen

- 1. From the Welcome Screen, Click Reports on the toolbar to display the Available Reports page
- 2. **Scroll** down to the *Standard Report Templates* module. Show me...



- 3. From the Report drop-down menu, Select Sample Receipt
- 4. From the **Protocol** drop-down menu, **Select** a protocol
- 5. Click the Create Report Definition button to display the criteria selection page

Step 2: Visit Criteria

Visit Descriptions (Required)

1. **Select** all or a combination of visits that should appear on the report.



Date Specimen Collected (Optional)

2. If desired, Filter the report by the date the specimens were collected from the subject



Step 3: Other Criteria Groups (Required)

- 1. **Select** one of the following options:
 - Select Groups* View containers that apply to the selected test group
 - All Containers Shows all samples/containers on the report, will include long/short-term (SM) storage samples

Specimen Type (Required)

2. **Select** All or a combination of specific specimen types to appear on the report.*



^{*}Selecting by group may significantly increase the report size. A individual container can have multiple associate test groups that would cause the container to appear on the report multiple times.

*Selecting specific groups with specific specimen types can substantially reduce the amount of data expected on your report. Best practice is to select All Containers when using this option

Status (Required)

- **3. Select** one of the following:
 - All to view both received and non-received containers
 - o Received displays a list of containers that have been received by Labcorp CLS
 - Not Received displays a list of containers that have not been received by Labcorp CLS

Expected Condition (Required)

Select to view All or a combination of container expected receipt conditions

Step 4: Save, Save and Schedule, Reset, or Run Report

Choose one of the following:

- Save the Report
 - Allows to you to save criteria selection for manual report generation or future scheduling of the report from LabLink+'s Report page
 - Type an identifying name in the Query Name: text box and Click the button
- Save and Schedule
 - Allows you to schedule the report to run automatically based upon a user-defined recurrence patter and selected criteria.
 - Type an identifying name in the Query Name: text box and Click the
 Save and Schedule button
- Reset
 - Allows you to quickly clear all selected criteria in this report.
 - Click the button
- o Run Report
 - Allows you to run the report based upon the selected criteria, viewable from the Reports List module.
 - Click the Mun Report button

Investigator Data

Investigator Site Details

Navigate to the Investigator Summary Module

The Investigator page displays a variety of information related to the specified investigator. The options and data modules presented allow you to:

- View summary information relative to subjects, kits, cancellations, and pending results (visit specific kit received by Labcorp CLS but resulting not complete)
- View a subject listing for the investigator site
- View kit inventory details for the investigator site



To View the Investigator Page

- 1. From the Homepage, Select a protocol from the Protocol drop-down menu on the toolbar
- 2. **Select** an investigator from the Investigator drop-down menu on the toolbar



Protocol Cancellations Graph

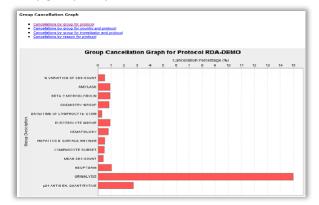
How to View Test Groups That Have Been Cancelled

A listing of cancelled test groups are available from this module and are displayed in a graphical format. Raw data can also be viewed in this area.

Navigate to the Protocol Cancellation Graph

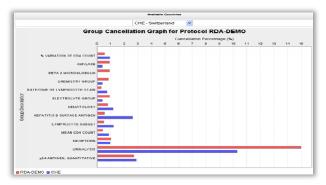
To view the graph of cancelled groups:

- 1. From the Homepage, select a protocol from the Protocol drop-down menu on the toolbar
- In the Protocol Summary, click the number (Groups: 197♥) next to Groups to display the cancellation graph for the protocol
- 3. By **clicking** the links on the top right-hand corner of the graph's window, you have the option to view:
 - Cancellations by group for protocol

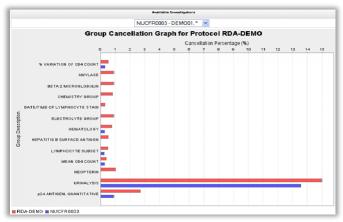


 Cancellations by group for country and protocol (Select a country from the drop-down list)

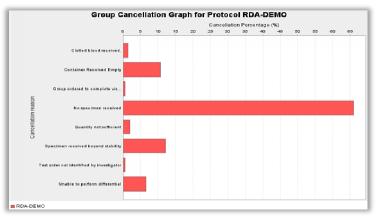




 Cancellations by group for investigator and protocol (Select an investigator from the drop- down list)



Cancellations by reason for protocol



To Export Raw Data:

- 1. **Select** the desired graph as outline in steps 1-3
- 2. Scroll down below the image and click on one of the following icons:
 - a. 🔼 outputs the data in an Adobe PDF printer-friendly format
 - b. 📴 outputs the data in a Microsoft Excel format



Subject and Visit Data

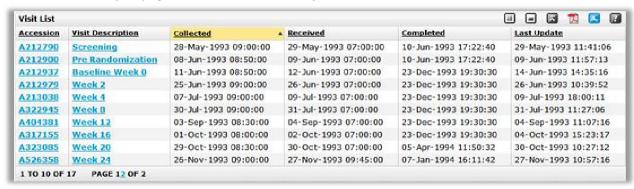
Subject Visit List

How to View a Listing of Visits a Subject Has Completed

The subject visit list module displays information relevant to the laboratory visits a subject has attended.

To View a Subject Visit List:

- 1. From the Homepage, Select a protocol from the Protocol drop-down menu on the toolbar
- 2. Select an investigator from the Investigator drop-down menu on the toolbar
- 3. Select a Subject from the Subject drop-down menu on the toolbar
- 4. On the Subject page, Scroll down to the Subject Visit List module



Tip: To continue navigate to the Visit Page, **Click** on the accession number in the Accession column or **Select** from the Visit drop-down list.

Note: The Visit List only displays visit information relevant to kits that have been received by Labcorp CLS.

The Visit List Module Contains This Information:

- Accession Number uniquely identifying the visit
- Visit Description Long description of Visit as outlined in the protocol's Statement of Work
- Collected Date and time visit data was taken
- Received Date and time requisition was received at Labcorp CLS
- Completed Date and time the agreed upon services were fully performed by Labcorp CLS
- Last Update Last date new data was made available in LabLink for the visit

Visit Completeness Report

How to Run a Report to Show the Status of Subject Visit Test Groups – Completed, Pending, Cancelled

The Visit Completeness Report allows you to stay up-to-date on visit progress by providing a detailed list of subject visits that are completed, have been cancelled, or are pending completion.

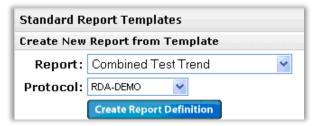
- Completed Shows all Visits where testing has been completed
- Cancelled Shows all Visits where testing has been cancelled and the reason for cancellation
- Pending Shows all Visits where the kit has been received, but testing has not been completed



To Run the Report

Step 1: Navigate to Report from Welcome Screen

- 1. From the Welcome Screen, Click Reports on the toolbar to display the Available Reports page
- 2. **Scroll** down to the *Standard Report Templates* module



- 3. From the Report drop-down menu, Select Visit Completeness
- 4. From the **Protocol** drop-down menu, **Select** a protocol
- 5. Click the Create Report Definition button to display the criteria selection page

Step 2: Investigator Criteria (Required)

- 1. Select the option to add investigator sites to the report by either Country or by Investigator
- 2. (If choosing by countries) **Click** the **Select All Countries** button or **Select** a combination of countries from the list
- 3. If choosing by investigators) **Click** the select All Investigators button or select a combination of investigator sites from the list



Tip: **Press and hold** Ctrl button on keyboard while **clicking** with mouse to make multiple selections in a list

Step 3: Visit Criteria

Visit Description (Required)

Select all or a combination of visits that should appear on the report



Date Specimen Collected (Optional)



o If desired, **Filter** the report by the date the specimens were collected from the subject

Step 4: Output Options (Required)

Groups Type

- 1. **Choose** one of the following output options: View Image...
 - Completed Shows all Visits where testing has been completed
 - o Cancelled Shows all Visits where testing has been cancelled and the reason why
 - Pending Shows all Visits where the kit has been received, but testing has not been completed

Step 5: Save, Save and Schedule, Reset, or Run Report

Choose one of the following:

- Save the Report
 - Allows to you to save criteria selection for manual report generation or future scheduling of the report from LabLink+'s Report page
 - Type an identifying name in the Query Name: text box and Click the button
- Save and Schedule
 - Allows you to schedule the report to run automatically based upon a user-defined recurrence patter and selected criteria.
 - Type an identifying name in the Query Name: text box and Click the
 button
- Reset
 - o Allows you to quickly clear all selected criteria in this report.
 - Click the button
- Run Report
 - Allows you to run the report based upon the selected criteria, viewable from the Reports List module.
 - o Click the Mun Report button

Complete Subject Listing

How to View a Study' Subject Listing

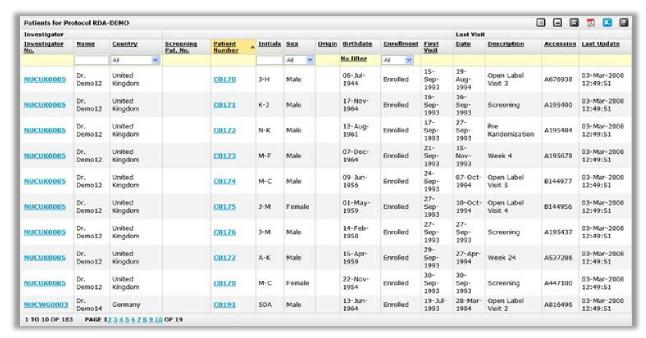
This module contains a complete listing of the study's subjects.

Navigate to the Complete Subject Listing Module

To view the Complete Subject Listing:

- 1. From the Homepage, Select a protocol from the Protocol drop-down menu on the toolbar
- 2. Click the View Complete Subject Listing button, and the Subjects module will load





Tip: To obtain a report detailing the last laboratory visit for each subject, export the Subject List module to Microsoft Excel by clicking the module's button.

Visit Progress

How to View a Protocol's Visit Progress Graph

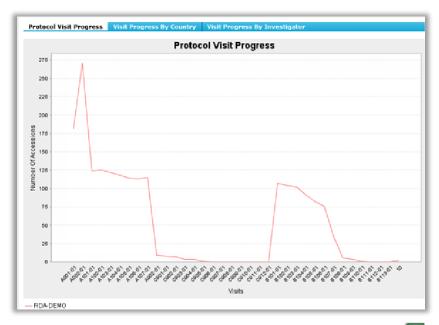
The visit progress (accessions received by Labcorp CLS) of the study, as a whole, by country and/or countries, or by investigator(s) can be tracked in a graphical representation. Raw data for each is also viewable.

Navigate to the Protocol Visit Graph

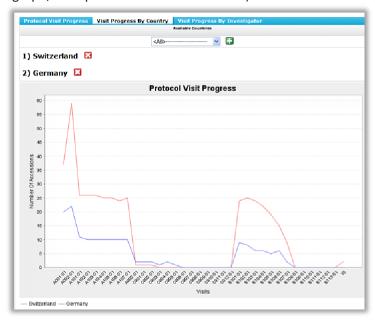
To view the graph:

- 1. From the Homepage, select a protocol from the Protocol drop-down menu on the toolbar
- 2. On the Protocol page, **click** the **Graph Protocol Visit Progress** button just below the Protocol Summary module to display the protocol visit progress graph for the protocol
- 3. Click one of the following tabs to display the graph by:
 - Protocol Visit Progress graph



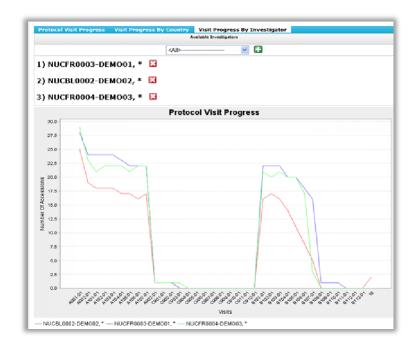


 Visit Progress By Country (Select the desired country and Click the button to add it to the graph, multiple countries can be added)



 Visit Progress By Investigator (Select the desired investigator and Click the button to add it to the graph, multiple sites can be added)





To Export Raw Data:

- 1. **Select** the desired graph as outline in steps 1-3.
- 2. Scroll down below the image and click on one of the following icons:
 - outputs the data in an Adobe PDF printer-friendly format
 - o utputs the data in a Microsoft Excel format

Subject Enrollment

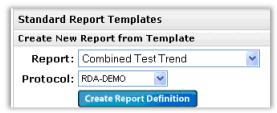
How to Run a Subject Enrollment Report

- O Q: What is the subject/patient enrollment report?
 - A: The subject enrollment report, sometimes referred to as patient enrollment, displays a timeline of each subject's visits in the visit schedule. Filterable by site, visit, tests, and output criteria selections, this report can also include a summary that is plays the total number of subject visits by site, by visit.

To Run the Report

Step 1: Navigate to Report from Welcome Screen

- 1. From the Welcome Screen, Click Reports on the toolbar to display the Available Reports page
- 2. **Scroll** down to the *Standard Report Templates* module





- 3. From the Report drop-down menu, Select Subject Enrollment
- 4. From the *Protocol* drop-down menu, **Select** a protocol
- 5. Click the Greate Report Definition button to display the criteria selection page

Step 2: Investigator Criteria (Required)

- 1. Select the options to add investigator sites to the report by either Country or by Investigator
 - a. (If choosing by countries) **Click** the **Select All Countries** button or **Select** a combination of countries from the list
 - b. (If choosing by investigators) **Click** the Select All Investigators button or select a combination of investigator sites from the list

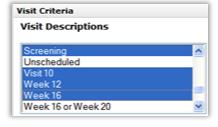


Tip: Press and hold Ctrl button on keyboard while clicking with mouse to make multiple selections in a list

Step 3: Visit Criteria

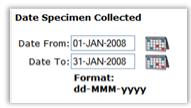
Visit Description (Required)

1. Select all or a combination of visits that should appear on the report



Date Collected (Optional)

2. If desired, **Filter** the report by the date the specimens were collected from the subject. See specifying a date range [Linked Here] for step-by-step instructions



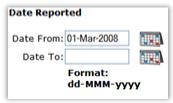
Step 4: Test Criteria (Optional)

Date Reported

1. If desired, Filter the report by the date the tests were reported by v. See <u>specifying a date</u> range [Linked Here] for step-by-step instructions



Tip: If you would like to see only tests that have been resulted since a specific date, enter a date in the Date From: text box and leave the Date To: field empty



Example: With 01-Mar-2008 in the *Date From*: field, the report will generate results that have been reported by Labcorp CLS since March 1st up until one hour from the current time

Step 5: Output Options (Required)

Available Summaries

- 1. **Choose** one of the following summary output options:
 - Yes, with summary This option displays a timeline of visits for each subject and a summary of subject visits by investigator site
 - o No, without summary This options displays only the timeline of visits for each subject
 - Only the summary This options displays only the summary of subject visits by investigator site

Step 6: Patient Status Options (Required)

Enrollment Status

- 1. **Choose** one of the following patient status options to appear on the report:
 - Enrolled Patients
 - Screening Patients
 - All Patients

Step 7: Save, Save and Schedule, Reset, or Run Report

Choose one of the following:

- Save the Report
 - Allows to you to save criteria selection for manual report generation or future scheduling of the report from LabLink+'s Report page
 - Type an identifying name in the Query Name: text box and Click the button
- Save and Schedule
 - Allows you to schedule the report to run automatically based upon a user-defined recurrence patter and selected criteria.
 - Type an identifying name in the Query Name: text box and Click the
 Save and Schedule button
- Reset
 - Allows you to quickly clear all selected criteria in this report.
 - Click the button
- Run Report



- Allows you to run the report based upon the selected criteria, viewable from the Reports List module.
- Click the button

Subject Listings

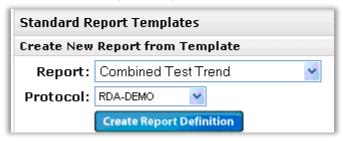
How to Run a Simple Subject Listing Report

- O Q: What is the Simple Subject Listing Report?
 - A: The Simple Subject Listing Report displays a list of subjects and their visits. If desired, the report can also display the date resulting was completed for each visit.

To Run the Report

Step 1: Navigate to Report from Welcome Screen

- 1. From the Welcome Screen, **Click** Reports on the toolbar to display the *Available Reports* page
- 2. **Scroll** down to the *Standard Report Templates* module



- 3. From the Report drop-down menu, **Select** Simple Patient Listing
- 4. From the *Protocol* drop-down menu, **Select** a protocol
- 5. Click the Greate Report Definition button to display the criteria selection page

Step 2: Investigator Criteria (Required)

- 1. **Select** the options to add investigator sites to the report by either Country or by Investigator
 - a. (If choosing by countries) **Click** the **Select All Countries** button or **Select** a combination of countries from the list
 - b. (If choosing by investigators) **Click** the Select All Investigators button or select a combination of investigator sites from the list



Tip: Press and hold Ctrl button on keyboard while clicking with mouse to make multiple selections in a list.



Step 3: Visit Criteria (Optional)

Date Collected

1. If desired, **Filter** the report by the date the specimens were collected from the subject. See specifying a date range [Linked Here] for step-by-step instructions.



Step 4: Test Criteria (Optional)

Date Reported

1. If desired, **Filter** the report by the date the tests were reported by Labcorp CLS. See specifying a date range [Linked Here] for step-by-step instructions

Tip: If you would like to see only visits where testing has been completed since a specific date, enter a date in the Date From: text box and leave the Date To: field empty.



Example: With 01-Mar-2008 in the *Date From*: field, the report will generate results that have been reported by Labcorp CLS since March 1st up until one hour from the current time

Step 5: Output Options (Optional)

Display Reported On Date

1. If you would like to see the date the results for each visit were reported, **Click** the box to display the reported on date

Step 6: Save, Save and Schedule, Reset, or Run Report

Choose one of the following:

- Save the Report
 - Allows to you to save criteria selection for manual report generation or future scheduling of the report from LabLink+'s Report page
 - Type an identifying name in the Query Name: text box and Click the button
- Save and Schedule
 - Allows you to schedule the report to run automatically based upon a user-defined recurrence patter and selected criteria.
 - Type an identifying name in the Query Name: text box and Click the
 Severand Schedule
 button
- Reset



- o Allows you to quickly clear all selected criteria in this report.
 - Click the Misse button
- o Run Report
 - Allows you to run the report based upon the selected criteria, viewable from the Reports List module.
 - o Click the Mun Report button

Test Results

Test Result Information

How to View Test Results for a Subject

A subject's results can be viewed a variety of ways. Below are step-by-step instructions on how to view results.

Step 1: Navigate to the Visit Activity List

- 1. From the Homepage, **Select** a protocol from the Protocol drop-down menu on the toolbar
- Select an investigator from the Investigator drop-down menu on the toolbar
- 3. **Select** a Subject from the Subject drop-down menu on the toolbar
- 4. **Select** a Visit from the Visit drop-down menu on the toolbar
- 5. **Scroll down** to the Visit Activity List

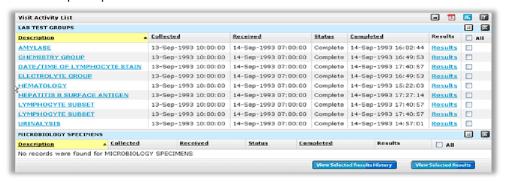
Step 2: How to View Results

The Subject's Results Can Be Viewed a Few Different Ways:

- A Single Group or Specimen for The Selected Visit
 - Click the Results link to view the selected visit's results for the desired Lab Test Group and/or Microbiology Specimen
- Multiple Groups and/or Specimens for The Selected Visit
 - Select the boxes under the All column for the desired Lab Test Groups and/or Microbiology Specimens. (Alternately, Select the All box to enable all Groups and Specimens)
 - Click the westerded Results button to display the selected visit's results for the selections made in step 1
- o A Single Group or Specimen for All Visits
 - Select the box under the All column for the desired Lab Test Group or Microbiology Specimen
- Multiple Groups and/or Specimens for All Visits
 - Select the boxes under the All column for the desired Lab Test Groups and/or Microbiology Specimens. (Alternately, Select the All box to enable all Groups and Specimens)



 Click the View Solocted Results Mistory button to display the test result history for the selected Group or Specimen



The Module Includes This Test Data:

- Description Name of the group (for lab test groups); name of the specimen (for microbiology specimens)
- Collected Date and time the group/specimen was taken
- Received Date and time requisition was received at Labcorp CLS
- Status Visits may be completed, pending, or cancelled
- Completed Date and time the agreed upon services were fully performed by Labcorp CLS
- Results Link to the test/visit activity results for the visit
- All Mark the checkbox and click the View Select Results History

Step 3: Viewing The Results

- When the results page displays after step 2, you can use the column options button to turn off either the Conventional or Standard International Units column. This can make for easier viewing
- For large volumes of data, it is convenient to export the results to either the Adobe PDF format or to Microsoft Excel

Tip: To view results for the entire study, run the Combined Test Trend report

Combined Test Trend Report

How to View Results for the Study

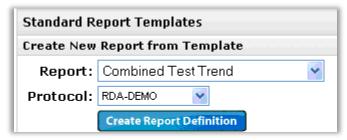
- Q: What is the Combined Test Trend Report
 - A: Filterable by investigator site, visit, subject, and test criteria, this report displays the
 protocol's test results. It outputs in an Excel compatible *.csv (comma separated value)
 and a printer-friendly Adobe PDF format.

To Run the Report

Step 1: Navigate to Report from Welcome Screen

- 1. From the Welcome Screen, **Click** Reports on the toolbar to display the *Available Reports* page
- 2. **Scroll** down to the *Standard Report Templates* module





- 3. From the Report drop-down menu, **Select** Combined Test Trend Report
- 4. From the *Protocol* drop-down menu, **Select** a protocol
- 5. Click the Greate Report Definition button to display the criteria selection page

Step 2: Investigator Criteria (Required)

- 1. Select the options to add investigator sites to the report by either Country or by Investigator
 - a. (If choosing by countries) **Click** the **Select All Countries** button or **Select** a combination of countries from the list
 - b. (If choosing by investigators) **Click** the Select All Investigators button or select a combination of investigator sites from the list

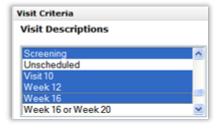


Tip: Press and hold Ctrl button on keyboard while clicking with mouse to make multiple selections in a list.

Step 3: Visit Criteria

Visit Descriptions (Required)

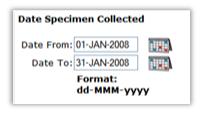
1. Select all or a combination of visits that should appear on the report



Date Specimen Collected (Optional)

2. If desired, **Filter** the report by the date the specimens were collected from the subject





Step 4: Subject Criteria

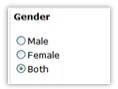
Date of Birth (Optional)

1. If desired, **Filter** the report by subject date of birth. See <u>specifying a date range [Linked Here]</u> for step-by-step instructions



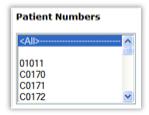
Gender (Optional)

2. If desired, **Filter** the report by gender



Subject Numbers (Required)

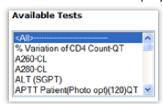
3. Select all or a combination of subjects that should appear on the report



Step 5: Test Criteria

Available Tests (Required)

1. **Select** all or a combination of tests that should display on the report





Abnormal Flags (Required)

- 2. **Select** one of the following Abnormal Flag options: (Note: Report will contain both Labcorp CLS standard and sponsor defined flags)
 - a. Click the Select All Flags button to generate a report that will only display result values that are out- of-range



b. **Select** <ALL> to generate a report that will display results values that are both in-range and out-of- range



c. **Select** a combination of flags, both Labcorp CLS and Sponsor defined, that will display on the report



Date Reported (Optional)

3. If desired, **Filter** the report by the date the tests were reported by Labcorp CLS

Tip: If you would like to see only tests that have been resulted since a specific date, enter a date in the Date From: text box and leave the Date To: field empty



Example: With 01-Mar-2008 in the *Date From*: field, the report will generate results that have been reported by Labcorp CLS since March 1st up until one hour from the current time.

Step 6: Output Options
Display Flag Info (Optional)



1. In the Excel compatible format of this report, the flags are placed in the same cell with the result value; **Uncheck** the check box to remove the flag indicator from the report, leaving only the result value. This comes in handy when charting or graphing trends

Available Summaries (Required)

- 2. **Choose** one of the following summary options:
 - a. Detailed Report This option displays the results of the previously selected criteria
 - b. Summary Report by % This option displays a statistical breakdown of the percentage of flags in the report by test, site, and visit
 - c. Both of the Above This options displays both the Detailed and Summary Report by % sections in the output of the report

Reporting Units (Required)

3. **Select** to have the report output the results in either *Conventional* or *SI* (Standard International) units

Step 7: Save, Save and Schedule, Reset, or Run Report

Choose one of the following:

- Save the Report
 - Allows to you to save criteria selection for manual report generation or future scheduling of the report from LabLink+'s Report page
 - Type an identifying name in the Query Name: text box and Click the button
- Save and Schedule
 - Allows you to schedule the report to run automatically based upon a user-defined recurrence patter and selected criteria.
 - Type an identifying name in the *Query Name*: text box and **Click** the button
- Reset
 - o Allows you to quickly clear all selected criteria in this report.
 - Click the button
- Run Report
 - Allows you to run the report based upon the selected criteria, viewable from the Reports List module.
 - Click the Mun Report button

Out-Of-Range Results

How to View All Out-Of-Range Values for a Subject

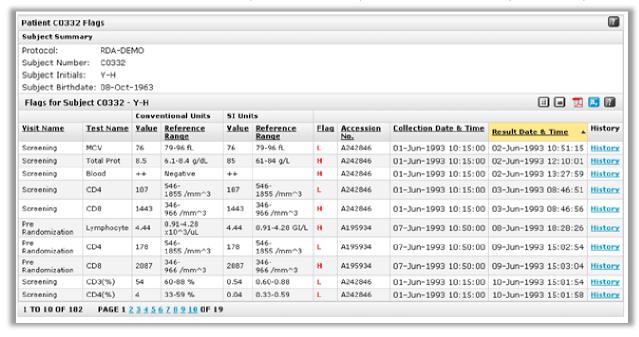
Clicking the View Subject Flags button displays all of the out-of-range values for the selected subject in the study.

How to Navigate and View All Subject Flags

- 1. From the Homepage, **select** a protocol from the Protocol drop-down menu on the toolbar
- Select an investigator from the Investigator drop-down menu on the toolbar



- 3. **Select** a Subject from the Subject drop-down menu on the toolbar
- 4. Click the Subject Hage button and a module will load displaying all of the Subject's flags for the study
- 5. If desired, **Click** on the History link to view the specific test's result history in the study



Tip: For more efficient viewing, this data can be exported into Adobe PDF and Microsoft Excel formats:

- \circ oxtime outputs the data in an Adobe PDF printer-friendly format
- $_{\circ}$ lacktriangle outputs the data in a Microsoft Excel format

The Subject Flags page includes the following information:

- Protocol Protocol's ID
- Subject Number ID assigned to the subject involved in the study
- Subject Initials First letters from the patient's first, middle, and last name
- Sex Gender of the patient
- Origin Ethnicity of the patient
- Patient Birthdate Day, month, and year of the patient's date of birth
- Visit Name Text identifying the visit
- Test Name Abbreviation for the test
- Conventional Units Value Test result value with conventional units
- Conventional Units Reference Range Reference range value with conventional units
- SI Units Value Test result value with Standard International units
- SI Units Reference Range Reference range value with Standard International units
- Flags Notation concerning an investigator, visit, or project that requires special attention in the review process. A flag is only applicable to Labcorp CLS results
- Accession Pre-defined identification number assigned to only one kit (by Labcorp CLS site) prior to shipping from Labcorp CLS. After return of the kit, test completion, and lab reports being



- sent, an accession number then becomes an identifier of the kit, project, visit, subject, test results, and lab report identifier
- Collection Date & Time Date and time of specimen was collected at the investigator site
- Result Date & Time Date and time tests were reported by Labcorp CLS
- History Display the Patient Flags Test History page

Test Result History Graph

How to View a Test Result History in a Graph

The Result History Graph will display a graphical historical trend of a selected test result for a selected subject. It will also display the Upper and lower reference ranges.

How to Navigate and View the Result History Graph

- 1. From the Homepage, select a protocol from the Protocol drop-down menu on the toolbar
- 2. **Select** an investigator from the Investigator drop-down menu on the toolbar
- 3. **Select** a Subject from the Subject drop-down menu on the toolbar
- 4. **Click** the button and the *Result History Graph* window will open
- 5. **Select** a test from the Select a test drop-down list
- 6. **Select** the desired units *Conventional* or *SI* (Standard International) from the *Reporting units*
- 7. To select a different test, **Repeat** steps 5 and 6

Items to Note:

- There must be more than one subject visit in order to for a chart to display
- o The graph will display normal shifts in the reference range due to aging, etc...

Tips:

- For more efficient viewing, the raw data can be exported into Adobe PDF and Microsoft Excel formats:
 - o Loutputs the data in an Adobe PDF printer-friendly format
 - outputs the data in a Microsoft Excel format
- The graph can be printed or saved by right-clicking directly on the graph and choosing either "Print Picture..." or "Save Picture As..."

Specimen Management Data

Specimen Management

How to Get a Simple Listing of Specimens and Their Current Status

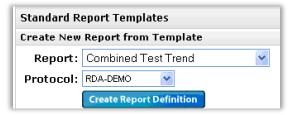
- O Q: What is the specimen management report?
 - A: The specimen management report provides a simple listing of each specimen, by container, in Labcorp CLS' inventory system. The report displays the current status of the sample and in cases when a specimen has been shipped, the location to where it was shipped to.



To Run the Report:

Step 1: Navigate to Report from Welcome Screen

- 1. From the Welcome Screen, **Click** Reports on the toolbar to display the *Available Reports* page
- 2. **Scroll** down to the *Standard Report Templates* module



- 3. From the Report drop-down menu, Select Specimen Management Inventory
- 4. From the *Protocol* drop-down menu, **Select** a protocol
- 5. Click the Greate Report Definition button to display the criteria selection page

Step 2: Investigator Criteria (Required)

- Select the options to add investigator sites to the report by either Country or by Investigator.
 - a. (If choosing by countries) **Click** the Select All Countries button or **Select** a combination of countries from the list
 - b. (If choosing by investigators) **Click** the Select All Investigators button or select a combination of investigator sites from the list



Tip: Press and hold Ctrl button on keyboard while clicking with mouse to make multiple selections in a list

Step 3: Visit Criteria

Date Collected (Optional)

If desired, Filter the report by the date the specimens were collected from the subject. See <u>specifying a</u> date range [Linked Here] for step-by-step instructions



Step 4: Specimen Criteria (Required)
Specimen Classes

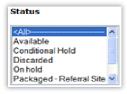


 Select <All> or a combination of specimens, by categorized class, that are to appear on the report.



Specimen Status

2. **Select** <All> or a combination of status types



Step 5: Save, Save and Schedule, Reset, or Run Report

Choose one of the following:

- Save the Report
 - Allows to you to save criteria selection for manual report generation or future scheduling of the report from LabLink+'s Report page
 - Type an identifying name in the Query Name: text box and Click the button
- Save and Schedule
 - Allows you to schedule the report to run automatically based upon a user-defined recurrence patter and selected criteria.
 - Type an identifying name in the Query Name: text box and Click the
 Severand Schedule button
- Reset
 - o Allows you to quickly clear all selected criteria in this report.
 - Click the button
- Run Report
 - Allows you to run the report based upon the selected criteria, viewable from the Reports List module.
 - Click the Mun Report button

Specimen Management

How to Get Summaries of Specimen Data by Subject by Visit

- O Q: What is the Specimen Management Inventory Analysis report?
 - A: The specimen management inventory analysis report provides summary data relative to the study's subjects, visits, along with a detailed listing of specimens contained within Labcorp CLS' specimen management inventory system. The report is categorized into three tabs of information:

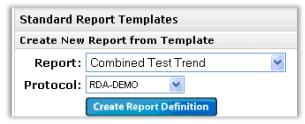


- Subject Summary: Provides counts of specimen by class for each subject. This section can also show the number of specimens collected by visit
- Visit Details: Similar to the subject summary, this tab provides counts of specimens by class for each subject visit. This section can also display selected test results by subject visit
- Specimen Details: displays a detailed listing of specimens and each one's current status. In the
 event a specimen has been shipped to an alternate location, this section also displays where the
 specimen was shipped along with the shipped date/time

To Run the Report

Step 1: Navigate to Report from Welcome Screen

- 1. From the Welcome Screen, **Click** *Reports* on the toolbar to display the *Available Reports* page
- 2. **Scroll** down to the *Standard Report Templates* module



- 3. From the Report drop-down menu, Select Specimen Management Inventory Analysis Report
- 4. From the *Protocol* drop-down menu, **Select** a protocol
- 5. Click the Greate Report Definition button to display the criteria selection page

Step 2: Investigator Criteria (Required)

- 1. **Select** the option to add investigator sites to the report by either Country or by Investigator
 - a. (If choosing by countries) **Click** the **Select All Countries** button or **Select** a combination of countries from the list
 - b. (If choosing by investigators) **Click** the Select All Investigators button or select a combination of investigator sites from the list

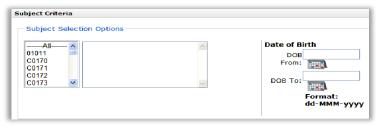


Tip: Press and hold Ctrl button on keyboard while clicking with mouse to make multiple selections in a list



Step 3: Subject Criteria (Required)

- 1. **Select** all or a combination of subjects that should appear on the report. (Required)
- 2. If desired, **Filter** the report by subject date of birth. See specifying a date range for step-by-step instructions (**Optional**)



Step 4: Advanced Filters (Optional)

Subject Sample Status Filter

The subject sample status filter allows you to filter the entire report to only show subjects or visits (depending on selection), with a desired number of samples for a chosen specimen class and status.

- 1. **Click** the *Subject Sample Status* check box to reveal the criteria options related to this filter
- Specify a specimen status, specimen class, the desired operator, and the quantity of samples
- 3. **Select** to have the filter apply to either Patients or Visits

Example 1: Will only show subjects that have 5 or more available serum samples in storage.



Example 2: Will only show subjects that have had 5 or less serum samples shipped.



Example 3: Will only show subject visits that have 5 available serum samples in a visit.



Example 4: Will only show subjects that have *less than 5 or more than 5* available serum samples in storage.



Example 5: Will only show subject visits that have had more than 5 samples shipped in a visit.

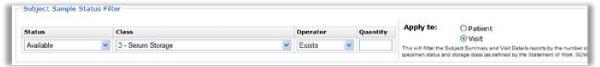




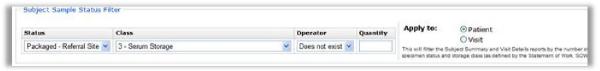
Example 6: Will only show subjects that have had fewer than 5 samples shipped across all visits.



Example 7: Will only show subject visits that have available serum samples.



Example 8: Will only show subjects that have had no serum samples shipped.



Test Results Filter

The test results filter allows you to filter the entire report to only show subjects or visits (depending on selection) that have a chosen result value for the specified test.

- 1. **Click** the *Test Results Filter* check box to reveal the criteria options related to this filter
- 2. **Specify** a test, the desired operator, and a test result value
- 3. **Select** to have the filter apply to either Patients or Visits

Example 1: Will only show subjects that have ALT results greater than or equal to 25.



Example 2: Will only show subject visits that have ALT results less than or equal to 25.



Example 3: Will only show subject visits that have ALT result equal to 25.



Example 6: Will only show subjects that have ALT results less than 25.





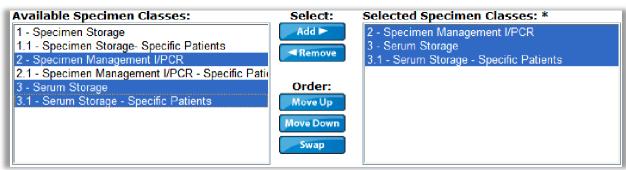
Example 8: Will only show subjects that do not have ALT results.



Step 5: Specimen Class Options (Required)

The specimen class option allows you to select which specimen classes are to appear on the Subject Summary, Visit Details, and the Specimen Details worksheets. You can also create custom columns that aggregate a user- defined selection of available specimen classes.

1. **Highlight** the desired specimen classes from the *Available Specimen Classes* list and Click to move them to the *Selected Specimens Classes* list (**Required**)



2. **Create** custom columns that aggregate a selection of available specimen classes with the Create Grouping option (**Optional**)

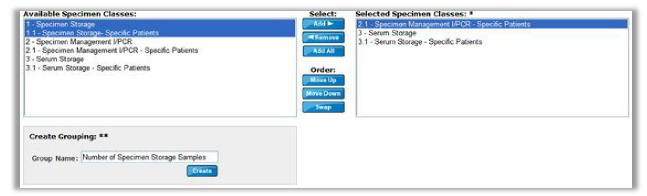
How to Create a Grouping

 Grouping Step 1: Highlight the sample classes that are to be included in the aggregate grouping from the Available Specimen Classes List

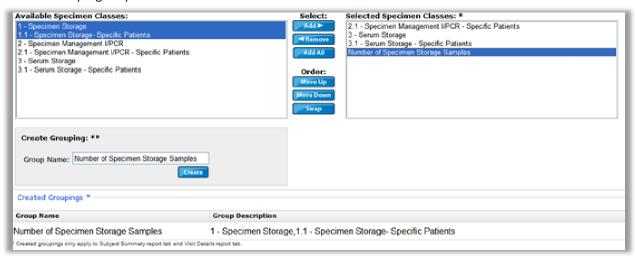


o Grouping Step 2: Type a column name for the grouping in the *Group Name* text field





Grouping Step 3: Click the freeten button



 Grouping Step 4: Repeat steps 1-3 as needed to create additional aggregate columns on the report

Note: The classes and custom groupings appear as columns on the Subject Summary and Visit Details worksheets and in the order shown in the Selected Specimen Classes list.

Step 6: Report Options (Minimum One Selection Required)

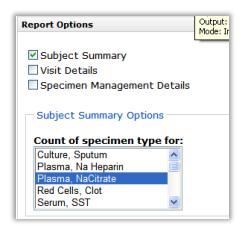
- 1. **Select** the check boxes next to the report options that are to appear on the report
- Select the appropriate criteria relative to each of the selected report options. See below for details regard each of the report options' specific criteria

Note: The report options control which worksheets are to appear on the report. Selecting a report option will reveal additional filtering that will be applicable to only that section of the report output.

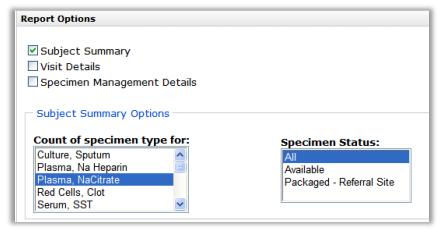
Subject Summary Options

1. From the *Count of specimen type* for: list, **Select** the specimens that will appear on the Subject Summary worksheet in the visit breakdown section. (**Optional**)





2. **Select** All or a combination of status types from the Specimen Status: list. (Required)

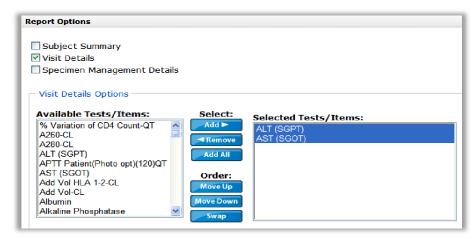


Note/Warning: The Count of specimen type for: criteria selection will display a column for each visit in the study's visit schedule for each of the selected specimens. The column data will be the count of the number of specimens a subject has for one of the criteria selected specimens. Because Microsoft Excel has a limit of 255 columns, multiple specimen selections can result in a report that is too large to generate.

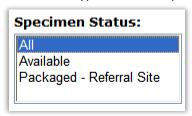
Visit Details Options

1. **Highlight** the desired tests or items from the *Available Tests/Items*: list and Click move them to the *Selected Tests/Items*: list. (**Optional**)





2. **Select** All or a combination of status types from the Specimen Status: list. (Required)



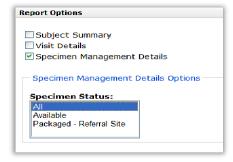
3. **Select** either *Conventional* or *SI* (Standard International) units regarding how the test results are to output. (**Optional**)



Note: Results will output on the Visit Details worksheet for the selected tests / items. An item is likely to be representative to an administrative question collected from a requisition. See your study's Statement of Work for clarification on potential administrative questions specific to your study. The order selected will be the order of the columns in the report.

Specimen Management Details Options

1. **Select** All or a combination of status types from the Specimen Status: list. (Required)





Step 7: Save, Save And Schedule, Reset, Or Run Report

Choose one of the following:

- Save the Report
 - Allows to you to save criteria selection for manual report generation or future scheduling of the report from LabLink+'s Report page
 - Type an identifying name in the Query Name: text box and Click the button
- Save and Schedule
 - Allows you to schedule the report to run automatically based upon a user-defined recurrence patter and selected criteria.
 - Type an identifying name in the Query Name: text box and Click the
 Save and Schedule button
- Reset
 - o Allows you to quickly clear all selected criteria in this report.
 - Click the button
- Run Report
 - Allows you to run the report based upon the selected criteria, viewable from the Reports List module.
 - Click the Mun Report button

Specimen Status Definitions

Every specimen in Labcorp CLS' specimen storage database is categorized by the following status types.

- Available
 - This status indicates the specimen is currently located at the Labcorp CLS storage location and is available for shipping with all patient information confirmed.
- Conditional Hold
 - Status used in Labcorp CLS' specimen management storage system to trigger a hold based on a unique visit and/or element defined within our system.
- Discard
 - This status indicates the specimen has been scanned out of our specimen management database and has been disposed of, as outlined in the protocol's Statement of Work.
- o On Hold
 - This status indicates the specimen is currently located at the Labcorp CLS storage location but is not available for shipping and requires additional information to be gathered from the investigator site.
- Packaged Referral Site
 - Specimens with the status of Packaged Referral Site have been shipped to third-party location as outlined in the protocol's Statement of Work.
- Pending Discard
 - This status indicates the specimen has been identified as requiring disposal, as outlined in the protocol's Statement of Work.
- Pre-Scan
 - This status indicates that the specimen has been scanned into Labcorp CLS' specimen management database as the first step to identify the sponsor and storage temperature.



 Both of LabLink+'s specimen management reports, Specimen Management Inventory and Specimen Management Inventory Analysis, allow for filtering of the report by status type.

Advanced - Custom Reports

Ad-Hoc Query

How to Build an Ad-Hoc Query

The ad-hoc functionality allows you to create your own customized report templates.

To Create an Ad-Hoc Query:

Step 1: Navigate to The Ad-Hoc Query from Welcome Screen

- 1. From the Welcome Screen, **Click** *Reports* on the toolbar to display the *Available Reports* page
- 2. **Scroll** down to the *Create New Ad-hoc Report Template* module



- 3. **Type** a descriptive name in the New Template Name: field (**Note**: Always enter a unique name in this field)
- 4. If necessary, **select** the desired protocol from the drop-down list
- 5. Click the Create Template button and the Ad-hoc Query page will display

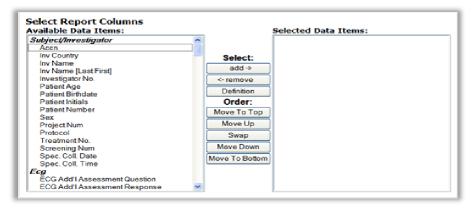


Step 2: Select Data Items

The data items you choose in this step are the columns that will appear in your report.

1. Click the Select Report Columns window





2. **Highlight** (hold down Ctrl button to make multiple selections) the desired data items from the *Available Data Items*: list and **Click** to move them to the *Selected Data Items* list

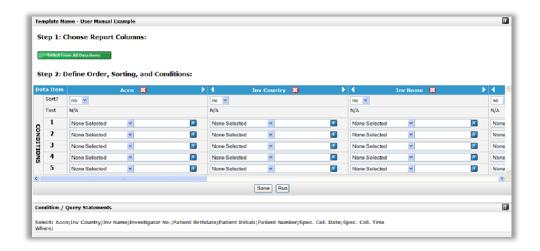


Tip: The order in which the data items appear in the Selected Data Items list (Top to Bottom) is the order they will appear on report (Left to Right). **Use** the Move To top, Move Up, Swap, Move Down, and Move to Bottom buttons to change the order of the Selected Data Items.

Tip: If you would like view the definition of a data item, **Select** the data item in the Available Data Items list and then **Click** the Definition button.

- Click the Save & Close button to save the query and send the selection to the Ad-hoc Builder Screen
 - a. Alternately: Click the Cancel button to start over
 - b. Alternately: **Click** the *Save* button to save the query, or **Click** the *Save & Close* button to save the query and send the selection to the Ad-hoc Builder Screen





Step 3: Defining Order, Sorting, and Conditions Sorting

- Sort? Select Yes from the drop-down list if you want the report data sorted in ascending order by this item
- Example of an effective sort: If you sort by: Investigator, Subject Number, and then Specimen Collection Date, the visit dates on the report will be in chronological order by Subject. The Subjects on the report will be grouped by Investigator Sit

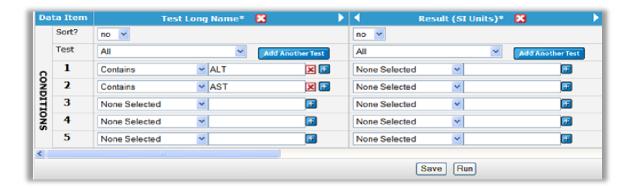
Test Selection

- Test For data items with tests associated with them, select the appropriate test from the dropdown list
- Add Another Test If you need additional tests, Click the Add Another Test button to duplicate the data item. Select the additional test from the drop-down list

Tip: If you would like to see all test results in a single column.

- 1. **Add** the data item Test Long Name or Test Short Name and Results (Conv or SI) to the query (refer to Step 2: Select Data Items)
- 2. **Add** a condition under the Test Name column that Contains the name of the test, such as *ALT*
- 3. **Add** a second condition under the Test Name column that Contains the name of another test, such *AST*
- 4. **Leave** the Results (Conv or SI) set to *All* Tests.
- 5. **Click** the *Save* button





Conditions

- Explanation
 - Every data item added to the query can be filtered by that data item's output. For example, the data item Investigator Country can be filtered by any of the studies participating countries, Argentina, United Kingdom, United States, Switzerland, and so on.

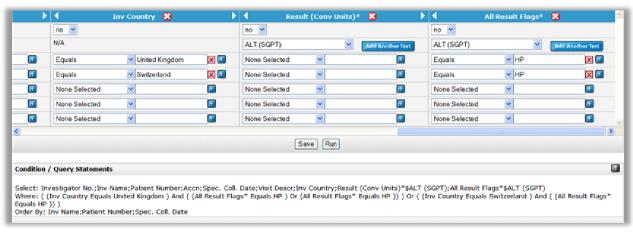


- Condition Logic "And" Statements
 - Up to 5 rows of conditions can be applied to a query. Each conditional row acts as an "And" statement. In order for data to appear on a report it must meet every condition in the row.
 - Example: If you need a report that displays investigator sites from the United Kingdom where subjects have ALT results that have High Panic values. Your query should look something like this:





- o In order for the data to appear on the query, it must meet all of the conditions set in row 1. The investigator country must equal United Kingdom *and* the Result Flags for ALT must equal HP (High Panic). Otherwise, the data will not display on the report.
- Condition Logic "Or" Statements
 - The previous example covers "And" statements. Now what if you want to also see another country on the same report. This where "Or" statements are useful. The data that outputs on the report must meet all of the conditions set in a conditional row. If more than one conditional row is set, the break between these two is an "Or" statement.
 - Example: You need a report that displays investigator sites from the United Kingdom and Switzerland where subjects have ALT results that have High Panic values. To get the right data output you will need to setup two condition rows, one with United Kingdom and one with Switzerland. Your query should look something like this:



- O In order for the data to appear on the query, it must meet all of the conditions set in row 1 or condition row 2. The investigator country must equal United Kingdom and the Result Flags for ALT must equal HP (High Panic) or the investigator country must equal Switzerland and the Result Flags for ALT must equal HP (High Panic). Otherwise, the data will not display on the report.
 - Note: Up to 5 conditional "Or" statements can be made in a single guery.
 - Note: The query logic can be viewed via the Condition / Query Statements area of the Query Builder screen.

How to Remove a Condition from a Data Item

○ Click to remove a data item's condition

Setting a Date Range

Under the appropriate data item, in the desired conditional row:

- 1. **Pull-down** the list and choose Greater Than
- 2. **Type** the earlier of the two dates into the field in this format DD-MMM-YYYY
- 3. Click the button in the condition row



- 4. In the same row, **Pull-down** the list and **Choose** Less Than
- 5. **Type** the most recent date into the field in this format: DD-MMM-YYYY
- 6. **Click** the Save button View Finished Example:



Remove a Data Item

1. Click to remove an entire data item.

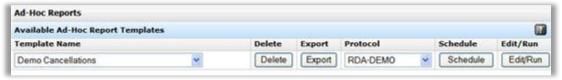
Step 4: Save and/or Run the Query

- Click the Save button to save the query
- o Click the Run button to submit the report and display the Available Reports page
- The report is viewable from the Reports List Module

How to Run an Existing Ad-Hoc Query

Step 1: Navigate to and Select the Existing Query

- 1. Click the Reports button on the navigation bar to display the Available Reports page
- 2. Scroll down to the Available Ad-Hoc Reports Templates module



- 3. **Select** a protocol from the *Protocol* drop-down list
- 4. Click the Edit/Run button to display the Ad-Hoc Query page

Step 2: Save and/or Run the Query

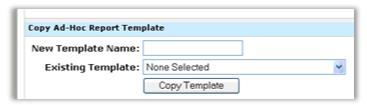
- 1. Click the Run button to submit the report and display the Available Reports page
 - The report is viewable from the Reports List Module

How to Copy an Ad-Hoc Query

To Copy and Save An Existing Ad-Hoc Query:

- 1. Click the Reports button on the navigation bar to display the Available Reports page
- 2. **Scroll down** to the *Copy Ad-Hoc Report Template* module





- 3. **Provide** this information:
 - New Template Name Type a descriptive name for the copied query
 - o Existing Template **Select** the query to be copied from the drop-down list
- 4. **Click** the *Copy Template* button to copy the query

The query will now be located in the Existing Template drop-down list.

How to Share an Ad-Hoc Query

There are three steps in sharing an ad-hoc query:

- 1. The individual with the query exports the query out of their account as an XML file
- 2. The query file is sent to the recipient
- 3. The recipient imports the query file into his/her account

Exporting Ad-Hoc Queries

To Download an Ad-Hoc Query Template:

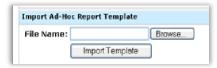
- 1. Click the Reports button on the navigation bar to display the Available Reports page
- 2. Scroll down to the Ad-Hoc Reports module
- 3. Click the Export button to display the File Download window



- 4. Click the Save button to display the Save As window
- 5. **Select** a location and **Click** the Save button

To Import the Ad-Hoc Query Template

- 1. Click the Reports button on the navigation bar to display the Available Reports page
- 2. Scroll down to the Import Ad-Hoc Report Template module



- 3. **Type** an identifying name in the File Name field
- 4. **Click** the Browse button and **double-click** the query you want to use
- 5. **Click** the Import Template button to load the query and display the updated Available Reports page



How to Schedule an Ad-Hoc Query

Step 1: Navigate to and Select the Query

- 1. Click the Reports button on the navigation bar to display the Available Reports page
- 2. Scroll down to the Available Ad-Hoc Reports Templates module
- 3. Select a protocol from the Protocol drop-down list
- 4. Click the Schedule button to display the Report Scheduler page

Step 2: Define Recurrence Pattern

- 1. Select the desired Recurrence Pattern and Set the appropriate recurrence options
 - One Time Only
 - Daily
 - Weekly
 - Monthly
- 2. **Select** Your Time zone from the drop-down list
- 3. **Set** the Start Time
- 4. Click the Save and Schedule button

Step 3: Manage The Scheduled Report

The scheduled report can be managed from Available Reports page via the Scheduled Reports module



- For select reports, the criteria can be adjusted by clicking on the scheduled report's name
- Click the We button to create a recurrence pattern
- Click the button to edit the recurrence patter
- Click the icon under the Enabled column to disable the scheduled report
- Click the icon under the Notify column to disable the automatic notification
- Click the ¹ button to delete the query out of the Scheduled Reports module

General Report Options

Report List Module

How to View a Generated Report

The Report List module displays data about each report generated for you by LabLink in the past 60 days. The module is available from the LabLink Welcome (Home) page, the Protocol page, and the Available reports page.



Navigate to The Report List Module

To Report List on Home Page

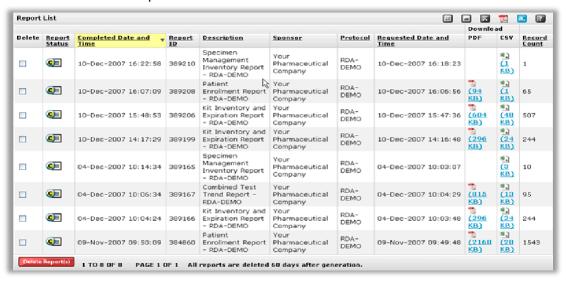
- 1. Log into LabLink (Default Protocol should not be enabled)
- 2. Scroll down to the Report List Module

To Protocol Specific Report List

- 1. From the Welcome Screen (Home), **Select** a protocol from the protocol drop-down menu on the toolbar
- 2. Scroll down to the Report List Module

To Report List on Available Reports Page

- 1. From the Welcome Screen (Home), **Click** the Reports button on the toolbar to display the Available Reports page
- 2. Scroll down to the Report List Module



The Report List Module Includes This Data:

- Delete Mark this checkbox and click the Delete Report(s) button to remove this report
- Report Status Icons to indicate one of these statuses: running, failed, too much data, no data, or completed
- Completed Date and Time Date and time that LabLink finished generating the report
- Report ID Unique number assigned to each report
- Description Name of the report
- Sponsor Name of the protocol's sponsor
- Protocol Name of the protocol
- Requested Data and Time Date and time that LabLink began generating the report. (If this
 report was generated from a schedule, the link displays the schedule.)
- PDF View or save the report in portable document format
- CSV View or save the report in Excel-compatible (comma-separated variable) format
- Record Count Number of records in the report



Scheduling Reports

How to Schedule a Report to Run Automatically

Things to Know

 To schedule a report to run automatically, you must first follow the steps to run a standard report, choosing the save and schedule option

To Run the Report

Step 1: Setup Report

Follow steps to run a Standard Report

Select the Save and Schedule button

Follow steps to schedule an Ad-hoc Query

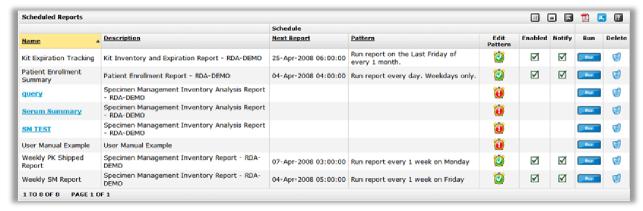
Select the Schedule button

Step 2: Define Recurrence Pattern

- 1. Select the desired Recurrence Pattern and Set the appropriate recurrence options
 - One Time Only
 - Daily
 - Weekly
 - Monthly
- 2. **Select** Your Time zone from the drop-down list
- 3. Set the Start Time
- 4. Click the Save and Schedule button

Step 3: Manage The Scheduled Report

The scheduled report can be managed from Available Reports page via the Scheduled Reports module



- o For select reports, the criteria can be adjusted by **clicking** on the scheduled report's name
- Click the button to create a recurrence pattern
- Click the button to edit the recurrence pattern
- \circ Click the lacksquare icon under the Enabled column to disable the scheduled report
- Click the icon under the Notify column to disable the automatic notification



○ Click the ¹ button to delete the query out of the Scheduled Reports module

Run A Saved Report

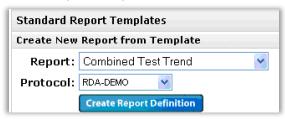
How to Save a Report Criteria Selection and Then Run It On Demand

LabLink+ allows you to save your criteria selection for any standard report. This saved report can be scheduled and also manually ran at any time.

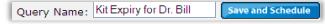
Note: Before you can run a saved report, you must first have saved* or scheduled a standard report

Step 1: Create a Saved Report

- 1. From the Welcome Screen, Click Reports on the toolbar to display the Available Reports page
- 2. Scroll down to the Standard Report Templates module



- 3. From the Report drop-down menu, Select a standard report
- 4. From the *Protocol* drop-down menu, **Select** a protocol
- 5. Click the Create Report Definition button to display the report's criteria selection page.
- 6. Make the criteria selection for the report **
- 7. In the Query Name: text field, **type** a name by which the report will be recognized



- 8. Click the Save and Schedule button
 - a. For the Specimen Management Inventory Analysis Report, you can either choose to Save and Schedule or to just Save the report criteria selection.
 - * If choosing Save, skip step 9
- 9. Schedule the report. Click here for detailed instructions

Step 2: Manually Generate a Report from a Saved Criteria Selection:

1. From the Available Reports page, Scroll down to the Scheduled Reports module



2. Click the button under the Run column for the saved report you wish to generate



3. When finished processing, **Download** the report from the *Report List* module

*Note: You can edit your saved criteria by Clicking on the Name link from the Scheduled Reports module

Report Options - Date Range

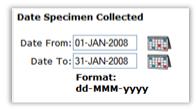
How to Specify a Date Range

- O Q: Where is it applicable to specify a date range?
 - A: In all or most of the standard reports, date ranges can be used as filters to scale down the output of the report. Examples: Specimen Collection Date, Date Specimen Collected, Date of Birth, Shipped Date, Kit Expiration, and Date Reported.

Specifying a Date Range

Manual Entry

- 1. In the From: field, type the earliest date in the text box. The format must be: DD-MMM-YYYY
- 2. In the To: field, type the most recent date in the text box to complete the range

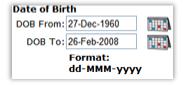


Calendar Entry

1. In the From: and To: rows, **click** the icon to open the Calendar Window



- 2. In the Calendar window, use < > to specify the month and year
- 3. Click on a day to make the date selection. The Calendar window closed and the date is entered into fields.



Things to Know:

The date format must be: dd-MMM-yyyy



- Leaving the From: field empty represents the earliest date available in the study
- Leaving the To: field empty, represents today's date
- Leaving both fields empty will produce a historical report
- Future dates are not allowed, except for the Kit Expiration Date Range in Kit Inventory and Expiration Report

Available Modules and Functionality

Data Modules

What Is a Module?

In LabLink, data Lists and information are now grouped into clusters called modules. Modules can be customized and provide you with quick access to data via links and also to a variety of summarized information.

LabLink modules can be:

- Filtered
- Adjusted to show only desired columns of data
- Maximized
- Hidden
- Exported to Adobe PDF and Microsoft Excel
- Used to access the online user manual

Note: The modules in LabLink will display up to 10 rows of data. The functionality options offered by LabLink allow you to quickly find the data you are looking for.

How to Customize Your LabLink+ View

The overall "view" of LabLink can be customized and saved to suit your preferences.

Customizing Modules

LabLink's view can be customized to suit your preference in the following ways:

- o Click the Hide icon (on the right-hand side of the module to hide the table
- Click the Show icon (on the right-hand side of the module to un-hide the table
- Click the Column Options icon (on the right-hand side of the module to display the Column Options window
 - 1. **Click** the *Off* button to hide a column
 - 2. **Click** the *On* button to display a column
 - 3. Click the Apply Changes button to adjust your module
- Click the underlined column heading to sort the data in ascending order (indicated by the up triangle)
- Click the heading again to sort the data in descending order (indicated by the down triangle)
- Click the Maximize icon (on the right-hand side of the module to expand the module
- Click the Minimize icon () on the right-hand side of the module to return the module back to its original size



To Restore Default Settings:

• Click the Default Settings button (or restore default settings on all pages

Please Remember the Following:

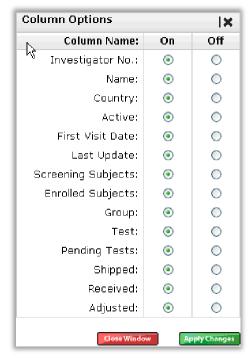
- Cookies must be enabled in your browser
- If cookies are deleted, the default settings will be restored
- Clicking the "Default Settings" button will restore default settings on all pages

How to Hide Columns in a Module

All columns in LabLink's modules can be displayed or hidden to suit your preference.

To Display or Hide a Module's Columns:

1. **Click** the Column Options icon (on the right-hand side of the module to display the Column Options window



- 2. Click the Off button to hide a column
- 3. Click the On button to display a column
- 4. Click the Apply Changes button to adjust your module

Important Note: When you view PDF or Excel files of your modules, only the displayed columns are included. If you print using the printer icon () under the Reports button, all columns are printed regardless of their visual status.

Note: These changes are not saved and return to default status when you log out of LabLink.



How to Filter Module Data

Module Functionality allows you to filter module list data to quickly find what you are looking for.

Note: Different modules will have varying degrees of filtering options. The following are ways to filter various module lists

Filtering by Drop-Down List

Some columns in LabLink can be sorted by selecting a preference from the drop-down list below the column heading. The drop-down list below the Sponsor heading is one example.

To Filter a Module by Sponsor

1. In the Sponsor column, **Select** a sponsor of interest to display only that sponsor's protocols



Note: These changes are removed when you log off of LabLink.

Filtering by Text Fields

Some columns in LabLink can be sorted by providing characters or numbers in the field below the column heading. The field below the Protocol heading is one example.

To Filter a Module by Protocols

- 1. In the field below the Protocol heading, Type all (or part) of a protocol's name
- 2. Press the Enter key on your keyboard to display only the matching protocols



Note:

- The filter text fields are not case sensitive and partial text is allowed.
- o Please **avoid** using wildcards as they will cause no data to be returned.
- To clear the filtering, delete the characters or numbers in the field and press the Enter key on your keyboard.

Filtering by Date

Some columns in LabLink's modules can be sorted according to conditions relative to a date (e.g., after 01-JAN- 1970). At first, these columns are identified by the No filter link.

To Filter a Module by Date:

1. Click the No filter link to display the LabLink Date Control window





2. Click a data filter that matches your time frame



- 3. **Provide** the date information
- 4. Click the Send button to change how the column is displayed

Note: These changes are removed when you log off of LabLink.

How to Hide and Restore a Module

All modules in LabLink can be hidden until you are ready to show them again.

Note: Currently the settings do not persist between user sessions.

To Hide Module Rows:

• Click the Hide icon (on the right-hand side of the module to hide the rows

Report List

To Show Rows Those Are Hidden:

○ Click the Show icon (≦) on the right-hand side of the module to hide the rows

How to Maximize or Minimize a Module

All modules in LabLink can be expanded to "cover" other modules to give you an uncluttered view. Likewise, you can "uncover" the modules by minimizing the expanded module again.

Note: Currently the settings do not persist between user sessions.



To Maximize a Module:

• Click the Maximize icon () on the right-hand side of the module to expand the module

Note: When a module is maximized, it has the capability to display \sim 170 rows of data. The rest of data will be paged.

To Minimize a Module:

• Click the Minimize icon (on the right-hand side of the module to return the module back to its original size

How to Print the Module's Data in a Printer-Friendly Format

The data in LabLink's modules can be viewed, printed, and export to Adobe PDF or Microsoft Excel files.

To View and Print a Module in Printer-Friendly Format PDF:

- 1. **Click** the View PDF Report icon (on the right-hand side of the module to display the File Download window
- 2. Click the Open button to display the module in Adobe's software
- 3. Select Print from the File menu to print your module

To View and Print a Module in Excel Format:

- 1. **Click** the View Excel Report icon (on the right-hand side of the module to display the File Download window
- 2. Click the Open button to display the module in Excel or compatible software
- 3. Select Print from the File menu to print your module

To Export and Save Module Data in PDF:

- 1. **Click** the View PDF Report icon (on the right-hand side of the module to display the File Download window.
- 2. Click the Save button to display the Save As window.
- 3. If needed, **Select** a folder and **Click** the Save button.

To Export and Save Module Data in Excel:

- 1. **Click** the View Excel Report icon () on the right-hand side of the module to display the File Download window
- 2. Click the Save button to display the Save As window
- 3. If needed, **Select** a folder and **Click** the Save button

Note: When you viewing, printing, or exporting to PDF or Excel files of your modules, only the displayed columns are included. If you print using the printer icon () under the Reports button, all columns are printed regardless of their visual status.

Note: Microsoft Excel (version 2003 and earlier) will only show 65,536 rows of data. Adobe PDF will show 50,000 rows of data. Please see these third-party companies' websites for more information.



Note: If your computer does not have the Adobe Acrobat Reader installed, you will not be able to view or print the Adobe PDF report. Please consult with your local IT department for software installation.

