LDMS™

LDMS for Windows User Manual

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LDMS User Manual

For The Laboratory Data Management System, Version 11.0

Frontier Science and Technology Research Foundation, Inc.

4033 Maple Road
Amherst
New York
14226-1056
United States
Tele: (716) 834-0900
Fax: (716) 833-0655

LDMS User Manual: For The Laboratory Data Management System, Version 11.0

by

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About This Manual

This user manual is for the current version of LDMS for Windows. For the most part, the content of this manual will also apply to previous versions of LDMS.

For more information about LDMS, visit the LDMS website [http://www.fstrf.org/ldms].

Chapter 1. Getting Started

What is LDMS?

The Laboratory Data Management System (or LDMS) is a comprehensive specimen management application built specifically for medical research laboratories. It is used by research institutions to manage specimen inventories, prepare and process specimen shipments, generate barcode labels, and much more.

Initially released in 1998 to collect data for the Adult and Pediatric AIDS Clinical Trials Groups (AACTG and PACTG), LDMS has been built with the needs of medical research laboratories in mind. While LDMS is most widely used among clinical trials networks that study HIV/AIDS and related infections, it is also used in many other medical research areas. In addition to using LDMS to complete work for certain trial networks, laboratories can use LDMS for managing independent work as well, such as studies or trials that are only taking place at one or two laboratories.

For small and medium sized research-oriented laboratories, the ease of adopting LDMS is very appealing. LDMS is designed to work out-of-the-box without any significant setup or configuration. LDMS User Support, which is included as part of LDMS's license agreement, can assist users with every aspect of using LDMS, including installation, seven days a week, 24 hours a day. This is a great help to laboratories without a dedicated I.T. support staff.

LDMS development is driven in significant ways by the needs of its users. Many features and updates in LDMS are added as a direct result of a user request. The LDMS team actively maintains relationships with network leadership and individual laboratories, and updates LDMS, organizes special training sessions, and writes custom documentation based on each one's unique needs.

Despite catering to smaller organizations, LDMS is built to scale to the size of the laboratory. A powerful Oracle® back-end allows LDMS to be capable of managing millions of specimens. This means that LDMS can be used at large repositories without sacrificing the ease of setup and maintenance that smaller laboratories enjoy.

Some research institutions use LDMS as a tool for transferring data to Frontier Science, a data management center for many research studies.

Who is Frontier Science?

Frontier Science and Technology Research Foundation (FSTRF /fis-triff/, or just Frontier Science), is the not-for-profit organization that develops and maintains LDMS.

Frontier Science provides data management services to research organizations—LDMS is one of those data management services. Many groups that use LDMS also utilize Frontier Science to manage that data. In fact, LDMS has a built-in mechanism for sending certain laboratory data to the Frontier Science Data Management Center (often referred to as the "DMC") in Amherst, New York.

Frontier Science is involved in many other statistical research efforts beyond LDMS. To learn more about the work that Frontier Science does, visit the Frontier Science website [http://www.fstrf.org].

Getting Started with LDMS

Getting LDMS Installed

If you do not have LDMS installed, contact Frontier Science as they will facilitate installation. As part of this process, your laboratory will be assigned a unique LDMS laboratory ID by Frontier Science. A *laboratory ID* is a 3-digit number that uniquely identifies a laboratory. This ID is used in several places in LDMS:

- It is used to generate *global specimen IDs* for specimens, a number that uniquely identifies a single specimen across all laboratories using LDMS.
- It is used for shipping specimens between laboratories.

Your LDMS laboratory ID will be assigned to you by Frontier Science prior to the installation of LDMS. Once this ID has been assigned to you, LDMS User Support will coordinate the installation of LDMS for you.

For more information on the process of getting LDMS installed, contact LDMS User Support. See the section called “Getting Help” on page 10.

Upgrading to the Latest version of LDMS

Frontier Science releases major updates for LDMS several times each year. An email notification is sent to users when a new version is available. It is important that you upgrade when a new version is released so that your laboratory has access to the most secure, stable, and feature-rich version available.

If you already have LDMS installed, you can upgrade to the latest version yourself by downloading and running a software update. To determine what version of LDMS you are currently using, click `HelpAbout` from the LDMS menu bar.

Important

If you are running LDMS in a client-server setup, you must upgrade LDMS on the server prior to upgrading the client machines.

Procedure 1.1. Upgrading LDMS

1. Prepare for installation.
   - Using LDMS, create a current backup of your LDMS database. See Procedure 9.6, “Manually generating a backup file”.
   - Close all programs (including LDMS) on the computer. It is a good idea to reboot the machine.
   - Ensure that you have full local administrative privileges on the computer. These will be required to complete installation.
2. Obtain the LDMS software update. There are two ways to get it:

- Visit the Frontier Science website [http://www.fstrf.org/portal]. Click the **Get LDMS Updates** link from the section entitled **LDMS User Support**. There you will find a link to download any available LDMS updates.
- Get an installation DVD by contacting LDMS User Support. See the section called "Getting Help" on page 10.

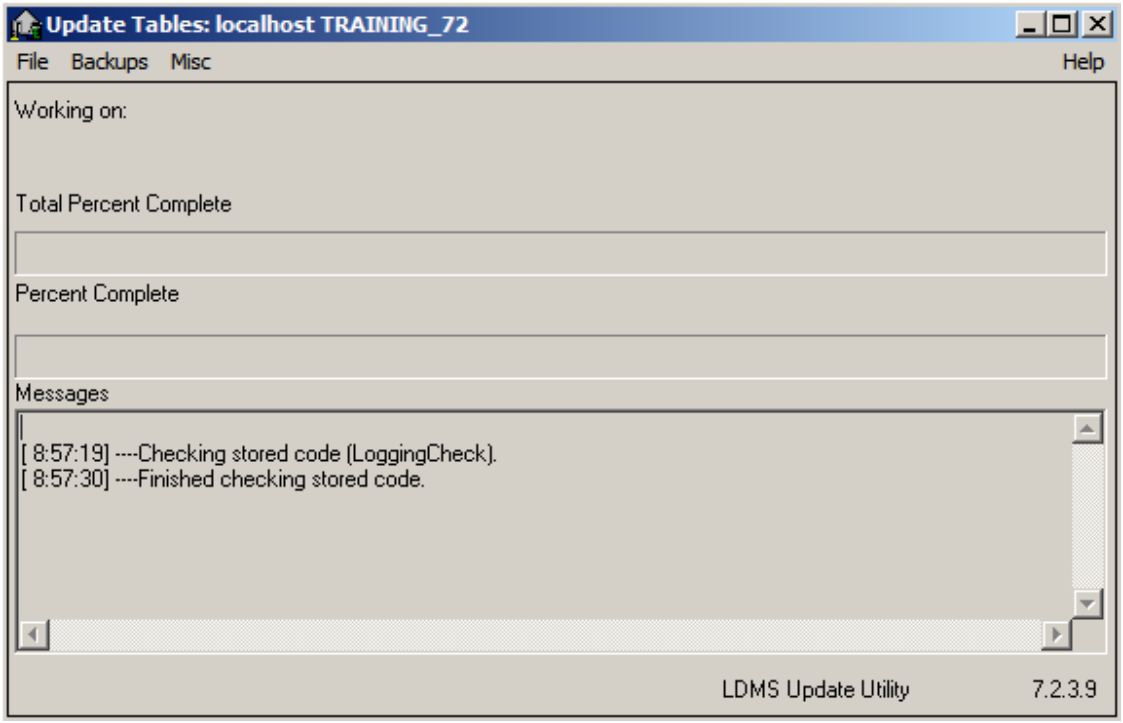
3. Run the installer.

   Important

   During installation, LDMS will need to update your LDMS database (see Figure 1.1). The time required to complete this process will vary, depending on the amount of data at your laboratory. For large laboratories, this process could take several hours. *Do not interrupt this process or turn off your computer*.

4. Once the update has finished, attempt to start LDMS. You will be prompted to contact LDMS User Support to unlock LDMS before you can use it again.

Figure 1.1. Table update screen



▲ This window will show the progress of updating your LDMS database during the upgrade; do not close this window or turn off your computer.

If you encounter any difficulties or need assistance upgrading, do not hesitate to contact LDMS User Support. See the section called "Getting Help" on page 10.

Setting up an LDMS Client-Server Environment

LDMS can be set up so that multiple computers running LDMS utilize the same LDMS database. LDMS is installed on one computer and acts as the server; LDMS is then installed on other computers (the clients) connected to the same local network, and access the LDMS database on the LDMS server. Doing this allows you to have multiple computers with LDMS installed that can access the same data. The LDMS sever does not need to be a dedicated sever either—you can use the sever like any other computer with LDMS to add specimens, read assay results, etc.

Important

The LDMS server and all clients must be running the same version of LDMS. Upgrades must be performed on all machines at once, with the server machine upgraded first.

Procedure 1.2. Installing LDMS for client-sever setups

1. Install LDMS on the computer to act as the LDMS server and perform any needed updates. See the section called “Getting LDMS Installed” on page 2.
2. Locate the LDMS reports directory on the server machine. This location will need to be accessible to LDMS clients, such as a shared network location. A typical location may be `\\[machine name]\[drive letter]\fstrf\reports`.

   ### Important

   This directory must be a shared directory and clients must have `full control` permissions for it. To make this directory more secure, you can obtain a list of Windows login usernames for the people that will be using LDMS and modify permissions on the `reports` directory so that only those users will have permissions to access it.
3. Install LDMS on each client computer that will be connecting to the LDMS server.
4. On the client machine(s), open `C:\fstrf\assay\bin\lldms.ini` in a text editor such as Notepad. Update the following settings (replace `###` with your 3-digit LDMS laboratory ID number):

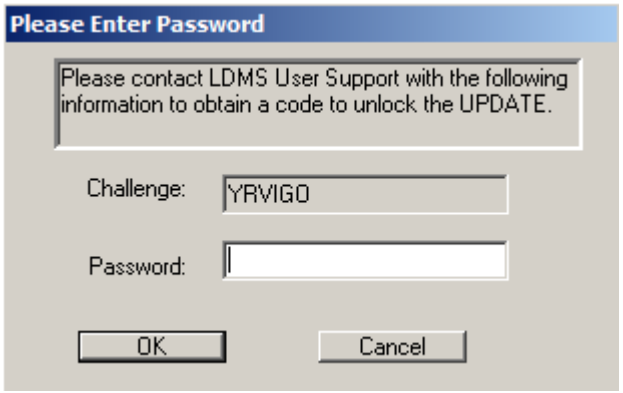
   ```
   OracleDatabaseServerName=servername:1521/xe
   OracleDatabaseSchemaName=LAB###
   DBPATH=\\servername\fstrf\reports
   REPPATH=\\servername\fstrf\reports
   ExportDir=\\servername\drive\fstrf\reports\Export
   ```
5. Start each LDMS client and ensure that all of them open without error.

You must set up a printer for each LDMS client individually (as well as the server, if you will be using it for normal work). For instructions on setting up a printer and why it is important in LDMS, see the section called “Setting Up a Printer for LDMS” on page 6.

LDMS and Challenge Passwords

The first time you start LDMS after installation or after an upgrade, or if you attempt to access specific features in LDMS, you will see a message asking for a password. See Figure 1.2.

Figure 1.2. Challenge password window



▲ You must give the **challenge** code to LDMS User Support, who will use it to generate the correct password.

This message means that you must contact LDMS User Support and provide them with the letters listed in the **Challenge** field. LDMS User Support will use this information to generate and provide you with a **Password** to enter.

> **Important**
>
> After providing LDMS User Support with a challenge code, do not close the challenge password window. Doing so will generate a new challenge code and thus a different password. Leave the password window open until you receive the password from LDMS User Support.

If LDMS encounters a serious problem and shuts down unexpectedly, you may also be asked to provide a challenge password. In these situations, there will be a description of the problem in the challenge password window. When contacting LDMS User Support, you will be asked to provide those details. This information is very important, not only for ensuring that there has been no damage to data at your laboratory, but also to help improve LDMS in general.

The purpose of this locking mechanism is protect LDMS's database from accidental damage. Due to the size and complexity of the data with which LDMS works, certain features could cause damage to your LDMS database if used incorrectly. Certain actions in LDMS also require the approval of leadership for certain networks, and this locking mechanism helps facilitate that process.

For instructions on how to contact LDMS User Support, see the section called “Getting Help” on page 10.

Logging into LDMS for the First Time

LDMS requires users to log in with their own, unique user name and password. The first time you start LDMS, you need to create a new user to act as your system administrator. This person will have the ability to create accounts for other users.

Procedure 1.3. Creating your first LDMS User

1. Log into LDMS with the temporary user `ADMIN`, and the password `admin`. This is the only time you will use this account.
2. From the LDMS menu bar, click `AdministrationUser Configuration`
3. Click the New User button to create an account for your system administrator.
4. Enter the login name for the person into the **User Name** field. User names must be unique at your laboratory. A good idea is to use person's first initial and last name (e.g. `jdoe` for "John Doe").
5. Enter the user's full name into the **Real Name** field.
6. Enter the user's initials into the **Initials** field. By default, the user's initials are used by LDMS in specific places to document the user making a change or entering data.
7. Click the **OK** button.
8. Enter a password for the user into the **New Password** and **Confirm Password** fields. The passwords must match.
9. Select the **System Administrator Capabilities** check box.
10. In the **Menu Permissions** list, click the column header labeled **Full** to give the user access to all features in LDMS.
11. Click the button from the LDMS toolbar.
12. From the **User ID** drop down list, select `ADMIN`.
13. Click the Delete button.

14. When prompted to save your changes, click the **Yes** button.

From now on, the user that you created will act as the administrator for your LDMS system. They will be able to create new users and manage what users can do within LDMS. You can create more than one user with these administrative capabilities. For more information on managing users, see the section called “Managing Users” on page 168.

Changing Users

You must be logged into LDMS to use it—there is no concept of a guess account in LDMS. The current user is displayed in the status bar at the bottom of the screen.

To change to a different user after logging in, click **Ctrl+Shift+L**`AdministrationSession Lock` from the LDMS menu bar. This is also how you would lock LDMS if you need to leave a computer station unattended. By Default, LDMS will automatically lock and require a user name and password after 30 minutes of inactivity.

Warning

If you click the **Cancel** button on the login screen, LDMS will close. If there is unsaved work on the screen, you will not be given the opportunity to save it.

Date and Time in LDMS

Every time you log into LDMS, you'll be asked to confirm the date and time. *It is very important that the date and time are correct as this information is used throughout LDMS*.

The date and time LDMS will use is pulled directly from your computer's system time. If the date or time is not correct, you must update it within Windows. This is typically done by right-clicking on the system clock on the Windows task bar.

Setting Up a Printer for LDMS

LDMS pulls the settings for your printer directly from Windows for certain tasks. This is especially important for generating labels. LDMS will access the driver software for your printer to get information such as the paper size, and use this information when generating the labels. If a printer is not specified in LDMS, the labels may not be generated correctly.

For instructions on setting the printer that LDMS uses to generate labels, see the section called “Setting the Printer Used to Generate Labels and Reports” on page 153.

Finding Your Way Around

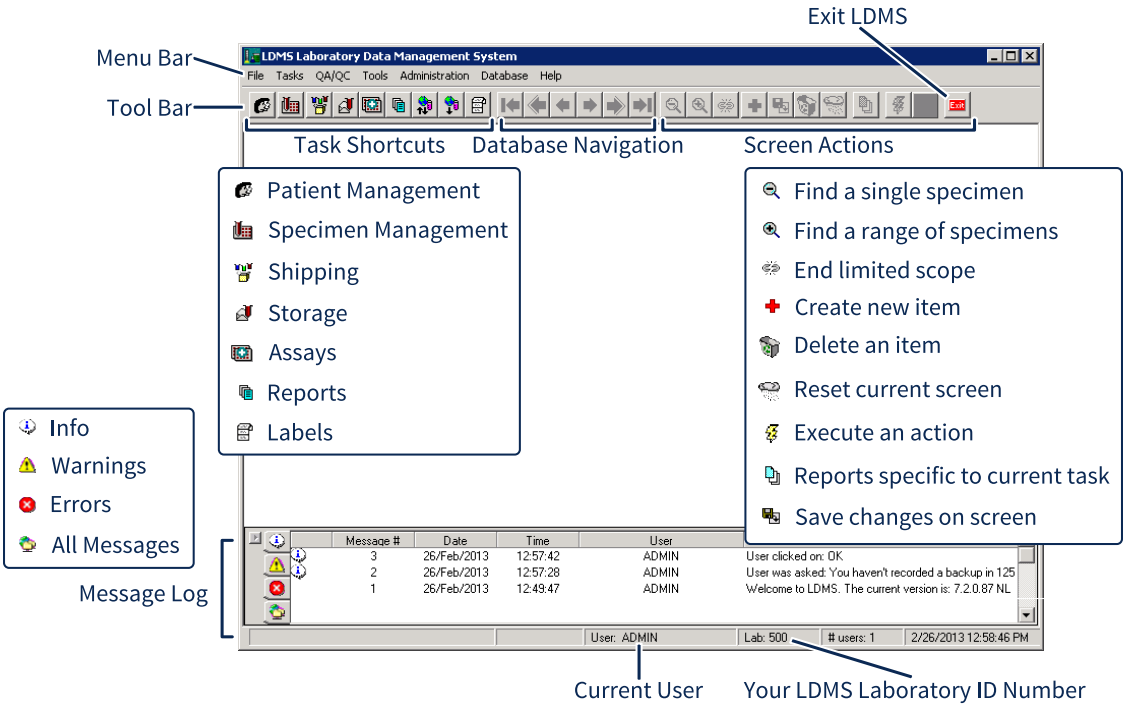
LDMS is task-oriented by design. When you start doing something, you are performing that task only. To switch from performing one task (such as entering specimens) to doing another (configuring an assay), you need to stop doing the first task. You can't be doing two tasks at once.

When LDMS first starts, you will see a white screen. To start working, select a task from the LDMS menu bar or tool bar. For example, you can click the  button to start Specimen Management and enter specimen data. To change tasks and ship the specimens you just entered, you'd need to click the  button to leave Specimen Management, and then click the  to open Shipping. This is why, when you start working, you'll notice that most of LDMS's menu and tool bar buttons become disabled.

Tip

The button is used to *leave* a task in LDMS; the Exit button is used to *exit* LDMS itself.

Figure 1.3. Main LDMS Screen



▲ A brief overview of where to find certain features in LDMS

All of the task shortcuts on the toolbar are identical to the tasks listed in the `Tasks` menu on the menu bar. Likewise the database actions in the toolbar can also be found in the `Database` menu.

Let's take a brief look at what each button does:

Add	This action *adds* something you're doing on a screen, such as creating a *new* report or adding a new specimen. Notice the distinction between and the **Save** button. Saving is what you do when you are modifying something that already exists; adding is what you do when you're saving something new.
Save	This action *saves changes* that you've made to a screen. It's different than adding a record in that the record already exists. On most screens in LDMS, you'll get a warning message if you try to leave without saving changes.
Execute	This action *does something*. For example, if you are on a screen that lets you search for something, the **execute** button will initiate that search.
Refresh	This action *clears* a screen of things you entered. It doesn't undo entering a record (LDMS does not have an undo function); it simply clears data that's been entered so that you can start fresh. So if you started entering information and just want to start again, click this button.
Specimen Management	This is where you go in LDMS to enter new specimens, and modify or view existing specimens. All specimens begin their

life in LDMS here. New study participants can be added to LDMS when you are creating specimens too. You can also print labels, flag specimens for shipment or for testing, and much more. Using Specimen Management is explained in detail in Chapter 2: “*Specimen Management*” on page 11.

Patient Management — This is where you go in LDMS to modify existing study participants, such as adding or correcting study enrollment. New participants can also (but are generally not) added here. Using Patient Management is explained in detail in Chapter 4: “*Patient Management*” on page 59.

Storage Management — This is where you go in LDMS to see or change a specimen's storage location. LDMS allows you to define a virtual storage structure in your LDMS database that corresponds to your real-life storage items. There are freezers, shelves, racks, etc. Using Storage Management is explained in detail in Chapter 3: “*Storage* ” on page 43.

Shipping — This is where you go in LDMS to send or receive specimens to or from another laboratory. LDMS transfers data between laboratories by creating shipping files. A shipping file contains specimen information that goes with a physical shipment of specimens. The receiving laboratory can import this shipping file to add the specimens to their own LDMS database. Using the Shipping feature is explained in detail in Chapter 5: “*Shipping*” on page 63.

Assays — This is where you go in LDMS to read assay data and associate it with specimens. LDMS supports a variety of assays and assay reader devices. All of the assays available and how to use them with LDMS is explained in detail in Chapter 6: “*Assays*” on page 81.

Reports — This is where you go in LDMS to generate a wide variety of pre-configured reports. There are dozens of reports available. For a description of all these reports, see the section called “Descriptions of Built-in Reports” on page 135. LDMS can also generate custom reports using the Data Retrieval tool, which is explained in the section called “Running Custom Data Retrieval Reports” on page 134.

Labels — This is where you go in LDMS to create new, custom label formats for specimens. You can also print labels for numerous specimens at once. The Labels feature and printer configuration in LDMS is explained in Chapter 8: “*Labels and Printer Configuration*” on page 149.

Database Navigation — These buttons are used in a few places in LDMS to move between entries. Most notably, they are used in LDMS Specimen Management to move between specimen records. They are also used on some assays to change between specimens when multiple specimens are being tested.

Browse and Extended Search — These two buttons are used to find specimens. Their primary purpose is in LDMS Specimen Management, where they are used to search for specimens. **Browse** is used to find exactly one specimen; **Extended Search** is used to find a range of specimens. Extended Search is also available in a few other places in LDMS to help find specimens. For instructions on using these features, see the section called “Finding Aliquots After Logging Them” on page 32.

Begin/Break	This button is only used in LDMS Specimen Management in conjunction with the button. When you use , you are limiting the specimens that are displayed. Clicking button removes this limited scope. For more information, see the section called “Finding Aliquots After Logging Them” on page 32.
Reports (feature specific)	This button's function is different than the button. The button is used to generate reports that are specific to whatever you are doing in LDMS at that moment. For example, if used while setting up an assay in LDMS, it will generate reports specific to your assay layout. If you use it in LDMS Shipping however, it will generate reports specific to shipping specimens. When you are doing something without any associated reports, this button will be disabled.
Close	This button is used to leave a feature in LDMS. For example, if you are using LDMS Specimen Management and you want to move to LDMS Shipping, you must click the button.
Exit	This button closes the LDMS program.

Keyboard Usage

Much of the work you will complete in LDMS is data entry. For these types of tasks, working with just the keyboard can be a lot faster than switching between the keyboard and a mouse pointer.

Many screens in LDMS are designs so that you can complete large sections of them quickly using just the keyboard. In Specimen Management, for example, you can press the **Tab** key after completing each field to move on to the next one.

LDMS menus can also be navigated using just the keyboard. Press the [Alt] key. Notice that certain letters in the menu bar are now underlined? If you press the corresponding key, those menus will open. You can also you your keyboard's arrow keys to navigate menus.

LDMS also has several key combinations that perform a specific function.

Shortcut	Toolbar Icon	Description
Alt+F3	--	Close current task
Alt+F4	--	Exit the LDMS program
Ctrl+A		Add record
Ctrl+D		Delete record
Ctrl+G		Refresh the screen
Ctrl+H	--	Show a helpful description of the currently selected item on the screen
Ctrl+S		Save changes made on a screen
Ctrl+B		(In Specimen Management) Exit restricted scope when using extended search
Ctrl+E		Display the last data record
Ctrl+P		Display the previous data record
Ctrl+N		Display the next data record

Shortcut	Toolbar Icon	Description
Ctrl+F	⏭	Display the first data record
Ctrl+W		(In Specimen Management) Open the Browse feature
Ctrl+Z	--	(In Shipping on the QA/QC tab) Pass the selected aliquot
Ctrl+X	--	(In Shipping, on the QA/QC tab) Fail the selected aliquot

Getting Help

One of the unique things about LDMS is that Frontier Science, the not-for-profit organization that develops and maintains LDMS, works closely with both laboratories and research groups. These relationships allow LDMS User Support and LDMS Training to cater to each laboratory's specific needs.

There is a lot of LDMS documentation available on the Frontier Science Portal [http://www.fstrf.org/portal]. Look for the **LDMS Documentation and Training** link under the **LDMS User Support** heading. In addition to this manual, there are also small, topic-specific reference and video tutorial that demonstrate how to use specific features in LDMS.

LDMS User Support is available to laboratories 24-hours per day, every day. They can assist you by telephone or by e-mail. They can even connect remotely to your LDMS computer to help. LDMS User Support can assist with more than just technical issues—they can also answer your questions about using specific features in LDMS.

LDMS Training is also available. In-depth training sessions are held at Frontier Science's data management center in Amherst, New York several times each year. There is no registration cost to attend these trainings (though travel accommodations are not provided by Frontier Science). Frontier Science can also arrange for a trainer to come to your site to assist you. Finally, web-based conference calls can be setup as needed to address specific LDMS usage topics.

LDMS Support Contact Information

Administrative Support	E-mail <ldmsinfo@fstrf.org>
LDMS Training	E-mail <ldms.training@fstrf.org>
LDMS User Support	E-mail <ldmshelp@fstrf.org> or call (716)-834-0900 extension 7311

For the latest LDMS news and training information, visit the LDMS website [http://www.fstrf.org/ldms].

Submitting Corrections and Questions For This Manual

We are always working to make corrections and improvements to this manual. If you have a suggestion or would like to submit a correction, or would like to request the inclusion of a new topic, please let us know by contacting <ldms.training@fstrf.org>.

Chapter 2. Specimen Management

Introduction

Context-Sensitive Help in LDMS

For many fields in LDMS, press **Ctrl**+**H** after selecting the field to open a help window. This works in drop-downs in Specimen Management, for example, to show you what address is associated with a clinic code or what an additive code actually means. Whenever you don't know what something is, select it and press **Ctrl**+**H**.

LDMS Specimen Management is the place where specimen information is entered and maintained in LDMS. This is where you can add new specimens, correct issues with existing specimens, add new participants, assign tests, mark specimens for shipment, etc. Specimen Management is the only place in LDMS where new specimens can be created.

To work with LDMS in general, there are two important points to understand:

1. LDMS is *aliquot-driven*: Records in LDMS's internal database are organized by primary and aliquot, and aliquots are the basic unit of information. All actions in LDMS (testing, shipping, and storing) happen to aliquots.
2. LDMS is also *group-driven*: When a group is selected in Specimen Management (and you must select a group), LDMS enforces rules for specimen entry determined by leadership for that group. Frontier Science works closely with network leadership to maintain each group's rules within LDMS.

Important terms in LDMS

aliquot	This is the derived unit from the primary.
frozen time	The time that specimen is put into a freezer and the freezing process begins.
global specimen ID	A number assigned by LDMS to every primary and aliquot. It is unique among all specimens at all LDMS laboratories, and clearly shows the relationship between primaries and aliquots.
group	Individual clinical trial networks, research groups, etc available in LDMS. Every specimen and participant enrollment must be associated with a group.
participant (or patient)	The individual from whom you've collected samples. The words participant and patient are used interchangeably in this manual.
participant (or patient) ID	
primary	This is the sample that was collected from the participant, such as a tube of blood.
processing time	The time that the processing laboratory *begins* to process a specimen into aliquots.
received date	

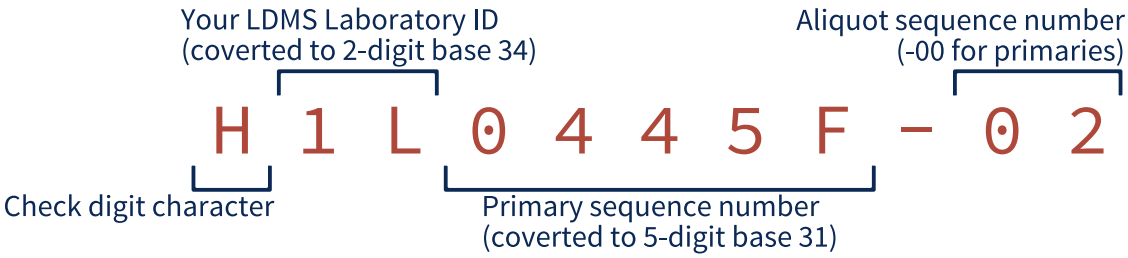
	The date that the specimen was received at the processing laboratory, where the primary was processed into aliquots.
received time	The time that the specimen was received at the processing laboratory.
specimen	This is a generic term for either primaries or aliquots.
specimen date	The date that the specimen was collected from the study participant.
specimen ID	An identifying number assigned by LDMS to primaries and aliquots that is not necessarily unique, and does not show the relationship between primaries and aliquots. By default, this number is unique per derivative type.
specimen time	The time that the specimen was collected from the study participant in 24-hour format.
visit ID	The combination of the visit and visit unit (such as `1 WK`).

Specimen Identifiers

Every specimen in LDMS is assigned two identifying numbers: *specimen ID* and *global specimen ID*. [1]

The *global specimen ID* is a unique number generated by LDMS for every specimen logged. It is unique not just at your laboratory but at all laboratories using LDMS. The global specimen ID is 10 characters long. The last two characters are the aliquot sequence, with the first aliquot numbered `-01`, the second being `-02`, etc. The aliquot sequence for a primary is `-00`.

Figure 2.1. Global specimen ID format



▲ An example *global specimen ID*; this number is unique for each aliquot and is assigned by LDMS.

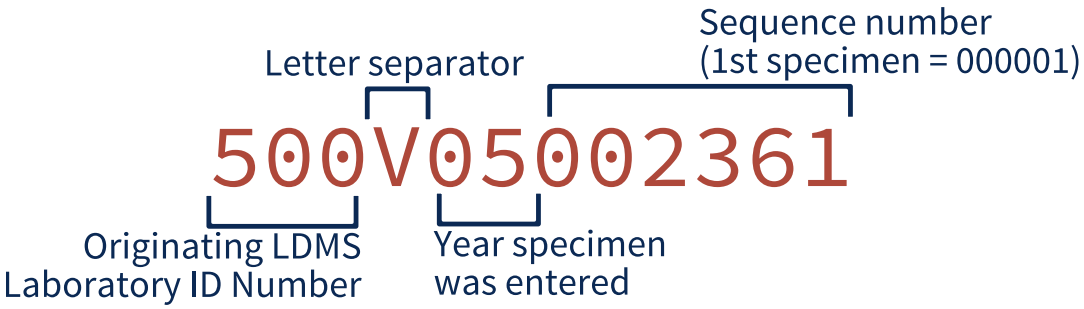
The *global specimen ID* is not generated until you actually add the specimens and aliquots to your database. Once used, the global specimen ID will never be reused, even if the specimen is deleted.

Specimen IDs, unlike global specimen IDs, are not necessarily unique. They are generated for a primary as soon as you've entered the primary and additive type. By default, primaries with the same type and additive will have the same specimen ID. For example, if you drew two vials of

[1] There is a third identifying number called the *other specimen ID*. LDMS does not generate the *other specimen ID*, nor does it enforce any rules for its usage. It is there to accommodate unique workflows, such as internal groups at a laboratory.

blood at the same visit and used the same additive, you essentially have 2 specimens that are the same. LDMS does provide users with the ability to customize how the specimen ID is generated.

Figure 2.2. Specimen ID format



▲ An example *specimen ID*; the six digit sequence resets back to `000001` at the beginning of each year.

Specimens Converted from RLMP

Early in LDMS's life, many specimens were imported from an another platform called the Retrovirus Laboratory Management Program (RLMP). These specimens have a unique specimen ID that you may encounter if you are working with older specimens (or data from older specimens). They appear in the format `048R98001145`, where 048 is the LDMS laboratory number and R indicates that the specimen was converted from RLMP.

The way LDMS generates *specimen IDs* (not *global specimen IDs*) can be adjusted. If you do adjust it, the changes will take effect for new specimens; existing *specimen IDs* will not be modified.

Procedure 2.1. Changing the default method for generating specimen IDs

1. Click `AdministrationDefine Specimen Numbering`.
2. Select one of the following options:
   - If you want all primaries to have the same *specimen ID* regardless of additive, select **No unique number**.
   - If you want primaries to have a unique *specimen ID* for each additive, select **Unique number for EACH additive**.
   - If you want the *specimen ID* to be unique for every primary, select **All unique number**.
   - (Optional) If you want the *specimen ID* to be unique for each aliquot of each type of derivative, select **Unique number for EACH derivative**.
3. Click the **OK** button.

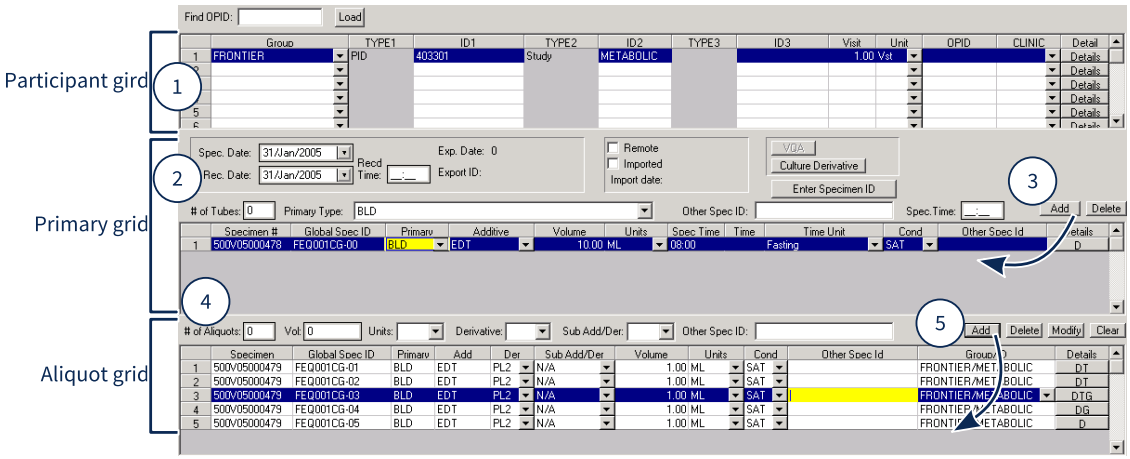
Warning

You can only change the way LDMS generates *specimen IDs* once. If you do change it, you will not be able to do so again.

Entering a New Specimen

Entering a specimen in LDMS is a multi-step process, and many networks have their own rules and workflows. You should always follow the procedures defined by individual groups. The material in this section should, however, apply to most specimen entries.

Figure 2.3. Specimen Entry Workflow



▲ The numbered call-outs are referenced in Procedure 2.2, “Entering a new specimen”.

Procedure 2.2. Entering a new specimen

1. Enter the participant's information into the **Patient Grid** at the top of the screen. (#1 in Figure 2.3)

    a. Select a **Group** (sometimes called the network) from the drop-down. This must be done first because it affects other fields.
    b. Enter **ID1** for the participant. For many groups, this is called the *PID* or patient identifier, and its format is specific to that group.
    c. Enter **ID2** for the participant. For many groups, this is a study or protocol number.

    Note

    For most groups, studies are selected from a pre-populated list. Studies can be added or removed by Frontier Science as needed. If you are looking for a study but find that it is not available, contact LDMS User Support. See the section called “Getting Help” on page 10.

    d. Enter **ID3** for the participant. This is often a sub-study number though some do not require or use this field.

    Note

    For networks that use ID3 for **SID** (study identifier), NOSID may be a valid entry. You would do this when a SID hasn't be assigned yet, then update the participant's information later once it has been assigned. For more information on how to correctly make this update, see the section called “Finding and Modifying Participant Information” on page 59.

    e. Enter the **Visit** and **[Visit] Unit** for the this particular specimen entry.
    f. Enter the clinic for this particular specimen entry. If you want to know what clinic is associated with a code, select it and press **Ctrl**+**H**
    g. To enter additional information, such as whether or not the participant was fasting, click the Details

2. Enter the information for the first primary into the **Primary Grid** in the middle of the screen (#2 in Figure 2.3).

    a. Enter the **Spec[imen] Date** from the drop-down. This is the date that the specimen *was collected from the participant*.

   b. Enter the **Rec[eived] Date** from the drop-down. This is the date that the specimen *was received by the processing laboratory*.
   c. Enter the **Rec[eive]d Time** into the bottom. This is the time (in 24-hour format) that the processing laboratory received the specimen.
   d. Enter the number of tubes collected for the primary into the **# of Tubes** box. If you're planning to pool multiple primaries together, enter one.
   e. Select the **Primary Type** from the drop-down. If you need to enter more than one type of primary, they must be added as separate tubes.
   f. (Optional) Enter the **Other Spec[imen] ID**.
   g. Enter the **Spec[imen] Time** in 24-hour format. This is the time that the specimen *was collected from the participant*.
3. Click the Add button (#3 in Figure 2.3). This will add the number of tubes you entered to the primary grid below.
4. For each primary added, select an **Additive** from the drop-down. After doing this, the *Specimen ID* will be generated (the *Global Specimen ID* isn't generated until you click the ✚ button later.
5. For each primary added, enter the **Volume** and **Units** for the primary. It is acceptable to pool primaries of the same type for the same participant together. (e.g. two 10 ML tubes drawn from the same participant, with the same additive, and the same **specimen time** can be entered as become one 20 ML tube).
6. Click a primary row to select it (it will be highlighted). When an aliquot is added, they will be derived from this primary.
7. Enter information for the first aliquot into the aliquot grid. (#4 in Figure 2.3)

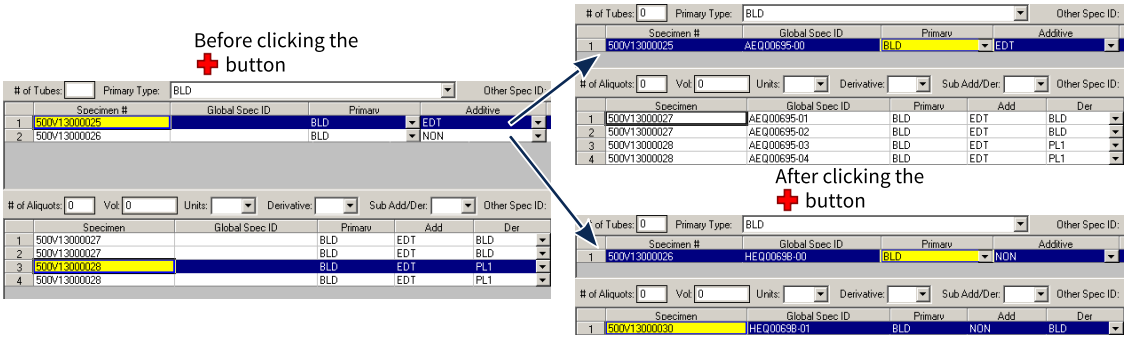
   a. Enter the number of aliquots that were derived from this primary for a specific derivative type into the **# of aliquots** field. If you have more than one type of derivative for the primary, they must be added separately.
   b. Enter the **Vol[ume]** and **[Volume] Units** for the aliquots. This is the volume *per aliquot*, not the total.

      Note

      `CEL` (cells) is expressed in millions in LDMS. For example, if you need to enter 2 million CEL, enter 2 into the **Vol** field, not `2,000,000`. When you click the ✚ button later to add the records later, the volume will automatically be converted to millions.
   c. Select the **Derivative** type from the drop-down.
   d. Select the **Sub Add[itive]/Der[ivative]**.
   e. Click the Add (#5 in Figure 2.3).
8. After all of the primaries and aliquots have been added, click the ✚ button from the LDMS toolbar.
9. If the group and ID1 combination have never been entered before, LDMS will prompt you to add the new participant to LDMS.
10. LDMS will prompt you to print labels for your aliquots. Select the group from the **Format** drop-down, the **Barcode Content** and label **Size**. For more information on labels, see Chapter 8: "*Labels and Printer Configuration*" on page 149.

When you are entering specimens, you'll see all the primaries for a particular visit, as well as all the aliquots derived from each primary on the same screen. *This is the only time you'll see all this visit information on the same screen*. Once you click the ✚ button, the entries will be split up by primaries. If you click the ⏭ button from the LDMS toolbar, you'll see the last primary. Using the database navigation buttons ⏮ ⏪ ◀ ▶ ⏩ ⏭ from the LDMS toolbar, you can see that all of the primaries for the visit are now on different screens.

Figure 2.4. The Specimen Management screen before and after adding records



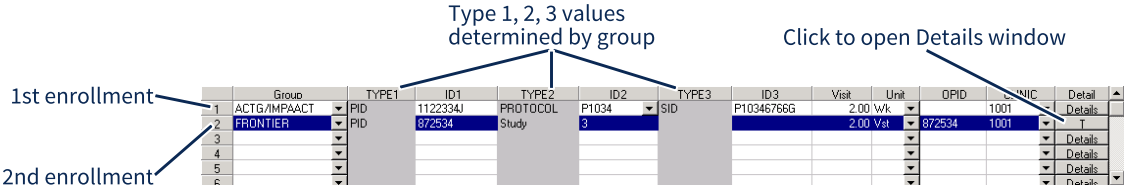
▲ The left side shows how a visit will appear when it is being entered; the right side shows how two different primaries are split into two different records.

Understanding the Specimen Management Screen

The Patient Grid

The patient grid is the top portion of the LDMS Specimen Management screen. This is where you enter participant information for the specimens you are about to enter. Specimens can only be entered for one participant at a time, however, co-enrollments (meaning one participant who is enrolled in more than one study) can be entered together.

Figure 2.5. The Patient Grid from the Specimen Management Screen



▲ This image shows how one participant can be enrolled in two studies at once. In this case, the participant is enrolled in ACTG/IMPAACT and FRONTIER studies.

Co-enrollments require additional handling when entering aliquots. Normally, when the participant is in one study, the aliquot will default to the first group (since it's the only group). With co-enrollments, you'll need to specify the group for each aliquot for using the **Group/ID** field in the aliquot grid. For more information on this, see the section called “The Aliquot Grid” on page 19.

The OPID (other patient identifier) is an optional identifier that some groups may utilize to track participant information instead of using ID1. LDMS is not strict on the format OPIDs, so they can contain up to 15 letters and numbers, as well as spaces. For some groups, OPID may not be available.

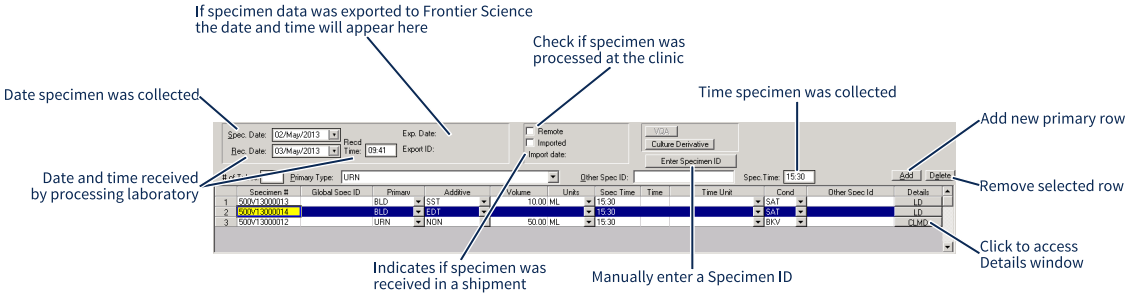
The Details button opens up the details window. For participants, this only has two fields: **Time** and **Time Unit**. These fields let you specify more details about the visit. For example, you might select `12` for the **Time** and `Fasting` for the **Time Unit** to indicate that the participant had been fasting for 12 hours at the time of the visit. You can tell if details have been set when

the button changes to a letter code. If it still reads "Details", then no options were specified; if it says "T", that means the time fields were specified.

The Primary Grid

The primary grid is the middle portion of the Specimen Management screen. This is where you enter information for the primaries that were processed. The top half is used for entering information for primaries; once they are added, they appear in the bottom half. You can enter as many primaries as you'd like at once, provided that they are for the same participant and the same visit.

Figure 2.6. The Primary Grid from the Specimen Management screen



To delete a primary after adding it, select it and click the Delete button.

Times Fields in LDMS

There are several "time" fields in LDMS:

Time	Description
Specimen Time	Time specimen was collected from study participant
Received Time	Time that the specimen was received by the processing laboratory
Processing Time	Time that the processing laboratory began processing the specimen into aliquots (i.e. the time that you opened the tube to start processing)
Frozen Time	Time that the specimen was placed in a freezer and the freezing process begins
Time	See below

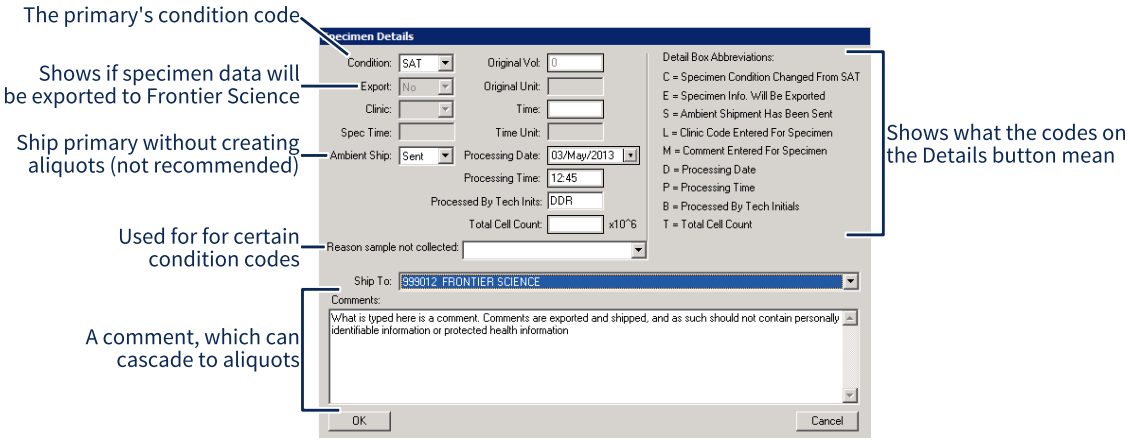
The field labeled simply **time** in the primary grid has several purposes. It can be used to indicate things such as the amount of time it took to process an aliquot, the amount of time a study participant was fasting, and even how many raw samples were pooled together to form the primary. For a list of all the time units available, see Chapter 12: "*LDMS Code Abbreviations*" on page 199.

A separate time field can also be found in the patient details window. The possible **time unit** values for this field are identical to the one found in the primary grid.

The **Time** field is typically used when testing pharmacology specimens. You can use the primary comments (found by clicking the **Details** button for the primary) to clarify how the time field was used, if necessary.

Some of the information you specify for primaries can be cascaded to derived aliquots. For example, if you had difficulty collecting a blood draw from a participant, and only collected about 80% of the tube, you can change that primary's **Cond[ition Code]** to `SHV` (short volume), and then cascade that condition code to aliquots. This will help show why the volume for each aliquot is slightly less than what would typically be collected for that visit. Cascading information from the primary to aliquots applies to **Cond[ition Code]**, **Other Spec[imen] ID**, and much of the information in the Details window, which is shown in Figure 2.7. LDMS will automatically prompt you if a change to the primary can be cascaded.

Figure 2.7. Primary Details window



▲ The Primary Details Window. Here, you can enter comments and set conditions that can be inherited by aliquots, and specify who processed the primary into aliquots and when.

Note

You might think that **Original Vol** and **Time** will show the original information from when the primary was entered if you modify it. This isn't the case. If you enter a primary with a volume of `10 ML`, then later change it to `7 ML`, the **Original Vol** will change to 7 ML.

Warning

Specimen comments are included when shipping specimens to another laboratory. They are also included with specimen records that are exported to Frontier Science. For this reason, comments should never contain *protected health information* or *personal identifying information* like a participant's name.

A key feature on this screen is the ability to send *ambient shipments*. Ambient shipment is the only way to ship a primary without creating aliquots (the name "ambient shipment" refers to the fact that it is shipped immediately after collection, usually at room temperature, instead of being frozen). To do this, change **Ambient Ship** to `Sent`, and then select the intended destination laboratory from the **Ship To** drop-down list. This will change the primary's status to sent in LDMS.

This method of shipping a primary has a significant disadvantage: you can't add the primary's information to a shipping file, meaning the destination laboratory can't import it; they have to re-enter the specimen information and manually enter the Specimen ID. The primary will also have a different *global specimen ID* at your laboratory and the receiving laboratory.

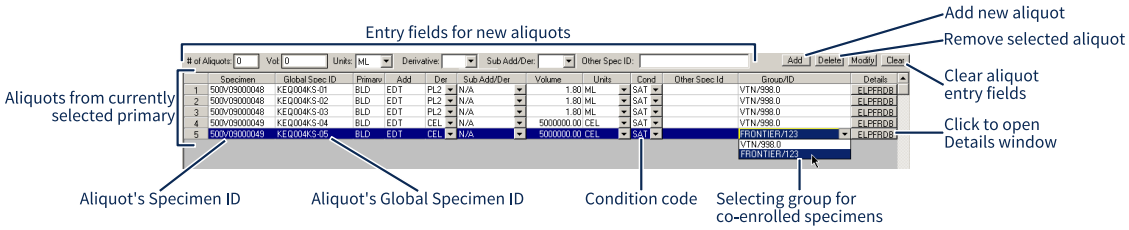
To ship a primary in LDMS in such a way that it *can* be added to a shipping file, create an aliquot with the exact same volume, derivative, etc as the primary you are shipping, then ship that aliquot like you would any other aliquot. This is referred to as creating a *ghost aliquot*.

For more information on creating shipments, see Chapter 5: "*Shipping*" on page 63.

The Aliquot Grid

The Aliquot Grid is the bottom portion of the Specimen Management screen. The aliquots derived from the currently selected primary in the Primary Grid are displayed. If a new aliquot is added, it is considered derived from the currently selected primary as well.

Figure 2.8. The Aliquot Grid



To add a new aliquot, complete the fields in the upper-left corner of the aliquot Grid, and then click the Add button. This will add as many aliquots as specified in the **# of Aliquots** field into the list of aliquots below. To delete an aliquot, simply select it and click the Delete button. You can select multiple aliquots at once by holding down the **Ctrl** or **Shift** key.

Warning

Other Spec[imen] ID can be used as an internal specimen identifier for both primaries and aliquots. There are no validation checks for this field, which allows it to be flexible. If you work with laboratories that are using LabWare version 1.x, however, you should leave this field blank. When reading shipping files, these versions of LabWare will incorrectly use the **other spec ID** instead of the *global specimen ID* as the primary identifier for that specimen. If *other specimen ID* is not present, however, the *global specimen ID* will be used correctly.

After entering an aliquot, you can modify it by simply changing a value in the table, and then clicking the button from the LDMS toolbar.

Tip

Want to modify more than one aliquot at once? Simply select those rows by holding down the **Ctrl** or **Shift** key and clicking them. Next, enter your corrections in the fields where you enter new aliquots. For example, if you want to correct the volume for multiple aliquots, enter the corrected volume into **Vol** field in the top-left, then click Modify button. This will cascade your changes down to all the selected aliquots.

If you are entering specimens for a co-enrollment (i.e. you entered two or more rows in the participant grid), you need to select which group/study combination will be assigned to the aliquot. To do this, click the **Group/ID** for the aliquot to show the group drop-down list. From this list, select the correct group and study combination.

The Aliquot Grid also has a handy right-click menu that lets you perform some functions on multiple aliquots.

Aliquot grid right-click menu options

All selected are never to be stored	Marks all aliquots to `never store`; this means they will not appear as available to be added to storage in LDMS; for more information on `never store`, see the section called "Using `Never Store`" on page 33

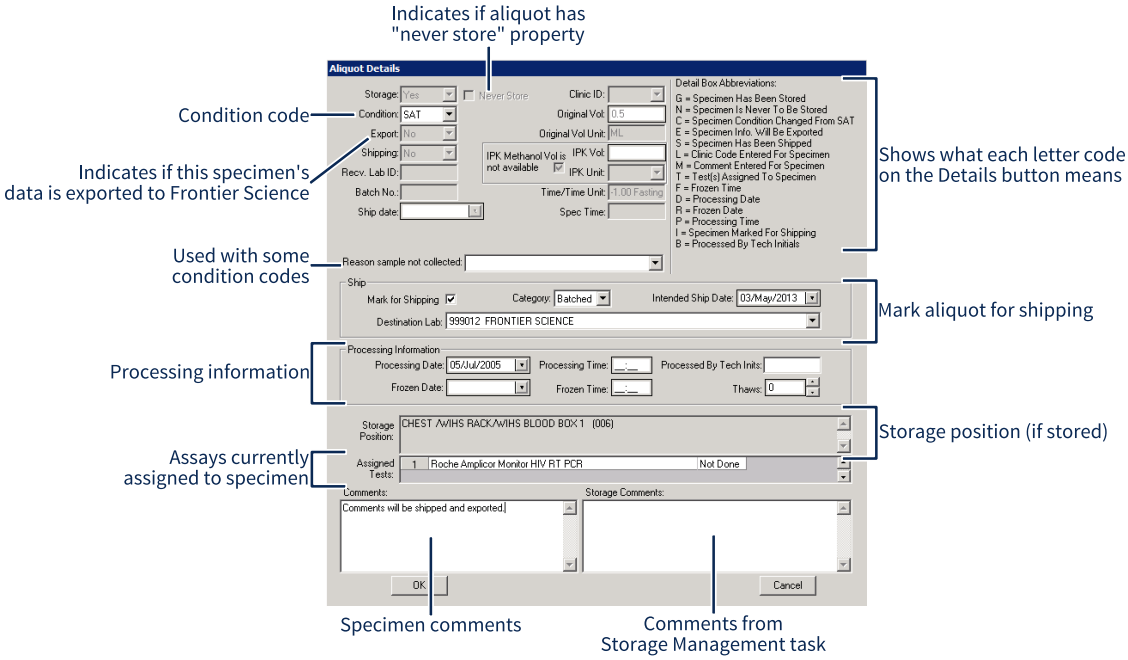
All selected can be stored	If the aliquots have been set to `never store`, this removes that flag
All selected mark for shipping	Makes it easier to find aliquots when setting up a shipment. For more information on how this works, see the section called "Finding Specimens to Ship" on page 65
Delete all selected	Same as Delete button: delete the selected aliquots
Frozen Date/Time	Enter a frozen date time for multiple aliquots. This is the same as opening up the Details Window for each aliquot and entering the same information one at a time
Modify all selected	Same as the Modify button: cascade changes from the entry fields above the aliquot grid to the selected aliquots
Print Labels for Selected Aliquots	Re-print aliquot labels; same as when you initially added the aliquots by clicking the button
Test Setup	Assign an assay in LDMS to a specimen. A test *must* be assigned to a specimen before you can actually setup the assay to be read in LDMS. For more information on adding specimens to assays, see the section called "Assigning an Assay to Aliquots" on page 34

The right column in each aliquot row is the aliquot details button. It has a series on single letter codes on it, similar to the primary details button. Click it to open up the Aliquot Details window.

Warning

A lot of information in the Aliquot Details window can be cascaded from the primary. For example, if you enter a condition code or processing information for a primary, you will be prompted to cascade that information to all aliquots derived from that primary. If you haven't entered aliquots yet, some of this information will *automatically* cascade when you add them. It's a good idea to review the aliquot details just to make sure that something didn't end up in them that you didn't intend.

Figure 2.9. The Aliquot Details window



Most fields in the Aliquot Details window can be cascaded to other aliquots too . If you make a change, LDMS will automatically prompt you if you want those changes to affect other aliquots of the same derivative type or all aliquots on the screen.

Preloads: Templates for Expected Specimen Collections

Using Preloads

A preload is a template for LDMS Specimen Management  that fills out the expected primaries and aliquot collections for a particular study and visit combination. A preload is triggered by entering information into the patient grid that meets the criteria for the preload. For example, a preload may be triggered by a `1 WK` visit for study `S103`. If you enter this information for the participant, LDMS will prompt you if you'd like to use a preload.

A preload automatically fills out the expected specimen collections for that visit. For example, if a study defines 3 vials on `BLD` on the visit `3 WK`, the preload will add those 3 primaries and the aliquots that are supposed to be produced from them. This will save you a lot of data entry work.

There are two types of preloads: FSTRF-defined and user-defined. FSTRF-defined preloads are created through collaboration between groups and Frontier Science, and are sent to laboratories through *deploys*. These preloads cannot be modified by individual LDMS users. Many groups also will not allow users to define their own preloads for those groups as well, preferring to define them at a leadership level instead. This is to prevent individual laboratories from creating an incorrect preload and logging specimens improperly. User-defined preloads are, of course, preloads created at your laboratory. You're free to use these as you see fit, though you won't be able to create them for some groups. There are no limitations to creating preloads for internal groups.

To see what preloads are available and how to trigger them you can do one of the following.

1. Click `AdministrationDefine Preloads` from the LDMS menu bar. Here, you can create, view, and modify preloads.
2. Generate the `Preload List` report, which is found by clicking `TasksReports`, then selecting `PreloadPreload List`.

Defining Preloads

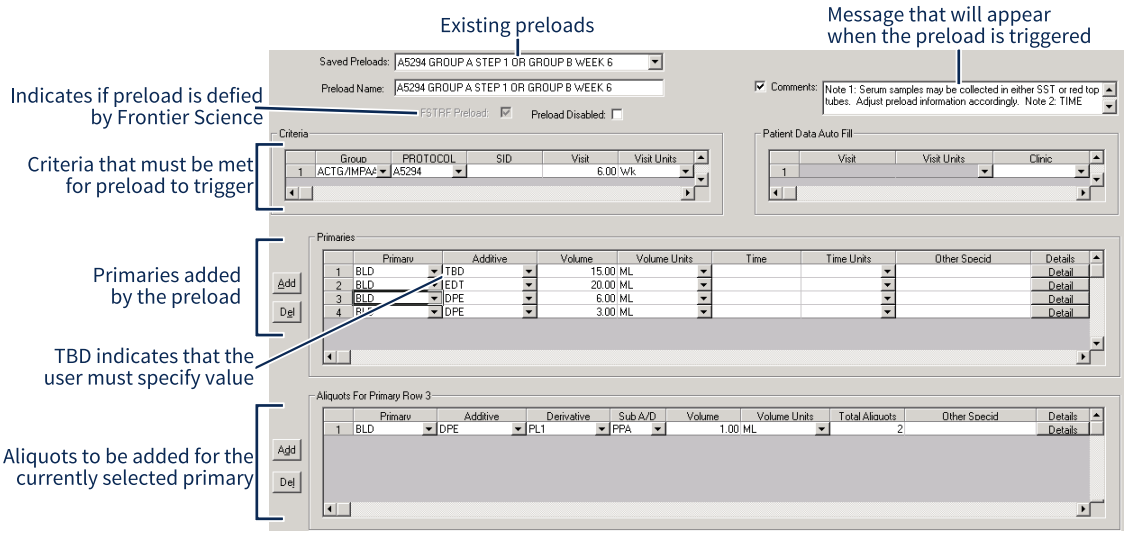
For groups that are hard-coded into LDMS, you cannot define your own preloads. Preloads for these groups are created by Frontier Science in collaboration with individual group leadership.

Tip

New preloads created by Frontier Science are added to LDMS regularly. Laboratories receive these updates when they perform an export. For more information, see the section called “Exports and Updates” on page 173.

You can create preloads for your own internal groups. For more information on creating internal groups see the section called “Group Configuration” on page 170.

Figure 2.10. Define preloads screen



▲ The define preload screen, showing a read-only FSTRF-defined preload.

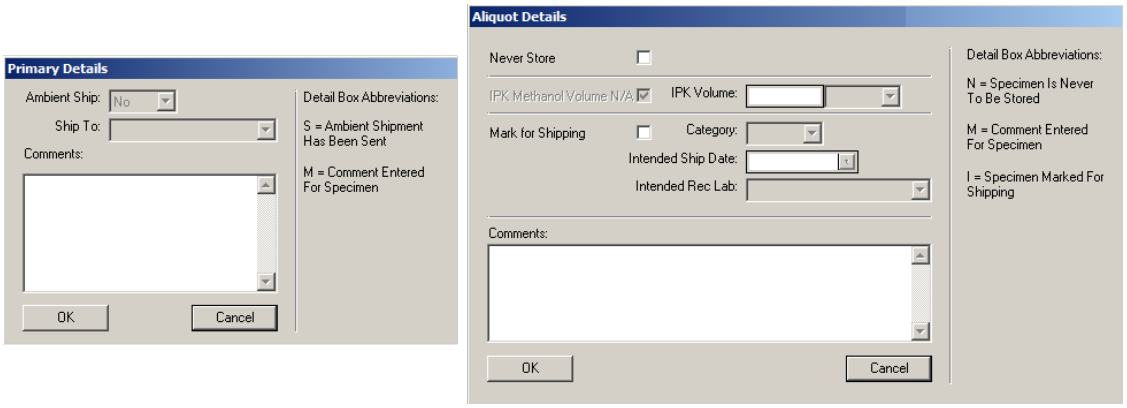
Warning

You cannot create modify and save an existing preload that was created by Frontier Science, nor can you use one as a base for creating a new one. You won't see this message until you click the ✚ or ⧉ button on the LDMS toolbar. New preloads must be derived from ones that you created or simply be new altogether. You can tell if a preload was defined by Frontier Science by looking at the **FSTRF Preload** check box beneath the preload name.

Procedure 2.3. Creating a new preload

1. Click `AdministrationDefine Preloads`
2. Enter a name for your preload into the **Preload Name** field *or* select a saved preload to be modified as the base for a new preload.
3. (Optional) Select the **Comments** check box and enter a message that will appear to the user when the preload is triggered. This is commonly used for providing instructions on the preload's usage.
4. In the **Criteria** section, enter the field values that must be met in Specimen Management for the preload to be triggered. For example, entering the study "14", visit "1", and visit unit "wk" will cause your preload to trigger when that combination is entered. Group is required; other fields are optional.
5. (Optional) Enter participant enrollment data that will automatically be added into the patient grid when the preload triggers into the **Patient Data Auto Fill** section.
6. Click the Add button next to the **Primaries** fields to add a primary row. Enter the information for the primary just as you would in Specimen Management. **Primary**, **Additive**, **Volume**, and **Volume Units** are required; other fields are optional.
7. (Optional) With a primary selected, click the Add button next to the **Aliquots** section to add a new aliquot to be derived from that primary.
8. Click the ✚ button to add the new preload.

Figure 2.11. Primary and aliquot details windows for preloads



▲ The primary details (left) and aliquot details (right) windows found in the define preloads feature.

The Detail windows for primaries and aliquots (Figure 2.11) are stripped-down versions of the ones you can find in Specimen Management. The most notable feature is that you can automatically mark specimens for shipment and select the intended destination laboratory.

You can modify an existing preload (that you created) by selecting it from the **Saved Preloads** drop-down, making your changes, and clicking the button from the LDMS toolbar. You can also disable a preload, which will prevent it from being triggered, by selecting the **Preload Disabled** check box. Preloads can be deleted clicking the button from the LDMS toolbar.

Using Condition Codes

What are condition codes?

A condition code is a 3-letter code that indicates the status of a specimen. Every primary and aliquot in LDMS has a condition code assigned to it. The default condition code for new specimens is SAT (satisfactory), but there are many others.

The majority of condition codes indicate a deviation from the expected handling for a specimen. For example, if a specimen has supposed to be collected in one type of tube but another was used, the INT (incorrect tube type) condition code could be used to indicate this.

There are several places where the condition code of specimens can be changed:

- In the Specimen Management task, there is a **Cond** column in both the Primary Grid and the Aliquot Grid that can be used to change the condition code.
- In the Specimen Management task, the condition code can also be changed in the primary or aliquot Details windows. See the section called “The Aliquot Grid” on page 19.
- When importing a shipping file, the condition code for the specimens being important can be changed. See the section called “Importing a Received Shipments” on page 77.
- In the Storage Management task, the condition code for all specimens in a storage item can be modified together. See the section called “Modifying All the Specimens in a Container” on page 52.

The most common use for condition codes is to use them in conjunction with a preload, a feature in LDMS that automatically enters expected specimen collection information when certain

criteria is met when entering a new specimen. For example, a preload may add 2 expected primaries. If the participant decided during the visit that they did not want to be stuck with another needle and only one of the primaries was collected, the second primary added by the preload would not exist. While you could simply delete the second primary, there will be no indication why the expected collection is not available in LDMS. Was it not entered in error? Does it not exist? Was it intentionally destroyed because the sample was of poor quality? At this point, there is no way to know for sure.

Using a condition code can solve this problem. By changing the condition code from SAT to SNC (sample not collected), you now know why the expected specimen is not available. There's an additional option within the Details window for aliquots called **Reason sample not collected**, which allows you to specify the exact reason why it was not collected. By using condition codes, you can document why an expected collection is missing.

Important

Not all networks permit preloads, and some networks do not want condition codes to be used in this manner. Always defer to instructions specific to your network.

Whenever a condition code is applied, it is strongly recommended that you add comments to the affected specimens to describe why the code was applied. These comments can help investigators diagnose discrepancies with study data without needing to contact your laboratory for clarification.

There is a related property to condition codes called never store. Never store indicates that the specimen is not available (for example, because it was never collected). For more information about the `never store` property, see the section called “Using `Never Store`” on page 33.

Individual condition codes

This section organizes condition codes into logical groups of similar codes. Condition codes in LDMS are updated often, therefore the codes available to you may differ slightly. You can generate a list of codes available at your laboratory by using the Reports task in LDMS. The code list reports are found in the **Misc** category.

Processing and procedural condition codes

These condition codes describe issues that can occur in the collection and processing environment. There are also codes in LDMS for describing the qualitative properties of a specimen described in the section called “Qualitative condition codes” on page 26.

Table 2.1. Processing and procedural condition codes

Code	Description	Usage
ANP	Aliquot Not Prepared	Indicate that an expected aliquot was not processed, but no other more specific condition code applies. The **Reason sample not obtained** field should be used in conjunction with `ANP`.
EQF	Equipment Failure	There was an issue with the processing equipment, such as a power failure during processing.
INV	Invalid	The specimen is not valid for testing purposes. Generally another condition code, such as `LBE` or `PST`, would be more appropriate.

Code	Description	Usage
LBE	Laboratory Error	The laboratory made a general error during processing, such as setting equipment up incorrectly or mislabeling specimens.
OPR	Outside Protocol Requirements	The specimen was drawn during the protocol-defined window, but not in a manner consistent with the protocol. For example, if a participant was supposed to be fasting but was not, this code would apply.
OSW	Outside Visit Window	The specimen was collected correctly, but outside the window for the visit as specified by the protocol.
PST	Processed After Specified Time	The specimen was collected and processed into aliquots, but the processing was done after the time frame specified by the protocol. This is commonly applicable for PBMC and pharmacology specimens.

Container condition codes

These condition codes describe physical problems with the specimen's container. If there is a qualitative issue with the specimen as a result of the container issue, a qualitative code may be more appropriate. See the section called "Qualitative condition codes" on page 26.

Table 2.2. Container condition codes

Code	Description	Usage
BKV	Broken Vial	The container was broken beyond recovery, such as being dropped and shattered on the ground.
DMG	Damaged	The container is not leaking, but is damaged in another way, such as a tear in a label or a dent in a plastic container.
EXP	Expired	The additive in a container, or some other component used during specimen collection, was expired.
INT	Incorrect Tube	A tube type other than the one specified by the protocol was used, and the tube used was determined to be an acceptable alternative by the study team.
LKD	Leaked	The specimen leaked from the container, and it was placed inside another container and recovered.

Temperature condition codes

Temperature condition codes are typically applicable if there was an issue during shipping (such as sublimed dry ice) or if a piece of storage equipment failed. Other codes are applied as part of routine and expected handling of specimens. For example the `FRO` condition code can be used to indicate that a specimen intended to be stored ambient or refrigerated was frozen.

Table 2.3. Temperature condition codes

Code	Description	Usage
DIM	Dry Ice Melted	The specimen was kept on dry ice, but the dry ice sublimed. This does not necessary imply that the specimen was damaged or `TNO`.

Code	Description	Usage
FRO	Frozen	The temperature of the specimen has been lowered below its freezing point. This applies only to specimens that were not intended to be frozen, such as specimens that were shipped at ambient temperature during the winter.
REF	Refrigerated	The specimen is cooler than room temperature but not below its freezing point. This applies only to specimens that were not intended to be refrigerated.
TNO	Temperature Not Optimal	The specimen was stored or shipped at any temperature other than the temperature specified by the protocol.
TWD	Thawed	The specimen was frozen, and has been warmed so that it is no longer frozen. LDMS has a field to track a thaw count, which can be used to keep track of how many times the specimen has been thawed. This information can be found on the Details Window for the aliquot in Specimen Management.

Shipping condition codes

These condition codes apply to issues with a specimen shipment where the specimens are unaccounted for or were received late. If the shipping issue damaged the specimens, a temperature-related code such as `DIM` (dry ice melted) may be more appropriate. See the section called “Temperature condition codes” on page 25.

Table 2.4. Shipping condition codes

Code	Description	Usage
DSH	Delayed Shipment	A shipment did not occur on schedule, but there is no obvious damage to the specimens. If there was obvious damage, a more descriptive, temperature-related code (such as `DIM` or `TNO`) may be more appropriate.
LSH	Lost Shipment	A shipment was created and sent, but did not arrive at the receiving laboratory. Neither the shipping or the receiving laboratory can locate it.
SNR	Sample Not Received	A data collection form, such as a CRF, was received, but a specimen listed on the form was not received. This differs from `LSH` in that only some specimens were not received, compared to an entire shipment.

Qualitative condition codes

These codes refer to the quality of a specimen. For example, if a blood specimen clotted, this is a qualitative issue that could prevent processing. If there was a qualitative or participant abnormality that would prevent processing but no other code is applicable, the `SNP` condition code can be used.

Table 2.5. Qualitative condition codes

Code	Description	Usage
CLT	Clotted	The specimen has clotted, often because the additive did not mix correctly with the specimen.

Code	Description	Usage
CTM	Contaminated	The specimen is visibly contaminated.
HEM	Hemolyzed	A blood specimen that has hemolyzed.
HUM	Humidity	The specimen has been exposed to high humidity.
ICT	Icteric	There are excessive amounts of bilirubin in the specimen.
LIP	Lipemic	There is excessive fat content in the specimen.
LYS	Lysed	There has been a breakdown of cells in the specimen other than hemolyzation.
SNP	Sample Not Processed	A generic code for when there is a qualitative issue that prevents an otherwise correctly collected primary from being processed into aliquots, but no other code applies. The **Reason sample not collected** field should be used in conjunction with `SNP`.

Quantitative condition codes

These condition codes refer to the volume of specimen collected.

Table 2.6. Quantitative condition codes

Code	Description	Usage
QNS	Quantity Not Sufficient	There was not enough specimen available to create the aliquot. For example, if specimen collected from the participant was supposed to be 10 mL but only 5 mL was collected, the aliquots that could not be created due to the low volume would be considered `QNS`. `QNS` means there is no volume at all for the aliquot, even though there was some volume for the primary.
SHV	Short Volume	The primary or aliquot specimen has at least some volume, but not the full expected volume.
SNC	Sample Not Collected	The primary specimen was not collected from the participant at all. This might happen if the participant declined to provide a specific sample.

Other condition codes

These condition codes are either automatically assigned to specimens or indicate some combination of issues. The default condition code that is assigned to all new specimens is `SAT` (satisfactory).

Table 2.7. Other condition codes

Code	Description	Usage
ANM	Anonymized	The specimen was created using the anonymization tool in LDMS. This code is automatically assigned by LDMS and cannot be assigned manually.
COC	Combination of Codes	More than one condition code applies; the comments field in LDMS can be used to list the applicable codes.
DSR	Destroyed	The specimen has been destroyed.

Code	Description	Usage
OTH	Other	There is something noteworthy or unusual about the specimen, but no other available condition code applies.
SAT	Satisfactory	The default condition code for new specimens, indicating that the specimen was collected, processed, and handled as expected.
UNK	Unknown	Indicates that there is a significant gap in knowledge in the specimen's history. For example, if the specimen was collected by another laboratory that was not using LDMS and is several years old, and it may have been stored or treated improperly, this code may be appropriate.

Condition codes and never store

Many condition codes indicate that a specimen is not available. For example, if a specimen has the condition code `SNC` (sample not collected), it does not exist, therefore will not be shipped or stored.

When certain condition codes are applied, the `never store` property will automatically be assigned to those specimens. These codes are listed in Table 2.8. There may be other situations where `never store` is not automatically assigned, but may still be appropriate.

Table 2.8. Condition codes that will automatically trigger never store

Code	Description
QNS	Quantity Not Sufficient
SNC	Sample Not Collected
SNP	Sample Not Processed
ANP	Aliquot Not Prepared
LSH	Lost Shipment
DSR	Destroyed

Some groups do not want specimens that are not available to be entered into LDMS at all. In these situations, it would be more appropriate to delete the specimen instead of applying a condition code. Always check with the team conducting the study to ensure that you are following the most appropriate course of action.

Correcting a Specimen Entry Error

General advice for correcting specimen data

Most data in LDMS can be corrected by a user simply by changing it and clicking the *Save* button from the LDMS toolbar. For example, if a specimen date was entered incorrectly, the specimen can be located in Specimen Management, the specimen date changed, and the records saved.

Changes that apply to a participant enrollment, such as PID or study, should be made in Patient Management, not Specimen Management, to avoid creating erroneous duplicate enrollments.

There are a few important points that need to be considered when modifying LDMS data:

- Different groups have different policies on what data can and cannot be corrected. *If you are not sure if a group permits a specific change, consult with leadership from that group.*
- If the specimen data was exported to Frontier Science previously, you will need to export again so that Frontier Science receives the corrected data. You can determine if information for a specific specimen exports to Frontier Science by looking at the **Exportable** field in the Details Window Specimen Management.
- If the specimen(s) was shipped to another laboratory, correcting data at the sending laboratory will not fix the error at the receiving laboratory. Both laboratories must make the change.
- If you change data it will not be apparent to others who made the change and why. LDMS has several data entry fields that can be used to help track changes (see below).
- If labels were already printed, those labels may now have incorrect information. LDMS will automatically ask if you would like to print new labels when saving modified specimens.

Warning

LDMS *does not* have an undo function. If you delete a record or click the  button, the changes you made are permanent. Think carefully before you act. If you're considering a significant change, or need to change records that were imported or shipped to another laboratory, contact LDMS User Support for assistance. See the section called “Getting Help” on page 10.

LDMS has several features to help users track specimen changes. All of these fields are accessed by clicking the **Details** button for the aliquot or primary in Specimen Management. These fields are described below:

Comments	The comments field can be used to enter free-form details about the change. So that others know about the change, it is important that you use this field to document it. Comments should include what information was changed for the specimen, the original data, the new data, the date it was changed, who made the change, and why.
Condition codes	Condition codes are 3-character codes that signify certain properties about the specimen. For example, the condition code DSR indicates that a specimen was destroyed, while the code SHV (Short Volume) indicates that the volume of the specimen is less than was expected. The default condition code for specimens is SAT , which indicates that the specimen is satisfactory and was collected and processed as expected. A full listing and descriptions of condition codes can be found in the section called “Using Condition Codes” on page 23.
Reason sample not collected	This field is a drop-down list on the details window that can be used to specify why an expected specimen was not collected from a participant. This field is typically used in conjunction with condition codes such as SNC (Sample Not Collected) that indicate that a specimen was not collected.

When making a change to a specimen, you will be asked if you’d like to cascade the change to aliquots, which can help if the data entry change was made to the primary specimen or if multiple

aliquots were affected. It is important that comments are made at the aliquot level (instead of or in addition to comments to the primary). The reason is because comments to aliquots will appear on shipping manifests, whereas comments for primaries will not.

Data corrections made for a specimen at one laboratory will not be automatically synchronized with that specimen's record at another laboratory. For most data corrections, if the specimens were shipped, both laboratories will need to make the corrections.

Example Corrections

Correcting an ID1 for a Specimen

In LDMS, ID1 is used to uniquely identify a study participant across many visits (and even across multiple studies). The name for ID1 varies across groups, including PID, PTID, MSCSID, etc. The integrity of this identifier is very important.

For this reason, many groups have specific instructions on how to remediate an error with an ID1 entry. Some groups will not permit any changes to an ID1 after it has been entered; other groups may allow changes but only after approval by the group has been given. The exact rules vary from group to group, so it is very important to discuss the issue with the affected group once the error is discovered.

If you do need to make an approved ID1 change, the safest way to do so is to use the extended search feature in Specimen Management. This will allow you to restrict Specimen Management to show only the affected records that need to be changed. This will help ensure that you change all of the records that need updated.

> **Important**
>
> If you are unsure if it is acceptable to make a change to enrollment information for a participant for a specific group, contact that group for further guidance before attempting to make a change. Some laboratories may also have their own stricter rules that prohibit modifying enrollment information.

If a participant was entered incorrectly such that two different participants are actually the same person this is a correction that you cannot make on your own. You will need to contact LDMS User Support for assistance merging the two participants.

After changing an ID1, corrected labels need to be printed and the specimens re-labeled. If the specimens have been shipped to another laboratory, the correction should be made at both laboratories as well.

Once all approved changes have been made, you should review the affective participants and specimens in Specimen Management to ensure that everything is correct. It is also important to confirm that any other laboratories that had the specimen(s) have also made the changes, so that LDMS data is consistent across laboratories.

Correcting specimen information (other than ID1)

When an error occurs to information other than ID1, groups generally allow corrections. This would include things such as fixing an incorrect specimen date or a specimen type code. If the specimens have been shipped to another laboratory, both laboratories will need to make the changes.

Using Specimen Management or Patient Management, find the specimen(s) or enrollments that were entered incorrectly. Correct the data that was entered incorrectly. For aliquots that were affected by the change, open the details window and explain what was changed in the comments

fields. To make the change as transparent as possible, the following information in comments is strongly encouraged:

- Field that was changed and its original value
- Who made the change
- When the change was made
- Why the change was made

If the comment was added it a primary, *it must be cascaded to all aliquots from the primary*. The reason the comment must be added to aliquots is because only aliquot comments will appear on shipping manifests. In addition to this, if the data is exported to Frontier Science, only aliquot comments will be exported. Once these changes have been made, click the  button from the LDMS toolbar.

Example 2.1. Example aliquot comment to document a data change

Aliquot volume changed from 1 mL to 10mL. This was a data entry error; the specimen has been verified to be 10mL. – Dr Doe, 17-Jan-2014

Upon Saving, LDMS will automatically ask if you would like to re-print labels. Depending on the label that was originally used and the data that was corrected, the labels on the specimens may now have inaccurate information. Laboratories may, at their discretion, re-print and re-label the modified specimens.

If the specimens have been shipped, both the sending and receiving laboratories would need to make the correction—the correction will not be synchronized across laboratories for shipped specimens.

> **Note**
>
> The **Specimen ID** (but not the **Global Specimen ID**) can be manually specified. You might want to do this if you deleted a primary and want to re-enter it using the same Specimen ID. Click the 
>
> button *before* you click the 
>
> button to add the primary. You won't see your entry immediately, but when you click the 
>
> button to add the primary, it will be assigned to the *specimen ID* that you entered. Once a specimen has been assigned a Specimen ID by the system, it cannot be manually changed.

Documenting specimens processed or frozen outside an expected window

Many specimens have specific time requirements for processing. These would include things like PBMCs, pharmacology, and single copy assay (SCA) specimens. Such specimens need to be collected, processed, and frozen following specific instructions.

LDMS has a set of condition codes that can be utilized when such specimens are not processed as scheduled.

Table 2.9. Condition codes for specimen processing exceptions

Code	Description	Usage
OPR	Outside Protocol Requirements	The specimen was drawn during the protocol-defined window, but not in a manner consistent with the protocol. For example, if a participant was supposed to be fasting but was not, this code would apply.
OSW	Outside Visit Window	The specimen was collected correctly, but outside the window for the visit as specified by the protocol.

Code	Description	Usage
PST	Processed After Specified Time	The specimen was collected and processed into aliquots, but the processing was done after the time frame specified by the protocol. This is commonly applicable for PBMC and pharmacology specimens.

If these conditions apply, the condition code should be set cascaded to all affected aliquots, or (if applicable) set at the primary. You should also use the comments field in the Details window for the aliquots to explain why the condition code was selected.

If the assay results are supposed to be entered or read by LDMS for the study, but the assay will not be run due to the improper specimen handling, you can document this in Specimen Management. Find the specimen(s) and right-click on it to select Test Setup . Assign the test (if not already assigned), but then select Test Not Run . Use the Reason field to indicate why the test will not be performed.

Doing Other Things with Aliquots

Finding Aliquots After Logging Them

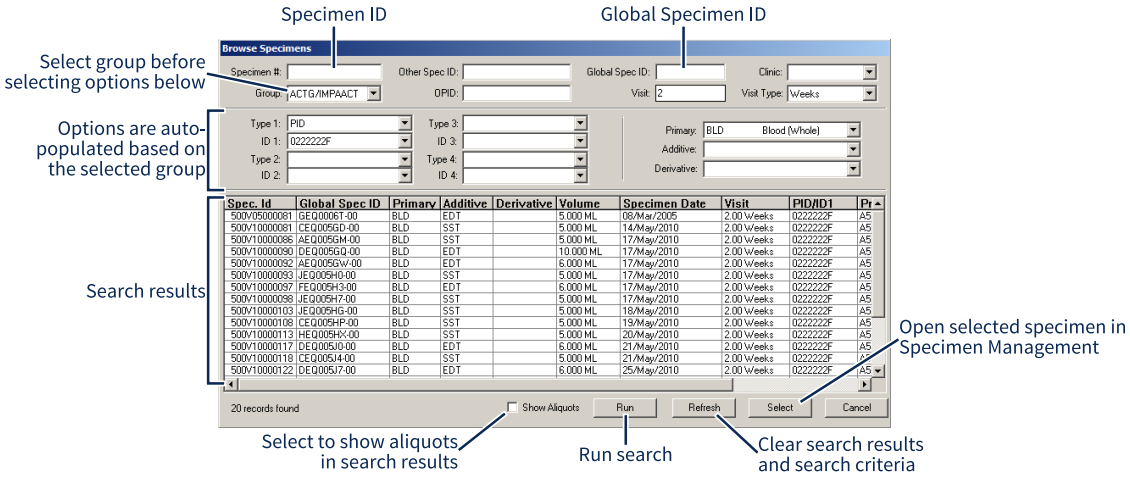
In Specimen Management, you can use the database navigation buttons on the LDMS toolbar move between specimen records. This is fine if you only have a few dozen primaries. For larger laboratories, though, this really doesn't scale.

There are several other ways to find records in LDMS:

1. Scan a barcode with LDMS Specimen Management open and the record associated with it will be displayed.
2. Use the Browse feature when you need to find exactly one specimen.
3. Use the Extended Search feature when you need to find a range of specimens based on certain criteria.

The browse feature is accessed by clicking the button from the LDMS toolbar within Specimen Management. It is used to find *exactly one*, specific specimen.

Figure 2.12. The Browse window

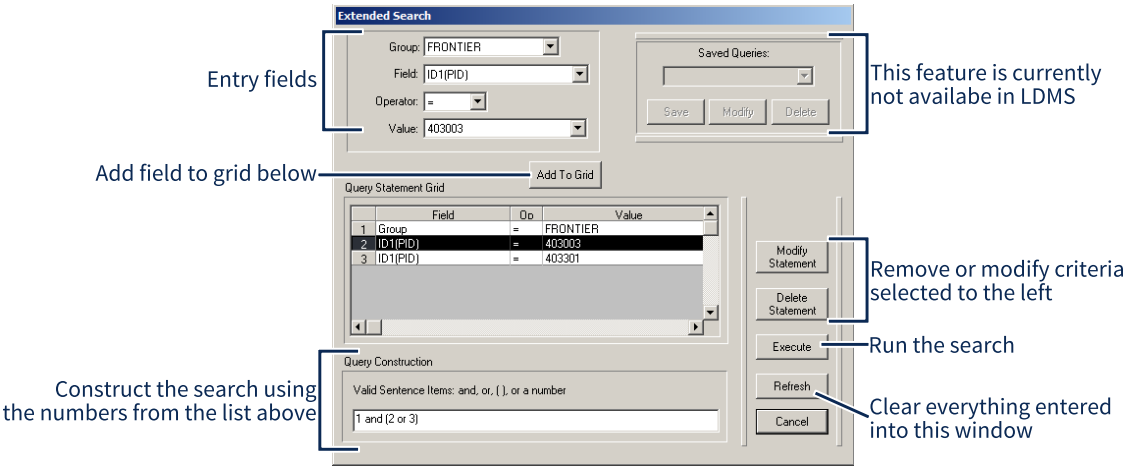


After selecting the **Group**, the options available in many of the drop-down lists below (e.g. **Type 1**, **Type 2**, etc) will change. Many of these are enumerated with entries already in your LDMS database. For example, if you select PID for **Type 1**, then the **ID1** list will be populated with all of the PIDs that have been entered for the selected group.

After entering search criteria, click the Run button. Next, select the record you want to see and click the Select button. By default, only primaries will be shown; select the **Show Aliquots** check box to also show aliquots in the search results.

Extended Search is accessed by clicking the button from the LDMS toolbar. Unlike Browse, Extended Search is used to find a range of one or more specimens, based on search criteria. You can then limit LDMS to only displaying those records, and then use the database navigation buttons to view records within a restricted scope.

Figure 2.13. Extended Search Window



Important

After clicking the Execute button, Specimen Management is in limited scope. If you look at the LDMS status bar, you'll see this message:

```
Primary 1 of 13 (restricted scope)
```

This means using the database navigation buttons only moves within these specimens. To leave restricted scope and see your full LDMS database again, click the button from the LDMS toolbar.

Using Never Store

Never store is a unique property that can be assigned to an aliquot in LDMS. It means that a specimen is *unavailable*. An examples of a specimen to which it would be appropriate to assign never store would be an aliquot that was destroyed—it will never be stored or shipped because it no longer exists.

In LDMS, an aliquot set with never store will not appear on the **Bulk Add** tab in LDMS Storage . It will still appear on shipping screens and can be shipped, but it will be highlighted in red.

You can see if an aliquot has never store assigned to it by clicking on the aliquot Details button in LDMS Specimen Management . If the aliquot hasn't been shipped or added to storage, this is also where you can change its status to never store.

Some condition codes will automatically cause an aliquot to be flagged with `never store`. Those condition codes are listed in Table 2.10.

Table 2.10. Condition codes that will automatically assign `never store` to a specimen

Code	Description
QNS	Quantity Not Sufficient
SNC	Sample Not Collected
SNP	Sample Not Processed
ANP	Aliquot Not Prepared
LSH	Lost Shipment
DSR	Destroyed

Marking Aliquots for Shipment

Marking aliquots for shipment makes them easier to find later when you're setting up a shipment. Marking for shipment is not the same as creating a shipment or adding aliquots to an existing shipment; it simply flags the aliquots as *intended* for shipment. You are not required to mark aliquots before shipping them, but doing so can make the processing easier.

Procedure 2.4. Marking aliquots for shipment

1. In the Aliquot Grid on the LDMS Specimen Management screen, select the aliquots to be marked for shipment (use **Ctrl** or **Shift** to select multiple aliquots).
2. Right-click on the aliquots, then select `All Selected Mark for Shipping`. (The `Mark for Shipping` option only marks the aliquot that was clicked, not all the ones that are highlighted.)
3. Enter the **Shipping Category**, **Intended Shipping Date**, and **Intended Receiving Lab**.

After marking aliquots for shipping, the Details will show the `I` code, meaning "intended for shipment".

The **Shipping Category**, **Intended Shipping Date**, and **Intended Receiving Lab** correspond to criteria that you can search for on the **Setup Shipment** tab in LDMS Shipping. They correspond to `MARKED SHIPS`, `INTENDED REC LAB`, and `INTENDED SHIP DATE` respectively. They have no enforced semantic meaning (meaning if you selected `monthly` for the **Shipping Category**, you're not locked into only sending that aliquot in a monthly shipment), though you will see a warning if the intended and actual destination differ. For more information on setting up and sending shipments, see Chapter 5: “*Shipping*” on page 63.

Assigning an Assay to Aliquots

Similar to marking aliquots for shipment, aliquots can also be flagged to be run on an assay. On the LDMS Assays screen, you can then quickly find all aliquots that have been assigned a specific assay but not yet tested.

Important

You *must* assign the aliquot the assay before results can be read by LDMS; this step is no optional. You will not find an aliquot in LDMS Assays until you assign it to a test. For more options on test assignment, see the section called “Assigning Assays to Aliquots” on page 84.

Procedure 2.5. Flagging an aliquot for an assay

1. Select the aliquot(s) to which you want to assign an assay from the Aliquot Grid.
2. Right click on the aliquot(s) and select `Test Setup`.
3. Find the assay you want to assign, and double click on it; this will added it to the **Tests Setup** table below.
4. Click the Save button, and *then* click the Done button.

Warning

Clicking the **Done** button without clicking the **Save** button will *not* save your changes.

You'll see that the Details button for the aliquots now has a `T` code on it, indicating that the aliquots have been assigned a test. To remove the test assignment, simply return to `Test Setup`, highlight the test, and click the Delete button.

Re-printing Labels

LDMS will prompt you to print labels whenever you enter new specimens or make changes to an existing specimen. You can also re-print labels manually at any time.

Procedure 2.6. Re-printing labels using LDMS Specimen Management

1. Find the aliquot(s) to be re-printed. See the section called “Finding Aliquots After Logging Them” on page 32.
2. Click on the aliquots to be re-printed in the aliquot grid.
3. Right-click on one of the selected aliquots and select `Print Labels for Selected Aliquots`.

This is not the only way to print labels after entering specimens. For more information about labels, see Chapter 8: “*Labels and Printer Configuration*” on page 149.

Entering Special Types of Specimens

Creating Anonymized Specimens

Note

Due to the nature of this feature, LDMS's anonymization tool is locked by default. If you would like to use the anonymization feature, contact LDMS User Support and it will be enabled for you.

Every specimen in LDMS is associated with a group and participant identifier. This information is entered into the patient grid in LDMS Specimen Management. Using this information in conjunction with information from other source could enable a user to determine a participant's real-life identify. For certain work, such as blinded studies, this is a significant problem.

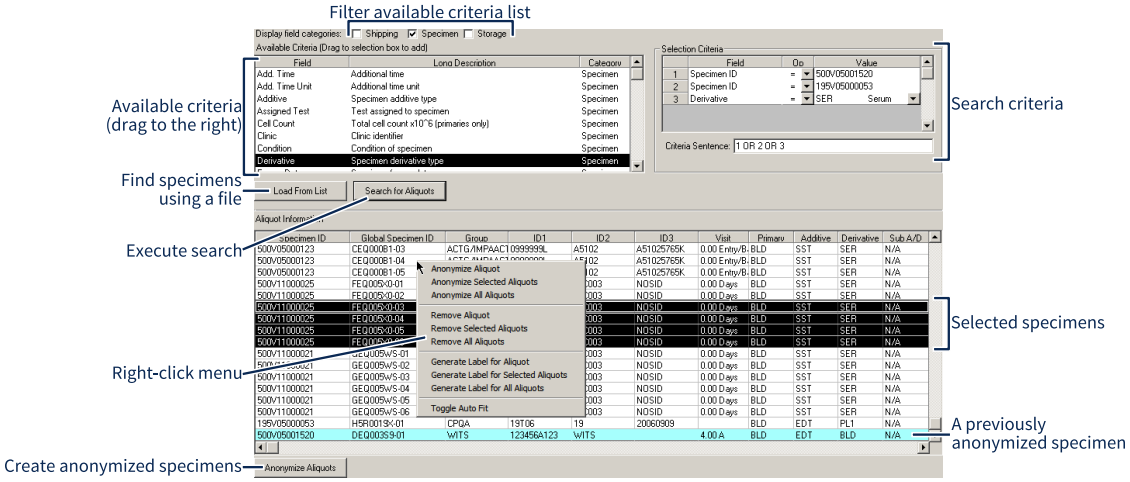
LDMS has a tool for creating specimens that have been stripped of identifying information. This process is called *anonymization*. Anonymized specimens are *new specimens* that have had certain identifying information removed; the original specimen is not modified or deleted. To see how the values for each field of the new anonymized specimens are determined, see Table 2.11.

Table 2.11. Anonymized specimen mapping

Original Specimen Field	Anonymized Specimen Value
Group	Changed to `ANON`
ID2/Study	Not modified
PID	Random number
Specimen ID	New specimen ID assigned
Specimen Date	Date of anonymization
Received Date	Date of anonymization
Clinic ID	empty
Other Specimen ID	empty
Comments	empty
Global Specimen ID	New global specimen ID assigned
Visit Unit	Changed to `UNK`
Visit value	Empty
OPID	Empty
ID3	Empty
Specimen Time	Empty
Processing fields (e.g. frozen date, initials, etc)	Empty

▲ This table shows how fields are mapped from an original specimen to the new, anonymized specimen

Figure 2.14. The Anonymization screen



▲ The anonymization screen. Note that some of the right-click menu options (such as `Anonymize Aliquot` apply to the aliquot that was clicked, not the selected aliquots.

Procedure 2.7. Creating anonymized specimens

1. Select `AdministrationSpecimen Anonymization` from the LDMS menu bar.
2. Find the specimens that you want to anonymize. There are two ways to do this:
   - Import a text file list of *specimen IDs* or *global specimen IDs*.
   - Enter search criteria to find and select the specimens to be anonymized.

3. To import a list of *specimen IDs* or *global specimen IDs*, click the Load From List button and select your file. This must be a list of either *specimen IDs* or *global specimen IDs*, with one ID per line.
4. To search for specimens:

    a. Drag the criteria you want to search from the **Available Criteria** list on the left to the **Selection Criteria** on the right.
    b. Select or enter a **Value** for each criteria.
    c. (Optional) Specify logic for the search in the **Criteria Sentence** box using the numbers from the **Selection Criteria** list, using `AND`, `OR`, and parenthesis (e.g. `1 AND (2 OR 3)`) If no logic is specified, LDMS will default to separating each criteria with `AND` (i.e. `1 AND 2 AND 3`... etc).
    d. Click the Search for Aliquots button to find aliquots that meet your criteria.

        Note

        Specimens that have been shipped, specimens in the `ANON` group, and specimens with condition codes that indicate the specimen does not exist (e.g. `DSR`) will not be displayed. Such specimens cannot be anonymized.
5. Select the aliquots that you would like to anonymize. Hold down the **Ctrl** and **Shift** keys to select multiple aliquots.
6. Click the Anonymize Aliquots button below the search results.
7. You will be prompted if you would like to mark the specimens for shipment. If yes, indicate the intended shipping information. For more information on how this information is used, see the section called “Marking Aliquots for Shipment” on page 34.
8. You will be prompted if you would like to change the derivative type for the anonymized specimens. If yes, select the new derivative type.
9. You will be prompted if you would like to remove the original specimens from storage and flag them as `never store`. For more information on `never store`, see the section called “Using `Never Store`” on page 33.
10. You will be prompted if you would like to view a report showing the linking between the original and new specimens that were just anonymized. This information can be obtained later by generated the Anonymous Patient Map report in LDMS Reports.

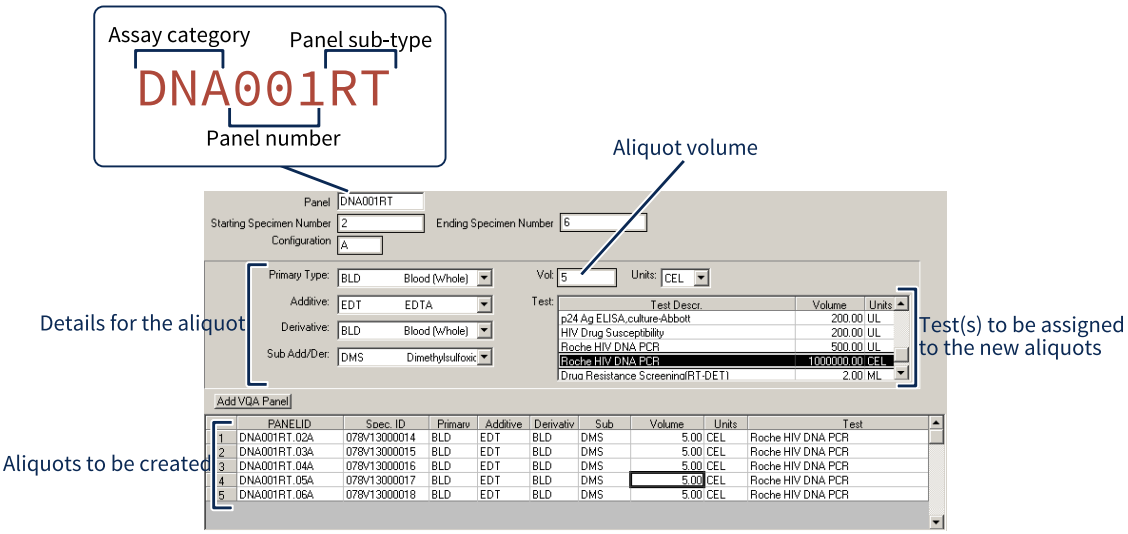
Adding Bulk VQA Records

Note

Access to this feature is only available to laboratories that prepare VQA panels to be sent to individual laboratories; it is not available to most users.

The VQA Bulk Plate Add feature can be used to create numerous specimens at once for VQA panel testing. These specimens can later be added to a shipping file for distribution to individual testing laboratories.

Figure 2.15. The Bulk VQA Plate Add Tool



▲ The VQA Bulk Plate Add feature allows many specimens to be added using a small sub-set of LDMS's specimen entry features.

Procedure 2.8. Using the Bulk VQA Plate Add tool

1. Open LDMS Specimen Management by clicking the button from the LDMS toolbar.
2. Click the VQA button from the top of the primary grid.
3. Enter the panel information into the top of the screen. See Figure 2.15.

   Note

   The **Panel** consists of the assay category, panel number, and panel sub-type only, not the full **PanelID**. The **specimen number** referrs to the VQA specimen number number for the panel, not the *specimen ID*. For more information about the VQA **PanelID** format, see the section called "VQA (Virology Quality Assurance)" on page 191.
4. Enter the **Primary Type**, **Additive**, **Derivative**, and **Sub Add/Der** for the aliquots to be added.
5. Enter the volume *for each aliquot* into the **Vol** field and select the desired **[volume] units**.
6. Select the desired test(s) to be assigned to each aliquot. Multiple tests can be selected and assigned.
7. Click the Add VQA Panel button. Aliquots will be added below for each specimen within the **starting specimen number** and **ending specimen number** range that you specified.
8. (Optional) If needed, repeat the above steps to add more aliquots to the list of specimens to be added.
9. Click the button from the LDMS toolbar.

When you are finished, click the button from the LDMS toolbar to return to LDMS Specimen Management. You can see the specimens you just added by using the database navigation buttons from the LDMS toolbar.

Pharmacology Specimens

Pharmacology protocols utilize the **Time** and **Time Unit** fields in the Primary Grid to record the *expected time* point for the draw. For example, if you were expected to draw a PK specimen at 2 hours, select 2 for the **time** and `hours` for the **time unit**. The **Spec[imen] Time** is stilled used to document the time the specimen was actually drawn (in 24-hour format).

Intracellular Pharmacology specimens have a few extra fields for entry. When you select the IPK derivative code for an aliquot, you'll automatically be prompted to enter this information.

Procedure 2.9. Entering Intracellular Pharmacology Aliquots

1. Enter the number of cells per aliquot into the **Volume** field and select CEL from the **Units** in the aliquot grid.
2. Select the **Derivative** type IPK.
3. Click the Add button to add the new aliquot. This will cause a dialogue window to appear asking for the methanol volume for the aliquot.
4. Enter the methanol volume and units *or* select **IPK Methanol Vol is not available**.

After entering the methanol volume, you can view or change it later by clicking on the aliquot Details button.

Pharmacology Controls

Note

This method of entering pharmacology controls should no longer be used. Use the PK QC Lot Entry feature. For more information, see the section called "Pharmacology QC and Calibration Lot Entry" on page 122.

Pharmacology control specimens must be entered into LDMS Specimen Management before they can be used on a pharmacology assay.

Procedure 2.10. Entering pharmacology control specimens

1. Open LDMS Specimen Management
2. From the **Group** selection field, select CONTROL.
3. Enter the **CONTROLNAME**, **PROTOCOL** and (optionally) **ID3**.
4. Enter the date that the control specimen was prepared into the **Spec[imen] Date** and **Rec[ieved] Date** fields.
5. Enter 00:00 into the **Spec[imen] Time** field.
6. Enter the number of control tubes into the **# of tubes** field, and then click the Add button.
7. In the **Time** field for the primary, enter 0.00 and select Random from the **Time Unit** list.
8. Complete the remaining specimen information as normal. See the section called "Entering a New Specimen" on page 13.

Once the controls are added, you will also need to assign them to the PK assay. You can do this while you create the control specimens by right-clicking them in the aliquot grid and selecting Test Setup, or by using the Assign Tests tool to locate specimens in the CONTROL group. For more information about assigning assays to specimens, seethe section called "Assigning Assays to Aliquots" on page 84.

Culture Derivative

Culture derivatives are the specimen remnants after a culture is terminated. Creating and terminating cultures is done in LDMS Assays. Since LDMS is aliquot-based, you can't do certain things with a culture itself (such assigning a storage location). To do these things, you'll need to create an aliquot (or aliquots) derived from the culture. For more information on cultures, see the section called "Cultures" on page 101.

Procedure 2.11. Logging a culture derivative

1. Locate the aliquot in LDMS Specimen Management that was used to create the culture. For various ways to find specimens, see the section called "Finding Aliquots After Logging Them" on page 32.

2. Click the Culture Derivative button.

   Note

   If you receive a message that no cultures were found, it means that you have not yet created the culture from this specimen in LDMS Assays. See the section called “Cultures” on page 101.
3. Select the culture from the top from which you will be creating an aliquot(s).
4. Complete the aliquot information (**# of Aliqots**, **Vol**, etc) as appropriate.
5. Click the Add button to create the aliquots.
6. You will be prompted as to whether you would like to specify a *specimen ID* manually (which will be applied to *all* of the aliquots you are creating).

Astro Numbered Specimen

Note

This feature is currently only available for the internal group `SIP-13`. This group must be created manually. For instructions on adding a new internal group, see the section called “Group Configuration” on page 170.

An astro number is a sequential hexadecimal number that is assigned to an aliquot's *other specimen ID*. It is pulled from a range of numbers that were specified by you. When entering an aliquot in LDMS Specimen Management, LDMS picks the next available number within that range, and assigns it to the aliquot.

Procedure 2.12. Specifying the astro number range

1. From the LDMS menu bar, select `AdministrationAdd Astro Number Block`
2. Enter an 8-digit hexadecimal number into the **Starting Number** and **Ending Number** fields
3. Click the **Add** button.
4. After all number ranges have been assigned, click the **Done** button.

You can also remove numbering blocks this way as well. Blocks can only be removed if they are not currently in use, which is indicated by the **In Use** column. This means that a specimen has been assigned an astro number from within that number range already.

In LDMS Specimen Management, astro numbers are triggered and assigned automatically, provided that you selected the `SIP-13` group. The astro number will be assigned to the *other specimen ID* for aliquots (but not primaries). Each aliquot is assigned a unique astro number.

Entering Reagent Information

In LDMS, reagents are not specimens nor are they directly associated with specimens. Instead, you can define a reagent used at your laboratory, and the dates that it was used. You can compare this information to the date a specimen was entered into LDMS to determine if that reagent was being used at that time.

LDMS currently supports two reagents: dimethylusulfoxide (DMS) and fetal bovine serum (FBS).

Procedure 2.13. Adding a reagent into LDMS

1. Click `AdministrationReagent Logging` from the LDMS menu.
2. Complete the fields at the bottom of the screen as applicable for your reagent.
3. Enter the date that use of the reagent began into the **start date** field.

Note

The **start date** can be a future date, allowing you to enter planned reagent use in advance.

4. (If applicable) Enter the date that the reagent was discontinued at your laboratory into the **End Date** field.
5. Click the button from the LDMS toolbar.

After a reagent has been entered, you can modify by selecting it from the list of reagents, changing the desired fields at the bottom of the screen, and clicking the  button from the LDMS toolbar.

Chapter 3. Storage

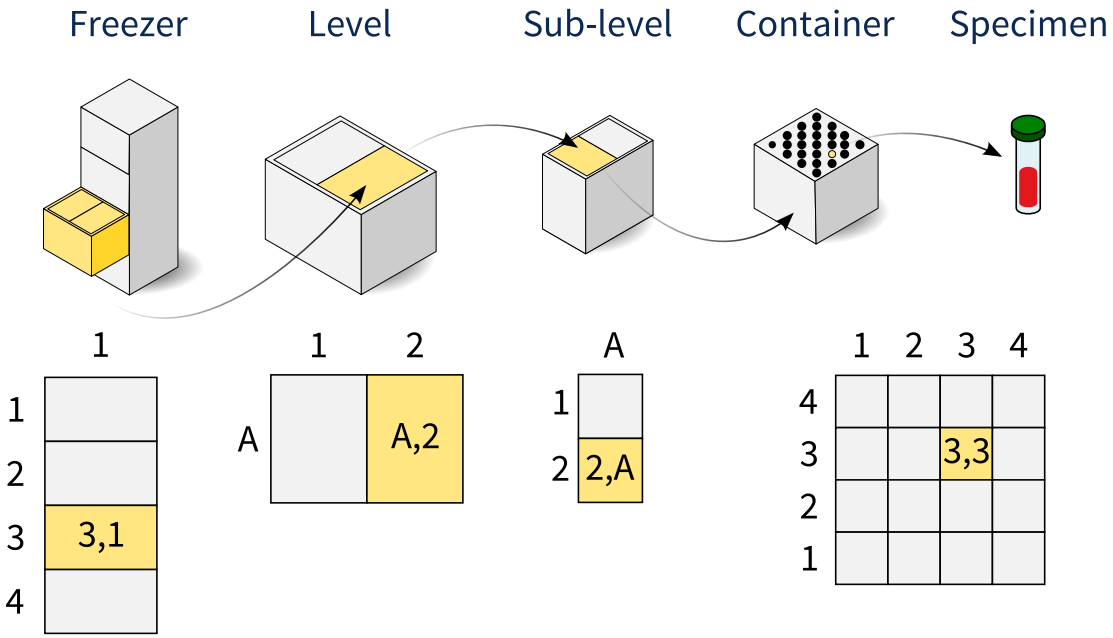
The LDMS Storage Hierarchy

LDMS Storage is a flexible tool for assigning aliquots to storage locations and keeping track of them. Storage works on the concepts of *containers* and *levels*, and represents the real-life physical arrangement of storage at your laboratory.

LDMS distinguishes between a storage unit's *configuration* and a named storage unit. For example, you might have dozens of boxes of a certain type, then there is a specific box of that type called "Box 3, Specimens For Testing". This distinction between the types of units and specific, named units allows you to define the type of unit once, then reuse it. This applies to all storage units, from the biggest freezers to small boxes.

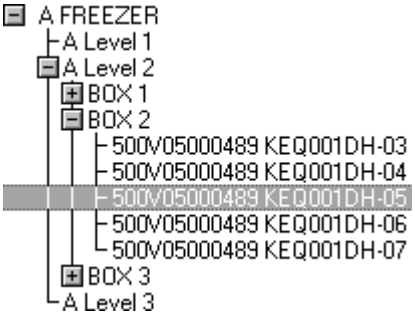
The three types of storage units in LDMS (from biggest to smallest) are *freezer*, *level*, and *container*. LDMS organizes these units in a tree structure, such that a freezer holds levels, levels hold more levels or containers, and containers hold individual aliquots. Figure 3.1 shows how these three types of units are organized and Figure 3.2 shows how this appears in LDMS.

Figure 3.1. An example storage hierarchy



▲ This example shows the different type of storage units in LDMS and the corresponding visual representation.

Figure 3.2. The Storage Tree In LDMS



▲ LDMS organizes the three types of units (freezers, levels, and containers), as a tree.

In LDMS, creating a storage system is a three part process.

1. *Define* the configurations for your storage—that is, you need to create templates and rules for storage containers, levels, and freezers.
2. *Create* the named storage units—that is, tell LDMS how the configurations you created are setup in your real-life storage.
3. *Add* specimens to storage containers.

Defining a Storage System

Defining Containers and Levels

In LDMS, a *container* is considered a rectangular object with places for individual specimens. It is the smallest storage unit in LDMS. An 8x8 container, for example, would contain 8 rows of 8 specimens, for a total of 64 aliquots in the container. Individual specimens have a unique storage position using the container's coordinates.

Before a container can be used in LDMS, you must define the type of container (its size, sorting method, etc) by creating a *configuration* for it. Adding a container configuration is done in LDMS Storage on the **Configuration** tab.

Procedure 3.1. Creating a storage container configuration

1. Select the **Container** radio button (this is selected by default).
2. Enter the **No. of Columns** and **No. of Rows** for your container. These are the dimensions for the number of specimens the container can hold.
3. (Optional) If needed, select an **Exclusion Type**. This allows you define a specific position, row, or column in the box that will not hold a specimens. For example, by excluding the top-left corner, you can use the empty spot as a reference point to determine which side of the box is the top.
4. Enter a descriptive name for the container into the **Label** field.

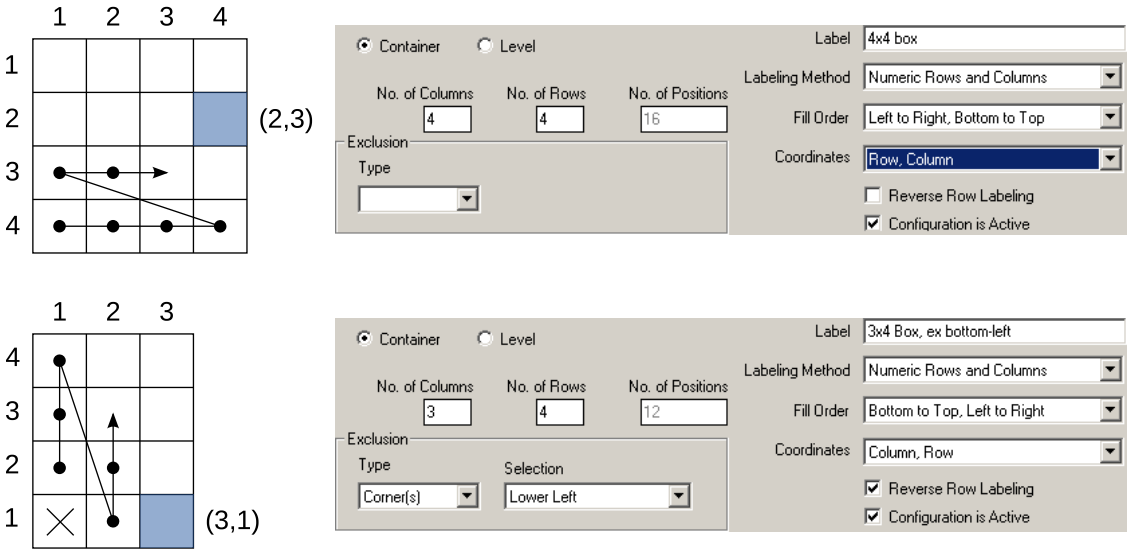
   Tip

   To make it easier to re-use configurations, consider using generic names. For example, `8x8 Box, no top-left corner` could be used for many groups, whereas `Frontier Group Box` implies that the box can't be used for other groups.
5. Select the **Labeling Method**. This is how coordinates for the container are labeled. You can chose from a combination of numeric or alphabetic rows and columns. You can also

chose `Positions Only`, which will assign a number to each specimen slot instead of coordinates.

6. Select the **Fill Order**. This how LDMS will add specimens to a container when positions are automatically assigned to specimens.
7. Select the format you want to use for coordinates from the **Coordinates** list. You can chose between (`row`, `column`) or (`column`, `row`)
8. (Optional) If the box's rows are organized in ascending order (e.g. F, E, D...) instead of the default (A, B, C...), select the **Reverse Row Labeling** check box.
9. Click the ✚ button from the LDMS toolbar to add the new storage container configuration.

Figure 3.3. Example container configurations



▲ Examples of the settings used for two different storage containers. The arrow indicates how the box will be filled; the shaded location illustrates the two different ways of displaying coordinates.

Storage level configurations are created the exact same way as containers. Storage levels have coordinates and positions just like containers. The difference is that instead of holding aliquots, levels hold containers or other levels. For example, a storage level with 1 row and 3 columns would equate to a shelf that can hold 3 boxes (one box per column).

Creating storage level configurations does offer one additional option, the ability to set the **Container for Level**. This field lets you restrict a level to only holding certain containers. For example, you can create a shelf that only lets you add a specific type of box to it. If a level is to be restricted, it can only be restricted to one specific type of container. If you anticipate needing to use more than one container type, leave the **Container for Level** field blank.

Modifying and Deactivating Containers and Levels

A container or level can be modified on the **Configuration** tab by selecting it in the **Storage Type** list, making any changes, and then clicking the button from the LDMS toolbar. (To modify a level, select the **Level** radio button instead; **Container** is selected by default).

If you want to remove a *container* or *level*, select it from the **Storage Type** list at the bottom, then click the from the LDMS toolbar.

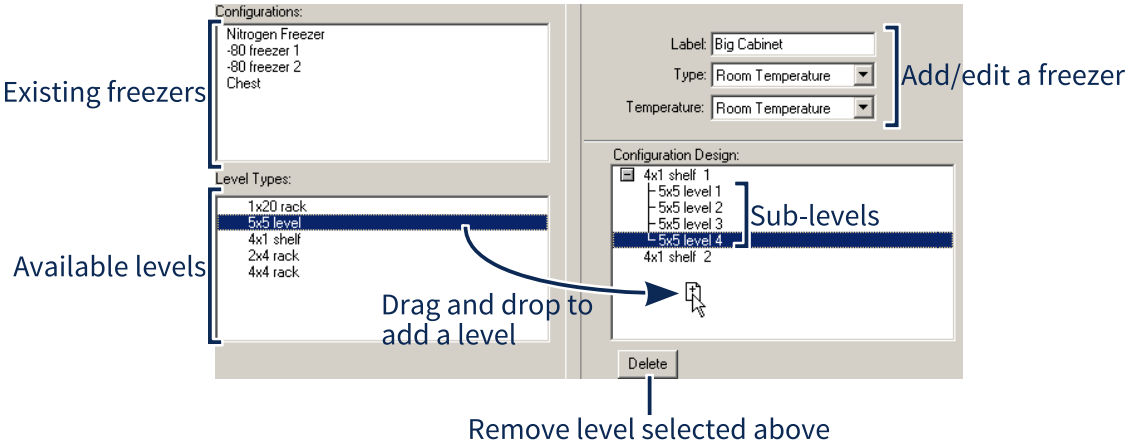
However, You cannot delete a container or level configuration that is currently in use. Instead, you must deactivate the storage unit. This prevents users from adding more units of that type to your storage. To de-activate a container or level, select it from the **Storage Type** list, unselect the **Configuration is Active** check box, then click the button from the LDMS toolbar.

Defining a Freezer Configuration

The largest unit in LDMS Storage is a *freezer*. A freezer contains one or more *levels*, which contain *containers*, which hold individual specimens. A freezer in LDMS isn't necessarily an actual freezer. For example, a refrigerator is considered a *freezer* since it is the largest storage unit. The term freezer was chosen simply because it is the most common large storage unit that laboratories use.

The **Freezer Cfg** tab in LDMS Storage is where you define a freezer configuration. Like containers and levels, a freezer configuration must be defined before a new freezer of that type can be created. The types of levels and combinations of levels that your freezer will accept are specified in the **Configuration Design** list in Figure 3.4. When this particular freezer is added to storage (e.g. when the user creates a new `Big Cabinet` freezer), it will automatically have these levels added exactly as shown. Additionally, the user will be restricted to only adding 4x1 shelves directly to freezers using this configuration.

Figure 3.4. The Freezer Configuration tab



▲ Levels and sub-levels are added to a freezer configuration by dragging them from the list on the left to the list on the right. In this example, users will only be able to add a **4x1 level** directly to the freezer.

Procedure 3.2. Creating a freezer configuration

1. Enter a descriptive name for your freezer into the **Label** field.
2. Select the type of "freezer" from the **Type** list.
3. Select the operating temperature for your freezer from the **Temperature** list.
4. Select a level from the **Level Types** list and drag it to the **Configuration Design** list. You must add at least one level to the freezer configuration. See Figure 3.4.

    a. (Optional) If the level is going to be a sub-level of another level, select the parent from the **Sub Level of** list; if it is not a sub-level, leave this field blank.
    b. Enter the number of levels to add into the **Number** field.
5. After all levels are added, click the button from the LDMS toolbar to create the configuration.

You can modify an existing freezer the same way. Select the freezer from the **Configurations** list in the top-left corner, make your changes, and then click the button from the LDMS toolbar.

Note

If the freezer configuration is already in use, only the **label**, **type**, and **temperature** can be modified; you can't modify the configuration design.

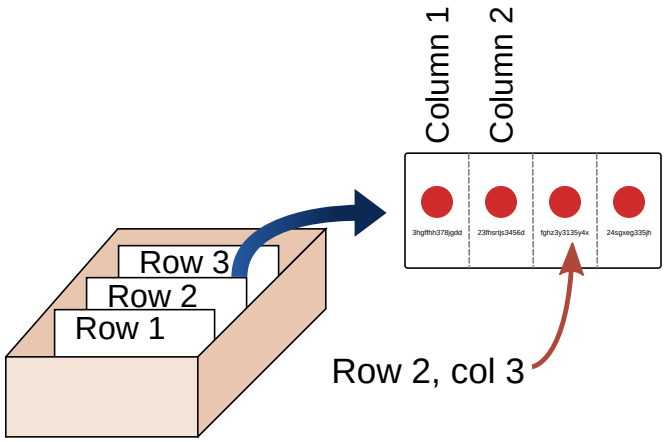
An Example: Storing Dried Blood Spot Cards

Figuring out how to define your storage is not always obvious. Certain specimens doesn't easily fit into a box with rows and columns. These types of scenarios may require some creativity to store things efficiently.

One such scenario is storing dried blood spots (DBS) cards that have multiple blood specimens on them. Each blood spot may have its own, unique *global specimen ID* in LDMS, thus a single DBS card isn't really a single specimen that can be placed into a box. Putting the cards into, for example, a 1x20 container would not be correct since it doesn't account for the individual spots on the card.

One way to solve this is to treat the spots on the card as columns in a storage container. Each row in the container would be one card, and each spot would be a column. Figure 3.5 shows how this would be done with a DBS card with 4 specimens on it.

Figure 3.5. Dried blood spot cards in storage



▲ The LDMS configuration (bottom) used to create a box of 40 DBS cards, where each card contains 4 blood spots.

Another way to approach this problem is to treat the DBS card itself as a container (meaning you would create a 1x4 container), and then treat the container that you are putting the cards into as a *level*. This would only work, however, if your freezer needs only one level in it, since LDMS limits you to two levels in a freezer. This would also require you to add many containers, one for each card.

There are many types of unusual specimens and container needs that exist. If you have trouble figuring out how to define a certain type of container in LDMS to meet your needs, LDMS User Support can help you. See the section called “Getting Help” on page 10.

Creating a Storage System in LDMS

What Each Tab in LDMS Storage Does

LDMS Storage has multiple tabs. While each tab does something different, many of them look very similar and some functionality is common across multiple screens. The behavior of the button is also a little different than in other places in LDMS.

Table 3.1. LDMS Storage tabs explained

Tab Name	What You Do on It	What the + Button Does
Main View	View the contents of a level or container	Add new freezers, levels and containers
Container View	View the contents of a container	Add new freezers, levels and containers
Move	Move stored specimens and containers from one location to another	Add new freezers, levels and containers
Configuration	Create and modify *level* and *container* configurations	Create a new container or level configuration using inputs on the screen
Freezer Cfg	Create and modify *freezer* configurations	Create a new freezer configuration using inputs on the screen
Bulk Add	Add one or more specimens to a container	Add new freezers, levels and containers
Compress	This tab is disabled; rearrange a storage container, use the **Move** tab	N/A
Search	Find specimens in storage; purge shipped specimens from storage	N/A
Transactions	View changes made in storage	N/A

On the **Main View** and **Container View** tabs, the button from the LDMS toolbar is used to *display* the contents of the currently selected freezer, level, or container.

Main View vs Container View

The difference between the **Main View** and **Container View** tabs might not be apparent at first. Both are used to view the contents of storage by finding a container and clicking the button from the LDMS toolbar. The **Container View** tab is limited to only displaying the contents of containers, while the **Main View** tab can be used to see levels as well.

The main difference is how they display information. The **Container View** tab shows each location in the container in large, graphic representation (you'll need to scroll to see all of them), whereas the **Main View** tab shows more familiar, tabular information. The content that is displayed is identical. For most users, the **Main View** tab will be more appropriate.

Adding and removing Freezers

Creating named freezers, as well as adding levels and containers to a freezer, is done on the **Main View** tab in LDMS Storage . You must create the freezer configuration on the **Freezer Cfg** tab before adding the freezer. For instructions on how to do this, see the section called “Defining a Freezer Configuration” on page 46

Procedure 3.3. Creating a new freezer in storage

1. On the **Main View** tab, click the + button from the LDMS toolbar.

2. You will be prompted to select the type of item you want to add. Select **FREEZER**.
3. Select the freezer configuration that you want to use. You must have already created the freezer configuration on the **Freezer Cfg** tab.
4. Enter a name for your freezer. This is for ease-of-use and can be changed later. It is okay to use a group name as part of a freezer name, if that's the freezer's primary purpose.

If the configuration used had levels added by default, you'll see those levels were already added to the newly created freezer.

To remove a freezer, select it on the **Main View** tab, then click the button from the LDMS toolbar. The freezer can contain levels and containers when it is deleted, but it cannot contain specimens; you'll need to remove the specimens from storage or move them to another location. For more information on deleting specimens, see the section called "Adding and Removing Specimens from Storage" on page 51. For more information on moving specimens, see the section called "Moving and Re-arranging Stored Items" on page 54.

Adding Levels and Containers to a Freezer

Levels can be added to and removed from freezers on the **Main View** tab. There are a few restrictions to how they can be added.

- Every freezer must have at least one level. Containers must be added to levels; they cannot be added directly to freezers.
- You cannot add more than one sub-level within a freezer.
- Levels that were not defined as part of your freezer configuration cannot be directly added to a freezer (any level configuration, however, can be added as a sub-level).

Procedure 3.4. Adding levels and containers to a freezer

1. Select the freezer or level that will hold the new level or container.
2. Click the button from the LDMS toolbar.
3. You will be prompted to select the type of item you want to add. Select **LEVEL** or **CONTAINER** as appropriate.
4. Choose the container or level that you want to add.
5. (For containers only) Enter the number of containers that you want to add to the selected level. If you need to cancel at this point, enter `0`.

Just as with freezers, you can remove levels and containers by selecting them, and then clicking the button from the LDMS toolbar. The level or container cannot contain any specimens when removing it.

Maintaining Storage

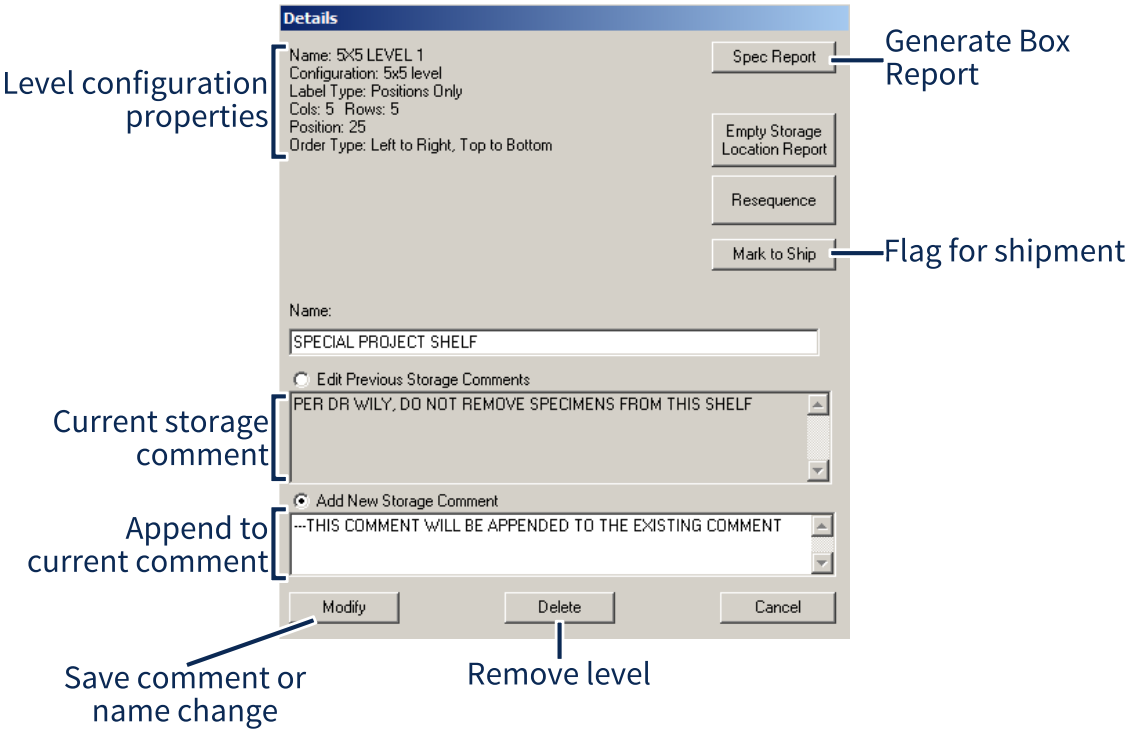
The Storage Structure List Explained

You may have noticed that the left side of the **Main View**, **Container View**, **Move**, and **Bulk Add** tabs in LDMS is identical. This list is called the **Storage Structure** and it shows your actual storage items and specimens. It also allows you to set a few options for storage levels/containers, and storage in general.

By selecting a storage item from the **Storage Structure** list and then clicking the Details button, you can access more options for that storage unit. This is similar to the details button in LDMS

Specimen Management in that it allows you to assign comments to storage locations and mark items for shipment.

Figure 3.6. The storage details window



The **Storage Comments** field allows you to add details about a storage level, such as special handling instructions. These comments can also be viewed in LDMS Specimen Management, on the Aliquot Details window. Storage comments, unlike Specimen Management comments, are not included when specimens are shipped and will not be exported to Frontier Science; they are for your internal use.

Note

If you append a storage comment to an existing comment, LDMS simply combines them. If you're going to use this feature, you need to add some sort of separator at the beginning of the appended comment, such as "---", so that the comments don't bleed together.

What does the Resequence button do?

You might think that the **Resequence** button on a the **Details** window is used to re-arrange specimens in a box. In truth, the button is actually a legacy feature for when many laboratories were converting data from RLMP, another laboratory software program, to LDMS. The feature has not been removed from LDMS, in the event that old data needs to be processed.

If you're looking for a way to re-arrange a container's contents, see the section called “Moving and Re-arranging Stored Items” on page 54.

There is also an Options button at the bottom of the list. This button allows you to access two settings that affect how storage items are added and moved. For more information, see the section called “Adding and Removing Specimens from Storage” on page 51.

Adding and Removing Specimens from Storage

Specimens can only be added to containers, and the container must already exist in storage (meaning you can't add specimens to a container, and then put the container in storage). There are three ways to put an aliquot in a storage location in LDMS:

- Use the **Bulk Add** tab in conjunction with a barcode scanner to simply scan a specimen.
- Use the **Bulk Add** tab to find specimens that meet your search criteria.
- Select the container from the **Storage Structure** list, and then click the button from the LDMS toolbar. LDMS will load a list of all specimens not currently in storage. This method is not recommended as the list can be slow to load and you can only add one specimen at a time.

Procedure 3.5. Using the Bulk Add tab to add specimens to a storage container

1. In the **Storage Structure** list, find the container to which you would like to add specimens. Specimens must be added to a *container*, not a *level*.
2. Enter the criteria for specimens you want to find in the search fields in the upper-right corner.
3. Click the button from the LDMS toolbar. LDMS will display all specimens that meet the criteria you entered.
4. Select one or more specimens from the search results. You can select multiple specimens by holding down the **Ctrl** or **Shift** keys.
5. Drag the specimens from the search results on the right to the desired storage container on the left. A red box will appear around the location where the specimens will be added.
6. Place the first specimen into the container by doing one of the following:
   - Select a location in the container, and then click the Put Here button. This must be done for every specimen being added. The order they are added is the order in which they were selected.
   - Select a starting location in the container, select the **Start here** check box, and then click the Automatic button. This will place the specimen into the container based on its *fill order*, starting with the selected location. This must be done for every specimen being added.
   - Select a starting location, select the **Start here** check box, and then click the Auto All button. This will add *all* specimens being added based on the container's *fill order*. *This will also enable the **Automatically Assign Positions** option*.
7. You will be prompted if you want to adjust the volume of the specimens. Select **Yes** or **No** (If you don't want to see this option again, select **Don't Ask Again**).
8. (Optional) If adjusting volume, select the specimen(s) that you want to modify, enter a new volume into the **Volume** field, and then click the **Modify** button. You can also adjust the volume in the **volume** column for each specimen.

Warning

If you select the Auto All button to automatically place all specimens into the box, LDMS will continue doing this automatically *every* time you add specimens to a container during the current session. To revert back to manually placing specimens into containers, click the Options button beneath the **Stoage Structure** list, and disable the **Automatically Assign Positions** option. This is also where you can re-enable the adjusting specimen volume when they are added to storage, if you ever select the **Don't Ask Again** button for that feature.

Removing a specimen from storage simply removes the specimen from a storage container; it does not delete the aliquot from LDMS. You can still find it if you go to LDMS Specimen Management and you can re-add it to storage.

Procedure 3.6. Removing specimens from storage

1. Select the specimen(s) that need to be removed from storage.
2. Click the button from the LDMS toolbar.
3. (Optional) If you want to flag the specimen as `Never Store`, select the **Permanent Delete From Storage** option.

   Note

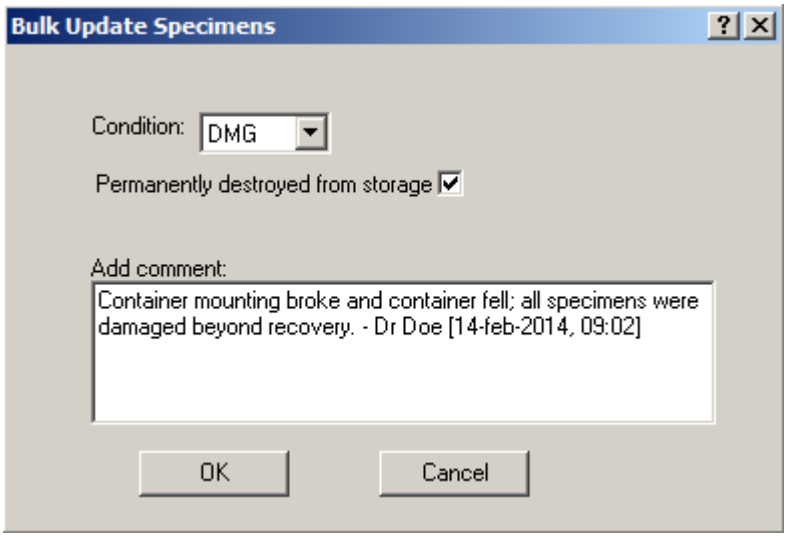
   If you want specimens to be set to `never store` by default when they are removed from storage, enable this option on the **Storage** tab in `AdministrationSystem Configuration`. For more information on `never store`, see the section called "Using `Never Store`" on page 33.
4. Click the **Yes** button to remove the specified aliquot or the **Yes to all** button to remove all aliquots that were selected.

Modifying All the Specimens in a Container

LDMS has a feature for changing the condition and specimen comments, and assigning the `never store` property to all specimens in a storage item at once. This feature can be useful if something happened to all of the specimens in a storage container. For example, if a freezer failed, you could use this feature to change the condition code for all of the specimens to thawed.

To access this feature in the Storage Management task, find the storage item in the **Storage Structure** on the left side of the screen, then right-click on the container and select `Bulk Update Specimens of Container`. Due to the large amount of data this feature can modify at once, using the bulk update feature requires a challenge password from LDMS User Support. For more information about challenge passwords, see the section called "LDMS and Challenge Passwords" on page 4.

Figure 3.7. Bulk specimen update window



▲ The bulk specimen update window. The comment will be added to the specimen comment, not the storage comment.

Note

The bulk update feature modifies the *specimen* comment, not the *storage* comment for the specimen. This is the comment that appears on shipping manifests and can be

viewed using the Specimen Management task. The bulk update feature will append to any existing comments for the specimen.

Shipping a Storage Unit

LDMS allows users to ship entire units. This is often easier and faster to do than selecting individual specimens to ship. Specimens can be added to a shipping container within a freezer, and then the container, level, or freezer itself can be shipped.

Shipping storage units is a two step process. First, you need to mark the storage unit for shipment, then you need to actually add it to a shipment in LDMS Shipping. Unlike shipping individual specimens, you *must* mark the storage unit for shipment, otherwise it will not appear in LDMS Shipping as available to ship.

Procedure 3.7. Marking a storage unit for shipment

1. Select the storage unit that you want to ship from the **Storage Structure** list.
2. Click the Details button.
3. Click the Mark to Ship button.

A storage unit cannot be marked to ship if any specimens or storage units in it have been shipped (which is indicated by a S icon next to it) or added to a shipping batch (indicated by a B icon).

Note

While you are permitted to ship a container without any restrictions, you will be prompted to contact LDMS User Support for a challenge password if you want to ship a level of freezer. This is because shipment of such a large storage unit generally requires coordination with group leadership and multiple laboratories. For more information about challenge passwords, see the section called “LDMS and Challenge Passwords” on page 4.

The same process is used to un-mark the storage unit for shipment. If a storage unit has been added to a shipping batch in LDMS shipping, it must be removed from the batch before it can be un-marked in LDMS Storage.

For instructions on how to add a container to a shipment after it has been marked for shipment, see the section called “Finding Containers to Ship” on page 65.

How LDMS Storage Handles Shipped Specimens

Specimens go through a two-part process when they are shipped in LDMS. First, they are added to a shipment (also called a *batch*). Next, the user creates a shipping file from that batch that contains the specimen information. This shipping file is sent to a receiving laboratory, where it is then imported into their LDMS database.

At no point during this process, however, does LDMS Storage remove specimens from the sending laboratory's storage. This means that when you send a shipping file to another laboratory and they import it, both laboratories now have the exact same specimen in LDMS. The **Storage Structure** list shows the shipment status of a specimen with an icon next to its name. For an explanation of what these icons mean, see Figure 3.8.

Figure 3.8. Storage Structure List Icons and Meaning

B Specimen has been added to a shipping batch

Item has been marked for shipment

S A shipping file with the specimen has been created (e.g. the specimen has been shipped)

You will need to periodically find and remove shipped specimens from your LDMS Storage . This will remove the specimens from storage, and since shipped specimens will not appear in the **Bulk Add** tab, you won't be able to add them to storage again. This only removes the specimens from storage; they will still appear in other places in LDMS, such as Specimen Management.

Warning

When a shipped specimen is purged from storage, it is automatically assigned the `never store` flag. For more information on never store, see the section called “Using `Never Store`” on page 33.

Procedure 3.8. Removing shipped specimens from LDMS Storage

1. In LDMS Storage , select the **Search** tab.
2. Click the Shipped Check button.
3. Enter a **Beginning** and **Ending** date to find specimens with a shipment date within that range. If you leave these blank, LDMS will find all shipped specimens in storage.
4. When prompted to purge items from storage, click **Yes**.

LDMS does not have a way to automatically perform this purge; you must do it yourself. A good practice would be to remove specimens after sending the physical shipment to the laboratory. If you purge them without contacting the receiving laboratory, you run the risk of something being wrong and no easy way to diagnose the problem.

Moving and Re-arranging Stored Items

Moving specimens between different containers (and within the same container), as well as moving levels within freezers and other levels, is done on the **Move** tab within LDMS Storage . This is also how you would re-arrange a storage unit's content.

Note

Only specimens and storage containers can be moved. Storage levels cannot be moved.

Procedure 3.9. Moving specimens or storage containers

1. Find and select the storage unit to be moved from the **Storage Structure** list on the left.
2. Find the destination storage unit from the **Destination** list on the right.
3. Select and drag the storage unit to be moved from the left side to the right.
4. Place the storage unit or specimens into the destination by doing one of the following:
   - Select a location in the container, and then click the Put Here button. This must be done for every unit being moved. The order they are added is the order in which they were selected.
   - Select a starting location in the container, select the **Start here** check box, and then click the Automatic button. This will place the specimen into the container based on its *fill order*, starting with the selected location. This must be done for every storage unit being moved.
   - Select a starting location, select the **Start here** option, and then click the Auto All button. This will add all specimens being added based on the container's *fill order*. This will also enable the **Automatically Assign Positions** option for the remainder of your LDMS Storage session.

Warning

There is no undo functionality when performing a move. Since moves take effect immediately, you will need to correct any mistakes by moving specimens or containers to the correct location.

Tip

If you want to re-arrange a unit's contents, such as rearranging specimens in a box, simply move them to the same container. For example, if you move specimens from one box, to the same box, you'll be allowed to select new locations for them.

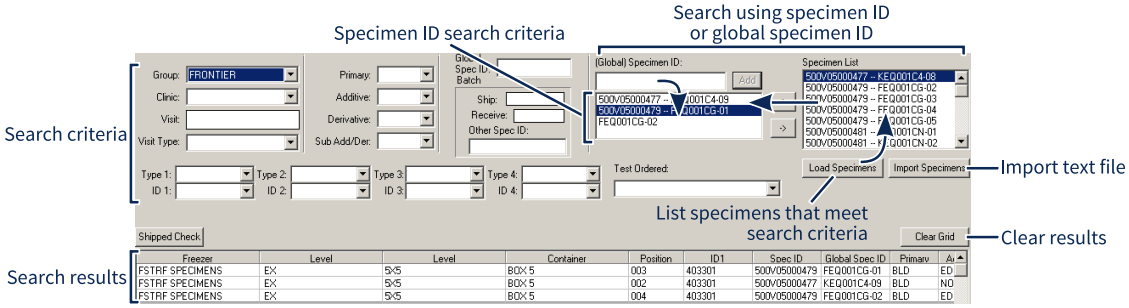
Finding Specimens in Storage

You have a few options for finding a specimen that is in LDMS Storage :

- Open the **Main View** tab and just scan the label with a bar code reader (this only works if you have the specimen in front of you or reprinted its label).
- Browse the **Storage Structure** list
- Use the simple search feature, accessed by clicking the Simple Search button below the **Storage Structure** list.
- Use the **Search** tab

Simple Search is used to locate a specimen with a specific *specimen ID*, *global specimen ID*, or *other specimen ID*. You can limit your search to a specific storage location by using the **Narrow Your Search** fields. If you need more advanced searching, use the **Search** tab.

Figure 3.9. The storage search tab



▲ On the search tab, you can also click the button from the LDMS toolbar to access the more familiar extended search feature.

To search, enter criteria to search, and then click the button from the LDMS toolbar. Specimens that meet *all* of your search criteria that are in storage will be displayed at the bottom of the screen. Specimens that are not in storage or do not meet *all* your search criteria will not be displayed. For example, in Figure 3.9, the user has specified the **Group** to be `Frontier` and they have also entered one or more **(Global) Specimen ID**s. Even though there are many more specimens in storage that are in the `Frontier` group, only the ones that also match the specimen IDs specified will be displayed.

Searching by *specimen ID* and *global specimen ID* can be confusing. Here are a few key points:

- The field **(Global) Specimen ID** accepts both *specimen IDs* and *global specimen IDs*.
- The only specimen IDs/global specimen IDs that will be shown will be the ones in the list *below* the **(Global) Specimen ID** field. They are added to this list by using the **Add** button or the **<-** button.
- Clicking the Load Specimens button will find all specimens in storage *that meet the search criteria you've already entered* and display them in the **Specimen List** box (this is identical to clicking the button) . You still need to select the specimens, and then click the **<-** button to move the specimen to the box to the right.
- Clicking the Import Specimens button will import a text file list of specimens to search. This text file must have one *global specimen ID* per line.

Tip

You can also use the **Extended Search** feature to find specimens in storage by clicking the button from the LDMS toolbar. Extended Search works the same way that it does in LDMS Specimen Management. For more information on how to use extended search, see the section called "Finding Aliquots After Logging Them" on page 32.

Storage Reports

There are a number of reports that are available within LDMS Storage .

Storage reports

Container Report	List specimens in a container, along with pertinent details, organized by container. To find this report, select a level from the **Storage Structure** list, click Details then click the **Spec Report** button.
Empty Storage Locations Report	List storage positions by container that do not have any specimens. Empty level locations are not shown; only containers. To find this report, select a level from the **Storage Structure** list, click Details then select **Empty Storage Locations Report**
Specimens not in Storage	After generating search results on the **Bulk Add** tab by clicking the button, click the button from the LDMS toolbar. This report shows specimens within your search results that are not currently in storage. For more information about this report, see the section called "Locating Specimens not in Storage" on page 58.
Specimens Stored from Bulk Add Report	Shows specimens that have been added to storage using the **Bulk Add** tab. To access this report, click the View Results button on the **Bulk Add** tab.
Storage Detail Report	Shows basic information about specimens that were found on the **Search** tab. You must click the button from the LDMS toolbar to generate search results before generating the report. To find this report, go to the **Search** tab and click the button from the LDMS toolbar.
Storage Move Report	Shows specimens that have been moved to a new location within storage on the **Move** tab. To access this report, click the View Results button on the **Bulk Add** tab.
Storage Transactions Report	Shows saved transactions that were found or (if no search criteria was entered) all saved transactions. To find this report, go to the **Transactions** tab and click the button from the LDMS toolbar.

There are more storage reports available in LDMS Reports. For a listing of those storage reports, see the section called "Storage Reports" on page 137.

Storage Change Log (Transactions)

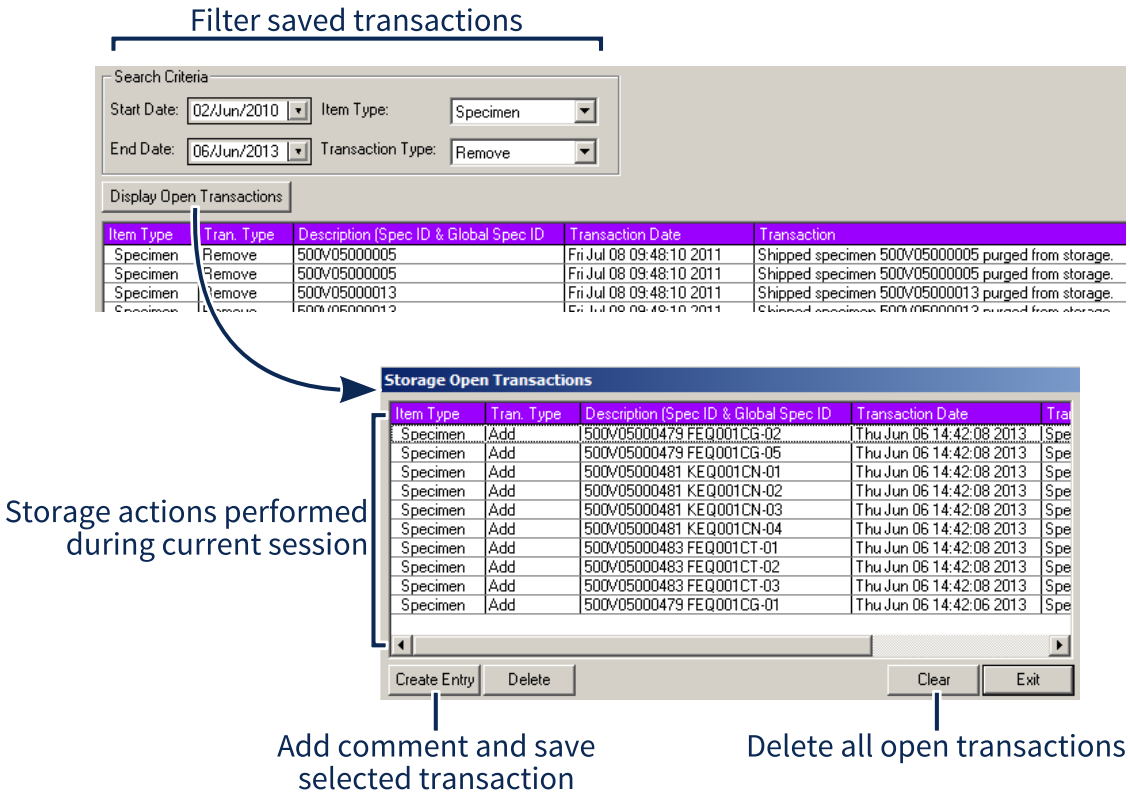
LDMS automatically tracks changes that you make to storage. The record of each change is called a *transaction*. When you exit LDMS, these transactions are automatically deleted. The change still happened; only the record of it is not saved.

For some networks and at some laboratories, you may need to have audit-able storage records on hand. To keep records of storage transactions, you need to manually save them. Saving a transaction is also synonymous with creating a comment for the transaction.

Warning

LDMS will *not* save transactions automatically; you must do this. If you exit LDMS entirely without saving them, they are lost forever.

Figure 3.10. The Transaction tab and Storage Open Transactions window



▲ The **Storage Open Transactions** window shows changes that were made during the current session. These records must be saved by you or they will be lost when you exit LDMS.

Procedure 3.10. Saving records of transactions from the current session

1. On the **Transactions** tab, click the Display Open Transactions button.
2. Select the transaction(s) that you want to save. Hold down the **Ctrl** or **Shift** key to select multiple transactions.
3. Click the Create Entry button.
4. (Optional) Enter a comment for each transactions. This comment can be used to track why you saved a transaction or what was significant about it. If you do not wish to enter a comment, leave it blank and simply click the **Save** button.
5. (Optional) If you selected multiple transactions, you can use the same comment for all of them (instead of being prompted for each transaction) by selecting the **Apply comment to all** check box.

If there are any transactions that have not been saved, you will be prompted to view them when you try to leave LDMS Storage . It's a good idea to review them and make sure that there are none that you need to save. You can use the **Delete** button to remove unsaved transactions that you know you don't need to save; the **Clear** button can be used to remove all unsaved transactions.

To view saved transactions, simply enter your search criteria (such as a date range or a type of transaction) and click the button. Saved transactions will appear at the bottom. For instructions on how to view saved transaction comments, see Procedure 3.11, “How to view saved transaction comments”.

Procedure 3.11. How to view saved transaction comments

1. Select the transaction that you would like to view.

2. Click the button from the LDMS toolbar.
3. (Optional) If you want to modify the comment, you can do so, and then click the **Save** button.

Tip

Want to view a summary of saved transactions and comments? Search for them and then click the button from the LDMS toolbar. This will generate the **Storage Transactions Report**. If you run this report without searching, you'll find *all* saved transactions.

Locating Specimens not in Storage

Accurate storage locations, processing times, storage conditions, and other information are vital to the long term study of specimens that your laboratory has in its possession. If the location where a specimen is stored is not documented using LDMS's Storage tool, it could be very difficult to locate it in the future.

Important

Several clinical trial groups *require* that all specimens be logged using LDMS Storage. Data management centers work with these networks to monitor the storage status in data that your laboratory has exported, and may contact laboratories to ensure that the mandates for these networks are being enforced.

LDMS has a built-in report that will tell you what specimens do not have a storage location documented in LDMS. You can use this report to find specimens and add them to storage. For instructions on adding specimens to storage in LDMS, see the section called “Adding and Removing Specimens from Storage” on page 51.

Procedure 3.12. Generating the Specimens Not In Storage Report

1. Click `TasksReports` or click the button from the LDMS toolbar.
2. Select the **Storage Reports** category, and then select the **Specimens Not in Storage** report.
3. (Optional) Add a group filter at the bottom of the screen if you want to only show specimens for a specific group.
4. Click the button from the LDMS toolbar.

If you need a more flexible report, you can also use LDMS's data retrieval tool to create a custom report. Simply create a report that selects and displays the **global specimen ID**, **stored**, and **never store** fields, and then sort by the **stored** field. For more information on using the data retrieval tool, see the section called “Running Custom Data Retrieval Reports” on page 134.

Note

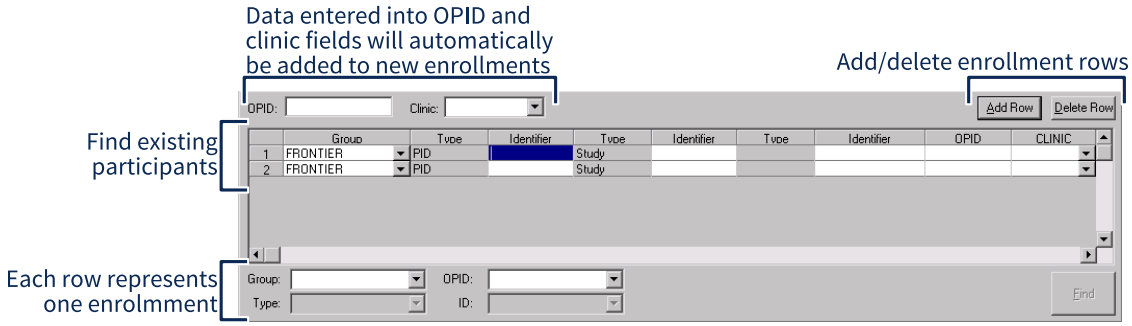
It is important to look at both the **stored** and **never store** fields. The reason being is that a specimen that has been flagged as **never store** would appear as not stored, even though you would never be expected to store it. For more information on `never store`, see the section called “Using `Never Store`” on page 33.

Chapter 4. Patient Management

Finding and Modifying Participant Information

LDMS Patient Management is used to add, view, or modify study participants in LDMS. This isn't the *only* way to add patients in LDMS (you can also use Specimen Management to add participants when entering specimen information), but it is the only way to modify an existing participant's information.

Figure 4.1. Patient Management Screen



You can bring up participants that have already been entered to add them to new studies, change their identifier (e.g. to fix a data entry error) and to add them to a new group.

Procedure 4.1. Modifying an existing participant

1. Click `TasksPatient Management` from the LDMS menu bar or click the button from the LDMS toolbar.
2. At the bottom of Patient Management screen, select the group from the drop-down.
3. Select the identifier from the drop-down.
4. Click the **Find** button.
5. Modify the patient information as necessary, such as adding or deleting rows, or modifying identifiers.
6. Click the button from the LDMS toolbar.

A common change you'll need to make is updating patients enrolled in the study `NOSID`. For many groups, it is acceptable to enter `NOSID` as the *study identifier* when entering specimens. After the participant is assigned to a study, you need to use Patient Management to update the patient information, which will cascade to all previously logged specimens.

Warning

If you entered specimens using `NOSID`, then (once an SID has been assigned) you start entering specimens with the new SID, you will end up with two different enrollments (one with the SID and one with `NOSID`) when there is in fact only one. This mistake can be difficult to correct and will usually require LDMS User Support's assistance. See the section called “Merging Participants” on page 60.

Once a SID has been assigned to a participant previously entered with `NOSID`, you must immediately update the NOSID before adding any more specimens for that participant.

Adding a New Participant

Typically, new participant enrollments are added in Specimen Management when new specimens are added to LDMS. This is typically more efficient than manually creating enrollments. For more information on using Specimen Management, see Chapter 2: "*Specimen Management*" on page 11.

Procedure 4.2. Adding a new enrollment using Patient Management (Not recommended)

1. Click the Add Row button.
2. Select the group for the participant from the **Group** drop-down menu. This will modify the values in the **Type** fields, depending on the group selected.
3. Enter the identifiers as required by the group.
4. Select the clinic ID with which the patient should be associated from the **Clinic** drop-down
5. Click the button from the LDMS toolbar.

You'll receive a confirmation message after the participant has been added. If you add multiple rows to the patient grid, LDMS treats them as the same patient in different studies. You cannot add two different *participants* at the same time, meaning enrollments in the same group can't have two different *PIDs*.

Using OPID

OPID (Other Patient Identifier) is a field that can be used as a supplement to ID1 (which is usually a PID, hence OPID) or as the primary identifier for patients in LDMS.

To use an OPID for a participant, simply enter a value into the OPID column when entering or modifying that patient's information.

Tip

You can pre-populate the OPID in multiple rows by typing it into the **OPID** box above the patient grid before clicking the Add Row button. You can also do the same thing with the clinic.

Merging Participants

Suppose you realize that you have a participant with two different enrollments. For example, you have two different participants enrolled in two different studies, then later realized that these two participants are actually the same person, and should have been listed under the same participant record as two different enrollments. This could happen if, when entering the specimens into LDMS, the user didn't add two rows to the participant grid and instead entered each set of specimens separately.

LDMS can correct issues like this by combining participant records. This feature, however, is not accessible to users. The reason for this restriction is because incorrect use of the feature could significantly damage data in your LDMS database in a way that would be difficult to correct.

If you need to combine participants, contact LDMS User Support. They will be able to access this feature and make the correction for you. See the section called “Getting Help” on page 10.

Chapter 5. Shipping

Shipping = Data Transfer

In LDMS, shipping specimens is the process of transferring specimen information from your local LDMS database to the database of another laboratory. It would be more accurate to say that a shipment in LDMS is actually a shipping file, not a container of specimens. You are shipping a file to another laboratory, and they read the file to add specimens to their LDMS database. It is a parallel process to physically sending specimens to another laboratory.

LDMS can...

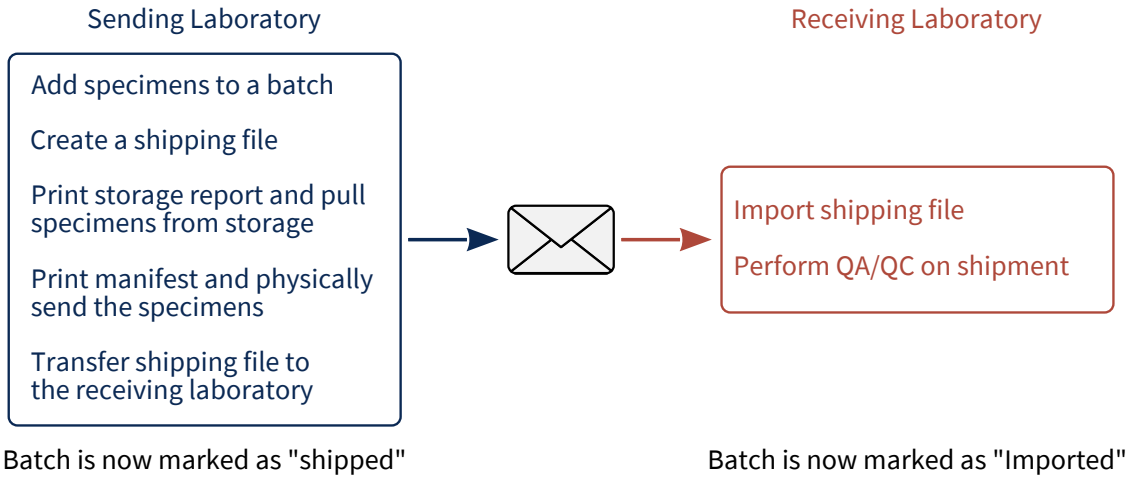
- Prepare a shipping computer file, which must then be sent to the receiving laboratory (on a CD, via FTP, attached to an email, etc); this file contains LDMS data for the specimens.
- Read a shipping file received from another laboratory, and add those specimens to your LDMS database.
- Create and print lists to help you pull specimens being shipped from storage, as well as manifest lists to include with the physical shipment.
- Provide tools to help verify that the physical specimens received match those in the shipping file that was received.
- Create shipping files for laboratories not using LDMS.

LDMS can *not*...

- Transmit shipping files or shipping information directly between laboratories; users must do this manually (e.g. on a CD-RW packed with the specimens).
- Keep LDMS databases at laboratories in sync. For example, if an aliquot is shipped from one laboratory to another where it is later destroyed, the initial laboratory will still have that specimen marked as "shipped" while the receiving laboratory will have it as "destroyed"; the destroyed status does not get sent back.
- Assist with actual shipping (printing mailing labels, arranging pick-up, etc); individual laboratories need to develop their own workflows for those processes.
- Track in-progress shipments or notify the receiving laboratory of incoming specimens.

To ship something in LDMS is a multi-step process that happens at both the sending and receiving laboratory. At a high level, the sending laboratory marks specimens for shipment, then prepares a shipping file and paperwork. They send the shipping file (through some method outside LDMS) to the receiving laboratory, along with the actual specimens. The receiving laboratory imports this data into LDMS and reviews it to make sure the specimens that were expected were actually received. See Figure 5.1.

Figure 5.1. Typical workflow for shipping specimens with LDMS



▲ The left side shows the steps performed by the sending laboratory while the right shows the receiving laboratory.

Preparing Shipments

Creating a New Shipment

Shipments are organized into *batches*. A batch is simply one shipment, either sent or received. Each batch has a **batch number**, which uniquely identifies the shipment in your local LDMS database.

Important

A **batch number** is not consistent between different LDMS laboratories. Each batch is assigned a sequential number, with the first batch starting at `1`. When a shipment is imported at a receiving laboratory, it is assigned the next available batch number *at that laboratory*. As a result, the same shipment may have a different batch number at the sending and receiving laboratories.

Procedure 5.1. Overview of creating a new batch

1. On the **View Shipment** tab, select the bottom, blank row from the batch listing. This row is designated for new shipments.
2. Change to the **Setup Shipment** tab. You will be prompted whether you want to ship **Specimens** (i.e. aliquots) or ship **Storage Items**, meaning boxes or other storage containers that contain multiple specimens.
3. Add items to your shipment.
   - If shipping a container, select the containers that you want to ship and click the **Add to batch** button. For more details on how to do this, see the section called “Finding Containers to Ship” on page 65.
   - If selecting individual aliquots to add to the shipment, search for them and select them. For more details on how to do this, see the section called “Finding Specimens to Ship” on page 65.
4. Change to the **Shipment Destination** tab. Select the person or laboratory to whom the shipment will be sent. For more information on how to do this, see the section called “Selecting a Shipment Destination” on page 67.

5. Click the ✚ button from the LDMS toolbar. This step creates the new (currently unsent) shipment.

The new batch can be found on the **View Shipment** tab. This batch will be the last batch on the list. It will have the status of `batched`, which means it has been prepared but not yet shipped. To ship the batch, see the section called "Sending a Shipment" on page 75.

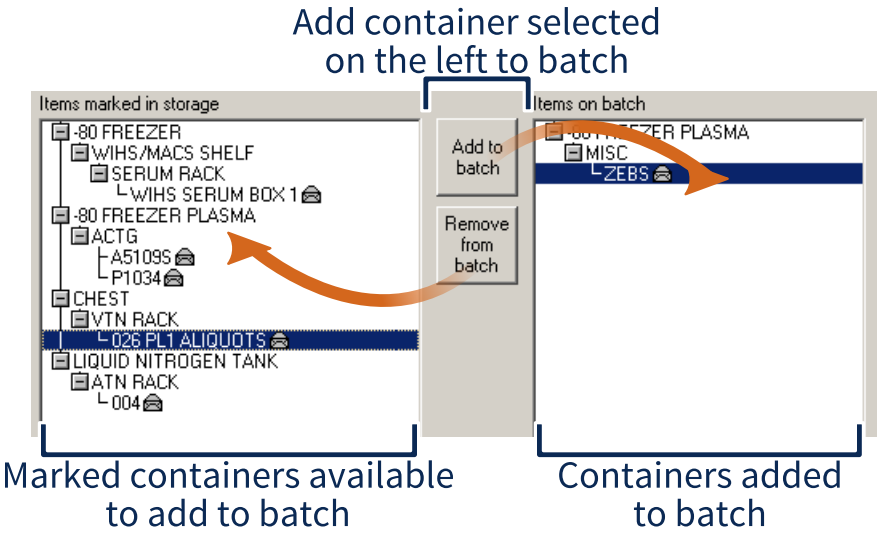
Finding Containers to Ship

It is possible to ship any storage unit in LDMS,[1] whether it be a container of specimens or an entire freezer. Shipping a container is in fact one of the most expedient ways to send aliquots to another laboratory. Simply add them to the container in LDMS Storage , then just ship the container. For many laboratories, this is a lot more efficient and a lot easier than finding all of the individual specimens that need to be shipped.

To ship any container, it must be *marked* for shipping in LDMS Storage . If it is not marked in LDMS Storage , it will not appear as available to Ship. For more information on how to mark storage items for shipping, see the section called "Shipping a Storage Unit" on page 53.

To select a container to ship, change to the **Setup Shipment** tab and select **Storage Items** button.

Figure 5.2. Adding storage items to a shipment



▲ On the left are *marked* storage items; on the right are storage items that have been added to the shipping batch. To move a storage item, select it and click the **Add to batch** or **Remove from batch** button respectively.

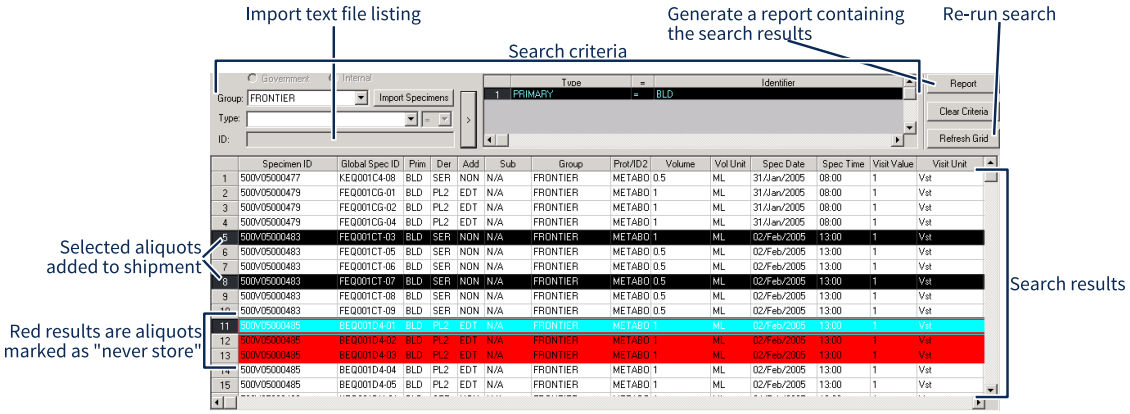
Finding Specimens to Ship

If you want to individually select specimens to ship (as opposed to shipping a container from storage), there are a few ways to do it:

- Use a text file containing a list of global specimen IDs
- Use the search features on the **Setup Shipment** tab
- Use the extended search feature on the **Setup Shipment** tab
- Scan them with a barcode reader

[1] Although large containers like freezers and shelves can be shipped, they will require approval. You will automatically be prompted by LDMS to obtain this approval. See the section called "Shipping a Storage Unit" on page 53.

Figure 5.3. Selecting individual specimens to ship



▲ The **Setup Shipment** tab. The selected specimens are those that will be added to the shipping file. Specimens in red are marked as `never store`.

Procedure 5.2. Finding specimens for shipment on the Setup Shipment tab

1. Select **Government** if you want to ship specimens from a built-in government group or select **Internal** to ship specimens from an internal group at your laboratory.

   Note

   You cannot ship government and custom-group specimens together in the same shipping file. If you need to ship both government and internal groups, you will need to create two separate shipping batches.
2. Select a group from the **Group** drop-down list (simply selecting it adds it to the criteria to be searched; the group won't appear in the list of search criteria on the right though).
3. Select a **Type** (i.e. field) and an **ID** (i.e. value), and then click the arrow button to the right to add it to the list of search criteria.
4. After adding all desired search criteria, click the button from the LDMS toolbar. This will bring up all the aliquots found that meet your criteria.
5. Click individual aliquots to select them and add them to the shipment. Hold down the **Ctrl** and **Shift** keys to select multiple aliquots.

   Important

   If you change the search criteria to something more narrow and then click the button again, you'll notice that aliquots that don't meet your new criteria are still displayed. This is because the search results are concatenated together. What you need to do is click the Refresh Grid button, which will clear your previous search results, and then click the button again. Don't click the button on the LDMS toolbar; that will actually clear your search and all the criteria, taking you back to the beginning.

If you need more refined searching (such as using AND/OR logic) you can use the **Extended Search** feature, which is accessed by clicking the button on the LDMS toolbar. This works the same way as it does in LDMS Specimen Management. For more information on how to use it, see the section called “Finding Aliquots After Logging Them” on page 32.

Marking Items for Shipping: What's the Point?

You can mark items for shipment in Specimen Management, setting the intended shipment date and destination. This allows you to specify the intent to ship while entering a specimen. For more information on doing this, see the section called "Marking Aliquots for Shipment" on page 34.

You might think that the button on the LDMS toolbar works the same way when no search criteria is specified in LDMS Shipping that it does in LDMS Assays—that is, it finds all specimens that have been marked for shipping. This is not the case; if no search criteria is specified, LDMS Shipping will show you *every* specimen available at your laboratory.

Marking an aliquot for shipment is still very useful, you just need to know where to search. Table 5.1 below shows how the fields on the Details screen in Specimen Management correspond to fields that can be searched in LDMS Shipping.

Table 5.1. Fields to search for finding *marked* specimens

Field in Specimen Management	Field (i.e. Type) to Search in Shipping
Shipping Category	MARKED SHIPMENTS
Intended Shipping Date	INTENDED SHIP DATE
Intended Receiving Lab	INTENDED REC LAB

While LDMS does not enforce the usage of these fields, you will receive a warning if you attempt to ship an aliquot to a destination other than the **Intended Receiving Lab**.

If you establish a good workflow at your laboratory, marking specimens for shipment can be a very useful, time-saving tool.

Selecting a Shipment Destination

LDMS shipping files can be generated for any laboratory. If the intended destination uses LDMS, all you need to do is select it from a list. If the laboratory is not using LDMS, you will need to enter additional information. This is done on the **Shipment Destination** tab.

Procedure 5.3. Shipping to an LDMS Laboratory

1. Select either the **Contact**, **Lab Number**, or **Lab Name** radio button, depending on which you want to look for.
2. Select the appropriate contact or laboratory from the drop down list.
3. Review the address information that was populated.
4. Select the person who should receive the shipment at the receiving laboratory from the **Contact at Sending Lab** section on the left; you can also enter in a new contact and telephone number.
5. Enter any additional comments for the recipient into the **comments** box; this information will appear on the shipping manifest and should not contain PHI or PII.

Procedure 5.4. Shipping to a Laboratory without LDMS

1. Select the **Lab Number** radio button.
2. Select one of the following:

- Select **0-Unassigned Lab Code** if this will be a one-time shipment or if the shipment is intended for a laboratory using Labware that has not been assigned an LDMS laboratory ID
- Select **999000 Select to Enter New Address** if you want to save the address for future use.

3. Enter the receiving laboratory's information; the contents of the comments field will appear on the shipping manifest and should not contain PHI or PII.
4. (Optional) Click the **Save Address** button.

The shipping information for LDMS laboratories

Frontier Science maintains a master database of laboratories using LDMS. The information that is stored includes the laboratory's shipping address and individuals working at the laboratory who are authorized to act as points of contact for receiving shipments.

When laboratories perform a data export, they automatically receive small database updates. Updates to contact information are one of these important updates. These updates are released several times each month. For more information about exporting, see the section called “Exports and Updates” on page 173.

If you need to update the shipping or shipping contact information for your laboratory or an employee at your laboratory, you can do so on the Frontier Science web portal [http://www.fstrf.org/portal]. Look for the **Submit Contact Changes** link under the **LDMS User Support** heading.

If you elected to save the address for future use, it will now appear in the laboratory drop-down with the laboratory ID number 999xxx, where xxx is the next available number.

If you've selected all the aliquots that you want to ship and the shipping destination, be sure to click the  button from the LDMS toolbar.

Setting up the Shipping Container

If you're shipping a marked storage container, LDMS already knows how your shipping container is organized (the same way it is organized in LDMS Storage ) . If you selected individual aliquots to ship, however, you'll need to tell LDMS about the container that you'll put them in for shipping.

This can be a little confusing because the settings for shipping containers are found on different tabs in LDMS Shipping  .

Table 5.2. Shipping container settings

Setting	Tab to find setting
Container size	Shipment Destination
Using letters or numbers for coordinates	Shipment Destination
Use position numbers instead of coordinates	Shipment Destination
How specimens will be put into the container	Shipment Destination
Specify how specimens are organized to put into the container	View Shipment

Setting	Tab to find setting
See a visual representation of the container	Shipment QA/QC

To view and change settings for the *container*, go to the **Shipment Destination** tab; to set how the *specimens* are ordered before filling them into the container, go to the **View Shipment** tab, and to see the container itself, go to the **Shipment QA/QC tab**.

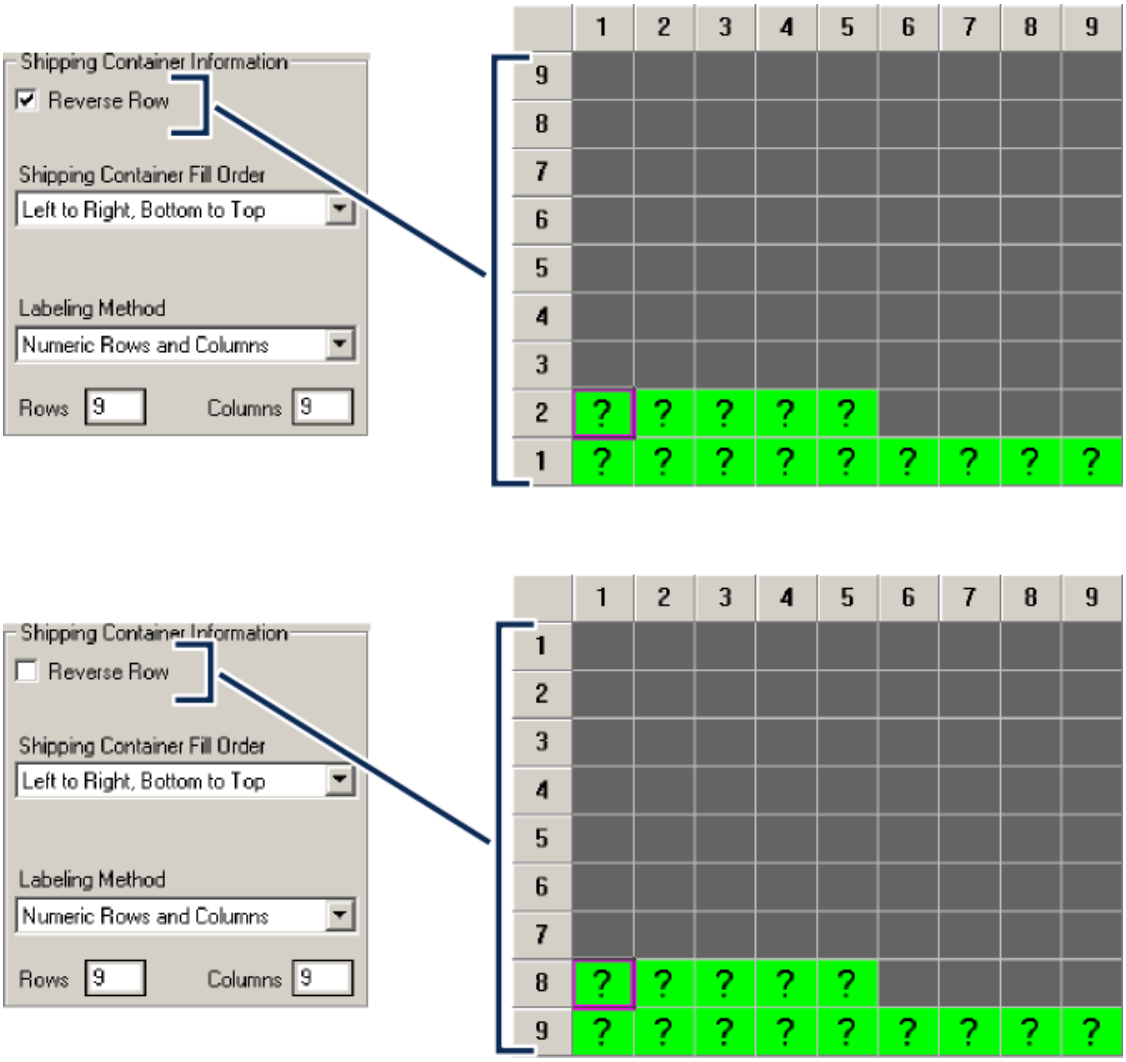
Note

If you change a setting for the container or specimen sort, you need to save your changes by clicking the  button from the LDMS toolbar. If you don't, the view won't be updated on the **Shipment QA/QC** tab.

Options available on the Shipment Destination tab for containers

Label Method	Set whether columns and rows are numbers or letters, or a combination of the two.
Reverse Row	Reverse the number of columns so that they start at the bottom instead of the top. This is often applicable when your fill order is bottom-to-top.
Rows & Columns	Set the height (rows) and width (columns) of the container. The default is 9x9.
Shipping Container Fill Order	How specimens will be put into the container. For example, `Left to Right, Bottom to Top` will put the first aliquot into the bottom-left corner, fill out the bottom row right to left, then move up towards the top until all aliquots are in the container.

Figure 5.4. Normal vs Reverse Rows



▲ This illustrates how the **Reverse Row** option affects a container. Essentially, it moves (1,1) from the top-left corner to bottom-left. There is no equivalent option for reversing column numbering.

Fill order (on the **Shipment Destination** tab) is not the same as the *sort order* (on the **View Shipment** tab). Fill order is *where* the specimens are placed into a shipping container; sort order is *how* the specimens themselves are organized. The sort order is found on the bottom of the **View Shipment Tab**. The sort order will affect both how aliquots are placed in a container and the order they appear on the manifest report.

Figure 5.5. Shipping container sort order on the View Shipment tab

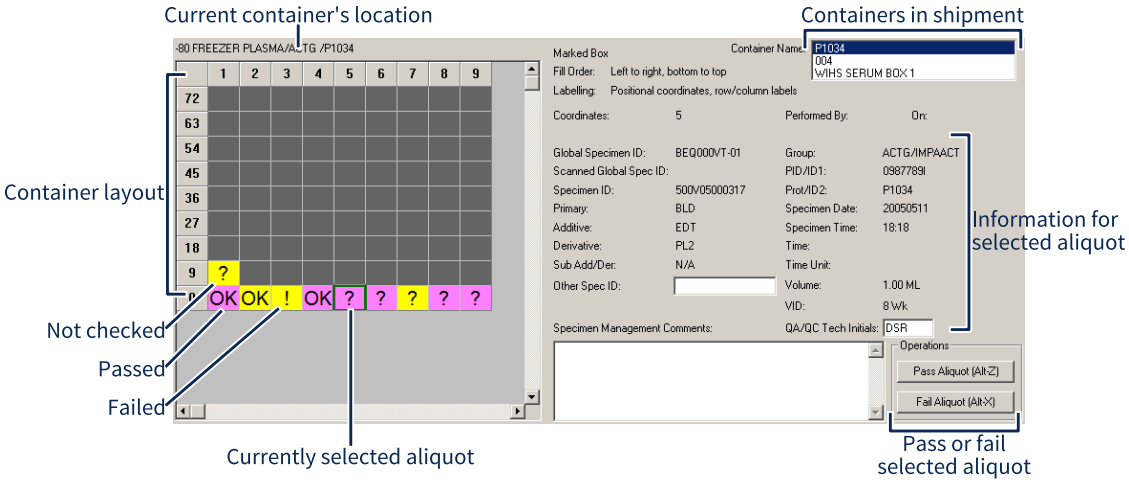
▲ A **Primary Sort Order** is required; the **Secondary Sort Order** is only required if the primary sort order is `Prot[ocol]/ID2`.

Performing Quality Control on a Shipment

It would be bad practice to not check the contents of a shipment before shipping it. Aliquots can get misplaced in storage, for example, and a mistake like that is much easier to correct before it has been shipped.

The process of checking each specimen's label against the information that LDMS will put on the shipping manifest and in the shipping file is called *QA/QC*. This is done in LDMS Shipping on the **Shipment QA/QC** tab. *QA/QC* should be performed at both the sending and receiving laboratories for the same shipment, to make certain what was sent is what was received.

Figure 5.6. The Shipment QA/QC tab



▲ Selecting **Pass** or **Fail** will advance automatically to the next aliquot. You can also simply scan the aliquot.

Note

If you're shipping individual aliquots (instead of shipping a container), you'll need to set the sort order on the **View Shipment** tab before you can perform QA/QC.

There are two ways to do QA/QC: manually or using barcode scanner. Using a barcode scanner is by far the easier (and more accurate) method.

Procedure 5.5. Performing QA/QC

1. Select the shipment batch for which you want to perform *QA/QC* from the **Setup Shipment** tab.
2. Select the current container (the one you're currently checking or filling) from the **Container Name** list.
3. Pull the first selected aliquot out of the container. Where the first aliquot is located in the container will depend on the sort order.
4. (Optional) If you want to assign an *other specimen ID* or comments, complete the appropriate field; this information will be appended to aliquots in your local LDMS database, as well as in the shipping file.
5. Do one of the following
   - Compare the aliquot's label to the information on the **QA/QC** tab. If the information matches, click the **Pass Aliquot** button, or press **Alt**+**Z**. If the information does not match, click the **Fail Aliquot** button, or press **Alt**+**X**.
   - Scan the aliquot with a barcode reader; LDMS will pass or fail the aliquot based on the *global specimen ID*.
6. Put the aliquot in the shipping container in the correct location.
7. Continue until all aliquots in the container have been checked.
8. Repeat for each container in the **Container Name** list in the upper-right corner.
9. After checking every container in the **Container Name** list, click the button from the LDMS toolbar.

Note

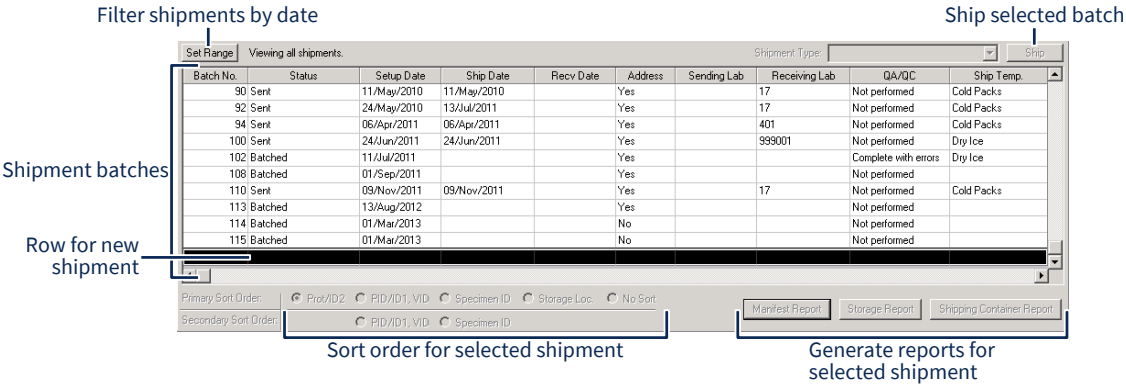
You might have noticed that the **other spec ID** and **Specimen Management Comments** fields are active. You can enter information into these fields while performing *QA/QC*. When you save, this information will be appended to aliquot records in LDMS Specimen Management, as well as updated in the shipping file.

The semantics are a little different, depending on whether you are shipping a storage container or individual aliquots. If you're shipping individual aliquots, you'll be putting aliquots into a new container, based on the sort order you selected on the **View Shipment** tab. If you're shipping a container, you're pulling the aliquot out of a container, checking it, and putting it back in the same spot. Other than that, the process is the same.

Viewing and Modifying Shipments

On the **View Shipment** tab, you can view all the shipments that your laboratory has prepared, sent, and received. Each row on the **View Shipment** tab represents one shipment. The status column shows you the type of shipment it is (with **Batched** being a shipment that you have prepared but not sent).

Figure 5.7. View Shipment Tab



To modify a shipment with the status of **Batched**, simply select it, then change to the appropriate tab, such as **Shipment Destination** to change the receiving laboratory or **Setup Shipment** to add more specimens. When you are done, click the button from the LDMS toolbar.

You *can* modify batches that have been shipped. This is because "shipping" in LDMS means generating a shipping file—you still likely have the shipment in your possession after generating the shipping file in LDMS, at least for a little while. If you discover that you made a mistake, you need to un-ship the batch in LDMS, which will allow you to make changes and generate a new shipping file and manifest.

To un-ship a batch after you have created a shipping file, right-click on the batch on the **View Shipment** tab and select `Unship Batch`. This will change its status from `Sent` back to `Batched` so you can edit it again. To change it back to `Sent`, you would follow the normal shipping process. You can use the right-click menu to delete a shipment with the status `Batched` as well.

Note

Un-shipping an LDMS batch requires the original shipping file. The shipping file must be in a directory named with the batch number (e.g. `C:\342\342` for batch number `342`); this is the same as the default location where LDMS creates new shipping files. If you do not have this shipping file, you will need to re-generate it (see the section called “Sending a Shipment” on page 75). This requirement does not apply to non-LDMS shipping files, such as CSV files.

Correcting Shipment Problems

Shipping file with an incorrect shipment date

When you create an LDMS Shipping File, LDMS will set the shipping date for the specimens to the current date. This date will be reflected in the shipping file and only shipping paper work generated by LDMS. If a shipment is created in LDMS and not shipped on the same day, the shipment date in the LDMS Shipping File and on paper work will not be correct.

Tip

To prevent shipping date errors from occurring, be sure to create the LDMS shipping file on the day the shipment is going to be sent.

If the correct shipment date is today’s date and the sending laboratory has a copy of the original shipping file, they can correct the error on their own. Un-ship the batch in LDMS, and then create a new shipping file. The shipment date will be updated to reflect the current date. If the laboratory does not have the original shipping file, they will need to contact LDMS User Support for a challenge password.

If the correct shipping date is a date in the past or if the sending laboratory no longer has the LDMS shipping file, the sending laboratory cannot correct the error on their own. They will need contact LDMS User Support for further assistance. See the section called “Getting Help” on page 10.

Error with shipment destination

The receiving laboratory must be specified when creating a shipment in LDMS. When the receiving laboratory attempts to import the shipping file, LDMS will check to verify that the laboratory that was supposed to get the shipment is that laboratory that received it. This is one way LDMS helps avoid the wrong laboratory getting the wrong shipment through human error.

It is possible, however, that the laboratory that prepared the shipment selected the wrong receiving laboratory in LDMS but shipped to the correct laboratory. If this error is discovered before the shipment was sent, the sending laboratory can simply unship it and make the correction. If the shipment has been sent, other steps would be needed.

If the sending laboratory still has a copy of the LDMS shipping file, then they must change the batch to unshipped, correct the shipment destination and then re-send the corrected shipping batch file to the receiving laboratory. If the sending laboratory no longer has a copy of the orig-

inal, incorrect shipping file, then the sending laboratory must contact LDMS User Support for assistance with updating the shipping file.

If the shipment has already been sent, the receiving laboratory will be given a warning about the discrepancy when trying to import the shipping file. At this point, the receiving laboratory should chose not to import the file and instead get a correct file from the sending laboratory. LDMS will allow the receiving laboratory to import the shipping file with the incorrect destination, but this issue is much more difficult to correct if the warning is ignored.

Discrepancy between expected and received shipment

When specimens are shipped using LDMS, a printed manifest is also sent. This printed paperwork, in conjunction with the LDMS Shipping File data, is used to confirm that the physical specimens that were received match what was expected. It may be that the specimens were not packaged correctly or the shipment was prepared incorrectly in LDMS. If there is a discrepancy between the printed paperwork and the actual specimens that were packaged, the corrective measure will depend on when the error is discovered.

Tip

Pay close attention to any specimen comments displayed on the Shipping Manifest Report. These comments could explain why there are discrepancies between the specimen label and the Shipping Manifest Report.

If the discrepancy is caught before the file is imported, the receiving laboratory should not import the file and instead contact the sending laboratory to get the correct shipping file. The sending laboratory should unship, correct, and re-create the shipping file and shipping paperwork, then send these to the receiving laboratory. The receiving laboratory can then safely import the corrected shipping file.

If the discrepancy is not caught until after the shipping file is imported, how to proceed will depend on the nature of the issue.

If the shipping file contained extra specimens that were not part of the physical shipment, the receiving laboratory now has these specimens listed at their laboratory in LDMS. Since the sending laboratory didn't actually send the physical specimens, the receiving laboratory will need to send those specimens back in LDMS. This will move the data for the specimens back to the sending laboratory, where the specimens are still located.

To do this, the laboratory that received the shipping file with extra specimens will create a new shipment with those specimens, and then send the shipping file back to the originating laboratory. Once that laboratory has imported the shipping file, the data for those specimens will have been successfully moved back to the laboratory.

If the laboratory received specimens that were not part of a shipping file, the receiving laboratory must notify the sending laboratory in writing. The sending laboratory will need to create a shipping file with these specimens and provide that to the receiving laboratory so that they can be imported.

If there are any discrepancies between the physical specimen labels and the shipping report, the two laboratories should work together to resolve the issue appropriately.

Lost or Unsatisfactory Shipment

If the entire shipment is lost and never received, LDMS information needs to be updated to reflect the event. If this does not happen, one laboratory will show the specimens have shipped

to another laboratory, where those specimens don’t exist. Later, when the data is viewed later, it won’t be clear where the specimens are located and what happened to them.

The receiving laboratory should import the affected shipment. During the import process, you will have the opportunity to adjust the condition of the specimens. If the shipment was lost, the condition code for all specimens in the shipment should be changed to `LSH` (Lost Shipment) and apply the never store property to all of the specimens. If another condition applies—for example, if the specimens were left outside during winter and frozen—that code should be selected. If the specimens are in a state that they will not be saved, the never story property should also be applied to them.

In either case, if replacement specimens are available, those specimens should be sent to the receiving laboratory.

Important Shipment Reports

There are a few reports that can be generated on the **View Shipment** tab. They are found in the bottom-right corner of the screen. There are more shipping-related reports available using the LDMS Reports feature. For a listing of those reports, see the section called “Shipping Reports” on page 136.

Shipment reports

Manifest Report	Details the specimens included in a shipment; should be printed and shipped along with the shipment; *this report must be generated before you can create a shipping file*
Shipping Container Report	Shows the layout for specimens in shipping containers, based on the *sort order* and *fill order*.
Storage Report	Contains the specimens and their storage location, useful if you've batched specimens together to be shipped but you still need to pull them from storage

Note

The manifest and shipping container reports should be included with the physical shipment of specimens.

Sending a Shipment

If a shipment's status is "batched", this means that the shipment has been prepared, but not sent. Sending a shipment is done on the **View Shipment** tab. You're not technically sending it; what you're doing is changing the status of the shipment to `shipped` in LDMS and creating the shipping file. The shipping file is a computer file that the you will send to the receiving laboratory to import into LDMS.

Note

The process for re-creating a shipping file is identical to creating it.

Procedure 5.6. Changing the status of a batch to shipped in LDMS

1. (When shipping loose specimens) Select the **primary sort order** from the bottom of the **view shipment** tab.
2. (When shipping loose specimens) Select the **secondary sort order**
3. Generate the shipping manifest by clicking the Manifest Report button.

   Note

   If your shipment contains specimens for `MACS` or `WIHS` groups, you will be prompted to chose between generating the standard manifest report or the SeraCare manifest. Export the SeraCare manifest as a CSV file; this is considered a SeraCare shipping file.
4. Select the type of shipping file to generate from the **Shipment Type** drop-down in the upper-right corner. For a description of these formats and the output files, see Table 5.3.

   Tip

   It is a very good idea to communicate with the receive laboratory to determine what software they are using and their preferred shipping file format. When both laboratories are using LDMS, the standard LDMS Shipping Batch format should be used.
5. Click the **Ship** button.
6. When prompted, select the temperature at which the shipment will be sent.
7. Click the appropriate drive where the shipping file should be created. This may be a removable media drive, such as a USB-drive or it may be the `C:\` drive.

   Note

   At this time, you cannot specify a specific directory to which to write the shipping file; you can only specify the drive.
8. A separate program called LDMS Data Exchange (sometimes called LDX) will appear. This program will show you the progress of pulling information from your LDMS database and creating the shipping file. To start, click the **Exchange** button.

   - (For LABWARE2 and Cross-LIMS only) Before selecting the **Exchange** button, click the **Configure** button in the **Destination** section. Specify the output location for the file.
9. Select the temperature at which you will be shipping the specimens. If you want to specify more information, use the comments field on the **Storage Destination** tab.

LDMS will create a folder named with the batch number in the drive that was specified (e.g. `C:\43\43`, where `43` without an extension is the shipping file). The corresponding batch will now have the status of `Sent` on the **View Shipment** tab.

Table 5.3. Available shipping file formats

Format	File extension	Encrypted?	Example filename
LDMS Shipping Batch	None	Yes	43
Excel or Comma Separated Text	.xls or csv	No	ship43.xls
Cross-LIMS Manifest	.txt	No	500-512-0000000043.txt
Labware Shipments	.csv	No	500-512-0000000043.csv

▲ In the file name examples, the batch number is "43", the sending laboratory is "500", and the receiving laboratory is "512."

How exactly the shipping file is given to the receiving laboratory will vary, depending on the group and laboratory. Only LDMS Shipping Batches are encrypted; all other formats are, by nature, plain text files that could be read outside of LDMS.

Importing a Received Shipments

Importing a Shipment from an LDMS Laboratory

LDMS can receive shipments in all the same shipping file formats that it can create.

Important

When the batch is imported into your LDMS, it will be assigned the next available batch number. It will not have the same batch number that was assigned to it at the sending laboratory. However, if you are receiving an LDMS Shipping Batch file, you do need to know the batch number from the sending laboratory to import it. This is a safeguard to keep paper manifest consistent with shipping files as they are imported. The batch number is printed on the LDMS-generated manifest.

Procedure 5.7. Importing a shipping file from another laboratory

1. In LDMS Shipping, select the bottom, blank row on the **View Shipment** tab.
2. Change to the **Import** tab.
3. Select the type of shipping file that you will be importing from the **Shipment Type** drop-down list.
4. (For LDMS Shipping Files) Enter the batch number from the receiving laboratory into the **Shipment No.** field. If this does not match the batch number in the shipping file, it will be rejected.
5. Click the Import button and select the shipping file that you received from the sending laboratory.
6. (For LDMS Shipping Files only) Change to the **Shipment QA/QC** tab and perform QA/QC on the shipment. For more information on how to do this, see the section called “Performing Quality Control on a Shipment” on page 70.
7. Change back to the **Import** tab, then click the Continue button from the bottom-left of the screen.
8. (Optional) Change the condition code of one or more specimens as needed to reflect the condition of the shipment as you received it. Hold down the **Ctrl** or **Shift** key to select more than one specimen, then change the condition code from the drop-down list. For an explanation of condition codes, see the section called “Using Condition Codes” on page 23.
9. Select whether to **Import associated Test (assay) Setup Information**. If yes, aliquots that were assigned a test at the sending laboratory will be assigned to those tests at your laboratory. If no, test assignments will be disregarded. See the section called “Assigning an Assay to Aliquots” on page 34.
10. Select the temperature at which you received the shipment from the **Select a shipping temperature** drop-down list.
11. (If the **import as is** feature is enabled) Selected whether you want to automatically import received containers into LDMS as-is. If yes, a temporary freezer will be created in LDMS Storage called `SHIPPING IMPORT` that contains the specimens from the shipping file. You would then move the specimens to the appropriate location in storage.

12. (Optional) If you do not want to ever store the specimens, select the **Mark specimens to never store** check box. For more information on never store, see the section called "Using `Never Store`" on page 33.
13. (For internal groups only) If the shipment contained an internal group, you'll be prompted to either create the new group in your local LDMS database or map the imported group to an existing internal group.

By default, specimens will not be added to your storage automatically after importing them. The **Bulk Add** tab in LDMS Storage has fields that allow you to search for specimens to store by batch number and received date. For more information on adding aliquots to storage, see the section called "Adding and Removing Specimens from Storage" on page 51.

If you would rather add specimens to your LDMS storage automatically when a shipping file is imported, you must enable the **Allow automatic storage of imported samples** option. This is option is found by clicking `AdministrationSystem Configuration` and then changing to the **Import** tab. For more information about this feature, see the section called "Import Tab" on page 168.

Text Shipping File

LDMS is capable of importing specimens from tab-delimited text files. The filename must be in the format described in Figure 5.8. The file must contain all of the fields listed in Table 5.4 separated by tabs. A header row should not be included.

Figure 5.8. Text shipping file filename format

```
aaa_bbbbbb_ddmmmyyyy.txt
OR
999aaa_bbbbbb_ddmmmyyyy.txt
```

Where `aaa` is the sending laboratory's LDMS laboratory ID number, `bbbbbb` is the batch number (with leading zeros added, if necessary), and ddmmmyyyy is the date the batch was created.

Important

Text shipping files *must* have exactly 22 columns, and the columns must be in the order specified below. If there are more or less than 22 columns, LDMS will not be able to correctly read the file. No columns can be removed, and extra columns cannot be added.

Table 5.4. Text shipping file fields

Field	Field Type/ Max Length	Example	Note
Group	Alpha / 20	ACTG/ IMPAACT	REQUIRED: The applicable group must be available in the Specimen Management at the receiving laboratory
PID/ID1	Alpha/Numeric / 25	0012345L	REQUIRED
Protocol/ID2	Alpha/Numeric / 25	A0000	
SID/ID3	Alpha/Numeric / 25	A00001234L	

Field	Field Type/ Max Length	Example	Note
VID	Numeric / 6	1.00	Visit number. Format: three numbers before the decimal and two numbers after the decimal
VID Unit	Alpha / 3	Vst	
Clinic	Numeric / 5	12301	The applicable clinic must be available in the LDMS
Specimen Date	Alpha/Numeric / 9	28May2009	REQUIRED: Format: DDMMMYYYY
Specimen Time	Alpha/Numeric / 5	13:00	Format: HH:MM (24-hour military format)
Received Date	Numeric / 9	29May2009	REQUIRED: Format: DDMMMYYYY
Received Time	Alpha/Numeric / 5	14:00	Format: HH:MM (24-hour military format).
Time	Numeric / 6	1.00	Format: three numbers before the decimal and two numbers after the decimal. Typically used for pharmacology and metabolic specimens.
Time Unit	Alpha / 3	Hrs	Typically used for pharmacology and metabolic specimens. See Times Fields in LDMS on page 17.
Global Specimen ID	Alpha / 11	A1234567-89	See the section called “Specimen Identifiers” on page 12.
Primary	Alpha / 3	BLD	REQUIRED: See Chapter 12: “*LDMS Code Abbreviations*” on page 199
Additive	Alpha / 3	EDT	REQUIRED: See Chapter 12: “*LDMS Code Abbreviations*” on page 199
Derivative	Alpha / 3	PL1	REQUIRED: See Chapter 12: “*LDMS Code Abbreviations*” on page 199
Sub/Add Derivative	Alpha / 3	N/A	REQUIRED: See Chapter 12: “*LDMS Code Abbreviations*” on page 199
Volume	Alpha/Numeric / 11	10.00	REQUIRED: Format: Nine numbers before the decimal and two numbers after the decimal.
Volume Unit	Alpha / 3	ML	See Chapter 12: “*LDMS Code Abbreviations*” on page 199

Field	Field Type/ Max Length	Example	Note
Condition	Alpha / 3	SAT	If blank, LDMS will default to SAT (satisfactory). For more information about condition codes, see the section called “Using Condition Codes” on page 23.
Other Specimen ID	Alpha/Numeric / 15		Optional identifier at specimen level

Removing a Received Shipment

A shipment that you've received in LDMS and imported via the **Import** tab in LDMS Shipping can be removed. To do so, simply find the shipment on the **View Shipment** tab, right-click on it, and then select `Unimport Batch`.

You will be required to contact LDMS User Support to complete this process (the section called “LDMS and Challenge Passwords” on page 4). This is because LDMS works under the assumption that your laboratory reviewed the shipment prior to importing it. If it needs to be removed, that implies that a serious or unique problem has occurred.

Compatibility with WebLDMS

LDMS for Windows is capable of importing shipments that were created using WebLDMS. In order ship files to or receive shipments from laboratories using WebLDMS, you must be using LDMS for Windows version 10.0 or higher.

There are a few key differences between LDMS for Windows and WebLDMS that can affect the shipment of specimens.

- WebLDMS uses a different format for the global specimen ID, however the global specimen ID will never be changed during shipment. This means that the global specimen ID will look different, depending on where the specimen originated.
- WebLDMS does not assigned a specimen ID. If you import a shipment sent from a WebLDMS laboratory, LDMS for Windows will assign a specimen ID automatically.
- WebLDMS allows the shipment and storage of primary specimens; LDMS for Windows does not. If you import a shipment in LDMS for Windows that contains a primary that has no aliquots, it will automatically be converted into an aliquot.

For more information about compatibility between LDMS for Windows and WebLDMS, see the WebLDMS User Manual [https://dev-alpha.fstrf.org/apps/cfmx/apps/ldms/webldmsManual/webhelp/index.html#topics/shipping/c_shipping_compatibility.html].

Chapter 6. Assays

Running an assay means reading data

The method of getting assay data into LDMS will vary, depending on the assay and available equipment at your laboratory. There are three ways to get assay data into LDMS:

- Read the assay output directly from the instrument
- Read an output file that was created when the assay was run
- Enter the assay results data by hand

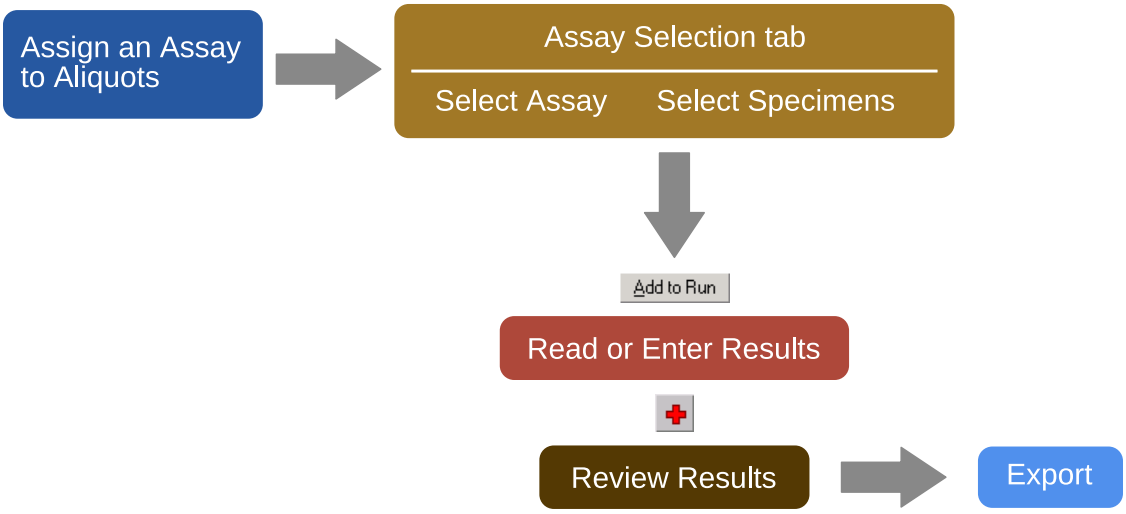
LDMS does not really run your assay; it is more accurate to say that LDMS *reads* assay data, and then stores it. This reading may or may not coincide with running the assay, since the direct read method is not available for all assays. Reading assay output using LDMS is also sometimes referred to as "resulting" an assay in LDMS, since the intent is to get assay results into LDMS's database for long-term storage.

> **Note**
>
> Throughout LDMS (and this manual), the terms "read" and "run" are used interchangeably. Many features in LDMS refer to running an assay when you may actually be reading an output file from an assay that was already run.

The process of reading an assay in LDMS varies, depending on the assay involved. Below are the steps that apply to most assays:

1. Select the assay and create a new run on the **Assay Selection** tab.
2. Find and chose the specimens in LDMS to be added to the run.
3. Set up the assay. This would include things like defining the locations of controls on plates, the settings used when running the assay, etc.
4. Run (i.e. read) the assay. The exact method involved will vary by assay.
5. Review and accept assay results.
6. (If the results are for a study where data is managed by Frontier Science) Perform an export.

Figure 6.1. Assay Workflow in LDMS



Supported Assays

Table 6.1. Assay Support in LDMS

Category	Assay	Direct Read[a]	File Transfer[b]	Data Entry[c]
Cultures	Qual. Macro.			●
	Qual. Micro			●
	Quant. Cell			●
	Quant Fluid			●
DNA PCR	COBAS TaqMan HIV-1 Qual		●	
	Roche HIV DNA PCR	●	●	
	Roche HIV DNA PCR 1.5	●	●	
Immunology	Advanced Flow			●
	Apoptosis by P.I.			●
	Cryopreservation			●
	LPA			●
	NK Assay			●
	TUNEL Assay			●
Misc	MT-2 Assay			●
P24 Antigen	Cult.-Dupont/PerkinElmer	●	●	
	Culture-Abbott	●	●	
	Culture-Coulter	●	●	

Category	Assay	Direct Read[a]	File Transfer[b]	Data Entry[c]
	Culture-Organon Teknika	●	●	
	[Teknika] VQA controls prior to 1997	●	●	
	Culture-ZeptoMetrix	●	●	
	ZeptoMetrix Extended	●	●	
	Dir.-Dupont/PerkinElmer	●	●	
	Direct, Mono-Abbott	●	●	
	Direct, Poly-Abbott	●	●	
	Direct-Coulter	●	●	
	ICD, mono-Abbott	●	●	
	ICD, mono-Coulter	●	●	
	ICD, poly-Abbott	●	●	
	ICD, Dupont/PerkinElmer	●	●	
PK Assays	[Various]			●
Viral Load RNA	Abbott Realtime HIV-1		●	
	Abbott Realtime HIV-1 with Calibrators		●	
	COBAS TaqMan HCV		●	
	COBAS TaqMan HIV-1		●	
	NASBA HIV RNA QT Assay		●	
	NASBA - No Negative Control		●	
	Nuclisens HIV RNA QT		●	
	Roche Amplicor Monitor HIV RT PCR	●	●	
	Roche Amplicor (Kit Controls)	●	●	
	Roche COBAS Amplicor		●	
	Roche COBAS Amplicor Ampliprep		●	
	Roche COBAS UltraSensitive		●	
	Roche COBAS UltraSensitive Ampliprep		●	
	Roche UltraSensitive HIV RT PCR	●	●	
	Roche UltraSensitive (4 control)	●	●	
	Roche UltraSensitive (Kit Control)	●	●	

[a]Assay is capable of being read directly by LDMS using compatible instruments.

[b]Assay produces output that must be copied to the computer with LDMS; LDMS can read these output files

[C]The user must manually enter or copy results into LDMS.

Creating and Reviewing Assay Runs

Assigning Assays to Aliquots

Important

Aliquots must be flagged for testing on a specific assay before results can be read or entered into LDMS. *If an aliquot is not assigned an assay, then it will not appear on the **Assay Selection** tab.*

There are two ways to assign an assay to an aliquot:

- Find the aliquot in LDMS Specimen Management, right-click on it and select `Test Setup`. This is useful if you need to assign tests to only a few aliquots, or want to tests to aliquots as you enter them. For instructions on doing this, see the section called “Assigning an Assay to Aliquots” on page 34.
- Use the Assign Test tool. This is useful if you need to assign tests to a large number of aliquots.

Tip

If you receive a shipment from another laboratory and that laboratory had assigned tests to the aliquots already, you can import those test setups. In this way, a processing laboratory can assign assays to specimens as they are entered into LDMS, and a testing laboratory doesn't need worry about that step.

Figure 6.2. Assign Tests Tool

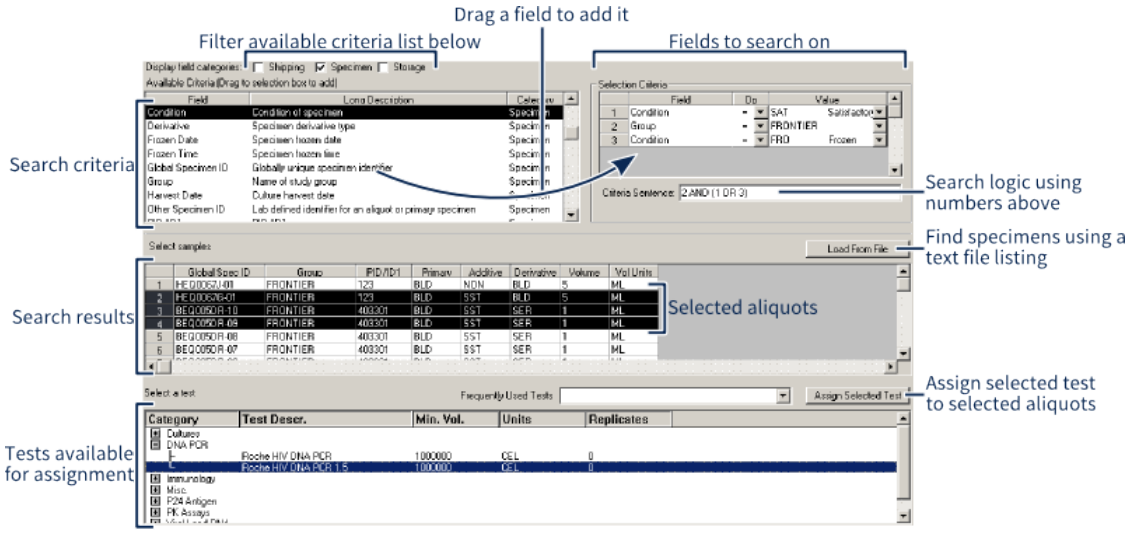
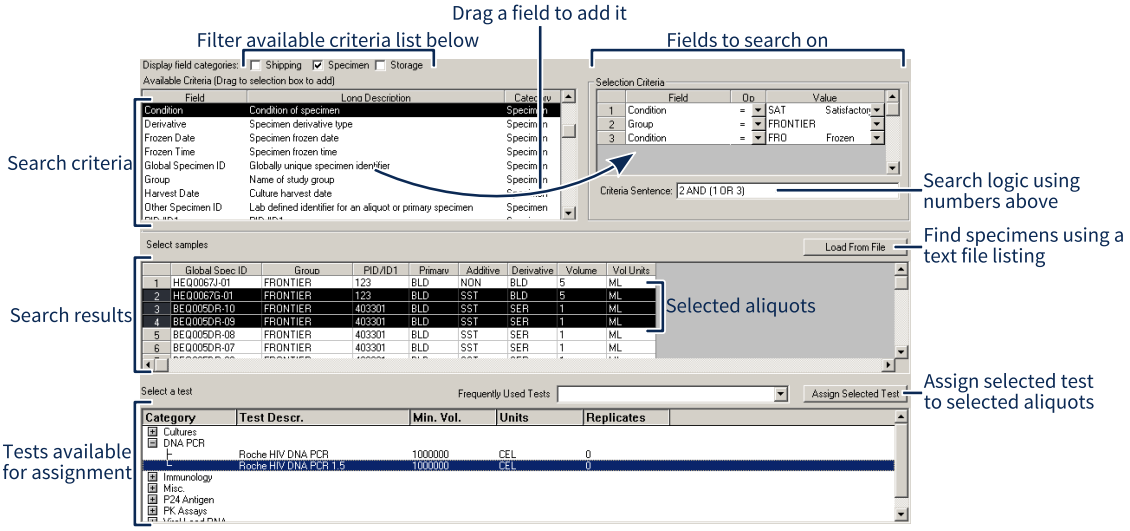


Figure 6.3. The Assign Tests Tool



▲ The Assign Tests tool.

Procedure 6.1. Using the Assign Tests Tool

1. Access the Assign Tests tool by clicking `ToolsAssign Tests` from the LDMS menu bar.
2. Drag a field from the **Available Criteria** list on the left to the **Selection Criteria** list on the right.
3. Enter an **Op[erator]** and **Value** for the field to be searched.
4. (Optional) After all fields needed have been added, enter the **Criteria Sentence** using the numbered fields above it. If left blank, LDMS will default to `1 AND 2 AND 3 AND... etc`.
5. Click the button from the LDMS toolbar.
6. Select the aliquots to be assigned to a test from the **Select samples** list.
7. Select an assay from the **Select a test** list.
8. Click the Assign Selected Test button.

You can also use a list of *Global Specimen IDs* instead of specifying search criteria. Click the Load From File button. This file must be a text file with exactly one global specimen ID per line.

If you want to see what specimens have been assigned to a specific assay, you can do so by generating a Pending Specimens report.

Procedure 6.2. Generating a pending specimens report

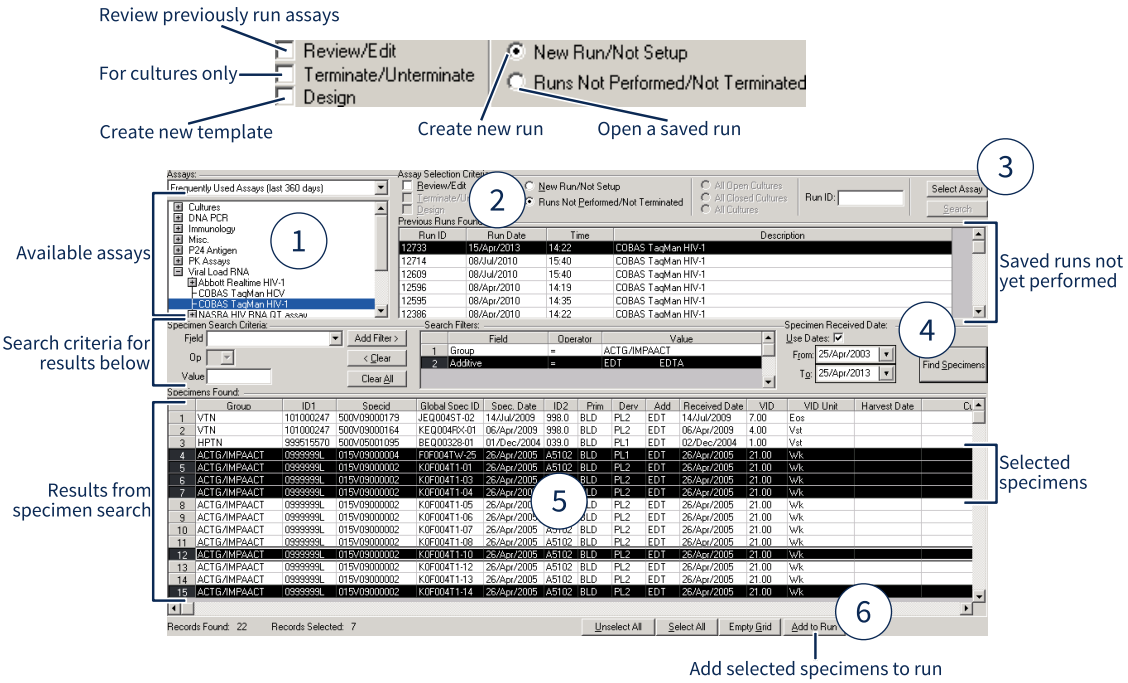
1. Click the button from the LDMS toolbar.
2. On the **Assay Selection** tab, select the assay for which you want to see assigned specimens from the **Assays** list in the upper-left corner.
3. Click the button from the LDMS toolbar.
4. Select **[Assay Name] Pending Specimens Report**.
5. Enter the desired date range to display.

There is a pending specimens report available for each assay in LDMS.

Creating a New Assay Run

The **Assay Selection** tab is where you specify the assay and specimens to test. After selecting an assay, only specimens that have been assigned that particular assay will be displayed. For instructions on how to assign assays to aliquots, see the section called “Assigning Assays to Aliquots” on page 84.

Figure 6.4. The Assay Selection screen



▲ Each number in this figure corresponds to a step below.

Procedure 6.3. Creating a new assay run

1. Select an assay from the **Assay Selection** box in the upper-left corner.
2. Select the **New Run/Not Setup** option.
3. Click the Select Assay button on the right.
4. Find and select the aliquots to be tested. There are three ways to do this:
   - Click the ⚡ or Find Specimens button without specifying any search criteria. This will find all aliquots that have been assigned the selected assay but not yet resulted in LDMS.
   - Scan the bar code on the aliquot. If you do this, LDMS will ask if you want to increment the specimen's thaw count.
   - Use the **Specimen Search Criteria** fields to find aliquots that meet specific criteria (and have been assigned the assay). This allows a narrower search than simply clicking the ⚡ button. To do this:

     a. Select the **Field**, **Op[erator]**, and **Value** under Specimen Searching Criteria, and then click the Add Filter > button. This will add your filter to the list on the right.

     b. Add more filters, as necessary.

     Note

     If more than one filter is used, they will be searched together, separated by AND statements.

     c. (Optional) Select the **Use Date** check box, and enter a start and end date to narrow down your criteria within a specific `Received Date` range.

     d. Click the ⚡ or Find Specimens button.

     Important

     If you change your search criteria (e.g. by adding a filter or changing the date range) you need to click the Empty Grid button. If you don't, your old

search results will be combined with your new search results, and it will look like your filters aren't working.

5. Click on each aliquot to select it and add it to the selected assay run.
6. Click the Add to Run button on the bottom. You'll automatically be taken to the appropriate screen to continue setting up the assay before running it.

Specimen Thaw Count

All specimens in LDMS have a *thaw count* property. This property is set to `0` by default when a specimen is created. The *thaw count* represents the number of times that a specimen has been removed from storage and warmed. There are two places in LDMS where this information is displayed:

- In the Specimen Management task, thaws are displayed in the Aliquot Details Window for all aliquots.
- In the Storage Management task, thaws are displayed by selecting a specimen in the storage view and clicking the Details button.

Since specimens generally need to be thawed when they are removed from storage for testing, LDMS will automatically ask if you would like to increment the *thaw count* for a specimen when you add it to a new assay run. This will only happen, however, if you are adding the specimen by scanning it with a barcode reader. If you are searching for the specimens to test and adding them manually, LDMS will not ask if you want to increment the *thaw count* (you can still do so using Specimen Management or Storage Management).

Adding Specimens and Controls not Logged into LDMS

There may be times where you need to test a specimen or control that is not entered into LDMS through Specimen Management. For example, you may have a control that is used on assay internally at your laboratory.

Procedure 6.4. Adding a specimen or control to an assay that was not logged into LDMS

1. Setup the assay as normal. See the section called “Creating a New Assay Run” on page 85.
2. On the **Preview** tab, click the button from the LDMS toolbar.
3. Enter an identifying name into the **specimen identifier** field. This is *not* an LDMS specimen ID (since the specimen was not added to LDMS), but rather a name for your usage.

Specimens added in this manner will always be placed into the next available location in your assay setup. These specimens will appear on the assay result report but will not be available to select for patient reports.

Recalling an Assay that has been Setup but not Read

LDMS allows you to set up an assay run and save it so that it can be completed later. This is done by clicking the Run Later button on the **Preview** tab for most assays. You can open these saved assays later and continue where you left off. This could be used, for example, to prepare an assay in LDMS before it is actually run.

Procedure 6.5. Finding assay runs that were set up but not run

1. Select an assay from the **Assay Selection** box in the upper-left corner.
2. Select the **Runs Not Performed/Not Terminated** radio button.
3. Click the Search button.
4. Select the run that you want to open from the **Previous Runs Found** list.
5. Click the Select Assay button.

Once you're back to the assay **Preview** screen, you can continue to configure or read the assay like normal.

Generating Layout Reports

For many assays, you need to tell LDMS the location of controls and specimens on your testing equipment. This is generally done on a grid in LDMS, where each position corresponds to a position on your instrument.

If you prepared the assay in LDMS before running it on your equipment, it may be helpful to have a print out of how you set it up in LDMS. This way, when you are setting up your equipment, you can be sure that it matches your LDMS setup.

To generate a layout report, click the button from the LDMS toolbar while setting up or reviewing an assay before it has been run. For instructions on recalling an assay, see the section called "Recalling an Assay that has been Setup but not Read" on page 87.

Reviewing Assay Results After They Have Been Read

The results of previously run assays are saved in your laboratory's LDMS database and can be viewed at any time. You can review data, generate result reports, censor results, enter review information, etc.

Procedure 6.6. Viewing a previously read assay

1. On the **Assay Selection** tab, select the assay for the results you want to review from the **Assays** list on the left.
2. Select the **Review/Edit** check box.
3. (Optional) If known, enter the **Run ID** for the assay results you're looking for.
4. Click the Search button on the right. This will list all assay runs for that assay in the **Previous Runs Found**
5. Select a run from the **Previous Runs Found** list, and then click the Select Assay button. The assay results will be displayed.
6. Review, modify, or censor the run as needed.

   Note

   The **Results** screen and options available when reviewing results will vary, depending on the assay selected.
7. If changes were made (including entering reviewer information), click the button from the LDMS toolbar.

Censor Codes

Censor codes are special indicators that can be assigned to assay results or individual specimens on an assay to document an issue. If an assay has no censors applied, the results are assumed to be fine; if there is a censor, the results should be examined more closely as they may be invalid. A censor code might indicate that a specimen on an assay plate was contaminated, or it might indicate that an equipment failure invalidated all the results for the run. If the results for a control specimen were significantly wrong, this tool would probably warrant a censor code.

Censor codes that are added by the user are called *user censors*; those added automatically by LDMS are called *system censors*. There are three types of censor codes:

run censors	These censor the results of an entire assay run. They indicate that something went wrong with the entire test.

specimen censors	These censor a single specimen on a run; other specimens on the run are unaffected.
test censors	These censors are assigned in LDMS Specimen Management and are used to explain why an assay that was expected to be run for the specimen was not run.

For a detailed listing of all the censor codes available in LDMS, see Chapter 12: "*LDMS Code Abbreviations*" on page 199.

Correcting Errors in Assay Runs

There may be times that you read an assay output file and, for whatever reason, there is an error in the run. This might happen, for example, if there is a discrepancy between the placement of a specimen in LDMS and your physical assay plate. In this case, there is nothing wrong with the results, but rather LDMS expects the specimens to be in a different plate location. You correct the position of specimens on the plate, LDMS will be able to read the results again, and they will now be correct. For other issues, only a single specimen by be affected, and it will be more cost efficient to test that one specimen on another plate to correct it.

This section will describe a few common errors that can occur and how to correct them.

Out of Sequence Errors

An out of sequence error occurs if a well's absorbance values do not decrease as the dilution factor increases across your plate. For Roche Virology assays, this is designated by the system-assigned specimen censor codes `L(HIV)` for specimens and `L(QS)` for controls, depending on the type of well.

Procedure 6.7. Manually correcting an out of sequence error

1. Open the completed run in LDMS Assays. See the section called "Reviewing Assay Results After They Have Been Read" on page 88.
2. Click the Options button.
3. Select the **Reselect Well** option and click the **OK** button.
4. In the **Change Selected Well** window, select the specimen(s) that must be updated and make your corrections.
5. Select the reason for your change from the **Reason well is being reselected** drop-down list.

The kit copies per mL will automatically be recalculated, and the censor code `C` (corrected) will be applied to the specimen that was modified. The `C` censor code will be used to document the change.

Controls with OD Ratio Failure

If a control in the assay results receives the system-assigned censor code `D` (OD Ratio Failure), the control can be re-detected to validate your assay results. To do this, you must run the control on another assay run where the control was detected correctly and is valid. You will need the following information from this valid run:

- The LDMS runid
- Control name
- Plate number that the control appeared on
- Position (column) on the plate (e.g. `1` for the first column, `2` for the second, etc.)

Procedure 6.8. Updating a run with an invalid control due to OD ratio failure

1. Open the completed run in LDMS Assays. See the section called "Reviewing Assay Results After They Have Been Read" on page 88.

2. Right-click on any specimen and select `Censor Run`.
3. Select the censor code `C` (control re-run and valid - assay is valid) and click the **OK** button.
4. Enter the runid, control name, plate number, and position on the plate (column) from the valid run into the appropriate fields.

If you look at your results now, you will see that the `D` or `DF` system censor is still applied, but the run is now valid and the user censor code `C` (corrected) has been added. The **Re-detect Runid** field will have the run ID for the run with the validated control.

Modifying Dilution and Recalculating

If the calculated viral load result for an assay's results is above the upper limit of the assay, the censor code `X4` will be applied. When this happens, you can modify the dilution and recalculate a specimen.

Procedure 6.9. Updating specimen dilution after an assay has been completed

1. Open the completed run in LDMS Assays  . See the section called "Reviewing Assay Results After They Have Been Read" on page 88.
2. Right-click on the specimen to be modified and select `Modify Specimen`.
3. Enter the new dilution into the **Sample Dilution** field, and click the **OK** button.

LDMS will re-calculate the results based on the new dilution factor.

Virology Assays

Abbott Realtime and COBAS TaqMan

LDMS supports the following Abbott Realtime and COBAS TaqMan assays:

- Abbott Realtime HIV-1
- Abbott Realtime HIV-1 with Calibrators
- COBAS TaqMan HIV-1
- COBAS TaqMan HCV

All of these assays are run relatively the same way in LDMS.

Note on Abbott Data

Exporting data from the Abbott assay is done using the Abbott m2000rt software. For detailed instructions on creating a result file with this software, refer to the documentation provided with m2000rt.

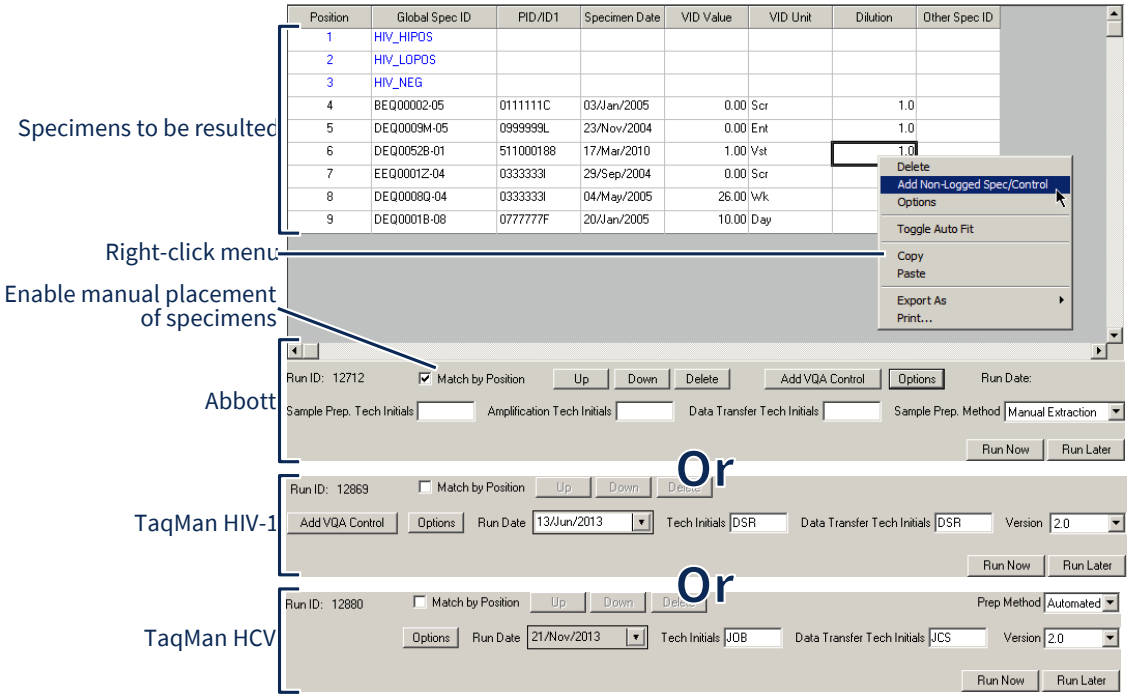
m2000rt will output a text file with a filename similar to this:

```
m2000rt serial number_PCR plate name_date_time.txt
```

Unlike other viral load assays, the Abbott and TaqMan are setup as a line listing instead of a plate layout on the **Preview** tab. Each row corresponds to one control or specimen on the run. To re-arrange the order of specimens and controls, select the **match by position** check box, and then use the Up and Down buttons. *If **match by position** is selected, the order of controls*

and specimens in LDMS must match the order of specimens and controls in the output file exactly. If this option is not selected, LDMS will match specimens to results using the *global specimen ID*, **PID/ID1**, or *other specimen ID* values. If the **match by position** option is not selected and the **PID/ID1** is used in the result file, there cannot be more than one specimen with that ID1 on the same run.

Figure 6.5. The Preview tab for the Abbott Realtime HIV-1 assay



▲ Shows the slight differences in the previous screen between the different assays.

Creating a required VQA200 control

For certain networks, the VQA200 control is required. LDMS expects that this control is named exactly `VQA200` in the assay output file. To add a VQA200 control:

1. Click the **Add VQA Control** button.
2. Specify the **Control Lot Number** by either:
   - Selecting a previously used lot number from the list, or
   - Entering a new lot number. The lot number must be in the format `VQA<control lot #><AR or RT>`. Use `AR` on the Abbott Realtime HIV-1 and `RT` on the COBAS TaqMan HIV-1. For example, enter `VQA11035079AR` for a lot number of 11035079 on an Abbottt run.
3. Enter the **expected value** of `200`.
4. Enter the **minimum value**. For Abbott Realtime HIV-1, enter `64`; for COBAS TaqMan HIV-1, use 98.
5. Enter the **maximum value**. For Abbott Realtime HIV-1, enter `642`; for COBAS TaqMan HIV-1, use `985`.

If you've used the control before, the minimum and maximum values will be set for you. While it is possible to bypass the VQA200 requirement for networks that require it, you will need a challenge password from LDMS User Support. See the section called “LDMS and Challenge Passwords” on page 4.

There are a couple of things you may want to do *before* reading the assay output:

- Generate the **Abbott Assay Run Preview** report. This report shows you the positions of the specimens and controls on the assay run, tube position, and bar codes for specimens.
- Modify the dilution. This is done by selecting the appropriate cell in the dilution column and changing the value.
- (Abbott and TaqMan HCV only) Change the **sample preparation method**. For Abbott, this can either be **manual** or using the **m2000sp**; for TaqMan HCV, select either **manual** or **automated**.
- (TaqMan only) Select the **version** of the assay that you used.
- Enter the **Data Transfer Tech initials**. This would be the person who loaded the assay result file into LDMS (i.e. you).

After reading the assay, the results screen will be displayed. There are a few things you can do on this screen.

- Review the assay results. Complete the **Reviewed by** and **Reviewed Date** fields, and then click the  button from the LDMS toolbar.
- Add a censor code for a specimen, control, or the entire run. This is done by right-clicking on the specimen or control and selecting the `Censor Specimen` or `Censor Run` option. For more information on censors, see the section called “Censor Codes” on page 88.
- Change between raw and calculated results using the **grid view** options in the bottom-right corner.
- View and print the assay results report by clicking the  button from the LDMS toolbar.
- View the patient report for patient specimens included on a valid assay run. This option is found by clicking the 

button.

After it has been run, the assay data will be available within LDMS for future review. For more information on recalling assay runs, see the section called “Reviewing Assay Results After They Have Been Read” on page 88.

Kit Entry for Abbott and TaqMan Assays

When you run the Abbott Realtime HIV-1 or COBAS TaqMan HIV-1 assays, kit information is automatically pulled from the assay result file. Two fields, however, are *not* pulled from the result file: **Date Rec[eived]** and **Storage Temp[erature]**. If this is your first time using the kit, you must complete these fields using the Kit Entry tool. For more information on how to do this, see the section called “Setting up Assay Kit Information” on page 118.

COBAS TaqMan HIV-1 Qualitative

The COBAS TaqMan HIV-1 *Qualitative* assay (not to be confused with the COBAS TaqMan HIV-1, which is described in the section called “Abbott Realtime and COBAS TaqMan” on page 90) can be found **DNA PCR** category. This assay is setup and the results are read differently than most other assays in LDMS. The result file is read during the setup process and LDMS will attempt to match results to individual specimens and controls by *global specimen ID* or *other specimen ID* and will show you any results that could not be automatically matched. You will have the opportunity to associate unmatched results by hand or simply ignore them.

You can either setup a 24-item run or a 48-item run. Like the name implies, these two options set the maximum number of specimens that can be tested in LDMS to either 24 or 48. Controls

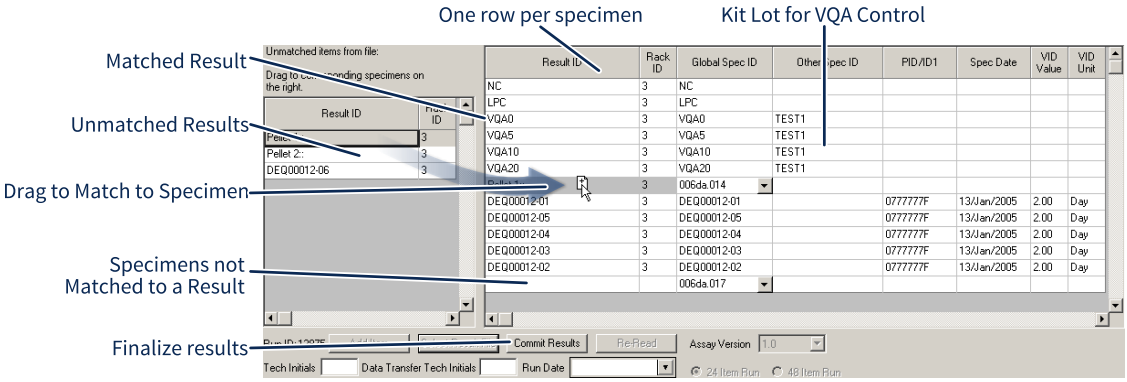
are automatically added to runs. Table 6.2 shows the number and types of controls that will automatically be added to a run.

Table 6.2. 24 and 48 item run comparisons

Control	24 item run	48 item run
Blind pellets	Two	Four (two per rack)
Kit positive	One	Two (one per rack)
Kit negative	One	Two (one per rack)
VQA controls	Four	Four
Maximum number of testing specimens (less controls)	16	36

VQA controls will only be added for certain groups. For example, if you tested specimens for an internal group, the VQA controls would not be added and you could test four additional specimens on the run.

Figure 6.6. COBAS TaqMan HIV-1 Qualitative Assay



▲ The COBAS TaqMan HIV-1 Qualitative assay after a result file has been selected and matching has taken place; unmatched results in the result file are displayed on the left.

Procedure 6.10. Reading COBAS TaqMan HIV-1 Qualitative results in LDMS

1. Create a new COBAS TaqMan HIV-1 Qualitative run and add assigned specimens to it. For instructions, see the section called "Creating and Reviewing Assay Runs" on page 84.
2. Select either **24 item run** or **48 item run** from the bottom of the screen. For a description of the differences between the two, see Table 6.2.
3. (Optional) To add more specimens, controls, and pellets, click the Add Item button.
4. Select the kit lot number for any VQA controls by right-clicking on the specimen and selecting `Select VQA lot number`. You can either select an existing lot number or enter a new one.
5. Specify the pellets that were used by selecting the appropriate pellet from the drop-down list next to each.
6. Click the Select Result File button. A window will appear allowing you to choose to the result file created when you ran the assay.
7. Complete specimen matching. Specimens in the result file will automatically be matched to specimens. This will be shown by the **Result ID** column. Specimens without a **Result ID** listed were not automatically matched. Unmatched results will appear on the left. To associate a result with a specimen, drag it from the list on the left to the desired specimen

on the right. You can also drag results back to the unmatched results to remove it, or move it to a different specimen.

Note

All specimens added to the run in LDMS must have an associated **Result ID**, however, there may be unused results in the file that are not associated with a specimen.

8. Select the version of the assay from the **Assay Version** box.
9. Enter the initials of the assay technician who ran the assay into the **Tech Initials field**.
10. Enter the date that the assay was run into the **Run Date** field.
11. Click the Commit Results button.

After committing the results, they will be immediately saved to your LDMS database. A screen will then appear, showing you the results and any censors that may have been automatically applied by LDMS. You can enter comments and reviewer information, and then click the button from the LDMS toolbar.

You can apply a censor to a specimen (or the entire run) by right-clicking on a specimen and selecting `Censor Specimen` or **Censor Run** respectively. To see a list of what individual censor codes mean, click the Options button. Because this assay can be run with multiple racks, it is possible for one rack to have a system assigned censor code applied to it while another rack has no censors.

There are two reports available after the TaqMan HIV-1 Qualitative assay has been run:

assay results report	Available by clicking the from the LDMS toolbar.
patient report	Click the Options button, and then select **Print Patient Report**.

These reports can be accessed at any time after results have been read by using the **Review/Edit** option on the **Assay Selection** tab. For instructions in recalling previously read assay, see the section called “Reviewing Assay Results After They Have Been Read” on page 88.

Template Based Virology Assays

Creating a Customized Virology Assay Template

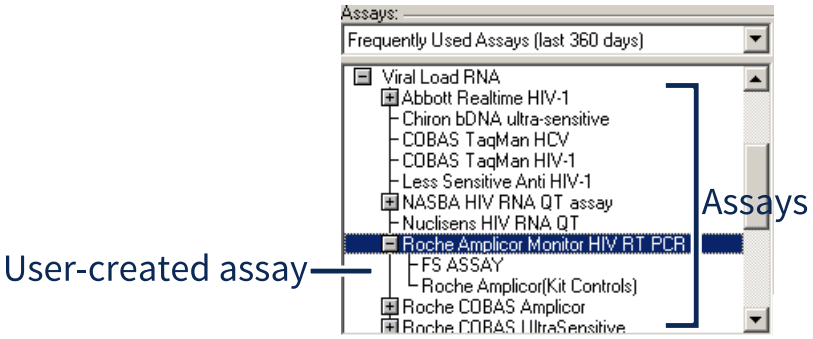
With the exceptions of Abbott and TaqMan, virology assays in LDMS are based around templates. Templates are custom configurations that you can create for an assay, with controls and settings for your specific assay needs. The following virology assays in LDMS utilize templates:

- NASBA HIV RNA QT
- Nuclisens HIV RNA QT
- Roche Amplicor Monitor HIV RT PCR
- Roche COBAS Amplicor
- Roche COBAS UltraSensitive
- Roche UltraSensitive HIV RT PCR
- Roche HIV DNA PCR (versions 1 and 1.5)[1]

Some templates lock specific features during template creation for certain assays (for example, you cannot modify the controls on some templates). User templates are listed under their respective assay, and are shown in the **Assay List** in all upper case.

[1]This assay appears in LDMS under the category **DNA PCR**; all other virology assays are in the category **Viral Load RNA**.

Figure 6.7. Virology assay selection list



▲ In this example, **FS ASSAY** is a user-created template for the Roche Amplicor assay; **Roche Amplicor (Kit Controls)** is a system template that comes with LDMS for the same assay.

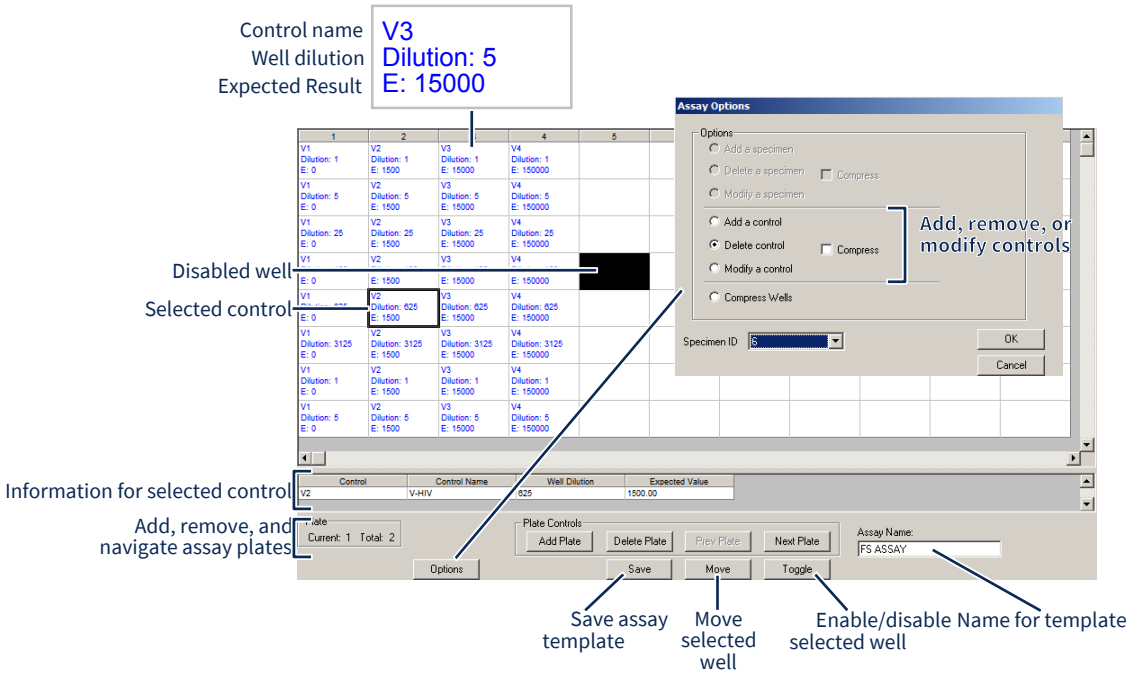
Procedure 6.11. Creating a virology assay template

1. On the **Assay Selection** tab, find the existing assay that you want to use as the basis of your customizations.
2. Select the **Design** check box.
3. Click the Select Assay button; this will automatically take you to the **Design** tab.
4. Make the changes that you need, such as adding plates, modifying controls, and toggling wells.
5. Enter a name for your custom assay template into the **Assay Name** field, and then click the Save button.

Warning

You must make all your changes to the assay before clicking the Save button. You cannot modify and re-save assay templates after they have been created.

Figure 6.8. Virology assay template design screen



▲ A typical plate layout. Each cell represents one well on the plate. The **Assay Options** window is also shown.

You can use the buttons in the **Plate Controls** section to add and remove plates from the assay, as well as change between plates. The current plate and total number of plates also appears at the bottom of the screen.

Individual wells can be enabled and disabled by selecting them, and then clicking the Toggle button. Disabled wells appear as black boxes on the plate. If you want to select multiple rows, hold down the **Ctrl** key. You can select an entire column by clicking the header row above the column.

Adding, deleting, and modifying controls is done by clicking the Options button. To add a control, you'll need to specify the **Control Number** and **Expected Value** for the control. While the control number will appear as written on the well in the template, they are also assigned a sequential control number in LDMS (1, 2, 3, etc.). If you need to modify or delete a control later, you'll need to know that sequential number. So, while you can technically enter anything for the **Control Number**, it's a good idea to use the number of the next available control. If you want to see what the next available control number is, select the **Modify a control** option, and then look in the **Specimen ID** list. That list shows the current controls. Now, change to the **Add a control** option and use the next number in the sequence.

Note

Modifying controls on the assay is not available for all templates. If the feature is not available for the assay that you have selected, the Options button will be disabled.

The **Compress** and **Compress Wells** options will remove empty wells by moving other wells to fill them. Wells will be moved right to left to fill out the empty space.

Important

When a new virology template is create, an assay reader device must be associated with it before it can be run in LDMS. For more information, see the section called “Associating an Assay with a Reader” on page 123.

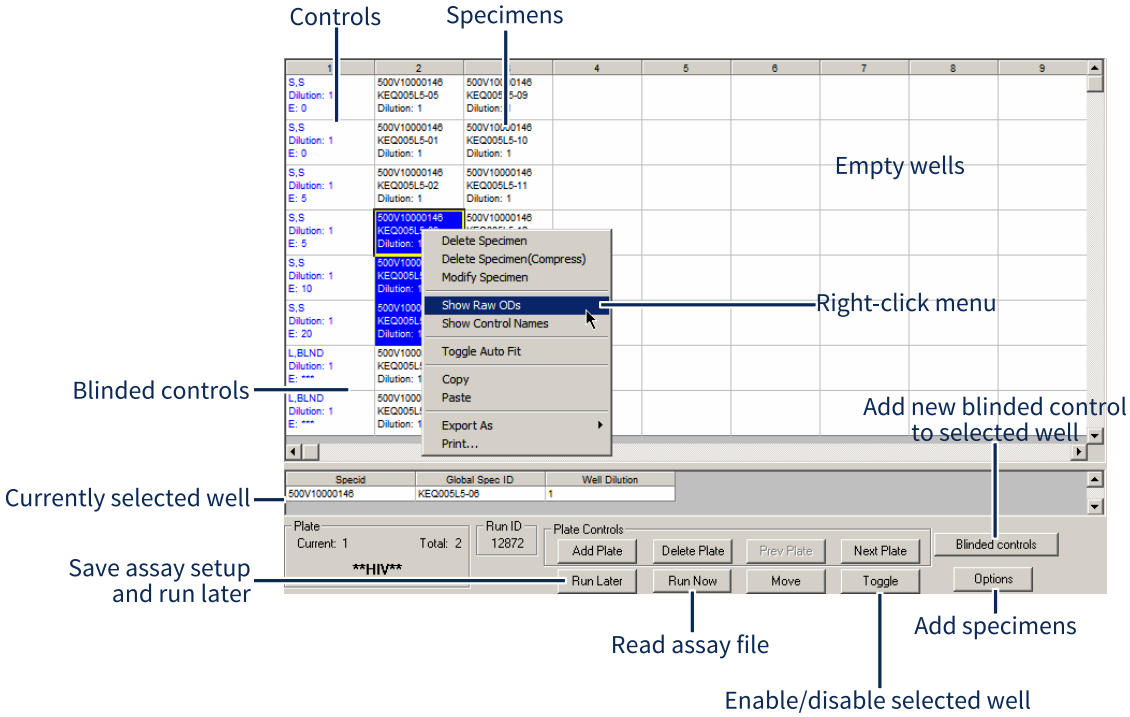
Running a Template-Based Assay

Important

While the basic steps in running template-based assays are largely identical across all virology assays, there are important, assay-specific differences. Before running an assay, be sure to review the section specific to that assay for those differences.

Virology assays can be run by using the templates that come with LDMS or by creating your own template. For instructions on creating your own template for an assay, see the section called “Creating a Customized Virology Assay Template” on page 94.

Figure 6.9. The Roche HIV DNA PCR 1.5 assay setup screen



▲ This screen shows the setup screen for the DNA PCR assay (v1.5). Most virology assays will have the features shown, though there are slight variations between assays.

The assay setup screen shows a visual representation of your assay plate(s). Each well on the plate corresponds to one cell on the setup screen.

Procedure 6.12. Setting up template based assays

1. On the **Assay Selection** tab, select the desired assay template from the **Assays** list and the specimens to run, then click the Add to Run button. For more detailed instructions on this initial setup, see the section called "Creating a New Assay Run" on page 85.
2. If needed, add additional specimen. There are two ways to do this:
   - Return to the **Assay Selection** tab, select additional specimens from the **Specimens Found** list, and then click the Add to Run button.
   - Click the Options button. You can enter a *global specimen ID* into the **Specimen ID** field, and then click the **Add** button. You can also click the **Import** button to import a text file list of *global specimen IDs*, with one ID per line.
3. If needed, modify specimens or controls. Do this by right-clicking on the specimen to modify and selecting **Modify Specimen/Control**. This is how you would update the specimen/control's dilution factor, volume, or expected result.
4. If needed, remove specimens or controls. Do this by right-clicking on the specimen or control and selecting **Delete Specimen/Control** or **Delete Specimen/Control (Compress)**. The Compress option will move wells from right-to-left to fill the gap created by the deleted specimen/control.
5. If needed, move specimens or controls. Do this by selecting the specimen/control to move, clicking the Move button, and then selecting the destination well.
6. If needed, add or remove plates by clicking the Add Plate or Delete Plate button respectively.
7. If needed, enable and disable wells. Do this by selecting the well, and then clicking the Toggle button.
8. If needed, add controls. Do this by clicking the Options button, and selecting the **Add Control** option.

Once you have the assay setup exactly as it is on your plate(s), click the Run Now button. You will be prompted to select kit and other information, depending on the assay being run. If you cannot find your assay kit, you need to enter it into LDMS. For instructions on doing this, see the section called “Setting up Assay Kit Information” on page 118.

LDMS will begin reading your assay results. When prompted, select the output file from your assay. For more information about reading assay output files, see the section called “Using Assay Device Readers” on page 123.

Special Information for Individual Template-Based Assays

NASBA HIV RNA QT

LDMS comes with two pre-defined templates for the NASBA assay, which are described in Table 6.3.

Table 6.3. Pre-defined NASBA assay templates

Template	Number of Controls	Expected Values
NASBA HIV RNA QT	4	0 / 15,000 / 150,000 / 1.5e +006 (i.e. 1,500,000)
NASBA - No Negative Control	3	15,000 / 150,000 / 1.5e +006 (i.e. 1,500,000)

The recommended maximum number of plates for the NASBA assay is three. If you attempt to add more than three plates, LDMS will prompt you with a warning message. LDMS will not automatically move or add controls when specimens are added beyond the first plate.

Nuclisens HIV RNA QT

LDMS comes with one pre-defined templates for the Nuclisens assay, which are described in Table 6.4.

Table 6.4. Pre-defined Nuclisens assay templates

Template	Number of Controls	Expected Values
Nuclisens HIV RNA QT	4	0 / 1,500 / 15,000 / 150,000

The recommended maximum number of plates for the Nuclisens assay is three. If you attempt to add more than three plates, LDMS will prompt you with a warning message. LDMS will not automatically move or add controls when specimens are added beyond the first plate.

Roche Amplicor Monitor HIV RT PCR

LDMS comes with two pre-configured PCR assay templates for the Roche Amplicor Monitor HIV RT PCR assay, which are described in Table 6.5.

Table 6.5. Pre-configured templates for the Roche Amplicor Monitor HIV RT PCR Assay

Assay	Number of controls	Controls/Expected Values
Roche Amplicor Monitor HIV RT PCR	4 VQA	`1`, `1,500`, `15,000`, and `150,000`
Roche Amplicor (Kit Controls)	3	`KN` (kit negative), `KLP` (kit low positive), and `KHP` (kit high positive)

The expected values for VQA controls will be displayed on the **Preview** tab before running the assay. The most plates recommended in a kit control assay is four. LDMS will automatically move controls to a new plate if a new plate is added while adding specimens. If there are more than four plates, a VQA control with an expected value of 1,500 will be added to the fifth (and all subsequent) plates.

Roche COBAS Amplicor

The Roche COBAS Amplicor is run identically to the Roche Amplicor Monitor HIV RT PCR assay. For this assay, a **plate** in LDMS refers to an A-ring on the real-life instrument. There are two pre-configured templates available for this assay, which are described in Table 6.6.

Table 6.6. Pre-configured templates for the Roche COBAS Amplicor Assay

Assay	Number of controls	Controls/Expected Values	Serial Dilutions
Roche COBAS Amplicor	3	`KN` (kit negative), `KLP` (kit low positive), and `KHP` (kit high positive)	1:9
Roche COBAS Amplicor Ampliprep	3	`KN` (kit negative), `KLP` (kit low positive), and `KHP` (kit high positive)	1:10

Roche COBAS UltraSensitive

The Roche COBAS UltraSensitive comes with two pre-configured templates.

Assay	Number of controls	Controls/Expected Values	Serial Dilutions
Roche COBAS Ultra-Sensitive	4 VQA	`0`, `150`, `1,500`, `15,000`	1:9
Roche COBAS Ultra-Sensitive Ampliprep	4	`KN` (kit negative), `KLP` (kit low positive), `KHP` (kit high positive), and `V` (VQA control with expected value of 1500)	1:10

The expected values for VQA controls will be displayed on the **Preview** tab before running the assay. The most plates recommended in a kit control assay is four. LDMS will automatically move controls to a new plate if a new plate is added while adding specimens. If there are more than four plates, a VQA control with an expected value of 1,500 will be added to the fifth (and all subsequent) plates.

Roche UltraSensitive HIV RT PCR

The Roche UltraSensitive HIV RT PCR is run identically to the Roche Amplicor Monitor HIV RT PCR assay. There are two pre-configured templates available for this assay, which are described in Table 6.7.

Table 6.7. Pre-configured templates for the Roche Amplicor Monitor HIV RT PCR Assay

Assay	Number of Controls/Expected Values
Roche UltraSensitive	4 `KN` (kit negative), `KLP` (kit low positive), `KHP` (kit high positive), and one control with an expected value of `1,500`
Roche UltraSensitive (Kit Controls)	4 `KN` (kit negative), `KLP` (kit low positive), and `KHP` (kit high positive), and one control with an expected value of `1,500`

Roche HIV DNA PCR

LDMS supports version 1.0 and 1.5 of the Roche HIV DNA PCR (version 1.0 is simply labeled **Roche HIV DNA PCR** without a version number). These assays are found under the category **DNA PCR** on the **Assay Selection** tab.

To run a DNA assay in LDMS, you must rename the two blinded controls (or "pellets") at the beginning of the assay plate to match the actual blinded controls that you will be using. If you add more blinded controls, those will need to be renamed as well.

Figure 6.10. Blind control well

▲ A blinded control well as it appears in LDMS. Notice that the expected value (**E:**) is hidden and the control is labeled as **BLND**.

Procedure 6.13. Adding or Renaming blinded controls for DNA assays

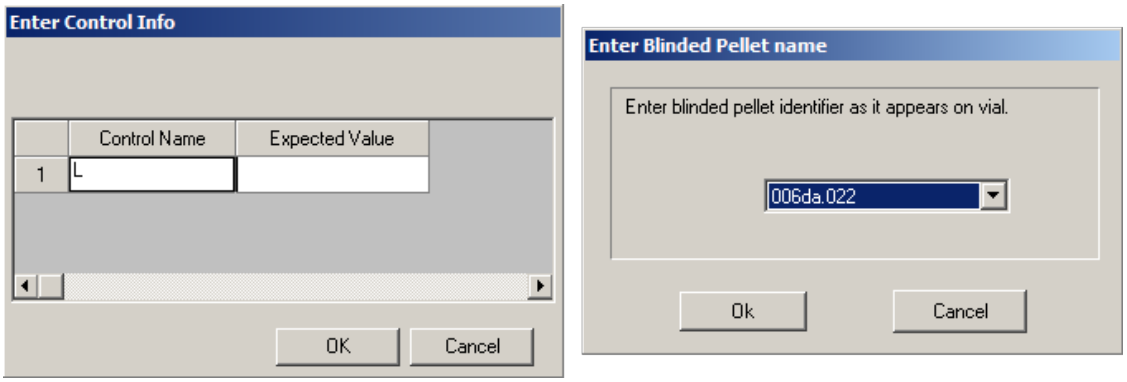
1. Do one of the following
   - To rename a control, right-click on the well with the blinded control and select `Modify Control`.
   - To add a new blinded control, click the Blinded controls button.
2. Enter or select the blinded control. See Figure 6.11.

Note

If you are looking for a blinded control that is not listed, try performing an export. For instructions on exporting, see the section called “Exports and Updates” on page 173. If that does not work, contact LDMS User Support for assistance.

LDMS uses the results of blinded controls when the assay is run to verify that the results of the plate are valid, and, if appropriate, will automatically apply some system censor codes. For more information about censor codes, see the section called “Censor Codes” on page 88.

Figure 6.11. Modify control screen for PCR assays



▲ The PCR version 1.0 (left) and version 1.5 (right) screens, accessed by right-clicking on a blinded control and selecting `Modify Control`.

Note

If you have added *more than 10 specimens* to a single PCR assay plate, LDMS expects you to add more blinded controls. To add more blinded controls, select the Blinded controls button.

When running the assay, LDMS expects 2 different results files: one for the specimen plate and another for the control plate. Single plate runs require special consideration and setup.

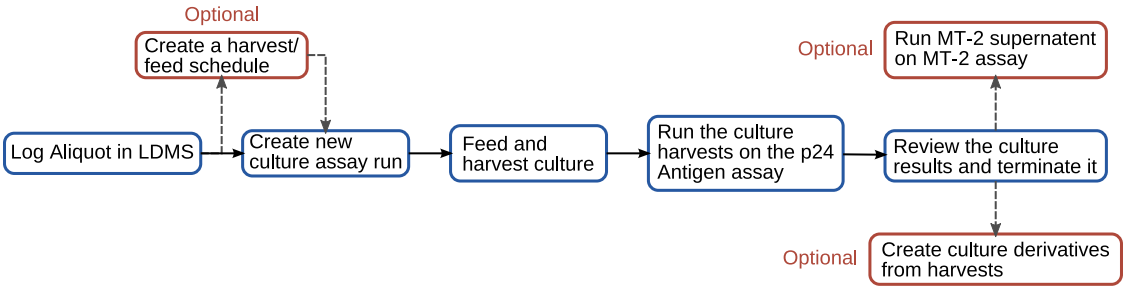
After reading all plates in the assay's output, LDMS will show you the results on the **Results** tab. You can generate an exportable version of these results by clicking the button from the LDMS toolbar.

Cultures

Culture Workflow Overview

Creating a culture assay in LDMS is a mult-step process. It involves running more than one assay, and working with special specimens derived from other aliquots. The high-level steps involved are shown in Figure 6.12.

Figure 6.12. Culture workflow



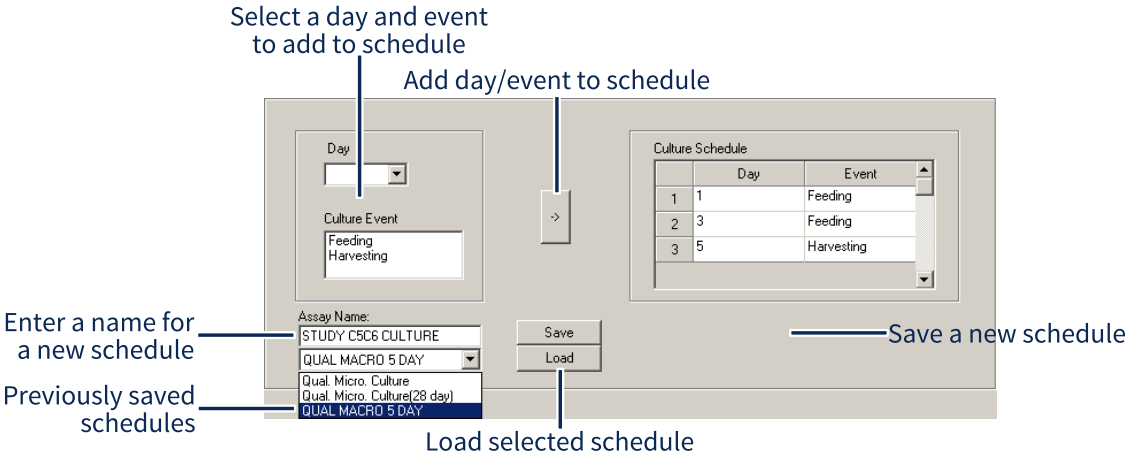
▲ The steps involved in creating and testing cultures in LDMS.

The rest of this section describes each step in this process in more detail.

Creating Culture Schedules

Culture schedules define the feeding and harvesting timeline for the culture(s) you are creating. You can create several schedules and reuse them many times. LDMS also comes preconfigured with a few standard schedules.

Figure 6.13. The culture schedule design screen



▲ The schedule design screen replaces the assay design screen for cultures. The actual schedule appears in the **Culture Schedule** list on the right.

Procedure 6.14. Creating culture schedules

1. On the **Assay Selection** tab, select the appropriate culture for which you want to create a schedule from the **Assay** list on the left side.
2. Select the **Design** check box.
3. Click the Select Assay button to enter design mode. This will automatically take you to the **Design** tab (Figure 6.13).
4. (Optional) To load a previously saved schedule and edit it, find it from the drop-down list on the bottom, and then click the Load button.
5. Select the **Day** the event will occur and **Culture Event** to add.

   Note

   The day that the culture is created is considered day `0`.
6. Click the `->` button to add the event to the schedule
7. After all events have been added, enter a name for your schedule into the **Assay Name** text field.
8. Click the Save button. *Do not use the* ✚ *from the LDMS toolbar.*

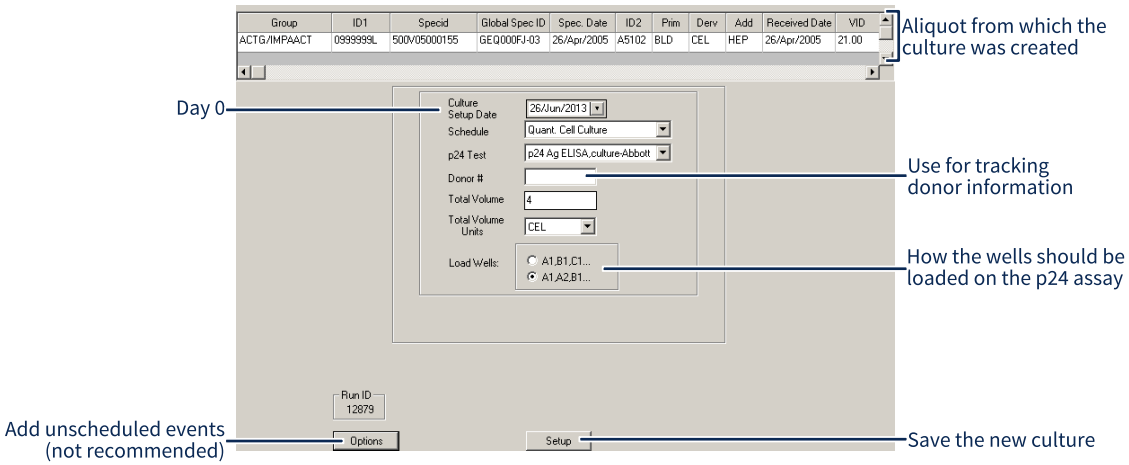
Creating a Culture

Unlike other assays in LDMS, you can only create a culture from a single aliquot; you cannot select multiple aliquots and create cultures for them at once. If you need to create multiple cultures, you must create each one individually. For more information on finding specimens and selecting an assay, see the section called “Creating a New Assay Run” on page 85.

Warning

If you select multiple specimens on the **Assay Selection** tab, a culture will only be created for the first specimen selected.

Figure 6.14. Creating a culture



Procedure 6.15. Creating a new culture

1. Create a new assay run, selecting the desired culture assay. For instructions, see the section called "Creating a New Assay Run" on page 85.
2. Enter the **Culture Setup Date**. This is the date that the culture was created (i.e. day 0).
3. Select the feeding and harvest **Schedule**. If you need to create a specific schedule, see the section called "Creating Culture Schedules" on page 102.

   Tip

   To view the events on a schedule, select it, and then click the button from the LDMS toolbar. To see a list of all available schedules and associated events, you can run the **Culture Schedule Report**, found in `TasksReports`, and then `CultureCulture Schedule Report`.
4. Select the p24 assay that will be run on the cultures. *The p24 assay must be run on cultures in LDMS.*
5. (Optional) Enter donor information into the **Donor #** field if you have an established method for tracking donors for cultures. LDMS does not enforce any particular usage of this field.
6. Enter the **Total Volume** and **Total Volume Units** for the prepared culture.
7. (For quantitative cultures only), specify the way harvests from the culture should be loaded onto p24 assay plates. To add them to the plate top-bottom/left-right, select **A1, B1, C1...**; to add them to the plate left-right/top-bottom, select **A1, A2, B1...**.
8. Click the Setup button.

Note

If you need to return to the culture setup later (for example, to update donor information), select the assay on the **Assay Selection** tab, and then select the **Runs Not Performed/Not Terminated** option.

Warning

The Options button on the culture setup screen allows you to add unscheduled feeding and harvest events. This is not recommended, as these events do not get tracked in LDMS and will not appear on reports. Unscheduled harvest events will *not* create additional samples to be run on p24 assays. If you need to create a custom schedule, it is more appropriate to delete the culture, create a custom schedule, and create a new culture.

Creating a culture creates special specimen from the original aliquot. These special specimens cannot be found in LDMS Specimen Management ; they can only be found by looking for specimens assigned to the appropriate p24 assay. They are identified using the same *global specimen ID*, but will have different harvest dates—specimen will be created for each harvest event in the schedule that was used for the culture.

These sub-aliquots are created automatically, but not immediately. For example, if you create a culture with harvests at days 3 and 10, you will not find them when trying to set up a p24 assay until you are 10 days past the culture setup date.

Culture Schedule and Harvest Labels

It may be useful to obtain a list of when cultures need to be fed and harvested. LDMS has a special report that does just that. This is also the same mechanism you would use to create printable labels for your culture harvests.

Procedure 6.16. Generating the Harvest/Feed report and labels

1. From the **Assay Selection** tab, click the button from the LDMS toolbar.
2. Select **Harvest Feed**.
3. Do one of the following:
   - Select the **Pending** option; this will find all cultures that have not been terminated.
   - Select the **group** for which you want to find all cultures.
4. Specify the date range; LDMS will find all culture events that occur within this date range.
5. Generate the event report or labels by selecting the **Generate Report** or **Generate Labels** button respectively.

Unlike labels for normal specimens, the labels for culture harvests cannot be customized. If you are planning to permanently store a culture, you'll need to create a *culture derivative*, which will open up the same label and storage options available to normal specimens. For more information, see the section called “Culture Derivative” on page 39.

Running Cultures on a p24 Antigen Assay

When you setup a culture, you were required to select the p24 Antigen assay to be run. After you have one or more harvests from the culture, you can begin running that p24 assay. You don't have to have all of the harvests for the culture when you run the assay (and you can put harvests from different cultures onto the same assay plate when you run it).

Procedure 6.17. Running culture harvests on a p24 antigen assay

1. Select the appropriate assay from the **Assays** list on the **Assay Selection** tab.
2. Select the **New Run/Not Setup** option, and then click the Select Assay button.
3. Find the culture harvest that you want to test by clicking the button from the LDMS toolbar or by using search criteria. See the section called “Creating a New Assay Run” on page 85.
4. All of the culture harvests that are from cultures assigned to the selected assay will appear in the **Specimens Found** list.

> **Note**
>
> You can differentiate harvests by looking at the **Culture Day** field. If you do not see all of the harvests that you were expecting, review the Harvest/Feed Report. Harvests are only created after the required number of days have passed,

per the schedule used. See the section called “Culture Schedule and Harvest Labels” on page 104.

5. Select the harvest that you will be testing, and then click the Add to Run button.
6. Configure the assay plate(s), wells, and controls like you would configure virology assays. See the section called “Creating a Customized Virology Assay Template” on page 94.
7. Click the Run Now button to read the assay output.

Reviewing Results and Terminating Cultures

After running the appropriate p24 antigen assay on your culture harvests, you must review and accept the results. These results are in two places:

- By selecting the p24 assay and the **Review/Edit** option
- By selecting the culture assay and the **Terminate/Unterminate** option.

In LDMS, *terminating* a culture is the process of reviewing the p24 assay results and approving them. This typically corresponds to the actual termination of the culture.

Procedure 6.18. Reviewing a culture's results and terminating it

1. Select the appropriate culture from the **Assay** list on the **Assay Selection** tab.
2. Select the **Terminate/Unterminate** option, and then click the Select Assay button.
3. Select either the **All Open Cultures**, **All Closed Cultures**, or **All Cultures** option, depending on which cultures you want to review, and then click the button from the LDMS toolbar.

   Note

   Closed and open cultures are the same as terminated and not-terminated cultures respectively.
4. Select the culture(s) you want to review. You can select multiple cultures and view more than one at the same time. Once they have all been selected, click the View Culture button.

   Warning

   While you can use the Terminate All and UnTerminate All buttons to terminate/unterminate multiple cultures at once, this is not recommended. When you terminate a culture, you are saying that you have reviewed and approved the results; by doing this *en masse*, you don't actually review the results.
5. Review the culture results. LDMS has already determined whether or not the culture is positive or negative based on the **status** of each harvest tested on the p24 assay. If you want to override these results, change the **Culture Result** option and enter a comment. If multiple cultures were selected, you can switch between them by using the database navigation buttons from the LDMS toolar.
6. Enter the initials of the person terminating the culture into the **Terminated by** and your initials into the **Reviewed by** fields, and then complete the **Reviewed Date**.
7. (Optional) If you want to create an MT-2 supernatant from one of your harvests and use it to run the MT-2 assay, select the **Generate MT-2 supernatant on termination** option. If you do select this option, you will be prompted for the harvest date of the harvest that you want to use when terminating the culture. See the section called “Enter MT-2 Culture Assay Results Using a Culture Supernatant” on page 106.
8. Select the **Terminate** option to accept the specimen results, the **UnTerminate** option to re-open a culture, or the **Save** option if you do not want to open or close the culture but want to save other changes.
9. Click the button from the LDMS toolbar.

How does LDMS determine if a culture result is positive or negative?

When you review a culture's results during the termination process, LDMS will automatically set the culture result to be `pos[itive]`, `neg[ative]`, or `ind[eterminate]` based on the status from the p24 antigen assay result. You can override this automatic determination, but you may want to know how LDMS actually figures it out.

p24 Results		Final Culture Result
14 Day	**21 Day**	
Positive	Not Run	Positive
Negative	Positive	Positive
Positive	Positive	Positive
Positive	Negative	Indeterminate
Negative	Not Run	Negative
Negative	Negative	Negative

The logic for determining if a result is positive or negative is as follows:

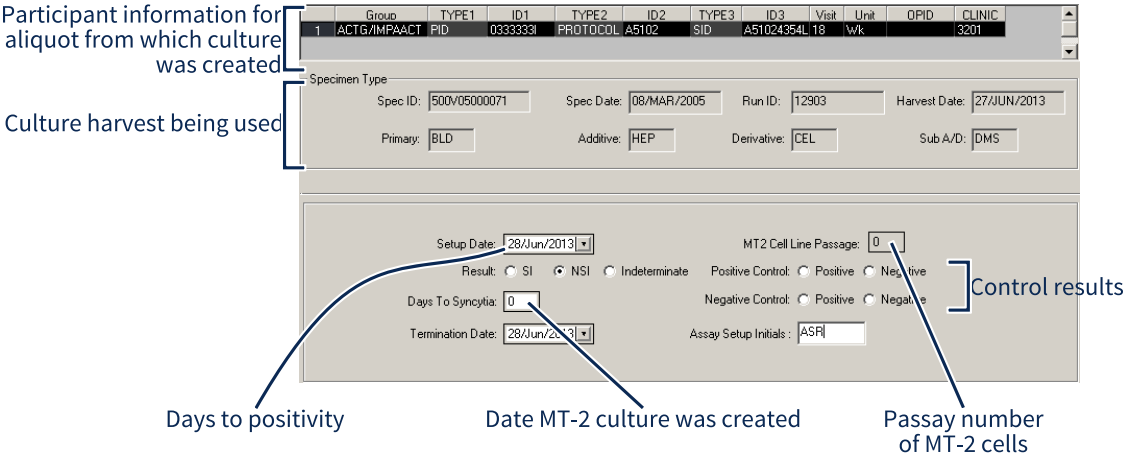
- If all p24 results are <30 pg/mL until at least day 28, the result is considered negative.
- If two consecutive p24 OD values are out of range (greater than or equal to 2.0 or 3.0, depending on the assay and reader), the result is considered positive.
- If there are two consecutive p24 values of > 30 pg/mL, and the second value is at least four times greater than the first value or is out of range, the result is considered positive.
- If there are three consecutive p24 values of > 30 pg/mL, where the third value is at least four times greater than the first value.

Enter MT-2 Culture Assay Results Using a Culture Supernatant

If you selected the option to generate a MT-2 supernatant, one will be created. The MT2 supernatant is a special specimen derived from the culture that has the same *global specimen ID* as the original aliquot (and culture) and is only viewable within LDMS Assays when setting up the MT-2 assay.

In LDMS, the MT-2 culture assay in LDMS is a data entry assay used after your work is completed. See Figure 6.15.

Figure 6.15. MT-2 Culture Assay screen



Procedure 6.19. Entering MT-2 Assay results

1. Select the MT-2 Assay, found in the **Assays** list in the **Misc** category, and click the Select Assay button.
2. Find the supernatant that you want to test by clicking the from the LDMS toolbar or by using search criteria, then click the Add to Run button. For more information on how to find specimens, see the section called "Creating a New Assay Run" on page 85.

   Note

   The supernatant will have the same *global specimen ID* as the culture from which it was created.
3. Enter the date that the MT-2 culture was created into the **Setup Date** field.
4. Select the results of your testing.
   - If the culture was positive for syncytium-inducing (SI), select **SI**.
   - If the culture was negative and non-syncytium-inducing (NSI), select **NSI**.
5. Enter the date that the MT-2 culture was terminated into the **Termination Date** field.
6. Enter the passage number of MT-2 cells into the **MT2 cell line passage** box; this must be a number between 1 and 100.
7. Enter the results for your controls into the **Positive Control** and **Negative Control** fields.
8. Enter the initials for the person who performed the culture work into the **Assay Setup Initials** box.
9. Click the button from the LDMS toolbar.

If you are testing multiple MT2 cultures, use the database navigation buttons on the LDMS toolbar to find them, then repeat the data entry process.

Creating a Specimen from a Culture Harvest

You typically can't find cultures and culture harvests in LDMS Specimen Management, in Shipping, or in Storage. This is due to the way harvests are derived from an aliquot, and most parts of LDMS were designed with aliquots as the smallest unit of information.

It is possible to create a special specimen from a culture harvest, allowing you to utilize LDMS's storage, shipping, etc. features, just like any other specimen. These special specimens are called *culture derivatives*. For specific instructions on how to create a culture derivative, see the section called "Culture Derivative" on page 39.

p24 Antigen Assays

There are two types of p24 antigen assays in LDMS: direct and culture. The culture version is used with culture harvests created in LDMS Assays. When you attempt to run the culture version, you will only find culture harvests that have already been created. Harvests are automatically created based on the culture's schedule and setup date (e.g. for the day 28 harvest to appear in LDMS, the current date must be 28 days after the culture's setup date).

The direct version, on the other hand, is used to test specimens that are *not* culture harvests. This means that the aliquots must be assigned to the assay in LDMS Specimen Management or using the Assign Tests tool. For instructions on how to do this, see the section called “Assigning Assays to Aliquots” on page 84.

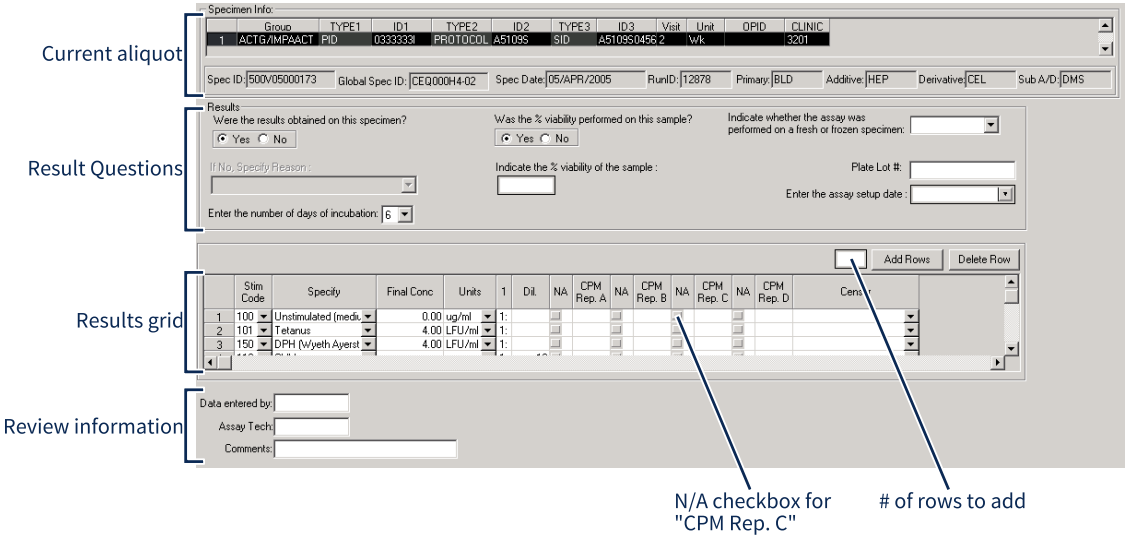
Other than the source, this assay is read the same way, regardless of specimen or instrument. For detailed instructions on this assay, see the section called “Running Cultures on a p24 Antigen Assay” on page 104.

Immunology Assays

Lymphocyte Proliferation Assay (LPA) Assay

The first specimen that was selected on the **Assay Selection** tab will appear in the **Specimen Info** box at the top of the **Results** tab screen. You can use the database navigation buttons ⏮ ◀ ◀ ▶ ▶ ⏭ to switch between specimens that were selected on the **Assay Selection** tab.

Figure 6.16. Lymphocyte Proliferation Assay (LPA) screen



▲ The LPA assay data entry screen.

Procedure 6.20. Entering LPA assay results into LDMS

1. Complete all of the fields in the **Results Questions**. All questions are required.
2. Complete all of the fields in every row in the **Results Grid** at the bottom of the screen.
   a. To add more rows, type a number into the **# of rows to add** text box and click the Add Row button.
   b. To remove a row, select it and then click the Delete Row button.
   c. Enter replicate information into **CPM Rep. A/B/C/D** columns *or*, if a stimulant was not run, select the **N/A** check box to the left of that replicate, and then select the appropriate censor code from the **Censor** drop-down.
3. Enter your initials into the **Data entered by** field.
4. Enter the initials of the assay technician into the **Assay Tech** field.
5. Click the button from the LDMS toolbar to add the results to LDMS.

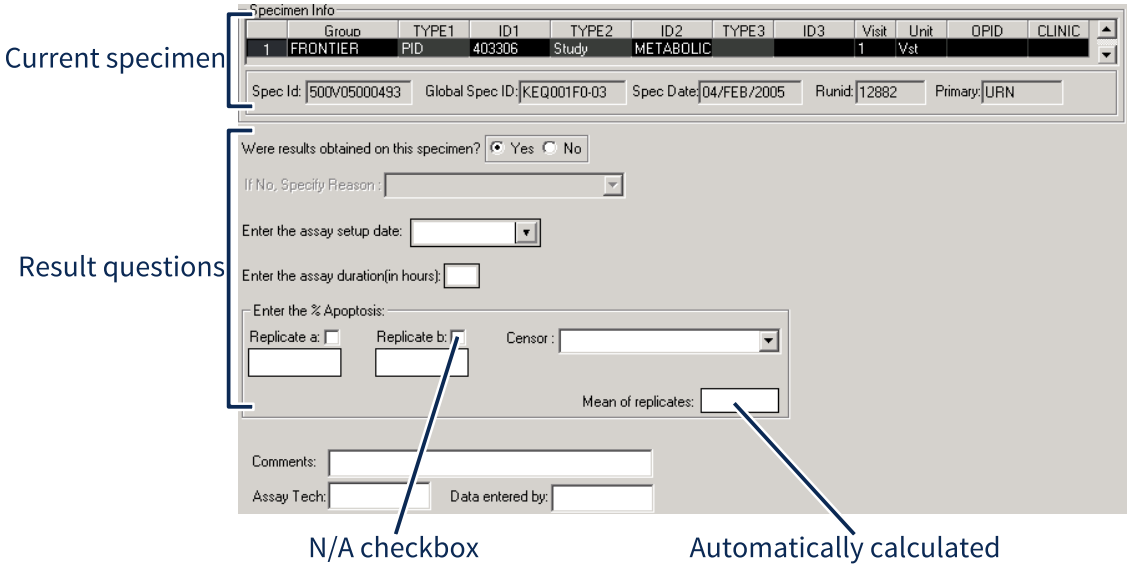
To view the LPA Patient Report after entering data for the specimens tested, click the button from the LDMS toolbar.

After you've finished with the first specimen, click the button from the LDMS tool bar and enter the results for the next specimen. Once all specimens have been entered and added, the data entry is complete. You can now return to the **Assay Selection** tab to perform more work.

Apoptosis by P.I. Assay

The first specimen that was selected on the **Assay Selection** tab will appear in the **Specimen Info** box at the top of the **Results** tab screen. You can use the database navigation buttons to switch between specimens that were selected on the **Assay Selection** tab.

Figure 6.17. Apoptosis assay screen



▲ Apoptosis assay data entry screen.

Procedure 6.21. Entering Apoptosis results into LDMS

1. Select whether or not results for the specimen were obtained from the **Were results obtained on this specimen** radio button.
2. Select the date that the Apoptosis assay was setup in the **Enter the assay setup date** box.
3. Enter the time that it took to complete the assay (in hours) in the **Enter the assay duration** box.

4. Enter the apoptosis percentage for **Replicant A** and **Replicant B**.
   - The **Mean of replicates** will be calculated automatically
   - If there are no results for that replicant, select the check box next to it, then select the appropriate censor from the **Censor** drop-down.
5. Enter the initials of the assay technician into the **Assay Tech** field
6. Enter your initials into the **Data entered by** field.
7. Click the ✚ button from the LDMS toolbar.

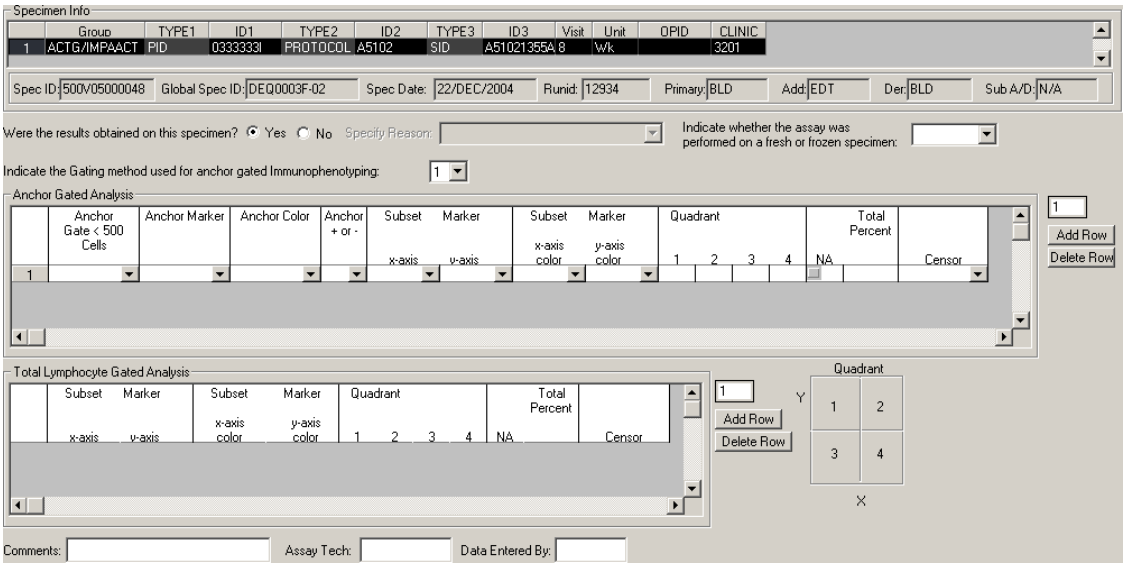
To view the LPA Patient Report after entering data for the specimens tested, click the button from the LDMS toolbar.

After you've finished with the first specimen, click the ➡ button from the LDMS tool bar and enter the results for the next specimen. Once all specimens have been entered and added, the data entry is complete. You can now return to the **Assay Selection** tab to perform more work.

Advanced Flow and TUNEL Assays

The first specimen that was selected on the **Assay Selection** tab will appear in the **Specimen Info** box at the top of the **Results** tab screen. The Advanced Flow and TUNEL assays have identical data entry screens. You can use the database navigation buttons ⏮ ◀◀ ◀ ▶ ▶▶ ⏭ to switch between specimens that were selected on the **Assay Selection** tab.

Figure 6.18. Advanced Flow and TUNEL assay screens



Procedure 6.22. Entering Advanced Flow and TUNEL assay data into LDMS

1. Select whether or not results for the specimen were obtained from the **Were results obtained on this specimen** radio button.
2. Indicate whether or not the sample was fresh or frozen in the **Indicate whether the assay was performed on a fresh or frozen specimen** box.
3. Select the gating method from the **Indicate the Gating method used for anchor Immunophenotyping** drop-down.
   - Method 1 gates all lymphocytes using FL/SS followed by a second gate on fluorescence histogram to select for the anchor marker.
   - Method 2 gates the anchor marker fluorescence versus SS histogram.
4. Complete all of the rows and columns **Anchor Gated Analysis** section.

- For Anchor Gate <500 cells, LDMS will auto-fill subsequent rows based on your selections for the first row of data. You can manually change individual marker sets in other rows if needed.
- Rows can be added or deleted by using the **Add Row** and **Delete Row** buttons to the right.
- If a marker was not run, select the N/A check box at the end of the row and select the appropriate **Censor** from the drop-down.
- The **Total Percent** field will automatically be calculated. The sum of the four quandrants should equal 100%; if it does not, the **Total Percent** will turn red.

5. Enter the subset marker and colors, and quadrant results into the **Total Lymphocyte Gated Analysis** fieldset.
6. Enter the assay technician's initials into the **Assay Tech** field.
7. Enter your initials into the **Data Entered By** field.
8. Click the button from the LDMS toolbar.

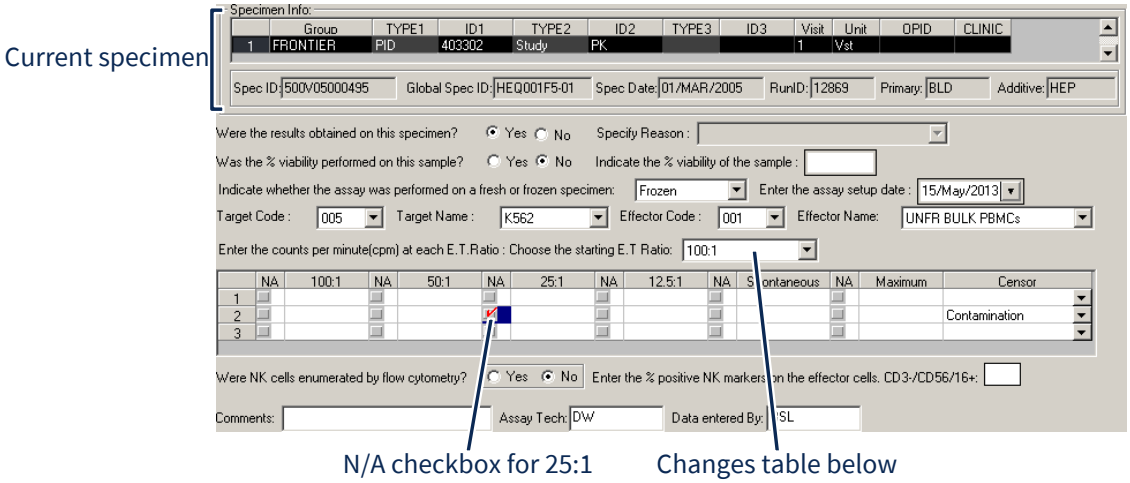
To view the Advanced Flow Patient Report after entering data for the specimens tested, click the button from the LDMS toolbar.

After you've finished with the first specimen, click the button from the LDMS tool bar and enter the results for the next specimen. Once all specimens have been entered and added, the data entry is complete. You can now return to the **Assay Selection** tab to perform more work.

Natural Killer Cell (NK) Assay

The first specimen that was selected on the **Assay Selection** tab will appear in the **Specimen Info** box at the top of the screen. All fields on the screen are required. You can use the database navigation buttons to switch between specimens that were selected on the **Assay Selection** tab.

Figure 6.19. Natural Killer Cell (NK) Assay screen



▲ Natural Killer Cell (NK) assay data entry screen.

Procedure 6.23. Entering NK results into LDMS

1. Indicate whether or not **Were the results obtained on this specimen**. If no, select an option from the **Specify Reason list**.
2. Indicate **Was the % viability performed on this sample**. If yes, enter a value into the **Indicate the % viability of the sample** field.
3. Select a value in the **Indicate whether the assay was performed on a fresh or frozen specimen**.

4. Enter the date that the assay was run into the **Enter the assay setup date** field.
5. Select the **Target Code** and **Target Name** from the drop-down lists.
6. Select the **Effector Code** and **Effector Name** from the drop-down lists.
7. Select the **Starting E.T. Ratio**. Your selection will change the table below.
8. For each row, enter the E.T. Ratios, **Spontaneous**, and **Maximum** values. If any were not performed, select the **N/A** check box *to the left of the field*, then select the appropriate reason from the **Censor** drop-down list in the right column.
9. Indicate whether or not **Were NK cells enumerated by flow cytometry**. If yes, enter the **% positive NK marker** into the field to the right.
10. Enter comments (optional), the initials of the **Assay Tech** who performed the run, and the intials of the person who entered the data into LDMS at the bottom.
11. Click the ✚ button from the LDMS toolbar.

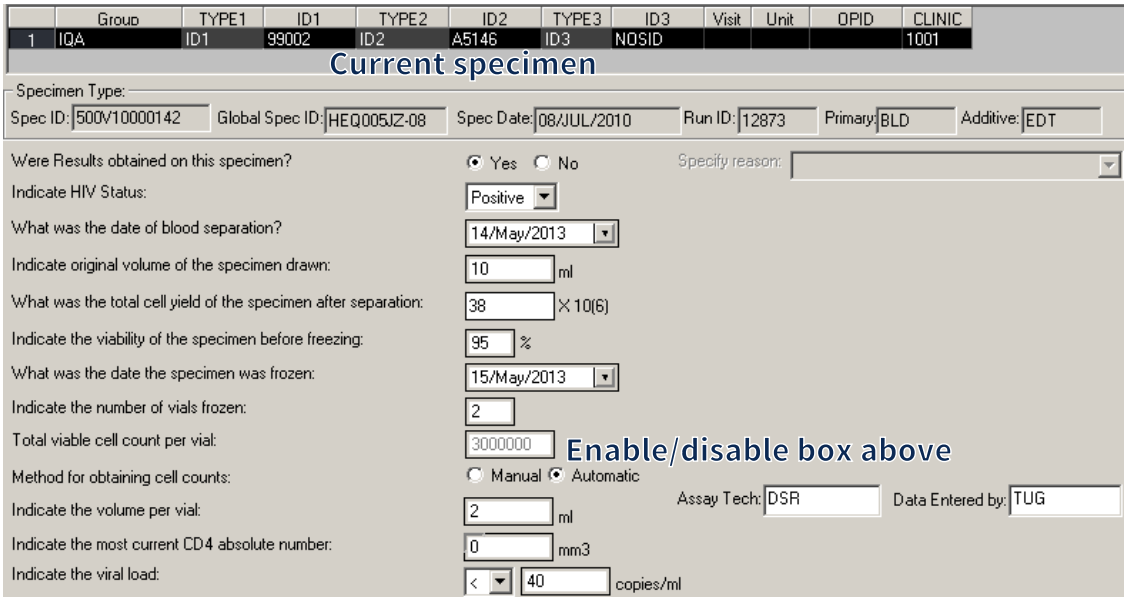
To view the NK Patient Report after entering data for the specimens tested, click the button from the LDMS toolbar.

After you've finished with the first specimen, click the ➡ button from the LDMS tool bar and enter the results for the next specimen. Once all specimens have been entered and added, the data entry is complete. You can now return to the **Assay Selection** tab to perform more work.

Cryopreservation

The first specimen that was selected on the **Assay Selection** tab will appear in the **Specimen Info** box at the top of the **Results** tab screen. You can use the database navigation buttons ⏮ ◀ ◀ ▶ ▶ ⏭ to switch between specimens that were selected on the **Assay Selection** tab.

Figure 6.20. The Cryopreservation assay screen



▲ Cryopreservation assay data entry screen.

Procedure 6.24. Entering cryopreservation assay results

1. Indicate whether or not **Were Results obtained on this specimen**. If No, select the appropriate option from the **Specify reason** list.
2. Complete the remaining fields.
   - Enter the initials for the person who ran the assay into the **Assay Tech** field and the initials of the person entering the results into LDMS into the **Data Entered by** field.

- To enable manual entry into the **Total viable cell count per visit** field, change the **Method for obtaining cell count** to `manual`.

3. Click the button from the LDMS toolbar.

To view the IQA Cryopreservation Patient Report after entering data for the specimens tested, click the button from the LDMS toolbar.

After you've finished with the first specimen, click the button from the LDMS tool bar and enter the results for the next specimen. Once all specimens have been entered and added, the data entry is complete. You can now return to the **Assay Selection** tab to perform more work.

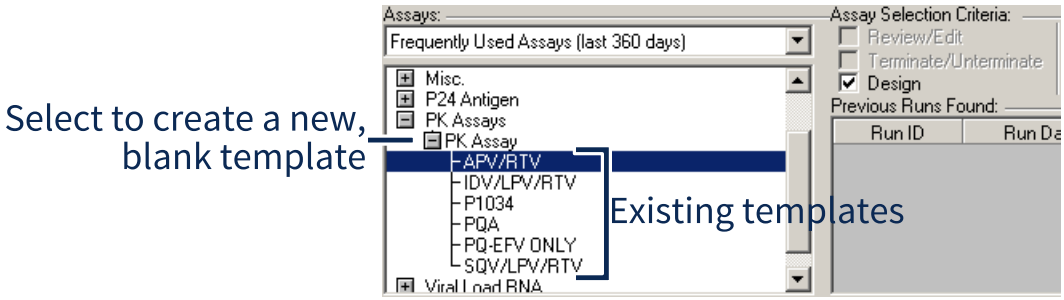
Pharmacology (PK) Assays

Creating PK Templates

PK templates are custom assay configurations that can be setup for the specific analytes that you are testing. Once created, the same template can be used multiple times. Different templates are necessary for every unique drug combination being tested at your laboratory.

User created PK templates appear on the **Assay Selection** tab under PK assays.

Figure 6.21. Select a new or existing PK template



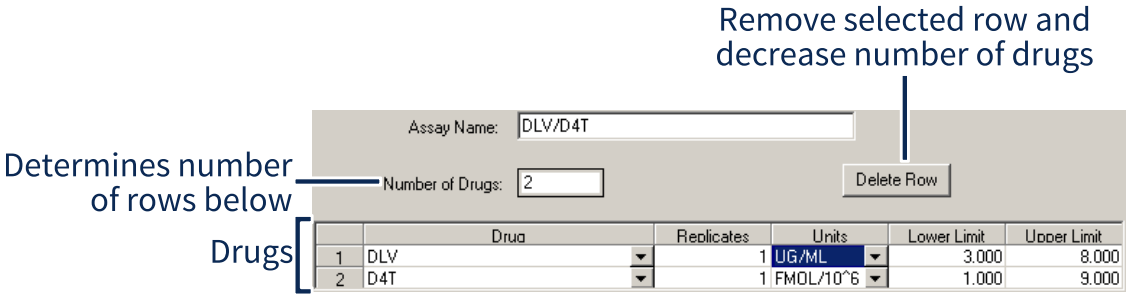
▲ To create a new PK template, select the top-level **PK Assays** item.

Procedure 6.25. Creating or modifying a PK template

1. On the **Assay Selection tab**, find the PK template you want to use from the **Assays** list on the left.
   - To create a new template, select **PK Assay** (the high-level item directly under **PK Assays**)
   - To edit or create a new template based on an existing template, select it from the **Assays** list.
2. Select the **Design** check box.
3. Click the Select Assay button on the right.
   - If creating a new template from an existing template, click the Create button.
   - If editing an existing template, click the Edit button.
4. Enter the name for your template as you want it to appear in the list of **Assays** on the **Assay Selection** tab.
5. Enter the **number of drugs** to be used. For each drug, a row will be added to the list below.
6. Select the drug(s) from the **Drug** drop-down list. Use the **Ctrl**+**H** shortcut if you do not know what a specific drug abbreviation means.

7. Enter the **Replicates**, **Units**, **Lower Limit**, and **Upper Limit**.
8. After every drug has been added, click the ✚ button from the LDMS toolbar.

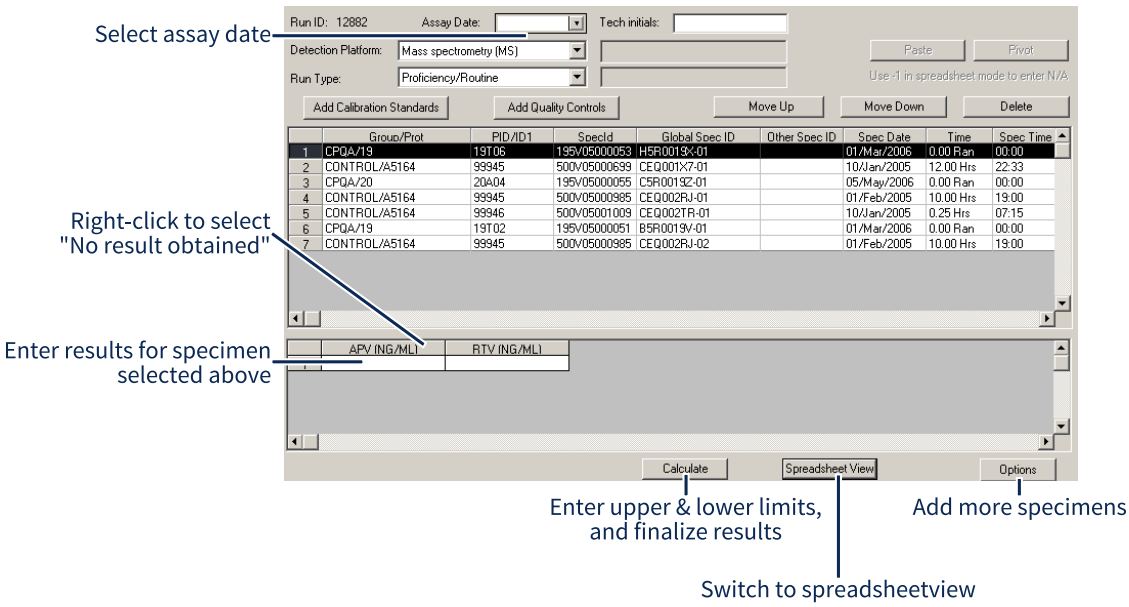
Figure 6.22. Creating an PK assay template



Entering PK Assay Results

In LDMS, PK assays are entered into LDMS through a data entry screen. In order to enter PK results, you must already have created a PK template for the analyte combination that you are testing.

Figure 6.23. Entering PK assay results



▲ PK assay results data entry screen in "traditional view".

Procedure 6.26. Entering PK assay results

1. Add any needed calibration or QC lots to the run.

   Do this on the preview screen by clicking the **Add Calibration Standard** or **Add Quality Controls** button. Select the lot, and whether you want to add one, two, or three to the run. Use the **Move Up** and **Move Down** button to arrange the lots in the correction position on the run.

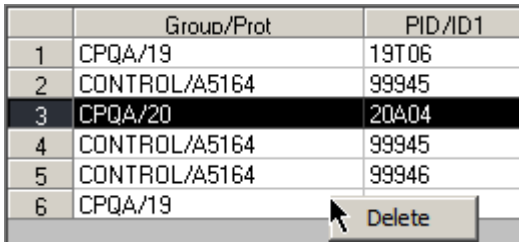
   ### Note

   For instructions on adding calibration standards and QC controls to LDMS, see the section called “Pharmacology QC and Calibration Lot Entry” on page 122.

2. Enter the date that the assay was actually run into the **Assay Date** field at the top of the screen.
3. Select the **Detection Platform** from the drop-down list.
4. Click Run Now button.
5. Enter the results. This is done in either Traditional View or Spreadsheet view. Use the Traditional View and Spreadsheet View buttons to change between them.
   - In Traditional View (the default view), select each specimen, and then enter the results for each analyte at the bottom of the screen. This must be done for each specimen.
   - In Spreadsheet View, enter the analyte results into the appropriate column for each specimen. This is useful if you want copy and past results from a spreadsheet program. See Procedure 6.27, "Copying results from a spreadsheet program (left) and pasting them into the appropriate cells in LDMS (center and left).".
6. (Optional) If a result was not obtained, click on the cell for the analyte to highlight it, and then right-click on it and select `No Result Obtained`. *You must highlight the cell before you right-click on it*.
7. Click the Calculate button.
8. In the **PK Run Limits** dialog window, enter your initials into the **Tech Initials** field, and enter the **Lower Limit** and **Upper Limit** for each analyte.
9. (If applicable) You may be prompted if you want specimens that were below the lower limit to be available for future runs. Select **Yes** or **No** as appropriate.

Warning

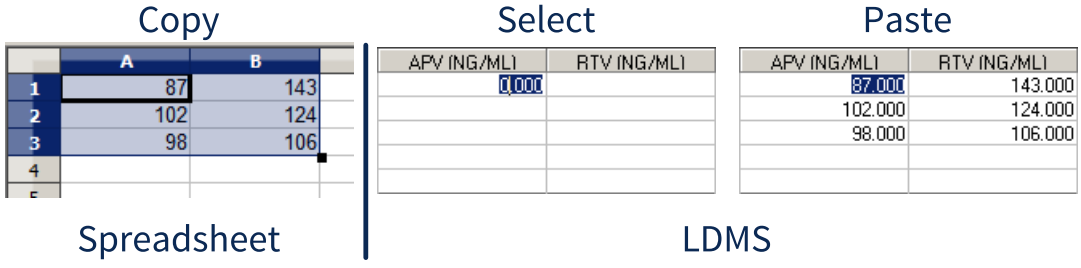
Be careful with using the `Right-clickDelete` option on individual specimens. It doesn't matter where you right-click, the *highlighted* specimen will be the one deleted.



▲ Even though this user has right-clicked on the 6th specimen, it will actually be the 3rd specimen that will be deleted.

You can copy and paste results from a spreadsheet program, such as LibreOffice Calc [http://www.libreoffice.org] or Microsoft Excel into LDMS. The file doesn't necessarily have to be native to the program you are using. For example, you can open a CSV file with Excel, and then copy the cells to LDMS.

Figure 6.24. Copying and pasting spreadsheet PK results into LDMS



Procedure 6.27. Copying results from a spreadsheet program (left) and pasting them into the appropriate cells in LDMS (center and left).

1. Open the file in your spreadsheet program.

2. If your data does not have rows and columns in the same order as they appear in LDMS, manually adjust your spreadsheet.
3. If any cells are `N/A`, enter `-1`.
4. Select the cells that you want to copy.
5. Copy the selected cells (typically **Ctrl**+**C** or `Right ClickCopy`)
6. In LDMS, click Spreadsheet View
7. (Optional) To change between one analyte per and analytes in separate columns, click the Pivot
8. Select the first destination cell in LDMS.
9. Click the Paste button.

LDMS may apply some censor codes based on the analyte results, and the upper and lower limits. You can apply user censor codes by clicking on the field to censor to select it, and then right-clicking and selecting `Assign User Censor`.

For more information on censor codes, see the section called "Censor Codes" on page 88.

To view the PK Assay Result Report after entering data for the specimens tested, click the button from the LDMS toolbar.

Reviewing and Accepting PK Results

If you export pharmacology data to Frontier Scie3nce, you must review and accept the results after they are entered. This finalizes the results so that they will be appropriately accessioned into the central LDMS database at Frontier Science.

Procedure 6.28. Reviewing and accepting PK assay results

1. Open the completed assay run that needs to be reviewed and approved. For instructions, see the section called "Reviewing Assay Results After They Have Been Read" on page 88.
2. Review the results by selecting a specimen from the top and checking the results at the bottom.
3. (Optional) Correct or censor results as needed.
   - To apply a censor code, right-click on the result in **Traditional View** (you cannot apply censors in **Spreadsheet View**).
4. Complete the **Reviewed by**, **Reviewed Date**, and (optionally) **Comments** fields at the bottom of the screen.
5. Click the button from the LDMS toolbar.

GeneXpert Assay

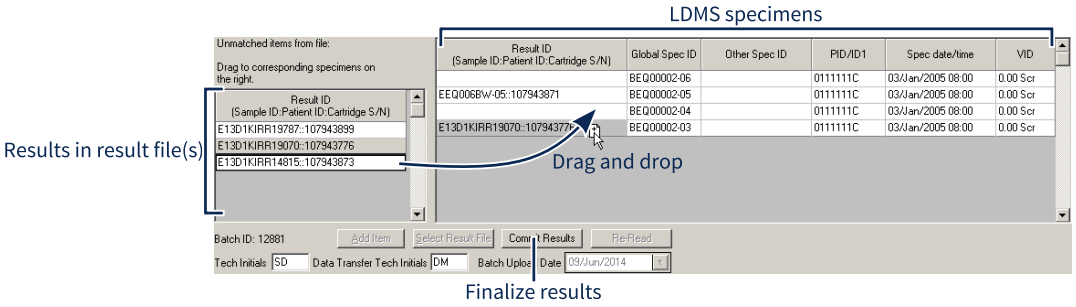
LDMS currently only supports the Xpert MTB/RIF assay. This assay is used to identify mycobacterium tuberculosis (MTB) resistance to rifampicin (RIF).

Procedure 6.29. Reading a GeneXpert assay result file

1. Create a new GeneXpert MTB-RIF assay run and add assigned specimens to it. For instructions, see the section called "Creating and Reviewing Assay Runs" on page 84.

   The **Preview** tab will open.

Figure 6.25. GeneXpert preview screen



2. (Optional) Add or modify the **Other Spec[imen] ID** for specimens in the right pane. This can be used to help LDMS automatically match specimens in the result file(s) to specimens in LDMS.
3. Click the Select Result File button.

   LDMS will prompt you if you want to run the assay. Select **Yes**. A window will open to select the result file.
4. Select the GeneXpert result file, and then click the **Open** button.

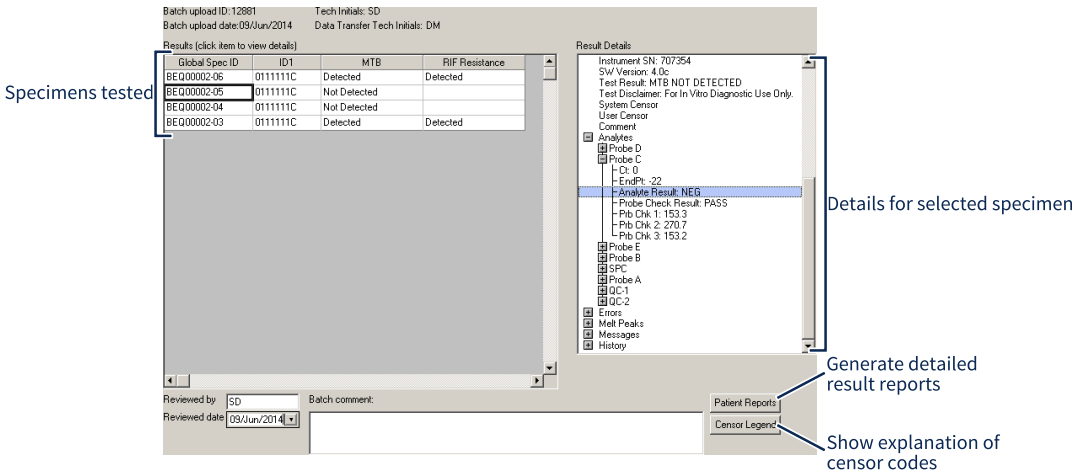
   After selecting the result file, LDMS will prompt you if you want to load another file. You can use multiple result files for the same assay run.

   Once all result files have been selected, LDMS will attempt to match results to specimens. Results that it was unable to match will be displayed in the left pane.
5. Drag and drop unmatched results from the left pane to the specimens in the right pane.
6. Review the specimens that were automatically matched by LDMS and ensure that they were matched correctly.

   If you find any errors, you can drag and drop the result to a different specimen to correct it.
7. Enter the initials of the assay technician into the **Tech Initials** box and your initials into the **Data Transfer Tech Initials** box.
8. After all results have been matched to a specimen, click the Commit Results button.

   The results screen will open.
9. Review the assay results.

Figure 6.26. GeneXpert results screen



By selecting a result on the left, details will be displayed on the right. Some of the items can be expanded to show more information.

10. (Optional) To apply a user censor code to a result, right click on the specimen in the left pane and select `Censor Specimen`.
11. Click the button from the LDMS toolbar.

There are two reports that can be generated from the results screen for the GeneXpert MTB-RIF assay:

GeneXpert MTB-RIF Report	This report is generated by clicking the from the LDMS toolbar. This report provides an overview of the assay run and the specimens that were tested.
Patient Report	This report is generated by clicking the **Patient Report** button at the bottom of the results screen. This report provides detailed information about one or more specimens on the assay run. You can select which specimens will appear on the report.

Managing Controls

Setting up Assay Kit Information

When reading certain assays in LDMS, you will be required to select kit lot information. For some of these assays, you will need to manually enter the kit information into LDMS using the Kit Entry tool; for newer assays, LDMS will automatically load kit information from your result file (though you will still need to use the Kit Entry tool to enter a few pieces of information that are not in assay result files).

Table 6.8 shows which assays require kit information when they are being read. It then breaks those assays down between those where kit information must have been entered manually prior to reading the assay and those where kit information can be read automatically from the output file.

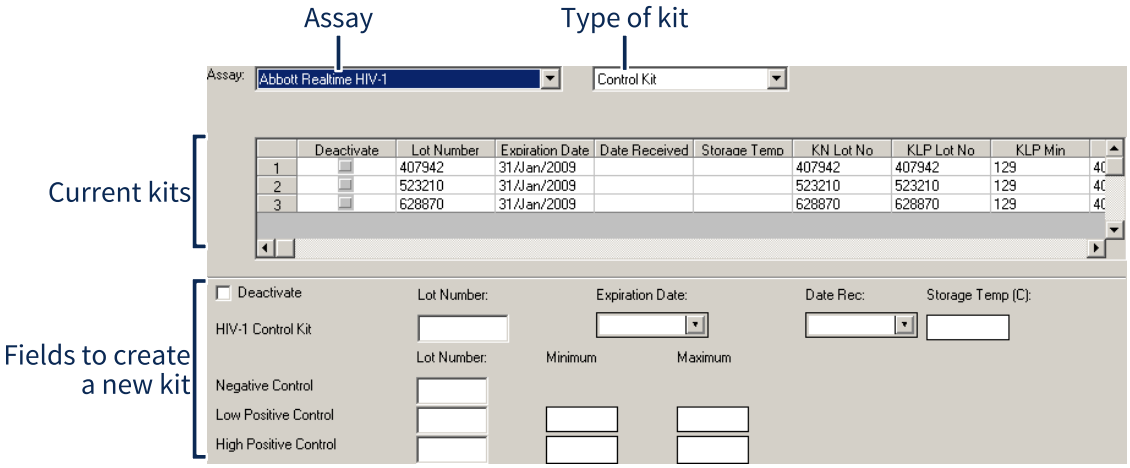
Table 6.8. Assays Requiring Kit Information

Assay	Manual	Automatic
Abbott Realtime HIV-1		●
COBAS TaqMan HCV		●
COBAS TaqMan HIV-1		●
Nuclisens HIV RNA QT	●	
Roche Amplicor Monitor HIV RT PCR	●	
Roche COBAS Amplicor	●	
Roche COBAS UltraSensitive	●	
Roche UltraSensitive HIV RT PCR	●	

Important

For assays where kit information is pulled from the result file automatically, you still must use the Kit Entry tool to enter the **Date Rec[eived]** and **Storage Temp[erature]** for the kit, as this information is not in the result file.

Figure 6.27. Kit Lot Entry Screen



▲ The kit entry screen for the Abbott Realtime HIV-1 assay.

Important

The fields available for kits and types of kits will vary, depending on the assay selected. The process of using the kit entry tool is the same for every assay; it is the fields that are unique.

Procedure 6.30. Manually creating a new kit lot

1. Access the Kit Entry tool by clicking `QA/QCKit Entry` from the LDMS menu bar.
2. Select the assay for the kit you are creating from the **Assay** drop-down list.
3. (If applicable) Select the type of kit from the drop-down list next to the assay. This field will not be displayed for assays that do not need it.
4. Complete all of the fields at the bottom of the screen using the information from your kit. The precise fields that are available will vary from assay to assay.
5. Click the ✚ button from the LDMS toolbar.

Kits can be updated after creating them. If you have read an assay that automatically collects kit information from the assay output file, modifying the existing kit is how you would complete the fields that are not read from the output. This update would only need to be done the first time the kit was used.

Procedure 6.31. Modifying an existing kit

1. Access the Kit Entry tool by clicking `QA/QCKit Entry` from the LDMS menu bar.
2. Select the assay for the kit you are modiying from the **Assay** drop-down list.
3. (If applicable) Select the type of kit from the drop-down list next to the assay. This field will not be displayed for assays that do not need it.
4. Select the kit that you want to modify from the list of existing kits. The fields at the bottom of the screen will be populated with the values for the selected kit.
5. Make the necessary changes to the kit fields.

6. Click the button from the LDMS toolbar.

One of the options available when modifying kits is to **deactivate** them. This prevents them from being selected when reading an assay without actually removing the kit from LDMS. If a kit has not yet been used, it can also be deleted by selecting the kit, and then clicking the button from the LDMS toolbar. Once an assay has been run with a kit, however, that kit cannot be deleted.

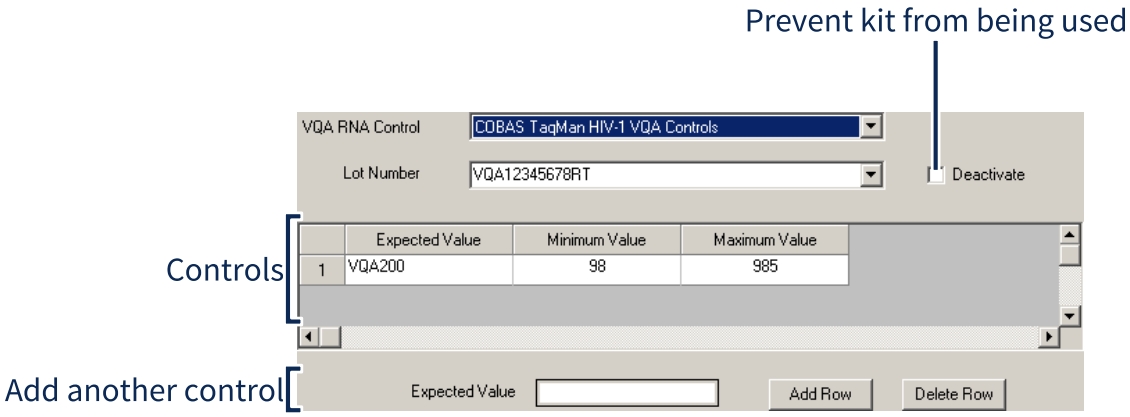
Setting up VQA Kits

Table 6.9. VQA Controls and Assays

VQA RNA Control	Applicable Assay
Abbott VQA Controls	Abbott Realtime HIV-1
COBAS TaqMan VQA Controls	COBAS TaqMan HIV-1
COBAS UltraSensitive VQA Controls	Roche COBAS UltraSensitive HIV-1
Standard VQA Nuclisens Controls	Nuclisens
Standard VQA RNA Controls	Roche Amplicor Monitor HIV RT PCR
UltraSensitive VQA RNA Controls	Roche UltraSensitive HIV RT PCR Assay

▲ This table shows the VQA controls in LDMS and the applicable assays for those controls.

Figure 6.28. VQA Control Login Screen



▲ Creating a new VQA control. This image shows the creation of a VQA200 control.

Procedure 6.32. Creating a new VQA Kit

1. Access the VQA Control Entry tool by clicking `QA/QCVQA Control Login` from the LDMS menu bar.
2. Select the desired control from the **VQA RNA Control** list. For an explanation of what controls match up with what assay, see Table 6.9.
3. Enter the VQA lot number into the **Lot Number** field.
4. Enter the expected value for the control into the **Expected value** field at the bottom of the screen, and then click the Add Row button.
5. Complete the **minimum value** and **maximum value** fields.
6. Click the button from the LDMS toolbar.

VQA controls can be modified by selected the desired **VQA RNA Control** and **Lot Number**, making any changes, and then clicking the button from the LDMS toolbar.

Pharmacology Control Charting

PK control charting is a feature in LDMS that allows you to evaluate your laboratory's control performance over a specified time, and generate a variety of reports. To access PK control charting reports in LDMS, select `QA/QCPK Control Charting` from the LDMS menu bar.

1. From the **PK Analytes**, **Lot Type**, and **Lot #**, select the applicable analyte, lot type, and lot number.
2. (Optional) To limit to runs within a specific date, use the **Run Date From** and **To** boxes.
3. Click **Search**.
4. Under **Rounds found**, select the runs that you want to appear on the report, and then click the v below the list to move it to **Runs selected**.
5. In the **Reports** list, select the report that you want to generate.
6. Click **Generate**.

Virology Control Charting

Control charting is a feature in LDMS that allows you to evaluate your laboratory's control performance over a specified time for virology assays. This tool generates Levey-Jennings charts. To access control charting in LDMS, select `QA/QCControl Charting` from the LDMS menu bar.

Procedure 6.33. Creating a Levey-Jennings chart in LDMS

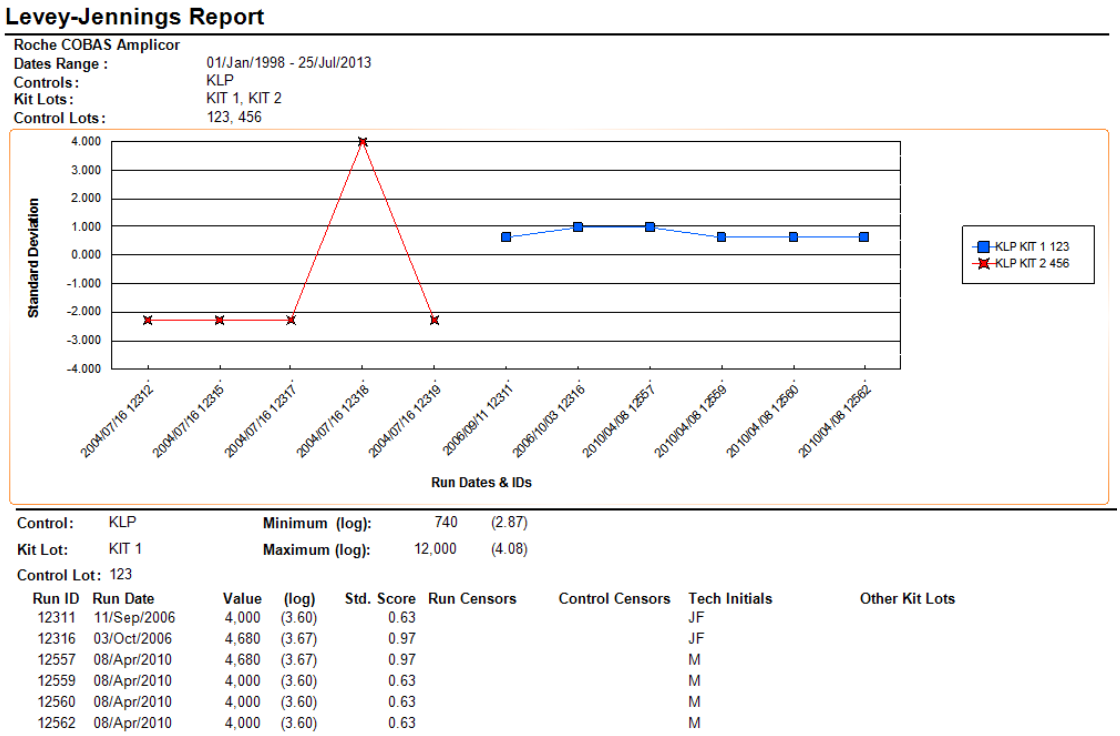
1. Select the virology assay with the control you want to chart from the **Assay** drop-down list.
2. Select the date range within which you want to view controls in the **Date From** and **Date To** fields.
3. (Optional) Select the control that you want to chart from the **Control Name** list.
4. (Optional) Select the desired kit and control lots from the **Kit Lot Number** and **Control Lot** fields.

   Note

   If the **Kit Lot Number** and **Control Lot** fields are disabled, no controls were found within the date range specified. Try broadening your date scope.
5. Click the ⚡ button from the LDMS toolbar.
6. Select desired control from the **Search Results** listing, and then click the v button below the list. This will move the control to the **Selected Controls** list.
7. Select one or more controls from the **Selected Controls** list. Hold down the **Ctrl** or **Shift** key to select multiple control.
8. Click the Graph button.

Up to seven distinct control lots can be displayed on the Levey-Jennings chart generated by LDMS. If multiple controls were selected, the chart will display both controls on the same chart. Use the key to the right to distinguish each control.

Figure 6.29. Control Charting Report



Control:	KLP	Minimum (log):	740	(2.87)
Kit Lot:	KIT 1	Maximum (log):	12,000	(4.08)
Control Lot:	123			

Run ID	Run Date	Value	(log)	Std. Score	Run Censors	Control Censors	Tech Initials	Other Kit Lots
12311	11/Sep/2006	4,000	(3.60)	0.63			JF	
12316	03/Oct/2006	4,680	(3.67)	0.97			JF	
12557	08/Apr/2010	4,680	(3.67)	0.97			M	
12559	08/Apr/2010	4,000	(3.60)	0.63			M	
12560	08/Apr/2010	4,000	(3.60)	0.63			M	
12562	08/Apr/2010	4,000	(3.60)	0.63			M	

▲ A Levey-Jennings Report generated by the control charting tool in LDMS, showing data for two controls.

Pharmacology QC and Calibration Lot Entry

PK control and calibration lots can be entered into LDMS. This allows you to use lots when entering PK assay results in LDMS.

1. From the LDMS menu bar, click `QA/QCPK QC Lot Entry` or `QA/QCPK Callibrator Lot Entry`.
2. Enter the following information for your lot:
   - Lot #
   - Creation date
   - Expiration date
   - Storage temperature (in Celsius)
   - Derivative or matrix type
3. For each control or calibration standard you want to add:
   a. Next to the **Controls** or **Calibration Standards**box, click **Add**.
   b. Select the control or calibration standard from the **Control** or **Calibrator** column.
   c. Enter a **Custom name**, if desired.
4. For each analyte for this lot:
   a. Next to the **Analytes** box, click **Add**.
   b. Select an analyte from the **Analyte** column.
   c. In the **Target** and **Unit** columns, select the appropriate target values for the analyte.
5. From the LDMS tool bar, click the ✚ button.

Once the lot has been successfully added, you can modify it by selecting it from the **Saved Lots** list, making your changes, and then clicking the button from the LDMS tool bar. If you want

to discontinue a lot so that it can no longer be selected when entering PK results in LDMS, select the **Deactivate** option for the lot.

Using Assay Device Readers

Associating an Assay with a Reader

For assays in LDMS that read instrument output, you must associate the assay with a reader device. For a list of reader hardware supported by LDMS, see Table 6.10.

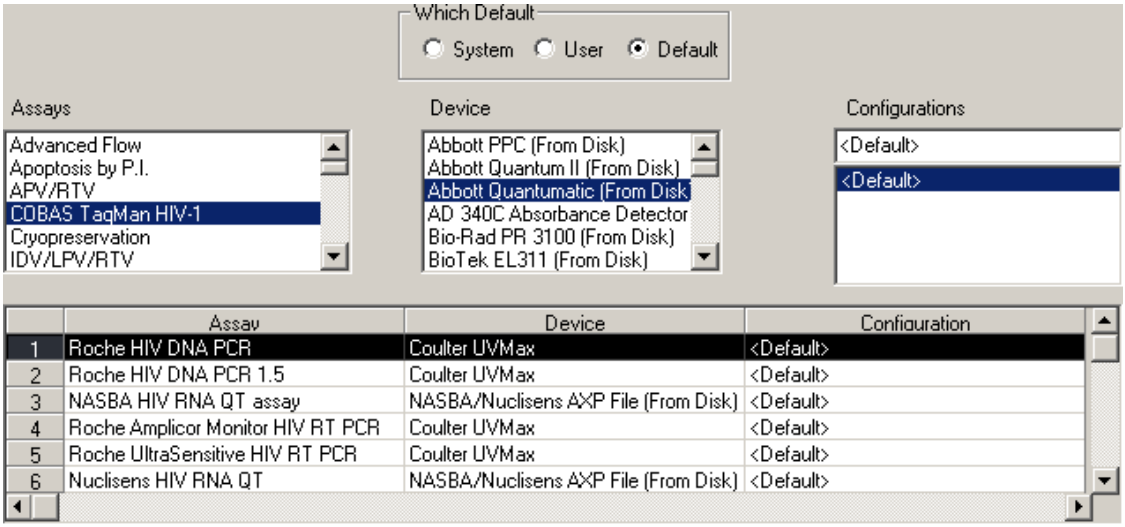
Procedure 6.34. Associating an assay with a reader in LDMS

1. Click `AdministrationSystem Configuration` from the LDMS menu bar.
2. Change to the **Assays** tab (Figure 6.30).
3. Select the assay or assay template to be associated with a reader from the **Assays** list.
4. Select the reader hardware that you will be using from the **Device** list.

   Note

   Devices named `Device Name` **(From Disk)** are to be used in conjunction with LDMS Remote Reader. See the section called “LDMS Remote Reader” on page 126.
5. Select the configuration that you want to use. The available configurations are based on the device selected. For instructions on creating a configuration for assays that can be read directly by LDMS, see the section called “Creating a Reader Configuration” on page 124.
6. Click the ✚ button from the LDMS toolbar. This will add the association to the list at the bottom of the screen.

Figure 6.30. Assay reader configuration in LDMS



▲ Associating an assay with a reader device in LDMS

Table 6.10. Reader hardware supported by LDMS

Remote Reader	Device File[a]	Remote Reader File[b]	Direct Read[c]
Abbott PPC		●	
Abbott Quantum II		●	
Abbott Quantumatic		●	
Abbott Realtime HIV-1 m2000	●		
AD 340C Absorbance Detector	●		
BioTek EL311		●	
BioTek EL312		●	
BioTek ELx800		●	
BioTek Powerwave XS	●		
Chiron Assay Reader	●		
COBAS Amplicor Analyzer		●	
Coulter MR5000		●	●
Coulter UVMax		●	●
Dupont VMax		●	●
Dynatech MR5000		●	●
Molecular Devices	●		
Molecular Devices UVMax		●	●
MultiSkan Ascent	●		
NASBA/Nuclisens AXP	●		
Organon Teknika 520		●	●
Roche AMPLILINK 1.3, 2.41, and 3.2 (for COBAS Amplicor Analyzer)	●		
Roche ELX800 with Gen5	●		
SoftMax	●		
SoftMax New	●		
SoftMax Partial Plate	●		
SpectraMax 250	●		
Tecan Sunrise	●		

[a] LDMS can read an output file with the results from the reader device

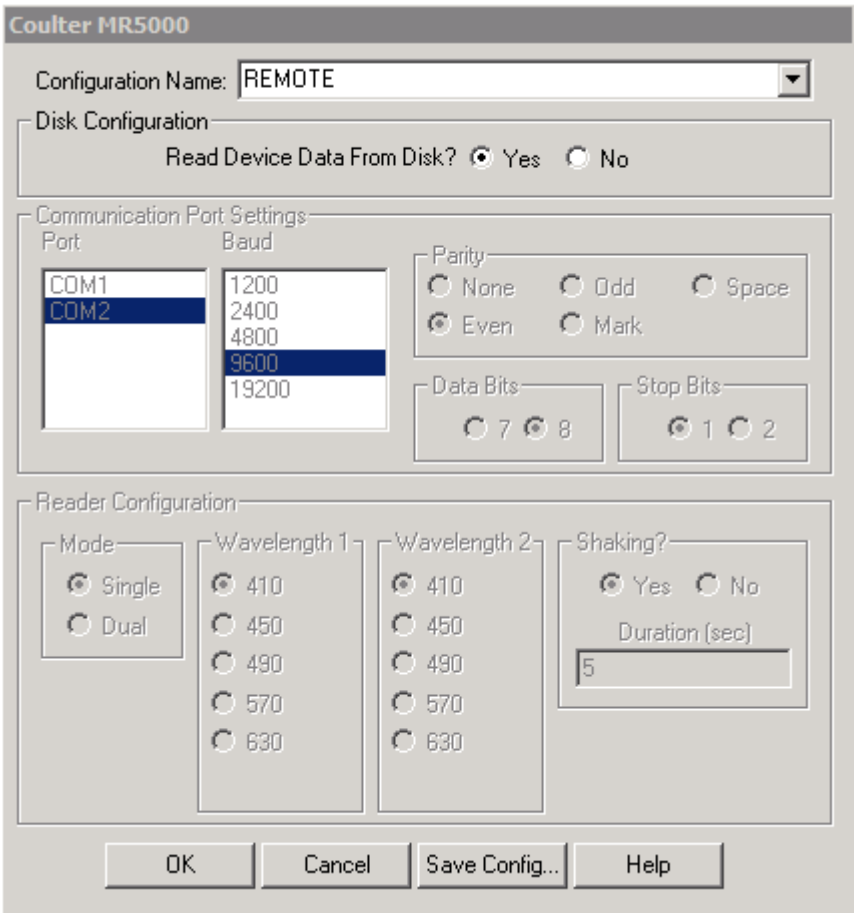
[b] Output from LDMS Remote Reader

[c] LDMS can read output directly from a device reader, without using an output file as an intermediary

Creating a Reader Configuration

Before you can use a reader device, you must tell LDMS how you have it setup. This is done on an individual instrument basis. You can either configure LDMS to read output from the device directly, or you can utilize LDMS Remote Reader to read the assay output on a different computer and then manually transfer the output to the computer with LDMS.

Figure 6.31. Instrument configuration in LDMS



▲ The configuration screen for the Coulter MR5000. The **Read Device Data From Disk** option indicates that LDMS Remote Reader will be used.

Procedure 6.35. Creating or modifying a reader configuration

1. Click `AdministrationInstrument SetupDevice Name` from the LDMS menu bar.
2. Type a name for your configuration into the **Configuration Name** box *or* select an existing configuration from the **Configuration Name** box to edit.
3. Change the **Read Device Data From Disk** option as follows:
   - If you want LDMS to read assay output directly from the device (i.e. it is connected to the same computer as LDMS), select `No`.
   - If you want to utilize LDMS Remote Reader, select `Yes`. You will need to configure LDMS Remote Reader to read from the device. For more information on LDMS Remote Reader, see the section called "LDMS Remote Reader" on page 126.
4. (For direct read only) Complete the appropriate **Communication Port Settings** and **Reader Configuration** settings for your setup.
5. Click the Save Config... button.

Once you have created a configuration for a device, that configuration can be selected when associating the hardware with an assay. For instructions on associating a reader device with an assay in LDMS, see the section called "Associating an Assay with a Reader" on page 123.

LDMS Remote Reader

What is LDMS Remote Reader

LDMS Remote Reader is a program separate from LDMS that can be used to read assay data and save it in a format that can be read by LDMS. It is capable of reading assay output directly from the instrument or device reader, and then generating an output file that can be read by LDMS. The purpose of LDMS Remote Reader is to read assay data when it is not possible to connect an instrument directly to the computer that is running LDMS. LDMS Remote Reader has significantly lower system requirements than LDMS, which makes it suitable for running on older hardware as well.

For a list of device readers that are compatible with LDMS Remote Reader, see Table 6.10 (page 124).

LDMS Remote Reader creates an output file after reading the assay from the instrument. You must manually transfer the output file to the computer with LDMS installed.

To obtain LDMS Remote Reader, contact LDMS User Support.

Configuring LDMS to use LDMS Remote Reader

To use LDMS Remote Reader with LDMS, you must first tell LDMS that you want to read an assay reader device on a remote computer.

Procedure 6.36. Configuring LDMS to read a device using LDMS Remote Reader

1. (For instruments that can be read directly by LDMS only) Create a new configuration for the instrument
    a. Click `AdministrationInstrument SetupDevice Name` from the LDMS menu bar.
    b. Enter a name for your configuration into the **Configuration Name** field. An easy name to help remember the purpose of the configuration is `REMOTE`.
    c. Click the **OK** button.
2. Click `AdministrationSystem Configuration` from the LDMS menu bar.
3. Change to the **Assays** tab.
4. Select the assay to be read using LDMS Remote Reader from the **Assays** list.
5. Select the reader device from the **Device** list.

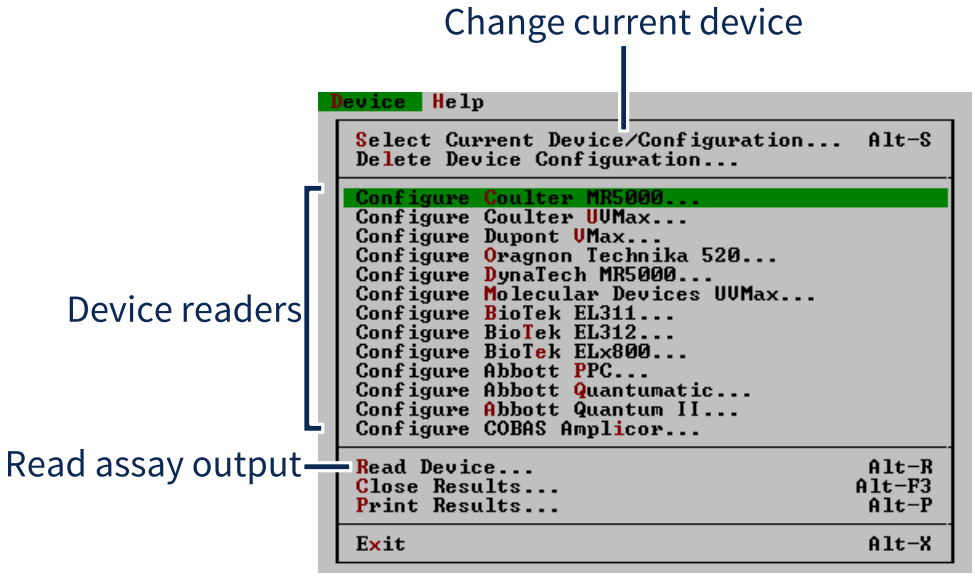
    Note

    Devices that can only be read using LDMS Remote Reader are labeled as `Assay Name` **(From Disk)**.
6. Select the appropriate configuration from the **Configurations** list. For instruments that could be read directly by LDMS, this will be the configuration that you created in Step 1.
7. Click the ✚ button from the LDMS toolbar.

Configuring LDMS Remote Reader

When you first start LDMS Remote Reader, it will show you the currently selected device and configuration. When you read an assay, this is the device reader that will be used. Before using an reader devices to read an assay, you must configure your hardware.

Figure 6.32. LDMS Remote Reader device menu



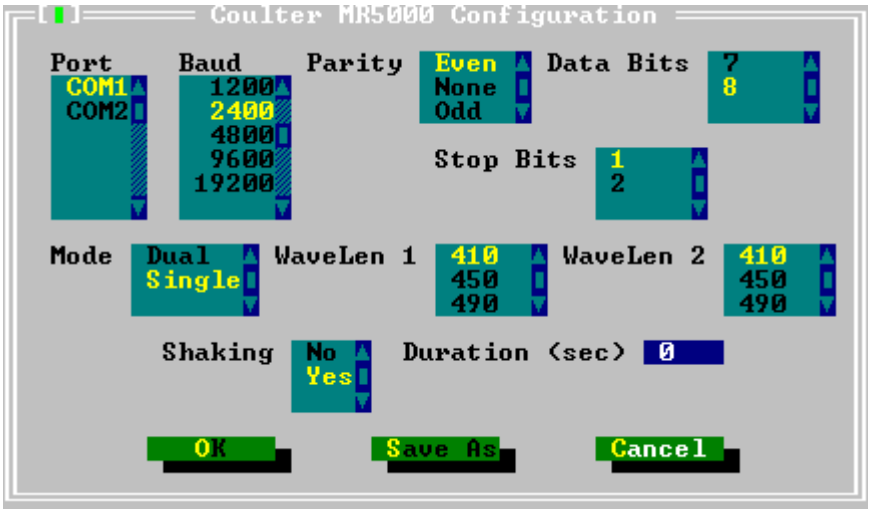
Procedure 6.37. Configuring a reader device

1. From the menu bar, click `Device`.
2. Select the device that you want to configure.
3. Select the configuration that you want to modify. If you are creating a new configuration, select `<Default>`.
4. Change the settings for your device.
5. Save your configuration by doing one of the following:
   - To save your changes to the configuration that you previously selected, click the **OK** button.
   - To save a new configuration, click the **Save As** button.

Warning

If you selected the `<Default>` configuration, this saving changes will overwrite the default settings. You cannot undo this change.

Figure 6.33. Device Configuration screen



▲ Assay configuration screen in LDMS Remote Reader has the same options as LDMS.

After creating or modifying a configuration, that reader device and configuration will automatically become your current reader. This means that when you go to read an assay, these are the settings that will be used.

If you have more than one reader device connected to the computer (or more than one configuration for a device), you will need to specify which one to use.

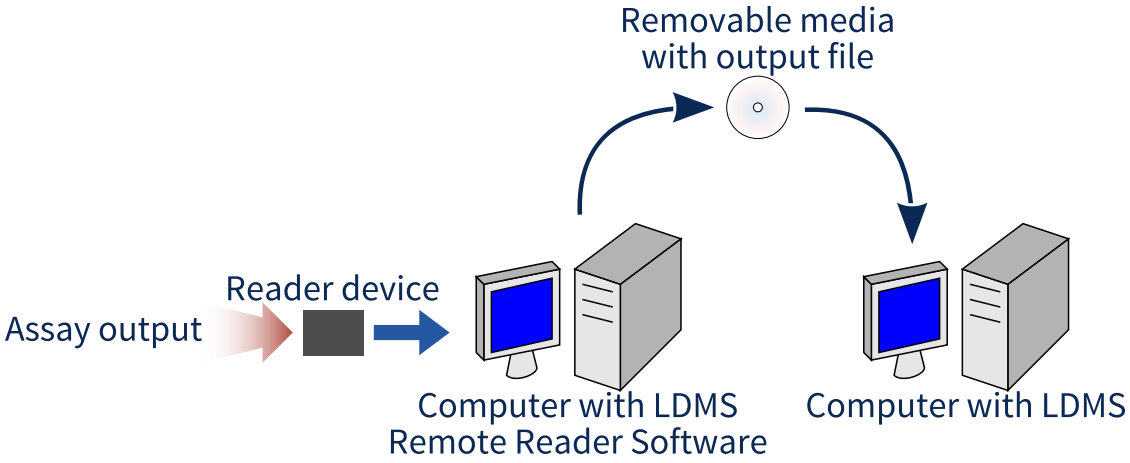
Procedure 6.38. Changing the current device and configuration used by LDMS Remote Reader

1. From the menu bar, select `DeviceSelect Current Device/Configuration...`.
2. Select the reader device that you want to read from the **Select Device** list.
3. Select the configuration that you want to use from the **Select Configuration** list.

Reading Assay Output using LDMS Remote Reader

LDMS Remote Reader acts as a go-between when the computer connected to your assay reader does not have LDMS installer. LDMS Remote Reader reads the device reader output, much like LDMS would read it, and creates an output file that you can transfer to the computer with LDMS.

Figure 6.34. LDMS Remote Reader workflow



▲ This diagram shows the basic steps involved in using LDMS Remote Reader to get assay output into LDMS.

After reading the assay output using a device reader, the output file is transferred to the computer with LDMS. Often, this is as simple as putting the output file on a removable USB drive.

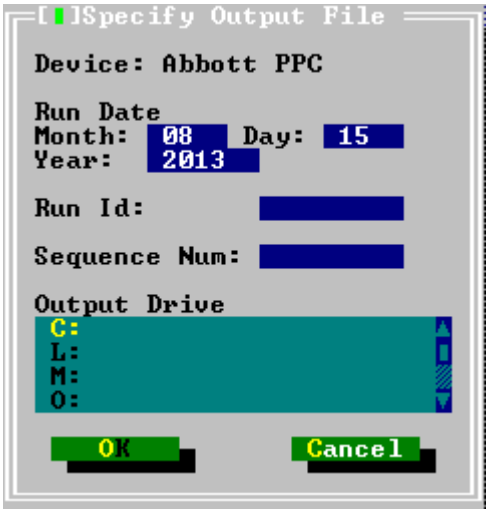
Procedure 6.39. Reading assay output using Remote Reader Software

1. On the computer with LDMS, setup the assay to be read. For more information on how to do this, see the section called "Creating a New Assay Run" on page 85.
2. In LDMS, generate a plate layout report for the assay by clicking the button from the LDMS toolbar while on the assay **Preview** tab.

   Important

   The plate layout report is required to use LDMS Remote Reader.
3. On the computer with LDMS Remote Reader, start LDMS Remote Reader.
4. Click `DeviceRead Device` from the menu bar.
5. Verify that the **Device** is correct. If you need to change the device being used, see the section called "Configuring LDMS Remote Reader" on page 126.
6. Verify that the **Run Date** is correct, and adjust it if necessary. See Figure 6.35.
7. In the **Run ID** field, enter the system generated run ID from the Plate Layout Report.
8. In the **Sequence Number** field, enter the plate number from your Plate Layout Report.
9. Select the drive where you want the output file to be written from the **Output Drive** list. For example, if you have a removable USB drive connected as the `E:`, select that drive.
10. Click **OK** to begin reading the assay output.

Figure 6.35. Reading and assay with LDMS Remote Reader



▲ Reading an assay using LDMS Remote Reader.

Once LDMS Remote Reader has finished reading the assay output from your device reader, a directory called `devdata` will be created in the drive you selected for the output (e.g. `E:\devdata`). This directory will contain your assay run data file. Files will be named according to the run ID and sequence number. These are the files that you will need to transfer to the computer with LDMS installed.

Now that you have the assay output, you need to read it using LDMS.

Procedure 6.40. Reading assay output captured by LDMS Remote Reader with LDMS

1. Copy the desired assay output files from the `devdata` directory to a removable media, then connect the removable media to the computer running the full version of LDMS.
2. In LDMS, click `TasksAssays` or the button from the LDMS toolbar.
3. On the **Assay Selection** tab, find the assay that you ran in the **Assays** list on the left.
4. Select the **Runs not Performed/Not Terminated** radio button.
5. Enter the run ID into the **Run ID** field. This number is found on the Plate Layout Report and entered in LDMS Remote Reader.
6. Click the Search button. All assay runs that were set up but have not been run will be listed under **Previous Runs Found**.
7. Select the assay for which you will be reading data, and then click the Select Assay.
8. Change to the **Preview** tab. (LDMS may change to this tab automatically after selecting an assay).
9. Enter run information as appropriate, depending on the assay.
   - For some assays, complete fields on the **Preview** tab, such as **Tech Initials** and **Sample Prep. Method**, then click the Run Now button.
   - For some assays, you don't complete anything on the **Preview** tab. Instead, click the Run Now button. The **Enter Run Information** window will appear with the fields that you must enter to complete the run. After entering this information, click the OK button.
10. A window will appear to select the assay output data file. Navigate to the location of your `devdata` directory (e.g. a USB drive) and select the appropriate file.

Chapter 7. Reports

LDMS as a Database Front-end

LDMS is a specialized database front-end, and while users can't interact with that data direct there are several ways to extract it. Virtually any set of data that LDMS stores can be pulled into a user-friendly report, which can then be printed or exported into a format that can be utilized by another program—you just need to know how to ask LDMS for it.

One of the most important tools at your disposal for retrieving data is LDMS Reports tool. To access reports, go to `TasksReports`, or click the  button from the LDMS toolbar. Another feature, **Data Retrieval**, can be used for more customized reports. Data Retrieval is found in `ToolsData Retrieval`.

Running LDMS's Built-in Reports

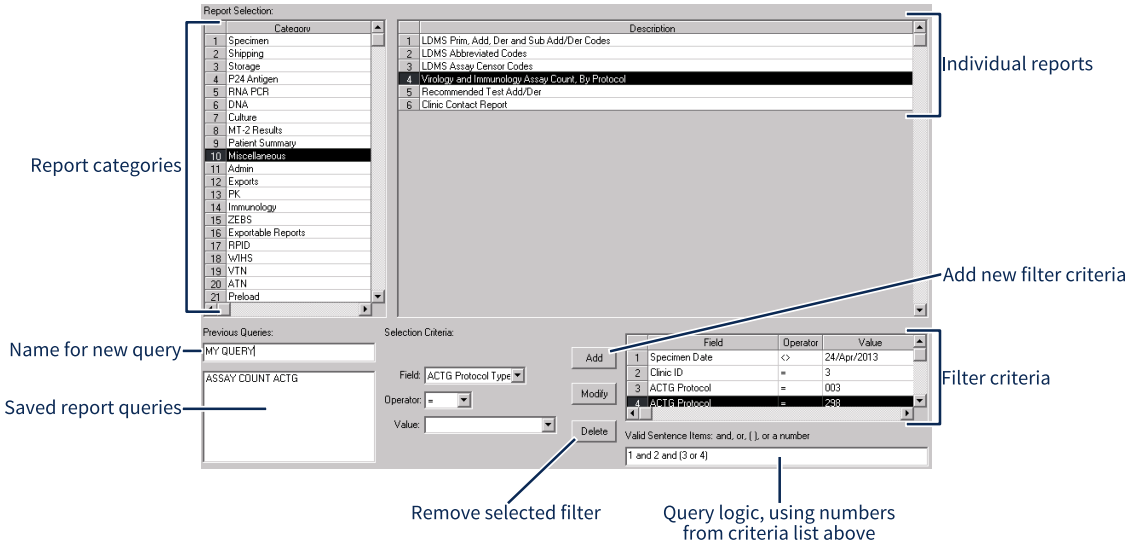
LDMS comes with many reports. To run a report, simply select a category on the left, the name of the report on the right, and then click the  button from the LDMS toolbar. After a short time (depending on the size of the report), a Crystal Reports® viewer window will appear.

> **Note**
>
> While there are many built-in reports, they may not meet everyone's needs. For instructions of building customized reports, see the section called “Running Custom Data Retrieval Reports” on page 134.

When you attempt to run a report without criteria, LDMS will give you a message that the report may take a long time to generate. You'll always receive this message if you don't select any criteria, even if the report you're about to generate won't be very big.

You can reduce the amount of information in your report by creating query criteria to filter it. For example, a filter of Specimen Date >= 24/Apr/2013 would only include records where the specimen date is on or after April 24, 2013 in your report.

Figure 7.1. Report generation screen



Procedure 7.1. Creating a report query criteria

1. Select the field that you want to filter from the **Field** drop-down.
2. Select the operator for your filter from the **Operator** drop-down.

   Note

   LDMS using the Pascal-like <> to indicate ≠ (not equal).
3. Enter a value for your filter.
4. Click the Add button.
5. Add more query criteria.
6. Enter a query statement, using the numbers assigned to each query criteria. If no query statement is entered, the default is to use each query criteria separated by AND.
7. (Optional) To save your query for later use, enter a name into the **Previous Queries** text box, then click the ✚ button from the LDMS tool bar.

Figure 7.2. Example query statement

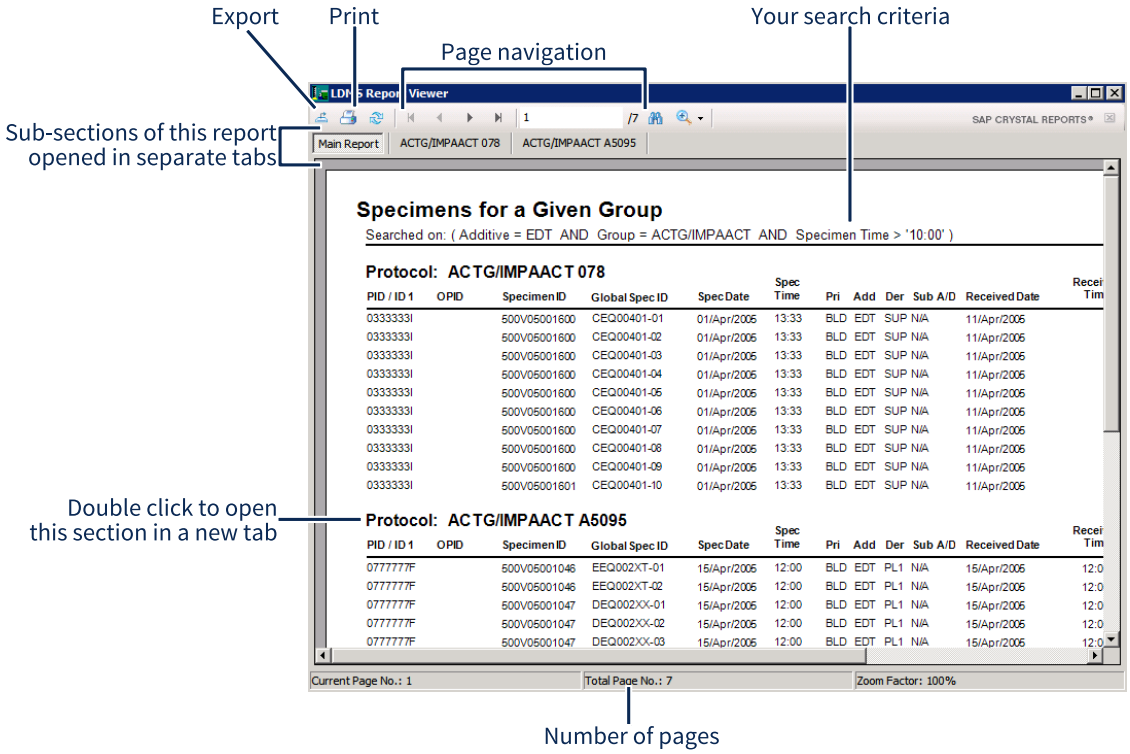
#	Field	Operator	Value
1	ACTG Protocol	=	003
2	ACTG Protocol	=	218
3	Specimen Date	>	24/Apr/2013

▲ In this example, a query statement of `(1 or 2) and 3` would find results where the ACTG Protocol is 003 OR 218, and the Specimen Date is after April 24, 2013.

If you choose to save your query for future use, you can select individual query criteria and modify or delete them using the Modify and Delete buttons respectively. Saving a report query is helpful if you need to run the same report on a regular basis.

LDMS uses Crystal Reports to generate and display information retrieved from its database. Crystal Reports opens in a new window; you cannot return to using LDMS until you close the Crystal Reports window.

Figure 7.3. SAP Crystal Reports Viewer



The Crystal Report Viewer is similar to many PDF viewers, with pages and the ability to zoom. Because Crystal Reports is data-aware, however, you have a few more options for exporting data so that you can use it for other purposes. To export from crystal reports, click the ; you can select different export formats from the drop-down at the bottom of the Save As window. For a list of supported export formats, see Table 7.1.

Table 7.1. Available export file formats for Crystal Reports

Format	Extension
Crystal Report	rpt
Portable Document Format	pdf
Comma separated values	csv
Microsoft Excel (97-2003) with headers	xls
Microsoft Excel (97-2003) without headers	xls
Microsoft Excel (2007+) without headers	xlsx
Microsoft Word (97-2003)	doc
Editable Microsoft Word	rtf
Rich Text	rtf
Crystal Reports XML	xml

Format	Extension
Tab separated text	ttx

Warning

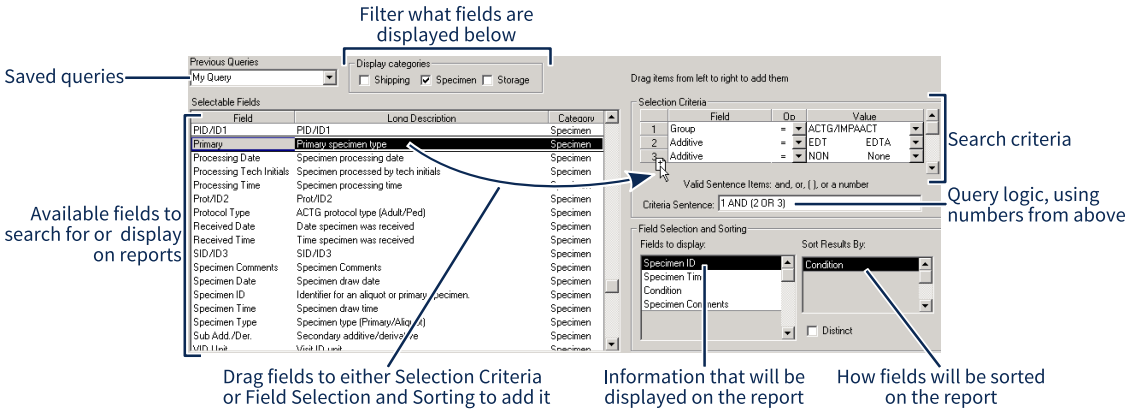
While it is possible to export all reports generated by LDMS, not all of them will export nicely into certain formats (all reports will export just fine into PDF). Some reports will export with formatting issues that would make the data difficult to use in a program like Microsoft Excel®. Reports that are in the category **Exportable Reports** were specifically designed to be export-friendly. If you need to manipulate and analyze data with an external program, **exportable reports** should be you first choice.

Running Custom Data Retrieval Reports

In addition to the reports that come with LDMS, you can create your own custom reports. This allows you to create advanced searches. You can find records based on almost any conceivable search criteria, and also set what information from those records will appear on the report. If none of the reports described in the section called "Descriptions of Built-in Reports" on page 135 meet your needs, you can probably create your own report that does.

The Data Retrieval tool is accessed by clicking `ToolsData Retrieval` from the LDMS menu bar.

Figure 7.4. Data Retrieval Screen



▲ Drag and drop fields on the left into the boxes on the right to add them. To remove a field from the right side, simply drag it out of the box.

Procedure 7.2. Creating a data retrieval query

1. Drag a field from the **Selectable Fields** listing on the left to the **Selection Criteria** box on the right.
2. In the **Selection Criteria** box, select the **Op[erator]** and **Value** that you want to use for your search.
3. Enter the logic for your search criteria into the **Criteria Sentence** box using the numbers for each field in the **Criteria Selection** box.
4. Drag fields that you want to be displayed on your report from the **Selectable Fields** listing on the left to the **Fields to display** box on the right.

5. To determine which fields to sort your results by, drag fields from the **Fields to display** list to the **Sort Results By** list.
6. (Optional) If needed, select the **Distinct** option. This means that if there are any results in your report that are identical (meaning all of the displayed fields are the same), the duplicates will be discarded.
7. (Optional) To save your report for future use, enter a name for your report into the **Previous Queries** text box, then click the button from the LDMS toolbar.
8. Click the button from the LDMS toolbar to generate your report.

Tip

You can save your query so that your report can be quickly run at a later time by typing a name for your report into the **Previous Queries** text box, and then click the button from the LDMS toolbar. To re-run it, just select the report from that drop-down and click the button. If you make changes to it and want to save them, use the button.

When you run your report, the results will appear in a table at the bottom of the screen rather than in a separate window. You can change between the results and the raw SQL statement by using the **Query** and **Results** radio buttons at the bottom of the screen.

To save the results of your report, select the file format that you want to save as from the **Export As** drop-down menu beneath the results, then click the Export button. If you want (or don't want) the headers for your columns that shows what data is in that column, toggle the **With headers** check box.

Descriptions of Built-in Reports

This section describes the reports available using the LDMS Reports tool, organized by the categories in which they appear in LDMS. The filtering criteria available varies from report to report.

Can't find a report you need?

While Frontier Science has attempted to maintain a comprehensive suite of reports, and the Data Retrieval tool is robust enough for most users, you may find that you are having difficulty generating a report with the exact information that you need.

Offering robust report options for laboratories is a priority for LDMS development. New reports (and new features for existing reports) are frequently implemented at the request of a user. Contact LDMS User Support for assistance; they may be able to help you use existing tools to get the information you need, and if not, they can initiate the process of updating LDMS.

Specimen Management Reports

Cell Yield QA/QC Summary	This report provides the user with a summary of the Draw Dates and Times, Total Cell Counts, Technician initials, Total Volumes, Additive Types and the calculated cell yield for the Viable PBMC's that are logged into the lab's LDMS. The report also provides the data plotted in a graph for visual representation. This report would be useful to the user to provide assistance with the Quality Control and Assurance of the lab by providing the cell yield for specimens in

	comparison to other variables which can identify if further investigation may be needed.
Lab 263 Summary of Specimens	This report provides the user with a summary of the total volume for a given (Group/Primary/Additive/Derivative/Sub Add/Der/Volume Unit) This report would be useful to the user to identify how much of a particular type of specimen is available for a given group.
Lab 348 Specimen Report	This report provides the user with the primaries for the specimens in a given Group/ID1 and includes the condition code and an aliquot count as well. A user would find this useful to generate the specimens for a given group report in a more consolidated report.
Primary Specimens Received	This report provides the user with a list of all of the primaries that have been received by a given lab. The report also summarizes some of the primary details and includes a total primaries received count. The user would find this report useful when attempting to identify how many primaries that they have received into their LDMS.
Specimen Count Report	This report provides the user with a summary of the number of specimens that the lab has logged for a given Group/ID1. The summary also provides the user with the number of specimens that are stored for the given Group/ID1, as well as the number of aliquots that have been shipped for the given Group/ID1.
Specimen Log Report	This report provides the user with a list of all of the specimens that the Lab has logged into their LDMS. The report also provides the primary and associated aliquot information for a given specimen. The user would find this report useful when identifying the amount of specimens that have been logged into their LDMS with selected criteria.
Specimen Processing Report	This report provides the user with a specific set of information for each of their logged specimens. The report will provide the user with the patient, primary, and aliquot information for each of their specimens. The report also provides the user with the processing information (if available) for the given specimens, specifically the Total Cell Count, Processing Date(Primary and Aliquot), Processing Time(Primary and Aliquot), Processed By initials, Frozen Date, and Frozen Time.
Specimens for a Given Group	This report provides the user with specimen details, while grouping the given specimens by the affiliated group, then ID1 they were assigned when logged. The user would find this report useful when trying to identify what specimens they have logged for a given group/ID1.
Specimens for a Given Group 2	This report provides the user with the LDMS specimen ID's for a given Group/ID1 and includes an aliquot count. A user would find this useful to generate the specimens for a given group report in a more consolidated report.
Specimens Missing Group Assignments	This report provides the user with a list of all specimens that do not have a Group assigned to them.
Time to Freeze QA/QC Summary	This report provides the user with a summary of the Draw Dates and Times, Frozen Dates and Times, Specimen Types and the calculated amount of time it took from the time a specimen was drawn to the time the specimen began the freezing process. The report also provides the data plotted in a graph for visual representation. This report would be useful to the user to identify how quickly the specimen goes from unprocessed primary to the freezing process of the aliquots.
Time to Process QA/QC Summary	This report provides the user with a summary of the Draw Dates and Times, Process Dates and Times, Frozen Dates and Times, Specimen Types and the calculated amount of time it took from the time a specimen started to be processed to the time the specimen began the freezing process. The report also provides the data plotted in a graph for visual representation. This report would be useful to the user to identify how quickly the lab is completing processing to the freezing process.

Shipping Reports

Ambient Shipments Report	This report provides the user with a summary of all of the primaries that have been marked for ambient shipment. This report would be useful to the user in

	that it provides a summary of all of the sample that have touched the labs LDMS but was not necessarily processed, and provides information such as specimen information and intended destinations.
Daily Imported Specimen Log	This report provides the user with a summary of the samples that a lab has imported grouped by Group/ID1, and provides the user with information regarding some of the samples that were imported, when the specimens were imported, what lab the samples came from and sample condition. This report would be useful to the user in that it will provide a easy means of identifying which samples have been imported for a given protocol, as well as an idea of when they have been received.
Detailed Imported Specimen Report	This report provides the user with a detailed summary of all the shipments that the lab has imported. This report would be useful to the user since it provides relatively detailed information regarding shipments they have imported, including the specimens that were imported, when they were Imported, who originally shipped the batch and the batch number.
Imported Specimen Report - Summary	Similar to the Detailed Imported Specimen Report, this report provides the user with a summary of all the shipments that the lab has imported but in a more compact nature. This report would be useful to the user since it provides information regarding shipments they have imported, including when it was Imported, who originally shipped the batch, the batch number, and an aliquot count per specimen type.
Lab 263 Summary Detail of Shipped Specimens	This report provides the user with a summary of the total volume that has been shipped to a particular destination for a given (Group/Primary/Additive/Derivative/Sub Add/Der/Volume Unit) This report would be useful to the user to identify how much of a particular type of specimen has been shipped for a given group and to their destinations.
Pending Specimens Marked for Shipping Report	This report provides the user with a summary of all the samples that the lab has marked to ship in the specimen management module, but has yet to ship. This report would prove useful to labs when trying to organize their shipments, with the ability to identify specimens that they anticipate on shipping but have yet to do so.
Shipped Specimen Report - Detail	This report provides the user with a detailed summary of all the shipments that the lab has completed. This report would be useful to the user since it provides relatively detailed information regarding their shipments, including what specimens were shipped, when they were shipped, who they were shipped to and the batch number.
Shipped Specimen Report - Summary	Similar to the Detailed Shipped Specimen Report, this report provides the user with a summary of all the shipments that the lab has completed but in a much more compact nature. This report would be useful to the user since it provides information regarding shipments they have shipped, including when they were shipped, the destination, the batch number, and an aliquot count.
Shipping Lab Contact Report	This report provides the user with a detailed summary of all of the contact information for a given lab. This report would be useful to the user when looking for contact information for a receiving or shipping lab, as well as contacts for resolving queries for destination labs.

Storage Reports

Inactive Storage Configurations Still In Use	This report identifies what storage configurations are no longer active, but are still being used.
Shipped Samples in Storage	This report provides the user with a location listing of shipped specimens that are still occupying space in the lab's storage structure hierarchy.
Shipped Samples in Storage (Export)	This report provides the user with a location listing of shipped specimens that are still occupying space in the lab's storage structure hierarchy, in an exportable format.
Specimens in Storage per PID	This report provides the user with a count of all specimens that remain in storage a given Group/ID1. This report is useful for a user who may need to know how many total specimens are in storage for a given PID.

Specimens Not In Storage Report	This report provides a summary of all of the specimens that are currently logged into a lab's LDMS that have yet to be logged into a storage container in the storage module. This report would prove to be useful in that it would give the user an idea of what specimen still need to be stored in the storage module.
Specimens Remaining in Storage	This report provides a user with a count of the number of aliquots that are still in the storage module for a given Group/ID1/ID2 sorted by Group. This report is useful for a user that may want to determine how many samples remain in storage for a given PID and where they are stored, especially in cases where additional aliquots may need to be identified.
Storage Container Location	This report identifies what freezer, shelf, rack a box is on and what position the box is in. This will allow a lab to easily confirm boxes are in the correct location.
Storage Count Report By Freezer	This report provides a count of specimens that are contained within a given freezer. This report would be useful in that it provides the user with a summary of the samples for a given Group/ID1/Specimen Type that a particular Freezer currently holds.
Storage Detail	This report provides the user with a summary of all the specimens that are stored in a particular storage container in the Storage module. This report would be useful to the user in that it provides a detailed summary of the exact specimens and location of all the aliquots that are stored in a container held within a lab's storage structure hierarchy.

P24 Antigen Reports

P24 Results by Study	This report provides the user with a summary of the various P24 assay results that have been completed in the Results module. This report is grouped by Group/ID1.

RNA PCR Reports

Abbott Realtime HIV1 Assay Report	This report provides the user with a summary of all the assay results for the Abbott Realtime HIV1 Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
Abbott Realtime HIV1 Patient Report	This report provides the user with a detailed listing of the assay results for the Abbott Realtime HIV1 Assays for a given patient/run. The report provides the Runid's and various censors, calculated results and watermarks
Abbott Repeat and Censored Run/Samples	This report provides the user with a summary of all the censored and repeated runs for a particular PID. The report is grouped by Group/ID1. This report would be useful for a user that wants to identify if there are issues running samples for a given PID.
Amplicor Repeat and Censored Run/Samples	This report provides the user with a summary of all the censored and repeated run for a particular PID. The report is grouped by Group/ID1. This report would be useful for a user that wants to identify whether they are having issues running samples for a given PID.
Blank Qual Nuclisens Report	This report provides an relatively empty report designed specifically for the Qual Nuclisens assay. The report would be useful for the user since it provides a report that can be generated and printed for manual inputs for lab use.
Cobas Amplicor Assay Report	This report provides the user with a summary of all the assay results for the COBAS Amplicor Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
Cobas Amplicor Patient Report	This report provides the user with a detailed listing of the assay results for the COBAS Amplicor Assays for a given patient/run. The report provides the Runid's and various censors, calculated results and watermarks
Cobas Ultrasensitive Assay Report	This report provides the user with a summary of all the assay results for the COBAS UltraSensitive Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.

Cobas Ultrasensitive Patient Report	This report provides the user with a detailed listing of the assay results for the COBAS Ultrasensitive Assays for a given patient/run. The report provides the Runid's and various censors, calculated results and watermarks
HIV RNA Assay Control Data	This report provides the user with a summary of all of the control data for a given run. The report is grouped by assay type and provides a multitude of different pieces of control data for the associated Runid.
RNA Nuclisens Report	This report provides the user with a summary of all the assay results for the RNA Nuclisens Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
RNA Organon Teknika NASBA Report	This report provides the user with a summary of all the assay results for the RNA Organaon Teknika Nasba Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
RNA Roche Amplicor Line Listing	This report provides the user with a summary of all of the results for a given PID. The report is grouped by PID/ID1 and also includes some run information, results, and censors. This report would be useful for a user that wants to identify all of the results that they currently have for a particular PID.
RNA Roche Amplicor Patient Report	This report provides the user with a detailed listing of the assay results for the RNA Roche Amplicor Assays for a given patient/run. The report provides the Runid's and various censors, calculated results and watermarks.
RNA Roche Amplicor Report	This report provides the user with a summary of all the assay results for the RNA Roche Amplicor Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
RNA Roche Ultra Lin Listing	This report provides the user with a summary of all of the results for a given PID. The report is grouped by PID/ID1 and also includes some run information, results, and censors. This report would be useful for a user that wants to identify all of the results that they currently have for a particular PID.
RNA Roche UltraSensitive Patient Report	This report provides the user with a detailed listing of the assay results for the RNA Roche Amplicor Assays for a given patient/run. The report provides the Runid's and various censors, calculated results and watermarks.
RNA Roche UltraSensitive Report	This report provides the user with a summary of all the assay results for the RNA Roche UltraSensitive Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
RNA Runs Not Reviewed	This report provides the user with a list of all the different assay runs that have been resulted but have yet to have been marked to review. This report would be useful for a user to identify which RNA assays still need to be reviewed.
Roche Amplicor Tech Audit Report	This report provides the user with a list of all the assay runs for the Roche Amplicor assays, specifically to list the multiple Technician initials associated with the Run. This report would be useful to the user to identify which technicians were associated with a particular run and/or to list all the runs for a specified technician.
Roche Ultrasensitive Tech Audit Report	This report provides the user with a list of all the assay runs for the Roche Ultrasensitive assays, specifically to list the multiple Technician initials associated with the Run. This report would be useful to the user to identify which technicians were associated with a particular run and/or to list all the runs for a specified technician.
Taqman HCV Repeat and Censored Run/Samples	This report provides the user with a summary of all the censored and repeated runs for a particular PID. The report is grouped by Group/ID1. This report would be useful for a user that wants to identify if there are issues running samples for a given PID.
TaqMan Realtime HCV Assay Report	This report provides the user with a summary of all the assay results for the TaqMan Realtime HCV Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
TaqMan Realtime HCV Patient Report	This report provides the user with a detailed listing of the assay results for the TaqMan Realtime HCV Assays for a given patient/run. The report provides the Runid's and various censors, calculated results and watermarks

TaqMan Realtime HIV1 Assay Report	This report provides the user with a summary of all the assay results for the TaqMan Realtime HIV1 Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
TaqMan Realtime HIV1 Patient Report	This report provides the user with a detailed listing of the assay results for the TaqMan Realtime HIV1 Assays for a given patient/run. The report provides the Runid's and various censors, calculated results and watermarks
Taqman Repeat and Censored Run/ Samples	This report provides the user with a summary of all the censored and repeated runs for a particular PID. The report is grouped by Group/ID1. This report would be useful for a user that wants to identify if there are issues running samples for a given PID.
UltraSensitive Repeat and Censored Run/Samples	This report provides the user with a summary of all the censored and repeated run for a particular PID. The report is grouped by Group/ID1. This report would be useful for a user that wants to identify whether they are having issues running samples for a given PID.

RNA Reports

DNA 1.5 Patient Report	This report provides the user with a detailed listing of the assay results for the DNA PCR 1.5 Assays for a given patient/run. The report provides the Runid's and various censors, results and watermarks
DNA 1.5 Tech Audit Report	This report provides the user with a list of all the assay runs technician initials for the DNA PCR 1.5 assays, specifically to list the multiple Technician initials associated with the Run. This report would be useful to the user to identify which technicians were associated with a particular run and/or to list all the runs for a specified technician.
DNA Patient Report	This report provides the user with a detailed listing of the assay results for the DNA PCR 1.0 Assays for a given patient/run. The report provides the Runid's and various censors, results and watermarks
HIV DNA PCR 1.5 Report	This report provides the user with a summary of all the assay results for the HIV DNA PCR 1.5 Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
HIV DNA PCR Report	This report provides the user with a summary of all the assay results for the HIV DNA PCR 1.0 Assays. The report is grouped by Group/ID1 and also provides the Runid's and various censors.
Unused Pellet Report	This report provides the user with a list of all of the remaining pellets that have not been used on a given DNA PCR run. This report would be useful to the user to track how many remaining control pellets that they have remaining.

Culture Reports

Culture Results by Protocol	This report provides the user with a list of all the results for a given culture. The report then groups these results by Protocol.
Culture Schedule Report	This report provides the user with the various feed and harvest schedules and groups them based on the type of culture it is defined by. This report would be useful to identify which harvest feed schedules are available and whether a new schedule is required.

MT-2 Results Reports

MT-2 Results Report	This report provides the user with a summary of the MT-2 assay results that have been completed in the Results tab. This report is grouped by Group/ID1.

Patient Summary Reports

Patient Identifiers	This report provides the user with a summary of all the PIDs that have been "enrolled" into the lab's database. This report is useful since it provides the user with the ID2s, ID3s and clinics that have been logged into the lab's database (grouped by ID1)

Miscellaneous Reports

Clinic Contact Report	This report provides the user with detailed contact information for all/selected clinics. This report would be useful for the user to print or reference when trying to identify the clinic that a logged sample may have come from.
LDMS Abbreviated Codes	This report provides the user with a complete list of all of the descriptions of the various abbreviated values used within the LDMS, such as but not limited to Measurement Units and Visit Units. This report would be useful for the user to print or reference when trying to identify the abbreviated codes for the specimens that need to be logged
LDMS Assay Censor Codes	This report provides the user with a complete list of all of the censor codes and their descriptions used within the LDMS. This report would be useful for the user to print or reference when trying to identify the censors for the assays that the lab uses.
LDMS Prim, Add, Der and Sub Add/Der Codes	This report provides the user with a complete list of all of the coded values and descriptions for the primaries, additives, derivatives, and sub additives/derivatives used within the LDMS. This report would be useful for the user to print or reference when trying to identify the code values for the specimens that need to be logged
Recommended Test Add/Der	This report provides the user with the recommended additives and/or derivatives used when assigning a test to an aliquot. This report would be useful for the user to print or reference when trying to identify which codes are recommended for a given assay.
Virology and Immunology Assay Count, By Protocol	This report provides the user with a complete count of how many assays have been run per Group/ID2 for the Virology and Immunology assays used within the LDMS. This report would be useful for the user to print or reference when trying to identify the censors for the assays that the lab uses.

Admin Reports

User Permissions	This report provides the user with a summary of all the users in the LDMS and lists their current permissions within the LDMS. This report would be useful to print or reference when trying to track a particular user's permissions.

Exports Reports

Export Status Report	This report provides the user with a summary of all of the export transactions that have occurred at the lab. The report provides information such as export number and its current status. This report would be useful for tracking the exports for the lab.

PK (Pharmacology) Reports

Pharmacology Drug Count	This report provides the user with a count of how many results are available for a given analyte. The report is then grouped by Group/ID2. This report would be useful for the user in determining how many results they have for a given assay to summarize or predict workload.
Pharmacology Drug List	This report provides the user with a list of all of the available drug codes currently in the LDMS and provides the description of what the drug code stands for. This report would be useful to print or reference when trying to identify the drugs currently available in the LDMS.
Pharmacology Proficiency Results	This report provides the user with a printable report to summarize the proficiency panel data for a given CPQA PK round. The lab is generally required to print out and sign off on this report for CPQA record keeping purposes.
PK Drug Limits By Run	This report provides the user with a list of all the PK assay runs that have been completed in the LDMS, as well as the Limits and Units that were entered for each run. This report would be useful for the user to reference what Limits have been used in the past.

PK Summary Report	This report provides the user with a summary of all the assay results for the PK Assays. The report is grouped by Group/ID1 and provides the Runid's, Analytes, and various censors.
PK Summary with Assay Name	This report is identical to the PK Summary Report, but with the addition of the assay name to the report.

Immunology Reports

Advanced Flow Check Report	This report provides the user with a summary of the results for any completed Advanced Flow Assay. The report is broken down on a specimen basis for the user to review.
Advanced Flow Codes	This report provides the user with a printable report that lists the various codes that would be used with the Advanced Flow assay in the LDMS. These codes include Anchor Gates, Color Codes, and Subset Marker Codes.
Advanced Flow Count By Protocol	This report provides the user with a simple count of how many Advanced flow assays have been completed for a given Group/ID2. This report would be helpful to the user to track work flow within the lab.
Advanced Flow Hardcoding Report	This report provides the user with a summary of the various anchors, markers, and colors that are associated with a given protocol/ID2. These fields were predetermined by the study and what was expected for the study.
Advanced Flow/Tunel Summary Report	This report provides the user with a summary of which samples have Advanced Flow or TUNEL results completed. It also provides if results were obtained as well as the test that was completed on the sample. These results are grouped by Group/ID2.
Apoptosis by P.I. Summary Report	This report provides the user with a summary of which samples have Apoptosis by P.I. results completed. These results are grouped by Group/ID2.
Blank Advanced Flow Patient Report	This report provides the user with a blank sheet that can be printed out that has all the necessary fields for a given study with the appropriate hardcoded fields already completed. The user can print this out and complete for each patient on the given study.
IQA Cryopreservation Summary Report	This report provides the user with a summary of which samples have IQA Cryopreservation Assay results completed as well as a viral load. These results are grouped by Group/ID2.
LPA Check Report	This report provides the user with a summary of the results for any completed LPA Assay. The report is broken down on a specimen basis for the user to review.
LPA Count By Protocol	This report provides the user with a simple count of how many LPA assays have been completed for a given Group/ID2. This report would be helpful to the user to track work flow within the lab.
LPA Stimulant Codes	This report provides the user with a printable report that lists the LPA Stimulant codes and descriptions that would be used with the LPA assay in the LDMS.
LPA Summary Report	This report provides the user with a summary of which samples have LPA Assay results completed. These results are grouped by Group/ID2.
NK Summary Report	This report provides the user with a summary of which samples have NK Assay results completed. These results are grouped by Group/ID2.

ZEBES Reports

Commented Specimens Report	This report provides a user with a line listing of specimens that have a comment assigned to them. It provides fields such as PID, Additive, Specimen ID, Specimen Date, Derivative, Global Specimen ID, Primary, Sub Add/Der, Comments, Non ACTG PID/ID1, and Derivative. This report is designed to not include headers or specific formatting for ease of export.
ZEBS Amplicor Report	This report provides a user with a line listing of Primaries that have a completed Roche Amplicor run for a ZEBS specimen and includes information such as

	Patid, VID/Unit, Viral Load, Censors, Specimen Date, and Derivative. This report is designed to not include headers or specific formatting for ease of export.
ZEBS Report	This report provides a user with a line listing of Primaries that include information such as Patid, Specimen Date, Condition, VID, and Primary. This report is designed to not include headers or specific formatting for ease of export.
ZEBS UltraReport	This report provides a user with a line listing of Primaries that have a completed Roche Ultrasensitive Assay run for a ZEBS specimen and includes information such as Patid, VID/Unit, Viral Load, Censors, Specimen Date, and Derivative. This report is designed to not include headers or specific formatting for ease of export.

Exportable Reports

A5184 Bayer bDNA HCV RNA Report	Lab 54 was performing three Assays for Protocol A5184 which are not supported in the LDMS. To make data entry easier for this lab when submitting the data by Excel to the DMC, three templates for this data were added to the LDMS. The lab could generate the Report with the specimen info (Protocol, PID, Specimen Date, Specimen ID and Visit) loaded onto the template based on the search criteria selected. The lab can export the report(s) into Excel and manually complete the remaining data portion of the template.
A5184 Bayer TMA HCV RNA Report	Lab 54 was performing three Assays for Protocol A5184 which are not supported in the LDMS. To make data entry easier for this lab when submitting the data by Excel to the DMC, three templates for this data were added to the LDMS. The lab could generate the Report with the specimen info (Protocol, PID, Specimen Date, Specimen ID and Visit) loaded onto the template based on the search criteria selected. The lab can export the report(s) into Excel and manually complete the remaining data portion of the template.
A5184 HCV Genotyping Report	Lab 54 was performing three Assays for Protocol A5184 which are not supported in the LDMS. To make data entry easier for this lab when submitting the data by Excel to the DMC, three templates for this data were added to the LDMS. The lab could generate the Report with the specimen info (Protocol, PID, Specimen Date, Specimen ID and Visit) loaded onto the template based on the search criteria selected. The lab can export the report(s) into Excel and manually complete the remaining data portion of the template.
Aliquot Count by Primary	This report was designed to provide the user with a list of the Primaries in the LDMS and provide them with a the number of aliquots associated with the given Primary. This report summarizes the inventory within the local database.
CFAR Export Report	This report provides the user with a list of specimens that are stored within the local LDMS and provides information regarding the specimens.
CFAR Storage Report	This report was designed based upon a request by lab 15 for a new storage report that would allow them to send their CFAR specimen information to their data manager at the CFAR Repository. This report is export friendly. The report provides a summary of the storage locations for specimens in the local lab's LDMS.
Database Dump Report	This report provides the user with a complete listing of all of the specimen information held within a local lab's database. This report would be useful to a user if they need to track a complete summary of their database.
Exportable Abbott Assay Report	Similar the RNA Abbott Assay report, this report was designed to be an exportable RNA Assay Result Report with the following fields: PID, Visit Value and Visit Unit, Primary, Specimen ID, Global ID, Specimen Date, Received Date, Import Date, Assay Date, RunID, Result, System Censor, User Censor, Run System Censor, and Run User Censor.
Exportable Roche Amplicor Report	Similar to the RNA Abbott Assay report, this report was designed to be an exportable RNA Assay Result Report with the following fields: PID, Visit value and Visit Unit, Primary, Specimen ID, Global ID, Specimen Date, Received Date, Import Date, Assay Date, RunID, Result, System Censor, User Censor, Run System Censor, and Run User Censor.
Exportable Roche Ultra Report	Similar to the RNA Abbott Assay report, this report was designed to be an exportable RNA Assay Result Report with the following fields: PID, Visit val-

	ue and Visit Unit, Primary, Specimen ID, Global ID, Specimen Date, Received Date, Import Date, Assay Date, RunID, Result, System Censor, User Censor, Run System Censor, and Run User Censor.
Lab 081 Billing report	This report was designed to provide lab 81 with an exportable report that they use for billing purposes. The following were the requested fields: Group/Protocol, PID/ID1, Specimen Date, Derivative, and Global Spec ID.
Lab 081 CNICS by Date	This report was designed to provide lab 81 with an exportable report that they use for billing purposes, the following were the requested fields: Group, Non ACTG Protocol/ID2, Spec Date, Received Date, Primary, Volume and Volume Units.
Lab 081 CNICS General	This report was designed to provide lab 81 with an exportable report that they use for billing purposes. The following were the requested fields: Non ACTG Protocol/ID2, PID/ID1, Specimen Date and Time, Received Date, Additive, Derivative, Sub Add/Der, Volume and Volume Units.
Lab 188 Storage	This report provides a summary of the samples that are available in the local LDMS database, as well as provide a summary of what has been stored. The report is sorted by Global Specimen ID and displays “Not Stored” if samples have yet to be placed in the virtual storage structure. This report would be helpful for a user in tracking of what has been stored and what still needs to be stored in their LDMS.
Lab 194 Billing Report	This report provides an exportable friendly repot of a summary of all the specimens within the local LDMS. The report provides the PID/ID1, Specimen ID, Global Spec ID, other Spec ID, PRI,ADD, DER, Specimen Date, Specimen Time, VID, VID Unit, Volume, and Volume Units.
Lab 40 LabKey Report	This report is designed to allow the lab to dump data into a specified format that can be read/imported into their LabKey program for some of their internal projects. The report provides basic specimen information including processing information, storage data, and shipping information.
Lab 48 Billing Report	This report was designed to provide the following requested fields: Specimen ID, group/protocol, PID/ID1, Visit/Visit Unit, Specimen Date, and Additive.
Lab 485 Aliquot Report	This report was designed to mimic the Specimen Export Report but to sort the results in the following order- Group, Non ACTG Protocol, Non ACTG PID, Visit Value, Primary, Additive, Derivative.
Lab 485 Specimen Count	This report provides a count for unique Primary/Additive/Derivative/Sub-Derivative combinations that can be ordered by: Group/Protocol/PTID/Visit combinations. The report is then grouped by Group/ID2.
Lab 485 Specimen Count With Volume	Similar to the Lab 485 Specimen Count report, this report was designed to provide a count for unique Primary/Additive/Derivative/Sub-Derivative combinations that can be ordered by: Group/Protocol/PTID/Visit combinations. The report is then grouped by Group/ID2.
Primary Specimen Database	This report provides the user with a list of the Primary LDMS Specimen Numbers and the associated Draw Date and Received Dates.
Quest Import Manifest Report	This report provides a summary of the batches that have been received via the LDMS Shipping file. The report will not list batches that have been received via text file.
Sample Counts for Specified Group	This report is designed to allow the lab to view the number of samples that are available of a given specimen type. The report is grouped by the samples Group. This would be helpful to a user to view a summary of available samples for a given group based on their sample type.
SCHARP GSC Assay Results	This report was designed to be used for reporting assay results to SCHARP. The first group of fields on the report contains basic specimen information that will be populated by LDMS. This is followed by a second group of fields that LDMS will leave blank and will be filled in by the lab (these are the assay result fields).
SCHARP GSS Assay Results	This report was designed to be used for reporting assay results to SCHARP. The first group of fields on the report contains basic specimen information that will

	be populated by LDMS. This is followed by a second group of fields that LDMS will leave blank and will be filled in by the lab (these are the assay result fields).
SCHARP Manifest Assay Results Tool	This report was designed to provide the labs with an exportable report, that they will be able to generate and send to SCHARP, which will have the data used for upload into SCHARP's assay result tool.
SCHARP VGC Assay Results	This report was designed to be used for reporting assay results to SCHARP. The first group of fields on the report contains basic specimen information that will be populated by LDMS. This is followed by a second group of fields that LDMS will leave blank and will be filled in by the lab (these are the assay result fields).
Specimen Export	This report was designed for when a user has logged in non-government group specimens into the Specimen Management module and has shipped these specimens via the shipping module.
Storage Export Report	Similar to the CFAR Export report, this report provides the user with a list of specimens that are stored within the local LDMS and provides information regarding the specimens. The major difference is that this report contains headers and displays the complete storage location.
Westat DNA 1.5 Export Report	Similar to the Westat DNA Export Report, this report is designed to mimic a DNA 1.5 Assay results by protocol report that was not useful for the folks at Westat, therefore, this report was created to provide similar DNA 1.5 Assay result data in a new format.
Westat DNA Export Report	This report is designed to mimic a DNA Results by Protocol Report that was not useful for the folks at Westat, therefore, this report was created to provide similar DNA result data in a new format.
Westat Nuclisens Export Report	Similar to the Westat DNA Export Report, this report is designed to mimic a Nuclisens Assay results by protocol report that was not useful for the folks at Westat, therefore, this report was created to provide similar Nuclisens Assay result data in a new format.
Westat PK Export Report	Similar to the Westat DNA Export Report, this report is designed to mimic a PK Assay results by protocol report that was not useful for the folks at Westat, therefore, this report was created to provide similar PK Assay result data in a new format.
Westat Roche Amplicor Export Report	Similar to the Westat DNA Export Report, this report is designed to mimic a Roche Amplicor Assay Results by Protocol Report that was not useful for the folks at Westat, therefore, this report was created to provide similar Roche Amplicor Assay result data in a new format.
Westat Roche Ultra Export Report	Similar to the Westat DNA Export Report, this report is designed to mimic a Roche Ultrasensitive Assay results by protocol report that was not useful for the folks at Westat, therefore, this report was created to provide similar Roche Ultrasensitive Assay result data in a new format.
WIHS Nuclisens Control	This report provides the user with a summary of the controls that are currently available for the Nuclisens Assay.
WIHS Nuclisens Specimen	This report provides the user with a summary of Nuclisens Assay results for WIHS samples that were completed in the lab's database.
WIHS Taqman RNA Specimen Export	This report was designed to be similar to the current WIHS Nuclisens RNA Specimens Export File Report in the Reports Module, but with information from the Taqman assay. The report contains a summary of the specimen and run information.
WITS Storage Detail Report	Similar to the Storage Export Report, this report provides the user with a list of specimens that are stored within the local LDMS and provides information regarding the specimens. The major difference is that this report contains Global Specimen ID's as opposed to LDMS Specimen ID's.

RPID Reports

Discrepancy Report	This report provides the linking of a Specimen ID and Other Specimen ID for a sample before importing through the RPID program and the corresponding

	Specimen ID and other Specimen ID after the sample has been moved through the RPID program. This report is only available for lab 223.
Lab 223 - LDMS to Oracle Mapping	This report provides the linking of the different Other Specimen ID's in the LDMS to their associated RPID based on local LDMS and lab 223's separate Oracle database.
Lab 223 Oracle to LDMS Mapping	This report provides the linking of the different codes that are held within lab 223's separate Oracle database to the associated fields in the LDMS. This provides the user with a sample and code from their separate Oracle database, and compares it to the currently linked Other Spec ID, and the associated RPID value.
Lab 223 RPID Oracle Merge Report	This report is designed strictly for lab 223 with the use of their local oracle database that is used to track details about the DNA extraction for the RPID samples. The data within this database is loaded into a temp table and merged with the specimens in the LDMS via the Other Specimen ID field and the sample number held within the oracle table.
Random PID Report	This report provides the user with the linking between the actual PID and the RPID for a particular specimen. This report would be useful for a user to have a summary of the confidential linking in one place.
RPID Specimen Request	This report provides lab 223 with a mapping of specimens from a submitted specimen request that would be dropped down to the labs tableset and provides the location of the specimens after the RPID program randomizes the information within the request.
Specimens for a given Other Spec ID	This report provides a list of Other Specimen ID's and their linking to their associated received Specimens. The report also provides the specimen type, as well as the receiving information.
Specimens Not Arrived	This report provides lab 223 with a list of specimens that were expected to be sent to lab 223 (based on a table request that is dropped to their lab) but have yet to arrive at the lab.

WIHS Reports

Processing Log - Lab 263	This report provides the user with a list of samples that fit a predefined criteria set by lab 263. When a certain subset of Specimen Type and Other Specimen ID entries are completed, the specimen appears on this report and provides the processing instructions based upon the Other Specimen ID code.
Viral Load Results	This report provides the user with a list of the different RNA assay runs that the lab has preformed, including specific details regarding the run (Test type, Control Information, Samples (including PID, Specimen/Received Dates, Specimen Type) as well as the results.
WIHS Batch Report	This report provides the user with details regarding assay results that have been completed for a given lab on. It provides summary information about the specimen as well as summary information about the run itself.
WIHS Visit Report	This report provides the user with a list of the different RNA assay runs that the lab has preformed, including specific details regarding the run (Test type, Control Information, Samples (including PID, Date, Specimen Type and Visit) as well as the results.

VTN Reports

Guspec and Storage Location Report	This report provides the user with a simple linking of all the specimens that are currently in a local lab's storage structure. The report provides the user with the Global Specimen ID and its corresponding Storage location.
SCHARP Export Report	This report provides the user with a summary of all of the specimens in a local LDMS. The user can export this report and provide a data management center, such as SCHARP, with a summary of specimens in the local LDMS with specific fields that make it somewhat different than a specimen log report.

ATN Reports

ATN Repository Report	This report provides the user with a summary of all the ATN assigned samples that have been imported into the local lab's LDMS. This report would be useful to a user to track the inventory of imported ATN samples.

Preload Reports

Preload List	This report provides the user with a list of all of the available preloads that are present in the local LDMS, including FSTRF-defined preloads. The report also summarizes all of the details of the preload, including criteria and output.

Anon[ymization] Reports

Anonymous Patient Map	This report shows the relationship between identifying information in an original specimen and anonymized specimens. The fields that are displayed are the ones relevant to anonymization, such as the original and new *PID*, and the original and new *global specimen ID*.

IQA Reports

IQA Sending Lab Reports	This report provides the IQA lab with a summary of the various cryopreservation fields imported from the processing labs. This report is searchable by Processing Lab or Thaw Date.
Percent Viability-Summary	This report provides the IQA lab with a summary of the Percent Viability at the IQA after the samples had been thawed for a given month. This report would be useful for the user to provide a summary of a labs performance in the IQA in a given timeframe for Percent Viability.
Percent Viable Recovery-Summary	This report provides the IQA lab with a summary of the Percent Viable Recovery at the IQA after the samples had been thawed for a given month. This report would be useful for the user to provide a summary of a lab's performance in the IQA in a give timeframe for Viable Recovery.

Chapter 8. Labels and Printer Configuration

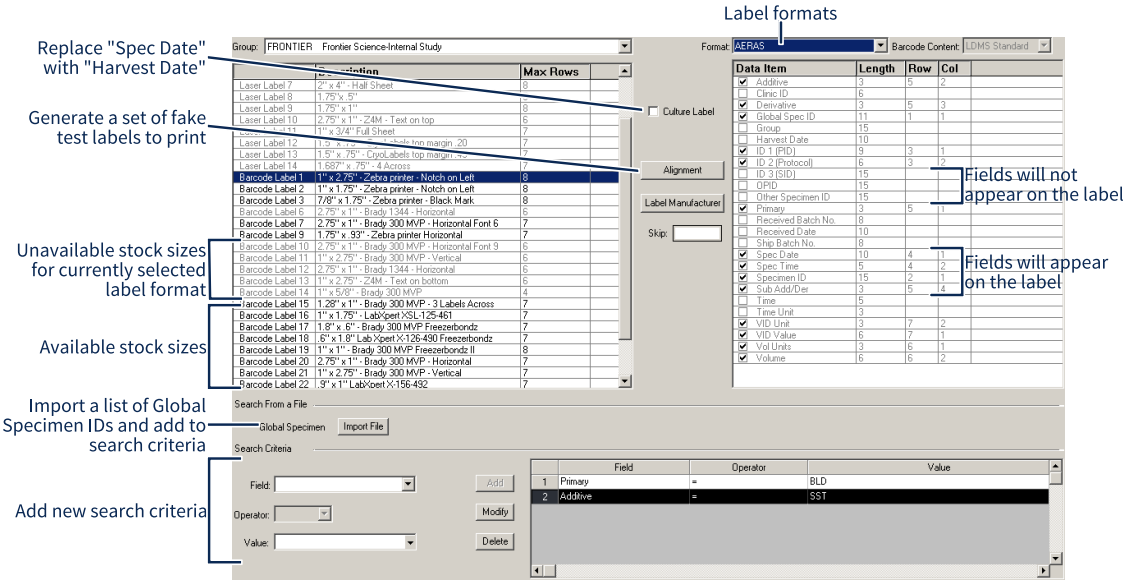
Advanced Label Printing

When you add or modify aliquots in the Specimen Management task, you will automatically be prompted to print labels. You can reprint labels in Specimen Management by right-clicking on an aliquot and selecting `Print Labels for Selected Aliquots`.

In Specimen Management, you can only generate labels for aliquots that are part of the same record. In contrast, the Labels task allows you to search for specimens instead, allowing you to generate multiple labels at once.

Access the Labels task by clicking the button from the LDMS toolbar.

Figure 8.1. LDMS Labels screen



▲ The labels format screen

Procedure 8.1. Printing labels

1. Select a **Group** from the drop-down list in the top-left of the screen.
2. Select the label **Format** from the drop-down list the top-right.
3. Select the label stock (i.e. paper) from the list beneath the **Group** list. (Stock that is disabled has too few rows for the label **Format** selected).
4. (Optional) If you have a list of *global specimen IDs*, click the Import File button. The file must be a list of Global Specimen IDs, where each line contains exactly one ID.
5. Select a field from the **Field** drop-down list.

Note

At least one of the following fields must be part of your search:

- Specimen ID
- Global Specimen ID
- Received Date
- Harvest Date (cultures only)
- Received Batch Number
- Ship Batch Number

6. Select an **Operator** for the search term.
7. Select a value to search for in the **Value** field.
8. Click the Add button. This will add your criteria to the list on the left.
9. Once you've added all the criteria you want to add, click the button from the LDMS toolbar.

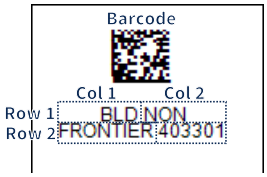
Tip

Were you printing labels and something went wrong? Rather than re-printing all of the labels, you can start in the middle to avoid re-printing labels that you already printed. Enter the number of labels that you don't want to print from the beginning of the labels into the **Skip** field. These labels won't be added to the labels generated.

Creating a New Label Format

Labels in LDMS are setup like tables. A label consists of an optional barcode, and rows and columns of fields. Everything on the barcode is center aligned. For each field, you need to select the row that it will appear in and the column (or position) in that row. You are limited to four fields per row.

Figure 8.2. Parts of a label

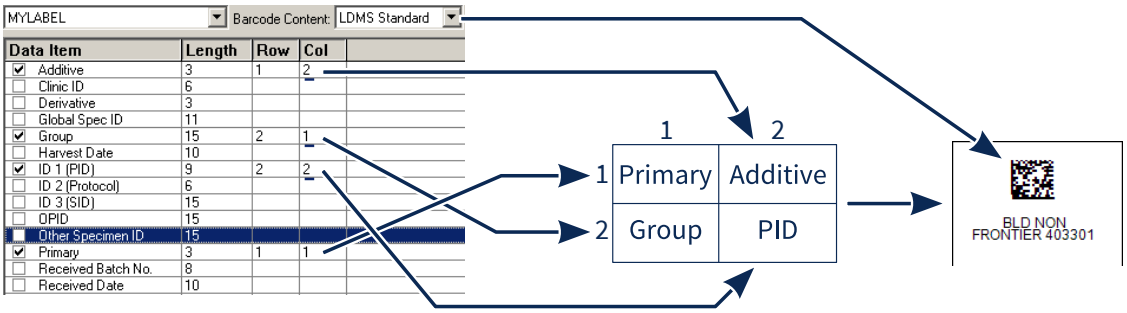


▲ A typical label, showing how each field corresponds to a row and column. If a barcode is selected, it will always appear first. Every row is center aligned, so columns may not necessarily be aligned.

Procedure 8.2. Creating a new label format

1. Select `TasksLabels` from the LDMS menu bar or click the button from the LDMS toolbar.
2. Select a group from the **Group** list.
3. (Optional) If you want to base your new label on an existing label, select an existing format from the **Format** menu, otherwise leave the **Format** field blank.
4. Click the button from the LDMS toolbar. You'll be prompted if you want to create a new label based on the label selected in the **Format** field (if no format was selected, LDMS will tell you that you are basing your label on ""). Select **Yes** or **No** as appropriate.
5. Enter the name for your label as you want it to appear in LDMS Specimen Management into the text box.

Figure 8.3. Label format settings and label output



▲ The label formatting settings used to achieve an output label.

This will create a new entry in the **Format** menu for the selected group. Your new label format will be blank though, so you need to configure it. This is done on the right side of the screen. To add a field, select the check box next to it, and then enter the **row** and **col[umn]** where the field should appear. To see how the selection of fields corresponds to an actual label, see Figure 8.3.

Format options

Barcode Content	The barcode for the label; this always appears at the top of the label, if selected.
Col	Enter the position in the row where the item should appear (e.g. 1 for first, 2 for second, etc).
Data Item	Name of the field from LDMS to display; click the check box next to a field to display it.
Length	The length of a field (in characters). This is how much space the field needs to appear on the label.
Row	Enter the row on the label where you want the field to appear.

You can see a preview of how your labels will look on a given stock to make sure that there will be no issues when you print actual labels. To do this, select your label format, then select a label stock on the left side of the screen. Next click the Alignment button. This will generated labels without real data so that you can test your printer with the new label format.

Note

The available label stock on the left will automatically reflect the label selected. Each stock is only capable of displaying so many rows (as shown in the **Max Rows** column). To learn more about a stock, select it and click the Label Manufacturer button.

Alignment options

Number of sample label rows	Number of labels of display.
Preview	Display the labels; this is the same thing you will see in LDMS Specimen Management when you actually generate the labels.
Show All Positions	This will show used rows as X and unused (but available) space as O.
Show Field Names	Display the name of each field; the extra text may cause readability issues (field names will never appear on actual labels though).

Once you've finished configuring your label's format, click the button from the LDMS toolbar.

Setting the Default Label Size and Format

When you add or modify specimens in LDMS Specimen Management, you will be prompted to print new labels for the specimens. You can change the default label size and format selected for different groups, to avoid needing to select this information every time. You'll still be given the opportunity before creating the labels, however, to override the default settings.

Procedure 8.3. Setting the default label size and format for a group

1. Click `AdministrationLabel Setup` from the LDMS menu bar.
2. Select the group for which you want to define the default label settings from the **Group** drop-down list.
3. Select the desired label format for new specimen labels for this group from the **Label Format** drop-down list.
4. Select the desired label stock size from the **Label Size** list.
5. Click the **OK** button.

This can be done for multiple groups, meaning the default setting for one group can be different than another. If you are printing labels for specimens from different groups (such as co-enrollments), you'll be prompted to print labels for each group separately with the appropriate default label settings selected.

Barcodes

LDMS supports different 2D barcode formats on labels. The barcode (if present) always appears first on the label, and contains the *global specimen ID*.

Barcode readers can be used in many different places in LDMS to scan a barcode and quickly do something with a specimen:

Barcode functions in LDMS

Assays	Scanning on the **Assay Selection** tab will add the specimen to the Specimens Found list.
Shipping	Scanning on the **Setup Shipment** tab will add the specimen to a shipping batch; scanning on the **QA/QC** tab will mark that specimen as `PASSED` of `FAILED`, depending on whether or not the *global specimen ID* matches.
Specimen Management	Scanning a barcode in LDMS Specimen Management will jump to the records associated with that *Global Specimen ID*.
Storage	Scanning on the **Bulk Add** tab will select the specimen for storage; scanning on the **Main View** tab will bring up that specimen's storage location.

To set the default barcode reader for LDMS, go to `AdministrationSystem Configuration` and change to the **Configuration** tab. Look for the **Barcode Reader** option. For most hardware, the **Code Reader** option should suffice.

Tip

Here are a few tips for using barcode readers with LDMS:

- Hold the scanner four to six inches away from the barcode
- Don't scan at a 90 degree angle
- If a barcode doesn't scan, let go of the trigger before trying to read it again
- Verify that a barcode scans before storing or shipping the specimen

If you need assistance getting a barcode reader to work, contact LDMS User Support. See the section called “Getting Help” on page 10.

Setting the Printer Used to Generate Labels and Reports

When LDMS generates reports or labels, it uses the driver for your printer to determine paper size and orientation. LDMS needs to know what printer you are using *before* generating any labels. *If this crucial step is not performed, labels will not be sized correctly for your label printer, even if you select the correct printer to actually print them*.

Important

If you want to modify the paper size or orientation for your printer, this *must* be done in your Microsoft Windows® printer settings. If you need assistance setting up printing hardware, contact LDMS User Support for assistance.

Procedure 8.4. Configuring the printer used to generate labels and reports

1. Select `AdministrationPrinter Configuration` from the LDMS menu bar.
2. From the **Report Printer** list on the left, select the printer's driver that should be used to generate reports.
3. From the **Label Printer** list on the right, select the printer's driver that should be used to generate labels.
4. Click the **OK** button.

Printing Test Labels

It is possible to print a set of test labels so that you can see how a specific label will appear when printed with your hardware. This can be done using fake information that takes up the maximum amount of space, allowing you to see if there are any places on your label where the text may not fit correctly.

Procedure 8.5. Printing test labels

1. Open the labels task by clicking the button from the LDMS toolbar.
2. Select a group from the **Group** list in the upper-left corner.
3. Select a label format from the **Format** box on the right.
4. Select a label size from the list of label stock on the left.
5. Click the Alignment button.

The **Create Alignment Report** window will open. The following options can be set:

Number of sample label rows	This is the number of rows test specimen labels to generate per page.
Preview	Whether or not to generate a preview. **Important** Do not deselect this option. This option must be enabled or the test labels will not be generated.
Show field names	The name of each item on the label will appear next to it. **Warning** This can affect the appearance of the labels, and should not be used as a representation of what the labels will actually look like.
Show all positions	Each row will show the amount of space used by the current label format and the amount available space, based on the label stock size. The `X` on the label means that information could be printed there, while `O` means that it is free space. For example, if a row has two items and each has a length of 8, then the row will have 26 `X` show, and the rest of the row will show `O`. This will help you see if your labels have extra spaced based on the size you are using.

6. (Optional) When the SAP Crystal Reports Viewer opens, click the **Print** button from the toolbar to print the test labels.

Setting up Specific Printers

Setting up the Brady BBP33 Printer

1. Install the driver for the printer.

   For assistance obtaining and installing the driver, contact your laboratory's IT support staff or Brady customer support [http://www.bradyid.com].
2. Open the printer settings from the Windows Start menu.

   These are typically found in `StartDevices and Printers`.
3. Right click on the BBP33 and select `Printing preferences`.
4. Click the **Advanced** button.
5. Click the **Properties** button next to **Paper Size**.
6. Select the paper size you are using from the **Paper Size** box.

   For example, if using the label stock B33-179-492, you would select `B33-179` from the **Paper Size** box.
7. Set the printer as your label printer in LDMS. For instructions on doing this, see the section called “Setting the Printer Used to Generate Labels and Reports” on page 153.
8. Print a set of test labels using the Labels task in LDMS.

For instructions on printing test labels, see the section called “Printing Test Labels” on page 153.

The Brady BBP33 is known to work with the following

label stock	B33-179-492 (1"x1")
LDMS label	Barcodelabel19

Setting up the Brady IP300 Printer

1. Install the driver for the printer.

   For assistance obtaining and installing the driver, contact your laboratory's IT support staff or Brady customer support [http://www.bradyid.com].
2. Contact LDMS User Support to obtain a specific update to Crystal Reports. This update is required to use the IP300 with LDMS.
3. On the control panel on the front of the printer, change the printer head to `+10mm` for the X axis and `-3.0mm` for the Y axis.

   Note

   These printer head adjustments have been tested with the label stock THT-183-461. Other label stocks may require different printer head adjustments settings.
4. Open the printer settings from the Windows Start menu.

   There are typically found in `StartDevices and Printers`.
5. Right click on the IP300 and select `Printing preferences`.
6. Click the **Advanced** button.
7. Click the **Properties** button next to **Paper Size**.
8. Select the paper size you are using from the **Paper Size** box.

   For example, if using the label stock THT-183-461-1, you would select `THT-183-461` from the **Paper Size** box.
9. Set the printer as your label printer in LDMS. For instructions on doing this, see the section called “Setting the Printer Used to Generate Labels and Reports” on page 153.
10. Print a set of test labels in LDMS.

    For instructions on printing test labels, see the section called “Printing Test Labels” on page 153.

The Brady IP300 is known to work with the following:

Label stock	THT-183-461
Stock size in LDMS	Barcode label 7

Setting up the Brady BMP53 Printer

1. Install the driver for the printer.

   For assistance obtaining and installing the driver, contact your laboratory's IT support staff or Brady customer support [http://www.bradyid.com].
2. Open the printer settings from the Windows Start menu.

   There are typically found in `StartDevices and Printers`.
3. Right click on the BMP51(53) and select `Printing preferences`.
4. Click the **Advanced** button.

5. Click the **Properties** button next to **Paper Size**.
6. Select the paper size you are using from the **Paper Size** box.

   For example, if using the label stock M-156-492, you would select `M-156` from the **Paper Size** box.
7. Set the printer as your label printer in LDMS. For instructions on doing this, see the section called “Setting the Printer Used to Generate Labels and Reports” on page 153.
8. Print a set of test labels in LDMS.

   For instructions on printing test labels, see the section called “Printing Test Labels” on page 153.

The Brady IP300 is known to work with the following

Cartridge	M-156-492
Stock size in LDMS	Barcode Label 16

Setting up the Brady BP-PR 300 Printer

1. Install the driver for the printer.

   For assistance obtaining and installing the driver, contact your laboratory's IT support staff or Brady customer support [http://www.bradyid.com].
2. Open the printer settings from the Windows Start menu.

   There are typically found in `StartDevices and Printers`.
3. Right click on the Brady BP-PR 300 PLUS and select `Properties`.
4. On the **General** tab, click the **Preferences** button.
5. In the **Size** section, change the **Width** and **Height** to the size of the label stock you are using.

   For example, if the label stock is 1.75"x1.0", change the **Width**to `1.75` and change the **Height** to `1.0`.
6. Set the printer as your label printer in LDMS. For instructions on doing this, see the section called “Setting the Printer Used to Generate Labels and Reports” on page 153.
7. Print a set of test labels in LDMS.

   For instructions on printing test labels, see the section called “Printing Test Labels” on page 153.

Setting up the Brady BBP11-34L Printer

1. Open the printer settings from the Windows Start menu.

   There are typically found in `StartDevices and Printers`.
2. Right click on the BBP33 and select `Printing preferences`.
3. On the **Page Setup** tab, click the **New** button under **Stock** and enter the dimensions 1.75in x 1.00in.

   These are the dimensions for the THT-183-461-0.5-SC label stock.
4. Click the **Advanced Options** button.

   Verify that the horizontal and vertical offset options are set to `0in`.
5. Change to the **Stock** tab.

   Enter the following into the **Media settings** section:

Field	Value
Method	Thermal transfer
Type	Labels with marks
Mark height	0.08 in
Mark offset	0.00 in

6. Change to the **Options** tab.

   Set the following in the **Printer options** section:

Field	Value
Print speed	2.00 in/sec
Darkness	10

7. Click the **OK** button.
8. Set the printer as your label printer in LDMS. For instructions on doing this, see the section called “Setting the Printer Used to Generate Labels and Reports” on page 153.

The BBP11-34L is known to work with the following:

Label stock	THT-183-461-0.5-SC
Stock size in LDMS	Barcode Label 9

Setting up the LabXpert Printer

1. Open the printer settings from the Windows Start menu.

   There are typically found in `StartDevices and Printers`.
2. Right click on the LabXpert and select `Printing preferences`.
3. Expand the **Paper/Output** setting, and click the **Properties** button next to **Paper Size**.
4. Select the paper size that appear on the top of the label cartridge from the **Paper Size** box, and then click the **OK** button.
5. Click the **OK** button to close the **Printing preferences** window.
6. In the **Devices and Printers** window, right-click on the LabXpert printer and select `Properties`
7. Change to the **Ports** tab.
8. Click the **Configure Port** button.

   Enter the following settings:

Field	Value
Bits per second	115200
Data bits	8
Parity	None
Stop bits	1
Flow control	Xon/Xoff

9. Configure the LabXpert printer to accept input from the LDMS computer.

   Important

   This must completed every time the printer is turned on.

a. On the LabXpert print, press the **Menu** button.
b. Press the **Next** button three times.
c. Click the **PC** button.
d. Set the printer as your label printer in LDMS. For instructions on doing this, see the section called “Setting the Printer Used to Generate Labels and Reports” on page 153.

Setting up the Brady MVP 300 Printer

1. Open the printer settings from the Windows Start menu.

   There are typically found in `StartDevices and Printers`.
2. Right click on the Brady THT 300 MVP and select `Printing preferences`.
3. Expand the **Paper/Output** setting.

   Select **User Defined** from the **Paper Size** box.

   Click the **Customize** button.

   a. Enter the dimensions of paper into the **Width** and **Height** in the **Paper Sizes** boxes.
   b. Select `Inches` from the **Unit of Measurement** box.
   c. Click the **OK** button to close the **Paper Size Setup** window.
4. Click the **OK** button to close the **Printing preferences** window.
5. In the **Devices and Printers** window, right-click on the Brady THT 300 MVP printer and select `Properties`.
6. Change to the **Printer** tab.
7. Expand `Device OptionsHead SettingsPrint Darkness`
8. Change the **Print Darkness** setting to 22.
9. Expand the **Speed Settings**.

   Enter the following settings:

Field	Value to enter
Print speed	2.00 in/sec
Slew speed	2.00 in/sec
Back feed speed	2.00 in/sec

10. Change to the **Ports** tab.
11. Click the **Configure Port** button.

    Enter the following settings:

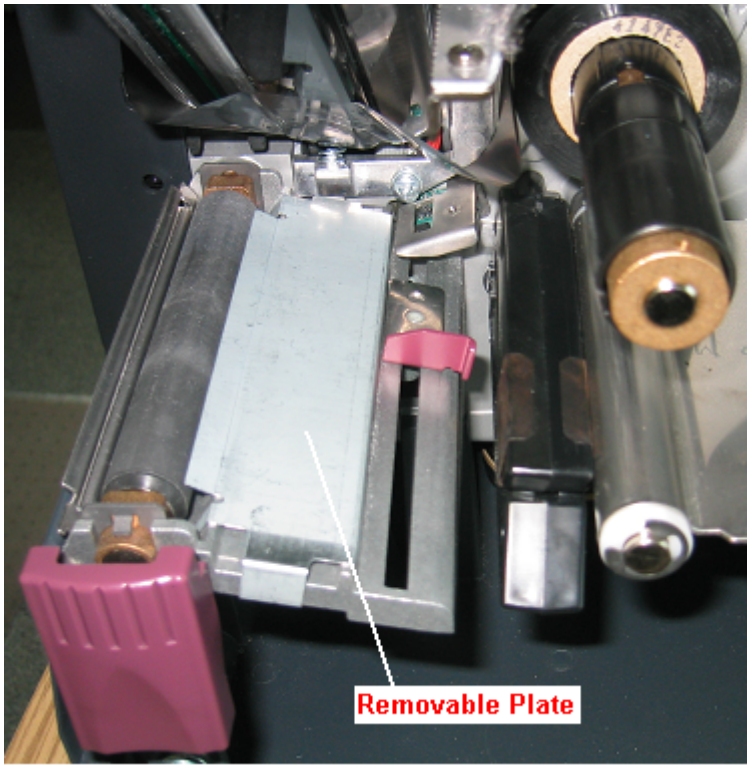
Field	Value
Bits per second	115200
Data bits	8
Parity	None
Stop bits	1
Flow control	Xon/Xoff

12. Physically configure the printer. (See Procedure 8.6, “Physically configuring the Brady MVP 300”)
13. Set the printer as your label printer in LDMS. For instructions on doing this, see the section called “Setting the Printer Used to Generate Labels and Reports” on page 153.

Procedure 8.6. Physically configuring the Brady MVP 300

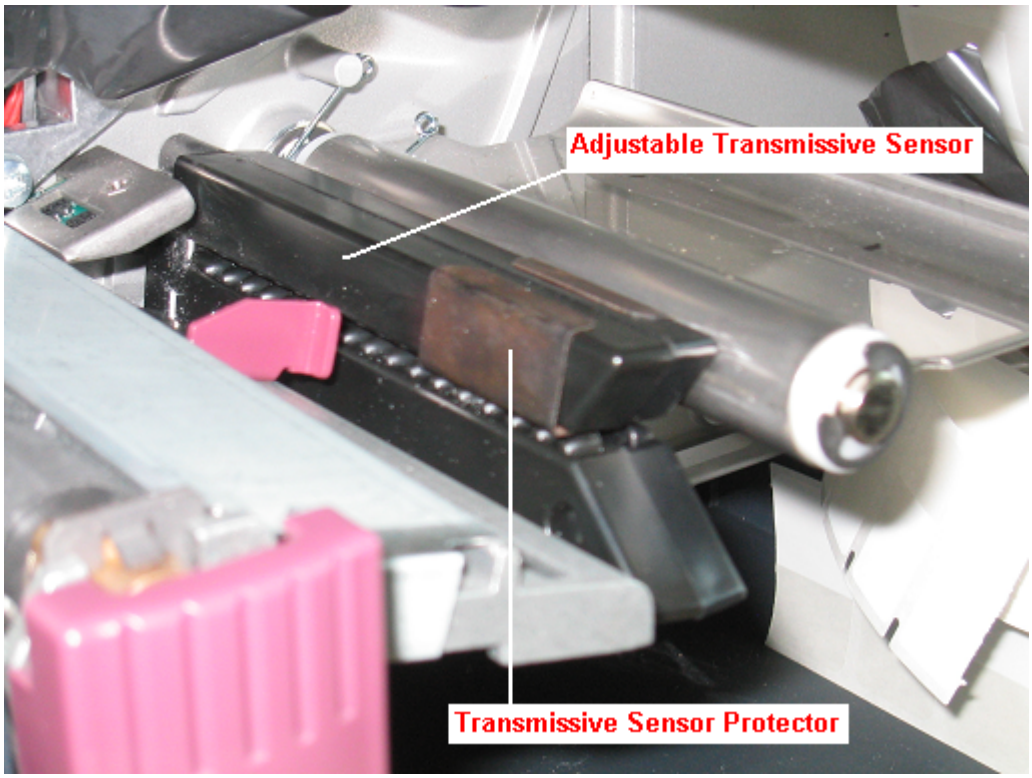
1. Open the printer and remove the protective plate that is covering the ribbon sensor.

   Figure 8.4. Removable plate within the MVP 300

2. Slide the transmissive sensor protector to the outside of the adjustable transmissive sensor.

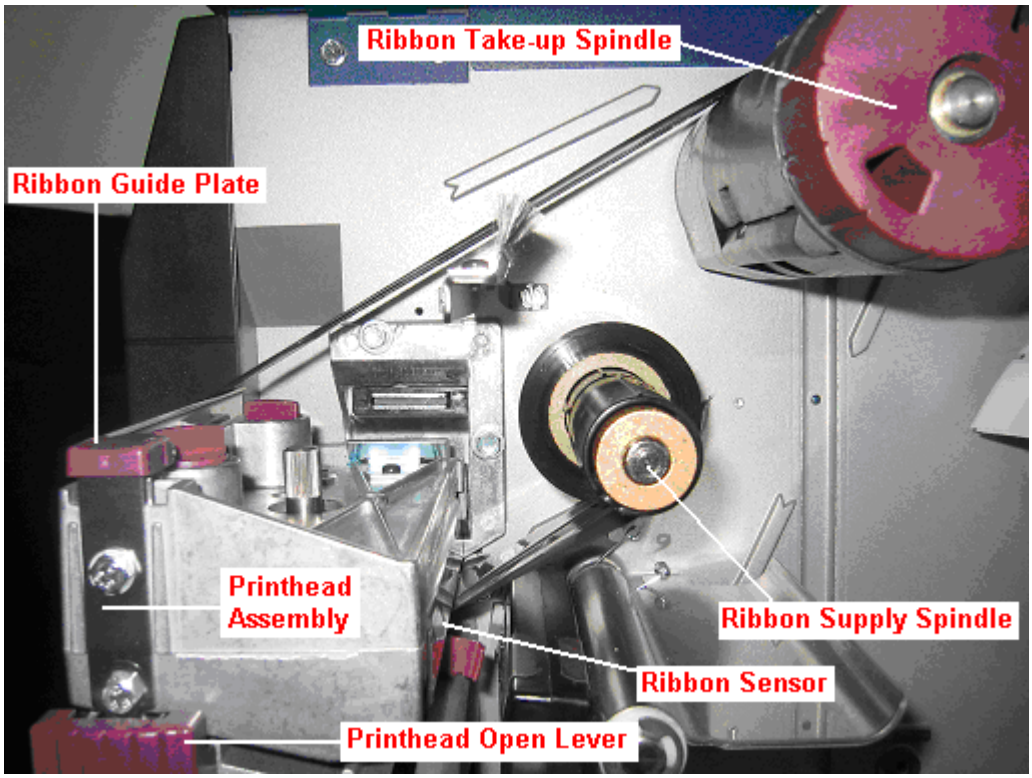
Figure 8.5. Adjustable transmissive sensor and protector



3. Place the ribbon on the ribbon supply spindle.

   The shiny side of the ribbon must be facing up.

Figure 8.6. Placing ribbon on spindle

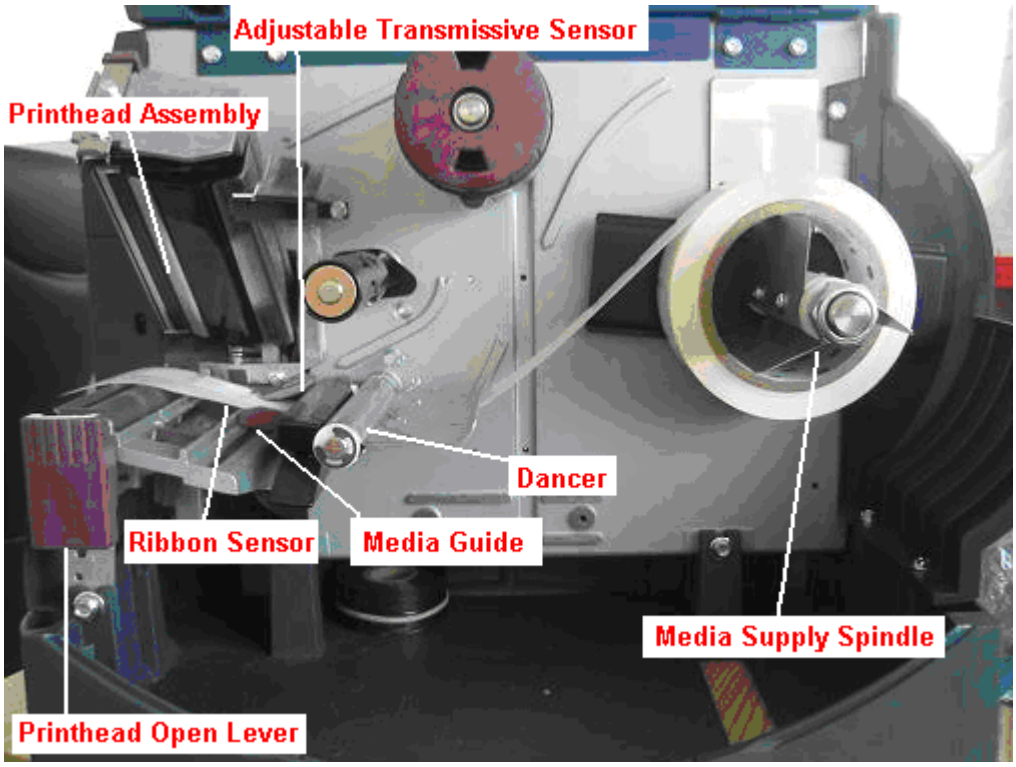


4. Feed the ribbon through the ribbon sensor and around the print head assembly.
5. Wrap the ribbon around the ribbon take-up spindle until it is tight.

   Tip

   You can attach a piece of tape to the end of the ribbon to help keep it tight during the loading processing.
6. Place the labels on the media supply spindle. The printable side of the label must be face-up.

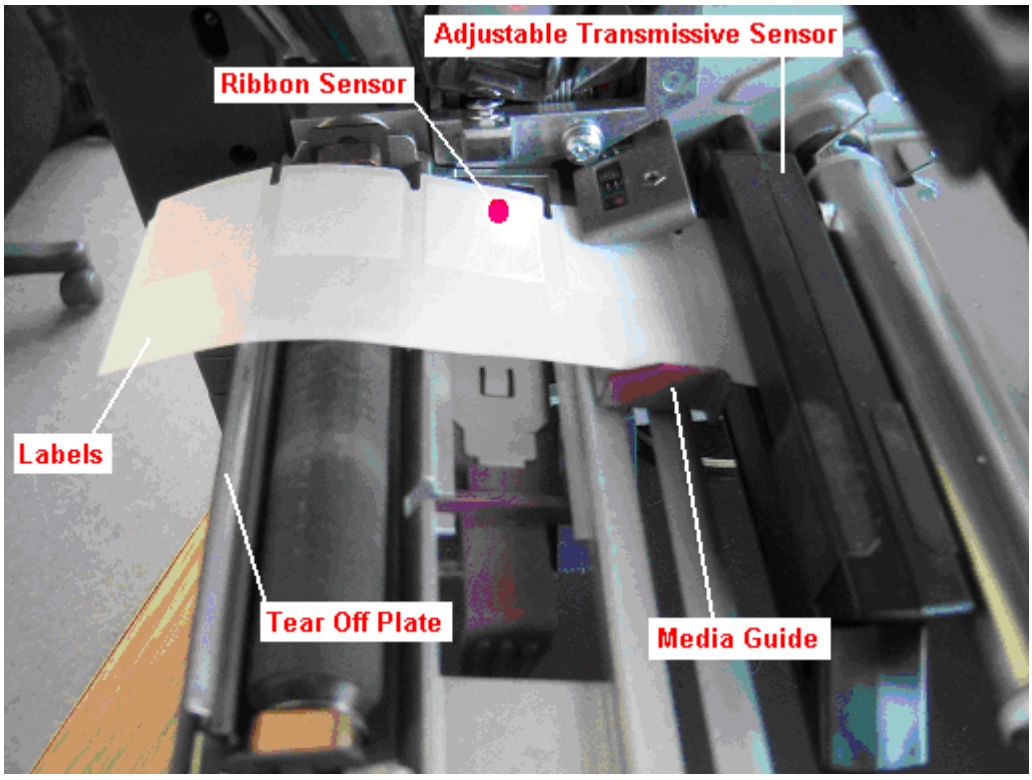
Figure 8.7. Side view of printer showing media supply spindle



7. Place the labels through the media guide and align the notch between labels with the tear-off plate of the printer.
8. Adjust the ribbon sensor so that the notch of the label will cross the ribbon sensor.

   The ribbon sensor is the red light under the label.

Figure 8.8. MVP 300 ribbon sensor and labels

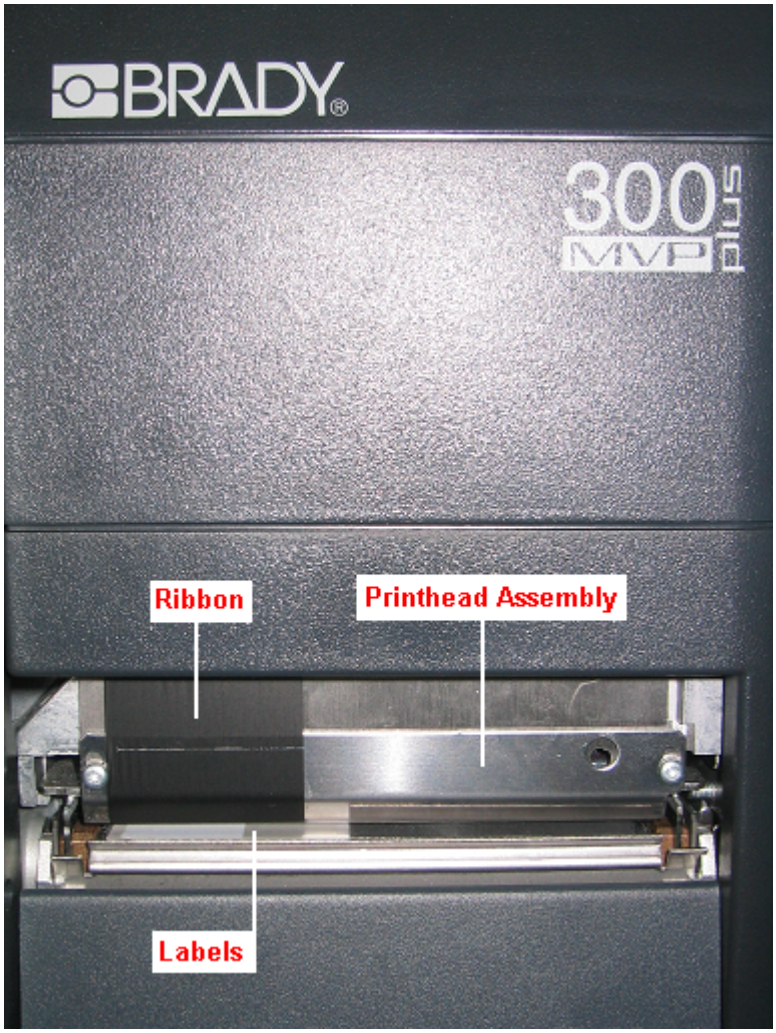


9. Close the print head and ensure that the ribbon is aligned with the left side of the label.

Note

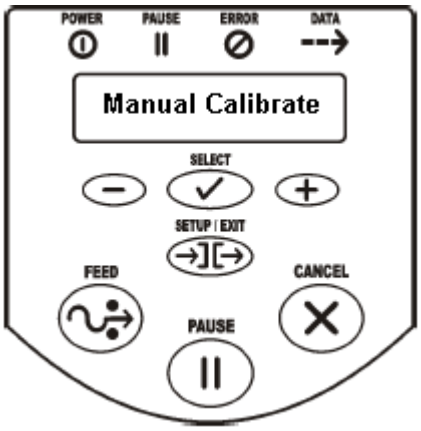
This adjustment may require you to slide the ribbon across the print head assembly.

Figure 8.9. Front view of MVP 300



10. Close the printer
11. Press the SETUP / EXIT button on the control pad on the front of the printer.

Figure 8.10. MVP 300 control pad



12. Press the + button until the printer displays **Manual Calibrate**.
13. Press the SELECT button.

14. Press the ⊕ button.

    The printer will re-calibrate its label settings.
15. Press the SETUP / EXIT button, and then press the ⊕ button to save the changes.

Setting up the Zebra GX 430t printer

Before you begin:

- Install the driver for your printer. For assistance obtaining and installing the driver, contact your laboratory's local IT department or the manufacturer's customer support.
- Load the printer with label stock and ribbon according to the printer's manual.

1. Open the printer settings from the Windows **Start** menu.

   These are typically found in `StartDevices and Printers`.
2. Right click the icon for your printer, and click `Printing preferences`.
3. On the **Options** tab, change the **Speed** to `2`.
4. Change the **Print Darkness** to about `27`.

   This setting should be adjusted up or down, depending on whether labels are too light or too dark.
5. In **Paper format**, select `inches`.
6. In **Paper Size**, set the **Width** to `4.00` and the **Height** to `1.75`.
7. On the **Advanced Setup** tab, click **Calibrate**.
8. On the **Advanced Setup** tab, verify that the **Tracking Mode** is set to `Web Sensing`.
9. In LDMS, set the printer as your label printer.

After the printer is set up, you should print a set of test labels to ensure that it is working correctly.

Setting up other printers

Label printers that do not have specific instructions in this manual may also work with LDMS, however they have not been tested by LDMS User Support.

For a current list of recommended printers for use with LDMS, contact LDMS User Support.

Chapter 9. System Administration and Maintenance

System Configuration

Configuration Tab

The following options are available on the **Configuration** tab in `AdministrationSystem Configuration`:

Auditor Mode	This option is disabled and not available to users.
Barcode Reader	Set the barcode reader used by LDMS. For most hardware, the **Code Reader** option will work. For more information on barcodes and labels, see Chapter 8: "*Labels and Printer Configuration*" on page 149.
Date Format	This option is disabled and not available to users. LDMS uses the date format dd/Mon/yyyy (e.g. 09/Apr/2013).
Date Separator	This option is disabled and not available for use.
Idle Time Out	(Default = enabled) If selected, LDMS will automatically lock after the specified amount of time of inactivity. LDMS will ask for a user name and password (it need not be the same as the user last using LDMS when it locked) before it will open again.
Module Login	(Default = disabled) If selected, users will need to re-enter their username and password to access almost every feature in LDMS. This security feature is useful if you want to prevent users from using LDMS while another person is logged in.
Process Tech Initials default to current user	(Default = enabled) The initials for the current user will be entered automatically in fields for the tech's initials throughout LDMS. To set or update a user's initials, see the section called "Managing Users" on page 168.

Internet Tab

The **Internet** configuration tab was used back when Frontier Science used a dedicated phone line to receive exportable data via a dial-up modem. This service is currently not used and these settings should not be modified.

Storage Tab

By default, if you remove an aliquot from storage, it will be assigned the `never store` flag. Never store prevents the aliquot from appearing as available on the **Bulk Add** tab in storage and semantically indicates that the specimen does not exist at your laboratory.

If you would rather have LDMS not assign specimens the `never store` flag when they are removed from storage, go to `AdministrationSystem Configuration`, then change to the **Storage** tab and deselect the **Permanent Delete Default Setting**. This feature is enabled by default.

Note

Contrary to the wording, having this setting enabled does not *permanently* delete specimens. For example, if you go to LDMS Specimen Management  , you will still find the specimen. When this feature is enabled, removing from storage only adds `never store`; the specimen itself is not deleted.

For more information on never store, see the section called "Using Never Store" on page 33.

Assays Tab

The Assays tab is where you go to associate an assay in LDMS with reader hardware. For instructions on doing this, see the section called "Associating an Assay with a Reader" on page 123.

Import Tab

LDMS has an **import as is** feature that allows you to keep the existing storage structure of specimens that you received in a shipment. For example, suppose specimens came to you in a box configuration. Rather than importing the specimens and then adding them to storage, you can import the box, keep the specimens current storage positions, and just add the box to your storage.

Procedure 9.1. Enabling and setting up import as is

1. Click AdministrationSystem Configuration from the LDMS menu bar.
2. Change to the **Import** tab.
3. Select the **Allow automatic storage of imported samples** option.
4. (Optional) To override any setting from the shipping file, select the appropriate **Override** option.

For more information on importing specimens from another laboratory, see the section called "Importing a Shipment from an LDMS Laboratory" on page 77.

Managing Users

Creating New Users

LDMS is a user-based system. LDMS cannot be used without a valid user name and password. User names and passwords in LDMS are not tied to your computer's login credentials. By using individual user accounts, it is possible to keep track of who did what in LDMS, and prevent users from accessing advanced features that they should not be using.

When LDMS is installed, it comes with one default account, ADMIN (the password is also admin). The first time you start LDMS, you should immediately create one or more user accounts, and then remove the admin account. See the section called "Logging into LDMS for the First Time" on page 5.

Important

Using the ADMIN account for daily work is strongly discouraged. It should be deleted as soon as you have added at least one user with system administrative privileges.

Procedure 9.2. Adding a new user account

1. Click AdministrationUser Configuration from the LDMS menu bar.
2. On the User Configuration screen, click the 

button.
3. Complete the **User Name** field. This field must be unique among other user names at your laboratory.
4. Enter the user's **Real Name**. This field can contain spaces.

5. Enter the user's **Initials**.
6. Enter the password for the new user.

> **Note**
>
> Passwords in LDMS are *not* case-sensitive.

By default, a user's **Initials** will be used throughout LDMS to populate fields with the user's initials when appropriate. This behavior can be changed. See the section called "Configuration Tab" on page 167.

Adjusting User Permissions

Every user in LDMS is assigned privileges. When you create a new user, you should review the default privileges that are assigned to all new users and adjust them accordingly.

Every privilege corresponds to a menu item in LDMS. For example, the **Kit Entry** permission controls access to `QA/QCKit Entry`. If you want to know what a particular permission does, find the LDMS menu item of the same name.

Procedure 9.3. Modifying a user's permissions

1. Click `AdministrationUser Configuration` from the LDMS menu bar.
2. Select the user that you want to modify from the **User ID** drop-down list.
3. Select the permissions desired.
   - The **View** permission allows a user to see the records (e.g. viewing aliquots in Specimen Management ).
   - The **delete** permission allows a user to remove records (e.g. deleting an aliquot).
   - The **modify** permission allows a user to change records (e.g. changing an aliquot's volume); the **view** permission would also be required separately.
   - The **add** permission allows a user to create new records (e.g. adding new specimens); this can be independent of the ability to view records, so a person could enter data without being able to see existing data.
   - The **full** permission is the same as giving a user access to view, add, modify, and delete.
4. (Optional) To make a user a system administrator, select the **System Administrator Capabilities** option.
5. Click the  button from the LDMS toolbar.

> **Tip**
>
> Click on a column header to select or unselect all of the permissions in that column. This is useful if you want to quickly give someone **full** permission to everything in LDMS.

System Administrator Capabilities

At least one user at your laboratory *must* have System Administrator Capabilities. This gives the user access the certain features:

- Reset and change passwords for other users
- Lock out and unlock user accounts
- Delete users
- Designate other system administrators

By default, the original ADMIN account has system administrator privileges. Before deleting the ADMIN account, make certain that at least one user has system administrator capabilities.

Modifying Users and Passwords

While a user's login name cannot be modified, their full name and initials can. You would need to do this, for example, if a user's last name changed.

Procedure 9.4. Updating a user

1. Click `AdministratorUser Configuration` from the LDMS menu bar.
2. Select the user to modify from the **User ID** drop-down list.
3. Do one of the following:
   - To update the user's full name or initials, click the Edit User button.
   - To delete the user's account, click the Delete button.
   - To change the user's password without the current password, click the Reset Password button (requires system administrator capabilities).
   - To prevent the user from logging in without deleting the account, click the Lock Out button (requires system administrator capabilities).

     Note

     The message entered when locking out a user will be displayed if that user attempts to log in.
   - To change the user's password when you know the current password, click the Change Password button.
4. Click the button from the LDMS toolbar.

Tip

If you want to allow users to change their own passwords without being able to make any other user account changes, give them `view` access to **User Configuration**. They will only be able to access the Change Password button for their own account.

Adjusting Login Security

In addition to adjusting individual user permissions, there are a few security settings that you can change to help prevent users for using LDMS under another person's user account:

- Require login when trying to use a specific feature. Even if users are logged into LDMS, they will still be required to provide their password to move between tasks.
- Adjust the time frame when LDMS will automatically lock. A username and password will be required to access LDMS again.
- Train laboratory staff to lock LDMS manually when leaving a workstation. This is done by clicking **`Ctrl+Shift+L`**`AdministrationSession Lock` from the LDMS menu bar.

For the first two items, see the section called “Configuration Tab” on page 167.

Group Configuration

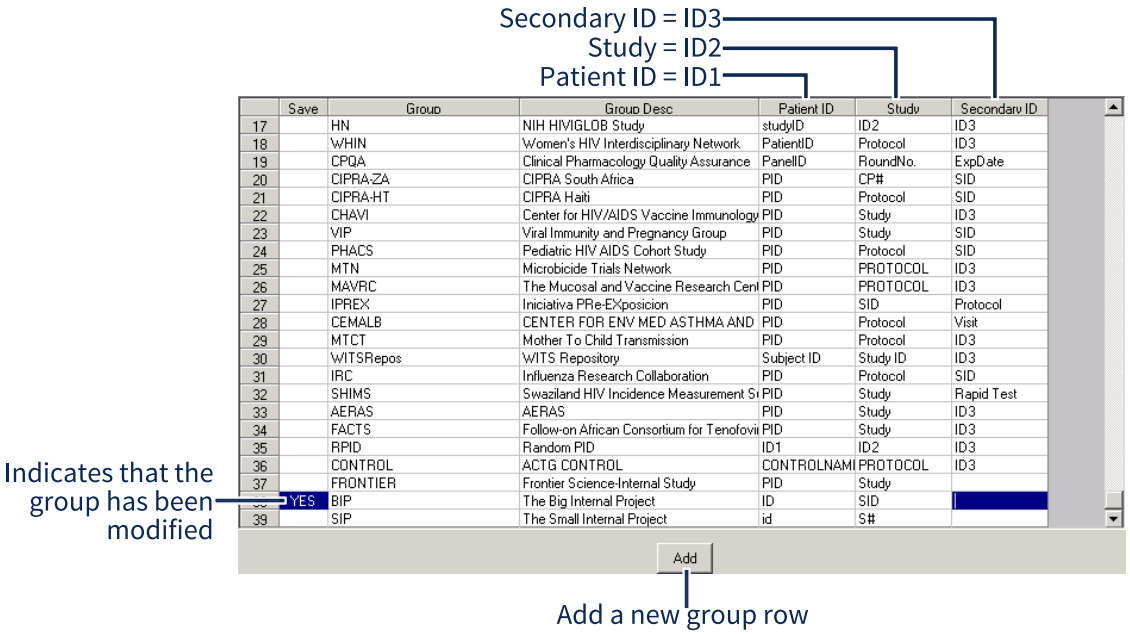
LDMS has many hard-coded groups (typically government-sponsored networks like ACTG and IMPAACT). When one of these groups is selected in LDMS Specimen Management , LDMS enforces certain rules specific to that network on what fields are required and what are valid

entries. These groups are defined by Frontier Science in collaboration with individual networks, and cannot be modified by users.

Laboratories can, however, add their own groups for internal use. Internal groups can be modified and used as a laboratory sees fit.

To view groups and add new internal groups, click `AdministrationGroup Configuration`. You'll see a list of all groups in your LDMS installation, along with the labels for the ID1, ID2, and ID3 fields in Specimen Management .

Figure 9.1. Group Configuration



	Save	Group	Group Desc	Patient ID	Study	Secondary ID
17		HN	NIH HIVIGLOB Study	studyID	ID2	ID3
18		WHIN	Women's HIV Interdisciplinary Network	PatientID	Protocol	ID3
19		CPQA	Clinical Pharmacology Quality Assurance	PanelID	RoundNo.	ExpDate
20		CIPRA-ZA	CIPRA South Africa	PID	CP#	SID
21		CIPRA-HT	CIPRA Haiti	PID	Protocol	SID
22		CHAVI	Center for HIV/AIDS Vaccine Immunology	PID	Study	ID3
23		VIP	Viral Immunity and Pregnancy Group	PID	Study	SID
24		PHACS	Pediatric HIV AIDS Cohort Study	PID	Protocol	SID
25		MTN	Microbicide Trials Network	PID	PROTOCOL	ID3
26		MAVRC	The Mucosal and Vaccine Research Cent	PID	PROTOCOL	ID3
27		IPREX	Iniciativa PRe-EXposicion	PID	SID	Protocol
28		CEMALB	CENTER FOR ENV MED ASTHMA AND	PID	Protocol	Visit
29		MTCT	Mother To Child Transmission	PID	Protocol	ID3
30		WITSRepos	WITS Repository	Subject ID	Study ID	ID3
31		IRC	Influenza Research Collaboration	PID	Protocol	SID
32		SHIMS	Swaziland HIV Incidence Measurement Si	PID	Study	Rapid Test
33		AERAS	AERAS	PID	Study	ID3
34		FACTS	Follow-on African Consortium for Tenofovi	PID	Study	ID3
35		RPID	Random PID	ID1	ID2	ID3
36		CONTROL	ACTG CONTROL	CONTROLNAMI	PROTOCOL	ID3
37		FRONTIER	Frontier Science Internal Study	PID	Study	
	YES	BIP	The Big Internal Project	ID	SID	
39		SIP	The Small Internal Project	id	S#	

▲ Viewing and configuring groups in LDMS; only internal created by your laboratory can groups can be modified.

Procedure 9.5. Adding a new internal group to LDMS

1. Click `AdministrationGroup Configuration` from the LDMS menu bar.
2. Click the Add button to add a new row to the listing of groups.
3. Enter the name for the group as you want it to appear throughout LDMS into the **Group** field.
4. Enter a description for your group into the **Group Desc[ription]** field. This information will appear if a user presses **Ctrl**+**H** with your group selected.
5. Enter the label that you want to use for the **ID1**, **ID2**, and (optionally) **ID3** fields in LDMS Specimen Management into the **Patient ID**, **Study**, and **Secondary ID** fields respectively.
6. Click the button from the LDMS toolbar.

You can only modify groups that you have created. If you attempt to modify a group that is hard-coded into LDMS, you will receive an error message.

Internal Groups and shipping

Since internal groups are created at individual laboratories, only that laboratory has the group available. If you want to ship specimens in an internal group to another laboratory, there are a few options:

- The group from the sending laboratory can be mapped to an existing group at the receiving laboratory
- A new group can be created at the receiving laboratory

The receiving laboratory will automatically be prompted to do one of these when the shipping file is imported.

This distinction between internal and government groups prevents the two from be added to the same shipping file in LDMS.

Backups

When bad things happen, a recent backup can be the difference between simply copying a few files to re-entering hundreds of specimens. This is not an overstatement. Every year, inevitably, several laboratories experience a hardware failure and their most recent backup stored off of the computer is outdated.

To help avoid this painful scenario, LDMS automatically creates a backup of your database once per day. By default, these backups are generated every day at noon and placed in `C:\fstrf\backup`. Since this backup is stored locally on the same computer as LDMS, you'll need to copy it to another location. If you want to change the time that auto backups are created, contact LDMS User Support for assistance.

Figure 9.2. LDMS backup file name format

```
[LabID]_[year][month][day].BK
```

▲ The format of backup file names in `C:\fstrf\backup`.

Important

LDMS only keeps its automatic backups files in `C:\fstrf\backup` for seven days. After that, the oldest backups will be deleted to help conserve hard drive space.

Frontier Science strongly recommends that laboratories copy the latest backup file in `C:\fstrf\backup` to a safe location at least once each week. It is a good idea to keep backups on removable media, such as a tape or CD-RW, since backups that are on the same computer as LDMS will not be helpful if you experience a computer failure.

In addition to back-up files that are automatically generated every day at noon, it is possible to manually generate a new backup file. This is useful if you performed a significant amount of work in LDMS in the afternoon and want to ensure that you have a backup file for that work.

Procedure 9.6. Manually generating a backup file

1. Click `AdministrationBackup Tracking` from the LDMS menu bar.

2. Click the **Create backup** button in the upper-right corner.

   A Windows command prompt window will open. This is the backup tool in LDMS.
3. Wait until the backup tool finishes creating the backup.

The backup file will appear in the same location as backup files automatically generated by LDMS.

Procedure 9.7. Verifying the integrity of a backup file

1. Make a copy of the backup file
2. Open the backup file with a ZIP archive program.

   If you want to open the backup file using Windows, change the file extension of the backup file from `.BK` to `.ZIP`. This will allow you to open it using Windows Explorer.
3. Open the backup log file.

   The log file will have the same names as the backup file, with the file extension `.export` added. For example, if you open a backup file named `999_20140418120001.bk`, the log file in it will be named `999_20140418120001.dmp.export`.
4. Look at the last line of the log file.

   If the last line reads as follows, the backup was successful:

   ```
   Job successfully completed at [time backup ran]
   ```

   If the log file ends with anything else, the backup was a failure and should not be saved.

   Important

   Do not retain the copy of the backup file that you opened. If the backup is confirmed to be complete, save the original instead.

LDMS has a mechanism for manually tracking when you have copied a backup file to a safe location, and will show a list of automatic backups.

Procedure 9.8. Using the Backup Tracking tool

1. After copying the most recent backup file from `C:\fstrf\backup`, click `Administration` `Backup Tracking` from the LDMS menu bar.
2. Enter the date that the backup was created by LDMS into the **Backup Date** field.
3. Enter the initials of the person who copied the backup into the **Tech Initials** field.
4. Enter how you copied the database backup into the **Method** field. This might be an external filesystem location, removable media, etc.
5. Enter any additional information into the **Comment** field. This could be used, for example, if your laboratory has a system for uniquely identifying backups.
6. Click the ✚ button from the LDMS toolbar.

Exports and Updates

Data you collect and enter into LDMS at your laboratory exists only in your laboratory's database. It is not automatically transferred, sent to anyone, or synchronized with other laboratories. For many research groups, Frontier Science performs data management services and maintains a central database of specimen information for the group. The process of sending this centrally managed data from your laboratory to Frontier Science is called *exporting*.

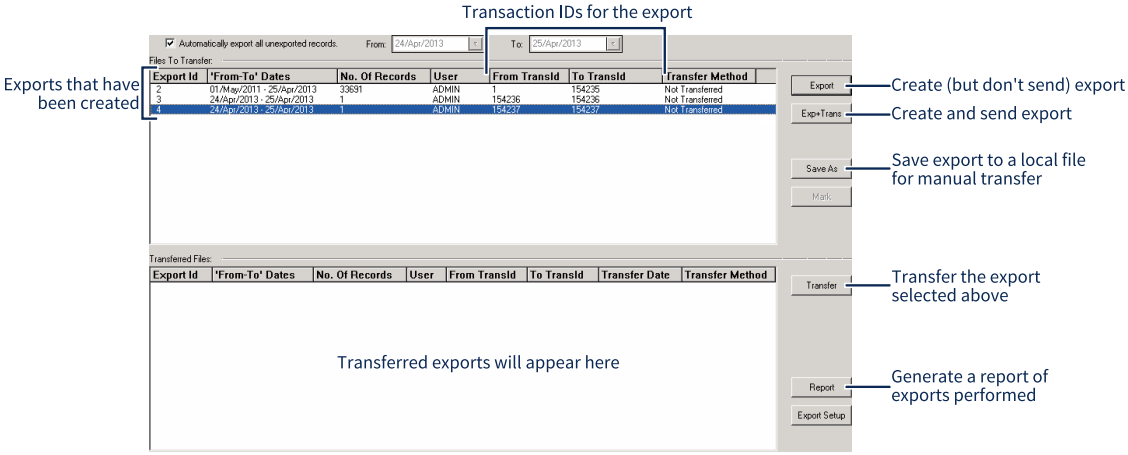
Exporting does *not* back up your local LDMS database. Only a portion of your laboratory's data is sent through an export; it is not possible to reconstruct your laboratory's database using exported data.

When your laboratory performs an export, LDMS will check to see if there are any minor updates (called *deploys*) available. If there are updates, LDMS will automatically download and install them. These updates include changes to laboratory contact information, new preloads, specimen code updates, etc.

Note

The types of updates that LDMS can download automatically are small, incremental changes. LDMS will not download or install major LDMS upgrades (in other words, if you are running LDMS 7.2, you will not automatically be upgraded to LDMS 8.0 after exporting). Larger LDMS updates that require you to download and run an installer are announced by Frontier Science when they are released.

Figure 9.3. Exporting data to Frontier Science



Procedure 9.9. Exporting data to Frontier Science and downloading LDMS updates

1. Click `TasksExport` from the LDMS menu bar or click the button from the LDMS toolbar.
2. Click the Exp+Trans button. A series of messages will appear as the export is created and then transferred.

There may be occasions when you cannot perform an export as intended. For example, if your laboratory is located in a region with sporadic Internet connectivity, it may be difficult to reliably perform an export. While it is not optimal, it is possible to manually create and send exportable data to Frontier Science. Before attempting to do this, you should contact LDMS User Support as they will need to be involved in several steps. See the section called “Getting Help” on page 10.

Procedure 9.10. Manually exporting data to Frontier Science

1. Click `TasksExport` from the LDMS menu bar or click the button from the LDMS toolbar.

2. Generate an export file by clicking the Export button. If there is already an existing file in the **Files to Transfer** list, skip this step.
3. Select the export from the **Files to Transfer** section, and then click the Save As button. You will be prompted to save the export file to your computer.
4. Contact LDMS User support. They will work with you to determine the most convenient method for transferring the export file to Frontier Science.
5. After the export file has been acquired by LDMS User Support, LDMS User Support will provide you with a password. With the export tool open, select the file that was transferred manually and click the **Mark** button. You will be prompted to enter the password supplied by LDMS User Support. The manual export is now complete.

If you perform a manual export, keep in mind that you will *not* have received any deploy updates. It is possible for LDMS Use Support to manually provide these updates for you. For more information, contact LDMS User Support.

What is and is not Exported

Exporting is the only process in LDMS where data is transmitted between Frontier Science and a laboratory. This isn't just a process for sending data to Frontier Science, but also the easiest way for your laboratory will receive important incremental LDMS updates. For this reason, it's important for every laboratory to perform regular exports, even if Frontier Science is not managing your data.

You might be wondering what data is sent when you export. The following information is exported to Frontier Science from all laboratories:

- All specimen and assay data for the following groups: ANON, ACTG/IMPAACT, VQA, AIEDRP, HPTN, VTN, ATN, CPQA, CHAVI, VIP, PHACS, MTN, IPREX, WITSRepos, IRC, SHIMS, AERAS, FACTS, CONTROL, CIPRA, RPID.
- Reagent information
- Oracle database usage statistics (e.g. database size, number of records)
- LDMS user account information, such as names and initials

The following information is *not* exported:

- LDMS user passwords
- Data for groups not listed above
- Data for internal groups that you created at your laboratory
- Data and information stored on your computer not related to LDMS.

You can identify if an individual specimen will be exported in Specimen Management  . Any primary or aliquot with the **Details** code `E` will be exported.

Activity Log

LDMS keeps an activity log while the user is working. This log is displayed for the current session only, and once LDMS is closed, it is no longer accessible to users. This information is always displayed at the bottom of LDMS, organized by the type of activity.

Shows all activities

Show only error messages (sometimes referred to as "hard warnings")

Show only warning messages (sometimes referred to as "soft warnings")

Show only informational messages

It is possible to extract and save this information from the current session.

Procedure 9.11. Saving activity log information

1. Select the type of logs you want to save by clicking the appropriate tab to the left. I you want all logs, select the tab.
2. Right-click anywhere in the log window, then select `Export As[Format]`, where `[Format]` is the file format to save the logs as.
3. Follow the prompts on your screen to save the file to your computer.

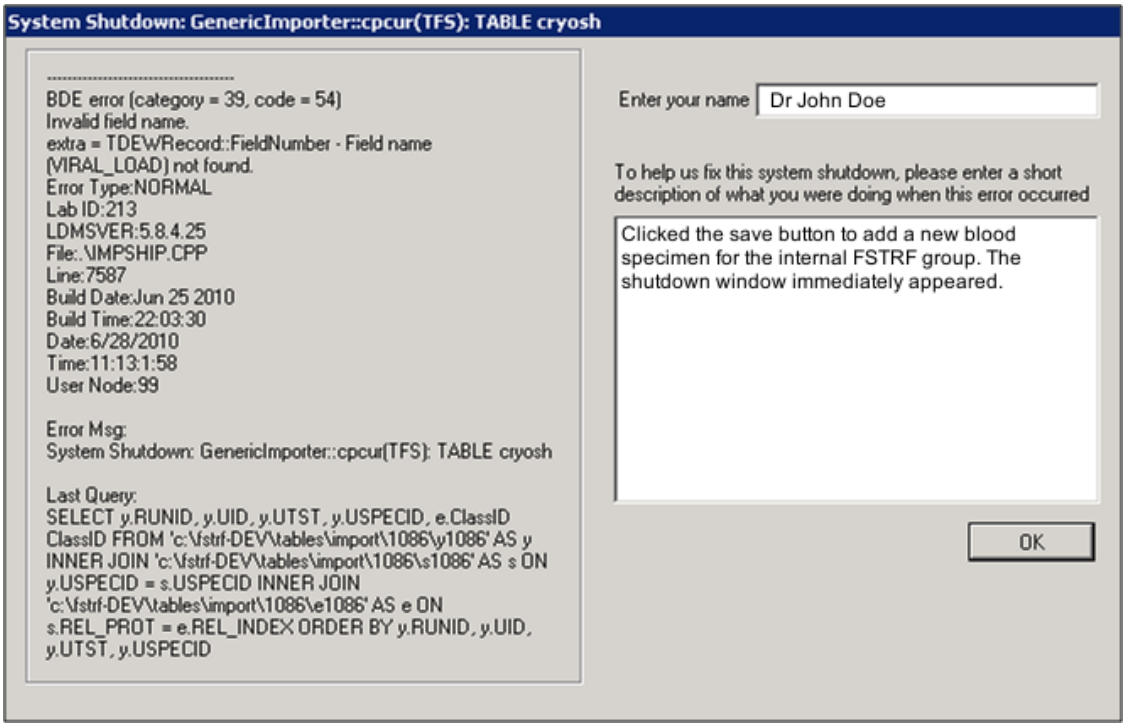
The `Export As` menu is actually available in many places throughout LDMS. Because the feature is not context-sensitive (that is, it attempts to pull raw data from LDMS and automatically format it), the output may not always be optimal. In general, you should utilize the built-in reports and feature-specific reports that are available throughout LDMS instead.

Recovering from an Unexpected Shutdown

While every effort has been made to test LDMS in a variety of working conditions, it is possible that there may be unexpected behavior in the program that could cause a problem for your laboratory. It is also possible that an issue unrelated to LDMS may affect how LDMS runs. For example, an unreliable Internet connection may cause a problem with how LDMS exports data to Frontier Science. Likewise a power failure at your laboratory during a critical moment could cause an issue with your laboratory's database.

If LDMS shuts down unexpectedly, you will see the window displayed in Figure 9.4. Please provide a detailed description of how you were using LDMS at the time that it shut down unexpectedly. For example if LDMS shutdown when you were trying to save a change to an existing specimen, providing that information can better help LDMS User Support diagnose the issue. The more details that you can provide about what you were doing, the more likely it will be that Frontier Science will be able to permanently fix the issue.

Figure 9.4. System Shutdown Dialog Window



▲ The dialog window that appears if LDMS shuts down unexpectedly. Provide as many details as you can in the space provided.

If LDMS does shutdown unexpectedly, it will lock. The next time you attempt to start LDMS, you will be provided with the details of the shutdown and prompted to contact LDMS User Support to obtain a challenge password. Copy and paste the details of the shutdown and provide them to LDMS User Support. *LDMS User Support needs the details of the shutdown before they can provide you with a password to unlock LDMS.*

Important

Never close LDMS by terminating it using the Windows Task Manager (typically accessed by pressing **Ctrl**+**Alt**+**Delete**). Doing so could cause damage to your LDMS database. If LDMS becomes unresponsive, contact LDMS User Support for assistance instead of trying to close it on your own.

If you have LDMS installed in a network and one of the client machines shuts down unexpectedly, all LDMS computers on the network will be locked as well. The unlocking process only needs to be completed on one computer to unlock all of the LDMS machines on the network.

For more information about challenge passwords, see the section called “LDMS and Challenge Passwords” on page 4.

Computer requirements and recommendations for LDMS

The exact hardware you will need to run LDMS will vary, depending on the work performed at your laboratory. For example, a large repository will need much more hard drive space since it will have a larger LDMS database than a smaller laboratory.

Table 9.1 and Table 9.2 show the computer requirements and recommendations for running LDMS. The recommendations should be sufficient for most laboratories. If you are unsure if you meet the system requirements, talk to your laboratory's IT support staff

Table 9.1. LDMS system requirements

Component	Requirement
Operating System	Windows Vista, Windows 7, Windows 8, Windows 8.1, Windows Server 2008, or Windows Server 2012 64-bit[ab]
Microsoft .NET Framework	Version 4.0 (full profile) or higher (If you are using Windows 8 or higher, you already meet this requirement)
Screen Resolution	1024x768
Hard Drive	Size requirements vary by number of specimens managed
Input	Keyboard and 2-button mouse
Video	Monitor and video card capable of at least 1024x768 resolution and 16-bit color depth

[a]LDMS has been reported to function appropriately on thin clients and virtual machines, but these have not been thoroughly tested and are not supported by Frontier Science.
[b]Home editions of Microsoft Windows are not supported.

Table 9.2. LDMS system recommendations

Component	Recommendation
CPU	3.0+ GHz Intel Core 2 or AMD processor
Networking	100/1000 mbps Ethernet card with high-speed Internet connection
Hard drive	100 GB free space (more if managing a large laboratory)
Removable Storage	High capacity removable storage, e.g. CD-RW, DVD-RW, USB drive, etc.
Printer	Microsoft Windows compatible printer[a]
Memory	2 GB or more of RAM
Barcode Reader	Microsoft Windows compatible barcode scanner
Power	An uninterruptible power supply (UPS) to protect against data loss caused by power failure.

[a]Printers and barcode readers may have additional requirements. consult your hardware's documentation for more information.

If you have questions about hardware compatibility or purchasing equipment for your laboratory, contact LDMS User Support. See the section called “Getting Help” on page 10.

Chapter 10. Group-Specific Information

Many features in LDMS are driven by the selected group. For example, in LDMS Specimen Management  , many of the fields available for participant entry are different for each group. Other features behavior differently or are only accessible to certain groups. For example, if you are creating a shipping file to send to another laboratory and your shipment contains specimens for certain groups, you'll be prompted to generate a special manifest.

Many groups also want laboratories to use LDMS in a specific way when handling their specimens. For example, if a specimen is destroyed through a laboratory accident, some groups want the user to delete that specimen from LDMS while others want the specimen to remain in LDMS, but with the condition code `LBE` (laboratory error) added.

This section describes some of the group-specific behavior in LDMS. This behavior is determined by the group itself, and implemented in LDMS at the group's request.

If you are performing work for a group, always defer to documentation and guidelines that are provided to you for that group. LDMS User Support LDMS usage questions; group-specific questions should be directed to the appropriate contact for that group.

ACTG (AIDS Clinical Trials Group)

- ACTG uses the standard LDMS Shipping File format to ship between ACTG laboratories using LDMS.
- ACTG requires specimens to be labeled with a 2D barcode and label from LDMS; LDMS comes with label formats for ACTG setup and ready to use.
- ACTG and IMPAACT are listed as a combined group throughout LDMS (i.e. `ACTG/IMPACT`)
- Preloads are permitted for the ACTG group, but users are not permitted to create their own. All ACTG preloads are created by Frontier Science in collaboration with network leadership. For more information about preloads, see the section called “Preloads: Templates for Expected Specimen Collections” on page 21.

Table 10.1. Specimen Management Fields for ACTG

Field	Required?	Note
ID1 (PID)	Required	8 characters long, 7 numbers and one letter between A and L; if the PID does not have 7 numbers, add leading zeros to the front of it.
ID2 (Protocol)	Required	Select from the pre-defined list of protocols.

Field	Required?	Note
ID3 (SID)	Required	Study Identifier; LDMS will remember previously entered SIDs and automatically populate ID3 when the same group-PID-protocol combination is entered. If you do not know the SID or a SID has not yet been assigned, enter `NOSID`. For more information on updating participants entered with NOSID, see the section called "Finding and Modifying Participant Information" on page 59.
Visit	Required	Select from pre-defined list of visit units.
OPID	Available	
Clinic	Required	LDMS will automatically populate the clinic using one previously entered for the same PID, protocol, and SID combination.
Specimen Time	Depends	If you do not have a specimen time recorded on your CRF, contact the clinic that collected the specimen from the participant. This field is required for specimens with a specimen date of 01 January 2004 or later; it is optional for specimens prior to that date. This requirement can be overridden for specimens after this date, if necessary.
Received Time	Optional	

Aeras

Preloads can be utilized for Aeras. For more information about preloads, see the section called "Preloads: Templates for Expected Specimen Collections" on page 21.

Table 10.2. Specimen Management Fields for Aeras

Field	Required?	Note
ID1 (PID)	Required	11-digits of any combination of letters and numbers.
ID2 (Study)	Required	Selected from pre-populated list. Once selected, the LDMS will check that the PID is associated with the selected protocol.
ID3	Disabled	This field is not used by Aeras
Visit	Required	Select from pre-defined list of visit units.
OPID	Disabled	This field is not used by AERAS

Field	Required?	Note
Clinic	Required	LDMS will default to the clinic `ARSxx`, where `xx` are the 5th and 6th digits from the PID
Specimen Time	Required	
Received Time	Optional	

ATN (Adolescent Medicine Trials Network)

Preloads can be utilized for ATN. For more information about preloads, see the section called “Preloads: Templates for Expected Specimen Collections” on page 21.

Table 10.3. Specimen Management Fields for ATN

Field	Required?	Note
ID1 (PID)	Required	A 6-digit number between 10001 and 999999. If the PID is less than 6 digits, leading zeros will automatically be added. LDMS will check that the PID is valid.
ID2 (Protocol)	Required	Entered manually
ID3 (SID)	Required	An 8-digit number between 40001 and 999999999. If the SID is less than 8-digits, leading zeros will automatically be added. 7-digit SIDs can still be imported by LDMS. If the same PID-protocol combination has been entered, LDMS will automatically default to the previously used SID. `NOSID` is a valid entry for ATN. For more information about `NOSID`, see the section called “Finding and Modifying Participant Information” on page 59.
Visit	Required	Select from pre-defined list of visit units.
OPID	Available	
Clinic	Optional	
Specimen Time	Required	
Received Time	Optional	

CHAVI (Center for HIV-AIDS Vaccine Immunology)

- Barcode labels are required. A CHAVI label format is already configured in LDMS.
- Primary and aliquot volume units will default to `ML`.

Table 10.4. Specimen Management Fields for CHAVI

Field	Required?	Note
ID1 (PID)	Required	9 numerical digits
ID2 (Study)	Required	Select study from the pre-populated list. LDMS will check that the PID is associated with the selected study.
ID3	Disabled	This field is not used by CHAVI.
Visit	Required	The visit unit will automatically be set to `VST`.
OPID	Depends	This field is not used by CHAVI, unless ID2 is `008A`
Clinic	Optional	The clinic will be automatically populated based on the PID. It will be the letter `C`, followed by the first three digits in the PID (e.g. `C452`). This value can be overriden if necessary.
Specimen Time	Optional	This field is not required, but recommended
Received Time	Required	

CPQA (Clinical Pharmacology Quality Assurance and Quality Control)

- CPQA uses the standard LDMS Shipping File format.
- There are CPQA barcode options available in LDMS.
- While preloads can be used for CPQA, users are not expected to use this feature.
- The Pharmacology Proficiency Results report can be generated for Clinical Laboratory Improvement Amendments (CLIA). It is found in LDMS Reports, under the **PK** category. This is sometimes referred to as the "CLIA Report".

Figure 10.1. CPQA PanelID Format

```
22A00
[CPQA round number][letter ID for panel][2 numbers]
```

Table 10.5. Specimen Management Fields for CPQA

Field	Required?	Note
ID1 (PanelID)	Required	Must be five characters in length. See Figure 10.1.
ID2 (RoundNo)	Required	This is the same as the first 2 digits of the **PanelID**. This field will automatically be populated by LDMS.

Field	Required?	Note
ID3 (ExpDate)	Optional	
Visit	Optional	Select from pre-defined list of visit units.
OPID	Optional	
Clinic	Optional	
Specimen Time	Optional	
Received Time	Optional	

FACTS (Follow-on African Consortium for Tenofovir Studies)

Preloads can be utilized for FACTS. For more information about preloads, see the section called “Preloads: Templates for Expected Specimen Collections” on page 21.

Table 10.6. Specimen Management Fields for FACTS

Field	Required?	Note
ID1 (PID)	Required	A 7-digit number. LDMS will verify that the PID is valid.
ID2 (Study)	Required	Select from pre-populated list
ID3	Disabled	This field is not used by FACTS
Visit	Required	Select from pre-defined list of visit units.
OPID	Disabled	This field is not used by FACTS
Clinic	Disabled	This field is not used by FACTS
Specimen Time	Required	
Received Time	Optional	

HPTN (HIV Prevention Trials Network)

- There are several HPTN label formats available in LDMS.
- Primary and aliquot volumes will default to `ML`.
- Preloads are not permitted for HPTN.

Table 10.7. Specimen Management Fields for HPTN

Field	Required?	Note
ID1 (PID)	Required	LDMS performs a checks to make sure the PID is valid. Based on the protocol, LDMS will determine whether a 9-digit or 10-digit PID must be used.

Field	Required?	Note
ID2 (Protocol)	Required	Special PID checks are enforced if the protocol is `043.0`. For `043.0`, the visit will also be set to `2.0 VST`, and the user will not be able to modify it.
ID3	Depends	This field is disabled for all protocols except `043.0`. It allows up to 12 characters, and should be scanned from the blood ID number.
Visit	Required	Defaults to the **visit unit** of `VST`. Interim, unscheduled visits should be entered by incrementing the visit value (e.g. 1.10 for the first unscheduled visit, 1.20 for the second, etc). If the protocol is `043.0`, the visit will also be set to `2.0 VST`, and the user will not be able to modify it.
OPID	Disabled	
Clinic	Disabled	
Specimen Time	Required	
Received Time	Optional	You will be warned if received time is blank

HVTN (HIV Vaccine Trials Network)

- The HVTN group is listed in LDMS as `VTN`.
- The volume for primaries and aliquots automatically defaults to `ML`.
- The LDMS shipping files are sometimes referred to as the “e-manifest”
- If sending a shipment that contains HVTN specimens, LDMS will prompt you whether you want to print a standard LDMS Shipping Manifest or a SeraCare Shipping Manifest. The LDMS Manifest should be used.
- Barcodes are required to be on labels.
- Preloads are not permitted for HVTN.

Table 10.8. Specimen Management Fields for HVTN

Field	Required?	Note
ID1 (PID)	Required	LDMS checks that the PID is valid. A PID cannot be corrected in LDMS without approval from HVTN laboratory leadership. An LDMS challenge code is required to do this.
ID2 (Protocol)	Required	LDMS checks that the PID and protocol combination are valid.
ID3	Disabled	

Field	Required?	Note
Visit unit	Required	Use the visit unit `VST` for routine HIV diagnostic visits, otherwise use the appropriate visit unit. The visit unit is used by certain laboratories for driving testing algorithms.
OPID	Disabled	
Clinic	Required	The clinic is automatically populated based on the PID; the same clinical location can be associated with multiple clinic IDs (e.g. for Phase I/II or Phase II/III). VTN clinics start with the letter `V` (e.g. `V101` instead of `101`). LDMS will verify that a VTN clinic was selected.
Specimen Time	Required	HVTN requires that laboratories complete the specimen time.
Received Time	Required	

IMPAACT (International Maternal Pediatric Adolescent AIDS Clinical Trials)

- IMPAACT uses the standard LDMS Shipping File format to ship between laboratories using LDMS.
- IMPAACT requires specimens to be labeled with a 2D barcode and label from LDMS; LDMS comes with label formats for IMPAACT setup and ready to use.
- Preloads can be used for IMPAACT but users are not permitted to create them. All IMPAACT preloads are created by Frontier Science in collaboration with network leadership. For more information about preloads, see the section called “Preloads: Templates for Expected Specimen Collections” on page 21.
- ACTG and IMPAACT are listed as a combined group throughout LDMS (i.e. `ACTG/IMPAACT`)

Table 10.9. Specimen Management Fields for IMPAACT

Field	Required?	Note
ID1 (PID)	Required	8 characters long, 7 numbers and one letter between A and L; if the PID does not have 7 numbers, add leading zeros to the front of it.
ID2 (Protocol)	Required	Select from the pre-defined list of protocols.

Field	Required?	Note
ID3 (SID)	Required	Study Identifier; LDMS will remember previously entered SIDs and automatically populate ID3 when the same group-PID-protocol combination is entered. If you do not know the SID or a SID has not yet been assigned, enter `NOSID`. For more information on updating participants entered with NOSID, see the section called “Finding and Modifying Participant Information” on page 59.
Visit	Required	Select from pre-defined list of visit units.
OPID	Available	
Clinic	Required	LDMS will automatically populate the clinic using one previously entered for the same PID, protocol, and SID combination.
Specimen Time	Depends	If you do not have a specimen time recorded on your CRF, contact the clinic that collected the specimen from the participant. This field is required for specimens with a specimen date of 01 January 2004 or later; it is optional for specimens prior to that date. This requirement can be overridden for specimens after this date, if necessary.
Received Time	Optional	

iPrEx (Pre Exposure Prophylaxis Initiative)

Preloads can be utilized for iPrEx. For more information about preloads, see the section called “Preloads: Templates for Expected Specimen Collections” on page 21.

- iPrEx uses the standard LDMS Shipping File format.
- When entering seroconversion specimens, the visit unit of `SC` should be used; the visit week numbering will be the same as the originally scheduled visit.
- When entering sero-positive visits, the visit unit `SP` should be used, and the visit number should be the number of weeks after the seroconversion visit
- `NOPID` cannot be used in conjunction with `NOSID`.

Table 10.10. Specimen Management Fields for iPrEx

Field	Required?	Note
ID1 (PID)	Required	LDMS will check that the PID is valid. `NOPID` may be entered for screening visits, though the original `NOPID` entry should be updated for the participant once a valid PID has been assigned. See the section called "Finding and Modifying Participant Information" on page 59.
ID2 (SID)	Required	Screening ID; LDMS will automatically enter the previously entered SID for a given participant, though this may be overridden. SID is 7 digits long, with the first 2 digits representing the clinic, followed by a 5 digit screening number (e.g. 9080001). When entering specimens for the ESN protocol, NOSID is a valid entry.
ID3 (Protocol)	Required	Select from a pre-defined list.
Visit	Required	The visit defaults to `WK`
OPID	Optional	
Clinic	Required	The clinic is automatically populated based on the PID using the first 2 digits of the PID
Specimen Time	Optional	This field is optional, but recommended.
Received Time	Optional	This field is optional, but recommended.

MACS (Multicenter AIDS Cohort Study)

Preloads can be utilized for MACS. For more information about preloads, see the section called "Preloads: Templates for Expected Specimen Collections" on page 21.

If sending a shipment that contains MACS specimens, LDMS will prompt you whether you want to print a standard LDMS Shipping Manifest or a SeraCare Shipping Manifest. The SeraCare manifest is used to ship specimens to the MACS repository.

Table 10.11. Specimen Management Fields for MACS

Field	Required?	Note
ID1 (MACSID)	Required	MACS Identifier
ID2 (Study)	Required	
ID3	Optional	Previously entered ID3s will be automatically populated by LDMS for the MACSID and study combination
Visit	Optional	Select from pre-defined list of visit units.

Field	Required?	Note
OPID	Optional	
Clinic	Optional	Previously entered clinics will be automatically populated by LDMS for the MACSID and study combination
Specimen Time	Optional	
Received Time	Optional	

MTN (Microbicide Trials Network)

- The primary and aliquot volume will default to `ML`
- There are two MTN label options, one with a barcode and one without.
- Preloads can be utilized for MTN. For more information about preloads, see the section called “Preloads: Templates for Expected Specimen Collections” on page 21.

Table 10.12. Specimen Management Fields for MTN

Field	Required?	Note
ID1 (PID)	Required	9 characters long
ID2 (Protocol)	Required	Select from a pre-populated list
ID3	Disabled	Not used for MTN
Visit	Required	Visit unit defaults to `VST`, but this can be overridden
OPID	Disabled	Not used for MTN
Clinic	Disabled	Not used for MTN
Specimen Time	Optional	This field is not required, but recommended
Received Time	Optional	This field is not required, but recommended

NICHD-WESTAT

NICHD-WESTAT has identical validation and rules to the ACTG/IMPAACT group.

Table 10.13. Specimen Management Fields for NICHD-WESTAT

Field	Required?	Note
ID1 (PID)	Required	8 characters long, 7 numbers and one letter between A and L; if the PID does not have 7 numbers, add leading zeros to the front of it.

Field	Required?	Note
ID2 (Protocol)	Required	Select from the pre-defined list of protocols.
ID3 (SID)	Required	Study Identifier; LDMS will remember previously entered SIDs and automatically populate ID3 when the same group-PID-protocol combination is entered. If you do not know the SID or a SID has not yet been assigned, enter `NOSID`. For more information on updating participants entered with NOSID, see the section called "Finding and Modifying Participant Information" on page 59.
Visit	Required	Select from pre-defined list of visit units.
OPID	Available	
Clinic	Required	LDMS will automatically populate the clinic using one previously entered for the same PID, protocol, and SID combination.
Specimen Time	Depends	If you do not have a specimen time recorded on your CRF, contact the clinic that collected the specimen from the participant. This field is required for specimens with a specimen date of 01 January 2004 or later; it is optional for specimens prior to that date. This requirement can be overridden for specimens after this date, if necessary.
Received Time	Optional	

PHACS (Pediatric HIV/AIDS Cohort Study)

- PHACS uses the standard LDMS Shipping File format
- There are two label options for PHACS, one with a barcode and one without a barcode
- Preloads are permitted for the PHACS group, but users are not permitted to create their own. All PHACS preloads are created by Frontier Science in collaboration with network leadership. For more information about preloads, see the section called "Preloads: Templates for Expected Specimen Collections" on page 21.

Table 10.14. Specimen Management Fields for PHACS

Field	Required?	Note
ID1 (PID)	Required	8 characters long, 7 numbers with a letter at the end

Field	Required?	Note
ID2 (Protocol)	Required	Select from a pre-populated list; all protocols are in the format PHXXX (e.g. PH200).
ID3	N/A	Not used by PHACS
Visit	Required	Select from pre-defined list of visit units.
OPID	Optional	
Clinic	Required	Will automatically populate using the previous clinic for the group, PID, and protocol combination entered; PHACS clinics range between 1 and 24. LDMS will check that a valid clinic was selected.
Specimen Time	Optional	This field is optional, but recommended
Received Time	Optional	This field is optional, but recommended

PHIA (Population-Based HIV Impact Assessments)

- User-defined preloads are not permitted for PHIA.
- LDMS shipping files should be used for shipping to LDMS laboratories; CSV files, for non-LDMS laboratories.
- Only the PHIA barcode label can be used for PHIA specimens.

Table 10.15. Specimen Management Fields for PHACS

Field	Required?	Note
ID1 (PTID)	Required	8 characters long, 2 letters followed by 6 numbers
ID2 (Country)	Required	Select from a pre-populated list of country initials (select a code and press **Ctrl+H** to see the full name of the country). This will typically match the first two characters in the PTID.
ID3 (HIVRT)	Required	Select from list (positive, negative, or indeterminate)
Visit	Required	Select from pre-defined list of visit units.
OPID	Optional	
Clinic	Required	In the format AABBB, where AA is the country code and BBB is the clinic number.
Specimen Time	Optional	This field is optional, but recommended
Received Time	Optional	This field is optional, but recommended

REPRIEVE

REPRIEVE has identical validation and rules to the ACTG/IMPAACT group.

Table 10.16. Specimen Management Fields for REPRIEVE

Field	Required?	Note
ID1 (PID)	Required	8 characters long, 7 numbers and one letter between A and L; if the PID does not have 7 numbers, add leading zeros to the front of it.
ID2 (Protocol)	Required	Select from the pre-defined list of protocols.
ID3 (SID)	Required	Study Identifier; LDMS will remember previously entered SIDs and automatically populate ID3 when the same group-PID-protocol combination is entered. If you do not know the SID or a SID has not yet been assigned, enter `NOSID`. For more information on updating participants entered with NOSID, see the section called “Finding and Modifying Participant Information” on page 59.
Visit	Required	Select from pre-defined list of visit units.
OPID	Available	
Clinic	Required	LDMS will automatically populate the clinic using one previously entered for the same PID, protocol, and SID combination.
Specimen Time	Depends	If you do not have a specimen time recorded on your CRF, contact the clinic that collected the specimen from the participant. This field is required for specimens with a specimen date of 01 January 2004 or later; it is optional for specimens prior to that date. This requirement can be overridden for specimens after this date, if necessary.
Received Time	Optional	

VQA (Virology Quality Assurance)

Preloads can be utilized for VQA. For more information about preloads, see the section called “Preloads: Templates for Expected Specimen Collections” on page 21.

Figure 10.2. VQA PanelID Format

```
AAAPPPSS.YYZ
[Assay category][panel #][panel subtype].[00-99][panel config]

Example
 DNA001RT.01A
```

assay categories: RNA, DNA, CUL (cultures)

panel number: 000 to 999

panel sub-type:

Subtype	Description
UM	Ultrasensitive RNA
SM	Standard RNA
RT	DNA proficiency panel
PQ	DNA pre-qualification panel
CC	Culture panel

2 digit string: 01 to 99

panel configuration: A, B, or C

Table 10.17. Specimen Management Fields for VQA

Field	Required?	Note
ID1 (PanelID)	Required	LDMS will determine if this field is valid based on the logic described in Figure 10.2[a]
ID2	N/A	This field is not used by VQA
ID3	N/A	This field is not used by VQA
Visit	N/A	This field is not used by VQA
OPID	N/A	This field is not used by VQA
Clinic	N/A	This field is not used by VQA
Specimen Time	N/A	This field is not used by VQA
Received Time	N/A	This field is not used by VQA

[a]This validation check is only performed on specimens entered in LDMS Specimen Management; specimens entered using the bulk feature available to specific laboratories, or specimens entered or imported prior to 01-July-2007 will not be validated.

WIHS (Women's Interagency HIV Study)

- If sending a shipment that contains WIHS specimens, LDMS will prompt you whether you want to print a standard LDMS Shipping Manifest or a SeraCare Shipping Manifest. The SeraCare manifest is used to ship specimens to the MACS repository.
- Preloads are available for WIHS, and laboratories are expected to create and use them for entering specimens. For more information about preloads, see the section called "Preloads: Templates for Expected Specimen Collections" on page 21.
- **Spec[imen] Date** and **Rec[eived] Date** are automatically populated using your computer's current system time. For this reason, it is important to verify that your computer's current date and time are correct prior to entering specimens. LDMS automatically prompts users to check their system time whenever LDMS is started.

Figure 10.3. WIHS PID Format

```
SBBPPPPC
[site number][recruitment number][participant number][check digit]
```

site number

Site	Description
1	NYC (Bronx)
2	Brooklyn
3	Washington, D.C.
4	Los Angeles
5	San Francisco
6	Chicago

recruitment number

#	Description
2B	New recruit
0B	Original recruit
1B	Original recruit

check digit: Any character; an algorithm will determine if the character is valid

Table 10.18. Specimen Management Fields for WIHS

Field	Required?	Note
ID1 (PID)	Required	See Figure 10.3
ID2 (Protocol)	Required	Select from pre-populated list
ID3 (SID)	Optional	
Visit	Required	The visit unit will default to `VST`, and the visit number will be automatically populated using on the current date.
OPID	Optional	
Clinic	Optional	
Specimen Time	Optional	
Received Time	Optional	

Chapter 11. Frequently Asked Questions about LDMS

11.1. About LDMS Development and Frontier Science

Q: What is the difference between LDMS and Frontier Science?

A: LDMS is a computer program; Frontier Science is the company that created and maintains LDMS.

Q: Can I request a change or new feature for LDMS?

A: Yes—in fact, many features are added to LDMS specifically at the request of an individual laboratory or group. For more information, see the section called “Getting Help” on page 10.

Q: How often is LDMS Updated?

A: New versions of LDMS are released, several times each year. Small incremental updates, however, are made available to laboratories several times each month. These small updates (sometimes referred to as "deploy files") are downloaded and installed during an export. For more information, see the section called “Exports and Updates” on page 173.

11.2. Administrative Issues

Q: What are the minimum computer requirements for LDMS?

A: For guidance on what hardware to select for using LDMS, see the section called “Computer requirements and recommendations for LDMS” on page 177.

Q: What Operating Systems does LDMS support?

A: LDMS is only compatibly with Microsoft Windows. LDMS is not compatible with Home Editions of Windows, OS X, Linux, or other operating systems at this time. For a list of supported versions, see the section called “Computer requirements and recommendations for LDMS” on page 177.

Q: How much does LDMS cost?

A: The support cost for LDMS varies depending on your laboratory's affiliations. For more information, contact <ldmsinfo@fstrf.org>.

Q: How long are LDMS licenses issued?

A: LDMS licenses are typically issued for up to one year. When the license expires, you will be prompted by LDMS to contact LDMS User Support. The re-licensing process will vary, depending on the research groups with which you are affiliated.

11.3. General LDMS Usage

Q: I received a message telling me to contact LDMS User Support to unlock LDMS. What happened?

A: LDMS is automatically locks under certain conditions. For example, if you recently performed an upgrade or if LDMS shutdown unexpectedly, LDMS will lock. By calling LDMS User Support, this allows them to verify that there are no database problems. Certain features are also locked to users and require approval to access. For more information, see the section called “LDMS and Challenge Passwords” on page 4.

Q: I locked myself out of LDMS on a weekend. How can I unlock LDMS?

A: While LDMS User Support has regular hours, they are available on-call 24-hours a day, every day of the week (including all holidays). See the section called “Getting Help” on page 10.

Q: I made a mistake—does LDMS have an undo button?

A: No. When you make a change in LDMS and save it, that change is permanent. If you made a change to a screen but have no yet saved it, you can sometimes clear you entries by clicking the  button from the LDMS toolbar.

Q: I'm creating a query statement or executing a search, and I see <> listed as an operator. What does this mean?

A: When generating search in LDMS, you often build the search terms independently. For example, you might select

Field	Value
Field	Primary Type
Operator	<>
Value	Blood

The operator <> in this case means "not equal to". In other words, this search will find primaries where the type is not blood. This is Pascal-like syntax, and is used throughout LDMS.

Q: How can I get help on using LDMS?

A: Frontier Science offers a number of resources to LDMS users, including trainings, video tutorials, documentation, and 24-hour user support. You can also request See the section called “Getting Help” on page 10.

11.4. Specimen Management Questions

Q: What is the difference between a *specimen ID* and a *global specimen ID*?

A: While both can be used to identify a specimen, the *global specimen ID* will always be unique for each aliquot. The *global specimen ID* will also show the relationship between primary and aliquot, since they will share a predictable ID number. For more information on these two identifies, see the section called “Specimen Identifiers” on page 12.

Q: How can I ship a primary that hasn't been processed into aliquots?

A: You have two options: use the ambient ship feature or create a single aliquot that is identical to the primary. For instructions on shipping primaries, see the section called “The Primary Grid” on page 17.

Q: We need to correct some specimens that we've already entered into LDMS. How do you make these types of changes?

A: It can vary. Certain groups want LDMS users to make changes for their data one way; other groups will want it done another way. Consult with the data center or group for specific instructions. For general instructions on how to change specimen records in LDMS, see the section called “Correcting a Specimen Entry Error” on page 28.

Q: What do all those letters on the button in the **Details** column mean?

A: They are codes that indicate that certain properties have been set for that specimen row. If you click on that button, you will see a key that explains what each code means.

Q: I have a specimen that was drawn for two different studies. How do I enter this in LDMS?

A: This is referred to as a co-enrolled primary. In the participant grid in the top portion of the Specimen Management screen, enter one enrollment in each row. When you are adding your aliquots, select the appropriate study from the **Group/ID** field in the aliquot grid. For more information, see the section called “The Patient Grid” on page 16.

Q: We have two tubes of blood drawn from a participant with the same additive from the same visit that were collected at the same time, and both tubes were collected at the same time. Since they are essentially identical, can we pool them together in LDMS?

A: Yes. For example, if you have two blood primaries with the same additive, and both tubes are `10 mL`, you can enter one primary with a volume of `20 mL`.

11.5. Shipping Questions

Q: How to I update the shipping information for our laboratory or our shipping contacts?

A: You can request a change to your contact information by using the **Submit Contact Changes** link on the Frontier Science web portal [http://www.fstrf.org/portal]. You can use this tool to view and update contact information for your laboratory.

Q: All of the specimens that I want to ship are in the same box, and I already have their storage location in LDMS. Can I just ship the box?

A: Yes. In fact, many users find this to be the easiest way to setup shipments in LDMS. For instructions, see the section called "Finding Containers to Ship" on page 65.

Q: I marked a storage container for shipment, but it was the wrong container. How do I un-mark it for shipment?

A: In Storage, select the storage unit that you need to un-mark and click the Details button. Now, click the **Unship** button.

Q: I shipped some specimens that were in storage at out laboratory. Those specimens still appear in storage, even though they are no longer in our possession. How can I remove them?

A: There is a special feature in Storage to remove these specimens. See the section called "How LDMS Storage Handles Shipped Specimens" on page 53.

Q: What is the difference between a shipment batch and an export batch?

A: A shipping batch refers to a shipment that has been prepared in LDMS, but you have not yet generated a shipping file to send to another laboratory. An export batch reports to data that has been sent to Frontier Science for groups that utilize Frontier Science as a central data management center.

Q: What does it mean when a shipment has the status **received disk**?

A: A shipment with the status **received disk** means that the shipment was imported from another laboratory.

11.6. Specimen Storage

Q: Our laboratory performs work for a group that requires all specimens to have a storage location documented in LDMS. Is there an easy way to find out what specimens were entered into LDMS using Specimen Management, but not Storage?

A: Yes. LDMS has a built-in report for getting this information. Click button from the LDMS toolbar, and then run the **Specimens Not In Storage** report under the **Storage Reports** category. For more information about finding these specimens, see the section called "Locating Specimens not in Storage" on page 58.

11.7. Labels and Printing

Q: Why do my labels look strange when I create them?

A: LDMS pulls information about paper size directly from the printer's driver when generating the preview of the labels. Since the preview is pulled directly from the printer, the preview should look just like the actual results when you print them. However, if you don't tell LDMS what printer you are using, it will generate labels for the wrong printer. See the section called "Setting the Printer Used to Generate Labels and Reports" on page 153.

Q: Is it possible to print labels in bulk instead of individually (e.g. printing labels for all of the specimens for a particular shipment)?

A: Yes. Use the Labels feature. For instructions, see the section called "Advanced Label Printing" on page 149.

11.8. Assaying Specimens

Q: I've already setup an assay in LDMS to read the output file, but now I see that I missed a specimen when setting it up in LDMS. How do I add another specimen so that LDMS will read the output file correctly?

A: Open the assay run, just as you would to run it. Once you have clicked the Select Assay button, change back to the **Assay Selection** tab. Now, search for the specimens that you need to add. Once this is done, click the Add to Run button and continue to read the assay as normal.

Q: How do I set up the blinded controls on a DNA assay?

A: In Assays, on the **Preview** tab, right-click on the control and select **Modify Control**. For more information see the section called "Roche HIV DNA PCR" on page 100.

Q: How do I add a VQA200 control to an RNA assay run?

A: For instructions on how to do this, see the section called "Abbott Realtime and COBAS TaqMan" on page 90.

Q: When I click the Run Now button to run an assay, I receive the following message: "Please define a default device for each assay." What does this message mean?

A: This message will appear if no assay reader device has been associated with the assay. Without this information, LDMS doesn't know where and how to read your assay. Every assay that reads an input file must have an associated device. For instructions on associating an assay with a device, see the section called "Associating an Assay with a Reader" on page 123.

Q: I'm trying to add a specimen to an assay run. I know that I entered the specimen in LDMS Specimen Management but I don't see it in LDMS Assays. Why can't I find it?

A: To add a specimen to an assay run, you must assign it the assay first; simply adding the specimen to LDMS is not enough. For instructions on assigning assays, see the section called "Assigning Assays to Aliquots" on page 84.

Q: Our laboratory is having trouble adding results for a specific assay to LDMS. What can we do?

A: LDMS User Support or the LDMS Training Team can assist you with specific assays. See the section called "Getting Help" on page 10.

11.9. System Configuration

Q: When configuring users, what does **System Administrator Capabilities** give a user?

A: It allows the user to reset and change passwords for other users, lock out users, delete users, and designate other administrators. Your laboratory must have at least one user with these capabilities. See the section called "Adjusting User Permissions" on page 169.

Chapter 12. LDMS Code Abbreviations

Important Note on Code Availability

New codes are often added to LDMS via deploys that are received during the export process. For this reason, different versions of LDMS (and even different installations of the same version of LDMS) can have a slightly different set of codes available. To view the absolute latest and most up-to-date list of codes available at your laboratory, a special report is available within LDMS:

Procedure 12.1. Generating a list of codes and abbreviations from LDMS

1. Click `TasksReports` from the LDMS menu bar.
2. Select the **Misc** category on the left.
3. Select the desired code list on the right.
4. Click the  button from the LDMS toolbar.

Codes list in this manual may not represent the full list of codes available at your laboratory.

List of codes used in LDMS

The full list of codes that are used in LDMS can be found in the LDMS for the Web User Manual [https://www.fstrf.org/apps/cfmx/apps/ldms/webldmsManual/webhelp/index.html#topics/webldms/codes/r_codes.html].

Assay censor codes

Table 12.1. Abbott user censor codes

Code	Description	Validity	Numeric Value
F	Invalid Control	Invalid	1000000.000000
G	Result less than lower limit of quantification	Valid	0.000100
H	No Result	Invalid	10000000.000000
J	Undetectable	Valid	1.000000
X4	Results greater than upper limit of quantification	Valid, but needs repeat	10000.000000

Table 12.2. COBAS TaqMan HCV assay censor codes

Code	Description	Validity	Numeric Value
G	Result less than lower limit of quantification	Valid	0.0001

Code	Description	Validity	Numeric Value
J	Undetectable	Valid	1
X4	Results greater than upper limit of quantification	Valid	10000
I	QS Invalid	Invalid	100000
F	Invalid Control	Invalid	1000000
H	No Result	Invalid	10000000

Table 12.3. COBAS TaqMan HIV-1 Qual assay censor codes

Code	Description	Validity	Numeric Value
A	0 control not negative	Invalid	1
B	10 control not positive	Invalid	10
C	20 control not positive	Invalid	100
E	Blinded pellet fails validation	Invalid	10000
F	Assay locked	Na	100000
H	No result	Invalid	10000000000
K	Invalid control	Invalid	1000000
L	Low positive control out of range or invalid	Invalid	1E+14
N	Negative control out of range or invalid	Invalid	10000000
O	Run based validity override	Valid	1E+12
P	Insufficient blinded pellets assigned to rack	Invalid	1000000000
Q	Insufficient VQA controls assigned to rack	Invalid	1E+13
R	Re-read	Valid	100000000
S	5 control invalid	Invalid	1E+11

Table 12.4. HIV DNA PCR (Roche Amplicor Detect)

Code	Description	Validity	Numeric Value
A	0 control not negative	Invalid	1
B	10 control not positive	Invalid	10
C	20 control not positive	Invalid	100
D	20 control OD < 2.000	Invalid	1,000
E	Blind pellet invalid	Invalid	10,000
F	Previous runs invalid - assay locked	Descriptive only	100,000
G	Converted from RLMP - Contamination	Invalid	0.010000
H	Converted from RLMP - Clotted	Invalid	1×10^{10}
L	Converted from RLMP - Missing well	Invalid	0.100000

Code	Description	Validity	Numeric Value
M	Converted from RLMP - Out of range controls	Invalid	1,000,000
N	Converted from RLMP - Lipemia	Invalid	10,000,000
O	Converted from RLMP - Lab error	Invalid	1×10^{12}
P	Converted from RLMP - Equipment failure	Invalid	0.001000
Q	Converted from RLMP - QNS	Invalid	1×10^{13}
R	Re-read	Valid Run	100,000,000
T	Converted from RLMP - Prerequisite test failed	Invalid	1×10^{11}
U	Converted from RLMP - Unable to calculate	Invalid	1,000,000,000
W	Converted from RLMP - Material didn’t amplify	Invalid	1×10^{14}
Y	Converted from RLMP - No description available	Invalid	1×10^{15}

Table 12.5. HIV DNA PCR (Roche Amplicor Detect) 1.5

Code	Description	Validity	Numeric Value
A	0 control not negative	Invalid	1
B	10 control not positive	Invalid	10
C	20 control not positive	Invalid	100
D	20 control OD < 2.000	Invalid	1,000
E	Blind pellet invalid	Invalid	10,000
F	Previous runs invalid - assay locked	Descriptive only	100,000
I	Internal Control Invalid	Invalid	1,000,000
R	Re-read	Valid Run	10,000,000

Table 12.6. Reasons why results were not obtained for immunology assays

Code	Description	Numeric Value
A	Wrong Anticoagulant	65804
C	Contamination	65800
E	Tech Error/Lab Error	65801
K	Kit/Reagent Problem	65806
P	Results Reported Under A Different Protocol	65807
S	Quantity Not Sufficient	65802
U	Unsatisfactory Sample	65803
V	Poor Viability	65805

Table 12.7. Immunology user censor codes

Code	Description	Numeric Value
C	Contamination	10,000.000000
E	Tech error/Lab error	100.000000
K	Kit/Reagent problem	100,000.000000
N	Not done	1.000000
R	Not required	10.000000
S	Quantity not sufficient	1,000.000000
V	Poor viability	1,000,000.000000

Table 12.8. NASBA HIV-1 RNA assay censor codes

Code	Description	Validity	Numeric Value
A	Invalid standards - slope negative	Invalid Run	1
B	Controls out of sequence	Invalid Run	10
D	Converted from RLMP - Contamination	Invalid	10,000
E	Converted from RLMP - Poor viability	Invalid	1,000,000
F	Converted from RLMP - Incorrect tube	Invalid	.001
G	Converted from RLMP - QNS	Invalid	.0001
H	Converted from RLMP - Broken tube	Invalid	.00001
I	Invalid specimen	Invalid	100
J	WT < LDL, Undetectable	Valid	1,000
K	Converted from RLMP - No sample received	Valid	1×10^{13}
L	Converted from RLMP - Laboratory accident	Invalid	.01
M	Converted from RLMP - Out of range controls	Invalid	.000001
O	Converted from RLMP - Lab error	Invalid	1×10^{12}
P	Converted from RLMP - Equipment failure	Invalid	.1
Q	Converted from RLMP - Improper/Questionable ID	Invalid	10,000,000
R	Re-read	Valid Run	100,000,000
T	Converted from RLMP - Prerequisite test failed	Invalid	100,000
U	Converted from RLMP - Unable to calculate	Invalid	1,000,000,000
V	Converted from RLMP - Over amplified	Invalid	10,000,000,000

Code	Description	Validity	Numeric Value
W	Converted from RLMP - Material didn’t amplify	Invalid	1×10^{11}
X	Converted from RLMP - Delayed shipment	Invalid	1×10^{14}
Y	Converted from RLMP - Missing well	Invalid	1×10^{15}

Table 12.9. Nuclisens HIV-1 QT assay censor codes

Code	Description
A	Invalid slope
B	Controls out of sequence
I	Invalid specimen
J	WT < LDL, Undetectable
R	Re-read
M	Converted from RLMP - Out of range controls
H	Converted from RLMP - Broken tube
G	Converted from RLMP - QNS
F	Converted from RLMP - Incorrect tube
L	Converted from RLMP - Laboratory accident
P	Converted from RLMP - Equipment failure
D	Converted from RLMP - Contamination
T	Converted from RLMP - Prerequisite test failed
E	Converted from RLMP - Poor viability
Q	Converted from RLMP - Improper/Questionable ID
U	Converted from RLMP - Unable to calculate
V	Converted from RLMP - Over amplified
W	Converted from RLMP - Material didn’t amplify
O	Converted from RLMP - Lab error
K	Converted from RLMP - No sample received
X	Converted from RLMP - Delayed shipment
Y	Converted from RLMP - Missing well

Table 12.10. P24 system censor codes

Code	Description
A	Invalid standards - slope negative
B	VQA standards out of sequence
C	Missing media controls
D	Kit controls out of sequence
R	Re-read

Table 12.11. Pharmacology analyte codes

Code	Description
Boc3007	SCH783007
3TC	Lamivudine
3TCDP	3TC diphosphate
3TCDP-PC	3TC diphosphate choline
3TCDP-PE	3TC diphosphate ethanolamine
3TCMP	3TC monophosphate
3TCTP	3TC triphosphate
6BHC	6 Beta Hydroxycortsol
AAG	Alpha-1 Acid Glycoprotein
ABC	Abacavir
ABC-CARB	Abacavir carboxylate
ABC-GLU	Abacavir glucronide
ABT-267	ABT-267
ABT-333	ABT-333
ABT-450	ABT-450
ACL	Acetyl-Isoniazid
ADF	Adefovir
AL	Artemether-lumefantrine
ALB	Albumin
AML	Amlodipine
AMP/DXAMP	Amphetamine/Dextroamphetamine
APV	Amprenavir
ARM	Artemether
ASV	Asunaprevir
ATV	Atazanavir
Atorvast	Atorvastatin
BCV	Becllabuvir
BDQ	Bedaquiline
BDQ-M2	N-monodesmethyl metabolite of Bedaquiline
BLM	Bleomycin Sulfate
BMS-936559	BMS-936559
BZD	Benznidazole
Boc3004	SCH783004
Boc3005	SCH783005
Boc3006	SCH783006
Boc4128	SCH534128

Code	Description
Boc4129	SCH534129
Bocepvr	Boceprevir
CAB	Cabotegravir
CBVTP	carbovir triphosphate
CLF	Clofazimine
CLQ	Chloroquine
CMS	Colistin Methane Sulfonate
CMS - ColA	ColA metabolite of Colistin Methane Sulfonate
CMS - ColB	ColB metabolite of Colistin Methane Sulfonate
COBI	Cobicistat
CORT	Cortisol
CS	Cycloserine
D4T	Stavudine
DCB	Daclatasvir
DDC	Zalcitabine
DES	Desogestrel
DES - ENG	Etonogestrel metabolite of Desogestrel
DHA	Dihydroartemisinin
DHPG	Ganciclovir
DLT	Diltiazem
DLM	Delamanid
DLM-DM6705	DM6705
DLT- AL	Desacetyldiltiazem metabolite of DLT
DLT- MT	Desmethyldiltiazem metabolite of DLT
DLV	Delavirdine
DMPA	Medroxyprogesterone Acetate
DOX	Doxorubicin (liposomal-encapsulated and free)
DOXOL	Doxorubicinol
DPV	Dapivirine
DRV	Darunavir
DSI	Desipramine
DTG	Dolutegravir
DXAMPS	Dextroamphetamine sulfate
DXM	Dextromethorphan
DXM - DXO	Dextrorphan metabolite of Dextromethorphan
DXMPH	Dexmethylphenidate
E8OH	8-hydroxy efavirenz

Code	Description
EE	Ethinyl Estradiol
EFV	Efavirenz
EMB	Ethambutol HCL
ENF	Enfuvirtide
ET	Etoposide
ETR	Etravirine
EVG	Elvitegravir
FCZ	Fluconazole
FOS	Foscarnet
FTC	Emtricitabine
FTC-TP	Emtricitabine Tri-phosphate
HU	Hydroxyurea
IDV	Indinavir
INH	Isoniazid
IQP-0528	IQP-0528
ISO	Isotretinoin
ISO-4OXO	4-OXO-Isotretinoin Metabolite
ITX 5061	ITX 5061
Ibalzb	Ibalizumab
KAN	Kanamycin
KYN	Kynurenine
LDV	Lepipasvir
LF	Lumefantrine
LF-DBL	Desbutyl Lumefantrine
LPV	Lopinavir
LVF	Levofloxacin
M3	N-didesmethyl metabolite of bedaquiline (TMC207)
M8	NFV Metabolite
MK-3475	MK-3475
MPA	Mycophenolic Acid
MPAF	Free Mycophenolic Acid
MPAG	Mycophenolic Acid Metabolite
MPH	Methylphenidate
MTD	Methadone HCl
MTX	Methotrexate
MVC	Maraviroc
MXF	Moxifloxacin

Code	Description
Minocyclene/Placebo	Minocyclene/Placebo
N-DLV	Delavirdine’s Metabolite
NFV	Nelfinavir
NFX	Nifurtimox
NVP	Nevirapine
OFX	Ofloxacin
OXT	Oxytocin
P4	Progesterone
PA824	PA-824
PAS	aminosalicylic acid
PEG-IFN	Pegylated-Interferon alfa 2b
PLD	Pegylated Liposomal Doxorubicin
PMPA	(9 - [2 - (R) - (phosphonomethoxy)propyl] adenine)
PNU -101603	PNU -101603 metabolite of Sutezolid
STZ	Sutezolid
PTX	Paclitaxel
PZA	Pyrazinamide
PZQ	Praziquantel
PZQ-4OH	4-Hydroxy metabolite of Praziquante
RBT	rifabutin
RFP	rifapentine
RGV	Raltegravir
RMD	Romidepsin
RMP	Rifampicin
RPV	Rilpivirine
RTV	Ritonavir
RUX	Ruxolitinib
RV	Ribavirin
RV-TP	Ribavirin Triphosphate
SOF	Sofosbuvir
SOF-GS-331007	GS-331007 metabolite of SOF
SOF-GS-566500	GS-566500 metabolite of SOF
SQ109	SQ109
SQV	Saquinavir
TFV	Tenofovir
TFVDP	Tenofovir Diphosphate

Code	Description
THA	Thalidomide
TPV	Tipranavir
TRP	Tryptophan
VCR	Vincristine Sulfate
VRC01	VRC-HIVMAB060-00-AB
VCV	Vicriviroc
ZDV	Zidovudine
ZDVDP	Zidovudine diphosphate
ZDVMP	Zidovudine monophosphate
ZDVTP	Zidovudine triphosphate
d4TTP	d4T triphosphate
ddATP	dideoxyadenosine triphosphate
ddI	Didanosine
des RBT	des rifabutin
des RFP	des rifapentine
des RMP	des rifampicin

Table 12.12. Pharmacology system censor codes

Code	Description	Validity	Numeric Value
A	Invalid. Greater than the upper limit, dilute and repeat	Invalid	256
B	Below quantifiable limit	Valid	8
L	Lower limit adjusted up for this run	Valid	1
R	Repeat (with L system censor only)	Invalid	4

Table 12.13. Pharmacology concentration units

Code	Description
%	percentage
FMOL/10^6 CELLS	femtomol per 10^6 cells
FMOL/ML	femtomol per milliliter
FMOLE	femtomol
NG/ML	nanogram per milliliter
NG/SAMPLE	nanogram per sample
NMOL	nanomol
PMOL/10^6 CELLS	picomol per 10^6 cells
PMOLE	picomol
UG/ML	microgram per milliliter
UMOL	micromol

Code	Description
pg/mL	picogram per milliliter

Table 12.14. Pharmacology assay user censor codes

Code	Description	Validity	Numeric Value
B	Below Quantifiable Limit or No Peak	Valid	2048
D	Drug not required to be assayed	Valid[a]	512
O	QC out of range, dilute and repeat	Invalid	4
P	Not Able to Interpret Result	Invalid	8192
S[b]	Quantity not sufficient	Valid	10,000,000
U	Sample Diluted	Valid	1,000,000,000,000
X	Per lab, sample must be repeated	Invalid	1024
Z	No Result, Lab Issue	4096	Invalid

[a]Results removed from final views

[b]This censor code was removed in LDMS version 5.8.1; it can no longer be assigned but is listed here for historical reference.

Table 12.15. Reasons for not running an assay censor codes

Code	Description	Numeric Value
COR	COR Controls Out of Range	10431
CTM	Contaminated	10430
EQF	Equipment Failure	10432
LBA	Laboratory Accident	10434
LBE	Lab Error	10433
MSW	Missing Well	10435
NPA	Sample Drawn Without Participant Adherence to Regimen	10440
OUT	Resulted outside LDMS	10439
PSW	Sample not Drawn Within Protocol Specified Win-dow	10441
QNS	Quantity Not Sufficient	10436
STO	Specimen too old to run on test	10442
WCT	Wrong Controls	10437

Table 12.16. Roche Amplicor HIV Monitor (RT PCR) assay censor codes

Code	Description	Validity	Numeric Value
A	QS wells below lower limit	Invalid	.1
B	QS wells above upper limit	Invalid	.01
C	User re-selected well for algorithm	Valid	.0001
D	OD ratio failure - repeat	Invalid/Invalid Run[a]	1,000,000,000
F	Control out of range	Invalid Run[b]	1,000,000

Code	Description	Validity	Numeric Value
I	No QS wells in range	Invalid	100,000
J	HIV wells below lower limit - no HIV RNA detected	Valid[c]	1
K	HIV wells above upper limit	Invalid	10
L	QS wells out of sequence	Valid with C censor	100
L	HIV wells out of sequence	Valid with C censor	.001
R	Re-read	Valid Run	100,000,000
U	Undetectable sample above cutoff - repeat	Valid[d]	.00001
X2	Invalid standards - slope negative	Invalid Run	1,000
X3	Invalid/Out of sequence control	Invalid Run	10,000,000
X4	Copies greater than upper limit of quantification - dilute and repeat	Valid	10,000

[a]If the run is repeated, the censor will be changed to C

[b]If the F censor is used in conjunction with a D or X3 censor on the same control, it can be re-detected and corrected.

[c]Specimen should be re-tested, if possible

[d]Specimen should be re-tested, if possible

Table 12.17. Roche Amplicor HIV-1 Monitor UltraSensitive assay censor codes

Code	Description	Validity	Numeric Value
A	QS wells below lower limit	Invalid	.1
B	QS wells above upper limit	Invalid	.01
C	User re-selected well for algorithm	Valid	.0001
D	OD ratio failure - repeat	Invalid/Invalid Run[a]	1,000,000,000
F	Control out of range	Invalid Run[b]	1,000,000
I	No QS wells in range	Invalid	100,000
J	HIV wells below lower limit - no HIV RNA detected	Valid[c]	1
K	HIV wells above upper limit	Invalid	10
L	QS wells out of sequence	Valid with C censor	100
L	HIV wells out of sequence	Valid with C censor	.001
R	Re-read	Valid Run	100,000,000
U	Undetectable sample above cutoff - repeat	Valid[d]	.00001
X2	Invalid standards - slope negative	Invalid Run	1,000
X3	Invalid/Out of sequence control	Invalid Run	10,000,000

Code	Description	Validity	Numeric Value
X4	Copies greater than upper limit of quantification - dilute and repeat	Valid	10,000

[a]If the run is repeated, the censor will be changed to C

[b]If the F censor is used in conjunction with a D or X3 censor on the same control, it can be re-detected and corrected.

[c]Specimen should be re-tested, if possible

[d]Specimen should be re-tested, if possible

Table 12.18. Roche COBAS Amplicor HIV-1 MONITOR assay censor codes

Code	Description	Validity	Numeric Value
F	Invalid Control	Invalid	1,000,000
G	Copies less than lower limit of quantification	Valid	0.0001
I	No QS wells in range	Invalid	100,000
J	Undetectable	Valid	1
K	wells out of range	Invalid	10
L	HIV wells out of sequence	Invalid	0.001
L	QS wells out of sequence	Invalid	100
R	Re-Read		
X3	Invalid/Out of sequence control		
X4	Copies greater than upper limit of quantification	Valid, but needs repeat	10,000

Table 12.19. Roche COBAS Amplicor HIV-1 MONITOR Test, UltraSensitive

Code	Description	Validity	Numeric Value
F	Invalid Control	Invalid	1,000,000
G	Copies less than lower limit of quantification	Valid	0.0001
I	No QS wells in range	Invalid	100,000
J	Undetectable	Valid	1
K	wells out of range	Invalid	10
L	HIV wells out of sequence	Invalid	0.001
L	QS wells out of sequence	Invalid	100
R	Re-Read		
X3	Invalid/Out of sequence control		
X4	Copies greater than upper limit of quantification	Valid, but needs repeat	10,000

Table 12.20. Roche COBAS Ampliprep/COBAS TaqMan HIV-1 assay censor codes

Code	Description	Validity	Numeric Value
G	Result less than lower limit of quantification	Valid	0.000100
J	Undetectable	Valid	1.000000

Code	Description	Validity	Numeric Value
X4	Results greater than upper limit of quantification	Valid, but needs repeat	10000.000000
I	No QS wells in range	Invalid	100000.000000
F	Invalid control	Invalid	1000000.000000
H	No Result	Invalid	10000000.000000

Table 12.21. Virology user censor codes

Code	Description	Validity	Numeric Value
B1	BOOM extraction used	Valid	100
C	Control re-run and valid - assay is valid	Valid	1,000
D	Contamination	Invalid	10,000
E	Poor viability	Invalid	1,000,000
K	Kit/Reagent Problem	Invalid	1
O	Lab error/Lab accident	Invalid	100,000,000
P	Equipment failure	Invalid	0.1
Q	Kit QC out of range - repeat	Invalid	10
R	Re-detected	Valid	1,000,000,000,000
V	Over amplified	Invalid	10,000,000
W	Inhibitory/Material didn’t amplify	Invalid	100,000
Z	Per lab - Do not use	Invalid	0.001

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Glossary

aliquot
: A smaller specimen derived from a primary, used for testing purposes; the basic specimen unit used throughout LDMS

ambient shipment
: A primary that is marked as shipped in Speicmen Management, but is not shipped as part of a batch in LDMS

anonymization
: The process of creating new aliquots from existing specimens that are stripped of potentially identifying information like clinic ID and visit date, for use in blinded studies

batch
: A shipment that has been prepared in LDMS to be shipped to another laboratory

blinded control
: A control specimen that is added to an assay in which the user does not know the expected results

censor
: A special flag applied to an assay run's results that indicates an issue with the results
See Also system censor, user censor.

client
: In LDMS, a computer with LDMS installed that accesses the shared LDMS database of an LDMS server
See Also server.

configuration
: (in LDMS Storage) a definition for a storage unit, such as a freezer or box, so that more than one of that type of storage unit can be created and used.

container
: The smallest storage unit in LDMS, such as a box; holds individual specimens

culture derivative
: A culture harvest that the user has stored as an aliquot in LDMS and can be viewed, shipped, etc like any other specimen

deploy
: An update containing new specimen codes, new deploys, etc that is received by a laboratory during the export process

expected value
: The results that a user expects to receive from a control on an assay run

export
: Sending some data from your laboratory's local LDMS database to Frontier Science; what data is sent varies by network (internal groups are not exported)

fill order
: The method that LDMS will use to add specimens to a container, such as filling from left-to-right, then from top-to-bottom
See Also sort order.

freezer
: The largest storage unit in LDMS, such as a refridgerator or freezer

ghost aliquot
: An aliquot create with the exact specimen type and volume of its primary for the sole purpose of shipping a primary that was not processed into aliquots

global specimen ID
: A unique ID that is assigned to each primary and aliquot in LDMS

internal group
: A group that is created locally at your laboratory and is not present in other laboratories' databases; internal group information is never exported but can be shipped

laboratory ID
: A unique, 3-digit number assigned to every laboratory that uses LDMS that uniquely identifies that laboratory

level
: An intermediate storage unit in LDMS, such as a shelf in a freezer, which can contain sub-levels or containers
See Also container, freezer.

manifest
: A list of a shipment's contents, printed and packaged with a shipment of specimens

marked
: A storage unit (or specimen) in LDMS that has been flagged by the user with the intent to ship it

OPID
: See other participant identifier.

other participant identifier
: An identifier for participants in LDMS that has no logical checks or rules; laboratories can use this field as needed

other specimen ID
: An identifier that can be assigned to primaries and aliquots in LDMS that has no logical checks or rules; laboratories can use this field as needed

participant
: A person who participants in a study and has an associated PID

participant identifier
: A unique number assigned to every study participant within LDMS

patient
: See participant.

personal identifying information
: Information, such as an address or birth date, that can be used to link a record to an actual person

PID
: See participant identifier.

primary
: The specimen that the clinician collects from a patient and is made into aliquots

protected health information
: Health information that is protected by HIPPA

QA/QC
: In LDMS, the process of reviewing a specimen shipment before it is sent and when it was received to make certain that the physical specimens match what is in the shipping file

Retrovirus Laboratory Management Program
: A legacy laboratory management platform; many laboratories migrated from this platform to LDMS and as a result there are some features implemented to ease database migration.

server
: In LDMS, an LDMS computer that shares its database to other computers using LDMS on the same local network
See Also client.

ship
: In LDMS, to create a shipping file that contains specimen information, which can then be sent to a receiving laboratory where the file can be imported and the specimens added to the receiving laboratory's LDMS database

sort order
: The method that LDMS will use to sort specimens in a container, such as by specimen ID or by network
See Also fill order.

specimen ID
: An identifier assigned to every specimen, which is not necessarily unique
See Also global specimen ID.

study identifier
: A unique identification number assigned to a study, also known as a protocol number

system censor
: A censor code applied to an assay run's results automatically by LDMS to indicate an issue with the results; these censors cannot be removed by the user
See Also user censor.

terminate
: In LDMS, to review and approve the results of a culture, typically coinciding with the physical termination and destruction of the culture

thaw count
: The number of times that the specimen has been removed from storage and thawed; can be viewed in the Aliquot Details window in Specimen Management

transaction
: (in LDMS Storage) a record of a change within storage, such as a specimen being

added or moved, that can be saved for audit purposes.

user censor
: A censor code applied to an assay run's results manually by the user to indicate an issue with the results
See Also system censor.

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