

## IQA Cryopreservation Panel Procedure

This document describes how to complete the IQA Cryopreservation and Viability Panel in the LDMS. It is divided into two sections, sending labs and IQA lab. Please follow the instructions below. For additional assistance, please call LDMS User Support at 716-834-0900 x7311 or via e-mail at [ldmshelp@fstrf.org](mailto:ldmshelp@fstrf.org).

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## **Sending Labs**

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The immunology sending labs are required to perform four steps in the LDMS when preparing the IQA specimens:

1. Log the specimen(s) into the Specimen Management module and assign the Cryopreservation Assay in Test Setup to each aliquot.
2. Generate labels for IQA aliquots.
3. Result the IQA aliquots in the IQA Cryopreservation and Viability Data Entry Screen in the Assay module.
4. Ship the IQA aliquots to the IQA lab using the Shipping module.

The remainder of the document provides a description of the various modules in the LDMS that must be utilized to complete the above steps.

## Specimen Management Module

### Entering IQA Specimens

To open the Specimen Management module, go to **Tasks – Specimen Mgt** on the menu bar or click on the **Specimen Management** button on the LDMS toolbar. The Entry Tab displays.

The screenshot shows the 'Entry' tab of the Specimen Management module. It includes a 'Find OPID' field with a 'Load' button. Below this is a table with columns: Group, TYPE1, ID1, TYPE2, ID2, TYPE3, ID3, Visit, Unit, OPID, CLINIC, and Detail. The first row is populated with 'IQA', 'ID1', '99001', 'ID2', and 'ID3'. Below the table are input fields for 'Spec. Date' (12/Dec/2007), 'Rec. Date' (12/Dec/2007), 'Exp. Date' (0), 'Recd Time', 'Export ID', 'Remote', 'Imported', 'Import date', 'VQA', 'Culture Derivative', and 'Enter Specimen ID'. There are also fields for '# of Tubes' (0), 'Primary Type' (BLD), 'Blood (Whole)', 'Other Spec ID', and 'Spec. Time'. Below these are two more tables. The first table has columns: Specimen #, Global Spec ID, Primary, Additive, Volume, Units, Spec Time, Time, Time Unit, Cond, Other Spec Id, and Details. The second table is for 'Aliquots' and has columns: Specimen, Global Spec ID, Primary, Add, Der, Sub Add/Der, Volume, Units, Cond, Other Spec Id, Group/ID, and Details. The primary table has one row with specimen 500V07000013. The aliquots table has four rows with specimens 500V07000014.

1. Select **IQA** from the **Group** box.
2. Enter the donor number or PID in the **ID1** field.
3. Select the specimen and received dates from the **Spec. Date** and **Rec. Date** boxes.

Note: Use the Current Date for this exercise.

4. Enter the following information above the primary grid:
  - # of tubes = 1
  - Primary Type = BLD
5. Click **Add**. The primary loads in the grid.
6. Enter the following into the primary grid:
  - Additive = ACD, EDT or HEP
  - Volume = 20
  - Units = ML
7. Click on the Primary Details button. Enter the Processing Date, Processing Time, Processed by Tech Inits, and Total Cell Count.
8. Enter the following information above the aliquot grid:


- # of Aliquots = 4
- Vol = 5
- Units = CEL
- Derivative = CEL

**Note:** By entering the units of CEL, the LDMS will automatically multiply the volume by one million.

9. Click **Add**. The aliquots load into the grid.

10. Click on the **Aliquot Details** button. Enter the processing information for each aliquot.

**Note:** If you are resulting and shipping these aliquots to the IQA real-time you can utilize the Do Not Store feature. This will prevent the aliquots from appearing in your bulk add list in storage. These aliquots will also appear highlighted in red in the Shipping module so that you can easily identify those that have been set aside to ship. Refer to the Specimen Management chapter of the LDMS User Manual for additional information.

11. Click the **Add**  button on the LDMS toolbar. The Save Successful message box will appear.

**Note:** If entering specimens for a patient or donor that has not been entered in your labs database, an Enroll dialog box will appear. Click **Enroll** to add the record to the database.

12. Click **OK**. A Label Dialog box will appear asking if you would like to generate labels.

13. If you wish to print labels for the aliquots that were just added, select the IQA format from the box, select the label size from the list, and click **Yes**.

**Note:** To print labels for more aliquots than those on the Entry screen, refer to the Generating Labels for IQA section on page 3.

## Ordering the Cryopreservation Assay via Assign Tests

1. Enter the **Assign Tests** module via the **Tools** listing on the LDMS Toolbar.

Display field categories:  Shipping  Specimen  Storage

Available Criteria (Drag to selection box to add)

Field	Long Description	Category
Prot/ID2	Prot/ID2	Specimen
Protocol Type	ACTG protocol type (Adult/Ped)	Specimen
Received Date	Date specimen was received	Specimen
Received Time	Time specimen was received	Specimen
SID/ID3	SID/ID3	Specimen
Specimen Date	Specimen draw date	Specimen
Specimen ID	Identifier for an aliquot or primary specimen.	Specimen
Specimen Time	Specimen draw time	Specimen

Selection Criteria

	Field	Op	Value
1	Group	=	IQA
2	Specimen Date	=	27/Jan/2012

Criteria Sentence:

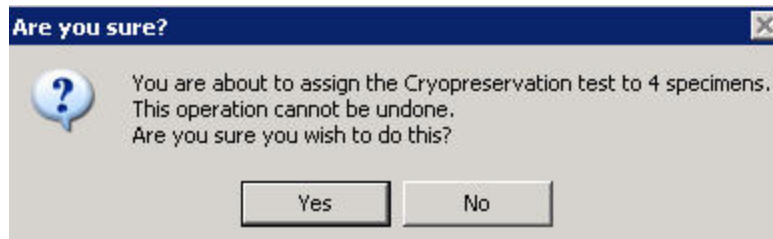
Select samples Load From File

	Global Spec ID	Group	PID/ID1	Primary	Additive	Derivative	Volume	Vol Units
1	A9S00673-01	IQA	123456	BLD	EDT	CEL	500000	CEL
2	A9S00673-02	IQA	123456	BLD	EDT	CEL	500000	CEL
3	A9S00673-03	IQA	123456	BLD	EDT	CEL	500000	CEL
4	A9S00673-04	IQA	123456	BLD	EDT	CEL	500000	CEL

Select a test Frequently Used Tests  Assign Selected Test

Category	Test Descr.	Min. Vol.	Units	Replicates
+ Cultures				
+ DNA PCR				
+ Immunology				
+ Misc.				
+ P24 Antigen				
+ PK Assays				
+ Viral Load RNA				

2. **Click** to select the **Specimen** field category.
3. Add the following data items to the Selection Criteria:
  - Group = IQA
  - Specimen Date = Current Date
4. **Execute** to populate the Select Samples grid.
5. Highlight the four specimens.
6. **Click** on the **+ sign** next to **Immunology** and highlight **Cryopreservation**.
7. Click **Assign Selected Test**. A message box appears.



8. Click **Yes**. The **Success** message appears.

## Labels Module

### Generating Labels for IQA

Group: **IQA Immunology Quality Assurance** Format: **IQA Barcode** Barcode Content: **LDMS Standard**

Description	Max Rows
Laser Label 12	7
Laser Label 13	7
Laser Label 14	7
Barcode Label 1	8
Barcode Label 2	8
Barcode Label 3	8
Barcode Label 6	6
Barcode Label 7	7
Barcode Label 9	7
Barcode Label 10	6
Barcode Label 11	6
Barcode Label 12	6
Barcode Label 13	6
Barcode Label 14	4
Barcode Label 15	7
Barcode Label 16	7

Culture Label

Alignment

Label Manufacturer

Skip:

Data Item	Length	Row	Col
<input checked="" type="checkbox"/> Additive	3	5	2
<input type="checkbox"/> Clinic ID	6		
<input checked="" type="checkbox"/> Derivative	3	5	3
<input checked="" type="checkbox"/> Global Spec ID	11	2	1
<input type="checkbox"/> Group	15		
<input type="checkbox"/> Harvest Date	10		
<input checked="" type="checkbox"/> ID 1 (PID)	9	3	1
<input type="checkbox"/> ID 2 (Protocol)	6		
<input checked="" type="checkbox"/> ID 3 (SID)	15	3	2
<input type="checkbox"/> OPID	15		
<input type="checkbox"/> Other Specimen ID	15		
<input checked="" type="checkbox"/> Primary	3	5	1
<input type="checkbox"/> Received Batch No.	8		
<input type="checkbox"/> Received Date	10		
<input type="checkbox"/> Ship Batch No.	8		
<input checked="" type="checkbox"/> Spec Date	10	4	1

Search From a File

Global Specimen


Search Criteria

Field:  Add

Operator:  Modify

Value:  Delete

Field	Operator	Value
1 Received Date	=	20120127

1. In the Labels module, select **IQA** from the **Group** box, the appropriate format from the **Format** box, and the appropriate **label size** from the grid.
2. Enter the **Received Date** in the **Field** box and the current date in **Value**. Click **Add** to populate the search criteria grid.
3. Click the **Execute**  button on the LDMS toolbar.
4. Click the **Print** button on the Report toolbar.


Below is an example of an IQA label created in the LDMS:



## Assay Module

Prior to shipping the samples to the IQA lab, each aliquot must be resulted in the Assay module.

### Completing the Cryopreservation Data Entry Screen

To open the Assays module, go to **Tasks – Assays** on the menu bar or click the **Assay**  button on the LDMS toolbar.

Run ID	Run Date	Time	Description
Previous Runs Found (Empty)			

Field	Operator	Value
1 Received Date	=	27/Jan/2012

Group	ID1	Specid	Global Spec ID	Spec. Date	ID2	Prim	Derv	Add	Received Date	VID	VID Unit	Harvest Date	Culture Tv
1	IQA	123456	332V12000008	A9S00673-01	27/Jan/2012	BLD	CEL	EDT	27/Jan/2012	0.00			
2	IQA	123456	332V12000008	A9S00673-02	27/Jan/2012	BLD	CEL	EDT	27/Jan/2012	0.00			
3	IQA	123456	332V12000008	A9S00673-03	27/Jan/2012	BLD	CEL	EDT	27/Jan/2012	0.00			
4	IQA	123456	332V12000008	A9S00673-04	27/Jan/2012	BLD	CEL	EDT	27/Jan/2012	0.00			

To complete the Cryopreservation Data Entry screen:

1. Click the **plus (+)** sign next to the **Immunology** category.
2. Click **Cryopreservation**.
3. Click **New Run/Not Setup**.
4. Click **Select Assay**.
5. Enter the specimen **Received Date** in the **From** box, or create a query statement in the **Filters/Criteria** tab.
 

**Note:** You may generate a pending specimen report from the **Filters/Criteria** tab by clicking the **Report** button on the LDMS toolbar.
6. Click **Find Specimens**. The **Specimens Found** grid populates with specimens.
7. Select the IQA aliquots to be resulted and click **Add to Run**. The **Results** tab opens.

Assay Selection				Preview				Results			
Group	TYPE1	ID1	TYPE2	ID2	TYPE3	ID3	Visit	Unit	OPID	CLINIC	
1	IQA	ID1	123456	ID2	ID3						

Specimen Type:  
 Spec ID: 332V12000008    Global Spec ID: A9S00673-03    Spec Date: 27/JAN/2012    Run ID: 12854    Primary: BLD    Additive: EDT    Derivative: CEL    Sub A/D: N/A

Were Results obtained on this specimen?     Yes     No    Specify reason: \_\_\_\_\_

Indicate HIV Status:    Positive

What was the date of blood separation?    27/Jan/2012

Indicate original volume of the specimen drawn:    20 ml

What was the total cell yield of the specimen after separation:    40 × 10<sup>6</sup>

Indicate the viability of the specimen before freezing:    99 %

What was the date the specimen was frozen:    27/Jan/2012

Indicate the number of vials frozen:    4

Total viable cell count per vial:    5000000



Method for obtaining cell counts:     Manual     Automatic

Indicate the volume per vial:    0.5 ml    Assay Tech: MWC    Data Entered by: MWC

Indicate the most current CD4 absolute number:    157 mm<sup>3</sup>

Indicate the viral load:    7420 copies/ml

Notes:            The Viral Load field is optional. The CD4 field is optional, even for positive HIV status.

8. Enter data or select responses for each of the fields.
9. Click the **Add**  button on the LDMS toolbar to save the record.
10. Click the **Report**  button on the LDMS toolbar to print a patient report.
11. Use the VCR buttons to scroll to the next record to result.
12. Repeat steps 8–11 for the remaining samples.



## Shipping Module



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Once the aliquots have been resulted in the Assay module, the last step is to create a Shipping diskette and Manifest Report to send with the frozen aliquots to the IQA lab.

### Creating a Shipping Diskette and Manifest Report

To open the Shipping module, go to **Tasks – Shipping** on the menu bar or click the **Shipping**  button on the toolbar.

To create a shipping diskette and Manifest Report:

1. Click the **Setup Shipment** tab to search for your samples.
2. Select **IQA** from the **Group** box.
3. Select **Received Date** from the **Type** box and enter the received date into the **ID** box.
4. Click the arrow button to move the criteria into the query grid.
5. Click the **Execute**  button on the LDMS toolbar.
6. Select two aliquots from each blood donor by clicking on the rows to highlight them.  
**Note:** Aliquots that were marked as Do Not Store in the Specimen Management module will be highlighted in red.
7. Click the Shipment Destination tab and select **213 Immunology Quality Assessment Center** from the **Lab** box.
8. Select a contact from the **Contact Person** box.
9. Select a contact from the **Contact @ Sending Lab** box.
10. Click the **Add**  button on the LDMS toolbar to batch the shipment.
11. In the View Shipment screen, select your batch and click **Manifest Report**. If applicable, print the Box Map Report.
12. Click on the Shipment QA/QC tab to perform QA/QC on the batch to be shipped.
13. QA/QC the shipment via barcode scanning or visual inspection. Click on the **Save** button on the LDMS toolbar.
14. Click on the View Shipment tab, select your batch, and select LDMS Shipping Batch from the **Shipment Type** box.
15. Click on the **Ship** button.
16. Click **OK** to continue or **Cancel** to view the Storage Report. A message box appears.
17. Click **Yes** to ship the batch.
18. Select the Shipping Box temperature and click **OK**.
19. Select your disk drive and click **OK**.
20. The success message appears.
21. Click **OK** and note the shipping batch number.

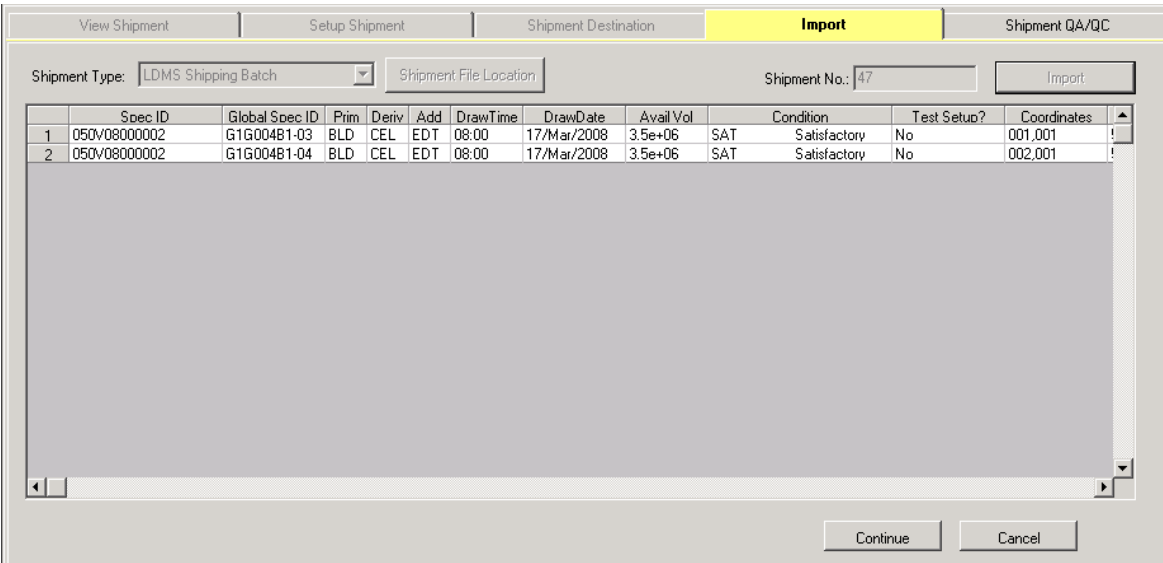
## For the IQA Laboratory (213) only

The IQA receiving lab is required to perform three steps in the LDMS when receiving the IQA specimens:

1. Import the IQA aliquots into the LDMS using the Shipping module.
2. Result the IQA aliquots in the IQA Cryopreservation and Viability Data Entry Screen in the Assay module.
3. Delete extra aliquots from the Pending list.

### Shipping Module: Importing IQA Samples

To open the Shipping module, go to **Tasks – Shipping** on the menu bar or click the **Shipping**  button on the LDMS toolbar.



	Spec ID	Global Spec ID	Prim	Deriv	Add	DrawTime	DrawDate	Avail Vol	Condition	Test Setup?	Coordinates	
1	050V08000002	G1G004B1-03	BLD	CEL	EDT	08:00	17/Mar/2008	3.5e+06	SAT	Satisfactory	No	001,001
2	050V08000002	G1G004B1-04	BLD	CEL	EDT	08:00	17/Mar/2008	3.5e+06	SAT	Satisfactory	No	002,001

To import IQA samples:

1. Click the **Import** tab.
2. Select LDMS Shipping Batch from the **Shipment Type** box.
3. Click **Shipment File Location**.
4. Select a drive on your PC.
5. Click **OK**.
6. Enter the batch number from the Shipping Manifest in the **Shipment No.** field.
7. Click **Import**. The shipping batch information will load into the grid.
8. Click on the Shipment QA/QC tab to perform QA/QC on the batch to be imported.
9. QA/QC the shipment via barcode scanning or visual inspection.
10. Click the Import tab.
11. Click **Continue**. A message box appears.

12. Click **OK** to continue with the import or click **Cancel** to abort the import.

If you would like the aliquots never to appear in the bulk add list of the Storage module, click **Yes** on the message box. If you want the specimens to appear in the bulk add list, click **No** on the message box.

If the condition of the samples is something other than what appears in the import screen, click **Yes** on the message box. The Adjust Conditions dialog box appears.

13. Select the aliquots that should be changed by clicking on each, select the new sample condition from the box, and click **OK**. If the condition of the aliquots are satisfactory, click **No**. The Success dialog box appears.

14. Click **YES** to import the associated test (Assay) information.

15. **Select** the appropriate temperature for the shipment and click **OK**.

16. Click **OK**. The Shipping Batch message box appears.

17. Click **OK** in the dialog box that displays the importing process was completed successfully.

18. Click **OK** to acknowledge the Shipment/Batch number.


19. A message will appear indicating that the Storage module must be run separately for the imported specimens.

20. Click **OK** to complete the import process.

**Note:** Your imported IQA samples will automatically show up in Specimen Management with the imported box checked, the imported date, the Cryopreservation test ordered and the sending labs results available in the Assay Module.

## Assay Module: Completing the Cryopreservation Data Entry Screen

After the samples have been imported and tested, you must enter the results for each aliquot in the Assay module.

To open the Assay module, go to **Tasks – Assay** on the menu bar or click on the **Assay** () button on the LDMS toolbar.

To complete the Cryopreservation data entry screen:

1. Click on the plus (+) sign next to the Immunology category.
2. Click **Cryopreservation**.
3. Click **New Run/Not Setup**.
4. Click **Select Assay**
5. Enter search criteria in the specimen search grid.
6. Verify that the **IQA Review** check box is selected (by default it will be selected) and click **Find Specimens**. The specimens found grid will populate with specimens meeting the above entered search criteria.
7. Select specimens to add to the run.
8. Click **Add to Run**.

Group	TYPE1	ID1	TYPE2	ID2	TYPE3	ID3	Visit	Unit	OPID	CLINIC
1	IQA	ID1	99003	ID2	A5146	ID3	NOSID	24	Wk	1002

Specimen Type: \_\_\_\_\_

Spec ID: 500V05001587    Global Spec ID: CEQ003Z7-01    Spec Date: 15/JUN/2005    Run ID: 12410    Primary: BLD    Additive: ACD    Derivative: CEL    Sub A/D: N/A

Were Results obtained on this specimen?  Yes  No    Specify reason: \_\_\_\_\_

Indicate HIV Status:

What was the date of blood separation?

Indicate original volume of the specimen drawn:  ml

What was the total cell yield of the specimen after separation:  × 10<sup>(6)</sup>

Indicate the viability of the specimen before freezing:  %

What was the date the specimen was frozen:

Indicate the number of vials frozen:

Total viable cell count per vial:

Method for obtaining cell counts:  Manual  Automatic

Indicate the volume per vial:  ml

Indicate the most current CD4 absolute number:  mm<sup>3</sup>

Indicate the viral load:  copies/ml

Date specimen Thawed:

Indicate the viability of the sample after thawing:  %

Indicate the total viable cell count:  × 10<sup>(6)</sup>

What is the viable cell recovery:  %

Comments:

Data Entered by:

Assay Tech:     Data Entered by:

9. Enter data or select responses for each of the fields on the Result screen.

**Note:** The left side of the result screen displays the sending lab's specimen information. These fields are grayed out and the results cannot be changed.

10. Click the **Save**  button on the LDMS toolbar to save the record.

11. Click the **Report**  button on the LDMS toolbar to print a patient report.


12. Use the VCR buttons to scroll to the next record to result.

13. Repeat steps 9–11 for all remaining samples.

## Specimen Management Module: Deleting Extra Aliquots from the Pending List

After the IQA lab's results have been entered for each aliquot tested, there may be extra aliquots that have been sent and have been ordered for the Cryopreservation Assay. To remove the aliquots from the pending list you must delete the test from the Test Setup tab in the Specimen Management module.

To open the Specimen Management module, go to **Tasks – Specimen Mgt** on the menu bar or click on the **Specimen Management**  button on the LDMS toolbar.

1. Click the **Browse**  button on the LDMS toolbar.
2. Type in the specimen number of the aliquot.
3. Click **Run** and click on a row to highlight a specimen and then click **Select**.
4. Highlight the specimen in the aliquot grid.
5. Right-click on the highlighted aliquot and select **Test Setup** from the menu.
6. From the Test Setup screen, highlight the Cryopreservation test in the Test Setup grid and click **Delete**. The Delete Test message box appears.
7. Click **Yes**.
8. Click **Done** on the Test Setup screen to return to the Specimen Management screen.

**Note:** Deleting the test will not remove the specimen record from the LDMS Specimen Management module