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.

Sending Labs

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

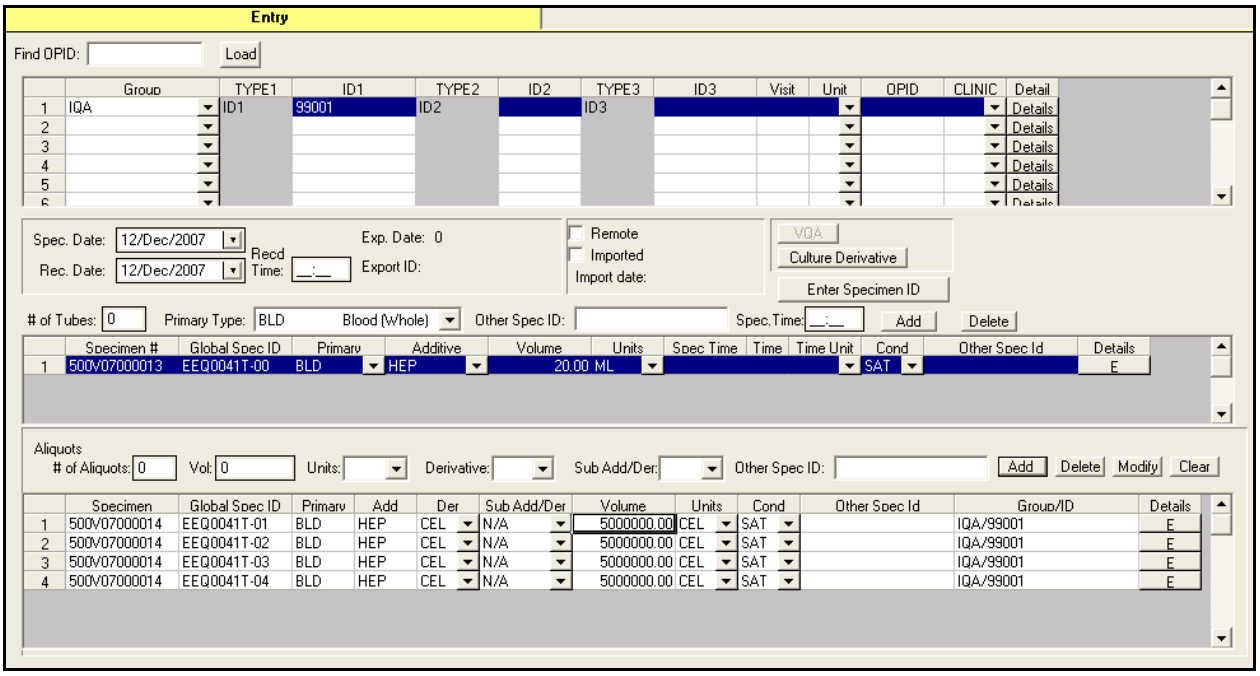
1. Log the specimen(s) into the Specimen Management module and assign the Cryopreservation Assay in Test Setup to each aliquot.
2. Generate labels for IQA aliquots.
3. Result the IQA aliquots in the IQA Cryopreservation and Viability Data Entry Screen in the Assay module.
4. Ship the IQA aliquots to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



To enter IQA specimens:

1. Select **IQA** from the **Group** box.
2. Enter the donor number or PID in the **ID1** field.
3. Enter your labs network affiliation/processing method in the **ID3** field.
    a. For example, a laboratory processing PBMC's for the IPREX network would enter "IPREX" in the ID3 field.
4. Select the specimen and received dates from the **Spec. Date** and **Rec. Date** boxes.
5. Note: Use the Current Date for this exercise.
6. Enter the following information above the primary grid:
    - # of tubes = 1
    - Primary Type = BLD
7. Click **Add**. The primary loads in the grid.
8. Enter the following into the primary grid:
    - Additive = ACD, EDT or HEP
    - Volume = 20
    - Units = ML
9. Click on the **Primary Details** button. Enter the **Processing Date, Processing Time, Processed by Tech Inits,** and **Total Cell Count.**
10. 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.

11. Click **Add**. The aliquots load into the grid.
12. 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.

13. 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.

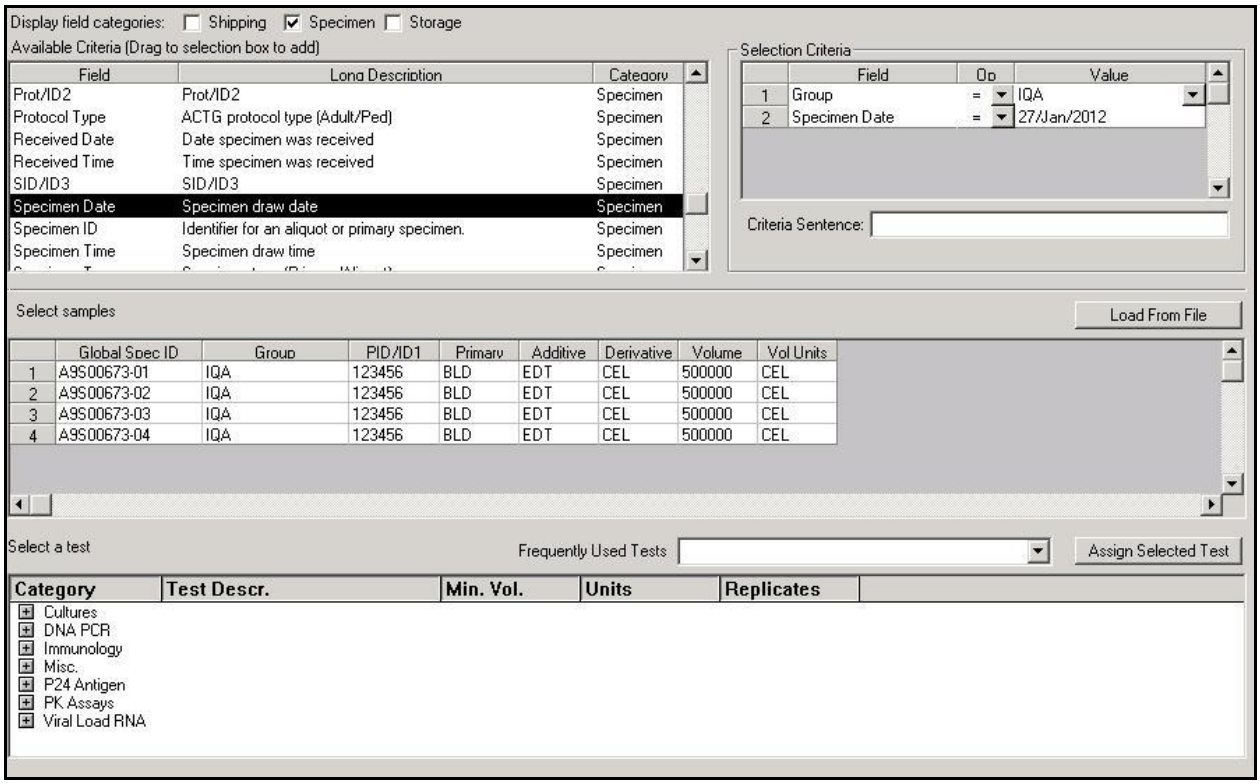
14. Click **OK**. A Label Dialog box will appear asking if you would like to generate labels.

15. 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**.

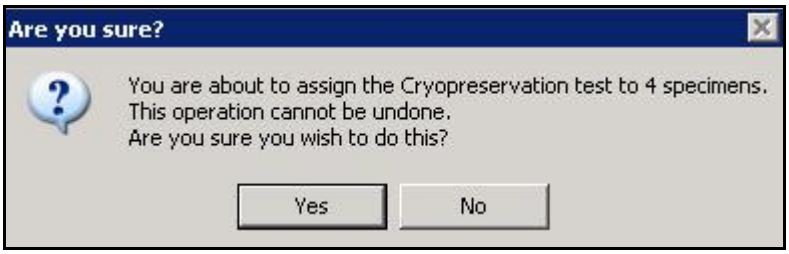
Note: To print labels for more aliquots than those on the Entry screen, refer to the Generating Labels for IQA section on page 3.

Ordering the Cryopreservation Assay via Assign Tests

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



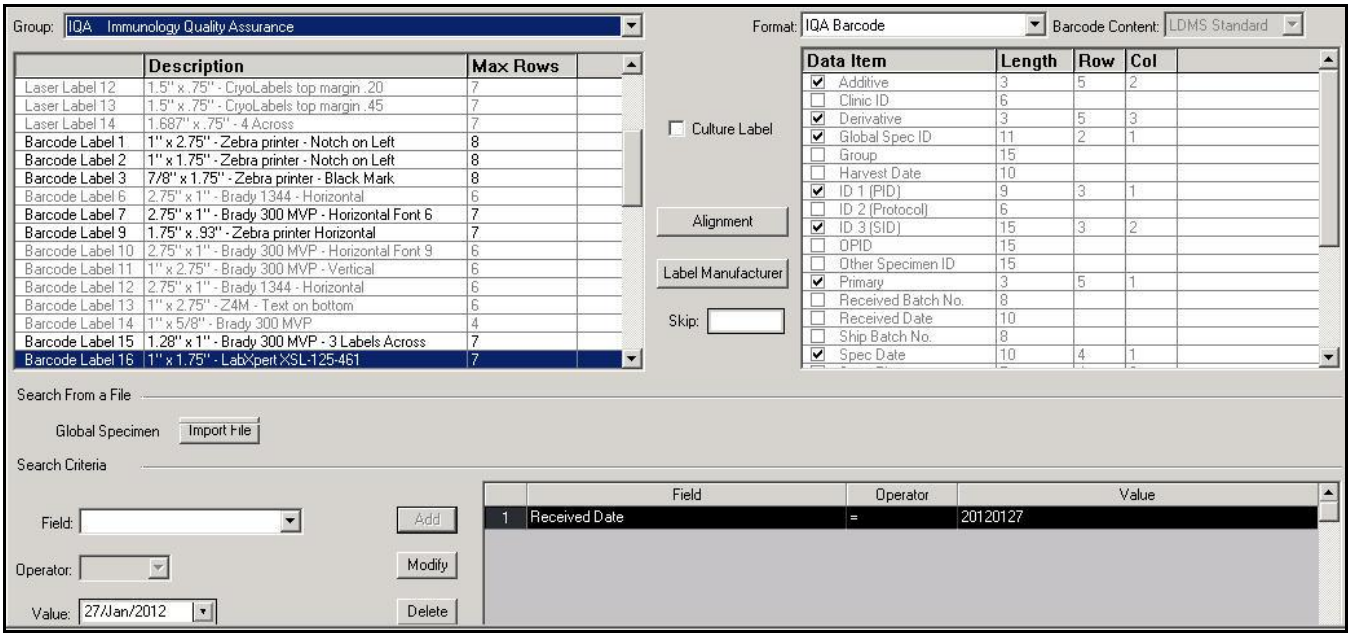
2. **Click** to select the **Specimen** field category.
3. Add the following data items to the Selection Criteria:
   - **Group = IQA**
   - **Specimen Date = Current Date**
4. **Execute** to populate the Select Samples grid.
5. Highlight the four specimens.
6. **Click** on the **+ sign** next to **Immunology** 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



To generate IQA labels:

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:

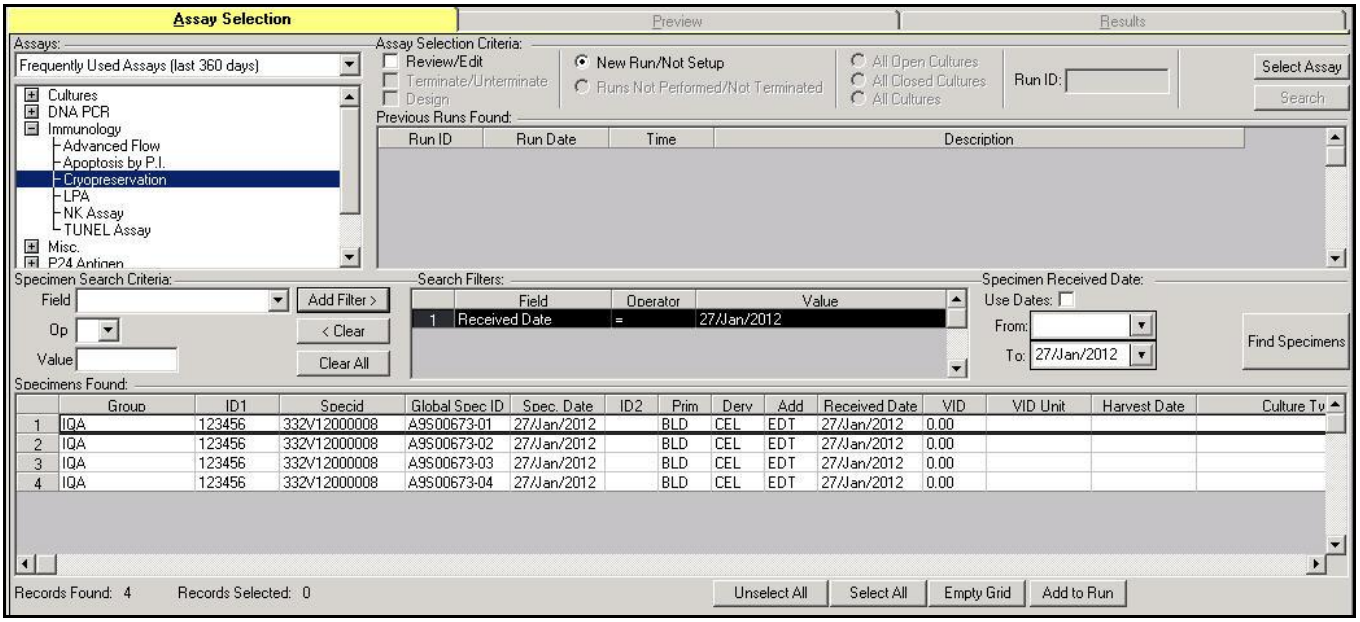

500V12000004
KEQ0066X-01
123456 IPREX
15/Feb/2012
BLD EDT CEL N/A
5e+006 CEL

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.

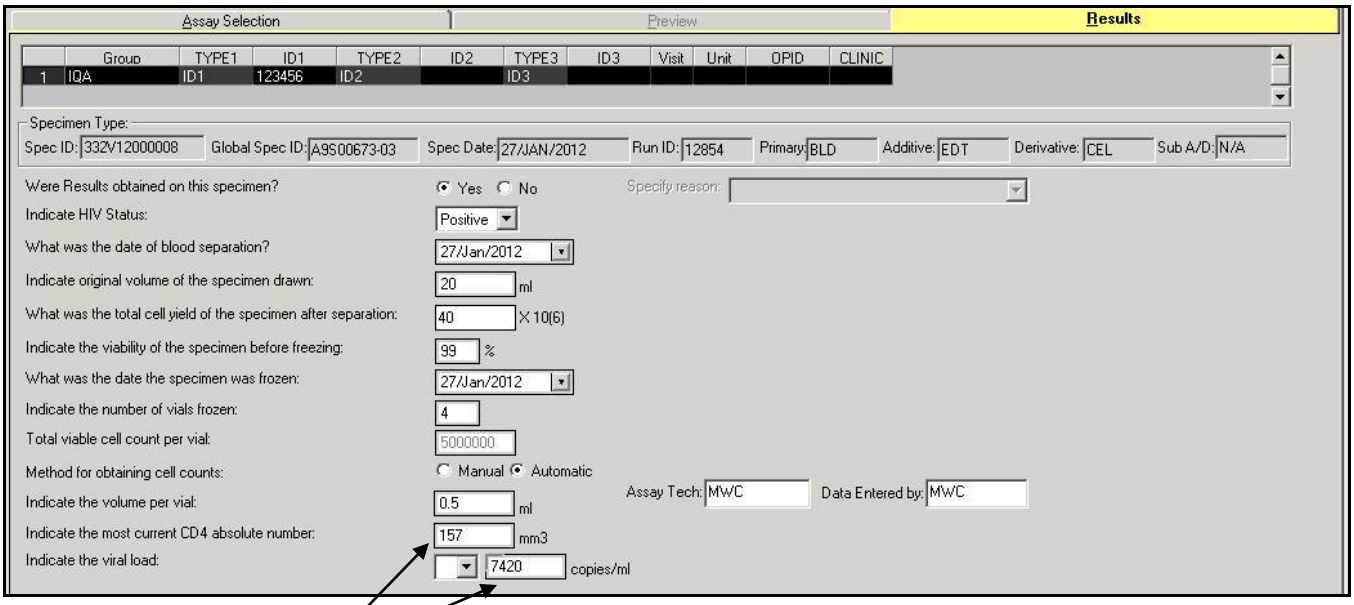


To complete the Cryopreservation Data Entry screen:

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.



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

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 University of Miami** 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.

IQA Lab: LDMS #213

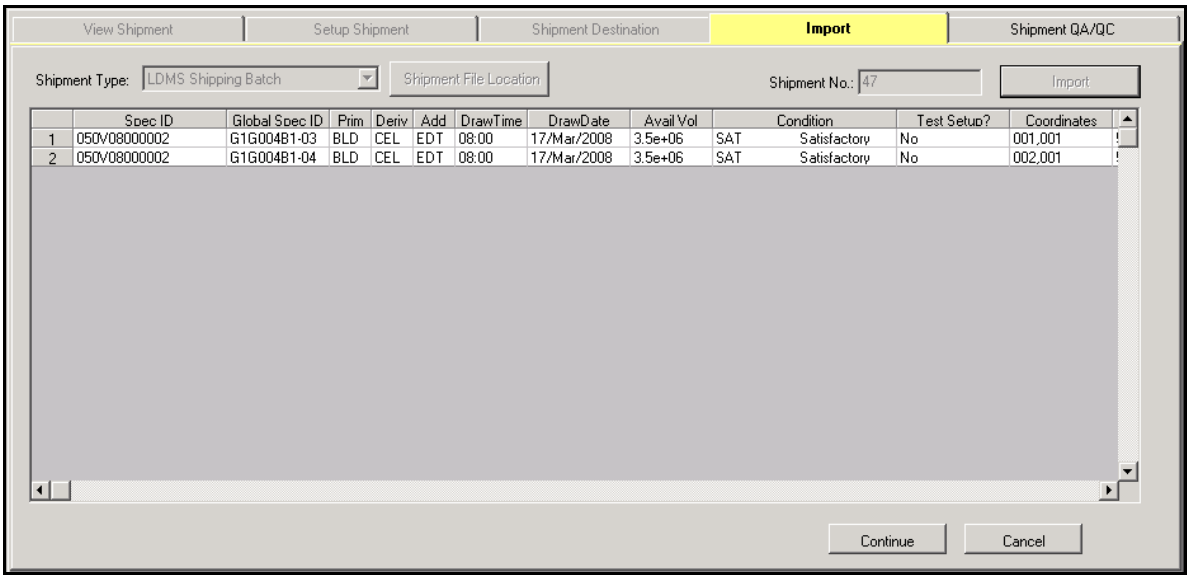
The IQA receiving lab is required to perform three steps in the LDMS when receiving the IQA specimens:

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.



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.
13. 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.
14. 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.
15. 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.
16. Click **YES** to import the associated test (Assay) information.
17. **Select** the appropriate temperature for the shipment and click **OK.**
18. Click **OK**. The Shipping Batch message box appears.
19. Click **OK** in the dialog box that displays the importing process was completed successfully.
20. Click **OK** to acknowledge the Shipment/Batch number.
21. A message will appear indicating that the Storage module must be run separately for the imported specimens.
22. 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

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

Completing the Cryopreservation Data Entry Screen

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

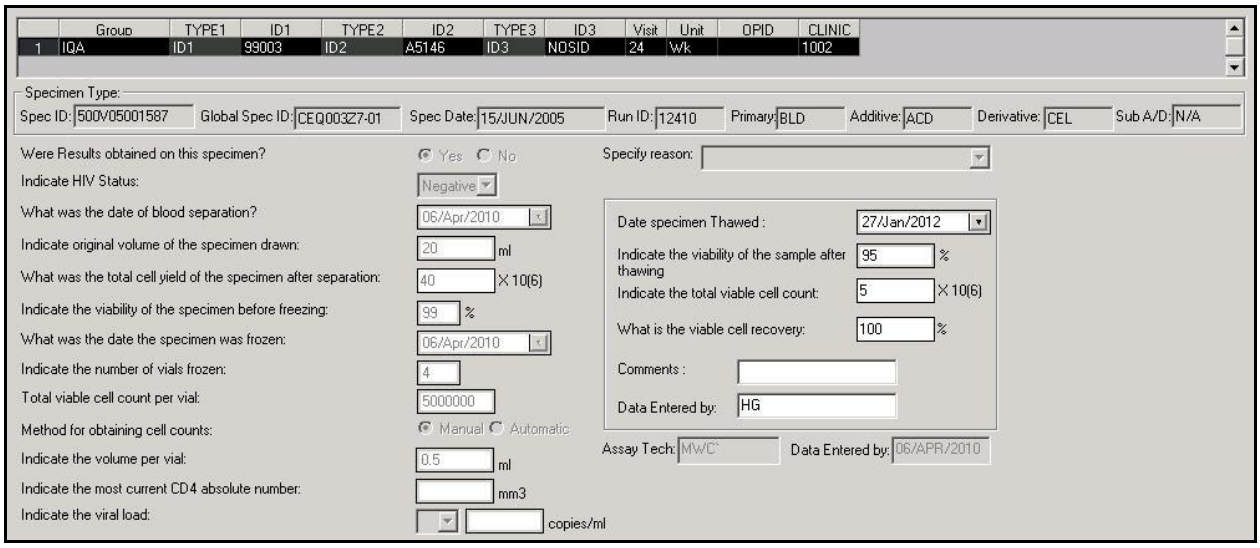
To complete the Cryopreservation data entry screen:

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**.



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

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.

Deleting Extra Aliquots from the Pending List

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