Abbott Realtime HIV-1 Instructions

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Creating the Abbott Realtime HIV-1 Assay Result File

The following procedure is performed within the Abbott m2000rt™ program. Refer to the latest version of the Abbott m2000rt™ Operations Manual for additional information and the most up-to-date instructions on exporting Abbott data.

1. Select **Results**, and then **View By Plate**.
2. Highlight (select) the run that you wish to export.
3. Insert a writable CD into the CD drive.
4. Select **Archive** from the **Plate Tasks** menu. The Archiving Plate Results screen displays.
5. When the CD drive status display "Ready," click **Start**.
6. A text file will be written to the CD with the following file name format:

***m2000rt* serial number_PCR plate name_date_time.txt.**

Note: The user may choose to rename the Abbott result file, but the contents should not be modified in any way. If opened and viewed with an another software program, such as a text editor or Excel, it is recommended that the user does not click "save" within that program.

Reading the Abbott Realtime HIV-1 Assay Result File into LDMS

1. Go to **Tasks – Assays** on the menu bar or click the **Assays** ( ) button on the LDMS toolbar.
2. Click the **plus sign (+)** next to the Viral Load RNA category.
3. Click the **plus sign (+)** next to the Abbott Realtime HIV-1 category.
4. Click **Abbott Realtime HIV-1** or **Abbott Realtime HIV-1 with Calibrators**. (See **Figure 1**.)

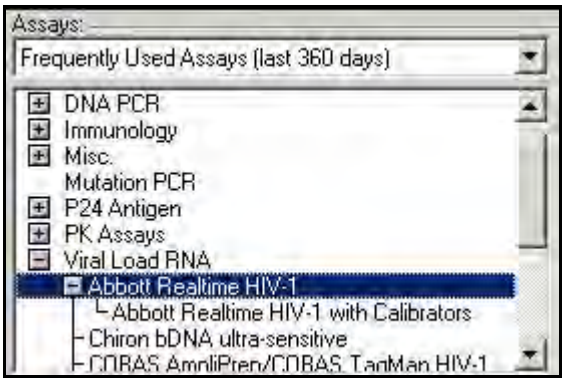


Figure 1. Assays

5. Click **Select Assay.** (See **Figure 2**)

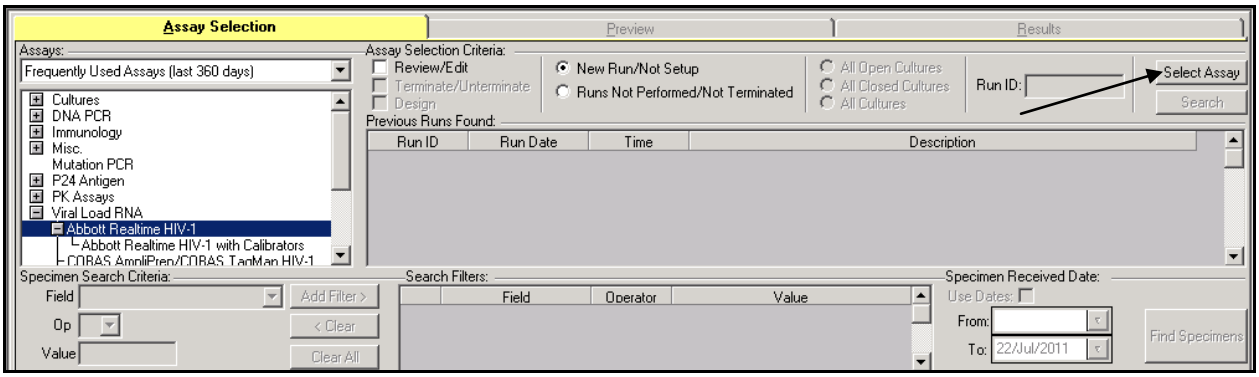


Figure 2. Assay Selection Box

6. Enter any desired search criteria in the **Specimen Search** section. If you wish to find specimens by the **Specimen Received Date**, select the **Use Dates** check box and enter the appropriate dates in the **From** and **To** fields.
7. Click **Find Specimens**. The **Specimens Found** grid loads with specimens that match the search criteria.

Note: Specimens should first be imported through the Shipping module or logged into the Specimen Management module, and have the Abbott test assigned, before they will display in the Specimens Found grid in the Assay module. (See **Figure 3**.)

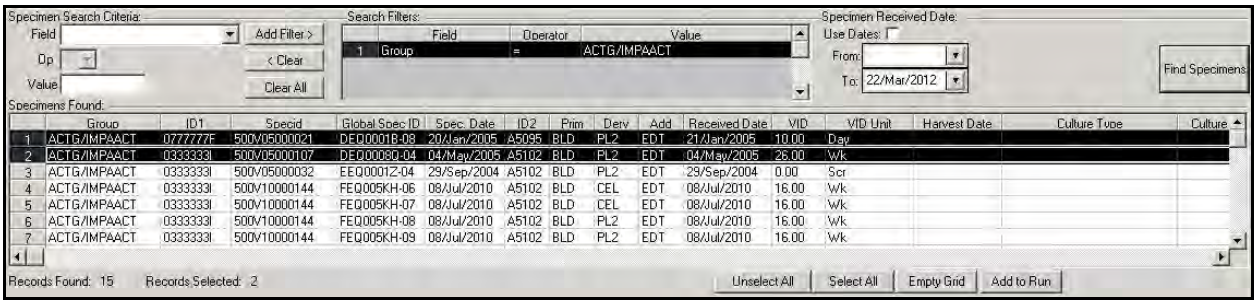


Figure 3. Specimens Found

8. Click the specimens that you wish to add to the run. Selected specimens appear in black.
9. Click **Add to Run**. The Preview tab opens. (See **Figure 4**.)

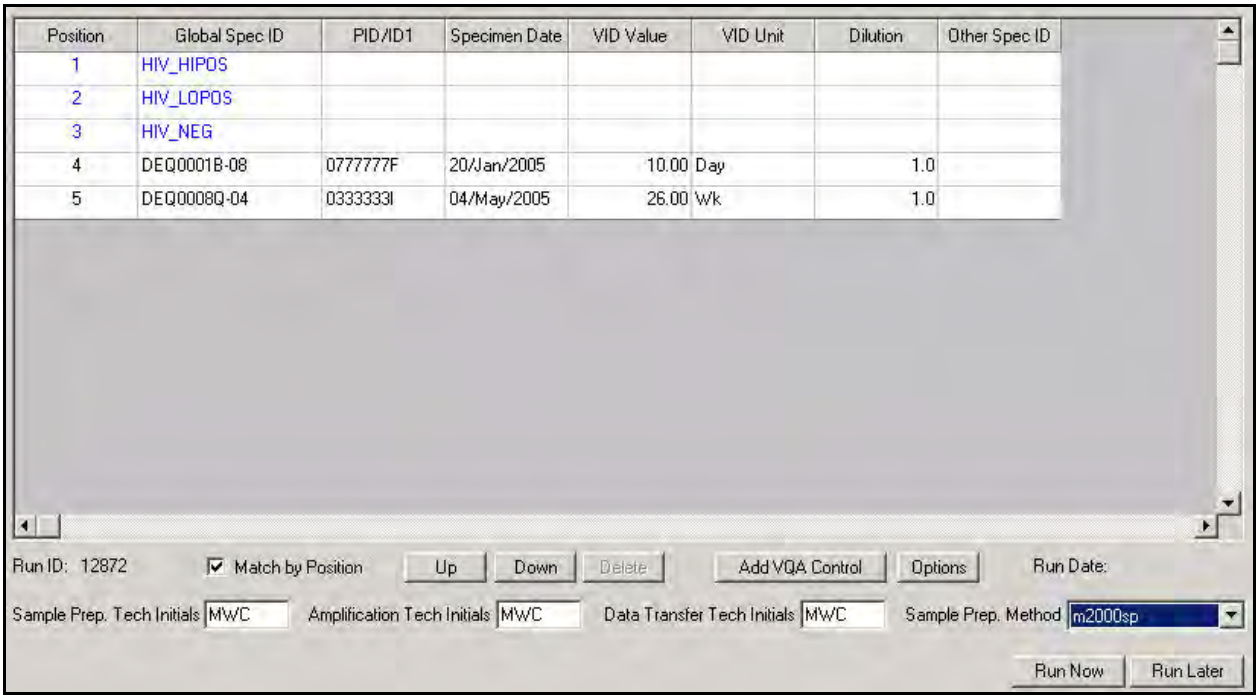


Figure 4. Preview Tab

Note: The Preview screen for the Abbott Realtime HIV-1 assay is set up as a line listing, rather than a plate layout like other Viral Load assays.

10. To assign positions for all sample types, including controls, verify that the **Match by Position** check box is selected. Arrange the line listing as desired using the **Up** and **Down** buttons. The order of the samples can also be rearranged by clicking in the position column and entering the desired column position.

Note: If Match by Position is selected, the order of control and patient samples in the Abbott result file must match the LDMS preview screen exactly.

OR

To match the results to specimens on a run by Global Specimen ID (or PID/ID1), clear the **Match by Position** check box. The **Up** and **Down** buttons will become unavailable

Important: If the Match by Position check box is ***not*** selected:

- The LDMS will automatically match to the controls and calibrators in the Abbott result file.
- The LDMS will match specimens on the run to the Global Specimen ID or PID/ID1 values found in the Sample ID field of the Abbott result file.
- If you are using PID/ID1 in the Abbott result file, there cannot be more than one sample for a particular PID/ID1 on the same run.

Note: Any run containing ACTG, IMPAACT, or VQA samples must include a VQA200 copy control The LDMS expects that the VQA200 control is named **exactly** "VQA200" in the Abbott result file.

11. To add a VQA control to the run, click **Add VQA Control**. The Add VQA Lot dialog box appears. (See **Figure 5**.)

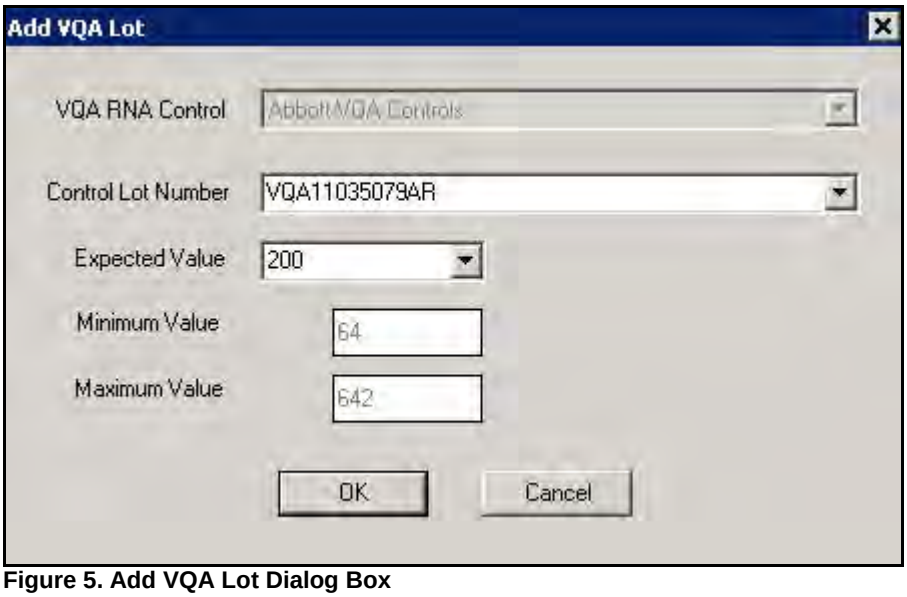


Figure 5. Add VQA Lot Dialog Box

a. If using a previously entered control, select a VQA control lot number in the **Control Lot Number** box and the expected value in the **Expected Value** box.

b. If a new **Control Lot Number** is being entered, use the format VQAnnnnnnnnAR, where nnnnnnnn is the control lot number. Enter 200 in the Expected Value field, 64 in the Minimum Value field, and 642 in the Maximum Value field.

Note: When selecting a previously entered Control Lot Number and Expected Value, the Minimum Value and Maximum Value fields will automatically load with the information previously entered (see Appendix: Entering Abbott Realtime HIV-1 VQA Control Information).

c. Click **OK**.

12. To modify a dilution, click the **Dilution field** of the desired sample and enter the new dilution value in the grid.
13. Enter the initials of the technician(s) who completed the sample preparation and amplification where indicated.
14. Select the Sample Preparation Method. Click **OK.**

15. Click **Run Now**. Click **Yes** in the Run Abbott Assay box.
16. Browse to the desired Abbott Realtime HIV-1 result file and Click **Open**.
17. The **Enter Run Date** dialog box appears. (See **Figure 6**.)

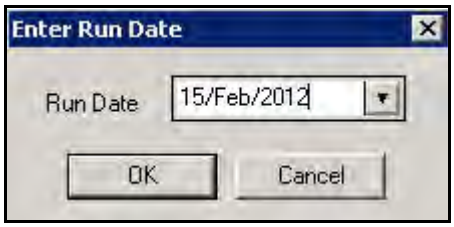


Figure 6. Enter Run Information Dialog Box

18. Select the date in the **Run Date** field. Click **OK**.

The LDMS begins reading the Abbott result file. When the assay is complete, the LDMS will display the results of your assay on the Results screen. By default, Calculated Results is selected as the Grid View option. (See **Figure 7**.)

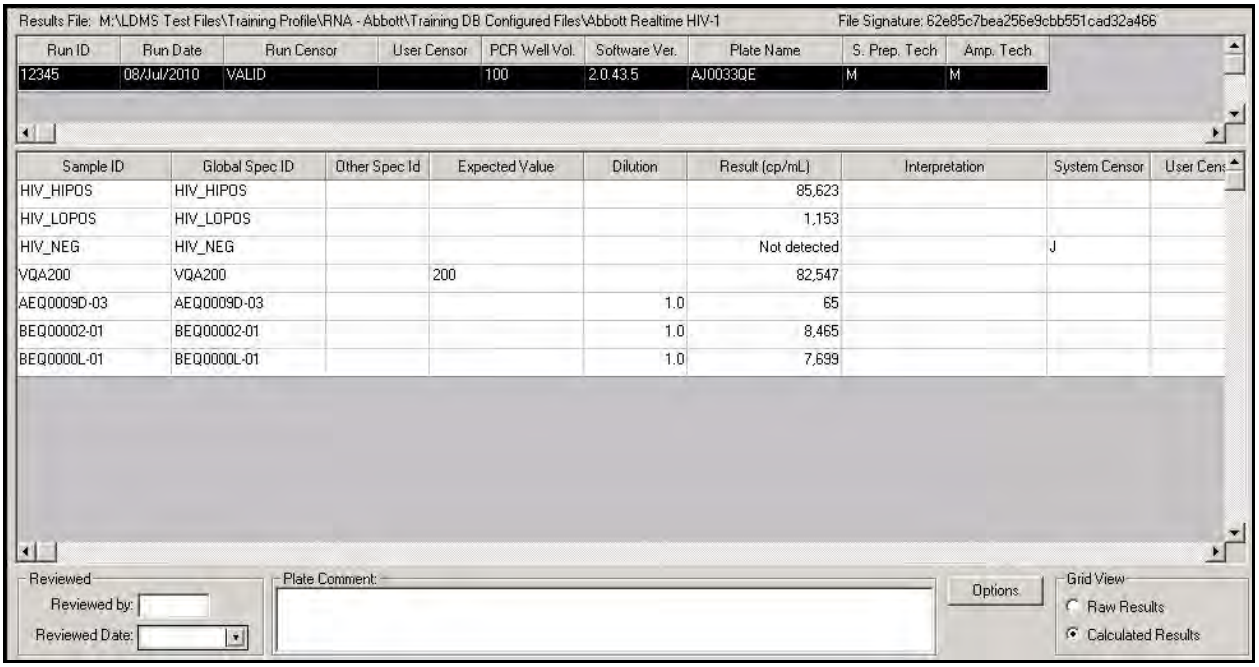


Figure 7. Calculated Results Screen

To display Raw Results as the Grid View option, click **Raw Results**. (See **Figure 8**.)

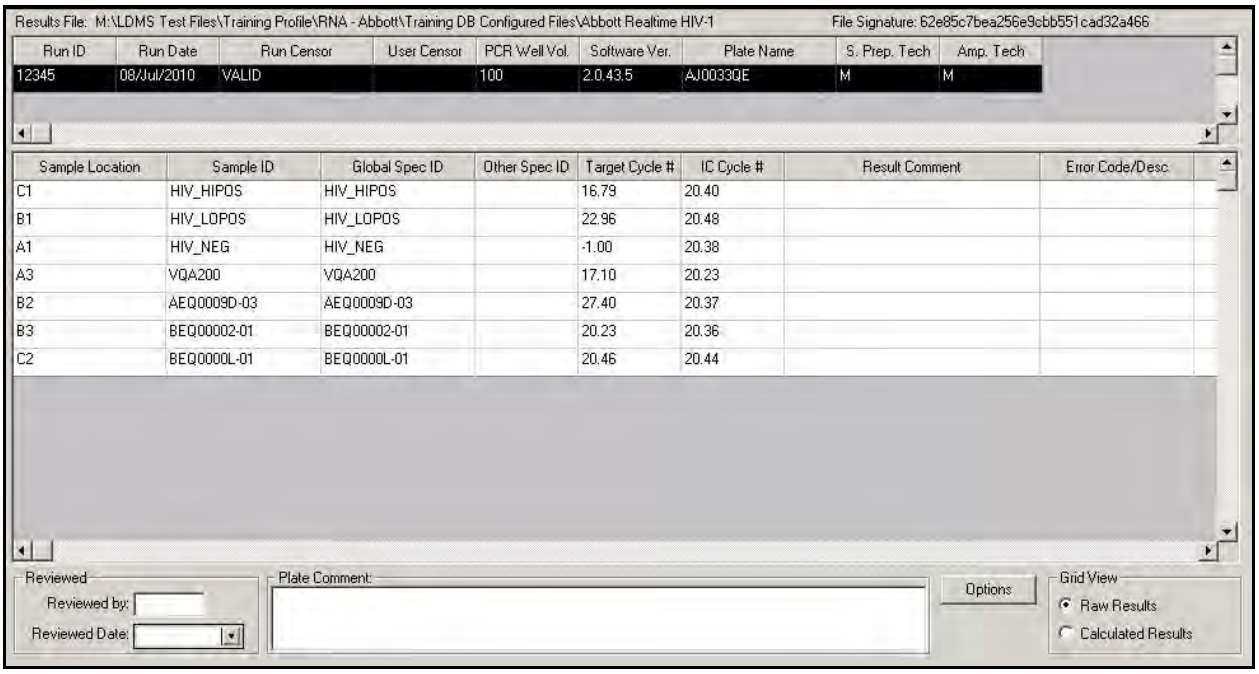


Figure 8. Raw Results Screen

Adding Comments and User Censors, Reviewing the Run

Adding Comments

1. From the Results screen, click on the Raw Results Grid View and type in the Result Comment column in the grid to enter result comments for a specimen
2. Type in the Plate Comment field in order to enter a comment on the run.
3. Click the Save button in the LDMS toolbar.

Censoring a Specimen

4. From the Results screen, right-click on the specimen that you wish to censor.
5. Select **Censor Specimen** from the shortcut menu. (See **Figure 9**.) The LDMS Censor Codes dialog box appears. (See **Figure 10**.)

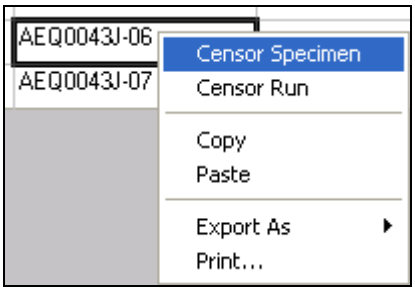


Figure 9. Shortcut Menu

6. Click the appropriate censor and Click **OK**.

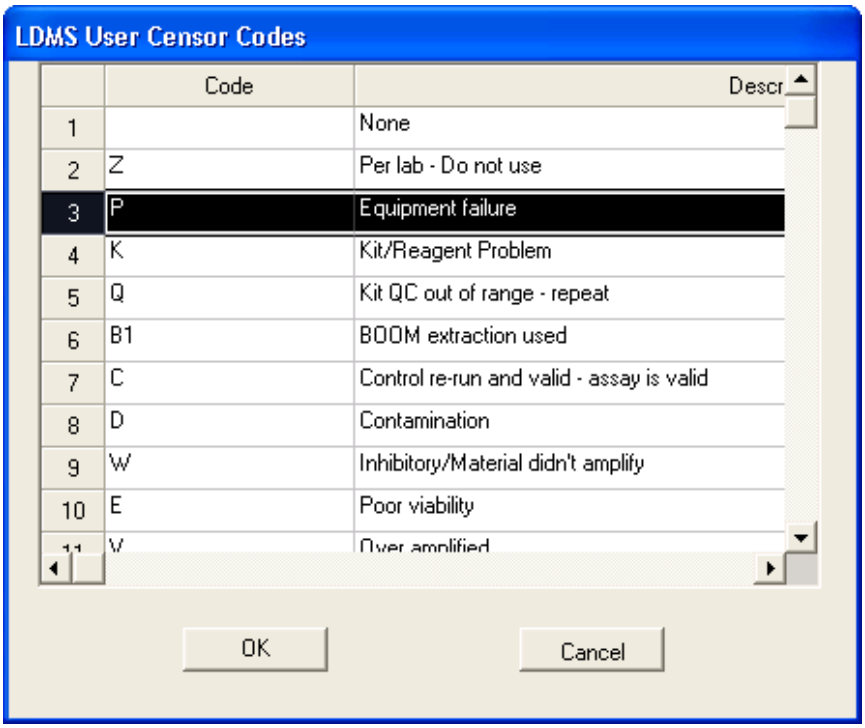


Figure 10. LDMS User Censor Codes Dialog Box

7. The new user censor code will display.

Censoring an Assay Run

1. From the Results screen, Right-click on a specimen on the assay plate.
2. Select **Censor Run** from the shortcut menu. (See **Figure 11**.) The LDMS User Censor Codes dialog box appears.

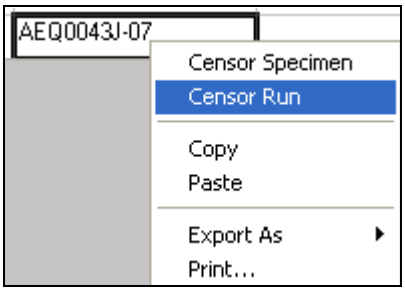


Figure 11. Shortcut Menu

3. Click on the appropriate censor and Click **OK**. (See **Figure 12**.)

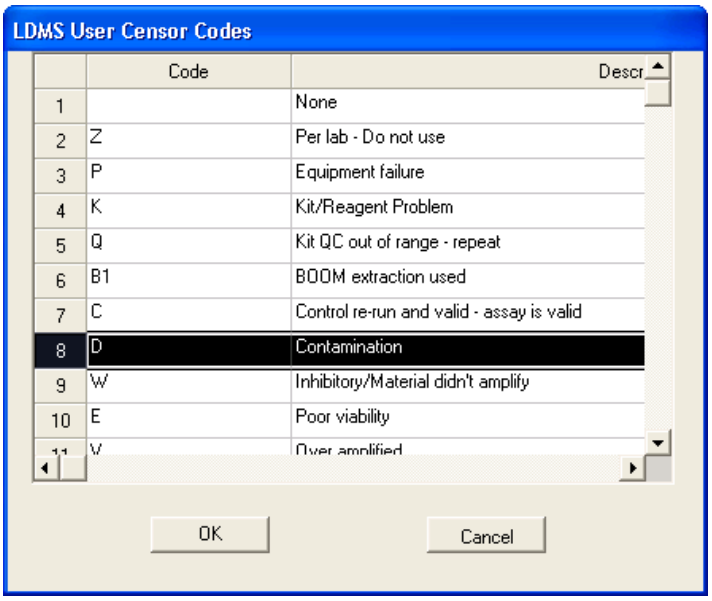


Figure 12. LDMS User Censor Codes Dialog Box

4. The new censor code will display.

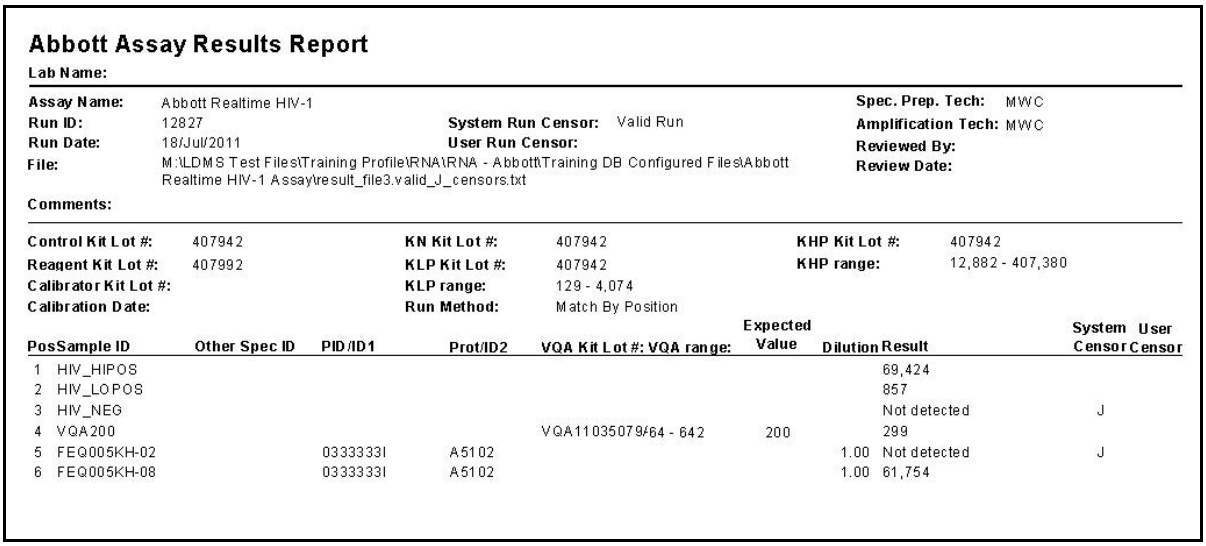
Reviewing the Run

1. Review the results of the run to confirm their accuracy.
2. From the Results screen, type the initials of the reviewer in the Reviewed by field.
3. Select a date in the Reviewed Date field.
4. Click the Save button in the LDMS toolbar.

Printing the Assay Result Report

The Assay Result Report can be printed/reprinted at any time after an assay has been run, either directly after the running the assay, or upon assay review at a later date. If you will be printing the Assay Result Report immediately after running the assay, follow the steps below. If you have already run the assay, use the Review/Edit feature as described in the *Virology* chapter of the LDMS User Manual to retrieve the Results screen for the assay, then follow the steps below.

1. From the Results screen, click the **Reports** () button on the LDMS toolbar. The Assay Result Report appears. (See **Figure 13**.)



Abbott Assay Results Report

Lab Name:

Assay Name:	Abbott Realtime HIV-1			Spec. Prep. Tech:	MWC
Run ID:	12827	System Run Censor:	Valid Run	Amplification Tech:	MWC
Run Date:	18/Jul/2011	User Run Censor:		Reviewed By:	
File:	M:\LDMS Test Files\Training Profile\RNA\RNA - Abbott\Training DB Configured Files\Abbott Realtime HIV-1 Assay\result_file3.valid_J_censors.txt			Review Date:	
Comments:					

Control Kit Lot #:	407942	KN Kit Lot #:	407942	KHP Kit Lot #:	407942
Reagent Kit Lot #:	407992	KLP Kit Lot #:	407942	KHP range:	12,882 - 407,380
Calibrator Kit Lot #:		KLP range:	129 - 4,074		
Calibration Date:		Run Method:	Match By Position		

Pos	Sample ID	Other Spec ID	PID/ID1	Prot/ID2	VQA Kit Lot #: VQA range:	Expected Value	Dilution	Result	System Censor	User Censor
1	HIV_HIPOS							69,424		
2	HIV_LOPOS							857		
3	HIV_NEG							Not detected		J
4	VQA200				VQA11035079/64 - 642	200		299		
5	FEQ005KH-02		0333333I	A5102			1.00	Not detected		J
6	FEQ005KH-08		0333333I	A5102			1.00	61,754		

Figure 13. Assay Result Report

2. Click the **Print** () button on the Crystal Reports toolbar.

Printing the Patient Report

The Patient Report can be printed after the assay has been run, or at a later date from the Review/Edit or the Reports module.

Note: A Patient Report can be generated for a valid result only.

1. From the Results screen, click **Options**. The Result Options dialog box appears. (See **Figure 14**.)
2. Select **Print Patient Report (Clinical)** and click **OK**. The Patient Report Selection dialog box appears. (See **Figure 15**.)

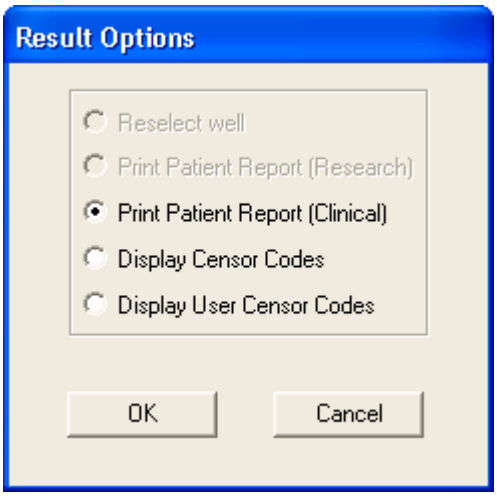


Figure 14. Result Options Dialog Box

3. Select a single specimen or select the **Select all** check box.

   Note: You can also press **CTRL** or **SHIFT** to select multiple specimens.

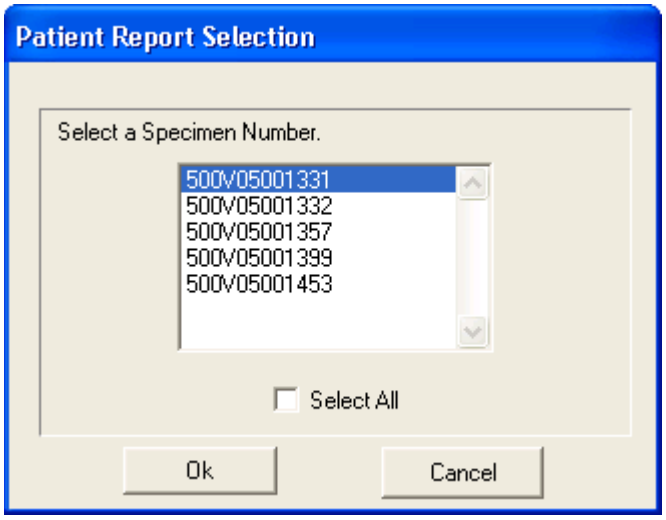
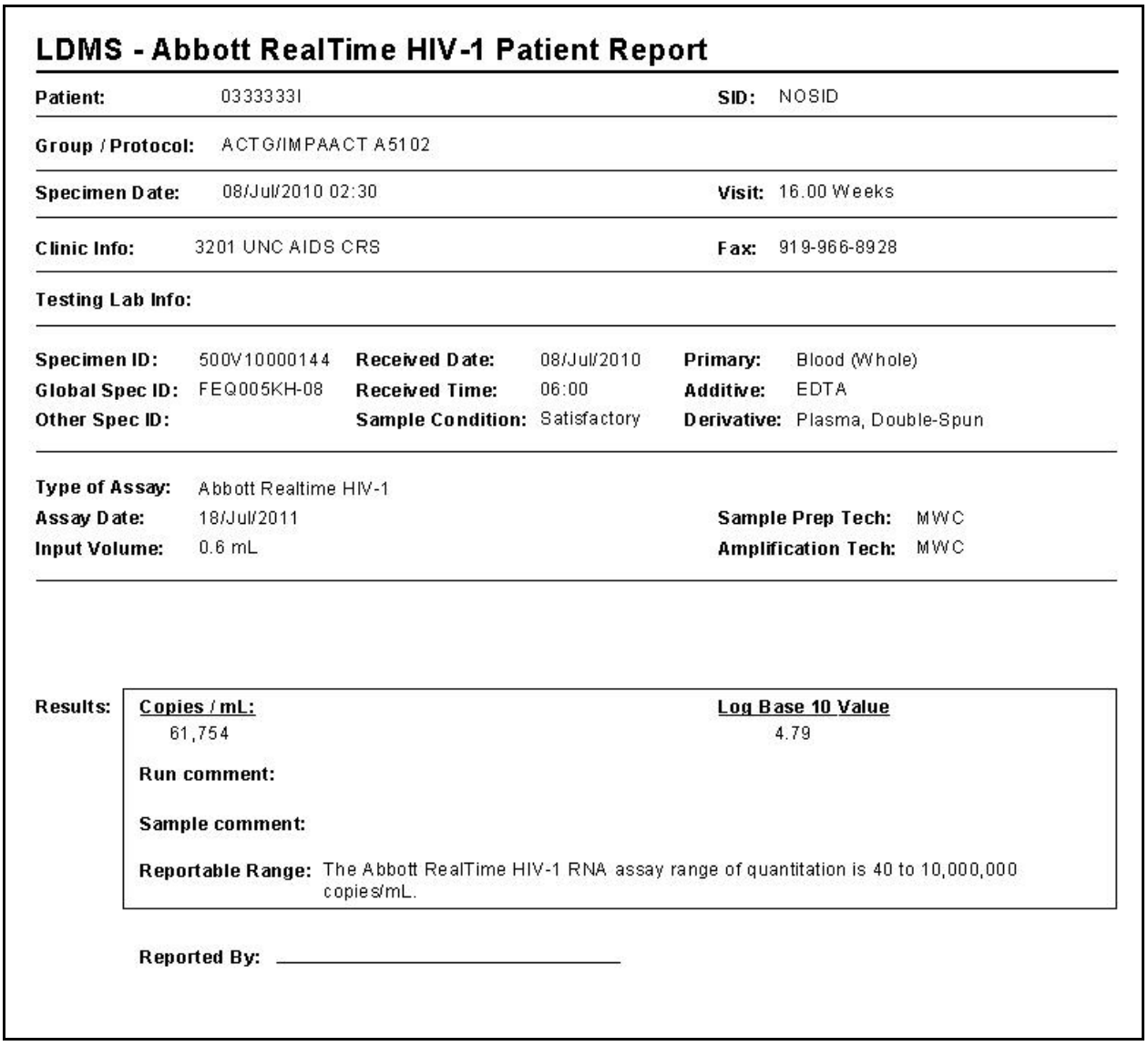


Figure 15. Patient Report Selection Dialog Box

4. Click **OK**. The Patient Report will be displayed for the selected specimen(s). (See **Figure 16**.)
5. Click the **Print** () button on the Crystal Reports toolbar.



LDMS - Abbott RealTime HIV-1 Patient Report

Patient: 0333333I **SID:** NOSID

Group / Protocol: ACTG/IMPAACT A5102

Specimen Date: 08/Jul/2010 02:30 **Visit:** 16.00 Weeks

Clinic Info: 3201 UNC AIDS CRS **Fax:** 919-966-8928

Testing Lab Info:

Specimen ID:	500V10000144	**Received Date:**	08/Jul/2010	**Primary:**	Blood (Whole)
Global Spec ID:	FEQ005KH-08	**Received Time:**	06:00	**Additive:**	EDTA
Other Spec ID:		**Sample Condition:**	Satisfactory	**Derivative:**	Plasma, Double-Spun

Type of Assay: Abbott Realtime HIV-1

Assay Date: 18/Jul/2011 **Sample Prep Tech:** MWC

Input Volume: 0.6 mL **Amplification Tech:** MWC

Results:

Copies / mL:	Log Base 10 Value
61,754	4.79

Run comment:

Sample comment:

Reportable Range: The Abbott RealTime HIV-1 RNA assay range of quantitation is 40 to 10,000,000 copies/mL.

Reported By: _____

Figure 16. Patient Report

Appendix: Kit Entry and VQA Control Login

Kit Entry Module Screens

When the Abbott Realtime HIV-1 assay is run, the information on the control kit, reagent kit, and calibrator kit (if applicable) screens is automatically populated from the Abbott result file. Below are examples of the Kit Entry module screens after the assay is run showing the data pulled from the Abbott result file. To complete the remaining fields, go to **QA/QC – Kit Entry Module**, select the appropriate kit, and enter any missing information.

Note: The **Date Received** and **Storage Temp** fields are not automatically loaded and will need to be manually entered in the Kit Entry module following the assay run.

Control Kit Screen

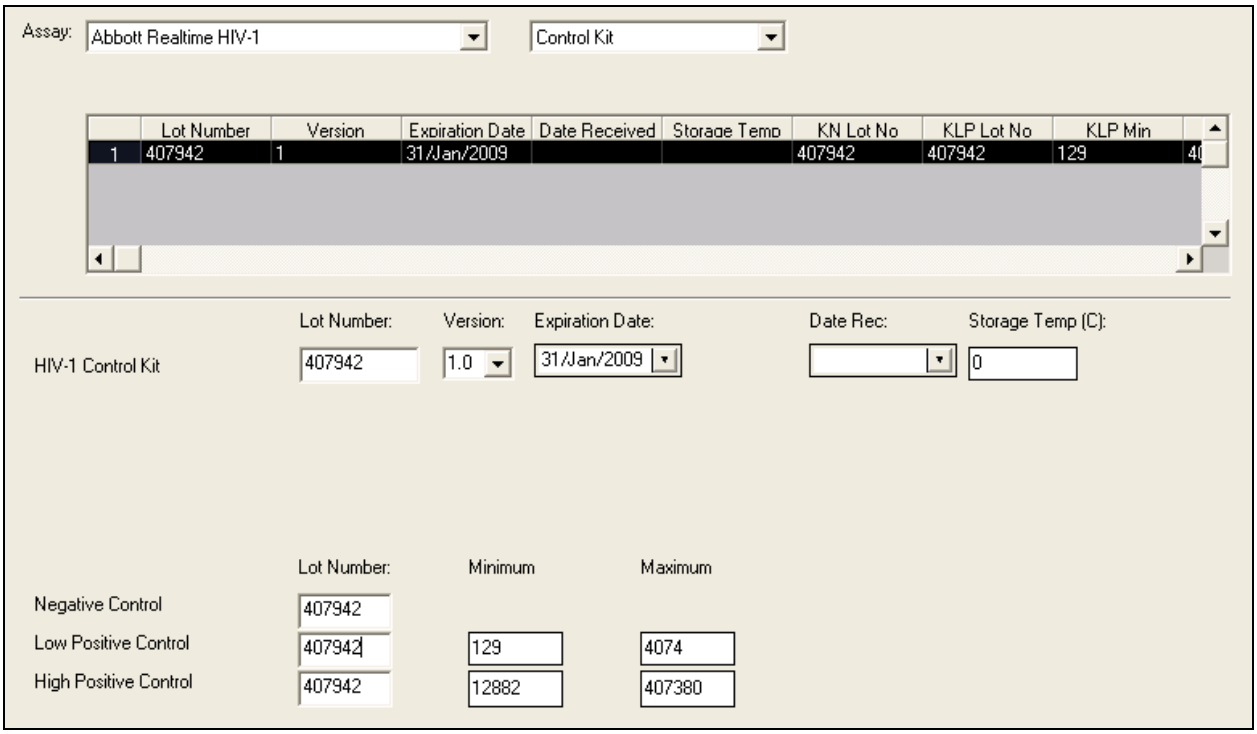


Figure 17. Abbott Control Kit Information

Reagent Kit Screen

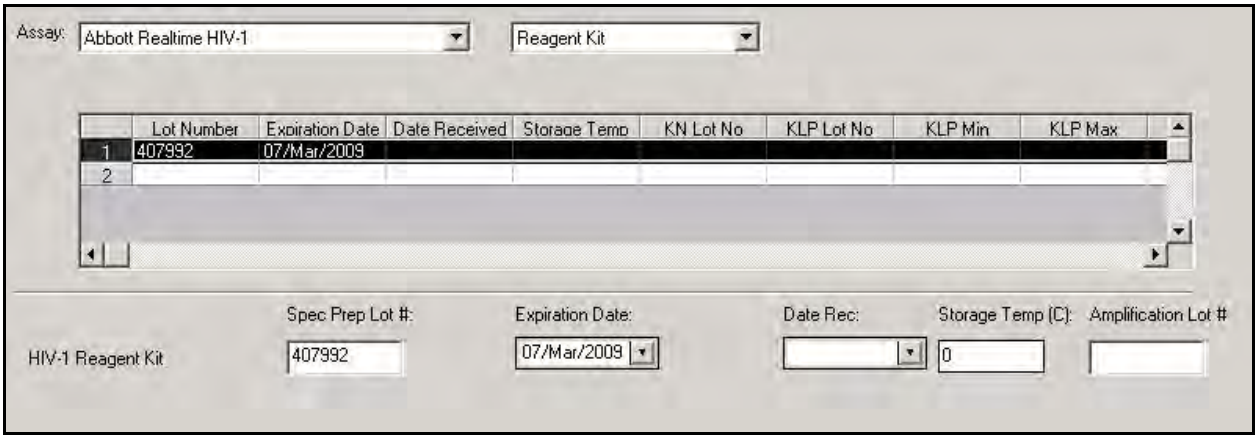


Figure 18. Abbott Reagent Kit Information

Calibrator Kit Screen

This information is only needed by the LDMS if running the Abbott Realtime HIV-1 with Calibrators system template.

Figure 19. Abbott Calibrator Kit Information

Entering Control Information

VQA Control information can be entered either on the Preview screen of the Abbott assay or in the QA/QC module as described below:

1. Go to **QA/QC – VQA Control Login** on the LDMS menu bar.
2. Select **Abbott VQA Controls** from the **VQA RNA Control** box. (See **Figure 20**.)
3. Enter the new Control Lot Numbers (format = VQAnnnnnnnnAR, where nnnnnnnn is the control lot number) in the **Lot Number** box.
4. Enter 200 in the **Expected Value** box. Click on **Add Row** button.
5. Enter 64 in the **Minimum Value** field and 642 in the **Maximum Value** field in the grid for the VQA200 control.
6. Click the **Add** ( ) button on the LDMS toolbar. A success message appears.
7. Click **OK**.

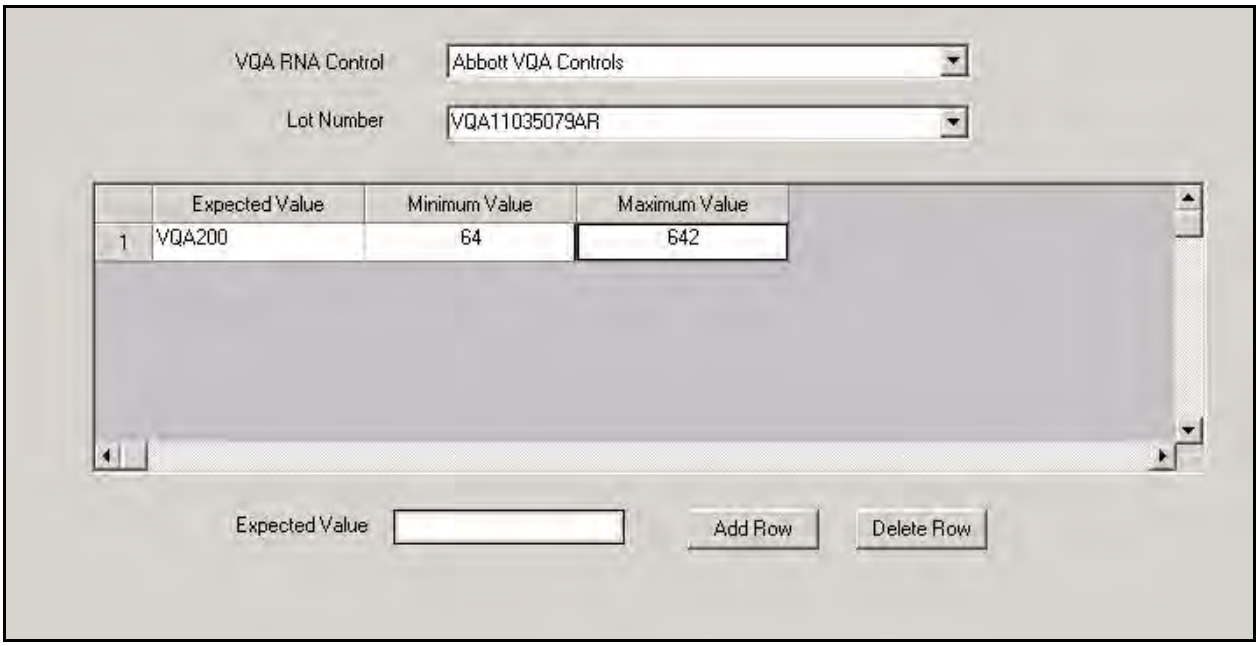


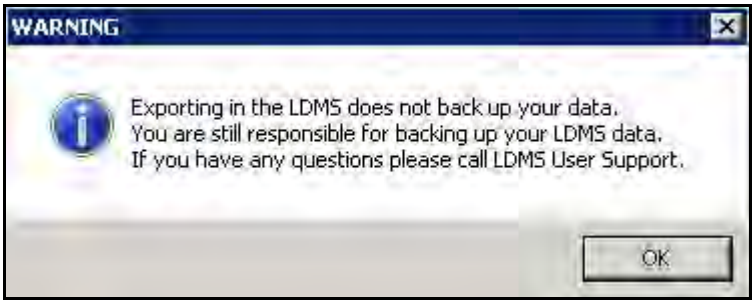
Figure 20. Abbott VQA Kit Information

Exporting Data to Frontier Science

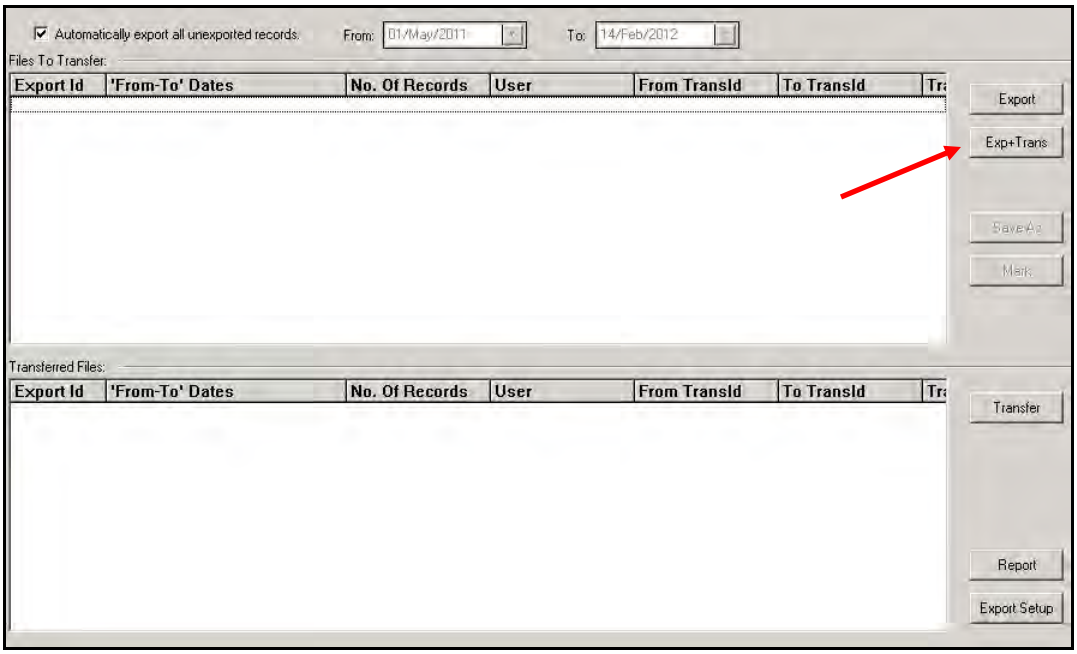
Laboratory data should be exported to Frontier Science on a regular basis. The frequency of data export often depends on the size of the laboratory database and workload.

To open the Export module:

1. Go to **Tasks – Export** on the menu bar, or click the **Export** () button on the LDMS toolbar. A warning message appears.



2. Click **OK**. The Data Export screen appears.



Using the Exp+Trans Button

Exp+Trans is the recommended method to create your export file and transfer the file to Frontier Science. The **Exp+Trans** button allows you to export in one step.

From the Export screen, click **Exp+Trans**. A progress box appears displaying the status of the data export. When the export is complete, the export file appears in the **Transferred Files** section.