

# Abbott Realtime HIV-1 Instructions

Table of Contents	
Abbott Realtime HIV-1 Instructions	1
Creating the Abbott Realtime HIV-1 Assay Result File	2
Reading the Abbott Realtime HIV-1 Assay Result File into LDMS	2
Adding Comments and User Censors, Reviewing the Run	6
Adding Comments	6
Censoring a Specimen	6
Censoring an Assay Run	7
Reviewing the Run	8
Printing the Assay Result Report	8
Printing the Patient Report	9
Appendix: Kit Entry and VQA Control Login	12
Kit Entry Module Screens	12
Control Kit Screen	12
Reagent Kit Screen	13
Calibrator Kit Screen	13
Entering Control Information	13
Exporting Data to Frontier Science	14
Using the Exp+Trans Button	15

## 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.)

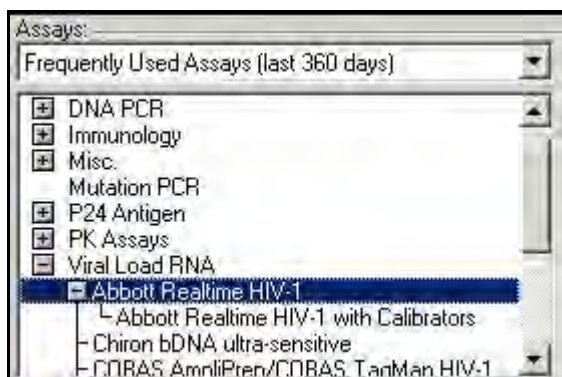


Figure 1. Assays

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

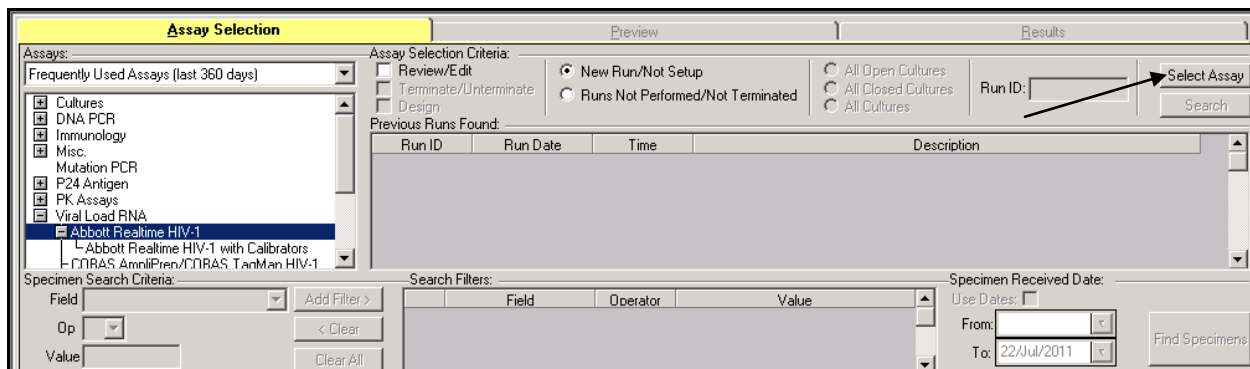


Figure 2. Assay Selection Box

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**.)

Group	ID1	Specid	Global Spec ID	Spec. Date	ID2	Prim	Deriv	Add	Received Date	VID	VID Unit	Harvest Date	Culture Type	Culture
ACTG/IMPAACT	077777F	500V05000021	DEQ0001B-08	20/Jan/2005	A5095	BLD	PL2	EDT	21/Jan/2005	10.00	Day			
ACTG/IMPAACT	0333333I	500V050000107	DEQ0008Q-04	04/May/2005	A5102	BLD	PL2	EDT	04/May/2005	26.00	Wk			
ACTG/IMPAACT	0333333I	500V050000032	EEQ0001Z-04	29/Sep/2004	A5102	BLD	PL2	EDT	29/Sep/2004	0.00	Scr			
ACTG/IMPAACT	0333333I	500V10000144	FEQ0005KH-06	08/Jul/2010	A5102	BLD	CEL	EDT	08/Jul/2010	16.00	Wk			
ACTG/IMPAACT	0333333I	500V10000144	FEQ0005KH-07	08/Jul/2010	A5102	BLD	CEL	EDT	08/Jul/2010	16.00	Wk			
ACTG/IMPAACT	0333333I	500V10000144	FEQ0005KH-08	08/Jul/2010	A5102	BLD	PL2	EDT	08/Jul/2010	16.00	Wk			
ACTG/IMPAACT	0333333I	500V10000144	FEQ0005KH-09	08/Jul/2010	A5102	BLD	PL2	EDT	08/Jul/2010	16.00	Wk			

Records Found: 15    Records Selected: 2    Unselect All    Select All    Empty Grid    Add to Run

**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**.)

Position	Global Spec ID	PID/ID1	Specimen Date	VID Value	VID Unit	Dilution	Other Spec ID
1	HIV_HIPOS						
2	HIV_LOPOS						
3	HIV_NEG						
4	DEQ0001B-08	0777777F	20/Jan/2005	10.00	Day	1.0	
5	DEQ0008Q-04	0333333I	04/May/2005	26.00	Wk	1.0	

Run ID: 12872     Match by Position    Up    Down    Delete    Add VQA Control    Options    Run Date:

Sample Prep. Tech Initials: MWC    Amplification Tech Initials: MWC    Data Transfer Tech Initials: MWC    Sample Prep. Method: m2000sp

Run Now    Run Later

**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.

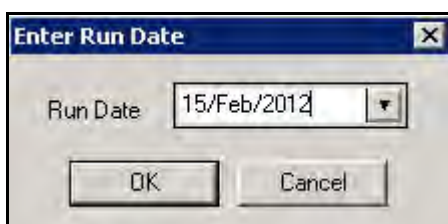
11. To add a VQA control to the run, click **Add VQA Control**. The Add VQA Lot dialog box appears. (See **Figure 5**.)

**Figure 5. Add VQA Lot Dialog Box**

- 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.
- 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**.)

Results File: M:\LDMS Test Files\Training Profile\RNA - Abbott\Training DB Configured Files\Abbott Realtime HIV-1 File Signature: 62e85c7bea256e9cbb551cad32a486

Run ID	Run Date	Run Censor	User Censor	PCR Well Vol.	Software Ver.	Plate Name	S. Prep. Tech	Amp. Tech
12345	08/Jul/2010	VALID		100	2.0.43.5	AJ0033QE	M	M

Sample ID	Global Spec ID	Other Spec Id	Expected Value	Dilution	Result (cp/mL)	Interpretation	System Censor	User Cens
HIV_HIPOS	HIV_HIPOS				85,623			
HIV_LOPOS	HIV_LOPOS				1,153			
HIV_NEG	HIV_NEG				Not detected		J	
VQA200	VQA200	200			82,547			
AEQ0009D-03	AEQ0009D-03			1.0	65			
BEQ00002-01	BEQ00002-01			1.0	8,465			
BEQ0000L-01	BEQ0000L-01			1.0	7,699			

Reviewed: Reviewed by: [ ] Reviewed Date: [ ] Plate Comment: [ ] Options: Grid View:  Raw Results  Calculated Results

**Figure 7. Calculated Results Screen**

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



Results File: M:\LDMS Test Files\Training Profile\RNA - Abbott\Training DB Configured Files\Abbott Realtime HIV-1 File Signature: 62e85c7bea256e9cbb551cad32a466

Run ID	Run Date	Run Censor	User Censor	PCR Well Vol	Software Ver.	Plate Name	S. Prep. Tech	Amp. Tech
12345	08/Jul/2010	VALID		100	2.0.43.5	AJ00330E	M	M

Sample Location	Sample ID	Global Spec ID	Other Spec ID	Target Cycle #	IC Cycle #	Result Comment	Error Code/Desc.
C1	HIV_HIPOS	HIV_HIPOS		16.79	20.40		
B1	HIV_LOPOS	HIV_LOPOS		22.96	20.48		
A1	HIV_NEG	HIV_NEG		-1.00	20.38		
A3	VQA200	VQA200		17.10	20.23		
B2	AEQ0009D-03	AEQ0009D-03		27.40	20.37		
B3	BEQ00002-01	BEQ00002-01		20.23	20.36		
C2	BEQ0000L-01	BEQ0000L-01		20.46	20.44		

Reviewed: Reviewed by: Reviewed Date: Plate Comment: Options: Grid View  Raw Results  Calculated Results

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**.)

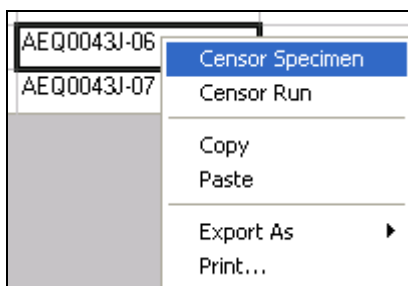


Figure 9. Shortcut Menu

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

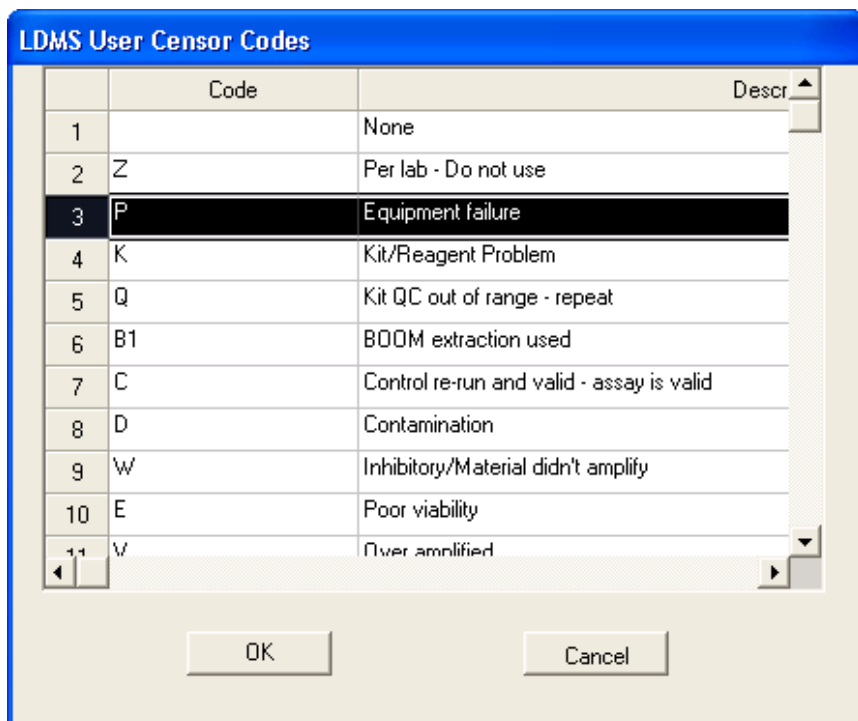


Figure 10. LDMS User Censor Codes Dialog Box

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.

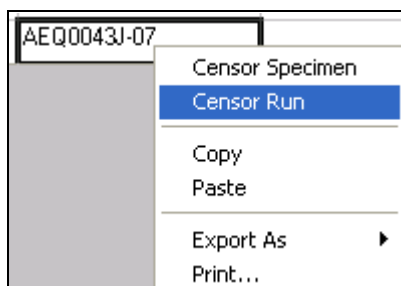


Figure 11. Shortcut Menu

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

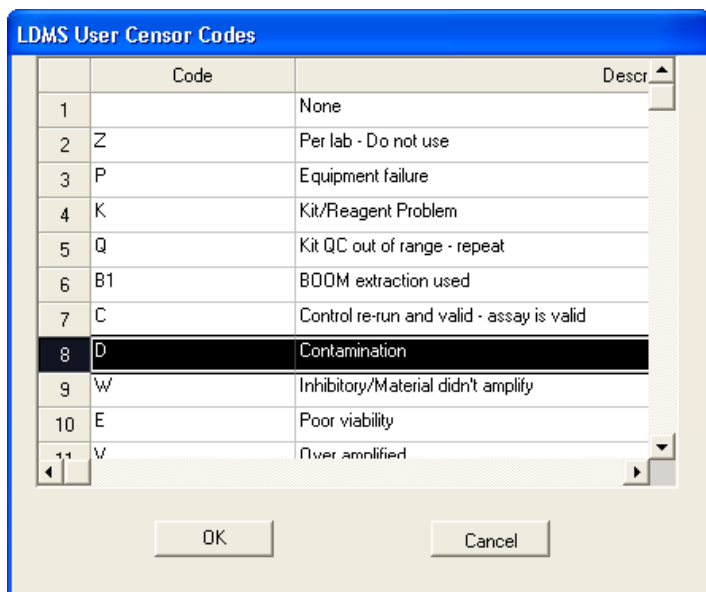


Figure 12. LDMS User Censor Codes Dialog Box


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										
<b>Lab Name:</b>										
<b>Assay Name:</b> Abbott Realtime HIV-1		<b>System Run Censor:</b> Valid Run		<b>Spec. Prep. Tech:</b> MWC						
<b>Run ID:</b> 12827		<b>User Run Censor:</b>		<b>Amplification Tech:</b> MWC						
<b>Run Date:</b> 18/JUL/2011				<b>Reviewed By:</b>						
<b>File:</b> M:\LDMS Test Files\Training Profile\RNA\RNA - Abbott\Training DB Configured Files\Abbott Realtime HIV-1 Assay\result_file3.valid_J_censors.txt				<b>Review Date:</b>						
<b>Comments:</b>										
<b>Control Kit Lot #:</b> 407942	<b>KN Kit Lot #:</b> 407942	<b>KHP Kit Lot #:</b> 407942								
<b>Reagent Kit Lot #:</b> 407992	<b>KLP Kit Lot #:</b> 407942	<b>KHP range:</b> 12,882 - 407,380								
<b>Calibrator Kit Lot #:</b>	<b>KLP range:</b> 129 - 4,074									
<b>Calibration Date:</b>	<b>Run Method:</b> 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		03333331	A5102			1.00	Not detected		J
6	FEQ005KH-08		03333331	A5102			1.00	61,754		

Figure 13. Assay Result Report

- 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.

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

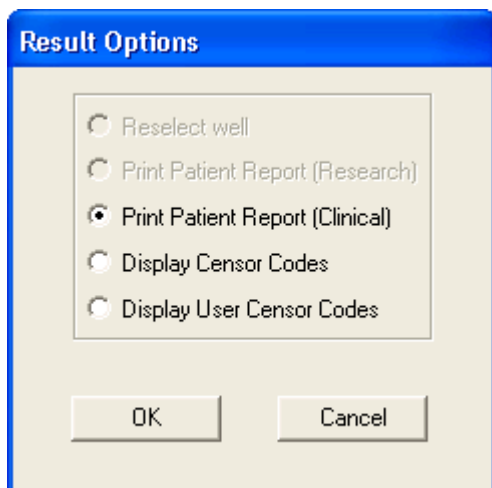
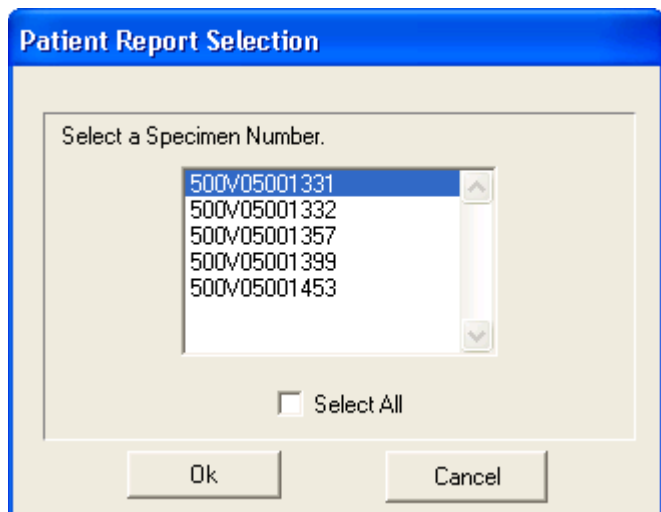



Figure 14. Result Options Dialog Box

- 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.

<b>LDMS - Abbott RealTime HIV-1 Patient Report</b>													
<b>Patient:</b>	03333331	<b>SID:</b>	NOSID										
<b>Group / Protocol:</b>	ACTG/IMPAACT A5102												
<b>Specimen Date:</b>	08/Jul/2010 02:30	<b>Visit:</b>	16.00 Weeks										
<b>Clinic Info:</b>	3201 UNC AIDS CRS	<b>Fax:</b>	919-966-8928										
<b>Testing Lab Info:</b>													
<b>Specimen ID:</b>	500V10000144	<b>Received Date:</b>	08/Jul/2010										
<b>Global Spec ID:</b>	FEQ005KH-08	<b>Received Time:</b>	06:00										
<b>Other Spec ID:</b>		<b>Sample Condition:</b>	Satisfactory										
		<b>Primary:</b>	Blood (Whole)										
		<b>Additive:</b>	EDTA										
		<b>Derivative:</b>	Plasma, Double-Spun										
<b>Type of Assay:</b>	Abbott RealTime HIV-1												
<b>Assay Date:</b>	18/Jul/2011	<b>Sample Prep Tech:</b>	MWC										
<b>Input Volume:</b>	0.6 mL	<b>Amplification Tech:</b>	MWC										
<b>Results:</b>	<table border="1"> <thead> <tr> <th><u>Copies / mL:</u></th> <th><u>Log Base 10 Value</u></th> </tr> </thead> <tbody> <tr> <td>61,754</td> <td>4.79</td> </tr> <tr> <td colspan="2"><b>Run comment:</b></td> </tr> <tr> <td colspan="2"><b>Sample comment:</b></td> </tr> <tr> <td colspan="2"><b>Reportable Range:</b> The Abbott RealTime HIV-1 RNA assay range of quantitation is 40 to 10,000,000 copies/mL.</td> </tr> </tbody> </table>			<u>Copies / mL:</u>	<u>Log Base 10 Value</u>	61,754	4.79	<b>Run comment:</b>		<b>Sample comment:</b>		<b>Reportable Range:</b> The Abbott RealTime HIV-1 RNA assay range of quantitation is 40 to 10,000,000 copies/mL.	
<u>Copies / mL:</u>	<u>Log Base 10 Value</u>												
61,754	4.79												
<b>Run comment:</b>													
<b>Sample comment:</b>													
<b>Reportable Range:</b> The Abbott RealTime HIV-1 RNA assay range of quantitation is 40 to 10,000,000 copies/mL.													
<b>Reported By:</b>	_____												

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

Assay:	Abbott Realtime HIV-1	Control Kit							
	Lot Number	Version	Expiration Date	Date Received	Storage Temp	KN Lot No	KLP Lot No	KLP Min	
	1	407942	1	31/Jan/2009		407942	407942	129	4074

HIV-1 Control Kit	Lot Number:	Version:	Expiration Date:	Date Rec:	Storage Temp (C):
	407942	1.0	31/Jan/2009		0

	Lot Number:	Minimum	Maximum
Negative Control	407942		
Low Positive Control	407942	129	4074
High Positive Control	407942	12882	407380

Figure 17. Abbott Control Kit Information

## Reagent Kit Screen

Assay:

	Lot Number	Expiration Date	Date Received	Storage Temp	KN Lot No	KLP Lot No	KLP Min	KLP Max	
1	407992	07/Mar/2009							
2									

HIV-1 Reagent Kit      Spec Prep Lot #:       Expiration Date:       Date Rec:       Storage Temp (C):       Amplification Lot #:

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.

Assay:


	Lot Number	Expiration Date	Date Received	Storage Temp	KN Lot No	KLP Lot No	KLP Min	KLP Max	
1	407992	07/Mar/2009							
2									

HIV-1 Calibrator Kit      Lot Number:       Expiration Date:       Date Rec:       Storage Temp (C):

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**.

VQA RNA Control

Lot Number

	Expected Value	Minimum Value	Maximum Value
1	VQA200	64	642


Expected Value

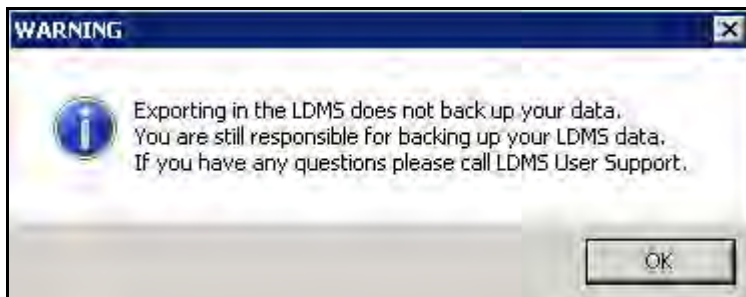
Figure 20. Abbott VQA Kit Information

## 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.

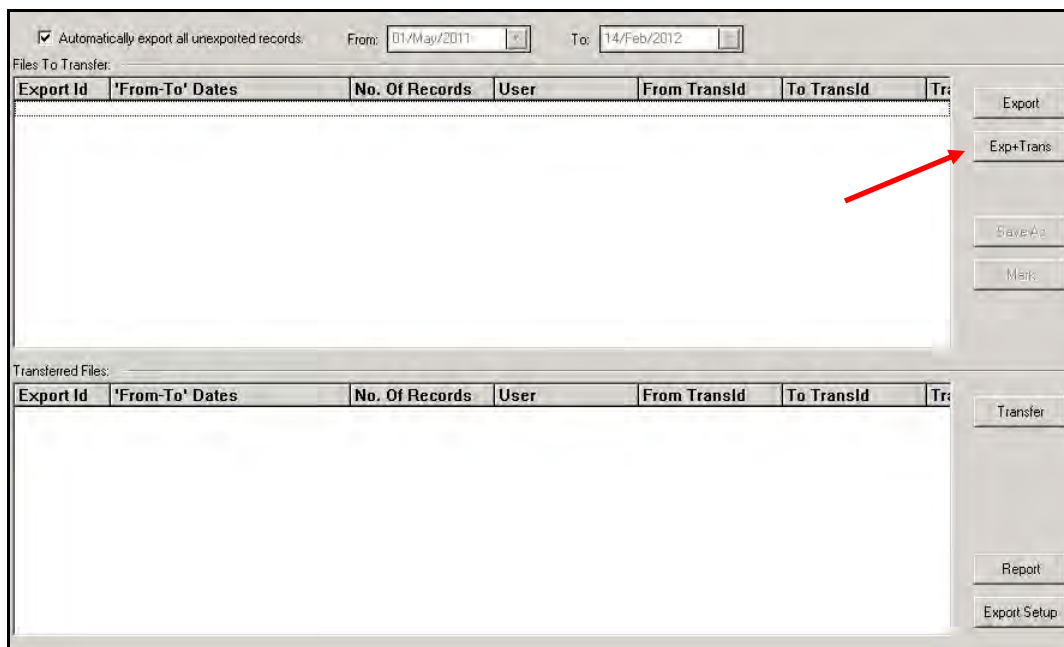
To open the Export module:

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.





The screenshot shows a software interface with a 'Files To Transfer' section. At the top, there is a checkbox labeled 'Automatically export all unexported records.' and two date pickers: 'From: 01/May/2011' and 'To: 14/Feb/2012'. Below this is a table with the following columns: 'Export Id', 'From-To' Dates, 'No. Of Records', 'User', 'From TransId', 'To TransId', and 'Tr'. The table is currently empty. To the right of the table are several buttons: 'Export', 'Exp+Trans', 'Save As', and 'Mark'. A red arrow points to the 'Exp+Trans' button. Below the table is a 'Transferred Files' section with a similar table structure, also empty. To the right of this section are buttons for 'Transfer', 'Report', and 'Export Setup'.

### ***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.