COBAS TaqMan HIV-1 Test Instructions

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Kit Entry

The general, sample prep., and PCR kit information is automatically loaded into the Kit Entry module from the TaqMan result file.
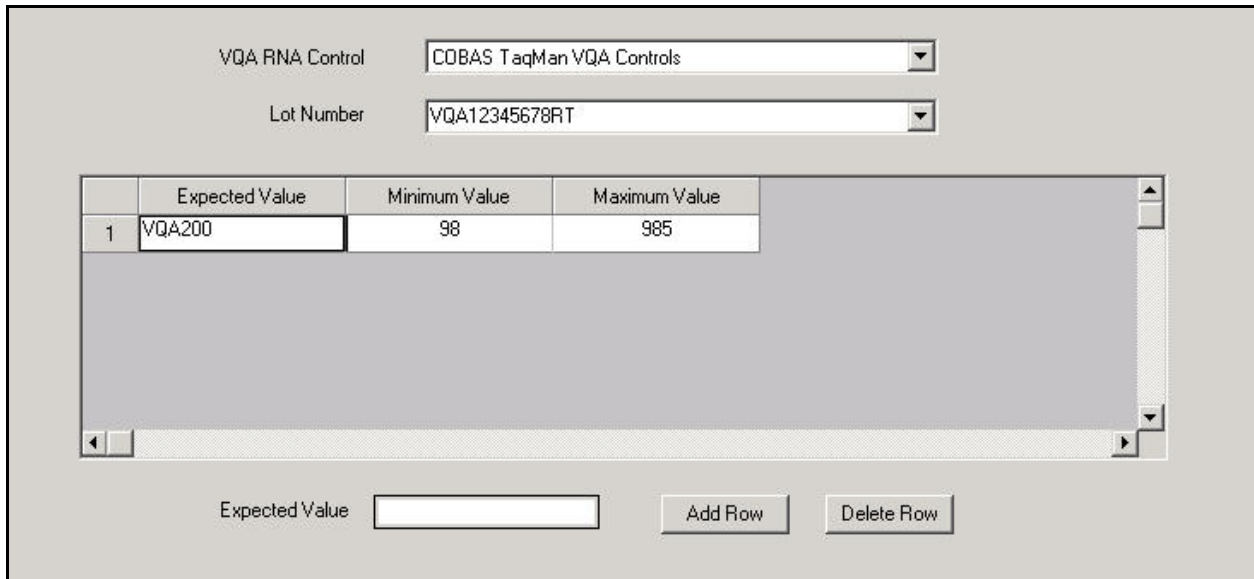
> **Note:** The **Received Date** and **Storage Temp** fields are not automatically loaded and will need to be manually entered in the Kit Entry module following the assay run. Appendix I: Kit Entry Screens shows the appearance of each of the kit entry screens following an assay run.

If a VQA control is included on the run, follow the steps below to enter the VQA kit information.

> **Note:** Any run containing ACTG, IMPAACT, or VQA samples must include a VQA200 copy control.

Entering VQA Kit Information

1. Go to **QA/QC – VQA Kit Entry** on the LDMS menu bar.
2. Select **COBAS TaqMan VQA Controls** from the **VQA RNA Control** box.
3. Enter the VQA kit lot number in the **Lot Number** field (format = VQAnnnnnnnnRT, where nnnnnnnn is the control lot number).
4. Enter 200 in the **Expected Value** box. Click on **Add Row** button.
5. Enter the **Minimum** and **Maximum** control values in the appropriate fields in the grid for the VQA 200 control.
6. Click the **Add** (➕) button on the LDMS toolbar. A success message appears.
7. Click **OK**.

Figure 1: TaqMan VQA Kit Entry Screen

> **Note:** VQA kit information can also be entered on the Preview screen of the TaqMan assay, by clicking **Add VQA Control** and entering the requested information in the Add VQA Lot dialog box.

Running the COBAS TaqMan HIV-1 Test

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.
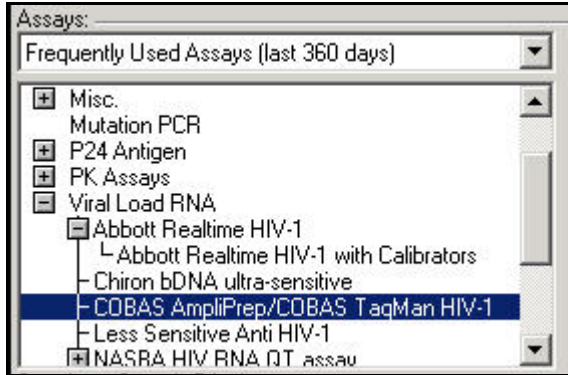3. Click **COBAS AmpliPrep/COBAS TaqMan HIV-1**. (See **Figure 2.**).

Figure 2: Assays

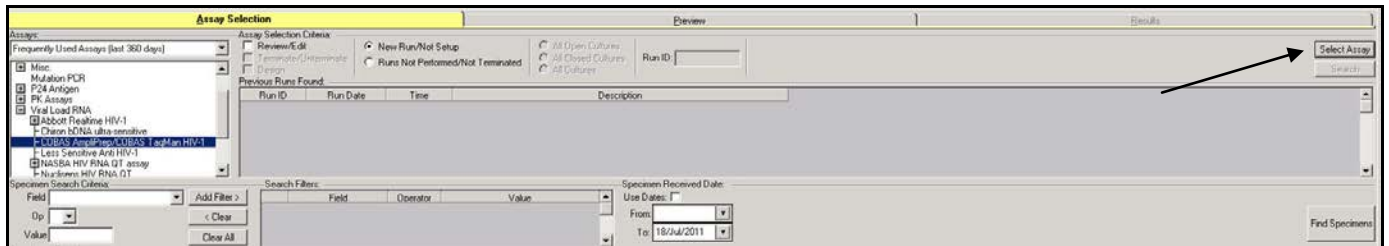4. Click **Select Assay (See Figure 3.**).

Figure 3: Assay Selection

5. Enter any desired search criteria in the Specimen Search section and click **Find Specimens**. The Specimens Found grid loads with specimens that match the search criteria and have the COBAS AmpliPrep/COBAS TaqMan HIV-1 test assigned. (See **Figure 4**.)

   Note: 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.
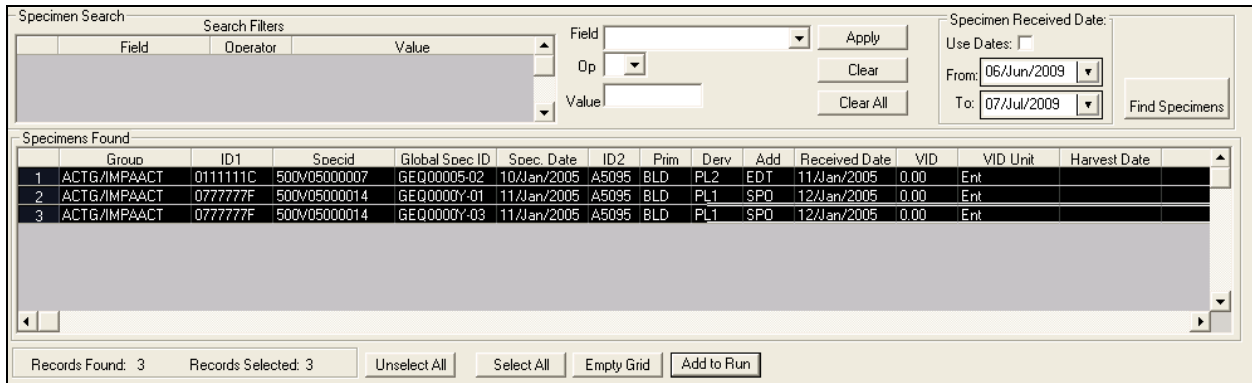

Figure 4: Specimens Found

6. Click the specimens that you wish to add to the run. Selected specimens appear in black.
7. Click **Add to Run**. The Preview tab opens. (See **Figure 5**.)

Position	Global Spec ID	PID/ID1	Specimen Date	VID Value	VID Unit	Dilution	Other Spec ID
1	NC						
2	LPC						
3	HPC						
4	VQA200						
5	BEQ00328-03	999515570	01/Dec/2004	1.00	Vst	1.0	
6	DEQ004SH-02	101000247	08/Jun/2009	6.00	Vst	1.0	
7	EEQ0031C-03	999515570	14/Sep/2004	0.00	Ent	1.0	

Run ID: 12714 ☑ Match by Position Up Down Delete

Add VQA Control Options Run Date 20/Jul/2011 ▼ Tech Initials MWC Version 1.0 ▼ Run Now Run Later

Figure 5: Preview Tab

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

8. To match the results to specimens on a run by Global Specimen ID (or Patid), verify that the **Match by Position** check box is not selected. By default, this option is not selected.

   OR

   To assign positions for all sample types, including controls, select the **Match by Position** check box. Arrange the line listing as desired using the **Up** and **Down** buttons. You can also re-arrange the order of the samples by clicking in the position column and renumbering the rows as needed.

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

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

- The LDMS will automatically match to the controls in the TaqMan result file.

- The LDMS will match specimens on the run to the Global Specimen ID, PID/ID1, or Other Spec ID values found in the Order Number or Specimen ID field of the TaqMan result file.

- If you are using PID/ID1 in the TaqMan result file, there cannot be more than one sample for a particular PID/ID1 on the same run.

9. To add a VQA control to the run, click **Add VQA Control**. The Add VQA Lot dialog box appears. (See **Figure 6**.)

Figure 6:   Add VQA Lot Dialog Box

    a.   Enter or select a VQA control lot number in the **Control Lot Number** box and the expected value in the **Expected Value** box.

         Note: The Minimum Value and Maximum Value fields will automatically load with the information previously entered.

    b.   Click **OK**.

10. If you wish to modify a dilution, click the **Dilution** field for the sample that you wish to modify and enter the new dilution value in the grid.
11. Enter a Run Date
12. Enter the technician's initials in the **Tech Initials** field.
13. Select a version of the assay from the Version field drop down menu.
14. Click **Run Now**. A message appears asking if you wish to run the assay.
15. Click **OK**. The Open dialog box appears.
16. Locate the appropriate file and click **Open**.

The LDMS begins reading the TaqMan 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 a User Censor

Censoring a Specimen or Assay Run

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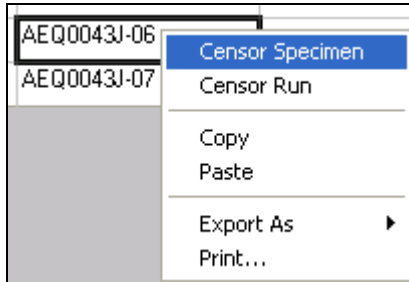

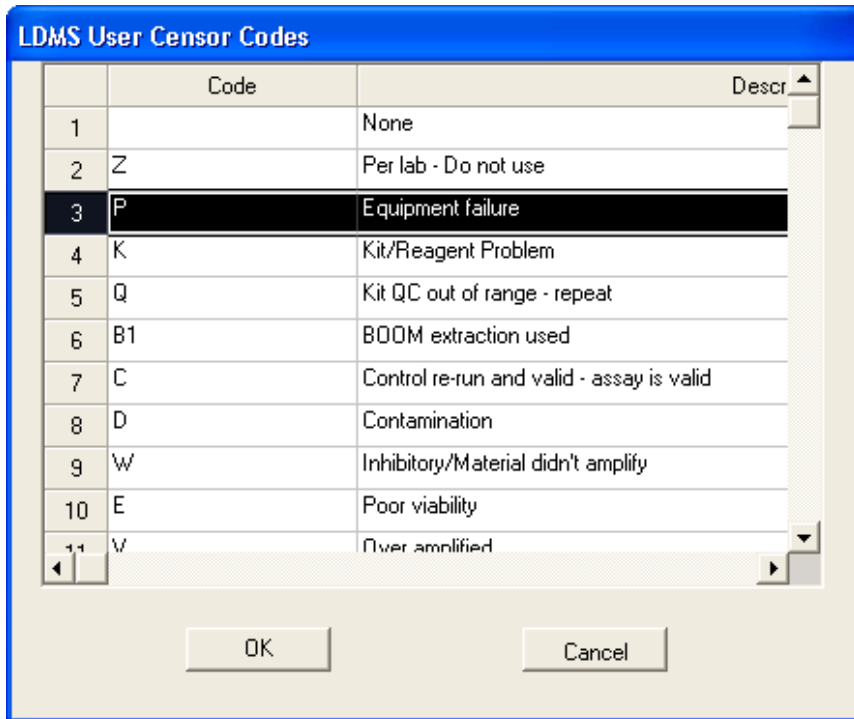**Figure 9: Shortcut Menu**

3. Click the appropriate censor. Click **OK**.

Figure 10: LDMS User Censor Codes Dialog Box

Note: The Specimen censor code is displayed in the User Censor column on the Calculated Results screen. The Run censor code is displayed in the User Censor field at the top of the Results screen.

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 11**.)

COBAS AmpliPrep/COBAS TaqMan HIV-1 Test Report
Lab Name:

Assay Name:	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test			Spec. Prep. Tech:	MWC
Run ID:	12832	System Run Censor:	Invalid	Reviewed By:	
Run Date:	18/Jul/2011	User Run Censor:	P	Review Date:	
File:	M:\LDMS Test Files\Training Profile\RNA\RNA - TaqMan\Training DB Configured Files\TaqMan Assay\taqman G censor valid run.csv				
Comments:					

General Kit Lot #:	K0458400000	KN Kit Lot #:	K0458400000	KHP Kit Lot #:	K0458400000
Sample prep Kit Lot #:		KLP Kit Lot #:	K0458400000	KHP range:	74,000 - 670,000
PCR Kit Lot #:		KLP range:	120 - 1,400		

Pos	Sample ID	Other Spec ID	PRI DER PID/ID1	Prot/ID2	VQA Kit Lot #: VQA range:	Expected Value	Result	System Censor	User Censor
9	K0F004T1-05		BLD PL2 0999999L	A5102			254 cp/mL		
8	K0F004T1-07		BLD PL2 0999999L	A5102			116 cp/mL		
7	K0F004T1-10		BLD PL2 0999999L	A5102			45988 cp/mL		
6	K0F004T1-21		BLD PL2 0999999L	A5102			403 cp/mL		P
5	K0F004T1-13		BLD PL2 0999999L	A5102			< 48 cp/mL	G	
4	VQA200				VQA11035079F98 - 985	200	227 cp/mL		
3	HPC						215591 cp/mL		
2	LPC						341 cp/mL		
1	NC						Target Not Detected	J	

Figure 11: 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 12**.)
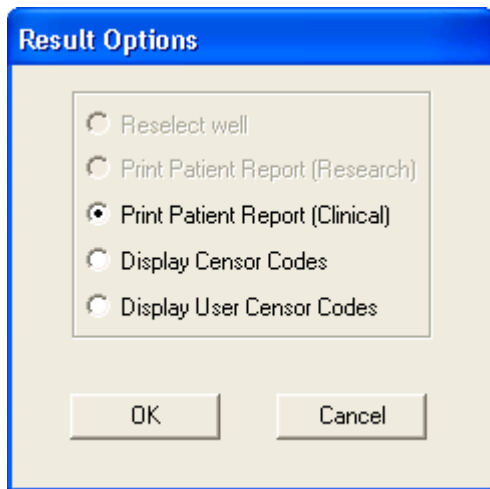2. Select **Print Patient Report (Clinical)** and click **OK**. The Patient Report Selection dialog box appears. (See **Figure 13**.)

Figure 3: 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.
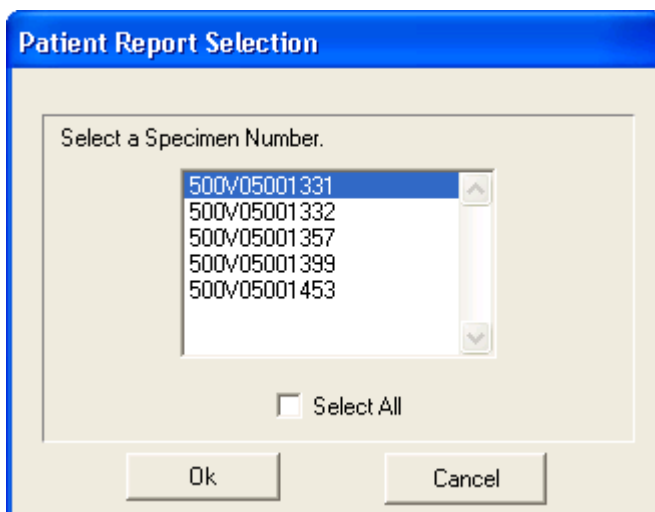
Figure 13: Patient Report Selection Dialog Box

4. Click **OK**. The Patient Report will be displayed for the selected specimen(s). (See **Figure 14**.)

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

LDMS - COBAS AmpliPrep/COBAS TaqMan HIV-1 Test Patient Report

Patient:	0999999L	**SID:**	A51029292I

Group / Protocol: ACTG/IMPAACT A5102

Specimen Date:	26/Apr/2005 10:00	**Visit:**	21.00 Weeks

Clinic Info:	901 Univ. of Miami AIDS CRS	**Fax:**	305-243-5765

Testing Lab Info:

Specimen ID:	015V09000002	**Received Date:**	26/Apr/2005	**Primary:**	Blood (Whole)
Global Spec ID:	K0F004T1-07	**Received Time:**		**Additive:**	EDTA
Other Spec ID:		**Sample Condition:**	Satisfactory	**Derivative:**	Plasma, Double-Spun

Type of Assay: COBAS AmpliPrep/COBAS TaqMan HIV-1 Test
Assay Date: 18/Jul/2011   **Sample Prep Tech:** MWC

Results:

Copies / mL:	Log Base 10 Value
116	2.06

Run comment:

Sample comment:

Reportable Range: The COBAS AmpliPrep/COBAS TaqMan HIV-1 Test assay range of quantitation is 48 to 10,000,000 copies/mL.

Reported By: _____

Figure 4: Patient Report

Appendix I: Kit Entry Module Screens

When the COBAS TaqMan HIV-1 test is run, the information on the general kit, sample prep. kit, and PCR kit screens is automatically populated from the TaqMan result file. Below are examples of the Kit Entry module screens after the assay is run showing the data pulled from the TaqMan result file. To complete the remaining fields, go to **QA/QC – Kit Entry Module**, select the appropriate kit, and enter any missing information.

General Kit Screen

Figure 5: TaqMan General Kit Information

Sample Prep. Kit Screen

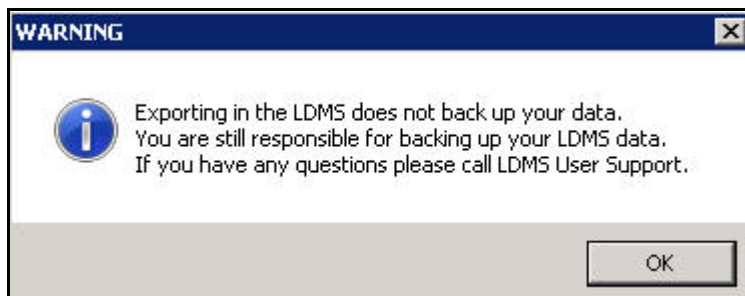**Figure 6. TaqMan Sample Prep. Kit Information**

PCR Kit Screen

Figure 7: TaqMan PCR 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.