COBAS TaqMan HCV 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.

Running the COBAS TaqMan HCV 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 HCV**. (See **Figure 2.**).

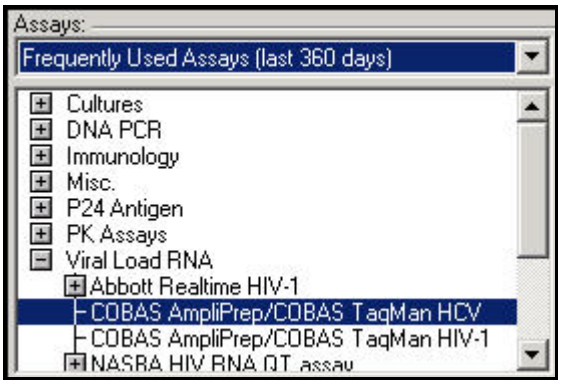


Figure 1. Assays

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

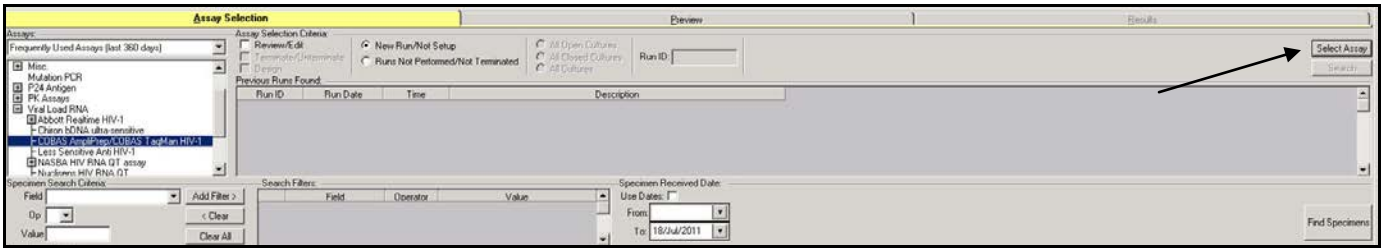


Figure 3. Assay Selection

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 HCV 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.

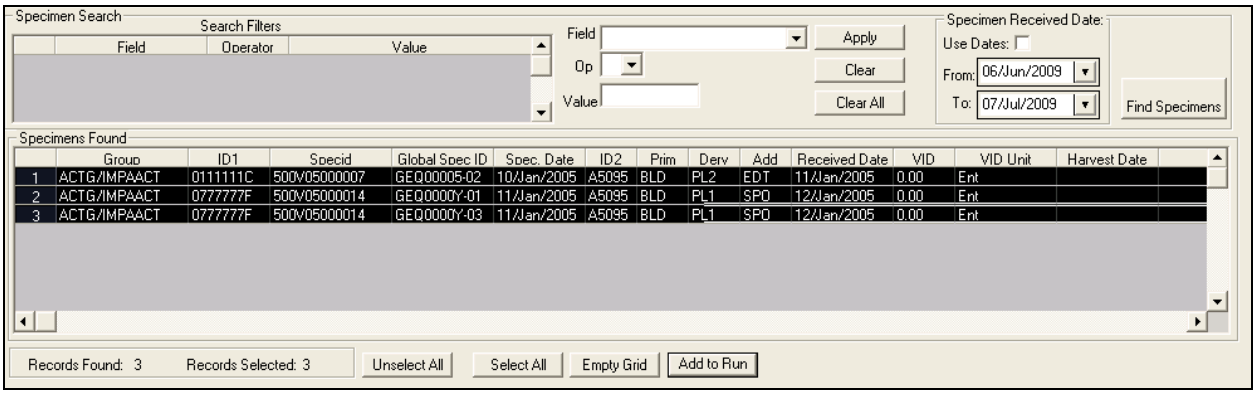


Figure 4. Specimens Found

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**.)

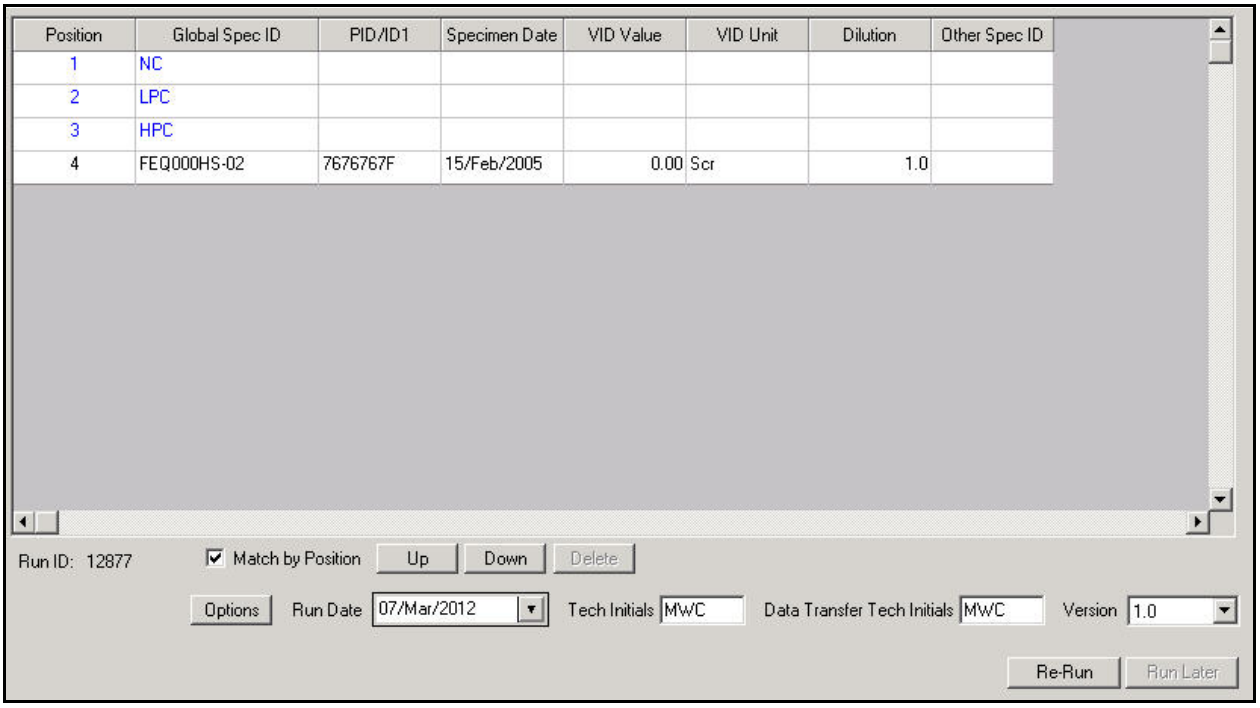


Figure 5. Preview Tab

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 or PID/ID1 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. 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.
10. Enter a Run Date
11. Enter the technician's initials in the **Tech Initials** field.
12. Select a version of the assay from the Version field drop down menu.
13. Click **Run Now**. A message appears asking if you wish to run the assay.
14. Click **OK**. The Open dialog box appears.
15. 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 6**.)

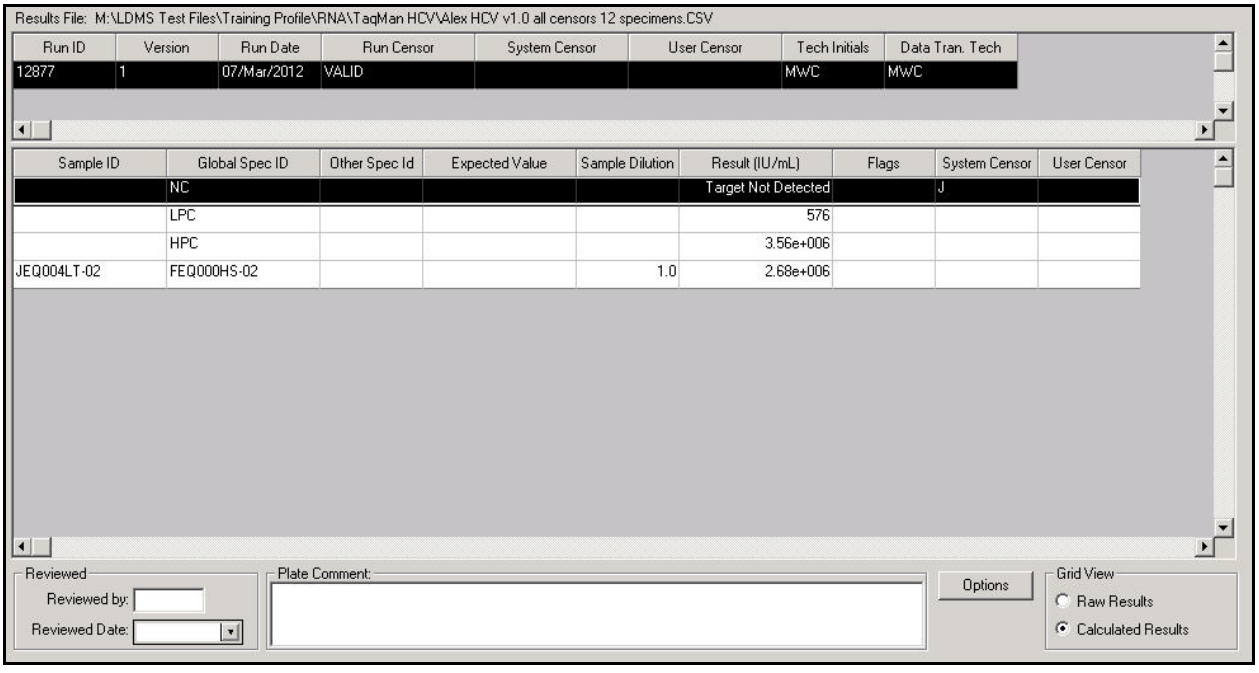


Figure 2. Calculated Results Screen

To display Raw Results as the Grid View option, click **Raw Results**. (See **Figure 7**.)

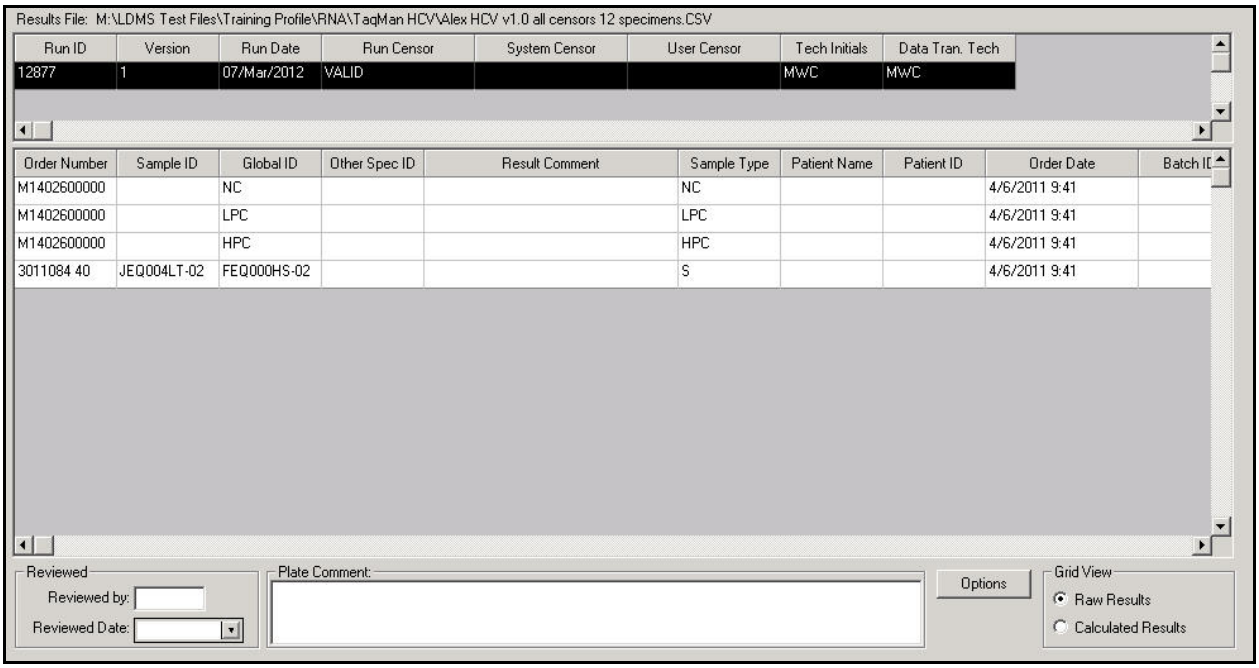


Figure 3. Raw Results Screen

Adding a User Censor

Censoring a Specimen

1. From the Results screen, right-click on the specimen that you wish to censor.
2. Select **Censor Specimen** from the shortcut menu. (See **Figure 8**.) The LDMS Censor Codes dialog box appears. (See **Figure 9**.)

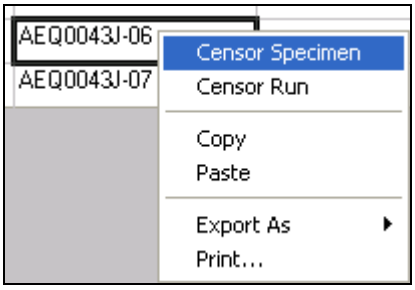


Figure 4. Shortcut Menu

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

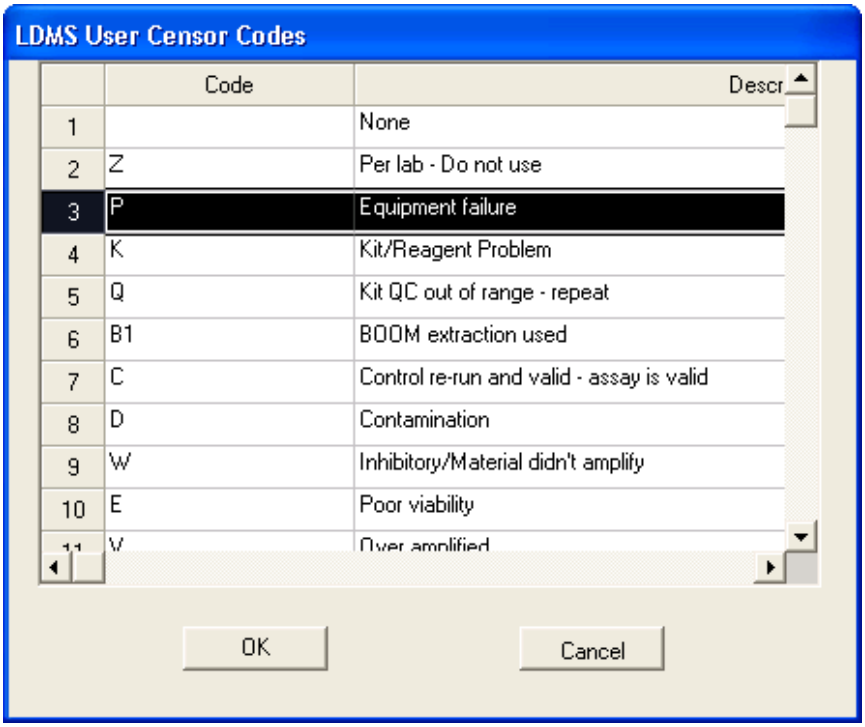


Figure 5. LDMS User Censor Codes Dialog Box

4. The censor code is displayed in the User Censor column on the Calculated Results screen.

Censoring an Assay Run

1. After viewing the assay results on the Result screen, click the **Preview** tab.
2. Right-click on a specimen on the assay plate.
3. Select **Censor Run** from the shortcut menu. (See **Figure 10**.) The LDMS User Censor Codes dialog box appears.

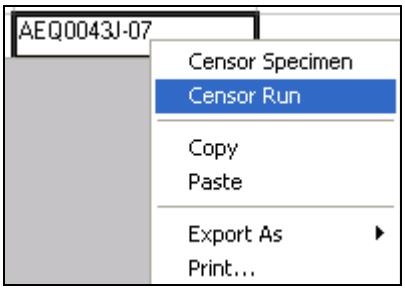


Figure 6. Shortcut Menu

4. Click on the appropriate censor. (See **Figure 11**.)

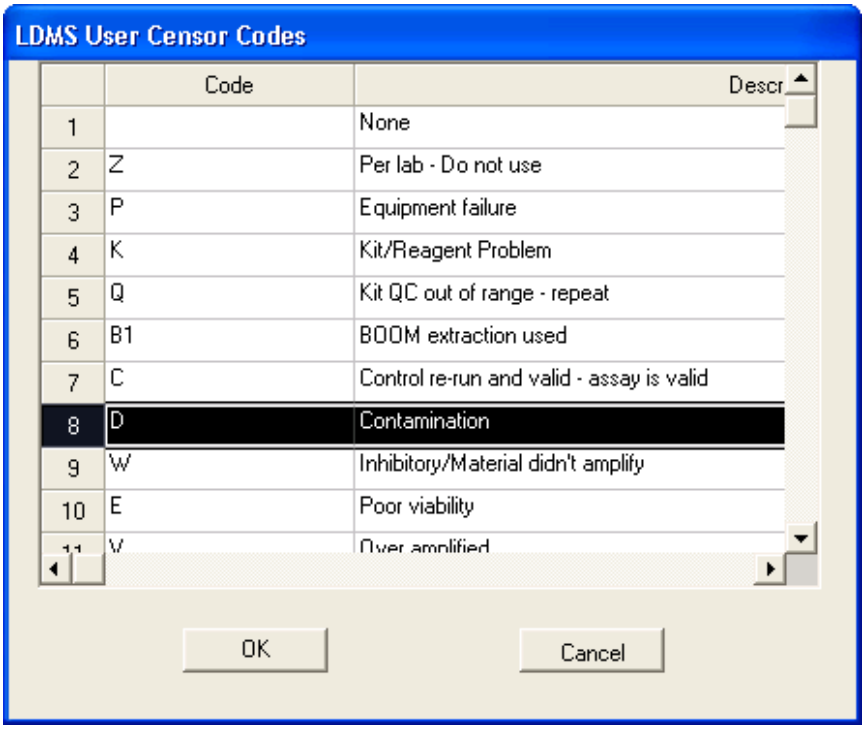


Figure 7. LDMS User Censor Codes Dialog Box

5. Click **OK**. The 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 12**.)

COBAS AmpliPrep /COBAS TaqMan HCV Test Report

Lab Name:

Assay Name : COBAS AmpliPrep/COBAS TaqMan HCV Test
Run ID: 12877 **System Run Censor :** Valid **Spec. Prep. Tech:** MWC
Run Date: 07/Mar/2012 **User Run Censor :** **Data Transfer Tech:** MWC
Reviewed By: **Review Date:**
File: M:\LDMS Test Files\Training Profile\RNA\TaqMan HCV\Alex HCV v1.0 all censors 12 specimens.CSV

Comments:

General Kit Lot #: M1402600005 **KLP range:** 220 - 2,200 **KHP range:** 1,100,000 - 11,000,000
Sample prep Kit Lot #:

Pos	Sample ID	Other Spec ID	PRI DER PID/ID1	Prot/ID2	VQA Kit Lot # : VQA range:	Expected Value	Result	System Censor	User Censor
1	NC						Target Not Detected	J	
2	LPC						576 IU/mL		
3	HPC						3.56e+006 IU/mL		
4	FEQ000HS-02		BLD PL2 7676767F	A5102			2.68e+006 IU/mL		

Figure 8. 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 13**.)
2. Select **Print Patient Report (Clinical)** and click **OK**. The Patient Report Selection dialog box appears. (See **Figure 14**.)

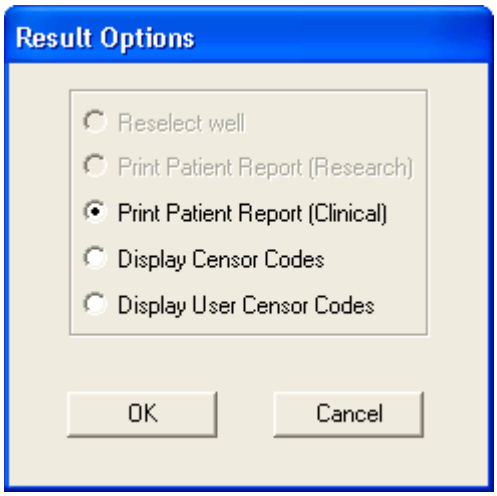


Figure 9. Result Options Dialog Box

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

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

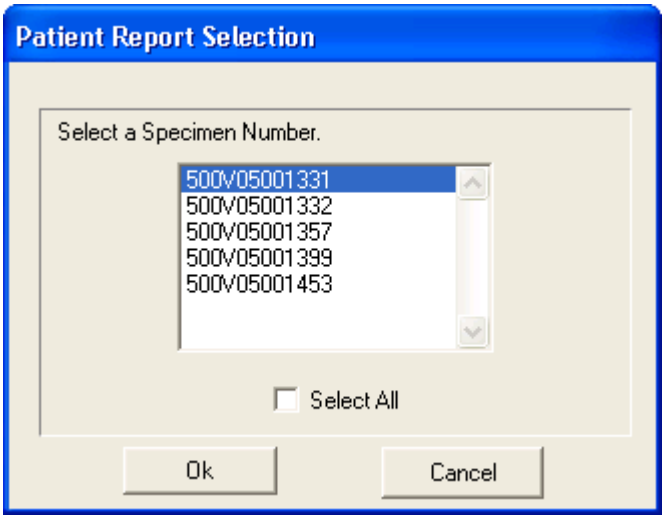


Figure 10. Patient Report Selection Dialog Box

4. Click **OK**. The Patient Report will be displayed for the selected specimen(s). (See **Figure 15**.)

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

LDMS - COBAS AmpliPrep/COBAS TaqMan HCV Test Patient Report

Patient:	7676767F			**SID:**	A51020447H
Group / Protocol:	ACTG/IMPAACT A5102				
Specimen Date:	15/Feb/2005 10:32			**Visit:**	0.00 Screening
Clinic Info:	701 UCSD, AVRC CRS			**Fax:**	619-298-6476
Testing Lab Info:					
Specimen ID:	500V05000185	**Received Date:**	15/Feb/2005	**Primary:**	Blood (Whole)
Global Spec ID:	FEQ000HS-02	**Received Time:**		**Additive:**	EDTA
Other Spec ID:		**Sample Condition:**	Satisfactory	**Derivative:**	Plasma, Double-Spun
Type of Assay:	COBAS AmpliPrep/COBAS TaqMan HCV Test				
Assay Date:	07/Mar/2012			**Sample Prep Tech:**	MWC
				Data Transfer Tech:	MWC

Results:

IU/mL	Log Base 10 Value
2,680,000	6.43

Run comment:

Sample comment:

Reportable Range: The COBAS AmpliPrep/COBAS TaqMan HCV Test assay range of quantitation is 43 to 69,000,000.00 IU/mL.

Figure 11. Patient Report

Appendix I: Kit Entry Module Screens

When the COBAS TaqMan HCV test is run, the information on the general kit, sample prep. kit, or 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

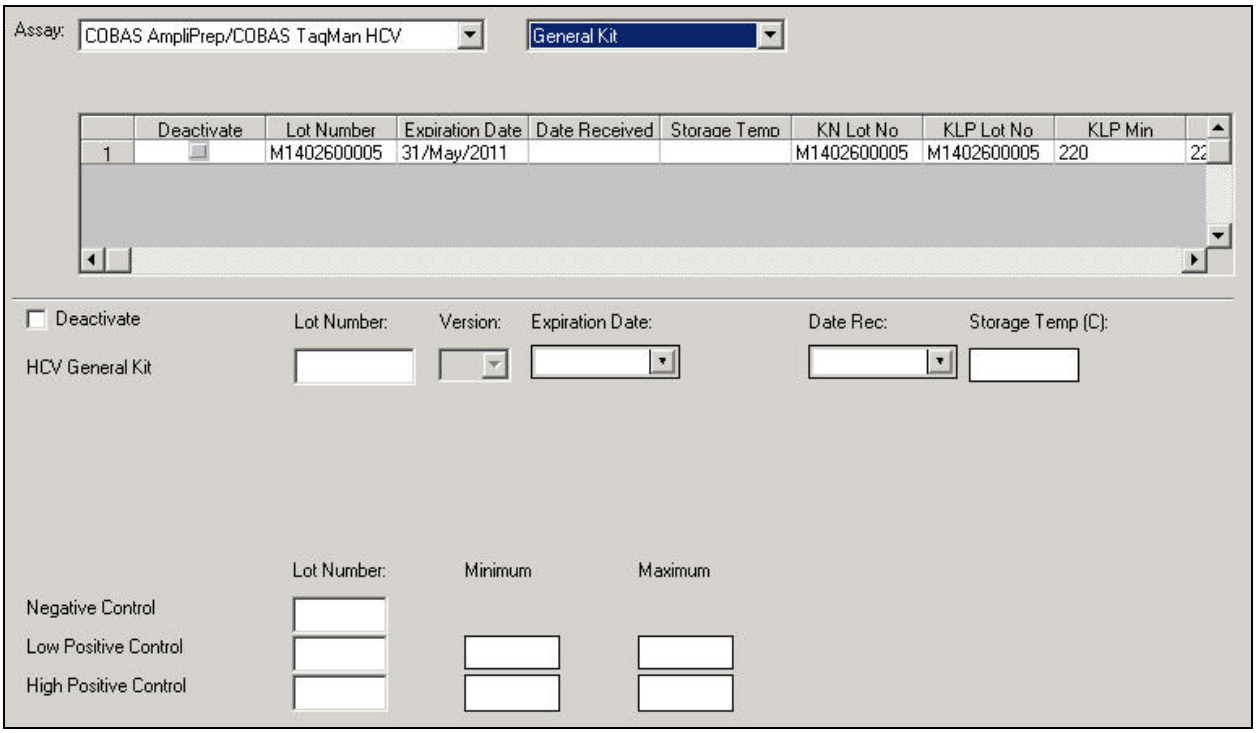


Figure 12. TaqMan General Kit Information

Sample Prep. Kit Screen

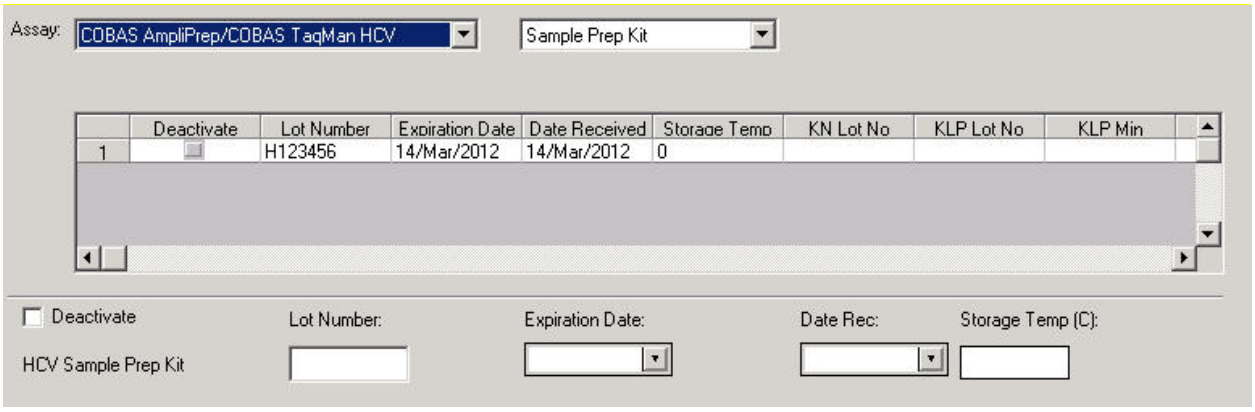


Figure 13. TaqMan Sample Prep. Kit Information

PCR Kit Screen

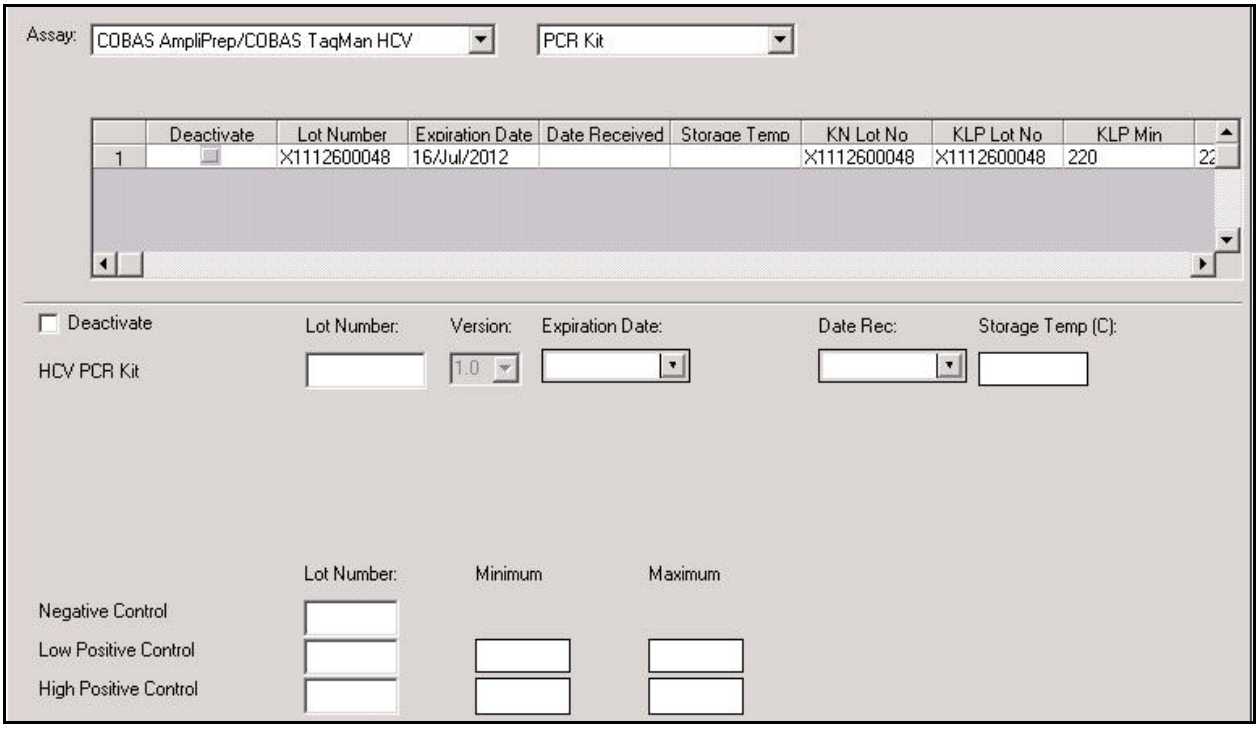


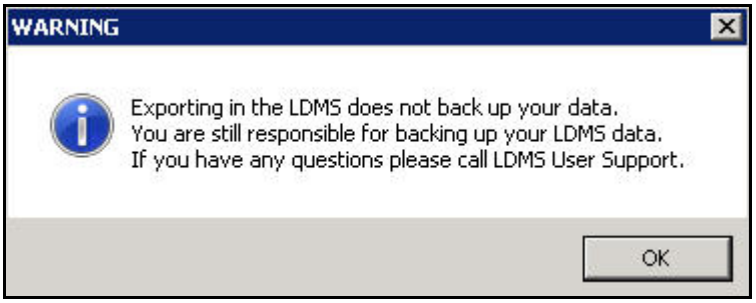
Figure 14. TaqMan PCR Kit Information

Exporting Data to Frontier Science

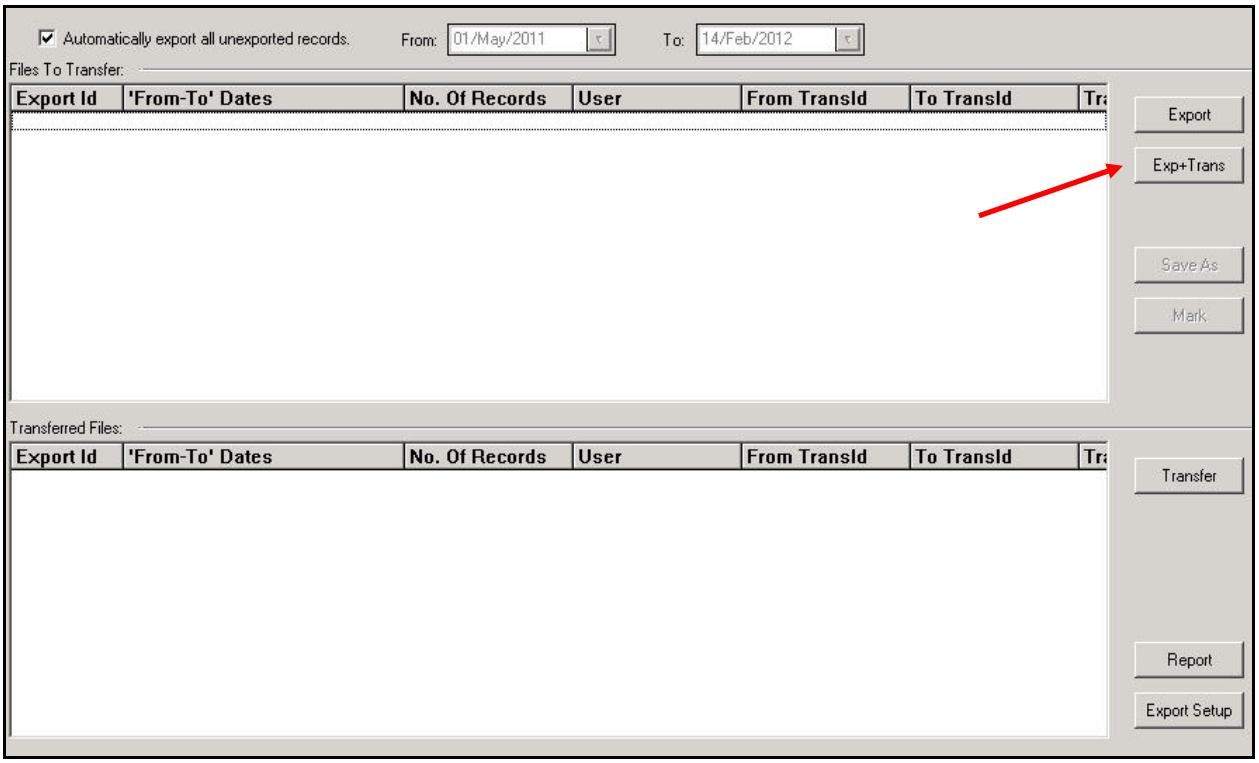
Laboratory data should be exported to Frontier Science on a regular basis. The frequency of data export often depends on the size of the laboratory database and workload.

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.