


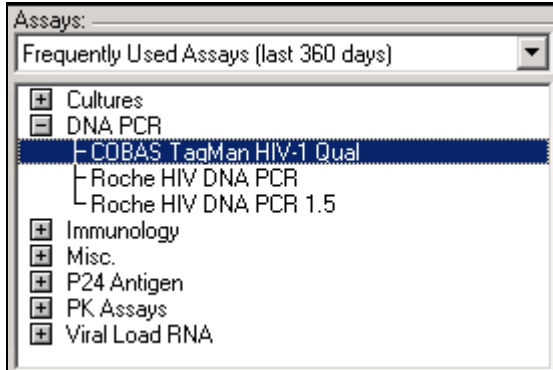
# COBAS Ampliprep/COBAS TaqMan HIV-1 Qualitative Test Instructions

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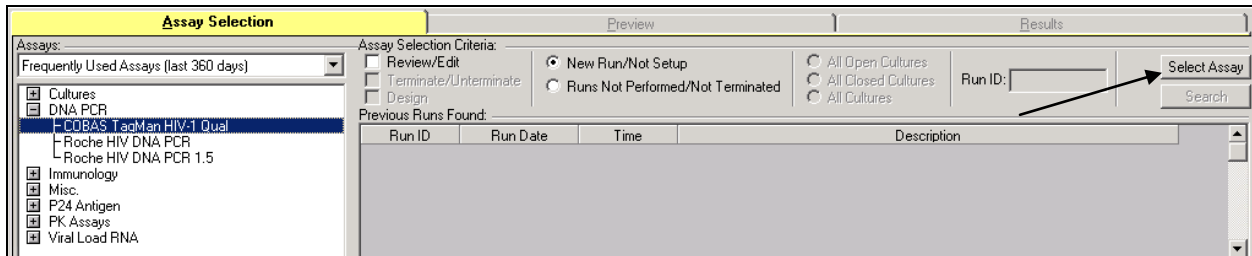
## Running the COBAS Ampliprep/COBAS TaqMan HIV-1 Qualitative Test

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 DNA PCR category.
3. Click **COBAS TaqMan HIV-1 Qual..** (See **Figure 1.**)



**Figure 1: Assays**

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



**Figure 2: 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 TaqMan HIV-1 Qual test assigned. (See **Figure 3.**)

**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.

| Specimens Found: |           |          |              |                |             |       |      |       |     |               |       |          |              |        |
|------------------|-----------|----------|--------------|----------------|-------------|-------|------|-------|-----|---------------|-------|----------|--------------|--------|
|                  | Group     | ID1      | Specid       | Global Spec ID | Spec. Date  | ID2   | Prim | Deriv | Add | Received Date | VID   | VID Unit | Harvest Date | Cultur |
| 1                | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-01    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |
| 2                | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-02    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |
| 3                | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-03    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |
| 4                | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-04    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |
| 5                | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-05    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |
| 6                | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-06    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |
| 7                | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-07    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |
| 8                | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-08    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |
| 9                | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-09    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |
| 10               | ACTG/IMPA | 2345323B | 500V05000668 | EEQ001TZ-10    | 09/Jun/2005 | P1057 | BLD  | PL2   | EDT | 10/Jun/2005   | 28.00 | Day      |              |        |

**Figure 3: Specimens Found**

6. Click the specimens that you wish to add to the run. Selected specimens appear in black.

**Notes:**

**24 Item Run (One Rack):**

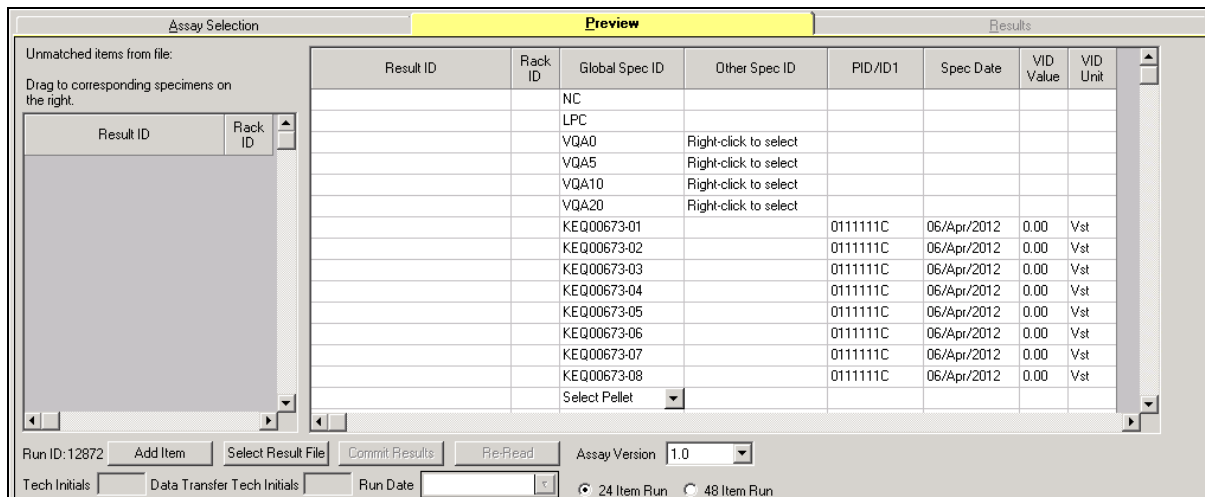
- The system will populate one Kit Positive and one Kit Negative control for a 24 item run.
- A user may add up to **16** specimens from the following groups to a **24 Item Run**:  
ACTG/IMPAACT, HPTN, VTN, MTN, or VQA.
  - Two blinded pellets and four VQA copy controls (VQA0, VQA5, VQA10, and VQA20) will be added to a 24 Item Run containing specimens from the above-listed groups.
- A user may add up to **22** specimens when adding non-logged specimens or specimens from groups other than those listed above.

**48 Item Run (Two Racks):**

- The system will populate two Kit Positive and two Kit Negative controls for a 48 item run.
  - Kit controls should be split between the racks, so that each rack has it's own positive and negative control
- Adding **17-36** specimens from the following groups will result in a **48 Item Run**:  
ACTG/IMPAACT, HPTN, VTN, MTN, or VQA.
  - Two blinded pellets and four VQA copy controls (VQA0, VQA5, VQA10, and VQA20) will be added to a 48 Item Run containing specimens from the above-listed groups.
  - Blinded pellets should be split up, so each rack has two pellets.
  - The VQA controls should be split between the two racks\*, as follows:
    - VQA0 and VQA10 on one rack
    - VQA5 and VQA20 on one rack
- A user may add up to **44** specimens when adding non-logged specimens or specimens from groups other than those listed above.
- The results of a 48 Item Run may span two result files.

\*Specimens are held accountable to controls on the rack on which they are located. It is possible to have one valid rack and one invalid rack on a 48 Item Run. Although the results for the specimens on the valid rack will be valid, the results of the samples on the invalid rack will be considered invalid. Any run containing one or more invalid racks will be counted as one invalid run in the LDMS. Two consecutive invalid runs or three invalid runs out of ten will result in an assay lockout. Users will need to contact the VQA lab ([vqa@rush.edu](mailto:vqa@rush.edu)) and LDMS User Support ([ldmshelp@fstrf.org](mailto:ldmshelp@fstrf.org)) if locked out of the COBAS Taqman HIV-1 Qual assay.

7. Click **Add to Run**. The Preview tab opens. (See **Figure 4.**)



**Figure 4: Preview Tab**

- Right click on the VQA items in the listing, to **Select VQA lot number**. The Add VQA Lot dialog box appears. (See **Figure 5**.)

**Note:** A new lot number can also be typed into the Add VQA Lot dialog box.

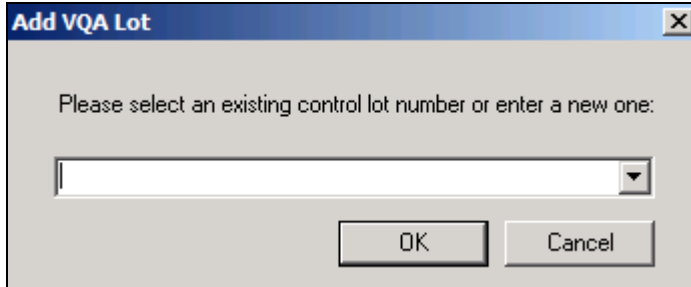


Figure 5: Add VQA Lot Dialog Box

- Enter or select a VQA control lot number. Click **OK**. If adding a new control lot number, a **Save** message will appear. (See **Figure 6**.) Click **Yes** to add the new control lot number.

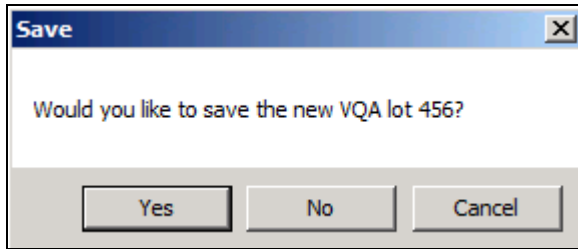


Figure 6: Save Message

- Select the pellet identifiers for each pellet added to the run. (See **Figure 7**.)

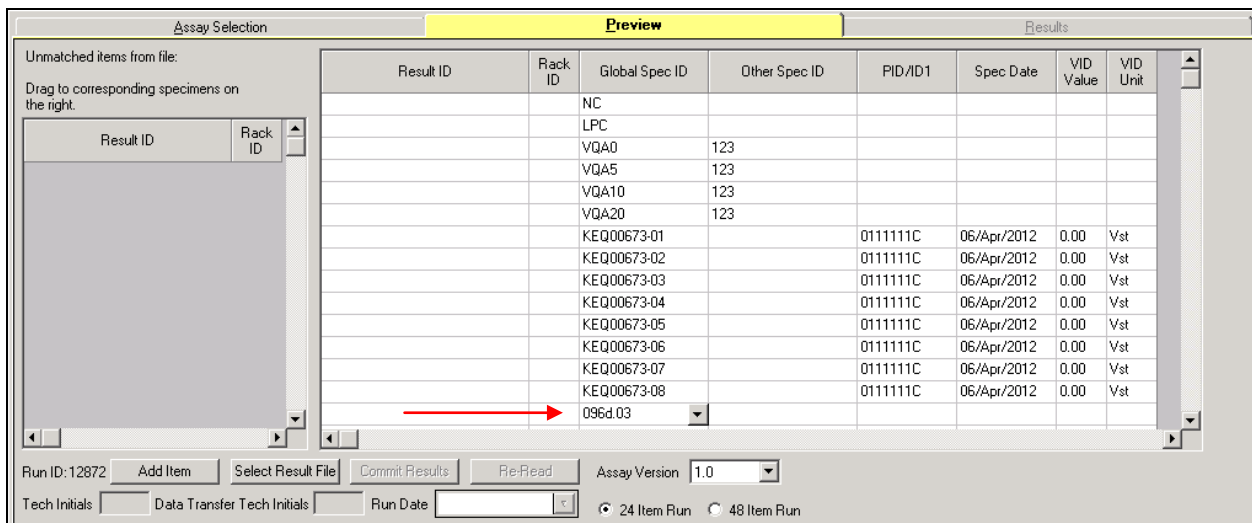


Figure 7: Select Pellet

- Generate the **COBAS TaqMan HIV-1 Qual Test Run Preview Report** by clicking on the Report button on the LDMS toolbar. (See **Figure 8**.)



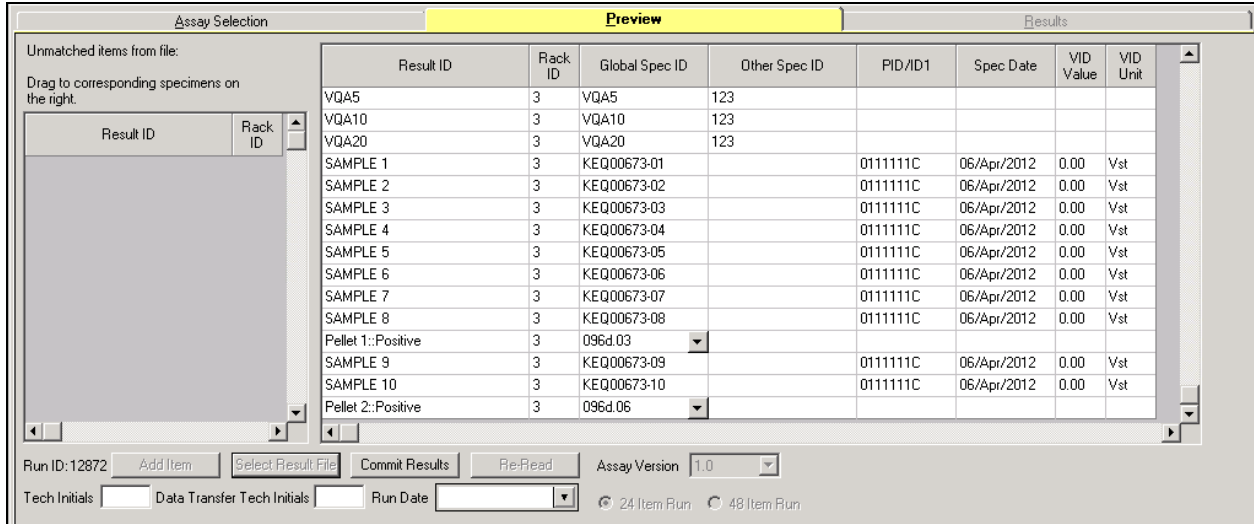


Figure 10: User Completed Matching

15. When matching is complete, enter the technician's initials in the **Tech Initials** fields and indicate the **Run Date**.
16. Click **Commit Results**. The LDMS will match the listing to the results in the result file. The **Results** screen will appear. (See Figure 11.)

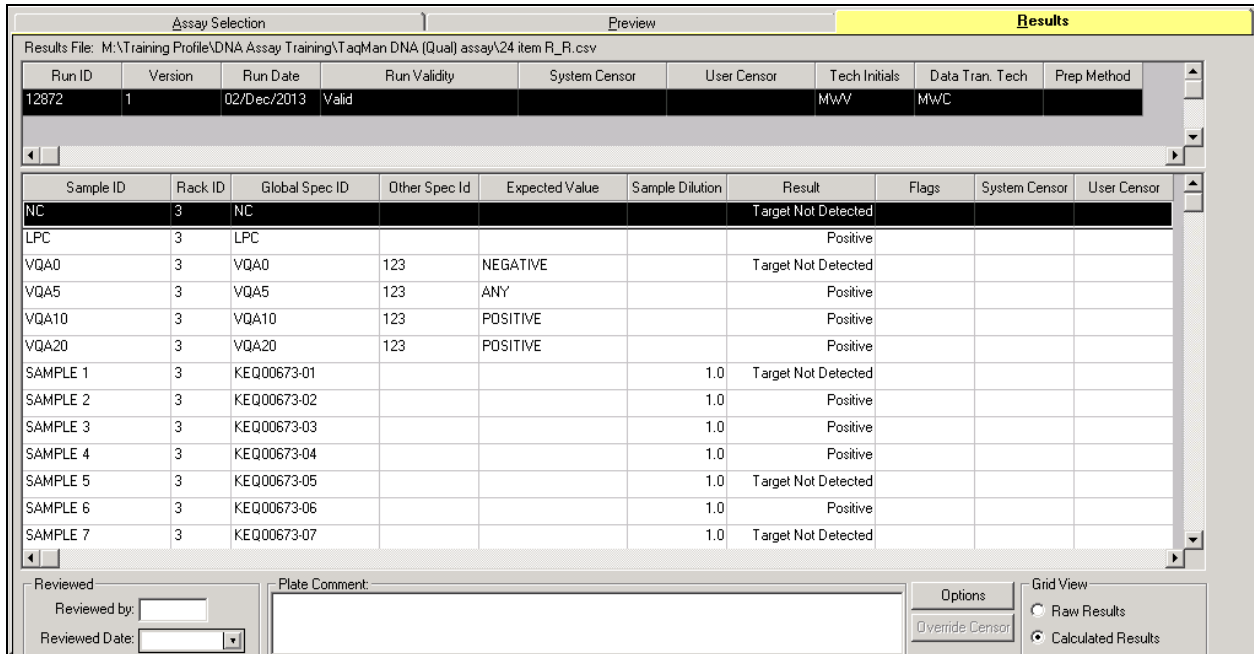


Figure 11: Calculated Results Screen

17. To display Raw Results as the Grid View option, click **Raw Results**.

## Incorrect Result File Selection

If the incorrect result file is selected and you are unable to match results properly:

1. Click on the **Close** button to leave the **Assay** module.
2. Click **Yes** to continue and discard the results.
3. Re-enter the Assay module and locate the desired run via **Runs Not Performed/Not Terminated**.
4. Select the desired result file and proceed as normal.

## Deleting a Run Before Committing Results

The user may delete a run, after all specimens have been removed from the template.

1. Select the **Runs Not Performed/Not Terminated** radio button on the **Assay Selection** tab, and click **Search**.
2. Locate the desired run, highlight it, and click **Select Assay**.
3. Right-click on each specimen (except NC and LPC) on the **Preview** tab and select **Delete Item**.
4. When all specimens have been removed from the run (except NC and LPC), click **Save** on the LDMS toolbar.
5. Click on the **Assay Selection** tab.
6. Right-click on the run in the listing and select **Delete Run**. Confirm that you want to delete the run. The specimens will be available to place on a new run.

## Deleting a Run After Committing Results

The user may delete a run, after all specimens have been removed from the template.

1. Select the **Review/Edit** check box on the **Assay Selection** tab, and click **Search**.
2. Locate the desired run, highlight it, and click **Select Assay**.
3. Click on the **Preview** tab.
4. Click **Re-Read** and click **Yes** in the Re-Read confirmation message.
5. Right-click on each specimen (except NC and LPC) on the **Preview** tab and select **Delete Item**.
6. When all specimens have been removed from the run (except NC and LPC), click **Save** on the LDMS toolbar.
7. Click on the **Assay Selection** tab.
8. **Uncheck** the **Review/Edit** check box and select the **Runs Not Performed/Not Terminated** radio button. Click **Search**.
9. Right-click on the run in the listing and select **Delete Run**. Confirm that you want to delete the run. The specimens will be available to place on a new run.

## Adding a User Censor

### *Censoring a Specimen or Assay Run*

1. From the **Results** screen, **right-click** on the specimen ID that you wish to censor.
2. Select **Censor Specimen** or **Censor Run** from the shortcut menu. (See **Figure 12.**) The LDMS User Censor Codes dialog box appears. (See **Figure 13.**)

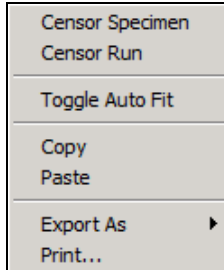


Figure 12: Shortcut Menu

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

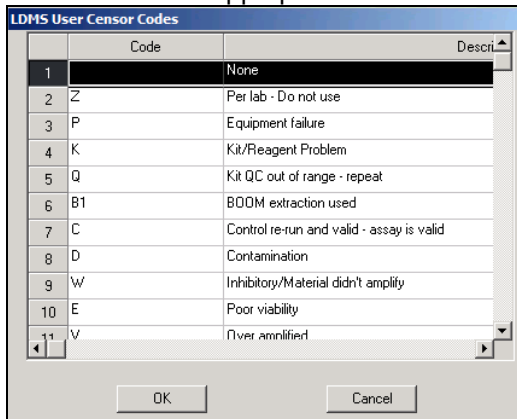



Figure 13: LDMS User Censor Codes Dialog Box

**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 14**.)

| COBAS TaqMan HIV-1 Qual, version 1.0 TestReport       |  |                    |     |                   |          |                     |                |                     |               |             |
|---|--|--------------------|-----|-------------------|----------|---------------------|----------------|---------------------|---------------|-------------|
| Lab Name:   |  |                    |     |                   |          |                     |                |                     |               |             |
| Assay Name: COBAS TaqMan HIV-1 Qual, version 1.0 Test |  |                    |     |                   |          |                     |                |                     |               |             |
| Run ID:   | 12872  | System Run Censor: |     | Valid             |          | Spec. Prep. Tech:   |                | MWW                 |               |             |
| Run Date:   | 02/Dec/2013  | User Run Censor:   |     |                   |          | Data Transfer Tech: |                | MWC                 |               |             |
| Reviewed By:  |  | Review Date:       |     |                   |          |                     |                |                     |               |             |
| File:   | M:\Training Profile\DNA Assay Training\TaqMan DNA (Qual) assay\24\item R_R.csv |                    |     |                   |          |                     |                |                     |               |             |
| Comments:   |  |                    |     |                   |          |                     |                |                     |               |             |
| General Kit Lot #:                                    | P1598300000  |                    |     |                   |          |                     |                |                     |               |             |
| Sample prep Kit Lot #:                                |  |                    |     |                   |          |                     |                |                     |               |             |
| Sample ID   | Other Spec ID  | PRI                | DER | PID/ID1           | Prot/ID2 | VQA Kit Lot #:      | Expected Value | Result              | System Censor | User Censor |
| NC  |  |                    |     |                   |          |                     |                | Target Not Detected |               |             |
| LPC   |  |                    |     |                   |          |                     |                | Positive            |               |             |
| VQA0  | 123  |                    |     |                   |          | 123                 | NEGATIVE       | Target Not Detected |               |             |
| VQA5  | 123  |                    |     |                   |          | 123                 | ANY            | Positive            |               |             |
| VQA10   | 123  |                    |     |                   |          | 123                 | POSITIVE       | Positive            |               |             |
| VQA20   | 123  |                    |     |                   |          | 123                 | POSITIVE       | Positive            |               |             |
| KEQ00673-01   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Target Not Detected |               |             |
| KEQ00673-02   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Positive            |               |             |
| KEQ00673-03   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Positive            |               |             |
| KEQ00673-04   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Positive            |               |             |
| KEQ00673-05   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Target Not Detected |               |             |
| KEQ00673-06   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Positive            |               |             |
| KEQ00673-07   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Target Not Detected |               |             |
| KEQ00673-08   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Positive            |               |             |
| 096d.03   |  |                    |     |                   |          |                     | POSITIVE       | Positive            |               |             |
| KEQ00673-09   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Positive            |               |             |
| KEQ00673-10   |  |                    |     | BLD PL1 01111111C | A5175    |                     |                | Positive            |               |             |
| 096d.06   |  |                    |     |                   |          |                     | POSITIVE       | Positive            |               |             |

Figure 14: 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 screen 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 15**.)
2. Select **Print Patient Report** and click **OK**. The Patient Report Selection dialog box appears. (See **Figure 16**.)

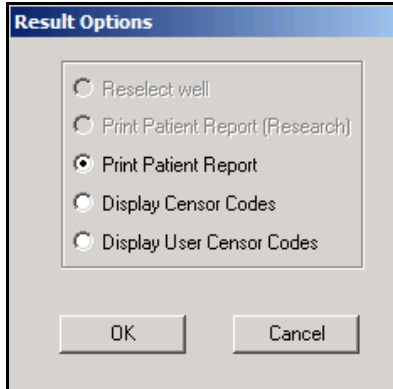


Figure 15: Result Options Dialog Box

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

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

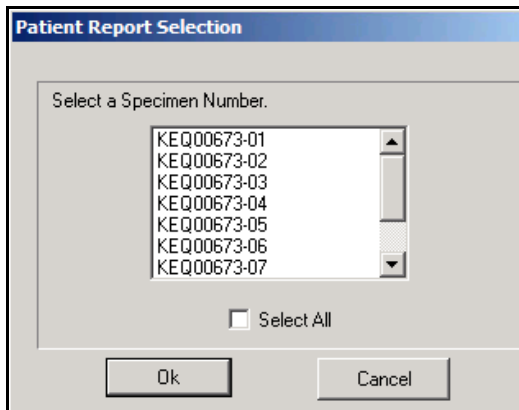



Figure 16: Patient Report Selection Dialog Box

4. Click **OK**. The Patient Report will be displayed for the selected specimen(s). (See **Figure 17**.)
5. Click the **Print** () button on the Crystal Reports toolbar.


| LDMS - COBAS TaqMan HIV-1 Qual Version 1.0 Test Patient Report |   |                     |                     |
|--|---|---------------------|---------------------|
| Patient:   | 0111111C                                  | SID:                | NOSID               |
| Group / Protocol:  | ACTG/IMPAACTA5175                         |                     |                     |
| Specimen Date:   | 06/Apr/2012 08:00                         | Visit:              | 0.00 Vist           |
| Clinic Info:   | 1001 Pitt CRS                             | Fax:                | 412-647-6253        |
| Testing Lab Info:  |   |                     |                     |
| Specimen ID:   | 500V12000006                              | Received Date:      | 06/Apr/2012         |
| Global Spec ID:  | KEQ00673-05                               | Received Time:      | 10:00               |
| Other Spec ID:   |   | Sample Condition:   | Satisfactory        |
|  |   | Primary:            | Blood (Whole)       |
|  |   | Additive:           | EDTA                |
|  |   | Derivative:         | Plasma, Single-Spun |
| Type of Assay:   | COBAS TaqMan HIV-1 Qual, version 1.0 Test |                     |                     |
| Assay Date:  | 02/Dec/2013                               | Sample Prep Tech:   | MWV                 |
|  |   | Data Transfer Tech: | MWC                 |
| Result: Target Not Detected                                    |   |                     |                     |
| Result comment: HIV-1 RNA or proviral DNA not detected         |   |                     |                     |
| Run comment:   |   |                     |                     |
| Sample comment:  |   |                     |                     |

Figure 17: Patient Report

## 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. (See **Figure 18**.)

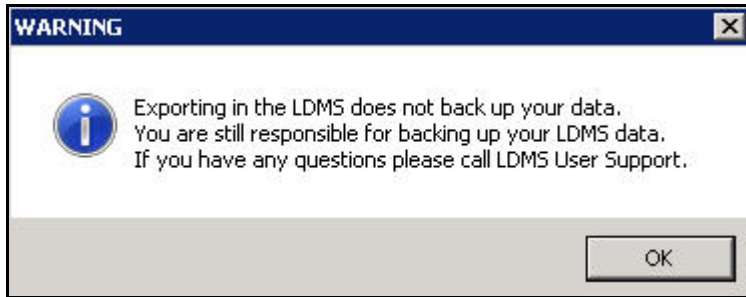


Figure 18: Export Warning

2. Click **OK**. The Data Export window appears. (See **Figure 19**.)

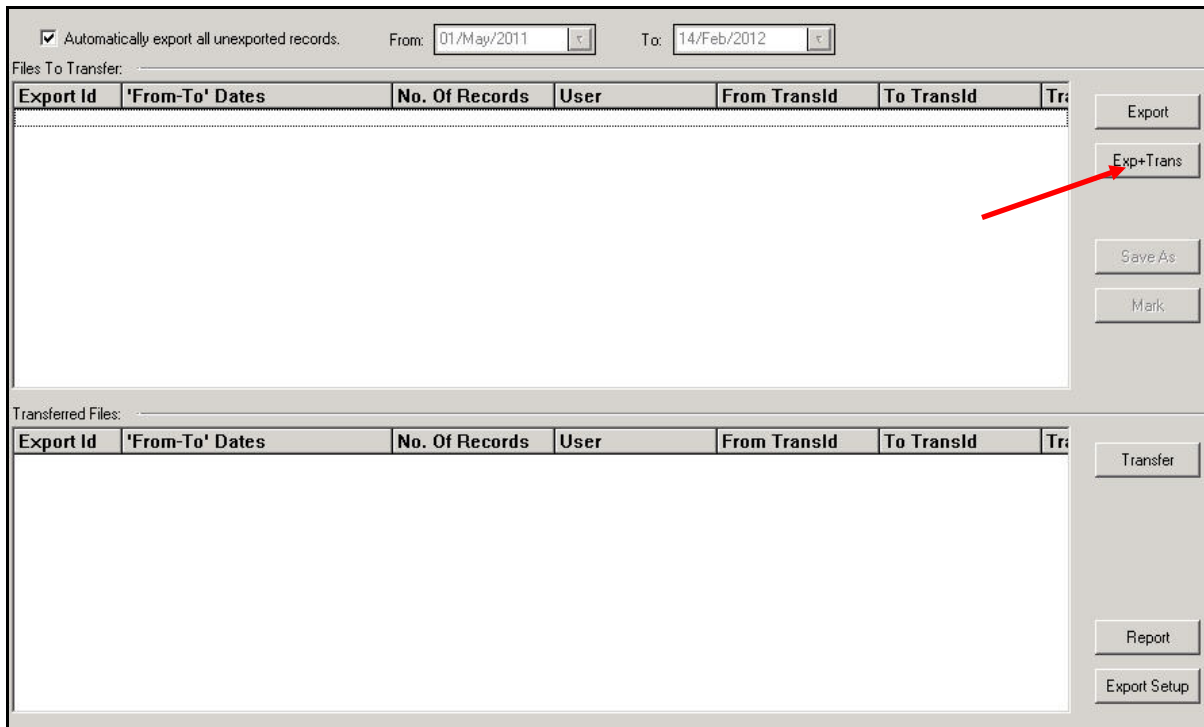


Figure 19: Data Export Window

### 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.