COBAS Ampliprep/COBAS TaqMan HIV-1 Qualitative Test

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.**).

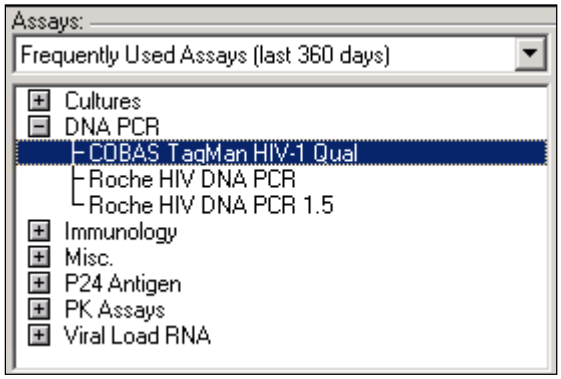


Figure 1: Assays

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

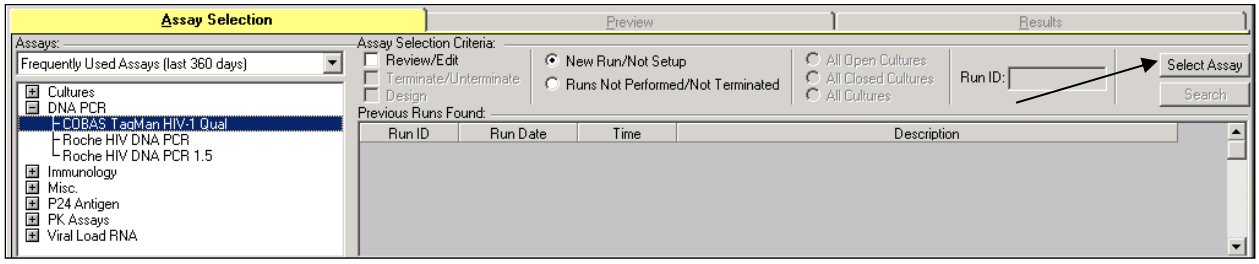
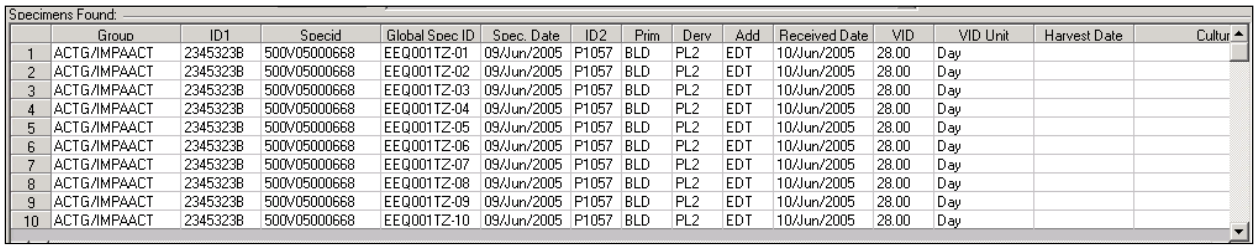


Figure 2: Assay Selection

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.



	Group	ID1	Specid	Global Spec ID	Spec. Date	ID2	Prim	Derv	Add	Received Date	VID	VID Unit	Harvest Date	Cultur
1	ACTG/IMPAACT	2345323B	500V05000668	EEQ001TZ-01	09/Jun/2005	P1057	BLD	PL2	EDT	10/Jun/2005	28.00	Day		
2	ACTG/IMPAACT	2345323B	500V05000668	EEQ001TZ-02	09/Jun/2005	P1057	BLD	PL2	EDT	10/Jun/2005	28.00	Day		
3	ACTG/IMPAACT	2345323B	500V05000668	EEQ001TZ-03	09/Jun/2005	P1057	BLD	PL2	EDT	10/Jun/2005	28.00	Day		
4	ACTG/IMPAACT	2345323B	500V05000668	EEQ001TZ-04	09/Jun/2005	P1057	BLD	PL2	EDT	10/Jun/2005	28.00	Day		
5	ACTG/IMPAACT	2345323B	500V05000668	EEQ001TZ-05	09/Jun/2005	P1057	BLD	PL2	EDT	10/Jun/2005	28.00	Day		
6	ACTG/IMPAACT	2345323B	500V05000668	EEQ001TZ-06	09/Jun/2005	P1057	BLD	PL2	EDT	10/Jun/2005	28.00	Day		
7	ACTG/IMPAACT	2345323B	500V05000668	EEQ001TZ-07	09/Jun/2005	P1057	BLD	PL2	EDT	10/Jun/2005	28.00	Day		
8	ACTG/IMPAACT	2345323B	500V05000668	EEQ001TZ-08	09/Jun/2005	P1057	BLD	PL2	EDT	10/Jun/2005	28.00	Day		
9	ACTG/IMPAACT	2345323B	500V05000668	EEQ001TZ-09	09/Jun/2005	P1057	BLD	PL2	EDT	10/Jun/2005	28.00	Day		
10	ACTG/IMPAACT	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.
  - Four 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) and LDMS User Support (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**.)

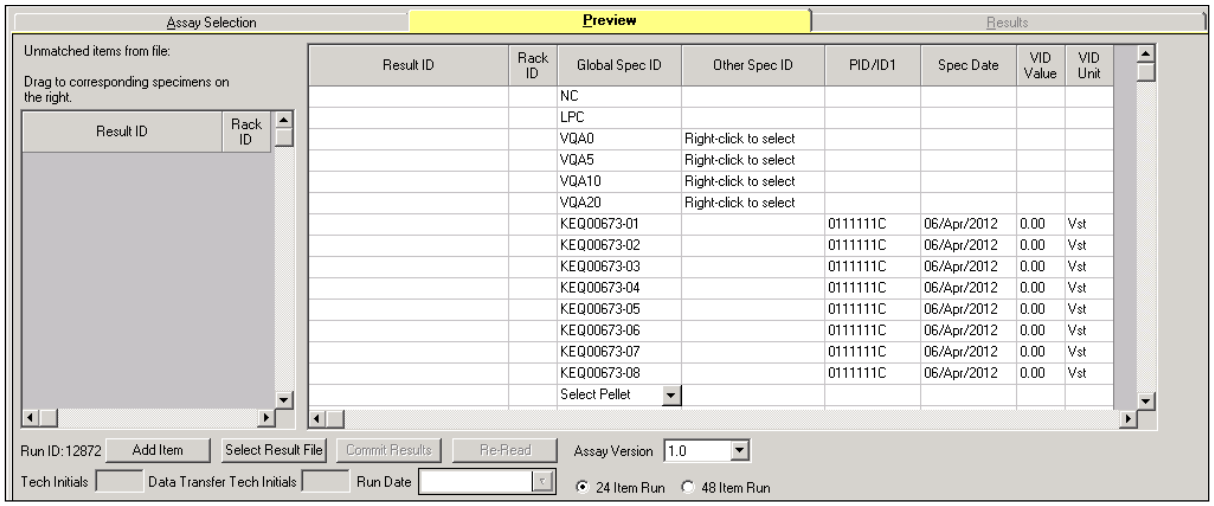


Figure 4: Preview Tab

8. 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.

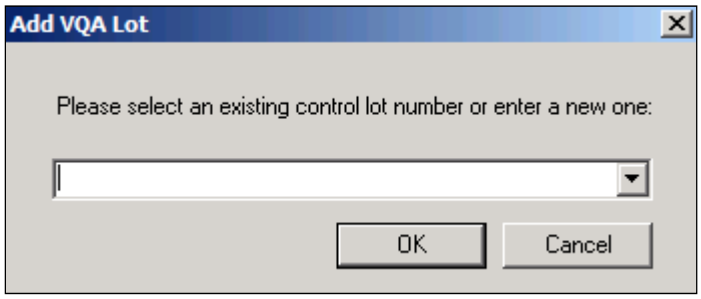


Figure 5: Add VQA Lot Dialog Box

9. **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.**

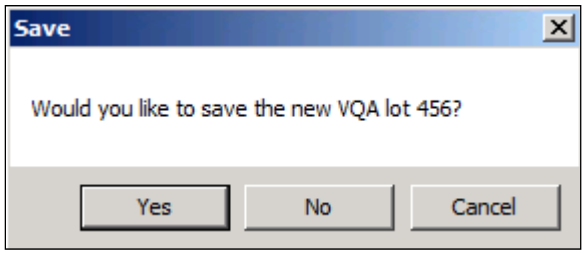


Figure 6: Save Message

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

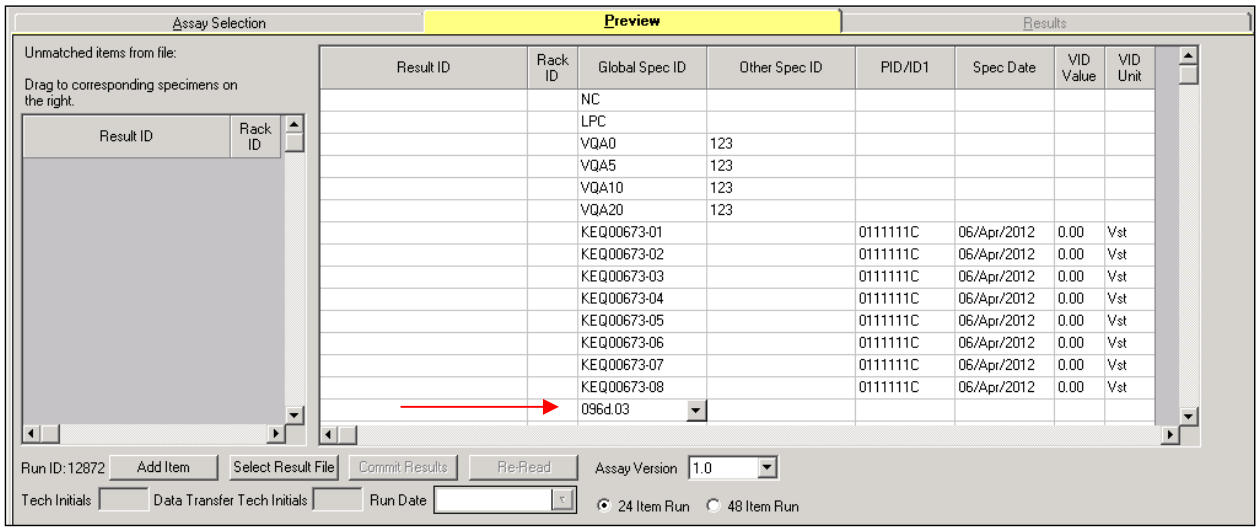


Figure 7: Select Pellet

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

COBAS TaqMan HIV-1 Qual Version 1.0 Test Run Preview

Run ID 12872 **AssayName** COBAS TaqMan HIV-1 Qual

Position	Global Spec ID	PID/ID1	Spec Date	VID	VID Unit	Other Spec ID	Dilution	Barcode
1	NC							
2	LPC							
3	VQA0					123		
4	VQA5					123		
5	VQA10					123		
6	VQA20					123		
7	KEQ00673-01	0111111C	06/Apr/2012	0.00	Vst		1.0	
8	KEQ00673-02	0111111C	06/Apr/2012	0.00	Vst		1.0	
9	KEQ00673-03	0111111C	06/Apr/2012	0.00	Vst		1.0	
10	KEQ00673-04	0111111C	06/Apr/2012	0.00	Vst		1.0	
11	KEQ00673-05	0111111C	06/Apr/2012	0.00	Vst		1.0	
12	KEQ00673-06	0111111C	06/Apr/2012	0.00	Vst		1.0	
13	KEQ00673-07	0111111C	06/Apr/2012	0.00	Vst		1.0	
14	KEQ00673-08	0111111C	06/Apr/2012	0.00	Vst		1.0	
15	096d.03							
16	KEQ00673-09	0111111C	06/Apr/2012	0.00	Vst		1.0	
17	KEQ00673-10	0111111C	06/Apr/2012	0.00	Vst		1.0	
18	096d.06							

Figure 8: Run Preview Report

12. Click **Select Result File**. Click **Yes** in the **Run Assay** message that appears.

13. Browse to the desired result file. Select the file and click Open. The LDMS begins matching the TaqMan result file to the listing of specimens added to the run. (See **Figure 9.**)

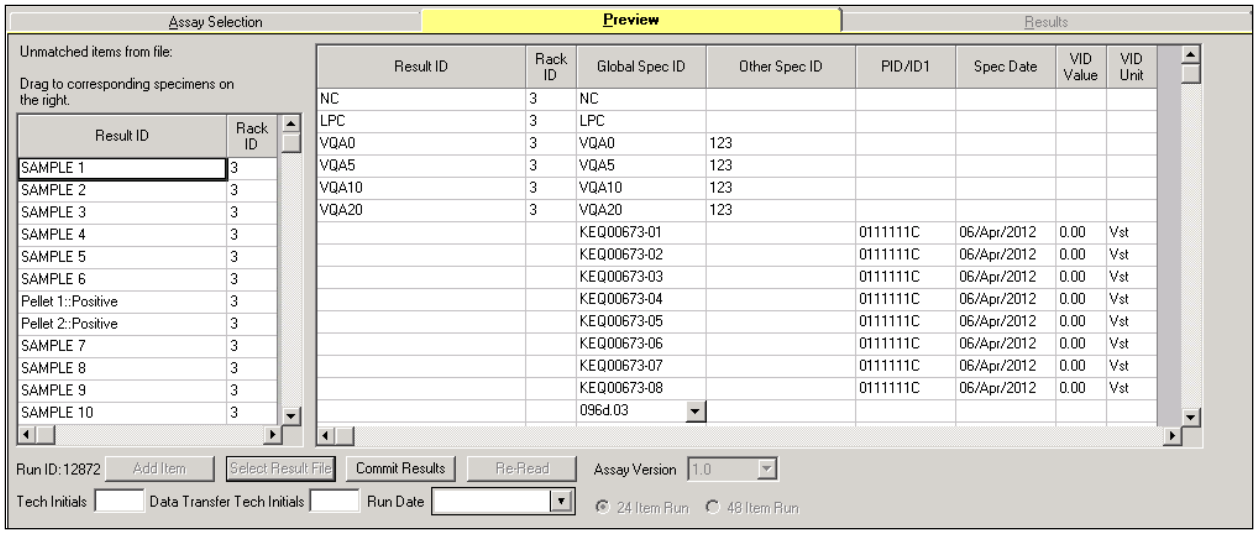


Figure 9: LDMS Matching

14. Select any unmatched results from the result file and drag them to the right, to match the result to the appropriate specimen in the listing. (See **Figure 10.**)

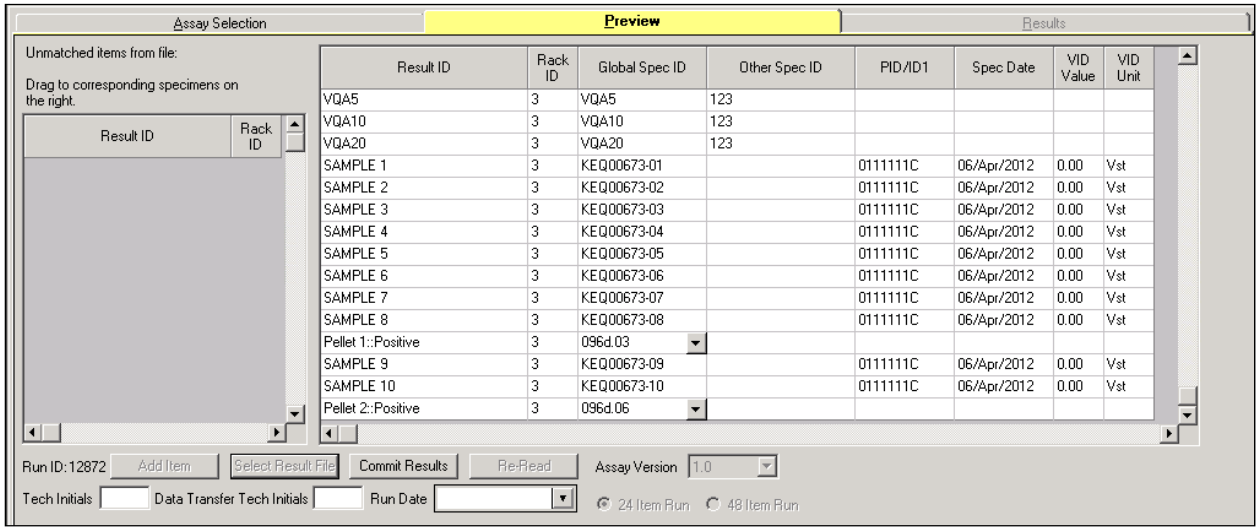


Figure 10: User Completed Matching

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.**)

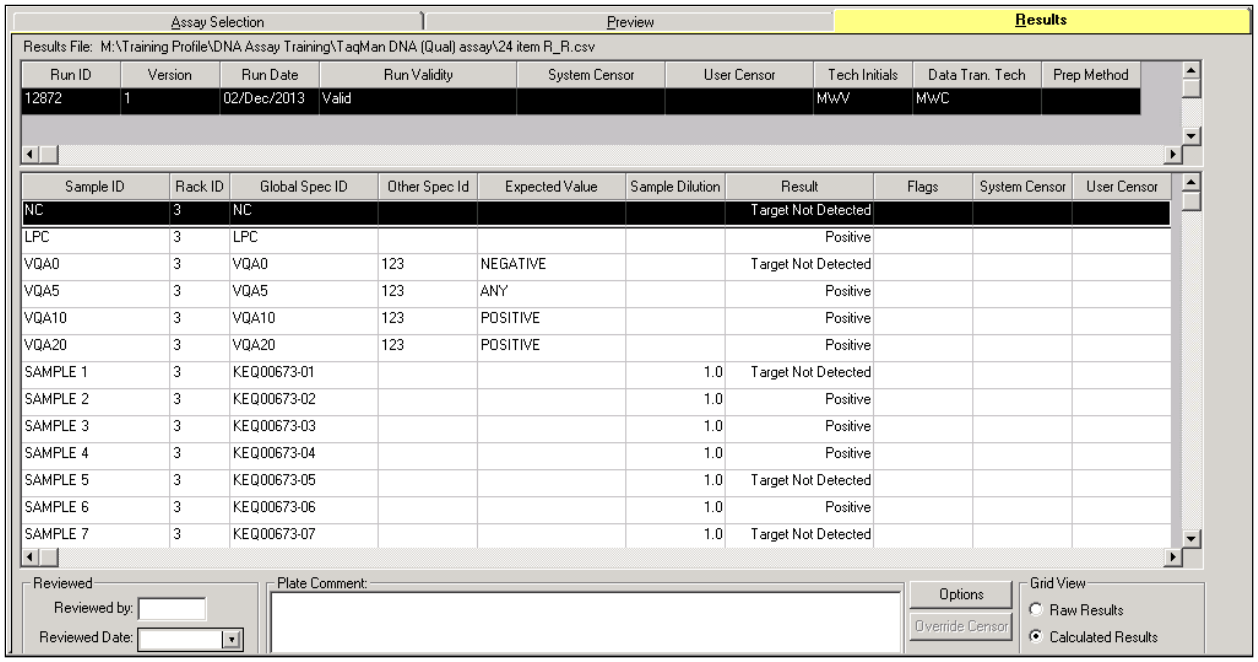


Figure 11: Calculated Results Screen

17. To display Raw Results as the Grid View option, click **Raw Results**. (See **Figure 12**.)

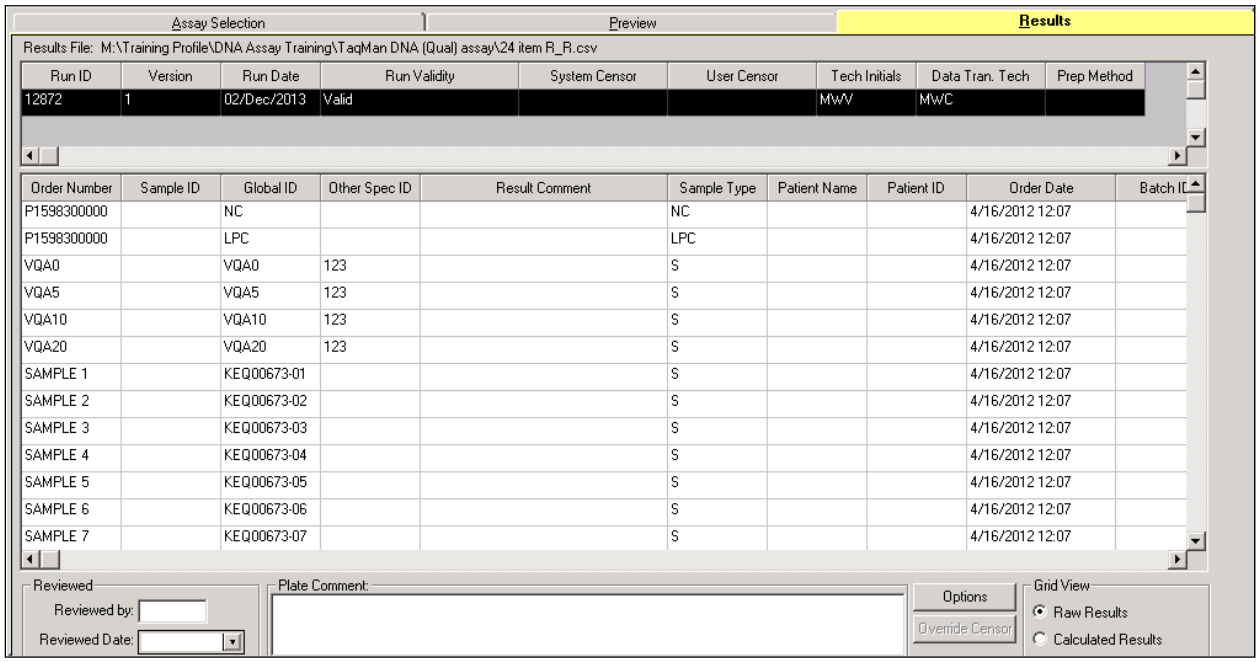


Figure 12: Raw Results Screen

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 13**.) The LDMS User Censor Codes dialog box appears. (See **Figure 14**.)

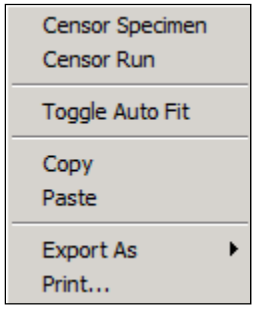


Figure 13: Shortcut Menu

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

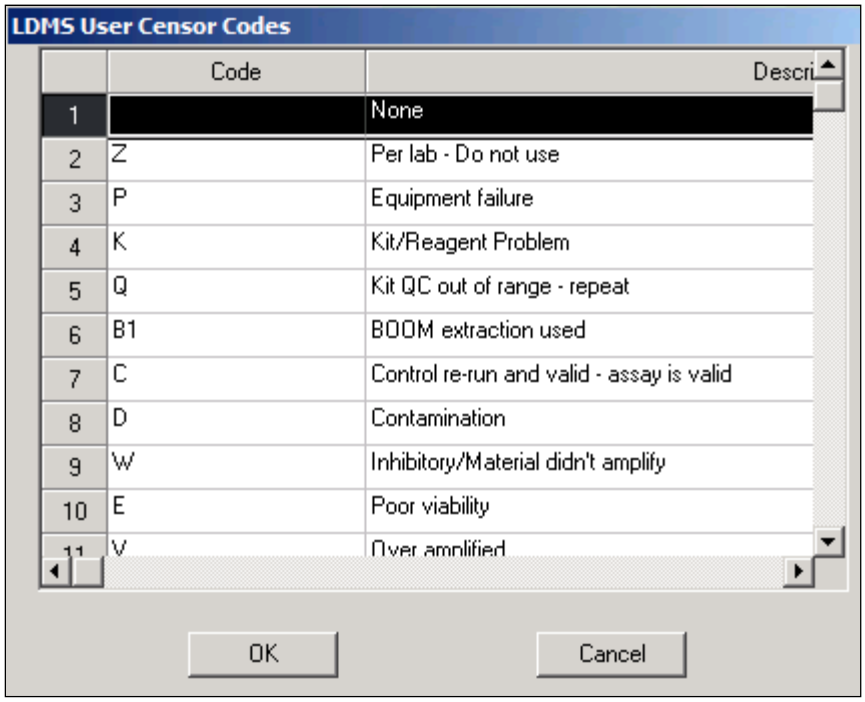


Figure 14: LDMS User Censor Codes Dialog Box

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 15**.)

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:** MWV
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 0111111C	A5175			Target Not Detected		
KEQ00673-02		BLD PL1 0111111C	A5175			Positive		
KEQ00673-03		BLD PL1 0111111C	A5175			Positive		
KEQ00673-04		BLD PL1 0111111C	A5175			Positive		
KEQ00673-05		BLD PL1 0111111C	A5175			Target Not Detected		
KEQ00673-06		BLD PL1 0111111C	A5175			Positive		
KEQ00673-07		BLD PL1 0111111C	A5175			Target Not Detected		
KEQ00673-08		BLD PL1 0111111C	A5175			Positive		
096d.03					POSITIVE	Positive		
KEQ00673-09		BLD PL1 0111111C	A5175			Positive		
KEQ00673-10		BLD PL1 0111111C	A5175			Positive		
096d.06					POSITIVE	Positive		

Figure 15: 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 16**.)
2. Select **Print Patient Report** and click **OK**. The Patient Report Selection dialog box appears. (See **Figure 17**.)

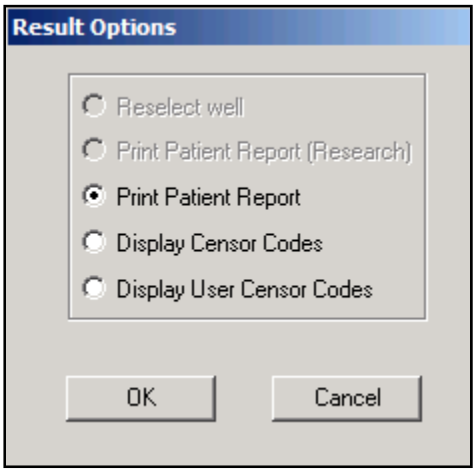


Figure 1: Result Options Dialog Box

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

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

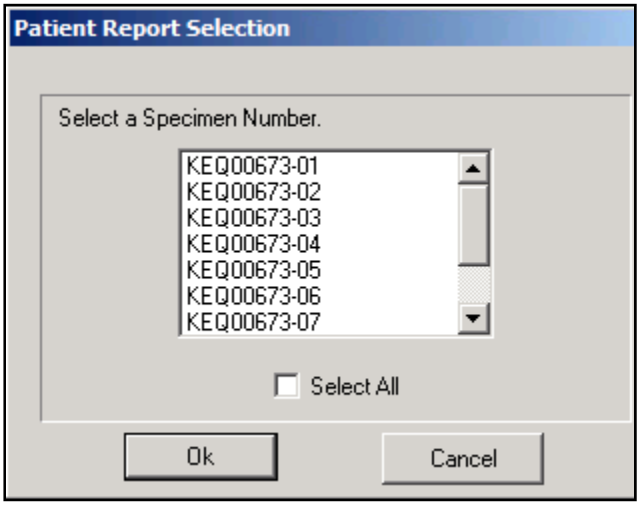
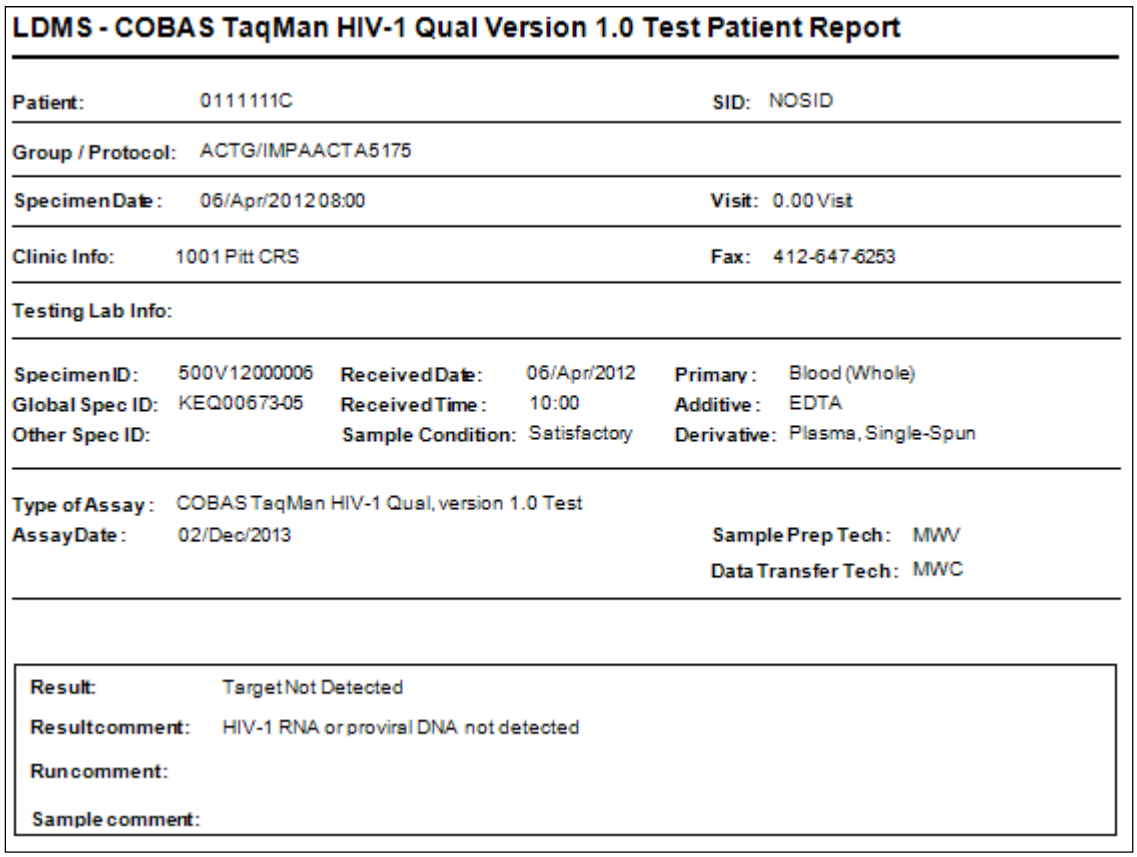


Figure 17: Patient Report Selection Dialog Box

4. Click **OK**. The Patient Report will be displayed for the selected specimen(s). (See **Figure 18**.)
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 Visit
Clinic Info:	1001 Pitt CRS	**Fax:**	412-647-6253
Testing Lab Info:			

Specimen ID:	500V12000006	**Received Date:**	06/Apr/2012	**Primary:**	Blood (Whole)
Global Spec ID:	KEQ00673-05	**Received Time:**	10:00	**Additive:**	EDTA
Other Spec ID:		**Sample Condition:**	Satisfactory	**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 2: Patient Report

Scenario #1: Setting up a 24 Item Run

1. Add the following 16 specimens to a TaqMan HIV-1 Qual run:
   - GEQ00699-06 - GEQ00699-21
2. Select a VQA lot for the VQA controls.
3. Define the blinded pellets as follows:
   - Pellet 1 = 096d.39
   - Pellet 2 = 096d.40
4. Generate the run preview report.
5. Save the run as a Run Not Performed.

Scenario #2: Resulting a 24 Item Run

1. Locate the Run Not Performed from Scenario 1 and select the assay.
2. Click **Select Result File** and browse to the following:
   Training Profile\DNA Assay Training\TaqMan DNA (Qual) assay\Scenario2.csv
3. Match any results that need to be matched.
4. Enter the **Tech Initials** and **Run Date**.
5. Click **Commit Results**.
6. Generate the results report for the run.

Scenario #3: Setting up a 48 Item Run

1. Add the following 23 specimens to a TaqMan HIV-1 Qual run:
   - GEQ00699-22, and HEQ0067T-01 - HEQ0067T-22
2. Type **Sample 1** in the **Other Spec ID** field for the GEQ00699-22 specimen.
3. Add a new VQA lot for the VQA controls.
4. Define the blinded pellets as follows:
   - Pellet 1 = 096d.28
   - Pellet 2 = 096d.30
   - Pellet 3 = 096d.29
   - Pellet 4 = 096d.33
5. Generate the run preview report.
6. Save the run as a Run Not Performed.

Scenario #4: Resulting a 48 Item Run

1. Click **Select Result File** and browse to the following:
   Training Profile\DNA Assay Training\TaqMan DNA (Qual) assay\Scenario4.csv
2. Match any results that need to be matched. The result file may contain extra results, i.e., specimens on the same instrument run, but not added to the run in the LDMS. These results will remain in the Unmatched Items column.
3. Enter the **Tech Initials** and **Run Date**.
4. Click **Commit Results**.
5. Generate the results report for the run.