LDMS Training Workbook - Assays

LDMS (Windows)

Contents

Version 1.7 070318

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Abbott Realtime HIV-1 Assay

Review LDMS User Manual section **Assays—Virology—Abbott Realtime and COBAS TaqMan**

Exercise 1: Reading the Abbott Realtime HIV-1 Assay Result File into LDMS

Part 1: Assign test

Review LDMS User Manual section **Assays— Managing assay runs--Assigning assays to specimens**

1. In **Specimen Management**, use the search function to find the following four specimens
    - Type 1: PID   PID: 0666666C
    - Filter: Derivative   DER: PL2
2. **Select** two aliquots.
3. **Right-click** on the selected plasma aliquots in the Aliquot grid, and select **Test Setup** from the shortcut menu. The Test Setup dialog box appears.
4. **Click** on the plus sign next to the **Viral Load RNA** listing to display the available tests in the category. **Double-click** on **Abbott Realtime HIV-1 Assay**
5. Click **Save** to save the test assignment to your lab database.
6. Click **OK** in the Save message. The assigned test will populate in the Test Setup window.
7. Click **Done** in the Test Setup dialog box.
8. Click the **Save** button in the LDMS toolbar.   Click **No**, in the Label menu.
9. **Repeat** for the following PIDs:
    - 0777777F
    - 0888888I
    - 0999999L

Notes on Specimen ID matching:
- ➢ 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.

Part 2: Selecting an assay/Adding Specimens to a Run

Review LDMS User Manual section **Assays— Managing assay runs-- Creating a new assay run**

1. Click on the plus sign (+) next to **Viral Load RNA**
2. Click to highlight **Abbott Realtime HIV-1 Assay**

3. Note the **New Run** radio button is highlighted. Click **Select Assay**
4. Click **Find Specimens**
5. Select the -01 aliquots for the four PIDs in Part 1
6. Click **Add to Run**. The Preview tab opens

Part 3: Resulting a run

1. To add a VQA control to the run, click **Add VQA Control**. The Add VQA Lot dialog box appears.
   a. 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.
   b. If a new Control Lot Number is being entered, use the format VQAnnnnnnnnRT, 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.
   c. Click OK
2. To modify a dilution, click the Dilution field of the sample and enter the new dilution value in the grid.
3. Click the **Report** button on the LDMS toolbar to generate the **Assay Run Preview Report**
4. Enter the **Sample Prep Tech Initials, Amplification Tech Initials**, and **Data Transfer Tech Initials**. Select the **Sample Prep Method**
5. Click **Run Now**. Click **Yes** in the Run Abbott Assay box
6. Browse to the desired Abbott Realtime HIV-1 result file and Click Open
   • Abbott_RNA_Exercise_1
7. The Enter Run Information dialog box appears. Enter the **Run Date** and click **OK**
8. The Results tab is populated with the results
9. Review the application of **censors** by using the **right click menu**
10. Review the **Report** button
11. Review the **Options** button
12. When completed enter initials in **Reviewed By** and set **the Reviewed Date**
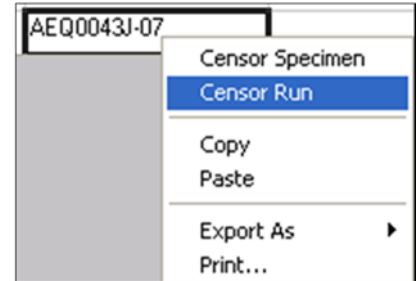
Exercise 2: Resulting an invalid run

Part 1: Selecting an assay/Adding Specimens to a Run

Review LDMS User Manual section **Assays— Managing assay runs-- Creating a new assay run**

1. Click on the plus sign (+) next to **Viral Load RNA**
2. Click to highlight **Abbott Realtime HIV-1 Assay**
3. Click **Select Assay**
4. Click **Find Specimens**
5. **Select** the -02 aliquots for the four PIDs in Part 1
6. Click **Add to Run**. The Preview tab opens

Part 2: Resulting a run

1. To add a VQA control to the run, click Add VQA Control. The Add VQA Lot dialog box appears.
    a. 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.
    b. If a new Control Lot Number is being entered, use the format VQAnnnnnnnnRT, 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.
    c. Click OK

2. To modify a dilution, click the Dilution field of the sample and enter the new dilution value in the grid.

3. Click the **Report** button on the LDMS toolbar to generate the **Assay Run Preview Report**. **Note the Run ID** _____

4. Click **Run Later**. Confirm by clicking **Yes**.

5. Return to **Assay Selection menu**. Click the **Refresh** button.

6. Click on the plus sign (+) next to **Viral Load RNA**

7. Click to highlight **Abbott Realtime HIV-1 Assay**

8. Select the **Runs Not Performed** radio button. Click **Search**.

9. Highlight the **Run ID** and click **Select Assay**

13. Enter the Sample Prep Tech Initials, Amplification Tech Initials, and **Data Transfer Tech Initials**. Select the **Sample Prep Method**

14. Click **Run Now**. Click **Yes** in the Run Abbott Assay box

15. Browse to the desired Abbott Realtime HIV-1 result file and Click Open
    - Abbott_RNA_Exercise_2

16. The Enter Run Information dialog box appears. Enter the **Run Date** and click **OK**

17. The Results tab is populated with the results

18. Review the **censors codes** used in the **Options** button

19. When completed enter initials in **Reviewed By** and set the **Reviewed Date**

Exercise 3: Kit Entry Module Screens

Review LDMS User Manual section **Assays—Virology—Abbott Realtime and COBAS TaqMan— Kit Entry for Abbott and TaqMan Assays**

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. Follow the steps below to complete the remaining fields.

1. Go to **QA/QC – Kit Entry Module**
2. Select **Abbott Realtime HIV-1 Assay**
3. Select the **Control kit**
4. Enter information into the **Date Received** and **Storage Temp** fields
5. Click **Save**

6. Select the **Reagent Prep Kit** from the drop down menu
7. Enter information into the **Date Received** and **Storage Temp** fields
8. Click **Save**
9. Select the **Calibrator Kit** from the drop down menu
10. Enter information into the **Date Received** and **Storage Temp** fields
11. Click **Save**

Exercise 4: Entering VQA Control Information

Review LDMS User Manual section **Assays—Virology—Abbott Realtime and COBAS TaqMan—**

Creating a required VQA200 control

Note: VQA kit information can be entered on the Preview screen of the Abbott Realtime HIV-1

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 Realtime HIV-1 Controls** from the **VQA RNA Control box**.
3. Enter the new **Control Lot Numbers** (format = VQAnnnnnnnnnRT, 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 the Minimum Value field and **642** in the Maximum Value field in the grid for the VQA 200 control.
6. Click the **Add** ![red plus button] button on the LDMS toolbar. A success message appears.
7. Click **OK**.

Exercise 5: Control Charting - Abbott Realtime HIV-1 Assay

1. Select **Abbott Realtime HIV-1** in the Assay field.
2. Enter the current date in the **Date From** field
3. Enter the current date in the **Date To** field.
4. Select **VQA200** from the Control Name box.
5. Click the **Execute** button ![execute button] The Search Results will display in the grid.
6. **Highlight** one of the rows of the results grid and click the **Down Arrow** button ![down arrow button] The results from the same Control Lot will move to the Selected Controls grid.
7. **Repeat steps 4-5** for **HIPOS** and **LOPOS** controls. It will be necessary to add both result rows separately to the Selected Controls grid.

Once all of search results are moved into the Selected Controls grid, click on the Graph button. The Levey-Jennings report displays.

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COBAS TaqMan HIV-1 Assay

Review LDMS User Manual section **Assays—Virology—Abbott Realtime and COBAS TaqMan**

Exercise 1: Reading the COBAS TaqMan HIV-1 Assay Result File into LDMS

Part 1: Assign test

Review LDMS User Manual section **Assays— Managing assay runs--Assigning assays to specimens**

1. In **Specimen Management**, use the search function to find the following four specimens
   - Type 1: PID   PID: 0666666C
   - Filter: Derivative   DER: PL2
2. **Select** two aliquots.
3. **Right-click** on the selected plasma aliquots in the Aliquot grid, and select **Test Setup** from the shortcut menu. The Test Setup dialog box appears.
4. **Click** on the plus sign next to the **Viral Load RNA** listing to display the available tests in the category. **Double-click** on **COBAS TaqMan HIV-1 Assay**
5. Click **Save** to save the test assignment to your lab database.
6. Click **OK** in the Save message. The assigned test will populate in the Test Setup window.
7. Click **Done** in the Test Setup dialog box.
8. Click the **Save** button in the LDMS toolbar.   Click **No**, in the Label menu.
9. **Repeat** for the following PIDs:
   - 0777777F
   - 0888888I
   - 0999999L

Notes on Specimen ID matching:
- ➤ The LDMS will automatically match to the controls and calibrators 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 Sample ID or Order Number 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.

Part 2: Selecting an assay/Adding Specimens to a Run

Review LDMS User Manual section **Assays— Managing assay runs-- Creating a new assay run**

1. Click on the plus sign (+) next to **Viral Load RNA**
2. Click to highlight **COBAS TaqMan HIV-1 Assay**
3. Note the **New Run** radio button is highlighted. Click **Select Assay**

4. Click **Find Specimens**
5. Select the -01 aliquots for the four PIDs in Part 1
6. Click **Add to Run**. The Preview tab opens

Part 3: Resulting a run

1. To add a VQA control to the run, click **Add VQA Control**. The Add VQA Lot dialog box appears.
   a. 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.
   b. If a new Control Lot Number is being entered, use the format VQAnnnnnnnnnRT, 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.
   c. Click OK
2. To modify a dilution, click the Dilution field of the sample and enter the new dilution value in the grid.
3. Enter a **Run Date**.
4. Enter the technician's initials in the **Tech Initials** field.
5. Select a version of the assay from the **Version** field combo box.
6. Click **Run Now**. Click **Yes** in the Run TaqMan assay box.
7. Browse to the desired COBAS TaqMan HIV-1 result file and **Click Open**.
   • RNA – TaqMan Assay Training Valid Run.csv
8. The Results tab is populated with the results
9. Review the application of censors by using the right click menu

10. Review the **Report** [button icon] button
11. Review the **Options** button
12. When completed enter initials in **Reviewed By** and set the **Reviewed Date**

AEQ0043J-07

Censor Specimen
Censor Run

Copy
Paste

Export As   ▶
Print...

Exercise 2: Resulting an invalid run

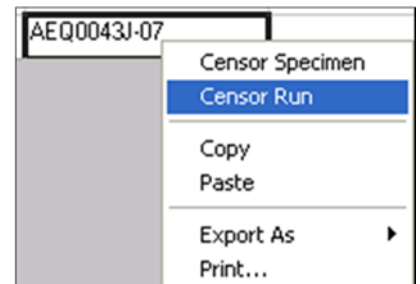## Part 1: Selecting an assay/Adding Specimens to a Run

Review LDMS User Manual section **Assays— Managing assay runs-- Creating a new assay run**

1. Click on the plus sign (+) next to **Viral Load RNA**
2. Click to highlight **COBAS TaqMan HIV-1 Assay**
3. Click **Select Assay**
4. Click **Find Specimens**
5. **Select** the -02 aliquots for the four PIDs in Part 1
6. Click **Add to Run**. The Preview tab opens

Part 2: Resulting a run

10. To add a VQA control to the run, click Add VQA Control. The Add VQA Lot dialog box appears.

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a. 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.

b. If a new Control Lot Number is being entered, use the format VQAnnnnnnnnRT, 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.

c. Click OK

11. To modify a dilution, click the **Dilution** field of the sample and enter the new dilution value in the grid.

12. Click the **Report** button on the LDMS toolbar to generate the **Assay Run Preview Report**. **Note the Run ID** _____

13. Click **Run Later**. Confirm by clicking **Yes**.

14. Return to **Assay Selection menu**. Click the **Refresh** button.

15. Click on the plus sign (+) next to **Viral Load RNA**

16. Click to highlight **COBAS TaqMan HIV-1 Assay**

17. Select the **Runs Not Performed** radio button. Click **Search**.

18. Highlight the **Run ID** and click **Select Assay**

20. Enter the Sample Prep Tech Initials, Amplification Tech Initials, and **Data Transfer Tech Initials**. Select the **Sample Prep Method**

21. Click **Run Now**. Click **Yes** in the Run Abbott Assay box

22. Browse to the desired **COBAS TaqMan HIV-1 Assay** result file and Click Open
   - RNA – TaqMan Assay Training Invalid Run.csv

23. The Enter Run Information dialog box appears. Enter the **Run Date** and click **OK**

24. The Results tab is populated with the results

25. Review the **censors codes** used in the **Options** button

26. When completed enter initials in **Reviewed By** and set the **Reviewed Date**

Exercise 3: Kit Entry Module Screens

Review LDMS User Manual section **Assays—Virology—Abbott Realtime and COBAS TaqMan—Kit Entry for Abbott and TaqMan Assays**

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. Follow the steps below to complete the remaining fields.

1. Go to **QA/QC – Kit Entry Module**
2. Select **COBAS TaqMan HIV-1 Assay**
3. Select the **Control kit**
4. Enter information into the **Date Received** and **Storage Temp** fields
5. Click **Save**
6. Select the **Reagent Prep Kit** from the drop down menu
7. Enter information into the **Date Received** and **Storage Temp** fields

8. Click **Save**
9. Select the **Calibrator Kit** from the drop down menu
10. Enter information into the **Date Received** and **Storage Temp** fields
11. Click **Save**

Exercise 4: Entering VQA Control Information

Review LDMS User Manual section **Assays—Virology—Abbott Realtime and COBAS TaqMan—**

Creating a required VQA200 control

Note: VQA kit information can be entered on the Preview screen of the TaqMan 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 **COBAS TaqMan HIV-1 Controls** from the **VQA RNA Control box**.
3. Enter the new **Control Lot Numbers** (format = VQAnnnnnnnnnRT, 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 the Minimum Value field and **642** in the Maximum Value field in the grid for the VQA 200 control.
6. Click the **Add** button on the LDMS toolbar. A success message appears.
7. Click **OK**.

RNA Reports Available in the Reports Module

Abbott Realtime HIV1 Assay Report

- This report provides the user with a summary of all the assay results for the Abbott Realtime HIV1 Assays. The report is grouped by Group/ID1 and also provides the Run IDs and various censors.

Abbott Realtime HIV-1 Assay Report
No search criteria specified.

Group/Prot: ACTG/IMPAACT A5095

PID	SID	Visit	PRI Specimen ID	Other Spec ID	Global Spec ID	Spec Date	Assay Date	RUN ID	Result	System Censor	User Censor	Run System Censor	Run User Censor
0111111C	A50951234F	0.00 Scr	BLD 500V05000002		BEQ00002-01	03/Jan/2005	08/Jul/2010	12345	8465 Copies / mL				
0111111C	A50951234F	0.00 Scr	BLD 500V05000002		BEQ00002-02	03/Jan/2005	11/Jun/2008	12334	55 Copies / mL			F	
0777777F	A50956543H	0.00 Scr	BLD 500V05000009		BEQ0000L-01	03/Jan/2005	08/Jul/2010	12345	7699 Copies / mL				
0777777F	A50956543H	0.00 Scr	BLD 500V05000009		BEQ0000L-04	03/Jan/2005	11/Jun/2008	12334	7578 Copies / mL			F	
0111111C	A50951234F	0.00 Ent	BLD 500V05000007		GEQ00005-01	10/Jan/2005	11/Jun/2008	12338	Not detected	J			
0777777F	A50956543H	0.00 Ent	BLD 500V05000012		CEQ0000P-01	11/Jan/2005	11/Jun/2008	12338	74172 Copies / mL				
8900890H	A50958881K	0.00 Ent	BLD 500V05000026		GEQ0001J-01	10/Jan/2005	25/May/2010	12760	65 Copies / mL				
0111111C	A50951234F	0.00 Ent	BLD 500V05000007		GEQ00005-04	10/Jan/2005	24/May/2010	12753	82547 Copies / mL				
0111111C	A50951234F	0.00 Ent	BLD 500V05000007		GEQ00005-06	10/Jan/2005	02/Jun/2008	12332	53 Copies / mL				
0777777F	A50956543H	0.00 Ent	BLD 500V05000012		CEQ0000P-03	11/Jan/2005	02/Jun/2008	12332	Not detected	J			
0777777F	A50956543H	0.00 Ent	BLD 500V05000012		CEQ0000P-05	11/Jan/2005	11/Jun/2008	12334	102 Copies / mL			F	
8900890H	A50958881K	0.00 Ent	BLD 500V05000026		GEQ0001J-02	10/Jan/2005	25/May/2010	12761	77539 Copies / mL			F	
0111111C	A50951234F	0.00 Ent	BLD 500V05000007		GEQ00005-08	10/Jan/2005	24/May/2010	12745	65 Copies / mL				
0777777F	A50955522A	2.00 Day	BLD 500V05000016		DEQ00012-01	13/Jan/2005	08/Apr/2010	12588	8465 Copies / mL				
0777777F	A50955522A	2.00 Day	BLD 500V05000016		DEQ00012-02	13/Jan/2005	02/Jun/2008	12332	61754 Copies / mL				
0777777F	A50955522A	10.00 Day	BLD 500V05000021		DEQ0001B-01	20/Jan/2005	08/Apr/2010	12594	73271 Copies / mL			F	
0777777F	A50955522A	7.00 Day	BLD 500V05000019		GEQ00017-03	17/Jan/2005	24/May/2010	12753	65 Copies / mL				

Abbott Realtime HIV1 Patient Report

- This report provides the user with a detailed listing of the assay results for the Abbott Realtime HIV1 Assays for a given patient/run. The report provides the Run IDs and various censors, calculated results and watermarks

TaqMan Realtime HIV1 Assay Report

- This report provides the user with a summary of all the assay results for the TaqMan Realtime HIV1 Assays. The report is grouped by Group/ID1 and also provides the Run IDs and various censors.

TaqMan Realtime HIV1 Patient Report

- This report provides the user with a detailed listing of the assay results for the TaqMan Realtime HIV1 Assays for a given patient/run. The report provides the Run IDs and various censors, calculated results and watermarks

Abbott Repeat and Censored Run/Samples

- This report provides the user with a summary of all the censored and repeated runs for a particular PID. The report is grouped by Group/ID1. This report would be useful for a user that wants to identify if there are issues running samples for a given PID.

Abbott Realtime HIV-1 Repeats and Censored Run/Samples
No search criteria specified.

Group/Prot: ACTG/IMPAACT A5095

System Censor	Run System Censor	User Censor	Run User Censor	Specimen ID	Global Spec ID	PID	Spec Date	RUN ID	Run Valid/ Invalid	Assay Date	Result
				500V05000016	DEQ00012-02	0777777F	13/Jan/2005	12332	Valid	02/Jun/2008	61754 Copies / mL
				500V05000007	GEQ00005-06	0111111C	10/Jan/2005	12332	Valid	02/Jun/2008	53 Copies / mL
J				500V05000012	CEQ0000P-03	0777777F	11/Jan/2005	12332	Valid	02/Jun/2008	Not detected
J				500V05000021	DEQ0001B-04	0777777F	20/Jan/2005	12332	Valid	02/Jun/2008	Not detected
		F		500V05000002	BEQ00002-02	0111111C	03/Jan/2005	12334	Invalid	11/Jun/2008	55 Copies / mL
		F		500V05000009	BEQ0000L-04	0777777F	03/Jan/2005	12334	Invalid	11/Jun/2008	7578 Copies / mL
		F		500V05000012	CEQ0000P-05	0777777F	11/Jan/2005	12334	Invalid	11/Jun/2008	102 Copies / mL
		F		500V05000019	GEQ00017-05	0777777F	17/Jan/2005	12334	Invalid	11/Jun/2008	212 Copies / mL
J				500V05000007	GEQ00005-01	0111111C	10/Jan/2005	12338	Valid	11/Jun/2008	Not detected
				500V05000012	CEQ0000P-01	0777777F	11/Jan/2005	12338	Valid	11/Jun/2008	74172 Copies / mL
				500V05000002	BEQ00002-01	0111111C	03/Jan/2005	12345	Valid	08/Jul/2010	8465 Copies / mL
				500V05000009	BEQ0000L-01	0777777F	03/Jan/2005	12345	Valid	08/Jul/2010	7699 Copies / mL
				500V05000016	DEQ00012-01	0777777F	13/Jan/2005	12588	Valid	08/Apr/2010	8465 Copies / mL

TaqMan Repeat and Censored Run/Samples

- This report provides the user with a summary of all the censored and repeated runs for a particular PID. The report is grouped by Group/ID1. This report would be useful for a user that wants to identify if there are issues running samples for a given PID.

HIV RNA Assay Control Data

- This report provides the user with a summary of all of the control data for a given run. The report is grouped by assay type and provides a multitude of different pieces of control data for the associated Run ID.

Abbott Realtime HIV-1

Run ID	Control Name	Control Lot	Range	Run Date	Result (cp/mL)	Prep Tech Initials	Sample Prep Lot	Amp Lot
12332	HIV_HIPOS	407942	12,882 - 407,380	02/Jun/2008	69424	JF	407992	
12332	HIV_LOPOS	407942	129 - 4,074	02/Jun/2008	857	JF	407992	
12332	HIV_NEG	407942		02/Jun/2008	Not detected	JF	407992	

COBAS TaqMan HCV

Review LDMS User Manual section **Assays—Virology—Abbott Realtime and COBAS TaqMan**

Exercise 1:   Assign test

Review LDMS User Manual section **Assays— Managing assay runs--Assigning assays to specimens**

10. In **Specimen Management**, use the search function to find the following four specimens
    - Type 1: PID   PID: 0666666C
    - Filter: Derivative   DER: PL2
11. **Select** two aliquots.
12. **Right-click** on the selected plasma aliquots in the Aliquot grid, and select **Test Setup** from the shortcut menu. The Test Setup dialog box appears.
13. **Click** on the plus sign next to the **Viral Load RNA** listing to display the available tests in the category. **Double-click** on **COBAS TaqMan HCV**
14. Click **Save** to save the test assignment to your lab database.
15. Click **OK** in the Save message. The assigned test will populate in the Test Setup window.
16. Click **Done** in the Test Setup dialog box.
17. Click the **Save** button in the LDMS toolbar.   Click **No**, in the Label menu.
18. **Repeat** for the following PIDs:
    - 0777777F
    - 0888888I
    - 0999999L

## Exercise 2: Selecting an assay/Adding Specimens to a Run

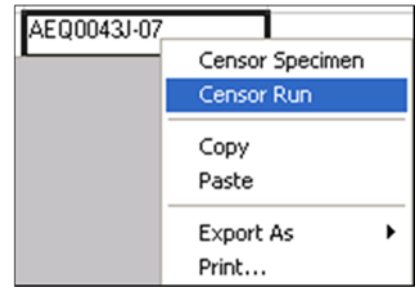*Review LDMS User Manual section* **Assays—Managing assay runs-- Creating a new assay run**

1. Click on the plus sign (+) next to **Viral Load RNA**
2. Click to highlight **COBAS TaqMan HCV**
3. Note the **New Run** radio button is highlighted. Click **Select Assay**
4. Click **Find Specimens**
5. Select the -01 aliquots for the four PIDs in Part 1
6. Click **Add to Run**. The Preview tab opens

Exercise 3: Resulting a run

1. Enter the **Run Date, Tech Initials, Data Transfer Tech Initials, Automated Prep Method**, and **Version number**

2. Click **Run Now** and select the following result file:
   - TaqMan HCV Result File Valid Run.txt
3. The Results tab is populated with the results
4. Review the application of **censors** by using the right click menu
5. Review the **Report** button
6. Review the **Options** button
7. When completed enter initials in **Reviewed By** and set the **Reviewed Date**

GeneXpert

Review LDMS User Manual section **Assays— GeneXpert Assay**

Exercise 1: Assign test

Review LDMS User Manual section **Assays— Managing assay runs--Assigning assays to**
specimens

1. In **Specimen Management**, use the search to find the following four specimens
     - Filter: ID1   PID: 0123456B
     - Filter: Derivative   DER: SPT
2. **Highlight** all four sputum specimens in the aliquot grid.
3. Right-click on the highlighted aliquots and select **Test Setup** from the menu. The Test Setup dialog box appears.
4. Click on the plus sign next to the **GeneXpert Assays** listing to display the available tests in the category. **Double-click** on **GeneXpert MTB-RIF**
5. Click **Save** to save the test assignment to your lab database.
6. Click **OK** in the Save message. The assigned test will populate in the Test Setup window.
7. Click **Done** in the Test Setup dialog box.

Exercise 2: Running the GeneXpert MTB-RIF Assay

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 **GeneXpert** Assays category.
3. Click **GeneXpert MTB-RIF**.
4. Click **Select Assay**.
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 GeneXpert MTB-RIF test assigned.
   > 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.
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.
   > Note: The Other Spec ID is editable, prior to clicking the Select Result File button.
8. Generate the **GeneXpert MTB-RIF Run Preview Report** by clicking on the **Report** button on the LDMS toolbar.
9. Click **Select Result File**. Click **Yes** in the Run Assay message that appears.
10. Browse to the desired result file. Select the file and click **Open**.
    - GeneXpert Exercise 1

11. Click **No**, when prompted to load additional result files, if desired/needed.
12. The LDMS will match the GeneXpert MTB-RIF result file to the listing of specimens added to the run.
13. 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.
14. When matching is complete, enter the technician's initials in the **Tech Initials** fields.
15. Click **Commit Results**. The LDMS will match the listing to the results in the result file. The Results screen will appear.

IQA Cryopreservation panel

Exercise 1: Entering IQA Specimens

Review LDMS User Manual section **Specimen Management-- Entering a New Specimen**

In the Participant Grid, enter the following information

Project	IQA
PID	[Donor #] ex. 99001

In the Primary Grid, enter the following information

Specimen Date	Current Date
Received Date	Current Date
Specimen Time	08:15
# of Tubes	1
Primary Type	BLD

Click Add above the Primary grid.

Additive Type	ACD, EDT or HEP
Volume	20
Volume Unit	ML

In the Aliquot Grid, enter the following information

# of Aliquots: 4   Volume: 5   Units: CEL   Derivative: CEL   Sub Add/Der: DMS

Click Add above the Aliquot grid

1. Click on the **Primary Details** button. Enter the **Processing Date, Processing Time**, **Processed by Tech Inits**, and **Total Cell Count**.
2. Highlight all four PBMC specimens in the aliquot grid.
3. Right click in the aliquot grid and select **Frozen Date/Time** from the menu
4. Enter the **Frozen Date** and **Frozen Time** and click **OK**.
5. Click the **Add** button on the LDMS toolbar.
   > **Note**: If entering specimens for a patient or donor that has not been entered in your labs database, an Enroll dialog box will appear. Click Enroll to add the record to the database.
6. Click **Enroll** in the message box that appears.
7. Click **OK** in the **Saving** message. Select the **IQA Barcode** format and a label size, and then click **Yes** on the dialog box. **Close** the Crystal Reports window.
8. **Highlight** all four PBMC specimens in the aliquot grid.

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9. **Right-click** on the highlighted aliquots and select **Test Setup** from the menu. The Test Setup dialog box appears.
10. **Click** on the plus sign next to the **Immunology** assay listing. Double-click on **Cryopreservation**
11. Click **Save** to save the test assignment to your lab database.
12. Click **OK** in the Save message. The assigned test will populate in the Test Setup window.
13. Click **Done** in the Test Setup dialog box.

Exercise 2: Assay Module--Completing the Cryopreservation Data Entry Screen

Review LDMS User Manual section **Assays— Managing assay runs-- Creating a new assay run**

To open the Assays module, go to **Tasks – Assays** on the menu bar or click the Assays button on the toolbar

1. Click the plus (+) sign next to the **Immunology** category
2. Click **Cryopreservation**
3. Click **New Run/Not Setup**
4. Click **Select Assay**
5. Enter the specimen **Received Date** in the **From** box, or create a query statement in the Filters/Criteria tab

    Note: You may generate a pending specimen report from the Filters/Criteria tab by clicking the Report   button on the LDMS toolbar.

6. Click **Find Specimens**. The Specimens Found grid populates with specimens.
7. Select the IQA aliquots to be resulted and click **Add** to Run. The Results tab opens.

    Notes: The Viral Load field is optional. The CD4 field is optional, even for positive HIV status.

8. Enter data or select responses for each of the fields.
9. Click the **Add** button on the LDMS toolbar to save the record.
10. Click the **Report** button on the LDMS toolbar to print a patient report.
11. Use the navigation buttons to scroll to the next record to result.
12. **Repeat** steps 8–11 for the remaining samples.

Exercise 3: Shipping Module--Creating a Shipping File and Manifest Report

To open the Shipping module, go to Tasks – Shipping on the menu bar or click the Shipping button on the toolbar.

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1. Click the **Setup Shipment** tab to search for your samples.
2. Select **IQA** from the **Group** box.
3. Select **Received Date** from the **Type** box and enter the received date into the **ID** box.
4. Click the **arrow button** to move the criteria into the query grid.
5. Click the **Execute** button on the LDMS toolbar.
6. Select two **(2)** aliquots from each blood donor by clicking on the rows to highlight them.
7. Click the Shipment Destination tab and select **213 Immunology Quality Assessment Center** from the Lab box.
8. Select a contact from the **Contact Person** box.
9. Select a contact from the **Contact @ Sending Lab** box.
10. Click the **Add** button on the LDMS toolbar to batch the shipment.
11. In the **View Shipment** screen, select your batch and click **Manifest Report**. If applicable, print the Box Map Report.
12. Click on the **Shipment QA/QC** tab to perform QA/QC on the batch to be shipped.
13. QA/QC the shipment via barcode scanning or visual inspection. Click on the **Save** button on the LDMS toolbar.
14. Click on the **View Shipment** tab, select your batch, and select **LDMS Shipping Batch** from the **Shipment Type** box.
15. Click on the **Ship** button.
16. Click **OK** to continue or Cancel to view the Storage Report. A message box appears.
17. Click **Yes** to ship the batch.
18. Select the Shipping Box **temperature** and click **OK**.
19. Select your **disk drive** and click **OK**.
20. The success message appears.
21. Click **OK** and note the shipping batch number.

For the IQA Laboratory (213) only

The IQA receiving lab is required to perform three steps in the LDMS when receiving the IQA specimens:

1. Import the IQA aliquots into the LDMS using the Shipping module.
2. Result the IQA aliquots in the IQA Cryopreservation and Viability Data Entry Screen in the Assay module.
3. Delete extra aliquots from the Pending list.

Shipping Module: Importing IQA Samples

To open the Shipping module, go to Tasks – Shipping on the menu bar or click the Shipping button on the LDMS toolbar.

To import IQA samples:

1. Click the Import tab.
2. Select LDMS Shipping Batch from the Shipment Type box.

3. Click Shipment File Location.

4. Select a drive on your PC.

5. Click OK.

6. Enter the batch number from the Shipping Manifest in the Shipment No. field.

7. Click Import. The shipping batch information will load into the grid.

8. Click on the Shipment QA/QC tab to perform QA/QC on the batch to be imported.

9. QA/QC the shipment via barcode scanning or visual inspection.

10. Click the Import tab.

11. Click Continue. A message box appears.

12. Click OK to continue with the import or click Cancel to abort the import.

If you would like the aliquots never to appear in the bulk add list of the Storage module, click Yes on the message box. If you want the specimens to appear in the bulk add list, click No on the message box.

If the condition of the samples is something other than what appears in the import screen, click Yes on the message box. The Adjust Conditions dialog box appears.

13. Select the aliquots that should be changed by clicking on each, select the new sample condition from the box, and click OK. If the condition of the aliquots are satisfactory, click No. The Success dialog box appears.

14. Click YES to import the associated test (Assay) information.

15. Select the appropriate temperature for the shipment and click OK.

16. Click OK. The Shipping Batch message box appears.

17. Click OK in the dialog box that displays the importing process was completed successfully.

18. Click OK to acknowledge the Shipment/Batch number.

19. A message will appear indicating that the Storage module must be run separately for the imported specimens.

20. Click OK to complete the import process.

> Note: Your imported IQA samples will automatically show up in Specimen Management with the imported box checked, the imported date, the Cryopreservation test ordered and the sending labs results available in the Assay Module.

Assay Module: Completing the Cryopreservation Data Entry Screen

After the samples have been imported and tested, you must enter the results for each aliquot in the Assay module.

To open the Assay module, go to Tasks – Assay on the menu bar or click on the Assay button on the LDMS toolbar.

To complete the Cryopreservation data entry screen:

1. Click on the plus (+) sign next to the Immunology category.

2. Click Cryopreservation.

3. Click New Run/Not Setup.

4. Click Select Assay

5. Enter search criteria in the specimen search grid.

6. Verify that the IQA Review check box is selected (by default it will be selected) and click Find Specimens. The specimens found grid will populate with specimens meeting the above entered search criteria.

7. Select specimens to add to the run.

8. Click Add to Run.

9. Enter data or select responses for each of the fields on the Result screen.

> Note: The left side of the result screen displays the sending lab's specimen information. These fields are grayed out and the results cannot be changed.

10. Click the Save button on the LDMS toolbar to save the record.

11. Click the Report button on the LDMS toolbar to print a patient report.

12. Use the VCR buttons to scroll to the next record to result.

13. Repeat steps 9–11 for all remaining samples.

Specimen Management Module: Deleting Extra Aliquots from the Pending List

After the IQA lab's results have been entered for each aliquot tested, there may be extra aliquots that have been sent and have been ordered for the Cryopreservation Assay. To remove the aliquots from the pending list you must delete the test from the Test Setup tab in the Specimen Management module.

To open the Specimen Management module, go to Tasks – Specimen Mgt on the menu bar or click on the Specimen Management button on the LDMS toolbar.

1. Click the Browse button on the LDMS toolbar.
2. Type in the specimen number of the aliquot.
3. Click Run and click on a row to highlight a specimen and then click Select.
4. Highlight the specimen in the aliquot grid.
5. Right-click on the highlighted aliquot and select Test Setup from the menu.
6. From the Test Setup screen, highlight the Cryopreservation test in the Test Setup grid and click Delete. The Delete Test message box appears.
7. Click Yes.

Click Done on the Test Setup screen to return to the Specimen Management screen.