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Running a DNA Assay in the LDMS

This document describes the steps involved in setting up and running a Roche HIV DNA PCR 1.5 assay in the Laboratory Data Management System (LDMS).

Ordering the DNA Assay

Before you are able to run a DNA assay, the assay must be assigned to the desired aliquots. The Test Setup feature in the Specimen Management module can be utilized to order the assay. (See **Figure 1**.) The Assign Tests module may also be used to assign an assay to specimens. Please refer to the online LDMS User Manual (Chapter 13 – Tools) for more information.

1. Go to **Tasks – Specimen Management** on the LDMS menu bar, or click the **Specimen Management** ( ) button on the LDMS toolbar.
2. Locate the specimen(s) that you wish to assign the assay to.
3. Select the aliquot(s) that need to be assigned to the DNA assay.

Note: Hold down the **CTRL** key while clicking the mouse to select multiple aliquots.

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4. Right-click on any of the selected aliquots and select **Test Setup** from the shortcut menu. (See **Figure 1**.) The Test Setup window appears. (See **Figure 2**.)
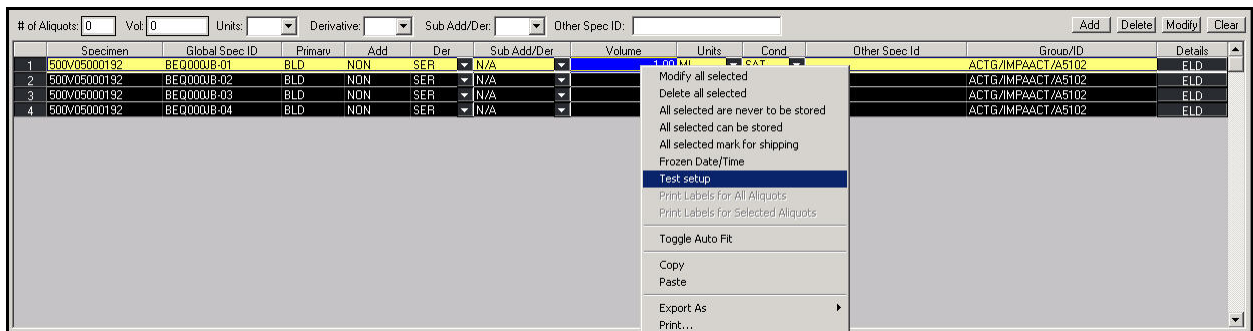
**Figure 1. Aliquot Grid Shortcut Menu**
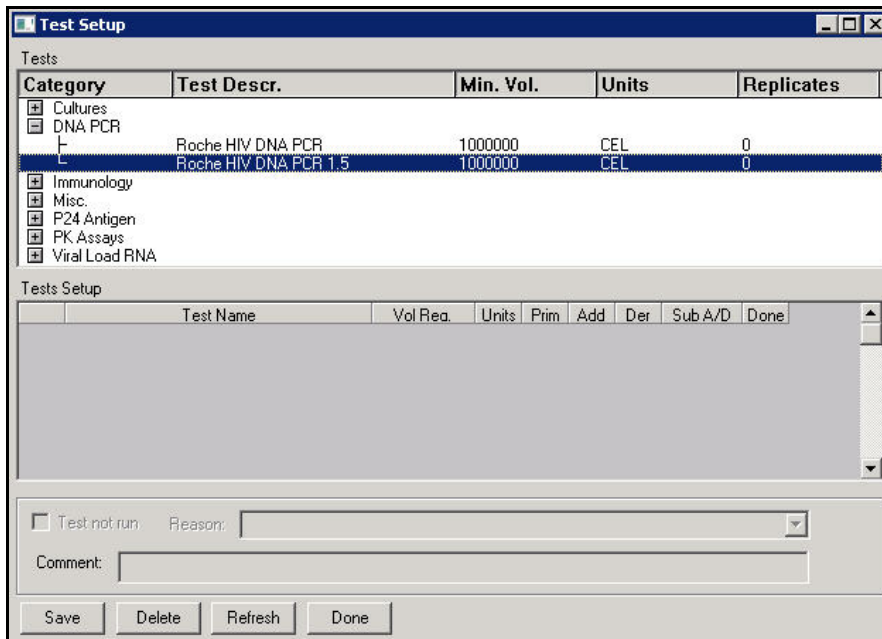
Figure 2. Test Setup Window

5. Locate the DNA PCR category and **double-click** on **Roche HIV DNA PCR 1.5**. The test will appear in the **Tests Setup** grid for the aliquot(s) selected.
6. Click **Save**. The Saving message appears. Click **OK**.
7. Click **Done** to return to the Specimen Management – Entry screen.
8. Click the **Close** ( ) button on the LDMS toolbar to exit the Specimen Management module.

Setting up the DNA Assay

Before you are able to run a DNA assay, a default device must be assigned in the Administration module. This is only required for the initial setup in the LDMS. Please refer to the online LDMS User Manual (Chapter 12 – Administration) for more information.

1. Go to **Tasks – Assays** on the LDMS menu bar, or click the **Assays** ( ) button on the LDMS toolbar.
2. Click the **plus sign (+)** next to **DNA PCR** in the Assay Selection list.
3. Select **Roche HIV DNA PCR 1.5**. (See **Figure 3**.)
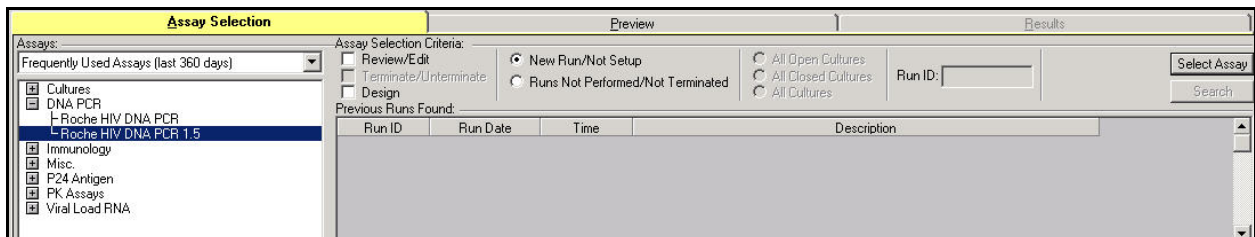
Figure 3. Assay Selection List

4. Click **New Run/Not Setup**.
5. Click **Select Assay**.

6. Enter your search criteria in the Specimen Search section to find the specimens assigned to the selected assay. (See **Figure 4**.)

Notes:
- To search by the Specimen Received Date, select the **Use Dates** check box and select the desired dates from the **To** and **From** boxes.
- To narrow your search results, select added criteria from the **Field** and **Value** boxes and click **Add Filter** to load the statement into the grid.

Figure 4. Specimen Search Grid

7. Click **Find Specimens**. The Specimens Found grid loads with specimens that meet your search criteria. (See **Figure 5**.)

Figure 5. Specimens Found Grid

8. Select the specimens that you wish to include on the run.
9. Click **Add to Run**. The Preview screen appears. (See **Figure 6**.)

Figure 6. Preview Screen

10. Right-click on the first blinded control (**L, BLND**) and select **Modify Control**. The Enter Blinded Pellet name dialog box appears. (See **Figure 7**.)

11. Select or enter the blinded pellet identifier, exactly as it appears on the vial—from the box.

DNA Assay Instructions
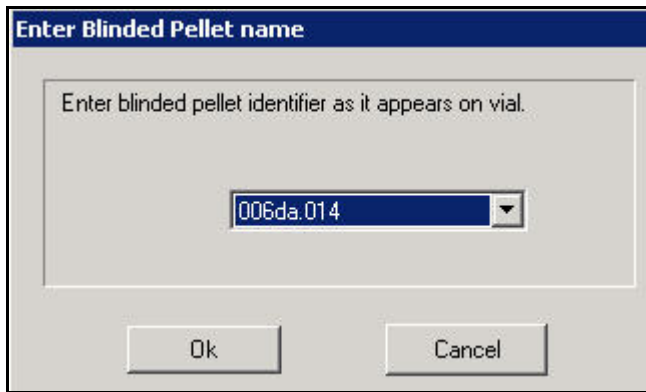
**Figure 7. Enter Blinded Pellet Name Dialog Box**

    12. Click **Ok**.
    13. Repeat steps 10–12 for the other blinded pellet control.

Note: If 11 or more specimens are on the plate, the LDMS will prompt you to add more blinded pellets.

Click **Blinded controls** and select the blinded pellet—exactly as it appears on the vial—from the box and click **Ok**. Based on the number of specimens on the plate, the appropriate number of dialog boxes will appear (one after another) for each additional blinded pellet that needs to be added.

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    14. Click **Run Later**. A message appears asking if you wish to print a copy of the Assay Plate Layout Report.
    15. Click **Yes**. The Assay Plate Layout Report appears. (See **Figure 8**.)
    16. Click the **Print** (🖶) button on the LDMS Report Viewer toolbar to print the report.

Figure 8. Assay Plate Layout Report

17. Close the LDMS Report Viewer window.

Running the DNA Assay

1. From the Assay Selection tab, click on the **plus sign (+)** next to **DNA PCR** in the Assay Selection list.
2. Select **Roche HIV DNA PCR 1.5**.
3. Click **Runs Not Performed/Not Terminated**.
4. Click **Search**. Any runs that were previously saved, but not run, will appear in the Previous Runs Found grid. (See **Figure 9**.)

Figure 9. Previous Runs Found Grid

5. Click on the appropriate run in the Previous Runs Found grid and click **Select Assay**.
6. Click the **Preview** tab.
7. Click **Run Now**. The Enter Run Information dialog box appears. (See **Figure 10**.)

Figure 10. Enter Run Information Dialog Box

8. Enter the **Lot #** for each kit in the appropriate fields.
9. Enter the lab technician's initials in the **Specimen Prep.**, **Amplification** and **Detection** fields, and select the corresponding dates.
10. Click **OK**. Browse to the result file for Plate 1 and click to select it.
11. The Read Plate dialog box appears. (See **Figure 11**.)

Figure 11. Read Plate Dialog Box

12. If you have more than one plate, click **Read Next Plate** and repeat **Step 10**.
13. Click **OK**.

> **Note:** After all plates have been read, the **Read Next Plate** option will be unavailable.

14. Click **Complete/Abort Read** and click **OK**. The Note: Assay Saved message appears.
15. Click **OK**. The Results screen appears. (See **Figure 12**.)

Figure 12. Results Screen

Validating Controls

The LDMS automatically verifies your control results (including blinded pellets) and displays a result of "**Valid**", "**Invalid**" in the **Run Censor** field. (See **Figure 12**.)

Note: If you have two consecutive invalid runs, or if three out of 10 runs are invalid, the LDMS will prevent you from running any more DNA assays.

Applicable System Censors will be displayed in the System Censor column. Click the **Options** button to view the LDMS Censor Codes. (See Figure 13.)

Figure 13. LDMS Censor Codes

Printing a DNA Assay Result Report

1. From the Results screen in the Assay module, click the **Reports** (⬚) button on the LDMS toolbar. The Assay Result Report displays on the LDMS Report Viewer. (See **Figure 14**.)

ROCHE HIV DNA PCR 1.5 Assay Result Report

Lab Name:

Assay Name:	Roche HIV DNA PCR 1.5	Amplification Kit: 2	Spec Prep Tech:	M	Reviewed By:
Run ID:	12864	Whole Blood Kit: 1	Spec Prep Date:	19/Oct/2012	Review Date:
Run Time:	09:57	Detection Kit: 3	Amplification Tech:	M	
Run Date:	19/Oct/2012		Amplification Date:	19/Oct/2012	
Run System Censor :	VALID RUN		Detection Tech:	M	
Run User Censor :			Detection Date:	19/Oct/2012	

Sample ID	Global Spec ID	PID/ID 1	Spec Date	VID	HIV OD 1	HIV OD 2	IC OD 1	IC OD 2	Expected Value	Qual Result	System Censor	User Censor
S					0.000	0.000	0.500	0.500	0	N		
S					0.050	0.050	0.500	0.500	5	N		
S					1.000		0.500		10	R		
S					2.000		0.500		20	R		
006da.032					0.000		0.500		***	N		
006da.028					1.000		0.500		***	R		
500V10000146	KEQ005L5-10	0333333I	08/Jul/2010	16.00 Wk	1.000		0.500			R		
500V10000146	KEQ005L5-14	0333333I	08/Jul/2010	16.00 Wk	1.000		0.300			R		
500V10000146	KEQ005L5-17	0333333I	08/Jul/2010	16.00 Wk	0.300		0.500			I		

Figure 13. Assay Result Report

2. Click the **Print** (🖶) button on the LDMS Report Viewer toolbar.

Exporting the Assay Result Report

1. From the LDMS Report Viewer window, click the **Export** (⬆) button on the toolbar. The **Save As** dialog box appears. (See **Figure 15**.)
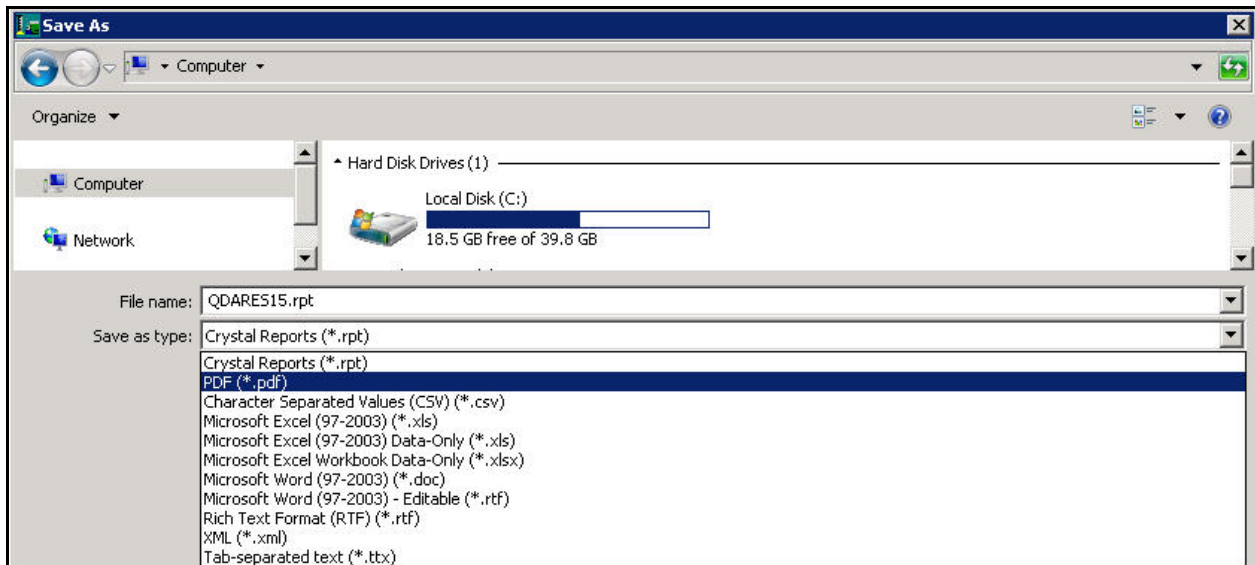

Figure 14. Export Dialog Box

2. Browse to the desired drive, enter a report name, and select a file format from the **Save as type** listing.
3. Click **Save**. The **Export Complete** message will appear.

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.
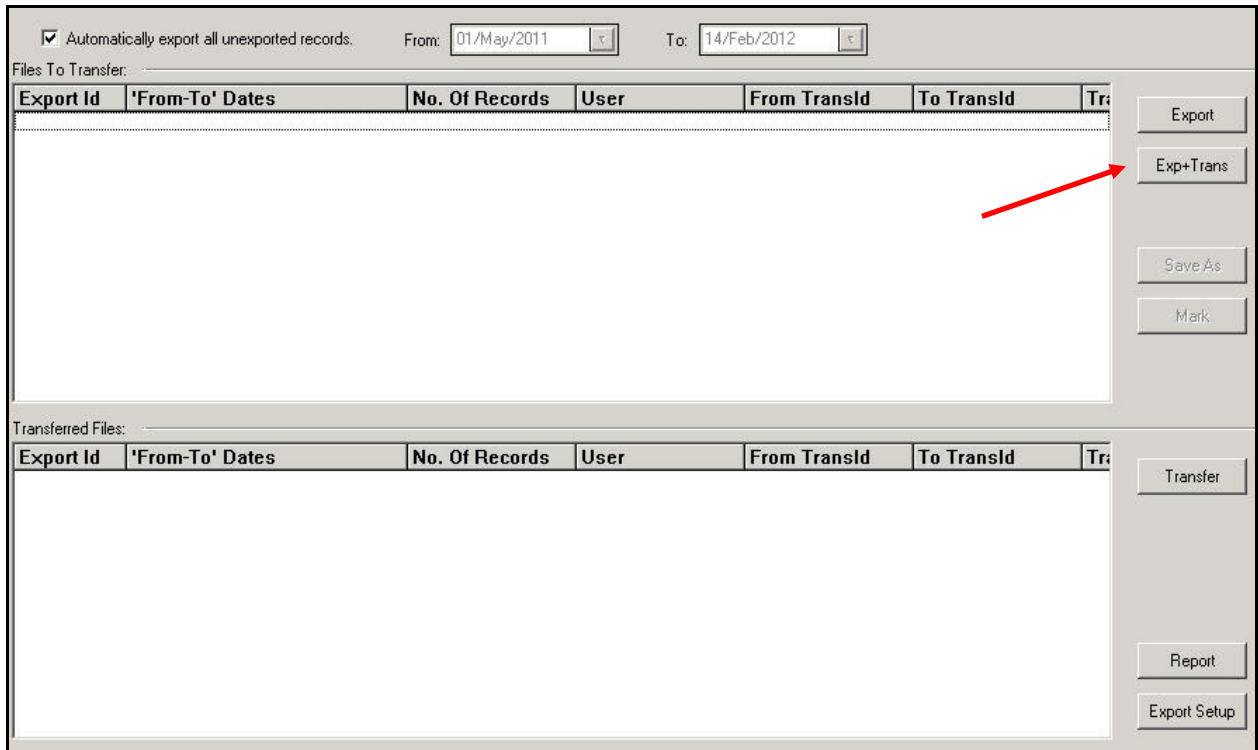
To open the Export module:

1. Go to **Tasks – Export** on the menu bar, or click the **Export** ( ) button on the LDMS toolbar. A warning message appears.
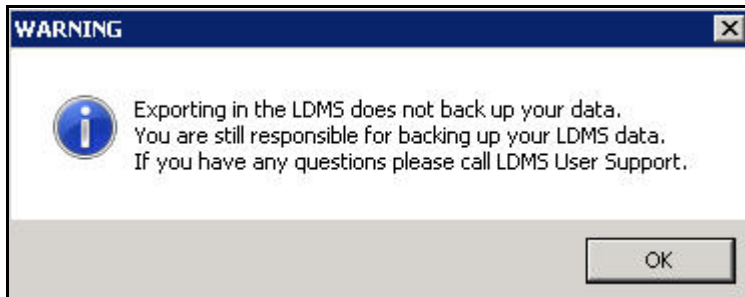
Figure 16. Export Warning

2. Click **OK**. The **Data Export** screen appears.

Figure 19. Data Export

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.