Entering and Resulting PK Controls in the LDMS

This document describes how to enter and result PK controls in the LDMS.

Entering PK Control Specimens

Enter the Specimen Management module by clicking on the **Specimen Management** button ( ) on the LDMS toolbar or by selecting **Specimen Management** from the Tasks listing on the LDMS menu bar.

1. Select **Control** from the **Group** combo box.
2. Enter the control name in the **ID1** field.
3. Enter the study number in the **ID2** field.
4. If needed, enter any additional information in the **ID3** field.
5. Select the date the control was prepared from the **Spec. Date** and **Rec. Date** combo boxes.
6. Enter the number of control tubes in the **# of tubes** field.
7. Select the primary from the **Primary Type** combo box.
8. Click the **Add** button above the primary grid.
9. Select the additive type from the **Additive** combo box.
10. Enter the primary volume in the **Volume** and **Units** fields.
11. Enter **00:00** in the **Spec Time** field.
12. Enter **0.00** in the **Time** field and select **Random** from the **Time Unit** combo box.
13. Enter the aliquot information based on your processing results of the primary sample.

14. Click the **Add** button on the LDMS toolbar.
15. Click the **Enroll** button on the dialog box that appears.

Note: Repeat the above steps for each unique control sample.

Ordering the PK Assay

Bulk assigning of tests can be completed in the **Assign Tests** module of the LDMS. The Assign Tests module can be accessed via the Tools listing on the LDMS menu bar.

1. Enter the Assign Tests module.
2. Click to highlight the **Group** data item and drag it into the **Selection Criteria** grid.
    Define Group = **Control**.
3. Continue to add data items to the Selection Criteria grid, to define the specimens of interest.
4. Click **Execute** to populate the **Select Samples** listing with specimens satisfying the selection criteria.
5. Click to highlight the desired specimens, for which the PK assay will be assigned.
6. Locate and highlight the **PK assay** from the **Select a test** listing.

7. Click the **Assign Selected Test** button. Click **Yes** to confirm test assignment to the specimens.
8. Click **OK** on the **Success** message.

Once the PK Control samples have been entered into the LDMS and the PK Assay has been assigned to each control, the PK assay template can be designed.

Setting up the PK Assay

Enter the Assay module by clicking on the **Assays** button ([icon])on the LDMS toolbar, or by selecting Assays from the Tasks listing on the LDMS menu bar.

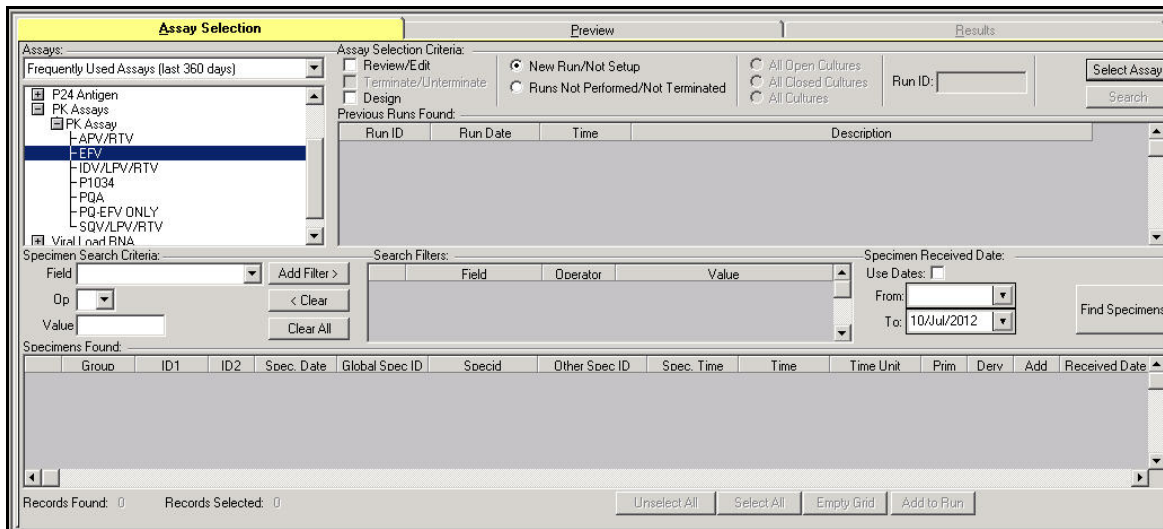1. Click on the plus sign (+) next to the **PK Assays** category.
2. Click on the plus sign (+) next to the design PK Assay template.
3. Click on the designed PK template.
4. Select the New Run/Not Setup radio button.
5. Click the Select button on the Assay Selection screen.

6. Select **Group = CONTROL** in the **Specimen Search Criteria.**
7. Click **Add Filter** to add the criteria to the **Search Filters** grid.
8. Click the **Find Specimens** button.
9. Click to highlight the specimens and controls of interest in the **Specimens Found** grid.
10. Click **Add to Run.**

11. Click the Report button on the LDMS toolbar, if a **Pending Specimen Report** is desired. This Report will display detailed information about the specimens on the template in addition to storage location information. Print the report, if desired.

12. To result the specimens, click **Run Now** on the Preview screen. To result the specimens at a later time, click **Run Later**.
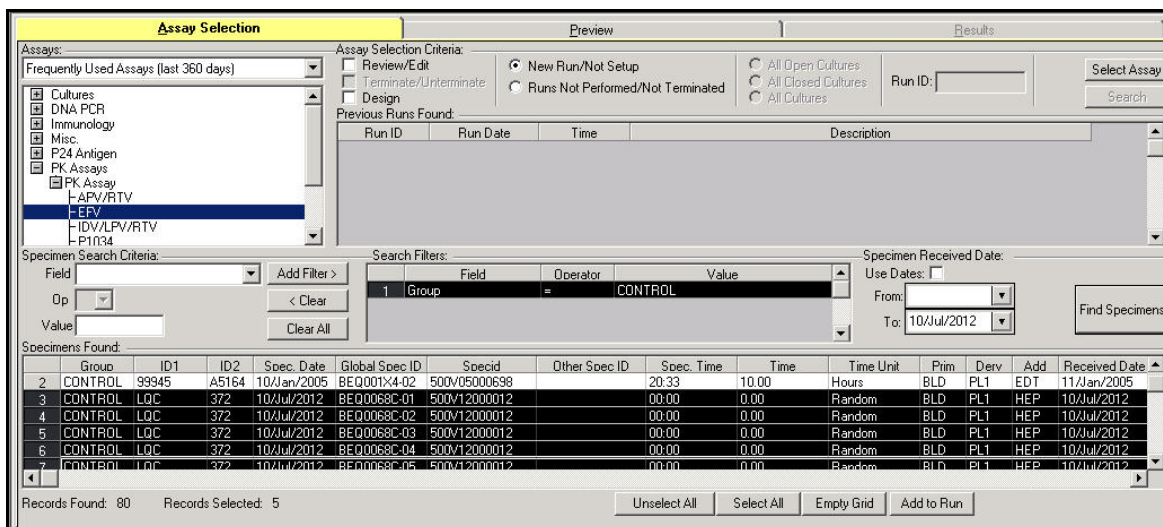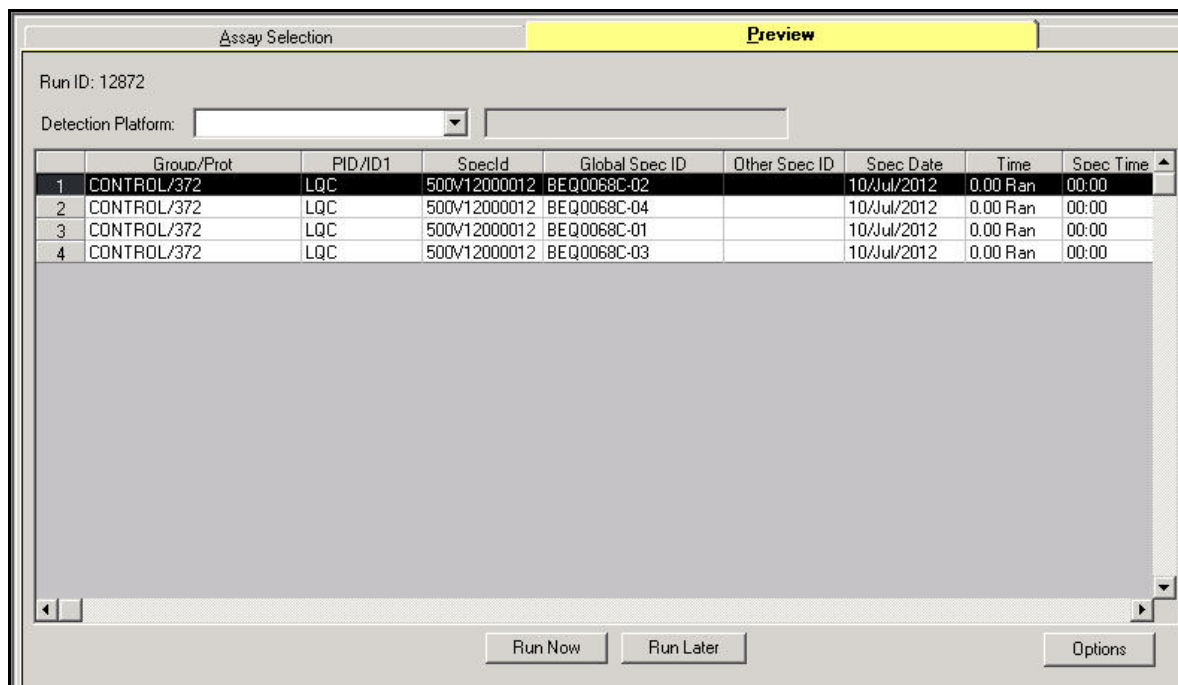
Entering PK Assay Results

Enter the Assay module by clicking on the **Assays** button ( )on the LDMS toolbar, or by selecting Assays from the Tasks listing on the LDMS menu bar.

1. Click on the plus sign (+) next to the **PK Assays** category.
2. Click on the plus sign (+) next to the desired PK Assay template.
3. Click the **Runs Not Performed/Not Terminated** radio button.
4. Click **Search** on the Assay Selection screen.
5. Click on the row containing the run ID for the PK specimens you would like to result.
6. Click **Select** on the Assay Selection screen.
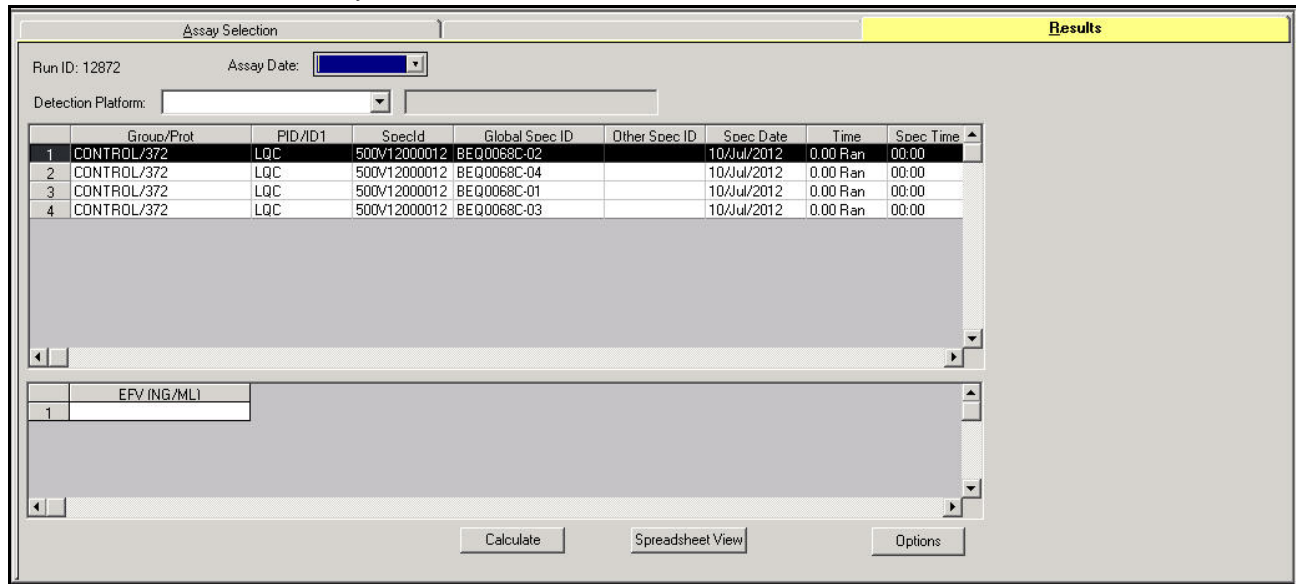
7. Click on the first specimen in the top grid. Enter the results for the sample in the lower grid.
8. Repeat step 7 for each specimen.
9. Enter the assay date of the specimens in the lab into the **Assay Date** field.
10. Select the appropriate **Detection Platform** from the combo box.
11. Click **Calculate** on the bottom of the Result tab.
12. Click **Yes** to continue calculating the assay results.
13. Enter the **Tech Initials** and **Run Limits** for each drug in the **PK Run Limits** dialog box. Click **OK**.
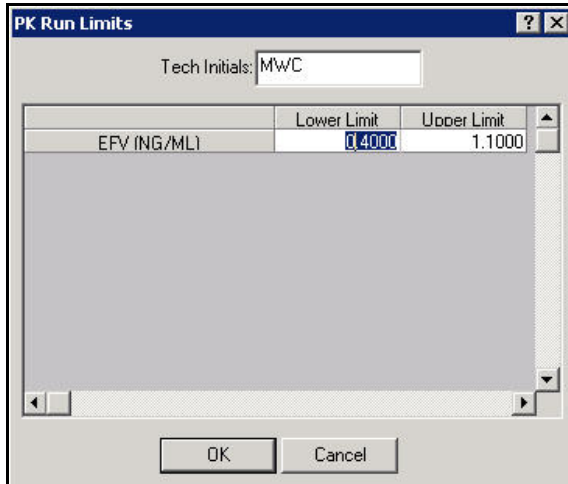
14. A **Success** message appears. Click **OK**.

Note: **Traditional View** allows the lab to enter the patient results manually and will only show one patient's results at a time. **Spreadsheet View** allows the lab to view the entire run on one screen and resembles an Excel format. The data can be viewed with the drugs reported in columns or rows. In Spreadsheet View, the lab has the ability to manually enter results in individual cells or copy and paste results.

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15. Click the **Report** button on the LDMS toolbar to generate the **Assay Result Report**.

PK Assay Result Report

Assay Name: EFV **Reviewed by:**

Run ID: 12872 **Review Date:**

Run Date: 10/Jul/2012 **Tech Initials:** MWC

Drug	Units	Replicates	Lower Limit	Upper Limit	Run Lower Limit	Run Upper Limit	User Censor Summary
EFV	NG/ML	1	0.500	1.000	0.50	1.00	

| Group/Protocol	PID/ID1	Spec Date	Specid	Global Spec ID	Other Spec ID	Spec Time	Time/ Time Unit	SEQ	Add/Der	Drug	Conc	Units	Censors
CONTROL 372	LQC	10/Jul/2012	500V12000012	BEQ0068C-02		00:00	0.00 Ran	1	HEP PL1	EFV	1.000	NG/ML	
CONTROL 372	LQC	10/Jul/2012	500V12000012	BEQ0068C-04		00:00	0.00 Ran	1	HEP PL1	EFV	1.000	NG/ML	
CONTROL 372	LQC	10/Jul/2012	500V12000012	BEQ0068C-01		00:00	0.00 Ran	1	HEP PL1	EFV	0.500	NG/ML	
CONTROL 372	LQC	10/Jul/2012	500V12000012	BEQ0068C-03		00:00	0.00 Ran	1	HEP PL1	EFV	0.500	NG/ML	

Reviewing and Editing Pharmacology Assay Results

The Review/Edit screen allows you to:

- Recalculate All Censors
- View/Modify Run Lower Limits
- Display System Censors
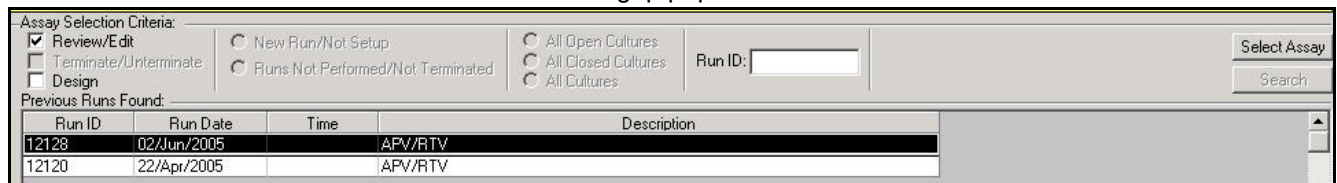- Display User Censors

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Note: To allow the data to be available for statistical analysis purposes, the data must be reviewed.

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1. Select the appropriate PK assay from the available assays listing.
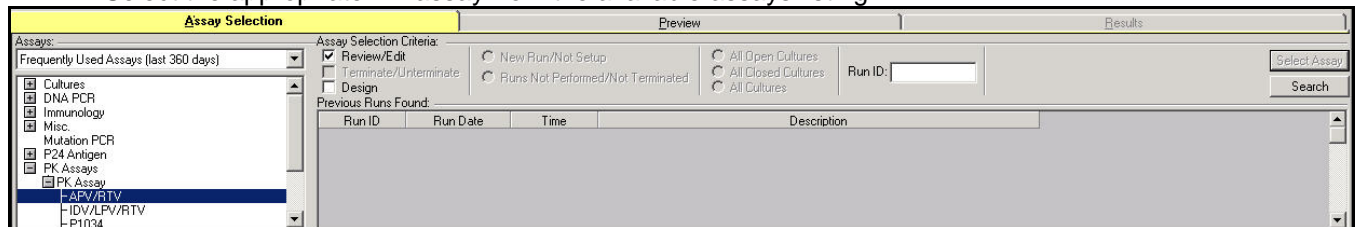
2. Check the **Review/Edit** box.
3. Click **Search**. The **Previous Runs Found** grip populates with the available runs.

4. Select the desired run and click **Select Assay**. The assay results display.

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5. Review the results and enter the **Reviewed by** initials, **Reviewed Date**, and any desired **Comments**.
6. Click **Save** on the LDMS toolbar.