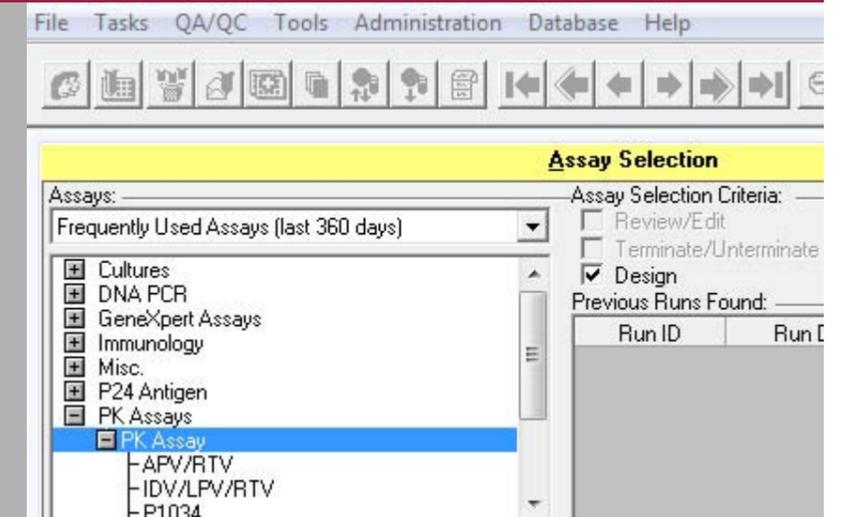


PK Module—Template design



PK Assay Workflow

- Build template and define analytes
- Build QC and Calibrator lots
- Create a run in the Assay module
- Upload results in the Results tab
- Chart aggregated QC values



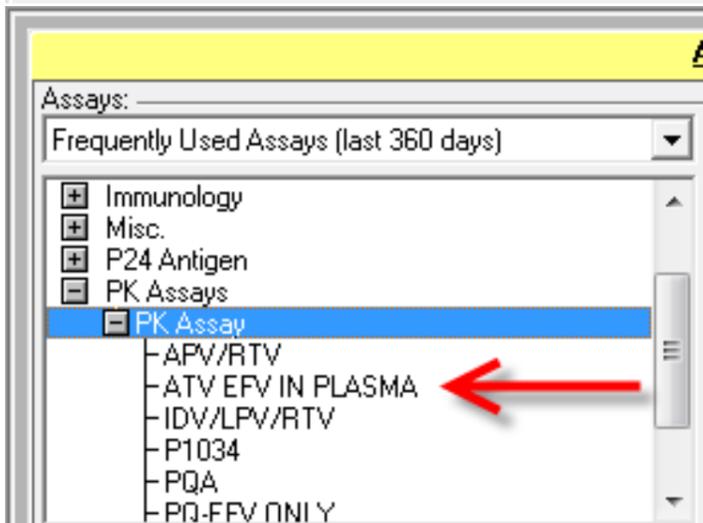
Assay Name:

Number of Drugs:

Delete Row

	Drug	Units	Lower Limit	Upper Limit
1	ATV	NG/ML	100.000	15000.000
2	EFV	NG/ML	100.000	15000.000

- Starting in the assay module, expand the **PK Assays** menu and select **PK Assay**
- Check **Design**
- Enter a unique **Assay Name**
- Enter number of drugs
- For each line select a **Drug** from the drop down list



- Select the **Unit** of measurement
- Set the **Lower** and **Upper Limits**
- Click the red plus sign, the new template is now ready to use
- The **PK QC** and **PK Calibrator** lots must be entered in the **QA/QC** menu before setting up a run

PK QC Lot Entry

- Select **PK QC Lot Entry** from the **QA/QC** menu
- Enter a unique name or number in the **QC Lot #** field
- Set the **Creation Date** and **Expiration Date** using the drop down calendars
- Enter the **Storage Temp** and select the **Derivative/Matrix Type** from the drop down menu
- Add lines to **Controls**, select control from drop down menu, edit the control name (optional)
- Highlight the first control and click the add button in the **Analytes** field
- Select the **Analyte**, enter the **Target**, **Unit**, and **Variance (+/- %)** the minimum and maximum are automatically calculated
- Repeat for other controls
- When complete, save with the **Plus** icon 

PK Calibrator Lot Entry

- Select **PK Calibrator Lot Entry** from the **QA/QC** menu
- Enter a unique name or number in the **Calibrator Lot #** field
- Set the **Creation Date** and **Expiration Date** using the drop down calendars
- Enter the **Storage Temp** and select the **Derivative/Matrix Type** from the drop down menu
- Add lines to **Calibration Standards**, select calibrator from drop down menu, edit the calibrator name (optional)
- Highlight the first calibrator and click the add button in the **Analytes** field
- Select the **Analyte**, enter the **Target**, **Unit**, and **Variance (+/- %)** the minimum and maximum are automatically calculated, repeat for other calibrators
- When complete, save with the **Plus** icon 

Saved Lots:

QC Lot #:

Deactivate

Creation Date:

Expiration Date:

Storage Temp (C):

Derivative/Matrix Type:

Saved Lots:

Calibrator Lot #:

Deactivate

Creation Date:

Expiration Date:

Storage Temp (C):

Derivative/Matrix Type:

Controls

	Control	Custom name
1	HQC	HQC
2	MQC	MQC
3	LQC	LQC
4	LLOQ	LLOQ
5	HOQ	HOQ

Add

Delete

Calibration Standards

	Calibrator	Custom name
1	CAL 1	CAL 1
2	CAL 2	CAL 2
3	CAL 3	CAL 3
4	CAL 4	CAL 4
5	CAL 5	CAL 5
6	CAL 6	CAL 6
7	BLANK -IS	BLANK -IS
8	BLANK +IS	BLANK +IS

Add

Delete

Analytes of HQC

	Analyte	Target	Unit	+/- %	Minimum	Maximum
1	ATV	12000.00	NG/ML	15.00	10200.00	13800.00
2	EFV	12000.00	NG/ML	15.00	10200.00	13800.00

Add

Delete

Analytes of CAL 1

	Analyte	Target	Unit	+/- %	Minimum	Maximum
1	ATV	100.00	NG/ML	20.00	80.00	120.00
2	EFV	100.00	NG/ML	20.00	80.00	120.00

Add

Delete

Assay Selection | Preview | Results

Assays: Frequently Used Assays (last 360 days)

- Immunology
- Misc.
- P24 Antigen
- PK Assays
 - ATV EFV IN PLASMA
 - IBV LFPV RTV
 - P1034
 - PQA
 - PQ.FFV INI Y

Assay Selection Criteria:

- Review/Edit
- New Run/Not Setup
- Terminate/Unterminate
- Design
- All Open Cultures
- All Closed Cultures
- All Cultures

Run ID:

Previous Runs Found:

Run ID	Run Date	Time	Description

Specimen Search Criteria:

Field: Operator: Value:

Search Filters:

Field	Operator	Value
1 Group	=	CPQA

Specimen Received Date: From: To: 13/Jan/2016

Specimens Found:

Group	ID1	ID2	Spec. Date	Global Spec ID	Specid	Other Spec ID	Spec. Time	Time	Time Unit	Prim	Derv	Add	Received Date	VID	VID Unit	Harvest Date	Culture Type	Culture Day	Order
CPQA	21B04	21	21/Jul/2006	A5R001B9-01	195V05000065		00:00	0.00	Random	BLD	PL1	EDT	21/Jul/2006	0.00					00000
CPQA	21T02	21	21/Jul/2006	C5R001BF-01	195V05000069		00:00	0.00	Random	BLD	PL1	EDT	21/Jul/2006	0.00					00000
CPQA	23A02	23	04/Apr/2007	C5R001BP-01	195V05000077		00:00	0.00	Random	BLD	PL1	EDT	04/Apr/2007	0.00					00000
CPQA	22A02	22	10/Oct/2006	D5R001BH-01	195V05000071		00:00	0.00	Random	BLD	PL1	EDT	10/Oct/2006	0.00					00000
CPQA	23T02	23	04/Apr/2007	D5R001BR-01	195V05000079		00:00	0.00	Random	BLD	PL1	EDT	04/Apr/2007	0.00					00000
CPQA	20T04	20	25/May/2006	F5R001B3-01	195V05000059		00:00	0.00	Random	BLD	PL1	EDT	25/May/2006	0.00					00000
CPQA	21T02	21	21/Jul/2006	F5R001BC-01	195V05000067		00:00	0.00	Random	BLD	PL1	EDT	21/Jul/2006	0.00					00000
CPQA	22T04	22	03/Nov/2006	F5R001BM-01	195V05000075		00:00	0.00	Random	BLD	PL1	EDT	03/Nov/2006	0.00					00000
CPQA	20T06	20	25/May/2006	G5R001B5-01	195V05000061		00:00	0.00	Random	BLD	PL1	EDT	25/May/2006	0.00					00000
CPQA	19B02	19	14/Feb/2006	J5R0019Q-01	195V05000047		00:00	0.00	Random	BLD	PL1	EDT	14/Feb/2006	0.00					00000
CPQA	21A01	21	07/Jul/2006	J5R001B7-01	195V05000063		00:00	0.00	Random	BLD	PL1	EDT	07/Jul/2006	0.00					00000
CPQA	24A02	24	12/Dec/2007	J5R001BT-01	195V05000081		00:00	0.00	Random	BLD	PL1	EDT	12/Dec/2007	0.00					00000
CPQA	20B02	20	25/May/2006	K5R001B1-01	195V05000057		00:00	0.00	Random	BLD	PL1	EDT	25/May/2006	0.00					00000

Unselect All | Select All | Empty Grid | Add to Run

Run ID: 12881

Detection Platform:

Run Type:

Add Calibration Standards | Add Quality Controls | Move Up | Move Down | Delete

Group/Prot / Ctrl Lot#	PID/ID1	Spec ID	Global Spec ID / Ctrl Name	Other Spec ID	Spec Date	Time	Spec Time	Add/Drv
1 CPQA/19	19A01	195V05000044	H5R0019N-01		02/Feb/2006	0.00 Ran	00:00	EDT/PL1
2 CPQA/19	19C04	195V05000049	A5R0019S-01		28/Feb/2006	0.00 Ran	00:00	EDT/PL1
3 CPQA/19	19T06	195V05000053	H5R0019X-01		01/Mar/2006	0.00 Ran	00:00	EDT/PL1

Run Now | Run Later | Options

PK Lot Selection

Add this lot:

Control quantity:

Single Duplicate Triplicate

OK | Cancel

- To start any run, select the PK Assay from the drop down menu, check New Run/Not Setup
- Click Select Assay
- (Optional) set Search Filters and select Find Specimens, only specimens with the test assigned will appear in the search results
- Highlight samples, click Add to Run
- In the Preview tab set the Detection Platform and Run Type: **Routine***, **Proficiency/Routine***, **Matrix**, **Calibration**, **Validation**, **Proficiency***, **Stability**, etc.
 - *LDMS specimens may be added to these runs

Results

- In **Traditional View**, each specimen is highlighted and the analyte results are entered individually
- **Spreadsheet View** displays the analytes in vertical columns to allow cutting and pasting from Excel

Run ID: 12881 Assay Date: 14/Jan/2016 Tech initials: FS

Detection Platform: Mass spectrometry (MS) Run Type: Proficiency/Routine

Buttons: Add Calibration Standards, Add Quality Controls, Move Up, Move Down, Delete, Paste, Pivot, Use -1 in spreadsheet mode to enter N/A

	Group/Prot / Ctrl Lot#	PID/ID1	Spec ID	Global Spec ID / Ctrl Name	Other Spec ID	Spec Date	Time	Spec Time	Add/Drv
1	CPQA/19	19A01	195V05000044	H5R0019N-01		02/Feb/2006	0.00 Ran	00:00	EDT/PL1
2	CPQA/19	19C04	195V05000049	A5R0019S-01		28/Feb/2006	0.00 Ran	00:00	EDT/PL1
3	CPQA/19	19T06	195V05000053	H5R0019X-01		01/Mar/2006	0.00 Ran	00:00	EDT/PL1
4	QC ATV EFV IN PLASMA			HQC					
5	QC ATV EFV IN PLASMA			MQC					
6	QC ATV EFV IN PLASMA			LQC					
7	QC ATV EFV IN PLASMA			LLOQ					
8	QC ATV EFV IN PLASMA			HQC					

Spreadsheet View:

	ATV (NG/ML)	EFV (NG/ML)
1		

Buttons: Calculate, Spreadsheet View, Results Options, Calculate, Traditional View, Results Options

Censors

A Censor : Invalid

Greater than the upper limit, dilute and repeat

This **system** censor will now be **automatically** calculated by the LDMS. The LDMS will compare the result entered to the design upper limit for this run. If the result entered is above the upper limit for the assay LDMS will automatically assign the (A) censor. The user will no longer be able to manually assign the (A) censor. It is expected that (A) censored results will be diluted and run again.

Note: To avoid getting an (A) censor on the diluted result, it is expected the user will enter the new diluted result, assign the (U) censor, and specify the dilution factor.

	EFV (NG/ML)	Censor
1	41000.000	(A)

Calculation

System censors have been calculated for this run

OK

U Censor : Sample Diluted

This **user** censor now requires the entry of a **Dilution Factor**.

PK User Censors

This user censor should apply to:

- One result
- All results for this sample
- All results for this analyte on the run
- All results on the run

Make censored specimen(s) available to place on a new run

OK Cancel

PK Sample Dilution

Please enter the dilution for these specimens:

	Global Spec ID	Dilution
1	H5R0019X-01	0.0

OK Cancel

F Censor : Failed

This **user** censor can now be applied **manually**, to fail a specimen. Right-clicking in the Censor field and clicking on Assign User Censor will open the PK User Censor Code options.

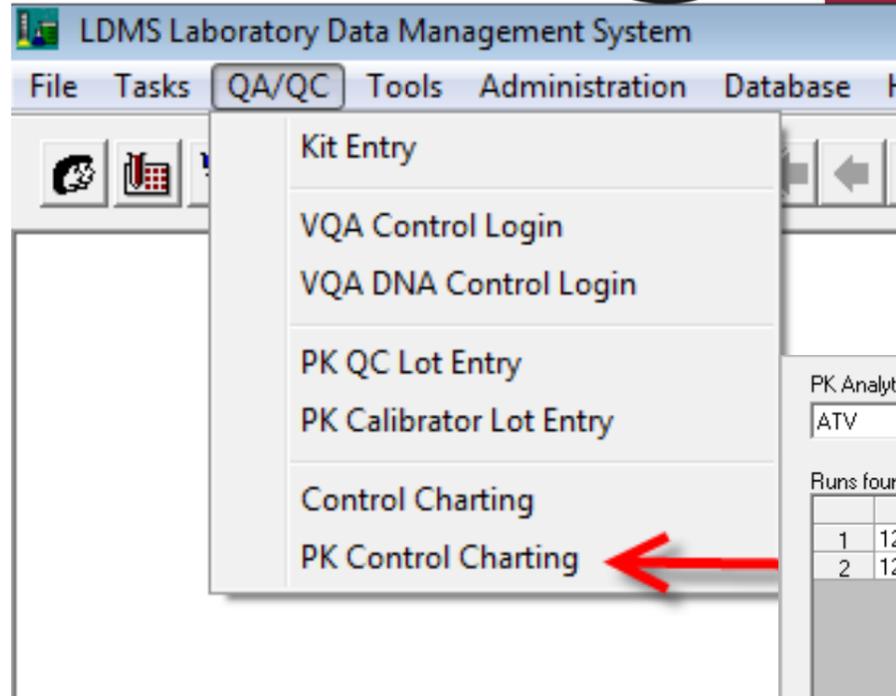
	EFV (NG/ML)	Censor	RTV (NG/ML)	Censor
1	200.000		500.000	

Assign User Censor

PK User Censor Codes

Code	Description
1	None
2	QC out of range, dilute and repeat
3	Drug not required to be assayed
4	Per lab, sample must be repeated
5	Below Quantifiable Limit or No Peak
6	No Result, Lab Issue
7	Not Able to Interpret Result
8	Sample diluted
9	Failed

OK Cancel



The **PK Control Charting** module is used to create CPQA required reports by pulling data from multiple runs to track the performance of QC Lots. Some reports are empty templates where data is entered manually.

Note: Only one Analyte, Lot Type, and Lot Number can be set in the search criteria. Multiple runs can be included in the report.

PK Analytes: Lot Type: Lot #: Run Date From: To:

Runs found:

	Run ID	Run Date	Technician's Initials	Detection Platform	PK Run Type
1	12884	23/Dec/2015	AB	Mass spectrometry (MS)	Stability - BENCH TOP
2	12885	23/Dec/2015	AB	Mass spectrometry (MS)	Stability - FREEZE THAW

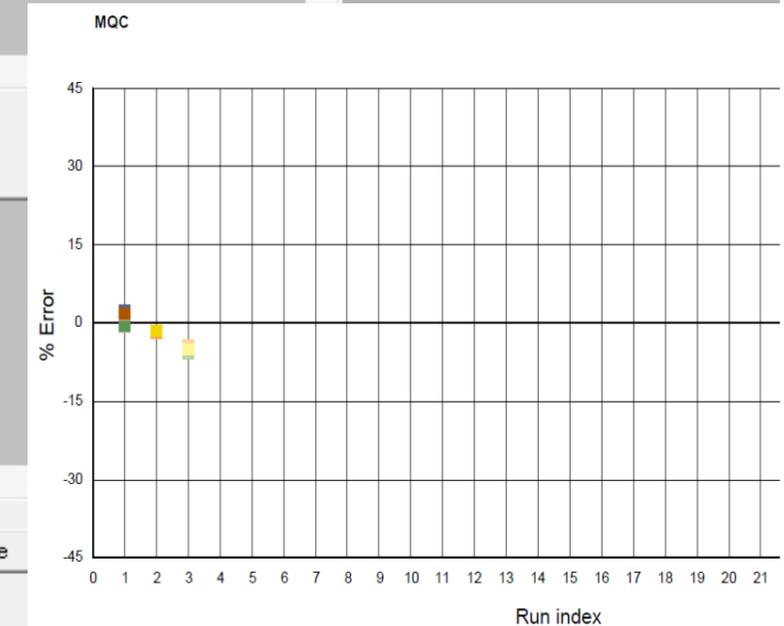
Runs selected:

	Run ID	Run Date	HQC	MQC	LQC	LLOQ	HQD
1	12887	23/Dec/2015	12154.44	8073.11	314.11	114.00	14873.33
2	12889	23/Dec/2015	11978.33	7863.33	291.00	98.00	14426.67
3	12890	23/Dec/2015	11745.67	7596.67	281.33	90.33	14305.00

Reports:

PK Control Charting

- Select **Analyte**, **Lot Type**, and **Lot Number**.
- Limit the results by date range using the **Run Date From/To** fields (optional)
- Click the **Search** button
- Runs that match search criteria appear in the **Runs found** field
- Select one or more runs and use the down arrow button to add to the **Runs selected** field, runs can be removed using the up arrow
- Select the type of **Report** in the drop down menu and click **Generate**



Run Index	Run ID
1	12887
2	12889
3	12890

Available Reports

Inter-day Average Back Calculated Calibration Standards
 Accuracy and Precision for Quality Control
 Performance Charts for Quality Control
 Stability

Inter-Day Average Back Calculated Calibration Standards for ATV (NG/ML)

Run ID	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5	CAL 6	slope	y int.	R^2
12887	115.00	220.00	1099.00	1490.00	8325.00	14425.00			
12888	119.00	240.00	950.00	1404.00	8111.00	14960.00			
Theoretical conc.	100.00	250.00	1000.00	1500.00	8000.00	15000.00			
Mean	117.00	230.00	1024.50	1447.00	8218.00	14692.50			
SD	2.828	14.142	105.359	60.811	151.321	378.302			
%cv	2.417	6.149	10.284	4.203	1.841	2.575			
%dev	17.000	-8.000	2.450	-3.533	2.725	-2.050			
n	2	2	2	2	2	2			

ATV Stability (NG/ML)

BENCH TOP	HQC	MQC	LQC	LLOQ	HOQ	HQC	MQC	LQC	LLOQ	HOQ
Run 12889	11990.00	7880.00	290.00	98.00	14400.00	Ctrl Mean				
	11980.00	7850.00	292.00	97.00	14490.00	mean	11978.33	7863.33	291.00	98.00
	11965.00	7860.00	291.00	99.00	14390.00	SD	12.583	15.275	1.000	1.000
						%CV	0.105	0.194	0.344	1.020
						%diff.				

Available Templates

Partial Volumes Precision and Accuracy
 Matrix Recovery Effects Template 1
 Matrix Recovery Effects Template 2
 Matrix Recovery Effects Template 3

Partial Volumes Precision and Accuracy (NG/ML)

	ATV 1/5	ATV 1/10
1		
2		
3		
Theoretical Conc		
Mean		
SD		
%CV		
%dev		