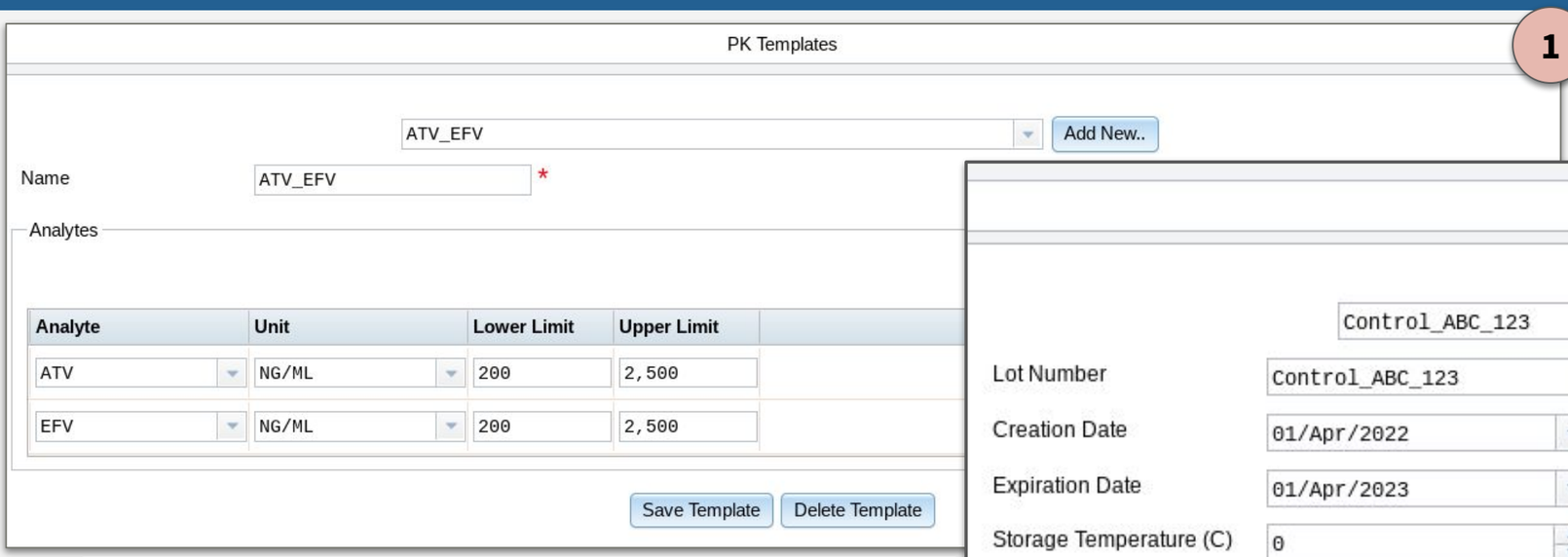
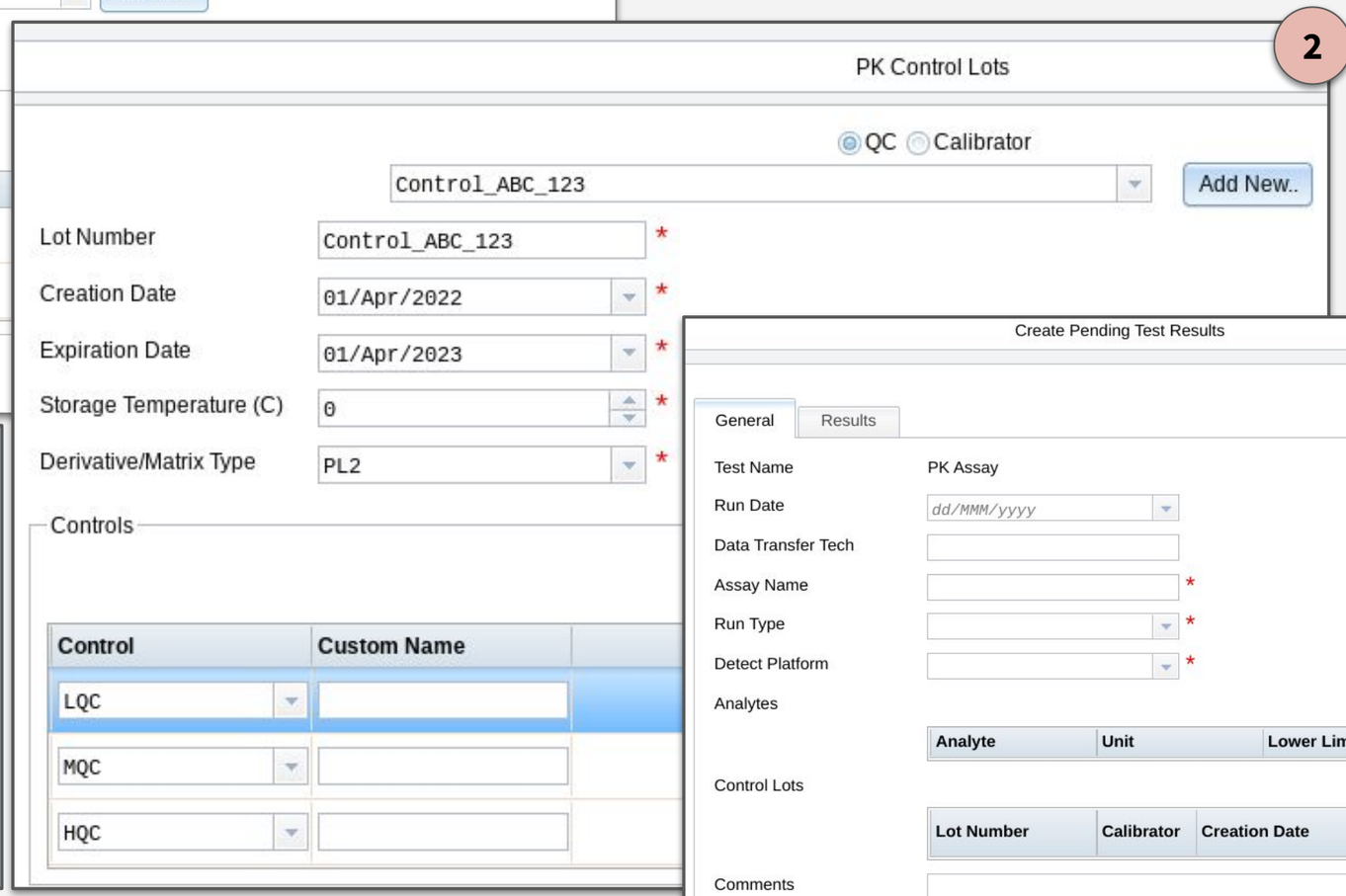
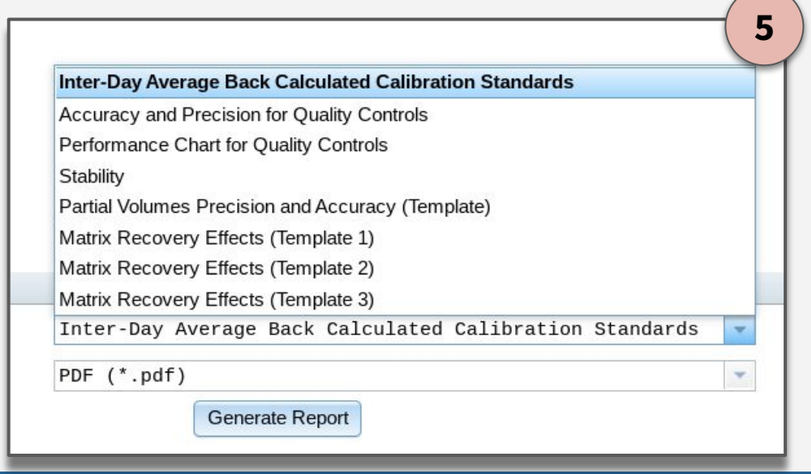
Test Results Module - Pharmacokinetics Overview

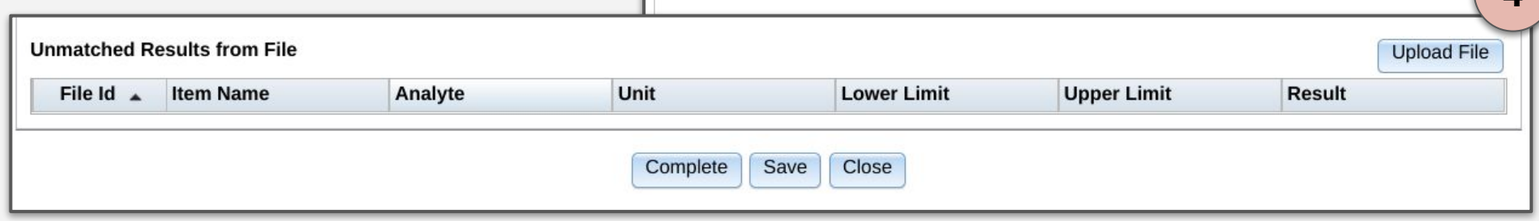
PK Assay Workflow

1. Build template and define analytes
2. Build QC and Calibrator lots
3. Create a run in the Assay module
4. Upload results in the Results tab
5. Chart aggregated QC values





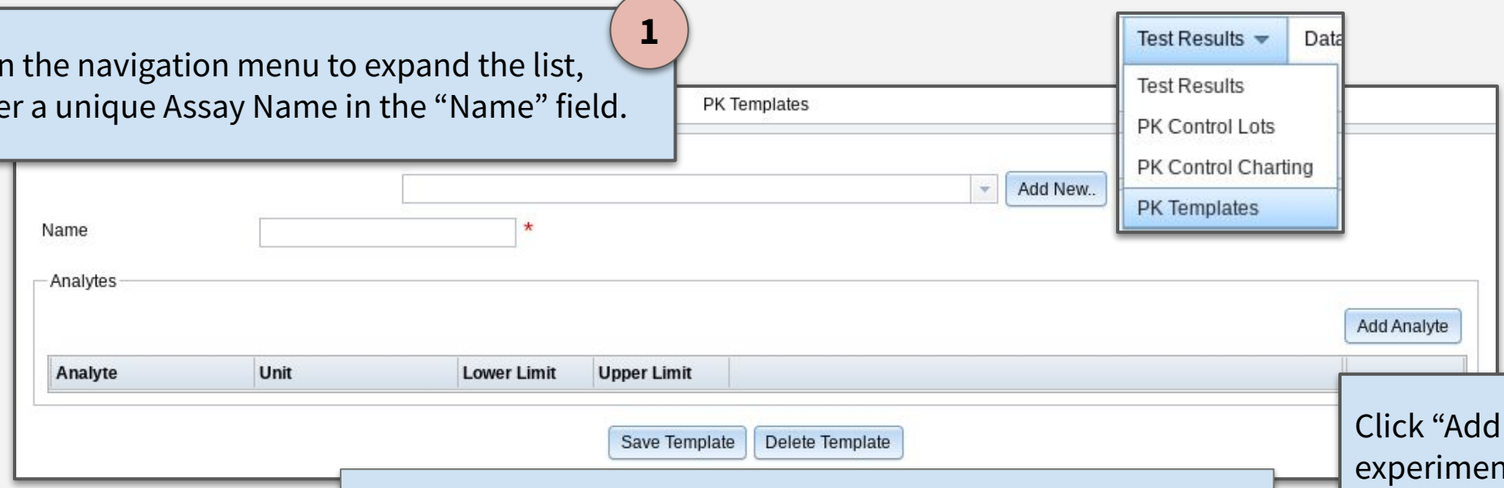




PK Module—Template Design

1

Hover over “Test Results” in the navigation menu to expand the list, select “PK Templates”. Enter a unique Assay Name in the “Name” field.

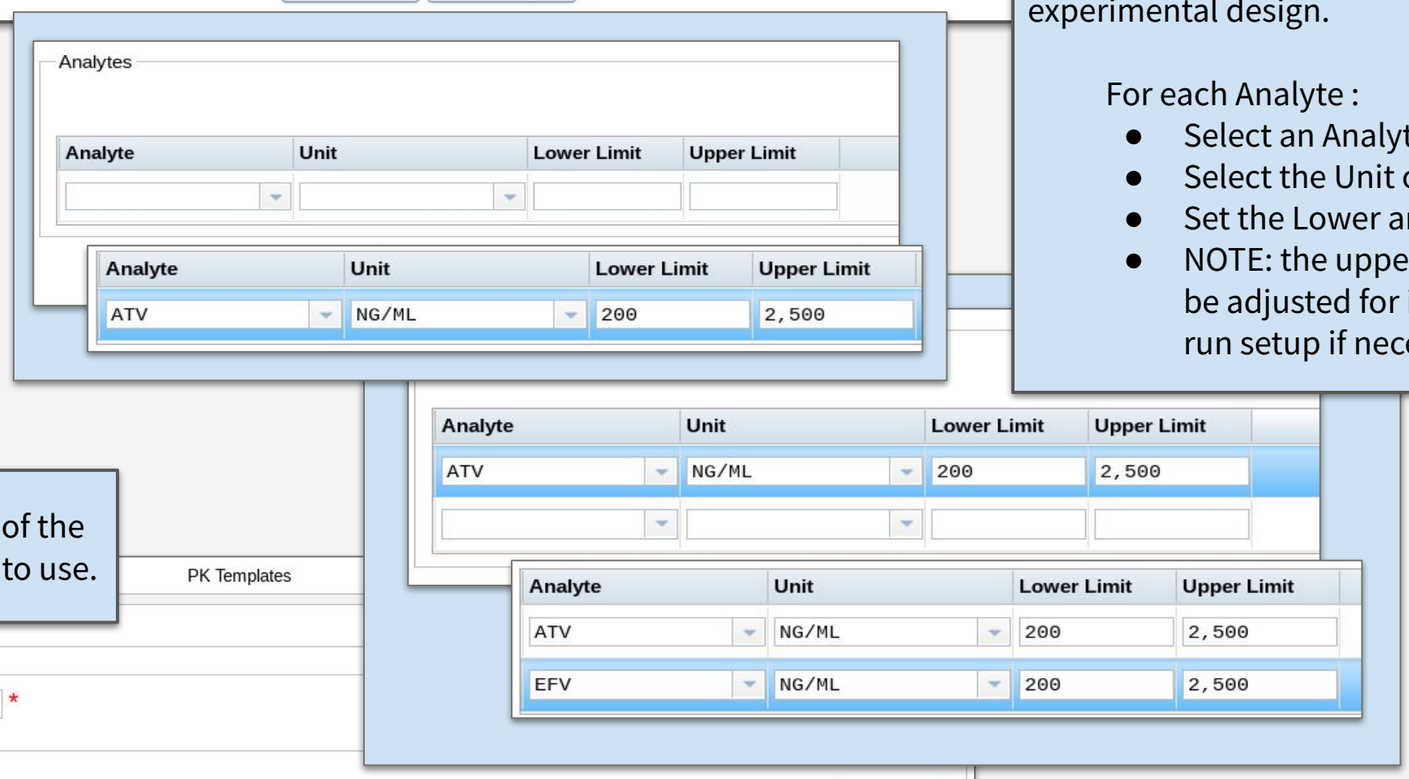


2

Click “Add Analyte” for each drug/analyte in the experimental design.

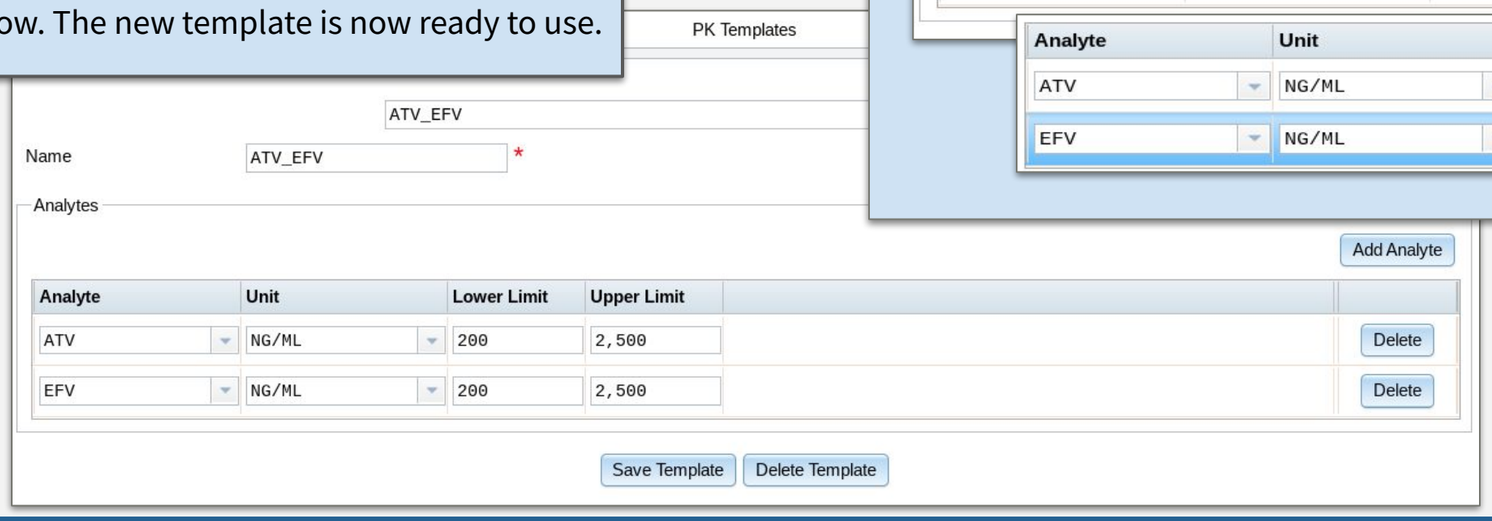
For each Analyte :

- Select an Analyte
- Select the Unit of measurement
- Set the Lower and Upper Limits
- NOTE: the upper and lower limits can be adjusted for individual runs during run setup if necessary.

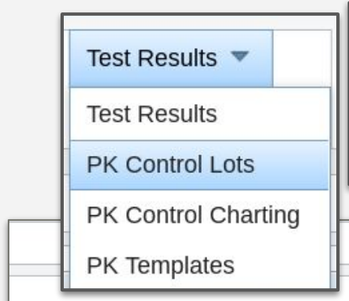


3

Click the “Save Template” at the bottom of the window. The new template is now ready to use.

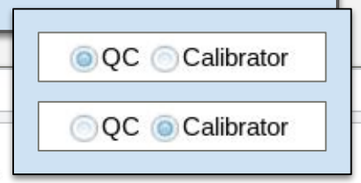


PK Module—Calibrators and QC Lot Entry



1

Hover over “Test Results” in the navigation menu to expand the list, select “PK Control Lots”.
Select QC or Calibrator from the radio buttons



2

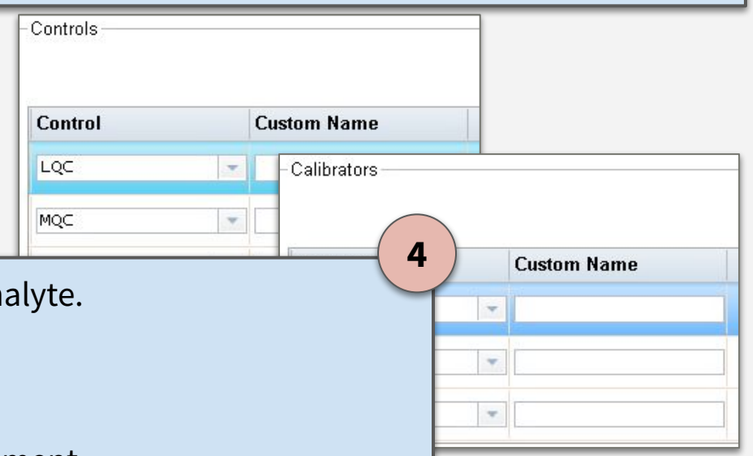
For the QC or Calibrator lot:

- Enter a unique name or number in the “Lot Number” field
- Set the Creation Date and Expiration Date using the drop down calendars
- Enter the Storage Temp
- Select the Derivative/Matrix Type from the drop down menu

3

Click “Add New” for each Control or Calibrator
For each:

- Define the Control or Calibrator from the dropdown
- Define a Custom Name (optional)



4

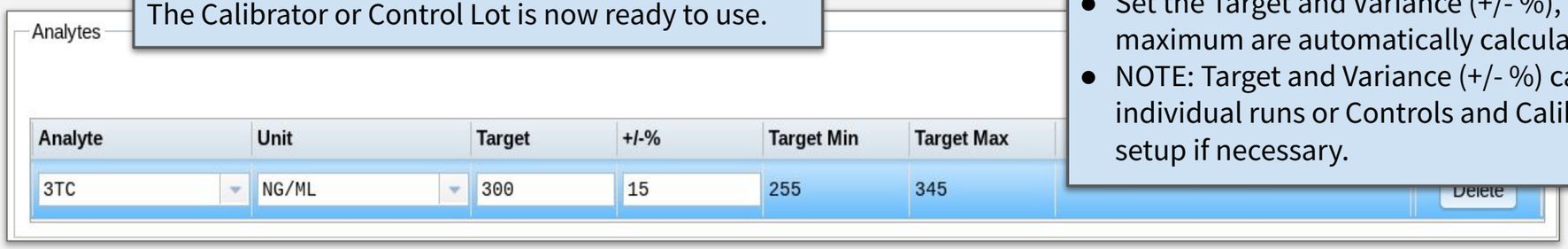
Click “Add New” to add an Analyte.

For each Analyte :

- Select an Analyte
- Select the Unit of measurement
- Set the Target and Variance (+/- %), the minimum and maximum are automatically calculated
- NOTE: Target and Variance (+/- %) can be adjusted on individual runs or Controls and Calibrators during run setup if necessary.

5

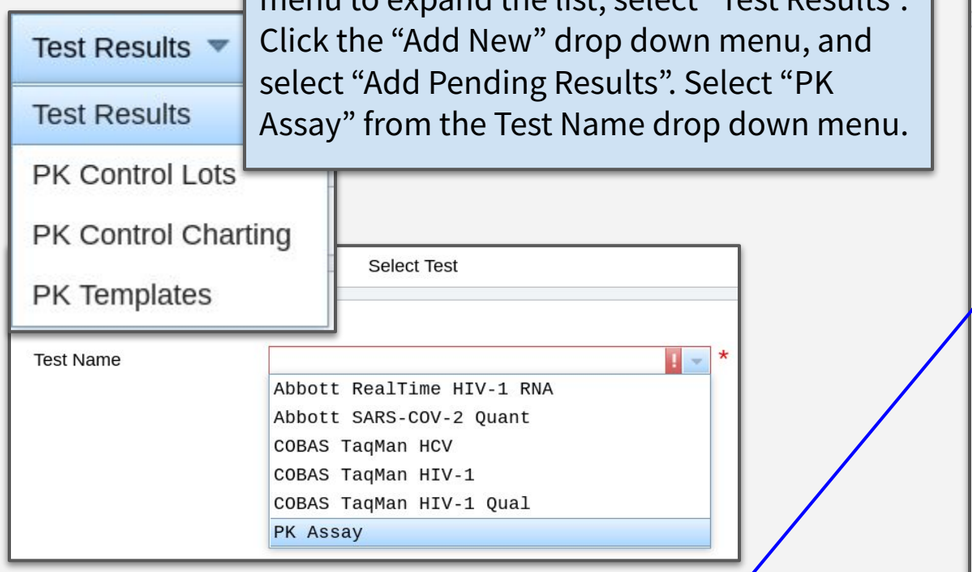
Click the “Save Lot” at the bottom of the window.
The Calibrator or Control Lot is now ready to use.

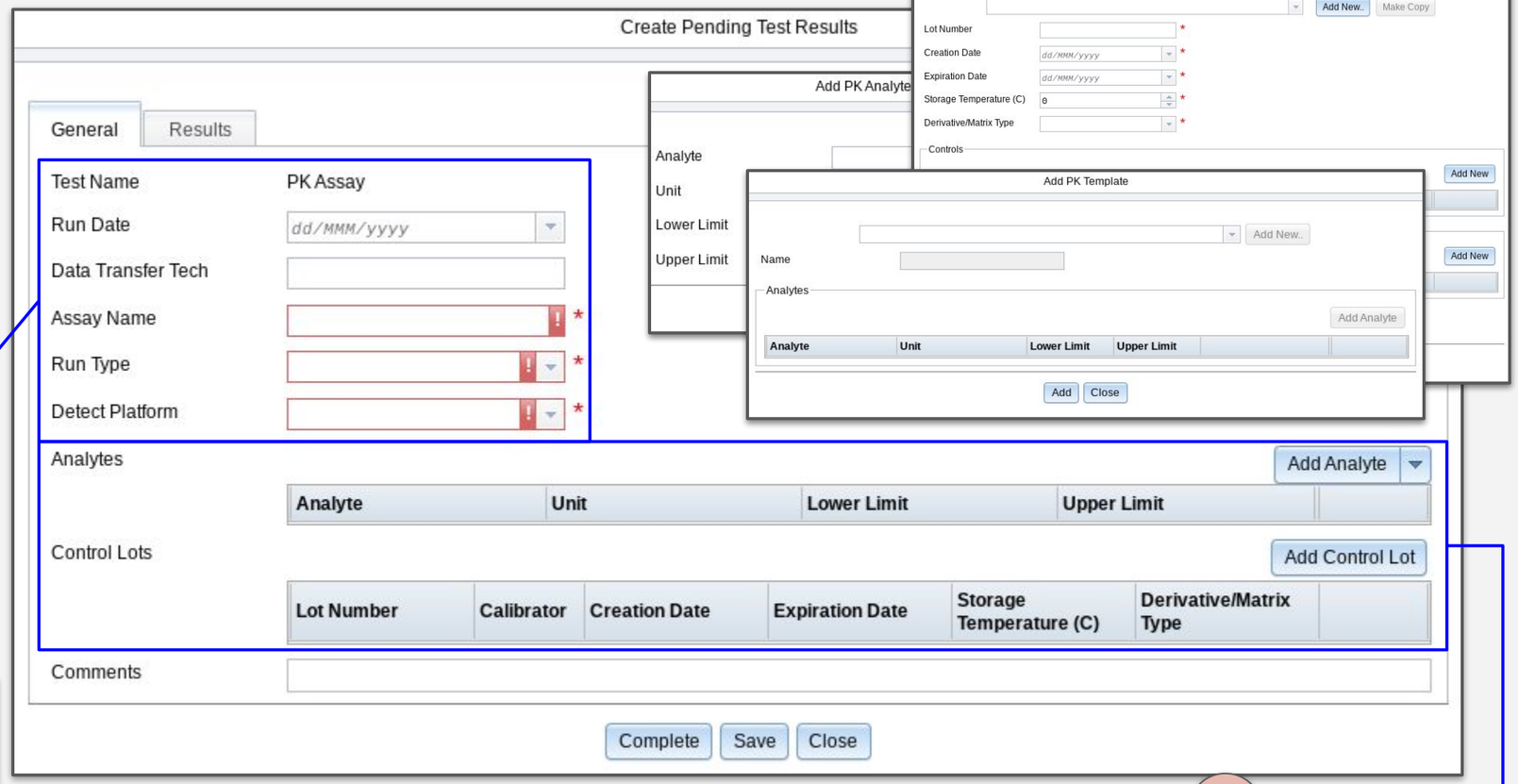


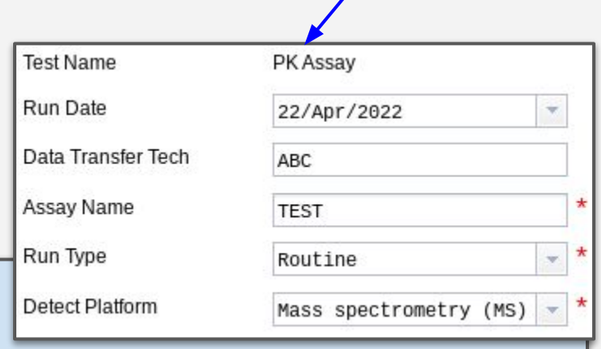
PK Module—Pending Test Results

1

Hover over “Test Results” in the navigation menu to expand the list, select “Test Results”. Click the “Add New” drop down menu, and select “Add Pending Results”. Select “PK Assay” from the Test Name drop down menu.







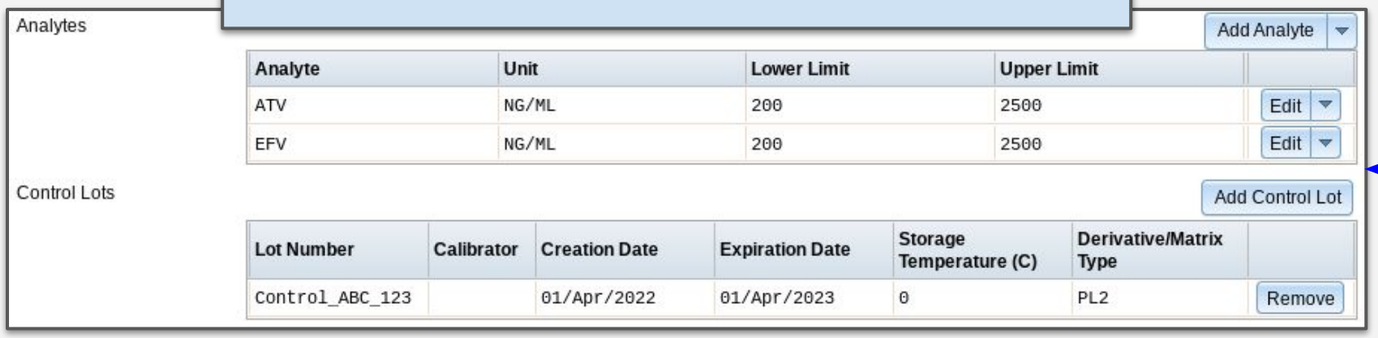
2

Fill out the Run Details:

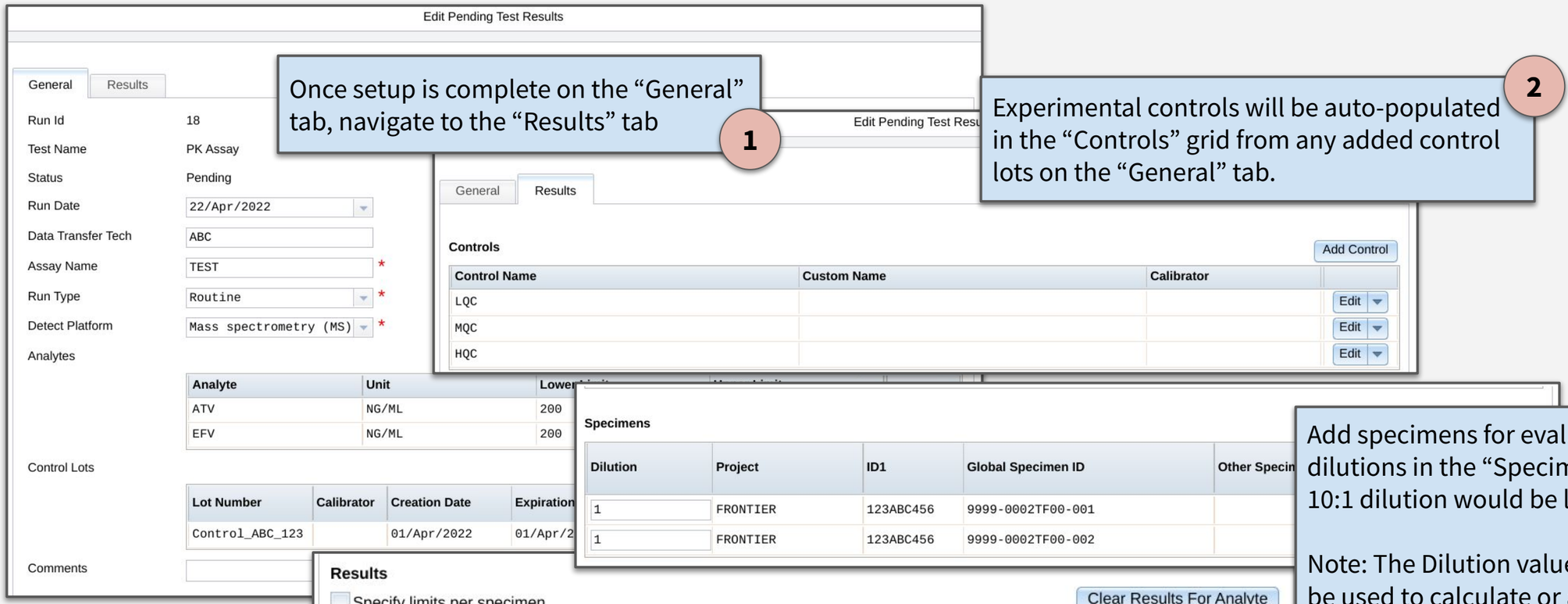
- Define “Run Date” using the drop down calendar
- Define “Data Transfer Tech” initials
- Define “Assay Name”
- Select “Run Type” from the drop down menu
- Select “Detection Platform” from the drop down menu

3

Add Analytes and Controls. Analytes and Controls can be added individually or from preset templates and lots.



PK Module—Pending Test Results

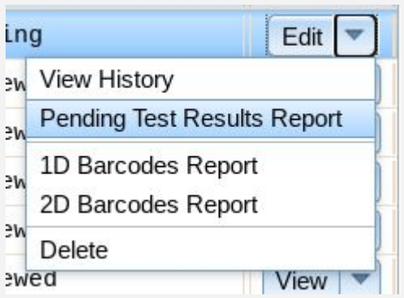


Once setup is complete on the “General” tab, navigate to the “Results” tab

1

Experimental controls will be auto-populated in the “Controls” grid from any added control lots on the “General” tab.

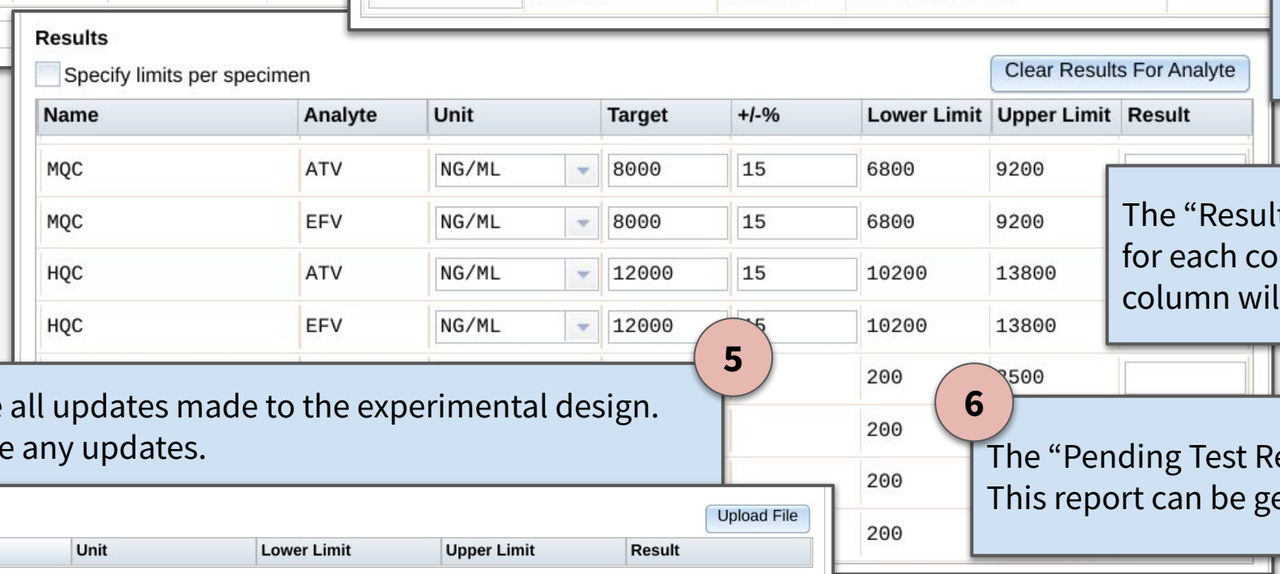
2



Add specimens for evaluation and define their dilutions in the “Specimens” grid. For example, a 10:1 dilution would be listed as “10”.

Note: The Dilution value is informational and will not be used to calculate or adjust the final results.

3



The “Results” grid will be populated with analyte rows for each control and selected specimen. The “Result” column will remain empty until results file is uploaded.

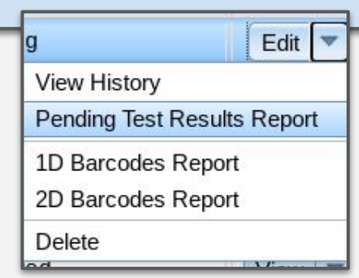
4

Click “Save” in order to save all updates made to the experimental design. Clicking “Close” will not save any updates.

5

6

The “Pending Test Results” report will be available after saving the run setup. This report can be generated and printed to aid in setting up the physical run.



PK Module—Completing Results

Results

Specify limits per specimen — Clear Results For Analyte

Name	Analyte	Unit	Target	+/-%	Lower Limit	Upper Limit	Result
MQC	ATV	NG/ML	8000	15	6800	9200	
MQC	EFV	NG/ML	8000	15	6800	9200	
HQC	ATV	NG/ML	12000	15	10200	13800	
HQC	EFV	NG/ML	12000	15	10200	13800	
9999-0002TF00-001	ATV	NG/ML			200	2500	
9999-0002TF00-001	EFV	NG/ML			200	2500	
9999-0002TF00-002	ATV	NG/ML			200	2500	
9999-0002TF00-002	EFV	NG/ML			200	2500	

Unmatched Results from File — Upload File

File Id	Item Name	Analyte	Unit	Lower Limit	Upper Limit	Result

Complete | Save | Close

1

Upload a results file once assay is completed. Results entered to LDMS should be the final calculated result and must already account for dilutions.

2

Results will auto-match as long as sample names match the names of the samples in the results file. Auto-matches can be made using Global Specimen ID, Participant ID, or Other Specimen ID.

Results

Specify limits per specimen — Clear Results For Analyte

Name	Analyte	Unit	Target	+/-%	Lower Limit	Upper Limit	Result
LQC	ATV	NG/ML	300	15	255	345	295
LQC	EFV	NG/ML	300	15	255	345	290
MQC	ATV	NG/ML	8000	15	6800	9200	7980
MQC	EFV	NG/ML	8000	15	6800	9200	7990
HQC	ATV	NG/ML	12000	15	10200	13800	11090
HQC	EFV	NG/ML	12000	15	10200	13800	11080

3

If the naming conventions do not align, individual sample results can be dragged from the “Unmatched Results” grid and dropped to match the results to the appropriate samples.

HQC	ATV	NG/ML	12000	15	10200	13800	11090
HQC	EFV	NG/ML	12000	15	10200	13800	11080
9999-0002TF00-001	ATV	NG/ML			200	2500	1234
9999-0002TF00-001	EFV	NG/ML			200	2500	
9999-0002TF00-002	ATV	NG/ML					
9999-0002TF00-002	EFV	NG/ML					

1
Result: 6543

		NG/ML	8000	15	6800	9200	7990
		NG/ML	12000	15	10200	13800	11090
		NG/ML	12000	15	10200	13800	11080
9999-0002TF00-001	ATV	NG/ML			200	2500	1234
9999-0002TF00-001	EFV	NG/ML			200	2500	6543
9999-0002TF00-002	ATV	NG/ML			200	2500	4321
9999-0002TF00-002	EFV	NG/ML			200	2500	3456

4

Click “Save” in order to save all updated test results.
Click “Complete” to finalize results of the run.

NOTE- Result censoring is completed during the Review Results steps on the next slides.

Unmatched Results from File

File Id	Item Name	Analyte	Unit	Lower Limit	Upper Limi

Complete | Save | Close

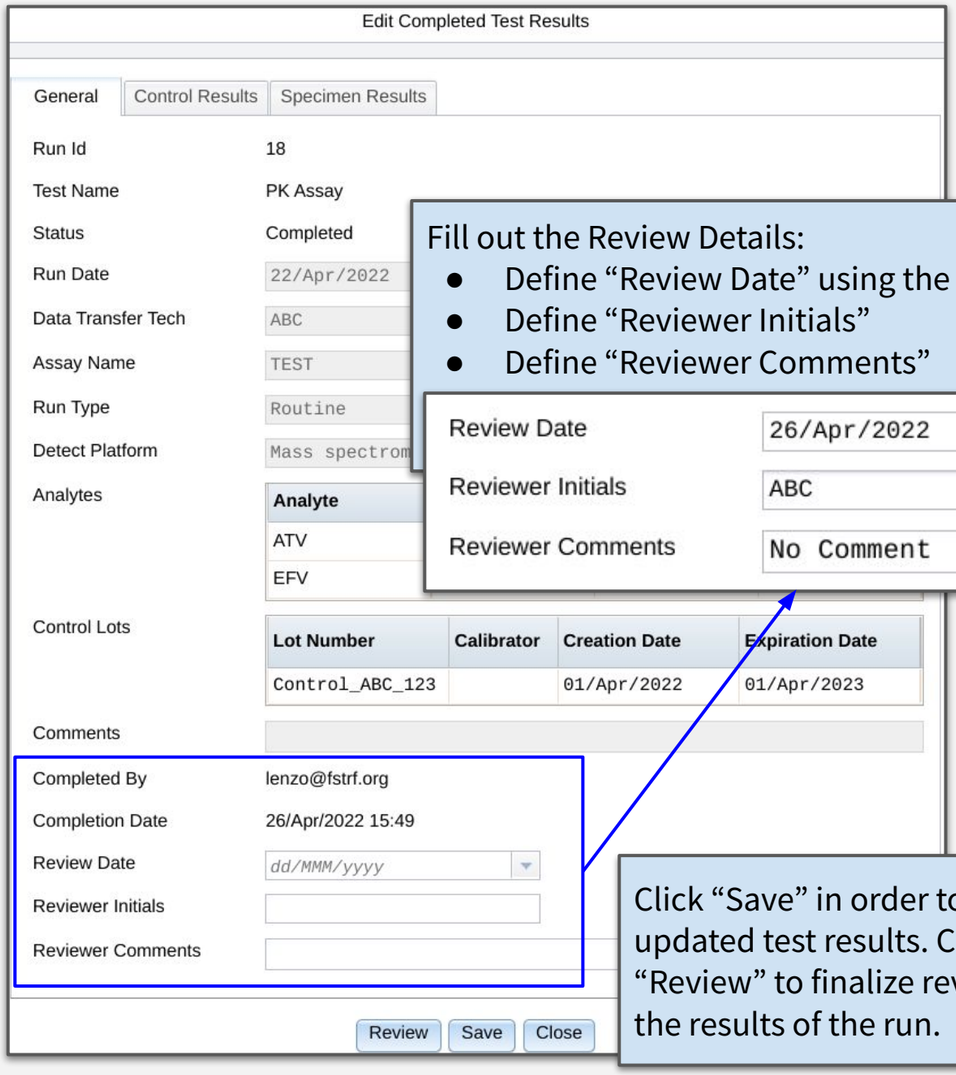
5

NOTE- If a result was not obtained for a specific specimen leave the result field for that row Blank / Null. Leaving a result Blank / Null may be necessary in scenarios such as a template including an analyte that was not tested for, a sample on the run having insufficient volume, or an issue in interpreting the final result. LDMS will allow you to apply a User Censor to Null/Blank results when Reviewing the run.

PK Module—Reviewing Results

1

Once Results have been “Completed” they can be now be “Reviewed”



2

Fill out the Review Details:

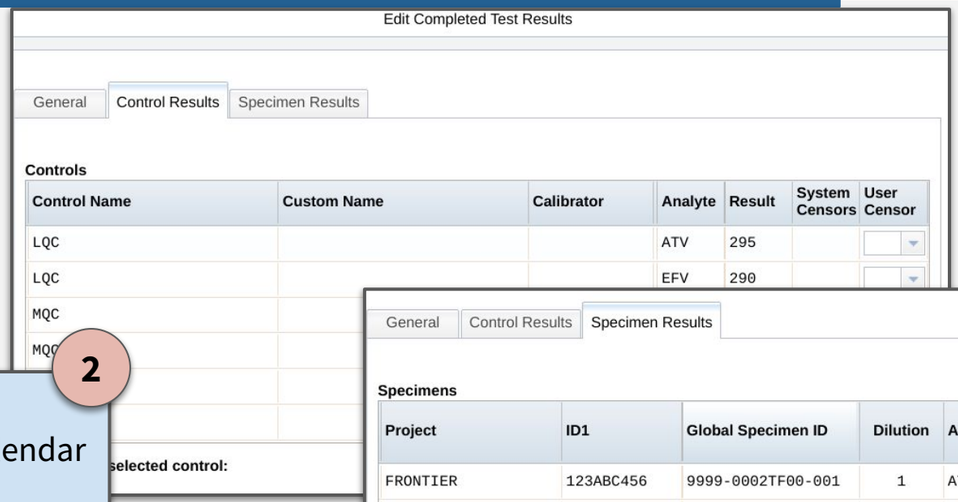
- Define “Review Date” using the drop down calendar
- Define “Reviewer Initials”
- Define “Reviewer Comments”

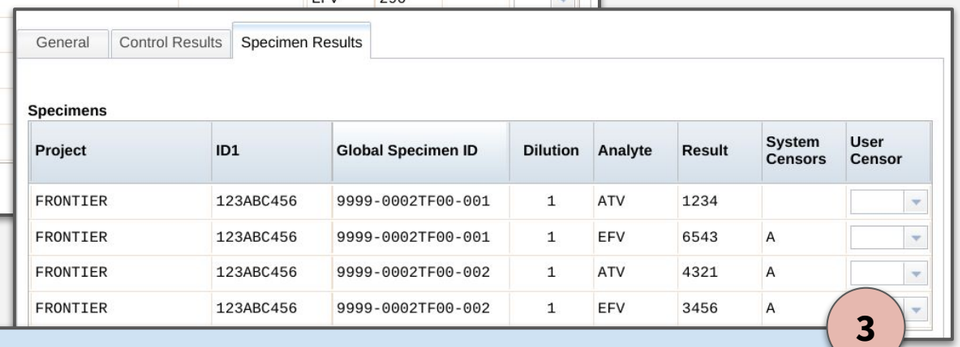
4

Click “Save” in order to save all updated test results. Click “Review” to finalize reviewing the results of the run.

5

NOTE- Result censoring can only be completed during the Review Results steps. If Review has been completed and censors still need to be applied, the run will need to be reset to “Pending”

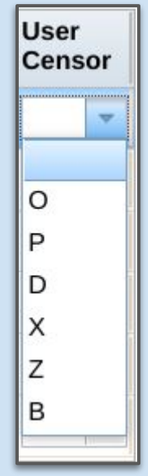




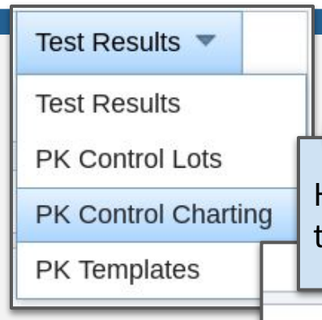
3

Results for Controls and Specimens can be assigned a Censor to each control and each specimen evaluated by the User (U) or the System (S):

- A^S - Invalid. Greater than the upper limit, dilute and repeat
- B^{US}- Below Quantifiable Limit or No Peak
- D^U - Drug not required to be assayed
- F^S - Failed
- H^S - Unacceptable HQC
- I^S - Unacceptable HQC
- L^S - Lower limit adjusted up for this run
- M^S - Unacceptable MQC
- N^U - Not Detected
- O^U - QC out of range, dilute and repeat
- P^U - Not Able to Interpret Result
- Q^S - Unacceptable LQC/ LQC1/LQC2
- R^S - Repeat (with L system censor only)
- S^U - Quantity not sufficient
- U^S - Sample Diluted
- X^U - Per lab, sample must be repeated
- Z^U - No Result, Lab Issue



PK Module—Control Charting

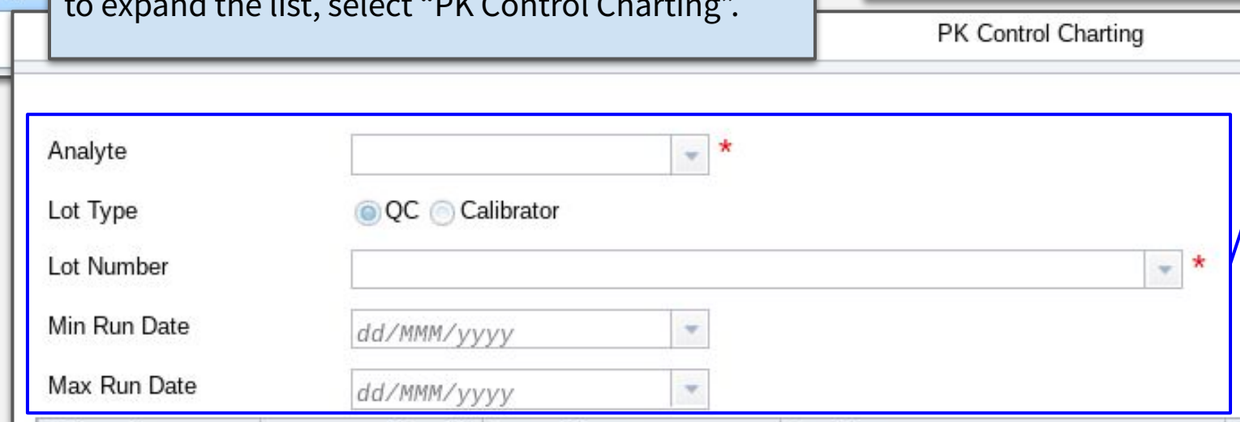


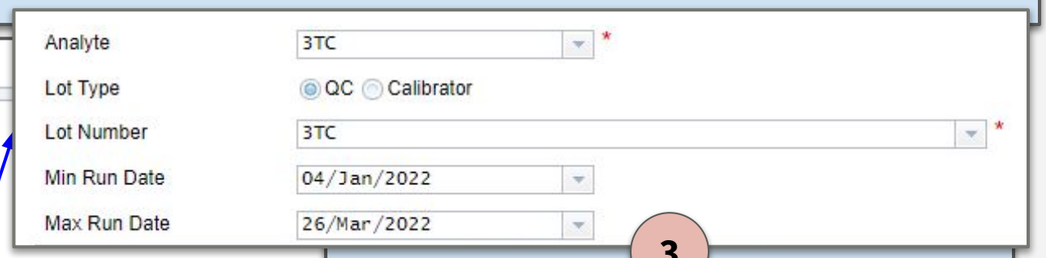
2

Hover over “Test Results” in the navigation menu to expand the list, select “PK Control Charting”.

1

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





3

To search for runs:

- Select Analyte
- Select Lot Type
- Select Lot Number
- Limit the results by date range using the Min and Max Run Date fields

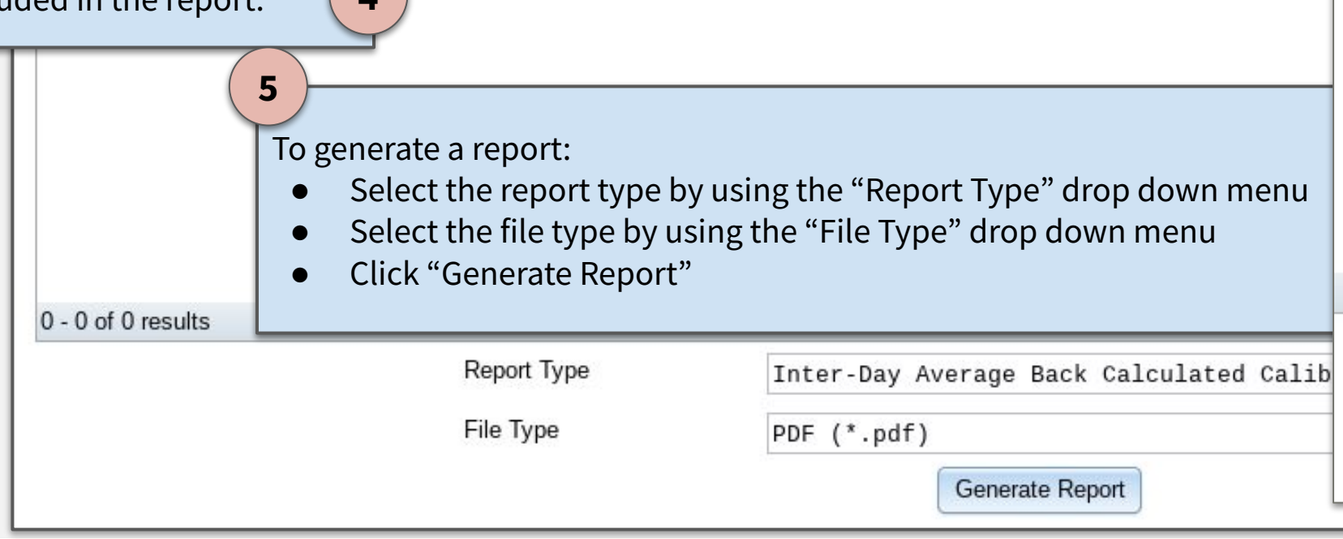
Runs that match search criteria appear in the Runs grid. Select one or more runs to be included in the report.

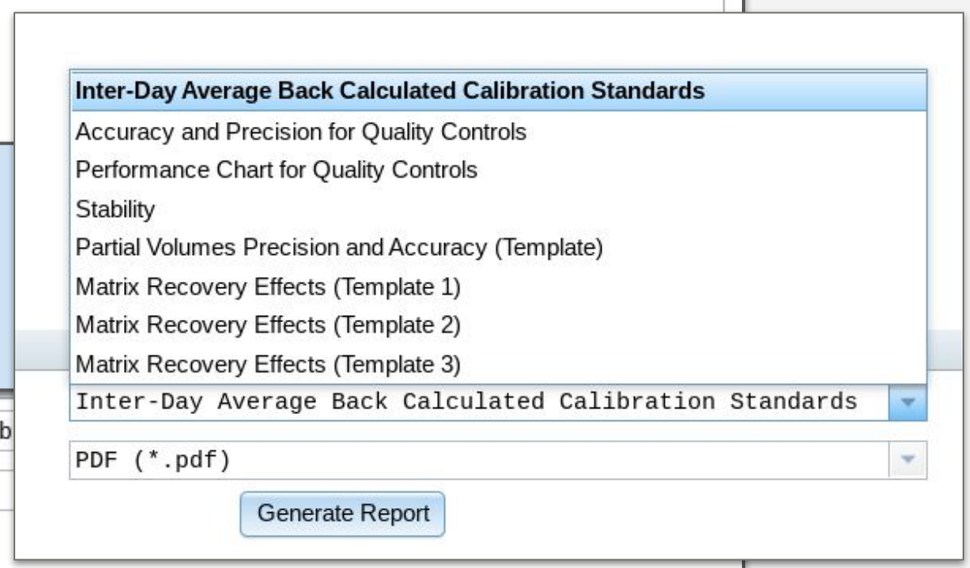
4

5

To generate a report:

- Select the report type by using the “Report Type” drop down menu
- Select the file type by using the “File Type” drop down menu
- Click “Generate Report”



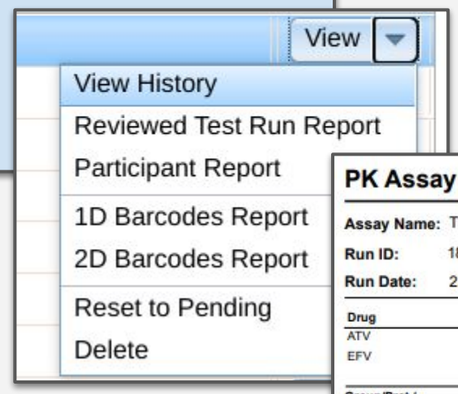


PK Module—Reports

1

Some PK reports can be generated from the dropdown menu inside of the Test Results Module:

- PK Assay Results Report
- Participant Report
- 1D & 2D Barcodes Report
- And More



2D Barcode Report

Searched on: Run ID = 18

Global Spec ID	Project	ID2	ID1	Collection Date	Vid	Vid Unit	Other Spec ID
9999-0002TF00-001	FRONTIER	STUDYABC	123ABC456	2021-08-04	2.00	Vst	

1D Barcode Report

Searched on: Run ID = 18

Global Spec ID	Project	ID2	ID1	Collection Date	Other Spec ID	Vid	Vid Unit
9999-0002TF00-001	FRONTIER	STUDYABC	123ABC456	2021-08-04		2.00	Vst
9999-0002TF00-002	FRONTIER	STUDYABC	123ABC456	2021-08-04		2.00	Vst

PK Assay Result Report

Assay Name: TEST
Run ID: 18
Run Date: 22/Apr/2022

Drug	Units
ATV	NG/ML
EFV	NG/ML

Group/Prot / Ctrl Lot#	PID/ID1	Spec Date	Specid	Global Spec ID / Ctrl Name	Other Spec ID	Spec Time	Time/ Time Unit	Add/Der	Drug	Conc	Units	Lower Limit	Upper Limit	Censors
FRONTIER/STUDYABC	123ABC456	04/Aug/2021		9999-0002TF00-001		08:30		EDTA Plasi	ATV	1234.000	NG/ML	200.000	2500.000	()
FRONTIER/STUDYABC	123ABC456	04/Aug/2021		9999-0002TF00-001		08:30		EDTA Plasi	EFV	6543.000	NG/ML	200.000	2500.000	(A)
FRONTIER/STUDYABC	123ABC456	04/Aug/2021		9999-0002TF00-002		08:30		EDTA Plasi	ATV	4321.000	NG/ML	200.000	2500.000	(A)
FRONTIER/STUDYABC	123ABC456	04/Aug/2021		9999-0002TF00-002		08:30		EDTA Plasi	EFV	3456.000	NG/ML	200.000	2500.000	(A)

2

Additional PK reports can be generated from Standard Reports inside of the Reports Module:

- Pharmacology Drug Count
- Pharmacology Drug List
- Pharmacology Proficiency Results
- PK Drug Limits by Run
- PK Participant Report
- PK SUmmary Report
- PK Summary with Assay Name