

LabKey User Conference 2019

Quality Control with LabKey Server

October 4, 2019



QC with LabKey Server: Agenda



- During import
- Assessing quality
- Tagging data
- Sharing with others

During Import



- **Field validators**
 - Simple checks, set up by admins
 - Numeric ranges, regular expressions
- **Transform scripts**
 - Assay-specific, acts on whole file at once
 - Invoked externally (R, Python, Perl, Java etc)
- **Trigger scripts**
 - Per-row validation
 - Runs inside server, written in JavaScript
 - Part of a LabKey module

Assessing Quality



- Domain-specific checks
 - Leverage knowledge about how things should be
 - Typically has to be custom-coded in each module
- Generalized approaches
 - Statistical process control
 - Levey-Jennings, moving range, cumulative sum, etc
 - Can be applied to any type of standard/control

Domain-specific Example



- Primate electronic health record
 - Hematology, biochemistry, and other panels
 - Well-established normal ranges based on species, sex, age
 - Multiple views

Reference Ranges ▾

GRID VIEWS ▾ EXPORT ▾ PRINT PAGING ▾ 1 - 100 of 159 Next ▾

Date ▾	Test Id	Result	Units	Qualitative Result	Age At Time	Ref Range Min	Ref Range Max	Status	Status
2012-08-27 00:00	LUC	0.0			10.6				Completed
2012-08-27 00:00	WBC	6.0			10.6	4.2	13.6	Normal	Completed
2012-08-27 00:00	NEUT%	59.0			10.6	49.9	79.7	Normal	Completed
2012-08-27 00:00	BAND%	0.0			10.6				Completed
2012-08-27 00:00	LYMPH%	34.1			10.6	14.9	40.6	Normal	Completed
2012-08-27 00:00	MONO%	3.9			10.6	2.7	8.8	Normal	Completed
2012-08-27 00:00	EOS%	2.2			10.6	0.6	11.0	Normal	Completed
2012-08-27 00:00	BASO%	0.8			10.6	0.3	0.9	Normal	Completed
2012-08-27 00:00	HCT	40.3			10.6	32.9	41.8	Normal	Completed
2012-08-27 00:00	HGB	12.3			10.6	10.7	13.8	Normal	Completed
2012-08-27 00:00	RBC	5.67			10.6	4.5	5.84	Normal	Completed
2012-08-27 00:00	MCV	71.0			10.6	65.6	76.4	Normal	Completed
2012-08-27 00:00	MCH	21.7			10.6	21.2	25.2	Normal	Completed
2012-08-27						31.7	33.7	Low	Completed
2012-08-27						119.0	471.0	Normal	Completed
2012-07-10									Completed
2012-07-10	WBC:	6.0	Normal	(4.2-13.6)		4.2	13.6	Normal	Completed
2012-07-10	NEUT%:	59.0	Normal	(49.9-79.7)		49.9	79.7	Low	Completed
2012-07-10	BAND%:	0.0				14.9	40.6	High	Completed
2012-07-10						2.7	8.8	Normal	Completed

Results:

WBC: 6.0 Normal (4.2-13.6)

NEUT%: 59.0 Normal (49.9-79.7)

BAND%: 0.0

LYMPH%: 34.1 Normal (14.9-40.6)

MONO%: 3.9 Normal (2.7-8.8)

EOS%: 2.2 Normal (0.6-11)

BASO%: 0.8 Normal (0.3-0.9)

HCT: 40.3 Normal (32.9-41.8)

HGB: 12.3 Normal (10.7-13.8)

RBC: 5.67 Normal (4.5-5.84)

MCV: 71.0 Normal (65.6-76.4)

MCH: 21.7 Normal (21.2-25.2)

MCHC: 30.5 Low (31.7-33.7)

PLT: 229.0 Normal (119-471)

LUC: 0.0

5

Levey-Jennings Charts

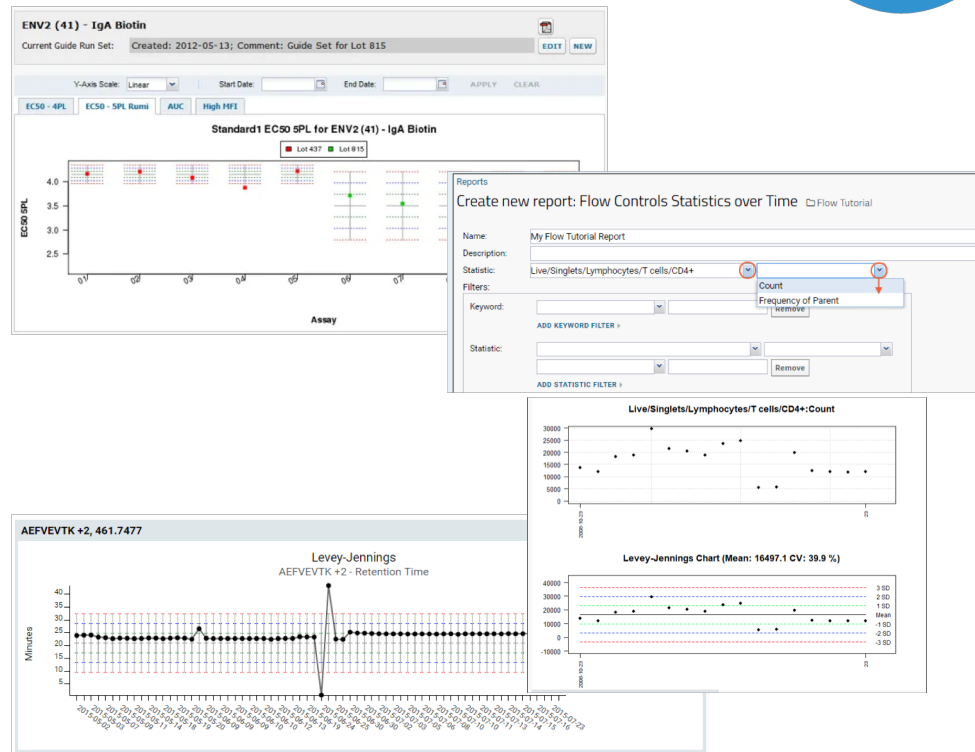


- AKA Shewhart or process-behavior charts
- Longitudinal tracking for metrics
- Identify outliers based on standard deviation relative to expected behavior

L-J Availability in LabKey Server



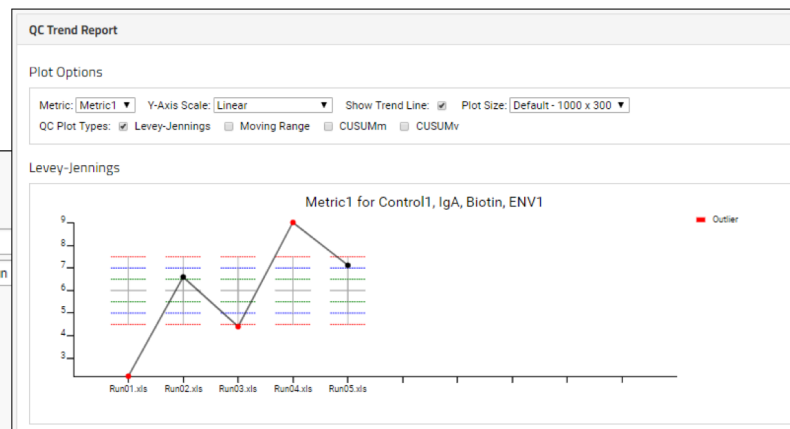
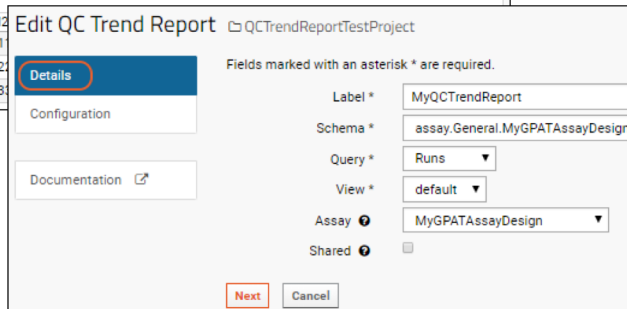
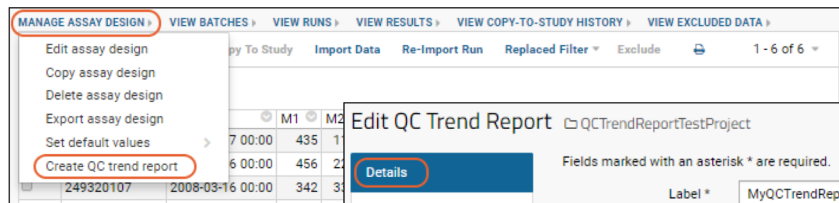
- First in Luminex module
- Later in flow and targeted mass spec modules



QC Trend Report



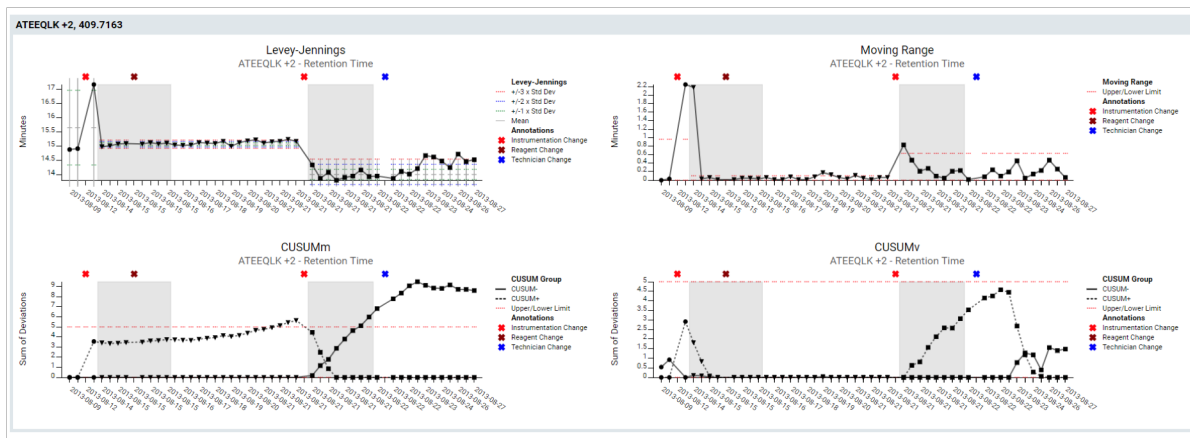
- Available to use with any data
 - Need date and measurement
 - Use “raw” data directly, or use custom SQL query
- Special UI integration with assays



More Chart Types



- Moving range (mR)
 - Optimized for continuous data feeds
- Cumulative sum (CUSUM)
 - Variability and mean
 - Identify increased variability or more gradual drifts



Additional Controls



- Guide sets
 - Establish normal ranges for values, including mean and standard deviation
 - Auto-calculated or set values directly
- Use parameters to segment data

The 'Edit Current Guide Set' dialog box contains the following fields and controls:

- Start Date *: 2018-02-03 (with a calendar icon)
- Name: MyNewGuideSet
- Comment: (empty text area)
- Metric1: Mean: 23 (with up/down arrows), Std Dev: 1 (with up/down arrows)
- Metric2: Mean: (empty), Std Dev: (empty) (both with up/down arrows)
- * Required field
- Buttons: Cancel, Submit

The 'MyQCTrendReport' interface displays a table with the following columns: Row Id, Flag, Assay Id, Comments, Created, Created By, Modified, Modified By, and Folder. A 'View Graph' button is highlighted in the top toolbar. A 'Choose Graph Parameters' dialog box is open, showing 'Conjugate' and 'Isotype' dropdown menus, and a 'View Report' button.

Row Id	Flag	Assay Id	Comments	Created	Created By	Modified	Modified By	Folder
GR				2018-12-11 14:16	your_username	2018-12-11 14:16	your_username	QCTrendReportTest
GR				2018-12-11 14:16	your_username	2018-12-11 14:16	your_username	QCTrendReportTest
GR				2018-12-11 14:17	your_username	2018-12-11 14:17	your_username	QCTrendReportTest

☆ Premium Feature

Variability Across Replicates



- Common to run replicates
 - Biological
 - Technical
- Report on mean, standard deviation, coefficient of variation, etc
 - Built-in to a few assay types like Luminex
 - Pre-calculate via transform script
 - Calculate on-demand via SQL query

Tracking Status



- Explicitly tag data rows
- Typically part of QC workflow
- Study datasets
 - Administrator configured set of QC states
 - Special UI for filtering based on status
 - Not permission-based

Manage Dataset QC States HIV Study

Currently Defined Dataset QC States

State Name	State Description	Public Data ¹
[none]	Applies to data that has not been assigned an explicit QC State	<input checked="" type="checkbox"/> [in use] ²
Not Yet Reviewed	Data that has not been reviewed by the committee.	<input checked="" type="checkbox"/> [in use] ²
Reviewed - Passed	Data that has cleared the qc committee criteria.	<input checked="" type="checkbox"/> [in use] ²
Reviewed - Rejected	Data that has failed the qc committee criteria.	<input checked="" type="checkbox"/> [in use] ²

New dataset QC state:

Default states for dataset data

These settings allow different default QC states depending on data source. If set, all imported data without an explicit QC state will have the selected state automatically assigned.

Pipeline imported datasets:

Assay data copied to this study:

Directly inserted/updated dataset data:

Data visibility

This setting determines whether users see non-public data by default. Users can always explicitly choose to see data in any QC state.

Default visibility:

Manage Groups **QC State** View Specimens

Participant ID	Date	Weight (kg)	Temperature (C)	<input checked="" type="checkbox"/> Public/approved data	<input checked="" type="checkbox"/> All data	Pulse	Clinician Signature/Date
101344	2008-05-25	69	36.0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	71	
101344	2008-06-22	71	36.0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	68	
101344	2008-08-17	73	36.0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	74	
101344	2008-10-12	72	36.0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	66	
101344	2009-01-04	72	37.0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	66	
101344	2009-10-09	82	36.0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	70	
101344	2009-11-06	83	37.2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	68	
101344	2009-12-04	83	36.0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	74	

QC State dropdown menu:

- Not Yet Reviewed
- Reviewed - Passed
- Reviewed - Rejected
- Update state of selected rows
- Manage states

Assay QC States



- Enabled in assay design
- Uses same states as datasets
- Tracked at run level
- Non-public states
 - Hidden from users not in QC analyst role
 - Prevents copying to a study
- Also available in Biologics

☆ Premium Feature

Manage Assay QC States Assay Tutorial

Currently Defined Assay QC States

State Name	State Description	Public Data ¹ In Use
[none]	Applies to data that has not been assigned an explicit QC State	<input type="checkbox"/> <input checked="" type="radio"/>
Not Yet Reviewed	Data that is awaiting review	<input checked="" type="checkbox"/> <input checked="" type="radio"/>
Reviewed - Passed	Data that meets all qc criteria	<input checked="" type="checkbox"/> <input type="radio"/>
Reviewed - Rejected	Data that has failed the qc criteria	<input checked="" type="checkbox"/> <input checked="" type="radio"/>

[Add State](#) [Delete Unused QC States](#)

Default states for assay data

These settings allow different default QC states depending on data source. If set, all imported data without an explicit QC state will have the selected state automatically assigned.

Default

Generic Assay Runs Assay Tutorial

[Save](#) [MANAGE ASSAY DESIGN](#) [VIEW BATCHES](#) [VIEW RUNS](#) [VIEW RESULTS](#) [VIEW COPY-TO-STUDY HISTORY](#) [VIEW EXCLUDED DATA](#)

[Show Results](#) [QC State](#) [Replaced Filter](#)

Update state of selected rows

Flag	Assay Id	Created	Cre By	Batch	Target Study	Operator Email	Instrument
<input checked="" type="checkbox"/>	Run4	2019-07-05 11:21	mohara	23	2019-07-05 batch	john.doe@email.com	ABI QSTAR
<input type="checkbox"/>	Run3	2019-07-05 11:21	mohara	233	2019-07-05 batch	john.doe@email.com	ABI QSTAR

Change QC State Assay Tutorial

New State: ☐ Not Yet Reviewed

Comment: This run has not been reviewed but the setting looks off...

[Update](#) [Cancel](#)

Sharing and Snapshotting



- Query snapshot
 - Save the results of a query as a study dataset
 - Filter to exclude unwanted data
 - Can auto-refresh, or remain static
- Study publish
 - Copy a subset of study data to another folder
 - Set up different permissions from the source data
 - Can auto-refresh, or remain static

Electronic Signatures



- Designed to comply with FDA CFR Title 21 Part 11
- Capture snapshot of data
 - Capture reason
 - Stored as a file in the database
 - Audit trail

Select rows, then export

Excel Text Script

- Excel Workbook (.xlsx) Maximum 1,048,576 rows and 16,384 columns.
- Excel Old Binary Workbook (.xls) Maximum 65,536 rows and 256 columns.
- Refreshable Web Query (.iqy)

Column headers: Caption

☒ Export/Sign selected rows

Export Sign Data

	Participant ID	Date	Start Date	Country	Primary Language	Gender	Treatment Group	Cohort
<input checked="" type="checkbox"/>	101344	2008-04-27	2008-04-27	Germany	German	f	ARV	Group 1: Acute HIV-1
<input checked="" type="checkbox"/>	103505	2008-04-24	2008-04-24	Germany	French	f	ARV	Group 1: Acute HIV-1
<input checked="" type="checkbox"/>	103866	2008-04-21	2008-04-21	USA	German	m	Natural Controller	Group 1: Acute HIV-1

Sign Data Snapshot

Email: mohara@labkey.com

Password:

Reason: Finalize study candidates

Cancel Submit

Admin Console

Audit Log

Signed snapshots

	Date	Container	Created By	Impersonated By	Datesigned	Schema	Table	Reason	Comment
	2019-02-24 11:45	HIV Study	your_username		2019-02-13 20:49	study	Demographics	Finalize study candidates	Snapshot downloaded
	2019-02-13 20:52	HIV Study	your_username		2019-02-13 20:52	study	Physical Exam	Selected candidates for final review	Snapshot signed
	2019-02-13 20:49	HIV Study	your_username		2019-02-13 20:49	study	Demographics	Finalize study candidates	Snapshot signed

☆ Premium Feature

Any questions?