Quanterix

Powering a Revolution in Healthcare

Simoa Best Practices–Day 2

Hohn Doe,
Field Applications Scientist

September 2017

Day 2: Basic Kit Training Agenda

Time	Agenda	Location
9 am	Instrument and Software Review, review Run 2 data	Lab
10 am	Start of Day Maintenance	Lab
10:30 am	Kit Assay Set Up-Run 3	Lab
Noon	Lunch Break	
1:00 pm	End of Day Shutdown Maintenance	Lab
1:30 pm	Maintenance and Best Practices Presentation	Conference Room
3 pm	Data Analysis- review Run 3	Conference Room
4 pm	Introduce HB training; Review, Q and A session	Conference Room

Simoa Best Practices

- Instrument Maintenance & Best Practices
- Overview of software Data Review
- Troubleshooting Review and Resources
- Latest updates

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INSTRUMENT MAINTENANCE AND BEST PRACTICES

Maintenance Checklist

Monthly Tasks	Performed by Enter initials and date completed below											
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
Database Maintenance*												
Cleaned Surfaces												
Bulk Fluid Containers Rinsed												
Check for Leaks												
Check for Oil Leaks												
Temporary Files Cleanup												
Send Quanterix Reporting Tool data (QuaRT) if you report manually												

If you use your instrument four days per week or more, Quanterix recommends that you run the Database Maintenance task at **least once per week instead of once per month.*

Maintenance Tasks- Best Practices

Task	Default Interval	Description
Start of Day	After initialization	Prepares instrument systems to start a run. See “Performing the Start of Day Task” on page 155.
End of Day	Daily after the last run of the day	Cleans the system at the end of the day.
Idle Fluid Prime	After 240 idle minutes	Primes the system fluids and resets the idle time counter.
Monthly Fluid Prime	Monthly	Primes the system fluids three times the normal length, approximately 30 minutes.
Replenish Oil	When the seal oil is empty	Primes sealing oil through the entire line.
Database Clean	Database size limit reached, at least weekly	Cleans up the database. See “Performing the Database Clean Task” on page 158.
Temporary Files Clean	Monthly	Removes temporary files.
Disk Defragmentation	Once a week	Performs disk utility that improves data access speeds.

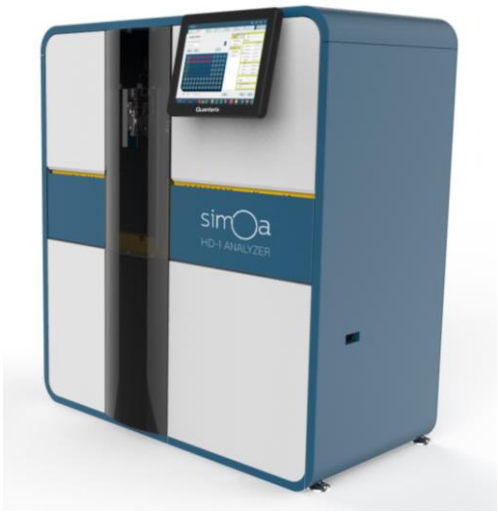
Monthly Maintenance

- System fluid container cleaning and tubing rinse
- Cleaning the touchscreen with wet paper towel sprayed with glass cleaner (non ammonia)
- Clean external surfaces with wet cloth sprayed with 10% ethanol or water
- Clean other surfaces with 70% ethanol
  - System resource drawers
  - Sample and Reagent Bays
  - Bottom cabinet

Maintenance at Start of Day and End of Day

- If the instrument **has** completed an End of Day shutdown
  - Power cycle the instrument
  - Run Start of Day maintenance

- If the instrument **has not** completed an End of Day shutdown
  - Perform the End of day shutdown
  - Power cycle the instrument
  - Run Start of Day maintenance



Instrument Idle Best Practice

- If the instrument will not be used for less than 4 weeks, do the following twice per week of inactivity
  - Power on the computer and instrument
  - Do a Start of Day and End of Day
  - Power off the computer and instrument

- If the instrument will not be used for greater than 4 weeks,
  - Schedule a visit with Quanterix Service to perform maintenance before and after the scheduled idle period.

Instrument Maintenance & Best Practices

Customer Portal - Documentation

- Simoa HD-1 Analyzer ™ User Guide Software version 1.5
  - Chapter 11: Maintaining the Simoa HD-1 Analyzer
- Simoa HD-1 Analyzer™ Short Operating Procedure
- Simoa HD-1 Analyzer Monthly Maintenance Instructions
  - Tech Bulletin: Impact of Monthly Maintenance on Data Quality

Instrument Maintenance & Best Practices

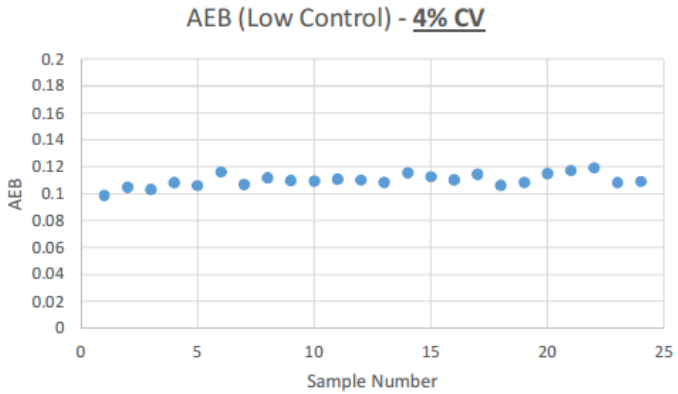
Customer Portal - Troubleshooting & Tech Bulletins

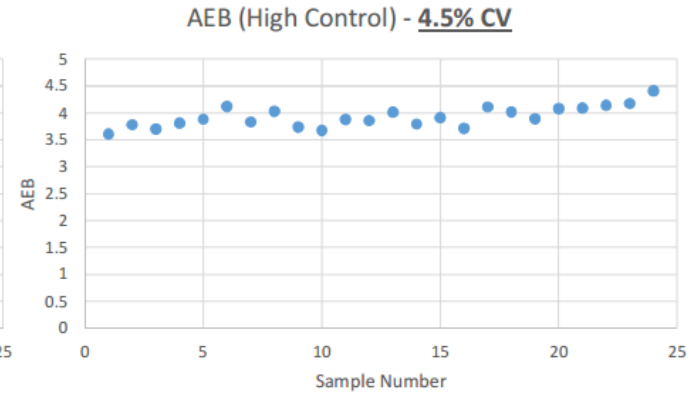
- Simoa HD-1 Analyzer Instrument Troubleshooting Guide
- Simoa Best Practices for Software Version 1.5
- Simoa Instrument Maintenance for Version 1.5 Software

Training Videos

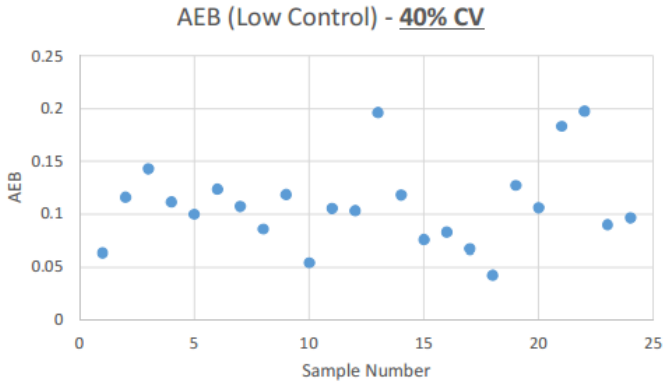
Instrument Maintenance

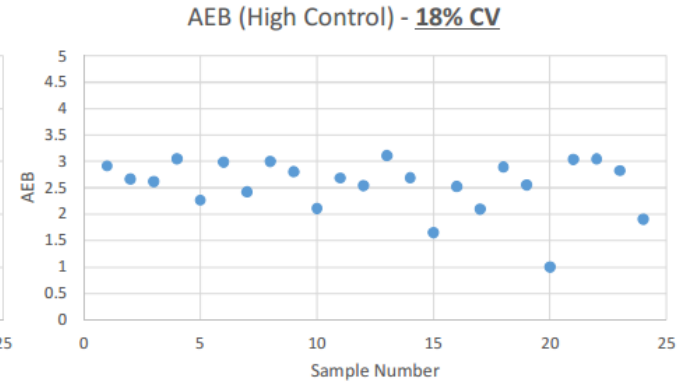
- Typical performance with required maintenance procedures being performed





- Performance when required maintenance tasks are ignored





Tech Bulletin: *Impact of Monthly Maintenance on Data Quality*
Simoa Instrument Maintenance for Version 1.5 Software

Training Videos

- Changing the Sealing Oil Bag

Modifying Calibration Curves and Recalculating Samples

- Modifying Calibration Curves and Recalculating Samples

Custom Assays

- Custom Assay Overview
- Creating a New Assay
- Creating New Reagent

Monthly Maintenance

- Monthly Maintenance Full Video
  - Secondary Container and Reservoir
  - Priming the System with DI Water
  - Priming the System with Wash Buffer

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OVERVIEW OF SOFTWARE DATA REVIEW

Data Review

Customer Portal – Documentation

- Simoa HD-1 Analyzer ™ User Guide Software version 1.5 (Chapter 9)
- Simoa HD-1 Data Analysis for Software Version 1.5

Customer Portal - Troubleshooting & Tech Bulletins

- Troubleshooting & Tech Bulletin: Simoa HD-1 Analyzer Data Analysis Troubleshooting Guide

Training Videos

Training Videos

Run Setup

- Overview of Run Setup

For best results, watch this video first.

- Assigning Calibrations
- Assigning Samples

Instrument Startup

Loading Reagents

System Resources

Modifying Calibration Curves and Recalculating Samples

Custom Assays

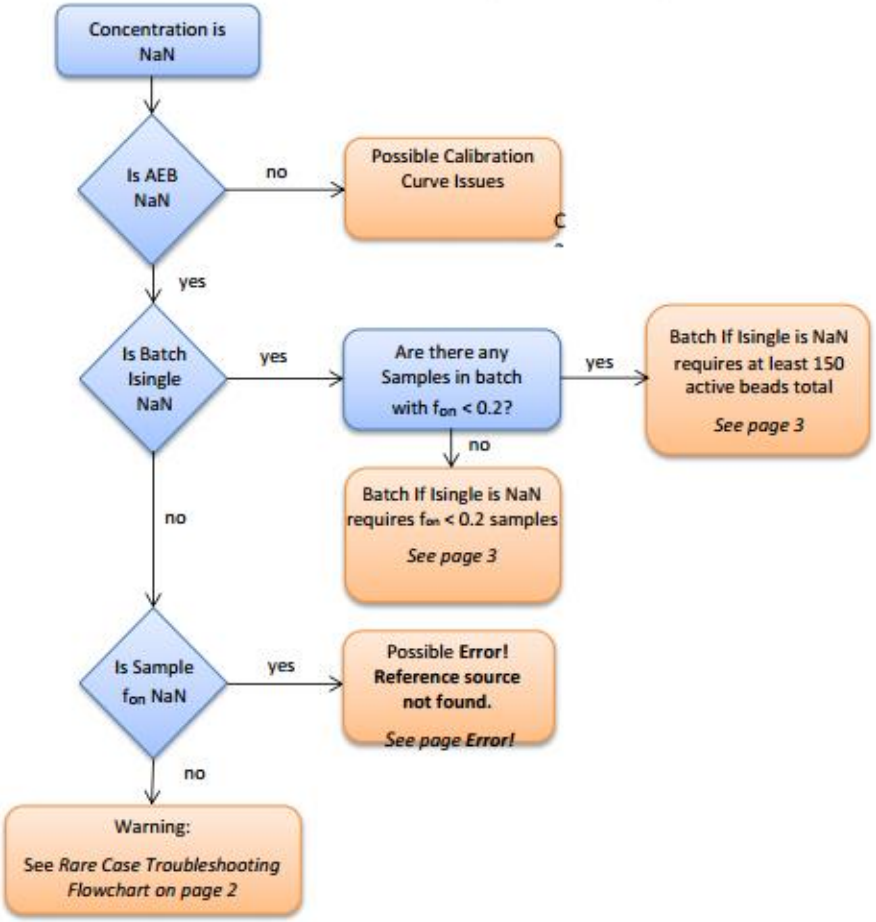
Monthly Maintenance

- Monthly Maintenance Full Video

Troubleshooting Flowchart

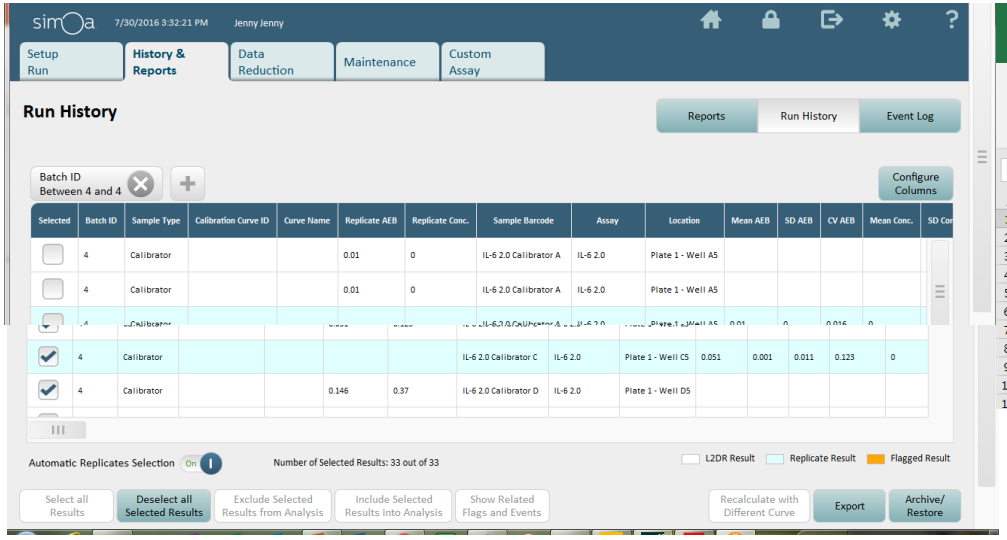
Troubleshooting Flowchart

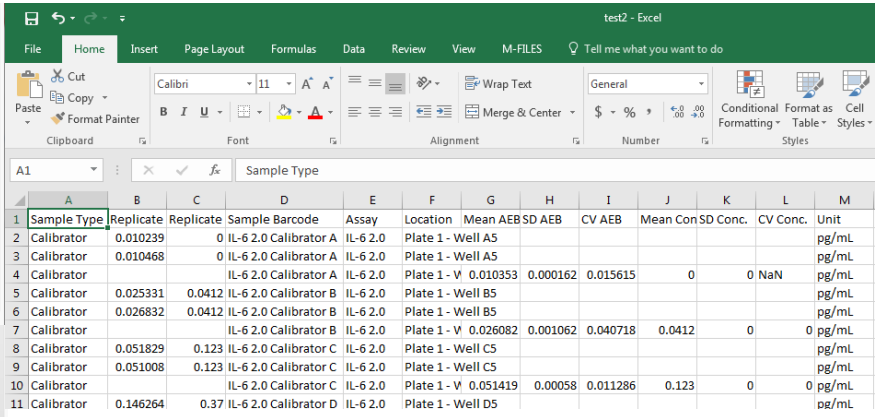
Use this flowchart to identify and navigate to a troubleshooting topic. If you have a specific error message, see *Sample Error Messages* on page 11. If troubleshooting results in a rare case outcome, see the *Rare Case Troubleshooting Flowchart* on page 2.



Data Review

- Exporting Data – History & Reports Tab, Filter for Batch, Select all Results and Export CSV file of results
  - Add/Remove Columns and change column order using Configure Columns
- Exporting Batch Calibration Report – History & Reports Tab
- Calibration Curve – Data Reduction Tab

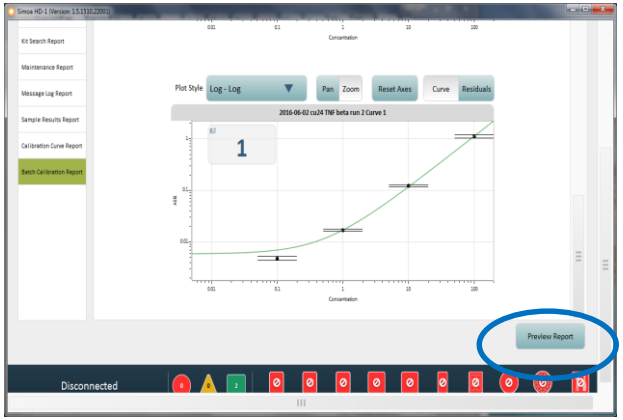


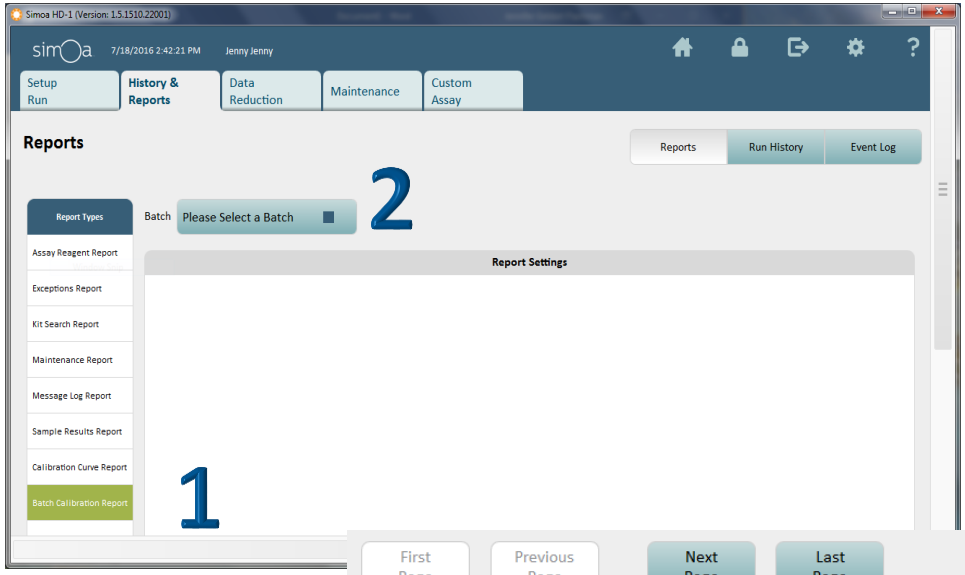


	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Sample Type	Replicate	Replicate	Sample Barcode	Assay	Location	Mean AEB	SD AEB	CV AEB	Mean Con	SD Conc.	CV Conc.	Unit
2	Calibrator	0.010239	0	IL-6 2.0 Calibrator A	IL-6 2.0	Plate 1 - Well A5							pg/mL
3	Calibrator	0.010468	0	IL-6 2.0 Calibrator A	IL-6 2.0	Plate 1 - Well A5							pg/mL
4	Calibrator			IL-6 2.0 Calibrator A	IL-6 2.0	Plate 1 - W	0.010353	0.000162	0.015615	0	0	NaN	pg/mL
5	Calibrator	0.025331	0.0412	IL-6 2.0 Calibrator B	IL-6 2.0	Plate 1 - Well B5							pg/mL
6	Calibrator	0.026832	0.0412	IL-6 2.0 Calibrator B	IL-6 2.0	Plate 1 - Well B5							pg/mL
7	Calibrator			IL-6 2.0 Calibrator B	IL-6 2.0	Plate 1 - W	0.026082	0.001062	0.040718	0.0412	0	0	pg/mL
8	Calibrator	0.051829	0.123	IL-6 2.0 Calibrator C	IL-6 2.0	Plate 1 - Well C5							pg/mL
9	Calibrator	0.051008	0.123	IL-6 2.0 Calibrator C	IL-6 2.0	Plate 1 - Well C5							pg/mL
10	Calibrator			IL-6 2.0 Calibrator C	IL-6 2.0	Plate 1 - W	0.051419	0.00058	0.011286	0.123	0	0	pg/mL
11	Calibrator	0.146264	0.37	IL-6 2.0 Calibrator D	IL-6 2.0	Plate 1 - Well D5							pg/mL

History & Reports Tab – Reports Section
Calibration Batch Report

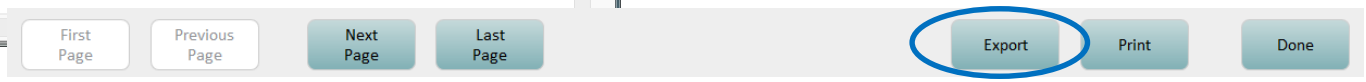
- Select "Batch Calibration Report" from the left menu
- Select the Batch (pop up menu will appear) and press done





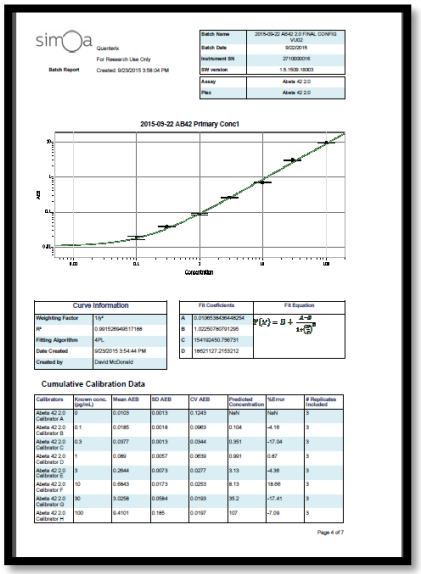
↑ A calibration curve preview will appear. Curve appearance can be adjusted
  – Press Preview Report

↓ Report Preview screen - press "Export" to save as a PDF or XLS.

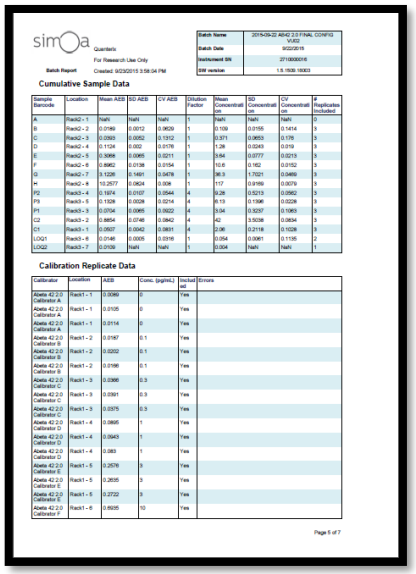


Simoa HD-1 Analyzer ™ User Guide Software version 1.5 (Chapter 9)

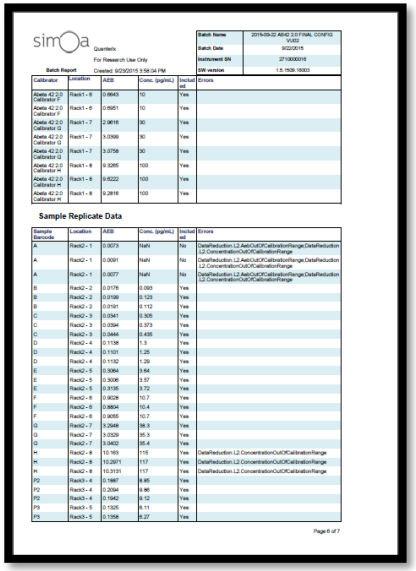
History & Reports Tab – Reports Section
Calibration Batch Report



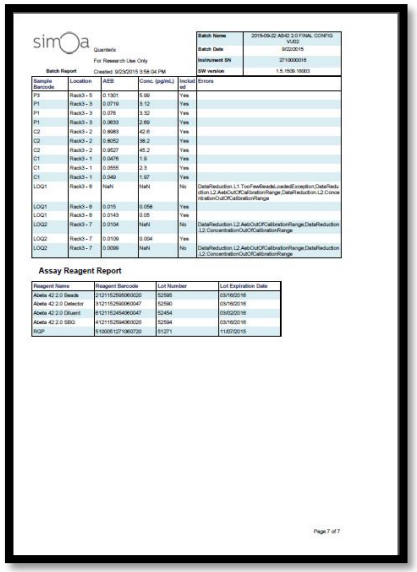
Graph of Curve
- Curve Info.
- Fit Coefficients
- Fit Equation



Cumulative
- Calibration Data
- Sample Data



Replicate
- Calibration Data
- Sample Data
- Error Msg.

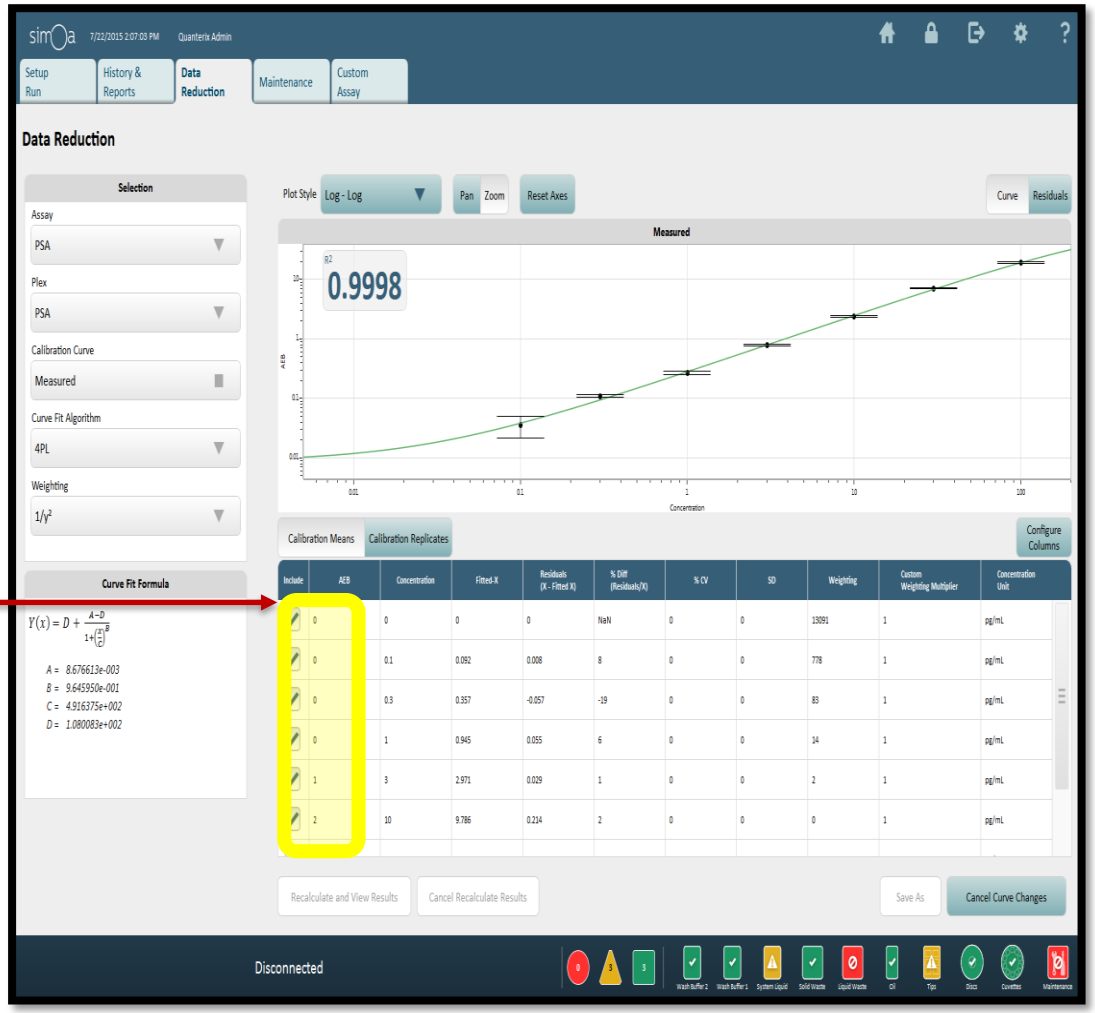


Assay Reagents Used Summary
- Lot Number
- Expiration

Data Reduction – Calibration Curve

- View Curve
  - Curve fit formula
- Adjust Curve
  - Remove single outliers
  - Remove calibrator level
  - Edit concentration values
- Press “Save As” when done
- Use New Curve to reprocess sample data

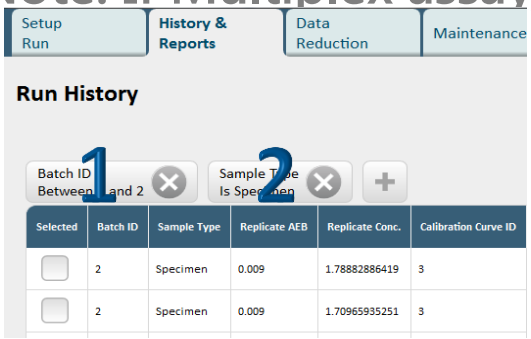
(History & Reports tab)



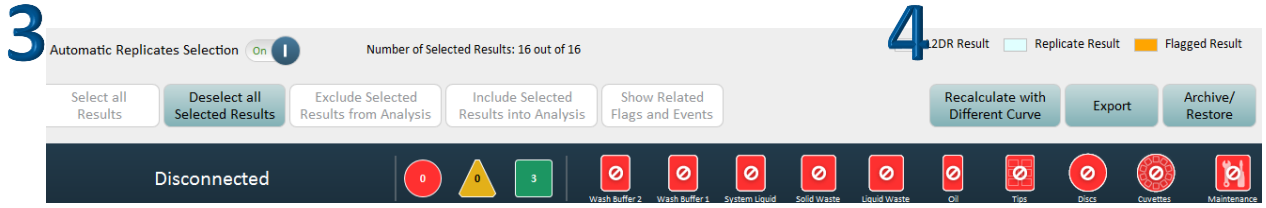
Simoa HD-1 Data Analysis for Software Version 1.5

Re-analyzing Data – Changing Calibration Curve Values

- History and Reports Tab
  1. Filter for your batch
  2. Then add an additional filter for Sample type = Specimen
     - Note: If Multiplex assay, add an additional filter for the plex



  3. Select all the samples you want to reprocess with the new curve
  4. Press "Recalculate with Different Curve". This will take you to the Data Reduction Tab



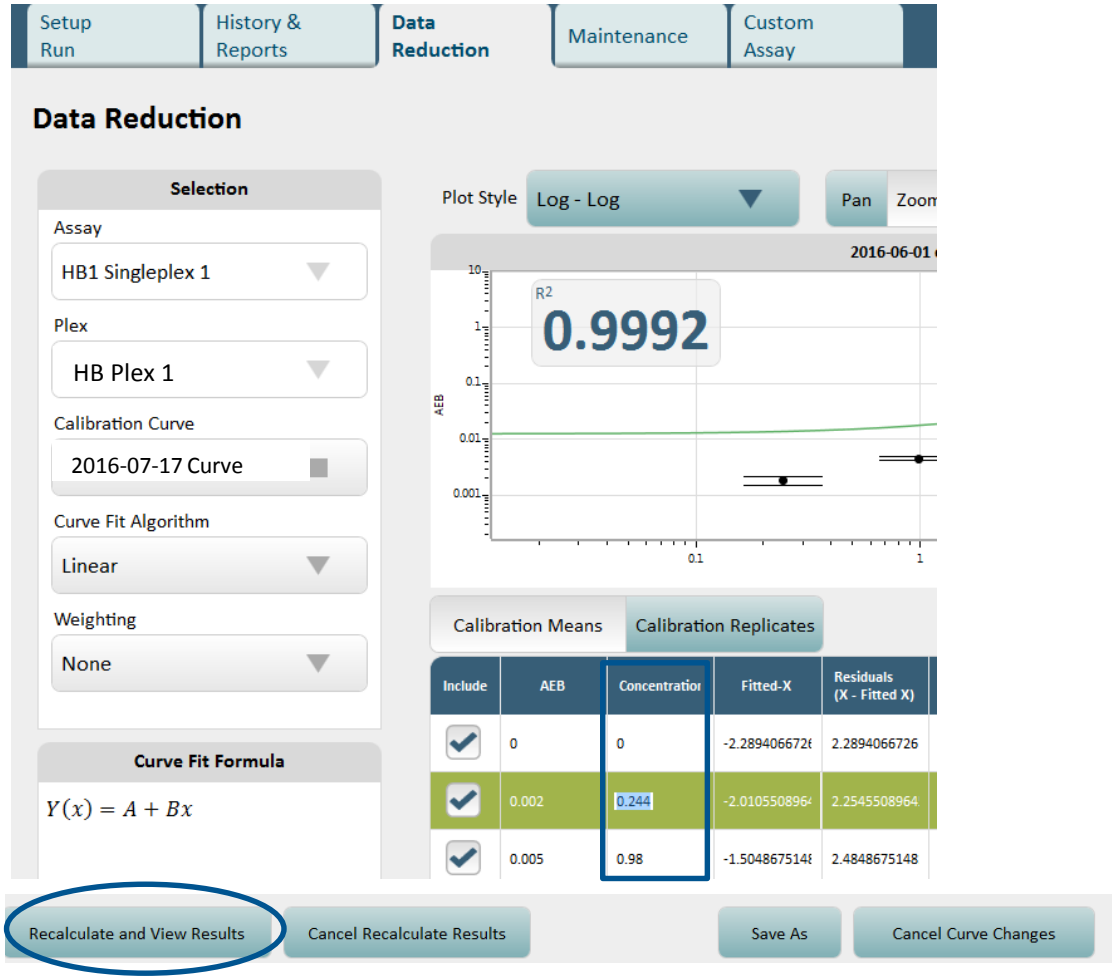
Re-analyzing Data – Changing Calibration Curve Values

- Choose the new calibration curve:
- Data Reduction tab
  - On left side of the screen, selection box:

  Assay & Plex are filled in automatically, cannot be changed.

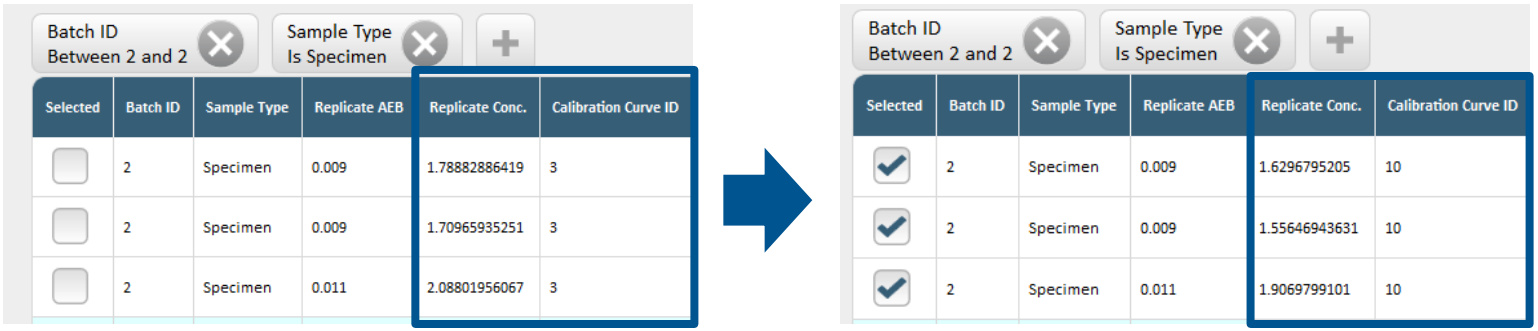
  Select the Calibration curve you would like to use to recalculate your data

  - Press "Recalculate and View Results"



Re-analyzing Data – Changing Calibration Curve Values

- This will take you back to the History & Reports tab
- It takes a few seconds for the re-calculation to complete. If you check the Calibration curve ID or name it will have the new value



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CUSTOMER SUPPORT TOOL

Customer Support Tool / Team Viewer

Customer Portal – Documentation

- Quanterix Customer Support Tool User Guide
- Trouble shooting errors
  - Create Support Package
  - Export Images: Full or White light Thumbnails
- Generate QuaRT Reliability Data
- Generate SQT Report

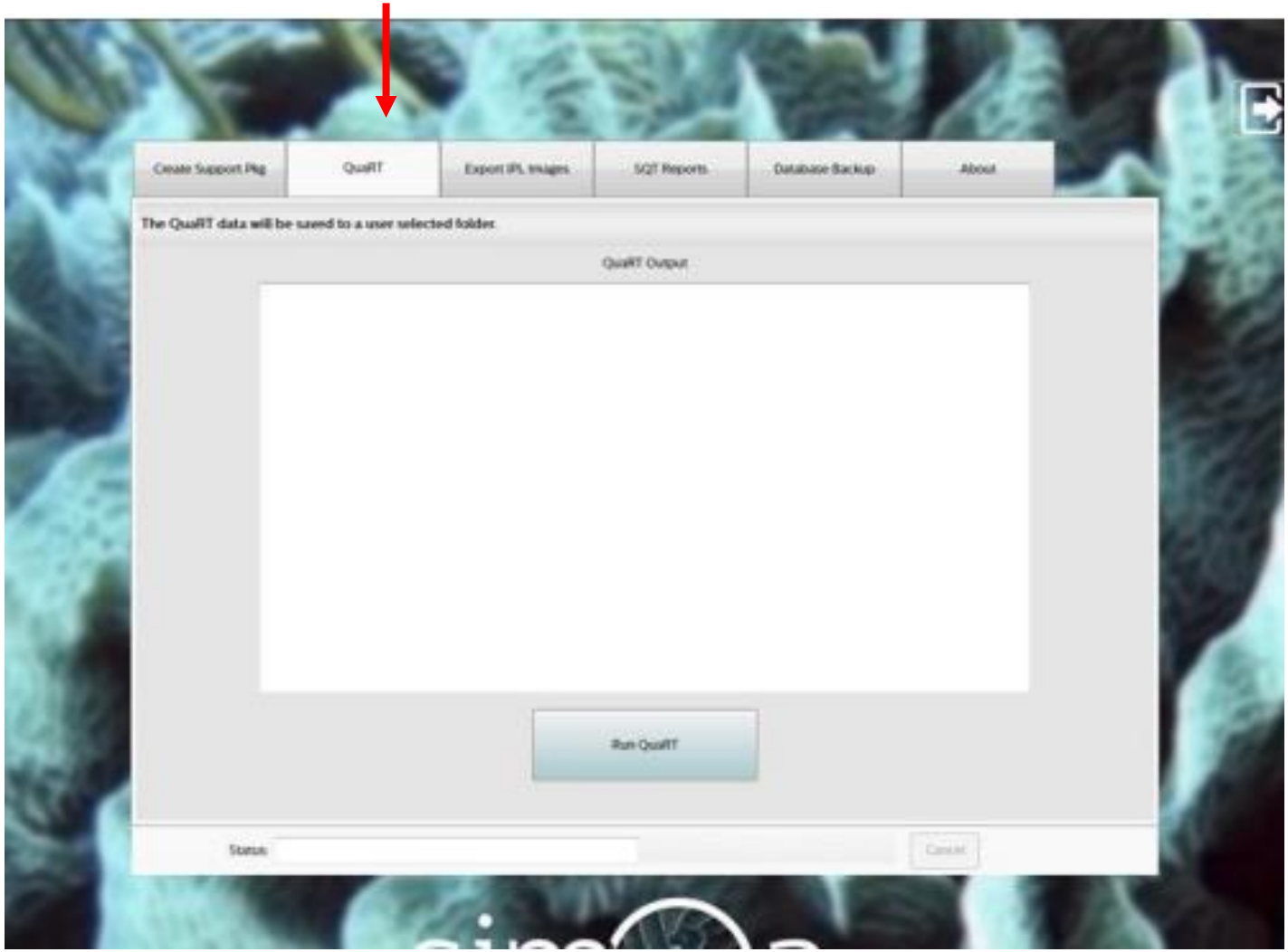
Can be configured to be uploaded to Quanterix automatically

If internet is not available for your instrument, another file share system (i.e. dropbox) can be used

Team Viewer

- Remote access if need assistance

QuaRT monitors reliability and performance of the HD-1



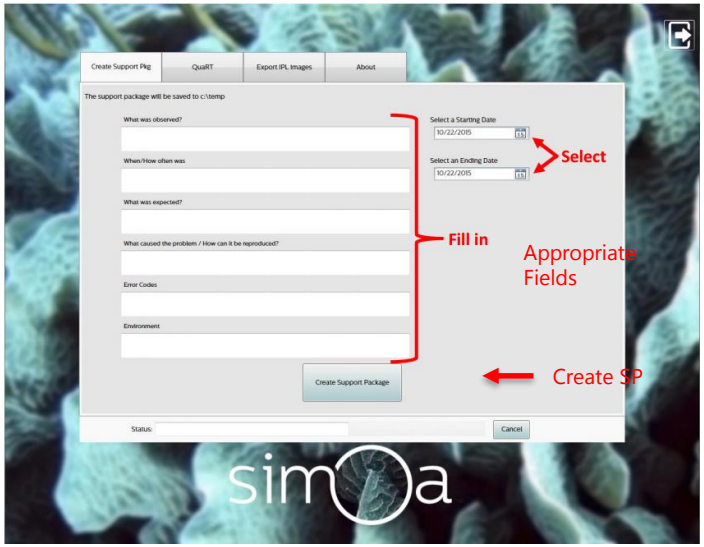
QuaRT Data

- Tracks performance on collected data
- Provide the customer feedback on instrument performance
- QuaRT obfuscates data from the database for some parameters that are considered customer-specific, sensitive, or proprietary
- As an example, a customer assay with the name "Homebrew Assay 1" is reported by QuaRT with a value of "EF0CD653EA048DA0994E8DBE91D6EE98" where the exact value is unique to each assay on each HD-1 Analyzer

Customer Support Tool

- Generate Support Package
  - Fill in info about error
  - Collects log files for selected date(s)

- Generate IPL image files for selected batch
  - All image files (no boxes checked)
  - Failed images only (left box)
  - White Light images



Other Troubleshooting Resources

- Simoa HD-1 Analyzer Instrument Troubleshooting Guide
- Instrument issue, email techsupport@quanterix.com and include:
  - Support Package
  - Details about the issue observed
- Simoa HD-1 Analyzer Data Analysis Troubleshooting Guide
  - Data yield/data quality
  - Value missing: Troubleshooting flow chart (p. 1)
  - Lost/canceled Job: Sample error messages (p. 10)
  - Email FAS and techsupport@quanterix.com
    - Details about the issue you observed
    - Include a Support Package & CSV file (with all columns included)
      - You may be requested to send white light images or full IPL images

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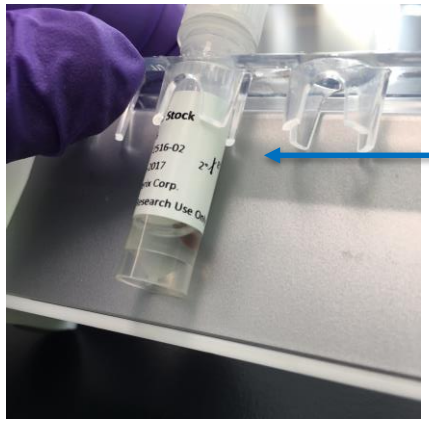
WHAT'S NEW?

Discovery Kits

- Contains enough reagents for 2 plates (192 tests)
- Follow setup according to assay package insert (download from customer portal)
  - Calibrator curve made by diluting calibrator concentrate. Dilute per package insert instructions
  - Reagents (Beads, Detector, SBG) are concentrated. Dilute to working concentration prior to running on instrument
  - A magnet is required to wash beads before diluting to working concentration



Pellet beads against magnet to remove buffer and wash.