Quanterix

Powering a Revolution in Healthcare

Simoa HD-X Best Practices

Simoa Best Practices–Day 2

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Simoa Best Practices

- Instrument Maintenances
- Overview of software Data Review
- Troubleshooting Review and Resources

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INSTRUMENT MAINTENANCE

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 156.
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 sealing 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 159.
Computer Memory Management	Monthly	Removes temporary files and 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.

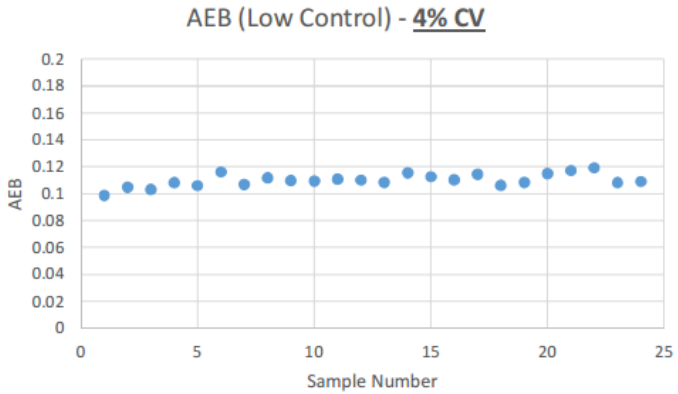
Instrument Maintenance

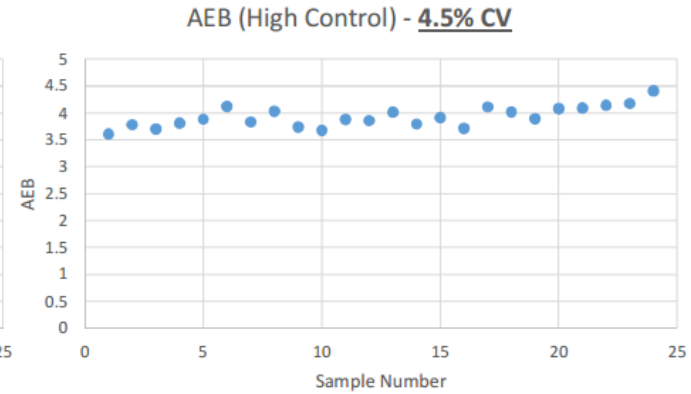
Customer Portal - Documentation

- Simoa HD-X Analyzer ™ User Guide
  - Chapter 11: Maintaining the Simoa HD-X Analyze
- Simoa HD-X Analyzer Quick Start Guide
- Simoa HD-X Analyzer Monthly Maintenance Guide

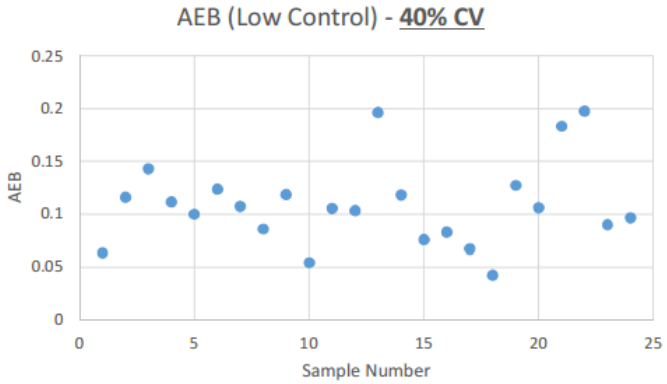
Instrument Maintenance

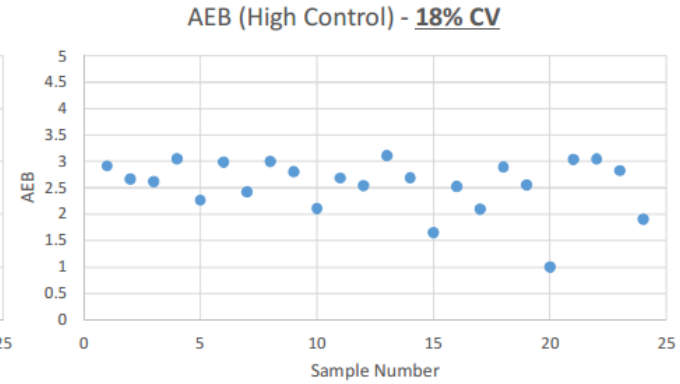
- Typical performance with required maintenance procedures being performed





- Performance when required maintenance tasks are ignored





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

Assay Considerations: Sample Volume

Minimal Volume Calculation:

(Recommended sample volume (neat or divided by dilution factor) x Number of Replicates) + 30 uL dead volume for plates or 50 uL dead volume for Nalgene 5 mL tubes

Example for a recommended total volume of 100 uL – ASSAY DEPENDENT – check your kit instructions/package insert for correct volumes and dilutions

Calibrators (neat) in triplicates:

(100 uL x 3 replicates) + 30 uL dead volume = 330 uL/well

Samples (4X dilution) in duplicates

((100/4X dilution factor) uL x 2 replicates) + 30 uL dead volume = (25 x 2) + 30 = 80 uL/well

REMEMBER NOT TO LOAD MORE THAN 350 uL / well – Separate replicates in different wells if necessary

Discovery Kits

- Contains enough reagents for 192 tests
- Follow setup according to assay kit instructions/package insert.
  - Calibrator curve made by diluting calibrator concentrate. Dilute per kit instructions.
  - Reagents (Beads, Detector, SBG) are concentrated. Dilute to working concentration prior to running on instrument. Dilute SBG to final volume as soon as kit arrives
  - A magnet is required to wash beads before diluting to working concentration.

Advantage Kits with Cal Concentrate or Ref Cals

- Kits that come with a calibrator concentrate – check concentration on CoA (Certificate of Analysis) and prepare curve according to kit instructions/package insert
- Some of our kits come with pre-made reference calibrators. Check concentration of each calibration point on CoA (Certificate of Analysis), go to Assay Definition, Save As new definition, untick Read-Only and change concentrations under Plexes or change directly at the play layout

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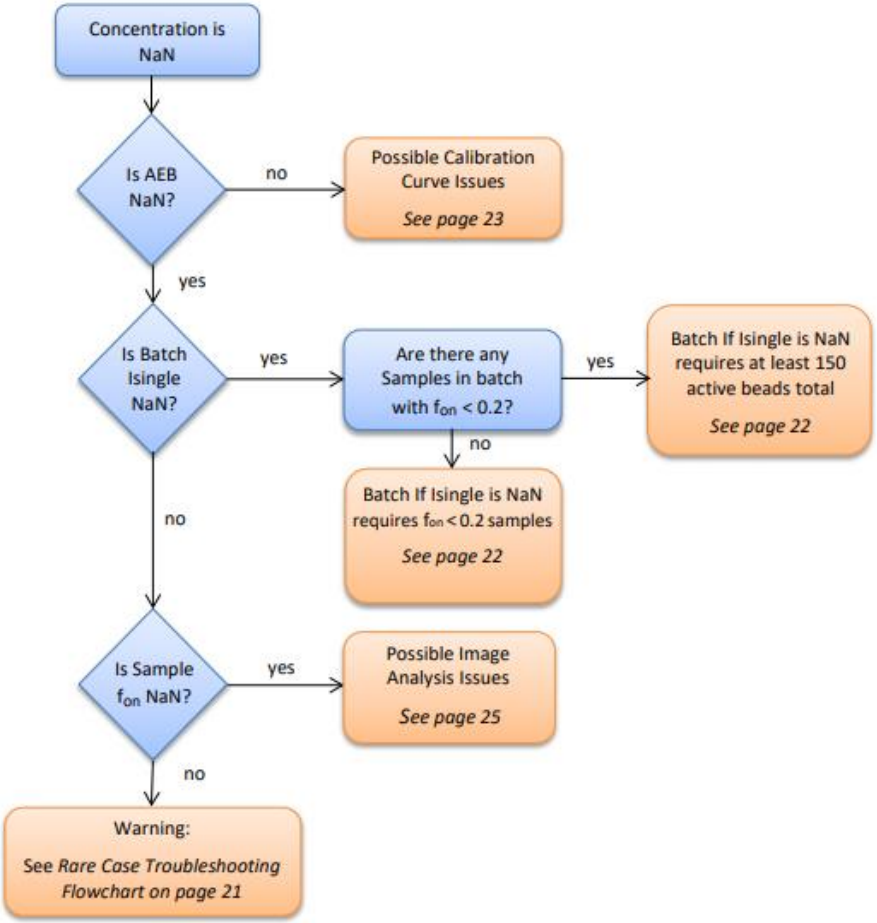
OVERVIEW OF SOFTWARE DATA REVIEW

Data Review

Customer Portal – Documentation

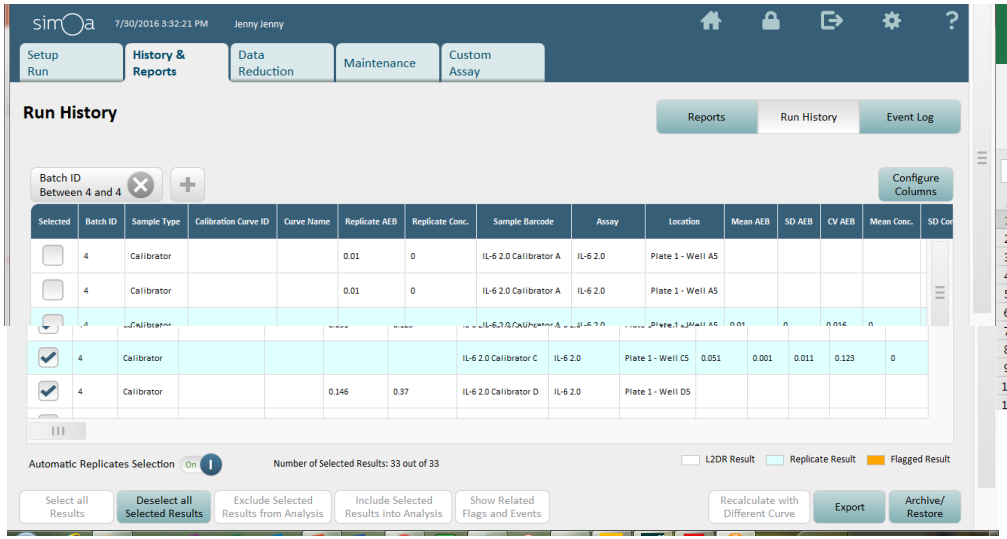
- Simoa HD-X Analyzer User Guide Software (Chapter 9) Analyzing Run Data
- Simoa HD-X Analyzer Data Analysis Guide
  - Chapter 5-Recalculating Sample Results with a Different Calibration Curve
  - Chapter 6-Troubleshooting

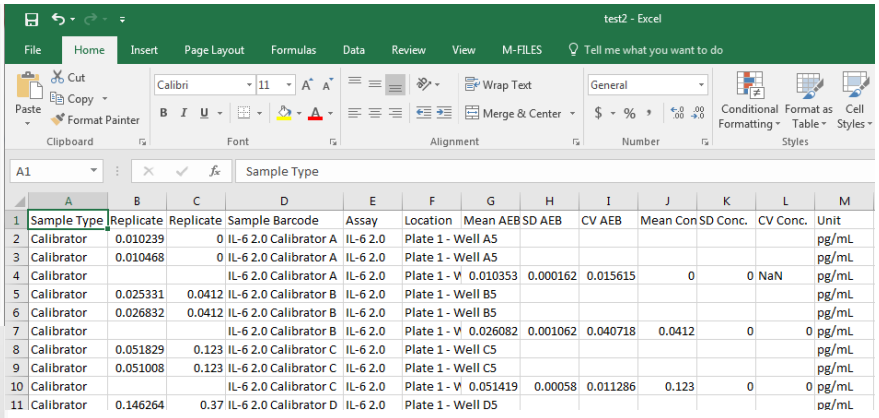
Troubleshooting Flowchart



Data Review

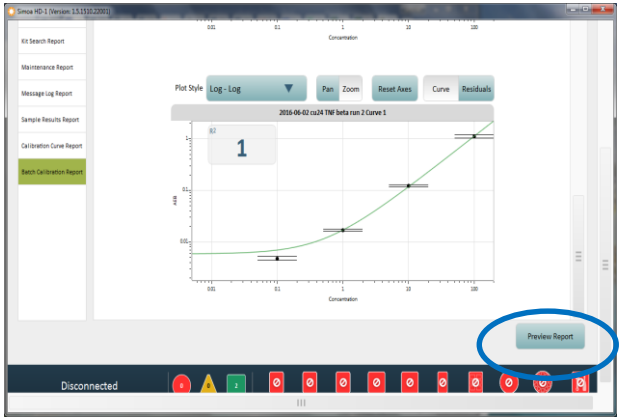
- Exporting Data – History & Reports Tab, Filter for Batch, Select all Results and Export CSV file of results
  - Add/Remove Columns and change column order using Configure Columns
- Exporting Batch Calibration Report – History & Reports Tab
- Calibration Curve – Data Reduction Tab

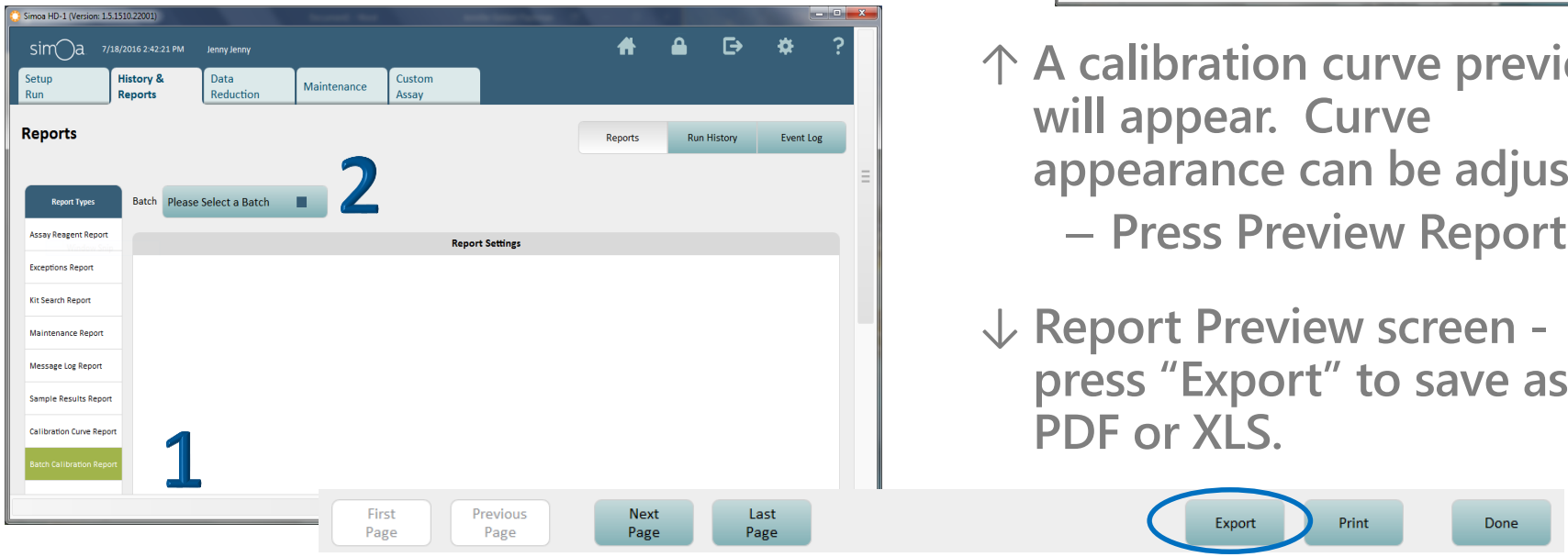




History & Reports Tab – Reports Section
Calibration Batch Report

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



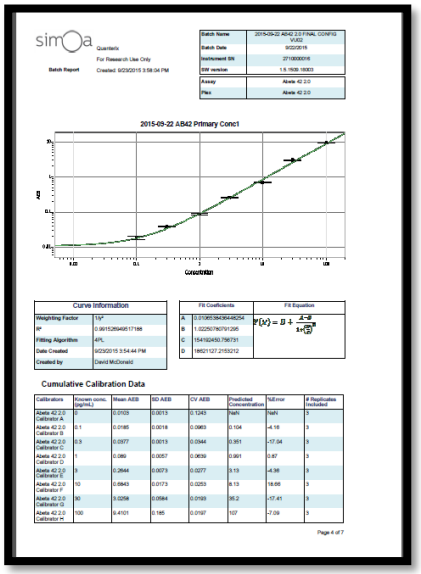


↑ A calibration curve preview will appear. Curve appearance can be adjusted
  – Press Preview Report

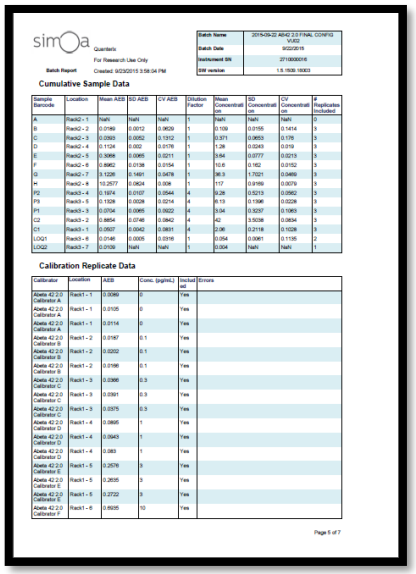
↓ Report Preview screen - press "Export" to save as a PDF or XLS.

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

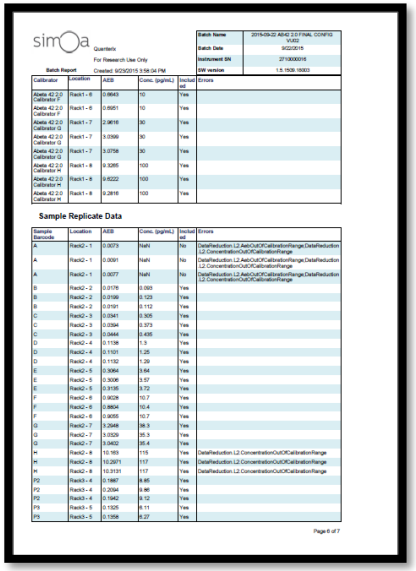
History & Reports Tab – Reports Section
Calibration Batch Report



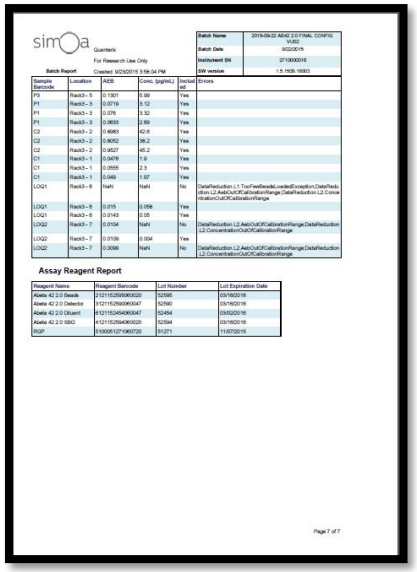
Graph of Curve
- Curve Info.
- Fit Coefficients
- Fit Equation



Cumulative
- Calibration Data
- Sample Data



Replicate
- Calibration Data
- Sample Data
- Error Msg.

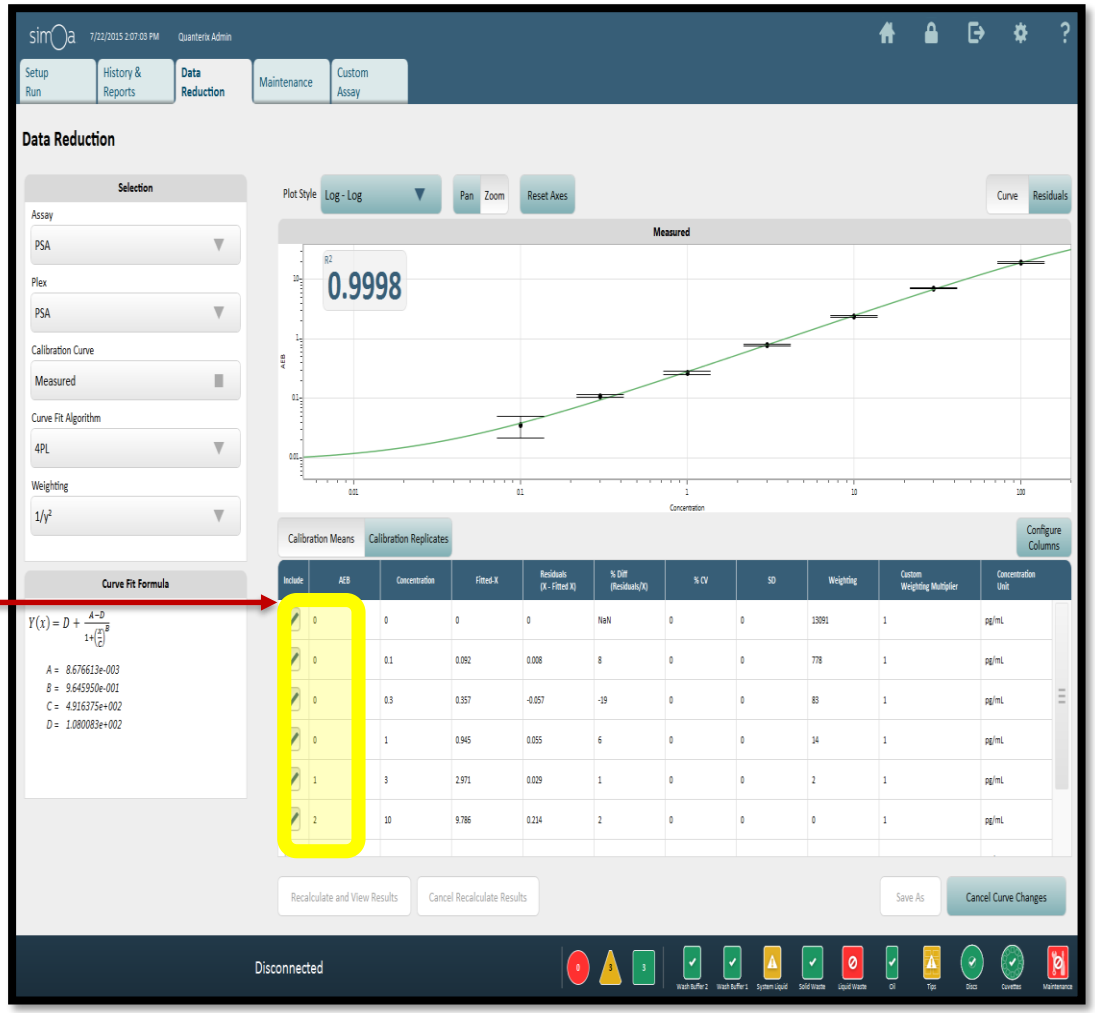


Assay Reagents Used Summary
- Lot Number
- Expiration

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

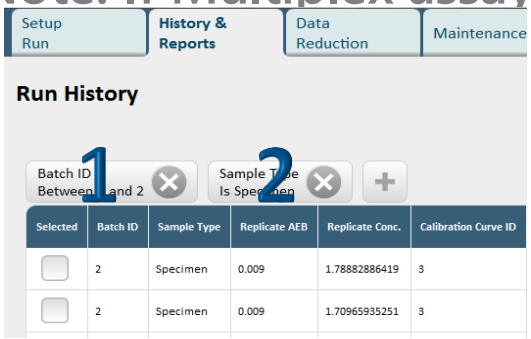
(History & Reports tab)



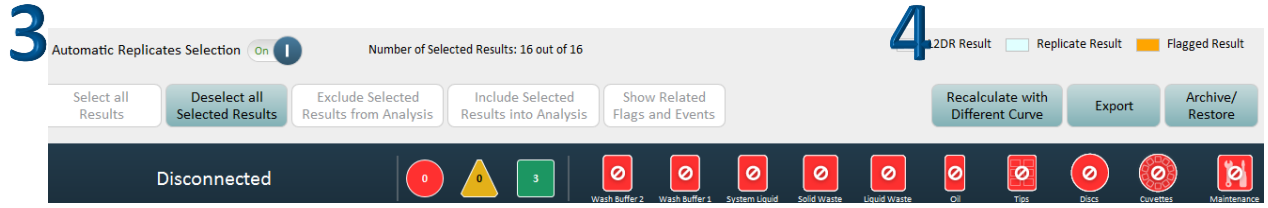
Simoa HD-X Data Analysis for Software Version 1.5

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



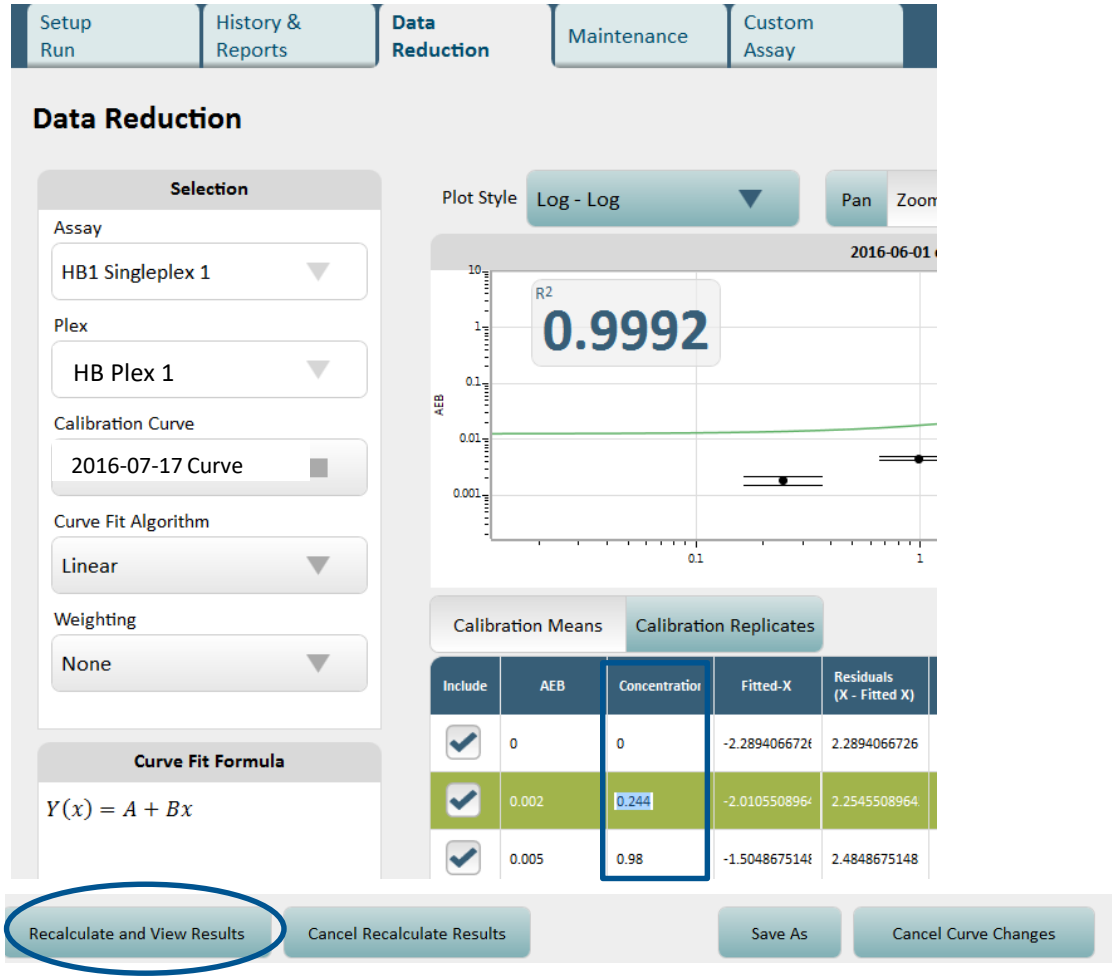
Re-analyzing Data – Changing Calibration Curve Values

- 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.

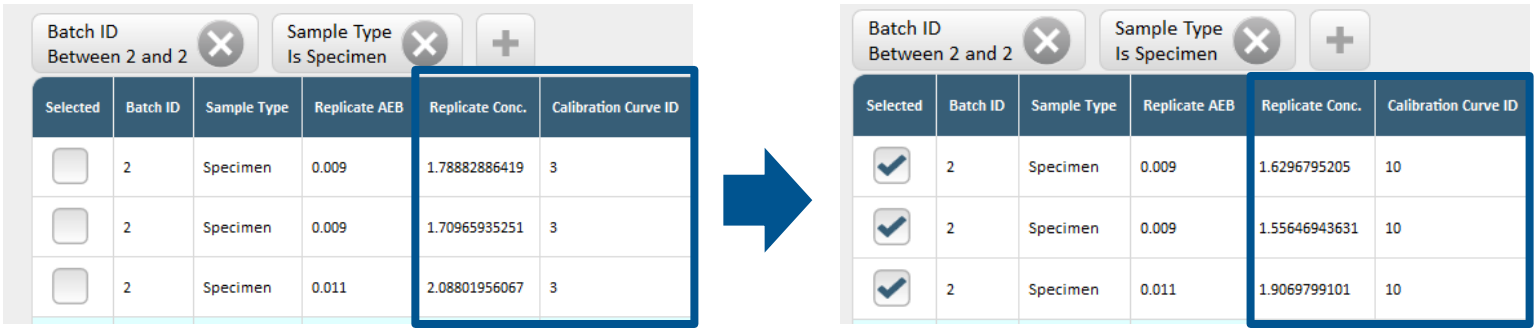
  Select the Calibration curve you would like to use to recalculate your data

  - 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

- Simoa HD-X Analyzer Customer Support Tool User Guide
  - Generate SQT Report
  - Export IPL images
  - Generate QuaRT Report
  - Database BackUp
- Simoa HD-X Analyzer Reporting Tool Technical Information (QuaRT)

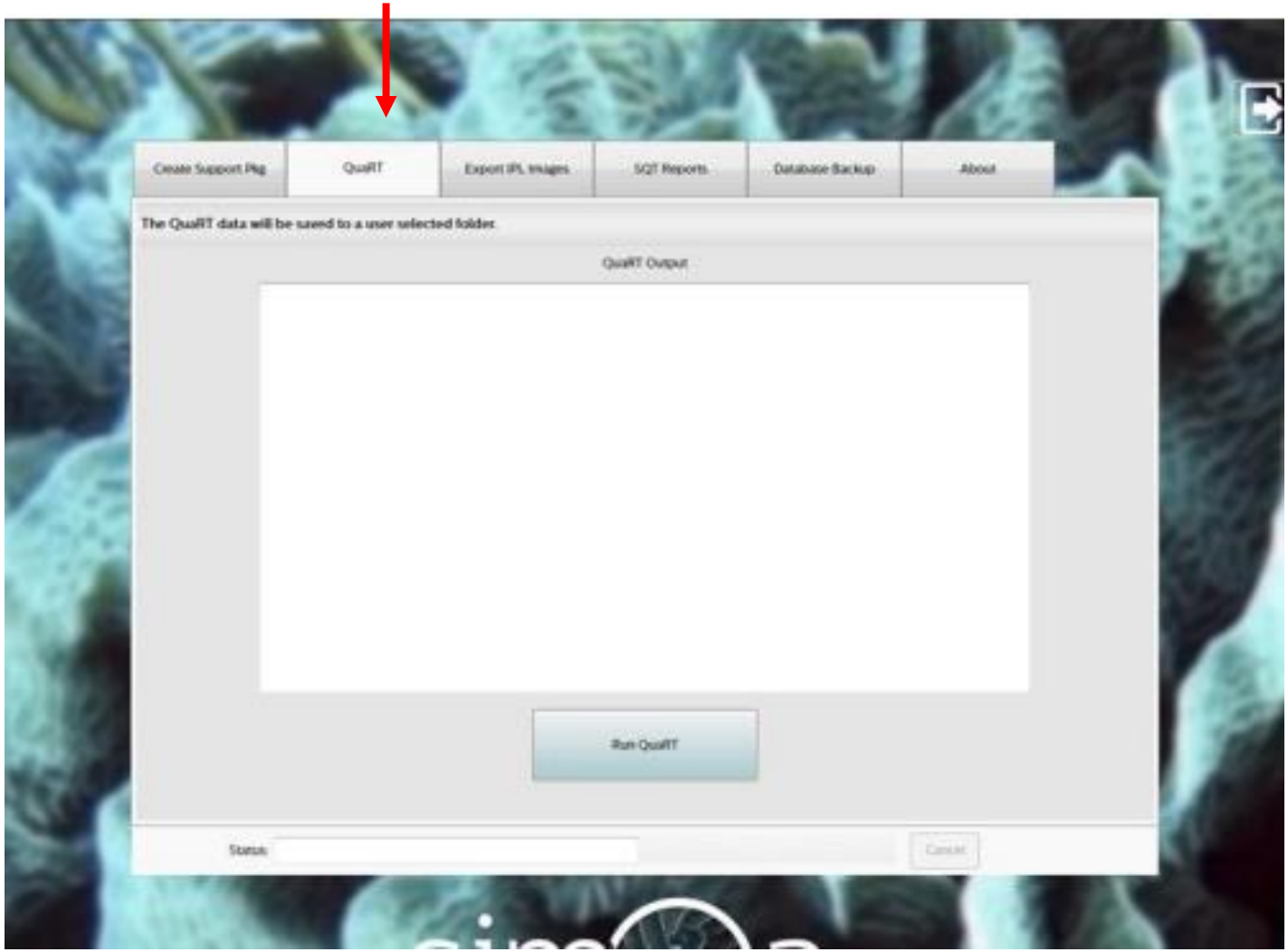
Can be configured to be uploaded to Quanterix automatically

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-X



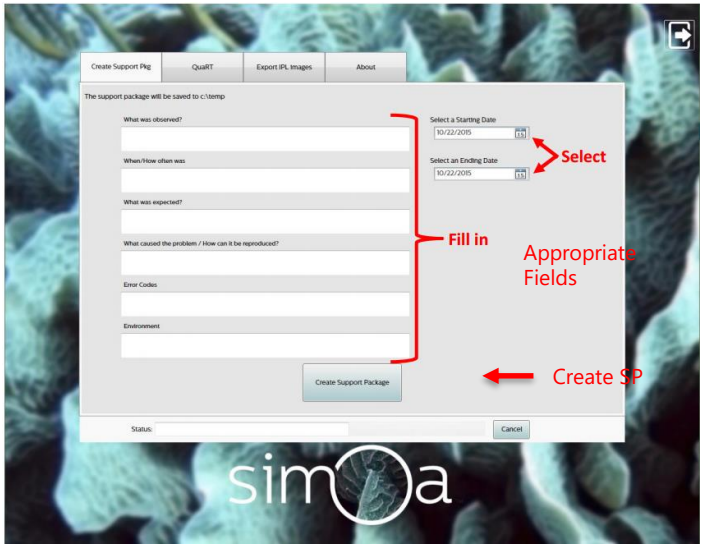
QuaRT Data

- 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-X 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



Instrument / Assay Issues

- Upload **support package** for the day the issue was observed

- Upload **White Light Images** for the specific run

- Send the **csv file** for specific run and explain the problem and assay setup to techsupport@quanterix.com