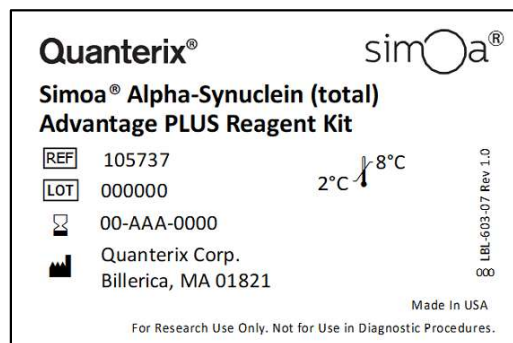


Quanterix SR-X® Compatibility for Simoa® Alpha-Synuclein (total) Advantage PLUS Assay

Overview

This document describes compatibility of the Simoa® Alpha-Synuclein (total) Advantage PLUS assay (Item #105737) on the Quanterix SR-X® platform. This compatibility report aims to complement and expand upon the validation data presented in the Alpha-Synuclein (total) Advantage PLUS Validation Report, available on the Quanterix® customer portal¹. The validation report details analytical assay performance, including LLOQ, LOD, and measurement of normal samples. Compatibility of the Alpha-Synuclein Advantage PLUS assay was demonstrated through comparative analysis of the assay's performance across the Simoa HD-X Analyzer® and SR-X platforms using a sub-set of parameters from the validation report. Further validation of assay performance may be required prior to initiating large projects with the assay on the SR-X platform, depending on specific in-house regulations. Users should build familiarity with the workflow for the assay kits on the SR-X, following the Kit Instructions provided, for optimal results. If further information is needed, please contact Techsupport@Quanterix.com.



Assay Performance

The analytical performance of Alpha-Synuclein (total) Advantage PLUS assay on the HD-X platform can be obtained from the HD-X Data Sheet available on the Quanterix customer portal². Table 1 compares the quantitation limit, and the detection limit and Figures 1-3 provide curve comparisons and sample reading correlation between HD-X and SR-X platforms for Alpha-Synuclein (total) Advantage PLUS.

Tables 1. Quantification and detection limits Alpha-Synuclein (total) Advantage PLUS assays across HD-X and SR-X platforms. Refer to the assay specific HD-X data sheet for additional details on HD-X, like detectability and quantifiability². Triplicate measurements of serially diluted calibrator were read back on the calibration curve over one run for one reagent lot, across one instrument on the SR-X platform.

Assay Parameters Comparison Alpha-Synuclein (total)		
	HD-X per Data Sheet	SR-X
Curve profiling LLOQ	8.7040 pg/mL	8.7600 pg/mL
Functional LLOQ Plasma/Serum (Analytical LLOQ x MRD)	278.5280 pg/mL	280.3200 pg/mL
Functional LLOQ CSF (Analytical LLOQ x MRD)	69.6320 pg/mL	70.0800 pg/mL
LOD	2.4736 pg/mL	2.0900 pg/mL

I. Calibrator Comparison

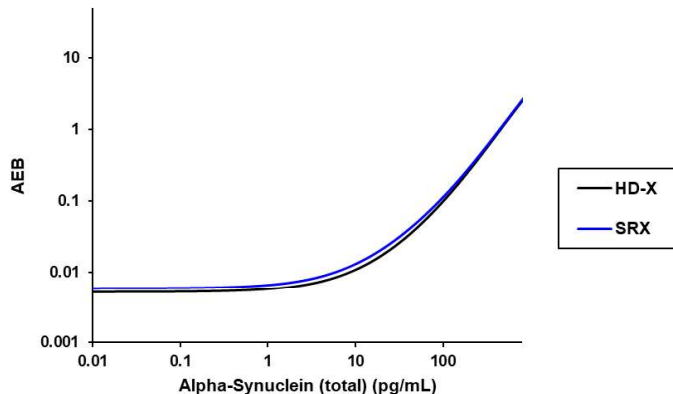


Figure 1. Comparison of the calibration curves for **Alpha-Synuclein (total)** Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms for one reagent kit lot.

II. Sample reading correlation between SR-X and HD-X

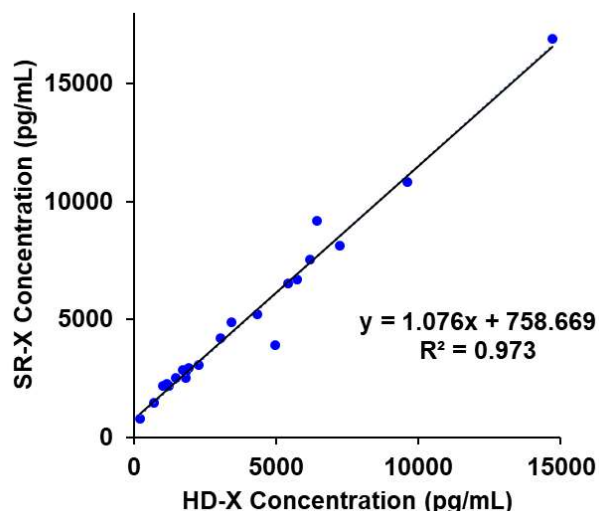


Figure 2. Correlation between HD-X and SR-X for **Alpha-Synuclein (total)** Advantage PLUS assay for 11 normal human serum and 11 normal human EDTA plasma samples (Slope = 1.076, $R^2 = 0.973$) for one reagent kit lot.

III. Sample Reading

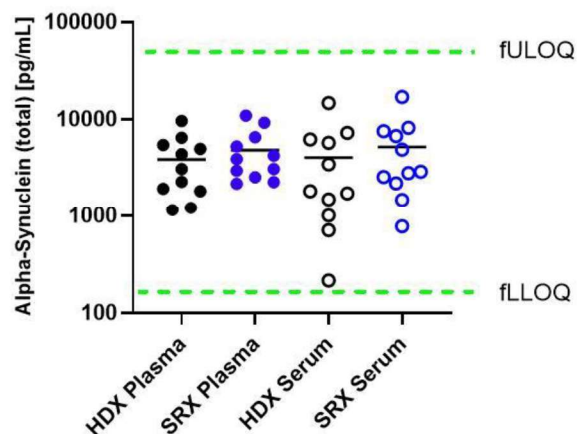


Figure 3. **Alpha-Synuclein (total)** levels for 11 serum and 11 EDTA plasma samples from presumably healthy individual donors on HD-X and SR-X instruments for one reagent kit lot. The green dashed lines indicate the fULOQ and fLLOQ of the Alpha-Synuclein (total) Advantage PLUS assays.

Summary

Comparability of the Simoa® Alpha-Synuclein (total) Advantage PLUS (Item #105737) between the Simoa HD-X Analyzer® and Quanterix SR-X® platforms was evaluated by measuring LLOQ, LOD, and sample reading correlation. The Alpha-Synuclein (total) Advantage PLUS assay demonstrated similar sensitivity on the SR-X platform when compared to the HD-X platform. Overall, the Alpha-Synuclein (total) Advantage PLUS assay was shown to function on the SR-X platform and with data highly comparable to that generated on the HD-X platform.

For more information on the Alpha-Synuclein (total) Advantage PLUS assay and other Simoa® assay kits, please visit the Customer Portal: <https://portal.quanterix.com>

References

1. Alpha-Synuclein (total) Advantage PLUS Validation Report
2. Alpha-Synuclein (total) Advantage PLUS Data Sheet