

SR-X Compatibility for Simoa® Cytokine 4-plex A Advantage PLUS Assay

Overview

This document describes compatibility of the Cytokine 4-plex A (C4PA) Advantage PLUS assay (Item #104979) on the Quanterix SR-X® platform. This compatibility report aims to complement and expand upon the validation data presented in the C4PA Advantage PLUS Validation Report, available on the Quanterix customer portal¹. The validation report details analytical assay performance, including LLOQ, LOD, precision, spike and recovery, dilution linearity and measurement of normal samples. Compatibility of the C4PA 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 C4PA Advantage PLUS assay on the HD-X platform can be obtained from the HD-X Data sheet available on the Quanterix® customer portal². Tables 1-4 compare the quantitation limit and the detection limit and Figures 1-4 provide curve comparisons and sample reading correlation between HD-X and SR-X platforms for C4PA Advantage PLUS.

Tables 1-4. Quantification and detection limits for C4PA Advantage PLUS assays across HD-X and SR-X platforms. Triplicate measurements of serially diluted calibrator were read back on the calibration curve over two runs each for one reagent lot across two instruments on SR-X platform. Twenty matched EDTA plasma and serum samples were tested for detectability and quantifiability.

Table 1: Assay Parameters Comparison IL-1β (C4PA)

	HD-X as per Data Sheet	SR-X
Curve profiling LLOQ	0.0100 pg/mL	0.0130 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	0.0400 pg/mL	0.0520 pg/mL
LOD	0.0025 pg/mL	0.0042 pg/mL

Table 2: Assay Parameters Comparison IL-6 (C4PA)

	HD-X	SR-X
Curve profiling LLOQ	0.0280 pg/mL	0.0370 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	0.1120 pg/mL	0.1480 pg/mL
LOD	0.0085 pg/mL	0.0101 pg/mL

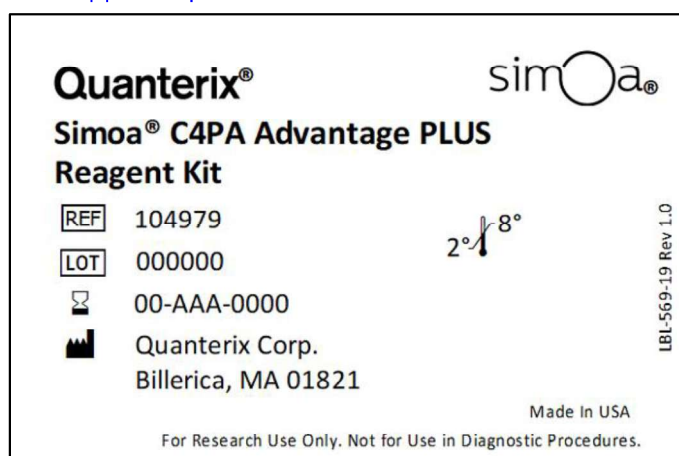


Table 3: Assay Parameters Comparison IL-10 (C4PA)

	HD-X	SR-X
Curve profiling LLOQ	0.1430 pg/mL	0.0560 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	0.5720 pg/mL	0.2240 pg/mL
LOD	0.0330 pg/mL	0.0124 pg/mL

Table 4: Assay Parameters Comparison TNFα (C4PA)

	HD-X	SR-X
Curve profiling LLOQ	0.4806 pg/mL	0.3595 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	1.9224 pg/mL	1.4380 pg/mL
LOD	0.0613 pg/mL	0.0866 pg/mL

I. Calibrator Comparison

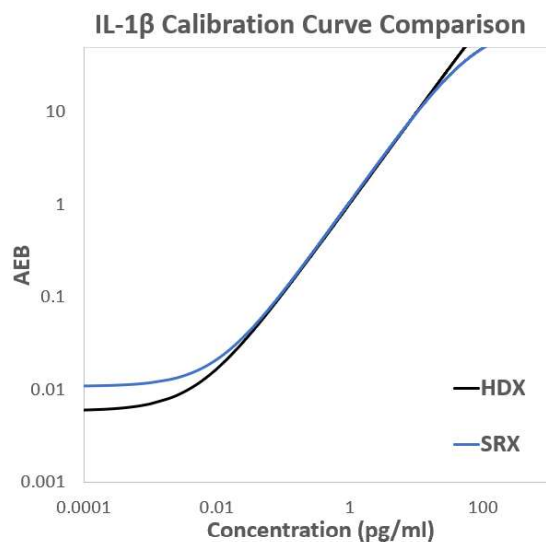


Figure 1. Comparison of the calibration curves for IL-1β in C4PA Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms for one reagent kit lot.

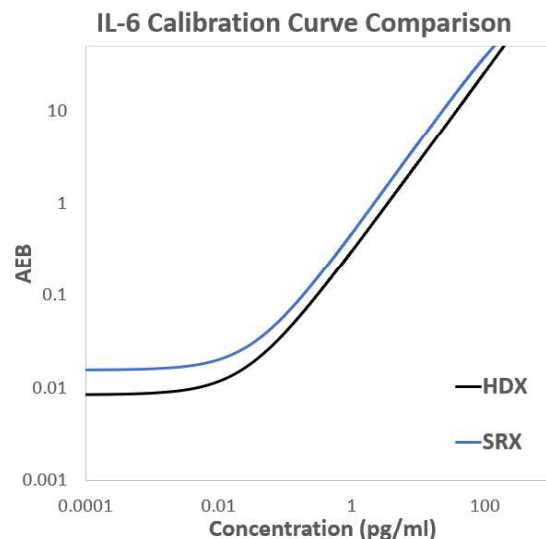


Figure 2. Comparison of the calibration curves for IL-6 in C4PA Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms for one reagent kit lot.

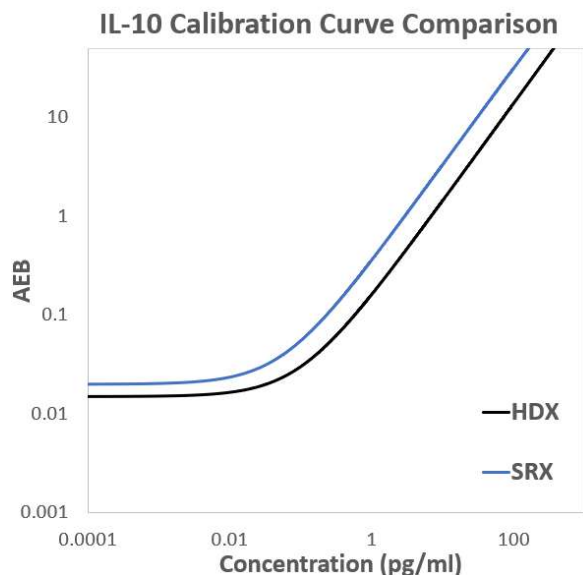


Figure 3. Comparison of the calibration curves for IL-10 in C4PA Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms for one reagent kit lot.

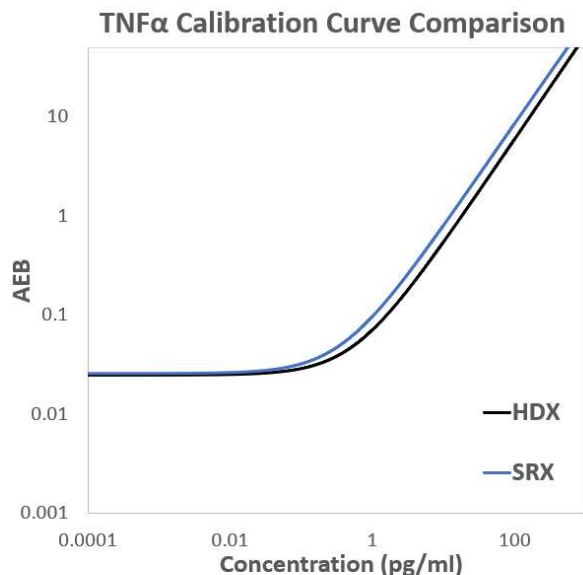


Figure 4. Comparison of the calibration curves for TNFα in C4PA Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms for one reagent kit lot.

II. Sample Reading

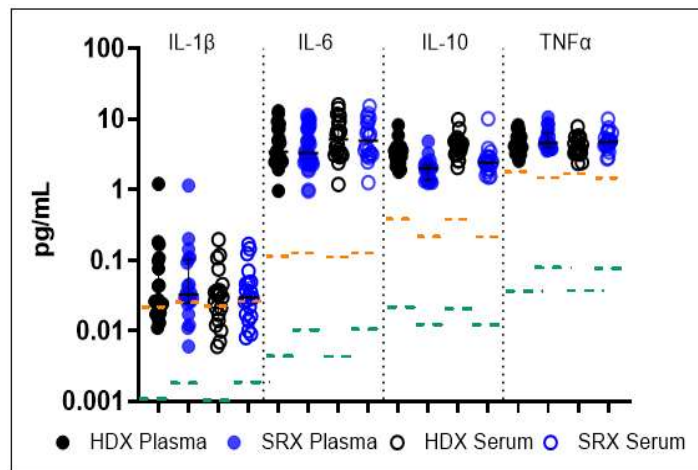


Figure 5. C4PA levels for 20 serum and 20 EDTA plasma matched samples from presumably healthy individual donors on HD-X and SR-X instruments for one reagent kit lot. The orange dashed lines indicate the functional LLOQ and green dashed line indicate the LOD of the C4PA Advantage PLUS assays.

III. Sample Comparison

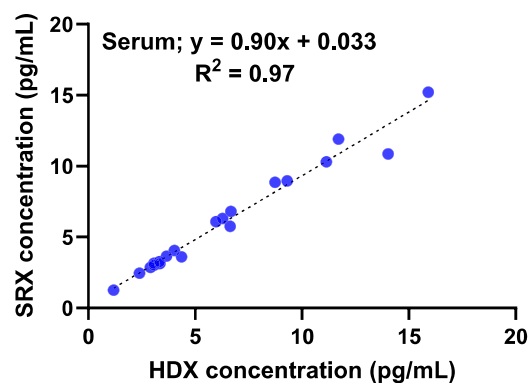
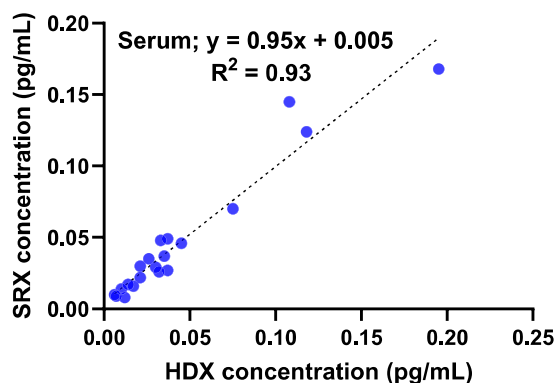
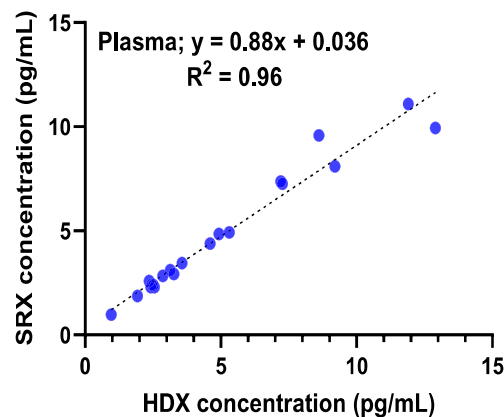
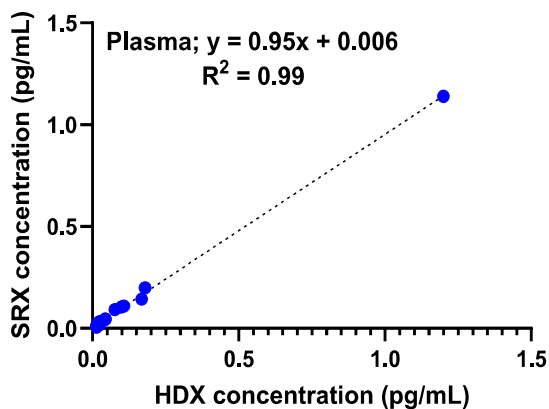


Figure 6. Correlation between HD-X and SR-X for IL-1 β in C4PA Advantage PLUS assay for the 20 EDTA plasma (Slope 0.95, R² 0.99) and 20 serum (Slope 0.95, R² 0.93) matched samples for one reagent kit lot.

Figure 7. Correlation between HD-X and SR-X for IL-6 in C4PA Advantage PLUS assay for the 20 EDTA plasma (Slope 0.88, R² 0.96) and 20 serum (Slope 0.90, R² 0.97) matched samples from one reagent kit lot.

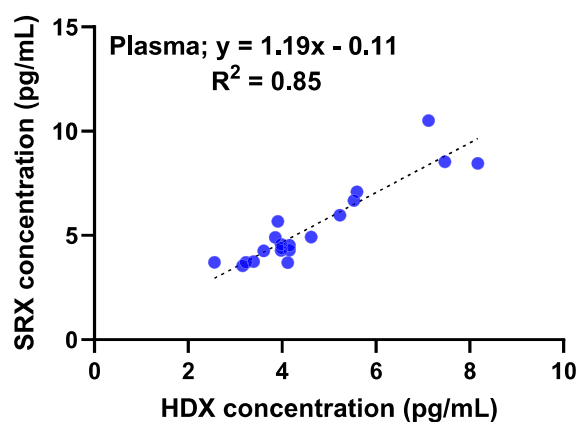
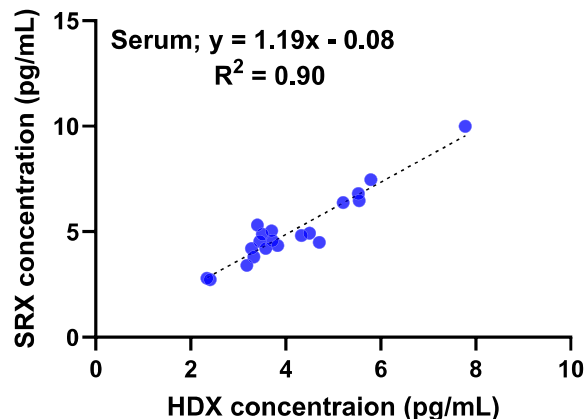
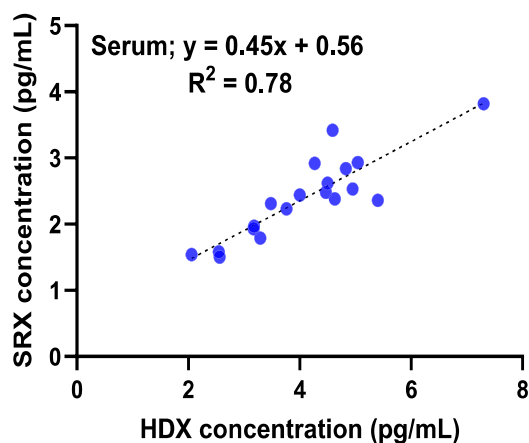
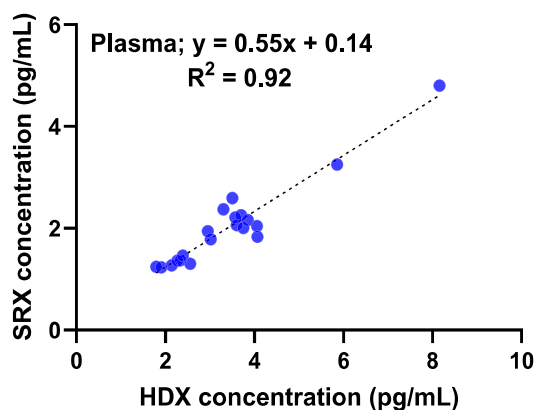


Figure 9. Correlation between HD-X and SR-X for TNFα in C4PA Advantage PLUS assay for the 20 EDTA plasma (Slope 1.19, R² 0.85) and 20 serum (Slope 1.19, R² 0.90) matched samples for one reagent kit lot.

Figure 8. Correlation between HD-X and SR-X for IL-10 in C4PA Advantage PLUS assay for the 20 EDTA plasma (Slope 0.55, R² 0.92) and 19 serum (Slope 0.45, R² 0.78) matched samples for one reagent kit lot.

Summary

Comparability of the C4PA Advantage PLUS (item #104979) between the Simoa HD-X Analyzer® and Quanterix SR-X® platforms was evaluated by measuring LLOQ, LOD, precision, detectability and quantifiability. The CAPA Advantage PLUS assay demonstrated similar sensitivity on the SR-X platform when compared to the HD-X platform. The difference in sensitivity had a minor impact on sample detectability and quantifiability. C4PA detectability on the SR-X achieved 100% in both EDTA plasma and serum and quantifiability achieved 100% in both EDTA plasma and serum in IL-6, IL-10, and TNFα. IL-1β of C4PA showed comparable detectability and quantifiability to HD-X, although a slope comparison indicates that, for some analytes, sample readout values may slightly differ across instruments. Overall, the C4PA Advantage PLUS assay was shown to function on the SR-X platform.

For more information on the C4PA Advantage PLUS assay and other Simoa® assay kits, please visit the Customer Portal: <https://portal.quanterix.com>

References

1. Cytokine 4-plex A Advantage PLUS Validation Report
2. Cytokine 4-plex A Advantage PLUS Data Sheet