

SR-X Compatibility for Simoa® sTREM-2 Advantage PLUS Assay

Overview

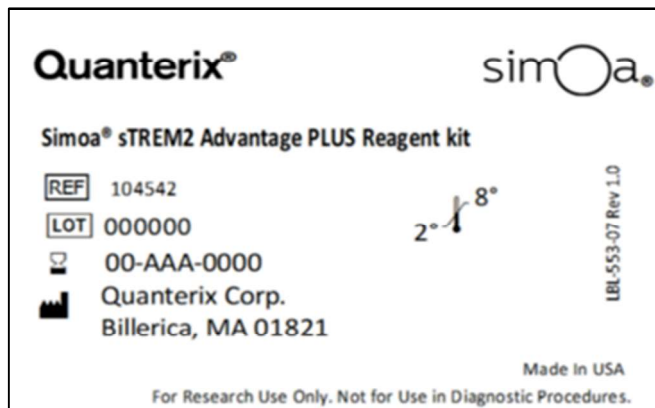
This document describes compatibility of the sTREM-2 Advantage PLUS assay (Item #104542) on the Quanterix SR-X platform. This compatibility report aims to complement and expand upon the validation data presented in the sTREM-2 Advantage PLUS Validation Report, available on the Quanterix customer portal¹. The validation report details analytical assay performance, including LLOQ, LOD, precision, spike and recovery, dilution linearity, measurement of normal samples and kit stability. Compatibility of the sTREM-2 Advantage PLUS assay was demonstrated through comparative analysis of the assay's performance across the HD-X 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. Extra SBG diluent (Item #100376), not included in the kit, is required to perform the run. If further information is needed, please contact Techsupport@Quanterix.com.

Assay Performance

The analytical performance of sTREM-2 Advantage PLUS assay on the HD-X platform can be obtained from the Data sheet available on the Quanterix customer portal¹. Figures 1-3 compare quantitation limit, detection limit, detectability, and quantifiability from the sTREM-2 Advantage PLUS across HD-X and SR-X platforms.

Table 1. Assay performance parameters for sTREM-2 Advantage PLUS assays across HD-X and SR-X platforms. Refer to the assay specific data sheet for additional details¹. 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 samples were tested for detectability and quantifiability.

Assay Parameters Comparison		
	sTREM-2 Advantage PLUS on HD-X	sTREM-2 Advantage PLUS on SR-X
Curve profiling LLOQ	4.12 pg/mL	1.56 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	65.9 pg/mL	25 pg/mL
LOD	0.905 pg/mL	0.281 pg/mL
Detectability	Plasma: 100%	Plasma: 100%
Quantifiability	Plasma: 100%	Plasma: 100%



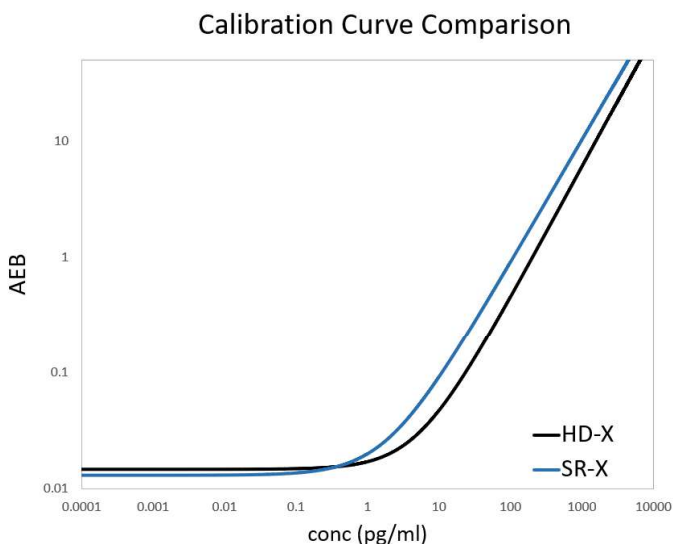


Figure 1. Comparison of the calibration curves for sTREM-2 Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms.

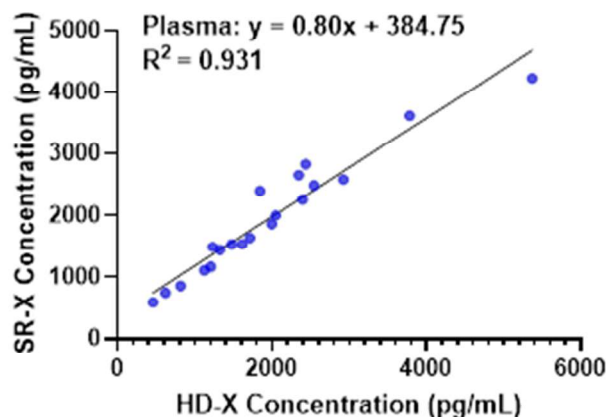


Figure 3. Correlation between HD-X and SR-X for sTREM-2 Advantage PLUS assay for 20 matched normal human plasma (Slope 0.79, R² 0.996).

Summary

Comparability of the sTREM-2 Advantage PLUS assay (Item #104542) between the HD-X and SR-X platforms was evaluated by measuring LLOQ, LOD, detectability and quantifiability. The sensitivity of the assay on the SR-X platform demonstrated lower values as compared to the HD-X platform. The SR-X had functional LLOQ and LOD values of 25 and .281 pg/mL. The HD-X had functional LLOQ and LOD values of 65.9 and .905 pg/mL. The improvement in sensitivity did not impact sample detectability and quantifiability as the HD-X platform already provided 100% detectability and quantifiability in plasma. sTREM-2 detectability and quantifiability on the SR-X achieved 100% in plasma. Overall, the sTREM-2 Advantage PLUS assay was shown to function on the HD-X platform and with data highly comparable to that generated on the SR-X platform.

For more information on the sTREM-2 Advantage PLUS assay and other Simoa assay kits, please visit the Customer Portal: <https://portal.quanterix.com>

References

1. sTREM-2 Advantage PLUS Validation Report
2. sTREM-2 Advantage PLUS Data Sheet

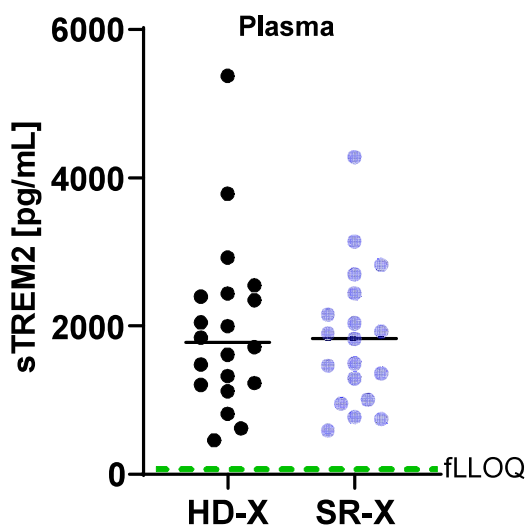


Figure 2. sTREM-2 levels for 20 non-matched EDTA plasma samples from presumably healthy individual donors on HD-X and SR-X instruments. The dotted green lines indicate the functional LLOQ of the Advantage PLUS assays.