

SR-X Compatibility for Simoa® IL-17A Advantage PLUS Assay

Overview

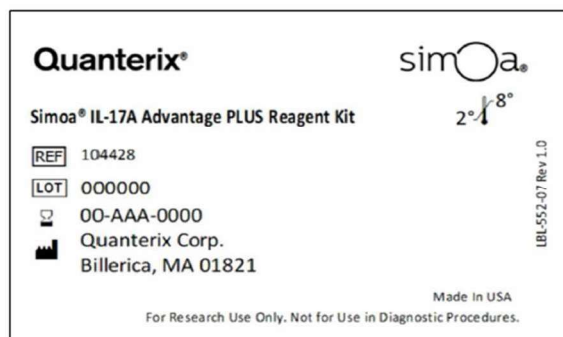
This document describes the compatibility for IL-17A Advantage PLUS assay (Item #104428) on the Quanterix SR-X platform. This compatibility report aims to complement and expand upon the validation data presented in the IL17-A Advantage PLUS assay Validation Report, available on the Quanterix customer 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 IL17-A 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 #103158), 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 IL-17A Advantage PLUS assay on the HD-X platform can be obtained from the Data sheet available on the Quanterix customer portal². Figures 1-3 compare quantitation limit, detection limit, detectability, and quantifiability from the IL-17A Advantage PLUS across HD-X and SR-X platforms.

Table 1. Assay performance parameters for IL-17A Advantage PLUS assays across HD-X and SR-X platforms. Refer assay specific data sheet for additional details². 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 non-matched EDTA plasma and serum were tested for detectability and quantifiability.

Assay Parameters Comparison		
	IL-17A Advantage PLUS on HD-X	IL-17A Advantage PLUS on SR-X
Curve profiling LLOQ	0.006 pg/mL	0.006 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	0.012 pg/mL	0.012 pg/mL
LOD	0.002 pg/mL	0.004 pg/mL
Detectability	Plasma: 100% Serum: 100%	Plasma: 100% Serum: 100%
Quantifiability	Plasma: 90% Serum: 85%	Plasma: 90% Serum: 90%



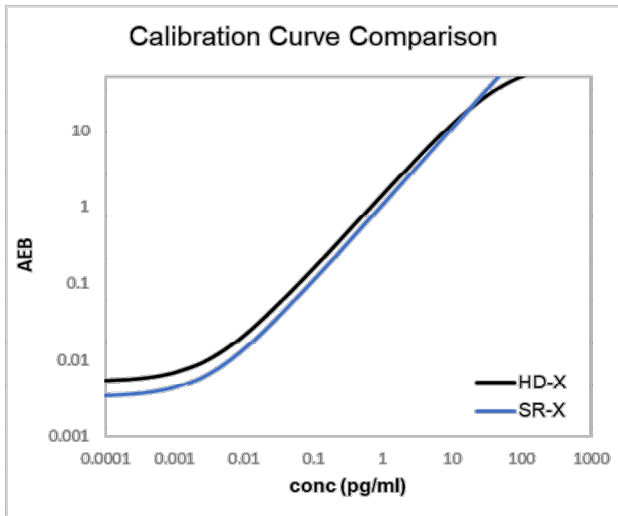


Figure 1. Comparison of the calibration curves for IL-17A Advantage PLUS kits across HD-X and SR-X platforms. The black line indicates the calibration from HD-X, and the blue line indicates the calibration from SR-X for IL-17A Advantage PLUS kits.

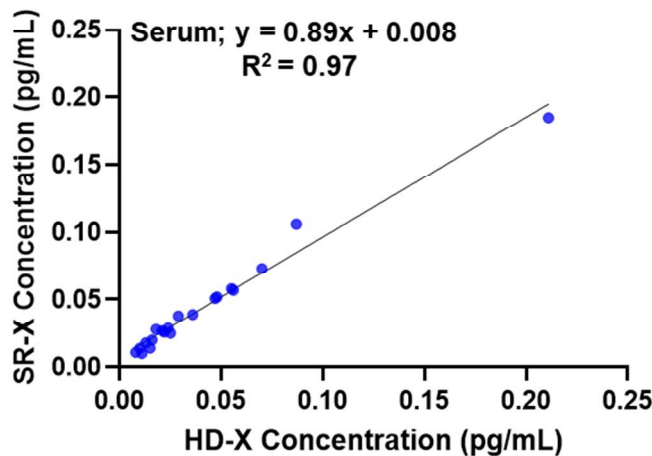
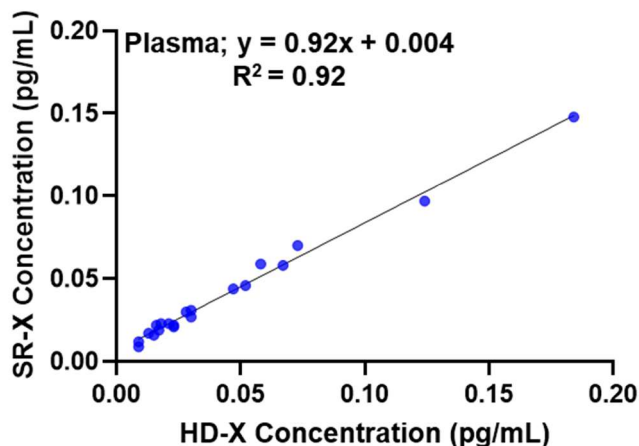


Figure 3. Correlation between HD-X and SR-X for IL-17A Advantage PLUS assay for 20 non-matched normal human plasma (Slope 0.77, R^2 0.99) and serum (Slope 0.89, R^2 0.97) samples.

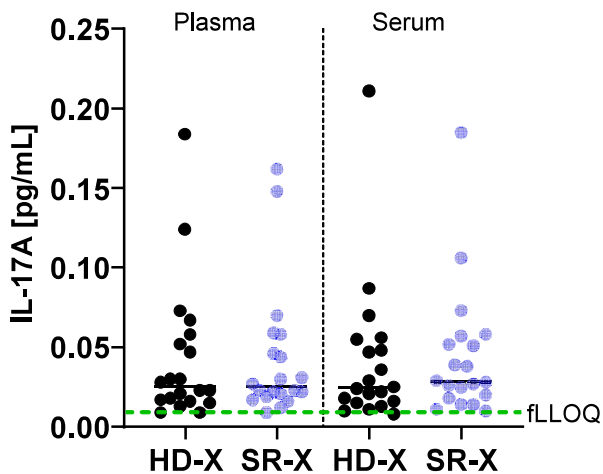


Figure 2. IL-17A levels for 20 non-matched EDTA plasma and serum samples from presumably healthy individual donors on IL-17A Advantage PLUS assays on HD-X and SR-X instruments. The dotted green lines indicate the functional LLOQ of the Advantage PLUS assays.

Summary

Comparability of the IL-17A Advantage PLUS assay (item #104570) 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 and HD-X platforms were found to be highly similar. Both the SR-X and HD-X platforms had functional LLOQ and LOD values of .012 and .002 pg/mL. Similar detectability and quantifiability were also observed. Percent detected or quantitated on the SR-X platform was within 5% of the values of the HD-X platform for both plasma and serum.

For more information on the IL-17A Advantage PLUS assay and other Simoa assay kits, please visit the Customer Portal: <https://portal.quanterix.com>

References

1. IL-17A Advantage PLUS Validation Report
2. IL-17A Advantage PLUS Data Sheet