

SR-X Compatibility for Simoa® Nf-Light Advantage PLUS Assay

Overview

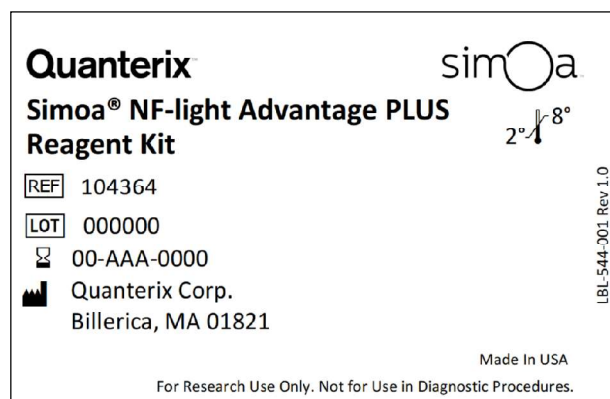
This document describes compatibility of the Nf-Light Advantage PLUS assay (Item #104364) on the Quanterix SR-X platform. This compatibility report aims to complement and expand upon the validation data presented in the Nf-Light Advantage PLUS Validation Report, available on the Quanterix customer portal¹. 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 Nf-Light 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. If further information is needed, please contact Techsupport@Quanterix.com.

Assay Performance

The analytical performance of Nf-Light 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 Nf-Light Advantage PLUS across HD-X and SR-X platforms.

Table 1. Assay performance parameters for Nf-Light Advantage PLUS assays across HD-X and SR-X platforms. Refer to the assay specific data sheet for additional details. 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.

Assay Parameters Comparison		
	Nf-Light Advantage PLUS on HD-X	Nf-Light Advantage PLUS on SR-X
Curve profiling LLOQ	0.309 pg/mL	0.308 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	1.24 pg/mL	1.23 pg/mL
LOD	0.062 pg/mL	0.048 pg/mL
Detectability	Plasma: 100% Serum: 100%	Plasma: 100% Serum: 100%
Quantifiability	Plasma: 100% Serum: 100%	Plasma: 100% Serum: 100%



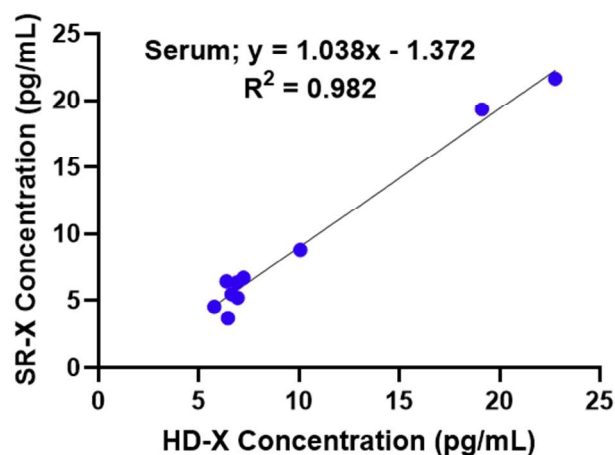
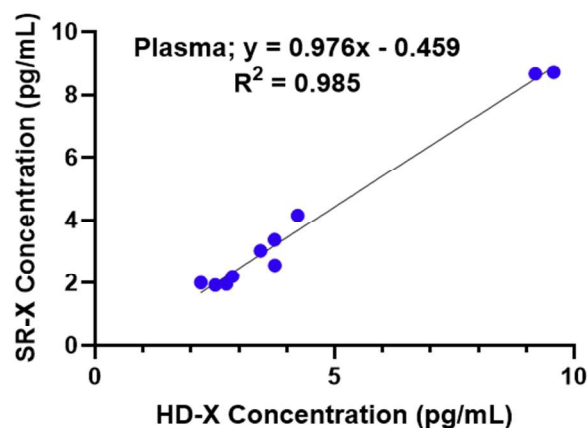
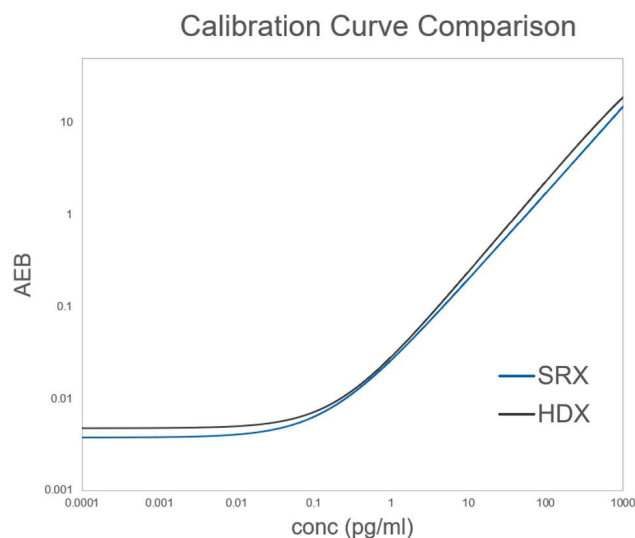


Figure 1. Comparison of the calibration curves for Nf-Light Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms.

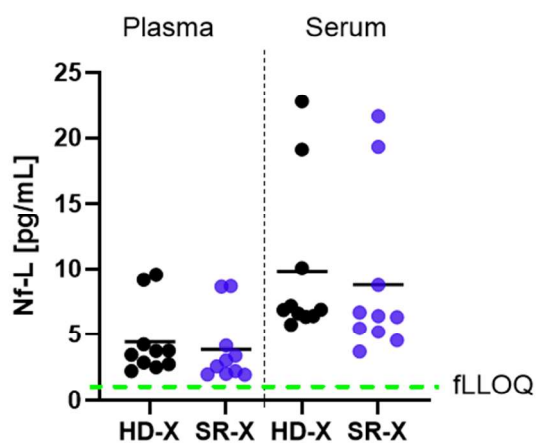


Figure 3. Correlation between HD-X and SR-X for Nf-Light Advantage PLUS assay for 10 EDTA plasma (Slope 0.976, R² 0.985) and 10 serum (Slope 1.038, R² 0.982) samples.

Figure 2. Nf-Light levels for 10 EDTA plasma and 10 serum 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.

Summary

Comparability of the Nf-Light Advantage PLUS (item #104364) between the HD-X and SR-X platforms was evaluated by measuring LLOQ, LOD, precision, detectability and quantifiability. The sensitivity of the assay on the SR-X platform demonstrated similar values as compared to the HD-X platform. The SR-X had functional LLOQ and LOD values of 1.23 and 0.048 pg/mL. The HD-X had functional LLOQ and LOD values of 1.24 and 0.062 pg/mL. The difference in sensitivity had a minor impact on sample detectability and quantifiability. Nf-Light detectability on the SR-X achieved 100% in both EDTA plasma and serum and quantifiability achieved 100% in both EDTA plasma and serum. Overall, the Nf-Light 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 Nf-Light Advantage PLUS assay and other Simoa assay kits, please visit the Customer Portal: <https://portal.quanterix.com>

References

1. Nf-Light Advantage PLUS Validation Report
2. Nf-Light Advantage PLUS Data Sheet