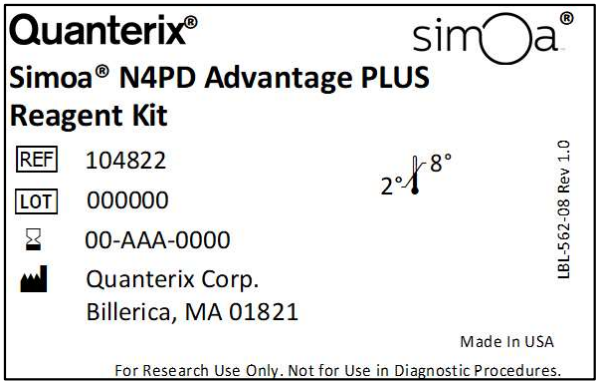
SR-X Compatibility for Simoa® Neuro 4-Plex D Advantage PLUS Assay

Overview

This document describes compatibility of the Neuro 4-Plex D Advantage PLUS assay (Item #104822) on the Quanterix SR-X platform. This compatibility report aims to complement and expand upon the validation data presented in the Neuro 4-Plex D Advantage PLUS Validation Report, available on the Quanterix customer portal[1]. The validation report details analytical assay performance, including LLOQ, LOD, precision, spike and recovery, dilution linearity, and measurement of normal samples. Compatibility of the Neuro 4-Plex D 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 Neuro 4-Plex D Advantage PLUS assay on the HD-X platform can be obtained from the Data Sheet available on the Quanterix customer portal[2]. Tables 1-4 compare the lower limit of detection (LOD) and the lower limit of quantitation (LLOQ) between the HD-X and SR-X platforms. Figures 1-8 depict calibration curve comparison and the sample measurement correlation between HD-X and SR-X platforms for N4PD Advantage PLUS, respectively. Refer to the assay specific data sheet for detectability and quantifiability information.

Tables 1-4. Assay performance parameters for Neuro 4-Plex D Advantage PLUS assays across HD-X and SR-X platforms. Refer to the assay specific data sheet for additional details[2]. 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 BD-Tau (Neuro 4-Plex D)		
	HD-X per Data Sheet	SR-X
Curve profiling LLOQ	0.2590 pg/mL	0.0780 pg/mL
Functional LLOQ Plasma/Serum (Analytical LLOQ x MRD)	1.0360 pg/mL	0.3120 pg/mL
Functional LLOQ CSF (Analytical LLOQ x MRD)	25.9000 pg/mL	7.8000 pg/mL
LOD	0.0286 pg/mL	0.0098 pg/mL

Assay Parameters Comparison GFAP (Neuro 4-Plex D)		
	HD-X per Data Sheet	SR-X
Curve profiling LLOQ	0.8050 pg/mL	0.7210 pg/mL
Functional LLOQ Serum/Plasma (Analytical LLOQ x MRD)	3.2200 pg/mL	2.8840 pg/mL
Functional LLOQ CSF (Analytical LLOQ x MRD)	80.5000 pg/mL	72.1000 pg/mL
LOD	0.1215 pg/mL	0.3021 pg/mL

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Assay Parameters Comparison NF-Light (Neuro 4-Plex D)		
	HD-X per Data Sheet	SR-X
Curve profiling LLOQ	0.3550 pg/mL	0.4430 pg/mL
Functional LLOQ Plasma/Serum (Analytical LLOQ x MRD)	1.4200 pg/mL	1.7720 pg/mL
Functional LLOQ CSF (Analytical LLOQ x MRD)	35.5000 pg/mL	43.3000 pg/mL
LOD	0.0942 pg/mL	0.2416 pg/mL

Assay Parameters Comparison UCH-L1 (Neuro 4-Plex D)		
	HD-X per Data Sheet	SR-X
Curve profiling LLOQ	3.4750 pg/mL	1.6100 pg/mL
Functional LLOQ Plasma/Serum (Analytical LLOQ x MRD)	13.9000 pg/mL	6.4400 pg/mL
Functional LLOQ CSF (Analytical LLOQ x MRD)	347.5000 pg/mL	161.0000 pg/mL
LOD	0.5768 pg/mL	1.4939 pg/mL

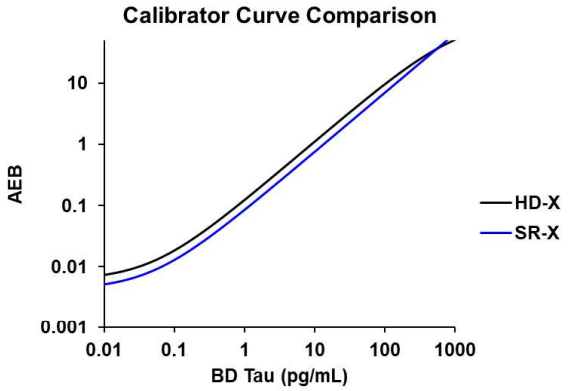

Figure 1. Comparison of the calibration curves for BD-Tau (Neuro 4-Plex D) Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms.

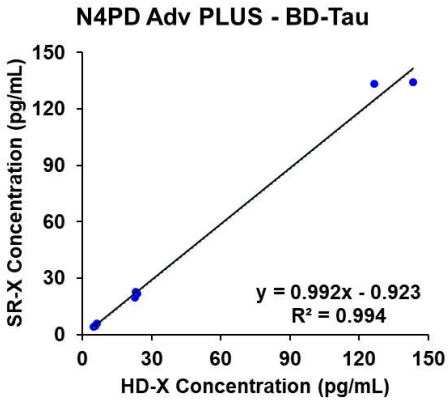

Figure 2. Correlation between HD-X and SR-X for BD-Tau (Neuro 4-Plex D) Advantage PLUS assay for 8 spiked plasma samples (Slope 0.992, R^2 0.994).

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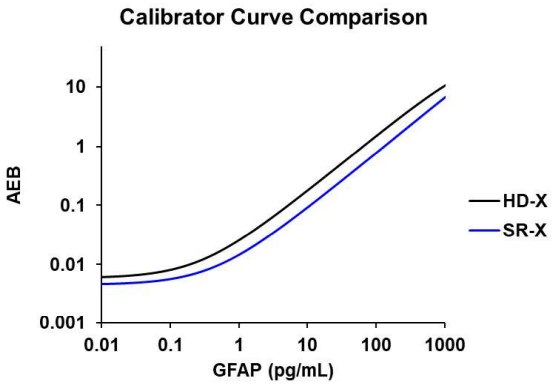

Figure 3. Comparison of the calibration curves for GFAP (Neuro 4-Plex D) Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms.

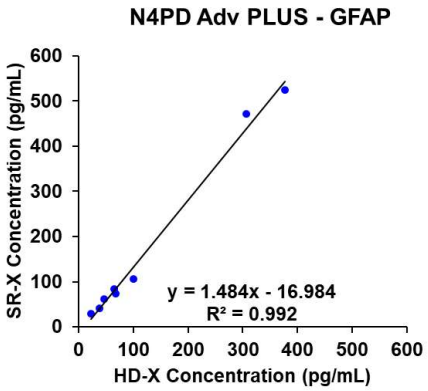

Figure 4. Correlation between HD-X and SR-X for GFAP (Neuro 4-Plex D) Advantage PLUS assay for 8 spiked plasma samples (Slope 1.484, R^2 0.992).

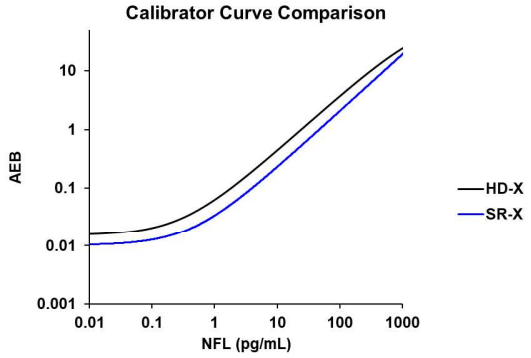

Figure 5. Comparison of the calibration curves for NF-Light (Neuro 4-Plex D) Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms.

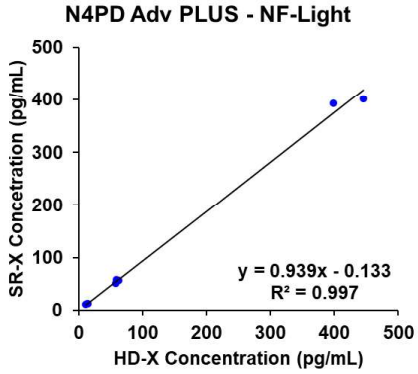

Figure 6. Correlation between HD-X and SR-X for NF-Light (Neuro 4-Plex D) Advantage PLUS assay for 8 spiked plasma samples (Slope 0.939, R^2 0.997).

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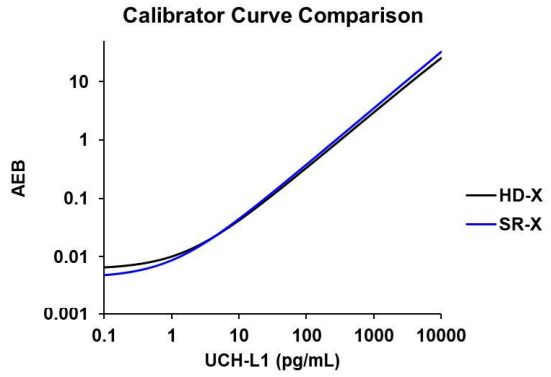

Figure 7. Comparison of the calibration curves for UCH-L1 (Neuro 4-Plex D) Advantage PLUS kits across HD-X (black) and SR-X (blue) platforms.

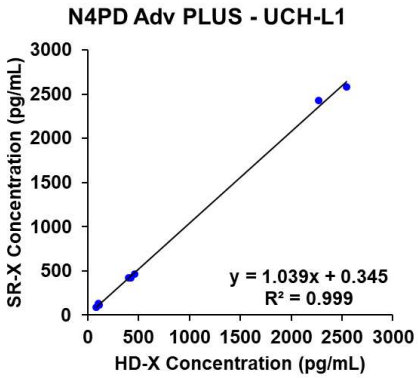

Figure 8. Correlation between HD-X and SR-X for UCH-L1 (Neuro 4-Plex D) Advantage PLUS assay for 8 spiked plasma samples (Slope 1.039, R^2 0.999).

Summary

Comparability of the Neuro 4-Plex D Advantage PLUS (Item #104822) between the HD-X and SR-X platforms was evaluated by measuring LLOQ, LOD, and sample reading correlation. The Neuro 4-Plex D Advantage PLUS assay demonstrated similar sensitivity on the SR-X platform when compared to the HD-X platform. Overall, the Neuro 4-Plex D Advantage PLUS assay was shown to function on the SR-X platform.

It is worth noting that GFAP calibration curves on the SR-X platform exhibited slightly higher coefficient of variation (CV) values compared to those on the HD-X. However, this CV variability was only observed in the calibration curve, not in samples.

For more information on the Neuro 4-Plex D Advantage PLUS assay and other Simoa assay kits, please visit the Customer Portal: https://portal.quanterix.com

References

1. Neuro 4-Plex D Advantage PLUS Validation Report
2. Neuro 4-Plex D Advantage PLUS Data Sheet

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