

Quanterix SR-X® Compatibility for Simoa® p-Tau 205 Advantage PLUS Assay

Overview

This document describes compatibility of the Simoa p-Tau 205 Advantage PLUS assay (Item #105634) on the Quanterix SR-X® platform. This compatibility report aims to complement and expand upon the validation data presented in the p-Tau 205 Advantage PLUS Validation Report, available on the Quanterix® customer portal¹. The validation report details analytical assay performance, including LLOQ, LOD, and measurement of normal samples. Compatibility of the p-Tau 205 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 p-Tau 205 Advantage PLUS assay on the HD-X platform can be obtained from the HD-X Data Sheet available on the Quanterix customer portal². Table 1 compares the quantitation limit and the detection limit and Figures 1-2 provide curve comparisons and sample reading correlation between HD-X and SR-X platforms for p-Tau 205 Advantage PLUS.

Table 1. Quantification and detection limits for p-Tau 205 Advantage PLUS assays across HD-X and SR-X platforms. Refer to the assay specific HD-X data sheet for additional details on HD-X, like detectability and quantifiability². 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 p-Tau 205		
	HD-X per Data Sheet	SR-X
Curve profiling LLOQ	0.2250 pg/mL	0.1810 pg/mL
Functional LLOQ Plasma/Serum (Analytical LLOQ x MRD)	0.4500 pg/mL	0.3620 pg/mL
Functional LLOQ CSF (Analytical LLOQ x MRD)	1.8000 pg/mL	1.4240 pg/mL
LOD	0.0470 pg/mL	0.0197 pg/mL

I. Calibrator Comparison

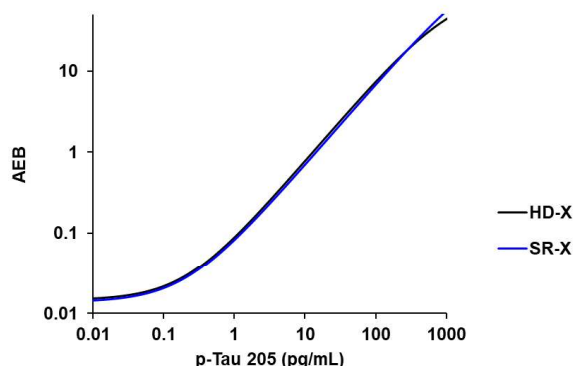


Figure 1. Comparison of the calibration curves for **p-Tau 205 Advantage PLUS** kits across HD-X (black) and SR-X (blue) platforms for one reagent kit lot.

II. Sample reading correlation between SR-X and HD-X

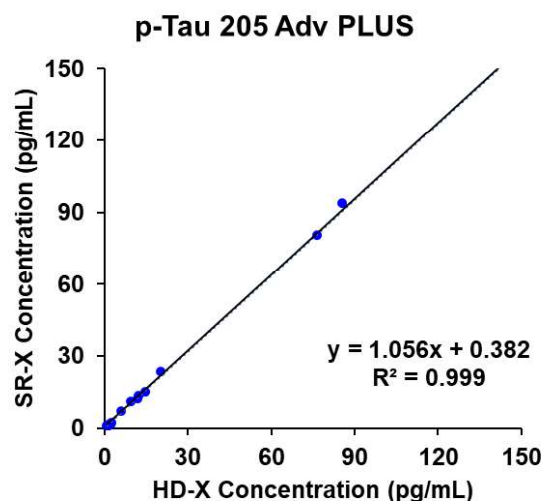


Figure 2. Correlation between HD-X and SR-X for **p-Tau 205 Advantage PLUS** assay for 16 spiked plasma samples (Slope 1.056, R^2 0.999) for one reagent kit lot.

Summary

Comparability of the Simoa® p-Tau 205 Advantage PLUS (Item #105634) between the Simoa HD-X Analyzer® and Quanterix SR-X® platforms was evaluated by measuring LLOQ, LOD, and sample reading correlation. The p-Tau 205 Advantage PLUS assay demonstrated similar sensitivity on the SR-X platform when compared to the HD-X platform. Overall, the p-Tau 205 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 p-Tau 205 Advantage PLUS assay and other Simoa® assay kits, please visit the Customer Portal: <https://portal.quanterix.com>

References

1. p-Tau 205 Advantage PLUS Validation Report
2. p-Tau 205 Advantage PLUS Data Sheet