

SR-X Compatibility for Simoa® ALZpath p-Tau 217 Advantage PLUS Assay

Overview

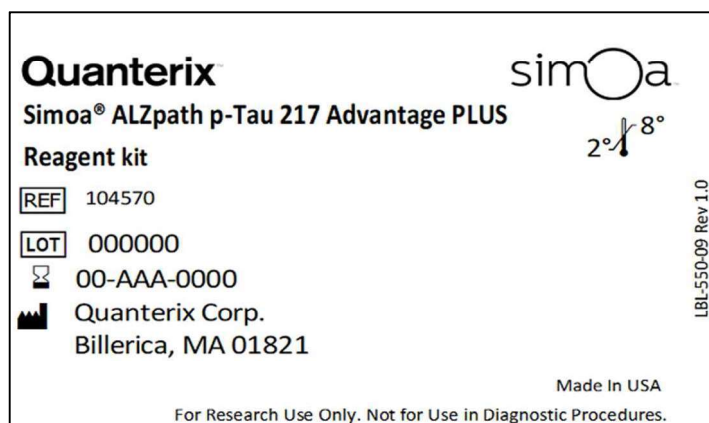
This document describes the compatibility for ALZpath p-Tau 217 Advantage PLUS assay (Item #104570) on the Quanterix SR-X platform. This compatibility report aims to complement and expand upon the validation data presented in the ALZpath p-Tau 217 Advantage PLUS assay Validation Report, available on 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 ALZpath p-Tau 217 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

Details for analytical performance of ALZpath p-Tau 217 Advantage PLUS on the HD-X platform can be obtained from the Data sheet on the Quanterix customer portal¹. Figures 1-3 compare results from the ALZpath p-Tau 217 Advantage PLUS across HD-X and SR-X platforms.

Table 1. Assay performance parameters for ALZpath p-Tau 217 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.

Assay Parameters Comparison		
	ALZpath p-Tau 217 Advantage PLUS on HD-X	ALZpath p-Tau 217 Advantage PLUS on SR-X
Curve profiling LLOQ	0.00413 pg/mL	0.00433 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	0.01239 pg/mL	0.01299 pg/mL
LOD	0.0006 pg/mL	0.0004 pg/mL



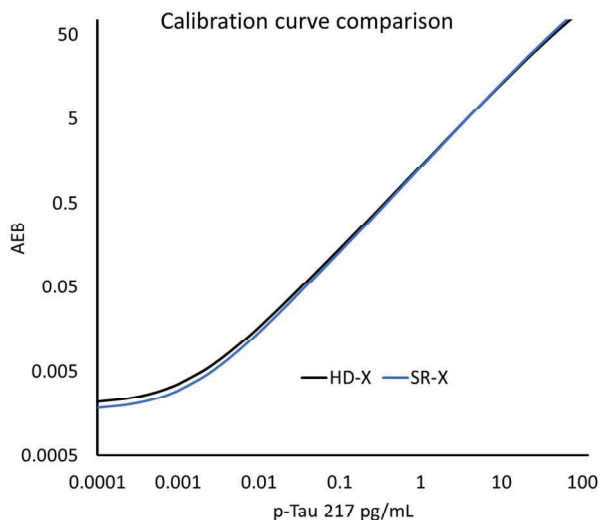


Figure 1. Comparison of the calibration curves ALZpath p-Tau 217 Advantage PLUS assay across HD-X (black) and SR-X (blue) platforms.

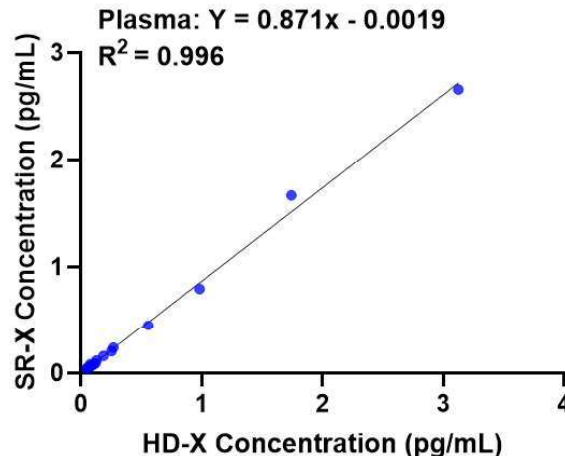


Figure 3. Correlation between HD-X and SR-X for ALZpath p-Tau 217 Advantage PLUS assay for 21 plasma-based bridging panel samples (Slope 0.871, R² 0.996).

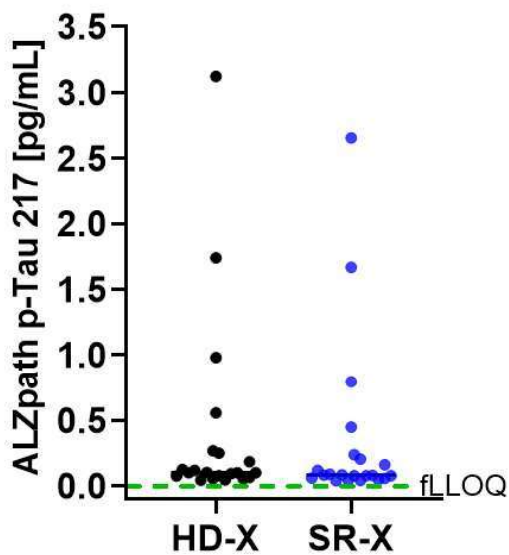


Figure 2. p-Tau 217 levels for 21 plasma-based bridging panel samples on ALZpath p-Tau 217 Advantage PLUS assays on HD-X and SR-X instruments. The dotted lines indicate the functional LLOQ of the Advantage PLUS assays.

Summary

Comparability of the p-Tau 217 Advantage PLUS assay (item #104570) between the HD-X and SR-X platforms was evaluated by measuring LLOQ and LOD. The sensitivity of the assay on the SR-X and HD-X platforms were found to be highly similar. The SR-X had functional LLOQ and LOD values of .0129 and .0004 pg/mL. The HD-X had functional LLOQ and LOD values of .01239 and .0006 pg/mL.

For more information on the ALZpath p-Tau 217 Advantage PLUS assay and other Simoa assay kits, please visit the Customer Portal: <https://portal.quanterix.com>

References

1. ALZpath p-Tau 217 Advantage PLUS Validation Report
2. ALZpath p-Tau 217 Advantage PLUS Data sheet