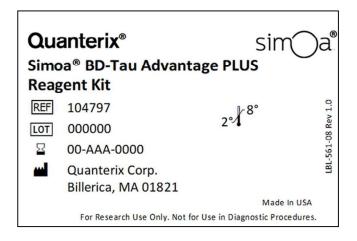
SR-X Compatibility Advantage PLUS Assay

Overview

This document provides the compatibility for BD-Tau Advantage PLUS assay (Item #104797) on the Quanterix SR-X platform. This compatibility report aims to complement and expand upon the validation data presented in the BD-Tau Advantage PLUS Validation Report, available on the Quanterix customer portal¹. Details on the overall analytical assay performance of the BD-Tau Advantage PLUS assay, on the HD-X platform, are thoroughly documented in the validation report and will not be reiterated here. Instead, this compatibility report focuses on the comparative analysis of the assay's performance across the HD-X and SR-X platforms. Further validation of assay performance may be required prior to initiating large-scale projects with the assay on the SR-X platform, depending on specific in-house regulations. Users should be familiar 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.



for Simoa® BD-Tau

Assay Performance

Details for analytical performance of BD-Tau Advantage PLUS on the HD-X platform can be obtained from the Data sheet available on the Quanterix customer portal². Figures 1-3 compare results from the BD-Tau Advantage PLUS across HD-X and SR-X platforms.

Table 1. Assay performance parameters for BD-Tau 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.

Assay Parameters Comparison		
	BD-Tau Advantage PLUS on HD-X	BD-Tau Advantage PLUS on SR-X
Curve profiling LLOQ	0.157 pg/mL	0.200 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	0.628 pg/mL	0.800 pg/mL
LOD	0.043 pg/mL	0.039 pg/mL

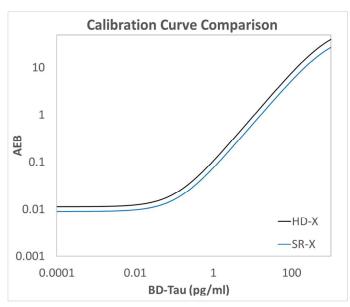


Figure 1. Comparison of the calibration curves for BD-Tau Advantage PLUS kits across HD-X and SR-X platforms. The black line indicates the calibration from HD-X, and the blue line indicates the calibration from SR-X for BD-Tau Advantage PLUS kits.

Simoa® BD-Tau Advantage PLUS Kit SR-X Compatibility Report

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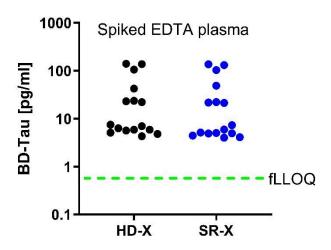


Figure 2. BD-Tau levels for 16 spiked human EDTA plasma samples were measured using BD-Tau Advantage PLUS assays on HD-X and SR-X instruments. The black dots indicates the mean of measured samples. The dotted green line indicates the functional LLOQ of the BD-Tau Advantage PLUS assay on HD-X.

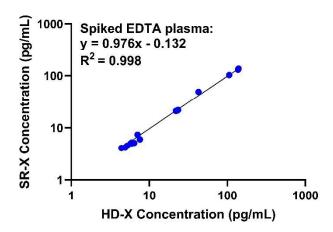


Figure 3. Correlation between HD-X and SR-X for BD-Tau Advantage PLUS assay for 16 spiked human EDTA plasma (Slope = 0.976, R2 = 0.998) samples.

Summary

Compatibility of the BD-Tau Advantage PLUS assay (Item #104797) 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 slightly higher values as compared to the HD-X platform. The SR-X had functional LLOQ and LOD values of 0.800 and 0.039 pg/mL. The HD-X had functional LLOQ and LOD values of 0.628 and 0.043 pg/mL. The difference in sensitivity did not have an impact on sample detectability and quantifiability. BD-Tau detectability and quantifiability on SR-X achieved 100% in EDTA plasma. Overall, the BD-tau Advantage PLUS assay was shown to function on the SR-X platform and with data comparable to that generated on the HD-X platform.

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

References

- **BD-Tau Advantage PLUS Validation Report**
- **BD-Tau Advantage PLUS Data Sheet**