

Quanterix SR-X® Compatibility for Simoa® SNAP-25 Advantage V2 Assay

Overview

This document describes compatibility of the Simoa® SNAP-25 Advantage V2 assay (Item #104955) on the Quanterix SR-X® platform. This compatibility report aims to complement and expand upon the validation data presented in the SNAP-25 Advantage V2 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 SNAP-25 Advantage V2 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 SNAP-25 Advantage V2 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 lower limit of detection (LOD) and the lower limit of quantitation (LLOQ) between the HD-X and SR-X platforms. Figures 1 and 2 depict calibration curve comparison and the sample measurement correlation between HD-X and SR-X platforms for SNAP-25 Advantage V2, respectively. Figure 3 depicts the distribution of normal samples measured across the range of the assay, all of which are above the LLOQ.

Table 1. Quantification and detection limits for SNAP-25 Advantage V2 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 SNAP-25		
	HD-X per Data Sheet	SR-X
LLOQ	2.5600 pg/mL	1.1400 pg/mL
Functional LLOQ (Analytical LLOQ x MRD)	10.2400 pg/mL	4.5600 pg/mL
LOD	1.4715 pg/mL	0.4830 pg/mL



I. Calibrator Comparison

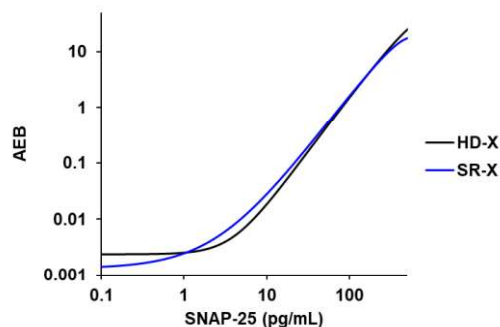


Figure 1. Comparison of the calibration curves for **SNAP-25** Advantage V2 kits across HD-X (black) and SR-X (blue) platforms for one reagent kit lot.

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

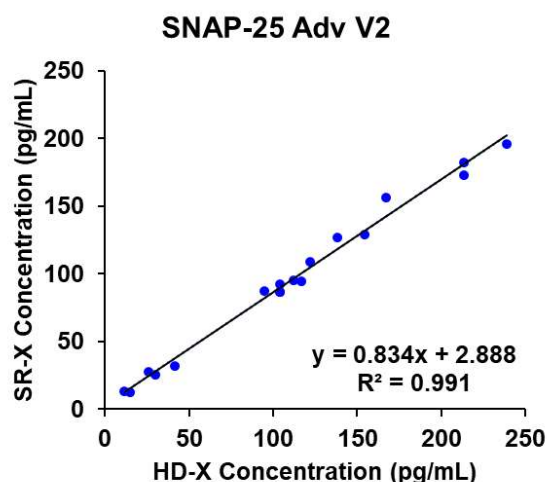


Figure 2. Correlation between HD-X and SR-X for **SNAP-25** Advantage V2 assay for 18 CSF samples (Slope of 0.834, $R^2 = 0.991$) for one reagent kit lot.

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

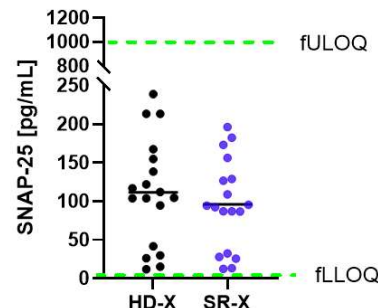


Figure 3. SNAP-25 levels for 18 CSF samples from presumably healthy individual donors on HD-X and SR-X instruments for one reagent kit lot. The dotted green lines indicate the functional LLOQ and ULOQ of the Advantage PLUS assays.

Summary

Comparability of the Simoa® SNAP-25 Advantage V2 (Item #104955) between the Simoa HD-X Analyzer® and Quanterix SR-X® platforms was evaluated by measuring LLOQ, LOD, and sample reading correlation. The SNAP-25 Advantage V2 assay demonstrated similar sensitivity on the SR-X platform when compared to the HD-X platform. Overall, the SNAP-25 Advantage V2 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 SNAP-25 Advantage V2 assay and other Simoa assay kits, please visit the Customer Portal: <https://portal.quanterix.com>

References

1. SNAP-25 Advantage V2 Validation Report
2. SNAP-25 Advantage V2 Data Sheet