Quanterix™
The Science of Precision Health

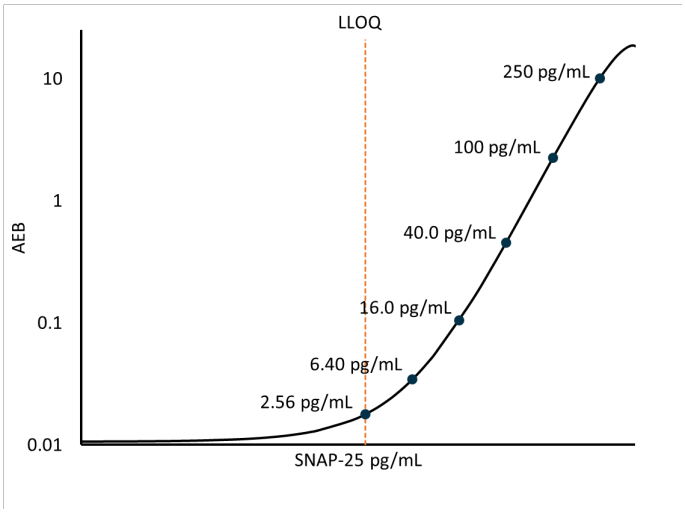
Simoa® SNAP-25 Advantage Kit
HD-1/HD-X Data Sheet

Item 103575

Description

The Simoa SNAP-25 assay targets the soluble N-terminal fragment of SNAP-25 (aa 2-47) which has been shown to distinguish between AD patients and nondemented controls. SNAP-25 (Synaptosomal- associated protein, 25kDa) is one of the major proteins involved in the formation of the SNARE (Soluble N-ethylmaleimide-sensitive factor attachment protein receptors) protein complex. The complex formation is an important step in the exocytotic release of neurotransmitters during synaptic transmission. SNAP-25 is also involved in neurite extension, neuron repair and synaptogenesis and in LTP and formation of long-term memory. Cognitive decline in Alzheimer's disease can be predicted by synaptic dysfunction and degeneration. Synaptic damage can be detected at the earliest stages of AD. MCI patients show loss of presynaptic proteins like synaptophysin and SNAP-25 and PSM like PSD-95 and Shank. Synaptic loss is closely related to severity of clinical disease and therefore SNAP-25 may be a good biomarker for early diagnosis and as a disease progression predictor. SNAP-25 levels correlate with levels of T-tau and P-tau in control groups and patients with dementia due to AD. Therefore, SNAP-25 may be an important alternate marker in future clinical treatment studies with tau-based-modifying drugs.

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted.



Minimum Required Dilution (MRD)

Diluted Sample Volume	100 µL per measurement
CSF Dilution	1:4
Tests per kit	96

See Kit Instruction for details.

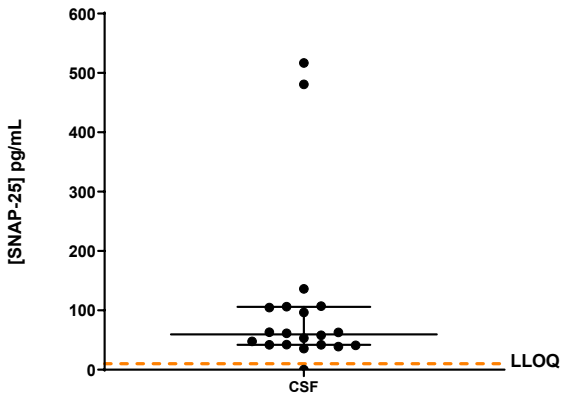
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 3 runs per lot, for 2 reagent lots across 2 instruments (12 runs total). The functional LLOQ (fLLOQ) values below are for CSF.

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 3 runs per lot, for 2 reagent lots across 2 instruments (12 runs total).

Assay Range: The upper end of the dynamic range is equal to the top calibrator concentration multiplied by MRD. The ranges below are for CSF.

Analytical LLOQ	**2.56 pg/mL** pooled CV 15.9% mean recovery 99.1%
Functional LLOQ (CSF)	**10.24 pg/mL**
LOD	**0.880 pg/mL** Range 0.549–1.53 pg/mL
Dynamic Range (CSF)	0 –1000 pg/mL

Endogenous Sample Reading: Normal CSF samples (n=20) were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



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Sample Type	Mean SNAP-25 pg/mL	Median SNAP-25 pg/mL	% Above LOD	% Above LLOQ
CSF	112.4	59.6	95%	95%

*Values below LLOQ are not included in the mean

Precision: Measurements of 3 CSF-based panels and 2 calibrator-based controls. Triplicate measurements were made for 3 runs each for 2 reagent lots across 2 instruments (12 runs total, 36 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV	Between Lot CV
Control 1	56.6	3.7%	4.8%	3.1%	6.1%
Control 2	450	2.4%	4.0%	0.4%	4.0%
Panel 1	66.2	4.0%	6.0%	0.3%	7.2%
Panel 2	82.6	2.7%	5.7%	1.2%	6.9%
Panel 3	511	3.7%	4.4%	4.9%	4.7%

Spike and Recovery: 3 CSF samples were spiked at high and low concentrations within the range of the assay.

Dilution Linearity: 4 endogenous CSF were diluted 2x serially from MRD (4x) to 32x with Sample Diluent.

Spike and Recovery	**Mean 101%** range 94.5–110%
Dilution Linearity (32x)	**Mean 102%** range 80–124%

Curve Storage: Measurements of one spiked and two endogenous CSF-based panels and 2 calibrator-based controls. Triplicate measurements were made for 5 runs on 4 different days on the same instrument using one lot of reagents (5 runs total).

Drift: Measurements of one spiked CSF-based panel, one endogenous CSF-based panel, and 2 calibrator-based controls. Controls and panels were run across three plates with a total of 54 replicates per sample.

Sample Freeze-Thaw Stability: Measurements of three endogenous CSF-based panels. Triplicate measurements were made for 3 Freeze-Thaw cycles on the same instrument using one lot of reagents.

Calibrator and Sample Stability: Measurements of 3 endogenous CSF-based samples and calibrator concentrate. Triplicate measurements were made for 3 stability time points (3-hr and 7-hr stability at room temperature and 24-hr stability at 4˚C) on the same instrument using one lot of reagents.

Curve Storage	**Mean Bias: 4.8%** range 2.6–6.5%
Drift (Three-plate Variance)	**Plate 1:** 9.5% **Plate 1+2:** 5.5% **Plate 1+2+3:** 4.6%
Drift (Three-plate Precision)	**Mean 4.63%** range 3.7–5.4%
Sample Freeze-Thaw Stability Bias (CSF) - After 3 F/T cycles	**Mean 100%** range 96.0-104%
Calibrator Stability Bias (7hours at Room Temp)	**Mean 97.4%** range 86.7-105%
Sample Stability Bias (7 hours at Room Temp)	**Mean 99.3%** range 94.5–102%

The Simoa SNAP-25 assay kit is formulated for use on the SR-X, HD-1, or HD-X platform. Some differences in performance claims between the HD and SR-X platforms may be observed when comparing data sheets for these platforms. This may be due to experiments run at different time-points with different reagent lots and different samples or may be due to minor differences in antibody and analyte behavior in the different assay formats.

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