Quanterix™
The Science of Precision Health

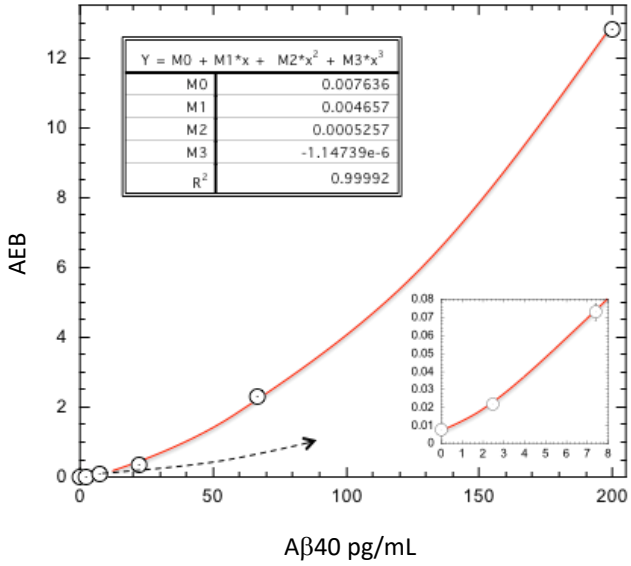
Simoa® Aβ40 Advantage Kit
HD-1/HD-X Data Sheet

Item 101672

Description

Aβ40 is a 40 amino acid proteolytic product from the amyloid precursor protein (APP) that has gained attention as a biomarker correlating with Alzheimer disease (AD) onset, mild cognitive impairment, vascular dementia, and other cognitive disorders. Beta-secretase cleavage of APP initially results in the production of an APP fragment that is further cleaved by gamma-secretase at residues 40-42 to generate two main forms of amyloid beta, Aβ40 and Aβ42. Amyloid beta (Aβ) peptides (including a shorter Aβ38 isoform) are produced by different cell types in the body, but the expression is particularly high in the brain. Accumulation of Aβ in the form of extracellular plaques is a neuropathological hallmark of AD and believed to play a central role in the neurodegenerative process. Aβ40 is the major amyloid component in these plaques and is thought to be an initiating factor of AD plaques. In healthy and disease states Aβ40 is the most abundant form of the amyloid peptides in both cerebrospinal fluid (CSF) and plasma (10–20X higher than Aβ42). Recent studies suggest that a decrease in the ratio of Aβ42/Aβ40 may indicate AD progression.

Calibration Curve: Four-parameter curve fit parameters are depicted.



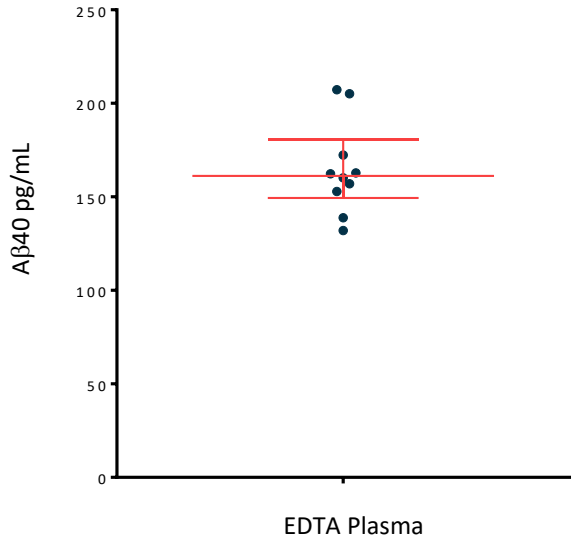
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (10 runs total).

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

LLOQ	**1.23 pg/mL** pooled CV 16.7% recovery 92–119%
LOD	**0.522 pg/mL** range 0.068–1.30 pg/mL
Dynamic range (EDTA plasma)	0–800 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

Endogenous Sample Reading: Healthy donor EDTA plasma (n=10) was measured. 10 CSF samples were measured. Error bars depict median with interquartile range.



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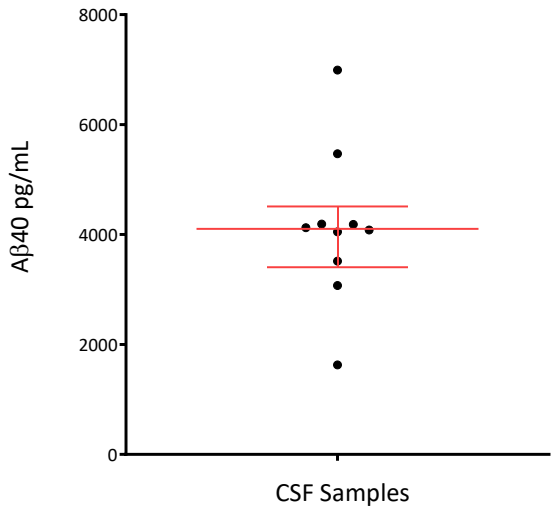

Sample Type	Median Aβ40 pg/mL	% Above LOD
CSF Samples	4125	100%
EDTA Plasma	169	100%

Precision: Five samples consisting of three plasma-based panels and two Aβ40 controls were assayed in replicates of three at two separate times per day for five days using a single lot of reagents and calibrators. Analysis of variance (fully nested ANOVA) results are summarized in the following table.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between day CV
Control 1	27.5	6.0%	5.6%	0.0%
Control 2	348	2.4%	6.4%	2.6%
Panel 1	8.16	7.7%	8.3%	9.1%
Panel 2	21.4	8.0%	8.2%	2.5%
Panel 3	40.8	6.7%	5.7%	5.9%

Spike and Recovery: Aβ40 spiked into 2 plasma samples at 2 levels.

Admixture Linearity: High Aβ40 plasma sample admixed with low Aβ40 sample, mean of 10 levels.

Dilution Linearity: 1 plasma sample diluted 2x serially from MRD (4x) to 128x with Sample Diluent.

Spike and Recovery (Plasma)	**Mean = 78.4%** Range: 70.7-88.8%
Admixture Linearity	**Mean = 107%**
Dilution Linearity (128x)	**Mean = 96.2%** Range: 88.0-101%

The Simoa Aβ40 Advantage assay kit is formulated for use on the SR-X®, HD-1, or HD-X® platform. Data in this document was obtained from runs on the HD-1 platform unless otherwise noted. Some differences in performance claims between SR-X and HD-1/HD-X may be observed when comparing datasheets for these platforms. This may be due to experiments run at different time-points with different reagent lots and different samples, or it may be due to minor differences in antibody and analyte behavior in the different assay formats.

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