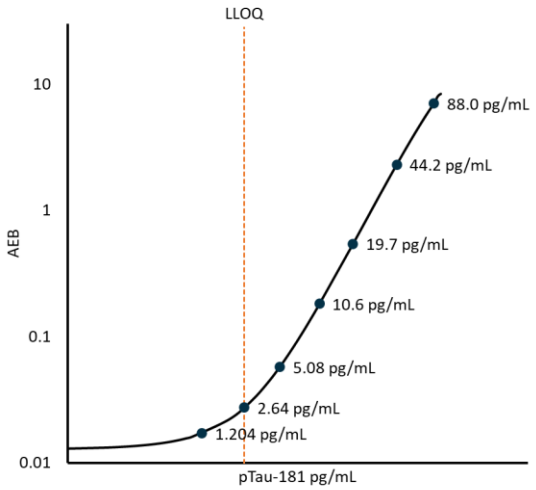
Simoa® pTau-181 Advantage Kit
HD-1/HD-X Data Sheet

Item 103377

Description

Threonine 181 is one of the phosphorylation sites of human tau protein (pTau-181). Tau is a microtubule-stabilizing protein primarily localized in neurons of the central nervous system but also expressed at low levels in astrocytes and oligodendrocytes. Tau consists of six isoforms in the human brain with molecular weights of 48,000 to 67,000 Daltons, depending on isoform. The Simoa pTau-181 assay targets the proline rich region of the Tau protein which is highly conserved amongst these isoforms. Tau elevation is observed in the cerebrospinal fluid (CSF) of patients with neurodegenerative disease and severe head injuries, suggesting its extracellular release during neuronal damage and a role as a biomarker with specificity for brain injury. In Alzheimer's disease (AD) and related neurodegenerative diseases, including chronic traumatic encephalopathy, tau is abnormally phosphorylated and aggregated into bundles of filaments. pTau181 has been found to be more strongly associated with markers of AD than total tau. Both are considered "core" AD biomarkers in CSF that have been successfully validated by controlled large-scale multi-center studies.

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



Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 12 runs each for 2 reagent lots across 2 instruments (12 runs total). Functional LLOQ = Analytical LLOQ x MRD (minimum required dilution).

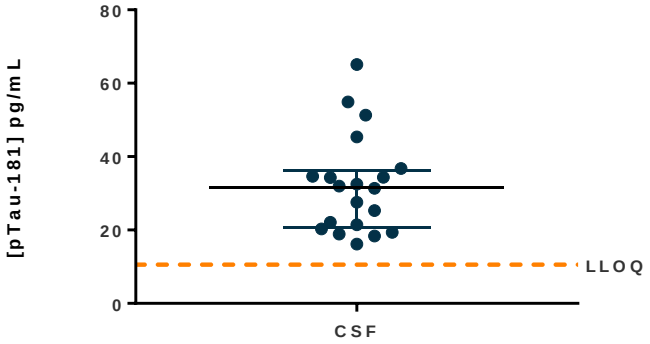
Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 12 runs each for 2 reagent lots across 2 instruments (12 runs total). Functional LOD = Analytical LOD x MRD (minimum required dilution).

MRD (CSF)	4x
Analytical LLOQ*	**2.640 pg/mL** pooled CV 19% mean recovery 110%
Analytical LOD*	**0.724 pg/mL** range 0.250-1.35 pg/mL
Analytical dynamic range*	0 – ~85 pg/mL
Diluted sample volume**	100 µL per measurement
Tests per kit	96

***Analytical LLOQ, LOD or dynamic range must be multiplied by MRD (minimum required dilution) to obtain functional LLOQ, LOD or dynamic range, for comparison to sample concentrations.**

****See Kit Instruction for details**

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



Sample Type	Mean pTau-181 pg/mL	Median pTau-181 pg/mL	% Above LLOQ
CSF	32.1	32.0	100%

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Precision: Measurements of 3 endogenous CSF panels and 2 calibrator-based controls. Triplicate measurements were made for 12 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	20.3	3.6%	3.5%	0.7%	1.6%
Control 2	158	2.2%	2.8%	0.1%	3.0%
Panel 1	32.4	2.6%	3.8%	1.7%	3.8%
Panel 2	39.3	3.1%	4.4%	0.2%	4.1%
Panel 3	22.2	5.0%	4.8%	0.3%	5.3%

Spike and Recovery: 3 CSF samples were spiked at high and low concentrations within the range of the assay and analyzed on HD-1.

Dilution Linearity: 2 CSF samples spiked with recombinant pTau-181 calibrator were diluted 2x serially from MRD (4x) to 128x with Sample Diluent.

Spike and Recovery (CSF)	**Mean = 91%** Range: 71–109%
Dilution Linearity (128x)	**Mean = 101%** Range: 75–137%

The Simoa pTau-181 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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