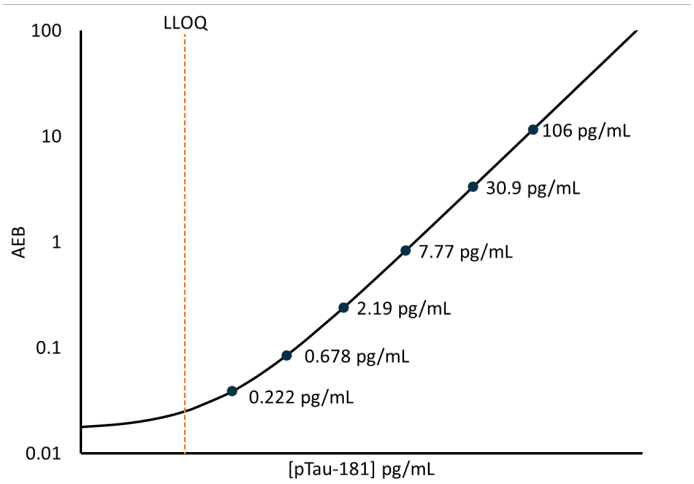
Simoa® pTau-181 Advantage V2 Kit

SR-X Data Sheet Item 103714

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. pTau-181 has been found to be more strongly associated with markers of AD than total tau.

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted (calibrator levels may change for different manufacturing lot).



Minimum Required Dilution (MRD)

Diluted Sample Volume	100 µL per measurement
Serum and Plasma Dilution	1:4
CSF Dilution	1:10
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 12 runs each for 2 reagent lots across 2 instruments (12 runs total). The functional LLOQ (fLLOQ) values below are for serum and plasma. The fLLOQ for CSF is 2.5x the fLLOQ for serum and plasma.

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).

Assay Range: The upper end of the dynamic range is equal to the top calibrator concentration multiplied by MRD. The ranges below are for serum and plasma. The Upper Limit of Quantification (ULOQ) for CSF is 2.5x the ULOQ for serum and plasma.

Analytical LLOQ	**0.085 pg/mL** pooled CV 19.9% mean recovery 100%
Functional LLOQ (serum and plasma)	**0.338 pg/mL**
LOD	**0.041 pg/mL** range 0.018–0.060pg/mL
Dynamic Range (serum and plasma)	0 – 424 pg/mL

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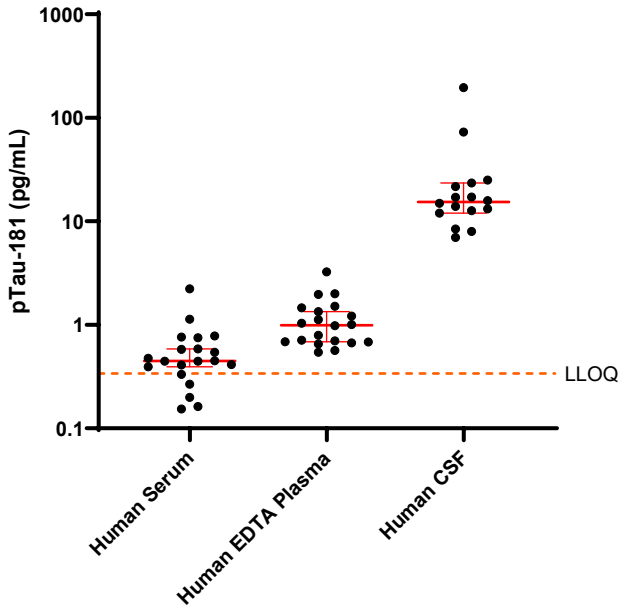
Endogenous Sample Reading: Healthy donor matched human EDTA plasma (n=20) and serum (n=20), and unmatched CSF (n=16) samples were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean pTau-181 pg/mL	Median pTau-181 pg/mL	% Above LOD	% Above LLOQ
Human Serum	0.575	0.448	100%	75%
Human EDTA Plasma	1.14	0.99	100%	100%
Human CSF	29.9	15.4	100%	100%

Precision: Measurements of one spiked serum-based, one endogenous plasma-based, one endogenous CSF-based panels and 2 calibrator-based controls. Triplicate measurements were made for 12 runs each for 2 reagent lot 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	2.89	6.3%	6.4%	3.3%	9.0%
Control 2	44.6	5.4%	8.4%	1.2%	16.1%
Panel 1	0.69	15.1%	18.9%	2.5%	10.4%
Panel 2	1.37	7.4%	10.6%	2.0%	6.4%
Panel 3	2.29	8.8%	8.5%	5.5%	6.6%

Spike and Recovery: 4 serum and 4 EDTA plasma samples were spiked at high and low concentrations within the range of the assay and analyzed on SR-X.

Dilution Linearity (Serum/Plasma): 1 endogenous & 4 spiked serum and 4 endogenous & 4 spiked EDTA plasma samples were diluted 2x serially from MRD (4x) up to 128x with sample diluent.

Dilution Linearity (CSF): 4 endogenous CSF samples were diluted 2x serially from MRD (10x) up to 320x with sample diluent.

Spike and Recovery (Serum)	**Mean 76.2%** range 67.0–87.4%
Spike and Recovery (Plasma)	**Mean 76.9%** range 58.7–90.9%
Dilution Linearity (Endogenous Serum, 32x)	**Mean 113%** range 89.9–128%
Dilution Linearity (Spiked Serum, 128x)	**Mean 113%** range 94.0–128%
Dilution Linearity (Endogenous Plasma, 16x)	**Mean 115%** range 89.0–140%
Dilution Linearity (Spiked Plasma, 64x)	**Mean 114%** range 74.1–145%
Dilution Linearity (Endogenous CSF, 320x)	**Mean 99.1%** range 81.8–124%

The Simoa pTau-181 Advantage V2 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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