Quanterix™
The Science of Precision Health

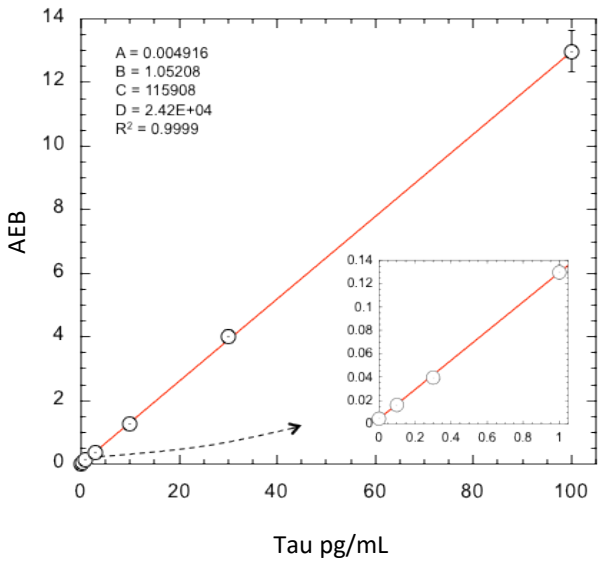
Simoa® Tau Advantage Kit
HD-1/HD-X Data Sheet

Item 101552

Description

Tau is a microtubule-stabilizing protein primarily localized in central nervous system neurons, 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. Tau elevation is observed in the cerebrospinal fluid (CSF) of patients with neurodegenerative disease and head injuries, suggesting its extracellular release during neuronal damage and a role as a biomarker with specificity for brain injury. Potential movement of elevated CSF tau across the blood-brain barrier presents a possibility that measurements of tau in blood could provide a convenient peripheral window into brain/CSF status. Studies of tau in serum and plasma have been hampered by its low abundance (typically low pg/mL), and there are relatively few reports characterizing the appearance of tau in blood or evaluating the usefulness of this biomarker for brain injury assessment. Recent reports using digital immunoassay technology have shown elevation in peripheral tau associated with hypoxic brain injury, concussed hockey players, and repetitive minimal head injury in Olympic boxing. The Simoa™ Human Total Tau assay uses a combination of monoclonal antibodies that react with both normal and phosphorylated tau. With an epitope in the midregion of the molecule, the assay recognizes all tau isoforms.

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



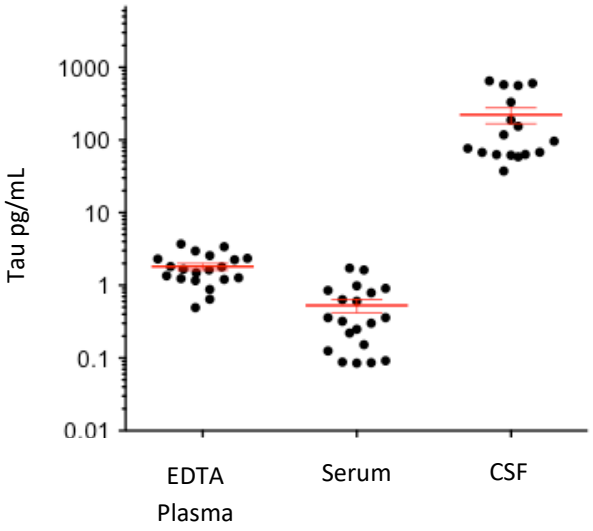
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (12 runs total).

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	**0.062 pg/mL**
LOD	**0.019 pg/mL** range 0.005–0.039 pg/mL
Dynamic range (serum and plasma)	0–360 pg/mL
Diluted Sample volume*	152 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

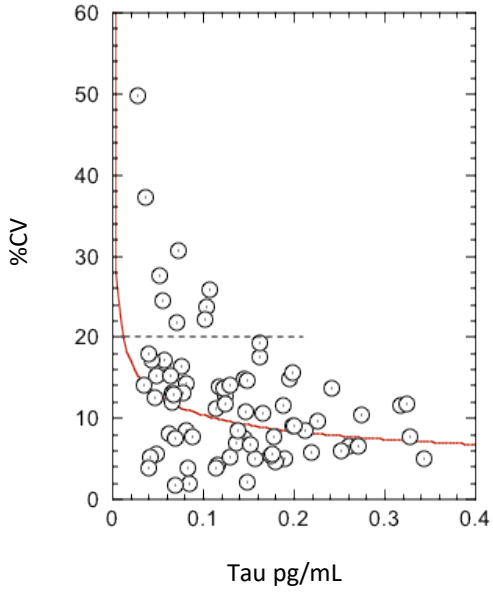
Endogenous Sample Reading: Health donor matched EDTA plasma (n=20) and serum (n=20) samples were measured. 17 CSF samples were measured. Error bars depict mean and SEM.



Quanterix Corporation
900 Middlesex Turnpike, Billerica, MA 01821
techsupport@quanterix.com

Sample Type	Median Tau pg/mL	% Above LOD
EDTA Plasma	1.65	100%
Serum	0.339	100%
CSF	86.4	100%

Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (75 measurements).

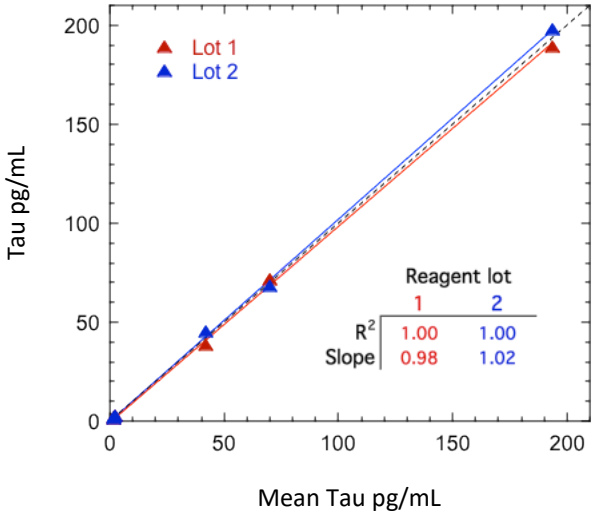


Inter Lot CV: Pool of CVs from 6 samples (range: 1.34-201 pg/mL) tested with 2 reagent lots across 2 runs x 3 instruments.

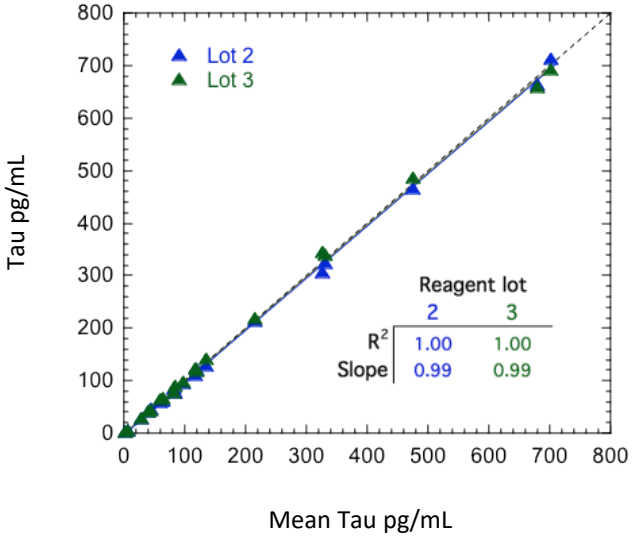
Inter Instrument CV: Pool of CVs from 6 samples (range: 1.34-201 pg/mL) tested with 3 instruments across 2 runs x 2 reagent lots.

Inter Lot CV	**Mean = 7.1%**
Inter Instrument CV	**Mean = 8.6%**

Reproducibility across Lots: Six native and spiked serum and plasma tau samples tested across 2 runs x 3 instruments each lot.

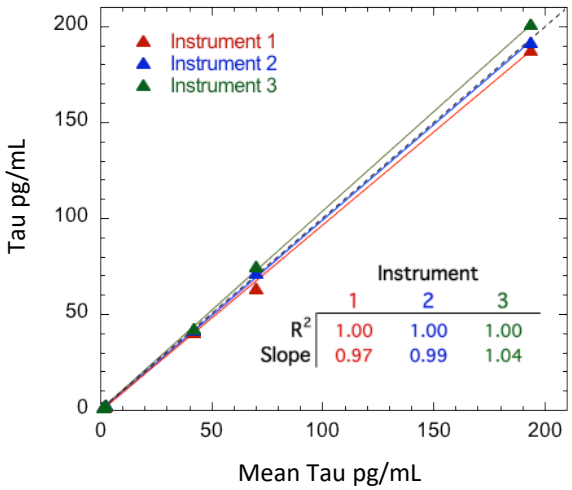


Reproducibility across Lots: 17 spiked and native serum tau samples (range 1.71-487 pg/mL, and 9 CSF samples (range 119-713 pg/mL) tested with 2 reagent lots on a single instrument in a single run.



Quanterix Corporation
900 Middlesex Turnpike, Billerica, MA 01821
techsupport@quanterix.com

Reproducibility across Instruments: Six native and spiked serum and plasma tau samples tested across 2 runs x 2 reagent lots each instrument.



Reproducibility Precision: Six samples consisting of three serum panels, one plasma panel, and two tau controls were assayed in replicates of three for two runs on each of three instruments and two reagent lots. Analysis of variance (nested ANOVA) results are summarized in the following table.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between lot CV	Between instrument CV
Control 1	1.48	6.8%	0.8%	7.3%	6.7%
Control 2	70.2	4.8%	7.1%	0.0%	7.5%
Panel 1*	2.48	8.4%	6.4%	3.5%	14.5%
Panel 2	1.86	8.6%	3.2%	3.4%	6.0%
Panel 3	41.9	7.3%	6.3%	11.3%	0.0%
Panel 4	192	4.5%	7.8%	0.0%	0.0%

*Plasma

Repeatability Precision: Six samples consisting of three serum panels, one plasma panel, and two tau 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 (nested ANOVA) results are summarized in the following table.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between day CV
Control 1	1.43	8.9%	13.9%	0.0%
Control 2	69.5	5.9%	8.7%	3.6%
Panel 1*	2.30	4.1%	4.9%	7.1%
Panel 2	1.79	8.8%	2.1%	4.9%
Panel 3	37.9	4.2%	6.4%	2.3%
Panel 4	192	5.8%	7.3%	4.1%

*Plasma

Spike and Recovery (Serum/Plasma): Tau 441 spiked into 12 samples at 5 and 50 pg/mL.

Spike and Recovery (CSF): Tau 441 spiked into 4 CSF samples at 20 and 200 pg/mL.

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

Dilution Linearity (Serum): Spiked serum serially diluted with Sample Diluent from 4x (MRD) to 128x.

Dilution Linearity (CSF): CSF diluted with Sample Diluent from 10x (MRD) to 640x.

Spike and Recovery (Serum/Plasma)	**Mean = 81.7%** Range: 37.6–128%
Spike and Recovery (CSF)	**Mean = 102%** Range: 91.8–114%
Admixture Linearity	**Mean = 112%** Range: 101–117%
Dilution Linearity (Serum, 128x)	**Mean = 115%** Range: 110–124%
Dilution Linearity (CSF, 640x)	**Mean = 91.8%** Range: 81.6–107%

The Simoa Tau 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.

Quanterix Corporation
900 Middlesex Turnpike, Billerica, MA 01821
techsupport@quanterix.com