Quanterix™
The Science of Precision Health

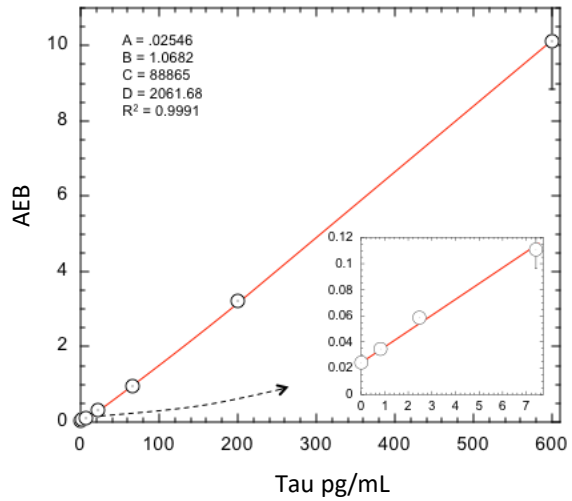
Simoa® Mouse Tau Discovery Kit
HD-1/HD-X Data Sheet

Item 10229

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. The antibodies used in the Simoa mouse Tau Discovery assay recognize epitopes 207–214 and 174–184 of the murine sequence (epitopes 218–225 and 185–195 of the human sequence) as described by J Schelle et al.* Tau elevation is observed in the cerebrospinal fluid (CSF) of patients with neuro-degenerative 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. It is currently unclear whether these tau aggregates are a primary causative factor in the disease etiology. Potential movement of elevated CSF tau across the blood-brain barrier presents a possibility that measuring tau in blood could provide a convenient peripheral window into brain/CSF status.

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



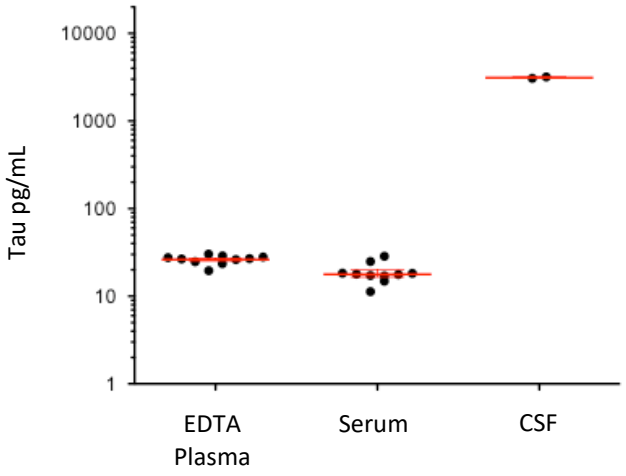
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot across 2 instruments (5 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 1 reagent lot across 2 instruments (5 runs total).

LLOQ	**0.823 pg/mL** pooled CV 11.9% mean recovery 119%
LOD	**0.615 pg/mL** range 0.0228–0.954 pg/mL
Dynamic range (serum and plasma)	0–2400 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	192

***See Kit Instruction for details**

Endogenous Sample Reading: Tau in EDTA plasma (n=10), serum (n=10), and cerebral spinal fluid (CSF, n=2) from non-medicated, non-immunized mice. Error bars depict median and interquartile ranges.



Sample Type	Median Tau pg/mL
EDTA Plasma	26.7
Serum	17.8
CSF	3123

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Precision: Representative precision was estimated with repeated assay of plasma and serum panels using two instruments and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect average CVs across 5 experiments of 3 replicates each.

Sample	Mean (pg/mL)	Within run CV	Between run CV
Plasma Panel 1	22.4	6.8%	8.7%
Serum Panel 2	24.8	8.2%	11.3%
Plasma Panel 3	34.3	6.3%	15.1%
Serum Panel 4	18.2	9.6%	10.4%

Spike and Recovery (Serum): Tau spiked into 4 serum samples at 2 levels.

Dilution Linearity (Serum): Spiked serum diluted 2x serially from MRD (4x) to 256x with Sample Diluent.

Spike and Recovery (Serum)	**Mean = 113.8%** Range: 105.3–134.9%
Dilution Linearity (Serum, 256x)	**Mean = 110.7%** Range: 80.6–130.1%

The Simoa Mouse Tau Discovery 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.