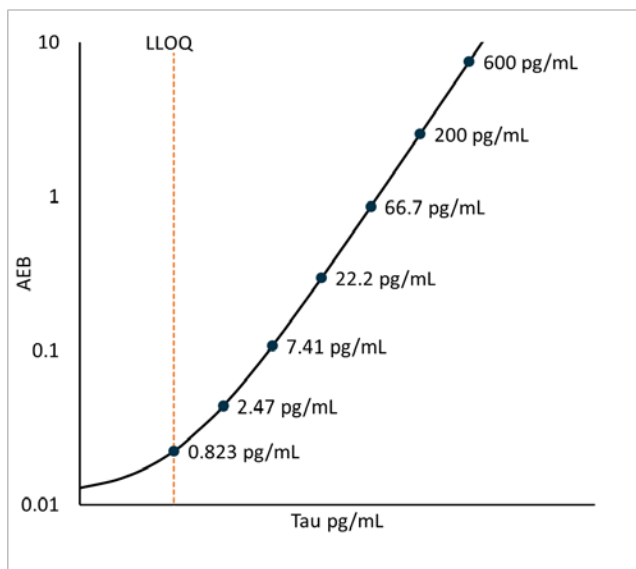


**Description**

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). 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. 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:** Calibrator concentrations and Lower Limit of Quantification depicted.



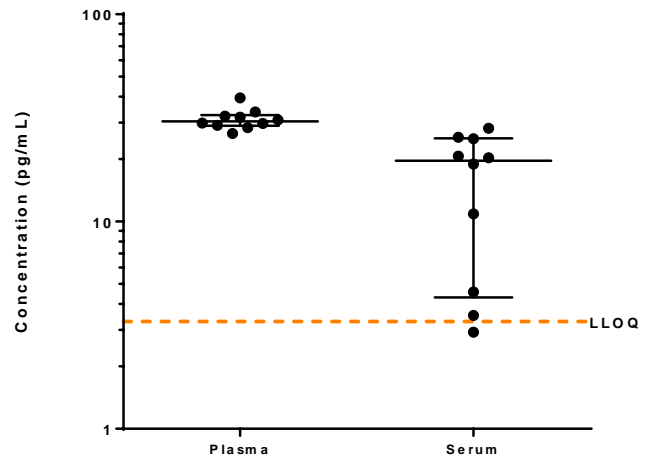
**Lower Limit of Quantification (LLOQ):** Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

**Limit of Detection (LOD):** Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

<b>LLOQ</b>	<b>0.823 pg/mL</b> pooled CV 18% mean recovery 101%
<b>LOD</b>	<b>0.428 pg/mL</b> range 0.023-0.975 pg/mL
<b>Dynamic range (serum and plasma)</b>	0-2.40 ng/mL
<b>Diluted Sample volume*</b>	100 µL per measurement
<b>Tests per kit</b>	192

\* Kit Instruction for details

**Endogenous Sample Reading:** Unmatched mouse EDTA plasma (n=10), and serum (n=10) pools were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean Tau pg/mL	Median Tau pg/mL	% Above LOD
Serum	16.1	19.6	100%
Plasma	31.2	30.4	100%

**Precision:** Measurements of 3 serum and EDTA plasma-based panels and 2 calibrator based controls. Triplicate measurements were made for 6 runs each for 1 reagent lot across 2 instruments (6 runs total, 18 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV
Control 1	20.9	7.8%	7.0%	0.9%
Control 2	720	5.9%	12.0%	11.9%
Panel 1	21.5	8.7%	11.2%	0.5%
Panel 2	12.5	8.7%	10.3%	6.2%
Panel 3	20.2	5.8%	11.0%	6.0%

**Spike and Recovery:** 2 serum and 2 EDTA plasma samples were spiked at high and low concentrations within the range of the assay and analyzed on SR-X.

**Dilution Linearity:** 1 spiked EDTA plasma, 1 endogenous EDTA plasma, 1 spiked serum, and 1 endogenous serum sample were diluted 2x serially from MRD (4x) to 32x with Sample Diluent.

<b>Spike and Recovery (Serum/Plasma)</b>	<b>Mean = 102%</b> Range: 90–109%
<b>Dilution Linearity (32x)</b>	<b>Mean = 120%</b> Range: 91–175%

The Simoa Mouse Tau assay kit is formulated for use on either the SR-X or HD-1 platform. Data in this document was obtained from runs on the SR-X platform unless otherwise noted. Some differences in performance claims between the HD-1 and SR-X may be observed when comparing datasheets for the two 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.