Quanterix
Discovery Fueled by Ultra-Sensitivity

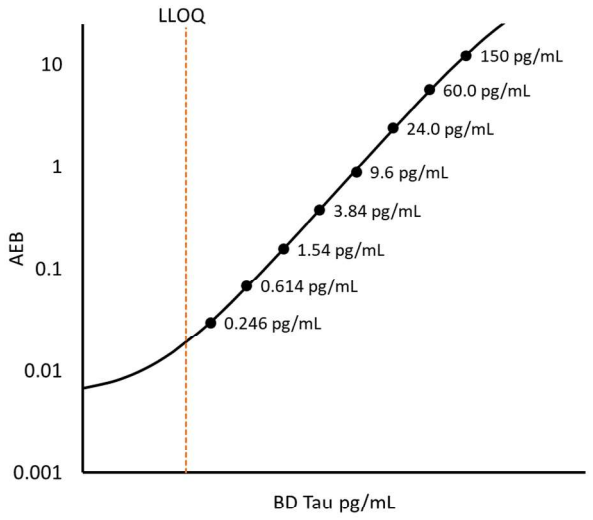
Simoa® BD Tau Advantage PLUS Kit

HD-X Data Sheet Item 104797

Description: This datasheet summarizes data from analytical validation performed at Quanterix to characterize performance of the BD Tau Advantage PLUS kit on the HD-X platform. Data provided includes Calibration Curve, Minimum Required Dilution (MRD), Lower Limit of Qualification (LLOQ), Limit of Detection (LOD), Assay Range, Precision, Spike and Recovery, and Dilution Linearity.

BD-Tau: Brain Derived (BD) Tau has been shown to be a more specific measurement of neurodegenerative disease than total Tau in blood in that it allows for discrimination of brain Tau from those originating from other tissues. Moreover, blood BD-Tau levels correlate with BD-Tau in CSF. BD-Tau is emerging as a blood biomarker that outperforms total Tau and NF-L in distinguishing Alzheimer's disease (AD) from other neurodegenerative diseases. Precise measurement of BD-Tau provides a valuable tool in characterizing the role of BD-Tau in AD and will prove valuable in both diagnostic and clinical trial settings.

Calibration Curve: Representative calibrator concentrations and Lower Limit of Quantification (LLOQ) depicted.



Minimum Required Dilution (MRD)

Diluted Sample Volume	100 µL per measurement
Serum and EDTA Plasma Dilution	1:4
CSF Dilution	1:100
Tests per kit	96

See Kit Instruction for details.

Lower Limit of Quantification (LLOQ): The analytical LLOQ was set at the lowest concentration that read back within 80 – 120% of the expected value with a CV < 20%. The functional LLOQ values below represent the analytical LLOQ multiplied by the dilution factor used for the samples.

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 8 runs across 2 instruments (8 runs total).

Assay Range: The upper end of the dynamic range is equal to the top calibrator concentration multiplied by MRD. The representative ranges below are for serum and EDTA plasma. The Upper Limit of Quantification (ULOQ) for CSF is 25x the ULOQ for serum and EDTA plasma.

Analytical LLOQ	**0.133 pg/mL** Pooled CV: 14.2% Mean Recovery: 96.5%
Functional LLOQ	Serum/EDTA Plasma (4x): 0.533 pg/mL CSF (100x): 13.3 pg/mL
Functional ULOQ	Serum/EDTA Plasma (4x): 600 pg/mL CSF (100x): 15 ng/mL
LOD	**0.044 pg/mL** Range: 0.007 - 0.146 pg/mL
Dynamic Range	Serum/EDTA Plasma (4x): 0 - 600 pg/mL CSF (100x): 0 - 15 ng/mL

Endogenous Sample Reading: Concentrations (pg/mL) for matched serum (n=20), EDTA plasma (n=20) and unmatched CSF (n=20) from normal human donors were sourced from the N4PD Advantage PLUS validation report. Bars depict median with interquartile range. The red lines represent functional LLOQ.

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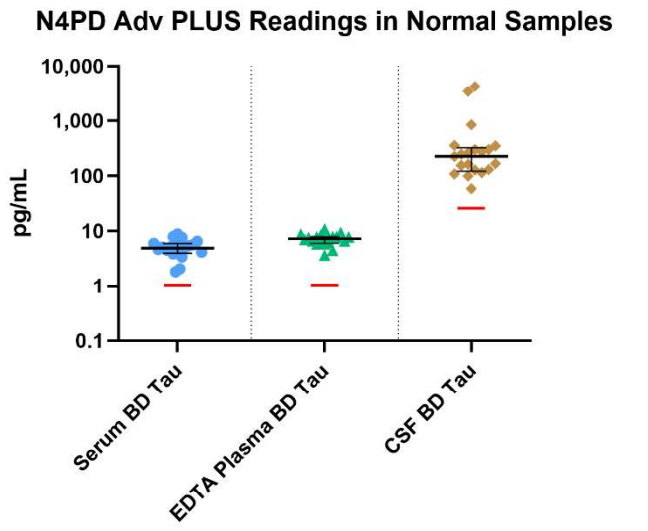

Sample Type	Mean pg/mL	Median pg/mL	% Above LOD	% Above LLOQ
Serum	5.14	5.05	100%	100%
EDTA Plasma	7.22	7.40	100%	100%
CSF	597	236	100%	100%

Precision: Measurements of 2 serum-based panels, 2 EDTA plasma-based panels, 2 CSF-based panels, and 2 calibrator-based controls. Triplicate measurements were made for 8 runs each for across 2 instruments (8 runs total, 24 measurements). All samples were diluted at the appropriate MRD for the sample matrix.

Sample	Mean (pg/mL)	Within Run CV	Between Run CV	Between Lot CV	Between Instr CV
Control 1	8.26	4.4%	11.4%	10.9%	1.2%
Control 2	357	2.3%	9.3%	11.3%	3.9%
Panel 1	16.3	4.0%	7.6%	4.8%	0.3%
Panel 2	142	4.5%	6.2%	3.6%	3.2%
Panel 3	28.2	3.2%	7.0%	5.4%	2.7%
Panel 4	147	4.1%	8.1%	8.0%	0.3%
Panel 5	5456	4.8%	7.0%	7.0%	0.4%
Panel 6	14247	4.3%	7.4%	7.0%	1.5%

Spike and Recovery: 4 serum, 4 EDTA plasma and 4 CSF samples were spiked at low and high concentrations within the range of the assay and analyzed on HD-X. Percent recovery is defined as the difference between the measured concentration in the spiked sample and the measured concentration in unspiked sample relative to the concentration in spiked plasma or CSF sample diluent, respectively.

Dilution Linearity: 4 serum, 4 EDTA plasma, and 4 CSF samples were serially diluted 2x with sample diluent and then tested at MRD. Total dilution of each sample ranged from 4x to 256x and is reported as such. For valid comparison between results, it is recommended to run all samples at a consistent dilution.

Mean Spike and Recovery Serum	**102.9%** Range: 91.6 - 123%
Mean Spike and Recovery EDTA Plasma	**101.5%** Range: 93.2 - 108.7%
Mean Spike and Recovery CSF	**98.3%** Range: 97.1 - 99.6%
Mean Dilution Linearity Serum	**107.8%** Range: 96.7 - 120.2%
Mean Dilution Linearity EDTA Plasma	**102.4%** Range: 94.4 - 111.3%
Mean Dilution Linearity CSF	**109.1%** Range: 107.8 - 110.3%

The Simoa BD Tau Advantage PLUS Assay kit is formulated for use on the HD-X platform. Verification and validation results for the fully automated HD-X instrument are summarized here. Implementing this assay on the SR-X instrument may result in performance differences due to the manual steps involved in reagent preparation incubations, wash steps, and bead loading. Assay protocol may have to be modified to obtain equivalent results.

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