Quanterix™
The Science of Precision Health

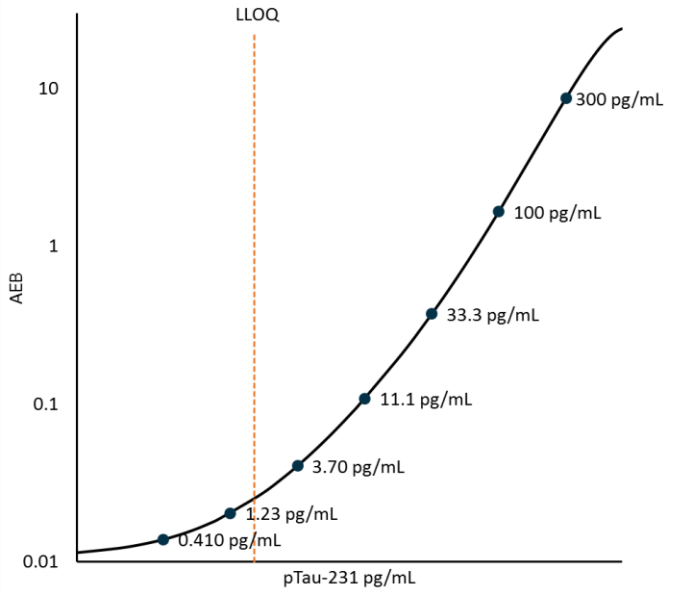
Simoa® pTau-231 Advantage Kit
HD-1/HD-X Data Sheet

Item 102292

Description

Threonine 231 is one of the phosphorylation sites of human tau protein. Tau is a microtubule-stabilizing protein primarily localized in neurons of the central nervous system but is 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 the isoform.[1] Tau elevation is observed in the cerebrospinal fluid (CSF) of patients with neurodegenerative disease[2,3] and severe head injuries[4] suggesting its extracellular release during neuronal damage and its potential role as a specific biomarker for brain injury. In Alzheimer's disease (AD) and related neurodegenerative diseases, including chronic traumatic encephalopathy (CTE), tau is abnormally phosphorylated and aggregated into bundles of filaments.[5] Phosphorylated tau is believed to be a more relevant biomarker for Alzheimer's disease. Tau phosphorylated at threonine 231 has been shown to differentiate Alzheimer's disease from healthy controls.[6]

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted.



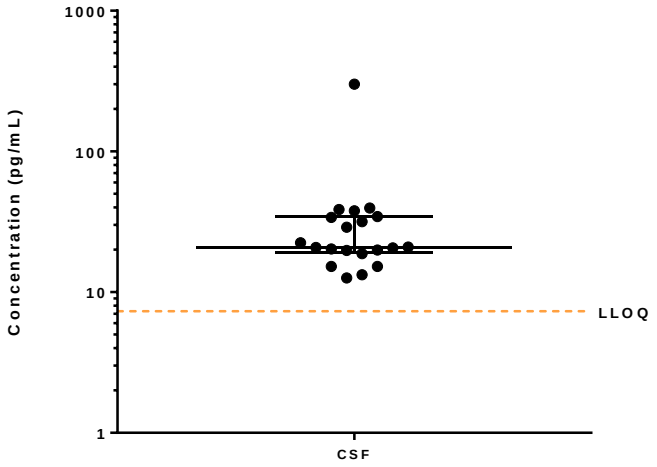
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 12 runs total over 2 reagent lots across 2 instruments.

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 total over 2 reagent lots across 2 instruments.

LLOQ	**1.83 pg/mL** pooled CV 15% mean recovery 111%
LOD	**0.621 pg/mL** range 0.109-1.850 pg/mL
Dynamic range (CSF)	0 - ~1200 pg/mL
Diluted Sample volume*	152 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

Endogenous Sample Reading: No diagnosis individual patients were measured (CSF, n=20). Bars depict median with interquartile range. Orange line represents functional LLOQ.



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Sample Type	Mean pTau-231 pg/mL	Median pTau-231 pg/mL	% Above LLOQ
CSF	38.3	20.8	100%

Precision: Measurements of 2 calibrator-based controls, 1 serum and 1 plasma panel spiked with recombinant antigen, and 2 endogenous CSF panels. Triplicate measurements were made for 12 runs total over 2 reagent lots across 2 instruments.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV	Between Lot CV
Control 1	12.4	10.5%	7.0%	1.4%	0.2%
Control 2	382	1.8%	2.6%	0.5%	1.2%
Panel 1	20.4	7.2%	7.3%	4.6%	2.3%
Panel 2	17.0	7.1%	8.2%	1.1%	3.9%
Panel 3	47.9	4.7%	5.6%	2.2%	3.4%
Panel 4	81.3	2.3%	6.9%	3.6%	4.9%

Spike and Recovery: 2 CSF samples were spiked at ~10x mean normal sample concentration reading within the range of the assay and analyzed on HD-1.

Dilution Linearity: 2 CSF samples (spiked with recombinant antigen) were diluted 2x serially from MRD (4x) to 256x with Sample Diluent.

Spike and Recovery (CSF)	**Mean = 111%** Range: 110-113%
Spiked Dilution Linearity (256x)	**Mean = 90%** Range: 81–97%

The Simoa pTau-231 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.

References

1. Avila J, Lucas JJ, Perez M, Hernandez F. Role of tau protein in both physiological and pathological conditions. Physiol Rev 2004; 84:361–84.

2. Kapaki E, Kilidireas K, Paraskevas GP, Michalopoulou M, Patsouris E. Highly increased CSF tau protein and decreased β-amyloid (1–42) in sporadic CJD: a discrimination from Alzheimer's disease? J Neurol Neurosurg Psychiatry 2001; 71:401–403.

3. Tapiola T, Alafuzoff I, Herukka SK, Parkkinen L, Hartikainen P, Soininen H, Pirttilä T. Cerebrospinal fluid β-amyloid 42 and tau proteins as biomarkers of Alzheimer-type pathologic changes in the brain. Arch Neurol 2009; 66:382– 89.

4. Franz G, Beer R, Kampfl A, Engelhardt K, Schmutzhard E, Ulmer H, et al. Amyloid beta 1-42 and tau in cerebrospinal fluid after severe traumatic brain injury. Neurology 2003; 60(9):1457–61.

5. Iqbal K, Liu F, Gong CX, Grundke-Iqbal I. Tau in Alzheimer disease and related tauopathies. Curr Alzheimer Res 2010 Dec; 7(8):656–64.

6. Hampel H, Blennow K, Shaw LM, et al. Total and Phosphorylated Tau Protein as Biological Markers of Alzheimer's Disease. Exp Gerontol. 2010. 45(1): 30.

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