

SPLASH™ Kit: BD pTau-217 Singleplex

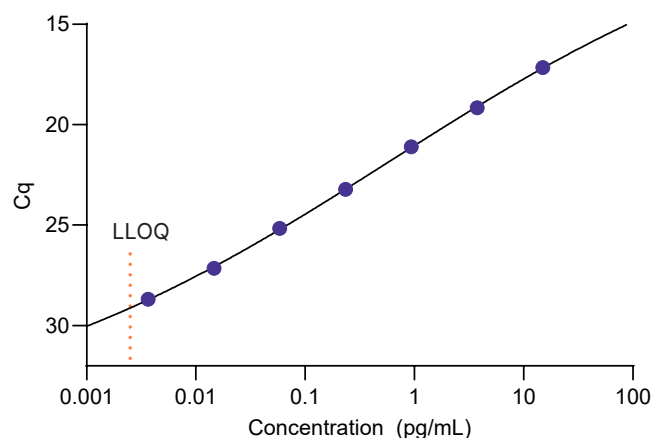
P/N: TSK-00012

Description

This data sheet summarizes the analytical validation performed at Taudia to characterize the performance of the SPLASH Kit: BD pTau-217 Singleplex on a conventional qPCR instrument. Please see below for more details or reach out to hello@taudia.com for any questions.

Calibration Curve

A representative calibration curve is shown below using a four parameter logistic regression (4PL). The lower limit of quantification (LLOQ) is depicted in orange.



Assay Sensitivity and Range

Lower limit of quantification (LLOQ): Six replicates of serially diluted standard material were read back on the calibration curve over three runs. The LLOQ value for each run was determined as the lowest concentration that read back between 80% and 120% of the expected value and had a %CV lower than 20%. The overall LLOQ was determined as the median value across the three runs. fLLOQ is the LLOQ multiplied by the dilution factor

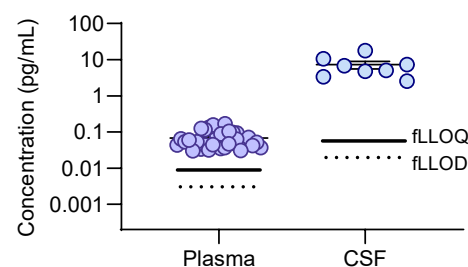
Lower limit of detection (LLOD): 15 replicates of sample buffer were read back on the calibration curve over three runs. The LLOD value for each run was determined as the 2.5 times the standard deviation of the background values above the mean background value. The overall LLOD was determined as the median value across the three runs.

Assay range: The assay range is determined as the functional LLOD (fLLOD) to 4X the highest standard point.

Specification	Plasma	CSF
Dilution factor	4X	25X
Sample volume per rxn	12.5 µL	2 µL
Sample quantifiability	100%	100%
LLOD (pg/mL)	0.0008	
LLOQ (pg/mL)	0.0025	
Assay range	0.003 - 80 pg/mL	

Endogenous Sample Reading

Human EDTA plasma (n=24) and CSF (n=8) from apparently healthy donors (aged 55+) were tested in triplicate. Plasma samples were diluted 4X and CSF was diluted 25X. Bars depict median with interquartile range. Solid lines show fLLOQ; dotted lines show functional lower limit of detection (fLLOD).

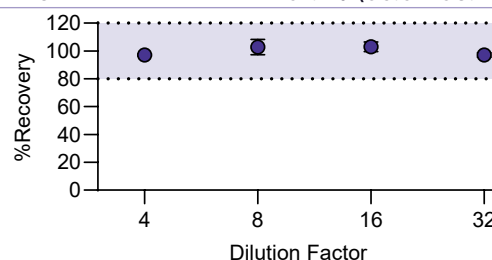


	Mean (pg/mL)	% Above fLLOQ
Plasma	0.068	100%
CSF	7.294	100%

Dilution Linearity

2 EDTA plasma samples from apparently healthy donors were serially diluted 4x to 32x. Percent recovery was calculated as the measured sample concentration divided by the expected concentration.

Dilution	% Recovery
4x	97.1% (96.6 - 97.5%)
8x	102.9% (99.0 - 106.8%)
16x	103.0% (100.6 - 105.4%)
32x	97.1% (95.9 - 98.2%)



Precision

4 replicates of 2 EDTA plasma samples were tested across three individual runs of the assay. The intra-run %CV values across the three runs and 2 samples were averaged to determine the intra-run %CV. The inter-run %CV was determined as the %CV of the average values for each of the 3 runs and 2 samples.

	Average Conc. (pg/mL)	Intra-Run (%CV)	Inter-Run (%CV)
BD pTau-217	0.0542	2.95%	2.20%

