TAUDIA

Data Sheet
TDS-00004 | Rev. A.0

SPLASH™ Kit: NfL Singleplex

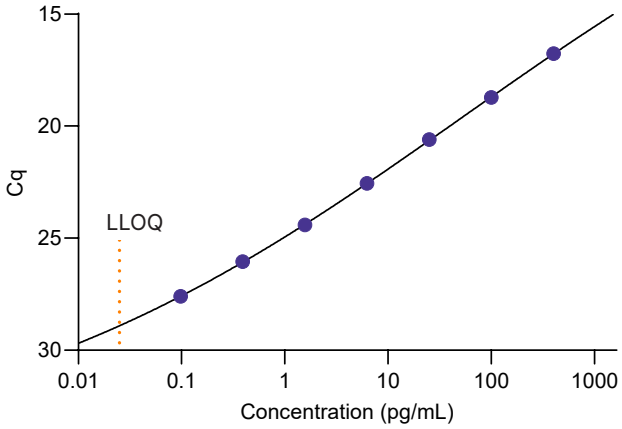
P/N: TSK-00004 and TSK-00016

Description

This data sheet summarizes the analyticlal validation performed at Taudia to characterize the performance of the SPLASH Kit: NfL 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 six 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 six runs. fLLOQ is the LLOQ multiplied by the dilution factor

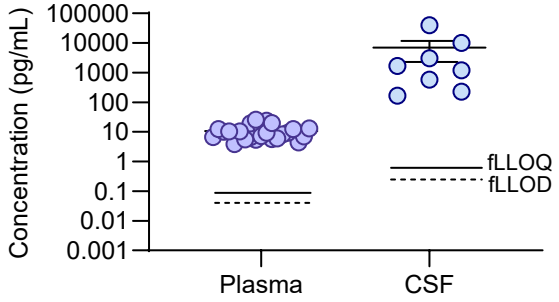
Lower limit of detection (LLOD): 15 replicates of sample buffer were read back on the calibration curve over six runs. The LLOD value for each run was determined as the 2.5 times the standard deviation of the background values above the mean background value. The overall LLOD was determined as the median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

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

Spike and recovery: 2 EDTA plasma samples were spiked at low and high concentrations within the range of the assay. Spike recovery is defined as the concentration difference between the measured concentration in the spiked sample and the unspiked sample relative to the spiked concentration in sample buffer. The average value of the spike recovery across the two spike concentrations and two samples is reported.

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).

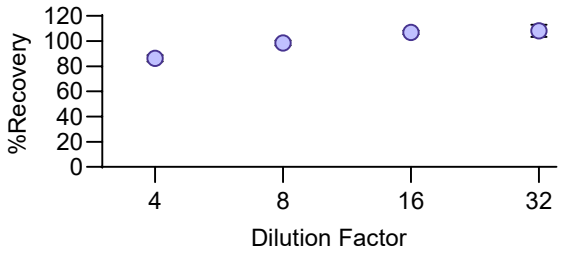


	Mean (pg/mL)	% Above fLLOQ
Plasma	10.78	100%
CSF	7055.15	100%

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	86.4% (78.7 - 96.4%)
8x	98.5% (94.2 - 106.0%)
16x	106.9% (101.7 - 112.3%)
32x	108.3% (90.7 - 119%)



Specification	Plasma	CSF
Dilution factor	4X	25X
Sample volume per rxn	12.5 µL	2 µL
Sample quantifiability	100%	100%
LLOD (pg/mL)	0.011	
Functional LLOQ (pg/mL)	0.10	0.63
Assay range	0.044 - 1600 pg/mL	
Spike and recovery	121.7%	