

SPLASH™ Kit: AD 5-plex

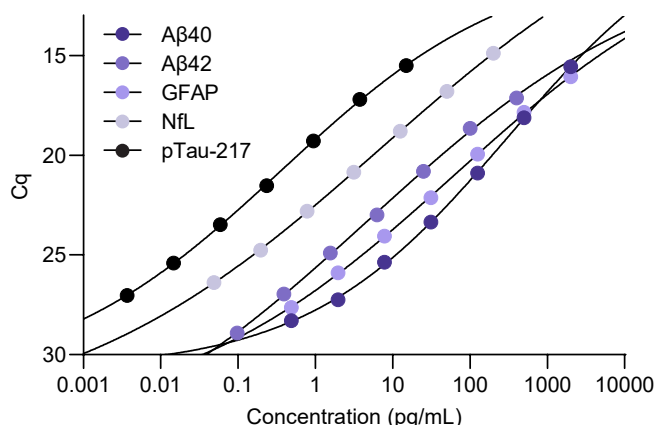
P/N: TSK-00010

Description

This data sheet summarizes the analytical validation performed at Taudia to characterize the performance of the SPLASH Kit: AD 5-plex 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).



Assay Specifications

More details are listed on the next page.

Specification	Plasma	CSF
Dilution factor	4X	25X
Sample volume per rxn	12.5 μ L	2 μ L
Sample quantifiability	100%	100%

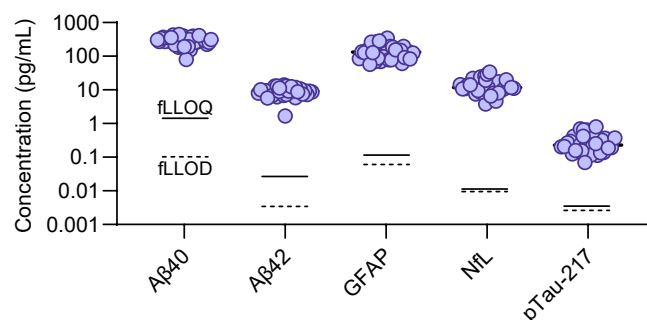
LLOD (pg/mL)	A β 40	0.124
	A β 42	0.007
	GFAP	0.079
	NfL	0.018
	pTau-217	0.0007

LLOQ (pg/mL)	A β 40	1.063
	A β 42	0.038
	GFAP	0.125
	NfL	0.019
	pTau-217	0.0009

Assay Range in Plasma (pg/mL)	A β 40	0.494 - 8000
	A β 42	0.028 - 1600
	GFAP	0.316 - 8000
	NfL	0.071 - 800
	pTau-217	.003 - 60

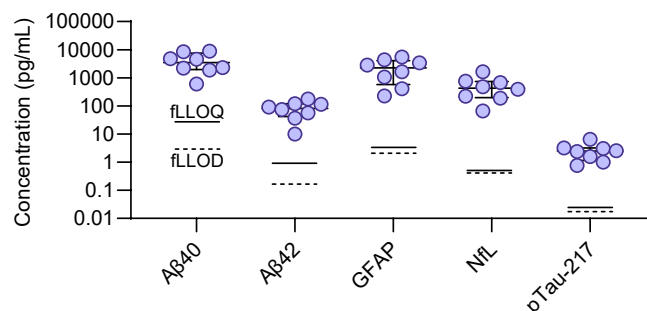
Endogenous Sample Reading

Human EDTA plasma (n=35) were tested in triplicate. Plasma samples were diluted 4X. Bars depict median with interquartile range. Solid lines show fLLOQ; dotted lines show functional lower limit of detection (fLLOD).



	Mean (pg/mL)	% Above fLLOQ
A β 40	290.91	100%
A β 42	9.34	100%
GFAP	142.41	100%
NfL	13.50	100%
pTau-217	0.292	100%

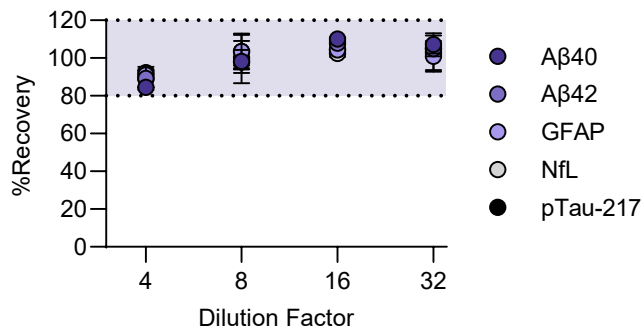
Human CSF (n=8) were tested in triplicate. Plasma samples were diluted 4X. Bars depict median with interquartile range. Solid lines show fLLOQ; dotted lines show functional lower limit of detection (fLLOD). The pTau-217 fLLOQ (0.023 pg/mL) and fLLOD (0.017 pg/mL) are not shown.



	Mean (pg/mL)	% Above fLLOQ
A β 40	4229.60	100%
A β 42	84.78	100%
GFAP	2436.77	100%
NfL	549.95	100%
pTau-217	2.642	100%

Parallelism

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	Aβ40 % Recovery
4x	84.6% (84.4 - 84.7%)
8x	98.2% (93.9 - 102.5%)
16x	110.1% (109.4 - 110.8%)
32x	107.2% (103.7 - 110.6%)

Dilution	Aβ42 % Recovery
4x	89.3% (84.9 - 93.7%)
8x	97.8% (89.8 - 105.8%)
16x	107.9% (107.2 - 108.5%)
32x	105.1% (102.1 - 108.0%)

Dilution	GFAP % Recovery
4x	91.2% (89.7 - 92.6%)
8x	103.6% (97.3 - 109.8%)
16x	104.4% (104.0 - 104.8%)
32x	100.9% (95.7 - 106.1%)

Dilution	NfL % Recovery
4x	92.3% (91.0 - 93.6%)
8x	100.0% (97.1 - 102.9%)
16x	102.5% (102.2 - 102.8%)
32x	105.2% (103.9 - 106.5%)

Dilution	pTau-217 % Recovery
4x	89.0% (85.7 - 92.2%)
8x	103.4% (96.6 - 110.2%)
16x	104.7% (101.8 - 107.6%)
32x	103.0% (95.8 - 110.1%)

Precision

4 replicates of 2 EDTA plasma samples were tested across three individual runs of the assay. The average concentration and the %CV was calculated for each sample in each run. 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)
Aβ40	84.25	5.1%	6.7%
Aβ42	3.145	5.3%	2.7%
GFAP	50.05	3.5%	4.5%
NfL	10.21	3.3%	3.4%
pTau-217	0.153	5.0%	9.9%

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.