SPEAR UltraDetect™ BD-pTau 217

Item SPR90027 Datasheet

Description

SPEAR UltraDetect™ BD-pTau 217 (Brain Derived Tau phosphorylated at threonine 217) was analytically verified for use in human EDTA plasma specimens.**

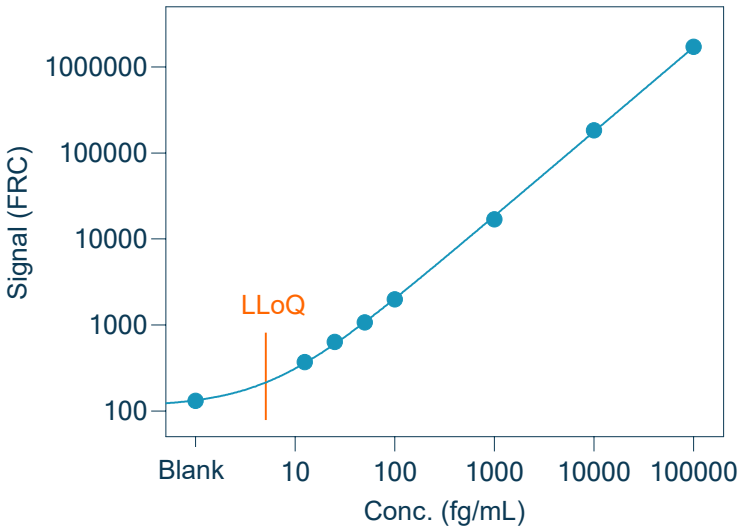
Assay Sensitivity and Range

Lower limit of detection (LLoD) was calculated as 2.5x standard deviations added to the mean blank. Lower limit of quantification (LLoQ) was calculated as lowest concentration with mean CV under 20% and 80-120% recovery. Results were generated from a minimum of 6 independent runs.

Specification	Result
Analytical LLoD (range)	2.6 fg/mL (1.6 – 3.8)
Functional LLoD	10.4 fg/mL
Analytical LLoQ	6.3 fg/mL
Functional LLoQ	25.0 fg/mL
Minimum required dilution (MRD)	4x
Functional Assay Range	25.0 – 400000 fg/mL

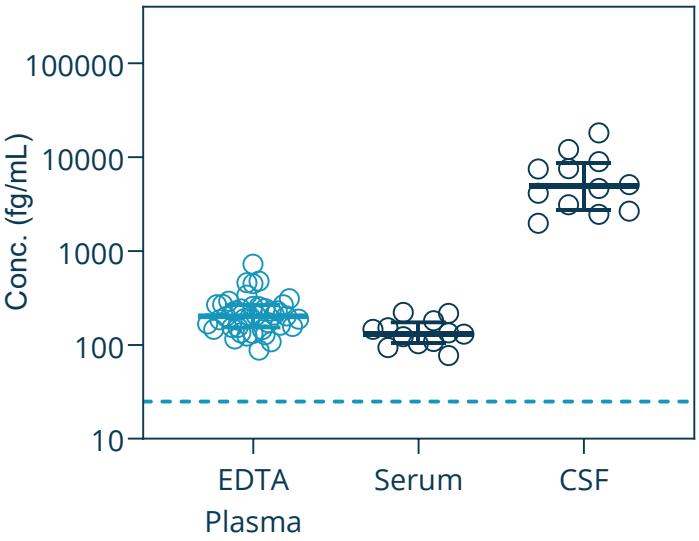
Calibration Curve

Representative calibration curve fitted with 4PL $1/y^2$ weighting. Analytical LLoQ is indicated in orange.



Endogenous Levels

Human EDTA plasma, serum*, and CSF* from apparently healthy donors were tested. All samples were diluted 4x. Medians with interquartile ranges are shown for each specimen type with functional LLoQ depicted as dashed horizontal line.



Sample Type (donors)	Mean Conc. (range)	Above LLoD %	Above LLoQ %
EDTA Plasma (40 donors)	230 fg/mL (88.3 - 725)	100%	100%
Serum* (12 donors)	140 fg/mL (76.8 – 222)	100%	100%
CSF* (12 donors)	6536 fg/mL (1972 – 18216)	100%	100%

*Endogenous levels for Serum and CSF were tested for reference only. Full verification of assay performance is recommended before using these matrices in studies.

**All data shown were generated in 384-well runs with F.A.S.T. workflow and qPCR amplification on QuantStudio instruments.

Spike Recovery

To assess the selectivity of the assay, EDTA plasma samples from apparently healthy donors (n = 3) were spiked with calibrator at low, medium, and high concentrations (respective to endogenous levels and assay dynamic range) and diluted at MRD. Percent recovery was calculated as the endogenous-subtracted spiked sample concentration divided by the measured concentration of the spike material.

Sample Type (donors)	Spike Conc.	Mean Recovery (Range)	Recovery
EDTA Plasma (3 donors)	Low	116% (108 - 121%)	121%
	Med	122% (117 - 127%)	
	High	124% (119 – 131%)	

Dilution Linearity

To assess the accuracy of the assay, EDTA plasma samples from apparently healthy donors (n = 3) were spiked with calibrator and serially diluted 2x to 16x above assay MRD. Percent recovery was calculated as the sample concentration at higher dilution divided by the sample concentration at MRD.

Sample Type (donors)	Dilution	Mean Recovery (Range)	Recovery
EDTA Plasma (3 donors)	2x	101% (100 - 102%)	88.5%
	4x	91.6% (87.9 – 94.6%)	
	8x	83.1% (79.5 – 90.1%)	
	16x	78.3% (74.6 – 83.9%)	

Precision

Unspiked EDTA plasma or EDTA plasma spiked with CSF or calibrator, representing six different analyte concentrations were run in duplicates per run across a minimum of 6 runs to assess intra- and inter-assay precision.

Sample Type	Conc. fg/mL	Mean Intra-assay CV (range)	Inter-assay CV
EDTA Plasma	909	3.4% (0.3 – 7.5%)	5.7%
	1096	1.6% (0.3 – 3.9%)	6.9%
	5301	2.2% (0.9 – 2.9%)	4.3%
	10283	3.8% (0.1 – 6.7%)	5.4%
	9965	2.8% (1.1 – 4.2%)	6.2%
	14705	1.5% (0.2 – 4.1%)	4.1%

Specificity & Interference

Similar proteins were evaluated for cross-reactivity at 25x the top calibrator concentration and potential interference at 2x endogenous levels. No significant cross-reactivity or interference was observed for:

- BD-Tau (no phosphorylation at threonine 217)

Potential interference was evaluated at low, medium, and high biologically relevant levels for hemoglobin (Hb), triglycerides (TG), conjugated bilirubin (CB), and unconjugated bilirubin (UB). Table below shows the highest concentration at which no significant interference was observed with percent difference from vehicle reported.

Potential Interferent & Conc.		EDTA Plasma % diff.
Hb	High conc. 400 mg/dL	-18.2%
TG	High conc. 500 mg/dL	0.0%
CB	High conc. 2.5 mg/dL	-4.4%
UB	High conc. 2.5 mg/dL	-7.3%

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