



Biomarker Qualification Sheet

Qualified Imperacer® Assay for the Quantification of Human Tau Protein (pTau) in Human Plasma

Human Tau Protein (pTau):

The human tau protein (pTau) stabilizes microtubules and is expressed in neurons, astrocytes and oligodendrocytes. Phosphorylation on site 181 (pTau 181) is associated with Alzheimer's Disease (AD), even stronger than total tau. Abnormal phosphorylation leads to aggregation and is seen in AD and chronic traumatic encephalopathy. Elevated pTau levels in CSF are observed in patients with neurodegenerative diseases and severe head injuries, which makes it interesting as a potential biomarker.

Table 1: Assay setup

Analyte:	Human Tau Protein (pTau)
Platform:	Imperacer® (Immuno-PCR)
Matrix:	Human plasma
Status:	Qualified

Table 2: Assay details

Lower limit of quantification:	4 pg/ml
Upper limit of quantification:	8,748 pg/ml
Assay range:	4 – 8,748 pg/ml
Minimum required dilution:	1:2
Minimum sample volume:	35 µl