

Lumipulse® G Total Tau

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Chapter 1: Name

Chapter 2: Intended use

Chapter 3: Summary and explanation of the assay

AD, the most common form of dementia, is a neurodegenerative disorder histologically characterized by the accumulation of extracellular amyloid plaques and intracellular neurofibrillary tangles throughout the cortical and limbic brain regions. The ultrastructure of neurofibrillary tangles is made up of paired helical filaments composed mainly of abnormally hyperphosphorylated Tau protein (P-Tau). The major components of the amyloid deposits are the 40- and 42-amino acid-long β -amyloid peptides, which are derived from integral membrane-bound amyloid precursor protein.^[1] This assay is designed to detect total Tau. This peptide is a neuronal protein which binds to microtubules in the neuronal axons, thereby promoting microtubule assembly and stability. The combination of decreased concentrations of β -amyloid1-42 and increased CSF concentrations of total Tau and P-Tau are considered to be a pathological CSF biomarker signature that is diagnostic for AD.^[2,3,4] Total Tau can also be substantially increased in certain conditions like stroke and Creutzfeldt-Jakob's disease.^[5, 6, 7]

Chapter 4: Principle of the procedure

Chapter 5: Materials provided

Chapter 6: Materials provided separately

Chapter 7: Materials not provided but required

Chapter 8: Warnings and precautions

Safety precautions

Precautions for handling

Precautions for use

Precautions for waste

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Chapter 12: Specimen collection and preparation

Chapter 13: Assay procedure

Chapter 14: Calibration

Chapter 15: Results

Chapter 16: Quality control

Quality control material preparation

Quality control procedure

Chapter 17: Limitations of the procedure

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Sensitivity

Interference

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High dose hook

Measurement comparison

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