Information Sheet

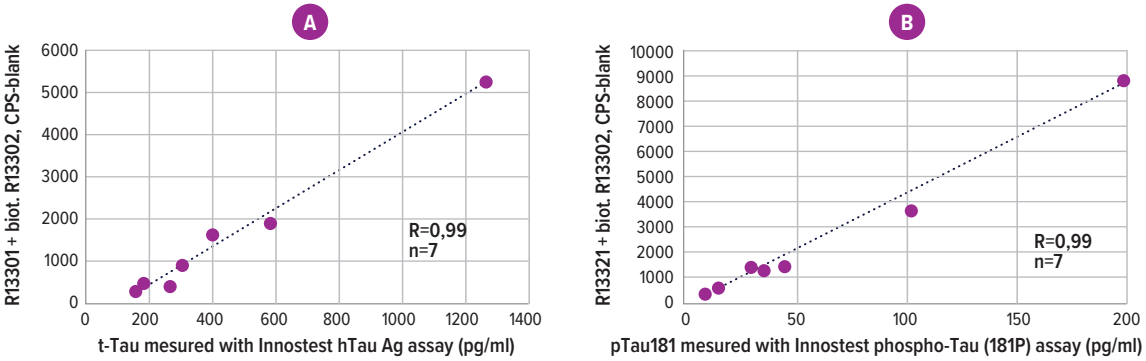
Alzheimer's Disease: Immunoassay Biomarkers

Tau and Amyloid-beta proteins as key diagnostic tools

Alzheimer's disease (AD), responsible for over 50% of global dementia cases, is a progressive neurodegenerative condition impacting several cognitive behaviors including memory and speech. There are currently 55 million dementia cases globally, and this number is projected to rise to 139 million by 2050. Early diagnosis using Amyloid-beta and Tau protein markers, as recommended by the NIA-AA, aids in managing the disease[1-3].

Tau proteins in the neurons of the central nervous system (CNS) help stabilize axonal microtubules. Hyperphosphorylated Tau loses this ability, leading to neurofibrillary tangle (NFT) formation. Key phosphorylation sites for AD markers are p-Tau181, p-Tau231, and p-Tau217. Elevated cerebrospinal fluid (CSF) total Tau is a marker for neuronal degeneration which correlates with NFT stage and load in AD. When detecting total Tau in blood samples for neurodegenerative disorder diagnosis, specificity to the CNS-derived Tau form is crucial, as is excluding larger isoforms from the peripheral nervous system[4-5].

Medix Biochemica has developed high sensitivity recombinant antibodies that enable total Tau and p-Tau detection from CSF samples.



A. Total Tau detection from CSF clinical samples using Medix Biochemica antibody pair R13301+R13302 showed good correlation to Fujirebio's Innotest hTau Ag assay. B. p-Tau181 detection from CSF clinical samples using Medix Biochemica antibody pair R13321+R13302 showed good correlation to Fujirebio's Innotest Phospho Tau 181 (181P) assay.

Amyloid-beta (Aβ) peptides are produced by the cleavage of amyloid precursor protein into extracellular space. Aβ1-42 is the predominant form linked to Alzheimer's disease (AD) and due to it's sticky nature it forms amyloid plaques in the brain, a hallmark of AD pathology. Decreased levels of Aβ1-42 in cerebrospinal fluid (CSF) or blood are evident in AD and can aid in diagnosing the disease, when normalized with the levels of Aβ1-40 or total Tau[4].

Available neurology related analytes:

- NfL
- Alpha-synuclein
- S100B
- GFAP
- UCH-L1

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Pair recommendations

			Detection		
			R13301	R13302	R13303
Capture	(t-Tau)	R13301		■	■
	(t-Tau)	R13302	■		■
	(t-Tau)	R13303	■	■	
	(p-Tau181)	R13321	■	■	■

Coming soon in 2024

- CNS specific Tau and p-Tau217
- Amyloid-beta 1-40 & 1-42
- GFAP

Products and Ordering

Tau antibodies

Product Code	Description	Subclass
140036	*Pre-launch samples:* Anti-h p-Tau231 R13322 SPTN-5	IgG_1
140037	Anti-h p-Tau181 R13321 SPTN-5	IgG_1
140038	Anti-h Tau R13301 SPTN-5	IgG_1
140039	Anti-h Tau R13302 SPTN-5	IgG_1
140040	Anti-h Tau R13303 SPTN-5	IgG_1

Medix Biochemica offers Tau antibodies with:

- Proven detection from CSF samples
- Detection of total Tau (in CSF), p-Tau181 and p-Tau231 forms
- Sensitivity of ~100 pg/mL for Tau and ~10 pg/mL for p-Tau181
- Good correlation to established tests

Related biospecimens

Product Code	Description
991-19-S	Cerebrospinal Fluid - Single Donors
991-19-P	Cerebrospinal Fluid - Pooled Donors
991-24-S-ALZ	Serum - Alzheimer's Disease
991-58-S-ALZ	Plasma - Alzheimer's Disease
991-24-S-PD	Serum - Parkinson's Disease
991-58-S-PD	Plasma - Parkinson's Disease
991-24-S-MCI	Serum - Mild Cognitive Impairment
991-24-S-MS	Plasma - Mild Cognitive Impairment
991-58-S-MS	Serum - Multiple Sclerosis
991-58-S-MS	Plasma - Multiple Sclerosis

Medix Biochemica provides a wide selection of high-quality antibodies and biospecimen materials to support diagnosis of AD and other neurological disorders. We also offer a broad range of antibodies related to diagnosis in several other clinical areas.

References

1. Masters C, Bateman R, Blennow K et al. (2015). Alzheimer's disease. Nat Rev Dis Primers Oct 15:1:15056.
2. Hansson O, Seibyl J, Stomrud E et al. (2018). CSF biomarkers of Alzheimer's disease concord with amyloid-β PETand predict clinical progression: A study of fully automated immunoassays in BioFINDER and ADNI cohorts. Alzheimers Dement. 14:1470-1481.
3. Alzheimer's disease | Alzheimer's Disease International (ADI) (alzint.org). Accessed 13.10.2023
4. Milà-Alomà, M, Ashton NJ, Shekari M. et al.(2022). Plasma p-tau231 and p-tau217 as state markers of amyloid-β pathology in preclinical Alzheimer's disease. Nat Med 28:1797–1801.
5. Andersen E, Casteigne B, Chapman W et al. (2021). Diagnostic biomarkers in Alzheimer's disease. Biomarkers in Neuropsychiatry 5.

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