Quanterix

Plasma pTau181



Simoa[®] technology enables breakthrough research.

In late 2021, Quanterix announced that its Simoa[®] phospho-Tau 181 (pTau181) blood test was granted **Breakthrough Device Designation by the U.S. Food and Drug Administration** (FDA) as an aid in diagnostic evaluation of Alzheimer's Disease (AD). A distiction not shared by any other company

This designation is a major milestone for AD research and underscores the potential of the Simoa technology to revolutionize AD research and help bring much needed clarity to what has been a very complex and difficult disease to diagnose.

The need for a more sensitive method of measuring pTau181, a critical biomarker associated with Alzheimer's Disease (AD), is becoming increasingly important as we continue to see a rise in this disease worldwide. Researchers globally have demonstrated that the Simoa pTau181 assay by Quanterix plays a pivotal role in the pursuit of breakthroughs in early detection and prevention of AD.

QUANTERIX OFFERS THE FOLLOWING OPTIONS BASED ON YOUR RESEARCH NEEDS.

- Purchase assay Simoa 181 assay kits, available on either the HD-X or SR-X testing platforms
- · Submit samples to our Accelerator Laboratory for analysis
- Partner with us to customize your own pTau181 assay that suit your research goals

SIM a technology systems

The Quanterix SR-X™:

The first benchtop instrument to offer true multiplex detection at both acute and baseline levels.





The Simoa HD-X Analyzer™:

Delivering fully-automated ultra sensitive biomarker detection you can count on.

Visit quanterix.com for more information



For more information or scan the QR code with your smart phone camera to be directed to a complete archive of publications.

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Quanterix provides industry leading ultrasensitive biomarker detection devices and technology. Our Simoa precision instruments, wide-ranging menu of assay kits, and custom assay development services empower researchers to bring new discoveries in disease and treatment to the forefront and help transform the future of healthcare.

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Simoa pTau181 assay has powered more than 60 peer-reviewed publications on the alone in 2022

Diagnostic and prognostic value of serum NfL and p-Tau(181) in frontotemporal lobar degeneration.

Journal of neurology, neurosurgery, and psychiatry. doi:10.1136/jnnp-2020-323487

Individualized prognosis of cognitive decline and dementia in mild cognitive impairment based on plasma biomarker combinations.

Nature Aging. 2020/11/30 2020 doi:10.1038/s43587-020-00003-5

Plasma phosphorylated tau181 and

neurodegeneration in Alzheimer's disease. Annals of clinical and translational neurology. doi:10.1002/acn3.51253

Diagnostic performance and prediction of clinical progression of plasma phospho-tau181 in the Alzheimer's Disease Neuroimaging Initiative. Molecular psychiatry.

doi:10.1038/s41380-020-00923-z

Head-to-head comparison of clinical performance of CSF phospho-tau T181 and T217 biomarkers for Alzheimer's disease diagnosis.

Alzheimer's & dementia : the journal of the Alzheimer's Association. 2020;doi:10.1002/alz.12236

Blood phosphorylated tau 181 as a biomarker for Alzheimer's disease: a diagnostic performance and prediction modelling study using data from four prospective cohorts.

The Lancet Neurology. doi:10.1016/s1474-4422(20)30071-5

Plasma p-tau181 accurately predicts Alzheimer's disease pathology at least 8 years prior to post-mortem and improves the clinical characterisation of cognitive decline.

Acta neuropathologica. doi:10.1007/s00401-020-02195-x

Time course of phosphorylated-tau181 in blood across the Alzheimer's disease spectrum.

Brain : a journal of neurology. doi:10.1093/brain/awaa399

Plasma phospho-tau181 in presymptomatic and symptomatic familial Alzheimer's disease: a longitudinal cohort study.

Molecular psychiatry. doi:10.1038/s41380-020-0838-x

Use of plasma biomarkers for AT(N)

classification of neurodegenerative dementias. Journal of neurology, neurosurgery, and psychiatry.

doi:10.1136/jnnp-2021-326603

Effects of pre-analytical procedures on blood biomarkers for Alzheimer's pathophysiology, glial activation, and neurodegeneration.

Alzheimer's & dementia (Amsterdam, Netherlands). doi:10.1002/dad2.12168

Clinical and analytical comparison of six Simoa assays for plasma P-tau isoforms P-tau181, P-tau217, and P-tau231.

Alzheimers Res Ther. doi:10.1186/s13195-021-00939-9

Association of Apolipoprotein Eɛ4 Allele With Clinical and Multimodal Biomarker Changes of Alzheimer Disease in Adults With Down Syndrome.

JAMA Neurol. doi:10.1001/jamaneurol.2021.1893

Differences Between Plasma and Cerebrospinal Fluid Glial Fibrillary Acidic Protein Levels Across the Alzheimer Disease Continuum.

JAMA Neurol. doi:10.1001/jamaneurol.2021.3671

Diagnostic and prognostic plasma biomarkers for preclinical Alzheimer's disease.

Alzheimer's & dementia : the journal of the Alzheimer's Association. doi:10.1002/alz.12447

Longitudinal plasma phosphorylated tau 181 tracks disease progression in Alzheimer's disease.

Translational psychiatry. doi:10.1038/s41398-021-01476-7

Plasma P-tau181 to A β 42 ratio is associated with brain amyloid burden and hippocampal atrophy in an Asian cohort of Alzheimer's disease patients with concomitant cerebrovascular disease.

Alzheimer's & dementia : the journal of the Alzheimer's Association. doi:10.1002/alz.12332

Plasma neurofilament light and phosphorylated tau 181 as biomarkers of Alzheimer's disease pathology and clinical disease progression.

Alzheimers Res Ther. doi:10.1186/s13195-021-00805-8

Plasma p-tau(181) shows stronger network association to Alzheimer's disease dementia than neurofilament light and total tau.

Alzheimer's & dementia : the journal of the Alzheimer's Association. doi:10.1002/alz.12508

Water exchange rate across the blood-brain barrier is associated with CSF amyloid- β 42 in healthy older adults.

Alzheimer's & dementia : the journal of the Alzheimer's Association. doi:10.1002/alz.12357 Association of Plasma p-tau181 and p-tau231 Concentrations With Cognitive Decline in Patients With Probable Dementia With Lewy Bodies. JAMA Neurology.

doi:10.1001/jamaneurol.2021.4222

Associations of Fully Automated CSF and Novel Plasma Biomarkers With Alzheimer Disease Neuropathology at Autopsy.

Neurology. doi:10.1212/wnl.000000000012513

Characterization of Alzheimer's tau biomarker discordance using plasma, CSF, and PET. Alzheimers Res Ther. doi:10.1186/s13195-021-00834-3

Large-scale plasma proteomic profiling identifies a high-performance biomarker panel for Alzheimer's disease screening and staging.

Alzheimer's & dementia : the journal of the Alzheimer's Association. doi:10.1002/alz.12369

Population-based blood screening for preclinical Alzheimer's disease in a British birth cohort at age 70.

Brain : a journal of neurology. doi:10.1093/brain/awaa403

Biomarker-Based Prediction of Longitudinal Tau Positron Emission Tomography in Alzheimer Disease.

JAMA Neurol. doi:10.1001/jamaneurol.2021.4654

Blood-brain barrier breakdown in relationship to Alzheimer and vascular disease.

Ann Neurol. doi:10.1002/ana.26134

Phosphorylated tau181 in plasma as a potential biomarker for Alzheimer's disease in adults with Down syndrome.

Nature communications. doi:10.1038/s41467-021-24319-x

A genome-wide association study of plasma phosphorylated tau181.

Neurobiology of aging. doi:10.1016/j.neurobiolaging.2021.04.018

Plasma levels of phosphorylated tau 181 are associated with cerebral metabolic dysfunction in cognitively impaired and amyloid-positive individuals.

Brain Communications. doi:10.1093/braincomms/fcab073 Comparison of Plasma Phosphorylated Tau Species With Amyloid and Tau Positron Emission Tomography, Neurodegeneration, Vascular Pathology, and Cognitive Outcomes.

JAMA Neurology. doi:10.1001/jamaneurol.2021.2293



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Longitudinal Associations of Blood Phosphorylated Tau181 and Neurofilament Light Chain With Neurodegeneration in Alzheimer Disease.

JAMA Neurol. doi:10.1001/jamaneurol.2020.4986

Tau PET correlates with different Alzheimer's disease-related features compared to CSF and plasma p-tau biomarkers.

EMBO molecular medicine. doi:10.15252/emmm.202114398

Cohort Analysis of the Association of Delirium Severity with Cerebrospinal Fluid Amyloid-Tau-Neurodegeneration Pathologies.

J Gerontol A Biol Sci Med Sci. doi:10.1093/gerona/glab203

Novel genetic variants in MAPT and alterations in tau phosphorylation in amyotrophic lateral sclerosis post-mortem motor cortex and cerebrospinal fluid. Brain Pathol.

doi:10.1111/bpa.13035

Associations of longitudinal plasma p-tau181 and NfL with tau-PET, A β -PET and cognition.

Journal of neurology, neurosurgery, and psychiatry. doi:10.1136/jnnp-2020-325537

Plasma phosphorylated-tau181 as a predictive biomarker for Alzheimer's amyloid, tau and FDG PET status.

Translational psychiatry. doi:10.1038/s41398-021-01709-9

Reducing acetylated tau is neuroprotective in brain injury.

Cell. doi:10.1016/j.cell.2021.03.032

Heterogeneity in α-synuclein fibril activity correlates to disease phenotypes in Lewy body dementia. Acta neuropathologica.

doi:10.1007/s00401-021-02288-1

Plasma neurofilament L to amyloid β42 ratio in differentiating Alzheimer's type from non-Alzheimer's dementia: A cross-sectional pilot study from India.

Asian Journal of Psychiatry. doi:https://doi.org/10.1016/j.ajp.2021.102914

The Japan-Multimodal Intervention Trial for Prevention of Dementia (J-MINT): The Study Protocol for an 18-Month, Multicenter, Randomized, Controlled Trial.

The Journal of Prevention of Alzheimer's Disease. doi:10.14283/jpad.2021.29

Association of plasma P-tau181 with memory decline in non-demented adults.

doi:10.1093/braincomms/fcab136

Plasma pTau181 predicts cortical brain atrophy in aging and Alzheimer's disease. Alzheimers Res Ther.

doi:10.1186/s13195-021-00802-x

Detection of β -amyloid positivity in Alzheimer's Disease Neuroimaging Initiative participants with demographics, cognition, MRI and plasma biomarkers.

Brain Communications. doi:10.1093/braincomms/fcab008

Development of a Plasma Biomarker Diagnostic Model Incorporating Ultrasensitive Digital Immunoassay as a Screening Strategy for Alzheimer Disease in a Chinese Population. Clin Chem.

doi:10.1093/clinchem/hvab192

Plasma biomarker profiles and the correlation with cognitive function across the clinical spectrum of Alzheimer's disease. Alzheimers Res Ther doi:10.1186/s13195-021-00864-x

Association between polygenic risk score of Alzheimer's disease and plasma phosphorylated tau in individuals from the Alzheimer's Disease Neuroimaging Initiative. Alzheimers

doi:10.1186/s13195-020-00754-8

Cerebrospinal fluid p-tau231 as an early indicator of emerging pathology in Alzheimer's disease. EBioMedicine.

doi:10.1016/j.ebiom.2022.103836

The accuracy and robustness of plasma biomarker models for amyloid PET positivity. Alzheimer's Research & Therapy. doi:10.1186/s13195-021-00942-0

Two Randomized Phase 3 Studies of

Aducanumab in Early Alzheimer's Disease. The Journal of Prevention of Alzheimer's Disease. doi:10.14283/jpad.2022.30

Differential levels of plasma biomarkers of neurodegeneration in Lewy body dementia, Alzheimer's disease, frontotemporal dementia and progressive supranuclear palsy.

Journal of neurology, neurosurgery, and psychiatry. doi:10.1136/jnnp-2021-327788

Blood amyloid and tau biomarkers as predictors of cerebrospinal fluid profiles.

J Neural Transm (Vienna). doi:10.1007/s00702-022-02474-9

Crosswalk study on blood collection-tube types for Alzheimer's disease biomarkers.

Alzheimer's & dementia (Amsterdam, Netherlands) doi:10.1002/dad2.12266

Comparing the effect of xenon and sevoflurane anesthesia on postoperative neural injury biomarkers: a randomized controlled trial. Med Gas Res. doi:10.4103/2045-9912.324591

Plasma p-tau231, p-tau181, PET biomarkers and cognitive change in older adults. Ann Neurol.

Ann Neurol. doi:10.1002/ana.26308

CSF biomarkers and plasma p-tau181 as predictors of longitudinal tau accumulation: Implications for clinical trial design.

Alzheimer's & dementia: the journal of the Alzheimer's Association. doi:10.1002/alz.12570

Plasma phosphorylated-tau181 levels reflect white matter microstructural changes across Alzheimer's disease progression.

Metabolic Brain Disease. doi:10.1007/s11011-022-00908-7

Plasma α-synuclein and phosphorylated tau 181 as a diagnostic biomarker panel for de novo Parkinson's Disease.

Journal of neurochemistry. doi:10.1111/jnc.15601

Plasma biomarkers for Alzheimer's Disease in relation to neuropathology and cognitive change.

Acta neuropathologica. doi:10.1007/s00401-022-02408-5

ASIC-E4: Interplay of Beta-Amyloid, Synaptic Density and Neuroinflammation in Cognitively Normal Volunteers With Three Levels of Genetic Risk for Late-Onset Alzheimer's Disease - Study Protocol and Baseline Characteristics.

Frontiers in neurology. doi:10.3389/fneur.2022.826423

N-terminal and mid-region tau fragments as fluid biomarkers in neurological diseases.

Brain : a journal of neurology. doi:10.1093/brain/awab481

Association of plasma biomarkers, p-tau181, glial fibrillary acidic protein, and neurofilament light, with intermediate and long-term clinical Alzheimer's disease risk: Results from a prospective cohort followed over 17 years.

Alzheimer's & dementia: the journal of the Alzheimer's Association. doi:10.1002/alz.12614

A Longitudinal Study of Plasma pTau181 in Mild Cognitive Impairment with Lewy Bodies and Alzheimer's Disease.

Movement disorders: official journal of the Movement Disorder Society. doi:10.1002/mds.28994

Tissot C, Therriault J, Kunach P, et al. Comparing tau status determined via plasma pTau181, pTau231 and [18F]MK6240 tau-PET. eBioMedicine. 2

doi:https://doi.org/10.1016/j.ebiom.2022.103837

Examining the association between blood-based biomarkers and human post mortem neuropathology in the University of Kentucky Alzheimer's Disease Research Center autopsy cohort.

Alzheimer's & Dementia. doi:https://doi.org/10.1002/alz.12639

