



MAYO CLINIC
LABORATORIES

Dementia testing

Empowering research and
the development pipeline

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An urgent challenge

The medical toll of managing the physical and mental manifestations of Alzheimer's disease is tremendous, and the need for new treatments has never been greater.

60–80%

of dementia patients have Alzheimer's disease¹

1 in 3

seniors worldwide die with dementia¹

\$2.8T

estimated global financial burden of Alzheimer's disease and related dementias²

Empowering research

Amyloid deposition is typically a requirement for many dementia-related clinical trials. Testing for cerebrospinal fluid biomarkers to identify brain amyloid pathology has been the standard for detection. These tests can have drawbacks: **cost, patient health risks due to the invasive nature of specimen collection, and lack of access to a facility and/or clinician to perform the specimen collection.**

New laboratory tests for Alzheimer's disease blood-based biomarkers that have high concordance to amyloid PET allow clinicians and investigators to more accurately diagnose mild cognitive impairment (MCI) and dementia due to Alzheimer's disease, simplifying clinical trial design, recruitment, and research.

90%
of physicians agree that diagnosing MCI due to Alzheimer's disease is important³

51%
of physicians report MCI due to Alzheimer's disease being difficult to diagnose³



A proactive approach

The discovery that **phosphorylated Tau proteins in the blood** can identify brain amyloid pathology propelled the development of plasma-based biomarker testing. Accurate answers simplify and accelerate clinical research.

Fast time to results

Cost savings

Noninvasive

Improved accuracy

Professor of Laboratory Medicine and Pathology Alicia Algeciras-Schimmich, Ph.D., and clinical laboratory technician Meaghan Kroska examine tubes of patient plasma samples before processing.

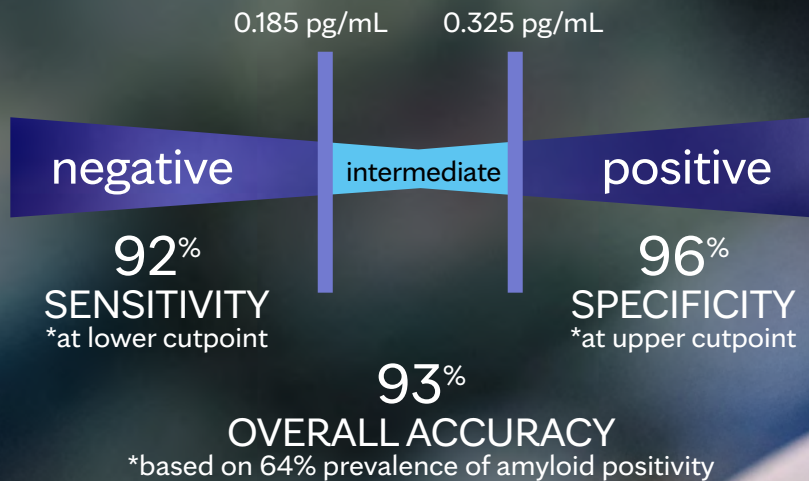


Innovating at the edge of discovery

Mayo Clinic Laboratories' plasma biomarker testing uses the clinically supported p-Tau217 protein to identify A β pathology. Research has revealed that p-Tau217 exhibits high diagnostic accuracy in predicting A β positivity.⁴

Our **p-Tau217 plasma biomarker assay** is just one of our innovative tests available to support biomarker-driven therapeutic research and development.

Two-cutpoint result interpretation



The highest level of diagnostic accuracy

This test uses a two-cutpoint model that provides the highest diagnostic accuracy for result interpretation.

Using **two cutpoints enables increased sensitivity and specificity and overall greater accuracy** than single cutpoint testing.⁵

Groundbreaking collaborations

With physician scientists actively engaged in research into new Alzheimer's disease-related biomarkers, we are uniquely positioned to understand the testing needs of the research community and provide expert insights to support the development of relevant assays. Our team of internationally recognized dementia testing experts can:

- Consult on the development of new tests to support specific research initiatives.
- Provide custom validation on new biomarker assays.
- Offer early insights into industry innovation and unique access to expertise from collaborations with IVD partners.





Comprehensive dementia testing

Our Alzheimer's disease and dementia test menu includes the most clinically relevant biomarkers available. Our testing, which provides rapid results, accelerates research with the industry's most dynamic dementia testing menu.

- **Turnaround time difference**
- **Competitive price vs. amyloid PET scan**
- **More accessible than amyloid PET scan**

Broad array of biomarker analysis

Plasma-based biomarker testing menu

Platform: Fujirebio Lumipulse

BIOMARKER	UTILITY
Aβeta 42/40 ratio	Core biomarker of Alzheimer's disease This test includes the reporting of single biomarkers (Aβeta 42 and Aβeta 40)
Glial fibrillary acidic protein (GFAP)	Biomarker of astrocyte activation
Neurofilament light chain (NfL)	Biomarker of axonal damage and neurodegeneration
Phosphorylated Tau 181 (p-Tau181)	Core biomarker of Alzheimer's disease
Phosphorylated Tau 217 (p-Tau217)	Core biomarker of Alzheimer's disease
p-Tau217/βeta-amyloid 1-42 ratio	Core biomarker of Alzheimer's disease

CSF-based biomarker testing menu

Platform: Fujirebio Lumipulse or Roche Cobas

BIOMARKER	PLATFORM	UTILITY
Aβeta 42/40 ratio	Fujirebio Lumipulse	Core biomarker of Alzheimer's disease
p-Tau181/Aβeta42 ratio with total Tau	Roche Cobas	Core biomarker of Alzheimer's disease This test includes the reporting of single ratio biomarkers (p-Tau181 and Aβeta42) as well as total Tau
Neurofilament light chain (NfL)	Fujirebio Lumipulse	Biomarker of axonal damage and neurodegeneration
Total Tau (t-Tau)	Fujirebio Lumipulse	Biomarker of neurodegeneration
p-Tau181	Fujirebio Lumipulse	Core biomarker of Alzheimer's disease

Susan Ashrafzadeh Kian, a clinical laboratory technician, prepares serum samples for plasma biomarker testing in the Clinical Immunoassay Laboratory at Mayo Clinic.



One-stop testing solution

Mayo Clinic Laboratories BioPharma Diagnostics’ industry-leading test menu for dementias and other neurodegenerative disorders supports a wide range of neurology research.

RAPID PROGRESSIVE DEMENTIA	GENETIC ASSOCIATIONS	NEURODEGENERATION BIOMARKERS	DEMENTIA WITH LEWY BODIES
Rapidly progressive dementia (Mayo ID: RPDE)	Apolipoprotein E genotyping (Mayo ID: APOEG)	Neurofilament light chain (NFL) (Mayo ID: NFLP)	Alpha-synuclein biomarker testing (Mayo ID: ASYNC)
Creutzfeldt-Jakob disease (Mayo ID: CJDE)	Notch3 full gene analysis (Mayo ID: NTC3Z)	Glial fibrillar acidic protein (Mayo ID: BGFAP)	
	C9orf72 hexanucleotide analysis (Mayo ID: C9ORF)		
	Frontotemporal dementia and amyotrophic lateral sclerosis, 50-gene panel (Mayo ID: AFTDP)		
	Single gene testing (APP, PSEN1, PSEN2)		

A large, close-up photograph of a woman's face, focusing on her eyes and forehead. She has brown hair and is looking directly at the camera with a slight smile.

Unmatched expertise and experience

The collaboration of Mayo Clinic Laboratories with the Mayo Clinic Behavioral Neurology practice enables the development of the most clinically relevant tests. Our dementia physicians, laboratory scientists, and genetic counselors are available to collaborate on clinical studies.

Access the industry's most sophisticated dementia test menu.



Alicia Algeciras-Schimnich, Ph.D., Professor of Laboratory Medicine and Pathology and co-director of the Clinical Immunoassay Laboratory at Mayo Clinic Laboratories



References

¹2024 Alzheimer's disease facts and figures. *Alzheimers Dement*. 2024 May;20(5):3708-3821. doi:10.1002/alz.13809. Epub 2024 Apr 30. PMID: 38689398; PMCID: PMC11095490. ²Wong W. Economic burden of Alzheimer's disease and managed care considerations. *Am J Manag Care*. 2020;26:S177-S183. <https://doi.org/10.37765/ajmc.2020.88482> ³Alzheimer's disease facts and figures. Alzheimer's Association. 2022 Alzheimer's Disease Facts and Figures. <https://www.alz.org/alzheimers-dementia/facts-figures> ⁴Ashton NJ, Brum WS, Di Molfetta G, et al. Diagnostic accuracy of a plasma phosphorylated tau 217 immunoassay for Alzheimer disease pathology. *JAMA Neurol*. 2024 Mar 1;81(3):255-263. doi:10.1001/jamaneurol.2023.5319. PMID: 38252443; PMCID: PMC10804282. ⁵Therriault J, Brum WS, Trudel L, et al. Blood phosphorylated tau for the diagnosis of Alzheimer's disease: a systematic review and meta-analysis. *Lancet Neurol*. Sep 2025;24(9):740-752. doi:10.1016/S1474-4422(25)00227-3



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