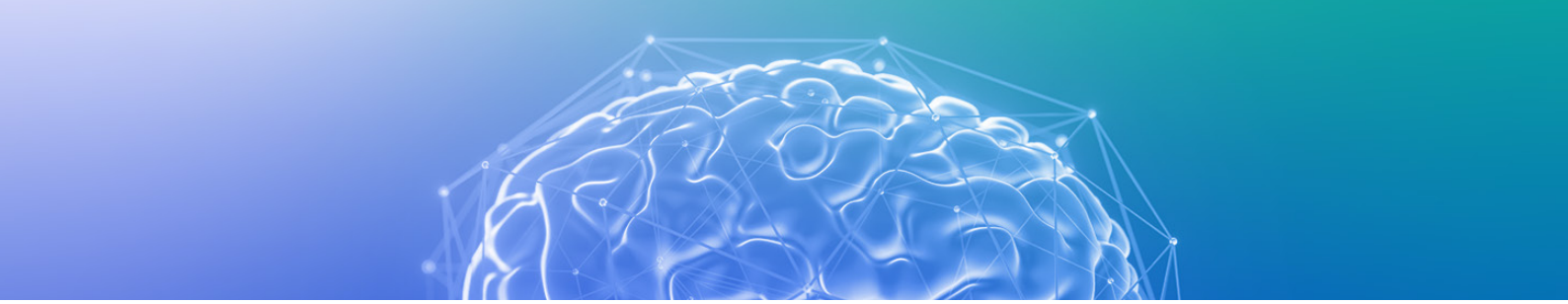
Elecsys® Phospho-Tau (217P) Plasma

The power of ONE assay.
Redefining Alzheimer's diagnosis.



Elecsys® Phospho-Tau (217P) Plasma

The power of ONE assay: standalone, real-world clinically validated, IVD-cleared blood test with a unified dual-cut-off designed to rule-in and rule-out Alzheimer's-associated amyloid pathology across settings.[1,2]

Alzheimer's disease (AD) is a progressive, neurodegenerative disease associated with cognitive dysfunction and behavioural impairments. It represents the most common form of dementia, contributing to at least 60 % of cases.[2] The accumulation of β-amyloid and tau are regarded as one of the earliest signs of the AD pathological cascade, taking place decades earlier prior to symptom onset.[3–5]

It has been demonstrated that Tau phosphorylation at threonine 217 occurs as a reaction to amyloid-β plaques and thus is closely linked to amyloid-β pathology.[6] Specifically, it has been shown that pTau217 levels rise closer to the time when amyloid-β plaques become detectable by positron emission tomography (PET) imaging than to the time when neurofibrillary tangles (NFT) are detectable.[6–8] Therefore, pTau217 has been proposed as a marker of amyloid-β proteinopathy.[9]

The pTau217 blood-based biomarker is considered a core one diagnostic biomarker in the Alzheimer's Association research framework[10]; the International Working Group considers the pTau217 biomarker as one of the most specific for AD pathology.[7]

pTau217 is an accurate blood-based biomarker with strong potential to improve routine clinical diagnosis of AD, particularly as an initial screening or triage test before confirmatory CSF (Cerebrospinal Fluid) or PET testing.[10]

Elecsys® Phospho-Tau (217P) Plasma redefines the current diagnosis of Alzheimer's disease

Elecsys® pTau217 is the best performing plasma assay in terms of detection of amyloid pathology (ROC AUC analysis)[11]

Accurate and robust

- Clinically validated, IVD-cleared, real-world / routine samples
- High performance across diverse populations

Simplicity across settings

- Simple "draw and go" sample handling without pre-analytical limitations
- Standalone assay with unified dual cut-off across primary and secondary care settings

Enhanced clarity

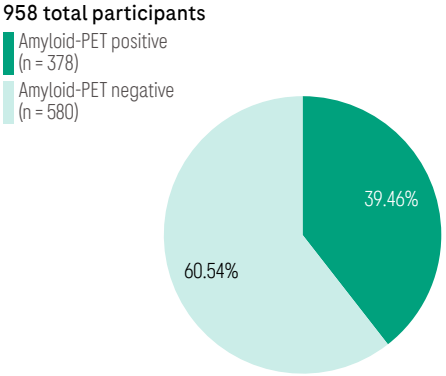
- Allowing targeted CSF and PET testing to effectively identify amyloid pathology[7–9]
- Supporting diagnosis of early stages of AD for improved treatment options

IVD: In Vitro Diagnostics; ROC: Receiver Operating Characteristic; AUC: Area Under the Curve.

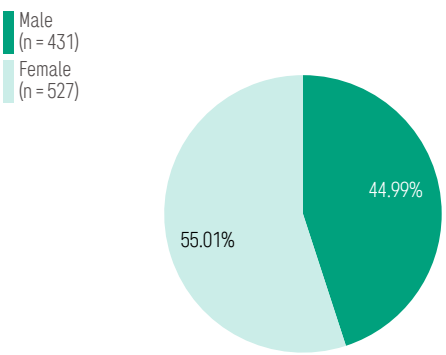
Elecsys® Phospho-Tau (217P) Plasma redefines the current diagnosis of Alzheimer's disease[1]

Ensuring demographic equity and unrestricted access by providing an operationally simple test that works consistently across diverse populations and care-settings – removing diagnostic access barriers.

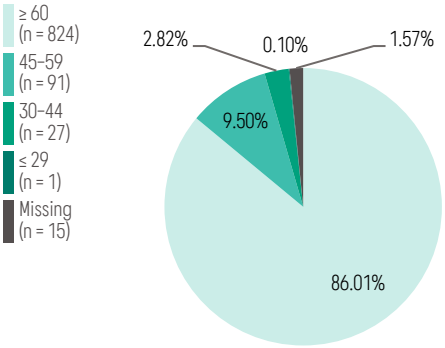
958 total participants



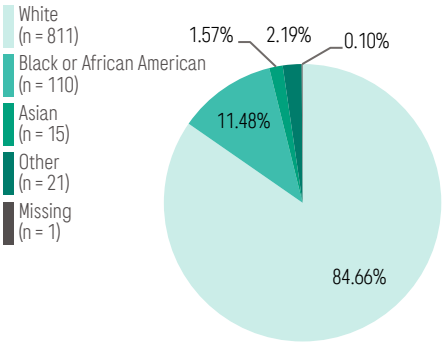
Gender



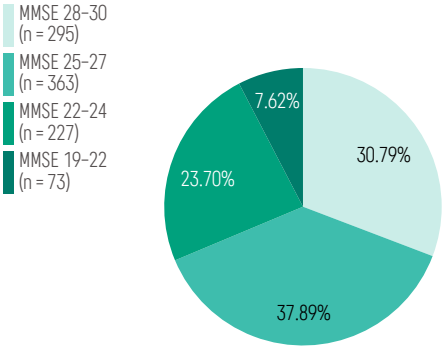
eGFR



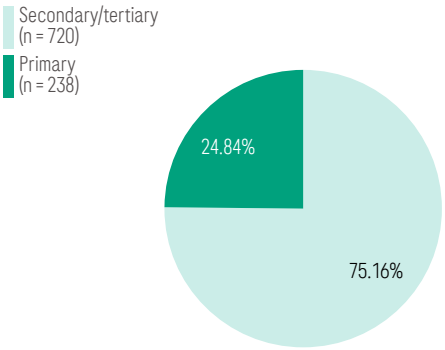
Race



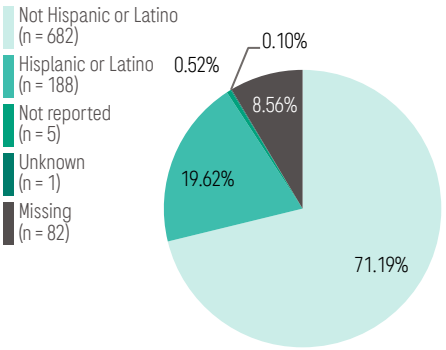
Clinical stage assesment (based on MMSE)



Care setting



Ethnicity



Body mass index (BMI) kg/m²

Mean (SD)	27.9 (5.55)
Median	27.0
Q1–Q3	24.2–30.6
Min-Max	16.0–61.4
Missing	n = 72 (7.52%)

MMSE: Mini-Mental State Examination.

A unique approach to validation of Elecsys® Phospho-Tau (217P) Plasma

Clinical performance validated in diverse populations that match characteristics of real patients

Broad population of symptomatic patients evaluated for cognitive decline.[1]

Included patients that are normally excluded in research cohorts.[1]

30 sites (18 of which were used for the validation of the data) collected the intended use population (race heterogeneity, multiple comorbidities).[1]

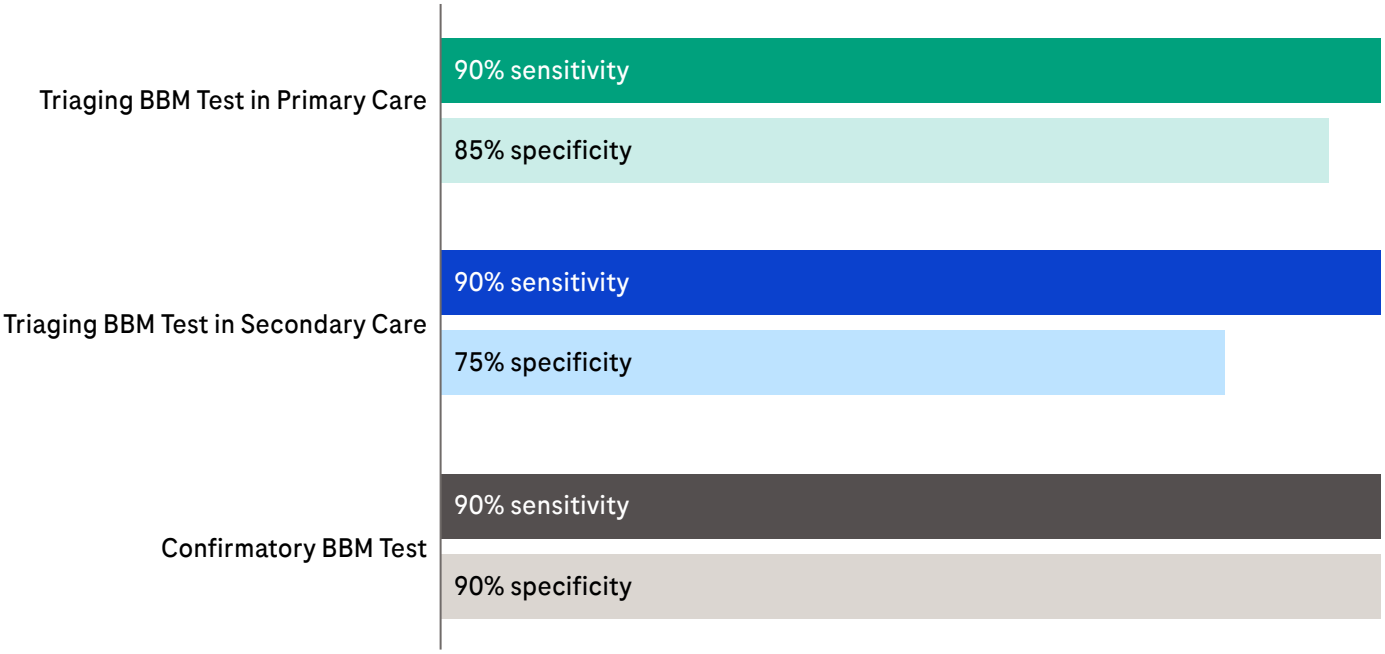
	Primary Care (low prevalence of 21.4%)	Secondary Care (moderate prevalence of 45.4%)
Negative predictive value (NPV)	98.6%	93.7%
Positive predictive value (PPV)	78.3%	90.2%
Positive percentage agreement (PPA, "sensitivity")	96.1%	94.2%
Negative percentage agreement (NPA, "specificity")	94.7%	93.1%

Prevalence of amyloid pathology (pretest probability) affects NPV and PPV performance

Primary Care patients
Subject self-refers/presents to the site or was referred by a primary care physician and has not seen a specialist before.

Secondary/Tertiary Care patients
Subject presents to centre or is recruited from a patient repository or has been referred by a specialist physician or has seen a specialist (neurologist, psychiatrist, geriatrician) before.

Based on the recently published CEOi Performance Standards for Blood-based Biomarkers (BBM, below), Elecsys® pTau217 is fulfilling all proposed criteria for triaging patients across care settings to confirmatory testing[12]



Accurate and robust blood test for patient management[1]

AUC (%) of plasma biomarkers with increasing added Coefficient of Variation (CV).

All plasma biomarkers except for plasma Aβ42/Aβ40 showed less than 10% decline in AUC at 15% added CV and were thus considered stable.

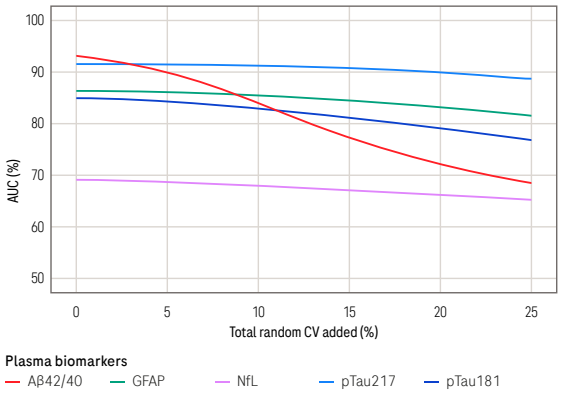


Figure: presents AUC of plasma biomarkers with increasing added Coefficient of Variation (CV). All plasma biomarkers except for plasma Aβ42/Aβ40 showed less than 10% decline in AUC at 15% added CV and were thus considered stable.

Elecsys® pTau217 – A biomarker designed to support early diagnostic decisions for those who benefit most from therapeutic interventions[13-15]

Stage	Preclinical AD		MCI due to AD	Mild AD Dementia	Moderate AD Dementia	Severe AD Dementia
NIA-AA staging	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6
MMSE score	30–27		27–25	24–19	18–10	9–0
No. of patients	295		363	300		

AUC: Area Under the Curve; GFAP: Glial Fibrillary Acidic Protein; NfL: Neurofilament Light Chain; MCI: Mild Cognitive Impairment; MMSE: Mini-Mental State Examination; NIA-AA: National Institute on Aging and Alzheimer's Association

References

1. Elecsys® phospho-Tau (217P) plasma method sheet Roche Diagnostics GmbH.
2. Brum WS, et al. Nat Aging. 2023;3:1079-90.
3. Chong FP, et al. Tau Proteins and Tauopathies in Alzheimer's Disease. Cell Mol Neurobiol. 2018 Jul;38(5):965-980.
4. Smet-Nocca C. 1st Ed. Tau Protein: Methods and Protocols; Methods in Molecular Biology; Springer New York: New York, NY, 2017; Vol. 1523.
5. Wang Y, Mandelkow E. Tau in physiology and pathology. Nat Rev Neurosci. 2016 Jan;17(1):5-21.
6. Pichet Binette A, et al. Amyloid-associated increases in soluble tau relate to tau aggregation rates and cognitive decline in early Alzheimer's disease. Nat Commun. 2022 Nov 4;13(1):6635.
7. Barthélemy NR, et al. A soluble phosphorylated tau signature links tau, amyloid and the evolution of stages of dominantly inherited Alzheimer's disease. Nat Med. 2020 Mar;26(3):398-407.
8. Mattsson-Carlgren N, et al. Aβ deposition is associated with increases in soluble and phosphorylated tau that precede a positive Tau PET in Alzheimer's disease. Sci Adv. 2020 Apr 15;6(16):eaaz2387.
9. Therriault J, et al. Association of Phosphorylated Tau Biomarkers With Amyloid Positron Emission Tomography vs Tau Positron Emission Tomography. JAMA Neurol. 2023 Feb 1;80(2):188-199.
10. Jack CR Jr, et al. Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup. Alzheimers Dement. 2024 Aug;20(8):5143-5169.
11. Ashton, N. J., Keshavan, A., Brum, W. S., et al. (2025). The Alzheimer's Association Global Biomarker Standardization Consortium (GBSC) plasma phospho-tau Round Robin study. Alzheimer's & Dementia. https://doi.org/10.1002/alz.14508
12. Schindler, S. E., Galasko, D., Pereira, A. C., et al. (2024). Acceptable performance of blood biomarker tests of amyloid pathology — recommendations from the Global CEO Initiative on Alzheimer's Disease. Nature Reviews Neurology, 20, 426–439. https://doi.org/10.1038/s41582-024-00977-5
13. Ding Z, Leung PY, Lee TL, Chan AS. Effectiveness of lifestyle medicine on cognitive functions in mild cognitive impairments and dementia: A systematic review on randomized controlled trials. Ageing Res Rev. 2023 Apr;86:101886. doi: 10.1016/j.arr.2023.101886. Epub 2023 Feb 18. PMID: 36806378
14. Barnett JH, Lewis L, Blackwell AD, Taylor M. Early intervention in Alzheimer's disease: a health economic study of the effects of diagnostic timing. BMC Neurol. 2014 May 7;14:101. doi: 10.1186/1471-2377-14-101. PMID: 24885474; PMCID: PMC4032565.
15. Rafii MS, Aisen PS. Detection and treatment of Alzheimer's disease in its preclinical stage. Nat Aging. 2023 May;3(5):520-531. doi: 10.1038/s43587-023-00410-4. Epub 2023 May 18. PMID: 37202518; PMCID: PMC11110912.

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