

Biomarkers for neurological disorders

Accelerating the path to reliable, accessible and actionable answers in your clinical practice

September 2026



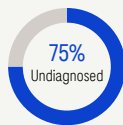
Clarity and confidence in diagnosing neurological disorders

Clarity in complex diagnostic pathways is essential. As neurological conditions continue to rise globally, with prevalence of neurological conditions expected to double by 2050,¹ **precise and unambiguous results** become crucial to enable **faster, more confident decisions**.

Greater certainty in interpretation and confidence in the results can **help shorten the path to answers**. Valuable time can be **redirected where it matters most** - towards meaningful patient interaction throughout their care journey.



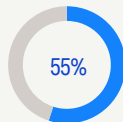
The immense burden of Alzheimer's disease



Up to 75% of people living with symptoms of Alzheimer's disease globally **have not been diagnosed**.² The time to diagnose Alzheimer's disease takes **more than 2 years**.³



Unmet need for managing Multiple Sclerosis



55% of treated MS patients are on low efficacy treatment.⁴ **40% of MS patients** remain untreated.^{5,6}



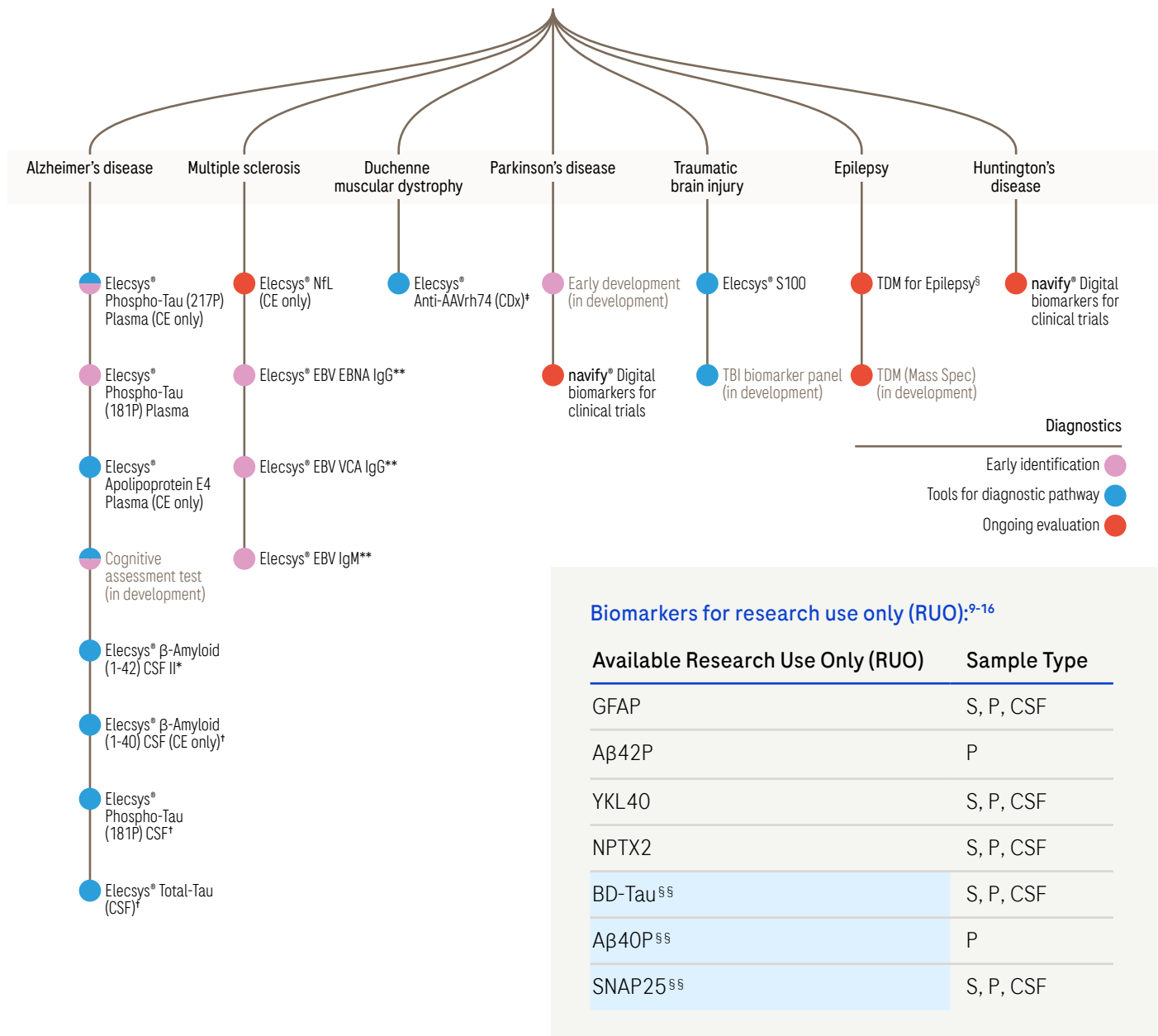
High incidence of Traumatic Brain Injury



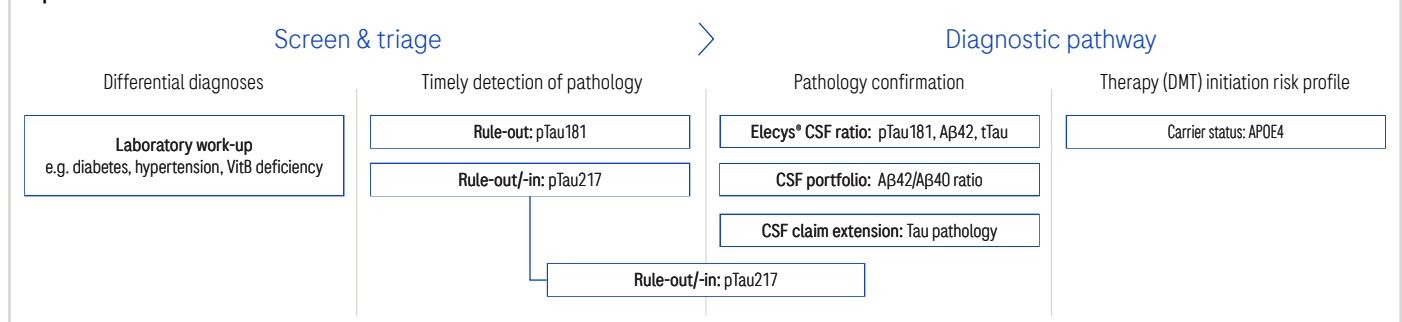
Over **69 million** people worldwide experience Traumatic Brain Injury annually.⁷



Portfolio of neurological biomarkers that span the care pathway:



Specific biomarkers for Alzheimer's disease:¹⁷⁻²²



* To be used standalone or as a ratio with tTau or pTau181; pTau181/A β 42 CSF ratio has claims for both Amyloid and Tau PET concordance in CE/EU. ** Identification of people at risk of MS. † To be used in a ratio with Elecsys® β -Amyloid (1-42) CSF II. ‡ CDx, Companion Diagnostics (currently only in Japan). § Carbamazepine, Phenytoin, Phenobarbital and Valproic acid on ClinChem. ¶ Laboratory developed test, not for use in diagnostic procedures. §§ In development. TDM: Therapeutic Drug Monitoring. Please note not all products are available in every market.

In the spotlight: Elecsys® Phospho-Tau (217P) Plasma

Elecsys® pTau217

The power of ONE assay: redefining Alzheimer's diagnosis¹⁷



Accurate and robust

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



Simplicity across settings

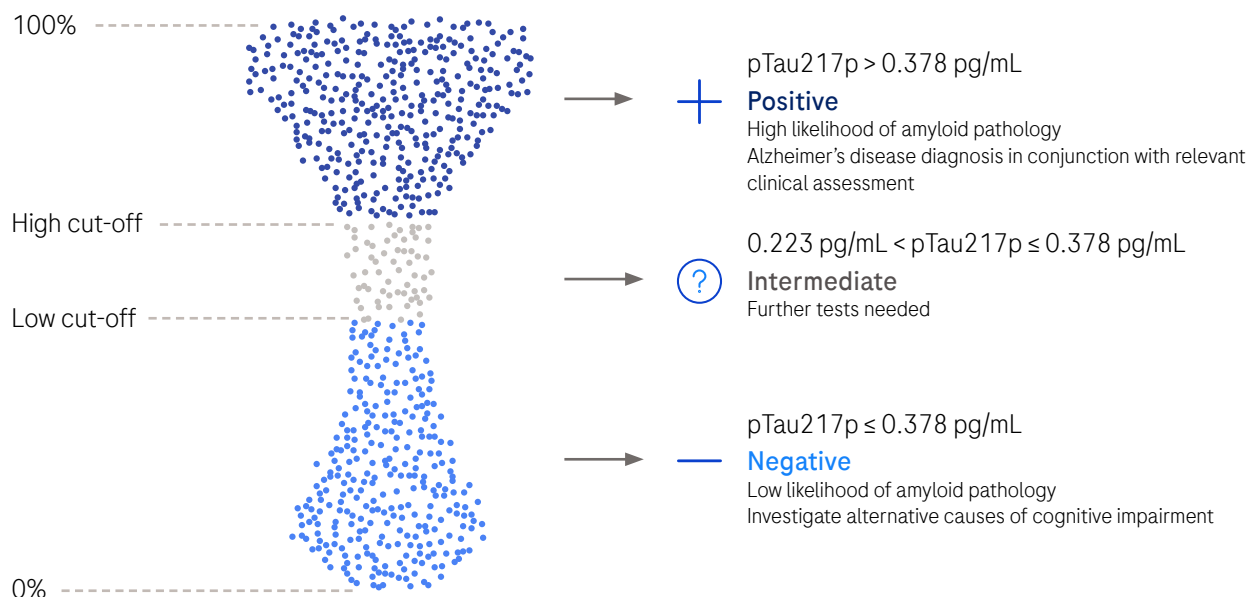
- Simple 'draw-and-go' sample handling without pre-analytical limitations
- Standalone assay with unified dual cut-off across primary and secondary care settings



Enhanced clarity

- Allowing targeted CSF and PET testing to effectively identify amyloid pathology^{23,25}
- Supporting diagnosis of early stages of Alzheimer's disease for improved treatment options

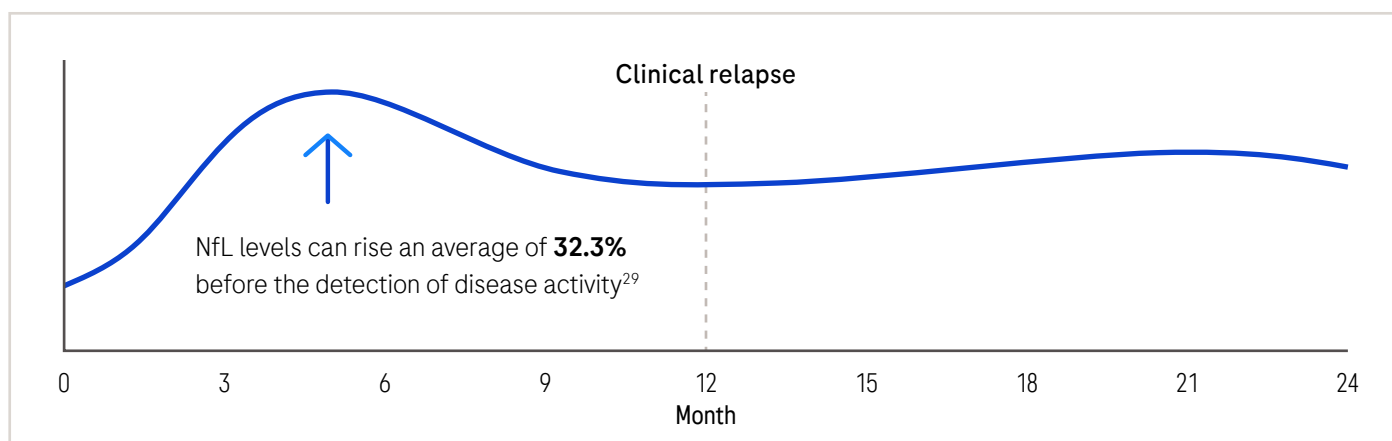
Two Elecsys® pTau217 cut-off values can improve classification accuracy and help to optimise clinical performance:^{18,26}



In the spotlight: Elecsys® NfL

Elecsys® NfL: Bridging the gap in MS management

Relapsing remitting Multiple Sclerosis (RRMS) progression is often “under the radar”, occurring below the threshold of clinical symptoms or standard MRI detection.²⁷ In between MRI scans, NfL can provide a minimally invasive biological readout of active neuroaxonal damage,²⁸ acting as a complementary signal to drive accurate and efficient management of MS patients, sooner.



Seeing what MRI may miss

Without Elecsys® NfL:



With Elecsys® NfL:



Minimally invasive



Objective measure



Accessible



Personalised medicine



Supporting your daily clinical routine: High performing neurological biomarkers deliver clarity and confidence

Because clearer answers return valuable time for meaningful patient care.

Assay	Sample type	Clinical explanation
Alzheimer's blood based biomarkers		
Elecsys® Phospho-Tau (217P) Plasma	P	Standalone IVD assay to aid in ruling in or ruling out of amyloid pathology. This test uses a unified dual cut-off approach to maximise clinical performance across care settings. ¹⁸
Elecsys® Phospho-Tau (181P) Plasma	P	Single cut-off IVD assay to be used as a single marker to support early triage rule-out of amyloid pathology. ¹⁷
Elecsys® Apolipoprotein E4 Plasma	P	IVD qualitative immunoassay to identify Apolipoprotein E4 (ApoE4) carrier status (carrier or non-carrier) in human plasma. 100% concordance with APOE genotyping by Sanger bidirectional sequencing. ²²
Alzheimer's CSF biomarkers		
Elecsys® β-Amyloid (1-42) CSF II	CSF	Single cut-off IVD assay to be used as single marker or in combination with pTau181, tTau or AB40 as a ratio to determine amyloid pathology in concordance with Amyloid PET and tau pathology in concordance with tau PET (in CE/EU). ¹⁹
Elecsys® β-Amyloid (1-40) CSF	CSF	Single cut-off IVD assay to be used in combination with AB42 as a ratio to determine amyloid pathology in concordance with Amyloid PET. ²⁰
Elecsys® Phospho-Tau (181P) CSF	CSF	Single cut-off IVD assay to be used in combination with AB42 as a ratio to determine amyloid pathology and tau pathology in concordance with Amyloid PET and tau PET respectively (in CE/EU). ³⁰
Elecsys® Total-Tau (CSF)	CSF	Single cut-off IVD assay to be used in combination with AB42 as a ratio to determine amyloid pathology in concordance with Amyloid PET. ²¹
Multiple sclerosis		
Elecsys® NFL	S, P	IVD assay to reflect neuroinflammation in adult subjects diagnosed with relapsing-remitting multiple sclerosis. ³¹
Traumatic brain injury		
Elecsys® S100	S	IVD assay to rule out suspected mild traumatic brain injury. ³²
Excerpt of other supporting biomarkers		
EBV EBNA IgG	S, P	Detection of IgG antibodies against the Epstein-Barr virus (EBV) nuclear antigen-1 (EBNA-1). ³³
IgA	CSF*, S, P	Cerebrospinal fluid diagnostics to identify a blood-cerebrospinal fluid barrier disorder, intrathecal synthesis, and to calculate specific intrathecal antibody synthesis. ³⁴
IgM	CSF*, S, P	
IgG*	CSF, S, P	
Albumin*	CSF, S, P	
Glucose	CSF, S, P	Measuring glucose levels in cerebrospinal fluid can be used to support the diagnosis and monitoring of infections of the central nervous system such as meningitis and encephalitis of various etiologies. ³⁵
Total Protein	CSF, S, P	Plausibility check; assessment of functional disorders of the blood-brain barrier in conditions such as meningitis, brain tumors, and infections of the central nervous system. ³⁶
Lactate	CSF, S, P	Acute inflammation in the CNS: Lactate levels in the cerebrospinal fluid are elevated in both bacterial and fungal meningitis, but not in viral meningitis. ³⁷
Vitamin B12	S, P	Detection of vitamin B12 deficiency to identify a potential cause of neurological and neurocognitive impairment, including peripheral neuropathy, gait disturbance, and cognitive dysfunction. ³⁸
Vitamin D	S, P	Assessment of vitamin D status to identify deficiency states that may be associated with impaired neurological function, cognitive performance and mood. ³⁹
TSH	S, P	Detection of thyroid dysfunction to identify endocrine disorders that may present with neurological-like symptoms such as cognitive slowing, fatigue, and brain fog. ^{40,41}

* Measurement of liquor and serum on one calibration curve.



For more information visit our website

<https://go.roche.com/diagnostics.neurology>



1. REF-123434 - World Federation of Neurology. Number of people living with brain disease expected to double by 2050 [Internet; cited 2025 Oct 31]. Available from: <https://wfneurology.org/activities/news-events/archived-news/2023-10-16-wcn>.
2. REF-128275 - Alzheimer's Disease International (ADI). [Internet; cited 2025 Nov 3]. Available from: <https://www.alzint.org/resource/world-alzheimer-report-2022/>.
3. REF-128478 - Kusoro O, et al. Time to Diagnosis in Dementia: A Systematic Review With Meta-Analysis. *Int J Geriatr Psychiatry*. 2025 Jul;40(7):e70129.
4. IQVIA - patient share US.
5. European Multiple Sclerosis Platform [Internet; cited 2026 May]. Available from: emsp.org/wp-content/uploads/2021/03/MSBarometer2020-Final-Full-Report-Web.pdf.
6. Roche internal Epidemiology.
7. REF-121711 - Dewan, M.C, et al. Estimating the global incidence of traumatic brain injury. *Journal of Neurosurgery*. 2018 Apr 27 130(4):1080-1097.
8. Roche [Internet; cited 2025 Dec 1]. Available from: <https://sites.google.com/roche.com/cmp/home?authuser=0>.
9. GFAP RUO bx: Elecsys® Method Sheet: ms_10151897520 V2.0.
10. NfL RUO bx: Elecsys® Method Sheet: ms_1015d115520 V1.0.
11. AB42P RUO: Elecsys® Method Sheet: ms_106B3716520 V2.0
12. YKL40 RUO: Elecsys® Method Sheet: ms_10683724520 V1.0.
13. NPTX2 RUO: Elecsys® Method Sheet: ms_10151897430 V2.0.
14. BD-Tau RUO: Elecsys® Method Sheet: XXXXX
15. AB40P RUO: Elecsys® Method Sheet: XXXXX
16. SNAP25 RUO: Elecsys® Method Sheet: ms_10066458430 V1.3.
17. REF-123732 - Elecsys® Phospho-Tau (181P) Plasma Method Sheet.
18. Method Sheet Elecsys® PhosphoTau 217P Plasma 10285583190.en and internal clinical validation data.
19. REF-41180 - Elecsys® β -Amyloid (1-42) CSF Method Sheet.
20. REF-126733 - Elecsys® β -Amyloid (1-40) CSF Package insert.
21. REF -123993 - Elecsys® Total-Tau CSF Package insert.
22. REF-128066 - Elecsys® Apolipoprotein E4 Plasma method sheet 09697888500V1.0 English. Roche Diagnostics GmbH.
23. Brum WS, et al. *Nat Aging*. 2023;3:1079-9.
24. Li Y, et al. *J Prev Alzheimers Dis*. 2026;13:100474.
25. Matthe S, et al. *J Prev Alzheimers Dis*. 2025;12:100219.
26. Schindler SE, et al. Acceptable performance of blood biomarker tests of amyloid pathology - recommendations from the global CEQ initiative on Alzheimer's disease. *Nature Reviews Neurology* 2024 20:426-439.
27. Thebault S, et al. *Mult Scler Relat Disord*. 2022;59:103535.
28. Benkert P, et al. *Lancet Neurol*. 2022;21:246-57.
29. Rosso et al., Temporal association of sNfL and gad-enhancing lesions in multiple sclerosis 10.1002/acn3.51060 2020
30. REF-121693 - Elecsys® pTau 181 CSF Package insert.
31. REF-129969 - Roche Diagnostics-Method Sheet-2025 Elecsys® NfL - Package Insert (v1.0).
32. REF-121720 - Elecsys® S100_Roche_Roche Diagnostics_2023.
33. Lupo J, et al. Comparison of Elecsys and Liaison immunoassays to determine Epstein-Barr virus serological status using further diagnostic approaches to clarify discrepant results. *J Med Virol*. 2023 Jan;95(1):e28166.
34. Huang X, et al. Intrathecal immunoglobulin synthesis and its role in patients with neurosyphilis. *Front Public Health*. 2022 Nov 7;10:1008595.
35. Mahroum N, et al. The Evaluation of a Rapid Syndromic Multiplex Meningitis/Encephalitis RT-qPCR MX-17 Panel. *Diagnostics (Basel)*. 2025 Oct 17;15(20):2629.
36. Kelbich P, et al. Basic Analysis of the Cerebrospinal Fluid: An Important Framework for Laboratory Diagnostics of the Impairment of the Central Nervous System. *Curr Issues Mol Biol*. 2022 Aug 14;44(8):3666-3680.
37. Poplin V, et al. Methods for rapid diagnosis of meningitis etiology in adults. *Biomark Med*. 2020 Apr;14(6):459-479.
38. Hamza Ali AA, et al. The Neurological Sequelae of Vitamin B12 Deficiency: A Systematic Review and Randomized Controlled Trial. *Cureus*. 2025 May 7;17(5):e83668.
39. Etgen T, et al. Vitamin D deficiency, cognitive impairment and dementia: a systematic review and meta-analysis. *Dement Geriatr Cogn Disord*. 2012;33(5):297-305.
40. Eslami-Amirabadi M, Sajjadi SA. The relation between thyroid dysregulation and impaired cognition/behaviour: An integrative review. *J Neuroendocrinol*. 2021 Mar;33(3):e12948.
41. Ettleson MD, et al. Brain Fog in Hypothyroidism: Understanding the Patient's Perspective. *Endocr Pract*. 2022 Mar;28(3):257-264.

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