Biomarkers for neurological disorders

Seamless integration into your lab with known workflows, performance and quality of Elecsys® assays

September 2026



Rising urgency of neurology: the crucial role of the lab

Neurological disorders are one of the greatest challenges of our century, threatening the very essence of who we are. With a continuous global rise, prevalence is expected to double by 2050.[1] Historically, neurological tests have been sporadic and often accessible via specialized labs only.

Bringing **advanced neuro biomarkers** into your **routine lab** is a gamechanger. Fully integrated systems with known workflows and consistent, robust and reliable performance deliver critical neurological answers to clinicians fast. With symptoms often complex and overlapping, accessible and scalable solutions with **reproducible and high-quality biomarkers** provide the clarity and precision needed for **confident, informed decision-making** supporting diagnosis, disease monitoring, and therapy evaluation.[2,3]

Diagnostics influence approximately **70% of healthcare decisions,** making laboratory testing a cornerstone of modern medicine - from early disease detection and diagnosis to treatment selection and patient monitoring.[4]

	The immense burden of Alzheimer's disease	3 seconds	**Every 3 seconds** someone in the world develops dementia[5], where Alzheimer's disease is the most common cause, predicted to rise to **83 million in 2030.**[6]
	Unmet need for managing Multiple Sclerosis	2.9+ million	**2.9 million** people are affected worldwide with a new diagnosis **every 5 minutes.**[7,8]
	High incidence of Traumatic Brain Injury	69+ million	Over **69 million** people worldwide experience Traumatic Brain Injury annually.[9]

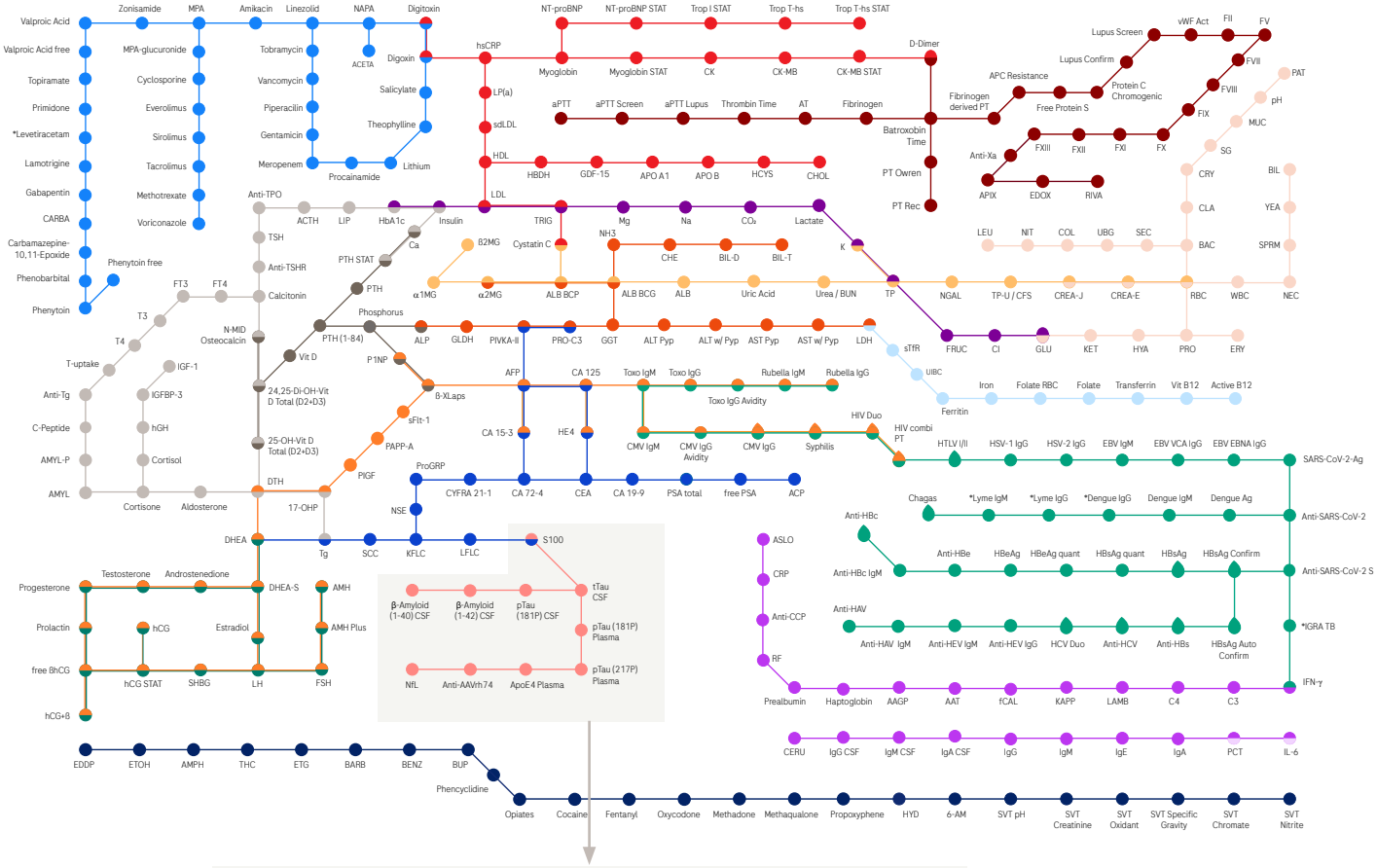


Channelling decades of innovation and expertise into diagnostic certainty for neurology

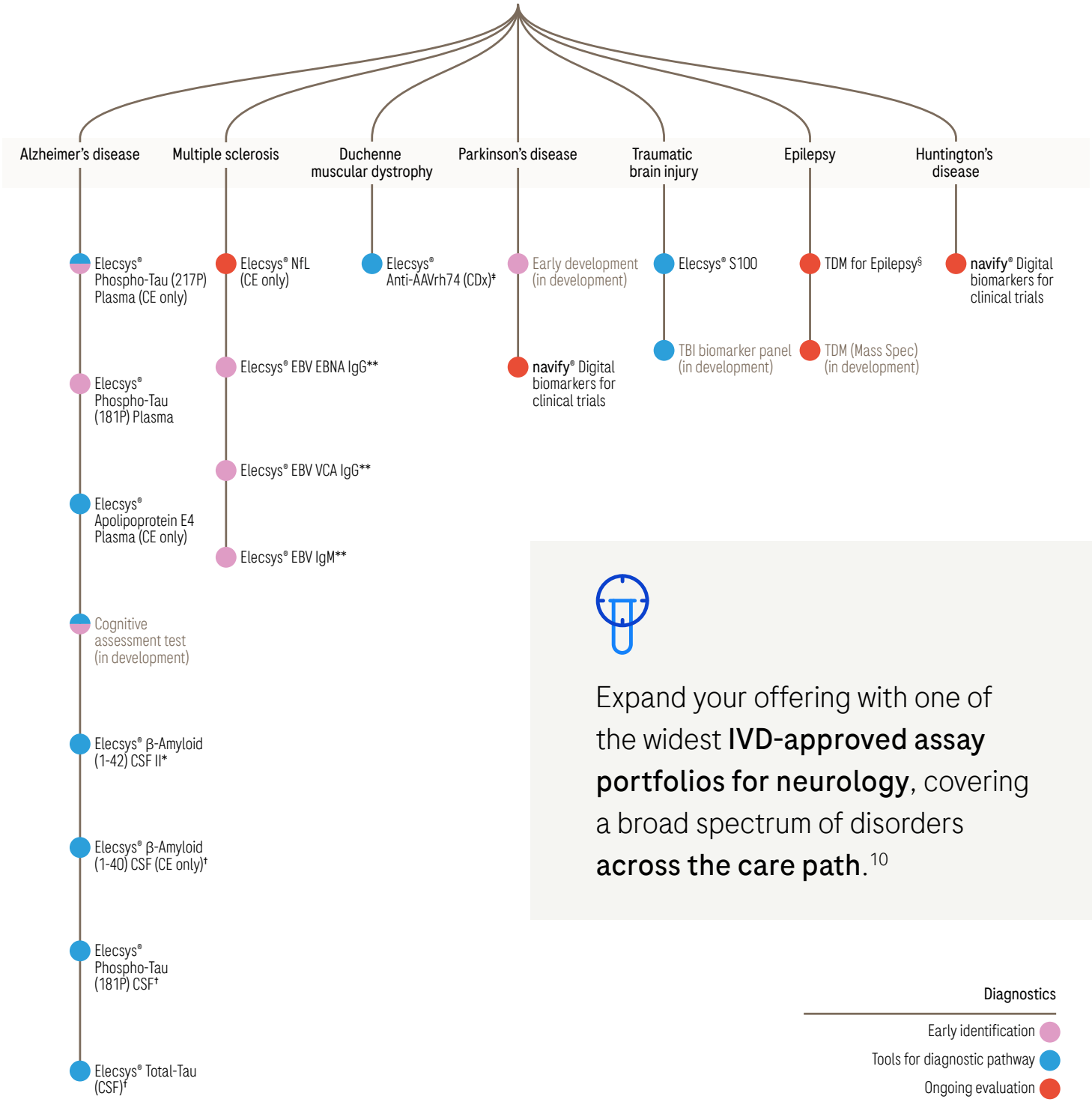
Tackling the major health challenges of our time has long shaped our innovation, leading to the development of scalable solutions that drive real impact. Labs play a central role in providing the excellent diagnostics that support confident clinical decisions.

As the need for earlier, more accessible assessment and monitoring of neurological disorders continues to grow, neurological biomarkers are opening new opportunities for labs. Clinically-validated, robust and reproducible assays bring high-quality and precise testing to the core lab.

The Elecsys® neurology biomarkers are designed to integrate seamlessly into your lab today, so you can drive better patient outcomes tomorrow.



Unlock a comprehensive portfolio of neuro biomarkers, designed to deliver impact



Expand your offering with one of the widest **IVD-approved assay portfolios for neurology**, covering a broad spectrum of disorders **across the care path**.[10]

* To be used standalone or as a ratio with tTau or pTau181; pTau181/Elecsys® β-Amyloid (1-42) CSF II 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.
TDM: Therapeutic Drug Monitoring

Please note not all products are available in every market.

A breakthrough biomarker is only as powerful as the instrument providing the reading

cobas® integrated solutions: scalable, efficient and reliable[11]

Outstanding reliability and uptime

Industry-leading reagent and calibration stability[12] enable high result integrity, meanwhile automation maximises testing output with lower risk of manual errors.

Scalability and flexibility

Choose from a variety of instruments sizes and throughputs to meet your lab's needs now and in the future, with seamless integration of new innovations.



cobas® e 801



cobas® e 402

Comprehensive efficiency

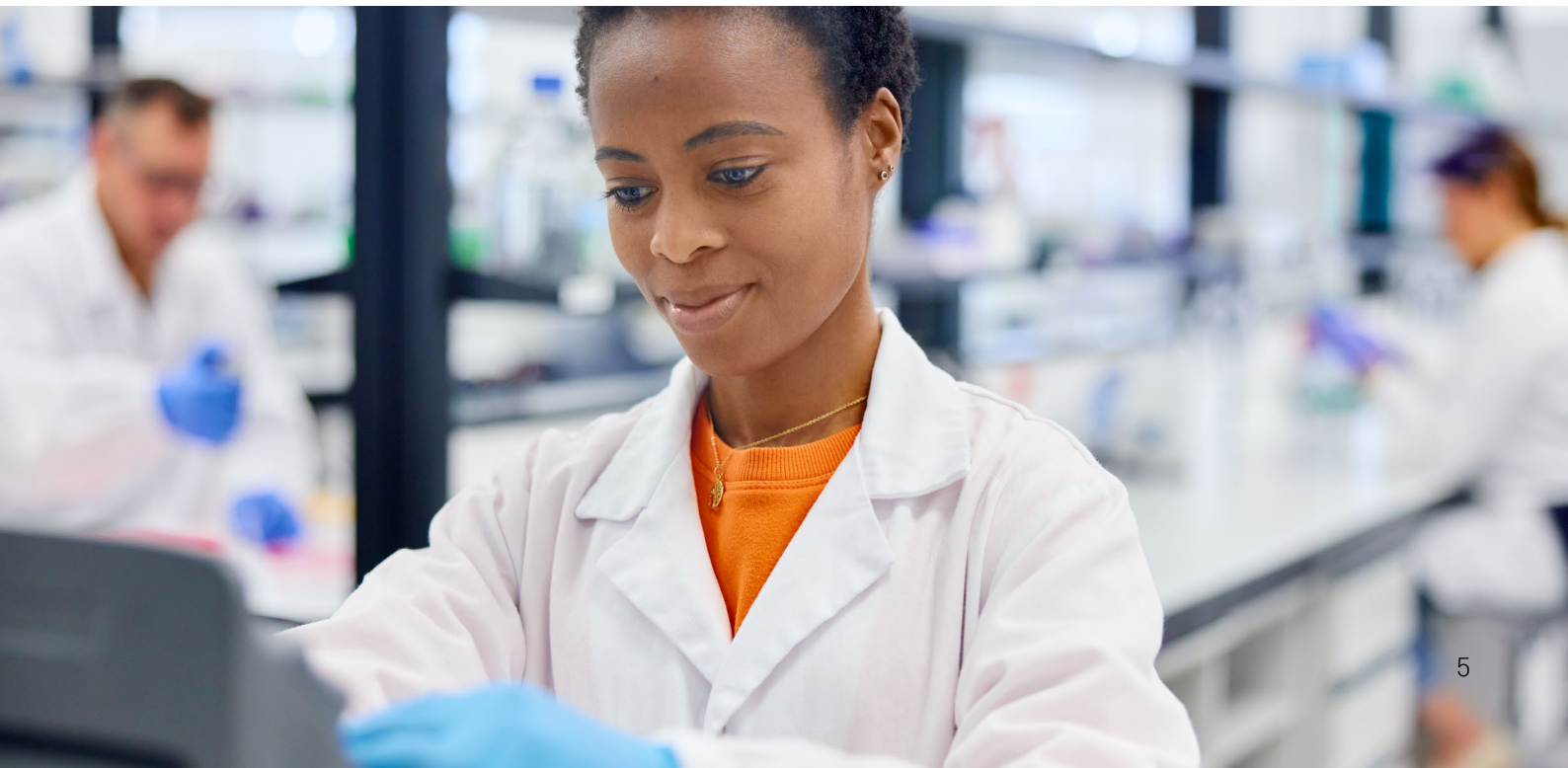
Minimal hands-on time and rapid reaction times of 18 mins or less.[12-14]

Advanced automation and integration[15]

Digital solutions help optimise your end-to-end workflow, while our common reagent and platform concept simplifies training and standardised results.

Broadest diagnostic menu[16]

Consolidate your testing onto a single platform and unlock a rapidly expanding Core Lab assay menu.



Overview of IVD biomarkers for Alzheimer's disease across platforms

Alzheimer's disease	Explanation	System	Sample material	Sample volume	Sample stability	Measuring range	Intermediate precision	Onboard stability	Calibration frequency: Per new reagent lot	Calibration frequency: Within same lot	Calibration frequency: Within same rackpack	Calibration frequency: As required
Elecsys® Phospho-Tau (217P) Plasma	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.[17]	● ●	Plasma (K2-EDTA)	60 µL	2 days at 20–25 °C, 7 days at 2–8 °C, 3 months at -20 °C (± 5 °C) 1 freeze/ thaw cycle	0.056–2.40 pg/mL	● ≤ 5.0% ; ● ≤ 5.3 %	16 weeks	✓	12 weeks	28 days	✓
Elecsys® Phospho-Tau (181P) Plasma	Single cut-off IVD assay to be used as a single marker to support early triage rule-out of amyloid pathology.[18]		Plasma (K2/K3-EDTA)	30 µl	2 days at 20–25 °C, 7 days at 2–8 °C, 3 months at -20 °C (± 5 °C) 1 freeze/ thaw cycle	0.300–10 pg/mL	● ≤ 5.5% ; ● ≤ 5.4 %					
Elecsys® Apolipoprotein E4 Plasma	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.[19]		Plasma (K2/K3-EDTA)	4 µl	Stable for 8 hours at 20–25°C, 2 days at 2–8°C, 4 weeks at -20 °C (± 5 °C)	n/a	● ≤ 10.2% ● ≤ 9.7%					
Elecsys® ß-Amyloid (1-42) CSF II	Single cut-off IVD assay to be used as single marker or in combination with pTau181, tTau or Aß40 as a ratio to determine amyloid pathology in concordance with Amyloid PET and tau pathology in concordance with tau PET (in CE/EU).[20]	● ● ● ●	Cerebrospinal Fluid (CSF)	◐ 30 µL ◐ 50 µL	5 days at 20–25 °C, 14 days at 2–8 °C, 8 weeks at -20 °C (± 5 °C) 1 freeze/ thaw cycle	150–2500 pg/mL	◐ 2.4% ● 5.1% ● 4.4%	◐ 16 weeks ◐ 4 weeks	✓	4 weeks	7 days	✓
Elecsys® Phospho-Tau (181P) 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).[21]		Cerebrospinal Fluid (CSF)		5 days at 20–25 °C, 14 days at 2–8 °C, 8 weeks at -20 °C (± 5 °C) 1 freeze/ thaw cycle	8–120 pg/mL	◐ 1.7% ● 2.1% ● 2.0%					
Elecsys® Total-Tau (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.[22]		Cerebrospinal Fluid (CSF)		5 days at 20–25 °C, 14 days at 2–8 °C, 8 weeks at -20 °C (± 5 °C) 1 freeze/ thaw cycle	80–1300 pg/mL	◐ 1.2% ● 6.6% ● 4.9%					
Elecsys® ß-Amyloid (1-40) 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.[23]	● ●	Cerebrospinal Fluid (CSF)	12 µl	5 days at 20–25 °C, 14 days at 2–8 °C	750–20,000 pg/mL	◐ 5.5%	16 weeks	✓	12 weeks	28 days	✓

Each IVD neurology biomarker has a rapid testing time of **18 min**

Key: ● **cobas®** e 801 ● **cobas®** e 402 ● **cobas®** e 411 ● **cobas®** e 601/ **cobas®** e 602

High quality assays using trusted technology
Your plus: Known workflows, performance and quality of Elecsys® assays with seamless integration of new neurological biomarkers.

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

Elecsys® pTau217

The power of ONE assay: redefining Alzheimer's diagnosis[17]

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

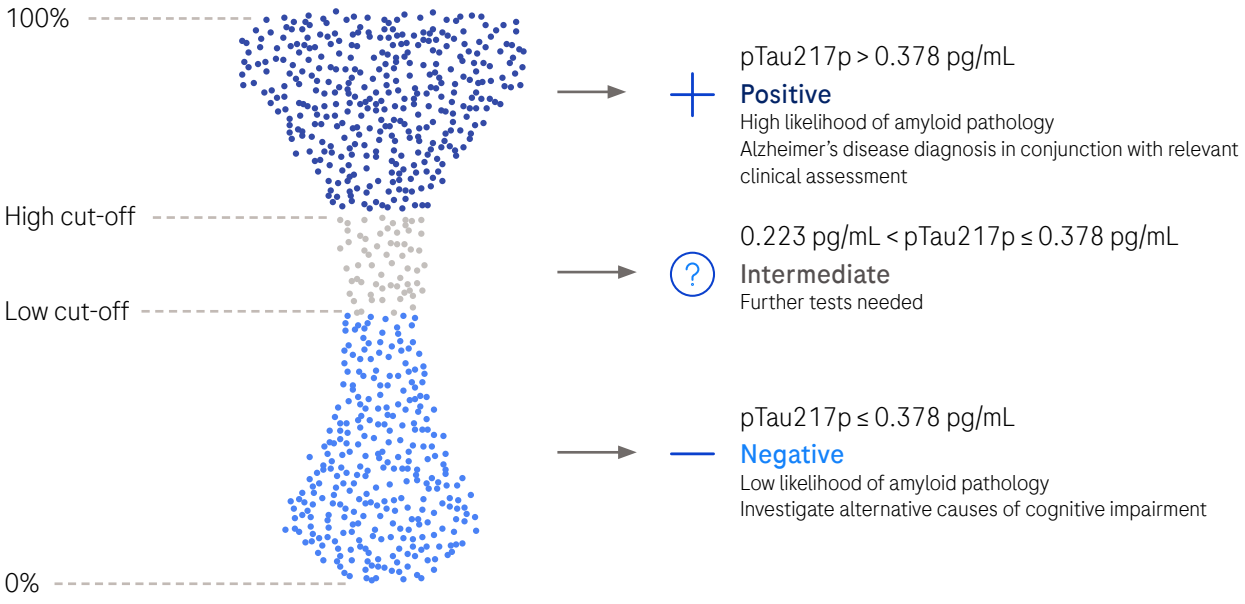
Enhanced clarity

- Allowing targeted CSF and PET testing to effectively identify amyloid pathology[24-26]
- Supporting diagnosis of early stages of Alzheimer's disease for improved treatment options

Product performance[17]

	Sensitivity (%, PPA)	Specificity (%, NPA)	Interdeterminate zone (%)	PPV	NPV
Primary Care (21.4% prevalence)	96.1	94.7	19.7	78.3	98.6
Secondary Care (45.4% prevalence)	94.2	93.1	20.0	90.2	93.7

Two Elecsys® pTau217 cut-off values can improve classification accuracy and help to optimise clinical performance:[27]



Overview of IVD biomarkers for Multiple Sclerosis and Traumatic Brain Injury across platforms

	Explanation	System	Sample material	Sample volume	Sample stability	Measuring range	Intermediate precision	Onboard stability	Calibration frequency			
									Per new lot	Within same lot	Within same rackpack	As required
Multiple Sclerosis												
Elecsys® NfL	IVD assay to reflect neuroinflammation in adult subjects diagnosed with relapsing-remitting Multiple Sclerosis.[28]	● ●	Plasma (Li-heparin, K2/K3-EDTA) Serum	48 µl	2 days at 20–25°C, 7 days at 2–8 °C , 3 months at -20°C (± 5 °C), (except Li-Hep) 1 freeze/thaw cycle	0.3–500 pg/ml	2.2–8.5%	16 weeks	✓	12 weeks	28 days	✓
Traumatic Brain Injury												
Elecsys® S100	IVD assay to rule out suspected mild Traumatic Brain Injury.[29]	● ● ● ●	Serum	12 µl 20 µl	8 hours at 20–25 °C, 2 days at 2–8 °C, 3 months at -20 °C (± 5 °C). The samples may be frozen 5 times.	0.015–30 µg/l 0.005–39 µg/l	2.9–7.8% 2.2–7.9% 2.7–4.3%	16 weeks 8 weeks	✓	12 weeks	28 days 7 days	✓

Each IVD neurology biomarker has a rapid testing time of **18 min**

Key: ● **cobas®** e 801 ● **cobas®** e 402 ● **cobas®** e 411 ● **cobas®** e 601/ **cobas®** e 602

In the spotlight: Elecsys® NfL

Elecsys® NfL

Elecsys® NfL provides traceable and accurate test results within a comprehensive neurological test menu and superior result interpretation directly addressing the limitations of existing solutions.

Age-specific percentiles

Percentiles provide clinical meaningful data, allowing easier comparison to healthy population for additional insights of disease activity based on biological signal.[30,31]

Performance

Elecsys® NfL is ensuring accuracy and reliability results. Results are comparable within all Elecsys® instruments in different labs and across reagent lots allowing seamless interpretation and monitoring decisions.[30]

Traceability

Elecsys® NfL is traceable to NIST.* This is currently the highest possible standard since there is no official listed reference material available ensuring standardized and accurate results.[30]

* NIST, The National Institute of Standards and Technology

Overview of Research Use Only (RUO) neurology biomarkers

Empowering researchers to advance scientific discovery

Early access to Innovation

Gain early access to cutting-edge biomarkers, putting your work at the forefront.

Fuel biomarker research

Accelerate disease understanding and deepen scientific insights.

Advanced assays

Engineered for reliable results with high specificity and sensitivity.

Workflow synergy

Perform RUO research directly on existing Roche clinical platforms, often without new instrumentation.

	Available Research Use Only (RUO)				In development Research Use Only (RUO)		
Sample type	GFAP	Aß42P	NPTX2	YKL40	BD-Tau	Aß40P	SNAP25
Plasma	✓	✓	✓	✓	✓	✓	✓
Serum	✓		✓	✓	✓		✓
CSF	✓		✓	✓	✓		✓

All RUO assays utilize electrochemiluminescence immunoassay (ECLIA) technology.
They can be run on the automated **cobas**® e 801 and **cobas**® e 402 immunoassay analyzers.

CSF, Cerebrospinal Fluid; P, Plasma.
Please be aware that products may not be available in all markets. For Research Use Only (RUO), not for use in diagnostic procedures.



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-121035 - Fornari A, et al. Inequities in neurological care: Access to services, care gaps, and other barriers – A systematic review. Neurology. 2022;98(3):123–131.
3. REF-129445 - Zaman MS, et al. Barriers to accessing healthcare services for people with Parkinson's disease: A scoping review. Parkinsons Dis. 2023;2023:1–10.
4. World Health Organization. Diagnostics. WHO Health Topics. "Diagnostics results influence approximately 70% of healthcare decisions." Available from: https://www.who.int/health-topics/diagnostics.
5. Alzheimer's Disease International Dementia statistics [Internet; accessed June 2025]. Available from: https://www.alzint.org/about/dementia-facts-figures/dementia-statistics/.
6. GBD 2019 Dementia Forecasting Collaborators, et al. Lancet Public Health. 2022;7:105–25.
7. MS international federation. Atlas of MS 2020 – Epidemiology report [Internet; cited 2025 Oct 12]. Available from: https://www.msif.org/resource/atlas-of-ms-2020/.
8. Walton C, et al. Rising prevalence of Multiple Sclerosis worldwide: insights from the Atlas of MS, third edition. Multiple Sclerosis Journal. 2020 Nov 11; 26(14):1816-1821.
9. 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.
10. Roche. Competitive Marketing Program. Menu Overview [Internet; cited 2025 Dec 1]. Available from: https://sites.google.com/roche.com/cmp/home?authuser=0.
11. F. Hoffmann-La Roche Ltd. Diagnostic solutions [Internet; cited 2025 Dec 1]. Available from: https://www.roche.com/solutions/diagnostics.
12. REF-124996 – SWA assay menu and reagent specifications analysis | Data on file | Source: Reagent method sheets Roche Diagnostics cobas c & cobas e pack, Siemens Atellica® CH & IM, Abbott Alinity ci-series, Beckman Coulter AU & Access UniCel DxI, Mindray BS & CL, Snibe Maglumin | Status as of September 2025.
13. REF-102221 | Atellica IM Analyzers | Publication version · CLS-24-3235-76 · QR700006277 | 2024-Q3 | Siemens Healthcare Diagnostics Inc.
14. REF-34062 - Alinity ci-series | Operations Manual - 2021-10-19 | Abbott Diagnostics.
15. Integrated Solutions customer deck - MC--16580.
16. REF-125558- Test Menu Overview - Number of SWA tests | Data on file | Source: Reagent method sheets Roche Diagnostics cobas c & cobas e pack, Siemens Atellica® CH & IM, Abbott Alinity ci-series, Beckman Coulter AU & Access UniCel DxI, Mindray BS & CL, Snibe Maglumin | Status as of October 2025.
17. Method Sheet Elecsys PhosphoTau 217P Plasma10285583190.en and internal clinical validation data
18. REF-123732 Elecsys Phospho-Tau (181P) Plasma Method Sheet.
19. REF-128066 Elecsys® Apolipoprotein E4 Plasma method sheet 09697888500V1.0 English. Roche Diagnostics GmbH.
20. Elecsys ß-Amyloid (1-42) CSF II_Roche Diagnostics_Roche Diagnostics_2023.
21. REF-121693 Elecsys pTau 181 CSF Package insert.
22. REF -123993 Elecsys Total-Tau CSF Package insert.
23. REF-126733 Elecsys ß-Amyloid (1-40) CSF Package insert.
24. Brum WS, et al. Nat Aging. 2023;3:1079-9
25. Li Y, et al. J Prev Alzheimers Dis. 2026;13:100474.
26. Mattke S, et al. J Prev Alzheimers Dis. 2025;12:100219
27. 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.
28. REF-129969 Roche Diagnostics-Method Sheet-2025- Elecsys NfL -PackageInsert (v1.0).
29. REF-121720 – Elecsys S100_Roche Diagnostics_2023
30. Elecsys® NfL ms_09880488500V1.0. Roche Diagnostics GmbH.
31. Benkert P, et al. Lancet Neurol. 2022;21:246–57.

Roche Diagnostics International Ltd
CH-6343 Rotkreuz
Switzerland

© 2026 Roche.
COBAS, ELECSYS and NAVIFY are trademarks of Roche.

diagnostics.roche.com

Date of preparation: September 2026