Media & Investor Release

Roche receives CE mark for new Elecsys NfL blood test to detect neuroinflammation in multiple sclerosis

- **The Elecsys NfL blood test detects neuroaxonal damage associated with neuroinflammation in adults diagnosed with relapsing remitting multiple sclerosis.[1]**
- **This minimally invasive blood test enables greater patient access to monitoring of neuroinflammatory status versus current standard of care methods.**
- **By providing deeper insight into underlying neuroinflammatory activity, Elecsys NfL has the potential to enable effective MS monitoring and earlier clinical intervention. [2,3]**

Basel, 13 April 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that its Elecsys® Neurofilament Light Chain (NfL) test has received CE mark approval for the detection of neuroinflammation in patients diagnosed with relapsing remitting multiple sclerosis (RRMS).[1] The test brings meaningful innovation to MS disease management, offering clinicians a minimally invasive way to monitor the biological damage caused by multiple sclerosis. Using a simple blood test to measure NfL – a protein released during nerve cell injury – Elecsys NfL provides a picture of the neuroinflammation associated with multiple sclerosis, and could help to make more regular monitoring a reality for more people living with the disease.

Multiple sclerosis is a chronic disease that affects more than 2.9 million people worldwide.[8] Early and regular monitoring of disease activity is critical to optimising treatment, yet some patients can find it difficult to access routine assessments such as MRI scanning that would allow timely detection of changes in their condition. The Elecsys NfL test provides a different type of insight by measuring biological markers of neuroaxonal damage that reflect neuroinflammation. These insights complement routine clinical assessments and MRI, potentially aiding in earlier and better-informed clinical management.

“This approval marks a transformative step forward in how we support adults with relapsing-remitting multiple sclerosis (RRMS),” said Matt Sause, CEO of Roche Diagnostics. “The availability of a simple blood-based test has the potential to complement resource-intensive MRI scans and improve access for patients with RRMS. The Elecsys NfL test will help healthcare providers support timely clinical reassessment, enabling better disease management and more personalised care for patients.”

Performed on Roche’s widely available cobas instruments, the Elecsys NfL test provides standardised and consistent results,[1] ensuring reliable insights regardless of where the test is carried out. Requiring only a simple blood sample, collections can be done locally, reducing the need for patients to travel to specialist centres. With traditional testing for multiple

sclerosis often limited by geographic, financial, or logistical barriers, Elecsys NfL makes frequent monitoring more practical and accessible.

About NfL

Neurofilament Light Chain (NfL) is an abundant cytoskeletal protein[4] found almost exclusively in neurons[5] and is a sensitive indicator of neuroaxonal damage[2,6]. Under normal conditions, NfL is released at low levels from axons[4]; however, release increases with age[7] and following neuroaxonal damage.[4] Consequently, abnormally elevated NfL concentrations can be measured in cerebrospinal fluid and blood in a range of acute and chronic neurological disorders.[2, 4, 6]

About Elecsys® NfL

Roche's Elecsys NfL is an in vitro quantitative immunoassay for the measurement of NfL protein in human serum and plasma. Elecsys NfL is intended to be used to reflect neuroinflammation in adult subjects diagnosed with relapsing-remitting multiple sclerosis.[2]

The test was granted Breakthrough Device Designation by the US FDA in November 2023. Following CE Mark approval, broad access to testing will exist through the large number of instruments currently available in countries accepting CE mark.

About Roche in neurology

Neurology is a major focus of research and development at Roche. Our goal is to pursue groundbreaking science to develop new diagnostics and treatments that help improve the lives of people with chronic and potentially devastating diseases globally.

Roche is investigating more than a dozen medicines for neurological conditions, including multiple sclerosis, spinal muscular atrophy, neuromyelitis optica spectrum disorder, Alzheimer's disease, Huntington's disease, Parkinson's disease and Duchenne muscular dystrophy. Roche Diagnostics has developed a broad range of approved and investigational tools, including digital and blood-based tests and Cerebrospinal Fluid (CSF) assays, aiming to more effectively detect, diagnose and monitor neurological conditions.

Together with our partners, we are committed to pushing the boundaries of scientific understanding to solve some of the most difficult challenges in neurology today.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.
Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

References

[1] Roche Diagnostics GmbH. Elecsys NfL. Method Sheet 09880488500 V1.0. Roche Diagnostics GmbH; 2025.
[2] Khalil M, et al. Nat Rev Neurol 2018;14:577–89. https://doi.org/10.1038/s41582-018-0058-z
[3] Bar-Or A, et al. EBioMedicine 2023;93:104662. https://doi.org/10.1016/j.ebiom.2023.104662
[4] Gaetani L, et al. J Neurol Neurosurg Psychiatry 2019;90:870–81. https://doi.org/10.1136/jnnp-2018-320106
[5] Gafson AR, et al. Brain 2020;143:1975–98. https://doi.org/10.1093/brain/awaa098
[6] Freedman MS, et al. EBioMedicine 2024;101:104970. https://doi.org/10.1016/j.ebiom.2024.104970
[7] Itorralba J, Schneider R. Pract Neurol (US) 2024;23(2):18–21. https://practicalneurology.com/diseases-diagnoses/ms-immune-disorders/the-prognostic-utility-of-neurofilament-light-chain-in-multiple-sclerosis-a-narrative-review/32098/
[8] MS International Federation. Atlas of MS: Number of people with MS. Accessed 1 April 2026. https://atlasofms.org/map/global/epidemiology/number-of-people-with-ms

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