Elecsys® pTau181 plasma Announcement

I am delighted to share that the **Elecsys® pTau181 plasma, Roche's blood-based biomarker to rule out Alzheimer's Disease-associated amyloid pathology, is now approved for use in Australia**[1].

The Elecsys pTau181 blood test arrives at a pivotal time for Alzheimer's Disease (AD) care, as new disease-modifying therapies (DMTs) targeting amyloid pathology emerge. Collectively, these innovations are creating new hope for patients and their families by transforming the way we diagnose and treat the disease.

A milestone in Roche's commitment to advance Alzheimer's Disease diagnostics

The Elecsys pTau181 blood test offers a simple and effective way to rule out AD-associated amyloid pathology for clinicians in any setting. With a negative predictive value (NPV) of 93.8%[2], this test is a powerful tool to confidently reduce the need for more invasive tests like cerebrospinal fluid (CSF) biomarkers or amyloid PET (Positron Emission Tomography) imaging for patients presenting with cognitive complaints, mild cognitive impairment (MCI), or suspected AD. With its potential to reduce inefficiencies in the current diagnostic pathway, earlier diagnosis of AD is possible.

Primary Care - General Practitioners

Using a simple, single cutoff, the Elecsys pTau181 blood test can help primary care practitioners make more confident clinical decisions. The test provides an early indication of likelihood that a patient does not have underlying AD pathology. Alongside other clinical information, this test helps clinicians make more informed decisions about which patients should proceed with further, more definitive evaluations, potentially years before advanced symptoms appear.[3,4,5]

In memory clinic settings

The Elecsys pTau181 blood test could streamline patient triage, identifying those who most need advanced confirmatory tests like CSF or PET imaging by effectively ruling out those who are unlikely to have AD-associated amyloid pathology. This more efficient use of resources can lead to a reduction in the time to diagnosis.

Streamlining the diagnostic pathway enables earlier diagnosis

Late diagnosis remains a critical bottleneck in Alzheimer's care, limiting patients' access to new DMTs. Since amyloid targeting treatments are most effective in the early stages of the disease (MCI or early dementia)[6], early diagnosis is crucial.

The Elecsys pTau181 blood test empowers primary and secondary care providers to more confidently rule out AD-associated amyloid pathology. By reducing the number of patients referred for confirmatory biomarker testing, more efficient use of diagnostic resources facilitates the identification of patients eligible for DMTs earlier in the disease process.

We are entering a new era in the fight against Alzheimer's disease. By leveraging advanced diagnostic tools such as the Elecsys pTau181 blood test, we can work towards reducing delays, making more efficient use of healthcare resources, to ultimately ensure patients receive the timely and accurate diagnosis they need to access life-changing care and support.

Clinical performance

The clinical performance of the Elecsys pTau181 blood test was assessed in a prospective multicentre study, in which subjects were enrolled at 18 clinical sites across the US, Europe, and Australia. The patient group was diverse and representative of real-world clinical settings, accounting for differences in sex, race, and ethnicity, including those with comorbidities, and covering both primary and specialist care. This approach captures the complexities of diagnostic pathways and provides the most robust evidence of the test's performance[3].

Roche's commitment to neuroscience continues

Currently under development, Roche's rich pipeline of biomarker assays aims to further advance the diagnosis and management of neurological conditions. Among these is the Elecsys pTau217 blood test[*], designed to aid in identifying amyloid pathology with both rule-in and rule-out capabilities, and the Elecsys APOE4 blood test[*] designed to identify carriers of the APOE4 gene. These assays are expected to be available in Australia in the first half of 2026[#].

Access the Elecsys pTau181 plasma brochure for further details

Evaluating the Impact on Diagnostic Performance and Healthcare Resource Utilization of Introducing a plasma rule-out test in the Alzheimer's Disease Diagnostic Pathway

How can your patients get the Elecsys pTau181 blood test?

The NDDL at the Florey Institute, Victoria will be the initial reference site for Australia, with testing expected to commence in approximately mid-October. We will update you as additional testing sites come onboard.

For any questions in regard to referring samples for pTau181 plasma testing, please contact

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Please contact me should you have any questions.

Kind regards,

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References:
1. Elecsys pTau181 plasma is included on the Australian Register of Therapeutic Goods (ARTG) (ARTG entry 200275)
2. Elecsys Phospho-Tau (181P) Plasma method sheet 09697870190
3.Kirste I et al. Revamping Alzheimer's disease diagnostics: evaluating future IVD plasma p-Tau 181 and ApoE4 immunoassays for amyloid detection in a multi-centre study reflective of routine clinical practice. Presented at: 17th CTAD Conference; 2024, Oct 29 - Nov 01; Madrid, Spain. Abstract# LP065.
4.Karikari TK et al. Plasma phosphorylated tau 181 as a biomarker for Alzheimer's disease: a diagnostic performance and prediction modelling study using data from four prospective cohorts. The Lancet Neurology. 2020;19(11):942-954.
5.Moscoso A et al. Time course of phosphorylated-tau181 in blood across the Alzheimer's disease spectrum. Brain. 2021;144(1):325-337.
6. Mielke, M. M., et al. (2024). Recommendations for clinical implementation of blood-based biomarkers for Alzheimer's disease. Alzheimer's & Dementia, 20(S1), e12558
*. Products are currently under development and pending inclusion on the ARTG
#. Timelines are indicative only and subject to change.

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