Accelerating the path to Alzheimer's diagnosis

In treating patients with suspected Alzheimer's disease, early diagnosis is key, as access to new therapies and lifestyle interventions can slow down cognitive decline and delay the progression if implemented in early disease stages.[1,2] *It also allows patients and their families to plan for the future.* ***Nearly 2,000 patients each day progress from mild to moderate dementia,*[3] *meaning time is of the essence.***

A new frontier for Alzheimer's disease testing

The Elecsys® β-Amyloid (1-42) CSF II, Elecsys Phospho-Tau (181P) CSF and Elecsys tTau CSF assays are FDA-cleared in vitro electrochemiluminescence immunoassays for the measurement of the β-Amyloid (1-42) (Abeta42), Phospho-Tau (181P) (pTau181), respectively total-Tau protein concentrations in cerebrospinal fluid (CSF) from adult patients aged 55 years and older being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment to generate a pTau181/Abeta42 ratio, respectively a total-Tau/Abeta42 ratio value.[3]

A positive pTau181/Abeta42 or tTau/Abeta42 ratio result in CSF does not establish a diagnosis of Alzheimer's disease (AD) and should always be interpreted in conjunction with clinical information. The performance of the test for African-American, Asian, and other races had high uncertainty due to the limited number of patients studied.

Here are three things to know about the Roche Elecsys AD CSF assays:

1. The Appropriate Use Recommendations for the new amyloid removal therapies specify amyloid positivity confirmation with AD CSF biomarker testing or an amyloid PET scan.[4]
2. The FDA-cleared Roche Elecsys pTau/abeta42 and tTau/Abeta42 ratio assays provide necessary amyloid confirmation due to their ~90% concordance with β-Amyloid PET scan results.[3]
3. Due to their concordance with amyloid PET, availability, possibility for reimbursement, lower cost and higher access compared with PET scans, these assays can now be integrated into the AD patient pathway and be an adjunct to clinical diagnosis.

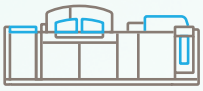
Available for every size laboratory

Scalable and economical, all Elecsys AD CSF assays can be added to any of Roche's widely available **cobas**® fully-automated immunoassay analyzers, giving patients broad access to high-quality testing in a timely manner.[3]

The cobas® family:

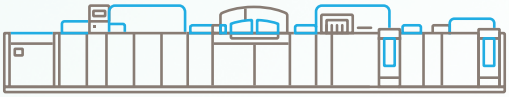
cobas® 4000
analyzer series

cobas® pure
integrated solutions



cobas® 6000
analyzer series

cobas® pro
integrated solutions



cobas® 8000
modular analyzer series

Help bring hope to more people with suspected Alzheimer's disease.

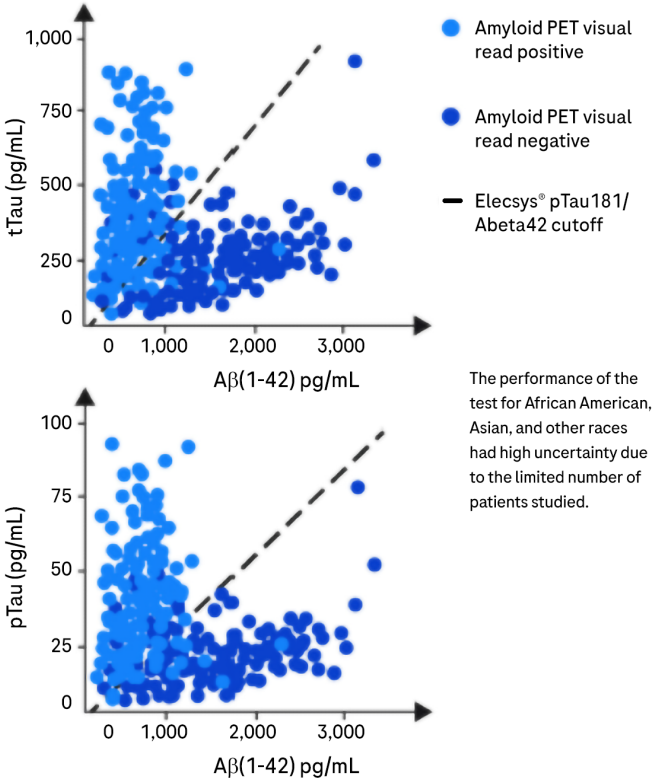
Roche AD CSF assays: precision, access and affordability combined

Results are reliable with Elecsys β-Amyloid (1-42) CSF II, Phospho-Tau (181P) CSF and tTau CSF assays,[3] and their clinical performance reflects their ability to detect amyloid pathology not just in patients with dementia due to Alzheimer's but also earlier, in the mild cognitive impairment (MCI) disease stage.[3,5]

Confirmation of amyloid pathology via FDA-cleared Alzheimer's CSF biomarker testing or amyloid PET is recommended in the appropriate use recommendations for recently approved amyloid removal therapies that have been shown to slow down cognitive decline when administered in early-disease stages.[4]

As depicted in the PET visual read classification graph below, the pTau181/Abeta42 and the tTau/Abeta42 ratios results were able to distinguish between the amyloid PET classifications of positive and negative.[5]

Amyloid PET read classification



The performance of the test for African American, Asian, and other races had high uncertainty due to the limited number of patients studied.

Four reasons to partner with Roche on the Elecsys AD CSF assays

1. **Aid in diagnosis and efficient clinical assessment for therapy:** The CSF assays can help neurologists improve patient management by providing efficient confirmation of amyloid pathology needed for access to new AD therapies.[3,7]
2. **Confidence in results:** The Elecsys pTau181/Abeta42 and tTau/Abeta42 have a ~90% overall agreement with amyloid PET, and the assays are traceable to reference materials to ensure accuracy.[3,5]
3. **Reduce costs associated with AD diagnosis:** The cost for the AD CSF assays (and associated lumbar puncture procedure) is estimated to be lower than an amyloid PET scan. Offering the Elecsys AD CSF test in-house (within a health system) will also likely result in a lower cost versus sending it out to a reference lab.
4. **Provide broad access to patients:** Compared to a PET scan, Elecsys CSF ratios can be part of the typical clinical laboratory test menu; lumbar punctures can be conducted in a variety of outpatient and inpatient settings (HCP offices, LP clinics, radiology centers, etc.), which translates into increased patient access.

Let's Talk: Contact your Roche Account Executive to explore the use of the Elecsys AD CSF assays today.

References:

1. Alzheimer's Association. 2023 Alzheimer's Disease Facts and Figures. Alzheimer's Dement 2023;19(4).
2. Alzheimer's Disease International. https://www.alzint.org/about/symptoms-of-dementia/importance-of-early-diagnosis/?ad-whatisit Accessed June 30, 2023.
3. Elecsys Method Sheet: ms_08821941190, ms_08846693160, ms_08846685190
4. Cummings, J., Apostolova, L., Rabinovici, G.D. et al. Lecanemab: Appropriate Use Recommendations. J Prev Alzheimers Dis (2023).
5. Hansson O, et al. Alzheimers Dement. 2018;14(11):1470-1481.
6. Bittner T, et al. Alzheimers Dement. 2016;12(5):517-526.
7. Cognat E, et al. BMJ Open. 2019

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256

diagnostics.roche.com