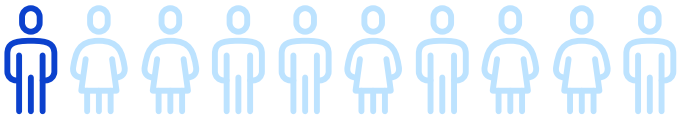
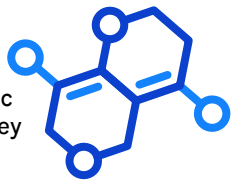
Benefits of Biomarker Testing for Early Symptomatic Alzheimer's Disease Diagnosis

~90% **of the expected 8 million Americans with mild cognitive impairment remain undiagnosed.**[1]



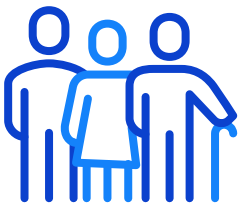
Early disease-stage diagnosis of patients with cognitive decline is key for:

Access to disease-specific therapies: FDA-approved amyloid targeting therapies (lecanemab and donanemab) are indicated for individuals in early symptomatic stages (i.e. MCI and mild dementia) where they are most effective.[2,3]



Clinical trial enrollment: Patients may access programs to connect them with innovative research and enable continued research into new, more effective therapies.

Emotional and societal benefits: Families may plan for the future (advanced care planning) and prompt safety measures for driving and medication adherence.



Cognitive preservation via lifestyle changes: Ongoing research (US POINTER) supports the initiation of structured lifestyle interventions including diet, exercise, cognitive training and vascular risk management to preserve cognitive function.[4]

Biomarker testing in patients with cognitive impairment

pTau blood-based biomarkers can help detect brain amyloid: Levels of phosphorylated Tau protein (pTau) in cerebrospinal fluid (CSF) and plasma correlate well with abnormalities appearing on amyloid positron emission tomography (PET) imaging.[5] Multiple studies demonstrated that pTau217 is the best performing plasma biomarker for detection of amyloid pathology.[6,7]

Facilitate early detection and early diagnosis in primary and secondary care: Using BBM testing in addition to other clinical investigations allows primary care providers to detect patients with early disease and streamline referral to specialists for more comprehensive assessments and final diagnosis.[8] The Elecsys pTau217 plasma test has the same dual rule out and rule in cutoffs, validated in primary and specialty care, ensuring consistent result reporting and a more streamlined patient pathway.[9]

Improve diagnosis accuracy: The Elecsys pTau217 plasma test can rule out / rule in amyloid pathology at cutoffs established at > 90% sensitivity and >90% specificity, with </= 20% of the patients' results in the intermediate zone, which align with the CEOi recommendations for performance.[8,9]

Can preserve specialty resources: Blood tests may prevent unnecessary specialist referrals and reduce costly or invasive confirmatory testing

Understanding The Elecsys® Phospho-Tau217 Plasma Assay

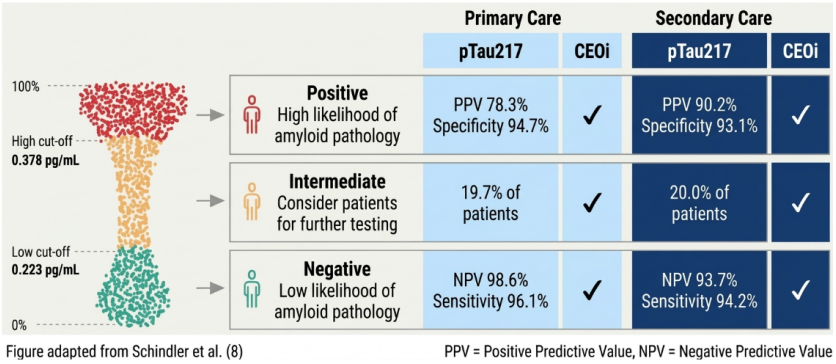
Single biomarker assay using the same validated cut-off across primary and secondary care[9]

The Elecsys Phospho-Tau (217P) Plasma assay is FDA cleared for use in primary and specialty care using the same cutoffs to identify a patients likelihood for amyloid pathology.

A positive result indicates a high likelihood of amyloid pathology. An intermediate result is indeterminate for the presence of amyloid pathology. It is recommended to consider these patients for further testing. A negative result indicates a low likelihood of amyloid pathology. Further clinical investigation into other causes of cognitive decline is recommended for these patients.[9]

The assay is intended for use as an aid in identifying patients with amyloid pathology presenting with signs, symptoms, or complaints of cognitive decline associated with Alzheimer's disease in individuals aged 55 years and older.[9]

The Elecsys Phospho-Tau (217P) Plasma assay result must be used in the diagnostic pathway in conjunction with other clinical information. positive test does not diagnose Alzheimer's disease. The test should not be used in the absence of cognitive symptoms to predict disease. The test should not be used to monitor disease treatments.[9]



	Primary Care		Secondary Care	
	pTau217	CEOi	pTau217	CEOi
Positive High likelihood of amyloid pathology	PPV 78.3% Specificity 94.7%	✓	PPV 90.2% Specificity 93.1%	✓
Intermediate Consider patients for further testing	19.7% of patients	✓	20.0% of patients	✓
Negative Low likelihood of amyloid pathology	NPV 98.6% Sensitivity 96.1%	✓	NPV 93.7% Sensitivity 94.2%	✓

Figure adapted from Schindler et al. (8)

PPV = Positive Predictive Value, NPV = Negative Predictive Value

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