HELP IDENTIFY EARLY SYMPTOMATIC ALZHEIMER'S DISEASE (AD)

By integrating blood biomarkers into your clinical assessment[1]

In conjunction with clinical assessments, blood biomarkers can be used to detect or rule out evidence of AD pathology, including amyloid, primarily for patients aged ≥65 years, given their higher rate of amyloid positivity. Younger patients who meet the test's intended use may also be considered.[2,3]

PET scans and CSF tests are also available to help assess amyloid pathology in patients with suspected AD.[3]

Blood-based biomarkers could be a key step in the diagnostic process.[4]

CMS recognizes Alzheimer's disease (AD) blood biomarkers (BBM) as an option to confirm the presence of amyloid pathology when using the CMS registry as a coverage pathway for amyloid-targeting therapies.

Commercially available blood tests are not standalone tests. The results must be interpreted in conjunction with clinical assessment results. Patients must meet testing criteria.[3]

CMS=Centers for Medicare & Medicaid Services; CSF=cerebrospinal fluid; PET=positron emission tomography.

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Blood biomarkers that include P-tau217 can be highly accurate and accessible diagnostic options to aid in the diagnosis of early symptomatic AD[3,5]

Phosphorylated tau, or P-tau, is a key AD blood biomarker, and P-tau217 is considered the most reliable blood biomarker in helping to detect evidence of AD pathology, including amyloid.[3,5]

In conjunction with clinical assessment, P-tau217 has a strong correlation with amyloid PET scans, making it a valuable blood biomarker for detecting AD pathology, including amyloid, in its initial stages.[3,5]

Some blood biomarkers that include P-tau217 are available through major national labs and can be ordered online.[6,7]

Blood biomarkers, in conjunction with clinical assessments, can enhance diagnostic accuracy for AD pathology, including amyloid[1]

Many blood biomarkers that include P-tau217 demonstrate accuracy of approximately 90%, similar to FDA-approved CSF IVD tests, and are concordant with amyloid PET status in cognitively impaired individuals.[1,5,8]

A head-to-head study* of leading AD blood biomarkers identified plasma P-tau217 as the most accurate for detecting AD pathology. The study also showed %P-tau217[†] had a slightly stronger correlation with amyloid PET than P-tau assays alone.[8‡]

P-TAU217 RATIO (%P-TAU217) DEMONSTRATES CLINICAL UTILITY IN DIAGNOSING AD[1a]

<6 out of 10 patients

accurately identified with AD pathology using standard clinical evaluation

9 out of 10 patients

accurately identified with AD pathology using %P-tau217 in conjunction with standard clinical evaluation

[a]In a study of 1213 patients with cognitive symptoms, blood tests were evaluated for AD pathology. The study used predefined cutoff values to assess the ability of %P-tau217 levels (the ratio of P-tau217/non-phosphorylated-tau217) alone and combined with the Aß42/Aß40 ratio as a composite amyloid probability score (APS2) to identify AD pathology. Blood samples from both primary and secondary care groups were analyzed as a single batch or biweekly, comparing diagnostic accuracy between the blood tests and primary care physicians or dementia specialists. Secondary objectives included examining biomarker performance at various cognitive stages and testing different cutoff values.[1]

%P-tau217=ratio of P-tau217 to non–P-tau217 (expressed as percentage of P-tau217); Aß=amyloid beta.

Commercially available P-tau217 blood biomarkers are not standalone tests. The results must be utilized with clinical assessment results.[3]

*This study compared the performance of leading plasma biomarkers in detecting AD pathology and guiding treatment and clinical trial inclusion. A total of 1,179 plasma samples from 393 Alzheimer's Disease Neuroimaging Initiative (ADNI) participants were analyzed using assays from C2N Diagnostics, Fujirebio, ALZpath Quanterix, Janssen LucentAD Quanterix, and Roche NeuroToolKit. Plasma biomarkers P-tau217, P-tau181, and Aß42/Aß40 were assessed for their ability to classify amyloid PET status, tau PET status, cortical thickness, and cognitive impairment, with clinical assessments including the Clinical Dementia Rating (CDR).[8]

[†]P-tau217 used as a ratio, calculated as P-tau217 divided by non-phosphorylated tau217.[8]

[‡]%P-tau217 demonstrated an AUC of up to 0.93, outperforming other P-tau217 assays, which ranged from 0.88 to 0.90.[8]

IVD=in vitro diagnostics.

Many commercially available blood biomarker (BBM) tests can serve as a confirmatory test in patients with suspected Alzheimer's disease (AD), according to standards of performance[9]

When BBM tests are used for confirmation of AD in patients with cognitive impairment, they should have ≥90% sensitivity and specificity[†]. The AD Blood Test Performance Database can be used to view how the performance data of some available tests compare to the Global CEOi BBM Workgroup[‡] recommendations.[10]

COMMERCIALLY AVAILABLE P-TAU217 ASSAYS IN THE UNITED STATES WITH ≥90% SENSITIVITY AND SPECIFICITY FOR CONFIRMATORY USE[6,10-18]

Company	Test Name	Ordering Information
ARUP® Laboratories	Phospho-Tau 217	
C2N Diagnostics	PrecivityAD2™	
Labcorp®	Phosphorylated Tau 217/ Beta Amyloid 42 ratio	
	Lumipulse P-tau217/Beta Amyloid 42/40 ratio	
Lucent Diagnostics	LucentAD® Complete	
Mayo Clinic	Phospho-Tau217	
Neurocode	ALZpath Dx: Plasma Phosphorylated Tau 217 (p-Tau 217)	
Quest Diagnostics	AD-Detect™ ABeta 42/40 and p-tau217 Evaluation	

[a]This list includes most LDTs for use in the United States and may not be available in all states due to state licensure requirements.

[b]Labcorp Lumipulse test is intended for specialty care only.

LDTs are diagnostic tests that are designed, manufactured, and used in a single laboratory. The Food and Drug Administration (FDA) can approve or clear IVD tests, but the LDTs included here have not been evaluated, approved, or cleared by the FDA. Only certain labs are certified under Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical testing.

IVD=in vitro diagnostics; LDT=laboratory-developed test.

This list only includes some commercially available tests. It is only intended for informational purposes and your consideration and is based on publicly available information as of February 26, 2026. Eli Lilly and Company (Lilly) makes no representations regarding the clinical or analytical validity, manufacturing quality, or design of the testing offered by the vendors included on this list. Inclusion on this list does not represent an endorsement, referral, or recommendation by Lilly nor representation of assay performance compared to CEOi* acceptable performance criteria for a confirmatory or triage assay. Contact the laboratory vendor for more information. All trademarks are property of their respective owners.

Commercially available P-tau217 blood tests are not standalone tests. The results must be interpreted in conjunction with clinical assessment results.[3]

PET scans and CSF tests are also available to help assess amyloid pathology in patients with suspected AD, and there are additional AD biomarkers beyond P-tau217 that could be considered in a diagnostic workup.[3]

If a BBM is appropriate for your patient, refer to the chart to the right for potential ICD-10 codes that may be used for billing.[19§]

[§]This list does not include all possible ICD-10 codes.

Code	Description
G31	Other degenerative diseases of nervous system, not elsewhere classified
G30	Alzheimer's disease
R41	Other symptoms and signs involving cognitive functions and awareness
F02	Dementia in other diseases classified elsewhere
F03	Unspecified dementia

*The Global CEOi BBM Workgroup is a partnership consisting of individuals in academia who help validate blood biomarkers tests and diagnostics, the medical device companies that develop them, pharmaceutical companies developing treatment pathways where blood biomarkers may be useful, and patient advocacy groups that aim to improve AD care and treatment. Together, CEOi works to address major challenges in the field of AD, and the BBM Workgroup was established to examine the minimum acceptable performance standards of blood biomarker tests in clinical use. Their recommendations are based on an assay's validation performance data, and real-world results may vary depending on clinical setting.[3]

[†]The BBM Workgroup recommends tests should result no more than 15–20% of intermediate values.[3]

[‡]The predictive values of all biomarker tests vary according to the pre-test probability of amyloid pathology and must be interpreted in the complete clinical context. Use of BBM tests that meet these performance standards could enable more people to receive an accurate and timely AD diagnosis and potentially benefit from new treatments.[3]

BBM=blood biomarker; CEOi=CEO initiative; ICD=International Classification of Diseases, Tenth Revision; CSF=cerebrospinal fluid; PET=positron emission tomography; P-tau=phosphorylated tau.

Along with clinical assessment, AD blood biomarkers can help rule out or provide evidence of AD pathology[1,2]

FOR REFERRING PROVIDERS: THOUGHT LEADER CONSENSUS FOR INTERPRETING BLOOD BIOMARKERS[3]

	Result Concordance With Amyloid PET	Recommended Next Steps
	**Positive** Along with full clinical assessment, supports increased likelihood of having AD pathology, including amyloid	**Refer to specialist** Refer patient to a specialist for further evaluation and additional workup
	Intermediate Does not provide a clear answer regarding status of AD pathology, including amyloid	**Refer to specialist** Consider referral to a specialist for further evaluation and additional workup
	Negative Strongly supports absence of AD pathology, including amyloid	**Further assessment needed** Consider further assessment for causes of cognitive impairment other than AD

BLOOD BIOMARKERS CAN ENHANCE THE PATIENT JOURNEY FROM ASSESSMENT TO TREATMENT.

They are low-cost, scalable, and globally accessible. These tests help ensure patients are referred to the right specialists based on results, directing patients that present with AD pathology to appropriate care while reducing unnecessary referrals of patients without AD.[3, 9, 20]

Commercially available blood biomarkers used to detect amyloid positivity are not standalone tests. The results must be interpreted in conjunction with clinical assessment results. Patients must meet testing criteria.[3]

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