Test Definition: AD2

PrecivityAD2, Plasma

Overview

Useful For

Assisting in the evaluation of adults aged 40 years and older, who present with signs or symptoms of cognitive impairment undergoing evaluation for Alzheimer disease or other forms of cognitive decline

This test is **not intended for** use as a screening or stand-alone diagnostic test. The safety and effectiveness of the PrecivityAD2 test have not been established for predicting development of dementia or other neurologic conditions, or for monitoring responses to therapies.

Highlights

The PrecivityAD2 test is a US Food and Drug Administration-cleared blood test that helps healthcare professionals evaluate whether a patient's cognitive symptoms are likely to be due to Alzheimer disease. The PrecivityAD2 test is indicated for use in adults aged 40 years and older who present with signs or symptoms of cognitive impairment undergoing evaluation for Alzheimer disease or other forms of cognitive decline. The PrecivityAD2 test is intended to be used in conjunction with clinical assessment to aid healthcare professionals experienced in the evaluation of cognitive impairment to identify patients with amyloid pathology associated with Alzheimer disease. The test is not intended as a screening or stand-alone diagnostic test.

The test measures plasma amyloid beta 42/40 ratio and percent tau phosphorylated at threonine-217. The two ratios are combined in a proprietary algorithm to calculate the Amyloid Probability Score 2 (APS2), a whole number from 0 to 100 reported as negative, likely positive, or positive. Only the APS2 result with reference intervals in the interpretation is reported.

Method Name

Immunoprecipitation/Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS)

NY State Available

Yes

Specimen

Specimen Type

Plasma

Ordering Guidance

This blood test is intended for use in adults aged 40 years and older who present with signs or symptoms of cognitive impairment undergoing evaluation for Alzheimer disease or other forms of cognitive decline. The test is not intended as a screening or stand-alone diagnostic test.

Shipping Instructions

1. Specimens must be shipped frozen on dry ice.
2. Place labeled aliquot tubes inside a larger tube or vial for transport.

Specimen Required

Supplies: Screw cap micro tube, 2 mL, PCR Performance Tested, Low protein-binding (T983)
Collection Container/Tube: 10 mL Purple top (K2-EDTA)
Submission Container/Tube: Two 2-mL screw cap micro tubes
Specimen Volume: 3 mL Plasma in 2 tubes, each containing 1.5 mL plasma
Collection Instructions:
1. Label two 2-mL screw-cap micro tubes.
2. Within 2 hours of collection, centrifuge and aliquot 1.5 mL of plasma into each labeled micro tube.
3. Freeze plasma (no longer than 2 hours after collection) at or below -20 degrees C.
Note: If plasma sample is not being shipped on the day of collection/processing, the sample needs to be stored at -80 degrees C.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Outside of age range	Reject
Specimen collected outside of testing range (too long in storage before arrival to testing facility)	Reject
Insufficient volume	Reject
Incorrect labeling	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma	Frozen		

Clinical & Interpretive

Clinical Information

The US Food and Drug Administration-cleared PrecivityAD2 test directly quantifies 4 plasma analytes using immunoprecipitation followed by liquid chromatography tandem mass spectrometry. These measurements are combined into two ratios: plasma amyloid beta 42/40 ratio (Abeta42/40) and the percentage of tau phosphorylated at threonine-217 (%p-tau217). Measuring each biomarker against its own reference protein improves diagnostic performance compared with individual biomarker concentrations alone. This approach improves specificity for amyloid pathology in the presence of advancing age and comorbidities commonly associated with aging, such as chronic kidney disease, obesity, and anemia.(1-6)

Results are reported as positive, negative, or likely positive. A positive or negative result is intended to help the healthcare professional rule in or rule out amyloid pathology associated with Alzheimer disease. When combined with clinical assessment, these results help improve diagnostic accuracy compared with clinical assessment alone. A likely positive result suggests the presence of amyloid pathology. It identifies the smaller group of patients whose biomarker profiles fall between the high and low-cut points, where additional evaluation or testing may be appropriate.

The clinical performance of this test was evaluated in a multicohort study of 1142 patients with subjective cognitive decline, mild cognitive impairment, or dementia. The test demonstrated high predictive value for brain amyloid status, as determined by amyloid positron emission tomography (PET; visual read) or cerebrospinal fluid biomarker analysis. At an overall brain amyloid prevalence of 52.7%, the positive predictive value (PPV) of a positive result was 97.6%. The negative predictive value (NPV) of a negative result was 93.1%, derived from the 6.9% predictive value for brain amyloid pathology among patients with negative results.(7) The PPV of a likely positive result was 77.3%. Likely positive results occurred in 17.3% of patients. Diagnostic performance was consistent across symptom severity, ages ranging from 40 to older than 80 years, and the number of comorbidities (one, two, or three or more). Comorbidities included atrial fibrillation, autoimmune or inflammatory disease, chronic heart failure, chronic kidney disease, coronary heart disease, depression, diabetes, dyslipidemia, history of cancer, history of stroke or transient ischemic attack, hypertension, and obesity.(7)

Reference Values

Amyloid Probability Score 2 (APS2) (range of 0-100):

Positive
>66.5 is consistent with brain amyloid pathology

Likely Positive
>27.5 to < 66.5 is likely consistent with brain amyloid pathology

Negative
<27.5 is not consistent with brain amyloid pathology
APS2 results are reported as whole numbers from 0-100. The reporting ranges shown above are based on the APS2 cut points specified in the FDA-cleared PrecivityAD2 labeling.

Interpretation

Table. Amyloid Probability Score 2 (APS2) Clinical Cutoffs and Test Result Interpretation

APS2 Value	Result	Result interpretation
APS2 > 66.5	Positive	An APS2 result >66.5 is Positive and consistent with the presence of brain amyloid pathology. This result increases the likelihood that a patient's clinical presentation is due to Alzheimer disease. The APS2 result alone does not establish a diagnosis of clinical Alzheimer disease. Clinical correlation is recommended.
APS2 > 27.5 to < 66.5	Likely Positive	An APS2 result >27.5 and <66.5 is Likely Positive and likely consistent with the presence of brain amyloid pathology. The result increases the likelihood that a patient's clinical presentation is due to Alzheimer disease. The APS2 result alone does not establish a diagnosis of clinical Alzheimer disease. Additional evaluations or further testing may be appropriate.
APS2 < 27.5	Negative	An APS2 result <27.5 is Negative and not consistent with the presence of brain amyloid pathology. The result decreases the likelihood that a patient's clinical presentation is due to Alzheimer disease. Other potential causes for the patient's cognitive symptoms should be considered.

Cautions

The results of other analyte tests using other methodologies cannot be interpreted in the context of the PrecivityAD2 test.

Limitations:
The PrecivityAD2 test is for prescription use only.

The PrecivityAD2 test is for in vitro diagnostic use: only performed at C2N Diagnostics Laboratory.

This test is intended to be performed only on qualified, serial number-controlled instruments at C2N Diagnostics Laboratory. All instruments used for patient testing are controlled under C2N's Quality Management System and must successfully complete the required qualification and validation activities before implementation.

Always interpret the PrecivityAD2 test in conjunction with the patient's medical history, clinical presentation, physical assessment, and other findings.

The safety and effectiveness of the PrecivityAD2 test have not been established for:
-Predicting development of dementia or other neurologic conditions
-Monitoring responses to therapies

The performance of the PrecivityAD2 test across racial subgroups has not been fully established because of the relatively small number of subjects who report racial categories other than White and the large proportion of subjects in the pooled validation cohort with missing racial categorization. Results for these subgroups should be interpreted with caution.

Warnings:
Erroneous results may occur due to improper specimen collection, handling, storage, shipping, or unevaluated interfering substances.

Hemoglobin concentrations over 150 mg/dL may interfere with analyte measurement and affect the Amyloid Probability Score 2 result.

Clinical Reference

1. Meyer MR, Kirmess KM, Eastwood S, et al. Clinical validation of the PrecivityAD2 blood test: A mass spectrometry-based test with algorithm combining %p-tau217 and Abeta42/40 ratio to identify presence of brain amyloid. Alzheimers Dement. 2024;20(5):3179-3192. doi:10.1002/alz.13764
2. Karlsson L, Janelidze S, Barthelemy NR, et al. Reference proteins to improve Core 1 and Core 2 Alzheimer's disease CSF and plasma biomarkers. Brain. 2026;149(4):1153-1167. doi:10.1093/brain/awaf375
3. Bornhorst JA, Lundgreen CS, Weigand SD, et al. Quantitative assessment of the effect of chronic kidney disease on plasma P-Tau217 concentrations. Neurology. 2025;104(3):e210287. doi:10.1212/WNL.0000000000210287
4. Yun J, Lee J, Shin D, et al. Plasma phosphorylated Tau 217 cutoffs for amyloid pathology and kidney function, body mass index, and anemia. JAMA Neurol. 2026;83(3):269-279. doi:10.1001/jamaneurol.2025.5530
5. Pichet Binette A, Janelidze S, Cullen N, et al. Confounding factors of Alzheimer's disease plasma biomarkers and their impact on clinical performance. Alzheimers Dement. 2023;19(4):1403-1414. doi:10.1002/alz.12787
6. Palmqvist S, Warmenhoven N, Anastasi F, et al. Plasma phospho-tau217 for Alzheimer's disease diagnosis in primary and secondary care using a fully automated platform. Nat Med. 2025;31(6):2036-2043. doi:10.1038/s41591-025-03622-w
7. C2N Diagnostics, LLC. PrecivityAD2 test labeling. 510(k) K253240. Issued August 17, 2026. Available at www.accessdata.fda.gov/cdrh_docs/pdf25/K253240.pdf
8. Jack CR Jr, Andrews JS, Beach TG, et al. Revised criteria for diagnosis and staging of Alzheimer’s disease: Alzheimer’s Association Workgroup. Alzheimers Dement. 2024;20(8):5143-5169. doi:10.1002/alz.13859

Performance

Method Description

Liquid chromatography tandem mass spectrometry (LC-MS/MS) following immunoprecipitation is utilized for quantification of concentrations of AD Core 1 biomarkers (Abeta42 and p-tau217) and their reference proteins (Abeta40 and np-tau217) for normalizing ratio calculations. A proprietary algorithm combines Abeta42/40 ratio and p-tau217/np-tau217 X 100 (%p-tau217) to generate the Amyloid Probability Score 2 (APS2), a whole number ranging from 0-100, that determines whether a patient is positive, likely positive or negative for the presence of brain amyloid pathology.

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

13 days post sample receipt from MCL

Specimen Retention Time

60 days

Performing Laboratory Location

C2N Diagnostics LLC

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared by the U.S. Food and Drug Administration (FDA) under 510(k) K253240 and is performed according to the FDA-cleared labeling at C2N Diagnostics Laboratory. For prescription use only.

CPT Code Information

0503U

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
AD2	PrecivityAD2	Not Provided

Result ID	Test Result Name	Result LOINC® Value
PD2A	Amyloid Probability Score	Not Provided
PD2B	APS2 Result	Not Provided
PD2C	Interpretation	Not Provided
PD2D	Indication for Use of the Test	Not Provided
PD2E	Test Description and Clinical Performance	Not Provided
PD2F	Limitations	Not Provided
PD2G	Report Comment	Not Provided
PD2H	Performing Site	Not Provided