The PrecivityAD2® Blood Test Specifications

Overview

The PrecivityAD2® test is an FDA-cleared blood test for adults aged 40 years and older who present with signs or symptoms of cognitive impairment undergoing evaluation for Alzheimer's disease or other forms of cognitive decline. The APS2 result indicates the likelihood of brain amyloid pathology, reported as Positive, Likely Positive, or Negative. The test is not intended as a screening or stand-alone diagnostic test.

Clinical Information

The PrecivityAD2® test is an FDA-cleared blood test that helps health care professionals evaluate whether a patient's cognitive symptoms are likely to be due to Alzheimer's 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's disease or other forms of cognitive decline and is intended to be used in conjunction with clinical assessment to aid health care professionals experienced in the evaluation of cognitive impairment to identify patients with amyloid pathology associated with Alzheimer's disease. This test is not intended as a screening or stand-alone diagnostic test.[1]

The test quantifies four plasma analytes by immunoprecipitation followed by liquid chromatography-tandem mass spectrometry and combines them into two ratios: Aβ42/40 and %p-tau217. Measuring each biomarker against its own reference protein has been shown to provide greater diagnostic performance than the individual biomarker concentrations alone, with improved specificity for amyloid pathology in the presence of advancing age and comorbidities such as chronic kidney disease, obesity, and anemia.[2-7]

Results are reported in three categories. A Positive or Negative result is intended to help the ordering health care professional rule in or rule out amyloid pathology associated with Alzheimer's disease and make a more accurate clinical diagnosis when combined with clinical assessment compared to clinical assessment alone. A Likely Positive result is likely consistent with the presence of amyloid pathology. It identifies the smaller group of patients whose biomarker profile falls between the high and low-cut points, where additional evaluation or further testing may be appropriate.[1]

Indication for Use

The PrecivityAD2® test is an in vitro device that uses immunoprecipitation followed by liquid chromatography-tandem mass spectrometry (LC-MS/MS) to quantify β-Amyloid 1-42 (Aβ42) and β-Amyloid 1-40 (Aβ40) peptide concentrations and phosphorylated and non-phosphorylated tau protein at amino acid threonine, position 217 (p-tau217 and np-tau217) peptide concentrations in human K2-EDTA plasma.

An algorithm combines the Aβ42/40 ratio and the p-tau217/np-tau217 ratio x 100 (%p-tau217) to generate the Amyloid Probability Score 2 (APS2) result, a numeric value ranging from 0-100.

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The PrecivityAD2® test is intended to be used in conjunction with clinical assessment to aid health care professionals experienced in the evaluation of cognitive impairment to identify patients with amyloid pathology associated with Alzheimer's disease.

The test is not intended as a screening or stand-alone diagnostic test.[1]

Ordering Requirements

The PrecivityAD2® test is a prescription-use-only test that must be ordered by a health care professional. The following must be completed and signed; incomplete forms will delay processing:

- Requisition Form (order code 1004) – submit completed/signed form with specimen.
- Informed Consent Form – retain completed/signed form in medical records.

Test Methodologies

LC-MS/MS following immunoprecipitation is used to quantify the AD Core 1 biomarkers (Aβ42 and p-tau217)[8] and their reference proteins (Aβ40 and np-tau217) for normalizing ratio calculations, in two multiplexed assays: the C2N-Aβ42/40 Assay and the C2N-%p-tau217 Assay. The APS2 is a whole number between 0 and 100 evaluated against clinical cutoffs.[1]

Only the APS2 result and its interpretation are reported. Individual Aβ42, Aβ40, p-tau217, and np-tau217 concentrations and the Aβ42/40 and %p-tau217 ratios are not reported.[1]

Specimen Requirements

Patient preparation	None
Specimen collection	Collect blood from an antecubital or other suitable vein; completely fill the 10-mL K2-EDTA collection tube and gently invert 10–12 times. Centrifuge within 120 minutes of collection at 1,500–1,800 x g for 15 minutes (for settings above 1,800 x g, up to 2,000 x g for 10 minutes). Transfer at least 1.5 mL of plasma into two labeled 2.0-mL low-bind protein microtubes, dividing volume equally or as needed.
Specimen shipping	Frozen: immediately freeze plasma at −80 °C; C2N's designated courier packs with dry ice. Refrigerated: refrigerate within 2 hours of collection and ship the same day.

Specimen stability: 280 days frozen at -80 °C, 48 hours refrigerated at 2-8 °C, 3 hours ambient, and up to 3 freeze-thaw cycles.[1]

Test Details

Test Performance

Results[a]	Frequency (n/N)	PPV/NPV[b] (95% CI)
Positive	37.0% (423/1,142)	PPV 97.6% (95.7-98.7)
Likely Positive	17.3% (198/1,142)	PPV 77.3% (70.9-82.6)
Negative	45.6% (521/1,142)	NPV 93.1% (90.6-95.0)[c]

[a] Pooled Validation Cohort of 1,142 individuals with signs or symptoms of cognitive impairment. Reference standard: amyloid PET imaging or CSF analysis with the FDA-authorized Fujirebio Lumipulse G β-Amyloid Ratio (1-42/1-40) CSF test.[1]

[b] At the observed amyloid prevalence of 52.7% (602/1,142). Positive predictive value (PPV) for Positive and Likely Positive results correspond to the predictive value (PV) while the negative predictive value (NPV) for Negative results is calculated as 100%-PV.[1]

[c] Derived from 6.9% predictive value for brain amyloid pathology in Negative results reported in the labeling (95% CI 5.0%-9.4%).[1]

The test demonstrated consistent diagnostic performance regardless of patient age, number of comorbidities (one, two, or three or more), or the individual comorbidities studied, including atrial fibrillation, autoimmune / inflammatory disease, chronic heart failure, chronic kidney disease, coronary heart disease, depression, diabetes, dyslipidemia, history of cancer, history of stroke / transient ischemic attack, hypertension, and obesity.[1]

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Analytical Performance

Analytical measuring intervals are 50 to 1,000 pg/mL for Aβ40, 5 to 100 pg/mL for Aβ42, 1.3 to 50 pg/mL for p-atu217, and 6.6 to 400 pg/mL for np-tau217. Precision, interfering substances, and specimen stability are described in the FDA-cleared labeling.[1]

APS2 Clinical Cutoffs and Test Result Interpretation

APS2	Interpretation
Positive APS2 > 66.5 (67 to 100)	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's disease. The APS2 result alone does not establish a diagnosis of clinical Alzheimer's disease. Clinical correlation is recommended.
Likely Positive 27.5 < APS2 < 66.5 (28 to 66)	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's disease. The APS2 result alone does not establish a diagnosis of clinical Alzheimer's disease. Additional evaluations and/or further testing may be appropriate.
Negative APS2 < 27.5 (0 to 27)	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's disease. Other potential causes for the patient's cognitive symptoms should be considered.

APS2 is reported as a whole number between 0 and 100.[1]

Test Classification

The PrecivityAD2® test has been cleared by the U.S. Food and Drug Administration under 510(k) K253240 as a Class II in vitro diagnostic device.[1] The test is performed only at C2N Diagnostics Laboratory, St. Louis, Missouri, a CLIA-certified, CAP-accredited laboratory.

Unique Device Identifier (UDI)

8 60007 06974 1

Device Identifier: 00860007069741

PrecivityAD2® test, 510(k) K253240[1]

Test Availability

This test is available in all 50 U.S. states, the District of Columbia, and Puerto Rico. For availability outside the United States, contact Client Services at 1-877-226-3424.

Test Limitations and Warnings

The Limitations and Warnings below are reproduced from the FDA-cleared labeling.[1]

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 concentration >150 mg/dL may interfere with analyte measurement and affect the APS2 result.

Reporting & Turnaround Time

The PrecivityAD2® test report is issued to the ordering health care professional within 10 business days from receipt of sample and completed paperwork.

If APS2 cannot initially be calculated because one or more analyte results are outside the applicable Analytical Measuring Interval (AMI) (with the exception for p-tau217 below the limit of quantitation [LOQ]), the submitted specimen will not be retested and further recollection for APS2 testing is not recommended. If one or more mass spectrometry flags (i.e., ion ratio failure) are present, the submitted specimen will be retested. If the mass spectrometry flag persists upon retesting, an APS2 result cannot be determined. A new specimen may be collected and tested to address potential specimen-specific or pre-analytical factors.[1]

To Order

Authorized health care professionals: go to www.PrecivityAD2.com, click the **Providers: Order Test Kits** button, select **Create an Account**, and complete the registration form, or call 1-877-226-3424. Use order code 1004.

Background Information

Alzheimer's disease (AD) is the most common form of dementia. An estimated 7.4 million Americans age 65 and older are living with Alzheimer's dementia.[9] Clinical characteristics include gradual onset of MCI, behavioral changes such as apathy, withdrawal, or agitation, and disease progression to middle and later stage dementia.[9] Currently, there is no test that detects AD pathology in patients in the clinic with 100% accuracy.[10] Increasing age, APOE ε4 carrier status, and family history of a close relative with AD are known risk factors for developing AD.[9,11]

References

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