MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: November 4, 2026
Effective Date: November 12, 2026

PrecivityAD2, Plasma

Test ID: AD2

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.

Methods:

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

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.

Specimen Requirements:

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.

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Minimum Volume: See Specimen Required

Specimen Stability Information:

Specimen Type	Temperature	Time
Plasma	Frozen	

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.

CPT Code:

0503U

Day(s) Performed: Monday through Friday **Report Available:** 13 days post sample receipt from MCL

Questions

Contact Bethany Feind, Laboratory Resource Coordinator at 800-533-1710.

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