Patient ID	Patient Name		Birth Date	Sex	Age
SA00168897	SAMPLE, REPORT		1961-02-25	F	63
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00168897	SA00168897	CLIENT,CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		10 Jun 2024 08:00			

PrecivityAD2

Amyloid Probability Score 2 (APS2)

Y350

Reference Value
0–47

⚠ Abn 84

APS2 Result

Y350

POSITIVE

APS2 Result Interpretation

Y350

This patient has a positive APS2 value. A positive APS2 (48–100) is consistent with a positive amyloid PET scan; it reflects a high likelihood of brain amyloid plaques and is therefore consistent with a neuropathological diagnosis of Alzheimer's disease (AD). The APS2 result should be interpreted in conjunction with other patient information. Clinical correlation is recommended.

APS2 Result Reference Interval

Y350

0–47 consistent with absence of brain amyloid plaques

APS2 Description

Y350

The APS2 result is a composite score ranging from 0–100 that demonstrates a significantly more robust and better fitting model output that more closely matches brain amyloid pathology as compared to the individual biomarkers (Abeta42/40 Ratio or %p-tau217) considered separately. Discordance between values for the APS2 result and the individual biomarkers may occur.

Percent p-tau217

Y350

Reference Value
<4.2

9.6 %

Percent p-tau217 Reference Interval

Y350

< 4.2% consistent with absence of brain amyloid plaques

Percent p-tau217 Description

Y350

%p-tau217 (p-tau217/np-tau217) - concentration of phosphorylated tau at threonine 217 (p-tau217) divided by nonphosphorylated tau at threonine 217 (np-tau217), multiplied by 100

Test Environment PATHBV Template

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
Y350	C2N Diagnostics LLC	4340 Duncan Avenue, St. Louis, MO 631101110		

Patient ID	Patient Name		Birth Date	Sex	Age
SA00168897	SAMPLE, REPORT		1961-02-25	F	63
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00168897	SA00168897	CLIENT,CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		10 Jun 2024 08:00			

Abeta42/40 Ratio

Y350

0.102

Reference Value
>0.095

Abeta42/40 Ratio Reference Interval

Y350

> 0.095 consistent with absence of brain amyloid plaques

Abeta42/40 Ratio Description

Y350

Abeta42/40 Ratio - concentration of amyloid beta(Abeta)42 divided by Abeta40.

Test Description

Y350

Alzheimer's disease is defined pathologically by the presence of amyloid plaques and neurofibrillary tangles in the brain. This test measures the ratio of Abeta peptides 42 and 40 (Abeta42/40 Ratio) and the ratio of p-tau217 and np-tau217 peptides (%p-tau217) in plasma to calculate the Amyloid Probability Score 2 (APS2). APS2 is used to estimate the likelihood - ranging from zero to 100 - that the patient is amyloid positive on an amyloid PET scan. The APS2 result significantly correlates with brain amyloidosis. Clinical performance of this test was established in a study of 583 patients with mild cognitive impairment or dementia. In this study, the APS2 result correctly identified brain amyloid status as determined by quantitative amyloid PET scan (Centiloid > 25) in 88% of patients in a population with a 53% prevalence of brain amyloidosis. Sensitivity and specificity were 88% and 89%, respectively, and PPV and NPV were 90% and 87%, respectively (Meyer, 2024). The APS2 is not a percent likelihood value and should not be interpreted as such.

Limitations of Test Result

Y350

False positive or false negative test results may occur. Interpretive data were derived from clinical studies in a U.S. predominantly Caucasian population with mild cognitive impairment or dementia. The extent of the differences in results based on patients of other racial and ethnic groups has not yet been established. The PrecivityAD2(TM) test is not intended for use as a screening or stand-alone diagnostic test. Currently, there is insufficient evidence to support serial testing for assessment of longitudinal changes in biomarkers, including monitoring response to therapy.

Methods and Assay Category

Y350

Mass spectrometry measures the concentrations of Abeta42, Abeta40, p-tau217 and np-tau217. C2N Diagnostics has developed and determined the analytical performance characteristics of this Laboratory Developed Test. This assay has not been cleared or approved by the FDA. This assay has been validated pursuant to CLIA regulations and is used for clinical purposes.

References

Y350

Refer to the PrecivityAD2(TM) Blood Test Specifications.

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
Y350	C2N Diagnostics LLC	4340 Duncan Avenue, St. Louis, MO 631101110		

MAYO CLINIC LABORATORIES

Patient ID	Patient Name		Birth Date	Sex	Age
SA00168897	SAMPLE, REPORT		1961-02-25	F	63
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00168897	SA00168897	CLIENT,CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		10 Jun 2024 08:00			

Performing Site Y350

C2N Diagnostics, LLC, 4340 Duncan Avenue, St. Louis, MO 63110−1−877-C2N-DIAG (226−3424) - CLIA license #26D2184292 CAP# 8488006 Laboratory Director: John Contois PhD, DABCC, FADLM PrecivityAD2(TM) is a trademark of C2N Diagnostics, LLC. (C) 2024 C2N Diagnostics, LLC. All Rights Reserved.

Received: 11 Jun 2024 14:30 **Reported:** 14 Jun 2024 07:47

Test Environment PATHDX Template

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
Y350	C2N Diagnostics LLC	4340 Duncan Avenue, St. Louis, MO 631101110		