

PrecivityAD2, Reflex to Apolipoprotein E, Plasma

Test ID: AD2AR

Useful for:

Assisting in the evaluation of adult patients, aged 55 years and older, with signs or symptoms of mild cognitive impairment or dementia who are being assessed for Alzheimer disease and other causes of cognitive decline.

This is **not intended for** patients younger than 55 years, or for use as a screening test in patients without signs or symptoms of cognitive impairment, or for serial testing for assessment of longitudinal changes.

Reflex Tests:

| Test ID | Reporting Name | Available Separately | Always Performed |
|---------|----------------|----------------------|------------------|
| C2NAP | Precivity-ApoE | No | No |

Methods:

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

Reference Values:

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

Negative 0-47

Positive 48-100

Abeta42/40 Ratio:

> or =0.095 Consistent with absence of amyloid plaques

Percent p-tau217:

<4.2% consistent with absence of brain amyloid plaques

ApoE Proteotype

E2/E2, E2/E3, E2/E4, E3/E3, E3/E4, E4/E4

-E3 is the most common allele.

-E4 allele is associated with increased risk of amyloid plaques.

-E2 allele is associated with lower risk of amyloid plaques.

Specimen Requirements:

| | |
|-----------------------------------|--|
| Supplies: | Screw cap micro tube, 2 mL, PCR Performance Tested, Low protein-binding (T983) |
| Collection Container/Tube: | 10 mL Purple top (K EDTA) |
| Submission Container/Tube: | Two 2-mL screw cap micro tubes |
| Specimen Volume: | 3 mL in 2 tubes, each containing 1.5 mL |
| Collection Instructions: | <ol style="list-style-type: none">1. Centrifuge within two hours of collection2. Aliquot plasma into a 2 mL micro tube.3. Freeze plasma (no longer than 2 hours after collection) at -20 degrees C or below. |
| Minimum Volume: | 1.5 mL |

Specimen Stability Information:

| Specimen Type | Temperature | Time |
|---------------|-------------|------|
| Plasma | Frozen | |

Cautions:

This test is not a standalone test; positive or negative Amyloid Probability Score 2 (APS2) values alone neither rule in nor rule out a diagnosis of Alzheimer disease (AD).

Test results should be used in conjunction with other diagnostic tools such as neurological examination, neurobehavioral tests, imaging, and routine laboratory tests.

False-positive and false-negative test results may occur.

This test uses interpretive data that were derived from clinical studies in a predominantly White US population of patients with mild cognitive impairment or early dementia. The extent of the differences in results (if any) based on individuals of other racial and ethnic groups has not yet been firmly established.

Currently, there is insufficient evidence to support serial testing for the assessment of longitudinal changes in biomarkers, including monitoring response to therapy.

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

Apolipoprotein E

This test detects only peptides from E2, E3 and E4 proteins and does not detect peptides from rare apolipoprotein E (ApoE) phenotypes.

Although multiple epidemiological studies of diverse ethnic populations have demonstrated increased frequency of the E4 allele in late-onset AD cohorts, the extent of differences in individual risk estimates across different ethnicities has not been established.(22)

The E4 allele is neither necessary nor sufficient for the development of AD; thus, ApoE isoform/*APOE* allele status cannot be used alone for the diagnosis of AD.(18)

CPT Code:

81599

Day(s) Performed: Monday through Friday **Report Available:** 10 days post sample receipt from MCL

Questions

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