MAYO CLINIC LABORATORIES

Mayo Clinic BioPharma Diagnostics

Test Definition: BAMYP

Beta-Amyloid 1-42 and 1-40 with Ratio (1-42/1-40), Plasma

Overview

Useful For
Evaluation of amyloid pathology in adult patients presenting with cognitive impairment and being considered for clinical trials recruitment.

Highlights
BioPharma Diagnostics Use Only

Method Name
Chemiluminescent Enzyme Immunoassay (CLEIA)

NY State Available
Yes

Reporting Name
Beta-Amyloid 1-42, 1-40, Ratio, P

Aliases
Ab42/Ab40 ratio
Amyloid Beta 40
Amyloid Beta 42
Amyloid ratio
Beta-Amyloid 40
Beta-Amyloid 42

Specimen

Specimen Type
Plasma

Specimen Required
Supplies: Sarstedt Aliquot Tube 5 mL (T914)
Collection Container/Tube: Lavender top (EDTA)
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Information: Centrifuge and aliquot plasma into a plastic vial. Do not submit in original tube.

Specimen Minimum Volume
0.75 mL

Reject Due To

Gross hemolysis	OK
Thawing	Cold reject; Warm reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
EDTA Plasma	Frozen	90 days	

Clinical & Interpretive

Clinical Information
One of the neuropathologic features found in the brain of patients with Alzheimer disease (AD) is the presence of plaques composed of beta-amyloid. The two beta-amyloid peptides evaluated by this assay are 1-40 and 1-42. Beta-amyloid 1-40 typically exists at a higher physiological concentration than beta-amyloid 1-42. In AD, beta-amyloid 1-42 accumulation, either by overproduction or decreased clearance, leads to aggregation into plaques and neurotoxicity. Beta-amyloid 1-40 is much less prone to aggregation, with levels remaining unchanged when comparing patients with AD to healthy individuals.

Current research indicates that plasma Abeta42/40 ratio may be used to predict brain beta-amyloid burden. It could reduce the number of lumbar punctures (for spinal fluid biomarker testing) or amyloid-positron emission tomography (PET) scans in light of clinical trial recruitment and be used as a tool to evaluate target engagement and efficacy of disease-modifying drugs.

Reference Values
Beta-Amyloid Ratio (1-42/1-40): > or =0.077

Interpretation
A normal beta-amyloid ratio (1-42/1-40) greater than or equal to 0.077 is suggestive of a negative (normal) amyloid positron emission tomography (PET) scan result. This result indicates a reduced likelihood that a patient's cognitive impairment is due to Alzheimer disease (AD).

An abnormal beta-amyloid Ratio (1-42/1-40) less than 0.077 is suggestive of a positive (abnormal) amyloid PET scan result. This result does not establish a diagnosis of AD or other cognitive disorder.

Cautions
The beta-amyloid ratio (1-42/1-40) results must be interpreted in conjunction with other diagnostic tools such as neurological examination, neurobehavioral tests, imaging, and routine laboratory tests.

The safety and effectiveness of this test have not been established for monitoring the effect of any therapeutic product or for predicting development of dementia or other neurologic conditions.

Results obtained with different assay methods or kits may be different and cannot be used interchangeably.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies) that may cause interference in some immunoassays. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference
1. Figdore DJ, Wiste HJ, Bornhorst JA, et al. Performance of the Lumipulse plasma Abeta42/40 and pTau181 immunoassays in the detection of amyloid pathology. Alzheimers Dement (Amst). 2024;16(1):e12545. doi:10.1002/dad2.12545
2. Hansson O, Blennow K, Zetterberg H, Dage J. Blood biomarkers for Alzheimer's disease in clinical practice and trials. Nat Aging. 2023;3(5):506-519. doi:10.1038/s43587-023-00403-3

Performance

Method Description
beta-Amyloid 1-42:
The Lumipulse G beta-amyloid 1-42 Plasma assay is an assay system for the quantitative measurement of beta-amyloid 1-42 in plasma specimens based on chemiluminescent enzyme immunoassay (CLEIA) technology by a specific two-step sandwich immunoassay method on the Lumipulse G System. The specimen and biotinylated antibody solution are both added to the antibody-coated particle solution. The beta-amyloid 1-42 in the specimen specifically binds to anti-beta-amyloid 1-42 monoclonal mouse antibody on the particles and biotinylated mouse antibody. Biotinylated antibody-antigen immunocomplexes are formed. The particles are washed and rinsed to remove unbound materials. Alkaline phosphatase-labeled streptavidin specifically binds to biotinylated immunocomplexes on the particles. The particles are washed and rinsed to remove unbound materials. Substrate solution is added and mixed with the particles. 3-(2'-Spiroadamantane)-4-methoxy-4-(3"-phosphoryloxy) phenyl-1, 2 dioxetane disodium (AMPPD) contained in the substrate solution is dephosphorylated by the catalysis of alkaline phosphatase indirectly conjugated to particles. Luminescence (at a maximum wavelength of 477 nm) is generated by the cleavage reaction of dephosphorylated AMPPD. The luminescent signal reflects the amount of beta-amyloid 1-42 present in the sample.(Package insert: Lumipulse G B-Amyloid 1-42 Plasma. Fujirebio Inc; 03/2022)

beta-Amyloid 1-40:
The Lumipulse G beta-Amyloid 1-40 Plasma assay is an assay system for the quantitative measurement of beta-amyloid 1-40 in plasma specimens based on CLEIA technology by a specific two-step sandwich immunoassay method on the Lumipulse G System. The specimen is added to the particle solution. The beta-amyloid 1-40 in the specimen specifically binds to anti-beta-amyloid 1-40 monoclonal mouse antibody on the particles and antigen-antibody immunocomplexes are formed. The particles are then washed and rinsed to remove unbound materials. Alkaline phosphatase labeled anti-beta-amyloid monoclonal antibody is added that specifically binds to the prior formed immunocomplexes on the particles, and additional immunocomplexes are formed. The particles are washed and rinsed to remove unbound materials. Substrate solution is added and mixed with the particles. AMPPD contained in the substrate solution is dephosphorylated by the catalysis of alkaline phosphatase indirectly conjugated to particles. Luminescence (at a maximum wavelength of 477 nm) is generated by the cleavage reaction of dephosphorylated AMPPD. The luminescent signal reflects the amount of beta-amyloid 1-40 in the sample.(Package insert: Lumipulse G B-Amyloid 1-40 Plasma. Fujirebio Inc; 03/2022)

Ratio:
The beta-amyloid ratio is calculated by using individual measurements of beta-amyloid 1-42 and beta-amyloid 1-40.

Day(s) Performed
Tuesday. Days performed may be flexible if samples are scheduled to arrive in a batch.

Report Available
1 to 9 days

Specimen Retention Time
3 months

Performing Laboratory Location
Rochester

CLIA Laboratory Number
24D1040592

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.