Overview

Useful For
Evaluation of astrocyte activity related to various neurodegenerative diseases

Highlights
BioPharma Diagnostics Use Only

This assay is designed to specifically measure the glial fibrillary acidic protein in human plasma.

Method Name
Chemiluminescent Enzyme Immunoassay (CLEIA)

NY State Available
Yes

Reporting Name
Glial Fibrillary Acidic Protein, P

Aliases
Alzheimer's Disease
Dementia

Specimen

Specimen Type
Plasma

Specimen Required
Patient Preparation:
Fasting: 8 hours, preferred but not 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
0.5 mL

Reject Due To

Gross hemolysis	Ok
Thawing	Cold, ok; Warm, reject
Gross lipemia	Ok
Gross icterus	Ok

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
EDTA Plasma	Frozen (preferred)	90 days	
	Ambient	72 hours	
	Refrigerated	14 days	

Clinical & Interpretive

Clinical Information
Glial fibrillary acidic protein (GFAP) is the specific intermediate filament protein component of the cytoskeleton of astrocytes. Damage to astrocytes results in the release of GFAP into the cerebrospinal fluid (CSF) and, ultimately, the blood. Due to this, GFAP has gained interest as a candidate marker of neurodegeneration.

Reference Values
<40 years: < or =32.6 pg/mL
40-49 years: < or =50.5 pg/mL
50-59 years: < or =67.5 pg/mL
60-69 years: < or =90.3 pg/mL
> or =70 years: < or =120.8 pg/mL

Interpretation
Elevations of glial fibrillary acidic protein (GFAP) have been reported in a number of neurological conditions. No disease specific interpretation thresholds are available currently, and interpretation of the results is based on the reference intervals. Some of the potential applications of GFAP are described below.

In traumatic brain injury (TBI), GFAP concentrations are increased in patients following mild to moderate TBI, and it may predict unfavorable outcome following TBI.(1) GFAP has been shown to be detectable within one hour of injury, continues to rise and appears to peak within 20 to 24 hours, and then declines over 72 hours with a biological half-life of 24-48 hours.(2,3) Many studies have examined the utility of GFAP for identifying patients with intracranial abnormalities following TBI.(4) GFAP may be useful for this purpose given that it is specific to brain injury and has a relatively long half-life compared to other biomarkers.

In stroke, several studies have demonstrated that blood GFAP may be used as a biomarker of glial injury indicative of intracerebral hemorrhage in patients presenting with acute stroke symptoms. In this context, GFAP concentrations were higher in patients with intracerebral hemorrhage than in patients with ischemic stroke. (5)

In multiple sclerosis (MS), GFAP concentrations have been shown to be higher in patients with MS compared to healthy controls and individuals with non-inflammatory neurological diseases. Multiple studies have found a correlation between blood GFAP concentration and severity of disability in patients with MS. (6,7) Increased levels of GFAP have also been reported in patients with neuromyelitis optica spectrum disorder. (8)

In Alzheimer disease (AD), GFAP concentrations have been reported to predict future conversion to Alzheimer dementia in patients with mild cognitive impairment. Increased blood GFAP concentrations have been detected in AD patients, with rising levels observed at the preclinical phase of the disease. (9) Higher GFAP concentrations have been associated with an increased risk for future progression to dementia and a steeper cognitive decline. (10)

Cautions
Glial fibrillary acidic protein (GFAP) results must be interpreted in conjunction with other diagnostic tools, such as neurological examination, neurobehavioral tests, imaging, and routine laboratory tests.

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

All immunometric assays can, on rare occasions, be subject to a hooking effect at extremely high analyte concentrations (false-low results), heterophilic antibody interference (false-high results), or autoantibody interference (unpredictable effects). If the laboratory result does not fit the clinical picture, these possibilities should be considered.

Dietary patterns may influence blood biomarker levels. It is recommended samples are collected after an 8 hour fast.

Clinical Reference

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2. Papa L, Brophy GM, Welch RD, et al. Time course and diagnostic accuracy of glial and neuronal blood biomarkers GFAP and UCH-L1 in a large cohort of trauma patients with and without mild traumatic brain injury. JAMA Neurol. 2016;73(5):551-560. doi:10.1001/jamaneurol.2016.0039
3. Thelin EP, Zeiler FA, Ercole A, et al. Serial sampling of serum protein biomarkers for monitoring human traumatic brain injury dynamics: A systematic review. Front Neurol. 2017;8:300. Published 2017 Jul 3. doi:10.3389/fneur.2017.00300
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5. Foerch C, Curdt I, Yan B, et al. Serum glial fibrillary acidic protein as a biomarker for intracerebral haemorrhage in patients with acute stroke. J Neurol Neurosurg Psychiatry. 2006;77(2):181-184. doi:10.1136/jnnp.2005.074823
6. Hogel H, Rissanen E, Barro C, et al. Serum glial fibrillary acidic protein correlates with multiple sclerosis disease severity. Mult Scler. 2020;26(2):210-219. doi:10.1177/1352458518819380
7. Ayrignac X, Le Bars E, Duflos C, et al. Serum GFAP in multiple sclerosis: correlation with disease type and MRI markers of disease severity. Sci Rep. 2020;10(1):10923. Published 2020 Jul 2. doi:10.1038/s41598-020-67934-2
8. Aktas O, Smith MA, Rees WA, et al. Serum glial fibrillary acidic protein: a neuromyelitis optica spectrum disorder biomarker. Ann Neurol. 2021;89(5):895-910. doi:10.1002/ana.26067
9. Oeckl P, Halbgebauer S, Anderl-Straub S, et al. Glial fibrillary acidic protein in serum is increased in Alzheimers disease and correlates with cognitive impairment. J Alzheimers Dis. 2019;67(2):481-488. doi:10.3233/JAD-180325
10. Cicognola C, Janelidze S, Hertze J, et al. Plasma glial fibrillary acidic protein detects Alzheimer pathology and predicts future conversion to Alzheimer dementia in patients with mild cognitive impairment. Alzheimers Res Ther. 2021;13(1):68. Published 2021 Mar 27. doi:10.1186/s13195-021-00804-9

Performance

Method Description

The Lumipulse G GFAP Immunoreaction is an assay system for the quantitative measurement of glial fibrillary acidic protein (GFAP) in plasma specimens based on chemiluminescent enzyme immunoassay technology by a specific two-step immunoassay method on the Lumipulse G System. The specimen and assay-specific diluent are both added to the antibody-coated particle solution. The GFAP in the specimen specifically binds to anti-GFAP monoclonal mouse antibody on the particles and antigen-antibody immunocomplexes are formed. The particles are washed and rinsed to remove unbound materials. Alkaline phosphatase-labeled anti-GFAP monoclonal antibodies specifically bind to 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'-Spiroadamantyl)-4-methoxy-4-(3"-phosphoryloxy)-phenyl-1,2-dioxetane (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 GFAP present in the sample. (Package insert: Lumipulse G GFAP. Fujirebio, Inc; ver 1, 07/2024)

Day(s) Performed

Tuesday. Testing may be performed on additional days per client request.

Report Available

1 to 7 days

Specimen Retention Time
90 days

Performing Laboratory Location
Rochester

CLIA Laboratory Number
24D1040592

Test Classification
This test was developed and its performance characteristics were 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.