PRODUCT INFORMATION SHEET

AssayProven™

Monoclonal Antibody to Human GFAP

Cat. No. AXGFA02RAB	Recombinant Antibody	STORE AT −20 °C

Validated Assay Configuration – The following configuration represents the AssayProven™ recommended reagent combination for the validated application listed below.

VALIDATED APPLICATION	CLIA
CAPTURE REAGENT	AXGFA01RAB
DETECTION REAGENT	AXGFA02RAB
PERFORMANCE EVALUATION MATERIAL	Human serum, EDTA plasma, and GFAP reference materials

Product Characteristics

SPECIES OR SEQUENCE ORIGIN	Mouse
PRODUCT SOURCE	Culture-derived
PRODUCTION SYSTEM	CHO cells
RECOMBINANT	Yes
ISOTYPE	IgG1
MOLECULAR WEIGHT	150 kDa
FULL-LENGTH PROTEIN	Yes
APPEARANCE	Clear, colorless liquid
FORMAT	Liquid
CONCENTRATION	≥4 mg/mL
METHOD TO DETERMINE CONCENTRATION	UV absorbance (wavelength not specified)
LYOPHILIZED	No
RECONSTITUTION METHOD	Not applicable
SONICATION REQUIRED PRIOR TO USE	No

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Meridian Life Science, Inc.
5171 Wilfong Road
Memphis , TN 38134
USA

www.meridianlifescience.com
Tel: (+1) 901-382-8716
Email: info@meridianlifescience.com
Orders: orders@meridianlifescience.com

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Biological Characteristics

IMMUNOGEN	Recombinant human GFAP protein
IMMUNOGEN SEQUENCE	P14136 (UniProt ID)
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not applicable
EPITOPE	Amino acids 60–383
CROSS-REACTIVITY	Paired-reagent specificity evaluation found no significant cross-reactivity/interference with NFL, NFM, NFH, alpha-internexin, peripherin, desmin, or vimentin; reported deviations were within ±4.0%.
IMMUNOREACTIVITY	Activity deviation within ±15% of control at the same working concentration.

Quality Attributes

PURITY	≥90%
METHOD TO DETERMINE PURITY	SEC-HPLC
PURIFICATION METHOD	Protein A affinity chromatography; ion-exchange chromatography
MAXIMUM BIOBURDEN	Not characterized

Binding Characteristics

ASSOCIATION RATE CONSTANT (K_a)	Not characterized
DISSOCIATION RATE CONSTANT (K_d)	Not characterized
EQUILIBRIUM DISSOCIATION CONSTANT (K_D)	4.4×10^{-11} M
BINDING DETERMINATION METHOD	Surface plasmon resonance (SPR)

Formulation

BUFFER / PH	20 mM citrate-phosphate buffer, 150 mM sodium chloride, pH 7.5
PRESERVATIVE	0.1% ProClin 300

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Storage & Stability

STORAGE TEMPERATURE	−20 °C
SHELF LIFE	36 months
STABILITY AT 2–8 °C	21 days
STABILITY AT −20 °C	36 months
STABILITY AT −40 °C	Not characterized
STABILITY AT −80 °C	Not characterized

Other Technical characteristics

ISOELECTRIC POINT (pI)	5.70–6.83
INACTIVATION METHOD	Not applicable

Notes & Safety Information

SAFETY INFORMATION	Refer to the appropriate Safety Data Sheet (SDS) for additional information.
NOTES	This reagent has been manufactured under ISO 13485 quality management system and is suitable for research or further manufacturing use only. Centrifuge before opening to ensure complete recovery of vial contents. Avoid multiple freeze/thaw cycles.

Performance Validation Report

The following pages contain the applicable AssayProven™ Performance Validation Report.

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AssayProven™ Recommended GFAP Antibody Pair

Recommended pair summary

Multiple antibody combinations were screened under standardized assay conditions to identify the optimal antibody pair for chemiluminescent immunoassay development. The recommended AssayProven™ GFAP antibody pair demonstrated the best overall analytical performance, including excellent analytical sensitivity, broad linearity, strong precision and recovery, strong correlation with a commercial comparator assay, and minimal cross-reactivity and interference, supporting its suitability for GFAP CLIA development.

Category	Target	Format	Item Type	Cat. #	Description	Function
Neurological Diseases & Trauma	GFAP	CLIA	Antibody	AXGFA01RAB	mAb to Human GFAP	Capture
			Antibody	AXGFA02RAB	mAb to Human GFAP	Detector

Method: 2-step magnetic bead-based sandwich CLIA assay

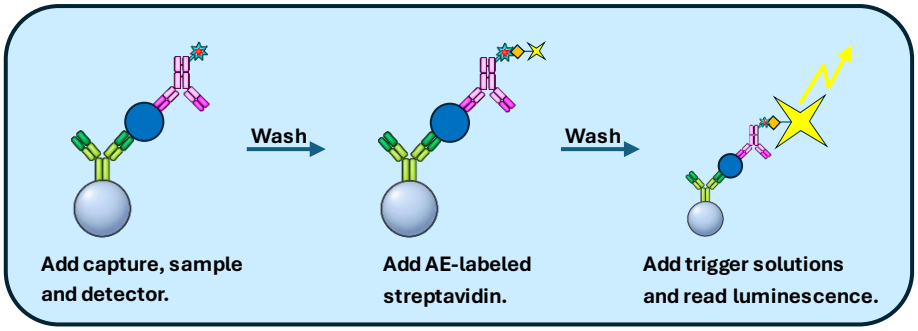


Figure 1. Schematic of a 2-step magnetic bead-based sandwich chemiluminescent immunoassay using AssayProven™ pairs.

Analytical performance overview

Performance evaluation materials: human serum and EDTA plasma specimens and GFAP reference materials.

Parameter	Reported Performance
Limit of Blank (LoB)	≤5.00 pg/mL
Limit of Detection (LoD)	≤10.00 pg/mL
Limit of Quantitation (LoQ)	≤10.00 pg/mL
Linear range	10-60,000 pg/mL

Table 1. Analytical sensitivity and linear range of the AssayProven™ GFAP antibody pair.

Hook effect: no high-dose hook effect was observed up to 600,000 pg/mL.

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Lot variability

Material	Mean GFAP	Intra-lot CV	Inter-lot CV
Reference material 1	170.77 pg/mL	2.3%	5.7%
Reference material 2	2,561.54 pg/mL	1.1%	2.0%
Reference material 3	19,923.08 pg/mL	1.7%	2.5%

Table 2. Precision across three GFAP concentrations. Intra-lot coefficients of variation (CVs) were ≤2.3%, and inter-lot CVs were ≤5.7%.

Method and specimen comparison

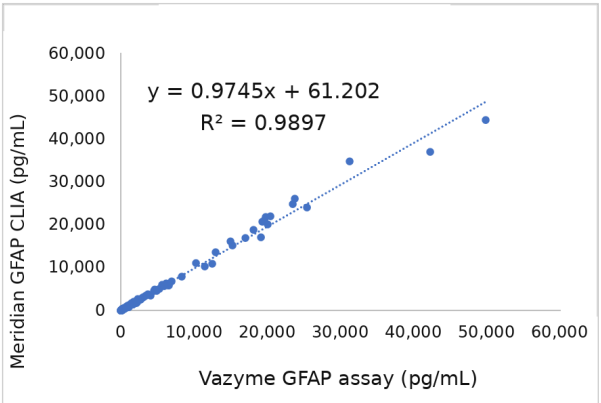


Figure 2. Correlation between the Meridian GFAP CLIA and the Vazyme GFAP assay using human serum specimens (n = 192). Range: 6.94-49,759.31 pg/mL; slope: 0.9745; intercept: 61.202 pg/mL; R^2 = 0.9897.

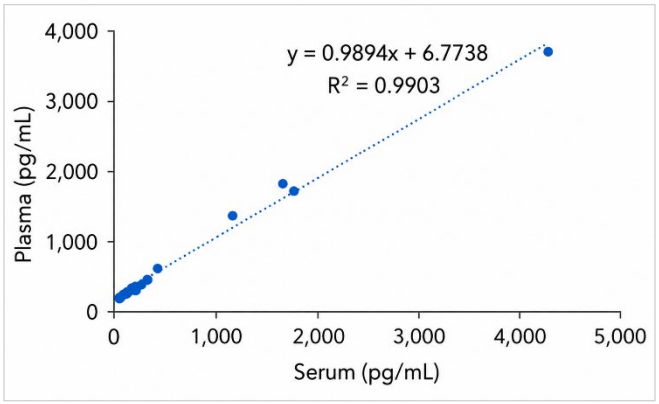


Figure 3. Agreement between GFAP measurements in matched human serum and EDTA plasma specimens (n = 65). Range: 34.15-4,072.85 pg/mL; slope: 0.9894; intercept: 6.7738 pg/mL; R^2 = 0.9903.

Recovery

Parameter	Result
Mean high reference material	19,660.09 pg/mL
Mean low reference material	181.96 pg/mL
Mixing ratio	1:9
Mean measured mixture	2,119.81 pg/mL
Reported recovery	99.4%

Table 3. Recovery after mixing high- and low-concentration GFAP reference materials at a 1:9 volume ratio.

Preliminary reference population study

Specimen	n	95th percentile
Serum	300	148.00 pg/mL
EDTA plasma	211	149.71 pg/mL

Table 4. Preliminary 95th-percentile GFAP values in health-check specimens. Health status was not confirmed; values are for reference only and are not diagnostic cutoffs.

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Analytical specificity and interference

Overall analytical specificity conclusion: no significant cross-reactivity or interference was observed with the tested related proteins, endogenous substances, or medications under the evaluated conditions.

Related Structural Protein Interference	Test Concentration	Relative Deviation
Alpha-internexin	100 ng/mL	0.6%
Vimentin	360 ng/mL	1.4%
Peripherin	156 ng/mL	-4.0%
Desmin	150 ng/mL	-2.0%
Neurofilament medium	79 ng/mL	3.0%
Neurofilament heavy	100 ng/mL	2.4%
Neurofilament light	134 ng/mL	-0.8%

Table 5. No significant interference was observed with related structural proteins at the tested concentrations; all relative deviations were within ±4.0%.

Endogenous Interference	Test Conc.	Low GFAP	High GFAP
Biotin	3,600 ng/mL	-1.0%	-1.1%
Total protein	80 mg/mL	-4.4%	-5.0%
Hemoglobin	5 mg/mL	0.7%	2.1%
Bilirubin	0.5 mg/mL	0.7%	0.5%
Lipid	10 mg/mL	-1.5%	-5.7%
HAMA	56.4 ng/mL	2.9%	0.0%
Rheumatoid factor	720 IU/mL	3.2%	0.3%

Table 6. Endogenous interference at low (170.77 pg/mL) and high (4,553.85 pg/mL) GFAP concentrations. All relative deviations were within ±5.7%.

Drug Interference	Test Concentration	Low GFAP	High GFAP
Donepezil hydrochloride	3 µg/mL	7%	3%
Galantamine hydrobromide	5 µg/mL	-1%	7%
Quetiapine fumarate	2 µg/mL	4%	5%
Rivastigmine hydrogen tartrate	40 µg/mL	-2%	4%
Memantine hydrochloride	1 µg/mL	8%	4%
Aripiprazole	0.7 µg/mL	1%	-2%
Olanzapine	0.9 µg/mL	5%	-5%
Caffeine	3 µg/mL	1%	-3%
Risperidone	200 µg/mL	0%	-4%

Table 7. Drug interference at low (170.77 pg/mL) and high (4,553.85 pg/mL) GFAP concentrations. All relative deviations were within ±8%.