PRODUCT INFORMATION SHEET

AssayProven™

Monoclonal Antibody to Human Neurofilament Light

Cat. No. AXNFL02RAB	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	AXNFL01RAB
DETECTION REAGENT	AXNFL02RAB
PERFORMANCE EVALUATION MATERIAL	Human serum, EDTA plasma, and NfL reference materials

Product Characteristics

SPECIES OR SEQUENCE ORIGIN	Mouse
PRODUCT SOURCE	Culture-derived
PRODUCTION SYSTEM	CHO cells
RECOMBINANT	Yes
ISOTYPE	IgG2b
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
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Orders: orders@meridianlifescience.com

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Biological Characteristics

IMMUNOGEN	Recombinant human neurofilament light protein
IMMUNOGEN SEQUENCE	P07196 (UniProt ID)
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not applicable
EPITOPE	Amino acids 316–370
CROSS-REACTIVITY	Paired-reagent specificity evaluation found no significant cross-reactivity/interference with NFM, NFH, GFAP, alpha-internexin, peripherin, desmin, or vimentin; reported deviations were within ±7.7%.
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)	5.5×10^{-10} M
BINDING DETERMINATION METHOD	Surface plasmon resonance (SPR)

Formulation

BUFFER / PH	20 mM citrate-phosphate buffer, 150 mM sodium chloride, pH 6.0
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)	6.95
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 NfL 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™ NfL antibody pair demonstrated the best overall analytical performance, including excellent analytical sensitivity, broad linearity, strong repeatability and recovery, strong correlation with a commercial comparator assay, and minimal cross-reactivity and interference, supporting its suitability for NfL CLIA development.

Category	Target	Format	Item Type	Cat. #	Description	Function
Neurological Diseases & Trauma	NfL	CLIA	Antibody	AXNFL01RAB	mAb to Human NfL	Capture
			Antibody	AXNFL02RAB	mAb to Human NfL	Detector

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

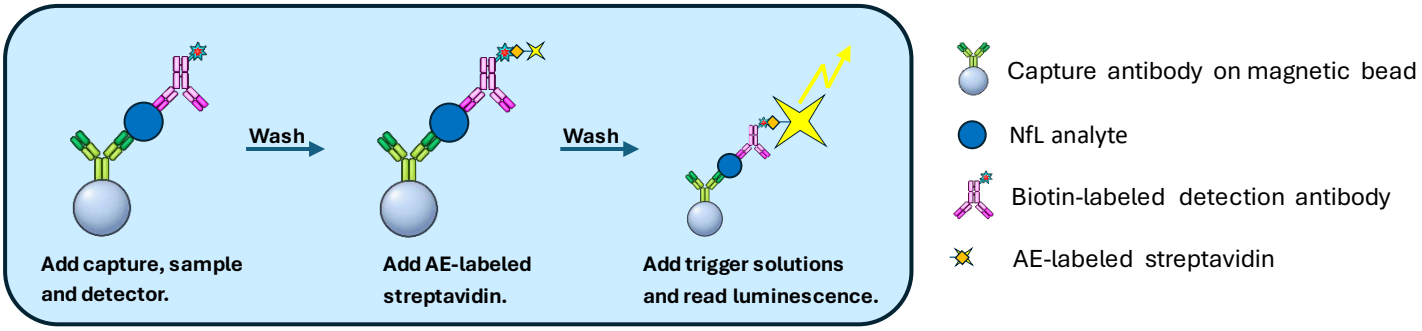


Figure 1. Schematic of a 2-step magnetic bead-based sandwich chemiluminescent immunoassay using AssayProven™ pairs.

Analytical performance overview

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

Parameter	Reported Performance
Limit of Blank (LoB)	≤1.00 pg/mL
Limit of Detection (LoD)	≤2.00 pg/mL
Limit of Quantitation (LoQ)	≤2.00 pg/mL
Linear range	2-1,500 pg/mL

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

Hook Effect: no high dose hook effect was observed up to 60,000 pg/mL.

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Assay precision

Material	Mean NfL (pg/mL)	Intra-lot CV
Reference material 1	24.65	3.1%
Reference material 2	78.16	1.3%
Reference material 3	515.99	0.8%
Reference material 4	1,046.60	1.1%

Table 2. Precision at four NfL concentrations. Intra-lot coefficients of variation (CVs) were ≤3.1%.

Lot-to-lot consistency: signal deviations were within ±15% across the evaluated capture and detection antibody lots.

Method and specimen comparison

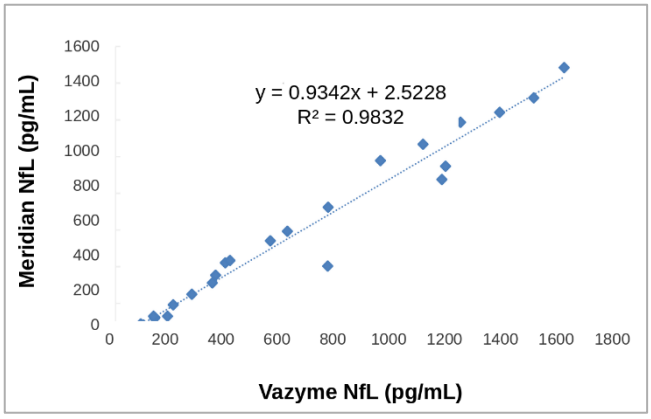


Figure 2. Correlation between the Meridian NfL CLIA and the Vazyme NfL assay in EDTA plasma (n = 82; slope = 0.9342; intercept = 2.5228 pg/mL; R^2 = 0.9832). Range: 3.43-1,532.58 pg/mL.

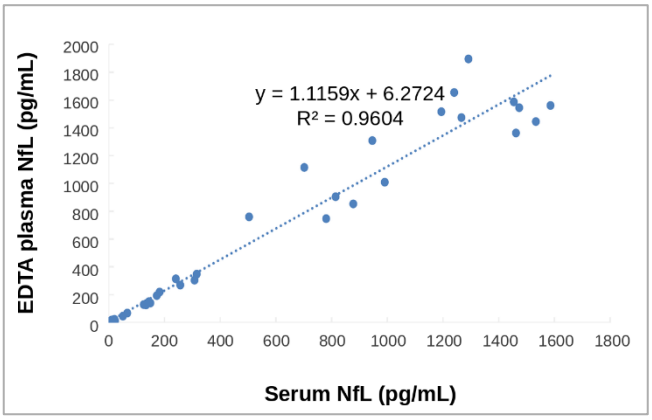


Figure 3. Correlation between matched serum and EDTA plasma NfL measurements (n = 56; slope = 1.1159; intercept = 6.2724 pg/mL; R^2 = 0.9604).

Recovery

Parameter	Result
High reference material	724.85 pg/mL
Low reference material	63.90 pg/mL
Mixing ratio	1:19
Mean measured mixture	93.53 pg/mL
Calculated recovery	90.6%

Table 3. Recovery after mixing high- and low-concentration NfL reference materials at a 1:19 volume ratio.

Preliminary reference population study

Specimen	n	95th percentile
EDTA plasma (<70 years)	382	126.93 pg/mL

Table 4. Preliminary 95th-percentile NfL value in health-check EDTA plasma specimens from individuals younger than 70. Health status was not confirmed; the value is for reference only and is not a diagnostic cutoff.

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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 Protein Interference	Test Concentration	Relative Deviation (Low/High)
Alpha-internexin	100 ng/mL	-5.0% / 2.7%
Vimentin	360 ng/mL	4.4% / 0.3%
Peripherin	156 ng/mL	1.3% / 0.6%
Desmin	150 ng/mL	-0.1% / 0.6%
Neurofilament medium	79 ng/mL	-1.4% / 2.5%
Neurofilament heavy	100 ng/mL	3.1% / 1.2%
GFAP	19.2 ng/mL	7.7% / -0.7%

Table 5. No significant interference was observed with related structural proteins at the tested concentrations; all relative deviations were within ±7.7%.

Endogenous Interference	Test Conc.	Low NfL	High NfL
Hemoglobin	5 mg/mL	1.8%	-3.5%
Bilirubin	0.5 mg/mL	1.8%	-2.9%
Lipid	10 mg/mL	4.0%	-3.6%
HAMA	56 ng/mL	-0.3%	1.2%

Table 6. Endogenous interference at low (approximately 30 pg/mL) and high (approximately 860 pg/mL) NfL concentrations. All relative deviations were within ±4.0%.

Drug Interference	Test Concentration	Low NfL	High NfL
Quetiapine fumarate	40 µg/mL	0.1%	-2.9%
Rivastigmine hydrogen tartrate	40 µg/mL	-3.0%	-3.9%
Memantine hydrochloride	3 µg/mL	3.0%	-4.5%

Table 7. Drug interference at low (approximately 30 pg/mL) and high (approximately 860 pg/mL) NfL concentrations. All relative deviations were within ±4.5%.