PRODUCT INFORMATION SHEET

AssayProven™

Monoclonal Antibody to Human Amyloid Beta 1–42

Cat. No. AXAMY01RAB	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	AXAMY01RAB
DETECTION REAGENT	AXAMY02RAB
PERFORMANCE EVALUATION MATERIAL	K2-EDTA plasma, reference materials, and antigen-spiked plasma

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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Biological Characteristics

IMMUNOGEN	Synthetic human amyloid beta peptide conjugate
IMMUNOGEN SEQUENCE	P05067 (UniProt ID)
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not applicable
EPITOPE	C-terminal
CROSS-REACTIVITY	Cross-reactivity <1.00% with Aβ1–37, Aβ1–38, Aβ1–40, Aβ1–43, APP669–711, and APP.
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)	7.0×10^{-9} M
BINDING DETERMINATION METHOD	Surface plasmon resonance (SPR)

Formulation

BUFFER / PH	20 mM citrate-phosphate buffer, 150 mM sodium chloride, pH 5.0
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)	6.68–7.73
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 Aβ1-42 Antibody Pair

Recommended pair summary

Multiple antibody combinations were screened under standardized conditions to identify the optimal pair for CLIA development. The recommended AssayProven™ Aβ1-42 pair demonstrated high analytical sensitivity, broad quantitative range, strong repeatability and accuracy, minimal cross-reactivity with related Aβ peptides and APP-related proteins, and correlation with a commercial comparator.

Category	Target	Format	Item Type	Cat. #	Description	Function
Neurological Diseases & Trauma	Aβ1-42	CLIA	Antibody	AXAMY01RAB	mAb to Human Amyloid beta 1-42	Capture
Neurological Diseases & Trauma	Aβ1-42	CLIA	Antibody	AXAMY02RAB	mAb to Human Amyloid beta	Detector

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

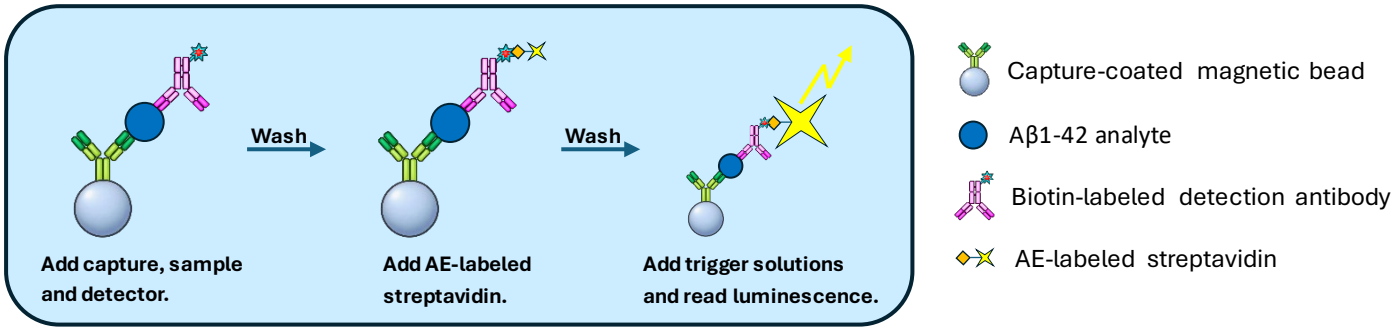


Figure 1. Two-step magnetic bead-based sandwich CLIA using AssayProven™ antibodies.

Analytical performance overview

Performance evaluation materials: K2-EDTA plasma, reference materials, and antigen-spiked plasma.

Parameter	Reported Performance
Limit of Blank (LoB)	≤0.50 pg/mL
Limit of Detection (LoD)	≤1.00 pg/mL
Limit of Quantitation (LoQ)	≤1.00 pg/mL
Linear range	1.00-100.00 pg/mL
Reportable interval	1-400 pg/mL (4-fold dilution >100 pg/mL)

Table 1. Analytical sensitivity and quantitative range; no high-dose hook effect was observed up to 2,000 pg/mL.

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Assay precision

Material	Mean Aβ1-42 (pg/mL)	Intra-lot CV
Reference material 1	8.61	2.92%
Reference material 2	27.32	3.02%

Table 2. Intra-lot precision at two Aβ1-42 concentrations (CV ≤3.02%). Lot-to-lot signal deviations were within ±15%.

Method comparison

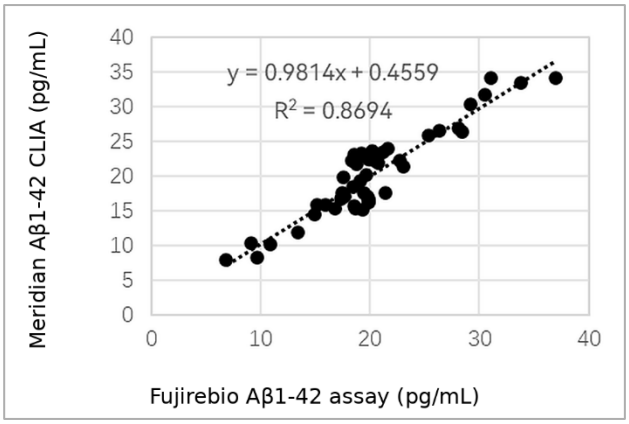


Figure 2. Correlation between the Meridian Aβ1-42 CLIA and Fujirebio Aβ1-42 assay using clinical K2-EDTA plasma specimens (n = 47; range = 1.00-40.00 pg/mL).

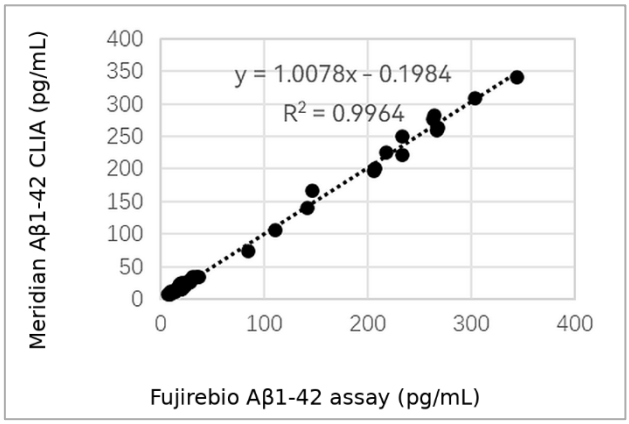


Figure 3. Extended-range correlation between the Meridian Aβ1-42 CLIA and Fujirebio Aβ1-42 assay using 47 clinical plasma and 15 antigen-spiked samples (n = 62; range = 1.00-400.00 pg/mL).

Preliminary Aβ1-42/Aβ1-40 ratio study

Specimen	n	Aβ1-42/Aβ1-40 95th percentile
K2-EDTA plasma	180	0.052

Table 3. Preliminary 95th-percentile Aβ1-42/Aβ1-40 ratio in health-check K2-EDTA plasma (n = 180). Health status was not confirmed; this is not a diagnostic cutoff.

Accuracy

Reference material	Assigned concentration (pg/mL)	Mean measured concentration (pg/mL)	Relative deviation
Reference material 1	5.32	5.13	-3.57%
Reference material 2	53.86	50.65	-5.96%
Reference material 3	212.34	206.75	-2.63%

Table 4. Analytical accuracy across three Aβ1-42 reference-material concentrations.

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Analytical Specificity

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 cross-reactivity	Test concentration	Unit	Cross-reactivity
Aβ1-37	1,000	pg/mL	0.078%
Aβ1-38	1,000	pg/mL	0.068%
Aβ1-40	1,000	pg/mL	0.288%
Aβ1-43	1,000	pg/mL	0.352%
APP669-711	1,000	pg/mL	0.024%
APP	300	ng/mL	0.149%

Table 5. Cross-reactivity with related Aβ peptides and APP-related proteins; all values were below 0.4%.

Endogenous interference	Test concentration	Low Aβ1-42	High Aβ1-42
Total protein	60 mg/mL	−6.5%	−9.8%
Hemoglobin	5 mg/mL	−9.5%	−9.3%
Bilirubin	0.2 mg/mL	4.4%	3.3%
Lipid	10 mg/mL	−0.5%	2.7%

Table 6. Endogenous interference at low and high Aβ1-42 concentrations. All relative deviations were within ±10%.

Drug interference	Test concentration	Low Aβ1-42	High Aβ1-42
Galantamine hydrobromide	5 µg/mL	−0.1%	−3.5%
Aripiprazole	2 µg/mL	3.9%	1.5%
Quetiapine fumarate	40 µg/mL	1.5%	−1.8%
Rivastigmine hydrogen tartrate	1 µg/mL	1.5%	−0.9%
Risperidone	0.7 µg/mL	3.2%	−2.1%
Olanzapine	0.9 µg/mL	−4.3%	−3.8%
Memantine hydrochloride	3 µg/mL	1.5%	1.3%
Caffeine	200 µg/mL	2.5%	6.0%

Table 7. Drug interference at low and high Aβ1-42 concentrations. All relative deviations were within ±6%.

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