PRODUCT INFORMATION SHEET

AssayProven™

Monoclonal Antibody to Human Amyloid Beta

Cat. No. AXAMY02RAB	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; AXAMY03RAB
DETECTION REAGENT	AXAMY02RAB
PERFORMANCE EVALUATION MATERIAL	Aβ1–42: K2-EDTA plasma, reference materials, and antigen-spiked plasma; Aβ1–40: human K2-EDTA plasma and Aβ1–40 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

Biological Characteristics

meridian LIFE SCIENCE®

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

PRODUCT INFORMATION SHEET

AssayProven™

IMMUNOGEN	Synthetic human amyloid beta peptide conjugate
IMMUNOGEN SEQUENCE	P05067 (UniProt ID)
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not applicable
EPITOPE	N-terminal
CROSS-REACTIVITY	Aβ1–42 configuration: Cross-reactivity <1.00% with Aβ1–37, Aβ1–38, Aβ1–40, Aβ1–43, APP669–711, and APP. Aβ1–40 configuration: Cross-reactivity <1.00% with Aβ1–37, Aβ1–38, Aβ1–42, 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)	2.9×10^{-10} M
BINDING DETERMINATION METHOD	Surface plasmon resonance (SPR)

Formulation

BUFFER / PH	20 mM citrate-phosphate buffer, 150 mM sodium chloride, pH 5.5
PRESERVATIVE	0.1% ProClin 300

meridian LIFE SCIENCE®

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

PRODUCT INFORMATION SHEET

AssayProven™

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)	7.56–8.91
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.

meridian LIFE SCIENCE®

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

PRODUCT INFORMATION SHEET

AssayProven™

AssayProven™ Recommended Aβ1-40 Antibody Pair

Recommended pair summary

Multiple antibody combinations were screened under standardized conditions to identify the optimal pair for CLIA development. The recommended AssayProven™ Aβ1-40 pair demonstrated high analytical sensitivity, broad linearity, strong repeatability and recovery, strong correlation with a commercial comparator, and minimal cross-reactivity with related Aβ peptides and APP-related proteins.

Category	Target	Format	Item Type	Cat. #	Description	Function
Neurological Diseases & Trauma	Aβ1-40	CLIA	Antibody	AXAMY03RAB	mAb to Human Amyloid beta 1-40	Capture
Neurological Diseases & Trauma	Aβ1-40	CLIA	Antibody	AXAMY02RAB	mAb to Human Amyloid beta	Detector

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

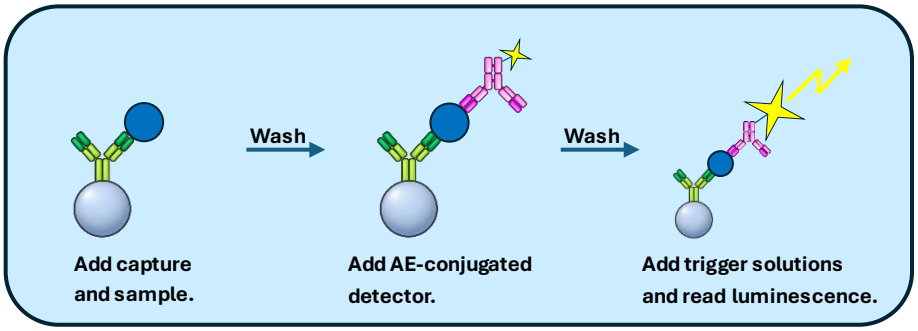


Figure 1. Two-step magnetic bead-based sandwich CLIA using AssayProven™ antibodies.

Analytical performance overview

Performance evaluation materials: human K2-EDTA plasma and Aβ1-40 reference materials.

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	1.00-1,000.00 pg/mL
High-dose hook effect	None observed up to 2,000 pg/mL

Table 1. Analytical sensitivity, linear range, and hook-effect performance of the AssayProven™ Aβ1-40 antibody pair.

meridian LIFE SCIENCE®

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

PRODUCT INFORMATION SHEET

AssayProven™

Assay precision

Material	Mean Aβ1-40 (pg/mL)	Intra-lot CV
Reference material 1	60.30	3.00%
Reference material 2	287.96	1.84%

Table 2. Intra-lot precision at two Aβ1-40 concentrations (CV ≤3.00%). Lot-to-lot signal deviations were within ±15%.

Method comparison

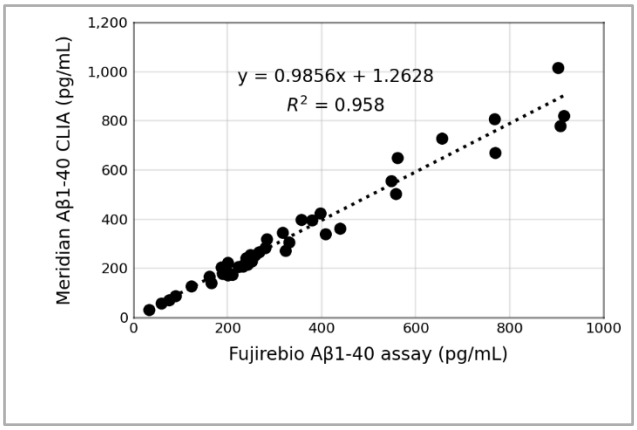


Figure 2. Correlation between the Meridian Aβ1-40 CLIA and Fujirebio Aβ1-40 assay in K2-EDTA plasma (n = 62; R^2 = 0.958).

Parameter	Result
Specimen type	K2-EDTA plasma
Number tested	62
Concentration range	1.00 – 1,000.00 pg/mL
Slope	0.9856
Intercept	1.2628 pg/mL
R^2	0.958

Table 3. Method-comparison statistics for the Meridian and Fujirebio Aβ1-40 assays.

Recovery

Parameter	Result
High reference material	512.05 pg/mL
Low reference material	1.04 pg/mL
Mixing ratio	1:9
Mean measured mixture	49.96 pg/mL
Reported recovery	95.74%

Table 4. Aβ1-40 recovery after 1:9 mixing.

Preliminary Aβ1-42/Aβ1-40 ratio study

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

Table 5. Preliminary Aβ1-42/Aβ1-40 ratio (n = 180). Health status was not confirmed; this value is for reference only and is not a diagnostic cutoff.

meridian LIFE SCIENCE®

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

Analytical specificity

Overall specificity conclusion: cross-reactivity was ≤0.072% for all tested related Aβ peptides and APP-related proteins.

Related analyte cross-reactivity	Test concentration	Unit	Cross-reactivity
Aβ1-37	1,000	pg/mL	0.001%
Aβ1-38	1,000	pg/mL	0.005%
Aβ1-42	1,000	pg/mL	0.005%
Aβ1-43	1,000	pg/mL	0.004%
APP669-711	1,000	pg/mL	0.072%
APP	300	ng/mL	0.004%

Table 6. Cross-reactivity with related Aβ peptides and APP-related proteins; maximum 0.072%.

Endogenous interference	Test concentration	Low Aβ1-40	High Aβ1-40
Total protein	32.5 mg/mL	2.4%	−9.4%
Total protein	65 mg/mL	−4.1%	−11.6%
Hemoglobin	5 mg/mL	−1.7%	6.9%
Bilirubin	0.2 mg/mL	−1.1%	4.9%
Lipid	10 mg/mL	0.5%	2.3%

Table 7. Endogenous interference at varying low and high Aβ1-40 concentrations. All relative deviations were within ±10%, except 65 mg/mL total protein at the high Aβ1-40 level.

Drug interference	Test concentration	Low Aβ1-40	High Aβ1-40
Galantamine hydrobromide	5 µg/mL	6.0%	4.4%
Aripiprazole	2 µg/mL	3.1%	−0.2%
Quetiapine fumarate	40 µg/mL	5.0%	2.9%
Rivastigmine hydrogen tartrate	1 µg/mL	3.2%	3.1%
Risperidone	0.7 µg/mL	4.0%	3.7%
Olanzapine	0.9 µg/mL	2.6%	1.0%
Memantine hydrochloride	3 µg/mL	2.2%	1.1%
Caffeine	200 µg/mL	6.0%	−1.1%

Table 8. Drug interference at low and high Aβ1-40 concentrations. All relative deviations were within ±6%.

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

PRODUCT INFORMATION SHEET

AssayProven™

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

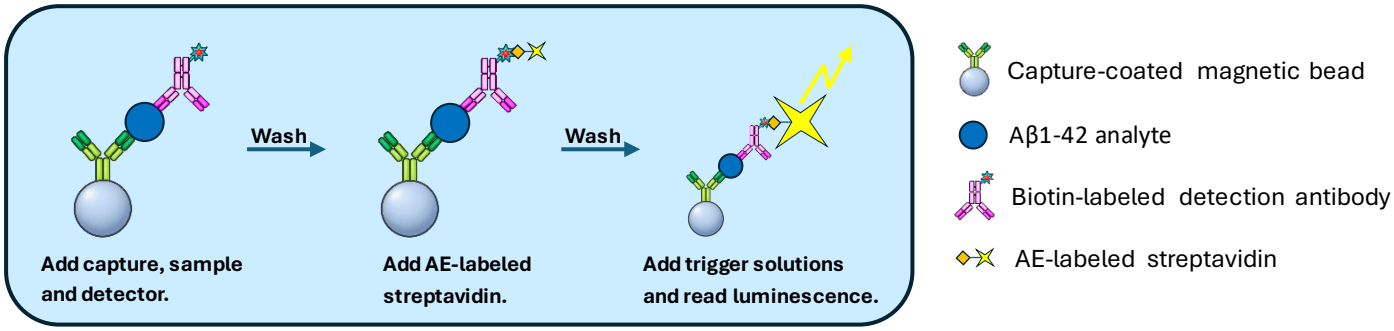


Figure 1. Two-step magnetic bead-based sandwich CLIA using AssayProven™ antibodies.

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.

meridian LIFE SCIENCE®

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

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

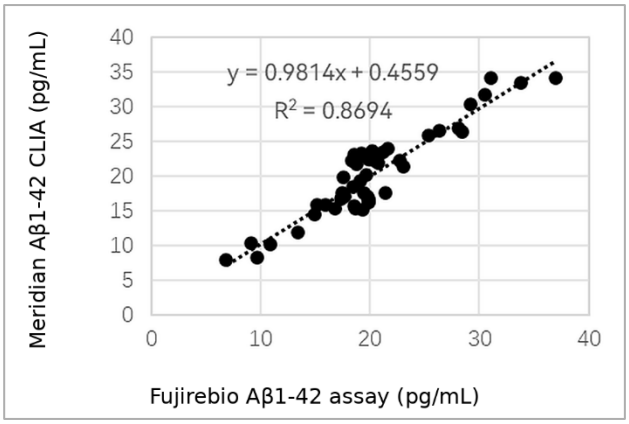


Figure 2. Correlation between the Meridian Aβ1-42 CLIA and Fujirebio Aβ1-42 assay using clinical K2-EDTA plasma specimens (n = 47; range = 1.00-40.00 pg/mL).

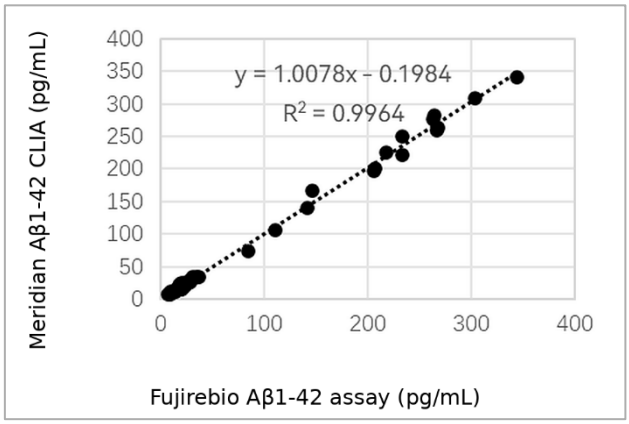


Figure 3. Extended-range correlation between the Meridian Aβ1-42 CLIA and Fujirebio Aβ1-42 assay using 47 clinical plasma and 15 antigen-spiked samples (n = 62; range = 1.00-400.00 pg/mL).

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.

meridian LIFE SCIENCE®

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

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%.

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