PRODUCT INFORMATION SHEET

AssayProven™

Monoclonal Antibody to Human Apolipoprotein E4

Cat. No. AXAPO02RAB	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	AXAPO01RAB
DETECTION REAGENT	AXAPO02RAB
PERFORMANCE EVALUATION MATERIAL	EDTA plasma of known APOE genotype and ApoE4 reference materials

Product Characteristics

SPECIES OR SEQUENCE ORIGIN	Rabbit
PRODUCT SOURCE	Culture-derived
PRODUCTION SYSTEM	CHO cells
RECOMBINANT	Yes
ISOTYPE	IgG
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	Human apolipoprotein E4
IMMUNOGEN SEQUENCE	P02649 (UniProt ID)
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not applicable
EPITOPE	Amino acids 100–124
CROSS-REACTIVITY	Paired-reagent specificity evaluation reported cross-reactivity <1.5% with ApoA2, ApoC3, ApoE2, and ApoE3.
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)	Not characterized
BINDING DETERMINATION METHOD	Not characterized

Formulation

BUFFER / PH	50 mM phosphate buffer, 50 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)	5.89–6.58
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 ApoE4 Antibody Pair

Recommended pair summary

Multiple antibody combinations were screened under standardized conditions to identify the optimal pair for CLIA development. The recommended AssayProven™ ApoE4 pair demonstrated strong analytical sensitivity and linearity, low intra- and inter-lot variability, 100% recovery, 100% sensitivity and specificity versus known APOE genotype, and minimal cross-reactivity and interference.

Category	Target	Format	Item Type	Cat. #	Description	Function
Neurological Diseases & Trauma	ApoE4	CLIA	Antibody	AXAPO01RAB	mAb to Human ApoE4	Capture
			Antibody	AXAPO02RAB	mAb to Human ApoE4	Detector

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

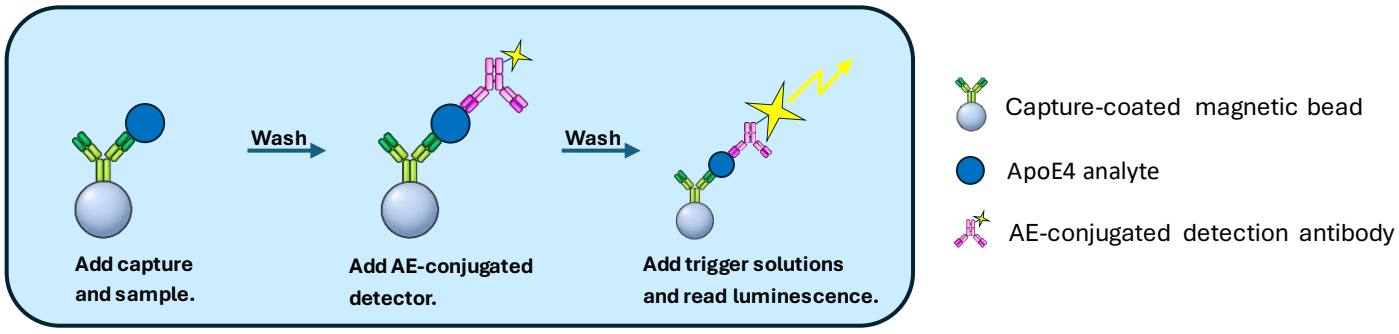


Figure 1. Two-step magnetic bead-based sandwich CLIA using AssayProven™ antibodies.

Analytical performance overview

Performance evaluation materials: EDTA plasma of known APOE genotype and ApoE4 reference materials.

Parameter	Reported Performance
Limit of Blank (LoB)	≤0.32 µg/mL
Limit of Detection (LoD)	≤0.93 µg/mL
Limit of Quantitation (LoQ)	≤0.93 µg/mL
Linear range	0.93-90.00 µg/mL

Table 1. Analytical sensitivity and linear range of the AssayProven™ ApoE4 antibody pair.

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Assay precision

Material	Mean ApoE4 (µg/mL)	Intra-lot CV	Inter-lot CV
Reference material 1	1.24	5.1%	5.8%
Reference material 2	5.66	3.1%	4.3%
Reference material 3	9.91	4.0%	4.1%

Table 2. ApoE4 precision (intra-lot ≤5.1%; inter-lot ≤5.8%).

Method comparison

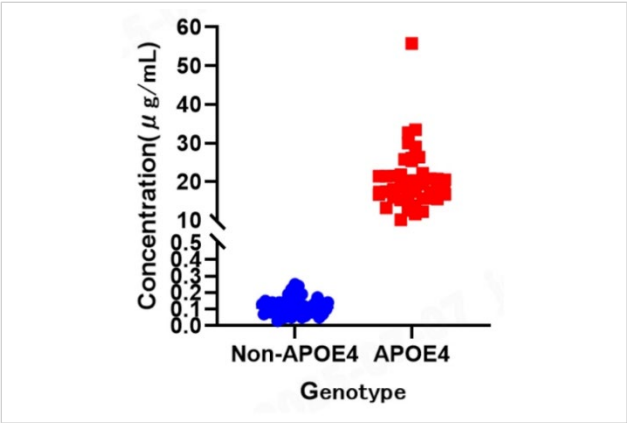


Figure 2. ApoE4 concentration by known genotype (n = 86).

Parameter	Result
Specimen type	EDTA plasma
Number tested	86
Concentration range	0.03-55.81 µg/mL
Sensitivity	100%
Specificity	100%

Table 3. Method-comparison summary. Known APOE genotypes were established using a Human APOE Genotyping Assay Kit based on a PCR-fluorescent probe method.

Recovery

Parameter	Result
Mean high reference material	11.84 µg/mL
Mean low reference material	1.73 µg/mL
Mixing ratio	1:9
Mean measured mixture	2.74 µg/mL
Reported recovery	100.0%

Table 4. ApoE4 recovery after mixing high- and low-concentration reference materials at a 1:9 volume ratio.

Preliminary genotype distribution

Population	n	Result
Non-ApoE4	154	95th pct.: <LoB
ApoE4	52	5th pct.: 4.10 µg/mL

Table 5. Preliminary ApoE4 genotype distribution in health-check EDTA plasma; health status was not confirmed, values are for reference only.

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Analytical specificity and interference

Overall analytical-specificity conclusion: Cross-reactivity was ≤0.16%, and all endogenous and drug interference results were within ±9.08%. ApoE4 remained below the LoB in non-ApoE4 specimens before and after all tested spikes.

Related Protein Cross-Reactivity	Test Concentration	Cross-Reactivity
ApoA2	500 µg/mL	0.00%
ApoC3	500 µg/mL	0.00%
ApoE2	1,000 µg/mL	0.16%
ApoE3	1,000 µg/mL	0.09%

Table 6. Cross-reactivity with related apolipoproteins; maximum observed cross-reactivity was 0.16%.

Endogenous Interference	Test Conc.	Low ApoE4	High ApoE4
Total protein	40 mg/mL	1.0%	-6.0%
Hemoglobin	5 mg/mL	-0.3%	-4.0%
Bilirubin	0.15 mg/mL	4.8%	2.9%
Lipid	10 mg/mL	-5.0%	-3.4%
HAMA	56.4 ng/mL	2.2%	3.8%
Rheumatoid factor	600 IU/mL	-0.1%	-1.8%

Table 7. Endogenous interference: all deviations were within ±6.0%.

Drug Interference	Test Concentration	Low ApoE4	High ApoE4
Donepezil hydrochloride	3 µg/mL	1.23%	1.47%
Galantamine hydrobromide	5 µg/mL	-1.36%	-1.70%
Aripiprazole	2 µg/mL	-0.85%	-5.10%
Quetiapine fumarate	40 µg/mL	-0.26%	-9.08%
Rivastigmine hydrogen tartrate	1 µg/mL	0.00%	0.36%
Risperidone	0.7 µg/mL	-1.59%	1.65%
Olanzapine	0.9 µg/mL	-5.42%	-6.97%
Memantine hydrochloride	3 µg/mL	-1.13%	1.32%
Caffeine	200 µg/mL	-4.04%	-8.49%

Table 8. Drug interference at 11.00 and 23.00 µg/mL ApoE4; all deviations were within ±9.08%.