PRODUCT INFORMATION SHEET

AssayProven™

Monoclonal Antibody to Human Total Tau

Cat. No. AXT2102RAB	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	AXT1801RAB; AXT2101RAB
DETECTION REAGENT	AXT2102RAB
PERFORMANCE EVALUATION MATERIAL	p-Tau181 and p-Tau217 reference materials and EDTA plasma specimens, including specimens classified by amyloid-PET status

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	Recombinant human total Tau protein
IMMUNOGEN SEQUENCE	P10636-8 (UniProt ID)
AMINO ACID SEQUENCE	Not characterized
TAG PROTEIN	Not applicable
EPITOPE	Amino acids 6–18
CROSS-REACTIVITY	Not characterized
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)	3.05×10^{-10} M
BINDING DETERMINATION METHOD	Surface plasmon resonance (SPR)

Formulation

BUFFER / PH	20 mM citrate buffer, 150 mM sodium chloride, pH 5.5
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)	6.18
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 p-tau181 Antibody Pair

Recommended pair summary

Multiple antibody combinations were screened under standardized conditions to identify the optimal pair for CLIA development. The recommended AssayProven™ p-tau181 pair demonstrated high analytical sensitivity, intra-lot repeatability, recovery within specification, strong discrimination by amyloid-PET status, and low cross-reactivity with the evaluated related tau forms.

Category	Target	Format	Item Type	Cat. #	Description	Function
Neurological Diseases & Trauma	p-tau181	CLIA	Antibody	AXT1801RAB	mAb to Human p-tau181	Capture
			Antibody	AXT2102RAB	mAb to Human total Tau	Detector

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

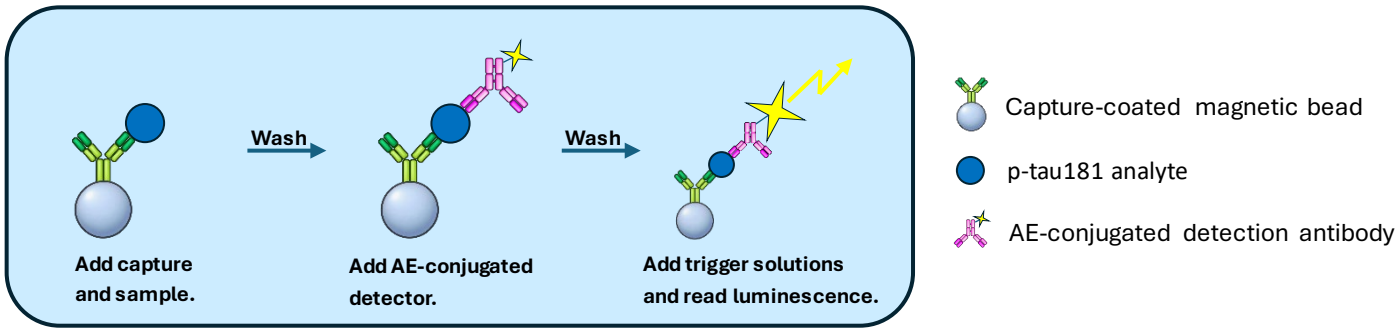


Figure 1. Two-step magnetic bead-based sandwich CLIA using AssayProven™ antibodies.

Analytical performance overview

Performance evaluation materials: p-tau reference materials and EDTA plasma specimens evaluated against amyloid-PET classification.

Parameter	Reported Performance
Limit of Blank (LoB)	≤0.50 pg/mL
Limit of Detection (LoD)	≤1.00 pg/mL
Limit of Quantitation (LoQ)	≤2.00 pg/mL
Linear range	1.00-200.00 pg/mL

Table 1. Analytical sensitivity and linear range of the AssayProven™ p-tau181 antibody pair.

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Assay precision

Material	Mean p-tau181 (pg/mL)	Intra-lot CV
Reference material 1	9.52	1.4%
Reference material 2	93.18	2.3%

Table 2. Intra-lot precision at two p-tau181 concentrations (CV ≤2.3%). Lot-to-lot signal deviations were within ±15%.

Method comparison

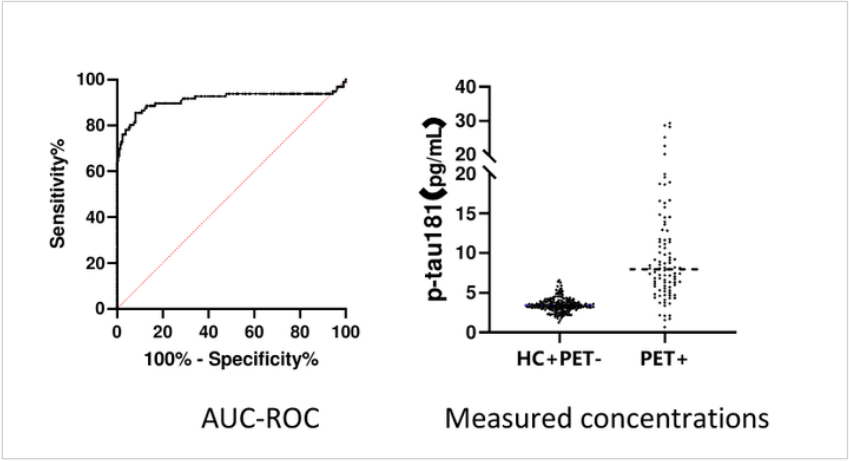


Figure 2. ROC analysis and p-tau181 concentration distribution in HC + PET-negative controls and PET-positive patients (n = 307).

Parameter	Result
Number tested	307
HC + PET- / PET+	211 / 96
AUC-ROC	0.9116
95% CI	0.8629–0.9603
Cutoff	4.74 pg/mL
Sensitivity	81.25% (95% CI: 72.30-87.80%)
Specificity	91.94% (95% CI: 87.48-94.91%)
PPV	82.11%
NPV	91.51%

Table 3. Method-comparison summary.

Recovery

Parameter	Result
High reference material	95.67 pg/mL
Low reference material	4.65 pg/mL
Mixing ratio	1:9
Mean measured mixture	13.93 pg/mL
Reported recovery	101.9%

Table 4. p-tau181 recovery after mixing high- and low-concentration reference materials at a 1:9 volume ratio.

Preliminary reference population

Specimen	n	Result
EDTA plasma	213	95th percentile: 4.74 pg/mL

Table 5. Preliminary 95th-percentile p-tau181 value in health-check EDTA plasma (n = 213); health status was not confirmed; this value is for reference only and is not a diagnostic cutoff.

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Specificity and interference

Overall analytical-specificity conclusion: maximum observed cross-reactivity was 0.030%. Endogenous and drug-interference deviations were within ±10%.

Related Tau Cross-Reactivity	100 pg/mL	1,000 pg/mL
p-tau217	0.030%	Not detected
p-tau205	0.003%	0.001%
p-tau212	0.027%	0.001%
p-tau231	0.013%	0.001%
Unphosphorylated tau	0.007%	Not detected

Table 6. Cross-reactivity with related tau proteins; all values were ≤0.030%.

Endogenous Interference	Test Concentration	Low p-tau181	High p-tau181
Total protein	80 mg/mL	−0.8%	−5.8%
Hemoglobin	10 mg/mL	−3.7%	−1.8%
Bilirubin	0.5 mg/mL	−1.9%	0.8%
Lipid	10 mg/mL	3.8%	−1.2%
Biotin	3,600 ng/mL	0.9%	0.5%

Table 7. Endogenous interference; all reported deviations were within ±10%.

Drug Interference	Test Concentration	**Results at low and high p-tau181**
Donepezil hydrochloride	3 µg/mL	Within ±10%
Galantamine hydrobromide	5 µg/mL	Within ±10%
Quetiapine fumarate	40 µg/mL	Within ±10%
Rivastigmine hydrogen tartrate	1 µg/mL	Within ±10%
Memantine hydrochloride	3 µg/mL	Within ±10%
Aripiprazole	2 µg/mL	Within ±10%
Olanzapine	0.9 µg/mL	Within ±10%
Caffeine	200 µg/mL	Within ±10%
Risperidone	0.7 µg/mL	Within ±10%

Table 8. Drug-interference substances and test concentrations evaluated for p-tau181.

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AssayProven™ Recommended p-tau217 Antibody Pair

Recommended pair summary

Multiple antibody combinations were screened under standardized conditions to identify the optimal pair for CLIA development. The recommended AssayProven™ p-tau217 pair demonstrated high analytical sensitivity, intra-lot repeatability, recovery within specification, strong discrimination by amyloid-PET status, minimal cross-reactivity, and limited drug interference.

Category	Target	Format	Item Type	Cat. #	Description	Function
Neurological Diseases & Trauma	p-tau217	CLIA	Antibody	AXT2101RAB	mAb to Human p-tau217	Capture
			Antibody	AXT2102RAB	mAb to Human total Tau	Detector

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

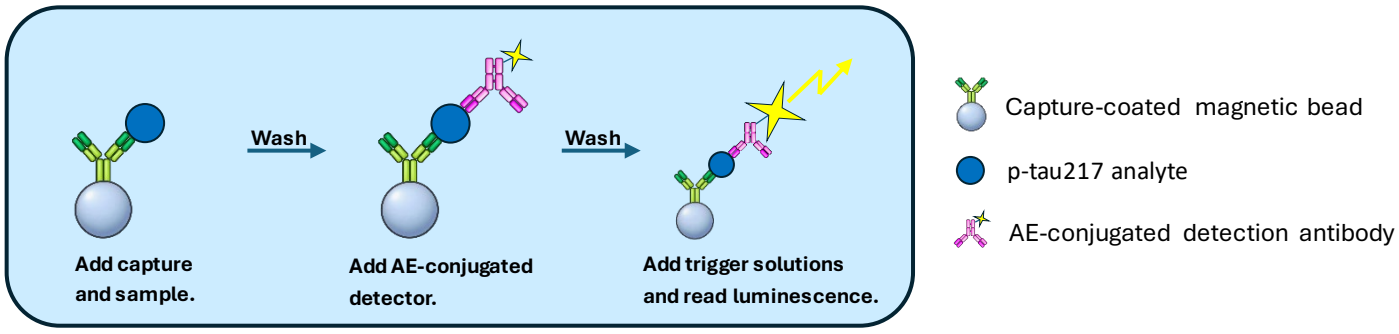


Figure 1. Two-step magnetic bead-based sandwich CLIA using AssayProven™ antibodies.

Analytical performance overview

Performance evaluation materials: p-tau reference materials and EDTA plasma specimens evaluated against amyloid-PET classification.

Parameter	Reported Performance
Limit of Blank (LoB)	≤0.10 pg/mL
Limit of Detection (LoD)	≤0.20 pg/mL
Limit of Quantitation (LoQ)	≤0.50 pg/mL
Linear range	0.20-20.00 pg/mL

Table 1. Analytical sensitivity and linear range of the AssayProven™ p-tau217 antibody pair.

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Assay precision

Material	Mean p-tau217 (pg/mL)	Intra-lot CV
Reference material 1	0.60	7.86%
Reference material 2	4.05	3.54%
Reference material 3	14.18	1.56%

Table 2. Intra-lot precision at three p-tau217 concentrations (CV ≤7.86%). Lot-to-lot signal deviations were within ±15%.

Method comparison

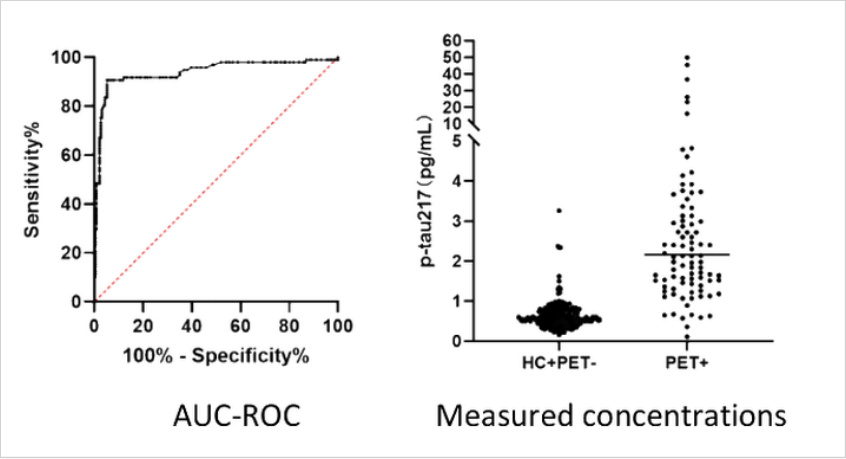


Figure 2. ROC analysis and p-tau217 concentration distribution in HC + PET-negative controls and PET-positive patients (n = 310).

Parameter	Result
Number tested	310
HC + PET- / PET+	213 / 97
AUC-ROC	0.9397
95% CI	0.9053–0.9740
Cutoff	1.04 pg/mL
Sensitivity	90.72% (95% CI: 83.30-95.04%)
Specificity	94.84% (95% CI: 90.99-97.09%)
PPV	88.89%
NPV	95.73%

Table 3. Method-comparison summary.

Recovery

Parameter	Result
High reference material	10.34 pg/mL
Low reference material	1.05 pg/mL
Mixing ratio	1:9
Mean measured mixture	1.83 pg/mL
Reported recovery	85.9%

Table 4. p-tau217 recovery after mixing high- and low-concentration reference materials at a 1:9 volume ratio.

Preliminary reference population

Specimen	n	Result
EDTA plasma	216	95th percentile: 1.04 pg/mL

Table 5. Preliminary 95th-percentile p-tau217 value in health-check EDTA plasma (n = 216); health status was not confirmed; this value is for reference only and is not a diagnostic cutoff.

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Specificity and interference

Overall analytical-specificity conclusion: Cross-reactivity was <1%; reported endogenous interference was within ±10%, and all measured drug-interference deviations were within ±8%.

Related Tau Cross-Reactivity	100 pg/mL	1,000 pg/mL
p-tau181	< 1%	< 1%
Unphosphorylated tau	< 1%	< 1%
p-tau205	Not detected	< 1%
p-tau212	Not detected	< 1%
p-tau231	Not detected	< 1%

Table 6. Cross-reactivity with related tau proteins; all values were below 1%.

Endogenous Interference	Test Concentration	Low p-tau217	High p-tau217
Total protein	80 mg/mL	−4.3%	−2.8%
Hemoglobin	10 mg/mL	−9.5%	3.2%
Bilirubin	0.5 mg/mL	3.4%	−0.9%
Lipid	10 mg/mL	−4.7%	−1.6%
Biotin	3,600 ng/mL	2.3%	0.4%

Table 7. Endogenous interference; all reported deviations were within ±10%.

Drug Interference	Test Concentration	Low p-tau217	High p-tau217
Donepezil hydrochloride	3 µg/mL	-1%	-3%
Galantamine hydrobromide	5 µg/mL	-5%	-2%
Quetiapine fumarate	2 µg/mL	-6%	3%
Rivastigmine hydrogen tartrate	40 µg/mL	-1%	1%
Memantine hydrochloride	1 µg/mL	-5%	-2%
Aripiprazole	0.7 µg/mL	8%	1%
Olanzapine	0.9 µg/mL	-1%	0%
Caffeine	3 µg/mL	-4%	-1%
Risperidone	200 µg/mL	-3%	-4%

Table 8. Drug interference at low and high p-tau217; all deviations were within ±8%.