PRODUCT INFORMATION SHEET

AssayProven™

# Monoclonal Antibody to Human p-Tau181

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

## 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 | Synthetic human Tau peptide phosphorylated at threonine 181 |
| IMMUNOGEN SEQUENCE | P10636-8 (UniProt ID) |
| AMINO ACID SEQUENCE | Not characterized |
| TAG PROTEIN | Not applicable |
| EPITOPE | Phosphorylated threonine 181 of human Tau |
| CROSS-REACTIVITY | Cross-reactivity <1.00% with p-Tau217, unphosphorylated Tau, p-Tau205, p-Tau212 and p-Tau231. |
| 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 ($K_D$) | $5.63 \times 10^{-11}$ M |
| BINDING DETERMINATION METHOD | Surface plasmon resonance (SPR) |

## Formulation

| | |
|---|---|
| BUFFER / PH | 20 mM citrate-phosphate buffer, 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) | 6.34 |
| 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

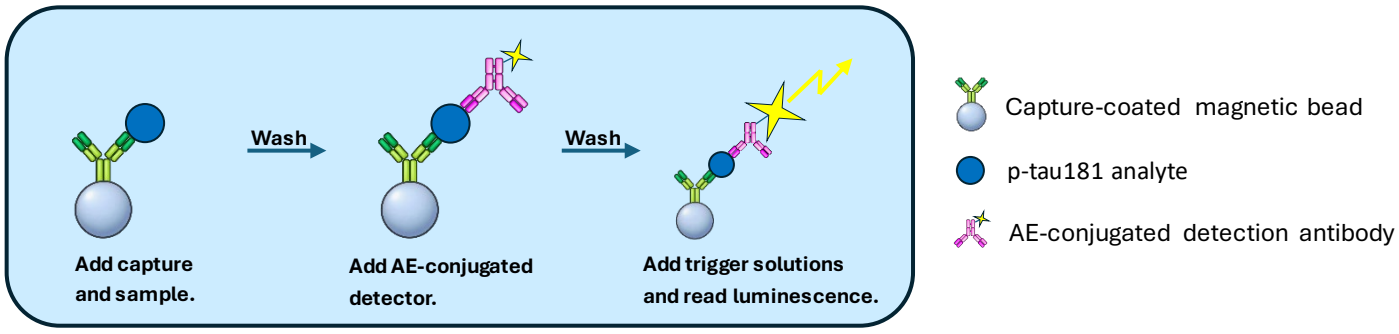



**Figure 1.** Two-step magnetic bead-based sandwich CLIA using AssayProven™ antibodies.

## 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

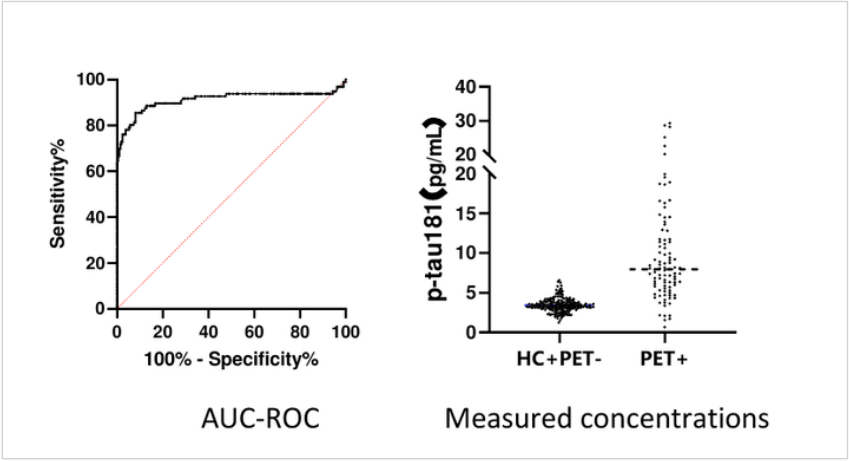



**Figure 2.** ROC analysis and p-tau181 concentration distribution in HC + PET-negative controls and PET-positive patients (n = 307).

| 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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