

Human Phospho-Tau (Thr217) Matched Antibody Pair & Calibrator

Target: Phosphorylated Tau (Thr217) • Biomarker for Clinical Alzheimer's Disease (AD) Staging

RUO / IVD RAW MATERIAL

1. MATCHED COMPONENT IDENTIFICATION & PHYSICAL FORMULATION

COMPONENT	CATALOG NO.	HOST / TYPE	TARGET / EPITOPE	FORMULATION BUFFER	PRESERVATIVE
Capture Antibody	RDM013	Mouse mAb (IgG1)	Human p-Tau217 Specific	10 mM PBS, 150 mM NaCl, pH 7.4	Azide-Free (0.22 µm)
Detection Antibody	RDM012	Mouse mAb (IgG2b)	Human Total Tau Sequence	10 mM PBS, 150 mM NaCl, pH 7.4	Conjugation-Ready
Recombinant Calibrator	RDP001	Synthetic / Recomb.	p-Tau217 (In vitro phosphorylated)	Lyophilized in Trehalose/PBS	Sterile Desiccated

2. QUALITY CONTROL STANDARDS & ANALYTICAL RELEASE CRITERIA

ANALYTICAL TEST ITEM	TESTING METHODOLOGY	RELEASE SPECIFICATION	RESULT
Visual Appearance	Visual Inspection	Clear, colorless solution, free of visible precipitates	CONFORMS
Protein Concentration	UV Absorbance (A280, ε=1.4)	2.00 - 4.00 mg/mL (Target Lot: 2.85 mg/mL)	2.85 mg/mL
Molecular Purity	Reducing & Non-reducing SDS-PAGE	≥ 95% intact IgG (Heavy chain ~50kDa, Light chain ~25kDa)	> 98.2%
Monomer Fraction	Analytical SEC-HPLC	≥ 95% monomer fraction; soluble aggregates < 2.0%	97.6%
Epitope Specificity	Cross-Reactivity Immunoassay	Cross-reactivity with non-phospho Tau, p-Tau181, p-Tau231 < 0.1%	< 0.05%
Functional Sandwich Titer	Magnetic Microparticle CLIA / Simoa	Sub-picogram detection limit: LLOD ≤ 0.20 pg/mL in plasma	0.12 pg/mL
Matrix Spike Recovery	Human Clinical EDTA Plasma	Analytical spike-and-recovery within 90% - 110%	98.4%

Recommended Assay Development Protocols

- Solid Phase Pairing:** Coat Capture mAb (RDM013) at 2.0 - 4.0 µg/mL on carboxyl magnetic particles or microplates.
- Detection Conjugation:** Label Detection mAb (RDM012) directly with Acridinium Ester (AE), Biotin, or HRP without pre-dialysis.
- Assay Range:** Standard curve range 0.5 pg/mL to 250 pg/mL in authentic human plasma or CSF matrices.

Stability, Storage & Handling Guidelines

- Liquid Antibodies:** Store at 2°C - 8°C for short-term working stock (≤ 1 month). Store at -20°C to -80°C for long-term (24 months).
- Lyophilized Calibrator:** Store at -20°C. Reconstitute with sterile deionized water. Avoid repeated freeze-thaw cycles (≤ 3 cycles).
- Lot Consistency:** Clonal hybridoma lineage guaranteed with zero kinetic drift across multi-gram batch scale-up.

3. FINAL QUALITY ASSURANCE INSPECTION & RELEASE SIGN-OFF

Manufactured By: Suzhou Renduan Biomedical Technology Co., Ltd.
Facility: Floor 6, Building 1, No. 2358 Chang'an Road, Wujiang, Suzhou, China
Batch Release Policy: Compliant with In-House Quality

QC Analyst: [Analyst Signature]
QC Reviewer: [Reviewer Signature]
Release Date: [YYYY-MM-DD]

RENDUAN BIOMED
QA RELEASED
LOT VERIFIED