

Human Amyloid Beta 1-42 (Aβ1-42) Matched Antibody Pair & Calibrator

Target: Amyloid Beta 1-42 C-Terminus • High Discrimination Against Aβ1-40 • AD Pathology

RUO / IVD RAW MATERIAL

1. MATCHED COMPONENT IDENTIFICATION & PHYSICAL FORMULATION

COMPONENT	CATALOG NO.	HOST / TYPE	TARGET / EPITOPE	FORMULATION BUFFER	PRESERVATIVE
Capture Monoclonal	RDM009	Mouse mAb (IgG1)	Human Aβ1-42 C-Terminal Specific	10 mM PBS, 150 mM NaCl, pH 7.4	Azide-Free (0.22 µm)
Detection Monoclonal	RDM011	Mouse mAb (IgG1)	Human Aβ N-Terminal / Internal	10 mM PBS, 150 mM NaCl, pH 7.4	Conjugation-Ready
Calibrator Standard	RDP004	Synthetic Peptide	Full-Length Human Aβ1-42 (42 aa)	Lyophilized with Stabilizer Matrix	Desiccated (-20°C)
Companion Calibrator	RDP005	Synthetic Peptide	Full-Length Human Aβ1-40 (For Ratio)	Lyophilized with Stabilizer Matrix	Desiccated (-20°C)

2. QUALITY CONTROL STANDARDS & ANALYTICAL RELEASE CRITERIA

ANALYTICAL TEST ITEM	TESTING METHODOLOGY	RELEASE SPECIFICATION	RESULT
Physical Clarity	Visual Inspection	Clear liquid, colorless, particle-free	CONFORMS
Protein Concentration	UV Spectrophotometry (A280)	2.00 - 4.00 mg/mL (Target Lot: 3.10 mg/mL)	3.10 mg/mL
Purity by SDS-PAGE	Coomassie Brilliant Blue Stain	≥ 95.0% total monomeric immunoglobulin bands	> 98.4%
Monomer Ratio	Analytical SEC-HPLC (PBS Mobile Phase)	≥ 95% monomer fraction; aggregates ≤ 2.5%	97.8%
Aβ42 vs Aβ40 Specificity	Competitive Binding ELISA / CLIA	Zero cross-reactivity toward high-concentration Aβ1-40 (< 0.05%)	< 0.01%
Analytical Sensitivity	Magnetic CLIA / Simoa Protocol	Lower Limit of Detection: LLOD ≤ 1.0 pg/mL in human plasma	0.45 pg/mL
Aβ42/Aβ40 Dual Linearity	Two-Site Sandwich Verification	Parallel dilution linearity R ² ≥ 0.992 in plasma/CSF	R ² = 0.998

Assay Optimization & Pairing Notes

- Capture Coupling:** Excellent coupling efficiency on tosyl or carboxyl magnetic beads (recommended: 30 - 50 µg antibody per mg beads).
- Oligomer Resistance:** Formulated to minimize non-specific aggregation artifacts common to amyloid beta peptides in aqueous buffers.
- Dual Ratio Utility:** Enables high-precision Aβ42/Aβ40 ratio testing when paired with companion standard RDP005.

Storage, Handling & Reconstitution

- Antibody Reagents:** Store at 2°C - 8°C for up to 30 days. Maintain at -20°C for long-term storage (24-month stability verified).
- Calibrator Reconstitution:** Reconstitute lyophilized peptide with specified buffer containing carrier protein (0.1% BSA or casein). Aliquot and freeze at -80°C.
- Preservative Note:** Preservative-free. Work under sterile cleanroom flow hoods to avoid microbial contamination.

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

QC Analyst: [Analyst Signature]

QC Reviewer: [Reviewer Signature]

Release Date: [YYYY-MM-DD]

RENDUAN BIOMED
QA RELEASED
LOT VERIFIED