

Human Neurofilament Light Chain (NFL) Matched Antibody Pair & Calibrator

Target: Human NFL • Neuro-Axonal Integrity Biomarker • Multi-Etiology Neurodegeneration (AD/ALS/MS)

RUO / IVD RAW MATERIAL

1. MATCHED COMPONENT IDENTIFICATION & PHYSICAL FORMULATION

COMPONENT	CATALOG NO.	HOST / TYPE	TARGET / EPITOPE	FORMULATION BUFFER	PRESERVATIVE
Capture Monoclonal	RDM014	Mouse mAb (IgG1)	Human NFL (Core Filament Specific)	10 mM PBS, 150 mM NaCl, pH 7.4	Azide-Free (0.22 µm)
Detection Monoclonal	RDM015	Mouse mAb (IgG2a)	Human NFL (Non-overlapping)	10 mM PBS, 150 mM NaCl, pH 7.4	Conjugation-Ready
Recombinant Calibrator	RDP007	Recomb. E. coli	Full-Length Human NFL (~68 kDa)	Lyophilized from PBS, Trehalose	Desiccated (-20°C)

2. QUALITY CONTROL STANDARDS & ANALYTICAL RELEASE CRITERIA

ANALYTICAL TEST ITEM	TESTING METHODOLOGY	RELEASE SPECIFICATION	RESULT
Visual Appearance	Visual Inspection	Clear, colorless liquid, free of turbidity or particulate	CONFORMS
Protein Concentration	UV Absorbance (A280, ε=1.4)	2.00 - 4.00 mg/mL (Target Lot: 2.90 mg/mL)	2.90 mg/mL
Purity by SDS-PAGE	Reducing & Non-reducing SDS-PAGE	≥ 95.0% intact IgG; Calibrator ≥ 95% single dominant band	> 98.1%
Monomer Fraction	Analytical SEC-HPLC	≥ 95.0% monomer fraction; soluble aggregates < 2.0%	97.5%
Subunit Specificity	Cross-Reactivity Screening	Zero cross-reactivity toward alpha-internexin, NF-M, or NF-H (< 0.1%)	< 0.05%
Sandwich Limit of Detection	Digital Single-Molecule (Simoa) / CLIA	Sub-picogram detection limit: LLOD ≤ 0.80 pg/mL in blood plasma	0.38 pg/mL
Blood-to-CSF Correlation	Matched Patient Cohort Verification	Peripheral blood to CSF measurement Pearson correlation r ≥ 0.88	r = 0.94

Analytical Performance Highlights

- Low Background Noise:** Engineered epitopes prevent non-specific binding from heterophilic antibodies and rheumatoid factors.
- Pan-Neurodegenerative Utility:** Broad quantitative performance across Alzheimer's Disease, Amyotrophic Lateral Sclerosis (ALS), and Multiple Sclerosis.
- High Signal Dynamic Range:** Linear calibration from 1.0 pg/mL up to 1,000 pg/mL on automated magnetic CLIA analyzers.

Handling, Storage & Quality Governance

- Buffer Matrix:** Standard sterile PBS (pH 7.4). Custom buffer matrices (Tris-HCl, carrier-free, custom pH) available upon request.
- Storage Conditions:** Stable at 2°C - 8°C for 1 month. Recommended storage at -20°C or -80°C for 24 months. Avoid repeated freeze-thaw cycles.
- Intellectual Property:** Proprietary hybridoma clone bank with enforceable mutual NDA protection for OEM clients.

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