

Human GFAP Matched Antibody Pair & Recombinant Calibrator

Target: Glial Fibrillary Acidic Protein • Astrocytic Activation • Traumatic Brain Injury (TBI)

RUO / IVD RAW MATERIAL

1. MATCHED COMPONENT IDENTIFICATION & PHYSICAL FORMULATION

COMPONENT	CATALOG NO.	HOST / TYPE	TARGET / EPITOPE	FORMULATION BUFFER	PRESERVATIVE
Capture Monoclonal	RDM016	Mouse mAb (IgG1)	Human GFAP (Specific Epitope)	10 mM PBS, 150 mM NaCl, pH 7.4	Azide-Free (0.22 µm)
Detection Monoclonal	RDM017	Mouse mAb (IgG1)	Human GFAP (Non-overlapping)	10 mM PBS, 150 mM NaCl, pH 7.4	Conjugation-Ready
Recombinant Calibrator	RDP006	Recomb. E. coli	Full-Length Human GFAP (~50 kDa)	Lyophilized from PBS, Trehalose	Desiccated (-20°C)

2. QUALITY CONTROL STANDARDS & ANALYTICAL RELEASE CRITERIA

ANALYTICAL TEST ITEM	TESTING METHODOLOGY	RELEASE SPECIFICATION	RESULT
Appearance	Visual Inspection	Clear, colorless liquid (Antibodies) / White cake (Calibrator)	CONFORMS
Protein Concentration	UV Absorbance (A280, ε=1.4)	2.00 - 4.00 mg/mL (Target Lot: 3.25 mg/mL)	3.25 mg/mL
Purity by SDS-PAGE	Reducing & Non-reducing SDS-PAGE	≥ 95.0% intact IgG; Calibrator ≥ 95% single main band	> 98.6%
Monomer Fraction	Analytical SEC-HPLC	≥ 95.0% monomer fraction; low multimer < 2.0%	98.1%
Intermediate Filament Cross-Reactivity	Direct / Indirect Microplate ELISA	Zero cross-reactivity toward human Vimentin, Desmin, and Peripherin (< 0.1%)	< 0.05%
Sandwich Limit of Detection	Magnetic Microparticle CLIA / POCT	Sub-picogram limit: LLOD ≤ 1.5 pg/mL in authentic blood plasma	0.85 pg/mL
Matrix Spike Recovery	Clinical Heparin & EDTA Plasma	Analytical spike-recovery 90% - 110% across biological range	101.2%

Assay Platform Applications

- Chemiluminescence (CLIA):** High signal-to-noise ratio in acridinium ester and alkaline phosphatase (ALP) automated platforms.
- POCT / Lateral Flow:** Proven compatibility with colloidal gold and time-resolved fluorescence (TRFIA) microspheres.
- Clinical Range:** Accommodates acute concussive TBI surges (> 5,000 pg/mL) down to baseline healthy plasma levels (< 50 pg/mL).

Handling, Packaging & Lot Stability

- Preservative-Free Formulation:** Formulated without sodium azide to prevent enzyme inhibition during direct labeling or cell culture testing.
- Bulk Lot Reservation:** Multi-gram single-batch manufacturing allows multi-year reservation for commercial kit production.
- Recommended Storage:** Stable at 2°C - 8°C for 4 weeks. Long-term storage at -20°C or -80°C for 24 months.

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
Bio-Security: Pathogen-Free Host Cell Line Certification

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

RENDUAN BIOMED
QA RELEASED
LOT VERIFIED