RULES BASED MEDICINE
an IQVIA business

Immunoassays to bring your neurodegenerative therapeutics to market

CNS biomarkers show promise in diagnosing neurological disorders and injuries, monitoring disease progression and evaluating potential therapies in clinical trials. Rules-Based Medicine offers Simoa-based, ultrasensitive immunoassays to support the development of new diagnostics and therapeutics for Alzheimer's and other neurodegenerative conditions.

While CSF protein biomarkers remain the gold standard, blood-based biomarkers offer the advantages of providing broader, more equitable access to testing, faster and easier sample collection and, ultimately, opportunities for earlier diagnosis and treatment. The Simoa ultrasensitive immunoassay platform is a reliable method for accurately quantifying the lower levels of CSF biomarkers leaking into the bloodstream, and RBM's assays are validated to clinical laboratory standards.

SIMOA-BASED BIOMARKERS	LLOQ*		VOLUME REQUIRED	
	Serum or plasma	Undiluted samples	Serum or plasma	Other fluids**
Alpha-synuclein (A-Syn)	0.20 ng/mL	0.01 ng/mL	100 µL	150 µL
Beta Amyloid 40 (AB40)	28 pg/mL	5.6 pg/mL	100 µL	150 µL
Beta Amyloid 42 (AB42)	47 pg/mL	4.7 pg/mL	50 µL	150 µL
Glial Fibrillary Acidic Protein (GFAP)	0.70 pg/mL	0.175 pg/mL	100 µL	150 µL
Myeloid cell surface antigen CD33 (CD33)	0.11 ng/mL	0.0022 ng/mL	100 µL	150 µL
Neurofilament Light Chain (NF-L)	1.00 pg/mL	0.25 pg/mL	100 µL	150 µL
Neurofilament heavy polypeptide – phosphorylated (pNF-H)	3.8 pg/mL	0.95 pg/mL	100 µL	150 µL
Phospho-Tau181 (pTau181)	0.28 pg/mL	1.4 pg/mL	150 µL	150 µL
Phospho-Tau217 (pTau217)	0.027 pg/mL	0.00675 pg/mL	100 µL	150 µL
Phospho-Tau231 (pTau231)	0.31 pg/mL	0.155 pg/mL	150 µL	150 µL
Tau	0.22 pg/mL	0.055 pg/mL	100 µL	150 µL
Triggering Receptor Expressed on Myeloid Cells-1 (TREM-1)	0.94 pg/mL	0.094 pg/mL	50 µL	50 µL
Triggering Receptor Expressed on Myeloid Cells 2 (TREM2)	0.59 ng/mL	0.59 ng/mL	100 µL	150 µL

In addition to Simoa-based markers, RBM also offers markers on our Luminex platform that support CNS trials, including glycoprotein non-metastatic melanoma protein B (GPNMB).

Contact your rep or email us at RBM_clientservices@iqvia.com to learn more.

* Lower limit of quantitation (LLOQ) represents the lowest amount of an analyte that can be quantitatively determined with acceptable precision. LLOQ is determined by performing 2-fold serial dilutions of standard to be tested in triplicate over three runs. The percent coefficient of variation (CV) is calculated for each of the dilution replicates, and the LLOQ is determined as the concentration at which the CV is 30%.

** Cerebrospinal fluid, urine, tissue culture supernatants, bronchoalveolar lavage, synovial fluid, tissue extracts, tears, skin washings, etc.