

"MagQu" Phosphorylated Tau Protein

[pT217] IMR Reagent

REF MF-PT2-0060R

RUO

MagQu

For Research Use Only

Intended Use

The "MagQu" Phosphorylated Tau Protein [pT217] IMR Reagent is used to quantitatively measure phosphorylated Tau protein 217 (p-Tau217) levels in human fluid specimen, such as plasma. Use "MagQu" Phosphorylated Tau Protein [pT217] IMR Reagent only with the XacPro-S System (MagQu Co., Ltd.)

Summary & Explanation

Tau is a microtubule-associated protein that has a stabilizing effect on neuronal microtubules, thereby promoting axonal growth. Tau with abnormal phosphorylation has a reduced affinity for microtubules, leading to mitochondrial damage and impairment of synaptic transmission, ultimately leading to neurodegenerative processes. Plasma phosphorylated Tau protein 217 (p-Tau217) increased in the preclinical and early clinical stages of Alzheimer's disease.

Principles of Test

The "MagQu" Phosphorylated Tau Protein [pT217] IMR Reagent is designed for rapid quantifying p-Tau217 by ImmunoMagnetic Reduction (IMR). We conjugate antibody on the surface of around 50 nm-in-diameter Fe₃O₄ magnetic particles. When the antibodies on the surface bind with p-tau217, the magnetic particles form clusters. Therefore, the ac susceptibility (Xac) of magnetic particles would be reduced in the adding ac magnetic field. By measuring the reduction of Xac, p-tau217 can be easily, rapidly and accurately quantified.¹

Reagents

"MagQu" Phosphorylated Tau Protein [pT217] IMR Reagent...4 x 1 mL
(64 tests)

Storage Conditions & Stability

Storage reagent at 2 ~ 8 °C (35.6 ~ 46.4 °F).

Please eye check whether there is some precipitation in the tube of "MagQu" Phosphorylated Tau Protein [pT217] IMR Reagent by inverting the tube. Do not use the reagent when it has something precipitated.

Please refer to the detail expiration date on the product label.

CAUTION: Do not use reagents beyond the expiration date.

CAUTION: Do not freeze.

Statement of Warnings



BIOHAZARD

All products or objects that encounter human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

Safety Data Sheet is available at www.magqu.com.

1. Do not freeze.
2. Please keep away from events with strong magnetism.
3. For research use only.
4. Do not use the reagent when it has left from 2 to 8 °C (35.6 to 46.4 °F) environment out over 24 hours.
5. Do not use the reagent when it has something precipitated.
6. Immediately after use reagent should be returned to cold storage (2 to 8 °C).
7. Do not use reagents beyond the expiration date printed on the vial.

Reagent Preparation

1. No preparation is necessary.
2. Please use the "MagQu" Phosphorylated Tau Protein [pT217] IMR Reagents at room temperature (15-30°C).

Specimen Collection & Preparation



BIOHAZARD

All products or objects that encounter human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

1. **Collection precautions:** Collect all blood samples by wearing protective equipment and following universal precautions for venipuncture.
2. 6 ~ 10 mL of whole blood into a blood collection tube prepared with EDTA as an anticoagulant (Lavender Top; K2-EDTA or K3-EDTA tube).

NOTE: Please collect the whole blood following the manual of blood collection tube from manufacturer.

3. Invert the tube smoothly 5-10 times and make sure the whole blood specimen is mixed well with EDTA.
4. Centrifuge the blood collection tubes for 15 minutes at 1,500 ~ 2,500 x g at room temperature to separate the plasma from the blood cells with swing-out(bucket) rotor.
5. After centrifugation, the upper layer of plasma sample can be assayed followed by "Procedure". The plasma sample must be labeled and deep frozen (-80°C) if it is not freshly used. Avoid repeated freezing and thawing.

CAUTION: Precipitant in plasma may interfere the assay.

CAUTION: Use blood collection tubes contain K2-EDTA or K3-EDTA only. The blood collection tubes of different brands may have a few different substances that may influence the assay.

Procedure

Material supplied

"MagQu" Phosphorylated Tau Protein [pT217] IMR Reagent

Materials required but not supplied

Magnetic Immunoassay Analyzer (XacPro-S)

Sample testing tubes

Transfer pipettes

1. Allow reagent and sample to reach room temperature before use.
2. Vortex them for about 5 ± 2 seconds.
3. Add 60 µL of sample into a clear sample testing tube.
4. Add 60 µL of "MagQu" Phosphorylated Tau Protein [pT217] IMR Reagent to tube.
5. Vortex them for about 5 ± 2 seconds. The rest of "MagQu" Phosphorylated Tau Protein [pT217] IMR Reagent return to 2~8 °C.
6. Insert the sample testing tube into the measuring slot of

Magnetic Immunoassay Analyzer (XacPro-S).

NOTE: Step 4 to 6 must be done within 20 minutes.

7. Process the measurement and data analysis according to the user's manual of Magnetic Immunoassay Analyzer (XacPro-S).
8. We suggest retesting sample if error signal (NaN) is displayed of Magnetic Immunoassay Analyzer (XacPro-S).

Performance Characteristics

Precision

The p-Tau 217 samples were measured in duplicate, twice per day over 20 days. Two different p-Tau 217 concentrations were used for the tests. The standard deviations of repeatability and within-lab for various p-Tau 217 concentrations were obtained:

Item tested	Mean of measured p-Tau 217 concentrations (pg/mL)	Standard deviation (%CV)	
		Repeatability	Within-Lab
pool 1	100	1.540 (1.6)	8.437 (8.5)
pool 2	0.1	0.009 (9.3)	0.006 (6.6)

Precision testing was determined according to CLSI/NCCLs document EP5-A3.

Interference (Specificity)

Plasma can contain interfering substances such as hemoglobin, bilirubin, or intra lipid because of common diseases, such as hemolysis, jaundice or hypertriglyceridemia. Other bio-substances that exist naturally in plasma, such as uric acid, rheumatoid factor, or albumin, are also interfering substances. Other interfering substances include drugs or chemicals in medicine that is used to treat inflammatory diseases, viral and bacterial infections, cancers and cardiovascular disease. The level of p-Tau 217 in each of these pools was then determined and normalized to the level without the respective substances.

Substance	Amount Added	Mean % Recovery (Spike/control x 100)
Hemoglobin	10000 µg/mL	98.8
Conjugated bilirubin	600 µg/mL	93.2
Intra lipid	30000 µg/mL	98.2
Uric acid	200 µg/mL	97.3
Rheumatoid factor	500 IU/mL	95.0
Albumin	60000 µg/mL	99.1
Acetylsalicylic acid	500 µg/mL	91.9
Ascorbic acid	300 µg/mL	92.5
Ampicillin sodium	1000 µg/mL	106.5
Quetiapine fumarate	100 ng/mL	107.9
Galantamine hydrobromide	90 ng/mL	105.7
Rivastigmine hydrogen tartrate	100 ng/mL	99.3
Tau	100 pg/mL	108.9
p-Tau181	20 pg/mL	100.7

Interference testing was based on the principle of CLSI/NCCLs document EP7-A2.

Analytical Sensitivity

The "MagQu" Phosphorylated Tau Protein [pT217] IMR reagent has an analytical sensitivity of 66 fg/mL.

Analytical Measuring Range (AMR)

The analytical measuring range of the reagent is from 0.1 to 100 pg/mL.

Results

By using XacPro-S, we can get two signals: one is the AC signal before the reaction (Xac_0) and the other is the AC signal after reaction (Xac). Then we can have the IMR (%) through two signals by following function:

$$IMR(\%) = \frac{Xac_0 - Xac}{Xac} \times 100$$

IMR (%), as functions of p-Tau217 concentration $\phi_{p-Tau217}$ are explored and are found to follow the logistic function:

$$IMR(\%) = \frac{A - B}{1 + \left(\frac{\phi_{p-Tau217}}{\phi_o}\right)^\gamma} + B$$

where A, B, ϕ_o , and γ are fitting parameters. For p-Tau 217, A = 2.63, B = 4.35, ϕ_o = 0.49, and γ = 9.57. The concentration of p-Tau217 can be obtained by following the equations, and can be converted from IMR(%) by Main-analyzer.

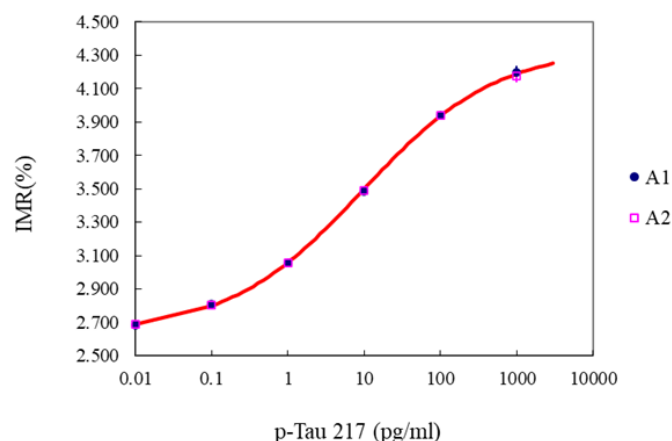


Fig.1 The IMR standard curve of p-Tau 217

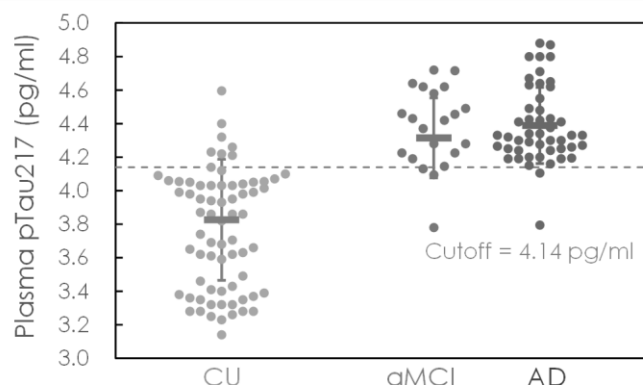
Limitations

1. The analytical range of reagent is from 0.1 to 100 pg/mL. When the specimen with p-Tau 217 > 100 pg/mL is to be determined, carry out the following procedures to obtain the accurate concentration. Dilute the specimen, re-assay, and multiply the assayed p-Tau217 value by the dilution factor.
2. Reagents should be used before the expiration date printed on the kit label.
3. Data is based upon human plasma sample.
4. Do not use the plasma sample when it has left -20°C more than 2 hours or it has something precipitated.
5. Glass testing tubes are single use only.

Clinical Performance

Plasma samples from normal controls (NC, n = 70), patients with mild cognition impairment (MCI, n = 21) and patients with Alzheimer's disease (AD, n = 48) were collected for p-Tau 217 assays using the p-Tau 217 reagent.

The higher the value, the higher the probability of Alzheimer's disease. Using this product, if the test value of the subject p-Tau 217 > 4.14 (Accuracy is 0.947), it is recommended to visit the relevant specialist for further Alzheimer's disease examination.



Cut-off value	Performance	REF
Normal vs. patients (AD or MCI due to AD) p-Tau 217 > 4.14	Accuracy: 0.947 Sensitivity: 92.8% Specificity: 90.0%	MF-PT2-0060

References

- Suárez-Calvet M, Karikari TK, Ashton NJ, Lantero Rodríguez J, Milà-Alomà M, Gispert JD, Salvadó G, Minguillon C, Fauria K, Shekari M, Grau-Rivera O, Arenaza-Urquijo EM, Sala-Vila A, Sánchez-Benavides G, González-de-Echávarri JM, Kollmorgen G, Stoops E, Vanmechelen E, Zetterberg H, Blennow K, Molinuevo JL; ALFA Study. Novel tau biomarkers phosphorylated at T181, T217 or T231 rise in the initial stages of the preclinical Alzheimer's continuum when only subtle changes in Aβ pathology are detected. EMBO Mol Med. 2020 Dec 7;12(12):e12921.
- Yang SY, Chiu MJ, Chen TF, Horng HE. Detection of Plasma Biomarkers Using Immunomagnetic Reduction: A Promising Method for the Early Diagnosis of Alzheimer's Disease. Neurol Ther. 2017 Jul;6(Suppl 1):37-56.
- Yang CC, Yang SY, Ho CS, Chang JF, Liu BH, Huang KW. Development of antibody functionalized magnetic nanoparticles for the immunoassay of carcinoembryonic antigen: a feasibility study for clinical use. J Nanobiotechnology. 2014 Nov 26;12:44.

Glossary/symbol definition :

SYMBOL	DESCRIPTION
	Caution, refer to accompanying documents
	Batch code
	Catalogue number
	Content
	Use by Expressed as: CCYY-MM-DD
	Biological risk
	Consult instructions for use.
	Temperature limitation
	For research use only
	Manufacturer
	Country and date of manufacture
	Do not use if package damaged



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