"MagQu" Phosphorylated Tau Protein [pT181] Control Solution

Concentration H



CL-PT1-000T Concentration L



For In Vitro Diagnostic & Professional Use

CL-PT1-005T

Intended Use

"MagQu" Phosphorylated Tau Protein [pT181] Control Solution is used as a standard control for "MagQu" Phosphorylated Tau Protein [pT181] IMR Reagent (MF-PT1-0060).

Special instrumentation requirement

Magnetic Immunoassay Analyzer (XacPro-S)

Product Description

Normal phosphorylated tau is essential to neuronal homeostasis. However, hyperphosphorylation of tau induces the protein to detach from the microtubules, thereby destabilizing microtubules and affecting its axonal transport. Previous reports showed hyperphosphorylated tau aggregates to from insoluble neurofibrillary tangles that interfere with fundamental cell functions. It has been classically associated with many neurodegenerative disease including Alzheimer disease, Parkinson's disease, Frontotemporal dementia and Lewy body disorders. "MagQu" Phosphorylated Tau Protein [pT181] IMR Reagent is an in vitro diagnostic device intended for the quantitative determination of p-tau 181 levels to help diagnosis neurodegenerative disease from human fluid specimen, such as plasma, by using the Magnetic Immunoassay Analyzer (XacPro-S).1

Principles of Test

"MagQu" Phosphorylated Tau Protein [pT181] Control Solution is used as a standard control for "MagQu" Phosphorylated Tau Protein [pT181] IMR Reagent (MF-PT1-0060). The antibody conjugated on the surface of Fe $_3$ O $_4$ magnetic particles (\sim 50 nm) could bind with Tau protein and form clusters. With the increase of cluster, the signal of ac susceptibility (χ_{ac}) will decrease in the applied ac magnetic field. That is the principle of Immuno Magnetic Reduction (IMR). By measuring the reduction of χ_{ac} , we can quantify the Tau protein in the sample easily and accurately.²

Storage & Stability

CAUTION: Do not use the product beyond the expiration date. **CAUTION:** Avoid repeated freezing and thawing cycles.

Statement of Warnings BIOHAZARD

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All products or objects that come in contact with human or animal body fluids should be handled carefully, 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. For in vitro diagnostic use only.
- 2. For professional use only.
- For clinical trials units (CTU), accredited laboratories, or accredited units use only.
- 4. Do not use the product if there is any precipitation.
- 5. Aliquot the product for first use. Avoid repeated freezing and thawing cycles.
- 6. Do not use the product beyond the expiration date.
- 7. Keep out of reach of children.
- 8. The disposal of the waste generated should follow the local rules.
- If there is any problem about the product, please contact the MagQu Co. Ltd.

Use Direction

- 1. For use with the "MagQu" Phosphorylated Tau Protein [pT181] IMR Reagent (MF-PT1-0060) at room temperature (15-30°C).
- 2. Use the product for each measurement.

Procedure

Materials required but not supplied

- Magnetic Immunoassay Analyzer (XacPro-S)
- "MagQu" Phosphorylated Tau Protein [pT181] IMR Reagent (MF-PT1-0060)
- Sample testing tubes
- Transfer pipettes

Thaw out the product on ice and then take it to room temperature (18 $^{\circ}\text{C} \sim 25 ~^{\circ}\text{C}$) before use. Mix the product thoroughly before use and then restore it to -15 $^{\circ}\text{C} \sim$ -30 $^{\circ}\text{C}$ as soon as possible.

- Aliquot the product when first use. Avoid repeated freezing and thawing cycles.
- 2. Add 40 µL of "MagQu" Phosphorylated Tau Protein [pT181] Control Solution into sample testing tube.
- 3. Add 80 μ L of "MagQu" Phosphorylated Tau Protein [pT181] IMR Reagent (MF-PT1-0060) into the same sample testing tube. Vortex for about 15 seconds to mix thoroughly.
- Insert the sample testing tube into the measuring slot of Magnetic Immunoassay Analyzer (XacPro-S).
- Process the measurement according to the operation & maintenance manual of Magnetic Immunoassay Analyzer (XacPro-S).
- The final concentration value is acceptable while it falls between ±20 % of the concentration value on COA.

References

- Mielke MM, Hagen CE, Xu J, Chai X, Vemuri P, Lowe VJ, Airey DC, Knopman DS, Roberts RO, Machulda MM, Jack CR Jr, Petersen RC, Dage JL, "Plasma phospho-tau181 increases with Alzheimer's disease clinical severity and is associated with tauand amyloid-positron emission tomography", Alzheimers Dement. 1-9, (2018)
- Che-Chuan Yang, Shieh-Yueh Yang, Jen-Jie Chieh, Herng-Er Horng, Chin-Yih Hong, Hong-Chang Yang, K. H. Chen, B. Y. Shih, Ta-Fu Chen, and Ming-Jang Chiu, "Biofunctionalized magnetic nanoparticles for specifically detecting biomarkers of Alzheimer's disease in vitro", ACS Chem. Neurosci. 2, 500 (2011).

Glossary/symbol definition:	
SYMBOL	DESCRIPTION
<u> </u>	Caution, refer to accompanying documents
LOT	Batch code
REF	Catalogue number,
CONT	Content
2002-03	Use by Expressed as: CCYY-MM-DD
₩	Biological risk
i	Consult instructions for use.
-30°C -15°C	Temperature limitation
EC REP	Authorized representative in the EU/EC.
IVD	In Vitro diagnostic medical device
	Manufacturer
	Do not use if package damaged
((CE MARK = CONFORM WITH EEC DIRECTIVES



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EC REP Authorized representative in the EU/EC

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