

“MagQu” TDP-43 Control Solution

REF CL-TDP-000T Concentration L
CL-TDP-001T Concentration H



For *In Vitro* Diagnostic & Professional Use

Intended Use

“MagQu” TDP-43 Control Solution is used as a standard control for “MagQu” TDP-43 IMR Reagent (MF-TDP-0060).

Special instrumentation requirement

Magnetic Immunoassay Analyzer (XacPro-S)

Product Description

The TAR DNA binding protein of 43 kDa (TDP-43) is a ubiquitously expressed nuclear protein with roles in transcription and splicing regulation. A hyper-phosphorylated, ubiquitinated and cleaved form of TDP-43, known as pathologic TDP-43 is the major disease protein in ubiquitin-positive, tau and α -synuclein-negative frontotemporal dementia (FTLD-TDP, previously referred to as FTLD-U) and in amyotrophic lateral sclerosis (ALS). Evidences indicates that TDP-43 can be detected in human plasma and CSF and levels are reportedly elevated in cases of ALS, FTLD and Alzheimer’s disease.^{1,2}

Principles of Test

“MagQu” TDP-43 Control Solution is used as a standard control for “MagQu” TDP-43 IMR Reagent (MF-TDP-0060). The antibody conjugated on the surface of Fe₃O₄ magnetic particles (~ 50 nm) could bind with TDP-43 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 phosphorylation of TDP-43 in the sample easily and accurately.

Storage & Stability

Storage the product at -15 to -30°C (5.0 to -22.0°F).

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

CAUTION: Do not use the product beyond the expiration date.

CAUTION: Avoid repeated freezing and thawing cycles.

Statement of Warnings



BIOHAZARD

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.
3. 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.
8. If there is any problem about the product, please contact the MagQu Co. Ltd.

Use Direction

1. For use with the “MagQu” TDP-43 IMR Reagent (MF-TDP-0060) at room temperature (15 to 30°C).
2. Use the product for each measurement.

Procedure

Materials required but not supplied

- Magnetic Immunoassay Analyzer (XacPro-S)
- “MagQu” TDP-43 IMR Reagent (MF-TDP-0060)
- Sample testing tubes
- Transfer pipettes








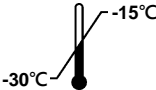







Thaw out the product on ice and then take it to room temperature (15 to 30°C) before use. Mix the product thoroughly before use and then restore it to -15 to -30°C as soon as possible.

1. Aliquot the product when first use. Avoid repeated freezing and thawing cycles.
2. Add 60 μ L of “MagQu” TDP-43 Control Solution into sample testing tube.
3. Add 60 μ L of “MagQu” TDP-43 IMR Reagent (MF-TDP-0060) into the same sample testing tube. Vortex for about 15 seconds to mix thoroughly.
4. Insert the sample testing tube into the measuring slot of Magnetic Immunoassay Analyzer (XacPro-S).
5. Process the measurement according to the operation & maintenance manual of Magnetic Immunoassay Analyzer (XacPro-S).
6. The final concentration value is acceptable while it falls between $\pm 20\%$ of the concentration value.

References

1. Foulds, P., McAuley, E., Gibbons, L., Davidson, Y., Pickering-Brown, S. M., Neary, D., Snowden, J. S., Allsop, D., Mann, D. M. (2008). TDP-43 protein in plasma may index TDP-43 brain pathology in Alzheimer’s disease and frontotemporal lobar degeneration. *Acta neuropathologica*, 116(2), 141-6.
2. Feneberg, E., Gray, E., Ansoorge, O., Talbot, K., & Turner, M. R. (2018). Towards a TDP-43-Based Biomarker for ALS and FTLD. *Molecular neurobiology*, 55(10), 7789-7801.

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
	Authorized representative in the EU/EC.
	In Vitro diagnostic medical device
	Manufacturer
	Country and date of manufacture
	Do not use if package damaged
	CE MARK = CONFORM WITH EEC DIRECTIVES
	Unique device identifier

 **Manufacturer**

MagQu Co., Ltd.

Rm3, 6F, No.95, Minquan Rd., Xindian Dist, New Taipei City
231625, Taiwan

Tel: +886-2-8667-1897

Fax: +886-2-8667-1809

E-mail: info@magqu.com

Website : www.magqu.com

 **Authorized representative in the EU/EC**

MedNet EC-REP GmbH

Borkstraße 10 48163 Münster Germany

Rev. Apr-25-2022