“MagQu” GFAP IMR Reagent

REF MF-GFA-0060

CE IVD

For *In Vitro* Diagnostic & Professional Use

Intended Use

The “MagQu” GFAP IMR Reagent is used to quantitatively measure glial fibrillary acidic protein (GFAP) in human fluid specimen, such as plasma. Use “MagQu” GFAP IMR Reagent only with the XacPro-S System (MagQu Co., Ltd.).

Summary & Explanation

Glial fibrillary acidic protein (GFAP) is the main constituent of the astrocytic cytoskeleton, which plays an important role in the structure and mobility of astrocytes and can affect astrocyte function[1]. The amount of GFAP in the blood begins to rise in the early stages of Alzheimer's disease[2]. Symptoms of astroglial cell deposition can be a sign of the onset of early events in AD. Therefore, GFAP can be used to predict the future onset of Alzheimer's disease, mild cognitive impairment, and changes in the structural features of brain MRI in the elderly.

Principles of Test

The “MagQu” GFAP IMR Reagent is designed for rapid quantifying GFAP by ImmunoMagnetic Reduction (IMR). We conjugate antibody on the surface of around 50 nm-in-diameter Fe_3O_4 magnetic particles. When the antibodies on the surface bind with GFAP, 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, GFAP can be easily, rapidly and accurately quantified.[3]

Reagents

“MagQu” GFAP IMR Reagent……4 x 1 mL (64 tests)

Storage Conditions & Stability

Storage reagent at 2 ~ 8 ℃ (35.6 ~ 46.4 ℉).

Please eye check whether there is some precipitation in the tube of “MagQu” GFAP 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 come in contact with 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 *in vitro* diagnostic use only.
4. For professional use only.
5. Do not use the reagent when it has left from 2 to 8 ℃ (35.6 to 46.4 ˚F) environment out over 24 hours.
6. Do not use the reagent when it has something precipitated.
7. Immediately after use reagent should be returned to cold storage (2 to 8 ℃).
8. Do not use reagents beyond the expiration date printed on the vial.

Reagent Preparation

1. No preparation is necessary.
2. Please use the “MagQu” GFAP IMR Reagents at room temperature (15-30℃).

Specimen Collection & Preparation

BIOHAZARD

All products or objects that come in contact with 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 tubes prepared with EDTA as an anticoagulant (Lavender Top; K2-EDTA or K3-EDTA tube).
   NOTE: Please collecting 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 mix 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(backet) 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℃) 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 difference brands may have a few difference substances that may influence the assay.

Procedure

Material supplied

“MagQu” GFAP 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” GFAP IMR Reagent to tube.
5. Vortex them for about 5 ± 2 seconds. The rest of “MagQu” GFAP IMR Reagent return to 2~8℃.
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 GFAP samples were measured in duplicate, twice per day over 20 days. Two different GFAP concentrations were used for the tests. The standard deviations of repeatability and within-lab for various GFAP concentrations ware obtained:

Item tested	Mean of measured GFAP concentrations (pg/mL)	Standard deviation (%CV)	
		Repeatability	Within-Lab
pool 1	101.50	0.92 (0.9)	5.01 (3.1)
pool 2	10.01	0.31 (3.4)	0.70 (7.0)

Precision testing was determined according to CLSI/NCCLs document EP5-A2.

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 GFAP 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	101.2
Conjugated bilirubin	600 μg/mL	99.6
Intra lipid	30000 μg/mL	108.0
Uric acid	200 μg/mL	100.3
Rheumatoid factor	500 IU/mL	98.9
Albumin	60000 μg/mL	100.2
Acetylsalicylic acid	500 μg/mL	99.9
Ascorbic acid	300 μg/mL	97.3
Ampicillin sodium	1000 μg/mL	104.9
Quetiapine fumarate	100 ng/mL	100.1
Galantamine hydrobromide	90 ng/mL	103.6
Rivastigmine hydrogen tartrate	100 ng/mL	102.8
Donepezil hydrochloride	1000 ng/mL	95.3
Memantine hydrochloride	150 ng/mL	105.7

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

Analytical Sensitivity

The “MagQu” GFAP IMR reagent has an analytical sensitivity of 0.0314 pg/mL.

Analytical Measuring Range (AMR)

The analytical measuring range of the reagent is from 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 GFAP concentration ϕ_{GFAP} are explored and are found to follow the logistic function:

$$IMR(\%) = \frac{A - B}{1 + (\frac{\phi_{GFAP}}{\phi_o})^{\gamma}} + B$$

where A, B, ϕ_o, and γ are fitting parameters. For GFAP, A = 2.82, B = 4.07, ϕ_o = 204.76, and γ = 0.46. The concentration of GFAP can be obtained by following the equations, and can be converted from IMR(%) by Main-analyzer.

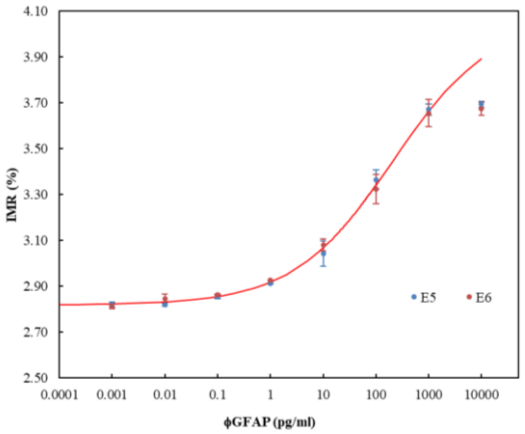


Fig.1 The IMR standard curve of GFAP

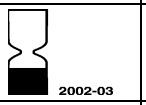
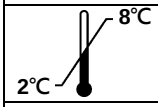
Limitations

1. The analytical range of reagent is from 1 to 100 pg/mL. When the specimen with GFAP > 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 GFAP 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 leaved -20°C more than 2 hours or it has something precipitated.
5. Glass testing tubes are single use only.

References

1. Schiff L, Hadker N, Weiser S, Rausch C. A literature review of the feasibility of glial fibrillary acidic protein as a biomarker for stroke and traumatic brain injury. Mol Diagn Ther. 2012;16(2):79-92.
2. Wharton SB, O'Callaghan JP, Savva GM, et al. Population variation in glial fibrillary acidic protein levels in brain ageing: relationship to Alzheimer-type pathology and dementia. Dement Geriatr Cogn Disord. 2009;27(5):465-473.
3. Yang CC, Yang SY, Chieh JJ, et al. Biofunctionalized magnetic nanoparticles for specifically detecting biomarkers of Alzheimer's disease in vitro. ACS Chem Neurosci. 2011;2(9):500-505.

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**

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