

# “MagQu” BDNF IMR Reagent

REF MF-BDN-0060



## Intended Use

The “MagQu” BDNF IMR Reagent is used to quantitatively measure Brain-derived neurotrophic factor in human fluid specimen, such as plasma. Use “MagQu” BDNF IMR Reagent only with the XacPro-S System (MagQu Co., Ltd.).

## Summary & Explanation

Brain-derived neurotrophic factor (BDNF) is a family of neurotrophic proteins that promote neuronal survival, normal function and development and plays an important role in the regulation of cognition and memory. BDNF has been previously found to be associated with depression and studies have found that depressed patients have a significant decrease in BDNF expression. In recent years, BDNF has also been found to be associated with dementia. Previous studies have shown that high levels of BDNF expression in the peripheral system can protect older adults against Alzheimer's disease. Therefore, low BDNF expression is considered to be a precursor to Alzheimer's disease. The reason for this low level of BDNF expression may be that when the neurons of dementia patients start to be damaged, the entire brain environment starts to deteriorate, and the nerves, glial cells and endothelial cells that secrete BDNF are also damaged, thus reducing the amount of secretion. This suggests that BDNF is a novel predictor of depression, dementia and Alzheimer's disease in healthy adults, as well as a biomarker of dementia risk and prognosis.<sup>1,2,3</sup>

## Principles of Test

The “MagQu” BDNF IMR Reagent is designed for rapid quantifying Brain-derived neurotrophic factor (BDNF) by ImmunoMagnetic Reduction (IMR). We conjugate antibody on the surface of around 50 nm-in-diameter Fe<sub>3</sub>O<sub>4</sub> magnetic particles. When the antibodies on the surface bind with BDNF, 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, Brain-derived neurotrophic factor can be easily, rapidly and accurately quantified.

## Reagents

“MagQu” BDNF 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” BDNF 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 be frozen.

## 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](http://www.magqu.com).

1. Do not be frozen.
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 °C (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 °C).
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” BDNF IMR Reagents at room temperature (15-30 °C).

## 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 tube prepared with EDTA as an anticoagulant (Lavender Top; 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 (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 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” BDNF 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 two clear sample testing tubes respectively.

- Add 60  $\mu\text{L}$  of "MagQu" BDNF IMR Reagent to each tubes respectively.
- Vortex them for about  $5 \pm 2$  seconds. The rest of "MagQu" BDNF IMR Reagent return to  $2\text{--}8^\circ\text{C}$ .
- 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.
- Process the measurement and data analysis according to the user's manual of Magnetic Immunoassay Analyzer (XacPro-S).
- We suggest retesting sample if error signal (NaN) is displayed of Magnetic Immunoassay Analyzer (XacPro-S).

## Performance Characteristics

### Precision

The Brain-derived neurotrophic factor (BDNF) samples were measured in duplicate, twice per day over 20 days. Two different BDNF concentrations were used for the tests. The standard deviations of repeatability and within-lab for various BDNF concentrations were obtained:

Item tested	Mean of measured BDNF concentrations (pg/mL)	Standard deviation (%CV)	
		Repeatability	Within-Lab
pool 1	101.65	0.92 (0.9)	8.91 (8.8)
pool 2	10.00	0.21 (2.1)	0.20 (2.0)

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 Brain-derived neurotrophic factor in each of these pools was then determined and normalized to the level without the respective substances.

Substance	Amount Added	% Recovery (Spike/control x 100)
Hemoglobin	10000 $\mu\text{g/mL}$	104.0
Conjugated bilirubin	600 $\mu\text{g/mL}$	102.2
Intra lipid	30000 $\mu\text{g/mL}$	103.7
Uric acid	200 $\mu\text{g/mL}$	105.2
Rheumatoid factor	500 IU/mL	98.7
Albumin	60000 $\mu\text{g/mL}$	103.8
Acetylsalicylic acid	500 $\mu\text{g/mL}$	95.2
Ascorbic acid	300 $\mu\text{g/mL}$	107.9
Ampicillin sodium	1000 $\mu\text{g/mL}$	104.2
Quetiapine fumarate	100 ng/mL	103.2
Galantamine hydrobromide	90 ng/mL	98.6
Rivastigmine hydrogen tartrate	100 ng/mL	104.2
Donepezil hydrochloride	1000 ng/mL	100.3
Memantine hydrochloride	150 ng/mL	96.5

Interference testing was based on the principle of CLSI/NCCLS document EP7

### Analytical Sensitivity

The "MagQu" BDNF IMR reagent has an analytical sensitivity of 3 fg/mL.

### Analytical Measuring Range (AMR)

The analytical measuring range of the reagent is from 10 to 1000 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 Brain-derived neurotrophic factor (BDNF) concentration  $\phi_{\text{BDNF}}$  are explored and are found to follow the logistic function:

$$IMR(\%) = \frac{A-B}{1 + \left(\frac{\phi_{\text{BDNF}}}{\phi_0}\right)^\gamma} + B$$

where A, B,  $\phi_0$ , and  $\gamma$  are fitting parameters. For BDNF, A = 2.70, B = 5.17,  $\phi_0 = 244.46$ , and  $\gamma = 0.31$ . The concentration of BDNF can be available by Main-analyzer.

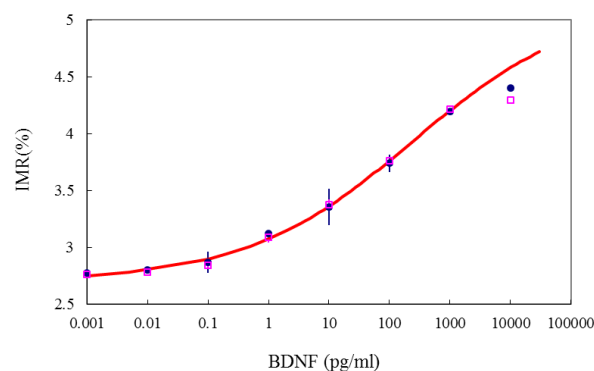


Fig.1 The IMR standard curve of BDNF








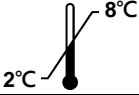







## Limitations

- The analytical range of reagent is from 10 to 1000 pg/mL. When the specimen with BDNF > 1000 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 BDNF value by the dilution factor.
- Reagents should be used before the expiration date printed on the kit label.
- Data is based upon human plasma sample.
- Do not use the plasma sample when it has leaved  $-20^\circ\text{C}$  more than 2 hours or it has something precipitated.
- Glass testing tubes are single use only.

## References

- Xie B, Zhou H, Liu W, Yu W, Liu Z, Jiang L, Zhang R, Cui D, Shi Z, Xu S. Evaluation of the diagnostic value of peripheral BDNF levels for Alzheimer's disease and mild cognitive impairment: results of a meta-analysis. *Int J Neurosci*. 2020 Mar;130(3):218-230.
- Laske C, Stransky E, Leyhe T, Eschweiler GW, Wittorf A, Richartz E, Bartels M, Buchkremer G, Schott K. Stage-dependent BDNF serum concentrations in Alzheimer's disease. *J Neural Transm (Vienna)*. 2006 Sep;113(9):1217-24
- Ng TKS, Ho CSH, Tam WWS, Kua EH, Ho RC. Decreased Serum Brain-Derived Neurotrophic Factor (BDNF) Levels in Patients with Alzheimer's Disease (AD): A Systematic Review and Meta-Analysis. *Int J Mol Sci*. 2019 Jan 10;20(2):257.

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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