“MagQu” Neurofilament light IMR Reagent

REF MF-NFL-0060

For *In Vitro* Diagnostic & Professional Use

Intended Use

The “MagQu” Neurofilament light IMR Reagent is used to quantitatively measure neurofilament light (NfL) in human fluid specimen, such as plasma. Use “MagQu” Neurofilament light IMR Reagent only with the XacPro-S System (MagQu Co., Ltd.).

Summary & Explanation

NfL is a specific cytoskeletal protein highly expressed in largely myelinated axons. Increased levels of NfL in CSF and blood are clinically useful biomarkers in many neurodegenerative diseases including Alzheimer’s disease (AD), Parkinson’s disease (PD), Huntington disease (HD). [1,2]

Principles of Test

The “MagQu” Neurofilament light IMR Reagent is designed for rapid quantifying NfL 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 NfL, 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, NfL can be easily, rapidly and accurately quantified.

Reagents

“MagQu” Neurofilament light IMR Reagent …4 x 1 mL (65 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” Neurofilament light 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.maggu.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 ℃ (35.6 to 46.4 ℉) 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” Neurofilament light 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; 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 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” Neurofilament light 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 3 seconds.
3. Add 60 µL of sample into two clear sample testing tubes respectively.
4. Add 60 µL of “MagQu” Neurofilament light IMR Reagent to each tubes respectively.
5. Vortex them for about 3 seconds. The rest of “MagQu” Neurofilament light 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. Calculate the average value for each concentration.
9. We suggest retesting sample if error signal (NaN) is displayed of Magnetic Immunoassay Analyzer (XacPro-S) or coefficient of

variation (CV, %) above 20%.

$$\text{Coefficient of Variation (CV, \%)} = \frac{\text{standard deviation}}{\text{mean}} \times 100$$

Performance Characteristics

Analytical Sensitivity

The “MagQu” Neurofilament light IMR reagent has an analytical sensitivity of 3.3 fg/mL.

Analytical Measuring Range (AMR)

The analytical measuring range of the reagent is from 0.0033 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 NfL concentration ϕ NfL are explored and are found to follow the logistic function:

$$IMR(\%) = \frac{A - B}{1 + (\frac{\varphi_{NfL}}{\varphi_o})^{\gamma}} + B$$

where A, B, ϕ_o, and γ are fitting parameters. For NfL, A = 1.840, B = 4.538, ϕ_o = 1.166, and γ = 0.428. The concentration of NfL can be available by Main-analyzer.

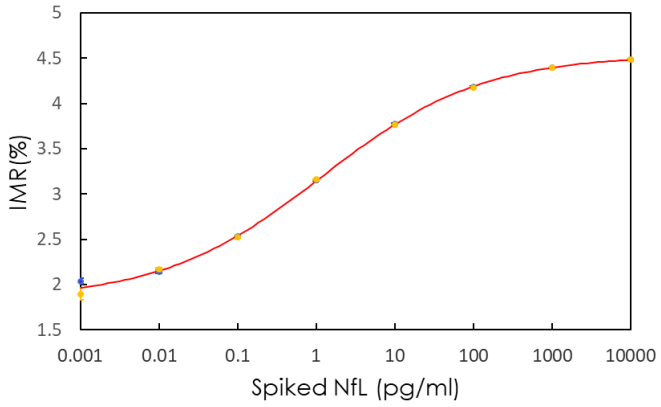


Fig.1 The IMR standard curve of NfL

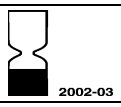
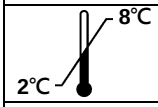
Limitations

1. The analytical range of reagent is from 0.0033 to 1000 pg/mL. When the specimen with NfL > 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 NfL 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 ℃ more than 2 hours or it has something precipitated.
5. Glass testing tubes are single use only.

References

1. Lewczuk, P., Ermann, N., Andreasson, U., Schultheis, C., Podhorna, J., Spitzer, P., Maler, J. M., Kornhuber, J., Blennow, K., Zetterberg, H. (2018). Plasma neurofilament light as a potential biomarker of neurodegeneration in Alzheimer's disease. Alzheimer's research & therapy, 10(1), 71. doi:10.1186/s13195-018-0404-9
2. Hansson, O., Janelidze, S., Hall, S., Magdalinou, N., Lees, A. J., Andreasson, U., Norgren, N., Linder, J., Forsgren, L., Constantinescu, R., Zetterberg, H., Blennow, K., Swedish BioFINDER study (2017). Blood-based NfL: A biomarker for differential diagnosis of parkinsonian disorder. Neurology, 88(10), 930-937.

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
	Manufacturer
	Do not use if package damaged

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