



mAlb Fast Test Kit (Immunofluorescence Assay)

IF1009 for Getein1100
IF5009 for Getein1160
IF2009 for Getein1600
IF3009 for Getein1180
IF4009 for Getein1200



User Manual

INTENDED USE

mAlb Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of microalbuminuria (mAlb) in human urine samples. An elevated mAlb concentration below the proteinuric level has long been recognized as a marker of kidney disease and increased cardiovascular risk in diabetic nephropathy.

SUMMARY

Albumin is one of the major plasma proteins. In normal circumstances, albumin molecules are too large to cross the glomerular basement membrane. Therefore, albumin is usually present in very low concentration in urine. Damage to the glomerular basement membrane can alter its permeability. Albumin is then able to enter the urine. Sustained elevation of urinary albumin concentration is called microalbuminuria (mAlb). mAlb arises from increased leakage of glomerular basement membrane. So, mAlb is recognized as a marker of kidney damage. The epidemiology of microalbuminuria reveals a close association between systemic endothelial dysfunction and vascular disease, also implicating glomerular endothelial dysfunction in microalbuminuria.

Recent years, determination of mAlb is linked with increased risk for cardiovascular events rather than progression to endstage kidney diseases. It is a valuable tool for the detection of cardiovascular risk in diabetic nephropathy. Early detection of microalbuminuria in diabetics is critical because immediate intervention can slow the progression of disease.

PRINCIPLE

The test is based on the competition immune-detection method and uses an anti-human mAlb monoclonal antibody conjugated with fluorescence latex and recombi-

nant mAlb antigen coated on the test strip. After the sample has been applied to the test strip, mAlb in the sample will compete with recombinant mAlb antigen on nitrocellulose matrix for fluorescence latex-labelled mAlb monoclonal antibody. As a result, the concentration of mAlb antigen in specimen shows inverse proportionally with the fluorescence intensity of mAlb.

Insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of mAlb in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:

- Package specifications: 25 tests/kit, 10 tests/kit
- 1) mAlb test card in a sealed pouch with desiccant
 - 2) Disposable pipet
 - 3) User manual: 1 piece/kit
 - 4) SD card: 1 piece/kit

2. A kit for Getein1160/Getein1180 contains:

- Package specifications: 25 tests/kit, 10 tests/kit
- 1) mAlb test card in a sealed pouch with desiccant
 - 2) Capillary pipet
 - 3) Sample diluent
 - 4) User manual: 1 piece/kit
 - 5) SD card: 1 piece/kit

3. A kit for Getein1200/Getein1600 contains:

- Package specifications: 2×24 tests/kit, 2×48 tests/kit
- 1) Sealed cartridge with 24/48 Getein mAlb test cards
 - 2) User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

- 1) Sample diluent: 1 bottle/kit
- 2) Box with pipette tips: 96 tips/kit
- 3) Mixing plate: 1 piece/kit

4. Sample diluent:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

5. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled

anti-human mAlb monoclonal antibodies, the test line is coated with mAlb recombinant antigen, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.

Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **urine sample**.
2. **Urine sample** can be preserved at room temperature for 4 hours, please test it as soon as possible. If testing is delayed, urine sample may be stored up to 3 days at 2~8°C before testing .
3. Do not use frozen urine sample.
4. Samples should be brought to room temperature before testing.

Do not use heat-inactivated samples.

6. **SAMPLE VOLUME (for Getein1100): 100 μ L.**
(for Getein1160/Getein1180): 10 μ L.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver **100 μ L** of sample into the sample well on the test card.
5. **Reaction time: 3 minutes.** Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Enter testing interface of Getein 1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver **10 μ L** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100 μ L** of sample mixture into the sample well on the test card.
6. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (3 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item,

Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. Please follow the procedure in user manual of Getein1100/Getein1160/Getein1180 for result printing. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

EXPECTED VALUE

The expected normal value for mAlb was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for mAlb is 20.0 mg/L. (The probability that value of a normal person below 20.0 mg/L is 95%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

| | |
|-----------------------|-----------------|
| Measuring Range | 10.0~200.0 mg/L |
| Lower Detection Limit | ≤10.0 mg/L |
| Within-Run Precision | ≤10% |
| Between-Run Precision | ≤15% |

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.














| Interferent | Creatinine | Glucose | Urea |
|---------------------|------------|---------|---------|
| Concentration (Max) | 10 g/L | 10 g/L | 100 g/L |

REFERENCES

1. Cöl M, Ocaktan E, Ozdemir O, et al. Microalbuminuria: prevalence in hypertensives and diabetics. Acta Med Austriaca. 2004, 31(1):23-29.
2. McTaggart MP, Price CP, Pinnock RG, et al. The diagnostic accuracy of a urine albumin - creatinine ratio point-of-care test for detection of albuminuria in primary care. Am J Kidney Dis. 2012, 60(5):787-794.
3. Denis Sviridov, Glen L. Hortin. Urine albumin measurement: Effects of urine matrix constituents. Clinica Chimica Acta. 2009, 404(2):140-143.
4. Reboldi G, Gentile G, Angeli F, et al. Microalbuminuria and hypertension. Minerva Med. 2005, 96(4):261-75.
5. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on mAlb Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

| Key to symbols used | | | |
|---|---|---|--|
|  | Manufacturer |  | Use-by date |
|  | Do not re-use |  | Date of manufacture |
|  | Consult instructions for use or consult electronic instructions for use |  | Batch code |
|  | Temperature limit |  | In vitro diagnostic medical device |
|  | Contains sufficient for <n> tests |  | Authorized representative in the European Community/European Union |
|  | CE mark |  | Do not use if package is damaged and consult instructions for use |
|  | Catalogue number | | |

Thank you for purchasing mAlb Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF10-S01-03



Getein Biotech, Inc.

Addr.: No.9 Bofu Road, Luhe District, Nanjing,

211505, China

Tel: +86-25-68568508

Fax: +86-25-68568500

E-mail: tech@getein.com.cn

overseas@getein.com.cn

Website: www.getein.com



CMC Medical Devices & Drugs S.L.

Addr.: C/ Horacio Lengo N° 18, CP 29006,

Málaga, Spain

Tel: +34951214054