

**mAlb Fast Test Kit (Immunofluorescence Assay)  
For *in vitro* Diagnostic Use**

**User Manual**

**INTENDED USE**

mAlb Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of microalbuminuria (mAlb) in urine. 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 end-stage 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 uses an anti-human mAlb polyclonal antibody conjugated with fluorescence latex and mAlb recombinant antigen coated on the test line. After the sample has been applied to the test strip, the fluorescence-labelled anti-human mAlb polyclonal antibody binds with the mAlb in sample and forms an antigen-antibody complex. The complex moves to the test card detection zone by capillary action. Then the complex will be captured on the test line by mAlb recombinant antigen. The fluorescence intensity of the test line increases in proportion to the amount of mAlb in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100), the concentration of mAlb in sample will be measured and displayed on the screen. The value will be stored in Getein1100 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

**CONTENTS**

A kit contains:

- 1. Getein mAlb test card in a sealed pouch with desiccant ..... 25
- 2. Disposable pipet ..... 25
- 3. User manual ..... 1
- 4. SD card ..... 1

A test card consists of:

A plastic shell and a reagent strip which is composed of sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence-labelled anti-human mAlb polyclonal antibody, the test line is coated with mAlb recombinant antigen, and the control line is coated with rabbit anti-goat IgG antibody), absorbent paper and liner.

Blood sample diluent:

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

**Note: Components from different batches must not be interchanged.**

**APPLICABLE DEVICE**

Getein1100 Immunofluorescence Quantitative Analyzer

**STORAGE AND STABILITY**

Store the test card at 4~30°C with a valid period of 24 months.  
Use the test card within 1 hour once the foil pouch is opened.

**PRECAUTIONS**

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow the 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 will be delayed, urine sample may be stored up to 3 days at 2~8°C prior to being tested.
3. Do not freeze urine sample.
4. Do not use frozen urine sample.
5. Samples should be brought to room temperature prior to testing.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME: 100 µl.

**TEST PROCEDURE**

1. Collect specimen according to manual.
2. Test card, sample should be brought to room temperature prior to testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver 100 µl of sample (or 3-4 drops of sample when using disposable pipet) into the sample port on the test card.
8. After 3 minutes, insert the test card into Getein1100 and press "ENT" button. The result will be shown on the screen and printed automatically.

**Notes:**

1. It is required to perform "SD Card Calib" calibration when using a new batch of kit.
2. It is suggested to calibrate once for one batch of kit.
3. Make sure the test card insertion is correct and complete.

**TEST RESULTS**

Getein1100 can scan the test card automatically and display the result on the screen. Please follow the procedure in user manual of Getein1100 for result printing.

For additional information, please refer to the user manual of Getein1100.

**EXPECTED VALUE**

The expected normal value for mAlb was determined by testing samples from 500 apparently healthy individuals. The 99<sup>th</sup> percentile of the concentration for mAlb is 20.0 mg/L.

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 mg/L

Within-Run Precision: ≤10%

Between-Run Precision: ≤15%

Method Comparison:

The assay was compared to Olympus AU5400 analyzer and its matching Randox mAlb test kits with 200 urine samples (62 positive samples and 138 negative samples). The correlation coefficient (r) is 0.984.

**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. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.












Interferent	Concentration (Max)
Creatinine	10 g/L
Glucose	10 g/L
Urea	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 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009).

#### 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 detail in the European Standard EN 980: 2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration Date
	Do not re-use		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		In vitro diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE marking		

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

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