GETEIN BIOTECHNOLOGY

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One Step Test for mAlb (Colloidal Gold)
For *In Vitro* Diagnostic Use

Manual

INTENDED USE

One Step Test for mAlb (Colloidal Gold) applies colloidal gold immunochromatography to detect microalbuminuria (mAlb) in urine samples quantitatively. 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 elevations of urinary albumin concentrations are called Microalbuminuria (mAlb). mAlb arises from increased leakage of glomerular basement membrane. So, mAlb is recognized as a marker of kidney damage.

Recent years, determination of mAlb is linked with increased risk for cardiovascular events rather than progression to end-stage kidney disease. It is a valuable tool for the detection of cardiovascular risk of diabetic nephropathy. Early detection of microalbuminuria in diabetes is critical because immediate intervention can slow the progression of disease. The epidemiology of microalbuminuria reveals a close association between systemic endothelial dysfunction and vascular disease, also implicating glomerular endothelial dysfunction in microalbuminuria.

PRINCIPLE OF THE EXAMINATION METHOD

The test uses an anti-human mAlb polyclonal antibody conjugated with colloidal gold and mAlb recombinant antigen coated on the test line. After the urine sample has been applied to the test strip, the gold-labelled anti-human mAlb polyclonal antibody binds to the mAlb in sample and forms a marked antigen-antibody complex. The complex and unbonded gold-labelled anti-human mAlb polyclonal antibody move to the test card detection zone by capillary action. Then the mAlb in sample and mAlb recombinant antigen on the test line compete to bind gold-labelled anti-human mAlb polyclonal antibody. The color intensity of the test line is in inverse proportion to the amout of mAlb in sample.

Then insert test card into the FIA8000 Quantitative Immunoassay Analyzer (hereafter referred to as FIA8000), the concentration of mAlb in sample will be measured and displayed on the screen. The values will be stored in FIA8000 and available for downloading on demand. The result can be transmitted to the laboratory or hospital information system, if it is connected to FIA8000.

CONTENTS

A kit contains:

1. Foil bag, which contains one test card and one desiccant ……25
2. Pipette……25
3. Manual …… 1
4. SD card ……1

A test card consists of:

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

Note: Components from different batches cannot be exchanged.

MATCHING EQUIPMENT

FIA8000 Quantitative Immunoassay 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 bag is opened.

WARNINGS AND PRECAUTIONS

1. For *In-Vitro* diagnostic use.
2. For use by healthcare professionals.
3. Do not use the kit beyond the expiration date printed on the outside of the box.
4. Keep the test card in the sealed pouch until ready to use. Do not reuse the used cards.
5. The pipette should not be used for multiple samples. Discard it after single use.
6. Patient samples, used test cards and pipettes may be potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully follow the instructions and procedures described in this manual.

SAMPLE COLLECTION AND PREPARATION

1. A urine sample is required for testing with this product.
2. Urine sample can be preserved at room temperature only for 4 h, please test it as soon as possible. If testing cannot be completed immediately, the urine sample should be stored up to 3 days at 2~8°C until it can be tested.
3. Do not freeze urine sample. Urine sample in freezing preservation cannot be used for testing.
4. Samples must be recovered to room temperature before testing.
5. Avoid heating the samples, which can cause protein denaturation.
6. SAMPLE VOLUME: 120 µl urine.

TEST PROCEDURE

1. Restore samples and sealed test-card foil bags to room temperature before using. Open the foil bag, label cards with numbers and use the test cards immediately.
2. Confirm SD card lot No. in accord with test kit lot No.. Perform “QC SD” operation (Details refer to 8.3.1 of FIA8000 User’s Manual) when necessary.
3. Take 120 µl urine sample and drop vertically to the sample port on the test card.
4. Wait for 3 minutes, insert the card immediately into FIA8000 and press "OK" button, the test card can be detected and the result will be printed automatically.

Note:

1. It is required to perform SD card calibration operation when using a new batch of kits; Only one SD card calibration is required for the same batch.
2. Assure of card side towards FIA8000 is correct and insert the card completely.

TEST RESULTS

When a purplish-red band appears in the control area, use the FIA8000 to analyse the test card and get a quantitative result.

If no purplish-red band appears in the control area, it indicates that the operation is incorrect or the test card has passed its expiration date. In this case, please read the manual again carefully and use a new test card to try again, if the problem persists, please stop using all products of the same batch immediately and contact with your supplier.

EXPECTED VALUE

mAlb concentration is determined using samples obtained from 500 apparently healthy individuals. The 99th percentile of the concentration for mAlb is 20.0 mg/L.

PERFORMANCE CHARACTERISTICS

Measurement Range: 10.0mg/L~200.0mg/L
Minimum Detection Limit: ≤10mg/L
Within-Run Precision: ≤10%
Between-Run Precision: ≤15%
Method Comparison:

Compared to Olympus AU5400 analyzer and matching Randox mAlb test kits with 200 patient urine samples (62 positive samples, 138 negative samples). The correlation coefficient (r) is 0.980.

LIMITATIONS OF THE PROCEDURE

1. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.
2. Some substances in urine sample as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of them is as follows:

Interfering Substance	Concentration (Max)
Creatinine	10g/L
Glucose	10g/L
Urea	100g/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 One Step Test for mAlb (Colloidal Gold) 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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
Σ	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE marking		

Thank you for purchasing One Step Test for mAlb (Colloidal Gold), Please read this manual carefully before operating to ensure proper use.

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