Finecare™ Microalbumin Rapid Test

Catalog No. W206

INTENDED USE

The Finecare™ Microalbumin Rapid Test along with Finecare™ FIA Meter is intended for vitro quantitative determination of urine microalbumin (MAU) in human urine.
- Fluorescence immunoassay
- Diagnosis of kidney damage

For in vitro diagnostic use only. For professional use only.

SUMMARY

The emergence of urine microalbumin (MAU) is an early markers of kidney damage. Under normal circumstances, the majority protein cannot pass filtration membrane proteins, however, in the pathological conditions (e.g.: inflammation, metabolic disorder and immune damage), the glomerular become hemodynamic abnormalities. Glomerular filtration membrane damage is an important reason for the increasing of urine microalbumin

Normal reference values: < 20mg/L
Notice: Individual reference range is suggested to be established for each laboratory.

PRINCIPLE

The Finecare™ Microalbumin Rapid Test is based on fluorescence immunoassay technology. The Finecare™ Microalbumin Rapid Test uses a sandwich immunodetection method, when sample is added to the sample well of the test cartridge, the fluorescence-labeled detector MAU antibody on the membrane binds to MAU antigen in urine specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and MAU are captured to MAU antibody that has been immobilized on test strip. Thus the more MAU antigen is in urine specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of MAU captured and Finecare™ FIA Meter shows MAU concentrations in urine specimen. The default results unit of Finecare™ Microalbumin Rapid Test is displayed as XXX mg/L from Finecare™ FIA Meter. The working range and the detection limit of the MAU Test system are 5～300 mg/L and 5 mg/L.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Don't use Test Cartridge if its lot # does not match with ID Chip # that is inserted onto the equipment.
5. The Finecare™ Microalbumin Rapid Test kit is only operational in the Finecare™ FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens.
9. Urine specimens, used Test Cartridges, pipette tips and detector buffer vials should be handed and disposable in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

MATERIAL

Material Provided

Test Cartridge	25
Test Cartridge ID Chip	1
Leaflet with instructions for use	

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set (100 µL size)
3. Specimen Collection Containers
4. Timer

STORAGE AND STABILITY

1. Store Finecare™ Microalbumin Rapid Test Cartridge at 4～30℃, shelf life is up to 24 months.
2. Test Cartridge should be used within 1 hour after opening the pack.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with only urine.

For Urine:
1. Use the fresh specimens. If the specimens cannot be test at once. They may be stored at 2℃～8℃ for up to 48 hours. For long-term storage, specimens should be kept below -20℃.

TEST PROCEDURE

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature.
Step1:Preparation
Check/insert ID Chip into the equipment.
Step2: Loading
Draw 75µL of urine with a transfer pipette and load it to the sample well of the Test Cartridge.
Step3:Testing
1. Finecare™ FIA meter:
Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click "Test". 3 minutes later, the result will show in the display and print out when click "Print".
Quick test: Put the Test Cartridge on the operation platform. 3 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click "Test". The result will show in the display and print out when click "Print".
2. Finecare™ multi-channel FIA meter:
Insert the Test Cartridge onto the Test Cartridge Holder. 3 minutes later, the result will show in the display and print out when click "Print".

Please refer to the Operation in user manual of Finecare™ FIA Meter for details.

QUALITY CONTROL

Each Finecare™ Microalbumin Rapid Test Cartridge contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the Test Cartridge was inserted and read properly by Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human urine specimen only.
2. The results of Finecare™ Microalbumin Rapid Test should be evaluated with all clinical and laboratory data available. If MAU test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results may come from cross-reactions with some similar antibodies in urine; and similar epitopes from non-specific components in urine capturing fluorescent labeled antibodies.
4. The false negative results may from some unknown substance blocking epitope adhering antibodies, unstable or degenerated MAU that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
5. Other factors may interfere with Finecare™ Microalbumin Rapid Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in urine specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

Test cartridges from same batch were tested with MAU control of 20 mg/L, 50

mg/L and 200 mg/L mean and Bias% were calculated, Bias% was within 15%.

Assay Range and Detection Limit

- **Assay Range:** 5~300 mg/L
- **Detection Limit:** 5 mg/L

Linearity

A serial concentration of MAU controls at 10 mg/L, 20 mg/L, 50 mg/L, 100 mg/L and 200 mg/L were tested, the Correlation Coefficient (R) is ≥ 0.99

Precision

Intra-Run
Within-run precision has been determined by using 10 replicates from same batch to test with 50 mg/L MAU control. C.V. is ≤ 15%.
Inter-Run
Between-run precision has been determined by using 3 replicates from random 3 continuous batches to test with 50 mg/L MAU control C.V. is ≤ 15%.

BIBLIOGRAPHY OF SUGGESTED READING

1. Rowe DJ, Dawnay A, Watts GF. Microalbuminuria in diabetes mellitus: review and recommendations for the measurement of albumin in urine. Ann Clin Biochem. 1990 Jul; 27:297-312.
2. Doumas BT, Peters T Jr. Serum and urine albumin: a progress report on their measurement and clinical significance. Clin Chim Acta.1997 Feb 3;258(1):3-20.
3. 1993. London: Science Press
4. Waugh J, Kilby M, Lambert P, et al. Validation of the DCA 2000 microalbumin: creatinine ratio urinanalyzer for its use in pregnancy and preeclampsia. Hypertens Pregnancy. 2003; 22(1): 77-92.
5. Mogensen CE, Christensen CK. Predicting diabetic nephropathy in insulin-dependent patients. N Engl J Med. 1984 Jul 12;311(2):89-93.
6. Viberti GC, Hill RD, Jarrett RJ, et al. Microalbuminuria as a predictor of clinical nephropathy in insulin-dependent diabetes mellitus. Lancet. 1982 Jun 26; 1(8287):1430-2.
7. Mathiesen ER, Ronn B, Jensen T, Relationship between blood pressure and urinary albumin excretion in development of microalbuminuria. Diabetes. 1990 Feb; 39(2):245-9.
8. Brooks DE, Devine DV, Harris PC, et al. RAMP(™): A Rapid, Quantitative Whole Blood Immunochromatographic Platform for Point-of-Care Testing. Clin Chem. 1999 Sep; 45(9):1676-1678.
9. Oh SW, Moon JD, Park SY, et al. Evaluation of fluorescence hs-CRP immunoassay for point-of-care testing. Clin Chim Acta. 2005 Jun;356(1-2):172-7. Epub 2005 Mar 31.

IVD	In Vitro Diagnostic Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Manufacturing Date		Keep Dry
LOT	Batch Number	EC REP	Authorized Representative		Keep away from Sunlight
	Manufacturer		Do not reuse	REF	Catalog #
4°C 30°C	Store between 4～30℃				

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