Finecare™ One Step MAU Rapid Quantitative Test

Catalog No. W206

INTENDED USE

The Finecare™ One Step MAU Rapid Quantitative Test along with Finecare™ FIA Meters (Model No.: FS-112, FS-113, FS-114, FS-205) is a fluorescence immunoassay for quantitative measurement of urine microalbumin (MAU) in human urine. This test is used as an aid in diagnosis of kidney damage.

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

SUMMARY

Albumin (also known as micro-albuminuria, Micoralbuminuria, MAU) is appearing in the urine microalbumin. Albumin is a protein in the blood of normal, under normal physiological conditions, there will be very little urine microalbumin excretion usually 30 mg/day (or 20 mg/L) within. Human urine albumin reached in 30~300 mg/day or 20~200 mg/L concentration is called albumin, albumin concentrations greater than 300 mg/day or 200 mg/L, called a lot of albumin. Microalbumin (MAU) of non-normal appearance is generally considered renal failure, diabetes and cardiovascular disease complications and other important clinical signs. Therefore, the presence of albumin in the urine levels of detection for kidney disease, diabetes and cardiovascular disease, early diagnosis, early treatment and reduce the risk of important reference value is of clinical significant.

PRINCIPLE

The Finecare™ One Step MAU Rapid Quantitative Test is based on fluorescence immunoassay technology, specifically the competitive immunodetection method. When specimen is added into the sample well of the Test Cartridge, the fluorescence-labeled detector antibody on the nitrocellulose membrane will bind to antigen in specimen and form immune complexes. As the sample mixture migrates on the nitrocellulose membrane of test strip by capillary action, it can't be captured by MAU antigens that have been immobilized on membrane. But the excess unbound fluorescence-labeled detector MAU antibodies are captured. Thus the more MAU in blood, the less unbound fluorescence-labeled antibodies are accumulated on membrane.
Signal intensity of detector MAU antibodies reflect the amount of antigens and Finecare™ FIA Meters show MAU concentrations in urine specimen. The default results unit of Finecare™ One Step MAU Rapid Quantitative Test is displayed as XXX.X mg/L from Finecare™ FIA Meters.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date printed on the package.
4. Do not use Test Cartridge if its Lot No. does not match with Lot No. of ID Chip that is inserted to the Finecare™ FIA Meters.
5. The desiccant is for storage purpose only, is not used in the test procedures.
6. The Finecare™ One Step MAU Rapid Quantitative Test kit is only operational in the Finecare™ FIA Meters. Tests should be applied by well-trained healthcare professionals, and conducted in laboratories, GP offices, clinics, pharmacies, etc.
7. The Test Cartridge should remain in its original sealed pouch until ready to use. Do not use the Test Cartridge if the pouch is punctured or not well sealed. Discard after single use.
8. There is a blue line on the test membrane, it will disappear after sample adding. This indicates that Test Cartridge has been used. Do not reuse the Test Cartridge.
9. Do not use damaged or stained materials provided in the test kit.
10. The test kit and instrument should be used away from vibration and magnetic field. During normal usage, the instrument may introduce minute vibration, which should be regarded normal.
11. The Pipette Tips should be used for one specimen only. Discard after single use.
12. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
13. The urine specimens and used materials, such as Test Cartridges and Pipette Tips, are potentially infectious. Proper safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by biological hazard materials.
14. The Finecare™ One Step MAU Rapid Quantitative Test should not be used as absolute evidence for kidney damage. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
15. The test will be applied on a routine basis and not in emergency situations.
16. If you have any questions or need help, please contact the local distributor to solve problems timely.
17. Notice to the users: Any serious incident that has occurred in relation to the Finecare™ One Step MAU Rapid Quantitative Test shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

MATERIAL

Material Provided

1. 25 individual sealed pouches, each containing:
   - Test Cartridge
   - Desiccant Pouch
2. ID Chip
3. Leaflet with Instructions For Use
4. 25 Pipette Tips (for 100 µL transfer pipette set)

Material Required But Not Provided

Function	Material Name	Note
Test instrument	Finecare™ FIA Meter	Model No.: FS-112
	Finecare™ FIA Meter Plus	Model No.: FS-113
	Finecare™ FIA Meter II Plus SE	Model No.: FS-114
	Finecare™ FIA Meter III Plus	Model No.: FS-205
Quality control	Finecare™ MAU Control	Catalog No. W813
Sampling	Transfer pipette sets	100 µL specification
	Medical gloves	Well-fitting
Timekeeping for specific test step	Timer	/

STORAGE AND STABILITY

1. Store test kit for 24 months at 4 ~ 30°C.
2. Do not remove the Test Cartridge from the pouch until ready to use. The Test Cartridge should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with urine only.
2. Collect the urine sample in the urine container. If the specimens cannot be test at once, they may be stored at 2 °C～8 °C for up to 48 hours. For long-term storage, specimens should be kept below -20 °C.

Note: *Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear specimens can be used.*

TEST PROCEDURE

For complete information and operating procedures, please refer to Finecare™ FIA Meters Operation Manual. Bring all materials to room temperature before use. Tests should be performed at room temperature.

Step 1: Preparation
Ensure that the lot number of Test Cartridge matches the lot number of ID Chip. Insert ID Chip into Finecare™ FIA Meters. Be aware not to touch the insertion tip of the ID chip.

Step 2: Loading
Draw 75 µL urine and load it into the sample well of Test Cartridge.

Step 3: Testing
There are two test modes for Finecare™ FIA Meters, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA Meters for details.
a) For Standard Test Mode:
insert the Test Cartridge into the Test Cartridge holder of Finecare™ FIA Meters right after adding sample to the sample well. Press "Start Test" to start test. For FS-205, press "Test" then input the specimen types, press "Start" then insert the Test Cartridge into the Test Cartridge holder of Finecare™ FIA Meters right after adding sample to the sample well to start test. The test result will be displayed on the screen after 3 minutes.

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b) For Quick Test Mode: Set the timer and count down right after adding urine into the sample well and leave the Test Cartridge at room temperature for 3 minutes. Then immediately insert the Test Cartridge into the holder of Finecare™ FIA Meters. Press “Start Test” to start testing (Apply to FS-112, FS-113, FS-114). The instrument will automatically start to scan the Test Cartridge immediately. Read the results on the display screen of Finecare™ FIA Meters.

Step 4: Printing
If needed, test result can be printed by clicking “Print”.

INTERPRETATION OF RESULTS

The Finecare™ FIA Meters calculates MAU test results automatically and displays the exact concentrations of MAU on the screen as form of XXX.X mg/L.

Normal Reference Value:0 ~ 20 mg/L

Note: *Each laboratory should establish a reference interval that is representative of the population to be evaluated. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.*

Invalid: When the Finecare™ FIA Meters remind that no sample or sample volume is insufficient, it indicates an invalid test (the signal on the scan strip is below the preset minimum signal). Please retest.

QUALITY CONTROL

Finecare™ MAU Control (Catalog No. W813) is recommended for Finecare™ One Step MAU Rapid Quantitative Test and can be used in the following cases:
·When a box of a new lot is opened;
·In case the Finecare™ FIA Meters or Finecare™ One Step MAU Rapid Quantitative Test are not working properly;
·In case the result and the symptoms are not consistent or if there are doubts about their accuracy.

Note: *Please refer to the Instructions For Use of Finecare™ MAU Control for detailed operation.*

TRACEABILITY

Finecare™ One Step MAU Rapid Quantitative Test has been standardized against the internal reference material.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human urine specimen only.
2. This test has been verified for healthcare professionals use. Refer to point 6 of the PRECAUTIONS in this instruction for requirements of training and qualifications required by the users. Note that this test is not used for self-testing.
3. The results of Finecare™ One Step MAU Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If the test results do not agree with the clinical evaluation, additional tests should be performed.
4. The false positive results include non-specific adhesion of some components in specimen that have similar epitopes to bind captured and detector antibodies.
5. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of MAU, resulting in degradation with time or temperature, such that they become no longer recognizable by antibodies.
6. Other factors may interfere with Finecare™ One Step MAU Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in urine specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparative study was tested for 100 clinical samples using Finecare™ One Step MAU Rapid Quantitative Test and the Orion MAU assay. The Correlation Coefficient (r) was 0.987.

Measuring Range and Detection Capability

- **Measuring Range**: 5.0 ~ 300.0 mg/L
- **Limit of Detection (LoD)**: 2.0 mg/L

Precision

Intra-Lot Precision:
Within-lot precision has been determined by using MAU precision controls with one lot of test, the CV was ≤ 15%.

Inter-Lot Precision:
Between-lot precision has been determined by using MAU precision controls with three lots of tests, the CV was ≤ 15%.

Linearity

A serial concentration of MAU linear controls were each tested for three times, the Correlation Coefficient (r) was ≥ 0.9900.

Analytical Specificity

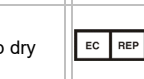
The following substances did not interfere with the test results at the indicated concentrations:

Substance	Concentration
bilirubin	≤ 25 mg/dL
hemoglobin	≤ 1g/dL
creatinine	≤ 4 mg/mL

BIBLIOGRAPHY OF SUGGESTED READING

1. Rowe D J, Dawnay A, Watts G F. Microalbuminuria in diabetes mellitus: review and recommendations for the measurement of albumin in urine[J]. Ann Clin Biochem, 1990, 27 (Pt 4):297-312.
2. Doumas B T, Peters T Jr. Serum and urine albumin: a progress report on their measurement and clinical significance[J]. Clin Chim Acta, 1997, 258(1):3-20.
3. Waugh J, Kilby M, Lambert P, et al. Validation of the DCA 2000 microalbumin:creatinine ratio urinanalyzer for its use in pregnancy and preeclampsia[J]. Hypertens Pregnancy, 2003, 22 (1):77-92.
4. Mogensen C E, Christensen C K. Predicting diabetic nephropathy in insulin-dependent patients[J]. N Engl J Med, 1984, 311 (2):89-93.
5. Viberti G C, Hill R D, Jarrett R J, et al. Microalbuminuria as a predictor of clinical nephropathy in insulin-dependent diabetes mellitus[J]. Lancet. 1982, 1 (8287):1430-2.
6. Mathiesen E R, Ronn B, Jensen T, et al. Relationship between blood pressure and urinary albumin excretion in development of microalbuminuria [J]. Diabetes, 1990, 39 (2):245-9.
7. Brooks D E, Devine D V, Harris P C, et al. RAMP (TM): A Rapid, Quantitative Whole Blood Immunochromatographic Platform for Point-of-Care Testing[J]. Clin Chem, 1999, 45 (9):1676-1678.
8. Oh S W, Moon J D, Park S Y, et al. Evaluation of fluorescence hs-CRP immunoassay for point-of-care testing [J]. Clin Chim Acta, 2005, 356(1-2):172-177.

INDEX OF SYMBOLS

	See Instructions for Use		Tests per kit		Manufacturing date
	For *in vitro* diagnostic use only		Expiration date		Do not reuse
	Store between 4 ~ 30 °C		Batch number		Catalog number
	Keep away from sunlight		Keep dry		Authorized Representative
	Manufacturer				

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R.China
Tel: (+86) 400-830-8768
E-mail: Finecare@wondfo.com.cn
Website: en.wondfo.com.cn

Qarad BV
Cipalstraat 3
2440 Geel, Belgium

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