CE

MAU Rapid Test Kit

Instructions for use

IVD For in vitro diagnostic use only.

REF A02040002

Σ 25 Tests

【Product Name】

MAU Rapid Test Kit

【Intended Use】

The MAU Rapid Test Kit along with Anbio FIA Meter is a fluorescence immunoassay for quantitative measurement of Microalbumin (MAU) in human urine. This test is mainly used to auxiliary diagnosis of kidney damage.

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 (eg: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.

【Test Principle】

The Anbio MAU Rapid Test Kit is based on fluorescence immunoassay technology. The Anbio MAU Rapid Test Kit uses a competitive immuno detection method. When sample is added to the sample well of the Test Device, the fluorescence-labeled detector MAU antibody binds to MAU antigen in urine specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the antigen-antibody complexes can't be captured to MAU antigen that has been immobilized on test strip, but the rest of fluorescence-labeled antibody is captured. Thus the more antigen in urine specimen, the less fluorescence-labeled antibody is accumulated on test strip. Signal intensity of detector antibody reflects the amount of MAU captured and Anbio FIA Meter shows MAU concentration in urine specimen.

【Main Components】

The following components are included in the MAU Rapid Test Kit:

Supplied Materials:

Component	Main Ingredients
Test Cartridge	1) T line:MAU antigen (coated) 2) C line: Goat anti-rabbit IgG polyclonal antibody 3) Binding pad: Fluorescent microsphere-labeled mouse anti-MAU monoclonal antibody (labeled) and fluorescent microsphere-labeled rabbit IgG polyclonal antibody
IC Card	/

Materials Required but not Provided:

1. Transfer Pipette Set
2. Specimen Collection Containers
3. Timer
4. Anbio FIA Meter (model number: AF-100, AF-100s, AF-1200, AF-100C)

【Storage Conditions and Shelf Life】

Component	Storage- Temperature limitation	Stability
Test Cartridge		The shelf life is up to 24 months. Please refer to use-by date on the label. Test Cartridge should be used within 1 hour after opening the pack.
IC Card		/

【Warnings and 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. Do not use Test Cartridge if its lot # does not match with IC Card # that is inserted onto the equipment.
5. The Anbio MAU Rapid Test Kit is only operational in the Anbio 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 as normal.
8. Use separate clean pipette tips for different specimens.
9. Specimen, used Test Cartridges, pipette tips should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

【Specimen Collection and Preparation】

The test can be performed with human 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 Anbio FIA Meter Operation Manual (attached to Anbio FIA Meter) for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1:Preparation

Check/ Swipe the IC Card information to the equipment.

Step2: Loading

Take 50μL of urine sample with a transfer pipette and load it into the sample well of the Test Cartridge

Step3:Testing

Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click "Timing Test". 15 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.15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click "Quick Test". The result will show in the display and print out when click "Print".

【Limitations of Procedure】

1. This test has been developed for testing human urine specimen.
2. The results of Anbio MAU Rapid Test Kit 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. Incorrect results can be caused by interference from some similar substance in the sample.
4. Other factors may interfere with Anbio MAU Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in urine specimen.

【Quality Control】

Internal procedural controls are included in the test. When testing, the quality control line (C line) will show a certain luminescence intensity, which is an internal procedural control. It confirms that a sufficient volume of samples has been added and that the correct procedure has been performed.

【Interpretation of Results】

The Anbio FIA Meter calculate the test result automatically and displays MAU concentration of the test sample in terms of mg/L.

1. The Reference Value

<20mg/L

Note: Individual reference range is suggested to be established for each laboratory.

【Performance Characteristics】

Limits and Range

Limit of Detection: 5.0 mg/L;
Limit of Quantitation: 5.0 mg/L;
Measuring Range: 5.0~200.0 mg/L.

Precision

Precision was determined with Anbio test kits, samples, and controls according to the CLSI (clinical and Laboratory Standards Institute) protocol (EP05- A3):

(1) 3 batches of test kits, repeated 10 times per batch (n=30).

mg/L	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV	SD	CV	SD	CV	SD	CV
20.21	0.867	4.21%	1.332	6.54%	1.404	7.14%	1.249	6.18%
101.40	6.493	6.53%	5.247	5.06%	6.525	6.45%	6.149	6.06%

(2) 3 laboratories with duplicate testing 5 times a day for 5 days (n = 75).

mg/L	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV	SD	CV	SD	CV
19.97	1.42	7.11%	1.42	7.11%	1.42	7.11%
100.31	7.625	7.60%	7.401	7.38%	7.439	7.42%

Limitations-Interference

Detection of the effects of the following endogenous substances on assay performance. Interfering substances detected in the listed concentration range had no effect on the results.

Compound	Concentration
Bilirubin	350μmol/L
Hemoglobin	2g/L
Creatinine	20mmol/L
Glucose	15mmol/L
Urea	80mmol/L
Urea acid	1mmol/L

Limitations-Cross-Reactivity

The following substances do not interfere with the MAU test results at the indicated concentrations.

Cross material	Concentration (μg/mL)
CEA	500
PSA	500
AFP	500
ALT	500
Troponin I	500
CRP	500
Myoglobin	500

【Bibliography of Suggested Reading】

1.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.
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.

【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
EC REP	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
30℃ 2℃	Temperature limit	LOT	Batch code
	Use-by date		Keep dry
	Keep away from sunlight	REF	Catalog number
	Date of manufacture	Σ	Contains sufficient for <n> tests
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

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