# MAU Rapid Quantitative Test

**Catalog No.: BT2601**

## INTENDED USE

The Biotime MAU Rapid Quantitative Test is intended to quantify the concentration of MAU in human urine on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of renal disease.
-Fluorescent immunoassay
- Renal disease
For in vitro diagnostic use only. For professional use only.

## INTRODUCTION

Microalbuminuria is a term to describe a moderate increase in the level of urine albumin. It occurs when the kidney leaks small amounts of albumin into the urine, in other words, when an abnormally high permeability for albumin in the glomerulus of the kidney occurs. Normally, the kidneys filter albumin, so if albumin is found in the urine, then it is a marker of kidney disease. The term microalbuminuria is now discouraged by Kidney Disease Improving[1-3] .

## PRINCIPLE

This reagent is based on competitive fluorescent lateral flow immunoassay. When the sample and the buffer are mixed and applied into the test cartridge, the albumin in the sample and the anti-albumin monoclonal antibody labeled with fluorescent microsphere form a reaction complex.During lateral flow, the reaction complex and the residual albumin mouse-anti monoclonal antibody labeled with fluorescent microsphere move along with the nitrocellulose membrane to a detection line (T-line: coated with albumin antigen). The residual anti-albumin monoclonal antibody labeled with fluorescent microsphere will be captured by T-line, while the labeled antibody in reaction complex will pass through the T-line. The more albumin in sample the less residual antibody will be capture by T-line to give fluorescent signal. Thus the fluorescent signal on detection line is negatively correlated with the concentration of albumin in sample.
The fluorescent signal from T-line will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of albumin in urine.

## PRECAUTIONS

1. This reagent is used for in vitro diagnosis only. Please do not use expired products.
2. All samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for single time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and strong electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. Oherwise, it may cause damages to the instrument.

## MATERIAL

**Material Provided**
1. Test cartridge 25 tests/kit
2. Detection buffer 25 tubes/kit
3. SD Card 1 piece/kit
4. Instructions for use 1 copy/kit

**Material Required But Not Provided**
1. Biotime FIA Analyzer
2. Transfer Pipette Set and pipette tips (range 5~50μL and 10~100μL)
3. Specimen collection containers
4. Timer

## STORAGE AND STABILITY

1. Store the detection buffer at 2-30℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

## SPECIMEN COLLECTION AND PREPARATION

1. The specimen should be urine.
2. The specimen collection container should be urine cup for urine sample.
3. If the sample can't be detected in time, it can be stored in refrigerator at 2-8℃ for no more than 2 days, or at -20℃ for no more than 3 months. Samples should be recovered to the room temperature before test.

## TEST PROCEDURE

Please refer to the operation manual of Biotime FIA analyzers for details.
The test should be operated at room temperature (~25℃).

**Step 1: Preparation**
Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.
**Step 2: Sampling**
Take 10μL of urine with a transfer pipette and add it into the buffer tube.
**Step 3: Mixing**
Mix well the specimen with buffer by tapping or inverting the tube several times.
**Step 4: Loading**
Take 80μL of sample mixture and load it into the well of the test cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.
**Step 5: Testing**
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 10 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

## REFERENCE INTERVAL

Normal Reference Value:＜20mg/L
Note: Individual reference range is suggested to be established for each laboratory.

## LIMITATIONS OF PROCEDURE

1. The test sample should be human urine.
2. Human anti-mouse antibody (HAMA) may be presented in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies [4-5].
3. Other factors also can induce the false results, including the technology, operational error and other sample factors.

## PERFORMANCE CHARACTERISTICS

**Accuracy**
Test cartridges from same lot were tested with MAU control of three different levels of concentration, mean and Bias% was within ±15%.
**Assay Range and Detection Limit**
**Assay Range:** 2.0~300.0mg/L
**The Lowest Detection Limit:** 2.0mg/L
**Linearity**
A serial concentration of MAU controls at 2.0~300.0mg/L were tested, the Correlation Coefficient (R) is ≥0.9900.
**Precision**
**Intra-lot Precision**
Intra-lot precision was determined by testing of MAU reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15%.
**Inter-lot Precision**
Inter-lot precision was determined by testing of MAU reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ≤ 20%.
**Specificity**

| Specific antigen | Concentration | Test result |
|---|---|---|
| Bence-Jone protein | 10g/L | ＜2.0mg/L |
| B2 microglobulin | 10mg/L | ＜2.0mg/L |
| α1 globulin | 50mg/L | ＜2.0mg/L |
| Acetoacetic acid | 5g/L | ＜2.0mg/L |
| Acetone | 10g/L | ＜2.0mg/L |
| Glucose | 100mol/L | ＜2.0mg/L |
| Bilirubin | 100mg/L | ＜2.0mg/L |
| Urobilinogen | 50mg/L | ＜2.0mg/L |

## SYMBOLS

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| REF | Catalogue number | IVD | In vitro diagnostic medical device |
| LOT | Lot number | | Consult instructions for use |
| | Date of manufacture | | Keep dry |
| | Expiry date | | Keep away from sunlight |

| | | | |
|---|---|---|---|
| | Manufacturer | 30℃ 2℃ | Store at 2-30℃ |
| | Do not re-use | EC REP | European authorized representative |
| CE | CE mark | | |

## BIBLIOGRAPHY OF SUGGESTED READING

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