BIOBASE

# Microalbuminuria (MALB) Test Kit
## (Immunoturbidimetric)

**【NAME】**

Microalbuminuria (MALB) Test Kit (Immunoturbidimetric)

**【INTEND USE】**

The reagent is intended for the in vitro quantitative determination of Microalbuminuria (MALB) in human serum. Applications of MALB measurement is known as one of two contributions 80s Diabetic Studies. mALB determination not only to improve the early diagnosis and prognosis of diabetic nephropathy has important significance, but also for a variety of hypertensive nephropathy and kidney damage caused by toxic substances have important diagnostic value has been measured .mALB early renal damage monitoring and tracking important biochemical indicators.

**【METHODOLOGY】**

Using Goat anti human albumin antibodies and samples of albumin to antigen antibody reaction. After the completion of the reaction, using transmission turbidimetry test absorbance changes reflect the albumin concentrations.

**【STABILITY AND STORAGE】**

Unopened, avoid light preservation in 2 ~ 8 ℃, valid for 12 months;
Opened, avoid light preservation in 2 ~ 8 ℃, valid for 1 month.
Reagent is not allowed frozen.

**【SPECIMEN COLLECTION AND HANDLING】**

It is best to fresh urine or 24 hours urine(with about 5ml/L toluene or 0.02% sodium azide as a preservative). Timely submission to collect specimens, centrifugal supernatant were detected from turbidity. Detection of urine samples can be preserved two weeks in 2 ~ 8 ℃.

**【APPLICABLE INSTRUMENT】**

Fully automatic biochemical analyzer.

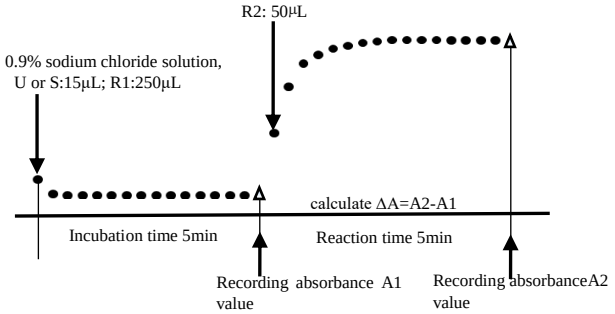
**【TESTING SPECIFICATION】**

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group

| | |
|---|---|
| Temperature | 37° C |
| Cuvette light path | 1.0cm |
| Primary Wavelength | 415 nm |
| Secondary Wavelength | 700nm |
| Assay Type | Two Point End |
| Direction | Increase |
| Sample : Reagent 1: Reagent 2 Ratio | 15:250:50 |
| eg : Sample Vol | 15μL |
| Reagent1 Vol | 250 μL |
| Reagent2 Vol | 50 μL |
| Linearity | 0～350mg/L |
| Testing | Deducting the reagent blank |

**【OPERATION STEPS】**

R1: Reagent 1 R2: Reagent 2 S: Calibrator U: Sample




**【CALCULATION】**

ΔA = ΔAbs = [（A2- A1）Calibrator or Sample] － [（A2- A1）Blank]
According to the calibration requirements, with 5 different levels of calibration solution, together with 9g/L Sodium Chloride Solution as blank. The measured automatically by the instrument, the corresponding amount of calibrator through mathematical models such as Logit/Log right, quasi synthetic calibration curve. Using it to calibrate instrument ,within the scope of the reportable results, the instrument directly report reliable test results.

**【REFERENCE RANGE】**

Urine: ＜30mg/L
By clinical trials, choose no less than 100 newborn or adults blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.

**【THE LIMITATION OF TEST RESULTS】**

Microalbuminuria (MALB) testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

**【THE INTERPRETATION OF TEST RESULTS】**

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result； When one sample deviates from the expected value too far, need to be tested again.

**【PERFORMANCE INDEX】**

1. Reagent blank absorbance≤0.3, (415nm, lcm optical path).
2. Precision: repeatability CV≤5%; batch variations R≤8%.
3. Accuracy: relative deviation ≤10%.
4. Linearity range: 0～350mg/L, r≥0.990.
5. Stability: All package reagent, unopened and avoid light, preservation in 2~8 ℃, stable 12 months, once opened, avoid light, preservation in 2~8 ℃,stable 30 days.

**【ATTENTION】**

1.Reagent contains sodium azide (toxic) preservatives, avoid contact with skin and mucous membrane. If necessary preventive measures should be taken use of reagents, reagent contact with skin and mucous membrane, please rinse with water, please go to a doctor if necessary.
2.The maximum linearity is 350mg/L.If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.
3.Liquid waste disposal: Suggest follow local regulations.
4.Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

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