Bioway Chemistry Reagent Series
Microalbuminuria Test Kit

Detection of Microalbuminuria in Human Serum on Chemistry Analyzers

Cat. No. R045k11 ***MALB Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

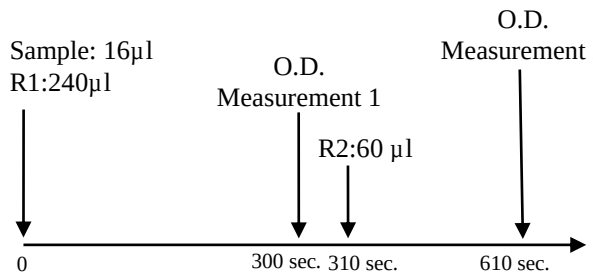

Table 1: Instrument Parameters*

Calibration method	6 point non-linear	Slope of reaction	increase
Wavelength	Pr: 340nm Se: 700nm	Sample volume	16 µl
Test method	2 point end	R1 volume	240 µl
Reaction temperature	37℃	R2 volume	60 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Microalbuminuria Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of Microalbuminuria in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Microalbuminuria (MALB; urinary albumin excretion of 30-300mg /24hrs) is used as the first marker of having diabetic nephropathy, which is a common cause of renal glomerular damage. The course of disease may take several years to develop from microalbuminuria to macroalbuminuria (urinary albumin >300mg /24hrs) and then transform to kidney failure. The testing result of Microalbuminuria has been seen as a standard detection of diabetic complications.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the MALB level in human serum or plasma. During the test, MALB in the sample binds with the specific MALB antibody which is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of MALB in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Phosphate buffer solution	10mmol/L
	NaCl	150mmol/L
	PEG	4%
R2	Latex particles coated with sheep anti-human MALB	≧100ml/L
	NaCl	150mmol/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. MALB calibrator set and control set (available for purchase)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect urine samples and store them at 2- 4° C for up to 2 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 6 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 16 µl of sample and 240 µl of R1; mix well and incubate at 37°C for 300 seconds.
2. Take optical density measurement OD 1.
3. Add 60 µl of R2, mix well and incubate at 37°C for 5 minutes.
4. Take optical density measurement OD 2 at 610 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The MALB value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

0~25 mg/L or 0~30 mg/day

It is recommended for each laboratory to establish its own expected values. MALB levels can be influenced by hereditary factors and vary with geographical location and ethnic population.

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QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 300 mg/L ($R^2 \geq 0.990$)

Precision: Within Run: CV≤5%;
Run-to-Run: CV≤10%

Reagent Blank Absorbance: at 340nm wavelength and 10 mm optical diameter, O.D. ≤ 0.5.

REFERENCES

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3. CLSI/NCCLS, Interference Test in Clinical Chemistry, EP7-P, 1986.
4. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, 5th Edition 2000.
5. American Diabetes Association, Diabetic Nephropathy, Diabetes Care 25:(Suppl. 1):S85-S89.
6. CLSI/NCCLS Evaluation Protocol EP5-T2, 1992.

Not Intended for Sale in the United States.

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