TURBICHEM MICROALBUMIN UREA (mALB)

(Turbilatex Method)

KIT NAME	KIT SIZE	CAT. NO
Turbichem - mALB	1 x 50 ml	TMAL000050M

GENUINE BIOSYSTEM

INTRODUCTION

MicroAlbuminurea is intended for Invitro quantitative determination of MicroAlbuminurea in human urine. Microalbuminurea (mALB), urinary albumin excretion of 30-300 mg/24 hrs is used as the first marker of having diabetic nephropathy, which is common cause of renal glomerular damage.The course of disease may take several years to develop from microalbuminurea to macroalbuminurea (urinary albumin > 300 mg/24 hrs) andthen transform to kidney failure. The testing result of Macroalbuminurea has been seen as a standard detection of diabetic complications.

METHOD PRINCIPLE

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.

KIT CONTENTS

R1 - mALB Buffer	1 x 40 ml
R2 - mALB Latex	1 x 10 ml
R3 - mALB Calibrator	1 vial

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 10 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate 4 parts of R1-mALB and 2 parts of R2-mALB reagents or can make working reagents of 4 parts of R1 and 1 Part of R2.

CONCENTRATIONS IN THE TEST

mALB Reagent(R1) : Phosphate buffer 100 mM, NaCl 150mmol/L, PEG 4%

mALB Reagent(R2) : Latex particles with Goat anti-human mAlb antibody ≥ 100 ml/L, NaCl 150 mmol/L

WARNINGS AND NOTES

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 disposin

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 600 nm;
- Thermostat at 37ºC;
- General laboratory equipment;

SPECIMEN

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.

PLOTTING OF MULTIPOINT CURVE

The Turbichem mALB is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial Dilution Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE

These reagents may be used both for manual assay and in several automatic analyzers. Applications for them are available on request.

Wavelength 600 nm
Temperature 37°C
Cuvette 1 cm

Reagent	Calibrator (C)	Test (T)
Working Reagent	1000 µl	1000 µl
Bring up the temperature of determination. Then add,		
Calibrator	10 µl	-
Sample - Urine	-	10 µl

Mix well, after about 10 sec. (37°C) read the absorbance A1 of the test (T) and calibrator (C) against air or water.After exactly 120 secs. (for all temperature) read the absorbance A2 of the test (T) and calibrator (C). Calculate ΔA/min. (A2 - A1) for the test and calibrator.

CALCULATION

$$\text{Concentration in mg/L} = \frac{\text{Abs.Test}}{\text{Abs.Calibrator}} \times \text{Calibrator Concentration}$$

REFERENCE VALUES

upto 25 md/L or 30 mg/day

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

PERFORMANCE CHARACTERISTICS

- **Sensitivity / Limit of Quantitation:** 5 to 300 mg/L
- **Linearity:** up to 300 mg/L. Samples that give higher concentration should be diluted in saline Nacl 0.9% (1+4) and the final results have to be multiplied by 5

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Wild D(Ed.)., The Immunology Handbook 1994.
2. Tietz, N.W., Textbook of Clinical Chemistry Second Edition, Burtis E.A. and Ashwood, E.R. eds. W.B. Saunders Company, 1994
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.

SYSTEM PARAMETERS

Method	Fixed Time (2-Point)
Wavelength	600 nm
Zero Setting	Distilled Water
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	----
Delay Time	10 secs
Read Time	120 secs
No. of Reading	2
Interval Time	----
Sample Volume	0.01 ml (10 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	Refer Calibrator vial
Units	mg/L
Factor	----
Reaction Slope	Increasing
Linearity	300 mg/L

IVD CE

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