

Nephchem MicroAlbuminurea (Nephelometry method)



KIT NAME	KIT SIZE	CAT. NO
Nephchem - mALB	25 Tests	NMAL01025T

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) and then 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 urine by GB NEPHCHEM (Nephelometry method) 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 GB NEPHCHEM, 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

Reagent kit - box	
R1 - mALB buffer	1x 6.5 ml
R2 - mALB antibody	1 x 1.6 ml
Test Card	1 no
Accessories kit box	
Cuvettes	25 nos
Big tips	25 nos
small tips	50 nos

Working reagent preparation and stability

Reagent R1 and R2 are ready to use liquid stable at 2-8°C till the expiry date printed on the package.

Concentrations in the test

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

Warnings and notes

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
- 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

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.

GBPL/NCMLAB/02 9.19

PROCEDURE

It is very important for antigen-antibody reaction needs the pre-warm of both reagents and samples. Along with GB NEPHCHEM equipment, dry bath incubator will be provided, in that dedicated R1, R2 and sample positions were available. Please use the respective positions for desired pre-warm temperature of 37°C

- Step 1:** Insert Test Card to Card reader slot and display will show promptly add R1 + S (sample)
- Step 2:** Pipette out 240 µl of R1 into dedicated cuvette and add 5 µl of sample (urine) and place the cuvette in the reading chamber
- Step 3:** After the incubation, the display will show promptly add R2
- Step 4:** Pipette out 60 µl of R2 using sensor pipette connected with machine into the cuvette
- Step 5:** Once the reaction time got over, the result will show in the display and (if external printer connected then it will get print out)

REFERENCE VALUES

0 to 25 mg/L or 0 to 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 kit can be cross checked with commercially available third party Immunological quality control or use recommended GB Immunology Quality control.

PERFORMANCE CHARACTERISTICS

- Linearity:** 0.0 to 300 mg/L
- Precision:** within Run CV ≤ 5 %

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

- Wild D(Ed.), The Immunology Handbook 1994.
- Tietz, N.W., Textbook of Clinical Chemistry Second Edition, Burtis E.A. and Ashwood, E.R. eds. W.B. Saunders Company, 1994
- CLSI/NCCLS, Interference Test in Clinical Chemistry, EP7-P, 1986.
- Young, D.S., Effects of Drugs on Clinical Laboratory Tests, AACCPress, 5th Edition 2000.
- American Diabetes Association, Diabetic Nephropathy, Diabetes Care 25:(Suppl. 1):S85-S89.



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