NEPHSTAR®
Urine Micro Albumin（mALB）Kit

Catalog No. **DK061**

1. Intended Use
This product is used on NEPHSTAR® protein analysis system for quantitative determination of human Micro Albumin (mALB) in urine as an aid in diagnosis of abnormal mALB metabolism.

2. Summary
Microalbuminuria is defined as a condition characterized by urinary albumin excretion above 19 mg/l, normal urinary excretion for adults, in the absence of clinically detectable nephropathy. A number of investigators using immunoassays for albumin have established a range of 20 or 30 mg/l to 200 mg/l as diagnostic for microalbuminuria. Individuals with an established diagnosis of diabetes or essential hypertension represent the most important groups to be followed for elevations in albumin excretion rates. Microalbuminuria may have causes other than incipient diabetic nephropathy. Subclinical elevations in urinary albumin excretion rates may be caused by urinary tract infections, congestive heart disease, hypertension, exercise, non-diabetic renal disease and poor diabetic control.

3. Test Principle
Immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antiserum, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antiserum is in excess. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA061	mALB Antiserum	1×2.0 ml
DB061	mALB Reaction buffer	1×25.0 mL
DC061	mALB Magnetic card	1
DM061	mALB Control	1×0.5mL
	Manual	1

5. Materials required but not supplied
5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Electronic pipette（YB201）
5.4 Pipette 5-50uL (YB301)
5.5 Pipette 100-1000uL(YB302)
5.6 Equipment for collection of Samples

6. Storage and Stability
The unopened reagent kit should be stored under 2-8℃ and can be used until the expiry date labeled on the kit. Do not freeze! The buffer should be equilibrated to room temperature before use. Once opened store the antisera and control at 2-8℃ and the buffer at room temperature(**18-25℃) and be sure to screw on the cap tightly.** Under these conditions the buffer is stable for 3 months, antisera and control for 1 month.

7. Sample Collection And Preparation
Use freshly collected urine samples: these should be centrifuged prior to analysis to remove particulate matter. Sample dilutions should be freshly prepared on the day of assay. Testing of the following types of urine sample may result in misleading values:

- Microbially contaminated or turbid samples may not be suitable for nephelometric measurements and should not be used unless they have been centrifuged or prepared in some appropriate manner. An alternative assay method, e.g. radial immunodiffusion, is recommended if background turbidity cannot be removed.

8. Test Procedure
Summary: Reagent volumes added to the cuvette

Reagent	Volume
Sample（undiluted）	20ul
mALB Reaction Buffer	400ul
mALB Antiserum	40ul

8.1 Switch NEPHSTAR on.
8.2 Enter chemistry number. Enter chemistry number of mALB kit (mALB=61). If mALB assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.
8.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is identical to that printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.
8.4 Dilute samples or controls using NEPHSTAR Sample Diluent supplied in NEPHSTAR Accessory pack (Cat. No: DK110)if necessary. The default dilution scheme for mALB assay is 1/1 (undiluted) .
8.5 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 20uL of undiluted sample carefully to the bottom of the cuvette.
8.6 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.
8.7 Enter sample dilution: 1. Accept the default sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.
8.8 Place cuvette in chamber. Place the cuvette containing a stirring bar and 20uL of sample in the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.
8.9 Add reagent. Add 400 uL mALB reaction buffer and 40 uL mALB antiserum simultaneously into the cuvette using the electronic pipette （Cat. No.: YB201）supplied with NEPHSTAR. NEPHSTAR will sense the addition of reagents. With movement of the stirring bar, the assay begins after blanking and result will be printed automatically at the end of the assay.
8.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. Sample ID will increase sequentially. For alteration of the ID press BACK twice and tip in the right number.
8.11 If NEPHSTAR indicates result is higher than measurement range, reassay the sample at a higher dilution of e.g. 1/11 （200μL sample diluent + 20μL sample）. Accordingly the sample dilution should be altered to 1/11 （press BACK and then the number keys to alter the sample dilution）。
8.12 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accord with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.

10. Sensitivity and measuring range

The sensitivity limit is 10.0 mg/L and the upper limit is 220.0 mg/L when the default dilution scheme is applied. The sensitivity limit is 110 mg/L when samples are diluted at 1/11.

11. Antigen Excess

Sample concentration of less than 1900 mg/L will not result in antigen excess, when the results will be misleadingly low. On suspicion of antigen excess please reassay the sample at dilution of 1/40 (780uL sample diluent + 20uL undiluted sample).

12. Reference Range

12.1 According to IFCC, normal range of mALB concentration in random urine of healthy adult is: 25.0 mg/L. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of mALB. The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

13. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

mALB（mg/L）	CV （%）
19	2.63
188	2.29

14. Correlation Study

A correlation study is performed on 20 clinical serum samples using this kit on NEPHSTAR and Behring mALB reagent on BNII. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=1.12X-2.35

(Y= NEPHSTAR® mALB, X=BNII mALB)

Correlation coefficient r=0.978

15. Caution And Warning

15.1 The reagents are only for in vitro diagnostic use。

15.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.

15.3 All sera have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

15.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.

15.5 All components of kit are NEPHSTAR® specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

16. Referrences

1. Müller-Eberhard, H.H., Ann. Rev. Biochem. 44, 697 (1975)
2. Zilva, JF & Pannall, PR (1984). Clinical Chemistry in diagnosis and treatment. Publ. Lloyd-Luke (Medical Books) Ltd, London, 341- 343.

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