MICROALBUMIN

(Turbilatex Method)

Intended Use

Microalbumin is a reagent kit used for the determination of albumin (urine) concentration in urine. The reagents are for *in-vitro* diagnostic use.

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.

Reagent provided

1. Reagent 1 – Buffer
2. Reagent 2 – Latex
3. Reagent 3 – Calibrator

Working Reagent Preparation

Prepare working reagent by mixing **Reagent R1** and **Reagent R2** in the ratio 4:1 as per the number of tests required.

Reagent storage and stability

Store all the reagents at 2-8°C.

Specimen collection and preservation

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.

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 Dilution	Neat	1/2	1/4	1/8	1/16

System Parameters

Method	**Fixed Time (2-Point)**
Wavelength	**630 nm**
Zero Setting	**Distilled Water**
Temperature Setting	**37°C**
Incubation Temperature	**37°C**
Incubation Time	**-**
Delay Time	**10 sec**
Read Time	**120 sec**
No. of Reading	**2**
Reagent 1 Volume	**800 µl**
Reagent 2 Volume	**200 µl**
Sample Volume	**10 µl**
Standard Concentration	**Refer Calibrator Vial**
Units	**mg/L**
Factor	**-**
Reaction Slope	**Increasing**
Linearity	**300 mg/L**

Assay guidelines for Analyzers
These reagents may be used both for manual assay and in several automatic analyzers.

Reagent	Calibrator (C)	Test (T)
R1 Buffer	800 µl	800 µl
R2 Antibody	200 µl	200 µl
Bring up the temperature of determination. Then add		
Calibrator	10 µl	-
Sample	-	10 µl

Mix well, after about 10 sec (37°C) read the absorbance A1 of the test (T) and calibrator (C) against**Distilled** water. After exactly 120 sec (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

$$\text{mALB Conc. (mg/L)} = \frac{Abs.Test}{Abs\ Cal} XConc.Cal$$

Normal Range
Up to 25 md/L or 30 mg/day
It is recommended that each laboratory establish its own normal range.

Limitation

1. For in vitro diagnostic use only, Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators and controls must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Exercise the normal precautions required for handling laboratory reagents.
4. Reagents with different lot numbers should not be interchanged or mixed.

Quality Control
To ensure adequate quality control, it is recommended that each batch should include a commercially available control material with established values determined by this method. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, and cleanliness of glassware and accuracy of pipetting.

References

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4. Weissman, N., Pileggi, V.J., in Clinical Chemistry: Principles and Technics,
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7. Henry, J.B., Clinical Diagnosis and Management by Laboratory Methods,
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Symbols

IVD In Vitro Diagnostics. Caution. Keep away from sun light. Date of Manufacture.
LOT Batch No. Read Instructions. Fragile. Product Expiry Date.
CONT Content. Storage Temperature. Keep Dry. Manufactured By.
REF Catalogue No.

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