

AGD

TurbiPak MICROALBUMIN(mALB)

(Turbilatex-Method)



Code	AGD-MAL25	AGD-MAL50
Pack Size	R1-1 x 20mL R2-1 x 5mL Calibrator - 1 X 1mL	R1-2 x 20mL R2-2 x 5mL Calibrator - 1 X 1mL

INTENDED USE

This Kit is intended for Invitro quantitative determination of Microalbumin in human urine.

CLINICAL SIGNIFICANCE

Microalbumin Kit (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 Microalbumin to macroalbumin (urinary albumin >300 mg/24 hrs) and then transform to kidney failure. The testing result of microalbumin has been seen as a standard detection of diabetic complications.

PRINCIPLE

The Kit utilizes latex-enhanced immunoturbidimetry to measure the mALB level in urine. 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 COMPOSITION

Reagent 1

Phosphate Buffer	100mm
NaCl	150mmol/L
PEG	4%

Reagent 2

Latex particles with Goat anti-human mALB antibody	4g/dL
NaCl	150mmol/L

WORKING REAGENT

Mix 4 parts of mALB R1 and 1 Part of mALB R2.

STORAGE AND STABILITY

The reagent is stable till the expiry date stated on the label when stored at 2-8°C. Protect from light and avoid contamination.

SAMPLE MATERIAL

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. Urine should be centrifuged before testing.

PARAMETERS

Reaction Type	Fixed Point
Wavelength	630nm (600 - 650nm)
Light Path	1cm
Reaction Temperature	37°C
Blank/Zero Setting	Distilled Water
Reagent Volume	1000µL (working reagent)
Sample Volume	10µL
Delay Time	10 secs
Read Time	120secs
Linearity	300mg/L
Calibrator Concentration	Refer Calibrator vial

PROCEDURE OF MULTIPOINT CURVE

Microalbumin is based on Non-Linear Reactions, hence it is strongly recommended to run Spline mode to plot the Multi-point curve to have better accuracy and precision result.

Serial Dilution Step

Dilution Table	Tube 1	Tube 2	Tube 3	Tube 4	Tube 5
Calibrator Volume	100µL	50µL from 1 st Tube	50µL from 2 nd Tube	50µL from 3 rd Tube	50µL from 4 th Tube
Normal Saline	-	50µL	50µL	50µL	50µL
Ratio of dilution	Neat	1/2	1/4	1/8	1/16

PROCEDURE

Wavelength : 630nm (600 - 650nm)

Cuvette : 1cm light

path Temperature: 37°C

Measure against distilled water blank.

	Calibrator	Test
Working Reagent	1000µL	1000µL
Calibrator	10µL	-----
Sample	-----	10µL

Mix and aspirate immediately.

CALCULATION

$$\text{Microalbumin (mg/L)} = \frac{A_{\text{sample}}}{A_{\text{Calibrator}}} \times \text{Conc. of Calibrator (mg/L)}$$

LINEARITY

The reagent is linear up to 300 mg/L.

If the sample give higher Concentration should be diluted in saline Nacl 0.9% (1+4) 1 part of sample & 4 part of saline & then multiply with dilution factor by 5

NORMAL REFERENCE RANGE

Upto 25 mg/L or 30mg/day

It is recommended that each laboratory should assign its own normal range.

QUALITY CONTROL

To ensure adequate quality control, it is recommended that the laboratory should use a normal and abnormal commercial reference control serum. The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Storage conditions as mentioned on the kit to be adhered.
- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Before the assay bring all the reagents to room temperature.
- Avoid contamination of all the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly observed as any change to it affects the result.
- In case reagent comes in contact with eyes, immediately rinse with plenty of water and seek medical advice.

REFERENCES

- 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.



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