PATHOZYME DIAGNOSTICS

MICROALBUMIN

(TURBIDIMETRY METHOD)

CAT NO.: MAL

Reagent kit for quantitative estimation of Microalbumin in Urine.

DIAGNOSTIC SIGNIFICANCE:

Microalbuminuria is an increased urinary albumin excretion (UAE) in the range of 20 to 200 µg/min (or 30-300 mg/24h) as a consequence of changes in glomerular permeability. Increased UAE precedes and is highly predictive of diabetic nephropathy, end-stage renal disease, and proliferative retinopathy in type 1 diabetes. In patients with type 2 diabetes, increased UAE is an independence predictor of progressive renal disease, atherosclerotic disease, and cardiovascular mortality. In fact, microalbuminuria may show to be a risk factor of cardiovascular disease among otherwise apparently healthy people.

PRINCIPLE:

Latex particles coated with specific antibodies anti-human albumin are agglutinated when they react with samples that contain albumin. The latex particles agglutination is proportional to the concentration of the albumin in the sample and can be measured by turbidimetry.

SPECIMEN COLLECTION:

Fresh morning urine. It is recommended to adjust the pH at 7.0 with NaOH/HCl 1 mol/L. Stable for 7 days at 2-8ºC when Sodium Azide 1 g/L is added to prevent contamination. Urine should be centrifuged before testing.

KIT PRESENTATION:

Pack Size	1 X 25 ml	1 X 50 ml
R1 - Microalbumin (Buffer Reagent)	1 X 20 ml	1 X 40 ml
R2 - Microalbumin (Latex Reagent)	1 X 05 ml	1 X 10 ml
Microalbumin Calibrator	1 Vial	1 Vial

WORKING REAGENT PREPARATION:

R1 – Microalbumin (Buffer Reagent), R2 – Microalbumin (Latex Reagent) and Calibrator are Ready To Use.

REAGENT STORAGE AND STABILITY:

All reagents are stable at 2-8ºC until the expiry date stated on the label.

MULTI POINT CALIBRATION: Prepare the following calibrators. After that use these diluted calibrators for calibration curve.

Calibrator F: Calibrator As is (Calib. conc as it is)
Calibrator E: 100µl calib+100 µl saline (Calib. Conc /2)
Calibrator D: 100 µl E+100 µl Saline (Calib. Conc /4)
Calibrator C: 100 µl D+100 µl saline (Calib. Conc /8)
Calibrator B: 100 µl C+100 µl saline (Calib. Conc /16)
Calibrator A: Saline (Conc. Zero)

NOTE: At time of calibration (Multi Point) keep the sequence of calibrators as A, B, C, D, E and F.

ASSAY PARAMETERS:

Reaction	: Fix Time	Sample Volume	: 10 µl
Wavelength	: 546 nm	R1 + R2 Volume	: 800 µl + 200 µl
Flow Cell Temp.	: 37ºC	Calibrator Conc.	: As On Vial
Initial Delay	: 5 Sec	Reaction Slope	: Increasing
Interval Time	: 120 Sec	Zero Setting	: Dist. Water
Read Time	: 120 Sec	Linearity	: 160 mg/L
No. of Reading	: 01	Unit	: mg/L

PROCEDURE:

Pipette into TT	Calibrator	Test
R1 - Microalbumin (Buffer Reagent)	800 µl	800 µl
Microalbumin Calibrator	10 µl	--
Sample (Test)	--	10 µl
R2 - Microalbumin (Latex Reagent)	200 µl	200 µl

Mix & aspirate immediately and read difference in absorbance between 5 seconds (AT_1) and 125 seconds (AT_2) for Calibrator and Test.

CALCULATION:

$$\text{Microalbumin (mg/L)} = \frac{\Delta\text{Abs of Test X Calibrator Conc.}}{\Delta\text{Abs of Calibrator}}$$

Where $\Delta Abs = (AT_2) - (AT_1)$

NORMAL VALUES:

Method	Microalbumin in 24 hr urine specimen	Microalbumin in 1st morning urine	Microalbumin to Creatinine Ratio
Normal Range	<30 mg/24 hrs	< 20 mg/L	< 30 mg/g for women < 20 mg/g for men
Microalbuminuria	30 –300 mg/24 hrs	20 – 200 mg/L	30 – 300 mg/g for women 20 – 200 mg/g for men
Macroalbuminuria	>300mg/24 hrs	>200 mg/L	>300 mg/g for women >200 mg/g for men

Each laboratory should establish its own reference range

LINEARITY:

This method is linear up to **160 mg/L**. For values above 160 mg/L, dilute the sample suitably with 0.9 % saline, and repeat the assay. Apply correction due to dilution to arrive at a final result.

Detection limit: Values less than 2 mg/L give non reproducible results.
Analytical sensitivity: 3.8 mA mg/L.
Prozone effect: Up to 1000 mg/L.

INTERFERENCES:

Bilirubin (10 mg/dL), Hemoglobin (12 g/L), Urea (100 mg/L) and Creatinine (300 mg/L), do not interfere. Other substances may interfere.

NOTE:

1. Do not re-use plastic cuvettes, as they may produce erroneous values. Use a new cuvette for each microalbumin assay.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES:

1. Feldt-Rasmussen B et al. J Diab Comp 8 :137 (1994). (1999).
2. Tietz Textbook of Clinical Chemistry, 3rd Ed. Burtis CA, Ashwood ER.WB Saunders Co., (1999).
3. Young DS. Effects of drugs on clinical laboratory tests. 3th ed. AACC Press (1997).

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Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

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