

Microalbumin (mALB) Diagnostic Reagent Kit (Immunoturbidimetry Method) Product Instruction

Product name

Generic Name: Microalbumin (mALB) Diagnostic Reagent Kit (Immunoturbidimetry Method)
Abbreviation: mALB

Package Specifications

R1	R2
60ml×1	15ml×1
800ml×1	200ml×1
8000ml×1	2000ml×1

Calibrator (liquid):

Specification 1 (1.0mL×6; 6 levels);

Quality Control (liquid):

Specification 1 (1.0mL×2; 2 levels);

Intended use

Microalbumin (mALB) diagnostic reagent is used for quantitative in vitro determination of microalbumin in human urine on photometric systems.

Clinical significance

Diabetic nephropathy, which is accompanied by irreversible kidney damage and persistent proteinuria, is a major cause of death in persons with insulin-dependent diabetes mellitus. An early sign of diabetic nephropathy are small Albumin secretions in urine, i.e. Microalbuminuria. Therefore, detection of kidney (glomerular) damage that is minimal and reversible is important.

Principle

The assay of microalbumin is based on turbidimetric measurement. Turbidity is caused by the formation of antigen-antibody insoluble immuno-complexes.

Main ingredient

Composition	Main ingredients
R1	Tris buffer pH7.4 100mmol/L
	PEG (polyethylene glycol) 2%
	NaCl 3%
	Preservative 0.1%
R2	Tris buffer pH7.4 100mmol/L
	Goat anti-human mALB antibody 40ml/L
	NaCl 0.9g/L
	Preservative 0.1%
Calibration	PBS buffer 50mM
	Sucrose 5%
	BSA 8%
	ALB

Quality control	PBS buffer 50mM
	Sucrose 5%
	BSA 8%
	ALB

Storage and stability

This kit stays stable for 18 months when stored in a dark condition at 2-8° C (do not freeze). After being opened for the first time, the kit can be stored at 2-8° C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation

Urine.

It is recommended to collect mid-morning fasting urine or 24-hour urine. Random mid-section urine can be collected from outpatient and emergency patients (if the urine is turbid, the urine should be centrifuged and liquid supernatant be collected for testing). The sample should be tested in time after collection. If the urine cannot be tested in time, it should be stored in a refrigerator at 2°C~8°C and tested within 4 hours. And if it cannot be completed within 4 hours, it should be stored at -20°C; keep it sealed and avoid repeated freezing and thawing.

Assay procedure

1. Reagent preparation

This reagent is liquid and can be used directly.

Main wavelength	340nm	Sample (S)	8 μl
Subwavelength	700nm	Reagent 1	280 μl
Reaction temperature	37°C	Reagent 2	70 μl
Cuvette light path	1cm	Reaction type	Two Point End

2. Operation steps

Add to the cuvette:	
Sample (S)	8 μl
R1	280 μl
Mix well, incubate at 37° C for 5 minutes, then add	
R2	70 μl
Mix well, incubate at 37°C for 1 minute, absorbance A1; incubate at 37°C for 5 minutes, absorbance A2 ΔA= A2-A1	

Calculations

Calculate and plot $\Delta A = (A2 - A1)$ of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and read values in mg/L on the reference curve. Samples yielding absorbances

above highest calibrator should be retested after further dilution.

Reference interval

0~30mg/L

It is recommended that each laboratory should establish its own reference interval.

Quality control

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics

1. Measuring range

5-400mg/L

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

2. Sensitivity

When a control serum (25 mg/dl) is used as a sample, the range of absorbance change is 0.005-0.12.

Interference

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Heparin	100 mg/dl
Triglycerides	2500 mg/dl
Bilirubin	15 mg/dl
Haemoglobin	500 mg/dl
Na-citrate	2000 mg/dl
Turbidity	2.5 %

Automation

Special adaptations for automatic analyzers can be made on request.

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution. Reagents with different lot numbers should not be

interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Program settings

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	16-34
Wave Length Sec	700
Wave Length Prim	340
ABS. Limit	32000
Sample Volume (uL)	8
R1 Volume (uL)	280
R2 Volume (uL)	0
R3 Volume (uL)	70
Calibration Type	SPLINE
Calibration Point	6
Span Point	4
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume (uL)	8
Sample DIL. VOL.	/
R1 Volume (uL)	280
R2 Volume (uL)	70
Reagent DIL. VOL.	/
Measure Wave 1	340
Measure Wave 2	700
METHOD	END
SLOPE	-
Method Point	9-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5

LAST	-2.0-+2.5
Dynamic Range L	0
Dynamic Range H	400
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	6AB
Formula	spline
STD(1) Conc.#	*
Unit	mg/L

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