Microalbumin Assay Kit (mALB)

Method: Immunoturbidimetric

Cat . No.	Size	Instrument
GS3381S	R1:1×60 ml R2:1×20 ml	For Hitachi 7170/7180& Olympus AU640/400/600
GB3380S	R1:1×60ml R2:1×20ml	For Hitachi 7060/7150& ShimadzuCL7200/8000
GX3381S	R1:1×60ml R2:1×20 ml	For Beckman

INTENDED USE

For the *in vitro* quantitative determination of Microalbumin in urine.

CLINICAL SIGNIFICANCE

A slightly increased albumin excretion rate is considered predictive for the onset of clinical nephropathy and retinopathy. Because this slightly increased rate may be decreased by strictcontrolof glycemia or concomitant hypertension, there is an increasing interest in screening and monitoring the excretion of albumin in diabetics.

ASSAY PRINCIPLE

Urine albumin reacts with antibody specific for human aibumin. The formation of the antibody-antigen complex results in an increase in turbidity at 340nm. By constructing the standard curve, the concentration of urine albumin can be determined.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris/HCl buffer	20 mmol/L
Polyethylene Glycol	6%
NaCl	150 mmol/L
Reagent 2 (R2)	
Tris/HCl buffer	20 mmol/L
Anti (human) albumin	5%
NaCl	150 mmol/L

SAMPLE COLLECTION AND PREPARATION

For random urine test, use urina sanguinis or the urine sample when the patients is in quiescent condition. If the urine sample is turbid, centrifuge the sample.

If test the elimination factor of mALB, mix the samples collected at different time.Avoid strenuous exercise during collecting urine sample.

Urine sample is stable for 2 weeks at 2-8℃,after added antiseptic substance.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8℃

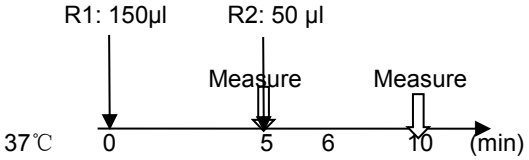
ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi 7180)

Assay Mode: 2 Point End 16-34

Wave length (sub/main): 700/340nm

Sample 10 µl



CALIBRATION

Recommend using Gcell calibrator (Cat .No. GC-mALB).

CALCULATIONS OF RESULTS

Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of mALB in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

For quality control, use Randox Assay Urine Chemistry Control AU2352/AU2353 as daily quality control and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Category	24-h collection (mg/24h)	Timed collection (ug/min)	Spot collection (ug/mg creatinine)
Normal	<30	<20	<30
Microalbuminuria	30-299	20-199	30-299
Clinical albuminuria	300	200	300

It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

In the range of 4 ~ 200 mg/L , the linear correlation coefficient r ≥ 0.990. In the range of 4 ~ 30 mg/L (containing 30mg/L), linearity deviation shall not exceed ± 3 mg/L. Between 30 ~ 200 mg/L, the linear deviation should not exceed ± 10%.

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CE version 2014

PRECISION

The CV of the test should be ≤ 5%.

Intar assay precision		
N=20	level 1	level 2
Mean(mg/L)	27.43	187.01
SD	0.58	2.62
CV(%)	2.10	1.40

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mgl/L)	25.37	25.17	25.77
$\bar{x}$	25.43		
(Xmax-Xmin)/$\bar{x}$	(25.77-25.17)/25.43*100=2.36%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Ascorbic acid: up to 4 g/L
Bilirubin: up to 250 mg/L
Creatinine: up to 4 g/L
Glucose: up to 40 g/L
potassium chloride: up to 10 g/L
sodium chloride: up to 20 g/L
Urea: up to 40 g/L
Hemoglobin: up to 10g/L
Intralipid: up to 250mg/L

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Elving, L.D., et al., Clin Chem. 1989; 35/2: 308.
2. Bakker, A.J., Clin. Chem. 1988; 34/1: 82.
3. Mogensen, C.E., Christensen, C.K., N. Engl. J.Med.1984; 311: 89.
4. Fielding, B.A., Price, D.A., Houlton, C.A., Clin. Chem.1983; 29/2: 355.

INDEX OF SYMBOLS


Manufacture

Catalogue Number

Lot number


Date of manufacture


Use by(Expiration date)

For In-Vitro Diagnostic use only

Stored at 2-8℃


Attention:See instruction for use

Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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