SPECTRUM

The Creative Approach to Bioscience

MICROALBUMIN (MAU)
Immuno Turbidimetry

REF: 600 001 100 test
R1 Buffer 2 x 20 ml
R_2 Antiserum 1 x 6 ml
Standard 1 x 0.5 ml

SYMBOLS IN PRODUCT LABELLING	
EC REP Authorised Representative	Use by/Expiration Date
IVD For in-vitro diagnostic use	CAUTION. Consult instructions for use
LOT Batch Code/Lot number	Manufactured by
REF Catalogue Number	(Xi) - Irritant
Consult instructions for use	
Temperature Limitation	

Intended Use

In vitro diagnostic reagents for the quantitative determination of Microalbumin (MAU) in urine by means of particle-enhanced turbidimetric immunoassay in clinical chemistry analyzers.

Background

Increased albumin excretion detectable only by sensitive immunoassay (microalbuminuria) has been used for some years as a predictor of incipient nephropathy and cardiovascular disease in diabetic patients. Microalbuminuria has also been associated with hypertension and increased risk of cardiovascular disease in non-diabetic patients. Microalbuminuria occurs in response to acute inflammatory conditions such as ischaemia, trauma, surgery, pancreatitis, and inflammatory bowel disease. In many of these conditions albumin excretion increases within minutes or hours of the initiating stimulus and only last for 24 to 72 h. The degree of microalburninuria is proportional to the severity of the inflammatory insult, is predictive of outcome, and is not associated with any other features of renal impairment. Conventional dip-stick and acid precipitation tests for detecting protein in urine lack the sensitivity required to delineate this condition. Dip-stick may yield negative or trace results even when the albumin excretion rate is 10 or 20 times normal; and the rate must increase to 200 or 300 micrograms per minute (µg/min) before nephropathy becomes clinically apparent as persistent proteinuria. Interest in measuring subclinical elevations in the albumin excretion rate has focused on individuals with an already established diagnosis of diabetes or essential hypertension. Providing proper care is taken to minimise the influence of exercise and poor metabolic control of the albumin excretion rate, the urinary albumin level has proved to be an excellent predictor of the progression to overt nephropaty in both insulin-dependent and non-insulin dependent diabetes.

Test Principle

This MAU test is based upon the MAU antigen-antibody reaction.

Reagents

***R1* Buffer**
Saline (9 g/L).
Accelerator.
Sodium azide (0.95 g/L)

R2 Antiserum
Phosphate buffered saline.
Polyclonal goat anti-human Albumin(variable).
Sodium azide (0.95 g/L).

Standard
Microalbumin concentration is stated on the vial label.

Materials required but not provided with the kit

Controls

Precautions and Warnings

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices. Disposal of all waste material should be in accordance with local guidelines.
As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Reagent Preparation , Storage and Stability

All reagents are supplied ready to use.
Reagents in the original vial are stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).

Standard:
The standard is stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).
Once opened the standard is stable for 6 weeks if stored tightly closed at 2 - 8 ºC after use.

Specimen Collection and Preparation

Collect urine during 24 hours or as a random midstream sample.If the test can not be carried out on the same day,the urine may be stored at (2 - 8 ºC)for 48 hours.If stored for a longer period,the sample should be frozen.
The use of centrifuged urine is recommended.

Procedure

1 - Bring the reagents and the photometer to room temperature

2 - Assay conditions:
Wavelength 340 nm
Temperature room temperature
Cuvette 1cm light path

3 - Adjust the instrument to zero with distilled water .
4 - Pipette into a cuvette :

	standard	Sample
Reagent (R1)	400 µl	400 µl
Standard	25 µl	-----
Sample	----	25 µl

Mix and leave for 30 seconds then add

Reagent (R2)	60 µl	60 µl

Read immediately A1 and after 5 minutes read A2

Calculation

Generate a reference curve by successive 1 : 2 dilutions of standard in saline (At Least 4 points are recommended). Use Saline as zero point. Determine Δ absorbance of the sample and each standard as following:
Δ absorbance of sample = (A2 - A1) sample
Δ absorbance of each calibrator = (A2 - A1) for each standard
Plot the calibration curve and obtain the result

Sensitivity

0.7 mg/L

Linearity

400 mg/L

Quality Control

Control sera are recommended to monitor the perfomance of manual and automated assay procedures .
Each laboratory should establish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerances.

Expected Values

0-25 mg/L

Each laboratory should establish an expected range for the geographical area in which it is located.

References

1-Medcalf E A et al. Clin Chem 1990; 36/3: 446-449.
2- Mount,J.N.J. Chin pathology,22,12(1986)
3-Panuyiotou B N. Journal International Medical Research 1994; 22: 181-201.
4- Shmidtz,A,et al, Diabetic Medicine,5,126(1988).

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
600 001	100 test

Spectrum For Diagnostic Industries - Free Zone
Ismailia Free Zone Industrial Area, Block 5 .
Cairo- Port said Avenue.
Ismailia,Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

CE

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