Spectrum For Diagnostic Industries

MICROALBUMIN (MAU)
Immuno Turbidimetry

IVD

REF.	Pack size
399 02 020	100 tests R1 Buffer 2 x 20 ml R2 Antiserum 1 X 6 ml Standard 1 x 0.2 ml

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).Open vials are stable for 3 months at the specified temperature.

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.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

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).

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use
LOT	Batch Code/Lot number
REF	Catalogue Number
	Consult instructions for use
	Temperature Limitation
	Use by/Expiration Date
	CAUTION. Consult instructions for use
	Manufactured by

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