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MICROALBUMIN (MAU)

REF: L-9570T
B-9470T

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

Diagnostic Relevance

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. Microalburninuria has also been associated with hypertension and increased risk of cardiovascular disease in non-diabetic patients. Microalbuininuria occurs in response to acute inflammatory conditions such as ischaemia, trauma,and termal injury, 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.

Principle

This Microalbumin test is based upon the reactions between albumin and latex-covalently bound antibodies against human albumin. Albumin values are determined turbidimetrically using fixed-time measurement with sample blank correction. The relationship between absorbance and concentration permits a multipoint calibration with a measuring range between 0 and 250 mg/L. The measuring temperature is 37ºC. The assay can be performed on all instruments allowing turbidimetric measurements at 500 to 600 nm.

Reagents

Buffer - Glycine buffer pH 8.5, containing protein stabilisers and < 0,1 % sodium azide as preservative.

Latex reagent –suspension of latex microparticles covalently bound anti-albumin antibodies suspended in a neutral aqueous solution, and < 0,1 % sodium azide as preservative.

Precautions

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.

Materials required

Automatic analyzer. Diluent solution. Calibrator. Controls.

Storage and Stability

Reagents are ready to use. Shake the latex reagent gently before dispensing its content into the appropriate plastic vials. Reagents in the original bottle are stable to the expiration date indicated on the label when capped and stored at +2…+8ºC. Do not freeze.

The Microalbumin buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.

The Microalbumin latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarted.

Specimens

Use 12 or 24 hour collection. centrifuge urine specimens. Screen these specimens using an albumin test strip. If the result is negative (approx. below 300 mg/L), analyse the specimens undiluted. If the result is positive, dilute the specimen with specific protein sample diluent to obtain a concentration below 150 mg/L. We recommend to dilute samples with a saline solution containing 1g/L Tween 200 detergent or 0.1% gelatine. Urine specimens for albumin in urine measurements should either be analysed as fresh specimens or stored at 4ºC (Microalbumin remain stable for 4 weeks at +4 – +8º C) and assayed as soon as possible.

Procedure

The reagents are ready to use as supplied. Latex reagent should be gently shaken (invert the recipient 3-4 times) before each use.

Volume R1/working reagent:	Volume R2/start reagent:	Volume sample:
250 µl	60 µl	3 µl
Step 1: mix R1 and R2, add sample and read 1st reading immediately after mixing.		
Step 2: 6 min after read 2nd reading.		
Wavelength: 600 nm	Incubation Time at 37º C:6 min	

** Volume, time and wavelength are recommended. Adjust them depending of analyser features.*

This reagent is intended to be used in clinical chemistry analysers. Adaptations for some of them are available.

Calibration. Quality Control

Standardization: use Biolatex Calibrator or other suitable calibrator material. The method was standardized against the CRM 470 international standard lot 5.

For quality control use Biolatex Control or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Calculation

The turbidimetric analysers automatically calculate the Microalbumin concentration of each sample. Conversion: mg/l = µg/ml.

Reference Values

For timed overnight urine collections an albumin excretion rate greater than 20 µg/min is considered to abnormal. These data are to be interpreted as a guide. Each laboratory should establish its own reference intervals.

Automatic Analyzer

This product is performed for use it in turbidimetric automatic analysers or in manual procedures.

Specific Performance Characteristics*

As is well known, the analytical characteristics of a clinical chemistry reagent depend on both the reagents and the instrument used. Multicenter studies indicate important differences in analytical characteristics among similar instruments. Therefore, this data must be calculated by each instrument.

(*) Analytical characteristics obtained in a single experiment in a Cobas-Mira plus analyser could be provided under demand.

Literature

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Significados de los símbolos indicados en las etiquetas. Explanation of symbols used on labelling. Explication des symbols figurant sur les etiquettes. Spiegazione dei simboli utilizzati sull'etichetta. Significado dos símbolos indicados nas etiquetas. Erläuterung der symbole auf den etiketten.

		LOT	IVD	REF	CE		REAG	CAL	Buffer	LYOPH	Conc.	Control H / Control L
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