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α_1-MICROGLOBULIN (α_1-m)

REF: L-9580T
B-9480T

In vitro diagnostic reagents for the quantitative determination of alpha-1-microglobulin (α1 - microglobulin) in urine by means of particle-enhanced turbidimetric immunoassay.

Diagnostic Relevance

α1- microglobulin (α1- m) is a low molecular weight glycoprotein (24,000- 33,000 g/mol) which was initially isolated from the urine of patients with renal tubular disorders in 1975. It is mainly synthesized in the liver and is widely distributed in various body fluids. Determination of α1- microglobulin in urine can be of aid in the diagnosis of tubular proteinuria. Detection of elevated concentrations of low molecular weight proteins in urine such as α1- microglobulin indicates tubular damage, which can occur in the course of advanced diabetic nephropathy, after heavy metal exposure or in the course of nephritis or others pathologies.

Principle

In the development of alpha-1-microglobulin (α1- microglobulin) test, antibody to human α1- m bound to latex particles is brought into contact with α1- m in a sample. The increase in light scatter resulting from the agglutination reaction is proportional to the concentration of α1- m in the sample. The relationship between absorbance and concentration permits a multipoint calibration with a measuring range between 0 and 90 mg/L. Incubation takes place at 37ºC. The assay can be performed on all instruments allowing turbidimetric measurements at 500 to 600 nm.

A range of standards are generated by successive dilution of the main standard in saline. The blank consists of saline.

Reagents

A.- Buffer - TRIS buffer, pH: 7,2, containing detergents, polyethyleneglycol and <0.1 % sodium azide as preservative.

B.- Latex reagent – suspension of latex microparticules covalently bound antibodies to human α1- microglobulin suspended in a neutral aqueous solution, with < 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. Saline solution. Calibrator. Controls.

Storage and Stability

The α1- microglobulin reagents should be stored tightly capped at +2…+8ºC when not in use. Do not freeze. Reagents in the original vials are stable to the expiration date on the vial label when capped and stored at +2...+8ºC. Immediately following the completion of an assay run, the reagent vials should be capped until next use in order to maximize curve stability. Once opened the reagent can be used within 1 month if stored tightly closed at +2...+8ºC after use. The α1- microglobulin buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted. The α1- microglobulin 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

Urine. All samples should be centrifuged prior to assay. α1- m remain stable in urine for 4 weeks at +2 to +8ºC. If the test should be performed later, it is recommended to freeze the urine. Avoid successive freezing and thawing.

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	2 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: 500 nm	Incubation Time at 37º C: 7 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 Calibrators. The method was standardized with reference to highly purified proteins preparation. The α1- m concentration of the Standard and Control is given on the label. Prepare the following dilutions of the standards using saline solution: 1; 1/2; 1/4; 1/8; 1/16, saline. The standard dilutions are to be used for measurement within 4 hours.

This curve is stored in memory by the analyser and recalled for later use. Calibration curves are stable for up to 14 days, after which a new curve must be generated. Additionally, recalibration must be performed whenever reagent lots are changed.

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 α1- m concentration of each sample. Conversion: mg/l = µg/ml.

Reference Values

Values < 10 mg/l (<14 mg/24h) are within the normal range. This data must 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

Berggard B, Ekstrom B and Akerstrom B. α1-microglobulin. Scand. J.Clin Lab. Invest. 1980:40; Suppl.154.

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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'eticheta. Significado dos símbolos indicados nas etiquetas. Erläuterung der symbole auf den etiketten.

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