biolatex

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β_2-MICROGLOBULIN (β_2-m)

REF: L-9530T
B-9430T

In vitro diagnostic reagents for the quantitative determination of β2- microglobulin (β2-m) in serum and urine by means of particle-enhanced turbidimetric immunoassay.

Diagnostic Relevance

β2-microglobulin (β2-m) , an 11,800-Da protein consisting of 100 aminoacid residues, first isolated from urine by Berggard and Bearn, is located on the surface of lymphocytes and other nucleated cells and was identified to be the light chain of the class I major histocompatibility complex. The cell membrane turnover is the main source of β2-m in serum, where its level rises when its production rate increases. Free β2-m is filtered by the glomerulus and subsequently reabsorbed almost completely in the proximal tubular cells, where it is catabolized. Increased urinary excretion of β2-m is a sensitive indicator of renal tubular disorders and has been used to detected early nephotoxicity in patients treated with gentamicin and other nephrotoxic drugs. Besides renal insufficiency serum level of β2-m was shown to be elevated in a variety of diseases including carcinomas and lymphoid tumours and inflammatory and autoimmune diseases such as Sjögren`s syndrome and rheumatoid arthritis. Detection of elevated serum β2-m has also been reported as a useful marker of acquired immune deficiency syndrome and in myeloma patients. This test provides the advantage of being economical, rapid, precise, accurate and suitable for the analysis of large series of serum and urine specimens.

Principle

The β2-m test is based upon the reactions between β2-m in the sample and latex-covalently bound rabbit antihuman β2-m antibodies. β2-m values are determined turbidimetrically using fixed-time measurement with sample blank correction. The relationship between absorbance and β2-m concentration permits a multipoint calibration with a measuring range between 0 and 12,0 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 - TRIS buffer containing detergents, polyethyleneglycol and < 0.1 % sodium azide as preservative.

Latex reagent – a suspension of latex microparticules covalently bound rabbit antihuman β2-m antibodies in a glycine buffer, containing NaCL and bovine serum albumin. Preservative: Sodium azide < 0.1%.

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

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 ß2- m buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded. The ß2- m 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 discarded.

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Specimens

Serum specimens should be collected by venipuncture following good laboratory practices. Suitable assay specimens are human serum samples, as fresh as possible (stored up to 7 days at +2...+8ºC) or deep-frozen. Any additional clotting or precipitation which occurs due to the freeze/thaw cycle should be removed by centrifugation prior to assay. Lipemic specimens, or turbid frozen specimens after thawing, must be clarified before the assay by high-speed centrifugation (10 min at approx. 15.000 rpm). Heat-inactivation of the serum samples can lead to a loss of the antigenic properties of the β2-microglobulin and must therefore be avoided.

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

Volume R1/working reagent: 250 µl	Volume R2/start reagent: 50 µl	Volume sample: 2 µl
Step 1: mix R1 and R2, add sample and read 1st reading immediately after mixing.		
Step 2: 4 min after read 2nd reading.		
Wavelength: 600 nm	Incubation Time at 37º C: 4 min	

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. The β2-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 ß2- m concentration of each sample.

Conversion: mg/l = µg/ml.

Reference Values

Values from 0,8 to 2,4 mg/l 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

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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.

		LOT	IVD	REF	CE		REAG	CAL	Buffer	LYOPH	Conc.	Control H / Control L
Fecha de Caducidad Expirate Date Date de Péremption Data di Scadenza Data Expiração Verwendbar bis	Temperatura de almacén Storage Temperature Temperature de Conservation Temperatura de Conservazione Temperatura de Conservação Lagertemperatur	Número de Lote Lot Number Número de Lot Numero di Lotto Número de Lote Chargen-Nr	Para Diagnóstico In Vitro For In Vitro Diagnostic Usage In Vitro Per Uso Diagnostico In Vitro Utilizar em Diagnostico In Vitro In Vitro Diagnosticum	Número de catálogo Catalog Number Numéro de catalogue Numero di catalogo Número de catálogo Katalognummer	Conformidad Europea European Conformity Conformité aux normes européennes Conformità europea Comformidade com as normas europeias CE-Konformitätskennzeichnung	Fabricado por Manufactured by Fabriqué par Fabbricato da Fabricado por Hergestellt	Reactivo Reagent Réactif Reagenti Reagente Reagenz	Calibrador Calibrator Calibrateur Calibratore Calibrador Kalibrator	Tampón Buffer Tampon Tampone Buffer Puffer	Liofilizado Lyophilised Lyophilisé Liofilo Liofilizado Lyophilisiert	Concentración Concentration Concentration Concentrazione Concentraçao Koncentration	Control Alto / Control Bajo Control High / Control Low Contrôle élevé / Contrôle Bas Controllo Alto / Controllo Basso Controlo Alto / Controlo Baixo Kontrolle Hoch / Kontrolle Niegrid