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β_2-MICROGLOBULIN

REF: K-9530M

MONOREAGENT PROCEDURE

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 tumors 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

This β2-m test is based upon the reactions between β2-m in the sample and latex-covalently bound goat antihuman β2-m antibodies. β2-m values are determined photometrically.

Reagents

Each β2-m kit contains:

A.- Buffer – 42.5 mL of TRIS buffer, pH: 7,2, containing detergents, polyethyleneglycol and 0,09 % sodium azide as preservative.

B.- Latex reagent – 8.5 mL of a suspension of latex microparticules covalently bound goat antihuman β2-m antibodies in a glycine buffer (0,1 M), containing NaCL (0,15 M) and bovine serum albumin (0,5%). Preservative: Sodium azide 0,075%.

C.- Calibrator – 1 mL. Human - based reference fluid. Preservative: sodium azide, 0.075 %. All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases

Reagent Preparation

Working Reagent is prepared with 1 part of Latex Reagent and 5 parts of Buffer Reagent. Prepare a fresh WR based on its workload. Shake gently the reagents before pipetting.

It is recommended that each Laboratory prepares a fresh Working Reagent based on its workload.

Calibration Curve and Controls

Analytical Range up to 20 mg/L.

Calibrator 1	100 µl of Biolatex β2-m Calibrator*
Calibrator 2	100 µl of Calibrator 1 + 100 µl of Saline Solution
Calibrator 3	100 µl of Calibrator 2 + 100 µl of Saline Solution
Calibrator 4	100 µl of Calibrator 3 + 100 µl of Saline Solution
Calibrator 5	100 µl of Calibrator 4 + 100 µl of Saline Solution
Calibrator 6	100 µl of Saline Solution

(*) See values on the label or on the insert. Multiply by the appropriate factor.

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.

Storage and Stability

Reagents in the original vial is 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 vial 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. Do not freeze reagents.

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The β2-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 discarted.

The β2-m buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.

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

Spectrophotometric analyser. Saline solution. Controls.

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-m and must therefore be avoided.

Procedure

Wavelength			600 nm
Temperature			37ºC
Cuvette			1cm light path
Measurement against distilled water blank.			
Bring the reagents at 37ºC and pipette:			
	Calibrator	Sample	Blank
Calibrator	3.5 µl	---	---
Sample	---	3.5 µl	---
Distilled Water	---	---	3.5 µl
Work. Reagent	500 µl	500 µl	500 µl
Mix and measure absorbance immediately (A1) incubate 5 min (37ºC), after incubation read absorbance (A2).			

Calculation

Plot the calibration curve and the sample concentration is obtained by interpolation the sample absorbance (A2-A1) in the calibration curve.

If is an one point calibration:

$$\frac{(A2-A1)_{sample} - (A2-A1)_{blank}}{(A2-A1)_{calibrator} - (A2-A1)_{blank}} x Calibrator Concentration$$

Reference Values

Values from 0,8 to 2,4 mg/L are within the normal range. Each laboratory should establish an expected range for the geographical area in which it is located.

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, the data must be calculated by each instrument.

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.

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