B_2-MICROGLOBULIN

Latex Turbidimetry

CE

REF. 6741 40+10 ml

IVD

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of β_2-Microglobulin (β_2-m) in serum, plasma and urine.

PRINCIPLE

Latex particles coated with antibodies anti- β_2-m are agglutinated when mixed with samples containing β_2-m .The agglutination causes an absorbance change, dependent upon the β_2-m contents of sample that can be quantified by comparison from a calibrator of known β_2-m concentration.

SAMPLE

Fresh serum. Stable 7 days at 2-8°C or 3 months at -20°C.
Urine. Adjust samples to pH 7-8 by the addition of K_2PO_4. Urine samples are stable 2 days at 2-8°C or 2 months at -20°C.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

KIT COMPONENTS

Reagent (A) β_2-m Diluent Volume = 20 ml	Tris buffer 20 mmol/l, pH 8.2 Preservative
Reagent (B) β_2-m Latex Volume = 4 ml	Particles coated with goat IgG anti-human β_2-m , pH 7.5 Preservative
Calibrator β_2-m Volume = 1 ml	**β_2-m concentration is stated on the label**

Optional: β_2-Microglobulin Control – REF. 6734
The Control is not included in the kit.

Control β_2-m Volume = 2 ml	**β_2-Microglobulin Control REF. 6734**

The reagents are stable until the expiration date indicated on the label if stored tightly closed at 2-8°C . Once opened, the reagents are stable at least 4 weeks at 2-8°C protected from light and in the absence of contamination.
keep bottles closed when not in use.

REAGENT PREPARATION

Working solution: Shake the latex vial gently before use.
Prepare the necessary amount as follows:

1 ml Reagent B (Latex) + 4 ml Reagent A (Diluent)

The working solution (A+B) is stable 30 days at 2-8°C.
β_2-Microglobulin Calibrator: Reconstitute with 1.0 ml of distilled water. Mix gently and bring to room temperature for about 10 minutes before use.
Urine method: Dilute reconstituted calibrator 1:6 with saline (50 µl calibrator + 250 µl NaCl 9 g/l).

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
Components from human origin have been tested and found to be negative for the presence of HbsAg, HCV and antibody to HIV 1/2. However handle cautiously as potentially infectious.
Dispose of waste according to local laws.

PROCEDURE

Wavelength:	540 nm (530-550)
Lightpath:	1 cm
Temperature:	37°C

Adjust the instrument to zero with distilled water

pipette:	
Working solution (A+B)	1000 µl
Sample or calibrator	10 µl (Serum), 50 µl (Urine),

Mix and read the absorbance immediately (A1) and after 3 minutes (A2) of the sample addition.

RESULTS CALCULATION

Serum:

β_2-m (mg/l) = $(A2 - A1)_{Sample} / (A2 - A1)_{Calibrator}$ x Calibrator conc.

Urine:

β_2-m (mg/l) = $(A2 - A1)_{Sample} / (A2 - A1)_{Calibrator}$ x Calibrator conc. /6

EXPECTED VALUES

Serum: 1.0 – 3.0 mg/l
Urine: 0.1 – 0.3 mg/l

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of control serum:
β_2 -Microglobulin Control - REF. 6734.

PERFORMANCE

Sensitivity: the sensitivity of the method is: 0.22 mg/l (serum) and 0.04 mg/l (urine). Lower values give non-reproducible results.
Prozone effect: No prozone effect was detected upon 100 mg/l (serum) and 20 mg/l (urine).
Linearity: the method is linear up to 18 mg/l (serum) and 3 mg/l (urine). For higher values, dilute 1:5 with saline the samples and multiply the result by 5.
Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (mg/l)	1	3.2	8.5
CV %	2.8	2.0	1.2

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (mg/l)	1	3.2	8.5
CV %	1.7	1.5	1.2

Interferences:
Serum method: bilirubin does not interfere up to 20 mg/dl. Hemoglobin up to 10 g/l, and lipids up to 10 g/l do not interfere. Rheumatoid factors in a concentration equal to 150 U/ml interfere.
Urine method: Urea (urine) up to 50 g/l, uric acid 20 g/l and glucose up to 100 g/l do not interfere.
Correlation against a reference method: Y = 1.709x - 2.627 r = 0.97

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