β2-Microglobulin

INTENDED USE

For the quantitative determination of human Beta-2 Microglobulin (β2M) in serum or plasma by immune-turbidimetric assay. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY AND BACKGROUND OF THE CLINICAL UTILITY

β2M is a low molecular weight protein (11.8kD) found on the surface of most nucleated cells. It forms the light chain component of the histocompatibility antigen and is eliminated via the kidneys. Following filtration through the glomeruli it is reabsorbed and catabolised by the proximal tubular cells. Normally only trace amounts are excreted in the urine. However this is markedly increased in tubulo-interstitial disorders. Raised serum levels of β2M are associated with renal disease and rheumatoid arthritis. Elevated serum levels can also occur with systemic lupus erythematosus, malignant lymphoma and myeloma.

TEST PRINCIPAL

This β2M test is based upon the reactions between β2M in the sample and latex-covalently bound goat antihuman β2M antibodies. β2M values are determined photometrically.

KIT COMPOSITION

Reagents are ready for use.

R1: Tris buffer 20 mmol/L, pH 8.2. Preservative.

R2: Particles coated with goat IgG anti-human ·β2M, pH 7.5. Preservative.

REAGENT STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8 ℃ and contaminations are prevented during use. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Fresh serum. Stable 7 days at 2-8 ℃ or 3 months at -20 ℃. The samples with particles or fibrin should be centrifuged before testing. Do not use hemolyzed or lipemic samples.

TEST MANUAL PROCEDURE

Wavelength:	546 nm
Temperature:	37 °C
Cuvette:	1 cm light path
Direction:	Increase
Zero adjustment:	Reagent blank

	Sample	Calibrator
Sample	10 µL	-
Standard		10 µL
Reagent R1	1000 µL	1000 µL
Mix well separately R1 and sample and, incubate for 5 minutes at 37℃		
Reagent R2	250 µL	250 µL
Than add R2. Mix well separately, incubate for 30 second at 37℃, read the absorbance A1, then incubate for 5 minutes, read the absorbance A2, calculate the change of absorbance △A.		

CALCULATION

The concentration of β2M in patient must be calculated from the Spline or Linear Interapolate calibration chart.

REFERENCE VALUES

Serum or plasma; 0.3 – 3.0 mg/L

This range is given for orientation only; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring Range:	0.3 18 0 mg/L
Detection Limit:	0.2 mg/L
Hook-effect:	No risk
Sensitivity:	0.025 ABS/Conc. unit

SYMBOLS USED

IVD **For in vitro diagnostic medical use**

LOT **Batch Code**

Use by

Temperature limitation

need help? scan here

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