



β_2 - microglobulin

Turbilatex

Qualitative determination

Cat.No. 101-0470

Size 1x45 ml / 1x5 ml

PRINCIPLE:

Latex particles coated with anti-human 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 the patient sample, that can be quantified by comparison from a calibrator of known concentration.

CLINICAL SIGNIFICANCE:

β_2 -microglobulin is a protein located on the surface of human lymphocytes and other nucleated cells. Free β_2 -m is filtered by the glomerulus and subsequently reabsorbed in the proximal tubular cells. Increased urinary excretion of β_2 -m is a sensitive indicator of renal insufficiency. Also, the β_2 -m level in serum is a useful marker of other diseases including carcinomas, lymphoid tumors, rheumatoid arthritis and AIDS.

REAGENTS:

1. Reagent 1 (1x45 ml)

Diluent; TRIS buffer pH 8.2 20 mmol/L
Sodium azide 0.95 g/L

2. Reagent 2 (1x5 ml)

β_2 - m latex
Sodium azide 0.95 g/L

3. Reagent 3 (1x1 ml)

β_2 - m Calibrator
Concentration see on the vial label

Optional: 101-0471 β_2 - m Control

Components from human origin have been tested and found to be negative for the presence of HBsAg and HCV, and of antibody to HIV (1/2). However handle cautiously as potentially infectious.

CALIBRATION:

The assay is calibrated to the 1st International β_2 -m Standard from WHO. The use of other commercially available β_2 -m calibrators is not recommended.

REAGENT PREPARATION AND STABILITY:

Working reagent: Shake the latex vial gently before use. Prepare the necessary amount as follow: 1 mL Latex Reagent + 9 mL Diluent. Stable for 30 days at 2-8°C.

β_2 -m Calibrator:

Serum method: Reconstitute with 1.0 mL of distilled water. Stable for 1 month at 2-8°C or 3 months at -20°C.

Urine method: Dilute reconstituted calibrator 1/6 with NaCl 9 g/L (50 μ L calibrator + 250 μ L NaCl 9 g/L)

All the components of the kit are stable until the expiration date on the label when stored at 2-8°C. Do not use reagents over the expiration date. Do not freeze; frozen reagents could change the functionality of the test.

SAMPLES:

Fresh serum. Stable 8 days at 2-8°C or 3 months at -20°C.

Fresh urine. Adjust samples to pH 7-8 by the addition of K₂HPO₄. Stable 2 days at 2-8°C or 2 months at -20°C.

The samples with particles or fibrin should be centrifuged to eliminate them. Do not use haemolized or lipemic samples.

PROCEDURE:

Wavelength: 540 nm (530-550)
Cuvette: 1 cm light path
Temperature: 37 °C
Zero: Distilled water

Pipette into a cuvette:	Calibrator	Sample
Working reagent	1000 μ l	1000 μ l
Calibrator	5 μ l	--
Sample	--	5 μ l
Mix and read the absorbance immediately (A ₁) and after 3 minutes (A ₂) of the latex addition.		

Chronolab has instruction sheets available for several automatic analyzers. Instructions for many of them are available on request.

QUALITY CONTROL:

Serum controls are recommended to monitor the performance of manual and automated assay procedures.

Chronolab β_2 -m control is available (Cat.No. 101-0471)

CALCULATION:

Serum:

$$\frac{(A_2 - A_1)_{\text{sample}}}{(A_2 - A_1)_{\text{Calibrator}}} \times \text{Calibrator concentration} = \text{mg/L } \beta_2\text{-m}$$

Urine:

$$\frac{(A_2 - A_1)_{\text{sample}}}{(A_2 - A_1)_{\text{Calibrator}}} \times \frac{\text{Calibrator concentration}}{6} = \text{mg/L } \beta_2\text{-m}$$

REFERENCE VALUES

Serum: between 1.0 to 3.0 mg/L.

Urine: between 0.1 to 0.3 mg/L

Each laboratory should establish its own reference range

PERFORMANCE CHARACTERISTICS:

- Measurement interval:** 0.2 – 18 mg/L (serum) and 0.04 – 3 mg/L (urine), under the described assay conditions. The measurement range depends on the sample to reagent ratio. The upper limit of the range will be higher by decreasing sample volume, although the sensitivity will be reduced
- Prozone effect:** No prozone effect was detected upon 100 mg/L
- Sensitivity:** Values less than 0.2 mg/L (serum) and 0.04 mg/L (urine) give non reproducible results.
- Precision:**

	Intra-assay (n=20)			Inter-assay (n=20)		
Mean (mg/L)	0.96	2.76	7.65	0.96	2.76	7.65
SD	0.034	0.090	0.155	0.045	0.220	0.601
CV	3.47	3.26	2.06	4.70	7.99	7.86

INTERFERENCES:

Bilirubin: up to 20 mg/L, **Hemoglobin:** up to 10 g/L, **Lipids:** up to 10 g/L, **Urea (urine):** up to 50 g/L, **Uric ac. (urine):** up to 20 g/L, and **Glucose (urine):** up to 100 g/L, do not interfere.

REFERENCES:

- AJ Pesce et al. Methods in Clinical Chemistry. The CV Mosby Company, St. Louis, MO, 1987
- Killinnsworth LM et al. Clin Chem 1973; 19: 403
- Tietz Textbook of Clinical Chemistry. Carl a Burtis, Ph D
- Clinical Guide Laboratory Tests, Edited by NW. Tietz WB Saunders Co. Philadelphia, 483, 1983