Gesan

CE Ref. 9820175

β_2-m turbilatex

Latex turbidimetry

Quantitative determination of β_2-microglobulin (β_2-m)
IVD

Store 2 - 8ºC.

PRINCIPLE OF THE METHOD

The β_2-m Turbilatex is a quantitative turbidimetric test for the measurement of β_2-microglobulin (β_2-m) in human serum, plasma or urine.
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-m 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

β_2-m Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Preservative.
β_2-m Latex (R2)	Particles coated with goat IgG anti-human β2-m, pH 7.5. Preservative.
β_2-m CAL	Calibrator. β_2-m concentration is stated on the vial label.
Optional:	β_2-m Control.

PRECAUTIONS

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.

CALIBRATION

Use β2- Microglobulin Calibrator.
The sensitivity of the assay and the target value of the calibrator have been standardized against the 1st International β_2-m Standard from WHO.
The calibration is stable for 1 month.
Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

PREPARATION

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

1 mL Latex Reagent + 4 mL Diluent

β_2-m Calibrator:

Serum method: 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 NaCl 9 g/L (50 µL calibrator + 250 µL NaCl 9 g/L).

STORAGE AND STABILITY

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

Reagent deterioration: Presence of particles and turbidity.
Working reagent: Stable for 30 days at 2-8ºC.
β_2-m Calibrator: Stable for 1 month at 2-8ºC or 3 months at –20ºC.

Do not freeze; frozen Latex or Diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 540 nm filter.

SAMPLES

Fresh serum. Stable 7 days at 2-8ºC o 3 months at -20ºC.
Fresh urine. Adjust samples to pH 7-8 by the addition of K_2HPO_4. Stable 2 days at 2-8ºC or 2 months at –20ºC.
The samples with particles or fibrin should be centrifuged before testing. Do not use hemolized or lipemic samples.

PROCEDURE

1. Bring the Reagents and the photometer (cuvette holder) to 37ºC.

2. Assay conditions:
   Wavelength: 540 nm (530-550).
   Temperature: 37ºC
   Cuvette light path: 1 cm.
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

W. Reagent (mL)	1.0
Calibrator or sample (µL)	10 (serum), 50 (urine)

5. Mix and read the absorbance immediately (A_1) and after 3 minutes (A_2) of the sample addition.

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

CALCULATIONS

Serum:

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

Urine:

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

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. It should be used the GESAN β_2-m Control. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Serum: from 1.0 to 3.0 mg/L.
Urine: from 0.1 to 0.3 mg/L.
Each laboratory should establish its own reference range

PERFORMANCE CHARACTERISTICS

1. **Linearity limit:** Up to 18 mg/L (serum) and 3 mg/L (urine), under the described assay conditions. Samples higher results should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity depends on the sample-reagent ratio, as well as the analyzer used. It will be higher by decreasing sample volume, although the sensitivity of the test will be proportionally decreased.
2. **Detection limit:** Values less than 0.22 mg/L (serum) and 0.04 mg/L (urine) give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected up to 100 mg/L (serum) and 20 mg/L (urine).
4. **Sensitivity:** Δ 0.048 A. mg/L (serum) and Δ 0.228 A. mg/L (urine).
5. **Precision:** The reagent has been tested for 20 days, using three different β2-m concentrations in a EP5-based study.

EP5	CV (%)		
	+/- 1 mg/L	+/- 3.2 mg/L	+/- 8.5 mg/L
Total	4.0%	3.4%	1.7%
Within Run	2.8%	2.0%	1.2%
Between Run	1.7%	1.5%	1.2%
Between Day	2.2%	2.4%	0.0%

6. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 36 samples of different concentrations of β2-m were assayed. The correlation coefficient (r) was 0.97 and the regression equation y = 1.709x –2.627.
   The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Serum method: bilirubin (20 mg/L), hemoglobin (10 g/L) and lipids (10 g/L), do not interfere. Rheumatoid factors (150 IU/mL), interfere.
Urine method: urea (urine)(50 g/L), uric ac. (20 g/L) and glucose (100 g/L), do not interfere.
Other substances may interfere[7].

BIBLIOGRAPHY

1. Bhalla, R.B. et al. Clinical Chemistry 1983; 29: 1560.
2. Malaguarnera M et al. Digestive Diseases and Sciences 1997; 42: 762-766.
3. Chironna et al. Int J Clin Lab Rws 1994; 24: 90-93.
4. Wibell L et al. Nephron 1973; 10: 320-331.
5. Berggard B et al. Scand J Clin Lab Invest 1980; 40: 13-25.
6. Davey P G et al. Clin Chem 1982; 28/6: 1330-1333.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Pres, 1995.

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