Quantitative determination of β2-microglobulin (β2-m)

Only for professional in vitro diagnostic use.

Store at 2-8°C.

**PRINCIPLE OF THE METHOD**

The β2-microglobulin MonlabTest is a quantitative turbidimetric test for the measurement of β2-microglobulin (β2-m) in human serum, plasma or urine. Latex particles coated with anti-human β2-m are agglutinated when mixed with samples containing β2-m. The agglutination causes an absorbance change, dependent upon the β2-m contents of the patient sample that can be quantified by comparison from a calibrator of known concentration.

**CLINICAL SIGNIFICANCE**

β2-m is a protein located on the surface of human lymphocytes and other nucleated cells. Free β2-m is filtered by the glomerulus and subsequently reabsorbed in the proximal tubular cells. Increased urinary excretion of β2-m is a sensitive indicator of renal insufficiency. Also, the β2-m level in serum is a useful marker of other diseases including carcinomas, lymphoid tumors, rheumatoid arthritis and AIDS.

**REAGENTS**

- β2-m Diluent (R1)
- β2-m Latex (R2)
- β2-m CAL

Optional:

Ref: MO-165054 (β2-m Control MonlabTest).

**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 MonlabTest (MO-165053). The sensitivity of the assay and the target value of the calibrator have been standardized against the 1st International β2-m Standard from WHO. Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

**PREPARATION**

- β2-m Calibrator:
  - Serum method: Reconstitute (-9) 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 2-8°C and contaminations are prevented during use. Do not use reagents over the expiration date.

**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 interfere7.

**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 above assay conditions. Samples higher than the limits 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 0.09 mg/L (serum) and 0.01 mg/L (urine) give non-reproducible results.

3. Prozone effect: No prozone effect was detected up to 60 mg/L (serum) and 20 mg/L (urine).

4. Sensitivity: 0.048 A. mg/L (serum) and 0.028 A. mg/L (urine).

5. Precision: The reagent has been tested for 20 days, using three different β2-m concentrations in an EPS-based study.

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 – 6.627. The results of the performance characteristics depend on the analyzer used.

**BIBLIOGRAPHY**