

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

Store 2 - 8°C.

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

R1	Tris buffer 20 mmol/L, sodium azide 0.95 g/L, pH 8.2.
R2	Particles coated with goat IgG anti-human β_2 -m, pH 8.0. Sodium azide 0.95 g/L.
Saline Solution	NaCl 9% (for samples predilution)
Optional	Ref: ACC16-029 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

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.

PREPARATION

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

- 1 mL Latex Reagent + 9 mL Diluent

Samples and Controls Predilution:

- 50 μ L sample or control + 400 μ L NaCl 9 g/L (1:9)

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.

Reagent deterioration: Presence of particles and turbidity.

Working reagent: Stable for 30 days at 2-8°C.

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

ADDITIONAL EQUIPMENT

- Pipette 100 - 1000 μ L
- Pipette 10 - 100 μ L
- Cuvettes and microstirrers (ref. code ACC16-037)

SAMPLES

Fresh serum. Stable 7 days at 2-8°C o 3 months at -20°C.

The samples with particles or fibrin should be centrifuged before testing. Do not use hemolized or lipemic samples.

TEST PARAMETER

Filter: set filter on position A

Reading time: 180 seconds

PROCEDURE

1. Pipette into an appropriate number of cuvettes:

kind of reagent	μ L
Working Reagent	500

2. Incubate the cuvettes in positions 1-4 for at least 1 minute
3. Transfer each cuvette in the reading channel and, when requested on the display, add 50 μ L of pediluted sample or control
4. Read the result which will appear automatically on the reader's display after 180 sec.

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Vital Diagnostics SERUM PROT CONTROL BILEVEL (Cod.: ACC16-038) is available.

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.

Each laboratory should establish its own reference range

PERFORMANCE CHARACTERISTICS

1. **Linearity limit:** Up to 8 mg/L (serum) 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 0.2 mg/L (serum) give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected upon 100 mg/L.
4. **Sensitivity:** Δ 0.048 A. mg/L (serum) and Δ 0.228 A. mg/L (urine).
5. **Precision:**

	Mean	SD	CV%
Intra-assay (n=10)	0.96	0.034	3.47
Inter-assay (n=10)	0.96	0.045	7.7

Accuracy: Results obtained using this reagent (y) were compared to those obtained using the IMX of Abbot (x). 81 ranging from 1 to 20 mg/L of β_2 -m were assayed. The correlation coefficient (r) was 0.97 and the regression equation $y = 1.230x + 0.343$.

INTERFERENCES

Bilirubin (20 mg/L), hemoglobin (10 g/L) and lipids (10 g/L), do not interfere. Rheumatoid factors (150 IU/mL), interfere. Other substances may interfere².

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.

PACKAGING

Ref.: ACC16-020	Cont.	:1 x 45 mL R1
		:1 x 5 mL R2
		:1 x 50 mL Saline Solution