

CORMAY BETA 2-MICROGLOBULIN

DIAGNOSTIC KIT FOR DETERMINATION OF β 2-MICROGLOBULIN CONCENTRATION



Kit name	Kit size	Cat. No
CORMAY BETA 2-MICROGLOBULIN	1 x 100 ml	6-306

INTRODUCTION

β 2-microglobulin (BMG) is a low molecular weight protein (M.W.: 11800 D) which is found in minute quantities in various body fluids such as blood, urine and cerebrospinal fluid. The measurement of serum BMG level is useful in the diagnosis of functional renal disorders, various malignant tumors, and also for the assessment of treatment and disease prognosis.

METHOD PRINCIPLE

When an antigen-antibody reaction occurs between BMG in a sample and anti-BMG antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of BMG in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

REAGENTS

Package	
1-Reagent	1 x 50 ml
2-Reagent	1 x 50 ml

Reagent preparation and stability

The reagents are ready to use.

The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. Protect from light!

Concentrations in the test

suspension of latex particles sensitized with (rabbit) anti-BMG antibodies (pH 7.3) 0.20 w/v%
glycine buffer solution (pH 9.0)

Warnings and notes

- Product for in vitro diagnostic use only.
- Reagent bottles should be shaken before use by gently inverting several times.
- After measurements are taken, reagent bottles should be capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum, plasma or 24- hours urine.

It is recommended to perform the assay with freshly collected samples. Samples can be stored for 1 week at 2-8°C or for 1 year at -20°C. Repeated freezing and thawing should be avoided.

Urine should be refrigerated and alkalized as soon as possible following collection. If the urine sample contains any floating substances, the sample should be centrifuged and the supernatant take for further testing. Properly collected urine specimens can be stored for 2 days at 2-8°C or for up to 2 months at -20°C.

Samples which contain an excessive amount of BMG should be diluted with physiological saline and re-tested.

PROCEDURE

wavelength	572 nm
temperature	37°C

These reagents may be used in automatic analysers according to their service manual. These reagents may be used directly in HITACHI 911/912 analysers. Applications for analysers are available on request.

REFERENCE VALUES

serum, plasma	0.8 – 1.8 mg/l
24- hours urine	0.03 – 0.10 mg/24h

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL II (Cat. No 4-290) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY BETA 2-MGLOB CALIBRATORS (S) (Cat. No 4-283) for serum samples and the CORMAY BETA 2-MGLOB CALIBRATORS (U) (Cat. No 4-284) for urine samples are recommended. A calibration curve should be drawn, each time the test performed. The standard solutions should be measured at least twice.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser HITACHI 917. Results may vary if a different instrument is used.

- Analytical range:** 0.3 – 30 mg/l (serum)
0.05 – 4.5 mg/l (urine).
- Antigen excess:** up to 100 mg/l.
- Specificity / Interferences**
Haemoglobin up to 500 mg/dl, bilirubin up to 30 mg/dl and intralipid up to 5% do not interfere with the test in serum.
Ascorbate up to 500 mg/dl, NH₄Cl do 400 mg/dl, haemoglobin up to 200 mg/dl, bilirubin up to 10 mg/dl do not interfere with the test in urine.

Precision

Repeatability (within run) n = 30	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	0.047	0.009	19.94
level 2	0.182	0.004	2.36
level 3	0.411	0.004	1.10

Reproducibility (run to run) n = 10	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	0.050	0.005	9.75
level 2	0.520	0.005	0.97
level 3	1.020	0.012	1.19

Method comparison

A comparison between CORMAY reagent (y) and commercially available assay (x) using 55 serum samples gave following results:

$$y = 1.20x - 0.38 \text{ mg/l;}$$

$$R = 0.992 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Galvin J. P. et al.: Particle enhanced photometric immunoassay systems., Clin. Lab. Assays (Pap. Annu. Clin. Lab. Assays Conf.), 4th, 73 (1983).
2. Singer J. M. et al.: The latex fixation test. I. Application to the serologic diagnosis of rheumatoid arthritis, Amer. J. Med., 21, 888 (1956).
3. Kaplan L.A., Pesce A. J.,: Clinical Chemistry, 3rd ed. St Louis, Mosby, 994-995 (1996).

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