β2-Microglobulin Assay Kit (BMG)

Method:Latex Enhanced IT

Cat .No.	Size	Instrument
GS341S	R1:1×60 ml R2:1×20 ml	For Hitachi917 &OlympusAU640/400/600
GB340S	R1:1×60 ml R2:1×20 ml	For Hitachi 717 &ShimadzuCL7200/8000
GT341S	R1:1×18 ml R2:1× 6 ml	For TOSHIBA
GX341S	R1: 1×60 ml R2: 1×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GD341S	R1: 8×3.8 ml R2: 4×2.6 ml	For DATE DEMENSION
GS9341S	R1: 3×15 ml R2: 1×15 ml	For Hitachi917 &OlympusAU640/400/600
GB9340S	R1: 3×15 ml R2: 1×15 ml	For Hitachi 717 &ShimadzuCL7200/8000
GT9341S	R1: 1×45 ml R2: 1×15 ml	For TOSHIBA
GX9341S	R1: 1×45 ml R2: 1×15 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GD9341S	R1: 8×3.8 ml R2: 4×2.6 ml	For DATE DEMENSION

INTENDED USE

For the *in vitro* quantitative determination of BMG in human serum or urine .

CLINICAL SIGNIFICANCE

β_2-microglobulin (BMG) is expressed by the nucleated cells of the body and on many tumor lines. BMG is a low molecular weight protein (MW 11600) consisting of a single polypeptide chain of 99 amino acids. It is filtered out of the body by the kidney glomeruli and almost completely reabsorbed by the kidney proximal tubules. It is found at low levels in the serum and urine of normal individuals. Elevated serum concentrations in the presence of normal glomerular filtration rate suggest increased BMG production or release. In patients with rheumatoid arthritis, systemic lupus erythematosus, sarcoidosis and some viral diseases including cytomegalovirus, non-A and non-B hepatitis and infectious mononucleosis, the BMG serum level changes in relation to disease activity. Typically only trace amounts of BMG are excreted in the urine and higher rates are interpreted as evidence of tubular dysfunction. Urinary excretion is markedly increased in tubulointerstitial disorders, and where aminoglycosides and anti-inflammatory compounds are present. The Gcell BMG Kit provides a sensitive and reliable wide detection range. This assay is for the measurement of β_2-microglobulin not only in human serum but also in human urine in just a few minutes.

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 (570 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.

SPECIMEN COLLECTION

Fresh serum or urine samples.

REAGENT COMPOSITION

Contents
R1
Amino acetic acid buffer
R2
0.12w/v% latex particles, Hypersensitivity of the BMG antibody solution

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.

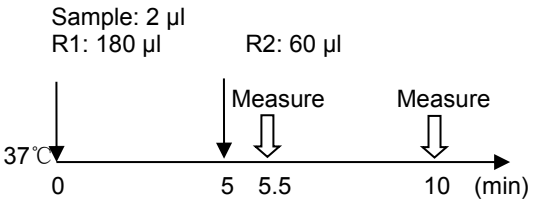
ASSAY PROCEDURE

Test procedure for analyzers (HITACHI 917, serum)

Assay Mode: 2 Point End

Measure point: 19, 28

Wavelength(main/sub) 570 nm/800 nm



1. Mix 2 µl sample with 180 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 60 µl R2 into cuvette, mix and incubate for 30 seconds at 37℃.
3. Read initial absorbance A_1 and incubate for another 4.5 minutes, read final absorbance A_2.
4. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALIBRATION

Gcell BMG calibrator (Cat .No: GC-BMG/S for serum, GC-BMG/U for urine)

CALCULATIONS OF RESULTS

Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of BMG in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

Gcell BMG Control (Cat.No: GQ-BMG/H for high level, GQ-BMG/L for low level)
The control intervals and limits should be adapted to each laboratory's individual requirement. Values obtained should fall within specified limits. If the control values fall outside these ranges and repetition excludes technical error, the following steps should be taken:

1. Check wavelength setting and light source.
2. Ensure that cuvettes are not dirty and that all glassware in use has been cleaned thoroughly.

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3. Check water, contaminants, ie. bacterial growth, may contribute to inaccurate results.
4. Check that assay temperature is accurate.
5. Ensure that reagent pack contents are still within expiry date.

NORMAL RANGES

Serum： 0.8-1.8 mg/L
Urine: 0.03-0.10 mg/24h
It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The assay range is approximate 0.4–60 mg/L for serum and 0.03–7.00 mg/L for urine. If sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor. It is recommended that results falling below the concentration of the lowest calibrator be reported as less than the concentration of the lowest calibrator.

PRECISION

The CV of the test should be ≤ 5%.

Intra assay precision (serum)		
N=20	Level 1	Level 2
Mean (mg/dL)	1.51	7.66
SD	0.06	0.06
CV	3.89%	0.82%
Intra assay precision (urine)		
N=20	Level 1	Level 2
Mean (mg/dL)	1.55	7.24
SD	0.02	0.06
CV	1.32%	0.84%

SENSITIVITY

The minimum detectable level of BMG with an acceptable level of precision has been determined as 0.08 mg/L.

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Intralipid:	6%
Bilirubin:	30 mg/dl
Hemoglobin:	520 mg/dl
VC:	500 mg/dl
RF:	500 IU/ml

CORRELATION（serum）

Correlation between this test (y) and a latex-enhanced turbidimetric immunoassay from another company (x) is given below;
n = 70, y = 1.0143+0.0124 , r^2 = 0.9992

CORRELATION（urine）

Correlation between this test (y) and a latex-enhanced turbidimetric immunoassay from another company (x) is given below;
n = 85, y = 0.9534x + 0.0326, r^2 = 0.9955

PROZONE

No prozone phenomenon occurs when BMG ≤ 180 mg/L in serum and BMG ≤ 30 mg/L in urine.

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Elving,L.D.,et al., Cline Chem.1989;35/2:308.
2. Bakker,A.J.,Clin.Chem.1988;34/1:82.
3. Mogensen,C.E.,Christensen,C.K.,N.Engl.J.Med.1984;311:89.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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