ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

Beta -2 Microglobulin– Instructions for use

IVD

R1: 1x 50 mL REF A-R1100001801
R2: 1x 7,5 mL

CE

SUMMARY AND EXPLANATION OF THE TEST

BMG is a low molecular weight (11,000 Daltons) protein found on the membranes of virtually all body cells. Free BMG is a product of cell breakdown. It is secreted by the renal glomeruli, then absorbed and catabolized by the renal tubular cells. Decreased glomural filtration is associated with high serum levels of BMG, whereas tubular insufficiency is associated with normal serum and high urine levels. Markedly increased cell breakdown, as in acute leukaemia, may also be associated with high serum levels.

PRINCIPLE OF THE TEST

Measurement of antigen-antibody reaction by the end-point method.

β-2 Microglobulin Reagent Kit
Code A-R1100001801
Reagent 1 (R1) - Buffer - 1 x 48.5 mL/vial
Reagent 2 (R2) - Latex - 1 x 7.0 mL/vial
Each vial is ready to use and contains:

Reagent 1:	**Conc.**	**U.M.**
Saline	9	g/L
Sodium azide	0,95	g/L
Reagent 2:	**Conc.**	**U.M.**
Glycine Buffer (pH 8.21)	/	/
Goat anti-human β2-Microglobulin sensitized latex	0.20	%
Sodium azide	0,95	g/L

Reagent Preparation:
Liquids reagents ready for use.

Storage and Stability:
If stored at 2 - 8°C avoiding direct light, the reactants remain stable until the expiration date printed on the label.
Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.
Do not freeze the reagents.

EQUIPMENT / ACCESSORIES REQUIRED AND NOT SUPPLIED

General laboratory equipment
Saline (9 g/L)
Calibrators and/or Control
(Pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Value is stated in the insert)

PRECAUTIONS AND LIMITATIONS

For *in vitro* diagnostic use.
Only experienced laboratory personnel should use this test and handling should be in agreement with Good Laboratory Practice (GLP).
Reagents from different lots must not be interchanged.

Safety Precautions

1. Each donor unit used in the preparation of the reagents, standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA
2. Do not pipet by mouth.
3. Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
4. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
5. Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols.
6. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
7. In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components is lower than the limits reported by the current directive sand following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
8. All human samples must be handled and disposed of as potentially infectious materials.
9. For information about safe handling, read carefully the Material Safety Data Sheet (MSDS).

Disposal of Reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

SPECIMEN COLLECTION AND STORAGE

Use fresh serum or fresh centrifuged urine.
If the test can not be carried out on the same day, the serum or urine may be stored at 2 - 8°C for 48 hours.
If stored for a longer period, the sample should be frozen.

ASSAYPROCEDURE

Allow reagents to reach working temperature before using.

Quality control
It's necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Automation
All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Procedures
Manual:
Sample/Control/Standard: dilute 1:2 in saline 9 g/L.
Reference curve: generate a reference curve by β-2 Microalbumine Standard Kit
Ref: R-1300002601. Use saline 9 g/L as zero point.

Method for automated instrumentation

Analyzer:	**Miura Family**		
Analyte Name :	**β-2 Microglobulin**	Ref.:	A-R1100001801
Method Code:	**BMG**		
Type:	**Different. Sample Blk.**		
Unit:	**mg/dL**		
Filter F1:	**578 nm**		
Blank in calculation:	**Not Used**		
Step	**Reaction volume**		**U.M.**
Sample volume:	**3**		µL
Volume Reagent 1:	**250**		µL
Volume Reagent 2:	**35**		µL
Incubation Time	**60**		Sec.
Reading Time:	**300**		Sec.
Calibration	**See Reference Curve**		

EXPECTED VALUES

Serum 0.8 -1.8 mg/L
Urine < 0.5 mg/L
Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

PERFORMANCE CHARACTERISTICS

The performance characteristics for the β2 Microglobulin reagents were measured on a clinical chemistry analyzer.
Measuring Range: 0 - 11 mg/L
Detection Limit: 0.15 mg/L
Hookeffect: No risk
Sensitivity: 0.054 ABS units/concentration unit

Precision: [%CV]		Low	Medium	High
	Intra-Run	3.8	2.95	1.52
	Inter-Run	/	/	/
Accuracy: [mg/dL]	Control	Assigned	Measured	
	Aptec	2.75 (2.34 - 3.16)	2.86	
	Dede Behring	1.94 (1.65 - 2.23)	2.07	

Specificity: Monospecific
Interferences: No interference for haemoglobin (200 mg/dL), bilrubin (10 mg/dL), ascorbic acid (500 mg/dL) and ammonium chloride (400 mg/dL).
Limitations: None
Comparison with Nephelometry: y = 1.4725x + 0.0469 / r = 0.9595
Stability at 4°C: at least 3 years after production

BIBLIOGRAPHY

1. Galvin, J.P. et al. Particle Enhanced Photometric Immunoassay Clin. Lab. Assays 73 (1983)
2. Goldman, M.H. et al. b2-Microglobulin and the diagnosis of C. T. R. Transplantation 36, 209 (1983)
3. Evrin, P.E. et al. Serum levels and urinary secretion of b2-Microglobulin. Scand. J. Lab. Invest., 29 69-74 (1972)

LOT Numero lotto / Lot numer
Consultare la metodica operativa / consult instructions for use
IVD Per uso diagnostico in-vitro / For in-vitro diagnostic use
Prodotto da / manufactured by
Data di scadenza / expiry date
Temp. Di Conservazione / storage temperature

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