

**β₂-MG Fast Test Kit (Immunofluorescence Assay)
For *in vitro* Diagnostic Use**

User Manual

INTENDED USE

β₂-MG Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of beta 2-microglobulin (β₂-MG) in serum, plasma or whole blood. Measurement of β₂-MG is useful for the detection and evaluation of glomerular filtration rate, renal transplantation and renal function.

SUMMARY

β₂-MG is an 11.8-kD protein, which forms one of the chains of the major histocompatibility complex (MHC) class I molecule normally present on the surface of every nucleated cell in the human body. Ninety percent of β₂-MG is eliminated via glomerular filtration and almost completely reabsorbed by the proximal tubule. β₂-MG is present in small amounts in serum, csf, and urine of normal people, and to a much greater degree in the urine and plasma of patients with tubular proteinemia, renal failure, or kidney transplants.

Among the uremic toxins in the "middle molecule" range, β₂-MG is certainly one of the most frequently studied compounds. Its serum level increases with the progression of chronic kidney disease, to reach very high concentrations in patients with end-stage kidney disease. It is the major protein component of dialysis-related amyloidosis, a dramatic complication which results from high extracellular concentration and posttranslational modification of β₂-MG and a number of other promoters of amyloid fibril formation and deposition in osteo-articular tissues. Effective removal of β₂-MG can be achieved with highly effective hemodialysis and hemodiafiltration techniques but predialysis session serum levels cannot be normalized. The prevalence and severity of β₂-MG amyloidosis appear to decrease in the last 20 years, although its occurrence may simply be delayed.

PRINCIPLE

The test uses an anti-human β₂-MG monoclonal antibody conjugated with fluorescence and another anti-human β₂-MG monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence-labelled anti-human β₂-MG monoclonal antibody binds with the β₂-MG in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action, then be captured on the test line by another anti-human β₂-MG monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of β₂-MG in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100), the concentration of β₂-MG in sample will be measured and displayed on the screen. The value will be stored in Getein1100 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

A kit contains:

- 1. Getein β₂-MG test card in a sealed pouch with desiccant 25
- 2. Disposable pipet 25
- 3. User manual 1
- 4. SD card 1
- 5. Blood sample diluent 25

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence-labelled anti-human β₂-MG monoclonal antibody, the test line is coated with another anti-human β₂-MG monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Blood sample diluent:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

Note: Components from different batches must not be interchanged.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.

Use the test card within 1 hour once the foil pouch is opened.

Store the blood sample diluent at 0~30°C with a valid period of 24 months.

Store the blood sample diluent at 2~8°C for better results.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow the manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum, plasma and whole blood samples. Sodium citrate or EDTA should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest to use serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of blood sample diluent must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8 °C or stored at -20 °C for 6 months prior to being tested (whole blood sample may be stored up to 3 days at 2~8 °C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous prior to testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME: 10 µl.

TEST PROCEDURE

1. Collect specimen according to manual.
2. Test card, sample and reagent should be brought to room temperature prior to testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver 10 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100 µl of sample mixture (or 3-4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
8. After 3 minutes, insert the test card into Getein1100 and press "ENT" button. The result will be shown on the screen and printed automatically.

Notes:

1. It is required to perform "SD Card Calib" calibration when using a new batch of kit.
2. It is suggested to calibrate once for one batch of kit.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100 can scan the test card automatically and display the result on the screen. Please follow the procedure in user manual of Getein1100 for result printing.

For additional information, please refer to the user manual of Getein1100.

EXPECTED VALUE

The expected normal value for β₂-MG was determined by testing samples from 345 apparently healthy individuals. The reference range of β₂-MG is 0.8 mg/L~3.0 mg/L calculated by using normal distribution methods.

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range: 0.5~20.0 mg/L
 Lower Detection Limit: ≤ 0.5 mg/L
 Within-Run Precision: $\leq 10\%$
 Between-Run Precision: $\leq 15\%$
 Method Comparison:

The assay was compared to HITACHI 7170A and its matching β_2 -MG test kits with 207 serum samples (157 positive samples and 50 negative samples). The correlation coefficient (r) is 0.986.

LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Concentration (Max)
Hemoglobin	5 g/L
Triglyceride	10 g/L
Bilirubin	0.2 g/L

REFERENCES

- Madsen MG, Nørregaard R, Palmfeldt J, et al. Urinary NGAL, cystatin C, β_2 -microglobulin, and osteopontin significance in hydronephrotic children. *Pediatr Nephrol.* 2012, 27(11): 2099-2106.
- Drüeke TB. β_2 -microglobulin and amyloidosis. *Nephrol Dial Transplant.* 2000, 15 (Suppl 1):17-24.
- Li ZM, Zhu YJ, Sun J, et al. Serum beta2-microglobulin is a predictor of prognosis in patients with upper aerodigestive tract NK/T-cell lymphoma. *Ann Hematol.* 2012, 91(8):1265-1270.
- EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on β_2 -MG Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN 980: 2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration Date
	Do not re-use		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE marking		

Thank you for purchasing β_2 -MG Fast Test Kit (Immunofluorescence Assay).
 Please read this manual carefully before operating to ensure proper use.

Version: WIF-DLSM-12-01



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