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CE IVD

β_2-MG
Fast Test Kit
(Immunofluorescence Assay)

IF1011 for Getein1100
IF5011 for Getein1160
IF3011 for Getein1180
IF4011 for Getein1200
IF2011 for Getein1600

REF

Instructions for Use

INTENDED USE

β_2-MG Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of beta 2-microglobulin (β_2-MG) in human serum, plasma or whole blood samples. Measurement of β_2-MG is useful for the detection and evaluation of glomerular filtration rate, renal transplantation and renal function.

SUMMARY

β_2-MG is an 11.8 kDa 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 β_2-MG is eliminated via glomerular filtration and almost completely reabsorbed by the proximal tubule. β_2-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, β_2-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 β_2-MG and a number of other promoters of amyloid fibril formation and deposition in osteo-articular tissues.

PRINCIPLE

The test uses an anti-human β_2-MG monoclonal antibody conjugated with fluorescence latex and another anti-human β_2-MG monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human β_2-MG monoclonal antibody binds with the β_2-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 β_2-MG monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of β_2-MG in sample.
Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of β_2-MG in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

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1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) β_2-MG test card in a sealed pouch with desiccant
2) Capillary pipet
3) Sample diluent
4) User manual: 1 piece/kit
5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein β_2-MG test cards
2) User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. 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 latex-labelled anti-human β_2-MG monoclonal antibody, the test line is coated with another anti-human β_2-MG monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30℃ with a valid period of 24 months.
Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.
For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user 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 and EDTA*** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME (***for Getein1100/Getein1160/Getein1180*** **: *10 μL*.**

TEST PROCEDURE

1. Collect specimens according to instructions for use.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:
1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. 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 into the sample well on the test card (for disposable capillary pipet using, please refer to the directions in the package).
5. ***Reaction time: 3 minutes***. Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:
1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. 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 into the sample well on the test card (for disposable capillary pipet using, please refer to the directions in the package).
6. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (3 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:
1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:
1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user

manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

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 0.80 mg/L~3.00 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	0.50~20.00 mg/L
Lower Detection Limit	≤0.50 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. 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.
2. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

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

REFERENCES

1. Madsen MG, Nørregaard R, Palmfeldt J, et al. Urinary NGAL, cystatin C, β2-microglobulin, and osteopontin significance in hydronephrotic children. Pediatr Nephrol. 2012, 27(11):2099-2106.
2. Drüeke TB. β2-microglobulin and amyloidosis. Nephrol Dial Transplant. 2000, 15 (Suppl 1):17-24.
3. Li ZM, Zhu YJ, Sun J, et al. Serum beta2-microglobin is a predictor of prognosis in patients with upper aerodigestive tract NK/T-cell lymphoma. Ann Hematol. 2012, 91(8):1265-1270.
4. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on β2-MG Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing β2-MG Fast Test Kit (Immunofluorescence Assay). Please read this instructions for use carefully before operating to ensure proper use.

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