CE IVD

One Step Test for β_2-MG

(Colloidal Gold)

User Manual Cat.# CG1011

INTENDED USE

One Step Test for β_2-MG (Colloidal Gold) is intended for *in vitro* quantitative determination of beta 2-microglobulin (β_2-MG) in serum, plasma or whole blood. 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. Effective removal of β_2-MG can be achieved with highly effective hemodialysis and hemodiafiltration techniques but predialysis session serum levels cannot be normalized. The prevalence and severity of β_2-MG amyloidosis appear to decrease in the last 20 years, although its occurrence may simply be delayed.

PRINCIPLE

The test uses an anti-human β_2-MG monoclonal antibody conjugated with colloidal gold 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 gold-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 marked antigen-antibody complex is captured on the test line by another anti-human β_2-MG monoclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of β_2-MG in sample.

Then insert test card into FIA8000 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000), the concentration of β_2-MG in sample will be measured and displayed on the screen. The value will be stored in FIA8000 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

A kit contains:

1. Getein β_2-MG test card in a sealed pouch with desiccant 25
2. Disposable pipet 25
3. User manual 1
4. SD card 1
5. Sample diluent 25

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (a colloidal gold-labelled anti-human β_2-MG monoclonal antibody is coated at the border of the nitrocellulose membrane and sample pad, 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.

Sample diluent composition:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened.
Store the sample diluent at 0~30℃ with a valid period of 24 months.
Store the sample diluent at 2~8℃ 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 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 or EDTA*** can 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 prior to testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME: ***10 µl***.

TEST PROCEDURE

1. Collect specimen according to user 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 “QC (SD)” calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, 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 ***120 µl*** of sample mixture (or 4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
8. ***Reaction time: 3 minutes.*** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

1. It is required to perform “QC (SD)” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000 to analyze the test card and get the result.
Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

EXPECTED VALUE

The expected normal value for β_2-MG was determined by testing samples from 345 apparently healthy individuals. The reference range of β_2-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	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with 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 0.988.

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. Samples containing interferents 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, β_2-microglobulin, and osteopontin significance in hydronephrotic children. Pediatr Nephrol. 2012, 27(11): 2099-2106.
2. Drüeke TB. β_2-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 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. 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 One Step Test for β_2-MG (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing One Step Test for β_2-MG (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

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