β2-MG (Beta-2-Microglobulin) Rapid Quantitative Test

(Immunofluorescence Assay)

For in vitro diagnostic use only. For professional use only.

PRODUCT NAME

β2-MG (Beta-2-Microglobulin) Rapid Quantitative Test (Immunofluorescence Assay)

MODEL

1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit;

INTENDED USE

The β2-MG Rapid Quantitative Test along with Aehealth Fluorescence Immunoassay Analyzer (FIA) is intended for in vitro quantitative determination of β2-MG in human whole blood, serum or plasma.

SUMMARY

β2-MG (Beta-2-Microglobulin) is an 11.8 kDa amino acid polypeptide that forms the light chain of Class I MHC molecules. It is normally found on nearly all nucleated cells. Circulating β2-MG is generated during normal HLA turnover. It passes through the glomerular membrane, but it is 99% actively reabsorbed and degraded in the proximal tubule cells. Clinically, serum β2-MG has been noted to be increased in inflammatory diseases, some viral infections, renal dysfunction and autoimmune diseases.

Normal Reference Value: 1.0～2.7 mg/L;
Note: It is recommended that each laboratory establish a reference range suitable for this laboratory when necessary according to the population, age, gender, diet and other conditions in their respective regions.

PRINCIPLE

The Aehealth β2-MG (Beta-2-Microglobulin) Rapid Test is based on fluorescence immunoassay technology. The Aehealth β2-MG Rapid Quantitative Test uses a competitive immune detection method, when sample is added to the sample well of the test, the fluorescence-labeled detector β2-MG antibody on the membrane binds to β2-MG antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and β2-MG are captured to β2-MG antigen that has been immobilized on test strip. Thus the more β2-MG antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of β2-MG captured and Aehealth FIA Meter shows β2-MG concentrations in blood specimen.

Insert the reacted test cassette into the matching fluorescence immunoassay analyzer, and the measurement system of the instrument will automatically scan the test area (T), and quality control area (C) and obtain optical signals. The instrument analyzes and processes the obtained optical signals to quantify the concentration of the measured substance.

COMPONENT

The product consisits of test cassette, Instructions for use, buffer(10mM, pH 7.0 phosphate buffer). And in each test cassette bag, It includes one β2-MG detection card and one package of desiccant.

Test Cassette	IC Card	Instructions for use	Buffer
25 tests	1	1	25
For each test cassette bag, it contains one test cassette and one package of desicant.			

STORAGE AND STABILITY

1. Store the detector buffer at 2～30℃. The buffer is stable up to 18 months.

2. Store Aehealth β2-MG Rapid Quantitative test cassette at 2～30℃, shelf life is up to 18 months.
3. Test cassette should be used within 1 hour after opening the pack.

Materials Supplied

- Test Cassette
- Test Cassette IC Card
- Whole Blood Buffer (sample diluent)

MATERIALS REQUIRED BUT NOT PROVIDED

- Transfer Pipette Set (10μL, 100μL size)
- Specimen Collection Containers
- Sterile Lancets (for Fingerstick Whole Blood only)
- Alcohol Pads
- Centrifuge
- Timer

WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use test cassette if its lot # does not match with IC card# that is inserted onto the equipment.
5. The Aehealth β2-MG Rapid Quantitative Test kit is only operational in the Aehealth FIA Meter.
6. Do not use the test cassette if the pouch is punctured or not well sealed.
7. The test cassette and meter should be used away from vibration and magnetic field. During normal usage, the meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens.
9. Blood specimens, used test cassettes, pipette tips and detector buffer vials should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma or whole blood.

For Whole Blood Collected by Venipuncture:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA recommended)
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3. It's not suitable to test the whole blood samples storing at 2℃～8℃ for more than 2 days.

For Serum and Plasma:

1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

TEST PROCEDURE

Refer to Aehealth FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1: Preparation

Check/ swipe the IC Card information to the equipment.

Step2: Loading

Take 10 μL of specimen, load it onto the detection buffer, Mix well, take 75 μL of the mixed solution and drop it vertically to the sample point of the test cassette, and start timing;

Step3: Testing

Timing test: Insert the test cassette onto the test cassette holder and click “Timing Test”. the result will show in the display and print out when click “Print”.
Quick test: Put the test cassette on the operation platform. 10 minutes later, insert the test cassette onto the test cassette holder and click “Quick Test”. The result will show in the display and print out when click “Print”.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum and plasma specimen.
2. The results of Aehealth β2-MG Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If β2-MG test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. EDTA other than anticoagulants (e.g. heparin or citrate) is suggested to use for plasma.
5. Other factors may interfere with Aehealth β2-MG Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Detection Limit: 0.3 mg/L;
Linear Range: 0.3~20 mg/L;
Linear correlation coefficient R ⩾ 0.990;
Precision: within batch C.V. is ⩽ 15%; between batches C.V. is ⩽ 20%;
Accuracy: the relative deviation of the measurement results shall not exceed ± 15% when standardized accuracy calibrator is tested.

INDEX OF CE SYMBOLS

	Don’t use the product when the package is damaged		Do Not Reuse
	Expiration Date		Consult Instructions For Use
2℃ 30℃	Store at 2-30℃		Date of Manufacturer
	Manufacturer	LOT	Batch Code
	Keep Away From Sunlight		Keep Day
IVD	In Virto Diagnostic medical Device	CE	CE Mark
EC REP	Authorized Representative in the European Community		

BIBLIOGRAPHY OF SUGGESTED READING

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3. Kevin T. Nead, Margaret Zhou, Roxanne Diaz Caceres, et al. Usefulness of the addition of Beta-2-Microglobulin, Cystatin C and C-reactive protein to an Established Risk Factors Model to Improve Mortality Risk Prediction in Patients Undergoing Coronary Angiography[J]. Published in final edited form as: Am J Cardiol. 2013 March 15; 111(6): 851–856.

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