β2-MG FIA Rapid Test

(Whole Blood/Serum/Plasma)

FIA-B2MG-001

A rapid test for detecting Beta 2 Microglobulin (β2-MG) in whole blood, serum, or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser. For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda β2-MG FIA Rapid Test is based on Fluorescence Immunoassay for the quantitative determination of Beta 2 Microglobulin (β2-MG) in whole blood, serum, or plasma to aid in the diagnosis of renal function.

SUMMARY

β2 microglobulin also known as B2M is a relatively small molecular weight protein with a molecular weight of 11.8 kD. It is present in all nucleated cells except red blood cells and placental trophoblasts, especially in lymphocytes and monocytes, and plays an important role in its immune response effect. The ability of tumour cells to synthesize β2-MG is also very strong. It binds to the heavy chain as a light chain of HLA with a non-covalent bond. Due to its small molecular weight, it can pass through the glomerular filtration membrane. The filtered β2-MG is almost completely reabsorbed in the proximal tubules, and the absorption rate is 99.92%. The reabsorbed β2-MG is completely degraded in the renal tubules. .

β2-MG measurement is a sensitive indicator for the diagnosis of proximal convoluted tubule injury. Blood β2-MG is elevated and urinary β2-MG is normal, mainly due to decreased glomerular filtration function, which is common in acute nephritis and renal failure. Blood β2-MG is normal and urinary β2-MG is elevated, mainly due to the obvious impairment of renal tubular reabsorption function, which is found in congenital proximal convoluted tubule function, Fanconi syndrome, and renal transplant rejection. In addition, there is a certain value in the diagnosis of tumours.

β2-MG can also be used for the diagnosis and treatment monitoring of kidney transplantation, diabetic nephropathy, gout kidney and some malignant tumours.

PRINCIPLE

The β2-MG FIA Rapid Test detects β2-MG based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains β2-MG, it attaches to the β2-MG antibody which is conjugated with fluorescent microspheres. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane. The concentration of β2-MG in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of β2-MG in the sample can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show β2-MG concentrations in specimens.

REAGENTS

The test kit includes anti-β2-MG antibody coated particles and anti-β2-MG antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda β2-MG FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyser by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

- 10 x foil wrapped β2-MG test cassettes
- 10 x Specimen collection tubes with dilution buffer
- 1 x ID card (β2-MG)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it.

BLOOD SAMPLE TAKING

1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 1 day, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 2 days of collections. Do not freeze whole blood specimens.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA, and Heparin sodium can be used as the anticoagulant for collecting the blood specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. Transfer **10 µL of whole blood, serum, or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 8 hours on an ice pack if not used immediately. Allow sample to return to room temperature before testing.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Analyser Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. **Whole blood/Serum/plasma**: Transfer 10 µl of whole blood/ serum/ plasma into the buffer tube, mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette**: Pipette 75 µl of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay

Analyser; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser for details.

"Quick test" mode: Insert the test cassette into the Analyser at 10 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.

"Standard test" mode: Insert the test cassette into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 10 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for β2-MG is calculated by the Biopanda Fluorescence Immunoassay Analyser and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser.

Working range of the Biopanda β2-MG FIA Rapid Test is 0.2~20 mg/l.
Reference range: 0.8~2.2 mg/l.

QUALITY CONTROL

Each Biopanda β2-MG FIA Rapid Test Cassette contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Analyser. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Analyser indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Biopanda β2-MG FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of β2-MG.
2. The Biopanda β2-MG FIA Rapid Test Cassette will only indicate the presence of β2-MG in the specimen and should not be used as the sole criteria for clinical evaluation.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of the Biopanda β2-MG FIA Rapid Tests are based on measuring the levels of β2-MG in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
≤2.2mg/l	Negative
>2.2mg/l	Positive

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The β2-MG FIA Rapid Test can detect levels of β2-MG as low as 0.2mg/l in Whole Blood/Serum/Plasma.
3. **LINEARITY RANGE**: 0.2~20 mg/l. R≥0.990
4. **PRECISION**
   Intra-lot precision
   Within-run precision has been determined by using 10 replicates of 2 specimens containing 0.5mg/l, 2mg/l of β2MG. C.V. is ≤ 15%.
   Inter-lot precision
   Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 0.5mg/l, 2mg/l of β2MG, C.V. is ≤15%.
5. **INTERFERING SUBSTANCES**
   The following substances do not interfere with the test results at the indicated concentrations: Hemoglobin at 10g/l, Triglyceride at 30mg/ml, Bilirubin at 0.6mg/ml, cholesterol at 60mg/ml.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Storage temperature	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's β2-MG FIA Rapid Test. Please read this manual carefully before operating to ensure proper use.

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