



# β2-MG FIA Rapid Test Device

## (Whole Blood/Serum/Plasma)

### F12-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 Device (BR-FIA-2000). For professional *in vitro* diagnostic use only.

#### INTENDED USE

The Biopanda β2-MG FIA Rapid Test Device 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 Device 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 Device (BR-FIA-2000) 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 Device should only be used with the

Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) 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

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

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

#### 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. Blood collected from fingerstick samples cannot be used.
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.

#### DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

**Note:** There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 10 minutes. *Quick Test* mode provides an instant result but the user must monitor the 10 minute test time themselves. It is suitable when running multiple tests concurrently.

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

**Allow the test cassette, 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. Remove the test cassette from the sealed foil pouch and start testing as soon as possible.
4. **Whole blood/Serum/plasma:** Transfer 10 µl of whole blood/ serum/ plasma into the buffer tube, mix the specimen and the buffer well.
5. **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.
6. Test results should be read at **10 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

#### INTERPRETATION OF RESULTS

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

Linearity range of the Biopanda β2-MG FIA Rapid Test is 0.2-20 mg/L.

### QUALITY CONTROL

Each Biopanda  $\beta$ 2-MG FIA Rapid Test Device 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 Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. 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  $\beta$ 2-MG FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of  $\beta$ 2-MG in whole blood, serum, or plasma.
2. The Biopanda  $\beta$ 2-MG FIA Rapid Test Device will only indicate the presence of  $\beta$ 2-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  $\beta$ 2-MG FIA Rapid Tests are based on measuring the levels of  $\beta$ 2-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
$\leq 2.2$ mg/l	Negative
$> 2.2$ mg/l	Positive

### PERFORMANCE CHARACTERISTICS

1. **ACCURACY:** The test deviation is  $\leq \pm 15\%$ .
2. **SENSITIVITY:** The  $\beta$ 2-MG FIA Rapid Test can detect levels of  $\beta$ 2-MG as low as 0.2mg/L in Whole Blood/Serum/Plasma.
3. **LINEARITY RANGE:** 0.2-20 mg/L.  $R \geq 0.990$
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  $\beta$ 2MG. C.V. is  $\leq 15\%$ .
  - 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  $\beta$ 2MG, C.V. is  $\leq 15\%$ .
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.
6. **METHOD COMPARISON**  
The assay was compared with commercial Turbidimetric Inhibition Immunoassay test with 100 samples. The correlation coefficient(r) is 0.990.

### Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
	<i>In vitro</i> diagnostic medical device		Expiration date		Catalogue number
	Storage temperature		Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's  $\beta$ 2-MG FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.



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