

Dengue IgG/IgM FIA Rapid Test Device (Whole Blood/Serum/Plasma) FI2-DEN-001

A qualitative rapid test for the detection of Dengue IgG/IgM antibodies 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 Dengue IgG/IgM FIA Rapid Test Device is based on Fluorescence Immunoassay for the qualitative detection of Dengue IgG/IgM antibodies in whole blood, serum or plasma as an aid in the diagnosis of dengue infections.

SUMMARY

Dengue is a flavivirus, transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitoes. It is widely distributed throughout the tropical and subtropical areas of the world,¹ and causes up to 100 million infections annually.² Classic Dengue infection is characterized by a sudden onset of fever, intense headache, myalgia, arthralgia and rash.

Primary Dengue infection causes IgM antibodies to increase to a detectable level in 3 to 5 days after the onset of fever. IgM antibodies generally persist for 30 to 90 days.³ Most Dengue patients in endemic regions have secondary infections,⁴ resulting in high levels of specific IgG antibodies prior to or simultaneous with IgM response.⁵ Therefore, the detection of specific anti-Dengue IgM and IgG antibodies can also help to distinguish between primary and secondary infections.

The Dengue IgG/IgM FIA Rapid Test Device is a rapid test that utilizes a combination of Dengue antigen coated coloured particles for the detection of IgG and IgM Dengue antibodies in human whole blood, serum, or plasma.

PRINCIPLE

The Dengue IgG/IgM FIA Rapid Test Device is a membrane based fluorescence immunoassay for the detection of Dengue antibodies in whole blood, serum, or plasma. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Dengue IgG or/and IgM, it attaches to the fluorescent microspheres-conjugated Dengue antigen. Then the complex will be captured by the capture anti-human IgM or/and anti-human IgG coated on the nitrocellulose membrane (Test line). The concentration of Dengue IgG or/and IgM in the sample correlates with the fluorescence signal intensity captured on the T line, which can be scanned by the Biopanda Fluorescence Immunoassay Device (BR-FIA-200).

REAGENTS

The test contains Dengue antigen conjugated fluorophores and anti-human IgM, anti-human IgG 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 Dengue IgG/IgM FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device 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 Dengue IgG/IgM test devices
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (Dengue IgG/IgM)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

For Venipuncture Specimens

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days, 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 run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. 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.
5. EDTA K2, Heparin sodium, Citrate sodium, and Potassium Oxalate can be used as the anticoagulant for collecting the specimen. A clean tube without anticoagulants can be used to collect serum specimens.

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 15 minutes. *Quick Test* mode provides an instant result but the user must monitor the 15 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. Transfer **5 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 Device. Start the timer at the same time.
6. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The result of tests for Dengue IgG/IgM 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 (BR-FIA-2000).

NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Reference Value. This Value is calculated that a measured signal is divided by an appropriate cutoff value.

- Test results of a Value ≥ 1.00 are considered positive for Dengue IgG and/or

IgM.

- Test results of a Value < 1.00 are considered negative for Dengue IgG and/or IgM.

QUALITY CONTROL

Each Biopanda Dengue IgG/IgM 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 Dengue IgG/IgM FIA Rapid Test Device is to be used the qualitative detection of anti-Dengue IgM/IgG from blood specimens of the symptomatic patients.
2. Failure to follow the test procedure or improper sample collection may adversely affect test performance or invalidate the test result.
3. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
4. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
5. A negative test result may occur if the level of antibody in a sample is below the detection limit of the test or if the sample was collected, transported, or stored improperly.
6. Negative test results do not rule out possible other infections.
7. Positive test results do not rule out co-infection with other pathogens.
8. The Reference Value is not a quantitative value or the rate of anti-Dengue IgG /IgM concentration. This is only a qualitative test.

REFERENCES

1. Halstead SB, Selective primary health care: strategies for control of disease in the developing world: XI, Dengue. Rev. Infect. Dis. 1984; 6:251-264.
2. Halstead SB, Pathogenesis of dengue: challenges to molecular biology. Science 1988; 239:476-481.
3. Ruechusatsawat K, et al. Daily observation of antibody levels among dengue patients detected by enzyme-linked immunosorbent assay (ELISA). Japanese J. Trop. Med. Hygiene 1994; 22: 9-12
4. Lam SK. Dengue haemorrhagic fever. Rev. Med. Micro. 1995; 6:39-48
5. Dengue haemorrhagic fever: diagnosis, treatment, prevention and control. 2nd edition. Geneva: World Health Organization.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
	<i>In vitro</i> diagnostic medical device		Expiration date		Catalogue number
	Store between 4-30°C		Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's Dengue IgG/IgM FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.



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