Dengue NS1 FIA Rapid Test Device
(Whole Blood/Serum/Plasma)
FI2-DES-001

A qualitative rapid test for the detection of Dengue NS1 antigen 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 NS1 FIA Rapid Test Device is based on Fluorescence Immunoassay for the qualitative detection of Dengue NS1 antigen 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.
NS1 is one of 7 Dengue Virus non-structural proteins which are thought to be involved in viral replication. NS1 exists as a monomer in its immature form but is rapidly processed in the endoplasmic reticulum to form a stable dimer. A small amount of NS1 remains associated with intracellular organelles where it is thought to be involved in viral replication. The rest of NS1 is found either associated with the plasma membrane or secreted as a soluble hexadimer. NS1 is essential for viral viability but its precise biological function is unknown. Antibodies raised in response to NS1 in viral infection can cross react with cell surface antigens on epithelial cells and platelets and this has been implicated in the development of Dengue Hemorrhagic fever.
The Biopanda Dengue NS1 FIA Rapid Test Device is a rapid test that utilizes a combination of Dengue antibodies coated fluorescent microspheres particles for the detection of Dengue NS1 antigen in human whole blood, serum, or plasma.

PRINCIPLE
The Dengue NS1 FIA Rapid Test Device is a membrane based fluorescence immunoassay for the detection of Dengue NS1 antigen in whole blood, serum, or plasma. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Dengue NS1 antigen, it attaches to the fluorescent microspheres-conjugated Dengue antibody. Then the complex will be captured by the capture the Anti-Dengue NS1 in test line region. The concentration of Dengue NS1 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-2000).

REAGENTS
The test cassette contains anti-Dengue Ag conjugated fluorophores and Anti-Dengue NS1 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 NS1 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 NS1 test devices
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (Dengue NS1)
- 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. **Serum/Plasma:** Transfer **75 µl of serum/plasma** into the buffer tube, mix the specimen and the buffer well.
   Whole Blood: Transfer **100 µl of whole blood** 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 NS1 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 NS1.
- Test results of a Value < 1.00 are considered negative for Dengue NS1.

QUALITY CONTROL

Each Biopanda Dengue NS1 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 NS1 FIA Rapid Test Device is to be used the qualitative detection of Dengue NS1 antigen 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. If the symptom persists, while the result from Dengue NS1 Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device such as PCR, ELISA.
7. Serological cross-reactivity across the flavivirus group (Dengue 1, 2, 3 & 4, St. Louis encephalitis, West Nile virus, Japanese encephalitis and yellow fever viruses) is common.[3,4,5] Positive results should be confirmed by other means.
8. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
9. Results from immunosuppressed patients should be interpreted with caution
10. Negative test results do not rule out possible other infections.
11. Positive test results do not rule out co-infection with other pathogens.
12. The Value is not a quantitative value or the rate of Dengue NS1 antigen 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. Science1988; 239:476-481.
3. Yamada K, et al. Antibody responses determined for Japanese dengue fever patients by neutralization and hemagglutination inhibition assays demonstrate cross-reactivity between dengue and Japanese encephalitis viruses. Clin Diagn Lab Immunol. 2003 Jul; 10(4): 725-8.
4. Dobler G, et al. Cross reactions of patients with acute dengue fever to tick-borne encephalitis. Wien Med Wochenschr (in German). 1997; 147(19-20): 463-4
5. Makino Y, et al. Studies on serological cross-reaction in sequential flavivirus Microbiol Immunol. 1994; 38(12): 951-5.

Index of Symbols

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

Thank you for purchasing Biopanda's Dengue NS1 FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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