NT-proBNP FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

Catalogue No.: FI2-PBNP-001

A Fluorescence Immunoassay for the quantitative detection of NT-proBNP in whole blood, serum or plasma samples using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE

The NT-proBNP FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of human NT-proBNP in whole blood, serum or plasma samples as an aid in the diagnosis of heart failure.

BACKGROUND

The N-terminal of the prohormone brain natriuretic peptide (NT-proBNP) is a 76 amino acid N-terminal inactive protein that is cleaved from proBNP to release brain natriuretic peptide. Both BNP and NT-proBNP levels in the blood are used for screening, diagnosis of acute congestive heart failure (CHF) and may be useful to establish prognosis in heart failure, as both markers are typically higher in patients with worse outcome. The plasma concentrations of both BNP and NT-proBNP are also typically increased in patients with asymptomatic or symptomatic left ventricular dysfunction and is associated with coronary artery disease and myocardial ischemia.

TEST PRINCIPLE

The NT-proBNP FIA Rapid Test Device detects NT-proBNP based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains NT-proBNP, it attaches to the fluorescent microspheres-conjugated anti-NT-proBNP antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of NT-proBNP 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 NT-proBNP in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) to show NT-proBNP concentration in specimen.
The minimum detection level is 300 pg/mL.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package.
3. Do not use the test if the foil pouch is damaged.
4. Do not reuse tests.
5. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
6. Do not eat, drink or smoke in the same 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 safety glasses when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Extremes of humidity and temperatures can adversely affect results.
9. Used testing material must be discarded in accordance with local regulations.
10. Read the entire procedure carefully prior to any testing.
11. The Biopanda NT-proBNP 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. Do not freeze.
2. The test must remain in the sealed pouch until use.
3. Care should be taken to protect the kit and its contents 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 CONTENTS

- 25 x Foil wrapped NT-proBNP test devices
- 25 x Specimen collection tubes with extraction buffer
- 25 x Capillary droppers
- 25 x Disposable droppers
- 1 x ID card (NT-proBNP)
- 1 x Package insert

EQUIPMENT REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed 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, store 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 finger-prick 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 repeat freeze-thaw cycles.
5. If specimens are to be transported or shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

***For Finger-pricked Whole Blood Specimens, please refer to the DIRECTIONS FOR USE for further information*.**

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device User Manual for the complete instructions on operating the device. 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 simultaneously.

Refer to the user manual for further details.

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

1. Turn on the analyzer and insert the ID card into the analyzer 'Code' port and wait for the 'ID card imported successfully' pop-up. Fill in the necessary details in the 'Test Info' section.
2. Remove the test device from the sealed foil pouch and place on a clean, level surface.
3. Follow the appropriate steps below for the prepared specimen type:
   a. **<u>For venipuncture whole blood/serum/plasma specimens:</u>**
      i. Pipette **20 µL of whole blood/serum/plasma** into the buffer tube.
      ii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.
      iii. **Pipette 75 µL of diluted specimen** into the specimen well (S) of the test device.
   b. **<u>For finger-prick whole blood specimens:</u>**
      i. Wash hands with soap and warm water or clean finger with an alcohol pad. Allow to dry.
      ii. Massage the hand without touching the puncture site by applying pressure down the hand towards the finger to be pricked. The middle or ring finger is recommended.
      iii. Use a sterile lancet (not provided) to puncture the skin and wipe away the first sign of blood.
      iv. Gently apply pressure from palm to the pricked finger so a rounded drop of blood forms over the puncture site.

v. Using the capillary dropper provided and ensuring the dropper is level, touch the open end to the rounded drop of blood without squeezing the dropper bulb. **The dropper will automatically collect the correct volume of blood (approx. 20 µL),** *see Figure 1 below*.
vi. Dispense the whole blood specimen into the buffer tube by squeezing the dropper bulb.
vii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.
viii. Using a disposable dropper, **draw the diluted specimen to the fill line** marked on the dropper (approx. 75 µL), then add to the specimen well (S) of the test device.

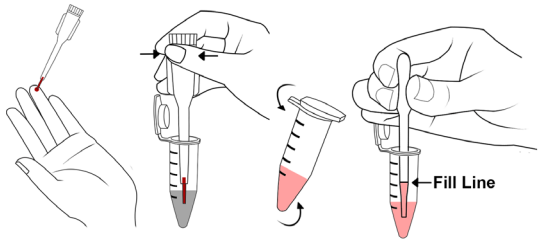

Figure 1

4. Insert the test device into the analyzer test device slot. According to user requirements, select either 'Standard test' or 'Quick test' mode.
5. **Test results should be interpreted at 15 minutes** using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

For individuals presenting symptoms of acute dyspnoea

Age	< 50 years	50–75 years	> 75 years	Acute Heart Failure (HF) Diagnosis
NT-proBNP Concentration (pg/mL)	≥ 450	≥ 900	≥ 1800	Acute HF likely
	300–400	300–900	300–1800	Acute HF less likely
	< 300	< 300	< 300	Acute HF unlikely

Test results are calculated by the Biopanda Fluorescence Immunoassay Device and displayed on the analyzer screen after testing is complete. For additional information, please refer to the user manual.

The linearity range of this test is 300–22,000 pg/mL.

Note: *Each laboratory can establish its own reference value range if necessary to ensure an accurate reflection of the situation of a particular population.*

QUALITY CONTROL

Each Biopanda NT-proBNP 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.

PERFORMANCE CHARACTERISTICS

1. **Accuracy**:
   The test deviation is ≤±15%
2. **Sensitivity**:
   The Biopanda NT-proBNP FIA Rapid Test Device can detect levels of NT-proBNP as low as 300 pg/mL in whole blood, serum or plasma.
3. **Detection range**:
   300–22,000 pg/mL
4. **Linearity range**:
   300–22,000 pg/mL, R≥0.990
5. **Precision**

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens of NT-proBNP. 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 of NT-proBNP. C.V. is ≤15%.

Cross-reactivity

Cross-reactivity studies were carried out with following analytes: HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens.
The results showed no cross-reactivity.

Interfering substances

The following potentially interfering substances were added to NT-proBNP negative and positive specimens:

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	20 mg/dL	Albumin:	10,500 mg/dL
Creatin:	200 mg/dL	Haemoglobin:	1,000 mg/dL
Bilirubin:	1,000 mg/dL	Oxalic Acid:	600 mg/dL
Cholesterol:	800mg/dL	Triglycerides:	1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

LIMITATIONS OF THE TEST

1. The Biopanda NT-proBNP FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of NT-proBNP.
2. This test will only indicate the presence of NT-proBNP in the specimen and should not be used as the sole criterion for evaluating heart failure.
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. High concentrations of NT-proBNP may produce a dose hook effect, resulting in incorrect interpretation of NT-proBNP levels. High dose hook effect has not been observed with this test for NT-proBNP levels of up to 22,000 pg/mL.
5. The haematocrit level of whole blood should be at 25%–65%.
6. Results are based on measuring the levels of NT-proBNP in a specimen. This should not be used as the sole criterion for treatment decisions. If a result is interpreted as positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

INDEX OF SYMBOLS

	Manufacturer	Σ	Tests per kit	2	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 NT-proBNP FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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