Cardiac Troponin I FIA Rapid Test
(Whole Blood/Serum/Plasma)
Catalogue Number: FIA-CTNI-001

Please read this manual carefully before operating to ensure proper use.
To be used with the Biopanda Fluorescence Immunoassay Analyser.
For professional in vitro diagnostic use only.

INTENDED USE
The Cardiac Troponin I FIA Rapid Test Cassette is intended for *in vitro* quantitative determination of human cardiac Troponin I (cTnI) in whole blood, serum or plasma samples as an aid in the diagnosis of Myocardial Infarction (MI).

BACKGROUND
Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa. Troponin I is one of three subunit complex – the other two being Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.
Troponin I is released into the blood stream 4-6 hours following acute myocardial infarction (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 6 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI. cTnI release has also been documented in cardiac conditions other than AMI, such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.
The current guidelines of The Joint European Society of Cardiology support the use of cTnI as a preferred marker of myocardial injury.

TEST PRINCIPLE
The Cardiac Troponin I FIA Rapid Test Cassette detects cardiac Troponin I (cTnI) based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains cTnI, it attaches to the fluorescent microspheres-conjugated anti-cTnI antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line).The concentration of cTnI in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of cTnI in the sample can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show cTnI concentration in specimen.

REAGENTS
The test kit includes anti-cTnI antibody coated fluorophores and anti-cTnI antibody coated on the membrane.

PRECAUTIONS
Read and follow the below points before testing:
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. Extremes of humidity and temperatures can 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 Cardiac Troponin I 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 foil pouch.
2. The test must remain in the sealed foil 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 CONTENTS
- 10 x Foil wrapped test cassettes with desiccant
- 10 x Specimen collection tubes with dilution buffer
- 10 x Capillary droppers (for finger-prick whole blood only)
- 10 x Disposable droppers (for finger-prick whole blood only)
- 1 x ID card (cTnI)
- 1 x Package insert

REQUIRED BUT NOT PROVIDED
- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION
For Venipuncture Specimens
1. Collect the specimen according to standard procedures.
2. Separate serum/plasma from whole blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens should 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 1 day; for long term storage keep below -20°C. Whole blood collected by venipuncture can be stored at 2-8°C for up to a day. 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. EDTA K2, heparin sodium, citrate sodium and potassium oxalate can be used as the anticoagulant for collecting blood specimens.

For Finger-prick Whole Blood Specimens, please refer to the DIRECTIONS FOR USE 4.2 for further information.

DIRECTIONS FOR USE
Refer to the Biopanda Fluorescence Immunoassay Analyser User Manual for the complete instructions on use of the test with the analyser. The test should be conducted at room temperature.
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 user requirements, select either "Standard test" or "Quick test" mode.
2. Take the ID card provided and insert it into the Analyser port.
3. Remove the test cassette from the sealed foil pouch and place on a clean, level surface. Start testing as soon as possible.
4. Follow the appropriate steps below for the specimen type prepared:

4.1 <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. Let the diluted specimen homogenise for approximately 1 minute. Diluted specimens should be used as soon as possible.
   iv. **Pipette 75 µl of diluted specimen** into the specimen well (S) of the test cassette and start the timer.

4.2 <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 to puncture the skin. 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), s*ee Figure 1 below*.

vi. Dispense the whole blood specimen into the buffer tube by squeezing the dropper bulb. Mix the whole blood and buffer using the same dropper by repeatedly aspirating and dispensing the solution 2-3 times.

vii. Close the tube cap and shake the tube for approximately **10 seconds** to further mix the specimen and buffer.

viii. Using a disposable dropper, **draw the diluted specimen to the fill line** marked on the dropper (approx. 75 µl), then transfer to the specimen well (S) of the test cassette. Start the timer.

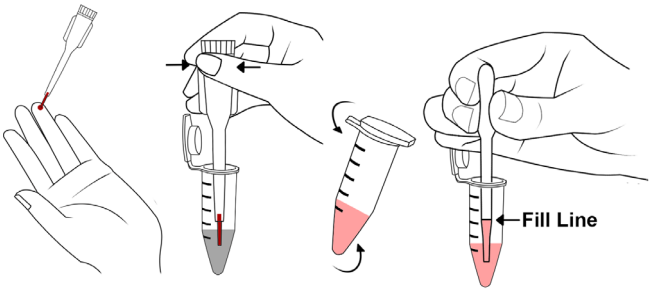

Figure 1

5. **Read results at 15 minutes** using the Biopanda Fluorescence Immunoassay Analyser.

Note: The Biopanda Fluorescence Immunoassay Analyser has two possible test modes: Standard Test mode and Quick Test mode. Please refer to the analyser manual for more details.

Quick test mode: Insert the test cassette into the analyser 15 minutes after specimen application and select "New Test". The analyser will display the test result after a few seconds.

Standard test mode: Insert the test cassette into the analyser immediately after specimen application and select "New Test". The analyser will start a timer for 15 minutes, after which the analyser will automatically display the test result.

INTERPRETATION OF RESULTS

Test results are calculated by the Biopanda Fluorescence Immunoassay Analyser and displayed on the analyser screen. For additional information, please refer to the operational manual.

Linearity range is 0.1–40 ng/ml.

QUALITY CONTROL

Each test contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient specimen 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.

EXPECTED RESULTS

Concentrations	Clinical Reference
<0.5 ng/ml	Not indicative of Acute Myocardial Infarction
>0.5 ng/ml	Indicative of Acute Myocardial Infarction

PERFORMANCE CHARACTERISTICS

1. **Accuracy**:
   The test deviation is ≤±15%.
2. **Sensitivity (Minimum detection limit)**:
   0.1 ng/ml
3. **Detection range**:
   0.1–40 ng/ml
4. **Linearity range**:
   0.1–40 ng/ml, R≥0.990
5. **Precision**

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 0.5ng/mL and 20ng/mL of cTnI. 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 0.5ng/mL and 20ng/mL of cTnI. C.V. is ≤15%.

Cross-reactivity

Cross-reactivity studies were carried out with following analytes:
10,000 ng/mL Skeletal Troponin I; 2,000 ng/mL Troponin T; 20,000 ng/mL Cardiac Myosin; 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 2 specimens containing 0.5 ng/mL and 20 ng/mL of cTnI.

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

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

6. **Method Comparison**
   The Biopanda Cardiac Troponin I FIA Rapid Test was compared with results obtained with a predicate rapid test device using 113 samples. The correlation coefficient(r) is 0.989.

LIMITATIONS OF THE TEST

1. The Biopanda Cardiac Troponin I FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of cardiac Troponin I (cTnI).
2. The test will only indicate the presence of cTnI antigens in the specimen and should not be used as the sole criterion for evaluating MI.
3. Like 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 cTnI may produce a dose hook effect, resulting in incorrect interpretation of cTnI levels. High dose hook effect has not been observed with this test up to 40mg/L of cTnI.
5. The haematocrit level of whole blood should be between 25% and 65%.
6. The test results are based on measuring the levels of cTnI 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.

SYMBOLS USED

	Manufacturer	Σ	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 Cardiac Troponin I FIA Rapid Test kit. Please read this manual carefully before operating to ensure proper use.

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