

# Cardiac Troponin T FIA Rapid Test

Catalogue Number: FIA-CTNT-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 Biopanda Cardiac Troponin T FIA Rapid Test Cassette is based on fluorescence immunoassay for the quantitative determination of cardiac troponin T (cTnT) in human whole blood, serum, or plasma as an aid in the diagnosis of myocardial infarction (MI).

## BACKGROUND

Cardiac Troponin T (cTnT) is a structurally bound protein found in striated muscle cells with a molecular weight of 37kD. Troponin T is part of a three subunit complex comprising of Troponin I 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. After acute myocardial infarction (AMI), serum cTnT levels are elevated 2 to 8 hours after onset, peaks between 12-24 hours and can persist for up to 14 days. Cardiac Troponin T (cTnT) is currently recognised as the most valuable diagnostic index for myocardial injury, and has shown broad application prospects, replacing creatine phosphate kinase MB isoenzyme (CK-MB) as the "gold standard" for judging myocardial injury, especially for diagnosing acute myocardial infarction. It plays an important role in the diagnosis of heart failure, unstable angina pectoris, myocarditis, drug-induced myocardial injury, cardiac injury monitoring in thoracic surgery, various critical diseases and multiple organ failure.

## TEST PRINCIPLE

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

## REAGENTS

The test includes anti-cTnT antibody coated fluorophore and anti-cTnT 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not interchange or mix reagents or ID cards from different lots.
7. Extremes of humidity and temperatures can affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire test procedure carefully prior to any testing.
10. The Biopanda Cardiac Troponin T FIA Rapid Test Cassette should only be used with the Biopanda Fluorescence Immunoassay Analyser by 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

### Provided:

- 10 x Foil wrapped test cassettes with desiccant
- 10 x Specimen collection tubes with buffer solution
- 10 x Capillary droppers (for finger-prick whole blood only)
- 10 x Disposable droppers (for finger-prick whole blood only)
- 1 x ID card (cTnT)
- 1 x Package insert

### Required but not provided:

- Timer
- Pipette
- Centrifuge
- 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 analyser. The test should be conducted at room temperature.

**Allow the test, 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 For venipuncture whole blood/serum/plasma specimens:**
    - 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 For finger-prick whole blood specimens:**
    - 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), see 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.

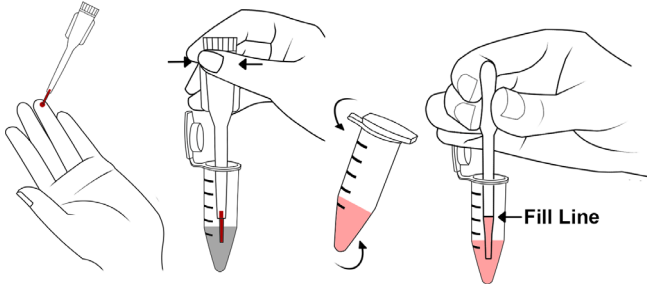


Figure 1

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 user manual.

Assay detection range is 0.2–40 ng/ml.

### QUALITY CONTROL

Each Biopanda Cardiac Troponin T FIA Rapid Test Cassette 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.

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 (AMI)
> 0.5 pg/ml	Indicative of acute myocardial infarction (AMI)

### PERFORMANCE CHARACTERISTICS

#### Accuracy

The test deviation is  $\leq \pm 15\%$

#### Sensitivity

0.2 ng/ml

#### Detection Range

0.2–40 ng/ml

#### Linearity Range

0.2–40 ng/ml,  $R \geq 0.990$

#### Precision

C.V. is  $\leq 15\%$

#### Method Comparison

The Biopanda Cardiac Troponin T FIA Rapid Test was compared with results

obtained with CLIA for 130 samples. The correlation coefficient (r) is  $R=0.992$ .

### LIMITATIONS OF THE TEST

1. The Biopanda Cardiac Troponin T FIA Rapid Test Cassette should be used only with the Biopanda Fluorescence Immunoassay Analyser.
2. The Biopanda Cardiac Troponin T FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of cardiac troponin T. This test should not be used as the sole criteria for clinical result. If the result is abnormal, other clinical findings and alternative test methods are recommended to reach proper medical treatments. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.
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 cardiac troponin T may produce a dose hook effect, resulting in an incorrect interpretation of cTnT levels. High dose hook effect has not been observed with this test up to 40 ng/ml of cTnT.
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

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test		<i>in vitro</i> diagnostic medical device
	Consult instructions for use		Batch code
	Storage temperature		Contains sufficient for <n> tests
	Catalogue number		Do not use if package is damaged

Thank you for purchasing Biopanda's Cardiac Troponin T FIA Rapid Test Kit. Please read this manual carefully before operating to ensure proper use.



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Revision Date: 02/06/2025