Cardiac Troponin T FIA Rapid Test Device

Catalogue No.: FI2-CTNT-001

For use with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda Cardiac Troponin T FIA Rapid Test Device is a 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.[1] 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.[2] 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.[3] 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.[4]

TEST PRINCIPLES

The Biopanda Cardiac Troponin T FIA Rapid Test Device detects cardiac Troponin T (cTnT) in a fluorescence immunoassay. The sample moves through the strip from the sample pad to absorbent pad. If the sample contains cTnT, it binds to the fluorescent microsphere-conjugated anti-cTnT antibodies. Any complexes will be captured by the capture antibodies coated on the nitrocellulose membrane (test line). The concentration of cTnT in the sample correlates with the fluorescence signal intensity captured on the T line. By comparing the intensity of the fluorescence signal to a standard curve, the concentration of cTnT in the sample can be calculated and displayed by the analyser.

REAGENTS

The test includes anti-cTnT detection antibody coated fluorophores and anti-cTnT capture antibody 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 samples by using a new sample collection container for each sample obtained.
4. Do not eat, drink or smoke in the area where the samples and tests are handled. Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of samples.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
6. Do not interchange or mix reagents or ID cards from different lots.
7. Humidity and temperature can adversely 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 Device 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 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

Materials Provided:

- 25 x Foil wrapped Devices
- 25 x Sample collection tubes with buffer solution
- 1 x ID card (cTnT)
- Package Insert

Materials required but not provided:

- Timer
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SAMPLE COLLECTION AND PREPARATION

Preparation and Sample Handling

- Collect the samples according to standard procedures.
- Do not leave samples at room temperature for prolonged periods. Serum and plasma samples may be stored at 2-8°C for up to 1 day. For long term storage, samples should be kept below -20°C.
  Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 1 day of collection. Do not freeze whole blood samples. Whole blood collected by finger prick should be tested immediately.
- Bring samples to room temperature (15-30°C) prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Avoid repeat freeze thaw cycles. Only use clear, non-haemolysed samples.
- EDTA, sodium citrate, can be used as the anticoagulant tube for collecting blood samples.

Sample dilution

- **75 µl of sample** (whole blood, serum or plasma) can be added directly with a micro pipette into the collection tubes with buffer solution.
- Close the lid on the tube and shake for approximately 10 seconds to mix the sample with dilution buffer well.
- Let the diluted sample homogenise for approximately 1 minute.
- The diluted sample can then be used immediately, store for no more than 2 hours at room temperature.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device User Manual for the complete instructions on use of the analyser. The test should be conducted at room temperature.

Allow the test, sample, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. **Choose test mode**: “Standard test” or “Quick test” according to requirements.
2. Take out the ID card and insert it into the ID Card Slot.
3. Remove the test Device from the foil pouch. For optimal results, perform test immediately after opening.
   Place the Device on a level and clean surface.
4. Pipette **75 µL of sample (whole blood, serum or plasma)** into the sample collection tube with buffer. Mix the sample and the buffer well.
5. Pipette **75 µL of diluted sample** into the sample well of the Device. Start the timer.
6. Test results should be interpreted at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Analyser.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. Please refer to the user manual of for full details.

“Quick test” mode: Insert the test Device into the analyser **15 minutes after sample application** and select “QUICK TEST”. Fill in the test information and select “NEW TEST”. The analyser will display the test result after a few seconds.

“Standard test” mode: Insert the test Device into the analyser immediately after sample application. Select “STANDARD TEST”, fill the test information and select "NEW TEST”, the analyser will automatically start a **15 minute timer**. The analyser will display the test result after the 15 minutes are up.

INTERPRETATION OF RESULTS

The result of each Biopanda Cardiac Troponin T FIA Rapid Test Device is

calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) 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 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 Analyser. An invalid result from the internal control causes an error "N/A" message on the analyser. Insufficient sample 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 OF THE TEST

1. The Biopanda Cardiac Troponin T FIA Rapid Test Device should be used only with the Biopanda Fluorescence Immunoassay Analyser.
2. The Biopanda Cardiac Troponin T FIA Rapid Test Device 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. A dose hook effect has not been observed in this test at up to 40 ng/ml of cTnT.
5. The haematocrit of the whole blood should be between 25% and 65%.

EXPECTED RESULTS

Concentrations	Clinical Reference
< 0.5 ng/ml	Not indicative of acute myocardial infarction (AMI)
> 0.5 ng/ml	Indicative of acute myocardial infarction (AMI)

PERFORMANCE CHARACTERISTICS

Accuracy

The test deviation is ≤±15%.

Sensitivity

The Biopanda Cardiac Troponin T FIA Rapid Test Device can detect levels of cardiac troponin T as low as 0.2 ng/ml.

Detection Range

0.2-40 ng/ml

Linearity Range

0.2-40 ng/ml, R ≥ 0.990

Precision

C.V. is ≤ 15%

REFERENCES

1. Mair, J., Artner-Dworzak, E., Lechleitner, P., Smidt, J., Wagner, I., Dienstl, F., & Puschendorf, B. (1991). Cardiac troponin T in diagnosis of acute myocardial infarction. *Clinical chemistry*, *37*(6), 845-852.
2. Mehegan, J. P., & Tobacman, L. S. (1991). Cooperative interactions between troponin molecules bound to the cardiac thin filament. *Journal of Biological Chemistry*, *266*(2), 966-972.
3. Katus, H. A., Remppis, A., Neumann, F. J., Scheffold, T., Diederich, K. W., Vinar, G., ... & Kuebler, W. (1991). Diagnostic efficiency of troponin T measurements in acute myocardial infarction. *Circulation*, *83*(3), 902-912.
4. Lv, X., Cai, X. (2012). Cardiac troponin T detection method and its clinical application. *International Journey of Laboratory Medicine*, *33*(13), 1627-2630.

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	IVD	*in vitro* diagnostic medical device
	Consult instructions for use	LOT	Batch code
	Storage temperature	Σ	Contains sufficient for <*n*> tests
REF	Catalogue number		Do not use if package is damaged

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

Biopanda Reagents Ltd.
Unit 14 Carrowreagh Business Park
Carrowreagh Road
Belfast, BT16 1QQ
United Kingdom
Tel: +44 (0) 28 95438774
E-mail: info@biopanda.co.uk
Website: www.biopanda.co.uk

Effective date: 24/01/2025