RAPID BIOTEC™

CE IVD

Cardiac Troponin T Test Device (Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-FICTNTD10/D-FICTNTD25

A Fluorescence Immunoassay for the detection of myocardial infarction (MI) to quantitatively detect cardiac Troponin T (cTnT) in human whole blood, serum or plasma with the use of the Fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

INTENDED USE
The Cardiac Troponin T Test Device (Whole Blood/Serum/Plasma) is intended for *in vitro* quantitative determination of human cardiac Troponin T in human whole blood, serum or plasma as an aid in the diagnosis of Myocardial Infarction (MI).

SUMMARY
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, peak in 12-24 hours and can persist for up to 14 days.[3] Cardiac Troponin T(cTnT) as currently recognized as the most valuable diagnostic index for myocardial injury, has shown broad application prospects and replaced 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]
The Cardiac Troponin T Test Device (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of anti-cTnT antibody coated particles and capture reagent to detect cTnT in whole blood, serum or plasma.

PRINCIPLE
The Cardiac Troponin T Test Device (Whole Blood/Serum/Plasma) detects cardiac Troponin T (cTnT) based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains cTnT, it attaches to the fluorescent microspheres-conjugated anti-cTnT antibodies. Then the complex 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. According to the fluorescence intensity of the test and product standard curve, the concentration of cTnT in the sample can be calculated by analyzer to show cTnT concentration in specimen.

REAGENTS
The test kit includes anti-cTnT antibody coated fluorophores and anti-cTnT 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 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 cTnT Test Device should only be used with the analyzer by medical professionals.

STORAGE AND STABILITY
1. The test 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.
5. 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.

SPECIMEN COLLECTION AND PREPARATION
1. Collect the specimen according to standard procedures.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
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, 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 used within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick 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 K_2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

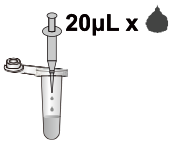
MATERIALS
Materials Provided
- Test Devices
- ID Card
- Specimen Collection Tubes with Buffer
- Package Insert
- Capillary Droppers
- Disposable Droppers

Materials Maybe Provided when Requested
- Sterile Lancets
- Alcohol Pads

Materials Required But Not Provided
- Timer
- Centrifuge
- Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

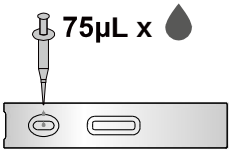
DIRECTIONS FOR USE
Refer to Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of the analyzer.
Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.
1. Turn on the Analyzer power.
2. Import the test information into the analyzer with the ID Card provided in the kit. Choose test mode and/or sample type according to needs.
3. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Place the test on a flat and clean surface.

For Venous whole blood/Serum/Plasma specimen:



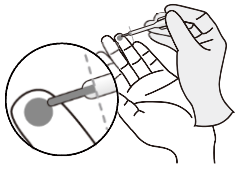
Pipette **20µL of whole blood/serum/ plasma** into the buffer tube.

Mix the specimen and the buffer well.

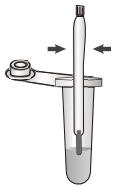


Pipette **75 µL of diluted specimen** into the sample well of the test device and start the timer.

For Fingerstick whole blood specimen:
- Wash the hand with soap and warm water or clean with an alcohol pad. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the fingerstick whole blood specimen as following:

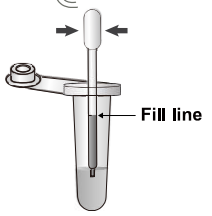


Without squeezing the **capillary dropper**, put the open end in contact with the blood. The blood will migrate into the capillary tube automatically.
Note: Make sure the dropper is **level** and do not squeeze the dropper bulb.

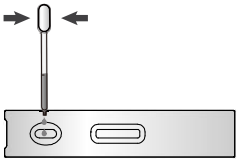


Dispense collected specimen into the buffer tube.
Mix specimen and buffer **2-3 times** by squeezing the bulb.

Mix the specimen and the buffer well.



Squeeze the bulb of the **disposable dropper and slowly release**; draw the diluted solution to the **fill line (Approx. 75µL)**.



Squeeze the bulb vertically to release **diluted solution** into the specimen well of the test device and start the timer.

5. Test results should be interpreted at **15 minutes** with the use of Fluorescence Immunoassay Analyzer.

Caution: Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF RESULTS
Results read by the Fluorescence Immunoassay Analyzer.
The result of tests for cTnT is calculated by Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.
Linearity range of cTnT Test is 0.2-40 ng/mL.

QUALITY CONTROL
Each cTnT Test Device contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test device was inserted and read properly by Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on Fluorescence Immunoassay Analyzer 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.

LIMITATIONS
1. The Cardiac Troponin T Test Device (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Cardiac Troponin T.
2. The Cardiac Troponin T Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Cardiac Troponin T antigen in the specimen and should not be used as the sole criteria for evaluating Myocardial Infarction.
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 incorrect interpretation of Cardiac Troponin T levels. High dose hook effect has not been

observed with this test up to 40ng/mL of Cardiac Troponin T.
5.The hematocrit of the whole blood should be between 25% and 65%.
6.The results of cTnT Test Devices are based on measuring the levels of cTnT 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.

EXPECTED VALUES

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
The Cardiac Troponin T Test Device (Whole Blood/Serum/Plasma) can detect levels of Cardiac Troponin T as low as 0.2ng/mL.
3. Detection range
0.2~40 ng/mL
4. Linearity range
0.2~40 ng/mL, R≥0.990
5. Precision
C.V.≤15%
6. Method comparison
The Cardiac Troponin T Test Device was compared with the results obtained with CLIA for 130 samples. The correlation coefficient (r) is R=0.992.

LITERATURE REFERENCES

1. Mair J, Artner-Dworzak E, Lechleitner P, et al. Cardiac troponin T in diagnosis of acute myocardial infarction[J]. Clin Chem, 1991, 37(6):845-852.
2. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament[J].Biol.Chem, 1991, 266:966.
3. Diagnostic efficiency of troponin T measurement in acute myocardial infarction[J]. Clin Chem, 1991, 83(3F):902-912.
4. Lv xing, Cai xiao-hui, qing zhi-ju. Cardiac troponin T detection method and its clinical application[J]. Int J Lab Med, 2012, 33(13):1627-1630.

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test		Do not reuse
IVD	*In vitro* diagnostic medical device		Use-by date	REF	Catalogue number
	Store between 4-30°C	LOT	Batch code		Date of manufacture
	Do not use if package is damaged and consult instructions for use		Manufacturer	EC REP	Authorized representative in the European Community/European Union

EC REP Advena Ltd. Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

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