GP

CE IVD

TnT

Fast Test Kit

(Immunofluorescence Assay)

IF1098 for Getein 1100
IF5098 for Getein 1160
IF3098 for Getein 1180
IF4098 for Getein 1200
IF2098 for Getein 1600
IF6098 for Getein 208

REF

User Manual

INTENDED USE

TnT Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of TnT in serum, plasma or whole blood samples. The test is indicated to be used as an auxiliary means for the early screening of acute myocardial infarction (AMI), heart failure, unstable angina pectoris, myocarditis and other myocardial injuries, it can also be used for the assessment of prognosis and risk stratification of acute pulmonary embolism and the monitoring of myocardial injury in thoracic surgery.

SUMMARY

Troponin T (TNT) is a substance that regulates the contraction of striated muscles. Although the function of TNT is the same in all rhabdom muscles, the myocardial production of TNT (TNT, molecular weight 39.7kD) is not the same as that of skeletal muscle TNT. Because of the high tissue specificity, cardiac troponin T (TnT) is a specific and highly sensitive marker of myocardial injury. Clinical studies have shown that TnT can be used for the early detection and screening of acute myocardial infarction (AMI), heart failure, unstable angina pectoris, myocarditis and other myocardial injuries, as well as for the assessment of prognosis and risk stratification of acute pulmonary embolism, and monitoring of myocardial injuries in thoracic surgery. At present, the clinical laboratory diagnostic methods of TNT include immune enhanced turbidimetry, colloidal gold assay, enzyme linked immunoassay and chemiluminescence.

PRINCIPLE

The test kit adopts a double-antibody sandwich method to quantitatively detect the concentration of TnT in human serum, plasma and whole blood samples.

After the sample has been applied to the test card, the fluorescence latex-labelled TnT monoclonal antibody Ⅰ binds with TnT in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by TnT monoclonal antibody Ⅱ coated on the detection area of nitrocellulose membrane, forming a double-antibody complex. The complex generates a fluorescent signal and the intensity increases in proportion to the amount of TnT in sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Getein208 Hand-held Integrated System/Automatically inserted by Getein1200/ Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100, Getein1160, Getein1180, Getein208, Getein1200 and Getein1600), the concentration of TnT in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/ Getein208/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180/Getein208 contains:

Package specifications: 25 tests/kit, 10 tests/kit

1) Getein TnT test card in a sealed pouch with desiccant
2) Disposable pipet
3) Whole blood buffer: 1 bottle/kit
4) User manual: 1 piece/kit
5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit

1) Sealed cartridge with 24/48 Getein TnT test cards
2) User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled TnT antibody I, the test line is coated with another TnT antibody Ⅱ and the control line is coated with goat anti-mouse immunoglobulin G antibody),absorbent paper and liner.

4. Whole blood buffer/sample diluent composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein208 Hand-held Integrated System
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.

Use the test card for Getein1100/Getein1160/Getein1180/Getein 208 within one hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. ***Serum, plasma or whole blood*** samples can be used for the test. Other body fluids and samples may not give accurate results. Samples should be free of hemolysis.
2. Venous blood should be collected under aseptic conditions; serum or plasma is preferred for testing.
3. Heparin, sodium citrate or EDTA can be used as the anticoagulant for plasma and whole blood samples.
4. The test should be performed at room temperature within 4 hours after sample collection.
5. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C and 6 months at -20°C before testing. Whole blood samples should not be frozen and can be stored at 2~8°C for 3 days. Do not heat inactivated samples or use hemolyzed blood samples.
6. Refrigerated or frozen sample should be reached to room temperature before testing. Frozen samples must be completely thawed, rewarmed and evenly mixed. Avoid multiple freeze-thaw cycles.
7. Sample volume ***(for Getein1100/Getein1160/Getein1180/ Getein208): 100μL***

TEST PROCEDURE

1.Collect specimens according to user manual.

2.Test card, sample and reagent should reach to room temperature before testing.

For Getein1100:

(1)Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.

(2)Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.

(3)Put the test card on a clean table, horizontally placed.

(4)Using sample transfer pipette, deliver ***100 μL*** of sample into the test well on the test card (for whole blood sample, one drop of whole blood buffer should be added after loading ***100 μL*** sample on the test card).

(5)***Reaction time: 15 minutes.*** Insert the test card into Getein1100 click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

(1)Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.

(2)Enter testing interface of Getein1160/Getein1180.

(3)Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.

(4)Put the test card on a clean table, horizontally placed.

(5)Using sample transfer pipette, deliver ***100 μL*** of sample into the test well on the test card (for whole blood sample, one drop of whole blood buffer should be added after loading ***100 μL*** sample on the test card).

(6)Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein208:

(1)Long press the Power Button to start the analyzer.

(2)The system will enter (Test) menu.

(3)Confirm SD card lot No.in accordance with test kit lot No.. Read the relevant information in the SD card for calibration.

(4)Insert test card according to the analyzer prompts.

Note: Do not move the test card after it is inserted.

(5)Add sample according to the analyzer prompts. Then draw ***60 μL*** of sample into the test well on the test card (for whole blood sample, one drop of whole blood buffer should be added after loading ***60 μL*** sample on the test card).

(6)After sample adding, the system starts react-time countdown automatically.

(7) After the countdown is over, the result will be shown on the screen.

For Getein1200/Getein1600:

(1)Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.

(2)Place the sample diluent at the correct position in Getein 1200/Getein1600.

(3)Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/ Getein1600 will do the testing and print the result automatically.

Notes:

1.It is required to perform “SD card” calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180/ Getein208.

2.It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180/Getein208.
3.Make sure the test card and the sample insertion are correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein208/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein208/Getein1200/Getein1600.

Others: Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ration should be less than 4 times.

EXPECTED VALUE

The expected normal value for TnT is determined by testing samples from 500 apparently healthy individuals. The upper 99th percentile value is 14.0 pg/mL.

It is recommended that each laboratory determine the applicability of the reference value through experiments and establish its own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	10.0~10000.0 pg/mL
Lower Detection Limit	≤10.0 pg/mL
Within-run Precision	≤10%
Between-run Precision	≤15%

LIMITATIONS

1. Bilirubin and triglyceride in the sample may interfere with the test results, and the maximum allowable concentrations are 0.1 mg/mL and 10 mg/mL respectively.
2. The test results of this kit are for clinical reference only, and should not be used as the sole criteria for clinical diagnosis. It is recommended to conduct a comprehensive analysis on the condition in combination with symptoms/signs, history and other laboratory tests.

REFERENCES

1. Gaggin HK, Motiwala S, Bhardwaj A, et. al. Soluble concentrations of the interleukin receptor family member cTnT and β-blocker therapy in chronic heart failure[J].Circ Heart Fail,2013,6(6):1-206-1213.
2. Weit RA, Miller AM, Murphy GE,e. al. Serum soluble cTnT A potential novel mediator in left ventricular and infarct remodeling after acute myocardial infarction[J].J Am Coll Cardiol,2010,55(3):-243-250.
3. Yu LL, Ruifrok WP, Meissner M et al. Genetic and pharmacological inhibition of galectin-3prevents cardiac remodeling by interfering with myocardial fibrogenesis[J].Circ Heart Fail,2013,6(1):107-117.
4. Marco M C, Francesca C, et al. A Novel Cardiac Bio-Marker: cTnT: A Review[J]. Molecules, 2013, 18: 15314-15328.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing TnT Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

Version: WIF69-S-05

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn,
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054