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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

Instructions for use REF

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 diagnostic 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. For professional and laboratory use.

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

TnT Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence latex-labelled TnT monoclonal antibody binds with the TnT in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another TnT monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of TnT in sample. Fluorescent signals intensity can be analyzed by applicable device thus the TnT in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
TnT test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10*0.3 mL/tube	25*0.3 mL/tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* TnT test card

A test card main consists of: Fluorescence latex-labelled TnT monoclonal antibody, TnT monoclonal antibody and polyclonal IgG antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 is 0.3 mL contained in each tube consists of:

- Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%).

(2) Sample diluent for Getein 1200/ Getein 1600 is an independent packing box consists of:

- Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%) (25 mL/bottle for Getein 1200, 30 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
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 Getein 1100/Getein 1160/Getein 1180 within one hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: 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 disposable 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 instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum, plasma and whole blood samples. Heparin, sodium citrate and EDTA** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. It is recommended to test the sample within 4 hours after collection. Stable in plasma for 5 days when stored at 2~8°C and 6 months when stored at -20°C. Stable in whole blood for 3 days when stored at 2~8°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
5. SAMPLE VOLUME: 100μL (**for Getein 1100/Getein 1160/ Getein 1180**).

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the instructions of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) Using disposable pipet or pipette, deliver ***100 μL*** of sample into one tube of sample diluent, mix thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card.
5) Reaction time: ***15 minutes***. After reaction time is elapsed, insert the test card into Getein1100 and press "ENT" button (click on "Start" icon for Android Getein1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the instructions of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
5) Using disposable pipet or pipette, deliver ***100 μL*** of sample into one tube of sample diluent, mix thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card.
6) Insert the test card into Getein 1160/Getein 1180 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 displayed automatically.

For Getein 1200/Getein 1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
2. Make sure the test card and the sample insertion are correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

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 pharmaco-logical inhibition of galectin-3prevents cardiac remodeling by interfering with myocardial fibrogenesis[J].Circ Heart Fail,20 13,6(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 TnT Fast Test Kit (Immunofluorescence Assay) 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		Caution

Thank you for using TnT Fast Test Kit (Immunofluorescence Assay). Please read this Instructions for use carefully before operating to ensure proper use.

Version: WIF69-S1-01

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