



# hs-TnT Fast Test Kit (Immunofluorescence Assay)

IF1145 for Getein 1100  
IF2145 for Getein 1600  
IF3145 for Getein 1180  
IF4145 for Getein 1200  
IF5145 for Getein 1160

## Instructions for use



## INTENDED USE

hs-TnT Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of TnT in serum, plasma or whole blood. The test is used as an aid in the diagnosis of acute myocardial infarction (AMI), heart failure, unstable angina pectoris, myocarditis, and other myocardial injuries. It is also applicable for assessing prognosis, risk stratification of acute pulmonary embolism, and monitoring myocardial injury during thoracic surgery. For professional and laboratory use only.

## 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 hs-TNT include immune enhanced turbidimetry, colloidal gold assay, enzyme linked immunoassay and chemiluminescence.

## PRINCIPLE

hs-TnT Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay designed with a sandwich format. When a

sample is applied to the test strip, the fluorescence-labeled TnT monoclonal antibody binds to the TnT in the sample, forming a labeled antigen-antibody complex. This complex then migrates to the detection zone of the test card via capillary action, where it is captured on the test line by another TnT monoclonal antibody. The fluorescence intensity at the test line increases proportionally with the amount of TnT in the sample. The fluorescent signal is analyzed by a compatible device, enabling the quantitative detection of TnT in the sample.

## 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
hs-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 tube	25 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

\* hs-TnT test card

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

\*\* Sample diluent

- Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 in each tube mainly consists of: phosphate buffer (20 mmol/L), Na<sub>3</sub> (<0.1%).
- Sample diluent for Getein 1200/ Getein 1600 is an independent packing box mainly consists of:
  - Phosphate buffer (20 mmol/L), Na<sub>3</sub> (<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:

- 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

Getein 1100 Immunofluorescence Quantitative Analyzer  
Getein 1160 Immunofluorescence Quantitative Analyzer  
Getein 1180 Immunofluorescence Quantitative Analyzer  
Getein 1200 Immunofluorescence Quantitative Analyzer  
Getein 1600 Immunofluorescence Quantitative Analyzer

## STORAGE AND STABILITY

### Realtime stability:

Store the test kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

### In-use stability:

- For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 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

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc.) when touching kits or samples.
- Proper handling and disposal methods should be followed in accordance with local regulations.

## SPECIMEN COLLECTION AND PREPARATION

- Serum, plasma, whole blood can be used as samples in the assay. Suggest using serum or plasma for better results.
- Heparin, sodium citrate and EDTA can be used as the antic-

ogulant for plasma and whole blood. Do not use hemolysis specimens.

- Serum and plasma are stable for 4 hours at room temperature (15~30°C), 5 days at 2~8°C, and 6 months at -20°C.
- Whole blood is stable for 4 hours at room temperature (15~30°C), 3 days at 2~8°C and avoid cryopreservation.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

## TEST PROCEDURE

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

### For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- 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.
- Reaction time: **15 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

### For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- 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) 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) Place the reagent cartridge in the cartridge zone. Each reagent cartridge for the Getein 1200/1600 comes with a specific RFID card (SD card) for automatic calibration.

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, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

## 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 sample diluent, and the dilution ration should be less than 4 times.

## EXPECTED VALUE

The expected normal value for hs-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	5.0~10000.0 pg/mL
Limit of Detection	≤5.0 pg/mL
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

## LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.















2. 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.

## REFERENCES

- 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.
- Weit RA, Miller AM, Murphy GE, et. 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.
- 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.
- 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 hs-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 <i>instructions for use</i> or consult <i>electronic instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult <i>instructions for use</i>
	Catalogue number		Caution

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

Version: WIF103-S-01



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