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CE IVD

hs-cTnI
Fast Test Kit
(Immunofluorescence Assay)

Instructions for Use

INTENDED USE

hs-cTnI Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cardiac Troponin I (cTnI) in human serum, plasma or whole blood samples. This test is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).
For professional and laboratory use only.

SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three regulatory proteins: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; C, which binds calcium. Cardiac Troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of Troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium.
Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarction (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.
The current guideline of The Joint European Society of Cardiology/American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current guidelines recommend using troponin results when making treatment decisions regarding unstable angina and. non-ST segment elevation MI (NSTEMI).

PRINCIPLE

hs-cTnI 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 labelled cTnI monoclonal antibody binds with the cTnI in sample and forms a marked antigen-antibody complex. The complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another cTnI monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of cTnI in sample. Fluorescent signals intensity can be analyzed by applicable device thus the cTnI in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1160/ Getein 1180		Getein 1150		Getein 1200/Getein 1600		
	10 T/kit	25 T/kit	10 T/kit	25 T/kit	2×12 T/kit	2×24 T/kit	2×48 T/kit
hs-cTnI test card*	10 pcs	25 pcs	10 pcs	25 pcs	2 cartridges, 12 pcs in each	2 cartridges, 24 pcs in each	2 cartridges, 48 pcs in each
Disposable pipet	10 pcs	25 pcs	10 pcs	25 pcs	/	/	/
Sample diluent**	10 tubes	25 tubes	10 tubes	25 tubes	1 box	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	/	/	1 pc in each cartridge	1 pc in each cartridge	1 pc in each cartridge

* hs-cTnI test card
A test card mainly consists of: Fluorescence labelled cTnI monoclonal antibody, cTnI monoclonal antibody.
** Sample diluent
(1) Sample diluent for Getein 1150/Getein 1160/Getein 1180 in each tube mainly consists of: phosphate buffer, NaN_3 (< 0.1%).
(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:
- phosphate buffer, NaN_3 (< 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. The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
3. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1150 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 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 1150/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

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until performing the test.
5. Samples must be added using the disposable pipet in the kit to avoid incorrect results. Do not reuse the disposable pipet.
6. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
7. It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum, plasma and whole blood samples. Heparin 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. Serum and plasma are stable for 4 hours at room temperature (15–30°C), 7 days at 2–8°C, and 6 months at -20°C.
4. Whole blood is stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

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 1160/Getein 1180:
1) Confirm SD card lot No.in accordance with the test kit lot No., perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (refer to the analyzer user manual for details).
3) Remove test card and disposable pipet from the sealed pouch immediately before use and put them on a clean table, horizontally placed.
4) Insert the disposable pipet into the sample, press the cap of the disposable pipet to the bottom, and deliver 100 µL of sample into one tube of sample diluent.
5) Press the cap of the disposable pipet to mix the sample until the lyophilized pellet is completely dissolved.
6) Deliver the sample mixture by pushing the cap of the disposable pipet and drop the sample mixture into the sample well on the test card.

Note: Please add samples mixture **immediately** after mixing. Adding samples mixture in advance or delay may not get the correct test results.
7) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1150:
1) Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code (**On the outer packaging box**) to complete calibration as prompted by the instrument.
2) Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
3) Insert the disposable pipet into the sample, press the cap of the disposable pipet to the bottom, and deliver 100 µL of sample into one tube of sample diluent.
4) Press the cap of the disposable pipet to mix the sample until the lyophilized pellet is completely dissolved.
5) Deliver the sample mixture by pushing the cap of the disposable pipet and drop the sample mixture into the sample well on the test card.

Note: Please add samples mixture **immediately** after mixing. Adding samples mixture in advance or delay may not get the correct test results.

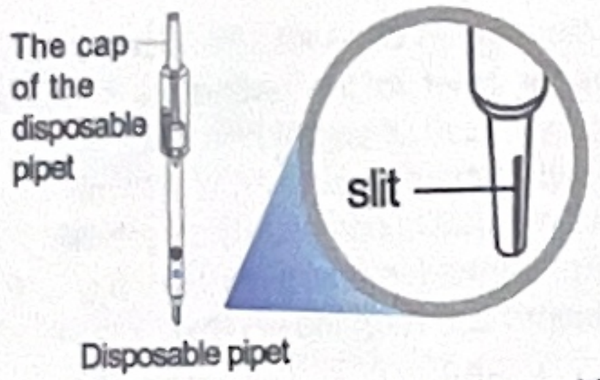
7) Press the "Start" button **immediately** after sample loading. The analyzer will initiate a 10-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD 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, 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.

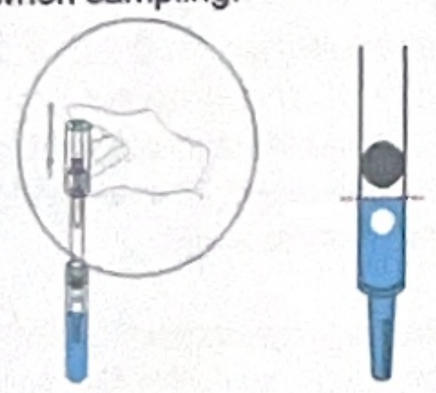
Precautions for Using Disposable Pipet

Note 1: Ensure the slit is fully submerged in the sample during sampling.

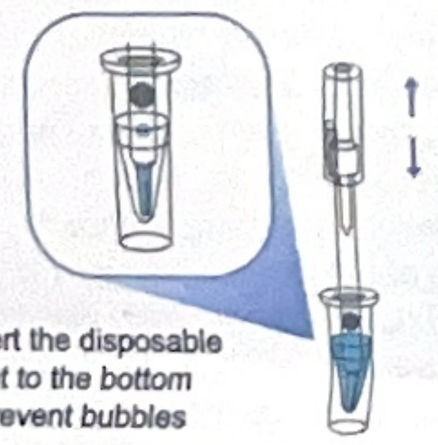


Disposable pipet

Note 2: Press the cap of the disposable pipet with your finger during sampling and do not repeatedly press the cap of the disposable pipet when sampling.



Note3: When mixing and sampling. Insert the disposable pipet to the bottom of tube to avoid the formation of bubbles.



Insert the disposable *pipet to the bottom to prevent bubbles*

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. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	500 mg/dL	1000 mg/dL	20 mg/dL

3. Patient samples may contain heterophilic antibodies (e.g. human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react in immunoassays to give a falsely elevated or depressed result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed.
4. The test was evaluated for cross-reactivity according to CLSI EP07-A3. The following substances do not cross-react when present in sample at the concentrations indicated.

Cross-reacting substances	cTnC	cTnT	sTnI
Concentration (Max)	1000 ng/mL	1000 ng/mL	1000 ng/mL

EXPECTED VALUE

The expected normal value for hs-cTnI was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for hs-cTnI is 0.040 ng/ml. (The probability that value of a normal person below 0.040 ng/ml is 99%.)

Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.010–50.000 ng/ml
Limit of Detection	≤ 0.010 ng/ml
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

REFERENCES

1. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction; A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of patients with acute myocardial infarction). J Am Coll Cardiol. 2004, 44 (3): E1-E211.
2. Kristian Thygesen, Joseph S Alpert, et al. Fourth Universal Definition of Myocardial Infarction (2018). J Am Coll Cardiol 2018, Aug 25: [Epub ahead of print];
3. Yader S, Korosh S, et al. Clinical Use of Cardiac Troponin for Acute Cardiac Care and Emerging Opportunities in the Outpatient Setting[J]. Minerva Medica, 2019, 110 (2): 139-56.
4. Ibanez B, James S, Agewall S, Antunes MJ, Bucciarelli-Ducci C, Bueno H, et al. 2017 ESC Guidelines for the Management of Acute Myocardial Infarction in Patients Presenting with ST-Segment Elevation: the Task Force for the Management of Acute Myocardial Infarction in Patients Presenting with ST-Segment Elevation of the Europea Society of Cardiology. Eur Heart J 2018,39:119-77

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on hs-cTnI 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	EU REP	Authorized representative
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		Keep dry
	Keep away from sunlight		Caution
UDI	Unique device identifier		

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

Version: WIF67-SD-02

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Catalogue number	Applicable analyzer	Package specification
IF8019-10T	Getein 1150	10 T/kit
IF8019	Getein 1150	25 T/kit
IF5019-10T	Getein 1160	10 T/kit
IF5019	Getein 1160	25 T/kit
IF3019-10T	Getein 1180	10 T/kit
IF3019	Getein 1180	25 T/kit
IF4019-24T	Getein 1200	2×12 T/kit
IF4019	Getein 1200	2×24 T/kit
IF4019-96T	Getein 1200	2×48 T/kit
IF2019-24T	Getein 1600	2×12 T/kit
IF2019	Getein 1600	2×24 T/kit
IF2019-96T	Getein 1600	2×48 T/kit