GP

CE IVD

Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)

Instructions for Use

INTENDED USE

Cardiac Troponin I 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

Cardiac Troponin I 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	
	10 T/kit	25 T/kit	10 T/kit	25 T/kit
cTnI test card*	10 pcs	25 pcs	10 pcs	25 pcs
Disposable pipet	10 pcs	25 pcs	10 pcs	25 pcs
Sample diluent**	10 tubes	25 tubes	10 tubes	25 tubes
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	/	/

* cTnI test card

A test card mainly consists of: Fluorescence labelled cTnI monoclonal antibody, cTnI monoclonal antibody.

** Sample diluent

Sample diluent for Getein 1150/Getein 1160/Getein 1180 in each tube mainly consists of: phosphate buffer, NaN_3 (< 0.1%).

Note:

1. The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.
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

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:

Use the test card within 1 hour once the foil pouch is opened.

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 disposable pipet cap at least 5 times to aspirate and mix the sample. After mixing, drop 100 μL of 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.

6) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will initiate a 10-minute reaction countdown 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.

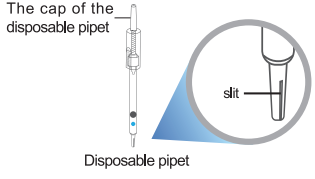
2) Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
3) Insert the disposable pipet into the sample, press the cap of the disposable pipet to the bottom, and deliver 100 µL of sample into one tube of sample diluent.
4) Press the disposable pipet cap at least 5 times to aspirate and mix the sample. After mixing, drop 100 µL of 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.

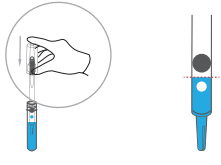
5) Press the "Start" button immediately after sample loading. The analyzer will initiate a 10-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion

Precautions for Using Disposable Pipet

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



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.

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 cTnI was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.10 ng/mL. (The probability that value of a normal person below 0.10 ng/mL is 99%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10–50.00 ng/mL
Limit of Detection	≤ 0.10 ng/mL
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

REFERENCES

1. Mauro Pantaghini. Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. 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 Manage 2004).
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cardiac Troponin I 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 Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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Catalogue number	Applicable analyzer	Package specification
IF8001-10T	Getein 1150	10 T/kit
IF8001	Getein 1150	25 T/kit
IF5001-10T	Getein 1160	10 T/kit
IF5001	Getein 1160	25 T/kit
IF3001-10T	Getein 1180	10 T/kit
IF3001	Getein 1180	25 T/kit