



# Cardiac Troponin I Fast Test Kit

## User Manual

**REF** CG1001 for FIA8000  
CG3001 for FIA8600

### INTENDED USE

Cardiac Troponin I Fast Test Kit is intended for *in vitro* quantitative determination of cardiac Troponin I (cTnI) in serum, plasma or whole blood. 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).

### 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 subunits: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and 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 infarctions (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

The test uses an anti-human cTnI monoclonal antibody conjugated with colloidal gold and another anti-human cTnI monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human cTnI monoclonal antibody binds with the cTnI 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 the anti-human cTnI monoclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of cTnI in sample.

Then insert test card into FIA8000/FIA8600 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000 and FIA8600), the concentration of cTnI in sample will be measured and displayed on the screen. The value will be stored in FIA8000/FIA8600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

### CONTENTS

#### 1. A kit for FIA8000/FIA8600 contains:

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

- 1) Getein cTnI 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 test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad (coated with a gold-labelled anti-human cTnI monoclonal antibody), nitrocellulose membrane (the test line is coated with another anti-human cTnI monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

#### 3. Whole blood buffer composition:

Phosphate buffered saline, proteins, detergent, preservative,

stabilizer.

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

### APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer  
FIA8600 Quantitative Immunoassay Analyzer

### STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened.

### 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 is damaged.
5. Do not open pouches 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. This test can be used for **serum, plasma and whole blood samples**. **Heparin and sodium citrate** can 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 or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME: **120 µL**.

### TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in according with test kit lot No.. Perform calibration when necessary (Details refer to FIA8000/8600 User Manual).
4. On the main interface of FIA8000/FIA8600, press "ENT" button (FIA8000) or click on "Measure" icon (FIA8000/8600) to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver **120 µL** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 µL sample on the test card).
8. **Reaction time: 15 minutes.** Insert the test card into FIA8000 /FIA8600, press "ENT" button (FIA8000) or click on "Measure" icon (FIA8000/FIA8600) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

#### Notes:

1. It is required to perform calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits.
3. Make sure the test card insertion is correct and complete.

#### TEST RESULTS

**Valid:** When a purplish-red band appears at the control area (C), use FIA8000/FIA8600 to analyze the test card and get the result.

**Invalid:** If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

**Others:** Dilute the sample which concentration is higher than the upper limit with calf serum, the dilution ratio should be less than 5 times.

#### EXPECTED VALUE

The expected normal value for cTnI was determined by testing samples from 500 apparently healthy individuals. The 99<sup>th</sup> percentile of the concentration for cTnI is 0.50 ng/ml. (The probability that value of a normal person below 0.50 ng/ml is 99%). It is recommended that each laboratory establish its own

expected values for the population it serves.

#### PERFORMANCE CHARACTERISTICS

Measuring Range	0.50~50.00 ng/ml
Lower Detection Limit	≤ 0.50 ng/ml
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%
Recovery	95% (mean)

#### 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)	5 g/L	10 g/L	0.2 g/L

#### REFERENCES

1. Mauro Pantanghini; 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 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		Batch code
	Temperature limit		In vitro 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 instructions for use
	Catalogue number		

Thank you for purchasing Cardiac Troponin I Fast Test Kit. Please read this user manual carefully before operating to ensure proper use.

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