CE IVD

# One Step Test for CK-MB/cTnI

## (Colloidal Gold)

**Instructions for Use** REF CG1012 for FIA8000 CG3012 for FIA8600

## INTENDED USE

One Step Test for CK-MB/cTnI (Colloidal Gold) is intended for *in vitro* quantitative determination of CK-MB/cTnI in serum, plasma or whole blood. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of myocardial injury such as Acute Myocardial Infarction, Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

## SUMMARY

Creatine kinases are dimer isozymes composed of two monomer subunits, CK-M (for skeletal muscle derived) and CK-B (for brain derived), which can form all three combinations of monomers: CK-BB, CK-MM, and CK-MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with trace amount of MB (around 1-4% of total CK activity). Cardiac muscles also contain the MM isoform, but higher amount of MB, typically around 20% of total CK activity. CK-MB is a more sensitive marker of myocardial injury than total CK activity, because it has a lower basal level and a much narrower normal range. Medical literatures commonly state that CK-MB levels are elevated in 4 to 6 hours, peak at 10 to 24 hours, and return to normal within 3 to 4 days after an acute myocardial infarction. Classically, an increase of the myocardial-specific enzyme CK-MB is considered as the hallmark of acute myocardial infarction, and increased levels are frequently interpreted by the clinician as objective evidence of myocardial cell damage.

Troponin complex 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; 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 myocardia.

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.

## PRINCIPLE

Mixed monoclonal antibodies against human CK-MB and cTnI were conjugated with colloidal gold and another set of anti-human CK-MB/cTnI monoclonal antibodies were coated on different test lines respectively. After the sample has been applied to the test strip, the gold-labelled anti-human CK-MB and cTnI monoclonal antibodies will bind with the CK-MB and cTnI in sample respectively and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by another set of monoclonal antibody against human CK-MB or cTnI respectively resulting in purplish red streaks appear on the test lines. The color intensity of each test line increases in proportion to the amount of CK-MB or cTnI in sample.

Then insert test card into FIA8000/FIA8600 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000 and FIA8600), the concentrations of CK-MB and cTnI in sample will be determined 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 CK-MB/cTnI test card in a sealed pouch with desiccant

2）Disposable pipet

3）Whole blood buffer: 1 bottle/kit

4）Instructions for use: 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 gold-labeled anti-human CK-MB and cTnI monoclonal antibodies), nitrocellulose membrane with 2 test lines (two test lines are coated with another anti-human CK-MB and another anti-human cTnI monoclonal antibody， respectively, and the control line C 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℃ 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. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. 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 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℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
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 instructions for use.
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 Instructions for Use).
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 120μL 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 CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99$^{th}$ percentile of the concentration for CK-MB is 5.00 ng/ml. (The probability that value of a normal person below 5.00 ng/ml is 99%.)

The expected normal value for cTnI was determined by testing samples from 500 apparently healthy individuals. The 99$^{th}$ 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

| | CK-MB | cTnI |
|---|---|---|
| Measuring Range | 2.50~80.00 ng/ml | 0.50~50.00 ng/ml |
| Lower Detection Limit | ≤ 2.50 ng/ml | ≤ 0.50 ng/ml |
| Recovery | 96%(mean) | 95%(mean) |
| Within-Run Precision | ≤10% | |
| Between-Run 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. Interferents in samples may influence the results.The table below listed the maximum allowance of these potential interferents.

| Interferent | Hemoglobin | Triglyceride | Bilirubin |
|---|---|---|---|
| Concentration (Max) | 10 g/L | 10 g/L | 0.2 g/L |

## 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 One Step Test for CK-MB/cTnI (Colloidal Gold) 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 | | |

Thank you for purchasing One Step Test for CK-MB/cTnI (Colloidal Gold). Please read this instructions for use carefully before operating to ensure proper use.

Version: WCG23-DL-S-09



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