CE IVD

One Step Test for CK-MB/cTnI/Myo

(Colloidal Gold)

User Manual REF CG2005

INTENDED USE

One Step Test for CK-MB/cTnI/Myo (Colloidal Gold) is intended for *in vitro* qualitative and semi-quantitative determination of CK-MB/cTnI/Myo 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 (AMI), 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.

Myoglobin is a small monomeric protein which serves as an intracellular oxygen storage site. It is found in abundance in the muscle and can get through into the blood circulation directly when myocardial cell is damaged mildly. Therefore, myoglobin has been advocated as a sensitive marker for early acute myocardial injury by American College of Cardiology Committee.

PRINCIPLE

Mixed monoclonal antibodies against human CK-MB, cTnI and Myo were conjugated with colloidal gold and another set of anti-human CK-MB/cTnI/Myo 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, cTnI and Myo monoclonal antibodies will bind with the CK-MB, cTnI and Myo 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, cTnI or Myo 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, cTnI or Myo in sample.

CONTENTS

A kit contains:

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

1. Getein CK-MB/cTnI/Myo test card in a sealed pouch with desiccant
2. Disposable pipet
3. User manual: 1 piece/box
4. Standard colorimetric card: 1 piece/box
5. Whole blood buffer: 1 bottle/box

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloid gold pad (coated with gold-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies), nitrocellulose membrane with 3 test lines (these three lines are coated with another anti-human CK-MB, another anti-human cTnI and another anti-human Myo monoclonal antibody, respectively, and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Whole blood buffer composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

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

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months.
Use the test card within 1 hour once the foil pouch is opened.
Store the whole blood buffer at 0~30℃ with a valid period of 24 months.
Store the whole blood buffer at 2~8℃ for better results.

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 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*** 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 or plasma can be used directly. For whole blood sample, whole blood buffer must be added before testing.
4. If testing will be 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: ***80 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. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver ***80 µl*** of sample (or 3 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 80 µl sample on the test card).
6. ***Read the results visually in 15~30 minutes.*** For semi-quantitative interpretation of results, please refer to the standard colorimetric card.

TEST RESULTS

Negative: A single purplish red band appears at the control area (C) without any other band at test lines is a valid negative result, indicating the concentration of CK-MB/cTnI/Myo in sample is below the cut-off value.
Positive: A single purplish red band appears at the control area (C) and purplish red colored bands appear in test lines is a valid positive result. The intensity of the purplish red color in each test line helps to read the semi-quantitative result visually according to the standard colorimetric card:

Color intensity	Reference Concentration (ng/ml) CK-MB	cTnI	Myo
−	<2.5	<0.5	<30
+−	2.5~5	0.5~1	30~70
+	5~20	1~5	70~150
++	20~50	5~15	150~300
+++	50~80	15~30	300~600
++++	>80	30~50	>600
++++		>50	

Invalid: If no colored band appears in the control area (C) in 15~30 minutes, 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.

EXPECTED VALUE

The expected normal value for CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th 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 99th 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%.)
The expected normal value for Myo was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for Myo is 50.0 ng/ml. The 97.5th percentile of the concentration for Myo is 70.0 ng/ml. (According to different Statistics methods, the probability that value of a normal person below 50.0 ng/ml is 95% or below 70.0 ng/ml is 97.5%.)
It is recommended that each laboratory establish its own expected values for the population it serves.

LIMITATIONS

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.

REFERENCES

1. Mauro Pantaghini. Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).Scienific 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 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for CK-MB/cTnI/Myo (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 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult 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
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

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

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