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CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay)

IF1005 for Getein1100
IF3005 for Getein1180
IF4005 for Getein1200
IF2005 for Getein1600
IF5005 for Getein1160
IF6005 for Getein208

REF

User Manual

INTENDED USE

CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of CK-MB/cTnI/Myo in human serum, plasma or whole blood samples. 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 myocardialspecific 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, and can be elevated 1~2 hours after myocardial injury. 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 are conjugated with fluorescence latex 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 fluorescence latex-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 antibodies against human CK-MB, cTnI or Myo respectively resulting in the accumulation of fluorescence particles on the test lines. The fluorescence intensity of each test line increases in proportion to the amount of CK-MB, cTnI or Myo in sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Getein208 Hand-held Integrated System /automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein208, Getein1200 and Getein1600), the concentrations of CK-MB, cTnI and Myo in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein208/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to LIS and HIS.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/box, 10 tests/box
1) CK-MB/cTnI/Myo test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/box
4) SD card: 1 piece/box
5) Whole blood buffer: 1 bottle/box

2. A kit for Getein1160/Getein1180/Getein208 contains:
Package specifications: 25 tests/box, 10 tests/box
1) CK-MB/cTnI/Myo test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box

3. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein CK-MB/cTnI/Myo test cards
2) User manual: 1 piece/box
Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

4. Sample diluent/Whole blood buffer composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

5. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies, 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.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein208 Hand-held Integrated System
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100/Getein1160/Getein1180/Getein-208 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: 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. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge 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 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 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 ***(for Getein1100/Getein1160/Getein1180): 100 μL.***

(for Getein208): 70 μL.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform SD card calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading ***100 μL*** sample on the test card).
7. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

8. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card"calibration when necessary.
9. Enter testing interface of Getein1160/Getein1180.
10. Remove the test card from the sealed pouch immediately before use.Label the test card with patient or control identifi-

cation.

11. Put the test card on a clean table,horizontally placed.
12. Using sample transfer pipette, deliver ***100μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100μL*** of sample mixture into the sample port on the test card.
13. ***Reaction time: 10 minutes.*** Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein208:

14. Long press the Power Button to start the analyzer
15. The system will enter (Test) menu.
16. Insert the MEMo memory chip which is with the same batch number as the test card.
17. Select (Test) menu, press (OK) to enter [Read Calibration Card] interface.
18. Press (OK) to automatically obtain the test item, batch number, serial number and sampling volume. Select the sample type by pressing＜or＞buttons.
19. Press (OK). The screen then prompts [Insert test card] and starts counting down from 60 sec. Insert test card within the 60 sec.

Note: Do not move the test card after it is inserted.

20. Add sample within 120 sec when the screen prompts [Wait for sample]. Then draw ***70 μL*** of sample and drop it into 150 μL of sample diluent. Then drop ***70 μL*** of sample mixture into the sample port on the test card.
21. After sample adding, the system starts react-time countdown automatically.
22. After the countdown is over, the system starts testing automatically. Please check and record test results then.

Note: Test results are saved automatically in the system.

23. Long Press (OK) to return to the main interface. Take out and discard the test card.

For Getein1200/Getein1600:

24. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
25. Place the sample diluent at the correct position in Getein1200/Getein1600.
26. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/ Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform SD card calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180/ Getein208.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180/Getein208.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein208/Getein1200/ Getein1600 can scan the test card auto-matically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/ Getein208/Getein1200/Getein1600.

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 0.10 ng/ml. (The probability that value of a normal person below 0.10 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 method, 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.

PERFORMANCE CHARACTERISTICS

	CK-MB	cTnI	Myo
Measuring Range	2.50~80.00 ng/ml	0.10~50.00 ng/ml	30.0~600.0 ng/ml
Lower Detection Limit	≤ 2.50 ng/ml	≤ 0.10 ng/ml	≤ 30.0 ng/ml
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. Samples containing interferents 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 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 CK-MB/ cTnI/Myo Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail 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 CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China.
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn, overseas@getein.com.cn
Website: www.getein.com

EC REP Lotus NL B.V.
Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com
Tel: +31644168999