



CK-MB Fast Test Kit (Immunofluorescence Assay)

Instructions for use

INTENDED USE

CK-MB Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of CK-MB in human serum, plasma or whole blood. This test is used as an aid in the diagnosis, prognosis and evaluation 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

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.

PRINCIPLE

CK-MB Fast Test Kit (Immunofluorescence Assay) is a lateral

immunoassay designed with a sandwich format. When a sample is applied to the test strip, the fluorescence-labeled CK-MB monoclonal antibody binds to the CK-MB in the sample, forming a labeled antigen-antibody complex. This complex then migrates to the detection zone of the test card via capillary action, where it is captured on the test line by another CK-MB monoclonal antibody. The fluorescence intensity at the test line increases proportionally with the amount of CK-MB in the sample. The fluorescent signal is analyzed by a compatible device, enabling the quantitative detection of CK-MB in the sample.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180/		Getein 1150		Getein 1200/Getein 1600		
	10 T/kit	25 T/kit	10 T/kit	25 T/kit	2×12 T/kit	2×24 T/kit	2×48 T/kit
CK-MB test card*	10 pcs	25 pcs	10 pcs	25 pcs	2 cartridges, 12 pcs in each	2 cartridges, 24 pcs in each	2 cartridges, 48 pcs in each
Disposable pipet	10 pcs	25 pcs	10 pcs	25 pcs	/	/	/
Sample diluent**	10 tubes	25 tubes	10 tubes	25 tubes	1 box	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	/	/	1 pc in each cartridge	1 pc in each cartridge	1 pc in each cartridge

* CK-MB test card

A test card mainly consists of: Fluorescence labelled CK-MB monoclonal antibody, CK-MB monoclonal antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180 in each tube mainly consists of: phosphate buffer (20 mmol/L), Na₂S₂O₃ (< 0.1%).

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:

- Phosphate buffer (20 mmol/L), Na₂S₂O₃ (< 0.1%) (25 mL/bottle for Getein 1200, 30 mL/bottle for Getein 1600),

- Box with pipette tips (96 tips/box),

- Mixing plate (1 piece/box).

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 1100 Immunofluorescence Quantitative Analyzer

Getein 1150 Immunofluorescence Quantitative Analyzer

Getein 1160 Immunofluorescence Quantitative Analyzer

Getein 1180 Immunofluorescence Quantitative Analyzer

Getein 1200 Immunofluorescence Quantitative Analyzer

Getein 1600 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:

For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: 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. 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 or the cartridge is damaged.

4. Do not open pouches until performing the test.

5. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.

6. It is recommended that operators take necessary

self-protection measures (work clothes, goggles and disposable gloves, etc.) when touching kits or samples.

7. Proper handling and disposal methods should be followed in accordance with local regulations.

SPECIMEN COLLECTION AND PREPARATION

1. Serum, plasma, whole blood can be used as samples in the assay. Suggest using serum or plasma for better results.

2. Heparin and EDTA can be used as the anticoagulant for plasma and whole blood. Do not use hemolysis specimens.

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.

6. **SAMPLE VOLUME (for Getein 1100/Getein 1150/Getein 1160/Getein 1180): 100 μ L**

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 1100:

(1) Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.

(2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).

(3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.

(4) Using disposable pipet or pipette, deliver **100 μ L** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 μ L** of sample mixture into the sample well on the test card.

(5) **Reaction time: 10 minutes.** After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button

(click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Using disposable pipet or pipette, deliver **100 µL** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (**10 minutes**) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1150:

- 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.
- Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
- Using disposable pipet or pipette, deliver **100 µL** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- 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.

For Getein 1200/Getein 1600:

- Place the reagent cartridge in the cartridge zone. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
- Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder,

insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

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.
- 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

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%.)

It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	2.50–80.00 ng/mL
Limit of Detection	2.50 ng/mL
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

REFERENCES

- 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.
- 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 Management 2004).

- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CK-MB 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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Keep dry
	Keep away from sunlight		Caution
	Unique device identifier		

Thank you for purchasing CK-MB 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
IF1018-10T	Getein 1100	10 T/kit
IF1018	Getein 1100	25 T/kit
IF8018-10T	Getein 1150	10 T/kit
IF8018	Getein 1150	25 T/kit
IF5018-10T	Getein 1160	10 T/kit
IF5018	Getein 1160	25 T/kit
IF3018-10T	Getein 1180	10 T/kit
IF3018	Getein 1180	25 T/kit
IF4018-24T	Getein 1200	2×12 T/kit
IF4018	Getein 1200	2×24 T/kit
IF4018-96T	Getein 1200	2×48 T/kit
IF2018-24T	Getein 1600	2×12 T/kit
IF2018	Getein 1600	2×24 T/kit
IF2018-96T	Getein 1600	2×48 T/kit