图纸名称	外贸荧光CK-MB/cTnI/H-FABP说明书	图纸编号	WIF21-S-08	尺　寸	210*140mm	设　计	梁安琪

基蛋生物 GeteinBiotech

适用范围：外贸荧光CK-MB/cTnI/H-FABP

变更内容：1. 升级
2. 增加1160和1200机型

技术要求：1. 图案样式大小参照图纸，以样品为准
2. 材质：105g铜版，纸质厚度均一
3. 图案清晰、完整、色彩均一，无明显色差、外观整洁
4. 文字内容正确，无重影、模糊不清，排版正确，字体不易刮花

颜色色值：C M Y K100

140mm

CE IVD

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

User Manual REF IF1016 for Getein1100 IF5016 for Getein1160 IF2016 for Getein1600 IF4016 for Getein1200

INTENDED USE
CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of CK-MB/cTnI/H-FABP 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 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 r egulatory 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 cardiac 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.
H-FABP (Heart-type Fatty Acid Binding Protein) that finds in abundance in cardiomyocytes is one of the Fatty acid-binding proteins (FABPs). The molecular weight of H-FABP is about 15 kDa, the combination of their low molecular weight and cytoplasmic location means that H-FABP proteins are released very rapidly following Acute Myocardial Infarction (AMI). H-FABP has been repeatedly shown to a highly sensitive early rise biomarker across the full spectrum of ACS, detectable as early as 30 minutes following the onset of an ischemic episode.

PRINCIPLE
Mixed monoclonal antibodies against human CK-MB, cTnI and H-FABP are conjugated with fluorescence latex and another set of anti-human CK-MB/cTnI/H-FABP monoclonal antibodies are coated on different test lines respectively. After the sample has been applied to the test strip, the fluorescence latex-labeled anti-human CK-MB, cTnI and H-FABP monoclonal antibodies will bind with the CK-MB, cTnI and H-FABP 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 H-FABP 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 and H-FABP in sample.
Insert test card into Getein1100/Getein1160 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600/Getein1200 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100/Getein1160 and Getein1600/Getein1200), the concentration of CK-MB, cTnI and H-FABP in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1600/Getein1200 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS
1. A kit for Getein1100/Getein1160 contains:
Package specifications: 25 tests/box, 10 tests/box
1) CK-MB/cTnI/H-FABP 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 Getein1600/Getein1200 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein CK-MB/cTnI/H-FABP test cards
2) User manual: 1 piece/box
Materials required for Getein1600/Getein1200:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

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

4. 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-labeled anti-human CK-MB, cTnI and H-FABP monoclonal antibodies, three test lines are coated with another anti-human CK-MB, another anti-human cTnI and another anti-human H-FABP monoclonal antibody, respectively. and the control line 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
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY
Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100/Getein1160 within 1 hour once the foil pouch is opened.
For test card of Getein1600/Getein1200: 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.
Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.
Store the sample diluent/whole blood buffer at 2~8°C 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, whole blood***. ***EDTA or Heparin*** can be used as the anticoagulant for plasma and whole blood sample. Samples should be free of hemolysis.
2. Serum or plasma are suggested for better result.
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 test (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature (15~30°C) and be homogeneous before test. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated or hemolysis samples.
7. SAMPLE VOLUME ***(for Getein1100/Getein1160): 100 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/Getein1160:
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/Getein1160 and press "ENT" button or click on "Start" icon (for Android Getein 1100/Getein1160) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600/Getein1200:
8. Each cartridge for Getein1600/Getein1200 contains a specific RFID card which can calibrate automatically.
9. Place the sample diluent at the correct position in Getein16-00/Getein1200.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600/Getein1200 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.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS
Getein1100/Getein1160/Getein1600/Getein1200 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1600/Getein1200.
Others: Measuring range of the test kit is CK-MB: 2.50 ng/ml~80.00 ng/ml, cTnI: 0.10 ng/ml~50.00 ng/ml, H-FABP: 2.00 ng/ml~100.00 ng/ml, dilute the sample which concentration is higher than the upper limit, the dilution ratio should be less than 3 times with fetal bovine serum or negative sample.

EXPECTED VALUE
The expected normal value for CK-MB was determined by testing samples from 385 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 493 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 H-FABP was determined by testing samples from 391 apparently healthy individuals. The 95th percentile of the concentration for H-FABP is 3.49 ng/ml, the 99th percentile of the concentration for H-FABP is 6.36 ng/ml (According to different statistics method, the probability that value of a normal person below 3.49 ng/ml is 95% or below 6.36 ng/ml is 99%.), results higher than or equal to 6.36 ng/ml are considered positive.The reference range of H-FABP in plasma and whole blood sample is the same.
It is recommended that each laboratory should establish its expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

	CK-MB	cTnI	H-FABP
Measuring Range	2.50~80.00 ng/ml	0.10~50.00 ng/ml	2.00~100.00ng/ml
Lower Detection Limit	≤2.50 ng/ml	≤0.10 ng/ml	≤2.00ng/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	25 g/L	0.1 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(11): 887~893.
2.Tanasijevic MJ, Cannon CP, Antman EM, et al. Myoglobin, creatine-kinase-MB and cardiac troponin-I 60-minute ratios predict infarct-related artery patency after thrombolysis for acute myocardial infarction. J Am Coll Cardiol. 1999, 34(3): 739~747.
3.Viswanathan K, Kilcullen N, Morrell C, et al. Heart-type fatty acid-binding protein predicts long-term mortality and re-infarction in consecutive patients with suspected acute coronary syndrome who are troponin-negative. J Am Coll Cardiol. 2010, 55(23): 2590-2598.
4.Body R, McDowell G, Carley S, et al. A FABP-ulous 'rule out' strategy? Heart fatty acid binding protein and troponin for rapid exclusion of acute myocardial infarction. Resuscitation. 2011, 82(8): 1041-1046.

5.EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6.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/H-FABP 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 15223-1:2016/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
Σ	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 CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

Version:WIF21-S-08

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140mm

210mm