Declaration of Conformity

according to Directive 98/79/EC, on in vitro diagnostic medical devices

Maker (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China		
Authorized Representative (Name, Address)	**Lotus Global Co., Ltd** 15 Alexandra Road, London UK, NW8 0DP		
Medical device	Description	:	FIA8000 Quantitative Immunoassay Analyzer Cardiac Troponin I Fast Test Kit One Step Test for NT-proBNP (Colloidal Gold) One Step Test for NT-proBNP/cTnI (Colloidal Gold) One Step Test for CK-MB/cTnI/Myo (Colloidal Gold) One Step Test for hs-CRP+CRP (Colloidal Gold) One Step Test for D-Dimer (Colloidal Gold) One Step Test for PCT (Colloidal Gold) One Step Test for β_2-MG (Colloidal Gold) One Step Test for mAlb (Colloidal Gold) One Step Test for NGAL (Colloidal Gold) One Step Test for CysC (Colloidal Gold) One Step Test for HCG+β (Colloidal Gold) One Step Test for CK-MB/cTnI (Colloidal Gold) One Step Test for CK-MB (Colloidal Gold) One Step Test for HbA1c (Colloidal Gold) One Step Test for TSH (Colloidal Gold) One Step Test for TSH/T3/T4 (Colloidal Gold)
	Classification of products according to directive	:	Others
	Batch/serial No. type，production term (if applicable)	:	
Applicable coordination standards:	EN ISO 14971:2012 EN 980:2008 EN-ISO 18113-2:2011 EN ISO 18113-2:2011 EN-IEC 61326-1:2013 EN-IEC 61326-2-2:2013	EN ISO 23640:2015 EN 13612:2002 EN 1041:2008 EN ISO 18113-3:2011 EN-IEC 61010-1:2010	EN ISO 13485:2016 EN ISO15223-1:2012 EN ISO 18113-1:2011 IEC 61010-2-101:2015

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager: Enben Su

Nanjing, 15th, June, 2016

(place and date of issue)

(name and signature or equivalent marking of authorized person)

Digitally signed by Monastirschii Viorica
Date: 2022.01.10 14:47:09 EET
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Location: Moldova

CE IVD

One Step Test for D-Dimer

(Colloidal Gold)

User Manual Cat.# CG1006

IINTENDED USE

One Step Test for D-Dimer (Colloidal Gold) is intended for *in vitro* quantitative determination of D-Dimer in plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of deep-vein thrombosis or pulmonary embolism.

SUMMARY

Deep-vein thrombosis is a common condition, with a lifetime cumulative incidence of 2 to 5 percent. Untreated deep-vein thrombosis can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of deep-vein thrombosis minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.
D-Dimer is a marker of endogenous fibrinolysis and should therefore be detectable in patients with deep-vein thrombosis. In recent years, an increasing number of studies have shown the D-Dimer assay has a high negative predictive value and D-Dimer is a sensitive but nonspecific marker of deep-vein thrombosis. Negative D-Dimer can exclude deep-vein thrombosis and pulmonary embolism.

PRINCIPLE

The test uses an anti-human D-Dimer monoclonal antibody conjugated with colloidal gold and another anti-human D-Dimer monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human D-Dimer monoclonal antibody binds with the D-Dimer in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human D-Dimer monoclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of D-Dimer in sample.
Then insert test card into FIA8000 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000), the concentration of D-Dimer in sample will be measured and displayed on the screen. The value will be stored in FIA8000 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

A kit contains:

1. Getein D-Dimer test card in a sealed pouch with desiccant 25
2. Disposable pipet 25
3. User manual 1
4. SD card 1
5. Sample diluent 25

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 a gold-labelled anti-human D-Dimer monoclonal antibody), nitrocellulose membrane (the test line is coated with another anti-human D-Dimer monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.
Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

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 sample diluent at 0~30℃ with a valid period of 24 months.
Store the sample diluent at 2~8℃ for better results.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***plasma and whole blood samples. Sodium citrate*** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using plasma for better results.
3. If testing will be delayed, plasma sample may be stored up to 3 days at 2~8℃ or stored at -20℃ for 1 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME: ***120 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. Confirm SD card lot No. in accordance with test kit lot No.. Perform “QC (SD)” calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button 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 one tube of sample diluent, mix gently and thoroughly. Then drop 120 µl (or 4 drops of sample when using disposable pipet) of sample mixture into the sample port on the test card.
8. ***Reaction time: 7 minutes.*** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

1. It is required to perform “QC (SD)” 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 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.

EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.5 mg/L. (The probability that value of a normal person below 0.5 mg/L is 95%.)
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~10.0 mg/L
Lower Detection Limit	≤0.1 mg/L
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%
Recovery	99%

Method Comparison:
The assay was compared with SIEMENS CA-7000 and its matching D-Dimer test kits with 200 plasma samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for D-Dimer is 0.978.

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 such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. 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. Sarig G, Klil-Drori AJ, Chap-Marshak D, Brenner B, Drugan A. Activation of coagulation in amniotic fluid during normal human pregnancy.Thromb Res. 2011 Apr 18.
2. Roldán V, Marín F, Muiña B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated Atrial Fibrillation Patients. J Am Coll Cardiol. 2011 Apr 11.
3. Sakamoto K, Yamamoto Y, Okamatsu H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. Hellenic J Cardiol. 2011 Mar-Apr; 52(2):123~127.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. 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 D-Dimer (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 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing One Step Test for D-Dimer (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

Version: WCG05-DL-S-01

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Declaration of Conformity

according to Directive 98/79/EC, on in vitro diagnostic medical devices

Maker (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China		
Authorized Representative (Name, Address)	**Lotus NL B.V.** Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.		
Medical device	Description	:	FIA8000 Quantitative Immunoassay Analyzer FIA8600 Quantitative Immunoassay Analyzer Cardiac Troponin I Fast Test Kit One Step Test for cTnI (Colloidal Gold) cTnI Rapid Test (Colloidal Gold Assay) One Step Test for NT-proBNP (Colloidal Gold) One Step Test for NT-proBNP/cTnI (Colloidal Gold) One Step Test for CK-MB/cTnI/Myo (Colloidal Gold) One Step Test for hs-CRP+CRP (Colloidal Gold) One Step Test for D-Dimer (Colloidal Gold) One Step Test for PCT (Colloidal Gold) One Step Test for β2-MG (Colloidal Gold) One Step Test for mAlb (Colloidal Gold) One Step Test for NGAL (Colloidal Gold) One Step Test for CysC (Colloidal Gold) One Step Test for HCG+β (Colloidal Gold) One Step Test for HbA1c (Colloidal Gold) One Step Test for PCT/CRP (Colloidal Gold) One Step Test for CK-MB/cTnI/H-FABP (Colloidal Gold) One Step Test for H-FABP (Colloidal Gold) One Step Test for CK-MB/cTnI (Colloidal Gold) One Step Test for CK-MB (Colloidal Gold) One Step Test for TSH (Colloidal Gold) One Step Test for T4/T3 (Colloidal Gold) One Step Test for T3 (Colloidal Gold) One Step Test for T4 (Colloidal Gold) One Step Test for 25-OH-VD (Colloidal Gold) One Step Test for FOB (Colloidal Gold) One Step Test for *H. pylori* (Colloidal Gold) One Step Test for SAA (Colloidal Gold) Getein1100 Immunofluorescence Quantitative Analyzer Getein1600 Immunofluorescence Quantitative Analyzer Getein1180 Immunofluorescence Quantitative Analyzer Getein1200 Immunofluorescence Quantitative Analyzer Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) NT-proBNP Fast Test Kit (Immunofluorescence Assay) hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) D-Dimer Fast Test Kit (Immunofluorescence Assay)

			PCT Fast Test Kit (Immunofluorescence Assay) β2-MG Fast Test Kit (Immunofluorescence Assay) mAlb Fast Test Kit (Immunofluorescence Assay) NGAL Fast Test Kit (Immunofluorescence Assay) CysC Fast Test Kit (Immunofluorescence Assay) CK-MB Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay) HCG+β Fast Test Kit (Immunofluorescence Assay) HbA1c Fast Test Kit (Immunofluorescence Assay) PCT/CRP Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay) H-FABP Fast Test Kit (Immunofluorescence Assay) 25-OH-VD Fast Test Kit (Immunofluorescence Assay) TSH Fast Test Kit (Immunofluorescence Assay) T3 Fast Test Kit (Immunofluorescence Assay) T4 Fast Test Kit (Immunofluorescence Assay 25-OH-VD Fast Test Kit (Immunofluorescence Assay) FOB Fast Test Kit (Immunofluorescence Assay) *H. pylori* Fast Test Kit (Immunofluorescence Assay) SAA Fast Test Kit (Immunofluorescence Assay) LH Fast Test Kit (Immunofluorescence Assay) FSH Fast Test Kit (Immunofluorescence Assay) AMH Fast Test Kit (Immunofluorescence Assay) PRL Fast Test Kit (Immunofluorescence Assay) CK-MB Control cTnI Control Myo Control NT-proBNP Control D-Dimer Control CRP Control PCT Control β2-MG Control mAlb Control NGAL Control CysC Control H-FABP Control HbA1c Control HCG+β Control CK-MB/cTnI/Myo Control CK-MB/cTnI Control NT-proBNP/cTnI Control TSH Control T4/T3 Control T3 Control T4 Control
	Classification of products according to directive	:	Others
	Batch/serial No. Type, production term (if applicable)	:	

Applicable coordination standards:	EN ISO 14971:2012 EN 13612:2002 EN 1041:2008 IEC 61010-1:2010 IEC 61326-1:2013	EN ISO 23640:2015 EN ISO15223-1:2012 EN ISO 18113-1:2011 IEC 61010-2-081:2015 IEC 61326-2-2:2013	EN ISO 13485:2016 EN ISO 18113-2:2011 EN ISO 18113-3:2011 IEC 61010-2-101:2015

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager: Enben Su

Nanjing, 20th, Jul, 2019

(place and date of issue)

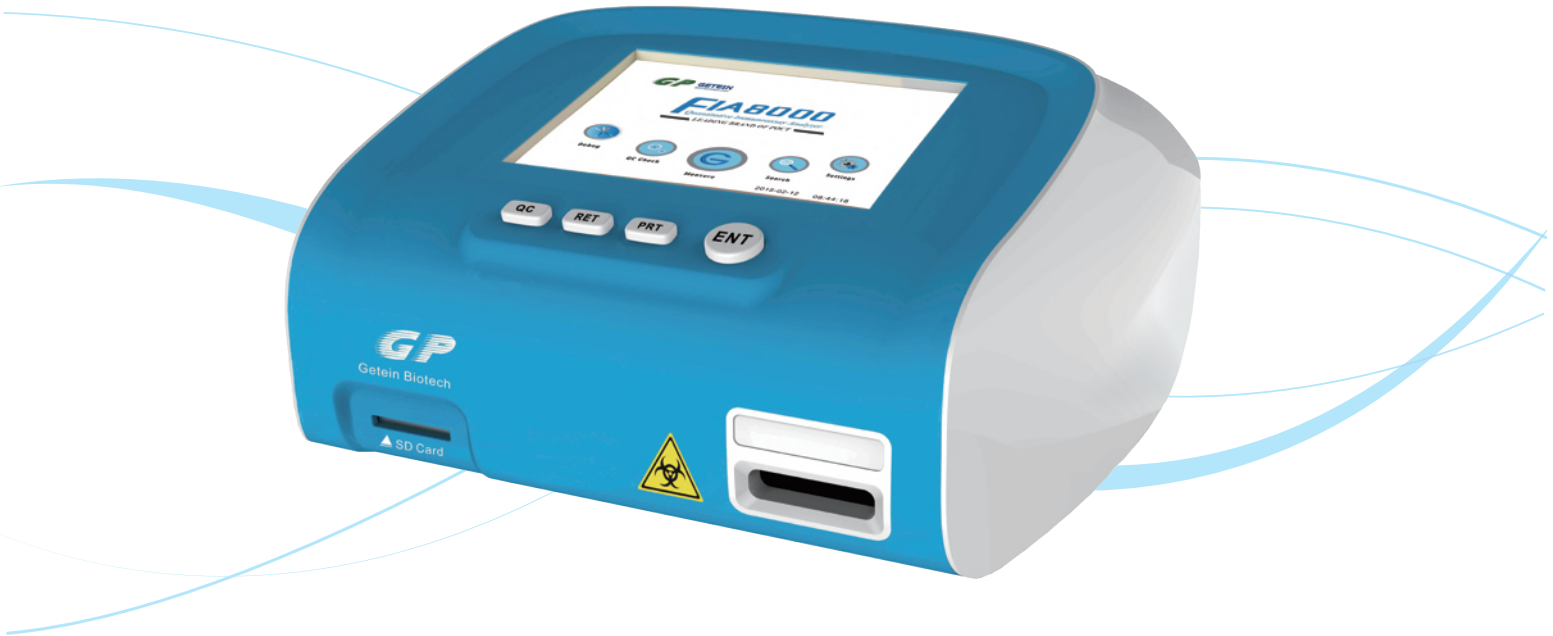
(name and signature or equivalent marking of authorized person)

IVD Industry
POCT Leading Brand

FIA8000

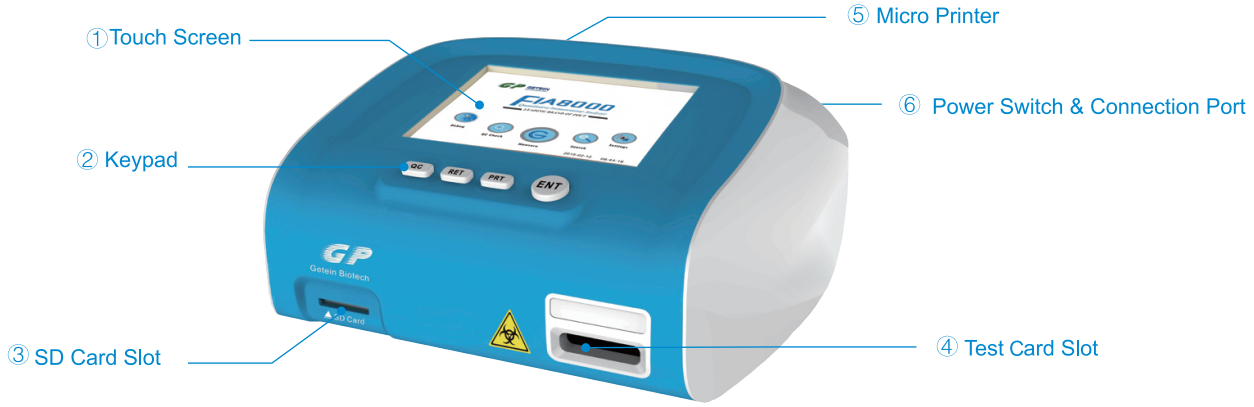
Quantitative Immunoassay Analyzer

PREMIUM POINT OF CARE SOLUTION



Getein Biotech, Inc.

FIA8000 *Quantitative Immunoassay Analyzer*



Highlights

- **Portable Design** — Small in size (250 x 250 x 120mm); Light in weight (1.8kg)
- **Multiplex Test Items** — Cardiac; Inflammation monitoring; Diabetes mellitus; Fertility; Renal function etc.
- **Easy to Use** — Ready-to-use cassette, one-step test, automatic print, quantitative result
- **Reliable Performance** — CV$\leqslant$1%; r$\geqslant$0.990
- **LIS and HIS Connectivity**

Test Items

CARDIAC	cTnI	NT-proBNP	NT-proBNP/cTnI	CK-MB/cTnI/Myo
	H-FABP	CK-MB/cTnI/H-FABP		
VENOUS THROMBOEMBOLISM	D-Dimer			
INFLAMMATION MONITORING	hs-CRP	PCT		
DIABETES CARE	HbA1c			
FERTILITY	HCG+β			
RENAL FUNCTION	β_2-MG	mAlb	CysC	NGAL

Application Department

The analyzer can be widely applied to clinical departments including Cardiology Dept., Clinical Laboratory, Emergency Dept., ICU, Oncology Dept., Nephrology Dept., Pediatrics Dept., Endocrinology Dept., Gynecology Dept., Respiratory Dept., Gastroenterology Dept., Urology Dept. etc.

Flexible Operation Modes

Inside Mode (Automatic Timing)

Sample dispense

Test card insert

Press "ENT" button

Result printed automatically after reaction

Outside Mode (Manual Timing)

Sample dispense

Timing the reaction manually

Test card insert

Result printed automatically in 5-8s

Technical Data

Assay Method	Lateral Flow Chromatography (Colloidal Gold)	
Test Result	Quantitative	
Language	Chinese/English/German/Spanish/Serbian (French,Russian,Arabic,Vietnamese etc. are under developing)	
Display	5.6 Inch Touch Screen; Resolution 640×480	
Printer	Internal Thermal Printer	
Working Environment	Temperature	+15℃ - 35℃
	Relative humidity	10% - 85%
	Air pressure	70.0kPa - 106.0kPa
Power Supply	AC 100~240V, 50~60 Hz	
Data Storage	10,000 results can be saved	
Dimensions	Height	120mm
	Width	250mm
	Length	250mm
Weight	1.8kg	

FIA8000 Parameters

Cat.#	Test Item	Disease	Measuring Range	Sample	Cut-off Value	Reaction Time
CG 1001	cTnI	Myocardial infarction	0.5~50.0ng/ml	S/P/W.B	0.5ng/ml	15min
CG 1002	NT-proBNP	Heart failure	100~35000pg/ml	S/P/W.B	300pg/ml	15min
CG 1003	hs-CRP	Cardiovascular inflammatory diseases; Inflammatory disorders	0.5~200mg/L	S/P/W.B/ Fingertip blood	3mg/L 10mg/L	90s
CG 1004	NT-proBNP /cTnI	Heart failure; Acute coronary syndrome	100~12000pg/ml 0.5~50.0ng/ml	S/P/W.B	300pg/ml 0.5ng/ml	18min
CG 1005	CK-MB /cTnI /Myo	Myocardial injury	2.5~80.0ng/ml 0.5~50.0ng/ml 30~1000ng/ml	S/P/W.B	5ng/ml 0.5ng/ml 70ng/ml	15 min
CG 1006	D-Dimer	Venous thromboembolism; Pulmonary embolism	0.1~10.0mg/L	P/W.B	0.5mg/L	7min
CG 1007	PCT	Sepsis; Septic shock	0.1~50ng/ml	S/P/W.B	0.1ng/ml	15min
CG 1008	CysC	Early diagnosis of kidney disease; Detection of kidney damage for surgery patients	0.5~10.0mg/L	S/P/W.B	0.51~1.09 mg/L	3min
CG 1009	mAlb	Early diagnosis and evaluation of diabetic nephropathy	10~200mg/L	Urine	20mg/L	3min
CG 1010	NGAL	The best indicator of early renal injury	50~5000ng/ml	S/Urine	Serum:200ng/ml Urine:100ng/ml	3min
CG 1011	β_2 - MG	Kidney damage for diabetic & hypertensive patients	0.5~20.0mg/L	S/P/W.B	0.8~3.0 mg/L	3min
CG 1012	CK-MB /cTnI	Myocardial injury	2.5~80.0ng/ml 0.5~50.0ng/ml	S/P/W.B	5ng/ml 0.5ng/ml	15min
CG 1013	HCG+β	Pregnancy early test	5~10000mIU/ml	S/P/W.B	5.1mIU/ml	10min
CG 1017	HbA1c	Diabetes mellitus	2%~14%	W.B	3.8%~5.8%	3min
CG 1018	CK-MB	Myocardial injury	2.5~80.0ng/ml	S/P/W.B	5ng/ml	15min

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Getein Biotech, Inc.
No.9 Bofu Road
Luhe District
Nanjing
Jiangsu
211505
China

基蛋生物科技股份有限公司
中国
江苏省
南京市
六合区
沿江工业开发区
博富路9号
邮编：211505

Holds Certificate No: **MD 728432**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay). Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay).
研发，生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂。
研发，生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂配套使用的分析仪。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-05-29
Latest Revision Date: 2020-07-22

Effective Date: 2020-07-26
Expiry Date: 2023-07-25

...making excellence a habit.™

Reference Code：GP-DT-018-07-19 Issued by 07/26/2019

CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

Completion of Getein Products Technical and Operational Training
& Qualification of After-sales Service

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Getein
Biotech, Inc.

CE IVD

Cardiac Troponin I Fast Test Kit

User Manual Cat.# CG2001

INTENDED USE

Cardiac Troponin I Fast Test Kit is intended for *in vitro* qualitative and semi-quantitative determination of cardiac Troponin I (cTnI) in serum, plasma or whole blood. This test is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three subunits: 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 myocardium.

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.

The current guideline of The Joint European Society of Cardiology/ American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current guidelines recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

PRINCIPLE

The test uses an anti-human cTnI monoclonal antibody conjugated with colloidal gold and another anti-human cTnI monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human cTnI monoclonal antibody binds with the cTnI in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human cTnI monoclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of cTnI in sample.

CONTENTS

A kit contains:

1. Getein cTnI test card in a sealed pouch with desiccant 25
2. Disposable pipet 25
3. User manual 1
4. Standard colorimetric card 1
5. Whole blood buffer 1

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 cTnI monoclonal antibody), nitrocellulose membrane (the test line is coated with anti-human cTnI monoclonal antibody, and the control line 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. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma or whole blood samples. Heparin,EDTA or 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 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 line is a valid negative result, indicating the concentration of cTnI in the sample is below the cut-off value.

Positive: A single purplish red band appears at the control area (C) and a purplish red colored band appears in test line is a valid positive result. The intensity of the purplish red color in the test line helps to read the semi-quantitative result visually according to the standard colorimetric card:

Color intensity	Reference Concentration (ng/ml)
−	<0.3
+−	0.3~1
+	1~5
++	5~15
+++	15~30
++++	30~50
++++	>50

Invalid: If no colored band appears in the control area (C) in 15 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 Troponin I was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.3 ng/ml, (The probability that value of a normal person below 0.3 ng/ml is 99%). cTnI concentration less than 0.3 ng/ml can be estimated as normal.

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). 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 (ISO18113-2:2011).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cardiac Troponin I Fast Test Kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223 – 1： 2012.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing Cardiac Troponin I Fast Test Kit. Please read this user manual carefully before operating to ensure proper use.

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