Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: 86-25-68568508 Email: overseas@geteincom.cn Web: www.bio-GP.com.cn

Document No.: GP-GMSQ-2024121101

Letter of Authorization

To whom it may concern,

We, Getein Biotech, Inc. (No.9 BoFu Road, Luhe District, Nanjing, 211505, China), hereby authorize Sanmedico SRL (Address: Republic of Moldova, Chisinau, MD-2059, Petricani street, 88/1, office 10) as our official and non-exclusive distributor for registration, promoting, selling, distributing and providing after-sale services of under-mentioned product in the territory of Moldova only:

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

Sanmedico SRL will comply with the laws and regulations of the countries and regions where they are located in and where they are selling mentioned product.

Sanmedico SRL will carry out marketing efforts to fulfill service and maintenance for above mentioned products and will provide with users benefits of having a local stock of above mentioned products and on time delivery with every order, supported by a local service in local language.

This authorization starts from Jan 1, 2025and will be valid to December 31 2025.

Getein Biotech, Inc. has the right to terminate the authorization before validity and will inform **Sanmedico SRL** with 10 days in advance.

Getein Biotech, Inc.

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Name: Steven Zhou
Position: Overseas Sales Director

Steven Zhou

Digitally signed by Dolgopol Iulian
Date: 2026.01.02 08:46:29 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-29
Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26
Expiry Date: 2026-07-25

...making excellence a habit.™

Certificate No: **MD 728432**

Registered Scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. 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), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.
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，传染病相关PCR分子诊断试剂和胶体金自测试剂。 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，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。

Original Registration Date: 2020-05-29
Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26
Expiry Date: 2026-07-25

Certificate No: **MD 728432**

Location	Registered Activities
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	Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. 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), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease. 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，传染病相关PCR分子诊断试剂和胶体金自测试剂。 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，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。
Getein Biotech, Inc. No. 6 KeFeng Road Jiangbei New District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京 江北新区 科丰路6号 邮编：211505	Manufacture of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), Colloidal Gold self-testing Assay to detect infectious disease. Manufacture of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease. 生产化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂和传染病相关胶体金自测试剂。 生产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，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。

Original Registration Date: 2020-05-29

Effective Date: 2023-07-26

Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

EC Declaration of Conformity

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

Ref. No.:20220513-A04

Manufacturer
(Name, Address)

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

Authorized Representative
(Name, Address)

CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Medical device

No.	Product Name
1	Getein 1160 Immunofluorescence Quantitative Analyzer
2	Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)
3	NT-proBNP Fast Test Kit (Immunofluorescence Assay)
4	hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay)
5	NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay)
6	CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay)
7	D-Dimer Fast Test Kit (Immunofluorescence Assay)
8	PCT Fast Test Kit (Immunofluorescence Assay)
9	CysC Fast Test Kit (Immunofluorescence Assay)
10	mAlb Fast Test Kit (Immunofluorescence Assay)
11	NGAL Fast Test Kit (Immunofluorescence Assay)
12	β2-MG Fast Test Kit (Immunofluorescence Assay)
13	CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)
14	HCG+β Fast Test Kit (Immunofluorescence Assay)
15	H-FABP Fast Test Kit (Immunofluorescence Assay)
16	PCT/CRP Fast Test Kit (Immunofluorescence Assay)
17	CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay)
18	HbA1c Fast Test Kit (Immunofluorescence Assay)
19	NT-proBNP/NGAL Fast Test Kit (Immunofluorescence Assay)
20	CK-MB Fast Test Kit (Immunofluorescence Assay)
21	hs-cTnI Fast Test Kit (Immunofluorescence Assay)
22	T3 Fast Test Kit (Immunofluorescence Assay)
23	T4 Fast Test Kit (Immunofluorescence Assay)
24	TSH Fast Test Kit (Immunofluorescence Assay)
25	Scr Fast Test Kit (Immunofluorescence Assay)
26	PLGF Fast Test Kit (Immunofluorescence Assay)

27	HCY Fast Test Kit (Immunofluorescence Assay)
28	Anti-CCP Fast Test Kit (Immunofluorescence Assay)
29	25-OH-VD Fast Test Kit (Immunofluorescence Assay)
30	Lp-PLA2 Fast Test Kit (Immunofluorescence Assay)
31	FOB Fast Test Kit (Immunofluorescence Assay)
32	SAA Fast Test Kit (Immunofluorescence Assay)
33	H. pylori Fast Test Kit (Immunofluorescence Assay)
34	PRL Fast Test Kit (Immunofluorescence Assay)
35	Transferrin Fast Test Kit (Immunofluorescence Assay)
36	Insulin Fast Test Kit (Immunofluorescence Assay)
37	PG Ⅰ /PG Ⅱ Fast Test Kit (Immunofluorescence Assay)
38	LH Fast Test Kit (Immunofluorescence Assay)
39	FSH Fast Test Kit (Immunofluorescence Assay)
40	Anti-TP Fast Test Kit (Immunofluorescence Assay)
41	AFP/CEA Fast Test Kit (Immunofluorescence Assay)
42	AMH Fast Test Kit (Immunofluorescence Assay)
43	fT3 Fast Test Kit (Immunofluorescence Assay)
44	fT4 Fast Test Kit (Immunofluorescence Assay)
45	Total IgE Fast Test Kit (Immunofluorescence Assay)
46	Vit-B12 Fast Test Kit (Immunofluorescence Assay)
47	Prog Fast Test Kit (Immunofluorescence Assay)
48	Testosterone Fast Test Kit (Immunofluorescence Assay)
49	E2 Fast Test Kit (Immunofluorescence Assay)
50	RF Fast Test Kit (Immunofluorescence Assay)
51	ASO Fast Test Kit (Immunofluorescence Assay)
52	Ferritin Fast Test Kit (Immunofluorescence Assay)
53	ST2 Fast Test Kit (Immunofluorescence Assay)
54	CA125 Fast Test Kit (Immunofluorescence Assay)
55	CA19-9 Fast Test Kit (Immunofluorescence Assay)
56	CA15-3 Fast Test Kit (Immunofluorescence Assay)
57	RSV/Influenza A/B Fast Test Kit (Immunofluorescence Assay)
58	Influenza A/B Fast Test Kit (Immunofluorescence Assay)
59	RSV Fast Test Kit (Immunofluorescence Assay)
60	IL-6 Fast Test Kit (Immunofluorescence Assay)
61	BNP Fast Test Kit (Immunofluorescence Assay)
62	SAA/CRP Fast Test Kit (Immunofluorescence Assay)
63	Folate acid Fast Test Kit (Immunofluorescence Assay)
64	hs-CRP Fast Test Kit (Immunofluorescence Assay)
65	TnT Fast Test Kit (Immunofluorescence Assay)
66	PCT/IL-6 Fast Test Kit (Immunofluorescence Assay)

67	HBP Fast Test Kit (Immunofluorescence Assay)
68	S100-β Fast Test Kit (Immunofluorescence Assay)
69	CK-MB/hs-cTnI/Myo Fast Test Kit (Immunofluorescence Assay)
70	Cortisol Fast Test Kit (Immunofluorescence Assay)
71	CEA Fast Test Kit (Immunofluorescence Assay)
72	AFP/CEA Fast Test Kit (Immunofluorescence Assay)

Classification Other device (according to Annex II of the directive 98/79/EC)

Conformity assessment route Annex III of the 98/79/EC

Applicable coordination standards

EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
EN ISO 23640:2015	EN ISO 13485:2016	ISO 780:2015
EN 61326-2-6:2006	IEC 61326-1:2013	
EN 61010-2-101:2002	IEC 61010-1:2010	

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 I.

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 BSI Group The Netherlands B. V. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

Nanjing, 13th May 2022
(place and date of issue)

Enben Su
(name and signature or equivalent marking of authorized person)

CE

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.

Getein Biotech, Inc.

STOCK CODE 603387

4 Incubation Channels,

1 Emergency Test Channel!

Getein 1160

Immunofluorescence Quantitative Analyzer

Getein 1160 Immunofluorescence Quantitative Analyzer is a rapid, compact, user-friendly, multi-item analyzer that provides point-of-care testing and saves diagnosis time for patients. With **4 test channels** and **32 °C constant incubation environment**, Getein 1160 could offer timely, accurate and efficient testing for a wide range of scenarios.

Benefits

Constant Temperature

32°C constant test environment, allowing for more accurate test results

Multiple Channels

4 incubation channels
+
1 emergency test channel

- **Portable**
  Dimensions：299 mm (W) × 276 mm (D) × 152 mm (H)
  Weight：4 kg
- **Detection Performance Improved**
  Reduced influence by temperature and improved detection accuracy
- **Convenient**
  Easy to operate, user friendly interface
- **Instant Results**
  Get results in 3-15 minutes
- **Reliable Accuracy**
  Good correlation with CLIA method
- **Auto Cartridge Collection**
  Automatically receive the used test cards when the test is finished

Technical Specifications

Large Display

- 10.1'' LCD touch screen
- Intuitive user interface

Built-in Thermal Printer

- Real-time auto-printing
- Support for external printer

RFID Card Calibration

Automatic reading of batch number and calibration information

Connectivity

- Ethernet port for LIS/HIS
  COM port for PC
- 2 USB ports for software update and file copy

Sampling

- Sample Type: serum, plasma, whole blood, capillary blood, urine, swab, saliva, stool
- Sample Volume: 10 ~ 200 μL depending on the assay

Language

English/Spanish/Chinese

Cases Storage

Over 100,000 test cases

Working Environment

- Temperature: 10°C ~ 35°C
- Relative humidity: ⩽ 70%
- Air pressure: 70.0 kPa ~ 106.0 kPa

Test Channel

- 4 incubation channels + 1 emergency test channel
- Multiple test items can be tested at the same time, saving operation time

Repeatability

- CV ⩽ 2% within range [100, 15000] mV
- CV ⩽ 10% within range [0, 100) mV

Android System

- Smooth operation
- Easy operating software updates

Application

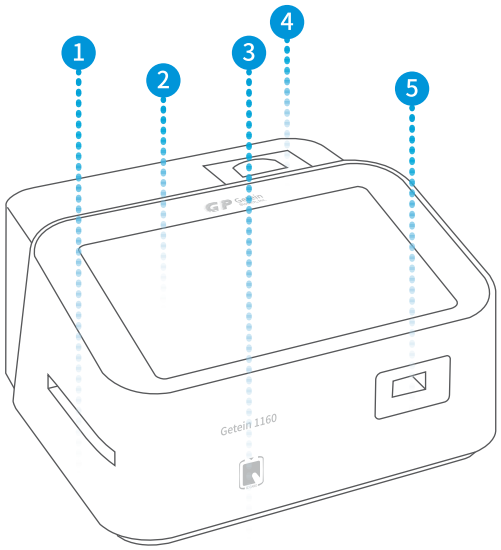
Laboratory

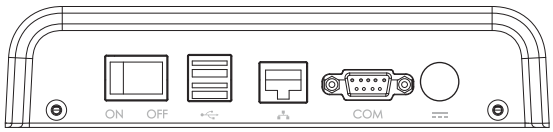
Clinic

Emergency

Ambulance

ICU





1 Card Exit

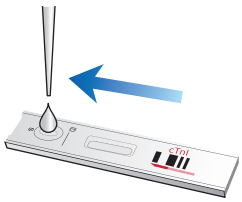
2 10.1-inch Touch Screen

3 RFID Card Recognition Zone

4 Built-in thermal Printer

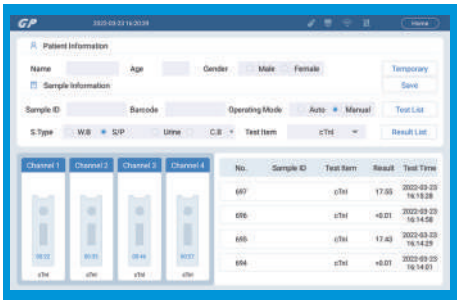
5 Card Inlet

Operation Procedure



1 Sample dispense

2 Insert test cards, four allowed at the same time



3 Waiting in incubation

4 Result show and print

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Cardiac Markers								
IF5001	cTnI	Myocardial infarction	0.10 ng/mL	S/P/WB	0.10-50.00 ng/mL	100 µL	10 min	NMPA CE
NEW IF5019	hs-cTnI	Myocardial infarction	0.040 ng/mL	S/P/WB	0.01-50.00 ng/mL	100 µL	10 min	NMPA CE
NEW IF5098	TnT	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	100 µL	15 min	CE
IF5089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	CE
IF5002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	100 µL	10 min	NMPA CE
IF5005	CK-MB/cTnI/Myo	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL Myo: 70.0 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 30.0-600.0 ng/mL	100 µL	10 min	NMPA CE
IF5012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL	100 µL	10 min	CE
IF5014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.00-120.00 ng/mL	100 µL	3 min	CE
IF5016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL H-FABP: 6.36 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 2.00-100.00 ng/mL	100 µL	10 min	CE
IF5018	CK-MB	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	100 µL	10 min	CE
Coagulation Markers								
IF5006	D-Dimer	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	100 µL	10 min	NMPA CE
Inflammation								
IF5003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3.0 mg/L 10.0 mg/L	S/P/WB/ Fingertip blood	0.5-200.0 mg/L	10 µL	3 min	CE
IF5007	PCT	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB	0.05-50.00 ng/mL	100 µL	15 min	NMPA CE
IF5044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	10 µL	5 min	NMPA CE
IF5090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Peripheral blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA CE
IF5088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	100 µL	15 min	CE
Renal Function								
IF5008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.50-10.00 mg/L	10 µL	3 min	NMPA CE
IF5009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	CE
IF5010	NGAL	Acute kidney injury	Serum: 200.0 ng/mL Urine: 100.0 ng/mL	S/Urine	50.0-5000.0 ng/mL	10 µL	10 min	NMPA CE
IF5011	β_2-MG	Acute and chronic kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	10 µL	3 min	NMPA CE
Diabetes Mellitus								
IF5017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	10 µL	5 min	NGSP NMPA IFCC CE
Metabolic Marker								
IF5031	25-OH-VD	Osteomalacia, osteoporosis	30.00-50.00 ng/mL	S/P	8.00-70.00 ng/mL	40 µL	15 min	CE
Thyroid Function								
IF5024	TSH	Thyroid malfunction	0.27-4.20 µIU/mL	S/P	0.10-50.00 µIU/mL	100 µL	15 min	NMPA CE
IF5022	T3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	40 µL	15 min	CE
IF5023	T4	Hyperthyroidism, hypothyroidism	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	100 µL	15 min	CE
IF5067	fT3	Hyperthyroidism, hypothyroidism	3.10-6.80 pmol/L	S/P/WB	0.40-50.00 pmol/L	40 µL	15 min	CE
IF5068	fT4	Hyperthyroidism, hypothyroidism	12.00-22.00 pmol/L	S/P/WB	0.30-100.00 pmol/L	40 µL	15 min	CE

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Reproduction/Fertility								
IF5013	HCG+β	Fertility	5.1 mIU/mL	S/P	5.0-100000.0 mIU/mL	100 μL	10 min	CE
IF5055	LH	PCOS, infertility evaluation	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	CE
IF5056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	CE
IF5066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	200 μL	15 min	CE
IF5048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.00 ng/mL	100 μL	15 min	NMPA CE
IF5071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	CE
Tumor Markers								
IF5053	tPSA	Prostate cancer	4.00 ng/mL	S/P	0.50-100.00 ng/mL	100 μL	15 min	
IF5072	fPSA	Prostate cancer	1.00 ng/mL	S/P	0.05-30.00 ng/mL	100 μL	10 min	
IF5050	AFP	Liver cancer, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	CE
IF5051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	CE
Infectious Disease								
IF5057	Anti-HCV	Hepatitis C	1.00 S/CO	S/P	1.00-20.00 S/CO	100 μL	15 min	
IF5058	Anti-TP	Syphilis	1.00 S/CO	S/P	1.00-50.00 S/CO	100 μL	15 min	CE
IF5059	Anti-HIV	AIDS	1.00 S/CO	S/P	1.00-1000.00 S/CO	100 μL	15 min	
IF5064	HBsAg	Hepatitis B	1.00 IU/mL	S/P	1.00-100.00 IU/mL	100 μL	15 min	
NEW IF5063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	100 μL	15 min	
IF5084	2019-nCoV IgM/IgG	COVID-19	1.00 COI	S/P/WB		100 μL	10 min	CE
NEW IF5091	SARS-CoV-2 Antigen	COVID-19	1.00 COI	Nasal swab/Saliva		100 μL	15 min	CE
NEW IF5095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB/ Fingertip blood		40 μL	15 min	CE
IF5047	*H. pylori*	*H. pylori* infection	5.0 ng/mL	Stool	1.0-200.0 ng/mL	3 drops (about 100 μL)	10 min	CE
NEW IF5086	Influenza A/B	Respiratory viral infection	1.00 COI	Nasal swab		100 μL	15 min	CE
Specific Protein and Rheumatism								
NEW IF5075	RF	Rheumatoid arthritis	15.9 IU/mL	S/P/WB	10.0-640.0 IU/mL	10 μL	10 min	CE
NEW IF5076	ASO	Rheumatic fever, acute glomerulonephritis, group A streptococcal infection	400.0 IU/mL	S/P/WB	60.0-1370.0 IU/mL	10 μL	10 min	CE
NEW IF5029	Anti-CCP	Rheumatoid arthritis	25.0 U/mL	S/P/WB	10.0-400.0 U/mL	10 μL	15 min	CE
Others								
NEW IF5077	Ferritin	Anemia/tumors	Male: 30.00-400.00 ng/mL Female: 13.00-150.00 ng/mL	S/P	0.50-1000.00 ng/mL	10 μL	15 min	CE
NEW IF5069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE

Coming Soon: E2, T, Folate…

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel.: +86-25-68568508/68568594
Fax: +86-25-68568500
E-mail: sales@getein.com.cn; overseas@getein.com.cn
Web.: www.getein.com

ISO13485 FSC CE NMPA NGSP IFCC IVD

GP

CE IVD

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 flow 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), NaN_3 (< 0.1%).
(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:
- Phosphate buffer (20 mmol/L), NaN_3 (< 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 µL***

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 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.
(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:

(1) Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration 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 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.

(5) 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:

(1) 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.

(2) Select the corresponding “Sample” mode on the analyzer (refer to the analyzer user manual for details).

(3) 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.

(4) 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:

(1) 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.

(2) Place the sample diluent at the correct position in Getein 1200/Getein 1600.

(3) 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

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. 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

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 (labeling)-Part 1: Terms, definitions and general requirements.
4. 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*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EU REP	Authorized representative
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		Keep dry
	Keep away from sunlight		Caution
UDI	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.

Version: WIF28-S-13

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

EU REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

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

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Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)

IF1001 for Getein1100
IF3001 for Getein1180
IF2001 for Getein1600
IF5001 for Getein1160
REF IF4001 for Getein1200
IF6001 for Getein208

User Manual

INTENDED USE

Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cardiac Troponin I (cTnI) in human serum, plasma or whole blood samples. 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 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; 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 infarction (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 fluorescence latex and another anti-human cTnI monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-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. The fluorescence intensity of the test line increases in proportion to the amount of cTnI 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, Getein-208, Getein1200 and Getein1600), the concentrations of cTnI 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 the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/box, 10 tests/box
1) cTnI 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) Getein cTnI 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 cTnI 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 a fluorescence latex-labelled anti-human cTnI monoclonal antibody, the test line is coated with another anti-human cTnI monoclonal antibody 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
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°C 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°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
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 identification.
11. Put the test card on a clean table,horizontally placed.
12. Using sample transfer pipette,deliver ***100 µL*** of sample into one tube of sample diluent,mix gently and thoroughly.Then drop ***100 µL*** 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 automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein-208/Getein1200/Getein1600.

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 0.10 ng/mL. (The probability that value of a normal person below 0.10 ng/ml is 99%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10~50.00 ng/ml
Lower Detection Limit	≤ 0.10 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 Cardiac Troponin I 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*	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 Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF02-S-13


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

CE IVD

D-Dimer
Fast Test Kit
(Immunofluorescence Assay)

IF1006 for Getein1100
IF3006 for Getein1180
IF4006 for Getein1200
IF2006 for Getein1600
REF IF5006 for Getein1160
IF6006 for Getein208

User Manual

INTENDED USE

D-Dimer Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of D-Dimer in human plasma or whole blood samples. 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 fluorescence latex and another anti-human D-Dimer monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-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 another anti-human D-Dimer monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of D-Dimer 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 D-Dimer 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 the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180/Getein208 contains:
Package specifications: 25 tests/box, 10 tests/box
1) D-Dimer 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

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein D-Dimer 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

3. Sample diluent 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 a fluorescence latex-labelled anti-human D-Dimer monoclonal antibody, 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.

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

APPLICABLE DEVICE

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

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 ***plasma and whole blood samples. Sodium citrate*** can 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 is delayed, plasma sample may be stored up to 3 days at 2~8℃ or stored at -20℃ for 1 month 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 ***(for Getein1100/Getein1160/Getein1180): 100 µL.***

(for Getein208): 60 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 one tube of sample diluent, mix gently and thoroughly. Then drop ***100 µL*** of sample mixture into the sample port 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 Getein1100) 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 identification.
11. Put the test card on a clean table,horizontally placed.
12. Using sample transfer pipette,deliver ***100 µL*** of sample into one tube of sample diluent,mix gently and thoroughly.Then drop ***100 µL*** 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 ***60 µL*** of sample and drop it into 1000 µL of sample diluent. Then drop ***60 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 automatically 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 D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.50 mg/L. (The probability that value of a normal person below 0.50 mg/L is 95%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10~10.00 mg/L
Lower Detection Limit	≤0.10 mg/L
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 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 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. 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 D-Dimer 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*	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 D-Dimer Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF05-S-13

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

GP

CE IVD

hs-CRP+CRP
Fast Test Kit
(Immunofluorescence Assay)

IF2003 for Getein1600
IF4003 for Getein1200
IF5003 for Getein1160
IF3003 for Getein1180
IF1003 for Getein1100
IF6003 for Getein208

REF

User Manual

INTENDED USE

hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of C-reactive protein (CRP) in human serum, plasma, whole blood or fingertip blood samples. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury and inflammatory disorders. Measurement of high sensitivity CRP (hs-CRP), when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes (ACS), may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or ACS.

SUMMARY

C-reactive protein is an acute-phase reactant that precipitated with Pneumococcal C-polysaccharide, and is a non-specific immune response component. CRP has wide distribution in our body, and is an acutephase protein produced in the liver in response to microbic infection or tissue injury, it measures general levels of inflammation in the body, and the hs-CRP can be used to detect lower concentrations of CRP in serum or plasma. Studies revealed hs-CRP levels seem to be correlated with Atherosclerosis and Acute Myocardial Infarction. And the hs-CRP is an inflammation "marker" for ACS patient and is helpful for primary prevention and risk assessment of cardiovascular disease. Its combination with the ratio of total cholesterol to HDL-C is more accurate than other risk factors in predicting cardiovascular disease.

The American Heart Association and US Centers for Disease Control and Prevention have advocated hs-CRP as a predictor of cardiovascular disease (CVD) to define risk groups: less than 1.0 mg/L indicates low risk, 1.0 to 3.0 mg/L means moderate risk, and the amount above 3.0 mg/L (lower than 10 mg/L) strongly suggests a high risk of CVD. Moreover, higher CRP levels are found in late pregnant women, mild inflammation and viral infections (10~40 mg/L), active inflammation, bacterial infection (40~200 mg/L), severe bacterial infections and burns (>200 mg/L).

PRINCIPLE

The test uses an anti-human CRP monoclonal antibody conjugated with fluorescence latex and another anti-human CRP monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human CRP monoclonal antibody binds with the CRP 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 CRP monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CRP 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(hereinafter referred to as Getein1100, Getein1160, Getein1180, Getein208, Getein1200 and Getein1600), the concentration of CRP 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 the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180/Getein208 contains:

Package specifications: 25 tests/box, 10 tests/box
1) hs-CRP+CRP test card in a sealed pouch with desiccant
2) Capillary pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box

2. A kit for Getein1200/Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein hs-CRP+CRP 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

3. Sample diluent 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 a fluorescence latex-labelled anti-human CRP monoclonal antibody, the test line is coated with another anti-human CRP monoclonal antibody 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
Getein1180 Immunofluorescence Quantitative Analyzer
Getein208 Hand-held Integrated System
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
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, whole blood and fingertip blood samples. Heparin, sodium citrate and EDTA*** can be used as the anticoagulant for plasma, whole blood and fingertip blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. 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℃).
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freezethaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME ***(for Getein1100/Getein1160/Getein1180/ Getein208): 10 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 ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card (for disposable capillary pipet using, please refer to the directions in the package).
7. ***Reaction time: 3 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein1100) 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 identification.
11. Put the test card on a clean table,horizontally placed.
12. Using sample transfer pipette, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
13. ***Reaction time: 3 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 ***10 μL*** of sample and drop it into 1000 μL of sample diluent. Then drop ***60 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 automatically 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

hs-CRP: The expected normal value for hs-CRP was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for hs-CRP is 3.0 mg/L. (The probability that hs-CRP value of a normal person below 3.0 mg/L is 95%.)

CRP: The expected normal value for CRP was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for CRP is 10.0 mg/L. (The probability that CRP value of a normal person below 10.0 mg/L is 95%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.5~200.0 mg/L
Lower Detection Limit	≤0.5 mg/L
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 lists the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	10 g/L	10 g/L	0.2 g/L

REFERENCES

1. Danesh J, Whincup P, Wslker M, et al. Low grade inflammation and coronary heart disease: prospective study and updated meta-analysis. BJM 2000; 321:199~204.
2. Rifai N, Ridker PM. Proposed cardiovascular risk assessment algorithm using high-sensitivity C-reactive protein and lipid screening. Clin Chem 2001; 47:28~30.
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 hs-CRP+CRP 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 hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF07-S-11

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

CE IVD

PCT
Fast Test Kit
(Immunofluorescence Assay)

IF1007 for Getein1100
IF2007 for Getein1600
IF5007 for Getein1160
IF3007 for Getein1180
REF IF4007 for Getein1200
IF6007 for Getein208

User Manual

INTENDED USE

PCT Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of Procalcitonin (PCT) in human serum, plasma or whole blood samples. The test is used as an aid in the assessment and evaluation of patients suspected of bacterial infection, trauma or shock.

SUMMARY

PCT is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine.

Measurement of PCT can be used as a marker of severe sepsis and generally grades well with the degree of sepsis, although levels of PCT in the blood are very low. PCT has the greatest sensitivity and specificity for differentiating patients with systemic inflammatory response syndrome (SIRS) from those with sepsis.

PCT levels may be useful to distinguish bacterial infections from nonbacterial infections. It has shown that PCT may help guide therapy and reduce antibiotic use, which can help save on cost of antibiotic prescriptions and drug resistance.

PRINCIPLE

The test uses an anti-human PCT monoclonal antibody conjugated with fluorescence latex. For PCT product, test line 1 was coated with anti-human PCT polyclonal antibody and test line 2 was coated with another anti-human PCT monoclonal antibody. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human PCT monoclonal anti-body binds with the PCT 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 other anti-human PCT monoclonal antibody or the polyclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of PCT 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 PCT 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 the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/box, 10 tests/box
1) PCT 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) PCT 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 PCT 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. Whole blood buffer/sample diluent 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, fluorescence latex pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human PCT monoclonal antibody, the test line are coated with another anti-human PCT monoclonal antibody and polyclonal antibody, 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

Getein1160 Immunofluorescence Quantitative Analyzer
Getein208 Hand-held Integrated System
Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 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/Getein208 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 the 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, 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): 100 μL.***
(for Getein1160/Getein1180/Getein208): 30 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: 15 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein1100) 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 identification.
11. Put the test card on a clean table,horizontally placed.
12. Using sample transfer pipette, deliver ***30μL*** 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: 15 minutes.*** Insert the test card into Getein 1160/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 ***30 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 automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein-208/Getein1200/Getein1600.

EXPECTED VALUE

The expected normal value for PCT was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for PCT is 0.10 ng/ml. (The probability that value of a normal person below 0.10 ng/ml is 99%.)
The table below comes from the research of ACCP/SCCM (American College of Chest Physicians/Society of Critical Care Medicine), showing the PCT value and its clinical meaning [4]:

PCT concentration	Clinical significance
< 0.50 ng/ml	Local bacterial infection is possible, systemic infection (sepsis) is not likely.
≥ 0.50 and < 2.00 ng/ml	Systemic infection (sepsis) is possible, a moderate risk of severe sepsis and/or septic shock.
≥ 2.00 ng/ml	Systemic infection (sepsis) is likely, a high risk of severe sepsis and/or septic shock.

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.05~50.00 ng/ml
Lower Detection Limit	≤0.05 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 interferent may influences 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. Balcl C, Sungurtekin H, Gürses E, Sungurtekin U, Kaptanog-lu B. Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit, Crit Care. 2003 February 7 (1):85~90.
2. Schuetz P, Christ-Crain M, Thomann R, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. Sep 9 2009; 302(10):1059-66.
3. Briel M, Schuetz P, Mueller B, et al. Procalcitonin-guided antibiotic use vs a standard approach for acute respiratory tract infections in primary care. Arch Intern Med. Oct 13 2008; 168(18):2000-7; discussion 2007-8.
4. Meisner M. Procalcitonin (PCT) - A New innovative infection parameter. Biochemical and clinical aspects. Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0.
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 PCT 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 PCT Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF06-SD-02

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