

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 N° 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	β 2-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	EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
coordination	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
standards	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)

(name and signature or equivalent marking of authorized person)



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

Page: 1 of 3



...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

Page: 2 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

A Member of the BSI Group of Companies.

Certificate No: **MD 728432**

Location

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

Registered Activities

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

Page: 3 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

A Member of the BSI Group of Companies.

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.



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.



- **Portable**

Dimensions: 276 mm(L) × 299 mm(W) × 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

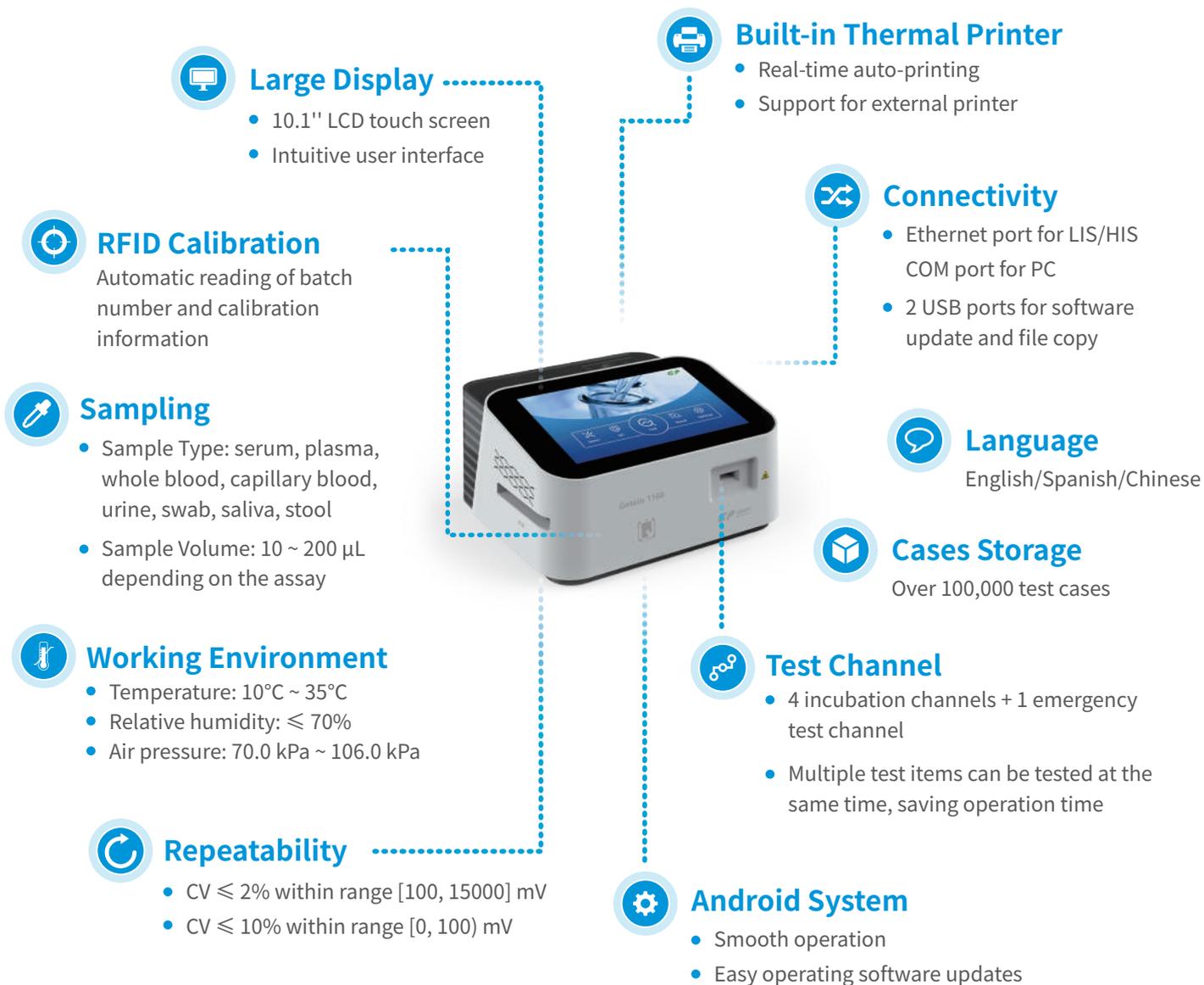
- **Reliable Accuracy**

Good correlation with CLIA method

- **Auto Cartridge Collection**

Automatically receive the used test cards when the test is finished

Technical Specifications



Application



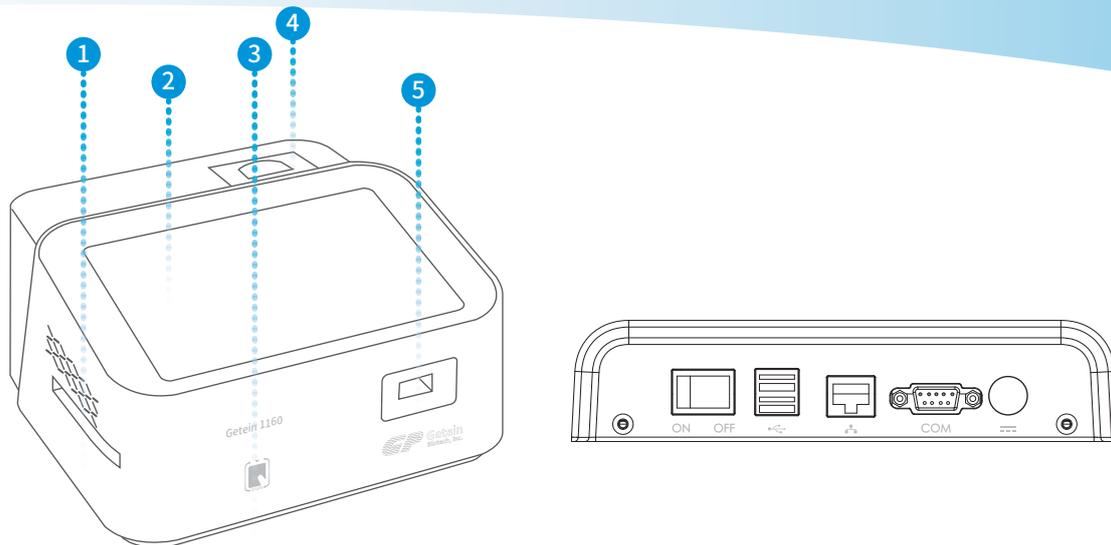
Laboratory



Clinic

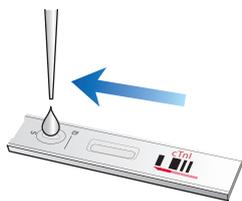


Emergency



- 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

Channel 1	Channel 2	Channel 3	Channel 4	No.	Sample ID	Test Item	Result	Test Time
16.12	16.12	16.12	16.12	697	cHc	17.05	2022-03-25 16:18:28	
16.12	16.12	16.12	16.12	696	sHc	+0.01	2022-03-25 16:14:58	
16.12	16.12	16.12	16.12	698	cHc	17.43	2022-03-25 16:14:29	
16.12	16.12	16.12	16.12	694	sHc	+0.01	2022-03-25 16:14:51	

- 3 Waiting in incubation



- 4 Results Output

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
IF5019	hs-cTnI	Acute myocardial infarction	0.04 ng/mL	S/P/WB	0.01-50.00 ng/mL	100 µL	10 min	NMPA CE
IF5098	TnT	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	100 µL	15 min	NMPA CE
IF5018	CK-MB	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	100 µL	10 min	NMPA CE
IF5089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	NMPA CE
IF5002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/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	NMPA CE
NEW IF5078	ST2	Chronic heart failure	35.0 ng/mL	S/P/WB	3.0-200.0 ng/mL	100 µL	15 min	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	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
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	NMPA CE
Coagulation Marker								
IF5006	D-Dimer	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	100 µL	10 min	NMPA 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	Thyroid Function	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	100 µL	15 min	NMPA CE
IF5023	T4	Thyroid Function	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	100 µL	15 min	NMPA CE
IF5067	ft3	Thyroid Function	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	100 µL	15 min	NMPA CE
IF5068	ft4	Thyroid Function	12.00-22.00 pmol/L	S/P/WB	0.30-100.00 pmol/L	100 µL	15 min	NMPA CE
Vitamin								
IF5031	25-OH-VD	Osteoporosis	20.00-50.00 ng/mL	S/P/WB/ Fingertip blood	8.00-100.00 ng/mL	20 µL	8 min	NMPA CE
NEW IF5094	Folate	Megaloblastic anemia	3.89 ng/mL~26.80 ng/mL (8.83 nmol/L-60.80 nmol/L)	S	1.2-40.0 ng/mL (2.72-90.8nmol/L)	20 µL	15 min	CE
NEW IF5070	Vitamin B12	Megaloblastic anemias	197.00-771.00 pg/mL (145.40-569.00 pmol/L)	S	100.0-2000.0 pg/mL or 73.8 -1476.0 pmol/L	100 µL	15 min	CE
Diabetes Mellitus								
IF5017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	10 µL	5 min	NGSP/IFCC NMPA CE
Inflammation								
IF5003	hs-CRP+CRP	Cardiovascular inflammation	3.0 mg/L 10.0 mg/L	S/P/WB Fingertip blood	0.5-200.0 mg/L	10 µL	3 min	NMPA 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
NEW IF5139	Calprotectin	Inflammatory bowel disease	<50.0 µg/g	Fecal specimen	10.0-600.0 µg/g	100 µL	15 min	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
IF5088	IL-6	Acute inflammation	Refer to user manual	S/P/WB Fingertip blood	1.5-4000.0 pg/mL	20 µL	15 min	NMPA CE
IF5015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.10 ng/mL CRP: 3.0 mg/L	S/P/WB	0.10-50.00 ng/mL 0.5-200.0 mg/L	20 µL	15 min	NMPA CE
IF5090	SAA/CRP	Sepsis, bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB Fingertip blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA CE
Renal Function								
IF5008	CysC	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	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA CE
IF5011	β₂-MG	Kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	10 µL	3 min	NMPA 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

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Fertility								
IF5013	HCG+β	Fertility	5.1 mIU/mL	S/P	5.0-100000.0 mIU/mL	10 μL	10 min	NMPA CE
IF5055	LH	PCOS, infertility evaluation	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF5056	FSH	PCOS, infertility evaluation	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF5066	AMH	Fertility, PCOS, gonadal function	Refer to User Manual	S/P	0.10-20.00 ng/mL	100 μL	15 min	NMPA CE
IF5048	PRL	Infertility	Refer to User Manual	S/P	0.50-200.00 ng/mL	100 μL	15 min	NMPA CE
IF5071	Prog	Infertility	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	NMPA CE
IF5138	Estradiol	Ovarian function	Refer to User Manual	S/P	40.0-4800.0 pg/mL	100 μL	15 min	CE
IF5073	Testosterone	Female PCOS	Male: 1.75-7.81 ng/mL Female: 0.10-0.75 ng/mL	S/P	0.10-16.00 ng/mL	100 μL	15 min	CE
Tumor Markers								
IF5053	tPSA	Prostate cancer	4.00 ng/mL	S/P	0.40-100.00 ng/mL	100 μL	15 min	NMPA
IF5072	fPSA	Prostate cancer	1.00 ng/mL	S/P	0.03-30.00 ng/mL	100 μL	10 min	NMPA
IF5050	AFP	Liver cancer, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	NMPA CE
IF5051	CEA	Malignant tumour screening	4.7 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	NMPA CE
IF5079	CA125	Ovarian cancer	35.0 U/mL	S/P/WB	2-500.0 U/mL	100 μL	15 min	CE
IF5080	CA19-9	Pancreatic cancer	27.0 U/mL	S/P/WB	2-1000.0 U/mL	100 μL	15 min	CE
IF5081	CA15-3	Breast cancer	26.2 U/mL	S/P/WB	1.5-300.0 U/mL	100 μL	10 min	CE
IF5052	PG I /PG II	Atrophic gastritis	PG I < 70.0 ng/mL PG I/PG II < 3.0 ng/mL	S/P	PG I: 1.0-200.0 ng/mL PG II: 1.0-100.0 ng/mL	100 μL	15 min	NMPA CE
Infectious Disease								
IF5057	Anti-HCV	Hepatitis C	1.00 S/CO	S/P	/	100 μL	15 min	
IF5058	Anti-TP	Syphilis	1.00 S/CO	S/P	/	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	1.00-100.00IU/mL	100 μL	15 min	
IF5063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	100 μL	15 min	
IF5091	SARS-CoV-2 Antigen	COVID-19	1.00 COI	Nasal swab	/	100 μL	15 min	CE
IF5047	H. pylori Antigen	H. pylori infection	5.0 ng/mL	Stool	1.0-200.0 ng/mL	10-50 mg	10 min	CE
IF5086	Influenza A/B	Respiratory viral infection	1.00 COI	Nasal swab	/	100 μL	15 min	CE
IF5136	Dengue NS1 Ag	Dengue virus infection	1.00 S/CO	S/P/WB	1.00-50.00 S/CO	100 μL	15 min	CE
IF5137	Dengue IgG/IgM Antibody	Dengue fever	COI<1.00	S/P/WB	0.50-100.00 COI	100 μL	15 min	CE
IF5140	H. Pylori Antibody	Functional dyspepsia	COI<1.0, S/CO	S/P/WB	0.50-100.00 S/CO	100 μL	15 min	CE
IF5085	RSV/Influenza A/B	Flu, LRTI	COI<1.00	Human nasal swab sample		100 μL	15 min	CE
Specific Protein and Rheumatism								
IF5075	RF	Rheumatoid arthritis	15.9 IU/mL	S/P/WB	10.0-640.0 IU/mL	10 μL	10 min	NMPA CE
IF5076	ASO	Rheumatoid arthritis	408.0 IU/mL	S/P/WB	60.0-1370.0 IU/mL	10 μL	10 min	NMPA CE
IF5029	Anti-CCP	Rheumatoid arthritis	25.0 U/mL	S/P/WB	10.0-400.0 U/mL	10 μL	15 min	CE
Metabolic Marker								
IF5112	Osteocalcin	Osteoporosis	Male: 14-70 ng/mL Female: 11-48 ng/mL	S/P	1.5-300.0 ng/mL	100 μL	15 min	CE
Others								
IF5110	Cortisol	Adrenal cortex function	Refer to User Manual	S/P	11-1655 nmol/L	100 μL	15 min	CE
IF5069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE
NEW IF5042	FOB	PUD	50 ng/mL	Fecal	25-1000 ng/mL	10-50 mg	10 min	CE
IF5077	Ferritin	Anemia/tumors	Male: 30.00-400.00 ng/mL Female: 13.00-150.00 ng/mL	S/P/WB Fingertip blood	0.50-1000.00 ng/mL	10 μL	15 min	NMPA CE





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

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



User Manual

INTENDED USE

CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of CK-MB/cTnI/Myo in human serum, plasma or whole blood samples. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Creatine kinases are dimer isozymes composed of two monomer subunits, CK-M (for skeletal muscle derived) and CK-B (for brain derived), which can form all three combinations of monomers: CK-BB, CK-MM, and CK-MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with trace amount of MB (around 1-4% of total CK activity). Cardiac muscles also contain the MM isoform, but higher amount of MB, typically around 20% of total CK activity. CK-MB is a more sensitive marker of myocardial injury than total CK activity, because it has a lower basal level and a much narrower normal range. Medical literatures commonly state that CK-MB levels are elevated in 4 to 6 hours, peak at 10 to 24 hours, and return to normal within 3 to 4 days after an acute myocardial infarction. Classically, an increase of the myocardial-specific enzyme CK-MB is considered as the hallmark of acute myocardial infarction, and increased levels are frequently interpreted by the clinician as objective evidence of myocardial cell damage.

Troponin complex consists of three regulatory proteins: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and C, which binds calcium. Cardiac troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardia.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of

chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

Myoglobin is a small monomeric protein which serves as an intracellular oxygen storage site. It is found in abundance in the muscle and can get through into the blood circulation directly when myocardial cell is damaged mildly, and can be elevated 1-2 hours after myocardial injury. Therefore, myoglobin has been advocated as a sensitive marker for early acute myocardial injury by American College of Cardiology Committee.

PRINCIPLE

Mixed monoclonal antibodies against human CK-MB, cTnI and Myo are conjugated with fluorescence latex and another set of anti-human CK-MB/cTnI/Myo monoclonal antibodies were coated on different test lines respectively. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies will bind with the CK-MB, cTnI and Myo in sample respectively and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by another set of monoclonal antibodies against human CK-MB, cTnI or Myo respectively resulting in the accumulation of fluorescence particles on the test lines. The fluorescence intensity of each test line increases in proportion to the amount of CK-MB, cTnI or Myo in sample.

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

CONTENTS

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

Package specifications: 25 tests/kit, 10 tests/kit

- 1) CK-MB/cTnI/Myo test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) User manual: 1 piece/kit
- 4) SD card: 1 piece/kit
- 5) Whole blood buffer: 1 bottle/kit

2. A kit for Getein208 contains:

Package specifications: 25 tests/kit, 10 tests/kit

- 1) CK-MB/cTnI/Myo test card in a sealed pouch with desiccant
- 2) Disposable pipet

- 3) Sample diluent
- 4) User manual: 1 piece/kit
- 5) SD card: 1 piece/kit

3. A kit for Getein1200/Getein1600 contains:

Package specifications: 2x24 tests/kit, 2x48 tests/kit

- 1) Sealed cartridge with 24/48 Getein CK-MB/cTnI/Myo test cards

- 2) User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

- 1) Sample diluent: 1 bottle/kit
- 2) Box with pipette tips: 96 tips/kit
- 3) Mixing plate: 1 piece/kit

4. Sample diluent/Whole blood buffer composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

5. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies, these three lines are coated with another anti-human CK-MB, another anti-human cTnI and another anti-human Myo monoclonal antibody, respectively, and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

Getein1180 Immunofluorescence Quantitative Analyzer

Getein1600 Immunofluorescence Quantitative Analyzer

Getein1160 Immunofluorescence Quantitative Analyzer

Getein208 Hand-held Integrated System

Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4-30°C 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 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 μ L.**

(for Getein208): 70 μ L.

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:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform SD card calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver **100 μ L** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading **100 μ L** sample on the test card).
5. **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:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.

- ation.
- Put the test card on a clean table, horizontally placed.
 - Using sample transfer pipette, deliver **100 µL** of sample into the sample well 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).
 - Insert the test card into Getein1160/Getein1180 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 Getein208:

- Long press the Power Button to start the analyzer.
 - The system will enter (Test) menu.
 - Confirm SD card lot No. in accordance with test kit lot No.. Read the relevant information in the SD card for calibration.
 - Insert test card according to the analyzer prompts.
- Note:** Do not move the test card after it is inserted.
- Add sample according to the analyzer prompts. Then draw **70 µL** of sample and drop it into sample diluent. Then drop **70 µL** of sample mixture into the sample port on the test card.
 - After sample adding, the system starts react-time countdown automatically.
 - After the countdown is over, the result will be shown on the screen.

For Getein1200/Getein1600:

- Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
- Place the sample diluent at the correct position in Getein1200/Getein1600.
- 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:

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

TEST RESULTS

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

EXPECTED VALUE

The expected normal value for CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for CK-MB is 5.00 ng/ml.

(The probability that value of a normal person below 5.00 ng/ml is 99%.)
The expected normal value for cTnI was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.10 ng/ml. (The probability that value of a normal person below 0.10 ng/ml is 99%.)

The expected normal value for Myo was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for Myo is 50.0 ng/ml. The 97.5th percentile of the concentration for Myo is 70.0 ng/ml. (According to different Statistics method, the probability that value of a normal person below 50.0 ng/ml is 95% or below 70.0 ng/ml is 97.5%.)

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

PERFORMANCE CHARACTERISTICS

	CK-MB	cTnI	Myo
Measuring Range	2.50~80.00 ng/ml	0.10~50.00 ng/ml	30.0~600.0 ng/ml
Lower Detection Limit	≤ 2.50 ng/ml	≤ 0.10 ng/ml	≤ 30.0 ng/ml
Within-Run Precision	≤ 10%		
Between-Run Precision	≤ 15%		

LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

- Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med. 1998, 36:887-893.
- Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
- EN ISO 18113-1:2011 In vitro diagnostic medical devices -

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

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult <i>instructions for use</i> of consult <i>electronic instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult <i>instructions for use</i>
	Catalogue number		

Thank you for purchasing CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF09-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



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



D-Dimer Fast Test Kit (Immunofluorescence Assay)

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 exclusion of deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in patient suspected of DVT or PE, and an aid in the diagnosis of disseminated intravascular coagulation (DIC).

For professional and laboratory use only.

SUMMARY

Thrombin converts fibrinogen to soluble fibrin by cleaving the fibrinopeptides A and B. The fibrin monomers polymerize spontaneously. Active factor XIII links two D domains and generates a solid fibrin clot. A new plasmin resistant antigenic determinant (D-dimer) is produced. Fragments containing D-dimer are accordingly formed during the degradation of a fibrin clot by plasmin. D-dimer antigens are specific markers of fibrin clot formation and fibrinolysis and may be clinically useful markers for excluding venous thromboembolism.

The primary diagnostic application of D-dimer testing is to rule out thromboembolic events, such as deep vein thrombosis or pulmonary embolism. If the D-dimer test result is below the decision threshold, a thromboembolic event can be ruled out by the negative predictive value (NPV) of the test. The D-dimer test, in combination with a well-validated preclinical trial probability score, is an effective and safe screening tool to rule out thromboembolic events. However, the presence of symptoms over a certain period of time, such as more than one week, may yield normal D-dimer values. Fibrin degradation products are a sensitive marker in disseminated intravascular coagulation (DIC).

In addition to DVT, PE and DIC, D-dimers may reflect other causes associated with fibrin formation, such as age, pregnancy complications, malignant disease or vascular

abnormalities. Therefore, elevated D-Dimer levels should be interpreted in the context of possible underlying disease and clinical symptoms.

PRINCIPLE

D-Dimer Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence labelled 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 D-Dimer monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of D-Dimer in sample. Fluorescent signals intensity can be analyzed by applicable device thus the D-Dimer in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1150/ Getein 208		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
D-Dimer 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

* D-Dimer test card

A test card mainly consists of: Fluorescence labelled D-Dimer monoclonal antibody and D-Dimer monoclonal antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180/Getein 208 in each tube mainly consists of: phosphate buffer, NaN₃ (< 0.1%).

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

- phosphate buffer, NaN₃ (< 0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

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

- Mixing plate (1 piece/box).

Note:

- 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.
- The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
- 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
Getein 208 Hand-held Integrated System

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/Getein 208: 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

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Do not reuse the test card and disposable pipet.
- Handle all specimens as potentially infectious. The foil bag is non-degradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

- 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.
- Suggest using plasma for better results.
- Plasma are stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C, and 1 month at -20°C.
- Whole blood and fingertip blood are stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.
- Reaction time: 10 minutes.** After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.

4) Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and 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) Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and 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 208:

1) Enter testing interface of Getein 208. Confirm SD card lot No. in accordance with test kit lot No. Read the relevant information in the SD card for calibration.

2) Select the corresponding “Sample” mode on the analyzer (refer to the analyzer user manual for details). Insert test card according to the analyzer prompts.

3) Deliver 60 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 60 µL of sample mixture into the sample well on the test card according to the analyzer prompts.

4) After sample adding, 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) 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	25 g/L	0.1 g/L

3. Patient samples may contain heterophilic antibodies (e.g. human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react in immunoassays to give a falsely elevated or depressed result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed.

EXPECTED VALUE

The expected 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.

Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10–10.0 mg/L
Limit of Detection	≤ 0.10 mg/L
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

REFERENCES

- MedlinePlus [Internet]. Bethesda (MD): National Library of Medicine (US); [updated Jun 24; cited 2020 Jul 1]. Available from: <https://medlineplus.gov/>.
- Sarig G, Kilil-Drori AJ, Chap-Marshak D, Brenner B, Drugan A. Activation of coagulation in amniotic fluid during normal human pregnancy. *Thromb Res.* 2011 Apr 18.
- Roldán V, Marín F, Muiña B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma

von Willibrand 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.

4. Sakamoto K, Yamamoto Y, Okamoto 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.

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 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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Keep dry
	Keep away from sunlight		Caution
	Unique device identifier		

Thank you for using D-Dimer Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Willbrandt 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.
 von Willbrandt 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.
 Sakamoto K, Yamamoto Y, Okamoto 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.
 EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
 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.
 CMC Medical Devices & Drugs S.L.
 Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
 Tel.: +34951214054
 Website: www.getein.com

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

Catalogue number	Applicable analyzer	Package specification
IF1006-10T	Getein 1100	10 T/kit
IF1006	Getein 1100	25 T/kit
IF8006-10T	Getein 1150	10 T/kit
IF8006	Getein 1150	25 T/kit
IF5006-10T	Getein 1160	10 T/kit
IF5006	Getein 1160	25 T/kit
IF3006-10T	Getein 1180	10 T/kit
IF3006	Getein 1180	25 T/kit
IF6006-10T	Getein 1200	10 T/kit
IF6006	Getein 208	25 T/kit
IF4006-24T	Getein 1200	2×12 T/kit
IF4006	Getein 1200	2×24 T/kit
IF4006-96T	Getein 1200	2×48 T/kit
IF2006-24T	Getein 1600	2×12 T/kit
IF2006	Getein 1600	2×24 T/kit
IF2006-96T	Getein 1600	2×48 T/kit



HCG+β Fast Test Kit (Immunofluorescence Assay)

Instructions for Use

INTENDED USE

HCG+β Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of human chorionic gonadotropin (HCG) in human serum, plasma and whole blood samples. This test is used as an aid in pregnancy test. For professional and laboratory use only. This test can NOT be used to guide the diagnosis of pair trisomy 21.

SUMMARY

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the placenta, a component of the fertilized egg, after conception. The biologically active hormone (intact HCG) is composed of non-covalently linked α and β subunit. The alpha subunit is similar to luteinizing hormone (LH), follicle-stimulating hormone (FSH), thyroid-stimulating hormone (TSH), whereas the beta subunit is unique to HCG and confers its biological and immunological specificity. During a normal pregnancy, HCG level can be detected soon after conception. It will double every 72 hours and reach its peak in the first 8–11 weeks of pregnancy.

HCG measurement with blood or urine can be used as an aid in pregnancy test. Regular HCG has been known as a promoter of corpus luteal progesterone production, even though this function only explains 3 weeks of a full gestations production of regular HCG. HCG-positive indicates an implanted blastocyst and mammalian embryogenesis. Elevated values of HCG during pregnancy are indicative of chorionic carcinoma, hydatidiform mole, or multiple pregnancy. HCG+β measurements can also be used in conjunction with other parameters during the second trimester of pregnancy to assess the risk of trisomy 21 (Down syndrome).

PRINCIPLE

HCG+β Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay based on the double antibody sandwich principle. After the sample has been applied to the test strip, the

fluorescence labelled anti-human β-HCG monoclonal antibody binds with the HCG and β-HCG in sample and forms an antigen-antibody complex. The complex moves to the test card detection zone by capillary action. In the detection zone, marked antigen-antibody complex will be captured on the test line by another anti-human β-HCG monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of HCG and β-HCG in sample. Fluorescent signals intensity can be analyzed by applicable device thus the HCG and β-HCG in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1160/Getein 1180/ Getein 208		Getein 1150	
	10 T/kit	25 T/kit	10 T/kit	25 T/kit
HCG+β test card*	10 pcs	25 pcs	10 pcs	25 pcs
Disposable pipet	10 pcs	25 pcs	10 pcs	25 pcs
Sample diluent**	10 tubes	25 tubes	10 tubes	25 tubes
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	/	/

- 1) Main key components in the kit
-Fluorescence labelled anti-human β-HCG monoclonal antibody, anti-human β-HCG monoclonal antibody.
- 2) Main key components in Sample diluent for Getein 208/Getein 1150/Getein 1160/Getein 1180
-Phosphate buffer (20 mmol/L), NaN₃ (< 0.1%).

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 1150 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 208 Hand-held Integrated System

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:

Use the test card within 1 hour once the foil pouch is opened.

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 is damaged.
4. Do not open pouches until performing the test.
5. Samples must be added using the disposable pipet in the kit to avoid incorrect results. Do not reuse the disposable pipet.
6. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
7. It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum, plasma and whole blood samples**. Heparin, sodium citrate and EDTA can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. 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 samples should not be frozen and can be stored at 2–8°C for 3 days.
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
4. SAMPLE VOLUME (for **Getein 1150/Getein 1160/Getein 1180/Getein 208**): **10 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 1160/Getein 1180:

- 1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- 2) Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
- 3) Remove test card and disposable pipet from the sealed pouch immediately before use and put them on a clean table, horizontally placed.
- 4) Use a disposable pipet to capillary aspirate **10 μL** of sample and add it into the sample dilution tube, then press the cap of the disposable pipet and aspirate to mix the sample until the

lyophilized particles are completely dissolved.

- 5) Press the cap of the disposable pipet to deliver the above sample mixture, and drop it into the sample well on the test card.

Note: Please add sample mixture to the test card immediately after mixing. Adding it in advance or delay may not get the correct test results.

- 6) 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) Use a disposable pipet to capillary aspirate **10 μL** of sample and add it into the sample dilution tube. Press the cap of the disposable pipet and aspirate to mix the sample until the lyophilized particles are completely dissolved.
- 4) Press the cap of the disposable pipet to deliver the above sample mixture, and drop it into the sample well on the test card.

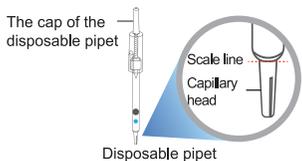
Note: Please add sample mixture to the test card immediately after mixing. Adding it in advance or delay may not get the correct test results.

- 5) 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 208:

- 1) Long press the Power Button to start the analyzer.
 - 2) The system will enter (Test) menu.
 - 3) Confirm SD card lot No. in accordance with test kit lot No. Read the relevant information in the SD card for calibration.
 - 4) Insert test card according to the analyzer prompts.
- Note:** Do not move the test card after it is inserted.
- 5) Use a disposable pipet to capillary aspirate **10 μL** of sample and add it into the sample dilution tube. Press the cap of the disposable pipet and aspirate to mix the sample until the lyophilized particles are completely dissolved.
 - 6) Press the cap of the disposable pipet to deliver the above sample mixture, and drop it into the sample well on the test card.
 - 7) After sample adding, the system will initiate a 10-minute reaction countdown automatically. After the countdown is over, the result will be shown on the screen.

Precautions for Using Disposable Pipet

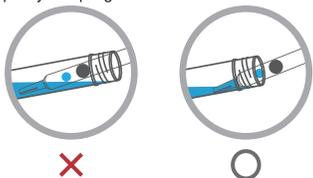


Disposable pipet

Note 1: Do not press the cap of the disposable pipet with your finger during capillary sampling.



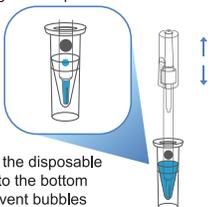
Note 2: Ensure that no part above the slit touches the sample during capillary sampling.



Note 3: During capillary sampling, ensure the sample volume reaches the scale line. If the sample is not sucked to the scale line, reinsert the disposable pipet into sample to the scale line to try again.



Note 4: Insert the disposable pipet to the bottom of tube to prevent bubbles when mixing the sample.



Insert the disposable pipet to the bottom to prevent bubbles

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.
- Interference in samples may influence the results. The table below listed the maximum allowance of these potential interference:

Interference	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L
Interference	RF	Human anti-mouse antibody	Biotin
Concentration (Max)	3000 IU/mL	120 g/L	80 ng/mL

EXPECTED VALUE

The expected normal value for HCG was determined by testing samples from 315 healthy, non-pregnant individuals. The 97.5th percentile of the concentration for HCG is 5.1 mIU/mL (IU/L). According to the literature, HCG results greater than or equal to 25.0 mIU/mL (IU/L) are considered positive. Representative HCG ranges during normal pregnancy are shown in the table below. Because other clinical reference citations may show different values, it is recommended that each laboratory establish its expected values for the population it serves.

Serum HCG Levels During Normal Pregnancy	
Gestational weeks	HCG (IU/L)
0.2-1 week	5-50
1-2 week	50-500
2-3 week	100-5,000
3-4 week	500-10,000
4-5 week	1,000-50,000
5-6 week	10,000-100,000
6-8 week	15,000-200,000

PERFORMANCE CHARACTERISTICS

Measuring Range	5.0–100000.0 mIU/mL
Limit of Detection	≤ 5.0 mIU/mL
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

REFERENCES

- Tietz NW, Clinical Guide to Laboratory Tests, 3rd Ed. 1995. p.134-136.
- Hohnadel DC, Kaplan LA. Beta-hCG. Methods in clinical

- chemistry. Edited by Pesc, AJ and Kaplan LA. St. Louis, MO: The C.V. Mosby Company, 1987.
- Cole LA. New discoveries on the biology and detection of human chorionic gonadotropin. *Reprod. Biol. Endocrinol.* 7: doi:10.1186/1477-7827-7-8.
 - Hoermann R, Spoettl G, Moncayo R, et al. Evidence for the presence of human chorionic gonadotropin (hCG) and free beta-subunit of hCG in the human pituitary. *J. Clin. Endocrinol. Metab.* 71 (1):179-186.
 - EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
 - 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 HCG+β 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 <i>instructions for use</i> or consult electronic <i>instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative
	CE mark		Do not use if package is damaged and consult <i>instructions for use</i>
	Catalogue number		Keep dry
	Keep away from sunlight		Caution
	Unique device identifier		

Thank you for using HCG+β Fast Test Kit (Immunofluorescence Assay). Please read this Instructions for use carefully before operating to ensure proper use.

Version: WIF17-SD-05

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

CMC Medical Devices & Drugs S.L.
 Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain
 Tel: +34951214054

Catalogue number	Applicable analyzer	Package specification
IF8013-10T	Getein 1150	10 T/kit
IF8013	Getein 1150	25 T/kit
IF5013-10T	Getein 1160	10 T/kit
IF5013	Getein 1160	25 T/kit
IF3013-10T	Getein 1180	10 T/kit
IF3013	Getein 1180	25 T/kit
IF6013-10T	Getein 208	10 T/kit
IF6013	Getein 208	25 T/kit



hs-cTnI Fast Test Kit (Immunofluorescence Assay)

Instructions for Use

INTENDED USE

hs-cTnI 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). For professional and laboratory use only.

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

hs-cTnI Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence labelled cTnI monoclonal antibody binds with the cTnI in sample and forms a marked antigen-antibody complex. The complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another cTnI monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of cTnI in sample. Fluorescent signals intensity can be analyzed by applicable device thus the cTnI in sample be detected quantitatively.

CONTENTS

Materials provided	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
hs-cTnI 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

* hs-cTnI test card

A test card mainly consists of: Fluorescence labelled cTnI monoclonal antibody, cTnI monoclonal antibody.

** Sample diluent

(1) Sample diluent for Getein 1150/Getein 1160/Getein 1180 in each tube mainly consists of: phosphate buffer, Na₂S (< 0.1%).

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

- phosphate buffer, Na₂S (< 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 standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".

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 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 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 is damaged.
4. Do not open pouches until performing the test.
5. Samples must be added using the disposable pipet in the kit to avoid incorrect results. Do not reuse the disposable pipet.
6. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
7. It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc) when touching kits or samples.

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 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.

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 1160/Getein 1180:

- 1) Confirm SD card lot No.in accordance with the test kit lot No., perform "SD card" calibration when necessary.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (refer to the analyzer user manual for details).
- 3) Remove test card and disposable pipet from the sealed pouch immediately before use and put them on a clean table, horizontally placed.
- 4) Insert the disposable pipet into the sample, press the cap of the disposable pipet to the bottom, and deliver 100 µL of sample into one tube of sample diluent.
- 5) Press the cap of the disposable pipet to mix the sample until the lyophilized pellet is completely dissolved.
- 6) Deliver the sample mixture by pushing the cap of the disposable pipet and drop the sample mixture into the sample well on the test card.

Note: Please add samples mixture **immediately** after mixing. Adding samples mixture in advance or delay may not get the correct test results.

7) 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) Insert the disposable pipet into the sample, press the cap of the disposable pipet to the bottom, and deliver 100 µL of sample into one tube of sample diluent.

4) Press the cap of the disposable pipet to mix the sample until the lyophilized pellet is completely dissolved.

5) Deliver the sample mixture by pushing the cap of the disposable pipet and drop the sample mixture into the sample well on the test card.

Note: Please add samples mixture **immediately** after mixing. Adding samples mixture in advance or delay may not get the correct test results.

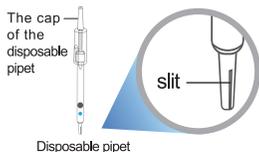
- 7) Press the "Start" button **immediately** after sample loading. The analyzer will initiate a 10-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
- Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

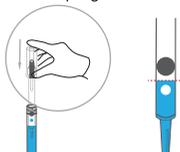
Precautions for Using Disposable Pipet

Note 1: Ensure the slit is fully submerged in the sample during sampling.

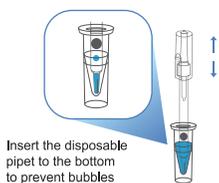


Disposable pipet

Note 2: Press the cap of the disposable pipet with your finger during sampling and do not repeatedly press the cap of the disposable pipet when sampling.



Note3: When mixing and sampling. Insert the disposable pipet to the bottom of tube to avoid the formation of bubbles.



Insert the disposable pipet to the bottom to prevent bubbles

LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis

should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.

- Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	500 mg/dL	1000 mg/dL	20 mg/dL

- Patient samples may contain heterophilic antibodies (e.g. human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react in immunoassays to give a falsely elevated or depressed result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed.
- The test was evaluated for cross-reactivity according to CLSI EP07-A3. The following substances do not cross-react when present in sample at the concentrations indicated.

Cross-reacting substances	cTnC	cTnT	sTnI
Concentration (Max)	1000 ng/mL	1000 ng/mL	1000 ng/mL

EXPECTED VALUE

The expected normal value for hs-cTnI was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for hs-cTnI is 0.040 ng/mL. (The probability that value of a normal person below 0.040 ng/mL is 99%.)

Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

Measuring Range	0,010–50,000 ng/mL
Limit of Detection	≤ 0,010 ng/mL
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

REFERENCES

- Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction; A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of patients with acute myocardial infarction). J Am Coll Cardiol. 2004, 44 (3): E1-E211.
- Kristian Thygesen, Joseph S Alpert, et al. Fourth Universal Definition of Myocardial Infarction (2018). J Am Coll Cardiol

2018, Aug 25: [Epub ahead of print];

- Yader S, Korosh S, et al. Clinical Use of Cardiac Troponin for Acute Cardiac Care and Emerging Opportunities in the Outpatient Setting[J]. Minerva Medica, 2019, 110 (2): 139-56.
- Ibanez B, James S, Agewall S, Antunes MJ, Bucciarelli-Ducci C, Bueno H, et al. 2017 ESC Guidelines for the Management of Acute Myocardial Infarction in Patients Presenting with ST-Segment Elevation: the Task Force for the Management of Acute Myocardial Infarction in Patients Presenting with ST-Segment Elevation of the Europea Society of Cardiology. Eur Heart J 2018,39:119-77

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on hs-cTnI Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Keep dry
	Keep away from sunlight		Caution
	Unique device identifier		

Thank you for using hs-cTnI Fast Test Kit (Immunofluorescence Assay). Please read this Instructions for use carefully before operating to ensure proper use.

Version: WIF67-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

CMC Medical Devices & Drugs S.L.
 Add.: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain
 Tel: +34951214054

Catalogue number	Applicable analyzer	Package specification
IF8019-10T	Getein 1150	10 T/kit
IF8019	Getein 1150	25 T/kit
IF5019-10T	Getein 1160	10 T/kit
IF5019	Getein 1160	25 T/kit
IF3019-10T	Getein 1180	10 T/kit
IF3019	Getein 1180	25 T/kit
IF4019-24T	Getein 1200	2×12 T/kit
IF4019	Getein 1200	2×24 T/kit
IF4019-96T	Getein 1200	2×48 T/kit
IF2019-24T	Getein 1600	2×12 T/kit
IF2019	Getein 1600	2×24 T/kit
IF2019-96T	Getein 1600	2×48 T/kit



cTnI Control

REF QC001

Instructions for use

PRODUCT NAME

cTnI Control

PRODUCT SPECIFICATION

Package:

- 1 level × 6 vials × 1mL, 1 level × 3 vials × 1mL
- 2 levels × 2 vials × 1mL, 2 levels × 1 vial × 1mL
- 2 levels × 3 vials × 1mL, 3 levels × 2 vials × 1mL
- 3 levels × 1 vial × 1mL

cTnI Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of cTnI on the Getein Platforms. For professional and laboratory use only.

PRINCIPLE

The lyophilized cTnI control is prepared from dissolving stable and high quality recombinant cTnI antigen into the matrix. With the matching analyzers and reagents, it can assess the performance characteristics of a certain detection system. As different analyzers and reagents have uncertainty to some extent, different results may appear.

CONTENTS

The kit for FIA 8000/FIA 8600/Getein 1100/Getein 1160/Getein 1180/Getein 200/Getein 208 contains:

1. cTnI Control - Level 1
cTnI Control - Level 2
cTnI Control - Level 3
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit

The kit for Getein 1600/Getein 1200/Getein 3200/Getein 3600/MAGICL 6000/MAGICL 6000i/MAGICL 6200/MAGICL 6800/MAGICL 8200/MAGICL 8500/MAGICL 8800 contains:

1. cTnI Control - Level 1
cTnI Control - Level 2
cTnI Control - Level 3
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit

4. Quality control holder - Level 1
Quality control holder - Level 2
Quality control holder - Level 3

Note: Each quality control holder is labelled with a barcode, in which the basic information (test item name, lot number, sample type, expiry date, etc.) of the corresponding test item is programmed.

MATCHING EQUIPMENTS

FIA 8000/8600 Quantitative Immunoassay Analyzer
 Getein 1100/1160/1180/1600/1200 Immunofluorescence Quantitative Analyzer
 Getein 200/208 Hand-held Integrated System
 Getein 3200/3600 Integrated System
 MAGICL 6000/MAGICL 6000i/MAGICL 6200/MAGICL 6800/MAGICL 8200/MAGICL 8500/MAGICL 8800 Chemiluminescence Immunoassay Analyzer

STORAGE AND STABILITY

UNOPENED: The control is stable for 18 months at 2-8°C.

OPENED: The Liquid control is stable for 15 days at 2-8°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

It's recommended to divide liquid control into smaller tubes for storing more time. Liquid control is stable for 30 days at -20°C to -70°C.

Note: Product should be protected from light. Excessive exposure to light may affect the test result.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein matching reagents
4. Getein matching analyzers

TEST PROCEDURE

Read the instructions for use carefully before using and operate according to the instructions for use to avoid incorrect results. Different batches of quality control products have different target values, please refer to the corresponding target value sheet.

1. Return the product to room temperature (15-30°C) before use. Open the vial carefully to avoid powder spillage.
2. Dissolve each vial of control with 1ml distilled water.

- Close the vial, let the mixture subside for approximately 10 minutes and then mix gently until all contents are dissolved completely.

For FIA 8000/FIA 8600/Getein 1100/Getein 200/Getein 208:

- Treat the control in the same manner as patient specimen. Refer to the instructions for use of reagents and analyzers.

For Getein 1160/Getein 1180:

- Enter the quality control interface, and manually input the barcode number or use a barcode scanner to scan the quality control barcode.
- After the quality control information prompt appears, manually input the target and standard deviation values according to the target value sheet.

- Start the QC test.

For Getein 1600/1200/3200/3600/MAGICL 6000/MAGICL 6000i/MAGICL 6200/MAGICL 6800/MAGICL 8200/MAGICL 8500/MAGICL 8800:

- Insert the quality control holder into the sample holder.
- Insert the sample holder into the sample chamber of the analyzer.
- The machine will automatically scan the barcode labelled on the quality control holder. After the quality control information prompt appears, manually input the target and standard

deviation values according to the target value sheet.

- Start the QC test.

ASSIGNED VALUES

Refer to values listed on the target value sheet.

If the result is beyond the range, it indicates the existence of some uncertain factors in the testing system.

Referring to the control graph helps judge the accuracy and stability of the testing system. The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

- Homogeneity: $\leq 10\%$
- Accuracy: the test result should be within the range of target value

LIMITATIONS

- This product can only be used on the Getein platforms.
- Variation exists between different analyzers developed by different methods even using the same control product.
- This product is not intended to be used as

standard material.

NOTES

- For *in vitro* diagnostic use only.
- Do not use the product beyond the expiration date.
- Avoid multiple freeze-thaw cycles.
- Do not use the product if it is contaminated with bacteria.
- Proper handling and disposal methods should be followed in accordance with local regulations.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on cTnI control 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
	CE mark		Date of manufacture
	Consult <i>instructions for use</i> or consult <i>electronic instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Catalogue number		Authorized representative in the European Community/European Union
	Biological risks		Keep away from sunlight

Thank you for purchasing cTnI Control.

Please read this instructions for use carefully before operating to ensure proper use. Please contact Getein Biotech, Inc. if you have any questions.



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



CMC Medical Devices & Drugs S.L.

Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain.

Tel: +34951214054



D-Dimer Control

REF QC006

Instructions for use

PRODUCT NAME

D-Dimer Control

PRODUCT SPECIFICATION

Package:

- 1 level × 6 vials × 1mL, 1 level × 3 vials × 1mL
- 2 levels × 2 vials × 1mL, 2 levels × 1 vial × 1mL
- 2 levels × 3 vials × 1mL, 3 levels × 2 vials × 1mL
- 3 levels × 1 vial × 1mL

D-Dimer Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of D-Dimer on the Getein Platforms. For professional and laboratory use only.

PRINCIPLE

The lyophilized D-Dimer control is prepared from

dissolving stable and high quality recombinant D-Dimer antigen into the matrix. With the matching analyzers and reagents, it can assess the performance characteristics of a certain detection system. As different analyzers and reagents have uncertainty to some extent, different results may appear.

CONTENTS

The kit for FIA 8000/FIA 8600/Getein 1100/Getein 1160/Getein 1180/Getein 200/Getein 208 contains:

1. D-Dimer Control - Level 1
D-Dimer Control - Level 2
D-Dimer Control - Level 3
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit

The kit for Getein 1600/Getein 1200/Getein 3200/Getein 3600/MAGICL 6000/MAGICL 6000i/MAGICL 6200/MAGICL 6800/MAGICL 8200/MAGICL 8500/MAGICL 8800 contains:

1. D-Dimer Control - Level 1
D-Dimer Control - Level 2
D-Dimer Control - Level 3
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit
4. Quality control holder - Level 1
Quality control holder - Level 2
Quality control holder - Level 3

Note: Each quality control holder is labelled with a barcode, in which the basic information (test item name, lot number, sample type, expiry date, etc.) of the corresponding test item is programmed.

MATCHING EQUIPMENTS

FIA 8000/8600 Quantitative Immunoassay Analyzer
Getein 1100/1160/1180/1600/1200 Immunofluorescence Quantitative Analyzer

Getein 200/208 Hand-held Integrated System

Getein 3200/3600 Integrated System

MAGICL 6000/MAGICL 6000i/MAGICL 6200/MAGICL 6800/MAGICL 8200/MAGICL 8500/MAGICL 8800 Chemiluminescence Immunoassay Analyzer

STORAGE AND STABILITY

UNOPENED: The control is stable for 18 months at 2-8°C.

OPENED: The Liquid control is stable for 15 days at 2-8°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

It's recommended to divide liquid control into smaller tubes for storing more time. Liquid control is stable for 30 days at -20°C to -70°C.

Note: Product should be protected from light.

Excessive exposure to light may affect the test result.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein matching reagents
4. Getein matching analyzers

TEST PROCEDURE

Read the instructions for use carefully before using and operate according to the instructions for use to avoid incorrect results. Different batches of quality control products have different target values, please refer to the corresponding target value sheet.

1. Return the product to room temperature (15-30°C) before use. Open the vial carefully to avoid powder spillage.
2. Dissolve each vial of control with 1ml distilled water.
3. Close the vial, let the mixture subside for approximately 10 minutes and then mix gently until all contents are dissolved completely.

For FIA 8000/FIA 8600/Getein 1100/Getein 200/Getein 208:

4. Treat the control in the same manner as patient specimen. Refer to the instructions for use of reagents and analyzers.

For Getein 1160/Getein 1180:

5. Enter the quality control interface, and manually input the barcode number or use a barcode scanner to scan the quality control barcode.

6. After the quality control information prompt appears, manually input the target and standard deviation values according to the target value sheet.

7. Start the QC test.

For Getein 1600/1200/3200/3600/MAGICL 6000/MAGICL 6000i/MAGICL 6200/MAGICL 6800/MAGICL 8200/MAGICL 8500/MAGICL 8800:

8. Insert the quality control holder into the sample holder.

9. Insert the sample holder into the sample chamber of the analyzer.

10. The machine will automatically scan the barcode labelled on the quality control holder. After the quality control information prompt appears, manually input the target and standard deviation values according to the target value sheet.

11. Start the QC test.

ASSIGNED VALUES

Refer to values listed on the target value sheet.

If the result is beyond the range, it indicates the existence of some uncertain factors in the testing system.

Referring to the control graph helps judge the accuracy and stability of the testing system. The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: $\leq 10\%$
2. Accuracy: the test result should be within the range of target value

LIMITATIONS

1. This product can only be used on the Getein platforms.
2. Variation exists between different analyzers developed by different methods even using the same control product.
3. This product is not intended to be used as standard material.

NOTES

1. For *in vitro* diagnostic use only.
2. Do not use the product beyond the expiration date.

3. Avoid multiple freeze-thaw cycles.

4. Do not use the product if it is contaminated with bacteria.

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

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer control 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
	CE mark		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Catalogue number		Authorized representative in the European Community/European Union
	Biological risks		Keep away from sunlight

Thank you for purchasing D-Dimer Control.

Please read this instructions for use carefully before operating to ensure proper use.

Please contact Getein Biotech, Inc. if you have any questions.



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



CMC Medical Devices & Drugs S.L.

Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain.

Tel: +34951214054



CK-MB/cTnI/Myo Control

REF QC016

User Manual

PRODUCT NAME

CK-MB/cTnI/Myo Control

PRODUCT SPECIFICATION

Package:

- 1 level x 6 vials x1ml, 1 level x 3 vials x1ml
 - 2 levels x 2 vials x1ml, 2 levels x 1 vial x1ml
 - 3 levels x 2 vials x1ml, 3 levels x 1 vial x1ml
- CK-MB/cTnI/Myo Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of CK-MB/cTnI/Myo on the Getein Platforms.

PRINCIPLE

The lyophilized CK-MB/cTnI/Myo control is prepared

from dissolving stable and high quality recombinant CK-MB antigen, cTnI antigen and Myo antigen into calf serum. With the matching analyzers and reagents, it can assess the performance characteristics of a certain detection system. As different analyzers and reagents have uncertainty to some extent, different results may appear.

CONTENTS

The kit for FIA8000/FIA8600/Getein1100/Getein1160/Getein1180/Getein200/Getein208 contains:

1. CK-MB/cTnI/Myo Control - Level 1
CK-MB/cTnI/Myo Control - Level 2
CK-MB/cTnI/Myo Control - Level 3
2. User manual: 1 piece/kit
3. Target value sheet: 1 piece/kit

The kit for Getein1600/Getein1200/Getein3200/Getein3600 contains:

1. CK-MB/cTnI/Myo Control - Level 1
CK-MB/cTnI/Myo Control - Level 2
CK-MB/cTnI/Myo Control - Level 3
2. User manual: 1 piece/kit
3. Target value sheet: 1 piece/kit
4. Quality control holder - Level 1
Quality control holder - Level 2
Quality control holder - Level 3

Note: Each quality control holder is labelled with a barcode, in which the basic information (test item

name, lot number, sample type, expiry date, etc.) of the corresponding test item is programmed.

MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer
Getein1100/1160/1180/1600/1200 Immunofluorescence Quantitative Analyzer

Getein200/208 Hand-held Integrated System
Getein3200/3600 Integrated System

STORAGE AND STABILITY

UNOPENED: The control is stable for 18 months at 2-8°C.

OPENED: The Liquid control is stable for 1 day at 2-8°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

It's recommended to divide liquid control into smaller tubes for storing more time. Liquid control is stable for 30 days at -20°C to -70°C.

Note: Product should be protected from light. Excessive exposure to light may affect the test result.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein matching reagents
4. Getein matching analyzers

TEST PROCEDURE

Read the manual carefully before using and operate according to the manual to avoid incorrect results. Different batches of quality control products have different target values, please refer to the corresponding target value sheet.

1. Return the product to room temperature (15-30°C) before use. Open the vial carefully to avoid powder spillage.
2. Dissolve each vial of control with 1ml distilled water.
3. Close the vial, let the mixture subside for approximately 10 minutes and then mix gently until all contents are dissolved completely.

For FIA8000/FIA8600/Getein1100/Getein200/Getein208:

4. Treat the control in the same manner as patient specimen. Refer to the User Manual of reagents and analyzers.

For Getein1160/Getein1180:

5. Enter the quality control interface, and manually input the barcode number or use a barcode scanner

to scan the quality control barcode.

6. After the quality control information prompt appears, manually input the target and standard deviation values according to the target value sheet.

7. Start the QC test.

For Getein1600/1200/3200/3600:

8. Insert the quality control holder into the sample holder.
9. Insert the sample holder into the sample chamber of the analyzer.
10. The machine will automatically scan the barcode labelled on the quality control holder. After the quality control information prompt appears, manually input the target and standard deviation values according to the target value sheet.
11. Start the QC test.

ASSIGNED VALUES

Refer to values listed on the target value sheet. If the result is beyond the range, it indicates the existence of some uncertain factors in the testing system.

Referring to the control graph helps judge the accuracy and stability of the testing system. The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: $\leq 10\%$
2. Accuracy: the test result should be within the range of target value

LIMITATIONS

1. This product can only be used on the Getein platforms.
2. Variation exists between different analyzers developed by different methods even using the same control product.
3. This product is not intended to be used as standard material.

NOTES

1. For *in vitro* diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Avoid multiple freeze-thaw cycles.
4. Do not use the product if it is contaminated with bacteria.
5. Proper handling and disposal methods should be followed in accordance with local regulations.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found

on CK-MB/cTnI/Myo control 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
	CE mark		Date of manufacture
	Consult <i>instructions for use</i> or consult electronic <i>instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Catalogue number		Authorized representative in the European Community/European Union
	Biological risks		Keep away from sunlight

Thank you for purchasing CK-MB/cTnI/Myo Control.

Please read this user manual carefully before operating to ensure proper use.

Please contact Getein Biotech, Inc. if you have any questions.



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



CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo N° 18, CP 29006,
Málaga, Spain.
Tel: +34951214054



free β -HCG Control

REF QC103

Instructions for use

PRODUCT NAME

free β -HCG Control

PRODUCT SPECIFICATION

Package:

- 1 level x 6 vials x1 mL, 1 level x 3 vials x1 mL
 - 2 levels x 3 vials x1 mL, 2 levels x 2 vials x1 mL,
 - 2 levels x 1 vial x1 mL
 - 3 levels x 2 vials x1 mL, 3 levels x 1 vial x1 mL
- free β -HCG Control - Level 1/2/3

INTENDED USE

This product is intended for in vitro diagnostic use in the quality control of free β -HCG on the Getein Platforms. This test can NOT be used to guide the diagnosis of pair trisomy 21. For professional and laboratory use only.

PRINCIPLE

The lyophilized free β -HCG control is prepared from dissolving stable and high quality recombinant free β -hCG antigen into the matrix. With the matching analyzers and reagents, it can assess the performance characteristics of a certain detection system. As different analyzers and reagents have uncertainty to some extent, different results may appear.

CONTENTS

The kit for FIA 8000/FIA 8600/Getein 1100/Getein 1160/Getein 1180/Getein 200/Getein 208 contains:

1. free β -HCG Control - Level 1
- free β -HCG Control - Level 2
- free β -HCG Control - Level 3
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit

The kit for Getein 1600/Getein 1200/Getein 3200/Getein 3600/MAGICL 6000/MAGICL 6000i/MAGICL 6200/MAGICL 6800/MAGICL 8200/MAGICL 8500/MAGICL 8800 contains:

1. free β -HCG Control - Level 1
- free β -HCG Control - Level 2
- free β -HCG Control - Level 3
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit
4. Quality control holder - Level 1

Quality control holder - Level 2

Quality control holder - Level 3

Note: Each quality control holder is labelled with a barcode, in which the basic information (test item name, lot number, sample type, expiry date, etc.) of the corresponding test item is programmed.

MATCHING EQUIPMENTS

FIA 8000/8600 Quantitative Immunoassay Analyzer
Getein 1100/1160/1180/1600/1200 Immunofluorescence Quantitative Analyzer
Getein 200/208 Hand-held Integrated System
Getein 3200/3600 Integrated System
MAGICL 6000/MAGICL 6000i/MAGICL 6200/MAGICL 6800/MAGICL 8200/MAGICL 8500/MAGICL 8800 Chemiluminescence Immunoassay Analyzer

STORAGE AND STABILITY

UNOPENED: The control is stable for 18 months at 2-8°C.

OPENED: The Liquid control is stable for 15 days at 2-8°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial. It's recommended to divide liquid control into smaller tubes for storing more time. Liquid control is stable for 30 days at -20°C to

-70°C. Avoid repeated freeze-thaw cycles.

Note: Product should be protected from light. Excessive exposure to light may affect the test result.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 mL pipette
2. Distilled water
3. Getein matching reagents
4. Getein matching analyzers

TEST PROCEDURE

Read the instructions for use carefully before using and operate according to the manual to avoid incorrect results. Different batches of quality control products have different target values, please refer to the corresponding target value sheet.

1. Return the product to room temperature (15-30°C) before use. Open the vial carefully to avoid powder spillage.
 2. Dissolve each vial of control with 1 mL distilled water.
 3. Close the vial, let the mixture subside for approximately 10 minutes and then mix gently until all contents are dissolved completely.
- For FIA 8000/FIA 8600/Getein 1100/Getein 200/Getein 208:
4. Treat the control in the same manner as patient

specimen. Refer to the Instructions for use of reagents and analyzers.

For Getein 1160/Getein 1180:

5. Enter the quality control interface, and manually input the barcode number or use a barcode scanner to scan the quality control barcode.
6. After the quality control information prompt appears, manually input the target and standard deviation values according to the target value sheet.
7. Start the QC test.

For Getein 1600/1200/3200/3600/MAGICL 6000/MAGICL 6000i/ MAGICL 6200/MAGICL 6800/MAGICL 8200/MAGICL 8500/MAGICL 8800:

8. Insert the quality control holder into the sample holder.
9. Insert the sample holder into the sample chamber of the analyzer.
10. The machine will automatically scan the barcode labelled on the quality control holder. After the quality control information prompt appears, manually input the target and standard deviation values according to the target value sheet.
11. Start the QC test.

ASSIGNED VALUES

Refer to values listed on the target value sheet. If the result is beyond the range, it indicates the existence of some uncertain factors in the testing

system.

Referring to the control graph helps judge the accuracy and stability of the testing system. The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: $\leq 10\%$
2. Accuracy: the test result should be within the range of target value

LIMITATIONS

1. This product can only be used on the Getein platforms.
2. Variation exists between different analyzers developed by different methods even using the same control product.
3. This product is not intended to be used as standard material.

NOTES

1. For *in vitro* diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Avoid multiple freeze-thaw cycles.
4. Do not use the product if it is contaminated with bacteria.
5. Proper handling and disposal methods should be

followed in accordance with local regulations.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on free β -HCG Control 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
	CE mark		Date of manufacture
	Consult <i>instructions for use</i> or consult electronic <i>instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Catalogue number		Authorized representative in the European Community/European Union
	Biological risks		Keep away from sunlight

Thank you for purchasing free β -HCG Control. Please read this Instructions for use carefully before operating to ensure proper use. Please contact Getein Biotech, Inc. if you have any questions.



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

 CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo N° 18, CP 29006,
Málaga, Spain.
Tel: +34951214054