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

Document No.: GP-GMSQ-2024121101

Letter of Authorization

To whom it may concern,

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

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

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

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

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

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

Getein Biotech, Inc.

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Name: Steven Zhou
Position: Overseas Sales Director

Steven Zhou

Digitally signed by Dolgopol Iulian
Date: 2026.02.19 08:42:07 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

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

Holds Certificate No: **MD 728432**

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

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

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

...making excellence a habit.™

Certificate No: **MD 728432**

Registered Scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.
研发，生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂和胶体金自测试剂。 研发，生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。

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

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

Certificate No: **MD 728432**

Location	Registered Activities
Getein Biotech, Inc. No.9 Bofu Road Luhe District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京市 六合区 沿江工业开发区 博富路9号 邮编：211505	Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease. 研发，生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂和胶体金自测试剂。 研发，生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。
Getein Biotech, Inc. No. 6 KeFeng Road Jiangbei New District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京 江北新区 科丰路6号 邮编：211505	Manufacture of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), Colloidal Gold self-testing Assay to detect infectious disease. Manufacture of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease. 生产化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂和传染病相关胶体金自测试剂。 生产用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。

Original Registration Date: 2020-05-29

Effective Date: 2023-07-26

Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

EC Declaration of Conformity

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

Ref. No.:20220513-A04

Manufacturer
(Name, Address)

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

Authorized Representative
(Name, Address)

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

Medical device

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

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

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

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

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

Applicable coordination standards

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

Signatory representative declares herein the above-mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex I.

This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by BSI Group The Netherlands B. V. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

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

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

CE

EC Declaration of Conformity

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

Ref. No.: 220324-A01

Maker (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China
Authorized Representative (Name, Address)	**CMC Medical Devices & Drugs S.L.** Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Medical device

Product Name

Myo Control

CK-MB Control

NT-proBNP Control

D-Dimer Control

PCT Control

CRP Control

cTnI Control

H-FABP Control

mAlb Control

NGAL Control

β_2-MG Control

CysC Control

CK-MB/cTnI/Myo Control

CK-MB/cTnI Control

NT-proBNP/cTnI Control

β-HCG Control

HbA1c Control

TSH Control

T4/T3 Control

T3 Control

T4 Control

FOB Control

H.Pylori Ag Control

SAA Control

LH Control

FSH Control

25-OH-VD Control

FT3 Control

FT4 Control

PRL Control

SARS-CoV-2 Ag Control

Progesterone Control

IL-6 Control

Ferritin Control

TnT Control

BNP Control

IgE Control

AMH Control

Anti-TPO Control

Anti-Tg Control

Testosterone Control

Estradiol Control

UE3 Control

CA50 Control

CA125 Control

CA15-3 Control

CA19-9 Control

CA242 Control

CA72-4 Control

CYFRA21-1 Control

NSE Control

AFP Control

CEA Control

HE4 Control

Insulin Control

C-Peptide Control

PTH Control

Osteocalcin Control

IAA Control

hGH Control

Cortisol Control

Syphilis Control

PGI Control

PGII Control

G17 Control

ProGRP Control

SCC Control

ST2 Control

Lp-PLA2 Control

CG Control

HA Control

LN Control

PIIIP N-P Control

CIV Control

SHBG Control

Renin Control

Tg Control

PIVKA-Ⅱ Control

HBP Control

Influenza A/B Ag Control

Anti-TSHR Control

RF Control

ASO Control

SAA/CRP Control

PCT/CRP Control

ALD Control

free β-HCG Control

S100 Control

Thyroid Markers Control

Tumor Markers Control

Cardiac Markers Control

Hormone markers Control

Vitamin B12 Control

t-PAIC Control

TNF-α Control

TMAb Control

TM Control

TAT Control

rT3 Control

PIC Control

PAPP-A Control

IL-10 Control

IL-8 Control

IL-2R Control

IL-1β Control

IGFBP-3 Control

HSV-I IgM Control

HSV-I IgG Control

	Folate Control
	DHEA-S Control
	Calcitonin Control
	Angiotensin II Control
	Angiotensin I Control
	AFP-L3 Control
	ACTH Control
	HSV-II IgG Control
	HSV-II IgM Control
	Anti-CCP Control
Classification	Others

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

Signatory representative declares herein the above-mentioned devices meet the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III.

This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by BSI Group The Netherlands B. V..

The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

CE

Nanjing, March 27, 2022

(place and date of issue)

Enben Su

(name and signature or equivalent marking of authorized person)

Getein Biotech, Inc.

STOCK CODE 603387

4 Incubation Channels,

1 Emergency Test Channel!

Getein 1160

Immunofluorescence Quantitative Analyzer

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

Constant Temperature

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

Multiple Channels

4 incubation channels
+
1 emergency test channel

- **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

Large Display
- 10.1'' LCD touch screen
- Intuitive user interface

Built-in Thermal Printer
- Real-time auto-printing
- Support for external printer

RFID Calibration
Automatic reading of batch number and calibration information

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

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

Language
English/Spanish/Chinese

Cases Storage
Over 100,000 test cases

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

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

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

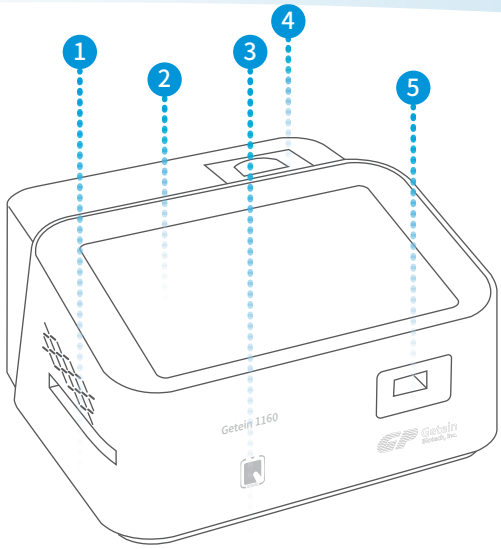
Android System
- Smooth operation
- Easy operating software updates

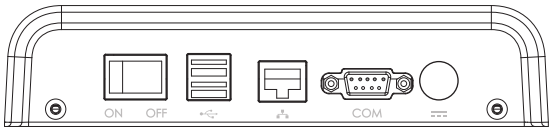
Application

Laboratory

Clinic

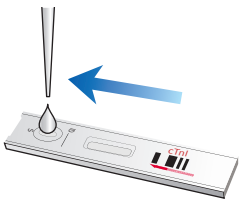
Emergency





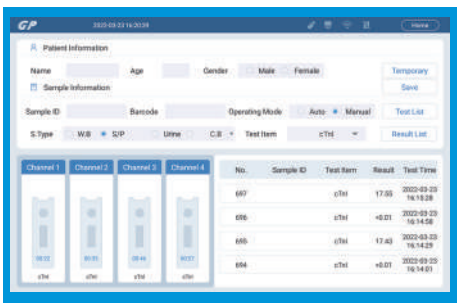
1. Card Exit
2. 10.1-inch Touch Screen
3. RFID Card Recognition Zone
4. Built-in Thermal Printer
5. Card Inlet

Operation Procedure



1 Sample dispense

2 Insert test cards, four allowed at the same time



3 Waiting in incubation

4 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 µlU/mL	S/P	0.10-50.00 µlU/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	**β_2-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

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ISO 9001:2015 ISO 13485 FSC CE NMPA MDSAP NGSP IFCC IVD

WPT3-1K16-09

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

CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

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

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Getein
Biotech, Inc.

GP

CE IVD

CK-MB
Fast Test Kit
(Immunofluorescence Assay)

Instructions for use

INTENDED USE

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

SUMMARY

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

PRINCIPLE

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

CONTENTS

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

* CK-MB test card
A test card mainly consists of: Fluorescence labelled CK-MB monoclonal antibody, CK-MB monoclonal antibody.
** Sample diluent
(1) Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180 in each tube mainly consists of: phosphate buffer (20 mmol/L), NaN_3 (< 0.1%).
(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:
- Phosphate buffer (20 mmol/L), NaN_3 (< 0.1%) (25 mL/bottle for Getein 1200, 30 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:
1. The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.
2. The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
3. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1150 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:
Store the kit at 4–30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
In-use stability:
For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. Serum, plasma, whole blood can be used as samples in the assay. Suggest using serum or plasma for better results.
2. Heparin and EDTA can be used as the anticoagulant for plasma and whole blood. Do not use hemolysis specimens.
3. Serum and plasma are stable for 4 hours at room temperature (15–30°C), 7 days at 2–8°C, and 6 months at -20°C.
4. Whole blood is stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. ***SAMPLE VOLUME (for Getein 1100/Getein 1150/Getein 1160/Getein 1180): 100 µL***

TEST PROCEDURE

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

For Getein 1100:
(1) Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
(2) Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
(3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
(4) Using disposable pipet or pipette, deliver ***100 µL*** of sample into one tube of sample diluent, mix thoroughly. Then drop ***100 µL*** of sample mixture into the sample well on the test card.
(5) ***Reaction time: 10 minutes***. After reaction time is elapsed, insert the test card into Getein 1100 and press “ENT” button

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

For Getein 1160/Getein 1180:

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

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

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

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

(5) Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (***10 minutes***) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1150:

(1) Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code **(On the outer packaging box)** to complete calibration as prompted by the instrument.

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

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

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

For Getein 1200/Getein 1600:

(1) Place the reagent cartridge in the cartridge zone. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.

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

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

LIMITATIONS

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

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

EXPECTED VALUE

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

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

PERFORMANCE CHARACTERISTICS

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

REFERENCES

1. Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

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

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

Thank you for purchasing CK-MB Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Version: WIF28-S-13

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EU REP CMC Medical Devices & Drugs S.L.
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Catalogue number	Applicable analyzer	Package specification
IF1018-10T	Getein 1100	10 T/kit
IF1018	Getein 1100	25 T/kit
IF8018-10T	Getein 1150	10 T/kit
IF8018	Getein 1150	25 T/kit
IF5018-10T	Getein 1160	10 T/kit
IF5018	Getein 1160	25 T/kit
IF3018-10T	Getein 1180	10 T/kit
IF3018	Getein 1180	25 T/kit
IF4018-24T	Getein 1200	2×12 T/kit
IF4018	Getein 1200	2×24 T/kit
IF4018-96T	Getein 1200	2×48 T/kit
IF2018-24T	Getein 1600	2×12 T/kit
IF2018	Getein 1600	2×24 T/kit
IF2018-96T	Getein 1600	2×48 T/kit

GP

CE IVD

Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)

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

Instructions for Use

INTENDED USE

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

SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three regulatory proteins: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; C, which binds calcium. Cardiac Troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of Troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarction (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

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

PRINCIPLE

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

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Getein208 Hand-held Integrated System/automatically inserted by Getein1200/ Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100, Getein1160, Getein1180, Getein208, Getein1200 and Getein1600), the concentration of cTnI in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/ Getein208/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) cTnI 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) cTnI 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: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein cTnI 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 a fluorescence latex-labelled anti-human cTnI monoclonal antibody, the test line is coated with another anti-human cTnI monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein208 Hand-held Integrated System
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 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/Getein-208 within 1 hour once the foil pouch is opened.
For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples. Heparin and EDTA*** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME***(for Getein1100/Getein1160/Getein1180): 100 μL.***

(for Getein208): 70 μL.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:
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 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).
5. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:
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.
4. Put the test card on a clean table,horizontally placed.
5. 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).
6. 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:
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. 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.
6. After sample adding, the system starts react-time countdown automatically.
7. After the countdown is over, the result will be shown on the screen.

For Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

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

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10~50.00 ng/ml
Lower Detection Limit	≤ 0.10 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. 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

1. Mauro Pantaghini. Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF02-S1-05

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GP

CE IVD

CysC
Fast Test Kit
(Immunofluorescence Assay)

User Manual

INTENDED USE

CysC Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cystatin C (CysC) in human serum, plasma or whole blood samples. The test result is used as an aid in the assessment and evaluation of index of glomerular filtration rate, and has important application value in renal function, kidney damage and renal transplantation.
For professional and laboratory use only.

SUMMARY

Cystatin C (CysC) is mainly used as a biomarker of kidney function. Cystatin C has a low molecular weight (approximately 13.3 kilodaltons), and it is removed from the bloodstream by glomerular filtration in the kidneys. If kidney function and glomerular filtration rate decline, the blood levels of cystatin C rise. Serum levels of cystatin C are a more precise test of kidney function (as represented by the glomerular filtration rate, GFR) than serum creatinine levels.
This finding is based mainly on cross-sectional studies (on a single point in time). Longitudinal studies (that follow cystatin C over time) are scarcer; some studies show promising results. Cystatin C levels are less dependent on age, sex, race and muscle mass compared to creatinine. Cystatin C measurement alone has not been shown to be superior to formula-adjusted estimations of kidney function. As opposed to previous claims, Cystatin C has been found to be influenced by body composition. It has been suggested that cystatin C might predict the risk of developing chronic kidney disease, thereby signaling a state of 'preclinical' kidney dysfunction.

PRINCIPLE

CysC 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 fluorescently labelled CysC monoclonal antibody specifically binds to target CysC molecules in the sample, forming a labeled antigen-antibody complex. The complex through capillary action to the detection zone, where it is captured by another CysC monoclonal antibody coated on the detection area of nitrocellulose membrane, ultimately forming a fluorescent double-antibody sandwich complex. The test line fluorescence intensity demonstrates proportional correlation with CysC concentration in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the CysC in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1150		Getein 1200/Getein 1600		
	10 T/kit	25 T/kit	10 T/kit	25 T/kit	2×12 T/kit	2×24 T/kit	2×48 T/kit
CysC 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

1) Main key components in the kit
- Fluorescence labelled CysC monoclonal antibody and CysC monoclonal antibody.
2) Main key components in Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180
- Phosphate buffer (20 mmol/L), NaN_3 (< 0.1%).
3) Main key components in Sample diluent for Getein 1600/Getein 1200
- Phosphate buffer (20 mmol/L), NaN_3 (< 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:
1. The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.
2. The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
3. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1150 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:
Store the kit at 4–30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
In-use stability:
For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Do not reuse the test card and disposable pipet.
6. 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.
7. 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

1. Serum, plasma and whole blood can be used as samples in the assay.
2. Sodium citrate and EDTA can be used as the anticoagulant for plasma and whole blood. Do not use hemolysis specimens.
3. Serum and plasma are stable for 4 hours at room temperature (15–30°C), 7 days at 2–8°C, and 6 months at -20°C.
4. Whole blood is stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. SAMPLE VOLUME (**for Getein 1100/Getein 1150/Getein 1160/Getein 1180**): 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 1100:
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” on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
4) Deliver ***10 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) ***Reaction time: 5 minutes***. After reaction time is elapsed, insert the test card into Getein 1100 and press “ENT” button (click on “Start” icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:
1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform “SD card” calibration when using a new batch of kits.
2) Select the corresponding “Sample” on the analyzer

according to the sample type (see the user manual of analyzer for details).

3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
4) Deliver ***10 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 (5 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 ***10 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 5-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

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

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

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

EXPECTED VALUE

The expected normal value for CysC was determined by testing samples from 233 apparently healthy individuals. The reference range of CysC is 0.51 mg/L to 1.09 mg/L calculated by using normal distribution methods.

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	0.50–10.00 mg/L
Limit of Detection	≤ 0.50 mg/L
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

REFERENCES

1. Bjurman C, Snygg-Martin U, Olaison L, et al. Cystatin C in a composite risk score for mortality in patients with infective endocarditis: a cohort study. BMJ Open. 2012, Jul 12, 2(4).
2. Chae HW, Shin JI, Kwon AR, et al. Spot urine albumin to creatinine ratio and serum cystatin C are effective for detection of diabetic nephropathy in childhood diabetic patients. J Korean Med Sci.2012, 27(7):784-787.
3. Odutayo A, Cherney D. Cystatin C and acute changes in glomerular filtration rate. Clin Nephrol. 2012, 78(1):64-75.
4. EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling)-Part1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling)-Part2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF13-S-17

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Catalogue number	Applicable analyzer	Package specification
IF1008-10T	Getein 1100	10 T/kit
IF1008	Getein 1100	25 T/kit
IF8008-10T	Getein 1150	10 T/kit
IF8008	Getein 1150	25 T/kit
IF5008-10T	Getein 1160	10 T/kit
IF5008	Getein 1160	25 T/kit
IF3008-10T	Getein 1180	10 T/kit
IF3008	Getein 1180	25 T/kit
IF4008-24T	Getein 1200	2×12 T/kit
IF4008	Getein 1200	2×24 T/kit
IF4008-96T	Getein 1200	2×48 T/kit
IF2008-24T	Getein 1600	2×12 T/kit
IF2008	Getein 1600	2×24 T/kit
IF2008-96T	Getein 1600	2×48 T/kit

GP

CE IVD

HbA1c
Fast Test Kit
(Immunofluorescence Assay)

Instructions for Use

REF IF5017 for Getein1160
IF3017 for Getein1180

INTENDED USE

HbA1c fast test kit is intended for the quantitative measurement of HbA1c in human whole blood samples. This test is used as an aid for monitoring glycemic control in diabetes. In addition, it can identify potential diabetes and for later monitoring. For professional and laboratory use only.

SUMMARY

Hemoglobin (Hb) is the protein molecule in red blood cells with the main function of transporting oxygen and carbon dioxide in blood. HbA1c belongs to the glycated hemoglobin, a fraction formed by the attachment of various saccharides to the Hb molecule and is proportional to the average blood glucose concentration over the last four weeks to three months. One advantage of using HbA1c for diagnosis is that the test does not require a fasting blood sample. Although HbA1c testing is mainly used for monitoring blood sugar control in patients with diabetes, the World Health Organization (WHO) now recommends that HbA1c can be used as a diagnostic test for diabetes, provided that stringent quality assurance tests are in place and assays are standardized to criteria aligned to the international reference values.

PRINCIPLE

Anti-human Hb monoclonal antibodies conjugated with fluorescence latex and anti-human HbA1c monoclonal antibodies are coated on the test line. After sample being added to the test strip, the fluorescence latex-labelled anti-human Hb monoclonal antibody binds to HbA1c and Hb in sample proportionally, forming marked antigen-antibody complex. The complex moves to the detection zone by capillary action. Then the marked antigen-antibody complex is captured on the test line by the anti-human HbA1c monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of HbA1c in sample. Fluorescent signals intensity can be analyzed by applicable device thus the HbA1c in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Component	10 T/kit	25 T/kit
HbA1c test card	Anti-human HbA1c monoclonal antibody and rabbit anti-mouse IgG antibody	10 pcs	25 pcs
Disposable pipet	/	10 pcs	25 pcs
Sample diluent	Phosphate buffer (20 mmol/L), proclin 300 (＜0.1%)	10*0.25 mL/tube	25*0.25 mL/tube
Instructions for use	/	1 pc	1 pc
SD card	/	1 pc	1 pc

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. Do not mix or interchange different batches of kits.

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

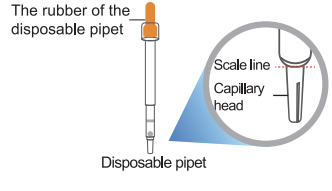
1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Samples must be added using the disposable pipet in the kit to 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. Carefully read and follow instructions for use to ensure proper test performance.
8. Extreme Hematocrit (below 25% or over 65%) may affet the test result.

SPECIMEN COLLECTION AND PREPARATION

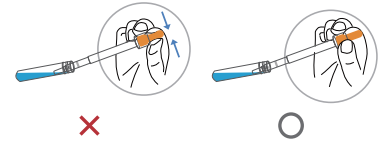
1. This assay was designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
2. **Whole blood samples** can be used in the assay. **EDTA** can be used as the anticoagulant under aseptic conditions.
3. This assay should be performed within 4 hours after whole blood being collected.
4. Specimens may be stored up to 3 days at 2~8℃ and avoid cryopreservation.
5. Specimens must be recovered to room temperature before testing.
6. Mix the blood sample thoroughly before testing.

TEST PROCEDURE

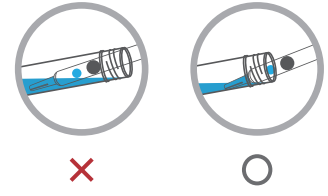
1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.
3. Confirm SD card lot No.in accordance with the test kit lot No. , perform “SD card” calibration when necessary.
4. Select the “W.B” on the analyzer according to the sample type.
5. Remove test card and disposable pipet from the sealed pouch immediately before use and put them on a clean table, horizontally placed.
6. Use disposable pipet to deliver 10 μL of sample into the sample diluent tube.



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



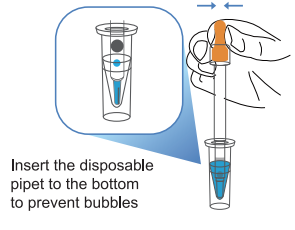
Note 2: The capillary head of disposable pipet touches the sample level gently and draws the sample.



Note 3: Do not take too more or less samples than 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.

7. Insert the disposable pipet into the sample diluent tube to mix the sample by pressing the rubber of the disposable pipet for 4-6 times.

Note: Insert the disposable pipet to the bottom of tube to prevent bubbles.



8. Deliver the sample mixture by pressing the rubber of the disposable pipet and drop the sample mixture into the sample port “S” on the test card.

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

9. Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (5 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

LIMITATIONS

1. The test results of this reagent are for clinical reference only, and cannot be used as the basis for diagnosis or exclusion of cases alone additional tests should be performed accordingly.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	2500 mg/dL
Bilirubin	10 mg/dL

EXPECTED VALUE

HbA1c concentration is determined using samples obtained from 345 apparently healthy individuals. The normal value for HbA1c is 3.80%-5.80%. It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	3.50%-14.00%
Limit of Detection	≤3.50%
Within-Run Precision	≤8%

REFERENCES

1. Cagliero E, Levina E V, Nathan D M. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients[J]. Diabetes care, 1999, 22(11): 1785-1789.
2. Özdamar Ö, Gün i, Keskin U, et al. The role of maternal serumbeta-HbA1c and PAPP-A levels at gestational weeks 10 to 14 in the prediction of pre-eclampsia[J]. 2014.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on HbA1c Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

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

Thank you for using HbA1c Fast Test Kit (Immunofluorescence Assay). Please read this instructions for use carefully before operating to ensure proper use.

Version: WIF22-SD5-01

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GP

CE IVD

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, NaN_3 (< 0.1%).
(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:
- phosphate buffer, NaN_3 (< 0.1%) (25 mL/bottle for Getein 1200, 30 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:
1. The 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.

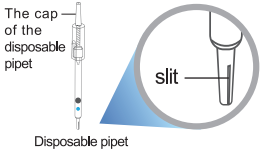
7) Press the "Start" button **immediately** after sample loading. The analyzer will initiate a 10-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

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.

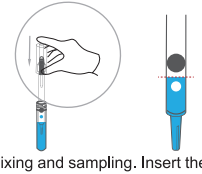
Precautions for Using Disposable Pipet

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

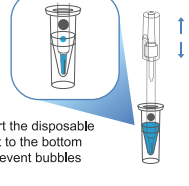


Disposable pipet

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.



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)	500 mg/dL	1000 mg/dL	20 mg/dL

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.
4. 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

1. 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.
2. 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];
3. 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.
4. 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*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EU REP	Authorized representative
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		Keep dry
	Keep away from sunlight		Caution
UDI	Unique device identifier		

Thank you for 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

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Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

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

Catalogue number	Applicable analyzer	Package specification
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

GP

CE IVD

NT-proBNP
Fast Test Kit
(Immunofluorescence Assay)

Instructions for use

INTENDED USE

NT-proBNP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of N-terminal B-type natriuretic peptide precursor (NT-proBNP) in human serum, plasma or whole blood samples. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of Heart Failure (HF). For professional and laboratory use only.

SUMMARY

N-terminal B-type natriuretic peptide precursor (NT-proBNP) is secreted from the left cardiac ventricle in response to volume and pressure overload. It's an inactive N-terminal fragment that split from BNP prohormone. NT-proBNP can be used to evaluate heart contractile, diastolic dysfunction, and ventricular segmental wall motion coordination. Besides, it has high sensitivity and negative predictive value (>97%). As a gold standard recommended by the European Society of Cardiology, American Heart Association, and American College of Cardiology for the diagnosis and prognosis of heart failure, NT-proBNP is used to indicate heart failure patients at the early stage, determine HF risk levels, monitor medical efficiency of HF drugs, evaluate prognosis of HF patients and to distinguish dyspnea that caused by HF from other diseases. Furthermore, NT-proBNP is a risk assessment indicator for Acute Coronary Syndrome.

PRINCIPLE

NT-proBNP 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 labeled NT-proBNP monoclonal antibody binds with the NT-proBNP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the NT-proBNP monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of NT-proBNP in sample. Fluorescent signals intensity can be analyzed by applicable device thus the NT-proBNP in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1150		Getein 1200/Getein 1600		
	10 T/kit	25 T/kit	10 T/kit	25 T/kit	2×12 T/kit	2×24 T/kit	2×48 T/kit
NT-proBNP 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

* NT-proBNP test card

A test card mainly consists of: Fluorescence labeled NT-proBNP monoclonal antibody, NT-proBNP monoclonal antibody and polyclonal IgG antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180 in each tube mainly consists of: phosphate buffer, NaN_3 (< 0.1%).

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

- Phosphate buffer, NaN_3 (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:

1. The SD card, also known as the standard curve data card, stores standard curve data for specific test items and uses RFID technology to transfer the data to analyzers via touch.
2. The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
3. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1150 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4–30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

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

For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Do not reuse the test card and disposable pipet.
6. 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.
7. 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

1. This test can be used for **serum, plasma and whole blood samples. Heparin, sodium citrate 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. It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 3 days when stored at 2–8°C and 3 months when stored at -20°C. Stable in whole blood for 3 days when stored at 2–8°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
5. SAMPLE VOLUME (**for Getein 1100/Getein 1150/Getein 1160/Getein 1180**): 100μL.

TEST PROCEDURE

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

For Getein 1100:

1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch 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) ***Reaction time: 10 minutes***. After reaction time is elapsed, insert the test card into Getein1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).

3) Remove the test card from the sealed pouch 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) Using disposable pipet or pipette, deliver 100 μL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 μL of sample mixture into the sample well on the test card.
4) Press the "Start" button **immediately** after sample loading. The analyzer will initiate a 10-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

1) 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.

TEST RESULTS

NT-proBNP Fast Test Kit (Immunofluorescence Assay) results are provided in pg/mL. Dilute the sample which concentration is higher than the upper limit with sample diluent, and the dilution ratio should be less than 3 times.

LIMITATIONS

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

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

EXPECTED VALUE

The expected normal value for NT-proBNP was determined by testing samples from 2,500 apparently healthy individuals. The 95th percentile of the concentration for NT-proBNP is 185 pg/mL and the 97.5th percentile of the concentration for NT-proBNP is 300 pg/mL. Because of the apparent difference of the concentration of NT-proBNP among different age groups, the reference values of the NT-proBNP are reported in groups. Details refer to Table 1. Clinical diagnosis value: refer to Roche criterion, details see Table 2.

Table 1 NT-proBNP reference value

Age / Percentile	≤44	45-54	55-64	65-74	≥75	Statistic analysis
95	98.5	130	215	290	530	185
97.5	116	170	270	350	740	300

Table 2 Standard of excluding/diagnosing HF by NT-proBNP

Age	<50	50-75	≥75	Diagnosis of HF
NT-proBNP (pg/mL)	≥450	≥900	≥1800	High probability of HF
	300-450	300-900	300-1800	Low probability of HF, need to combine with other clinical evaluation
	<300	<300	<300	Exclude HF

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	100–35000 pg/mL
Limit of Detection	≤ 100 pg/mL
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

REFERENCES

1. de Lemos JA, McGuire DK, Drazner MH. B-type natriuretic peptide in cardiovascular disease. Lancet 2003; 362:316-322.
2. Pfister R, Scholz M, Wielckens K, Erdmann E, Schneider CA. The value of natriuretic peptides NT-proBNP and BNP for the assessment of left-ventricular volume and function. A prospective study of 150 patients. Deutsche Medizinische Wochenschrift. 2002;127(49):2605-2609.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling)-Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling)-Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF03-S2-02

Getein Biotech, Inc.
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Fax: +86-25-68568500
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EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

Catalogue number	Applicable analyzer	Package specification
IF1002-10T	Getein 1100	10 T/kit
IF1002	Getein 1100	25 T/kit
IF8002-10T	Getein 1150	10 T/kit
IF8002	Getein 1150	25 T/kit
IF5002-10T	Getein 1160	10 T/kit
IF5002	Getein 1160	25 T/kit
IF3002-10T	Getein 1180	10 T/kit
IF3002	Getein 1180	25 T/kit
IF4002-24T	Getein 1200	2×12 T/kit
IF4002	Getein 1200	2×24 T/kit
IF4002-96T	Getein 1200	2×48 T/kit
IF2002-24T	Getein 1600	2×12 T/kit
IF2002	Getein 1600	2×24 T/kit
IF2002-96T	Getein 1600	2×48 T/kit

CE IVD

PCT Fast Test Kit
(Immunofluorescence Assay)

Instructions for use REF **IF1007 for Getein 1100**
IF5007 for Getein 1160
IF3007 for Getein 1180

INTENDED USE

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

SUMMARY

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

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

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

PRINCIPLE

PCT Fast Test Kit (Immunofluorescence Assay) is based on the lateral flow immunoassay technology in a sandwich design. Once the sample is applied to the test strip, the fluorescence latex-labelled PCT monoclonal antibody will bind with PCT in sample 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 test line by another PCT monoclonal antibody. Fluorescent signals intensity can be analyzed by applicable device thus the amount of PCT in the sample can be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180	
	10 T/kit	25 T/kit
PCT test card*	10 pcs	25 pcs
Disposable pipet	10 pcs	25 pcs
Sample diluent**	10 tube	25 tube
Instructions for use	1 pc	1 pc
SD card	1 pc	1 pc

* PCT test card

A test card main consists of: Fluorescence latex-labelled PCT monoclonal antibody, PCT monoclonal antibody and polyclonal IgG antibody.

** Sample diluent

Sample diluent main contained in each tube: Phosphate buffer (20 mmol/L), NaN3 (＜0.1%).

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. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1160 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 Getein 1100/Getein 1160/Getein 1180 within one hour once the foil pouch is opened.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum, plasma, whole blood and fingertip blood samples. Heparin, sodium citrate** 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. It is recommended to test the sample within 4 hours after collection. Stable in plasma for 5 days when stored at 2~8°C and 6 months when stored at -20°C. Stable in whole blood and fingertip blood for 3 days when stored at 2~8°C.
4. Refrigerated or frozen sample should reach room temperature 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.

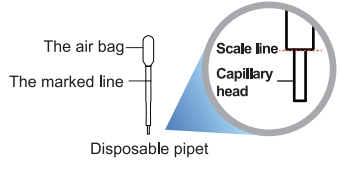
For Getein 1100:

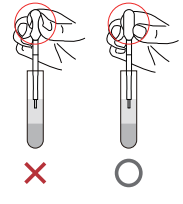
1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) Using disposable pipet or pipette, deliver ***20 μL*** of sample into one tube of sample diluent, mix thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card.
5) ***Reaction time: 15 minutes***. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

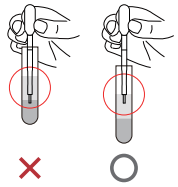
1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
5) Using disposable pipet or pipette, deliver ***20 μL*** of sample into one tube of sample diluent, mix thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card.
6) Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (***15 minutes***) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For using the disposable pipet:



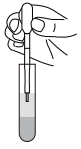


Note1: Do not depress the air bag of the disposable pipet with your finger during sampling.



Note 2: The capillary head of the disposable pipette touches the sample level gently and draws the sample automatically.

a.

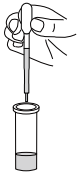


Gently hold the air bag of the disposable pipet and insert the disposable pipet into the sample collection tube until **the scale line** reaches the liquid level. The sample will be sucked into the disposable pipette by capillary action.

b.

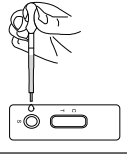
Insert the disposable pipette into the sample diluent. Squeeze the air bag 8 to 10 times to ensure the sample is fully mixed with the sample diluent.

c.



Squeeze the air bag, suck the sample mixed solution to **the marked line** on the disposable pipette.

d.



Add all the sucked sample vertically to the sampling area of test card.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits for Getein 1100/Getein 1160/Getein 1180.
2. Make sure the test card and the sample insertion are correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180.

Others: Dilute the sample which concentration is higher than the upper limit with sample diluent, and the dilution ration should be less than 5 times.

EXPECTED VALUE

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

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

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.05~50.00 ng/mL
Limit of Detection	≤0.05 ng/mL
Within-Lot Precision	≤10%
Between-Lot Precision	≤15%

LIMITATIONS

1. Bilirubin, triglyceride and hemoglobin in the sample may interfere with the test results, and the maximum allowable concentrations are 0.2 g/L, 10 g/L and 5 g/L respectively.
2. The test results of this kit are for clinical reference only, and should not be used as the sole criteria for clinical diagnosis. It is recommended to conduct a comprehensive analysis on the condition in combination with symptoms/signs, history and other laboratory tests.

REFERENCES

1. Balcl C, Sungurtekin H, Gürses E, Sungurtekin U, Kaptanoglu B. Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit, Crit Care. 2003 February 7 (1):85~90.
2. Schuetz P, Christ-Crain M, Thomann R, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. Sep 9 2009; 302(10):1059-66.
3. Briel M, Schuetz P, Mueller B, et al. Procalcitonin-guided antibiotic use vs a standard approach for acute respiratory tract infections in primary care. Arch Intern Med. Oct 13 2008; 168(18):2000-7; discussion 2007-8.
4. Meisner M. Procalcitonin (PCT) - A New innovative infection parameter. Biochemical and clinical aspects. Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0.
5. EN ISO 18113-1:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF06-SX-01

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overseas@getein.com.cn
Website: www.getein.com

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

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 8800contains:

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.

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: ≤ 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 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	CE mark		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
REF	Catalogue number	EC REP	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.
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Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

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

Version: WZK01-S-11

CE IVD

NT-proBNP Control

REF QC007

Instructions for use

PRODUCT NAME

NT-proBNP 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

NT-proBNP Control - Level 1/2/3

INTENDED USE

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

PRINCIPLE

The lyophilized NT-proBNP control is prepared from dissolving stable and high quality recombinant NT-proBNP 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. NT-proBNP Control – Level 1
   NT-proBNP Control – Level 2
   NT-proBNP 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 8800contains:

1. NT-proBNP Control – Level 1
   NT-proBNP Control – Level 2
   NT-proBNP 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: ≤ 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 NT-proBNP 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	CE mark		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
REF	Catalogue number	EC REP	Authorized representative in the European Community/European Union
	Biological risks		Keep away from sunlight

Thank you for purchasing NT-proBNP Control.
Please read this instructions for use carefully before operating to ensure proper use.
Please contact Getein Biotech, Inc. if you have any questions.

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Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
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Tel: +34951214054

Version: WZK02-S-11

GP CE IVD

PCT Control

REF QC004

Instructions for use

PRODUCT NAME

PCT 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

PCT Control - Level 1/2/3

INTENDED USE

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

PRINCIPLE

The lyophilized PCT control is prepared from dissolving stable and high quality recombinant PCT 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. PCT Control – Level 1
   PCT Control – Level 2
   PCT 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 8800contains:

1. PCT Control – Level 1
   PCT Control – Level 2
   PCT 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 instrustions for use carefully before using and operate according to the instrustions 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: ≤ 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 PCT 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	CE mark		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
REF	Catalogue number	EC REP	Authorized representative in the European Community/European Union
	Biological risks		Keep away from sunlight

Thank you for purchasing PCT Control.

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

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

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Tel: +34951214054

Version: WZK05-S-11

GP CE IVD

CK-MB Control

REF QC002

Instructions for use

PRODUCT NAME

CK-MB 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

CK-MB Control - Level 1/2/3

INTENDED USE

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

PRINCIPLE

The lyophilized CK-MB control is prepared from dissolving stable and high quality recombinant CK-MB 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. CK-MB Control – Level 1
   CK-MB Control – Level 2
   CK-MB 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 8800contains:

1. CK-MB Control – Level 1
   CK-MB Control – Level 2
   CK-MB 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℃.

OPENED: The liquid control is stable for 15 days at 2-8℃ 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℃ to -70℃.

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: ≤ 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 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	CE mark		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
REF	Catalogue number	EC REP	Authorized representative in the European Community/European Union
	Biological risks		Keep away from sunlight

Thank you for purchasing CK-MB Control.

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

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

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Version: WZK07-S-11

CysC Control

REF QC008

User Manual

PRODUCT NAME

CysC 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

CysC Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of CysC on the Getein Platforms.

PRINCIPLE

The lyophilized CysC control is prepared from dissolving stable and high quality recombinant CysC 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. CysC Control – Level 1
   CysC Control – Level 2
   CysC Control – Level 3
2. User manual: 1 piece/kit
3. Target value sheet: 1 piece/kit

The kit for Getein1600/Getein1200/Getein3200/Getein3600/MAGICL6000/MAGICL6200/MAGICL6800/MAGICL8200/MAGICL8500/MAGICL8800 contains:

1. CysC Control – Level 1
   CysC Control – Level 2
   CysC 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
MAGICL6000/MAGICL6200/MAGICL6800/MAGICL8200/MAGICL8500/MAGICL8800 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 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/MAGICL6000/MAGICL6200/MAGICL6800/MAGICL8200/MAGICL8500/MAGICL8800:

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: ≤ 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 CysC 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*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
REF	Catalogue number	EC REP	Authorized representative in the European Community/European Union
	Biological risks		Keep away from sunlight

Thank you for purchasing CysC Control.
Please read this user manual carefully before operating to ensure proper use.
Please contact Getein Biotech, Inc. if you have any questions.

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Version: WZK10-S-07

CE IVD

HbA1c Control

REF QC014

Instructions for use

PRODUCT NAME

HbA1c 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

HbA1c Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of HbA1c on the Getein Platforms. For professional and laboratory use only.

PRINCIPLE

The lyophilized HbA1c control is prepared from dissolving stable and high quality recombinant HbA1c 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. HbA1c Control – Level 1
   HbA1c Control – Level 2
   HbA1c 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 8800contains:

1. HbA1c Control – Level 1
   HbA1c Control – Level 2
   HbA1c 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: ≤ 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 HbA1c 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	CE mark		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
REF	Catalogue number	EC REP	Authorized representative in the European Community/European Union
	Biological risks		Keep away from sunlight

Thank you for purchasing HbA1c Control.

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

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

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Version: WZK14-S-11