

# EC Declaration of Conformity

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

Ref. No.:20220513-A05

**Manufacturer**  
(Name, Address)

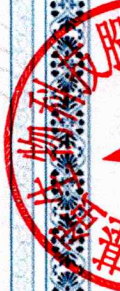
**Getein Biotech, Inc.**  
No. 9 Bofu Road, Luhe District, Nanjing, 211505, China

**Authorized Representative**  
(Name, Address)

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

**Medical device**

No.	Product Name
1	Getein 1100 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	$\beta$ 2-MG Fast Test Kit (Immunofluorescence Assay)
13	CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)
14	HCG+ $\beta$ 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

<b>Applicable coordination standards</b>	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*  
13<sup>th</sup>, May, 2022  
 (place and date of issue)

\_\_\_\_\_  
 (name and signature or equivalent marking of authorized person)




# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Getein Biotech, Inc.**  
No.9 Bofu Road  
Luhe District  
Nanjing  
Jiangsu  
211505  
China

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

Holds Certificate No: **MD 728432**

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

Please see scope page.

For and on behalf of BSI:

**Graeme Tunbridge, Senior Vice President Medical Devices**

Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 1 of 3



...making excellence a habit.™

Certificate No: **MD 728432**

## Registered Scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.

研发, 生产和销售化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂和胶体金自测试剂。 研发, 生产和销售用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂, 血脂异常疾病相关免疫荧光自测试剂, 血栓疾病相关血凝试剂配套使用的分析仪。



Original Registration Date: 2020-05-29

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Page: 2 of 3

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

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

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +86 10 8507 3000.

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

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

A Member of the BSI Group of Companies.

Certificate No: **MD 728432**

Location

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No.9 Bofu Road  
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211505  
China  
基蛋生物科技股份有限公司  
中国  
江苏省  
南京市  
六合区  
沿江工业开发区  
博富路9号  
邮编: 211505

Registered Activities

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

Getein Biotech, Inc.  
No. 6 KeFeng Road  
Jiangbei New District  
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基蛋生物科技股份有限公司  
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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。

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A Member of the BSI Group of Companies.

# CERTIFICATE

*Getein Biotech*

hereby certifies

**Mr. Vitalie Goreacii**

**from Sanmedico SRL.**

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

基蛋生物科技股份有限公司  
GETEIN BIOTECH, INC.





**Getein**  
Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION  
**MAKING TEST EASY**

# Getein 1100

Immunofluorescence Quantitative Analyzer



Cardiac  
Markers



Coagulation  
Markers



Diabetes  
Mellitus



Inflammation



Thyroid  
Function



Metabolic  
Marker



Renal  
Function



Tumor  
Markers



Reproduction  
/Fertility



Infectious  
Disease

# Getein 1100

Immunofluorescence Quantitative Analyzer



## HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control



## REAL-TIME AND RAPID TEST

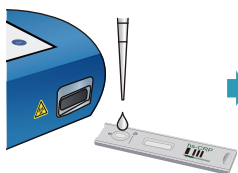
One-step test

3-15 min/test

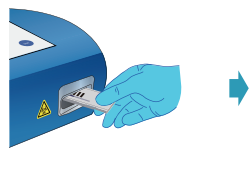
5 sec/test for multiple tests

## OPERATION MODES

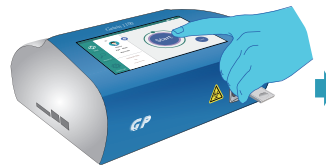
### Inside Mode (Single sample rapid test mode)



Sample Transfer



Test Card Insert



Click "Start" Icon

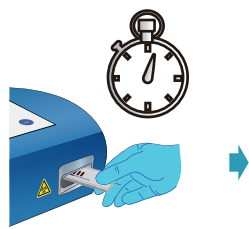


Results Output

### Outside Mode (Mass samples rapid test mode)



Sample Transfer



Timing the Reaction Manually



Click "Start" Icon



Results Output



## CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB ports

Handwriting input available

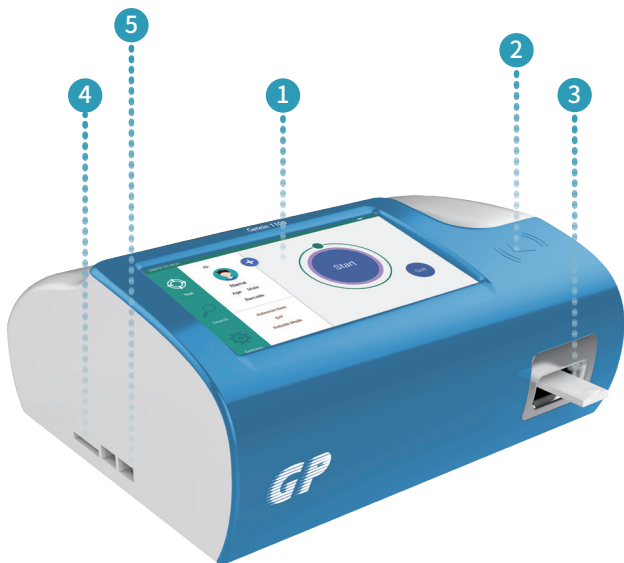
Continuous test for 3 hours with optional lithium battery



## USER-FRIENDLY INTERFACE

Android system

7-inch touch screen



1 7-inch Touch Screen

2 RFID Recognition Zone

3 Test Card Slot

4 SD Card Slot

5 USB Slot

6 Built-in Thermal Printer



## PORTABLE DESIGN

Small in size: 261\*241\*115 mm

Light in weight: 2.0 kg



## LARGE MEMORY

Up to 10,000 results storage capacity

## TECHNICAL PARAMETERS

### Methodology

Immunofluorescence

### Result

Quantitative

### Sample Type

WB, Plasma, Serum, Urine, Stool,  
Nasal swab, Saliva, Capillary blood

### Storage Capacity

10,000 data

### Language

English/Chinese/Spanish/Portuguese

### Screen

7-inch touch screen

### Power Supply

100-240 V ~ 50 Hz/60 Hz, 60 VA

### Working Environment

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

### Dimensions

261 mm(L) × 241 mm(W) × 115 mm(H)

### Weight

2.0 kg

# TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
<b>Cardiac Markers</b>								
IF1001	<b>cTnl</b>	Myocardial infarction	0.10 ng/mL	S/P/WB	0.10-50.00 ng/mL	100 µL	10 min	NMPA CE
IF1098	<b>TnT</b>	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	100 µL	15 min	NMPA CE
<b>NEW</b> IF1078	<b>ST2</b>	Chronic heart failure	35.0 ng/mL	S/P/WB	3.0-200.0 ng/mL	100 µL	15 min	CE
IF1089	<b>BNP</b>	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	NMPA CE
IF1002	<b>NT-proBNP</b>	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	100 µL	10 min	NMPA CE
IF1014	<b>H-FABP</b>	Myocardial damage	6.36 ng/mL	S/P/WB	1.00-120.00 ng/mL	100 µL	3 min	NMPA CE
IF1018	<b>CK-MB</b>	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	100 µL	10 min	NMPA CE
IF1004	<b>NT-proBNP/cTnl</b>	Heart failure/AMI	NT-proBNP: 185 pg/mL cTnl: 0.10 ng/mL	S/P/WB	100-15000 pg/mL 0.10-50.00 ng/mL	100 µL	10 min	NMPA CE
IF1012	<b>CK-MB/cTnl</b>	Myocardial damage/infarction	CK-MB: 5.00 ng/mL cTnl: 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
IF1005	<b>CK-MB/cTnl/Myo</b>	Myocardial damage/infarction	CK-MB: 5.00 ng/mL cTnl: 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
IF1016	<b>CK-MB/cTnl/H-FABP</b>	Myocardial damage/infarction	CK-MB: 5.00 ng/mL cTnl: 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
<b>Coagulation Marker</b>								
IF1006	<b>D-Dimer</b>	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	100 µL	10 min	NMPA CE
<b>Inflammation</b>								
IF1007	<b>PCT</b>	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB	0.05-50.00 ng/mL	100 µL	15 min	NMPA CE
<b>NEW</b> IF1139	<b>Calprotectin</b>	Inflammatory bowel disease	<50.0 µg/g	Fecal specimen	10.0-600.0 µg/g	100 µL	15 min	CE
IF1003	<b>hs-CRP+CRP</b>	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
IF1044	<b>SAA</b>	Bacterial/Virus infection	10.0 mg/L	S/P/WB Fingertip blood	5.0-200.0 mg/L	10 µL	5 min	NMPA CE
IF1088	<b>IL-6</b>	Acute inflammation	Refer to user manual	S/P/WB Fingertip blood	1.5-4000.0 pg/mL	20 µL	15 min	NMPA CE
IF1090	<b>SAA/CRP</b>	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
IF1015	<b>PCT/CRP</b>	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
<b>Renal Function</b>								
IF1008	<b>CysC</b>	Renal diseases	0.51-1.09 mg/L	S/P/WB	0.50-10.00 mg/L	10 µL	3 min	NMPA CE
IF1009	<b>mAlb</b>	Diabetic nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA CE
IF1011	<b>β<sub>2</sub>-MG</b>	Kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	10 µL	3 min	NMPA CE
IF1010	<b>NGAL</b>	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
<b>Diabetes Mellitus</b>								
IF1017	<b>HbA1c</b>	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	10 µL	5 min	NMPA NGSP/IFCC
<b>Metabolic Marker</b>								
IF1112	<b>Osteocalcin</b>	Osteoporosis	Male: 14-70 ng/mL Female: 11-48 ng/mL	S/P	1.5-300.0 ng/mL	100 µL	15 min	CE
<b>Thyroid Function</b>								
IF1024	<b>TSH</b>	Thyroid malfunction	0.27-4.20 µIU/mL	S/P	0.10-50.00 µIU/mL	100 µL	15 min	NMPA CE
IF1022	<b>T3</b>	Thyroid Function	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	100 µL	15 min	NMPA CE
IF1023	<b>T4</b>	Thyroid Function	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	100 µL	15 min	NMPA CE
IF1067	<b>ft3</b>	Thyroid Function	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	100 µL	15 min	NMPA CE
IF1068	<b>ft4</b>	Thyroid Function	12.00-22.00 pmol/L	S/P/WB	0.30-100.00 pmol/L	100 µL	15 min	NMPA CE





# HbA1c Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1017  
Getein1600: Cat.# IF2017

## User Manual

### INTENDED USE

HbA1c fast test kit is intended for the quantitative measurement of HbA1c in whole blood. This test is used as an aid for monitoring glycemic control in diabetics. In addition, it can identify people at risk of developing the disease and ongoing monitoring.

### SUMMARY

Hemoglobin is the protein molecule in red blood cells with the main function transport oxygen and carbon dioxide in blood. HbA1c belongs to the glycated hemoglobin, a fraction formed by the attachment of various sugars to the Hb molecule and is proportional to average blood glucose concentration over the previous 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 standardised to criteria aligned to the international reference values.

### PRINCIPLE

The test uses an anti-human Hb monoclonal antibody conjugated with fluorescence latex and an anti-human HbA1c monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human Hb monoclonal antibody binds with the HbA1c and Hb in sample proportionally and forms marked

antigen-antibody complex. The complex moves to the detection zone by capillary action. Then 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.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of HbA1c in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

### CONTENTS

- A kit for Getein1100 contains:
  - Getein HbA1c test card in a sealed pouch with desiccant ..... 25
  - Disposable pipet ..... 25
  - A1c diluent ..... 25
  - SD card ..... 1
  - User manual ..... 1
- A kit for Getein1600 contains:
  - Sealed cartridge with 24/48 Getein HbA1c test cards ... 2
  - User manual ..... 1
  - Package specifications:
  - 2x24 tests/kit, 2x48 tests/kit
  - Materials required for Getein1600:
  - A1c diluent..... 1
  - Box with pipette tips ..... 1
  - Coated wells ..... 1
- A1c diluent composition:
  - Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
- 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 Hb monoclonal antibody, the test line is coated with an anti-human HbA1c 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  
Getein1600 Immunofluorescence Quantitative Analyzer

### STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

Use the test card for Getein 1600 within 7 days once opened. Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8°C for better results.

### PRECAUTIONS

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

### SPECIMEN COLLECTION AND PREPARATION

- This test can be used for **whole blood samples**. **Heparin, sodium citrate and EDTA** can be used as the anticoagulant under aseptic conditions.
- The test is for human blood, other specimens or bodily fluids may not get accurate results.
- The test should be performed within 4 hours after whole blood collection.
- Samples could be kept for 7days at 2~8°C and avoid cryopreservation.

- Samples must be recovered to room temperature before testing.
- SAMPLE VOLUME (for Getein1100): 10 µl.

## TEST PROCEDURE

- Collect specimens according to user manual.
- Test card, sample should be brought to room temperature before testing.

For Getein1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "QC (SD)" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
- On the main interface of Getein1100, press "ENT" button to enter testing interface.
- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver 10 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100 µl of sample mixture (or 3-4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
- Reaction time: 5 minutes. Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

- Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

### Notes:

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

## TEST RESULTS

Getein1100/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/Getein1600.

## EXPECTED RANGE OF VALUE

HbA1c concentration is determined using samples obtained from 345 apparently healthy individuals. The normal value for HbA1c is 3.8%-5.8% .

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

## PERFORMANCE CHARACTERISTICS

Measuring Range 2%-14%

Lower Detection Limit ≤2%

Within-Run Precision (n=10) ≤10%

Between-Run Precision ≤15%

Accuracy: verify with comparison experiments, the correlation coefficient  $r \geq 0.990$ , the relative error  $\leq 20\%$ .

## LIMITATIONS

- The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.
- Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of them is as follows:













Interferent	Concentration (Max)
Triglyceride	25 g/L
Bilirubin	0.1 g/L

## REFERENCES

- 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.
- 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.

## 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 details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

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

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

Version: WIF22-S-02



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# Cardiac Troponin I

## Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1001

Getein1600: Cat.# IF2001

### User Manual

### INTENDED USE

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

### SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three 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 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of cTnI in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

### CONTENTS

- A kit for Getein1100 contains:
  - Getein cTnI test card in a sealed pouch with desiccant ..... 25
  - Disposable pipet ..... 25
  - Whole blood buffer ..... 1
  - SD card ..... 1
  - User manual ..... 1
- A kit for Getein1600 contains:
  - Sealed cartridge with 24/48 Getein cTnI test cards ..... 2
  - User manual ..... 1
  - Package specifications:
  - 2x24 tests/kit, 2x48 tests/kit
  - Materials required for Getein1600:
  - Sample diluent ..... 1
  - Box with pipette tips ..... 1
  - Mixing plate ..... 1
- Sample diluent/Whole blood buffer composition:
  - Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
- 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  
Getein1600 Immunofluorescence Quantitative Analyzer

### STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of 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.

Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8°C for better results.

### PRECAUTIONS

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

### SPECIMEN COLLECTION AND PREPARATION

- This test can be used for *serum, plasma and whole blood samples*. *Heparin and sodium citrate* should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.

- Suggest using serum or plasma for better results.
- Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
- If testing will be 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).
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples.
- SAMPLE VOLUME (for Getein1100): 100 µl.

## TEST PROCEDURE

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

### For Getein1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
- On the main interface of Getein1100, press "ENT" button to enter testing interface.
- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver 100 µl of sample (or 3–4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
- Reaction time: 10 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

### For Getein1600:

- Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

### Notes:

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

## TEST RESULTS

Getein1100/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/Getein1600.

## EXPECTED VALUE

The expected normal value for Troponin I was determined by testing samples from 500 apparently healthy individuals. The 99<sup>th</sup> percentile of the concentration for cTnI is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.)

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

## PERFORMANCE CHARACTERISTICS

Measuring Range	0.1–50 ng/ml
Lower Detection Limit	≤ 0.1 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

### Method Comparison:

The assay was compared with SIEMENS IMMULITE 2000 and its matching cTnI test kits with 200 serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for cTnI is 0.952.

## LIMITATIONS

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

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

## REFERENCES













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- 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 2004).

- EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on 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 980:2008 and International Standard ISO 15223-1:2007.

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

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

Version: WIF02-S-02



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# D-Dimer Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1006  
Getein1600: Cat.# IF2006

## User Manual

### INTENDED USE

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

### SUMMARY

Deep-vein thrombosis is a common condition, with a lifetime cumulative incidence of 2 to 5 percent. Untreated deep-vein thrombosis can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of deep-vein thrombosis minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.

D-Dimer is a marker of endogenous fibrinolysis and should therefore be detectable in patients with deep-vein thrombosis. In recent years, an increasing number of studies have shown the D-Dimer assay has a high negative predictive value and D-Dimer is a sensitive but nonspecific marker of deep-vein thrombosis. Negative D-Dimer can exclude deep-vein thrombosis and pulmonary embolism.

### PRINCIPLE

The test uses an anti-human D-Dimer monoclonal antibody conjugated with fluorescence latex and another anti-human D-Dimer monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human D-Dimer monoclonal antibody binds with the D-Dimer in sample and forms a marked antigen-antibody

complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another anti-human D-Dimer monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of D-Dimer in sample. Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of D-Dimer in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

### CONTENTS

- A kit for Getein1100 contains:
  - Getein D-Dimer test card in a sealed pouch with desiccant ..... 25
  - Disposable pipet ..... 25
  - Sample diluent ..... 25
  - SD card ..... 1
  - User manual ..... 1
- A kit for Getein1600 contains:
  - Sealed cartridge with 24/48 Getein D-Dimer test cards ..... 2
  - User manual ..... 1
  - Package specifications:
  - 2×24 tests/kit, 2×48 tests/kit
  - Materials required for Getein1600:
  - Sample diluent ..... 1
  - Box with pipette tips ..... 1
  - Mixing plate ..... 1
- Sample diluent composition:
  - Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
- A test card consists of:
  - A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human D-Dimer monoclonal antibody, the test line is coated with another anti-human D-Dimer monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

### APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer  
Getein1600 Immunofluorescence Quantitative Analyzer

### STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of 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.

Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8°C for better results.

### PRECAUTIONS

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

### SPECIMEN COLLECTION AND PREPARATION

- This test can be used for *plasma and whole blood samples*. *Sodium citrate* can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
- Suggest using plasma for better results.
- If testing will be delayed, plasma sample may be stored up to 3 days at 2~8°C or stored at -20°C for 1 month before testing (whole blood sample may be stored up to 3 days at 2~8°C).
- Refrigerated or frozen sample should reach room temperature

and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME (for *Getein1100*): 100  $\mu$ L.

## TEST PROCEDURE

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

### For *Getein1100*:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of *Getein1100* User Manual).
4. On the main interface of *Getein1100*, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver 100  $\mu$ L of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100  $\mu$ L of sample mixture (or 3-4 drops of sample when using disposable pipet) into the sample port on the test card.
8. **Reaction time: 10 minutes.** Insert the test card into *Getein1100* and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

### For *Getein1600*:

9. Each cartridge for *Getein1600* contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, *Getein1600* will do the testing and print the result automatically.

### Notes:

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

## TEST RESULTS

*Getein1100/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/Getein1600*.

## EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95<sup>th</sup> percentile of the concentration for D-Dimer is 0.5 mg/L. (The probability that value of a normal person below 0.5 mg/L is 95%.)

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

## PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~10.0 mg/L
Lower Detection Limit	$\leq$ 0.1 mg/L
Within-Run Precision	$\leq$ 10%
Between-Run Precision	$\leq$ 15%

### Method Comparison:

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

## LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferences such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. The table below listed the maximum allowance of these potential interferences.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L













## REFERENCES

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2. Roldán V, Marín F, Muiña B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated

- Atrial Fibrillation Patients. *J Am Coll Cardiol.* 2011 Apr 11.
3. Sakamoto K, Yamamoto Y, Okamatsu H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. *Hellenic J Cardiol.* 2011 Mar-Apr; 52(2):123-127.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

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

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

Version: WIF05-S-02



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(>200 mg/L).

# hs-CRP Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1003

Getein1600: Cat.# IF2003

## User Manual

### INTENDED USE

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

### SUMMARY

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

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

with another anti-human hs-CRP monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

### APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer  
Getein1600 Immunofluorescence Quantitative Analyzer

### STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of 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.

Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8°C for better results.

### PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. 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 pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

### SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for *serum, plasma, whole blood and fingertip blood samples*. *Heparin, sodium citrate and EDTA* can be used as the anticoagulant for plasma, whole blood and fingertip blood. Samples should be free of hemolysis.

### PRINCIPLE

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

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of hs-CRP in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

### CONTENTS

1. A kit for Getein1100 contains:
  - Getein hs-CRP test card in a sealed pouch with desiccant ..... 25
  - Disposable pipet ..... 25
  - Sample diluent ..... 25
  - SD card ..... 1
  - User manual ..... 1
2. A kit for Getein1600 contains:
  - Sealed cartridge with 24/48 Getein hs-CRP test cards .. 2
  - User manual ..... 1
  - Package specifications:
  - 2x24 tests/kit, 2x48 tests/kit
  - Materials required for Getein1600:
  - Sample diluent ..... 1
  - Box with pipette tips ..... 1
  - Mixing plate ..... 1
3. Sample diluent composition:
  - Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
  - A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human hs-CRP monoclonal antibody, the test line is coated

- Suggest using serum or plasma for better results.
- If testing will be 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).
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples.
- SAMPLE VOLUME (for Getein1100): 10 µl.

## TEST PROCEDURE

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

### For Getein1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
- On the main interface of Getein1100, press "ENT" button to enter testing interface.
- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver 10 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100 µl of sample mixture (or 3–4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
- Reaction time: 3 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

### For Getein1600:

- Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
- Place samples in the designated area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

## Notes:

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

## TEST RESULTS

Getein1100/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/Getein1600.

## EXPECTED VALUE

**hs-CRP:** The expected normal value for hs-CRP was determined by testing samples from 500 apparently healthy individuals. The 95<sup>th</sup> percentile of the concentration for hs-CRP is 3 mg/L. (The probability that hs-CRP value of a normal person below 3 mg/L is 95%.)

**CRP:** The expected normal value for CRP was determined by testing samples from 500 apparently healthy individuals. The 95<sup>th</sup> percentile of the concentration for CRP is 10 mg/L. (The probability that CRP value of a normal person below 10 mg/L is 95%.)

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

## PERFORMANCE CHARACTERISTICS

Measuring Range	0.5~200 mg/L
Lower Detection Limit	≤0.5 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

### Method Comparison:

The assay was compared with HITACHI 7600/OLYMPUS AU5400 and its matching hs-CRP test kits with 200 serum samples (61 positive samples and 139 negative samples). The correlation coefficient (r) for hs-CRP is 0.941.

## LIMITATIONS

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

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

## REFERENCES

- Danesh J, Whincup P, Wsiker M, et al. Low grade inflammation

and coronary heart disease: prospective study and updated meta-analysis. *BJM* 2000; 321:199–204.

- Rifai N, Ridker PM. Proposed cardiovascular risk assessment algorithm using high-sensitivity C-reactive protein and lipid screening. *Clin Chem* 2001; 47:28–30.
- EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on hs-CRP 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 980:2008 and International Standard ISO 15223-1:2007.

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

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

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