



**Getein**  
Biotech, Inc.

Stock Code: 603387

Cardiac  
Markers

Specific Protein  
and  
Rheumatism

Coagulation  
Markers

Inflammation

Diabetes  
Mellitus

Metabolic  
Marker

Renal  
Function

Thyroid  
Function

Infectious  
Disease

Reproduction  
/Fertility

Tumor  
Markers

Others

# Getein 1600

Immunofluorescence Quantitative Analyzer



**Hello, The Future of POCT!**

# Getein 1600

Immunofluorescence Quantitative Analyzer

Meeting multiple needs of emergency department and central laboratory



## Intellectualized Software System

- Android system
- User-friendly interface
- Diversified test modes: random, batch, STAT
- LIS/HIS connectivity
- WIFI/4G data transmission
- Network printer



## Simple Operation

- Fully-automatic detection
- Real-time monitoring of samples and consumables
- Visualized reagent interface





## High Throughput

48 samples/run

Continuous loading of different test items

Up to 150 tests/hour



## Accurate and Reliable Test Results

Fully-automatic sample adding system

Disposable tips with filter elements, which avoid cross-contamination

Automatic calibration, dilution and sample loading

Fully-automatic quality control

25 °C temperature control

# Leading the New Era of POCT !

## TRADITIONAL POCT VS AUTOMATIC POCT

	Automatic POCT	VS	Traditional POCT
Operation	Avoid the inaccuracy of results caused by human factors		Time-consuming, manual operation, human fallibility
Stability of Results	Stable		Easily affected by the operators
Detection Efficiency	Relatively high		Relatively low
Standardization	Easy for standardized management		Not easy for standardized management
Detection Cost	Relatively low (low labor costs)		Relatively high



## Traceability of Results

Automatic barcode scanning of test items  
Automatic recognition of reagents



## Easy for Standardized Management

Fully-automatic sample loading and detection  
Standard SOP documented  
Meet the requirements of clinical laboratory standards

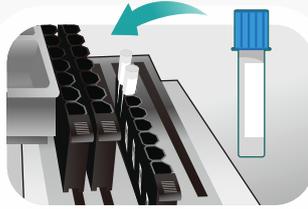
## TECHNICAL PARAMETERS

Methodology	Immunofluorescence
Result	Quantitative
Throughput	48 samples/run, 150 tests/hour
Sample Type	Whole blood, plasma, serum, urine, fingertip blood
Storage Capacity	500000 data
Language	English/Chinese
Screen Display	10.4 inch touch screen
Power Supply	100-240 V~50/60 Hz
Working Environment	Relative humidity $\leq$ 70%, air pressure 70.0~106.0 kpa
Dimension	639 mm $\times$ 562 mm $\times$ 728 mm (D $\times$ W $\times$ H)
Weight	45 kg

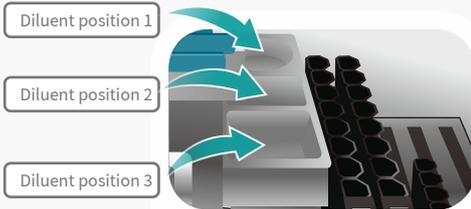
# TEST PROCEDURE



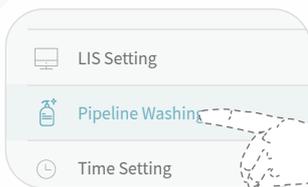
**1** Insert cartridge into the instrument, the instrument will recognize the test item automatically.



**2** Insert the sample holder into the sample chamber.



**3** Put the diluent into the instrument.



**4** Perform pipeline washing before daily test.

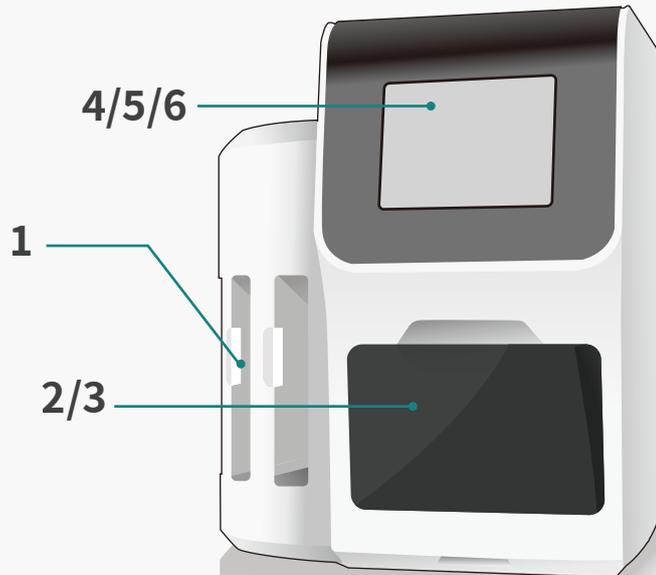


Emergency Give priority to emergency sample testing.

**5** Do test arrangement at parameters setting interface. **Select test item and sample type, review patient information, and press Start to start testing.**



**6** The test results will be shown at Result interface.



# TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	QUALIFICATION
<b>Cardiac Markers</b>						
IF2019	hs-cTnI	Myocardial infarction	0.040 ng/mL	S/P/WB	0.010-50.000 ng/mL	NMPA CE
IF2001	cTnI	Myocardial infarction	0.10 ng/mL	S/P/WB	0.10-50.00 ng/mL	NMPA CE
IF2098	TnT	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	NMPA CE
IF2089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	NMPA CE
IF2002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	NMPA CE
IF2005	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	NMPA CE
IF2012	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	CE
IF2014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.00-120.00 ng/mL	NMPA CE
IF2016	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	NMPA CE
IF2018	CK-MB	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	CE
<b>Coagulation Markers</b>						
IF2006	D-Dimer	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	NMPA CE
<b>Inflammation</b>						
IF2003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3.0 mg/L 10.0 mg/L	S/P/WB/ Fingertip blood	0.5-200.0 mg/L	NMPA CE
IF2007	PCT	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB/ Fingertip blood	0.05-50.00 ng/mL	NMPA CE
IF2015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.10 ng/mL CRP: 3.0 mg/L	S/P/WB/ Fingertip blood	0.10-50.00 ng/mL 0.5-200.0 mg/L	NMPA CE
IF2044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	NMPA CE
IF2090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Peripheral blood	5.0-200.0 mg/L 0.5-200.0 mg/L	NMPA CE
IF2088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	NMPA CE
<b>Renal Function</b>						
IF2008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.50-10.00 mg/L	NMPA CE
IF2009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	NMPA CE
IF2010	NGAL	Acute kidney injury	Serum: 200.0 ng/mL Urine: 100.0 ng/mL	S/Urine	50.0-5000.0 ng/mL	NMPA CE
IF2011	$\beta_2$ -MG	Acute and chronic kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	NMPA CE
<b>Diabetes Mellitus</b>						
IF2017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	NGSP NMPA IFCC CE
<b>Metabolic Marker</b>						
IF2031	25-OH-VD	Osteomalacia, osteoporosis	30.00-50.00 ng/mL	S/P	8.00-70.00 ng/mL	NMPA CE
<b>Thyroid Function</b>						
IF2024	TSH	Thyroid malfunction	0.27-4.20 $\mu$ U/mL	S/P	0.10-50.00 $\mu$ U/mL	NMPA CE
IF2022	T3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	NMPA CE
IF2023	T4	Hyperthyroidism, hypothyroidism	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	NMPA CE
 IF2067	ft3	Hyperthyroidism, hypothyroidism	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	CE
 IF2068	ft4	Hyperthyroidism, hypothyroidism	12.00-22.00 pmol/L	S/P/WB	0.30-100.00 pmol/L	CE

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	QUALIFICATION
<b>Reproduction/Fertility</b>						
IF2013	HCG+β	Fertility	5.1 mIU/mL	S/P	5.0-100000.0 mIU/mL	NMPA CE
IF2055	LH	Homeostasis fertility regulation	Refer to User Manual	S/P	0.20-150.00 mIU/mL	NMPA CE
IF2056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.20-150.00 mIU/mL	NMPA CE
IF2066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	CE
IF2048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.00 ng/mL	NMPA CE
NEW IF2071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	CE
NEW IF2073	Testosterone	Female polycystic ovary syndrome, male testosterone insufficiency	Male: 1.75-7.81 ng/mL Female: 0.10-0.75 ng/mL	S/P	0.10-16.00 ng/mL	CE
NEW IF2074	E2	Ovarian function	Refer to User Manual	S/P	40.0-4800.0 pg/mL	CE
<b>Tumor Markers</b>						
IF2053	tPSA	Prostate cancer	4.00 ng/mL	S/P	0.50-100.00 ng/mL	NMPA
NEW IF2072	fPSA	Prostate cancer	1.00 ng/mL	S/P	0.05-30.00 ng/mL	
NEW IF2050	AFP	Liver cancer, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	CE
NEW IF2051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P	2.0-500.0 ng/mL	CE
<b>Infectious Disease</b>						
NEW IF2057	Anti-HCV	Hepatitis C	1.00 S/CO	S/P	1.00-20.00 S/CO	
NEW IF2058	Anti-TP	Syphilis	1.00 S/CO	S/P	1.00-50.00 S/CO	CE
NEW IF2059	Anti-HIV	AIDS	1.00 S/CO	S/P	1.00-1000.00 S/CO	
NEW IF2064	HBsAg	Hepatitis B	1.00 IU/mL	S/P	1.00-100.00 IU/mL	
NEW IF2063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	
IF2084	2019-nCoV IgM/IgG	COVID-19	1.00 COI	S/P/WB		CE
NEW IF2095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB/ Fingertip blood		CE
NEW IF1136	Dengue NS1 Ag	Dengue virus infection	1.00 S/CO	S/P/WB	0.50-50.00 S/CO	CE
<b>Specific Protein and Rheumatism</b>						
NEW IF2075	RF	Rheumatoid arthritis	15.9 IU/mL	S/P/WB	10.0-640.0 IU/mL	CE
NEW IF2076	ASO	Rheumatic fever, acute glomerulonephritis, group A streptococcal infection	400.0 IU/mL	S/P/WB	60.0-1370.0 IU/mL	CE
NEW IF2029	Anti-CCP	Rheumatoid arthritis	25.0 U/mL	S/P/WB	10.0-400.0 U/mL	CE
<b>Others</b>						
NEW IF2077	Ferritin	Anemia/tumors	Male: 30.00-400.00 ng/mL Female: 13.00-150.00 ng/mL	S/P	0.50-1000.00 ng/mL	CE
NEW IF2069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	CE

Coming Soon: Folate...



## Getein 1600

**GP Getein Biotech, Inc.**

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Fax: +86-25-68568500

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Web: [www.getein.com](http://www.getein.com)



ISO  
13485

FSC



NMPA

NGSP

IFCC



# EC Declaration of Conformity

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

Ref. No.:20220513-A07

**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 1600 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</b>	EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
<b>coordination</b>	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
<b>standards</b>	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	

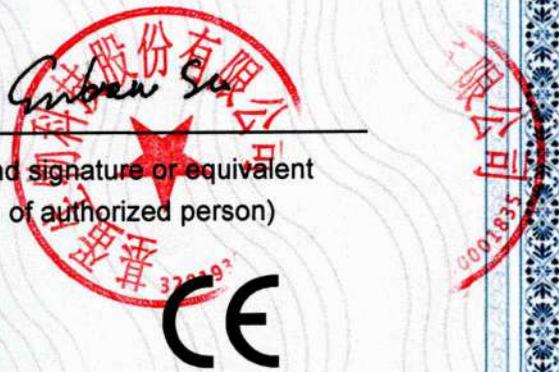
Signatory representative declares herein the above-mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex I.

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)

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



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

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

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

Holds Certificate No: **MD 728432**

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

Please see scope page.

For and on behalf of BSI:

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

Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 1 of 3



...making excellence a habit.™

Certificate No: **MD 728432**

## Registered Scope:

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

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



Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

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Page: 2 of 3

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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

Getein Biotech, Inc.  
No.9 Bofu Road  
Luhe District  
Nanjing  
Jiangsu  
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China  
基蛋生物科技股份有限公司  
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中国  
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南京  
江北新区  
科丰路6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。

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  
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基蛋生物科技股份有限公司  
GETEIN BIOTECH, INC.





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

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



User Manual

### INTENDED USE

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

### SUMMARY

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

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

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

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

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

### PRINCIPLE

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

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

### CONTENTS

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

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

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

#### 2. A kit for Getein208 contains:

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

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

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

#### 3. A kit for Getein1200/Getein1600 contains:

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

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

- 2) User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

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

#### 4. Sample diluent/Whole blood buffer composition:

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

#### 5. A test card consists of:

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

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

### APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

Getein1180 Immunofluorescence Quantitative Analyzer

Getein1600 Immunofluorescence Quantitative Analyzer

Getein1160 Immunofluorescence Quantitative Analyzer

Getein208 Hand-held Integrated System

Getein1200 Immunofluorescence Quantitative Analyzer

### STORAGE AND STABILITY

Store the test kit at 4-30°C with a valid period of 24 months.

Use the test card for Getein1100/Getein1160/Getein1180/Getein208 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

### PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.

5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

### SPECIMEN COLLECTION AND PREPARATION

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

(for Getein208): 70  $\mu$ 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:

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  $\mu$ L** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading **100  $\mu$ L** sample on the test card).
5. **Reaction time: 10 minutes.** Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android Getein1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

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

- ation.
- Put the test card on a clean table, horizontally placed.
  - Using sample transfer pipette, deliver **100 µL** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading **100 µL** sample on the test card).
  - Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

#### For Getein208:

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

#### For Getein1200/Getein1600:

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

#### Notes:

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

## TEST RESULTS

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

## EXPECTED VALUE

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

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

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

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

## PERFORMANCE CHARACTERISTICS

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

## LIMITATIONS

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

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

## REFERENCES

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

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

## DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF09-S-13

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## D-Dimer Fast Test Kit (Immunofluorescence Assay)

### User Manual

## INTENDED USE

D-Dimer Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of D-Dimer in human plasma or whole blood samples. The test is used as an aid in the exclusion of deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in patient suspected of DVT or PE, and an aid in the diagnosis of disseminated intravascular coagulation (DIC).

For professional and laboratory use only.

## SUMMARY

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

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

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

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

## PRINCIPLE

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

## CONTENTS

Materials provided	Getein 1100/ Getein 1150/ Getein 208		Getein 1150		Getein 1200/Getein 1600		
	10 T/kit	25 T/kit	10 T/kit	25 T/kit	2×12 T/kit	2×24 T/kit	2×48 T/kit
D-Dimer test card*	10 pcs	25 pcs	10 pcs	25 pcs	2 cartridges, 12 pcs in each	2 cartridges, 24 pcs in each	2 cartridges, 48 pcs in each
Disposable pipet	10 pcs	25 pcs	10 pcs	25 pcs	/	/	/
Sample diluent**	10 tubes	25 tubes	10 tubes	25 tubes	1 box	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	/	/	1 pc in each cartridge	1 pc in each cartridge	1 pc in each cartridge

\* D-Dimer test card

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

\*\* Sample diluent

(1) Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180/Getein 208 in each tube mainly consists of: phosphate buffer, NaN<sub>3</sub> (< 0.1%).

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

- phosphate buffer, NaN<sub>3</sub> (< 0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

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

- Mixing plate (1 piece/box).

### Note:

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

## APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer  
Getein 1150 Immunofluorescence Quantitative Analyzer  
Getein 1160 Immunofluorescence Quantitative Analyzer  
Getein 1180 Immunofluorescence Quantitative Analyzer  
Getein 1200 Immunofluorescence Quantitative Analyzer  
Getein 1600 Immunofluorescence Quantitative Analyzer  
Getein 208 Hand-held Integrated System

## STORAGE AND STABILITY

### Realtime stability:

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

### In-use stability:

For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180/Getein 208: Use the test card within 1 hour once the foil pouch is opened.

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

## PRECAUTIONS

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

## SPECIMEN COLLECTION AND PREPARATION

- This test can be used for **plasma and whole blood samples**. **Sodium citrate** can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
- Suggest using plasma for better results.
- Plasma are stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C, and 1 month at -20°C.
- Whole blood and fingertip blood are stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

## TEST PROCEDURE

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

### For Getein 1100:

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

### For Getein 1160/Getein 1180:

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

4) Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.

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

#### For Getein 1150:

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

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

3) Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.

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

#### For Getein 208:

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

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

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

4) After sample adding, the analyzer will initiate a 10-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

#### For Getein 1200/Getein 1600:

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

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

3) Place samples in the designated area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument,

Getein 1200/Getein 1600 will do the testing and print the result automatically.

## LIMITATIONS

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

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

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

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

## EXPECTED VALUE

The expected value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95<sup>th</sup> percentile of the concentration for D-Dimer is 0.50 mg/L.

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

## PERFORMANCE CHARACTERISTICS

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

## REFERENCES

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

von Willibrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated Atrial Fibrillation Patients. *J Am Coll Cardiol.* 2011 Apr 11.

4. Sakamoto K, Yamamoto Y, Okamoto M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. *Hellenic J Cardiol.* 2011 Mar-Apr; 52(2):123-127.

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

6. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

## DESCRIPTION OF SYMBOLS USED

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

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

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

Willbrandt Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated Atrial Fibrillation Patients. J Am Coll Cardiol. 2011 Apr 11.  
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Catalogue number	Applicable analyzer	Package specification
IF1006-10T	Getein 1100	10 T/kit
IF1006	Getein 1100	25 T/kit
IF8006-10T	Getein 1150	10 T/kit
IF8006	Getein 1150	25 T/kit
IF5006-10T	Getein 1160	10 T/kit
IF5006	Getein 1160	25 T/kit
IF3006-10T	Getein 1180	10 T/kit
IF3006	Getein 1180	25 T/kit
IF6006-10T	Getein 208	10 T/kit
IF6006	Getein 208	25 T/kit
IF4006-24T	Getein 1200	2×12 T/kit
IF4006	Getein 1200	2×24 T/kit
IF4006-96T	Getein 1200	2×48 T/kit
IF2006-24T	Getein 1600	2×12 T/kit
IF2006	Getein 1600	2×24 T/kit
IF2006-96T	Getein 1600	2×48 T/kit



# PCT

## Fast Test Kit

### (Immunofluorescence Assay)

#### Instructions for Use

#### INTENDED USE

PCT Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Procalcitonin (PCT) in human serum, plasma and whole blood. 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 only.

#### 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 a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence labelled PCT antibody binds with the PCT in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked

antigen-antibody complex is captured on the test line by another PCT antibody. The fluorescence intensity of the test line increases in proportion to the amount of PCT in sample. Fluorescent signals intensity can be analyzed by applicable device thus the PCT 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
PCT 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	/	/	/
Whole blood buffer	1*2 mL/tube	1*2 mL/tube	/	/	/	/	/
Sample diluent	/	/	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 PCT antibody and PCT antibody.
- 2) Main key components in Whole blood buffer for Getein 1100/Getein 1160/Getein 1180  
- Phosphate buffer, Na<sub>2</sub> (< 0.1%).
- 3) Main key components in Sample diluent for Getein 1150  
- Phosphate buffer, Na<sub>2</sub> (< 0.1%).
- 4) Main key components in Sample diluent for Getein 1600/Getein 1200  
- Phosphate buffer, Na<sub>2</sub> (< 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 DEVICES

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. Heparin and sodium citrate can be used as the anticoagulant for plasma and sodium citrate can be used as the anticoagulant for plasma and whole blood. Do not use hemolysis specimens.
3. Suggest using serum or plasma for better results.
4. 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.
5. Whole blood is stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
6. 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 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 the sample well on the test card using disposable pipet or pipette (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: 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. 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).

- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver **100 µL** of sample into the sample well on the test card using disposable pipet or pipette (for whole blood sample, one drop of whole blood buffer must be added after loading **100 µL** sample on the test card).
- Insert the test card into 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 printed automatically.

#### **For Getein 1150:**

- 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.
- Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
- Deliver **20 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.
- Press the "Start" button immediately after sample loading. The analyzer will initiate a 15-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

#### **For Getein 1200/Getein 1600:**

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

#### **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

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

- Measuring range of the PCT is 0.05–50.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with sample diluent, and the dilution ratio 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 99<sup>th</sup> 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<sup>[4]</sup>:

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.

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	0.05–50.00 ng/mL
Limit of Detection	≤ 0.05 ng/mL
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

#### **REFERENCES**

- Balç I, 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.

- 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.
- 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.
- Meisner M. Procalcitonin (PCT) - A New innovative infection parameter. Biochemical and clinical aspects. Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0.
- EN ISO 18113-1:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

#### **DESCRIPTION OF SYMBOLS USED**

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

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

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

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Catalogue number	Applicable analyzer	Package specification
IF1007-10T	Getein 1100	10 T/kit
IF1007	Getein 1100	25 T/kit
IF8007-10T	Getein 1150	10 T/kit
IF8007	Getein 1150	25 T/kit
IF5007-10T	Getein 1160	10 T/kit
IF5007	Getein 1160	25 T/kit
IF3007-10T	Getein 1180	10 T/kit
IF3007	Getein 1180	25 T/kit
IF4007-24T	Getein 1200	2×12 T/kit
IF4007	Getein 1200	2×24 T/kit
IF4007-96T	Getein 1200	2×48 T/kit
IF2007-24T	Getein 1600	2×12 T/kit
IF2007	Getein 1600	2×24 T/kit
IF2007-96T	Getein 1600	2×48 T/kit