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

Document No.: GP-GMSQ-2023121301

Letter of Authorization

To whom it may concern,

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

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

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

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

This authorization starts from **1st Jan, 2024** and will be valid to **31th, December, 2024** .

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

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Digitally signed by Dolgopol Iulian
Date: 2024.11.21 12:00:57 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Getein Biotech, Inc.
Seal & Signature

Steven Zhou

Authority Person Name: **Steven Zhou**
Authority Person Position: **Regional Manager**
Date: **2023.12.13**

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

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

Holds Certificate No: **MD 728432**

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

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

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

...making excellence a habit.

Certificate No: **MD 728432**

Registered Scope:

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

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

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

Certificate No: **MD 728432**

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

Original Registration Date: 2020-05-29

Effective Date: 2023-07-26

Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

EC Declaration of Conformity

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

Ref. No.:20220513-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 Nº 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	β2-MG Fast Test Kit (Immunofluorescence Assay)
13	CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)
14	HCG+β Fast Test Kit (Immunofluorescence Assay)
15	H-FABP Fast Test Kit (Immunofluorescence Assay)
16	PCT/CRP Fast Test Kit (Immunofluorescence Assay)
17	CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay)
18	HbA1c Fast Test Kit (Immunofluorescence Assay)
19	NT-proBNP/NGAL Fast Test Kit (Immunofluorescence Assay)
20	CK-MB Fast Test Kit (Immunofluorescence Assay)
21	hs-cTnI Fast Test Kit (Immunofluorescence Assay)
22	T3 Fast Test Kit (Immunofluorescence Assay)
23	T4 Fast Test Kit (Immunofluorescence Assay)
24	TSH Fast Test Kit (Immunofluorescence Assay)
25	Scr Fast Test Kit (Immunofluorescence Assay)
26	PLGF Fast Test Kit (Immunofluorescence Assay)

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

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

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

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

Applicable coordination standards

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

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

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

General Manager Enben Su

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

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

CE

EC Declaration of Conformity

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

Ref. No.:20220513-F02

Manufacturer (Name, Address)

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

Authorized Representative (Name, Address)

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

Medical device

No.	Product Name
1	Myo Control
2	CK-MB Control
3	NT-proBNP Control
4	D-Dimer Control
5	PCT Control
6	CRP Control
7	cTnI Control
8	H-FABP Control
9	mAlb Control
10	NGAL Control
11	β_2-MG Control
12	CysC Control
13	CK-MB/cTnI/Myo Control
14	CK-MB/cTnI Control
15	NT-proBNP/cTnI Control
16	HCG+β Control
17	HbA1c Control
18	TSH Control
19	T4 /T3 Control
20	T3 Control
21	T4 Control

22	FOB Control
23	H. pylori Control
24	SAA Control
25	LH Control
26	FSH Control
27	25-OH-VD Control
28	fT3 Control
29	fT4 Control
30	PRL Control
31	SARS-CoV-2 Control
32	Prog Control
33	IL-6 Control
34	Fer Control
35	cTnT Control
36	BNP Control
37	IGE Control
38	AMH Control
39	TPO Control
40	TG-Ab Control
41	T Control
42	E2 Control
43	E3 Control
44	HCG+β Control
45	CA50 Control
46	CA125 Control
47	CA15-3 Control
48	CA19-9 Control
49	CA242 Control
50	CA72-4 Control
51	CY21-1 Control
52	NSE Control

53	AFP Control
54	CEA Control
55	Fer Control
56	HE4 Control
57	cTnT Control
58	INS Control
59	C-P Control
60	PTH Control
61	BGP Control
62	IAA Control
63	IgE Control
64	GH Control
65	Cor Control
66	TP Control
67	PGI Control
68	PGII Control
69	G17 Control
70	Pro-GRP Control
71	SCC Control
72	ST2 Control
73	PLA2 Control
74	CG Control
70	HA Control
71	LN Control
72	III Control
73	CIV Control
74	SHBG Control
75	Renin Control
76	TG Control
77	PVK Control
78	HBP Control

79	PIIIP N-P Control
80	CIV Control
81	CRP Calibrator
82	β2-MG Calibrator
83	C3 Calibrator
84	C4 Calibrator
85	IgA Calibrator
86	CysC Calibrator
87	IgG Calibrator
88	IgM Calibrator
89	PA Calibrator
90	ApoA1 Calibrator
91	ApoB Calibrator

Classification	Other device (according to Annex II of the directive 98/79/EC)		
Conformity assessment route	Annex III of the 98/79/EC		
Applicable coordination standards	EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
	EN ISO 23640:2015	EN ISO 13485:2016	ISO 780:2015

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

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

General Manager Enben Su

Nanjing, 13th May 2022

(place and date of issue)

Enben Su

(name and signature or equivalent marking of authorized person)

CE

EC Declaration of Conformity

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

Ref. No.: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 Nº 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)
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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)
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37	PG Ⅰ /PG Ⅱ Fast Test Kit (Immunofluorescence Assay)
38	LH Fast Test Kit (Immunofluorescence Assay)
39	FSH Fast Test Kit (Immunofluorescence Assay)
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67	HBP Fast Test Kit (Immunofluorescence Assay)	
68	S100-β Fast Test Kit (Immunofluorescence Assay)	
69	CK-MB/hs-cTnI/Myo Fast Test Kit (Immunofluorescence Assay)	
70	Cortisol Fast Test Kit (Immunofluorescence Assay)	
71	CEA Fast Test Kit (Immunofluorescence Assay)	
72	AFP/CEA Fast Test Kit (Immunofluorescence Assay)	

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

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

Applicable coordination standards

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

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

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

General Manager Enben Su

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

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

CE

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

CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

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

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

GP Getein Biotech, Inc.

Cardiac Markers

Coagulation Markers

Diabetes Mellitus

Inflammation

Thyroid Function

Metabolic Marker

Renal Function

Tumor Markers

Reproduction /Fertility

Infectious Disease

Getein Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION

MAKING TEST EASY

Getein 1100

Immunofluorescence Quantitative Analyzer

Getein 1100

Immunofluorescence Quantitative Analyzer

HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control

REAL-TIME AND RAPID TEST

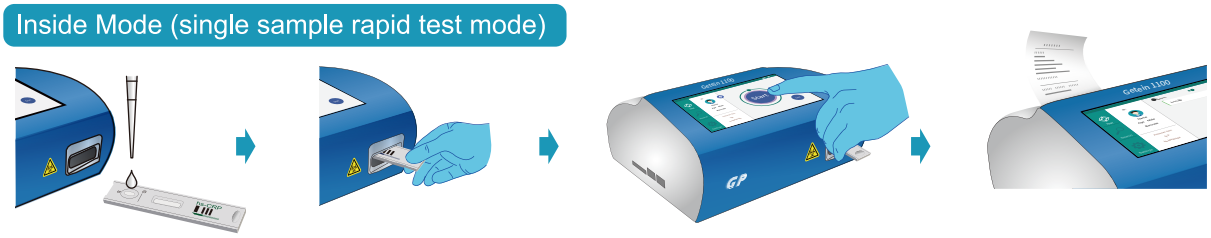
One-step test

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 | Result Show and Print

Quick mode (mass samples rapid test mode)

Sample Transfer | Timing the Reaction Manually | Click “Start” Icon | Result Show and Print

CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB port

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. SD Card 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	10000 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×241 mm×115 mm (D×W×H)
Weight	2.0 kg

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Cardiac Markers								
IF1001	cTnI	Myocardial infarction	0.10 ng/mL	S/P/WB	0.10-50.00 ng/mL	100 µL	10 min	NMPA CE
NEW IF1098	TnT	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	100 µL	15 min	NMPA CE
IF1089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	NMPA CE
IF1002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	100 µL	10 min	NMPA CE
IF1005	CK-MB/cTnI/Myo	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL Myo: 70.0 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 30.0-600.0 ng/mL	100 µL	10 min	NMPA CE
IF1012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL	100 µL	10 min	CE
IF1014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.00-120.00 ng/mL	100 µL	3 min	NMPA CE
IF1016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL H-FABP: 6.36 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 2.00-100.00 ng/mL	100 µL	10 min	NMPA CE
IF1018	CK-MB	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	100 µL	10 min	CE
Coagulation Marker								
IF1006	D-Dimer	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	100 µL	10 min	NMPA CE
Inflammation								
IF1003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3.0 mg/L 10.0 mg/L	S/P/WB/ Fingertip blood	0.5-200.0 mg/L	10 µL	3 min	NMPA CE
IF1007	PCT	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB	0.05-50.00 ng/mL	100 µL	15 min	NMPA CE
IF1015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.10 ng/mL CRP: 3.0 mg/L	S/P/WB	0.10-50.00 ng/mL 0.5-200.0 mg/L	100 µL	15 min	NMPA CE
IF1044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	10 µL	5 min	NMPA CE
IF1090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Peripheral blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA CE
IF1088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	100 µL	15 min	NMPA CE
Renal Function								
IF1008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.50-10.00 mg/L	10 µL	3 min	NMPA CE
IF1009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA CE
IF1010	NGAL	Acute kidney injury	Serum: 200.0 ng/mL Urine: 100.0 ng/mL	S/Urine	50.0-5000.0 ng/mL	10 µL	10 min	NMPA CE
IF1011	β_2-MG	Acute and chronic kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	10 µL	3 min	NMPA CE
Diabetes Mellitus								
IF1017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	10 µL	5 min	NGSP NMPA IFCC CE
Metabolic Marker								
IF1031	25-OH-VD	Osteomalacia, osteoporosis	30.00-50.00 ng/mL	S/P	8.00-70.00 ng/mL	40 µL	15 min	NMPA CE
Thyroid Function								
IF1024	TSH	Thyroid malfunction	0.27-4.20 µIU/mL	S/P	0.10-50.00 µIU/mL	100 µL	15 min	NMPA CE
IF1022	T3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	40 µL	15 min	NMPA CE
IF1023	T4	Hyperthyroidism, hypothyroidism	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	100 µL	15 min	NMPA CE
IF1067	fT3	Hyperthyroidism, hypothyroidism	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	100 µL	15 min	CE
IF1068	fT4	Hyperthyroidism, hypothyroidism	12.00-22.00 pmol/L	S/P/WB	0.30-100.00 pmol/L	100 µL	15 min	CE

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Reproduction/Fertility								
IF1013	HCG+β	Fertility	5.1 mIU/mL	S/P	5.0-100000.0 mIU/mL	100 µL	10 min	NMPA CE
IF1055	LH	PCOS, infertility evaluation	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 µL	15 min	NMPA CE
IF1056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 µL	15 min	NMPA CE
IF1066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	200 µL	15 min	CE
IF1048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.00 ng/mL	100 µL	15 min	NMPA CE
IF1071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 µL	15 min	CE
NEW IF1073	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	100 µL	15 min	CE
NEW IF1074	E2	Ovarian function	Refer to User Manual	S/P	40.0-4800.0 pg/mL	100 µL	15 min	CE
Tumor Markers								
IF1053	tPSA	Prostate cancer	4.00 ng/mL	S/P	0.50-100.00 ng/mL	100 µL	15 min	NMPA
IF1072	fPSA	Prostate cancer	1.00 ng/mL	S/P	0.05-30.00 ng/mL	100 µL	10 min	NMPA
IF1050	AFP	Liver cancer, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 µL	15 min	CE
IF1051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P	2.0-500.0 ng/mL	100 µL	15 min	CE
Infectious Disease								
IF1057	Anti-HCV	Hepatitis C	1.00 S/CO	S/P	1.00-20.00 S/CO	100 µL	15 min	
IF1058	Anti-TP	Syphilis	1.00 S/CO	S/P	1.00-50.00 S/CO	100 µL	15 min	CE
IF1059	Anti-HIV	AIDS	1.00 S/CO	S/P	1.00-1000.00 S/CO	100 µL	15 min	
IF1064	HBsAg	Hepatitis B	1.00 IU/mL	S/P	1.00-100.00 IU/mL	100 µL	15 min	
NEW IF1063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	100 µL	15 min	
IF1084	2019-nCoV IgM/IgG	COVID-19	1.00 COI	S/P/WB		100 µL	10 min	CE
NEW IF1091	SARS-CoV-2 Antigen	COVID-19	1.00 COI	Nasal swab/Saliva		100 µL	15 min	CE
NEW IF1095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB/ Fingertip blood		40 µL	15 min	CE
IF1047	*H. pylori*	*H. pylori* infection	5.0 ng/mL	Stool	1.0-200.0 ng/mL	3 drops (about 100 µL)	10 min	CE
NEW IF1086	Influenza A/B	Respiratory viral infection	1.00 S/CO	Nasal swab		100 µL	15 min	CE
NEW IF1136	Dengue NS1 Ag	Dengue virus infection	1.00 S/CO	S/P/WB	0.50-50.00 S/CO	100 µL	15 min	CE
Specific Protein and Rheumatism								
NEW IF1075	RF	Rheumatoid arthritis	15.9 IU/mL	S/P/WB	10.0-640.0 IU/mL	10 µL	10 min	CE
NEW IF1076	ASO	Rheumatic fever, acute glomerulonephritis, group A streptococcal infection	408.0 IU/mL	S/P/WB	60.0-1370.0 IU/mL	10 µL	10 min	CE
NEW IF1029	Anti-CCP	Rheumatoid arthritis	25.0 U/mL	S/P/WB	10.0-400.0 U/mL	10 µL	15 min	CE
Others								
NEW IF1077	Ferritin	Anemia/tumors	Male: 30.00-400.00 ng/mL Female: 13.00-150.00 ng/mL	S/P	0.50-1000.00 ng/mL	10 µL	15 min	CE
NEW IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 µL	15 min	CE
NEW IF1052	PG I/PG II	Atrophic gastritis, stomach cancer	PG I<70.0 ng/mL PG I/PG II<3.0 ng/mL	S/P	PG I: 1.0-200.0 ng/mL PG II: 1.0-100.0 ng/mL	100 µL	15 min	

Coming Soon: FOB, Folate…

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ISO13485 FSC CE NMPA NGSP IFCC IVD

WPT3.11-09

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		Traditional POCT
Operation	Avoid the inaccuracy of results caused by human factors	VS	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

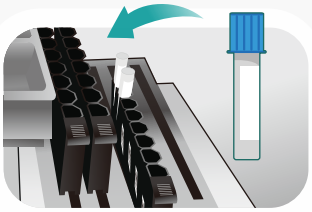
Meet the requirements of clinical laboratory standards

TECHNICAL PARAMETERS

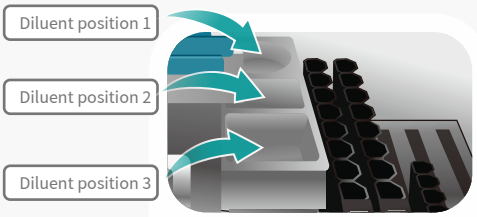
Methodology	Immunofluorescence
Result	Quantitative
Throughput	48 samples/run, 150 tests/hour
Sample Type	Whole blood, plasma, serum, urine, fingertip blood
Storage Capacity	500000 data
Language	English/Chinese
Screen Display	10.4 inch touch screen
Power Supply	100-240 V~50/60 Hz
Working Environment	Relative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

TEST PROCEDURE

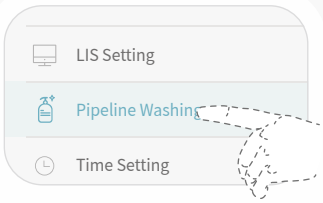
1 Insert cartridge into the instrument, the instrument will recognize the test item automatically.



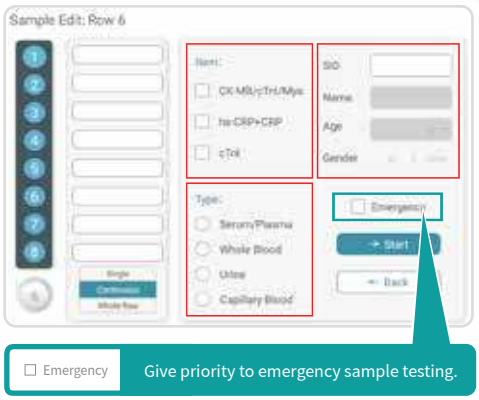
2 Insert the sample holder into the sample chamber.



3 Put the diluent into the instrument.

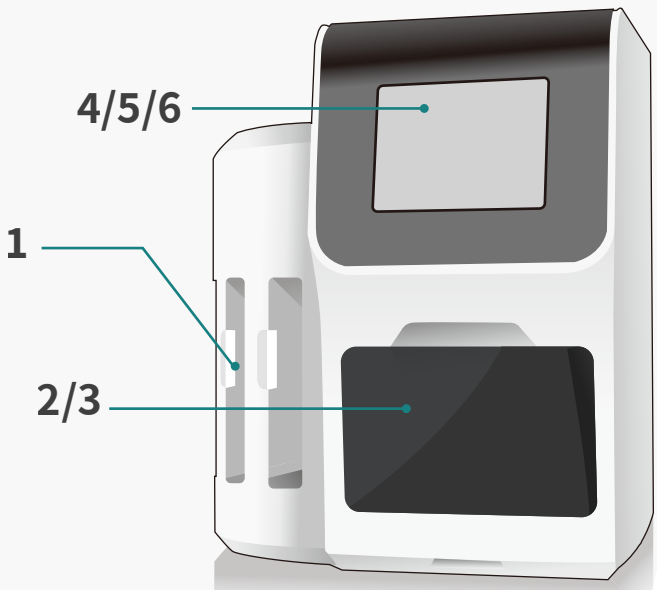


4 Perform pipeline washing before daily test.



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.



*The final interpretation is reserved by Getein Biotech

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	QUALIFICATION
Cardiac Markers						
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
Coagulation Markers						
IF2006	D-Dimer	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	NMPA CE
Inflammation						
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
Renal Function						
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	β_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
Diabetes Mellitus						
IF2017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	NGSP NMPA IFCC CE
Metabolic Marker						
IF2031	25-OH-VD	Osteomalacia, osteoporosis	30.00-50.00 ng/mL	S/P	8.00-70.00 ng/mL	NMPA CE
Thyroid Function						
IF2024	TSH	Thyroid malfunction	0.27-4.20 μIU/mL	S/P	0.10-50.00 μIU/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
NEW IF2067	fT3	Hyperthyroidism, hypothyroidism	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	CE
NEW 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
Reproduction/Fertility						
IF2013	HCG+β	Fertility	5.1 mIU/mL	S/P	5.0-100000.0 mIU/mL	NMPA CE
IF2055	LH	Homeostasis fertility regualtion	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
Tumor Markers						
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
Infectious Disease						
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
Specific Protein and Rheumatism						
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
Others						
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

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Web: www.getein.com

ISO ISO13485 FSC CE NMPA NGSP IFCC IVD

CE IVD

PCT

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1007
Getein1600: Cat.# IF2007

INTENDED USE

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

SUMMARY

PCT is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine.
Measurement of PCT can be used as a marker of severe sepsis and generally grades well with the degree of sepsis, although levels of PCT in the blood are very low. PCT has the greatest sensitivity and specificity for differentiating patients with systemic inflammatory response syndrome (SIRS) from those with sepsis.
PCT levels may be useful to distinguish bacterial infections from nonbacterial infections. It has shown that PCT may help guide therapy and reduce antibiotic use, which can help save on cost of antibiotic prescriptions and drug resistance.

PRINCIPLE

The test uses an anti-human PCT monoclonal antibody conjugated with fluorescence latex. For PCT product, test line 1 was coated with anti-human PCT polyclonal antibody and test line 2 was coated with another anti-human PCT monoclonal antibody. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human PCT monoclonal 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 the other anti-human PCT monoclonal antibody or the polyclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of PCT in sample.
Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of PCT 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 PCT test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   Whole blood buffer 1
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein PCT 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
3. Sample diluent/Whole blood buffer 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, fluorescence latex pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human PCT monoclonal antibody, the test line are coated with another anti-human PCT monoclonal antibody and polyclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 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℃ with a valid period of 24 months.
Store the sample diluent/whole blood buffer at 2~8℃ 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 the manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

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

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 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).
8. ***Reaction time: 15 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 PCT was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for PCT is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.) The table below comes from the research of ACCP/SCCM (American College of Chest Physicians/Society of Critical Care Medicine), showing the PCT value and its clinical meaning [4]:

PCT concentration	Clinical significance
< 0.5 ng/ml	Local bacterial infection is possible, systemic infection (sepsis) is not likely.
≥ 0.5 and < 2.0 ng/ml	Systemic infection (sepsis) is possible, a moderate risk of severe sepsis and/or septic shock.
≥ 2.0 ng/ml	Systemic infection (sepsis) is likely, a high risk of severe sepsis and/or septic shock.

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~50.0 ng/ml
Lower Detection Limit	≤0.1 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with Roche MODULAR ANALYTICS E170 automatic immunoassay system and its matching PCT test kits with 200 serum samples (68 positive samples and 132 negative samples). The correlation coefficient (r) for PCT is 0.983.

LIMITATIONS

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

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

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1. Balcl C, Sungurtekin H, Gürses E, Sungurtekin U, Kaptanoglu B. Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit, Crit Care. 2003 February 7 (1):85~90.
2. Schuetz P, Christ-Crain M, Thomann R, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. Sep 9 2009; 302(10):1059-66.
3. Briel M, Schuetz P, Mueller B, et al. Procalcitonin-guided antibiotic use vs a standard approach for acute respiratory tract infections in primary care. Arch Intern Med. Oct 13 2008; 168(18):2000-7; discussion 2007-8.
4. Meisner M. Procalcitonin (PCT) - A New innovative infection parameter. Biochemical and clinical aspects. Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0.
5. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. 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 PCT Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
	CE mark		Do not use if package is damaged

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

Version: WIF06-S-02

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Cardiac Troponin I
Fast Test Kit
(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1001
Getein1600: Cat.# IF2001

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

1. 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
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein cTnI 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
3. Sample diluent/Whole blood buffer 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 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℃ 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℃ with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8℃ 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 and whole blood samples. Heparin and sodium citrate*** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.

2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME *(for Getein1100): 100 µl*.

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 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).
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 Troponin I was determined by testing samples from 500 apparently healthy individuals. The 99th 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

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

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

REFERENCES

1. Mauro Pantaghini. Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. 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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
Σ	Sufficient for	EC REP	Authorized representative in the European Community
CE	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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CE IVD

D-Dimer

Fast Test Kit

(Immunofluorescence Assay)

User Manual

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

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

1. 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
2. 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
3. Sample diluent composition:
   Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
   A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human D-Dimer monoclonal antibody, the test line is coated with another anti-human D-Dimer monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 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℃ with a valid period of 24 months.

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

and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME *(for Getein1100): 100 µl*.

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card 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 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 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 95th 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	≤0.1 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤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 interferents such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. The table below listed the maximum allowance of these potential interferents.

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

REFERENCES

1. Sarig G, Klil-Drori AJ, Chap-Marshak D, Brenner B, Drugan A. Activation of coagulation in amniotic fluid during normal human pregnancy.Thromb Res. 2011 Apr 18.
2. Roldán V, Marín F, Muiña B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated Atrial Fibrillation Patients. J Am Coll Cardiol. 2011 Apr 11.
3. Sakamoto K, Yamamoto Y, Okamatsu H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. Hellenic J Cardiol. 2011 Mar-Apr; 52(2):123-127.
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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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	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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CE IVD

hs-CRP

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1003
Getein1600: Cat.# IF2003

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 microbic 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 (>200 mg/L).

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:
   2×24 tests/kit, 2×48 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 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℃ 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℃ with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8℃ 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.

2. Suggest using serum or plasma for better results.
3. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME *(for Getein1100): 10 µl*.

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card 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 *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.
8. *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:

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

hs-CRP: The expected normal value for hs-CRP was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for hs-CRP is 3 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 95th 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

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

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

REFERENCES

1. Danesh J, Whincup P, Wslker M, et al. Low grade inflammation and coronary heart disease: prospective study and updated meta-analysis. BJM 2000; 321:199~204.
2. Rifai N, Ridker PM. Proposed cardiovascular risk assessment algorithm using high-sensitivity C-reactive protein and lipid screening. Clin Chem 2001; 47:28~30.
3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. 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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
	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.

Version: WIF04-S-02

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mAlb

Fast Test Kit

(Immunofluorescence Assay)

User Manual Cat.# IF1009

INTENDED USE

mAlb Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of microalbuminuria (mAlb) in urine. An elevated mAlb concentration below the proteinuric level has long been recognized as a marker of kidney disease and increased cardiovascular risk in diabetic nephropathy.

SUMMARY

Albumin is one of the major plasma proteins. In normal circumstances, albumin molecules are too large to cross the glomerular basement membrane. Therefore, albumin is usually present in very low concentration in urine. Damage to the glomerular basement membrane can alter its permeability. Albumin is then able to enter the urine. Sustained elevation of urinary albumin concentration is called microalbuminuria (mAlb). mAlb arises from increased leakage of glomerular basement membrane. So, mAlb is recognized as a marker of kidney damage. The epidemiology of microalbuminuria reveals a close association between systemic endothelial dysfunction and vascular disease, also implicating glomerular endothelial dysfunction in microalbuminuria.

Recent years, determination of mAlb is linked with increased risk for cardiovascular events rather than progression to end-stage kidney diseases. It is a valuable tool for the detection if cardiovascular risk in diabetic nephropathy. Early detection of microalbuminuria in diabetics is critical because immediate intervention can slow the progression of disease.

PRINCIPLE

The test is based on the competition immune-detection method and uses an anti-human mAlb monoclonal antibody conjugated with fluorescence latex and recombinant mAlb antigen coated on the test line. After the sample has been applied to the test strip, mAlb in the sample will compete with recombinant mAlb antigen on nitrocellulose matrix for fluorescence latex-labelled mAlb monoclonal antibody. As a result, the concentration of mAlb antigen in specimen shows inverse proportionally with the fluorescence intensity of mAlb.

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

CONTENTS

A kit contains:

1. Getein mAlb test card in a sealed pouch with desiccant 25
2. Disposable pipet 25
3. User manual 1
4. SD card 1

A test card consists of:

A plastic shell and a reagent strip which is composed of sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human mAlb monoclonal antibody, the test line is coated with mAlb recombinant antigen, and the control line is coated with rabbit anti-goat IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches 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 ***urine sample***.
2. ***Urine sample*** can be preserved at room temperature for 4 hours, please test it as soon as possible. If testing will be delayed, urine sample may be stored up to 3 days at 2~8℃ before testing .
3. Do not use frozen urine sample.
4. Samples should be brought to room temperature before testing.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME: ***100 µl***.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample should be brought to room temperature before testing.
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 µl*** of sample (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card.
8. ***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.

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.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100 can scan the test card automatically and display the result on the screen. Please follow the procedure in user manual of Getein1100 for result printing. For additional information, please refer to the user manual of Getein1100.

EXPECTED VALUE

The expected normal value for mAlb was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for mAlb is 20.0 mg/L. (The probability that value of a normal person below 20.0 mg/L is 95%.)
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	10.0~200.0 mg/L
Lower Detection Limit	≤10 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with OLYMPUS AU5400 analyzer and its matching Randox mAlb test kits with 200 urine samples (62 positive samples and 138 negative samples). The correlation coefficient (r) is 0.984.

LIMITATIONS

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

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	10 g/L	10 g/L	100 g/L

REFERENCES

1. Cöl M, Ocaktan E, Ozdemir O, et al. Microalbuminuria: prevalence in hypertensives and diabetics. Acta Med Austriaca. 2004, 31(1):23-29.
2. McTaggart MP, Price CP, Pinnock RG, et al. The diagnostic accuracy of a urine albumin - creatinine ratio point-of-care test for detection of albuminuria in primary care. Am J Kidney Dis. 2012, 60(5):787-794.
3. Denis Sviridov, Glen L. Hortin. Urine albumin measurement: Effects of urine matrix constituents. Clinica Chimica Acta. 2009, 404(2):140-143.
4. Reboldi G, Gentile G, Angeli F, et al. Microalbuminuria and hypertension. Minerva Med. 2005, 96(4):261-75.
5. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. 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 mAlb 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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

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

Version: WIF10-S-01

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CE IVD

NT-proBNP

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1002
Getein1600: Cat.# IF2002

INTENDED USE

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

SUMMARY

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

PRINCIPLE

The test uses an anti-human NT-proBNP monoclonal antibody conjugated with fluorescence latex and an anti-human NT-proBNP polyclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human NT-proBNP monoclonal antibody binds with the NT-proBNP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human NT-proBNP polyclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of NT-proBNP 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 NT-proBNP 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 NT-proBNP test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   Whole blood buffer 1
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein NT-proBNP 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
3. Sample diluent/Whole blood buffer 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 NT-proBNP monoclonal antibody, the test line is coated with another anti-human NT-proBNP polyclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Components from different batches must not be interchanged.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months.
Use the test card for Getein1100 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℃ with a valid period of 24 months.
Store the sample diluent/whole blood buffer at 2~8℃ 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 the manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

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

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

Table 1 NT-proBNP reference value

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

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

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

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

PERFORMANCE CHARACTERISTICS

Measuring Range	100~35000 pg/ml
Lower Detection Limit	≤100 pg/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with Roche MODULAR ANALYTICS E170 and its matching NT-proBNP test kits with 200 serum samples (63 positive samples and 137 negative samples). The correlation coefficient (r) for NT-proBNP is 0.959.

LIMITATIONS

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

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

REFERENCES

1. de Lemos JA, McGuire DK, Drazner MH. B-type natriuretic peptide in cardiovascular disease. Lancet 2003; 362:316~322.
2. Pfister R, Scholz M, Wielckens K, Erdmann E, Schneider CA. The value of natriuretic peptides NT-pro-BNP and BNP for the assessment of left-ventricular volume and function. A prospective study of 150 patients. Deutsche medizinische Wochenschrift (1946) 2002; 127(49):2605.
3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. 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 NT-proBNP Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

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

Version: WIF03-S-02

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cTnI Control

REF QC001

User Manual

PRODUCT NAME

cTnI Control

PRODUCT SPECIFICATION

Package: 3(Level)*2(Vial)*1(ml), 3(Level)*1(Vial)*1(ml)
cTnI Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of Cardiac Troponin I (cTnI) on the Getein Platforms.

PRINCIPLE

The lyophilized cTnI control is prepared from dissolving stable and high quality recombinant cTnI antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

1. cTnI Control - Level 1
   cTnI Control - Level 2
   cTnI Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

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

Note: Each quality control holder is labelled with barcode which contains target value and level of different items.

MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months at -20℃ and for 30 days at 2 ~ 8℃ to avoid light.
OPENED: The product is stable for 1 day at 2 ~ 8℃ if kept capped in orginal container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70℃.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein test kit
4. Getein instrument

TEST PROCEDURE

1. The product should be brought to room temperature (15 ~ 30℃) prior to use.
2. Open the vial carefully in case of the loss of content.
3. Dissolve each control material with 1 ml distilled water.

4. Close the vial and mix gently until all contents are dissolved completely. Avoid violent shaking or foam formation.
5. Keep it at room temperature for 5 ~ 10 minutes before use.

For FIA8000/FIA8600/Getein1100:

6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

For Getein1600:

7. Insert quality control holder into sample holder.
8. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

ASSIGNED VALUES

Refer to values listed on the target value sheet.
If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.
The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Refer to the target value sheet

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on cTnI control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and EN ISO15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
	Catalogue number		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		*In vitro* diagnostic medical device
	Sufficient for		Biological risk
	CE mark		Authorized representative in the European Community

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

Version: WZK01-S-04

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Please contact Getein if you have any questions.

D-Dimer Control

REF QC006

User Manual

PRODUCT NAME

D-Dimer Control

PRODUCT SPECIFICATION

Package: 3(Level)*2(Vial)*1(ml), 3(Level)*1(Vial)*1(ml)
D-Dimer Control - Level 1/2/3

INTENDED USE

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

PRINCIPLE

The lyophilized D-Dimer control is prepared from dissolving stable and high quality recombinant D-Dimer antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

1. D-Dimer Control - Level 1
   D-Dimer Control - Level 2
   D-Dimer Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. D-Dimer Control - Level 1
   D-Dimer Control - Level 2
   D-Dimer Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box
4. Quality control holder - Level 1
   Quality control holder - Level 2
   Quality control holder - Level 3

Note: Each quality control holder is labelled with barcode which contains target value and level of different items.

MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months at -20℃ and for 90 days at 2 ~ 8℃ to avoid light.
OPENED: The product is stable for 15 days at 2 ~ 8℃ if kept capped in orginal container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70℃.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein test kit
4. Getein instrument

TEST PROCEDURE

1. The product should be brought to room temperature (15 ~ 30℃) prior to use.
2. Open the vial carefully in case of the loss of content.

3. Dissolve each control material with 1 ml distilled water.
4. Close the vial and mix gently until all contents are dissolved completely. Avoid violent shaking or foam formation.
5. Keep it at room temperature for 5 ~ 10 minutes before use.

For FIA8000/FIA8600/Getein1100:

6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

For Getein1600:

7. Insert quality control holder into sample holder.
8. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

ASSIGNED VALUES

Refer to values listed on the target value sheet.
If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.
The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Refer to the target value sheet

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and EN ISO15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
REF	Catalogue number		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
Σ	Sufficient for		Biological risk
CE	CE mark	EC REP	Authorized representative in the European Community

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

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Please contact Getein if you have any questions.

CE IVD

NT-proBNP Control

REF QC007

User Manual

PRODUCT NAME

NT-proBNP Control

PRODUCT SPECIFICATION

Package: 3(Level)*2(Vial)*1(ml), 3(Level)*1(Vial)*1(ml)
NT-proBNP Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of N-terminal B-type natriuretic peptide precursor (NT-proBNP) on the Getein Platforms.

PRINCIPLE

The lyophilized NT-proBNP control is prepared from dissolving stable and high quality recombinant NT-proBNP antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

1. NT-proBNP Control - Level 1
   NT-proBNP Control - Level 2
   NT-proBNP Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. NT-proBNP Control - Level 1
   NT-proBNP Control - Level 2
   NT-proBNP Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box
4. Quality control holder - Level 1
   Quality control holder - Level 2
   Quality control holder - Level 3

Note: Each quality control holder is labelled with barcode which contains target value and level of different items.

MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months at -20℃ and for 30 days at 2 ~ 8℃ to avoid light.
OPENED: The product is stable for 1 day at 2 ~ 8℃ if kept capped in orginal container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70℃.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein test kit
4. Getein instrument

TEST PROCEDURE

1. The product should be brought to room temperature (15 ~ 30℃) prior to use.
2. Open the vial carefully in case of the loss of content.
3. Dissolve each control material with 1 ml distilled water.
4. Close the vial and mix gently until all contents are dissolved

completely. Avoid violent shaking or foam formation.

5. Keep it at room temperature for 5 ~ 10 minutes before use.

For FIA8000/FIA8600/Getein1100:

6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

For Getein1600:

7. Insert quality control holder into sample holder.
8. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

ASSIGNED VALUES

Refer to values listed on the target value sheet.

If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.

The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Refer to the target value sheet

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on NT-proBNP control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and EN ISO15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
REF	Catalogue number		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for		Biological risk
CE	CE mark	EC REP	Authorized representative in the European Community

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

Version: WZK02-S-04

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