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

Document No.: GP-GMSQ-2024121101

Letter of Authorization

To whom it may concern,

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

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

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

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

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

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

Getein Biotech, Inc.

Name: Steven Zhou
Position: Overseas Sales Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Digitally signed by Dolgopol Iulian
Date: 2026.03.16 07:51:43 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

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

Holds Certificate No: **MD 728432**

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

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

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

...making excellence a habit.™

Certificate No: **MD 728432**

Registered Scope:

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

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

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

Certificate No: **MD 728432**

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

Original Registration Date: 2020-05-29

Effective Date: 2023-07-26

Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

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

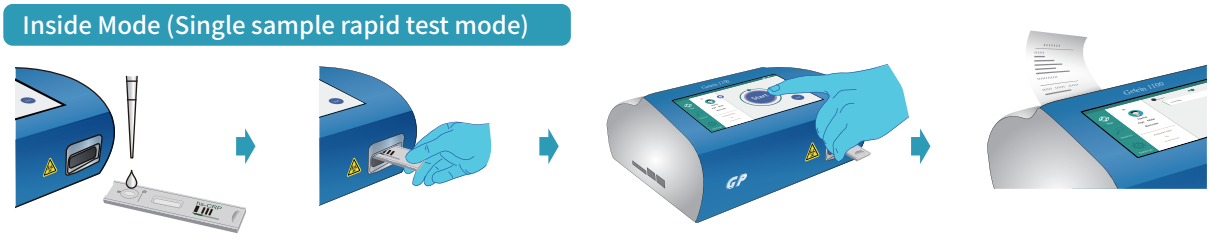
One-step test

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 | Results Output

Outside Mode (Mass samples rapid test mode)

Sample Transfer | Timing the Reaction Manually | Click “Start” Icon | Results Output

CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB ports

Handwriting input available

Continuous test for 3 hours with optional lithium battery

USER-FRIENDLY INTERFACE

Android system

7-inch touch screen

1. 7-inch Touch Screen
2. RFID Recognition Zone
3. Test Card Slot
4. SD Card Slot
5. USB Slot
6. Built-in Thermal Printer

PORTABLE DESIGN

Small in size: 261*241*115 mm

Light in weight: 2.0 kg

LARGE MEMORY

Up to 10, 000 results storage capacity

TECHNICAL PARAMETERS

Methodology	Immunofluorescence
Result	Quantitative
Sample Type	WB, Plasma, Serum, Urine, Stool, Nasal swab, Saliva, Capillary blood
Storage Capacity	10, 000 data
Language	English/Chinese/Spanish/Portuguese
Screen	7-inch touch screen
Power Supply	100-240 V ~ 50 Hz/60 Hz, 60 VA
Working Environment	Temperature: 10-35°C Relative humidity ⩽ 70% Air pressure 70.0 ~ 106.0 kpa
Dimensions	261 mm(L) × 241 mm(W) × 115 mm(H)
Weight	2.0 kg

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
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
IF1098	**TnT**	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	100 µL	15 min	NMPA CE
NEW IF1078	**ST2**	Chronic heart failure	35.0 ng/mL	S/P/WB	3.0-200.0 ng/mL	100 µL	15 min	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
IF1014	**H-FABP**	Myocardial damage	6.36 ng/mL	S/P/WB	1.00-120.00 ng/mL	100 µL	3 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	NMPA CE
IF1004	**NT-proBNP/cTnI**	Heart failure/AMI	NT-proBNP: 185 pg/mL cTnI: 0.10 ng/mL	S/P/WB	100-15000 pg/mL 0.10-50.00 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	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
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
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								
IF1007	**PCT**	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB	0.05-50.00 ng/mL	100 µL	15 min	NMPA CE
NEW IF1139	**Calprotectin**	Inflammatory bowel disease	＜50.0 µg/g	Fecal specimen	10.0-600.0 µg/g	100 µL	15 min	CE
IF1003	**hs-CRP+CRP**	Cardiovascular inflammation	3.0 mg/L 10.0 mg/L	S/P/WB Fingertip blood	0.5-200.0 mg/L	10 µL	3 min	NMPA CE
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
IF1088	**IL-6**	Acute inflammation	Refer to user manual	S/P/WB Fingertip blood	1.5-4000.0 pg/mL	20 µL	15 min	NMPA CE
IF1090	**SAA/CRP**	Sepsis, bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB Fingertip blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA CE
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	20 µL	15 min	NMPA CE
Renal Function								
IF1008	**CysC**	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	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA CE
IF1011	**β_2-MG**	Kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	10 µL	3 min	NMPA CE
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
Diabetes Mellitus								
IF1017	**HbA1c**	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	10 µL	5 min	NMPA CE NGSP/IFCC
Metabolic Marker								
IF1112	**Osteocalcin**	Osteoporosis	Male: 14-70 ng/mL Female:11-48 ng/mL	S/P	1.5-300.0 ng/mL	100 µL	15 min	CE
Thyroid Function								
IF1024	**TSH**	Thyroid malfunction	0.27-4.20 µlU/mL	S/P	0.10-50.00 µlU/mL	100 µL	15 min	NMPA CE
IF1022	**T3**	Thyroid Function	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	100 µL	15 min	NMPA CE
IF1023	**T4**	Thyroid Function	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	100 µL	15 min	NMPA CE
IF1067	**fT3**	Thyroid Function	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	100 µL	15 min	NMPA CE
IF1068	**fT4**	Thyroid Function	12.00-22.00 pmol/L	S/P/WB	0.30-100.00 pmol/L	100 µL	15 min	NMPA CE

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Vitamin								
IF1031	**25-OH-VD**	Osteoporosis	20.00-50.00 ng/mL	S/P/WB/ Fingertip blood	8.00-100.00 ng/ml	20 μL	8 min	NMPA CE
NEW IF1094	**Folate**	Megaloblastic anemia	3.89 ng/mL~26.80 ng/mL (8.83 nmol/L-60.80 nmol/L)	S	1.2-40.0 ng/mL (2.72-90.8 nmol/L)	20 μL	15 min	CE
NEW IF1070	**Vitamin B12**	Megaloblastic anemias	197.00-771.00 pg/mL (145.40-569.00 pmol/L)	S	100.0-2000.0 pg/mL or 73.8 -1476.0 pmol/L	100 μL	15 min	CE
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	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF1066	**AMH**	Fertility, PCOS	Refer to User Manual	S/P	0.10-20.00 ng/mL	100 μL	15 min	NMPA CE
IF1048	**PRL**	Infertility	Refer to User Manual	S/P	0.50-200.00 ng/mL	100 μL	15 min	NMPA CE
IF1071	**Prog**	Infertility	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	NMPA CE
IF1138	**Estradiol**	Ovarian function	Refer to User Manual	S/P	40.0-4800.0 pg/mL	100 μL	15 min	CE
IF1073	**Testosterone**	Female PCOS	Male: 1.75-7.81 ng/mL Female: 0.10-0.75 ng/mL	S/P	0.10-16.00 ng/mL	100 μL	15 min	CE
Tumor Markers								
IF1053	**tPSA**	Prostate cancer	4.00 ng/mL	S/P	0.40-100.00 ng/mL	100 μL	15 min	NMPA
IF1072	**fPSA**	Prostate cancer	1.00 ng/mL	S/P	0.03-30.00 ng/mL	100 μL	10 min	NMPA
IF1050	**AFP**	Liver cancer, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	NMPA CE
IF1051	**CEA**	Malignant tumour screening	4.7 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	NMPA CE
iF1079	**CA125**	Ovarian cancer	35.0 U/mL	S/P/WB	2-500.0 U/mL	100 μL	15 min	CE
IF1080	**CA19-9**	Pancreatic cancer	27.0 U/mL	S/P/WB	2-1000.0 U/mL	100 μL	15 min	CE
IF1081	**CA15-3**	Breast cancer	26.2 U/mL	S/P/WB	1.5-300.0 U/mL	100 μL	10 min	CE
IF1052	**PG I/PG II**	Atrophic gastritis	PG I < 70.0 ng/mL PG I/PG II < 3.0 ng/mL	S/P	PG I: 1.0-200.0 ng/mL PG II: 1.0-100.0 ng/mL	100 μL	15 min	NMPA CE
Infectious Disease								
IF1057	**Anti-HCV**	Hepatitis C	1.00 S/CO	S/P	/	100 μL	15 min	
IF1058	**Anti-TP**	Syphilis	1.00 S/CO	S/P	/	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	1.00-100.00IU/mL	100 μL	15 min	
IF1063	**Anti-HBs**	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	100 μL	15 min	
IF1091	**SARS-CoV-2 Antigen**	COVID-19	1.00 COI	Nasal swab	/	100 μL	15 min	CE
IF1047	***H. pylori* Antigen**	H. pylori infection	5.0 ng/mL	Stool	1.0-200.0 ng/mL	10-50 mg	10 min	CE
IF1086	**Influenza A/B**	Respiratory viral infection	1.00 COI	Nasal swab	/	100 μL	15 min	CE
IF1136	**Dengue NS1 Ag**	Dengue virus infection	1.00 S/CO	S/P/WB	1.00-50.00 S/CO	100 μL	15 min	CE
NEW IF1137	**Dengue IgG/IgM Antibody**	Dengue fever	COI<1.00	S/P/WB	0.50-100.00 COI	100 μL	15 min	CE
NEW IF1140	***H. Pylori* Antibody**	Functional dyspepsia	COI<1.0, S/CO	S/P/WB	0.50-100.00 S/CO	100 μL	15 min	CE
NEW IF1085	**RSV/Influenza A/B**	Flu, LRTI	COI<1.00	Human nasal swab sample		100 μL	15 min	CE
Specific Protein and Rheumatism								
IF1075	**RF**	Rheumatoid arthritis	15.9 IU/mL	S/P/WB	10.0-640.0 IU/mL	10 μL	10 min	NMPA CE
IF1076	**ASO**	Rheumatoid arthritis	408.0 IU/mL	S/P/WB	60.0-1370.0 IU/mL	10 μL	10 min	NMPA CE
IF1029	**Anti-CCP**	Rheumatoid arthritis	25.0 U/mL	S/P/WB	10.0-400.0 U/mL	10 μL	15 min	CE
Others								
IF1110	**Cortisol**	Adrenal cortex function	Refer to User Manual	S/P	11-1655 nmol/L	100 μL	15 min	CE
IF1069	**Total IgE**	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE
NEW IF1042	**FOB**	PUD	50 ng/mL	Fecal	25~1000 ng/mL	10-50 mg	10 min	CE
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	NMPA CE

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
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E-mail: overseas@getein.com.cn; marketing@getein.com.cn
Web.: www.getein.com

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

WPT3-11-14

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)
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

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

CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

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

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Getein
Biotech, Inc.

CE IVD

CK-MB/cTnI/Myo

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1005
Getein1600: Cat.# IF2005

INTENDED USE

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

SUMMARY

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

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

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

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

PRINCIPLE

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

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of CK-MB, cTnI and Myo 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 LIS and HIS.

CONTENTS

1. A kit for Getein1100 contains:
   Getein CK-MB/cTnI/Myo 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 CK-MB/cTnI/Myo 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 fluorescence latex-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies, these three lines are coated with another anti-human CK-MB, another anti-human cTnI and another anti-human Myo monoclonal antibody, respectively. and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
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: 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 CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for CK-MB is 5.0 ng/ml. (The probability that value of a normal person below 5.0 ng/ml is 99%.)

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

The expected normal value for Myo was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for Myo is 50 ng/ml. The 97.5th percentile of the concentration for Myo is 70 ng/ml. (According to different Statistics method, the probability that value of a normal person below 50 ng/ml is 95% or below 70 ng/ml is 97.5%.)

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

PERFORMANCE CHARACTERISTICS

	CK-MB	cTnI	Myo
Measuring Range	2.5~80.0 ng/ml	0.1~50.0 ng/ml	30.0~600.0 ng/ml
Lower Detection Limit	≤ 2.5 ng/ml	≤ 0.1 ng/ml	≤ 30.0 ng/ml
Within-Run Precision	≤10%		
Between-Run Precision	≤15%		

Method Comparison:

The assay was compared with HITACHI 7600/OLYMPUS AU5400 and its matching CK-MB test kits, SIEMENS IMMULITE 1000/2000 and its matching cTnI and Myo test kits with 200 serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for CK-MB is 0.928, the correlation coefficient (r) for cTnI is 0.952, the correlation coefficient (r) for Myo is 0.938.

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 CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more 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 CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF09-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.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

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

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	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

Ferritin

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1077 for Getein1100
IF3077 for Getein1180
IF2077 for Getein1600

INTENDED USE

Ferritin Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of ferritin in human serum and plasma samples. It can be used as an aid in the quantification of human ferritin and the diagnosis of iron deficiency anemia or iron overload related diseases.

SUMMARY

Ferritin has a molecular weight of 440 kD, depending on the iron content, and consists of a protein shell (apoferritin) that is composed of 24 subunits and an iron core containing an average of 2500 Fe^{3+} ions.
Latent iron deficiency is defined as a fall below the 12 ng/mL ferritin threshold. The two values are diagnostic even when the blood picture is still morphologically normal. A depressed ferritin level accompanied by hypochromic, microcytic anemia indicates manifest iron deficiency.
Elevated ferritin values are also encountered with the following tumors: acute leukemia, Hodgkin's disease and carcinoma of the lung, colon, liver, and prostate. Ferritin determinations have also proved to be of value in liver metastasis. Reasons for the elevated values could be cell necrosis, blocked erythropoiesis or increased synthesis in tumor tissue.

PRINCIPLE

The test uses an anti-human ferritin monoclonal antibody Ⅰ conjugated with fluorescence latex coated on the sample pad and another anti-human ferritin monoclonal antibody Ⅱ coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human ferritin antibody Ⅰ binds with the ferritin in sample and forms 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 anti-human ferritin antibody Ⅱ. The fluorescence intensity of test line increases in proportion to the amount of ferritin in sample.
Then insert test card into Getein1100/Getein1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1180 and Getein1600), the concentration of ferritin in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1180/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein Ferritin test card in a sealed pouch with desiccant
2) Capillary pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box
2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
Sealed cartridge with 24/48 Getein Ferritin test cards
User manual: 1 piece/box
Materials required for Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box
3. Sample diluent composition:
Phosphate buffered saline, protein stabilizer and surfactant.
4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad (the end of pad is coated with fluorescence latex-labelled anti-human Ferritin monoclonal antibody Ⅰ), nitrocellulose membrane (test line is coated with another Ferritin monoclonal antibody Ⅱ and the control line C is coated with goat anti-mouse IgG antibody), absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100/Getein1180 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 at 0~30°C with a valid period of 24 months.
Store the sample diluent at 2~8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples. Heparin, EDTA and sodium citrate*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing.
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 or hemolysis samples.
6. Sample volume (for Getein1100/Getein1180): ***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" calibration when necessary.
4. Enter testing interface of Getein1100.
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 disposable pipet, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
8. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1180:

9. Confirm SD card lot No.in accordance with test kit lot No..Perform "SD card"calibration when necessary.
10. Enter testing interface of Getein1180.
11. Remove the test card form the sealed pouch immediately before use.Label the test card with patient or control identification.
12. Put the test card on a clean table,horizontally placed.
13. Using disposable pipet, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
14. ***Reaction time: 15 minutes***. Insert the test card into Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shoe on the screen and printed automatically.

For Getein1600:

15. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
16. 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" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1180.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1180/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/Getein1180/Getein1600.

Others: Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ratio should be less than 50 times.

EXPECTED VALUE

The expected normal value for ferritin was determined by testing samples from apparently healthy male and women.

Group	Age	N	95% Reference Interval(ng/mL)
Male	20-60	254	30.00-400.00
Female	17-60	205	13.00-150.00

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.50 ~1000.00 ng/mL
Lower Detection Limit	≤0.50 ng/mL
Within-run Precision	≤10%
Between-run Precision	≤15%

LIMITATIONS

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

Interferent	Triglyceride	Bilirubin
Concentration(Max)	20g/L	0.1g/L

REFERENCES

1.Torti F M , Torti S V . Regulation of ferritin genes and protein.[J]. Blood, 2002, 99(10):3505.

2.Theil E C . Ferritin: Structure, Gene Regulation, and Cellular Function in Animals, Plants, and Microorganisms[J]. Annual Review of Biochemistry, 2003, 56(1):289-315.

3.Kell D B , Pretorius E . Serum ferritin is an important inflammatory disease marker, as it is mainly a leakage product from damaged cells[J]. Metallomics,

4.Cho M R , Park J K , Choi W J , et al. Serum ferritin level is po-sitively associated with insulin resistance and metabolic syndro-me in postmenopausal women: A nationwide population-based study[J]. Maturitas, 2017, 103:3.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Ferritin Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016.

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

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

Version: WIF84-S-05

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CE IVD

HbA1c

Fast Test Kit

(Immunofluorescence Assay)

User Manual

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

INTENDED USE

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

SUMMARY

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

PRINCIPLE

The test uses an anti-human Hb monoclonal antibody conjugated with fluorescence latex and an anti-human HbA1c monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human Hb monoclonal antibody binds with the HbA1c and Hb in sample proportionally and forms marked antigen-antibody complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human HbA1c monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of HbA1c in sample.

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

CONTENTS

1. A kit for Getein1100 contains:
   Getein HbA1c test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   A1c diluent 25
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein HbA1c test cards ··· 2
   User manual 1
   Package specifications:
   2×24 tests/kit, 2×48 tests/kit
   Materials required for Getein1600:
   A1c diluent..... 1
   Box with pipette tips 1
   Coated wells 1
3. A1c 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 Hb monoclonal antibody, the test line is coated with an anti-human HbA1c monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30˚C with a valid period of 24 months.
Use the test card for Getein1100 within 1 hour once the foil pouch is opened.
Use the test card for Getein 1600 within 7 days once opened.
Store the sample diluent/whole blood buffer at 0~30˚C with a valid period of 24 months.
Store the sample diluent/whole blood buffer at 2~8˚C for better results.

PRECAUTIONS

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

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

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “QC (SD)” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
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: 5 minutes.* Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

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 RANGE OF VALUE

HbA1c concentration is determined using samples obtained from 345 apparently healthy individuals. The normal value for HbA1c is 3.8%-5.8% .
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2%-14%
Lower Detection Limit	≤2%
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%

Accuracy: verify with comparison experiments, the correlation coefficient r ≥0.990, the relative error ≤20%.

LIMITATIONS

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

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

REFERENCES

1. Cagliero E, Levina E V, Nathan D M. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients[J]. Diabetes care, 1999, 22(11): 1785-1789.
2. Özdamar Ö, Gün i, Keskin U, et al. The role of maternal serumbeta-HbA1c and PAPP-A levels at gestational weeks 10 to 14 in the prediction of pre-eclampsia[J]. 2014.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on HbA1c Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	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 HbA1c Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF22-S-02

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GP

CE IVD

PRL

Fast Test Kit

(Immunofluorescence Assay)

IF1048 for Getein1100
IF5048 for Getein1160
IF3048 for Getein1180
REF IF4048 for Getein1200
IF2048 for Getein1600

User Manual

INTENDED USE

PRL Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of prolactin (PRL) in serum or plasma samples. This test can be used as an aid in the diagnosis of male and female infertility and pituitary dysfunction, monitoring of male and female gonadal disorders and management of amenorrhea and galactorrhea.

SUMMARY

Prolactin is a single chain polypeptide of 199 amino acids and a molecular weight of approximately 23,000 Daltons. It is produced by the anterior pituitary and its secretion is regulated physiologically by inhibitory and releasing factors of the hypothalamus.

The major physiologic action of PRL is the initiation and maintenance of lactation in women. In adults, basal circulating prolactin is present in concentrations up to 30 μg/L. During pregnancy and postpartum lactation, serum prolactin can increase 10 to 20 times. Exercise, stress and sleep also cause transient increases in prolactin levels.

Hyperprolactinemia has been established as a common cause of infertility and gonadal disorders in men and women. Prolactin has been shown to inhibit the secretion of ovarian steroids and to interfere with follicle maturation and the secretion of LH and FSH in the human female.

PRINCIPLE

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

Insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of PRL antigen in the sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. Results can be easily transmitted to a laboratory or hospital information system.

CONTENTS

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

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

1) Getein PRL test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/kit
4) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit

1) Sealed cartridge with 24/48 Getein PRL test cards
2) User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

1) Box with pipette tips: 96 tips/kit
2) Mixing plate: 1 piece/kit

3. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled PRL antibody I, the test line is coated with another PRL antibody II and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100/Getein1160/Getein1180 within one hour once the foil pouch is opened.

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples***. ***Heparin, sodium citrate and EDTA*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should performed within 4 hours after blood collection.
3. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing.
4. Refrigerated or frozen sample should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat inactivated or hemolysis samples.
6. Sample volume: ***(for Getein1100/Getein1160/Getein1180): 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:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample well on the test card.
5. Reaction time: ***15 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android Getein1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180 :

1. Confirm SD card lot No.in accordance with test kit lot No.. Perform "SD card"calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180 .
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver 100 μL of sample into the sample well on the test card.
6. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a

specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein 1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

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

TEST RESULTS

1.Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.
2. Due to different methodologies or antibody specificity, there may be deviations between the test results of different manufacturers, so they can’t be compared directly.

EXPECTED VALUE

The expected reference range for PRL was determined by testing serum samples from apparently 355 healthy adult males and females.

PRL expected range:

Reference Group		N	Median	Range(ng/mL)
Male		146	5.53	2.64-13.13
Female	Premenopausal (< 50 years)	121	8.28	3.34-26.72
	Postmenopausal (> 50 years)	88	6.20	2.74-19.64

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.50 ng/mL~200.00 ng/mL
Lower Detection Limit	≤ 0.50 ng/mL
Within-Run Precision	≤ 10%
Between-Run Precision	≤ 15%

LIMITATIONS

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

Interferent	Hemoglobin	Triglyceride	Bilirubin	Cholesterol
Concentration (Max)	500 mg/dL	1800 mg/dL	10 mg/dL	400 mg/dL

REFERENCES

1. Zhang SY, Li X, Chen XH, et al. Significant associations between prolactin gene polymorphisms and growth traits in the channel catfish (Ictalurus punctatus Rafinesque, 1818) core breeding population. Meta Gene, 2018.
2. Bo-Young Yun, Chunghee Cho, Byung-Nam Cho. Differential activity of 16K rat prolactin in different organic systems [J]. Animal Cells and Systems, 2019, 23 (2).
3. Cacho ND, Butjosa A, Cuadras D, et al. Prolactin levels in Drug-Naïve First Episode nonaffective Psychosis Patients compared with healthy controls. Sex differences [J]. Psychiatry Research, 2019.
4. Mohammad JA, Friedrich P. Prolactin and Prolactin-inducible protein (PIP) in the pathogenesis of primary acquired nasolacrimal duct obstruction (PANDO) [J]. Medical Hypotheses, 2019, 125.
5. Satoshi F, Motoshi K, Kishio T, et al. Orexin A modulates prolactin production by regulating BMP-4 activity in rat pituitary lactotorope cells [J]. Peptides, 2019, 113.
6. Siew H, Papillon G, David J, et al. Elevated Prolactin during Pregnancy Drives a Phenotypic Switch in Mouse Hypothalamic Dopaminergic Neurons [J]. Cell Reports, 2019, 26 (7).

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF55-S-07


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GP

IVD

tPSA
Fast Test Kit
(Immunofluorescence Assay)

IF2053 for Getein1600
IF1053 for Getein1100
IF3053 for Getein1180
REF IF4053 for Getein1200
IF5053 for Getein1160

User Manual

INTENDED USE

tPSA (total Prostate Specific Antigen) Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of tPSA in human serum and plasma samples. It can be used as an aid in the diagnosis and management of patients with prostate cancer.

SUMMARY

Prostate-specific antigen (PSA) is a single-chain glycoprotein with molecular weight of 34 kilodaltons. As a serine prostate with chymotrypsin-like activity, PSA belongs to the kallikrein family. PSA exists as a free or complex form with protease inhibitors such as α-1-antichymotrypsin (ACT) in blood. Total PSA represents the sum of both free and complex forms. Elevated PSA in serum or plasma is found in patients with prostate cancer, benign prostatic hypertrophy, or inflammatory tissues. PSA is uniquely associated with prostate tissues from normal, inflamed or cancerous stages.

PSA has been found in normal, benign hyperplastic, malignant prostatic tissue, metastatic prostatic carcinoma and also in prostatic fluid as well as in seminal fluid. PSA is not found in any other tissues in men, and it is not produced by cancers originating in the lung, colon, rectum, stomach, pancreas or thyroid. PSA measurement is an essential tool in assessing the status of disease in patients with prostate cancer when serial samples are measured over time. The clinical value realized by monitoring tPSA concentration in patients with prostate cancer regardless of the treatment regimen is well known.

PRINCIPLE

The test uses an anti-human PSA monoclonal antibody conjugated with fluorescence latex coated on the junction of nitrocellulose membrane and sample pad and another anti-human PSA monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled antihuman PSA antibody binds with the PSA in sample and forms 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 antihuman PSA antibody. The fluorescence intensity of test line increases in proportion to the amount of tPSA in sample.

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

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein tPSA test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/box
4) SD card: 1 piece/box

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
Sealed cartridge with 24/48 Getein tPSA test cards
User manual: 1 piece/box
Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

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 (the junction of sample pad and nitrocellulose membrane is coated with fluorescence latex-labelled anti-human PSA monoclonal antibody), nitrocellulose membrane (test line is coated with another fluorescence latex-labelled anti-human PSA monoclonal antibody and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

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

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples***. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be performed within 4 hours after whole blood collection.
3. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing.
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 or hemolysis samples.
6. SAMPLE VOLUME ***(for Getein1100/Getein1160/Getein1180): 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" calibration when necessary.
4. Enter testing interface of Getein1100.
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 the sample port on the test card.
8. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:
9. Confirm SD card lot No. in accordance with test kit lot No..Perform "SD card" calibration when necessary.
10. Enter testing interface of Getein1160/Getein1180.
11. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
12. Put the test card on a clean table,horizontally placed.
13. Using sample transfer pipette, deliver ***100 µL*** of sample into the sample port on the test card.
14. ***Reaction time: 15 minutes.*** Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

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

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

TEST RESULTS

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

Others:
Measuring range of the tPSA test kit is 0.50 ng/mL~100.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for tPSA was determined by testing samples from 1000 apparently healthy individuals. The reference range of tPSA is 4.00 ng/mL calculated by using normal distribution methods (95% confidence interval).

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.50~100.00 ng/mL
Lower Detection Limit	≤ 0.50 ng/mL
Within-Run Precision	≤ 10%
Between-Run Precision	≤ 15%

With-run Precision: Test tPSA with same batch for 10 times using tPSA control 1 (3.20~4.80 ng/mL) and tPSA control 2 (24.00~36.00 ng/mL) respectively, then calculate within-run precision which should not greater than 10%.

Between-run Precision: Randomly select 3 consecutive batches of tPSA products, and take 10 strips for each batch to test the quality control (24.00~36.00 ng/mL), calculate between-run precision which should not greater than 15%.

LIMITATIONS

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

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

REFERENCES

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2. Jun Seok Kim, Je-Guk Ryu, Jin Woong Kim, et al. Prostate-Specific Antigen fluctuation: what does it mean in diagnosis of prostate cancer? Br J Cancer. Int Braz J Urol. 2015, 41(2): 258-264.
3. Yasuhide Kitagawa, Mikio Namiki. Prostate-specific antigen-based population screening for prostate cancer: current status in Japan and future perspective in Asia. Asian J Androl. 2015, 17(3): 475-480.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on tPSA Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016.

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

Thank you for purchasing tPSA Fast Test Kit (Immunofluorescence Assay).

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

Version: WIF48-S-07

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CE IVD

PCT Fast Test Kit
(Immunofluorescence Assay)

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

INTENDED USE

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

SUMMARY

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

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

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

PRINCIPLE

PCT Fast Test Kit (Immunofluorescence Assay) is based on the lateral flow immunoassay technology in a sandwich design. Once the sample is applied to the test strip, the fluorescence latex-labelled PCT monoclonal antibody will bind with PCT in sample and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on test line by another PCT monoclonal antibody. Fluorescent signals intensity can be analyzed by applicable device thus the amount of PCT in the sample can be detected quantitatively.

CONTENTS

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

* PCT test card

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

** Sample diluent

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

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.
Use the test card for Getein 1100/Getein 1160/Getein 1180 within one hour once the foil pouch is opened.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum, plasma, whole blood and fingertip blood samples. Heparin, sodium citrate** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. It is recommended to test the sample within 4 hours after collection. Stable in plasma for 5 days when stored at 2~8°C and 6 months when stored at -20°C. Stable in whole blood and fingertip blood for 3 days when stored at 2~8°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

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

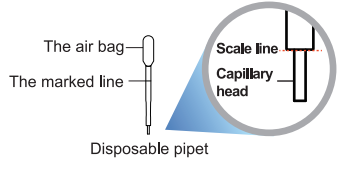
For Getein 1100:

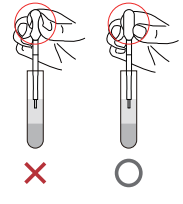
1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before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

For Getein 1160/Getein 1180:

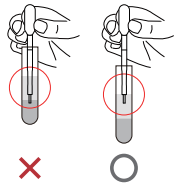
1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before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

For using the disposable pipet:



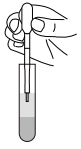


Note1: Do not depress the air bag of the disposable pipet with your finger during sampling.



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

a.

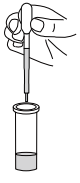


Gently hold the air bag of the disposable pipet and insert the disposable pipet into the sample collection tube until **the scale line** reaches the liquid level. The sample will be sucked into the disposable pipette by capillary action.

b.

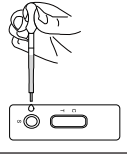
Insert the disposable pipette into the sample diluent. Squeeze the air bag 8 to 10 times to ensure the sample is fully mixed with the sample diluent.

c.



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

d.



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

Notes:

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

TEST RESULTS

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

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

EXPECTED VALUE

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

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

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

PERFORMANCE CHARACTERISTICS

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

LIMITATIONS

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

REFERENCES

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

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF06-SX-01

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