

Cardiac
Markers

Coagulation
Markers

Diabetes
Mellitus

Inflammation

Thyroid
Function

Metabolic
Marker

Renal
Function

Tumor
Markers

Reproduction
/Fertility

Digitally signed by Dolgopol Iulian
Date: 2025.12.24 09:19:35 EET
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

Infectious
Disease



Getein
Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION

MAKING TEST EASY

Getein 1100

Immunofluorescence Quantitative Analyzer



Getein 1100

Immunofluorescence Quantitative Analyzer



HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control



REAL-TIME AND RAPID TEST

One-step test

3-15 min/test

5 sec/test for multiple tests

OPERATION MODES

Inside Mode (Single sample rapid test mode)



Sample Transfer



Test Card Insert



Click "Start" Icon



Result Show and Print

Outside Mode (Mass samples rapid test mode)



Sample Transfer



Timing the Reaction Manually



Click "Start" Icon



Result Show and Print



CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB port

Handwriting input available

Continuous test for 3 hours with optional lithium battery



USER-FRIENDLY INTERFACE

Android system

7-inch touch screen



① 7-inch Touch Screen

② SD Card Recognition Zone

③ Test Card Slot

④ SD Card Slot

⑤ USB Slot

⑥ Built-in Thermal Printer



PORTABLE DESIGN

Small in size: 261*241*115 mm

Light in weight: 2.0 kg



LARGE MEMORY

Up to 10,000 results storage capacity

TECHNICAL PARAMETERS

Methodology

Immunofluorescence

Result

Quantitative

Sample Type

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

Storage Capacity

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*241 mm*115 mm (D*W*H)

Weight

2.0 kg

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION	
Cardiac Markers									
IF1001	cTnI	Myocardial infarction	0.10 ng/mL	S/P/WB	0.10-50.00 ng/mL	100 µL	10 min	NMPA	CE
IF1098	TnT	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	100 µL	15 min	NMPA	CE
IF1089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	NMPA	CE
IF1002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	100 µL	10 min	NMPA	CE
IF1004	NT-proBNP/cTnI	Heart failure/acute myocardial infarction/acute coronary syndrome	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
IF1005	CK-MB/cTnI/Myo	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL Myo: 70.0 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 30.0-600.0 ng/mL	100 µL	10 min	NMPA	CE
IF1012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL	100 µL	10 min	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
IF1016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL H-FABP: 6.36 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 2.00-100.00 ng/mL	100 µL	10 min	NMPA	CE
IF1018	CK-MB	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	100 µL	10 min	NMPA	CE
NEW IF1087	ST2	AMI and chronic heart failure	35.0 ng/mL	S/P/WB	3.0-200.0 ng/mL	100 µL	15 min		CE
Coagulation Marker									
IF1006	D-Dimer	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	100 µL	10 min	NMPA	CE
Inflammation									
IF1003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3.0 mg/L 10.0 mg/L	S/P/WB/ Fingertip blood	0.5-200.0 mg/L	10 µL	3 min	NMPA	CE
IF1007	PCT	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB	0.05-50.00 ng/mL	100 µL	15 min	NMPA	CE
IF1015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.10 ng/mL CRP: 3.0 mg/L	S/P/WB	0.10-50.00 ng/mL 0.5-200.0 mg/L	20 µL	15 min	NMPA	CE
IF1044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	10 µL	5 min	NMPA	CE
IF1090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Peripheral blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA	CE
IF1088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	40 µL	15 min	NMPA	CE
IF1096	hs-CRP	Cardiovascular disease, routine inflammation	Refer to user manual	S/P	0.5-200.0 mg/L	100 µL	3 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
Renal Function									
IF1008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.50-10.00 mg/L	10 µL	3 min	NMPA	CE
IF1009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA	CE
IF1010	NGAL	Acute kidney injury	Serum: 200.0 ng/mL Urine: 100.0 ng/mL	S/Urine	50.0-5000.0 ng/mL	10 µL	10 min	NMPA	CE
IF1011	β ₂ -MG	Acute and chronic kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	10 µL	3 min	NMPA	CE
Diabetes Mellitus									
IF1017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	10 µL	5 min	NGSP IFCC	NMPA CE
Metabolic Marker									
IF1031	25-OH-VD	Osteomalacia, osteoporosis	30.00-50.00 ng/mL	S/P/WB/ Capillary blood	8.00-70.00 ng/mL	20 µL	20 min	NMPA	CE
NEW IF1112	Osteocalcin	Osteoporosis	Male: 14-70 ng/mL Female: 11-48 ng/mL	S/P/WB	1.5-300.0 ng/mL	100 µL	15 min		CE
Thyroid Function									
IF1024	TSH	Thyroid malfunction	0.27-4.20 µIU/mL	S/P	0.10-50.00 µIU/mL	100 µL	15 min	NMPA	CE
IF1022	T3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	100 µL	15 min	NMPA	CE
IF1023	T4	Hyperthyroidism, hypothyroidism	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	100 µL	15 min	NMPA	CE
IF1067	fT3	Hyperthyroidism, hypothyroidism	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	100 µL	15 min	NMPA	CE
IF1068	fT4	Hyperthyroidism, hypothyroidism	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
Reproduction/Fertility								
IF1013	HCG+β	Fertility	5.1 mIU/mL	S/P	5.0-100000.0 mIU/mL	100 μL	10 min	NMPA CE
IF1055	LH	PCOS, infertility evaluation	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF1056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF1066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	100 μL	15 min	NMPA CE
IF1048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.00 ng/mL	100 μL	15 min	NMPA CE
IF1071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	CE
NEW IF1073	Testosterone	Female polycystic ovary syndrome, male testosterone insufficiency	Male: 1.75-7.81 ng/mL Female: 0.10-0.75 ng/mL	S/P	0.10-16.00 ng/mL	100 μL	15 min	CE
NEW IF1138	Estradiol	Ovarian function	Refer to User Manual	S/P	40.0-4800.0 pg/mL	100 μL	15 min	CE
Tumor Markers								
IF1053	tPSA	Prostate cancer	4.00 ng/mL	S/P	0.40-100.00 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, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	NMPA CE
IF1051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	NMPA CE
NEW IF1079	CA125	Ovarian cancer	35.0 U/mL	S/P/WB	2-500.0 U/mL	100 μL	15 min	CE
NEW IF1080	CA19-9	Pancreatic cancer	27.0 U/mL	S/P/WB	2-1000.0 U/mL	100 μL	15 min	CE
NEW IF1081	CA15-3	Breast cancer	26.2 U/mL	S/P/WB	1.5-300.0 U/mL	100 μL	15 min	CE
Infectious Disease								
IF1057	Anti-HCV	Hepatitis C	1.00 S/CO	S/P	1.00-20.00 S/CO	100 μL	15 min	
IF1058	Anti-TP	Syphilis	1.00 S/CO	S/P	1.00-50.00 S/CO	100 μL	15 min	CE
IF1059	Anti-HIV	AIDS	1.00 S/CO	S/P	1.00-1000.00 S/CO	100 μL	15 min	
IF1064	HBsAg	Hepatitis B	1.00 IU/mL	S/P	1.00-100.00 IU/mL	100 μL	15 min	
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	<i>H. pylori</i>	<i>H. pylori</i> 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
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	Rheumatic fever, acute glomerulonephritis, group A streptococcal infection	408.0 IU/mL	S/P/WB	60.0-1370.0 IU/mL	10 μL	10 min	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								
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
IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE
NEW IF1052	PG I/PG II	Atrophic gastritis, stomach cancer	PG I < 70.0 ng/mL PG I/PG II < 3.0 ng/mL	S/P	PG I: 1.0-200.0 ng/mL PG II: 1.0-100.0 ng/mL	100 μL	15 min	CE
IF1110	Cortisol	Adrenal cortex function	Refer to User Manual	S/P	11-1655 nmol/L	100 μL	15 min	CE

Coming soon: VB12, Folate...



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	β 2-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	EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
coordination	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
standards	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)

(name and signature or equivalent marking of authorized person)



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

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

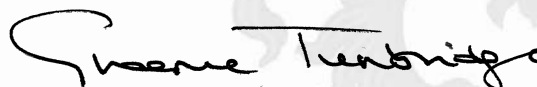
基蛋生物科技股份有限公司
中国
江苏省
南京市
六合区
沿江工业开发区
博富路9号
邮编: 211505

Holds Certificate No: **MD 728432**

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

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 1 of 3



...making excellence a habit.™

Certificate No: **MD 728432**

Registered Scope:

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

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



Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 2 of 3

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

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Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

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

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

A Member of the BSI Group of Companies.

Certificate No: **MD 728432**

Location	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。

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A Member of the BSI Group of Companies.

CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

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

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.





AFP

Fast Test Kit

(Immunofluorescence Assay)

IF1050 for Getein1100
IF5050 for Getein1160
IF3050 for Getein1180
IF2050 for Getein1600
IF4050 for Getein1200

REF

User Manual

INTENDED USE

AFP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of AFP in human serum or plasma samples. This test can be used as an aid in the diagnosis and management of patients with liver cancer or cancer of the ovaries or testicles, and also help to monitor the health of people with cirrhosis or hepatitis.

SUMMARY

Alpha-Fetoprotein (AFP) is a glycoprotein that in human is encoded by the AFP gene with a molecular weight of approximately 70 KD. AFP is made in the liver of a developing baby, which is a major plasma protein produced by the yolk sac and the fetal liver during fetal development. AFP levels are usually high when a baby is born, but fall to very low levels by the age of 1. Healthy adults should have very low levels of AFP. AFP is produced by fetal liver and passes into the amniotic fluid (AF) via fetal urine. A small amount crosses the membranes into the maternal circulation. Excluding fetal blood contamination, elevated AF/AFP levels indicate fetal demise or one of several abnormalities. The AFP elevations in maternal serum and amniotic fluid are valuable diagnostically in the detection of fetal abnormalities, particularly neural-tube defects. Most studies report elevated AFP concentrations in approximately 70% of patients with hepatocellular carcinoma. Elevated AFP concentrations are found in 50% to 70% of patients with nonseminomatous testicular tumors. It is widely recognized as a liver cancer marker as AFP levels can be elevated in the presence of a liver cancer (hepatocellular carcinoma). High levels of AFP can be a sign of liver cancer or cancer of the ovaries or testicles, as well as noncancerous liver diseases such as cirrhosis and hepatitis.

PRINCIPLE

The test uses an anti-human AFP monoclonal antibody I conjugated with fluorescence latex coated on the fluorescent pad and another anti-human AFP monoclonal antibody II coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labeled anti-human AFP antibody I binds with the AFP in sample and forms marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then the marked antigen-antibody complex is captured on the test line by anti-human AFP antibody II. The fluorescence intensity of the test line increases in proportion to the amount of AFP in the 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 AFP 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. 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 AFP test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) Sample diluent
- 4) User manual: 1 piece/box
- 5) SD card: 1 piece/box

2. A kit for Getein1200/Getein1600 contains:

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

Sealed cartridge with 24/48 Getein AFP 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, protein stabilizer and surfactant.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (the end of the membrane is coated with fluorescence latex-labeled anti-human AFP monoclonal antibody I, the test line is coated with another AFP monoclonal antibody II, 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
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 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/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 exposure to air. 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 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 blood collection.
3. If testing is delayed, serum samples may be stored up to 7 days at 2–8°C or stored at -20°C for 3 months before testing.
4. Refrigerated or frozen sample should be reached 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**(**Getein1100/Getein1160/Getein1180**) : **100 μL**

TEST PROCEDURE

1. Collect specimens according to user manual.
 2. Test card, sample and reagent should reach 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 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 click on "Start" icon 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 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 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. Put 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 and the sample 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 AFP test kit is 2.0 ng/mL~500.0 ng/mL. Dilute the sample which concentration is higher than the upper limit with negative diluent, and the recommended dilution ratio is less than 5 times.

EXPECTED VALUE

The expected normal value for AFP was determined by testing samples from 1000 apparently healthy individuals. The reference value of AFP is 7.0 ng/mL calculated by using normal distribution methods giving a level of confidence of approximately 95%. It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2.0~500.0 ng/mL
Lower Detection Limit	≤2.0 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 interferents.

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

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on AFP 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 of consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		

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

Version: WIF54-S-07



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ASO

Fast Test Kit

(Immunofluorescence Assay)

IF1076 for Getein1100
IF5076 for Getein1160
IF3076 for Getein1180
IF4076 for Getein1200
IF2076 for Getein1600

REF

User Manual

INTENDED USE

ASO Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of anti streptolysin "O" antibody (ASO) in serum, plasma or whole blood samples. ASO is a very valuable marker for the diagnosis of group A streptococcal infection, its titer can reflect the severity of infection. Some diseases will lead to a significant increase in ASO titer, such as wind damp heat, acute glomerulonephritis, nodular erythema, scarlet fever, acute tonsillitis.

SUMMARY

Streptolysin "O", a protein with hemolytic activity, is one of the important metabolites of group A Streptococcus. It can dissolve the red blood cells of human and some animals. Streptolysin "O" has strong antigenicity. When human is infected with group A hemolytic streptococcus, B lymphocytes will secrete corresponding antibodies under the stimulation of streptolysin "O", that is, anti streptolysin "O" (ASO). This antibody can neutralize streptolysin "O" and disable its hemolytic ability.

ASO began to rise one week after group A Streptococcus infection, peaked in 4-5 weeks and lasted for several months. As the infection subsides, ASO decreased and returned to normal value within 6 months. The disease condition can be judged by repeated measurements over time. The increase of ASO over time indicates the early stage of infection, decrease indicates the subsiding stage of infection. The lack of decline in ASO titer suggested the possibility of recurrent or chronic infection.

PRINCIPLE

The test kit adopts a double-antigen sandwich method to quantitatively detect the concentration of ASO in human serum, plasma and whole blood samples.

After the sample has been applied to the test card, the fluorescence latex-labelled ASO antigen I binds with ASO in

sample and forms a marked antibody complex. The complex moves to the detection area by capillary action, then it is captured by ASO antigen II coated on the detection area of nitrocellulose membrane, forming a double-antigen complex. The complex generates a fluorescent signal and the intensity increases in proportion to the amount of ASO in sample.

Then 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 ASO 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 ASO 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 Getein1200/Getein1600 contains:

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

- 1) Sealed cartridge with 24/48 Getein ASO test cards
- 2) 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. 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 ASO antigen I, the test line is coated with another ASO antigen II and the control line is coated with polyclonal goat anti streptolysin "O" antibody), absorbent paper and liner.

4. Sample diluent composition:

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer

Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 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/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. 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. **Serum, plasma or whole blood** samples can be used for the test. Other body fluids and samples may not give accurate results. Samples should be free of hemolysis.
2. Venous blood should be collected under aseptic conditions; serum or plasma is preferred for testing.
3. Heparin, sodium citrate or EDTA can be used as the anticoagulant for plasma and whole blood samples.
4. The test should be performed at room temperature within 4 hours after sample collection.
5. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2 ~ 8°C and 6 months at -20°C before testing. Whole blood samples should not be frozen and can be stored at 2 ~ 8°C for 3 days. Do not heat inactivated samples or use hemolyzed blood samples.
6. Refrigerated or frozen sample should be reached to room temperature before testing. Frozen samples must be

completely thawed, rewarmed and evenly mixed. Avoid multiple freeze-thaw cycles.

7. Sample volume (**for Getein1100/Getein1160/Getein1180**): **10 µL**.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature before test.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver **10 µL** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100µL** of sample mixture into the sample port on the test card.
7. **Reaction time: 10 minutes.** Insert the test card into Getein1100 and 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:

8. Confirm SD card lot No. in accordance with test kit lot No..Perform "SD card" calibration when necessary.
9. Enter testing interface of Getein1160/Getein1180.
10. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
11. Put the test card on a clean table, horizontally placed.
12. Using sample transfer pipette, deliver **10 µL** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100µL** of sample mixture into the sample port on the test card.
13. **Reaction time: 10 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:

14. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
15. Put the sample diluent at the correct position of Getein1200/Getein1600.
16. 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 are 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: Samples whose concentration exceeds the upper limit should be diluted no more than 4 times.

EXPECTED VALUE

The expected normal value for ASO is determined by testing samples from 282 apparently healthy individuals. The upper 80th percentile value is 200.0 IU/mL. The upper 95th percentile value is 400.0 IU/mL.

It is recommended that each laboratory determine the applicability of the reference value through experiments and establish its own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	60.0-1370.0 IU/mL
Lower Detection Limit	≤60.0 IU/mL
Within-run Precision	≤10%
Between-run Precision	≤15%

LIMITATIONS

- 1. Bilirubin and triglyceride in the sample may interfere with the test results, and the maximum allowable concentrations are 0.1 mg/mL and 10 mg/mL 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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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

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

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

Version: WIF83-S-03

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CEA

Fast Test Kit

(Immunofluorescence Assay)

IF1051 for Getein 1100
IF5051 for Getein 1160
IF3051 for Getein 1180
IF2051 for Getein 1600
IF4051 for Getein 1200



Instructions for Use

INTENDED USE

CEA Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of carcinoembryonic antigen (CEA) in serum or plasma samples. The test is used clinically as an aid in the diagnosis and management of cancer patients. For professional and laboratory use only. This test can NOT be used to guide the diagnosis of pair trisomy 21.

SUMMARY

CEA is a glycosylated molecule with a molecular weight of approximately 180,000 Daltons. CEA (Carcinoembryonic Antigen) is synthesized by epithelial tissues of the fetal gastrointestinal tract, pancreas, and liver cells. Typically, the levels of CEA increase during the first six months of pregnancy and become very low in the serum after birth. CEA is a non-organ-specific tumor-associated antigen, and tumors that secrete CEA are mostly located in hollow organs such as the gastrointestinal tract, respiratory tract, and urinary tract.

Normally, CEA is metabolized by the gastrointestinal tract, but in the presence of tumors, CEA enters the blood and lymphatic circulation, causing abnormally high serum CEA levels. This results in elevated serum CEA in patients with various types of tumors mentioned above.

Clinically, when CEA exceeds 60 µg/L, it can be seen in colon cancer, rectal cancer, gastric cancer, and lung cancer. Elevated CEA levels indicate the presence of residual or progressive lesions. For patients with lung cancer, breast cancer, bladder cancer, and ovarian cancer, serum CEA levels significantly increase, mostly indicating tumor infiltration, with about 70% being metastatic cancers. Generally, CEA levels return to normal 6 weeks after surgical resection; otherwise, it suggests the presence of residual tumor. If the CEA concentration continuously increases or its value exceeds the normal range

by 5-6 times, it indicates a poor prognosis.

PRINCIPLE

CEA Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After sample has been applied to the test strip, the fluorescence-labelled CEA monoclonal antibody binds with the CEA 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 another CEA monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CEA antigen in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the CEA in sample be detected quantitatively.

APPLICABLE DEVICE

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

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
CEA test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*CEA test card

A test card consists of: Fluorescence-labelled CEA monoclonal antibody, CEA monoclonal antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 1.0 mL contained in each tube consists of:

- Phosphate buffer (20 mmol/L), NaN₃ (<0.1%).

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

- Phosphate buffer (20 mmol/L), NaN₃ (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:

- The 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".
- Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

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

In-use stability:

- For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
- For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch is damaged.
- Do not open pouches until ready to perform the test.
- Do not reuse the test card.
- Do not reuse the pipet.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should follow by local regulations.
- Carefully read and follow the instructions for use to ensure an appropriate test performance.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for serum and plasma samples. Heparin, sodium citrate and EDTA can be used as the anticoagulant for plasma.
- The test should be performed within 4 hours after blood collection.
- 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.

- Refrigerated or frozen sample should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated or hemolysis samples.
- SAMPLE VOLUME (for Getein 1100/Getein 1160/Getein 1180): 100 µL.

TEST PROCEDURE

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

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
- Select the corresponding sample type on the analyzer (refer to the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample port "S" on the test card.
- 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:

- Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- Select the corresponding sample type on the analyzer (refer to the user manual of analyzer for details)
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample port "S" on the test card.
- Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.

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

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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the test card and the sample insertion are correct and complete.

RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 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/Getein 1200/Getein 1600.

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

LIMITATIONS

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

Interferent	Concentration (Max)
Triglyceride	1000 mg/dL
Bilirubin	20 mg/dL

EXPECTED VALUE

The expected normal value for CEA was determined by testing serum samples from 1000 apparently healthy individuals. The 95th percentile of CEA is 4.7 ng/mL.

It is recommended that each laboratory establish its own

expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2.0 ng/mL-500.0 ng/mL
Limit of Detection	≤ 2.0 ng/mL
Within-run Precision	≤ 10%
Between-lot Precision	≤ 15%

REFERENCES

1. Ren W, Benjie X, Mingming S , et al. Dynamic monitoring of serum CEA and CA19-9 predicts the prognosis of postoperative stage II colon cancer. [J]. European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology, 2023, 49 (12): 107138-107138.
2. Huang X, Zheng X ,Li Y , et al. Performance Evaluation of Combined Detection of Serum CEA, CYFRA21-1, CA125, and NSE in Patients with Lung Cancer by Fluorescence Flow Cytometry [J]. Proceedings of Anticancer Research, 2023, 7 (3).
3. Zhi L, Liming L, Yibin D , et al. Genetic susceptibility loci of lung cancer are associated with malignant risk of pulmonary nodules and improve malignancy diagnosis based on CEA levels. [J]. Chinese journal of cancer research = Chung-kuo yen cheng yen chiu, 2023, 35 (5): 501-510.
4. Lin Z, Jia L, Feng L. Serum tumor markers for detection of hepatocellular carcinoma. [J]. World journal of gastroenterology, 2006, 12 (8): 1175-81.
5. Das S, Kaushik S. Cancer antigen 125 (CA 125) and carcinoembryonic antigen (CEA) ratio can identify different stages of ovarian cancer preoperatively [J]. Clinica Chimica Acta, 2019, 493 (Supl.1): S116-S116.

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF49-S-10

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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

- 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
- 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
- Sample diluent/Whole blood buffer composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
- A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with 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°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

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

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

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for *serum, plasma and whole blood samples*. *Heparin and sodium citrate* should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
- Suggest using serum or plasma for better results.
- Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
- If testing will be delayed, serum and plasma samples may

- be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
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.
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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		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

Thank you for purchasing 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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CK-MB/cTnI Fast Test Kit

(Immunofluorescence Assay)

IF1012 for Getein1100
IF5012 for Getein1160
IF3012 for Getein1180
IF4012 for Getein1200
IF2012 for Getein1600

REF

Instructions for Use

INTENDED USE

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

SUMMARY

Creatine kinases are dimer isozymes composed of two monomer subunits, CK-M (for skeletal muscle derived) and CK-B (for brain derived), which can form all three combinations of monomers: CK-BB, CK-MM, and CK-MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM 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.

PRINCIPLE

Mixed monoclonal antibodies against human CK-MB and cTnI were conjugated with fluorescence latex and another set of anti-human CK-MB/cTnI 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 and cTnI monoclonal antibodies will bind with the CK-MB and cTnI 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 or cTnI 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 or cTnI 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 CK-MB and cTnI 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/kit, 10 tests/kit

1) CK-MB/cTnI test card in a sealed pouch with desiccant

2) Disposable pipet

3) User manual: 1 piece/kit

4) SD card: 1 piece/kit

5) Whole blood buffer: 1 bottle/kit

2. A kit for Getein1200/Getein1600 contains:

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

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

2) User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

1) Sample diluent: 1 bottle/kit

2) Box with pipette tips: 96 tips/kit

3) Mixing plate: 1 piece/kit

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 CK-MB and cTnI monoclonal antibodies, these two test lines are coated with another anti-human CK-MB monoclonal antibody and another anti-human cTnI monoclonal antibody, respectively. 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

Getein1160 Immunofluorescence Quantitative Analyzer

Getein1180 Immunofluorescence Quantitative Analyzer

Getein1200 Immunofluorescence Quantitative Analyzer

Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

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

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

PRECAUTIONS

1. For *in vitro* diagnostic use only.

2. Do not use the kit beyond the expiration date.

3. Do not use the test card if the foil pouch or the cartridge is damaged.

4. Do not open pouches or the cartridge until ready to perform the test.

5. Do not reuse the test card.

6. Do not reuse the pipet.

7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.

8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

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

2. Suggest using serum or plasma for better results.

3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.

4. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).

5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

6. Do not use heat-inactivated samples.

7. **SAMPLE VOLUME (for Getein1100/Getein1160/Getein1180): 100 µL**

TEST PROCEDURE

1. Collect specimens according to user manual.

2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.

2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.

3. Put the test card on a clean table, horizontally placed.

4. Using sample transfer pipette, deliver **100 µL** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µL sample on the test card).

5. **Reaction time: 10 minutes.** Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android 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 (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µL sample on the test card).

6.Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For 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, Getein 1200/Getein1600 will do the testing and print the result automatically.

Notes:

- 1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100/Getein1160/Getein 1180.
- 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

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/Getein 1180/Getein1200/Getein1600.

EXPECTED VALUE

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

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

It is recommended that each laboratory establish its own

expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

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

LIMITATIONS

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

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

REFERENCES

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

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF23-S-13

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CK-MB Fast Test Kit (Immunofluorescence Assay)

IF1018 for Getein1100
IF5018 for Getein1160
IF3018 for Getein1180
IF2018 for Getein1600
IF4018 for Getein1200

REF

User Manual

INTENDED USE

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

SUMMARY

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

PRINCIPLE

Monoclonal antibody against human CK-MB were conjugated with fluorescence latex and another set of anti-human CK-MB monoclonal antibodies were coated on test line. After the sample has been applied to the test strip, the latex-labeled anti-human CK-MB monoclonal antibody will bind with the CK-MB in sample and form marked antigen-antibody complex. This complex move to the test card detection zone by capillary action. Then marked antigen-antibody complex will be captured on test line by another set of monoclonal antibody against human CK-MB resulting in purplish red streaks appear on the test line. The color intensity of test line increases in proportion to the amount of CK-MB in sample.

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 concentrations of CK-MB in sample will be determined 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 LIS and HIS.

CONTENTS

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

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

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

2. A kit for Getein1200/Getein1600 contains:

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

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

Materials required for Getein1200/Getein1600:

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

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 CK-MB monoclonal antibody, the test line is coated with another anti-human CK-MB 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
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

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

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

PRECAUTIONS

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

TEST PROCEDURE

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

For Getein1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver **100 µL** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading **100 µL** sample on the test card).
5. **Reaction time: 10 minutes.** Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

1. Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
- 3.Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- 4.Put the test card on a clean table,horizontally placed.
- 5.Using sample transfer pipette, deliver **100 µL** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading **100 µL** sample on the test card).
- 6.Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

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

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180.
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

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.

EXPECTED VALUE

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

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

PERFORMANCE CHARACTERISTICS

Measuring Range	2.50~80.00 ng/ml
Lower Detection Limit	≤ 2.50 ng/ml
Within-Run Precision (n=10)	≤ 10%
Between-Run Precision	≤ 15%

LIMITATIONS

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

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

REFERENCES

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

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

DESCRIPTION OF SYMBOLS USED

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

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

Thank you for purchasing CK-MB Fast Test Kit (Immunofluorescence Assay).

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

Version: WIF28-S-11

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Cardiac Troponin I

Fast Test Kit

(Immunofluorescence Assay)

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

User Manual

INTENDED USE

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

SUMMARY

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

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

The current guideline of The Joint European Society of Cardiology/ American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current

guidelines recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

PRINCIPLE

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

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

CONTENTS

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:
 - 2x24 tests/kit, 2x48 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°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

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

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

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

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

TEST PROCEDURE

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

For Getein1100:

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

For Getein1600:

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

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

The expected normal value for Troponin I was determined by testing samples from 500 apparently healthy individuals. The 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

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

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

REFERENCES

- Mauro Pantaghini. Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
- Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice

Guidelines (Committee to Revise the 1999 Guidelines for the Management 2004).

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

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF02-S-02



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D-Dimer Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1006

Getein1600: Cat.# IF2006

User Manual

INTENDED USE

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

SUMMARY

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

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

PRINCIPLE

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

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

CONTENTS

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

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

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

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

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

5. Do not use heat-inactivated samples.
6. **SAMPLE VOLUME (for Getein1100): 100 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, Kil-Drori AJ, Chap-Marshak D, Brenner B, Drugan A. Activation of coagulation in amniotic fluid during normal human pregnancy. *Thromb Res.* 2011 Apr 18.
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4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF05-S-02



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Ferritin Fast Test Kit

(Immunofluorescence Assay)

User Manual



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 Fe³⁺ 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: 2x24 tests/box, 2x48 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 on-

ce 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 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. 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 μ L** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100 μ L** of sample mixture into the sample port on the test card.
8. **Reaction time: 15 minutes.** Insert the test card into Getein-1100 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 μ L** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100 μ L** of sample mixture into the sample port on the test card.
14. **Reaction time: 15 minutes.** Insert the test card into Getein-1180 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	$\leq$ 0.50 ng/mL
Within-run Precision	$\leq$ 10%
Between-run Precision	$\leq$ 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

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- 4.Cho M R , Park J K , Choi W J , et al. Serum ferritin level is positively associated with insulin resistance and metabolic syndrome 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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community
	CE mark		Do not use if package is damaged
	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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fPSA Fast Test Kit (Immunofluorescence Assay)

IF1072 for Getein 1100
IF5072 for Getein 1160
IF3072 for Getein 1180
IF2072 for Getein 1600
IF4072 for Getein 1200



Instructions for Use

INTENDED USE

fPSA Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of free PSA in human serum and plasma samples. It is mainly used for dynamic monitoring of patients with malignant tumors to assist in judging the disease process or treatment effect. It cannot be used as a basis for early diagnosis of malignant tumors, and is not suitable for tumor screening in the general population.

This assay is intended to be used in conjunction with the Getein total PSA test as an aid in distinguishing prostate cancer from benign prostatic conditions in men age 50 years or older who have a digital rectal examination (DRE) that is not suspicious for prostate cancer and the Getein total PSA value between 4 ng/mL and 10 ng/mL.

SUMMARY

Prostate-specific antigen (PSA) is a single-chain glycoprotein with molecular weight of 34 kilodaltons. As a serine protease 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-anti-chymotrypsin (ACT) in blood. PSA is produced mainly by the glandular epithelium of the prostate and is secreted into the seminal fluid in high concentrations. Low levels of PSA are found in the blood as a result of leakage of PSA from the prostate gland. The function of PSA is the proteolytic cleavage of gel forming proteins in the seminal fluid resulting in liquefaction of the seminal gel and increased sperm mobility.

PSA tests lack sufficient sensitivity and specificity to be considered ideal or absolutely diagnostic for screening or early detection because PSA is not specific for prostate cancer. PSA is organ specific, but has long been known to

be elevated in non-malignant conditions such as benign prostatic hyperplasia (BPH). A number of studies have found that the percent of free PSA was significantly lower in patients having prostate cancer than those with benign disease or normal controls. The ratio fPSA/tPSA has subsequently been demonstrated to improve the sensitivity and specificity in patients with tPSA values in the "gray zone" of 4-10 ng/mL.

An equimolar tPSA determination is the prerequisite for reliable ratios. In patients receiving therapy, particularly hormone withdrawal therapy, the fPSA/tPSA ratio cannot be utilized to differentiate prostate hyperplasia from cancer of the prostate. Combining tests from different manufacturers to determine tPSA and fPSA can produce erroneous values, since total PSA tests may be standardized by differing methods or detect free PSA to differing degrees.

PRINCIPLE

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

Then insert test card into Getein 1100/Getein 1160/Getein 1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein 1200/Getein 1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein 1100, Getein 1160, Getein 1180, Getein 1200 and Getein 1600), the concentration of fPSA in sample will be measured and displayed on the screen. The value will be stored in Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit

- 1) Getein fPSA test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) Sample diluent
- 4) Instructions for use: 1 piece/kit
- 5) SD card: 1 piece/kit

2. A kit for Getein 1200/Getein 1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein fPSA test cards
Instructions for use: 1 piece/kit

Materials required for Getein 1200/Getein 1600:

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

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 junction of sample pad and nitrocellulose membrane is coated with fluorescence latex-labeled anti-human fPSA monoclonal antibody I), nitrocellulose membrane (the test line is coated with another anti-human fPSA monoclonal antibody II and the control line is coated with goat anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 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 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional 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 instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum and plasma samples**, other bodily fluids may cause incorrect or inaccurate results.
2. **Heparin, sodium citrate and EDTA** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
3. The test should be performed within 4 hours after blood collection. 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 or hemolysis samples.
6. **SAMPLE VOLUME (for Getein 1100/Getein 1160/Getein 1180): 100 μ L**

TEST PROCEDURE

1. Collect specimens according to instructions for use.
2. Test card, sample and reagent should reach to room temperature before test.

For Getein 1100:

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 μ L** of sample

into one tube of sample diluent, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.

5. **Reaction time: 10 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 Getein 1160/Getein 1180:

1. Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
2. Enter testing interface of Getein 1160/Getein 1180.
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 one tube of sample diluent, mix gently and 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 (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1200/Getein 1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position of Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein 1100/Getein

1160/Getein 1180/Getein 1200/Getein 1600.
Others: Measuring range of the fPSA test kit is 0.03-30.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ration should be less than 4 times.

EXPECTED VALUE

The expected normal value for free PSA was determined by testing samples from 250 apparently healthy individuals. The reference range of free PSA is 1.00 ng/mL calculated by using normal distribution methods (95th percentile). It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.03-30.00 ng/mL
Lower Detection Limit	≤ 0.03 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 interferent.

Interferent	Triglyceride	Bilirubin
Concentration (Max)	25 g/L	0.6 g/L

REFERENCES

1. Chen R, Huang Y, Cai X, et al. Age-Specific Cutoff Value for the Application of Percent Free Prostate-Specific Antigen (PSA) in Chinese Men with Serum PSA Levels of 4.0-10.0 ng/ml. PLoS One. 2015, 10 (6): e0130308.
2. Ezenwa EV, Tijani KH, Jeje EA, et al. The value of percentage free prostate specific antigen (PSA) in the detection of prostate cancer among patients with intermediate levels of total PSA (4.0–10.0 ng/mL) in Nigeria. Arab J Urol. 2012, 10(4): 394-400.

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DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF74-S-07



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FSH

Fast Test Kit

(Immunofluorescence Assay)

IF1056 for Getein 1100
IF5056 for Getein 1160
IF3056 for Getein 1180
IF2056 for Getein 1600
IF4056 for Getein 1200

Instructions for Use



INTENDED USE

FSH Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of FSH in human serum and plasma. The test is used as an auxiliary diagnosis for evaluating pituitary endocrine function and ovarian diseases. For professional and laboratory use only.

SUMMARY

Follicle stimulating hormone (FSH) is one of the hormones essential to pubertal development and the function of women's ovaries and men's testes. Like other glycoproteins, such as LH, TSH and HCG, FSH consists of subunits designated as alpha and beta. Hormones of this type have alpha subunits that are very similarly structural, therefore the biological and immunological properties of each are dependent on the unique beta subunit.

In women, this hormone stimulates the growth of ovarian follicles in the ovary before the release of an egg from one follicle at ovulation. FSH levels are elevated after menopause, castration and in premature ovarian failure. In men, FSH stimulates seminiferous tubule testicular growth, and is involved in the early stages of spermatogenesis. Oligospermic males usually have elevated FSH levels. High levels of FSH in men may be found in primary testicular failure and Klinefelter syndrome. Elevated concentrations are also present in cases of starvation, renal failure, hyperthyroidism and cirrhosis.

FSH is a useful marker in the study of pituitary diseases, classification of pituitary tumors, and the differential diagnosis of primary and metastatic tumors of the pituitary.

PRINCIPLE

FSH Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay designed in a sandwich format. After the sample is applied to the test strip, the fluorescence-labelled FSH monoclonal antibody binds with the FSH in the sample to form a marked antigen-antibody complex. This complex moves to the detection zone on the test card by capillary action and is captured by another FSH monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of FSH in the sample. The fluorescent signal intensity can then be analyzed by an appropriate device to quantitatively detect the FSH in the sample.

APPLICABLE DEVICE

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

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
FSH test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* FSH test card

A test card mainly consists of: Fluorescence-labelled FSH monoclonal antibody, FSH monoclonal antibody.

Consumables for Getein 1200/ Getein 1600

- Box with pipette tips (96 tips/box)

- Mixing plate (1 piece/box)

Note:

- 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".
- Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Real-time stability:

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

In-use stability:

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

-For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

- 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.
- The test should be performed within 4 hours after blood collection.
- 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 3 months before testing.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze thaw cycles.
- Do not use heat-inactivated samples or hemolysis samples.
- Sample volume (**Getein 1100/Getein 1160/Getein 1180**): 100 µL.

TEST PROCEDURE

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

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

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

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- Put the consumables at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do

the testing and print the result automatically.

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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the insertion of test card and the sample are correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 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/Getein 1200/Getein 1600.

LIMITATIONS

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

Interferent	Concentration (Max)
Triglyceride	20.32 mmol/L
Bilirubin	171.0 umol/L
Hemoglobin	300mg/dL
Human serum albumin	3 g/dL

EXPECTED VALUE

The expected normal value for FSH was determined by testing blood samples from apparently healthy individuals. Reference range of FSH:

Group	No.		Reference Range (mIU/mL)
Male	220		1.22-19.25
Female	Mid-follicle	217	3.82-8.74
	Mid-cycle peak	195	4.59-22.59
	Mid-luteal phase	202	1.76-5.14
	Postmenopausal	197	16.01-114.08

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.20~150.00 mIU/mL
Limit of Detection	≤0.20 mIU/mL
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

REFERENCES

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2. Passing H, Bablok W, et al. A General regression procedure for method transformation [J]. J Clin Chem Clin Biochem, 1988, 26: 783-790.
3. Souvik SS, Amandeep V, Subeer M. Regulation of Hippo pathway components by FSH in testis [J]. Reproductive Biology, 2019.
4. Mia VG, Julia R, et al. Persistent organic pollutants as predictors of increased FSH: LH ratio in naturally cycling, reproductive age women [J]. Environmental Research 2018,164.
5. Piketty V, Kara E et al. Follide-stimulating hormone (FSH) activates extracellular signal-regulated kinase phosphorylation independently of beta-arrestin- and dynamin-mediated FSH receptor internalization [J]. Reproductive Biology and Endocrinology 2006, 4(1).

DESCRIPTION OF SYMBOLS USED

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

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

Thank you for using FSH Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

Version: WIF52-S-09

 Getein Biotech, Inc.
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Tel: +86-25-68568508
Fax: +86-25-68568500
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Website: www.getein.com

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



ft3

Fast Test Kit

(Immunofluorescence Assay)

IF1067 for Getein 1100
IF5067 for Getein 1160
IF1607 for Getein 1180
IF2067 for Getein 1600
IF4067 for Getein 1200



Instruction for Use

INTENDED USE

ft3 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of free triiodothyronine (ft3) in human serum, plasma and whole blood. It is used as an aid in clinical routine diagnostics for the assessment of the thyroid status.

SUMMARY

Triiodothyronine (T3) is a thyroid hormone. It plays an important role in the body's control of metabolism. T3 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T3 (ft3) is the unbound and biologically active form, which represents only 0.2-0.4% of the total T3. The remaining T3 is inactive and bound to serum proteins, while the distribution of T3 between these binding proteins (thyroxine binding globulin, pre-albumin, albumin) is controversially discussed. The detection of ft3 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins. Therefore, ft3 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status. Free T3 measurements support the differential diagnosis of thyroid disorders, are needed to distinguish different forms of hyperthyroidism, and to identify patients with T3 thyrotoxicosis.

PRINCIPLE

The test kit is based on immunofluorescence competitive method to quantitatively detect the content of ft3 in human serum, plasma or whole blood. The test uses an T3 monoclonal antibody conjugated with fluorescence and T3-BSA coated on the test line. After the sample has been applied to the test strip, the analyte

competes with T3-BSA coated on the test line to bind to fluorescent labeled T3 monoclonal antibody and forms different antigen-antibody complexes respectively. The fluorescence intensity of test line has relationship with the amount of free T3 in sample.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:

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

- 1) Getein ft3 test card in a sealed pouch with desiccant
- 2) Disposable pipette
- 3) Reaction tube
- 4) Sample diluent 5
- 5) Instruction for use: 1 piece/kit
- 6) SD card: 1 piece/kit

2. A kit for Getein 1200/Getein 1600 contains:

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

Sealed cartridge with 24/48 Getein ft3 test cards

Instruction for use: 1 piece/kit

Materials required for Getein 1200/Getein 1600:

- 1) Sample diluent 5: 1 bottle/kit
- 2) Box with pipette tips: 96 tips/kit
- 3) 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, fluorescent labeled T3 monoclonal antibody, T3-BSA, polyclonal IgG antibody, absorbent paper and liner.

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

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1200 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 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to

air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not reuse the test card.
6. Do not reuse the disposable pipette.
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 instruction for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum, plasma and whole blood samples**. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum and plasma samples for better results.
3. The test should be performed within 4 hours after whole blood collection.
4. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freezethaw cycles.
6. Do not use heat-inactivated samples or hemolysis samples.
7. **SAMPLE VOLUME (Getein 1100/Getein 1160/Getein 1180): 100 μ L.**

TEST PROCEDURE

1. Collect specimens according to instruction for use.
2. Test card, sample and reagent 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. Enter testing interface of Getein 1100.
3. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
4. Using a pipette or disposable pipette, add **100 μ L** sample to a reaction tube then **100 μ L** sample diluent 5 to the same reaction tube, mix gently and thoroughly and wait for **5-10 minutes**. Using a pipette or the same disposable pipette, deliver **100 μ L** of the mixture into the sample well on the test card.

Note:

- ① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, **make sure the liquid level is flush with the black scale line**, otherwise the sample volume will be inaccurate.
- ② It is recommended to wait **5-10 minutes** after mixing the samples, otherwise the test result will be inaccurate.
5. **Reaction time: 15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. 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. Enter testing interface of Getein 1160/Getein 1180.
3. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
- 5.Using a pipette or disposable pipette, add **100 μ L** sample to a reaction tube then **100 μ L** sample diluent 5 to the same reaction tube, mix gently and thoroughly and wait for **5-10 minutes**. Using a pipette or the same disposable pipette, deliver **100 μ L** of the mixture into the sample well on the test card.

Note:

- ① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, **make sure the liquid level is flush with the black scale line**, otherwise the sample volume will be inaccurate.
- ② It is recommended to wait **5-10 minutes** after mixing the samples, otherwise the test result will be inaccurate.
5. Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automati-

cally test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1200/Getein 1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent 5 at the correct position in Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instruction for use of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

Others: Measuring range of the test kit is 0.60 pmol/L~50.00 pmol/L.

EXPECTED VALUE

The expected normal value for fT3 and was determined by testing samples from 254 apparently healthy individuals. The reference range of fT3 is 3.10 pmol/L~6.80 pmol/L 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	0.60 pmol/L~50.00 pmol/L
Low of Detection	≤ 0.60 pmol/L
Within-run Precision	≤ 15%
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 interferent.

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

REFERENCES

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4. Klee GG. Clinical usage recommendations and analytic performance goals for total and free triiodothyronine measurements. *Clin Chem*. 1996, 42(1):155-159.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

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

Thank you for purchasing fT3 Fast Test Kit (Immunofluorescence Assay).

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

Version: WIF71-S-10



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ft4

Fast Test Kit

(Immunofluorescence Assay)

IF1068 for Getein 1100
IF5068 for Getein 1160
IF3068 for Getein 1180
IF2068 for Getein 1600
IF4068 for Getein 1200

REF

Instructions for Use

INTENDED USE

ft4 Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of free T4 in human serum, plasma and whole blood samples. This test can be used as an aid in the assessment of thyroid status.

SUMMARY

Thyroxine (T4) is the main thyroid hormone secreted into the bloodstream by the thyroid gland. Together with triiodothyronine (T3), it plays a vital role in regulating the body's metabolic rate, influences the cardiovascular system, growth and bone metabolism, and is important for normal development of gonadal functions and nervous system.

T4 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T4 (ft4) is the unbound and biologically active form, which represents only 0.03 % of the total T4. The remaining T4 is inactive and bound to serum proteins such as thyroxine binding globulin (TBG, 75%), pre-albumin (15%), and albumin (10%). The determination of free T4 has the advantage of being independent of changes in the concentrations and binding properties of these binding proteins; additional determination of a binding parameter (T uptake, TBG) is therefore unnecessary. Therefore, free T4 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status. It should be measured together with TSH if thyroid disorders are suspected and is also suitable for monitoring thyrostatic therapy.

PRINCIPLE

The test kit is based on immunofluorescence competitive method to quantitatively detect the content of T4 in human serum, plasma or whole blood.

The test uses a T4 monoclonal antibody conjugated with fluorescence and T4-BSA coated on the test line. After the sample has been applied to the test strip, the analyte competes with T4-BSA coated on the test line to bind to fluorescent labeled T4 monoclonal antibody and forms different antigen-antibody complexes respectively. The fluorescence intensity of test line has relationship with the amount of free T4 in sample.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:

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

- 1) Getein ft4 test card in a sealed pouch with desiccant
- 2) Disposable pipette
- 3) Reaction tube
- 4) Sample diluent
- 5) Instruction for use: 1 piece/kit
- 6) SD card: 1 piece/kit

2. A kit for Getein 1200/Getein 1600 contains:

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

Sealed cartridge with 24/48 Getein ft4 test cards

Instruction for use: 1 piece/kit

Materials required for Getein 1200/Getein 1600:

- 1) Sample diluent: 1 bottle/kit
- 2) Box with pipette tips: 96 tips/kit
- 3) 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, fluorescent labeled T4 monoclonal antibody, T4-BSA, polyclonal IgG antibody, absorbent paper and liner.

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

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer

Getein 1180 Immunofluorescence Quantitative Analyzer

Getein 1600 Immunofluorescence Quantitative Analyzer

Getein 1160 Immunofluorescence Quantitative Analyzer

Getein 1200 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 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: If the cartridge is

opened, it should be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional 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 pipette.
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 instruction for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

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

TEST PROCEDURE

1. Collect specimens according to instruction for use.
2. Test card, sample and reagent should be reached to room

temperature before test.

For Getein 1100:

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. Put the test card on a clean table, horizontally placed.
3. Using a pipette or disposable pipette, add **100 µL** sample to a reaction tube then **100 µL** sample diluent to the same reaction tube, mix gently and thoroughly and wait for **2-5 minutes**. Using a pipette or the same disposable pipette, deliver **100 µL** of the mixture into the sample well on the test card.

Note:

- ① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, **make sure the liquid level is flush with the black scale line**, otherwise the sample volume will be inaccurate.
- ② It is recommended to wait **2-5 minutes** after mixing the samples, otherwise the test result will be inaccurate.
4. Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. 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. Enter testing interface of Getein 1160/Getein 1180.
3. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
4. Using a pipette or disposable pipette, add **100 µL** sample to a reaction tube then **100 µL** sample diluent to the same reaction tube, mix gently and thoroughly and wait for **2-5 minutes**. Using a pipette or the same disposable pipette, deliver **100 µL** of the mixture into the sample well on the test card.

Note:

- ① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, **make sure the liquid level is flush with the black scale line**, otherwise the sample volume will be inaccurate.
- ② It is recommended to wait **2-5 minutes** after mixing the samples, otherwise the test result will be inaccurate.
5. Insert the test card into Getein 1160/Getein 1180 immediately

after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1200/Getein 1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position of Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instruction for use of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

Others: Measuring range of the fT4 test kit is 0.30-100.00 pmol/L.

EXPECTED VALUE

The expected normal value for fT4 was determined by testing samples from 261 apparently healthy individuals. The reference range of fT4 is 12.00-22.00 pmol/L calculated by using normal distribution methods (99% confidence interval). It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.30-100.00 pmol/L
Lower Detection Limit	≤0.30 pmol/L
Within-Run Precision	≤15%

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 interferent.

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

REFERENCES

1. Kronenberg HM, Melmed S, Polonsky KS, et al. Williams Textbook of Endocrinology. Saunders Elsevier, Philadelphia, 12th edition, 2011, chapter 10, p. 301-311.
2. DeGroot LJ, Larsen PR, Hennemann G. Transport of Thyroid Hormone and Cell Uptake. The Thyroid and Its Diseases. Wiley and Sons, New York, 1984:62-65.
3. Wu AHB. Tietz Clinical Guide to Laboratory Tests. Saunders Elsevier, Philadelphia, 4th edition, 2006.
4. Brent GA. Thyroid Function Testing. Springer, Berlin, 1st edition, 2010.
5. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; January 2007.
6. World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.
7. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline-Third Edition. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

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

Thank you for purchasing fT4 Fast Test Kit (Immunofluorescence Assay).

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

Version: WIF72-S-11

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HbA1c Fast Test Kit

(Immunofluorescence Assay)

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

User Manual

INTENDED USE

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

SUMMARY

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

PRINCIPLE

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

antigen-antibody complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human HbA1c monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of HbA1c in sample. Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of HbA1c in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

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 serum beta-HbA1c and PAPP-A levels at gestational weeks 10 to 14 in the prediction of pre-eclampsia[J]. 2014.

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF22-S-02

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hs-CRP Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1003

Getein1600: Cat.# IF2003

User Manual

INTENDED USE

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

SUMMARY

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

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

(>200 mg/L).

PRINCIPLE

The test uses an anti-human hs-CRP monoclonal antibody conjugated with fluorescence latex and another anti-human hs-CRP monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human hs-CRP monoclonal antibody binds with the hs-CRP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human hs-CRP monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of hs-CRP in sample. Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of hs-CRP in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:

Getein hs-CRP test card in a sealed pouch with desiccant	25
Disposable pipet	25
Sample diluent	25
SD card	1
User manual	1

2. A kit for Getein1600 contains:

Sealed cartridge with 24/48 Getein hs-CRP test cards ..	2
User manual	1
<u>Package specifications:</u>	
2×24 tests/kit, 2×48 tests/kit	
<u>Materials required for Getein1600:</u>	
Sample diluent	1
Box with pipette tips	1
Mixing plate	1

3. Sample diluent composition:

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

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human hs-CRP monoclonal antibody, the test line is coated

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

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

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

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

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

TEST PROCEDURE

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

For Getein1600:

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

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

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

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

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

PERFORMANCE CHARACTERISTICS

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

Method Comparison:

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

LIMITATIONS

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

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

REFERENCES

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

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

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

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF04-S-02

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Total IgE Fast Test Kit (Immunofluorescence Assay)

IF1069 for Getein1100
IF5069 for Getein1160
IF3069 for Getein1180
IF4069 for Getein1200
IF2069 for Getein1600

REF

User Manual

INTENDED USE

Total IgE Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of circulating total IgE antibodies in human serum, plasma and whole blood samples. This test can be used as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings.

SUMMARY

IgE is an immunoglobulin with a molecular weight of approximately 190,000 daltons. Produced by plasma cells, IgE has a significant role in atopic diseases such as allergic rhinitis, allergic asthma, and atopic dermatitis. IgE has a high affinity for receptors on mast cells and basophils, mediating the binding of allergens to these cells. The subsequent release of vasoactive amines, such as histamine, produce the clinical manifestations associated with atopic disease. Measurement of IgE serum levels can be important in the diagnosis and treatment of these disorders.

In most nonatopic patients, IgE serum levels are relatively low. However, certain parasitic or helminth infections have been associated with elevated IgE levels due to IgE sensitization of macrophages, eosinophils, and other inflammatory cells. The IgE concentration in a patient is dependent on both the extent of the allergic reaction and the number of different allergens to which the patient is sensitized. Nonallergic normal individuals have IgE concentrations that vary widely and increase steadily during childhood, reaching their highest levels at age 15 to

20, and thereafter remaining constant until about age 60 when they slowly decline.

PRINCIPLE

The test uses an anti-human IgE monoclonal antibody I conjugated with fluorescence latex coated on the sample pad, and another anti-human IgE monoclonal antibody II coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human IgE monoclonal antibody I binds with IgE in sample and forms a marked antigen-antibody complex. This complex moves to the test detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human IgE monoclonal antibody II. The fluorescence intensity of test line increases in proportion to the amount of IgE concentration 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 IgE 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/kit, 10 tests/kit

- 1) Getein Total IgE test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) Sample diluent
- 4) User manual: 1 piece/kit
- 5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein Total IgE test cards

User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

- 1) Sample diluent: 1 bottle/kit
- 2) Box with pipette tips: 96 tips/kit
- 3) Mixing plate: 1 piece/kit
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 (coated with fluorescence latex-labeled anti-human IgE monoclonal antibody I), nitrocellulose membrane (the test line is coated with another anti-human IgE monoclonal antibody II, and the control line 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
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

Use the test card for Getein1100/Getein1160/Getein1180 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 exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional 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, sodium citrate and EDTA can be used as the anti-coagulant for plasma. Samples should be free of hemolysis.
2. Suggest using serum and plasma for better results. The test should be performed within 4 hours after blood collection.
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 (whole blood samples may be stored up to 3 days at 2~8°C).
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 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 reach to room temperature before test.

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

4. Using sample transfer pipette, deliver **100 µL** of sample into one tube of sample diluent and mix thoroughly. Then drop **100 µL** of sample mixture into sample well on the test card.

5. **Reaction time: 15 minutes.** Insert the test card into Getein1100 and click on “Start” icon 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 one tube of sample diluent and mix thoroughly. Then drop **100 µL** of sample mixture into 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 printed automatically.

For Getein1200/Getein1600:

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

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits.
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

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 Total IgE test kit is 1.00-2000.00 IU/mL. Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ratio should be less than 3 times.

EXPECTED VALUE

The expected normal value for total IgE was determined by testing samples from 240 apparently healthy individuals. The reference range of total IgE is 1.00 IU/mL~165.00 IU/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	1.00-2000.00 IU/mL
Lower Detection Limit	≤1.00 IU/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 interferent.

Interferent	Hemoglobin	Triglyceride
Concentration (Max)	50 g/L	0.2 g/L

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Total

IgE Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

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

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

Version: WIF94-S-10

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LH

Fast Test Kit

(Immunofluorescence Assay)

IF1055 for Getein 1100
IF5055 for Getein 1160
IF3055 for Getein 1180
IF2055 for Getein 1600
IF4055 for Getein 1200



Instructions for Use

INTENDED USE

LH Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of LH in human serum and plasma. This test is used to determine menopause, pinpoint ovulation and monitor endocrine therapy. For professional and laboratory use only.

SUMMARY

Luteinizing hormone (LH) is produced in both men and women from the anterior pituitary gland in response to luteinizing hormone-releasing hormone (LH-RH or Gn-RH), which is released by the hypothalamus.

LH is a glycoprotein hormone having two subunits. The alpha subunit is similar to FSH, HCG and TSH. The beta subunit is different from those of the other glycoprotein hormones and confers its biochemical specificity.

In males, LH is also called interstitial cell-stimulating hormone (ICSH). In both males and females, LH secretion is regulated by a balance of positive and negative feedback mechanisms involving the hypothalamic-pituitary axis, the reproductive organs and the pituitary and sex steroid hormones. LH and the other pituitary gonadotropin, FSH, play a critical role in maintaining the normal function of the male and female reproductive systems.

Patients suffering from hypogonadism show increased concentration of serum LH. A decrease in steroid hormone production in females is a result of immature ovaries, primary ovarian failure, polycystic ovary disease or menopause. In these cases, LH secretion is not regulated. A similar loss of regulatory hormones occurs in males when the testes develop abnormally or anorchia exists. Increased concentrations of LH may be found in primary

hypothalamic failure, Klinefelter syndrome, renal failure, cirrhosis, hyperthyroidism and severe starvation. LH is a useful marker in determining the homeostasis fertility regulation via the hypothalamic-pituitary-gonadal axis.

PRINCIPLE

LH Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay designed in a sandwich format. After the sample is applied to the test strip, the fluorescence-labelled LH monoclonal antibody binds with the LH in the sample to form a marked antigen-antibody complex. This complex moves to the detection zone on the test card by capillary action and is captured by another LH monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of LH in the sample. The fluorescent signal intensity can then be analyzed by an appropriate device to quantitatively detect the LH in the sample.

APPLICABLE DEVICE

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

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
LH test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* LH test card

A test card mainly consists of: Fluorescence-labelled LH monoclonal antibody, LH monoclonal antibody. Consumables for Getein 1200/ Getein 1600 - Box with pipette tips (96 tips/box)

- Mixing plate (1 piece/box)

Note:

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

STORAGE AND STABILITY

Realtime stability:

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

In-use stability:

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

-For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and re-seal along the entire edge of zip-seal if not used up.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum and plasma samples**.
2. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma samples.
3. It is recommended to test the sample within 4 hours after collection. If testing is delayed, serum and plasma samples are stable for 7 days when stored at 2~8°C and

6 months when stored at -20°C.

4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. Sample volume (**Getein 1100/Getein 1160/Getein 1180**): 100 µL.

TEST PROCEDURE

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

For Getein 1100:

- 1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "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 before use and put the test card on a clean table, horizontally placed.
- 4) Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- 5) Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- 1) Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- 3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- 4) Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- 5) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (15 minutes) and automat-

ically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:

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

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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the insertion of test card and the sample are correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 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/Getein 1200/Getein 1600.

LIMITATIONS

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

Interferent	Concentration (Max)
Triglyceride	20.32 mmol/L
Bilirubin	171.0 umol/L
Hemoglobin	300 mg/dL
Human serum albumin	3 g/dL

EXPECTED VALUE

The expected normal value for LH was determined by testing blood samples from apparently healthy individuals. Reference range of LH:

Group	No.		Reference Range (mIU/mL)
Male	221		1.21-8.69
Female	Mid-follicle	210	2.03-11.21
	Mid-cycle peak	188	19.41-103.58
	Mid-luteal phase	211	1.28-12.82
	Postmenopausal	195	11.01-58.99

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.20~150.00 mIU/mL
Detection of Limit	≤0.20 mIU/mL
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

REFERENCES

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3. Mia VG, Julia R, et al. Persistent organic pollutants as predictors of increased FSH: LH ratio in naturally cycling, reproductive age women. Environmental Research 2018, 164.
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DESCRIPTION OF SYMBOLS USED

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

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

Thank you for using LH Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

Version: WIF53-S-09

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mAlb Fast Test Kit

(Immunofluorescence Assay)

User Manual

Cat.# IF1009

INTENDED USE

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

SUMMARY

Albumin is one of the major plasma proteins. In normal circumstances, albumin molecules are too large to cross the glomerular basement membrane. Therefore, albumin is usually present in very low concentration in urine. Damage to the glomerular basement membrane can alter its permeability. Albumin is then able to enter the urine. Sustained elevation of urinary albumin concentration is called microalbuminuria (mAlb). mAlb arises from increased leakage of glomerular basement membrane. So, mAlb is recognized as a marker of kidney damage. The epidemiology of microalbuminuria reveals a close association between systemic endothelial dysfunction and vascular disease, also implicating glomerular endothelial dysfunction in microalbuminuria. Recent years, determination of mAlb is linked with increased risk for cardiovascular events rather than progression to end-stage kidney diseases. It is a valuable tool for the detection of cardiovascular risk in diabetic nephropathy. Early detection of microalbuminuria in diabetics is critical because immediate intervention can slow the progression of disease.

PRINCIPLE

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

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

CONTENTS

A kit contains:

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

A test card consists of:

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **urine sample**.
2. **Urine sample** can be preserved at room temperature for 4 hours, please test it as soon as possible. If testing will be delayed, urine sample may be stored up to 3 days at 2~8°C before testing .
3. Do not use frozen urine sample.
4. Samples should be brought to room temperature before testing.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME: **100 µl**.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to

enter testing interface.

- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver **100 µl** of sample (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card.
- Reaction time: 3 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

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

PERFORMANCE CHARACTERISTICS

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

Method Comparison:

The assay was compared with OLYMPUS AU5400 analyzer

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

LIMITATIONS

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

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

REFERENCES

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- Reboldi G, Gentile G, Angeli F, et al. Microalbuminuria and hypertension. *Minerva Med*. 2005, 96(4):261-75.
- EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2: 2009).

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF10-S-01



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NT-proBNP Fast Test Kit

(Immunofluorescence Assay)

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

User Manual

INTENDED USE

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

SUMMARY

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

PRINCIPLE

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

intensity of the test line increases in proportion to the amount of NT-proBNP in sample.

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

CONTENTS

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

Note: Components from different batches must not be interchanged.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

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

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

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

TEST PROCEDURE

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

For Getein1100:

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

For Getein1600:

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

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

The expected normal value for NT-proBNP was determined by testing samples from 2,500 apparently healthy individuals. The 95th percentile of the concentration for NT-proBNP is 185 pg/ml and the 97.5th percentile of the concentration for NT-proBNP is 300 pg/ml. Because of the apparent difference of the concentration

of NT-proBNP among different age groups, the reference values of the NT-proBNP are reported in groups. Details refer to Table 1. Clinical diagnosis value: refer to Roche criterion, details see Table 2.

Table 1 NT-proBNP reference value

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

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

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

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

PERFORMANCE CHARACTERISTICS

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

Method Comparison:

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

LIMITATIONS

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

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

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

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF03-S-02



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PCT Fast Test Kit

(Immunofluorescence Assay)

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

User Manual

INTENDED USE

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

SUMMARY

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

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

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

PRINCIPLE

The test uses an anti-human PCT monoclonal antibody conjugated with fluorescence latex. For PCT product, test line 1 was coated with anti-human PCT polyclonal antibody and test line 2 was coated with another anti-human PCT monoclonal antibody. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human PCT monoclonal antibody binds with the PCT in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen

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

CONTENTS

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

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

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

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

TEST PROCEDURE

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

For Getein1100:

- 3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
 - 4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
 - 5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
 - 6. Put the test card on a clean table, horizontally placed.
 - 7. Using sample transfer pipette, deliver 100 µl of sample (or 3-4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
 - 8. **Reaction time: 15 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.
- For Getein1600:
- 9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
 - 10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

The expected normal value for PCT was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for PCT is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.) The table below comes from the research of ACCP/SCCM (American College of Chest Physicians/Society of Critical Care

Medicine), showing the PCT value and its clinical meaning^[4]:

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

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

PERFORMANCE CHARACTERISTICS

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

Method Comparison:

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

LIMITATIONS

- 1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- 2. Samples containing interferent may 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. Balci C, Sungurtekin H, Gürses E, Sungurtekin U, Kaptanoglu B. Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit, Crit Care. 2003 February 7 (1):85-90.
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- 5. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- 6. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF06-S-02



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PRL

Fast Test Kit

(Immunofluorescence Assay)

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

REF

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°C 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°C or stored at -20°C 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

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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		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/ European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	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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Prog Fast Test Kit (Immunofluorescence Assay)

IF1071 for Getein 1100
IF5071 for Getein 1160
IF3071 for Getein 1180
IF2071 for Getein 1600
IF4071 for Getein 1200

REF

Instructions for Use

INTENDED USE

Prog Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of progesterone in human serum and plasma samples. The test is used clinically as an aid in the diagnosis of diseases related to abnormal progesterone levels, such as threatened miscarriage and luteal phase defect. For professional and laboratory use only.

SUMMARY

Progesterone (P) is a steroid hormone secreted by the corpus luteum of the ovary, and its level varies with the physiological cycle, which is important for ovulation detection, luteal function, normal pregnancy, and placental function. Progesterone is secreted by the ovaries and adrenal glands in non-pregnant women, and the level of progesterone is very low in the follicular phase. After ovulation, the corpus luteum of the ovary produces a large amount of progesterone, which peaks 8-9 days after ovulation and then declines rapidly to follicular phase levels about 4 days before the next menstrual period. If the level of progesterone in the luteal phase is significantly lower than the physiologic value, it suggests possible luteal insufficiency. In early pregnancy, progesterone is secreted by the corpus luteum of pregnancy and serum progesterone levels continue to rise. If the corpus luteum secretes low levels of progesterone during this period, preeclampsia is likely to occur. After 8-10 weeks of pregnancy, the placenta replaces the corpus luteum as the main secretory gland of progesterone, and at this time, the level of progesterone is stable and gradually increases, if the serum progesterone level drops significantly during this period, suggesting that the placenta may be functionally impaired. Progesterone levels will be higher in late pregnancy.

During a woman's pregnancy, progesterone provides support and security for the early growth and development of the fetus. Progesterone levels have a close relationship with the activity of the pregnancy, and low levels of progesterone often indicate an abnormal pregnancy, and can even lead to miscarriage. Determination of progesterone in the blood is clinically important for regulating the female menstrual cycle, detecting luteal function and maintaining pregnancy.

PRINCIPLE

Prog Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a competitive design. After the sample has been applied to the test strip, the fluorescence-labelled progesterone monoclonal antibody binds with the progesterone in sample and forms a marked antigen-antibody complex. Meanwhile, the uncombined fluorescence-labelled progesterone monoclonal antibody binds with the progesterone antigen on the test line. The fluorescence intensity of the test line decreases in proportion to the amount of progesterone in sample. Fluorescent signals intensity can be analyzed by applicable device thus the progesterone in sample be detected quantitatively.

APPLICABLE DEVICE

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

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
Prog test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 pcs	25 pcs	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*Prog test card

A test card main consists of: Fluorescence-labelled prog monoclonal antibody and prog antigen.

**Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 0.2 mL contained in each tube consists of:

- Sample diluent main contains phosphate buffer (20 mmol/L), NaN_3 (<0.1%).

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

- Phosphate buffer (20 mmol/L), NaN_3 (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

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

- Mixing plate (1 piece/box)

Note:

- 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".
- Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

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

In-use stability:

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

-For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches or the cartridge until ready to perform the test.
- Do not reuse the test card or pipet.
- Handle all specimens as potentially infectious. Proper

handling and disposal methods should be followed in accordance with local regulations.

- Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for **serum and plasma samples**.
- Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma samples.
- It is recommended to test the sample within 4 hours after collection. If testing is delayed, serum and plasma samples are stable for 5 days when stored at 2~8°C and 6 months when stored at -20°C.
- Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples or hemolysis samples.
- Sample volume (**Getein 1100/Getein 1160/Getein 1180**): 100 μL .

TEST PROCEDURE

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

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette to drop 100 μL of sample into one tube of sample diluent, mix gently and thoroughly, then add 100 μL of sample mixture into the sample well on the test card.
- Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

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

For Getein 1200/Getein 1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the insertion of test card and the sample are correct and complete.

RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 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/Getein 1200/Getein 1600.

Prog Fast Test Kit (Immunofluorescence Assay) results are provided in ng/mL.

LIMITATIONS

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

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

EXPECTED VALUE

The expected normal value for Progesterone was determined by testing blood samples from apparently healthy individuals. Reference range of Progesterone:

Group		n	95% Reference range (ng/mL)
Healthy men		200	0.15-1.97
Healthy women	Follicular phase	121	0.34-1.52
	Luteal phase	58	5.20-18.76
	Post menopause	156	0.12-0.76
Healthy pregnant women	1 st trimester	135	4.73-50.21
	2 nd trimester	49	19.27-45.34

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

PERFORMANCE CHARACTERISTICS

1. Measuring Range 0.10~40.00 ng/mL
2. Limit of Detection ≤0.10 ng/mL
3. Within-Run Precision ≤10%
4. Between-lot Precision ≤15%

REFERENCES

1. Julia S, R J W, Pawel B, et al. Role of progesterone and

- progesterin therapy in threatened abortion and preterm labour[J]. Frontiers in bioscience: a journal and virtual library, 2008, 131981-90.
2. Julia S. Progesterone orchestrates foetal-maternal interactions in pregnancy[J]. Journal of Reproductive Immunology, 2023, 159.
3. Clinical and Laboratory Standards Institute. Protocols for determination of limits of quantitation; approved guideline-second edition, EP17-A, CLSI,2004.
4. Clinical and Laboratory Standards Institute. Evaluation of precision performance of quantitative measurement method; approved guideline-second edition, EP17-A, CLSI,2004.
5. National Committee for Clinical Laboratory. Method comparison and bias estimation using patient samples; approved guideline. EP9-A2, NCCLS, 2002.

DESCRIPTION OF SYMBOLS USED

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

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

Thank you for using Prog Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

 Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

 CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain
Tel: +34951214054



RF Fast Test Kit (Immunofluorescence Assay)

IF1075 for Getein1100
IF5075 for Getein1160
IF3075 for Getein1180
IF4075 for Getein1200
IF2075 for Getein1600

REF

User Manual

INTENDED USE

RF Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of rheumatoid factor (RF) in serum, plasma or whole blood samples. The test is designed to aid in the diagnosis of autoimmune diseases, such as rheumatoid arthritis (RA).

SUMMARY

Rheumatoid factor is an autoantibody targeting the Fc fragment of human or animal denatured IgG molecule. RF mainly includes four types of IgM, IgG, IgA and IgE, and IgM is the main type of RF. Under the direct stimulation of denatured IgG or Epstein-Barr virus, B cells in patients with rheumatoid arthritis will synthesize RF in large quantities. On the contrary, in healthy people, there are few clones of B cells that produce RF, and the soluble factors secreted by monocytes can inhibit the production of RF, which is generally difficult to be detected. RF is mainly used in the clinical diagnosis of RA. RF has a positive detection rate of 80% in RA patients. Positive RF is one of the criteria for RA classification by the American College of Rheumatology, but positive RF is not the sole basis for the diagnosis of RA.

PRINCIPLE

The test kit adopts a double-antigen sandwich method to quantitatively detect the concentration of RF in human serum, plasma and whole blood samples. After the sample has been applied to the test card, the fluorescence latex-labelled RF antigen binds with RF in

sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by RF antigen coated on the detection area of nitrocellulose membrane, forming a double- antigen complex. The complex generates a fluorescent signal and the intensity increases in proportion to the amount of RF in sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/ automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of RF 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/kit, 10 tests/kit

- 1) Getein RF test card in a sealed pouch with desiccant
- 2) Capillary pipet
- 3) Sample diluent
- 4) User manual: 1 piece/kit
- 5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:

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

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

Materials required for Getein1200/Getein1600:

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

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 RF antigen, the test line is coated with RF antigen and the control line is coated with polyclonal mouse anti human IgG antibody),absorbent paper and liner.

4. Sample diluent composition:

Phosphate buffered saline, proteins, detergent,

preservative, stabiliser.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 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. 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. **Serum, plasma or whole blood** samples can be used for the test. Other body fluids and samples may not give accurate results. Samples should be

free of hemolysis.

2. Venous blood should be collected under aseptic conditions; serum or plasma is preferred for testing.
3. Heparin, sodium citrate or EDTA can be used as the anticoagulant for plasma and whole blood samples.
4. The test should be performed at room temperature (15~30℃) within 4 hours after sample collection.
5. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ and 3 months at -20℃ before testing. Whole blood samples should not be frozen and can be stored at 2~8℃ for 3 days. Do not heat inactivated samples or use hemolyzed blood samples.
6. Refrigerated or frozen sample should be reached to room temperature (15~30℃) before testing. Frozen samples must be completely thawed, rewarmed and evenly mixed. Serum and plasma samples can freeze and thaw twice at most. Avoid multiple freeze-thaw cycles.
7. **SAMPLE VOLUME (for Getein1100/Getein1160/Getein1180): 10μL.**

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature before test.

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 **10 μL** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100μL** of sample mixture into the sample well on the test card.
5. **Reaction time: 10 minutes.** Insert the test card into Getein1100 and 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 **10 µL** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100 µL** of sample mixture 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 (10 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. Put the sample diluent at the correct position of Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder,insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kits.
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 are 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: Samples whose concentration exceeds the upper limit should be diluted no more than 4 times.

EXPECTED VALUE

The expected normal value for RF is determined by testing samples from 282 apparently healthy individuals. The upper 97.5th percentile value is 15.9 IU/mL.

It is recommended that each laboratory determine the applicability of the reference value through experiments and establish its own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	10.0-640.0 IU/mL
Lower Detection Limit	≤10.0 IU/mL
Within-run Precision	≤10%
Between-run Precision	≤15%

LIMITATIONS

1. Bilirubin and triglyceride in the sample may interfere with the test results, and the maximum allowable concentrations are 0.2 g/L and 10 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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2. Kolarz B, Podgorska D, Podgorski R. Insights of rheumatoid arthritis biomarkers.[J]. Biomarkers : biochemical indicators of exposure, response, and susceptibility to chemicals,2020: 1-34.
3. Nithya L, Jeremy S, Lauren J, et. al. Combination of anticitrullinated protein antibodies and rheumatoid factor is associated with increased systemic inflammatory mediators and more rapid progression from preclinical to clinical rheumatoid arthritis[J]. Clinical Immunology,2018,195:

119-126.

4. Veerle I, Xavier B, Daniël B, Ellen DL. Prevalence and clinical correlates of rheumatoid factor and anticitrullinated protein antibodies in patients with idiopathic inflammatory myopathy[J]. RMD Open,2018,4(2).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

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

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

Version: WIF82-S-05



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Tel: +86-25-68568508
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overseas@getein.com.cn
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CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain



T3

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1022 for Getein1100
IF2022 for Getein1600

INTENDED USE

T3 (Triiodothyronine) Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of T3 in serum and plasma. It can be used in the monitoring of hyperthyroidism and hypothyroidism, and also used as an aid in the functional diagnosis of thyroidea.

SUMMARY

The thyroid gland exerts powerful and essential regulatory influences on growth, differentiation, cellular metabolism and general hormonal balance, as well as on the maintenance of metabolic activity and the development of the skeletal and organ system. The hormones thyroxine (T4) and triiodothyronine (T3) circulate in the blood stream, mostly bound to the plasma protein, thyroxine binding globulin (TBG). The concentration of T3 is much less than that of T4, but its metabolic potency is much greater.

T3 is produced by the thyroid and secreted in response to TSH. T3 determination is an important factor in the diagnosis of thyroid disease. Its measurement has uncovered a variant of hyperthyroidism in thyrotoxic patients with elevated T3 levels and normal T4 levels. An increase in T3 without an increase in T4 is frequently a forerunner of recurrent thyrotoxicosis in previously treated patients. In other patients, euthyroidism attributable to normal T3, although their T4 values are subnormal.

In women, T3 levels are elevated during pregnancy, during estrogen treatment, and contraceptive hormone therapy. When T3 levels parallel TBG increases in a manner analogous to T4 levels, these changes are not reflection of altered thyroid status.

PRINCIPLE

The test uses an anti-human T3 monoclonal antibody

conjugated with fluorescence latex coated on fluorescent pad and another antibody conjugated with fluorescein isothiocyanate (FITC) coated on the test line, also a T3 antigen conjugated with FITC is coated on the junction of nitrocellulose membrane and sample pad. After the sample has been applied to the test strip, the T3 in sample and the T3 antigen conjugated with FITC will compete the fluorescence latex-labelled T3 antibody and form marked T3-FITC-T3 antibody and T3-T3 antibody, respectively. These complexes move to the test card detection zone by capillary action. Then marked T3-FITC-T3 antibody complexes will be captured on the test line by antibodies conjugated with FITC. The fluorescence intensity of test line increases in proportion to the amount of T3 in sample.

Then Insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein1600), the concentrations of T3 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:

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

- 1) Getein T3 test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) Sample treatment solution A and B
- 4) User manual: 1 piece/box
- 5) SD card/RFID card: 1 piece/box

2. A kit for Getein1600 contains:

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

- 1) Sealed cartridge with 24/48 Getein T3 test cards
- 2) 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 treatment solution/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 fluorescence latex-labelled anti-human T3 monoclonal antibody and T3 antigen, the test lines is coated with FITC 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
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 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 treatment solution/sample diluent at 0~30°C with a valid period of 24 months.

Store the sample treatment solution/sample diluent 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 is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

- 1. This test can be used for 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 will be delayed, serum and plasma samples may be stored up to 7 days at 2-8 C or stored at -20 C for 6 months before testing.
- 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): 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 or RFID card lot No. in accordance with test kit lot No.. Perform "SD card or RFID 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 10 µl sample treatment B into sample treatment A, and then deliver 100 µl of sample into sample treatment A. Mixing for 1 minute and then drop 100 µl of the sample mixture to 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 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 or RFID card" 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 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.

Others:Measuring range of the T3 test kit is 0.30 nmol/L~10.00 nmol/L. Dilute the sample which concentration is higher than the upper limit with calf serum or negative samples, and the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for T3 and was determined by testing samples from 391 apparently healthy individuals. The reference range of T3 is 1.30 nmol/L~3.10 nmol/L 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	0.30~10.00 nmol/L
Lower Detection Limit	≤0.30 nmol/L
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	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

REFERENCES

- 1. Spencer C A, LoPresti J S, Patel A, et al. Applications of a new chemiluminometric thyrotropin assay to subnormal measurement.J Clin Endocrinol Metab. 1990, 70(2):453-460.
- 2. Spencer C A, Takeuchi M, Kazarosyan M. Current status and performance goals for serum thyrolobulin assays. Clin Chem. 1996,42(1):164-173.
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- 4. Keffer JH. Preanalytical considerations in testing thyroid function.Clin. Chem. 1996, 42(1):125-134.
- 5. Lindstedt G, Berg G, Jansson S,et al. Clinical use of laboratory thyroid tests and investigations. J Int Fed Clin Chem. 1994, 6(4):136-141.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on T3 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 15223-1:2016

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

Thank you for purchasing T3 Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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T4

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1023 for Getein1100
IF2023 for Getein1600

INTENDED USE

T4 (Thyroxine) Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of T4 in serum and plasma. It can be used in the monitoring of hyperthyroidism and hypothyroidism, and also used as an aid in the functional diagnosis of thyroida.

SUMMARY

The thyroid gland exerts powerful and essential regulatory influences on growth, differentiation, cellular metabolism and general hormonal balance, as well as on the maintenance of metabolic activity and the development of the skeletal and organ system.

T4 is the most commonly measured substance in the assessment of thyroid function. Most of the thyroxine secreted into the bloodstream is bound to a transport protein, thyroxine binding globulin (TBG), and to albumin and pre-albumin. Only less than 1% of thyroxine remains unbound as free T4 in blood. Elevated total thyroxine levels have been associated with hyperthyroidism, a condition with an excess amount of circulating thyroid hormone and decreased total thyroxine levels have been associated with hypothyroidism, a condition with insufficient levels of thyroxine concentration. Primary malfunction of the thyroid gland or any diseases affecting the thyroid-pituitary-hypothalamus system may result in the abnormal thyroxine concentration in blood. Measurement of thyroxine has been one of the most widely used method for evaluation of an individual's thyroid status.

PRINCIPLE

The test uses an anti-human T4 monoclonal antibody conjugated with fluorescence latex coated on fluorescent pad

and another antibody conjugated with fluorescein isothiocyanate (FITC) coated on the test line, also a T4 antigen conjugated with FITC is coated on the junction of nitrocellulose membrane and sample pad. After the sample has been applied to the test strip, the T4 in sample and the T4 antigen conjugated with FITC will compete the fluorescence latex-labelled T4 antibody and form marked T4-FITC-T4 antibody and T4-T4 antibody, respectively. These complexes move to the test card detection zone by capillary action. Then marked T4-FITC-T4 antibody complexes will be captured on the test line by antibody conjugated with FITC. The fluorescence intensity of test line increases in proportion to the amount of T4 in sample.

Then Insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein1600), the concentrations of T4 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:

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

- 1) Getein T4 test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) Sample treatment solution A and B
- 4) User manual: 1 piece/box
- 5) SD card/RFID card: 1 piece/box

2. A kit for Getein1600 contains:

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

- 1) Sealed cartridge with 24/48 Getein T4 test cards
- 2) 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 treatment solution/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 fluorescence latex-labelled

anti-human T4 monoclonal antibody and T4 antigen, the test lines is coated with FITC 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
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 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 treatment solution/sample diluent at 0~30°C with a valid period of 24 months.

Store the sample treatment solution/sample diluent 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 is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for *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 will be delayed, serum and plasma samples may be stored up to 7 days at 2~8 °C or stored at -20 °C for 6 months before testing.
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*): **25 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 or RFID card lot No. in accordance with test kit lot No.. Perform "SD card or RFID 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 **10 µl** sample treatment B into sample treatment A, and then deliver **25 µl** of sample into sample treatment A. Mixing for 1 minute and then drop **100 µl** of the sample mixture to 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 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 or RFID card" 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 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.

Others: Measuring range of the T4 test kit is 5.4 nmol/L~320.0 nmol/L. Dilute the sample which concentration is higher than the upper limit with calf serum or negative samples, and the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for T4 and was determined by testing samples from 391 apparently healthy individuals. The reference range of T4 is 59.0 nmol/L~154.0 nmol/L 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	5.4~320.0 nmol/L
Lower Detection Limit	≤5.4 nmol/L
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	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

REFERENCES

1. Spencer C A, LoPresti J S, Patel A, et al. Applications of a new chemiluminometric thyrotropin assay to subnormal measurement. *J Clin Endocrinol Metab*. 1990, 70(2):453-460.
2. Spencer C A, Takeuchi M, Kazarosyan M. Current status and performance goals for serum thyrolobulin assays. *Clin Chem*. 1996, 42(1):164-173.
3. Koidl J, Hödl H, Schmid MG et al. Enantio recognition of triiodothyronine and thyroxine enantiomers using chiral selectors by HPLC and micro-HPLC. *J. Biochem Biophys Methods*. 2008, 70(6):1254-1260.
4. Keffer JH. Preanalytical considerations in testing thyroid function. *Clin. Chem*. 1996, 42(1):125-134.
5. Lindstedt G, Berg G, Jansson S, et al. Clinical use of laboratory thyroid tests and investigations. *J Int Fed Clin Chem*. 1994, 6(4):136-141.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on T4 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 15223-1:2016.

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

Thank you for purchasing T4 Fast Test Kit (Immunofluorescence Assay).

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



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Testosterone Fast Test Kit (Immunofluorescence Assay)

REF IF1073 for Getein1100
IF5073 for Getein1160
IF3073 for Getein1180

Instructions for Use

INTENDED USE

Testosterone Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Testosterone in human serum and plasma. Testosterone tests are used to assist in the diagnosis of female polycystic ovary syndrome and male testosterone insufficiency. For professional and laboratory use.

SUMMARY

Testosterone, one of the main sex hormones in the human body, is a steroid hormone with 19 carbon atoms synthesized from cholesterol. About 90% of male testosterone comes from leydig cells, and the rest is produced in adrenal cortex and other tissues; Testosterone in women synthesized by ovarian stromal cells, portal cells and adrenal cortex reticular zone, account for about 50% of total. The remaining 50% is mainly converted from androstenedione in liver, fat, skin and other tissues. It is the precursor of estradiol synthesis in the ovary, and has a certain role in maintaining the female gonadal function. Testosterone exists in blood in two forms: bound and free. The binding state is mainly bound with sex hormone binding protein, albumin and other proteins, accounting for 97%~99%; Free testosterone accounts for 1%~3%, which is the main form of biological activity in vivo. Detection of female testosterone can assist in the diagnosis of polycystic ovary syndrome (PCOS), masculinized tumors in women, congenital adrenal hyperplasia and adrenal tumors. Detection of male testosterone content can assist in the diagnosis of diseases with insufficient testosterone production, such as congenital testicular dysplasia, chromosomal abnormalities, and in addition, it can assist in the diagnosis of hypopituitarism, cirrhosis.

PRINCIPLE

Testosterone Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a competitive design. After the

sample has been applied to the test strip, the fluorescence latex-labelled testosterone monoclonal antibody binds with the testosterone in sample and forms a marked antigen-antibody complex. The uncombined fluorescence latex-labelled testosterone monoclonal antibody binds with the testosterone on the test line. The fluorescence intensity of the test line decreases in proportion to the amount of testosterone in sample. Fluorescent signals intensity can be analyzed by applicable device thus the testosterone in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180	
	10 T/kit	25 T/kit
Testosterone test card	10 pcs	25 pcs
Disposable pipet	10 pcs	25 pcs
Sample diluent 3	10 tube	25 tube
Instructions for use	1 pc	1 pc
SD card	1 pc	1 pc

Sample diluent 3 for Getein 1100/ Getein 1160/ Getein 1180 consists of:

Sample diluent 3 contains Carbonate buffer (50 mmol/L), ProClin™ 300 (0.1%).

A test card consists of:

Fluorescence latex-labelled testosterone monoclonal antibody, Fluorescence latex-labelled Chicken immunoglobulin Y natural protein, testosterone antigen and Goat anti chicken immunoglobulin Y polyclonal antibody.

Note:

- 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".
- Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

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

In-use stability:

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

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for **plasma and serum samples**.
- Heparin, sodium citrate or EDTA can be used as the anticoagulant for plasma samples.
- It is recommended to test the sample within 8 hours after collection. Stable in plasma for 7 days when stored at 2~8°C and 6 months when stored at -20°C.
- Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.

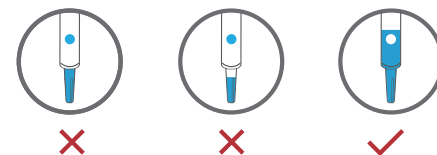
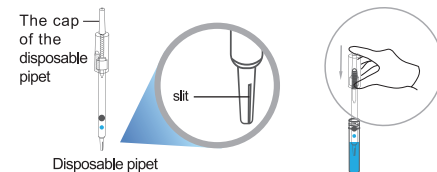
CALIBRATION AND TRACEABILITY

- Calibration: The regression equation fitting the concentration value of the working calibrator with the reaction signal value is written into the SD card in advance. Before detection, the SD card is written into the instrument, which can automatically read the calibration curve information in the SD card. During detection, the content of analyte can be calculated by substituting the obtained signal value into the regression equation.
Calibration Frequency: A new calibration is required when using a new reagent lot or a new instrument.

TEST PROCEDURE

- Before use, you must carefully read the instructions for use and operate in strict accordance with the instructions, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.
- Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
- Select the corresponding model on the analyzer according to

- the sample type (see the instructions for analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver **100 μ L** of sample into one tube of sample diluent 3 using **disposable pipet**, mix gently and thoroughly. (Samples must be added using the disposable pipet in the kit to avoid incorrect results).

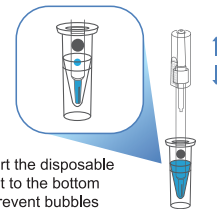


Note 1: Press the top of the disposable pipet to the bottom with your finger during sampling. Ensure that the slit is fully submerged in the sample.

Note 2: Thoroughly press the disposable pipette only once to take a sample, not repeatedly.

Note 3: Insert the disposable pipet into the sample diluent 3 tube to mix the sample by pushing the cap at the top of the disposable pipet for 4-6 times and wait 5~10 minutes.

Note 4: It is recommended to wait for 5-10 minutes after mixing the samples, and the results of early or overtime testing are inaccurate.



8. Deliver the sample mixture by pushing the cap at the top of the disposable pipet and dispense the sample mixture into the sample port "S" on the test card.

For Getein 1100:

Reaction time: **15 minutes**. Insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

RESULTS

Getein1100/Getein1160/Getein1180 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein1100/Getein1160/ Getein1180.

Testosterone Fast Test Kit (Immunofluorescence Assay) results are provided in ng/mL.

Results in ng/mL may be converted to nmol/mL as shown with an example below.

Testosterone Fast Test Kit (Immunofluorescence Assay) result as reported by the system (example) 1.00 ng/mL

The reported example result equals: 3.47 nmol/L

Others: Measuring range of the Testosterone Fast Test Kit is 0.10 ~ 16.00 ng/mL. Samples initially outside the measuring range may be diluted with 1% bovine serum albumin, upper limit can be up to 48.00 ng/mL through dilution.

PERFORMANCE CHARACTERISTICS

- | | |
|--------------------------|--------------------|
| 1. Measuring Range | 0.10 ~ 16.00 ng/mL |
| 2. Limit of Detection | ≤0.10 ng/mL |
| 3. Within-Run Precision | ≤10% |
| 4. Between-Run Precision | ≤15% |

LIMITATIONS

1. The test results of this kit are only for clinical reference and cannot be used as the basis for confirming or excluding cases alone. In order to achieve the purpose of diagnosis, this test result should be used in combination with clinical examination, medical history and other examination results.
2. Do not use the test card if the foil pouch or the cartridge is damaged.

3. Do not open pouches until performing the test.
4. Patient samples may contain heterophilic antibodies (e.g. human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react in immunoassays to give a falsely elevated or depressed result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed.
5. Triglyceride and bilirubin in the sample may interfere with the test results, and the maximum allowable concentrations are 18 g/L and 0.1 g/L respectively.

EXPECTED VALUE

The expected normal value for Testosterone was determined by testing samples from apparently healthy individuals.

Reference range of Testosterone:

Group	n	95% Reference range
		(ng/mL)
Healthy men	260	1.75-7.81
Healthy women	280	0.10-0.75

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

REFERENCES

1. Payne AH, Hales DB. Overview of steroidogenic enzymes in the pathway from cholesterol to active steroid hormones. Endocr Rev. 2004 Dec;25(6):947-70. doi: 10.1210/er.2003-0030. PMID: 15583024.
2. RICHARD, Sharpe M. Intratesticular Factors Controlling Testicular Function[J]. Biol Reprod. 1984;30 (1) : 29-49
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Testosterone Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European

Standard EN ISO 15223-1:2021.

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

Thank you for using Testosterone Fast Test Kit (Immunofluorescence Assay). Please read this instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

Document no.: WIF80-S-07

Effective date: 2023.08.29



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tPSA Fast Test Kit (Immunofluorescence Assay)

IF2053 for Getein1600
IF1053 for Getein1100
IF3053 for Getein1180
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 protease 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 μ l.**

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
- For Getein1100:
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" 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 μ l** 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 μ l** 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

- 1. Mc Jimpsey EL. Molecular Form Differences Between Prostate-Specific Antigen (PSA) Standards Create Quantitative Discordances in PSA ELISA Measurements. Scientific Reports. 2016, 6: 22050.
- 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		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		Do not use if package is damaged
	Catalogue number		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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TSH Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1024

Getein1600: Cat.# IF2024

User Manual

INTENDED USE

TSH Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of thyroid-stimulating hormone (TSH) in serum, plasma or whole blood. This test is used in the screening, clinical diagnosis, prognosis and therapeutic effect evaluation of thyroid diseases.

SUMMARY

Thyroid-stimulating hormone (TSH) is the main regulator of thyroid cell growth, thyroid hormone synthesis and secretion. TSH(MW 30 kDa) is synthesized and secreted by tsh cells of pituitary gland, it has negative feedback to the synthesis and secretion process. The fluctuation of TSH is faster and more significant than thyroid hormones when thyroid function was changed, it is a sensitive biomarker of hypothalamic-pituitary-thyroid function.

PRINCIPLE

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

Insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred

to as Getein1100 and Getein1600), the concentration of TSH 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 TSH test card in a sealed pouch with desiccant.....	25
Disposable pipet	25
User manual	1
SD card/RFID card	1
Whole blood buffer	1

2. A kit for Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit	
Sealed cartridge with 24/48 Getein TSH test cards.....	2
User manual	1
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 TSH monoclonal antibody, the test line is coated with another anti-human TSH monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards

can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days. Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months. Store the sample diluent/whole blood buffer at 2~8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

- 1.This test can be used for *serum, plasma and whole blood. Heparin, EDTA and sodium citrate* can be used as the anticoagulant for plasma and whole blood samples. 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°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze- thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME (for Getein1100): 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 or RFID card lot No. in accordance with test kit lot No.. Perform "SD card or RFID card Calib" 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 (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 start test 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 or RFID 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 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.

Others: Measuring range of the test kit is 0.10 µIU/mL~50.0 µIU/mL, dilute the sample which concentration is higher than the upper limit, the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for TSH was determined by testing samples from serum of 391 apparently healthy individuals. The reference range of TSH is 0.27 µIU/mL~ 4.20 µIU/mL

calculated by using normal distribution methods (95% confidence interval). It is recommended that each laboratory should establish its expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10 µIU/mL~ 50.00 µIU/mL
Lower Detection Limit	0.10 µIU/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 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	25 g/L	0.1 g/L

REFERENCES

1. Spencer C A, LoPresti J S, Patel A, et al. Applications of a new chemiluminometric Thyrotropin assay to subnormal assessment. Clin Endocrinol Metab. 1990, 70(2):453-460.
2. Sakai H, Fukuda G, Suzuki N, et al. Falsely Elevated Thyroid-Stimulating Hormone (TSH) Level Due to Macro-TSH. Endocr J. 2009, 56(3):435-440.
3. Abalovich M, Amino N, Barbour LA, et al. Management of thyroid dysfunction during pregnancy and postpartum: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2007, 92(8):1-47.
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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 (ISO 18113-2:2011).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on TSH 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 15223-1:2012.

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

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

Version: WIF26-S-02



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