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

Document No.: GP-GMSQ-2024121101

Letter of Authorization

To whom it may concern,

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

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

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

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

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

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

Getein Biotech, Inc.

Name: Steven Zhou
Position: Overseas Sales Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Digitally signed by Dolgopol Iulian
Date: 2025.02.12 11:12:22 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Cardiac Markers

Coagulation Markers

Diabetes Mellitus

Inflammation

Thyroid Function

Metabolic Marker

Renal Function

Tumor Markers

Reproduction /Fertility

Infectious Disease

Getein Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION

MAKING TEST EASY

Getein 1100

Immunofluorescence Quantitative Analyzer

Getein 1100

Immunofluorescence Quantitative Analyzer

HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control

REAL-TIME AND RAPID TEST

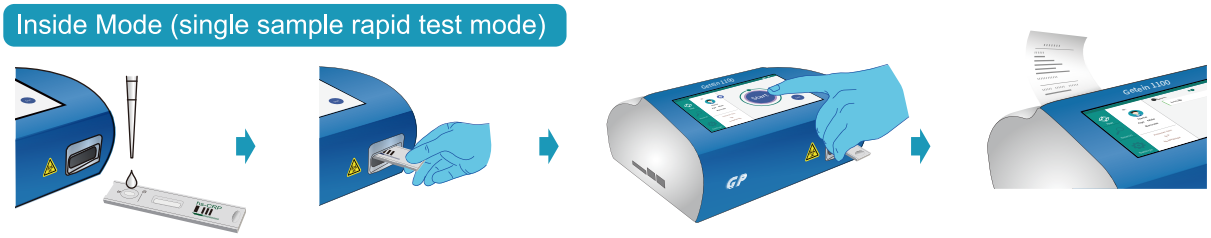
One-step test

3-15 min/test

5 sec/test for multiple tests

OPERATION MODES

Inside Mode (single sample rapid test mode)



Sample Transfer | Test Card Insert | Click “Start” Icon | Result Show and Print

Quick mode (mass samples rapid test mode)

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

CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB port

Handwriting input available

Continuous test for 3 hours with optional lithium battery

USER-FRIENDLY INTERFACE

Android system

7-inch touch screen

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

PORTABLE DESIGN

Small in size: 261 ×241 ×115 mm

Light in weight: 2.0 kg

LARGE MEMORY

Up to 10,000 results storage capacity

TECHNICAL PARAMETERS

Methodology	Immunofluorescence
Result	Quantitative
Sample Type	WB, Plasma, Serum, Urine, Stool, Nasal swab, Saliva, Capillary blood
Storage Capacity	10000 data
Language	English/Chinese/Spanish/Portuguese
Screen	7-inch touch screen
Power Supply	100-240 V~50 Hz/60 Hz, 60 VA
Working Environment	Temperature: 10-35°C Relative humidity ⩽70% Air pressure 70.0~106.0 kpa
Dimensions	261 mm×241 mm×115 mm (D×W×H)
Weight	2.0 kg

TEST ITEMS

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

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Reproduction/Fertility								
IF1013	HCG+β	Fertility	5.1 mIU/mL	S/P	5.0-100000.0 mIU/mL	100 µL	10 min	NMPA CE
IF1055	LH	PCOS, infertility evaluation	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 µL	15 min	NMPA CE
IF1056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 µL	15 min	NMPA CE
IF1066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	200 µL	15 min	CE
IF1048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.00 ng/mL	100 µL	15 min	NMPA CE
IF1071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 µL	15 min	CE
NEW IF1073	Testosterone	Female polycystic ovary syndrome, male testosterone insufficiency	Male: 1.75-7.81 ng/mL Female: 0.10-0.75 ng/mL	S/P	0.10-16.00 ng/mL	100 µL	15 min	CE
NEW IF1074	E2	Ovarian function	Refer to User Manual	S/P	40.0-4800.0 pg/mL	100 µL	15 min	CE
Tumor Markers								
IF1053	tPSA	Prostate cancer	4.00 ng/mL	S/P	0.50-100.00 ng/mL	100 µL	15 min	NMPA
IF1072	fPSA	Prostate cancer	1.00 ng/mL	S/P	0.05-30.00 ng/mL	100 µL	10 min	NMPA
IF1050	AFP	Liver cancer, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 µL	15 min	CE
IF1051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P	2.0-500.0 ng/mL	100 µL	15 min	CE
Infectious Disease								
IF1057	Anti-HCV	Hepatitis C	1.00 S/CO	S/P	1.00-20.00 S/CO	100 µL	15 min	
IF1058	Anti-TP	Syphilis	1.00 S/CO	S/P	1.00-50.00 S/CO	100 µL	15 min	CE
IF1059	Anti-HIV	AIDS	1.00 S/CO	S/P	1.00-1000.00 S/CO	100 µL	15 min	
IF1064	HBsAg	Hepatitis B	1.00 IU/mL	S/P	1.00-100.00 IU/mL	100 µL	15 min	
NEW IF1063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	100 µL	15 min	
IF1084	2019-nCoV IgM/IgG	COVID-19	1.00 COI	S/P/WB		100 µL	10 min	CE
NEW IF1091	SARS-CoV-2 Antigen	COVID-19	1.00 COI	Nasal swab/Saliva		100 µL	15 min	CE
NEW IF1095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB/ Fingertip blood		40 µL	15 min	CE
IF1047	*H. pylori*	*H. pylori* infection	5.0 ng/mL	Stool	1.0-200.0 ng/mL	3 drops (about 100 µL)	10 min	CE
NEW IF1086	Influenza A/B	Respiratory viral infection	1.00 S/CO	Nasal swab		100 µL	15 min	CE
NEW IF1136	Dengue NS1 Ag	Dengue virus infection	1.00 S/CO	S/P/WB	0.50-50.00 S/CO	100 µL	15 min	CE
Specific Protein and Rheumatism								
NEW IF1075	RF	Rheumatoid arthritis	15.9 IU/mL	S/P/WB	10.0-640.0 IU/mL	10 µL	10 min	CE
NEW IF1076	ASO	Rheumatic fever, acute glomerulonephritis, group A streptococcal infection	408.0 IU/mL	S/P/WB	60.0-1370.0 IU/mL	10 µL	10 min	CE
NEW IF1029	Anti-CCP	Rheumatoid arthritis	25.0 U/mL	S/P/WB	10.0-400.0 U/mL	10 µL	15 min	CE
Others								
NEW IF1077	Ferritin	Anemia/tumors	Male: 30.00-400.00 ng/mL Female: 13.00-150.00 ng/mL	S/P	0.50-1000.00 ng/mL	10 µL	15 min	CE
NEW IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 µL	15 min	CE
NEW IF1052	PG I/PG II	Atrophic gastritis, stomach cancer	PG I<70.0 ng/mL PG I/PG II<3.0 ng/mL	S/P	PG I: 1.0-200.0 ng/mL PG II: 1.0-100.0 ng/mL	100 µL	15 min	

Coming Soon: FOB, Folate…

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel.: +86-25-68568508/68568594
Fax: +86-25-68568500
E-mail: sales@getein.com.cn; overseas@getein.com.cn
Web.: www.getein.com

ISO13485 FSC CE NMPA NGSP IFCC IVD

WPT3.11-09

EC Declaration of Conformity

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

Ref. No.:20220513-A05

Manufacturer
(Name, Address)

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

Authorized Representative
(Name, Address）

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

Medical device

No.	Product Name
1	Getein 1100 Immunofluorescence Quantitative Analyzer
2	Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)
3	NT-proBNP Fast Test Kit (Immunofluorescence Assay)
4	hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay)
5	NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay)
6	CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay)
7	D-Dimer Fast Test Kit (Immunofluorescence Assay)
8	PCT Fast Test Kit (Immunofluorescence Assay)
9	CysC Fast Test Kit (Immunofluorescence Assay)
10	mAlb Fast Test Kit (Immunofluorescence Assay)
11	NGAL Fast Test Kit (Immunofluorescence Assay)
12	β2-MG Fast Test Kit (Immunofluorescence Assay)
13	CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)
14	HCG+β Fast Test Kit (Immunofluorescence Assay)
15	H-FABP Fast Test Kit (Immunofluorescence Assay)
16	PCT/CRP Fast Test Kit (Immunofluorescence Assay)
17	CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay)
18	HbA1c Fast Test Kit (Immunofluorescence Assay)
19	NT-proBNP/NGAL Fast Test Kit (Immunofluorescence Assay)
20	CK-MB Fast Test Kit (Immunofluorescence Assay)
21	hs-cTnI Fast Test Kit (Immunofluorescence Assay)
22	T3 Fast Test Kit (Immunofluorescence Assay)
23	T4 Fast Test Kit (Immunofluorescence Assay)
24	TSH Fast Test Kit (Immunofluorescence Assay)
25	Scr Fast Test Kit (Immunofluorescence Assay)
26	PLGF Fast Test Kit (Immunofluorescence Assay)

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

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

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

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

Applicable coordination standards

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

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

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

General Manager Enben Su

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

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

CE

Getein
Biotech, Inc.

CE

Getein 1100

Immunofluorescence Quantitative Analyzer

User Manual

Getein Biotech, Inc.

Warnings, Precautions and Limitations

a. Read this user manual carefully to obtain optimum performance from your analyzer.
b. Only used for in vitro diagnostic analysis of human whole blood, plasma, serum, urine, stool and swabs.
c. To avoid fire, electric shock or personal injuries, please turn off the power immediately and disconnect the power plug when any liquid seeps into the instrument, or the instrument leaks, emits smoke or a smell.
d. Take proper safeguard measures in accordance with health and safety standards in the local country.
e. Specimens and reagents may have potentially biological risks of infection. Operators should wear laboratory protective clothing and gloves required by the operation regulations of laboratory safety to avoid potential biological infection or contamination.
f. All the test kits and consumables should be disposed of after a single use. Proper handling and disposal methods should be established by the laboratory director in accordance with local, status and federal regulations.
g. Operators or person in charge shall be trained on cautions and operation instructions before operating the analyzer.
h. If the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

Symbols & Description

	Manufacturer
	Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*
	Serial number
	*In Vitro* diagnostic medical device
	Catalogue number
	CE Mark
	Authorized representative in the European Community/European Union
	Warning
	Warning; Biological hazard
	This way up
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Stacking limit by number
	Atmospheric pressure limitation
	Humidity limitation
	Temperature limit

Content

1.Introduction

1.1 Intended Use

Getein 1100 Immunofluorescence Quantitative Analyzer (hereinafter called Getein 1100) is an analyzer for processing Getein test kits and analysis of markers for cardiovascular diseases, renal diseases, inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid. This manual contains instructions for the use of Getein 1100 and general instructions for testing specimens and quality control materials.

1.2 Product Description

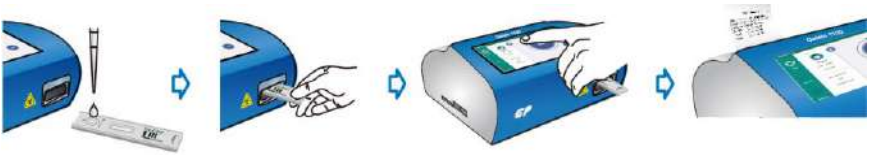
Getein 1100 is used to measure concentration of biomarkers in human whole blood, serum, plasma, urine, stool and swabs. The results can be used as an aid in clinical diagnosis of laboratory and point of care testing.

1.3 Product Principle

1.3.1 Overview: Running a Test

Apply sample (for example, serum) to the test card, insert the test card into Getein 1100 after a certain time (outside mode) or immediately (inside mode) and click the "Start" icon. Then the concentration of biomarkers in the sample will be measured and the result will be displayed (Fig.1-1). The test results can be transmitted to the lab or hospital information system (LIS or HIS) when the analyzer is connected to a computer.

Inside Mode (single sample rapid test mode)



Dispense sample Insert test card Click "Start" Show and print result

Quick mode (mass samples rapid test mode)

Dispense sample Time the reaction manually Click "Start" Show and print result

Fig.1-1 Running a Test

1.3.2 Working Principle

The detection element scans the binding area and converts the optical signal to electrical signal. The voltage variation between test line and background has a linear relationship with the antigen concentration which can be used to calculate the concentration. In conclusion, the antigen concentration in whole blood, plasma, serum, urine, stool and swabs can be calculated quantitatively according to the optical signal of the test line.

1.4 List of Icons

Icon	Name	Function
	Patient Information	Name, Gender, Age, Sample ID and Barcode can be edited here.
	Power Connection	Power is connected
	Battery	Built-in lithium battery.
	Search	Search results by name, sample ID or time.
	ON	Indicate the function is on.
	OFF	Indicate the function is off.

2.Installation

2.1 Unpacking

Check the analyzer and accessories with the packing list (Table 2-1). If you find any parts missing or any damages caused by improper transportation, contact your local agent or Getein's after-sales support immediately.

Table 2-1 Getein 1100 Packing List

No.	Description	Model	Unit	Quantity
1	Device	Getein 1100	set	1
2	Power Adapter	12 V 5 A	pc	1
3	Printing Paper	57 × 35 mm	pc	1
4	Data Cable		pc	1
5	User Manual (Device)		pc	1
6	Qualification Certificate & Warranty Card		pc	1
7	Lithium Battery	6.4 Ah	pc	Optional
8	Barcode Scanner		pc	Optional

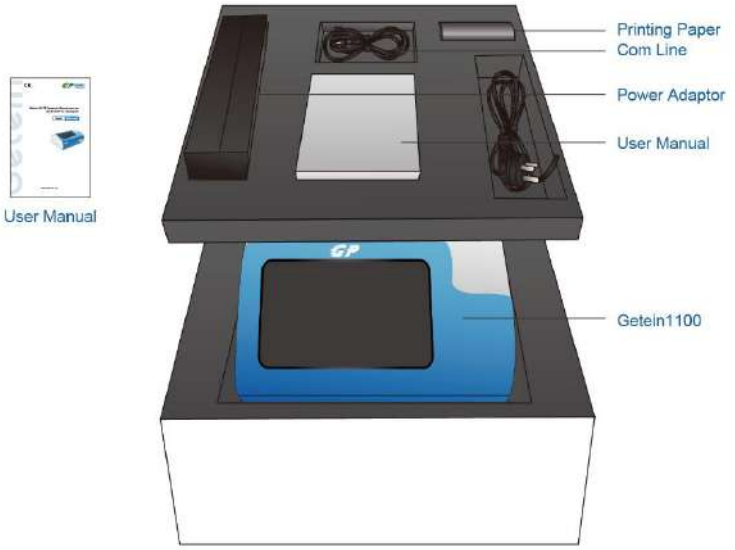


Fig.2-1 Getein 1100 and Main Accessories

2.2 Analyzer Configuration

Getein 1100 is composed of control system, optical system, display unit, analog signal acquisition system, mechanical drive system, etc.

Front and rear view of Getein 1100 are shown in Fig.2-2 and Fig.2-3.

Fig.2-2 Front View of Getein 1100

Fig.2-3 Rear View of Getein 1100

2.3 Main Interface

1 Status Information

It mainly includes the status of power, battery and SD card, current date and time.

2 Test Information

It mainly includes patient information, test card information and result information.

3 System Menu

It mainly includes Test, Search and Settings.

Test: see details in 3.4.

Search: see details in 3.5.

Settings: see details in 4.1~4.7.

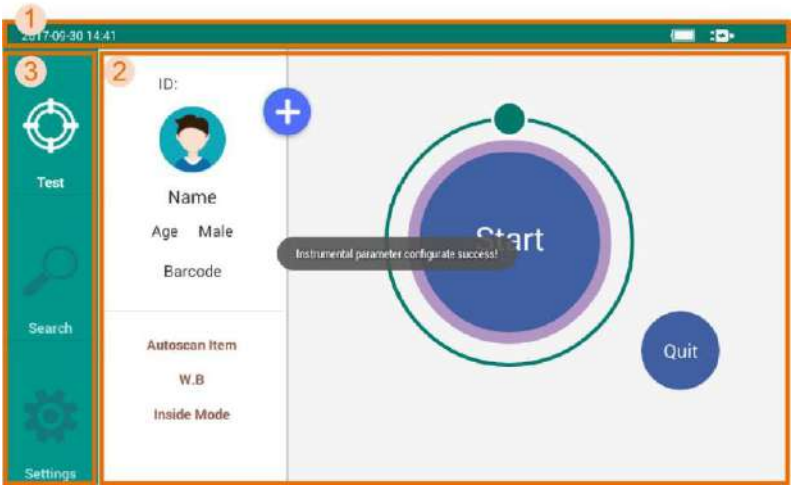


Fig.2-4 Main Interface

2.4 Performance Summary

2.4.1 Basic Parameters

Model	Operating Wavelength (nm)	Detection Range (mV)	Resolution (mV)
Getein 1100	635 ± 5	0 ~ 15000	1

2.4.2 Performance Indexes

Blank Count	Voltage of the blank QC card should be less than 100 mV
Linearity	r ≥ 0.95 in the detection range from 0 mV to 15000 mV
Repeatability	CV ≤ 2% within range [100-15000] mV; CV ≤ 10% within range [0-100) mV
Stability	The voltage variation of the same standard card with a fixed concentration tested within 1 hour should be within ±10%

2.4.3 Technical Specifications

Touch Screen	7-inch LCD touch screen, 1024 × 600
Communications	Two USB ports for barcode scanning and software update COM port for PC Ethernet port for LIS

Data Storage	10,000 data	
Dimensions	261mm × 241mm × 115mm	
Weight	2.0 kg	
Operating Environment	Temperature	10℃ ~ 35℃
	Relative humidity	≤ 70%
	Air pressure	70.0kPa ~ 106.0kPa
Storage	Temperature	-40℃ ~ +55℃
	Relative humidity	≤ 93%
	Air pressure	50.0kPa ~ 106.0kPa
Power Supply	100 - 240V~ 50/60Hz 60VA	

2.5 Installation Requirements

2.5.1 Environment

Dry, clean, flat and horizontal surface away from direct sunlight, wind, hot source, noise source, power interferences, electronic brush type engine and mechanical vibration.

2.5.2 Space Requirement

Place Getein 1100 at a horizontal position and reserve enough space for the reagents.

2.6 Setup

2.6.1 Loading Paper

1) Open the printer cover.
2) Place the printing paper into the printer with carbon sensitive surface facing the screen.
3) Pull out approximate 5 cm of paper from the roll, and then close the cover.

a). Open the printer cover b). Load paper c). Close the printer cover

Fig.2-5 Loading Paper

2.6.2 Barcode Scanner Connection (Optional)

Connect the barcode scanner via USB port in the lateral of the analyzer (see details in the instruction of scanner).

2.6.3 Lithium Battery (Optional)

1) The battery capacity can be shown by 4 icons. They are  which represent low, medium, high and full power respectively.
2) The charging time of lithium battery is 6 hours and the battery can work for at least 3 hours (Note: The charging time and working time will change over time).
3) To avoid being affected by the low power and extend battery lifetime, please charge the analyzer when a low battery is indicated .

2.6.4 Power Connection

1) Use the adapter packed together with Getein 1100.
   Power supply: 100 - 240V~, Frequency: 50/60Hz
2) Connect power with Getein 1100 through the AC/DC adapter.
3) Press the power switch to turn on the analyzer.

3. Operation

3.1 Preparations before Power On

Please confirm whether the analyzer is ready for use according to the following steps before turning on the power switch.

1) Check whether the power supply is ready or connected safely.

2) Check whether the printing paper is enough and correctly loaded.

3.2 Power On

Press the switch to turn on the analyzer, and then system will start its self-checking and then enter the Test Interface.

Test Interface mainly includes Patient Information, Test Card Information and Result Information. Users can input patient information and select test item, sample and test mode as required (Fig.3-1). Barcode can be scanned through the scanner or inputted by the user; No. is generated automatically and cannot be modified.

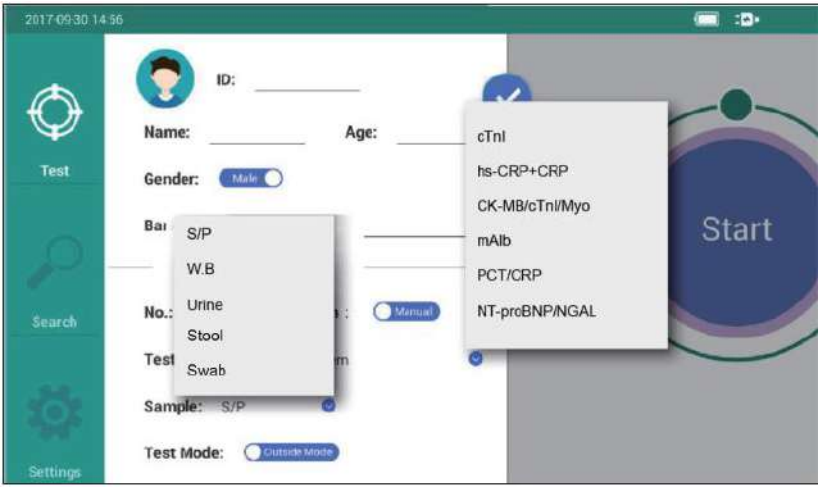


Fig.3-1 Test Interface

3.3 SD Card Calibration

To guarantee the accuracy of measurement and the comparability of data, calibration is required before patient samples testing. Please use the corresponding SD card to calibrate the analyzer before testing different batches of kits (Note: SD card for different batches cannot be exchanged).

Steps: Attach the SD card to the SD card recognition zone, and the analyzer would show the prompt. Click “OK” to import the test card parameters (Fig.3-2).

Note: User can also insert the SD card into the SD card slot to do the calibration.

Fig.3-2 SD Card Calibration

3.4 Sample Test

User can perform sample test by the following steps (Fig.3-3):

1) Edit patient's information if needed.
2) Click "Start" after inserting the card. Test item will be auto-recognized and the result will be shown on the screen after the test is completed. Users can also see the voltage waveform by sliding to the left.
3) Normally, the test card will auto-quit after testing. If not, click the "Quit" icon.

Fig.3-3 Sample Test

Note:

1) Do not switch the interfaces during the measurement.
2) Test items vary in sample volume and reaction time. Refer to theuser manual of the specific item for accurate information.

3.5 Result Query

3.5.1 Query

Click the “Search” icon to switch to result query interface. There are three ways to query results (Fig.3-4).

Fig.3-4 Query Interface

1) Input full or part of the Name or Sample ID (Fig.3-5).

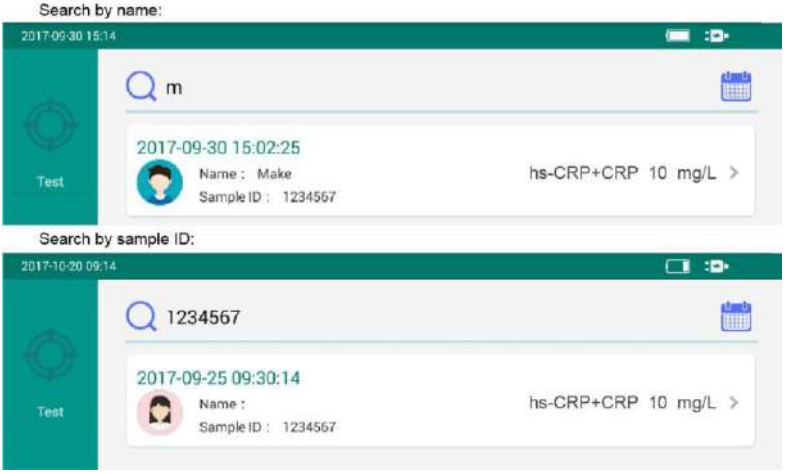


Fig.3-5 Search by Name and Sample ID

2) Select required Date & Time (Fig.3-6).

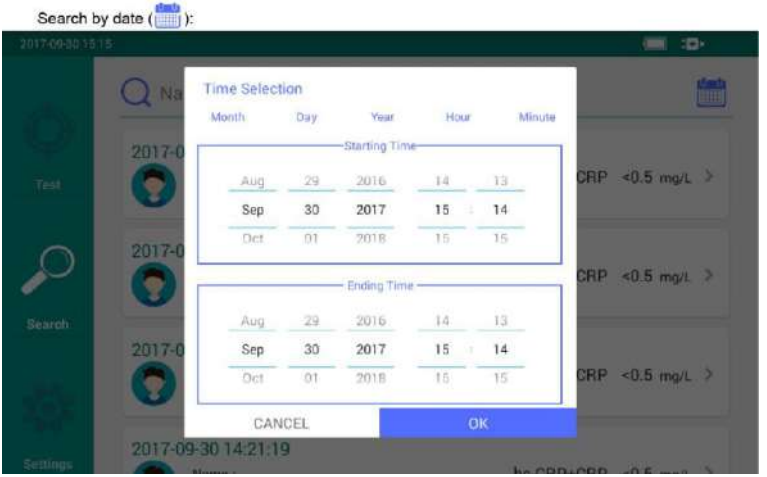


Fig.3-6 Search by Date & Time

3.5.2 Result Deletion

Select a result and slide it to the left. Click “Delete” and a prompt will be shown in the following interface (Fig.3-7). Then Click “OK” to delete it.

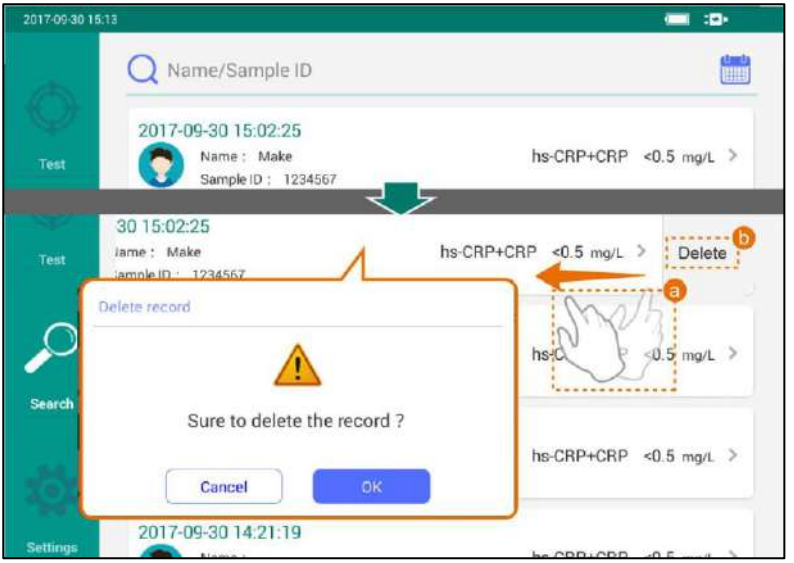


Fig.3-7 Result Deletion

3.5.3 Test Report

Click on the test result for the detailed test report (Fig.3-8). In the report interface, three icons “Print”, “Save” and “Upload” are listed. Slide to the left to view the test voltage waveform.

Print: click to print the test result.

Save: click to save the modifications.

Upload: click to transmit data to the information management system.

Fig.3-8 Test Report

Patient information is editable in case that user forgets to input or input wrong information. No., test item and result are not editable (Fig.3-9). Click the “Save” button after editing.

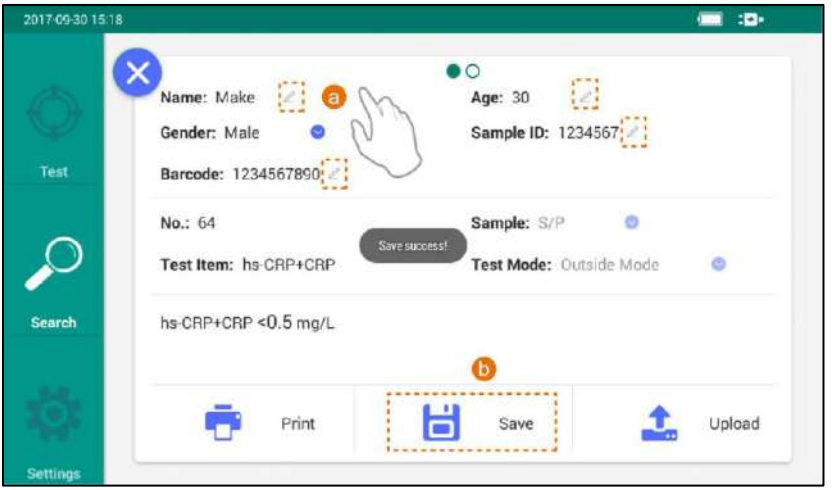


Fig.3-9 Edit Patient Information

3.6 Shutdown

In any interface, user can press the switch to shut off the analyzer directly.

3.7 Waste Disposal

Liquid waste, used test cards, consumables and other wastes, including instrument at the end of life, are considered as medical waste, industrial waste or source of infection. Please handle them properly in accordance with local regulations.

Biological hazard

- Follow and obey lab safety rules and guideline. Wear protective goggles, surgery gloves and laboratory coat to avoid the potential biological pollution risks.
- Disposal of medical wastes should be in accordance with the local regulations.

4.Settings

The installation and debugging of analyzer are performed before it leaves the factory. Operators can reset certain parameters in Settings to meet your laboratory's specific requirements.

Click the "Settings" icon to switch to the setting interface (Fig.4-1). There are 7 icons: Communications, Print Setting, Test Setting, Reaction Time, System Setting, System Version and Debug Mode.

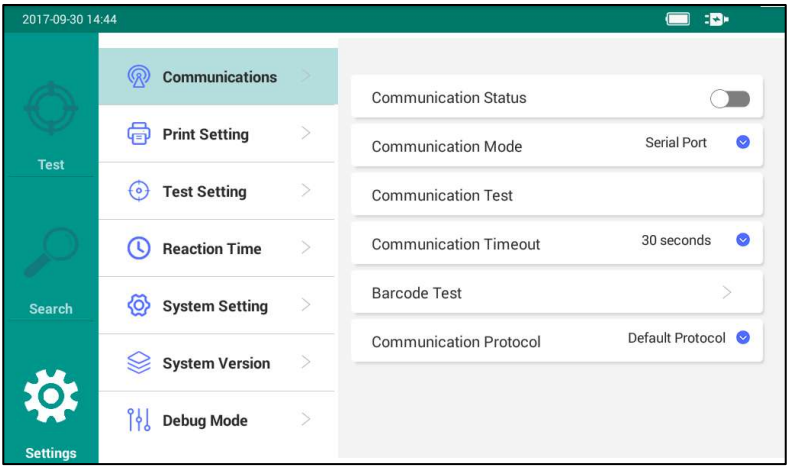


Fig.4-1 Settings

4.1 Communications Setting

It mainly includes Serial Port Status, Communication Mode, Communication Test, Communication Protocol, Communication Timeout and Barcode Test (Fig.4-2).

Note:

- Click " " to the right of Communication Status to enable communication function; the system baud rate is 9600.
- Communication Mode includes Serial Port and WiFi.
- Click Communication Test to send test data through the selected serial port or Ethernet port
- Communication Timeout (10s, 30s, 1min and 5min) can be selected as the disconnection standard of Getein 1100 with the host computer.
- Click Barcode Test to perform barcode testing with a barcode scanner. The test result will be displayed in Barcode Testing.
- Communication Protocol should be selected by or with the assistance of after-sales personnel.

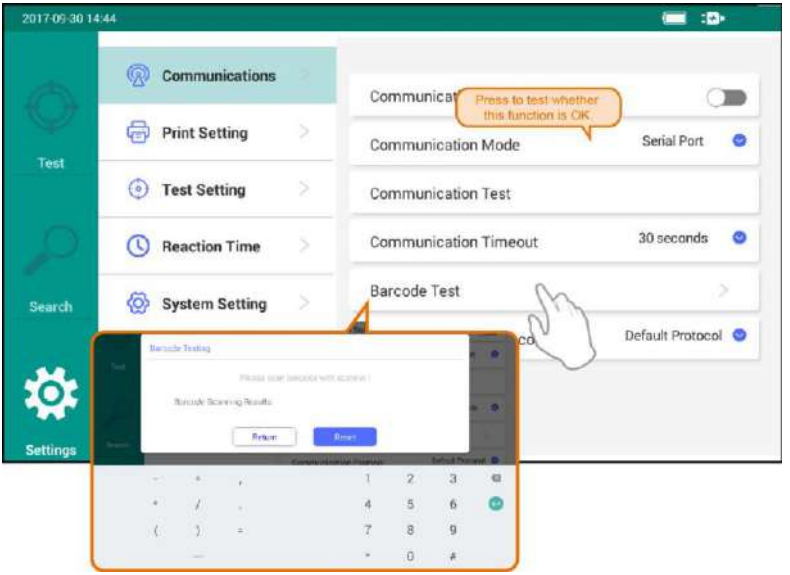


Fig.4-2 Communications Setting

4.2 Print Setting

It mainly includes Auto Print Status and Print Test (Fig.4-3).

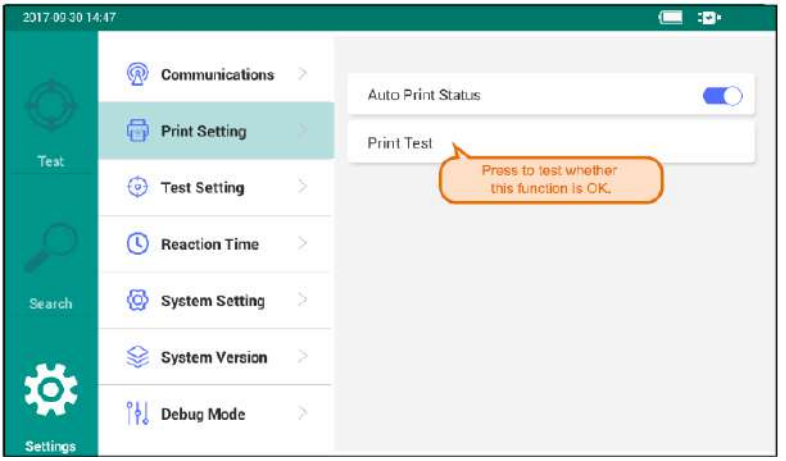


Fig.4-3 Print Setting

4.3 Test Setting

It mainly includes Sample and Test Mode (Fig.4-4).

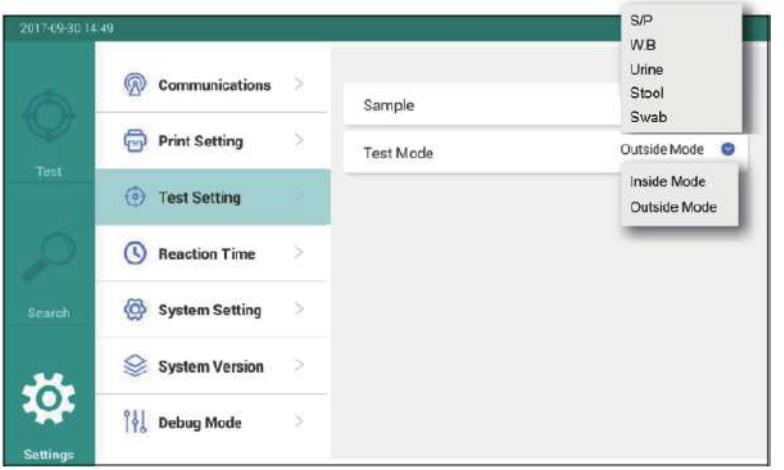


Fig.4-4 Test Setting

4.4 Reaction Time

This interface displays the reaction time imported from SD card (Fig.4-5).

Note: Do not change the reaction time manually unless it is incorrect.

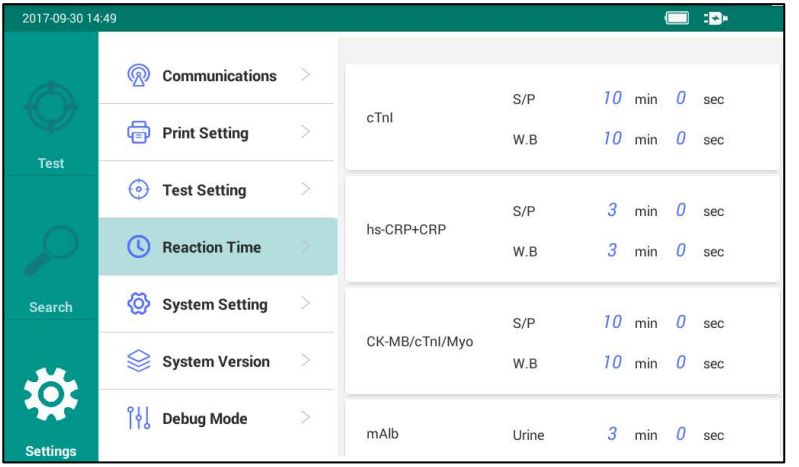


Fig.4-5 Reaction Time

4.5 System Setting

It mainly includes Screen Saver, Language, System Date/Time and Factory Reset (Fig.4-6).

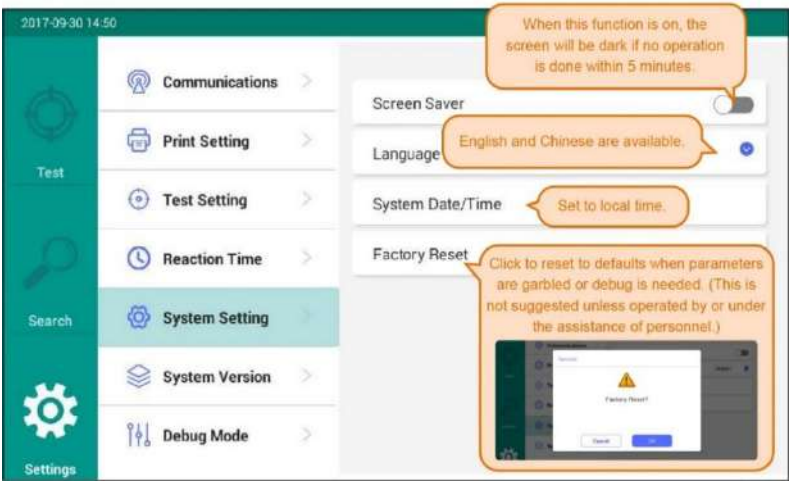


Fig.4-6 System Setting

4.6 System Version

In this interface, user can check the version of analyzer, serial number (SN) and the number of compatible assays (Fig.4-7).

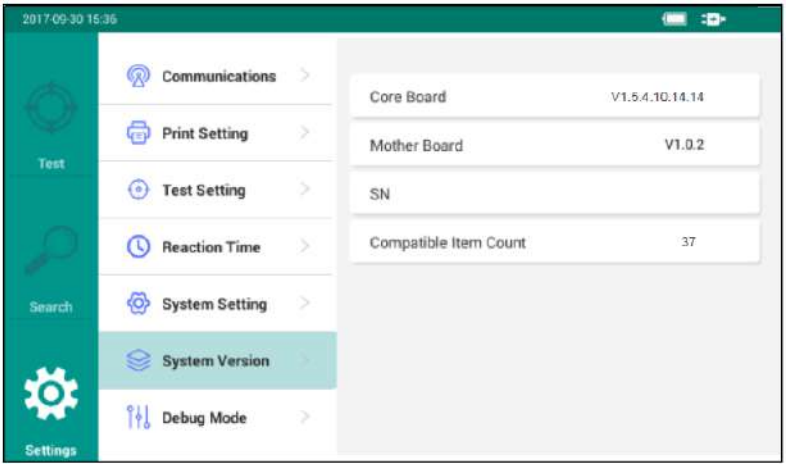


Fig.4-7 System Version

4.7 Debug Mode

Debugging functions are for Getein's after-sales support to debug the instrument. To avoid system parameters being modified by accident, users are not granted the access to the debugging interface.

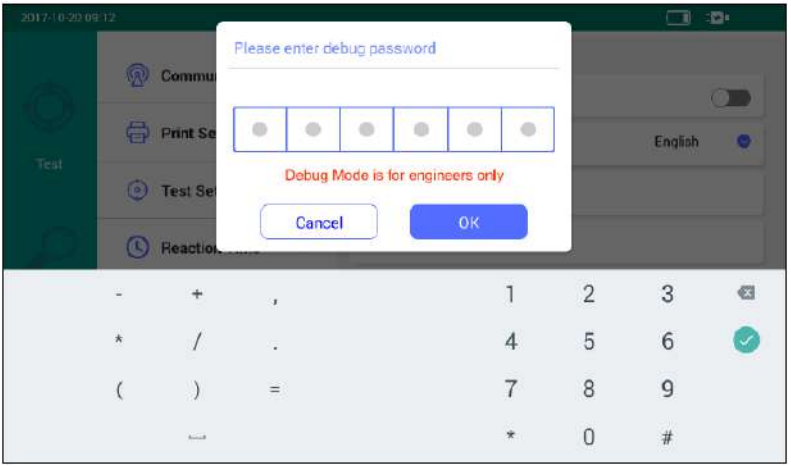


Fig.4-8 Debug Mode

5.Maintenance and Troubleshooting

5.1 Maintenance

Getein 1100 requires minimal maintenance. Clean the surface with wet cloth and 70% ethanol (Turn off the analyzer and ensure the power plug is unconnected before cleaning in case of short circuit and electric shock). Do not clean any internal parts or inner surface. Strong bleach solution (0.5% or higher) is forbidden as oxidant solvent may damage the surface or the touch screen of analyzer.

Maintenance Item	Every Day	Every Week	Every Month	When needed
Dedusting		√		
SD Calibration				A new batch used
Replace Printing Paper				Printing paper used up
Replace LED Lamp				Light intensity weakened
Replace Lithium Battery				Battery damaged

5.2 Precautions

1) Please place the analyzer at a horizontal position for good operation.
2) Under power outage situation, please wait for 30 seconds before restarting the analyzer.
3) Only reagents supplied by Getein can be used on Getein 1100. Refer to the specific user manual for more details.
4) Preheat the analyzer for 20 minutes before testing to ensure the accuracy and reliability of results.
5) Dispose of the used test cards in accordance with the local regulations, as the sample and reagents may have potential risk of biological infections.
6) Please operate the analyzer according to the requirements of the instruction for long-term reliable work.
7) The personnel who operate the PC software should be familiar with the Windows XP, Windows 7 system together with the software installation and uninstallation.
8) Results will be stored automatically in the analyzer and can be recovered automatically after the analyzer is powered off. All data will be cleared if users select "Factory Reset" function.
9) Do not disassemble the analyzer. Operation done by laypeople may damage analyzer.
10) Please charge the analyzer when low battery is indicated.

5.3 Troubleshooting

If there is a malfunction during operating, alarm prompts will pop up.

Error	Cause	Solution
Invalid test card	No C line or shallow C line	Check the shelf life and test again with a new card
Sample type selection error	Inconsistent test item and sample type	Correct the sample mode, and re-test
Test item recognition error	SD card calibration not performed or barcode recognition failure	Do SD card calibration. Change a new card with a clear barcode
Lot error	Inconsistent test card with information stored in the analyzer	Re-calibration with the SD card (same Lot No. with the test card)

6. Appendix

6.1 Copyright

Getein Biotech, Inc.
Instrument Name: Immunofluorescence Quantitative Analyzer
Model: Getein 1100
Version: V3.1
Issue Date: 2023.11

6.2 Statement

- Getein Biotech Inc. owns the copyright to this non-published manual and has the right to take it as confidential information. This manual is provided for operation, maintenance and repair for Getein 1100 only. Anyone has no right to make this manual public.
- This manual contains proprietary information which is protected by copyright law. Copyright of this manual belongs to Getein Biotech Inc. Any content in this manual cannot be copied, reproduced or translated into other languages without the written consent of Getein.
- No warranties of any kind are made by Getein regarding this manual. Getein takes no responsibility for any consequential damages caused by errors in this manual.
- Getein holds the authority of the modification for contents of the manual without informing prior to it.

6.3 Manufacturer Responsibility

- Getein will only be responsible for instrument safety, reliability and performance in following cases: installation, upgrade, calibration, repair and maintenance are done by personnel assigned by Getein; users develop a regular maintenance plan and perform strictly.
- Hospitals or institutions who use this instrument should make a regular maintenance plan and perform strictly, otherwise inappropriate operations may lead to instrument failure or even endanger people's health.
- Getein will conditionally provide circuit diagram, calibration specifications and other documents required to assist the appropriate personnel to finish maintenance or repair under situations users can do themselves.
- Use only as directed. Getein will take no responsibility for protection failure of the analyzer caused by the analyzer being used in a manner not consistent with the instructions in this manual.

6.4 Analyzer Lifespan

The lifespan of Getein 1100 is 8 years (continuous working time no more than eight hours every day) under standardized operation and proper maintenance.

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 Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

Pursue excellence

Deliver health

SVE6600052-RC

Getein
Biotech, Inc.
Stock Code: 603387

- Cardiac Markers
- Specific Protein and Rheumatism
- Coagulation Markers
- Inflammation
- Diabetes Mellitus
- Metabolic Marker
- Renal Function
- Thyroid Function
- Infectious Disease
- Reproduction /Fertility
- Tumor Markers
- Others

Getein 1600

Immunofluorescence Quantitative Analyzer

Hello,The Future of POCT!

Getein 1600

Immunofluorescence Quantitative Analyzer

Meeting multiple needs of emergency department and central laboratory

Intellectualized Software System

Android system

User-friendly interface

Diversified test modes: random, batch, STAT

LIS/HIS connectivity

WIFI/4G data transmission

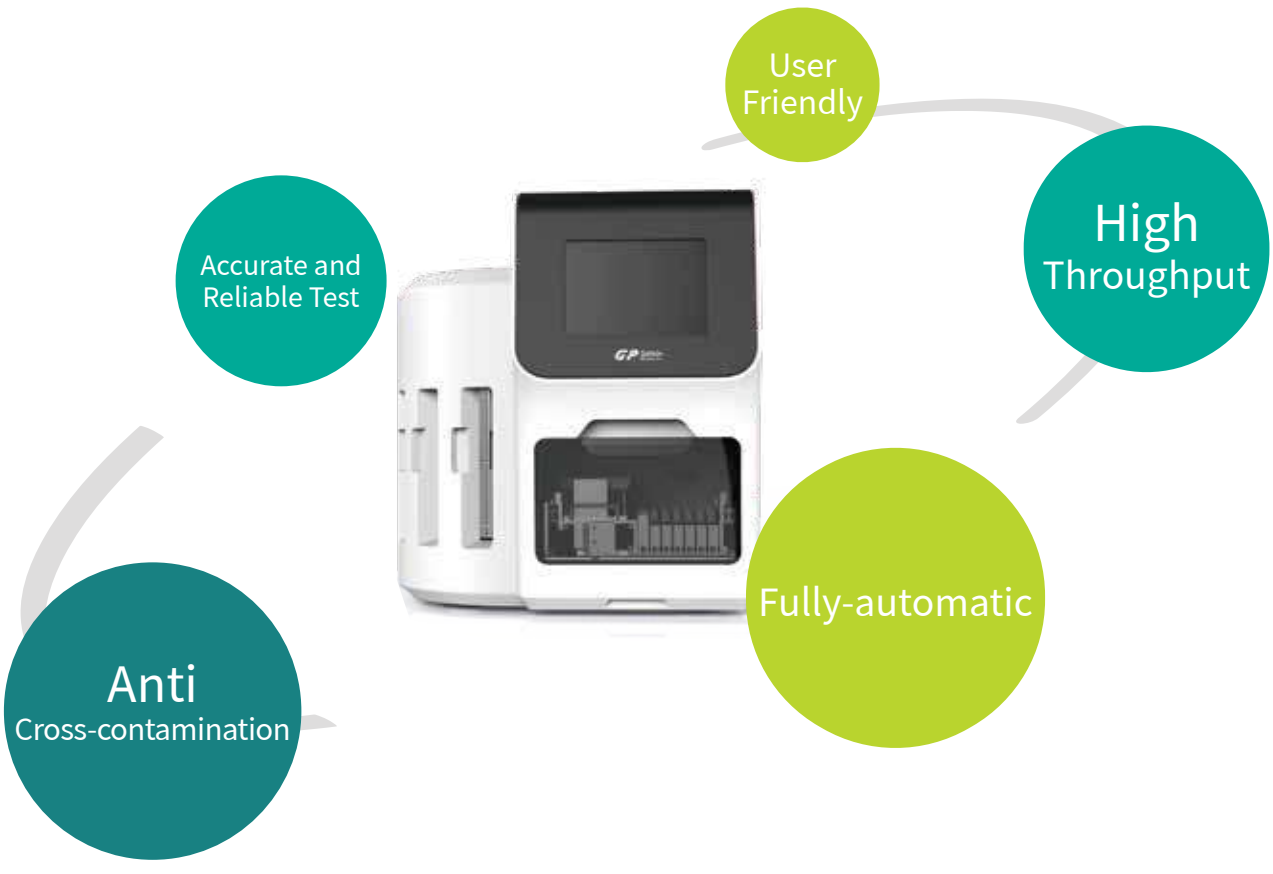
Network printer

Simple Operation

Fully-automatic detection

Real-time monitoring of samples and consumables

Visualized reagent interface



High Throughput

48 samples/run

Continuous loading of different test items

Up to 150 tests/hour

Accurate and Reliable Test Results

Fully-automatic sample adding system

Disposable tips with filter elements, which avoid cross-contamination

Automatic calibration, dilution and sample loading

Fully-automatic quality control

25 °C temperature control

Leading the New Era of POCT !

TRADITIONAL POCT VS AUTOMATIC POCT

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

Traceability of Results

Automatic barcode scanning of test items

Automatic recognition of reagents

Easy for Standardized Management

Fully-automatic sample loading and detection

Standard SOP documented

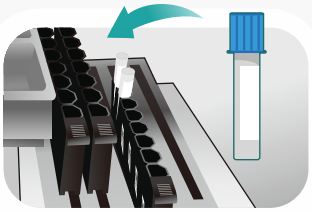
Meet the requirements of clinical laboratory standards

TECHNICAL PARAMETERS

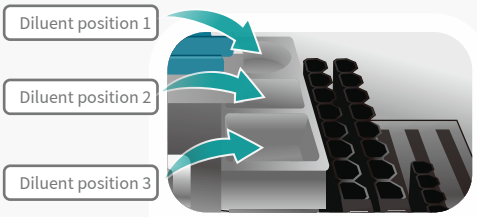
Methodology	Immunofluorescence
Result	Quantitative
Throughput	48 samples/run, 150 tests/hour
Sample Type	Whole blood, plasma, serum, urine, fingertip blood
Storage Capacity	500000 data
Language	English/Chinese
Screen Display	10.4 inch touch screen
Power Supply	100-240 V~50/60 Hz
Working Environment	Relative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

TEST PROCEDURE

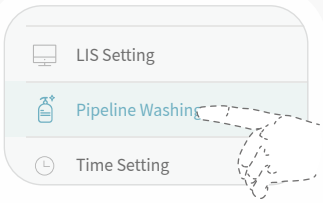
1 Insert cartridge into the instrument, the instrument will recognize the test item automatically.



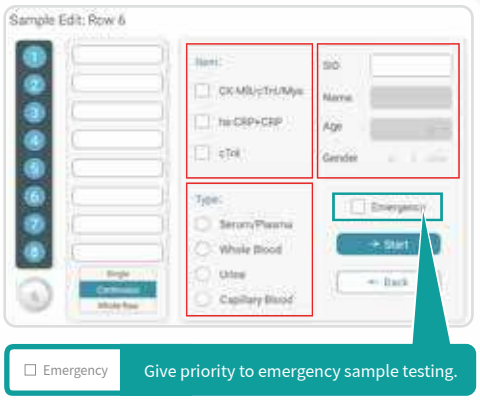
2 Insert the sample holder into the sample chamber.



3 Put the diluent into the instrument.

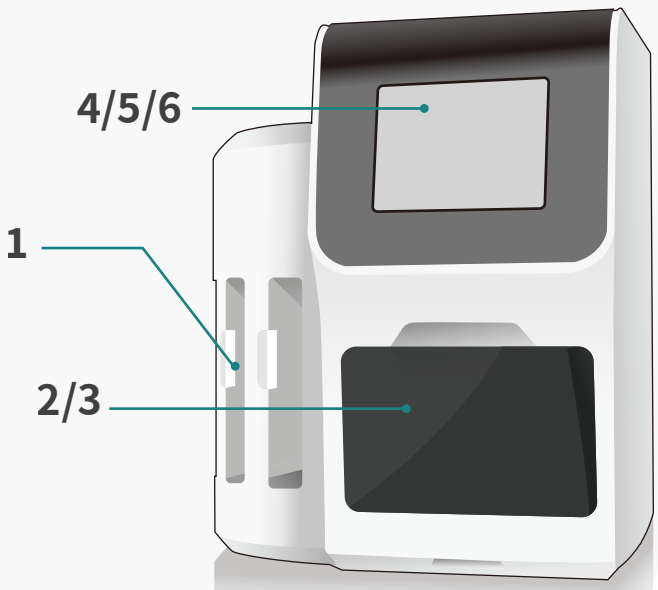


4 Perform pipeline washing before daily test.



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

6 The test results will be shown at Result interface.



*The final interpretation is reserved by Getein Biotech

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	QUALIFICATION
Cardiac Markers						
IF2019	hs-cTnI	Myocardial infarction	0.040 ng/mL	S/P/WB	0.010-50.000 ng/mL	NMPA CE
IF2001	cTnI	Myocardial infarction	0.10 ng/mL	S/P/WB	0.10-50.00 ng/mL	NMPA CE
IF2098	TnT	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	NMPA CE
IF2089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	NMPA CE
IF2002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	NMPA CE
IF2005	CK-MB/cTnI/Myo	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL Myo: 70.0 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 30.0-600.0 ng/mL	NMPA CE
IF2012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL	CE
IF2014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.00-120.00 ng/mL	NMPA CE
IF2016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL H-FABP: 6.36 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 2.00-100.00 ng/mL	NMPA CE
IF2018	CK-MB	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	CE
Coagulation Markers						
IF2006	D-Dimer	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	NMPA CE
Inflammation						
IF2003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3.0 mg/L 10.0 mg/L	S/P/WB/ Fingertip blood	0.5-200.0 mg/L	NMPA CE
IF2007	PCT	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB/ Fingertip blood	0.05-50.00 ng/mL	NMPA CE
IF2015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.10 ng/mL CRP: 3.0 mg/L	S/P/WB/ Fingertip blood	0.10-50.00 ng/mL 0.5-200.0 mg/L	NMPA CE
IF2044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	NMPA CE
IF2090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Peripheral blood	5.0-200.0 mg/L 0.5-200.0 mg/L	NMPA CE
IF2088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	NMPA CE
Renal Function						
IF2008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.50-10.00 mg/L	NMPA CE
IF2009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	NMPA CE
IF2010	NGAL	Acute kidney injury	Serum: 200.0 ng/mL Urine: 100.0 ng/mL	S/Urine	50.0-5000.0 ng/mL	NMPA CE
IF2011	β_2-MG	Acute and chronic kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	NMPA CE
Diabetes Mellitus						
IF2017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	NGSP NMPA IFCC CE
Metabolic Marker						
IF2031	25-OH-VD	Osteomalacia, osteoporosis	30.00-50.00 ng/mL	S/P	8.00-70.00 ng/mL	NMPA CE
Thyroid Function						
IF2024	TSH	Thyroid malfunction	0.27-4.20 μIU/mL	S/P	0.10-50.00 μIU/mL	NMPA CE
IF2022	T3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	NMPA CE
IF2023	T4	Hyperthyroidism, hypothyroidism	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	NMPA CE
NEW IF2067	fT3	Hyperthyroidism, hypothyroidism	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	CE
NEW IF2068	fT4	Hyperthyroidism, hypothyroidism	12.00-22.00 pmol/L	S/P/WB	0.30-100.00 pmol/L	CE

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

Coming Soon: Folate…

Getein 1600

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508/68568594
Fax: +86-25-68568500
E-mail: sales@getein.com.cn; overseas@getein.com.cn
Web: www.getein.com

ISO ISO13485 FSC CE NMPA NGSP IFCC IVD

EC Declaration of Conformity

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

Ref. No.:20220513-A07

Manufacturer
(Name, Address)

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

Authorized Representative
(Name, Address)

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

Medical device

No.	Product Name
1	Getein 1600 Immunofluorescence Quantitative Analyzer
2	Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)
3	NT-proBNP Fast Test Kit (Immunofluorescence Assay)
4	hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay)
5	NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay)
6	CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay)
7	D-Dimer Fast Test Kit (Immunofluorescence Assay)
8	PCT Fast Test Kit (Immunofluorescence Assay)
9	CysC Fast Test Kit (Immunofluorescence Assay)
10	mAlb Fast Test Kit (Immunofluorescence Assay)
11	NGAL Fast Test Kit (Immunofluorescence Assay)
12	β2-MG Fast Test Kit (Immunofluorescence Assay)
13	CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)
14	HCG+β Fast Test Kit (Immunofluorescence Assay)
15	H-FABP Fast Test Kit (Immunofluorescence Assay)
16	PCT/CRP Fast Test Kit (Immunofluorescence Assay)
17	CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay)
18	HbA1c Fast Test Kit (Immunofluorescence Assay)
19	NT-proBNP/NGAL Fast Test Kit (Immunofluorescence Assay)
20	CK-MB Fast Test Kit (Immunofluorescence Assay)
21	hs-cTnI Fast Test Kit (Immunofluorescence Assay)
22	T3 Fast Test Kit (Immunofluorescence Assay)
23	T4 Fast Test Kit (Immunofluorescence Assay)
24	TSH Fast Test Kit (Immunofluorescence Assay)
25	Scr Fast Test Kit (Immunofluorescence Assay)
26	PLGF Fast Test Kit (Immunofluorescence Assay)

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

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

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

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

Applicable coordination standards

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

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

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

General Manager Enben Su

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

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

CE

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

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

Holds Certificate No: **MD 728432**

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

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

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

...making excellence a habit.™

Certificate No: **MD 728432**

Registered Scope:

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

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

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

Certificate No: **MD 728432**

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

Original Registration Date: 2020-05-29

Effective Date: 2023-07-26

Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

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

CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

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

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Getein
Biotech, Inc.