

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

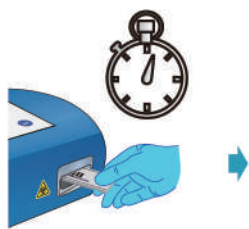


Result Show and Print

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

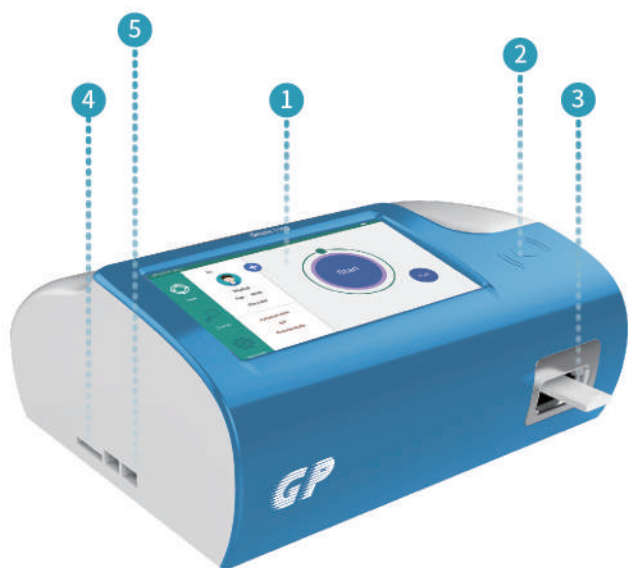
Continuous test for 3 hours with optional lithium battery



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...





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
<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
- 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.
2. Roldán V, Marín F, Muña B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated

Atrial Fibrillation Patients. *J Am Coll Cardiol.* 2011 Apr 11.

3. Sakamoto K, Yamamoto Y, Okamatsu H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. *Hellenic J Cardiol.* 2011 Mar-Apr; 52(2):123-127.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

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

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



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.bio-GP.com.cn



D-Dimer Control

REF QC006

User Manual

PRODUCT NAME

D-Dimer Control

PRODUCT SPECIFICATION

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

INTENDED USE

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

PRINCIPLE

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

CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

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

The kit for Getein1600 contains:

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

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

MATCHING EQUIPMENTS

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

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months at -20°C and for 90 days at 2 ~ 8°C to avoid light.

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

MATERIALS REQUIRED BUT NOT PROVIDED

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

TEST PROCEDURE

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

3. Dissolve each control material with 1 ml distilled water.
4. Close the vial and mix gently until all contents are dissolved completely. Avoid violent shaking or foam formation.
5. Keep it at room temperature for 5 ~ 10 minutes before use.
For FIA8000/FIA8600/Getein1100:

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

For Getein1600:

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

ASSIGNED VALUES

Refer to values listed on the target value sheet.

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

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

PERFORMANCE CHARACTERISTICS

1. Homogeneity: $\leq 15\%$
2. Accuracy range: Refer to the target value sheet

LIMITATIONS

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













NOTES

1. For *in vitro* diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Avoid multiple freeze-thaw cycles.
4. Do not use the product if it is contaminated with bacteria.

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

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WZK04-S-04



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.bio-GP.com.cn

Please contact Getein if you have any questions.

Getein 1100

Immunofluorescence Quantitative Analyzer

User Manual



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 <i>instructions for use</i> or consult electronic <i>instructions for use</i>
	Serial number
	<i>In Vitro</i> 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

Warnings, Precautions and Limitations	i
Symbols & Description	ii
1.Introduction.....	1
1.1 Intended Use	1
1.2 Product Description	1
1.3 Product Principle	1
1.3.1 Overview: Running a Test	1
1.3.2 Working Principle.....	2
1.4 List of Icons	2
2.Installation.....	3
2.1 Unpacking	3
2.2 Analyzer Configuration	4
2.3 Main Interface	4
2.4 Performance Summary	5
2.4.1 Basic Parameters	5
2.4.2 Performance Indexes	5
2.4.3 Technical Specifications.....	5
2.5 Installation Requirements.....	6
2.5.1 Environment	6
2.5.2 Space Requirement.....	6
2.6 Setup.....	7
2.6.1 Loading Paper	7
2.6.2 Barcode Scanner Connection (Optional).....	7
2.6.3 Lithium Battery (Optional)	7
2.6.4 Power Connection.....	7
3. Operation	8
3.1 Preparations before Power On	8
3.2 Power On	8
3.3 SD Card Calibration	8
3.4 Sample Test	9
3.5 Result Query	10
3.5.1 Query	10
3.5.2 Result Deletion.....	11
3.5.3 Test Report	12
3.6 Shutdown.....	13
3.7 Waste Disposal	13

4.Settings	14
4.1 Communications Setting.....	14
4.2 Print Setting	15
4.3 Test Setting	16
4.4 Reaction Time	16
4.5 System Setting	17
4.6 System Version.....	17
4.7 Debug Mode	18
5.Maintenance and Troubleshooting	19
5.1 Maintenance.....	19
5.2 Precautions	19
5.3 Troubleshooting.....	20
6. Appendix.....	21
6.1 Copyright	21
6.2 Statement	21
6.3 Manufacturer Responsibility.....	21
6.4 Analyzer Lifespan	22

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

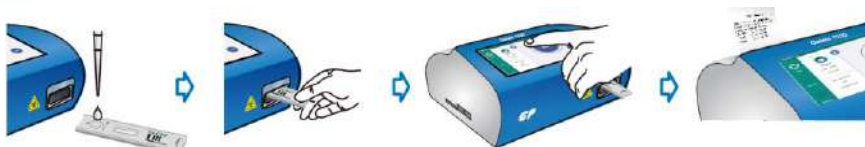
Getein 1100 is used to measure concentration of biomarkers in human whole blood, serum, plasma, urine, stool and swabs. The results can be used as an aid in clinical diagnosis of laboratory and point of care testing.

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

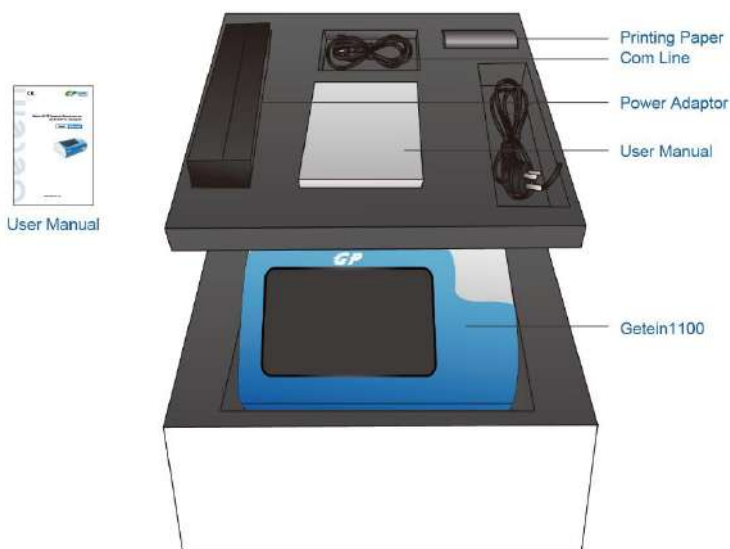


Fig.2-1 Getein 1100 and Main Accessories

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.

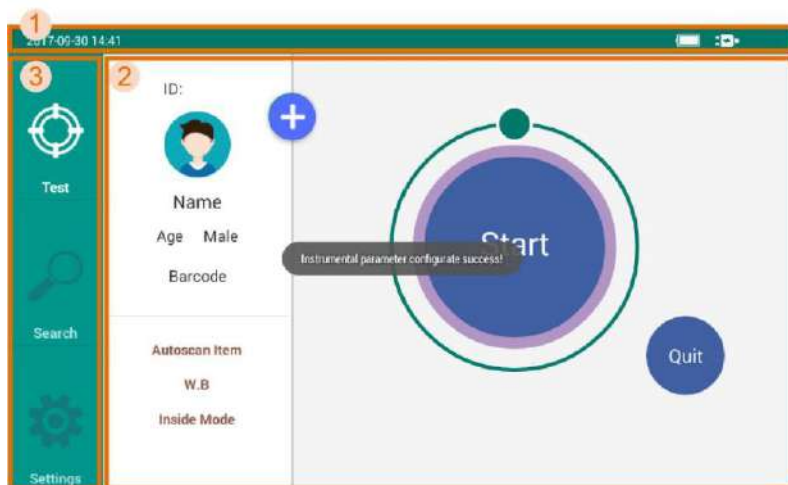


Fig.2-4 Main Interface

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	$r \geq 0.95$ 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°C ~ 35°C
	Relative humidity	≤ 70%
	Air pressure	70.0kPa ~ 106.0kPa
Storage	Temperature	-40°C ~ +55°C
	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.

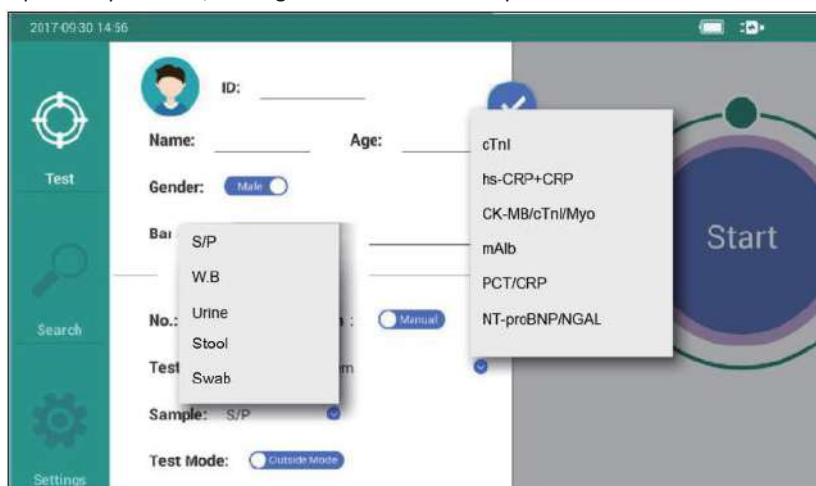


Fig.3-1 Test Interface

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.

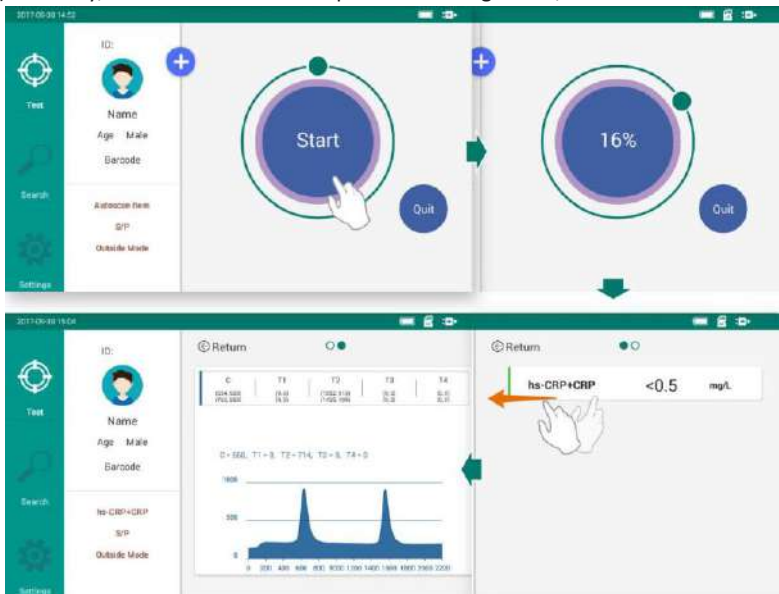


Fig.3-3 Sample Test

Note:

- 1) Do not switch the interfaces during the measurement.
- 2) Test items vary in sample volume and reaction time. Refer to the user 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).

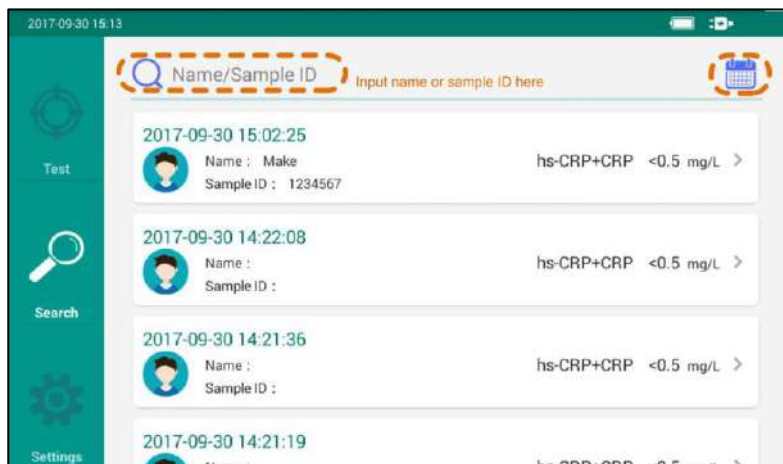


Fig.3-4 Query Interface

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

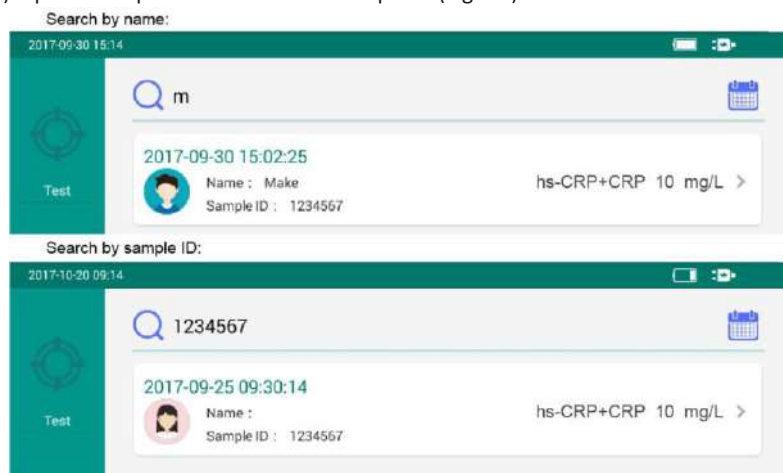


Fig.3-5 Search by Name and Sample ID

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

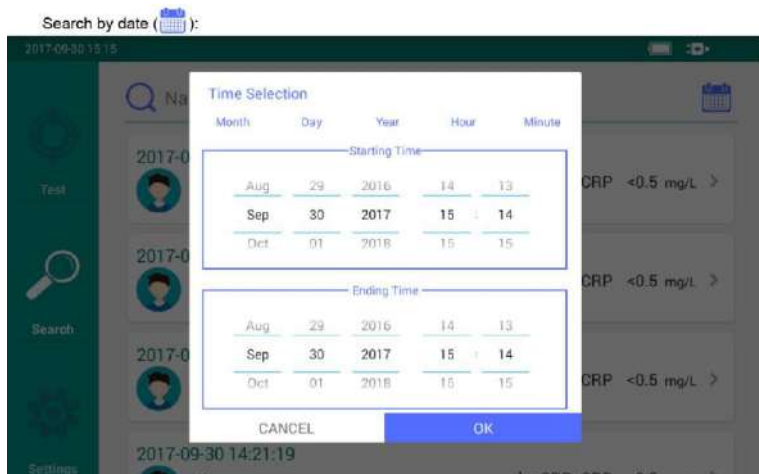


Fig.3-6 Search by Date & Time

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.

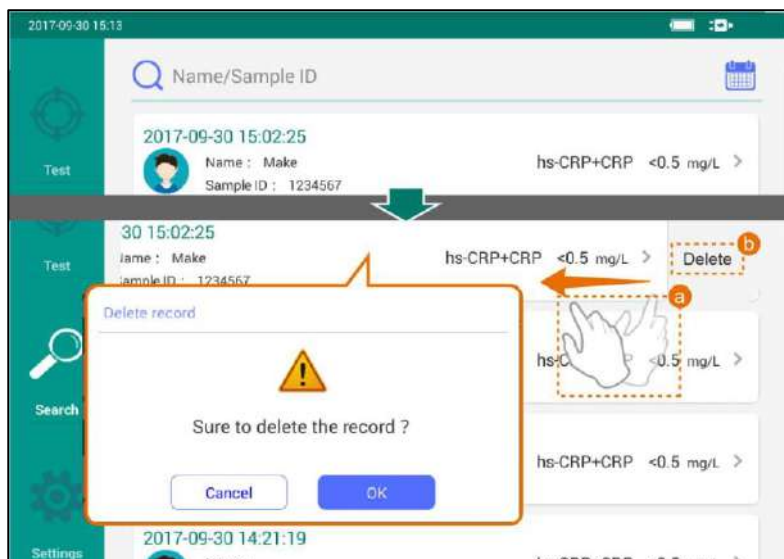


Fig.3-7 Result Deletion

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.

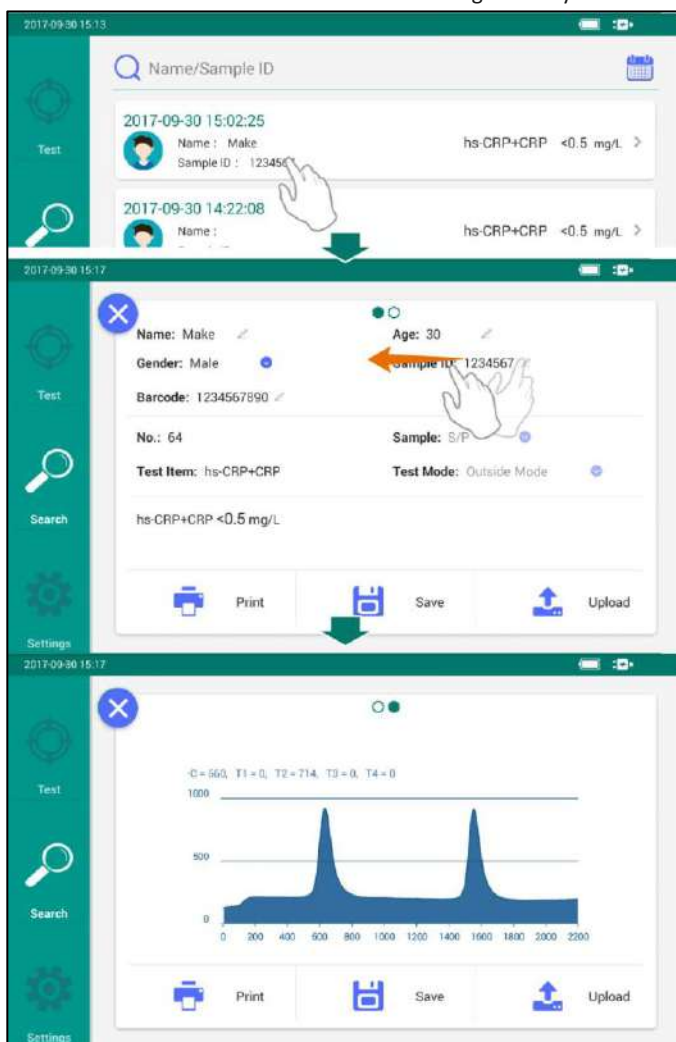


Fig.3-8 Test Report

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.

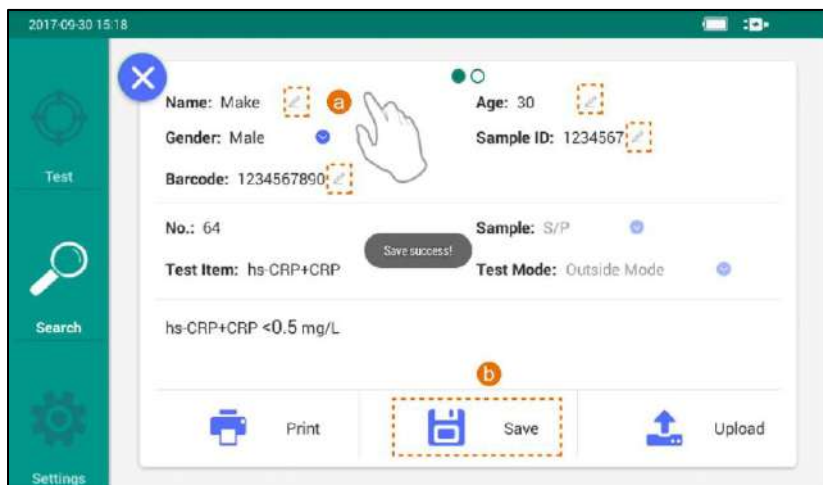


Fig.3-9 Edit Patient Information

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.

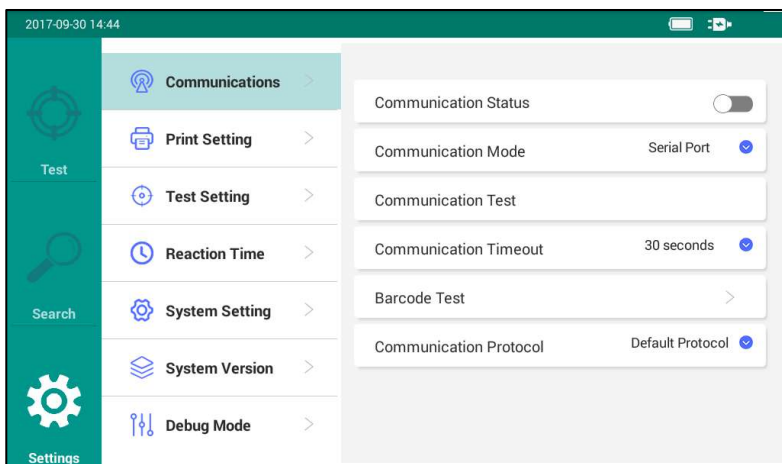



Fig.4-1 Settings

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 Gepin 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.

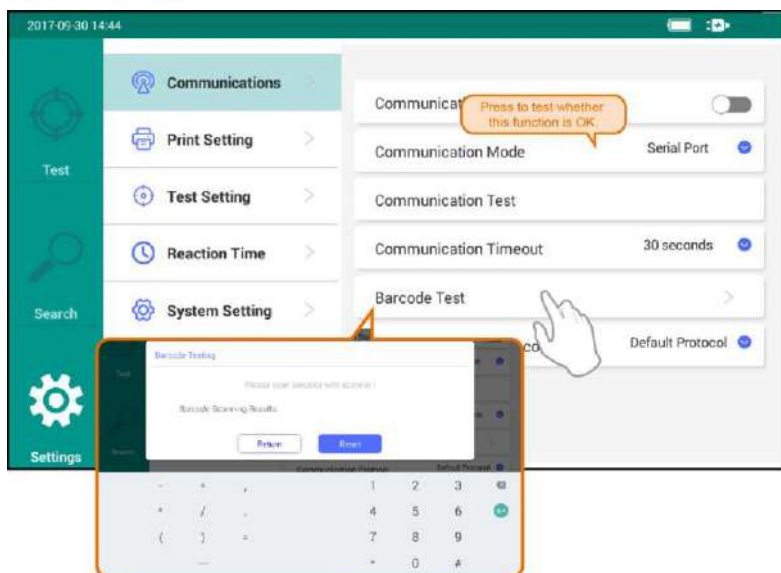


Fig.4-2 Communications Setting

4.2 Print Setting

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

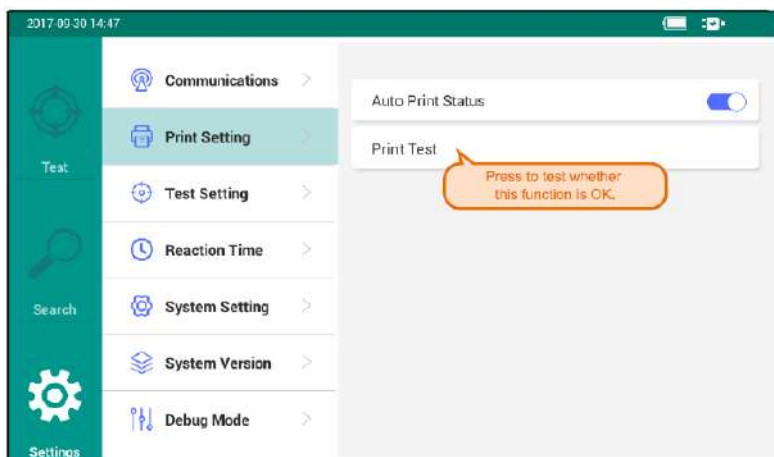


Fig.4-3 Print Setting

4.3 Test Setting

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

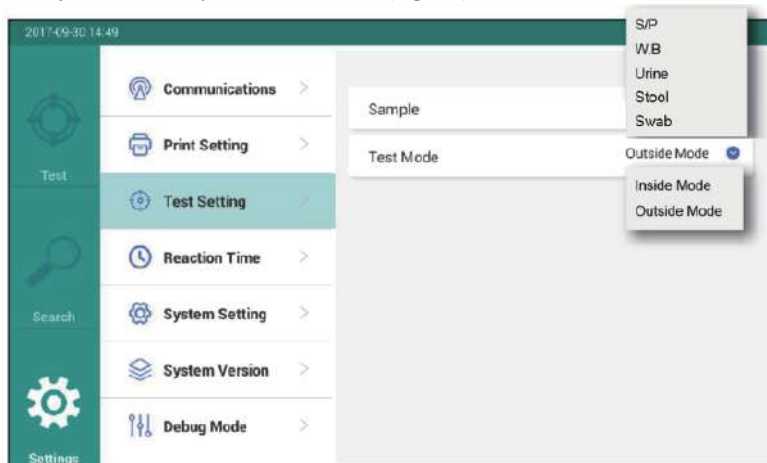


Fig.4-4 Test Setting

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.

2017-09-30 14:49

Test

Search

Settings

Communications

Print Setting

Test Setting

Reaction Time

System Setting

System Version

Debug Mode

cTnI

S/P

10 min 0 sec

W.B

10 min 0 sec

hs-CRP+CRP

S/P

3 min 0 sec

W.B

3 min 0 sec

CK-MB/cTnI/Myo

S/P

10 min 0 sec

W.B

10 min 0 sec

mAlb

Urine

3 min 0 sec

Fig.4-5 Reaction Time

4.5 System Setting

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

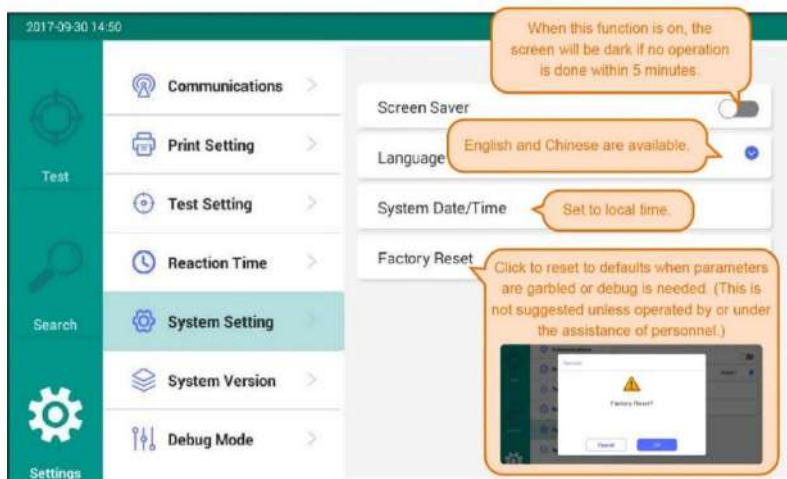


Fig.4-6 System Setting

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).

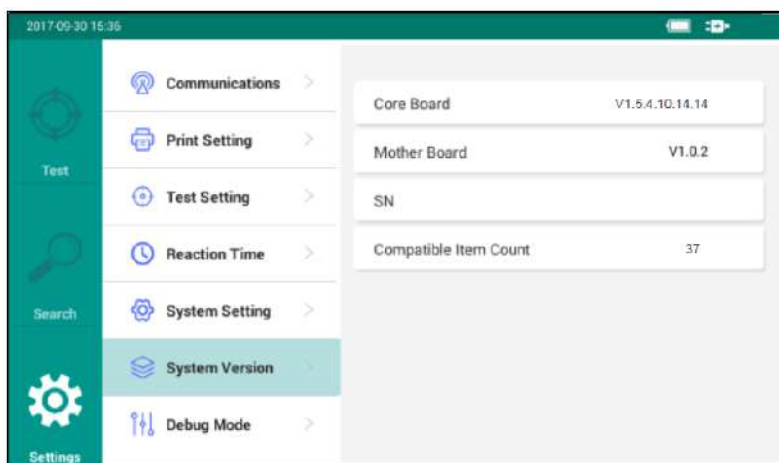


Fig.4-7 System Version

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.

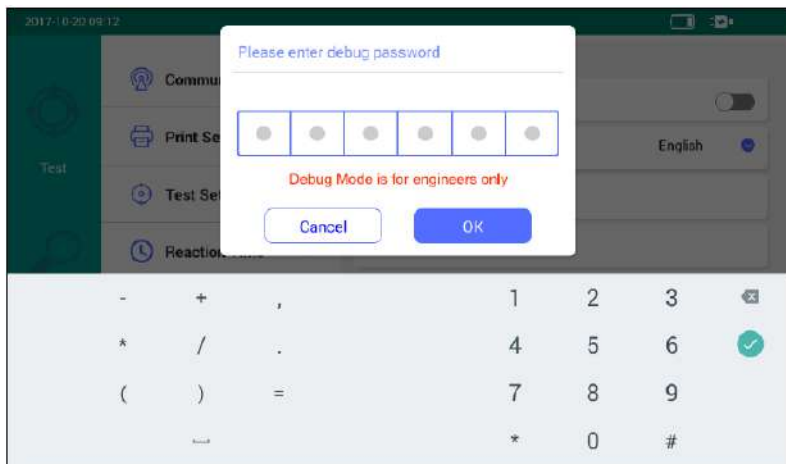


Fig.4-8 Debug Mode

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: ImmunofluorescenceQuantitativeAnalyzer

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 N° 18, CP 29006, Málaga, Spain

Tel: +34951214054

Pursue excellence

Deliver health