EC Declaration of Conformity

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

Ref. No.:20220513-F02

Manufacturer
(Name, Address)

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

Authorized Representative
(Name, Address)

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

Medical device

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

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Location: Moldova

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

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

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

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

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

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

General Manager Enben Su

Nanjing, 13th may 2022

(place and date of issue)

Enben Su

(name and signature or equivalent marking of authorized person)

CE

EC Declaration of Conformity

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

Ref. No.:20220513-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

Getein Biotech, Inc.
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Document No.: GP-GMSQ-2023121301

Letter of Authorization

To whom it may concern,

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

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

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

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

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

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

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Getein Biotech, Inc.
Seal & Signature

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

GP CE IVD

CK-MB/cTnI/Myo Control

REF QC016

User Manual

PRODUCT NAME

CK-MB/cTnI/Myo Control

PRODUCT SPECIFICATION

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

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of CK-MB/cTnI/Myo on the Getein Platforms.

PRINCIPLE

The lyophilized CK-MB/cTnI/Myo control is prepared from dissolving stable and high quality recombinant CK-MB/cTnI/Myo 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. CK-MB/cTnI/Myo Control - Level 1
   CK-MB/cTnI/Myo Control - Level 2
   CK-MB/cTnI/Myo Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. CK-MB/cTnI/Myo Control - Level 1
   CK-MB/cTnI/Myo Control - Level 2
   CK-MB/cTnI/Myo Control - Level 3
2. User manual: 1 piece/box
3. Quality control holder - Level 1
   Quality control holder - Level 2
   Quality control holder - Level 3

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

MATCHING EQUIPMENTS

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

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months at -20℃ and for 30 days at 2 ~ 8℃ to avoid light.
OPENED: The product is stable for 7 days at 2 ~ 8℃ if kept capped in orginal container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70℃.

MATERIALS REQUIRED BUT NOT PROVIDED

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

TEST PROCEDURE

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

3. Dissolve each control material with 1 ml distilled water.
4. Gently mix until all material has dissolved. Avoid violent shaking.
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. Match each vial with corresponding quality control holder.
8. Insert quality control holder into sample holder.
9. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

ASSIGNED VALUES

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

PERFORMANCE CHARACTERISTICS

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

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

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

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

Thank you for purchasing CK-MB/cTnI/Myo Control.
Please read this user manual carefully before operating to ensure proper use.

Version: WZK15-S-02

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Please contact Getein if you have any questions.

CE IVD

CK-MB/cTnI/Myo

Fast Test Kit

(Immunofluorescence Assay)

User Manual

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

INTENDED USE

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

SUMMARY

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

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

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

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

PRINCIPLE

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

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of CK-MB, cTnI and Myo in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to LIS and HIS.

CONTENTS

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

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

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

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).

5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME *(for Getein1100): 100 µl*.

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***100 µl*** of sample (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
8. *Reaction time: 15 minutes.* Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

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

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

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

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

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

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

PERFORMANCE CHARACTERISTICS

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

Method Comparison:

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

LIMITATIONS

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

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

REFERENCES

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

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF09-S-02

Getein Biotech, Inc.
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D-Dimer Control

REF QC006

User Manual

PRODUCT NAME

D-Dimer Control

PRODUCT SPECIFICATION

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

INTENDED USE

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

PRINCIPLE

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

CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

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

The kit for Getein1600 contains:

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

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

MATCHING EQUIPMENTS

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

STORAGE AND STABILITY

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

MATERIALS REQUIRED BUT NOT PROVIDED

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

TEST PROCEDURE

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

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

For FIA8000/FIA8600/Getein1100:

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

For Getein1600:

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

ASSIGNED VALUES

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

PERFORMANCE CHARACTERISTICS

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

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WZK04-S-04

Getein Biotech, Inc.
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Exclusive Distributor Agreement

This agreement is made and entered into by and between the parties concerned on 1th Jan, 2022 in Nanjing, China on the basis of equality and mutual benefit to develop business on terms and conditions mutually agreed upon as follows:

1. The Parties Concerned

Party A: Getein Biotech,Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing (211505) China.
Tel: 86-25-68568519
Fax: 86-25-68568500

Party B: Sanmedico SRL
Add: Republic of Moldova, Chisinau, MD-2059, Petricani street, 88/1, office 10
Tel: 373 22 62 30 32

2. Appointment

Party A hereby appoints Party B as its exclusive distributor in the Republic of Moldova for the promotion, sales, and after-sale services etc. of products (Refer to Item3) from Party A and Party B accepts and assumes such appointment.

3. Products List A

One Step Test for CK-MB/cTnI/Myo (Colloidal Gold)(Quantitative)
Cardiac Troponin I Fast Test Kit(Colloidal Gold)(Quantitative)
One Step Test for CK-MB (Colloidal Gold)(Quantitative)
One Step Test for CK-MB/cTnI (Colloidal Gold)(Quantitative)
One Step Test for H-FABP(Colloidal Gold)(Quantitative)
One Step Test for NT-proBNP/cTnI(Colloidal Gold)(Quantitative)
One Step Test for hs-CRP(Colloidal Gold)(Quantitative)
One Step Test for D-Dimer(Colloidal Gold)(Quantitative)
One Step Test for NT-proBNP(Colloidal Gold)(Quantitative)
One Step Test for HbA1c(Colloidal Gold)(Quantitative)
One Step Test for PCT(Colloidal Gold)(Quantitative)
One Step Test for HCG(Colloidal Gold)(Quantitative)
One Step Test for mAlb(Colloidal Gold)(Quantitative)
One Step Test for β2-MG(Colloidal Gold)(Quantitative)
One Step Test for CysC(Colloidal Gold)(Quantitative)
One Step Test for NAGL(Colloidal Gold)(Quantitative)
One Step Test for TSH(Colloidal Gold)(Quantitative)

CK-MB/cTnI/Myo Fast Test Kit(Immunofluorescence Assay)
Cardiac Troponin I Fast Test Kit(Immunofluorescence Assay)
NT-proBNP/cTnI Fast Test Kit(Immunofluorescence Assay)
hs-CRP Fast Test Kit(Immunofluorescence Assay)
D-Dimer Fast Test Kit(Immunofluorescence Assay)
NT-proBNP Fast Test Kit(Immunofluorescence Assay)
PCT Fast Test Kit(Immunofluorescence Assay)
mAlb Fast Test Kit(Immunofluorescence Assay)
B2-MG Fast Test Kit(Immunofluorescence Assay)
CysC Fast Test Kit(Immunofluorescence Assay)
NAGL Fast Test Kit(Immunofluorescence Assay)
HbA1c Fast Test Kit(Immunofluorescence Assay)
TSH Fast Test Kit(Immunofluorescence Assay)
T3 Fast Test Kit(Immunofluorescence Assay)
T4 Fast Test Kit(Immunofluorescence Assay)
PRL Fast Test Kit(Immunofluorescence Assay)
LH Fast Test Kit(Immunofluorescence Assay)
FSH Fast Test Kit(Immunofluorescence Assay)
AMH Fast Test Kit(Immunofluorescence Assay)
tPSA Fast Test Kit(Immunofluorescence Assay)
25-OH-VD Fast Test Kit(Immunofluorescence Assay)
Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

4. Territory:

In Republic of Moldova only.

Meanwhile Party B will not distribute for competitive firms identical or similar products, nor will associate directly or indirectly with the competitive firms in the field of products covered by this agreement; otherwise, party A has the right to decide whether to terminate the contract immediately or not.

5. Prices

Prices are stable for 12 months from the start of this agreement. Party A will not increase the prices subjectively, unless the raw material suppliers increase their prices. In case price increases have to be announced, Party B has to be informed at least one month (30 days) in advance.

This agreement shall come into force from Jan 1st,2022to Jan 1st,2024,is valid for 24 months.

6.Delivery

Party A shall establish a delivery term for each Party B's order, which shall not exceed 4 weeks after the payment is received. Party A will advise Party B about the day of dispatching, with all requested information concerning the dispatched products.

7. FORCE MAJEURE

If the performance of any part of this agreement interfered with new laws or governmental restrictions, war, civil commotions, riots, strike lockout, acts of God such as flood, fire or any other similar causes which are beyond the control of the parties, no party shall be responsible for delay or failure of performance of this agreement for such length of time and to the extent performance is made impossible. In this case, the parties shall immediately negotiate to what extent deliveries that could not be executed can be carried out executed.

8.Payment Term

Every order Party B shall pay 50% by TT in advance, the rest of 50% will be paid within 30-60 days after the goods arrives. Due to financial audition, all the credit payment should be cleared by December 31th, 2022.

If Party B is unable to pay, Party B will agree to use fixed assets or real estate to offset the loan. Party A has the right to bring a lawsuit against Party B in China according to relevant Chinese laws.

9. Sales target

Yearly sales volume is 200,000 USD, which include both analyzers and strips. Party B agrees and accepts the sales volume...

10. Governing Law

The agreement is subject to the International Trade Law. Any dispute concerning this agreement shall be settled in accordance with the International Trade Law either through negotiation or through legal proceedings if negotiation has failed.

11.Declaration of Conformity.

Getein Biotech,Inc. declares herein the above mentioned device (Refer to Item3) meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III.

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 TÜV Rheinland （Shanghai）Co., Ltd.

12. Intellectual Property Agreement

Party A reserves the right of goods design, drawing, plane graph specification, technology, data and information, technological process, the marketing plan of intellectual property rights which included the

Party A provide technical services to the Party B in the process of producing intellectual achievements . Without the Party A 's written consent, the Party B shall not disassemble the goods and the accompanying software, decoding, encoding, or any other reverse engineering by themselves or other third party.

13. Final Provisions

Attachments are an integral part of this contract, have the same legal effect with this contract; This contract was made in English with two originals, each party holds one, it is effective at the same time, and have the same legal effect.

Any change, modification, cancellation of this contract, to be replaced shall be made after agreed by both parties in writing.

Party A: Getein Biotech,Inc.
Date:
Represented by: Steven Zhou
Regional Sales Manager

Party B: Sanmedico SRL
Date:
Represented by: Vitalie Goreacii
Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

HCG+β Control

REF QC013

User Manual

PRODUCT NAME

HCG+β Control

PRODUCT SPECIFICATION

Package: 3(Level)*2(Vial)*1(ml), 3(Level)*1(Vial)*1(ml)
HCG+β Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of HCG+β on the Getein Platforms.

PRINCIPLE

The lyophilized HCG+β control is prepared from dissolving stable and high quality recombinant HCG 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. HCG+β Control - Level 1
   HCG+β Control - Level 2
   HCG+β Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. HCG+β Control - Level 1
   HCG+β Control - Level 2
   HCG+β Control - Level 3
2. User manual: 1 piece/box
3. Quality control holder - Level 1
   Quality control holder - Level 2
   Quality control holder - Level 3

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

MATCHING EQUIPMENTS

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

STORAGE AND STABILITY

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

MATERIALS REQUIRED BUT NOT PROVIDED

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

TEST PROCEDURE

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

3. Dissolve each control material with 1 ml distilled water.
4. Gently mix until all material has dissolved. Avoid violent shaking.
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. Match each vial with corresponding quality control holder.
8. Insert quality control holder into sample holder.
9. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

ASSIGNED VALUES

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

PERFORMANCE CHARACTERISTICS

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

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

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

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

Thank you for purchasing HCG+β Control.
Please read this user manual carefully before operating to ensure proper use.

Version: WZK13-S-04

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Website: www.bio-GP.com.cn

Please contact Getein if you have any questions.

CE IVD

HCG+β

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1013
Getein1600: Cat.# IF2013

INTENDED USE

HCG+β Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of human chorionic gonadotropin (HCG) in serum or plasma. This test is used as an aid in pregnancy test.

SUMMARY

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the placenta, a component of the fertilized egg, after conception. The biologically active hormone (intact HCG) is composed of noncovalently linked α and β subunit. The alpha subunit is similar to hormone (LH), follicle-stimulating hormone (FSH), thyroid-stimulating hormone (TSH). whereas beta subunits is unique to HCG and confers its biological and immunological specificity. During a normal pregnancy, HCG level can be detected soon after conception. It will double every 72 hours and reach its peak in the first 8~11 weeks of pregnancy. HCG measurement with blood or urine can be used as an aid in pregnancy test. Regular HCG has been known as a promoter of corpus luteal progesterone production, even though this function only explains 3 weeks of a full gestations production of regular HCG. HCG-positive indicates an implanted blastocyst and mammalian embryogenesis. Elevated values of HCG during pregnancy are indicative of chorionic carcinoma, hydatiform mole, or multiple pregnancy. HCG+β measurements can also be used in conjunction with other parameters during the second trimester of pregnancy to assess the risk of trisomy 21 (Down syndrome).

PRINCIPLE

The test based on the principle of sandwich immunoassay and competitive immunoassay together. The test uses two anti-human β-HCG monoclonal antibodies and a β-HCG recombinant antigen. One monoclonal antibody is coated on the sample pad, the other monoclonal antibody and β-HCG recombinant antigen are coated on the detection zone. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human β-HCG monoclonal antibody binds with the HCG and β-HCG in sample and forms an antigen-antibody complex. The complex moves to the test card detection zone by capillary action. In the dection zone, marked antigen-antibody complex will be captured on the test line by another set of monoclonal antibody against human β-HCG, meanwhile, HCG and β-HCG in the sample will compete with β-HCG recombinant antigen on nitrocellulose matrix for fluorescence latex-labelled anti-human β-HCG monoclonal antibody.

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

CONTENTS

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

TEST PROCEDURE

1. Collect specimens according to user manual.

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***100 µl*** of sample (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card.
8. ***Reaction time: 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 HCG was determined by testing samples from 315 healthy, non-pregnant individuals. The 97.5th percentile of the concentration for HCG is 5.1 mIU/ml. According to the literature, HCG results greater than or equal to 25 mIU/mL (IU/L) are considered positive. Representative HCG ranges during normal pregnancy are shown in the table below. Because other clinical reference citations may show different values, it is recommended that each laboratory establish its expected values for the population it serves.

Serum HCG Levels During Normal Pregnancy	
Gestational weeks	HCG (IU/L)
0.2-1 week	5-50
1-2 week	50-500
2-3 week	100-5,000
3-4 week	500-10,000
4-5 week	1,000-50,000
5-6 week	10,000-100,000
6-8 week	15,000-200,000

PERFORMANCE CHARACTERISTICS

Measuring Range	5~10000 mIU/ml
Lower Detection Limit	≤ 5 mIU/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with Roche Cobas E601 Immunology Analyzer and its matching HCG+β test kits with 200 serum samples (75 positive samples and 125 negative samples). The correlation coefficient (r) for HCG+β is 0.987.

LIMITATIONS

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

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L
Interferent	RF	Human anti-mouse antibody	Biotin
Concentration (Max)	3000 IU/mL	120 g/L	80 ng/mL

REFERENCES

1. Tietz NW, Clinical Guide to Laboratory Tests, 3rd Ed. 1995. p. 134-136.
2. Hohnadel DC, Kaplan LA. Beta-hCG. Methods in clinical chemistry. Edited by Pesc, AJ and Kaplan LA. St. Louis, MO: The C.V. Mosby Company, 1987.
3. Cole LA. New discoveries on the biology and detection of human chorionic gonadotropin. Reprod. Biol. Endocrinol. 7: . doi:10.1186/1477-7827-7-8.
4. Hoermann R, Spoettl G, Moncayo R, etal. Evidence for the presence of human chorionic gonadotropin (hCG) and free beta-subunit of hCG in the human pituitary. J. Clin. Endocrinol. Metab. 71 (1):179-186.
5. EN ISO 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF17-S-01

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Website: www.bio-GP.com.cn

CE IVD

D-Dimer

Fast Test Kit

(Immunofluorescence Assay)

User Manual

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

INTENDED USE

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

SUMMARY

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

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

PRINCIPLE

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

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

CONTENTS

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

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

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

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

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

TEST PROCEDURE

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

For Getein1100:

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

For Getein1600:

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

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.5 mg/L. (The probability that value of a normal person below 0.5 mg/L is 95%.)

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~10.0 mg/L
Lower Detection Limit	≤0.1 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with SIEMENS CA-7000 and its matching D-Dimer test kits with 200 plasma samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for D-Dimer is 0.978.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferents such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. The table below listed the maximum allowance of these potential interferents.

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

REFERENCES

1. Sarig G, Klil-Drori AJ, Chap-Marshak D, Brenner B, Drugan A. Activation of coagulation in amniotic fluid during normal human pregnancy.Thromb Res. 2011 Apr 18.
2. Roldán V, Marín F, Muiña B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated Atrial Fibrillation Patients. J Am Coll Cardiol. 2011 Apr 11.
3. Sakamoto K, Yamamoto Y, Okamatsu H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. Hellenic J Cardiol. 2011 Mar-Apr; 52(2):123-127.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WIF05-S-02

Getein Biotech, Inc.
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Website: www.bio-GP.com.cn

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.

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

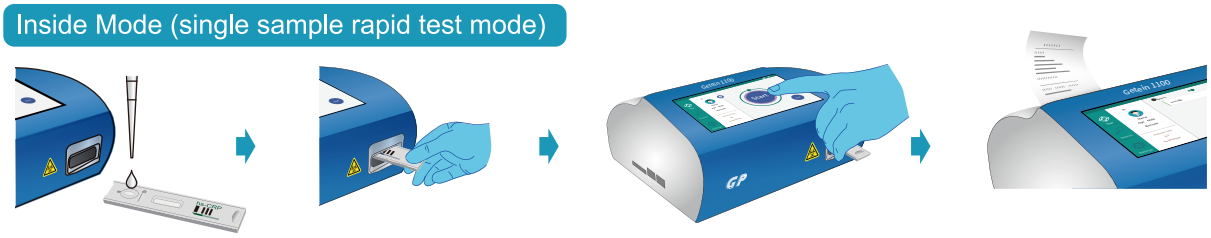
One-step test

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.
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ISO13485 FSC CE NMPA NGSP IFCC IVD

WPT3.11-09

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

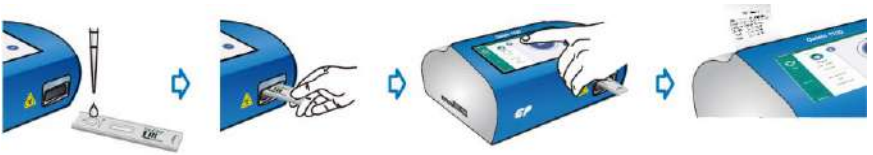
Getein 1100 is used to measure concentration of biomarkers in human whole blood, serum, plasma, urine, stool and swabs. The results can be used as an aid in clinical diagnosis of laboratory and point of care testing.

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

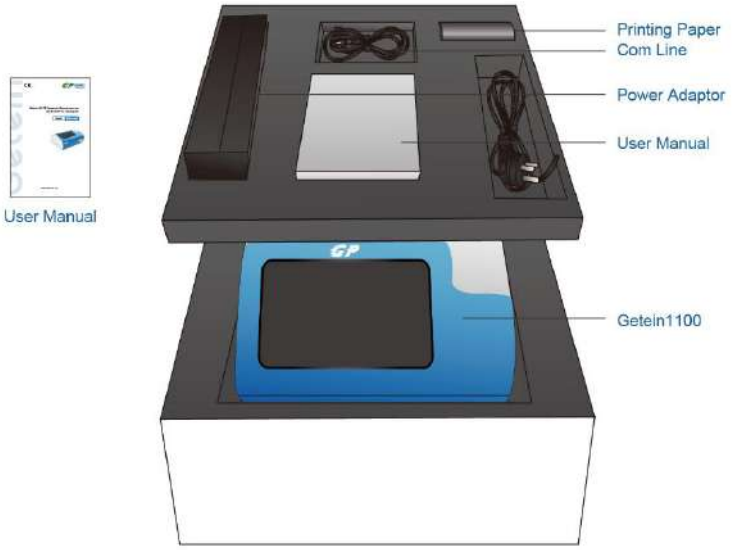


Fig.2-1 Getein 1100 and Main Accessories

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.

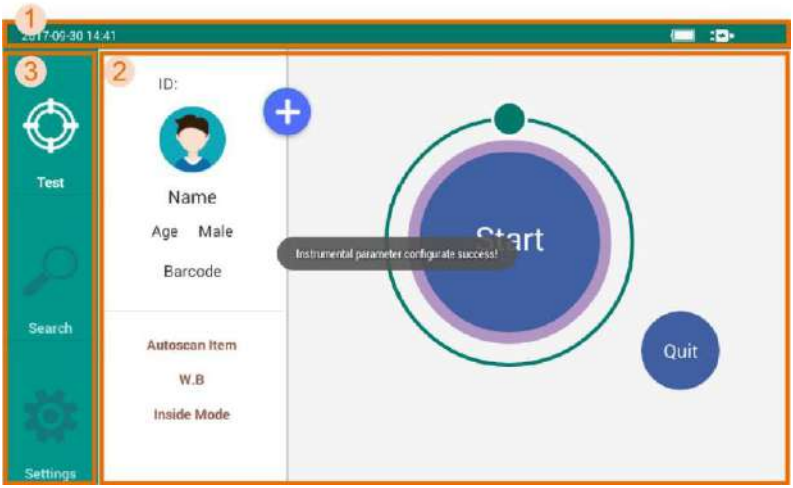


Fig.2-4 Main Interface

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.

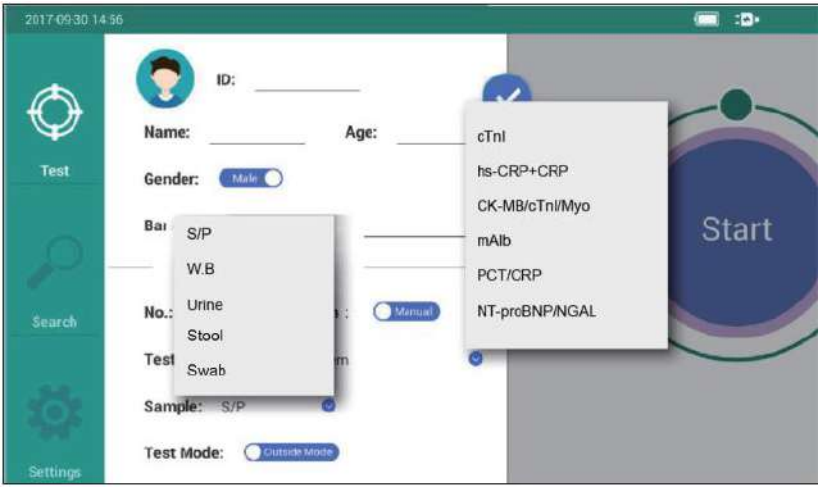


Fig.3-1 Test Interface

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).

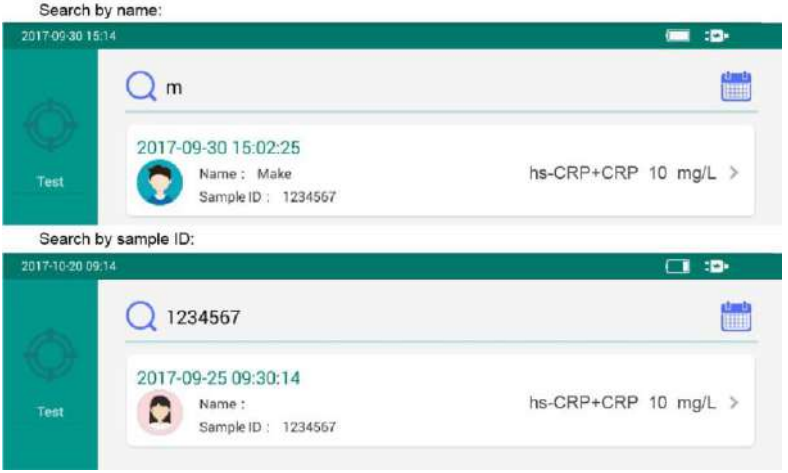


Fig.3-5 Search by Name and Sample ID

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

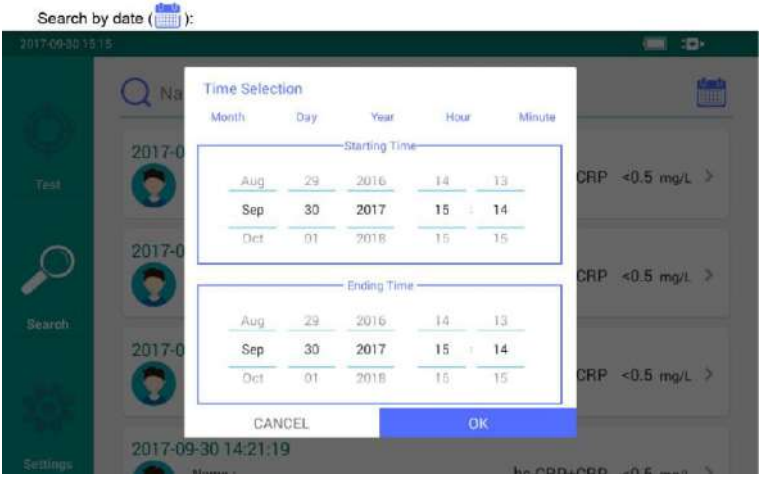


Fig.3-6 Search by Date & Time

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.

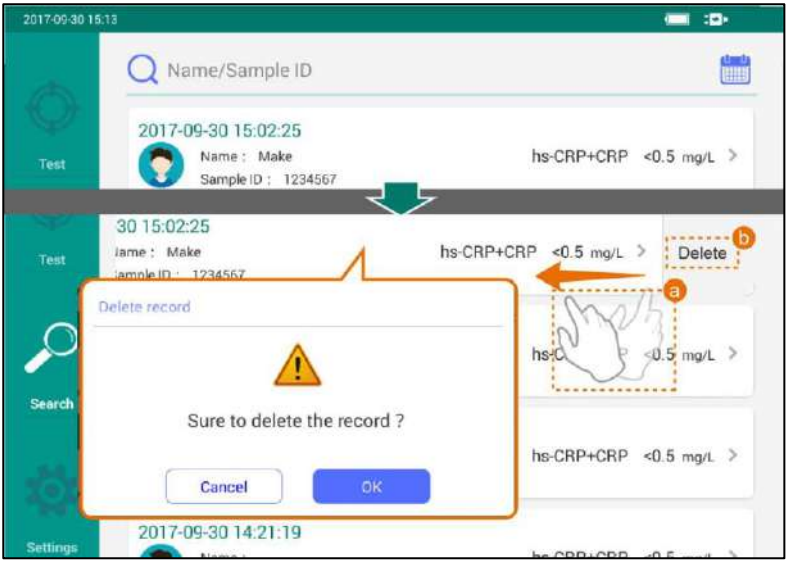


Fig.3-7 Result Deletion

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.

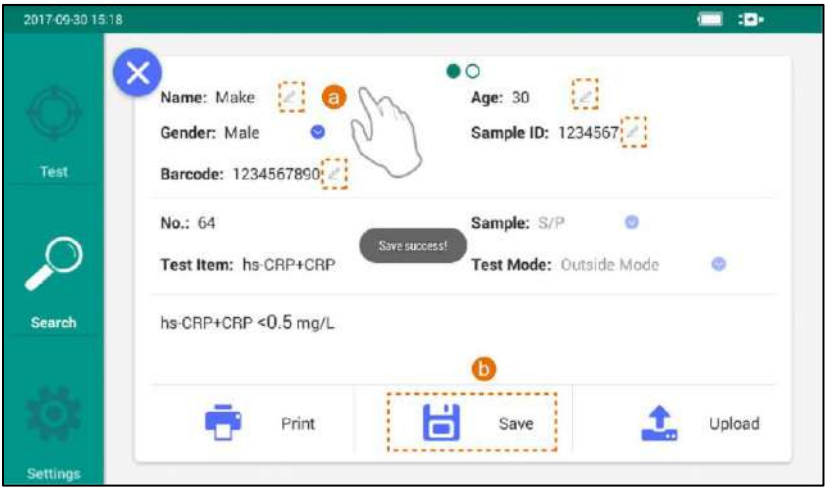


Fig.3-9 Edit Patient Information

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.

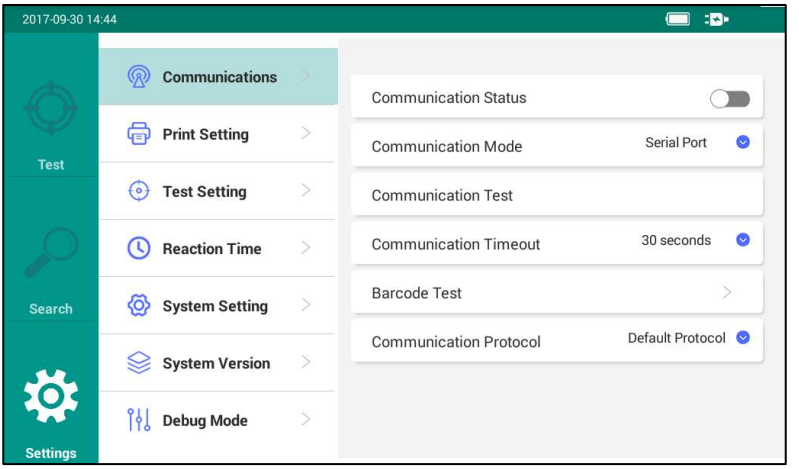


Fig.4-1 Settings

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.

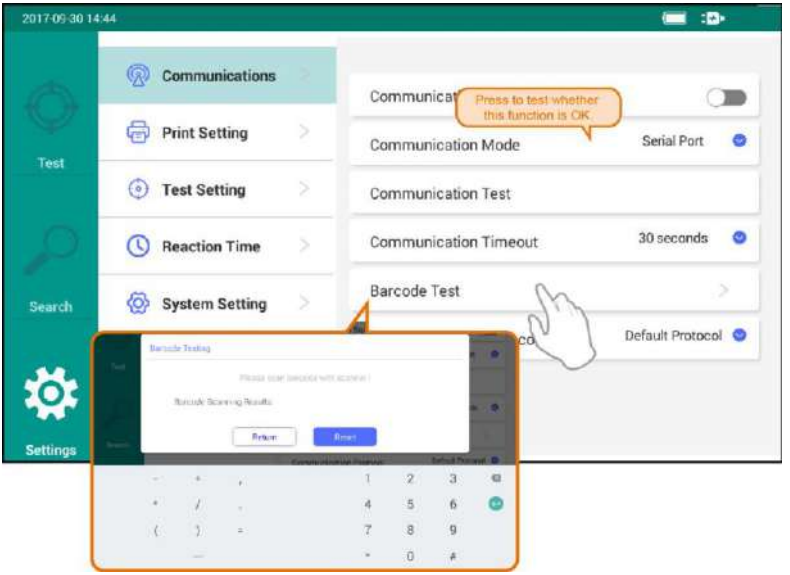


Fig.4-2 Communications Setting

4.2 Print Setting

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

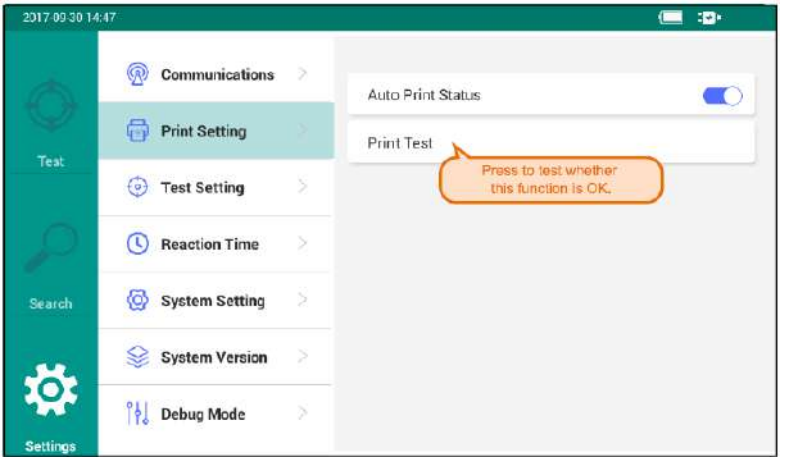


Fig.4-3 Print Setting

4.3 Test Setting

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

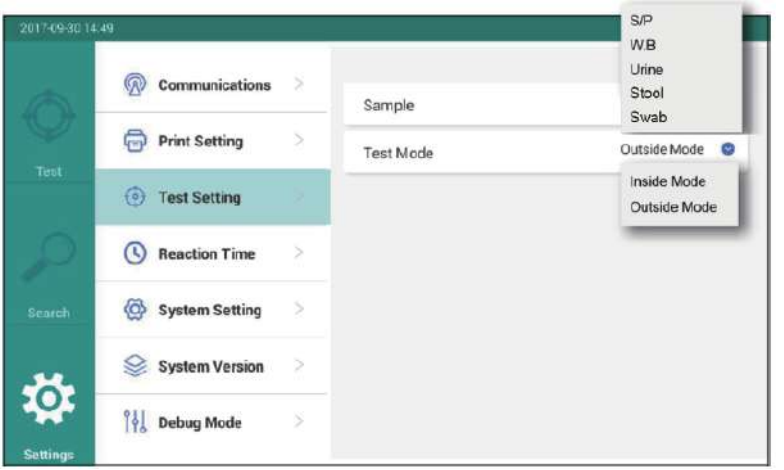


Fig.4-4 Test Setting

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.

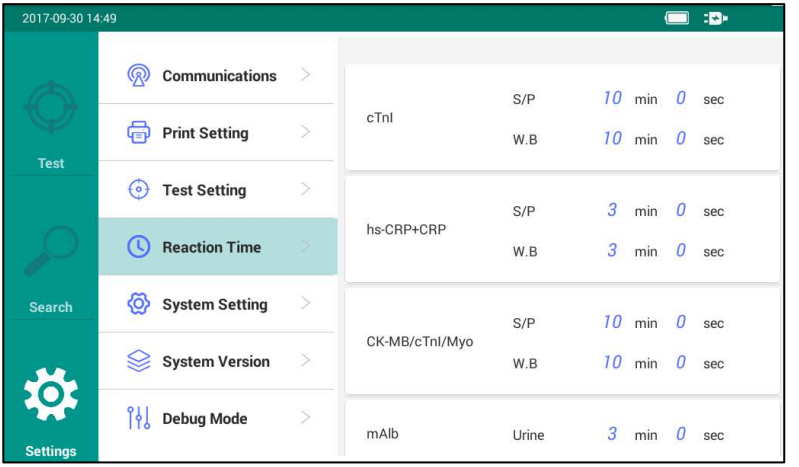


Fig.4-5 Reaction Time

4.5 System Setting

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

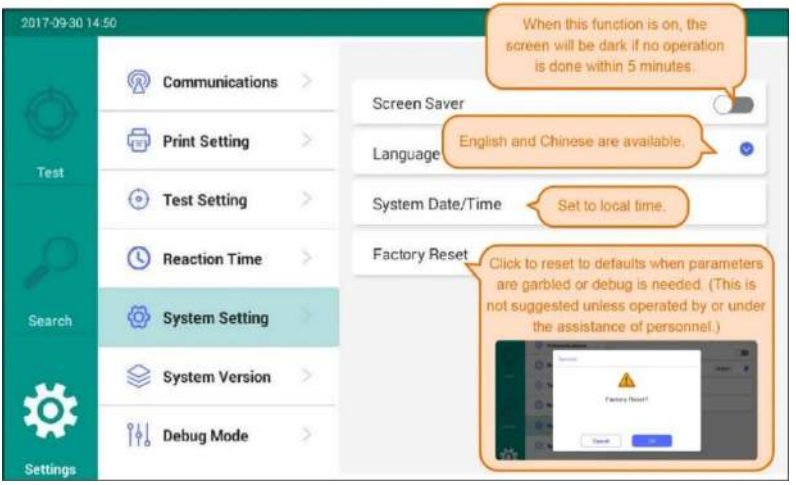


Fig.4-6 System Setting

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).

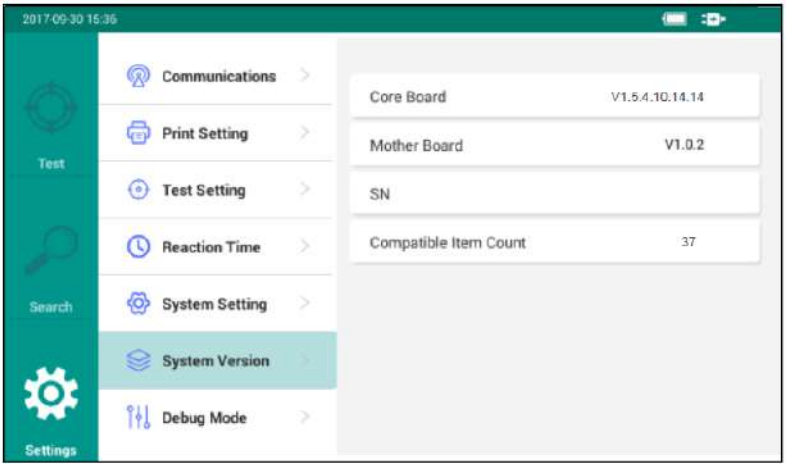


Fig.4-7 System Version

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.

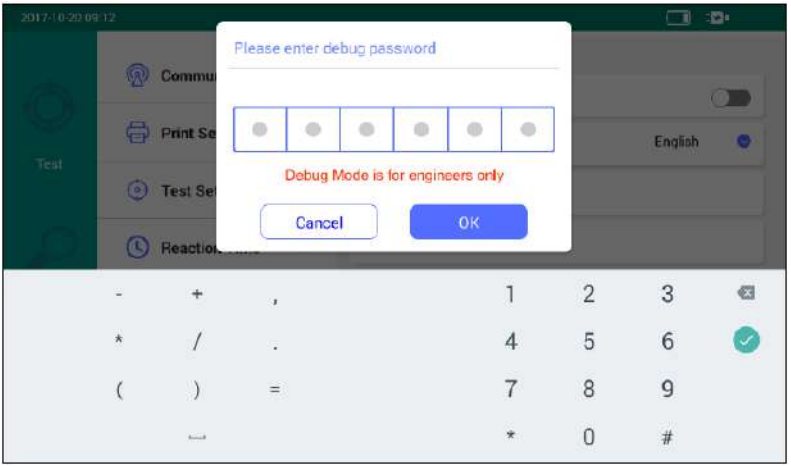


Fig.4-8 Debug Mode

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.

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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

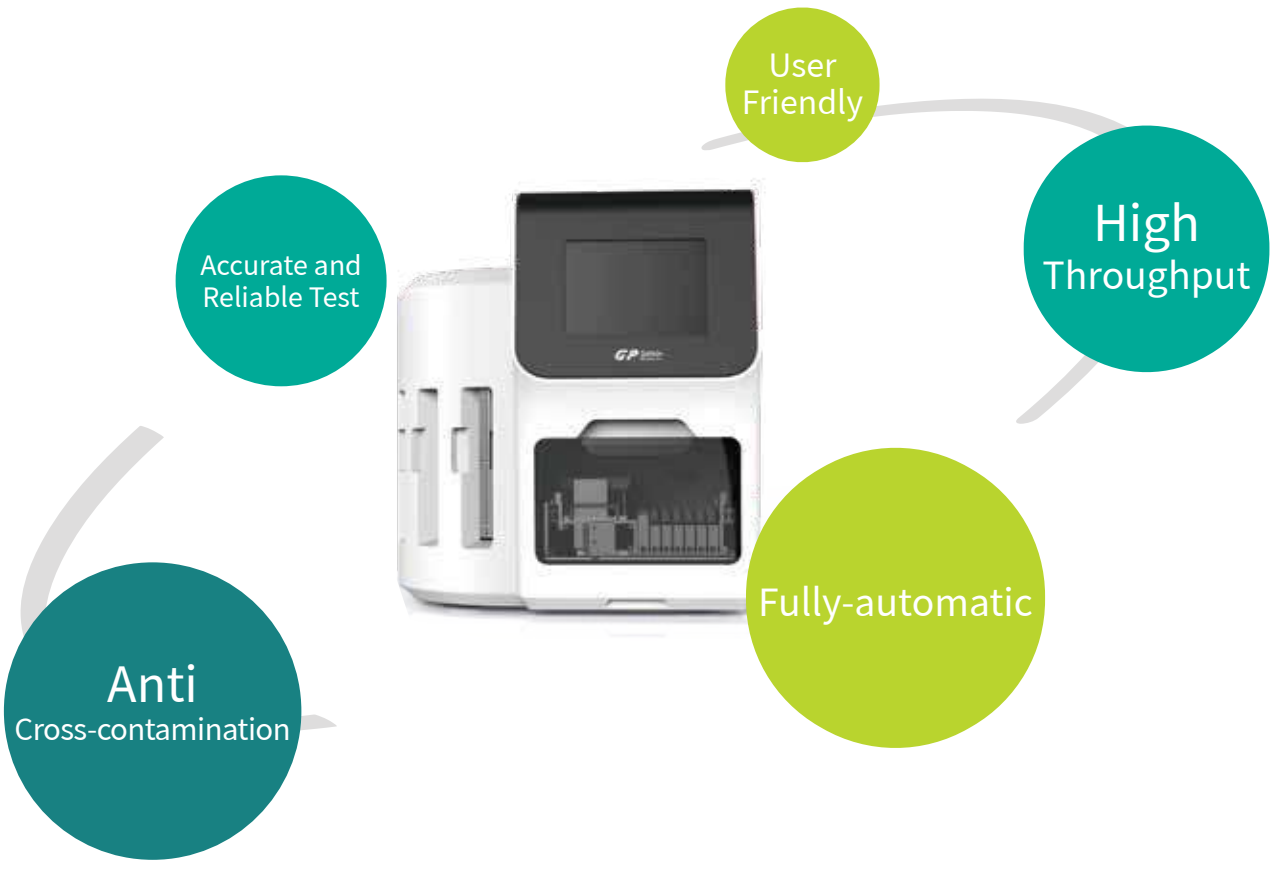
Network printer

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

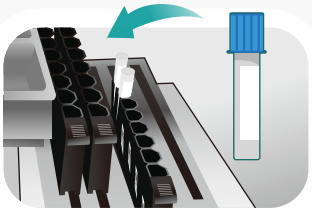
Meet the requirements of clinical laboratory standards

TECHNICAL PARAMETERS

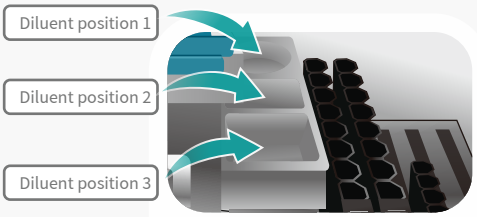
Methodology	Immunofluorescence
Result	Quantitative
Throughput	48 samples/run, 150 tests/hour
Sample Type	Whole blood, plasma, serum, urine, fingertip blood
Storage Capacity	500000 data
Language	English/Chinese
Screen Display	10.4 inch touch screen
Power Supply	100-240 V~50/60 Hz
Working Environment	Relative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

TEST PROCEDURE

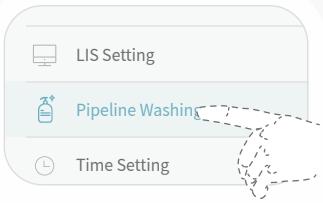
1 Insert cartridge into the instrument, the instrument will recognize the test item automatically.



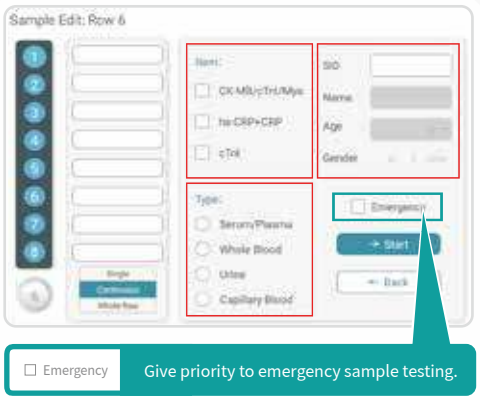
2 Insert the sample holder into the sample chamber.



3 Put the diluent into the instrument.

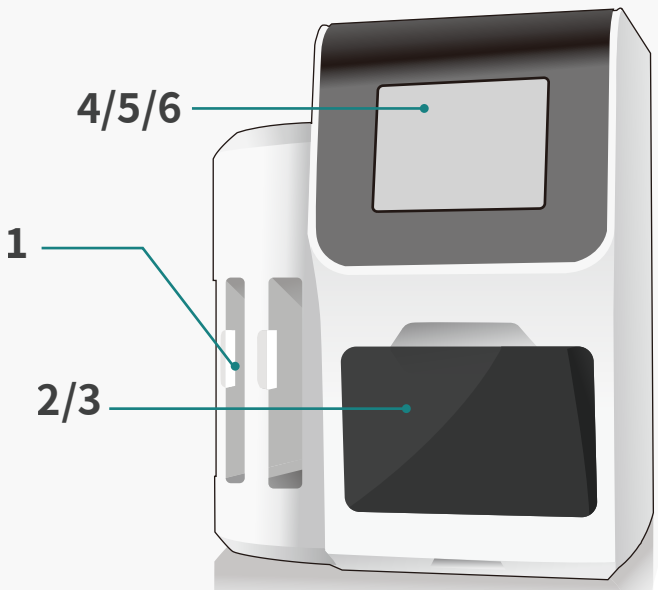


4 Perform pipeline washing before daily test.



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

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ISO ISO13485 FSC CE NMPA NGSP IFCC IVD

CE

Getein1600 Immunofluorescence Quantitative Analyzer

User Manual

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Contents

Chapter 1 INTRODUCTION

1.1 Summary

The manual consist of the operation instruction of Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1600) and the general maintenance method. Read this manual carefully and operate strictly to obtain optimum performance from your Getein1600.

Name and Model

Name：Getein1600 Immunofluorescence Quantitative Analyzer

Model：Getein1600

Intended Use

Getein1600 is used to quantitative detection of biomarkers in human whole blood, serum, plasma or urine samples with matching immunofluorescence assay test kits. The test result can be used as an aid in the clinical diagnosis. Together with different test kits, Getein1600 can be used to determine 14 different biomarkers in human blood or urine quantitatively:

1) cTnI, 2) NT-proBNP, 3) hs-CRP, 4) CK-MB, 5) Myo, 6) D-Dimer, 7) PCT, 8) mAlb, 9) CysC, 10) β_2-MG, 11) NGAL,12) HCG, 13) HbA1c, 14) H-FABP.

Test Kits

Test kits are suitable for Getein1600 as they constitute a whole system, the matching test kits produced by Getein Biotech, Inc. also.

NOTE

Please use the matching *in vitro* diagnostic test kits produced by Getein to ensure the analyzer work properly and get reliable result.

Examine each test card before use, as the card damage may affect the test result. If the packaging box is damaged, please check if damage exists in the internal and do not use the test card. Test kits should be used and preserved refer to the package insert included in the kit. Please pay attention to its matters need attention, when using chemical reagent.

CE

Getein Biotech, Inc.

NOTE

Please refer to the label and user manual of the test kits to operate properly and safely.

Maintenance Service

Please refer to the instructions of chapter 6 in this manual, if the device does not work normally.

Please contact with our service engineer if the malfunction cannot be solved after referring to chapter 6.

1.2 Detection Principle

The Principle of Matching Reagent

The test uses a monoclonal antibody conjugated with fluorescence latex and another capture monoclonal antibody. After the sample has been applied to the test strip, the fluorescence latex-labelled monoclonal antibody binds with the analyte 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 monoclonal antibody to form a ‘Sandwich’ complex.

The Principle of Analyzer

The measuring instrument scan the area the marker and the analyte binding with automatically to obtain an optical signal, then collect and analyze the optical signal to calculate the quantitative results.

1.3 Performance Summary

Instrument Classification

Medical Devices Category class: immunoassay system of clinical analytical instruments (code: 6840-3), administrative categorization is HLA-II.

Installation Category (transient overvoltage category): II

Degree of Pollution: n°2

Basic Parameters

Table 1-1 Basic parameters of Getein1600

Model	Work wavelength range (nm)	Detection range（mV）	Resolution（mV）
Getein1600	635 ± 5	0-3200	1

Performance Indexes

Blank count: The voltage of blank QC card should be less than 100 mV.

Linearity: r ≥ 0.95 in the detection range from 0mV to 3200 mV.

Repeatability: CV ≤ 2%

Stability: Voltage change should not larger than ±2% when test the standard card of the same concentration within 1 hour.

Sample Loading Characteristics

Serum，plasma，whole blood and urine sample volume：10~200 μl (different test items may have different sample type and sample volume, details refer to the reagent insert.)

Measurement Performance

Different items' concentration is got from the different reaction voltage and the particular performance parameters should combine with matching reagent performance, details refer to the reagent insert.

Display

10.4 inch LCD color touch screen, 800×600 resolution

Input and Output

Touch screen, two RS232 serial ports, ethernet interface, USB-A export, barcode scanner

Storage Capacity

10000 group data

Built-in Thermal Printer

Printer has been equipped with thermal printing paper

Reagent

The matching test kits

Power

Input: 100 V~240 V, 50 Hz~60 Hz

Power: 280 VA

Normal Operating Conditions

Temperature: 10℃~35℃

Relative humidity: ≤ 70%

Air pressure: 70.0 kPa~106.0 kPa

Supply voltage: AC100 V~AC240 V±10%

Power frequency: 50 Hz~60 Hz ± 1 Hz

Transportation and Storage Environment

Storage temperature: -40℃~+55℃

Storage humidity: ≤93%

Air pressure: 50.0 kPa~106.0 kPa

Size

639 mm (Length) × 562 mm (Width) × 728 mm (Height)

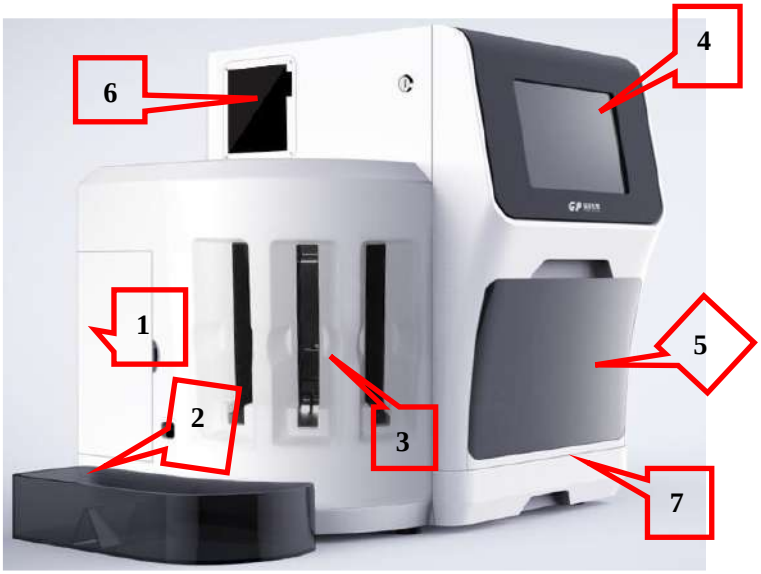
Net Weight

45 kg

1.4 Configuration and Operation

Getein1600 is composed of control system, optical system, display unit, analog signal acquisition system, mechanical drive system, software CD. Details as follows:

Main Engine



Interpretation on the figures above:

1. Storage zone for washing solution bottle and waste liquid bottle
2. Waste reagents container
3. Cartridge zone
4. Display screen
5. Sample chamber
6. Printer
7. Waste tip chamber
8. Serial port, Ethernet interface, USB interface, etc

Screen Display

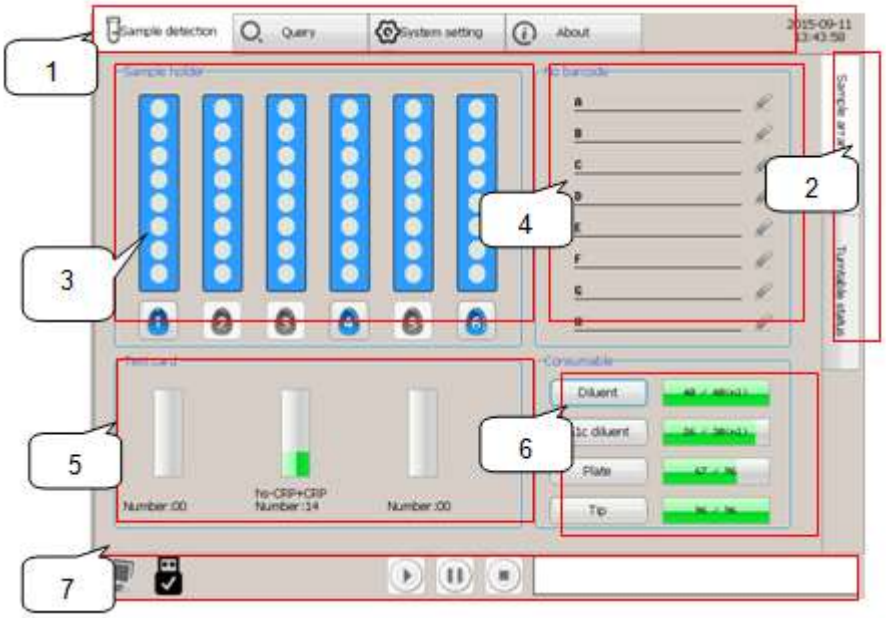


Fig.1-1 Screen structure chart

1. System menu zone: sample detection, result query, system settings and instrument information.

2. Sub-menu area for sample detection: click to check reaction time, detection status and consumable status.

3. Sample holder display zone: sample holder status and sample detection status will be displayed in real time.

4. Barcode information display zone: display the last barcode.

5. Test card status zone: display current test card's name, quantity, batch number and position.

6. Consumable information zone: display current status of diluent, tips and plate.

7. Instrument information zone: ①display LIS and U disk status ②count down the detection time and pause, continue, stop the operation can be chose ③display current prompt message and fault message.

Operation Principle

Getein1600 achieved the breakthrough that from a single index to multiple indexes detection that contributed to the combination of disk automatic testing device and the timing control software. It solved the problem of time allocation of different test items and improved

the testing efficiency in the maximum extent.

Disk automatic testing device is composed of a synchronous wheel, motor, belt, a plate, a bearing seat and the supporting shaft. When the test kit is delivered to the disk automatic testing device by propelling unit, the disk will prioritize the short reaction time item according to the set detection sequence and other items are awaiting to be detected. When the current test item detection is finished, then the awaiting items will get into the test window in succession and repeat the previous process.

After operator chose the detection items or analyzer read the items in database, software will read measuring sequence, analysis items and assign the detection task to each turntable position automatically. At the same time, the propelling unit will deliver the corresponding test kits to the matching turntable position. Moreover, the sample loading device will dilute the sample and add mixture to the corresponding test kits automatically. Finally, the software will processing and analysis the detection results according to the test items and arrange the next batch detection through coordinate all the operations.

In order to ensure the accuracy and the comparability of the data, each test kit has a information card for the correction of the instrument. The information card including test item, reaction time, sample volume and equation parameters. The instrument will read the card information automatically after putting in cartridge.

Chapter 2 INSTALLATION

2.1 Package

Please check the appearance after opening the package carefully, if you find any damage here, please contact with our customer service department immediately.

Please check the analyzer refer to packing list to ensure the configuration is complete, if you find any parts missing, contact our agents in your area, or contact our customer service department directly.

All accessories and consumables related to analyzer should be provided by the manufacturer, otherwise the stability and precision can be affected.

2.2 Installation Requirements

Installation Environment

The environment of the instrument placed should be dust-free, no mechanical vibration, no noise source and no power supply interference, far away from electronic brush type engine, flashing fluorescent lamp and electric devices used frequently. Avoid direct sunlight and away from heat and wind.

Space Requirement

The instrument should be placed on an experiment table where is convenient to place test kits. With the rear of the analyzer is the cooling fan, ensure that the distance from the rear wall is greater than 50 cm, so as to ensure proper cooling. Equipment installation should allow sufficient space for maintenance.

NOTE
The instrument should be placed in the horizontal plane.

Power Requirements

Power supply: AC100 V~AC240 V±10%

Power frequency: 50 Hz~60 Hz±1 Hz

Maximum power dissipation: 280 VA

2.3 Analyzer Installation

Printer Paper Installation

Open the printer door by pressing the key on the left side of the printer.

Put the printing paper into the printer, printing surface upside and back to the thermal head.

Leave the scrap of the paper outside of the door and close the printer door.

Power Installation

Use only the AC power adapter provided with the Getein1600 and connect the power plug with the electric outlet properly.

Chapter 3 TEST INSTRUCTION

3.1 Operation Preparation

Before power the system on, please check the system as the following steps to make sure the system can be used normally.

NOTE: Do not place the instrument close to the wall and in front of any obstacles which may lead to abnormal operations. If the instrument is still unavailable after these procedures, please turn off electrical power and contact our after-sales support. Clean and disinfect the edge of the instrument insertion port periodically with alcohol cotton.

Check Cable

Check if the power cable is broken and if the apparent copper exposed phenomenon existed, whether the power plug is connected with the electric outlet which conforms to the requirements. If you have any questions please replace the power line or other safety electric outlet.

Check Printer

Check if the printing paper is installed correctly and enough.

Check Sample and Diluent Zone

Pull the sample storehouse out, check if there are some foreign objects and take out. Check if there has tip on the mechanical arm and lift it down to avoid contamination to the new batch of samples.

3.2 Booting

1. Turn on the power switch of the analyzer after appearance inspection.

2. The system will check its plate, hardware, mechanical arm and optical system automatically.

3. After system initialization is complete, the system will enter the main interface, as shown in Fig.3-1.

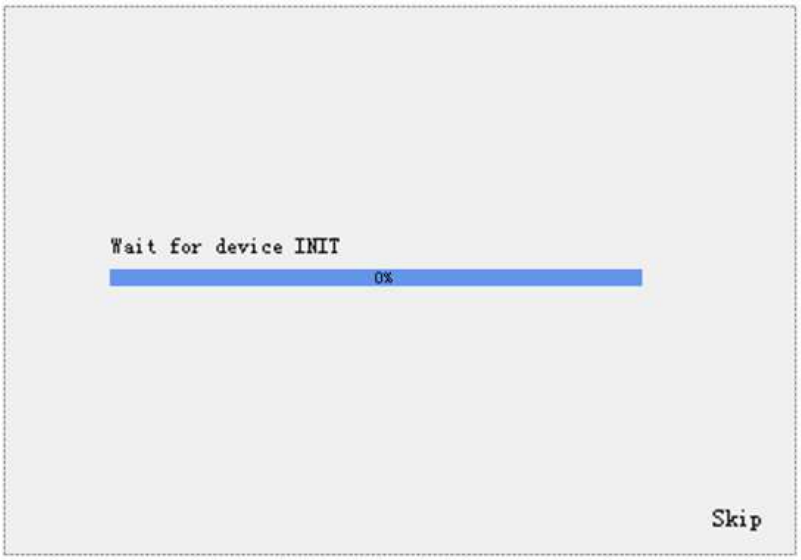


Fig 3-1 Initialization interface

3.3 Main Interface

The instrument enter into the main interface after power on (shown in Fig.3-2) and the display options allow the operator to specify sample loading, system parameter setting, movement parameter setting, consumables filling, fault alarm processing, pause and stop sample loading.

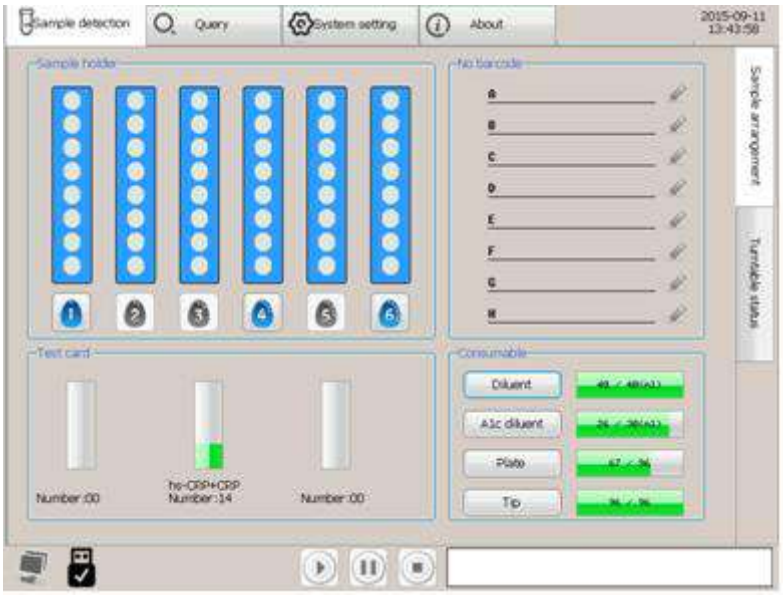


Fig.3-2 Main interface

Measurement system:

Following items can be tested: ‘cTnI’, ‘NT-proBNP’, ‘hs-CRP’, ‘NT-proBNP/cTnI’, ‘CK-MB/cTnI/Myo’, ‘D-Dimer’, ‘PCT’, ‘mAlb’, ‘CysC’, ‘β2-MG’, ‘NGAL’, ‘H-FABP’, ‘PCT/CRP’,

'CK-MB/cTnI/H-FABP', 'HbA1c', 'HCG'.

Sample loading system: touch button '1' to '6' for sample loading setting of 8 blood collection tube in each sample frame, single sample loading, load sample in whole row or continuous sample loading can be chose, if needed.

Barcode status: display the barcode of current blood collection tube in sample frame which is convenient to check the barcode information.

Consumables status: information of tips, 2 kinds of diluent, mixing plate and 3 kinds of cartridges needed are shown in the screen.

Turntable status: display the most current information on the sample and each cartridge on-plate the turntable.

Result and query: used to check current result and edit requirements for results query.

System settings: used to set analyzer basic status and operating parameters.

About: used to check the version and other basic information of analyzer.

External device status: used to display the status of LIS and U disk connection.

Test time remaining: display the time remaining to be completed for all the test.

Pause/continue: sample loading can be broken off when emergency circumstances happens, press "continue" button to continue measurement.

Stop sample loading: after pressing 'Stop' button, clear out all of arrangement information that waiting to measure except for test card in disk, and stop sample loading.

Alarm information: display current prompt and fault information of analyzer, press this window to check the specific treatment method and all of prompt information within 7 days.

Time status: current time and date are shown at the top right of the screen.

3.4 Sample loading

WARNING

Please do not contact with the patient's blood or urine directly!

Load the samples after processed in the detection zone, set the parameters according to the sample numbers and test items (one sample can be used to test three items at most). The sample holder can identify whether it is in right place automatically, while samples in wrong location unable to complete sample loading. Click the number on the sample zone to

add test item as shown in the Fig.3-3.

Selecting item and sample type firstly, if there are eight samples to be tested, click the button ‘Whole row sample loading’; if the number of samples is less than eight, select the sample to load by selecting the number corresponding to the desired sample, then click the number of samples you want to test, the instrument will automatically check the ‘Continuous sample loading’ mode, then click ‘Detect’ button to start.

Emergency test: click the button ‘Emergency test’ on the dialog box to ensure the sample be measured timely after prior test cards had been loaded sample.

Fig 3-3 Sample loading

Users can edit ID number according to requirement, ID number can accumulate automatically. Users can delete previous ID number and re-enter the new number when setting sample loading mode.

The following interface will appear the test sample arrangement completed.

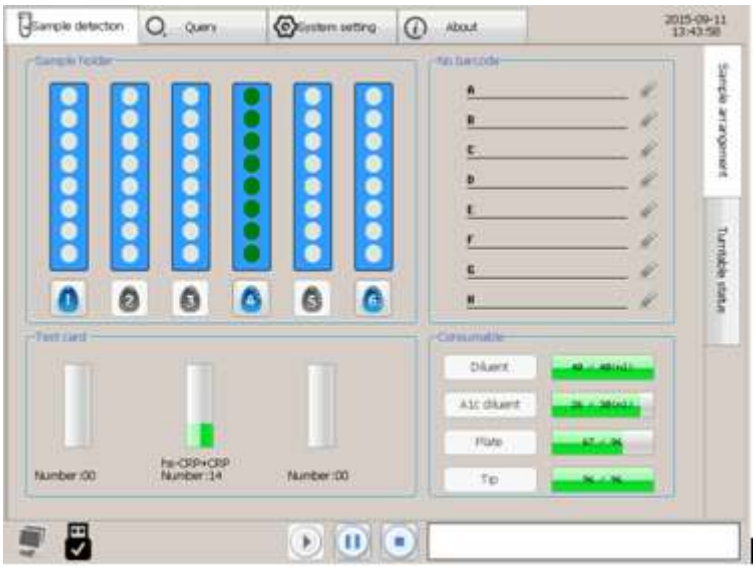


Fig 3-4 Sample loading results

The analyzer is equipped with automatic scanner, after connecting the bidirectional LIS, analyzer can automatically identify the number and items of samples required to measure. When scanning, sample to be tested should be inserted into sample frame according to direction of attached barcode scanning area, and insert sample frame into the instrument sample chamber with a constant speed, as shown in Fig 3-5.

Fig 3-5 Scan barcode

After connecting analyzer with LIS, analyzer can scan barcode automatically to obtain information of sample to be tested. Samples failed to be scanned will not be displayed on screen and barcode can be edited after pressing edit icon. As shown in Fig 3-6.

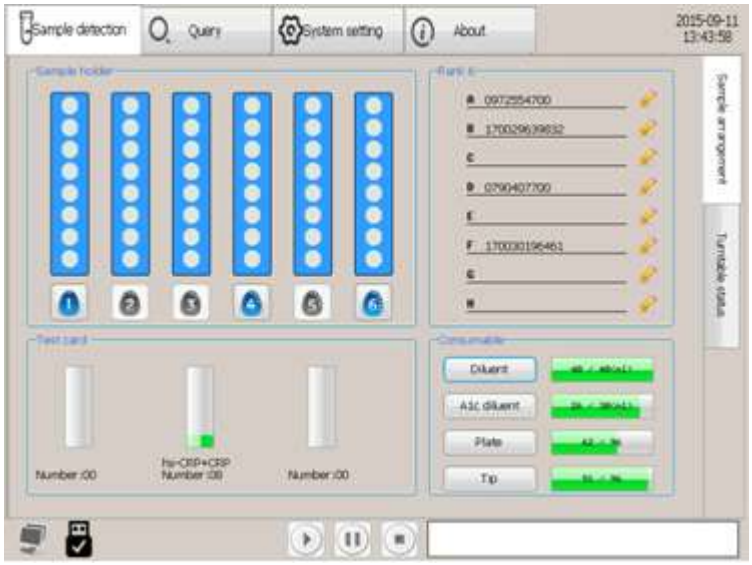


Fig 3-6 Scan barcode

After sample to be tested arranged finished, press ‘Start measure’ button to start pushing the card and sample loading. To view the arranged sample and test card state can click ‘Turntable Status’ button located on the right side of ‘sample testing’ home page, to view samples specific information this time. During the detection, sample projects has been added and the remaining test time shows in the interface.

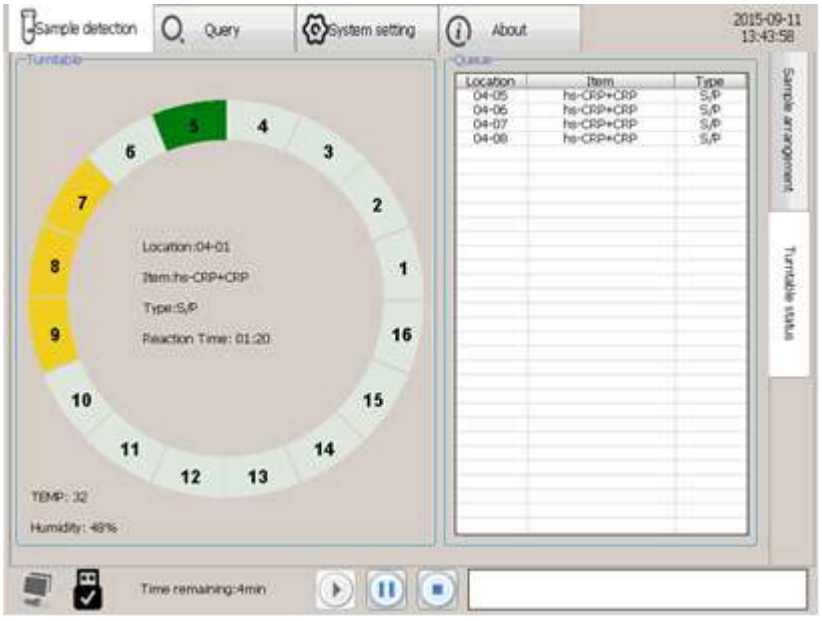


Fig 3-7 Turntable status

3.5 Sample Detection

48 dots in 6 column indicating samples detection status: Red means measurement completed, yellow means sampling completed, green means to be measured. It’s unable to

edit again when a column of sample haven't finish sample loading. Avoid pulling out of sample holder during the sample loading. Otherwise, analyzer will automatically cancel all of pre-arranged information including the test cartridges without the sample loading and stop measuring. To ensure stability and security of measurement process, some functions in system setting is shielded during measurement, while all of buttons will be available after completed.

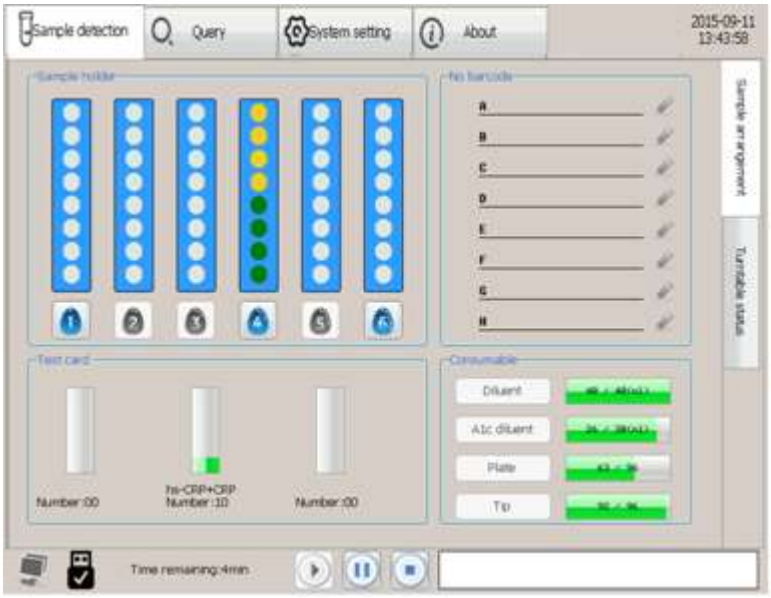


Fig 3-8 Measure interface

When the automatic print is selected, the results of each test is printed automatically after the completion of a test. All of the test information can be displayed on the screen by clicking the button 'Results', queried result can be printed and uploaded to LIS according to user's need.

3.6 Result

Press the button 'Result query' as shown in Fig 3-9. When the interface is the state of measuring results, all of test result will be shown on the screen. Slide the scroll bar to review results in measure interface, the current measuring results is displayed in default mode.

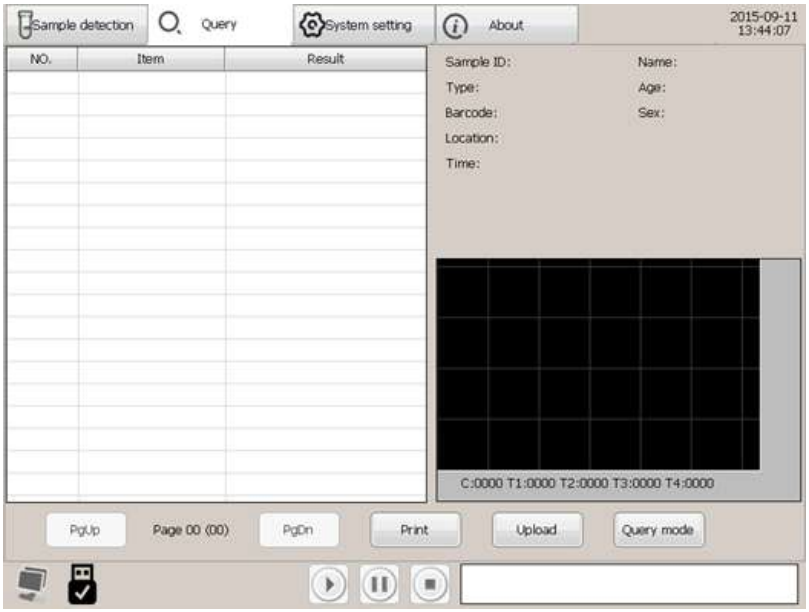


Fig 3-9 Result query

3.7 Result Query

Click ‘Query mode’ button on the result interface (as shown in Fig.3-9) to switch to query interface, then press ‘Query’ button, three query modes can be chose to query historical results, as shown in Fig 3-10. When inquired by date, results tested within 24 hours on same day will be displayed on the screen, press ‘PgUp’ or ‘PgDn’ to review.

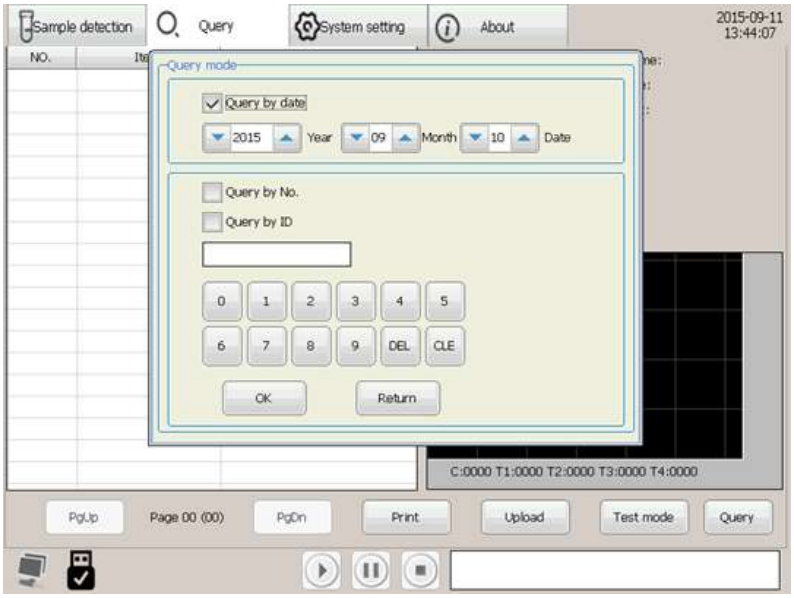


Fig 3-10 query setting

Chose a specific test result to view specific information and voltage waveforms in result query interface as shown in Figure 3-11. Select the ‘Print’ or ‘Upload’ to perform the operation according to user’s need.

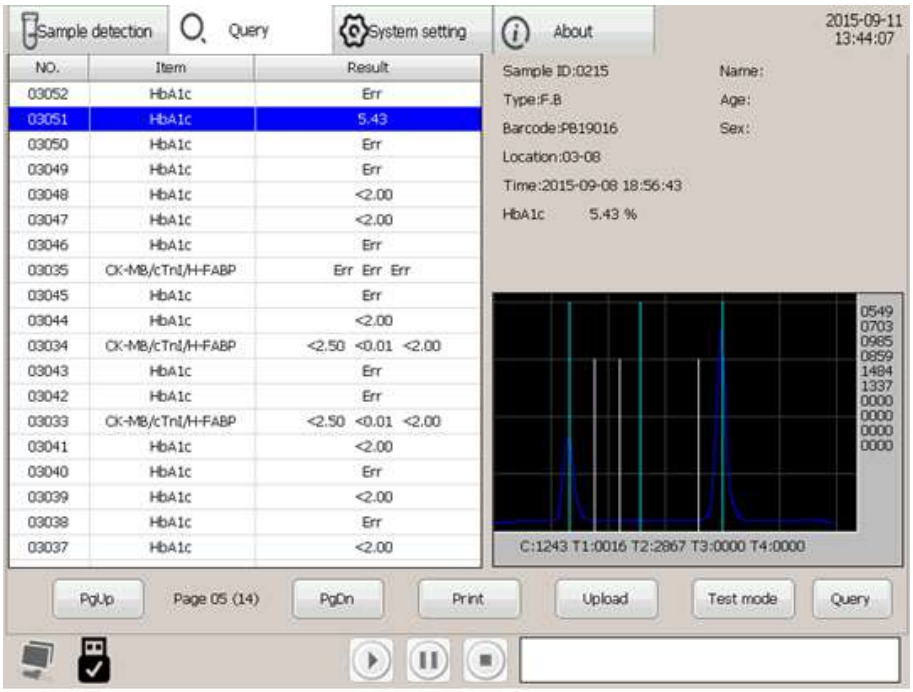


Fig 3-11 Query results

3.8 Waste Treatment

Waste liquids, test kits, consumables and other waste should be considered as medical waste, the source of infection and industrial waste, and should be properly handled in accordance with local regulations.

BIOOLOGICAL POLLUTION RISK
Follow and obey lab safety rules and guideline. Wear protective goggles, surgery gloves and laboratory coat to avoid the potential biological pollution risks.

WARNING
Disposal of medical wastes should be in accordance with the local regulations.

Chapter 4 SYSTEM SEETING AND ABOUT

Installation and commissioning of analyzer is done by the company sales and after-sales support personnel when purchasing. To meet the requirements of different laboratories, many system parameters can be reset by operators.

Click ‘System setting’ button in the measuring interface to enter the ‘System setting’ interface (Fig.4-1), corresponding setting can be set up. ‘System setting’ include ‘Update’, ‘Time setting’, ‘System debug’, ‘Comm Test’, ‘Screen calibration’, ‘Pipeline washing’, ‘Print test’, ‘IP setting’, ‘Language setting’, ‘Print setting’ and “Sensor setting”.

Press corresponding button to check basic information.

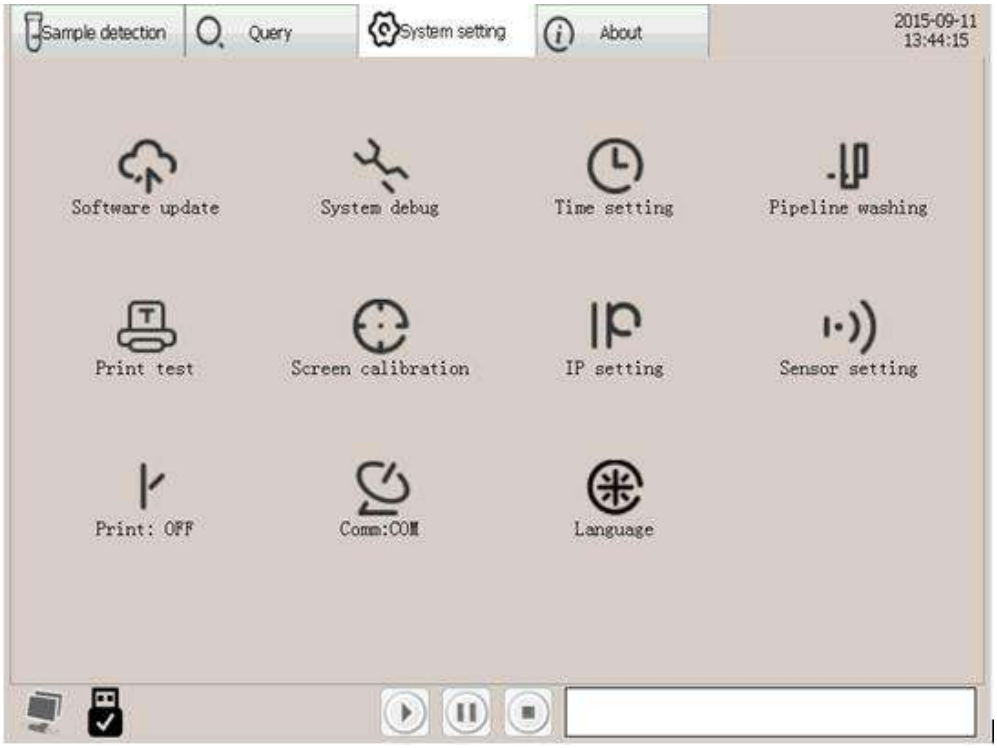


Fig 4-1 System setting

4.1 Software Update

Press ‘Software update’ on the operation interface to update the program through U disk, as Fig.4-2 shown. Press ‘File copy’ to obtain the parameters stored inside the instrument, after U disk inserted successfully, U disk icon on the left button of main interface will be marked by a tick.

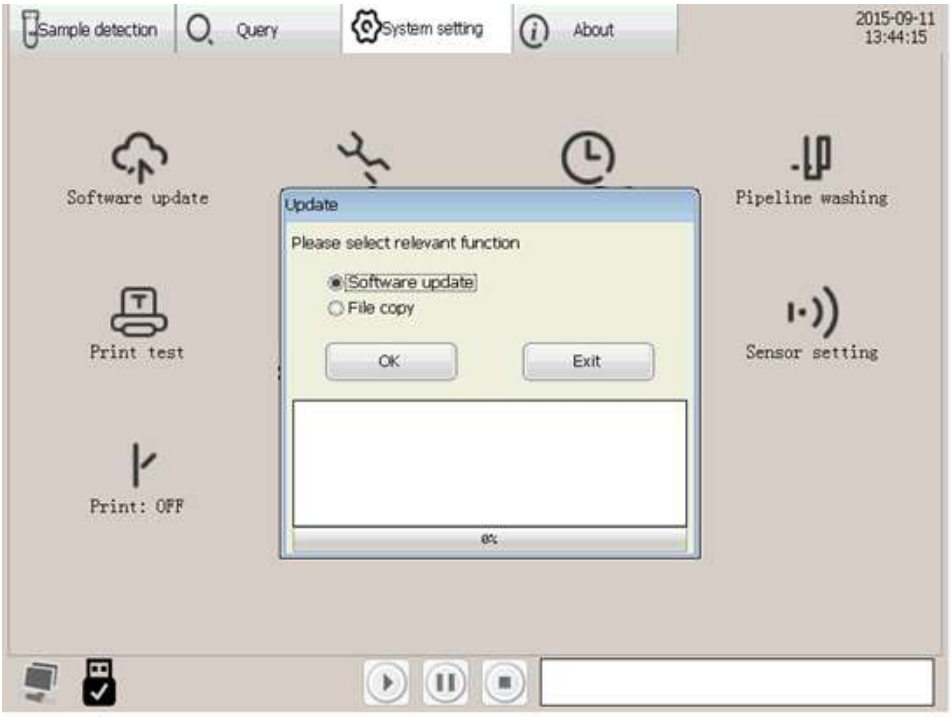


Fig 4-2 Software update

4.2 Comm Setting

Press ‘Comm Test’ icon to receive communication test information through serial port communication tool on the operation interface. After communication serial port set up successfully, the computer icon on the left button of main interface will be marked by a green plus.

4.3 System Debug

System debug should only be performed by trained and qualified personnel.

4.4 Print Test and Print Setting

‘Print test’ for checking if current printer connection is successful and print paper is enough. Press ‘Print test’ button to check current print function.

‘Print setting’ for setting up automatic print function after test finished.

4.5 Time Setting

In order to ensure the measuring performance of instrument, users can use ‘Time setting’ function to set correct time. Use the up and down arrow keys and touch screen to change the date and time, as shown in Fig.4-3. Press ‘Save’ button to save the settings.

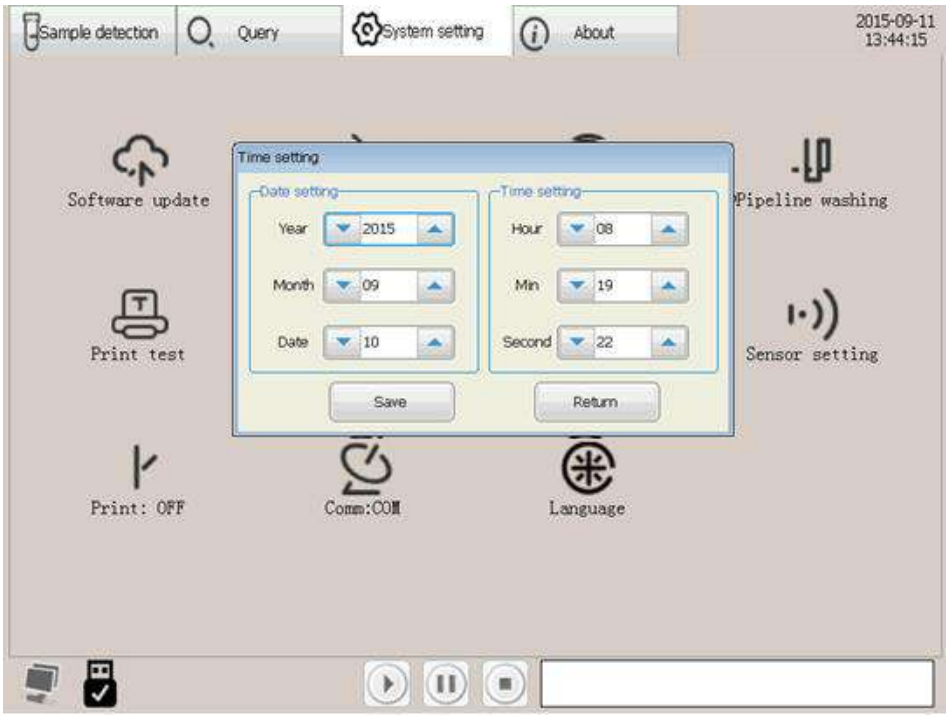


Fig.4-3 Time Setting

4.6 Screen Calibration

The subtitles position may shift when the analyzer is used for a long time, at this time you can re-calibrate the screen.

Click on the ‘Screen calibration’ icon and enter the interface of Fig. 4-4, click on the cross center on the screen according to the instructions. Five points located in the four corners and the center of the screen, when five points have been calibrated, the system will automatically determine the deviation. If the deviation is too big, the system will calibrate again until meet the requirements. Touch the screen at any place to exit the calibration interface.

Fig 4-4 Screen calibration

4.7 Language Setting

The instrument support multiple language switching function, click on the ‘language’ icon to switch required language.

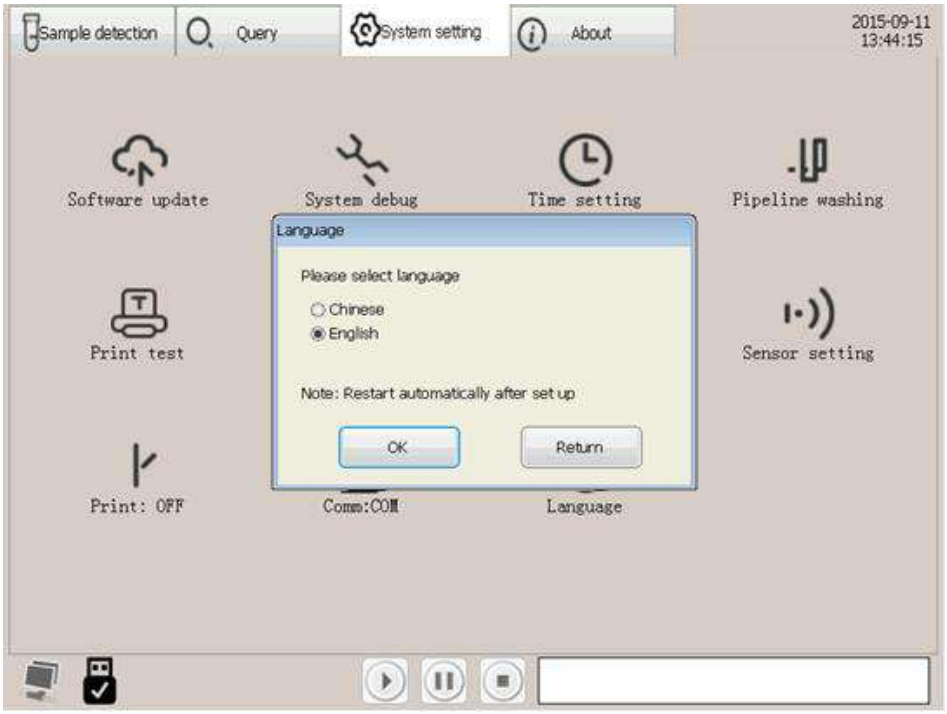


Fig 4-5 Switch language

4.8 Pipeline Washing

Pipeline washing is for periodic maintenance of the loading device. This instrument has cleaning and filling function which at regular time, users can do the conventional maintenance according to the service condition when test a large population (It is suggested to click ‘Pipeline washing’ icon once before everyday usage to ensure no air in the pipeline). As shown in Fig. 4-5:

Fig 4-6 Wash pipeline

4.9 IP Setting

IP setting is used for connecting analyzer with LIS, and analyzer can upload data to LIS. Serial port connected with computer and IP can be set up manually according to user’s demand.

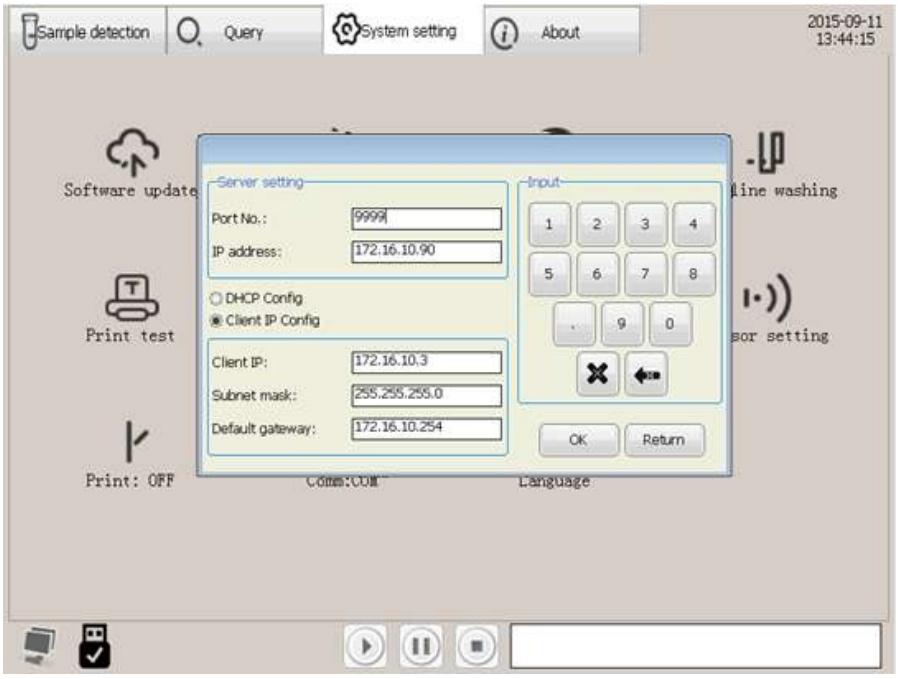


Fig 4-7 IP setting

4.10 Sensor Setting

Click on the box in front of the sensors required shielded, the state marked by a tick indicating normal alarm.

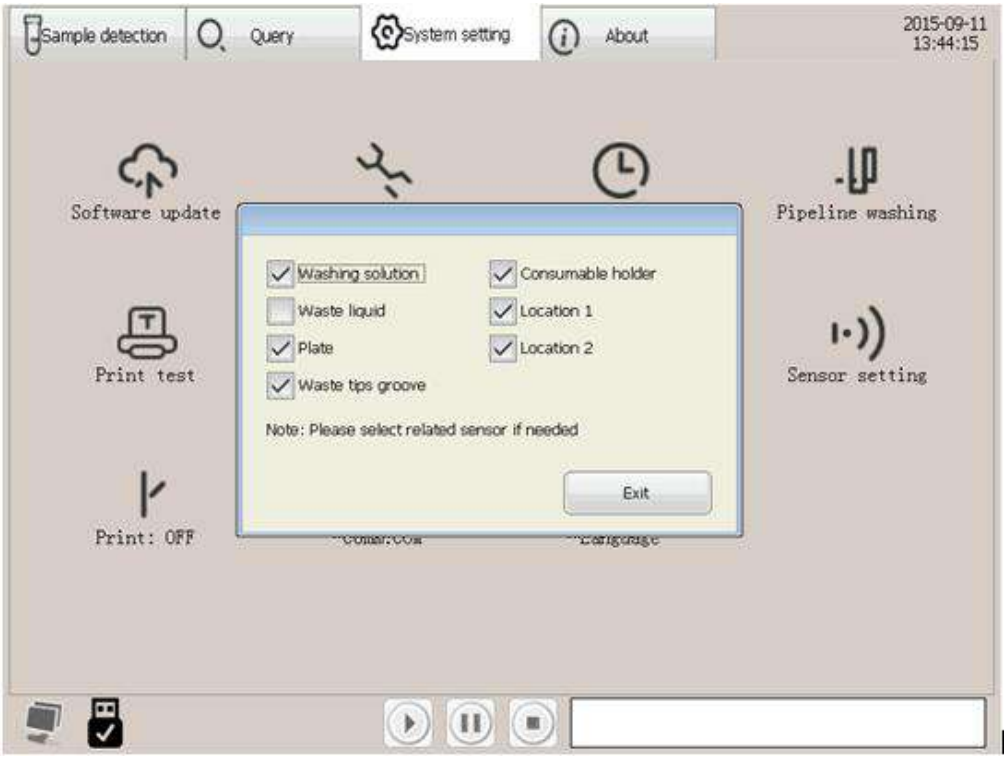


Fig 4-8 Sensor setting

4.11 About

Basic information about analyzer will be displayed on the screen after pressing ‘About’ button, as shown in Fig. 4-8, including ‘Instrument model’, ‘Serial No.’, ‘Software version’, ‘Configuration’ and other information. Services and assistance are accessible based on current prompt information.

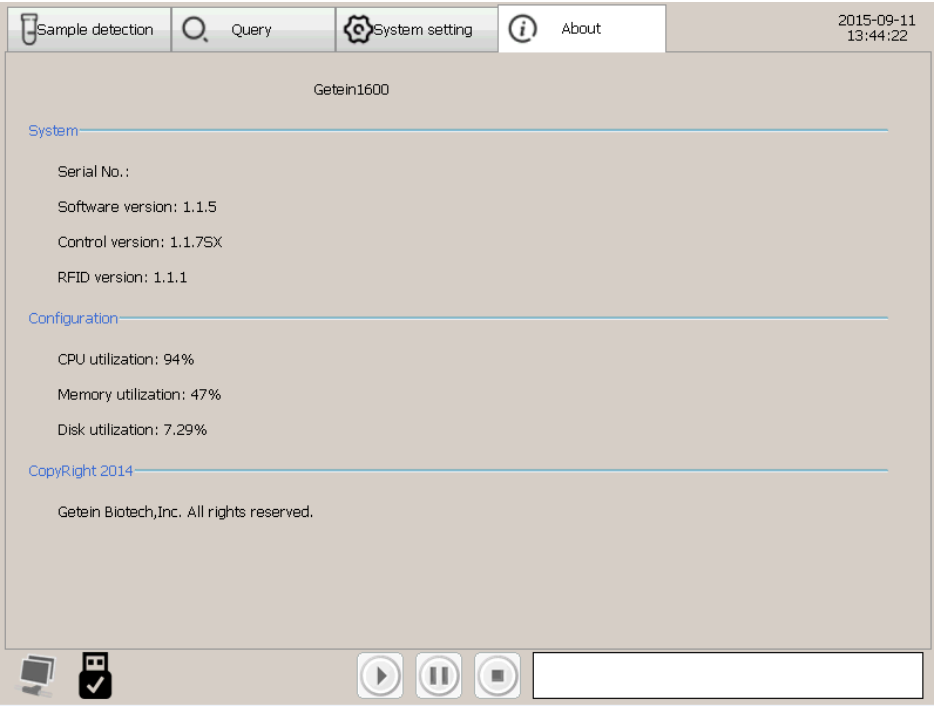


Fig 4-9 About

Chapter 5 COMMUNICATION (OPTIONAL)

5.1 Summary

Supervisory Computer Management Software has the data transmission function with Immunofluorescence Quantitative Analyzer, and can be set up the sending and reading of parameters, besides the software can display analyzer's status in real time. Supervisory Computer Management Software has other functions, for example, a user database creation, modification and saving, query browser, data statistics and database backup. Analyzer can link to Supervisory Computer Management Software when taking operation, to observe experiment status and receive experiment data, and the patients' test report can be browsed and printed by inputting patients' information after finishing the experiment.

5.2 Software Name and Version

Software Name: Supervisory Computer Management Software

Model: Getein1600

Version: V1.1

5.3 Environment Requirement

Hardware Environment

1. CPU ≥ Pentium IV, Memory ≥ 2 G，Hard Disk ≥ 10GB
2. Resolution ≥ 1024 × 768
3. Resolution of printer ≥ 600×600 dpi

Software Environment

Supervisory Computer Management Software applies to Windows XP Professional, Windows 7, Windows 8, Windows 10 and its compatible operating system.

5.4 Software Installation and Instructions

Details refer to *Supervisory Computer Management Software User Manual*.

Chapter 6 HELP

6.1 Notes

1．Getein 1600 only used with Immunofluorescence assay test kit produced by Getein Biotech, Inc.

2．Equipment installation and operation environment should be dust-free and indoor temperature should between 10 ℃ to 35 ℃, laboratory should be equipped with air conditioning.

3．In addition to paper, consumables, all components must be provided by the Getein Biotech, Inc.. Otherwise, any use fault should responsible by operators themselves.

4．Voltage limits: AC100 V~AC240 V±10%，50 Hz~60 Hz±1 Hz.

5．If the instrument shut down due to power outages and other reasons, wait for 30 seconds before rebooting it.

6．If any questions happens in Getein1600, please contact us in time. Any inspection and disassembly to any parts of Getein1600 without permission by our company is responsible by operators themselves.

6.2 Contraindication

The instrument use body fluids in vitro diagnostic use, no contraindications requirements.

6.3 Alerts

1．Getein1600 only used for the analysis of human blood or urine sample in vitro, do not used for any other specified purpose.

2．During the operation, avoid putting hands into sample loading area (including sample position area and test kits position area).

3．Please use the matching test kits mentioned in the manual, otherwise the reliability of the test results cannot be guaranteed.

4．Please read this manual carefully before use and keep it well.

5．Please cut off the power supply immediately to avoid fire, electric shock or personal

injury when the analyzer emits an odor or smoke, and contact with our service engineer.

6. Please cut off the power supply immediately to avoid fire, electric shock or personal injury if any liquid enters in the interior of the analyzer or liquid leakage, and contact with our service engineer.

7. Wear protective goggles, surgery gloves and laboratory coat, obey lab safety regulations, to avoid the potential biological pollution risks of samples and reagents.

8. The analyzer operator or the person in charge can use the analyzer only after accepted the training of customer service engineer for the analyzer notes and operation guide.

Safety Symbols

The standard symbols used for Getein1600 systems and their meanings can be found below:

	Biological risks		Caution, consult accompanying documents
	Warning laser		Risk of electric shock

Clean and disinfect the edge of the instrument insertion port with alcohol cotton periodically. The operator should wear rubber gloves for the above operations in order to avoid contacting with residual or drippy sample on the instrument detection port.

To ensure the accurate sample volume, the analyzer will exhaust air by filling pipeline at regular time. Users can observe if there has bubble in pipeline according to the actual circumstance and click ‘Wash’ manually to fill pipeline, details refer to section 4.8.

6.4 Maintenance

1. Getein1600 is a precise instrument, only operation and maintenance is strictly in accordance to manual, can provide a long-term reliable performance.

2. The instrument should be placed in appropriate temperature, dry indoor environment. In order to obtain the accuracy results, analyzer should use quality control card to do regularly calibration (recommended once a month).

3. Please open the instrument and warm up for 20 min before use to ensure the accuracy

of results.

4．Please use alcohol cotton to clean wipe around the instrument operation zone regularly. User should wear rubber gloves for the above operations, to prevent from the sample residual or drippy sample on the analyzer detecting port.

Consumables and Replacement Method

1．Pipette tip：The analyzer will give an alarm when pipette tip used up. Please add pipette tip to the tip container in the operation zone.

2．Printing paper: The red light will flicker when printing paper is insufficient, please put a new roll of printing paper into the printer on the left of the analyzer, the specific operation refer to printing paper installation in section 2.3.

3．Plate：Each slot of mixing plate can be used for one time only; when all of the slots are used up, the analyzer will give an alarm. Please put a new mixing plate on the holder.

4．Test card：Test card and matching analyzer constitute a whole system, each cartridge attached a information card that contains item, sample volume and equation parameters, analyzer will read the information automatically after place the cartridge. Analyzer will give an alarm when test cards are used up, please add a new cartridge to continue testing. Replace method: Put the plug out on the both sides of cartridge, clockwise rotate 90 degrees, take out the empty cartridge and replace a new one.

5．Washing solution: The analyzer will give an alarm when the washing solution is used up. Add an appropriate amount of washing solution into the washing solution bottle.

Alert

Getein1600 has a system for alerting you to the presence of an error. In the measurement process, analyzer will have a buzzer alarm and the details will be displayed on the screen if any exception occurs, as shown in Figure 6-1, abnormal situation can be solved manually according to prompt (red box stands for unhandled error).

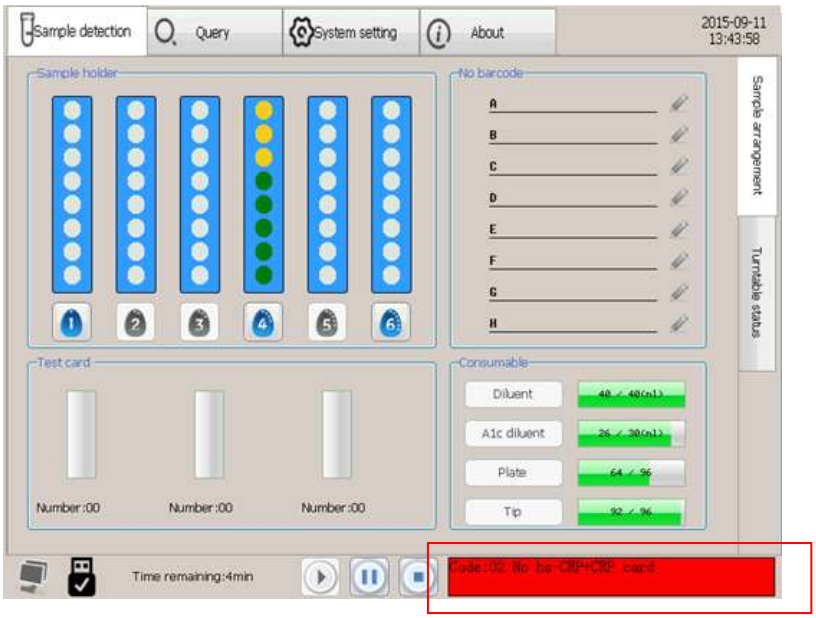


Fig 6-1 Alert information

Press the area marked by red (as shown in Fig. 6-1) and a display box including all of prompt message and alarm information within 7 days will pop out (Fig. 6-2). Prompt and alarm information displayed in the form of day, press ‘PgUp’ or ‘PgDn’ button can look over other information. When analyzer is prompted with no reagents card can simply replace a new cartridge. Prompt related to consumable need to change supplies first, then click the corresponding button to fill. Other operations require manual handling can be solved according to corresponding message box.

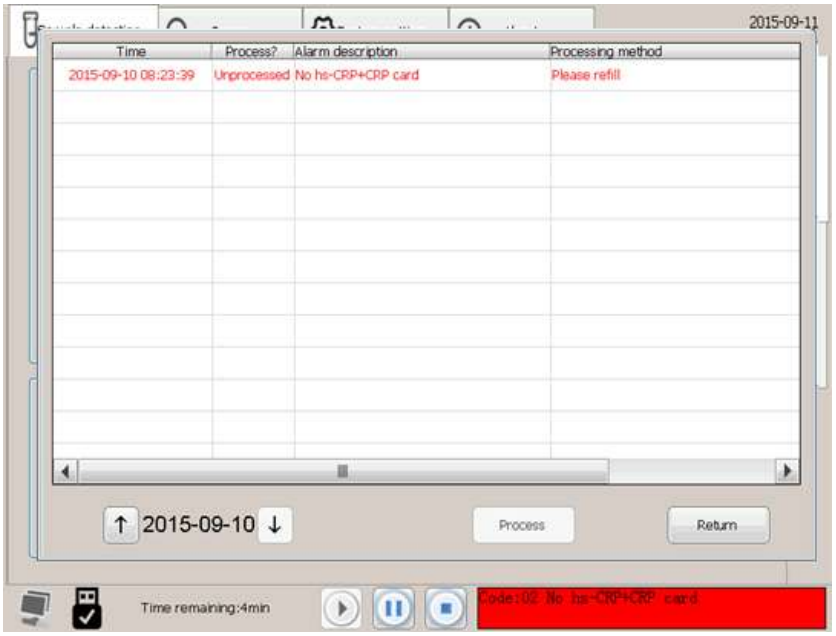


Fig 6-2 Alert information box

Prompt Interface	Solutions
Diluent used up	In this interface, click on the ‘Diluent’ button, it will pop out that whether fill in the dilution, click "OK" button, dilution added.
A1c diluent used up	In this interface, click on the "A1c diluent" button, it will pop out that whether fill in the diluent, click "OK" button, diluent added.
Tips used up	In this interface, click on the ‘Tip’ button, it will pop out that whether fill in tips, click "OK" button, tips added.
Plate used up	In this interface, click on the ‘-Plate’ button, it will pop out that whether fill in mixing plate, click "OK" button, mixing plate added.
No washing solution	Please change washing solution and press ‘OK’ button to start measurement.
Waste bottle is full	Please empty the waste bottle and press ‘OK’ button to start measurement.
Tip waste container is full	Please empty the discarded tip and press ‘OK’ button to start measurement.
No D-Dimer test card	In this interface, replace the empty cartridge with a new D-Dimer cartridge manually, then click “OK”.
Turntable Err	Open the instrument and observe whether the launched card in the pushing place has blocked reagent strips on other rotary table, if so, pull out the single clip manually and insert the reagent strip into the clip, install and pull out the cartridge. After this, click on the finish button, and then click OK, the rotary table will initialize automatically.
No. 1 cartridge test card delivery failure	Extract No.1 cartridge manually, observe whether the end of the reagent strip card is before the yellow pushing hook, if so, please push the hook forward a little manually; click the "pull-out" button followed by clicking the confirmation dialog box, after the treatment, reinsert the cartridge, then the instrument will continue measurement automatically.
No.2 cartridge test card delivery failure	The same operations as previous
No.3 cartridge test card delivery failure	The same operations as previous
Sample No.3 cannot be detected in row 3	If forgot to put the sample or sample size is too small in the measurement process, the machine will detect and alarm with “No sample”, please add the alarmed sample first and click “enter” button, then the instrument will test the abnormal sample as usual.

Consumable holder position Err	In the measurement process, analyzer will alert man-made extraction of dilution frame or not in place, in this case, please replace it correctly.
Arrangement information of Rank 2 will be cleared	In the measurement process, analyzer will hint that all of information for this column will be cleared when taken out the column haven't add sample.
Mechanical arm Err	There may be human caused mechanical arm error in the measurement process, click "OK" button, the instrument will finish manipulator initialization automatically. After the initialization is done, the instrument will continue loading sample and starting measurement.

6.5 Troubleshooting

During the operation process, the instrument will display error buzzer alarm and the interface dialog box will pop up if there is an abnormal situation and abnormal situation can be solved manually according to prompt.

Any cases that you can't handle well, please contact our customer service support department.

The above problems relates to the parts of the instrument, need to be determined by our service engineer and replacement parts should be supplied by our company.

6.6 Storage, Transport Conditions and Methods

Placement and Installation

1. The environment of the instrument placed should be dust-free, no mechanical vibration, no noise source and no power supply interference, far away from electronic brush type engine, flashing fluorescent lamp and electric devices used frequently. Avoid direct sunlight and away from heat and wind.

2. The instrument should be placed on a spacious position where is convenient to operate and maintenance.

3. The instrument should be placed where convenient to plug the electric outlet and turn on the power switch.

Transport and Storage Limit Conditions:

Temperature: -40℃~+55℃

Relative humidity: ≤ 93%

Air pressure: 50.0 kPa~106.0 kPa

To ensure stable performance and long lifespan of the analyzer, please place analyzer as follows:

Temperature: 10℃~35℃

Relative humidity: ≤ 70%

Air pressure: 70.0 kPa~106.0 kPa

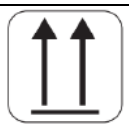
Supply voltage: AC100 V~AC240 V±10%

Power frequency: 50 Hz~60 Hz±1 Hz

Transport Requirements of Responsible Person

Equipment should be transported in disassembled packing cases, use wooden and bolts for protection and fixation. Transport responsible person should handle cargo based on the information provided on the packaging.

Transportation should pay attention to the following logo:

Transportation Logo	Explanation	Transportation Logo	Explanation
	Up		Keep dry
	Handle with care		Prohibit stacking

Store analyzer according to transport requirements after transportation. User cannot take out of analyzer from packaging box until after-sales engineers arrived. Any analyzer movement should obey instructions above.

Analyzer is available for storing in a cool clean room with room temperature using a container or covering with dust mask.

Handling Description

Getein1600 is a sophisticated laboratory equipment, please move with both hands to hold up the bottom of the analyzer. When transporting the analyzer, analyzer must be placed in the box and wrapped by the crash pad.

Biological Hazards Description

A special waste container should be prepared for the instrument and the dispose of the

waste should be in accordance with the regulations of local medical waste, infectious waste, industrial waste.

As the sample and reagent may have potential risk of biological infectious, the operators should wear laboratory protective clothing, gloves to abide by the operation regulations of laboratory safety.

Chapter 7 ATTACHMENT

Attachment 1: Packing list

Table 7-1 Getein 1600 packing list

No.	Attachment Name	Specifications	Quantity	Comment
1	Main Engine	Getein1600	1	
2	User Manual		1	
3	Certificate		1	
4	Power Line		1	
5	Printing Paper	80×80 mm	1	
6	Data Wire		1	
7	Software CD		1	
8	Supervisory Computer Management Software User Manual		1	
9	Warranty Certificate		1	
10	Sample Frame		6	

Attachment 2: Copyright statement

Copyright

Getein Biotech, Inc.

Copyright number： 5.0

Issuing date： 12/01/2015

Instrument name： Immunofluorescence Quantitative Analyzer

Specifications and models： Getein1600

Production date: Details refer to data plate

Statement

1．Getein biotech, Inc. have the copyright of the non-published manual and have the right to process it as confidential document. This manual is only used for Getein1600 instrument operation, maintenance and repair. Other people have no right to make the manual published.

2．This manual contains the data which protected by copyright. All rights reserved and without the written consent, anyone can not copy, reprint or translate into other language.

3．Manufacturer don’t take any kind of warranty for the manual and don’t responsible for any indirect loss caused by the errors in the manual.

4．Manufacturer have the right to revise the manual without notice.

Manufacturer responsibility

The manufacturer take the responsibility of instrument safety, reliability and performance only in the following situations:

1．Instrument installation, upgrade, system expansion, calibration, improvement and repair are done by authorized personnel by the manufacturer;

2．The hospital or institution who use the instrument should develop a regular maintenance plan, otherwise it may lead to the failure of the instrument or even endanger the health of operator;

3．The manufacturer will provide circuit diagram and calibration method, etc. that used to maintenance and repair the instrument, if needed;

4．The manufacturer don’t take any responsibility for the failure of maintenance if the user don’t performed as this manual described.

Analyzer lifespan

Getein1600’s lifespan is 8 year (continuous working time no more than eight hours every day) under standardized operation and proper maintenance.