



# Declaration of Conformity



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

<b>Maker</b> (Name, Address)	<b>Getein Biotech, Inc.</b> No. 9 Bofu Road, Luhe District, Nanjing, 211505, China	
<b>Authorized Representative</b> (Name, Address)	<b>Lotus NL B.V.</b> Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.	
<b>Medical device</b>	Description :	FIA8000 Quantitative Immunoassay Analyzer FIA8600 Quantitative Immunoassay Analyzer Cardiac Troponin I Fast Test Kit One Step Test for cTnI (Colloidal Gold) cTnI Rapid Test (Colloidal Gold Assay) One Step Test for NT-proBNP (Colloidal Gold) One Step Test for NT-proBNP/cTnI (Colloidal Gold) One Step Test for CK-MB/cTnI/Myo (Colloidal Gold) One Step Test for hs-CRP+CRP (Colloidal Gold) One Step Test for D-Dimer (Colloidal Gold) One Step Test for PCT (Colloidal Gold) One Step Test for $\beta$ 2-MG (Colloidal Gold) One Step Test for mAlb (Colloidal Gold) One Step Test for NGAL (Colloidal Gold) One Step Test for CysC (Colloidal Gold) One Step Test for HCG+ $\beta$ (Colloidal Gold) One Step Test for HbA1c (Colloidal Gold) One Step Test for PCT/CRP (Colloidal Gold) One Step Test for CK-MB/cTnI/H-FABP (Colloidal Gold) One Step Test for H-FABP (Colloidal Gold) One Step Test for CK-MB/cTnI (Colloidal Gold) One Step Test for CK-MB (Colloidal Gold) One Step Test for TSH (Colloidal Gold) One Step Test for T4/T3 (Colloidal Gold) One Step Test for T3 (Colloidal Gold) One Step Test for T4 (Colloidal Gold) One Step Test for 25-OH-VD (Colloidal Gold) One Step Test for FOB (Colloidal Gold) One Step Test for <i>H. pylori</i> (Colloidal Gold) One Step Test for SAA (Colloidal Gold) Getein1100 Immunofluorescence Quantitative Analyzer Getein1600 Immunofluorescence Quantitative Analyzer Getein1180 Immunofluorescence Quantitative Analyzer Getein1200 Immunofluorescence Quantitative Analyzer Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) NT-proBNP Fast Test Kit (Immunofluorescence Assay) hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) D-Dimer Fast Test Kit (Immunofluorescence Assay)



		<p>PCT Fast Test Kit (Immunofluorescence Assay)  β2-MG Fast Test Kit (Immunofluorescence Assay)  mAlb Fast Test Kit (Immunofluorescence Assay)  NGAL Fast Test Kit (Immunofluorescence Assay)  CysC Fast Test Kit (Immunofluorescence Assay)  CK-MB Fast Test Kit (Immunofluorescence Assay)  CK-MB/cTnl Fast Test Kit (Immunofluorescence Assay)  HCG+β Fast Test Kit (Immunofluorescence Assay)  HbA1c Fast Test Kit (Immunofluorescence Assay)  PCT/CRP Fast Test Kit (Immunofluorescence Assay)  CK-MB/cTnl/H-FABP Fast Test Kit (Immunofluorescence Assay)  H-FABP Fast Test Kit (Immunofluorescence Assay)  25-OH-VD Fast Test Kit (Immunofluorescence Assay)  TSH Fast Test Kit (Immunofluorescence Assay)  T3 Fast Test Kit (Immunofluorescence Assay)  T4 Fast Test Kit (Immunofluorescence Assay)  25-OH-VD Fast Test Kit (Immunofluorescence Assay)  FOB Fast Test Kit (Immunofluorescence Assay)  <i>H. pylori</i> Fast Test Kit (Immunofluorescence Assay)  SAA Fast Test Kit (Immunofluorescence Assay)  LH Fast Test Kit (Immunofluorescence Assay)  FSH Fast Test Kit (Immunofluorescence Assay)  AMH Fast Test Kit (Immunofluorescence Assay)  PRL Fast Test Kit (Immunofluorescence Assay)  CK-MB Control  cTnl Control  Myo Control  NT-proBNP Control  D-Dimer Control  CRP Control  PCT Control  β2-MG Control  mAlb Control  NGAL Control  CysC Control  H-FABP Control  HbA1c Control  HCG+β Control  CK-MB/cTnl/Myo Control  CK-MB/cTnl Control  NT-proBNP/cTnl Control  TSH Control  T4/T3 Control  T3 Control  T4 Control</p>	
	Classification of products according to directive	:	Others
	Batch/serial No. Type, production term (if applicable)	:	



Applicable coordination standards:	EN ISO 14971:2012	EN ISO 23640:2015	EN ISO 13485:2016
	EN 13612:2002	EN ISO15223-1:2012	EN ISO 18113-2:2011
	EN 1041:2008	EN ISO 18113-1:2011	EN ISO 18113-3:2011
	IEC 61010-1:2010	IEC 61010-2-081:2015	IEC 61010-2-101:2015
	IEC 61326-1:2013	IEC 61326-2-2:2013	

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 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.

General Manager: Enben Su

Nha Trang, 20th, Jul, 2019  
 (place and date of issue)

\_\_\_\_\_   
 (name and signature or equivalent marking of authorized person)






# 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.





Cardiac  
Markers

Coagulation  
Markers

Diabetes  
Mellitus

Inflammation

Thyroid  
Function

Metabolic  
Marker

Renal  
Function

Tumor  
Markers

Reproduction  
/Fertility

Infectious  
Disease



OPTIMIZED POINT-OF-CARE SOLUTION  
**MAKING TEST EASY**

# Getein1100

Immunofluorescence Quantitative Analyzer





# Getein1100

Immunofluorescence Quantitative Analyzer



## HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control



## REAL-TIME AND RAPID TEST

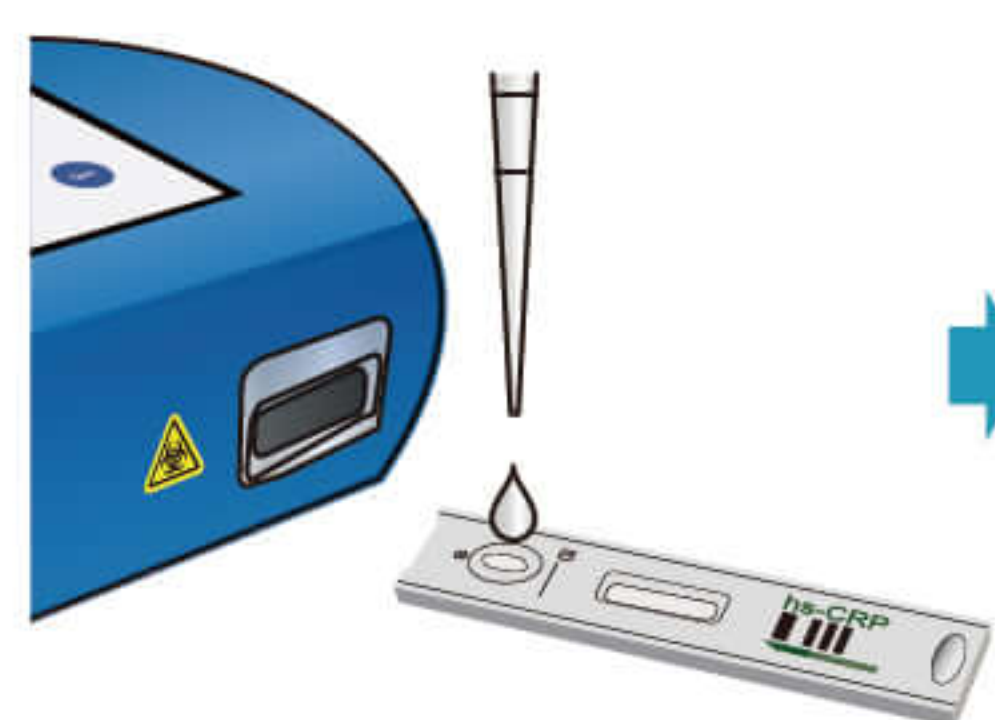
One-step test

3-15 min/test

5 sec/test for multiple tests

## OPERATION MODES

### Inside Mode (single sample rapid test mode)



Sample Dispense



Test Card Insert

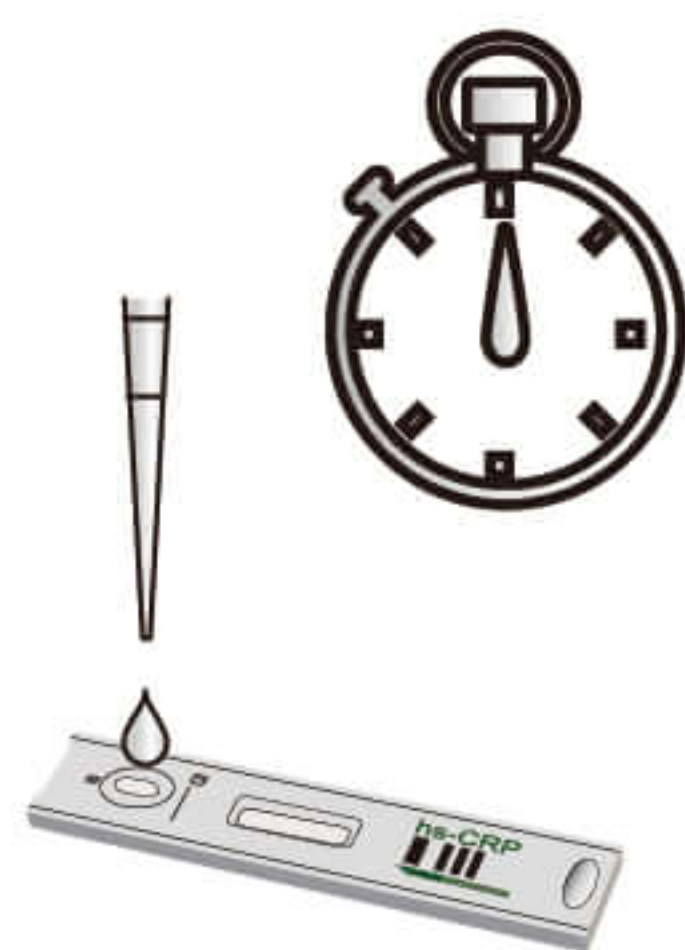


Click "Start" Icon

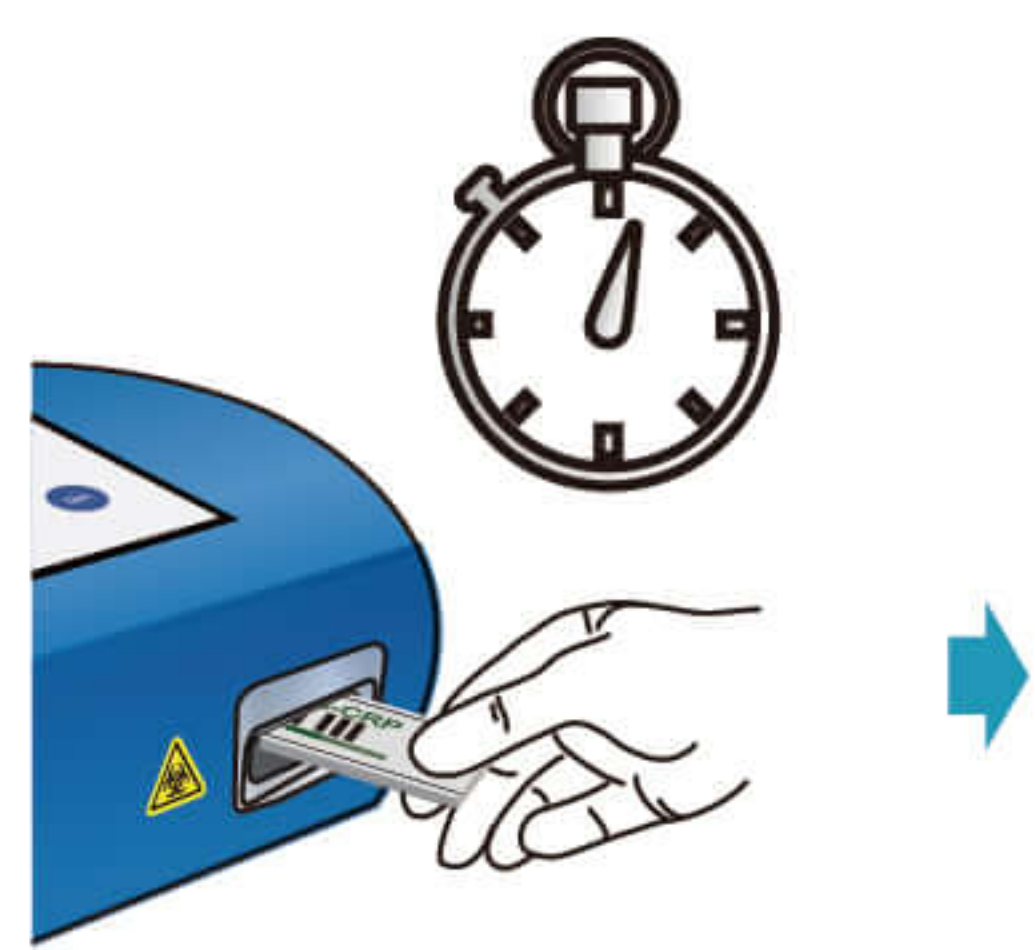


Result Show and Print

### Quick mode (mass samples rapid test mode)



Sample Dispense



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 lithium battery

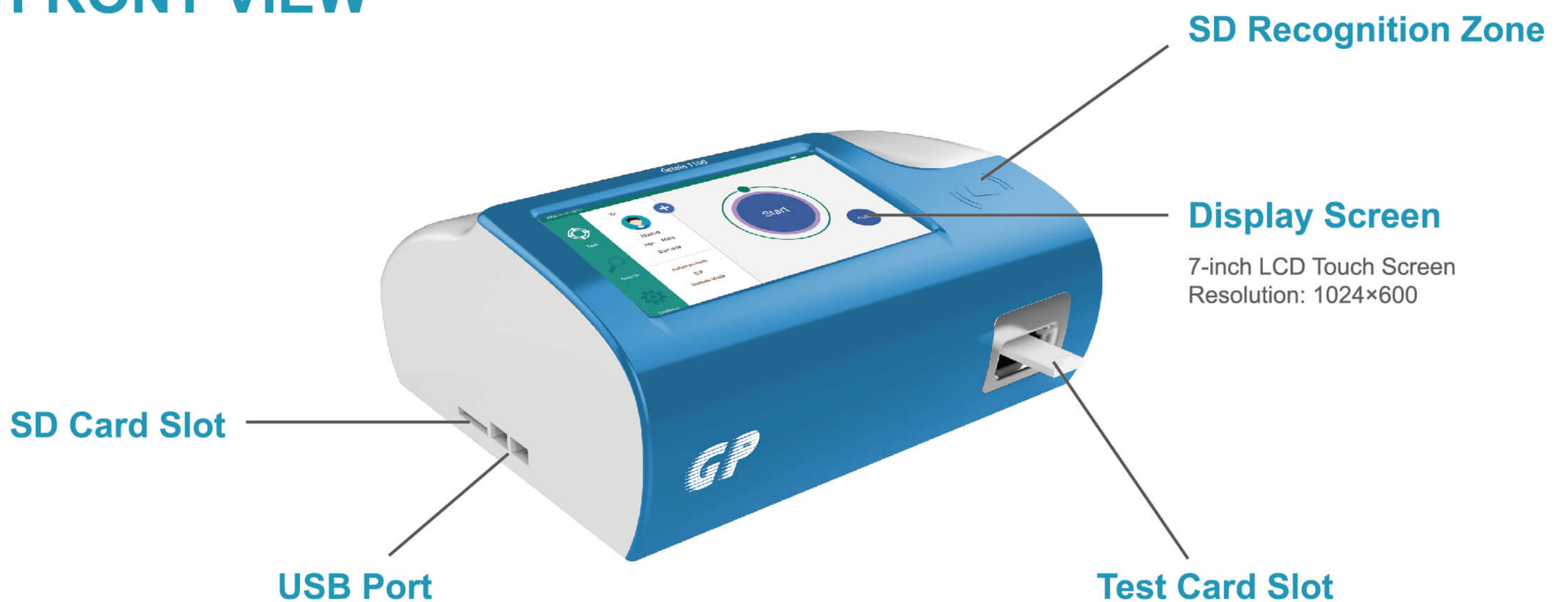


## USER-FRIENDLY INTERFACE

Android system

7 inch touch screen

## FRONT VIEW







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



# TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
<b>Cardiac Markers</b>								
IF1001	cTnI	Myocardial infarction	0.1 ng/mL	S/P/WB	0.1-50.0 ng/mL	100 µL	10 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: 5.0 ng/mL cTnI: 0.1 ng/mL Myo: 70 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL 30.0-600.0 ng/mL	100 µL	10 min	NMPA CE
IF1012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.0 ng/mL cTnI: 0.1 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL	100 µL	10 min	CE
IF1014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.0-120.0 ng/mL	100 µL	3 min	NMPA CE
IF1016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.0 ng/mL cTnI: 0.1 ng/mL H-FABP: 6.36 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL 2.0-100.0 ng/mL	100 µL	10 min	NMPA CE
IF1018	CK-MB	Myocardial injury	5.0 ng/mL	S/P/WB	2.5-80.0 ng/mL	100 µL	10 min	CE
<b>NEW</b> IF1078	ST2	Heart failure	35.0 ng/mL	S/P/WB	3.1-200.0 ng/mL	100 µL	10 min	CE
<b>Coagulation Markers</b>								
IF1006	D-Dimer	Venous thromboembolism	0.5 mg/L	P/WB	0.1-10.0 mg/L	100 µL	10 min	NMPA CE
<b>Inflammation</b>								
IF1003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3 mg/L 10 mg/L	S/P/WB/ Fingertip blood	0.5-200 mg/L	10 µL	3 min	NMPA CE
IF1007	PCT	Sepsis, bacterial infection	0.1 ng/mL	S/P/WB	0.1-50.0 ng/mL	100 µL	15 min	NMPA CE
IF1015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.1 ng/mL CRP: 3.0 mg/L	S/P/WB	0.1-50.0 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/ Capillary 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	CE
<b>Renal Function</b>								
IF1008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.5-10.0 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 ng/mL Urine: 100 ng/mL	S/Urine	50-5000 ng/mL	10 µL	10 min	NMPA CE
IF1011	β <sub>2</sub> -MG	Acute and chronic kidney diseases/tumours	0.8-3.0 mg/L	S/P/WB	0.5-20.0 mg/L	10 µL	3 min	NMPA CE
<b>Diabetes Mellitus</b>								
IF1017	HbA1c	Diabetes mellitus	3.8%-5.8%	WB	2%-14%	10 µL	5 min	NGSP NMPA IFCC CE
<b>Metabolic Marker</b>								
IF1031	25-OH-VD	Osteomalacia, osteoporosis	30.0-50.0 ng/mL	S/P	8.0-70.0 ng/mL	40 µL	15 min	NMPA CE
<b>Thyroid Function</b>								
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	CE
IF1023	T4	Hyperthyroidism, hypothyroidism	59.0-154.0 nmol/L	S/P	5.4-320.0 nmol/L	40 µL	15 min	CE
IF1067	ft3	Hyperthyroidism, hypothyroidism	3.1-6.8 pmol/L	S/P	0.4-50.0 pmol/L	100 µL	15 min	CE
IF1068	ft4	Hyperthyroidism, hypothyroidism	12.0-22.0 pmol/L	S/P	0.3-100.0 pmol/L	100 µL	15 min	CE



Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
<b>Reproduction/Fertility</b>								
IF1013	HCG+β	Fertility	5.1 mIU/mL	S/P	5-100000 mIU/mL	100 μL	10 min	NMPA CE
IF1055	LH	Homeostasis fertility regulation	Refer to User Manual	S/P	0.2-150.0 mIU/mL	100 μL	15 min	CE
IF1056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.2-150.0 mIU/mL	100 μL	15 min	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	0.50-200.0 ng/mL	100 μL	15 min	CE
IF1071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	CE
<b>Tumor Markers</b>								
IF1053	tPSA	Prostate cancer	4.0 ng/mL	S/P	0.50-100.00 ng/mL	100 μL	15 min	
IF1072	fPSA	Prostate cancer	1.0 ng/mL	S/P	0.10-30.00 ng/ml	100 μL	10 min	
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/WB	2.0-500.0 ng/mL	100 μL	15 min	CE
<b>Infectious Disease</b>								
IF1057	Anti-HCV	Hepatitis C	1 S/CO	S/P	1.00-20.00 S/CO	100 μL	15 min	
IF1058	Anti-TP	Syphilis	1 S/CO	S/P	1.00-50.00 S/CO	100 μL	15 min	CE
IF1059	Anti-HIV	AIDS	1 S/CO	S/P	1.00-1000.00 S/CO	100 μL	15 min	
IF1064	HBsAg	Hepatitis B	1 IU/mL	S/P	1.00-100.00 IU/mL	100 μL	15 min	
<b>NEW</b> 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 COI	S/P/WB		100 μL	10 min	CE
<b>NEW</b> IF1091	SARS-CoV-2 Antigen	COVID-19	1 COI	Nasal swab/Saliva		100 μL	15 min	CE
<b>NEW</b> IF1092	SARS-CoV-2 Total Antibody/ Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB		100 μL	10 min	CE
<b>NEW</b> IF1095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB		100 μL	10 min	
IF1047	<i>H. pylori</i>	<i>H. pylori</i> infection	5 ng/mL	Stool	1-200 ng/mL	150 mg	10 min	CE
<b>Others</b>								
<b>NEW</b> IF1077	Ferritin	Anemia/tumors	Male: 30-400 ng/mL Female: 13-150 ng/mL	S/P	0.50-2000.00 ng/mL	100 μL	15 min	CE
<b>NEW</b> IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE

Coming Soon: FOB, ASO, RF, anti-CCP, Folate...

**GP Getein Biotech, Inc.**

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



FSC CE NMPA NGSP IFCC IVD

