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.









HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control



REAL-TIME AND RAPID TEST

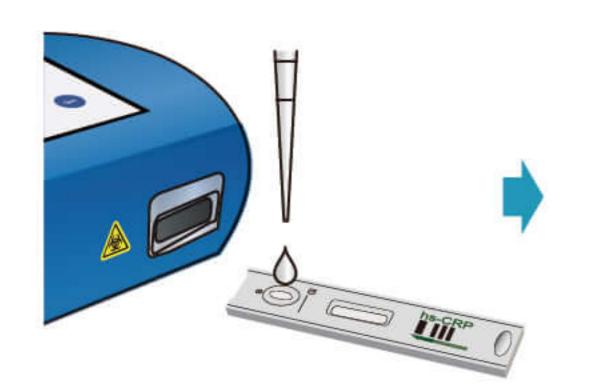
One-step test

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

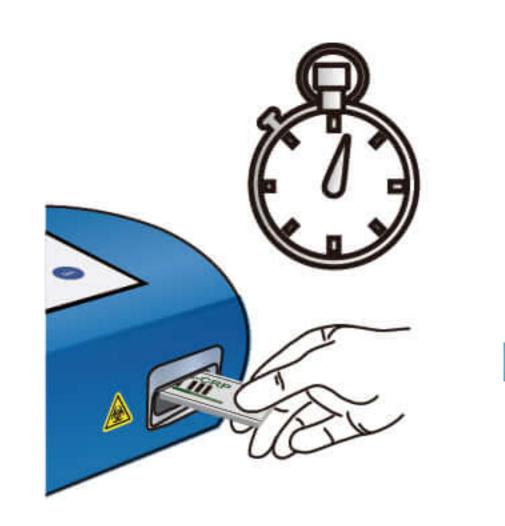


Result Show and Print

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

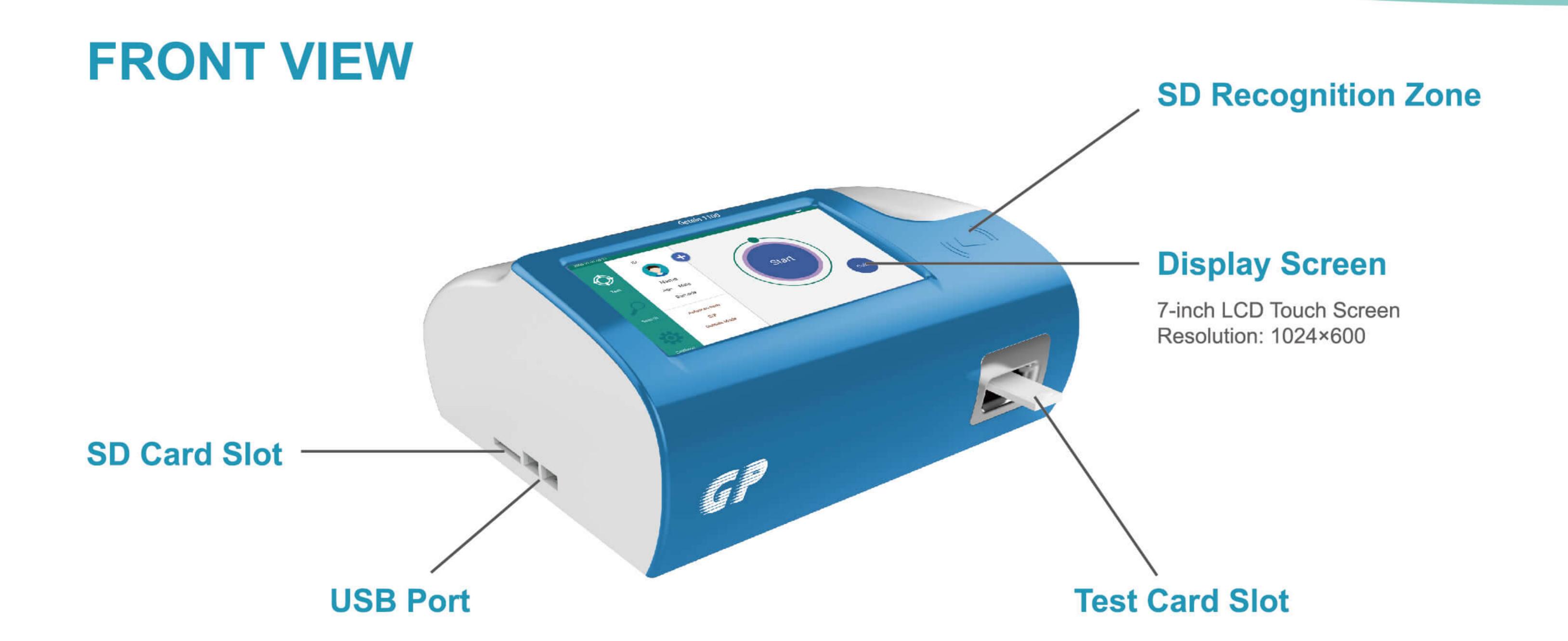
Continuous test for 3 hours with lithium battery



USER-FRIENDLY INTERFACE

Android system

7 inch touch screen







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

Tempreture: 10-35 °C
Relative humidity ≤70%
Air pressure 70.0~106.0 kpa

Dimension

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	QUALIFIC	CATIO
Cardia	ac Markers								
IF1001	cTnI	Myocardial infarction	0.1 ng/mL	S/P/WB	0.1-50.0 ng/mL	100 µL	10 min	NMPA	C€
IF1089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	NMPA	C€
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 cTnl: 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 cTnl: 0.1 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL	100 µL	10 min	C	ξ
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 cTnl: 0.1 ng/mL H-FABP: 6.36 ng/m	S/P/WB L	2.5-80.0 ng/mL 0.1-50.0 ng/mL 2.0-100.0 ng/mL	100 µL	10 min	NMPA	CE
F1018	CK-MB	Myocardial injury	5.0 ng/mL	S/P/WB	2.5-80.0 ng/mL	100 µL	10 min	(ξ
F1078	ST2	Heart failure	35.0 ng/mL	S/P/WB	3.1-200.0 ng/mL	100 µL	10 min	C	ξ
Coag	ulation Markers								
IF1006	D-Dimer	Venous thromboembolism	0.5 mg/L	P/WB	0.1-10.0 mg/L	100 µL	10 min	NMPA	CE
Inflam	mation								
F1003	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	CΕ
IF1007	PCT	Sepsis, bacterial infection	0.1 ng/mL	S/P/WB	0.1-50.0 ng/mL	100 µL	15 min	NMPA	CE
F1015	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
F1044	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
F1090	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	C€
F1088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	100 µL	15 min	(ξ
Renal	Function								
F1008	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	C€
F1009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA	C€
F1010	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 ₂ -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
Diabe	tes Mellitus								
F1017	HbA1c	Diabetes mellitus	3.8%-5.8%	WB	2%-14%	10 µL	5 min	NGSP	NMP/
Metab	oolic Marker								
F1031	25-OH-VD	Osteomalacia, osteoporosis	30.0-50.0 ng/mL	S/P	8.0-70.0 ng/mL	40 µL	15 min	NMPA	C€
Thyro	id Function								
F1024	TSH	Thyroid malfunction	0.27-4.20 µIU/mL	S/P	0.10-50.00 μIU/mL	100 µL	15 min	NMPA	CE
F1022	Т3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	40 µL	15 min	C	€
F1023	T4	Hyperthyroidism, hypothyroidism	59.0-154.0 nmol/L	S/P	5.4-320.0 nmol/L	40 µL	15 min	(ξ
IF1067	fT3	Hyperthyroidism, hypothyroidism	3.1-6.8 pmol/L	S/P	0.4-50.0 pmol/L	100 µL	15 min	C	ξ
	fT4	Hyperthyroidism,	12.0-22.0 pmol/L	S/P	0.3-100.0 pmol/L	100	15 min		

Cat.#	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES		SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Repro	duction/Fertility							
IF1013	HCG+β	Fertility	5.1 mIU/mL	S/P	5-100000 mIU/mL	100 µL	10 min	NMPA CE
IF1055	LH	Homeostasis fertility regualtion	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
Tumor	Markers							
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	C€
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
Infecti	ous Disease							
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	C€
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	
IF1063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/m	L100 µL	15 min	
IF1084	2019-nCoV lgM/lgG	COVID-19	1 COI	S/P/WB		100 µL	10 min	CE
IF1091	SARS-CoV-2 Antigen	COVID-19	1 COI Nasa	al swab/Sali	va	100 µL	15 min	CE
IF1092	SARS-CoV-2 Total Antibody/ Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB		100 µL	10 min	CE
IF1095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB		100 µL	10 min	
IF1047	H. pylori	H. pylori infection	5 ng/mL	Stool	1-200 ng/mL	150 mg	10 min	C€
Others	S							
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
IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 µL	15 min	C€

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



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