EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	cTnI/CK-MB/Myo Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

Immunofluorescence POCT Solution

Multi-Channel Analyzer & Reagents for IVD Manufacturers and Distributors

Guangdong Wesail Biotech Co., Ltd.

◎ Analyzer Features
WS-Mi6000

Rapid

180 T/H, result in 2~8 min for single parameter or 15 min for multi-parameters

Precision

±0.1°C precise temperature control improving test repeatability

Accurate

CV ≤2% between channels, CV ≤5% between analyzers

Display-Friendly

High resolution 11.1" large touch screen provides operational stability and quick response

Compact

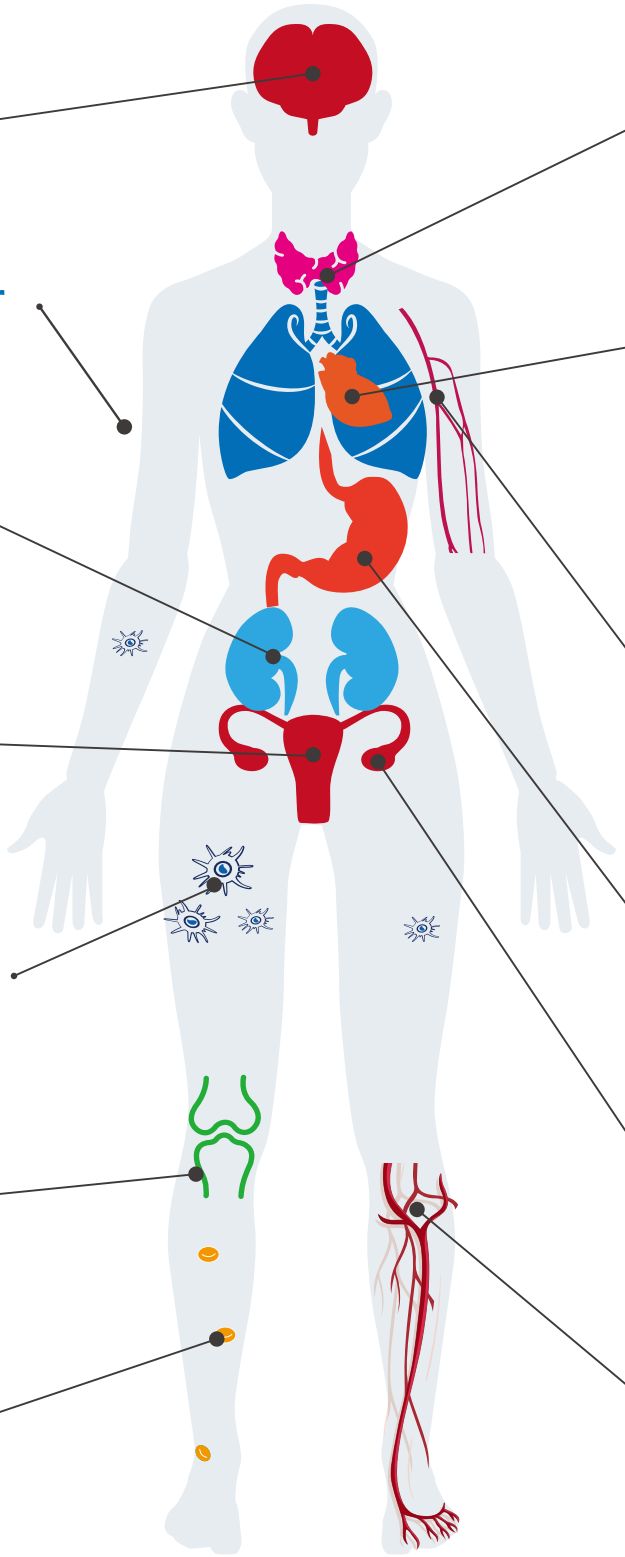
All-in-one analyzer with incubator, barcode reader and thermal printer, no extra step required from cartridge insert to result

◎ Specification - Multi-Channel

Test Speed	180 T/H
Dimension	395.5 × 223.5 × 193 (L x W x H) mm
Weight	≈ 6.4 kg
Display	11-inch Touchscreen
LIS System	Uni or Bi-directional
Data Processor	Intelligence
Sampling	Manual
Barcode Reader	Built-in (external available)
Parameters Import	Barcode
Printer	Built-in Thermal
Incubator	Built-in
Clot and Bubble Detection	No
Auto-dilution	No

Test Menu

Up to 32 tests available with expected expansion to 50 tests



Brain
S100β

Tumor Marker
CEA
AFP
PSA
fPSA ↑

Renal Injury
MAU
NGAL ↑
β2-MG ↑
Cys-C ↑

Pregnancy
β-hCG
FSH
LH
P ↑
PRL ↑
E2 ↑
T ↑
PIGF ↑
sFlt-1 ↑

Inflammation
hs-CRP+CRP
SAA
IL-6
PCT ↑
mPCT ↑

Bone Metabolism
Osteocalcin
25-OH VD

Anemia
Ferritin
Folate ↑
Vitamin B12 ↑

Thyroid
TSH
T4
T3
fT4 ↑
fT3 ↑

Cardiac Marker
hs-cTnI
CK-MB
H-FABP
Myoglobin
cTnI/CK-MB/Myo
ST2
Lp-PLA2
NT-proBNP
BNP

Thrombosis
D-Dimer

Stomach
PG I
PG II

Fertility
AMH
InhB ↑

Diabetes
HbA1c
C Peptide ↑
Insulin ↑

↑ Upcoming

◎ Feature Reagent Performances

Category	Product	Sample volume	Reaction time	Sample	Package	Detection range
Cardiac Marker	hs-cTnI	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.020 ng/mL-100.000 ng/mL
	CK-MB	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.200 ng/mL-300.000 ng/mL
	Myoglobin	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	7.80 ng/mL-2000.00 ng/mL
	cTnI/CK-MB/Myo	75 μL	12 mins	S/P/W	20 or 50 Tests/Kit	cTnI 0.200 ng/mL-80.000 ng/mL CK-MB: 2.000 ng/mL-150.000 ng/mL Myo: 10.00 ng/mL-500.00 ng/mL
	H-FABP	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.60 ng/mL-512.00 ng/mL
	ST2	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	2.0 ng/mL-1000.0 ng/mL
	Lp-PLA2	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	7.50 ng/mL-1200.00 ng/mL
	NT-proBNP	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	30 pg/mL-45000 pg/mL
	BNP	60 μL	8 mins	P/W	20 or 50 Tests/Kit	10.0 pg/mL-6000.0 pg/mL
Thrombosis	D-Dimer	60 μL	8 mins	P/W	20 or 50 Tests/Kit	0.150 mg/L FEU-35.000 mg/L FEU
Inflammation	hs-CRP+CRP	5 μL	2 mins	S/P/W	20 or 50 Tests/Kit	0.50 mg/L-350.00 mg/L
	SAA	5 μL	2 mins	S/P/W	20 or 50 Tests/Kit	0.50 mg/L-1000.00 mg/L
	IL-6	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	2.0 pg/mL-5000.0 pg/mL
	PCT	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.020 ng/mL-200.000 ng/mL
	mPCT	30 μL	5 mins	S/P/W	20 or 50 Tests/Kit	0.020 ng/mL-200.000 ng/mL
Diabetes	HbA1c	5 μL	5 mins	W	20 or 50 Tests/Kit	3.8 %-18.5 %
Thyroid	TSH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.010 μIU/mL-100.000 μIU/mL
	T4	60 μL	5 mins	S/P/W	24 or 48 Tests/Kit	5.00 nmol/L-320.00 nmol/L
	T3	60 μL	5 mins	S/P/W	24 or 48 Tests/Kit	0.20 nmol/L-10.00 nmol/L
Pregnancy	β-hCG	5 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.10 mIU/mL-10000.00 mIU/mL
	FSH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.15 mIU/mL-200.00 mIU/mL
	LH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.50 mIU/mL-200.00 mIU/mL
Fertility	AMH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.050 ng/mL-23.000 ng/mL

◎ Feature Reagent Performances

Category	Product	Sample volume	Reaction time	Sample	Package	Detection range
Stomach	PGI	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	1.00 ng/mL-200.00 ng/mL
	PGII	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.40 ng/mL-100.00 ng/mL
Tumor Marker	CEA	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.20 ng/mL-1200.00 ng/mL
	AFP	60 μL	8 mins	S/P/W	24 or 48 Tests/Kit	0.60 ng/mL-1210.00 ng/mL
	PSA	60 μL	8 mins	S/P/W	24 or 48 Tests/Kit	0.014 ng/mL-150.000 ng/mL
Renal Injury	MAU	60 μL	2 mins	Urine	20 or 50 Tests/Kit	5.00 mg/L-500.00 mg/L
Bone Metabolism	Osteocalcin	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.50 ng/mL-300.00 ng/mL
	25-OH VD	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	3.00 ng/mL-120.00 ng/mL (7.50 nmol/L-300.00 nmol/L)
Anemia	Ferritin	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.5 ng/mL-2000.0 ng/mL

Guangdong Wesail Biotech Co., Ltd.

Address : No.1 Taoyuan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, Dongguan, Guangdong, China

Website : http://en.wesailbio.com

E-mail : customer@wesailbio.com

Phone/Fax : 400-900-1339

Version : WS-SPOC-EN-20230719

Linker

Facebook

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20214579

Bijlagen
-

Uw aanvraag
5 juli 2021

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 8 juli 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 5 juli 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Guangdong Wesail Biotech Co., Ltd. met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

Glycated Hemoglobin A1c Test Kit (Immunofluorescence)
Pepsinogen I Test Kit (Immunofluorescence)
Pepsinogen II Test Kit (Immunofluorescence)
C Peptide Test Kit (Immunofluorescence)
Insulin Test Kit (Immunofluorescence)
Nucleic Acid Extraction Kit
(geen merknaam) (NL-CA002-2021-61009)
High Sensitivity Cardiac Troponin I Test Kit(Immunofluorescence)
N-terminal pro-Brain Natriuretic Peptide Test Kit(Immunofluorescence)
Heart Type Fatty Acid Binding Protein Test Kit(Immunofluorescence)
Handheld Immunofluorescence Analyzer
Incubator
(geen merknaam) (NL-CA002-2021-61006)
Microalbuminuria Test Kit(Immunofluorescence)
Thyroid Stimulating Hormone Test Kit(Immunofluorescence)
Osteocalcin Test Kit(Immunofluorescence)
Ferritin Test Kit(Immunofluorescence)
Central Nerve Specific Protein 100 β Test Kit(Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61010)
Myoglobin Test Kit(Immunofluorescence)
D-Dimer Test Kit(Immunofluorescence)
Soluble Growth Stimulation Expressed Gene 2 Protein Test Kit(Immunofluorescence)
cTnI/CK-MB/Myo Test Kit(Immunofluorescence)
Myeloperoxidase Test Kit(Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61007)

Procalcitonin Test Kit (Immunofluorescence)
Creatine Kinase Isoenzyme-MB Test Kit (Immunofluorescence)
C-Reactive Protein Test Kit (Immunofluorescence)
Human Serum Amyloid A Test Kit (Immunofluorescence)
Interleukin-6 Test Kit (Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61008)
β-human Chorionic Gonadotropin Test Kit (Immunofluorescence)
Luteinizing Hormone Test Kit (Immunofluorescence)
Anti-Mullerian Hormone Test Kit (Immunofluorescence)
Follicle Stimulating Hormone Test Kit (Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61011)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

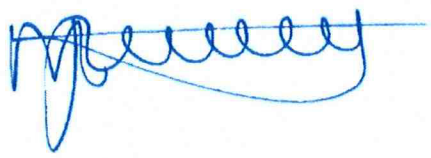
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Guangdong Wesail Biotech Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit).

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

16361

cTnI/CK-MB/Myo Test Kit (Immunofluorescence)

(For *In Vitro* Diagnostic Use Only)

[Product Name] cTnI/CK-MB/Myo Test Kit (Immunofluorescence)

[Package Specification& REF ID]

20 tests/kit(BA0130), 50 tests/kit(BA0131)

[Intended Use]

This kit applies to the simultaneous quantitative determination of cTnI, CK-MB and Myoglobin in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of myocardial infarction clinically.

Cardiac troponin I (cTnI) is a key regulatory protein in striated muscle tissue and is associated with muscle contraction. There are three subtypes of cardiac troponin I discovered so far, among which cardiac troponin I (cTnI) exhibits high specificity to cardiac tissue and can differentiate between skeletal muscle disease and myocardial injury. It is a highly sensitive marker for myocardial injury[1,2,3]. When myocardial infarction occurs, serum levels of cTnI begin to rise around 3-6 hours, reach the peak concentration between 12-16 hours, and can remain elevated for 4-9 days[3,4]. Elevated levels of cTnI are also observed in cases of unstable angina pectoris (UAP) and congestive heart failure (CHF)[5,6]. Additionally, cTnI is a mature predictor of short-term, medium-term, and even long-term prognosis in patients with acute coronary syndrome (ACS)[7,8]. In general, an increase in cTnI levels indicates the presence of myocardial injury, and if the clinical situation indicates non-cardiac ischemia, other causes of cardiac damage should be considered.

Creatine kinase-MB (CK-MB), mainly found in myocardium, is one of the classic and important serum enzyme markers for the diagnosis of myocardial infarction. When acute myocardial infarction (AMI) occurs, CK-MB is released into the blood and begins to rise within 2-4 hours, reaching peak concentration within 12 hours, and returning to normal levels within 48-72 hours[9,10]. When the blocked coronary artery reopens, CK-MB in myocardial cells is flushed into the bloodstream, causing an increase in CK-MB levels. Changes in CK-MB concentration can be used to evaluate the effectiveness of thrombolytic therapy[11]. Therefore, CK-MB can be used as an auxiliary diagnostic indicator for assessing the degree of myocardial injury, the effectiveness of thrombolytic therapy, re-occlusion or infarction range, and risk stratification.

Myoglobin, a unique protein in muscle tissue, can supply oxygen to muscles during energy-demanding activities. In acute myocardial injury, Myoglobin is first released into the bloodstream. Approximately 2-3 hours after the onset of symptoms, Myoglobin levels in the blood can exceed the normal upper limit. The levels peak at 9-12 hours and return to normal after 24-36 hours[12,13,14,15]. Continuous monitoring of Myoglobin levels for 6-12 hours in patients with chest pain, can rule out acute myocardial infarction (AMI) if there is no elevation[16]. Therefore, continuous monitoring of Myoglobin levels can be used for early diagnosis of AMI and has significant exclusionary value.

Although each of the three cardiac markers has its own unique advantages, due to the different sensitivity and specificity of each indicator, there are certain limitations when they are detected alone. Some highly specific markers may lack sensitivity and result in missed diagnoses, thereby causing patients to miss the optimal treatment opportunity. On the other hand, some highly sensitive markers may have low specificity, leading to misdiagnosis. Therefore, the combined detection of these three markers is particularly important for the diagnosis and prognosis of the disease[13,14].

The comprehensive use of these three markers is significant importance in the diagnosis of myocardial infarction, evaluation of the effectiveness of thrombolytic therapy, and assessment of re-occlusion or infarction range and severity.

Currently the common clinical test methods include colloidal gold method, solid phase immunochromatography, fluoroimmunoassay (FIA), etc.

[Principle]

The kit is based on the principle of the lateral flow fluorescence immunoassay utilizing an immuno-sandwich format. When the sample is added to the sample port, the sample first passes through the sample pad, and then cTnI, CK-MB and Myoglobin in the sample specifically binds to the fluorescent-conjugated cTnI, CK-MB and Myoglobin monoclonal antibody on the conjugate pad to form a fluorescent complex. When the fluorescence complex flows to the test band, it will bind to the cTnI, CK-MB and Myoglobin monoclonal antibody pre-coated on the nitrocellulose membrane and will be fixed on the test band. The antigen content in the complex is proportional to the fluorescence intensity of the test band. When the free fluorescence complex reaches the control band, the complex will specifically bind to the goat IgG pre-coated on the control band and therefore will be fixed on it. The immunofluorescence analyzer converts the received fluorescence signal value into electrical signal value, and automatically converts the concentration of cTnI, CK-MB and Myoglobin in the sample (ng/mL) by substituting the T/C value (T/C peak area) into the preset calibration curve.

[Components]

Composition	Main ingredients/information	20 tests/kit		50 tests/kit	
		BA0130		BA0131	
		Quantity	Specification	Quantity	Specification
Test Cassette	Nitrocellulose membrane (cTnI/CK-MB/Myoglobin monoclonal antibody, goat IgG), conjugate pad (fluorescent conjugated cTnI/CK-MB/Myoglobin monoclonal antibody), sample pad, absorbent pad	20	Individual package	50	Individual package
Certificate of conformity/ calibrate card	Product information (item name, item code, batch number, production date, expiration date), calibration curve	1 copy	----	1 copy	----
Product insert	/	1 copy	----	1 copy	----

The components in different batch of kits are not interchangeable.

[Storage and Stability]

Store at room temperature (2-30°C or 35.6-86°F) in a dry shady place. Avoid direct sunlight. 18 months of shelf life (production date to expiration date).
The test cassette should be used within half an hour as long as the aluminum foil bag is opened, and used immediately when the room temperature exceeds 25°C or in an environment with high humidity.
The kit can be transported for 30 days at the temperature of -20 °C to 45 °C.
Production batch number, production date and expiration date are shown on the packing label.

[Applicable Instrument]

Immunofluorescence analyzers: WS-Si1000, WS-Si1500 and WS-Mi6000 produced by Guangdong Wesail Biotech Co., Ltd.

[Sample Requirements]

1. Applicable to the following sample:
   Fresh venous serum, heparin plasma or whole blood samples, fasting blood collection is unnecessary.
2. Precautions during sample collection:

2.1 The sample shall be protected against hemolysis and free of fibrin and other impurities;
2.2 White blood cells or platelets should be avoided when collecting plasma samples.
2.3 Before testing, the serum/plasma samples should be centrifuged at room temperature (15°C~30°C) for 10 minutes at 1,300g~2,000g (generally 3,500~4,000rpm), which can be configured according to the Instructions for Use of the centrifuge.

3. Storage and preparation of samples:

3.1 The whole blood sample at room temperature should be used within 4 hours and, if it cannot be tested within 4 hours, it should be timely transferred for storage at 2°C~8°C. The samples that are not detected within 24 hours should be discarded and the blood has to be drawn again.

Sample type	Storage condition	Storage time
Plasma/Serum	≤-20°C	1 month
Plasma/Serum	2～8 °C	24 hours
Plasma/Serum	15～30 °C	8 hours
Whole Blood	15～30 °C	4 hours

3.2 The sample can only be frozen and thawed once after thawing.

[Test Procedure]

Before the test, you are required to thoroughly read the relevant operating instructions for this reagent and the immunofluorescence analyzers.

Model of Analyzer	Steps	Details	Notes
WS-Si1000	Preparation	1.1 Power on the analyzer and incubator, allow them to preheat and perform self-checking respectively. 1.2 After the self-check of the analyzer is completed, insert the calibrate card into the corresponding scanning area of the analyzer, click the QR code icon to identify and import the item information. 1.3 Set the incubator to 12 minutes, 18.5°C.	The samples and kits must be restored to room temperature before testing
	Sample addition	2.1 Pipette 75 μL sample into the sample port of the cassette, insert the cassette into the incubator immediately, and the incubator will count down for 12 minutes.	Avoid sample overflow the sample port
	Detection	3.1 The incubator will automatically alarm at the last 10 seconds of incubation. Pull out the cassette immediately and insert it into the analyzer which will automatically recognize the QR code information on the cassette and display it in the test interface. After confirming the information is correct, select sample type and click “Test”, and the analyzer will automatically scan the cassette. 3.2 The analyzer will convert the scanned signal value through the preset calibration curve, and display the test results in the test interface. 3.3 Click “Print” to print results.	It has to be inserted into the analyzer for detection immediately after incubation
WS-Si1500; WS-Mi6000	Preparation	1.1 Power on the analyzer, allow it to preheat and perform self-checking. 1.2 After the self-check of the analyzer is completed, put the calibrate card in the corresponding scanning area, click "import" and the analyzer will identify and import the QR code information. 1.3 Insert the cassette, the analyzer will automatically identify the item information, and then eject the cassette, exposing the sample port. Select sample type in the test interface.	The samples and kits must be restored to room temperature before testing
	Sample addition	2.1 Pipette 75 μL sample to the sample port, then immediately insert the cassette into the analyzer, and the incubation time will automatically count down.	Avoid sample overflow the sample port
	Detection	3.1 After incubation, automatic detection is performed. The analyzer will convert the scanned signal value through the preset calibration curve, and display the test results in the test interface. 3.2 Click “Print” to print results.	/

[Quality Control Procedure]

Periodic quality control shall be carried out to ensure the effectiveness and accuracy of test results.
The analyzer’s optical parts and moving parts are validated by the quality control card.
Periodic validation is performed on the validity and accuracy of reagent test results by using the Cardiac troponin I Control, Creatine kinase-MB Control and Myoglobin Control from Guangdong Wesail Biotech Co., Ltd.
The kit does not contain the Cardiac troponin I Control, Creatine kinase-MB Control and Myoglobin Control and the quality control card, if necessary, please contact the manufacturer.

[Reference Range]

1. Considering the differences in geography, race, gender and age, laboratories are recommended to establish their own reference intervals according to their own conditions.
2. The cTnI/CK-MB/Myo Test Kit (Immunofluorescence) from Guangdong Wesail Biotech Co., Ltd. was used to test 520

apparently healthy people. Based on the treatment by non-parametric method, the 95th percentile was taken as the upper limit of reference interval, the reference interval was confirmed as cTnI: 0 ng/mL-0.300 ng/mL, CK-MB: 0 ng/mL-4.000 ng/mL, and Myoglobin: 0 ng/mL -70.00 ng/mL.

[Interpretation of Test Results]

1. The detection range of cTnI in sample is 0.200 ng/mL-80.000 ng/mL. For the samples exceeding the upper detection limit the results are reported ">80.000 ng/mL", or less than the lower detection limit the results are reported "< 0.200 ng/mL".
2. The detection range of CK-MB in sample is 2.000 ng/mL-150.000 ng/mL. For the samples exceeding the upper detection limit the results are reported ">150.000ng/mL", or less than the lower detection limit the results are reported "<2.000 ng/mL".
3. The detection range of Myoglobin in sample is 10.00 ng/mL-500.00 ng/mL. For the samples exceeding the upper detection limit the results are reported ">500.00 ng/mL", or less than the lower detection limit the results are reported "<10.00 ng/mL".
4. When the test kit expires, the immunofluorescence analyzer will directly report “kit failure”.
5. When the control band exceeds the acceptable value set in the analyzer or the test cassette expires, the immunofluorescence analyzer will report “invalid detection”.
6. The test results of the kit are for clinical reference only and cannot be taken alone as the basis for diagnosis or exclusion of cases. For the purpose of diagnosis, the test results should be used in combination with clinical examination, medical history and other examination results.
7. It is not recommended to dilute the sample for detection when the sample concentration is greater than the upper detection limit.

[Limitations of Test Method]

1. The following may lead to false positive results: influence of cross reaction of similar antibody components in blood (such as high concentration of heterophile antibody or rheumatoid factor); some non-specific components in blood having similar epitopes which can be captured by the fluorescent conjugated antibodies.
2. The following may lead to false negative results: antigenic determinants blocked by some unknown components fail to bind with antibodies; unstable cTnI, CK-MB and Myoglobin antigens that gradually degenerate with time and temperature are not recognized by the antibody. Effective test results require a good test cassette and the proper sample storage environment.
3. Other factors may also lead to errors in cTnI, CK-MB and Myoglobin test result, including technical reasons, operational errors and other factors related to the sample. For the abnormal results caused by such factors, it is required to repeat the detection and avoid non-standard use process.
4. Interferent:
   This product employs the lateral flow fluorescence immunoassay method to detect and quantify cTnI/CK-MB/Myo in the sample at the corresponding position of the test cassette. However, the presence of hemolysis or high levels of triglycerides, cholesterol, bilirubin, rheumatoid factors and HAMA in the sample may affect the chromatography of the sample on the cellulose nitrate membrane or the normal reaction of the antigen-antibody, which may lead to erroneous test results. Therefore, if the sample contains any of the following interfering substances and exceeds a specific concentration, it should not be used for testing:
   Lipemia: with triglyceride exceeding 15 mg/mL;
   Hypercholesterolemia: with cholesterol exceeding 400 mg/dL;
   Jaundice: with bilirubin exceeding 40 mg/L;
   Hemolysis: with hemoglobin exceeding 6 mg/mL;
   Rheumatoid factor: with rheumatoid factor exceeding 200 IU/mL.
   HAMA: with HAMA exceeding 177.4 ng/mL
5. When the sample concentration is up to 400.000 ng/mL (cTnI), 10000.000 ng/mL (CK-MB) and 10000.00 ng/mL (Myoglobin), no high-dose hook effect is observed.
6. When the hematocrit of whole blood samples is within the range of 0.25-0.65, the chromatography can be performed normally. The deviation compared to the results obtained from homologous plasma testing is within ±15%.

[Product Performance Index]

1. The limit of detection shall not be greater than 0.200 ng/mL (cTnI), 2.000 ng/mL (CK-MB) and 10.00 ng/mL (Myoglobin).
2. Accuracy: When tested with the enterprise reference, the relative deviation between the test result and the calibration concentration shall not exceed ±15.0%.
3. Linearity:
   (1) cTnI:

Within the range of [0.200, 50.000] ng/mL, the correlation coefficient (r) of linear regression shall not be less than 0.9900.
(2) CK-MB:
Within the range of [2.000, 100.000] ng/mL, the correlation coefficient (r) of linear regression shall not be less than 0.9900.
(3) Myoglobin:
Within the range of [10.00, 300.00] ng/mL, the correlation coefficient (r) of linear regression shall not be less than 0.9900.

4. Repeatability: The intra-batch coefficient of variation (CV) shall not be greater than 10.0% when tested with the enterprise reference.
5. Inter-batch variation: The inter-batch coefficient of variation (CV) shall not be greater than 15.0% when tested with the enterprise reference.
6. Specificity: The test value of cTnI should be less than 0.300 ng/mL when tested with 1000 ng/mL cTnT, 1000 ng/mL cTnC and 1000 ng/mL sTnI; the test value of CK-MB should be less than 4.000 ng/mL when tested with 100 ng/mL CK-MM and 100 ng/mL CK-BB; the test value of Myoglobin should be less than 70.00 ng/mL when tested with 100 mg/mL hemoglobin.

[Precautions]

1. This product is used for in vitro testing only.
2. Do not test the samples with high fat chyle, jaundice, severe hemolysis and high rheumatoid factor.
3. Product performance cannot be guaranteed when other sample types, or sample collection and processing methods are used.
4. Do not use the test kit with damaged package, unclear mark or beyond expiry date.
5. Please operate in strict accordance with the instructions, and the test cannot be stopped halfway once the test starts. The test that is stopped halfway cannot be resumed. If retesting is required, a new test cassette must be used for retesting.
6. Retesting is required for an invalid result.
7. A corresponding calibrate card is provided for each batch of cassettes and must be updated in time.
8. Test cassettes, which are disposable, should be handled as biological products after use according to relevant regulations.
9. The desiccant in the aluminum foil bag cannot be taken internally.
10. Biosafety warning: clinical samples, test wastes, disposable articles and other materials exposed in the test shall be handled as potential infectious substances, and corresponding preventive measures shall be taken.
11. The test results cannot serve as the absolute basis for diagnosis, and should be interpreted by the doctors according to clinical characteristics and other test results.
12. Due to methodology or antibody specificity, testing the same sample with kits from different manufacturers may produce different test results. Therefore, direct comparison should not be conducted among different kits.

[References]

1. Wilkinson JM, Grand RJA. Comparison of amino acid sequence of troponin I from different striated muscles.
2. Nature 1978;271:31-35. 2.Cummins P, Perry V. Troponin I from human skeletal and cardiac muscles. Biochem J 1978; 171:251-259.
3. Mair J, Genser N, Morandell D, et al. Cardiac troponin I in the diagnosis of myocardial injury and infarction. Clinica Chimica Acta 1996;245:19-38.
4. Mair J, Morandell D, Genser N, et al. Equivalent early sensitivities of myoglobin, creatine kinase MB mass, creatine kinase isoform ratios, and cardiac troponins I and T for acute myocardial infarction. Clin Chem 1995;41;1266-1272.
5. Galvani M, Ottani F, Ferrini D, et al. Prognostic influence of elevated values of cardiac troponin I in patients with unstable angina. Circulation 1997;95:2053-2059.
6. Missov ED, De Marco T. Clinical insights on the use of highly sensitive cardiac troponin assays. Clin Chem Acta 1999; 284:175-185.
7. Antman EM, Tanasijevic MJ, Thompson B, et al. Cardiac-specific troponin I levels to predict the risk of mortality in patients with acute coronary syndromes. N Engl J Med 1996;335:1342-1349.
8. Antman EM, Fox KM. Guidelines for the diagnosis and management of unstable angina and non-Q-wave myocardial infarction: Proposed revisions. Am Heart J 2000;139:461-475.
9. Apple FS. Acute myocardial infarction and coronary reperfusion. Serum cardiac markers for the 1990s. Am J Clin Pathol 1992;97(2):217-26.
10. Adam JE, Abendschein DR, Jaffe AS. Biochemical Markers of Myocardial Injury. Circulation 1993; 88(2): 750-763.
11. Apple F, Preese L. Creatine Kinase-MB: Detection of Myocardial Infarction and Monitoring Reperfusion. Journal of Clinical Immunoassay 1994; 17(1): 24-29.
12. Bhayana V, Cohoe S, Pellar T, et al. Combination (Multiple) Testing for Myocardial Infarction Using Myoglobin, Creatine

Kinase-2 (Mass), and Troponin T. Clinical Biochemistry 1994;27:395-406.
13. Collinson PO, Young LJ, Foo AY, et al. Early Diagnosis of Acute Myocardial Infarction. Ann Clin Bioche 1994;31:301-2.
14. Bastagli L, Guardigli G, Ru☒ni M. Changes in plasma myoglobin levels in ischemic heart diseases. G. Clin. Med. et al. 1989;70:733-742.
15. Ohman EM, Casey C, Bengtson JR, et al. Early detection of acute myocardial infarction: additional diagnostic information from serum concentrations of myoglobin in patients without ST elevation. Br Heart J 1990;63:335-338.
16. Expert consensus group for joint detection of biomarkers of acute nontraumatic chest pain. Expert consensus on joint detection of biomarkers of acute nontraumatic chest pain [J] Chinese Journal of Emergency Medicine, 2015, 24(009):940-951.
17. Jun Li. Comparison of the value of myocardial enzymes and troponin in the diagnosis of myocardial injury [J] Medical Information, 2014, 28(9): 393-396.
18. Yanfang Li. The value of detection of serum cardiac troponin I, myoglobin and creatine kinase isoenzyme in early diagnosis of coronary heart disease [J] Chinese Laboratory Diagnostics, 2014, 18(5):812-815.

Guangdong Wesail Biotech Co., Ltd.

Address: 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China

Tel : 400-900-1339

E-mail : customer@wesailbio.com

Website: http://en.wesailbio.com

EC REP **Lotus NL B.V.**

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail : peter@lotusnl.com

SYMBOL	DESCRIPTION
	Manufacturer
EC REP	Authorized representative in the European Community
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch Code
	Use-by date
2°C 30°C	Temperature Limitation
CE	CE Mark
REF	Catalogue number
	Biological risks
	Do not re-use
Σ	Contains Sufficient for <n> Tests
	Date of manufacture
	Keep Away From Sunlight
	Consult instructions for use
	Keep Dry

EU DECLARATION OF CONFORMITY

According to Art. 17 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Manufacturer:	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
Trademark:	WESAIL
SRN:	CN-MF-000008828
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany
SRN:	DE-AR-000000087
Product or trade name:	Immunofluorescence Analyzer
Product Model:	WS-Mi6000
Basic UDI-DI :	697384100B600055
Intended Use:	The Immunofluorescence Analyzer should be used along with WESAIL reagents for qualitative or quantitative detection and analysis of human samples to be tested.
Classification acc. to IVDR Ax. VIII:	Class A, rule 5
Applied Standard & Common Specification:	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612:2002, EN ISO 15223-1:2021, EN ISO 23640:2015, EN 62366-1:2015, EN IEC 61010-2-081:2020, EN 61010-1:2010+A1:2019, EN IEC 61010-2-010:2020, IEC 61010-2-101:2018, EN IEC 61326-1:2021, EN IEC 61326-2-6:2021
Conformity assessment procedure:	Article 17 + Ax. II + Ax. III

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Signed this Day/ 28th of Month/ August of Year/ 2023, Place Dongguan , China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

Devices/Systems/Procedure packs

Search criteria

Manufacturer/Producer (and Authorised Representative) name: WESAIL ✕ **Status:** On the EU market ✕ New search

6 records found.

UDI-DI/ EUDAMED ID	Version	Basic UDI-DI/ EUDAMED DI	Trade name	Risk class	Manufacturer/Producer (and Authorised Representative) name	Actor ID/SRN	Action
06973841000826	1 (Current)	697384100B15004T	Immunofluorescence Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (MedPath GmbH)	CN-MF-000008828 (DE-AR-000000087)	
06973841000307	1 (Current)	697384100B600055	Immunofluorescence Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (MedPath GmbH)	CN-MF-000008828 (DE-AR-000000087)	
06973841000789	2 (Current)	697384100B100042	Immunofluorescence Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (MedPath GmbH)	CN-MF-000008828 (DE-AR-000000087)	
06973841000284	1 (Current)	697384100H14006Q	Handheld Colloidalgold Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (Lotus NL B.V.)	CN-MF-000008828 (NL-AR-000000121)	
06973841000734	1 (Current)	697384100C60005G	Incubator	Class A	Guangdong Wesail Biotech Co., Ltd. (Lotus NL B.V.)	CN-MF-000008828 (NL-AR-000000121)	
06973841000277	1 (Current)	697384100B13004H	Handheld Immunofluorescence Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (Lotus NL B.V.)	CN-MF-000008828 (NL-AR-000000121)	

« ‹ 1 › » 25

About us

About EUDAMED

Related sites

Medical devices

European Commission

European Commission

Contact the European Commission

Follow the European Commission on social media

Resources for partners

Language policy

Cookies

Privacy policy

Legal notice

Training Certificate

Its hereby certified that

Sergiu Sorocovici
From "GBG-MLD"SRL, has successfully completed all technical training course of Immunofluorescence analyzer Model WS-Mi6000, WS-Si1000 and WS-i60 including installation, Use, Service, Scientific and Technical Support, and is qualified to offer technical support for above mentioned products.

FOR & ON BEHALF OF

广东唯实生物技术有限公司

Guangdong Wesail Biotech Co., Ltd. (WESAIL)

国际营销总监/日期： Vincent NONG

Director of International Sales & Marketing /Date

Company Web：www.wesailbio.com
Company Phone/Fax:：86-769-22890969
Company address：Room 403, Building 1, 1 Taoyuan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, Dongguan, Guangdong, 523808, China

IVD CE

Immunofluorescence Analyzer

User Manual

WESAIL

Declaration

This manual describes the main structure, specification, installation, operation, maintenance, storage, and safety precautions of the product. Please refer to the corresponding chapters for more details.

Contents

1 Overview

1.1 Product Name

Immunofluorescence Analyzer

1.2 Product Model

WS-Mi6000

1.3 Intended Use

The Immunofluorescence Analyzer should be used along with WESAIL reagents for qualitative or quantitative detection and analysis of human samples to be tested.

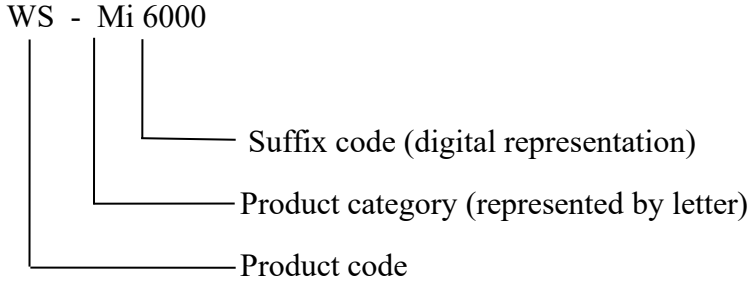
Intended User: Suitable for use by clinical medical professionals.

1.4 Software Version

(1) Basic information:

1. Software name: WS-Mi series Immunofluorescence Analyzer software
2. Software model: WS-Mi6000

   Model and designation：



3. Released version of the software：V1

4. Complete software version：V1.0.0.1

Software Version Naming Rules

Software version naming convention：VA.B.C.D

V: Abbreviation for the word Version.

A: Major version number, the value is ≥1. This field is incremented by 1 when there is a major enhancement update or major network security update to the software.

.：spacer. This field does not change when the release version changes.

B： Minor version number. Starting from 0, this field is incremented by 1 when a minor enhancement class update or minor network security update occurs to the software.

C：Build (0-99). Start from 0.

D：Revision number (0-99). Start at 1.

(2) Operating environment:

Hardware Configuration：four-core ARM-A55 64-bit processor，2.0GHz

Storage：2G RAM,16G ROM

Software Environment: Android 11

Network conditions: WIFI

1.5 Contraindications

Immunofluorescence Analyzer is in-vitro diagnostic medical device with no requirement for contraindications.

1.6 Product Lifetime

1. Production date: printed on the product label
2. Product lifetime: 8 years

2 Main Parameters

Table 1 Product Specification

Repeatability	CV≤ 5%
Accuracy	The relative deviation should be within ± 15%.
Stability	The relative deviation should be within ± 5%.
Linearity	Linear correlation coefficient r should be ≥ 0.990.
Clinical Items	Suitable for clinical testing of 12 disease categories including cardiovascular, inflammation, pregnancy, thrombosis, eugenics, diabetes, bone metabolism, renal function, gastric function, anemia, tumor, and brain injury.
Test time	The duration from insertion of test cassette to display of test results is less than 1min.
Product size	Length × Width × Height : 417mm × 245mm × 204mm.
Weight	Net weight: about 8 kg Gross weight: about 10.8 kg
Storage conditions	temperature：0℃～55℃ relevant humidity ：≤ 93%

3 Points for attention

For safety and convenience, please read this user manual carefully first, and operate the analyzer according to the demands. If the analyzer is not used according to the requirements specified by the manufacturer, the protection mechanism of analyzer may become invalid. Please keep this user manual properly after reading, so that you can refer to it at any time you need.

3.1 Danger of Power Supply

1 Do not use a power adapter that is not supplied by the original factory.
2 Do not plug or unplug the power cord with wet hands, otherwise you may get an electric shock.
3 A well-grounded power outlet must be used, otherwise an electric shock may result when the analyzer leaks.
4 Do not damage the power cord, do not stamp, twist or pull the cord. If damaged power cords are used, electric shock or fire may happen.
5 If any abnormal operation or malfunction happens, you should stop the operation immediately, turn off the power and unplug the power cord, and contact the dealer or manufacturer. Do not open the device without authorization, connect the power supply, or turn on the power of the device, so as to avoid secondary equipment damage and danger to the human body.
6 If there is any inadvertent flow of liquid into the analyzer during the operation or the analyzer emits smell of burning or smokes, stop the operation immediately, turn off the power, unplug the power cord, and contact the dealer or manufacturer.
7 Turn off the power and unplug the power cord after use or when it is not in use for a long time.

3.2 Protection against Biochemical Hazards

1. While this analyzer is operated, please follow the recognized laboratory rules,

thoroughly clean your hands, wear disposable gloves and lab coats, avoid exposing any parts of the body to the splashing or spilling infectious solution. All surfaces in contact with biological fluids should be considered as the areas with biological hazard.

2. When the analyzer is out of use, it is necessary to disinfect the analyzer to reduce biological hazards before transportation or scrapping.
3. The manufacturer reminds that all parts of the analyzer may be in direct contact with human plasma, serum and urine and must be treated as a potential infectious agent.
4. If the sample comes into contact with the skin, please follow the operators' working standards or consult a physician to take remedial action.
5. Once the hands or clothing come into contact with the reagents, please clean with soap and water thoroughly.
6. If the reagent gets into your eyes, please rinse with plenty of water immediately and consult a physician for further processing.

3.3 Liquid Waste Disposal

1 The wastes generated during the analyzer operation such as test cassettes, quality controls and samples are subject to pollution regulations and discarding standards. They shall be disposed of in accordance with local regulatory requirements and the relevant manufacturer must be consulted.

2 After the use of the analyzer, the remaining test samples and their appurtenances should be disposed of properly before discard so that it can comply with national regulations and the requirements of local environmental organization.

3.4 Other Precautions

1. This analyzer is limited to the operation and use by the professionally trained medical and health inspectors, doctors or laboratory technicians. For retraining, please contact the dealer or manufacturer. All parts and components of the analyzer can only be inspected or supplied by the dealer or manufacturer.
2. When the analyzer starts testing, do not touch the test cassette or put your finger into the channel to avoid the reagent card falling and blocking the channel when the test slot is sent out, damaging the analyzer, or pinching your fingers. This process should

be operated, only if the operator has been warned of potential hazards and has been taught how to operate the analyzer as safe as possible.

3. Please read the User Manual of each kit carefully before testing.
4. It is strictly forbidden for users to disassemble and repair the analyzer without authorization. They should contact the dealer or the manufacturer and arrange for a professional maintenance engineer to check and repair the analyzer.
5. If a screw or metal object falls into the analyzer, stop the operation immediately, please contact the dealer or the manufacturer, and ask professional maintenance personnel to remove the metal object and check that the analyzer can operate normally before starting the operation. May cause analyzer failure.
6. Please place the analyzer on a level surface to avoid collision, otherwise it will affect the analyzer test results.
7. Do not put liquids such as reagents and water on the analyzer table to prevent liquids from leaking into the analyzer and causing damage to the analyzer.
8. Manufacturer's statement that the analyzer and its internal parts are designed and manufactured to avoid hazards to operator safety.
9. It is the user's responsibility to ensure the electromagnetic compatibility environment of the equipment so that the equipment can work normally. It is recommended to evaluate the electromagnetic environment before using the equipment.
10. Do not use this equipment near strong radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the normal operation of the equipment.
11. This product is designed and tested according to Class A equipment in CISPR 11 In a domestic environment, this equipment may cause radio interference, requiring precautions.
12. This product complies with the emission and immunity requirements specified in EN IEC 61326-1 and EN IEC 61326-2-6, see Appendix A.
13. When the exposure of moving parts in normal use is unavoidable, please pay attention to the entrance and exit of the parts next to the movement warning label on the instrument to prevent accidental injury.

4 Unpacking and Operating Requirements

4.1 Unpacking Inspection

When unpacking for the first time, please check whether there is physical damage to the outer box of the analyzer. If there is any damage, please contact the dealer or manufacturer immediately. If not, unpack according to the following steps:

1. Stand the packing case upright.
2. Use a tool to open the packing tape on the case, take out the packing list to check whether the contents are complete, if anything missed, please contact the dealer or manufacturer immediately.
3. Remove the upper fixing foam cover, take out the analyzer from the packing case and place it on a steady table.
4. Check the outer surface of the analyzer for any damage, such as nicks, dents, scratches, etc. Then check all objects. If there is any damage, please contact the dealer or manufacturer immediately.

4.2 Installation Requirement

Table 2 Installation Instructions

Item	Requirements
Basic environment	The ambient temperature should be 10℃~30℃, the relative humidity should be ≤ 85%, no condensation. For indoor use, the installation environment should be kept dry and ventilated, and free from direct sunlight, large amount of dust, mechanical vibration, loud noise source and power supply interference as much as possible. Do not place the device close to a strong electromagnetic interference source, so as not to affect the normal operation of the

	device. Do not place the device in a position where it is difficult to unplug the device. Do not put the device near brush-type motors, flashing fluorescent lamps, or frequently switched electrical equipment.
Space requirement	Considering enough heat dissipation, the ease use of the power switch and multiple interface on side of the analyzer, the installation must meet the following requirements: The space reserved between the left and right sides of the analyzer and the walls should be ≥ 20cm. The space reserved between the analyzer back panel and the wall should be ≥ 20cm.
Reserved space for power plug	There should be enough space for the power cord where it is plugged into the network power supply (a.c 100-240V, 50Hz/60Hz), ensuring that the lower power plug can be quickly removed from the power outlet in case of emergency.
Desktop requirements	A horizontal, flat and steady desktop.
Protective grounding	The protective grounding of the analyzer uses the method of connecting the power cord plug to the protective ground wire of the network power supply, so the analyzer is required to work with the power cord plug must be plugged into the network power supply (a.c. 100-240V, 50Hz/60Hz) socket with reliable protective grounding.
Altitude requirement	The altitude does not exceed 2,000m.

4.3 Power Environment

1. Power supply voltage:100V-240V～，50Hz/60Hz；
2. Input power：350W；

Note： The analyzer shall be protected against dust and shock, away from strong electromagnetic interference and corrosion. In addition, the analyzer has no strong electromagnetic interference to the power grid supply and other equipment.

4.4 Operating Environment

The conditions of normal operation of the analyzer should meet the following requirements:

1. Power supply voltage：100V-240V～，50Hz/60Hz；
2. Input power：350W；
3. Ambient temperature：10℃～30℃；
4. Relative humidity：≤85%，no condensation；
5. Atmospheric pressure：80.0kPa～106.0kPa；
6. Altitude：≤2000m；
7. Keep away from interference sources of strong electromagnetic field
8. Avoid direct sunlight
9. Good grounding environment

5 Detection Principle and Structure Composition

5.1 Detection Principle

Immunofluorescence Analyzer is used along with WESAIL reagents. During the detection process, the analyte in the sample and the fluorescent labeled antibody form an immune complex. The immune complex and the fluorescent labeled antibody are captured in the detection area and the control area respectively after chromatography. The excitation light source scans the detection area and the control area, excites the captured fluorescent immune

complex, and the emitted light is collected and converted into an electrical signal. The strength of the electrical signal is related to the number of fluorescent molecules. The analyzer automatically calculates the content of analyte in the sample to be tested according to the read signal.

5.2 Structure and Components

The Immunofluorescence Analyzer is mainly composed of upper shell assembly, gantry assembly, and bottom assembly.

5.2.1 Exterior

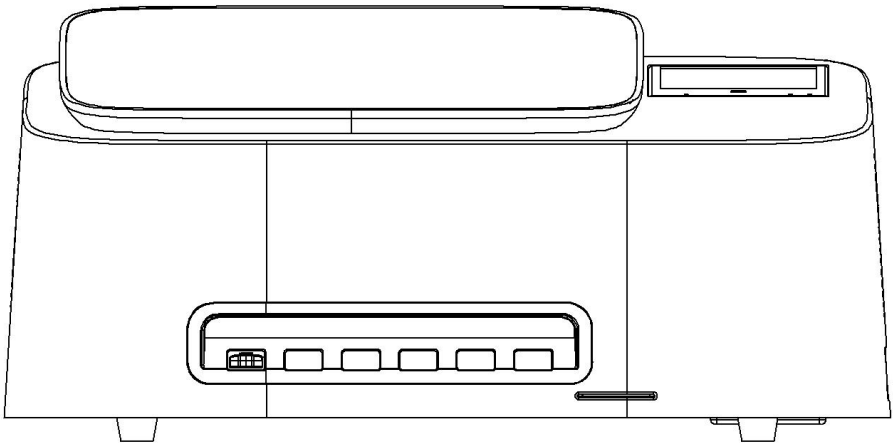


Figure 1 Front View

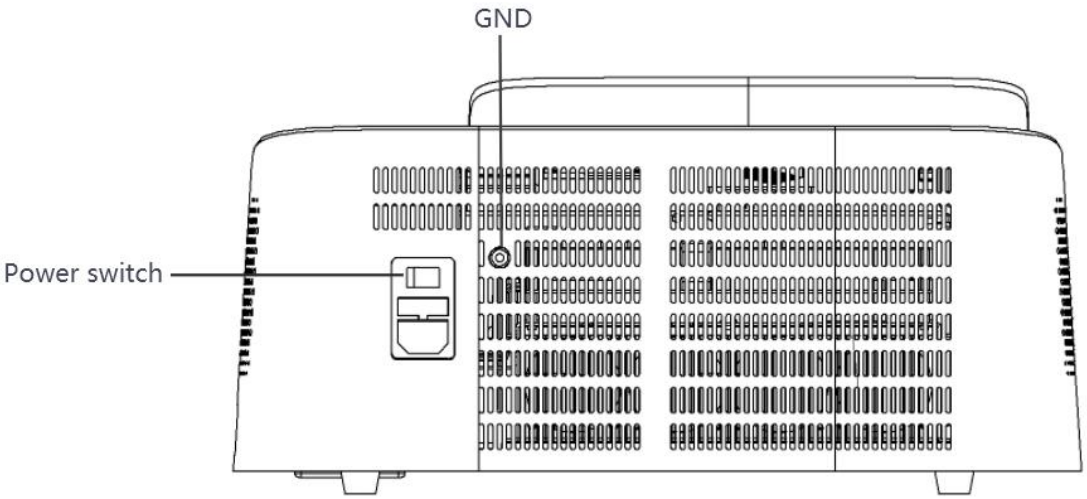


Figure 2 Rear View

5.2.2 Holistic structure

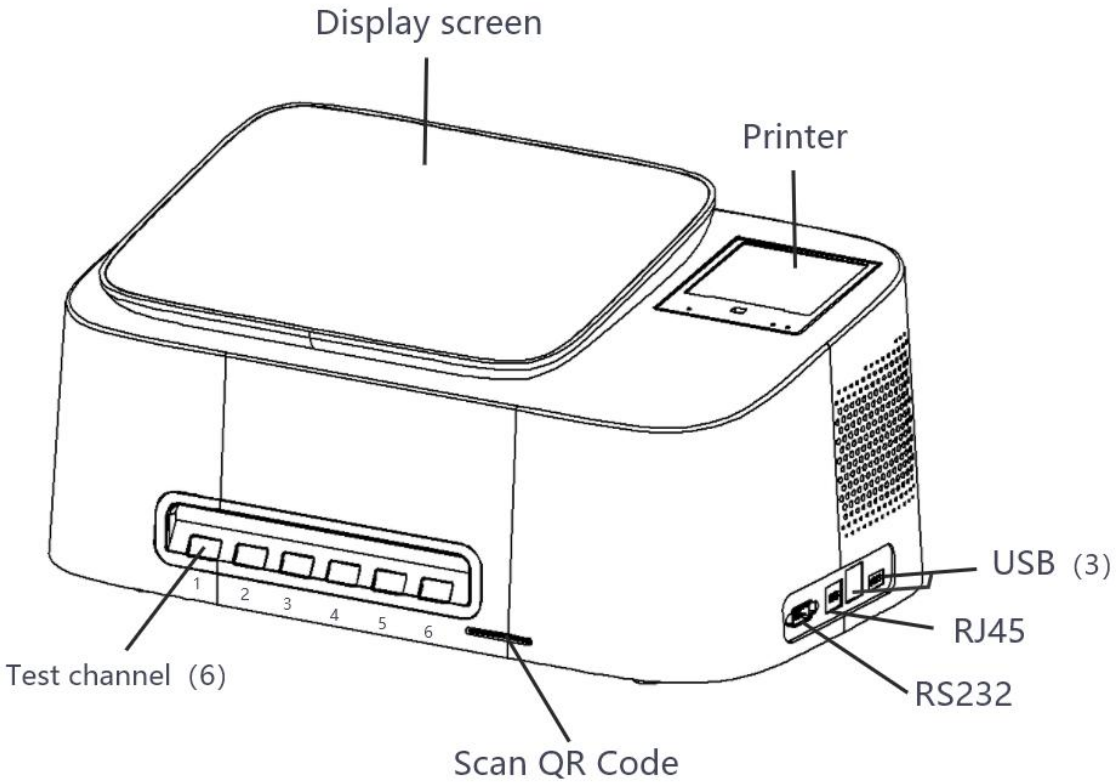


Figure 3 Analyzer Overview

5.2.3 Upper shell assembly

The upper case assembly mainly consists of the bottom PCBA assembly, display screen, printer, and housing.

5.2.4 Gantry assembly

The gantry assembly is mainly composed of motion assembly, optical path assembly, scanning and releasing assembly, etc.

5.2.5 Bottom assembly

The bottom assembly consists of control board PCBA assembly, incubation assembly, heat sink assembly, switching power supply, etc.

6 Operation Instructions

6.1 Startup

1. Before each startup, the operator should check whether the power plug of the host is securely inserted into the power outlet to ensure that the system is ready.
2. After the analyzer is properly connected to the power outlet, power on the analyzer, which is located on the rear side of the analyzer.
3. After power on, the analyzer starts and performs initialization and self-inspection process (including checking whether the basic software and hardware functions are normal), and after passing the self-inspection process, it directly enters the login interface.

Figure 4 Start-up screen 1

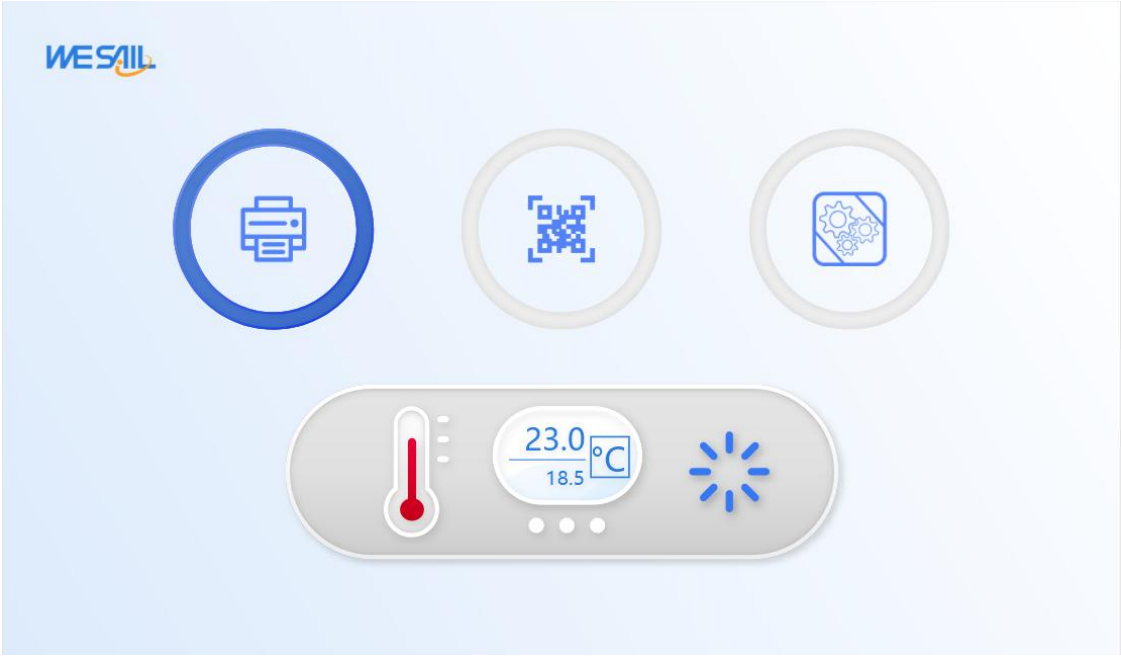


Figure 5 Start-up screen 2

4. When the self-inspection process does not pass, the self-inspection result dialog box is displayed, prompting to shut down or select emergency use.

6.2 Interface function

6.2.1 User Access Definition

This analyzer has user access control function. When running, user name and password are required to log in. After login, users can set different parameters by different levels of accounts.

There are three levels of permissions: Administrator, Supervisor and Operator. The level of users can be identified via the account name and password, including:

(1) Administrator: all operation permissions.

(2) Supervisor: the basic permissions and Operator accounts creation permission.

(3) Operator: the basic permissions.

6.2.2 Login Interface

After the self-inspection is completed and the result is correct, enter the login screen:

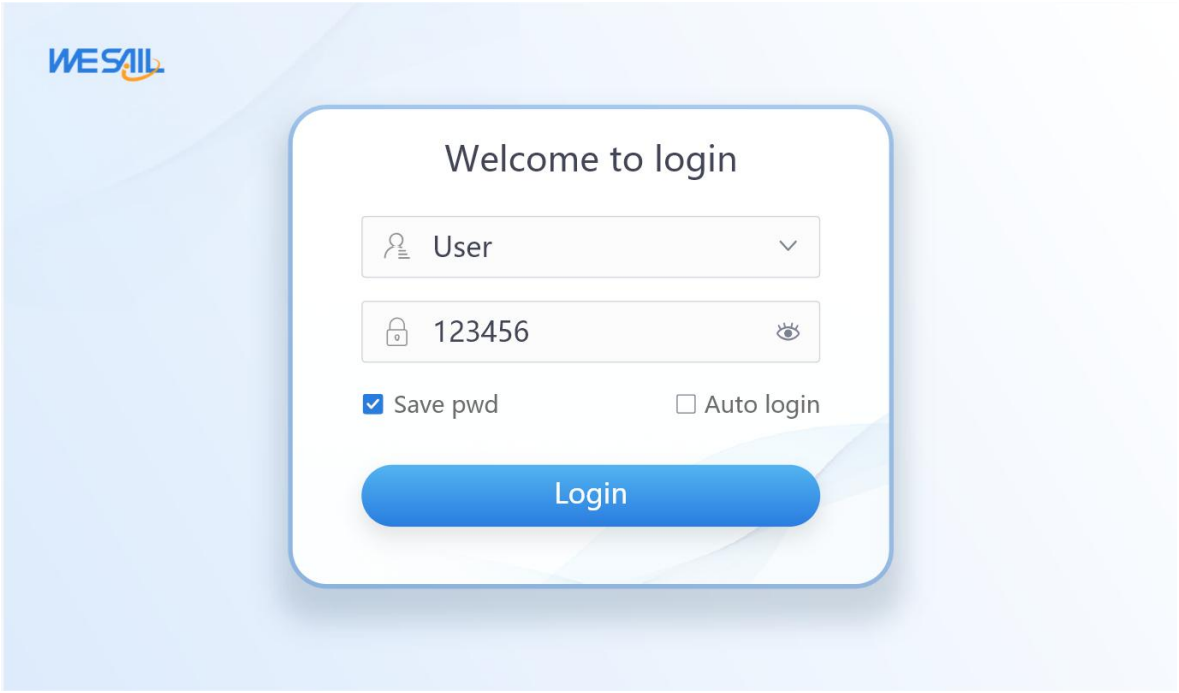


Figure 6 Login interface

1. Login successfully and enter the main interface.
2. If the user who logged in before the last shutdown of the analyzer is the default user, and "Remember password" and "Auto-login" are checked during the login, the analyzer will enter the main interface directly after the self-inspection is completed and there are no errors.

6.2.3 Software main interface

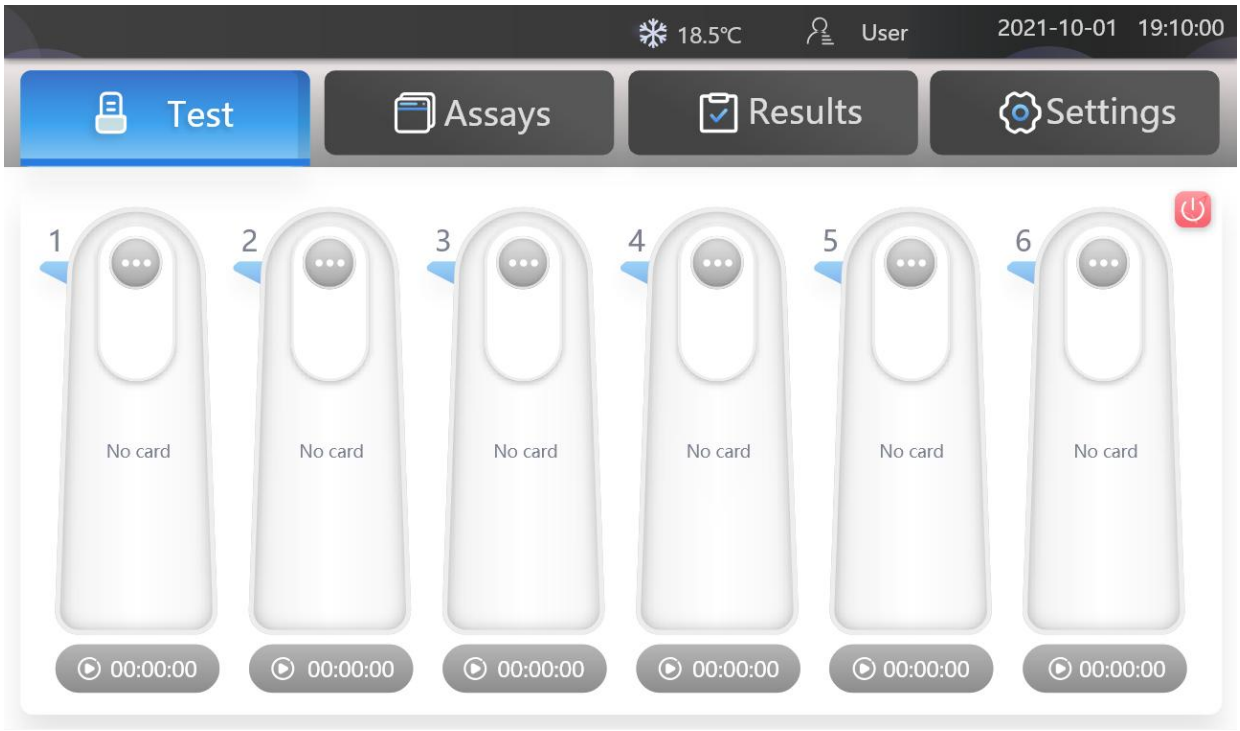
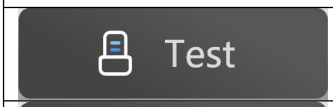
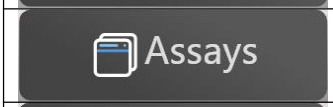
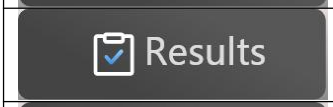


Figure 7 Main interface

1. The analyzer enters the main interface, i.e., the testing interface, clicks on the operation area controls, and the function area displays the corresponding function module.
2. You can click the shutdown button in the upper right corner to perform a quick shutdown operation.
3. Long press the shutdown button in the upper right corner to reset the channel status.

6.2.4 Main buttons Description

Table 3 Control Description

Button icon	Name	Function
	Test	Enter the Test interface
	Assays	Enter the Assays interface
	Results	Enter the Results interface
	Setting	Enter the Setting interface

6.2.5 Overview of software functions

According to the operation to be completed, the user can refer to the following table to select the corresponding button.

Table 4 Description of Main Functions

Button name	**Main functions**
Test	View the status of the test channel with information on the corresponding test Assays, incubation status, test progress and test results, and operate the test, edit the sample number, select the sample type, perform a quick test, and print the results.
Assays	Manage project information, you can import, overwrite, edit and view projects.
Results	Count or view sample information and sample corresponding test item information, edit sample information, result transmission, test item data analysis view, query, export, print and other functions.
Settings	1. Quality control operation 2. General settings: barcode function settings, network settings, language settings, printing, serial port settings. 3. User settings: You can enter the user settings interface to add,

	edit and delete users. 4. Logout: support re-login function 5. Help: Display operating instructions and FAQ documents 6. Shutdown: Supports shutting down the analyzer through the shutdown button 7. About: Display the basic information of the instrument and the current software version information 8. Unit: Hospital information, LIS settings and cloud settings

6.2.6Functional Detailed Explanation

6.2.6.1Test

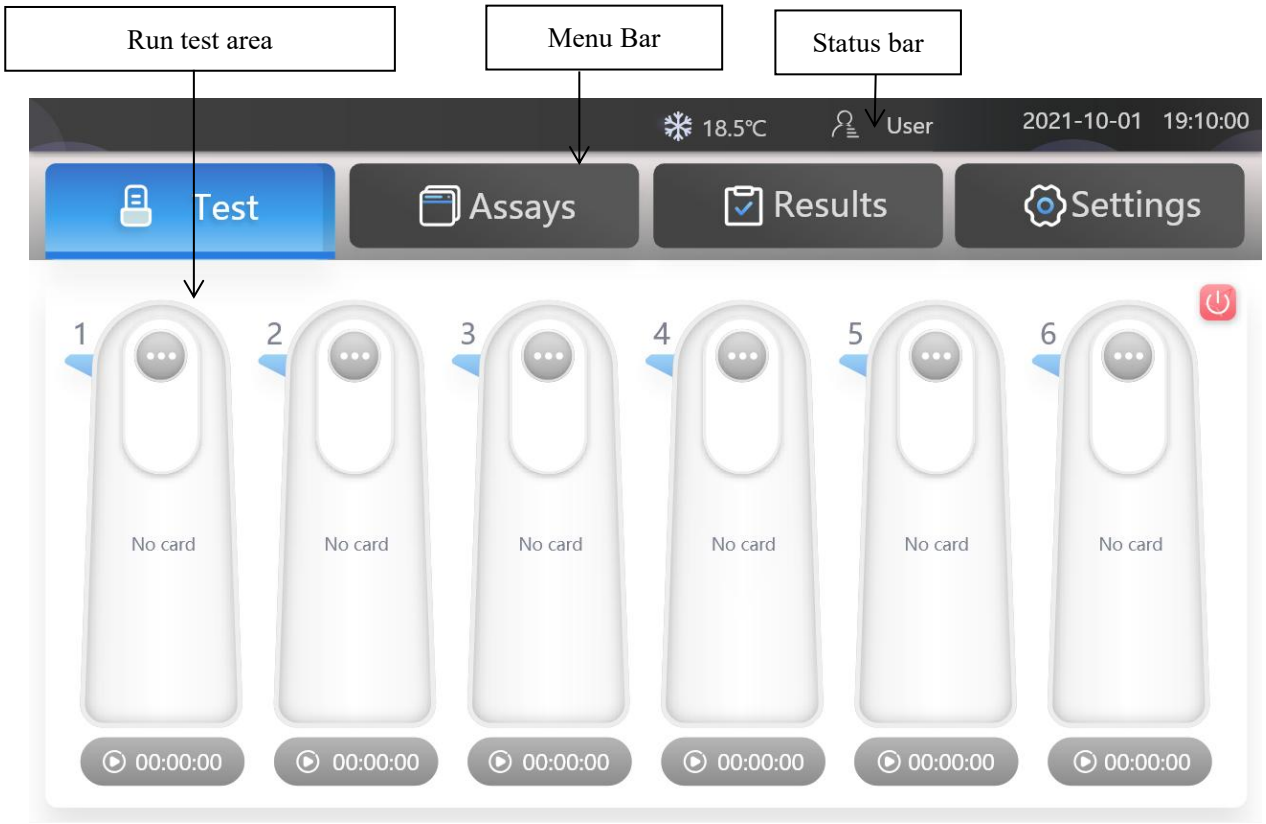


Figure 8 Test interface

1. After the initialization of the power on is completed or after clicking the Test button at the menu bar, enter the main interface of detection.
2. Area description:

1) Menu bar: The default menu bar has four major functional controls such as 

2) Status bar: Default status bar showing status alert messages, incubation temperature, currently logged in user, and system time.

3) Detection operation area: Sample information and test result display, printing, instant detection function, real-time view of the status of each channel detection and incubation.

3. Testing

Please import the appropriate test items before testing.

1) Insert the test cassette, the analyzer automatically scans the QR code information of the test cassette, returns the test cassette and displays the sample information window for entry of information.

2) Enter the information, enter the sample number and select the sample type.

3) Add the sample to the sample well of the test cassette, push it in again and incubate. If you need to skip the incubation phase, click the .  button to perform the quick test.

Note: Before adding samples for testing, please read the Immunofluorescence Assay Kit instructions for use in detail and follow the requirements.

4) Test cassettes that have completed incubation are automatically tested.

Note: The number and sample type cannot be empty when testing.

5) The detection result is displayed on the corresponding channel.

6) Click the 

button to print the results after the test is completed.

7) After the test is complete the test cassette can be removed for the next test cassette test.

8) After completing the test, click on “Power off” and turn off the power switch.

6.2.6.2 Assays

1. Click the Assays button at the menu bar to enter the Assays interface.

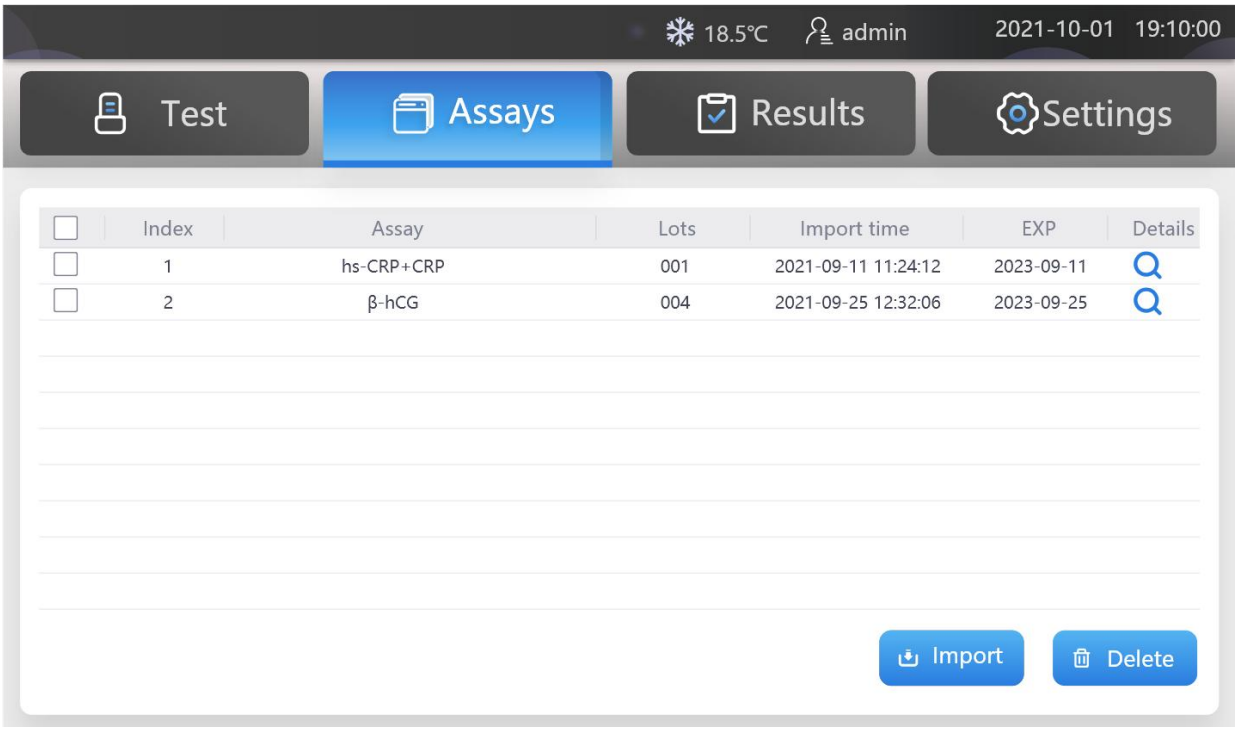


Figure 9 Assays interface

2. Click the Import button, the analyzer starts the function of recognizing the QR code and scan the QR code of the assay table on the calibration card. After successful scanning, the assay import dialog box is displayed, click the Save button, import the assay (assay table), If the Cancel button is clicked, the import of the assay (assay table) is canceled. The dialog box disappears after clicking the button operation.

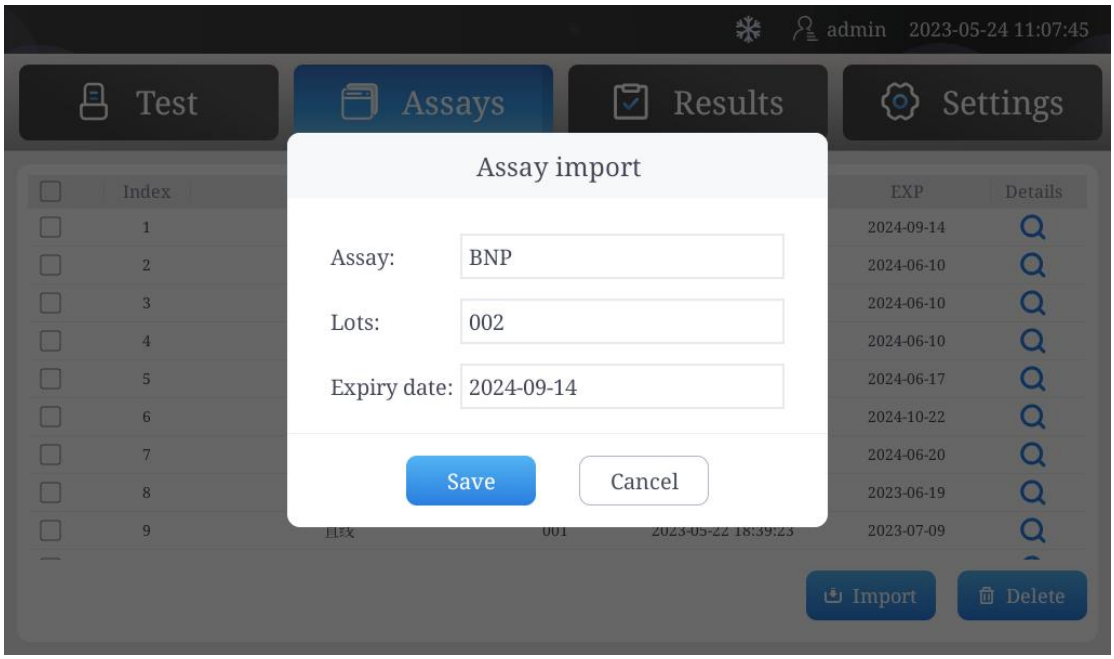


Figure 10 Assay interface

3. Click the Delete button, you can delete the selected assay.

4. Click the button, you can view current assay details.

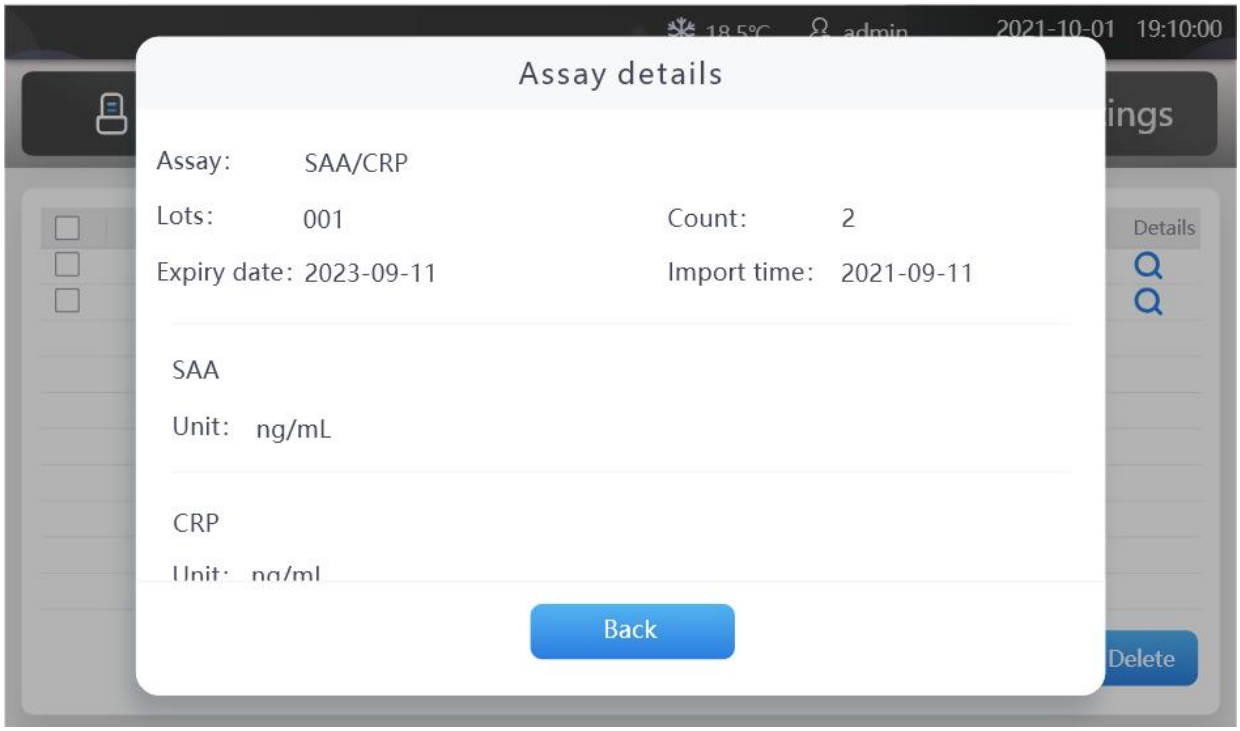


Figure 11 Assay detail interface

6.2.6.3 Result

1. After clicking the 

button at the menu bar, you will enter the Results interface.

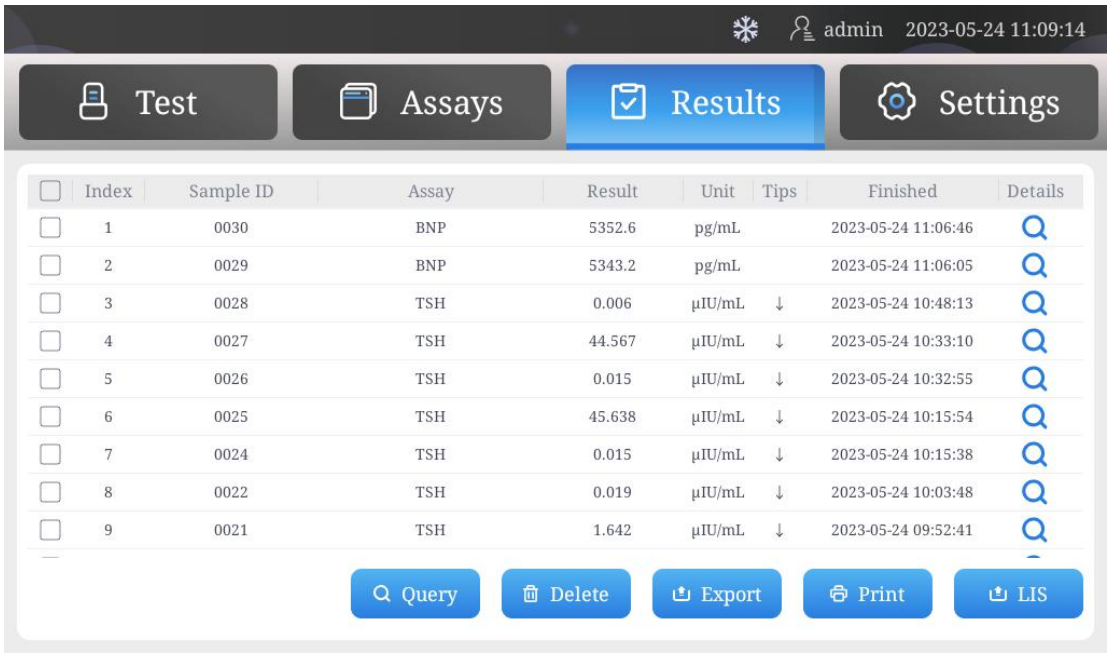


Figure 12 Test result interface

2. Click the 

button to display the result query dialog box, and filter the results for multiple dimensions of assay, sample ID, name, age, gender and time limit. After clicking the query, the results that meet the query conditions are displayed in the result list.

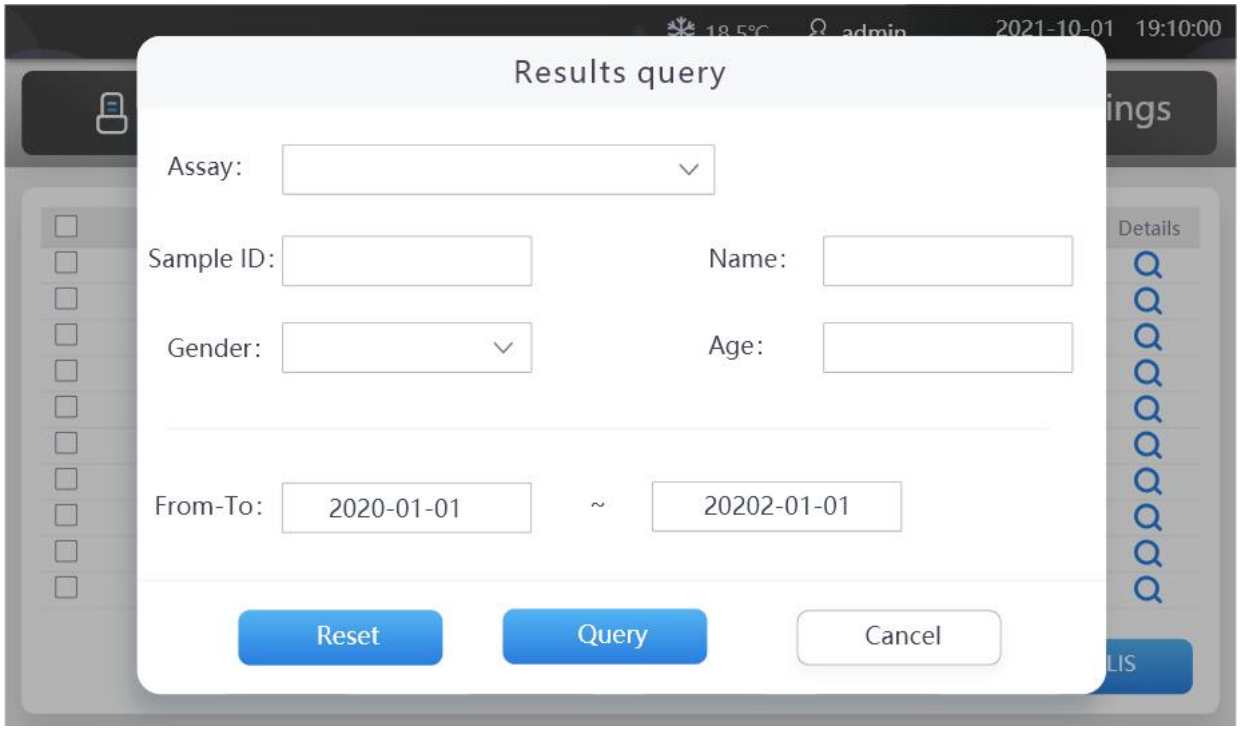


Figure 13 Result query interface

3. Users can Delete、Export、Print、LIS and other functional operations on the results.

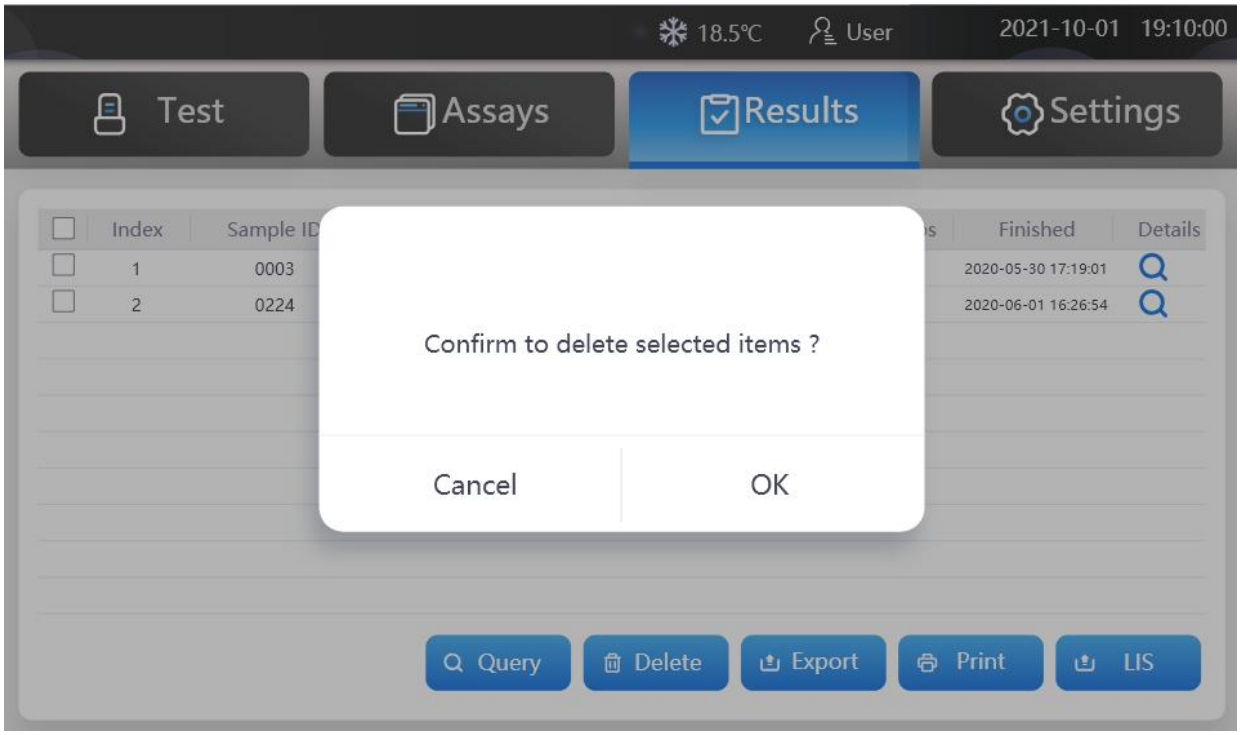


Figure 14 Result deleting interface

4. Click the button to view the current result details, click the Edit button to edit the patient's name, age and gender, and click the Save button to save the edited information.

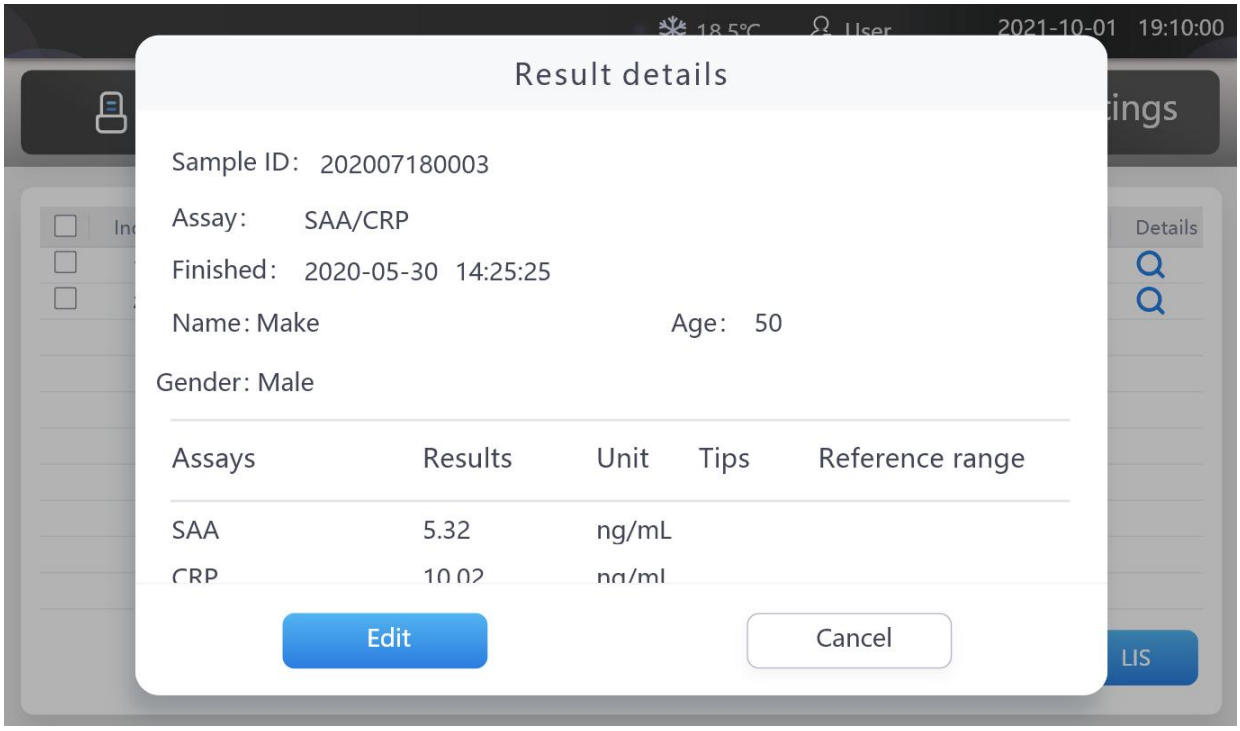


Figure 15 Result editing interface

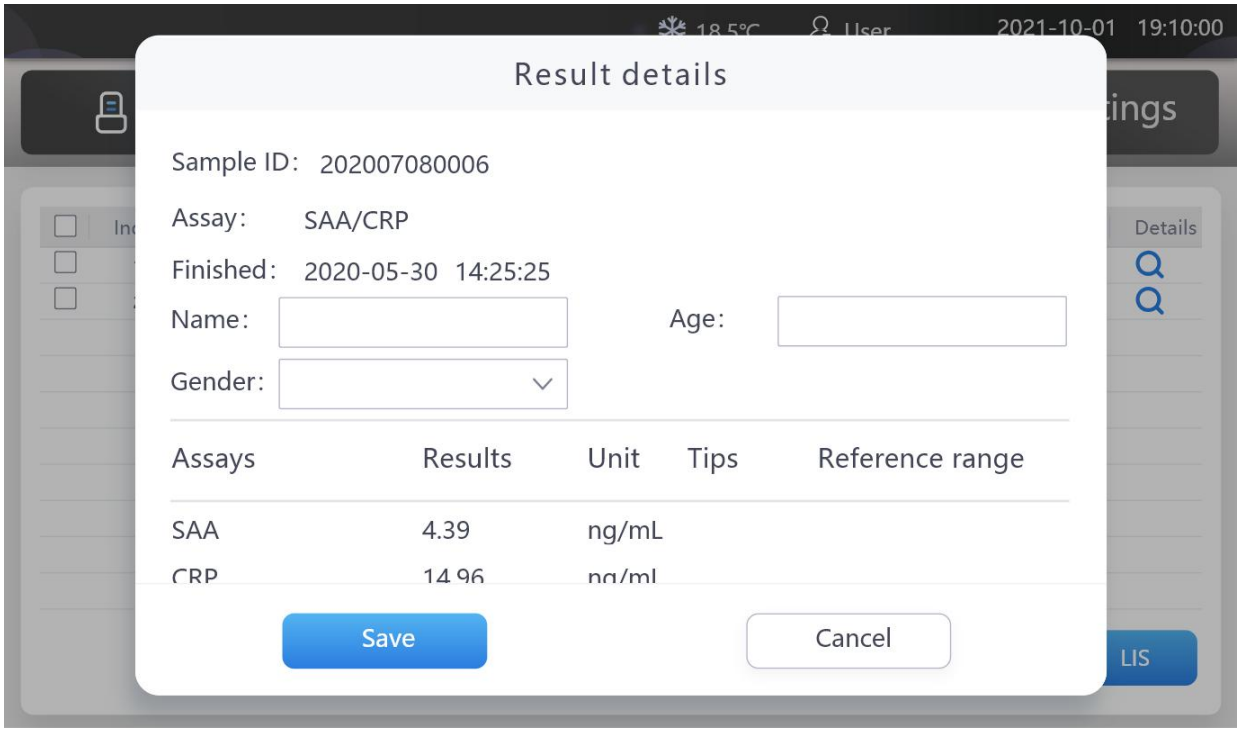


Figure 16 Result saving interface

6.2.6.4 Settings

After clicking the 

button at the menu bar, you will enter the Setting interface.

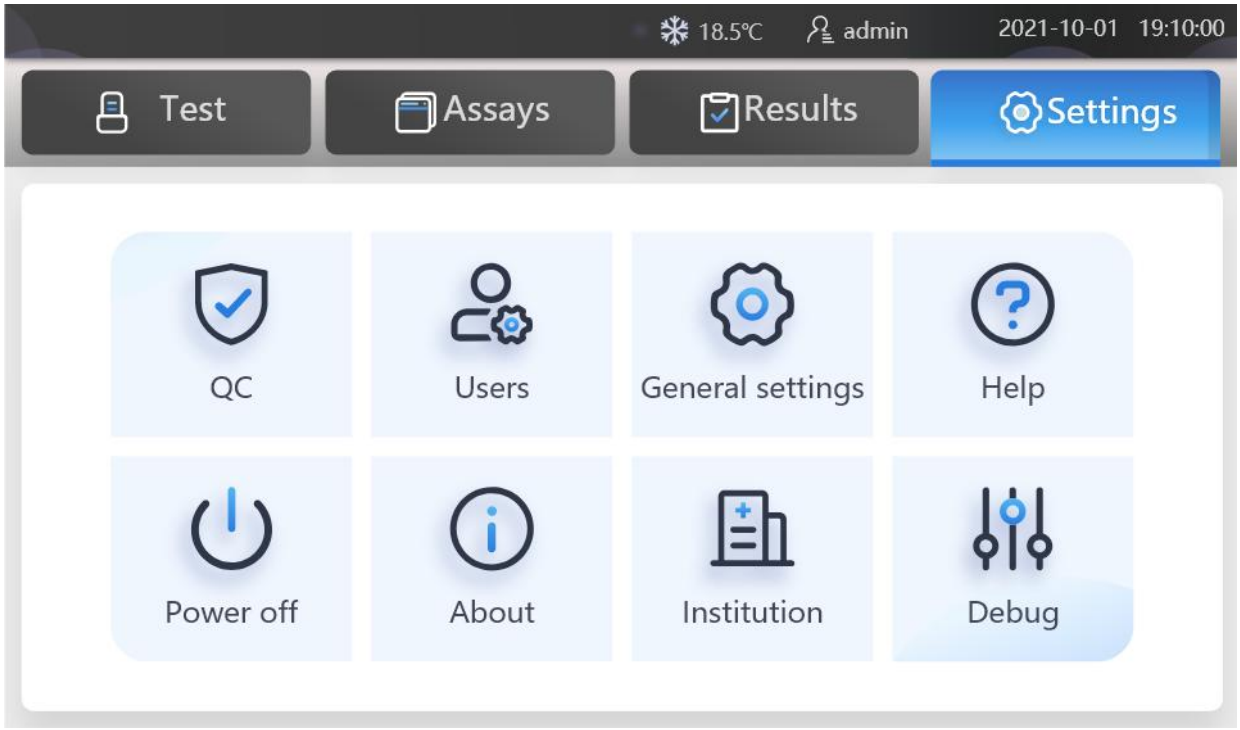


Figure 17 Setting interface

1. After clicking the 

button on the Setting interface, enter the QC function interface and operate the QC card/Controls/Graph/Results respectively.
2. Click the “QC card” button to enter the QC card operation interface, which includes assay entry, management and testing functions.

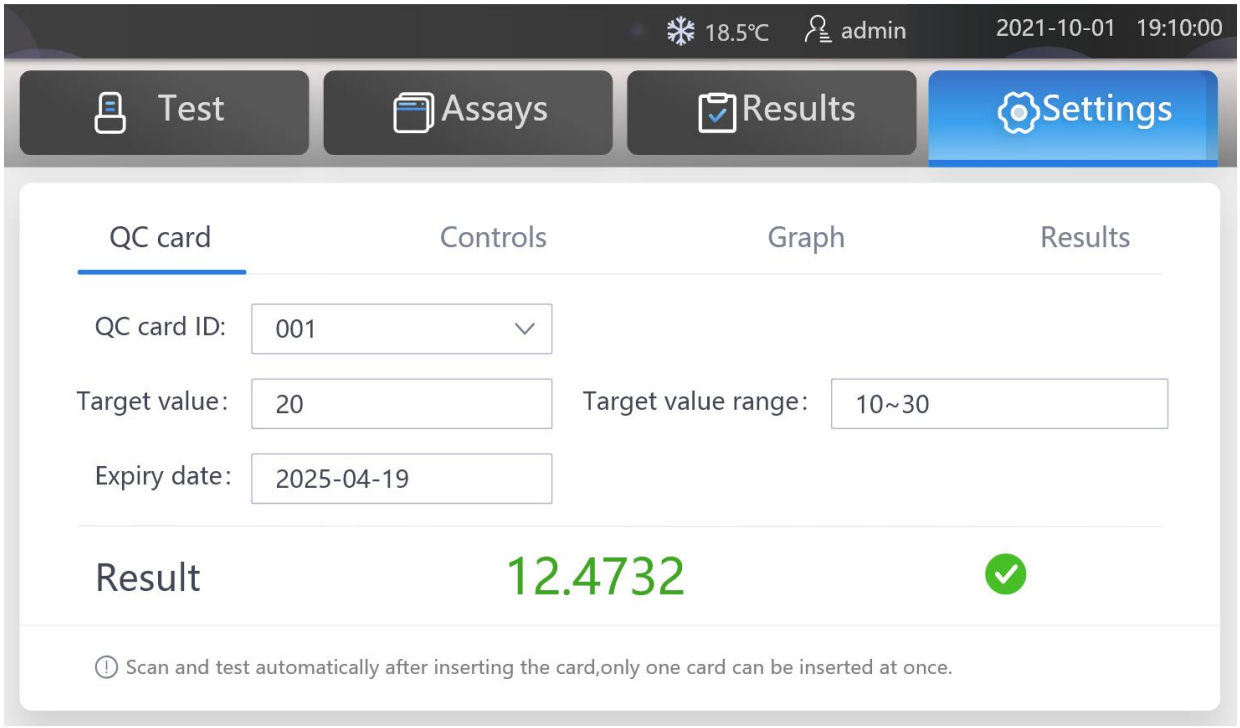


Figure 18 QC card operation interface

3 . Scan and test automatically after inserting the card,only one card can be inserted at once.

4. Click the “Controls” button to enter the control material operation interface.

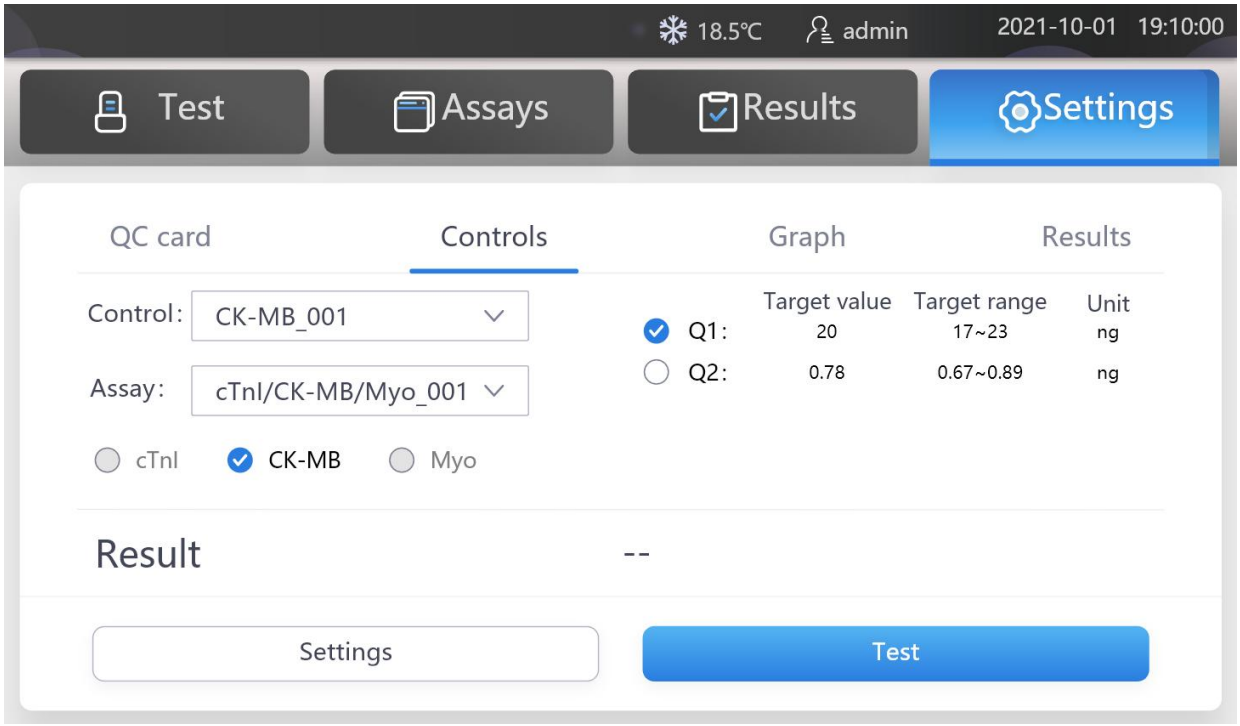


Figure 19 Control material operation interface

5. Click on the Settings button to enter the controls management

interface, you can enter and delete controls and other management operations; After selecting the control material and the corresponding level, insert the card in any channel, scan the code to match the corresponding test item and the object to be tested, click on the Test button, then the test starts.

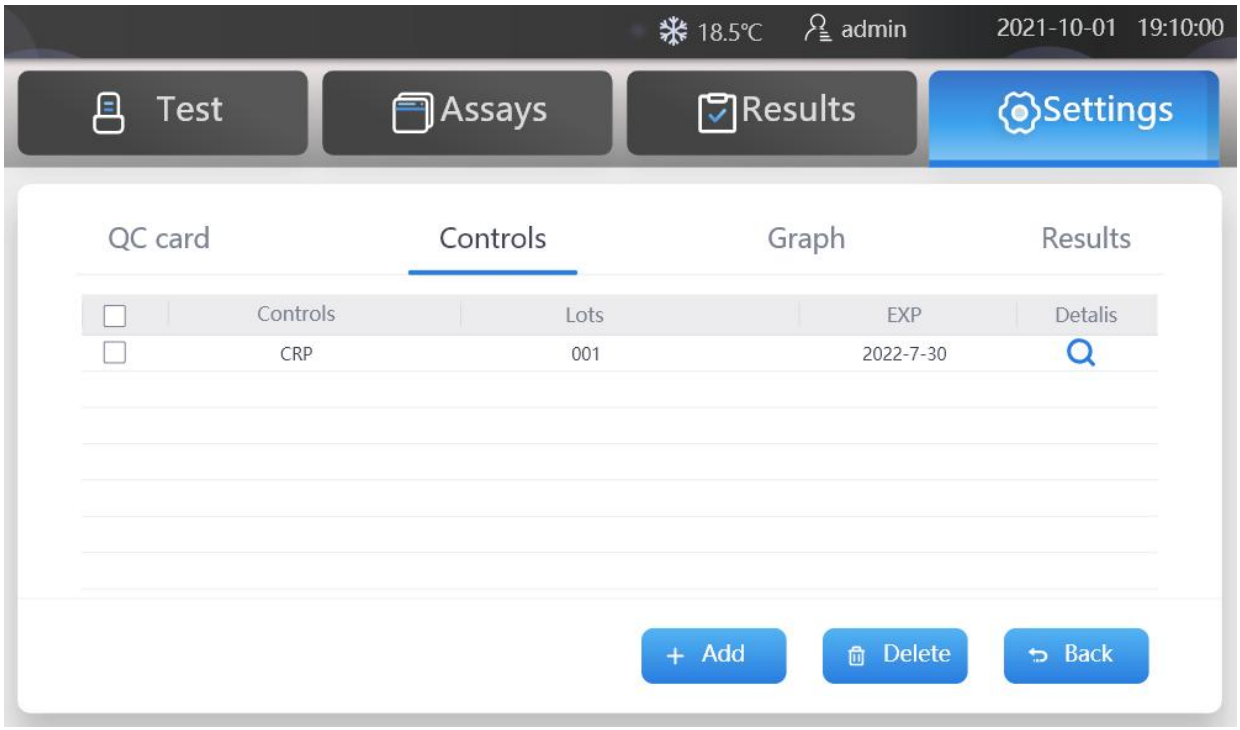


Figure 20 Control material setting interface

6.Click the + Add button to enter the control material entry interface.

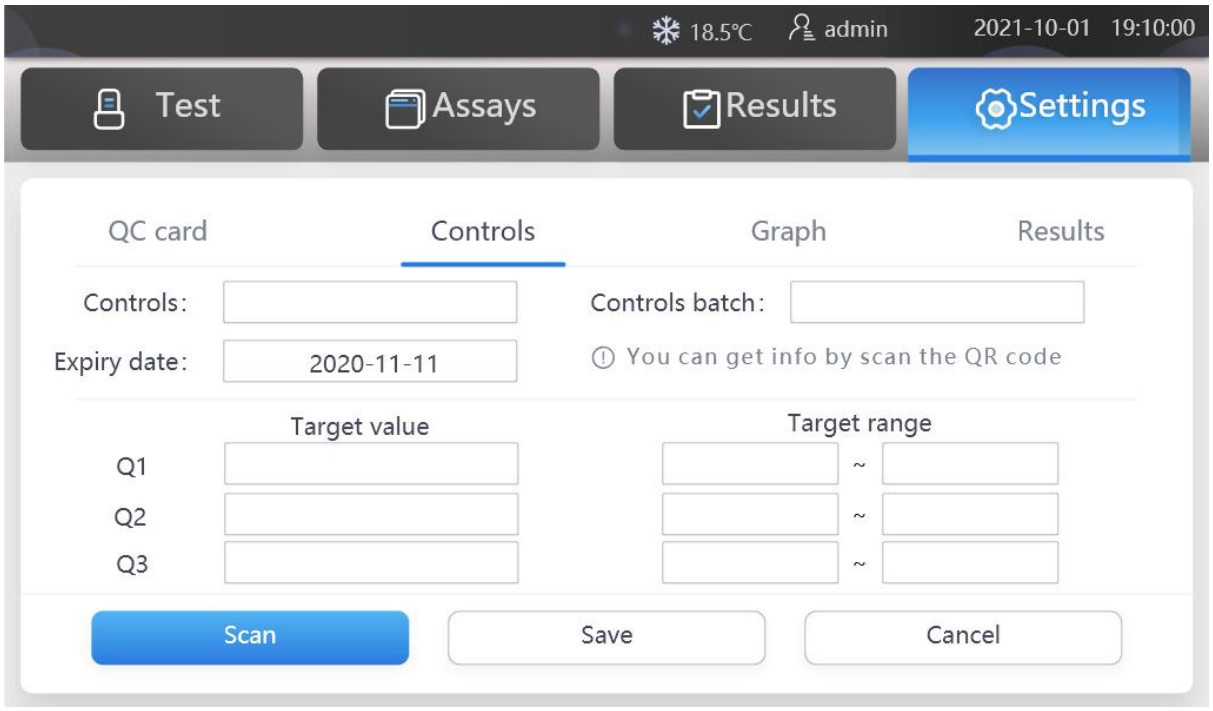


Figure 21 Control material entry interface

7. Click the “Graph” button to enter the QC graph interface.

Figure 22 QC graph interface

8. Click the Search button to filter the results of QC card or controls by condition, so that the results that meet the conditions are displayed on the interface in the form of dots and line graphs.

9. Click the QC results button to enter the QC results interface, you can query the results of QC card or controls according to the conditions, and the results that meet the conditions after a successful query are displayed in the results list, which can be printed or deleted according to demand.

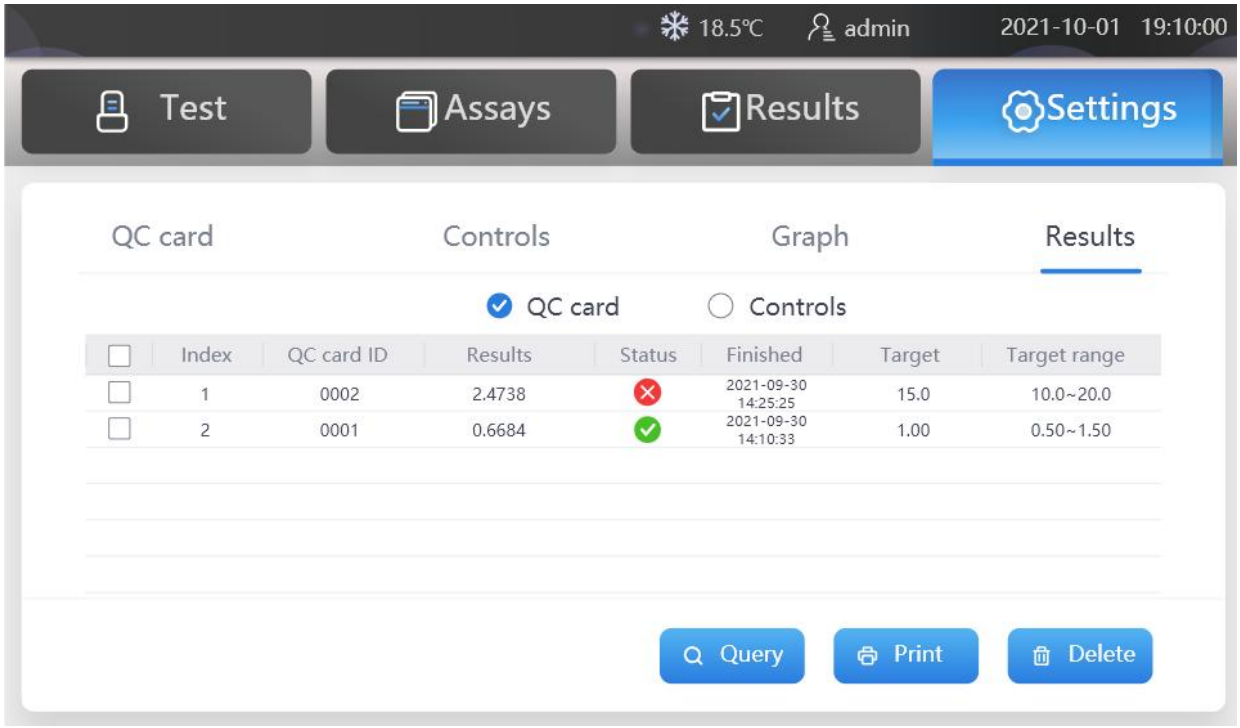


Figure 23 QC card result interface

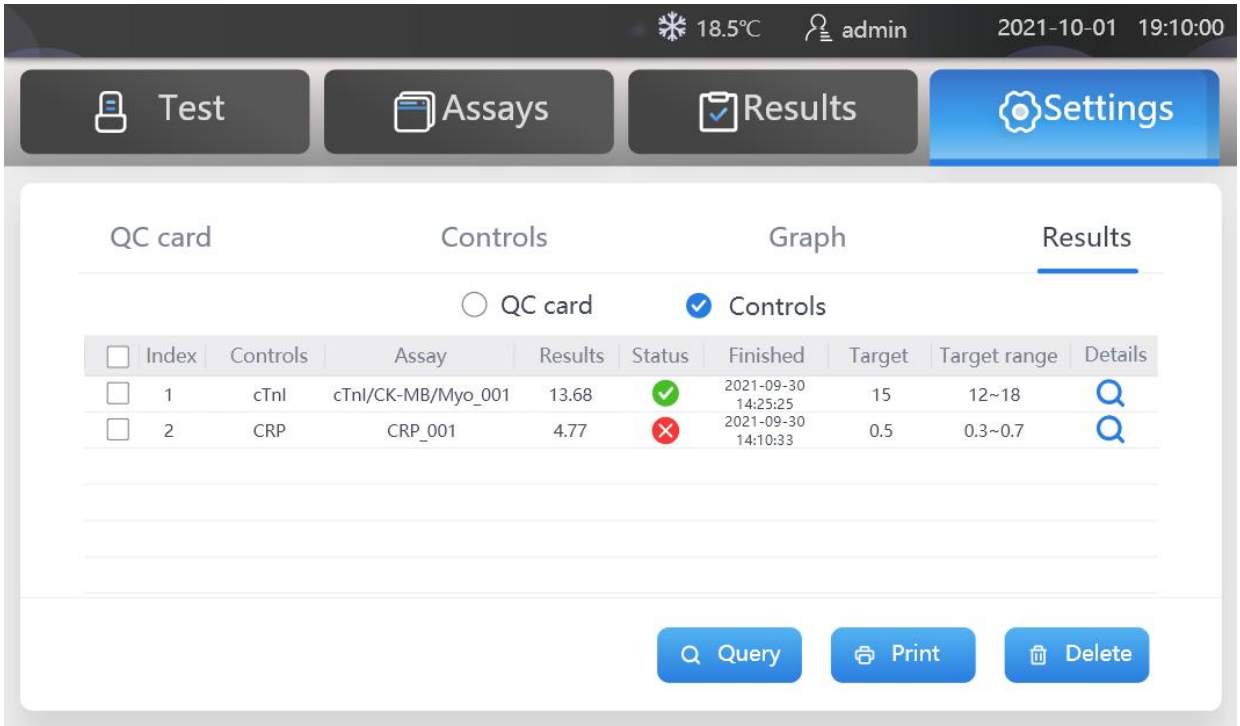
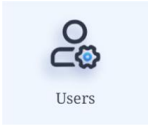


Figure 24 Controls result interface

10. Click the 

button on the setting interface to enter the user setting interface, you will enter the user setting interface, where you can perform operations such as logout/edit/add/delete, as shown in the figure below

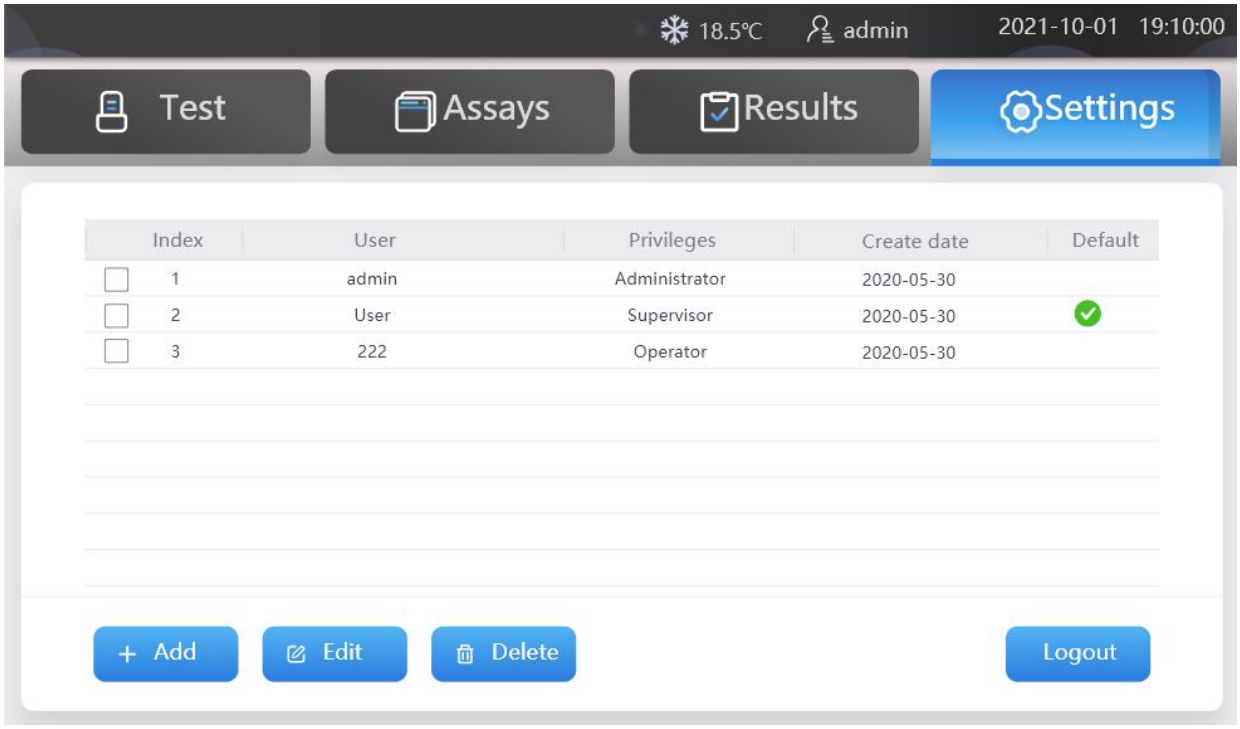


Figure 25 User setting interface

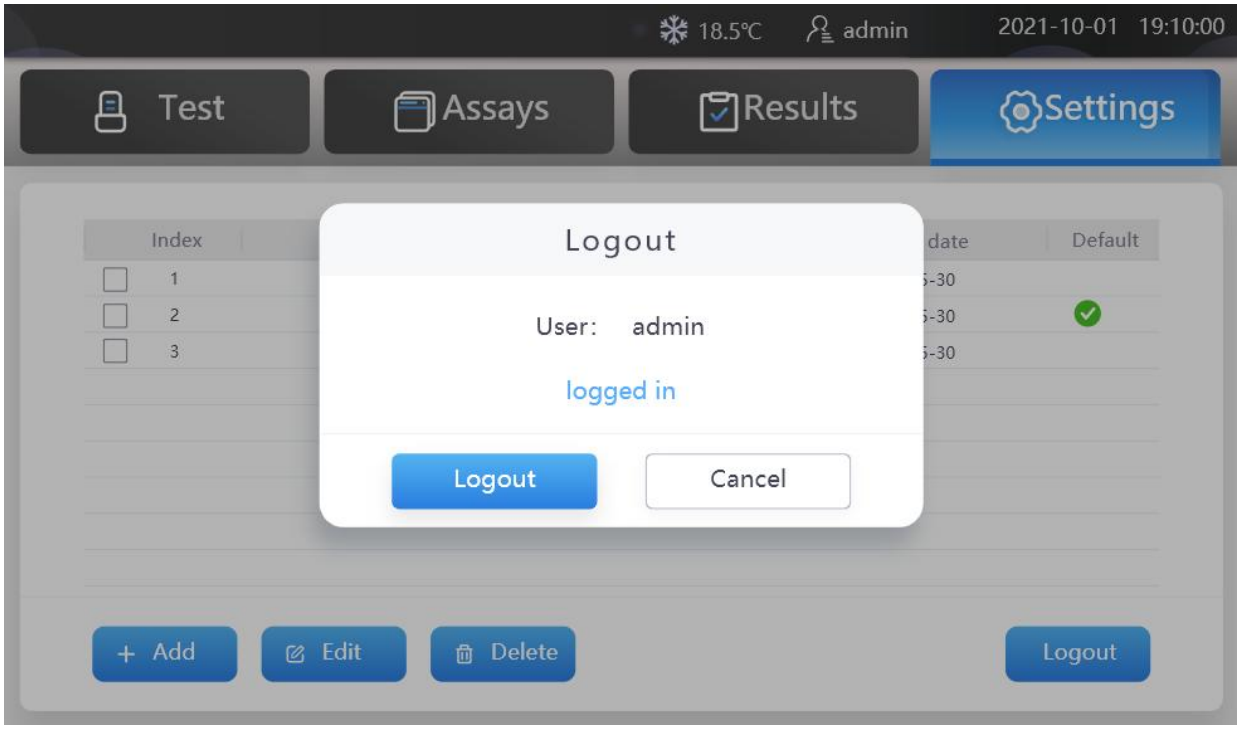


Figure26 User logout interface

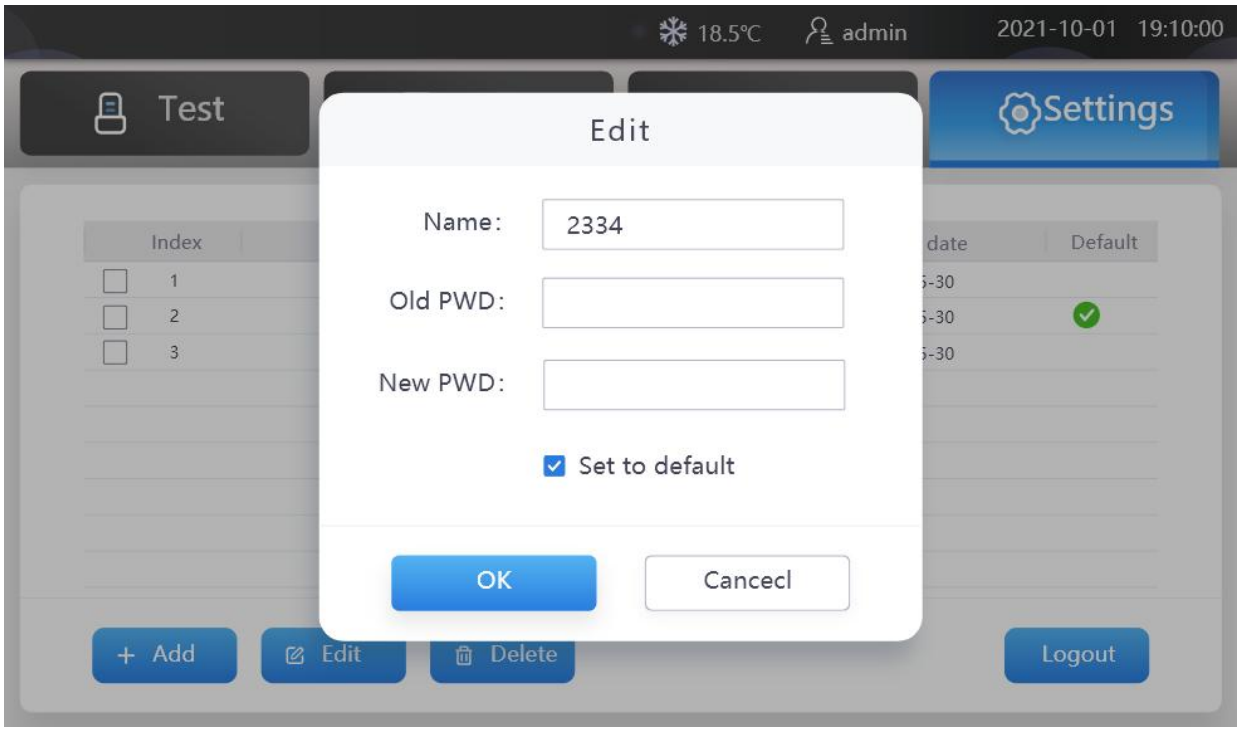


Figure 27 User editing interface

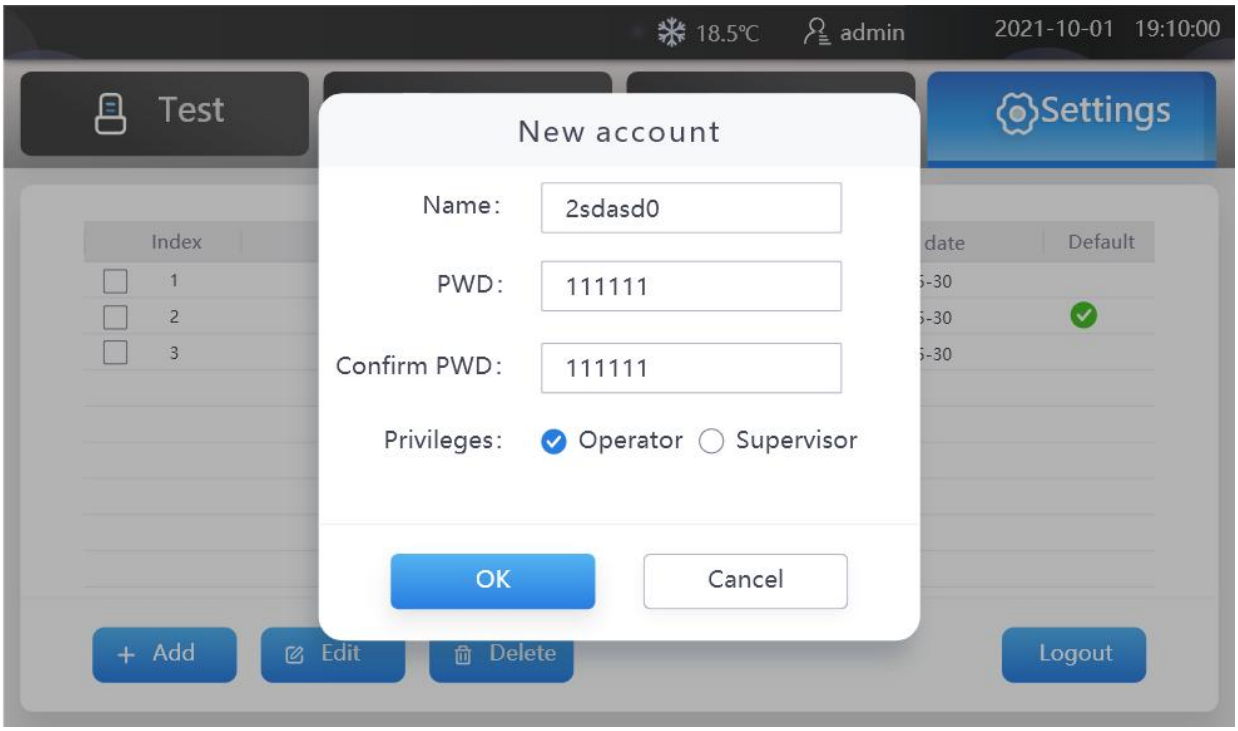


Figure 28 User creating interface

11. After clicking the 

button in the setting interface, the following interface will appear, which has 5 major functions: barcode, network, language, print, and serial port.

12. Click the QR Code button, for the channel scanning QR code function can choose to close or open, set to open, in the detection interface when inserting the card will scan the QR code on the test cassette to match the corresponding items, after a successful match to the project incubation, detection; When set to off, you need to manually select the test items corresponding to the test cassette, and then incubate and test. In addition, if you need to use an external code scanner, you can set the "use code scanner" function to open here.

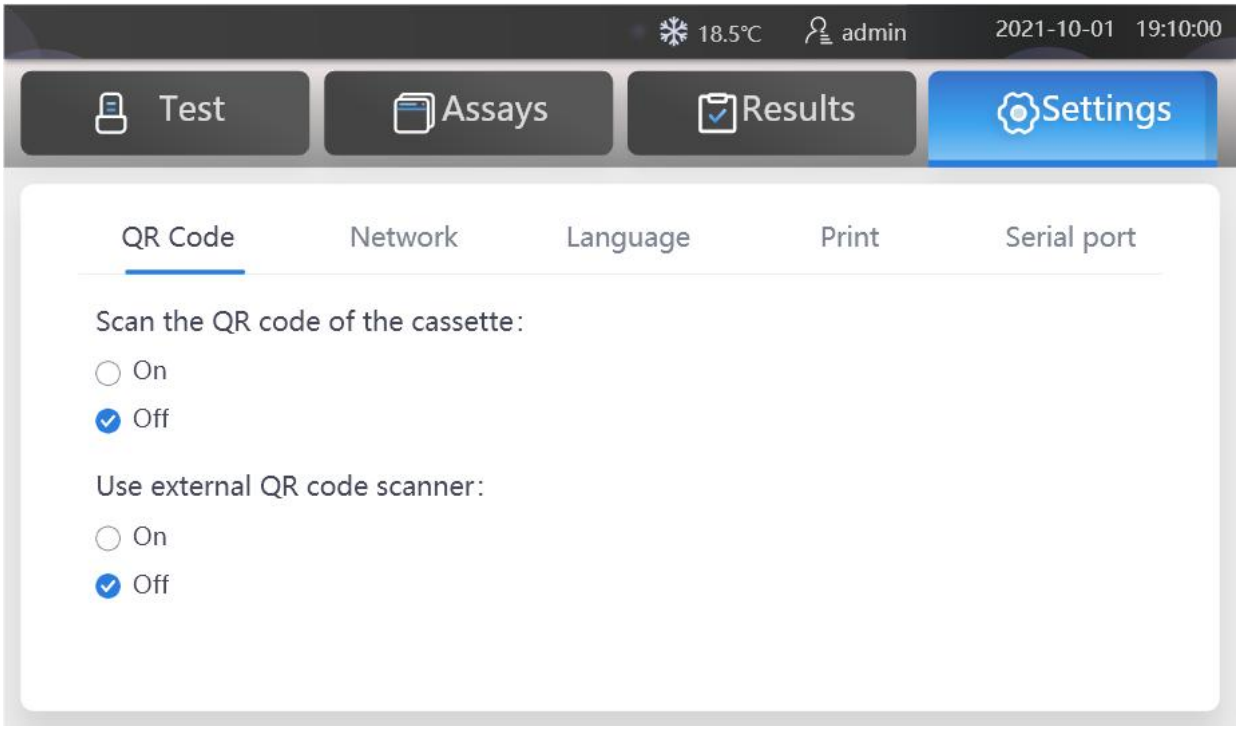


Figure 29 Setting-QR code interface

13. Similarly, the other function buttons can be operated separately in the operation interface of the previous step, and when you click the network button, you can make settings such as connecting to WiFi network.

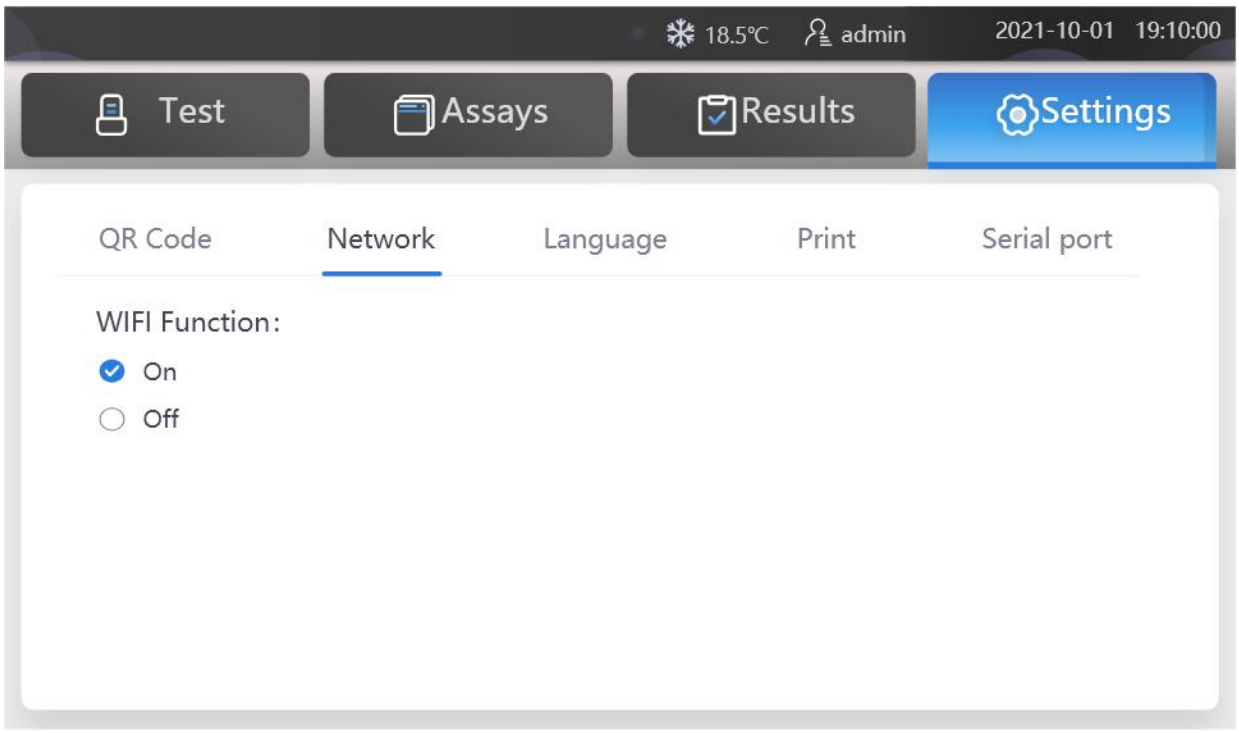


Figure 30 Setting-network interface

14. Click the Language button to switch between Chinese and English (single click operation).

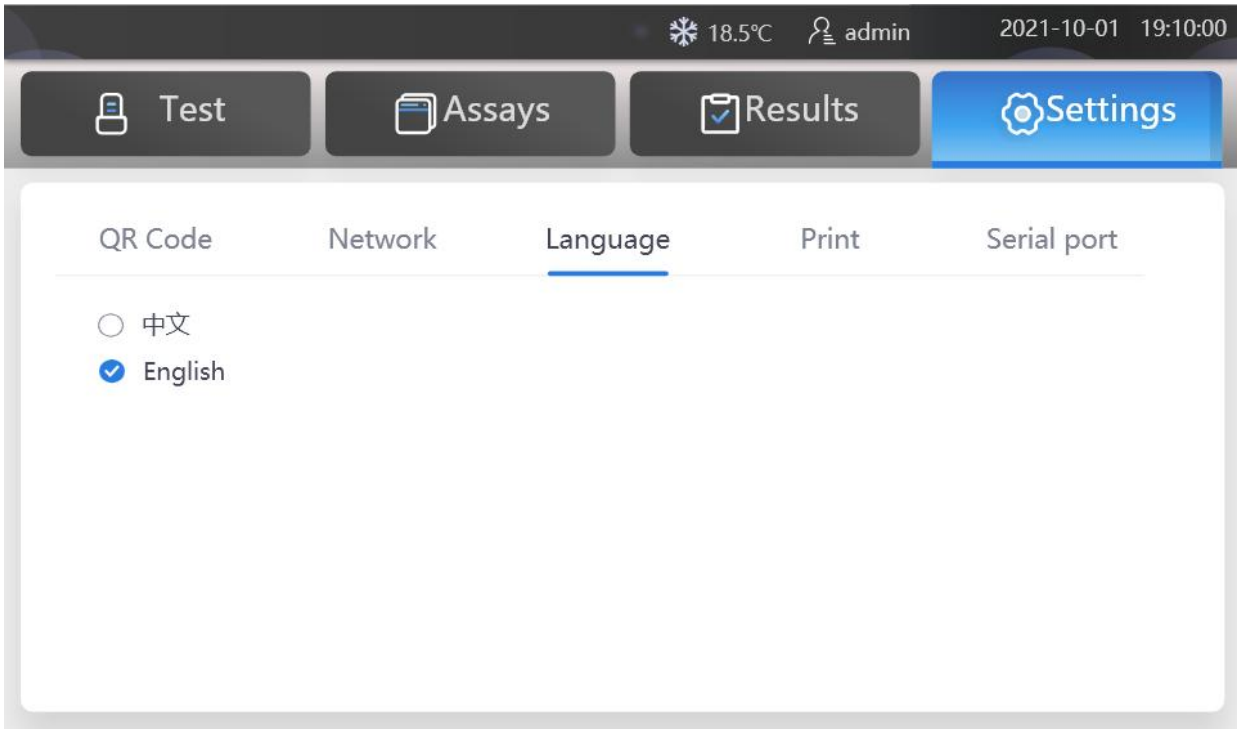


Figure 31 Setting-language interface

15.Click the Print button to set the instrument to automatically print the test report after completing a test operation.

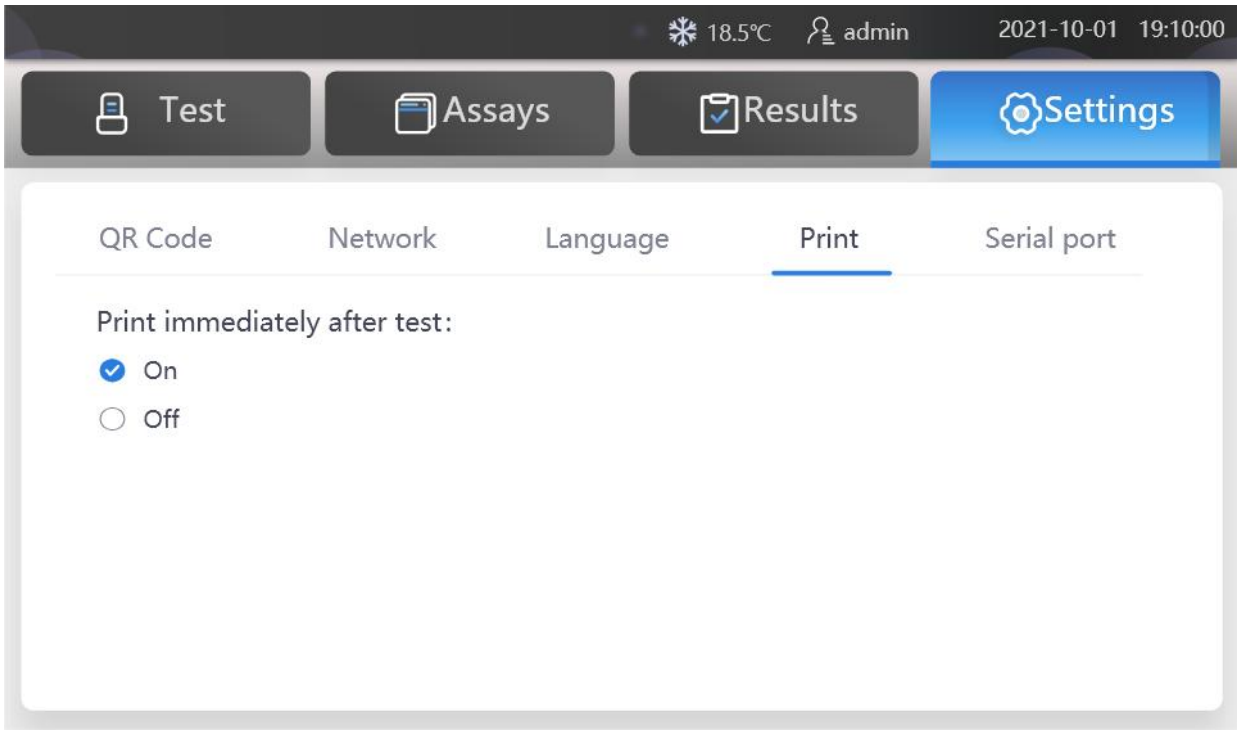


Figure 32 Setting-print interface

16.Click the Serial port button to configure the RS232 serial port to communicate with LIS or engineering software (internal test software).

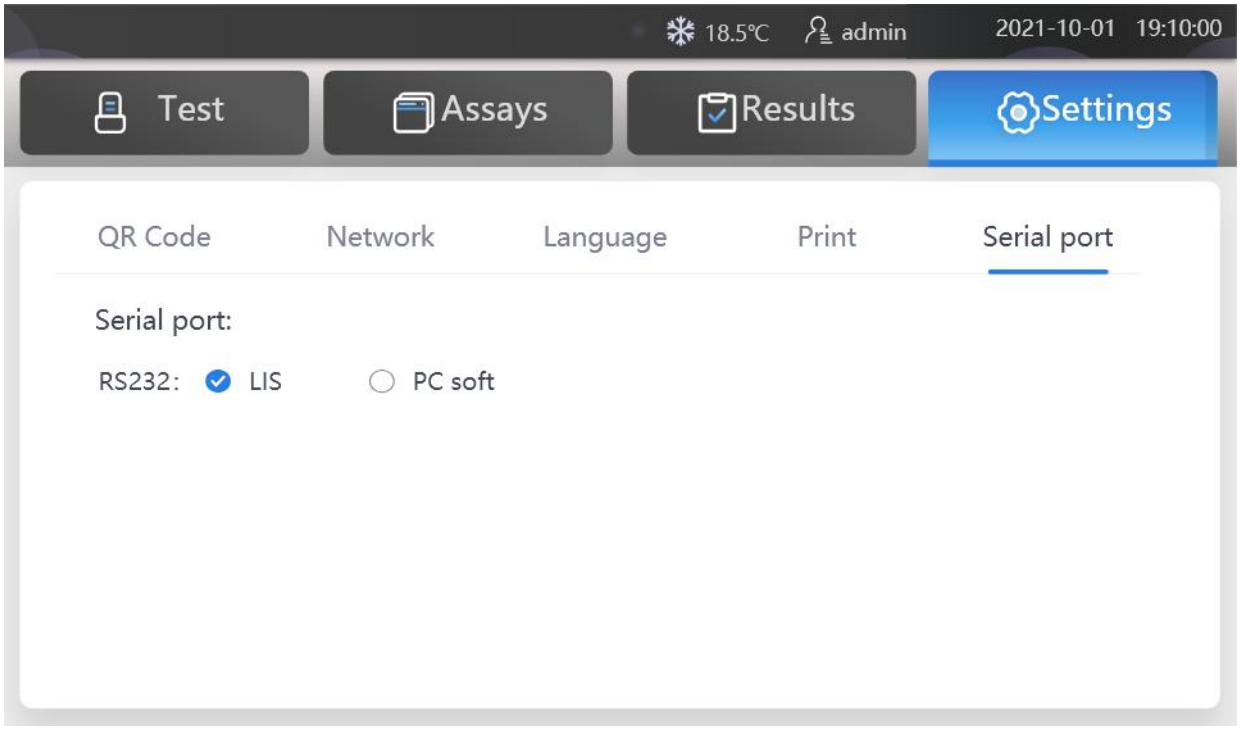
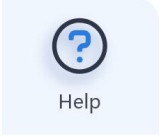


Figure 33 Setting-serial port interface

17. Click the 

button on the setting interface and then enter the Help interface.

18. After clicking the 

button on the Setting interface, the Power Off dialog box is displayed.

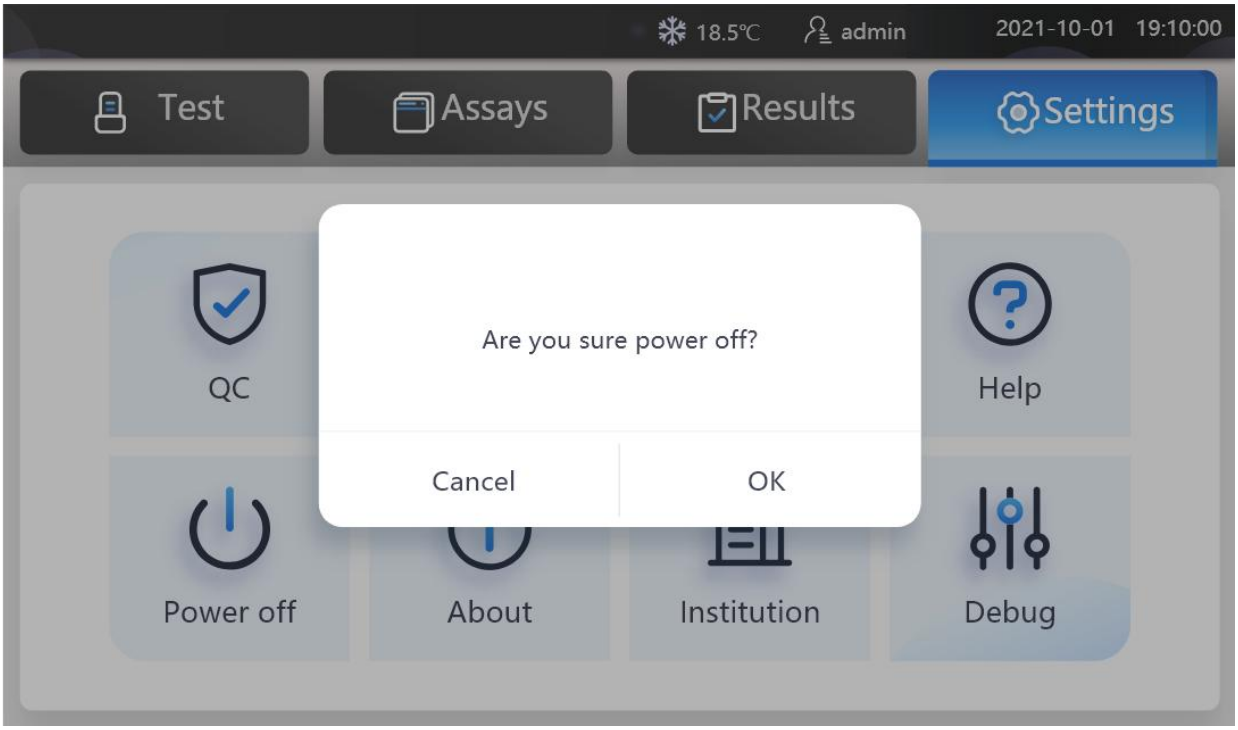
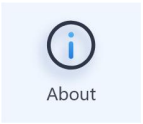


Figure 34 Power off operation interface

19. Click on the 

button in the Setting interface.

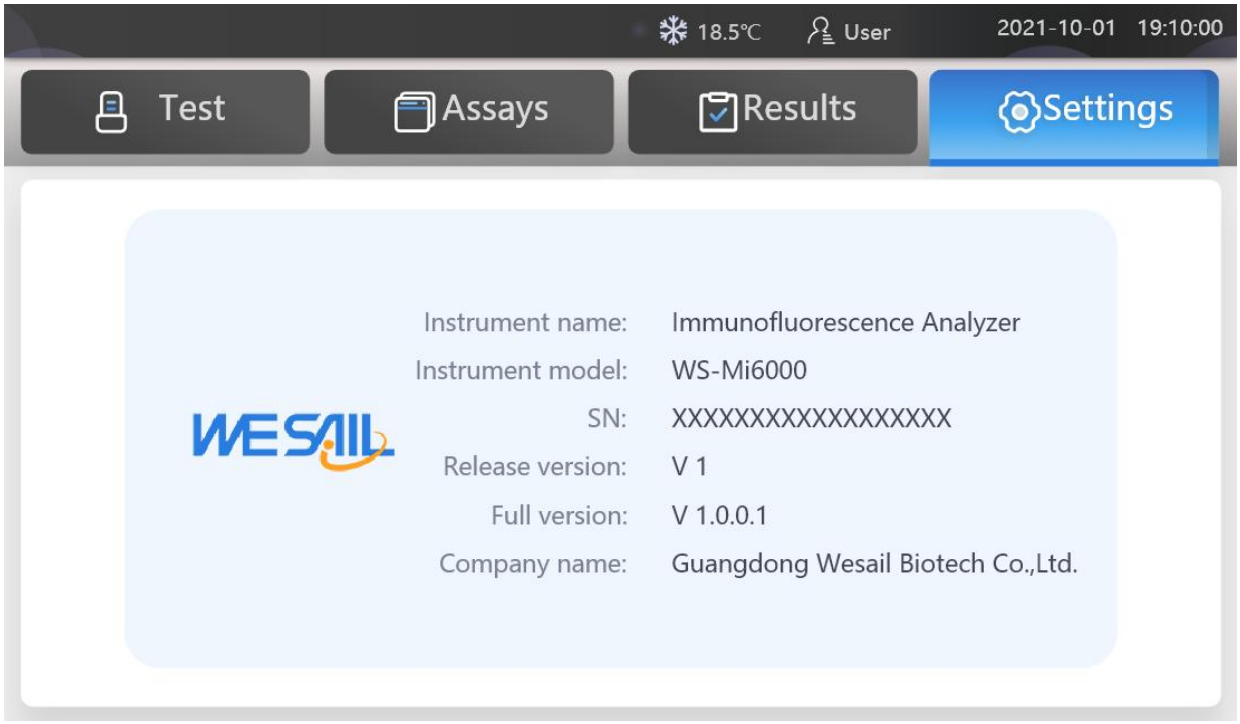


Figure 35 Setting interface

20. After clicking the 

button on the Setting interface, the following interface will be displayed, and the institution name can be changed and saved. 

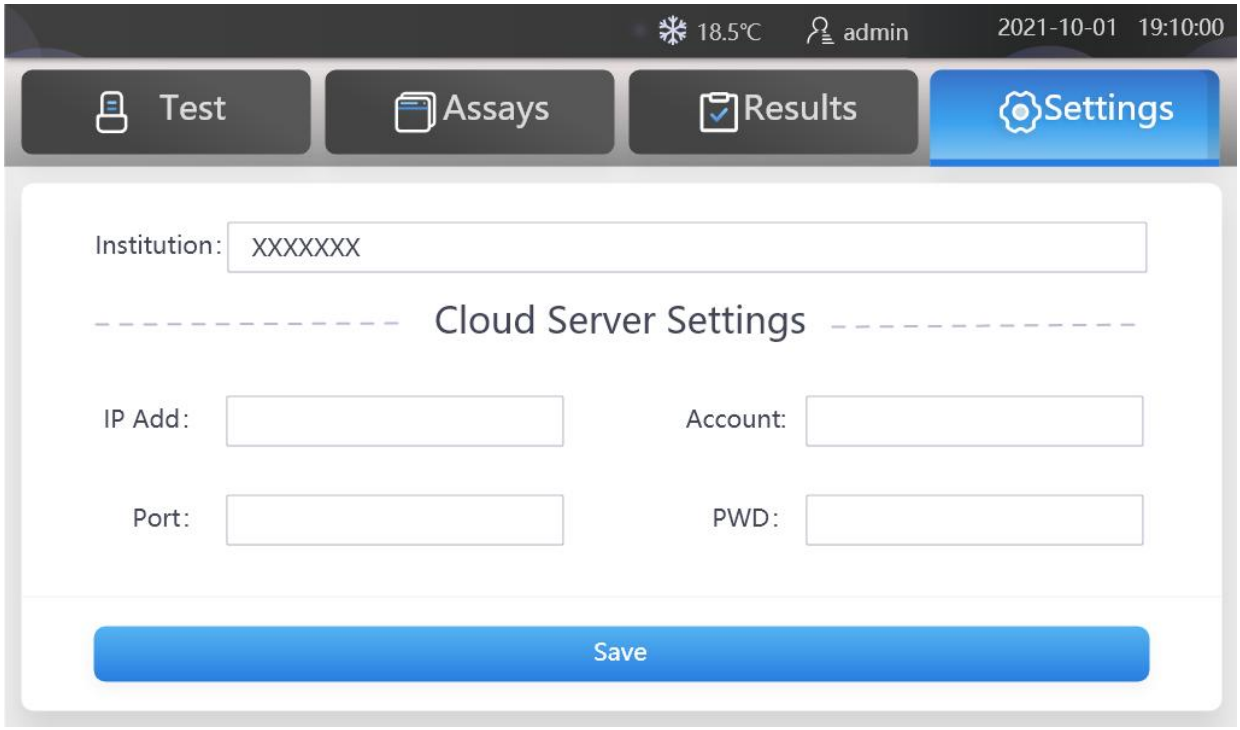


Figure 36 Institution information interface

6.2.7 Data transportation and Device (System) Interface

The data interface is a transmission protocol, and the test results of the analyzer can be sent to the LIS system through the network using the HL7 (Health Level Seven) protocol.

Data backup: The data will be backed up in the instrument system.

Disaster recovery: When the data fails catastrophically, the data can be obtained from the USB interface of the instrument or the instrument can be restarted to recover.

7 Product Maintenance

7.1 Daily Maintenance

1. Make sure the analyzer is powered off and unplugged before cleaning.
2. Clean the analyzer at regular intervals. When cleaning, the operator must wear disposable gloves.
3. External cleaning: Clean the outer surface with a damp cloth soaked by 0.5% bleach, 70% Isopropanol or 70% medical alcohol. To prevent damage to the outer surface and screen of the analyzer, it is prohibited to use strong bleach and other chemical detergents.
4. When cleaning, avoid liquid from flowing into the analyzer, which may cause damage to the analyzer.
5. Do not use chemical reagents such as turpentine oil or benzene to clean stains on the outer surface of the analyzer, as they may cause discoloration and deformation.

7.2 Regular Maintenance

1. Regular Maintenance: The analyzer does not contain components that can be maintained by the operators. To avoid electric shocks and damage to the analyzer, regular maintenance must be performed by an authorized maintenance technician.

8 Troubleshooting Guide

This list shows the faults that may occur during the use of the analyzer and the Prompts message on the screen. Please refer to the solutions provided in this list to determine and resolve the fault.

Table 5 Troubleshooting guide

Fault code table				
Fault code	**Fault type**	**Problems**	**Reasons**	**Solutions**
E201	Integrated fault	Failed to identify the QR code on the Calibration card	No Calibration card was inserted	Please insert the Calibration card
			The QR code of the Calibration card is damaged	Please replace the Calibration card
			The inserted Calibration card is out of position	Please insert it at the bottom
			QR code Scanner Malfunction	Contact the dealer or manufacturer
E202	Integrated fault	The current test item has expired	Conditions that trigger the instrument to analyzer failure	Contact the dealer or manufacturer
E204	Operation fault	No corresponding test items were retrieved	The test item for the tested test cassette does not exist	Please import the corresponding test item
			Test cassette QR code is incorrect	Please check if the test cassette is matching
			No selection of test items	Manually select the corresponding item when the test item needs to be selected
			No test items are imported	Import test items according to the user manual
E206	Integrated fault	The test result is invalid	The area of the quality control line is less than the set threshold	Replace the test cassette for detection
			Abnormal operation causes abnormal calculation of test results	Please operate the test according to the user manual
			Analyzer signal link anomaly	Contact the dealer or manufacturer
E218	Operation fault	Failed to connect the external QR code scanner	The external QR code scanner is not inserted	Connect the QR code scanner first, then set up to use the scanner
E219	Integrated fault	The identified assay table does not correspond to the instrument version	The assay table format is incorrect	Contact the dealer or manufacturer

		QR code parsing failure	Assay tables with illegal data	Contact the dealer or manufacturer
E221	Integrated fault	Failed to identify the QR code on the test cassette	The QR code of the test cassette is damaged	Please replace the test cassette
			The inserted test cassette is out of position	Please insert it at the bottom
			QR code Scanner Malfunction	Contact the dealer or manufacturer
E222	Operation fault	No sample number was entered during analysis	The analyzer cannot test without the sample numbe	Please enter the sample number
E224	Instrument fault	Card Return Failure	Solenoid is not working properly	Contact the dealer or manufacturer
E225	Operation fault	Sample testing interruption (adding sample timeout)	No operation within 5 minutes after returning the test cassette	Please complete the operation of filling in the sample information, adding the sample and inserting the test cassette within the specified time.
E226	Operation fault	Abnormally pulling out the test cassette in the channel	Pulling out the test cassette during incubation	Test according to the user manual
	Operation fault		Pulling out the test cassette during testing	Test according to the user manual
E227	Operation fault	Channel Abnormal Occupancy	When other interfaces enter the testing interface, it is recognized that the channel is occupied	Please pull out the occupied test cassette
	Operation fault		Micro switch failure	Contact the dealer or manufacturer
E102	Instrument fault	Motion mechanism failure	Exceeds the limit of the working temperature	Please work at the temperature specified in the user manual
			Internal failure causing obstruction of X or Y axis motor movement	Contact the dealer or manufacturer
E107	Operation fault	Unsuccessful export of data results	No USB drive presence detected during export	Please insert the U disk / replace the USB insert U disk
E108	Instrument fault	Print failure	Printer out of paper/busy/timeout not responding	Check print paper/re-initiate printing
E110	Instrument fault		Printer communication failure	Contact the dealer or manufacturer
/	Instrument fault	The instrument cannot be started	The power switch is not turned on	Please turn on the power switch
			No input voltage	Please check the power input
			Instrument failure	Contact the dealer or manufacturer
/	Instrument fault	Screen show abnormal	Instrument failure	Contact the dealer or manufacturer

9 Product After-sales and Maintenance

1. A one-year standard warranty is provided for the product
2. The warranty period begins with the “Acceptance Date” specified on the “Warranty Card” accompanying the product. The Warranty Card is the sole document for calculating the warranty period. If not specified, the warranty period will be calculated 60 days later than the “Ex-factory Date” identified on the packing case. The warranty card needs safekeeping.
3. During the warranty period, the product is provided with free after-sales service. Upon the expiration of the period, the manufacturer may continue to provide paid maintenance service.
4. During the warranty period, if the product needs to be repaired due to the following reasons, the manufacturer will provided paid repair service and you need to pay the maintenance fee and accessories fee.
    1) Artificial damage or improper use.
    2) Grid voltage is beyond the specified scope of the product.
    3) Irresistible natural disasters.
    4) Replace or use components, accessories and consumables that are not approved by the manufacturer.
    5) Instrument failure caused by the maintenance performed by personnel not authorized by the manufacturer.
    6) Other failures not caused by the product itself.

10 Storage and Transportation

1. Storage conditions of packaged analyzer：
   1) Temperature：0℃～55℃
   2) Relative humidity：≤93%
   3) Atmospheric pressure：86.0kPa～106.0kPa
   4) non-corrosive gas
   5) Well-ventilated room
2. Transport conditions of packaged analyzer
   1) General transportation is acceptable
   2) Need protection against moisture, sunshine and shock in-transit

Appendix A: Schedule of Electromagnetic Compatibility

Note

1. The Immunofluorescence Analyzer complies with the emission and immunity requirements specified in EN IEC 61326-1: 2021 EN IEC 61326-2-6: 2021, see the table below.
2. It is the user's responsibility to ensure the electromagnetic compatibility environment of the equipment so that the equipment can work normally.
3. It is recommended to evaluate the electromagnetic environment before using the equipment.

Note

1. The Immunofluorescence Analyzer is designed and tested according to the Class A equipment in CISPR 11. In a domestic environment, this equipment may cause radio interference, requiring precautions.
2. Do not use this equipment near strong radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the normal operation of the equipment.

Table 6 Electromagnetic Emission

Emission		
Emission Test	**Basic standard**	**Conformity**
Radiated Emission	EN IEC 61326-2-1:2021 EN IEC 61326-2-6:2021 CISPR11:2015+A1:2016+A2:2019	Class A
Conducted Disturbance	EN IEC 61326-2-1:2021 EN IEC 61326-2-6:2021 CISPR11:2015+A1:2016+A2:2019	Class A
Harmonic Current	EN 61000-3-2:2019	N/A
Voltage Fluctuation and Flicke	EN 61000-3-3:2019+A1:2019	N/A

Table 7 Electromagnetic Immunity

Electromagnetic Immunity			
Immunity test item	**Basic standard**	**Test value**	**Performance criterion**
Electrostatic Discharge	EN 61000-4-2:2009	Contact Discharge：±2kV、±4kV Air Discharge：±2kV、±4kV、±8kV	A
Radiated	EN 61000-4-3:2006+A1:2007+A2:2010	3 V/m，80MHz ~6000MHz，AM: 80 %	A
Electrical Fast Transient/Burst	EN 61000-4-4:2012	±1kV，5kHz，60s	A
Surge	EN 61000-4-5:2014+A1:2017	line-to-ground: ±1KV Line to line: ± 0.5kV	A
Conducted Susceptibility	EN 61000-4-6:2014	3V,0.15 MHz to 80 MHz,80%AM	A
Power Frequency Magnetic Field Susceptibility Test	EN 61000-4-8:2010	3A/m，50/60Hz	A
Voltage Dips and Interruptions Test	EN 61000-4-11:2004+A1:2017	Duration0.5/0.5,Test Level 0% 50/60HZ Duration1/1,Test Level 0% 50/60HZ Duration25/30,Test Level 70% 50/60HZ Duration250/300,Test Level 0%	A C C C

Appendix B: Graphical Symbols

Table 8 Description of Graphical Symbol

Graphical Symbols	Description	Graphical Symbols	Description
	Caution		Fragile, handle with care
	Consult instructions for use or consult electronic instructions for use		This way up
	Serial number		Keep dry
	IVD medical device		Protection against Sunshine
	Symbol of separate disposal of discarded electrical and electronic equipment (please comply with local laws and regulations)		Biohazard
	Stacking Limitation		Ground Protection
	Prevent pinching hands		high-temperature warning

Appendix C: Product Configuration

1. List of product configuration

Table 9 List of product configuration

No.	Items	QTY	Unit	Replacement cycle	Replacement method
1	Analyzer	1	set	8 years	Contact the manufacturer
2	Power cord	1	set	/	Contact the manufacturer
3	Printer paper	1	copy	/	Contact the manufacturer
4	User Manual	1	copy	/	/
5	Quick-Start Guide	1	PCS	/	/
6	Qualified Certificate	1	copy	/	Contact the manufacturer
7	Warranty Card	1	copy	/	Contact the manufacturer
8	Packing List	1	copy	/	Contact the manufacturer

Appendix D: Registration Information

Guangdong Wesail Biotech Co., Ltd.

Address: 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China

Tel: 400-900-1339

E-mail: customer@wesailbio.com

Website: http://en.wesailbio.com

EC REP MedPath GmbH

Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Tel: +49(0)89 189174474

E-mail: info@medpath.pro

Website: www.medpath.de

Revision Date: 2023-09-19

Version：0001

Approval Date: 2023-09-26

Date of Issue: 2023-09-28

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 108683 0001 Rev. 01

Holder of Certificate: **Guangdong Wesail Biotech Co., Ltd.**
2F, Building 1, 5 Hualian Street
Songshan Lake Science and Technology Industrial Park
Songshan Lake
523808 Dongguan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Immunochemistry.**
Design and Development, Production, Distribution and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 108683 0001 Rev. 01

Report No.: GZ2355001 / GZ2355001_CN

Valid from: 2023-10-13
Valid until: 2026-10-12

Date, 2023-09-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 108683 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Guangdong Wesail Biotech Co., Ltd.
2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of In Vitro Diagnostic Reagents for Immunochemistry.
Distribution of In Vitro Diagnostic Reagents and Instruments for Immunochemistry.

Guangdong Wesail Biotech Co., Ltd.
Room 201, Building 10, 19 Alishan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®