PRODUCT CATALOG

Hangzhou Laihe Biotech Co., Ltd.

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Professional and only in IVD Products

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Profile

Founded in 2012, Hangzhou Laihe Biotech Co.,Ltd.(hereinafter referred to as Laihe Biotech), a national high-tech enterprise, has always focused on the development and industrialization of POCT instant diagnosis, monitoring and health information technology field, and is committed to providing fast, accurate and reliable health detection products and services to public.

The company can continuously provide following products:

1. Drug Urine, Saliva, Hair Testing;
2. Inflammation (hs-CRP, PCT, CRP-SAA, PCR-IL6) Testing;
3. Cardiac Markers (cTn I, NT-proBNP, CMA) Testing;
4. Tumor Markers (AFP, CEA, PSA) Testing;
5. Torch Testing;
6. Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Test;
7. Novel Coronavirus (COVID-19) Antigen Test;
8. COVID-19 and Influenza AB antigent test。

Main Achievements:

1. ISO13485 quality system certification and USA FDA certified factory;
2. More than 30 registration certificates of NMPA medical device;
3. Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Test Kit is EUA certified (US FDA) , and has got CE, Australia TGA, Brazil ANVISA, Thailand and the Philippines COE certification, meanwhile registration in China NMPA, WHO is in process;
4. 4.Drug test products have been listed in the Ministry of Public Security Drug Test Kit recommended Purchasing Catalogue;
5. Laihe Biotech researches and develops independently the 'Quantum Dot Fluorescence - a technological innovation platform for Hair Drug Trace Rapid Detection' which is as '13th Five-Year' national key R&D project, being as the industrialization cooperation unit for drug detection and drug of abuse control technology & equipment research project topic 5 research results;
6. Patents Obtained: more than 30 international and Chinese invention patents.

We always take 'Integrity, Practicality, Efficiency, and Innovation' as the corporate spirit. Laihe Biotech, committed to becoming an internationally competitive biotechnology enterprise, strives to provide health testing products and services to public with scientific progress as the force and excellent talents as foundation.

Product module

1/ Drugs of abuse hair test analyzer

2/ Hand-held drug urine/saliva test reader

3/ Drugs of abuse urine test

4/ Drugs of abuse saliva test

5/ POCT analyzer

6/ Cardiac marker test

7/ Tumor marker test

8/ TORCH & Fertility test

9/ Infectious disease test

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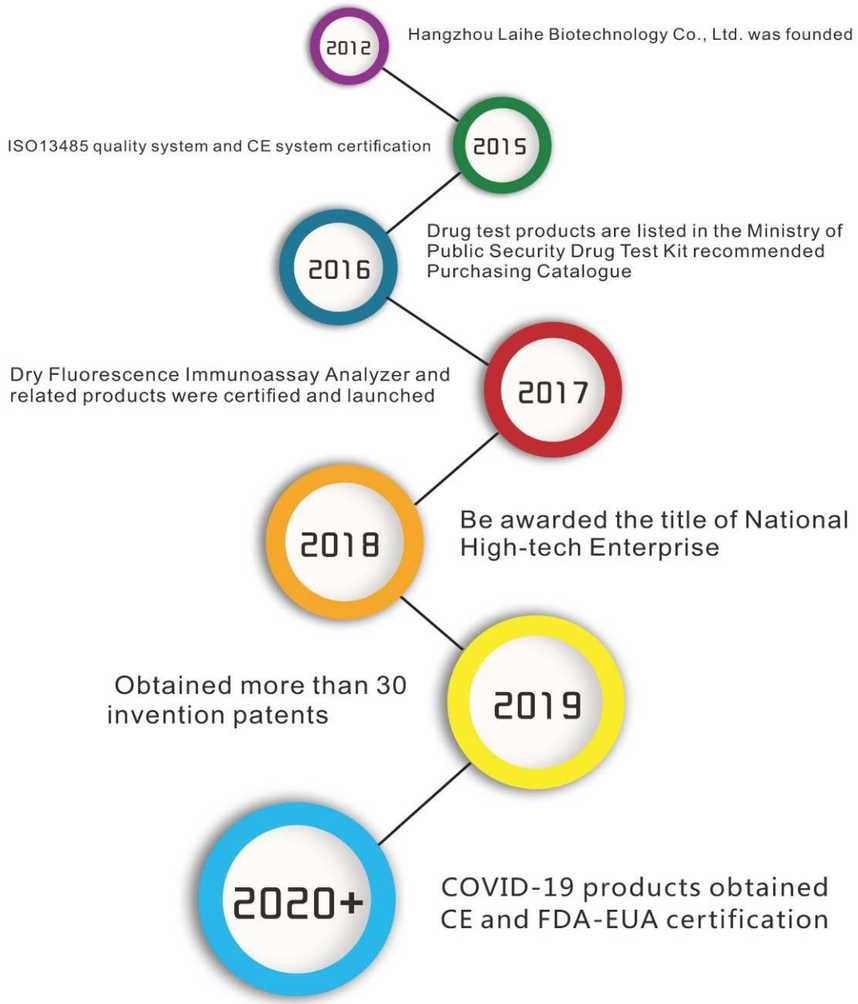
Focus on the research and development, production, sales and service of POCT diagnostic products



Our attitude: "Do professional things with a professional heart"

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Novel Coronavirus IgG/IgM Antibody Test Kit (Colloidal Gold)

Antibody is product of the humoral immune response after infection with virus .in general, IGM antibodies appear early in the infection and IgG antibodies appear in the middle and late stages of infection. Titers have a continuous process of increasing and stay in circulation for a longer period of time. Test for specific antibodies can determine whether a patient has "recently or previously infected 2019-nCOV ".

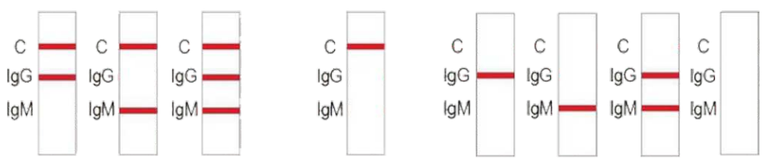
Complementary to nucleic acid testing helps to avoid "false negatives"

OPERATION PROCESS

1. Drop blood specimen
   drop vertically blood into the specimen well
   serum or plasma :10μL
   whole blood :20μL
2. Add diluent
   add vertically 2 drops of diluent into the specimen well
3. Read the results
   observe and record the results within 10 mins

INTERPRETATION OF RESULTS

*Take combo test as example



Product Features

- Rapid Detection: reslut within 10 mins to reduce wating time.
- Smiple Operation :no professional training required and accessible in basic labs.
- Easy Sampling :whole blood.serum or plasma.
- Qualitative Test: no instrument required and no laboratory space occupied.

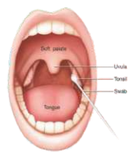
Novel Coronavirus (COVID-19) Antigen Test Kit(Colloidal Gold)

Specimen Collection

Nasopharyngeal Swab

① Tilt the head back 70°
② Insert the sterile swab through nares parallel to palate until resistance is met
③ Rotate the sterile swab a few times against the nasopharyngeal wall and leave swab in place for several seconds to absorb secretions
④Remove the sterile swab from the nostril carefully
⑤Specimen should be tested as soon as possible after collection

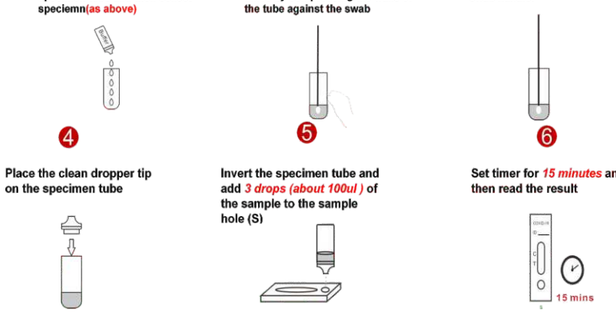
Oropharyngeal Swab



① Tilt the head back slightly, open the mouth wide to expose the tonsils and back of the throat
② Use the tongue depressor to hold the tongue away from the back of the throat
③ Locate the areas of the redness and white spots on the tonsils
④ Rub the swab over the area, back and forth, aviod touching the tongue or roof of the mouth
⑤ Specimen should be tested as soon as possible after collection

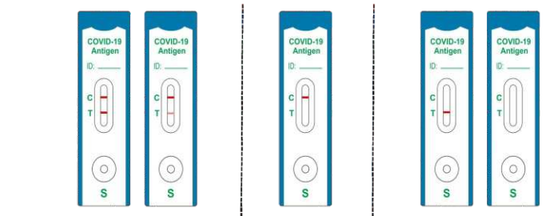
Test Procedure

1. Add *10 drops (about 300ul)* of specimen extraction buffer to the specimen tube and then collect speciemn(as above)
2. Insert the swab into the extraction buffer and Squeeze the swab *10-15 times* by compressing the walls of the tube against the swab
3. Let the swab stand for *2 minutes* or longer and then discard the swab handle.



4. Place the clean dropper tip on the specimen tube
5. Invert the specimen tube and add *3 drops (about 100ul)* of the sample to the sample hole (S)
6. Set timer for *15 minutes* and then read the result

Interpretation of Results



Clinical Performance

- Relative Sensitivity: 96.43%(91.86%-98.83%)
- Relative Specificity：99.06%(94.83%-99.98%)
- Accurary :97.56%(94. 77%-99.10%)

Product Features

- CE Marked
  CE
- Result in 15 mins
- Easty to collect samples
- No equipment needed
- Resu lts a re easy to read
- Roomtemperature storage

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COVID-19 and Influenza A/B Antigen Test Kit

At present, the prevention and control of new coronavirus pneumonia (NPV) has entered a critical period, however, the prevalence of influenza A/B virus infection is gradually increasing, and its clinical manifestations are similar to npv pneumonia, it is difficult to be differentiated by clinical manifestation and chest imaging, and the treatment of the two infections is quite different.

The rapid differential detection protocol for influenza virus and new coronavirus infection is helpful for rapid, safe and labor-saving differential diagnosis of influenza A/B virus and new coronavirus infection, as well as identification of co-infection.

Product Features

- Nasopharyngeal specimen and Oropharyngeal specimen Available
- Test results within 15 minutes
- No professional training required and accessible in basic labs
- Room temperature storage (2-30 ℃)
- 18 Months shelf life

Clinical Performance

	COVID-19 新冠抗原	Influenza A 甲流	Inluenza B 乙流
Clinical Sensitivity	96.23% (91.10%,100.00%)	100.00% (99.64%,100.00%)	94.44% (83.86%,100.00%)
Clinical Sensitivity	100.00% (99.82%,100.00%)	100.00% (99.84%,100.00%)	100.00% (99.84%,100.00%)
Total Coincidence Rate	98.96% (97.53%,100.00%)	100.00% (99.85%,100.00%)	99.48% (98.47%,100.00%)

New and Hot products

▶Hair drug trace rapid analyzer

model：FA-LF100C

Methodology：Dot fluorescent immunoassay

Product introduction

Hair drug trace rapid analyzer FA-LF100C is a Dot fluorescent immunoassay system. Which is used to detect the concentration of drugs in hair.

The world's first quantum dot fluorescence technology platform.

Test item

MET MOP KET COC MDMA MOP / MET MOP / MET/KET

Achievements

- First dot fluorescent immunoassay analyzer to detect the drug concentration of the hair
- The first research institute of the Ministry Of Public Security Producer
- Obtain the inspection report of the Security And Police Electronic Products Quality Inspection Center Of The Ministry Of Public Security
- The important national research project

Research and development background

The hair growth rate is about 1 cm per month, and the drug combined with hair will grow forward with hair instead of spreading along the hair shaft. Hair is marked as roots, ends and cut into several sections, and each section was measured separately. According to the measurement of result and the growth rate of hair, the time of drug absorption and the amount of drug use could be speculated roughly. This is the blood, urine toxicity analysis which are currently unable to do, and that is one of the reasons for the preference of toxicological analysis workers.

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Product advantage

- Rapid quantitative test: reacting time of test kit only need 3 minutes. It could finish detection of drug concentration in hair specimen of suspected drug abusers within 5 minutes.
- Ultra high sensitivity: minimum detection limit: 0.1 ng/mg.
- Long test window period: not affected by drug metabolism in the body.
- Convenient sampling: sampling on site, only need little hair and can effectively avoid sample fraud or transfer.
- Complete testing items: detect morphine, methamphetamine, ketamine, cocaine and other drug content in hair .
- Patented technology , exclusive patented hair lysate that quickly cleaves the surface structure of hair and extracts drugs from hair within 30 seconds.
- Patents: 5 invention patents, 8 utility model patents, 5 appearance patents, 2 software copyrights .

Application

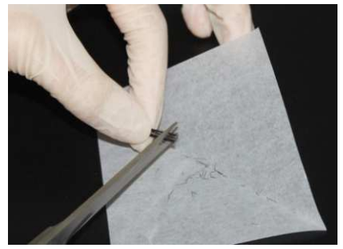
- For regular detection and evaluation drug addicts, community drug addicts and community rehabilitation personnel
- Conscription, civil service recruitment, entertainment venues employees
- Screening drugs testing of suspects involved in drug trafficking
- Teenagers
- Driving spot testing
- Tracking the process of detoxifying treatment in addiction treatment centre
- Drugs testing of customs and entry-exit personnel
- Forensic identification

User Instruction of Hair Drug Trace Test Box

1.Remove and place the analyzerhorizontally, connect power adapter, turn on the left switch and right card slot. Remove hair lysate and test cassette, let them return to room temperature

2.Remove the ID card and insert it into analyzer, click “Read ID Card” detect the test kit after finishing the reading

3.Close to scalp, cut 5 mg hairs (About 10cm each of 10 hairs)



4.Cut hair into small pieces of 1-2mm on weighing paper

5.Pour shredded hairs into a bottle containing hair lysate, cover the cap, shake for 1 minute

6.Suck supernatant of the hair lysate with a dropper, add 2 drops in reagent well

7.Insert test kitimmediately into the analyzer after 3-minute reaction. Click “Test” to get drug concentration result

Result interpretation

The result is less than 0.1, which means NEGATIVE
The result is more than or equal to 0.1, which means POSITIVE. The result needs read after 3 minutes and will be invalid after 5 minutes.

Precautions

- When collecting hair samples, you need to close the scalp and cut the collected hair in a clean paper bag or valve bag.
- When collecting the hair of different people, wipe the scissors with alcohol cotton in the box to prevent cross-contamination.
- Different batches of test kits cannot be mixed, and ID cards and test cards must not be mixed with different batches.
- The tests card and its components are only applicable to the Hair Drug Trace Rapid Analyzer produced by Hangzhou Laihe Biotech Co., Ltd.

Order Information

Test Item	Code	Specimen	Range	Test Time
Mornphine (MOP)	HMO-101	Hair	0.1ng/mg-10ng/mg	In 5minutes
Methamphetamine(MET)	HME-102	Hair	0.1ng/mg-10ng/mg	In 5minutes
Ketamine (KET)	HKE-103	Hair	0.1ng/mg-10ng/mg	In 5minutes
Ecstasy(MDMA)	MDMA-104	Hair	0.2ng/mg-10ng/mg	In 5minutes
Cocaine(COC)	COC-105	Hair	0.2ng/mg-10ng/mg	In 5minutes
MOP/MET	MOM-106	Hair	0.1ng/mg-10ng/mg	In 5minutes
MOP/MET/KET	MMK-107	Hair	0.1ng/mg-10ng/mg	In 5minutes

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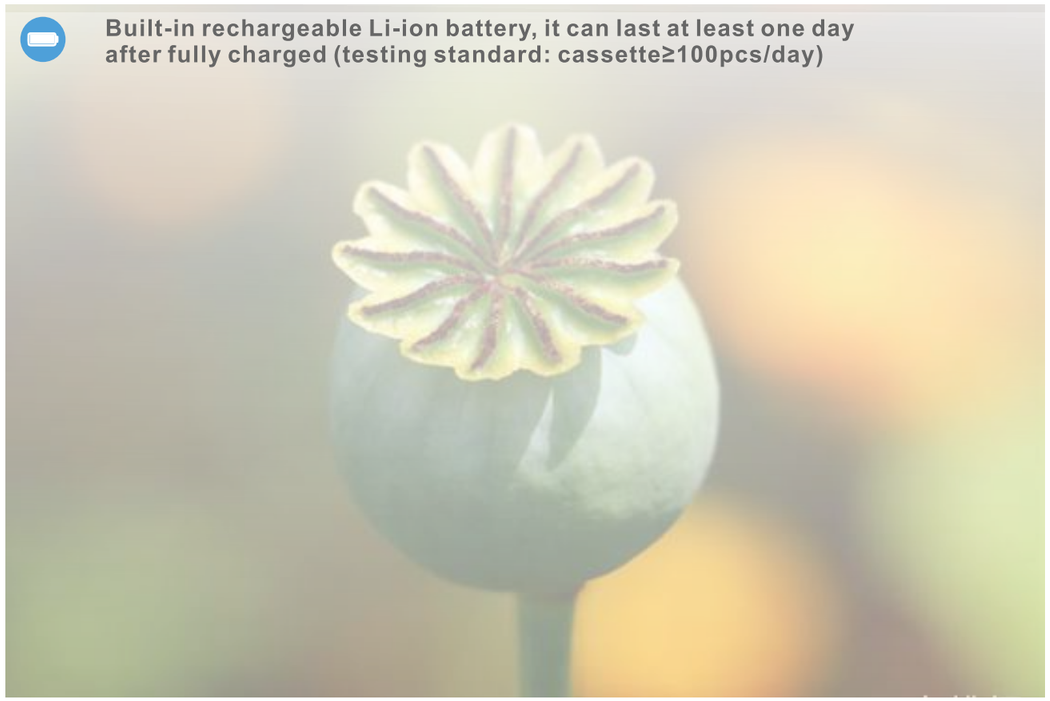
▶ Hand-held Hair Drug Trace Rapid Analyzer

Application

With the growing of the global drug problem which is affecting the international community, with the trafficking of methamphetamine, cocaine, ecstasy and heroin and the threat of emerging drugs such as fentanyl, bath salts and Spice.Suspected drug identification is a serious challenge for law enforcement officials, who need quick access to get information. LYHER hand-held hair drug trace analyzer will make narcotics agents, customs, border patrol agents, and others are able to test multiple drugs in easier and get clear, definitive results

- **LED HD display**
- **Built-in HD camera, supporting to identify one-dimensional code or two-dimensional code**
- **Built-in thermal printer, supporting instant printing of results**
- **Built-in rechargeable Li-ion battery, it can last at least one day after fully charged (testing standard: cassette≥100pcs/day)**



Basic parameter	Description
Operation Interface	5.5 inch 720P color page LCD display (capacitive touch screen)
Human-machine Interaction	3G/4G, wifi sopport, touch screen operation, synchronize records to PC through USB
Prompt Function	1. Touch screen prompt tone and detection end prompt tone 2. Status indicator, low power indicator, charging indicator, detection start/end indicator
Cassette Specification	Customizable
Machine Specification	255mm(L)*100mm(W)*60mm(thickness of handle)
Battery Capacity	HHRS-1002

Order Information

Item	Code	Specimen	Test item	Test Time
Morphine (MOP)	HHA-101	Hair	0.1ng/mg-10ng/mg	In 5 minutes
Methamphetamine (MET)	HHA-102	Hair	0.1ng/mg-10ng/mg	In 5 minutes
Ketamine (KET)	HHA-103	Hair	0.1ng/mg-10ng/mg	In 5 minutes
Marijuana (THC)	HHA-104	Hair	0.1ng/mg-10ng/mg	In 5 minutes
MOP/MET	HHA-106	Hair	0.1ng/mg-10ng/mg	In 5 minutes
MOP/MET/KEP	HHA-107	Hair	0.1ng/mg-10ng/mg	In 5 minutes

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▶Hand-held urine/saliva drug test reader

product description

The LYHER Hand-held Urine/Saliva drug test reader is a fast, accurate mean of testing urine and oral fluid specimen for drugs of abuse, such as Morphine, Methamphetamine, Cannabinoids , Cocaine , MDMA , Amphetamines, Opiates, and Methadone.

Specimen: Urine & Saliva

Application

- Roadside controls, prisons or hospitals
- Screening drugs testing of suspects involved in drug trafficking
- Teenagers
- Driving spot testing
- Tracking the process of detoxifying treatment in addiction treatment center
- Multi-drug testing of customs and entry-exit personnel

Product features

1/ Read the results by equipment to avoid different results read by Interpretation of person.

2/ Hand-held one for spot testing

3/ Multi-drugs combo tests for urine and saliva

4/ Read results in 5minutes

Item	Code	Specimen	Test item	Test Time
Saliva 3 in 1 drugs test	HHRS-1001	Saliva	MET/MOP/KET	In 5 minutes
Urine 6 in 1 drugs test	HHRU-1002	Urine	KET/THC/MOP MDMA/MET/COC	In 5 minutes

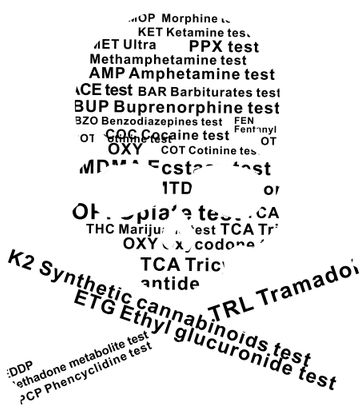
▶Colloid Gold Drug urine & saliva test kit

Application

1.Community drug addicts
2. Conscription, civil service recruitment, entertainment venues employees
3. Teenagers
4. Driving spot testing
5. Drugs testing of Customs and entry-exit personnel

Items	Form	Advantage	Specimen	Read times
1	Strip/Cassette	Single test one by one for more than 25 kinds of drugs	Urine/Saliva	5-10 minutes
2	Dipstick, Panel	Multi - drug tests for 2-10 kinds of drugs tests in one kit	Urine/Saliva	5-10 minutes
3	Simple cup	Multi - drug tests for 2-15 kinds of drugs tests in one cup. Recognizing Urine adulteration	Urine/Saliva	5-10 minutes
4	Key Cup	Multi - drug tests for 2-15 kinds of drugs tests in one cup. Recognizing Urine adulteration Control the test time with the key	Urine	5-10 minutes

Tests Items



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Point of care fluorescent immunoassay analyzer

Model：FA-LF100B

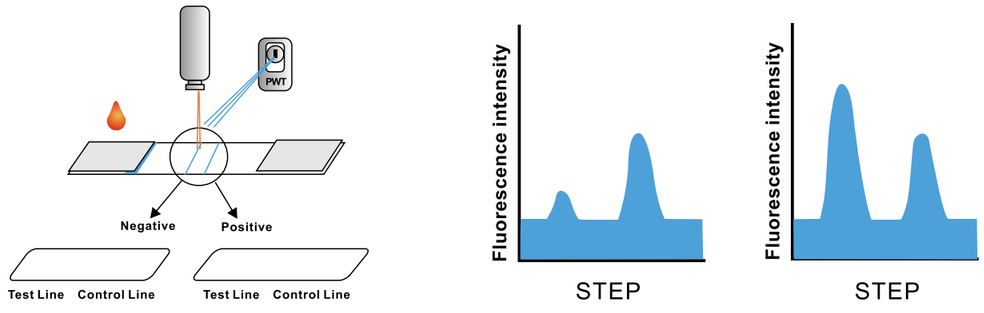
Methodology： Fluorescent Immunoassay

Product introduction

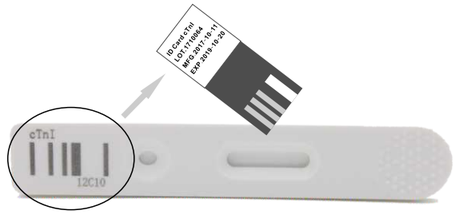
Point of care fluorescent immunoassay analyzer FA-LF100B is a fluorescent Immunoassaysystem. It includes single and multi-tests system providing accurate diagnostic results to your Labotory. Application and operation: One-step operation, the reagent loader automatically extends to receive reagent kit after starting up. User should insert the sample kit into the analyzer. The analyzer will identify the reagent and test automatically, then upload the test results to LIS system and printing test report. After testing, the test kits will pop up from the side. No need to carry out other operation.

Assay Principle

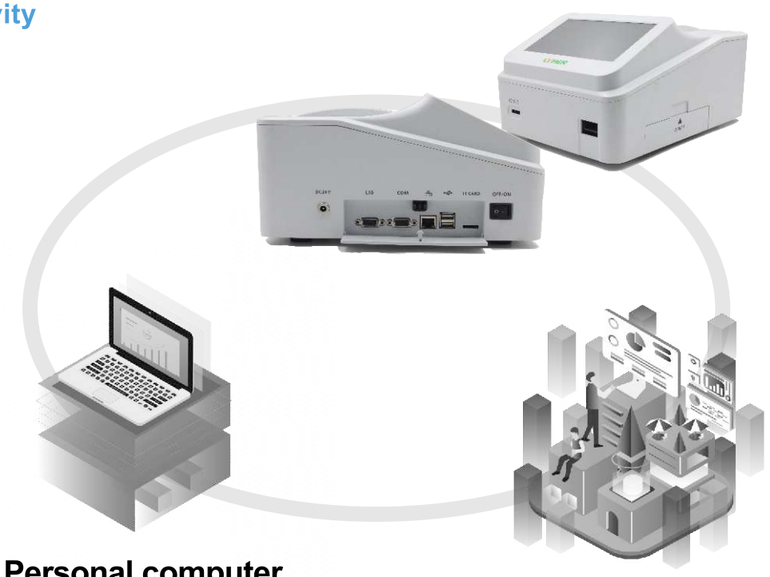
POC Fluorometer System



Device Matched with ID Card



Connectivity



Direct cable

- STANDARD F Analyzers connect With computer via the direct cable

LIS connectinity

- Conect to the majorty of existing Information systems

Technical Specification

- Software version: Version 1
- Operating system: Linux
- Light: LED or diode laser
- Port: a. USB *4
  b. Ethernet *1
  c. Double serial ports
  Port 1: LIS system self-uploading
  Port 2: connecting PC with deploying reagent
- Display: 24-color LCD
- Sample: whole blood, serum/plasma and urine
- Power: host input: DC 24V 3A
  Adapter input: 100-240VAC, 50-60Hz
- Standard curve:
  Storage: a standard 4K ID card, storing up to 10 curves
  Fitting: 4 standard methods (linear fitting, polynomial segmentation fitting, MMF growth model fitting and SPLINE cubic fitting)

Main features

- Repeatability: CV≤10%
- Stability: σ≤±8%
- Linear dependence: r≥0.97
- Accuracy: Δn≤±15%

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▶cTnI Troponin I Test Kit Fluorescence Immunochromatography

Product Feature

Rich specimen type: whole blood, serum, plasma
Short reading time: 12 mins
Wide linear range: 0.1~50ng/ml
Intra-batch difference: ≤10%
Inter-batch difference: ≤15%
Stable product performance: relative deviation≤10%
Specimen size: 75 μL serum/plasma, 150 μL whole blood
Simple operation

Interpretation of clinical results

Test Item	Test Result	Clinical Significance
cTnI	<0.3ng/ml	Normal levels and indicate no risk of myocardial infarction
	≥0.3ng/ml	indicate the patient is at risk for myocardial infarction

Clinical Application

- Diagnosis of perioperative cardiac complications
- Assess the area of myocardial ischemia injury
- Clinical efficacy evaluation of certain therapeutic agents
- Primary hypertension left ventricular hypertrophy, left ventricular function evaluation
- Early diagnosis of acute coronary syndrome , Postoperative Evaluation , risk stratification
- Gold standard for myocardial infarction

▶N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) Test Kit Fluorescence Immunochromatography

Product Feature

Rich specimen type: whole blood, serum, plasma
Short reading time: 12 mins
Wide linear range: 100-32000 Pg/mL
Intra assay variations: ≤10%
Inter assay variations: ≤15%
Stable product performance: relative deviation≤10%
Specimen size: 75 μL serum/plasma, 150 μL whole blood
Simple operation

Interpretation of clinical results

Test Item	Test Result	Clinical Significance
NT-proBNP	＜300 pg/ml	HF impossible. Further assess the noncardiogenic nature of dyspnea.
	Grey zone	HF possible. Perform appropriate triage and diagnosis consistent with clinical presentation.
	＜50 years old, ＞450 pg/ml	HF possible. Perform appropriate triage and diagnosis. if you have had HP and dry-NTproBNP＞25%.
	50-70 years old, ＞900 pg/ml	
	＞75 years old, ＞1800 pg/ml	
	＞10000 pg/ml	HF Impossibly and possibly serious. Close attention in hospital.

Clinical Application

- Early detection of heart failure (HF) in patients
- Treatment detection and prognosis evaluation of HF
- ACS risk stratification
- Complications of hypertension, coronary heart disease, coronary artery syndrome and other diseases
- Distinction of dyspnea cause by HF and other diseases
- Diagnosis and risk stratification of HF

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▶Diagnostic Kit for the Quantitative Determination of Tumor Marker

Application:

This product needs to be used with the dry fluorescence Immunoassay analyzer

model: FA-LF100B

produced by Hangzhou Laihe Biotech Co.,Ltd.

- Malignant tumor efficacy observation, prognosis and recurrence detection---CEA carcinoembryonic antigen test
- Screening and efficacy evaluation of primary liver cancer and embryonal tumor–AFP Alpha-fetoprotein
- Screening for prostate cancer, efficacy evaluation and recurrence detection--tPSA Prostate specific antigen

Feature: One step operation

Specifications

Item	Specimen	Test time	Test range	Intraassay variations (%CV)	Inter assay variations (%CV)	Cut-off
tPSA	Serum/Plasma	12min	0.5-100ng/ml	⩽10%	⩽10%	4.0ng/ml
CEA	Serum/Plasma	12min	3-500ng/ml	⩽10%	⩽10%	5.0ng/ml
AFP	Serum/Plasma	12min	5-350ng/ml	⩽10%	⩽10%	20ng/ml

▶Diagnostic Kit for the Quantitative Determination of Total IgE Fluorescence immunochromatography

Immunoglobulin E (IgE) is an antibody which is produced by the body's immune system in response to a perceived threat. It is one of the five classes of immunoglobulins (A, G, M, D, and E) and it normally present in the blood in very small amounts. This test measures the amount of IgE in the blood.

Immunoglobulin E is associated with allergic responses, including asthma, and to a lesser degree with immunity to parasites. With allergies, the body overreacts to one or more substances in the environment called allergens that do not typically cause a response in other people. Someone may develop an allergy when that person is exposed to an allergen, such as plant pollen, peanuts, eggs, strawberries, bee venom, and hundreds of other potential substances.Each time an allergic person is exposed to a specific allergen(s) after the initial exposure, IgE is rapidly produced, increasing to levels that trigger an allergic reaction. The severity of the reaction and symptoms associated with each episode can range from a localized reddening and itching of the skin, to respiratory distress, to vomiting and diarrhea, and in some cases to life-threatening anaphylaxis. Severity will vary from person to person, can vary from episode to episode, and may worsen over time.

Feature

1.Quantitative test
2.Read results in 12mins
3.Specimen: whole blood, serum plasma
4.One step operation

Application

allergic diseases, helminthiasis, eczema or non-eczema dermatitis,IgE Myeloma and other preliminary judgment.

Normal range

Age	New born	1-6months	7-12months	1-5years	6-9years	10-15years	≥16years
Upper limit	1.2IU/ml	7.2IU/ml	12.7IU/ml	60IU/ml	155IU/ml	199IU/ml	100IU/ml

Clinical Significance

- IgE Myeloma
- Bronchial asthma , allergic rhinitis , atopic dermatitis, allergic bronchopulmonary aspergillosis and other parasitic infection
- T cell Hyporesponsiveness, high IgE syndrome, wiskott-aldrich, DiGeroger syndrome,
- Selective IgA Deficiency (SIG AD), Severe complex immune dysfunction etc.
- Soft tissue eosinophilic granuloma, Hodgkig, Oxyhepatitis, liver cirrhosis, primary carcinoma of the liver, rheumatic arthritis, kawasaki disease, infantile diarrhea etc.
- Multiple myeloma Ataxia, telangiectasia
- Chronic Paranasal sinus and nasal cavity cancer, pulmonary sarcomatoid carcinoma,
- PSC, chronic lymphocytic leukaemia, CLL
- Silicosis, asbestosis

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▶ Procalcitonin (PCT) Test Kit
Fluorescence Immunochromatography

Product Feature

Rich specimen type: whole blood, serum, plasma
Short reading time: 12 mins
Wide linear range: 0.1-100 ng/mL
Intra assay variations: ≤10%
Inter assay variations: ≤15%
Stable product performance: relative deviation≤10%
Specimen size: 75 μL serum/plasma, 150 μL whole blood

Interpretation of clinical results

Test Item	Test Result	Clinical Significance
PCT	＜0.5 ng/ml	Predict no or mild systemic inflammatory response, possibly local inflammation or local infection.
	0.5-2.0 ng/ml	Predict moderate systemic inflammatory response, maybe infection or other conditions.
	2-10 ng/ml	Probably sepsis, inflammatory sepsis or septic shock. High risk of organ dysfunction.
	＞10 ng/ml	Almost severe bacterial sepsis or septic shock. Often accompanied by organ failure, high risk of death.

Clinical Application

- Indicator of systemic bacterial and viral infections
- Differential diagnosis and monitoring of radiotherapy, chemotherapy, autoimmune diseases and perioperative infection
- Auxiliary diagnosis and efficacy monitoring of septicemia and sepsis
- Auxiliary diagnosis and efficacy evaluation of other relavant diseases

▶ C-reactive protein (CRP) Test Kit
Fluorescence Immunochromatography

Product Feature

Rich specimen type: whole blood/serum/plasma
Short reading time: 3 mins
Wide linear range: 0.5-200 mg/L
Intra assay variations: ≤10%
Inter assay variations: ≤15%
Stable product performance: relative deviation≤10%
Specimen size: 5 μL
Simple operation
More widely used with combination of HsCRP and CRP

Interpretation of clinical results

Test Item	Test Result	Clinical Significance
CRP	＜10 mg/L	Indicate the possibility of other infections (bacterial or viral infection)
	10-20 mg/L	Suggest viral infection or mild bacterial infection
	20-50 mg/L	Suggest common bacterial infection
	＞50 mg/L	Suggest severe bacterial infection
hsCRP	＜1.0 mg/L	Cardiovascular risk assessment: low risk
	1.0-3.0 mg/L	Cardiovascular risk assessment: moderate risk, anti-inflammatory therapyt is recommended
	＞3.0 mg/L	Cardiovascular risk assessment: high risk, anti-inflammatory and anti-thrombotic therapy are recommended

Clinical Application

- Indicator of bacterial or viral infection (preferred indicator)
- Metabolic syndrome
- Guidance, observation and efficacy evaluation of antibiotic treatment
- Monitoring of connective tissue disease, cardiovascular and cerebrovascular diseases
- Monitoring of noncardiac perioperative infection
- Risk assessment and efficacy observation of cardiovascular and cerebrovascular diseases

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▶ High-sensitivity C-reactive protein (hs-CRP) Test Kit Fluorescence Immunochromatography

Product Feature

Rich specimen type: whole blood/serum/plasma
Short reading time: 1 min(high-sensitivity)
Wide linear range: 0.5-200 mg/L

▶ Serum amyloid A (SAA) and C-reactive protein (CRP) Test Kit (Fluorescence Immunochromatography

Product Feature

- Rich specimen type: whole blood/serum/plasma
- Short reading time: 1.5 min
- Wide linear range: CRP: 5-200 mg/L; SAA: 5-200 mg/L
- Specimen size: 5 μL
- Limit of detection: 5 mg/L
- Degree of precision: ±10%
- Degree of accuracy: ±10%

Clinical Application

- Indicator and diagnosis of bacterial or viral infection
- Guidance of antibiotic use for respiratory tract infection (RTI)
- Indicator and diagnosis of fever and abnorma WBC
- Guidance of treatment plan for children with colds or RTI
- Early detection of postoperative infection

▶ Dengue Combo Test （Dengue IgG/IgM + NS1 Test）

A dengue fever test is used to find out if you have been infected with the dengue virus. It is mostly used for people who have symptoms of illness and have recently traveled to an area where dengue infections are common.

Clinical Application

- Excellent diagnostic for the dengue infection in all stage
- High Accuracy
- Cover Dengue NS1 Ag, IgG and IgM
- Combo test to cover all stage and without limit of single test
- Specimen for whole blood, plasma and serum

Specifications

Code	Product	Format	Specimen	Result	Packing
IDE-402	Dengue Ns1 test	Device	Whole Blood/Serum/Plasma	15-20mins	25tests
IDE-403	Dengue IgG/IgM test	Device	WholeBlood/Serum/Plasma s	15-20mins	25tests
IDE-404	Dengue NS1+IgG/IgM test	Device	WholeBlood/Serum/Plasma s	15-20mins	20tests

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Products Catalogue

InfectiousDiseaseLateralFlowAssayTest

Code	Products	Format	Specimen	Certification
303002	NovelCoronavirusIgG/IgMAntibodyTest Kit(ColloidalGold)	Device	WholeBlood/Serum/Plasma	FDAEUA/CE/FSC
303035	NovelCoronavirus(COVID-19)AntigenTestKit(ColloidalGold）	Device	Oropharyngeal/NasopharyngealSwab	CE/FSC
303050	COVID-19andInfluenzaABantigenttestkit	Device	Oropharyngeal/NasopharyngealSwab	CE/FSC
IFL402	InfluenzaA/Btest	Device	Oropharyngeal/NasopharyngealSwab	CE/FSC
IDE-402	DengueNS1test	Device	WholeBlood/Serum/Plasma	CE/FSC
IDE-403	DengueIgG/IgMtest	Device	WholeBlood/Serum/Plasma	CE/FSC
IDE-404	DengueIgG/IgM+NS1test	Device	WholeBlood/Serum/Plasma	CE/FSC

UrineandSalivaLateralFlowAssayTest

Code	Products	Format	Specimen	Certification
DAM-101	AMPAmphetamineTest	Strip/Device	Urine/Saliva	CE/FSC
DKE-101	KETKetamineTest	Strip/Device	Urine/Saliva	CE/FSC/CFDA
DMO-101	MOPMorphineTest	Strip/Device	Urine/Saliva	CE/FSC/CFDA
BAR-101	BARBarbituratesTest	Strip/Device	Urine/Saliva	CE/FSC
BUP-101	BUPBuprenorphine Test	Strip/Device	Urine/Saliva	CE/FSC
DBZ-101	BZOBenzodiazepinesTest	Strip/Device	Urine/Saliva	CE/FSC
DCO-101	COCCocaineTest	Strip/Device	Urine/Saliva	CE/FSC
DCT-101	COTCotinineTest	Strip/Device	Urine/Saliva	CE/FSC
DMD-101	MDMAEcstasyTest	Strip/Device	Urine/Saliva	CE/FSC
DME-Z101	METUltraMethamphetamine	Strip/Device	Urine/Saliva	CE/FSC/CFDA
DTH-101	THCMarijuanaTest	Strip/Device	Urine/Saliva	CE/FSC
DMT-101	MTDMethadoneTest	Strip/Device	Urine/Saliva	CE/FSC
DOP-101	OPIOpiateTest	Strip/Device	Urine/Saliva	CE/FSC
DPC-101	PCPPhencyclidineTest	Strip/Device	Urine/Saliva	CE/FSC
FEN101	FENfentanylTest	Strip/Device	Urine/Saliva	CE/FSC
OXY101	OXYOxycodonetest	Strip/Device	Urine/Saliva	CE/FSC
K2-101	SyntheticcannabinesTest	Strip	Urine/Saliva	CE/FSC
EDDP	ethylenediamine-dimethylphosphinic acidTest	Strip	Urine/Saliva	CE/FSC
MTC-101	methcathinoneTest	Strip	Urine/Saliva	CE/FSC
DOA10X	Multi-Drugstest	Panel	Urine/Saliva	CE/FSC
DOA20X	Multi-Drugstest	Cup	Urine/Saliva	CE/FSC
DOA30X	Multi-Drugstest	Device	Urine/Saliva	CE/FSC

FALF100CQuantitativeHairdrugtraceanalyzerandtests

Code	Products	Format	Specimen	Certification
FALF100C	Hairdrugtraceanalyzer	Analyzer	/	CE/FSC
HMO-101	MOPMorphineTest	Device	Hair	CE/FSC
HME-102	METMethamphetamineTest	Device	Hair	CE/FSC
HKE-103	KETKetaminetest	Device	Hair	CE/FSC
HCO-105	COCCocainetest	Device	Hair	CE/FSC
MDMA-106	MDMAEcstasytest	Device	Hair	CE/FSC
HDOA-407	MET/MOPtest	Device	Hair	CE/FSC
HDOA-408	MET/KETtest	Device	Hair	CE/FSC
HDOA-408	MET/MOP/KETtest	Device	Hair	CE/FSC
HOXY-409	OXYOxycodonetest	Device	Hair	CE/FSC
HBZO-410	BenzodiazepinesTest	Device	Hair	CE/FSC
HPCP-411	PCPPhencyclidineTest	Device	Hair	CE/FSC

FALF100DHand-HeldUrine/Salivadrugtestreaderand Device

Code	Products	Format	Specimen	Certification
FALF100D	Hand-Helddrugtestreader	Analyzer	/	CE/FSC

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HHRS-1001	Saliva3in1Drugstest	Device	Saliva	CE/FSC
HHRU-1002	Urine6in1drugstest	Device	Urine	CE/FSC

FALF100BPointofcareImmunoassayanalyzerandtestdevice

Code	Products	Format	Specimen	Certification
FALF100B	PointofcareImmuno assayanalyzer	Analyzer	/	CE/FSC/CFDA
CTI-Z40X	TroponinItest	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA
CMY-Z40X	Myoglobintest	Device	WholeBlood/Ser um/Plasma	CE/FSC
CCK-Z40X	CK-MBtest	Device	WholeBlood/Ser um/Plasma	CE/FSC
CMA-Z435	Myoglobin/CK-MB/cTnICombotest kit	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA
QCR-101	CRP/HSCRPC-reactionproteintest	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA
QCS-101	HSCRP+SAAComb otest	Device	WholeBlood/Ser um/Plasma	CE/FSC
QNT-104	NT-ProBNPN-terminalpro-BrainNatriureticPept ide	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA
QPC-102	PCTProcalcitonin	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA
IGE107	TotalIgEImmunoglo bulinEtest	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA

Cardiacmarkeronesteprapidtest

Code	Products	Format	Specimen	Certification
TI-Z40X	TroponinItest	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA
CMY-Z40X	Myoglobintest	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA
CCK-Z40X	CK-MBtest	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA
CMA-Z435	Myoglobin/CK-MB/cTnICombotest	Device	WholeBlood/Ser um/Plasma	CE/FSC/CFDA

FALF600CHand-HeldQuantitativeHairdrugtraceanalyzerandtests

Code	Products	Format	Specimen	Certification
FALF600C	Hand-HeldHairdrugtracea nalyzer	Analyzer	/	CE/FSC
HMO-1011	MOPMorphineTest	Device	Hair	CE/FSC
HME-1022	METMethampheta mineTest	Device	Hair	CE/FSC
HKE-1033	KETKetaminetest	Device	Hair	CE/FSC
HCO-1054	COCCocainetest	Device	Hair	CE/FSC
MDMA-1065	MDMAEcstasytest	Device	Hair	CE/FSC
HDOA-4076	MET/MOPtest	Device	Hair	CE/FSC
HDOA-4087	MET/KETtest	Device	Hair	CE/FSC
HDOA-4088	MET/MOP/KETtest	Device	Hair	CE/FSC
HOXY-4099	OXYOxycodonetest	Device	Hair	CE/FSC
HBZO-4100	BenzodiazepinesTe st	Device	Hair	CE/FSC
HPCP-4117	PCPPhencyclidineT est	Device	Hair	CE/FSC

FertilityLateralFlowAssaytest

Code	Products	Format	Specimen	Certification
FHC-101	HCGPregnancytest	Strip/Midstream/ device	Urine	CE/FSC
DHCG-102	Digitalpregnancytes t	Digitalmidstrea m	Urine	CE/FSC
FLH-10X	Ovulationtest	Strip	Urine	CE/FSC
FFS-10X	FSHMenopausetest	Strip	Urine	CE/FSC