



SemiQ®

SemiQ, Help you



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Fluorescent Immunology Product Brochure

Jinan Chuangxingwell Biotech Co., Ltd.



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- **Coagulation Marker:** D-Dimer
- **Renal Injury Marker:** MAU
- **Diabetes Marker:** HbA1c
- **Tumor Markers:** AFP, PSA

Fluorescent Immunoanalyzer

CX-RDTD19H



CX-HD19H



Fluorescent Assay Product



CX-RDTD20



Automatic immunofluorescence detection system is based on the principle of photoelectricity detection, which needs to be used with special fluorescent immune reagent. It is widely used in disease detection, medical care, epidemic monitoring, food inspection, quarantine and other fields. Apply to various kinds of medium and small medical institutions and rescue centers.

- | | | | | |
|---|---------------|----------------|---|-------------------------------|
| 1 | Easy to Carry | Characteristic | 4 | Ultra-Sensitive |
| 2 | Easy to Use | | 5 | Ultra-Stable |
| 3 | 3-15 Minutes | | 6 | Fluorescent immunoassay (FIA) |

CHUANGXINGWELL APPLICATION SCENARIO



Hospital

Laboratory

Private Doctor

Pharmacy Test

Pet Hospital

CX-RDTD19H

- Dimension: 270*238*146mm
- Weight: 2.8 Kg

Connection

- Direct connection to LIS/HIS

ID chip inlet

- Automatically reading of batch number and calibration information in the ID chip



Built-in Thermal Printer

- Real-time auto-printing
- Support for external printers

Large Display

- 7" LCD Touch Screen
- Intuitive user interface

Test Channel

- Multiple testing modes available
- Unique quick mode for large number of samples

CX-HD19H

- Dimension: 255mm*100mm*60mm
- Weight: 0.78 Kg

on/off switch

- Control equipment switches

ID chip inlet

- Automatically reading of batch number and calibration information in the ID chip



Built-in Thermal Printer

- Real-time auto-printing
- Support for external printers

Large Display

- 5" LCD Touch Screen
- Intuitive user interface

Test Channel

- Multiple testing modes available
- Unique quick mode for large number of samples

Specification

Item	Specification
Testing Principle	Fluorescence immunoassay
Testing channel	Single-channeled
Testing speed	Time for one Test < 10 s
Sample type	Unlimited (Serum, plasma, whole blood, urine, etc.)
Test project code	Maximum 255 test projects
Number of tests per card	Multiple items in one card (up to 5 test lines)
Screen size	7-inch touch screen
Operating system	Linux
Data Storage	Unlimited
Data transmission	USB, LIS transmission
Language	Chinese, English (customizable)
Printer	Built-in thermal printer / External Printer
Barcode scanning	Barcode, QR code
Adapted card type	ID card
Instrument size	215mm*302mm*1550mm
Net weight	3kg

Specification

Item	Specification
Testing Principle	Fluorescence immunoassay
Testing channel	Single-channeled
Testing speed	Time for one Test < 10s
Sample type	Unlimited (Serum, plasma, whole blood, urine, etc.)
Test project code	Maximum 255 test projects
Number of tests per card	Multiple items in one card (up to 5 test lines)
Screen size	5-inch touch screen
Operating system	Linux
Data Storage	Unlimited
Data transmission	USB / 4G transmission
Language	Chinese, English (customizable)
Printer	Built-in thermal printer
Barcode scanning	Barcode, QR code
Adapted card type	ID card
Instrument size	255mm*100mm*60mm
Net weight	0.78kg



Fluorescent Assay Catalog

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Cat. No.	Category	Test Item	Diseases	Specimen Type	Specimen Volume	Reaction Time	Measuring Range	Qualification
CX-CFRMA-61	COVID-19	COVID-19/FLUA/B/RSV/ADV /MPCCombo Rapid Test Kit	COVID-19	Fingerstick or Venous	20µL	15 mins	Quantitative	CE
CX-HbA1c	Blood	HbA1c	Diabetes Mellitus	WB/ S/P	10 µL	15 mins	Qualitative	
CXFIA-INS		INS	Insulin	WB	10 µL	10 mins	Qualitative	CE
CXFIA-VD	Bone Metabolism	25-OH-VD	Bone Metabolism	S/P	75 µL	15 mins	Qualitative	CE
CX-ALCU	Breast milk alcohol + drugs	Breast Milk Alcohol	Breast Milk Alcohol	Milk			5~100 ng/mL	CE
CX-MultiM-21		Drugs of Abuse+Alcohol	Alcohol	Milk		5 mins	4.0~14.5%	CE
CX-ALCU		Alcohol	Breast Milk	Saliva &Urine			5~300 mg/L	CE
CX-MALB	Kidney Function Markers	MALB	Urine microalbumin	Urine	75 µL	3 mins	0.2~10 mg/L	CE
CXFIA-Cys-C		CysC	Cystatin C	S/P/WB	10 µL	5 mins	10~1500 ng/mL	CE
CX-NGAL-01		NGAL	Kidney	Urine	75 µL	15 mins	0.3~20 mg/L	CE
CXFIA-TT3-01	Thyroid Function	TT3	Thyroid Malfunction	S/P/WB	75 µL	15 mins	0.61~9.22 nmol/L	CE
CXFIA-TT4-01		TT4	Thyroid Malfunction	S/P/WB	75 µL	15 mins	12.87~300 nmol/L	CE
CXFIA-TSH-01		TSH	Thyroid Malfunction	S/P/WB	75 µL	15 mins	0.1~100 mIU/L	CE
CXFIA-FT3-01		ft3	Thyroid Malfunction	S/P/WB	75 µL	15 mins	0.40~50.00 pmol/L or 0.26~32.55 pg/mL	
CXFIA-FT4-01		ft4	Thyroid Malfunction	S/P/WB	75 µL	15 mins	1.00~100 pmol/L or 0.078~7.77 ng/dL	
CX-HCGU-01	Sex Hormone Markers	β-HCG	Fertility	S/P/WB	20 µL	15 mins	2~200,000 mIU/mL	CE
CX-LHU-01		LH	Fertility	S/P/WB	75 µL	15 mins	1~100 mIU/mL	CE
CX-FSHU-01		FSH	Fertility	S/P/WB	75 µL	15 mins	1~100 mIU/mL	CE
CX-PROG-01		Prog	Fertility	S/P/WB	75 µL	15 mins	1.5~60 ng/mL	CE
CX-FFN-01		ffN	Fertility	S/P/WB	75 µL	15 mins	1~200 ng/mL	CE
CXFIA-E2-01		E2	Fertility	S/P/WB	75 µL	15 mins	9~3000 pg/mL	CE
CX-SP10-01		SP-10	Fertility	S/P/WB	75 µL	15 mins	0.2~15 ng/mL	CE
CX-AMH-01		AMH	Fertility	S/P/WB	75 µL	15 mins	0.1~16 ng/mL	CE
CXFIA-NBNP-01		NT-proBNP	Heart Failure	S/P/WB	75 µL	15 mins	18~35000 pg/mL	CE
CXFIA-FABP-01		H-FABP	Myocardial Infarction	S/P/WB	75 µL	15 mins	0.1~50 ng/mL	CE
CXFIA-MCC-31	3 in 1 (cTn I/Myo/CK-MB)	Myocardial Infarction	S/P/WB	75 µL	15 mins	2.0~400 ng/mL	CE	
CXFIA-D-Dimer01	D-Dimer	Myocardial Infarction	S/P/WB	75 µL	15 mins	0.3~100 ng/mL	CE	
CX-COTU-01	COT	Cotinine	S/P/WB	75 µL	3-5 mins	1~120 ng/mL	CE	
CX-ETGU-01	ETG	Ethyl Glucuronide	S/P/WB	75 µL	3-5 mins	Same with	CE	
CX-THCU-01	THC	Marijuana	S/P/WB	75 µL	3-5 mins	single items	CE	
CX-FYLU-01	Drugs of Abuse	FYL	Fentanyl	P/WB	15 µL for whole blood	3-5 mins	0.1~10 mg/L	CE
CX-BZOU-01		BZO	Benzodiazepines	S/P/WB	75 µL	3-5 mins	Same with single items	CE
CX-MultiS-N01		Multi-Drug	Multi-Drug	Urine	75 µL	3-5 mins		CE
CX-MultiS-N01		Multi-Drug	Multi-Drug	Saliva	75 µL	3-5 mins		CE

Cat. No.	Category	Test Item	Diseases	Specimen Type	Specimen Volume	Reaction Time	Measuring Range	Qualification
CX-CTG-31	Gynecology	3 in 1	Candida albicans+Trichomonas vaginalis+Gardnerella vaginalis		75 µL	15 mins		CE
CX-GV-01		Vaginitis	Vaginitis		75 µL	15 mins		CE
CXFIA-PGI/PGII-21	Gastrointestina	PGI/PGII	Pepsinogen I/Pepsinogen II	S/P/WB	75 µL	15 mins	0.05~10 ng/mL	CE
CX-RAN-31		3 in 1 (ROTA-ADENO-NORO)	Rotavirus /Adenovirus/ Norovirus	P/WB	100 µL for whole blood 75 µL for plasma/serum	15 mins	0.1~10 mg/L	CE
CX-PCT-01		PCT	Procalcitonin	S/P/WB	75 µL for whole blood 50 µL for plasma/serum	15 mins	0.1~100 ng/mL	CE
CX-CALP-01		CALP	Infection	S/P/WB	8.5 µL for whole blood 5 µL for plasma/serum	15 mins	0.5~200 mg/L	CE
CX-C/S-21	Inflammation Markers	2 in 1 (CRP+SAA)	Cancer	S/P/WB	75 µL	15 mins	CRP:0.5~150 mg/L PCT:0.1~100 ng/mL	CE
CXFIA-HB-01		HBP	Infection	8.5 µL for whole blood 5 µL for plasma/serum	75 µL	15 mins	1 ~ 500 mg/L	CE
CXFIA-IL6-01		IL-6	Infection	S/P/WB	75 µL	15 mins	3~4000 pg/mL	CE
CXFIA-AFP-01		AFP	Infection	S/P/WB	75 µL	15 mins	5~400 ng/mL	CE
CX-TRF-01	Tumor Markers	TRF	Liver Cancer	S/P/WB	75 µL	15 mins	2~100 ng/mL	
CXFIA-CEA-01		CEA	Prostate Cancer	S/P/WB	75 µL	15 mins	1~500 ng/mL	CE
CX-FT-21/22		FOB/TRF	Gastrointestinal bleeding	Feces	stick to sample at 6	15 mins	25~1000 ng/mL	
CX-StrepA-01		Strep A	Infectious disease			15 mins		
CX-Dengue-01		Dengue NS1 Ag	Infectious disease	S/P/WB	75 µL	12 mins	Qualitative	
CX-TP-01	Infections Disease	TP	Infectious disease	Feces	6 different parts of the feces	10 mins	Qualitative	
CX-TB-01		TB	Allergic diseases	S/P/WB	75 µL	10 mins	1~1000 IU/mL	
CX-STP-21		S.typhi+S.paratyphi	Cortisol disorders	S/P/WB	75 µL	15 mins	50~1000 nmol/L	
CX-HP-01		HP	Iron metabolism	S/P/WB	75 µL	10 mins	5 ~ 1000 ng/mL	
CXFIA-FVF-31	Anaemia	FA+VB12+Ferr	Rheumatic fever and glomerulonephritis	S/P/WB	10 µL	15 mins	20~1000 IU/mL	CE
CX-LAC-01	other	Lactose Intolerance	Rheumatoid Arthritis	S/P/WB	10 µL	15 mins	10 ~ 650 IU/mL	CE
CX-CCP-01		Anti-CCP	Rheumatoid Arthritis	S/P/WB	10 µL	10 mins	3.5-300 U/mL	CE

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 Website: www.icxbio.com

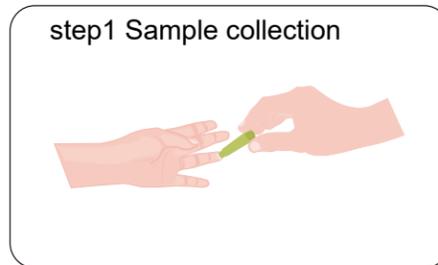




Test Procedure

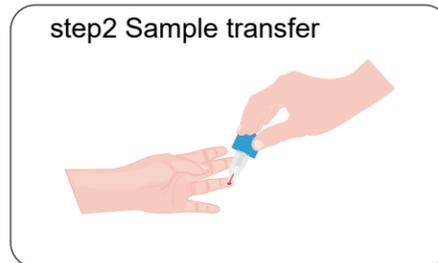
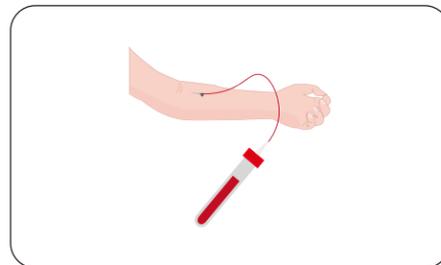
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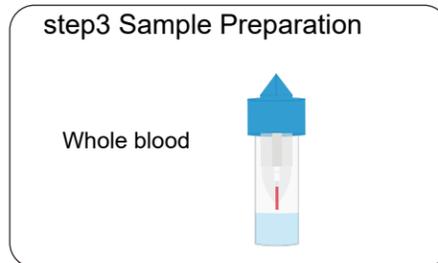
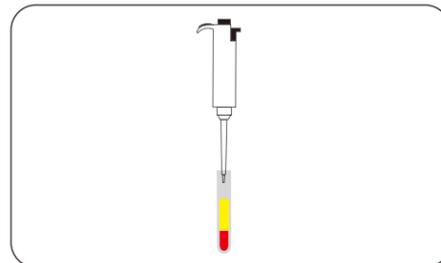
step1 Sample collection

or



step2 Sample transfer

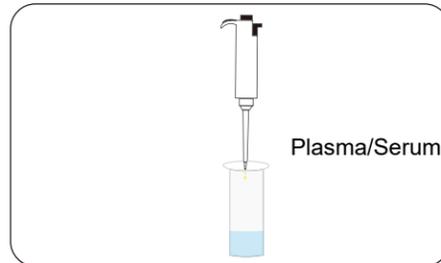
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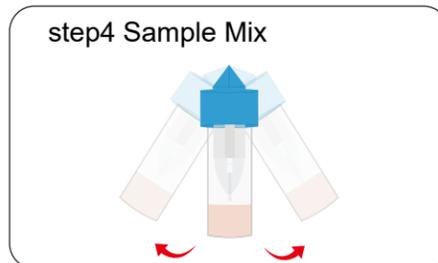
step3 Sample Preparation

Whole blood

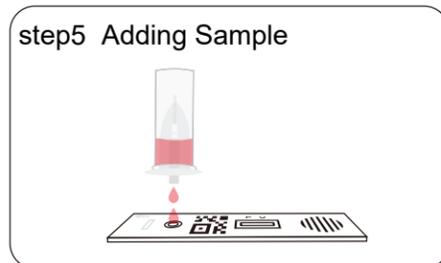
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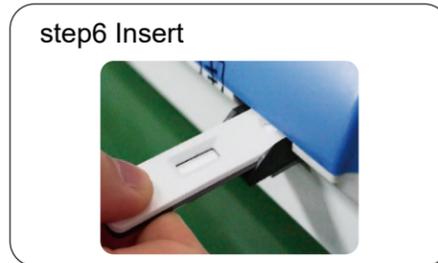
Plasma/Serum



step4 Sample Mix



step5 Adding Sample



step6 Insert



step7 Read



step8 Drop



step9 Print results



CRP (C-reactive Protein) Rapid Quantitative Test

CRP

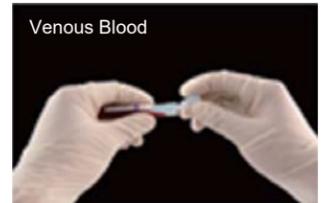
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CRP is a protein found in the blood, the rise of CRP levels response to inflammation. Combination of CRP and blood routine test increases diagnosis accuracy.

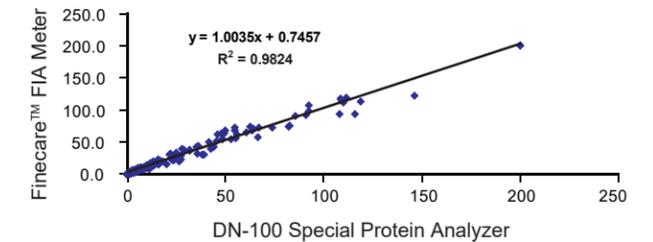
Characteristic:

- Rapid (Reaction time = 3min. TAT≤10min)
- Fluorescence signaling, higher sensitivity and specificity
- Whole range (hsCRP+CRP)
- Both venous blood and capillary blood are applicable
- CRP control

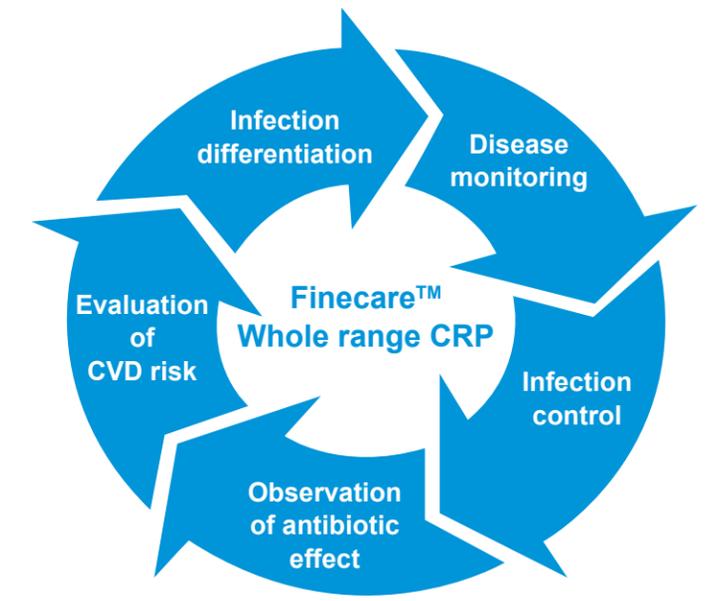
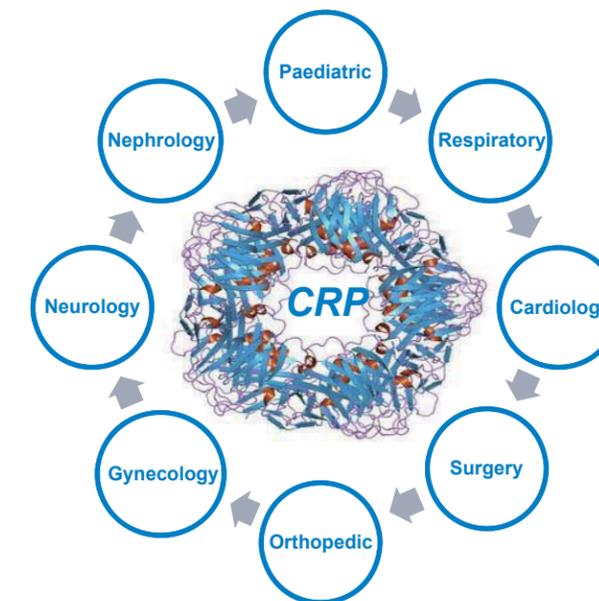


Performance:

Reaction time	3 minutes
Test time	10 seconds
Linear range	0.5 – 200 mg/L
Reference value	hsCRP < 1.0, CRP < 10



Application:

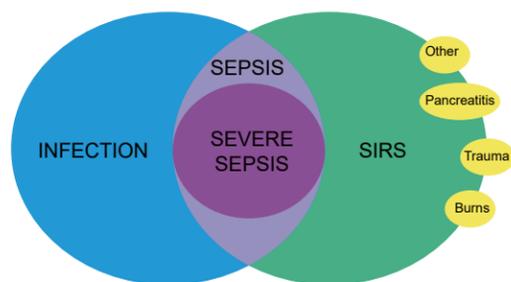




PCT is a peptide precursor of the hormone calcitonin. Measurement of PCT can be used as a marker of severe sepsis caused by bacteria and generally grades well with the degree of sepsis.

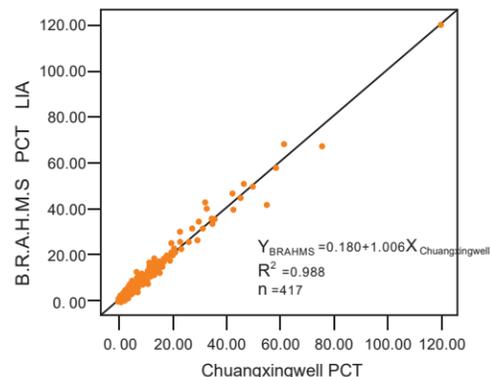
Characteristic:

- Rapid (Reaction time =15min)
- Fluorescence signaling, higher sensitivity and specificity
- Preferred indicator of bacterial infection and sepsis
- PCT control

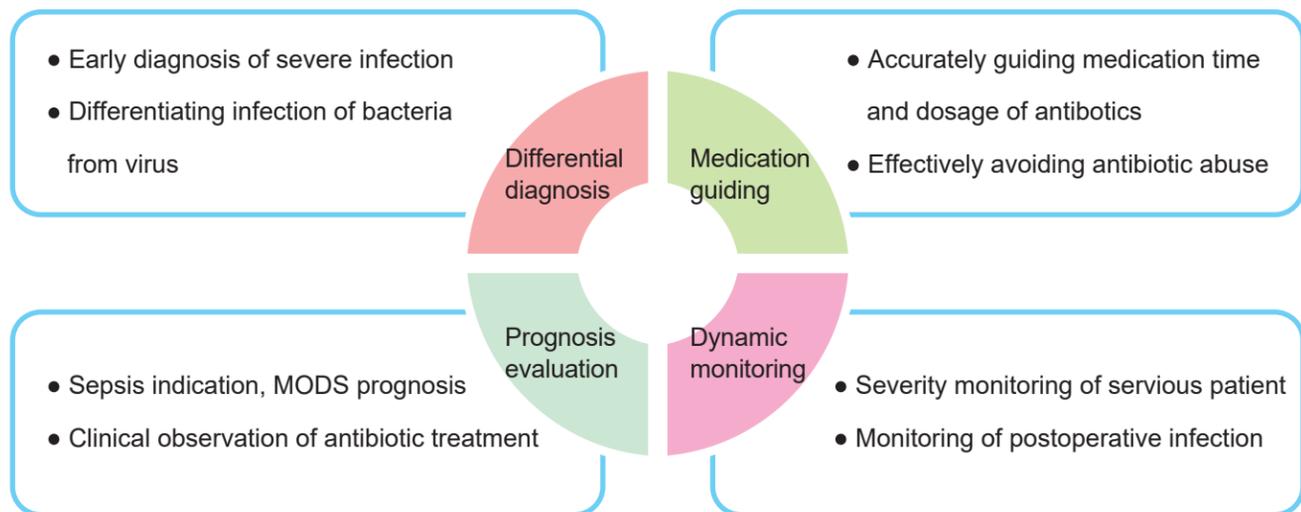


Performance:

Reaction time	15 minutes
Test time	10 seconds
Linear range	0.1 – 100ng/mL
Specimen type	Whole blood/Serum/Plasma
Precision	CV≤15%



Application:



Application mainly in Emergency, ICU, Pediatric, Respiratory, Surgical department etc.



Cardiac markers are used in the diagnosis and risk stratification of patients with chest pain, suspected acute coronary syndrome (ACS) and heart failure (HF). In Chuangxingwell cardiac markers platforms, whole blood/serum/plasma tests can quantitatively detect multiple analytes on immunofluorescence meter, the detection sensitivity is up to pg/ml level.

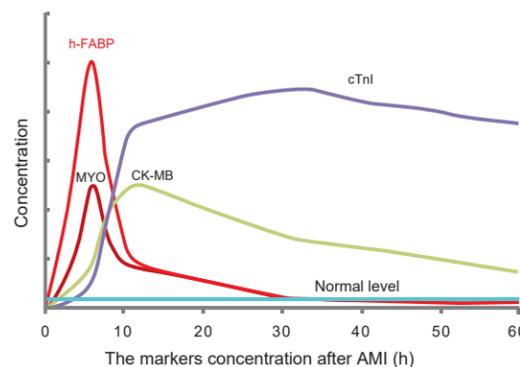
Clinical application:

Disease	Test item
HF	NT-proBNP
ACS	cTnI, Myo, CK-MB
Chest pain	H-FABP, cTnI, Myo, CK-MB, hsCRP
Dyspnea	D-Dimer, NT-proBNP, H-FABP, cTnI, Myo, CK-MB, hsCRP

Performance:

Reaction time	15 minutes
Test time	10 seconds
Linear range	0.01 – 300ng/mL
Specimen type	Whole blood/Serum/Plasma
Precision	CV≤15%

Signification of combine diagnosis:



Diagnosis suggestion of myocardial injury markers

- <2h H-FABP+Myo
- 2-6h H-FABP+Myo+cTnI+CK-MB
- 4-8h cTnI+CK-MB
- >8h cTnI

- Early diagnosis of AMI
- Prognosis of ACS risk assessment and stratification
- Myocardial infarct size estimates

- ACS early judgment
- Detect myocardial damage degree after surgery
- Indicator after AMI thrombolytic and treatment

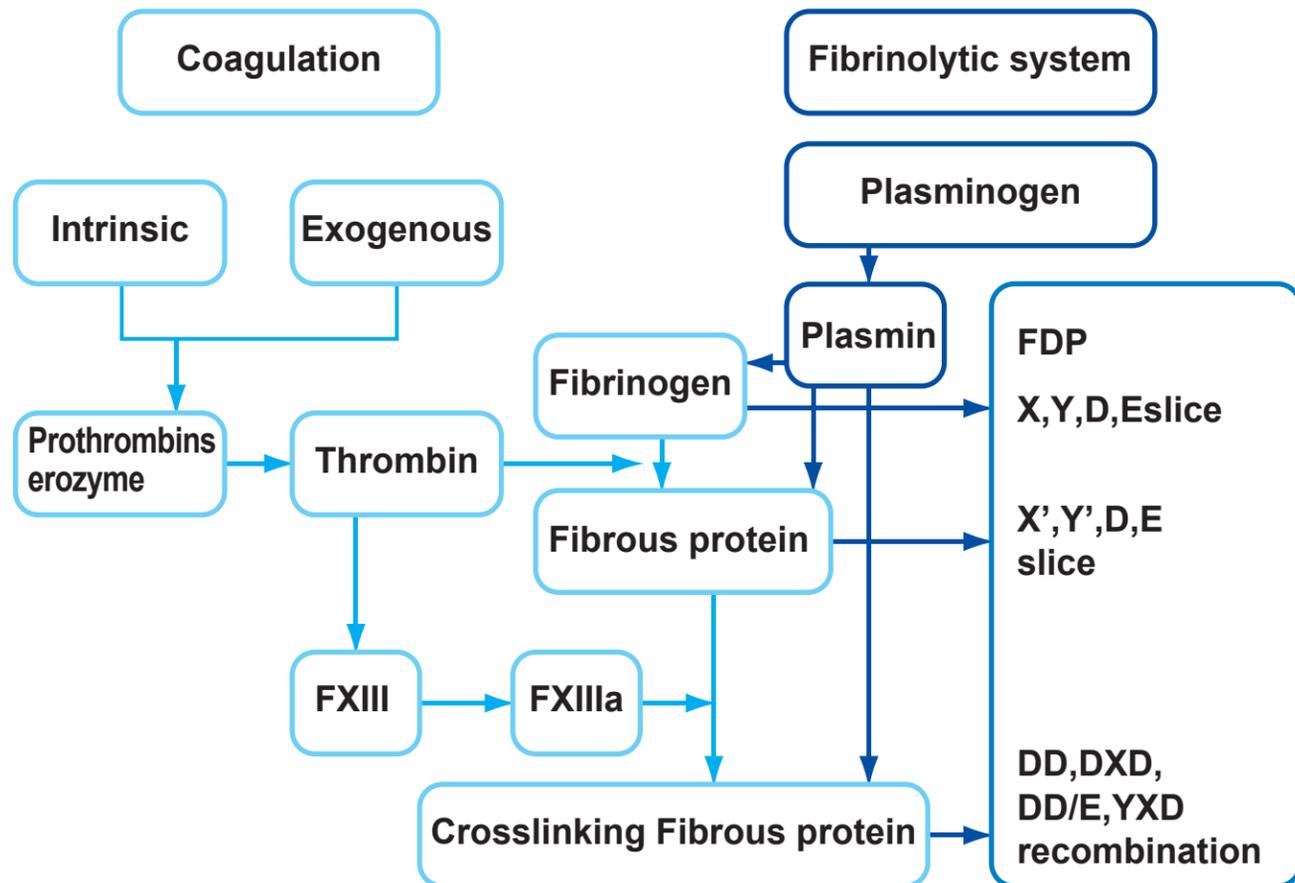


D-Dimer is a fibrin degradation product, a small protein fragment present in the blood after a blood-clot is degraded by fibrinolysis. In early diagnosis of diseases (chest pain, dizziness, dyspnea such as pulmonary embolism, myocardial infarction and cerebral infarction), D-Dimer can improve efficiency and optimize process diagnosis.

Characteristic:

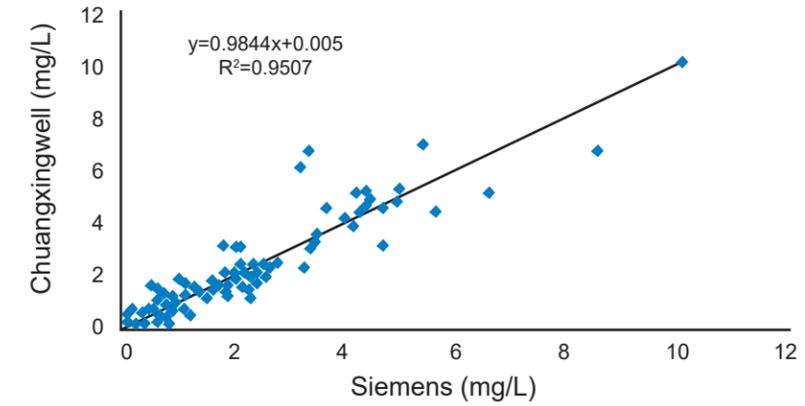
- Rapid (Reaction time = 3min)
- Quantitative detection
- High accuracy and sensitivity
- Convenient and simple operation

Mechanism of D-Dimer:



Performance:

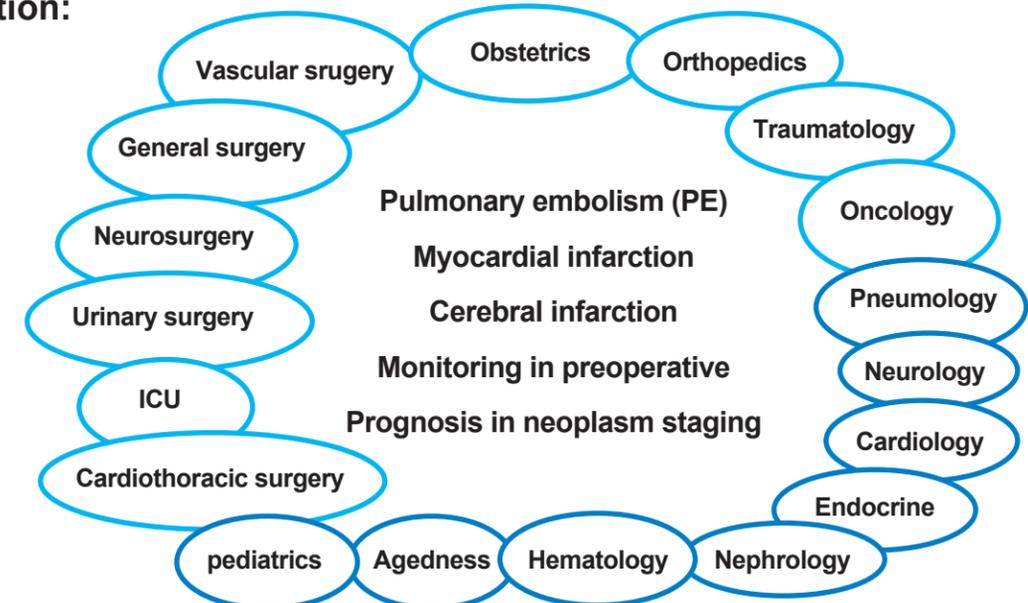
D-Dimer comparison test of whole blood specimen between Chuangxingwell and Siemens



Compared with 356 test results of D-Dimer specimens conducted by Siemens, Chuangxingwell CX-RDTD19H has high accuracy in D-Dimer test (5-35 na/ml), the correlation $R^2=0.951$, positive coincidence rates 96.3%, negative coincidence rate is 88.4%, total coincidence rate is 92.8%, which can satisfy the clinical requirement.

Linear range	0.1~10mg/L
Reference value	<0.5mg/L
Reaction time	3min
Plasma	18uL
Whole blood	15uL

Application:

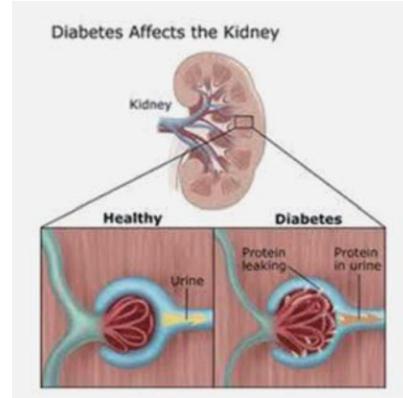




MAU (Urine albumin) occurs when the kidney leaks small amounts of albumin into the urine, when there is an abnormally high permeability for albumin in the renal glomerulus. In a properly functioning body, albumin is not normally present in urine because it is retained in the blood stream by the kidneys.

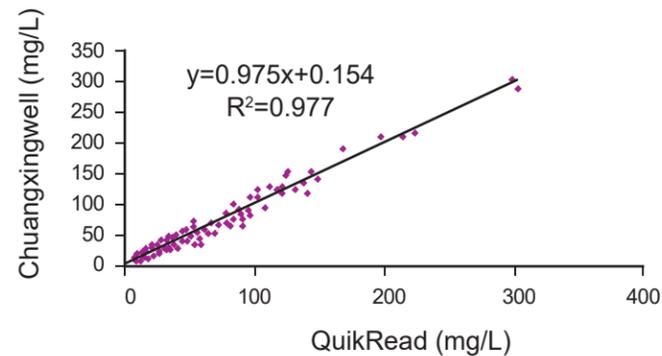
Characteristic:

- Rapid (Test time =10min)
- Fluorescence signaling, higher sensitivity and specificity
- Most sensitive and reliable indicator of Nephropathy
- MAU control

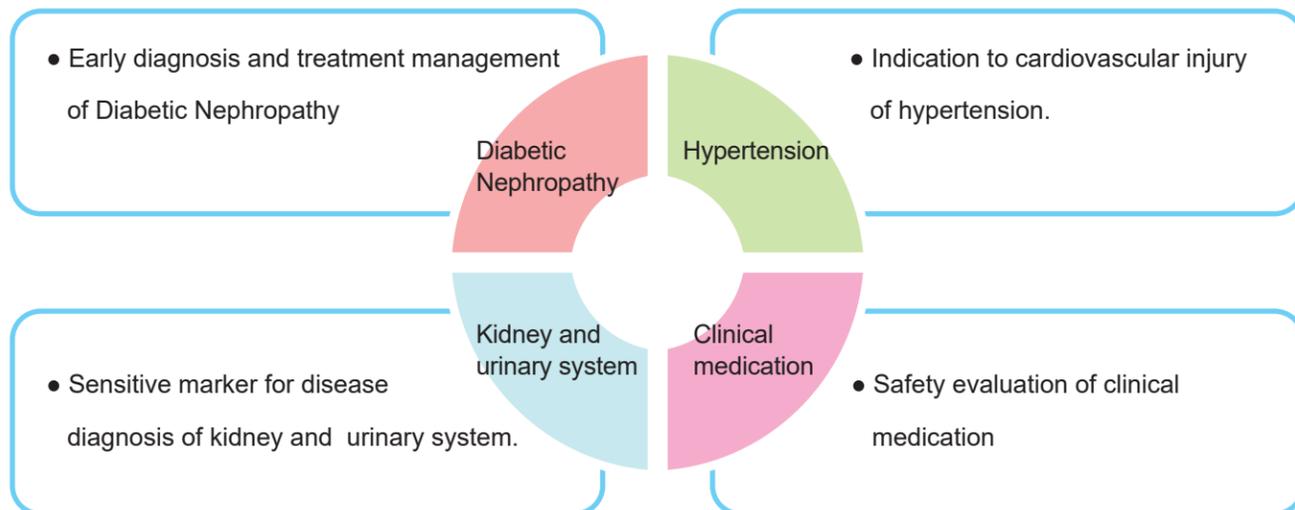


Performance:

Reaction time	10 minutes
Specimen volume	10 uL
Linear range	5 – 300mg/L
Specimen	Urine
Precision	CV≤15%



Application:



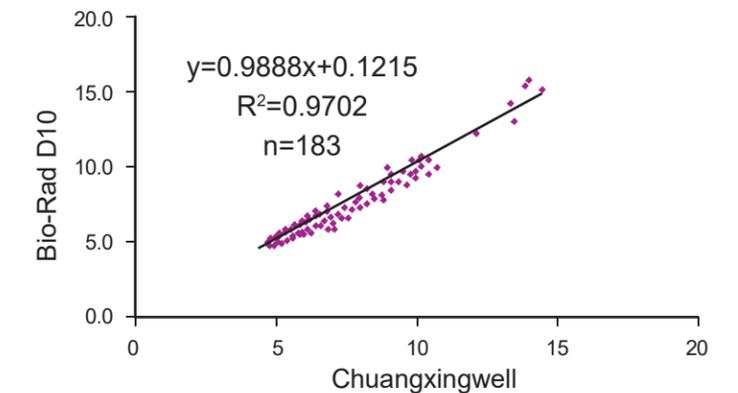
HbA1c is the product of the hemoglobin combining with blood glucose in red blood cells, which can reflect the average blood glucose level 2 ~ 3 months prior to the measurement. HbA1c is the "gold standard" of evaluation for long-term blood glucose control. Chuangxingwell HbA1c Rapid Quantitative Test applying sandwich fluorescence immunoassay technology can achieve high sensitivity and specificity.

Characteristic:

- Simpler: Immunofluorescence technology—rapid and convenient operation procedure
- Higher sensitive: Fluorescence signaling cascade enhancement technology—accurate detection for low concentration of analyte.
- More accurate: IQC/EQC- double quality control technology—Minimizing system/random errors
- Better time fault tolerance—no remarkable difference in 5-30min test results

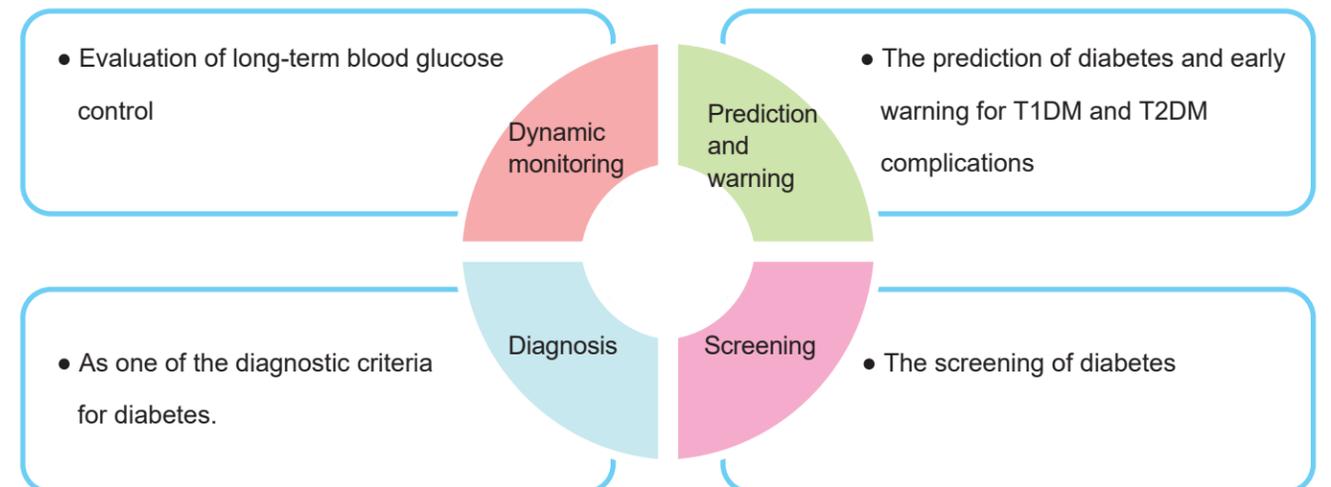
Performance:

Performance	Technical Specifications
Reaction time	5 minutes
Test time	10 seconds
Linear range	4.5 ~ 14.5%
Cutoff value	6%
Precision	CV<10%



Compared with 183 test results of HbA1c specimens (whole blood conducted by Bio-Rad D10 automatic analyzer, Chuangxingwell CX-RDTD19H has high accuracy in HbA1c test (4.5~14.5%), the correlation $R^2 > 0.97$, which can satisfy the clinical requirement.

Application:





AFP (Alpha Fetal Protein) Rapid Quantitative Test

AFP

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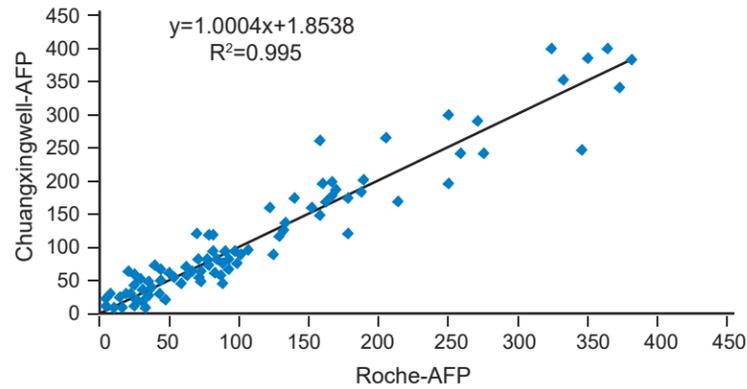
AFP is a glycoprotein, mainly coming from embryo liver cells. AFP is the most sensitive and specific indicator for primary liver cancer diagnosis. Chuangxingwell AFP Rapid Quantitative Test applying sandwich fluorescence immunoassay technology can achieve high sensitivity and specificity.

Characteristic:

- Accurate quantification
- Rapid test, result in 15 minutes
- The most sensitive and specific indicator for primary liver cancer
- AFP control

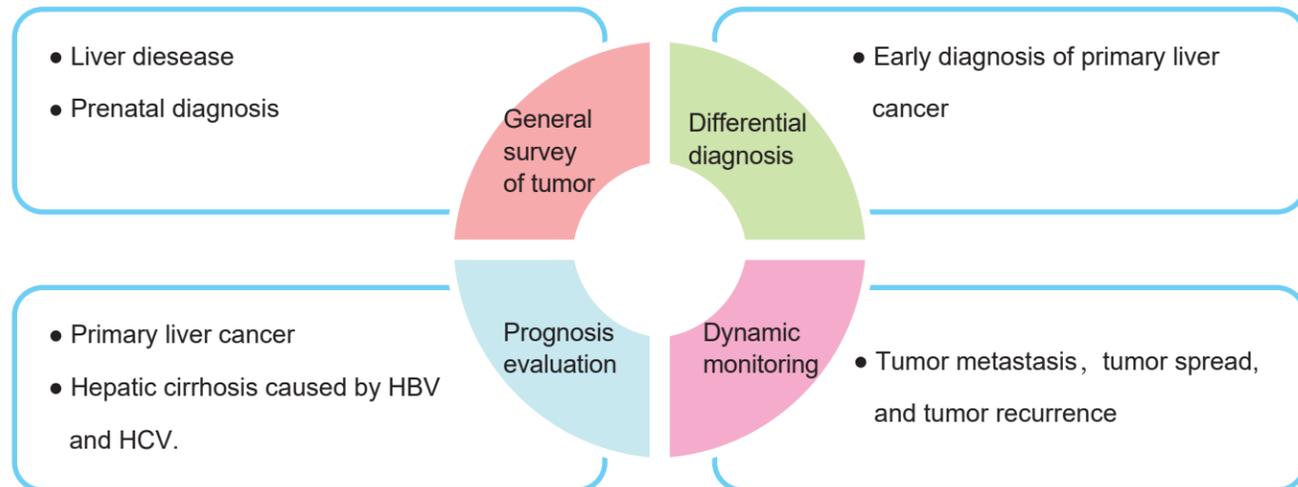
Performance:

Reaction time	15 minutes
Test time	10 seconds
Linear range	5 – 350 ng/mL
Cutoff value	20 ng/mL



Compared with 629 test results of AFP specimens conducted by Roche, Chuangxingwell CX-RDTD19H high accuracy in AFP test (5-350 ng/ml), the correlation $R^2=0.995$, which can satisfy the clinical requirement.

Application:



PSA (Prostate Specific Antigen) Rapid Quantitative Test

PSA

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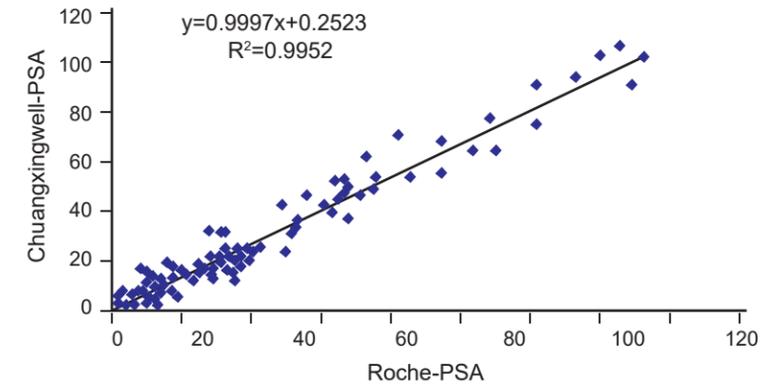
PSA is a glycoprotein, secreted by the prostate epithelium. The normal value of PSA in serum is lower than 4ng/mL. Chuangxingwell PSA rapid quantitative test applying sandwich fluorescence immunoassay technology can achieve high sensitivity and specificity.

Characteristic:

- Accurate quantification
- Rapid test, result in 15 min
- PSA control

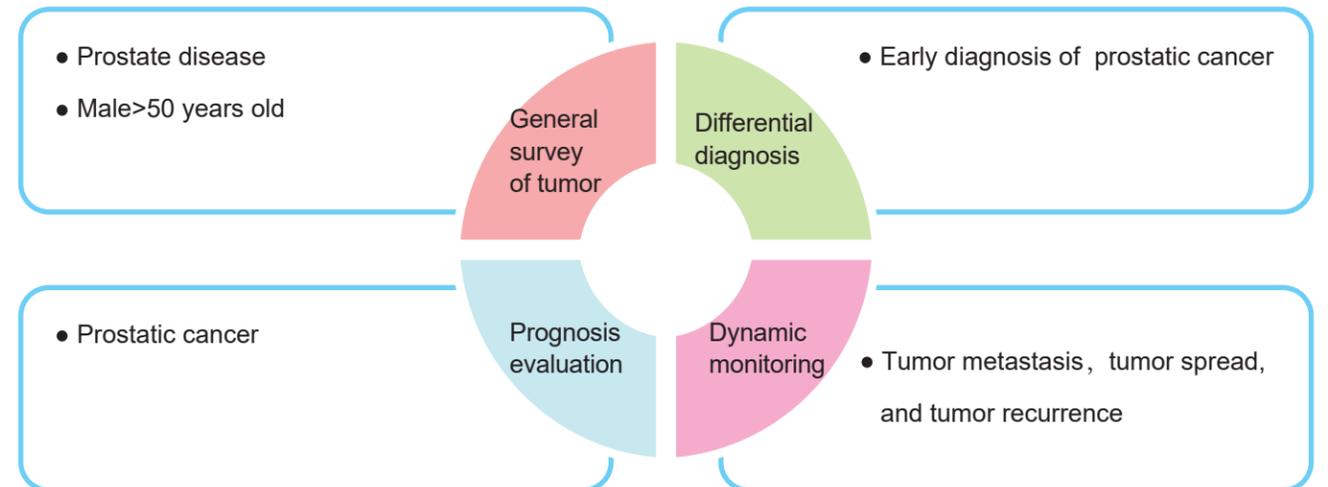
Performance:

Reaction time	15 minutes
Test time	10 seconds
Linear range	2– 100 ng/mL
Cutoff value	4 ng/mL
Precision	CV≤ 15%



Compared with 829 test results of PSA specimens conducted by Roche, Chuangxingwell CX-RDTD19H has high accuracy in PSA test (2-100 ng/ml), the correlation $R^2=0.9952$, which can satisfy the clinical requirement.

Application:





Company Qualification

chuangxingwell

www.icxbio.com

Certification

ISO 13485 and CE CERTIFICATION

CERTIFICATE 认证证书

POSI CERTIFICATE

This is to certify that the Quality Management System of

Jinan Chuangxingwell Biotech Co., Ltd.

Business License Number: 91370100MA3QXPQAIR
Registered Address: Building 1-2B-402, Liando U Valley, Gangyuan Sixth Road, Jinan Zhangjin Comprehensive Bonded Zone, Gaoxin District, Jinan City, Shandong Province, China
Audit Address: Building 1-2B-402, Liando U Valley, Gangyuan Sixth Road, Jinan Zhangjin Comprehensive Bonded Zone, Gaoxin District, Jinan City, Shandong Province, China

applicable to

Production and Distribution of In Vitro Diagnostic Kits for protein test, drug of abuse (immunochemistry), Infectious Diseases (export only)

has been assessed and registered by POSI against the provisions of

GB/T 42061-2022/ISO 13485:2016

This registration is subject to the company maintaining a Quality Management System, to the above standard, which will be monitored by POSI.

Certified organization shall accept regular surveillance audit, the validity of certificates shall be maintained for the positive result of audit.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



Certificate Registration No.: 381240177805
Initial issue date: 2024.05.29 Issue date: 2024.05.29 Valid until: 2027.05.28
Shanghai POSI Certification Co., Ltd.
Room 1402A, No.1500, Century Avenue, China (Shanghai) P4H Free Trade Zone. Email: info@posicert.com

CE Declaration of Conformity

Manufacturer: Jinan Chuangxingwell Biotech Co., Ltd.
Add: Building 1-2B-402, Liando U Valley, Gangyuan Sixth Road, Jinan Zhangjin Comprehensive Bonded Zone, Gaoxin District, Jinan city, Shandong Province, China.

Whose Single Authorized EU-Representative: Riomavix S.L.
Add: Calle de Almansa 55, 1D, Madrid 28039 Spain
E-mail: leis@riomavix.com
Tel.: +34 658 396 230 (SRN: ES-AR-000001202)

Product Name: Breast Milk Alcohol Rapid Test kit
Intended Use: The adjuvant for safe breastfeeding.

Classification: Others of ANNEX II of IVDD
Conformity Assessment Route: Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:
EN ISO 13485:2016, EN ISO 15223-1:2021, EN ISO 14971:2019/A11:2021, EN 13641:2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 13612:2002, EN ISO 23640:2015, EN ISO 20417:2021

Signature: _____
Name: General manager
Title: _____
Place/Date: China, Mar. 21, 2022

CE Declaration of Conformity, DOC No.: CXWICE-DoC-1, A/0

OFICIO

Comunicación: RPS/1720/2024
Nº AEMPS: 24-02465
Fecha: 17/06/2024
Asunto: Anotación de la comunicación en el Registro de Responsables de la puesta en el mercado de Productos Sanitarios

Con fecha 17/06/2024 ha sido registrada en la aplicación de Registro de Responsables de la puesta en el mercado de Productos Sanitarios (RPS) de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) la comunicación presentada por RIOMAVIX SL, con la siguiente información:

1. Número de identificación asignado en el registro: **RPS/1720/2024**

2. Responsable de la puesta en el mercado de los productos sanitarios

Empresa: **RIOMAVIX SL**
Calle de Almansa 55, 1D
28039 - Madrid (MADRID)
Madrid, Comunidad de

En calidad de Representante

3. Legislación que declara cumplir:
D07 - Directiva 98/79/EC

4. Párrafos adicionales de productos sanitarios incluidos en esta comunicación.
REGISTRO DE RESPONSABLES DE LA PUESTA EN EL MERCADO DE PRODUCTOS SANITARIOS
DEPARTAMENTO DE PRODUCTOS SANITARIOS

Nota: Esta modificación no tiene el carácter de una anotación sanitaria de comercialización, se establece en primer lugar la conformidad del producto con la legislación vigente. Consecuentemente anula el cumplimiento del Registro de Responsables según el artículo 9 del RD 1662/2007 por el que se regulan los Productos Sanitarios para Dispositivos in vitro.

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) CV: P722W9HTJ2SP42QZ8E8
Fecha de la firma: 17/06/2024
Puede consultarse la autenticidad del documento en la sede de la AEMPS: <https://portal.aemps.gob.es>

EXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

comercial	Fecha de introducción en el mercado
α Milk Alcohol Rapid Test kit	01/05/2022

«GENÉRICO IN VITRO»
Fabricante: Jinan Chuangxingwell Biotech Co., Ltd.
REPUBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA

RIOMAVIX

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L performed all notification duties and responsibilities as the European Authorized Representative.

MANUFACTURER: Jinan Chuangxingwell Biotech Co., Ltd.
ADDRESS: Building 1-2B-402, Liando U Valley, Gangyuan Sixth Road, Jinan Zhangjin Comprehensive Bonded Zone, Gaoxin District, Jinan city.

The manufacturer has provided Riomavix S.L with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity certifying that its in vitro diagnostic medical device as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices: Breast Milk Alcohol Rapid Test kit
Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notified of the manufacturer's device and has allocated registration. The registration number is: RPS/1720/2024.

Issue date: 17/Jun/2024
Cert. No.: 020240598-01

CE



Company Profile

chuangxingwell

www.icxbio.com

Company History



- 2015**: Company establishment.
- 2016**: Developed platform software. Obtained many certifications and copy rights.
- 2019**: Started development and production of drug analysers and test reagents.
- 2021**: Drug testing sales reached \$1 million.
- 2023**: Invested 8 million to buy production workshop.
- 2024**: Obtained CE certification for 70+IVDD products started cross-border e-commerce.....

Company Strength



Technology R&D Center

The company has a professional biological research and development team of more than 20 engineer, focusing on improving the development process of reagents and equipment.



Production R&D Center

Conduct weekly training and assessment for people on duty, strictly implement system documents, and improve production and quality control capabilities.



Professional Equipment

We have multiple professional production equipment and a complete set of processes, focusing on technology platforms such as colloidal gold, fluorescence chromatography, and chemiluminescence.



Standard Workshop

We have a production workshop of over 800 square meters, which complies with the quality management standards for medical device production.