

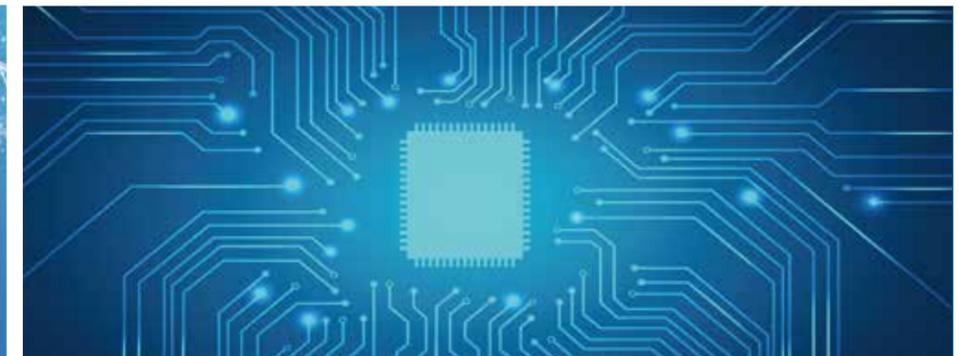
SemiQ®



chuangxingwell



SemiQ, Help you



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SemiQ,
Help you

Semiquantitative Self-Testing IVD Product Catalogue

Jinan Chuangxingwell Biotech Co., Ltd.



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Jinan Chuangxingwell Biotech Co., Ltd. is a biotechnology company specializing in the development, production, and distribution of in vitro diagnostic (IVD) devices and reagents. With a focus on innovation and quality, the company offers a diverse product portfolio, including **drug abuse detection kits, medical diagnostic reagents, and food safety testing solutions**. Equipped with a dedicated R&D team, state-of-the-art manufacturing facilities, and certifications such as **ISO 13485 and CE** marking for multiple products, Chuangxingwell ensures compliance with international standards.

Jinan Chuangxingwell Biotech Co., Ltd. excels in semiquantitative self-testing reagents, leveraging advanced technologies like Fluorescence Immunoassay, colloidal gold assays and dry chemistry methods to deliver rapid, user-friendly diagnostic tools. Additionally, it integrates artificial intelligence (AI) into IVD systems to enhance data analysis and result interpretation, improving accuracy and efficiency.

Serving a global clientele across **Southeast Asia, Europe, and South America**, Jinan Chuangxingwell Biotech is committed to advancing accessible and reliable diagnostics for healthcare, public safety, and environmental monitoring. Its core strengths lie in cost-effective semiquantitative solutions and cutting-edge AI-driven innovations, positioning it as a competitive player in the global IVD market.

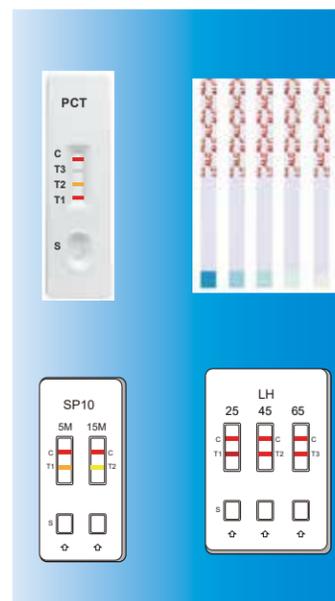
Definition and Principle

Defintion

A semiquantitative test is a diagnostic method that provides approximate measurements of a target substance (e.g., hormones, biomarkers) within predefined concentration ranges, rather than precise numerical values. It bridges the gap between: Qualitative tests (yes/no results, e.g., pregnancy strip tests). Quantitative tests (exact measurements, e.g., lab-based blood tests).

The FDA classifies semiquantitative tests as:

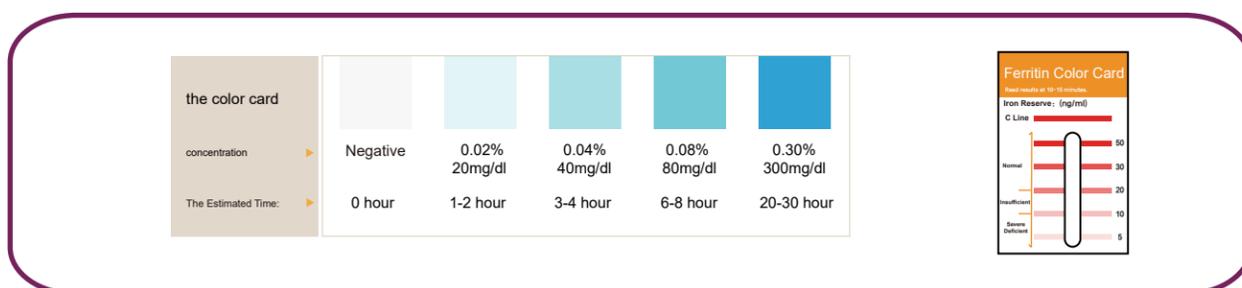
"Tests that provide results in a graded or proportional manner (e.g., low/medium/high) to estimate analyte levels, validated against predefined thresholds."



Principle

Principle of semiquantitative testing: The relative amount of a substance is estimated by observing certain measurable indicators (e.g. colour change, intensity of bands, fluorescence signal, etc.). It usually divides the results into classes or ranges, e.g. the results can be determined by comparison with a standard colour card.

Semiquantitative tests strike a balance between simplicity and actionable clinical data, making them invaluable for initial screening in obstetrics, emergency care, and resource-limited settings. For definitive diagnosis, quantitative lab tests remain the gold standard.



Comparison of Testing Methods

Qualitative Testing

It is mainly used to determine whether a substance contains the substance to be tested, and does not involve the amount of content.

Only "yes" or "no" results.

The analysis is quick and simple.

Commonly used for initial test and identification of substances.

Semiquantitative Testing

The relative content of the substance to be measured is given, but no specific value is given.

Results are expressed as ranges or ranks.

The analysis method is relatively simple and fast.

This is usually determined using visual phenomena such as colour change and precipitation formation.

Quantitative Testing

An accurate measurement of the content of a substance to be tested in a sample, usually given as a specific value.

Provides accurate value results.

The need to use calibrated instruments and standards.

The analysis process can be complex and time-consuming.

Testing Methods	Qualitative Testing	Semiquantitative Testing	Quantitative Testing
Precision	+	++	+++
Ease of operation	+++	+++	+
Rapid	+++	+++	+
Cost	+	++	+++

Forms of Realisation

Semiquantitative testing is usually achieved by several forms of design: colourimetric card comparisons, comparisons of multiple testing (T) lines, comparisons of multiple control (C) lines, sensitivity differences, and device reading.



Standard Colour Cards

The reaction of the sample with the reagent produces a colour change, and by comparing it with the standard colour on the colorimetric card, the relative amount of the substance in the sample can be estimated.

Multi-test Line

Multiple testing lines (T-lines) are set up for the same reagent strip, with each line corresponding to a different analyte concentration. Semiquantitative analysis can be performed by observing the presence or absence of these lines or shades of colour.

Multi-control Line

Design multiple C-lines, each line corresponds to different test conditions or standards, the comparison of C-lines can ensure the accuracy of test results.

Sensitivity Differences

Testing lines with different sensitivities are designed according to the sensitivity of the substance to be tested. This design will provide more detailed analyses in different concentration ranges.

Device Reading

Use optical sensors, phone cameras, or other electronic devices to read colour changes or light signals from samples and convert these signals to digital signals for more accurate semiquantitative analysis.

SemiQ® Trademark: Meaning and Brand Philosophy



The name SemiQ® combines "Semi-" (partial or intermediate) and "Q" (symbolizing Quantitative precision). It reflects a balance between two core principles:

1. Hybrid Innovation

Bridging rapid qualitative screening with quantitative accuracy in diagnostics.

2. Core Brand Message

"Smart Semi-Quantification": Targets scenarios requiring approximate yet actionable data without full laboratory precision.

"Efficiency Meets Reliability": Ideal for point-of-care devices, home testing kits, or industrial sensors prioritizing speed and cost-effectiveness.

Product Advantages



Easy Specimen Collection



Colloidal gold method with high sensitivity



Instant diagnosis at all times



Convenient procedure and fast results reading



Stable and reliable results, high accuracy



Home self-test for privacy

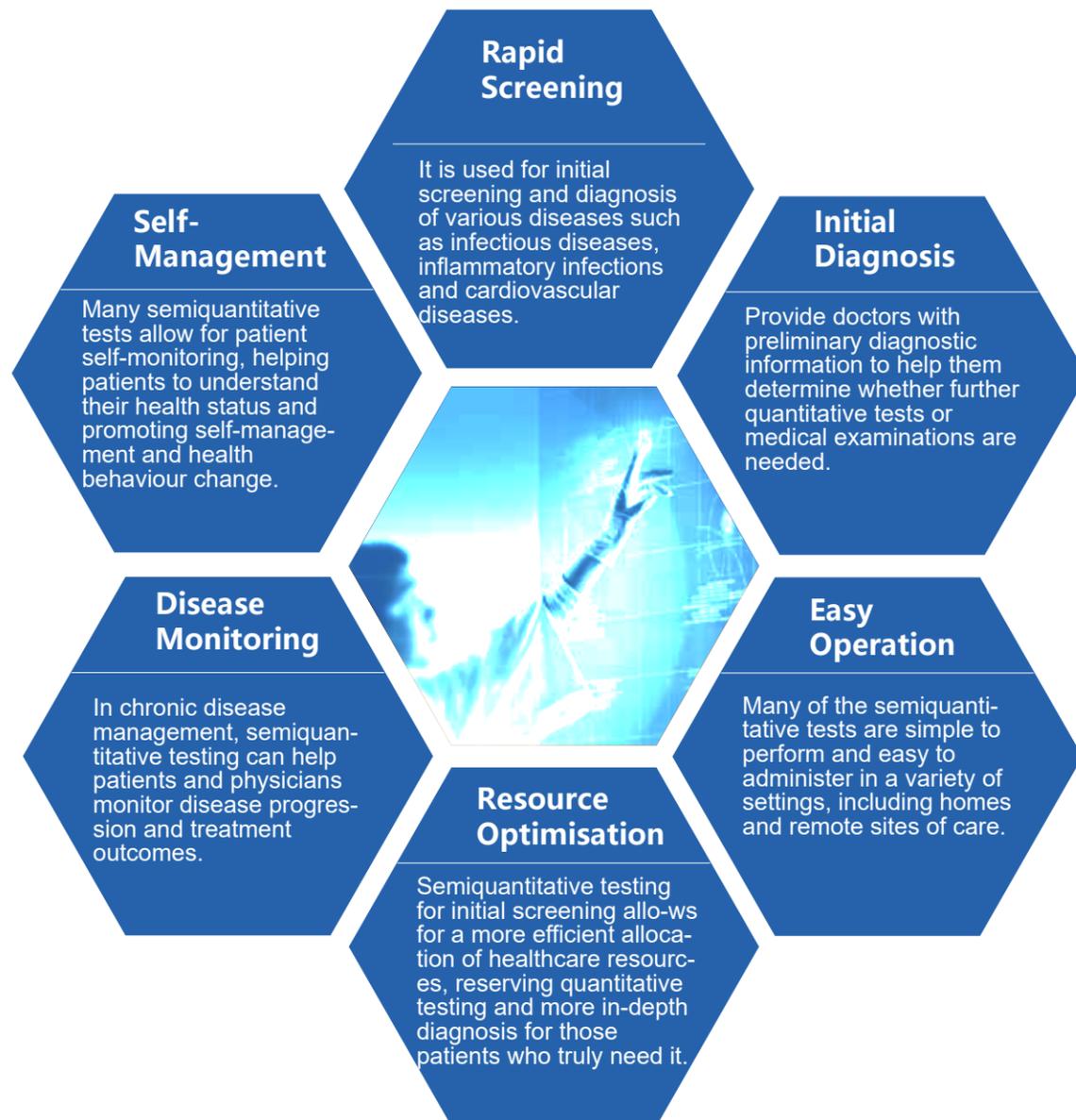
Important Significance

Semiquantitative test is typically used when precise quantification of data is not a priority, but rather when a rapid assessment or comparison of the relative amounts of substances in different samples is required. This method is characterised by its simplicity, lower cost and speed, making it suitable for initial screening or rapid assessment. It has a wide range of applications in several fields.

Self-testing capability: Users can perform tests independently (e.g., fingerstick blood, saliva, or urine samples).

Semiquantitative results: Results are categorized into tiers (e.g., "insufficient," "adequate," "high") for easy interpretation.

Rapid turnaround: Most tests deliver results within minutes (e.g., 10–15 minutes).



Application scenarios



Medical Diagnosis

It is used for initial screening and diagnosis of various diseases such as infectious diseases, inflammatory infections and cardiovascular



Chronic Disease Management (CDM)

Monitor changes in the condition of patients with chronic diseases, such as diabetes, hypertension,



Eugenics Testing

Semiquantitative tests for ovulation and early pregnancy to assist in family planning and early pregnancy diagnosis.



Drug Monitoring

Monitor drug concentrations to assess therapeutic effects or adjust dosage.



Drug Development

In the development of new drugs, it is used for the evaluation of drug efficacy and safety .



Alcohol Testing

Assessment of alcohol intake, commonly used in traffic enforcement, occupational health screening, safe breastfeeding, etc.



Primary Care Organisations

Semiquantitative tests are suitable for initial screening and diagnosis in primary care due to their simplicity and low cost.



Home Self-testing

Some semiquantitative test kits provide convenience for individuals to do their own tests at home, such as blood glucose and ovulation.



Forensic Medicine

It can be used for preliminary assessment of the content of certain chemical substances in physical evidence, such as drug testing.



Environment Monitoring

Testing for pollutants in the environment, such as water quality, air, etc.



Food Safety

Detect harmful substances in food, such as pesticide residues, food additives, etc.



Testing of Major Epidemics

Outbreaks allow for mass screening and rapid response in emergencies.

Product Catalog



Product Catalog	Product Name	Specimen	Format	Sensitivity	Certificate
Fertility Test	Human Chorionic Gonadotropin (HCG) Pregnancy Rapid Test Kit	Urine	Cup/Pannel/Cassette	20-100-600-2000-10000 mIU/ml	CE
	Luteinizing Hormone (LH) Ovulation Rapid Test Kit	Urine	Cassette/Pannel	25-45-65 mIU/ml	CE
	Follicle Stimulating Hormone (FSH) Rapid Test Kit	Urine	Cassette/Pannel/Midstream	5-10-25 mIU/ml	CE
	Sperm SP-10 Protein (SP-10)Male Fertility Rapid Test Kit	Sperm	Cassette	5-15 million/ml	CE
Inflammation Marker Test	C-Reactive Protein (CRP) Rapid Test Kit	whole blood/serum/plasma	Cassette	10-25-50mg/L	CE
	Procalcitonin (PCT) Rapid Test Kit	whole blood/serum/plasma	Cassette	0.25-0.5-2 ng/ml	CE
	Calprotectin (CALP) Rapid Test Kit	Faeces	Cassette	50-200 ug/g	CE
Anaemia Test	Ferritin (FRT) Iron Deficiency Rapid Test Kit	whole blood/serum/plasma	Cassette	10-20 ng/ml	CE
Kidney Function Test	Microalbumin (MALB) Rapid Test Kit	Urine	Cassette/Pannel/Midstream	20-200 mg/L	CE
	Neutrophil Gelatinase Associated Lipocalin (NGAL) Rapid Test Kit	Urine	Cassette/Pannel/Midstream	20-120 ng/ml	CE
Alcohol Test	Breast Milk Alcohol Rapid Test kit	Breast Milk	Cassette/Pannel/strip	20-40-80-300mg/dl	CE
Bone Metabolism Test	25-Hydroxy Vitamin D (25-OH VD) Rapid Test Kit	Whole Blood	Cassette	10-30 ng/ml	CE
Drugs of Abuse Test	Fentanyl(FYL) Rapid Test Kit	Saliva/Urine	Cassette/Pannel	1-5-10-20-50 ng/ml	CE
	Tetrahydrocannabinol(THC)Rapid Test Kit	Saliva/Urine	Cassette/Pannel	10-20-50 ng/ml	CE

HCG Pregnancy Rapid Test

This product is a rapid, accurate and simple semiquantitative test for detecting human chorionic gonadotropin (HCG) in urine specimen to aid in the early detection of pregnancy levels and changes in the urine of women of childbearing age, which can be used to determine early pregnancy ; to assist in the screening of ectopic pregnancies, foetal termination and preeclampsia; and to provide personalised information on pregnancy monitoring.

Product Information

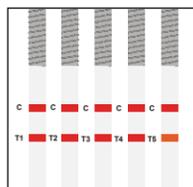
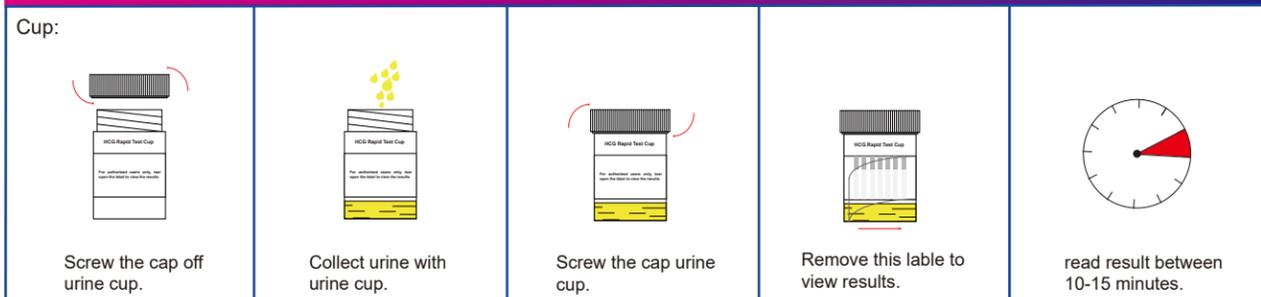
Accuracy: >99.5%
 Format: Cup/Cassette/Pannel
 Specimen: Urine
 Test time: 10 minutes
 Test Value: 20-100-600-2000-10000 mIU/ml



Product Advantage

- Clear results, week of pregnancy at a glance.
- Early pregnancy can be determined in 3-7 days.
- Ectopic pregnancy can be detected early.
- High accuracy and sensitivity up to 20 mIU/ml.
- Home self-test, simple and easy, fast results.
- Clean and hygienic, individually sealed package.

Test Procedure



Reagent display	HCG concentration and gestational age
No lines appears in the test line region (T).	HCG concentration (<20 mIU/ml) ,Not pregnant.
Colored lines appear in T1 only.	HCG concentration (20-100mIU/ml) ,pregnancy for 0.2-1 week.
Colored lines appear in T1/T2 only.	HCG concentration (100-600 mIU/ml) ,pregnancy for 1-2 weeks.
Colored lines appear in T1/T2/T3 only.	HCG concentration (600-2000 mIU/ml) ,pregnancy for 2-3 weeks.
Colored lines appear in T1/T2/T3/T4 only.	HCG concentration (2000-10000 mIU/ml) ,pregnancy for 3-4 weeks.
Colored lines appear in T1/T2/T3/T4/T5.	HCG concentration (≥10000 mIU/ml) ,equal to or more than 4 weeks.
Control lines fails to appear.	INVALID,Need to retest.

LH Ovulation Rapid Test

This product is a rapid, accurate and simple semiquantitative test for detecting the luteinizing hormone (LH) surge and changes in female urine, which can be used to predict the time of ovulation, monitor the status of ovulation, and target the optimal period for conception; assess gonadal function; and screen for and diagnose pregnancy and related complications.

Product Information

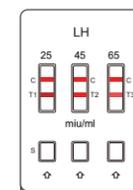
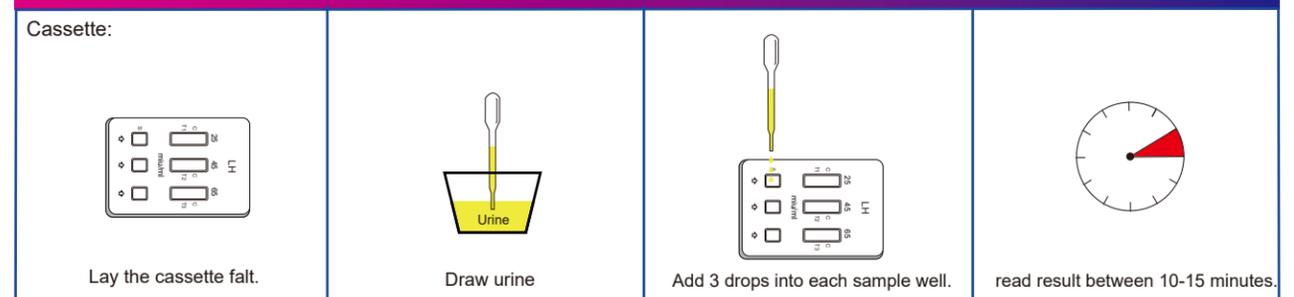
Accuracy: >99.5%
 Format: Cassette/Pannel
 Specimen: Urine
 Test time: 10 minutes
 Test Value: 25-45-65 mIU/ml



Product Advantage

- Test Range:0-65 mIU/ml.
- Accurate Time:Ovulation Day in hours.
- Test Principle:Peak to fade is true ovulation.
- Home self-test, simple and easy.
- Recognising Low Peak Ovulation.
- Locking in the Prime Time to Conceive.

Test Procedure



Reagent display	LH concentration and Pregnancy advice
all the test line region (T) is lighter than C line.	LH concentration (<25 mIU/ml) ,Not easy to get pregnant.
only T1 is similar or darker than C line.	LH concentration (25-45 mIU/ml) ,Ovulation in 24-48 hours
T1 and T2 are similar or darker than C line.	LH concentration (45-65 mIU/ml) ,Ovulation in 12-28 hours
T1/T2/T3 are similar or darker than C line.	LH concentration (≥65 mIU/ml) ,The Best Golden Pregnancy Time.
Control lines fails to appear.	INVALID,Need to retest.

FSH Rapid Test

This product is a semiquantitative measurement of FSH in female urine, which can be used as a reference for women who are preparing for pregnancy and are concerned about ovarian health and fertility, as well as for evaluating pituitary endocrine function; and as an aid in the diagnosis of gonadotropic dysfunction.

Product Information

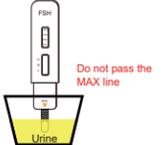
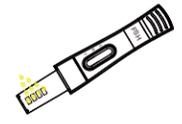
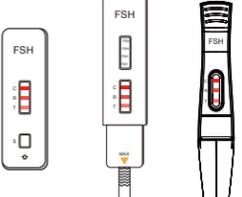
Accuracy: >99.5%
 Format: Cassette/Pannel/Midstream
 Specimen: Urine
 Test time: 10 minutes
 Test Value: 5-10-25 mIU/ml

Product Advantage

- Multi-age and multifunctional assessment.
- Colloidal gold for fast and accurate results.
- Home self-test to avoid embarrassment and protect privacy.
- Testing at any time, regardless of the menstrual cycle.
- High sensitivity up to 5 mIU/ml.
- Hospital-free, affordable and time-saving.



Test Procedure

Cassette:  Lay the cassette flat.	 Draw urine.	 Add 3 drops into the sample well.	 read result between 10-15 minutes.												
Pannel:  immerse the strip in the urine for at least 5 seconds	 Lay the pannel flat and read result between 10-15 minutes.	Midstream:  Remove the lid, urinate on the absorbent tip until it is moist for 5 seconds.	 Lay the Midstream flat and read result between 10-15 minutes.												
 <table border="1"> <thead> <tr> <th>Reagent display</th> <th>FSH concentration and Ovarian function assessment</th> </tr> </thead> <tbody> <tr> <td>No lines appears in the test line region (T).</td> <td>FSH concentration (<5 mIU/ml) ,Maybe immature follicular development.</td> </tr> <tr> <td>Line color contrast: T-line ≤ R-line</td> <td>FSH concentration (5-10 mIU/ml) ,Normal ovarian function.</td> </tr> <tr> <td>Line color contrast: R-line <T-line < C-line .</td> <td>FSH concentration (10-25 mIU/ml) ,Maybe Ovarian dysfunction.</td> </tr> <tr> <td>Line color contrast: T-line ≥ C-line .</td> <td>FSH concentration (≥25 mIU/ml) ,Premature ovarian failure.</td> </tr> <tr> <td>Control lines(C/R) fails to appear.</td> <td>INVALID,Need to retest.</td> </tr> </tbody> </table>		Reagent display	FSH concentration and Ovarian function assessment	No lines appears in the test line region (T).	FSH concentration (<5 mIU/ml) ,Maybe immature follicular development.	Line color contrast: T-line ≤ R-line	FSH concentration (5-10 mIU/ml) ,Normal ovarian function.	Line color contrast: R-line <T-line < C-line .	FSH concentration (10-25 mIU/ml) ,Maybe Ovarian dysfunction.	Line color contrast: T-line ≥ C-line .	FSH concentration (≥25 mIU/ml) ,Premature ovarian failure.	Control lines(C/R) fails to appear.	INVALID,Need to retest.		
Reagent display	FSH concentration and Ovarian function assessment														
No lines appears in the test line region (T).	FSH concentration (<5 mIU/ml) ,Maybe immature follicular development.														
Line color contrast: T-line ≤ R-line	FSH concentration (5-10 mIU/ml) ,Normal ovarian function.														
Line color contrast: R-line <T-line < C-line .	FSH concentration (10-25 mIU/ml) ,Maybe Ovarian dysfunction.														
Line color contrast: T-line ≥ C-line .	FSH concentration (≥25 mIU/ml) ,Premature ovarian failure.														
Control lines(C/R) fails to appear.	INVALID,Need to retest.														

SP10 Rapid Test

This product is used for in vitro semiquantitative detection of sperm SP10 protein in human semen to assess male fertility for pregnancy preparation and to assist in the diagnosis of male infertility.

Product Information

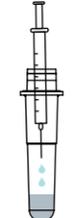
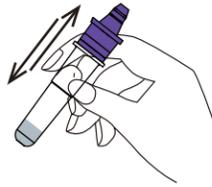
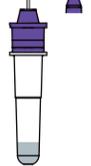
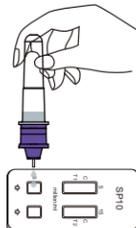
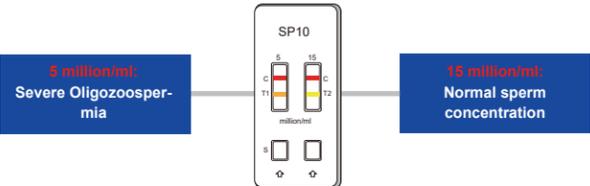
Accuracy: >99.5%
 Format: Cassette
 Specimen: Sperm
 Test time: 10 minutes
 Test Value: 5-15 million/ml

Product Advantage

- Avoid embarrassment with home self-test.
- Convenient operation and 10-15 minute results.
- Cheap cost and economical.
- Colloidal gold results are more accurate.
- High sensitivity and specificity.
- Private delivery, no worry about privacy.



Test Procedure

Cassette:  Collect 3 drops of sperm.	 Stir sperm 10 times.	 Transfer the sperm liquid into buffer.	 Screw the cap of tube tightly. Shake up and down 5-10 times.	 Unscrew the cap of the collection tube.
 Add 2 drops of mixed sample to each sample well.	 read result between 10-15 minutes.	 <p>5 million/ml: Severe Oligozoospermia</p> <p>15 million/ml: Normal sperm concentration</p>		
According to the criteria of the World Health Organisation (WHO) Laboratory Manual for the Examination and Processing of Human Semen, 5th edition, a sperm concentration of <15 million sperms/ml is considered oligozoospermia and a sperm concentration of <5 million sperms/ml is considered severe oligozoospermia.				

CRP Rapid Test

This product can perform semi quantitative evaluation of C-reactive protein(CRP) levels in whole blood, serum or plasma, and can be used for rapid diagnosis of infection, monitoring of postoperative infection, observation of antibiotic efficacy, prediction of cardiovascular disease risk, etc.

Product Information

Accuracy: >99.5%
 Format: Cassette
 Specimen: Whole Blood/Serum/Plasm
 Test time: 10 minutes
 Test Value: 10-25-50 mg/l



Product Advantage

- Differential diagnosis of bacterial/viral infections.
- fast and easy to read results.
- hsCPT High sensitivity up to 1 mg/L.
- Self-test at home, saving time and money.
- Colloidal gold results are more accurate.
- Applicable to a wide range of people.

Test Procedure

<p>Cassette:</p> <p>Carefully pull off and dispose the released cap of the lancet.</p>	<p>Use the alcohol pad to clean the fingertip of the middle or ring finger as the puncturesite.</p>	<p>Press the lancet, on the side from where the cap was extracted; against the fingertip (it is advisable the ring finger side).The tip retracts automatically and safely after use.</p>	<p>Without touching the puncture site, massage the hand towards the fingertip, keeping the hand pointing downwards to obtain the sample of blood.</p>
<p>Use quantitative dropper to draw the blood sample up to the demarcation line at the thin tip of the dropper . Massage your finger again to obtain more blood If there's not enough blood. Avoid air bubbles.</p>	<p>Transfer all collected blood samples of capillary tube into the buffer bottle, by squeezing the dropper bulb.</p>	<p>After screwing the cap of tube tightly.Shake up and down, Add 2 drops of mixed sample to each sample well (S) of the cassette.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>



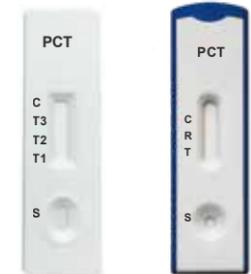
Reagent display	CRP concentration and Interpretation of results
No lines appears in the test line region (T).	CRP concentration (<10 mg/L) ,Well-being.
Colored lines appear in T1 only.	CRP concentration (10-25 mg/L) ,Viral infection or mild bacterial infection.
Colored lines appear in T1/T2 only.	CRP concentration (25-50 mg/L) ,General bacterial infection.
Colored lines appear in T1/T2/T3 only.	CRP concentration (>50 mg/L) ,Serious bacterial infection.

PCT Rapid Test

This product can quickly and conveniently perform semi quantitative evaluation of procalcitonin(PCT)levels in whole blood, serum, or plasma, and differentiate between bacterial and non bacterial infections and inflammations; Assist in the diagnosis and control of severe bacterial infections and sepsis treatment; Monitor the degree of human infection and determine whether antibiotics can be discontinued.

Product Information

Accuracy: >99.5%
 Format: Cassette
 Specimen: Whole Blood/Serum/Plasm
 Test time: 10 minutes
 Test Value: 0.25-0.5-2 ng/ml



Product Advantage

- Distinguishes bacterial infections from other types of infections.
- High sensitivity up to 0.25 ng/ml.
- Self-testing at home for rapid point-of-care testing .
- Hospital-free, time-saving and money-saving.
- Colloidal gold for fast and accurate results.
- Applicable to a wide range of people and applications.

Test Procedure

<p>Cassette:</p> <p>Carefully pull off and dispose the released cap of the lancet.</p>	<p>Use the alcohol pad to clean the fingertip of the middle or ring finger as the puncturesite.</p>	<p>Press the lancet, on the side from where the cap was extracted; against the fingertip (it is advisable the ring finger side).The tip retracts automatically and safely after use.</p>	<p>Without touching the puncture site, massage the hand towards the fingertip, keeping the hand pointing downwards to obtain the sample of blood.</p>
<p>Use quantitative dropper to draw the blood sample up to the demarcation line at the thin tip of the dropper . Massage your finger again to obtain more blood If there's not enough blood. Avoid air bubbles.</p>	<p>Transfer all collected blood samples of capillary tube into the sample well (S) of the cassette, by squeezing the dropper bulb.</p>	<p>After all blood completely absorbed, add about 1-2 drops of diluent buffer into the sample well (S) of the cassette.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>



Reagent display	PCT concentration and Interpretation of results
No lines appears in the test line region (T).	PCT concentration (<0.25 ng/ml) ,Well-being.
Colored lines appear in T1 only.	PCT concentration (0.25-0.5ng/ml) ,Viral infection or mild bacterial infection.
Colored lines appear in T1/T2 only.	PCT concentration (0.5-2ng/ml) ,Moderate bacterial Infection.
Colored lines appear in T1/T2/T3 only.	PCT concentration (≥2 ng/ml) ,Severe infection(sepsis).

CALP Rapid Test

This product is intended for the in vitro semiquantitative determination of calreticulin(CALP) in human faecal extracts as an aid to the diagnosis and therapeutic monitoring of Inflammatory Bowel Disease (IBD).

Product Information

Accuracy: >99.5%
 Format: Cassette
 Specimen: Faeces
 Test time: 10 minutes
 Test Value: 50 - 200 ug/g



Product Advantage

- Distinguishing inflammatory from non-inflammatory bowel disease.
- Avoiding invasive colonoscopy reduces intestinal damage.
- Low cost and affordable to avoid expensive tests.
- Home self-testing for rapid point-of-care testing (POCT).
- Wide range of people and applications.

Test Procedure

<p>Cassette:</p> <p>Unscrew the cap of the feces collection tube and take out the applicator stick.</p>	<p>Dip the applicator stick into stool specimen at 3 different sites.</p>	<p>Replace the applicator in the tube and tighten securely. Shake well before use.</p>	<p>Then add 2-3 drops into the sample well.</p>	<p>read result between 10-15 minutes.</p>
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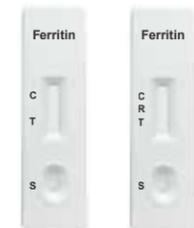
Reagent display	CALP concentration and Interpretation of results
No lines appears in the test line region (T).	CALP concentration (<50 ug/g) ,Low risk IBD.
Colored lines appear in T1 only.	CALP concentration (50-200 ug/g) ,Medium risk IBD.
Colored lines appear in T1/T2.	CALP concentration (≥200 ug/g) ,High risk IBD.
Control lines fails to appear.	INVALID,Need to retest.

Ferritin Rapid Test

This product is intended for the semiquantitative determination of ferritin in human whole blood, serum or plasma samples for use as an aid in the diagnosis of iron-deficiency anaemia and other diseases associated with iron metabolism.

Product Information

Accuracy: >99.5%
 Format: Cassette
 Specimen: Whole Blood/Serum/Plasm
 Test time: 10-15 minutes
 Test Value: 10-20 ng/ml

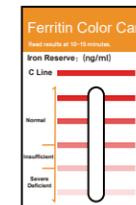


Product Advantage

- Identify anaemia symptoms earlier
- Rapid 10-15 minute interpretation of results
- Colloidal gold method is accurate and stable
- Highly sensitive and easy to develop colours
- Home- test, convenient and rapid
- Hospital-free, time-saving and money-saving.

Test Procedure

<p>Cassette:</p> <p>Carefully pull off and dispose the released cap of the lancet.</p>	<p>Use the alcohol pad to clean the fingertip of the middle or ring finger as the puncturesite.</p>	<p>Press the lancet, on the side from where the cap was extracted; against the fingertip (it is advisable the ring finger side).The tip retracts automatically and safely after use.</p>	<p>Without touching the puncture site, massage the hand towards the fingertip, keeping the hand pointing downwards to obtain the sample of blood.</p>
<p>Use quantitative dropper to draw the blood sample up to the demarcation line at the thin tip of the dropper . Massage your finger again to obtain more blood if there's not enough blood. Avoid air bubbles.</p>	<p>Transfer all collected blood samples of capillary tube into the sample well (S) of the cassette, by squeezing the dropper bulb.</p>	<p>After all blood completely absorbed, add about 1-2 drops of diluent buffer into the sample well (S) of the cassette.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>



Method	FRT concentration	Iron Reserve
Place the test cassette next to the color card and compare the color of the test line(T) with the color card provided.	FRT concentration (≥20ng/ml)	Normal
	FRT concentration (10-20ng/ml)	Insufficient
	FRT concentration (<10ng/ml)	Severe Deficient
	Control line(C) fails to appear	INVALID,Need to retest

MALB Rapid Test

This product is used for the semiquantitative measurement of microalbumin(MALB) in urine, which is useful for the early diagnosis of glomerulopathy, and for the diagnosis and treatment of early stage renal disease in patients with diabetes mellitus and hypertension.

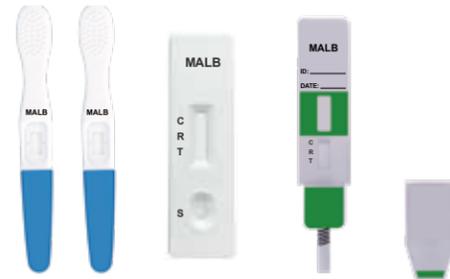
Product Information

Accuracy: >99.5%
 Format: Cassette/Pannel/Midstream
 Specimen: Urine
 Test time: 10 minutes
 Test Value: 20-200mg/L



Product Advantage

- Home self-test, worry-free privacy.
- Results in 10 minutes, rapid and reliable.
- High sensitivity, easy to show colour.
- Cheap cost and economical.
- Hospital-free, save time and effort.
- Clean and hygienic, individually sealed package.



Test Procedure

Cassette: Lay the cassette falt.	 Draw urine.	 Add 3 drops into the sample well.	 read result between 10-15 minutes.																								
Pannel: immerse the strip in the urine for at least 5 seconds	 Lay the pannel falt and read result between 10-15 minutes.	Midstream: Remove the lid, urinate on the absorbent tip until it is moist for 5 seconds.	 Lay the Midstream falt and read result between 10-15 minutes.																								
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NGAL Rapid Test

This product is used for the semiquantitative measurement of Neutrophil Gelatinase-Associated Lipocalin(NGAL) in urine, which is useful for the early diagnosis of glomerulopathy, and for the diagnosis and treatment of early screening of kidney damage.

Product Information

Accuracy: >99.5%
 Format: Cassette/Pannel/Midstream
 Specimen: Urine
 Test time: 10 minutes
 Test Value: 20-120ng/mL



Product Advantage

- Home self-test, worry-free privacy.
- Results in 10 minutes, rapid and reliable.
- High sensitivity, easy to show colour.
- Cheap cost and economical.
- Hospital-free, save time and effort.
- Clean and hygienic, individually sealed package.



Test Procedure

Cassette: Lay the cassette falt.	 Draw urine.	 Add 3 drops into the sample well.	 read result between 10-15 minutes.																								
Pannel: immerse the strip in the urine for at least 5 seconds	 Lay the pannel falt and read result between 10-15 minutes.	Midstream: Remove the lid, urinate on the absorbent tip until it is moist for 5 seconds.	 Lay the Midstream falt and read result between 10-15 minutes.																								
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ALC Rapid Test

This product is used for the in vitro semiquantitative determination of the relative alcohol concentration in breast milk (0.02% to 0.30%) and to know the time to zero alcohol in breast milk before resuming breastfeeding, and is primarily intended to assist in the safe feeding of breastmilk.

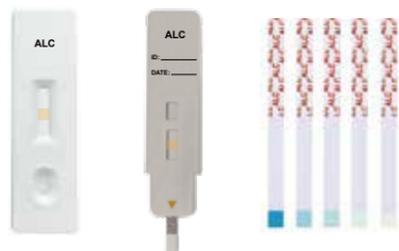
Product Information

Accuracy: >99.5%
 Format: Cassette/Pannel/Strip
 Specimen: Breast Milk
 Test time: 2 minutes
 Test Value: 20-40-80-300mg/dl



Product Advantage

- Rapid Results in Just 2 Minutes.
- User-Friendly: Simply dip and read!
- Know the time to zero alcohol in breast milk.
- Home self-test for privacy.
- High sensitivity for safe breastfeeding.
- Individually Sealed & Easy to Carry & Store.



Test Procedure

Cassette: Lay the cassette flat.	 Draw breast milk.	 Add 3 drops into the sample well.	 read result between 2-3 minutes.												
Pannel: immerse the pannel in the milk for at least 5 seconds	 Lay the pannel flat and read result between 5-10 minutes.	Midstream: immerse the strip in the milk for 2-3 seconds.	 Lay the strip flat and read result between 2-3 minutes.												
<p>the color card</p> <table border="1"> <tr> <td>ALC concentration</td> <td>Negative</td> <td>0.02% 20mg/dl</td> <td>0.04% 40mg/dl</td> <td>0.08% 80mg/dl</td> <td>0.30% 300mg/dl</td> </tr> <tr> <td>The Estimated Time: Alcohol will be eliminated from breast milk and for the next check.</td> <td>0 hour</td> <td>1-2 hour</td> <td>3-4 hour</td> <td>6-8 hour</td> <td>20-30 hour</td> </tr> </table>				ALC concentration	Negative	0.02% 20mg/dl	0.04% 40mg/dl	0.08% 80mg/dl	0.30% 300mg/dl	The Estimated Time: Alcohol will be eliminated from breast milk and for the next check.	0 hour	1-2 hour	3-4 hour	6-8 hour	20-30 hour
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VD Rapid Test

This product is designed for the in vitro semiquantitative measurement of 25-Hydroxy Vitamin D (25-OH VD) in human blood and can be used to screen for vitamin D deficiency.

Product Information

Accuracy: >99.5%
 Format: Cassette
 Specimen: Whole Blood
 Test time: 10 minutes
 Test Value: 10-30 ng/ml



Product Advantage

- Save time and money by avoiding hospitals.
- Home self-testing for rapid point-of-care testing .
- Easy to operate, no need for complex instrumentation.
- Highly sensitive and easy to show colours.
- Results in 10-15 minutes, rapid interpretation.



Test Procedure

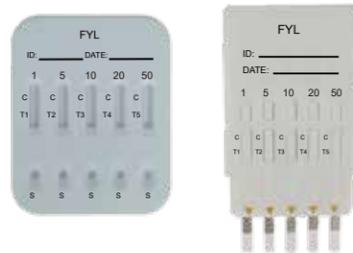
Cassette: Carefully pull off and dispose the released cap of the lancet.	 Use the alcohol pad to clean the fingertip of the middle or ring finger as the puncturesite.	 Press the lancet, on the side from where the cap was extracted; against the fingertip (it is advisable the ring finger side).The tip retracts automatically and safely after use.	 Without touching the puncture site, massage the hand towards the fingertip, keeping the hand pointing downwards to obtain the sample of blood.												
 Use quantitative dropper to draw the blood sample up to the demarcation line at the thin tip of the dropper . Massage your finger again to obtain more blood If there's not enough blood. Avoid air bubbles.	 Transfer all collected blood samples of capillary tube into the sample well (S) of the cassette, by squeezing the dropper bulb.	 After all blood completely absorbed, add about 2 drops of diluent buffer into the sample well (S) of the cassette.	 Read results at 10-15 minutes. Do not interpret the result after 30 minutes.												
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Control lines(C/R) fails to appear.	INVALID,Need to retest.														

FYL Rapid Test

This product is designed for the semiquantitative determination of Fentanyl (FYL) in blood, hair, saliva or urine samples to assist in the clinical monitoring of drug efficacy and safety, as well as to monitor occupational safety and assist in forensic evidence.

Product Information

Accuracy: >99.5%
 Format: Cassette/Pannel
 Specimen: Urine
 Test time: 5 minutes
 Test Value: 1-5-10-20-50 ng/ml



Product Advantage

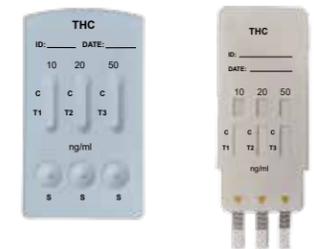
- Quick and easy 5 minute reading.
- Home monitoring to prevent abuse and relapse.
- Stable and reliable results refer to international and national standards for test thresholds.
- Home self-test for privacy.
- Instant diagnosis at all times.

THC Rapid Test

This product is intended for the semiquantitative detection of Tetrahydrocannabinol (THC) concentrations in blood, hair, saliva or urine samples, which helps to clinically monitor the efficacy and safety of drugs and screen for drug abuse, as well as to monitor occupational safety and assist in judicial forensics.

Product Information

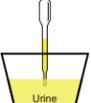
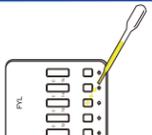
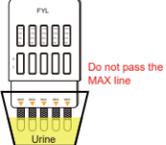
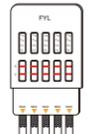
Accuracy: >99.5%
 Format: Cassette/Pannel
 Specimen: Urine
 Test time: 5 minutes
 Test Value: 10-20-50 ng/ml

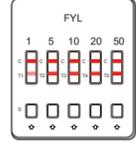
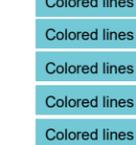
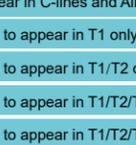
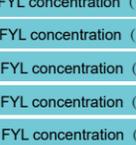


Product Advantage

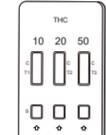
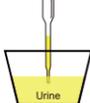
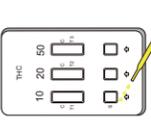
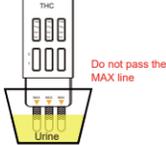
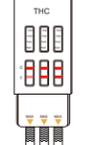
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- Home self-testing for privacy.
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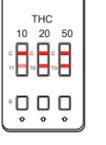
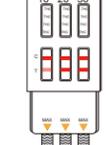
Test Procedure

Cassette:  Lay the cassette flat.	 Draw urine.	 Add 3 drops into each sample well.	 read result between 5-10 minutes.
Pannel:  remove the lid of pannel.	 immerse the strip in the urine for at least 15 seconds <small>Do not pass the MAX line</small>	 Lay the pannel flat.	 read result between 5-10 minutes.

Reagent display	Interpretation of results
	FYL concentration (<1 ng/ml) .
	FYL concentration (1-5 ng/ml) .
	FYL concentration (5-10 ng/ml) .
	FYL concentration (10-20ng/ml) .
	FYL concentration (20-50 ng/ml) .
	FYL concentration (≥50 ng/ml) .

Test Procedure

Cassette:  Lay the cassette flat.	 Draw urine.	 Add 3 drops into each sample well.	 read result between 5-10 minutes.
Pannel:  remove the lid of pannel.	 immerse the strip in the urine for at least 15 seconds <small>Do not pass the MAX line</small>	 Lay the pannel flat.	 read result between 5-10 minutes.

Reagent display	Interpretation of results
	THC concentration (<10ng/ml) .
	THC concentration (10-20 ng/ml) .
	THC concentration (20-50 ng/ml) .
	THC concentration (≥50 ng/ml) .

Certification

ISO 13485 and CE CERTIFICATION

POSI CERTIFICATE
This is to certify that the Quality Management System of **Jinan Chuangxingwell Biotech Co., Ltd.** has been assessed and registered by POSI against the provisions of GB/T 42061-2022/ISO 13485:2014. The certificate is applicable to the Production and Distribution of In Vitro Diagnostic Kits for protein test, drug of abuse (immunochemistry), Infectious Diseases (report only).

CE Declaration of Conformity
Manufacturer: Jinan Chuangxingwell Biotech Co., Ltd. Product Name: Breast Milk Alcohol Rapid Test kit. Intended Use: The adjunct for safe breastfeeding. Classification: Others of ANNEX II of MDD. Conforms to EN ISO 13485:2016, EN ISO 14223-1:2021, EN ISO 14971:2013, EN ISO 13641:2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002, EN ISO 22842:2015, EN ISO 20417:2021.

Company History



Company Strength

RIOMAVIX
NOTIFICATION OF REGISTRATION
This is to certify that, according to the European Council Directive 90/269/EEC, Annex II, performed of verification duties and responsibilities as the European Authorized Representative.

ENX- PRODUCTOS SANITARIOS COMERCIALIZADOS POR EL RESPONSABLE
Comercialización: RIOMAVIX SL, Calle de Alameda 55 JD, 28009 - Madrid, MADRID, Madrid, Comunidad de Madrid, España.



Technology R&D Center

Production R&D Center

Professional Equipment

Standard Workshop

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

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

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

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