

SemiQ®



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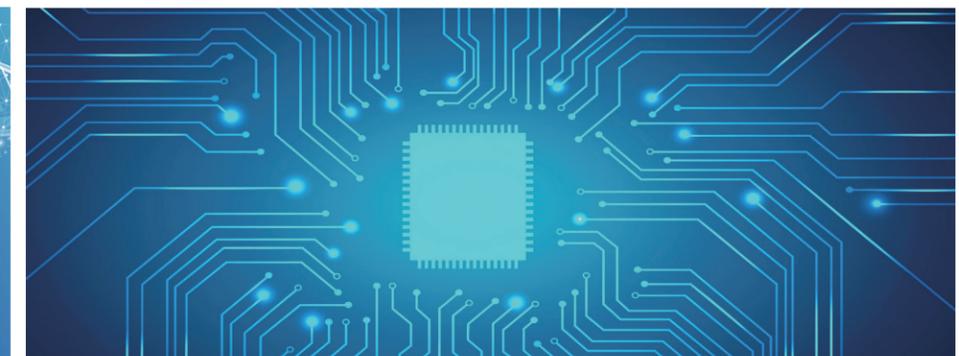
SemiQ,
Help you



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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.

HCG Pregnancy Rapid Test Kit



HCG Pregnancy Test is for the rapid, visual and qualitative determination of human chorionic gonadotropin (HCG) in urine or urine/serum specimen to aid in the early detection of pregnancy.

Specimen: Urine/Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months

Luteinizing Hormone (LH) Ovulation Rapid Test Kit



LH Ovulation Test is a complete system to help predict the time of ovulation and peak fertility. It is during this fertile time that pregnancy is most likely to occur. LH Ovulation Test detects the luteinizing hormone (LH) surge in urine, signaling that ovulation is likely to occur in the next 24-48 hours.

Specimen: Urine/Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months

When To Start Testing

To determine when to start testing you must firstly determine the length of your Menstrual Cycle. Your menstrual cycle length is the number of days from the first day of your period to the last day before your next period starts. Then refer to the Cycle Chart to determine on which day you should begin testing.

NOTE: If you are unsure about your cycle length, you may begin the test 11th day after your first period. Perform 1 test each day over a 5 days period or until the LH surge has been detected.

		Cycle Chart																		
Your cycle	21 days	22 days	23 days	24 days	25 days	26 days	27 days	28 days	29 days	30 days	31 days	32 days	33 days	34 days	35 days	36 days	37 days	38 days	39 days	Yore then 40 days
Start to test on	day 6	day 6	day 7	day 7	day 8	day 9	day 10	day 11	day 12	day 13	day 14	day 15	day 16	day 17	day 18	day 19	day 20	day 21	day 22	Consult to doctor

Test Procedure				
Cassette: Lay the cassette flat	 Draw urine	 Dispense 3 drops into the sample well.	 read result between 5-10 minutes	 Positive Negative Invalid

LH Surge: you will probably ovulate in the next 24-48 hours.
 No LH Surge: no LH Surge has been detected and you should continue daily testing.

Test Procedure				
Cassette: Lay the cassette flat	 Draw urine	 Dispense 3 drops into the sample well.	 read result between 5-10 minutes	 Positive Negative Invalid
Strip: immerse the strip in the urine for at least 5 seconds	 Lay the strip flat	 read result between 5-10 minutes	 Positive Negative Invalid	
Midstream: Remove the cap, Urinate on the absorbent tip directly till it is thoroughly wet at least 5 seconds.	 Lay the strip flat	 read result between 5-10 minutes	 Positive Negative Invalid	

Follicle-Stimulating Hormone(FSH)Test



FSH (Follicle-Stimulating Hormone) Test is used to detect FSH in the urine; this helps to check the function of the pituitary gland and check if hormone levels are normal. The test can be used to see if a woman has started the menopause. The product may also be used (along with other tests) to test for possible causes of both male and female infertility.

Specimen: Urine
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Sperm Concentration Test



Sperm Concentration Test is an in vitro qualitative detection of semen sperm SP10 proteins and can be used in the auxiliary diagnosis of male infertility. At the same time, it provides fertility guidance for age-appropriate couples.

Specimen: Semen
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Strip: Cost effective. Different sizes of strips are available
 Cassette: Customized based on requirements

Test Procedure				
Cassette: Lay the cassette flat	 Draw urine	 Dispense 3 drops into the sample well.	 read result between 5-10 minutes	 Positive Negative Invalid
Strip: immerse the strip in the urine for at least 5 seconds	 Lay the strip flat	 read result between 5-10 minutes	 Positive Negative Invalid	 read result between 5-10 minutes
Midstream: Remove the cap, Urinate on the absorbent tip directly till it is thoroughly wet at least 5 seconds.	 Lay the strip flat	 read result between 5-10 minutes	 Positive Negative Invalid	 read result between 5-10 minutes

Test Procedure			
 Collect sperm by provided. Dispense 3 drops into the cup and stay 60 minutes.	 Stir sperm 10 times by translocator.	 Transfer the sperm liquid into the chasing 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 into the sample well.	 read result between 5-10 minutes	 Positive Negative Invalid

Anti-Müllerian Hormone (AMH) Rapid Test Kit



The AMH Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of the anti-Mullerian Hormone in whole blood, serum or plasma to aid in the diagnosis of ovarian functions.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months



Fetal Fibronectin (fFN) Rapid Test Kit

The fetal fibronectin (fFN) Rapid Test Kit is an immunochromatographic test kit for detection of fFN in vaginal secretions during pregnancy. The test is intended for professional use to help diagnose if the preterm delivery is likely to occur in pregnant women. The test may be run on patients between 24 and 34 weeks gestation.

Specimen: Vaginal Swab
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure			
<p>Collect vaginal secretion by swab,insert the swab in collectiontube to the bottom.</p>	<p>Rotate and squeeze the tubeseveral times with fingers fromoutside of the tube to unwater theswab. Remove the swab.</p>	<p>Screw the cap on the sampletube.</p>	<p>Screw the cap of tube tightly.Shake up and down 5-10 times.</p>
<p>Unscrew the cap of the collection tube.</p>	<p>Add 2 drops of mixed sample into sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Progesterone (PROG) Rapid Test Kit

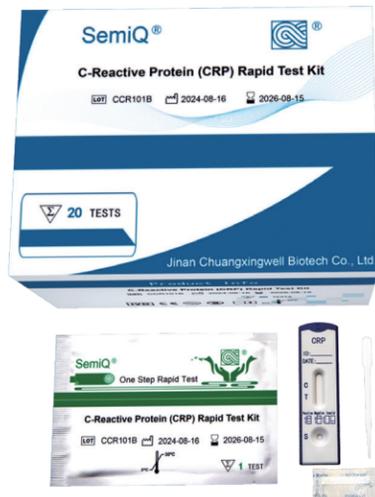


The Progesterone (PROG) Rapid Test Kit is used for in vitro quantitative determination of progesterone concentration in human serum or plasma specimen. The test is used as an aid to track ovulation, monitor the effect of progesterone therapies and in early pregnancy to help diagnose an ectopic or failing pregnancy.

Specimen: Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure					
Product Name	Specimen	Format	Sensitivity	Package Size	Certificate
HCG Pregnancy Rapid Test Kit	Urine/Serum/plasma	Strip	25mIU/ml	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
		Cassette			
		Midstream			
HCG Pregnancy Test is for the rapid, visual and qualitative determination of human chorionic gonadotropin (HCG) in urine or urine/serum specimen to aid in the early detection of pregnancy.					
Luteinizing Hormone (LH) Ovulation Rapid Test Kit	Urine	Strip	25mIU/ml	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
		Cassette			
		Midstream			
LH Ovulation Test is a complete system to help predict the time of ovulation and peak fertility. It is during this fertile time that pregnancy is most likely to occur. LH Ovulation Test detects the luteinizing hormone (LH) surge in urine, signaling that ovulation is likely to occur in the next 24-48 hours.					
Follicle-Stimulating Hormone(FSH)Test	Urine	Strip	25mIU/ml	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
		Cassette			
		Midstream			
FSH (Follicle-Stimulating Hormone) Test is used to detect FSH in the urine; this helps to check the function of the pituitary gland and check if hormone levels are normal.The test can be used to see if a woman has started the menopause. The product may also be used (along with other tests) to test for possible causes of both male and female infertility.					
Sperm Concentration Test	sperm	Cassette	15 million sperm/ml	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
Sperm Concentration Test is in vitro qualitative detection of semen sperm SP10 proteins and can be used in the auxiliary diagnosis of male infertility. At the same time provide fertility guidance for age-appropriate couples.					
Anti-Müllerian Hormone (AMH) Rapid Test Kit	whole blood	Cassette	7mIU/ml	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
The AMH Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of the anti-Müllerian Hormone in whole blood, serum or plasma to aid in the diagnosis of ovarian functions.					
Fetal Fibronectin (fFN) Rapid Test Kit	Vaginal Swab	Cassette	50mIU/ml	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
The fetal fibronectin (fFN) Rapid Test Kit is an immunochromatographic test kit for detection of fFN in vaginal secretions during pregnancy. The test is intended for professional use to help diagnose if the preterm delivery is likely to occur in pregnant women. The test may be run on patients between 24 and 34 weeks gestation.					
Progesterone (PROG) Rapid Test Kit	Serum/plasma	Cassette	5mIU/ml	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
The Progesterone (PROG) Rapid Test Kit is used for in vitro quantitative determination of progesterone concentration in human serum or plasma specimen. The test is used as an aid to track ovulation, monitor the effect of progesterone therapies and in early pregnancy to help diagnose an ectopic or failing pregnancy.					



C-Reactive Protein (CRP) Rapid Test Kit

The C-Reactive Protein (CRP) Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human CRP in whole blood, serum or plasma as an aid in the diagnosis of inflammatory condition.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months



Serum Amyloid A (SAA) Rapid Test Kit

The SAA Rapid Test is for the qualitative detection of human SAA in whole blood, serum or plasma as an aid in the diagnosis of inflammatory condition.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

CRP/SAA Combo Rapid Test Kit



The CRP/SAA Combo Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human SAA and CRP in whole blood, serum or plasma as an aid in the diagnosis of inflammatory condition. The cutoff for SAA is 10 µg/mL and cut-off for CRP is 10 µg/mL.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Procalcitonin (PCT) Rapid Test Kit



The PCT Rapid Test Device (Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of Procalcitonin in human whole blood, serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of inflammation.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Interleukin-6 (IL-6) Rapid Test Kit



The Interleukin-6 (IL-6) Rapid Test Kit is designed for the semi-quantitative evaluation of human Interleukin-6 (IL-6) in serum or plasma. IL-6 is an early marker in acute inflammation and this test is mainly used for the auxiliary diagnosis of bacterial infectious diseases, sepsis and septicemia.

Specimen: Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months



Calprotectin (CALP) Rapid Test Kit

The Calprotectin (CALP) Rapid Test Kit is a rapid immunological test intended for the qualitative detection of Calprotectin in human feces specimen. The test is used as an aid in the diagnosis of inflammatory bowel disease.

Specimen: Feces
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months

Test Procedure		
<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. 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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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 5-10 minutes.</p>	<p>Positive Negative Invalid</p>

Test Procedure

Product Name	Specimen	Format	Sensitivity	Package Size	Certificate
C-Reactive Protein (CRP) Rapid Test Kit	Whole Blood /Serum/Plasma	Cassette	10mg/l	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
The C-Reactive Protein (CRP) Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human CRP in whole blood, serum or plasma as an aid in the diagnosis of inflammatory condition.					
Serum Amyloid A (SAA) Rapid Test Kit	Whole Blood /Serum/Plasma	Cassette	10mg/l	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
The SAA Rapid Test is for the qualitative detection of human SAA in whole blood, serum or plasma as an aid in the diagnosis of inflammatory condition.					
CRP/SAA Combo Rapid Test Kit	Whole Blood /Serum/Plasma	Cassette	CRP:10mg/l SAA:10mg/l	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
The CRP/SAA Combo Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human SAA and CRP in whole blood, serum or plasma as an aid in the diagnosis of inflammatory condition. The cutoff for SAA is 10 µg/mL and cut-off for CRP is 10 µg/mL.					
Procalcitonin (PCT) Rapid Test Kit	Whole Blood /Serum/Plasma	Cassette	0.5ng/ml	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
The PCT Rapid Test Device (Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of Procalcitonin in human whole blood, serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of inflammation.					
Interleukin-6 (IL-6) Rapid Test Kit	Serum/Plasma	Cassette	100pg/ml	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
The Interleukin-6 (IL-6) Rapid Test Kit is designed for the semi-quantitative evaluation of human Interleukin-6 (IL-6) in serum or plasma. IL-6 is an early marker in acute inflammation and this test is mainly used for the auxiliary diagnosis of bacterial infectious diseases, sepsis and septicemia.					
Calprotectin (CALP) Rapid Test Kit	Feces	Cassette	50ug/g	1 pcs/bag 25 pcs/box 40 boxes/carton	CE
The Calprotectin (CALP) Rapid Test Kit is a rapid immunological test intended for the qualitative detection of Calprotectin in human feces specimen . The test is used as an aid in the diagnosis of inflammatory bowel disease.					

COVID-19 Rapid Test Kit

The COVID-19 Antigen Rapid Test Kit is a state-of-the-art diagnostic tool designed for the qualitative detection of SARS-CoV-2 viral nucleocapsid antigens in human nasal swab samples. Ideal for both professional and at-home use, enabling timely decision-making for infection control.

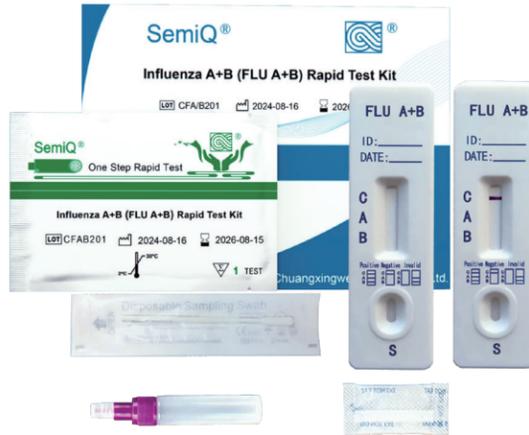


Specimen: Nasal / Throat Swab
 Result time: 15 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure

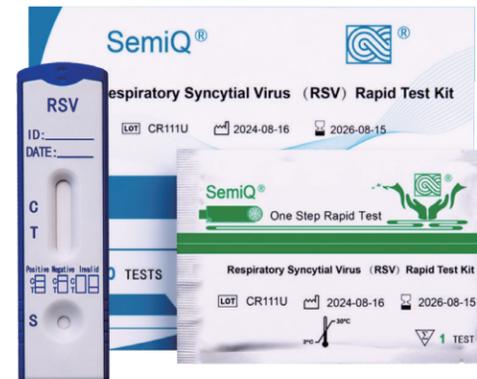
<p>Place the swab into one of patient's nostrils until reaches the posterior nasopharynx.</p>	<p>Slowly rotate the swab 3-5 times over the surface of the posterior nasopharynx.</p>	<p>Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.</p>
<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Shake well before using.</p>
<p>Add 3 drops of specimen to the sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Influenza A+B Rapid Test Kit



Influenza A+B Ag Test is the chromatographic assay used for qualitative detection of influenza virus type A and B nucleoprotein antigens in human nasopharyngeal swab or nasal swab specimens.

Specimen: Nasopharyngeal Swab/ Throat Swab
 Result time: 15 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months



Respiratory Syncytial Virus (RSV) Rapid Test Kit

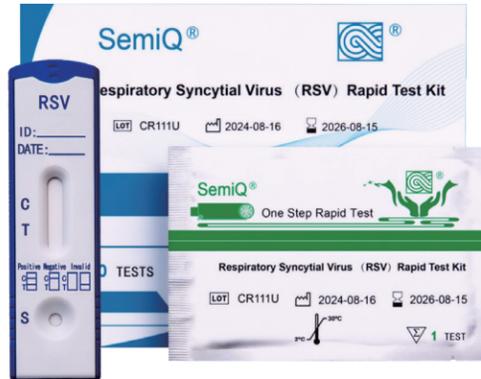
RSV Ag Test is a rapid chromatographic immunoassay for the qualitative detection of Respiratory syncytial virus antigen in human nasopharyngeal swab specimens to aid the diagnosis of Respiratory syncytial virus infection. An essential testing for protecting your health when you suspect infect Respiratory syncytial virus.

Specimen: Nasopharyngeal Swab
 Result time: 15 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure		
<p>Place the swab into one of patient's nostrils until reaches the posterior nasopharynx.</p>	<p>Slowly rotate the swab 3-5 times over the surface of the posterior nasopharynx.</p>	<p>Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.</p>
<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Shake well before using.</p>
<p>Add 3 drops of specimen to the sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Test Procedure		
<p>Place the swab into one of patient's nostrils until reaches the posterior nasopharynx.</p>	<p>Slowly rotate the swab 3-5 times over the surface of the posterior nasopharynx.</p>	<p>Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.</p>
<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Shake well before using.</p>
<p>Add 3 drops of specimen to the sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Mycoplasma Pneumoniae (MP) Rapid Test Kit



Mycoplasma Pneumoniae (MP) Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Mycoplasma pneumoniae (MP) antigens in nasopharyngeal swab or throat swab. It is intended to aid in the rapid differential diagnosis of MP infections.

Specimen: Nasopharyngeal Swab/ Throat Swab
 Result time: 15 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Adenovirus (ADV) Rapid Test Kit



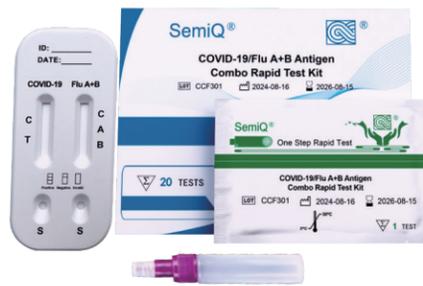
Mycoplasma Pneumoniae (MP) Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Mycoplasma pneumoniae (MP) antigens in nasopharyngeal swab or throat swab. It is intended to aid in the rapid differential diagnosis of MP infections.

Specimen: Nasopharyngeal Swab/ Throat Swab
 Result time: 15 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure		
<p>Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx.</p>	<p>Slowly rotate the swab 3-5 times over the surface of the posterior nasopharynx.</p>	<p>Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.</p>
<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Shake well before using.</p>
<p>Add 3 drops of specimen to the sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Test Procedure		
<p>Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx.</p>	<p>Slowly rotate the swab 3-5 times over the surface of the posterior nasopharynx.</p>	<p>Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.</p>
<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Shake well before using.</p>
<p>Add 3 drops of specimen to the sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

COVID-19/Flu A+B Antigen Combo Rapid Test Kit



Mycoplasma Pneumoniae (MP) Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Mycoplasma pneumoniae (MP) antigens in nasopharyngeal swab or throat swab. It is intended to aid in the rapid differential diagnosis of MP infections.

Specimen: Nasal/Nasopharyngeal Swab
 Result time: 15 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months

Test Procedure		
<p>Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx.</p>	<p>Slowly rotate the swab 3-5 times over the surface of the posterior nasopharynx.</p>	<p>Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.</p>
<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Shake well before using.</p>
<p>Add 3 drops of specimen to the sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

COVID-19/FLU A+B/RSV Antigen Combo Rapid Test Kit



Mycoplasma Pneumoniae (MP) Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Mycoplasma pneumoniae (MP) antigens in nasopharyngeal swab or throat swab. It is intended to aid in the rapid differential diagnosis of MP infections.

Specimen: Nasal/Nasopharyngeal Swab
 Result time: 15 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months

Test Procedure		
<p>Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx.</p>	<p>Slowly rotate the swab 3-5 times over the surface of the posterior nasopharynx.</p>	<p>Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.</p>
<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Shake well before using.</p>
<p>Add 3 drops of specimen to the sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

COVID-19/FLU A+B/RSV/MP/ADV Combo Rapid Test Kit



This kit is only used for the in vitro qualitative detection of respiratory multipathogen antigen COVID-19/Influenza A virus/Influenza B virus/Respiratory syncytialvirus/Mycoplasma pneumoniae/Adenovirus from human nasal/nasopharyngeal Swabspecimens. The test is intended for the differentiation of SARS-CoV-2/Influenza A virus/Influenza B virus/Respiratory syncytial virus/Mycoplasma pneumoniae/Adenovirus from individuals who are suspected of respiratory tract disease infection.

Strep A Antigen Rapid Test Kit



Accurate • User-Friendly • CLIA-Waived
Our Strep A Rapid Test Cassette is a state-of-the-art immunochromatographic assay designed for the qualitative detection of Group A Streptococcus antigen in throat swab specimens. Engineered for precision and efficiency, this test delivers reliable results within 15 minutes, empowering healthcare professionals to make timely clinical decisions.

Specimen: Throat Swab
Result time: 15 minutes
Material: Plastic
Certification: CE, ISO13485
Storage Temperature: 2-30 °C
Shelf Life: 24 Months

Test Procedure		
<p>Place the swab into one of patient's nostrils until reaches the posterior nasopharynx.</p>	<p>Slowly rotate the swab 3-5 times over the surface of the posterior nasopharynx.</p>	<p>Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.</p>
<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Shake well before using.</p>
<p>Add 3 drops of specimen to the sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Test Procedure		
<p>Place the swab into one of patient's nostrils until reaches the posterior nasopharynx.</p>	<p>Slowly rotate the swab 3-5 times over the surface of the posterior nasopharynx.</p>	<p>Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.</p>
<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Shake well before using.</p>
<p>Add 3 drops of specimen to the sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Tuberculosis (TB) Rapid Test Kit



The Tuberculosis (TB) Rapid Test Kit (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens. This test is intended for the rapid diagnosis of active tuberculosis (TB).

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months



S.typhi/S.paratyphi Antigen Rapid Test Kit

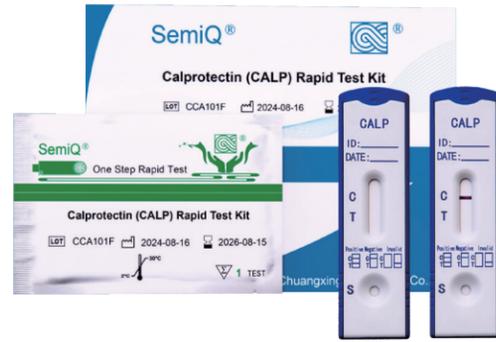
The S.typhi/S.paratyphi Antigen Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Salmonella typhi and Salmonella paratyphi antigens in human fecal specimens to aid in the diagnosis of Salmonella typhi and paratyphi infection.

Specimen: Feces
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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 5-10 minutes.</p>	<p>Positive Negative Invalid</p>

H.pylori Antigen Rapid Test Kit



The H. pylori Rapid Test Kit is a cutting-edge immunochromatographic assay designed for the qualitative detection of Helicobacter pylori antibodies (IgG/IgA) in human serum, plasma, or whole blood samples. Aiding in the prompt identification of H. pylori infections linked to gastritis, peptic ulcers, and gastric cancer risk.

Specimen: Feces
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Syphilis (TP) Antibody Rapid Test Kit



The Syphilis (TP) Rapid Test Kit is a highly sensitive immunochromatographic assay designed for the qualitative detection of Treponema pallidum antibodies (IgG/IgM) in human serum, plasma, or whole blood samples. Allows for timely screening and management of syphilis infections, a critical step in preventing severe complications such as neurosyphilis and congenital transmission.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure		
<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 5-10 minutes.</p>	<p>Positive Negative Invalid</p>

Test Procedure		
<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. 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>	<p>Positive Negative Invalid</p>

Dengue Combo Rapid Test kit



The Tuberculosis (TB) Rapid Test Kit (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens. This test is intended for the rapid diagnosis of active tuberculosis (TB).

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months



Thyroid Stimulating Hormone (TSH) Rapid Test Kit

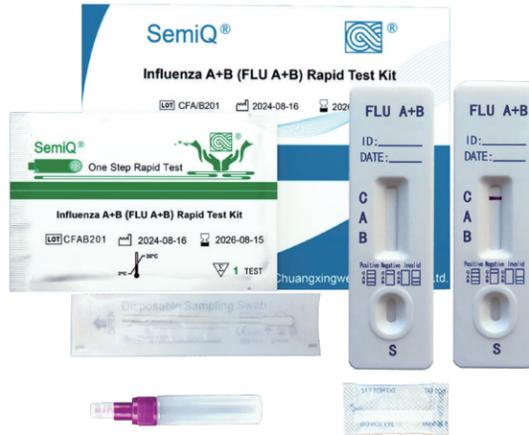
The TSH Rapid Quantitative Test Kit is a highly precise immunoassay designed for the quantitative measurement of thyroid-stimulating hormone (TSH) in human serum, plasma, or whole blood. This advanced diagnostic tool aids in the evaluation of thyroid function, supporting the diagnosis and management of thyroid disorders.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months
 Sensitivity: 5 µIU/ml

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Myoglobin (MYO) Rapid Test Kit



The Tuberculosis (TB) Rapid Test Kit (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens. This test is intended for the rapid diagnosis of active tuberculosis (TB).

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months



Creatine Kinase MB (CK-MB) Rapid Test Kit

The CK-MB Rapid Test is a highly accurate immunochromatographic assay for the detection of creatine kinase-MB isozymes in human serum or plasma samples. As an important biomarker of myocardial injury, this kit supports timely clinical decision making in emergency and critical care settings by enabling rapid and reliable diagnosis of acute myocardial infarction (AMI).

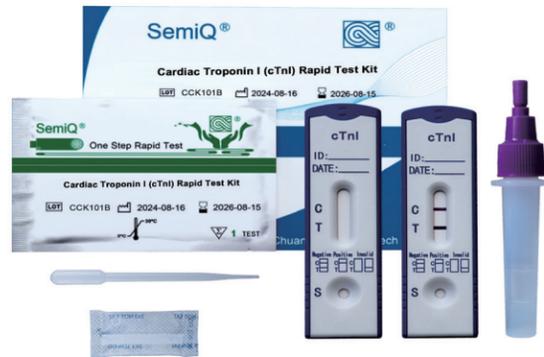
Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months



Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Cardiac Troponin I (cTnI) Rapid Test Kit



The Tuberculosis (TB) Rapid Test Kit (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens. This test is intended for the rapid diagnosis of active tuberculosis (TB).

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

MYO/CKMB/cTnI Combo Rapid Test Kit



The MYO/CK-MB/cTnI Combo Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human Myoglobin, CK-MB and cardiac Troponin I in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

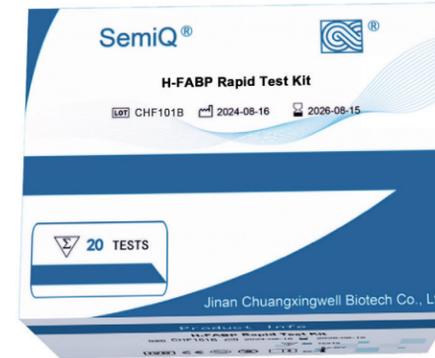
NT-proBNP Rapid Test Kit



The NT-proBNP Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of human NT-proBNP in whole blood, serum or plasma as an aid in the diagnosis of congestive heart failure (CHF).

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 C
 Shelf Life: 24 Months

H-FABP Rapid Test Kit



The H-FABP Rapid Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of Heart Type Fatty Acid Binding Protein (H-FABP) in human whole blood, serum, and plasma samples as an aid in the diagnosis of acute myocardial infarction (AMI) (heart attack).

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 C
 Shelf Life: 24 Months



Test Procedure		
<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>	<p>Positive Negative Invalid</p>

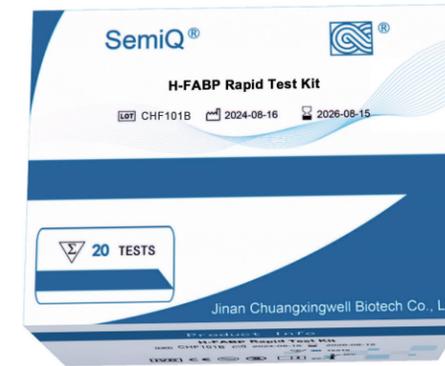
Test Procedure		
<p>Carefully pull off and dispose the released cap of the lancet.</p>	<p>Use the alcohol pad to clean the fingertip of the middle or ring finger as the puncturesite.</p>	<p>Press the lancet, on the side from where the cap was extracted; against the fingertip (it is advisable the ring 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>	<p>Positive Negative Invalid</p>

D-Dimer Rapid Test Kit



A CLIA-waived immunochromatographic assay for detecting D-Dimer ($\geq 0.5 \mu\text{g/mL}$) in whole blood, plasma, or serum. Utilizes monoclonal antibodies to deliver results in 15 minutes with >98% sensitivity and >95% specificity. CE-marked, ISO 13485 compliant, ideal for point-of-care thrombosis screening.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months
 Sensitivity: 500 ng/ml



Carcinoembryonic (CEA) Rapid Test Kit

A rapid immunochromatographic assay for semi-quantitative detection of Carcinoembryonic Antigen (CEA) in serum/plasma. Delivers results in 15 minutes with >95% sensitivity and >90% specificity, aiding colorectal cancer screening, therapy monitoring, and recurrence assessment. CE-certified, CLIA-waived, and operable at room temperature. Ideal for labs and clinics.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months
 Sensitivity: 5 ng/mL

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

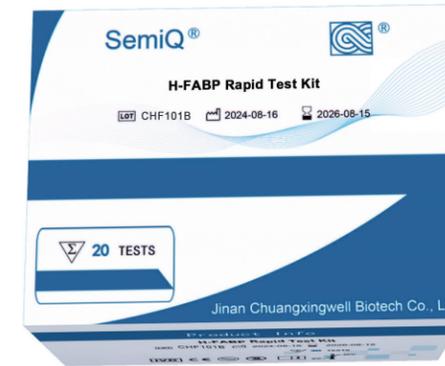
Test Procedure		
<p>Carefully pull off and dispose the released cap of the lancet.</p>	<p>Use the alcohol pad to clean the fingertip of the middle or ring finger as the puncturesite.</p>	<p>Press the lancet, on the side from where the cap was extracted; against the fingertip (it is advisable the ring 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>	<p>Positive Negative Invalid</p>

Alpha Fetoprotein (AFP) Rapid Test Kit



A rapid immunochromatographic assay for qualitative detection of AFP in serum, plasma, or whole blood. Utilizing monoclonal antibodies, it delivers results in 15 minutes, aiding in hepatocellular carcinoma screening, prenatal neural tube defect assessment, and germ cell tumor monitoring. CLIA-waived with >97% sensitivity/specificity. CE-marked for point-of-care use.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months
 Sensitivity: 10 ng/mL



Fecal Occult Blood (FOB) Rapid Test Kit

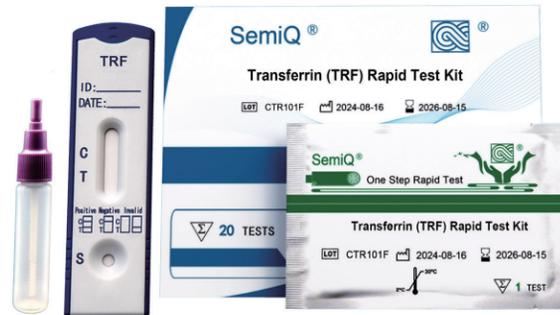
A rapid, non-invasive diagnostic tool using colloidal gold immunochromatography to detect occult blood in stool samples within 5–10 minutes. Ideal for colorectal cancer screening and GI bleeding assessment, with >99% sensitivity, CE/FDA certification, and no instrumentation required. Suitable for clinics, labs, and home use.

Specimen: Feces
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months
 Sensitivity: 50 ng/mL

Test Procedure		
<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. 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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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 5-10 minutes.</p>	<p>Positive Negative Invalid</p>

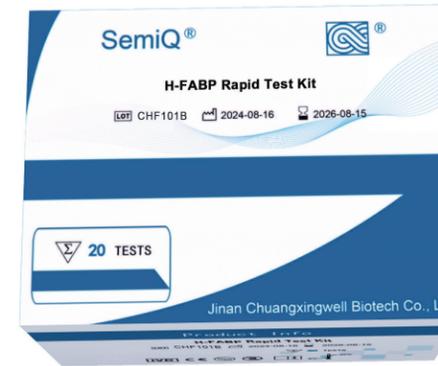
Transferrin (TRF) Rapid Test Kit



A rapid immunochromatographic assay for qualitative/semi-quantitative detection of transferrin in human serum, plasma, or urine. Utilizing monoclonal antibody technology, it delivers results in 10 minutes with >97% sensitivity/specificity, aiding diagnosis of iron-deficiency anemia, protein-losing enteropathy, and renal disorders.

Specimen: Feces
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months
 Sensitivity: 40 ng/mL

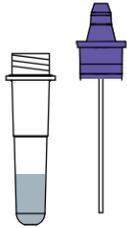
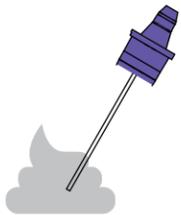
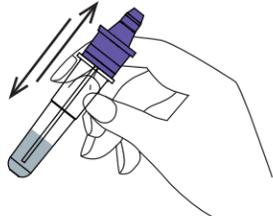
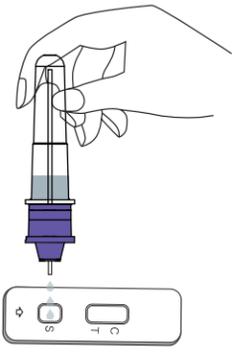
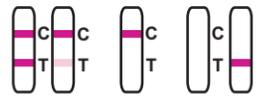
Fecal Occult Blood/Transferrin (FOB/TRF) Rapid Test Kit



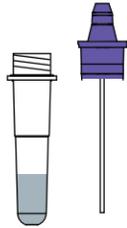
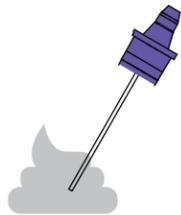
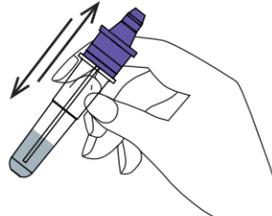
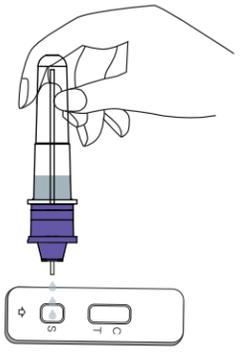
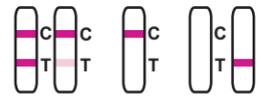
This immunochromatographic assay enables simultaneous detection of occult blood and transferrin in stool samples, aiding in gastrointestinal bleeding screening. With >95% sensitivity/specificity, it differentiates lower/upper GI bleeding within 10 minutes. CE-marked and CLIA-waived, ideal for clinics, labs, and home testing. No instrumentation required. Storage: 2-30°C.

Specimen: Feces
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30°C
 Shelf Life: 24 Months
 Sensitivity: FOB: 50 ng/mL FOB: 50 ng/mL

Test Procedure

 <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 5-10 minutes.</p>	 <p>Positive Negative Invalid</p>

Test Procedure

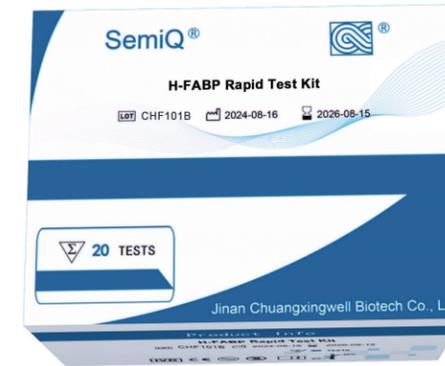
 <p>Unscrew the cap of the feces collection tube and take out the applicator stick.</p>	 <p>Dip the applicator stick into stool specimen at 3 different sites.</p>	 <p>Replace the applicator in the tube and tighten securely. Shake well before use.</p>
 <p>Then add 2-3 drops into the sample well.</p>	 <p>read result between 5-10 minutes.</p>	 <p>Positive Negative Invalid</p>

Ferritin (Fer) Rapid Test Kit



A rapid immunochromatographic assay for quantitative detection of ferritin in serum/plasma. Delivers results in 10-15 minutes with >95% sensitivity and >90% specificity. CE-certified and ISO 13485 compliant, it enables precise anemia diagnosis, iron deficiency screening, and chronic disease monitoring in clinics, labs, and emergency settings. No instrumentation required.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months
 Sensitivity:20 ng/mL



Thyroid Stimulating Hormone (TSH) Rapid Test Kit

A CLIA-waived immunochromatographic assay for quantitative TSH detection in serum, plasma, or whole blood. Delivers results in 10 minutes with >99% clinical accuracy, aiding diagnosis of hypothyroidism and hyperthyroidism. CE/ISO-certified, ideal for point-of-care clinics and laboratories.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months
 Sensitivity:5 µU/ml

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Prostate Specific Antigen (PSA) Rapid Test Kit



This immunochromatographic assay provides rapid, semi-quantitative detection of PSA in serum, plasma, or whole blood within 15 minutes. Utilizing monoclonal antibody technology, it delivers >95% sensitivity/specificity for prostate health monitoring and early cancer screening. CLIA-waived, CE-marked, and ideal for point-of-care use in clinics or labs.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months
 Sensitivity: 4 ng/mL

25-OH VD Rapid Test Kit



This immunochromatographic assay quantitatively detects 25-hydroxy vitamin D in serum/plasma/fingerstick blood within 15 minutes. Featuring 95% sensitivity and 97% specificity (cutoff: 20 ng/mL), its CLIA-waived design requires no instruments, ideal for primary care and home monitoring. CE-marked and ISO 13485-certified, ensuring reliable vitamin D status assessment.

Specimen: Whole Blood /Serum/Plasma
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months
 Sensitivity: 30 ng/mL

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Test Procedure		
<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>	<p>Positive Negative Invalid</p>

Candida albicans Antigen Rapid Test Kit



Candida albicans Antigen Rapid Test Kit is an immunochromatographic test kit for the rapid detection of Candida albicans infections, which is mainly used in clinical aids for the diagnosis of Candida vaginitis and other infections.

Specimen: Vaginal Swab
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 C
 Shelf Life: 24 Months

Test Procedure			
<p>Collect vaginal secretion by swab. Insert the swab in collection tube to the bottom.</p>	<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Screw the cap of tube tightly. Shake up and down 5-10 times.</p>
<p>Unscrew the cap of the collection tube.</p>	<p>Add 2 drops of mixed sample into sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Trichomonas vaginalis Antigen Rapid Test Kit



Trichomonas vaginalis Antigen Rapid Test Kit is an immunochromatographic test kit for the rapid detection of Trichomonas vaginalis antigen for the clinical diagnosis of Trichomonas vaginitis/urethritis.

Specimen: Vaginal Swab
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 C
 Shelf Life: 24 Months

Test Procedure			
<p>Collect vaginal secretion by swab. Insert the swab in collection tube to the bottom.</p>	<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Screw the cap of tube tightly. Shake up and down 5-10 times.</p>
<p>Unscrew the cap of the collection tube.</p>	<p>Add 2 drops of mixed sample into sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Gardnerella vaginalis Antigen Rapid Test Kit



Gardnerella vaginalis antigen rapid test kit is an immunochromatographic test kit for the detection of Gardnerella vaginalis antigen, mainly used to assist in the diagnosis of bacterial vaginosis.

Specimen: Vaginal Swab
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure			
<p>Collect vaginal secretion by swab, insert the swab in collection tube to the bottom.</p>	<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Screw the cap of tube tightly. Shake up and down 5-10 times.</p>
<p>Unscrew the cap of the collection tube.</p>	<p>Add 2 drops of mixed sample into sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Vaginitis Combo Rapid Test Kit



Vaginitis Combo Rapid Test Kit is an immunochromatographic test kit for the detection of Candida albicans, Trichomonas vaginalis, Gardnerella vaginalis in vaginal secretions and is suitable for assisting in the diagnosis of vaginitis and urethritis.

Specimen: Vaginal Swab
 Result time: 10 minutes
 Material: Plastic
 Certification: CE, ISO13485
 Storage Temperature: 2-30 °C
 Shelf Life: 24 Months

Test Procedure			
<p>Collect vaginal secretion by swab, insert the swab in collection tube to the bottom.</p>	<p>Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.</p>	<p>Screw the cap on the sample tube.</p>	<p>Screw the cap of tube tightly. Shake up and down 5-10 times.</p>
<p>Unscrew the cap of the collection tube.</p>	<p>Add 2 drops of mixed sample into sample well.</p>	<p>Read results at 10-15 minutes. Do not interpret the result after 30 minutes.</p>	<p>Positive Negative Invalid</p>

Certification

ISO 13485 and CE CERTIFICATION

POSI CERTIFICATE

This is to certify that the Quality Management System of **Jinan Chuangxingwell Biotech Co., Ltd.**

Business License Number: 91370100MA3QPQA1R
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

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 **GBT 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: 381240177R05
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) Pilot 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: ies@riomavix.com
Tel.: +34 658 386 230 (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 13612:2002, EN ISO 23640:2015, EN ISO 20417:2021

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

EC Declaration of Conformity, DOC No.: CXWICE-DoC-1, A0

Company History



Company Strength

DEPARTAMENTO DE PRODUCTOS SANITARIOS

PS/1720/2024

EXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Comercial	Fecha de introducción en el mercado
Industria	Finalidad
α Milk Alcohol Rapid Test kit	01/05/2022
DIAGNOSTICO "IN VITRO"	El condonante para una lactancia segura.
Fabricante	País
Jinan Chuangxingwell Biotech Co., Ltd.	REPUBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

Con fecha 17/06/2024 ha sido registrada en la aplicación de Registro de Responsables de la puesta de 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: RIOMAVIX SL, Calle de Almansa 55, 1D, 28039 - Madrid (MADRID), Madrid, Comunidad de

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

4. Página(s) adicional(es) de productos sanitarios incluidos en esta comunicación: REGISTRO DE RESPONSABLES DE LA PUESTA EN EL MERCADO DE PRODUCTOS SANITARIOS DEPARTAMENTO DE PRODUCTOS SANITARIOS

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 confirming 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.: R2204039-B

Riomavix S.L. (ES-AR-000001202)
Calle de Almansa 55, 1D, Madrid 28039 Spain

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.