

YOUR RELIABLE PARTNER
IN IVD PRODUCTS
您可信赖的诊断试剂合作伙伴

PRODUCT CATALOGUE

产 品 宣 传 册

XC-001-01, Version Number: 3.2

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深圳康生保生物技术有限公司

Shenzhen Kang Sheng Bao Biotechnology Co., Ltd.

COMPANY PROFILE



Shenzhen Kang sheng Bao Biotechnology Co., Ltd. is a high-tech company specializing in the R & D, production and sales of IVD diagnosis reagents. Our company is committed to delivering high-quality products and maintaining a high level of customer service.

From its establishment in 2001, the company has been committed to building and maintaining its quality management system. It obtained ISO 13485 certification in 2008 and has held it continuously since then. The company's quality system integrates multinational regulatory requirements and is continuously improved, providing a solid foundation for product quality and strong support for customer service.

We focus on colloidal gold and fluorescent chromatographic technologies, forming four product lines: tumor markers, infection markers, cardiac markers, and hormone testing. Currently, more than 30 products are CE-certified, and 90% of our products are sold in the European market.

QUALIFICATIONS AND AWARDS

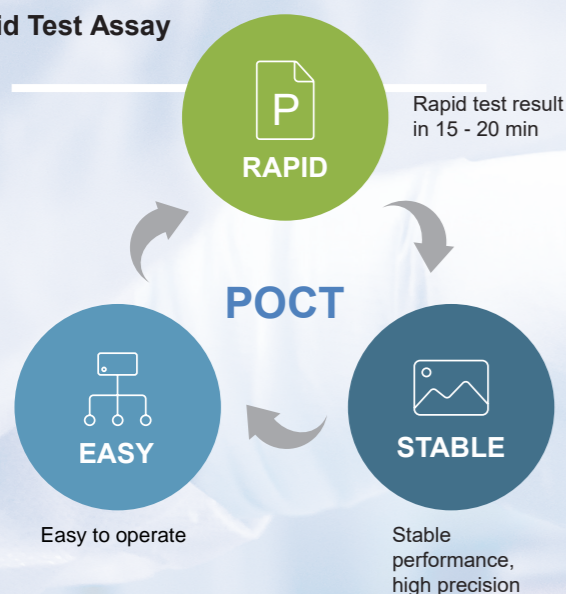


Cardiac Markers



Tumor Markers

Rapid Test Assay



Rapid test for cardiac markers includes:

H-FABP, cTnI, NT-proBNP
D-Dimer, CK-MB, Myo, cTnI/Myo/CK-MB, D-Dimer

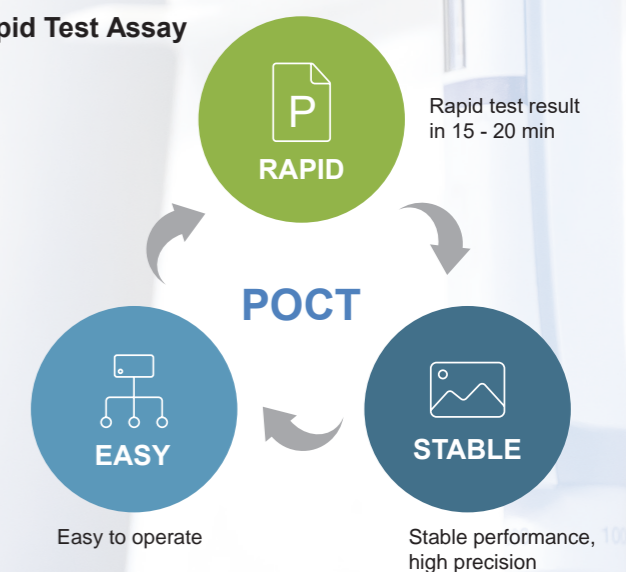
Specification: 20 tests / kit



Myocardial injury markers mainly include troponin T, troponin I, creatine kinase-MB (CK-MB), and myoglobin. When the myocardial cell membrane is intact, cardiac troponins do not pass into the bloodstream. Only when myocardial cells are damaged are troponins released into the blood circulation. The concentration of troponin in the blood is directly proportional to the extent of myocardial injury and has a half-life of up to 15 days, making it a key indicator for retrospective detection.

Tumor markers refer to substances that are characteristically present in malignant tumor cells, abnormally produced by malignant tumor cells, or produced by the host in response to tumor stimulation. They can reflect the occurrence and development of tumors and are used to monitor tumor response to treatment. Tumor markers are present in the tissues, body fluids, and excreta of cancer patients and can be detected by immunological, biological, and chemical methods.

Rapid Test Assay



Rapid test for tumor markers includes:

CEA
CA199
CA153
fPSA
t-PSA
FOB
AFP
CA125

Specification: 20 tests / kit



PSA/fPSA Rapid Test



INTENDED USE

The PSA/fPSA Rapid Test is a chromatographic immunoassay for the quantitative detection of total prostate-specific antigen (PSA) and free PSA in human serum or plasma. PSA/fPSA testing is intended as a screening tool for the early detection of prostate cancer.

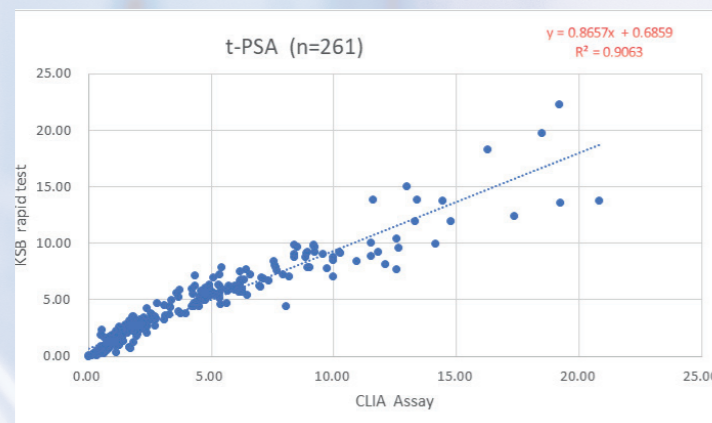
Specimen Type: Plasma / Serum
Measuring range: 0.5–10 ng/ml
Expected values: PSA <4 ng/ml
Reaction time: 20 min

Precision Performance

PSA Sample	Replicates	Mean (ng/mL)	SD	CV (%)
Level 1	80	3.95	0.30	7.5
Level 2	80	9.51	0.83	8.7

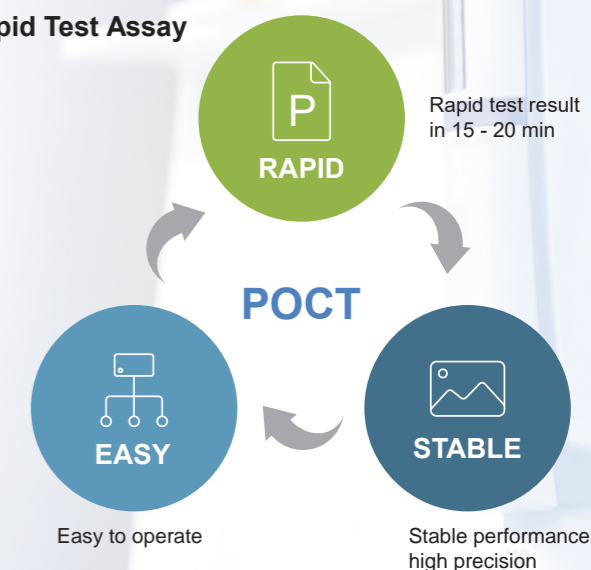
FPSA Sample	Replicates	Mean (ng/mL)	SD	CV (%)
Level 1	80	2	0.263	13.1
Level 2	80	5.99	0.698	11.6

Method Comparison



Inflammation Markers

Rapid Test Assay



Inflammation is a common pathological process in clinical practice and can occur in tissues and organs throughout the body. It is associated with conditions such as folliculitis, tonsillitis, pneumonia, hepatitis, and nephritis. Acute inflammation is typically characterized by redness, swelling, heat, pain, and impaired function. It is often accompanied by systemic responses such as fever and leukocytosis.

Rapid inflammatory marker tests includes:

NeoPT
PCT
hsCRP+CRP
IL-6
PCT/IL-6
CRP/SAA
S100 β
25-OH Vitamin D
Ferritin

Specification: 20 tests / kit

CRP Rapid Test



INTENDED USE

C-reactive protein (CRP) is an acute-phase protein that increases rapidly in plasma when the body is infected or tissues are damaged. The CRP Rapid Test is an in vitro immunochromatographic assay for the quantitative detection of C-reactive protein in whole blood, plasma, or serum. It is intended to aid in the detection of bacterial infections.

Specimen Type: Plasma / Serum / Whole Blood

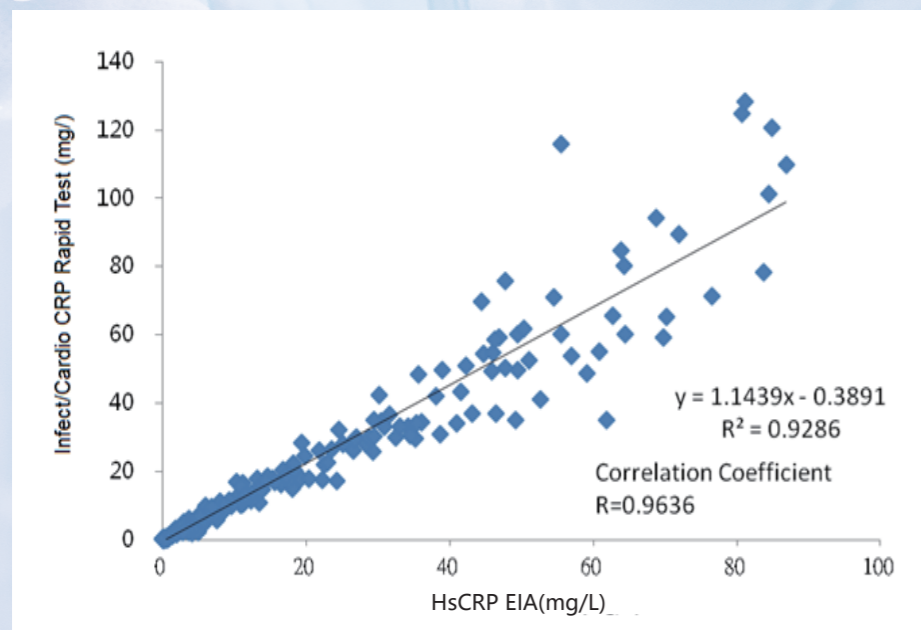
Measuring range: 0.5–100 mg/L

Expected values: ≤ 10 mg/L

Reaction time: 15 min

Precision: CV < 10%

Method Comparison



Hormone Markers

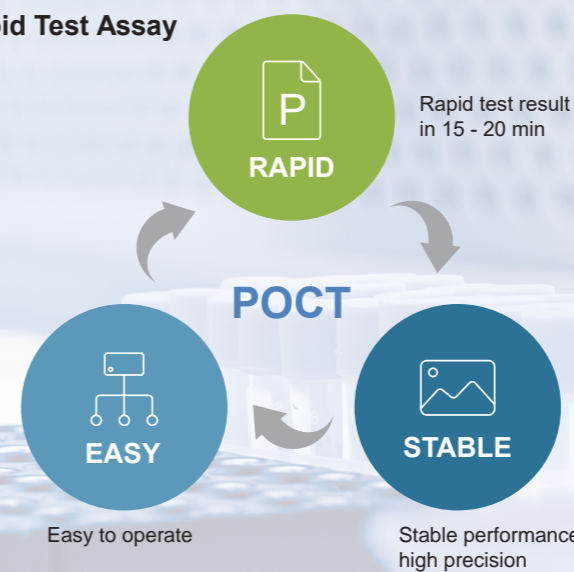


Rapid test for hormone markers includes:

β-HCG
FSH
LH
LH & FSH
TSH
Testosterone
E2
TSH
T3
T4
FT3
FT4
AMH
LH
PROG
PRL
SHBG

By measuring hormone levels, these tests help evaluate endocrine function and support the diagnosis of endocrine-related disorders. Commonly used hormone markers include follicle-stimulating hormone (FSH), luteinizing hormone (LH), estradiol (E2), progesterone (P), testosterone (T), and prolactin (PRL). These tests are used to support clinicians in screening for endocrine disorders and in assessing overall physiological function.

Rapid Test Assay



Specification: 20 tests / kit

Testosterone Rapid Test



INTENDED USE

The Testosterone rapid test is an in vitro immunochromatographic assay for the quantitative detection of testosterone in whole blood, plasma, or serum. It provides rapid results to support clinical assessment of androgen levels in a variety of diagnostic settings.

Specimen Type: Plasma / Serum / Whole Blood

Measuring range: 0.2–15 ng/mL.

Reaction time: 15 min

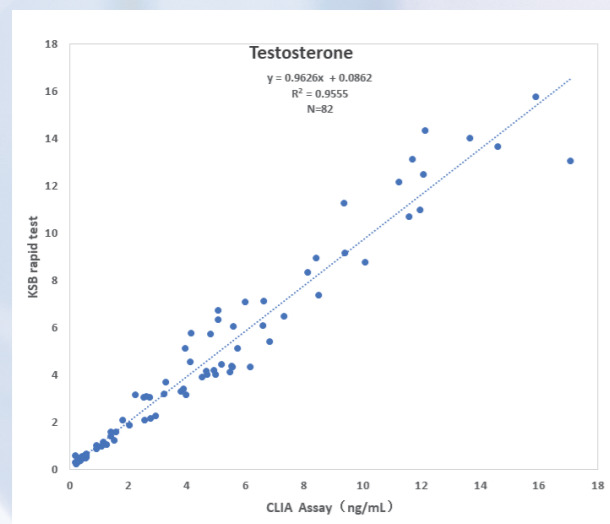
Expected values:

Male: 1.61–8.41 ng/mL

Female: < 0.61 ng/mL

Precision: CV < 15% (0.5–10 ng/mL)

Method Comparison



FSH Rapid Test



INTENDED USE

The FSH Rapid Test is an in vitro immunochromatographic assay for the quantitative detection of follicle-stimulating hormone (FSH) in whole blood, plasma, or serum. It is intended for the assessment of reproductive and endocrine function.

Specimen Type: Plasma / Serum / Whole Blood

Measuring range: 1–100 mIU/mL

Reaction time: 15 min

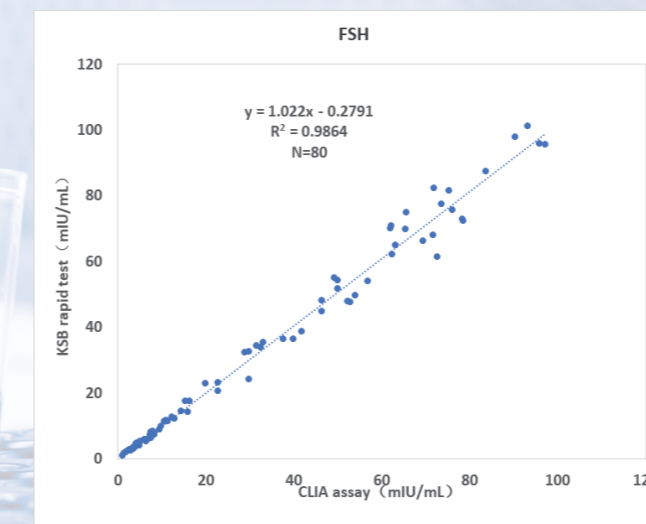
Reference Range

Female	
Follicular phase	4.46-12.43 mIU/mL
Mid-cycle	4.88-20.96 mIU/mL
Luteal phase	1.96-7.70 mIU/mL
Postmenopausal	22.70-130.00 mIU/mL

Male
1.5-12.40 mIU/mL

Precision: CV < 10% (1–100 mIU/mL)

Method Comparison



AMH Rapid Test



INTENDED USE

The AMH Rapid Test is an in vitro immunochromatographic assay for the quantitative detection of anti-Müllerian hormone (AMH) in human whole blood, plasma, or serum. It is intended to support the assessment of ovarian reserve and reproductive function.

Specimen Type: Plasma / Serum / Whole Blood

Measuring range: 0.1–16 ng/mL.

Reaction time: 15 min

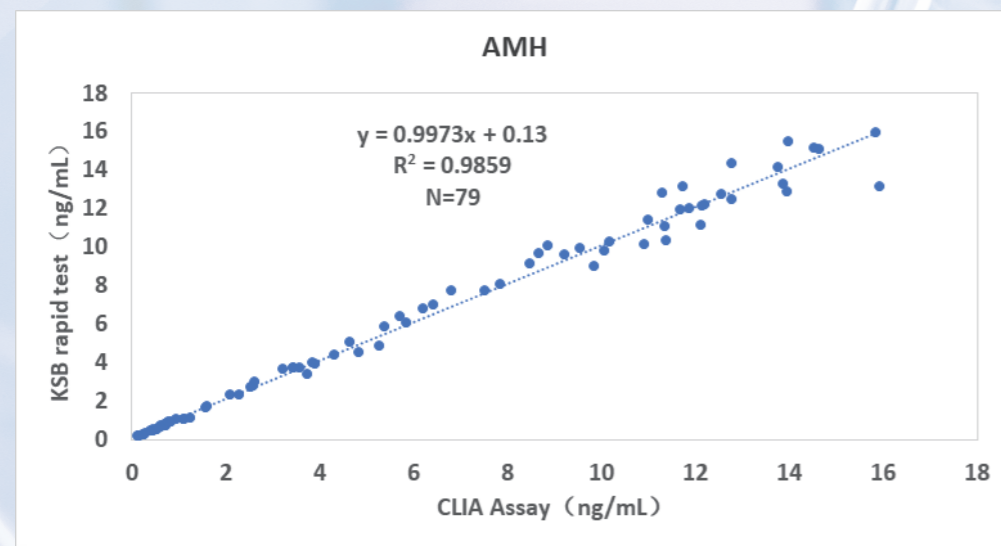
Reference Range

Female	
Age	Reference value
20-29	0.88-10.35 ng/ml
30-39	0.31-7.86 ng/ml
40-50	≤ 5.07 ng/ml

Male	
Age	Reference value
20-60	0.92-13.89 ng/ml

Precision: CV < 10% (0.3–16 ng/mL)

Method Comparison



PRL Rapid Test



INTENDED USE

The PRL Rapid Test is an in vitro immunochromatographic assay for the quantitative detection of prolactin in human whole blood, plasma, or serum. It is intended to support the evaluation of pituitary and endocrine function.

Specimen Type: Plasma / Serum / Whole Blood

Measuring range: 1–200 ng/mL.

Reaction time: 15 min

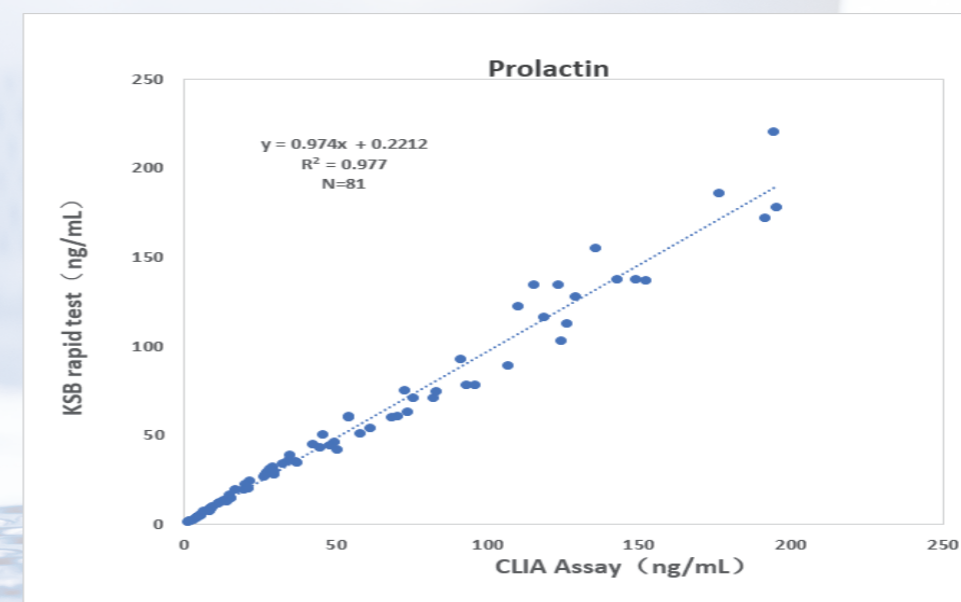
Reference Range

Male	3.45-17.42 ng/ml
Female	4.60-25.07 ng/ml

Precision Performance

1-100ng/ml	CV ≤ 10%
100-200ng/ml	CV ≤ 15%

Method Comparison



Vitamin D Rapid Test

INTENDED USE

The Vitamin D Rapid Test is intended for the in vitro quantitative measurement of 25-hydroxyvitamin D concentration in human serum, plasma, and whole blood samples. It is mainly used as an aid in the clinical diagnosis of conditions related to vitamin D deficiency.

Specimen Type: Plasma / Serum / Whole Blood / **Fingertip Blood**

Measuring Range: 5–100 ng/mL

Expected values:

Deficient: ≤ 20 ng/mL

Insufficient: 20–30 ng/mL

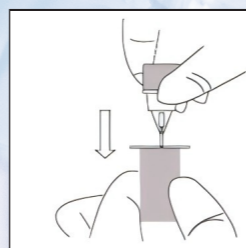
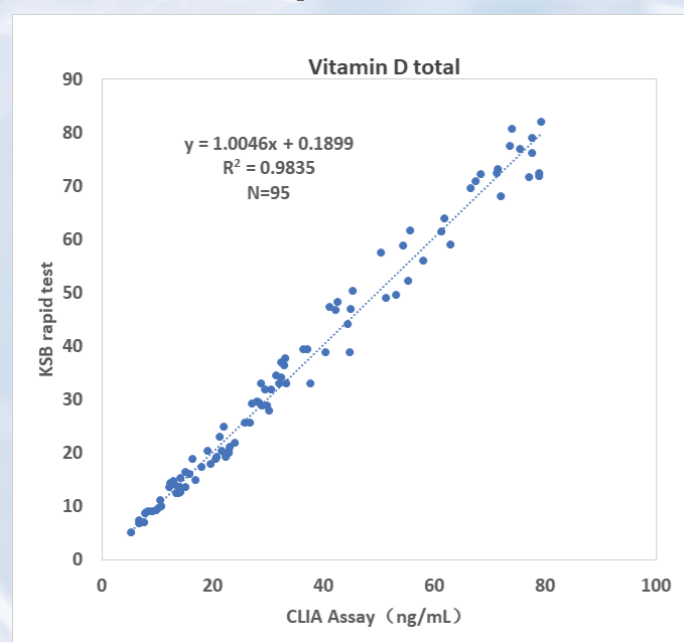
Sufficient: 30–100 ng/mL

Toxicity: > 100 ng/mL

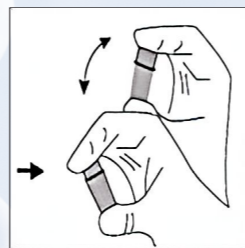
Reaction time: 15 min

Precision: CV $< 10\%$ (15–70 ng/mL)

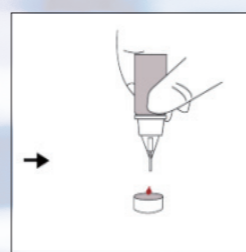
Method Comparison



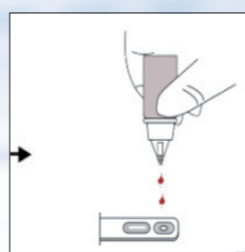
Tear open the aluminum foil pouch. After sampling, close the sampler and the sample diluent tube, then transfer the sample into the sample diluent.



Thoroughly mix the sample with the sample diluent.



Invert the sampler and dispense the first drop of the solution into the sampling cap, ensuring that no air bubbles are present at the sample application end.



Then add 4 drops vertically to the sample loading well of the test card.



Ferritin Rapid Test

INTENDED USE

The Ferritin rapid test is intended for the in vitro quantitative measurement of ferritin concentration in human serum, plasma, and whole blood samples. It is used as an aid in the assessment of iron storage status and related clinical conditions.

Specimen Type: Plasma / Serum / Whole Blood / **Fingertip Blood**

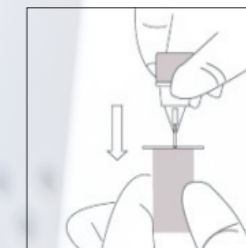
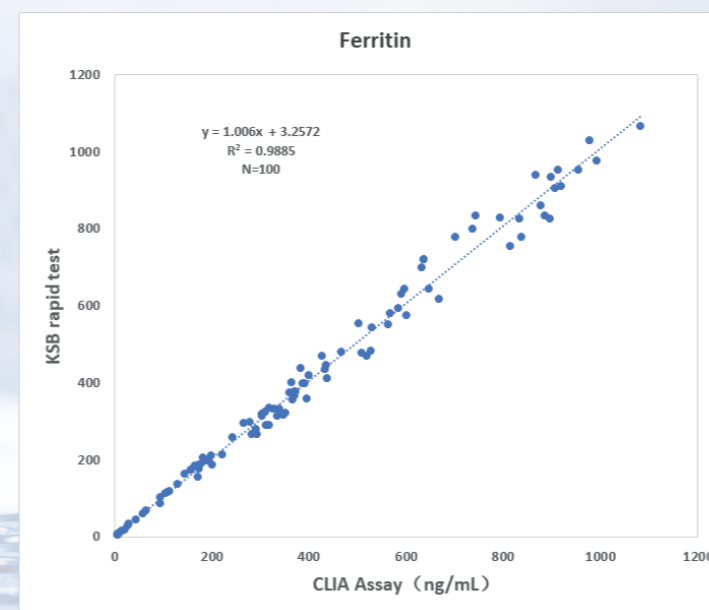
Measuring Range: 5–1000 ng/mL

Reference Range

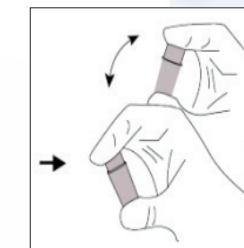
Male	Female
30-400ng/ml	13-150ng/ml

Precision: CV $< 10\%$ (5–1000 ng/mL)

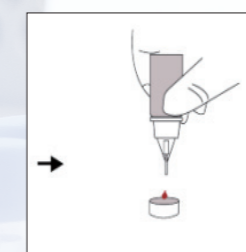
Method Comparison



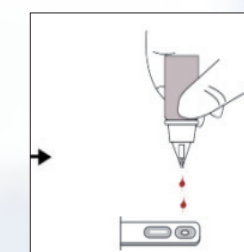
Tear open the aluminum foil pouch. After sampling, close the sampler and the sample diluent tube, then transfer the sample into the sample diluent.



Thoroughly mix the sample with the sample diluent.



Invert the sampler and dispense the first drop of the solution into the sampling cap, ensuring that no air bubbles are present at the sample application end.



Then add 3 drops vertically to the sample loading well of the test card.

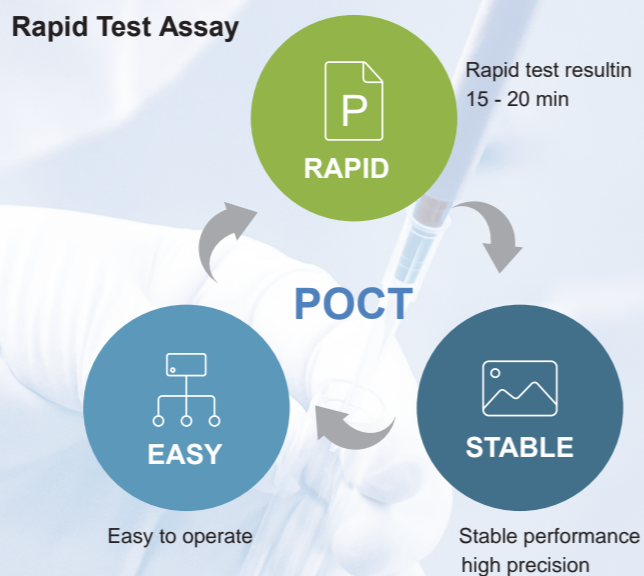


Infectious Markers



SARS-CoV-2/RSV/FluA/FluB Antigen Rapid Test

Our company proudly presents a comprehensive range of colloidal gold-based rapid test kits designed for the accurate detection of various infectious agents. This platform provides efficient solutions for both gastrointestinal and respiratory infections, delivering rapid and reliable results to support timely clinical decision-making.



Our product portfolio covers:

Gastrointestinal Infections: Test kits for *Helicobacter pylori*, Rotavirus, and Adenovirus, supporting the rapid diagnosis of common causes of viral gastroenteritis, gastritis, and other digestive disorders.

Respiratory Infections: A range of antigen detection kits for Influenza A & B, SARS-CoV-2 (COVID-19), Respiratory Syncytial Virus (RSV), and Streptococcus. These tests are essential for identifying the causative pathogens responsible for flu-like symptoms, sore throat, and other respiratory tract infections.

Rapid test for infectious markers includes:

Adenovirus Rapid Test
Rotavirus Rapid Test
Flu A & Flu B Rapid Test
<i>H.pylori</i> Ab Rapid Test
<i>H.pylori</i> Ag Rapid Test
RSV Rapid Test
Rotavirus & Adenovirus Rapid Test
Strep A Rapid Test
SARS-CoV-2/RSV/FluA/FluB Antigen Rapid Test

Specification: 20 tests / kit



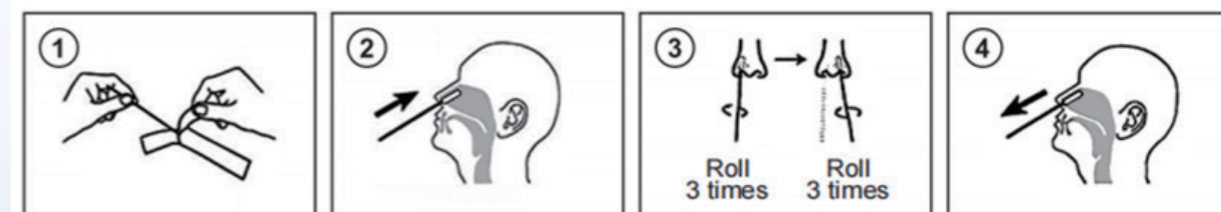
INTENDED USE

This kit is used for the in vitro qualitative detection of SARS-CoV-2 antigen, Influenza A virus antigen, Influenza B virus antigen, and Respiratory Syncytial Virus (RSV) antigen in human nasal swab samples.

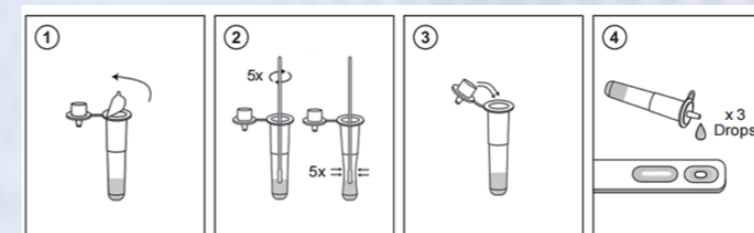
Kit components

- 20 × test cassette (with desiccant, sealed foil pouch)
- 20 × extraction buffer vials
- 20 × sterile swab
- 1 × instructions for use (IFU)

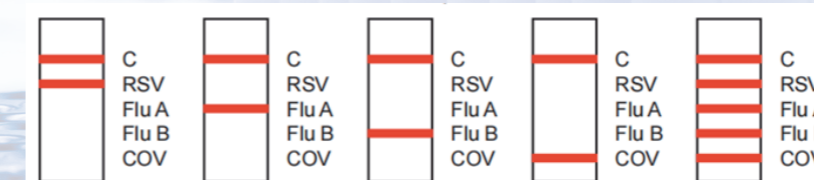
Specimen collection and preparation



Test procedure



Example results

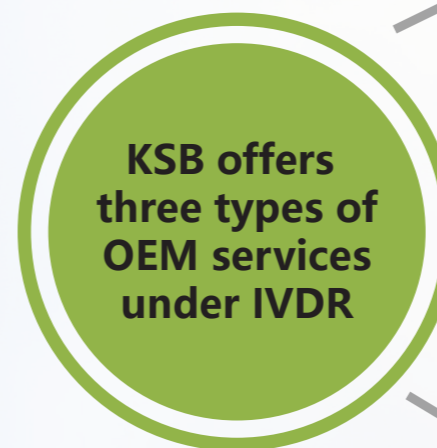


OEM BUSINESS

OEM

Colloidal gold & FIA Contract Manufacturing Services

KSB provides integrated manufacturing solutions for colloidal gold and fluorescent immunoassay (FIA) products. We offer membrane production, test strip assembly, packaging, and related processing services. We deliver consistent quality and scalable mass manufacturing solutions tailored to customer requirements.



Full Technology Transfer

The customer provides complete technical documentation, including starting material sourcing information and process technology. KSB is responsible for the entire manufacturing process, from material procurement to finished product.

Partial Technology Transfer

The customer provides key materials to KSB. KSB is responsible for procuring selected common materials and managing the full production process through to the finished product.

Packing and Assembling

The customer provides pre-assembled laminated sheets. KSB is responsible for device assembly and final packaging.

CMO/CDMO

End-to-End Technical Development and CMO/CDMO Services

1. Technical transfer to KSB
2. Technical transfer from KSB (we own proprietary R&D technologies for more than 60 products)
3. New product development

Our advantages

1

Experience

15 years of experience working with overseas clients, with more than 20 successful technology transfers.

2

Professionalism

Professional R&D team with responsive and highly effective customer communication.

3

Operations

20 years of high-quality system operation with sustained process optimization.