COVID-19 Antigen Rapid Test Card (Colloidal Gold)

COVID-19 Antigen Rapid Test Card (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 Antigen (Nucleocapsid protein) in human saliva samples in vitro.

1. Product Introduction of COVID-19 Antigen Rapid Test Card (Colloidal Gold)

COVID-19 Antigen Rapid Test Card (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 Antigen (Nucleocapsid protein) in human saliva samples in vitro.

Which are applied to the following scenarios：

1. mass population screening，such as hospital, airport, station, community, etc.
2. short-term continuous surveillance.

2. Product Features of COVID-19 Antigen Rapid Test Card (Colloidal Gold)

* Anterior nasal swab specimen, noninvasive

* Very simple to use

* Convenient, no instrument required

* Rapid, results within 15~20 minutes

* Cost-efficient

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749 E-mail: info@bailimedical.com

3. Product Details of COVID-19 Antigen Rapid Test Card (Colloidal Gold)

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

E-mail: info@bailimedical.com

BAILI MEDICAL

Baili Medical Supplies(Xiamen)Co.,LTD. is a high-tech biomedical company, devoted to the field of rapid diagnostic reagents and instrument. Baili is located in Xiamen, China, established in July 2013, which is a listed enterprises in Na-tional Equities and Quotations. As a technology-driven company that prides itself on its scientific excellence, Baili focused on technological innovation and roduct innovation with 15 authorized patents, each of our products embod-ies the creativity of our excellent scientists, who are working hard to continu-ously bring novel products to the China and world markets. SARS-CoV-2 rapid detection series of products, including SARS-CoV-2 antigen, antibody and influenza differential detection, are produced by Baili, which can easily and quickly carry out screening of SARS-CoV-2 in a large number of people, adding strength to epidemic prevention and control.

BAILI MEDICAL SUPPLIES(XIAMEN)CO.,LTD

COVID-19 Antigen Rapid Test Card

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

E-mail: info@bailimedical.com

COVID-19 Antigen Rapid Test Card
(Colloidal Gold)

- Anterior nasal swab specimen, noninvasive
- Very simple to use
- Convenient, no instrument required
- Rapid, results within 15~20 minutes
- Cost-efficient

www.bailimedical.com

CE

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

E-mail: info@bailimedical.com

PRODUCTS DISPLAY

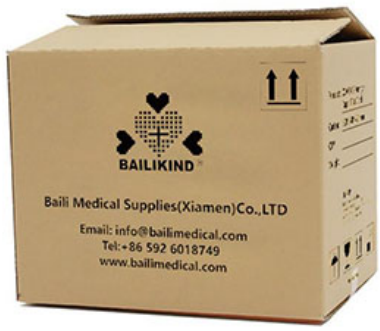
COVID-19 Antigen Rapid Test Card
(Colloidal Gold) 1Test/kit

COVID-19 Antigen Rapid Test Card
(Colloidal Gold) 5Tests/kit

COVID-19 Antigen Rapid Test Card
(Colloidal Gold) 10Tests/kit

Specification	1Test	5Test	10Test
Box size(mm)	150*60*15mm	160*80*40mm	150*100*80mm
Volume (Single Box)	0.00135m³	0.00512m³	0.0012m³
Box N.W.(g)	36g	100g	175g
FCL	400Box (400kit)	120Box (600kit)	40Box (400kit)
Carton size(mm)	520*240*420mm	520*240*420mm	520*240*420mm
Volume (Single Carton)	0.05242m³	0.05242m³	0.05242m³
Carton G.W.(kg)	14.5kg	12.0kg	7.0kg

PACKING AND SHIPPING



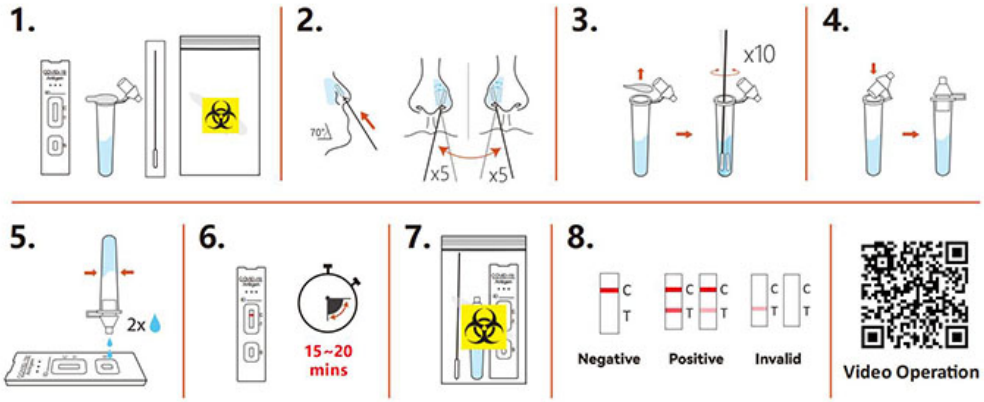
LOGISTICS	BY SEA \ BY RAILWAY \ BY EXPRESS
PACKAGING	FCL \LCL
EXPRESS	DHL \ TNT \ FEDEX \ UPS \ EMS
PAYMENT	L/C,T/T, Paypal Western Union， MoneyGram payments e-Checking， Credit Card through trade assurance

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

E-mail: info@bailimedical.com

QUICK REFERENCE GUIDE



CLINICAL PERFORMANCE

Test Results	Reference PCR Results		
	Positive	Negative	Total
Positive	113	0	113
Negative	2	456	458
Total	115	456	571

Sensitivity: **98.26%** (95%C.I. 93.86%~99.79%)
Positive Predictive Value: **100%** (95%C.I. 96.79%~100.00%)
Overall Percent Agreement: **99.65%** (95%C.I. 98.74~99.96%)

Specificity: **100.00%** (95%C.I. 99.19%~100.00%)
Negativity Predictive Value: **99.56%** (95%C.I. 98.43%~99.95%)

CERTIFICATE

HUMISS

Certificate of EU Medical Device Notification

This is to certify that, according Directive 98/79/EC of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in vitro diagnostic medical devices,

Humiss International B.V.
Address: Joop Geesinkweg 701, 1114AB Amsterdam-Duivendrecht, the Netherlands

has fulfilled all notification responsibility and duty as the European Authorized representative of:

Manufacturer: Baili Medical Supplies (Xiamen) Co., LTD
Address: 1903-3-1, No. 266 Lujiang Road, Siming District, Xiamen, Fujian, 361000, China

The manufacturer has provided with all the appropriate declaration according the Directive 98/79/EC requirements including the EC Declaration of Conformity confirming that the in vitro diagnostic medical devices, as stipulated here below, is fulfilling the applicable r

Product(s): COVID-19 Antigen Rapid Test Card (Colloida
CIBG number: (geen merknaam) (NL-CA002-2022-67510
Model(s): BAITEST1, BAITEST5, BAILITEST10, BAITEST
Classification: Other

Where then manufacturer affixes the CE marking to the prod requirements of the appropriate EU regulation(s) have and c

The notification of aforementioned device(s) has been comp in Netherlands, the Netherlands Competent Authority has no medical device above and has allocated registration.

Signature of Executive Director
James St. WU

Cert. N°: H-YQ-MIV-220318147/01V
Issue date:Mar.18, 2022
Valid until: Mar.17, 2027

HUMISS

Declaration of Conformity

Manufacturer: Baili Medical Supplies (Xiamen) Co., LTD
Address: 1903-3-1, No. 266 Lujiang Road, Siming District, Xiamen, Fujian, 361000, China

Product name:	COVID-19 Antigen Rapid Test Card (Colloidal gold)
Models:	BAITEST1, BAITEST5, BAILITEST10, BAITESTL1, BAITESTL10, BAILITEST20
Classification:	Other

The above product(s) meet(s) the provisions of In Vitro Diagnostic Medical Devices Directive (IVDD) 98/79/EC which apply to them, the medical device above has been assigned as OTHER IVDs according to Article 9 of the IVD Directive 98/79/EC.

The product concerned has been manufactured following the principles of quality assurance as set out in Annex III of the IVD Directive 98/79/EC. Following the procedure related to the EC declaration of Conformity set out in Annex III of Directive 98/79/EC. This Declaration of Conformity covers all In Vitro Diagnostic Medical Devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above-mentioned declaration of conformity is exclusively under the responsibility of
Company: Baili Medical Supplies (Xiamen) Co., LTD
Address: 1903-3-1, No. 266 Lujiang Road, Siming District, Xiamen, Fujian, 361000, China

European Authorized Representative
Humiss International B.V.
Address: Joop Geesinkweg 701, 1114AB Amsterdam-Duivendrecht, the Netherlands
Tel: +31 (0)20 369 8116, Fax: +31 (0)20 369 8114
E-mail: ce-tech@humiss.com

CE

This is only a CE mark sample which is only use for reference.

Title: General manager

DOC N°: H-YQ-MIV-220318147/01V
Issue date: Mar. 18, 2022

FACTORY

Our one hundred thousand grade clean and dust-free workshop is operated strictly under ISO13485:2016 and GMP guidelines. With the automatic production line, efficient production process, strict quality control, we always produce the products timely to meet customers' request.

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

E-mail: info@bailimedical.com

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

E-mail: info@bailimedical.com

We provide

OEM Services

- **FIVE MILLION** kits/day
- **PRICE CONCESSIONS** for You
- **QUALITY ASSURANCE** for You
- **BAILIKIND** Own Brand
- **SEMI FINISHED** Expor
- **COOPERATE** with Listing
- **VERIFIABLE** Factory

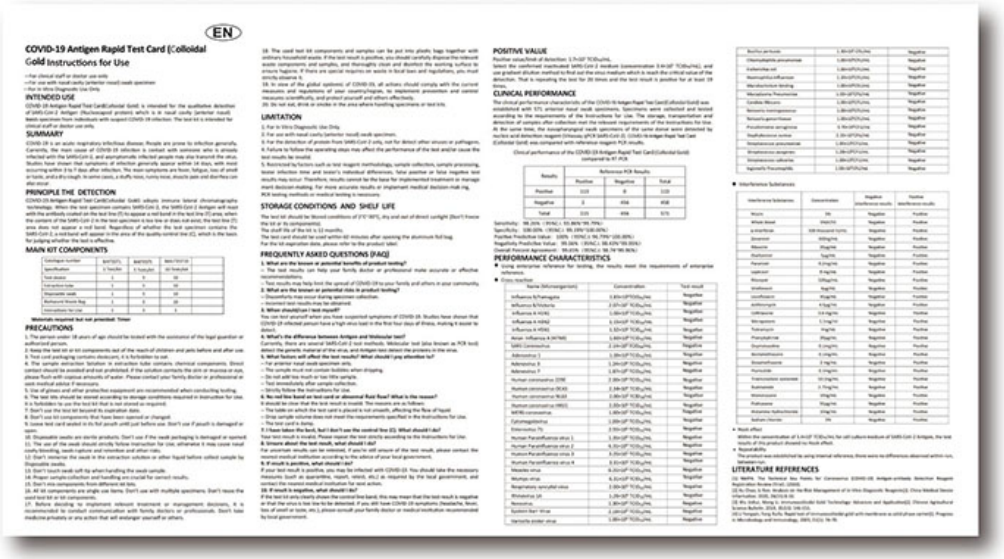
Baili Medical Supplies (Xiamen) Co.,Ltd.

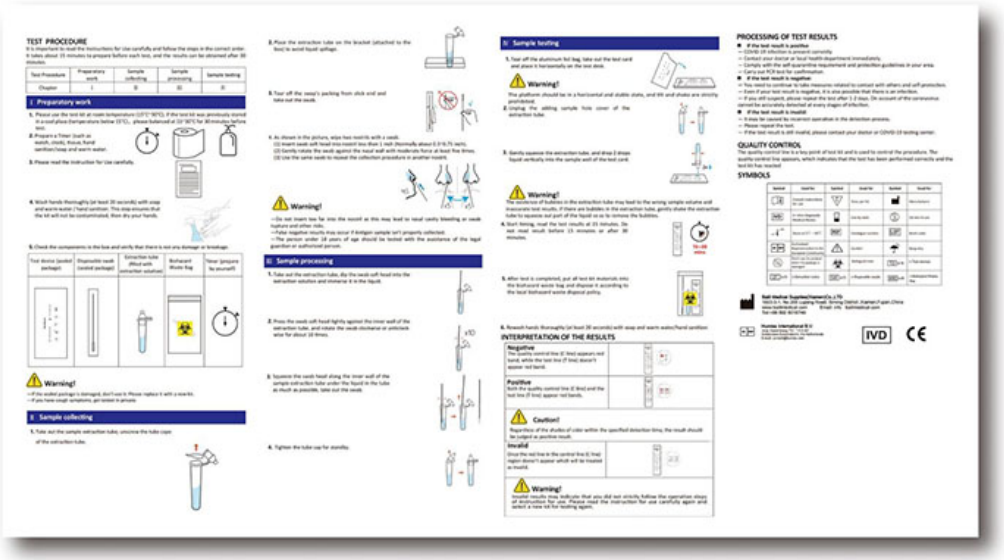
Tel: +86-592-6018749

E-mail: info@bailimedical.com

INSTRUCTIONS FOR USE

EN





Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749 E-mail: info@bailimedical.com

CONTACT US

BAILIKIND®

CONTACT US

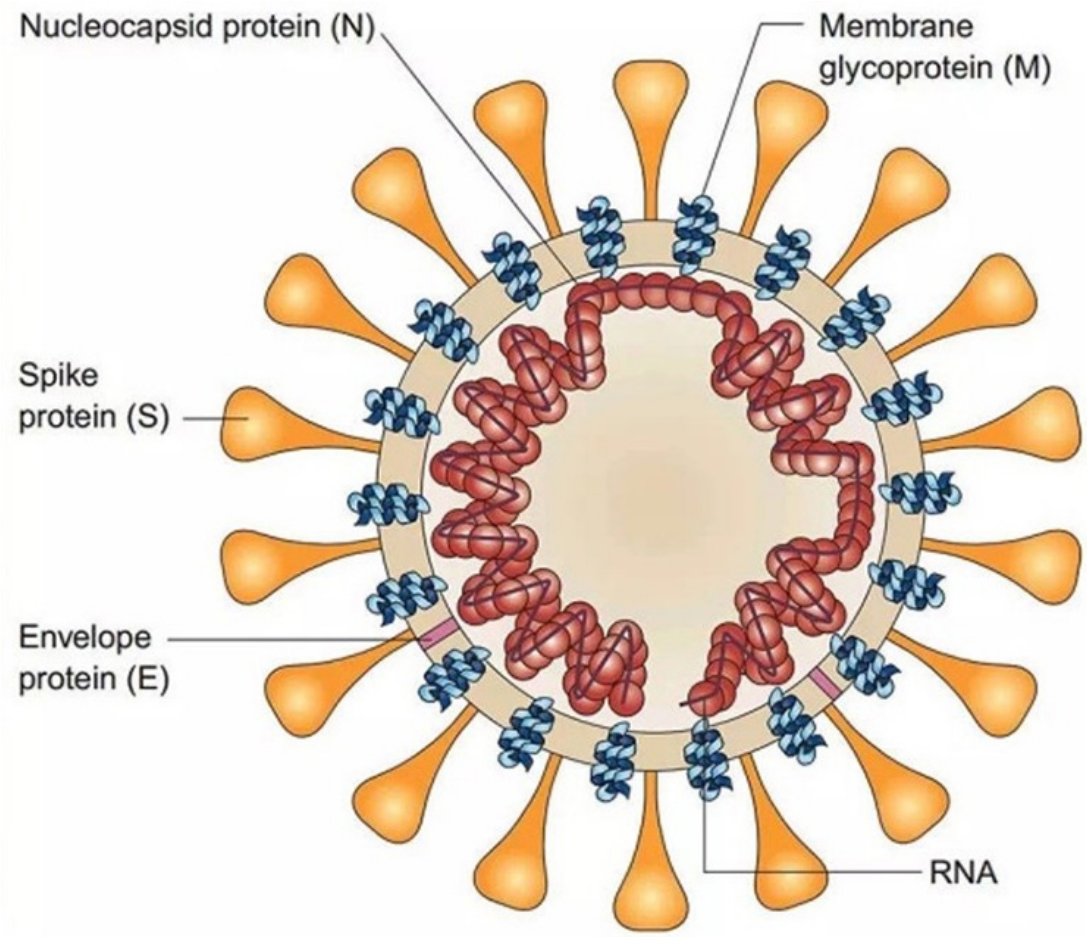
Baili Medical Supplies(Xiamen)Co.,LTD

Whatsapp: +86 18505951488
Email: info@bailimedical.com
Tel:+86 592 6018749 Fax:+86 592 6018749
www.bailimedical.com
Head Office: No.266 Lujiang Road, Siming District ,Xiamen,China
Factory1: Baili Industrial area,Taiwanese Investment Zone,Quanzhou City,Fujian,China
Factory2: Haicang biomedical general Area, Xinyang Street, Xiamen City, China

4. How to detect SARS-CoV-2 virus?

The SARS-CoV-2 virus particle is made up of five components: an RNA gene chain and four proteins. The outermost layer of the particle is a Spike Protein (S), and the viral Envelope below the Spike is composed of Envelope Protein (E) and Membrane Protein (M). The core contained within the envelope is a helical folded structure composed of

RNA gene chains and Nucleocapsid proteins (N). Using the principle of specific binding of antigen and antibody, the presence of SARS-CoV-2 antigen(Nucleocapsid protein) can be detected by antibody.



Advantages over Elisa and PCR

Method	ELISA Kit	RT-PCR	Colloidal Gold Test Kit (Colloidal Gold)
Instrument Cost	Expensive	Expensive	Cheap
Detection Time	Longer	Longer	Short
Amplification Specificity	Stronger	Stronger	Stronger
Environmental Requirements	High	High	Low
Operation Difficulty	High	High	Low

The performance of the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) was established with 859 specimens prospectively collected from individual symptomatic patients who were suspected of COVID-19. Anterior nasal swab specimens were

collected and tested according to the requirements of the Instructions for Use. The storage, transportation and detection of samples after collection met the relevant requirements of the Instructions for Use. At the same time, SARS-CoV-2 was detected by emergency nucleic acid detection reagent.

Clinical performance summary of the WIZ'S SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)

Test Results	Reference PCR Results		
	Positive	Negative	Total
Positive	328	0	328
Negative	14	517	531
Total	342	517	859

PPA: 95.91% (C.I. 93.25%~97.55%)

NPA: 100.00% (C.I. 99.26%~100.00%)

OPA: 98.37% (C.I. 97.28%~99.03%)

We, the manufacturer, herewith, declares that the product(s) as specified above meet(s) the applicable provisions of the European Directive 98/79/EC on in vitro Diagnostic Medical Devices. All supporting technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the Authorized Representative in Europe.

5. Product Packing of COVID-19 Antigen Rapid Test Card (Colloidal Gold)

Company Certification

COMPANY CERTIFICATION

Company Profile

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

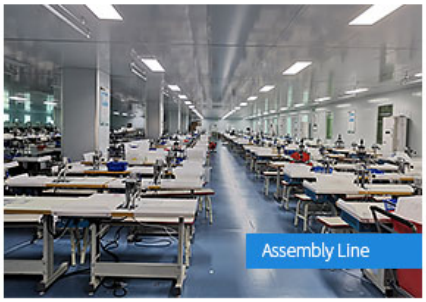
E-mail: info@bailimedical.com

ABOUT BAILIKIND

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

E-mail: info@bailimedical.com



Company Exhibition

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

E-mail: info@bailimedical.com

COMPANY EXHIBITION

Baili Medical Supplies (Xiamen) Co.,Ltd.

Tel: +86-592-6018749

E-mail: info@bailimedical.com

6. Deliver,Shipping and Serving Of COVID-19 Antigen Rapid Test Card (Colloidal Gold)

Shipping Method	Shipping Terms	Area
Express	TNT /FEDEX /DHL/ UPS	All Countries
Sea	FOB/ CIF /CFR /DDU	All Countries
Railway	DDP	Europe Countries
Ocean +Express	DDP	Europe Countries /USA/Canada/Australia /Southeast Asia /Middle East

7. FAQ of COVID-19 Antigen Rapid Test Card (Colloidal Gold)

Q1. Are you factory or trading company?
A:Both.We have been in this field for more than 7years.With superior quality products and competitive price,we sincerely hope to develop mutual-beneficial business with our customers all over the world.

Q2. What is your terms of payment?
A: T/T,L/C,D/A,D/P and so on.

Q3. What is your terms of delivery?
A: EXW, FOB, CFR, CIF, DDU and so on.

Q4. How about the delivery time of COVID-19 Antigen Rapid Test Card (Colloidal Gold)?
A: Normally, it will take 15 to 30 days after receiving the deposit The specific delivery time depends on the items and the quantity of your order.

Q5. Can you arrange production according to samples?
A: Yes, we can produce by your samples or technical drawings.

Q6. What is your sample policy?
A: If the quantity is small, the samples will be free, but the customers have to pay the courier cost.

Q7. Do you test all your goods before delivery?
A: Yes, we have 100% test before delivery.

Q8. How do you make our business long-term and good relationship?
A: We keep good quality and competitive price to ensure our customers benefit ; and we respect every customer as our friend and we sincerely do business and make friends with them.