Skyray Instrument 贝西生物

Stock code:300165

COVID-19 Rapid Test Kits

Suitable for large-scale screening
Simultaneous detection of both IgM and IgG antibodies

Current detection status of SARS-CoV-2:

Detection method: SARS-CoV-2 nucleic acid detection (needs to be performed in PCR laboratory)；

Detection time: Generally takes more than two hours at the fastest;

Detection capability: High technical threshold and needs professional laboratories,special instruments and technical staff.

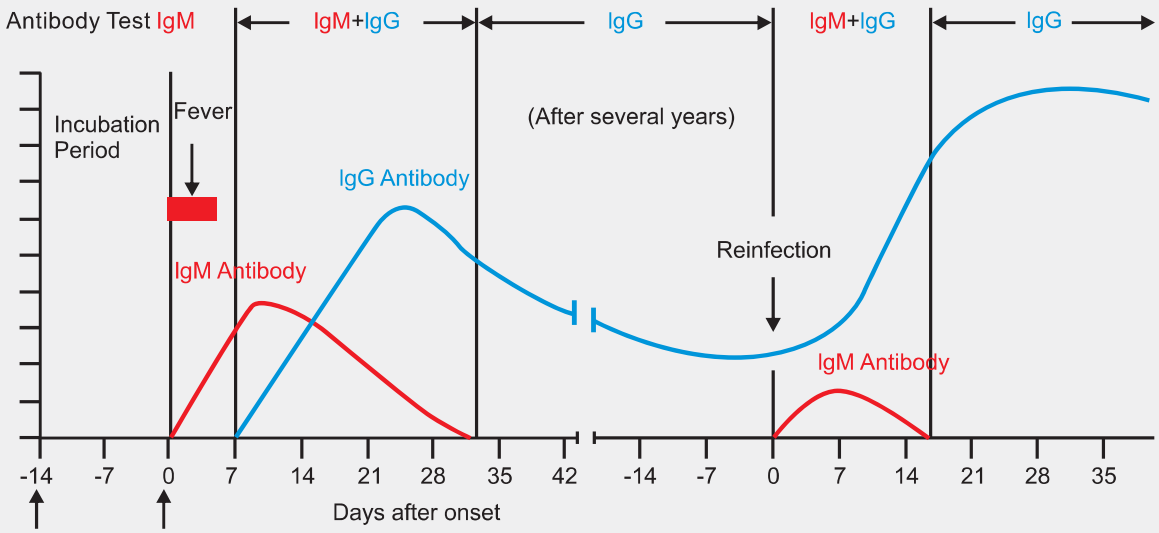
Due to the high cost, and long detection time, this method can not fully meet the detection of infection suspects, let alone meet the needs of large-scale screening.

SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)

IgM and IgG are the first antibodies appearing in the human immune system during infection. Because of their high specificity, when detecting acute SARS-CoV-2 infection, IgM and IgG antibodies have the advantages of high sensitivity, early diagnosis, and the ability to judge whether a suspect is infected.

IgM and IgG antibodies can only be produced after several days of viral infection and differ between individuals.

Using IgM/IgG antibody detection can find infections 0-7 days in advance.



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SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)

The kit detects IgM and IgG antibodies simultaneously, reducing workload and risk.

- On-site screening:Results can be read directly without equipment.
- Simple sampling:Fingertip blood and earlobe blood.
- Fast test speed:It takes 3 minutes to obtain results,and the whole process only takes 8 minutes.
- Low risk:Reduces the risk of individuals becoming infected in the hospital.

Special Notice SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)

1. Fast test reagents can only be used as auxiliary screening tools.
2. Accuracy and detectable rate cannot reach 100%.
3. If positive samples are detected, please go to the hospital for reexamination in time.
4. The test principle of the reagent kits is not detecting the virus itself, but detecting the antibodies produced after the virus enters the body. Antibodies can be produced several days after viral infection and can be detected as early as in the 1st week. Because there are differences between individuals, multiple tests may be required.

Application Scenarios

Center for Disease Control and Prevention

Test on high-risk groups such as quarantined persons, contacts, and returned workers of developed cities.

Primary Health Care Institution

Test on suspected persons, and persons with fever and cold on site, which is convenient for immediately reporting and transferring infection-positive patients.

Government Department / Public Institution State-Owned Enterprise / Large Company

On duty inspection / regular screening of government staff.

Industrial Production Enterprise

Start-up inspection and regular screening.

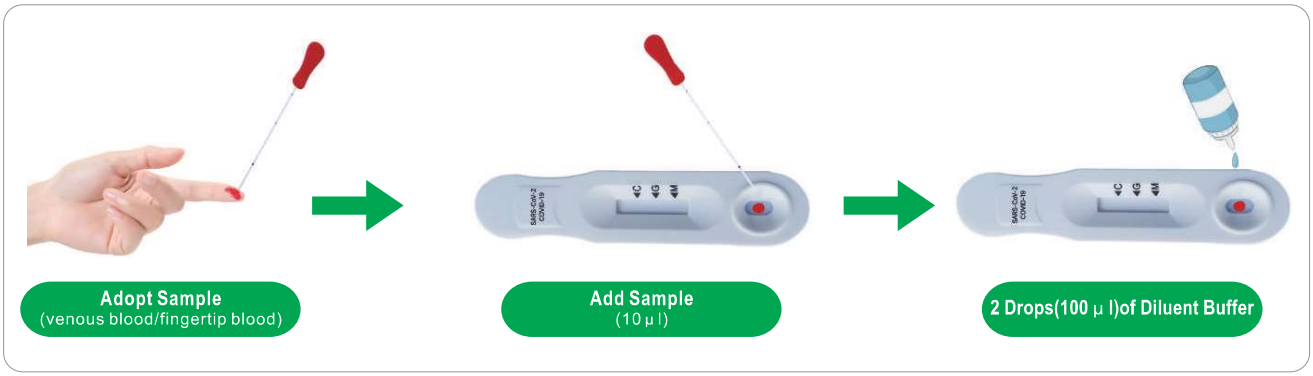
School

Start-up inspection and regular screening.

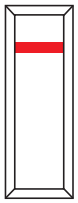
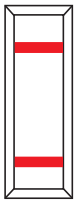
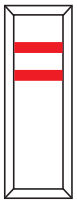
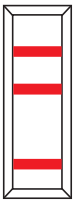
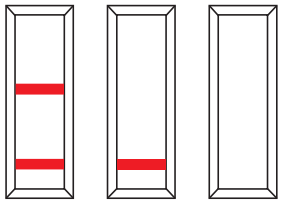
Prison / Detention Center / Drug Rehabilitation Center

Regular screening.

Operation Steps&Result Description



Reaction 15min View Result

	VALID				INVALID
C IgG IgM					
IgG	NEGATIVE	NEGATIVE	POSITIVE	POSITIVE	The quality control line is not visualized
IgM	NEGATIVE	POSITIVE	NEGATIVE	POSITIVE	

Clinical Validation

Result	Clinical Diagnosis		TOTAL
	Diagnosed	Excluded	
IgG/IgM Positive	57	3	60
IgG/IgM Negative	2	45	47
TOTAL	59	48	107

Clinical validation shows excellent diagnostic performance,IgM and IgG combined sensitivity and specificity is 96.6% and 93.8% respectively.

CE

DECLARATION OF CONFORMITY

Certificate No.:BC20200318008

According to Directive 98/79/E Conin vitro diagnostic medical devices, AnnexIII.

Manufacturer: Shanghai B&C Biological Technology Co., Ltd.
Address: No.20 Lane 222 Guangdan Road, Pudong New District, Shanghai China.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koning in Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- SARS-CoV-2 IgM/IgG Antibody Test （Colloidal Gold Chromatography Method）
- SARS-CoV-2 IgM/IgG Antibody Test （Latex Chromatography Method）

Category: Others

Conformity assessment route: Declaration of Conformity IVDD AnnexIII

Applicable Standards:

ISO13485:2016	*ENISO18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO23640:2015*
ENISO18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
ENISO18113-2:2011		

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed: **Name of authorized signatory:**
Position held in the company: General Manager
Signature:

Shanghai B&C Biological Technology Co.,Ltd. 3223960955

Place: Shanghai, China

Shanghai B&C Biological Technology Co., Ltd.