Package Insert of SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method)

FOR PROFESSIONAL USE

Product Name

SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method)

Package Size

1 strip/foil bag, 1 strip/box, 2 strips/box, 5 strips/box, 20 strips/box, 25 strips/box, 30 strips/box, 40 strips/box, 50 strips/box, 100 strips/box

Intended Use

The SARS-CoV-2 Antibody Test Strip is for the qualitative detection of SARS-CoV-2 antibody in human serum, plasma or whole blood sample. It is intended for use outside the body only (in vitro diagnostic use) for professional use.

Summary

On December 31, 2019, several cases of pneumonia were reported to the World Health Organization (WHO). The novel virus, now known as SARS-CoV-2 (previously known as 2019-nCoV), has spread in many countries and regions around the world. The WHO has named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (abbreviated "COVID-19").

Test Principle

SARS-CoV-2 Antibody Test Strip is based on colloidal gold immunochromatography assay to test SARS-CoV-2 antibody. Colloidal gold marked goat anti-chicken IgY polyclonal antibody and recombinant SARS-CoV-2 antigen are coated in reagent conjugate pad. Mouse anti-human IgG monoclonal antibody and mouse anti-human IgM monoclonal antibody are coated in test zone of nitrocellulose membrane. Chicken IgY is coated in control zone of nitrocellulose membrane. During test, specific SARS-CoV-2 antibody in blood sample conjugates with colloidal gold marked recombinant SARS-CoV-2 antigen to form immune complex. Owing to capillary action, immune complex flow across the membrane. If blood sample contain specific SARS-CoV-2 antibody, it will be captured by the test area coated mouse anti-human monoclonal antibody and form a visible line in test area (test line). Excess colloidal gold marked goat anti-chicken IgY polyclonal antibody keeps moving, specific binding with control area coated Chicken IgY and from a visible line in control area (control line). If blood sample doesn' t contain SARS-CoV-2 antibody, only control line will be appeared.

Precautions

1.For in vitro diagnostic use only.
2.For single use only.
3.Do not use expired strip.
4.Do not use the kit if the pouch is punctured or not well sealed.
5.All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in the collection, handling, storage and disposal of patient samples and used kit contents.

6.Wear appropriate personal protective equipment (e.g. gowns, gloves, goggles) when handling the contents of this kit.
7.Testing should be applied by professionally trained staff working in certified laboratories or clinics where the sample is taken by qualified medical personnel.
8.Avoid high temperature test condition. Product which store at low temperature need to equilibrate to room temperature before take out it from foil bag to avoid getting damp.
9.The intensity of color can' t be used to judge antibody titer level in sample.
10.Treat used strip as a potential biological risk. Dispose used test strips in appropriate container.
11.Do not swallow desiccant in foil bag. Keep away from children.
12.The final diagnosis result should be judged by the doctor based on various detection indicators and clinical symptoms.

Composition

The kit is composed by test strip, sample diluent (droppi ng bottle) and dropper.

Test strip is mainly composed by mouse anti-human IgG monoclonal antibody, mouse anti-human IgM monoclonal antibody, chicken IgY, nitrocellulose membrane, colloidal gold marked recombinant SARS-CoV-2 antigen and colloidal gold marked goat anti-chicken IgY polyclonal antibody.

Specification are described as below:

Specification	Contains
1 strip/foil bag	1 test strip，5.0mL sample diluent, 1 dropper
1 strip/box	1 test strip，5.0mL sample diluent, 1 dropper
2 strips/box	2 test strips，5.0mL sample diluent, 2 droppers
5 strips/box	5 test strips，5.0mL sample diluent, 5 droppers
20 strips/box	20 test strips，5.0mL sample diluent, 20 droppers
25 strips/box	25 test strips，5.0mL sample diluent, 25 droppers
30 strips/box	30 test strips，5.0mL sample diluent, 30 droppers
40 strips/box	40 test strips，10.0mL sample diluent, 40 droppers
50 strips/box	50 test strips，10.0mL sample diluent, 50 droppers
100 strips/box	100 test strips，15.0mL sample diluent, 100 droppers

Do not mix or exchange components from different lot kits.

Materials Required but Not Provided
1.Sample collection containers
2.Timer
3.Personal protective equipment, such as protective gloves, surgery mask, goggles and lab coat.
4.Appropriate biohazard waste container and disinfectants.

Storage and Stability

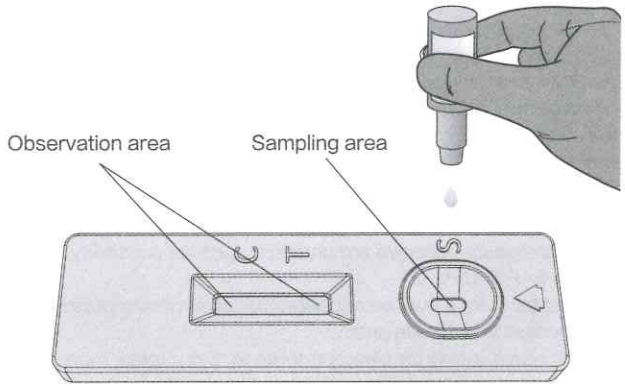
Shelf life: 6 months if stored between 4℃~30 ℃.
1.Store at 4℃~30 ℃ in the sealed pouch. Keep away from direct sunlight, moisture and heat. Do not freeze.
2.Test strip should be used within 10 minutes after taking out from the foil bag.
3.Sample diluent should be re-capped in time after use. Store at 4 ℃~30℃.
4.Do not use the test strips or sample diluent beyond the expiry date. Manufacture date and expiry date please refer to product label.

Sample Requirements

The test can be performed with serum, or plasma/whole blood sample which collected in EDTA or heparin blood collection tube. Serum or plasma sample can be stored at 2℃~8℃ for up to 3 days or −20℃ for 9 days. Avoid repeated freezing and thawing. It is recommended to test whole blood sample within 3 days after collected. Whole blood sample should be stored at 2℃~8℃. Do not freeze. Do not use hemolytic sample or contaminated sample to perform test.

Test Method

Read the package insert carefully before test.
1.Allow the test strip and samples to equilibrate to room temperature before testing.
2.Check expiry date of strip. Do not use test strip which beyond expiry date printed on the label.
3.Take out a strip from foil bag and place it on a dry level surface.
4.Use dropper apply 10 μ L serum or plasma or whole blood sample to sampling area on strip.
5.Gently squeeze the dropping bottle of sample diluent, add 2 drops diluent vertically into sampling area (see picture 1).



Picture 1-Adding diluent into sampling area
(Picture is for reference only. Please refer to the actual products)

6.Wait for 15~20 minutes and observe the results. Results are invalid if it appeared exceed 20 minutes.

WARNING! Treat used test strips as a biological risk. Dispose used test strips in appropriate container.

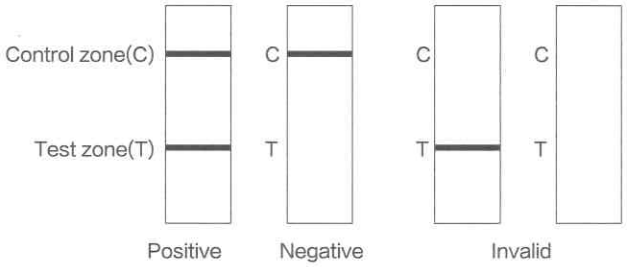
Explanation of Test Results

Positive: Two red lines appear. One line should be in the control zone (C) and another line should be in the test zone (T) (See picture 2).

Negative: One red line appears in the control zone (C). No red line appears in the test zone (T) (See picture 2).

Invalid: Control line fails to appear (See picture 2). Test result is invalid.

When test result is invalid, make sure whether test method is correct, especially whether sample volume is sufficient, and use new test strip to test it again. If test strip is still invalid, stop using this batch of product and contact with Changsha Sinocare Inc.



Picture 2-Result interpretation

Quality Control

A colored line appearing in the control zone (C) is considered an internal procedure control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedure technique.

Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

Limitations

1.Even test result is negative are unable to exclude possibility of infected with SARS-CoV-2.

2.Incorrect test result may be appeared because of misoperation. Retest suspected test results again.

3.The test result is only for clinical reference. Symptoms, medical history, other lab test (especially etiological examination) and epidemiology information should be comprehensive considered before further clinical management.

4.For immunologic function damaged patient or patient who receive immunosuppressive therapy, the diagnosis results should be evaluated by doctor.

5.It is only for qualitative detection of SARS-CoV-2 antibody in blood sample. It can't be quantitative detection of SARS-CoV-2 antibody in blood sample, nor direct reflect whether SARS-CoV-2 is exist in blood sample or not.

6.Interference as below will not interfere with SARS-CoV-2 antibody test strip.

Interference	Concentration	Interference	Concentration
Hemoglobin	5 g/L	Heparin Sodium	3000U/L
Normal Person IgG	20 g/L	EDTA-2Na	3.4 μ M
Normal Person IgM	5 g/L	Intra-Lipid	1000mg/dL
HAMA	5000ng/mL	Uric Acid	1.4mM
RF	80IU/mL	Bilirubin	342 μ M

7. Drugs as below will not interfere with SARS-CoV-2 antibody test strip.

Drug Type	Drug	Concentration
Antiviral Drug	α-interferon	1.25ml/L
	Zanamivir	25mg/L
	Ribavirin	375mg/L
	Oseltamivir	187.5mg/L
	Peramivir	750mg/L
	Lopinavir	500mg/L
	Ritonavir	125mg/L
	Arbidol	0.5g/L
Antibiotics	Levofloxacin	1.25g/L
	Azitromycin	2.5g/L
	Ceftriaxone	2.5g/L
	MeropeneM	500mg/L
General Antibacterials	Tobramycin	100mg/L
Allergic Symptoms Remission Drug	Histamine Hydrochloride	0.25mg/L

Performance Characteristics

1.Clinical Evaluation

Total test on 320 patients, include 240 excluded patients, 60 confirmed patients and 20 cured patients.

Sample type	Sensitivity	Specificity
Serum/Plasma	96.3%	99.6%
Whole blood	95.0%	99.2%

2.Precision

	Repeatability	Intermediate Precision
Negative reference coincidence rate (-/-)	100%	100%
Positive reference coincidence rate (+/+)	100%	100%

References

1.Kricka L. Interferences in immunoassays-still a threat. Clin Chem, 2000, 46: 1037 - 1038.

2.Bjerner J, et al. Immunometric assay interference: incidence and prevention. Clin Chem, 2002, 48: 613 - 621.

3.SARS-CoV-2 pneumonia treatment protocol, pilot version 7.

Explanation of Symbols

Symbol	Explanations	Symbol	Explanations
IVD	In vitro diagnostic medical device		Keep away from sunlight
	Consult instructions for use		Keep dry
LOT	Batch code		Manufacturer
	Temperature limitation (store at)		Manufacture date
	Use by date, Expiry date	CE	CE marking
	Do not re-use	EC REP	Authorized representative in the European Community

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