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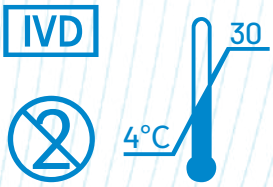

SARS-CoV-2 Antigen Test Kit
(Colloidal Gold Method)

For Rapid Detection of SARS-CoV-2.

Kit configured for testing throat swab and nasal swab samples freshly collected.

SARS-CoV-2 Antigen Test Kit

(Colloidal Gold Method)

PRODUCT NAME

SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)

SPECIFICATION

1test/box,20 tests/box,25tests/box,50 tests/box

INTENDED USE

This product is used for in vitro qualitative detection of novel coronavirus (2019-nCoV) antigens in human throat swabs and nasal swabs.

This product is limited to medical institutions.

The novel coronavirus belongs to the B genus. Novel coronavirus pneumonia is an acute respiratory infectious disease, and the population is generally susceptible. The main source of infection is the patients who has been infected by the novel coronavirus, and the asymptomatic carrier may also be the source of infection. Based on the current epidemiological investigation, the incubation period is 1-14 days, mostly 3-7 days. The main manifestations are fever, dry cough, and fatigue. A small number of patients are accompanied by nasal congestion, runny nose, sore throat, myalgia and diarrhea.

PRINCIPLE

The novel coronavirus (2019-nCoV) antigen detection kit (colloidal gold method) uses immunochromatography technology and adopts the principle of double antibody sandwich method for detection. During the chromatography, the novel coronavirus (2019-nCoV) antigen in the sample reacts with the colloidal gold-labeled novel coronavirus (2019-nCoV) antibody 1 to form a complex, which moves forward along the nitrocellulose membrane under the action of chromatography. In the detection area, it combines with the novel coronavirus (2019-nCoV) antibody 2 coated on the nitrocellulose membrane to form a sandwich complex and deposits on the detection line (T line) to form a purple-red band; on the contrary, if the sample does not contain the novel coronavirus (2019-nCoV) antigen, the purple-red band will not form on the detection line (T line). Regardless of whether the sample contains the novel coronavirus (2019-nCoV) antigen, the chicken IgY in the gold label pad and the goat anti-chicken IgY on the detection line (C line) will form a specific binding, which forms a purple-red band at the position of the detection line (C line).

MATERIALS AND COMPONENT

Number	Name	Composition
1	SARS-CoV-2 Antigen Test Device (Colloidal Gold Method)	• The packaging bag for each person contains a test card and a desiccant. • The test card is composed of a plastic shell and a test strip. • The test strip consists of a sample pad and a gold label pad (fixed with a colloidal gold-labeled novel coronavirus (2019-nCoV) antibody 1), nitrocellulose membrane (coated with novel coronavirus (2019-nCoV) antibody 2 as the detection line (T line), goat anti-chicken IgY polyclonal antibody as the quality control line (C line)), absorbent paper and PVC rubber plate composition.
2	Extraction Solution	1mL / tube of extraction solution for1 test/box 15mL/bottle of extraction solution for 25tests/box
3	Sterilized Swab	1pcs for 1 test
4	Extraction Tube	1 tube for 1 test

Materials Required but not provided:
Timer, workstation, any necessary personal protective equipment.

STORAGE AND STABILITY

The test device is sealed in an aluminum foil bag, which may be stored at 4˚C~30˚C for 24 months. Once the aluminum foil bag is opened, please use it within 1 hour .

WARNINGS AND PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use this kit beyond the expiration date printed on the package label.
4. To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
5. Do not reuse any kit components.
6. Proper specimen collection, storage and transport are critical to the performance of this test.
7. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
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9. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.

SPECIMEN COLLECTION AND HANDLING

Specimen Collection and Preparation

Acceptable specimens for testing with this kit include nasal swab and throat swabs specimens obtained by correct collection method. It is essential that correct specimen collection and preparation methods be followed. Specimens obtained at an early stage will contain the highest viral titers; Compared with RT-PCR assay, specimens obtained 5 days after the onset of symptoms are more likely to produce negative results.

Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

Specimen Transport and Storage

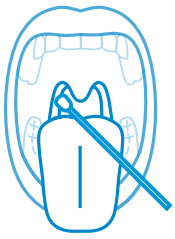
Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. It is essential that correct specimen collection and preparation methods be followed.

Nasal Swab Specimen Collection

The sampler gently supports the head of the sampled person with one hand, and the sampler holds the swab with the other hand, inserts the swab through the nostril, and then penetrates slowly back along the bottom of the lower nasal cavity, avoiding vigorously. Traumatic bleeding. When the tip of the swab reaches the back wall of the nasopharyngeal cavity, gently rotate it one round (to prevent reflex cough, stop for one minute), and then slowly remove the swab.

Throat Swab Specimen Collection

The head of the sampled person was slightly tilted and the mouth opened wide, exposing the pharyngeal tonsils on both sides. Wipe the base of the tongue with the swab, gently wipe the pharyngeal tonsils on both sides of the recipient at least 3 times, and then wipe the posterior wall of the pharyngeal up and down at least 3 times.



Specimen Handling

Add 10-11 drops of extraction solution to the extraction tube, then immerse the sampled swab in the extraction solution to make the extraction solution completely penetrate the swab, rotate and squeeze the swab 10 times, and then remove the swab. Take out the remaining liquid for testing.

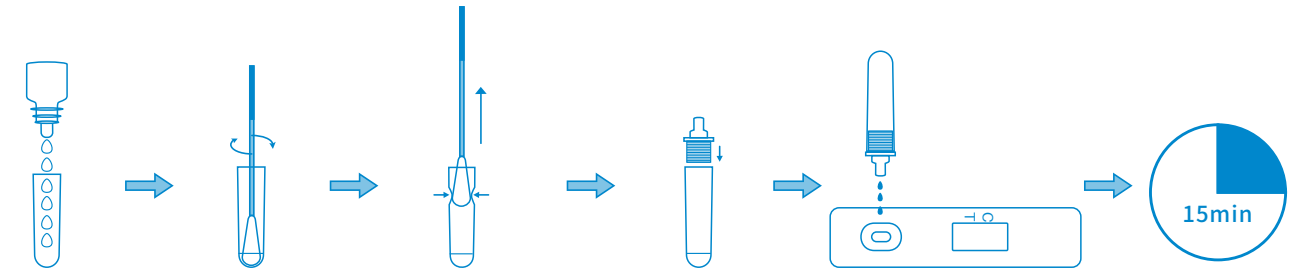
TEST PROCEDURE

Please read this instruction carefully before use.

A) Place the test kit and sample to be tested at room temperature.

B) Open the inner packaging of the test card and take out the test card; take 2 drops (about 100μL) of the processed sample and drop them vertically into the sample hole of the test card.

C) Observe the test results after 15 minutes, and the results are invalid for more than 30 minutes.



Use the extraction bottle to add 10-11 drops of extraction solution vertically into the extraction tube

Insert the throat or nasal swab collected by the swab into the extraction tube, rotate and squeeze the swab 10 times

Squeeze the wall of the extraction tube with your fingers, try to squeeze the solution on the swab and take it out

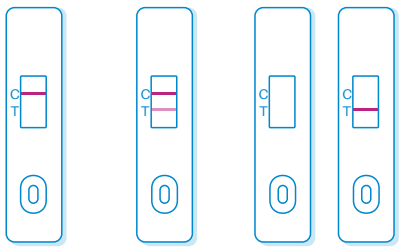
Insert the dripper of the extraction rube into the extraction tube

Add 2 drops of liquid to the sample hole of the test card

Obseerve the result after 15 minutes, the resule is invalid after 30 minutes

INTERPRETATION OF RESULTS

1. Positive result: If both the C-line and the T-line appear, it means that SARSCoV-2 antigen is detected, and the result is positive.
2. Negative result: If only C-line appears, it means that SARS-CoV-2 antigen is not detected, and the result is negative.
3. Invalid result: If C- line is not observed, it is invalid whether there is a detection line or not, and the sample should be re-tested using a new test card.



LIMITATIONS

1. Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.
2. Users should test specimens as quickly as possible after specimen collection.
3. Positive test results do not rule out co-infections with other pathogens.
4. Results should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
5. A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
6. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
7. Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
8. Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
9. This device has been evaluated for use with human specimen material only.
10. Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection, and within one hour after specimen collection.

PERFORMANCE CHARACTERISTICS

Clinical Performance

Clinical validation study of the SARS-CoV-2 Antigen Test Kit was conducted at three sites in China in 2020. Throat swabs and nasal swabs specimens were evaluated from 250 subjects. Out of the 250 samples, 101 subjects were COVID-19 cases confirmed positive by an RT-PCR assay while 149 subjects were confirmed PCR negative. All patients who were confirmed positive exhibited clinical signs or symptoms of COVID-19.Of the 101 positive samples, 99 were reactive on the SARS-CoV-2 Antigen Test Kit, and of the 149 negative samples, 148 were non-reactive. The kit demonstrated the overall Positive Percent Agreement (PPA) of 98% (99/101) and the Negative Percent Agreement (NPA) of 99.3% (148/149), as indicated in the table below.

The SARS-CoV-2 Antigen Test Kit evaluation centers

Clinical institution	PCR Positive (Cases)	PCR Negative (Cases)	Total
Site 1	25	45	70
Site 2	48	60	108
Site 3	28	44	72
Total	101	149	250

Summary of clinical evaluation results

Cases		PCR Comparator SARS-CoV-2 results		Total
		Positive	Negative	
SARS-CoV-2 Antigen Test Kit	Positive	99	1	100
	Negative	2	148	150
Total		101	149	250

Summary of clinical performance

Performance	Results	95% CI
PPA	98.02%	93.07%~99.46%
NPA	99.30%	96.30%~99.88%

Limit Of Detection

The LOD for the SARS-CoV-2 Antigen Test Kit was established using limiting dilutions of a inactivated viral sample. The material was supplied at a concentration of 2.8 x 10^5 $TCID_{50}$/mL. In this study, designed to estimate the LOD of the assay when using a direct throat swab or nasal swab, the starting material was spiked into a volume of pooled human throat swab or nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices in triplicate using a 10-fold dilution series. At each dilution, 100 µL samples were added to swabs and then tested. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LOD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

Starting Material Concentration	Estimated LOD	No. Positive/Total	% Positive
2.8 x 10^5 $TCID_{50}$/mL	1.0 x 10^2 $TCID_{50}$/mL	20/20	100%

Cross-Reactivity

Cross-reactivity for SARS-CoV-2 Antigen Test Kit was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with SARS-CoV-2 Antigen Test Kit. Each organism and virus was tested in triplicate. The final concentration of each organism is documented in the following table.

Potential Cross–Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E (heat inactivated)	1.0×10^5 U/mL	No
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No
Adenovirus	1.0×10^5 $TCID_{50}$/mL	No
Human Metapneumovirus	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	5.2×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4	1.6×10^4 $TCID_{50}$/mL	No
Influenza A	2.5×10^5 $TCID_{50}$/mL	No
Influenza B	2.9×10^5 $TCID_{50}$/mL	No
Enterovirus	4.0×10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	4.0×10^5 $TCID_{50}$/mL	No
Rhinovirus	1.1×10^5 PFU/mL	No
SARS-coronavirus	4.5×10^5 PFU/mL	No
MERS-coronavirus	1.5×10^5 $TCID_{50}$/mL	No
Haemophilus influenza	1.4×10^6 CFU/mL	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No
Streptococcus pyogenes	1.6×10^6 CFU/mL	No
Candida albicans	1.8×10^6 CFU/mL	No
Pooled human nasal wash	100%	No
Bordetella pertussis	1.4×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No
Chlamydia pneumoniae	1.0×10^6 IFU/mL	No
Legionella pneumophila	1.0×10^6 CFU/mL	No

Hook Effect

No impact on test performance or high dose hook effect was observed up to2.8 x 105 TCID50/mL of gamma-irradiated SARS-CoV-2 with the SARS-CoV-2 Antigen Test Kit.

MANUFACTURER

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Index of Symbols

	Consult instructions for use		Use by		Do not reuse
IVD	For in vitro diagnostic use only	LOT	Lot Number		Keep dry
	Store between 4-30°C		Manufacturer		Date of manufacture
	Contents sufficient for <n> tests	EC REP	Authorized Representative	CE	CE Mark
	Do not use if package is damaged				

Instruction Approval and Revision Date
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Revision Date: