RapidFor™ SARS-CoV-2 Ag Test Kit (Colloidal Gold)
Catalog Number: VSCD02-1

INTENDED USE

This kit is used for in vitro qualitative detection of SARS-CoV-2 antigen. It is a lateral flow sandwich assay, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP), nasal (NS) and oropharyngeal swab specimens directly.

This test is only for home testing, and cannot be used as the basis for the diagnosis and exclusion of pneumonia caused by new coronavirus infection.

A positive test result needs further confirmation. A negative test result cannot rule out the possibility of infection.

The kit and test results are for clinical reference only. It is recommended to combine the patient's clinical manifestations and other laboratory tests for a comprehensive analysis of the condition.

SUMMARY AND EXPLANATION

The novel coronaviruses belong to the βgenus, a positive strand RNA virus. SARS-COV-2 is an acute respiratory infectious disease which people are susceptible to infection. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be spread the virus. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, loss of smell and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE OF THE TEST

This reagent uses double-antibody sandwich to legally detect the antigen of novel coronavirus (SARS-CoV-2) in nasopharyngeal swab and oropharyngeal swab samples. During detection, the gold labeled anti-SARS-CoV-2 monoclonal antibody in the labeling pad binds to the SARS-CoV-2 antigen in the sample to form a complex, and the reaction complex moves forward along the nitrocellulose membrane under the action of chromatography, where it is captured by the anti-SARS-CoV-2 monoclonal antibody pre- coated by the detection zone (T) on the nitrocellulose membrane, and finally a red color reaction line is formed in the T zone. If the sample does not contain SARS-CoV- 2 antigen, are color reaction line cannot be formed in the T zone. Regardless of whether the sample to be tested contains SARS-CoV-2 antigen, a red reaction line will always form in the quality control area (C).

MATERIALS AND COMPONENTS

Materials provided with the test kits

1.Test Card, 1 kit
2.Swab, 1 unit
3.Sample buffer, 1 bottle
4.Manual instruction for use.

Note: The components in different batches of the kit cannot be mixed.

STORAGE AND STABILITY

1.Store at 2°C - 30°C in the sealed pouch up to the expiration date printed on the package, forbidden to store under 2°C and avoid using expired products.
2.The test card is used within 15 minutes after taking out from the foil envelope. Buffer solution are re-capped in time after use.
3.MFG date and EXP date: marked on the label. The product will be expired after 12 months.

TEST PROCEDURE

Before test, please read the instruction manual and apply 15 steps below carefully. Test procedure contains following steps: Sample collection, sample processing and test operation.

SAMPLE COLLECTION REQUIREMENTS

1.Collection of nasopharyngeal secretion: Insert the sterile swab into the place where the nasopharyngeal secretions are the most and rotate the swab close to the inner wall of the nasal cavity 3 times, remove the swab.
or Collection of oropharyngeal secretion: Insert the sterile swab from mouth completely into the oropharyngeal swelling, centering on the red part of the throat wall, epicondylosis, and tonsils, wipe and rotate 10 times with moderate force to avoid touching the tongue and remove the swab.
or Collection from nasal secretion: Insert the sterile swab into the place where the nasal secretions are the most at the front nose and rotate the swab close to the inner wall of the nasal cavity 3 times, remove the swab.
2.The samples should be used as soon as possible after collected (within half an hour).
3.Samples should not be inactivated.

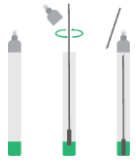
SAMPLE PROCESSING

4.The tube contains 500 µl extraction buffer.
5. Open the cap of the extraction tube and mix with sample swab.
6. Rotate the sample against the inner wall of the tube approximately 10 times or squeeze the tube 10 times to elute the sample to ensure that the sample on the swab is fully eluted into the buffer.
7. Squeeze the swab head along the inner wall of the tube to keep the liquid in the tube as much as possible.
8. Break the upper part of the swab from the breaking point so that the lower part remains in the tube and close the cap cover the drip head to mix the liquid thoroughly.
9. Samples should be eluted and used immediately after collection; at the same time, the samples should not be inactivated, stored, or frozen and thawed.
***Note:** Recommend using a pipette to transfer the samples to reduce deviations.

TEST OPERATION

10.Take the required reagents and test cards to equilibrate to room temperature.
11.Unpack the aluminum foil bag, place the reagent card horizontally on the table and mark it.
12.Add 100µL (3 drops) of the processed sample to the sample well, and timed. It is recommended to use a pipette to take buffer/samples to reduce deviations.
13.When the test starts to run, liquid moving up through the result window will be visible.
14.Wait 15 minutes and read the results. Do not read the results after 30 minutes.

Sample collection



Sample processing

Test operation

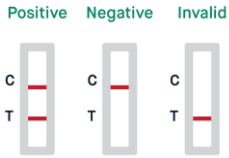
INTERPRETATION OF TEST RESULTS

This product can only perform qualitative analysis on th detection object.

Positive Result: If both C and T lines are visible within 15 minutes, the test result is positive and valid.

Negative Result: If test area (T line) has no color and the control area displays a colored line, the result is negative and valid.

Invalid Result: The test result is invalid if a colored line does not form in the control region. The sample must be re-tested, using a new test cassette.



LIMITATIONS

1.The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information and further clinical data.
2.The contents of this kit are to be used for the qualitative detection of SARS- CoV-2 antigens from nasal swab, throat and nasopharyngeal swab.
3.This test detects both viable (live) and non-viable, SARS-CoV-2.
4.Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
5.The Sample buffer and test card must be equilibrated to room temperature (18℃~26℃) before used, otherwise the results may be incorrect.
6.A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
7.Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
8.Results interpreted less than 10 minutes may lead a false negative result or more than 10 minutes may lead a false positive result.
9.Positive test results do not rule out co-infections with other pathogens.
10.Positive test results do not differentiate between SARS- CoV and SARS-CoV- 2.
11.Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
12.Negative results should be treated as presumptive and confirmed with a molecular assay.
13.Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
14.Users should test specimens as quickly as possible after specimen collection.
15.If the sample volume is not enough, the chromatography cannot be carried out successfully. Please pay attention to the prompt information of the instrument. It is recommended to use a pipette to add samples.

PERFORMANCE CHARACTERISTIC

1.Clinical Verification

Performance of the SARS-Cov-2 Rapid Ag Test Kit (Colloidal Gold) was collected using 630 nasopharyngeal swabs from symptomatic patients who appeared with symptoms within 7 days.

SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	RT-PCR comparative test result		
	Positive (+	Negative (-)	Total
Positive	613	5	618
Negative	17	520	537
Total	630	525	1155
Sensitivity : 613/630 97.3%, (95% CI: 95.7, 98.42)			
Specificity : 520/525 99.0%, (95% CI:97.79, 99.69)			
Accuracy: (520+613)/ 1155(613+5+17+520) x 100% = 98.09%			

Positive results few days after the onset of symptoms:	RT-PCR Positive (+)	SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	PPA
1	16	16	100%
2	36	36	100%
3	60	60	100%
4	90	90	100%
5	120	120	100%
6	98	98	100%
7	180	164	91.1%
Asymptomatic Patients	30	29	96.6%

Number of patients with symptoms for more than seven days as well as asymptomatic patients were included in the clinical study (n = 630). The sample size was relatively significant, positive was 97.3% (613/630) and negative consent was 99% (520/525).

2.Limit of Detection

At a viral culture concentration of 100 $TCID_{50}$/mL and above, the positive level was greater than or equal to 95%. With a viral culture concentration of 50 TCID50/mL and less, the positive level is no more than 95%, so the minimum detection limit of the SARS-CoV-2 Ag rapid test kit is 100 TCID50/mL.

3.Cross-reactivity

Cross-reactivity of the Kit was evaluated. The results showed no cross reactivity with the following specimen.

No.	Specimen Type	Result
1	HCoV-HKU1	10^5 TCID50/mL
2	Staphylococcus aureus	10^6 CFU /mL
3	Streptococcus pyogenes	10^6 CFU /mL
4	Measles virus	10^5 TCID50/mL
5	Paramyxovirus parotitis	10^5 TCID50/mL
6	Adenovirus 3	10^5 TCID50/mL
7	Mycoplasma pneumoniae	10^6 CFU / mL
8	Parainfluenza virus 2	10^5 TCID50/mL
9	Human Metapneumovirus (hMPV)	10^5TCID50/mL
10	Human coronavirus OC43	10^5 TCID50/mL
11	Human coronavirus NL63	10^5 TCID50/mL
12	Human coronavirus 229E	10^5 TCID50/mL
13	MERS Coronavirus	10^5 TCID50/mL
14	Bordetella parapertussia	10^6 CFU / mL
15	Influenza B (Victoria strain)	10^5 TCID50/mL
16	Influenza B (Ystrain)	10^5 TCID50/mL
17	Influenza A (H1N1 2009)	10^5 TCID50/mL
18	Influenza A (H3N2)	10^5 TCID50/mL
19	Avian influenza virus (H7N9)	10^5 TCID50/mL
20	Avian influenza virus (H5N1)	10^5 TCID50/mL
21	Epstein-Barr virus	10^5 TCID50/mL
22	Enterovirus CA16	10^5 TCID50/mL
23	Human rhinovirus type 1	10^5 TCID50/mL
24	Human rhinovirus type 14	10^5 TCID50/mL
25	Respiratory syncytial virus A	10^5 $TCID_{50}$/mL
26	Respiratory syncytial virus B	10^5 TCID50/mL
27	Streptococcus pneumoniae	10^6 CFU / mL
28	Candida albicans	10^6 CFU / mL
29	Chlamydia pneumoniae	10^6 CFU / mL
30	Bordetella pertussis	10^6 CFU /mL
31	Pneumocystis jirovecii	10^6 CFU /mL
32	Mycobacterium tuberculosis	10^6 CFU / mL
33	Legionella pneumophila	10^6 CFU / mL
34	Human para-flu virus type 1	10^5 $TCID_{50}$/mL
35	Human para-flu virus type 2	10^5 $TCID_{50}$/mL
36	Human para-flu virus type 3	10^5 $TCID_{50}$/mL
37	Human para-flu virus type 4	10^5 $TCID_{50}$/mL

4.Interference Substances

The test results do not be interfered with the substance at the following concentration:

No.	Contaminants	Result
1	Whole Blood	4%
2	Ibuprofen	1mg / mL
3	Tetracycline	3μg / mL
4	Chloramphenicol	3μg / mL
5	Erythromycin	3μg / mL
6	Tobramycin	5%
7	Throat spray (Menthol)	15%
8	Mupirocine	10mg/mL
9	Throat lozenge (Menthol)	1.5mg/mL
10	Tamiflu (Oseltamivir)	5mg/mL
11	Naphthoxoline hydrochloride nasal drops	15%
12	Mucin	0.50%
13	Fisherman's Friend	1.5mg/mL
14	Compound Benzocain Gel	1.5mg/mL
15	Cromoglycate	15%
16	Sinex (Phenylephrine Hydrochloride)	15%
17	Afrin (Oxymetazoline)	15%
18	Fluticasone propionate spray	15%

5. Precision

1.10 replicates of negative and positive samples were tested by using the reference materials of enterprises. The negative agreement and the positive agreement were 100%.

2.Three different lots including positive and negative reference materials of enterprises were tested. The negative results and the positive results were 100%

6.Hook Effect

There was no Hook effect detected when the concentration of inactivated virus stock solution raised up to 4.0×10^5 $TCID_{50}$/mL.

PRECAUTIONS

1.For in vitro diagnostic use.

2.Do not use the kit contents beyond the expiration date printed on the outside of the box.

3.Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.

4.Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.

5.Do not reuse the used Test Card, Reagent Tubes or Swabs.

6.The user should never open the foil pouch of the Test Card exposing it to the ambient environment until the Test Card is ready for immediate use.

7.Discard and do not use any damaged or dropped Test Card or material.

8.The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.

9.Inadequate or inappropriate sample collection, storage, and transport may yield false test results.

10.Sample collection and handling procedures require specific training and guidance.

11.Use the appropriate Fixed Volume Pipette in accordance with test procedures.

12.To obtain accurate results, do not use visually bloody or overly viscous samples.

13.Do not write on the barcode of the Test Card.

14.As the detection reagent is a fluorescent compound, no visible results will form on the test strip.

15.To obtain accurate results, an opened and exposed Test Card should not be used inside a laminar flow hood or in a heavily ventilated area.

16.Testing should be performed in an area with adequate ventilation.

17.Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.

18.Wash hands thoroughly after handling.

KEY TO SYMBOLS USED

COMPONENT	Material Included
TEST CARD	Test Card
TUBE	Tube
SWAB	Swab
IFU	Instruction for Use
	Consult Instruction for Use
	Store at 2℃ ~ 30℃
	Expiration Date
	Manufacturer
	Keep Dry
LOT	Lot Number
DILUENT	Sample Buffer
	Date of Manufacture
	Do Not Reuse
REF	Catalogue Number
	Keep Away From Sunlight
	Tests per Kit
IVD	In Vitro Diagnostic Medical Device
	Do not use if the package is damaged
	Biohazard
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device

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