RapidForTM SARS-CoV-2 Saliva Ag Test Kit (Colloidal Gold)
Catalog Number: VSCD05-1

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 gargled water or saliva specimens.
This test is only for clinical laboratory use or for immediate inspection by medical personnel, not for home testing, and cannot be used as the basis for the diagnosis and exclusion of pneumonia caused by new coronavirus infection and is not suitable for screening by the general population.
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 β genus, 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 gargled water or saliva 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, a red 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

1.1 test cassette
2.1 piece collecting apparatus
3.1 piece tube with extraction buffer
4.1 package insert.

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 storeunder2°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.
.MFG date and EXP date: marked on the label. The roduct will be expired after 12 months.

TEST PROCEDURE

1.Must be used at least 2 hours after eating or drinking for 95% accuracy.
2. Put your saliva to the aluminium foil at the package which assigned to it.
3. With help of the pasteur pipette, take 1 ml (30 drop) of saliva to the buffer tube which already filled with extraction buffer. And close the cap of the tube.

Test operation

Before test, please read the instruction manual.
4.Open the aluminum package including test cassette.
5.Add 3 drops of saliva-extraction buffer mixture to the sample well.
6.Wait for 10 minutes for sample to move along on the test cassette.
7.At the end of the 10 minutes, interpret the results.

INTERPRETATION OF TESTRESULTS

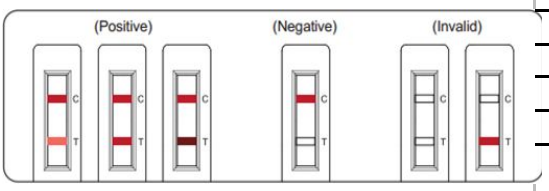
This product can only perform qualitative analysis on the detection object.

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

Note: Specimens containing very low levels of target antibodies may develop two colored lines over 15 minutes.

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 saliva samples.

3.This test detects both viable (live) and non-viable, SARS-CoV and SARS-CoV-2. 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.

4.The Sample buffer and test card must be equilibrated to room temperature (18℃~26℃) before used, otherwise the results may be incorrect

5.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.

6.Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

7.React less than 10 minutes may lead a false negative result; React more than 10 minutes may lead a false positive result.

8.Positive test results do not rule out co-infections with other pathogens.

9.Positive test results do not differentiate between SARS-CoV and SARS-CoV- 2.

10.Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

11.Negative results should be treated as presumptive and confirmed with a molecular assay.

12.Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.

13.Users should test specimens as quickly as possible after specimen collection.

14.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 Saliva Ag Test Kit (Colloidal Gold) was collected using 194 saliva sample from symptomatic patients who appeared with symptoms within 7 days.

SARS-CoV-2 Saliva Ag Test Kit (Colloidal Gold)	RT-PCR comparative test result		
	Positive (+	Negative (-)	Total
Positive	185	2	187
Negative	9	241	250
Total	194	243	437
Sensitivity : 185/194 95.3%, (95% CI: 92.31,97.42)			
Specificity : 241/243 99.1%, (95% CI:93.56, 98.93)			
Accuracy: (185+241)/ 437 x 100% = 97.4%			

The performance of the SARS-CoV-2 Saliva Ag Test Kits (Colloidal Gold) was collected and evaluated with positive results stratified by the Cycle threshold (Ct) comparison method in order to better understand the correlation between assay performance and the cycle threshold;

As shown in the table below, the SARS-Cov-2 Saliva Ag Test Kit (Colloidal Gold) corresponds positively to samples with a Ct number greater than 25.

SARS-CoV-2 Saliva Ag Test Kit (Colloidal Gold)	Comparative RT-PCR method (Positive according to Ct value)	
	Positive (Ct<25)	Positive (25<Ct<30
Positive	104	81
Negative	2	7
Total	106	88
Positive	98.1%	92.0%

Patients with symptoms for more than seven days as well as asymptomatic patients were included in the clinical study (n = 194). The sample size was relatively significant, positive was 95.3% (185/194) and negative consent was 99.1% (241/243). The test is intended for professional use.

A limited number of patients with symptoms fo more than seven days as well as asymptomati

patients were included in the clinical study (n = 600). The sample size was relatively significant, positive was 95.6% (574/600) and negative consent was 99.4% (522/525). The test is intended for professional use.

2.Limit of detection

At a viral culture concentration of 100 TCID50/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 Saliva Ag 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 $TCID_{50}$/mL
2	Staphylococcus aureus	10^6 CFU /mL
3	Streptococcus pyogenes	10^6 CFU /mL
4	Measles virus	10^5 $TCID_{50}$/mL
5	Paramyxovirus parotitis	10^5 $TCID_{50}$/mL
6	Adenovirus 3	10^5 $TCID_{50}$/mL
7	Mycoplasma pneumoniae	10^6 CFU / mL
8	Parainfluenza virus 2	10^5 $TCID_{50}$/mL
9	Human Metapneumovirus (hMPV)	$10^5$$TCID_{50}$/mL
10	Human coronavirus OC43	10^5 $TCID_{50}$/mL
11	Human coronavirus NL63	10^5 $TCID_{50}$/mL
12	Human coronavirus 229E	10^5 $TCID_{50}$/mL
13	MERS Coronavirus	10^5 $TCID_{50}$/mL
14	Bordetella parapertussia	10^6 CFU / mL
15	Influenza B (Victoria strain)	10^5 $TCID_{50}$/mL
16	Influenza B (Ystrain)	10^5 $TCID_{50}$/mL
17	Influenza A (H1N1 2009)	10^5 $TCID_{50}$/mL
18	Influenza A (H3N2)	10^5 $TCID_{50}$/mL
19	Avian influenza virus (H7N9)	10^5 $TCID_{50}$/mL
20	Avian influenza virus (H5N1)	10^5 $TCID_{50}$/mL
21	Epstein-Barr virus	10^5 $TCID_{50}$/mL
22	Enterovirus CA16	10^5 $TCID_{50}$/mL
23	Human rhinovirus type 1	10^5 $TCID_{50}$/mL
24	Human rhinovirus type 14	10^5 $TCID_{50}$/mL
25	Respiratory syncytial virus A	10^5 $TCID_{50}$/mL
26	Respiratory syncytial virus B	10^5 $TCID_{50}$/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 4.0×105 TCID50/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
Σ	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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