RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit
Catalog Number: VSCD02
For professional use only

IVD

INTENDED USE

The RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit is a lateral flow sandwich assay designed for the in vitro qualitative detection of the nucleocapsid antigen of SARS-CoV-2 in nasal, nasopharyngeal and oropharyngeal swab specimens.
This test is intended for use in the clinical laboratory or for near-patient testing by professionals only, as an aid in the diagnosis of SARS-CoV-2 infection. The test is not intended for self-testing. A positive test result needs further confirmation by using RT-PCR. A negative test result does not rule out SARS-CoV-2 infection. It is recommended that the patient's clinical manifestations and other laboratory tests be combined to obtain a comprehensive analysis of the disease.

SUMMARY AND EXPLANATION

The novel coronavirus SARS-CoV-2 is a positive-strand RNA virus and belongs to the β-genus of coronaviruses. COVID-19 is an acute respiratory infectious disease to which humans are susceptible. Currently, patients infected with SARS-CoV-2 are the main source of infection; asymptomatic infected persons can also transmit the virus. Based on current epidemiological investigation, the incubation period is 1 to 14 days, most commonly 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 occur in a few cases.

PRINCIPLE OF THE TEST

This reagent uses a double-antibody sandwich method for the qualitative detection of the Nucleocapsid antigen of SARS-CoV-2. During the test run, a colloidal gold-labelled anti-SARS-CoV-2 monoclonal antibody binds to the SARS-CoV-2 antigen in the sample. This reaction complex moves forward chromatographically on the nitrocellulose membrane, binding to the anti-SARS-CoV-2 monoclonal antibody pre-coated in the detection zone (T) on the test membrane, where it forms a red-stained reaction line. If the sample does not contain SARS-CoV- 2 antigen, no red color reaction line can be formed in the T zone.
At the same time, during the test run, a chicken IgY gold conjugate also moves along the membrane, binds to an anti-chicken IgY monoclonal antibody pre-coated in the quality control area C, and forms a red reaction line there. Regardless of whether the sample to be tested contains SARS-CoV-2 antigen, a red reaction line always forms in the quality control area (C).

MATERIALS AND COMPONENTS

Materials provided with the test kits

COMPONENT	1 Test /box	25 Tests /box
Test Device	1 Test cassette (1Test/pouch x 1 pouch)	25 Test cassettes (1 Test/pouch x 25 pouches)
Buffer	1 single-use bottle, each with 500 µL extraction buffers	25 single-use bottles, each with 500 µL extraction buffers
Specimen sampling swabs	1 sterile, single use specimen sampling swab	25 sterile, single use specimen sampling swabs
Packing Insert	1 instruction for use	1 instruction for use

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

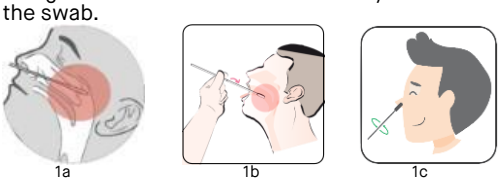
Active components of the test cassette
Reagents
- mAb anti-COVID-19 antibody
- mAb anti-chicken IgY
- mAb anti-COVID-19 gold-conjugated antibody
- Purified chicken IgY gold conjugate
- Recombinant COVID-19 nucleocapsid protein

STORAGE AND STABILITY

1.Store the test kit at 2°C - 30°C. Do not store or freeze the kit below 2°C. All components must be brought to room temperature before testing.
2.The test cassette must be used within 15 minutes after removal from the foil pouch.
3.The kit must not be used after the expiry date. The expiry date is stated on the label/packaging.

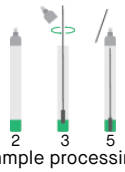
TEST PROCEDURE

Read the instructions for use carefully before testing and carry out the following instructions as described. Make sure that the test components are at room temperature when used. The test procedure includes the following steps: sample collection, sample processing and test performance.
Caution: The sample collection procedure differs between the individual swab samples. Please perform only one of the indicated swab samples (1a - 1c).
1a.Nasopharyngeal swab: Ask the patient to place the head slightly in the neck. Then slowly insert the sterile swab head first trans nasally into the nasopharynx until you feel a slight resistance. Turn the swab 3 times close to the inner wall of the nasal cavity and carefully remove the swab from the nose. Avoid contact with the nasal mucosa when inserting and removing.
or 1b.Oropharyngeal swab: Pass the sterile swab past the palatal cusp, to the posterior pharyngeal wall. Swab and rotate the swab 10 times along the posterior pharyngeal wall and both tonsils. Then remove the swab. Avoid contact of the swab head with the tongue during specimen collection.
or 1c.Anterior nasal swab: Insert the sterile swab into the anterior nasal section and rotate the swab 3 times along the inner wall of the nasal cavity. Then remove the swab.



1a Nasopharyngeal swab | 1b Oropharyngeal swab | 1c Anterior nasal swab
Sample collection

2.Open the cap of the extraction tube and insert the used swab with the swab head first into the extraction tube.
3.Rotate the swab in the extraction buffer 10 times along the inner wall of the extraction tube. Then push the swab head out along the inner wall to ensure that the sample on the swab is completely eluted into the buffer.
4.Squeeze the swab head along the inner wall to ensure that the sample is completely eluted from the swab.
5.Break the swab at the marked predetermined breaking point. Make sure that the swab head remains in the extraction tube during the procedure. Close the extraction tube again with the dropper head.



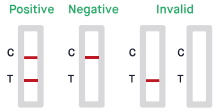
2 3 5
Sample processing

6.Take the required reagents and test cards to equilibrate to room temperature.
7.Unpack the aluminum foil bag and place the test cassette horizontally on the table.
8.Add 3 drops from the extraction tube with the processed sample into the sample well and start a timer.
9.Read the test result after 15 minutes. After 20 minutes, the test result is no longer valid, and the test must be repeated.
10.Dispose of all samples and materials used in the test as biohazardous waste. Laboratory chemicals and biohazardous waste must be disposed of in accordance with local regulations.

8
Test Operation

INTERPRETATION OF TEST RESULTS

This product is for the qualitative detection of SARS-CoV-2 antigen only.
Positive: If both C- and T-line are visible after 15-20 minutes, the test result is positive and valid. If your test result is positive, please consult your local healthcare professional immediately by doing the RT-PCR test for confirmation of the result. To reduce the risk of transmission, rapid isolation, and adherence to the Standard Operating Procedure for you and your close contacts in accordance with the current national guidance and protocols and seeking medical attention is strongly advised.
Negative: If after 15-20 minutes only the C-line is visible but no T-line, the test result is negative and valid. If you develop Covid-19 symptoms, you and your household must self-isolate and get the RT-PCR test for confirmation of the result. You must adhere to the Standard Operating Procedure as per protocol and continue to follow national and local rules and guidelines including regular handwashing, social distancing and wearing face coverings and when required seek medical attention.
Invalid: The test result is invalid if no C-line is visible after 15-20 minutes. The test result is also invalid if the T-line is visible but no C-line. In both cases, the test must be performed with a new test cassette.



LIMITATIONS

1.The result of the product must not be considered as a confirmed diagnosis. The evaluation of the test results must be done together 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, oropharyngeal and nasopharyngeal swabs. Other specimen types may not be used.
3.This test detects both viable (live) and non-viable antigens of 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.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 20 minutes may lead a false positive result.
8.Positive test results do not rule out co-infections with other pathogens.
9.Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
10.Negative results should be treated as presumptive and confirmed with a molecular assay.

PERFORMANCE DATA

1.Clinical verification
The clinical performance of the RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit was determined by comparison with an RT-PCR assay. Samples were taken within 7 days of symptom onset.

a) Nasopharyngeal Swab
The performance of the SARS-CoV-2 Rapid Antigen Test Kit was assessed using 630 nasopharyngeal swabs from patients.

SARS-CoV-2 Rapid Antigen Test Kit	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; 99.05%, (95% CI:97.79, 99.69)			
Accuracy: 1133/1155x100%; 98.09%			

b) Oropharyngeal Swab
The performance of the SARS-CoV-2 Rapid Antigen Test Kit was assessed using 149 oropharyngeal swabs from patients.

SARS-CoV-2 Rapid Antigen Test-Kit	RT-PCR comparative test results		
	Positive (+)	Negative (-)	Total
Positive	142	0	142
Negative	7	100	107
Total	149	100	249
Sensitivity: 95.30%: (142/149), (95% CI: 90.56,98.09%)			
Specificity: 100%: (100/100), (95% CI: 96.38 – 100.00%)			
Accuracy: 97.19% (142+100) /249			

c) Nasal swab
The performance of the SARS-CoV-2 Rapid Antigen Test Kit was assessed using 216 nasal swabs from patients.

SARS-CoV-2 Rapid Antigen Test-Kit	RT-PCR-comparative test result		
	Positive (+)	Negative (-)	Total
Positive	209	2	211
Negative	7	279	286
Total	216	281	497
Sensitivity: 96.76%: (209/216), (95% CI: 93.44 - 98.69)			
Specificity: 99.29%: (279/281), (95% CI: 97.45 - 99.91)			
Accuracy: 98.19%: (279+209) / (209+2+7+279)			

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%. The minimum detection limit of the SARS-CoV-2 Rapid Antigen Test is 100 $TCID_{50}$/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	Human coronavirus-HKU1	10^6 $TCID_{50}$/mL(In-silico)
2	Staphylococcus aureus	3x10^6 CFU /mL
3	Streptococcus pyogenes	1.6x10^6 CFU /mL
4	Measles virus	1.8x10^5 $TCID_{50}$/mL
5	Paramyxovirus parotitis	1.0x10^5 $TCID_{50}$/mL
6	Mycoplasma pneumoniae	1.3x 10^7 CFU / mL
7	Human Metapneumovirus (hMPV)	2.4x10^5 $TCID_{50}$/mL
8	Human coronavirus OC43	1.8x10^5 $TCID_{50}$/mL
9	Human coronavirus NL63	1.8x10^5 $TCID_{50}$/mL
10	Human coronavirus 229E	2.5x10^5 $TCID_{50}$/mL
11	MERS Coronavirus	8.9x10^5 $TCID_{50}$/mL
12	Bordetella parapertussia	1.0x10^5 CFU/mL
13	Influenza B (Victoria strain)	1.5x10^5 TCID50/mL
14	Influenza B (Ystrain)	2.0x10^5 TCID50/mL
15	Influenza A (H1N1 2009)	1.8x10^5 $TCID_{50}$/mL
16	Influenza A (H3N2)	2.0x10^5 $TCID_{50}$/mL
17	Avian influenza virus (H7N9)	1.0x10^5 $TCID_{50}$/mL
18	Avian influenza virus (H5N1)	1.0x10^5 $TCID_{50}$/mL
19	Epstein-Barr virus	1.0x10^7 copies/mL
20	Enterovirus CA16	1.0x10^5 $TCID_{50}$/mL
21	Human rhinovirus type 1	1.0x10^5 $TCID_{50}$/mL
22	Human rhinovirus type 14	1.0x10^5 $TCID_{50}$/mL
23	Respiratory syncytial virus A	1.2x10^5 $TCID_{50}$/mL
24	Respiratory syncytial virus B	2.4x10^5 $TCID_{50}$/mL
25	Streptococcus pneumoniae	1.8x10^6 CFU / mL
26	Candida albicans	1.3x10^6 CFU / mL
27	Chlamydia pneumoniae	1.0x10^5 CFU/mL
28	Bordetella pertussis	5.8x10^6 CFU /mL
29	Pneumocystis jirovecii	10^6 CFU /mL(In-silico)
30	Mycobacterium tuberculosis	10^6 CFU / mL(In-silico)
31	Legionella pneumophila	2.0x10^6 CFU / mL
32	Human para-flu virus type 1	1.0x10^5 $TCID_{50}$/mL
33	Human para-flu virus type 2	1.0x10^5 $TCID_{50}$/mL
34	Human para-flu virus type 3	1.0x10^5 $TCID_{50}$/mL
35	Human para-flu virus type 4	1.0x10^5 $TCID_{50}$/mL
36	Haemophilus influenzae	2.7x10^6 CFU/mL
37	SARS-coronavirus	2.5x10^5 PFU/mL
38	Staphylococcus epidermidis	1.2x10^7 CFU /mL
39	Mumps virus	3.2x$10^5$$TCID_{50}$/mL
40	Enterovirus 70	3.1x10^5 $TCID_{50}$/mL
41	Human rhinovirus B70	1.0x10^5 $TCID_{50}$/mL
42	Parainfluenza virus 1	1.8x10^5 $TCID_{50}$/mL
43	Parainfluenza virus 2	4.3x10^5 $TCID_{50}$/mL
44	Parainfluenza virus 3	1.6x10^5 $TCID_{50}$/mL
45	Parainfluenza virus 4	1.3x10^5 $TCID_{50}$/mL
46	Adenovirus Type 3	1.0x10^5 $TCID_{50}$/mL
47	Adenovirus Type 5	1.8x10^5 $TCID_{50}$/mL
48	Adenovirus Type 7	1.8x10^5 $TCID_{50}$/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 Eye Drops	5%
7	Throat spray (Menthol)	15%
8	Mupirocine	10mg/mL
9	Ice Throat candy (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%
19	Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
20	Naso GEL (NeilMed)	5%
21	CVS Nasal Spray (Cromolyn)	15%
22	Zicam Cold Remedy	5%
23	Homeopathic (Alkalol)	%10
24	Sodium Cromolyn Eye Drops	15%
25	Alkalol Nasal Wash	10%
26	Throat Lozenge	1.5 mg/mL
27	Sore Throat Phenol Spray	15%

5.Precision
1.10 replicates of negative and positive samples were tested by using the reference materials of enterprises. The agreement between the negative and positive results was 100%.
2.Three different batches were tested with positive and negative reference materials. The agreement between the negative and positive results was 100%.

6.Hook Effect
No hook effect was detected at a concentration of 5.0x$10^6$$TCID_{50}$/mL SARS-CoV-2.

PRECAUTIONS
1.For in vitro diagnostic use.
2. All users must read the instructions for use carefully before carrying out the test.
3.Do not use the kit contents beyond the expiration date printed on the outside of the box.
4.Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
5.The sample buffer and test card must be equilibrated to room temperature (18℃-30℃) before used, otherwise the results may be incorrect.
6.Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
7.Do not reuse the used Test Card, Reagent Tubes or Swabs.
8.Discard and do not use any damaged or dropped Test Card or material.
9.The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
10.Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
11.Sample collection and handling procedures require specific training and guidance.
12. Users should test specimens as quickly as possible after specimen collection.
13.To obtain accurate results, do not use visually bloody or overly viscous samples.
14.Do not write on the barcode of the Test Card.
15.If the sample volume is not enough, the chromatography cannot be carried out successfully.
16. 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.
17.Testing should be performed in an area with adequate ventilation.
18.Wash hands thoroughly after handling.

SYMBOLS USED

COMPONENT	Material Included
TEST CARD	Test Card
TUBE	Tube
SWAB	Swab
IFU	Instruction for Use
	Consult Instruction for Use
2°C 30°C	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
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device

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