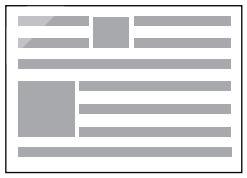
RapidFor™

RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (Nasal)
REF NO : VSCD02ST
Specimen type : Nasal Swab

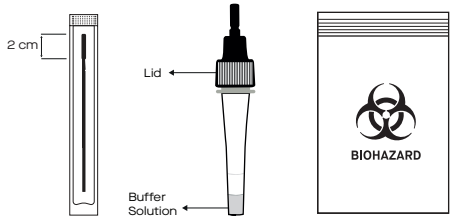
STEP 1 PREPARATION

1 Components of product



Instruction for Use

Test Package



Swab | Extraction buffer tube | Biological waste pochette

Familiarize yourself with the contents of the test kit in advance without opening the packaging of the components.
Make sure to perform the test package contains the test cassette, a bottle with extraction buffer, a sterile swab, waste pochette and information for use.

2 Read IFU and Scan QR

Please read the instructions for use carefully before starting the test and scan the QR code to watch "how to use" video

Scan Me

3 Before testing

- **All components must be brought to room temperature before testing.**
- Clear a flat surface and dry it.
- Have a watch ready.
- **To obtain accurate results, an opened and exposed Test Card should not be used in a heavily ventilated and moistured area.**
- Do not store the test kit in direct sunlight.

CAUTION: The test card is for one-time use only and cannot be reused or used by more than one person at a time.

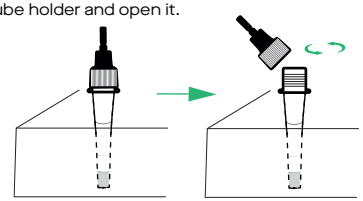
Wash your hand before testing

STEP 2 SAMPLE COLLECTION & PROCESSING

CAUTION: Samples should be used as soon as possible after collection.

4 Place the buffer tube into holder

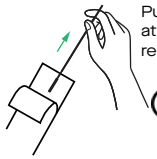
Place the bottle containing the extraction buffer solution into the tube holder and open it.



CAUTION: Be careful not to spill any of the liquid.

CAUTION: Do not drink the extraction solution in the tube. Immediately consult your healthcare professional if you drink it.

5 Take the swab



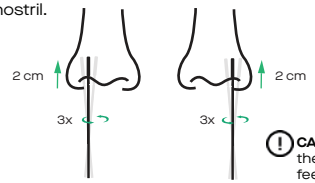
Pull open the swab packaging at the marked point and remove the swab.

CAUTION:
The soft, textile tip of the swab should not come into contact with hands or objects.

CAUTION: Do not open the swab until you are going to use it in couple minutes.

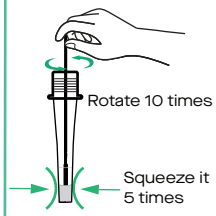
6 Sample collection

Carefully insert the sterile swab 2 cm into one nostril and rotate the swab 3 times close to the inner wall of the nose. Repeat the procedure with the same swab in the other nostril.



CAUTION: Do not insert the swab deeper if you feel strong resistance or pain.

7 Insert the swab

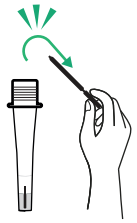


Then take the buffer tube and insert the swab with the swab sample into the bottle and dip the tip into the extraction buffer. Rotate the swab tip with the swab sample 10 times along the inner wall of the bottle. Squeeze the tip of the swab along the inner wall of the bottle to keep as much liquid in the bottle as possible.

*Make sure that the sample on the swab is detached as completely as possible into the buffer/test liquid.
*This process should take at least 20 seconds.

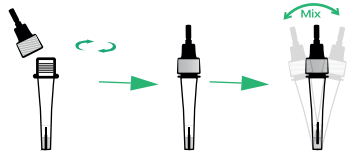
8 Break off the swab

Break off the upper half of the swab from the breaking point, leaving the lower half in the bottle , and close the cap back.



CAUTION: If squeezing of tube is not made correctly, sample swab absorbs much more extraction buffer and that will yield wrong results.

9 Close and mix the bottle

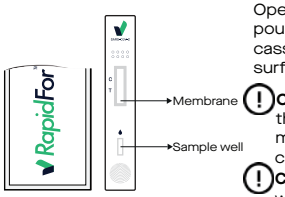


CAUTION: Do not drink the sample extraction solution with swab. If you accidentally drink it immediately consult your healthcare professionals.

CAUTION: Do not spill any of the sample extraction solution. If you spill it, sterilize the area and if the amount of the sample extraction solution mixture is not enough to perform the test, repeat the test by using new sampling swab and extraction solution tube.

STEP 3 TEST OPERATION

10 Take out the cassette

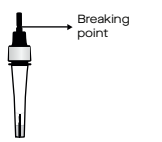


Open the aluminum foil pouch and place the test cassette on a clean, flat surface.

CAUTION: Do not touch the sample well or the membrane of the test cassette.

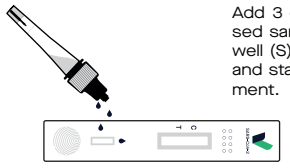
CAUTION: Must be used within 15 min after removal from foil pouch.

11 Break off the tip



The cap contains an opening, carefully break off the tip of the cap with your thumb, this allows dropwise dispensing of the processed sample during the following test procedure.

12 Test Operation



Add 3 drops of the processed sample into the sample well (S) of the test cassette and start the time measurement.

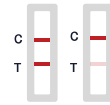
Read the result **after 15 minutes.**

CAUTION: Do not read **after 20 minutes.**

STEP 4 INTERPRETATION OF THE RESULTS

This product is for the qualitative detection of SARS-CoV-2 antigen only. Please consult your physician for medical advice before any kind of medical decision.

Positive



If both C- and T-line are appear, it indicates that SARS-CoV-2 antigen has been detected and the results is positive

If the test result is positive:

- Currently, there is a suspected infection of COVID-19
- Contact your doctor or local health department immediately
- Comply with the local self-isolation guidelines
- Perform PCR test for confirmation

Note: The intensity of the color in the test line region will vary depending on the concentration of COVID-19 antigen in the specimen. Therefore, any shade of color in the test region should be considered positive.

Negative

If there is only a control line (C) appeared and the test line (T) is colorless, it indicates that SARSCoV-2 antigen has not been detected and the result is negative.

If the test result is negative:

- Continue to comply with all applicable rules regarding contact and protective measures.
- Even if the test is negative, there may be an infection.
- In case of doubt, repeat the test after 1-2 days because the SARS-CoV-2 cannot be accurately detected at all stages of infection.

Invalid

If the control line (C) is not observed, the test is considered to be invalid whether the test line (T) is visible or not. A new test needs to be performed using a new test device.

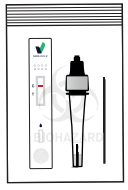
If the test result is invalid, it may be caused by incorrect test operation. Please repeat the test.If the test result is still invalid, please contact your doctor or COVID-19 testing center.

STEP 5 BIOHAZARD WASTE DISPOSAL PROCEDURE

13 Clean the area

Sterilize or clean the area where the test is performed.

14 Disposal



To safely dispose of the test kit, place all the used material during the test (sample swab, extraction buffer tube, test cassette) in the biological waste pochette and seal it properly. Dispose the entire biological waste pochette immediately in the general waste bin.

Wash hands with soap thoroughly or sanitize your hands after handling.

Version: 21042022

RapidFor™

RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (Nasal)
Reference Number: VSCD02ST
For personal use only
In-vitro diagnostic test for self-testing
Instructions for use

INTENDED USE

The RapidFor™ SARS-CoV-2 Rapid Antigen Test (Nasal) is a lateral flow test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in human nasal swab specimens. The kit provides a rapid, on-the-spot result on the possible presence of COVID-19 infection in the individual person being tested. The test kit is designed for self-testing and does not require any special training for sample collection, processing, or test operation. The test can be performed by individuals older than ≥ 18 years old and users between 4-18 years old required guidance by adults. This kit is not suitable for children under 4 years old. The self-test is also used for monitoring of an existing disease, only adapt the treatment if he has received the appropriate training to do so.

Positive test result: A positive result provides evidence of SARS-CoV-2 infection. Please go into quarantine and contact a physician. A confirmatory test by using RT-PCR is necessary!

Negative test result: A negative result does not exclude an infection with SARS-CoV-2. A negative test result is only a snapshot.

Invalid Test Result: In the event of an invalid result, please repeat the test.

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 required and provided with the test kits

CATALOG NO	VSCD02ST01	VSCD02ST02	VSCD02ST05
COMPONENT	(1 Test/Box)	(2 Tests/Box)	(5 Tests/Box)
Test Device	1 Test cassette (1Test/pouch x 1 pouch)	2 Test cassettes (1Test/pouch x 2 pouches)	5 Test cassettes (1 Test/pouch x 5 pouches)
Buffer	1 single-use bottle, each with 500 µL extraction buffer	2 single-use bottles, each with 500 µL extraction buffers	5 single-use bottles, each with 500 µL extraction buffers
Specimen sampling swabs	1 sterile, single use specimen sampling swab	2 sterile, single use specimen sampling swabs	5 sterile, single use specimen sampling swabs
Biological waste pochette	1 single-use, biological waste labeled pochette	1 single-use, biological waste labeled pochette	1 single-use, biological waste labeled pochette
Packing Insert	1 instruction for use	1 instruction for use	1 instruction for use

Materials required but not provided with the test kit
- Timer

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

STORAGE AND STABILITY

1.Store the test kit at 2°C - 30°C. Do not store or freeze the kit below 2°C. Do not store the test kit in direct sunlight. 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.

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 the kits are intended for the qualitative detection of SARS-CoV-2 in nasal samples. Neither the SARS-CoV-2 concentration nor the increase in concentration can be measured.
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 the results of a virus culture performed on the same sample.
5.A negative test result may occur if the antigen concentration in a specimen is below the detection limit of the test or if the specimen was improperly collected or transported.
6.Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
7.A negative test result does not exclude the possibility of SARS-CoV-2 infection at any time. Negative results can occur, for example, when the viral load is low, such as in the early incubation phase or from the second week after symptom onset and in asymptomatic individual. However, a false-negative test result can also occur if the sample was taken improperly, or the amount of virus is below the detection limit of the test. Please observe the hygiene rules and repeat the test if necessary.
8.If symptoms are ongoing after test results came negative, test again within 1-2 days to eliminate high risks and if your sample tests positive, please contact a health institution. A confirmatory test is necessary. To reduce the risk of transmission, rapid isolation after a positive test result is necessary. By contacting the doctor/health institution, entry into the reporting system then also takes place, in the case of a confirmed test result.
9.A positive test result does not exclude co-infections with other pathogens.
10.Negative test results do not exclude viral or bacterial infections other than SARS.
11.Negative results should be treated as presumptive and confirmed with a molecular assay.
12. If new SARS-COV-2 variants that may occur in the detection region may affect the detection limit of the test.

QUALITY CONTROL

A colored line in the control area (C) is considered an internal process control. It confirms complete penetration of the membrane with the sample, reactivity of the reagents, and correct test performance.

PERFORMANCE CHARACTERISTICS

1.Clinical Performance:
The clinical performance of the RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (Nasal) was determined by comparison with an RT-PCR assay. Samples were taken within 7 days of symptom onset.
The performance of the RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (Nasal) was assessed using 663 nasal swabs.

RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (Nasal)	PCR-RT comparative test result		
	Positive (+)	Negative (-)	Total
Positive	198	3	201
Negative	6	456	462
Total	204	459	663
Diagnostic Sensitivity: 198/204x 100 % = 97.06% , (95% CI: 93,71 – 98.91)			
Diagnostic Specificity: 456/459 x 100 % = 99.35%, (95% CI: 98.10 – 99.87)			
Accuracy: (198+456)/663 x 100 % = 98,64%, (95% CI: 97.44 – 99,38)			

***Diagnostic Sensitivity:** The ability of a device to identify the presence of a target marker associated with SARS-CoV-2.
***Diagnostic Specificity:** The ability of a device to recognise the absence of a target marker associated with SARS CoV-2.
***95% CI:** Confidence intervals measure the degree of certainty in a sampling method. 95% chance that the population mean lies within the interval.

2. Analytical Performance:
a. Analytical Sensitivity
Limit of Detection (LOD)
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 RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (Nasal) is 100 $TCID_{50}$/mL.

Variants
The test kit can detect the existing variants of SARS-CoV-2 (Alpha, Beta, Eta, Gamma, Delta, Omicron)

b. Analytical Specificity
Cross Reactivity
The cross-reactivity of the kit was evaluated. The results showed no cross-reactivity with the following samples the following samples

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)	$1.5x10^5$ $TCID_{50}$/mL
14	Influenza B (Ystrain)	$2.0x10^5$ $TCID_{50}$/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	$1.0x10^6$ $TCID_{50}$/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	$3.2x10^5$ $TCID_{50}$/mL
40	Enterovirus 70	$3.1x10^5$ $TCID_{50}$/mL
41	Human rhinovirus B70	$1.0x10^5$ $TCID_{50}$/mL
42	Parainfluenza virus 1	$1.8x10^6$ $TCID_{50}$/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	$1.8x10^6$ $TCID_{50}$/mL
48	Adenovirus Type 7	$1.8x10^5$ $TCID_{50}$/mL
49	Streptococcus salivarius	$1.0x10^5$ CFU/mL
50	Pseudomonas aeruginosa	$1.0x10^5$ CFU/mL

Interference Substances
The test results are not interfered by the substance in 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%

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%.

Hook Effect
No hook effect was detected at a concentration of $5.0x10^6$ $TCID_{50}$/mL SARS-CoV-2.

Usability Study
The usability study of the RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (Nasal) was determined by comparison with an RT-PCR assay. Samples were taken within 7 days of symptom onset.
The performance of the RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (Nasal) was assessed using 462 nasal swabs from patients.

RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (Nasal)	PCR-RT comparative test result		
	Positive (+)	Negative (-)	Total
Positive	448	4	452
Negative	14	462	476
Total	462	466	928
Sensitivity: 448/462 x 100 % = 96.97%, (95% CI: 94.97 – 98.33)			
Specificity: 462/468 x 100 % = 99.14%, (95% CI: 97.82 – 99.77)			
Accuracy: (448+462)/928 x 100 % = 98.06%, (95% CI: 96.95 – 98.85)			

PRECAUTIONS

1.Do not use the kit contents beyond the expiration date printed on the outside of the box.
2.Do not reuse the used Test Card, Reagent Tube or Swab.
3.The aluminum pouch includes a test cassette and a silica gel. Silica gel is required to protect test cassette against environmental conditions. Do not use the test kit if the aluminum pouch does not include silica gel. Do not swallow the silica gel. When swallowed, immediately consult your healthcare profesional.
4.All users must read the instructions for use carefully before carrying out the test.
5.The sample buffer and test cassette must be brought to room temperature (18°C~30°C) before use, otherwise the results may be false.
6.Discard and do not use any damaged or dropped Test Card or material.
7.Users should test specimens as soon as possible after sample collection.
8. Do not spill any of the sample extraction solution. If you spill it, sterilize the area and if the amount of the sample extraction solution mixture is not enough to perform the test, repeat the test bey using new sampling swab and extraction solution tube.
9.Do not drink the extraction solution in the tube with or without swab. Immediately consult your healthcare professional if you drink it.
10.If the sample volume is insufficient, the assay will not perform successfully.
11.The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
12.Inadequate or inappropriate storage and transport of all components and sample collection may yield false test results.
13.To obtain accurate results, do not use visually bloody or overly viscous specimens.
14.To obtain accurate results, an opened and exposed Test Card should not be used in a heavily ventilated and moistured area.
15.Wash hands thoroughly after handling.
16.Do not touch the sample well or the membrane of the test cassette.

SYMBOLS USED

COMPONENT	Material included
	This Side Up
	Fragile
IFU	Instruction for Use
	Consult Instruction for Use
Warning	Warning
2°C 36°F 30°C 86°F	Store at 2°C – 30°C (36 °F ~ 86 °F)
EXP	Expiration Date
	Manufacturer
	Keep Dry
LOT	Lot Number
BUFFER	Sample Buffer
	Date of Manufacture
	Do Not Reuse
REF	Reference Number
	Keep Away From Sunlight
	Tests per Kit
IVD	In Vitro Diagnostic Medical Device
	Do not use if the package is damaged
STERILE R	Sterilized with radiation
STERILE EO	Sterilized with ethylene oxide
	Keep away from children's reach

CE

VITROSENS BIOTECHNOLOGY

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