RapidFor™ SARS-CoV-2 Rapid Antigen Test (FIA)
Catalog Number: VSCD03
For professional use only

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) swab specimens directly.
This test is only for clinical laboratory use or for immediate inspection by medical personnel, not for home testing.
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 nasopharyngeal swab samples. During detection, the EU-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 immunofluorescence assay, there is no formation of visible bands. It will be visible via device when the test cassette is placed into the reader jack. If the sample does not contain SARS-CoV- 2 antigen, fluorescence line cannot be formed in the T zone. Regardless of whether the sample to be tested contains SARS-CoV-2 antigen, a fluorescence line will always form in the quality control area (C).

MATERIALS AND COMPONENTS

Materials provided with the test kits

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

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

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.

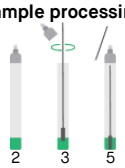
1.Ask the patient to place the head slightly in the neck. Then slowly insert the sterile swab head first trans nasally into the nasopharynx until you feel a slight resistance. Turn the swab 3 times close to the inner wall of the nasal cavity and carefully remove the swab from the nose. Avoid contact with the nasal mucosa when inserting and removing.

Sample Collection

1

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.

Sample processing



2 3 5

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.

Test Operation

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9.Turn on the device.
10.Place the ID Chip that stated place.
11. Press "*Read ID Chip*" part on the screen of the device.

12. Testing

Caution: Put the test cassette must insert first to the device.

Standard test:
After the sample is added, insert the test card into the instrument and click "start test". The instrument automatically counts the time. After the reaction countdown of 10 minutes is over, the instrument automatically performs the test, and records, reads and prints the test results.

Quick test:
After adding the sample, time 10 minutes with a timer, no more than 15 minutes. When the time is up, insert the test card into the instrument, and click "Start Test". The instrument automatically performs the test, and records, reads, and prints the test results. If the test card fails to be tested in time within 10-15 minutes, it will be deemed as invalid test, and the sample need to be retested with a new test card.

13. Dispose all the materials used during the test to biological waste.

Positive Judgement Value

- The positive judgment threshold of this product is 0.05ng / mL.
- The positive judgment value is only a reference guide for clinical diagnosis.
- The test results only reflect the current state of the sample.
- The diagnosis must be comprehensively evaluated in combination with clinical symptoms and other experimental results.
- It is recommended that each laboratory establish its own reference range based on actual conditions.

INTERPRETATION OF TEST RESULTS

This product can only perform qualitative analysis on the detection object. The applicable instrument automatically determines the positive or negative of the sample according to the comparison between the detection value of the detection line and the positive reference value, and directly outputs the qualitative result.

·Positive: indicates that both the detection line and the control line detect a fluorescent signal, and the detection line detection value is ≥0.05ng / mL, which is interpreted as positive.

·Negative: indicates that the fluorescent signal is detected on the control line, and the detection value of the detection line is <0.05ng / mL, which is interpreted as negative.

· Invalid: indicates that no fluorescent signal is detected or only the fluorescent signal is detected on the detection line, the interpretation is invalid, and the sample should be re-tested as required.

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 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 CHARACTERISTIC

1.Clinical Verification

The clinical performance of the RapidFor™ SARS-CoV-2 Rapid Antigen Test (FIA) was determined by comparison with an RT-PCR assay. Samples were taken within 7 days of symptom onset.
Performance of the SARS-CoV-2 Rapid Antigen Test (FIA) was collected using 450 nasopharyngeal swabs from patients.

SARS-CoV-2 Rapid Antigen Test (FIA)	RT-PCR comparative test result		
	Positive (+)	Negative (-)	Total
Positive	445	3	448
Negative	5	547	552
Total	450	550	1000
Sensitivity : 445/450 = 98.9%, (95% CI:97.43, 99.64)			
Specificity : 547/550 = 99.5%, (95% CI:98.41, 99.89)			
Accuracy: (445/547)/1000 = 99.2% (95% CI: 98.43, 99.65)			

2.Limit of Detection

At a viral culture concentration of 50 $TCID_{50}$/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 (FIA)is 50 $TCID_{50}$/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	$3.2x10^5$$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	$1.8x10^5$ $TCID_{50}$/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 $5.0x10^6$$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℃
ID CHIP	ID Chip
	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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