



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 human saliva.

This test is for use in the clinical laboratory or for near-patient testing by professionals only and is intended as an aid in the diagnosis of SARS-CoV-2 infection. The test is not intended for self-testing.

A positive test result requires further confirmation by using RT-PCR. A negative test result does not exclude 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
Saliva bag	1 piece	25 pieces
Pasteur pipette	1 piece	25 pieces
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

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 performing the test 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.

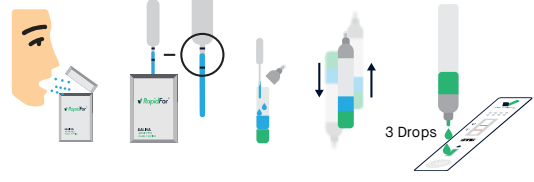
Caution: Before collecting the saliva sample, the patient must not have eaten or drunk anything for at least 30 minutes.

Caution: Samples should be used as soon as possible after collection. After half an hour, the sample must no longer be used, and a new sample collection should be performed with a new sample collection swab.

Caution: The samples must not be inactivated.

- 1.Put your saliva to the aluminum foil at the package which assigned to it.
- 2.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.

- 3.Open the aluminum package including test cassette.
- 4.Add 3 drops of saliva-extraction buffer mixture to the sample well.
- 5.Wait for 15 minutes for sample to move along on the test cassette.
- 6.At the end of the 15 minutes, interpret the results.



INTERPRETATION OF TESTRESULTS

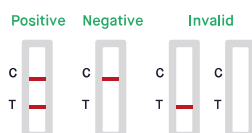
This product is for the qualitative detection of SARS-CoV-2 antigen only.

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 saliva samples.
- 3.This test detects both viable (live) and non-viable antigens of viable 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.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.
- 5.Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- 6.React less than 10 minutes may lead a false negative result; React more than 20 minutes may lead a false positive result.
- 7.Positive test results do not rule out co-infections with other pathogens.
- 8.Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- 9.Negative results should be treated as presumptive and confirmed with a molecular assay.

PERFORMANCE DATA

1.Clinical Verification

Performance of the SARS-Cov-2 Rapid Antigen Test Kit was collected using 194 saliva sample from patients.

SARS-CoV-2 Rapid Antigen Test Kit	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 Rapid Antigen Test Kits 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 Rapid Antigen Test Kit corresponds positively to samples with a Ct number greater than 25.

SARS-CoV-2 Rapid Antigen Test Kit	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.

2.Limit of detection

At a viral culture concentration of 50 TCID₅₀/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 kit is 50 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	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 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 5.0x10⁶TCID₅₀/mL SARS-CoV-2.

PRECAUTIONS

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

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



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