Wondfo

Quick Guide

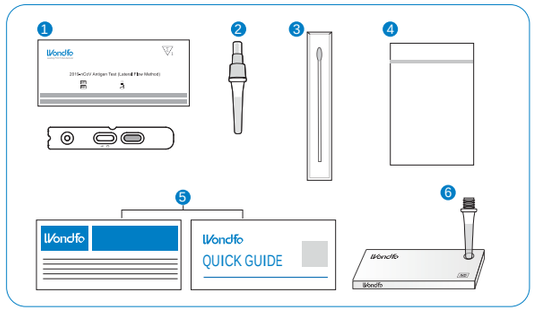
Please scan the QR code for more information including the "how-to-use" video, a copy of IFU, and answers to frequently asked questions.

What Does The Kit Test?

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is a rapid test that is used for detecting novel coronaviruses (2019-nCoV) N protein antigen extracted from the nasal swab specimen.It is intended as an aid in the diagnosis of coronavirus infection disease (COVID-19) for symptomatic patients within 7 days after onset of symptoms, which is caused by 2019-nCoV.
For *in vitro* diagnostic use only. For self-testing use.
According to usability study on lay user, the test can be correctly performed by anyone aged 18 years or above. If the test is to be used on a child or teenager under 18 years of age, the test must be performed by an adult or under adult supervision.

Make Sure Your Test Kit Contains

1. Sealed Pouch
2. Extraction Buffer
3. Disposable Sterile Swab
4. Waste Bag
5. Instruction for Use
6. Tube Rack (in the outer box)



Other required items (not included in the test kit)

Clock or timer

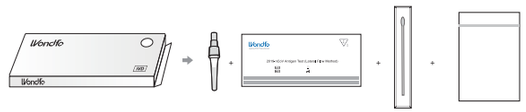
Warning and Precaution

1. Read the instruction for use completely before using the product. Follow the instructions carefully. Failure to do so may result in an inaccurate result.
2. This kit is for external use only, do not swallow.
3. Avoid getting the buffer solution into the eyes or skins.
4. Keep out of reach children.
5. The test kit is for single use only, do not reuse any components of the test kit.
6. Do not use this test beyond the expiration date printed on the outer package. Always check expiry date prior to testing.
7. Do not touch the reaction area of the test cassette.
8. Do not use the kit if the pouch is punctured or not well sealed.
9. DISPOSAL: The used device with all components should be packed in the waste bag provided and locked well . The zip locked waste bag may be disposed of with normal household waste.
10. Do not eat, drink or smoke in the area where handling specimens or test kits.
11. Children under the age of 18 should be supported or under the supervision by an adult.

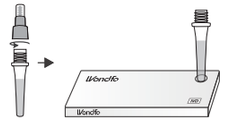
How To Use The Test

Choose a location to do this test where it can sit UNDISTURBED for 20 minutes. Bring the test components to room temperature (10~30°C).

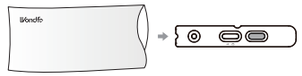
Step 1
Wash and dry hands before you begin to perform the test. Please check the expiration date printed on the BOX . Do not use it beyond the expiration date.



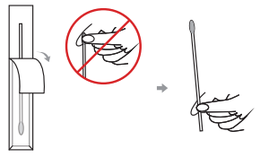
Step 2
Take out the Extraction Buffer Tube, unscrew the lid and place the tube in the tube rack (The tube rack is in the outer box.)



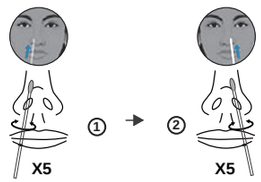
Step 3
Take out the Test Cassette from foil pouch and lay it flat.



Step 4
Remove the swab from the container, being careful **NOT** to touch the soft end, which is the absorbent tip.

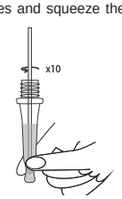


Step 5
Carefully insert the **ENTIRE** absorbent tip of the swab into your nostrils. Firmly sample the nasal wall by rotating the swab in a circular path **five** times against the nasal wall. Slowly remove swab from the nostril. (This step should take approximately 15 seconds, ensuring to collect mucous and cells.)
Repeat the above sampling in other nostril with the **same swab**.

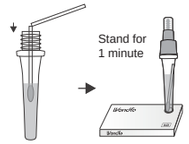


NOTE: Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 15 seconds is not a proper technique and may result in an insufficient sample. ***CAUTION: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.***

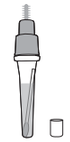
Step 6
Insert the swab into the Extraction Buffer Tube and immerse the entire tip of swab into the Extraction Buffer. Rotate about 10 times and squeeze the absorbent tip through the lower buffer tube.



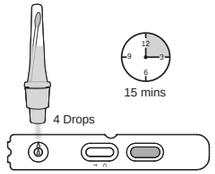
Step 7
Snap off the swab at the break point, leave the swab tip in the tube, cap the lid and leave the tube on the tube rack for 1 minute.



Step 8
Unscrew the small cap at the top of the Extraction Buffer Tube.

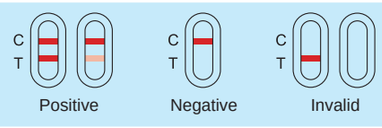


Step 9
Lay the Cassette flat and add 4 drops processed specimen into the sample well. Wait for 15 minutes and read the results. **DO NOT** read results after 20 minutes.

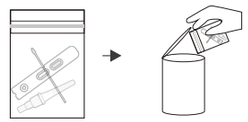


Step 10
Result interpretation

Positive Result (+)
Two red lines will appear. One on the top half and one on the bottom half. COVID-19 was detected.
NOTE: It does not matter if one of the lines that make up the test line (T) is lighter or darker than the other; the result is "Positive".
If you have a POSITIVE result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
(Please refer to Q5 in the Instruction for Use for details)
Negative Result (-)
A single red line on the top half. COVID-19 was not detected. **Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance .**
(Please refer to Q6 in the Instruction for Use for details)
Invalid
If you see no line appearing on the top half, the test is invalid. It is recommended to repeat the test from collecting a new nasal swab.



Step 11
After test is completed, put all test kit materials into the waste bag. Lock the bag well. Dispose used kit materials in household waste.



Step 12
Re-apply hand sanitizer.

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Operation hour:
9:00 am to 7:00 pm (AEST), 7 days per week
https://www.aubiotech.com.au

In the event you are experiencing problems with the test, please contact Australia Biotech Pty Ltd.

Additionally, you may wish to report poor performance or usability issues directly to the Therapeutic Goods Administration (TGA) via the Medical Device Incident Reporting scheme, email iris@tga.gov.au or call 1800 809 361.

To contact your local state/territory health department, click on the following link:
https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments

Local state and territory health departments

Australia Capital Territory Department of Health	General enquiries 02 5124 9213 Coronavirus helpline (8am to 8pm daily) 02 6207 7244	ACT Health
New South Wales Department of Health	General enquiries 1300 066 055 Coronavirus hotline (Service NSW, 24/7) 137 788	NSW Health
Northern Territory Department of Health	General enquiries 08 8922 8044 Coronavirus hotline (National helpline) 1800 020 080	Department of Health Northern Territory
Queensland Department of Health	13HEALTH 13 432 584 Coronavirus hotline: 134COVID 134 268	Queensland Health
South Australian Department of Health	General enquiries 1300 232 272 Coronavirus hotline (9am to 5pm daily) 1800 253 787	SA Health
Tasmanian Department of Health	General enquiries 1300 135 513 Public Health Hotline (coronavirus) 1800 671 738	Department of Health Tasmania
Victorian Department of Health	Department of Health and Human Services 1300 650 172 Victorian coronavirus hotline (24/7) 1800 675 398	Department of Health and Human Service Victoria
Western Australian Department of Health	General enquiries 08 9222 4222 Coronavirus hotline: 13COVID (8am to 6pm, Mon-Fri) 1800 595 206	WA Health

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2019-nCoV Antigen Test (Lateral Flow Method)

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SPECIFICATIONS

Components / REF	W634P0038	W634P0039
Sealed Pouch(pcs)	1	5
Extraction Buffer	1	5
Disposable Sterile Swab (pcs)	1	5
Waste Bag (pcs)	1	5
Instruction for Use (pcs)	1	1

WHAT ELSE DO YOU NEED? — Timer or watch.

STORAGE AND STABILITY

1. The test kit should be stored at 2~30°C (storage in refrigerator is permitted). Do not store the kit in the freezer. Improper storage may result in an inaccurate result.
2. The test cassette is sensitive to humidity and temperature. Once removed from foil pouch, test cassette is stable for up to 1 hour.
3. The test kit is stable until the expiration date printed on outer package. Do not use it beyond the expiration date.
4. The test cassette must remain in the sealed pouch until use.

LIMITATIONS OF PROCEDURE

1. This reagent is designed to detect 2019-nCoV antigen in human nasal swab specimen.
2. Failure to follow the instructions for the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
3. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.
4. The sample collection process will affect the accuracy of the test, such as improper sample collection, improper sample storage, etc.
5. This reagent is a qualitative assay. As it is with any diagnostic procedure, a confirmed 2019-nCoV infection diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
6. Negative test results may occur if the level of antigen in a sample is below the detection limit of the test, or from improper sample collection, and the negative results are not intended to exclude other non 2019-nCoV virus infections.
7. A negative test result does not rule out a coronavirus infection and does not exempt you from the applicable rules for spread control (e.g. contact restrictions and protective measures). Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
8. Positive test results do not exclude co-infections with other pathogens or identify specific 2019-nCoV virus subtype (like SARS-CoV virus), and cannot necessarily determine whether a person is infectious.
9. This is a presumptive test only. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
10. False negative results may occur if testing is not performed within the first 7 days of symptom onset.
11. This test is less reliable in the later phase of infection and in asymptomatic individuals.
12. Repeated testing (within 1-3 days) is recommended in case of ongoing suspicion of infection, exposure to occupational risk or being in a high risk setting.
13. 2019-nCoV variants including Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1) and Delta (B.1.617.2) have been detected out by Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

QUESTION & ANSWER

Q1. How does the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) work?

The Wondfo 2019-nCoV Antigen Test is an antigen test that is to detect the presence of protein fragments (antigen) from the 2019-nCoV in nasal swab specimen.

Q2. What is the difference between a COVID-19 antigen, molecular, and antibody test?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus.

The Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is an antigen test which detects small parts or proteins from the virus. Antigen tests are very specific for the virus but are not as sensitive as molecular tests.

Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection.

Q3. Will this test hurt?

No, the disposable sterile swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly.

Q4. Why do I swab both nostrils?

Swabbing both nostrils gives you the best chance of collecting sufficient sample to generate an accurate result. It has been observed in some cases that only one nostril has detectable virus, so it is important to collect from both nostrils. Correct swabbing is important to obtain a correct result.

Q5. What does it mean if I have a positive test result?

A positive result means that you may have COVID-19 disease. If you have a POSITIVE result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance. It is likely you will be asked to isolate yourself at home to avoid spreading the virus to others, wear a face mask when recommended and wash your hands regularly with soap and water. A positive result does not in any way guarantee that you are or will be immune and therefore cannot (or can no longer) become infected.

Q6. What does it mean if I have a negative test result?

A negative result means the virus that causes COVID-19 was not found in your sample.

A negative test result does not guarantee that you do not or have never had COVID-19, nor does it confirm whether or not you are currently contagious. Do you have cold symptoms in addition to the negative at-home test? Since the at-home test does not provide complete certainty, you should assume that you have COVID-19. Repeated testing (within 1-3 days) is recommended in case of ongoing suspicion of infection, exposure to occupational risk or being in a high risk setting.In the meantime, try to avoid leaving your home and have as little contact as possible with others, including the people you live with. Use disposable tissues and throw them straight in the bin. Sneeze and cough into the crook of your elbow. Wash your hands regularly and wear a face mask. Are your symptoms getting worse (difficulty breathing, high fever, etc.)? Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance..

Q7. How accurate is the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)?

The test has been shown in field clinical evaluations performed by professional health care persons to correctly identify 91.63% (230 out of 251) of 2019-nCoV positive samples (known as the test's sensitivity) and 99.84% (622 out of 623) of 2019-nCoV negative samples (known as the test's specificity), when compared with RT-PCR test.

The test has also been shown in field clinical evaluations performed by lay users to correctly identify 92.96% (66/71) of 2019-nCoV positive samples and 98.53% (335/340) of 2019-nCoV negative samples, when compared with RT-PCR test.

Detection Limit:

The detection limit of Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is 457 $TCID_{50}$/mL.

Q8. Is there any chance that I get a "false" negative result with this test?

It is possible for this test to give an incorrect negative (false negative) result". This means that you could still have COVID-19 even though the test result is negative. If your result is negative and you still experience symptoms related to COVID-19， such as fever, cough and/or shortness of breath, you should follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Q9. Is there any chance that I get an incorrect positive result?

There is a very small chance that this test gives you a positive result that is incorrect (false positive). If you get a positive result, you should self-isolate and follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Q10. I have used the test but no colored band appears at control line (C). What should I do?

If there is no colored band appears at control line (C) within 15 minutes of performing the test, then the test has not worked. You should test again, using a new test, taking care to follow the instruction.

Q11.Can any medication or medical conditions affect the results?

Yes, It may affect your test result, consult your doctor, and always read the manufacturers' instructions for any medication you are taking before conducting the test.

Besides, the test result will not be affected by the presence of following potentially interfering and cross-reactive substances in the specimens:

Mucin	Human coronavirus 229E	Enterovirus
Chloraseptic (Menthol/Benzocaine)	Human coronavirus OC43	Respiratory syncytial virus
Naso GEL (NeilMed)	Human coronavirus NL63	Rhinovirus Type 1A
CVS Nasal Drops (Phenylephrine)	MERS-coronavirus	Haemophilus influenzae Type b
Afrin (Oxymetazoline)	Human Adenovirus 1	Streptococcus pneumonia
CVS Nasal Spray (Cromolyn)	Human Metapneumovirus 3 (hMPV-3) Type B1	Streptococcus pyogenes
Zicam	Parainfluenza virus Type 1	Candida albicans
Homeopathic (Alkalol)	Parainfluenza virus Type 2	pooled human nasal wash
Sore Throat Phenol Spray	Parainfluenza virus Type 3	Bordetella pertussis
Tobramycin	Parainfluenza virus Type 4A	Mycoplasma pneumonia
Mupirocin	Influenza A (H3N2)	Chlamydia pneumonia
Fluticasone Propionate	Influenza A (H1N1)	Legionella pneumophila
Tamiflu (Oseltamivir Phosphate)	Influenza B (Victoria lineage)	Staphylococcus aureus
	Influenza B (Yamagata lineage)	Staphylococcus epidermidis

Q12. What are the possible risks of this test?

Possible Risks:

- Discomfort during the sampling
- Incorrect test results (see Interpreting Results and Limitations Sections).

BIBLIOGRAPHY

1. Centers for Disease Control and Prevention (CDC). Interim Guidelines for Collecting, Handling, and Testing for Patients with Suspected Novel Influenza A (H1N1) Virus Infection. Available online at: https://www.cdc.gov/h1n1flu/specimencollection.htm
2. Song F, Zhang X, Zha Y, Liu W. COVID-19: Recommended sampling sites at different stages of the disease. J Med Virol. 2020;92(9):1383-1385. doi:10.1002/jmv.25892.
3. Tu YP, O'Leary TJ. Testing for Severe Acute Respir'tory Syndrome-Coronavirus 2: Challenges in Getting Good Specimens, Choosing the Right Test, and Interpreting the Results. Crit Care Med. 2020;48(11):1680-1689. doi:10.1097/CCM.0000000000004594.

INDEX OF SYMBOL

Do Not Reuse	See Instruction for Use	Expiry Date	Store Between 2~30°C
Manufacturing Date	Keep Dry	LOT Batch Number	IVD *In Vitro* Diagnostic Use
Keep Away from Sunlight	Manufacturer	REF Catalog #	Tests Per Kit

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Operation hour:
9:00 am to 7:00 pm (AEST), 7 days per week

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