EN

# 2019-nCoV Antigen Test (Lateral Flow Method)

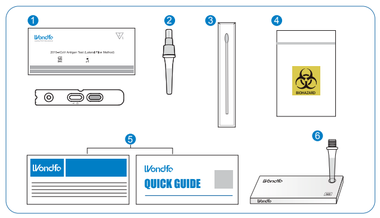
Please scan the QR code to watch the demonstration video.

## WHAT DOES THE KIT TEST?

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is a rapid test that is used for laymen of 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 asymptomatic patients and/or 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 laymen user, the test can be correctly performed for anyone age over 18. However, children under the age of 18 should be supported or under the supervision by an adult.

## MAKE SURE YOUR TEST KIT CONTAINS

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




## Specifications

| Components / REF | W634P0024 | W634P0028 | W634P0025 | W634P0026 | W634P0027 |
|---|---|---|---|---|---|
| Sealed Pouch(pcs) | 1 | 2 | 5 | 10 | 20 |
| Extraction Buffer | 1 | 2 | 5 | 10 | 20 |
| Disposable Sterile Swab(pcs) | 1 | 2 | 5 | 10 | 20 |
| Biohazard Waste Bag(pcs) | 1 | 2 | 5 | 10 | 20 |
| Instruction for Use(pcs) | 1 | 1 | 1 | 1 | 1 |

## WHAT ELSE DO YOU NEED? — Timer or watch.

## 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. DIPOSAL: All specimens and the used-kit has the infectious risk. Discard all the test components in the provided biohazard waste bag after use. The process of disposing the diagnostic kit must follow the local, state and federal infectious disposal laws/regulations.
10. Do not eat, drink or smoke in the area where handling specimens or test kits.

## STORAGE AND STABILITY

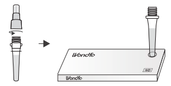
1. The test kit should be stored at 2~30°C (storage in refrigerator is permitted). Do not store the kit in the freezer. Improper storage may result in an inaccurate result.
2. The test cassette is sensitive to humidity and temperature. Once removed from foil pouch, test cassette is stable for up to 1 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.

## 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).

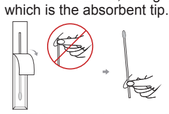
1. Wash and dry hands before you begin to perform the test.
2. Please check the expiration date printed on the BOX. Do not use it beyond the expiration date.

3. 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, see below).

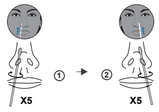


4. Take out the Test Cassette from sealed pouch and lay it flat.

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

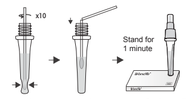


6. Carefully insert the ENTIRE absorbent tip of the swab into your nostrils.
7. Slowly sample the nasal wall by rotating the swab in a circular path 5 times against the nasal wall. Slowly remove swab from the nostril. Repeat the same process with the same swab in the other nostril.
**NOTE:** This step should take approximately 15 seconds, ensuring to collect mucous and cells.
**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.



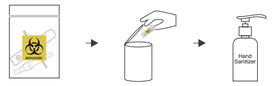

***CAUTION: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.***

8. 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.
9. 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.




10. Unscrew the small cap at the top of the Extraction Buffer Tube. Lay the Cassette flat and add 4 drops processed specimen into the sample well.
11. Wait for 15 minutes and read the results. Do not read results after 20 minutes.


12. After test is completed, put all test kit materials into the biohazard waste bag and dispose it according to the local biohazard waste disposal policy.
13. Re-apply hand sanitizer.




## HOW TO READ THE RESULTS?

**Positive Result**
Two red lines will appear. One on the top half and one on the bottom half. COVID-19 was detected. (Please see Q5 for details)
**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".
**Negative Result**
A single red line on the top half. COVID-19 was not detected. (Please see Q6 for details)
**Invalid Result**
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 disposable sterile swab.


## 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). Symptomatic patient must seek further testing (e.g. immediate PCR), even though negative result occurs.
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. Laboratory PCR test confirmation and follow-up clinical care are required for positive result.
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. SARS-CoV virus 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. Please contact your doctor for further medical suggestion. 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. You can contact your doctor to find out if another test is needed. 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.)? Contact your doctor/health provider immediately.

***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 99.90% (963 out of 964) of 2019-nCoV negative samples (known as the test's specificity), when compared with RT-PCR test. Further, in field clinical evaluations conducted in Germany, US and UK, the test correctly identified 98.53% (335/340) 2019-nCoV negative samples when performed by lay users, and compared with RT-PCR test. The test has also been shown in field clinical evaluations performed by professional health care persons to correctly identify 92.40% (304 out of 329) of 2019-nCoV positive samples (known as the test's sensitivity), when compared with RT-PCR test. Further, in field clinical evaluations conducted in Germany, US and UK, the test correctly identified 92.96% (66/71) of 2019-nCoV positive samples when performed by lay users, and compared with RT-PCR test.
Among the 319 RT-PCR positive samples, when the CT≤25, the detectable rate of the test is 100% (145 out of 145); when the CT≤28, the detectable rate of the test is 98.02%(198 out of 202); when the CT≤30, the detectable rate of the test is 95.88%(233 out of 243); when the CT≤35, the detectable rate of the test is 92.83% (285 out of 307); Thereinto 468 are from symptomatic patients. The test can correctly identify 100% (161 out of 161) 2019-nCoV negative samples and 91.67% (242 out of 264) 2019-nCoV positive samples, when the specimens collected within 7 days after onset of symptoms. Thereinto 425 are from asymptomatic patients. The test can correctly identify 100% (380 out of 380) 2019-nCoV negative samples and 95.56% (43 out of 45) 2019-nCoV positive samples, for the specimens collected from asymptomatic patients.

**Detection limit**
The detection limit of Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is $5.0\times10^3$ $TCID_{50}$/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 seek help from your healthcare provider.

***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 seek medical help from you healthcare provider.

***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 medication manufacturers' instructions for anymedication 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 |
| Manufacturing Date | Keep Dry | Batch Number |
| Keep Away from Sunlight | Manufacturer | Catalog # |
| Tests Per Kit | *In Vitro* Diagnostic Use | Authorized Representative |
| Store Between 2~30°C | | |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E-mail: service@wondfo.com.cn


0123
Qarad EC-REP BV
Pas 257
2440 Geel
Belgium

### Suppliers of disposable sterile swab

1. **Miraclean Technology Co., Ltd. CE 0197 (according to Directive 93/42/EEC)**
No.18, Rongshuxia Industrial Zone Tongle Community, Longgang District Shenzhen 518116 Guangdong China
EC representative name: Share Info Consultant Service LLC Repräsentanzbüro
EC representative address: Heerdter Lohweg 83, 40549 Düsseldorf Heerdter Lohweg 83, 40549 Düsseldorf, Germany
2. **Jiangsu Changfeng Medical Industry Co., Ltd. CE 0197 (according to Directive 93/42/EEC)**
Touqiao Town, Guangling District Yangzhou 225109 Jiangsu P.R.China
EC representative name: Llins Service & Consulting Gmbh
EC representative address: Obere Seegasse 34/2, 69124 Heidelberg, Germany
3. **Medico Biomedical Technology Co., Ltd. CE 0413 (according to Directive 93/42/EEC)**
Room 201 of Building 14th and Building 17th, Hengyi Lane, Yuanhu Road, Zhangbei Industrial Park, Longcheng Street, Longgang District, Shenzhen, Guangdong, China
EC representative name: Wellkang Ltd
EC representative address: Enterprise Hub, NW Business Complex,1 BeraghmoreRd. Derry, BT488SE, N. Ireland. UK
4. **Jiangsu Hanheng Medical Technology co., Ltd.CE 0197 (according to Directive 93/42/EEC)**
16-B4, #1 North Qingyang Road, Tianning District, 213017 Changzhou, Jiangsu, China
EC representative name: Luxus Lebenswelt GmbH
EC representative address: Kochstr. 1, 47877, Willich, Germany
5. **Shenzhen KangDaAn Biological Technology Co., Ltd.**
**CE0197 (according to Directive 93/42/EEC)**
East-1, 3rd floor, Building 2, Shunheda Factory Liuxiandong industrial zone, Xili street Nanshan district, Shenzhen 518055 Guangdong P.R. China
EC representative name: Share Info Consultant Service LLC Repräsentanzbüro
EC representative address: Heerdter Lohweg 83, 40549 Düsseldorf Heerdter Lohweg 83, 40549 Düsseldorf, Germany

# Quick Guide

2019-nCoV Antigen Test (Lateral Flow Method)

Operation Video

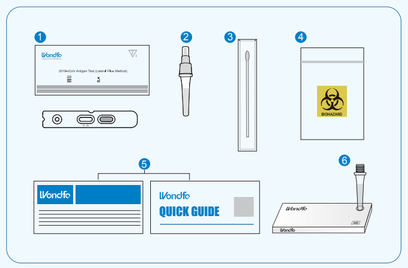
- According to usability study on laymen user, the test can be correctly performed for anyone age over 18. However, children under the age of 18 should be supported or under the supervision by an adult.
- The test result must be read in 15 minutes, DO NOT read the result after 20 minutes.
- Please wash or disinfect your hands carefully before and after performing the test.
- Please take the necessary security measures when testing other people (e.g. face mask, gloves).
- This test is intended as an aid in the diagnosis of 2019-nCoV infection for asymptomatic patients and/or symptomatic patients within 7 days after onset of symptoms.
- Once removed from foil pouch, test cassette is stable for up to 1 hour.

## Product Components

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

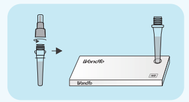
## Other required items (not included in the test kit)

Clock or timer

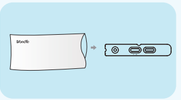



## Test Procedure

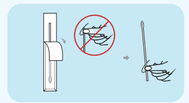
**Step 1**
Take out the Extraction Buffer Tube, unscrew the lid and place the tube in the tube rack (The tube rack is in the outer box.)



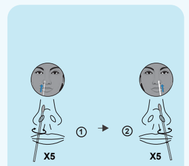
**Step 2**
Take out the Test Cassette from foil pouch and lay it flat.



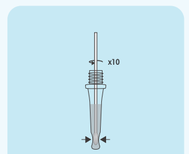
**Step 3**
Remove the swab from the container, being careful **NOT** to touch the soft end, which is the absorbent tip.



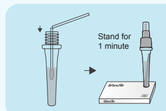
**Step 4**
Carefully insert the **ENTIRE** absorbent tip of the swab into your nostrils. Firmly sample the nasal wall by rotating the swab in a circular path **five** times against the nasal wall. Slowly remove swab from the nostril. (This step should take approximately 15 seconds, ensuring to collect mucous and cells.)
Repeat the above sampling in other nostril with the **same swab**.




**Step 5**
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.

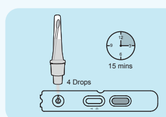



**Step 6**
Snap off the swab at the break point, leave the swab tip in the tube, cap the lid and leave the tube on the tube rack for 1 minute.




**Step 7**
Unscrew the small cap at the top of the Extraction Buffer Tube.

**Step 8**
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 9**
After test is completed, put all test kit materials into the biohazard waste bag and dispose it according to the local biohazard waste disposal policy.

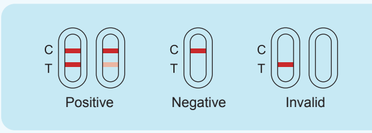
**Step 10**
Re-apply hand sanitizer.


**Step 11**
Result interpretation

**Positive (+)**
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". (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. (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.





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**Special Requirement from Each Country**