



2019-nCoV Antigen Test (Lateral Flow Method)

Please scan the QR code to watch the demonstration video.



WHAT DOES THE KIT TEST?

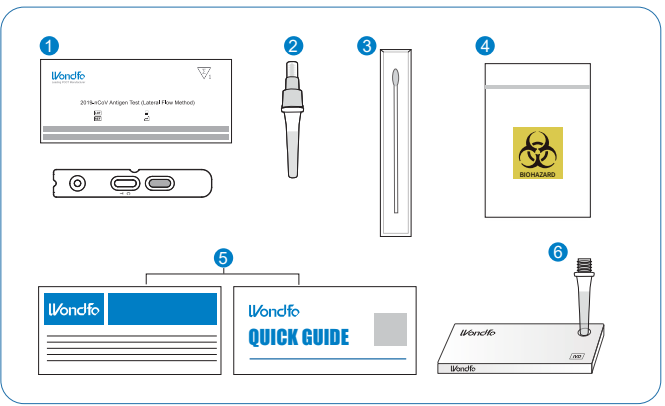
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is a rapid test that is used for laymen of detecting novel coronaviruses (2019-nCoV) N protein antigen extracted from the nasal swab specimen. It is intended as an aid in the diagnosis of coronavirus infection disease (COVID-19) for symptomatic patients 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 use, the test can be correctly performed for anyone age over 18. However, nasal swab specimen from individuals aged below 18 years old should be collected and performed by another adult. While the users age over 75 should be aware of the removal of their nasal swab or have nasal swabs assist.

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)



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 99.84% (622 out of 623) of 2019-nCoV negative samples (known as the test's specificity). Further, in field clinical evaluations conducted in Germany and US, the test correctly identified 100% (129/129) 2019-nCoV negative samples when performed by self test users. The test has also 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). Further, in field clinical evaluations conducted in Germany and US, the test correctly identified 89.66% (26/29) of 2019-nCoV positive samples when performed by self test users.

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 your 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 manufacturers' instructions for any medication you are taking before conducting the test.

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



Prueba de Antígeno 2019-nCoV (Método de Flujo Lateral)

Escanee el código QR para ver el video de demostración por favor.



¿QUÉ ES EL CONJUNTO DE PRUEBA?

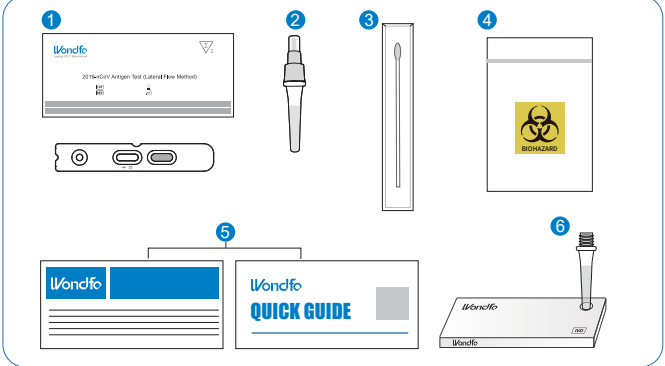
La prueba de antígeno 2019-nCoV de Wondfo (Método de Flujo Lateral) es una prueba rápida que se utiliza para los legos que detectan el antígeno de la proteína N de nuevos coronavirus (2019-nCoV) extraído desde la muestra de hisopo nasofaríngeo. Esta prueba está destinada a ser un auxilio en el diagnóstico de coronavirus, enfermedad infecciosa (COVID-19), para pacientes asintomáticos dentro de los 7 días posteriores al inicio de los síntomas, que son causados por 2019-nCoV.

Sólo para uso diagnóstico *in vitro*. Para uso de auto-prueba.

Según un estudio de usabilidad sobre el uso de legos, la prueba se puede realizar correctamente para cualquier persona mayor de 18 años. Sin embargo, la muestra de hisopo nasal de personas menores de 18 años debe ser recoigido y realizado por otro adulto. Mientras que los usuarios mayores de 75 años deben ser consciente de la extracción de su hisopo nasofaríngeo o tener la asistencia de los hisopo nasofaríngeos.

ASEGÚRESE DE QUE EL CONJUNTO DE PRUEBA CONTIENE

1. Bolsa Sellada
2. Tampón de Extracción
3. Hisopo Estéril Desechable
4. Bolsa de Residuos de Riesgo Biológico
5. Instrucción de Uso
6. Gradilla para el Tubo (en la caja exterior)



Specifications

Components	REF	W634P0024	W634P0028	W634P0029
Sealed Pouch(pcs)		1	2	3
Extraction Buffer		1	2	3
Disposable Sterile Swab (pcs)		1	2	3
Biohazard Waste Bag (pcs)		1	2	3
Instruction for Use (pcs)		1	1	1

Components	REF	W634P0025	W634P0026	W634P0027
Sealed Pouch(pcs)		5	10	20
Extraction Buffer		5	10	20
Disposable Sterile Swab (pcs)		5	10	20
Biohazard Waste Bag (pcs)		5	10	20
Instruction for Use (pcs)		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 of 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: 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.

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>

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.

Tu YP, O'Leary TJ. Testing for Severe Acute Respiratory 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				

Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Luogang District,
510663 Guangzhou, P.R. China
Tel: 0086-20-3229-9890/00-20-3229-9786
Website: www.wondfo.com.cn
E-mail: service@wondfo.com.cn

Grand EC-REP BV
Pas 257
2440 Geel
Belgium

Suppliers of disposable sterile swab

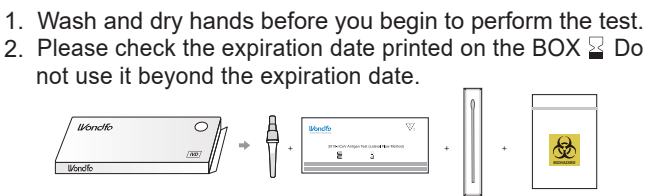
1. Miraclean Technology Co., Ltd. (according to Directive 93/42/EEC)
No.18, Rongxiuxia Industrial Zone Tongli Community, Longgang District
Shenzhen 518116 Guangdong China
EC representative name: Share Info Consultant Service LLC Repräsentanzbüro
EC representative address: Heerdter Lohweg 83, 40549 Düsseldorf Heerdter
Lohweg 83, 40549 Düsseldorf, Germany
2. Jiangsu Changfeng Medical Industry Co., Ltd. (according to Directive 93/42/EEC)
Touqiao Town, Gunagling District Yangzhou 225109 Jiangsu P.R.China
EC representative name: Lims Service & Consulting GmbH
EC representative address: Obere Seesäule 34/2, 69124 Heidelberg, Germany
3. Medico Biomedical Technology Co., Ltd. (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: Weikang Ltd
EC representative address: Enterprise Hub, NW Business Complex,1
Beraghmore Rd, Derry, BT488SE, N. Ireland, UK
4. Jiangsu Hanheng Medical Technology Co., Ltd. (according to Directive 93/42/EEC)
16-54, #1 North Qingyang Road, Tanning District, 213017 Changzhou, Jiangsu, China
EC representative name: Luxus Lebenswelt GmbH
EC representative address: Kochstr. 1, 47677, Willich, Germany
5. Shenzhen KangDaAn Biological Technology Co., Ltd. (according to Directive 93/42/EEC)
East-1, 3rd floor, Building 2, Shunfeda Factory Lixiangdong 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

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).



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

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.

14. 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.

15. Re-apply hand sanitizer.

16. 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.

17. Re-apply hand sanitizer.

18. 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.

19. Re-apply hand sanitizer.

20. 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.

21. Re-apply hand sanitizer.

22. 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.

23. Re-apply hand sanitizer.

24. 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.

25. Re-apply hand sanitizer.

26. 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.

27. Re-apply hand sanitizer.

28. 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.

29. Re-apply hand sanitizer.

30. 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.

31. Re-apply hand sanitizer.

32. 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.

33. Re-apply hand sanitizer.

34. 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.

35. Re-apply hand sanitizer.

36. 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.

37. Re-apply hand sanitizer.

38. 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.

39. Re-apply hand sanitizer.

40. 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.

41. Re-apply hand sanitizer.

42. 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.

43. Re-apply hand sanitizer.

44. 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.

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.



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

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.

14. 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.

15. Re-apply hand sanitizer.

16. 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.

17. Re-apply hand sanitizer.

18. 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.

19. Re-apply hand sanitizer.

20. 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.

21. Re-apply hand sanitizer.

22. 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.

23. Re-apply hand sanitizer.

24. 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.

25. Re-apply hand sanitizer.

26. 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.

27. Re-apply hand sanitizer.

28. 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.

29. Re-apply hand sanitizer.

30. 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.

31. Re-apply hand sanitizer.

32. 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.

33. Re-apply hand sanitizer.

34. 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.

35. Re-apply hand sanitizer.

36. 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.

37. Re-apply hand sanitizer.

38. 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.

39. Re-apply hand sanitizer.

40. 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.

41. Re-apply hand sanitizer.

42. 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.

43. Re-apply hand sanitizer.

44. 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.

45. Re-apply hand sanitizer.

46. 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.

47. Re-apply hand sanitizer.

48. 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.

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)

