EN

2019-nCoV Antigen Test (Lateral Flow Method)

Please scan the QR code to watch the demonstration video.

WHAT DOES THE KIT TEST?

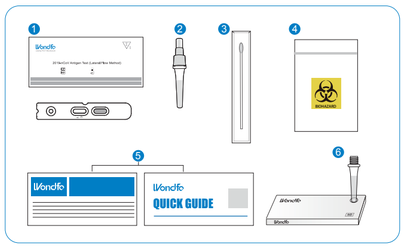
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is a rapid test that is used for laymen of detecting novel coronaviruses (2019-nCoV) N protein antigen extracted from the nasal swab specimen.It is intended as an aid in the diagnosis of coronavirus infection disease (COVID-19) for symptomatic patients 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)



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 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

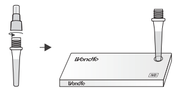
1. The test kit should be stored at 2-30°C (storage in refrigerator is permitted). Do not store the kit in the freezer. Improper storage may result in an inaccurate result.
2. The test cassette is sensitive to humidity and temperature. Once removed from foil pouch, test cassette is stable for up to 1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

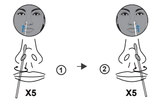
3. Take out the Extraction Buffer Tube, unscrew the lid and place the tube in the tube rack (The tube rack is in the outer box, see below).



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

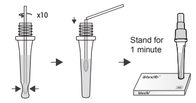
5. Remove the swab from the container, being careful NOT to touch the soft end, which is the absorbent tip.

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. Positive test results do not exclude co-infections with other pathogens and does not identify specific 2019-nCoV virus subtypes, like SARS-CoV virus.
8. 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).

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 99.84% (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 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 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 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	LOT Batch Number
Keep Away from Sunlight	Manufacturer	REF Catalog #
Tests Per Kit	IVD *In Vitro* Diagnostic Use	EC REP 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/ 0086-20-3229-9786
Website: www.wondfo.com.cn
E-mail: service@wondfo.com.cn

CE 0123 EC REP 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.**
   CE 0197 **(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

Wondfo

Quick Guide

2019-nCoV Antigen Test (Lateral Flow Method)

Operation Video

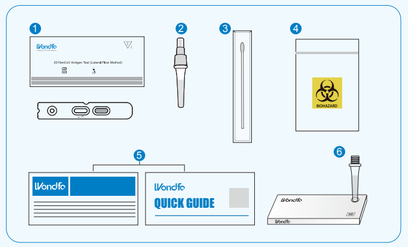
- Nasal swab specimen from individuals aged below 18 years old should be collected and performed by another adult.
- Individuals aged over 75 should be aware of the removal of the nasal swab, or need a collection assistant if necessary.
- The test result must be read in 15 minutes, DO NOT read the result 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).

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)

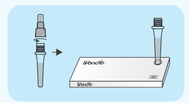
Other required items (not included in the test kit)

Clock or timer

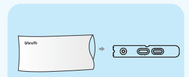


Test Procedure

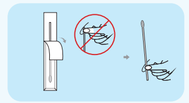
Step 1
Take out the Extraction Buffer Tube, unscrew the lid and place the tube in the tube rack (The tube rack is in the outer box.)



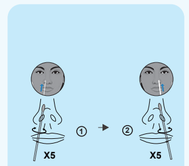
Step 2
Take out the Test Cassette from foil pouch and lay it flat.



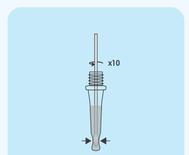
Step 3
Remove the swab from the container, being careful **NOT** to touch the soft end, which is the absorbent tip.



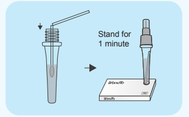
Step 4
Carefully insert the **ENTIRE** absorbent tip of the swab into your nostrils. Firmly sample the nasal wall by rotating the swab in a circular path **five** times against the nasal wall. Slowly remove swab from the nostril. (This step should take approximately 15 seconds, ensuring to collect mucous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

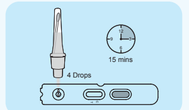


Step 6
Snap off the swab at the break point, leave the swab tip in the tube, cap the lid and leave the tube on the tube rack for 1 minute.



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.

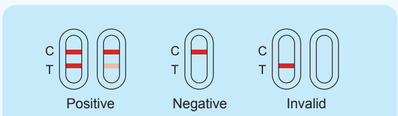
Step 10
Re-apply hand sanitizer.

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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Tel: 0086-20-3229-9890/ 0086-20-3229-9786
Website: www.wondfo.com.cn
E-mail: service@wondfo.com.cn

Authorized Representative (Malaysia):
Medical Innovation Ventures Sdn. Bhd. (MEDI VEN)

Procedure in reporting positive result via MySejahtera:

1.Scan the QR code above to link you to MySejahtera Helpdesk page.
2.Select whether you are reporting for yourself or for your dependent.
3.Once select, you are required to update individual particulars (i.e name, mobile, identification number, and email address) as required.
4.Stay on the Helpdesk page and continue to update with your home address.
5.Stay on the Helpdesk page and select one of the options ("hospital/clinic"; "online"; "pharmacy"; "corporate", or "others") as to where you've obtained the self-test kits from.
6.Stay on the Helpdesk page and select one of the options ("saliva"; "nasal", or "others") as to what was tested with the self-test kits.
7.To submit the self-test results, on the following page, select one of the options ("positive"; "negative", or "invalid").

BM

2019-nCoV Antigen Test (Kaedah Aliran Lateral)

Untuk video demonstrasi sila imbas QR kod berikut.

APAKAH TUJUAN KIT UJIAN ?

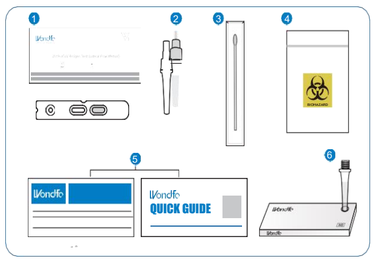
Wondfo 2019-nCoV Antigen Test (Kaedah aliran lateral) adalah kit ujian pantas yang digunakan untuk orang awam untuk mengesan antigen protein koronavirus (2019-nCoV) yang diekstrak dari sampel ronga hidung. Kit ujian ini bertindak sebagai bantuan awal dalam mengdiagnosis penyakit jangkitan koronavirus (COVID-19) terhadap pesakit yang mempunyai simptom dalam tempoh 7 hari selepas mengalami gejala yang disebabkan oleh 2019-nCoV

Untuk kegunaan *in vitro* diagnostik sahaja Kit ujian kendiri ini kegunaan orang awam

Menurut ujian kebolehgunaan terhadap orang awam, ujian ini dapat diakukan dengan betol untuk sesiapa sahaja yang berumur 18 tahun ke atas.Walaubagaimanapun sampel rongga hidung dari individu yang berumur 18 tahun kebawah boleh diambil dan dilakukan oleh orang dewasa yang lain.Sementara pengguna yang berumur 75 tahun ke atas patut berhati-hati melakukan sampel swab hidung ataupun meminta pertolongan dari orang.

PASTIKAN KIT UJIAN MENGANDUNGI

1. Pek ujian.
2. Ekstrak Buffer
3. Steril Swab pakai buang
4. Beg Biokeselamatan pakai buang
5. Risalah pengguna
6. Rak Tiub (di luar kotak)



Spesifikasi:

Komponen	W634P0024	W634P0028	W634P0029
Pek ujian.	1	2	3
Buffer pengekstrak	1	2	3
Swabsteril pakai buang	1	2	3
Beg Sisa Biokeselamatan pakai buang	1	2	3
Risalah Arahan Pengguna	1	1	1

Komponen	W634P0025	W634P0026	W634P0027
Pek ujian.	5	10	20
Buffer pengekstrak	5	10	20
Swabsteril pakai buang	5	10	20
Beg Sisa Biokeselamatan pakai buang	5	10	20
Risalah Arahan Pengguna	1	1	1

ALATAN LAIN YANG DIPERLUKAN? — Pemasa atau jam.

PERINGATAN DAN AMARAN

1. Baca risalah arahan pengguna dengan betul sebelum menggunakan produk. Ikot arahan dengan berhati-hati.Kegagalan berbuat demikian boleh menyebabkan keputusan yang diperoleh tidak tepat.
2. Kit ujian ini untuk kegunaan luaran sahaja. Jangan menelan.
3. Elakkan campuran buffer terkena pada mata dan kulit.
4. Jauhkan daripada capaian kanak-kanak.
5. Kit ujian ini hanya untuk kegunaan sekali sahaja, jangan mengunakan mana-mana komponen kit ini.
6. Jangan mengunakan kit ujian ini jika sudah melebihi Tarikh luput. Sentiasa semak tarikh luput sebelum menjalankan ujian.
7. Jangan sentuh kawasan tindak balas pada kit ujian.
8. Jangan menggunakan kit ujian jika pek sudah terkoyak atau rosak.
9. PELUPUSAN: Semua sampel dan kit ujiian menpunyai risiko jangkitan. Buang semua komponen ujian kedalam beg biokeselamatan yang disertakan selepas guna. Proses pelupusan diagnostik kit mestilah mengikut undang -undang/peraturan pelupusan yang ditetapkan oleh jabatan yang berkenaan.
10. Janganmakan,minum atau merokok semasa mengendalikan sampel atau kit ujian.

PENYIMPANAN DAN KESTABILAN

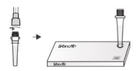
1. Kit ujian hendaklah disimpan pada suhu 2-30°C (penyimpanan di dalam peti sejuk dibenarkan). Jangan simpan kit ujian di dalam peti sejuk beku. Penyimpanan yang tidak betul boleh menyebabkan keputusan ujian yang tidak tepat.
2. Kaset ujian sensitif terhadap kelembapan dan suhu. Selepas dikeluarkan dari pek tertutup, kaset ujian stabil sehingga 1 jam.
3. Kit ujian stabil sehingga tarikh luput. Jangan menggunakan kit ujian ini jika sudah melebihi tarikh luput.
4. Kaset ujian mesti berada di dalam pek tertutup sehingga digunakan.

BAGAIMANA MENGGUNAKAN KIT UJIAN?

Jalankan ujian ini di tempat yang TIADA GANGGUAN selama 20 minit. Bawa kesemua komponen produk ke tempat bersuhu bilik (10~30°C).

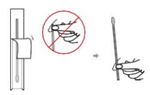
1. Basuh dan keringkan tangan sebelum memulakan ujian.
2. Sila semak tarikh luput pada kotak. Jangan menggunakan kit ujian sekiranya telah melebihi tarikh luput.

3. Keluarkan tiub buffer pengekstrak, buka penutup dan letak tiub di rak tiub (di luar kotak).

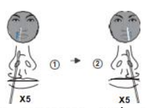


4. Keluarkan kaset ujian dari beg tertutup dan letakkan di atas permukaan rata.

5. Keluarkan swab dari pembalut plastik dengan berhati-hati supaya TIDAK menyentuh bahagian hujung lembut swab yang merupakan tempat penyerapan sampel.

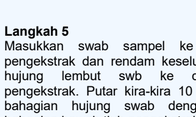


6. Masukkan bahagian hujung lembut swab secara KESELURUHAN ke dalam rongga hidung anda. Ambil sampel dari permukaan dinding hidung dengan memutarkan swab sebanyak lima kali.
7. Perlahan-lahan keluarkan swab sampel dari rongga hidung. Ulang proses pengumpulan sampel pada rongga hidung bersebelahan dengan swab yang sama.
   NOTA: Langkah ini akan mengambil masa lebih kurang 15 saat untuk memastikan cecair dan sel hidung berjaya diambil..
   NOTA: Memutarkan swab pada satu bahagian dinding hidung sahaja atau membiarkan swab di dalam rongga hidung selama 15 saat bukan teknik yang tepat dan boleh menyebabkan pengambilan sampel yang tidak mencukupi.



PERHATIAN: Sekiranya pemengang swab patah semasa proses pengumpulan sampel, ulang semula proses dengan swab yang baru.

8. Masukkan swab sampel ke dalam tiub pengekstrak dan rendam keseluruh bahagian hujung lembut swab ke dalam buffer pengekstrak. Putar kira-kira 10 kali dan picit bahagian hujung swab dengan menekan bahagian bawah tiub pengekstrak.
9. Biarkan bahagian hujung lembut swab di dalam tiub pengekstrak, tutup penutup dan tinggalkan di rak tiub selama 1 minit.



10. Buka penutup kecil di bahagian atas tiub buffer pengekstrak. Letakkan kaset ujian di atas permukaan yang rata dan titiskan 4 titik sampel ke dalam lubang sampel.
11. Tunggu 15 minit sebelum membaca keputusan. Jangan baca keputusan selepas 20 minit.

12. Setelah ujian selesai, masukkan kesemua bahan kit ujian ke dalam beg sisa Biohazard dan buang sisa Biohazard mengikut polisi pembuangan sisa Biohazard tempatan.
13. Sembur semula pembersih tangan.

BAGAIMANA MENGINTERPRETASIKAN KEPUTUSAN UJIAN?

Keputusan Positif
Dua garis merah akan terlihat. Satu pada bahagian (C), satu pada bahagian (T). Ini menunjukkan COVID-19 dikesan. (Sila rujuk S5 untuk keterangan).
NOTA: lanya tidak menjadi masalah sekiranya salah satu garis yang membentuk garis keputusan (T) samar atau gelap daripada yang lain, keputusan adalah "Positif".

- Jika keputusan positif diperoleh, maklumkan kepada Kementerian Kesihatan sama ada melalui notifikasi kendiri dalam sistem MySejahtera atau hubungi Pejabat Kesihatan Daerah secara terus.
- Individu yang didapati positif Covid-19 perlu menghubungi Pusat Penilaian COVID-19 (http://covid-19.moh.gov.my/hotline) yang berhampiran untuk pemberitahuan dan mendapatkan nasihat untuk tindakan lanjut.

1. Imbas kod QR di atas untuk ke pautan halaman MySejahtera Helpdesk.
2. Pilih samaada anda ingin membuat laporan kendiri atau tanggungan anda.
3. Setelah memilih, anda dikehendaki mengemas kini butiran individu (iaitu nama, nombor telefon, nombor kad pengenalan dan alamat emel) seperti yang diperlukan.
4. Kekal di halaman Helpdesk dan terus mengemas kini alamat rumah anda.
5. Kekal di halaman Helpdesk dan pilih salah satu daripada pilihan ("hospital/klinik"; "dalam talian"; "farmasi"; "korporat", atau "lain-lain") sebagai pilihan di mana kit ujian kendiri diperoleh.
6. Kekal di halaman Helpdesk dan pilih salah satu daripada pilihan ("air liur"; "hidung", atau "lain-lain") sebagai pilihan jenis spesimen yang diuji.
7. Untuk menghantar keputusan ujian kendiri pada halaman berikut, pilih salah satu pilihan ("positif"; "negatif", atau "tidak sah").

Keputusan Negatif
Hanya satu garis merah kelihatan di bahagian (C). Ini menunjukkan COVID-19 tidak dikesan. (Sila rujuk S6 dalam Risalah Arahan Pengguna untuk keterangan).

Keputusan Tidak Sah
Tiada garis merah kelihatan bahagian (C) menunjukkan keputusan ujian tidak sah. Disarankan mengulangi ujian bermula dari proses pengumpulan sampel swab hidung yang baru.

HAD PROSEDUR PENGGUNAAN

1. Kit ini bertujuan untuk mengesan antigen 2019-nCoV dalam sampel swab hidung manusia.
2. Kegagalan untuk mengikuti arahan prosedur ujian boleh menjejaskan prestasi ujian dan/atau menghasilkan keputusan yang tidak sah.
3. Membaca keputusan ujian dalam masa kurang 15 minit atau lebih dari 20 minit boleh menghasilakn keputusan yang salah.
4. Proses pengumpulan sampel akan mempengaruhi ketepatan ujian seperti pengumpulan dan penyimpanan sampel yang tidak betul, dll.
5. Kit ujian ini adalah ujian kualitatif. Seperti mana prosedur diagnostik, diagnosis jangkitan 2019-nCoV hanya boleh disahkan oleh doktor dengan penilaian semula ujian klinikal dan makmal.
6. Keputusan negatif munkin berlaku jika tahap antigen di dalam sampel berada di bawah had pengesanan ujian, atau dari proses pengumpulan sampel yang tidak tepat. Keputusan negatif tidak menunjukkan pengecualian jangkitan virus 2019-nCoV yang lain.
7. Keputusan positive tidak megecualikan jangkitan virus 2019-nCoV yang lain dan tidak dikenal pasti sebagai subjenis virus 2019-nCoV, seperti virus SARS-CoV.
8. Keputusan negatif tidak mengesampingkan jangkitan koronavirus dan tidak mengecualiakan anda dari peraturan kawalan penyebaran virus COVID-19. (Seperti sekatan kontak dan langkah-angkah perlindungan).

SOALAN DAN JAWAPAN

Q1: Bagaimana Kit Ujian *Wondfo 2019-nCoV Antigen Test (Kaedah aliran lateral)* berfungsi?
Kit ujian *Wondfo 2019-nCoV Antigen Test* berfungsi untuk mengesan kehadiran antigen virus 2019-nCoV di dalam sampel swab hidung.

Q2: Apakah perbezaan diantara antigen COVID-19, ujian molekul, dan antibodi?
Terdapat pelbagai jenis ujian untuk mengdiagnosis COVID-19. Ujian molekul (juka dikenali sebagai ujian PCR) mengesan bahan genetik dari virus. Kit ujian *Wondfo 2019-nCoV Antigen Test* (Kaedah aliran lateral) adalah ujian antigen yang mengesan bahagian kecil atau protein dari virus. Ujian antigen sangat spesifik untuk mengesan virus tetapi tidak sespesifik ujian molekul. Jenis ujian lain adalah ujian antibodi. Ujian antibodi COVID-19 mengesan antibodi yang telah dirembeskan oleh sistem ketahan badan sebagai tindak balas terhadap jangkitan COVID-19 sebelumnya.

Q3: Adakah ujian ini menyakitkan?
Tidak, swab yang digunakan tidak tajam dan tidak akan meyebabkan luka. Namun, boleh menyebabkan ketidakselesaan pada sesetengah keadaan.

Q4: Megapa perlu mengambil sampel dari kedua-dua rongga hidung?
Mengambil sampel dari kedua-dua rongga hidung akan menghasilkan pengumpulan sampel yang mencukupi untuk mendapatkan keputusan yang tepat. Dalam beberapa kes, hanya satu rongga hidung yang mengandungi virus, jadi penting untuk melakukan proses pengumpulan sampel dari kedua-dua rongga hidung. Proses pengumpulan yang betul pentung untuk mendapatkan keputusan yang tepat.

Q5: Apakah maksud sekiranya saya mendapat keputusan positif?
Keputusan positif menunjukkan bahawa anda munkin mempunyai jangkitan COVID-19. Sila hubungi doktor perubatan anda untuk mendapatkan cadangan rawatan lanjut. Anda kemungkinan akan diminta untuk mengasingkan diri di dalam rumah untuk mengelakkan penyebaran virus kepada orang lain, pakai penutup muka dan basuh tangan dengan kerap menggunakan sabun dan air. Keputusan positif tidak menjamin bahawa anda akan menjadi imun dari jangkitan dan tidak akan kembali mendapat jangkitan.

Q6: Apakah maksud sekiranya saya mendapat keputusan negatif?
Keputusan negatif bermaksud virus yang menyebabkan COVID-19 tidak dijumpai dalam sampel anda. Keputusan negatif tidak menjamin bahawa anda tidak atau tidak pernah dijangkiti COVID-19, dan juga tidak mengesahkan sama ada anda tidak atau sedang dijangkiti. Adakah anda mempunyai simptom selesema dismaping mendapatkan keputusan negatif dari ujian kendiri? Oleh kerana ujian kendiri tidak memberi kepastian sepenuhnya, anda harus menganggap bahawa anda munkin mempunyai COVID-19. Anda boleh menghubungi doktor perubatan anda untuk mendapatkan kepastian jika ujian lain diperlukan. Sementara itu, elakkan dari berkunjung atau berhubung dengan individu lain termasuk individu yang tinggal bersama-sama anda.
Buang tisu yang telah digunakan ke dalam tong sampah. Tutup mulut dan hidung mengguankan celahan siku ketika bersin dan batuk. Basuh tangan anda dengan kerap dan pakai penutup muka. Adakah gejala anda semakin teruk (kesukarab bernafas, demam tnggi, dll.)? Segera hubungi doktor perubatan atau perunding kesihatan anda.

Q7: Sejauh mana ketepatan kit ujian Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)?
Keputusan ujian yang telah dijalankan oleh profesional dalam penjagaan kesihatan melalui penilaian klinikal lapangan menunjukan ketepatan 99.84% dengan keputusan 622 daripada 623 sampel 2019-nCoV negatif (dikenali sebagai ujian kekhususan). Tambahan, ujian klinikal lapangan telah dijalankan oleh pengguna ujian kendiri di Jerman dan AS, dengan keputusan ketepatan 100% (129/129) sampel negatif 2019-nCoV. Ujian yang sama juga telah dilaksanakan oleh profesional dalam penjagaan kesihatan dengan ketepatan 91.63% (230/251) sampel positif 2019-nCoV (dikenali sebagai ujian kepekaan) dan memberi keputusan ketepatan 89.66% (26/29) apabila diuji oleh pengguna ujian kendiri.

Q8: Adakah saya berkemungkinan untuk mendapat keputusan negatif "palsu" dengan menggunakan kit ujian ini?
Kit ujian ini berkemungkinan untuk memberikan keputusan negatif yang salah. Sekiranya keputusan adalah negatif dan anda masih mengalami gejala COVID-19 seperti demam, batuk dan /atau sesak nafas, anda hara mendapatkan bantuan dari doktor perubatan anda.

Q9: Adakah saya berkemungkinan untuk mendapat keputusan positif yang salah?
Terdapat kemungkinan yang sangat rendah untuk kit ujian ini memberikan keputusan positif yang salah. Sekiranya anda memperoleh keputusan positif, anda harus mengasingkan diri dan mendapatkan bantuan dari doktor perubatan anda.

Q10: Saya telah menggunakan kit ujian ini tetapi tiada jalur bewarna pada garisan kawalan (C). Apakah yang saya patut lakukan?
Sekiranya tiada jalur bewarna muncul di garisan kawalan (C) dalam masa 15 minit ujian dijalankan, bermaksud ujian beum dimulakan. Anda harus menggunakan kit ujian baru dan berhati-hati ketika menjalankan prosedur ujian.

Q11: Bolehkah sebarang ubat atau keadaan perubatan mempengaruhi keputusan ujian?
Ya, ia boleh mempengaruhi keputusan ujian anda. Dapatkan nasihat doktor prubatan anda dan pastikan anda membaca arahan pengeluar produk perubatan anda sebelum menjalankan ujian.

Q12: Apakah kemungkinan risko ujian ini?
Kemungkinan risiko yang dihadapi

- Ketidakselesaan semasa pengambilan sampel
- Keputusan ujian yang tidak betul (sila rujuk bahagian interpretasi ujian)

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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.

SIMBOL INDEKS

	Jangan guna semula		Risalah arahan pengguna		Tarikh luput
	Tarikh dikilangkan		Simpan di tempat yang kering	LOT	Nombor lot
	Jauhkan dari cahaya matahari		Pengilang	REF	Katalog #
	Kuantiti kit ujian	IVD	Untuk kegunaan *in vitro* diaknostik	EC REP	Pihak perwakilan
	Penyimpanan				

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Pembekal swab steril pakai buang

1. **Miraclean Technology Co., Ltd.** CE0197 (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
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   EC representative address: Enterprise Hub, NW Business Complex,1 BeraghmoreRd. Derry, BT488SE, N. Ireland. UK
4. **Jiangsu Hanheng Medical Technology co., Ltd.** CE0197 (according to Directive 93/42/EEC)
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   EC representative name: Share Info Consultant Service LLC Repräsentanzbüro EC representative address: Heerdter Lohweg 83, 40549 Düsseldorf Heerdter Lohweg 83, 40549 Düsseldorf, Germany

Wondfo Panduan Ringkas

2019-nCoV Antigen Test (Lateral Flow Method) Video Demonstrasi

- Sampel swab hidung bagi individu berusia di bawah 18 tahun harus dikumpul dan diambil oleh orang dewasa.
- Individu yang berumur lebih 75 tahun harus berhati-hati ketika proses pengumpulan sampel swab, atau dapatkan bantuan pembantu sekiranya perlu.
- Keputusan ujian mesti dibaca dalam tempoh 15 minit, JANGAN membaca keputusan selepas 20 minit
- Sila basuh atau diinfeksi tangan anda dengan teliti sebelum dan selepas melakukan ujian.
- Sila ambil langkah keselamatan yang diperlukan semasa menjalankan ujian ke atas individu lain (seperti penutup muka, sarung tangan, dll.)

Komponen Produk

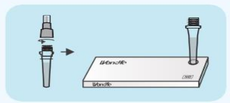
1. Pek ujian
2. Buffer pengekstrak
3. Swab steril pakai buang
4. Beg sisa Biokeselamatan
5. Risalah Arahan Pengguna
6. Rak tiub (di luar kotak)

Item lain yang diperlukan (tidak termasuk dalam kit ujian)

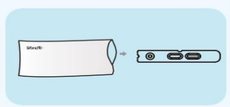
Jam atau pemasa

Prosedur Ujian

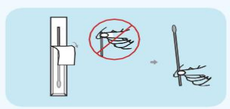
Langkah 1
Keluarkan tiub buffer pengekstrak, buka penutup dan letak tiub di rak tiub (di luar kotak)



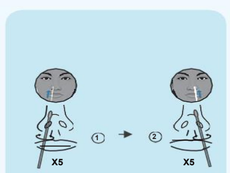
Langkah 2
Keluarkan kaset ujian dari beg tertutup dan letakkan di atas permukaan rata.



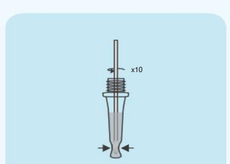
Langkah 3
Keluarkan swab dari pembalut plastik dengan berhati-hati supaya TIDAK menyentuh bahagian hujung lembut swab yang merupakan tempat penyerapan sampel.



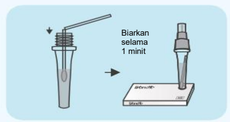
Langkah 4
Masukkan bahagian hujung lembut swab secara KESELURUHAN ke dalam rongga hidung anda. Ambil sampel dari permukaan dinding hidung dengan memutarkan swab sebanyak lima kali. Perlahan-lahan keluarkan swab sampel dari rongga hidung. (Langkah ini akan mengambil masa lebih kurang 15 saat untuk memastikan cecair dan sel hidung berjaya diambil.)
Ulang proses pengumpulan sampel pada rongga hidung bersebelahan dengan swab yang sama.



Langkah 5
Masukkan swab sampel ke dalam tiub pengekstrak dan rendam keseluruh bahagian hujung lembut swb ke dalam buffer pengekstrak. Putar kira-kira 10 kali dan picit bahagian hujung swab dengan menekan bahagian bawah tiub pengekstrak.

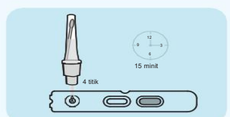


Langkah 6
Biarkan bahagian hujung lembut swab di dalam tiub pengekstrak, tutup penutup dan tinggalkan di rak tiub selama 1 minit.



Langkah 7
Buka penutup kecil di bahagian atas tiub buffer pengekstrak.

Langkah 8
Letakkan kaset ujian di atas permukaan yang rata dan titiskan 4 titik sampel ke dalam lubang sampel. Baca keputusan setelah menunggu selama 15 minit. JANGAN BACA keputusan selepas 20 minit.



Langkah 9
Setelah ujian selesai, masukkan kesemua bahan kit ujian ke dalam beg sisa Biohazard dan buang sisa Biohazard mengikut polisi pembuangan sisa Biohazard tempatan.

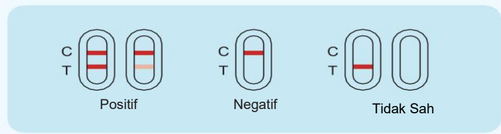
Langkah 10
Sembur semula pembersih tangan.

Langkah 11
Interpretasi keputusan

Positif (+)
Dua garis merah akan terlihat. Satu pada bahagian (C), satu pada bahagian (T). Ini menunjukkan COVID-19 dikesan.
NOTA: lanya tidak menjadi masalah sekiranya salah satu garis yang membentuk garis keputusan (T) samar atau gelap daripada yang lain, keputusan adalah "Positif". (Rujuk S5 dalam Risalah Arahan Penggunan untuk keterangan)

Negatif (-)
Hanya satu garis merah kelihatan di bahagian (C). Ini menunjukkan COVID-19 tidak dikesan. (Sila rujuk S6 dalam Risalah Arahan Pengguna untuk keterangan)

Tidak Sah
Tiada garis merah kelihatan bahagian (C) menunjukkan keputusan ujian tidak sah. Disarankan mengulangi ujian bermula dari proses pengumpulan sampel swab hidung yang baru.



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Rev. A2
Rel.:2021/05/28