Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

INTENDED USE

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of novel coronaviruses (2019-nCoV) antigen extracted from the human saliva or sputum specimen. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by 2019-nCoV.

The test provides preliminary test results. Negative results cannot exclude 2019-nCoV infection and they cannot be used as the sole basis for treatment or other management decision.

For *in vitro* diagnostic use only. For professional use only.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days.The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is based on the principle of immunochromatography sandwich for determination of 2019-nCoV antigen extracted from the saliva or sputum specimen. When the extracted specimen is added into the test device, the specimen is absorbed into the device by capillary action, reacts with the 2019-nCoV antibody-dye conjugate and flows across the pre-coated membrane.

When the 2019-nCoV antigen level in the specimen is at or above the target cutoff (the detection limit of the test), the antigen bound to the antibody-dye conjugate are combined by 2019-nCoV antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the 2019-nCoV antigen level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

PRECAUTION

1. This kit is for *in vitro* diagnostic use only.
2. All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in the collection, handling, storage and disposal of patient samples and used kit contents.
3. Wear appropriate personal protective equipment (e.g. protective gloves, medical mask, goggles and lab coat) when handing the contents of this kit.
4. Proper specimen collection, storage and transport are critical to the performance of this test.
5. Discard after first use. The sample extraction tube, the sampler, the dropper, the Paper pouch, Cotton swab and the test device cannot be used more than once.
6. Avoid excessively high temperature in the experiment environment. Test cards and detection buffer stored at low temperature need to be returned to room temperature before opening to avoid moisture absorption.
7. Do not touch the reaction area of test strip.
8. Do not use test kit beyond the expiration date.
9. Do not use the kit if the pouch is punctured or not well sealed.
10. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
11. DISPOSAL OF THE DIAGNOSTIC: All specimens and the used-kit has the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.

MATERIALS

Materials Provided

Components / REF	W633P0001	W633P0002	W633P0003	W633P0007
Sealed Pouches*(pcs)	1	5	10	20
Extraction Buffer (600 μL/tube)	1	5	10	20
Sampler (pcs)	1	5	10	20
Dropper	1	5	10	20
Medical Waste Bag	1	5	10	20
Procedure Card (pcs)	1	1	1	1
IFU (pcs)	1	1	1	1

Components / REF	W633P0004	W633P0005	W633P0006	W633P0008
Sealed Pouches*(pcs)	1	5	10	20
Pre-installed Extraction Buffer (1000 μL/tube)	1	5	10	20
Paper Pouch	1	5	10	20
Dropper	1	5	10	20
Cotton Swab	1	5	10	20
Medical Waste Bag	1	5	10	20
Procedure Card (pcs)	1	1	1	1
IFU (pcs)	1	1	1	1

Note: **Each sealed pouches containing: 1 Test Cassette and 1 Desiccant Pouch.*

Materials Required but Not Provided

1. Timer
2. Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
3. Appropriate biohazard waste container and disinfectants.

STORAGE AND STABILITY

1. Store at 2~30°C in the sealed pouch up to the expiration date printed on the package. Do not freeze.
2. The test cassette should be used within 1 hour after taking out from the sealed pouch. Buffer solution should be re-capped in time after use.
3. Keep away from sunlight, moisture and heat.
4. Kit contents are stable until the expiration date printed on the outer box.
5. The production date is printed on the outer box.

SPECIMEN COLLECTION AND PREPARATION

PROCEDURE Ⅰ (For W633P0001, W633P0002, W633P0003, W633P0007)

1. Rinse your mouth with water 30 minutes before sampling, and do not eat, smoke, drink alcohol or drinks after rinsing.

2.1 (Option A) Saliva specimen collection: Place the tip of tongue against the upper or lower tooth root to enrich saliva, open the lid and directly spit saliva into a sampler, then cover the lid and leave to set for 5 mins.

2.2 (Option B) Sputum specimen collection: Open the lid and directly expectorate deep cough sputum into a sampler, then cover the lid and leave to set for 5 min.

3. The volume of sample collected should be between the MIN scale and the MAX scale. If it is beyond the range, the excess volume can be taken out with a dropper. The sample should not be inactivated.
4. It is recommended that the specimen is tested at the time of specimen collection. If the specimens cannot be tested immediately, it could be stored at 2~8°C for 4 hours and long-term storage is not recommended.

PROCEDURE Ⅱ (For W633P0004, W633P0005, W633P0006, W633P0008)

1. Rinse your mouth with water 30 minutes before sampling, and do not eat, smoke, drink alcohol or drinks after rinsing.

2.1 (Option A) Saliva specimen collection: Place the tip of tongue against the upper or lower tooth root to enrich saliva, open a paper pouch and directly spit saliva into it.

2.2 (Option B) Sputum specimen collection: Directly expectorate deep cough sputum into a paper pouch.

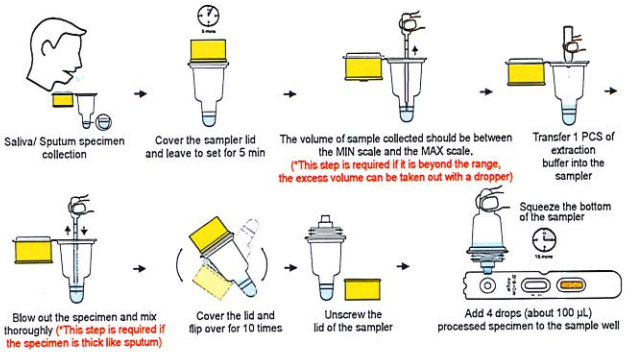
3. The volume of sample should be sufficient, otherwise repeat the sampling procedure. The sample should not be inactivated.
4. It is recommended that the specimen is tested at the time of specimen collection. If the specimens cannot be tested immediately, it could be stored at 2~8°C for 4 hours and long-term storage is not recommended.

TEST PROCEDURE

PROCEDURE Ⅰ (For W633P0001, W633P0002, W633P0003, W633P0007)

1. Saliva specimen test procedure

1) Open the lid, twist off the head of extraction buffer and transfer all into the sampler.
2) If the sample is thick like sputum, blow out the liquid and mix thoroughly with a dropper to expose the sample to the extraction buffer as much as possible, then cover the lid and flip over for 10 times to mix well.
3) Remove a test cassette from the sealed pouch by tearing at the notch and place it on a level surface.
4) Unscrew the lid of the extraction tube, invert the sampler, hold the sampler vertically and add 4 drops processed specimen to the sample well. Start the timer.
5) As the test begins to work, you will see purple color move across the result window in the center of the test device.
6) Wait for 15~20 minutes and read the results. **Do not read results after 20 minutes.**



PROCEDURE Ⅱ (For W633P0004, W633P0005, W633P0006, W633P0008)

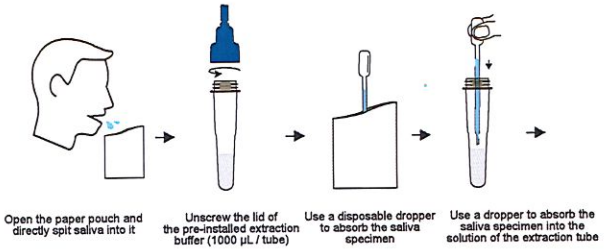
1. Unscrew the lid of the pre-installed extraction buffer (1000 μL/tube)

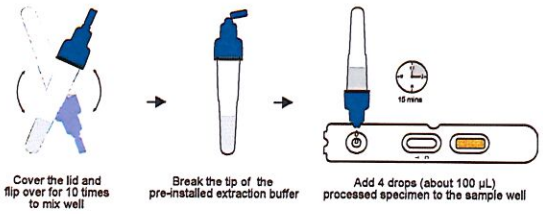
2.1 (Option A) Saliva specimen: Use a dropper to absorb the Saliva specimen into the solution of the extraction tube, then cover the lid and flip over for 10 times to mix well.

2.2 (Option B) Sputum specimen: use a cotton swab to pick up 10~50 mg sample (equivalent to the size of a match head). Open the extraction buffer tube, put the cotton swab into it and break off the remaining part of the cotton swab outside the extraction tube. Cover the lid of the extraction buffer tube and shake to mix the sample completely. Leave the swab in the extraction buffer tube for 1 minute.

3. Remove a test cassette from the sealed pouch by tearing at the notch and place it on a level surface.
4. Invert the sample extraction tube, hold the extraction tube vertically and add 4 drops processed specimen to the sample well. Start the timer.
5. As the test begins to work, you will see purple color move across the result window in the center of the test device.
6. Wait for 15~20 minutes and read the results. **Do not read results after 20 minutes.**

(Option A) Saliva specimen



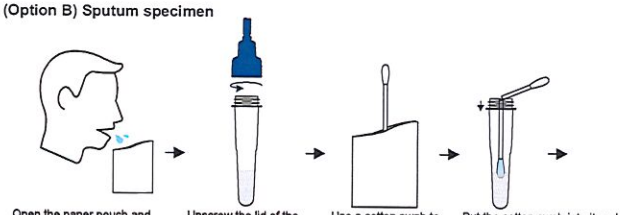


Cover the lid and flip over for 10 times to mix well

Break the tip of the pre-installed extraction buffer

Add 4 drops (about 100 μL) processed specimen to the sample well

(Option B) Sputum specimen

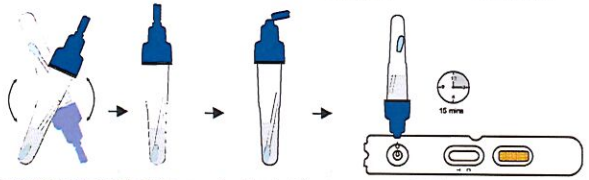


Open the paper pouch and directly spit sputum into it

Unscrew the lid of the pre-installed extraction buffer (1000 μL / tube)

Use a cotton swab to pick up 10~50mg sample (equivalent to the size of a match head)

Put the cotton swab into it and break off the remaining part of the cotton swab outside the extraction tube



Cover the lid and shake to mix the specimen completely. Leave the swab in the extraction tube for 1 minute.

Break the tip of the pre-installed extraction buffer

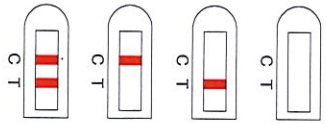
Add 4 drops (about 100 μL) processed specimen to the sample well

RESULT INTERPRETATION

Positive Result
Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the 2019-nCoV antigen in the specimen.

Negative Result
Colored band appears at control line (C) only. It indicates that the concentration of the 2019-nCoV antigen is zero or below the detection limit of the test.

Invalid Result
No visible colored band appears at control line after performing the test. The directions may have not been followed correctly or the test may have deteriorated. It is recommended to re-sampling and test.



Positive Negative Invalid Invalid

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient liquid volume, adequate membrane wicking and correct procedural technique.

Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE

1. This reagent is designed to detect 2019-nCoV antigen N protein in human saliva or sputum specimen.
2. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.
3. This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of 2019-nCoV antigen. If you need to test the quantitative concentration, please use the relevant professional instruments.
4. The test results of this reagent are for clinical reference only and should not be used as the sole basis clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered based on their symptoms / signs, medical history, other laboratory examinations and treatment response.
5. Limited by the method of antigen test reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.
6. Positive test results do not rule out co-infections with other pathogens. A negative result of this reagent can be caused by:
   1) Improper sample collection, improper sample transfer or handing, the virus titer in the sample is too low;
   2) The level of 2019-nCoV antigen is below the detection limit of the test.
   3) Variations in viral genes may cause changes in antigens determinants.

PERFORMANCE CHARACTERISTICS

A. Sensitivity and Specificity

504 clinical case samples which include 121 confirmed as COVID-19 positive and 383 confirmed as COVID-19 negative by PCR assay, were obtained for testing, and then compared the test results between Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) and the PCR results. The results are shown below.

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	PCR		Total
	Positive	Negative	
2019-nCoV Positive	118	2	120
2019-nCoV Negative	3	381	384
Total	121	383	504

Sensitivity: 97.52% (95%CI: 92.93%~99.49%)
Specificity: 99.48% (95%CI: 98.13%~99.94%)
Total agreement: 99.01% (95%CI: 97.70%~99.68%)

B. Cross-reactivity

Cross-reactivity of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was evaluated using specimens containing the antigens listed below. The results showed no cross-reactivity with the following:

Common coronavirus (NL63, 229E, OC43) antigen
Coronavirus (MERS) antigen
Influenza A H1N1 antigen
Influenza A H3N2 antigen
Influenza B Yamagata antigen
Influenza B Victoria antigen
Respiratory syncytial virus A/B antigen
Rhinovirus-A/-B antigen
Adenovirus-1/-2/-3/-4/-5/-7/55 antigen
Enterovirus A/B/C/D antigen
EB virus antigen
Measles virus antigen
Human Cytomegalovirus antigen
Rotavirus antigen
Norovirus antigen
Mumps virus antigen
Varicella-zoster virus positive sample
Mycoplasma pneumoniae antigen

C. Interference

The test result of Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is not interfered with the following substance:

Type	Substance
Allergic symptoms	Histamine Dihydrochloride
Antiviral drugs	Interferon alpha
	Zanamivir
	Ribavirin
	Oseltamivir
	Palamivir
	Lopenavir
	Ritonavir
	Abidor
Antibiotics	Levofloxacin
	Azithromycin
	Ceftriaxone
	Meropenem
Systemic Antibacterial Drugs	Tobramycin

D. Hook effect

Within the titer range of clinically positive samples of 2019-nCoV antigens, there is no hook effect in the test results of this product.

E. Precision

1. Within run precision was determined by testing positive specimens in 10 times. The agreement rate was 100%.
2. Between run precision was determined by testing different specimens including positive and negative in 3 different lots of test devices. The negative agreement rate and the positive agreement rate were 100%.

F. Limit of Detection

The LoD of this test is 1.1×10^2 $TCID_{50}$/mL

BIBLIOGRAPHY

[1] Chen H, Wurm T, Britton P, et al. Interaction of the Coronavirus Nucleoprotein with Nucleolar Antigens and the Host Cell [J]. Journal of Virology, 2002, 76 (10).

INDEX OF SYMBOL

IVD	*In Vitro* Diagnostic Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Manufacturing Date		Keep Dry
LOT	Batch Number	EC REP	Authorized Representative		Keep away from Sunlight
	Manufacturer		Do not reuse	REF	Catalog #
30°C 2°C	Store between 2~30°C				

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, 510663,Guangzhou, P.R.China
Tel: +86-20-3229 6083 400-888-5268 (Toll Free)
Fax: +86-20-3229 6063
E-mail: sales@wondfo.com.cn
Website: www.wondfo.com.cn

EC REP
Qarad BV
Cipalstraat 3
2440 Geel , Belgium

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