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 nasopharyngeal swab or oropharyngeal swab 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 nasopharyngeal swab or oropharyngeal swab specimen. When the extracted specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes 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. If the virus sampling solution is used for specimen processing, it can be directly detected without using extraction buffer.
5. Proper specimen collection, storage and transport are critical to the performance of this test.
6. Discard after first use. The sample extraction tube, the dropper and the test device cannot be used more than once.
7. 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.
8. Do not touch the reaction area of test strip.
9. Do not use test kit beyond the expiration date.
10. Do not use the kit if the pouch is punctured or not well sealed.
11. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
12. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
13. 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	W196P0005	W196P0006	W196P0007	W196P0011
Sealed Pouches* (pcs)	1	5	20	20
Drippers (pcs)	1	5	20	20
Extraction Buffer (400 μL/tube)	1	5	20	20
Sample Extraction Tube (pcs)	1	5	20	20
Nasopharyngeal Swab** (pcs)	1	5	20	20
Test Tube Rack (pcs)	/	/	1	1
Positive Control Swab (pcs)	/	/	/	1
Negative Control Swab (pcs)	/	/	/	1
Procedure Card (pcs)	1	1	1	1
IFU (pcs)	1	1	1	1

Components / REF	W196P0008	W196P0009	W196P0010	W196P0012
Sealed Pouches* (pcs)	1	5	20	20
Pre-installed Extraction Buffer (400 μL/tube)	1	5	20	20
Nasopharyngeal Swab** (pcs)	1	5	20	20
Test Tube Rack (pcs)	/	/	1	1
Positive Control Swab (pcs)	/	/	/	1
Negative Control Swab (pcs)	/	/	/	1
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*

***CE information of nasopharyngeal swab:* CE 0197 MDD 93/42/EEC

Materials Required but Not Provided

1. Viral Transport Media (VTM)
2. Tongue depressor
3. Timer
4. Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
5. 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

The test can be performed with nasopharyngeal swab or oropharyngeal swab specimen.

1. According to standard nasopharyngeal swab or oropharyngeal swab specimen collection procedure.
2. Nasopharyngeal swab specimen collection: Tilt patient's head back 70 degrees. Insert swab into nostril (Swab should reach depth equal to distance from nostrils to outer opening of the ear). Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.
3. Oropharyngeal swab specimen collection: Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
4. It is recommended that the specimen is tested at the time of specimen collection. If the specimens are not tested immediately, they should be stored in a dry, disinfected tube and tightly sealed (Place tip of swab into a tube and snap/cut off the applicator stick). They may be stored at 2～8°C for up to 8 hours, or they may be stored at -70°C for a long time.

NOTE: If the viral transport medium (VTM) is needed for transporting samples, the dilution ratio for samples should be controlled at minimum level, since large diluent volume could result in false negative. If possible, the diluent volume should not exceed 1 mL (however, the tip of the swab must be immersed in the liquid). Taking influenza virus as a reference, the nasal swab or nasopharyngeal swab in the VTM can stay stable for up to 72 hours at 2 ~ 8°C.

TEST PROCEDURE

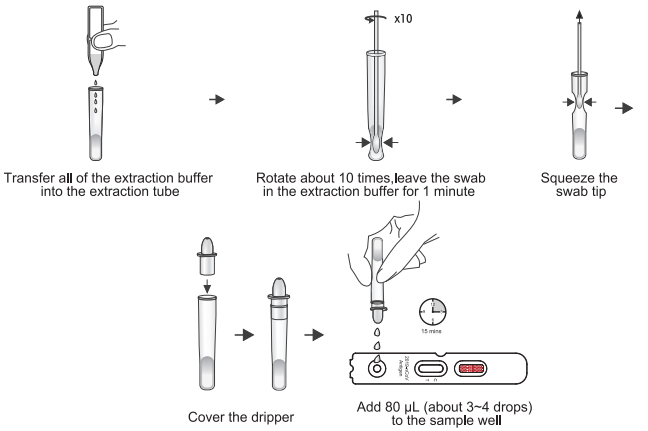
Please read the instructions for use carefully before performing the test.

TEST PROCEDURE Ⅰ(with Extraction Buffer)

For W196P0005 / W196P0006 / W196P0007 / W196P0011

1. Nasopharyngeal / oropharyngeal swab or positive/negative control swab specimen extraction
   1) Transfer all of the extraction buffer into the extraction tube.
   2) Insert the swab which has collected secretions into the sample extraction tube, rotate the swab tip 10 times against the bottom and sides of the extraction tube to release the specimen from the swab tip. Return the sample extraction tube to the test tube rack (If applicable) and leave the swab in the extraction buffer for 1 minute.
   3) Take out the swab while squeezing the middle of the extraction tube to release the liquid from the swab. Discard the used swab in accordance with the biohazard waste disposal protocol.
   4) Cover the dripper.

2. Test procedure
   1) Remove a test cassette from the sealed pouch by tearing at the notch and place it on a level surface.
   2) Invert the sample extraction tube, hold the sample extraction tube vertically and add 80 μL (about 3~4 drops) processed specimen to the sample well. Start the timer.
   3) As the test begins to work, you will see purple color move across the result window in the center of the test device.
   4) Wait for 15~20 minutes and read the results. **Do not read results after 30 minutes.**



Transfer all of the extraction buffer into the extraction tube | Rotate about 10 times,leave the swab in the extraction buffer for 1 minute | Squeeze the swab tip

Cover the dripper | Add 80 μL (about 3~4 drops) to the sample well

TEST PROCEDURE Ⅱ (with Pre-installed Extraction Buffer)

For W196P0008 / W196P0009 / W196P00010 / W196P0012

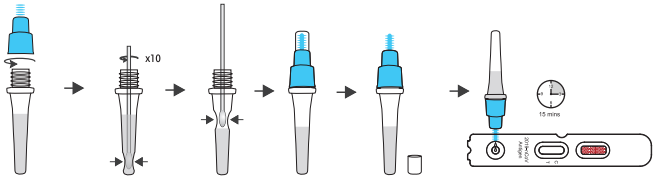
1. Nasopharyngeal / oropharyngeal swab or positive/negative control swab specimen extraction
   1) Unscrew the lid of the extraction tube.
   2) Insert the swab which has collected secretions into the extraction tube (Pre-installed Extraction Buffer), rotate the swab tip 10 times against the bottom and sides of the extraction tube to release the specimen from the swab tip. Return the extraction tube to

the test tube rack (If applicable) and leave the swab in the extraction buffer for 1 minute.

3) Take out the swab while squeezing the middle of the extraction tube to release the liquid from the swab. Discard the used swab in accordance with the biohazard waste disposal protocol.
4) Cover the lid.

2. Test procedure

1) Remove a test cassette from the sealed pouch by tearing at the notch and place it on a level surface.
2) Unscrew the small cap at the top of the extraction tube, Invert the extraction tube, hold the extraction tube vertically and add 80μL (about 3~4 drops) processed specimen to the sample well. Start the timer.
3) As the test begins to work, you will see purple color move across the result window in the center of the test device.
4) Wait for 15~20 minutes and read the results. **Do not read results after 30 minutes.**



Unscrew the lid of the extraction tube | Rotate about 10 times, leave the swab in the extraction buffer for 1 minute | Squeeze the swab tip | Cover the lid | Unscrew the small cap at the top of the extraction tube | Add 80 μL (about 3~4 drops) to the sample well

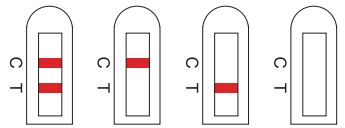
NOTE: To obtain accurate results, avoid mucoid substances when filling the micropipette with patient sample in VTM.

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 in human nasopharyngeal or oropharyngeal swab specimen.
2. The accuracy of the test depends on the sample collection process. 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

574 clinical case samples which include 212 confirmed as COVID-19 positive and 362 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.

Reagents		PCR		Total
		Positive	Negative	
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Positive	208	1	209
	Negative	4	361	365
Total		212	362	574

Sensitivity: 98.11% (95%CI: 95.24%~99.48%)
Specificity: 99.72% (95%CI: 98.47%~99.99%)
Total agreement: 99.13% (95%CI: 97.98%~99.72%)

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) do not be 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 three 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				

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