Jesse Industrial Supply
Der PSA Spezialist im igefa-Verbund

NEU IM SORTIMENT
sofort verfügbar

WONDFO SARS-COV-2 ANTIGEN TEST

Lateral-Flow-Methode

Zertifiziert durch das Robert-Koch- und Paul-Ehrlich-Institut.
Für den Verkauf auf dem deutschen Markt zugelassen.
Beim BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) unter der Nummer 5640-S-179/21 für die Anwendung durch Laien zugelassen. Der Hinweis auf der Verpackung ist nicht mehr gültig.

Wondfo Sars-Cov-2 Antigen-Test

Gelistet beim BfArM*

- Test zum qualitativen Nachweis spezifischer Antigene aus SARSCoV-2 direkt von Personen, bei denen der Verdacht auf COVID-19 besteht
- für Nasen- und Rachenabstrich
- leichte Handhabung
- schnelle und zuverlässige Ergebnisse in 15-20 Minuten
- Sensitivität 96,18 %; Spezifität 99,72 %
- Lagerung bei 4-30 C⁰

Art.-Nr. 600210996

Packung (Inhalt je Packung: 20 Testkassetten, 20 Pufferlösungen, 20 Extraktionsröhrchen, 20 Abstrichtupfer und eine deutschsprachige Gebrauchsanweisung

Testkassette | Pufferlösung | Extraktionsröhrchen | steriler Abstrichtupfer

Weiterführende Informationen zum Wondfo Antigen-Test finden Sie im nachfolgenden original Produktflyer.

** Bitte beachten Sie: Nur für Antigen-Tests, die in der Liste des BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) aufgenommen sind, sind Erstattungen möglich. Diese Tests entsprechen den vom Paul-Ehrlich-Institut in Abstimmung mit dem Robert-Koch Institut festgelegten Mindestkriterien zur Sicherheit und Funktionsweise. Die aktuelle Liste finden Sie unter www.bfarm.de/antigentests.*

Wir weisen darauf hin, dass wir für medizinische Produkte wie den Antigen-Schnelltest keine Produktberatung vornehmen können, sondern uns ausschließlich auf die Lieferung der Produkte beschränken. Trotzdem freuen wir uns, wenn wir Sie und Ihre Mitarbeiter auf diese Weise im Kampf gegen das Virus wirkungsvoll unterstützen können.

Denken Sie auch an ergänzende Produkte zum persönlichen Schutz bei der Durchführung der Antigen-Schnelltests. Hier beraten wir Sie gern. →

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igefa

Jesse Industrial Supply
Der PSA Spezialist im igefa-Verbund

Jesse GmbH & Co. KG
Triftstraße 33
38723 Seesen
Deutschland

05381 9470-0
05381 9470-77
info@jesseonline.de
www.jesseonline.de

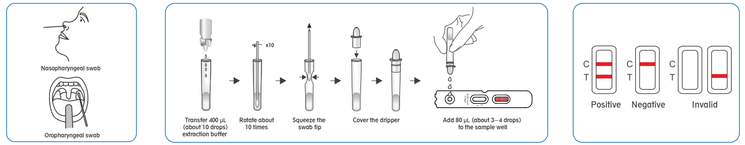
Rev. A9 Rel.: 2020/10/21

PRODUCT SPECIFICATIONS

Product Components

Test cassette | Extraction buffer | Extraction tube | Swab

Operation procedure



Performance

Reagents		PCR		Total
		Positive	Negative	
Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	Positive	478	1	479
	Negative	19	361	380
Total		497	362	859

Sensitivity: 96.18% (95%CI: 96.43%~98.49%)
Specificity: 99.72% (95%CI: 98.45%~99.95%)
Total agreement: 97.67% (95%CI: 94.11%~97.54%)

Order information

Catalog No.	Product Name	Packing Size	Sample Type	Storage Condition	Shelf Life	Qualification
W196	SARS-CoV-2 Antigen Test (Lateral Flow Method)	20T	Nasopharyngeal swab or oropharyngeal swab	2~30 ℃	12 months	CE

WONDFO BIOTECH
WeAreWorkingForYourHealth

Guangzhou Wondfo Biotech Co., Ltd.
Add: No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China
Tel: +86-20-32296083 Fax: +86-20-32296063
E-mail: sales@wondfo.com.cn Websites: en.wondfo.com.cn

WONDFO SARS-COV-2 ANTIGEN TEST

Speed Up the **COVID-19** Control !

Guangzhou Wondfo Biotech Co., Ltd.

WONDFO SARS-COV-2 ANTIGEN TEST

Direct detection of the virus

Instant results within 15mins

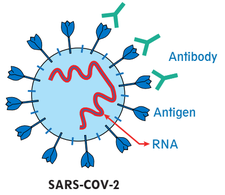
Easy to use, no equipment required

Room temperature storage(2~30°C)

Non-invasive sampling
(sample type: nasopharyngeal or oropharyngeal swab)

Early detection of COVID-19
(WHO recommends the testing period is from 3 days before to 5-7 days after symptoms onset)

CURRENT DIAGNOSTIC METHODS FOR COVID-19



SARS-COV-2

Antigen test
Detect the antigen of the virus, indicating the active viral infection.

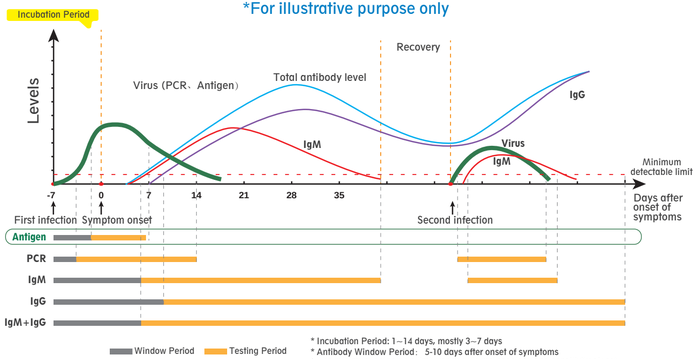
RT-PCR
Detect the RNA of virus, indicating the active viral infection.

Antibody test
Detect the antibody generated by immune response after viral infection, indicating the active or past viral infection.

WHEN TO USE ANTIGEN TEST?

Releasing profile

Levels of SARS-CoV-2 virus and antibodies after infection
*For illustrative purpose only



* Incubation Period: 1~14 days, mostly 3~7 days
* Antibody Window Period: 5-10 days after onset of symptoms
* The minimum detectable limit varies with methodology and sensitivity of test

ANTIGEN TEST ADVANTAGES

Antigen test OVER RT-PCR

- Short turn-around time
  (Antigen test: 20mins vs. RT-PCR: 2hours)
- Inexpensive cost, no equipment required and simple operation make antigen test suitable for point-of-care (POC) setting usage.

Antigen test OVER Antibody test

- Detect the virus directly, allowing the early detection of COVID-19
- Non-invasive sampling
  (sampling type: blood vs. swab)

ANTIGEN TEST APPLICATION

Similar to RT-PCR, the detection of antigen indicates the active infection. Under the circumstance that the area(s) still undergo widespread community transmission with limited RT-PCR resources, antigen can be used for aiding in the diagnosis of COVID-19 suspect patients.

* American CDC also recommends to use rapid antigen tests for screening testing in high-risk congregate settings where the immediate result is required.

Result interpretation

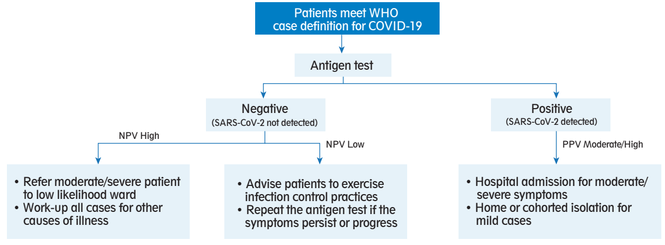
POSITIVE
The patient is undergo active SARS-CoV-2 infection. Further isolation is required.

NEGATIVE
The patient should be further evaluated by RT-PCR, especially if the result of the antigen test is inconsistent with the clinical context.

ANTIGEN TEST OFFICIAL GUIDELINES

World Health Organization

Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays



NPV- negative predictive value PPV- positive predictive value
*The value for NPV and PPV is decided based on products preformance and disease prevalence in applied scenarios.

Other antigen test related guidelines

- Interim Guidance for Rapid Antigen Testing for SARS-CoV-2, American CDC (8-16-20)
- Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes, American CDC (8-27-20)
- Antigen-Detection in the Diagnosis of SARS-CoV-2 Infection Using Rapid Immunoassays, WHO (9-11-20)
- Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing, APHL (9-2-20)

SARS-CoV-2 Antigen Test (Lateral Flow Method)

Catalog No.: W196

INTENDED USE

Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) 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 SARS-CoV-2.

The test provides preliminary test results. Negative results cannot exclude SARS-CoV-2 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 SARS-CoV-2 Antigen Test (Lateral Flow Method) is based on the principle of Immunochromatography sandwich for determination of SARS-CoV-2 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 SARS-CoV-2 antibody-dye conjugate and flows across the pre-coated membrane.

When the SARS-CoV-2 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 SARS-CoV-2 antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV-2 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

1. 20 Individual sealed pouches, each pouch contains:
   - 1 x Test Cassette
   - 1 x Desiccant Pouch
2. 20 Sample Extraction Tube
3. 20 Dripper
4. 20 Sterile Swabs CE 0197 MDD 93/42/EEC
   (Shenzhen Miraclean Technology Co., Ltd., China)
5. Extraction Buffer (2*6 mL)
6. Instructions for Use

Materials Required but Not Provided

1. Nasopharyngeal Swab
2. Viral Transport Media (VTM)
3. Tongue Depressor
4. Timer
5. Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
6. Appropriate biohazard waste container and disinfectants.

STORAGE AND STABILITY

1. Store at 2~30℃ 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 foiled 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℃ for up to 8 hours, or they may be stored at -70℃ 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

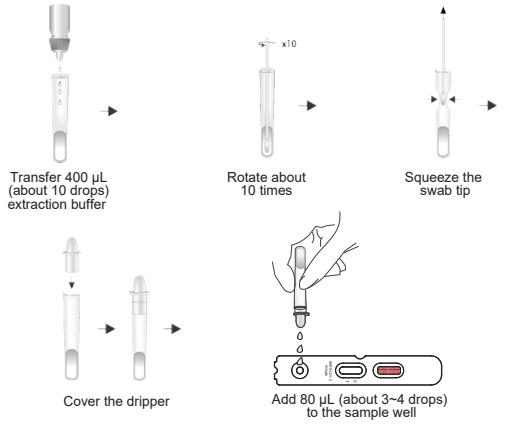
Please read the instructions for use carefully before performing the test.

1. Nasopharyngeal or oropharyngeal swab specimen extraction

1) Transfer 400 µL (about 10 drops) extraction buffer to the sample extraction tube vertically.
2) Insert the swab which has collected secretions into the specimen extraction buffer and rotate about 10 times to dissolve the specimen in the solution as much as possible.
3) Squeeze the swab tip to keep the liquid in the tube as much as possible.
4) Cover the dripper.

2. Test procedure

1) Remove a test cassette from the foiled pouch by tearing at the notch and place it on a level surface.
2) Add 80 µL (about 3~4 drops) processed specimen to the sample well.
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.**



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

RESULT INTERPRETATION

Positive Result

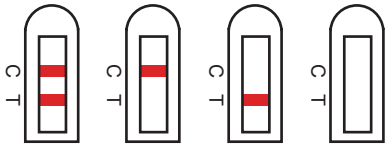
Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 antigen in the specimen.

Negative Result

Colored band appear at control line (C) only. It indicates that the concentration of the SARS-CoV-2 antigen is zero or below the detection limit of the test.

Invalid Result

No visible colored band appear at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



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 SARS-CoV-2 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 SARS-CoV-2 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 SARS-CoV-2 antigen is below the detection limit of the test.
   3) variations in viral genes may cause changes in antibodies determinants.

PERFORMANCE CHARACTERISTICS

A. Sensitivity and Specificity

859 clinical case samples which include 497 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 SARS-CoV-2 Antigen Test (Lateral Flow Method) and the PCR results. The results are shown below.

Reagents		PCR		Total
		Positive	Negative	
Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	Positive	478	1	479
	Negative	19	361	380
Total		497	362	859

Sensitivity: 96.18% (95%CI: 96.43%~98.49%)
Specificity: 99.72% (95%CI: 98.45%~99.95%)
Total agreement: 97.67% (95%CI: 94.11%~97.54%)

B. Cross-reactivity

Cross-reactivity of the Wondfo SARS-CoV-2 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
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 SARS-CoV-2 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 SARS-CoV-2 antigens, there is no hook effect in the test results of this product.

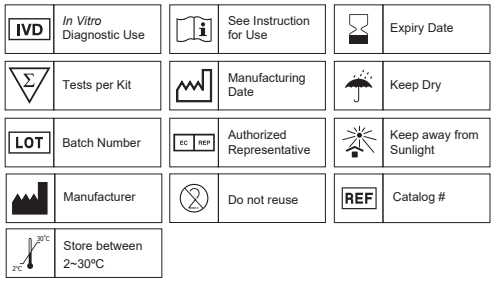
E. Precision

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%.

BIBLIOGRAPHY

[1] Su S, Wong G, Shi W, et al. Epidemiology, Genetic Recombination and Pathogenesis of Coronaviruses. Trends Microbiol 2016;24 (6):490-502..

INDEX OF SYMBOL



Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, 510663,Guangzhou,
P.R.China
Tel: +86-20-32296083 400-888-5268(Toll Free)
Fax: +86-20-32296063
E-mail: sales@wondfo.com.cn
Website: www.wondfo.com.cn

EC REP
Qarad BV
Cipalstraat 3
2440 Geel , Belgium

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