P1

Coronavirus Antigen Repid Test Kit

Brand: Wondfo

Type No.: 2019-nCOV Antigen Rapid Test

Features: Lateral Flow Method

EU Standard & Classifications: Tested by Qarad Belguim

Qualification: On the government procurement whitelist in the most European countries

Specifications: For use by clinical laboratories or healthcare workers

Shelf Life: 1 years

Storage Condition: 2-30 ℃

Packing specifications: 20 pcs. / per box, 30 boxes / per carton

P2


Wondfo
Leading POCT Manufacturer
SARS-CoV-2 Antigen Test
(Lateral Flow Method)
IVD
Sterile Swab


Wondfo
Leading POCT Manufacturer
2019-nCoV Antigen Test
(Lateral Flow Method)
Contents :
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
5. Extraction buffer (2*6 mL)
6. Instructions for use
Rev. A3
Rel. 2020.11.04
IVD
We Are Working For Your Health

P3


Wondfo
Leading POCT Manufacturer
Bio-Activity Guaranteed
FOR IN VITRO DIAGNOSTIC USE ONLY
FOR PROFESSIONAL USE ONLY


Wondfo
Leading POCT Manufacturer
Bio-Activity Guaranteed

**Wondfo 2019-nCoV Antigen Test**

**(Lateral Flow Method)**

**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. Extraction buffer (2*6 mL)

5. Instructions for use

6.Nasopharyngeal swab or oropharyngeal swab

**Package Information &HS code**

| T/box | Box/Carton | T/Carton | GW/Carton | Carton Size | HS code |
|---|---|---|---|---|---|
| **20** | 30 | 600 | 11KG | 60*44*44 | 3002150090 |

(Remark: The picture is for reference only, and the actual object shall prevail)


Wondfo
WONDFO
2019-nCoV
ANTIGEN
TEST
Speed Up the COVID-19 Control !
Guangzhou Wondfo Biotech Co., Ltd.

# PRODUCT SPECIFICATIONS

## Product Components

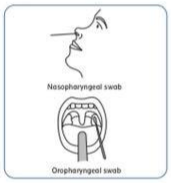

Test cassette

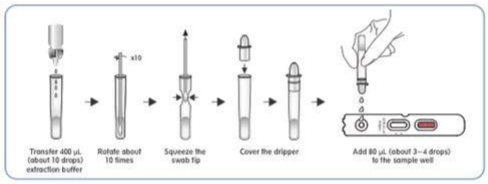

Extraction buffer

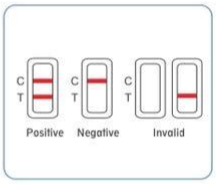

Extraction tube


Swab

## Operation procedure




## Performance

| Reagents | | PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Wondfo 2019-nCoV 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 | 2019-nCoV Antigen Test (Lateral Flow Method) | 20T | Nasopharyngeal swab or oropharyngeal swab | 2~30 °C | 12 months | CE |

# WONDFO
# 2019-nCoV
# ANTIGEN TEST


Direct detection of the virus

Instant results within 15mins

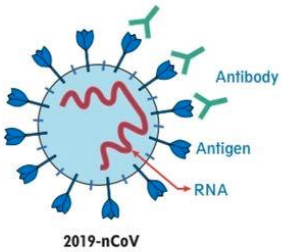
Easy to use, no equipment required

Room temperature storage( 2~30℃ )

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




**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.

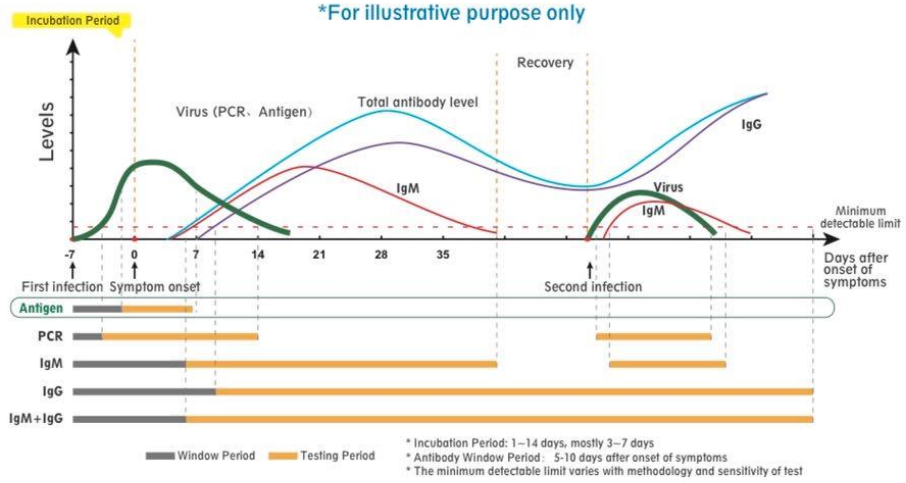
**Antibody test**
Detect the antibody generated by immune response after viral infection, indicating the active or past viral infection.

## WHEN TO USE ANTIGEN TEST?

**Releasing profile**

Levels of 2019-nCoV virus and antibodies after infection

*For illustrative purpose only



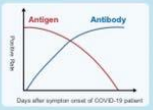

## ANTIGEN TEST ADVANTAGES

### 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)

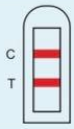


## ANTIGEN TEST APPLICATION

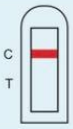
Similar to RT-PCR, the detection of antigen indicates the active infection. Under the circumstance that the area(s) still undergo widespread community transmission with limited RT-PCR resources, antigen can be used for aiding in the diagnosis of COVID-19 suspect patients.

* 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 2019-nCoV infection. Further isolation is required.

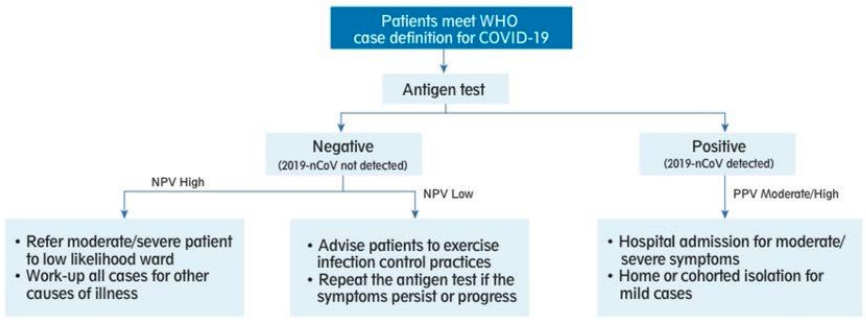



**NEGATIVE**
The patient should be further evaluated by RT-PCR, especially if the result of the antigen test is inconsistent with the clinical context.

## ANTIGEN TEST OFFICIAL GUIDELINES

World Health Organization

Antigen-detection in the diagnosis of novel coronavirus (2019-nCoV) 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 2019-nCoV, American CDC (8-16-20)
- Considerations for Use of 2019-nCoV Antigen Testing in Nursing Homes, American CDC (8-27-20)
- Antigen-Detection in the Diagnosis of 2019-nCoV Infection Using Rapid Immunoassays, WHO (9-11-20)
- Considerations for Implementation of 2019-nCoV Rapid Antigen Testing, APHL (9-2-20)

# 2019-nCoV Antigen Test (Lateral Flow Method)

Catalog No.: W196

## 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

1. 20 Individual sealed pouches, each pouch contains:
   - 1 x Test cassette
   - 1 x Desiccant pouch
2. 20 Sample extraction tubes
3. 20 Drippers
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 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℃ 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

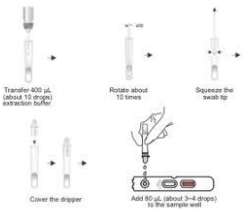
*Please read the instructions for use carefully before performing the test.*

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 sealed 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**

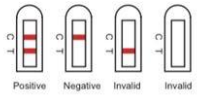
Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the 2019-nCoV antigen in the specimen.

**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 that the specimen should 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 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 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 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 | 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 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 |
| 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.

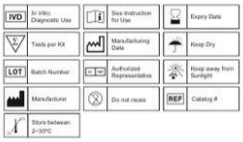
**E. Precision**

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%.

## 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




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

Qarad BV
Cipalstraat 3
2440 Geel , Belgium

Rev. A4
Rel.:2020/11/05

**Guangzhou Wondfo Biotech Co., Ltd.**
No. 8 Lizhishan Road, Science City, Luogang District,
510663 Guangzhou, P.R. China

# Material Safety Data Sheet

Valid from: March 14th, 2019

## 1. Chemical product and company identification

**Product Name:** 2019-nCoV Antigen Test (Lateral Flow Method)
**Catalogue Number:** W196
**Chemical Family:** *in-vitro* diagnostic medical device
**Manufacturer:** Guangzhou Wondfo Biotech Co., Ltd.
**Manufacturer's Address:** No.8 Lizhishan Road, Science City, Luogang District, 510663 Guangzhou, P.R. China

## 2. Composition/Information on Ingredients

| Component | Application | Dangerous substance |
|---|---|---|
| Nitrocellulose membrane | Coating membrane | N/A |
| Glass fiber membrane | Combination pad and sample pad | N/A |
| Absorbent paper | Guide chromatography process | N/A |
| PVC board | Base plate for carrying membrane, colloidal gold, auxiliary materials and other components | N/A |
| Desiccant | Silica gel, keep reagent dry | N/A |
| 2019-nCoV marking antibody | Marking material | N/A |
| 2019-nCoV coating antibody | Coating material in test (T) line | N/A |
| Anti-mouse IgG clonal antibody | Coating material in control (C) line | N/A |

## 3. Hazards Identification

**Information Pertaining to Particular Dangers for Man and Environment:**
The preparation is not classified as dangerous according to Directive 1272/2008/EC.
**Classification System:**
The classification is in line with current EC (European Community)-directives. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

## 4. First Aid Measure

- **Skin Contact:** Remove from source of exposure. Wash affected area with soap and water. If

signs of infection occur, seek medical attention.
- **Eye Contact:** Remove from source of exposure, immediately flush skin with cool water. Obtain medical attention if needed or if irritation or other symptoms develop.
- **Ingestion:** If irritation or signs of toxicity occur, seek medical attention.

## 5. Fire-fighting Measures

**Extinguishing Media:** Use water spray, dry chemical, carbon dioxide, or chemical foam.

## 6. Accidental Release Measures

**General Information:** Use proper personal protective equipment to clean up.
**Spills/Leaks:** Clean up and wash hands with water.

## 7. Handling and Storage

**Handling:** Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.
**Storage:** Stored in 2 ℃ ~ 30 ℃ in the sealed pouch, do not freeze.

## 8. Exposure Controls/Personal Protection

**See section 6, 7**
**Personal Protective Equipment (PPE):**
**Breathing Protection:** Not necessary, if room is well-ventilated.
**Eye Protection:** Wear safety glasses or full face shield.
**Skin Protection:** Wear protective clothing or gloves.

## 9. Physical and Chemical Properties

**Physical state:** Cassette
**Odor:** Odorless
**Solubility:** Insoluble in water
**Specific Gravity:** Not available
**Boiling Point:** Not available
**Melting Point:** Not available
**Fresh Point:** Not applicable
**Flammable Limits:** Not applicable
**Auto Ignition Temperature:** Not applicable

## 10. Stability and Reactivity

**Chemical Stability:** Stable under ordinary conditions of use and storage. See Section 7.
**Material to be Avoid:** None know
**Hazardous Polymerization:** will not occur

## 11. Toxicological Information

**Acute Toxicity:** Quantitative data on the toxic effects of this product is not available.
This product is used in vitro. No sensitizing effect known.

## 12. Ecological Information

No energy harm is involved for this product.

## 13. Disposal Considerations

In general laboratory waste is under the special supervision of the authorities. Refer to applicable local regulations.

## 14. Transport Information

**Land Transport ADR/RID (Cross-Border):** not restricted
**Air Transport ICAO-TI and IATA-DGR:** The substance is not subject to IATA DGR 60TH, 2020. Not restricted in IATA DGR.

## 15. Regulatory Information

**Designation according to EC Guidelines:** No marking required.

## 16. Additional Information

NA

# DECLARATION OF NOTIFICATION

Date: November 6, 2020

The undersigned, Sara Van Wouwe, Device Compliance Assistant of Qarad BV hereby declares that:

Guangzhou Wondfo Biotech Co. Ltd.
No. 8 Lizhishan Road, Science City Luogang District,
Guangzhou 510663
PR China

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD product (for professional use only):

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) (REF: W196)

The notification to the Belgian Competent Authorities has been carried out on August 11, 2020 by Qarad BV, the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd. On November 6th, a notification of change was carried out during which the new product name Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was notified.

Sara Van Wouwe
Device Compliance Assistant
Qarad BV
Authorized Representative

Digitally signed by Sara Van Wouwe (Signature)
Date: 2020.11.06 15:33:05 +01'00'

Qarad BV | Office Address: Pas 257, B-2440 Geel, Belgium | Social Siege: Cipalstraat 3, B-2440 Geel, Belgium
Tel. +32 (0)14 49 04 22 | ECREP@qarad.com | www.qarad.com

**Guangzhou Wondfo Biotech Co., Ltd.**
**RF-008-00** **Effective date: 2017-11-2**

EC DECLARATION OF CONFORMITY
According the In Vitro Diagnostic Medical Device Directive 98/79/EC

| | | |
|---|---|---|
| **Manufacturer:** | Guangzhou Wondfo Biotech Co. Ltd. | |
| **Address:** | No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China | |
| **In vitro diagnostic device(s):** | **Product Name:** | **Cat. No.:** |
| | Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) | W196 |
| | **IVDD Classification:** Other, for professional use | |

This declaration of conformity is issued under the sole responsibility of the manufacturer that that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices.

The following (harmonized) standards have been applied:

| | | |
|---|---|---|
| EN ISO 13485: 2016 | EN ISO 14971: 2012 | EN 13612:2002 |
| EN ISO 15223-1:2016 | EN ISO 18113-1: 2011 | EN ISO 18113-2: 2011 |
| EN ISO 23640: 2015 | EN 13641: 2002 | EN 62366: 2008 |

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: Annex III**, excluding 6**

**Notified Body (if consulted):** Not applicable.

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

**Qarad BV**, Cipalstraat 3, 2440 GEEL, Belgium

| | |
|---|---|
| Guangzhou Nov. 6, 2020 | Yaqin Chi, Regulatory Affairs Director<br>Yaqin Chi |
| (Place and date of issue) | (name and signature or equivalent marking of authorized person) |

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

# Certificate

**No. Q5 058008 0025 Rev. 00**

**Holder of Certificate:** **GUANGZHOU WONDFO BIOTECH CO., LTD.**
No. 8 Lizhishan Road, Science City
Luogang District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City, Luogang District, 510663 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

**Scope of Certificate:** **Design, Production and Distribution of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Test, Fluorescence Immunoassay System, Blood Glucose Monitoring System, Control Materials for Tumor Markers, ECG Event Recorder**

**Applied Standard(s):** EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1814116

**Valid from:** 2019-03-11
**Valid until:** 2021-01-31

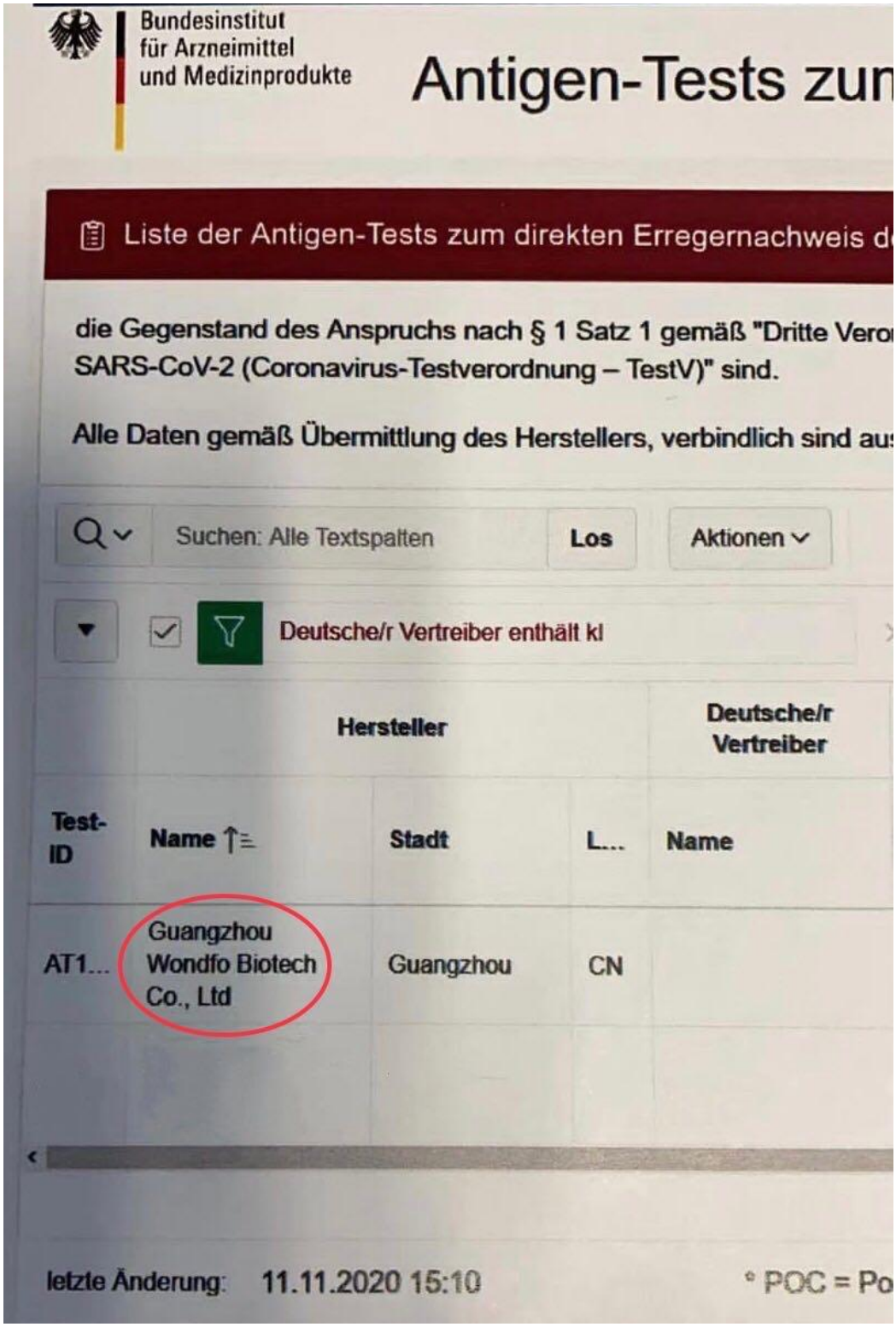
**Date,** 2019-03-11

Stefan Preiß

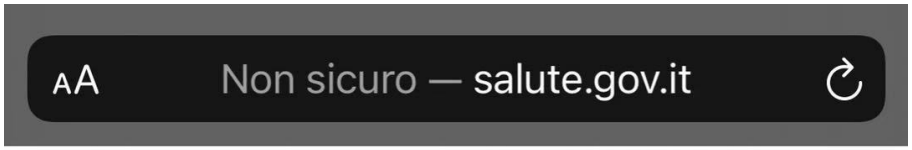
A4 / 07.17


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®


Bundesinstitut
für Arzneimittel
und Medizinprodukte
Antigen-Tests zun
Liste der Antigen-Tests zum direkten Erregernachweis d
die Gegenstand des Anspruchs nach § 1 Satz 1 gemäß "Dritte Vero
SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.
Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind au
Suchen: Alle Textspalten
Los
Aktionen
Deutsche/r Vertreiber enthält kl
Hersteller
Deutsche/r Vertreiber
Test-ID
Name
Stadt
L...
Name
AT1...
Guangzhou Wondfo Biotech Co., Ltd
Guangzhou
CN
letzte Änderung: 11.11.2020 15:10
° POC = Po

P18






Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

**Criteri di ricerca:**
Denominazione fabbricante: **guangzhou wondfo**
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM:
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

**Elenco dispositivi individuati**

Dati aggiornati al:15/11/2020

| DISPOSITIVO MEDICO/ASSEMBLATO | | | | | | | | | FABBRICANTE/ASSEMBLATORE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TIPOLOGIA DISPOSITIVO | IDENTIFICATIVO DI REGISTRAZIONE BD/RDM | ISCRITTO AL REPERTORIO | CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE | NOME COMMERCIALE E MODELLO | CND | CLASSE CE | DATA PRIMA PUBBLICAZIONE | DATA FINE IMMISSIONE IN COMMERCIO | RUOLO AZIENDA | DENOMINAZIONE | CODICE FISCALE | PARTITA IVA/VAT NUMBER | NAZIONE |
| Dispositivo | 1166007 | N | 00023010100000 | TEST DI GRAVIDANZA PIC SOLUTION PERSONAL TEST 1PZ | W0102160302 - HCG - TEST RAPIDO | ST - Test autodiagnostici (non inclusi nell'all. II) | 20/06/2014 | | FABBRICANTE | GUANGZHOU WONDFO BIOTECH CO. LTD | | | CN |
| | | | | | | | | | MANDATARIO | QARAD BVBA | | 0471972009 | BE |
| Dispositivo | 1166029 | N | 00023011100000 | TEST DI GRAVIDANZA PIC SOLUTION PERSONAL TEST 2PZ | W0102160302 - HCG - TEST RAPIDO | ST - Test autodiagnostici (non inclusi nell'all. II) | 20/06/2014 | | FABBRICANTE | GUANGZHOU WONDFO BIOTECH CO. LTD | | | CN |
| | | | | | | | | | MANDATARIO | QARAD BVBA | | 0471972009 | BE |
| Dispositivo | 1165844 | N | 00061437200000 | TEST DI GRAVIDANZA ANALYSIS 1PZ | W0102160302 - HCG - TEST RAPIDI E "POINT OF CARE" | ST - Test autodiagnostici (non inclusi nell'all. II) | 20/06/2014 | | FABBRICANTE | GUANGZHOU WONDFO BIOTECH CO. LTD | | | CN |
| | | | | | | | | | MANDATARIO | QARAD BVBA | | 0471972009 | BE |
| Dispositivo | 1165972 | N | 00061438200000 | TEST DI GRAVIDANZA ANALYSIS 2PZ | W0102160302 - HCG - TEST RAPIDI E "POINT OF CARE" | ST - Test autodiagnostici (non inclusi nell'all. II) | 20/06/2014 | | FABBRICANTE | GUANGZHOU WONDFO BIOTECH CO. LTD | | | CN |
| | | | | | | | | | MANDATARIO | QARAD BVBA | | 0471972009 | BE |
| Dispositivo | 1623698 | S | 02023010100000 | TEST DI GRAVIDANZA PIC SOLUTION PERSONAL TEST 1PZ | W0102160302 - HCG - TEST RAPIDI E "POINT OF CARE" | ST - Test autodiagnostici (non inclusi nell'all. II) | 31/10/2017 | | FABBRICANTE | GUANGZHOU WONDFO BIOTECH CO. LTD | | | CN |
| | | | | | | | | | MANDATARIO | QARAD BVBA | | 0471972009 | BE |
| Dispositivo | 1623713 | S | 02023011100000 | TEST DI GRAVIDANZA PIC SOLUTION PERSONAL TEST 2PZ | W0102160302 - HCG - TEST RAPIDI E "POINT OF CARE" | ST - Test autodiagnostici (non inclusi nell'all. II) | 31/10/2017 | | FABBRICANTE | GUANGZHOU WONDFO BIOTECH CO. LTD | | | CN |
| | | | | | | | | | MANDATARIO | QARAD BVBA | | 0471972009 | BE |
| Dispositivo | 1623715 | S | 02083800000000 | TEST DI GRAVIDANZA DR. MARCUS | W0102160302 - HCG - TEST RAPIDI E "POINT OF CARE" | ST - Test autodiagnostici (non inclusi nell'all. II) | 31/10/2017 | | FABBRICANTE | GUANGZHOU WONDFO BIOTECH CO. LTD | | | CN |
| | | | | | | | | | MANDATARIO | QARAD BVBA | | 0471972009 | BE |
| Dispositivo | 1755107 | S | 02083900000000 | TEST DI GRAVIDANZA DR. MARCUS | W0102160302 - HCG - TEST RAPIDI E "POINT OF CARE" | ST - Test autodiagnostici (non inclusi nell'all. II) | 10/10/2018 | | FABBRICANTE | GUANGZHOU WONDFO BIOTECH CO. LTD | | | CN |
| | | | | | | | | | MANDATARIO | QARAD BVBA | | 0471972009 | BE |
| | | | | | | | | | | GUANGZHOU | | | |

**P19**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Dispositivo | 1936702 | S | W195 | SARS-COV-2 ANTIBODY TEST(LATERAL FLOW METHOD) | W0105040599 - TEST DI VIROLOGIA - REAGENTI NAS - ALTRI | IVD - Altro tipo di IVD | 21/03/2020 | |
| Dispositivo | 2000527 | N | W196 | SARS-COV-2 ANTIGEN TEST | W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI | IVD - Altro tipo di IVD | 01/10/2020 | |