SARS-CoV-2 Antigen Test

(Lateral Flow Method)

Summary Data

Guangzhou Wondfo Biotech Co., Ltd.

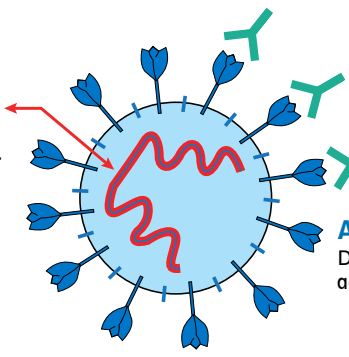
目录(Contents)

1. 产品彩页(PRODUCT BROCHURE) 2
2. 公司介绍（COMPANY PROFILE） 3
3. 符合性声明(DECLARATION OF CONFORMITY).....4
4. CE 注册证(CERTIFICATE OF EU PRODUCT NOTIFICATION).....5
5. 说明书(INSTRUCTIONS FOR USE) 6-7
6. 包装信息(PACKING INFORMATION) 8
7. 临床验证报告(CLINICAL TRIAL SUMMARY REPORT)..... 9-34
8. MSDS（MATERIAL SAFETY DATA SHEET） 35-40
9. ISO13485 认证(ISO13485 CERTIFICATE) 41
10. 企业资质(ENTERPRISE QUALIFICATION) 42-47

WONDFO COVID-19 DIAGNOSTIC SOLUTION

Wondfo is the **ONLY ONE** in China that offers the **MOST COMPLETE** COVID-19 diagnostic solution.

CURRENT DIAGNOSTIC METHODS FOR COVID-19



RT-PCR
Detect RNA;
indicate active infection.

Antibody Test
Detect antibody; indicate active or past infection.

Antigen Test
Detect antigen, indicate active infection.

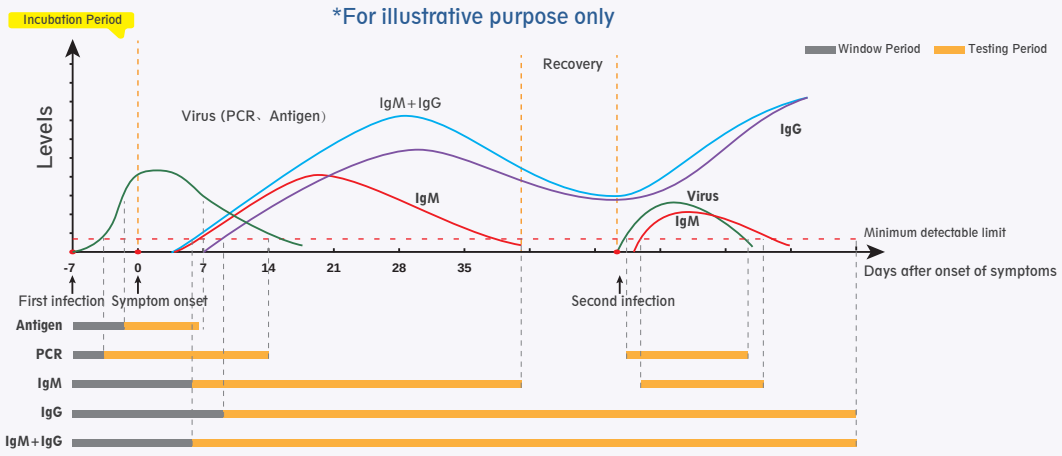
SARS-COV-2

Features of RT-PCR:
- Gold standard diagnosis
- Turn-around time around 2 hours
- High equipment requirement

Features of Antigen & Antibody Test:
- Inexpensive cost
- Turn-around time around 15 mins
- Less equipment required

• Releasing profile

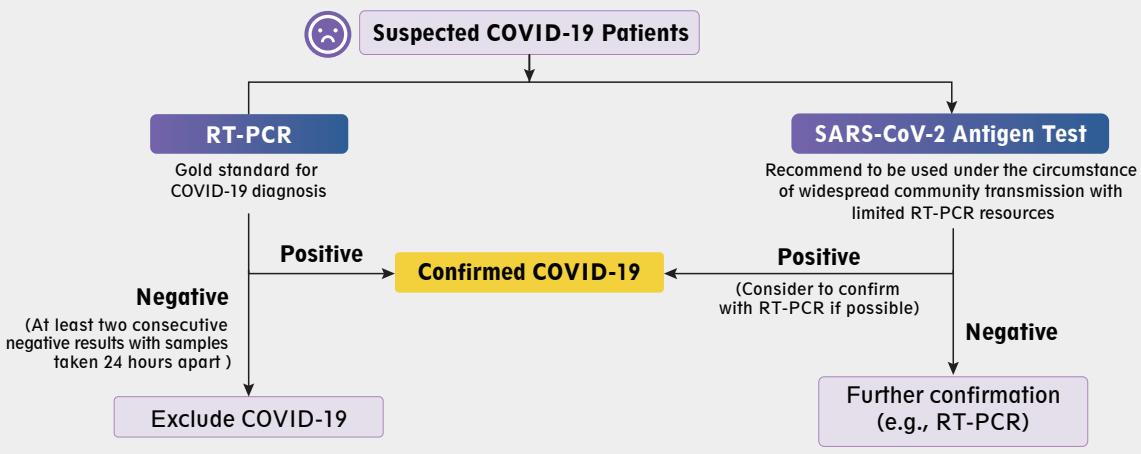
Levels of SARS-CoV-2 virus and antibodies after infection
*For illustrative purpose only



* 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

APPLICATIONS

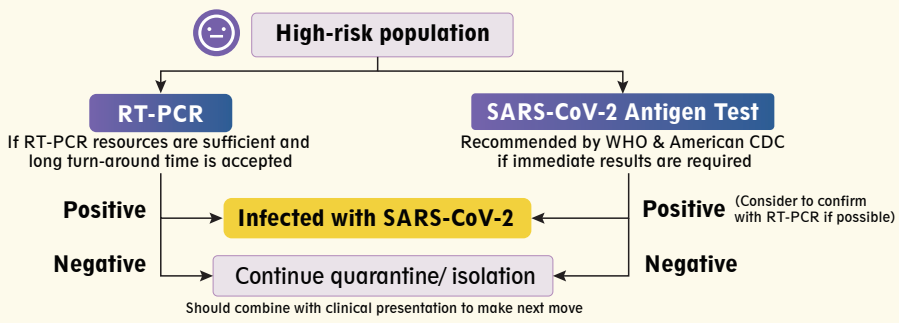
1 Diagnosis for suspected COVID-19 patients



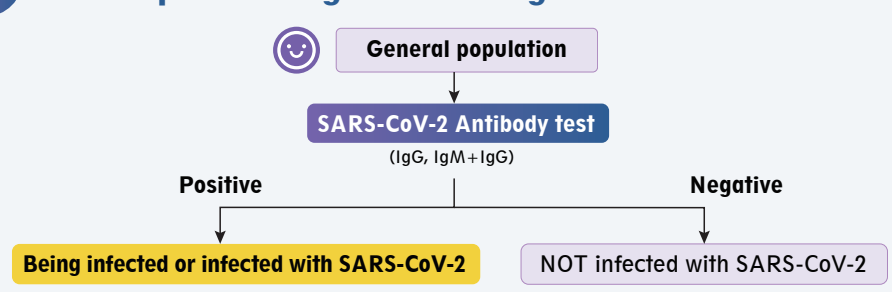
+ SARS-CoV-2 Antibody Test

RT-PCR or antigen test combining with antibody test can:
Improve detection rate for the whole disease course!

2 Screening in high-risk congregate



3 Sero-epidemiological investigation



• Application scenarios

Border | Lab | Primary Care Unit | Designated Hospital | CDC (Centers for Disease Control and Prevention) | Fever Clinic

WONDFO COVID-19 DIAGNOSTIC FAMILY

Platform	Product Name	Specimen	Reaction Time	Storage Condition	Shelf Life	Qualification	Packing Size	Catalog No.
	Hot Wondfo SARS-CoV-2 Real-Time RT-PCR Assay	Oropharyngeal swab / Nasopharyngeal swab / Sputum	＜60 mins after extraction	10~30 ℃	12 months	CE	24T	W275P001 W275P003
							48 T	W275P002 W275P004
	New Wondfo SARS-CoV-2 Antigen Test(Lateral Flow Method)	Oropharyngeal swab / Nasopharyngeal swab	15 mins	2~30 ℃	12 months	CE	20 T	W196
	Hot Wondfo SARS-CoV-2 Antibody Test(Lateral Flow Method)	Venous whole blood / Serum/ Plasma	15 mins	2~30 ℃	6 months	CE NMPA	20 T	W195
	Wondfo SARS-CoV-2 IgM Antibody Test(Lateral Flow Method)				12 months	CE	20 T	W197
	Wondfo SARS-CoV-2 IgG Antibody Test(Lateral Flow Method)				12 months	CE	20 T	W198
	Finecare™ SARS-CoV-2 Antigen Test	Oropharyngeal swab / Nasopharyngeal swab	15 mins	2~30 ℃	12 months	CE	25 T	W286
	New Finecare™ SARS-CoV-2 IgM/IgG Test	Venous whole blood / Serum/ Plasma	10 mins	2~30 ℃	12 months	CE	25 T	W278
	Hot Finecare™ SARS-CoV-2 Antibody Test					CE	25 T	W276
	Hot Finecare™ SARS-CoV-2 IgM Test					CE	25 T	W277
	Finecare™ SARS-CoV-2 IgG Test					CE	25 T	W280

Wondfo®
Rev. A8 Rel.: 2020/10/16

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 reserves all rights. All contents of this brochure are copyrighted by Wondfo.

WONDFO PROFILE

Founded in 1992, Wondfo was one of the earliest high-tech biological companies focusing on rapid diagnostics in China. Apart from the Guangzhou headquarters, Wondfo also owns two overseas labs , one branch in Chicago and other eleven overseas offices. Wondfo has won good reputation around the world for our quality products and professional services. We have got CE certificates, FDA certificates, FSC certificates, ISO 9001:2008 and ISO 13485:2012 quality system certification.

Wondfo is consistently paying much attention to the R & D, regarding innovation as the soul of the enterprise's development. So far, over 30% of the staff have obtained master and doctorate degree from prestigious worldwide institutions. Wondfo owns research laboratories covering nearly 5,000 square meters in Guangzhou.

With our international leading production lines and highly experienced staff, Wondfo's daily production capacity reaches to 1.5 million test strips. Wondfo also provides a number of customized services to professional distributors and partnering affiliates.

Wondfo's sales network has covered more than 140 countries and areas, providing an exciting opportunity for distribution of quality products at a very competitive price. Every aspect of the company's operation is strictly measured, and that provides customers with all-
around technical support and counselling all the time.

We are dedicated to making the world a better place by providing people with high quality products and services.

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 SARS-CoV-2 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 August/9/2020	Yaqin Chi, Regulatory Affairs Director Yaqin Chi
(Place and date of issue)	(name and signature or equivalent marking of authorized person)

DECLARATION OF NOTIFICATION

Date: August 11, 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 SARS-CoV-2 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.

Sara Van Wouwe
Device Compliance Assistant
Qarad BV
Authorized Representative

Digitally signed by Sara Van Wouwe (Signature)
Date: 2020.08.11 12:58:37 +02'00'

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

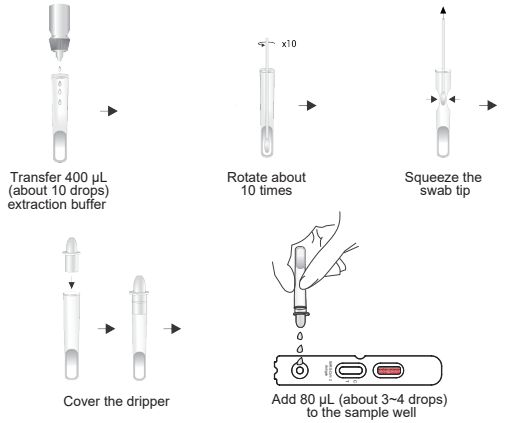
Please read the instructions for use carefully before performing the test.

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

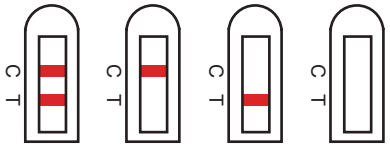
Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 antigen in the specimen.

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.

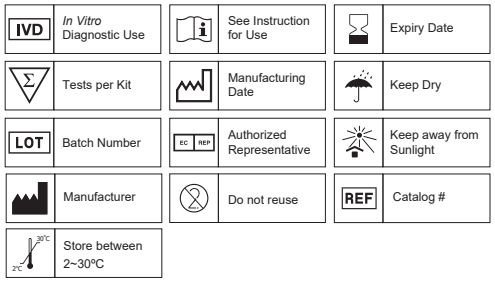
E. Precision

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

Rev. A3
Rel.:2020/10/20

SARS-CoV-2 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	42	840	14.5KG	60*44*44	3002150090

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

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

Guangzhou Wondfo Biotech Co., Ltd.

Clinical Evaluation Report

Date of Issue: Oct. 20, 2020

Sponsor： Guangzhou Wondfo Biotech Co., Ltd

No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou P.R.China

Content

1. Introduction and description of the assay 3
2. Evaluation method 3
3. Clinical samples 4
4. Clinical trial period 4
5. Results and Analysis 4
6. Conclusion 5
Annex I Clinical Verification Data List 6

1. Introduction and description of the assay

Introduction

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.

Description of the assay (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.

2. Evaluation method

In this trial, based on the comparison of PCR diagnosis results of the patients, clinical application study of Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) was conducted and thus verified the safety and effectiveness of such reagents manufactured by Guangzhou Wondfo Biotech Co., Ltd.

3. Clinical samples

A total of 859 clinical oropharyngeal swab samples were included in this trial.

4. Clinical trial period

October 12 to October 20, 2020

5. Results and Analysis

5.1 Test procedure

Throughout the evaluation, all samples should be tested with the Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) according to the 'Test procedure' described in the Instruction for Use supplied with the reagent.

5.2 Comparative Analysis of Trial Results

Trial Completion

A total of 497 PCR positive cases and 362 PCR negative cases were included in this trial of *2* clinical sites.

Major Effectiveness Statistical Methods

Compared with PCR results, calculate the sensitivity, specificity, overall consistency and the 95% confidence interval (CI) of test reagents. Sensitivity, specificity, overall consistency: range from 0%~100%, the closer the value is to 100%, the higher the degree of compliance with clinical diagnosis.

5.3 Result Analysis

Test results are shown as Table 1, and clinical trial results are detailed in Annex I Clinical verification data list.

Table 1: 2 × 2 Contingency Table Analysis of PCR Results and Evaluation Reagent Test Results

	COVID-19		
Evaluation Reagents	PCR Positive	PCR Negative	Total
SARS-CoV-2 Antigen positive	478	1	479
SARS-CoV-2 Antigen 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 conformity rate	97.67%	95%CI:	94.11%~97.54%

There were 478 positive samples and 361 negative samples whose SARS-CoV-2 antigen detection results were consistent with PCR results. 19 cases were confirmed PCR positive and meanwhile tested negative by Wondfo SARS-CoV-2 Antigen Test (Lateral flow method) and 1 case was confirmed PCR negative and meanwhile tested positive by Wondfo SARS-CoV-2 Antigen Test (Lateral flow method).

6. Conclusion

From the results of 859 clinical samples, it is conducted that Wondfo SARS-CoV-2 Antigen Test (Lateral flow method) developed by Guangzhou Wondfo Biotech Co., Ltd. can meet the requirement of clinical intended use.

Annex I Clinical Verification Data List

Results of negative samples:

Sample	Clinical site	Date of testing	Wondfo result	PCR result	Coincidence
1	Site 1	12-Oct-20	N	N	Yes
2	Site 1	12-Oct-20	N	N	Yes
3	Site 1	12-Oct-20	N	N	Yes
4	Site 1	12-Oct-20	N	N	Yes
5	Site 1	12-Oct-20	N	N	Yes
6	Site 1	12-Oct-20	N	N	Yes
7	Site 1	12-Oct-20	N	N	Yes
8	Site 1	12-Oct-20	N	N	Yes
9	Site 1	12-Oct-20	N	N	Yes
10	Site 1	12-Oct-20	N	N	Yes
11	Site 1	12-Oct-20	N	N	Yes
12	Site 1	12-Oct-20	N	N	Yes
13	Site 1	12-Oct-20	N	N	Yes
14	Site 1	12-Oct-20	N	N	Yes
15	Site 1	12-Oct-20	N	N	Yes
16	Site 1	12-Oct-20	N	N	Yes
17	Site 1	12-Oct-20	N	N	Yes
18	Site 1	12-Oct-20	N	N	Yes
19	Site 1	12-Oct-20	N	N	Yes
20	Site 1	12-Oct-20	N	N	Yes
21	Site 1	12-Oct-20	N	N	Yes
22	Site 1	12-Oct-20	N	N	Yes
23	Site 1	13-Oct-20	N	N	Yes
24	Site 1	13-Oct-20	N	N	Yes
25	Site 1	13-Oct-20	N	N	Yes
26	Site 1	13-Oct-20	N	N	Yes
27	Site 1	13-Oct-20	N	N	Yes
28	Site 1	13-Oct-20	N	N	Yes
29	Site 1	13-Oct-20	N	N	Yes
30	Site 1	13-Oct-20	N	N	Yes
31	Site 1	13-Oct-20	N	N	Yes
32	Site 1	13-Oct-20	N	N	Yes
33	Site 1	13-Oct-20	N	N	Yes
34	Site 1	13-Oct-20	N	N	Yes
35	Site 1	13-Oct-20	N	N	Yes
36	Site 1	13-Oct-20	N	N	Yes
37	Site 1	13-Oct-20	N	N	Yes
38	Site 1	13-Oct-20	N	N	Yes
39	Site 1	13-Oct-20	N	N	Yes

40	Site 1	13-Oct-20	N	N	Yes
41	Site 1	13-Oct-20	N	N	Yes
42	Site 1	13-Oct-20	N	N	Yes
43	Site 1	13-Oct-20	N	N	Yes
44	Site 1	14-Oct-20	N	N	Yes
45	Site 1	14-Oct-20	N	N	Yes
46	Site 1	14-Oct-20	N	N	Yes
47	Site 1	14-Oct-20	N	N	Yes
48	Site 1	14-Oct-20	N	N	Yes
49	Site 1	14-Oct-20	N	N	Yes
50	Site 1	14-Oct-20	N	N	Yes
51	Site 1	14-Oct-20	N	N	Yes
52	Site 1	14-Oct-20	N	N	Yes
53	Site 1	14-Oct-20	N	N	Yes
54	Site 1	14-Oct-20	N	N	Yes
55	Site 1	14-Oct-20	P	N	No
56	Site 1	14-Oct-20	N	N	Yes
57	Site 1	14-Oct-20	N	N	Yes
58	Site 1	14-Oct-20	N	N	Yes
59	Site 1	14-Oct-20	N	N	Yes
60	Site 1	14-Oct-20	N	N	Yes
61	Site 1	14-Oct-20	N	N	Yes
62	Site 1	14-Oct-20	N	N	Yes
63	Site 1	14-Oct-20	N	N	Yes
64	Site 1	14-Oct-20	N	N	Yes
65	Site 1	14-Oct-20	N	N	Yes
66	Site 1	14-Oct-20	N	N	Yes
67	Site 1	14-Oct-20	N	N	Yes
68	Site 1	14-Oct-20	N	N	Yes
69	Site 1	14-Oct-20	N	N	Yes
70	Site 1	14-Oct-20	N	N	Yes
71	Site 1	14-Oct-20	N	N	Yes
72	Site 1	14-Oct-20	N	N	Yes
73	Site 1	14-Oct-20	N	N	Yes
74	Site 1	14-Oct-20	N	N	Yes
75	Site 1	14-Oct-20	N	N	Yes
76	Site 1	14-Oct-20	N	N	Yes
77	Site 1	14-Oct-20	N	N	Yes
78	Site 1	14-Oct-20	N	N	Yes
79	Site 1	14-Oct-20	N	N	Yes
80	Site 1	14-Oct-20	N	N	Yes
81	Site 1	14-Oct-20	N	N	Yes
82	Site 1	14-Oct-20	N	N	Yes

83	Site 1	14-Oct-20	N	N	Yes
84	Site 1	14-Oct-20	N	N	Yes
85	Site 1	14-Oct-20	N	N	Yes
86	Site 1	14-Oct-20	N	N	Yes
87	Site 1	14-Oct-20	N	N	Yes
88	Site 1	14-Oct-20	N	N	Yes
89	Site 1	14-Oct-20	N	N	Yes
90	Site 1	14-Oct-20	N	N	Yes
91	Site 1	14-Oct-20	N	N	Yes
92	Site 1	15-Oct-20	N	N	Yes
93	Site 1	15-Oct-20	N	N	Yes
94	Site 1	15-Oct-20	N	N	Yes
95	Site 1	15-Oct-20	N	N	Yes
96	Site 1	15-Oct-20	N	N	Yes
97	Site 1	15-Oct-20	N	N	Yes
98	Site 1	15-Oct-20	N	N	Yes
99	Site 1	15-Oct-20	N	N	Yes
100	Site 1	15-Oct-20	N	N	Yes
101	Site 1	15-Oct-20	N	N	Yes
102	Site 1	15-Oct-20	N	N	Yes
103	Site 1	15-Oct-20	N	N	Yes
104	Site 1	15-Oct-20	N	N	Yes
105	Site 1	15-Oct-20	N	N	Yes
106	Site 1	15-Oct-20	N	N	Yes
107	Site 1	15-Oct-20	N	N	Yes
108	Site 1	15-Oct-20	N	N	Yes
109	Site 1	15-Oct-20	N	N	Yes
110	Site 1	15-Oct-20	N	N	Yes
111	Site 1	15-Oct-20	N	N	Yes
112	Site 1	15-Oct-20	N	N	Yes
113	Site 1	15-Oct-20	N	N	Yes
114	Site 1	15-Oct-20	N	N	Yes
115	Site 1	15-Oct-20	N	N	Yes
116	Site 1	15-Oct-20	N	N	Yes
117	Site 1	15-Oct-20	N	N	Yes
118	Site 1	15-Oct-20	N	N	Yes
119	Site 1	15-Oct-20	N	N	Yes
120	Site 1	15-Oct-20	N	N	Yes
121	Site 1	15-Oct-20	N	N	Yes
122	Site 1	15-Oct-20	N	N	Yes
123	Site 1	15-Oct-20	N	N	Yes
124	Site 1	15-Oct-20	N	N	Yes
125	Site 1	15-Oct-20	N	N	Yes

126	Site 1	15-Oct-20	N	N	Yes
127	Site 1	15-Oct-20	N	N	Yes
128	Site 1	15-Oct-20	N	N	Yes
129	Site 1	15-Oct-20	N	N	Yes
130	Site 1	15-Oct-20	N	N	Yes
131	Site 1	15-Oct-20	N	N	Yes
132	Site 1	15-Oct-20	N	N	Yes
133	Site 1	16-Oct-20	N	N	Yes
134	Site 1	16-Oct-20	N	N	Yes
135	Site 1	16-Oct-20	N	N	Yes
136	Site 1	16-Oct-20	N	N	Yes
137	Site 1	16-Oct-20	N	N	Yes
138	Site 1	16-Oct-20	N	N	Yes
139	Site 1	16-Oct-20	N	N	Yes
140	Site 1	16-Oct-20	Y	N	No
141	Site 1	16-Oct-20	N	N	Yes
142	Site 1	16-Oct-20	N	N	Yes
143	Site 1	16-Oct-20	N	N	Yes
144	Site 1	16-Oct-20	N	N	Yes
145	Site 1	16-Oct-20	N	N	Yes
146	Site 1	16-Oct-20	N	N	Yes
147	Site 1	16-Oct-20	N	N	Yes
148	Site 1	16-Oct-20	N	N	Yes
149	Site 1	16-Oct-20	N	N	Yes
150	Site 1	16-Oct-20	N	N	Yes
151	Site 1	16-Oct-20	N	N	Yes
152	Site 1	16-Oct-20	N	N	Yes
153	Site 1	16-Oct-20	N	N	Yes
154	Site 1	16-Oct-20	N	N	Yes
155	Site 1	16-Oct-20	N	N	Yes
156	Site 1	16-Oct-20	N	N	Yes
157	Site 1	16-Oct-20	N	N	Yes
158	Site 1	16-Oct-20	N	N	Yes
159	Site 1	16-Oct-20	N	N	Yes
160	Site 1	16-Oct-20	N	N	Yes
161	Site 1	19-Oct-20	N	N	Yes
162	Site 1	19-Oct-20	N	N	Yes
163	Site 1	19-Oct-20	N	N	Yes
164	Site 1	19-Oct-20	N	N	Yes
165	Site 1	19-Oct-20	N	N	Yes
166	Site 1	19-Oct-20	N	N	Yes
167	Site 1	19-Oct-20	N	N	Yes
168	Site 1	19-Oct-20	N	N	Yes

169	Site 1	19-Oct-20	N	N	Yes
170	Site 1	19-Oct-20	N	N	Yes
171	Site 1	19-Oct-20	N	N	Yes
172	Site 1	19-Oct-20	N	N	Yes
173	Site 1	19-Oct-20	N	N	Yes
174	Site 1	19-Oct-20	N	N	Yes
175	Site 1	19-Oct-20	N	N	Yes
176	Site 1	19-Oct-20	N	N	Yes
177	Site 1	19-Oct-20	N	N	Yes
178	Site 1	19-Oct-20	N	N	Yes
179	Site 1	19-Oct-20	N	N	Yes
180	Site 1	19-Oct-20	N	N	Yes
181	Site 1	19-Oct-20	N	N	Yes
182	Site 1	19-Oct-20	N	N	Yes
183	Site 1	19-Oct-20	N	N	Yes
184	Site 1	19-Oct-20	N	N	Yes
185	Site 1	19-Oct-20	N	N	Yes
186	Site 1	19-Oct-20	N	N	Yes
187	Site 1	19-Oct-20	N	N	Yes
188	Site 1	19-Oct-20	N	N	Yes
189	Site 1	19-Oct-20	N	N	Yes
190	Site 1	19-Oct-20	N	N	Yes
191	Site 1	19-Oct-20	N	N	Yes
192	Site 1	19-Oct-20	N	N	Yes
193	Site 1	19-Oct-20	N	N	Yes
194	Site 1	19-Oct-20	N	N	Yes
195	Site 1	19-Oct-20	N	N	Yes
196	Site 1	19-Oct-20	N	N	Yes
197	Site 1	19-Oct-20	N	N	Yes
198	Site 1	19-Oct-20	N	N	Yes
199	Site 1	19-Oct-20	N	N	Yes
200	Site 1	19-Oct-20	N	N	Yes
201	Site 1	19-Oct-20	N	N	Yes
202	Site 1	19-Oct-20	N	N	Yes
203	Site 1	19-Oct-20	N	N	Yes
204	Site 1	19-Oct-20	N	N	Yes
205	Site 1	19-Oct-20	N	N	Yes
206	Site 1	19-Oct-20	N	N	Yes
207	Site 1	19-Oct-20	N	N	Yes
208	Site 1	19-Oct-20	N	N	Yes
209	Site 1	19-Oct-20	N	N	Yes
210	Site 1	19-Oct-20	N	N	Yes
211	Site 1	19-Oct-20	N	N	Yes

212	Site 1	19-Oct-20	N	N	Yes
213	Site 1	19-Oct-20	N	N	Yes
214	Site 1	19-Oct-20	N	N	Yes
215	Site 1	19-Oct-20	N	N	Yes
216	Site 1	19-Oct-20	N	N	Yes
217	Site 1	19-Oct-20	N	N	Yes
218	Site 1	19-Oct-20	N	N	Yes
219	Site 1	19-Oct-20	N	N	Yes
220	Site 1	19-Oct-20	N	N	Yes
221	Site 1	19-Oct-20	N	N	Yes
222	Site 1	19-Oct-20	N	N	Yes
223	Site 1	19-Oct-20	N	N	Yes
224	Site 1	19-Oct-20	N	N	Yes
225	Site 1	19-Oct-20	N	N	Yes
226	Site 1	19-Oct-20	N	N	Yes
227	Site 1	19-Oct-20	N	N	Yes
228	Site 1	19-Oct-20	N	N	Yes
229	Site 1	19-Oct-20	N	N	Yes
230	Site 1	19-Oct-20	N	N	Yes
231	Site 1	19-Oct-20	N	N	Yes
232	Site 1	19-Oct-20	N	N	Yes
233	Site 1	20-Oct-20	N	N	Yes
234	Site 1	20-Oct-20	N	N	Yes
235	Site 1	20-Oct-20	N	N	Yes
236	Site 1	20-Oct-20	N	N	Yes
237	Site 1	20-Oct-20	N	N	Yes
238	Site 1	20-Oct-20	N	N	Yes
239	Site 1	20-Oct-20	N	N	Yes
240	Site 1	20-Oct-20	N	N	Yes
241	Site 1	20-Oct-20	N	N	Yes
242	Site 1	20-Oct-20	N	N	Yes
243	Site 1	20-Oct-20	N	N	Yes
244	Site 1	20-Oct-20	N	N	Yes
245	Site 1	20-Oct-20	N	N	Yes
246	Site 1	20-Oct-20	N	N	Yes
247	Site 1	20-Oct-20	N	N	Yes
248	Site 1	20-Oct-20	N	N	Yes
249	Site 2	12-Oct-20	N	N	Yes
250	Site 2	12-Oct-20	N	N	Yes
251	Site 2	12-Oct-20	N	N	Yes
252	Site 2	12-Oct-20	N	N	Yes
253	Site 2	12-Oct-20	N	N	Yes
254	Site 2	12-Oct-20	N	N	Yes

255	Site 2	12-Oct-20	N	N	Yes
256	Site 2	12-Oct-20	N	N	Yes
257	Site 2	12-Oct-20	N	N	Yes
258	Site 2	12-Oct-20	N	N	Yes
259	Site 2	12-Oct-20	N	N	Yes
260	Site 2	12-Oct-20	N	N	Yes
261	Site 2	12-Oct-20	N	N	Yes
262	Site 2	12-Oct-20	N	N	Yes
263	Site 2	12-Oct-20	N	N	Yes
264	Site 2	12-Oct-20	N	N	Yes
265	Site 2	12-Oct-20	N	N	Yes
266	Site 2	12-Oct-20	N	N	Yes
267	Site 2	13-Oct-20	N	N	Yes
268	Site 2	13-Oct-20	N	N	Yes
269	Site 2	13-Oct-20	N	N	Yes
270	Site 2	13-Oct-20	N	N	Yes
271	Site 2	13-Oct-20	N	N	Yes
272	Site 2	13-Oct-20	N	N	Yes
273	Site 2	13-Oct-20	N	N	Yes
274	Site 2	13-Oct-20	N	N	Yes
275	Site 2	13-Oct-20	N	N	Yes
276	Site 2	13-Oct-20	N	N	Yes
277	Site 2	13-Oct-20	N	N	Yes
278	Site 2	13-Oct-20	N	N	Yes
279	Site 2	13-Oct-20	N	N	Yes
280	Site 2	14-Oct-20	N	N	Yes
281	Site 2	14-Oct-20	N	N	Yes
282	Site 2	14-Oct-20	N	N	Yes
283	Site 2	14-Oct-20	N	N	Yes
284	Site 2	14-Oct-20	N	N	Yes
285	Site 2	14-Oct-20	N	N	Yes
286	Site 2	14-Oct-20	N	N	Yes
287	Site 2	14-Oct-20	N	N	Yes
288	Site 2	14-Oct-20	N	N	Yes
289	Site 2	14-Oct-20	N	N	Yes
290	Site 2	14-Oct-20	N	N	Yes
291	Site 2	14-Oct-20	N	N	Yes
292	Site 2	14-Oct-20	N	N	Yes
293	Site 2	14-Oct-20	N	N	Yes
294	Site 2	14-Oct-20	N	N	Yes
295	Site 2	14-Oct-20	N	N	Yes
296	Site 2	14-Oct-20	N	N	Yes
297	Site 2	15-Oct-20	N	N	Yes

298	Site 2	15-Oct-20	N	N	Yes
299	Site 2	15-Oct-20	N	N	Yes
300	Site 2	15-Oct-20	N	N	Yes
301	Site 2	15-Oct-20	N	N	Yes
302	Site 2	15-Oct-20	N	N	Yes
303	Site 2	15-Oct-20	N	N	Yes
304	Site 2	15-Oct-20	N	N	Yes
305	Site 2	15-Oct-20	N	N	Yes
306	Site 2	15-Oct-20	N	N	Yes
307	Site 2	15-Oct-20	N	N	Yes
308	Site 2	15-Oct-20	N	N	Yes
309	Site 2	15-Oct-20	N	N	Yes
310	Site 2	16-Oct-20	N	N	Yes
311	Site 2	16-Oct-20	N	N	Yes
312	Site 2	16-Oct-20	N	N	Yes
313	Site 2	16-Oct-20	N	N	Yes
314	Site 2	16-Oct-20	N	N	Yes
315	Site 2	16-Oct-20	N	N	Yes
316	Site 2	16-Oct-20	N	N	Yes
317	Site 2	16-Oct-20	N	N	Yes
318	Site 2	16-Oct-20	N	N	Yes
319	Site 2	16-Oct-20	N	N	Yes
320	Site 2	16-Oct-20	N	N	Yes
321	Site 2	16-Oct-20	N	N	Yes
322	Site 2	19-Oct-20	N	N	Yes
323	Site 2	19-Oct-20	N	N	Yes
324	Site 2	19-Oct-20	N	N	Yes
325	Site 2	19-Oct-20	N	N	Yes
326	Site 2	19-Oct-20	N	N	Yes
327	Site 2	19-Oct-20	N	N	Yes
328	Site 2	19-Oct-20	N	N	Yes
329	Site 2	19-Oct-20	N	N	Yes
330	Site 2	19-Oct-20	N	N	Yes
331	Site 2	19-Oct-20	N	N	Yes
332	Site 2	19-Oct-20	N	N	Yes
333	Site 2	19-Oct-20	N	N	Yes
334	Site 2	19-Oct-20	N	N	Yes
335	Site 2	19-Oct-20	N	N	Yes
336	Site 2	19-Oct-20	N	N	Yes
337	Site 2	19-Oct-20	N	N	Yes
338	Site 2	19-Oct-20	N	N	Yes
339	Site 2	19-Oct-20	N	N	Yes
340	Site 2	19-Oct-20	N	N	Yes

341	Site 2	19-Oct-20	N	N	Yes
342	Site 2	19-Oct-20	N	N	Yes
343	Site 2	20-Oct-20	N	N	Yes
344	Site 2	20-Oct-20	N	N	Yes
345	Site 2	20-Oct-20	N	N	Yes
346	Site 2	20-Oct-20	N	N	Yes
347	Site 2	20-Oct-20	N	N	Yes
348	Site 2	20-Oct-20	N	N	Yes
349	Site 2	20-Oct-20	N	N	Yes
350	Site 2	20-Oct-20	N	N	Yes
351	Site 2	20-Oct-20	N	N	Yes
352	Site 2	20-Oct-20	N	N	Yes
353	Site 2	20-Oct-20	N	N	Yes
354	Site 2	20-Oct-20	N	N	Yes
355	Site 2	20-Oct-20	N	N	Yes
356	Site 2	20-Oct-20	N	N	Yes
357	Site 2	20-Oct-20	N	N	Yes
358	Site 2	20-Oct-20	N	N	Yes
359	Site 2	20-Oct-20	N	N	Yes
360	Site 2	20-Oct-20	N	N	Yes
361	Site 2	20-Oct-20	N	N	Yes
362	Site 2	20-Oct-20	N	N	Yes

Note: N=Negative, P=Positive

Results of positive samples:

Sample	Clinical site	Date of testing	Wondfo result	PCR result	Coincidence
1	Site 1	12-Oct-20	P	P	Yes
2	Site 1	12-Oct-20	P	P	Yes
3	Site 1	12-Oct-20	P	P	Yes
4	Site 1	12-Oct-20	P	P	Yes
5	Site 1	12-Oct-20	P	P	Yes
6	Site 1	12-Oct-20	P	P	Yes
7	Site 1	12-Oct-20	P	P	Yes
8	Site 1	12-Oct-20	P	P	Yes
9	Site 1	12-Oct-20	N	P	No
10	Site 1	12-Oct-20	P	P	Yes
11	Site 1	12-Oct-20	P	P	Yes
12	Site 1	12-Oct-20	P	P	Yes
13	Site 1	12-Oct-20	P	P	Yes
14	Site 1	12-Oct-20	P	P	Yes
15	Site 1	12-Oct-20	P	P	Yes
16	Site 1	12-Oct-20	P	P	Yes
17	Site 1	12-Oct-20	P	P	Yes

18	Site 1	12-Oct-20	P	P	Yes
19	Site 1	12-Oct-20	P	P	Yes
20	Site 1	12-Oct-20	P	P	Yes
21	Site 1	12-Oct-20	P	P	Yes
22	Site 1	12-Oct-20	P	P	Yes
23	Site 1	12-Oct-20	P	P	Yes
24	Site 1	12-Oct-20	P	P	Yes
25	Site 1	12-Oct-20	P	P	Yes
26	Site 1	12-Oct-20	N	P	No
27	Site 1	12-Oct-20	P	P	Yes
28	Site 1	12-Oct-20	P	P	Yes
29	Site 1	12-Oct-20	P	P	Yes
30	Site 1	12-Oct-20	P	P	Yes
31	Site 1	12-Oct-20	P	P	Yes
32	Site 1	12-Oct-20	P	P	Yes
33	Site 1	12-Oct-20	P	P	Yes
34	Site 1	12-Oct-20	P	P	Yes
35	Site 1	12-Oct-20	N	P	No
36	Site 1	12-Oct-20	P	P	Yes
37	Site 1	12-Oct-20	P	P	Yes
38	Site 1	12-Oct-20	P	P	Yes
39	Site 1	13-Oct-20	N	P	No
40	Site 1	13-Oct-20	P	P	Yes
41	Site 1	13-Oct-20	P	P	Yes
42	Site 1	13-Oct-20	P	P	Yes
43	Site 1	13-Oct-20	P	P	Yes
44	Site 1	13-Oct-20	P	P	Yes
45	Site 1	13-Oct-20	P	P	Yes
46	Site 1	13-Oct-20	P	P	Yes
47	Site 1	13-Oct-20	P	P	Yes
48	Site 1	13-Oct-20	N	P	No
49	Site 1	13-Oct-20	P	P	Yes
50	Site 1	13-Oct-20	P	P	Yes
51	Site 1	13-Oct-20	N	P	No
52	Site 1	13-Oct-20	P	P	Yes
53	Site 1	13-Oct-20	P	P	Yes
54	Site 1	13-Oct-20	P	P	Yes
55	Site 1	13-Oct-20	P	P	Yes
56	Site 1	13-Oct-20	P	P	Yes
57	Site 1	13-Oct-20	P	P	Yes
58	Site 1	13-Oct-20	P	P	Yes
59	Site 1	13-Oct-20	P	P	Yes
60	Site 1	13-Oct-20	P	P	Yes

61	Site 1	13-Oct-20	N	P	No
62	Site 1	13-Oct-20	P	P	Yes
63	Site 1	13-Oct-20	N	P	No
64	Site 1	13-Oct-20	P	P	Yes
65	Site 1	13-Oct-20	P	P	Yes
66	Site 1	13-Oct-20	P	P	Yes
67	Site 1	13-Oct-20	P	P	Yes
68	Site 1	13-Oct-20	P	P	Yes
69	Site 1	13-Oct-20	P	P	Yes
70	Site 1	13-Oct-20	P	P	Yes
71	Site 1	13-Oct-20	P	P	Yes
72	Site 1	14-Oct-20	P	P	Yes
73	Site 1	14-Oct-20	P	P	Yes
74	Site 1	14-Oct-20	P	P	Yes
75	Site 1	14-Oct-20	P	P	Yes
76	Site 1	14-Oct-20	P	P	Yes
77	Site 1	14-Oct-20	P	P	Yes
78	Site 1	14-Oct-20	P	P	Yes
79	Site 1	14-Oct-20	P	P	Yes
80	Site 1	14-Oct-20	P	P	Yes
81	Site 1	14-Oct-20	P	P	Yes
82	Site 1	14-Oct-20	P	P	Yes
83	Site 1	14-Oct-20	P	P	Yes
84	Site 1	14-Oct-20	P	P	Yes
85	Site 1	14-Oct-20	N	P	No
86	Site 1	14-Oct-20	P	P	Yes
87	Site 1	14-Oct-20	P	P	Yes
88	Site 1	14-Oct-20	P	P	Yes
89	Site 1	15-Oct-20	P	P	Yes
90	Site 1	15-Oct-20	P	P	Yes
91	Site 1	15-Oct-20	P	P	Yes
92	Site 1	15-Oct-20	P	P	Yes
93	Site 1	15-Oct-20	P	P	Yes
94	Site 1	15-Oct-20	P	P	Yes
95	Site 1	15-Oct-20	P	P	Yes
96	Site 1	15-Oct-20	P	P	Yes
97	Site 1	15-Oct-20	P	P	Yes
98	Site 1	15-Oct-20	P	P	Yes
99	Site 1	15-Oct-20	P	P	Yes
100	Site 1	15-Oct-20	P	P	Yes
101	Site 1	15-Oct-20	P	P	Yes
102	Site 1	15-Oct-20	P	P	Yes
103	Site 1	15-Oct-20	P	P	Yes

104	Site 1	15-Oct-20	P	P	Yes
105	Site 1	15-Oct-20	P	P	Yes
106	Site 1	15-Oct-20	P	P	Yes
107	Site 1	15-Oct-20	P	P	Yes
108	Site 1	15-Oct-20	P	P	Yes
109	Site 1	15-Oct-20	P	P	Yes
110	Site 1	15-Oct-20	P	P	Yes
111	Site 1	15-Oct-20	P	P	Yes
112	Site 1	15-Oct-20	P	P	Yes
113	Site 1	16-Oct-20	P	P	Yes
114	Site 1	16-Oct-20	P	P	Yes
115	Site 1	16-Oct-20	P	P	Yes
116	Site 1	16-Oct-20	P	P	Yes
117	Site 1	16-Oct-20	P	P	Yes
118	Site 1	16-Oct-20	P	P	Yes
119	Site 1	16-Oct-20	P	P	Yes
120	Site 1	16-Oct-20	P	P	Yes
121	Site 1	16-Oct-20	P	P	Yes
122	Site 1	16-Oct-20	P	P	Yes
123	Site 1	16-Oct-20	P	P	Yes
124	Site 1	16-Oct-20	P	P	Yes
125	Site 1	16-Oct-20	P	P	Yes
126	Site 1	16-Oct-20	P	P	Yes
127	Site 1	16-Oct-20	P	P	Yes
128	Site 1	16-Oct-20	P	P	Yes
129	Site 1	16-Oct-20	P	P	Yes
130	Site 1	16-Oct-20	N	P	No
131	Site 1	16-Oct-20	P	P	Yes
132	Site 1	16-Oct-20	P	P	Yes
133	Site 1	16-Oct-20	P	P	Yes
134	Site 1	16-Oct-20	P	P	Yes
135	Site 1	16-Oct-20	P	P	Yes
136	Site 1	16-Oct-20	P	P	Yes
137	Site 1	16-Oct-20	P	P	Yes
138	Site 1	16-Oct-20	P	P	Yes
139	Site 1	16-Oct-20	P	P	Yes
140	Site 1	16-Oct-20	P	P	Yes
141	Site 1	16-Oct-20	P	P	Yes
142	Site 1	16-Oct-20	P	P	Yes
143	Site 1	16-Oct-20	P	P	Yes
144	Site 1	16-Oct-20	P	P	Yes
145	Site 1	16-Oct-20	P	P	Yes
146	Site 1	16-Oct-20	P	P	Yes

147	Site 1	16-Oct-20	P	P	Yes
148	Site 1	16-Oct-20	P	P	Yes
149	Site 1	16-Oct-20	P	P	Yes
150	Site 1	16-Oct-20	P	P	Yes
151	Site 1	16-Oct-20	P	P	Yes
152	Site 1	16-Oct-20	P	P	Yes
153	Site 1	16-Oct-20	P	P	Yes
154	Site 1	19-Oct-20	P	P	Yes
155	Site 1	19-Oct-20	P	P	Yes
156	Site 1	19-Oct-20	P	P	Yes
157	Site 1	19-Oct-20	P	P	Yes
158	Site 1	19-Oct-20	P	P	Yes
159	Site 1	19-Oct-20	P	P	Yes
160	Site 1	19-Oct-20	P	P	Yes
161	Site 1	19-Oct-20	P	P	Yes
162	Site 1	19-Oct-20	P	P	Yes
163	Site 1	19-Oct-20	P	P	Yes
164	Site 1	19-Oct-20	P	P	Yes
165	Site 1	19-Oct-20	P	P	Yes
166	Site 1	19-Oct-20	P	P	Yes
167	Site 1	19-Oct-20	P	P	Yes
168	Site 1	19-Oct-20	P	P	Yes
169	Site 1	19-Oct-20	P	P	Yes
170	Site 1	19-Oct-20	P	P	Yes
171	Site 1	19-Oct-20	P	P	Yes
172	Site 1	19-Oct-20	P	P	Yes
173	Site 1	19-Oct-20	P	P	Yes
174	Site 1	19-Oct-20	P	P	Yes
175	Site 1	19-Oct-20	P	P	Yes
176	Site 1	19-Oct-20	P	P	Yes
177	Site 1	19-Oct-20	P	P	Yes
178	Site 1	19-Oct-20	P	P	Yes
179	Site 1	19-Oct-20	P	P	Yes
180	Site 1	19-Oct-20	P	P	Yes
181	Site 1	19-Oct-20	P	P	Yes
182	Site 1	19-Oct-20	P	P	Yes
183	Site 1	19-Oct-20	P	P	Yes
184	Site 1	19-Oct-20	P	P	Yes
185	Site 1	19-Oct-20	P	P	Yes
186	Site 1	19-Oct-20	P	P	Yes
187	Site 1	19-Oct-20	P	P	Yes
188	Site 1	19-Oct-20	N	P	No
189	Site 1	19-Oct-20	P	P	Yes

190	Site 1	19-Oct-20	P	P	Yes
191	Site 1	19-Oct-20	P	P	Yes
192	Site 1	19-Oct-20	P	P	Yes
193	Site 1	19-Oct-20	P	P	Yes
194	Site 1	19-Oct-20	P	P	Yes
195	Site 1	19-Oct-20	P	P	Yes
196	Site 1	19-Oct-20	P	P	Yes
197	Site 1	19-Oct-20	P	P	Yes
198	Site 1	19-Oct-20	P	P	Yes
199	Site 1	19-Oct-20	P	P	Yes
200	Site 1	19-Oct-20	P	P	Yes
201	Site 1	19-Oct-20	P	P	Yes
202	Site 1	19-Oct-20	P	P	Yes
203	Site 1	19-Oct-20	P	P	Yes
204	Site 1	19-Oct-20	P	P	Yes
205	Site 1	19-Oct-20	P	P	Yes
206	Site 1	19-Oct-20	P	P	Yes
207	Site 1	19-Oct-20	P	P	Yes
208	Site 1	19-Oct-20	P	P	Yes
209	Site 1	19-Oct-20	P	P	Yes
210	Site 1	19-Oct-20	P	P	Yes
211	Site 1	19-Oct-20	P	P	Yes
212	Site 1	19-Oct-20	P	P	Yes
213	Site 1	19-Oct-20	P	P	Yes
214	Site 1	19-Oct-20	P	P	Yes
215	Site 1	19-Oct-20	P	P	Yes
216	Site 1	19-Oct-20	P	P	Yes
217	Site 1	19-Oct-20	P	P	Yes
218	Site 1	19-Oct-20	P	P	Yes
219	Site 1	19-Oct-20	P	P	Yes
220	Site 1	19-Oct-20	P	P	Yes
221	Site 1	19-Oct-20	P	P	Yes
222	Site 1	19-Oct-20	P	P	Yes
223	Site 1	19-Oct-20	P	P	Yes
224	Site 1	19-Oct-20	P	P	Yes
225	Site 1	19-Oct-20	P	P	Yes
226	Site 1	19-Oct-20	P	P	Yes
227	Site 1	19-Oct-20	P	P	Yes
228	Site 1	19-Oct-20	P	P	Yes
229	Site 1	19-Oct-20	N	P	No
230	Site 1	19-Oct-20	P	P	Yes
231	Site 1	19-Oct-20	P	P	Yes
232	Site 1	19-Oct-20	P	P	Yes

233	Site 1	19-Oct-20	P	P	Yes
234	Site 1	19-Oct-20	P	P	Yes
235	Site 1	19-Oct-20	P	P	Yes
236	Site 1	19-Oct-20	P	P	Yes
237	Site 1	19-Oct-20	P	P	Yes
238	Site 1	19-Oct-20	P	P	Yes
239	Site 1	19-Oct-20	P	P	Yes
240	Site 1	19-Oct-20	P	P	Yes
241	Site 1	19-Oct-20	P	P	Yes
242	Site 1	19-Oct-20	P	P	Yes
243	Site 1	19-Oct-20	P	P	Yes
244	Site 1	19-Oct-20	P	P	Yes
245	Site 1	19-Oct-20	P	P	Yes
246	Site 1	19-Oct-20	P	P	Yes
247	Site 1	19-Oct-20	P	P	Yes
248	Site 1	19-Oct-20	P	P	Yes
249	Site 1	19-Oct-20	P	P	Yes
250	Site 1	19-Oct-20	P	P	Yes
251	Site 1	19-Oct-20	P	P	Yes
252	Site 1	19-Oct-20	P	P	Yes
253	Site 1	19-Oct-20	P	P	Yes
254	Site 1	19-Oct-20	P	P	Yes
255	Site 1	19-Oct-20	P	P	Yes
256	Site 1	19-Oct-20	P	P	Yes
257	Site 1	19-Oct-20	P	P	Yes
258	Site 1	19-Oct-20	P	P	Yes
259	Site 1	19-Oct-20	P	P	Yes
260	Site 1	19-Oct-20	P	P	Yes
261	Site 1	19-Oct-20	P	P	Yes
262	Site 1	19-Oct-20	P	P	Yes
263	Site 1	19-Oct-20	P	P	Yes
264	Site 1	19-Oct-20	P	P	Yes
265	Site 1	19-Oct-20	P	P	Yes
266	Site 1	19-Oct-20	P	P	Yes
267	Site 1	19-Oct-20	P	P	Yes
268	Site 1	19-Oct-20	P	P	Yes
269	Site 1	19-Oct-20	P	P	Yes
270	Site 1	19-Oct-20	P	P	Yes
271	Site 1	19-Oct-20	P	P	Yes
272	Site 1	19-Oct-20	P	P	Yes
273	Site 1	19-Oct-20	P	P	Yes
274	Site 1	19-Oct-20	P	P	Yes
275	Site 1	19-Oct-20	P	P	Yes

276	Site 1	19-Oct-20	P	P	Yes
277	Site 1	20-Oct-20	P	P	Yes
278	Site 1	20-Oct-20	P	P	Yes
279	Site 1	20-Oct-20	P	P	Yes
280	Site 1	20-Oct-20	P	P	Yes
281	Site 1	20-Oct-20	P	P	Yes
282	Site 1	20-Oct-20	P	P	Yes
283	Site 1	20-Oct-20	P	P	Yes
284	Site 1	20-Oct-20	P	P	Yes
285	Site 1	20-Oct-20	P	P	Yes
286	Site 1	20-Oct-20	P	P	Yes
287	Site 1	20-Oct-20	P	P	Yes
288	Site 1	20-Oct-20	P	P	Yes
289	Site 1	20-Oct-20	P	P	Yes
290	Site 1	20-Oct-20	P	P	Yes
291	Site 1	20-Oct-20	P	P	Yes
292	Site 1	20-Oct-20	P	P	Yes
293	Site 1	20-Oct-20	P	P	Yes
294	Site 1	20-Oct-20	P	P	Yes
295	Site 1	20-Oct-20	P	P	Yes
296	Site 1	20-Oct-20	P	P	Yes
297	Site 1	20-Oct-20	P	P	Yes
298	Site 1	20-Oct-20	P	P	Yes
299	Site 1	20-Oct-20	P	P	Yes
300	Site 1	20-Oct-20	P	P	Yes
301	Site 1	20-Oct-20	P	P	Yes
302	Site 1	20-Oct-20	P	P	Yes
303	Site 1	20-Oct-20	P	P	Yes
304	Site 1	20-Oct-20	P	P	Yes
305	Site 1	20-Oct-20	P	P	Yes
306	Site 2	12-Oct-20	P	P	Yes
307	Site 2	12-Oct-20	P	P	Yes
308	Site 2	12-Oct-20	P	P	Yes
309	Site 2	12-Oct-20	P	P	Yes
310	Site 2	12-Oct-20	P	P	Yes
311	Site 2	12-Oct-20	P	P	Yes
312	Site 2	12-Oct-20	P	P	Yes
313	Site 2	12-Oct-20	P	P	Yes
314	Site 2	12-Oct-20	P	P	Yes
315	Site 2	12-Oct-20	P	P	Yes
316	Site 2	12-Oct-20	P	P	Yes
317	Site 2	12-Oct-20	P	P	Yes
318	Site 2	12-Oct-20	P	P	Yes

319	Site 2	12-Oct-20	P	P	Yes
320	Site 2	12-Oct-20	P	P	Yes
321	Site 2	12-Oct-20	P	P	Yes
322	Site 2	12-Oct-20	P	P	Yes
323	Site 2	12-Oct-20	P	P	Yes
324	Site 2	12-Oct-20	P	P	Yes
325	Site 2	12-Oct-20	P	P	Yes
326	Site 2	12-Oct-20	P	P	Yes
327	Site 2	12-Oct-20	P	P	Yes
328	Site 2	12-Oct-20	P	P	Yes
329	Site 2	12-Oct-20	P	P	Yes
330	Site 2	12-Oct-20	P	P	Yes
331	Site 2	12-Oct-20	P	P	Yes
332	Site 2	13-Oct-20	P	P	Yes
333	Site 2	13-Oct-20	P	P	Yes
334	Site 2	13-Oct-20	P	P	Yes
335	Site 2	13-Oct-20	N	P	No
336	Site 2	13-Oct-20	P	P	Yes
337	Site 2	13-Oct-20	P	P	Yes
338	Site 2	13-Oct-20	P	P	Yes
339	Site 2	13-Oct-20	P	P	Yes
340	Site 2	13-Oct-20	P	P	Yes
341	Site 2	13-Oct-20	P	P	Yes
342	Site 2	13-Oct-20	P	P	Yes
343	Site 2	13-Oct-20	P	P	Yes
344	Site 2	13-Oct-20	P	P	Yes
345	Site 2	13-Oct-20	P	P	Yes
346	Site 2	13-Oct-20	P	P	Yes
347	Site 2	13-Oct-20	N	P	No
348	Site 2	13-Oct-20	P	P	Yes
349	Site 2	13-Oct-20	P	P	Yes
350	Site 2	13-Oct-20	P	P	Yes
351	Site 2	13-Oct-20	P	P	Yes
352	Site 2	14-Oct-20	P	P	Yes
353	Site 2	14-Oct-20	P	P	Yes
354	Site 2	14-Oct-20	P	P	Yes
355	Site 2	14-Oct-20	P	P	Yes
356	Site 2	14-Oct-20	P	P	Yes
357	Site 2	14-Oct-20	P	P	Yes
358	Site 2	14-Oct-20	P	P	Yes
359	Site 2	14-Oct-20	P	P	Yes
360	Site 2	14-Oct-20	P	P	Yes
361	Site 2	14-Oct-20	P	P	Yes

362	Site 2	14-Oct-20	P	P	Yes
363	Site 2	14-Oct-20	P	P	Yes
364	Site 2	14-Oct-20	P	P	Yes
365	Site 2	14-Oct-20	P	P	Yes
366	Site 2	14-Oct-20	P	P	Yes
367	Site 2	15-Oct-20	P	P	Yes
368	Site 2	15-Oct-20	P	P	Yes
369	Site 2	15-Oct-20	P	P	Yes
370	Site 2	15-Oct-20	P	P	Yes
371	Site 2	15-Oct-20	P	P	Yes
372	Site 2	15-Oct-20	P	P	Yes
373	Site 2	15-Oct-20	P	P	Yes
374	Site 2	15-Oct-20	P	P	Yes
375	Site 2	15-Oct-20	P	P	Yes
376	Site 2	15-Oct-20	P	P	Yes
377	Site 2	15-Oct-20	P	P	Yes
378	Site 2	15-Oct-20	P	P	Yes
379	Site 2	15-Oct-20	P	P	Yes
380	Site 2	15-Oct-20	P	P	Yes
381	Site 2	15-Oct-20	P	P	Yes
382	Site 2	15-Oct-20	N	P	No
383	Site 2	15-Oct-20	P	P	Yes
384	Site 2	15-Oct-20	P	P	Yes
385	Site 2	15-Oct-20	P	P	Yes
386	Site 2	15-Oct-20	P	P	Yes
387	Site 2	15-Oct-20	P	P	Yes
388	Site 2	15-Oct-20	P	P	Yes
389	Site 2	15-Oct-20	P	P	Yes
390	Site 2	15-Oct-20	P	P	Yes
391	Site 2	16-Oct-20	P	P	Yes
392	Site 2	16-Oct-20	P	P	Yes
393	Site 2	16-Oct-20	P	P	Yes
394	Site 2	16-Oct-20	P	P	Yes
395	Site 2	16-Oct-20	P	P	Yes
396	Site 2	16-Oct-20	P	P	Yes
397	Site 2	16-Oct-20	P	P	Yes
398	Site 2	16-Oct-20	P	P	Yes
399	Site 2	16-Oct-20	P	P	Yes
400	Site 2	16-Oct-20	P	P	Yes
401	Site 2	16-Oct-20	P	P	Yes
402	Site 2	16-Oct-20	P	P	Yes
403	Site 2	16-Oct-20	P	P	Yes
404	Site 2	16-Oct-20	P	P	Yes

405	Site 2	16-Oct-20	P	P	Yes
406	Site 2	16-Oct-20	P	P	Yes
407	Site 2	16-Oct-20	P	P	Yes
408	Site 2	16-Oct-20	P	P	Yes
409	Site 2	16-Oct-20	P	P	Yes
410	Site 2	16-Oct-20	P	P	Yes
411	Site 2	16-Oct-20	P	P	Yes
412	Site 2	16-Oct-20	P	P	Yes
413	Site 2	16-Oct-20	P	P	Yes
414	Site 2	16-Oct-20	P	P	Yes
415	Site 2	16-Oct-20	P	P	Yes
416	Site 2	16-Oct-20	P	P	Yes
417	Site 2	16-Oct-20	P	P	Yes
418	Site 2	16-Oct-20	P	P	Yes
419	Site 2	16-Oct-20	P	P	Yes
420	Site 2	16-Oct-20	P	P	Yes
421	Site 2	16-Oct-20	P	P	Yes
422	Site 2	16-Oct-20	P	P	Yes
423	Site 2	16-Oct-20	N	P	No
424	Site 2	16-Oct-20	P	P	Yes
425	Site 2	16-Oct-20	P	P	Yes
426	Site 2	16-Oct-20	N	P	No
427	Site 2	16-Oct-20	P	P	Yes
428	Site 2	16-Oct-20	P	P	Yes
429	Site 2	16-Oct-20	P	P	Yes
430	Site 2	16-Oct-20	P	P	Yes
431	Site 2	16-Oct-20	P	P	Yes
432	Site 2	16-Oct-20	P	P	Yes
433	Site 2	16-Oct-20	P	P	Yes
434	Site 2	16-Oct-20	P	P	Yes
435	Site 2	16-Oct-20	P	P	Yes
436	Site 2	16-Oct-20	P	P	Yes
437	Site 2	16-Oct-20	P	P	Yes
438	Site 2	16-Oct-20	P	P	Yes
439	Site 2	16-Oct-20	P	P	Yes
440	Site 2	16-Oct-20	P	P	Yes
441	Site 2	16-Oct-20	P	P	Yes
442	Site 2	16-Oct-20	P	P	Yes
443	Site 2	16-Oct-20	P	P	Yes
444	Site 2	16-Oct-20	P	P	Yes
445	Site 2	16-Oct-20	P	P	Yes
446	Site 2	16-Oct-20	P	P	Yes
447	Site 2	19-Oct-20	P	P	Yes

448	Site 2	19-Oct-20	P	P	Yes
449	Site 2	19-Oct-20	P	P	Yes
450	Site 2	19-Oct-20	P	P	Yes
451	Site 2	19-Oct-20	P	P	Yes
452	Site 2	19-Oct-20	P	P	Yes
453	Site 2	19-Oct-20	P	P	Yes
454	Site 2	19-Oct-20	P	P	Yes
455	Site 2	19-Oct-20	P	P	Yes
456	Site 2	19-Oct-20	P	P	Yes
457	Site 2	19-Oct-20	P	P	Yes
458	Site 2	19-Oct-20	P	P	Yes
459	Site 2	19-Oct-20	P	P	Yes
460	Site 2	19-Oct-20	P	P	Yes
461	Site 2	19-Oct-20	N	P	No
462	Site 2	19-Oct-20	P	P	Yes
463	Site 2	19-Oct-20	P	P	Yes
464	Site 2	19-Oct-20	P	P	Yes
465	Site 2	19-Oct-20	P	P	Yes
466	Site 2	20-Oct-20	P	P	Yes
467	Site 2	20-Oct-20	P	P	Yes
468	Site 2	20-Oct-20	P	P	Yes
469	Site 2	20-Oct-20	P	P	Yes
470	Site 2	20-Oct-20	P	P	Yes
471	Site 2	20-Oct-20	P	P	Yes
472	Site 2	20-Oct-20	P	P	Yes
473	Site 2	20-Oct-20	P	P	Yes
474	Site 2	20-Oct-20	P	P	Yes
475	Site 2	20-Oct-20	P	P	Yes
476	Site 2	20-Oct-20	P	P	Yes
477	Site 2	20-Oct-20	P	P	Yes
478	Site 2	20-Oct-20	P	P	Yes
479	Site 2	20-Oct-20	P	P	Yes
480	Site 2	20-Oct-20	P	P	Yes
481	Site 2	20-Oct-20	P	P	Yes
482	Site 2	20-Oct-20	P	P	Yes
483	Site 2	20-Oct-20	P	P	Yes
484	Site 2	20-Oct-20	P	P	Yes
485	Site 2	20-Oct-20	P	P	Yes
486	Site 2	20-Oct-20	P	P	Yes
487	Site 2	20-Oct-20	P	P	Yes
488	Site 2	20-Oct-20	P	P	Yes
489	Site 2	20-Oct-20	P	P	Yes
490	Site 2	20-Oct-20	P	P	Yes

491	Site 2	20-Oct-20	P	P	Yes
492	Site 2	20-Oct-20	N	P	No
493	Site 2	20-Oct-20	P	P	Yes
494	Site 2	20-Oct-20	P	P	Yes
495	Site 2	20-Oct-20	P	P	Yes
496	Site 2	20-Oct-20	P	P	Yes
497	Site 2	20-Oct-20	P	P	Yes

Note: N=Negative, P=Positive

Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Luogang District,
510663 Guangzhou, P.R.China
TEL: 0086-20-3229-6083 FAX: 0086-20-3229-6062
E-mail: sales@wondfo.com.cn
Website: http://www.wondfo.com.cn

MATERIAL SAFETY DATA SHEETS

Catalog Number:	W196
Product Name:	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)

This document contains MSDS for the following kit components:

Pages	**Component Name:**
2-6	Detection Buffer

Note:
Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) is a kit and does not require an MSDS.

Material Safety Data Sheet

according to 1907/2006/EC, Article 31
Version: Jul. 18, 2020

1. Identification of Substance:

Product Name: Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) detection buffer
Application of the Substance / the Preparation: Component of Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) (catalog # W196). For use in the qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal swab or oropharyngeal swab specimen. For *in vitro* diagnostic use only. For professional use only.

Supplier:
Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City,
Luogang District,
510663 Guangzhou, P.R.China
Tel: 0086-20-3229-6083
Emergency Information: sales@wondfo.com.cn

2. 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.

3. Composition/Information on Ingredients

Chemical Characterization

Description:
In vitro diagnostic reagent. Aqueous preparation. The buffer contains:
Per 1000mL buffer containing
0.1M Tris-Hcl
0.5% Tween-20
8.5g NaCl
0.02% proclin 300 as preservative

Product Use: *in vitro* diagnostic use only

Dangerous Components:
The preparation does not contain reportable quantities of hazardous components.

4. First Aid Measure

General Information:
If signs of infection occur, seek medical attention.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

Inhalation:
If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:
Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:
In case of contact, immediately flush skin with cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:
In case of ingestion, please gargle, vomiting is forbidden. Contact a poison control center or physician for instructions if feel uncomfortable.

5. Fire-fighting Measures

Flammable Properties:
Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:
Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:
Unknown.

Specific Hazards Arising from the Chemical:
When heated to decomposition, may product carbon oxides, nitrogen oxides(NOx), sulfur oxides, hydrogen chloride gas.

Standard Protective Equipment and Precautions for Firefighters:
Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental Release Measures

Personal Precautions:
Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

This preparation contains a small amount of proclin 300 which is toxic to aquatic life. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and Materials for Containment and Clean-Up:
Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

Reference to other sections
For disposal see section 13.

7. Handling and Storage

Handling:
Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:
Store at 2℃～30℃. See Section 10.

8. Exposure Controls/Personal Protection

Components with Limit Values that Require Monitoring at the Workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

Additional information: The lists that were valid during the compilation were used as basis.

Personal Protective Equipment (PPE):

General Protective and Hygienic Measures:
Adhere to good laboratory practices (GLP).
Wash hands during breaks and at the end of the work.

Breathing Equipment:
Not necessary, if room is well-ventilated.
Take precautions, if chemical concentrations exceed the exposure limits (if any) listed above.

Protection of Hands:
The gloves serve to protect the user against splashes. For safety reasons they should be changed immediately after wetting.
Since the product is in fact a preparation out of several substances, no specific information can be given on the permeation breakthrough time. The choice of suitable gloves depends not only on the material, but also on other quality features and must, therefore, be checked with the respective manufacturer. As far as we know, disposable gloves, among other things out of nitriles, are suitable. Nevertheless, this recommendation is not intended to replace a suitability test, which is essential and must be carried out under the respective conditions of use.

Eye Protection: Safety glasses recommended during refilling.

9. Physical and Chemical Properties

Appearance:	Clear, colorless liquid	pH:	8.0 (approximate)
Odor:	Not available	Solubility:	Water-soluble
Specific Gravity:	Not available	Vapor Pressure:	Not available
Boiling Point:	Not available	Partition Coefficient (n-octanol/water):	Not available
Melting Point:	Not available	Vapor Density:	Not available
Freezing Point:	Not available	Chemical Family:	Alkaline solution
Flammability/Explosivity Limits in Air, Lower:		Not available	
Flammability/Explosivity Limits in Air, Upper:		Not available	
Auto-Ignition Temperature:		Not available	
Flash Point:		Not available	

10. Stability and Reactivity

Chemical Stability: Stable under ordinary conditions of use and storage. See Section 7.
Material to be Avoid: No data about it.
Hazardous Reaction: No data about it.
Hazardous Decomposition Products: When heated to decomposition, may product carbon oxides, nitrogen oxides (NOx), sulfur oxides, hydrogen chloride gas. See section 5.

11. Toxicological Information

Acute Toxicity: Quantitative data on the toxic effects of this product is not available.
Primary Irritant Effect:
· **After Skin Contact:** No irritating effects anticipated.
· **After Eye Contact:** No irritating effects anticipated.
· **After Ingestion:** Possible systemic effects following ingestion of substantial quantities: headache, dizziness, nausea, vomiting, CNS disorders, drop in blood pressure, cardiovascular failure, collapse.
· **Sensitization:** No sensitizing effect known.

12. Ecological Information

· **General Notes:** Generally not hazardous for water.

13. Disposal Considerations

Product: buffer solution

General Notes:
In general laboratory waste is under the special supervision of the authorities. Refer to applicable

local regulations.

European Waste Catalogue:
Please consult the responsible regulatory body for the assignment of disposal codes according to European Waste Catalogue.

Following Waste Disposal Key Number Are Possible:
18 01 07 chemicals other than those mentioned in 18 01 06.

Packagings:
Disposal must be made in accordance with the local waste management regulations.
Contaminated packaging must be disposed of in the same manner as the product.
Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

14. Transport Information

Land Transport ADR/RID (Cross-Border)

- ADR/RID-GGVS/E Class: -
- Remarks: not restricted
- IMDG Class: -
- Marine pollutant: No

Air Transport ICAO-TI and IATA-DGR:

- ICAO/IATA Class: -
- Remarks: not restricted

15. Regulatory Information

Designation according to EC Guidelines:
No marking required.

Water Hazard Class (Germany): WGK 1 – slightly hazardous for water.

16. Other Information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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

Product Service

Certificate

No. Q5 058008 0025 Rev. 01

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:

tuv-sud.com/ps-cert

Scope of Certificate: Design and Development, 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 Tests, Fluorescence Immunoassay Systems, Blood Glucose Monitoring Systems, Control Materials for Tumor Markers, Biochemical Reagents and Instruments

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.: SH1914118

Valid from: 2020-02-10
Valid until: 2021-01-31

Date, 2020-02-10

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

A4 / 07.17

对外贸易经营者备案登记表

备案登记表编号：01559977　　进出口企业代码：4401618640472

经营者中文名称	广州万孚生物技术股份有限公司		
经营者英文名称	GUANGZHOU WONDFO BIOTECH.CO.LTD.		
组织机构代码	618640472	经营者类型 （由备案登记机关填写）	私营有限责任公司
住　所	广州市萝岗区科学城荔枝山路8号		
经营场所（中文）	广州市萝岗区科学城荔枝山路8号		
经营场所（英文）	No.8 Lizhishan Road,Scientific City,Luogang District,Guangzhou 510663		
联系电话	020-32299999	联系传真	020-32296063
邮政编码	510663	电子邮箱	XZB@WONDFO.COM.CN
工商登记注册日期	1992-11-13	工商登记注册号	440101000008134

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	李文美	有效证件号	220104196210271511
注册资金	陆仟陆佰万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人/个体工商负责人姓名		有效证件号	
企业资产/个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关（签章）

2012 年 06 月 15 日

仅供备案使用

本对外贸易经营者作如下保证：

一、遵守《中华人民共和国对外贸易法》及其配套法规、规章。

二、遵守与进出口贸易相关的海关、外汇、税务、检验检疫、环保、知识产权等中华人民共和国其他法律、法规、规章。

三、遵守中华人民共和国关于核、生物、化学、导弹等各类敏感物项和技术出口管制法规以及其他相关法律、法规、规章，不从事任何危害国家安全和社会公共利益的活动。

四、不伪造、变造、涂改、出租、出借、转让、出卖《对外贸易经营者备案登记表》。

五、在备案登记表中所填写的信息是完整的、准确的、真实的；所提交的所有材料是完整的、准确的、合法的。

六、《对外贸易经营者备案登记表》上填写的任何事项发生变化之日起，30 日内到原备案登记机关办理《对外贸易经营者备案登记表》的变更手续。

以上如有违反，将承担一切法律责任。

对外贸易经营者签字、盖章

2012年 6月 15日

注：1、备案登记表中“组织机构代码”一栏，由企业、组织和取得组织机构代码的个体工商户填写。

2、依法办理工商登记的外国（地区）企业，在经营活动中，承担有限 / 无限责任。依法办理工商登记的个体工商户（独资经营者），在经营活动中，承担无限责任。

3、工商登记营业执照中，如经营范围不包括进口商品的分销业务，备案登记机关应在备注栏中注明“无进口商品分销业务”。

1702526

医疗器械经营许可证

许可证编号：粤穗食药监械经营许 20150015 号

企业名称：广州万孚生物技术股份有限公司　　法定代表人：王继华

经营方式：批发　　企业负责人：李文美

住　　所：广州市萝岗区科学城荔枝山路 8 号　　经营范围：Ⅲ类：6821 医用电子仪器设备（6821-1、6821-2、6821-3 除外）、6822 医用光学器具、仪器及内窥镜设备、6823 医用超声仪器及有关设备、6825 医用高频仪器设备、6826 物理治疗及康复设备、6830 医用 X 射线设备、6840 临床检验分析仪器、6854 手术室、急救室、诊疗室设备及器具、6870 软件；体外诊断试剂（特殊管理诊断试剂除外）**

经营场所：广州市萝岗区科学城荔枝山路 8 号

库房地址：广州市开发区崖鹰石路 18 号（4）栋 1 层；广州科学城崖鹰石路 25 号康盛药业新建厂房 A3 六楼　　发证部门：广东省食品药品监督管理局

有效期限：至 2020 年 01 月 26 日　　发证日期：2017 年 08 月 02日

国家食品药品监督管理总局制

1702526

医疗器械经营许可证

许可证编号：粤穗食药监械经营许 20150015 号

企业名称：广州万孚生物技术股份有限公司　　法定代表人：王继华

经营方式：批发　　企业负责人：李文美

住　　所：广州市萝岗区科学城荔枝山路 8 号　　经营范围：Ⅲ类：6821 医用电子仪器设备（6821-1、6821-2、6821-3 除外）、6822 医用光学器具、仪器及内窥镜设备、6823 医用超声仪器及有关设备、6825 医用高频仪器设备、6826 物理治疗及康复设备、6830 医用 X 射线设备、6840 临床检验分析仪器、6854 手术室、急救室、诊疗室设备及器具、6870 软件；体外诊断试剂（特殊管理诊断试剂除外）**

经营场所：广州市萝岗区科学城荔枝山路 8 号

库房地址：广州市开发区崖鹰石路 18 号（4）栋 1 层；广州科学城崖鹰石路 25 号康盛药业新建厂房 A3 六楼　　发证部门：广东省食品药品监督管理局

有效期限：至 2020 年 01 月 26 日　　发证日期：2017 年 08 月 02日

仅供备案使用

国家食品药品监督管理总局制

医疗器械生产许可证

许可证编号：粤食药监械生产许20030645号

企业名称：广州万孚生物技术股份有限公司

生产地址：广州市萝岗区科学城荔枝山路8号

法定代表人：王继华

生产范围：见医疗器械生产产品登记表

企业负责人：李文美

住　　所：广州市萝岗区科学城荔枝山路8号

发证部门：广东省药品监督管理局

有效期限：至 2022 **年** 05 **月** 11 **日**

发证日期： 2019 **年** 11 **月** 19 **日**

国家食品药品监督管理总局制

编号：S0112018007784

统一社会信用代码

91440101618640472W

营业执照

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

名　　称 广州万孚生物技术股份有限公司

类　　型 股份有限公司(上市、自然人投资或控股)

法定代表人 王继华

经营范围 批发业（具体经营项目请登录广州市商事主体信息公示平台查询，网址：http://cri.gz.gov.cn/。依法须经批准的项目，经相关部门批准后方可开展经营活动。）

注册资本 叁亿肆仟贰佰陆拾玖万叁仟壹佰伍拾叁元（人民币）

成立日期 1992年11月13日

营业期限 1992年11月13日 至 长期

住　　所 广州市萝岗区科学城荔枝山路8号

登记机关 广州市市场监督管理局

2019 年 11 月 27 日

仅供备案使用

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

国家市场监督管理总局监制