WHO Emergency Use Assessment SARS-CoV-2 IVDs
PUBLIC REPORT

Product: Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)
Manufacturer: Guangzhou Wondfo Biotech Co., Ltd
EUL Number: EUL 0676-004-00
Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: desk-top review of the manufacturer's Quality Management System documentation and specific manufacturing documents.
- Product Dossier Review: assessment of the documentary evidence of safety and performance. This evaluation of limited scope is to verify critical analytical and performance characteristics.

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) with product codes W634P0013, W634P0014, W634P0015, rest of world regulatory version manufactured by Guangzhou Wondfo Biotech Co., Ltd, No. 8 Lizhishan Road, Science City, Luogang District, 510663 Guangzhou, China, was listed as eligible for WHO procurement on 18 July 2022.

Intended use

According to the claim of intended use from Guangzhou Wondfo Biotech Co., Ltd, "*Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of novel coronavirus antigen extracted from the nasal swab specimen collected from the individuals who are suspected of novel coronavirus infection, with or without symptoms. The test is to be used as an aid in the diagnosis of coronavirus disease (COVID-19), which is caused by novel coronavirus. Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is for professional use only. The test may be used in any laboratory and non-laboratory settings that meet the requirements specified in the instructions*

for use and local regulation. The test provides preliminary test results. Negative results cannot exclude novel coronavirus infection and they cannot be used as the sole basis for treatment or other management decision. For in vitro diagnostic use only. ”

Specimen type that was validated: Nasal swab specimens.

Assay description

According to the claim of assay description from Guangzhou Wondfo Biotech Co., Ltd, “*Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is based on the principle of Immunochromatography, using colloidal gold as the label for detection of novel coronavirus antigen extracted from the nasal swab specimen. When the extracted specimen is added into the test device, the specimen is absorbed into the device by capillary action, reacts with the novel coronavirus antibody-dye conjugate and flows across the precoated membrane.*

When the novel coronavirus antigen level in the specimen is at or above the target cutoff (the detection limit of the test), it will react with the antibody labeled with colloidal gold to form a complex. Through capillary action, the reaction complex moves forward along the nitrocellulose membrane to the detection region (T), where it reacts with the precoated antibodies on the nitrocellulose membrane to form an antibody-antigen-antibody complex, and this produces a colored test band that indicates a positive result. When the novel coronavirus antigen level in the specimen is zero or below the target cutoff, there is no a visible colored band in the detection region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored band will appear at the control region (C) if the test has been performed properly.”

Test kit contents

Components / **Catalog No.**	**W634P0013**	**W634P0014**	**W634P0015**
Sealed Pouches* (pcs)	20	100	20
Extraction Buffer (6mL/vial)	2	10	2
Sample Extraction Tube (pcs)	20	100	20
Drippers (pcs)	20	100	20
Nasal Swab (pcs)	20	100	20
Positive Control Swab (pcs)	\	1	1
Negative Control Swab (pcs)	\	1	1
IFU (pcs)	1	1	1

Note: **Each sealed pouch contains: 1 Test Cassette and 1 Desiccant Pouch*

Items required but not provided

1. Timer
2. Test tube rack
3. Personal protective equipment, such as protective gloves, medical mask, goggles and lab coat.
4. Appropriate biohazard waste container and disinfectants.

Storage
The test kit should be stored at 2-30 °C.

Shelf-life upon manufacture
Nine months (real-time stability studies are ongoing)

Warnings/limitations
Please refer to the attached instructions of use (IFU).

Product dossier assessment

Guangzhou Wondfo Biotech Co., Ltd submitted a product dossier for the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen (PQDx_0347)"*. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and an external assessor appointed by WHO.

Post listing Commitments for EUL

As a requirement for listing, the manufacturer is required to:

1. When available, assess the traceability of the materials used to validate the product with the WHO International Standard for SARS-CoV-2 antigen and provide the report to WHO.
2. Estimate the limit of detection (LoD) of the product with the WHO International Standard for SARS-CoV-2 antigen when available and provide the report to WHO within one month of completion of the study.
3. Partake in an independent performance evaluation conducted by a laboratory commissioned by WHO. Any such performance evaluation testing will be performed using the protocol and technical criteria established by WHO.
4. Provide evidence supporting the equivalence of inactivated virus samples with samples containing the live virus, per PQDx_347 requirements.

5. Provide a study protocol and report characterizing the inactivated virus stocks by PCR to be consistent with the PQDx_347 requirements, and the stock concentration will be given in copies/mL.
6. Provide clinical evidence supporting the required proportion of samples collected at different times post-onset symptoms, consistent with PQDx_347 requirements. Additionally, Wondfo commits to providing the clinical protocol/reports of the clinical studies and the claimed performance in IFU to be adjusted accordingly.
7. Provide a revised IFU including the in-use (after opened) stability claim for the extraction buffer to include the claim supported by the conclusion presented in the respective stability study report.
8. Provide a revised IFU, which will include information about enrolled subjects in the clinical performance to match the information provided in the trial design outlined in section 4 of the clinical studies.

Risk-benefit assessment conclusion is acceptable.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Guangzhou Wondfo Biotech Co., Ltd was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff and external technical experts (assessors), it was established that sufficient information was provided by Guangzhou Wondfo Biotech Co., Ltd to fulfil the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen(PQDx_ 347)"*.

The quality management documentation assessment conclusion is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods, and processes is a critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-prequalification activities are required to maintain the prequalification status:

1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic" (document number PQDx_121*); and
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics* " (ISBN 978-92-4-001531-9).

Guangzhou Wondfo Biotech Co., Ltd is also required to report complaints related to the product. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality, and performance monitoring activities are in place, which are in accordance with WHO guidance "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics."*[1]

Scope and duration of procurement eligibility

The Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) with product codes W634P0013, W634P0014, and W634P0015, manufactured by Guangzhou Wondfo Biotech Co., Ltd, is considered eligible for WHO procurement for 12 months from the day of listing. The assay may detect the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, Guangzhou Wondfo Biotech Co., Ltd must engage in post-market surveillance activities to ensure that the product meets safety, quality, and performance requirements, Guangzhou Wondfo Biotech Co., Ltd must notify WHO of any complaints, including adverse events related to the use of the product, within 7 days and any changes made to the product.

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

[1] https://www.who.int/publications/i/item/9789240015319

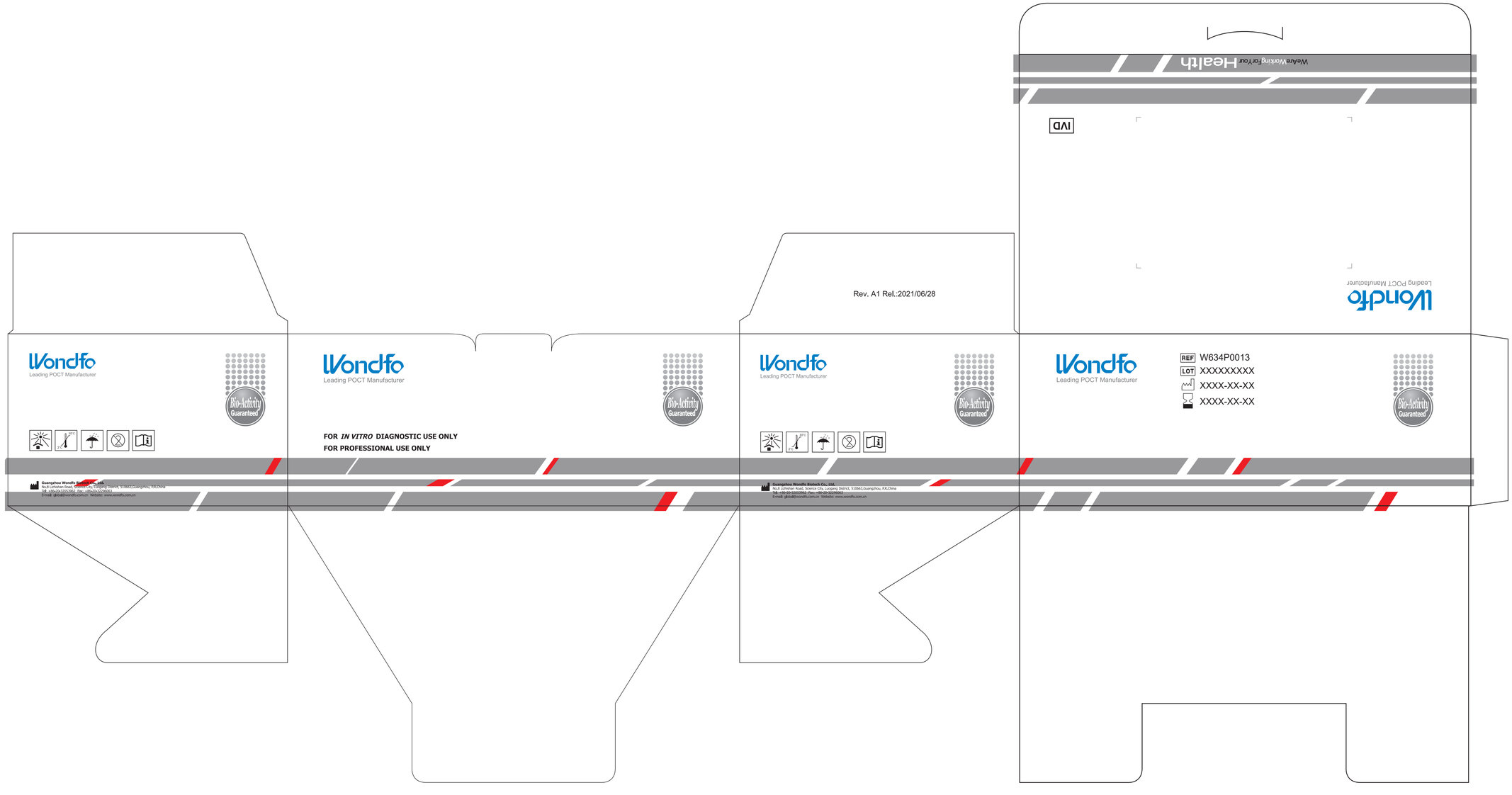
Labelling

1. **Labels**
2. **Instructions for use**

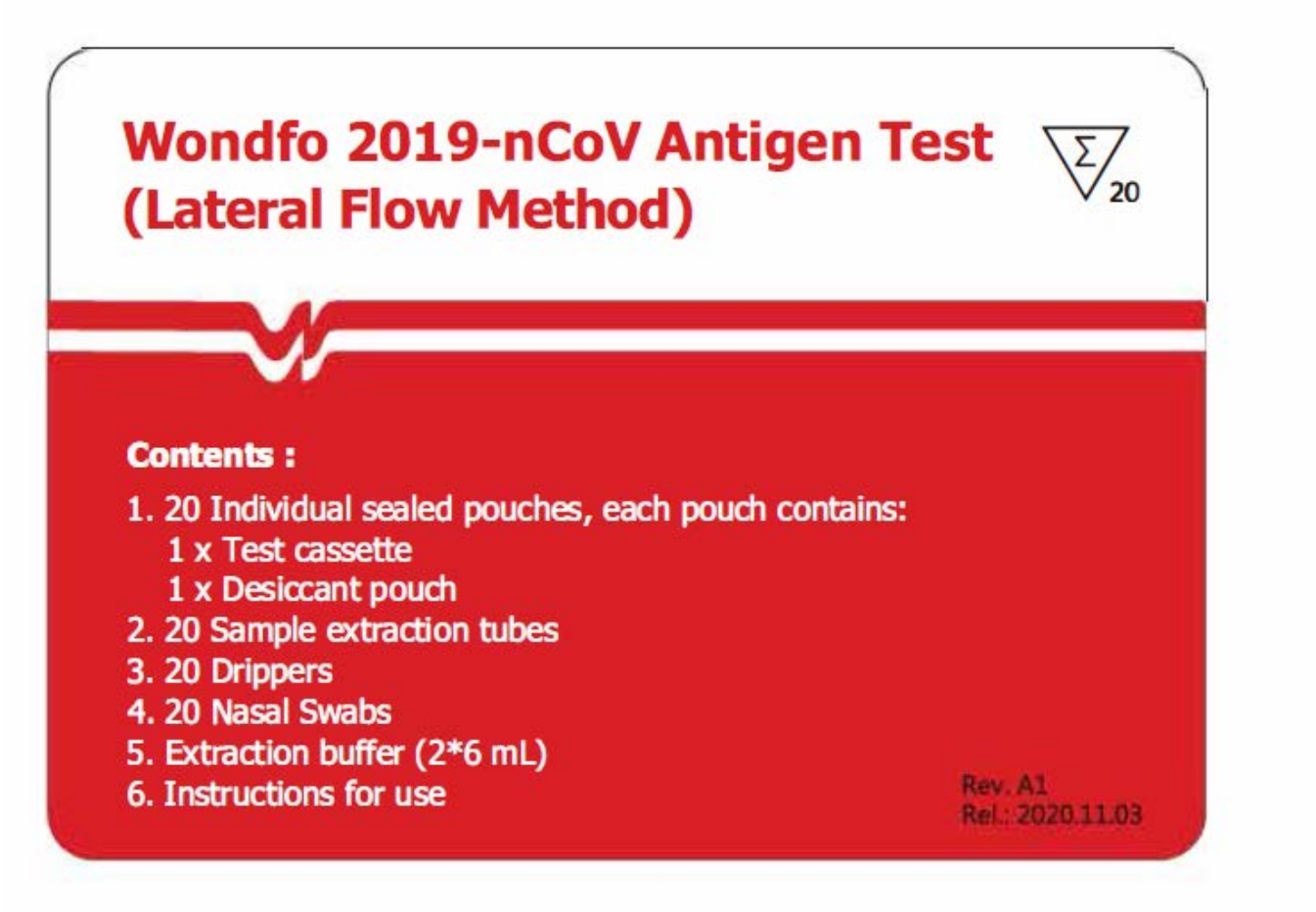
1.0 Labels

1.1 Product code W634P0013 (20 T/kit)

1.1.1. Kit box design


Wondfo
Leading POCT Manufacturer
Bio-Activity Guaranteed
FOR IN VITRO DIAGNOSTIC USE ONLY
FOR PROFESSIONAL USE ONLY
Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lihshan Road, Science City, Luogang District, 510663,Guangzhou, P.R.China
Tel: +86-20-32053963 Fax: +86-20-32296053
E-mail: global@wondfo.com.cn Website: www.wondfo.com.cn
Rev. A1 Rel.:2021/06/28
IVD
We Are Working For You Health
Wondfo
Leading POCT Manufacturer
REF W634P0013
LOT XXXXXXXXX
XXXX-XX-XX
XXXX-XX-XX

1.1.2 kit box label



1.1.3 Test cassette pouch

18mm

Wondfo
Leading POCT Manufacturer

Σ 1

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

LOT XXXXXXXXX
REF W634P0013

XXXX-XX-XX
XXXX-XX-XX

Rev. A2 Rel.: 2021.03.03

FOR *IN VITRO* DIAGNOSTIC USE ONLY

Wondfo

Guangzhou Wondfo Biotech Co., Ltd.
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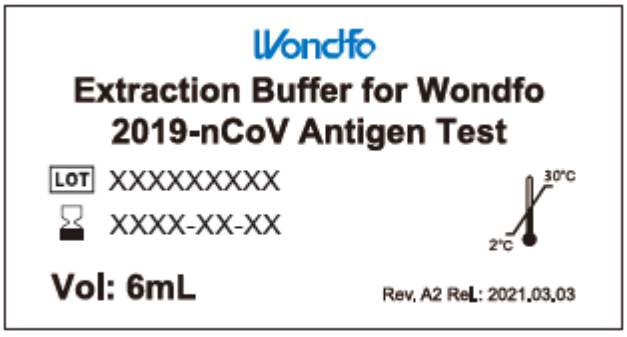
Tel: +86-20-32053962 Fax: +86-20-32296063
E-mail: global@wondfo.com.cn Website: www.wondfo.com.cn

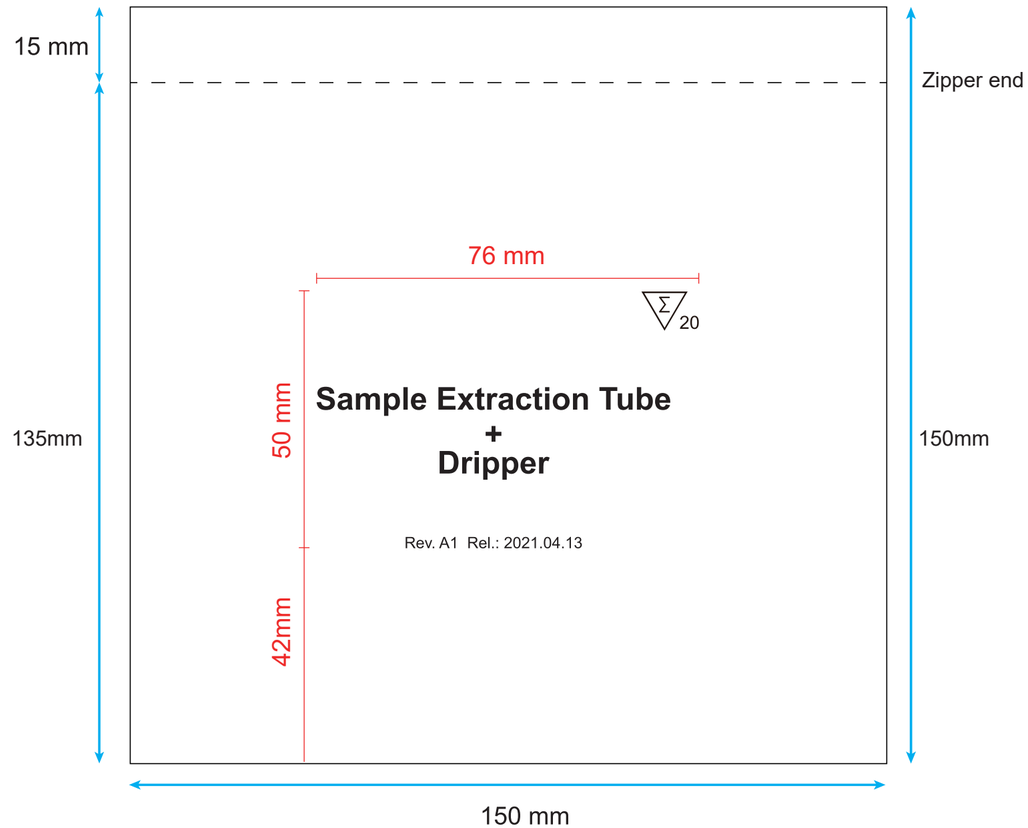
1.1.4 Round sticker

1.1.5 Extraction buffer label

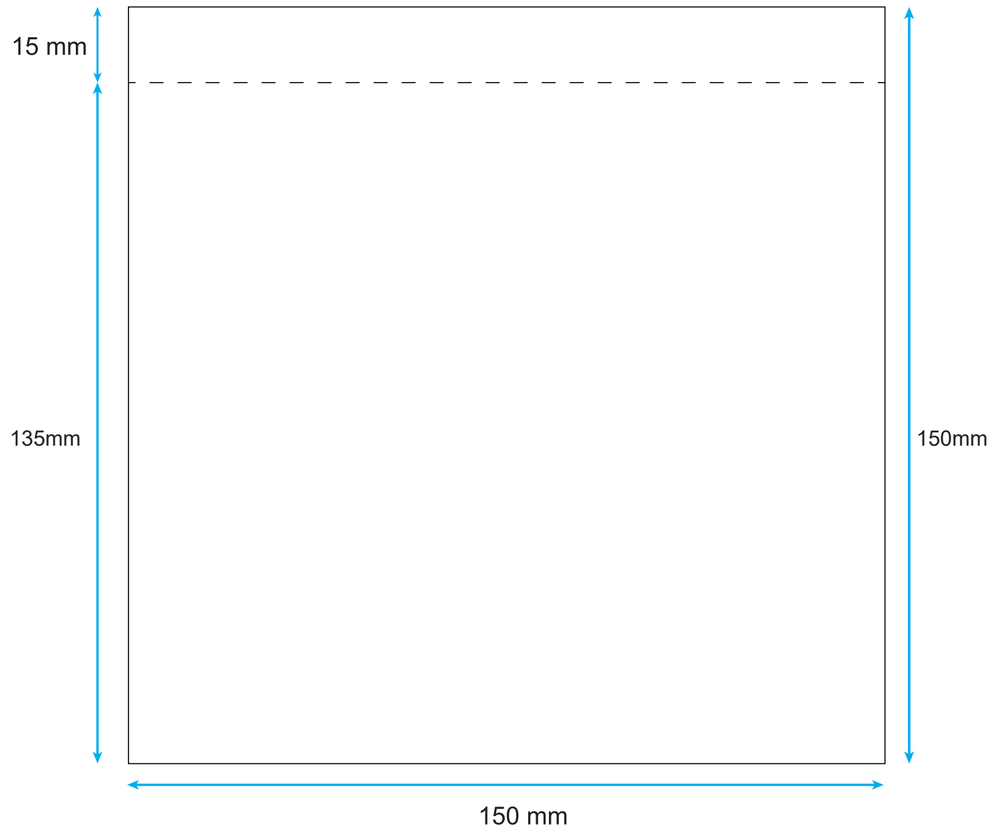


1.1.6 Sample extraction tube + dripper label

Front


15 mm
Zipper end
76 mm
Σ 20
50 mm
Sample Extraction Tube
+
Dripper
Rev. A1 Rel.: 2021.04.13
135mm
150mm
42mm
150 mm

Back


15 mm
135mm
150mm
150 mm

1.1.7 Nasal swab label

205.0 mm

185.0 mm

38.0 mm

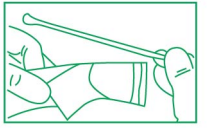
25.0 mm

PEEL HERE

Disposable swabs

CF 150-P 3 B

STERILE | EO



1、Single use only.
2、There is a risk of cross- infection if re-use
3、Do not use if package is damaged

EC REP

CF101 Rev.00 Date201701

6.5

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Obere Seegasse 34/2,69124
Heidelberg,Germany
Email: info@llins-service.com

CE 0197

LOT 20210206JZ

2024/02/05

Jiangsu Changfeng Medical Industry Co., Ltd
Touqiao Town,Guangling District,Yangzhou,
Jiangsu 225109 China

10

1.2 Product code W634P0014 (100 T/kit)

1.2.1 Kit box design

Rev. A1 Rel. 2021/04/15

IVD

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REF W634P0014
LOT XXXXXXXXX
XXXX-XX-XX
XXXX-XX-XX

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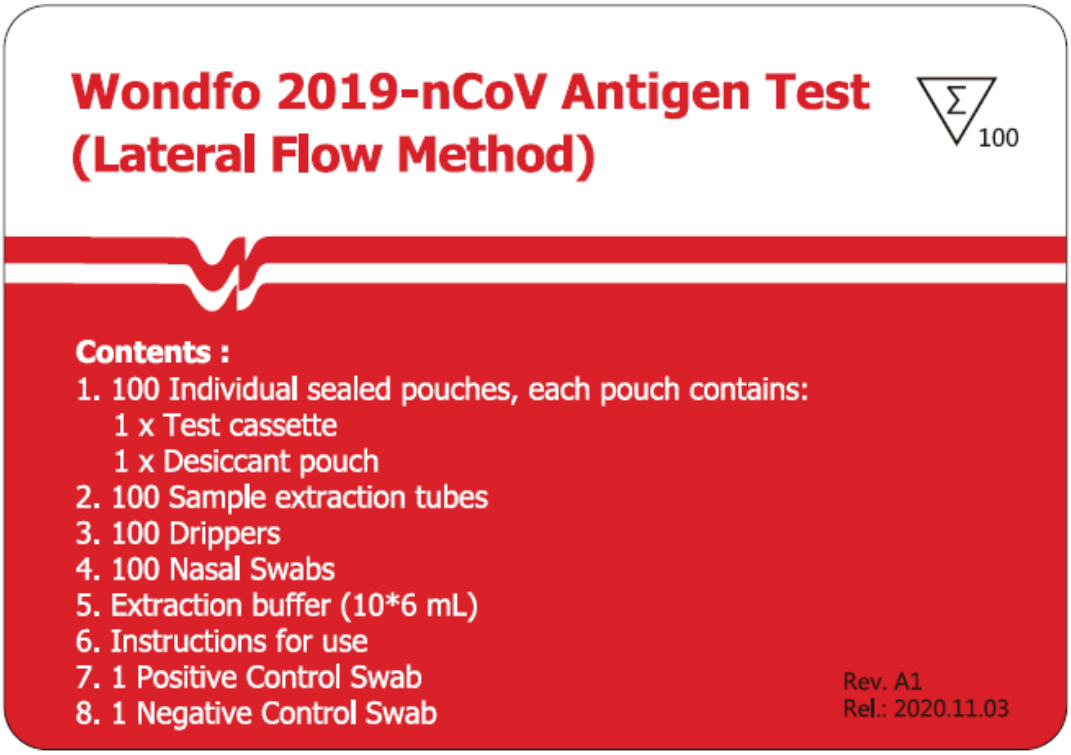
FOR PROFESSIONAL USE ONLY

1.2.2 Kit box label



1.2.3 Test cassette pouch

18mm

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Σ 1

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

LOT XXXXXXXXX
REF W634P0014

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XXXX-XX-XX

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30°C
2°C
IVD

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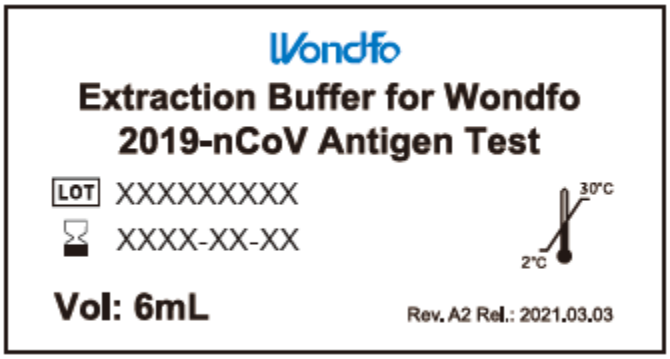
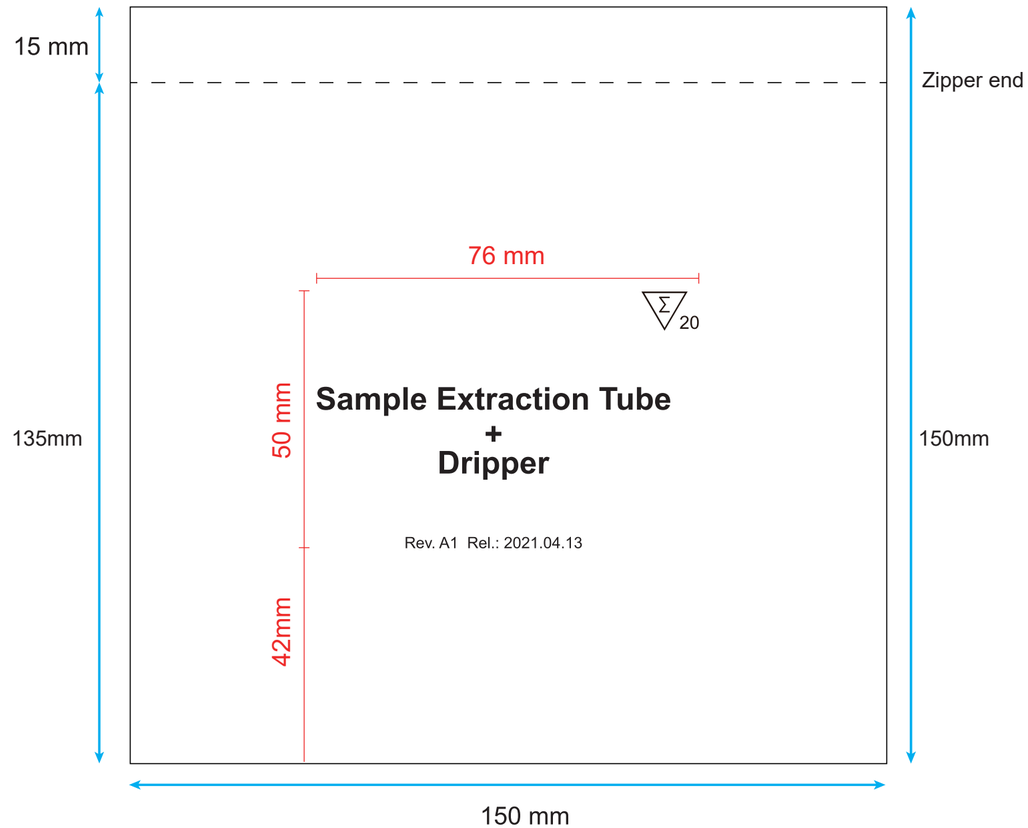
1.2.4 Round sticker

1.2.5 Extraction buffer label

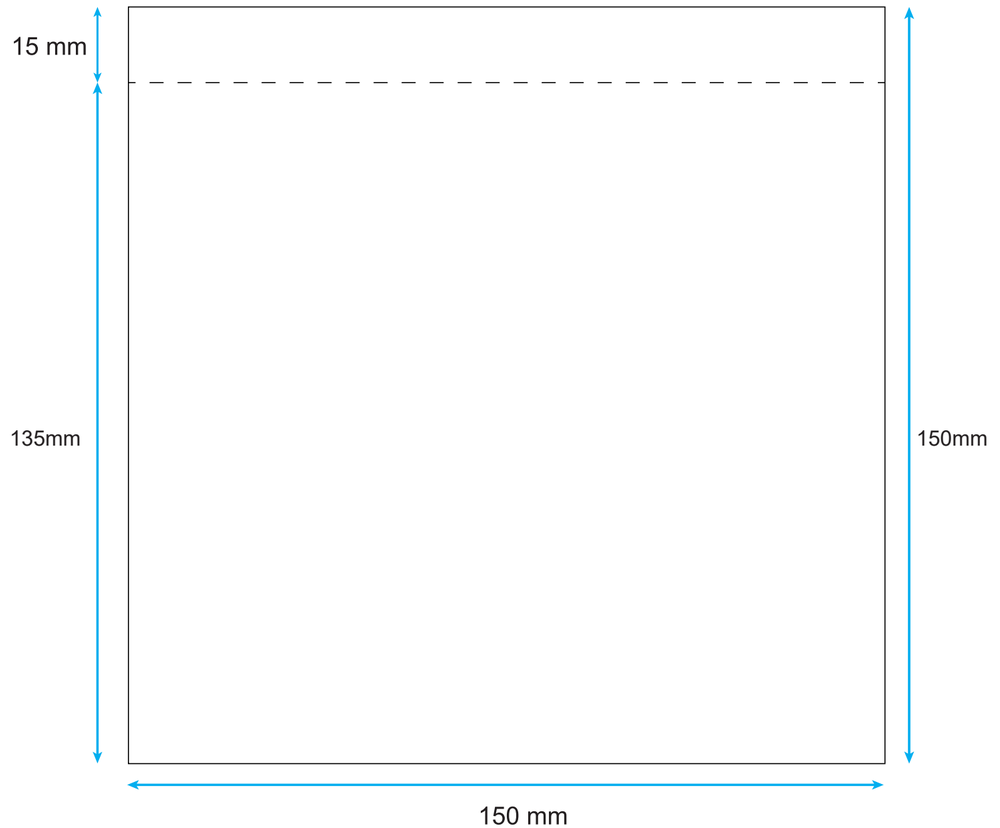


1.2.6 Sample extraction tube + dripper label

Front


15 mm
Zipper end
76 mm
Σ 20
50 mm
Sample Extraction Tube
+
Dripper
Rev. A1 Rel.: 2021.04.13
135mm
150mm
42mm
150 mm

Back


15 mm
135mm
150mm
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1.2.7 Nasal swab label

205.0 mm

185.0 mm

38.0 mm

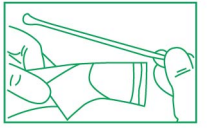
25.0 mm

PEEL HERE

Disposable swabs

CF 150-P 3 B

STERILE | EO



1、Single use only.
2、There is a risk of cross- infection if re-use
3、Do not use if package is damaged

EC REP

CF101 Rev.00 Date201701

6.5

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CE 0197

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2024/02/05

Jiangsu Changfeng Medical Industry Co., Ltd
Touqiao Town,Guangling District,Yangzhou,
Jiangsu 225109 China

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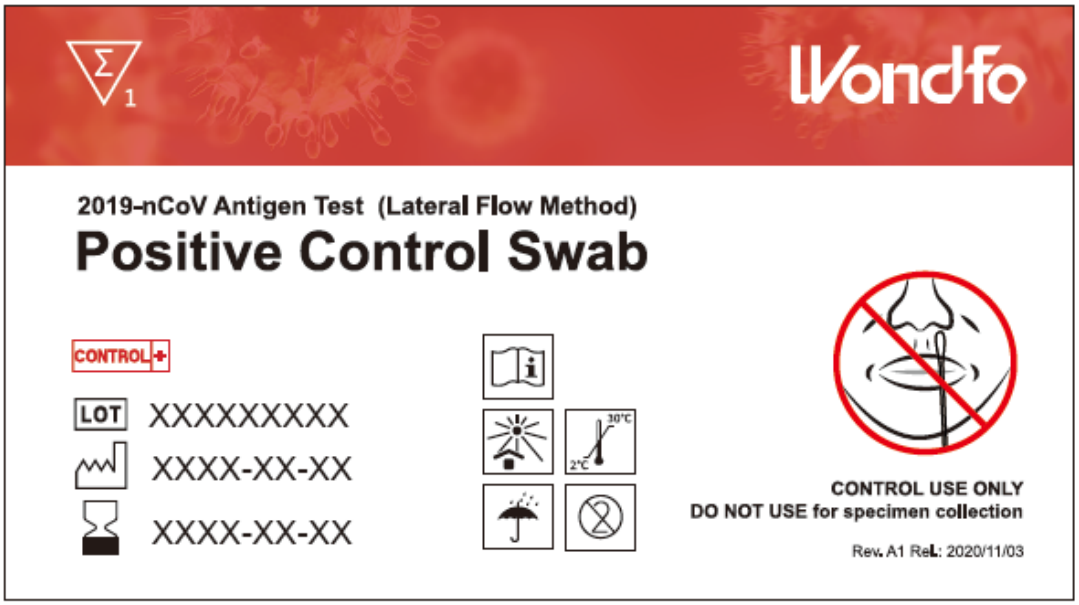
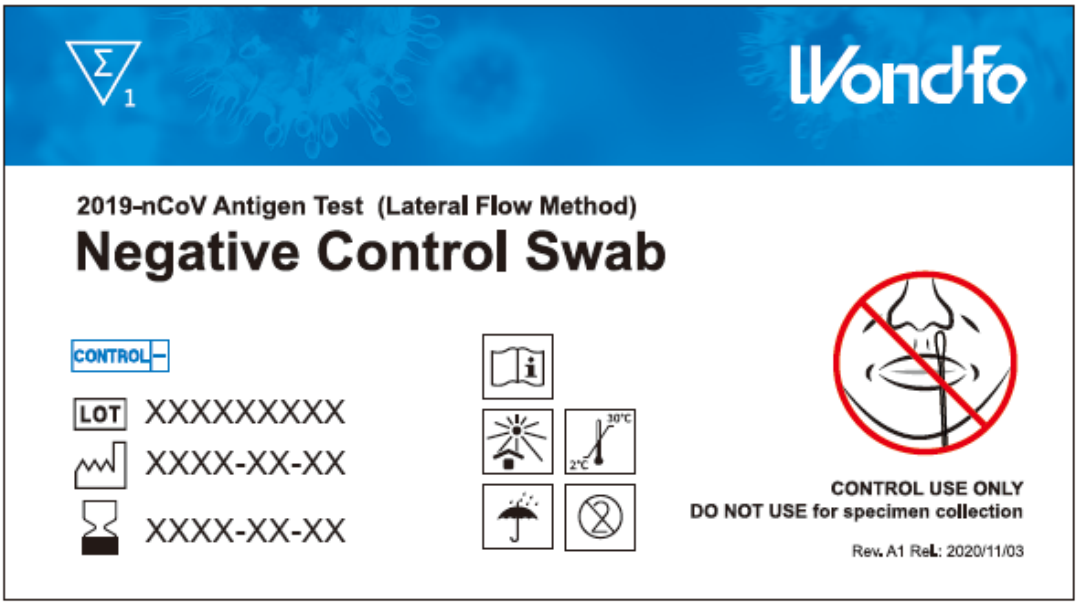
1.2.8 Positive control swab label

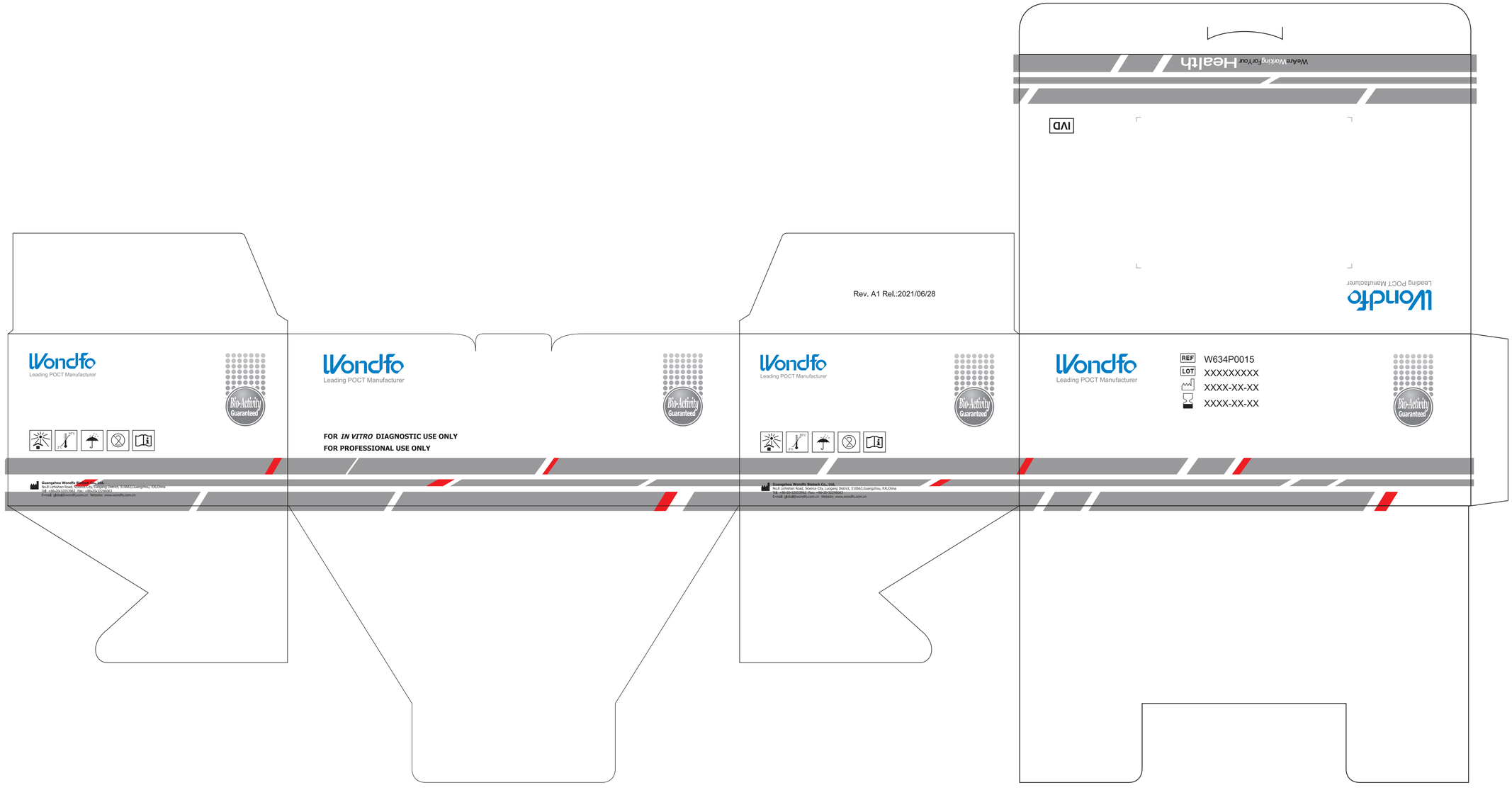


1.2.9 Negative control swab label



1.3 Product code W634P0015 (20 T/kit)

1.3.1 Kit box design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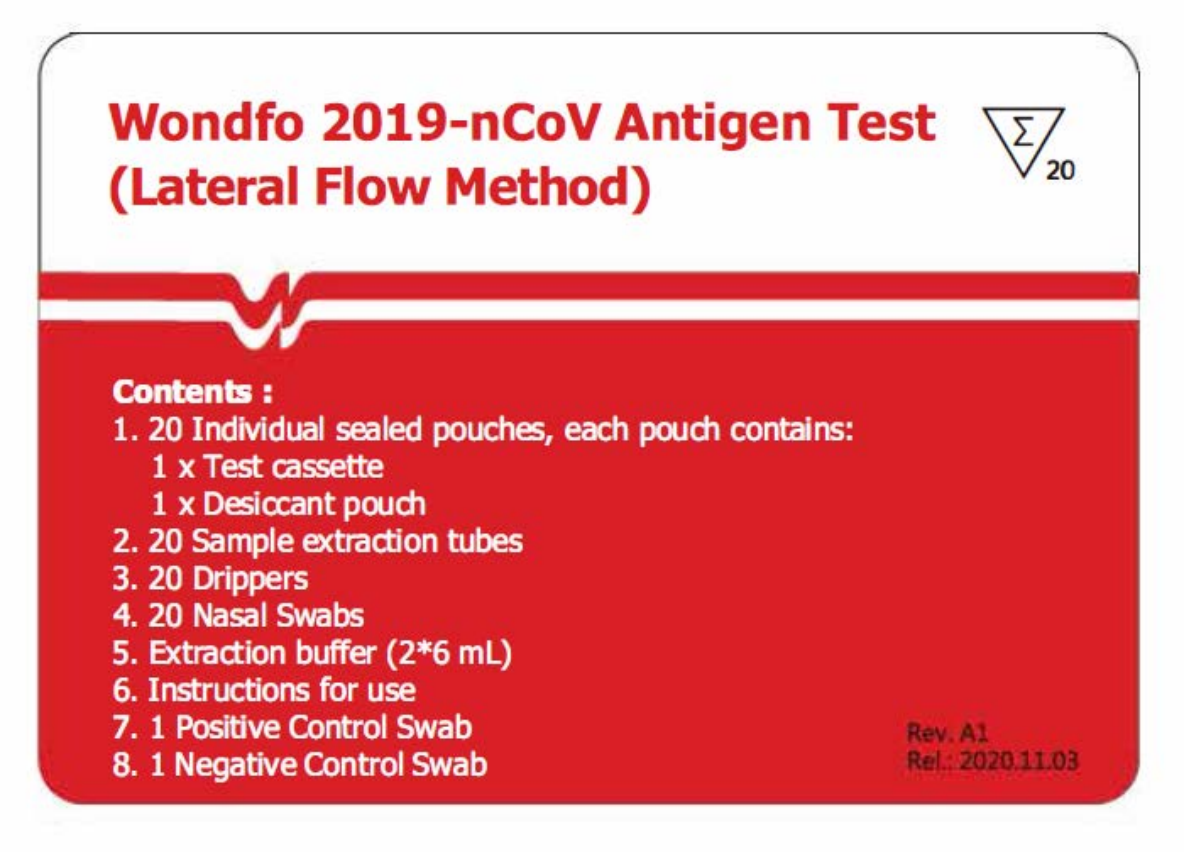
Rev. A1 Rel.:2021/06/28
IVD
We Are Working For You Health
REF W634P0015
LOT XXXXXXXXX
XXXX-XX-XX
XXXX-XX-XX

1.3.2 kit box label



1.3.3 Test cassette pouch

18mm

Wondfo
Leading POCT Manufacturer

Σ 1

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

LOT XXXXXXXXX
REF W634P0015

XXXX-XX-XX
XXXX-XX-XX

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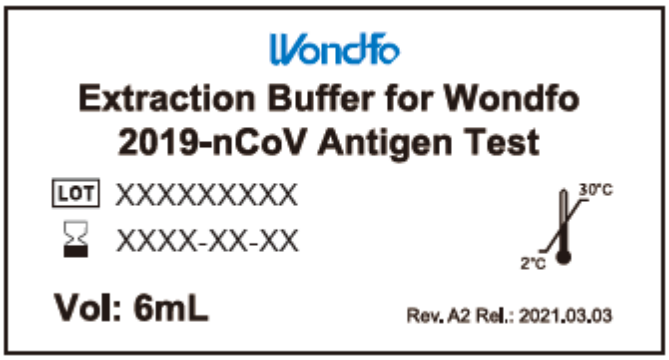
E-mail: global@wondfo.com.cn Website: www.wondfo.com.cn

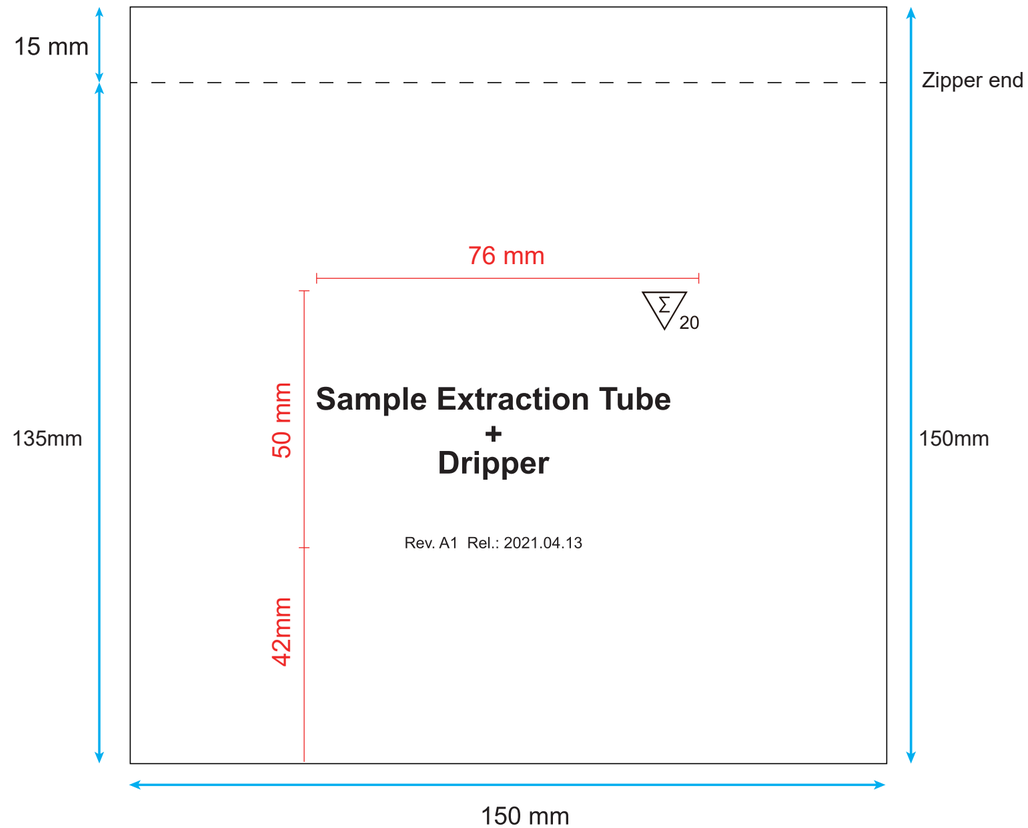
1.3.4 Round sticker

1.3.5 Extraction buffer label



1.3.6 Sample extraction tube + dripper label

Front


15 mm
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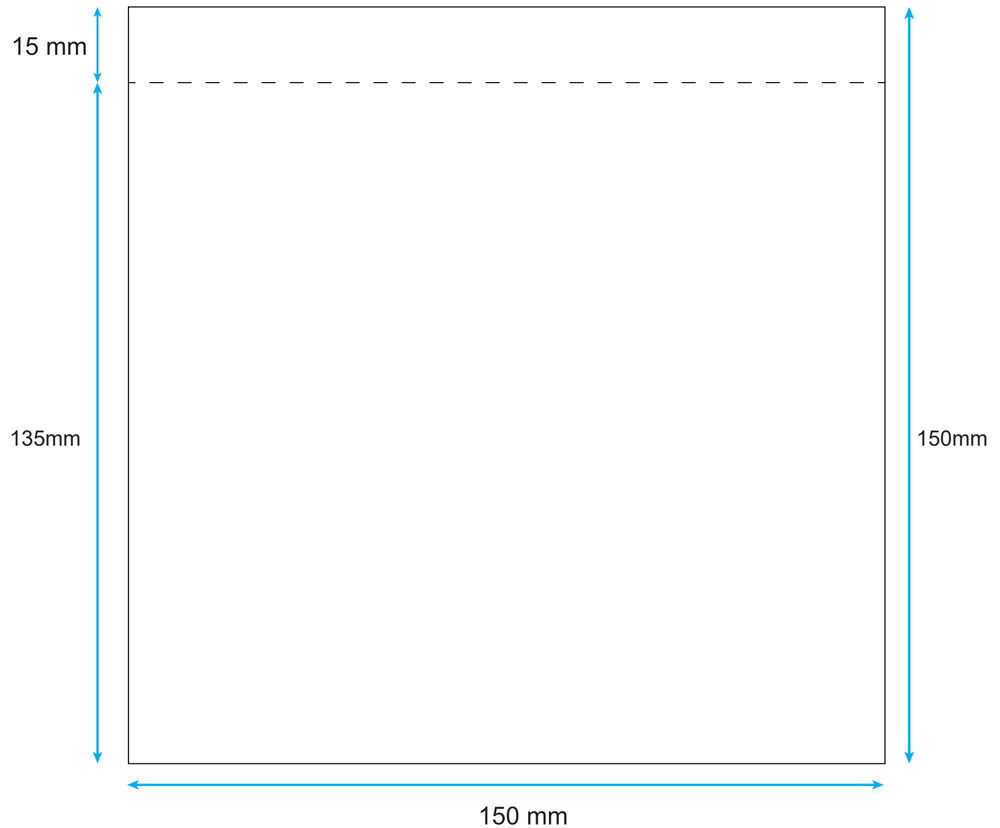
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1.3.7 Nasal swab label

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Disposable swabs

CF 150-P 3 B

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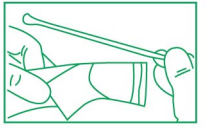

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3、Do not use if package is damaged

EC REP

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LOT 20210206JZ

2024/02/05

Jiangsu Changfeng Medical Industry Co., Ltd
Touqiao Town,Guangling District,Yangzhou,
Jiangsu 225109 China

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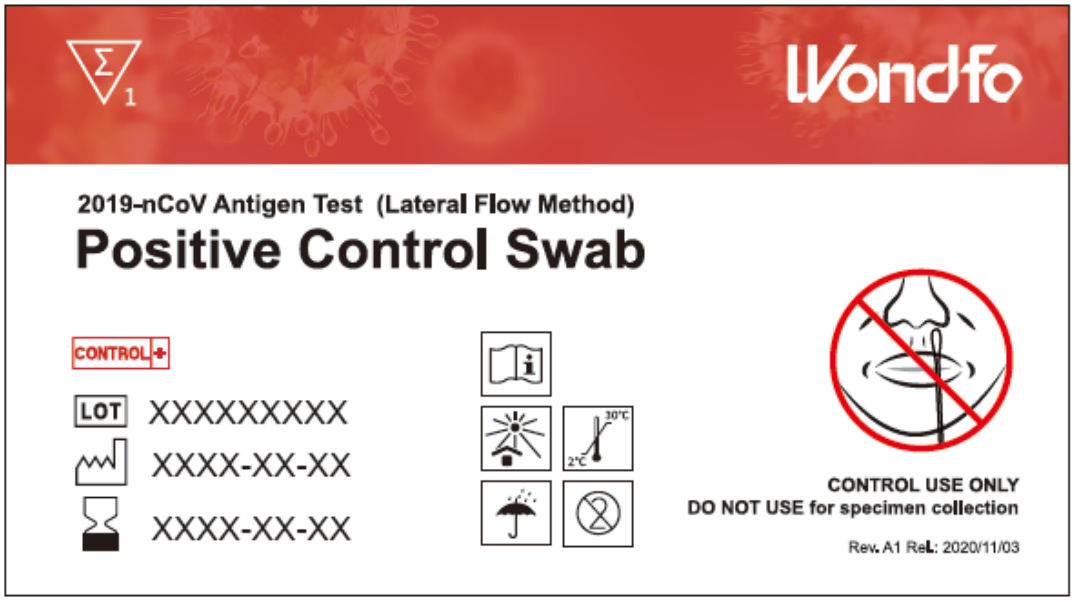
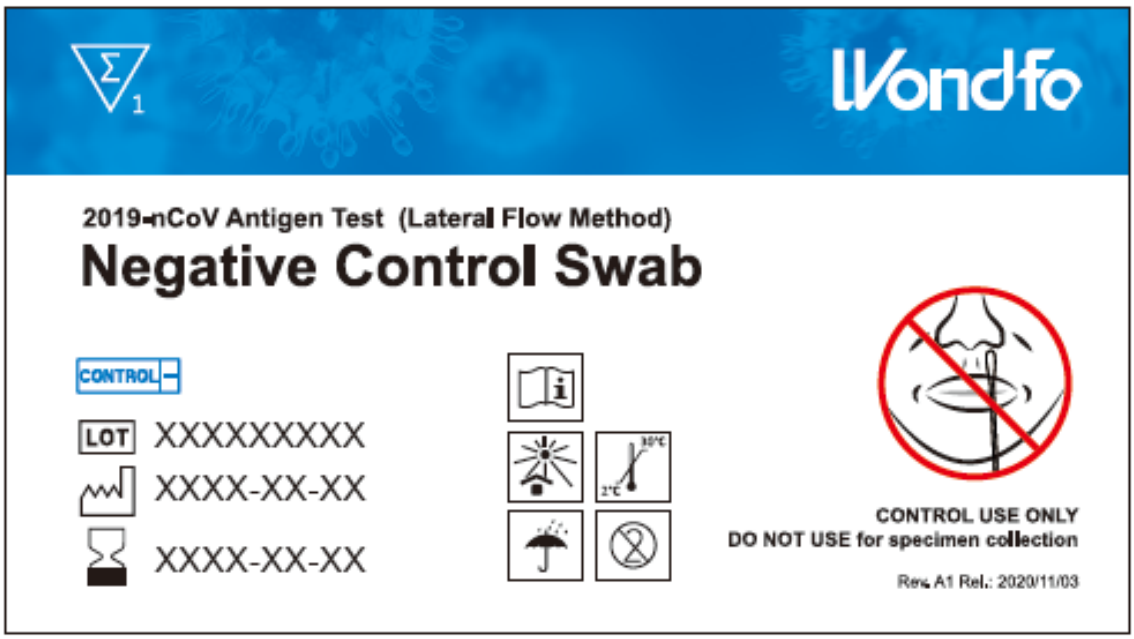
1.3.8 Positive control swab



1.3.9 Negative control swab



2.0 Instructions for use (IFU)[2]

[2] English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

CATALOG NO.

W634P0013 W634P0014 W634P0015

INTENDED USE

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For *in vitro* diagnostic use only.

SUMMARY

COVID-19 is an acute respiratory infectious disease. Novel coronavirus transmission occurs with high efficacy and infectivity mainly through the respiratory route, such as oral fluid, sneezing, physical contact, and other air droplets [1-3]. Novel coronavirus can be transmitted by symptomatic or asymptomatic infected individuals [4]. The current epidemiological investigation suggests a mean incubation period of 5 to 7 days and a median incubation period of 3 days (range: 0–24 days) [5]. In symptomatic patients, the clinical manifestations of the disease usually start after less than a week, consisting of fever, cough, nasal congestion, fatigue, and other signs of upper respiratory tract infections [6]. The availability of a cost-effective, rapid point of care diagnostic test is critical to enable healthcare professionals to aid in the diagnosis of patients and prevent further spread of the virus. As a rapid test with a 15-20 min testing time, Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is an useful diagnosis tool for cornoravirus infection. The test results are for clinical reference only and cannot be used as a basis for confirming or excluding cases alone.

PRINCIPLE

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is based on the principle of Immunochromatography, using colloidal gold as the label for detection of novel coronavirus antigen extracted from the nasal swab specimen. When the extracted specimen is added into the test device, the specimen is absorbed into the device by capillary action, reacts with the novel coronavirus antibody-dye conjugate and flows across the pre-coated membrane.

When the novel coronavirus antigen level in the specimen is at or above the target cutoff (the detection limit of the test), it will react with the antibody labeled with colloidal gold to form a complex. Through capillary action, the reaction complex moves forward along the nitrocellulose membrane to the detection region (T), where it reacts with the precoated antibodies on the nitrocellulose membrane to form an antibody-antigen-antibody complex, and this produces a colored test band that indicates a positive result. When the novel coronavirus antigen level in the specimen is zero or below the target cutoff, there is no a visible colored band in the detection region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored band 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 contagious. Use appropriate precautions in the collection, handling, storage and disposal of patient specimens and used kit contents.
3. Wear appropriate personal protective equipment (e.g. protective gloves, medical mask, goggles and lab coat) when handing the contents of this kit.
4. Proper specimen collection, storage, and transport are critical to the performance of this test.
5. Discard after first use. Do not reuse the test device and kit components.
6. Avoid excessively high or low temperature in the experiment environment. When stored in a refrigerator, all kit components must be brought to room temperature for a minimum of 30 minutes prior to performing the test. Do not open the pouch while components come to room temperature.
7. **Do not** touch the reaction area of the test strip.
8. **Do not** use if the test kit is beyond expiration date.
9. **Do not** use the kit if the pouch is punctured or not well sealed.
10. **Do not** dilute the collected swab with any solution except with the provided extraction buffer.
11. Components from different lots must not be mixed or used together.
12. The test result should be interpreted by the professional along with clinical findings and other laboratory test results.
13. DISPOSAL OF THE USED KIT: All specimens and the used kit have the infectious risk. The process of disposing used kit must follow the local infectious disposal law or laboratory regulation.

MATERIALS

Materials Provided

Components \ REF	W634P0013	W634P0014	W634P0015
Sealed Pouches* (pcs)	20	100	20
Extraction Buffer (6mL/vial)	2	10	2
Sample Extraction Tube (pcs)	20	100	20
Drippers (pcs)	20	100	20
Nasal Swab (pcs)	20	100	20
Positive Control Swab (pcs)	/	1	1
Negative Control Swab (pcs)	/	1	1
IFU (pcs)	1	1	1

Note: **Each sealed pouch contains: 1 Test Cassette and 1 Desiccant Pouch*

Materials Required but Not Provided

1. Timer
2. Test tube rack
3. Personal protective equipment, such as protective gloves, medical mask, goggles and lab coat.
4. Appropriate biohazard waste container and disinfectants.

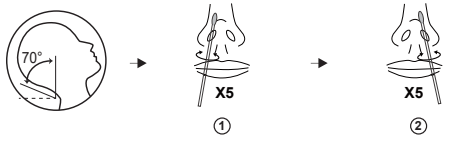
STORAGE AND STABILITY

1. The test kit should be stored at a temperature between 2-30 °C. The validity period of this product is 24 months. **Do not** freeze.
2. The test cassette should be used within 1 hour after taking out from the sealed pouch. Bottled buffer solution should be re-capped after use. Store the opened buffer at 2~30 ℃ for no more than 10 weeks.
3. Keep away from sunlight, moisture, and heat.
4. Kit contents are stable until the expiration date printed on the outer package.
5. The manufacturing date is printed on the outer package.

SPECIMEN COLLECTION AND PREPARATION

Bring the test components to room temperature.Take out the nasal swab from the notch of the package.

1. Tilt the head of the patient backwards (about 70 degrees).
2. Gently twist the swab, insert the entire absorbent tip of the nasal swab into a nostril to about 1.5 cm deep.
3. Perform the first sampling by rubbing the nasal wall firmly with the nasal swab, turning it five times against the nasal walls so that the absorbent surface of the nasal swab is wetted all round.
   Note:
   a) Be careful not to hurt the patient.
   b) This process may take about 15 seconds.
4. Slowly remove the nasal swab from the first nostril.
5. Repeat the collection process with the same nasal swab in the other nostril.



Nasal Swab Collection

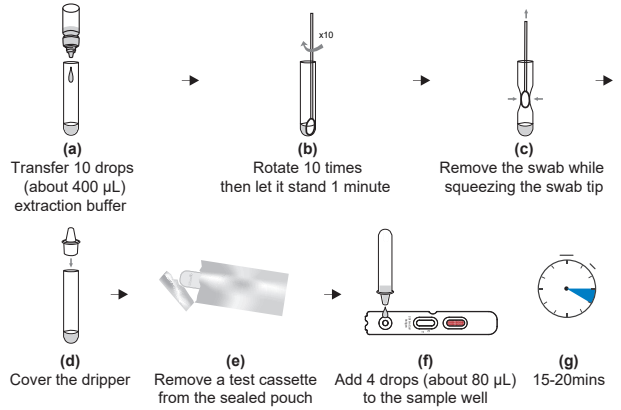
Note: *Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 15 seconds* ***is not*** *a proper technique and may result in an insufficient specimen.*

TEST PROCEDURE

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

Nasal Swab Testing: For W634P0013/W634P0014/ W634P0015

a. Transfer 10 drops(about 400 µL) extraction buffer to the sample extraction tube, holding buffer vial vertically.
b. Insert the moist swab tip with nasal secretions into the sample extraction tube; place the nasal swab tip against the bottom of the extraction tube and rotate gently for 10 times to release the secretion from the tip of the nasal swab. Place the sample extraction tube on the test tube rack (if applicable) and leave the swab in the extraction buffer for 1 minute.
c. While squeezing the middle of the extraction tube, slowly pull out the nasal swab to extract as much liquid as possible from the tip of the nasal swab. Discard the used swab in accordance with the biohazard waste disposal protocol.
d. Tightly close the extraction tube with dripper.
   Note: *Swab specimens should be tested immediately after collection. If it is not possible to test immediately, the swab specimen can be kept in an extraction tube filled with extraction buffer at room temperature (10~40 ℃) for up to 2 hours prior to testing. And used within 3 hours when stored at 2 ℃~8 ℃.*
e. Remove a test cassette from the sealed pouch by tearing at the notch and place it on a level surface.
f. Turn the sample extraction tube upside down, hold it vertically and add 4 drops (about 80 µL) processed specimen into the small, round, white sample well. The result window (C T) now turns purple.
g. Start the timer. Read the results at 15~20 minutes. **Do not read results after 20 minutes.**



Positive/Negative Control Swab Testing: For W634P0014/ W634P0015

Caution: *The positive and negative control swab are for control use only.* ***Do not*** *use the control swabs for specimen collection.*

Transfer about 10 drops(about 400 µL) extraction buffer to the sample extraction tube vertically. Take out the positive or negative swab and insert the swab into the extraction buffer, rotate the swab tip 10 times against the bottom and sides of the extraction tube to release the specimen from the swab tip. Return the sample extraction tube to the test tube rack (If applicable) and leave the swab in the extraction buffer for 1 minute. Then follow the above test procedure c-g of **[Nasal Swab Testing]**

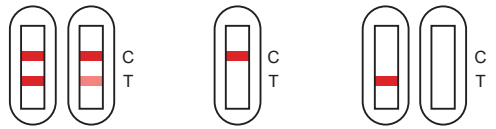
Note:
1. Please refer to the ***RESULT INTERPRETATION*** *section of this instructions for use to interpret the results.*
2. Please refer to the ***External Quality Control*** *section of this instructions for use for the frequency of testing control swabs.*

RESULT INTERPRETATION

Positive Result
Colored bands appear at both test line (T) and control line (C) indicating a positive result for the novel coronavirus antigen in the specimen.

Negative Result
Colored band appears at control line (C) only indicating that the concentration of the novel coronavirus 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 kit may have deteriorated. It is recommended to re-sample and re-test.



QUALITY CONTROL

1.Internal Quality Control

A procedural control is included in the test. A colored band appearing in the control region (C) is considered an internal procedural control. If the test procedure is performed properly and the test reagents of the control line are working, then the control line will always appear and the test result is considered valid.

2.External Quality Control

Good laboratory practice recommends the use of the control swabs to ensure that the test reagent is working and the test is properly performed.

It is recommended that the control swabs are performed at any of the following scenarios:

(1) New users run the control swabs prior to testing patient specimens;
(2) When receiving a new test reagent lot;
(3) When receiving a new test shipment;
(4) Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control swabs.

LIMITATIONS OF PROCEDURE

1. This reagent is designed to detect novel coronavirus antigen N protein in human nasal swab specimen.
2. The specimen collection process will affect the accuracy of the test, such as improper specimen collection, improper specimen storage, or repeated freezing and thawing of the specimen etc.
3. This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of novel coronavirus antigen. If you need to test the quantitative concentration, please refer to the instructions of relevant professional instruments or reagents for quantitative assay.
4. The test results of this reagent are for clinical reference only and should not be used as the sole basis for 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, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation for negative test results.
6. Positive test results do not rule out co-infections with other pathogens. A negative result of this reagent can be caused by improper specimen collection, improper specimen transfer or handling.

PERFORMANCE CHARACTERISTICS

A. Clinical Performance

1. Clinical Trial of Wondfo 2019-nCoV Antigen Test (Symptomatic)

The clinical performance of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was evaluated by testing nasal swab specimens collected from symptomatic subjects who were suspected of COVID-19. A total of 793 clinical specimens were tested using the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) and were compared to the results of oropharyngeal swab/Nasopharyngeal swab tested with molecular (RT-PCR) assay.

Clinical Performance of Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) vs RT-PCR Assay.

Wondfo 2019-nCoV Antigen Test (Nasal swab)	RT-PCR Test		Total
	Positive	Negative	
Positive	191	5	196
Negative	14	583	597
Total	205	588	793

Sensitivity: 93.17%(95%CI:88.86-95.89%)
Specificity: 99.15%(95%CI:98.03-99.64%)
Overall Percent Agreement: 97.60%(95%CI:96.29-98.46%)

Stratification of the positive specimens post onset of symptoms or suspected exposure between 0-3 days has a sensitivity of 91.78% (n=73) and 4-7 days has a sensitivity of 92.31% (n=91).
Positive agreement of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is higher with specimens of Ct values ≤30 with a sensitivity of 97.04%.

2. Clinical Trial of Wondfo 2019-nCoV Antigen Test (Asymptomatic)

The clinical performance of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was evaluated by testing nasal swab specimens collected from asymptomatic subjects. A total of 509 clinical specimens were tested using the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) and were compared to the results of oropharyngeal swab tested with an Emergency Use Authorized molecular (RT-PCR) assay.

A total of 78 specimens with PCR positive results are stratified based on the Ct value of the target gene amplification as presented in the table below:

The specificity (n=431) was 100% with 95% CI [99.12%-100%].

Clinical Performance of Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) vs FDA EUA RT-PCR Assay.

	Total (n)	Sensitivity (%)	95% CI
CT≤25	29	96.55	82.82-99.39
CT≤30	63	92.06	82.73-96.56
CT≤33	72	83.33	73.09-90.20
RT-PCR positive	78	78.21	67.84-85.92

B. Limit of Detection

The Limit of Detection (LoD) of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was determined using limiting dilutions of UV-inactivated novel coronavirus (ZeptoMetrix 0810587UV). The ZeptoMetrix material is a preparation of SARS-Related Coronavirus 2, isolate USA-WA1/2020. The material was supplied frozen at a concentration of 4.57×10^6 $TCID_{50}$/mL.
The Limit of Detection (LoD) of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was confirmed as 1.5×10^2 $TCID_{50}$/mL.

C. Analytical Reactivity/Inclusivity

The analytical reactivity of the novel coronavirus in the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) were evaluated with currently available novel coronavirus strains (see table below).

Virus Strain/WHO Label	Lineage#	Isolate	Concentration
UV-Inactivated SARS-CoV-2 virus Culture Fluid	/	USA-WA1/2020	1.5×10^2 $TCID_{50}$/mL
Alpha	B.1.1.7	IQTC34925	4.0×10^1 PFU/mL
Beta	B.1.351	IQTC22239	4.0×10^1 PFU/mL
Delta	B.1.617.2	GDPCC	4.0×10^1 PFU/mL

D. Interference

The test result of Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is not influenced by the presence of following substances/conditions:

No.	Types of Specimen	Interfering Substances	Concentration
1	Nasal gel or Nasal sprays or drops	Naso GEL (NeilMed)	5% v/v
2		Oxymetazoline hydrochloride	15% v/v
3		CVS Nasal Spray (Cromolyn)	15% v/v
4		CVS Nasal Drops (Phenylephrine)	15% v/v
5	Nasal cortico-steroids	Budesonide	15% v/v
6		Beclomethasone	15% v/v
7		Fluticasone Propionate	5% v/v
8	Throat durgs	Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
9		Sore Throat Phenol Spray	15% v/v
10	Antibiotic and Antibacterial	Tobramycin	24.0 μg/mL
11		Levofloxacin	0.1 mg /mL
12		Azithromycin	1.0 mg/mL
13		Ceftriaxone	0.8 mg/mL
14		Meropenem	0.5 mg/mL
15		Mupirocin	10.0 mg/mL
16		Amoxicillin	0.25 mg/mL

No.	Types of Specimen	Interfering Substances	Concentration
17	Anti-viral drugs	Ribavirin	10.0 μg/mL
18		Oseltamivir	0.5 mg/mL
19		Zanamivir	10.0 μg/mL
20		Ritonavir	2.0 mg/mL
21		Lopenavir	0.5 mg/mL
22		Interferon alpha	5% v/v
23		Palamivir	0.15 mg/mL
24		Abidor	1.0 mg/mL
25	Allergy medication	Diphenhydramine	10.0 μg/mL
26		Chlorpheniramine	10.0 μg/mL
27	Anti-inflammatory medication	Acetylsalicylic acid	1.0 mg/mL
28		Ibuprofen	1.0 mg/mL
29	Others	Mucin	0.5% v/v
30		Whole Blood	4% v/v
31		Biotin	0.1 mg/mL
32		HAMA	0.5% v/v

E. Cross-reactivity and Microbial Interference

No cross-reactivity or interference was observed with the following microorganisms when tested at the concentrations presented in the table below.

No.	Types of Specimen	Cross Reaction Substance	Concentration
1	Other high priority pathogens from the same virus family	Human coronavirus 229E	4.68×10^4 $TCID_{50}$/mL
2		Human coronavirus OC43	1×10^5 $TCID_{50}$/mL
3		Human coronavirus NL63	1×10^5 $TCID_{50}$/mL
4		MERS-coronavirus	1×10^5 $TCID_{50}$/mL
5		Human coronavirus HKU1	0.25 mg/mL
6		SARS-coronavirus	0.25 mg/mL
7	Other high priority organisms	Adenovirus-1	1×10^5 $TCID_{50}$/mL
8		Adenovirus-2	1×10^5 $TCID_{50}$/mL
9		Adenovirus-3	1×10^5 $TCID_{50}$/mL
10		Adenovirus-4	1×10^5 $TCID_{50}$/mL
11		Adenovirus-5	1×10^5 $TCID_{50}$/mL
12		Adenovirus-7	1×10^5 $TCID_{50}$/mL
13		Adenovirus-55	1×10^5 $TCID_{50}$/mL
14		Human Metapneumovirus (hMPV-3)	1×10^5 $TCID_{50}$/mL
15		Parainfluenza virus 1	1×10^7 $TCID_{50}$/mL
16		Parainfluenza virus 2	1×10^5 $TCID_{50}$/mL
17		Parainfluenza virus 3	1×10^7 $TCID_{50}$/mL
18		Parainfluenza virus 4	1×10^5 $TCID_{50}$/mL
19		Epstein-Barr virus	1×10^5 $TCID_{50}$/mL
20		Measles virus	1×10^5 $TCID_{50}$/mL
21		Human Cytomegalovirus	1×10^5 $TCID_{50}$/mL
22		Rotavirus	1×10^5 $TCID_{50}$/mL
23		Norovirus	0.1 mg/mL
24		Mumps virus	1×10^5 $TCID_{50}$/mL
25		Varicella-zoster virus	1×10^5 $TCID_{50}$/mL
26		Influenza A H1N1	1×10^5 $TCID_{50}$/mL
27		Influenza A H3N2	1×10^5 $TCID_{50}$/mL
28		Influenza B Victoria	4.68×10^4 $TCID_{50}$/mL
29		Influenza B Yamagata	1×10^5 $TCID_{50}$/mL
30		Enterovirus Group A (CA16)	1×10^5 $TCID_{50}$/mL
31		Enterovirus Group B (CB1)	1×10^5 $TCID_{50}$/mL
32		Enterovirus Group C (CA24)	1×10^5 $TCID_{50}$/mL
33		Enterovirus Group D (EV68)	'1×10^5 $TCID_{50}$/mL
34		Respiratory syncytial virus (RSV) type A	1×10^5 $TCID_{50}$/mL
35		Respiratory syncytial virus (RSV) type B	1×10^5 $TCID_{50}$/mL
36		Rhinovirus-A	1×10^5 $TCID_{50}$/mL
37		Rhinovirus-B	1×10^5 $TCID_{50}$/mL
38		Chlamydia pneumoniae	1×10^7 IFU/mL
39		Haemophilus influenzae	1×10^7 CFU/mL
40		Legionella pneumophila	1×10^7 CFU/mL
41		Mycobacterium tuberculosis	1.0 mg/mL
42		Streptococcus pneumoniae	1×10^7 CFU/mL
43		Streptococcus pyrogens	1×10^7 CFU/mL
44		Bordetella pertussis	1×10^7 CFU/mL
45		Mycoplasma pneumoniae	1×10^7 CCU/mL
46		Pneumocystis jirovecii (PJP)	N/A
47		Pooled human nasal wash	N/A

*Pneumocystis jirovecii (PJP) have not been tested.There is no significant similarities in Amino Acid between the nucleocapsid phosphoprotein of SARS-CoV-2 and the PJP.

F. Hook Effect

Within the titer range of the following novel coronavirus culture, there is no hook effect in the test results of this product.

Virus Strain/WHO Label	Lineage#	Isolate	Concentration
UV-Inactivated SARS-CoV-2 virus Culture Fluid	/	USA-WA1/2020	4.57×10^6 $TCID_{50}$/mL
Alpha	B.1.1.7	IQTC34925	8.6×10^5 PFU/mL
Beta	B.1.351	IQTC22239	2.0×10^5 PFU/mL
Delta	B.1.617.2	GDPCC	2.0×10^5 PFU/mL

G. Precision

Repeatability & Reproducibility of Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was established using in-house reference panels containing negative specimens and a range of positive specimens. There were no differences observed within-run, between-run, between-lots, between-sites, and between-days.

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INDEX OF SYMBOL

IVD *In Vitro* Diagnostic Use	See Instruction for Use	Expiry Date	Tests per Kit
Manufacturing Date	Keep Dry	LOT Batch Number	REF Catalog number
Keep away from Sunlight	Manufacturer	Do not reuse	2°C 30°C Store between 2~30℃
CONTROL + Positive Control	CONTROL − Negative Control	CONTROL USE ONLY DO NOT USE for specimen collection	

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