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:

- 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.
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

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</tbody>
</table>
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

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.

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\(^1\) [https://www.who.int/publications/i/item/9789240015319](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
1.1.2 kit box label

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

Contents:
1. 20 Individual sealed pouches, each pouch contains:
   1 x Test cassette
   1 x Desiccant pouch
2. 20 Sample extraction tubes
3. 20 Drippers
4. 20 Nasal Swabs
5. Extraction buffer (2*6 mL)
6. Instructions for use

1.1.3 Test cassette pouch
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

LOT XXXXXXXX
REF W634P0013

FOR IN VITRO DIAGNOSTIC USE ONLY

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhihan Road, Science City, Luogang
District, 510663, Guangzhou, PR. China
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
Sample Extraction Tube + Dripper

1.1.7 Nasal swab label
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

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

0197
20210206/LZ
2024020105

产品名称:DISPOSABLE SWABS
客户名称:扬州源通
产品编号:HF0457-00352-01
色序: 354-U K

日期: 20210706
1.2 Product code W634P0014 (100 T/kit)

1.2.1 Kit box design
1.2.2 Kit box label

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

Contents:
1. 100 Individual sealed pouches, each pouch contains:
   1 x Test cassette
   1 x Desiccant pouch
2. 100 Sample extraction tubes
3. 100 Drippers
4. 100 Nasal Swabs
5. Extraction buffer (10*6 mL)
6. Instructions for use
7. 1 Positive Control Swab
8. 1 Negative Control Swab

Rev. A1
Ref: 2020.11.03

1.2.3 Test cassette pouch
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

LOT XXXXXXXXXX
REF W634P0014

FOR IN VITRO DIAGNOSTIC USE ONLY

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, PR, China
Tel: +86-20-32053962 Fax: +86-20-32296063
E-mail: global@wondfo.com.cn Website: www.wondfo.com.cn
1.2.4 Round sticker

1.2.5 Extraction buffer label

1.2.6 Sample extraction tube + dripper label
Sample Extraction Tube + Dripper

Rev. A1 Rel.: 2021.04.13
1.2.7 Nasal swab label
1.2.8 Positive control swab label

![Positive control swab label image]

1.2.9 Negative control swab label

![Negative control swab label image]
1.3 Product code W634P0015 (20 T/kit)

1.3.1 Kit box design
1.3.2 Kit box label

![Kit box label image]

1.3.3 Test cassette pouch
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

LOT: XXXXXXXXX
REF: W634P0015

FOR IN VITRO DIAGNOSTIC USE ONLY

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang
District, 510663, Guangzhou, PR China
Tel: +86-20-32053962 Fax: +86-20-32296063
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
Sample Extraction Tube + Dripper

1.3.7 Nasal swab label
1.3.8 Positive control swab

![Positive Control Swab Image]

1.3.9 Negative control swab

![Negative Control Swab Image]
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.
INTENDED USE

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 all 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.

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 [25]. Novel coronavirus can be transmitted by symptomatic or asymptomatic infected individuals [31]. 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) [6]. 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 [1]. 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 diagnostic tool for coronavirus infection. The test results are for clinical reference only and cannot be used as a basis for confirming or excluding cases alone.

MATERIALS

MATERIALS Provided

<table>
<thead>
<tr>
<th>Components</th>
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<tr>
<td>Sealed Pouches (pcs)</td>
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<td>Extraction Buffer (ml/mL)</td>
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<td>IFO (pcs)</td>
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</table>

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 for up to 2 hours prior to testing. And used within 3 hours when stored at 2-4°C.
2. Store at room temperature (about 20°C) for up to 24 months.
3. Do not freeze.
4. Keep away from sun light, moisture, and heat.
5. Kit contents are stable until the expiration date printed on the outer package.
6. 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 NABOT 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 into the nasal passage.
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 around.
4. Slowly remove the nasal swab from the anterior nostril.
5. Repeat the collection process with the same nasal swab in the other nostril.

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 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

1. Transfer 10 drops (about 400 μL) extraction buffer into the test device.
2. Insert the moist swab tip into the extraction tube, rotate the swab tip 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.
3. 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.
4. Tightly close the extraction tube with a rubber cap.
5. When 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 test result window (C) now turns purple.
6. 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 not have been followed correctly or the test kit may have deteriorated. It is recommended to re-sample and re-test.
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 properly performed 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. When testing new patients
2. When testing new reagents or new kits
3. When retesting the same patient
4. Patients should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control swabs.

LIMITATIONS OF PROCEDURE

1. This kit is for diagnostic use only.

2. This kit is not intended for use in vitro diagnostic use.

3. This kit is not intended for use in any laboratory and non-laboratory settings that meet the requirements specified in the instructions for use.

4. This kit is intended for use in settings where the collected specimen can be tested within 1 hour of collection.

5. This kit is not intended for use in any setting where the collected specimen cannot be tested within 1 hour of collection.

6. This test is not intended for use in any setting where the collected specimen cannot be tested within 1 hour of collection.

PERFORMANCE CHARACTERISTICS

A. Clinical Performance

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

The clinical performance of the Wondfo 2019-nCoV Antigen Test (Asymptomatic) was evaluated by testing nasopharyngeal swabs from symptomatic subjects who were suspected of COVID-19. A total of 703 clinical specimens were tested using the Wondfo 2019-nCoV Antigen Test (Asymptomatic) and were compared to the results of oropharyngeal swab/Nasopharyngeal swab tested with molecular (RT-PCR) assay. The clinical performance of the Wondfo 2019-nCoV Antigen Test (Asymptomatic) was evaluated by testing nasopharyngeal swabs from asymptomatic subjects. A total of 509 clinical specimens were tested using the Wondfo 2019-nCoV Antigen Test (Asymptomatic) and were compared to the results of oropharyngeal swab tested with an Emergency Use Authorized molecular (RT-PCR) assay.

B. Limit of Detection

The Limit of Detection (LoD) of the Wondfo 2019-nCoV Antigen Test (Asymptomatic) was determined using limiting dilutions of UV-inactivated novel coronavirus (ZetopMetix (0.1U/8IU)). The ZetopMetix material is a preparation of SARS-Related Coronavirus 2. Its concentration was USA-WA1/2020. The material was frozen at a concentration of 4.57x10^6 TCID50/mL.

C. Analytical Reactivity/Inclusivity

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

D. Interference

The test result of Wondfo 2019-nCoV Antigen Test (Asymptomatic) was not influenced by the presence of the following substances/conditions:

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.

F. Hook Effect

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

G. Precision

Repeatability & Reproducibility of Wondfo 2019-nCoV Antigen Test (Asymptomatic) 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.

BIBLIOGRAPHY


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<td>Negative Control</td>
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<td>DO NOT USE for specimen collection</td>
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Guangzhou Wondfo Biotech Co., Ltd.
No.2 Liushan Road, Science City, Guangzhou Science City District, 510663, Guangzhou, P.R.China
Tel: +86-20-32053942 400-888-5268(Toll Free)
Fax: +86-20-32296669 E-mail: global@wondfo.com.cn
Website: www.en.wondfo.com.cn

Language: English
Rev.: 20200715

2/2