September 30, 2024

Guangzhou Wondfo Biotech Co., Ltd.
Xiao Kaiyu
Regulatory Affairs Manager
No.8 Lizhishan Road, Science City, Huangpu District
Guangzhou, 510663
China

Re: K241317
Trade/Device Name: Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens
Regulatory Class: Class II
Product Code: QYT
Dated: May 9, 2024
Received: May 10, 2024

Dear Xiao Kaiyu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2024.09.30 13:17:20 -04'00'

Silke Schlottmann, Ph.D.
Deputy Assistant Director
Bacteriology Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241317

Device Name

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)

Indications for Use *(Describe)*

The Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is a visually read lateral flow immunoassay test intended for the qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.
This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.
All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not rule out SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.
This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.
The performance characteristics for SARS-CoV-2 were established from April, 2023 to February, 2024 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Applicant Information

Submitter Name	Guangzhou Wondfo Biotech Co., Ltd.
Address	No.8 Lizhishan Road, Science City, Huangpu District, 510663 Guangzhou, Guangdong, China
Contact Person	Kaiyu Xiao Senior Regulatory Affairs Manager Tel: +86-15005196892 E-mail: kaiyu.xiao@wondfo.com.cn
Date Prepared	September 28, 2024

Device Information

Trade Name	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)
Common Name	2019-nCoV Antigen Test
Classification	Class II
Classification Name	Over-the-counter covid-19 antigen test
Product Code	QYT
Regulation Number	21 CFR 866.3984
Review Panel	Microbiology

Legally Marketed Predicate Device

Trade Name	Flowflex COVID-19 Antigen Home Test
510(k) Number	K230828
Product Code	QYT
Review Panel	Microbiology

1 Device Description

The Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is a lateral flow immunoassay intended for non-prescription home use qualitative detection of nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 within the first five (5) days of symptom onset. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The test cassette in the test kit is assembled with a test strip in a plastic housing that contains a nitrocellulose membrane with two lines: a test line (T line) and a control line (C line).
The device is for *in vitro* diagnostic use only.
The Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) consists of the following components:

- Tube Holder (located in kit box)
- Test Cassette
- Tube (pre-filled extraction buffer)
- Swab
- Quick Reference Instructions

2 Indications for Use

The Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is a visually read lateral flow immunoassay test intended for the qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not rule out SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from April 2023 to February 2024 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

3 Comparison to Predicate Device

The Wondfo 2019-nCoV Antigen Test is substantially equivalent in principle and performance to Flowflex COVID-19 Antigen Home Test (K230828) which had been cleared by FDA. The comparison to predicate device is as follows the table below:

Table 1: Comparison to Predicate Device

Item	**Predicate Device** Flowflex COVID-19 Antigen Home Test (K230828)	**Candidate Device** Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)
Similarities		
Intended Use/ Indications for Use	The Flowflex COVID-19 Antigen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 within the first 6 days of symptom onset. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72	The Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is a visually read lateral flow immunoassay test intended for the qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not rule out SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.

	hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from December 2022 to March 2023 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.	This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from April 2023 to February 2024 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
Test Principle	Lateral flow immunoassay	Lateral flow immunoassay
Sample type	Anterior nasal swab specimens	Anterior nasal swab specimens
Assay targets	SARS-CoV-2 nucleocapsid protein antigens	SARS-CoV-2 nucleocapsid protein antigens

Assay Type	Qualitative	Qualitative
Read Results	Visual	Visual
Intended users and use location	OTC, Patients or its guardians, At home or similar place	OTC, Patients or its guardians, At home or similar place
Storage Temperature	2°C to 30°C	2°C to 30°C
Assay Control	Internal procedural control	Internal procedural control
Differences		
Time to Result	15 minutes to 30 minutes	10 minutes to 20 minutes

4 Operation Principle

The Wondfo 2019-nCoV Antigen Test is a sandwich immunochromatographic assay that uses antibodies to detect SARS-CoV-2 nucleocapsid antigen extracted from nasal swab specimen.

A nasal swab sample is collected by the lay user and then inserted into the extraction buffer during which the extraction buffer disrupts the virus particles in the specimen to expose internal viral nucleocapsid antigens. The extracted specimen is added into the sample well of the test cassette. When an adequate volume of the specimen is added the sample well (S) of the test cassette, the specimen migrated by capillary action from the sample well over the conjugated pad and across the nitrocellulose membrane test strip. During the migration the reagents in the conjugated pad are solubilized. If SARS-CoV-2 nucleocapsid antigens are present in the sample, the antigens bind to the specific annti-SARS-CoV-2 antibody conjugated with dye particles on the conjugated pad and the antigen-antibody complexes captured by the anti-SARS-CoV-2 antibody immobilized at the test line region (T) to form sandwich complexes to generate a visible colored test line. Unbound conjugates continue to migrate across the nitrocellulose membrane and are captured at the control line region (C) to result in a visible colored control line that indicates adequate operations and sample flow during the test. If no SARS-CoV-2 nucleocapsid antigens are present in the sample, the conjugate will only be captured at the control line of the test.

Results are interpreted between 10 and 20 minutes after adding the extracted sample into the sample well. A false negative or false positive result may occur if the test result before 10 minutes or after 20 minutes.

5 Non-clinical Performance

5.1 Lot-to-Lot Precision

Precision was assessed by measuring repeatability using three levels of samples including negative samples, weak positive sample and a positive sample. Samples were prepared in negative clinical nasal swab matrix (NCM), blinded and randomized. 50uL were pipetted onto each swab and swabs were processed per the IFU. The following results were obtained from three kit lots testing each sample in duplicate per run by three operators and two runs per day over 20 days (3 lots × 3 operators × 2 replicates/sample × 2 runs/day/operator × 20 days). A total of 720 tests were run per panel member.
In addition, a supplemental precision study was conducted testing negative samples and a sample below the LoD (0.9 x LoD) to demonstrate potential lot variability. These samples were tested with three lots by two operators for two replicates per run and two run per day over three days (3 lots × 2 operators × 2 replicates/sample × 2 runs/day/operator × 3 days).

Sample Level	% Agreement with Expected Result			
	Lot 1	Lot2	Lot 3	Total
Negative	240/240 (100%)	240/240 (100%)	240/240 (100%)	720/720 (100%)
Weak positive (1.5 x LoD)	240/240 (100%)	240/240 (100%)	240/240 (100%)	720/720 (100%)
Positive (3 x LoD)	240/240 (100%)	240/240 (100%)	240/240 (100%)	720/720 (100%)
Negative	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
0.9x LoD SARS-CoV-2	20/24 (83.33%)	20/24 (83.33%)	24/24 (100%)	64/72 (88.89%)

5.2 Analytical Sensitivity: Limit of Detection

The Limit of Detection (LoD) of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was determined by evaluating different dilutions of two (2) variants of inactivated SARS-CoV-2 in pooled negative nasal swab matrix. A 10-fold dilution series was made to determine the preliminary LoD, which was measured using three (3) device lots in triplicate measurements (n=3/lot). 50uL were pipetted onto each swab and swabs were processed per the IFU. The LoD was confirmed using 20 replicates for each of the same three (3) lots. The lowest viral concentration that was detected greater than or equal to 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive) was determined to be the LoD for that strain. The LoD was the same for all three lots tested.

Variant	Virus Strain	LoD	
		$TCID_{50}$/mL	$TCID_{50}$/swab
Original	USA-WA1/2020	1.0×10^4	500

Omicron BA.5	USA/COR-22-063113/2022	3.33×10^3	166.7

WHO Standard Testing

The Limit of Detection (LoD) of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was determined by using different dilutions of 1st WHO International Standard for SARS-CoV-2 antigen (NIBS code: 21/368) in pooled negative nasal swab matrix. 50uL were pipetted onto each swab and swabs were processed per the IFU. The LoD was determined for three different reagent lots as the lowest virus concentration that was detected ⩾ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The LoD was the same for all three lots tested.

WHO Standard		LoD	
		IU/mL	IU/swab
SARS-CoV-2 antigen	NIBSC code: 21/368	$2.00\text{x}10^2$	10

5.3 Inclusivity (Analytical Reactivity)

Analytical reactivity for Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was demonstrated using six (6) additional strains of SARS CoV-2 virus and one (1) SARS-CoV-2 JN.1 clinical specimen, in an LoD-like study. For six (6) additional strains of SARS CoV-2 virus, a 10-fold dilution series was made to determine the preliminary analytical reactivity concentration, which was measured using three (3) device lots and in triplicate measurements (n=3). The preliminary analytical reactivity concentration was confirmed using 20 replicates in triplicate using the same three (3) lots. 50uL were pipetted onto each swab and swabs were processed per the IFU. The lowest viral concentration that was detected greater than or equal to 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive) was determined to be the analytical reactivity concentration for that strain. For JN.1 variant testing, one (1) clinical specimen was serially diluted and tested with 5 replicates per dilution/concentration. The lowest concentration that detected 5 positive out of 5 samples represents analytical reactivity concentration for JN.1. The analytical reactivity of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) with the variants is shown in table below:

Variant	Virus Strain	Lowest Reactivity Concentration
Alpha	England/204820464/2020	1.0×10^3 $TCID_{50}$/mL
Beta	South_Africa/KRISP-K005325/2020	$1.0\text{x}10^3$ $TCID_{50}$/mL
Gamma	Japan/TY7-503/2021	1.0×10^3 $TCID_{50}$/mL
Delta	USA/PHC658/2021	1.0×10^2 $TCID_{50}$/mL
Omicron B.1.1.529	USA/MD-HP20874/2021	1.0×10^2 $TCID_{50}$/mL
Omicron BA.2.3	USA/MD-HP24556/2022	3.33×10^2 $TCID_{50}$/mL
JN.1	Clinical specimen	Ct=27.9 (2.28×10^4 GE/mL)

5.4 Analytical Specificity

Microorganism Cross-Reactivity and Microbial Interferences

To demonstrate that the device does not react with related viruses, other infectious pathogens, and normal flora that are reasonably likely to be encountered in nasal swab specimens cross-Reactivity and Microbial Interference of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was evaluated by testing 30 microorganisms diluted into negative clinical nasal swab matrix and a sample of pooled nasal wash. Each microorganism was tested in three (3) replicates in the absence and presence of SARS-CoV-2 (USA/COR-22-063113/2022) at 2xLoD. None of the organisms and viruses evaluated demonstrated cross-reactivity or microbial interference in this assay at the concentrations tested.

Microorganism	**Final Concentration**	**Cross-Reactivity** (no analyte) (# pos reps/total reps)	**Interference** (2xLoD SARS-CoV-2) (# pos reps/total reps)
Human coronavirus 229E	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Human coronavirus OC43	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Human coronavirus NL63	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
MERS-coronavirus	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Coronavirus HKU 1 (n=2)*	Ct = 20.5 - 22	0/6	6/6
SARS-CoV Nucleocapsid Protein (His Tag)#	0.25 ng/mL	0/3	3/3
Human Adenovirus 1	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Human Metapneumovirus (hMPV-5) Type B1	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 1	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 2	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 3	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 4A	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Enterovirus	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Rhinovirus	5.62 x $10^4$$TCID_{50}$/mL	0/3	3/3
Influenza A/Victoria/4897/22	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza A/Darwin/6/21	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza B/Washington/02/19	2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza B/Florida/04/06	1.17 x $10^5$$TCID_{50}$/mL	0/3	3/3
Haemophilus influenzae type b	2 x 10^6 CFU/mL	0/3	3/3
Bordetella pertussis	2 x 10^6 CFU/mL	0/3	3/3
Candida albicans	2 x 10^6 CFU/mL	0/3	3/3
Chlamydia pneumoniae	2 x 10^6 IFU/mL	0/3	3/3
Legionella pneumophila	2 x 10^6 CFU/mL	0/3	3/3
Mycoplasma tuberculosis	2 x 10^6 CFU/mL	0/3	3/3
Mycoplasma pneumoniae	2 x 10^6 CCU/mL	0/3	3/3
Staphylococcus aureus MRSA	2 x 10^6 CCU/mL	0/3	3/3
Staphylococcus epidermidis	2 x 10^6 CFU/mL	0/3	3/3

Streptococcus pneumoniae	2 x 10^6 CFU/mL	0/3	3/3
Streptococcus pyogenes	2 x 10^6 CFU/mL	0/3	3/3
Pneumocystis jirovecii (PJP) - S. cerevisiae#	2x10^6 CFU/mL	0/3	3/3
Pooled human nasal wash	NA	0/3	3/3
**Clinical specimens were evaluated* *#Recombinant protein/strains were tested as the live or inactivated strains were hard to obtain*			

Interfering Substances

Forty-two (42) potentially interfering substances, diluted in negative nasal swab matrix, were tested with the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method). Each substance was tested in three (3) replicates in the absence and presence of heat-inactivated SARS-CoV-2 (isolate USA/COR-22-063113/2022) at 2xLoD. The endogenous and exogenous interfering substances do not cross-react or interfere with the performance of the device at the concentrations tested.

Interfering Substances	**Concentration**	**Cross-Reactivity** (no analyte) (# pos reps/total reps)	**Interference** (2xLoD SARS-CoV-2) (# pos reps/total reps)
Whole Blood	2.5%	0/3	3/3
Mucin	2.5mg/mL	0/3	3/3
Chloraseptic sore throat lozenges (Benzocaine)	3mg/mL	0/3	3/3
Chloraseptic sore throat lozenges (Menthol)	3mg/mL	0/3	3/3
NeilMed (Sodium chloride with preservatives)	15% v/v	0/3	3/3
CVS Nasal Drops (Phenylephrine)	15% v/v	0/3	3/3
Afrin (Oxymetazoline)	15% v/v	0/3	3/3
CVS Nasal Spray (Cromolyn)	15% v/v	0/3	3/3
Zicam	15% v/v	0/3	3/3
Homeopathic (Alkalol)	15% v/v	0/3	3/3
Sore Throat Phenol Spray	5% w/v	0/3	3/3
Tobramycin	4 µg/mL	0/3	3/3
Mupirocin	10 mg/mL	0/3	3/3
Fluticasone Propionate	15% v/v	0/3	3/3
Tamiflu (Oseltamivir Phosphate)	5mg/mL	0/3	3/3
Biotin	3.5 µg/mL	0/3	3/3
Menthol	0.015% w/v	0/3	3/3
Bleach	0.01% v/v	0/3	3/3
Dish Soap	1% v/v	0/3	3/3
Laundry Detergent	1% v/v	0/3	3/3
Multisurface Cleaner	1% v/v	0/3	3/3
Hand Soap	1% v/v	0/3	3/3

Interfering Substances	Concentration	Cross-Reactivity (no analyte) (# pos reps/total reps)	Interference (2xLoD SARS-CoV-2) (# pos reps/total reps)
Laundry Detergent	1% w/v	0/3	3/3
Bar Soap	1% w/v	0/3	3/3
Multipurpose Cleaner	1% v/v	0/3	3/3
Hand Sanitizer	1% v/v	0/3	3/3
Aspirin	15 mg/mL	0/3	3/3
Motrin (Ibuprofen)	50 mg/mL	0/3	3/3
Naproxen	20 mg/mL	0/3	3/3
Budesonide	15% v/v	0/3	3/3
Flunisolide	15% v/v	0/3	3/3
Triamcinolone	15% v/v	0/3	3/3
Dexamethasone	5 mg/mL	0/3	3/3
Beclomethasone	15% v/v	0/3	3/3
Remdesivir	5 mg/mL	0/3	3/3
Molnupiravir	5 mg/mL	0/3	3/3
Leukocytes	≥1 x10^6 cells/mL	0/3	3/3
Zinc	15% v/v	0/3	3/3
Luffa opperculata	1.25%	0/3	3/3
Galphimia glauca	15% v/v	0/3	3/3
Histaminum hydrochloricum	15% v/v	0/3	3/3
Zanamivir	10mg/mL	0/3	3/3

5.5 High Dose Hook Effect

No high-dose hook effect was observed when Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was used to test specimens containing SARS-CoV-2 Omicron Lineage BA.5 (hCoV19/USA/COR-22-063113/2022) viral concentration as high as 1.98 x 10^6 $TCID_{50}$/mL.

5.6 Usability and User Comprehension Studies

Usability Study

A usability study was conducted to assess the lay user's ability to understand the instructions for use and to adequately execute the device accordingly. A total of 30 participants, aged 14 years and older and caregiver-child (ages 2-13 years) pairs and caregiver-adult pairs, were enrolled in the study and were observed during testing. A total of 30 participants completed testing monitored by investigators. Following the usability study, all subjects were assessed for their understanding and were issued a questionnaire to assess users' comprehension of the test. The questionnaire was completed by 30 subjects. The questionnaire assessed users' understanding of concepts such as the test

purpose and interpretation of results. The results of each study were deemed acceptable and demonstrated that the instructions for use were easy to follow.

Readability Study

The purpose of this study was to evaluate whether lay users (patients or their caregivers) can interpret test results correctly with low positive samples from the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method). The Readability Study was conducted in a simulated home environment. A total of 50 lay users with diverse gender, ages and educational background who met the study inclusion criteria, were enrolled for the Readability Study. Each lay user was asked to interpret two panels of 5 test devices with three different concentrations that were arranged in blinded test panels with the following sample results; the order of the results within the panel was randomized:

- Panel 1: Negative, 1.5xLoD, 1.5xLoD, 5xLoD, Invalid
- Panel 2: Negative, Negative, 1.5xLoD, 5xLoD, Invalid

42% (21/50) of the study participants were male and 58% (29/50) of the study participants were female. 64% (32/50) of individuals were vision impaired, and 18% (9/50) of individuals were either still at high school or had a high school degree as their highest level of education. Readability outcomes are shown in the table below.

Sample Level	Number of Test Results Across all Participants	Number of Correct Interpretation	Observed Performance (%)
Negative	150	146	97.33%
1.5xLoD	150	140	93.33%
5xLoD	100	100	100%
Invalid	100	100	100%

6 Clinical studies

A prospective study was performed in which one thousand and fifty-three (1053) direct anterior nasal swab specimens were sequentially enrolled (between April 2023 and February 2024) and tested fresh with the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method). The samples were collected from symptomatic patients suspected of infection with respiratory symptoms, at nine (9) clinical sites. Subjects performed testing on self-collected swab samples in age groups 14 and older, and adult collected samples for age groups 2-13, in a simulated at-home environment. To be enrolled in the study, patients had to present at the participating study site with signs and symptoms of respiratory infection generally observed from SARS-CoV-2 during the study period. Two anterior nasal swab specimens were collected from each patient: one swab was collected by a healthcare professional and sent for testing using an FDA-cleared highly sensitive molecular comparator method, and the other swab was self-collected and tested immediately with the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) per the test procedure. Out of 1053 enrolled subjects, there were 1032 evaluable subjects within 5 days of symptom onset (DPSO).

Subjects Demographics

Characteristic	# Evaluable Subjects	% of Total
2-13 years of age	117	11.34%
14-21 years of age	86	8.33%
22-64 years of age	698	67.64%
> 65 years of age	131	12.69%
Total	**1032**	**100%**
Male	414	40.12%
Female	618	59.88%
Total	**1032**	**100%**
Self-collected sample	900	87.21%
Sample collected by other	132	12.79%
Total	**1032**	**100%**

Performance of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) in Symptomatic subjects

		FDA-Cleared Comparator Method		
		Positive	**Negative**	**Total**
The proposed device	**Positive**	108	3	111
	Negative	20	901	921
	Total	128	904	1032
Positive Percent Agreement (PPA)		84.38% (108/128) (95% CI:77.10% - 89.65%)		
Negative Percent Agreement (NPA)		99.67% (901/904) (95% CI:99.03% - 99.89%)		

Clinical Performance in Subjects on Days Post Symptoms Onset

Days Since Symptom Onset	PPA	NPA
0	100.00% (5/5)	100.00% (19/19)
1	90.91% (20/22)	100.00% (153/153)
2	82.35% (28/34)	99.69% (318/319)
3	83.33% (25/30)	99.13% (228/230)
4	86.36% (19/22)	100.00% (116/116)
5	73.33% (11/15)	100.00% (67/67)
Total	**84.38% (108/128)**	**99.67% (901/904)**

7 Conclusion

The information provided in this Premarket Notification [510(k)] demonstrates that the performance of the Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is substantially equivalent in intended use, technological characteristics, and performance to the predicate device.