October 22, 2025

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

Re: K251289
Trade/Device Name: WELLlife COVID-19 Antigen Test Rx
Regulation Number: 21 CFR 866.3982
Regulation Name: Simple Point-Of-Care Device To Directly Detect SARS-Cov-2 Viral Targets From Clinical Specimens In Near-Patient Settings
Regulatory Class: Class II
Product Code: QVF
Dated: April 25, 2025
Received: April 25, 2025

Dear Kaiyu Xiao:

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,

JOSEPH BRIGGS -S

Joseph Briggs, Ph.D.
Deputy Division Director
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.

510(k) Number *(if known)*
K251289

Device Name
WELLlife COVID-19 Antigen Test Rx

Indications for Use *(Describe)*
The WELLlife COVID-19 Antigen Test Rx 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 upper respiratory infection. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the WELLlife COVID-19 Antigen Test Rx and followed with a molecular test.

A negative test result is presumptive, and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Positive results do not rule out co-infection with other respiratory pathogens and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Performance characteristics for SARS-CoV-2 were established from April 2023 to February 2024 when SARS-CoV-2 Omicron was dominant. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.

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.

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510(k) Summary

Applicant Information

Date Prepared	October 17, 2025
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

Device Information

Trade Name	WELLlife COVID-19 Antigen Test Rx
Common Name	COVID-19 Antigen Test
Classification	Class II
Classification Name	Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings
Product Code	QVF
Regulation Number	21 CFR 866.3982
Review Panel	Microbiology

Legally Marketed Predicate Device

Trade Name	Nano-Check COVID-19 Antigen Test
510(k) Number	K231187
Product Code	QVF
Review Panel	Microbiology

1 Device Description

The WELLlife COVID-19 Antigen Test Rx is a lateral flow immunoassay intended for 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 device is for prescription use only.

The WELLlife COVID-19 Antigen Test Rx consists of the following components:

- Test Cassette
- Tube (pre-filled extraction buffer)
- Swab
- Tube Holder
- Quick Reference Instructions (QRI)
- Instructions for Use (IFU)

2 Indications for Use

The WELLlife COVID-19 Antigen Test Rx 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 upper respiratory infection. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the WELLlife COVID-19 Antigen Test Rx and followed with a molecular test.

A negative test result is presumptive, and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Positive results do not rule out co-infection with other respiratory pathogens and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Performance characteristics for SARS-CoV-2 were established from April 2023 to February 2024 when SARS-CoV-2 Omicron was dominant. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.

3 Comparison to Predicate Device

The WELLlife COVID-19 Antigen Test Rx is substantially equivalent in principle and performance to Nano-Check COVID-19 Antigen Test (K231187) which had been cleared by FDA. The comparison to predicate device is as follows the table below:

Table 1: Comparison to Predicate Device

Item	Device	Predicate K231187
Device Trade Name	WELLlife COVID-19 Antigen Test Rx	Nano-Check COVID-19 Antigen Test
General Device Characteristic Similarities		
Intended Use/ Indications for Use	The WELLlife COVID-19 Antigen Test Rx 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 upper respiratory infection. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the WELLlife COVID-19 Antigen Test Rx and followed with a molecular test. A negative test result is presumptive, and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Positive results do not rule out co-infection with other respiratory pathogens and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Performance characteristics for SARS-CoV-2 were established from April 2023 to February 2024 when SARS-CoV-2 Omicron was dominant. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.	The Nano-Check COVID-19 Antigen Test is a lateral flow immunochromatographic assay for the rapid, qualitative detection of SARS-CoV-2 nucleoprotein protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 4 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the Nano-Check COVID-19 Antigen Test and followed with a molecular test. The test does not differentiate between SARS-CoV or SARS-CoV-2. A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Positive results do not rule out co-infection with other bacteria or viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Performance characteristics for SARS-CoV-2 were established during the 2022 SARS-CoV-2 pandemic when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variants are emerging, performance

		characteristics may vary.
Regulation Number	21 CFR 866.3982	Same
Disease Population	COVID-19	Same
Intended Use Setting	Point-of-Care	Same
Test Principle	Lateral flow immunoassay	Same
Sample Type	Direct anterior nasal swab	Same
Assay Target	SARS-CoV-2 nucleocapsid protein antigens	Same
Assay Type	Qualitative	Same
Mode of Results	Visual	Same
Assay Control	Internal procedural control External Control	Same
General Device Characteristic Differences		
Test Time	10 minutes	15 minutes

4 Operation Principle

The WELLlife COVID-19 Antigen Test Rx 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 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.

External positive control and negative control swabs are provided with each kit of WELLlife COVID-19 Antigen Test Rx and should be processed according to the IFU upon receiving a new lot of test

kits. The control swabs are intended to be used as quality control samples representative of positive and negative test samples to demonstrate that the reagents are functional, and the assay procedure is performed correctly.

5 Non-clinical Performance

5.1 Precision

a. Lot-to-Lot Precision

A precision study was conducted to assess variability with respect to days, operators, and device lots. The study included three device lots, each tested every day by three operators for 20 days; testing was conducted in duplicates for each sample concentration (i.e., 3 operators x 20 days x 3 lots x 2 runs per day x 2 replicates per sample per run = 720 results per sample panel member). Three levels of heat inactivated SARS-CoV-2 Omicron Variant lineage BA.5 (Isolate USA/COR-22-063113/2022) were spiked into negative clinical nasal swab matrix (NCM) as follows:

- Negative Sample
- Below LoD Sample at 0.9xLoD
- Low Positive Sample at 1.5xLoD
- Positive Sample at 3xLoD

50µL of each sample was applied to dry nasal swabs. After blinding and randomizing, samples were processed per the IFU of the candidate device.

Precision was observed to be 100% for all replicates prepared at 1.5xLoD and 3xLoD, demonstrating no variability in the performance of the candidate assay across the conditions, operators, lots, and days tested.

Precision study samples were therefore prepared at 0.9xLoD using the same materials for sample preparation as for the original study. These samples were then tested as follows: 2 operators x 3 lots x 3 days x 2 runs per day x 2 replicates per sample per run and resulted in a total of 72 replicates. The precision for the 0.9xLoD sample was less than 100%, which is expected based on the random error for a sample below the LoD. However, the performance was consistent across all three lots tested.

Table 2: Lot-to-Lot Precision Study Results

Sample	**Negative (n/N)**			**Below LoD (0.9xLoD) (n/N)**		**Low Positive (1.5xLoD) (n/N)**			**Positive (3xLoD) (n/N)**		
Operator	**1**	**2**	**3**	**1**	**2**	**1**	**2**	**3**	**1**	**2**	**3**
Lot 1	0/80	0/80	0/80	11/12	9/12	80/80	80/80	80/80	80/80	80/80	80/80
Lot 2	0/80	0/80	0/80	10/12	10/12	80/80	80/80	80/80	80/80	80/80	80/80
Lot 3	0/80	0/80	0/80	12/12	12/12	80/80	80/80	80/80	80/80	80/80	80/80
Agreement	**NPA = 100% (720/720)**			**PPA = 88.89% (64/72)**		**PPA = 100% (720/720)**			**PPA = 100% (720/720)**		
95%CI	99.47%, 100%			79.58%, 94.26%		99.47%, 100%			99.47%, 100%		

b. Site-to-site Reproducibility

A multisite precision study was performed at three external CLIA-waived testing sites to evaluate reproducibility of the WELLlife COVID-19 Antigen Test Rx. Testing consisted of three replicates each of positive (3x LoD), weak positive (1x LoD), low positive (0.8x LoD), high negative (0.1x LoD) and negative samples tested by three (3) untrained operators per site over 5 days, i.e., 3 replicates × 3 operators × 3 sites × 5 days = 135 replicates per concentration for a total of 675 total data points collected. Fifty (50) µL of the prepared sample were applied to kit swabs, shipped and stored frozen until testing.

Table 3. Site-to-Site Reproducibility Study Results

Site	Operator	True Negative	High Negative	Low Positive	Weak Positive	Moderate Positive
A	n=3	45/45	45/45	40/45	44/45	45/45
B	n=3	45/45	45/45	40/45	45/45	45/45
C	n=3	45/45	45/45	39/45	45/45	45/45
Total		135/135	135/135	119/135	134/135	135/135
%Agreement		100%	100%	88.2%	99.3%	100%
95% CI		97.2%-100%	97.2%-100%	81.6%-92.6%	95.9%-99.9%	97.2%-100%

5.2 Detection Limit

a. Limit of Detection

The limit of detection of the WELLlife COVID-19 Antigen Test Rx was determined with UV-inactivated SARS-CoV-2 USA-WA1/2020, BA.5 Omicron and heat inactivated XBB Omicron isolates. Inactivated SAR-CoV-2 virus was diluted into NCM in 10-fold dilutions. Fifty (50) µl of each dilution was added directly to the test swab and the sample was then processed per the instructions for use. The LoD was assessed with three independent device lots. For the preliminary LoD study, testing was performed with three replicates and the lowest concentration with >95% detection was then tested with 20 replicates to confirm the LoD.

Table 4. LoD Study Study Results

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
Omicron XBB	hCoV-19/USA/CA-STANFORD-109_S21/2022	1.0×10^4	500

b. Limit of Detection with the 1st WHO International Standard (NIBSC 21/368)

SARS-CoV-2 antigen (NIBSC code: 21/368) spiked into pooled nasal swab sample in saline. The unitage of this material has an assigned value of 5,000 International Units (IU) of SARS-CoV-2 antigen per ampoule when reconstituted per instructions. A 10-fold dilution series was made to determine the preliminary LoD, which was measured using three (3) device lots and in triplicate measurements (n=3). The LoD was confirmed using 20 replicates (n=20) per dilution. The measurements were done by adding 50µl of each dilution directly to the test swab and processing the

sample per the test's instructions for use. The lowest concentration of the SARS-CoV-2 antigen at which a minimum of 95% of results were positive was confirmed to be 200 IU/mL or 10 IU/Swab.

Table 5. LoD Study Summary with 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368)

WHO Standard		LoD	
		IU/mL	IU/swab
SARS-CoV-2 antigen	NIBSC code: 21/368	$2.00x10^2$	10

5.3 Inclusivity

An evaluation of the sensitivity of the test for the detection of relevant SARS-CoV-2 variants was done in form of an LoD study with seven (7) different SARS-CoV-2 variant strains. Three lots of the WELLlife COVID-19 Antigen Test Rx were used. Samples for inclusivity testing were prepared with the same methodology as detailed above for the Limit of Detection study. Viral samples were tested per the IFU in triplicate to first establish the preliminary LoD and then subsequently in replicates of 20 for the confirmatory LoD. The lowest concentration that detected ≥95% of all replicates for each evaluated SARS-CoV-2 strain is shown below.

Beyond the testing described above, Omicron JN.1.1 was independently evaluated with the test showing detection down to 2.28 $x10^4$ GE/mL (corresponding to an average Ct of 27.9).

Table 6. Analytical Reactivity of SARS-CoV-2 Variants

Strain/Viral Material	Reactivity (Number positive/ Number tested)			LoD ($TCID_{50}$/mL)
	Lot 1	Lot 2	Lot 3	
SARS-CoV-2 Variant B.1.1.7 (Alpha Variant)	23/23	23/23	23/23	1×10^3
SARS-CoV-2 Lineage B.1.351 (Beta variant)	23/23	23/23	23/23	1×10^3
SARS-CoV-2 Variant Brazil Lineage P.1 (Gamma variant)	23/23	23/23	23/23	1×10^3
SARS-CoV-2 Lineage B.1.617.2 (Delta Variant)	23/23	23/23	23/23	1×10^2
SARS-CoV-2 Lineage B.1.1.529 (Omicron Variant)	23/23	23/23	23/23	1×10^2
SARS-CoV-2 Lineage BA 2.3 (Omicron Variant)	23/23	23/23	23/23	3.33×10^2
Strain/Viral Material	**Reactivity (Number positive/ Number tested)**			**LoD (GE/mL*)**
	Lot 4			
SARS-CoV-2 JN.1.1 (live)	5/5			$2.28 x10^4$

** GE: Genome equivalent/mL*

5.4 Analytical Specificity

a. Cross-Reactivity and Microbial Interference

A panel of microorganisms commonly found as either pathogens or normal flora in respiratory samples were individually spiked into NCM. In the cross-reactivity study, the organisms were evaluated for their ability to cross-react with the test by adding 50µl of each sample directly to the test

swab and then processing the sample swabs per the IFU. The microbial interference testing was conducted in the same manner but in the presence of SARS-CoV-2 Omicron Variant lineage BA.5 co-spiked into the samples at 2-3xLoD. The testing was performed in triplicates for each microorganism. Neither cross-reactivity nor microbial interference was observed for any of the tested microorganisms at the concentration used in the study.

Table 7. Cross-Reactivity and Microbial Interference Testing Results

Microorganism	**Final Concentration**	**Cross-Reactivity** (no analyte) (# pos reps/total reps)	**Interference** (3xLoD 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*#	Ct = 20.5 Ct = 22	0/3	3/3
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

Microorganism	**Final Concentration**	**Cross-Reactivity** (no analyte) (# pos reps/total reps)	**Interference** (3xLoD SARS-CoV-2) (# pos reps/total reps)
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
** Two different clinical samples were tested in replicates of three.* *# Tested with 2xLoD of SARS-CoV-2 Omicron Variant lineage BA.5 while the other potential cross-reactants/interferents were tested at 3xLoD.* *** Recombinant protein/strains were tested as the live or inactivated strains were hard to obtain.*			

b. Endogenous / Exogenous Interfering Substances Study

A panel of common endogenous and exogenous substances were evaluated for their potential to interfere with the performance of the test device. Samples were contrived by individually adding the substances listed in Table 8 below and testing them in NCM with or without SARS-CoV-2 virus at 2-3xLoD. 50 µL of each contrived sample was applied to the head of a swab and processed per the proposed IFU of the test. One device lot was used to test the potential interferents in triplicate measurements. No erroneous results were observed.

Table 8. Endogenous / Exogenous Interfering Substances Summary

Interfering Substances	**Concentration**	**Cross-Reactivity** (no analyte) (# pos reps/total reps)	**Interference** (3xLoD 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

Interfering Substances	**Concentration**	**Cross-Reactivity** (no analyte) (# pos reps/total reps)	**Interference** (3xLoD SARS-CoV-2) (# pos reps/total reps)
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
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
Sulfur*	1.25%	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
** Tested with 2xLoD of SARS-CoV-2 Omicron Variant lineage BA.5 while the other potential interferents were tested at 3xLoD.*			

5.5 High Dose Hook Effect

An assessment of whether a high dose hook effect exists for the test was done using a serial dilution of UV-inactivated SARS-CoV-2 virus strains. Multiple virus strains were tested, each spiked into negative NCM. 50µl of sample was added directly to the head of the swabs. Swabs were processed per the test's IFU/QRI. Testing was done across three device lots. Each of the 3 operators performed triplicate measurements for each concentration per lot. No high dose hook effect was observed in the study for any of the strains. Only the data for the most relevant contemporary strain tested in this study (i.e., SARS-CoV-2 Omicron Lineage BA.5) are shown in **Table 9** below.

Table 9. High Dose Hook Effect Data Summary

Virus Concentration ($TCID_{50}$/mL)	Test Results (Agreement #positive /# Total)		
	Lot 1	Lot 2	Lot 3
$1.98x10^6$	3/3	3/3	3/3
$1x10^5$	3/3	3/3	3/3
$1x10^4$	3/3	3/3	3/3
$1x10^3$	0/3	0/3	0/3
$1x10^2$	0/3	0/3	0/3
$1x10^1$	0/3	0/3	0/3

5.6 Usability and User Comprehension Studies

a. Usability Study

The usability of the test was assessed with a sub cohort of the clinical study. During this study, representative test kit users (self-testers aged 14+, caregiver-child pairs, and caregiver-adult pairs) were observed performing the WELLlife COVID-19 Antigen Test Rx while using the IFU/QRI. The observers recorded the proper execution of each task when the enrolled lay user study subject (n=30) conducted the test. The observers did not otherwise interfere with the study subject's sample collection and testing.

Table 10. Usability Study Results

Tasks	Critical (C) or Non-critical (NC)	Task Performed Correctly	Acceptability
Wash hands	NC	86.7% (26/30)	Yes
Check expiration date	NC	73.3% (22/30)	Yes
Unpack kit	NC	100% (30/30)	Yes
Open Tube Cap	NC	100% (30/30)	Yes
Place Tube in tube holder	NC	100% (30/30)	Yes
Remove swab from pouch without contamination/touching tip	C	100% (30/30)	Yes
Swab first nostril 5x/15sec	C	100% (30/30)	Yes
Swab second nostril 5x/15 sec	C	96.7% (29/30)	Yes
Insert swab into tube/touch bottom	C	100% (30/30)	Yes
Stir swab (15x or more)	C	100% (30/30)	Yes

Tasks	Critical (C) or Non-critical (NC)	Task Performed Correctly	Acceptability
Place tube in holder/Keep swab in tube for 1 minute	C	93.3% (28/30)	Yes
Remove swab while squeezing sides of tube	C	90% (27/30)	Yes
Cap tube	NC	100% (30/30)	Yes
Remove cassette from pouch & use within 1 hour	NC	100% (30/30)	Yes
Open Tube Cap	NC	96.7% (29/30)	Yes
Add 4 drops of sample to sample well	C	96.7% (29/30)	Yes
Set timer to wait 10 minutes (no more than 20 minutes) to read results	C	96.7% (29/30)	Yes

b. Readability Study

A readability and comprehension study with lay persons was conducted to evaluate the ability of the intended lay user to correctly read and interpret their test results. Fifty (50) participants were enrolled in the readability and comprehension study. Each study subject was provided with eight randomized mock tests (2 panels with 4 mock devices each) of different concentrations, which they were asked to interpret per the IFU. After interpreting the mock tests, the study subjects were provided with a questionnaire to assess their comprehension of the test results. Each lay user was asked to interpret two panels of 5 test devices with three different concentrations that were arranged in a randomized and blinded manner, with the following sample results:

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

Table 11. Mock Test Interpretation Summary Results

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 Flex Studies

To assess the robustness and risk for false results of the test when deviating from the IFU/QRI test steps, flex studies were conducted that assessed all major aspects of the test procedure (sample volume, reading time, swab extraction time, swab rotation, and tube squeezing) and variability of environmental test conditions that the test may be subjected to when in use (lighting, disturbance during use, temperature, and humidity stress conditions). Testing was performed with contrived positive nasal swabs generated by diluting SARS-CoV-2 virus into negative NCM at 2xLoD. False results are observed with too little sample volume and insufficient incubation time, specifically with less than two

drops of sample and with less than five minutes incubation. However, these failures are mitigated in the labeling with warning statements in the procedural steps. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

7 Clinical studies

A prospective lay person clinical study was conducted to assess the performance of the candidate test in a simulated at-home setting when compared to a highly sensitive 510(k)-cleared SARS-CoV-2 RT-PCR assay with an extraction step. The study enrolled symptomatic subjects at nine (9) clinical study sites between April 2023, and February 2024, when Omicron was the most prevalent SARS-CoV-2 strain in the U.S.

Both the comparator and the candidate test used anterior nasal swab samples, and the sample collection order was alternated (randomized) for each study subject. Comparator test samples were collected by health care professionals at the clinical study site and inserted into Universal Transport Media per the IFU of the comparator test. Samples for the candidate antigen test were collected per the test's QRI and were either self-collected by a lay user aged ≥14 years or collected by an adult (parent/guardian) from individuals aged 2 to <14 years.

This study enrolled a total of 1,053 individuals. Of the 1,053 results obtained, 21 were excluded and 1,032 were considered evaluable. The clinical performance estimates are based on these 1,032 study subjects between 0 and 5 DPSO. The 1,032 results consisted of 128 positive and 904 negative study subjects as defined by the comparator result. The WELLlife COVID-19 Antigen Test Rx demonstrated the following performance, when compared to the result of the SARS-CoV-2 RT-PCR comparator assay:

• Positive Percent Agreement (PPA) of 84.38% (108/128) (95% CI: 77.10%, 89.65%)

• Negative Percent Agreement (NPA) of 99.67% (901/904) (95% CI: 99.03%, 99.89%).

Table 12 Demographics - Clinical Study Participants

Characteristic	Number of Evaluable Subjects	% of Total
Age		
2-13 years of age	117	11.34%
14-21 years of age	86	8.33%
22-64 years of age	698	67.64%
≥ 65years of age	131	12.69%
Total	**1,032**	**100%**
Gender		
Male	414	40.12%
Female	618	59.88%
Total	**1,032**	**100%**
Sample Collector		
Self-collected sample	900	87.21%
Sample collected by other	132	12.79%
Total	**1,032**	**100%**

Table 13. Clinical Performance Estimates

Candidate Test	Comparator Test		
	Positive	**Negative**	**Total**
Positive	108	3	111
Negative	20	901	921
Total	**128**	**904**	**1,032**
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%)*			

Table 14. Clinical Performance Stratified by DPSO

Days Post Symptom Onset	PPA	NPA
0	100% (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)**

8 Conclusion

The information provided in this Premarket Notification [510(k)] demonstrates that the performance of the WELLlife COVID-19 Antigen Test Rx is substantially equivalent in intended use, technological characteristics, and performance to the predicate device.