January 16, 2025

Wondfo USA Co., Ltd.
Kaiyu Xiao
Senior Regulatory Affairs Manager
6720 Cobra Way
San Diego, California 92121

Re: K243256

Trade/Device Name:	WELLlife COVID-19 / Influenza A&B Home Test WELLlife COVID-19 / Influenza A&B AntigenTest
Regulation Number:	21 CFR 866.3987
Regulation Name:	Multi-Analyte Respiratory Virus Antigen Detection Test
Regulatory Class:	Class II
Product Code:	SCA
Dated:	October 14, 2024
Received:	October 15, 2024

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,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2025.01.16 18:19:24 -05'00'

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.

510(k) Number *(if known)*
K243256

Device Name
WeLLlife COVID-19 / Influenza A&B Home Test;
WeLLlife CVOID-19 / Influenza A&B Antigen Test

Indications for Use *(Describe)*

WELLlife COVID-19 / Influenza A&B Home Test :
The WELLlife™ COVID-19 / Influenza A&B Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. 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 and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens.
Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.
Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

WELLlife COVID-19 / Influenza A&B Antigen Test:
The WELLlife™ COVID-19 / Influenza A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing aged 2 years or older.
All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens.
Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers.
Positive results do not rule out co-infection with other respiratory pathogens.
Test results should not be used as the sole basis for treatment or other patient management decisions.

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

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the following 510(k) Summary for WELLlife COVID-19 / Influenza A&B Home Test / WELLlife COVID-19 / Influenza A&B Antigen Test is provided:

Applicant Information

Submitter Name	Wondfo USA Co., Ltd.
Address	6720 Cobra Way San Diego, CA, 92121
Contact Person	Kaiyu Xiao Senior Regulatory Affairs Manager Tel: +86-15005196892 E-mail: kaiyu@wondfousa.com
Date Prepared	January 9, 2025

Device Information

Trade Name	WELLlife COVID-19 / Influenza A&B Home Test WELLlife COVID-19 / Influenza A&B Antigen Test
Common Name	Multi-analyte respiratory virus antigen detection test
Classification	Class II
Classification Name	Multi-analyte respiratory virus antigen detection test
Product Code	SCA
Regulation Number	21 CFR 866.3987
Review Panel	Microbiology

Legally Marketed Predicate Device

Trade Name	Healgen Rapid Check COVID-19/flu A&B Antigen Test
510(k) Number	DEN240029
Product Code	SCA
Review Panel	Microbiology

1 Device Description

The WELLlife™ COVID-19 / Influenza A&B Home Test and the WELLlife™ COVID-19 / Influenza A&B Antigen Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens. The test has two versions, one for over the counter (OTC) use, the (WELLlife™ COVID-19 / Influenza A&B Home Test), and one for professional use (WELLlife™ COVID-19 / Influenza Antigen A&B). Both versions of the WELLlife™ COVID-19 / Influenza A&B Tests that have an identical general design and are intended for the qualitative detection of nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with respiratory signs and symptoms within the first four (4) days of symptom onset. Results are for the identification and differentiation of nucleocapsid protein antigen from SARS-CoV-2, nucleoprotein antigen from influenza A virus, and nucleoprotein antigen from influenza B virus. The test cassette in the test kit is assembled with a test strip in a plastic housing that contains a nitrocellulose membrane with four lines: three test lines (Flu A line, Flu B line and CoV line) and a control line (C line). The device is for in vitro diagnostic use only. The device is for over-the-counter use.

2 Indications for Use

The WELLlife™ COVID-19 / Influenza A&B Home Test:

The WELLlife™ COVID-19 / Influenza A&B Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. 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 and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens.

Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

The WELLlife™ COVID-19 / Influenza A&B Antigen Test:

The WELLlife™ COVID-19 / Influenza A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals

aged 14 years or older testing themselves, or adults testing aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens.

Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers.

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

Test results should not be used as the sole basis for treatment or other patient management decisions.

3 Comparison to Predicate Device

The WELLlife™ COVID-19 / Influenza A&B Home Test / WELLlife™ COVID-19 / Influenza A&B Antigen Test is substantially equivalent in principle and performance to Healgen Rapid Check COVID-19/Flu A&B Antigen Test (DEN240029) which had been granted by FDA. The comparison to predicate device is as follows the table below:

Table 1: Comparison with Predicate Device

Item	**Predicate Device** Healgen Rapid Check COVID-19/Flu A&B Antigen Test (DEN240029)	**Candidate Device** WELLlife COVID-19 / Influenza A&B Home Test WELLlife COVID-19 / Influenza A&B Antigen Test.
Intended Use/ Indications for Use	The Healgen Rapid Check COVID-19/Flu A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or	The WELLlife™ COVID-19 / Influenza A&B Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. 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 and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.

	adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.	Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up. The WELLlife™ COVID-19 / Influenza A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers. Positive results do not rule out co-infection with other respiratory pathogens. Test results should not be used as the sole basis for treatment or other patient management decisions.
Regulation Number	21 CFR 866.3987	Same
Disease Population	Respiratory tract infection	Same
Intended users / User Environment	OTC Lay User	Same
Test Principle	Lateral flow immunoassay	Same
Sample type	Anterior nasal swab specimens	Same
Assay targets	SARS-CoV-2 nucleocapsid protein antigens Nucleoprotein antigen from influenza A virus Nucleoprotein antigen from influenza B virus	Same
Assay Type	Qualitative	Same

Mode of Results	Visual	Same
Assay Control	Internal procedural control	Same
Storage Temperature	2°C to 30°C	Same
Differences		
Time to Result	15 minutes - 20 minutes	10 minutes - 20 minutes

4 Operation Principle

The WELLlife™ COVID-19 / Influenza A&B Home Test / WELLlife™ COVID-19 / Influenza A&B Antigen Test (generically referred to as WELLlife™ COVID-19 / Influenza A&B Tests for the remainder of this document) consist of a test cassette that separately detects influenza A, influenza B, and SARS-CoV-2 antigens. The test procedure requires the anterior nasal swab specimen to be inserted into the prefilled extraction buffer tube to be solubilized, and then the specimen is eluted. The virus particles in the specimen are disrupted by the chemicals in the extraction buffer, exposing internal viral nucleoproteins. After the release of specimen, the swab is discarded. The extracted specimen is then dropped into the sample well of the test cassette.

If SARS-CoV-2, influenza A and/or influenza B antigens are present in the specimen, they will react with SARS-CoV-2 antibody coupled to dye particles and/or influenza antibody coupled to dye particles, migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody line(s) on the membrane, and generate a colored pink to red line in the specific test line position. The rest of the sample and rabbit IgG dye particle complexes continue to migrate to the Control line position (C), where immobilized goat anti-rabbit IgG will capture the rabbit IgG dye particle complexes and form the Control line. Formation of the pink to red Control line serves as an internal control to demonstrate that test reagents are functional, antibody-dye conjugates in the dye pad have been hydrated and released and that sufficient sample has been applied to allow for migration through the Test and Control lines. If the Control line does not appear within the designated incubation time, the result is invalid, and the test should be repeated using a new test device and specimen.

If the antigen level is equal to or above the detection limit, a visible colored band appears at the test region. Absence of this pink to red colored band in the test region of test strip and only a visible control line will appear, suggests a negative result.

WELLlife™ COVID-19 / Influenza A&B Home Test has three Test lines, one for COVID-19, one for influenza A and one for influenza B. The three Test lines allow for the separate and differential identification of COVID-19, influenza A and/or B from a single specimen. If any Test line appears in the test result window, together with the Control line, the test result is positive for COVID-19 and/or influenza.

Results can be interpreted between 10 and 20 minutes after adding the extracted sample into the sample well.

5 Non-clinical Performance

The WELLlife™ COVID-19 / Influenza A&B Home Test and the WELLlife™ COVID-19 / Influenza A&B Antigen Test are generally identical in design but have slightly different instructions to accommodate lay users and professional users. The following performance data were generated using the WELLlife™ COVID-19 / Influenza A&B Home Test and its QRI, but are applicable to both versions/configurations of the test.

5.1 Lot-to-Lot Precision

A single-site lot-to-lot precision study was conducted to measure repeatability using three levels of contrived samples. A panel of three samples was tested: a negative sample (PNSM only), low positive sample (2x co-spike LoD of all analytes), moderate positive sample (5x co-spike LoD of all analytes). The strains used for testing were UV-inactivated SARS-CoV-2 USA-WA1/2020, live influenza A H1N1, and live influenza B Yamagata. One replicate per sample type was tested per run, per operator, and per lot across 10 days with two test runs per day for a total of 120 results per sample type (3 lots x 2 operators x 1 replicate x 10 days x 2 runs per day).

In addition, a supplemental precision study was conducted testing negative samples, a sample with spiked 0.9 x LoD SARS-CoV-2 and 0.8 x LoD Flu B and a sample spiked with 0.9 x LoD Flu A 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).

Repeatability was determined by comparing test results to expected results across all lots, operators, and days. Results are shown in the table below.

Table 2: Summary of Lot-Lot Precision Results

Sample	Analyte	% Agreement with Expected Result			
		Lot 1	Lot 2	Lot 3	Total
Negative	SARS-CoV-2	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu A	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu B	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
2x LoD	SARS-CoV-2	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu A	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu B	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
5x LoD	SARS-CoV-2	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu A	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu B	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
Negative	SARS-CoV-2	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
	Flu A	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
	Flu B	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
<1X LoD SARS-CoV-2 and Flu B Co-Spiked	SARS-CoV-2	16/24 (67%)	22/24 (92%)	20/24 (83%)	58/72 (81%)
	Flu A	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
	Flu B	22/24 (92%)	23/24 (96%)	18/24 (75%)	63/72 (88%)

Sample	Analyte	% Agreement with Expected Result			
		Lot 1	Lot 2	Lot 3	Total
<1X LoD Flu A	SARS-CoV-2	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
	Flu A	20/24 (83%)	24/24 (100%)	19/24 (79%)	63/72 (88%)
	Flu B	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)

5.2 Analytical Sensitivity: Limit of Detection

a) Limitation of Detection

The limit of detection (LoD) for SARS-CoV-2 and influenza A and B in WELLlife™ COVID-19 / Influenza A&B Home Test was determined by evaluating different concentrations of UV-inactivated SARS-CoV-2 and live influenza A and B viruses. The viruses were diluted in pooled negative swab matrix (PNSM) to generate virus dilutions for testing. Anterior nasal swab samples were prepared by adding 50µL of each virus dilution onto the sterile swab. The swab samples were tested according to the test procedure in package insert. Range-finding testing was conducted with three replicates at various dilutions and confirmatory testing was conducted with 20 replicates. The lowest concentration that generated ≥95% positive detection rate was set as the LoD concentration.

Table 3: Summary of Limit of Detection (LoD) Results

Virus Strains	Stock Concentration ($TCID_{50}$/mL)	LoD ($TCID_{50}$/mL)	LoD ($TCID_{50}$/Swab)	#Positive/ #Total	Percent Detected (%)
SARS-CoV-2 USA-WA1/2020 (UV inactivated)	3.16×10^{6}	7.90×10^{2}	39.5	60/60	100%
Influenza A A/Victoria/4897/2022(H1N1) (live)	2.02×10^{5}	1.01×10^{2}	5.05	60/60	100%
Influenza A A/Darwin/6/2021(H3N2) (live)	4.17×10^{5}	2.09×10^{2}	10.45	60/60	100%
Influenza B B/Washington/02/2019(Victoria) (live)	3.16×10^{6}	3.16×10^{3}	158	60/60	100%
Influenza B B/Florida/4/2006 (Yamagata) (live)	1.17×10^{5}	5.85×10^{1}	2.93	60/60	100%

b) 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368)

A preliminary LoD concentration of the WELLlife™ COVID-19 / Influenza A&B tests for the 1st WHO International Standard for SARS-CoV-2 antigen is determined by testing a series of 2-fold dilutions, starting with a 5-fold dilution from the stock

concentration (20,000 IU/mL) of the International Standard, spiked into PNSM. The lowest 2-fold dilution concentration at which all three replicates test positive is identified as the preliminary 1X LoD. The preliminary 1X LoD, and two concentrations (preliminary 0.33X LoD and preliminary 3X LoD) were confirmed by testing an additional twenty (20) spiked PNSM samples.

Table 4: Summary of LoD Results with the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC code:21/368)

Concentration of WHO International Standard for SARS-CoV-2 antigen		Positive results / Total
IU/mL	IU/Swab	
$5x10^2$ IU/mL	25	20/20

c) Inclusivity

The analytical reactivity of the antibodies targeting Influenza A, influenza B, and SARS-CoV-2 in WELLlife™ COVID-19 / Influenza A&B Home Test was evaluated with the currently available strains.

Table 5: Summary of Inclusivity Results

Influenza Virus (Type/Subtype)	Virus Strain Name	Minimum Detectable Concentration	Positive/ Replicates
SARS-CoV-2 (XBB.1.5)	hCoV-19/USA/MD-HP40900/2022	7.8 $x10^1$ $TCID_{50}$/mL	10/10
SARS-CoV-2 (JN.1)	JN.1 variant derived from clinical sample	9.18 x 10^4 GE/mL	5/5
A(H1N1)pdm09	A/California/04/2009	2.80 $x10^3$ $TCID_{50}$/mL	3/3
	A/Brisbane/02/18	1.51 $x10^2$ $TCID_{50}$/mL	3/3
	A/Michigan/45/15	1.86 $x10^1$ $TCID_{50}$/mL	3/3
	A/Guangdong-Maonan/SWL 1536/19	2.09 $x10^2$ $TCID_{50}$/mL	3/3
	A/NY/03/09	2.29 $x10^4$ $TCID_{50}$/mL	3/3
	A/Indiana/02/2020	9.70 $x10^6$ $CEID_{50}$/mL	3/3
	A/Wisconsin/588/2019	7.00 $x10^3$ FFU/mL	3/3
	A/Sydney/5/2021	4.80 $x10^3$ $TCID_{50}$/mL	3/3
	A/Hawaii/66/2019	1.85 $x10^7$ $CEID_{50}$/mL	3/3
	A/Wisconsin/67/22	4.21 $x10^2$ $TCID_{50}$/mL	3/3
A(H3N2)	A/Tasmania/503/2020	1.30 $x10^5$ FFU/mL	3/3
	A/New York/21/2020	2.60 $x10^5$ FFU/mL	3/3
	A/Alaska/01/2021	3.75 $x10^4$ FFU/mL	3/3
	A/Hong Kong/45/2019	1.50 $x10^4$ FFU/mL	3/3
	A/Hong Kong/2671/19	1.05 $x10^3$ $TCID_{50}$/mL	3/3

Influenza Virus (Type/Subtype)	Virus Strain Name	Minimum Detectable Concentration	Positive/ Replicates
	A/Indiana/08/2011	8.10 x10^2 $TCID_{50}$/mL	3/3
A(H1N1)	A/Ohio/09/2015	7.00 x10^5 $CEID_{50}$/mL	3/3
A(H1N2)	A/Minnesota/19/2011	4.00 x10^6 $CEID_{50}$/mL	3/3
A(H5N1)	A/mallard/Wisconsin/2576/2009	4.00 x10^5 $CEID_{50}$/mL	3/3
	A/duck/Guangxi/S11002/2024	3.38 x10^5 EID_{50}/mL	3/3
A(H5N6)	A/duck/Guangxi/S10888/2024	6.76 x10^5 EID_{50}/mL	3/3
A(H5N8)	A/goose/Liaoning/S1266/2021	6.76 x10^5 EID_{50}/mL	3/3
A(H7N3)	A/northern pintail/Illinois/10OS3959/2010	7.00 x10^5 $CEID_{50}$/mL	3/3
B(Non Victoria and Non Yamagata)	B/Maryland/1/59	3.38 x10^3 $CEID_{50}$/mL	3/3
B(Victoria lineage)	B/Brisbane/60/2008	1.29 $TCID_{50}$/mL	3/3
	B/Colorado/06/17	5.85 x10^1 $TCID_{50}$/mL	3/3
	B/Texas/02/2013	2.45 x10^1 $TCID_{50}$/mL	3/3
	B/Michigan/01/2021	1.43 x10^4 $TCID_{50}$/mL	3/3
B(Yamagata lineage)	Yamagata – B/Texas/06/2011	7.55 x10^2 $TCID_{50}$/mL	3/3
	Yamagata – B/Utah/09/2014	1.26 x10^3 $TCID_{50}$/mL	3/3
	B/Wisconsin/01/2010	1.78 x10^2 $TCID_{50}$/mL	3/3

5.3 Analytical Specificity

a) Microorganism Cross-Reactivity and Microbial Interference

Cross-reactivity of the WELLlife™ COVID-19 / Influenza A&B Home Test was evaluated by testing a panel of related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens and could potentially cross-react with the WELLlife™ COVID-19 / Influenza A&B Home Test including twenty (20) bacteria, twenty (20) viruses and one (1) negative matrix. Each organism and virus were tested in triplicate the absence (cross-reactivity) or presence (interference) of co-spiked UV-inactivated SARS-CoV-2, influenza A, and B at 3 x LoD. No cross-reactivity was observed with the listed microorganisms when tested at the concentration presented in the table below. No interference was observed with the listed microorganisms when tested at the concentration presented in the table below in the presence of the target analytes.

Table 6: Summary of Cross-reactivity and Microbial Interference Results

Potential Cross-Reactant	Concentration Tested
SARS-CoV-1	1.25 x10^5 PFU/ml
MERS-coronavirus	1.47 x10^5 $TCID_{50}$/mL
Human coronavirus HKU1	1.74 x10^7 GE/mL (Ct 20.7)

Potential Cross-Reactant	Concentration Tested
Human coronavirus OC43	7.00 x10^5 $TCID_{50}$/mL
Human coronavirus 229E	1.58 x10^5 $TCID_{50}$/mL
Human coronavirus NL63	7.05 x10^4 $TCID_{50}$/mL
Adenovirus Type 1	2.23 x10^5 $TCID_{50}$/mL
Adenovirus Type 7	1.58 x10^5 $TCID_{50}$/mL
Cytomegalovirus	7.05 x10^4 $TCID_{50}$/mL
Epstein Barr Virus	1.83 x10^6 CP/mL
Human Metapneumovirus	3.50 x10^5 $TCID_{50}$/mL
Parainfluenza virus 1	2.00 x10^5 $TCID_{50}$/mL
Parainfluenza virus 2	1.75 x10^5 $TCID_{50}$/mL
Parainfluenza virus 3	7.00 x10^5 $TCID_{50}$/mL
Parainfluenza virus 4	2.39 x10^5 $TCID_{50}$/mL
Enterovirus Type 68	2.23 x10^5 $TCID_{50}$/mL
Respiratory syncytial virus A	3.50 x10^5 $TCID_{50}$/mL
Respiratory syncytial virus B	2.29 x10^5 $TCID_{50}$/mL
Rhinovirus 1A	7.05 x10^4 $TCID_{50}$/mL
Bordetella pertussis	2.90 x10^8 CFU/mL
Candida albicans	1.21 x10^7 CFU/mL
Chlamydia pneumoniae	4.33 x10^6 IFU/mL
Corynebacterium xerosis	2.30 x10^7 CFU/mL
Escherichia coli	1.79 x10^8 CFU/mL
Hemophilus influenzae	9.68 x10^6 CFU/mL
Lactobacillus Acidophilus	1.21 x10^7 CFU/mL
Legionella spp pneumophila	6.50 x10^6 CFU/mL
Moraxella catarrhalis	2.50 x10^8 CFU/mL
Mycoplasma pneumoniae	2.50 x10^7 CFU/mL
Mycobacterium tuberculosis avirulent	3.03 x10^6 CFU/mL
Neisseria meningitidis	3.43 x10^6 CFU/mL
Neisseria sp. Elongata	2.68 x10^8 CFU/mL
Pneumocystis jirovecii	1.30 x10^7 CFU/mL
Pseudomonas aeruginosa	3.45 x10^8 CFU/mL
Staphylococcus aureus subsp. aureus	2.60 x10^8 CFU/mL
Staphylococcus epidermidis	9.00 x10^7 CFU/mL
Streptococcus salivarius	1.01 x10^6 CFU/mL
Streptococcus pneumoniae	1.81 x10^7 CFU/mL
Streptococcus pyogenes	7.50 x10^7 CFU/mL
Measles	8.48 x10^5 $TCID_{50}$/mL
Mumps	8.48 x10^5 $TCID_{50}$/mL
Pooled Negative Nasal Wash	NA

b) Competitive Interference

For co-infection, SARS-CoV-2 at levels near LoD was tested in the presence of high levels of influenza A or influenza B and influenza A and influenza B at levels near LoD were tested in the presence of high levels of SARS-CoV-2. No competitive interference was seen between high levels of SARS-CoV-2 and low levels of Influenza A and B and between high levels of Influenza A and low levels of SARS-CoV-2 and influenza B in this testing at the concentration listed in the tables below. Competitive inhibition were observed between high levels of influenza B(Yamagata Lineage) and low levels of Influenza A in this testing at the concentration listed in the tables below.

Table 7: Summary of Competitive Interference Study Results of SARS-CoV-2&Influenza A &Influenza B Virus (Yamagata Lineage)

SARS-CoV-2 (USA-WA1/2020)		Influenza A Virus (H1N1pdm09) A/Victoria/4897/2022		Influenza B Virus (Yamagata Lineage) B/Florida/4/2006	
Concentration ($TCID_{50}$/mL)	Percent Agreement	Concentration ($TCID_{50}$/mL)	Percent Agreement	Concentration ($TCID_{50}$/mL)	Percent Agreement
Negative	100%	$6.73x10^4$	100%	$1.76 x10^2$	100%
$2.37x10^3$	100%	$6.73x10^4$	100%	Negative	100%
$2.37x10^3$	100%	$6.73x10^4$	100%	$1.76 x10^2$	100%
Negative	100%	$3.03x10^2$	0	$3.90 x10^4$	100%
Negative	100%	$3.03x10^2$	0	$1.95 x10^4$	100%
Negative	100%	$3.03x10^2$	100%	$7.80 x10^3$	100%
Negative	100%	$3.03x10^2$	100%	$3.90 x10^3$	100%
$2.37x10^3$	100%	Negative	100%	$3.90 x10^4$	100%
$2.37x10^3$	100%	$3.03x10^2$	0	$3.90 x10^4$	100%
$2.37x10^3$	100%	$3.03x10^2$	0	$1.95 x10^4$	100%
$2.37x10^3$	100%	$3.03x10^2$	100%	$7.80 x10^3$	100%
$2.37x10^3$	100%	$3.03x10^2$	100%	$3.90 x10^3$	100%
$1.05x10^6$	100%	$3.03x10^2$	100%	Negative	100%
$1.05x10^6$	100%	Negative	100%	$1.76 x10^2$	100%
$1.05x10^6$	100%	$3.03x10^2$	100%	$1.76 x10^2$	100%

Table 8: Summary of Competitive Interference Study Results SARS-CoV-2&Influenza A &Influenza B Virus (Victoria Lineage)

SARS-CoV-2 (USA-WA1/2020)		Influenza A Virus (H1N1pdm09) A/Victoria/4897/2022		Influenza B Virus (Victoria Lineage) B/Washington/02/19	
Concentration ($TCID_{50}$/mL)	Percent Agreement	Concentration ($TCID_{50}$/mL)	Percent Agreement	Concentration ($TCID_{50}$/mL)	Percent Agreement
Negative	100%	$6.73 x10^4$	100%	$3.51 x10^2$	100%
$2.37 x10^3$	100%	$6.73 x10^4$	100%	Negative	100%
$2.37 x10^3$	100%	$6.73 x10^4$	100%	$3.51 x10^2$	100%

SARS-CoV-2 (USA-WA1/2020)		Influenza A Virus (H1N1pdm09) A/Victoria/4897/2022		Influenza B Virus (Victoria Lineage) B/Washington/02/19	
Concentration ($TCID_{50}$/mL)	**Percent Agreement**	**Concentration ($TCID_{50}$/mL)**	**Percent Agreement**	**Concentration ($TCID_{50}$/mL)**	**Percent Agreement**
Negative	100%	3.03×10^2	100%	1.05×10^6	100%
2.37×10^3	100%	Negative	100%	1.05×10^6	100%
2.37×10^3	100%	3.03×10^2	100%	1.05×10^6	100%
1.05×10^6	100%	3.03×10^2	100%	Negative	100%
1.05×10^6	100%	Negative	100%	3.51×10^2	100%
1.05×10^6	100%	3.03×10^2	100%	3.51×10^2	100%

c) Interfering Substances

The potential interference of endogenous substances with the antibodies used for the detection of SARS-CoV-2, influenza A and B was examined by testing nineteen (19) substances in a negative clinical matrix in triplicate, in the absence or presence of each virus at 3 x LoD concentrations for SARS-CoV-2, influenza A(H1N1), and influenza B(Yamagata). The interference study was conducted using medically relevant concentrations of the potentially interfering substances listed below to assess the potential interference of the substances on the performance of the WELLlife™ COVID-19 / Influenza A&B Home Test.

At 15% (v/v) and when diluted down to 0.75% (v/v), FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine yielded false positive results for Influenza A and Influenza B. At a dilution of 0.375% (v/v), the results were negative. Hand sanitizer containing 80% ethanol yielded false positive results for SARS-CoV-2 and Influenza B at a dilution of 15% (v/v) and when diluted down to 3.75% (v/v). At a dilution of 1.875% (v/v), the results were negative. At 15% (v/v) and when diluted down to 5% (v/v), the Zinc (TheraZinc Throat Spray) yielded false positive results for influenza A. At a dilution of 2.5% v/v, the results were negative. At 15% (v/v), the nasal corticosteroid (Fluticasone) yielded false negative results for SARS-CoV-2, Influenza A and Influenza B. At a dilution of 5%v/v, the results were positive. Two interferents produced false-negative results for Influenza B: hand sanitizer cream lotion (15% v/v) and hand soap liquid gel (10% w/v). All Influenza B results were positive when tested with 7.5% (v/v) hand sanitizer cream lotion and 0.05% (w/v) hand soap liquid gel.

No interference was observed with the other listed substances when tested at the concentration presented in the table below in the presence or absence of the target analytes.

Table 9: Summary of Interfering Substances Study Results

Potential Interferent	Concen-tration	Cross-reactivity (no analyte) (# pos reps / total reps)			Interference (3x LoD co-spiked analytes) (# pos reps / total reps)		
		SCV-2*	Flu A	Flu B	SCV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Mucin	0.50%	0/3	0/3	0/3	3/3	3/3	3/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Naso GEL (NeilMed)	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zicam	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic (Alkalol)	10% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Sore Throat Phenol Spray	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Tobramycin	4 µg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mupirocin	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Fluticasone Propionate	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
FluMist/ FluMist Quadrivalent Live intranasal influenza virus vaccine	15% v/v	0/3	3/3	3/3	3/3	3/3	3/3
	0.375% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zanamivir	282 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Biotin	3,500 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Body & Hand Lotion	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Lotion	5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	0/3	3/3	3/3	0/3
	7.5% v/v	-	-	-	3/3	3/3	3/3
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	3/3	0/3	2/3	3/3	3/3	3/3
	1.875% v/v	0/3	0/3	0/3	-	-	-
Hand soap liquid gel	10% w/v	0/3	0/3	0/3	3/3	3/3	0/3
	0.05% w/v	-	-	-	3/3	3/3	3/3
Throat lozenges (Menthol/Benzocaine)	3 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mucin from bovine submaxillary glands Type I-S	2.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Leukocytes	1×10^6	0/3	0/3	0/3	3/3	3/3	3/3

Potential Interferent	Concen-tration	Cross-reactivity (no analyte) (# pos reps / total reps)			Interference (3x LoD co-spiked analytes) (# pos reps / total reps)		
		SCV-2*	Flu A	Flu B	SCV-2	Flu A	Flu B
	cells/mL						
	5×10^5 cells/mL	-	-	-	3/3	3/3	3/3
Zinc (TheraZinc Throat Spray)	15% v/v	0/3	3/3	0/3	3/3	3/3	3/3
	5% v/v	0/3	3/3	0/3	-	-	-
	2.5% v/v	0/3	0/3	0/3	-	-	-
	1.5% v/v	0/3	0/3	0/3	-	-	-
Nasal spray (Saline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Dexamethasone (Nasal corticosteroid)	1 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Triamcinolone)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Fluticasone)	15% v/v	0/3	0/3	0/3	0/3	0/3	0/3
	5% v/v	-	-	-	3/3	3/3	3/3
Nasal gel (Galphimia glauca, Histanium hydrocloricum, Luffa operculata, Sulfur)	0.01	0/3	0/3	0/3	3/3	3/3	3/3
Zicam nasal spray (Galphimia glauca, Luffa operculata)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal spray (Alkalol)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic allergy relief (Histaminum hydrochloricum)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Anti-viral drug (Remdesivir)	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3

*SCV-2: SARS-CoV-2

6 Clinical Performance

a) Clinical Study Design

A prospective study was performed in which seven hundred eighty-seven (787) study subjects were sequentially enrolled (between December 2023 and March 2024) and tested fresh. Anterior nasal swab (ANS) samples were collected from symptomatic patients suspected of infection with respiratory symptoms, at nine (9) clinical sites. To be enrolled in the study, patients had to present at the participating study site within four (4) days of symptom onset with signs and symptoms of respiratory infection generally observed from SARS-CoV-2, influenza A and/or influenza B, 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 molecular comparator method, and the other swab was self-collected and tested immediately with the WELLlife™ COVID-19 / Influenza A&B Home Test per its summary instruction (QRI) test procedure. The collection order for the investigational and the comparator tests' ANS swab was randomized. 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. Out of 787 enrolled subjects, there were 705 evaluable subjects and 82 enrolled subjects were excluded.

b) Subject Demographics

Table 10: Subject Demographics

Characteristic	Lay-user/ Tester Collection N=160	Self-Collecting N=545	Overall N=705
Age			
Mean (SD)	8.7 (4.5)	45.8 (18.6)	37.4 (22.6)
Median[Min, Max]	8[2, 32]	43[14, 94]	35[2, 94]
Age Group			
<14	139 (86.9%)	0	139 (19.7%)
14-24	20 (12.5%)	79 (14.5%)	99 (14.0%)
25-64	1 (0.6%)	351 (64.4%)	352 (49.9%)
>64	0	115 (21.1%)	115 (16.3%)
Six at Birth			
Female	90 (56.3%)	343 (62.9%)	433 (61.4%)
Male	70 (43.8%)	202 (37.1%)	272 (38.6%)
Ethnicity			
Hispanic/Latino	87 (54.4%)	226 (41.5%)	313 (44.4%)
Not Hispanic/Latino	73 (45.6%)	304 (55.8%)	377 (53.5%)
Unknown/Prefer not to answer	0	15 (2.8%)	15 (2.1%)
Race			
American Indian or Alaskan Native	0	2(0.4%)	2(0.3%)
Asian	19 (11.9%)	150 (27.5%)	169 (24.0%)
Black or African American	36 (22.5%)	85 (15.6%)	121 (17.2%)
White	101 (63.1%)	267 (49.0%)	368 (52.2%)
Native Hawaiian or Other Pacific Islander	0	0	0
More than one race	1 (0.6%)	5 (0.9%)	6 (0.9%)

Characteristic	Lay-user/ Tester Collection N=160	Self-Collecting N=545	Overall N=705
Unknown/Prefer not to answer	2 (1.3%)	30 (5.5%)	32 (4.5%)
Other	1 (0.6%)	6 (1.1%)	7 (1.0%)

c) Clinical Performance

SARS-COV-2 PERFORMANCE

Table 11: WELLlife™ COVID-19 / Influenza A&B Home Test performance compared to reference PCR: SARS-CoV-2

SARS-CoV-2	Comparator Positives	Comparator Negatives	Total
Candidate Positives	101	1	102
Candidate Negatives	14	589	603
Total	**115**	**590**	**705**
Positive Percent Agreement (PPA) = 87.8% (101/115) 95% CI: 80.6% - 92.6%			
Negative Percent Agreement (NPA) = 99.8% (589/590) 95% CI: 99.1% - 100%			

Table 12: SARS-CoV-2 Performance stratified by Days Post Symptoms Onset

Days Post COVID-19 Symptoms	Number of Subject samples tested	WELLlife™ COVID-19 / Influenza A&B Test Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95%CI)
Day 0	39	3	5	12.80%	60.0% (23.1%, 88.2%)
Day 1	168	26	28	16.70%	92.9% (77.4%, 98.0%)
Day 2	236	30	36	15.25%	83.3% (68.1%, 92.1%)
Day 3	156	27	27	17.30%	96.3% (81.7%, 99.3%)
Day 4	106	16	19	17.90%	84.2% (62.4%, 94.5%)
Total	705	101	115	16.31%	87.8% (80.6%, 92.6%)

INFLUENZA A PERFORMANCE

Table 13: WELLlife™ COVID-19 / Influenza A&B Home Test performance compared to reference PCR: Influenza A

Influenza A	Comparator Positives	Comparator Negatives	Total
Candidate Positives	75	2	77
Candidate Negatives	11	617	628
Total	**86**	**619**	**705**
Positive Percent Agreement (PPA) = 87.2% (75/86) 95% CI: 78.5% - 92.7%			
Negative Percent Agreement (NPA) = 99.7% (617/619) 95% CI: 98.8% - 99.9%			

INFLUENZA B PERFORMANCE

Table 14: WELLlife™ COVID-19 / Influenza A&B Home Test performance compared to reference PCR: Influenza B

Influenza B	Comparator Positives	Comparator Negatives	Total
Candidate Positives	29	2	31
Candidate Negatives	4	670	674
Total	**33**	**672**	**705**
Positive Percent Agreement (PPA) = 87.9% (29/33) 95% CI: 72.7% - 95.2%			
Negative Percent Agreement (NPA) = 99.7% (670/672) 95% CI: 98.9% - 99.9%			

7 Conclusion

The information provided in this Premarket Notification [510(k)] demonstrates that the performance of the WELLlife™ COVID-19 / Influenza A&B Home Test and WELLlife™ COVID-19 / Influenza A&B Antigen Test are substantially equivalent in intended use, technological characteristics and performance to the predicate device.