August 20, 2025

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

Re: K251563
Trade/Device Name: WELLlife Flu A&B Home Test; WELLlife Influenza A&B Test
Regulation Number: 21 CFR 866.3987
Regulation Name: Multi-Analyte Respiratory Virus Antigen Detection Test
Regulatory Class: Class II
Product Code: SCA
Dated: May 20, 2025
Received: May 22, 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 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)*
K251563

Device Name
WELLlife Flu A&B Home Test;
WELLlife Influenza A&B Test

Indications for Use *(Describe)*

WELLlife Flu A&B Home Test:
The WELLlife Flu 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 directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing other 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 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 Influenza A&B Test:
The WELLlife Influenza A&B Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. This test is for use by individuals aged 14 years or older testing themselves, or adults testing other 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 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 Flu A&B Home Test / WELLlife Influenza A&B Test is provided:

Applicant Information

Date Prepared	August 19, 2025
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

Device Information

Trade Name	WELLlife Flu A&B Home Test WELLlife Influenza A&B Test
Common Name	WELLlife Flu A&B Home Test WELLlife Influenza A&B 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	WELLlife COVID-19 / Influenza A&B Home Test WELLlife COVID-19 / Influenza A&B Antigen Test
510(k) Number	K243256
Product Code	SCA
Review Panel	Microbiology

1 Device Description

The WELLlife Flu A&B Home Test and WELLlife Influenza A&B Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A and influenza B protein antigens. The test has two versions, one for over the counter (OTC) use (WELLlife Flu A&B Home Test) and one for professional use (WELLlife Influenza A&B Test). Both versions of the WELLlife Influenza A&B Test that have an identical general design and are intended for the qualitative detection of protein antigens directly in anterior nasal swab specimens from individuals with respiratory signs and symptoms. Results are for the identification and differentiation of 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 three lines: two test lines (Flu A line, Flu B line) and a control line (C line). The device is for in vitro diagnostic use only.

2 Indications for Use

WELLlife Flu A&B Home Test:

The WELLlife Flu 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 directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing other 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 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 Influenza A&B Test:

The WELLlife™ Influenza A&B Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. This test is for use by individuals aged 14 years or older testing themselves, or adults testing other 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 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 with Predicate(s)

The WELLlife Flu A&B Home Test and WELLlife Influenza A&B Test is substantially equivalent in principle and performance to WELLlife COVID-19 / Influenza A&B Home Test and WELLlife COVID-19 / Influenza A&B Antigen Test (K243256) which had been granted by FDA. The comparison to predicate device is as follows the table below:

Table 1: Comparison with Predicate Device

Device & predicate Device (s):	**Candidate Device**	**K243256**
Device Trade Name	WELLlife Flu A&B Home Test WELLlife Influenza A&B Test	WELLlife COVID-19 / Influenza A&B Home Test WELLlife COVID-19 / Influenza A&B Antigen Test
General Device Similarities		
Intended Use/ Indications for Use	**WELLlife Flu A&B Home Test:** The WELLlife Flu 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 directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing other 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 or other	**WELLlife COVID-19 / Influenza A&B Home Test** The WELLlife COVID-19 / Influenza A&B 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

Device & predicate Device (s):	Candidate Device	K243256
	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 Influenza A&B Test:** The WELLlife™ Influenza A&B Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. This test is for use by individuals aged 14 years or older testing themselves, or adults testing other 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 or other pathogens.	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

Device & predicate Device (s):	Candidate Device	K243256
	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.	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.
Sample Type	Nasal swab	Same
Test Results	Qualitative	Same
Test Principle	Immunochromatography	Same
Test Format	Lateral flow test	Same
Mode of Results	Visual	Same
Time to Results	10 minutes	Same
Assay Control	Internal procedural control	Same
Differences		
Test Targets	Nucleoprotein antigen from influenza A virus Nucleoprotein antigen from influenza B virus	**SARS-CoV-2 nucleocapsid protein antigens** Nucleoprotein antigen from influenza A virus Nucleoprotein antigen from influenza B virus

4 Operation Principle

The WELLlife Flu A&B Home Test and WELLlife Influenza A&B Test (generically referred to as WELLlife Influenza A&B Test for the remainder of this document) consists of a test cassette that separately detects influenza A and influenza B antigens. The test procedure requires an anterior nasal swab specimen to be inserted into the prefilled extraction buffer tube to elute the sample material for testing and disrupt the virus particles in the specimen. The eluted sample extract is then dropped into the sample well of the test cassette, and the swab is discarded.

If influenza A and/or influenza B antigens are present in the specimen, they will react with influenza A/B antibodies, all coupled to dye particles. They then migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody on the membrane's test line(s), and generate a colored pink to red line in the specific test line position. The rest of the sample and

rabbit-antibody-dye-particle complexes continue to migrate to the Control line position (C), where immobilized goat anti-rabbit antibodies will capture the rabbit-antibody-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™ Flu A&B Home Test has two Test lines, one for influenza A and one for influenza B. The two Test lines allow for the separate and differential identification of 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 influenza A and/or B.

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

5 Non-clinical Performance

5.1 Precision

a. Lot-to-Lot Precision

A single-site lot-to-lot precision study was conducted internally to measure repeatability using three levels of contrived samples. A panel of four samples was tested: a negative sample prepared in pooled negative swab matrix (PNSM), low positive sample (0.5x co-spiked LoD of Flu A and Flu B), weak positive sample (1x co-spiked LoD of Flu A and Flu B), moderate positive sample (3x co-spiked LoD of Flu A and Flu B). The strains used for testing were live influenza A H1N1 and live influenza B Yamagata. Two replicate per sample type was tested per run, per operator, and per lot across 5 days with two test runs per day for a total of 180 results per sample type (3 lots x 3 operators x 2 replicates per run x 2 runs per day x 5 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: Lot-Lot Reproducibility Study Results

Sample	Analyte	% Positive (# positive/replicates)			
		Lot 1	Lot 2	Lot 3	Total
Negative sample (PNSM only)	Flu A	0% (0/60)	0% (0/60)	0% (0/60)	0% (0/180) (0%-2.1%)
	Flu B	0% (0/60)	0% (0/60)	0% (0/60)	0% (0/180) (0%-2.1%)
Low positive sample (0.5x co-spiked LoD of Flu A and Flu B)	Flu A	46.7% (28/60)	55.0% (33/60)	53.3% (32/60)	51.7% (93/180) (44.4%-58.9%)
	Flu B	53.3% (32/60)	58.3% (35/60)	63.3% (38/60)	58.3% (105/180) (51.0%-65.3%)
Weak positive sample (1x co-	Flu A	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180) (97.9%-100%)

Sample	Analyte	% Positive (# positive/replicates)			
		Lot 1	Lot 2	Lot 3	Total
spiked LoD of Flu A and Flu B)	Flu B	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180) (97.9%-100%)
Moderate positive sample (3x co-spiked LoD of Flu A and Flu B)	Flu A	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180) (97.9%-100%)
	Flu B	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180) (97.9%-100%)

b. Site-to-Site Reproducibility

The reproducibility of WELLlife™ Flu A&B Home Test was evaluated at three external sites with three operators per site (a total of nine operators) over five days. The nine-member panel described below was tested in this study. The summary of results is presented in Table below.

Table 3: Site-to-Site Reproducibility Study Results

Sample	% Positive (# positive/replicates)				
	Site A	Site B	Site C	Total	(95%CI)
Negative Sample	0% (0/45)	0% (0/45)	0% (0/45)	0% (0/135)	0% - 2.8%
Flu A High Negative (0.1x LoD)	2.2% (1/45)	0% (0/45)	0% (0/45)	0.7% (1/135)	0.1% - 4.1%
Flu A Low Positive (0.8x LoD)	75.6% (34/45)	84.4% (38/45)	86.7% (39/45)	82.2% (111/135)	74.9% - 87.8%
Flu A Weak Positive (1x LoD)	95.6% (43/45)	97.8% (44/45)	97.8% (44/45)	97.0% (131/135)	92.6% - 98.8%
Flu A Moderate Positive (3 x LoD)	100% (45/45)	100% (45/45)	100% (45/45)	100% (135/135)	97.2% - 100%
Flu B High Negative (0.1x LoD)	0% (0/45)	0% (0/45)	2.2% (1/45)	0.7% (1/135)	0.1% - 4.1%
Flu B Low Positive (0.8x LoD)	91.1% (41/45)	88.9% (40/45)	88.9% (40/45)	89.6% (121/135)	83.3% - 93.7%
Flu B Weak Positive (1x LoD)	97.8% (44/45)	100% (45/45)	100% (45/45)	99.3% (134/135)	95.9% - 99.9%
Flu B Moderate Positive (3x LoD)	100% (45/45)	100% (45/45)	100% (45/45)	100% (135/135)	97.2% - 100%

5.2 Analytical Sensitivity: Limit of Detection

a. Limitation of Detection

Limit of detection (LoD) for influenza A and B in WELLlife™ Flu A&B Home Test was determined by evaluating different concentrations of live influenza A and B viruses. The viruses were diluted in 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 4: Limit of Detection (LoD) Study Results

Virus Strains		Stock Concentration ($TCID_{50}$/mL)	LoD ($TCID_{50}$/mL)	LoD ($TCID_{50}$/Swab)
Influenza A	A/California/07/2009 pdm (H1N1)	7.29×10^5	7.29×10^2	3.65×10^1
	A/Victoria/4897/2022(H1N1)	3.89×10^4	3.89×10^0	1.95×10^{-1}
	A/Darwin/6/2021(H3N2)	4.17×10^5	4.17×10^1	2.09×10^0
	A/Perth/16/09 (H3N2)	3.89×10^4	3.89×10^2	1.95×10^1
Influenza B	B/Washington/02/2019(Victoria)	3.16×10^6	1.05×10^3	5.25×10^1
	B/Malaysia/2506/2004 (Victoria)	3.16×10^6	1.05×10^2	5.25×10^0
	B/Florida/4/2006 (Yamagata)	1.17×10^5	1.17×10^1	5.85×10^{-1}
	B/Utah/9/14 (Yamagata)	4.17×10^5	4.17×10^1	2.09×10^0

b. Analytical Reactivity

The analytical reactivity of the antibodies targeting Influenza A and influenza B in WELLlife™ Flu A&B Home Test was evaluated with the currently available strains. A selection of temporally, geographically, and genetically diverse influenza strains were tested for analytical reactivity. A series of ten-fold dilutions of each virus was spiked into PNSM and tested in triplicate. Once the ten-fold LoD range was established for each strain, an additional three two-fold dilution series of the lowest positive ten-fold dilution for each virus was tested in triplicate to demonstrate analytical reactivity. Based on this dilution series, the minimum detectable concentration was defined as the lowest concentration for which all three replicates were detected. Results are summarized in the following table.

Table 5: Analytical Reactivity Study Results

Target Analyte		Strain	Minimum Detectable Concentration
Influenza A	H1N1	A/Victoria/2570/19 pdm	2.34×10^0 $TCID_{50}$/mL
		A/Taiwan/42/06	2.26×10^2 $TCID_{50}$/mL
		A/Solomon Islands/03/06	2.81×10^0 $TCID_{50}$/mL
		A/NY/02/09 pdm	2.37×10^2 $TCID_{50}$/mL
		A/Brisbane/02/18	2.21×10^0 $TCID_{50}$/mL
		A/Michigan/45/15 pdm	8.10×10^0 $TCID_{50}$/mL
		A/Wisconsin/67/22	4.21×10^1 $TCID_{50}$/mL
		A/Singapore/63/04	7.55×10^2 $TCID_{50}$/mL
		A/Wisconsin/588/19	6.30×10^1 $TCID_{50}$/mL
		A/Guangdong-Maonan/SWL 1536/19 pdm	5.85×10^1 $TCID_{50}$/mL
		A/California/04/2009*	2.80×10^3 $TCID_{50}$/mL
		A/Indiana/02/2020*	9.70×10^6 $CEID_{50}$/mL
		A/Hawaii/66/2019*	1.85×10^7 $CEID_{50}$/mL
	H3N2	A/Tasmania/503/20	1.41×10^3 $TCID_{50}$/mL
		A/Cambodia/E0826360/20	1.17×10^2 $TCID_{50}$/mL
		A/Michigan/173/20	5.25×10^1 $TCID_{50}$/mL
		A/Hong Kong/4801/14	8.88×10^2 $TCID_{50}$/mL
		A/Kansas/14/17	7.55×10^3 $TCID_{50}$/mL
		A/Singapore/INFIMH-16-0019/16	7.85×10^1 $TCID_{50}$/mL

Target Analyte		Strain	Minimum Detectable Concentration
		A/South Australia/55/14	3.15 x 10^1 $TCID_{50}$/mL
		A/Switzerland/9715293/13	3.80 x 10^1 $TCID_{50}$/mL
		A/Hong Kong/2671/19	1.26 x 10^1 $TCID_{50}$/mL
		A/Wisconsin/67/05	4.18 x 10^1 $TCID_{50}$/mL
		A/New York/21/2020*	2.60 x10^5 FFU/mL
		A/Alaska/01/2021*	3.75 x10^4 FFU/mL
		A/Indiana/08/2011*	8.10 x10^2 $TCID_{50}$/mL
	H3N8	A/blue-winged teal/Iowa/10OS2411/2010	1.40 x 10^4 $CEID_{50}$/mL
	H1N1	A/Ohio/09/2015*	7.00 x10^5 $CEID_{50}$/mL
	H1N2	A/Minnesota/19/2011*	4.00 x10^6 $CEID_{50}$/mL
	H5N1	A/mallard/Wisconsin/ 2576/2009	2.0 x 10^6 $CEID_{50}$/mL
	H5N6	A/duck/Guangxi/S10888/2024*	6.76 x10^5 EID_{50}/mL
	H5N8	A/goose/Liaoning/S1266/2021*	6.76 x10^5 EID_{50}/mL
	H7N3	A/northern pintail/Illinois/ 10OS3959/2010	1.6 x 10^6 $CEID_{50}$/mL
Influenza B	Victoria	B/Michigan/01/21	1.16 x 10^4 $TCID_{50}$/mL
		B/Austria/1359417/21	2.82 x 10^2 $TCID_{50}$/mL
		B/Singapore/WUH4618/21	2.93 x 10^2 $TCID_{50}$/mL
		B/Hong Kong/574/19	1.25 x 10^2 $TCID_{50}$/mL
		B/Brisbane/35/18	5.75 x 10^2 $TCID_{50}$/mL
	Yamagata	B/Wisconsin/1/2010	7.00 x 10^3 $CEID_{50}$/mL
		B/Phuket/3073/13	9.30 x 10^{-1} $TCID_{50}$/mL
		B/Brisbane/9/14	3.15 x 10^1 $TCID_{50}$/mL
		B/Texas/6/11	9.50 x 10^1 $TCID_{50}$/mL
		B/Brisbane/36/12	3.55 x 10^0 $TCID_{50}$/mL
		B/Lee/40	1.90 x 10^2 $TCID_{50}$/mL

*****These viruses were tested with the WELLlife COVID-19/Influenza A&B Home Test.

5.3 Analytical Specificity

a. Cross-Reactivity and Microbial Interference

Cross-reactivity of the WELLlife™ Flu 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™ Flu A&B Home Test including twenty-two (22) bacteria, twenty-three (23) viruses and one (1) negative matrix. Each organism and virus were tested in triplicate the absence (cross-reactivity) or presence (interference) of live influenza A or B virus at 3 x LoD concentration. 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: Cross-reactivity and Microbial Interference Study Results

Microorganism/ Virus	Concentration Tested	Cross-reactivity (# pos / total)		Microbial Interference (# pos / total)	
		Flu A	Flu B	Flu A	Flu B
Pooled Negative Swab Matrix (PNSM)	NA	0/3	0/3	3/3	3/3
Adenovirus Type 1	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Adenovirus Type 7A	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Human coronavirus OC43	1.70 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Human coronavirus 229E	1.29 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Human coronavirus NL63	5.62 x 10^4 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Human coronavirus HKU1*	Ct =22.0 Ct = 20.5	0/3	0/3	3/3	3/3
MERS-coronavirus	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Cytomegalovirus	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Enterovirus Type 68	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Epstein Barr Virus	2.00 x 10^5 cp/mL	0/3	0/3	3/3	3/3
Parainfluenza virus Type 1	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Parainfluenza virus Type 2	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Parainfluenza virus Type 3	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Parainfluenza virus Type 4A	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Measles Virus	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Human Metapneumovirus (hMPV-5)	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Mumps virus	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Respiratory syncytial virus Type A	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Respiratory syncytial virus Type B	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Rhinovirus	5.62 x 10^4 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Coxsackievirus Type A16	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
SARS-CoV-2 USA-WA1/2020	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
SARS-CoV-2 Omicron Variant	2.00 x 10^5 $TCID_{50}$/mL	0/3	0/3	3/3	3/3
Bordetella pertussis	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Candida albicans	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Chlamydia pneumoniae	2.00 x 10^6 IFU/mL	0/3	0/3	3/3	3/3
Corynebacterium diphtheriae	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Escherichia coli	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3

Microorganism/ Virus	Concentration Tested	Cross-reactivity (# pos / total)		Microbial Interference (# pos / total)	
		Flu A	Flu B	Flu A	Flu B
Haemophilus influenzae	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Lactobacillus acidophilus	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Legionella pneumophila Philadelphia	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Moraxella catarrhalis	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Mycobacterium tuberculosis	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Mycoplasma pneumoniae	2.00 x 10^6 CCU/mL	0/3	0/3	3/3	3/3
Neisseria meningitidis	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Neisseria gonorrhoeae	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Pseudomonas aeruginosa	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Staphylococcus aureus	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Staphylococcus epidermidis	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Streptococcus pneumoniae	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Streptococcus pyogenes	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Streptococcus salivarius	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Pneumocystis jirovecii - S.cerevisiae	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Neisseria subflava biovar flava	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3
Streptococcus mutans	2.00 x 10^6 CFU/mL	0/3	0/3	3/3	3/3

*Two different clinical samples were tested in replicates of three.

b. Endogenous Interfering Substances

The potential interference of endogenous substances with the antibodies used for the detection of influenza A and B was examined by testing fifty-one (51) substances in a negative clinical matrix in triplicate, in the absence or presence of influenza A(H1N1) or influenza B(Yamagata) at 3 x LoD concentration. 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™ Flu 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 at a dilution of 0.375% (v/v), the results were negative for influenza A. At 15% (v/v), FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine yielded false positive results for influenza B. And at a dilution of 6% (v/v), the results were negative for influenza B.

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

Table 7: Endogenous/Exogenous Interfering Substances Study Results

Potential Interferent	Concentration	Without analytes (# pos / total)		With analytes (3x LoD) (# pos / total)	
		Flu A	Flu B	Flu A	Flu B
Whole Blood	5 % v/v	0/3	0/3	3/3	3/3
Leukocytes	1 ×10^6 cells/mL	0/3	0/3	3/3	3/3
Mucin (Bovine submaxillary glands Type I-S or pooled mucous)	10 mg/mL	0/3	0/3	3/3	3/3
Benzocaine	10 mg/mL	0/3	0/3	3/3	3/3
Zinc*	15% v/v	0/3	0/3	3/3	3/3
Menthol	10 mg/mL	0/3	0/3	3/3	3/3
Luffa opperculata	15% v/v	0/3	0/3	3/3	3/3
Sulfur	15% v/v	0/3	0/3	3/3	3/3
Galphimia glauca	15% v/v	0/3	0/3	3/3	3/3
Histanium hydrocloricum	15% v/v	0/3	0/3	3/3	3/3
Phenylephrine	15% v/v	0/3	0/3	3/3	3/3
Oxymetazoline	15% v/v	0/3	0/3	3/3	3/3
Cromolyn	15% v/v	0/3	0/3	3/3	3/3
Sodium chloride with preservatives	15% v/v	0/3	0/3	3/3	3/3
Zicam	15% v/v	0/3	0/3	3/3	3/3
Alkalol	15% v/v	0/3	0/3	3/3	3/3
Phenol	15% v/v	0/3	0/3	3/3	3/3
Fluticasone*	15% v/v	0/3	0/3	3/3	3/3
Budesonide	15% v/v	0/3	0/3	3/3	3/3
Flunisolide	15% v/v	0/3	0/3	3/3	3/3
Dexamethasone	10 mg/mL	0/3	0/3	3/3	3/3
Beclomethasone	15% v/v	0/3	0/3	3/3	3/3
Triamcinolone	15% v/v	0/3	0/3	3/3	3/3
Mometasone	15% v/v	0/3	0/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	10 mg/mL	0/3	0/3	3/3	3/3
Tobramycin	10 mg/mL	0/3	0/3	3/3	3/3
Mupirocin	10 mg/mL	0/3	0/3	3/3	3/3
FluMist/ FluMist Quadrivalent Live intranasal influenza virus vaccine	15% v/v	3/3	3/3	3/3**	3/3***
	6% v/v	3/3	0/3	NT	3/3
	3% v/v	3/3	0/3	NT	3/3
	1.5% v/v	3/3	0/3	NT	NT
	0.75% v/v	3/3	0/3	NT	NT

Potential Interferent	Concentration	Without analytes (# pos / total)		With analytes (3x LoD) (# pos / total)	
		Flu A	Flu B	Flu A	Flu B
	0.375% v/v	0/3	0/3	3/3	NT
	0.188% v/v	0/3	0/3	3/3	NT
Zanamivir	10 mg/mL	0/3	0/3	3/3	3/3
Remdesivir	10 mg/mL	0/3	0/3	3/3	3/3
Molmupiravir	10 mg/mL	0/3	0/3	3/3	3/3
Biotin	3,500 ng/mL	0/3	0/3	3/3	3/3
Aspirin	15 mg/mL	0/3	0/3	3/3	3/3
Motrin (Ibuprofen)	50 mg/mL	0/3	0/3	3/3	3/3
Naproxen	20 mg/mL	0/3	0/3	3/3	3/3
Bleach	0.01% v/v	0/3	0/3	3/3	3/3
Dish soap	1% v/v	0/3	0/3	3/3	3/3
Laundry detergent (liquid)	1% v/v	0/3	0/3	3/3	3/3
Multi surface cleaner	1% v/v	0/3	0/3	3/3	3/3
Hand soap	1% v/v	0/3	0/3	3/3	3/3
Laundry detergent (solid)	1% w/v	0/3	0/3	3/3	3/3
Bar soap	1% w/v	0/3	0/3	3/3	3/3
Multipurpose cleaner	1% w/v	0/3	0/3	3/3	3/3
Hand sanitizer	1% v/v	0/3	0/3	3/3	3/3
Disinfectant spray-Lysol	1% v/v	0/3	0/3	3/3	3/3
Body & Hand Lotion	0.5% w/v	0/3	0/3	3/3	3/3
Hand Lotion	5% w/v	0/3	0/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	0/3	0/3	3/3	3/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	3/3	3/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	0/3	0/3	3/3	3/3
Hand soap liquid gel*	10% w/v	0/3	0/3	3/3	3/3
Hand Sanitizer, 80% ethanol, fast drying *	15% v/v	0/3	0/3	3/3	3/3

NT: Not tested.

* These substances showed interference with the WELLlife COVID-19/Influenza A&B Home Test at the same concentrations tested.

**When Flu A was in the sample, a false positive for Flu B was detected.

***When Flu B was in the sample, a false positive for Flu A was detected.

c. High Dose Hook Effect

A high-dose hook effect was not observed in WELLlife™ Flu A&B Home Test for the influenza A and B viral strains at the concentration listed below.

Table 8: High Dose Hook Effect Study Results

Subtype	Strain	Concentration ($TCID_{50}$/mL)	Positive Results / Total Results All Lots	
			Influenza A	Influenza B
Influenza A	A/California/07/2009 pdm	7.29×10^5	9/9	0/9
	A/Victoria/4897/22	3.89×10^4	9/9	0/9
	A/Darwin/6/21	4.17×10^5	9/9	0/9
	A/Perth/16/09	3.89×10^4	9/9	0/9
Influenza B	B/Washington/02/19	3.16×10^6	0/9	9/9
	B/Malaysia/2506/2004	3.16×10^6	0/9	9/9
	B/Florida/04/06	1.17×10^5	0/9	9/9
	B/Utah/9/14	4.17×10^5	0/9	9/9

d. Competitive Interference

The study was performed to evaluate if the WELLlife™ Flu A&B Home Test assay can detect low levels of influenza A in the presence of high levels of influenza B and vice versa. Four influenza strains were used in this study: influenza A/Victoria/4897/2022, influenza A/Perth/16/2009, influenza B/Washington/02/2019, and influenza B/Florida/04/2006. Testing was performed with different combinations of low (2 x LoD) and high concentrations (exceeding 10^4 $TCID_{50}$/mL, >1000 x LoD) of Influenza A and Influenza B. Using a pipette, 50 µL of each influenza sample was applied to a swab. The swabs were tested in triplicate. Low and high concentrations of the influenza strains used in this study are presented in Table below.

Table 9: Competitive Interference Study Results

Influenza A strain	Influenza B strain	Influenza A Positive Replicates	Influenza B Positive Replicates
A/Victoria/4897/2022 Low concentration	B/Washington/02/2019 High Concentration	9/9 (100%)	9/9 (100%)
A/Victoria/4897/2022 Low concentration	B/Florida/04/2006 High Concentration	9/9 (100%)	9/9 (100%)
A/Perth/16/2009 Low Concentration	B/Washington/02/2019 High Concentration	9/9 (100%)	9/9 (100%)
A/Perth/16/2009 Low Concentration	B/Florida/04/2006 High Concentration	9/9 (100%)	9/9 (100%)
A/Victoria/4897/2022 High Concentration	B/Washington/02/2019 Low Concentration	9/9 (100%)	9/9 (100%)
A/Victoria/4897/2022 High Concentration	B/Florida/04/2006 Low Concentration	9/9 (100%)	9/9 (100%)
A/Perth/16/2009 High Concentration	B/Washington/02/2019 Low Concentration	9/9 (100%)	9/9 (100%)
A/Perth/16/2009 High Concentration	B/Florida/04/2006 Low Concentration	9/9 (100%)	9/9 (100%)

6 Clinical Performance

Clinical Study Design

A prospective study was performed in which seven hundred sixty (766) subjects were sequentially enrolled (between January 2025 and March 2025) and tested fresh. Anterior nasal swab (ANS) samples were collected from symptomatic patients suspected of infection with respiratory symptoms, at six (6) clinical sites. 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 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™ Flu A&B Home Test per the 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 other individuals, in a simulated at-home environment. Out of 766 enrolled subjects, there were 680 evaluable subjects and 86 enrolled subjects were excluded.

Table 10: Subject Demographics

Characteristics	Number	Percent of Subjects
Age (years)		
2 to 13 years	167	24.6%
14 to 21 years	78	11.5%
22 to 59 years	346	50.9%
⩾60 years	89	13.1%
Total	680	100.0%
Sex		
Male	295	43.4%
Female	385	56.6%
Total	680	100.0%
Ethnicity		
Hispanic/Latino	260	38.2%
Not Hispanic/Latino	420	61.8%
Total	680	100.0%

Influenza A Performance

Table 11: Clinical Performance for Flu A

Influenza A	Comparator Positives	Comparator Negatives	Total
Candidate Positives	146	0	146
Candidate Negatives	12	522	534
Total	158	522	680
Positive Percent Agreement (PPA): 92.4% (95% CI: 87.2%-95.6%)			
Negative Percent Agreement (NPA): 100% (95% CI: 99.3%-100%)			

Influenza B Performance

Table 12: Clinical Performance for Flu B

Influenza B	Comparator Positives	Comparator Negatives	Total
Candidate Positives	32	0	32
Candidate Negatives	3	645	648
Total	35	645	680
Positive Percent Agreement (PPA): 91.4% (95% CI: 77.6%-97.0%)			
Negative Percent Agreement (NPA): 100.0% (95% CI: 99.4%-100%)			

7 Conclusion

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