510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251563

B Applicant

Wondfo USA Co., Ltd.

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SCA	Class II	21 CFR 866.3987 - Multi-Analyte Respiratory Virus Antigen Detection Test	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain 510(k) clearance for the WELLlife Flu A&B Home Test and WELLlife Influenza A&B Test.

B Measurand:

Influenza type A and type B nucleoprotein

C Type of Test:

Qualitative Lateral Flow Immunoassay

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

WELLlife Flu A&B Home Test:

The WELLlife Flu A&B Home Test is a 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 and 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.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The WELLlife Flu A&B Home Test and WELLlife Influenza A&B Test are lateral flow immunoassays intended for the qualitative detection and differentiation of influenza A and influenza B protein antigens. The WELLlife Flu A&B Home Test is intended for over-the-counter (OTC) use; the WELLlife Influenza A&B Test is intended for professional use. Both versions of the WELLlife Influenza A&B Test have 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.

Test kit components are:

- Nasal swab (sterile)
- Test cassette
- Extraction buffer tube
- Tube holder
- Quick Reference Instructions
- Instructions for Use (packaged only in the HCP version)

B Principle of Operation:

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) consist of a test cassette that separately detects influenza A, and influenza B 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 proteins. After the release of specimen, the swab is discarded. The extracted specimen is then dropped into the sample well of the test cassette.

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 Influenza A&B Test has two test lines, one for influenza A (A) and one for influenza B (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.

V Substantial Equivalence Information:

A Predicate Device Name(s):

WELLlife COVID-19/Influenza A&B Home Test; WELLlife COVID-19/Influenza A&B AntigenTest

B Predicate 510(k) Number(s):

K243256

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251563	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 Characteristic 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-	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

	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. <u>WELLlife Influenza A&B Test:</u> 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.	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. <u>WELLlife COVID-19/Influenza A&B Antigen Test</u> 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.
Prescription Use / Over-the-Counter	Over-the-Counter	Same
End user	Lay user	Same
Environment of use	Home or similar environment	Same
Intended use population	Symptomatic individuals 14 years of age and older testing themselves and adults testing individuals aged 2 years and older.	Same
Sample	Anterior nasal swab specimen	Same
Assay principle	Lateral flow	Same
Qualitative or quantitative	Qualitative	Same
Format	Test cassette	Same
Controls	Internal control	Same
Time to result	10-20 minutes	Same
Results	Positive, negative, or invalid	Same
Interpretation	Visually read	Same
General Device Characteristic Differences		
Test targets	Nucleoprotein antigen from influenza A and influenza B virus	SARS-CoV-2 nucleocapsid protein; Nucleoprotein antigen from influenza A and influenza B virus

VI Standards/Guidance Documents Referenced:

The following have been referenced for Conformity.

Document number	Title	Publishing Organization
11135 2nd edition 2014-07-15	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	ISO
109993-7 2nd edition 2008-10-15	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	ISO
10993-10 3rd edition 2010-08-01	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	ISO
10993-5 3rd edition	Biological evaluation of medical devices	ISO

Document number	Title	Publishing Organization
2009-06-01	Part 5: Tests for in vitro cytotoxicity	
10993-1:2018	Biological evaluation of medical devices- Part 1: Evaluation and testing within risk management process	ISO

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision:

Lot-to-lot Precision

The single site lot-to-lot precision study was conducted to assess variability between reagent lots, days, runs and operators. Three (3) concentrations of live influenza A (Flu A): H1N1pdm09/A/Victoria/ 4897/2022, and live influenza B (Flu B): Yamagata/B/Washington/ 02/2019 were spiked into pooled negative swab matrix (PNSM) to prepare the following test sample panel members at the indicated limit of detection (LoD) concentrations:

1. Negative sample (N), PNSM only
2. 0.5x LoD, co-spiked
3. 1x LoD, co-spiked
4. 3x LoD, co-spiked

Samples were blinded and randomized before allotting them to the operators. Fifty (50) µL of each sample was applied to dry nasal swabs and processed per the QRI of the candidate device. All panel members were tested with three (3) device lots, each in two (2) runs per day for each of three (3) operators, and the study was conducted for five (5) days (i.e., 1 site x 3 lots x 3 operators x 2 runs/day x 2 replicates/run x 5 days). 180 results were obtained for each panel member. All replicates for N, 1x LoD and 3x LoD, demonstrated 100% agreement across the operators, lots, days and runs tested. Precision estimates for samples below the LoD, the 0.5x LoD sample, are expected to be low due to the random errors of the testing procedure across different days and runs, paired with an operator's ability to read the line intensity for samples with very low analyte concentration.

Table 1: Lot-to-lot Precision Study Summary[1]

Sample	Analyte Test Lines	Lot 1		Lot 2		Lot 3		Overall Lot % Agt (Count)	95% CI[3]
		Count	% Agt[2]	Count	% Agt	Count	% Agt		
N	**Flu A**	60/60	100.0%	60/60	100.0%	60/60	100.0%	100.0% (180/180)	97.9-100.0%
	Flu B	60/60	100.0%	60/60	100.0%	60/60	100.0%	100.0% (180/180)	97.9-100.0%
0.5x LoD[4]	**Flu A**	28/60	46.7%	33/60	55.0%	32/60	53.3%	51.7% (93/180)	44.4-58.9%
	Flu B	32/60	53.3%	35/60	58.3%	38/60	63.3%	58.3% (105/180)	51.0-65.3%
1x LoD	**Flu A**	60/60	100.0%	60/60	100.0%	60/60	100.0%	100.0% (180/180)	97.9-100.0%
	Flu B	60/60	100.0%	60/60	100.0%	60/60	100.0%	100.0% (180/180)	97.9-100.0%

Sample	Analyte Test Lines	Lot 1		Lot 2		Lot 3		Overall Lot % Agt (Count)	95% CI[3]
		Count	% Agt[2]	Count	% Agt	Count	% Agt		
3x LoD	Flu A	60/60	100.0%	60/60	100.0%	60/60	100.0%	100.0% (180/180)	97.9-100.0%
	Flu B	60/60	100.0%	60/60	100.0%	60/60	100.0%	100.0% (180/180)	97.9-100.0%

[1]Additional precision data was considered from K243256 that included up to 10 days of testing.
[2]Agt = Agreement: Result matched expected result.
[3]95% CI = 2-sided 95% Confidence Interval
[4]Results are reported as percent positive vs. agreement with expected result.

2. Linearity:

This is a qualitative test and linearity is not applicable.

3. Analytical Specificity/Interference:

Cross-reactivity of the WELLlife Influenza A&B 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 Influenza A&B Test including. Each organism and virus were tested in triplicate in the absence (cross-reactivity) or presence (interference) of co-spiked live influenza A and B at 3 x LoD. No cross-reactivity or interference were observed with the listed microorganisms when tested at the concentration presented in the table below.

Table 2: Summary of Cross Reactivity and Microbial Interference Study Results

Microorganism/ Virus	Concentration Tested	Cross-reactivity		Microbial Interference	
		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

Microorganism/ Virus	Concentration Tested	Cross-reactivity		Microbial Interference	
		Flu A	Flu B	Flu A	Flu B
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
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

*ND – Not Detected

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

4. Competitive Interference

The study was performed to evaluate if the WELLlife Influenza A&B Test can detect low. levels of influenza A in the presence of high levels of influenza B and vice versa.

Competitive interference of the test's analytes with each other was tested with different combinations of low (2x single analyte LoD) and high (1000x single analyte LoD or the highest achievable concentration) concentrations of Flu A and Flu B spiked together into the same sample. 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. Samples were tested with three lots of the WELLlife Influenza A&B Test device in three replicates per test condition. The study used live influenza A and B virus strains; virus materials were spiked into PNSM.

The table below summarizes the results of the competitive interference study. For each condition tested all three replicates tested at the low target analyte condition tested positive in the presence of a second target analyte at high concentrations. No false positive results were observed for analytes that are not present in the sample.

Table 3: Competitive Interference Results Summary

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%)

5. Exogenous and Endogenous Interference Study

The WELLlife Influenza A&B Test was also evaluated for performance in the presence and absence of potentially interfering substances that might be present in a respiratory specimen. Interfering substances testing was performed using a panel of endogenous and exogenous substances tested at concentrations listed in the below table.

Negative specimens were evaluated in triplicates to confirm that the potentially interfering substances would not cause false positive results with the test. PNSM was individually spiked with either Flu A H1N1 Victoria/4897/2022 or Flu B Washington/02/19. Testing was performed in triplicates to confirm that Flu A and Flu B could still be detected if the test substances were present in the sample.

Table 4: 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
	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

Potential Interferent	Concentration	Without analytes (# pos / total)		With analytes (3x LoD) (# pos / total)	
		Flu A	Flu B	Flu A	Flu B
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 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.

6. Assay Reportable Range:

This section is not applicable as this device is a qualitative assay.

7. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

i. *Internal Controls*

Both the test strips enclosed in the test device independently feature an internal control, denoted directly on the user interface of the test device as "C". The internal control line needs to be present on each respective test strip to indicate that the test works adequately in each lay user performed test. The control line contains goat anti-rabbit IgG antibodies that capture the rabbit IgG dye particle complexes and form the pink to red C line. It 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 T and C lines. If the C 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.

ii. *External Controls*

External Quality Control materials are not included in the test kit but are available separately for use by professional users.

iii. *Stability*

Real Time Stability:

A real-time stability study is conducted internally at Wondfo to evaluate stability and determine the shelf-life of the unopened test kit. Three (3) lots of unopened WELLlife Influenza A&B Test kit components (test swabs, test devices, and extraction buffer vials) were stored under two conditions: 30°C (which is the upper end of the 15-30ºC room temperature range and representative of the 15-30ºC recommended storage conditions) and 2-8°C (relative humidity 37% for each). At defined intervals, an assessment of each lot with a two-membered sample panel was conducted. Baseline testing was performed within one month of device manufacture.

This study used PNSM as the negative clinical matrix. The two-member sample panel included the external positive and negative control swabs, negative samples (PNSM only), and co-spiked low positive samples prepared at 3x LoD with live influenza A/Victoria/4897/22 and live influenza B/Washington/02/19. All study data are 100% concordant with expected results and support a shelf-life of up to 3 months when stored between 2-30°C.

Open Kit Stability:

An opened test kit stability study was conducted to evaluate the length of time the test device can be left outside of its foil pouch at ambient temperature and humidity. Negative samples (PNSM only) and low positive samples (2x LoD co-spiked with live Influenza A/Victoria/4897/22 and live Influenza B/Washington/02/19) contrived in PNSM were prepared and tested in replicates of five (5). Three lots of test device were analyzed. Testing was conducted immediately after opening (0 min), 30 min, 60 min, and 90 min after the device foil packaging was opened and allowed to remain in the following conditions:

- 35% relative humidity (RH) at 22°C (ambient)
- 15% RH at 4°C
- 15% RH at 45°C
- 90% RH at 4°C
- 90% RH at 45°C

All results were as expected for all time points.

Transport Stability:

Transport stability under simulated summer (22ºC, 30ºC, 40ºC) and winter (-20ºC, 10ºC, 18ºC) shipping conditions was tested to evaluate worst-case shipping and handling conditions over an extended period of time. Performance of unopened test kits was assessed by comparing pre- (T0) and post-distribution (Td) results. Negative samples (PNSM only) and low positive samples (2x co-spike, live Influenza A and live Influenza B contrived in PNSM) were prepared and tested in replicates of five (5) each. All results were as expected for conditions and time points tested.

8. Detection Limit:

Single Analyte Limit of Detection (LoD):

The LoD study for influenza A and B for the WELLlife Influenza A&B Test was performed to determine the lowest detectable concentration of influenza A and influenza B at which at least 95% of all true positive replicates are consistently detected as positive. The LoD was assessed for each analyte in two parts, a preliminary range finding study, followed by a confirmatory LoD study.

The preliminary LoD was determined by first testing serial ten-fold dilutions of live influenza A and B virus stocks diluted into pooled negative swab matrix (PNSM) in 3 replicates per dilution and lot. Once the ten-fold LoD range was established, additional two-fold dilutions of the lowest positive ten-fold dilution were tested in triplicate to determine the preliminary LoD of each virus. Single analyte virus dilutions (50 µL/swab) were each spiked onto dry sterile swabs and tested per the IFU. Total of three test kit lots have been tested to demonstrate LOD consistency across different device lots.

LoD confirmatory testing was then performed individually for each of the viral strains by testing 20 replicates at the virus' preliminary (1X) LoD concentration, as determined above. For the LoD to be confirmed, at least 95% of the replicates (≥19/20) needed to test positive. Results of the LoD confirmation testing for each virus are summarized in the table below.

The LoD results for each individual virus strain is shown in the tables below.

Table 5: Preliminary Limit of Detection Study Summary

Virus Strain	Virus Concentration		Positive Results / Total Results All Lots	
	$TCID_{50}$/mL	$TCID_{50}$/Swab	Flu A	Flu B
A/California/07/2009 pdm (H1N1)	7.29×10^2	36.5	9/9	0/9
A/Victoria/4897/2022 (H1N1)	3.89×10^0	0.2	9/9	0/9
A/Darwin/6/2021 (H3N2)	4.17×10^1	2.1	9/9	0/9
A/Perth/16/09 (H3N2)	3.89×10^2	19.5	9/9	0/9
B/Washington/02/2019 (Victoria)	3.16×10^3	158	0/9	9/9
B/Malaysia/2506/2004	3.16×10^2	15.8	0/9	9/9
B/Florida/4/2006 (Yamagata)	1.17×10^1	0.6	0/9	9/9
B/Utah/9/14 (Yamagata)	4.17×10^1	2.1	0/9	9/9

Table 6: Confirmatory Limit of Detection Study Summary

Virus Strains		Virus Concentration		Positive Results / Total Results All Lots
		$TCID_{50}$/mL	**$TCID_{50}$/Swab**	
Influenza A	A/California/07/2009 pdm (H1N1)	2.19×10^{3}	1.10×10^{2}	60/60
		7.29×10^{2}	**3.65×10^{1}**	**60/60**
		2.43×10^{2}	1.22×10^{1}	21/60
	A/Victoria/4897/2022 (H1N1)	1.17×10^{1}	5.85×10^{-1}	60/60
		3.89×10^{0}	**1.95×10^{-1}**	**60/60**
		1.30×10^{0}	6.50×10^{-2}	17/60
	A/Darwin/6/2021 (H3N2)	1.25×10^{2}	6.25×10^{0}	60/60
		4.17×10^{1}	**2.09×10^{0}**	**60/60**
		1.39×10^{1}	6.95×10^{-1}	18/60
	A/Perth/16/09 (H3N2)	1.17×10^{3}	5.85×10^{1}	60/60
		3.89×10^{2}	**1.95×10^{1}**	**60/60**
		1.30×10^{2}	6.50×10^{0}	19/60
Influenza B	B/Washington/02/2019 (Victoria)	3.16×10^{3}	1.58×10^{2}	60/60
		1.05×10^{3}	**5.25×10^{1}**	**60/60**
		3.51×10^{2}	1.76×10^{1}	29/60
	B/Malaysia/2506/2004 (Victoria)	3.16×10^{2}	1.58×10^{1}	60/60
		1.05×10^{2}	**5.25×10^{0}**	**59/60**
		3.51×10^{1}	1.76×10^{0}	13/60
	B/Florida/4/2006 (Yamagata)	3.51×10^{1}	1.76×10^{0}	60/60
		1.17×10^{1}	**5.85×10^{-1}**	**60/60**
		3.90×10^{0}	1.95×10^{-1}	19/60
	B/Utah/9/14 (Yamagata)	1.25×10^{2}	6.25×10^{0}	60/60
		4.17×10^{1}	**2.09×10^{0}**	**60/60**
		1.39×10^{1}	2.95×10^{-1}	25/60

Co-spiked LoD:

After the single-analyte LoDs were established for the candidate device, co-spiked LoD equivalency testing with the two test analytes present in the same sample, was conducted to characterize performance with samples that contain more than one analyte at low concentrations.

Based on the individual analyte specific 1x LoD concentrations, co-spiked samples were prepared by mixing one strain of Flu A, Victoria/4897/22 and Flu B, Washington/02/19. The 1x co-spiked LoD concentration was tested with the candidate device in twenty (20) replicates with three lots and was considered confirmed (i.e., equivalent to the established single analyte LoD) if ≥19/20 replicates were positive for concentrations within 2x LoD of the established single analyte LoD.

The WELLlife Influenza A&B Test demonstrated co-spiked LoD equivalency for all analytes, Flu A and Flu B, to their respective established single analyte 1x LoD concentration using three lots of test device. Since all analytes are successfully detected by the candidate device when co-spiked at their single-analyte LoD, co-spiking of the analytes into the same positive sample/s is supported for use in the analytical studies. The summary of the co-spiked LoD is shown in the below table.

Table 7: Summary of Co-spike LoD Equivalency Results

Final Concentration		Positive Results / Total Results All Lots	
Flu A, Victoria/4897/22 ($TCID_{50}$/mL)	**Flu B, Washington/02/19 ($TCID_{50}$/ mL)**	**Flu A**	**Flu B**
3.89×10^{0}	1.05×10^{3}	60/60	60/60

9. High-Dose Hook Effect Study:

The WELLlife Influenza A&B Test was tested to determine if it was affected by a high-dose hook effect at high concentrations of the two analytes. A high dose of live influenza A and B were tested in this study. Fifty (50) microliters of each sample were added directly to the head of the swabs. Swabs were processed per the test's IFU/QRI with three device lots. No high dose hook effect was observed for the concentrations tested.

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

10. Inclusivity Study:

Analytical reactivity was performed for the WELLlife Influenza A&B Test to determine if the device can detect the target analytes across a variety of strains. A selection of temporally, geographically, and genetically diverse influenza strains were tested for inclusivity. A series of ten-fold dilutions of each virus was spiked into PNSM and tested. 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 inclusivity. 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 Table 9. Data demonstrate that the WELLlife Influenza A&B Test is inclusive for the influenza target analytes across a range of strains.

Table 9: Inclusivity Study Summary

Viral Target and Subtype		Strain	Minimum Detectable Concentration (with 3/3 positive results)
Influenza A	H1N1	A/California/04/2009	2.80×10^{3} $TCID_{50}$/mL
		A/Victoria/2570/19 pdm	2.34×10^{0} $TCID_{50}$/mL
		A/Brisbane/02/18	2.21×10^{0} $TCID_{50}$/mL
		A/Michigan/45/15	8.10×10^{0} $TCID_{50}$/mL

Viral Target and Subtype		Strain	Minimum Detectable Concentration (with 3/3 positive results)
		A/Guangdong-Maonan/SWL 1536/19	5.85 x 10^1 $TCID_{50}$/mL
		A/NY/03/09	2.37 x 10^2 $TCID_{50}$/mL
		A/Indiana/02/2020	9.70 x 10^6 $CEID_{50}$/mL
		A/Wisconsin/588/2019	6.30 x 10^1 $TCID_{50}$/mL
		A/Hawaii/66/2019	1.85 x 10^7 $CEID_{50}$/mL
		A/Wisconsin/67/22	4.21 x 10^1 $TCID_{50}$/mL
		A/Solomon Islands/03/06	2.81 x 10^0 $TCID_{50}$/mL
		A/Singapore/63/04	7.55 x 10^2 $TCID_{50}$/mL
		A/Taiwan/42/06	2.26 x 10^2 $TCID_{50}$/mL
	H3N2	A/Tasmania/503/2020	1.40 x 10^3 $TCID_{50}$/mL
		A/Cambodia/E0826360/20	1.17 x 10^2 $TCID_{50}$/mL
		A/Michigan/173/20	5.25 x 10^1 $TCID_{50}$/mL
		A/New York/21/2020	2.60 x 10^5 FFU/mL
		A/Alaska/01/2021	3.75 x 10^4 FFU/mL
		A/Hong Kong/4801/14	8.88 x 10^2 $TCID_{50}$/mL
		A/Hong Kong/2671/19	1.26x 10^1 $TCID_{50}$/mL
		A/Kansas/14/17	7.55 x 10^3 $TCID_{50}$/mL
		A/Singapore/INFIMH-16-0019/16	7.85 x 10^1 $TCID_{50}$/mL
		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/Wisconsin/67/05	4.18 x 10^1 $TCID_{50}$/mL
	H3N2v	A/Indiana/08/2011	8.10 x 10^2 $TCID_{50}$/mL
	H3N8	A/blue-winged teal/Iowa/10OS2411/2010	1.40 x 10^4 $CEID_{50}$/mL
	H1N2v	A/Minnesota/19/2011	4.00 x 10^6 $CEID_{50}$/mL
	H1N1v (Swine Flu)	A/Ohio/09/2015	7.00 x 10^5 $CEID_{50}$/mL
	H5N1	A/mallard/Wisconsin/2576/2009	2.00 x 10^6 $CEID_{50}$/mL
	H5N6	A/duck/Guangxi/S10888/2024	6.76 x 10^5 EID_{50}/mL
	H5N8	A/goose/Liaoning/S1266/2021	6.76 x 10^5 EID_{50}/mL
	H7N3 (Bird Flu)	A/northern pintail/Illinois/ 10OS3959/2010	1.60 x 10^6 $CEID_{50}$/mL
Influenza B	Victoria	B/Austria/1359417/21	2.82 x 10^2 $TCID_{50}$/mL
		B/Brisbane/35/2018	5.75 x 10^2 $TCID_{50}$/mL
		B/Singapore/WUH4618/21	2.93 x 10^2 $TCID_{50}$/mL
		B/Hong Hong/574/19	1.25 x 10^2 $TCID_{50}$/mL
		B/Michigan/01/2021	1.16 x 10^4 $TCID_{50}$/mL
	Yamagata	B/Texas/06/2011	9.50 x 10^1 $TCID_{50}$/mL
		B/Phuket/3073/13	9.30 x 10^{-1} $TCID_{50}$/mL
		B/Wisconsin/01/2010	7.00 x 10^3 $CEID_{50}$/mL
		B/Brisbane/36/12	3.55 x 10^0 $TCID_{50}$/mL
		B/Brisbane/9/14	3.15 x 10^1 $TCID_{50}$/mL
		B/Lee/40	1.90 x 10^2 $TCID_{50}$/mL

11. Assay Cut-Off:

Not applicable as this is a qualitative visually read assay.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Please refer to section VII.C (Clinical Studies) below for the clinical validation, regarding the method comparison studies.

2. Matrix Comparison:

The candidate device is only intended for qualitative detection of nucleoprotein from Flu A and Flu B in direct anterior nasal swab specimens. As no other sample types are claimed herein, a matrix comparison study is not applicable.

C Clinical Studies:

1. Clinical Performance:

A multi-center, prospective clinical study was conducted with lay users to assess the performance of WELLlife Flu A&B Home Test and WELLlife Influenza A&B Test in detecting nucleoprotein antigens extracted from influenza virus A and influenza virus B in self-collected and self-tested anterior nasal swab samples. The study enrolled subjects with two or more upper respiratory disease symptoms. Six (6) clinical sites across the U.S. conducted the study from January 10, 2025 to March 21, 2025. Both the comparator and the candidate test used anterior nasal swab samples, and the collection order was alternated by study subject. Comparator test samples were collected at the clinical study sites by operator and inserted into Viral Transport Media per the IFU of the comparator test. Samples were then sent to a reference laboratory for testing with highly sensitive RT-PCR tests detecting influenza A and influenza B. Samples for the candidate antigen test were either self-collected and tested by a lay user aged ≥14 years or were collected and tested by an adult (parent/guardian) from individuals aged 2 to <14 years per the test's quick reference instructions.

Out of 766 enrolled subjects, 680 subjects were evaluable for Flu A and B. The age of participants ranged from 2 years old to 94 years old, with a mean of 32.5 years. The education level of subjects ranged from less than high school diploma to doctorate degree. Detailed study subject demographics are listed below.

Table 10: Demographics

Characteristic	Number of Subjects (%)
Age (years)	
2-14	167 (24.6%)
14-24	116 (17.1%)
24-65	336 (49.4%)
≥65	61 (9.0%)
Gender	
Female	385 (56.6%)
Male	295 (43.4%)
Ethnicity	

Hispanic/Latino	260 (38.2%)
Not Hispanic/Latino	420 (61.8%)

Results obtained with the of WELLlife Flu A&B Home Test and WELLlife Influenza A&B Test were compared to the results obtained with highly sensitive RT-PCR comparator tests giving rise to the following performance estimates:

Table 11: Clinical Performance for Detection of Influenza A

Flu A	Comparator Positives	Comparator Negatives	Total
Candidate Positives	146	0	146
Candidate Negatives	12	522	534
Total	158	522	680

Positive Percent Agreement = (146/158) = 92.4% (95% CI: 87.2% - 95.6%)
Negative Percent Agreement = (522/522) = 100.0% (95% CI: 99.3% - 100.0%)

Table 12: Clinical Performance for Detection of Influenza B

Flu B	Comparator Positives	Comparator Negatives	Total
Candidate Positives	32	0	32
Candidate Negatives	3	645	648
Total	35	645	680

Positive Percent Agreement = (32/35) = 91.4% (95% CI: 77.6% - 97.0%)
Negative Percent Agreement = (645/645) = 100.0% (95% CI: 99.4% - 100.0%)

Clinical Sensitivity:

Please refer to Section VII.C (Clinical Studies) above for the clinical validation.

Clinical Specificity:

Please refer to Section VII.C (Clinical Studies) above for the clinical validation.

2. Usability Study:
The sponsor evaluated the usability of the WELLlife Flu A&B Home Test and the labeling and comprehension of the investigational test QRI when performed by lay users (n=34) in simulated home environment at two sites. The observers did not otherwise interfere with the study subject's sample collection and testing.

Table 13: Demographics of Subjects in the Usability Study

Factor	Number of Subjects (%) (N=34)
Age Group	
14 – 21 years of age	7 (20.6%)
22 – 59 years of age	24 (70.6%)
≥60 years of age	3 (8.8%)
Sex at Birth	
Male	18 (52.9%)
Female	16 (47.1%)

Overall, 99.7% of all critical tasks associated with sample collection and testing with the WELLlife Influenza A&B Test were performed correctly. 99.5% of all non-critical tasks were performed correctly.

Table 14: Critical vs. Non-critical Tasks Performed Correctly

Steps	Tasks performed correctly	Total number of tasks	Percentage of tasks performed correctly
Critical	305	306	99.7%
Non-critical	203	204	99.5%
Total	508	510	99.6%

The human factors assessment met the acceptance criteria for performing critical (≥90%) and non-critical (≥80%) tasks and supports the user comprehension and usability of the test device in the home environment. This is also supported by the results of the usability/user comprehension questionnaire. A total of 33 out of 34 participants (97.1%) found the instructions clear and easy to follow, 34 (100.0%) found sample collection easy to perform, and 33 (97.1%) found the results clear and easy to see.

3. Lay User Readability Study:

A readability study was conducted by providing a panel of ten (10) mock devices to 57 lay users to read the mock devices that reflected sample concentrations of 1.5x and 5x LOD in a simulated-home environment at two sites. Mock devices were blinded and random. About half of the study subjects were vision impaired (see table below for type of condition and respective frequency of occurrence). The study did not include individuals with any of the following: macular degeneration, color blindness, diabetic retinopathy, cataracts, amblyopia/strabismus, or glaucoma.

Table 15: Vision Characteristics of Readability Study Subjects

Type of vision impairment	Number of subjects	Percentage of total human factors participants (%)
Without impairment	26	45.6
Near Sightedness	13	22.8
Far Sightedness	16	28.1
Astigmatism	1	1.8
Not provided	1	1.8
Total	57	100.0

The overall accuracy of the test interpretation by the lay users, with and without visual impairment, is 97.0% (553/570).

Comparative results of the readability study between lay users with and without visual impairment are summarized below.

Table 16: Comparison of Results Interpreted by Lay Users with and without Visual Impairment

Panel	Concentration	Subjects without visual impairment (N=27*)	Subjects with visual impairment (N=30)
		Correct	Correct
Negative	NA	88.9% (24/27)	100.0% (30/30)
Flu A positive only	1.5x LoD	100.0% (27/27)	96.7% (29/30)
	5x LoD	96.2% (25/26)**	96.7% (29/30)
Flu B positive only	1.5x LoD	100.0% (27/27)	96.7% (29/30)
	5x LoD	100.0% (27/27)	96.7% (29/30)
Flu A and Flu B positive	1.5x LoD	96.3% (26/27)	100.0% (30/30)
	1.5x LoD	96.3% (26/27)	100.0% (30/30)
Flu A and Flu B positive	1.5x LoD	96.2% (25/26)**	100.0% (29/29)**
	5x LoD	96.2% (25/26)**	100.0% (29/29)**
Flu A and Flu B positive	5x LoD	96.3% (26/27)	100.0% (30/30)
	1.5x LoD	96.3% (26/27)	100.0% (30/30)
Flu A and Flu B positive	5x LoD	96.3% (26/27)	100.0% (30/30)
	5x LoD	96.3% (26/27)	100.0% (30/30)
Invalid	NA	96.3% (26/27)	96.7% (29/30)

*One subject whose vision condition was not provided was regarded as subject without vision impairment.
**One subjects didn't provide answers for this mock device.

Overall, the readability studies support the use of the WELLlife Flu A&B Home Test by lay users in a home/OTC environment.

D Clinical Cut-Off:

Not Applicable. The candidate device is a qualitative assay with a visually read binary result.

E Expected Values/Reference Range:

A patient sample is expected to be negative for influenza A and influenza B.

F Other Supportive Information:

1. 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, e.g., sample volume, buffer volume, reading time, swab extraction time, procedure (swab rotation) and environmental test conditions (lighting, disturbance during use, temperature and humidity). Testing was performed with negative PNSM samples and low positive samples co-spiked with Flu A and Flu B virus into negative PNSM at 2x LoD, co-spike.

   The results demonstrated that the test system is robust and that false results can be expected to be reasonably mitigated through labeling.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification supports a substantial equivalence decision.