510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251092

B Applicant

iHealth Labs, Inc

C Proprietary and Established Names

iHealth Flu A&B/COVID-19 Rapid Test; iHealth Flu A&B/COVID-19 Rapid Test Pro

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 iHealth Flu A&B/COVID-19 Rapid Test and iHealth Flu A&B/COVID-19 Rapid Test Pro

B Measurand:

SARS-CoV-2 nucleocapsid protein antigens, influenza A nucleoprotein antigens, and influenza B nucleoprotein antigens

C Type of Test:

Qualitative lateral flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

iHealth Flu A&B/COVID-19 Rapid Test:

The iHealth Flu A&B/COVID-19 Rapid 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 protein 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.

iHealth Flu A&B/COVID-19 Rapid Test Pro:

The iHealth Flu A&B/COVID-19 Rapid Test Pro 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 protein 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 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. I

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.

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 iHealth Flu A&B/COVID-19 Rapid Test and the iHealth Flu A&B/COVID-19 Rapid Test Pro is a lateral flow immunoassay device intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens.

Two versions are available for this over-the counter (OTC) test: one is labeled for lay-user use and one is labeled for professional use, both with identical designs and are intended to separately detect antigen from influenza A, influenza B, and SARS-CoV-2 in anterior nares swabs from individuals with signs and symptoms of respiratory infection.

The test card 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 SARS CoV-2 line) and a control line (Ctrl line) as shown in Figure 1 below:

Figure 1: iHealth Flu Flu A&B/COVID-19 Rapid Test/ Rapid Test Pro Cassette design.

The iHealth Flu A&B/COVID-19 Rapid Test consists of the following components:

- Test Card(s)
- Extraction Tubes
- Swab(s) (sterile)
- Test box with a slot in the bottom left corner that serves as the tube holder
- Quick Reference Instructions (QRI)

Materials Required but Not Provided

- A clock or timer

B Principle of Operation:

To begin the test, an anterior nasal swab sample is mixed with an extraction solution in a test tube. The liquid in the buffer tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The liquid in the extraction tube now containing the specimen is added to the sample well of the test card. The solution of extracted specimen flows onto the test strip and migrates through the pads and membrane of the test strip.

The pads contain detection antibodies and control antigen conjugated to latex microspheres and the membrane contains immobilized capture antibodies and control antibody.

If influenza A, influenza B, or SARS-CoV-2 antigens are present in the specimen, they will react with anti-influenza A or B antibodies labeled with latex microspheres or anti-SARS-CoV-2 antibody labeled with latex microspheres. The solution will then migrate through the membrane as antigen-antibody-latex microspheres complexes, bind to the immobilized capture antibody line(s) on the membrane, and generate a colored line in the specific test line position.

The rest of the sample and unbound/bound latex microspheres complexes continues to migrate to the control line position (Ctrl), where immobilized control antibodies capture the control antigen-latex microspheres complexes and form the control line. Formation of the control line serves as an internal control to demonstrate that test reagents are functional, antibody-latex microspheres conjugates in the latex microspheres 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.

V Substantial Equivalence Information:

A Predicate Device Name(s):

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

B Predicate 510(k) Number(s):

K243256

C Comparison with Predicate(s):

Device & Predicate Device(s):	**K251092 (candidate) iHealth Flu A&B/COVID-19 Rapid Test; iHealth Flu A&B/COVID-19 Rapid Test Pro**	**K243256 (predicate) 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	iHealth Flu A&B/COVID-19 Rapid Test: The iHealth Flu A&B/COVID-19 Rapid 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 protein directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of	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

	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. <u>iHealth Flu A&B/COVID-19 Rapid Test Pro:</u> The iHealth Flu A&B/COVID-19 Rapid Test Pro 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 protein 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 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.	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. <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.

	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. Test results should not be used as the sole basis for treatment or other patient management decisions.	Test results should not be used as the sole basis for treatment or other patient management decisions.
General Device Characteristic Similarities		
Test Principle	Lateral Flow Immunoassay	Same
Regulation Number	21 CFR 866.3987	Same
Product Code	SCA	Same
Analyte	SARS-CoV-2 nucleocapsid protein antigens, Influenza A nucleoprotein antigens, Influenza B nucleoprotein antigens	Same
Intended Use Population	Individuals with signs and symptoms of respiratory tract infection	Same
Test Result Type	Qualitative	Same
Detection Format	Visually Read	Same
Assay Control	Internal Procedure Control	Same
Storage Condition	2-30 °C	Same
General Device Characteristic Differences		
Time to Result	15 - 30 min	15 - 20 min

VI Standards/Guidance Documents Referenced:

Document	Title	Publisher	Applicable study
21 CFR 866.3987	Special controls for multi analyte respiratory virus antigen detection test, an in vitro diagnostic device intended for the detection and/or differentiation of respiratory viruses directly from respiratory clinical specimens.	FDA/CDRH	All studies

11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	ISO	Sterility
10993-7	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	ISO	Sterility
10993-1 Fifth edition 2018-08	Biological Evaluation of Medical Devices – Evaluation testing within risk management process	ISO	Biocompatibility
10993-5: Third Edition 2009-06-01	Biological Evaluation of Medical Devices - Tests for in vitro cytotoxicity	ISO	Biocompatibility
10993-10: 2021 Fourth Edition 2021-11	Biological Evaluation of Medical Devices –Tests for irritation and skin sensitization	ISO	Biocompatibility
14971:2019: Third Edition 2019-12	Biological Evaluation of Medical Devices – Application of risk management to medical devices	ISO	Biocompatibility

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A lot-to-lot precision study was conducted at a single site to evaluate assay variability between-lot, between-operator, between-run and between-day.

A panel of thirteen samples was tested, including one negative sample and six positive sample combinations: single spiked samples (SARS-CoV-2, Flu A, Flu B), doubly co-spiked samples (Flu A + Flu B, SARS-CoV-2 + Flu B), and triply co-spiked samples (Flu A + Flu B+ SARS-CoV-2), with each combination at two concentrations: 0.8X LoD and 3X LoD. All samples were spiked into pooled nasal fluid (PNF).

Two replicates per sample panel were tested per run, per operator, and per lot across 10 days with two test runs per day for a total of 240 results per sample panel (3 lots x 2 operators x 2 replicate x 10 days x 2 runs per day).

The results of this study are shown in **Table 1**. The results demonstrated 100% concordance with the expected result across sample types, device test lines, and lots with negative samples and 3X LoD samples. The expected lot to lot imprecision was observed with the 0.8X LoD samples.

Table 1: Precision Study Results

Analyte	Test line	No. of Positives / No. of Samples tested (%)			Total no. of positives / Total no. of samples (%)
		Lot 1	Lot 2	Lot 3	
Negative	SARS-CoV-2	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu A	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu B	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
0.8X LoD SARS-CoV-2	SARS-CoV-2	25/80 (31.3%)	18/80 (22.5%)	25/80 (31.3%)	68/240 (28.3%)
	Flu A	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu B	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
0.8X LoD Flu A	SARS-CoV-2	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu A	49/80 (61.3%)	49/80 (61.3%)	54/80 (67.5%)	152/240 (63.3%)
	Flu B	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
0.8X LoD Flu B	SARS-CoV-2	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu A	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu B	28/80 (35.0%)	39/80 (48.8%)	18/80 (22.5%)	85/240 (35.4%)
0.8X LoD Flu A/Flu B	SARS-CoV-2	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu A	28/80(35.0%)	39/80(48.8%	18/80(22.5%)	85/240 (35.4%)
	Flu B	40/80 (50.0%)	42/80 (52.5%)	49/80 (61.3%)	131/240 (54.6%)
0.8X LoD SARS-CoV-2/Flu A/Flu B	SARS-CoV-2	39/80 (48.8%)	29/80 (36.3%)	28/80 (35.0%)	96/240 (40.0%)
	Flu A	47/80 (58.8%)	47/80 (58.8%)	42/80 (52.5%)	136/240 (56.7%)
	Flu B	43/80 (53.8%)	45/80 (56.3%)	34/80 (42.5%)	122/240 (50.8%)
3X LoD SARS-CoV-2*	SARS-CoV-2	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (1000%)
	Flu A	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu B	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)

* *The 3X LoD samples were evaluated using the same combination of sample types and test conditions as those used for the 0.8X LoD testing, and all results were concordant, demonstrating 100% agreement*

2. Linearity:

   Not applicable, qualitative assay

3. Analytical Specificity/Interference:

   a. Cross Reactivity Microbial Interference

   Cross-reactivity and microbial interference studies were conducted to determine if other respiratory pathogens/microbial flora that may be present in nasal swab samples could cause a false positive test result or interfere with a true positive test result. A panel of microorganisms commonly found as either pathogens or normal flora in respiratory samples were individually spiked into PNF. In the cross-reactivity study, the organisms were evaluated for their ability to cross-react with the test by adding 50 µl of each sample directly to the test swab and then processing the sample swabs per the IFU. Each organism was tested in replicates of three (3) without SARS-CoV-2, influenza A, or influenza B present in the sample.

The microbial interference testing was conducted in the same manner, but samples were prepared in the presence of inactivated SARS-CoV-2, live influenza A and B co-spiked into the samples at 3X LoD. The testing was performed in triplicates for each microorganism. Results are summarized in Table 2. Neither cross-reactivity nor microbial interference was observed for any of the tested microorganisms at the concentration used in the study.

Table 2: Cross Reactivity Microbial Interference Results

Microorganism	Concentration	Cross-reactivity (positive results / total)	Interference (positive results / total)
SARS-CoV-1	1.25×10^5 PFU/mL	0/3	3/3
MERS-coronavirus	1.58×10^8 GE/mL	0/3	3/3
Human coronavirus OC43	7.00×10^5 $TCID_{50}$/mL	0/3	3/3
Human coronavirus 229E	1.40×10^5 $TCID_{50}$/mL	0/3	3/3
Human coronavirus NL63	8.00×10^4 $TCID_{50}$/mL	0/3	3/3
Adenovirus, Type 1	2.23×10^5 $TCID_{50}$/mL	0/3	3/3
Adenovirus Type 7	1.58×10^5 $TCID_{50}$/mL	0/3	3/3
Cytomegalovirus	1.00×10^5 PFU/mL	0/3	3/3
Epstein Barr Virus	1.83×10^6 CP/mL	0/3	3/3
Human Metapneumovirus (hMPV)	3.50×10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 1	2.00×10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 2	1.75×10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 3	7.00×10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 4	2.39×10^5 $TCID_{50}$/mL	0/3	3/3
Enterovirus	2.23×10^5 $TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus A	1.49×10^5 $TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus B	1.58×10^5 $TCID_{50}$/mL	0/3	3/3
Rhinovirus	2.23×10^6 $TCID_{50}$/mL	0/3	3/3
Bordetella pertussis	2.50×10^8 CFU/mL	0/3	3/3
Candida albicans	6.03×10^6 CFU/mL	0/3	3/3
Chlamydia pneumoniae	4.33×10^6 IFU/mL	0/3	3/3
Corynebacterium xerosis	2.30×10^7 CFU/mL	0/3	3/3
Escherichia coli	1.18×10^8 CFU/mL	0/3	3/3
Hemophilus influenzae	3.00×10^{10} CFU/mL	0/3	3/3
Lactobacillus	8.50×10^6 CFU/mL	0/3	3/3
Legionella pneumophila	6.50×10^6CFU/mL	0/3	3/3
Moraxella catarrhalis	2.50×10^8CFU/mL	0/3	3/3
Mycoplasma pneumoniae	2.50×10^7CFU/mL	0/3	3/3

Mycobacterium tuberculosis	4.15×10^6 CFU/mL	0/3	3/3
Neisseria meningitidis	3.43×10^6 CFU/mL	0/3	3/3
Neisseria elongata	2.68×10^8 CFU/mL	0/3	3/3
Pneumocystis jirovecii	1.30×10^7 CFU/mL	0/3	3/3
Pseudomonas aeruginosa	1.23×10^8 CFU/mL	0/3	3/3
Staphylococcus aureus	2.60×10^8 CFU/mL	0/3	3/3
Staphylococcus epidermidis	9.00×10^7 CFU/mL	0/3	3/3
Streptococcus salivarius	1.01×10^6 CFU/mL	0/3	3/3
Streptococcus pneumoniae	3.88×10^7 CFU/mL	0/3	3/3
Streptococcus pyogenes	7.50×10^7 CFU/mL	0/3	3/3
Measles	2.23×10^5 $TCID_{50}$/mL	0/3	3/3
Mumps	8.48×10^5 $TCID_{50}$/mL	0/3	3/3
PNF (Pooled Negative Nasal Fluid)	NA	0/3	3/3
Human coronavirus HKU1 (HKU1/UNC/2/2022)	4.34×10^6 GE/mL	0/3	3/3

b. Exogenous/Endogenous Interference

The iHealth Flu A&B/COVID-19 Rapid Test was evaluated for performance in the presence of potentially interfering substances that might be present in respiratory specimens. Negative PNF samples were evaluated in the presence of the interfering substances in triplicate to confirm these substances do not interfere with the detection of the target analytes.

Contrived positive samples containing 3X LoD co-spiked analytes for SARS-CoV-2, influenza A/H1N1, and influenza B/Victoria in PNF (same as the strains tested in the co-spiked LoD study) were evaluated in the presence of the interfering substances in triplicate to confirm that these substances do not interfere with the detection of the target analytes. Testing was performed with a panel of endogenous and exogenous substances diluted in PNF to the recommended concentration. Results are summarized in Table 3.

Interference was observed for FluMist Influenza Vaccine Live intranasal, Hand Sanitizer cream lotion and Hand Sanitizer (80% ethanol, fast drying) for influenza A and influenza B. All other tested substances exhibited no interference with all panel analytes.

Table 3: Endogenous/Exogenous Interference Study Results

Substance	**Concentration**	**Without Analytes (# pos / total)**			**With Analytes (3X LoD, co-spiked analytes) (# pos / total)**		
		SCV2	**Flu A**	**Flu B**	**SCV2**	**Flu A**	**Flu B**
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Leukocytes	1.67×10^6 cells/mL	0/3	0/3	0/3	3/3	3/3	3/3

Substance	Concentration	Without Analytes (# pos / total)			With Analytes (3X LoD, co-spiked analytes) (# pos / total)		
		SCV2	Flu A	Flu B	SCV2	Flu A	Flu B
Mucin	5mg/mL	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
	3 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Zinc (TheraZinc Throat Spray)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Naso GEL (NeilMed)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal gel (Galphimia glauca, Histanium hydrocloricum, Luffa operculata, Sulfur)	1.25% 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
Nasal spray (Saline)	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
Zicam Nasal Spray (Galphimia glauca,luffa operculata)	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
	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	3/3	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
Nasal corticosteroid (Fluticasone)	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Dexamethasone)	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
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	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
2024-25 FluMist Influenza Vaccine Live	15% v/v	0/3	3/3	3/3	3/3	3/3	3/3
	1.5% v/v	0/3	3/3	0/3	NT*	NT*	NT*

Substance	Concentration	Without Analytes (# pos / total)			With Analytes (3X LoD, co-spiked analytes) (# pos / total)		
		SCV2	Flu A	Flu B	SCV2	Flu A	Flu B
intranasal	0.75% v/v	0/3	3/3	0/3	NT*	NT*	NT*
	0.375% v/v	0/3	3/3	0/3	NT*	NT*	NT*
	0.1875% v/v	0/3	0/3	0/3	NT*	NT*	NT*
	0.15% v/v	0/3	0/3	0/3	NT*	NT*	NT*
Zanamivir	282 ng/mL	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
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, 80% ethanol, fast drying	15% v/v	0/3	0/3	0/3	3/3	0/3	0/3
	7.5% v/v	NT*	NT*	NT*	3/3	3/3	2/3
	3.75% v/v	NT*	NT*	NT*	3/3	3/3	2/3
	1.875% v/v	NT*	NT*	NT*	3/3	3/3	3/3
	1.5% v/v	NT*	NT*	NT*	3/3	3/3	3/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	0/3	3/3	0/3	0/3
	7.5% v/v	NT*	NT*	NT*	3/3	3/3	3/3
	1.5% v/v	NT*	NT*	NT*	3/3	3/3	3/3
Hand soap liquid gel	10% w/v	0/3	0/3	0/3	3/3	3/3	3/3
PNF only	N/A	0/3	0/3	0/3	NT*	NT*	NT*

*NT: not tested

c. Competitive Interference

Competitive interference of the test's analytes was tested with different combinations of low (3X LoD) and high concentrations of Flu A, Flu B and SARS-CoV-2 prepared in PNF. Inactivated SARS CoV-2, live influenza A, and live influenza B virus strains were used in this study.

Table 4 summarizes the results of the competitive interference study. For each condition tested, all three replicates at the low target analyte condition tested positive in the presence of a second target analyte at high concentrations.

Table 4: Competitive Interference Study Results

Sample	Competing virus		Target virus		Target analyte Percent Positivity
	Virus type	Concentration ($TCID_{50}$/mL)	Virus type	Concentration ($TCID_{50}$/mL)	
1	Influenza A/H1N1	6.73×10^{4}	Influenza B/Victoria	2.12×10^{3}	100%
2	Influenza A/H1N1	6.73×10^{4}	SARS-CoV-2	1.89×10^{1}	100%
3	Influenza A/H1N1	6.73×10^{4}	Influenza B/Victoria	2.12×10^{3}	100%
			SARS-CoV-2	1.89×10^{1}	
4	Influenza B/Victoria	9.40×10^{5}	Influenza A/H1N1	1.20×10^{2}	100%
5	Influenza B/Victoria	9.40×10^{5}	SARS-CoV-2	1.89×10^{1}	100%
6	Influenza B/Victoria	9.40×10^{5}	Influenza A/H1N1	1.20×10^{2}	100%
			SARS-CoV-2	1.89×10^{1}	
7	SARS-CoV-2	4.67×10^{4}	Influenza A/H1N1	1.20×10^{2}	100%
8	SARS-CoV-2	4.67×10^{4}	Influenza B/Victoria	2.12×10^{3}	100%
9	SARS-CoV-2	4.67×10^{4}	Influenza A/H1N1	1.20×10^{2}	100%
			Influenza B/Victoria	2.12×10^{3}	

4. Assay Reportable Range:

Not applicable, the device is a binary qualitative assay that is visually read.

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

a. Controls

i. Internal Procedural Controls:

A built-in internal procedural control is needed to indicate the test device is functioning properly and to ensure correct use of the device. The internal control is part of the test strip membrane and is therefore automatically run within the development time of each test. The internal procedural control consists of IgG antibodies that are immobilized at the "C"-Line of the test membrane in the device and captures leftover, unbound latex microsphere complexes to generate a color signal at the "C"-Line.

ii. External Controls:

External quality control materials are not included in the test kit but are available separately for optional use by professional users.

b. *Stability*

i. *Real Time Stability:*

A real-time stability study was conducted to evaluate stability and determine the shelf-life of the unopened test kit. Three lots of test kit components (test swabs, test devices, and extraction buffer vials) were stored under two conditions: 30 ± 2°C (which is the upper end of the 15-30º C room temperature range and representative of the 15-30ºC recommended storage conditions) and 5±3°C. Baseline testing was performed within one month of device manufacture.

This study used PNF as the negative clinical matrix. The sample panel includes negative samples (PNF only), and co-spiked low positive samples prepared at 3X LoD with inactivated SARS-CoV-2 (USA-WA1/2020), live influenza A (H1N1), or live influenza B (Victoria). All study data are 100% concordant with expected results and support a shelf-life of up to 9 months when stored between 2-30°C.

ii. *Transport Stability:*

Transport stability under simulated summer and winter shipping conditions was tested to evaluate worst-case shipping and handling conditions. A winter shipping simulation (3 lots of devices stored under -20°C for 7 hours and 18°C for 4 hours) was performed, then followed by summer shipping simulation (the same 3 lots of devices stored under 45°C for 7 days and 22°C for 4 hours). Negative samples (PNF only) and low positive samples (3X LoD of each panel analyte individually and 3X LoD co-spiked of inactivated SARS-CoV-2, live influenza A, and live influenza B in PNF) were prepared and tested in replicates of five (5) each. All results were as expected for all time points.

6. Detection Limit:

a. *Single analyte LoD*

A limit of detection (LoD) study was conducted to determine the lowest detectable concentration of SARS-CoV-2 (USA-WA1/2020, UV-inactivated), live influenza A (H1N1 and H3N2), and live influenza B (Victoria and Yamagata lineage) at which at least 95% of all true positive replicates tested positive. Testing was conducted on three lots of test devices.

A preliminary LoD was first determined by testing serial ten-fold dilutions of viral stocks diluted in PNW in triplicate. Once the lowest positive ten-fold dilution concentration was established, additional two-fold dilutions were tested in triplicate (n=3).

A 50 µL sample of each virus diluted in PNSM was pipetted onto the dry swab and thereafter processed per the instructions for use. The results of the preliminary LoD testing are summarized in Table 5 below. The preliminary LoD observed were identical for the three reagent lots tested.

Table 5: Preliminary Single Analyte LoD Study Results

Virus	Virus Strain	Kit Lot#	Concentration
SARS-CoV-2	SARS-CoV-2 (Omicron Variant, Lineage JN.1, USA/New York/PV96109/2023)	1 2 3	7.00×10^0 $TCID_{50}$/mL
Flu A-/H1N1	A/Victoria/4897/2022	1 2 3	5.05×10^1 $TCID_{50}$/mL
Flu A/H3N2	A/Darwin/6/2021	1 2 3	1.04×10^1 $TCID_{50}$/mL
Flu B/Victoria	B/Austria/1359417/2021	1 2 3	7.05×10^2 $TCID_{50}$/mL
Flu B/Yamagata	B/Phuket/3073/2013	1 2 3	2.75×10^5 $CEID_{50}$/mL

LoD confirmation testing was performed by testing twenty (20) replicates at the preliminary (1x) LoD concentration determined above. The acceptance criteria for confirmation of the LoD was that 95% of the replicates (19/20) test positive. LoD testing was conducted on three separate candidate device lots, with each lot generating its own LoD. The final candidate device LoD was determined by selecting the highest LoD from the three lots as the overall LoD for the candidate device. The results of confirmatory LoD testing are shown in Table 6 below.

Table 6: Confirmatory Single Analyte LoD Study Results

Strain	Virus Concentration		Positive Replicates
SARS-CoV-2	6.30×10^0 $TCID_{50}$/mL	3.15×10^{-1} $TCID_{50}$/swab	59/60
Flu A- H1N1	3.99×10^1 $TCID_{50}$/mL	2.00×10^0 $TCID_{50}$/swab	58/60
Flu A - H3N2	8.95×10^1 $TCID_{50}$/mL	4.48×10^0 $TCID_{50}$/swab	59/60
Flu B - Victoria	7.05×10^2 $TCID_{50}$/mL	3.53×10^1 $TCID_{50}$/swab	59/60
Flu B-Yamagata	2.06×10^5 $CEID_{50}$/mL	1.03×10^4 $CEID_{50}$/swab	59/60

b. *Co-spike LoD*

After single analyte LoDs were determined, co-spike equivalency testing was conducted to characterize the performance of samples that contained all analytes. Based on the individual analyte LoDs, 1X LoD co-spiked samples were prepared by mixing the three panel analytes into the same sample using PNSM as matrix. The influenza strains with the lowest confirmatory LoD in the single analyte study were selected for testing in the co-spiked LoD study. Twenty (20) replicates were prepared by pipetting 50 µL of co-spiked sample onto the test swab and testing with the device according to the instructions for use. As shown in Table

7, the co-spike LoD for the panel analytes was equivalent to the respective 1X single analyte LoDs. This study supports the use of co-spiked samples in subsequent analytical studies

Table 7: Co-Spike LoD Results

Virus Strains	Concentration Added to Swab (1X LoD)	Positive Replicates (# Positive/#Total)	% Positive
SARS-CoV-2 (Omicron, Lineage JN.1, USA/New York/PV96109/2023)	6.30×10^0 $TCID_{50}$/mL	20/20	100%
Influenza A/H1N1: A/Victoria/4897/2022	3.99×10^1 $TCID_{50}$/mL	20/20	100%
Influenza B (Victoria) B/Austria/1359417/2021	7.05×10^2 $TCID_{50}$/mL	19/20	95%

c. International Standard for SARS CoV-2

The LoD of the iHealth Flu A&B/COVID-19 Rapid Test; was also determined by evaluating different dilutions of the International Standard for SARS-CoV-2 antigen (NIBSC code: 32/368) in negative pooled nasal swab matrix. The International Standard for SARS-CoV-2 containing lyophilized SARS-CoV-2 antigen was reconstituted in ultra-pure water (for a final concentration of 20,000 IU/mL). The LoD was determined as the lowest virus concentration that was detected ≥95% of the time (i.e., concentration at which at least 19/20 replicates tested positive).

An initial five (5)-fold first dilution and subsequent 2-fold serial dilutions were made from the International Standard for SARS-CoV-2 antigen into negative clinical matrix (pooled nasal swab matrix). Three (3) replicates were tested for each dilution to determine the preliminary LoD concentration of the device. For each replicate, 50 µL of virus dilution was applied to a swab and the swab was processed according to the IFU. As shown in Table 8, the lowest concentration with all concordant positive results was considered the preliminary LoD.

Table 8: International Standard for SARS CoV-2 Preliminary LoD Determination

Dilution	Concentration (IU/mL)	Number of Positive Samples/Total
Master Stock	2.00×10^4	3/3
1:5	4.00×10^3	3/3
1:10	2.00×10^3	3/3
1:20	1.00×10^3	3/3
1:40	5.00×10^2	3/3
1:80	**2.50×10^2**	**3/3**
1:160	1.25×10^2	0/3

The preliminary LoD concentration was tested with an additional 20 replicates above and below the preliminary LoD to confirm the LoD. Samples were prepared as for the preliminary LoD study above. To confirm the LoD, at least 19 of 20 replicates (95%) should be positive. The results are summarized in Table 9 below. The confirmatory LoD

for the International SARS CoV-2 standard was determined to be 1.94×10^2 IU/mL (9.7 IU/swab).

Table 9: International Standard for SARS CoV-2 Confirmatory LoD Determination

Concentration Relative to Preliminary LoD)	Concentration (IU/mL)	Number of Positive Samples /Total
0.33X LoD	6.47×10^1	0/20
0.75X LoD	1.88×10^2	15/20
0.776X LoD	**1.94×10^2**	**19/20**
0.9X LoD	2.25×10^2	20/20
1X LoD	2.50×10^2	20/20
3X LoD	5.82×10^2	20/20

7. High Dose Hook Effect

The device was tested to determine if it was affected by a high dose hook effect at high concentrations of the three panel analytes. A high dose of inactivated SARS-CoV-2, and live influenza A and B were tested in this study. Fifty (50) microliters of each sample was added directly to the head of the swabs. Swabs were processed per the test's IFU. As shown in Table 10, no high dose hook effect was observed for the concentrations tested.

Table 10: High Dose Hook Effect Study Results

Sample	Concentration	Positive Results / Total Replicates		
		SARS-CoV-2	Flu A	Flu B
SARS-CoV-2	1.40×10^5 $TCID_{50}$/mL	3/3	0/3	0/3
Flu A- H1N1	2.02×10^5 $TCID_{50}$/mL	0/3	3/3	0/3
Flu A - H3N2	4.17×10^5 $TCID_{50}$/mL	0/3	3/3	0/3
Flu B - Victoria	2.82×10^6 $TCID_{50}$/mL	0/3	0/3	3/3
Flu B-Yamagata	1.10×10^9 $CEID_{50}$/mL	0/3	0/3	3/3

8. Inclusivity Study

Analytical reactivity was performed on a selection of temporally, geographically, and genetically diverse strains of the target analytes. A series of ten-fold dilutions of each virus was spiked into PNF 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 11 and demonstrate that the iHealth Flu A&B/COVID-19 Rapid Test is inclusive for the target analytes across a range of strains.

Table 11: Inclusivity Study Results

Virus/Subtype	Strain	MIC
Influenza A (H1N1)	A/NY/03/2009	2.29×10^4 $TCID_{50}$/mL
	A/Sydney/5/2021	1.20×10^3 $TCID_{50}$/mL
	A/Baltimore/JH-22377/2022	8.00×10^5 $TCID_{50}$/mL
	A/Wisconsin/67/2022	1.05×10^2 $TCID_{50}$/mL
	A/Hawaii/66/2019	1.85×10^7 $CEID_{50}$/mL
	A/Wisconsin/588/2019	3.50×10^3 FFU/mL
	A/Indiana/02/2020	2.43×10^6 $CEID_{50}$/mL
	A/California/04/2009	7.00×10^2 $TCID_{50}$/mL
	A/Ohio/09/2015	3.50×10^5 $CEID_{50}$/mL
Influenza A (H1N2)	A/Minnesota/19/2011	4.00×10^6 $CEID_{50}$/mL
Influenza A (H3N2)	A/Darwin/6/2021	1.04×10^2 $TCID_{50}$/mL
	A/Alaska/01/2021	7.50×10^3 FFU/mL
	A/New York/21/2020	1.30×10^5 FFU/mL
	A/Tasmania/503/2020	3.25×10^4 FFU/mL
	A/Montana/08/2023	1.30×10^5 FFU/mL
	A/Hong Kong/45/2019	7.50×10^3 FFU/mL
	A/Indiana/08/2011	2.03×10^2 $TCID_{50}$/mL
Influenza A (H5N1)	A/mallard/Wisconsin/ 2576/2009*	1.05×10^5 GE/mL
	A/bovine/Ohio/B24OSU-439/2024*	3.67×10^5 GE/mL
Influenza A (H5N6)	A/duck/Guangxi/S10888/2024	6.76×10^5 EID_{50}/mL
Influenza A (H5N8)	A/goose/Liaoning/S1266/2021	1.69×10^5 EID_{50}/mL
Influenza A (H7N3)	A/northern pintail/Illinois/10OS3959/2010	3.55×10^6 $CEID_{50}$/mL
Influenza B (non-Victoria non-Yamagata)	B/Maryland/1/1959	1.69×10^3 $CEID_{50}$/mL
Influenza B (Victoria Lineage)	B/Austria/1359417/2021	7.05×10^2 $TCID_{50}$/mL
	B/Michigan/01/2021	5.70×10^3 $TCID_{50}$/mL
	B/New Hampshire/01/2021	6.50×10^2 $TCID_{50}$/mL
	B/Washington/02/2019	7.90×10^2 $TCID_{50}$/mL
	B/Texas/02/2013	6.13×10^0 $TCID_{50}$/mL
Influenza B (Yamagata Lineage)	B/Phuket/3073/2013	2.75×10^5 $TCID_{50}$/mL
	B/Florida/04/2006	1.17×10^1 $TCID_{50}$/mL
	B/Texas/06/2011	1.60×10^6 $CEID_{50}$/mL
	B/Utah/09/2014	1.26×10^2 $TCID_{50}$/mL
SARS-CoV-2	USA/New York/PV96109/2023	7.00×10^0 $TCID_{50}$/mL
	USA-WA1/2020	3.16×10^2 $TCID_{50}$/mL
	USA/CA-Stanford-109-S21/2022	5.95×10^3 $TCID_{50}$/mL
	USA/NY-Wadsworth-23067147-01/2023	7.88×10^3 $TCID_{50}$/mL

* Strains were gamma-irradiated prior to wet-testing

9. Assay Cut-Off:

Not applicable as this is a qualitative visually read assay without numeric raw data.

B Comparison Studies:

1. Method Comparison with Predicate Device:

See Section C (Clinical Studies) below.

2. Matrix Comparison:

Not Applicable, the candidate device only uses one matrix (i.e., anterior nasal swab).

C Clinical Studies:

1. Clinical Sensitivity and Specificity:

A prospective lay person clinical study was conducted between November 2024 and March 2025 to assess the performance of the candidate test when compared to an FDA cleared RT-PCR assay. The study prospectively enrolled symptomatic subjects at fifteen (15) geographically distinct study located in the United State. sites in which five hundred ninety-two (592) study subjects were sequentially enrolled. Enrolled subjects were aged 2 years or older who exhibited symptoms of infection consistent with COVID-19 or influenza, at the time of collection and who were within 5 days post symptom onset (DPSO).

Testing was performed in a simulated home environment. Two anterior nasal (AN) swab specimens were collected from each patient: one swab was collected by a healthcare professional and placed into a transport tube containing universal transport media, and shipped on dry ice to a central laboratory for testing using a highly sensitive RT-PCR comparator assay. The other swab was collected according to the candidate test's QRI: either self-collected by a lay user aged ≥14 years or collected by an adult (parent/guardian) from individuals aged ≥2 years. This swab was tested immediately on-site using the iHealth Flu A&B/COVID-19 Rapid Test. The collection order for the investigational and the comparator AN swab was randomized.

Out of 592 enrolled subjects, 4 subjects were excluded resulting in a total of 588 evaluable subjects. The demographics of the evaluable subjects are shown in Table 12.

Table 12: Clinical Study Demographics

	Lay-user collection and testing (N=343)	Self-collecting and testing (N=245)	Overall (N=588)
Age			
Mean (SD)	9.9 (12.4)	39.6 (19.7)	22.3 (21.6)
Median [Min, Max]	8 [2,91]	38 [14,87]	12 [2,91]

Age Group			
≥2-<14 years of age	323 (54.9%)	0 (0%)	323 (54.9%)
14-21 years of age	8 (1.4%)	63 (10.7%)	71 (12.1%)
22-64 years of age	2 (0.3%)	148 (25.2%)	151 (25.7%)
>64 years of age	10 (1.7%)	34 (5.7%)	44 (7.5%)
Sex			
Female	157 (26.7%)	123 (20.9%)	280 (47.6%)
Male	185 (31.5%)	123 (20.9%)	308 (52.4%)

The iHealth Flu A&B/COVID-19 Rapid Test detected the panel analytes with the following percent positive and negative agreement when compared to the result of the RT-PCR comparator assay as detailed in Tables 13-16 below.

Table 13: SARS-CoV-2 Performance

SARS CoV-2	Comparator Positives	Comparator Negatives	Total
Candidate Positives	49	2	51
Candidate Negatives	4	533	538
Total	53	535	588
Positive Percent Agreement (PPA)	92.5% (49/53), 95% CI (82.1%, 97.0%)		
Negative Percent Agreement (NPA)	99.6% (534/536), 95% CI (98.6%, 99.9%)		

Table 14: SARS-CoV-2 Performance by DPSO

Days of COVID-19 Symptoms	Number of Subject samples tested	iHealth Flu A&B/COVID-19 Rapid Test Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA
Day 0	33	3	3	0.5%	100.0%
Day 1	156	19	19	3.2%	100.0%
Day 2	202	9	12	2.0%	75.0%
Day 3	131	12	13	2.2%	92.3%
Day 4	47	5	5	0.8%	100.0%
Day 5	19	1	1	0.2%	100.0%
Total	**588**	**49**	**53**	**9.0%**	**92.5%**

Table 15: Influenza A Performance

Influenza A	Comparator Positives	Comparator Negatives	Total
Candidate Positives	197	6	203
Candidate Negatives	29	356	386
Total	226	362	588
Positive Percent Agreement (PPA)	87.2% (197/226), 95% CI (82.2%, 90.9%)		
Negative Percent Agreement (NPA)	98.3% (357/363), 95% CI (96.4%, 99.2%)		

Table 16: Influenza B Performance

Influenza B	Comparator Positives	Comparator Negatives	Total
Candidate Positives	43	4	47
Candidate Negatives	7	534	542
Total	50	538	588
Positive Percent Agreement (PPA)	86.0% (43/50), 95% CI (73.8%, 93.0%)		
Negative Percent Agreement (NPA)	99.3% (535/539), 95% CI (98.1%, 99.7%)		

2. Usability/User Comprehension Study:

   The sponsor evaluated the usability of the test, and the comprehension of the investigational test QRI when performed by lay users (n=35) in a simulated home environment. The subjects represented typical intended users, with a diversity of ages and educational backgrounds. The observers did not otherwise interfere with the study subject's sample collection and testing.

   Overall, 98.9% of all critical (8) and 97.7% of all non-critical tasks (5) associated with sample collection and testing were performed correctly. 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 was also supported by the results of the usability/user comprehension questionnaire. All (100%) of participants found the instructions clear and easy to follow, sample collection easy to perform, and the results clear and easy to see.

3. Lay User Readability Study:

   A mock-device readability study was conducted during the prospective clinical study. The study aimed to assess the ability of lay users to accurately interpret iHealth COVID-19/Flu A&B Rapid Test results, particularly with weakly reactive samples near the assay cutoff, using a simulated test device for over-the-counter use.

   The cohort consisted of 28 subjects who self-collected and tested, their samples and 26 subjects who collected a sample and performed the testing on another subject (child or adult) for a total of 54 subjects. Twenty-two (40.7%) of these subjects had some type of vision impairment.

The acceptance criteria for subject/tester interpretation of mock results were a ≥ 90% rate for all correct interpretation of results. The subjects read pre-prepared blinded and randomized mock investigational devices in a panel and recorded their results. The test panels included 21 prepared devices with single analyte and multiple analyte results as high positive, low positive, negative and invalid results. 54 subjects testing 21 devices in a panel resulted in 1134 total results for evaluation. In summary, 99.82% (1132/1134) of the prepared devices were read and interpreted accurately. Overall, the readability studies support the use of the 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 without numeric raw data.

E Expected Values/Reference Range:

An individual sample is expected to be negative for SARS-CoV-2, influenza A, and influenza B.

F Other Supportive Information :

Flex Studies

To assess the robustness and risk for false results of the test when deviating from the IFU/QRI test steps, flex studies were conducted that assessed all major aspects of the test procedure (sample volume, reading time, other deviations from the procedure [delay in mixing, delay in addition of sample to the well, incubation time] and variability of environmental test conditions that the test may be subjected to when in use (lighting, disturbance during use, temperature and humidity stress conditions). Testing was performed with contrived positive nasal swabs generated by diluting virus into PNF at a co-spiked concentration of 2x LoD. False results are observed with reading at less than 10 minutes, when the sample swab is not mixed in the sample buffer and the use of only 1 drop of extracted sample for testing. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device

IX Conclusion:

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