December 12, 2025

iHealth Labs, Inc
Yange Wang
Associate Manager, QMS & RA
880 W Maude Ave
Sunnyvale, California 94085

Re: K251092
Trade/Device Name: iHealth Flu A&B/COVID-19 Rapid Test; iHealth Flu A&B/COVID-19 Rapid Test Pro
Regulation Number: 21 CFR 866.3987
Regulation Name: Multi-Analyte Respiratory Virus Antigen Detection Test
Regulatory Class: Class II
Product Code: SCA
Dated: April 9, 2025
Received: April 10, 2025

Dear Yange Wang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

Joseph W. Briggs, Ph.D.
Deputy Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251092

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

Indications for Use *(Describe)*

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.

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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

## 1.0 Submitter's information

Name: iHealth Labs, Inc.

Address: 880W Maude Ave Sunnyvale, CA 94085 USA

Phone number: 1-408-663-8349

Contact: Yange Wang

Contact email: policy@ihealthlabs.com

Date: December 11, 2025

## 2.0 Device information and Classification

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

Classification name: Multi analyte respiratory virus antigen detection test

Regulation number: 21 CFR 866.3987

Product code: SCA

Classification: Class II

Review Panel: Microbiology

## 3.0 Predicate device information

| | |
|---|---|
| **510(k) number** | K243256 |
| **Manufacturer** | Wondfo USA Co., Ltd. |
| **Trade/Proprietary Name** | WELLlife COVID-19 / Influenza A&B Home Test; WELLlife COVID-19 / Influenza A&B Antigen Test |
| **Classification Regulation** | 21 CFR 866.3987 - Multi analyte respiratory virus antigen detection test |
| **Classification** | Class II |
| **Product Code** | SCA |

## 4.0 Device description

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

This over the counter (OTC) test has two versions, one labeled for self-testing use, the (iHealth Flu A&B/COVID-19 Rapid Test), and one labeled for professional use (iHealth Flu A&B/COVID-19 Rapid Test Pro) (generically referred to as iHealth Flu A&B/COVID-19 Rapid Test for the remainder of this document). Both versions of the iHealth Flu A&B/COVID-19 Rapid Test have an identical general design 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 within the first five (5) days of symptom onset. The iHealth Flu A&B/COVID-19 Rapid Test is validated for testing direct anterior nares samples (ANS) without transport media. The iHealth Flu A&B/COVID-19 Rapid Test does not use biotin-streptavidin/avidin chemistry.

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).

## 5.0 Indications for use

<u>iHealth Flu A&B/COVID-19 Rapid Test</u>
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.

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.

## 6.0 Intended use

Same as Indications for Use above.

## 7.0 Technological Comparison

| **Characteristics** | **Subject device (K251092)** | **Predicate device** (K243256) | **Comparison** |
|---|---|---|---|
| Device Trade Name | iHealth Flu A&B/COVID-19 Rapid Test and iHealth Flu A&B/COVID-19 Rapid Test Pro | WELLlife COVID-19 / Influenza A&B Home Test and WELLlife COVID-19 / Influenza A&B AntigenTest | -- |
| Assay Target | SARS-CoV-2 nucleocapsid protein antigens<br>Influenza A nucleoprotein antigens<br>Influenza B nucleoprotein antigens | SARS-CoV-2 nucleocapsid protein antigens<br>Influenza A nucleoprotein antigens<br>Influenza B nucleoprotein antigens | Same |
| Indications For | iHealth Flu A&B/COVID-19 Rapid Test | WELLlife COVID-19 / Influenza A&B Home Test | Similar |

| | | | |
|---|---|---|---|
| Use / Intended use | 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.<br><br>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.<br><br>Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up. | The WELLlife COVID-19 / Influenza A&B Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.<br>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.<br>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.<br>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.<br><br><u>WELLlife COVID-19 / Influenza A&B Antigen Test</u> | |

| | | | |
|---|---|---|---|
| | <u>iHealth Flu A&B/COVID-19 Rapid Test Pro</u><br><br>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.<br><br>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.<br>Positive results do not rule out co-infection with other respiratory pathogens.<br>Test results should not be used as the sole basis for treatment | 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.<br><br>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.<br>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.<br>Positive results do not rule out co-infection with other respiratory pathogens.<br>Test results should not be used as the sole basis for treatment or other patient management decisions. | |

| | | | |
|---|---|---|---|
| | or other patient management decisions. | | |
| Test Principle | Lateral flow immunoassay | Lateral flow immunoassay | Same |
| Specimen Type | Anterior nasal | Anterior nasal | Same |
| Assay Result | Qualitative | Qualitative | Same |
| Detection Format | Visually read | Visually read | Same |
| Assay Control | Internal procedural control | Internal procedural control | Same |
| Intended Use Population | Individuals with signs and symptoms of respiratory tract infection | Individuals with signs and symptoms of respiratory tract infection | Same |
| Presentation or OTC | OTC | OTC | Same |
| Usage | Single use test | Single use test | Same |
| Time to Result | 15-30 min | 15-20 min | Different* |
| Storage Condition | 2-30 °C | 2-30 °C | Same |

## 8.0 Operation Principle

The iHealth Flu A&B/COVID-19 Rapid Test employs lateral flow immunoassay technology. Using this test allows for the rapid detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens.

To begin the test, a self-collected anterior nasal swab sample (in individuals aged 14 years and older or individuals between the ages of 2 to 13 with a swab collected by an adult) is inserted into the reagent buffer tube. The liquid in the reagent 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 reagent buffer 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, SARS-CoV-2 antigens are present in the specimen, they will react with either anti-influenza antibodies labeled with latex microspheres or anti-SARS-CoV-2 antibodies, 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 continue 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, the 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.

## 9.0 Non-clinical Performance summary

### 9.1 Precision Study

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

The following panel was tested: a negative sample (PNF only), a low positive sample (0.8x LoD of SARS-CoV-2, Flu A, Flu B, 0.8x co-spiked Flu A &Flu B, SARS-CoV-2 &Flu B, Flu A &Flu B & SARS-CoV-2), moderate positive samples (3x LoD of positive samples same as above). The strains used for testing were chemically inactivated SARS-CoV-2 Lineage JN.1, live influenza A/H1N1, and live influenza B Victoria.

Two replicates per sample panel was 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).

Precision was determined by comparing test results to expected results across all lots operators, and days. Results are shown in the table below. All replicates prepared at 3xLoD demonstrated 100% agreement across the operators, lots, days and runs tested. The expected lot to lot imprecision was observed with the 0.8X LoD samples. There were no invalid test results in the above study.

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*

## 9.2 Analytical Specificity/Interference:

### a) Cross Reactivity (Analytical Specificity) and Microbial Interference

A Cross-reactivity study was conducted by testing a panel of microorganisms commonly found as either pathogens or normal flora in respiratory samples individually spiked into Pooled Negative Nasal Fluid (PNF). 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 study was conducted in the same manner, but samples were prepared in the presence of chemical inactivated SARS-CoV-2, live influenza A and B co-

spiked into the samples at 3x LoD. The testing was performed in triplicate 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 and microbial interference results

| ***Microorganism*** | ***Working Concentration*** | ***Cross-reactivity Results (# pos / total)*** | ***Interference Results (# pos / total)*** |
|---|---|---|---|
| SARS-CoV-1* | $1.25\times10^5$ PFU/ml | 0/3 | 3/3 |
| MERS-coronavirus | $1.58\times10^8$ GE/mL | 0/3 | 3/3 |
| Human coronavirus HKU1 (HKU1/UNC/2/2022) | $4.34\times10^6$ GE/mL | 0/3 | 3/3 |
| Human coronavirus OC43 | $7.00\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Human coronavirus 229E | $1.40\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Human coronavirus NL63 | $8.00\times10^4$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Adenovirus,Type 1 | $2.23\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Adenovirus Type 7A | $1.58\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Cytomegalovirus | $1.00\times10^5$ PFU/mL | 0/3 | 3/3 |
| Epstein Barr Virus, Strain | $1.83\times10^6$ CP/mL | 0/3 | 3/3 |
| Human Metapneumovirus (hMPV) | $3.50\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Parainfluenza virus 1 | $2.00\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Parainfluenza virus 2 | $1.75\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Parainfluenza virus 3 | $7.00\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Parainfluenza virus 4 | $2.39\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Enterovirus Type 68 | $2.23\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Respiratory syncytial virus A | $1.49\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Respiratory syncytial virus B | $1.58\times10^5$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Rhinovirus | $2.23\times10^6$ $TCID_{50}$/mL | 0/3 | 3/3 |
| *Bordetella pertussis* | $2.50\times10^8$ CFU/mL | 0/3 | 3/3 |
| *Candida albicans* | $6.03\times10^6$ CFU/mL | 0/3 | 3/3 |
| *Chlamydia pneumoniae* | $4.33\times10^6$ IFU/mL | 0/3 | 3/3 |

| *Microorganism* | *Working Concentration* | *Cross-reactivity Results (# pos / total)* | *Interference Results (# pos / total)* |
|---|---|---|---|
| *Corynebacterium xerosis* | $2.30\times10^{7}$ CFU/mL | 0/3 | 3/3 |
| *Escherichia coli* | $1.18\times10^{8}$ CFU/mL | 0/3 | 3/3 |
| *Hemophilus influenzae* | $3.00\times10^{10}$ CFU/mL | 0/3 | 3/3 |
| *Lactobacillus sp* | $8.50\times10^{6}$ CFU/mL | 0/3 | 3/3 |
| *Legionella pneumophila* | $6.50\times10^{6}$ CFU/mL | 0/3 | 3/3 |
| *Moraxella catarrhalis* | $2.50\times10^{8}$ CFU/mL | 0/3 | 3/3 |
| *Mycoplasma pneumoniae* | $2.50\times10^{7}$ CFU/mL | 0/3 | 3/3 |
| *Mycobacterium tuberculosis* | $4.15\times10^{6}$ CFU/mL | 0/3 | 3/3 |
| *Neisseria meningitidis* | $3.43\times10^{6}$ CFU/mL | 0/3 | 3/3 |
| *Neisseria Elongata* | $2.68\times10^{8}$ CFU/mL | 0/3 | 3/3 |
| *Pneumocystis jirovecii* | $1.30\times10^{7}$ CFU/mL | 0/3 | 3/3 |
| *Pseudomonas aeruginosa* | $1.23\times10^{8}$ CFU/mL | 0/3 | 3/3 |
| *Staphylococcus aureus* | $2.60\times10^{8}$ CFU/mL | 0/3 | 3/3 |
| *Staphylococcus epidermidis* | $9.00\times10^{7}$ CFU/mL | 0/3 | 3/3 |
| *Streptococcus salivarius* | $1.01\times10^{6}$ CFU/mL | 0/3 | 3/3 |
| *Streptococcus pneumoniae* | $3.88\times10^{7}$ CFU/mL | 0/3 | 3/3 |
| *Streptococcus pyogenes* | $7.50\times10^{7}$ CFU/mL | 0/3 | 3/3 |
| Measles | $2.23\times10^{5}$ $TCID_{50}$/mL | 0/3 | 3/3 |
| Mumps | $8.48\times10^{5}$ $TCID_{50}$/mL | 0/3 | 3/3 |
| PNF(Pooled Negative Nasal Fluid) | NA | 0/3 | 3/3 |

* strains were gamma-irradiated prior to wet-testing.

**b) Exogenous and Endogenous Interference Study**

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 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 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.

Table 3. Endogenous/exogenous interfering substances study results

| ***Substance*** | ***Concentration*** | ***Cross-reactivity*** *(no analyte)* *(# pos reps / total reps)* | | | ***Interference*** *(3x LoD co-spiked analytes)* *(# pos reps / total reps)* | | |
|---|---|---|---|---|---|---|---|
| | | SARS-CoV-2 | Flu A | Flu B | SARS-CoV-2 | Flu A | Flu B |
| Human Whole Blood (EDTA tube) | 4% v/v | 0/3 | 0/3 | 0/3 | 3/3 | 3/3 | 3/3 |
| Leukocytes | $1.67\times10^6$ cells/mL | 0/3 | 0/3 | 0/3 | 3/3 | 3/3 | 3/3 |
| 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 |
| Homeopathic Nasal Spray (Alkalol) | 15% v/v | 0/3 | 0/3 | 0/3 | 3/3 | 3/3 | 3/3 |
| Zicam | 5% v/v | 0/3 | 0/3 | 0/3 | 3/3 | 3/3 | 3/3 |
| | 15% v/v | 0/3 | 0/3 | 0/3 | 3/3 | 3/3 | 3/3 |
| Homeopathic allergy relief (Histaminum hydrochloricum) | 15% v/v | 0/3 | 0/3 | 0/3 | 3/3 | 3/3 | 3/3 |

| ***Substance*** | ***Concentration*** | ***Cross-reactivity*** *(no analyte)* *(# pos reps / total reps)* | | | ***Interference*** *(3x LoD co-spiked analytes)* *(# pos reps / total reps)* | | |
|---|---|---|---|---|---|---|---|
| | | SARS-CoV-2 | Flu A | Flu B | SARS-CoV-2 | Flu A | Flu B |
| Sore Throat Phenol Spray | 15% v/v | 0/3 | 0/3 | 0/3 | 3/3 | 3/3 | 3/3 |
| Fluticasone Propionate | 5% v/v | 0/3 | 0/3 | 0/3 | 3/3 | 3/3 | 3/3 |
| | 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 intranasal* | 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 |
| | 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 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 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 |

| ***Substance*** | ***Concentration*** | ***Cross-reactivity*** *(no analyte)* *(# pos reps / total reps)* | | | ***Interference*** *(3x LoD co-spiked analytes)* *(# pos reps / total reps)* | | |
|---|---|---|---|---|---|---|---|
| | | SARS-CoV-2 | Flu A | Flu B | SARS-CoV-2 | Flu A | Flu B |
| Hand soap liquid gel | 10% w/v | 0/3 | 0/3 | 0/3 | 3/3 | 3/3 | 3/3 |
| None (only PNF) | N/A | 0/3 | 0/3 | 0/3 | NT | NT | NT |
| None (3x LoD Co-spike) | N/A | NT | NT | NT | 3/3 | 3/3 | 3/3 |

*NT: Not test.

### 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 2 live influenza B virus strains were used in this study.

The table below 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. No false positive results were observed.

Table 4. Competitive interference 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 | $6.73\times10^{4}$ | Influenza B/Victoria | $2.12\times10^{3}$ | 100% |
| 2 | Influenza A/H1N1 | $6.73\times10^{4}$ | SARS-CoV-2 | $1.89\times10^{1}$ | 100% |
| 3 | Influenza A/H1N1 | $6.73\times10^{4}$ | Influenza B/Victoria | $2.12\times10^{3}$ | 100% |
| | | | SARS-CoV-2 | $1.89\times10^{1}$ | |
| 4 | Influenza B/Victoria | $9.40\times10^{5}$ | Influenza A/H1N1 | $1.20\times10^{2}$ | 100% |
| 5 | Influenza B/Victoria | $9.40\times10^{5}$ | SARS-CoV-2 | $1.89\times10^{1}$ | 100% |
| 6 | Influenza B/Victoria | $9.40\times10^{5}$ | Influenza A/H1N1 | $1.20\times10^{2}$ | 100% |
| | | | SARS-CoV-2 | $1.89\times10^{1}$ | |

| | | | | | |
|---|---|---|---|---|---|
| 7 | SARS-CoV-2 | $4.67\times10^4$ | Influenza A/H1N1 | $1.20\times10^2$ | 100% |
| 8 | SARS-CoV-2 | $4.67\times10^4$ | Influenza B/Victoria | $2.12\times10^3$ | 100% |
| 9 | SARS-CoV-2 | $4.67\times10^4$ | Influenza A/H1N1 | $1.20\times10^2$ | 100% |
| | | | Influenza B/Victoria | $2.12\times10^3$ | |

## 10.3 Detection Limit

### a) Limit of Detection (LOD)

LoD studies determined the lowest detectable concentration of SARS-CoV-2, influenza A and influenza B at which 95% of all (true positive) replicates tested positive. A preliminary LoD was determined independently for two strains of Flu A, two strains of Flu B, and one strain of SARS-CoV-2 by first testing a series of ten-fold dilutions of each virus spiked into Pooled Negative Nasal Fluid (PNF). Once the ten-fold breakpoint was established, an additional series of three (3) two-fold dilutions of the lowest positive ten-fold dilution concentration for each virus were independently tested at triplicates to determine a preliminary LoD.

Confirmatory LoD 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 device lots, with each lot generating its own LoD. The final device LOD was determined by selecting the highest LoD from the three lots as the overall LOD for the device.

Table 5. Confirmatory LoD Determination

| ***Virus Strains*** | ***LoD in PNF*** | ***LoD per Swab*** | ***#Positive/#total Tested*** | ***Percent Detected (%)*** |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| SARS-CoV-2 (Chemical inactivated, Omicron Variant, Lineage JN.1, USA/New York/PV96109/2023) | $6.30 \times 10^{0}$ $TCID_{50}$/mL | $3.15 \times 10^{-1}$ $TCID_{50}$/swab | 59/60 | 98.3% |
| Influenza A A/Victoria/4897/2022(H1N1) | $3.99 \times 10^{1}$ $TCID_{50}$/mL | $2.00 \times 10^{0}$ $TCID_{50}$/swab | 58/60 | 96.7% |
| Influenza A A/Darwin/6/2021(H3N2) | $8.95 \times 10^{1}$ $TCID_{50}$/mL | $4.48 \times 10^{0}$ $TCID_{50}$/swab | 59/60 | 98.3% |
| Influenza B Victoria/B/Austria/1359417/2021 | $7.05 \times 10^{2}$ $TCID_{50}$/mL | $3.53 \times 10^{1}$ $TCID_{50}$/swab | 59/60 | 98.3% |
| Influenza B Yamagata/ B/Phuket/3073/2013 | $2.06 \times 10^{5}$ $CEID_{50}$/mL | $1.03 \times 10^{4}$ $CEID_{50}$/swab | 59/60 | 98.3% |

**b) Co-Spike LoD Equivalence**

After the single analyte LoDs were established for the candidate device, co-spike equivalency testing was conducted to characterize performance on samples that contained all analytes at low concentrations.

Based on individual analyte LoD, a 1X Co-spike concentration was prepared by mixing viruses (one each of SARS-CoV-2, Flu A, Flu B with most challenging (i.e., lowest) LoD determined to have the lowest (best) LoD.

The 1X prepared sample concentration was tested on the candidate device using twenty (20) replicates. The results show ≥19/20 (≥100%) replicates are positive, which complies with the acceptance criteria. Additionally, all (3/3) negative replicates tested negative. Therefore, the LoD in co-spiked samples was deemed equivalent to the LoD in samples prepared with single analytes.

Table 6. Confirmatory co-spike analyte LoD results

| *Virus Strain Co-Spiked in Sample* | *Final Concentration* | | *Positive Replicates* |
|---|---|---|---|
| SARS-CoV-2+Flu A-H1N1+Flu B-Victoria | 6.30 ×$10^0$ $TCID_{50}$/mL | 3.15×$10^{-1}$ $TCID_{50}$/swab | 20/20 |
| | 3.99 ×$10^1$ $TCID_{50}$/mL | 2.00 ×$10^0$ $TCID_{50}$/swab | 20/20 |
| | 7.05 ×$10^2$ $TCID_{50}$/mL | 3.53 ×$10^1$ $TCID_{50}$/swab | 19/20 |
| Negative | NA | | 0/3 |

**c) Detection Limit with the NIBSC 21/368 - WHO International Standard**

The LoD of the candidate device was determined with the First WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368). The preliminary LoD concentration was determined by testing a series of 2-fold dilutions in PNF with one device lot, starting with a 5-fold dilution from the stock concentration (20,000 IU/mL) of the WHO International Standard for SARS-CoV-2 Antigen. Each dilution tested triplicate (n=3) replicates. Once the lowest positive 2-fold dilution concentration was established. And the preliminary LoD concentration was determined.
LoD confirmation testing was performed by testing twenty (20) replicates at the preliminary (1X) LoD concentration determined above. The results of the confirmation LoD testing are summarized in Table 7 with the confirmation LoD in bold.

Table 7. Confirmation LoD determination for WHO International Standard

| *Concentration (IU/mL) in PNF* | *Result (number of positive/total number)* | | |
|---|---|---|---|
| | SARS-CoV-2 | Flu A | Flu B |
| 2.50 × $10^2$ | 20/20 | 0/20 | 0/20 |
| 2.25 × $10^2$ | 20/20 | 0/20 | 0/20 |
| **1.94 × $10^2$** | **19/20** | **0/20** | **0/20** |
| 1.88 × $10^2$ | 15/20 | 0/20 | 0/20 |
| 5.82 × $10^2$ | 20/20 | 0/20 | 0/20 |
| 6.47 × $10^1$ | 0/20 | 0/20 | 0/20 |

1.94 × $10^2$ IU/mL (9.7 IU/swab) was determined as the confirmatory LoD of the iHealth Flu A&B/COVID-19 Rapid Test using First WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368).

**9.4 High-Dose Hook Effect Study:**

The candidate device was tested to determine if it was affected by a high dose hook effect at high concentrations of the three analytes. A high dose of chemically inactivated SARS-

CoV-2, and live influenza A and B were tested in this study. No high dose hook effect was observed for any panel analytes at the concentrations tested.

Table 8. High-dose hook effect study results

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

## 9.5 Inclusivity Study:

Analytical reactivity was performed for the iHealth Flu A&B/COVID-19 Rapid Test on 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 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 9. Data demonstrate that the iHealth Flu A&B/COVID-19 Rapid Test is inclusive for the SARS-CoV-2 and influenza A and B analytes across a range of strains.

Table 9. Analytical reactivity with relevant variants

| ***Virus*** | ***Strain*** | ***Concentration*** |
|---|---|---|
| Influenza A (H1N1) | A/Victoria/4897/22 | 5.05×$10^1$ $TCID_{50}$/mL |
| | A/Brisbane/02/2018 | 3.78×$10^1$ $TCID_{50}$/mL |
| | A/Macha/O1453/2021 | 2.80×$10^5$ $TCID_{50}$/mL |
| | 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 | $4.00\times10^{6}$ $CEID_{50}$/mL |
| Influenza A (H3N2) | A/Darwin/6/2021 | $1.04\times10^{2}$ $TCID_{50}$/mL |
| | A/Alaska/01/2021 | $7.50\times10^{3}$ FFU/mL |
| | A/New York/21/2020 | $1.30\times10^{5}$ FFU/mL |
| | A/Tasmania/503/2020 | $3.25\times10^{4}$ FFU/mL |
| | A/Montana/08/2023 | $1.30\times10^{5}$ FFU/mL |
| | A/Hong Kong/45/2019 | $7.50\times10^{3}$ FFU/mL |
| | A/Indiana/08/2011 | $2.03\times10^{2}$ $TCID_{50}$/mL |
| Influenza A (H5N1) | A/mallard/Wisconsin/ 2576/2009 H5N1* | $1.05\times10^{5}$ GE/mL |
| | A/bovine/Ohio/B24OSU-439/2024 H5N1* | $3.67\times10^{5}$ GE/mL |
| Influenza A (H5N6) | A/duck/Guangxi/S10888/2024 H5N6 | $6.76\times10^{5}$ $EID_{50}$/mL |
| Influenza A (H5N8) | A/goose/Liaoning/S1266/2021 H5N8 | $1.69\times10^{5}$ $EID_{50}$/mL |
| Influenza A (H7N3) | A/northern pintail/Illinois/10OS3959/2010 | $3.55\times10^{6}$ $CEID_{50}$/mL |
| Influenza B (non-Victoria non-Yamagata) | B/Maryland/1/1959 | $1.69\times10^{3}$ $CEID_{50}$/mL |
| Influenza B (Victoria Lineage) | B/Austria/1359417/2021 | $7.05\times10^{2}$ $TCID_{50}$/mL |
| | B/Michigan/01/2021 | $5.70\times10^{3}$ $TCID_{50}$/mL |
| | B/New Hampshire/01/2021 | $6.50\times10^{2}$ $TCID_{50}$/mL |
| | B/Washington/02/2019 | $7.90\times10^{2}$ $TCID_{50}$/mL |
| | B/Texas/02/2013 | $6.13\times10^{0}$ $TCID_{50}$/mL |
| Influenza B (Yamagata Lineage) | B/Phuket/3073/2013 | $2.75\times10^{5}$ $TCID_{50}$/mL |
| | B/Florida/04/2006 | $1.17\times10^{1}$ $TCID_{50}$/mL |
| | B/Texas/06/2011 | $1.60\times10^{6}$ $CEID_{50}$/mL |
| | B/Utah/09/2014 | $1.26\times10^{2}$ $TCID_{50}$/mL |
| SARS-CoV-2 | USA/New York/PV96109/2023 | $7.00\times10^{0}$ $TCID_{50}$/mL |
| | USA-WA1/2020 | $3.16\times10^{2}$ $TCID_{50}$/mL |
| | USA/CA-Stanford-109-S21/2022 | $5.95\times10^{3}$ $TCID_{50}$/mL |
| | USA/NY-Wadsworth-23067147-01/2023 | $7.88\times10^{3}$ $TCID_{50}$/mL |

* strains were gamma-irradiated prior to wet-testing

## 10.0 Clinical Testing Summary

### a) Clinical Study Design

A prospective study was performed in which five hundred ninety-two (592) study subjects were sequentially enrolled (between November 2024 and March 2025). Anterior nasal swab (ANS) samples were collected from symptomatic patients suspected of infection with respiratory symptoms, at fifteen (15) clinical sites. To be enrolled in the study, patients had to present at the participating study site within five (5) days of symptom onset with signs and symptoms of respiratory infection generally observed from SARS-CoV-2, influenza A and/or influenza B, during the study period. Two anterior nasal swab specimens were collected from each patient: one swab was collected by a healthcare professional and sent for testing using a highly sensitive RT-PCR comparator assay. and the other swab was self-

collected and tested immediately with the iHealth Flu A&B/COVID-19 Rapid Test per the test procedure. The collection order for the investigational and the comparator tests' swab was randomized. Subjects performed testing on self-collected swab samples in age groups 14 and older, and adult collected samples for age groups 2-13, in a simulated at-home environment. Out of 592 enrolled subjects, there were 588 evaluable subjects and 4 enrolled subjects were excluded.

## b) Subject Demographics

Table 10. Subject Demographics

| | ***Subjects (by 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(19.8) | 22.3(21.6) |
| Median [Min, Max] | 8[2,91] | 38[14,87] | 12[2,91] |
| **Age Group** | | | |
| 2-13 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%) | 150(25.5%) |
| >64 years of age | 10(1.7%) | 34(5.8%) | 44(7.5%) |
| **Sex at Birth** | | | |
| Female | 158(26.9%) | 122(20.7%) | 280(47.6%) |
| Male | 185(31.5%) | 123(20.9%) | 308(52.4%) |

The performance of the candidate test when compared to FDA-cleared highly sensitive RT-PCR molecular assays are presented in the tables below.

## c) Clinical Performance

### SARS-COV-2 PERFORMANCE

Table 11. Clinical Performance Compared to Reference PCR: SARS-CoV-2

| ***SARS-CoV-2*** | ***Comparator Positives*** | ***Comparator Negatives*** | ***Sum*** |
|---|---|---|---|
| Candidate Positives | 49 | 2 | 51 |
| Candidate Negatives | 4 | 533 | 537 |
| **Sum** | 53 | 535 | 588 |

Positive Percent Agreement (PPA) =92.5% (49/53), 95% CI (82.1%, 97.0%)

Negative Percent Agreement (NPA) = 99.6% (533/535), 95% CI (98.6%, 99.9%)

*Table 12. SARS-CoV-2 Clinical Performance Stratified by Days Post Symptoms Onset*

| ***DPSO*** | ***Number of Subject samples tested*** | ***Candidate Positives*** | ***Comparator Positives*** | ***% Positive Rate (by Comparator)*** | ***PPA (95% CI)*** |
|---|---|---|---|---|---|
| **Day 0** | 33 | 3 | 3 | 0.5% | 100.0% **(43.8%, 100%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Day 1** | 156 | 19 | 19 | 3.2% | 100.0%<br>**(83.2%, 100%)** |
| **Day 2** | 202 | 9 | 12 | 2.0% | 75.0%<br>**(46.8%,91.1%)** |
| **Day 3** | 131 | 12 | 13 | 2.2% | 92.3%<br>**(66.7%, 98.6%)** |
| **Day 4** | 47 | 5 | 5 | 0.9% | 100.0%<br>**(56.6%,100%)** |
| **Day 5** | 19 | 1 | 1 | 0.2% | 100.0%<br>**(20.7%,100%)** |
| **Total** | **588** | **49** | **53** | **9.0%** | **92.5%<br>(82.1%-97.0%)** |

**INFLUENZA A PERFORMANCE**

*Table 13. Clinical Performance Compared to Reference PCR: Influenza A*

| ***FLU A*** | ***Comparators Positives*** | ***Comparators Negatives*** | ***Sum*** |
|---|---|---|---|
| Candidate Positives | 197 | 6 | 203 |
| Candidate Negatives | 29 | 356 | 385 |
| **Sum** | 226 | 362 | 588 |

Positive Percent Agreement (PPA) =87.2% (197/226), 95% CI (82.2%, 90.9%)

Negative Percent Agreement (NPA) = 98.3% (356/362), 95% CI (96.4%, 99.2%)

**INFLUENZA B PERFORMANCE**

*Table 14. Clinical Performance Compared to Reference PCR: Influenza B*

| ***FLU B*** | ***Comparators Positives*** | ***Comparators Negatives*** | ***Sum*** |
|---|---|---|---|
| Candidate Positives | 43 | 4 | 47 |
| Candidate Negatives | 7 | 534 | 541 |
| **Sum** | 50 | 538 | 588 |

Positive Percent Agreement (PPA) =86.0% (43/50), 95% CI (73.8%, 93.0%)

Negative Percent Agreement (NPA) = 99.3% (534/538), 95% CI (98.1%, 99.7%)

## 11.0 Other Supportive Information:

### Flex Studies

To assess the robustness and risk for false results of the test when deviating from the 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, uneven mixing, delay in addition of sample to the well, incubation time], variability of environmental test conditions that the test may be subjected to when in use [lighting, disturbance during use, temperature and humidity stress conditions, inadequate temperature equilibration, delayed use after opening the foil pouch], and interpretation by a colorblind user. Testing

was performed with contrived positive nasal swabs generated by diluting SARS-CoV-2 virus into negative PNF at 2x LoD. False results are observed with too little sample volume and insufficient incubation time, specifically with less than two drops of sample and with less than ten minutes incubation. Additionally, if the swab was not thoroughly mixed in the reagent buffer tube, it could also lead to false results. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

## 12.0 Conclusion

The information provided in this Premarket Notification demonstrates that the performance of the iHealth Flu A&B/COVID-19 Rapid Test and iHealth Flu A&B/COVID-19 Rapid Test Pro are substantially equivalent in intended use, technological characteristics and performance to the predicate device.