December 12, 2025

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

Re: K251085
Trade/Device Name: iHealth Flu A&B/COVID-19/RSV Rapid Test; iHealth Flu A&B/COVID-19/RSV 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 8, 2025
Received: April 9, 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)*
K251085

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

Indications for Use *(Describe)*

iHealth Flu A&B/COVID-19 Rapid Test:
The iHealth Flu A&B/COVID-19/RSV Rapid Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, influenza B, SARS-CoV-2, and respiratory syncytial virus (RSV) protein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to influenza, SARS-CoV-2, and RSV 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 six (6) months 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, RSV, or other pathogens.

Individuals who test negative and/or experience continued or worsening 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/RSV Rapid Test Pro is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, influenza B, SARS-CoV-2, and respiratory syncytial virus (RSV) protein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to influenza, SARS-CoV-2, and RSV can be similar.

This test is for use by individuals aged 14 years or older testing themselves, or adults testing individuals aged six (6) months 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, RSV, or other pathogens.

Individuals who test negative and/or 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 requirement 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 6, 2025

2.0 Device information

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

Classification name: Multi analyte respiratory virus antigen detection test

Regulation number: 21 CFR 866.3987

Product code: SCA

3.0 Classification

Product code: SCA

Classification Regulation: 21 CFR 866.3987 - Multi analyte respiratory virus antigen detection test

Classification: Class II

Review Panel: Microbiology

4.0 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 AntigenTest
Classification Regulation	21 CFR 866.3987 - Multi analyte respiratory virus antigen detection test
Classification	Class II
Product Code	SCA

5.0 Device description

The iHealth Flu A&B/COVID-19/RSV Rapid Test and iHealth Flu A&B/COVID-19/RSV Rapid Test Pro (both versions hereafter also referred to as the candidate device) are lateral flow immunoassay device intended for the qualitative detection and differentiation of influenza A, influenza B, SARS-CoV-2, and respiratory syncytial virus (RSV) 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. The candidate device detects antigens from influenza A, influenza B, SARS-CoV-2, and RSV in anterior nasal swabs collected from individuals exhibiting signs and symptoms of respiratory infection within the first six (6) days of symptom onset, when tested at least twice over a three-day period with a minimum of 48 hours between tests.

The device is validated for testing direct anterior nasal samples (ANS) without the use of transport media. The device does not utilize biotin-streptavidin or avidin chemistry.

The test card contains two test strips, each with a nitrocellulose membrane, enclosed in a plastic case. One test strip has four lines: three test lines (Flu A, Flu B, and CoV) and a control line (Ctrl), while the other test strip has two lines: one test line (RSV) and a control line (Ctrl).

6.0 Indications for use

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

The iHealth Flu A&B/COVID-19/RSV Rapid Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, influenza B, SARS-CoV-2, and respiratory syncytial virus (RSV) protein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to influenza, SARS-CoV-2, and RSV 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 six (6) months 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, RSV, or other pathogens.

Individuals who test negative and/or experience continued or worsening 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/RSV Rapid Test Pro is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, influenza B, SARS-CoV-2, and respiratory syncytial virus (RSV) protein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to influenza, SARS-CoV-2, and RSV can be similar.

This test is for use by individuals aged 14 years or older testing themselves, or adults testing individuals aged six (6) months 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, RSV, or other pathogens.

Individuals who test negative and/or experience continued or worsening 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.

7.0 Intended use

Same as Indications for Use above.

8.0 Technological Comparison

Table 1. Comparison with Predicate Device

Characteristics	**Candidate Device (K251085)**	**Predicate Device** (K243256)
Product Name	iHealth Flu A&B/COVID-19/RSV Rapid Test iHealth Flu A&B/COVID-19/RSV Rapid Test Pro	WELLlife™ COVID-19 / Influenza A&B Home Test; WELLlife™ COVID-19 / Influenza A&B AntigenTest

Characteristics	**Candidate Device (K251085)**	**Predicate Device** (K243256)
Intended Use/ Indications for Use	See Section 6.0 above for intended use of candidate device	WELLlife™ COVID-19 / Influenza A&B Home Test The WELLlife™ COVID-19 / Influenza A&B Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARSCoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up. WELLlife™ COVID-19 / Influenza A&B AntigenTest 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

Characteristics	**Candidate Device (K251085)**	**Predicate Device** (K243256)
		nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARSCoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers. Positive results do not rule out co-infection with other respiratory pathogens. Test results should not be used as the sole basis for treatment or other patient management decisions.
General Device Characteristic Similarities		
Product Code	SCA	Same
Regulation Number	866.3987	Same
Regulatory Class	II	Same
Patient Use	Over the counter use and Professional use	Same
Intended User	Individuals with signs and symptoms of respiratory tract infection	Same
Usage Type	Single use test	Same
Assay Control	Internal procedural control	Same
Test Principle	Lateral flow immunoassay	Same
Assay Target	SARS-CoV-2 nucleocapsid protein antigens Influenza A nucleoprotein antigens Influenza B nucleoprotein antigens RSV fusion protein antigens	SARS-CoV-2 nucleocapsid protein antigens Influenza A nucleoprotein antigens Influenza B nucleoprotein antigens
Specimen Type	Anterior nasal	Anterior nasal
Assay Result	Qualitative	Same
Detection Format	Visually read	Same

Characteristics	**Candidate Device (K251085)**	**Predicate Device** (K243256)
Time to Results	15-30 min	15 minutes - 20 minutes
Storage Condition	2°C to 30°C	Same
General Device Characteristic Differences		
Analytes Detected	SARS-CoV-2 nucleocapsid protein antigens, Influenza A nucleoprotein antigens, Influenza B nucleoprotein antigens, RSV fusion protein antigens	SARS-CoV-2 nucleocapsid protein antigens, Influenza A nucleoprotein antigens, Influenza B nucleoprotein antigens
Time to Result	15-30 min	15 - 20 min
Detection Period	within 6 days of symptom onset	within 4 days of symptom onset

9.0 Operation Principle

The candidate device uses lateral flow immunoassay technology. Using the candidate device enables the rapid detection and differentiation of SARS-CoV-2, influenza A, influenza B, and RSV protein antigens.

To begin the test, an anterior nasal swab sample (self-collected in individuals aged 14 years and older or individuals between the ages of 2 to 13 with a swab collected by an adult) is mixed with an extraction solution in the test tube. The extraction solution in the test tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The liquid in the test tube now containing the specimen is added to the sample well of the Test Card. When an adequate volume of the processed specimen is added to the sample well, the specimen migrates by capillary action across each of the two test strips migrating through the pads and membrane. 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 or RSV antigen, if present in the specimen, they will react with the specific antibody labeled with latex microspheres. The mixture then migrates towards the membrane as antigen-antibody-latex microspheres complexes, which then bind to the immobilized capture antibody line(s) on the membrane, producing a visible colored test line in the related test line region (Flu A/Flu B/ CoV/RSV).

The rest of the sample and unbound/bound latex microspheres complexes continue to migrate to the control line position (Ctrl) in each strip, where immobilized control antibodies capture the control antigen-latex microspheres complexes and form the control line. Formation of the control lines serves as an internal control to demonstrate that test reagents are functional, that 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 lines do not appear within the designated incubation time, the result is invalid, and the test should be repeated using a new test device and specimen.

10.0 Non-Clinical Performance Summary

10.1 Precision Study

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

A panel of nineteen samples was tested, including one negative sample and nine types of positive sample combinations: single samples (SARS-CoV-2, Flu A, Flu B, RSV), dual co-spiked samples (Flu A + Flu B, SARS-CoV-2 + RSV), triple co-spiked samples (Flu A + Flu B + SARS-CoV-2, Flu A + Flu B + RSV), and quadruple co-spiked samples (Flu A + Flu B + SARS-CoV-2 + RSV) with each combination at two concentrations: 0.8x LoD and 3x LoD.

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). All samples were prepared in pooled negative nasal fluid (PNF).

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. Results are shown in the table below.

Table 2. Lot-to Lot Precision

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%)
	RSV	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
0.8X LoD SARS-CoV-2	SARS-CoV-2	39/80 (48.8%)	46/80 (57.5%)	36/80 (45.0%)	121/240 (50.4%)
	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%)
	RSV	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	56/80 (70.0%)	35/80 (43.8%)	48/80 (60.0%)	139/240 (57.9%)
	Flu B	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	RSV	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	35/80 (43.8%)	31/80 (38.8%)	35/80 (43.8%)	101/240 (42.0%)
	RSV	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
0.8X LoD RSV	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%)

Analyte	Test line	No. of Positives / No. of Samples tested (%)			Total no. of positives / Total no. of samples (%)
		Lot 1	Lot 2	Lot 3	
	Flu B	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	RSV	53/80 (66.3%)	46/80 (57.5%)	41/80 (51.3%)	140/240 (58.3%)
0.8X LoD Flu A /Flu B	SARS-CoV-2	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu A	46/80 (57.5%)	40/80 (50.0%)	48/80 (60.0%)	134/240 (55.8%)
	Flu B	37/80 (46.3%)	39/80 (48.8%)	41/80 (51.3%)	117/240 (48.7%)
	RSV	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
0.8X LoD SARS-CoV-2 /RSV	SARS-CoV-2	41/80 (51.3%)	43/80 (53.8%)	44/80 (55.0%)	128/240 (53.3%)
	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%)
	RSV	48/80 (60.0%)	39/80 (48.8%)	36/80 (45.0%)	123/240 (51.2%)
0.8X LoD SARS-CoV-2 /Flu A/Flu B	SARS-CoV-2	43/80 (53.8%)	44/80 (55.0%)	41/80 (51.3%)	128/240 (53.3%)
	Flu A	50/80 (62.5%)	46/80 (57.5%)	48/80 (60.0%)	144/240 (60.0%)
	Flu B	47/80 (58.8%)	39/80 (48.8%)	42/80 (52.5%)	128/240 (53.3%)
	RSV	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
0.8X LoD Flu A /Flu B/RSV	SARS-CoV-2	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu A	51/80 (63.8%)	52/80 (65.0%)	49/80 (61.3%)	152/240 (63.3%)
	Flu B	42/80 (52.5%)	43/80 (53.8%)	37/80 (46.3%)	122/240 (50.8%)
	RSV	56/80 (70.0%)	47/80 (58.8%)	36/80 (45.0%)	139/240 (57.9%)
0.8X LoD SARS-CoV-2 /Flu A/Flu B /RSV	SARS-CoV-2	43/80 (53.8%)	48/80 (60.0%)	43/80 (53.8%)	134/240 (55.8%)
	Flu A	42/80 (52.5%)	50/80 (62.5%)	49/80 (61.3%)	141/240 (58.7%)
	Flu B	42/80 (52.5%)	46/80 (57.5%)	42/80 (52.5%)	130/240 (54.1%)
	RSV	53/80 (66.3%)	52/80 (65.0%)	39/80 (48.8%)	144/240 (60.0%)
3X LoD SARS-CoV-2	SARS-CoV-2	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	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%)
	RSV	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
3X LoD Flu A	SARS-CoV-2	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu A	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	Flu B	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	RSV	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
3X 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	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	RSV	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
3X LoD RSV	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%)
	RSV	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
3X LoD Flu A /Flu B	SARS-CoV-2	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu A	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	Flu B	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	RSV	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	SARS-CoV-2	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)

Analyte	Test line	No. of Positives / No. of Samples tested (%)			Total no. of positives / Total no. of samples (%)
		Lot 1	Lot 2	Lot 3	
3X LoD SARS-CoV-2/RSV	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%)
	RSV	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
3X LoD SARS-CoV-2/Flu A /Flu B	SARS-CoV-2	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	Flu A	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	Flu B	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	RSV	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
3X LoD Flu A /Flu B/RSV	SARS-CoV-2	0/80 (0%)	0/80 (0%)	0/80 (0%)	0/240 (0%)
	Flu A	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	Flu B	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	RSV	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
3X LoD SARS-CoV-2/Flu A /Flu B/RSV	SARS-CoV-2	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	Flu A	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	Flu B	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)
	RSV	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)

There were no invalid test results in the above study.

10.2 Analytical Specificity/Interference:

a) Cross Reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity of the iHealth Flu A&B/COVID-19/RSV Rapid Test was evaluated by testing a panel of related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens and could potentially cross-react with the iHealth Flu A&B/COVID-19/RSV Rapid Test including twenty (20) bacteria, twenty (20) viruses and one (1) negative matrix. Each organism and virus were tested in triplicate the absence (cross-reactivity) or presence (interference) of co-spiked chemically inactivated SARS-CoV-2, influenza A, influenza B, and RSV at 3 x LoD.

No cross-reactivity was observed with the listed microorganisms when tested at the concentration presented in the table below. No interference was observed with the listed microorganisms when tested at the concentration presented in the table below in the presence of the target analytes.

Table 3. Cross reactivity and microbial interference results

Microorganism	Working Concentration		Cross Reactivity Result (# pos / total)	Interference Result (# pos / 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

Microorganism	Working Concentration		Cross Reactivity Result (# pos / total)	Interference Result (# pos / total)
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	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
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 plantarum	8.50×10^{6}	CFU/mL	0/3	3/3
Legionella pneumophila	6.50×10^{6}	CFU/mL	0/3	3/3
Moraxella catarrhalis	2.50×10^{8}	CFU/mL	0/3	3/3
Mycoplasma pneumoniae	2.50×10^{7}	CFU/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, Strain Edmonston	2.23×10^{5}	$TCID_{50}$/mL	0/3	3/3
Mumps (Isolate 1)	8.48×10^{5}	$TCID_{50}$/mL	0/3	3/3
Human coronavirus HKU1	4.34×10^{6}	GE/mL	0/3	3/3
Pooled negative nasal fluid	N/A	NA	0/3	3/3

b) Exogenous and Endogenous Interference Study

The potential interference of endogenous substances with the antibodies used for the detection of influenza A, influenza B, RSV, and SARS-CoV-2 was examined by testing thirty-two (32) substances in a negative clinical matrix, in the absence or presence of each virus at 3 x LOD concentrations for influenza A (H1N1), influenza B (Victoria), SARS-CoV-2 and RSV.

The interference study was conducted using medically relevant concentrations of the potentially interfering substances listed below to assess the potential interference of the substances on the performance of the iHealth Flu A&B/COVID-19/RSV Rapid Test.

In the absence of influenza, SARS-CoV-2, and RSV B, all substances tested showed no interference except the 2024–25 FluMist live intranasal vaccine, which interfered at a concentration ≥ 0.375% v/v but was non-interfering at 0.1875% v/v, and 80% ethanol hand sanitizer, which caused invalid results at 15% v/v but showed no interference at concentrations ≤7.5% v/v .

In the presence of the target analytes, 80% ethanol hand sanitizer caused invalid results at 15% v/v. Additionally, 80% ethanol hand sanitizer at >3.75% v/v may interfere with Flu A and Flu B results and fluticasone propionate at >10% v/v may interfere with SARS-CoV-2, Flu B, and RSV results.

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

Table 4. Interfering Substances

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**	**RSV**	**SARS-CoV-2**	**Flu A**	**Flu B**	**RSV**
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Mucin	5mg/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Chloraseptic (Menthol/Benzocaine)	3 mg/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Naso GEL (NeilMed)	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Nasal corticosteroid (Dexamethasone)	1 mg/mL	0/3	0/3	0/3	0/3	3/3	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	0/3	3/3	3/3	3/3	3/3
Homeopathic allergy relief (Histaminum hydrochloricum)	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Zicam Nasal Spray (Galphimia glauca, luffa operculata)	5% v/v	0/3	0/3	0/3	0/3	3/3	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	RSV	SARS-CoV-2	Flu A	Flu B	RSV
Zicam Nasal Spray (Galphimia glauca, luffa operculata)	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Nasal Spray (Alkalol)	15% v/v	0/3	0/3	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	0/3	3/3	3/3	3/3	3/3
Tobramycin	4 µg/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Mupirocin	10 mg/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Anti-viral drug (Remdesivir)	10 mg/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Nasal corticosteroid (Fluticasone)	15% v/v	0/3	0/3	0/3	0/3	0/3	3/3	0/3	0/3
	10% v/v	N/A	N/A	N/A	N/A	3/3	3/3	3/3	3/3
	5% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
2024-25 FluMist® Influenza Vaccine Live intranasal	15% v/v	0/3	3/3	3/3	0/3	3/3	3/3	3/3	3/3
	1.5% v/v	0/3	3/3	0/3	0/3	N/A	N/A	N/A	N/A
	0.75% v/v	0/3	3/3	0/3	0/3	N/A	N/A	N/A	N/A
	0.375% v/v	0/3	3/3	0/3	0/3	N/A	N/A	N/A	N/A
	0.1875% v/v	0/3	0/3	0/3	0/3	N/A	N/A	N/A	N/A
	0.15% v/v	0/3	0/3	0/3	0/3	N/A	N/A	N/A	N/A
Zanamivir	282 ng/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Biotin	3,500 ng/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Zinc (TheraZinc Throat Spray)	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Leukocytes	1.67×10^6 cells/mL	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Body & Hand Lotion	0.5% w/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Hand Lotion	5% w/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	Invalid	Invalid	Invalid	Invalid	Invalid	Invalid	Invalid	Invalid
	7.5% v/v	0/3	0/3	0/3	0/3	3/3	0/3	0/3	3/3
	3.75% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
	1.5% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Hand soap liquid gel	10% w/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Nasal spray (Saline)	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3
Nasal corticosteroid (Triamcinolone)	15% v/v	0/3	0/3	0/3	0/3	3/3	3/3	3/3	3/3

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, SARS-CoV-2, and RSV prepared in PNF. Inactivated SARSCoV-2, live influenza A, live influenza B, and live RSV virus strains were used in this 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. Thus, no competitive interference between SARS-CoV-2, influenza A, influenza B, and RSV B were observed as shown in the table below.

Table 5. 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	RSV B	5.05×10^4	Influenza A/H1N1	1.36×10^2	100%
			Influenza B/Victoria	1.90×10^3	
2	RSV B	5.05×10^4	Influenza A/H1N1	1.36×10^2	100%
			SARS-CoV-2	2.10×10^1	
3	RSV B	5.05×10^4	Influenza B/Victoria	1.90×10^3	100%
			SARS-CoV-2	2.10×10^1	
4	RSV B	5.05×10^4	Influenza A/H1N1	1.36×10^2	100%
			Influenza B/Victoria	1.90×10^3	
			SARS-CoV-2	2.10×10^1	
5	RSV B	5.05×10^4	Influenza A/H1N1	1.36×10^2	100%
6	RSV B	5.05×10^4	SARS-CoV-2	2.10×10^1	100%
7	RSV B	5.05×10^4	Influenza B/Victoria	1.90×10^3	100%
8	Influenza A/H1N1	5.05×10^4	Influenza B/Victoria	1.90×10^3	100%
			RSV B	1.36×10^2	
9	Influenza A/H1N1	5.05×10^4	SARS-CoV-2	2.10×10^1	100%
			RSV B	1.36×10^2	
10	Influenza A/H1N1	5.05×10^4	Influenza B/Victoria	1.90×10^3	100%
			SARS-CoV-2	2.10×10^1	
11	Influenza A/H1N1	5.05×10^4	Influenza B/Victoria	1.90×10^3	100%
			SARS-CoV-2	2.10×10^1	
			RSV B	1.36×10^2	
12	Influenza A/H1N1	5.05×10^4	Influenza B/Victoria	1.90×10^3	100%
13	Influenza A/H1N1	5.05×10^4	SARS-CoV-2	2.10×10^1	100%
14	Influenza A/H1N1	5.05×10^4	RSV B	1.36×10^2	100%
15	Influenza B/Victoria	7.05×10^5	Influenza A/H1N1	1.36×10^2	100%
			RSV B	1.36×10^2	
16	Influenza B/Victoria	7.05×10^5	SARS-CoV-2	2.10×10^1	100%
			RSV B	1.36×10^2	
17	Influenza B/Victoria Influenza B/Victoria	7.05×10^5	Influenza A/H1N1	1.36×10^2	100%
			SARS-CoV-2	2.10×10^1	
18	Influenza B/Victoria	7.05×10^5	Influenza A/H1N1	1.36×10^2	100%
			SARS-CoV-2	2.10×10^1	
			RSV B	1.36×10^2	
19	Influenza B/Victoria	7.05×10^5	SARS-CoV-2	2.10×10^1	100%

Sample	Competing Virus		Target Virus		Target Analyte Percent Positivity
	Virus Type	Concentration ($TCID_{50}$/mL)	Virus Type	Concentration ($TCID_{50}$/mL)	
20	Influenza B/Victoria	7.05×10^5	Influenza A/H1N1	1.36×10^2	100%
21	Influenza B/Victoria	7.05×10^5	RSV B	1.36×10^2	100%
22	SARS-CoV-2	3.50×10^4	Influenza A/H1N1	1.36×10^2	100%
			RSV B	1.36×10^2	
23	SARS-CoV-2	3.50×10^4	Influenza B/Victoria	1.90×10^3	100%
			RSV B	1.36×10^2	
24	SARS-CoV-2	3.50×10^4	Influenza A/H1N1	1.36×10^2	100%
			Influenza B/Victoria	1.90×10^3	
25	SARS-CoV-2	3.50×10^4	Influenza A/H1N1	1.36×10^2	100%
			Influenza B/Victoria	1.90×10^3	
			RSV B	1.36×10^2	
26	SARS-CoV-2	3.50×10^4	Influenza B/Victoria	1.90×10^3	100%
27	SARS-CoV-2	3.50×10^4	Influenza A/H1N1	1.36×10^2	100%
28	SARS-CoV-2	3.50×10^4	Influenza B/Victoria	1.36×10^2	100%

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 and RSV at which at least 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, one strain of RSV A, one strain of RSV B, and one strain of SARS-CoV-2. A preliminary LoD was first determined by testing serial ten-fold dilutions of viral stocks diluted in pooled negative nasal fluid (PNF) in triplicate for three device lots for a total of 9 replicates per dilution. Once the lowest positive ten-fold dilution concentration was established, additional two-fold dilutions were tested in triplicate (n=3).

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 6. Confirmatory LoD Determination

Strain	Virus Concentration		Positive Replicates
SARS-CoV-2	7.00×10^0 $TCID_{50}$/mL	3.50×10^{-1} $TCID_{50}$/swab	59/60
Flu A- H1N1	4.55×10^1 $TCID_{50}$/mL	2.27×10^0 $TCID_{50}$/swab	59/60

Flu A - H3N2	9.38 $\times 10^1$ $TCID_{50}$/mL	4.69 $\times 10^0$ $TCID_{50}$/swab	59/60
Flu B - Victoria	6.35 $\times 10^2$ $TCID_{50}$/mL	3.17 $\times 10^1$ $TCID_{50}$/swab	58/60
Flu B-Yamagata	2.30 $\times 10^5$ $CEID_{50}$/mL	1.15 $\times 10^4$ $CEID_{50}$/swab	57/60
RSV A/A2023/06-12NSMM	1.26 $\times 10^3$ $TCID_{50}$/mL	6.30 $\times 10^1$ $TCID_{50}$/swab	59/60
RSV B/3/2015 lsolate #1	4.55 $\times 10^1$ $TCID_{50}$/mL	2.27 $\times 10^0$ $TCID_{50}$/swab	58/60

b) Co-Spike LoD Equivalence

After the single analyte LoDs were established for the candidate device, co-spike equivalency testing was conducted using PNF matrix 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, and RSV 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, and the result shows ≥19/20 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 7. Confirmatory co-spike analyte LoD results

Virus Type / Subtype	Virus Strains	Concentration Added to Swab	Positive Replicates (# Positive/#Total)
SARS-CoV-2	SARS-CoV-2 (Omicron, Lineage JN.1, Chemically inactivated; USA/New York/PV96109/2023)	7.00 $\times 10^0$ $TCID_{50}$/mL	20/20
Flu A-H1N1	H1N1pdm09: A/Victoria/4897/2022	4.55 $\times 10^1$ $TCID_{50}$/mL	20/20
Flu B-Victoria	Victoria: B/Austria/1359417/2021	6.35 $\times 10^2$ $TCID_{50}$/mL	20/20
RSV-B	3/2015 Isolate #1	4.55 $\times 10^1$ $TCID_{50}$/mL	20/20
Negative	NA	NA	0/3

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

The 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) was also tested to determine the LoD of SARS-CoV-2 antigen.

A preliminary LoD concentration was determined in the iHealth Flu A&B/COVID-19/RSV Rapid Test using the 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) by

first performing a five-fold dilution of the master stock equivalent to 20,000 IU/mL, followed by a series of two-fold dilutions. Three replicates were tested for each of two-fold dilutions to determine the preliminary LoD concentration of the candidate device. LoD confirmation testing was performed by testing twenty (20) replicates at the preliminary LoD concentration determined above. Acceptance criteria for confirmation of the 1X LoD was that 95% of the replicates (19/20) test positive. See the confirmed LOD in the table below.

Table 8. Confirmation LoD determination for WHO International Standard

Concentration (IU/mL)	**Result (number of positive/total number)**			
	SARS-CoV-2	**Flu A**	**Flu B**	**RSV**
5.80×10^2	20/20	0/20	0/20	0/20
2.50×10^2	20/20	0/20	0/20	0/20
2.25×10^2	20/20	0/20	0/20	0/20
1.93×10^2	**20/20**	**0/20**	**0/20**	**0/20**
1.92×10^2	18/20	0/20	0/20	0/20
1.88×10^2	13/20	0/20	0/20	0/20
6.44×10^1	0/20	0/20	0/20	0/20

1.93×10^2 IU/mL (9.6 IU/swab) was determined as the confirmatory LoD of candidate device using First WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368).

10.4 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 four panel analytes. A high dose of chemically inactivated SARS-CoV-2, live influenza A and B, and live RSV were tested in this study. Fifty (50) microliters of each sample were added directly to the head of the swabs. Swabs were processed per the test's IFU. As shown in Table 9, no high dose hook effect was observed for any panel analytes at the concentrations tested.

Table 9. High-dose hook effect study results

Strain	**Hook Effect Concentration.**	**Positive Replicates (# Positive/#Total)**	**% Positive**
SARS-CoV-2	1.40×10^5 $TCID_{50}$/mL	3/3	100
Flu A- H1N1	2.02×10^5 $TCID_{50}$/mL	3/3	100
Flu A - H3N2	4.17×10^5 $TCID_{50}$/mL	3/3	100
Flu B - Victoria	2.82×10^6 $TCID_{50}$/mL	3/3	100
Flu B-Yamagata	1.10×10^9 $CEID_{50}$/mL	3/3	100
RSV A	2.80×10^6 $TCID_{50}$/mL	3/3	100
RSV B	2.02×10^5 $TCID_{50}$/mL	3/3	100

10.5 Inclusivity Study:

Analytical reactivity testing for the candidate device was performed to ensure that the device can adequately detect a variety of strains for the influenza A, influenza B, SARS-CoV-2, and RSV viruses. A selection of temporally, geographically, and genetically diverse strains were tested for inclusivity, including 25 influenza A strains (11 H1N1, 9 H3N2, 2 H5N1, 1 H5N6, 1 H5N8, and 1 H7N3), 10 influenza B strains (1 non-Victoria non-Yamagata, 5 Victoria and 4 Yamagata lineages) 4 SARS-CoV-2 strains (1 Wild type and 3 Omicron), and 12 RSV strains (6 RSV A and 6 RSV B). The inclusivity result for Flu A strains, Flu B strains, RSV A, RSV B and SARS-CoV-2 strains indicates that the following strains can be detected.

Table 10. 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	2.11×10^{2} $TCID_{50}$/mL
	A/Hawaii/66/2019	1.85×10^{7} $CEID_{50}$/mL
	A/Wisconsin/588/2019	7.00×10^{3} FFU/mL
	A/Indiana/02/2020	4.85×10^{6} $CEID_{50}$/mL
	A/California/04/2009	7.00×10^{2} $TCID_{50}$/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
Influenza A (H1N1)v	A/Ohio/09/2015 (H1N1)v	3.50×10^{5} $CEID_{50}$/mL
Influenza A (H1N2)v	A/Minnesota/19/2011 (H1N2)v	4.00×10^{6} $CEID_{50}$/mL
Influenza A (H3N2)v	A/Indiana/08/2011 (H3N2)v	2.03×10^{2} $TCID_{50}$/mL
Influenza A (H5N1)*	A/mallard/Wisconsin/ 2576/2009 H5N1	1.05×10^{5} GE/mL
	A/bovine/Ohio/B24OSU-439/2024 H5N1	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	3.38×10^{5} EID_{50}/mL
Influenza A (H7N3)	A/northern pintail/lllinois/10OS3959/2010(H7N3)	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)	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

Virus	Strain	Concentration
Influenza B (Yamagata)	B/Phuket/3073/2013	2.75×10^5 $CEID_{50}$/mL
	B/Florida/04/2006	1.17×10^1 $TCID_{50}$/mL
	B/Texas/06/2011	8.00×10^5 $CEID_{50}$/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
RSV A	A2023/06-12NSMM	7.00×10^2 $TCID_{50}$/mL
	A1998/3-2	4.00×10^3 $TCID_{50}$/mL
	A2001/2-20	1.40×10^4 $TCID_{50}$/mL
	2013 Isolate	1.41×10^1 $TCID_{50}$/mL
	12/2014 Isolate 2	1.17×10^3 $TCID_{50}$/mL
	3/2015 Isolate #3	2.98×10^2 $TCID_{50}$/mL
RSV B	3/2015 Isolate #1	5.05×10^1 $TCID_{50}$/mL
	B1	8.00×10^2 $TCID_{50}$/mL
	CH93(18)-18	3.15×10^2 $TCID_{50}$/mL
	11/2014 Isolate #2	8.88×10^1 $TCID_{50}$/mL
	12/2014 Isolate #1	1.25×10^2 $TCID_{50}$/mL
	3/2015 Isolate #2	1.26×10^3 $TCID_{50}$/mL

* Strains were gamma-irradiated prior to wet-testing

11.0 Clinical Testing Summary

a) Clinical Study Design

A prospective study was performed in which one thousand one hundred and fifty-four (1154) study subjects were sequentially enrolled (between November 2024 and November 2025) and tested fresh. Anterior nasal swab (ANS) samples were collected from symptomatic patients suspected of infection with respiratory symptoms, at twenty-two (22) clinical sites. To be enrolled in the study, patients had to present at the participating study site within six (6) days of symptom onset with signs and symptoms of respiratory infection generally observed from influenza A, influenza B, SARS-CoV-2, and/or RSV, during the study period. Two anterior nasal (AN) swab specimens were collected from each participant. One swab was collected by a healthcare professional, 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 second 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 ≥6 months. This swab was tested immediately on-site using the iHealth Flu A&B/COVID-19/RSV Rapid Test. The order of collection for the investigational and comparator AN swab was randomized.

Out of 1154 enrolled subjects, there were 1119 evaluable subjects, and 35 enrolled subjects were excluded. The subject demographics of the evaluable subjects are shown below:

b) Subject Demographics

Table 11. Subject Demographics

	Subjects (by lay-user collection and testing (N=684)	Self- collecting and testing (N=435)	Overall (N=1119)
Age			
Mean (SD)	5.5 (8.4)	49.6 (22.7)	22.5 (26.6)
Median [Min, Max]	3 [0.5, 91]	51 [14, 92]	9 [0.5, 92]
Age Group			
6-11 months	103 (100.0%)	0 (0.0%)	103 (9.2%)
12-17 months	85 (100.0%)	0 (0.0%)	85 (7.6%)
18-24 months	78 (100.0%)	0 (0.0%)	78 (7.0%)
2-5 years	180 (100.0%)	0 (0.0%)	180 (16.1%)
6-14 years	217 (93.5%)	15 (6.5%)	232 (20.7%)
15-59 years	14 (6.0%)	221 (94.0%)	235 (21.0%)
≥60 years	7 (3.4%)	199 (96.6%)	206 (18.4%)
Sex at Birth			
Female	338 (55.9%)	267 (44.1%)	605 (54.1%)
Male	346 (67.3%)	168 (32.7%)	514 (45.9%)

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

Table 12. SARS-CoV-2 Performance

SARS-CoV-2	Comparator Positives	Comparator Negatives	Sum
Investigational Positives	67	1	68
Investigational Negatives	8	1043	1051
Sum	75	1044	1119

Positive Percent Agreement = (67/75) = 89.3% (95% CI: 80.3%- 94.5%)

Negative Percent Agreement = (1043/1044) = 99.9% (95% CI: 99.5%- 100.0%)

Table 13. 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	40	1	2	5.0%	50.0% (9.5%-90.5%)
Day 1	184	12	13	7.1%	92.3% (66.7%-98.6%)
Day 2	355	15	17	4.8%	88.2% (65.7%-96.7%)
Day 3	270	22	24	8.9%	91.7% (74.2%-97.7%)
Day 4	180	8	9	5.0%	88.9% (56.5%-98.0%)
Day 5	77	5	5	6.5%	100.00% (56.6%-100.0%)
Day 6	13	4	5	38.5%	80.0% (37.6%-96.4%)
Total	1119	67	75	6.7%	89.3% (80.3%-94.5%)

Table 14. Influenza A Performance

FLU A	Comparators Positives	Comparators Negatives	Sum
Investigational Positives	205	4	209
Investigational Negatives	29	881	910
Sum	234	885	1119

Positive Percent Agreement = (205/234) = 87.6% (95% CI: 82.8% - 91.2%)

Negative Percent Agreement = (881/885) = 99.5% (95% CI: 98.8%- 99.8%)

Table 15. Influenza B Performance

FLU B	Comparators Positives	Comparators Negatives	Sum
Investigational Positives	36	0	36
Investigational Negatives	3	1080	1083
Sum	39	1080	1119

Positive Percent Agreement = (36/39) = 92.3% (95% CI: 79.7% - 97.3%)

Negative Percent Agreement = (1080/1080) = 100.0% (95% CI: 99.6% - 100.0%)

Table 16 RSV Performance

RSV	Comparators Positives	Comparators Negatives	Sum
Investigational Positives	149	12	161
Investigational Negatives	21	937	958
Sum	170	949	1119

Positive Percent Agreement = (149/170) = 87.6% (95% CI: 81.9% - 91.8%)

Negative Percent Agreement = (937/949) = 98.7% (95% CI: 97.8% - 99.3%)

Table 17: RSV Performance Stratified by Age Group

Age group	Number of Subject samples tested	Candidate Positives	Comparator Positives	PPA (95% CI)
6-24 months	266	66	74	89.1% (80.0%-94.4%)
>2-5 years	180	41	47	87.2% (74.8%-94.0%)
6-14 years	232	19	21	90.4% (71.0%-97.3%)
15-59 years	235	14	19	73.6% (51.2%-88.1%)
>=60 years	206	9	9	100.0% (70.0%-100.0%)
Total	**1119**	**149**	**170**	**87.6% (81.8%, 91.7%)**

12.0 Other Supportive Information:

a) Usability and User Comprehension Studies

A two-phase usability and user comprehension assessment was conducted to evaluate whether intended lay users could correctly perform the test, collect specimens (including from infant), and accurately interpret results using the provided QRI and IFU under simulated home-use conditions.

Study 1 included 56 participants. Of these, 29 subjects aged ≥14 years self-collected nasal swab specimens and performed self-testing using the candidate device. In addition, adult-collected swabs were collected from 27 subjects (including 3 subjects 14-24 years of age, 20 subjects >24-64 years of age and 4 subjects ≥ 65 years of age) and tested per the QRI. Observers evaluated performance of all critical and non-critical tasks. All participants (100%) correctly completed every critical task, and 99.8% found the instructions clear and easy to use. Knowledge assessment accuracy was 96%, meeting acceptance criteria. No usability concerns were identified.

Study 2 was conducted with 113 participants (including 12 elderly adults and 101 young children aged 6–24 months) to supplement user comprehension and evaluate nasal swab collection for infants aged 6–24 months. Parents or guardians collected samples from young children and completed questionnaires. As in Study 1, all users (100%) correctly performed all critical and non-critical tasks. Sample collection in infants and toddlers did not reveal any major concerns. User feedback was generally positive, with a few non-critical suggestions for improvement (e.g., swab depth indicator, shorter wait time, extra swab).

Overall, across both studies, users demonstrated consistent ability to understand the labeling, perform sample collection (including from children aged 6–24 months), execute all critical procedures correctly, and accurately interpret results. No use-related concerns were identified regarding the usability of the candidate device.

b) Flex Studies

To evaluate the robustness of the test and the risk of false results when users deviate from the IFU/QRI instructions, flex studies were performed to assess all major aspects of the test procedure. These

included variations in sample volume, reading time, and other procedural deviations (e.g., delays in mixing, uneven mixing, delays in adding the sample to the well, and incubation time). The studies also assessed variability in environmental conditions that the test may encounter during use (e.g., lighting, disturbances during use, temperature and humidity stress, inadequate temperature equilibration, and delayed use after opening the foil pouch), as well as result interpretation by a colorblind user.

A test panel consisting of 5 negative samples (PNF only) and 5 low-positive samples (2× LoD in PNF) for each analyte was evaluated under varying conditions using the candidate device. The strains tested included SARS-CoV-2 Omicron variant JN.1, influenza A H1N1, influenza B Victoria, and RSV B. Samples were blinded and randomized for testing. All results were acceptable except in the following scenarios: false-negative results occurred when the test was read at 3 or 5 minutes, or when the swab was not mixed in the extraction buffer tube. Invalid results were obtained when only one drop of sample was applied to the device. The labeling clearly instructs users on these critical steps and provides adequate warnings to mitigate misuse. Therefore, the flex study results support that the test is robust when used as instructed and demonstrate an insignificant risk of erroneous results.

13.0 Conclusion

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