

# **iHealth® Flu A&B/COVID-19 Rapid Test Pro**

## **Instructions for Use**

Model: ICF-7000P

For *in vitro* diagnostic use.

For use with anterior nasal swab specimens.

For professional use.

### **INTENDED USE**

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.

### **SUMMARY AND EXPLANATION**

Along with the common cold, influenza is one of the most common acute respiratory infections, producing symptoms such as headache, chills, dry cough, body aches, and fever. It affects 5%-20% of the United States population annually, resulting in more than 200,000 hospitalizations and 36,000 deaths.<sup>1</sup> The influenza A virus is typically more prevalent and is associated with the most serious influenza epidemics, while influenza B infections usually present with milder symptoms. Diagnosis is difficult because the initial symptoms can be similar to those caused by other infectious agents. Considering that the

influenza virus is highly contagious, accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Accurate diagnosis and the ability to distinguish between A or B antigens can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe an antiviral therapy. Initiation of antiviral therapy should begin as soon as possible after onset, ideally within 48 hours of the appearance of symptoms, as treatment may reduce the duration of symptoms.<sup>2</sup>

Coronaviruses are enveloped RNA viruses that are found broadly among humans, other mammals, and birds. The viruses are known to cause mild symptoms, but sometimes severe respiratory, enteric, hepatic, and neurological diseases can occur. Seven coronavirus species are known to cause human disease, four of which (229E, OC43, NL63 and HKU-1) are quite prevalent and can cause mild cold symptoms, especially in immunocompetent people.<sup>3</sup> There are three other strains that are known to cause severe acute respiratory disease. These strains include severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV), and the 2019 Novel Coronavirus (COVID-19). These strains are all zoonotic in origin and have been linked to sometimes fatal respiratory illness. The prevalence of SARS and MERS has been quite low in recent years; the Novel Coronavirus (COVID-19) was recently identified in December 2019. The main manifestations of illness include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases. Most epidemiological studies suggest a 1-14 day incubation period. The median incubation period is estimated at 5.1 days, with most developing symptoms before 11.5 days.<sup>4</sup> Infected but asymptomatic people can also be an infectious source. The iHealth Flu A&B/COVID-19 Rapid Test Pro can provide rapid detection of influenza A, influenza B, and/or SARS-CoV-2 viral antigens from symptomatic patients.

## **PRINCIPLE OF THE PROCEDURE**

The iHealth Flu A&B/COVID-19 Rapid Test Pro consists of a Test Card that separately detects influenza A, influenza B, and SARS-CoV-2 antigens. The test procedure requires the solubilization of the nucleoproteins from a nasal swab sample by mixing the swab in a Test Tube that contains extraction buffer. The sample mixture is then dispensed into the sample well on the Test Card, which migrates along the membrane surface. If influenza A, influenza B, and/or SARS-CoV-2 viral antigens are present in the sample, it will form a complex with antibodies to influenza A, influenza B and/or SARS-CoV-2 conjugated to latex microspheres. The complex will then be bound by another anti-influenza A, anti-influenza B and/or anti SARS-CoV-2 antibody coated on the nitrocellulose membrane. A pink control line must appear in the control region of the Test Card for results to be valid. The appearance of a second and possibly third or fourth light pink line in the test line region indicates an influenza A, influenza B, and/or SARS-CoV-2 positive result. A visible control line with no test line is a negative result.

## PRODUCT DESCRIPTION

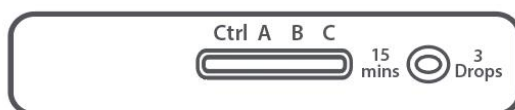
The iHealth Flu A&B/COVID-19 Rapid Test Pro requires the following elements for operation.

### Materials provided in the Test Kit:

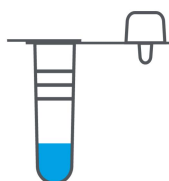
| Kit components               | Quantity     |              |
|------------------------------|--------------|--------------|
|                              | 25 Tests Kit | 40 Tests Kit |
| Flu A&B/COVID-19 Test Cards  | 25 ea/box    | 40 ea/box    |
| Nasal Swabs                  | 25 ea/box    | 40 ea/box    |
| Extraction Buffer Tubes      | 25 ea/box    | 40 ea/box    |
| Quick Reference Instructions | 1 ea/box     | 1 ea/box     |
| Tube Holder                  | 1 ea/box     | 1 ea/box     |

For the Instructions for Use, please see the company website:

<https://support.ihealthlabs.com/3-in-1-POC-IFU>



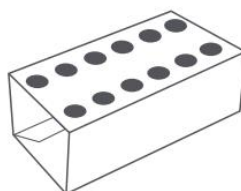
Flu A&B/COVID-19 Test Cards



Extraction Buffer Tubes



Swabs



Tube Holder

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

### Materials required but not provided in the kit:

- A clock or timer;

### Recommended materials (optional):

- External Control (iHealth Flu A&B/COVID-19 Rapid Test Pro Control Kit Model:CSW-ANSFC).

## WARNINGS AND PRECAUTIONS

- **Do not use the test if you have had symptoms for more than 5 days or no symptoms at all.**
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- An anterior nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Test components are single-use. Do not re-use the test card, extraction buffer tube, or swab.
- Only use the nasal swabs provided in the kit. Other swabs have not been validated for use with this test.
- Do not touch the swab tip prior to testing.
- Wash hands thoroughly with water to remove all traces of soap. Exposure to liquid soap may cause false negative results with this test.
- Ensure all kit components are at room temperature before use.
- Once removed from the pouch, the Test Card should be used immediately.
- **DO NOT read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**
- Make sure there is sufficient light for testing. For best results, read test in a well-lit area.
- Keep the test device on a flat surface during the testing.
- Do not use any nasal sprays, gels or creams at least 30 minutes before you collect a sample.
- Do not use this test if you have recently received a nasally administered influenza A or B vaccine.
- Remove any piercings from nose before starting the test.
- Do not conduct this test if prone to nosebleeds or if you have a nose injury.
- **Keep testing kit and kit components away from children and pets before and after use.**

- Do not ingest any kit components.
- The extraction solution contains harmful chemicals (see table in the next column). Avoid contact with your skin, eyes, nose, or mouth. If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If you have a known skin allergy or are sensitive to the use of aminoglycosides, we recommend the use of gloves while performing the test. If irritation persists, seek medical advice: <https://www.poisonhelp.org> or 1-800-222-1222.

| Chemical Name      | GHS Code for Each Ingredient                                                                                             | Concentration |
|--------------------|--------------------------------------------------------------------------------------------------------------------------|---------------|
| Triton X-100       | Harmful if swallowed (H302)<br>Causes skin irritation (H315)<br>Causes serious eye damage (H318)                         | 0.40%         |
| Proclin 300        | Causes skin irritation (H315)<br>Causes eye irritation (H320)                                                            | 0.10%         |
| Gentamicin Sulfate | Causes allergy or asthma symptoms or breathing difficulties if inhaled (H334)<br>Causes an allergic skin reaction (H317) | 0.25%         |

## STORAGE AND STABILITY

Store the iHealth Flu A&B/COVID-19 Rapid Test Pro at room temperature 36-86 °F (2-30 °C) in the original packaging, away from direct sunlight. Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. It is stable until the expiration date marked on the packaging.

- DO NOT FREEZE.
- Do not use Test Cards or Extraction Buffer Tubes after expiration date.
- Test Cards that have been outside of the pouch for more than one hour should be discarded.

## QUALITY CONTROL

### *Internal Procedural Controls*

Each iHealth Flu A&B/COVID-19 Rapid Test Pro has a built-in internal procedural control. The pink line appearing at the “Ctrl” position verifies proper assembly and capillary flow of the test strip. A distinct pink Control Line should always appear if the test has been performed correctly. If the Control Line does not appear, the test result is invalid, and a new test should be performed using a new swab and new test kit.

## ***Optional External Quality Control Testing***

We recommend running the External Quality Controls for iHealth Flu A&B/COVID-19 Rapid Test Pro, that are sold separately.

Use the controls to help ensure that the Test Cards are functioning properly and to demonstrate proper performance by the test operator. It is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure was run correctly and to verify the test is working properly. The external controls should be processed and tested in accordance with the nasal swab test procedure provided in the Instructions for Use or in the Quick Reference Instructions (QRI).

External quality control requirements should be established in accordance with your local, state, and federal regulations or accreditation requirements. To perform a positive or negative control test, complete the steps in the Test Procedure section, treating the control swab in the same manner as a patient swab. Minimally, iHealth recommends that Positive and Negative external controls be run with each new lot, shipment received, and with each new untrained operator. If external controls do not perform as expected, testing of individuals should not be performed. Repeat the test or contact **iHealth Technical Services** at (855) 816-7705 or [support@iHealthlabs.com](mailto:support@iHealthlabs.com)

## **TEST PROCEDURE**

### ***Video Instructions***

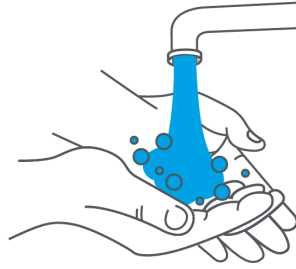


Scan the QR code to access the video tutorial.

### ***Before getting Started***

**Do not open the test contents until ready for use. Once opened, the test device should be used immediately.**

- 1) Check expiration date on the outside of the box. Do not use beyond the expiration date. Do not use if any of the test kit contents or packaging is damaged.**
- 2) Wash hands thoroughly for at least 20 seconds before testing.**



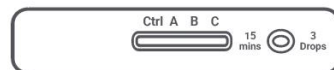
- 3) Clean the surface on which the test will be performed. Before testing, read instructions carefully. The test kit must be at room temperature (65-86 °F) for testing.

### ***Prepare the Materials***

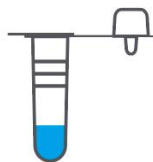
Materials Provided:



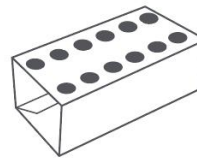
**1x Swab**



**1x Test Card in Pouch**



**1x Extraction Buffer Tube**



**1x Tube Holder**

Materials required but not provided:

A clock or timer;

Recommended materials (optional):

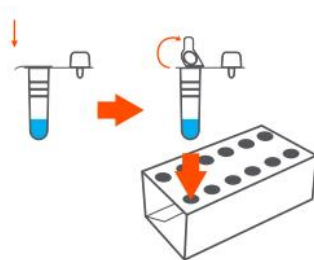
External Controls (iHealth Flu A&B/COVID-19 Rapid Test Pro Control Kit  
*Model:CSW-ANSFC*).

- 4) Arrange the materials on a clean, dry, flat surface.

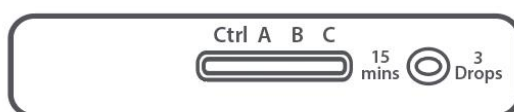
**DO NOT open the individual pouches until instructed to do so.**

- 5) Pick up the Extraction Buffer Tube and remove the sealing foil of the tube.

- 6) Place the Extraction Buffer Tube in the Tube Holder.



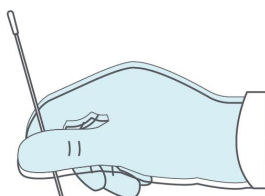
7) Remove the Test Card from its foil pouch.



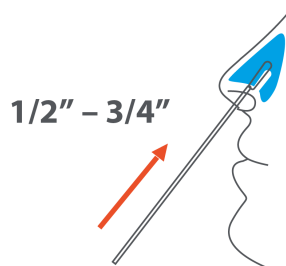
DO NOT remove the Test Card until you are ready to begin the test. **The unsealed test card is valid for 60 minutes.**

### ***Performing The Test***

8) Open the package from the swab's stick end and take out the swab by holding the stick. **DO NOT touch the swab head (soft end).**

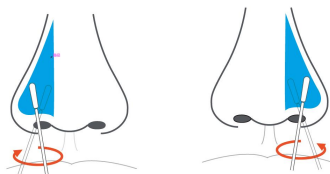


9) Gently insert the swab 1/2 to 3/4 inch into a nostril. **For young children, the swab should not be inserted more than 1/2 inch.**



**DO NOT insert the swab any farther if you feel any resistance.**

Using medium pressure, rub and rotate the swab against the inside walls of the nostril, making at least 5 circles.



**5x , each nostril**

**REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.**

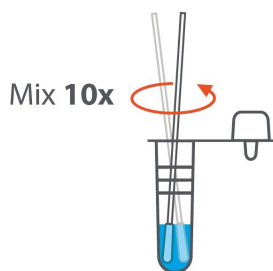
**NOTE:** With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

***STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal sample is not properly collected.***

10) Place the swab into the extraction solution making sure the swab head is completely immersed.

Swirl the swab in the solution by rotating the swab forcefully against the side of the extraction buffer tube **at least 10 times**, keeping the swab tip submerged in the extraction solution the entire time.

***Note: Failure to rotate the swab 10 times may lead to false negative results.***

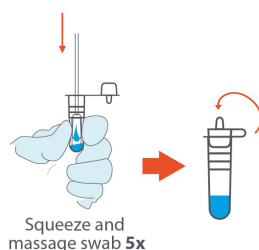


11) Squeeze the swab within the extraction buffer tube 5 times with your fingers to ensure that the sample on the swab is fully mixed into the extraction solution. Discard swab.

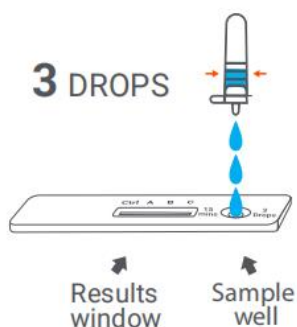
Close the dropper cap that is attached to the extraction buffer tube.

**Note: Failure to squeeze the swab within the extraction buffer tube may lead to false**

**negative results.**



12) Holding the dropper **VERTICALLY** over the sample well on the test card, squeeze out exactly 3 DROPS of the solution.



**DO NOT** squeeze more than 3 drops from the extraction buffer tube. Additional sample volume may yield inaccurate results.

13) Set a timer and read the test result at 15 minutes.



**DO NOT** disturb the card during this time. Inaccurate results can occur if the card is disturbed.



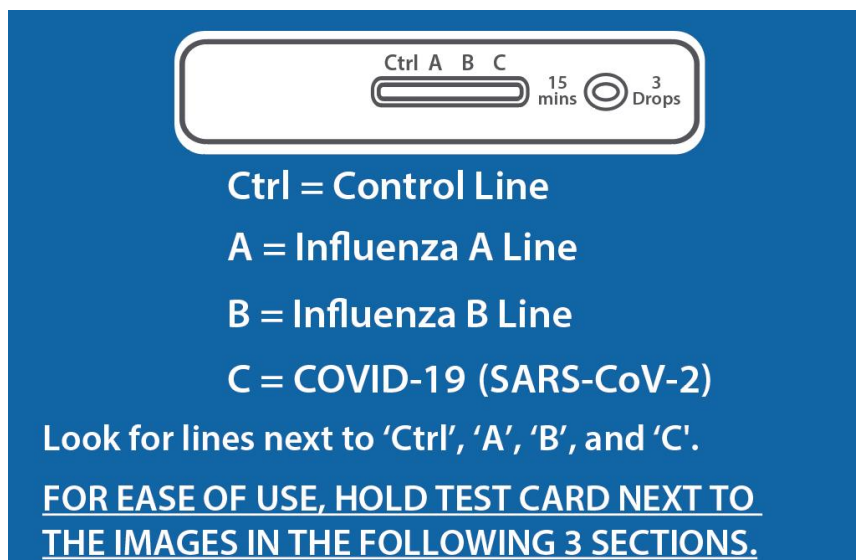
**Note: DO NOT** read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.



### ***Test Result Interpretation***

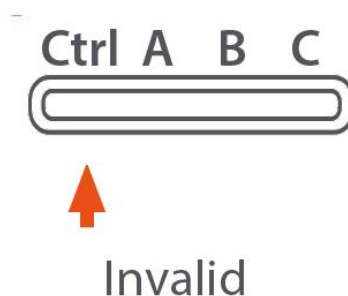
Test results are read and interpreted visually. Read result at 15 minutes with good lighting.

**WARNING: DO NOT read the result before 15 minutes or after 30 minutes. Inaccurate test interpretation may occur.**



### ***Invalid Results***

If a control line is not visible at “Ctrl” after 15 minutes, even if any other line is visible in the results window, the result is considered INVALID.



### ***UNDERSTANDING TEST RESULTS:***

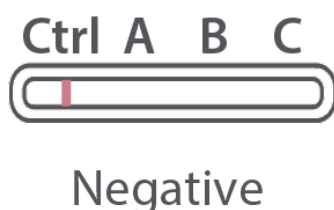
This test did not work. The result should not be used. The test cannot determine if the patient has influenza A (Flu A), influenza B (Flu B), or COVID-19. The test needs to be repeated with a new kit and sample.

***STOP: If the test is invalid, repeat the test procedure using a new kit and sample.***

**NOTE:** The image displayed above is one example only; additional invalid outcomes are possible. For a complete set of invalid results to go to <https://support.ihealthlabs.com/3-in-1-results>.

### ***Negative Results***

If the control line at “Ctrl” is visible and you do not see a line at ‘A’, ‘B’, or ‘C’, it means the test is negative.



Negative results should be reported as a presumptive negative for the presence of influenza and/or SARS-CoV-2 antigen.

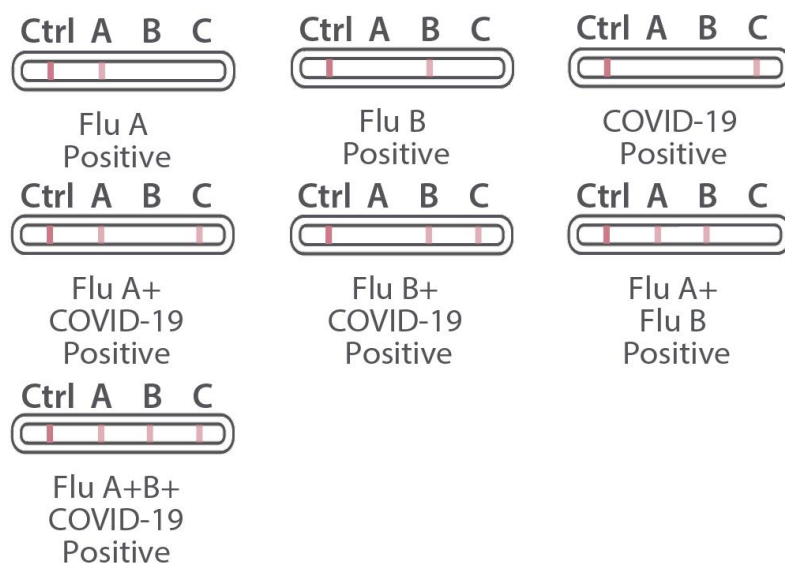
### ***UNDERSTANDING TEST RESULTS:***

A negative test result indicates that the virus that causes Flu A, Flu B, and/or COVID-19 was not detected in the sample. A negative result does not mean that the patient does not have Flu A, Flu B, and/or COVID-19 infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests.

If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered.

### ***Positive Results***

If the control line at “Ctrl” is visible and any other single line or multiple lines on ‘A’, ‘B’, and/or ‘C’ appear, the test is positive.



**NOTE:** Any pink line in the correct, indicated locations, no matter how faint, should be considered an indication of a positive result. See examples of faint lines in the images below.

Flu A Positive:



Flu B Positive:



COVID-19 Positive:



It is possible to have more than one positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2, the virus that causes COVID-19. If more than one positive Test Line is observed, retest with a new patient sample, Test Card and Extraction

Buffer Tube. A differing result should be followed by confirmatory testing with another test method, such as PCR.

### ***UNDERSTANDING TEST RESULTS:***

A positive test result means that the virus that causes influenza or COVID-19 was detected in the patient's sample. It is very likely that the patient has the respective infection(s) and are contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infections with other viruses. The agent detected may not be the definite cause of disease.

### **LIMITATIONS**

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2024 and March 2025. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of influenza and COVID-19 and their prevalence, which change over time. Additional testing with a laboratory-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected, handled or transported improperly.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with influenza and COVID-19 as compared to a molecular test, especially in samples with low viral load.
- Positive results do not rule out co-infection with other respiratory pathogens.
- False positive test results are more likely when the prevalence of Flu A/B, and SARS-CoV-2 is low in the community.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision. Because test lines can be very faint, users with conditions affecting their vision, such as far-sightedness, glaucoma, or color blindness, are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).

- Influenza A and influenza B false positive results were observed with this test when tested with intranasal FluMist Vaccine.
- Hand Sanitizer cream lotion and Hand Sanitizer(80% ethanol, fast drying) may cause false negative results with this test.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions) should contact a healthcare provider.
- This test does not differentiate between SARS-CoV and SARS-CoV-2 and does not detect influenza C.

## PERFORMANCE CHARACTERISTICS

### Limit of Detection (LOD)

The limit of detection (LoD) for the iHealth Flu A&B/COVID-19 Rapid Test Pro was established using serial dilutions of one strain of chemically inactivated SARS-Related Coronavirus 2 (Omicron Variant, Lineage JN.1), two live influenza A strains and two live influenza B strains in Pooled Negative Nasal Fluid (PNF).

In this study, range finding testing was followed by final dilution testing to determine the LoD of the assay. Range finding involved testing a series of 10-fold dilutions in replicates of three (3) to determine the starting point for the dilution series to determine preliminary LoD. The dilution of each virus which resulted in the lowest concentration that generated 100% positive detection rate was set as the target for the next dilution series, which involved testing three (3) replicates of two (2)-fold dilutions. The confirmed LoD concentration was that 95% of the replicates (19/20) test positive, see the table below. 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

| <b><i>Virus Strains</i></b>                                                                               | <b><i>LoD in PNF</i></b>                     | <b><i>LoD per Swab</i></b>                        | <b><i>#Positive/#total Tested</i></b> | <b><i>Percent Detected (%)</i></b> |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------|---------------------------------------------------|---------------------------------------|------------------------------------|
| SARS-CoV-2<br>(Chemically inactivated,<br>Omicron Variant, Lineage<br>JN.1, USA/New<br>York/PV96109/2023) | $6.30 \times 10^0$<br>TCID <sub>50</sub> /mL | $3.15 \times 10^{-1}$<br>TCID <sub>50</sub> /swab | 59/60                                 | 98.3%                              |

|                                                    |                                              |                                                |       |       |
|----------------------------------------------------|----------------------------------------------|------------------------------------------------|-------|-------|
| Influenza A<br>A/Victoria/4897/2022(H1N1)          | $3.99 \times 10^1$<br>TCID <sub>50</sub> /mL | $2.00 \times 10^0$<br>TCID <sub>50</sub> /swab | 58/60 | 96.7% |
| Influenza A<br>A/Darwin/6/2021(H3N2)               | $8.95 \times 10^1$<br>TCID <sub>50</sub> /mL | $4.48 \times 10^0$<br>TCID <sub>50</sub> /swab | 59/60 | 98.3% |
| Influenza B<br>Victoria/B/Austria/135941<br>7/2021 | $7.05 \times 10^2$<br>TCID <sub>50</sub> /mL | $3.53 \times 10^1$<br>TCID <sub>50</sub> /swab | 59/60 | 98.3% |
| Influenza B<br>Yamagata/<br>B/Phuket/3073/2013     | $2.06 \times 10^5$<br>CEID <sub>50</sub> /mL | $1.03 \times 10^4$<br>CEID <sub>50</sub> /swab | 59/60 | 98.3% |

## NIBSC - WHO Standard Testing

The 1<sup>st</sup> WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) was tested to determine the LoD of this material.

A preliminary LoD concentration was determined by first performing a five-fold dilution of the master stock equivalent to 20000 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 with 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 LoD was that 95% of the replicates (19/20) test positive. The confirmed LOD is shown in the table below.

| <b><i>Virus Strains</i></b>    | <b><i>LoD in PNF</i></b> | <b><i>LoD per Swab</i></b> | <b><i>#Positive/<br/>#total Tested</i></b> | <b><i>Percent<br/>Detected (%)</i></b> |
|--------------------------------|--------------------------|----------------------------|--------------------------------------------|----------------------------------------|
| WHO Standard (NIBSC<br>21/368) | $1.94 \times 10^2$ IU/mL | 9.7 IU/swab                | 19/20                                      | 95%                                    |

## Analytical Reactivity

The analytical reactivity of the test was evaluated using a panel of temporally, geographically, and genetically diverse strains of SARS-CoV-2, Influenza A, and Influenza B. Concentrations listed in the table below indicate the lowest detectable concentrations for which all three (3) replicates were positive.

| <b><i>Virus</i></b> | <b><i>Strain</i></b> | <b><i>Concentration</i></b>               |
|---------------------|----------------------|-------------------------------------------|
| Influenza A (H1N1)  | A/Victoria/4897/22   | $5.05 \times 10^1$ TCID <sub>50</sub> /mL |

|                                               |                                           |                                           |
|-----------------------------------------------|-------------------------------------------|-------------------------------------------|
|                                               | A/Brisbane/02/2018                        | $3.78 \times 10^1$ TCID <sub>50</sub> /mL |
|                                               | A/Macha/O1453/2021                        | $2.80 \times 10^5$ TCID <sub>50</sub> /mL |
|                                               | A/NY/03/2009                              | $2.29 \times 10^4$ TCID <sub>50</sub> /mL |
|                                               | A/Sydney/5/2021                           | $1.20 \times 10^3$ TCID <sub>50</sub> /mL |
|                                               | A/Baltimore/JH-22377/2022                 | $8.00 \times 10^5$ TCID <sub>50</sub> /mL |
|                                               | A/Wisconsin/67/2022                       | $1.05 \times 10^2$ TCID <sub>50</sub> /mL |
|                                               | A/Hawaii/66/2019                          | $1.85 \times 10^7$ CEID <sub>50</sub> /mL |
|                                               | A/Wisconsin/588/2019                      | $3.50 \times 10^3$ FFU/mL                 |
|                                               | A/Indiana/02/2020                         | $2.43 \times 10^6$ CEID <sub>50</sub> /mL |
|                                               | A/California/04/2009                      | $7.00 \times 10^2$ TCID <sub>50</sub> /mL |
|                                               | A/Ohio/09/2015                            | $3.50 \times 10^5$ CEID <sub>50</sub> /mL |
| Influenza A (H1N2)                            | A/Minnesota/19/2011                       | $4.00 \times 10^6$ CEID <sub>50</sub> /mL |
| Influenza A (H3N2)                            | A/Darwin/6/2021                           | $1.04 \times 10^2$ TCID <sub>50</sub> /mL |
|                                               | A/Alaska/01/2021                          | $7.50 \times 10^3$ FFU/mL                 |
|                                               | A/New York/21/2020                        | $1.30 \times 10^5$ FFU/mL                 |
|                                               | A/Tasmania/503/2020                       | $3.25 \times 10^4$ FFU/mL                 |
|                                               | A/Montana/08/2023                         | $1.30 \times 10^5$ FFU/mL                 |
|                                               | A/Hong Kong/45/2019                       | $7.50 \times 10^3$ FFU/mL                 |
| Influenza A (H5N1)                            | A/Indiana/08/2011                         | $2.03 \times 10^2$ TCID <sub>50</sub> /mL |
|                                               | A/mallard/Wisconsin/ 2576/2009 H5N1*      | $1.05 \times 10^5$ GE/mL                  |
|                                               | A/bovine/Ohio/B24OSU-439/2024 H5N1*       | $3.67 \times 10^5$ GE/mL                  |
| Influenza A (H5N6)                            | A/duck/Guangxi/S10888/2024 H5N6           | $6.76 \times 10^5$ EID <sub>50</sub> /mL  |
| Influenza A (H5N8)                            | A/goose/Liaoning/S1266/2021 H5N8          | $1.69 \times 10^5$ EID <sub>50</sub> /mL  |
| Influenza A (H7N3)                            | A/northern pintail/Illinois/10OS3959/2010 | $3.55 \times 10^6$ CEID <sub>50</sub> /mL |
| Influenza B<br>(non-Victoria<br>non-Yamagata) | B/Maryland/1/1959                         | $1.69 \times 10^3$ CEID <sub>50</sub> /mL |
| Influenza B (Victoria<br>Lineage)             | B/Austria/1359417/2021                    | $7.05 \times 10^2$ TCID <sub>50</sub> /mL |
|                                               | B/Michigan/01/2021                        | $5.70 \times 10^3$ TCID <sub>50</sub> /mL |
|                                               | B/New Hampshire/01/2021                   | $6.50 \times 10^2$ TCID <sub>50</sub> /mL |
|                                               | B/Washington/02/2019                      | $7.90 \times 10^2$ TCID <sub>50</sub> /mL |
|                                               | B/Texas/02/2013                           | $6.13 \times 10^0$ TCID <sub>50</sub> /mL |
| Influenza B (Yamagata<br>Lineage)             | B/Phuket/3073/2013                        | $2.75 \times 10^5$ TCID <sub>50</sub> /mL |
|                                               | B/Florida/04/2006                         | $1.17 \times 10^1$ TCID <sub>50</sub> /mL |
|                                               | B/Texas/06/2011                           | $1.60 \times 10^6$ CEID <sub>50</sub> /mL |
|                                               | B/Utah/09/2014                            | $1.26 \times 10^2$ TCID <sub>50</sub> /mL |
| SARS-CoV-2                                    | USA/New York/PV96109/2023                 | $7.00 \times 10^0$ TCID <sub>50</sub> /mL |
|                                               | USA-WA1/2020                              | $3.16 \times 10^2$ TCID <sub>50</sub> /mL |
|                                               | USA/CA-Stanford-109-S21/2022              | $5.95 \times 10^3$ TCID <sub>50</sub> /mL |
|                                               | USA/NY-Wadsworth-23067147-01/2023         | $7.88 \times 10^3$ TCID <sub>50</sub> /mL |

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

## Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity of the iHealth Flu A&B/COVID-19 Rapid Test Pro 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 Rapid Test Pro including twenty (20) bacteria, twenty-one (21) viruses and one (1) negative matrix. Each organism and virus were tested in triplicate in the absence (cross-reactivity) or presence (interference) of co-spiked chemically inactivated SARS-CoV-2, or live influenza A, and B 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.

| <i>Microorganism</i>                        | <i>Working Concentration</i>                | <i>Cross-reactivity<br/>Results (# pos /<br/>total)</i> | <i>Interference<br/>Results (# pos /<br/>total)</i> |
|---------------------------------------------|---------------------------------------------|---------------------------------------------------------|-----------------------------------------------------|
| SARS-CoV-1*                                 | 1.25×10 <sup>5</sup> PFU/ml                 | 0/3                                                     | 3/3                                                 |
| MERS-coronavirus                            | 1.58×10 <sup>8</sup> GE/mL                  | 0/3                                                     | 3/3                                                 |
| Human coronavirus HKU1<br>(HKU1/UNC/2/2022) | 4.34×10 <sup>6</sup> GE/mL                  | 0/3                                                     | 3/3                                                 |
| Human coronavirus OC43                      | 7.00×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Human coronavirus 229E                      | 1.40×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Human coronavirus NL63                      | 8.00×10 <sup>4</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Adenovirus, Type 1                          | 2.23×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Adenovirus Type 7A                          | 1.58×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Cytomegalovirus                             | 1.00×10 <sup>5</sup> PFU/mL                 | 0/3                                                     | 3/3                                                 |
| Epstein Barr Virus, Strain                  | 1.83×10 <sup>6</sup> CP/mL                  | 0/3                                                     | 3/3                                                 |
| Human Metapneumovirus (hMPV)                | 3.50×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Parainfluenza virus 1                       | 2.00×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Parainfluenza virus 2                       | 1.75×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Parainfluenza virus 3                       | 7.00×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Parainfluenza virus 4                       | 2.39×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Enterovirus Type 68                         | 2.23×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Respiratory syncytial virus A               | 1.49×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |

| <b>Microorganism</b>              | <b>Working Concentration</b>                | <b>Cross-reactivity<br/>Results (# pos /<br/>total)</b> | <b>Interference<br/>Results (# pos /<br/>total)</b> |
|-----------------------------------|---------------------------------------------|---------------------------------------------------------|-----------------------------------------------------|
| Respiratory syncytial virus B     | 1.58×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Rhinovirus                        | 2.23×10 <sup>6</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| <i>Bordetella pertussis</i>       | 2.50×10 <sup>8</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Candida albicans</i>           | 6.03×10 <sup>6</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Chlamydia pneumoniae</i>       | 4.33×10 <sup>6</sup> IFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Corynebacterium xerosis</i>    | 2.30×10 <sup>7</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Escherichia coli</i>           | 1.18×10 <sup>8</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Hemophilus influenzae</i>      | 3.00×10 <sup>10</sup> CFU/mL                | 0/3                                                     | 3/3                                                 |
| <i>Lactobacillus sp</i>           | 8.50×10 <sup>6</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Legionella pneumophila</i>     | 6.50×10 <sup>6</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Moraxella catarrhalis</i>      | 2.50×10 <sup>8</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Mycoplasma pneumoniae</i>      | 2.50×10 <sup>7</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Mycobacterium tuberculosis</i> | 4.15×10 <sup>6</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Neisseria meningitidis</i>     | 3.43×10 <sup>6</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Neisseria Elongata</i>         | 2.68×10 <sup>8</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Pneumocystis jirovecii</i>     | 1.30×10 <sup>7</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Pseudomonas aeruginosa</i>     | 1.23×10 <sup>8</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Staphylococcus aureus</i>      | 2.60×10 <sup>8</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Staphylococcus epidermidis</i> | 9.00×10 <sup>7</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Streptococcus salivarius</i>   | 1.01×10 <sup>6</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Streptococcus pneumoniae</i>   | 3.88×10 <sup>7</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| <i>Streptococcus pyogenes</i>     | 7.50×10 <sup>7</sup> CFU/mL                 | 0/3                                                     | 3/3                                                 |
| Measles                           | 2.23×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| Mumps                             | 8.48×10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/3                                                     | 3/3                                                 |
| PNF(Pooled Negative Nasal Fluid)  | NA                                          | 0/3                                                     | 3/3                                                 |

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

## Endogenous Interfering Substances

The potential interference of endogenous substances with the antibodies used for the detection of influenza A, influenza B, and SARS-CoV-2 was examined by testing thirty (30) 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), and SARS-CoV-2.

Interference (false positive results) was observed for 2024-25 FluMist® Influenza Vaccine Live intranasal for influenza A and influenza B.

Interference (false negative results) was observed for hand sanitizer cream lotion for influenza A and influenza B, and hand sanitizer (80% ethanol, fast drying) for influenza A and influenza B.

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.

| <b>Substance</b>                                                                 | <b>Concentration</b> | <b>Cross-reactivity<br/>(no analyte)<br/>(# pos reps / total reps)</b> |       |       | <b>Interference<br/>(3x LoD co-spiked<br/>analytes)<br/>(# pos reps / total<br/>reps)</b> |       |       |
|----------------------------------------------------------------------------------|----------------------|------------------------------------------------------------------------|-------|-------|-------------------------------------------------------------------------------------------|-------|-------|
|                                                                                  |                      | SARS-CoV-2                                                             | Flu A | Flu B | SAR S-Co V-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   |
| Mucin                                                                            | 0.5%                 | 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   |
| Naso GEL (NeilMed)                                                               | 15% 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 corticosteroid (Dexamethasone)                                             | 1 mg/mL              | 0/3                                                                    | 0/3   | 0/3   | 3/3                                                                                       | 3/3   | 3/3   |
| Nasal gel (Galphimia glauca, Histanium hydrochloricum, Luffa operculata, Sulfur) | 1.25% 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   |
| 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 Nasal Spray (Alkalol)                                                | 15% v/v              | 0/3                                                                    | 0/3   | 0/3   | 3/3                                                                                       | 3/3   | 3/3   |
| Sore Throat Phenol Spray                                                         | 15% v/v              | 0/3                                                                    | 0/3   | 0/3   | 3/3                                                                                       | 3/3   | 3/3   |
| Tobramycin                                                                       | 4 µg/mL              | 0/3                                                                    | 0/3   | 0/3   | 3/3                                                                                       | 3/3   | 3/3   |

| Substance                                           | Concentration                 | Cross-reactivity<br>(no analyte)<br>(# pos reps / total reps) |       |       | Interference<br>(3x LoD co-spiked<br>analytes)<br>(# pos reps / total<br>reps) |       |       |
|-----------------------------------------------------|-------------------------------|---------------------------------------------------------------|-------|-------|--------------------------------------------------------------------------------|-------|-------|
|                                                     |                               | SARS-CoV-2                                                    | Flu A | Flu B | SAR S-Co V-2                                                                   | Flu A | Flu B |
| Mupirocin                                           | 10 mg/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   |
| 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   |
| Tamiflu (Oseltamivir Phosphate)                     | 5 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    |
|                                                     | <b>0.1875% v/v</b>            | 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   |
| Biotin                                              | 3,500 ng/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   |
| Leukocytes                                          | 1.67×10 <sup>6</sup> cells/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   |
|                                                     | <b>7.5% v/v</b>               | 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   |
|                                                     | <b>1.875% v/v</b>             | NT                                                            | NT    | NT    | 3/3                                                                            | 3/3   | 3/3   |
|                                                     | 1.5% v/v                      | NT                                                            | NT    | NT    | 3/3                                                                            | 3/3   | 3/3   |
| Hand soap liquid gel                                | 10% w/v                       | 0/3                                                           | 0/3   | 0/3   | 3/3                                                                            | 3/3   | 3/3   |
| 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 tested

## High Dose Hook Effect

A high-dose hook effect was not observed for the iHealth Flu A&B/COVID-19 Rapid Test Pro for the following SARS-CoV-2, influenza A and B viral strains at the concentrations listed below.

| <b>Viral Strain Tested</b>                                                                   | <b>Concentration</b>                      |
|----------------------------------------------------------------------------------------------|-------------------------------------------|
| SARS-CoV-2(Chemically inactivated, Omicron Variant, Lineage JN.1, USA/New York/PV96109/2023) | $1.40 \times 10^5$ TCID <sub>50</sub> /mL |
| Influenza A - A/Victoria/4897/2022(H1N1)                                                     | $2.02 \times 10^5$ TCID <sub>50</sub> /mL |
| Influenza A - A/Darwin/6/2021(H3N2)                                                          | $4.17 \times 10^5$ TCID <sub>50</sub> /mL |
| Influenza B - Victoria/B/Austria/1359417/2021                                                | $2.82 \times 10^6$ TCID <sub>50</sub> /mL |
| Influenza B -Yamagata/ B/Phuket/3073/2013                                                    | $1.10 \times 10^9$ CEID <sub>50</sub> /mL |

## Competitive Interference

Competitive interference testing for iHealth Flu A&B/COVID-19 Rapid Test Pro was performed by testing SARS-CoV-2 at levels near the LoD in the presence of high levels of influenza A or influenza B. Influenza A and influenza B at levels near LoD were tested in the presence of high levels of SARS-CoV-2. No competitive interference was observed between high levels of SARS-CoV-2 and low levels of Influenza A and B, between high levels of Influenza A and low levels of SARS-CoV-2 and influenza B and between high levels of Influenza B and low levels of SARS-CoV-2 and influenza A in this testing at the concentrations listed in the tables below.

| <b>Sample</b> | <b>Competing virus</b> |                                                 | <b>Target virus</b>  |                                                 | <b>Target analyte<br/>Percent Positivity</b> |
|---------------|------------------------|-------------------------------------------------|----------------------|-------------------------------------------------|----------------------------------------------|
|               | <b>Virus type</b>      | <b>Concentration<br/>(TCID<sub>50</sub>/mL)</b> | <b>Virus type</b>    | <b>Concentration<br/>(TCID<sub>50</sub>/mL)</b> |                                              |
| 1             | Influenza A/H1N1       | $6.73 \times 10^4$                              | Influenza B/Victoria | $2.12 \times 10^3$                              | 100%                                         |
| 2             | Influenza A/H1N1       | $6.73 \times 10^4$                              | SARS-CoV-2           | $1.89 \times 10^1$                              | 100%                                         |
| 3             | Influenza A/H1N1       | $6.73 \times 10^4$                              | Influenza B/Victoria | $2.12 \times 10^3$                              | 100%                                         |
|               |                        |                                                 | SARS-CoV-2           | $1.89 \times 10^1$                              |                                              |
| 4             | Influenza B/Victoria   | $9.40 \times 10^5$                              | Influenza A/H1N1     | $1.20 \times 10^2$                              | 100%                                         |
| 5             | Influenza              | $9.40 \times 10^5$                              | SARS-CoV-2           | $1.89 \times 10^1$                              | 100%                                         |

|   |                         |                    |                         |                    |      |
|---|-------------------------|--------------------|-------------------------|--------------------|------|
|   | B/Victoria              |                    |                         |                    |      |
| 6 | Influenza<br>B/Victoria | $9.40 \times 10^5$ | Influenza<br>A/H1N1     | $1.20 \times 10^2$ | 100% |
|   |                         |                    | SARS-CoV-2              | $1.89 \times 10^1$ |      |
| 7 | SARS-CoV-2              | $4.67 \times 10^4$ | Influenza<br>A/H1N1     | $1.20 \times 10^2$ | 100% |
| 8 | SARS-CoV-2              | $4.67 \times 10^4$ | Influenza<br>B/Victoria | $2.12 \times 10^3$ | 100% |
| 9 | SARS-CoV-2              | $4.67 \times 10^4$ | Influenza<br>A/H1N1     | $1.20 \times 10^2$ | 100% |
|   |                         |                    | Influenza<br>B/Victoria | $2.12 \times 10^3$ |      |

### Lot-to-Lot Precision

A single-site lot-to-lot precision study was conducted to measure repeatability using three levels of contrived samples.

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 type (3 lots x 2 operators x 2 replicates 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.

| 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%)                                   |

| 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%)                                        |
| 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 (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%)                                        |

*\*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*

## CLINICAL PERFORMANCE

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 Pro per the test procedure. The collection order for the investigational and the comparator test's 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>Subjects (by lay-user collection and testing (N=343)</b> | <b>Self-collecting and testing (N=245)</b> | <b>Overall (N=588)</b> |
|------------|-------------------------------------------------------------|--------------------------------------------|------------------------|
| <b>Age</b> |                                                             |                                            |                        |
| 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]   |
| <b>Age Group</b>    |            |            |            |
| 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%)   |
| <b>Sex at Birth</b> |            |            |            |
| 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.

### SARS-COV-2 PERFORMANCE

#### Clinical Performance Compared to Reference PCR: SARS-CoV-2

| <b>SARS-CoV-2</b>   | <b>Comparator<br/>Positives</b> | <b>Comparator<br/>Negatives</b> | <b>Sum</b> |
|---------------------|---------------------------------|---------------------------------|------------|
| Candidate Positives | 49                              | 2                               | 51         |
| Candidate Negatives | 4                               | 533                             | 537        |
| <b>Sum</b>          | <b>53</b>                       | <b>535</b>                      | <b>588</b> |

*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%)*

#### SARS-CoV-2 Clinical Performance Stratified by Days Post Symptoms Onset

| <b>DPSO</b>  | <b>Number of<br/>Subject samples<br/>tested</b> | <b>Candidate<br/>Positives</b> | <b>Comparator<br/>Positives</b> | <b>% Positive Rate<br/>(by Comparator)</b> | <b>PPA (95% CI)</b>                  |
|--------------|-------------------------------------------------|--------------------------------|---------------------------------|--------------------------------------------|--------------------------------------|
| Day 0        | 33                                              | 3                              | 3                               | 0.5%                                       | 100.0%<br><b>(43.8%, 100%)</b>       |
| Day 1        | 156                                             | 19                             | 19                              | 3.2%                                       | 100.0%<br><b>(83.2%, 100%)</b>       |
| Day 2        | 202                                             | 9                              | 12                              | 2.0%                                       | 75.0%<br><b>(46.8%,91.1%)</b>        |
| Day 3        | 131                                             | 12                             | 13                              | 2.2%                                       | 92.3%<br><b>(66.7%, 98.6%)</b>       |
| Day 4        | 47                                              | 5                              | 5                               | 0.9%                                       | 100.0%<br><b>(56.6%,100%)</b>        |
| Day 5        | 19                                              | 1                              | 1                               | 0.2%                                       | 100.0%<br><b>(20.7%,100%)</b>        |
| <b>Total</b> | <b>588</b>                                      | <b>49</b>                      | <b>53</b>                       | <b>9.0%</b>                                | <b>92.5%</b><br><b>(82.1%-97.0%)</b> |

## INFLUENZA A PERFORMANCE

Clinical Performance Compared to Reference PCR: Influenza A

| <b>FLU A</b>        | <b>Comparators<br/>Positives</b> | <b>Comparators<br/>Negatives</b> | <b>Sum</b> |
|---------------------|----------------------------------|----------------------------------|------------|
| Candidate Positives | 197                              | 6                                | 203        |
| Candidate Negatives | 29                               | 356                              | 385        |
| <b>Sum</b>          | <b>226</b>                       | <b>362</b>                       | <b>588</b> |

*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

Clinical Performance Compared to Reference PCR: Influenza B

| <b>FLU B</b>        | <b>Comparators<br/>Positives</b> | <b>Comparators<br/>Negatives</b> | <b>Sum</b> |
|---------------------|----------------------------------|----------------------------------|------------|
| Candidate Positives | 43                               | 4                                | 47         |
| Candidate Negatives | 7                                | 534                              | 541        |
| <b>Sum</b>          | <b>50</b>                        | <b>538</b>                       | <b>588</b> |

*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%)*

## ASSISTANCE

If you have any questions regarding the use of this product, or if you want to report a problem with the iHealth Flu A&B/COVID-19 Rapid Test Pro, please contact iHealth Technical Services at (855) 816-7705 or [support@iHealthlabs.com](mailto:support@iHealthlabs.com).

## REFERENCES

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## SYMBOLS



Caution



Do not re-use



Consult instructions for use



In vitro diagnostic medical device



Temperature Limit



Date of manufacture



Catalogue number



Do not use if package is damaged



Manufacturer



Contains sufficient for <n> tests



Use-by date



Batch code



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