

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

Instructions for Use

Model: ICR-3000P

For professional use.

For *in vitro* diagnostic use.

For use with anterior nasal swab specimens.

INTENDED USE

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.

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.¹ 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.²

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.³ 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.⁴ Infected but asymptomatic people can also be an infectious source.

Respiratory Syncytial Virus (RSV) is a seasonal virus that significantly affects vulnerable populations—infants, older adults, and immunocompromised individuals—by potentially leading to severe respiratory conditions. While many infections start with mild symptoms like cough and fever, high-risk patients may experience complications such as pneumonia and bronchiolitis.

Both RSV and influenza viruses are known to cause seasonal epidemics of respiratory illness. Testing outside the typical RSV and flu season increases the risk of false results.

The iHealth Flu A&B/COVID-19/RSV Rapid Test Pro can provide rapid detection of influenza A, influenza B, SARS-CoV-2, and/or RSV viral antigens from symptomatic patients.

PRINCIPLE OF THE PROCEDURE

The iHealth Flu A&B/COVID-19/RSV Rapid Test Pro consists of a Test Card that separately detects influenza A, influenza B, SARS-CoV-2, and RSV antigens. The test procedure requires the solubilization of the target proteins from a nasal swab sample by mixing the swab in the test tube containing the extraction buffer. The sample mixture is then dispensed into the sample well on the Test Card, which migrates along the membrane surface. If

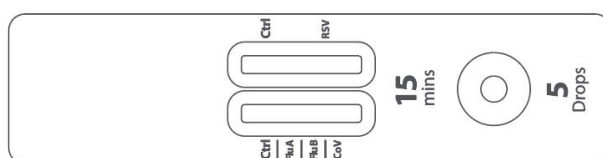
influenza A, influenza B, SARS-CoV-2, and/or RSV viral antigens are present in the sample, it will form a complex with antibodies to influenza A, influenza B, SARS-CoV-2, and/or RSV conjugated to latex microspheres. The complex will then be bound by another anti-influenza A, anti-influenza B, anti-SARS-CoV-2, and/or anti-RSV antibody coated on the nitrocellulose membrane. Only when a pink line appears in the control region of both test strips will the test result be valid. If a pink line appears in the test region labeled with influenza A, influenza B, SARS-CoV-2, and/or RSV, it indicates a positive result for the influenza A, influenza B, SARS-CoV-2, and/or RSV respectively. A visible control line with no test line is a negative result.

PRODUCT DESCRIPTION

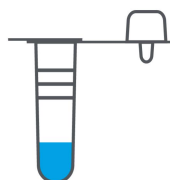
The iHealth Flu A&B/COVID-19/RSV Rapid Test Pro requires the following elements for operation.

Materials provided in the Test Kit:

Kit components	Quantity	
	25 Tests Kit	40 Tests Kit
Flu A&B/COVID-19 /RSVTest Cards	25 ea/box	40 ea/box
Nasal Swabs	25 ea/box	40 ea/box
Extraction Buffer Tube(s)	25 ea/box	40 ea/box
Quick Reference Instructions	1 ea/box	1 ea/box
Tube Holder	1 ea/box	1 ea/box



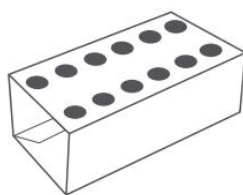
Flu A&B/COVID-19/RSV Test Card(s)



Extraction Buffer Tube(s)



Swab(s)



Tube Holder

iHealth Flu A&B/COVID-19/RSV 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/RSV Rapid Test Pro Control Kit Model:CSW-ANSCR).

WARNINGS AND PRECAUTIONS

- **Do not use the test if patient have had symptoms for more than 6 days or no symptoms at all.**
- **Do not use the test on anyone under 6 months of age.**
- **It is recommended that at least two adults are present to appropriately perform sample collection for ages Users aged 6 – 24 months.**
- **All viruses tested by this test can cause severe disease, especially RSV in infants and young children.**
- **Certain people should not use this test. These people could get much sicker very quickly or even die if they don't get medical help right away: persons showing signs or symptoms of ongoing severe disease, [e.g., short and shallow breathing, flaring of the nostrils or straining (retractions) of the chest or stomach while breathing, or turning blue around the lips and fingertips advance disease] infants born prematurely (birth before 29 weeks of gestation), certain types of congenital chronic lung or heart disease, neurologic or neuromuscular conditions especially those who have difficulty swallowing or clearing mucus secretions. If you or your child have any of these conditions, see a healthcare provider right away instead of using this test.**
- **Infants and young children can get hurt more easily when collecting the nose swab sample. If the swab is not used the right way, it could hurt the inside of the nose, causing nosebleeds. It could also mean not getting enough sample to test properly, which might provide the wrong test results.**
- **If your infant has received monoclonal antibodies (e.g., Clesrovimab-cfor), you may need a healthcare provider to interpret test results.**
- **This product is used only for the detection and differentiation of protein antigens from influenza A, influenza B, SARS-CoV-2 and respiratory syncytial virus (RSV), not for any other viruses or pathogens. This product does not detect influenza C.**
- **Test components are single use. Do not re-use the test card, extraction buffer tube, or**

swab.

- Do not touch the swab tip prior to testing. Accidental contamination can lead to inaccurate results. Repeat sample collection with a new test kit if swab head touches another surface.
- 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.
- The patient should not use any nasal sprays, gels or creams at least 30 minutes before you collect a nasal sample.
- Do not use this test if patient have recently received a nasally administered influenza A or B vaccine.
- Do not use this test if patient have recently used nasal fluticasone propionate.
- Do not conduct this test if the patient is prone to nose bleeds or has a nose injury.
- Remove any piercings from nose before starting the test.
- If the patient continues to have symptoms consistent with influenza, COVID-19, and RSV, the patient may not have influenza, COVID-19, or RSV, however, additional follow-up may be needed.
- All users should contact a healthcare provider if symptoms worsen.
- **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) Causes skin irritation (H315) Causes serious eye damage (H318)	0.40%
Proclin 300	Causes skin irritation (H315) Causes eye irritation (H320)	0.10%

Gentamicin Sulfate	Causes allergy or asthma symptoms or breathing difficulties if inhaled (H334) Causes an allergic skin reaction (H317)	0.25%
--------------------	--	-------

STORAGE AND STABILITY

Store iHealth Flu A&B/COVID-19/RSV Rapid Test Pro in a dry location between 36-86 °F (2-30 °C) out of 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.

- The unsealed test card is valid for one hour. It is recommended to use the test kit immediately after opening.
- DO NOT FREEZE.

QUALITY CONTROL

Each iHealth Flu A&B/COVID-19/RSV 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. Two distinct pink Control Lines 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.

External Quality Control Testing

We recommend running the External Quality Controls for iHealth Flu A&B/COVID-19/RSV 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**

TEST PROCEDURE

Video Instructions



Scan the QR code to access the video tutorial.

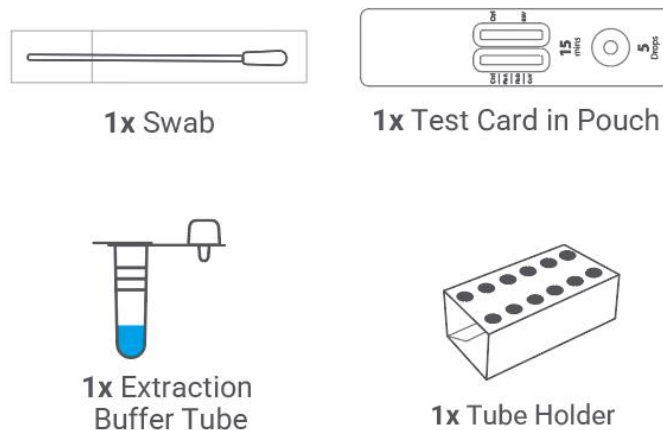
Before getting Started

- 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 your hands with soap and water for 20 seconds and dry them thoroughly before testing or use hand sanitizer.



Prepare the Materials

Materials Provided:



Materials required but not provided:

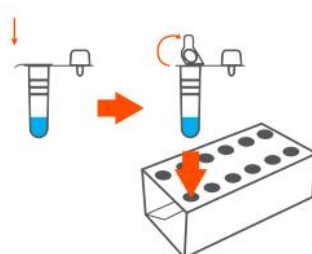
A clock or timer.

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

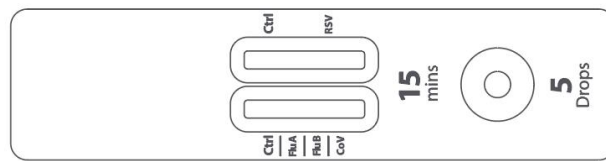


DO NOT open the test contents until ready for use.

3) Pick up the Extraction Buffer Tube and remove the sealing foil of the tube. Place the Extraction Buffer Tube in the Tube Holder.

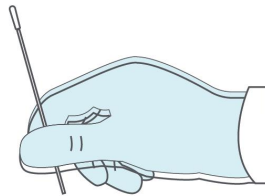


4) Remove the Test Card from its foil pouch. **The unsealed test card is valid for 60 minutes.**

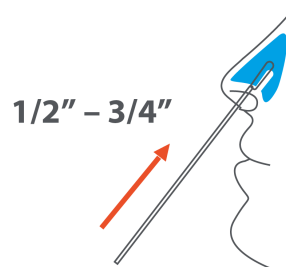


Performing The Test

5) 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).**

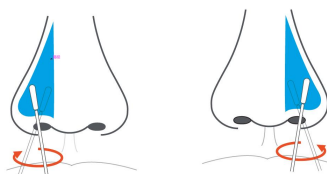


6) Gently insert the swab 1/2 to 3/4 inch into a nostril. **For young children, the swab should not be inserted more than 1/2 inch.**



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**. Repeat in the other nostril using the same swab.



5x , each nostril



Did you swab BOTH nostrils?

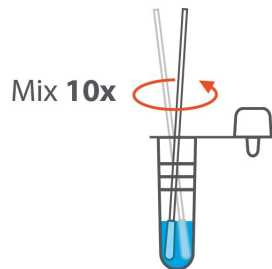
Inaccurate test results may occur if the nasal sample is not properly collected.

NOTE: If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril.

7) 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.

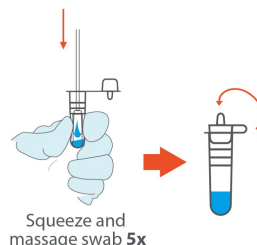
Note: Failure to rotate the swab 10 times may lead to false negative results.



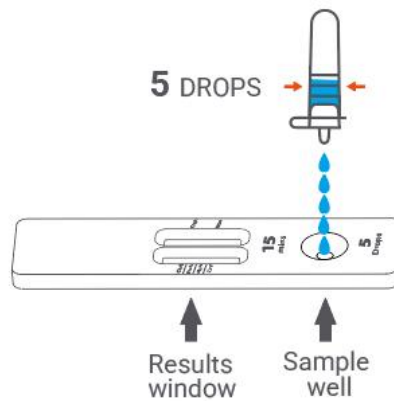
8) Squeeze the swab within the extraction buffer tube **5 times** with your fingers to ensure that the sample on the swab is fully mixed into the extraction solution. Discard swab.

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.



9) Holding the dropper **VERTICALLY** over the sample well on the test card, squeeze out exactly **5 DROPS** of the solution.



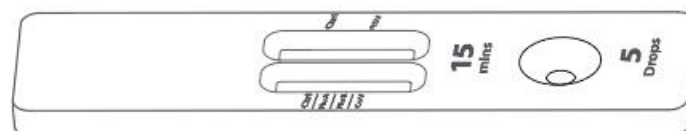
Note:

DO NOT squeeze more than 5 drops from the extraction buffer tube. Additional sample volume may yield inaccurate results.

10) 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.

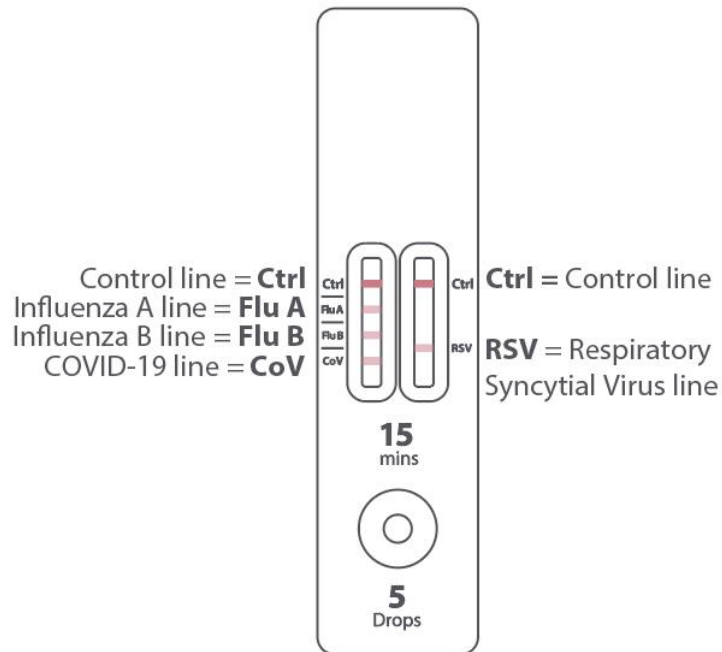


Note: DO NOT read the test result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.



Test Result Interpretation

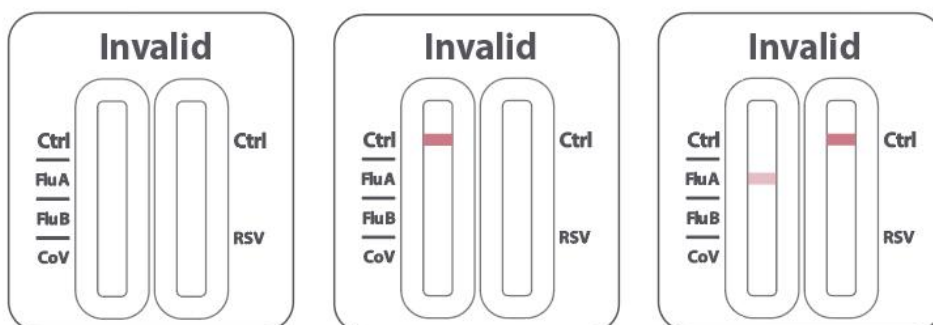
Test results are read and interpreted visually. Read result at 15 minutes with good lighting.



Look for lines next to 'Ctrl', 'Flu A', 'Flu B', 'CoV', and 'RSV'. Make sure there is a **visible line** next to '**Ctrl**' in **both** result windows.

Invalid Results

Missing 'Ctrl' line on ONE or BOTH strips



Check to see if a line is **visible** at the control line '**Ctrl**' on both strips. If one or both '**Ctrl**' lines are **missing**, even if any test line is visible in the result window, the result is **invalid**.

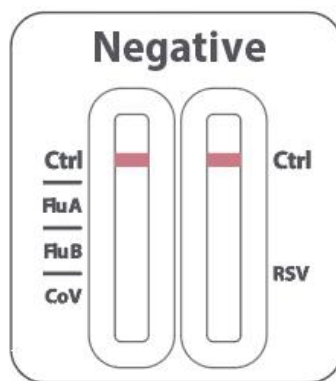
UNDERSTANDING TEST RESULTS:

The test could not tell whether or not the patient has influenza A (Flu A), influenza B (Flu B), COVID-19, or Respiratory Syncytial Virus (RSV). The test needs to be repeated with a new kit and sample.

NOTE: The 3 images displayed above are examples only; additional invalid outcomes are possible. For a complete set of invalid results, please go to <https://support.ihealthlabs.com/4-in-1-results>.

Negative Results

Both 'Ctrl' lines only



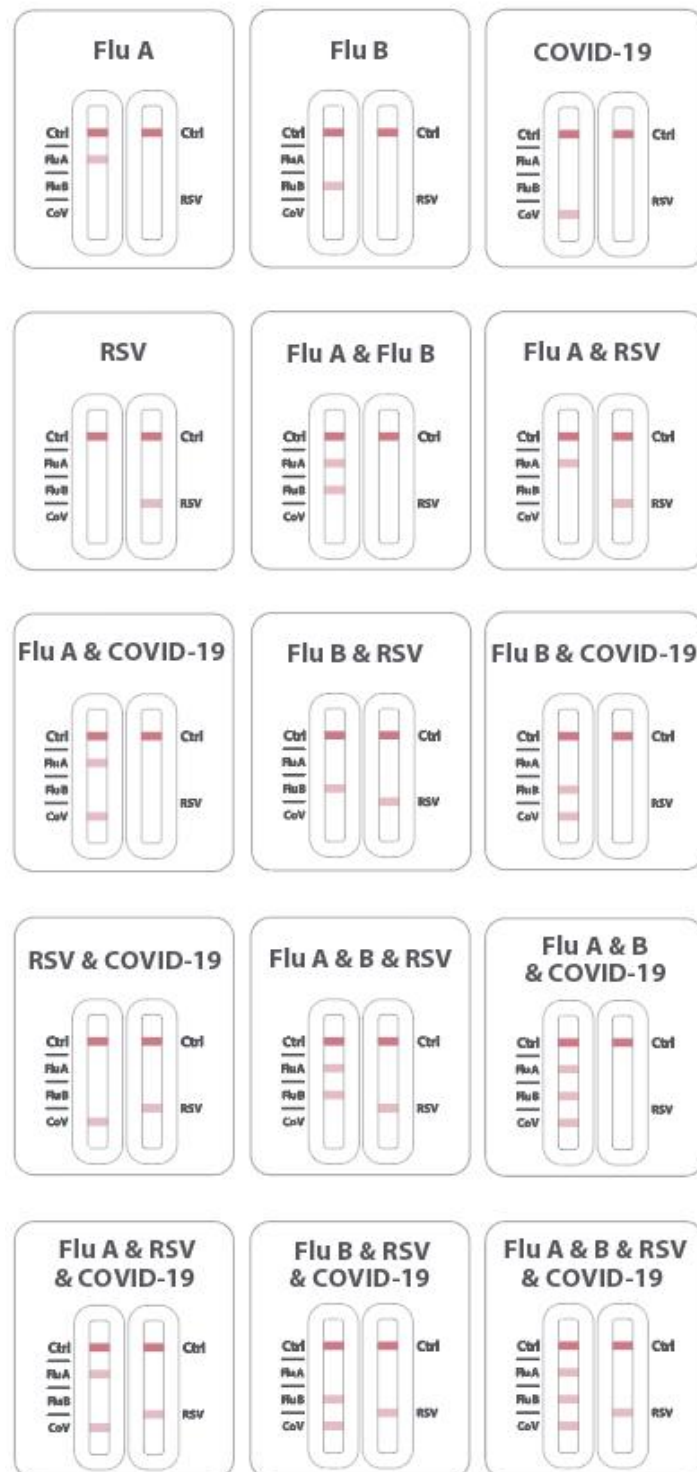
If the control lines at 'Ctrl' are **visible** and you **do not see** a line at 'Flu A', 'Flu B', 'CoV', or 'RSV', it means the test is **negative**.

UNDERSTANDING TEST RESULTS:

The virus from Flu A, Flu B, COVID-19, and/or RSV were not detected in the sample. A negative result does not mean it is certain that you do not have Flu A, Flu B, COVID-19, and/or RSV infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If you tested negative and continue to experience Flu A, Flu B, COVID-19, and/or RSV-like symptoms, you should seek follow-up care with your healthcare provider.

Positive Results

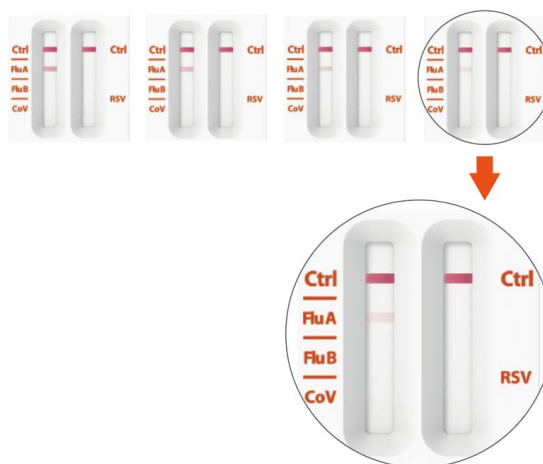
Both 'Ctrl' lines must be PRESENT



If the control lines at '**Ctrl**' are visible and any other single line **or** multiple lines on '**Flu A**', '**Flu B**', '**CoV**', and/or '**RSV**' 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.

For example, the images displayed below should all be considered Flu A positive.



UNDERSTANDING TEST RESULTS:

The Flu A, Flu B, COVID-19, and/or RSV virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive).

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

After test is completed, dispose of used materials in household trash and wash hands.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2024 and November 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, COVID-19, and RSV 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, COVID-19, or RSV 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.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., infants and young children, elderly individuals, chronic lung disease, heart disease, compromised immune system, diabetes and other conditions) should contact a healthcare provider; users should also contact a healthcare provider if symptoms persist or worsen, (specially for individuals 6 to 24 months of age), independently of test results, or if you have any concerns.
- False positive test results are more likely when the prevalence of RSV, 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).
- FluMist/FluMist quadrivalent live intranasal influenza virus vaccine may cause false positive influenza A and B results with this test.
- Fluticasone propionate at concentrations >10% v/v may interfere with SARS-CoV-2, Flu B, and RSV results.
- Hand Sanitizer (80% ethanol, fast drying) may cause false negative results with this test.
- This test does not differentiate between SARS-CoV and SARS-CoV-2 and does not detect influenza C.
- The performance of this test was evaluated with a limited number of RSV positive samples from individuals aged 60 years and older.

PERFORMANCE CHARACTERISTICS

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 at least 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.

Virus Strains	LoD in PNF	LoD per Swab	#Positive/#total Tested	Percent Detected (%)
SARS-CoV-2 (chemically inactivated, Omicron Variant, Lineage JN.1, USA/New York/PV96109/2023)	7.0×10^0 TCID ₅₀ /mL	3.50×10^{-1} TCID ₅₀ /swab	59/60	98.3%
Influenza A A/Victoria/4897/2022(H1N1)	4.55×10^1 TCID ₅₀ /mL	2.27×10^0 TCID ₅₀ /swab	59/60	98.3%
Influenza A A/Darwin/6/2021(H3N2)	9.38×10^1 TCID ₅₀ /mL	4.69×10^0 TCID ₅₀ /swab	59/60	98.3%
Influenza B Victoria/B/Austria/1359417/2021	6.35×10^2 TCID ₅₀ /mL	3.17×10^1 TCID ₅₀ /swab	58/60	96.7%
Influenza B Yamagata/ B/Phuket/3073/2013	2.30×10^5 CEID ₅₀ /mL	1.15×10^4 CEID ₅₀ /swab	57/60	95.0%
RSV A/A2023/06-12NSMM	1.26×10^3 TCID ₅₀ /mL	6.30×10^1 TCID ₅₀ /swab	59/60	98.3%
RSV B/3/2015 Isolate #1	4.55×10^1 TCID ₅₀ /mL	2.27×10^0 TCID ₅₀ /swab	58/60	96.7%

NIBSC - WHO Standard Testing

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 Pro 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.

Virus Strains	LoD in PNF	LoD per Swab	#Positive/#total Tested	Percent Detected (%)
WHO Standard (NIBSC 21/368)	1.93×10^2 IU/mL	9.6 IU/swab	20/20	100%

Analytical Reactivity

Analytical reactivity testing for the subject 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.

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/Illinois/10OS3959/2010(H7N3)	3.55×10^6 CEID ₅₀ /mL
Influenza B (non Victoria)	B/Maryland/1/1959	1.69×10^3 CEID ₅₀ /mL

Virus	Strain	Concentration
non-Yamagata)		
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
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**

Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity of the iHealth Flu A&B/COVID-19/RSV 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/RSV Rapid Test Pro 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.

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
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
<i>Bordetella pertussis</i>	2.50×10 ⁸	CFU/mL	0/3	3/3
<i>Candida albicans</i>	6.03×10 ⁶	CFU/mL	0/3	3/3
<i>Chlamydia pneumoniae</i>	4.33×10 ⁶	IFU/mL	0/3	3/3
<i>Corynebacterium xerosis</i>	2.30×10 ⁷	CFU/mL	0/3	3/3
<i>Escherichia coli</i>	1.18×10 ⁸	CFU/mL	0/3	3/3
<i>Hemophilus influenzae</i>	3.00×10 ¹⁰	CFU/mL	0/3	3/3
<i>Lactobacillus plantarum</i>	8.50×10 ⁶	CFU/mL	0/3	3/3
<i>Legionella spp pneumophila</i>	6.50×10 ⁶	CFU/mL	0/3	3/3
<i>Moraxella catarrhalis</i>	2.50×10 ⁸	CFU/mL	0/3	3/3
<i>Mycoplasma pneumoniae</i>	2.50×10 ⁷	CFU/mL	0/3	3/3
<i>Mycobacterium tuberculosis</i>	4.15×10 ⁶	CFU/mL	0/3	3/3
<i>Neisseria meningitidis</i>	3.43×10 ⁶	CFU/mL	0/3	3/3
<i>Neisseria elongata</i>	2.68×10 ⁸	CFU/mL	0/3	3/3
<i>Pneumocystis jirovecii</i>	1.30×10 ⁷	CFU/mL	0/3	3/3
<i>Pseudomonas aeruginosa</i>	1.23×10 ⁸	CFU/mL	0/3	3/3

Microorganism	Working Concentration		Cross Reactivity Result (# pos / total)	Interference Result (# pos / total)
<i>Staphylococcus aureus</i>	2.60×10 ⁸	CFU/mL	0/3	3/3
<i>Staphylococcus epidermidis</i>	9.00×10 ⁷	CFU/mL	0/3	3/3
<i>Streptococcus salivarius</i>	1.01×10 ⁶	CFU/mL	0/3	3/3
<i>Streptococcus pneumoniae</i>	3.88×10 ⁷	CFU/mL	0/3	3/3
<i>Streptococcus pyogenes</i>	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

Endogenous Interfering Substances

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 Pro.

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.

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 hydrochloricum, 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
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	15% 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
(Alkalol)									
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

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
	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

High Dose Hook Effect

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

Viral Strain Tested	Concentration
SARS-CoV-2(chemically inactivated, Omicron Variant, Lineage JN.1, USA/New York/PV96109/2023)	1.40 x 10 ⁵ TCID ₅₀ /mL
Influenza A - A/Victoria/4897/2022(H1N1)	2.02 x 10 ⁵ TCID ₅₀ /mL
Influenza A - A/Darwin/6/2021(H3N2)	4.17 x 10 ⁵ TCID ₅₀ /mL
Influenza B - Victoria/B/Austria/1359417/2021	2.82 x 10 ⁶ TCID ₅₀ /mL
Influenza B -Yamagata/ B/Phuket/3073/2013	1.10 x 10 ⁹ CEID ₅₀ /mL
RSV A-A2023/06-12NSMM	2.80 ×10 ⁶ TCID ₅₀ /mL
RSV B-3/2015 Isolate #1	2.02 ×10 ⁵ TCID ₅₀ /mL

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.

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	7.05×10 ⁵	Influenza A/H1N1	1.36×10 ²	100%
			SARS-CoV-2	2.10×10 ¹	
18	Influenza	7.05×10 ⁵	Influenza A/H1N1	1.36×10 ²	100%

Sample	Competing Virus		Target Virus		Target Analyte Percent Positivity
	Virus Type	Concentration (TCID ₅₀ /mL)	Virus Type	Concentration (TCID ₅₀ /mL)	
	B/Victoria		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%
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	RSV B	1.36×10 ²	100%

Lot-to-Lot Precision

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 1: Summary results of multi-lot precision study

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%)
	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%)

Analyte	Test line	No. of Positives / No. of Samples tested (%)			Total no. of positives / Total no. of samples (%)
		Lot 1	Lot 2	Lot 3	
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%)
3X LoD SARS-CoV-2 /RSV	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	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%)

CLINICAL PERFORMANCE

A prospective clinical study to establish the performance characteristics of the iHealth Flu A&B/COVID-19/RSV Rapid Test Pro was conducted with specimens prospectively collected from November 2024 to November 2025 at twenty-two (22) sites across the United States. Subjects performed testing on self-collected swab samples in age groups 14 and older, and adult collected samples for age 2 and older, in a simulated at-home environment.

Samples were collected from individuals with associated symptoms of respiratory infection, who provided informed consent. Two (2) nasal swabs were collected from each subject according to standard collection methods. 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 Pro. The order of collection for the investigational and comparator AN swab was randomized.

Nasal swab specimens were collected from 1154 subjects enrolled in the prospective clinical study. Of those, 35 swab samples were unevaluable due to eligibility criteria, candidate device invalid, or reference sample handling issues, leaving a total of 1119 evaluable samples for the SARS-CoV-2 performance evaluation. The subject demographics of the evaluable subjects are shown below:

	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.

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%)

SARS-CoV-2 Clinical Performance in Subjects on 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%)

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%)

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%)

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%)

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/RSV Rapid Test Pro, please contact iHealth Technical Services at (855) 816-7705 or support@iHealthlabs.com.

REFERENCES

1. US Department of Health and Human Services. National Institutes of Health. Influenza [Fact Sheet]. January 2011.
2. Montalto N, Byrd R. An Office-Based Approach to Influenza: Clinical Diagnosis and Laboratory Testing. American Family Physician. January 2003; 67:11-118.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:

181-192.

4. Lauer S, et al. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. Ann Intern Med 2020 May 5;172(9):577-582.

SYMBOLS



Caution



Do not re-use



Consult Instructions for Use



In Vitro Diagnostic Medical Device



Temperature Limit



Keep in a dry place



Keep away from direct sunlight



Do not use if package is damaged



Manufacturer



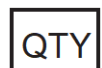
Contains sufficient for <n> tests



Use-by date



Batch code



Quantity

Manufactured for iHealth Labs, Inc.
880 W Maude Ave, Sunnyvale, CA 94085, USA
1-855-816-7705 www.ihealthlabs.com

Rev.10/13/2026