iHealth® COVID-19/Flu A&B Rapid Test

Healthcare Provider Instructions for Use

Model: ICF-3000

For use with anterior nasal swab specimens
For in vitro Diagnostic Use
For Emergency Use Authorization only

INTENDED USE

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

This test is authorized for non-prescription home use with self-collected anterior nares nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals two (2) years or older. This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first four (4) days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Results are for the simultaneous identification of SARS-CoV-2, influenza A virus, and influenza B virus protein antigens, but do not differentiate between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens.

The viral antigens targeted by this test are generally detectable from specimens collected using nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. 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. Individuals who test positive with the iHealth COVID-19/Flu A&B Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2, influenza A, and influenza B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms

consistent with SARS-CoV-2, influenza A, and influenza B infection.

Individuals who test negative and continue to experience SARS-CoV-2 and/or influenza-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 and/or influenza infection and should seek follow up care with their physician or healthcare provider.

The iHealth COVID-19/Flu A&B Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

COVID-19 (short for "Coronavirus Disease 2019") is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms. 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. 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.

PRINCIPLE OF THE PROCEDURES

The iHealth COVID-19/Flu A&B Rapid Test 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 Test Tube. The Test Card is then placed in the sample mixture, 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 colloidal gold. 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 or purple 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 or purple 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

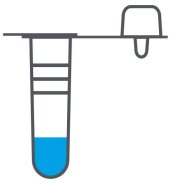
The iHealth COVID-19/Flu A&B Rapid Test requires the following elements for operation.

Materials provided in the Test Kit:

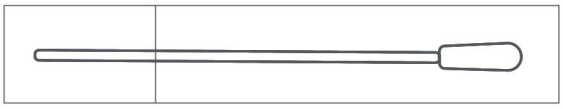
Kit components	Quantity						
	1 Test Kit	**2 Tests Kit**	**3 Tests Kit**	**4 Tests Kit**	**5 Tests Kit**	**25 Tests Kit**	**40 Tests Kit**
COVID-19/ Flu A&B Test Card(s)	1 ea/box	2 ea/box	3 ea/box	4 ea/box	5 ea/box	25 ea/box	40 ea/box
Nasal Swab(s)	1 ea/box	2 ea/box	3 ea/box	4 ea/box	5 ea/box	25 ea/box	40 ea/box
Tube(s)	1 ea/box	2 ea/box	3 ea/box	4 ea/box	5 ea/box	25 ea/box	40 ea/box
Lay User Quick Reference Instructions	1 ea/box	1 ea/box	1 ea/box	1 ea/box	1 ea/box	1 ea/box	1 ea/box

For Healthcare Provider Instructions for Use, please see the company website: https://www.ihealthlabs.com

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



Tube(s)



Swab(s)

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

Materials required but not provided in the kit:

- Timer or Clock
- Recommended materials: Disposable gloves and mask, if swabbing others.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

- For in vitro diagnostic use.
- This test may only be used in symptomatic individuals.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/ or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- **Serial testing should be performed in individuals with SARS-CoV-2 negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial testing**.
- **Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.**
- 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.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use the test card, test tube, or swab.
- If any liquid spills from the test tube, discard test components and re-start test using new test components.
- Do not use the test kit after its expiration date shown on the external packaging.
- Only use the nasal swabs provided in the kit.
- 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 opened, the test device 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**.
- Eyewear protection is recommended.
- Make sure there is sufficient light for testing. For best results, read test in a well-lit area.
- Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.
- 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 nasal sample.
- The test sample must be collected from both nostrils with the same swab.
- Do not conduct this test if prone to nose bleeds or have a nose injury. Exposure to blood may cause false negative results with this test.
- 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.poison-help.org or 1-800-222-1222.

Chemical Name	GHS Code for Each Ingredient	Concentration
Triton X-100	Harmful if swallowed (H302) Cause skin irritation (H315) Cause serious eye damage(H318)	0.50%
ProClin 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.10%
Gentamicin sulfate/1405-41-0	May cause allergy or asthma symptoms or breathing difficulties if inhaled (H334) May cause an allergic skin reaction (H317)	0.25%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: https://www.cdc.gov/COVID19

STORAGE AND STABILITY

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

• Store the test kit between 36-86°F (2-30°C) in a place out of direct sunlight
• Reagents and devices must be used at room temperature 65-86°F (18-30°C).
• The unsealed test card is valid for one hour. It is recommended to use the test kit immediately after opening.
• The expiration date is on the package.

QUALITY CONTROL

Each iHealth COVID-19/Flu A&B Rapid Test has a built-in internal procedural control. The pink or purple line appearing at the “C” position verifies proper assembly and capillary flow of the test strip. A distinct pink or purple 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.

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. For the most current expiration date information, refer to: https://www.fda.gov/covid-tests.

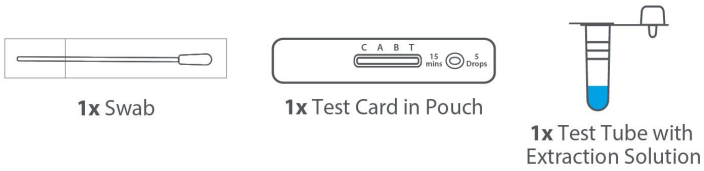
2) Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.

Note: It is recommended that gloves be worn during testing. A face mask should be worn if swabbing others.

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

Prepare the Materials

Materials Provided:



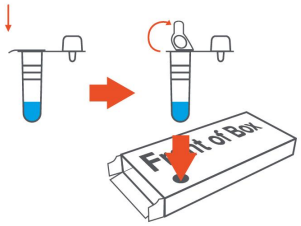
Materials required but not provided: A clock or timer; Recommended materials: Disposable gloves and mask, if swabbing others.

4) Arrange the materials on a clean, dry, flat surface. Your box may contain more than one test kit. Use only one of each of the materials provided for each test.

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

5) Pick up the Test Tube and remove the sealing foil of the tube.

6) Push the extraction buffer tube into the perforated tube holder located on the front of the box, and insert the Test Tube in the front of box labeled "Insert tube here."

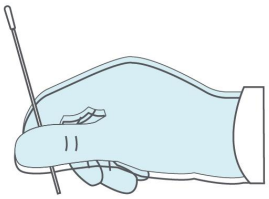


7) Remove the Test Card from its foil pouch.

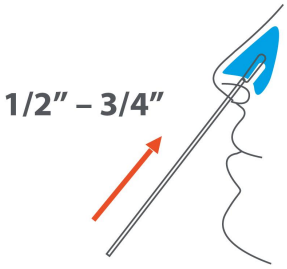
DO NOT remove the Test Card until you are ready to begin the test.

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).**

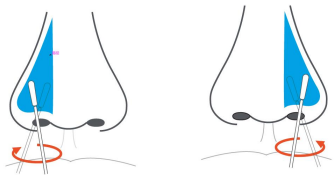


9) Gently insert the swab 1/2 to 3/4 inch into a nostril. For young children, swab should not be inserted more than 1/2 inch.



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

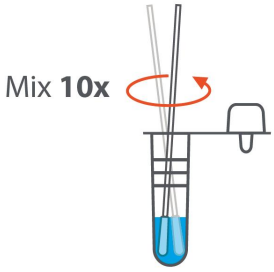
REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.

NOTE: 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. 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.

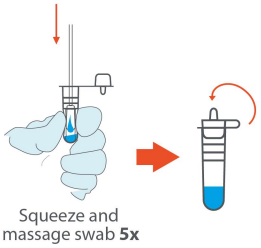
Swirl the swab in the solution by rotating the swab forcefully against the side of the tube at least 10 times, keeping the swab tip submerged in the extraction solution the entire time.



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

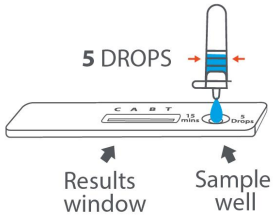
11) Squeeze the tube 5 times with your fingers to ensure that the sample on the swab is fully mixed into the extraction solution.

Close the dropper cap that is attached to the tube.



Note: Failure to squeeze the tube may lead to false negative results.

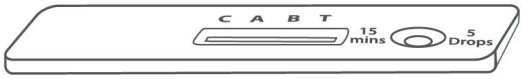
12) Holding the dropper vertically over the sample well on the test card, squeeze out exactly 5 DROPS of the solution.



DO NOT squeeze more than 5 drops from the 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.

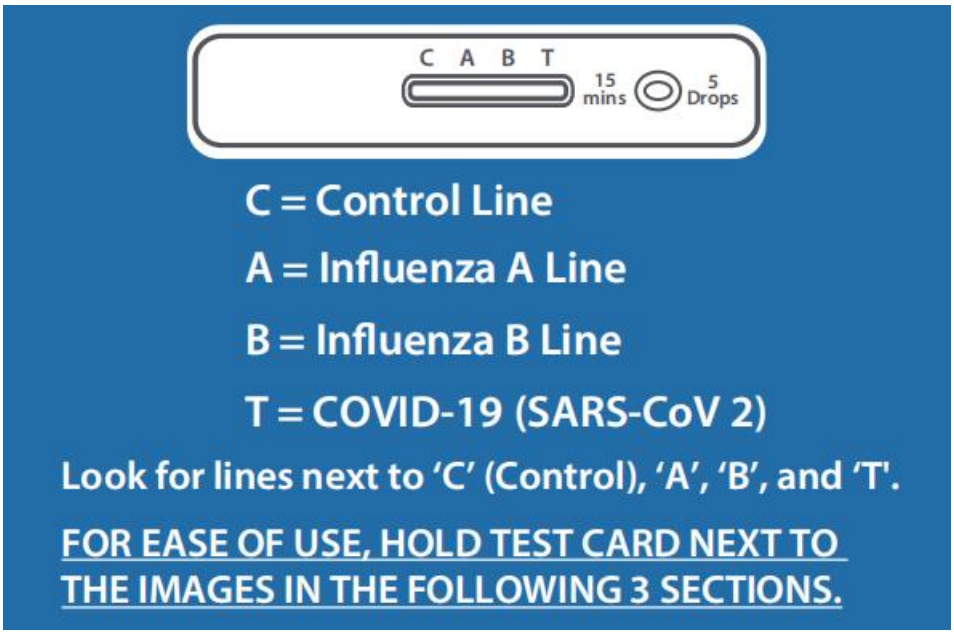


DO NOT interpret test result before 15 minutes or after 30 minutes.

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 interpretations may occur.



Invalid Results

If a control line is not visible at "C" after 15 minutes, even if any other line is visible in the results window, **THE TEST HAS FAILED** and is considered invalid.

UNDERSTANDING YOUR RESULTS:

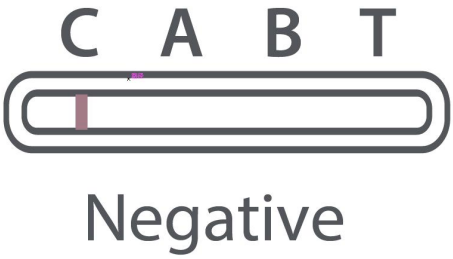
This test did not work. The result should not be used. The test cannot determine if you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

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



Negative

To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours if the individual has symptoms on the first day of testing.

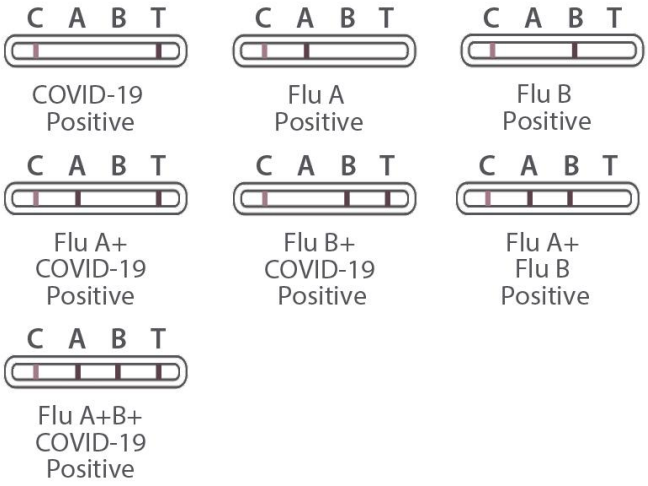
UNDERSTANDING YOUR RESULTS:

The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean that you do not have COVID-19, Flu A, and/or Flu B 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 COVID-19, Flu A, and/or Flu B-like symptoms, you should seek follow-up care with your healthcare provider.

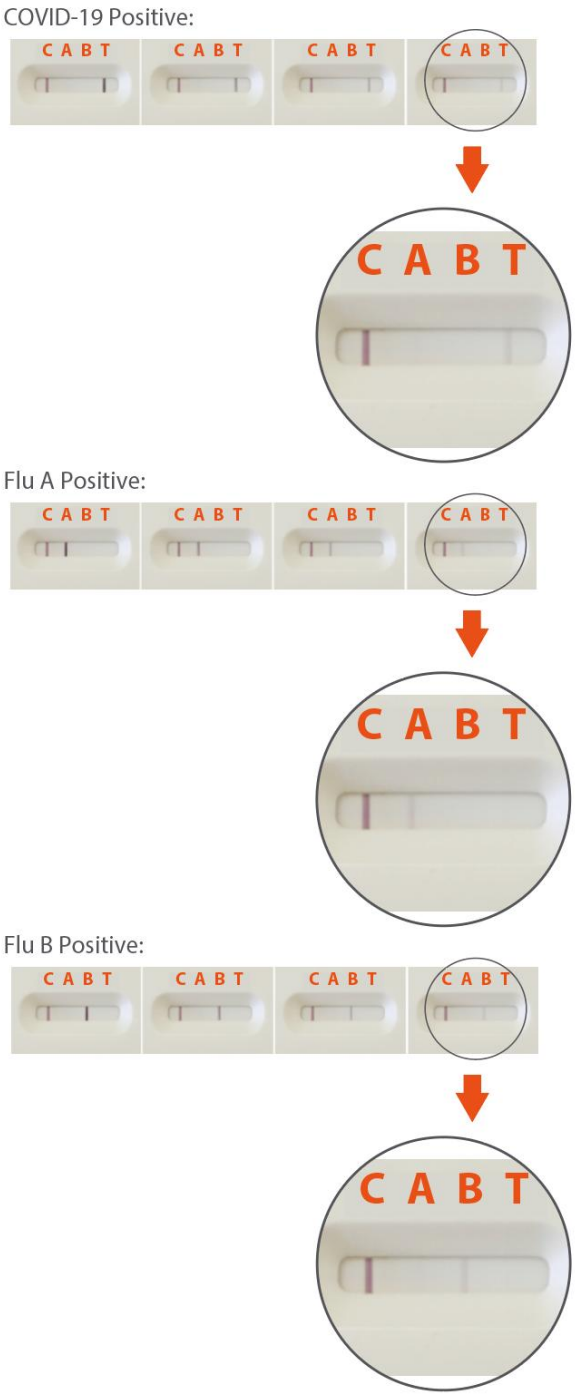
All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Positive Results

If the control line at “C” is visible and any other single line **or** multiple lines on ‘A’, ‘B’, and/or ’T’ appear, the test is positive.



NOTE: Any pink or purple 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.



UNDERSTANDING YOUR RESULTS:

Repeat testing does not need to be performed if individuals have a positive SARS-CoV-2 result at any time.

A positive test result means that the virus that causes COVID-19 or influenza infection was 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 or influenza

infection 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. If you tested positive with the iHealth COVID-19/Flu A&B Rapid Test, you should self isolate and seek follow-up care with your physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Repeat Testing is needed to improve test accuracy for SARS-CoV-2 for all samples that are negative for SARS-CoV-2 on the first day of testing, even if they are positive for influenza A and/or B. Please follow the table below when interpreting test results. Serial (repeat) testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

Status on First Day of Testing: With Symptoms			
Day 0 (First Test)	**Serial Testing?**	**Day 2 (Second Test)**	**Interpretation**
SARS-CoV-2(+) Influenza A and B(-)	NO	Not needed	Positive for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2(+) Influenza A and/or B(+)	NO	Not needed	Positive for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2(-) Influenza A and/or B(-)	YES	SARS-CoV-2(+) Influenza A and/or B(-)	Positive for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2(-) Influenza A and/or B(+)	YES	SARS-CoV-2(+) Influenza A and/or B(+)	Positive for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2(-) Influenza A and/or B(-)	YES	SARS-CoV-2(-) Influenza A and/or B(+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2(-) Influenza A and/or B(-)	YES	SARS-CoV-2(-) Influenza A and/or B(-)	Presumptive Negative for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2(-) Influenza A and/or B(-)	YES	SARS-CoV-2(+) Influenza A and/or B(+)	Positive for COVID-19 Positive for Influenza A and/or B

SARS-CoV-2(-) Influenza A and/or B(+)	YES	SARS-CoV-2(-) Influenza A and/or B(-)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2(-) Influenza A and/or B(+)	YES	SARS-CoV-2(-) Influenza A and/or B(+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2(-) Influenza A and/or B(+)	YES	SARS-CoV-2(+) Influenza A and/or B(+)	Positive for COVID-19 Positive for Influenza A and/or B

RESULTS REPORTING

Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

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 October 2023 and February 2024. 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 COVID-19 and influenza and their prevalence, which change over time.
- 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 COVID-19 and influenza as compared to a molecular test, especially in samples with low viral load.
- All antigen test negative results, for SARS-CoV-2 or influenza, are presumptive and confirmation with a molecular assay may be necessary.
- If the test is positive, then proteins from the viruses that causes COVID-19 or influenza have been found in the sample and the individual likely has a respiratory infection with SARS- CoV-2 or influenza.
- If you continue to have symptoms consistent with COVID-19 and influenza, and both your first and second tests are negative, you may not have COVID-19 or influenza; however, you should follow-up with a healthcare provider. Incorrect test results may

occur if a specimen is incorrectly collected or handled.

- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.
- The use of oral biotin supplements and use of biotin as a topical application may impact the performance of the test. Exposure to biotin may cause false negative results with this test.
- Based on sequence analysis, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exists. Wet testing for HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.
- This device is a qualitative test and does not provide information on the viral load present in the specimen. Incorrect test results may occur if a specimen is incorrectly collected or handled.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LOD)

The limit of detection (LoD) for the iHealth COVID-19/Flu A&B Rapid Test was established using dilutions of one SARS-Related Coronavirus 2 (SARS-CoV-2) (USA-WA1/2020), two influenza A strains (H1N1pdm09: A/Victoria/4897/2022, H3N2: A/Darwin/6/2021) and two influenza B strains (Victoria: B/Washington/02/2019, Yamagata: B/Florida/4/2006) in Pooled Negative Swab Matrix (PNSM). The isolate dilutions were tested by adding fifty (50) µL to the head of the nasal swab and extracting the swab per the iHealth COVID-19/Flu A&B Rapid Test Instructions for Use.

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 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. In the final dilution testing, the lowest concentration that generated ≥95% positive detection rate was set as the LoD concentration. Confirmatory testing was done on 1 day, totaling twenty (20) replicates.

Virus Strains	LoD in PNSM	LoD per Swab	#Positive/#total Tested	Percent Detected (%)
SARS-CoV-2 (UV inactivated, USA-WA1/2020)	1.58×10^{3} $TCID_{50}$/mL	7.9×10^{1} $TCID_{50}$/swab	20/20	100%
Influenza A A/Victoria/4897/2022(H1N1)	5.05×10^{2} $TCID_{50}$/mL	2.53×10^{1} $TCID_{50}$/swab	20/20	100%

Influenza A A/Darwin/6/2021(H3N2)	4.17×10^{2} $TCID_{50}$/mL	2.09×10^{1} $TCID_{50}$/swab	20/20	100%
Influenza B Victoria/Washington/02/2019	3.16×10^{3} $TCID_{50}$/mL	1.58×10^{2} $TCID_{50}$/swab	20/20	100%
Influenza B Yamagata/Florida/4/2006	5.85×10^{1} $TCID_{50}$/mL	2.93×10^{0} $TCID_{50}$/swab	20/20	100%

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 COVID-19/Flu A&B Rapid Test using the 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) by testing a series of two-fold dilutions of the master stock equivalent to 4000 IU/mL. Three replicates were tested for each of two-fold dilutions to determine the preliminary LoD concentration of the Candidate device. The preliminary LoD was confirmed by testing an additional twenty (20) replicates.

Virus Strains	LoD in PNSM	LoD per Swab	#Positive/ #total Tested	Percent Detected (%)
WHO Standard (NIBSC 21/368)	1.0×10^{3} IU/mL	50 IU/swab	20/20	100%

Analytical Reactivity

The analytical reactivity of the monoclonal antibodies targeting SARS-CoV-2 in the iHealth COVID-19/Flu A&B Rapid Test were evaluated with the currently available SARS-CoV-2 strains and influenza strains using a dilution series. Concentrations listed in the table below indicate the lowest detectable concentrations for which all three (3) replicates were positive.

Virus	Strain	Concentration
Influenza A (H1N1)	A/Victoria/4897/2022	5.05×10^{2} $TCID_{50}$/mL
	A/Brisbane/02/2018	7.55×10^{2} $TCID_{50}$/mL
	A/Guangdong-Maonan/SWL1536/2019	2.09×10^{3} $TCID_{50}$/mL
	A/NY/03/2009	4.57×10^{4} $TCID_{50}$/mL
	A/Sydney/5/2021	1.20×10^{4} $TCID_{50}$/mL
	A/Michigan/45/2015	9.30×10^{1} $TCID_{50}$/mL
	A/Wisconsin/67/22	2.11×10^{3} $TCID_{50}$/mL
	A/Hawaii/66/2019	7.40×10^{7} $CEID_{50}$/mL
	A/Wisconsin/588/2019	2.80×10^{4} FFU/mL
	A/Indiana/02/2020	9.70×10^{6} $CEID_{50}$/mL
	A/California/04/2009	1.40×10^{4} $TCID_{50}$/mL
	A/Ohio/09/2015	1.40×10^{6} $TCID_{50}$/mL
Influenza A (H1N2)	A/Minnesota/19/2011	8.00×10^{6} $TCID_{50}$/mL
Influenza A (H3N2)	A/Darwin/6/21	4.17×10^{2} $TCID_{50}$/mL
	A/Alaska/01/2021	7.50×10^{4} FFU/mL

	A/New York/21/2020	2.60×10^5 FFU/mL
	A/Tasmania/503/2020	1.30×10^5 FFU/mL
	A/Hong Kong/2671/2019	1.05×10^3 $TCID_{50}$/mL
	A/Hong Kong/45/2019	3.75×10^4 FFU/mL
	A/Indiana/08/2011	8.10×10^2 $TCID_{50}$/mL
Influenza A (H5N1)	A/mallard/Wisconsin/2576/2009 A/mallard/Wisconsin/2576/2009	1.60×10^6 $TCID_{50}$/mL
Influenza A (H7N3)	A/northern pintail/Illinois/10OS3959/2010	2.80×10^6 $TCID_{50}$/mL
Influenza B (non-Victoria non-Yamagata)	B/Maryland/1/1959	3.38×10^3 $CEID_{50}$/mL
Influenza B (B-like)	B/Brisbane/60/2008	1.29×10^0 $TCID_{50}$/mL
Influenza B (Victoria Lineage)	B/Michigan/01/2021	7.13×10^3 $TCID_{50}$/mL
	B/Washington/02/2019	3.16×10^3 $TCID_{50}$/mL
	B/Colorado/6/2017	2.93×10^1 $TCID_{50}$/mL
	B/Texas/02/ 2013	2.45×10^1 $TCID_{50}$/mL
Influenza B (Yamagata Lineage)	B/Utah/09/2014	6.30×10^2 $TCID_{50}$/mL
	B/Florida/4/2006	5.85×10^1 $TCID_{50}$/mL
	B/Texas/06/2011	7.55×10^2 $TCID_{50}$/mL
	B/Wisconsin/1/2010	1.78×10^2 $TCID_{50}$/mL
SARS-CoV-2	2019-nCoV/USA-WA1/2020	1.58×10^3 $TCID_{50}$/mL

Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity and microbial interference with related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen were evaluated with iHealth COVID-19/Flu A&B Rapid Test. Each organism was tested in replicates of three (3) at the concentration listed in the following table of test results.
For cross reactivity, the organisms listed below were tested in negative clinical matrix. Testing showed no evidence of cross-reactivity at the concentrations tested.

An *in-silico* analysis was performed using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) for Human Coronavirus HKU1:
• Human Coronavirus HKU1 shows 39.10% homology across 76% of the nucleocapsid sequence, which is relatively low. However, cross-reactivity cannot be ruled out.

Microorganism Introduced	**Concentration**	**Influenza A** Test Results (positive/total)	**Influenza B** Test Results (positive/total)	**SARS-CoV-2** Test Results (positive/total)

Microorganism Introduced	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
MERS-coronavirus	1.75×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Human coronavirus OC43*	8.50×10^4 $TCID_{50}$/mL	0/3	0/3	0/3
Human coronavirus 229E	1.58×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Human coronavirus NL63*	7.05×10^4 $TCID_{50}$/mL	0/3	0/3	0/3
Adenovirus, Type 1	1.02×10^6 $TCID_{50}$/mL	0/3	0/3	0/3
Adenovirus Type 7	1.58×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Cytomegalovirus*	7.05×10^4 $TCID_{50}$/mL	0/3	0/3	0/3
Epstein Barr Virus	1.83×10^6 CP/mL	0/3	0/3	0/3
Human Metapneumovirus (hMPV)	3.50×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Parainfluenza virus 1	2.00×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Parainfluenza virus 2	1.89×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Parainfluenza virus 3	2.29×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Parainfluenza virus 4A	2.88×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Enterovirus	2.23×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Respiratory syncytial virus A	3.50×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Respiratory syncytial virus B	2.29×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Rhinovirus 1A	1.76×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Bordetella pertussis	2.90×10^8 cfu/mL	0/3	0/3	0/3
Candida albicans	1.21×10^7 cfu/mL	0/3	0/3	0/3
Chlamydia pneumoniae	4.33×10^6 ifu/mL	0/3	0/3	0/3
Corynebacterium diphtheriae	8.58×10^6 cfu/mL	0/3	0/3	0/3
Escherichia coli	1.79×10^8 cfu/mL	0/3	0/3	0/3
Haemophilus influenzae	9.68×10^6 cfu/mL	0/3	0/3	0/3
Lactobacillus sp.	1.21×10^7 cfu/mL	0/3	0/3	0/3
Legionella pneumophila	6.50×10^6 cfu/mL	0/3	0/3	0/3
Moraxella catarrhalis	2.50×10^8 cfu/mL	0/3	0/3	0/3
Mycoplasma pneumoniae	2.50×10^7 cfu/mL	0/3	0/3	0/3
Mycobacterium tuberculosis	3.03×10^5 cfu/mL	0/3	0/3	0/3
Neisseria meningitidis	3.43×10^6 cfu/mL	0/3	0/3	0/3

Microorganism Introduced	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
Neisseria sp.	2.68×10^8 cfu/mL	0/3	0/3	0/3
Pneumocystis jirovecii	1.30×10^7 cfu/mL	0/3	0/3	0/3
Pseudomonas aeruginosa	3.45×10^8 cfu/mL	0/3	0/3	0/3
Staphylococcus aureus	2.60×10^8 cfu/mL	0/3	0/3	0/3
Staphylococcus epidermidis	1.71×10^8 cfu/mL	0/3	0/3	0/3
Streptococcus salivarius	1.01×10^6 cfu/mL	0/3	0/3	0/3
Streptococcus pneumoniae	1.81×10^7 cfu/mL	0/3	0/3	0/3
Streptococcus pyogenes	1.23×10^8 cfu/mL	0/3	0/3	0/3
Measles Virus	8.48×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Mumps Virus	8.48×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
PNSM (Pooled Negative Swab Matrix)	NA	0/3	0/3	0/3

** Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.*

Microbial interference

For evaluating microbial interference, each potential interfering microorganism was tested in the presence of spiked analyte. SARS-CoV-2 (UV inactivated, USA-WA1/2020), H3N2: A/Darwin/6/2021, and Yamagata: B/Florida/4/2006 were diluted to 3x LoD concentration in negative clinical matrix and tested in replicates of three (3). No microbial interference was seen with the organisms tested at the concentrations shown below.

Microorganism Introduced	Microorganism Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
SARS-CoV-1	1.25×10^5 pfu/mL	3/3	3/3	3/3
MERS-coronavirus	1.75×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Human coronavirus OC43*	8.50×10^4 $TCID_{50}$/mL	3/3	3/3	3/3
Human coronavirus 229E	1.58×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Human coronavirus NL63*	7.05×10^4 $TCID_{50}$/mL	3/3	3/3	3/3
Adenovirus, Type 1	1.02×10^6 $TCID_{50}$/mL	3/3	3/3	3/3
Adenovirus Type 7	1.58×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Cytomegalovirus*	7.05×10^4 $TCID_{50}$/mL	3/3	3/3	3/3
Epstein Barr Virus	1.83×10^6 CP/mL	3/3	3/3	3/3

Microorganism Introduced	**Microorganism Concentration**	**Influenza A** Test Results (positive/total)	**Influenza B** Test Results (positive/total)	**SARS-CoV-2** Test Results (positive/total)
Human Metapneumovirus (hMPV)	3.50×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Parainfluenza virus 1	2.00×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Parainfluenza virus 2	1.89×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Parainfluenza virus 3	2.29×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Parainfluenza virus 4A	2.88×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Enterovirus	2.23×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Respiratory syncytial virus A	3.50×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Respiratory syncytial virus B	2.29×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Rhinovirus 1A	1.76×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Bordetella pertussis	2.90×10^8 cfu/mL	3/3	3/3	3/3
Candida albicans	1.21×10^7 cfu/mL	3/3	3/3	3/3
Chlamydia pneumoniae	4.33×10^6 ifu/mL	3/3	3/3	3/3
Corynebacterium diphtheriae	8.58×10^6 cfu/mL	3/3	3/3	3/3
Escherichia coli	1.79×10^8 cfu/mL	3/3	3/3	3/3
Haemophilus influenzae	9.68×10^6 cfu/mL	3/3	3/3	3/3
Lactobacillus sp.	1.21×10^7 cfu/mL	3/3	3/3	3/3
Legionella pneumophila	6.50×10^6 cfu/mL	3/3	3/3	3/3
Moraxella catarrhalis	2.50×10^8 cfu/mL	3/3	3/3	3/3
Mycoplasma pneumoniae	*2.50×10^7 cfu/mL*	3/3	3/3	3/3
Mycobacterium tuberculosis	3.03×10^5 cfu/mL	3/3	3/3	3/3
Neisseria meningitidis	3.43×10^6 cfu/mL	3/3	3/3	3/3
Neisseria sp.	2.68×10^8 cfu/mL	3/3	3/3	3/3
Pneumocystis jirovecii	1.30×10^7 cfu/mL	3/3	3/3	3/3
Pseudomonas aeruginosa	3.45×10^8 cfu/mL	3/3	3/3	3/3
Staphylococcus aureus	2.60×10^8 cfu/mL	3/3	3/3	3/3
Staphylococcus epidermidis	1.71×10^8 cfu/mL	3/3	3/3	3/3
Streptococcus salivarius	1.01×10^6 cfu/mL	3/3	3/3	3/3
Streptococcus pneumoniae	1.81×10^7 cfu/mL	3/3	3/3	3/3
Streptococcus pyogenes	1.23×10^8 cfu/mL	3/3	3/3	3/3
Measles Virus	8.48×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Mumps Virus	8.48×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
PNSM (Pooled Negative Swab Matrix)	NA	3/3	3/3	3/3

** Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.*

Endogenous Interfering Substances

The potential interference of endogenous substances with the antibodies used for the detection of COVID-19, influenza A and B was examined by testing twenty-four (24) substances in a negative clinical matrix, in the absence of each virus, and at 3 x LOD concentrations for SARS-CoV-2, influenza A, and influenza B.

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 iHealth COVID-19/Flu A&B Rapid Test. The results showed that the test device was not interfered by the substances at the concentrations tested.

Viruses unspiked

Substance	Concentration in negative sample	SARS-CoV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3
Mucin	0.5%	0/3	0/3	0/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	0/3	0/3	0/3
Naso GEL (NeilMed)	5% v/v	0/3	0/3	0/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3
Zicam	5% v/v	0/3	0/3	0/3
Homeopathic (Alkalol)	10% v/v	0/3	0/3	0/3
Sore Throat Phenol Spray	15% v/v	0/3	0/3	0/3
Tobramycin	4 µg/mL	0/3	0/3	0/3
Mupirocin	10 mg/mL	0/3	0/3	0/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3
Fluticasone Propionate	5% v/v	0/3	0/3	0/3
FluMist®/ FluMist® Quadrivalent- Live intranasal influenza virus vaccine *	15% v/v	0/3	3/3	3/3
	6% v/v	0/3	3/3	3/3
	3% v/v	0/3	3/3	3/3
	0.5% v/v	0/3	3/3	3/3
	0.75% v/v	0/3	3/3	0/3
	0.375% v/v	0/3	0/3	0/3
Zanamivir	282 ng/mL	0/3	0/3	0/3
Biotin	3,500 ng/mL	0/3	0/3	0/3
Body & Hand Lotion	0.5% w/v	0/3	0/3	0/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3

Substance	Concentration in negative sample	SARS-CoV-2	Flu A	Flu B
Hand Lotion	5% w/v	0/3	0/3	0/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	0/3	0/3	0/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	0/3
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	0/3	0/3	0/3
Hand soap liquid gel	10% w/v	0/3	0/3	0/3

* Interference (false positive results) was observed for FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine for influenza A. Users who have received nasally administered vaccine recently should not use this test.

Viruses spiked

Substance	Concentration in negative sample	SARS-CoV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)*	4% v/v	3/3	0/3	3/3
	2% v/v	3/3	3/3	3/3
Mucin	0.5%	3/3	3/3	3/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	3/3	3/3	3/3
Naso GEL (NeilMed)	5% v/v	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	3/3	3/3	3/3
Zicam	5% v/v	3/3	3/3	3/3
Homeopathic (Alkalol)	10% v/v	3/3	3/3	3/3
Sore Throat Phenol Spray	15% v/v	3/3	3/3	3/3
Tobramycin	4 µg/mL	3/3	3/3	3/3
Mupirocin	10 mg/mL	3/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	3/3	3/3	3/3
Fluticasone Propionate	5% v/v	3/3	3/3	3/3
FluMist®/ FluMist® Quadrivalent- Live intranasal influenza virus vaccine	15% v/v	3/3	3/3	3/3
Zanamivir	282 ng/mL	3/3	3/3	3/3
Biotin **	3500 ng/mL	1/3	3/3	3/3
	1,750 ng/mL	3/3	3/3	3/3
Body & Hand Lotion	0.5% w/v	3/3	3/3	3/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	3/3	3/3	3/3
Hand Lotion	5% w/v	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl	5% v/v	3/3	3/3	3/3

Substance	Concentration in negative sample	SARS-CoV-2	Flu A	Flu B
alcohol				
Hand Sanitizer cream lotion	15% v/v	3/3	3/3	3/3
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	3/3	3/3	3/3
Hand soap liquid gel ***	10% w/v	3/3	3/3	0/3
	1% w/v	3/3	3/3	0/3
	0.1% w/v	3/3	3/3	0/3
	0.05% w/v	3/3	3/3	0/3
	0.03% w/v	3/3	3/3	3/3

* Interference (false negative results) was observed for Human Whole Blood for influenza A. Users who are prone to nose bleeds or have a nose injury should not use this test.

** Interference (false negative results) was observed for Biotin for SARS-CoV-2. Users who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin oral supplements should not use this test. Similarly, individuals who use topical products with biotin should not use this test.

*** Interference (false negative results) was observed for Hand soap liquid gel for influenza B. Users are directed to ensure that hands are washed thoroughly with water to remove all traces of soap.

High Dose Hook Effect

No high-dose hook effect was observed with the iHealth COVID-19/Flu A&B Rapid Test when testing high concentrations of SARS-CoV-2, Influenza A or Influenza B strains.

Viral Strain Tested	Concentration ($TCID_{50}$/mL)
SARS-CoV-2 (UV inactivated, USA-WA1/2020)	3.16×10^6
Influenza A/H1N1pdm09: A/Victoria/4897/2022	2.02×10^5
Influenza A/H3N2: A/Darwin/6/2021	4.17×10^5
Victoria: B/Washington/02/2019	3.16×10^6
Influenza B/Yamagata: B/Florida/4/2006	1.17×10^5

Competitive Interference

For co-infection, SARS-CoV-2 at levels near LoD was tested in the presence of high levels of influenza A or influenza B and near LoD influenza A and influenza B in the presence of high levels of SARS-CoV-2. Additionally, the performance of the iHealth COVID-19/Flu A&B Rapid Test was evaluated in the presence of high levels of influenza A in low levels of influenza B and high levels of influenza B in low levels of influenza A. No

competitive interference was observed between SARS-CoV-2 and influenza A and B as listed 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	H3N2	2.09×10^5	SARS-Cov-2	4.47×10^3	100%
2	Yamagata	5.85×10^3	SARS-Cov-2	4.47×10^3	100%
3	SAR-CoV-2	1.58×10^6	H3N2	1.25×10^3	100%
4	Yamagata	5.85×10^3	H3N2	1.25×10^3	100%
5	SAR-CoV-2	1.58×10^6	Yamagata	1.75×10^2	100%
6	H3N2	2.09×10^5	Yamagata	1.75×10^2	100%

CLINICAL PERFORMANCE

A prospective clinical study to establish the performance characteristics of the iHealth COVID-19/Flu A&B Rapid Test was conducted with specimens prospectively collected from October 2023 to February 2024 at thirteen (13) 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 (1) nasal swab was self-collected and used for immediate testing with the iHealth COVID-19/Flu A&B Rapid Test per the test procedure and the other nasal swab sample was collected by a healthcare professional that was stored in UTM. The HCP collected specimens were sent for testing using a high-sensitivity FDA-cleared RT-PCR molecular comparator test, within the allowable time frames of specimen collection per the product instructions.

Nasal swab specimens were collected from 592 subjects enrolled in the prospective clinical study. Of those, 55 swab samples were unevaluable due to eligibility criteria, candidate device invalid, or reference sample handling issues, leaving a total of 537 evaluable samples for the SARS-CoV-2 performance evaluation. In addition, 2 swab samples were not evaluable due to reference results not being available, leaving a total of 535 evaluable samples for the Flu A/B performance evaluation.

	Subjects (by lay-user collection and testing (N=288)	Self-collecting and testing (N=235)	Overall (N=537)

Age			
Mean (SD)	8.1 (5.1)	34.4 (17.6)	20.1 (18.1)
Median [Min, Max]	8 [2, 71]	29.5 [14, 85]	13 [2, 85]
Age Group			
≥2-<14 years of age	284 (96.9%)	0 (0.0%)	284 (52.9%)
14-17 years of age	8 (2.7%)	44 (18.0%)	52 (9.7%)
18-60 years of age	0 (0.0%)	174(71.3%)	174 (32.4%)
>60 years of age	1 (0.3%)	26 (10.7%)	27 (5.0%)
Sex at Birth			
Female	138 (47.1%)	149 (61.1%)	287 (53.4%)
Male	155 (52.9%)	95 (38.9%)	250 (46.6%)

SARS-COV-2 PERFORMANCE

Investigational Test results for SARS-CoV-2 vs. FDA-cleared molecular test

SARS-CoV-2	Comparator Positives	Comparator Negatives	Sum
Investigational Positives	80	7	87
Investigational Negatives	15	435	450
Sum	**95**	**442**	**537**

Positive Percent Agreement = (80/95) = 84.2% (95% CI: 75.6%-90.2%)

Negative Percent Agreement = (435/442) = 98.4% (95% CI: 96.8%-99.2%)

SARS-CoV-2 Clinical Performance in Subjects on Days Post Symptoms Onset

Days of COVID-19 Symptoms	Number of Subject samples tested	Investigational Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95% CI)
Day 0	**25**	**4**	**5**	**20.0%**	**80.0% (37.6%-96.4%)**
Day 1	**123**	**23**	**27**	**22.0%**	**85.2% (67.5%-94.1%)**
Day 2	**196**	**30**	**34**	**17.3%**	**88.2% (73.4%-95.3%)**
Day 3	**137**	**18**	**22**	**16.1%**	**81.8% (61.5%-92.7%)**
Day 4*	**56**	**5**	**7**	**12.5%**	**71.4% (35.9%-91.8%)**
Total	**537**	**80**	**95**	**18.2%**	**84.2% (75.6%-90.2%)**

*Note: * This stratum contains one SARS-CoV-2 and two Influence A samples that were positive by the comparator because the sample number for DPSO 5 was too low to generate a sufficiently robust point estimate to support inclusion of DPSO 5 into the intended use.*

INFLUENZA A PERFORMANCE

Investigational Test results for FLU A vs. FDA-cleared molecular test

FLU A	Comparators Positives	Comparators Negatives	Sum
Investigational Positives	84	1	85
Investigational Negatives	19	431	450
Sum	103	432	535

Positive Percent Agreement = (84/103) = 81.6% (95% CI: 73.0%-87.9%)

Negative Percent Agreement = (431/432) = 99.8% (95% CI: 98.7%-100.0%)

INFLUENZA B PERFORMANCE

Investigational Test results for FLU B vs. FDA-cleared molecular test

FLU B	Comparators Positives	Comparators Negatives	Sum
Investigational Positives	47	1	48
Investigational Negatives	10	477	487
Sum	57	478	535

Positive Percent Agreement = (47/57) = 82.5% (95% CI: 70.6%-90.2%)

Negative Percent Agreement = (477/478) = 99.8% (95% CI: 98.8%-100.0%)

SERIAL TESTING

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States.

Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator

method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection.

Performance of the antigen test with serial testing in symptomatic individuals is described in the table below. Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	SYMPTOMATIC ON FIRST DAY OF TESTING		
	AG POSITIVE / PCR POSITIVE (ANTIGEN TEST PERFORMANCE % PPA)		
	1 TEST	2 TEST	3 TEST
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100.0%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performance on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performance an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

CUSTOMER HELPLINE

If you have any questions about the iHealth COVID-19/Flu A&B Rapid Test or your result, please contact our toll-free Customer Helpline on 1-855-816-7705.

SYMBOLS IN USE

 Caution

 Do not re-use

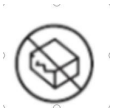
 Consult Instructions for Use

 In Vitro Diagnostic Medical Device

 Temperature limit

 Keep in a dry place

 Keep away from direct sunlight

 Do not use if package is damage

 Manufacturer

 Contains sufficient for <n> tests

 Use-by date

 Batch code

OTC Over-the-Counter

Technical Support:
If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact iHealth Labs Inc. at (855) 816-7705 or support@ihealthlabs.com.

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

Rev.05/07/2024