iHealth®

COVID-19/Flu A&B Rapid Test Pro

QUICK REFERENCE INSTRUCTIONS

IVD Rx ONLY

For use under Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use.

For use with anterior nasal swab specimens.

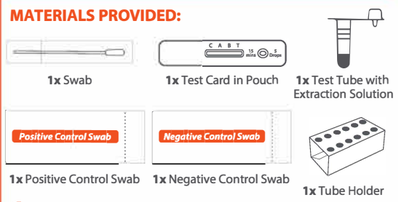
Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results. **Refer to the Instructions for Use (IFU) for more complete information.**

STORAGE AND STABILITY

Store kit between 36-86°F (2-30°C). Ensure all test components are at room temperature (65-86°F/18-30°C) before use.

PREPARE THE MATERIALS

MATERIALS PROVIDED:



1x Swab | **1x** Test Card in Pouch | **1x** Test Tube with Extraction Solution

1x Positive Control Swab | **1x** Negative Control Swab | **1x** Tube Holder

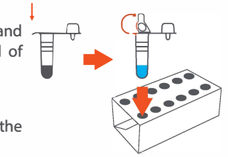
1.

Arrange the materials on a clean, dry, flat surface.

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

2.

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



3.

Place the Test Tube in the Tube Holder.

4.

Remove the Test Card from its foil pouch.

NOTE: Use the Test Card within one hour of opening the foil pouch.

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).

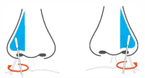
6.

Gently insert the swab 1/2 to 3/4 inch into a nostril.

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

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

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

7.

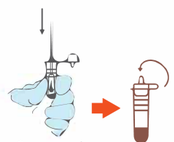
Place the swab into the extraction solution making sure the swab head is completely immersed.

Vigorously mix 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.

8.

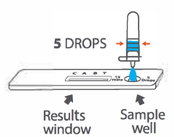
Squeeze the tube **5 times** with your fingers to ensure that the sample on the swab is fully mixed into the extraction solution.

Close the dropper cap that is attached to the tube.



9.

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.

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.

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.

C = Control Line

A = Influenza A Line

B = Influenza B Line

T = COVID-19 (SARS-CoV-2)

Look for lines next to 'C' (Control), 'A', 'B', and 'T'.

FOR EASE OF USE, HOLD TEST CARD NEXT TO THE IMAGES IN THE FOLLOWING 3 SECTIONS.

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.

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

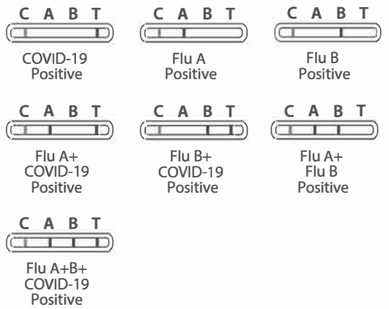
If the control line at "C" is visible and you do not see a line at 'A', 'B', or 'T', it means COVID-19, Flu A, or Flu B virus have not been detected.

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

Negative

POSITIVE RESULTS

If the control line at "C" is visible and any other line or multiple lines on 'A', 'B', and/or 'T' appear, the test is **positive.**



COVID-19 Positive | Flu A Positive | Flu B Positive

Flu A+ COVID-19 Positive | Flu B+ COVID-19 Positive | Flu A+ Flu B Positive

Flu A+B+ COVID-19 Positive

NOTE: Any pink or purple line, no matter how faint, should be considered an indication of a positive result.

It is possible to have more than one positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2, the virus that causes COVID-19. If more than one positive Test Line is observed, retest with a new patient sample, Test Card and Test Tube. A differing result should be followed by confirmatory testing with another test method, such as PCR.

SERIAL TESTING

Repeat Testing is needed 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. Repeat testing is needed to improve test accuracy for SARS-CoV-2. 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

EXTERNAL QUALITY CONTROL PROCEDURE

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.

WARNINGS AND PRECAUTIONS

- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- **Serial testing should be performed in individuals with 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 (repeat) testing.**
- This test may only be used in symptomatic individuals.

EUA - WARNINGS AND PRECAUTIONS

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, and influenza A and 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.

INTENDED USE

Please see the Instructions for Use for the full intended use.

The iHealth COVID-19/Flu A&B Rapid Test Pro is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with

iHealth

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Sunnyvale, CA 94085
Phone: 1-855-816-7705
www.ihealthlabs.com

Revision Date: 05/31/2024

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

Instructions for Use

Model: ICF-3000P

For use under Emergency Use Authorization (EUA) only
For in vitro diagnostic use
For use with anterior nasal swab specimens.

INTENDED USE

The iHealth COVID-19/Flu A&B Rapid Test Pro is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous in vitro detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus protein antigen, but do not differentiate, between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens.

These viral antigens are generally detectable in anterior nasal swab specimens 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.

All negative results are presumptive, and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out influenza or SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient

management decisions, including infection control measures 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 each respiratory infection.

The iHealth COVID-19/Flu A&B Rapid Test Pro is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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

PRINCIPLE OF THE PROCEDURE

The iHealth COVID-19/Flu A&B Rapid Test Pro consists of a Test Card that separately detects influenza A, influenza B, and SARS-CoV-2 antigens. The test procedure requires the solubilization of the nucleoproteins from a nasal swab sample by mixing the swab in 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 a 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 Pro requires the following elements for operation.

Materials provided in the Test Kit:

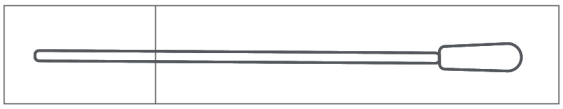
Kit components	Quantity	
	25 Tests Kit	**40 Tests Kit**
COVID-19/Flu A&B Test Cards	27 ea/box*	42 ea/box*
Nasal Swabs	25 ea/box	40 ea/box
Tubes	27 ea/box*	42 ea/box*
Quick Reference Instructions	1 ea/box	1 ea/box
COVID-19/Flu A&B Positive Control Swab	1 ea/box	1 ea/box
COVID-19/Flu A&B Negative Control Swab	1 ea/box	1 ea/box
Tube Holder	1 ea/box	1 ea/box

*NOTE: Two extra Test Cards and Tubes have been included in the kit for External Quality Control (QC) testing.

For the Instructions for Use, please see the company website:
https://support.ihealthlabs.com/3-in-1-POC-IFU

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

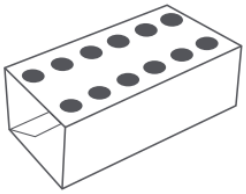
Tube(s)



Swab(s)

Positive Control Swab

Negative Control Swab



Tube Holder

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

Materials required but not provided in the kit:

- Timer or Clock
- iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit for additional quality control

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- 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.
- The test has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under the CLIA that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- **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 (repeat) 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.**
- This test may only be used in symptomatic individuals.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Do not use the test if the seal is broken or the pouch is damaged.
- Swabs, Tubes and Test Cards are for single use only (do not reuse).
- If any liquid spills from the test tube, discard test components and re-start test using new test components.
- The Test Tube contains only enough liquid for one test. Do not add a second Test

Stick to the same Test Tube as invalid or incorrect results may occur.

- Do not interchange or mix components from different test kits or test lots.
- Follow your clinical and/or laboratory safety guidelines and use appropriate precautions in the collection, handling, storage, and disposal of patient samples, all used kit contents, and all items exposed to patient samples.[5]
- Use of nitrile or latex (or other equivalent) gloves and other personal protective equipment are recommended when handling patient samples.[5]
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Only use the nasal swabs provided in the kit. Other swabs have not been validated for use with this test.
- Do not touch the swab tip prior to testing.
- 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**.
- Dispose of unused contents and containers in accordance with federal, state, and local regulations.
- Eyewear protection is recommended.
- Keep testing kit and kit components away from children and pets before and after use. 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, ush with large amounts of water. Do not ingest any kit components. 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).	0.5%
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).	0.1%
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: www.cdc.gov/COVID19

STORAGE AND STABILITY

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

• Do not freeze any of the test kit components.
• Do not use Test Cards or Test Tube after expiration date.
• Test Cards that have been outside of the pouch for more than one hour should be discarded.

SAMPLE HANDLING, TRANSPORT AND STORAGE

• Only nasal swabs can be used with this test. Use of nasal washes, nasal aspirates, or nasopharyngeal swabs has not been validated for use with this test.
• The test performance depends on the quality of the sample obtained as well as the handling and transport of the sample. Negative results can occur from inadequate sample collection and/or handling. Training in specimen collection is highly recommended because of the importance of specimen quality.
• When collecting anterior nasal swab specimens, make sure to use only the swab included in the iHealth® COVID-19/Flu A&B Rapid Test Pro test kit.
• To obtain accurate results, do not use visually bloody or overly viscous samples.
• If a culture result is desired for influenza, a separate swab must be collected for the culture.
• Freshly collected patient samples should be processed in the Test Tube as soon as possible after collection. If the sample cannot be processed immediately, the patient swab may be stored at room temperature (18-30ºC/65-86ºF) for up to one hour prior to testing in a clean dry container.
• Transport media should not be used. This test has not been validated or authorized for use with viral transport media.
• Once the swab has been mixed in the Test Tube, the extracted sample must be used immediately.

QUALITY CONTROL

The iHealth COVID-19/Flu A&B Rapid Test Pro provides two types of controls: internal procedural controls to aid in determining test validity, and two external controls, a positive and negative control swab.

Internal Procedural Controls

Several controls are incorporated into each Test Stick as routine quality checks for the test system and operator.

1. The appearance of the control line in the results window is an internal procedural control. If the control line does not appear at the read time, the test is invalid.
2. The clearing of the background in the results area is another internal procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light pink and not interfere with the reading of the test. If the background color does not clear and interferes with the test result, the test is invalid.

Contact iHealth Technical Services at (855) 816-7705 or support@iHealthlabs.com if you experience a problem.

External Quality Control Testing

The iHealth COVID-19/Flu A&B Rapid Test Pro includes one combined positive control swab that contains recombinant antigen for influenza A, influenza B, and SARS-CoV-2 and one negative control swab.

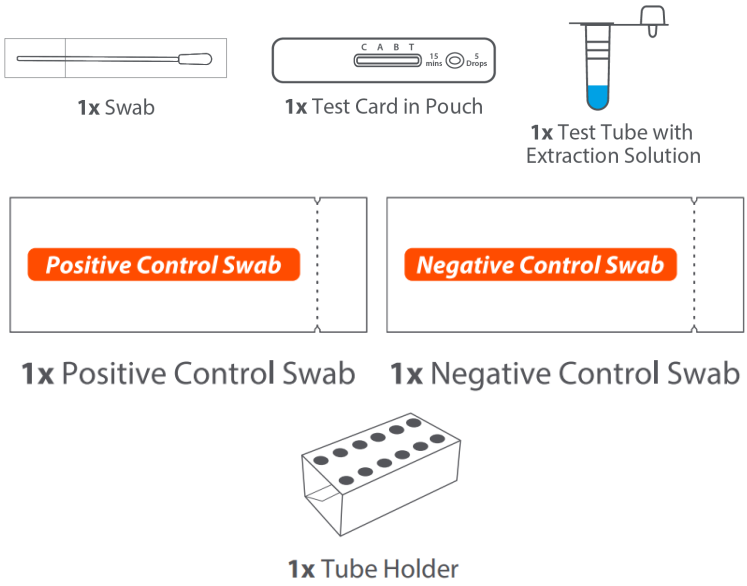
Use the controls to help ensure that the Test Cards are functioning properly and to demonstrate proper performance by the test operator. It is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure was run correctly and to verify the test is 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.

TEST PROCEDURE

Prepare the Materials

Materials Provided:



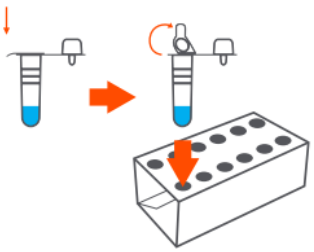
Materials required but not provided: A clock or timer.

1. Arrange the materials on a clean, dry, flat surface.

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

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

3. Place the Test Tube in the Tube Holder.

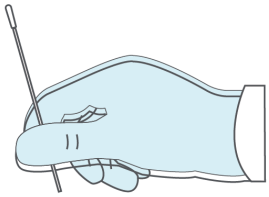


4. Remove the Test Card from its foil pouch.

NOTE: Use the Test Card within one hour of opening the foil pouch.

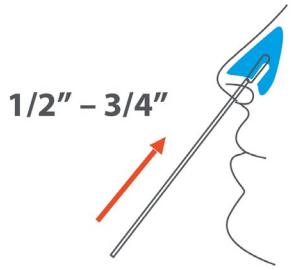
Performing The Test

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).**



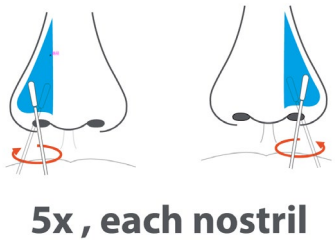
6. Gently insert the swab 1/2 to 3/4 inch into a nostril. For young children, swab should not be inserted more than 1/2 inch.

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



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.



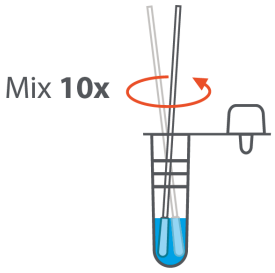
REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.

STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal

sample is not properly collected.

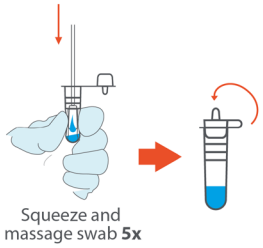
7. Place the swab into the extraction solution making sure the swab head is completely immersed.

Vigorously mix 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.

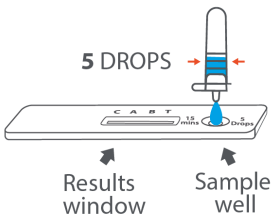


8. Squeeze the tube 5 times with your fingers to ensure that the sample on the swab is fully mixed into the extraction solution.

Close the dropper cap that is attached to the tube.



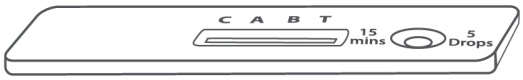
9. Holding the dropper vertically over the sample well on the test card, squeeze out exactly 5 DROPS of the solution.



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

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.

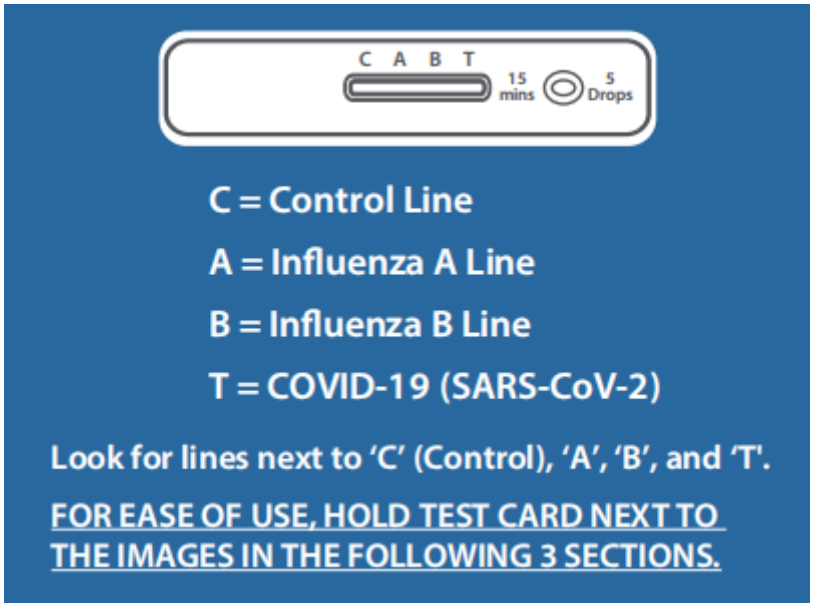


DO NOT interpret test result before 15 minutes or after 30 minutes.

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 TEST RESULTS:

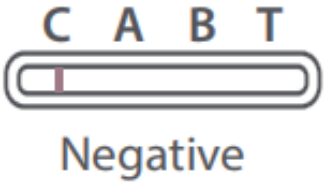
This test did not work. The result should not be used. The test cannot determine if the patient has COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

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

UNDERSTANDING TEST RESULTS:

COVID-19 Negative (-) Result

- **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.**

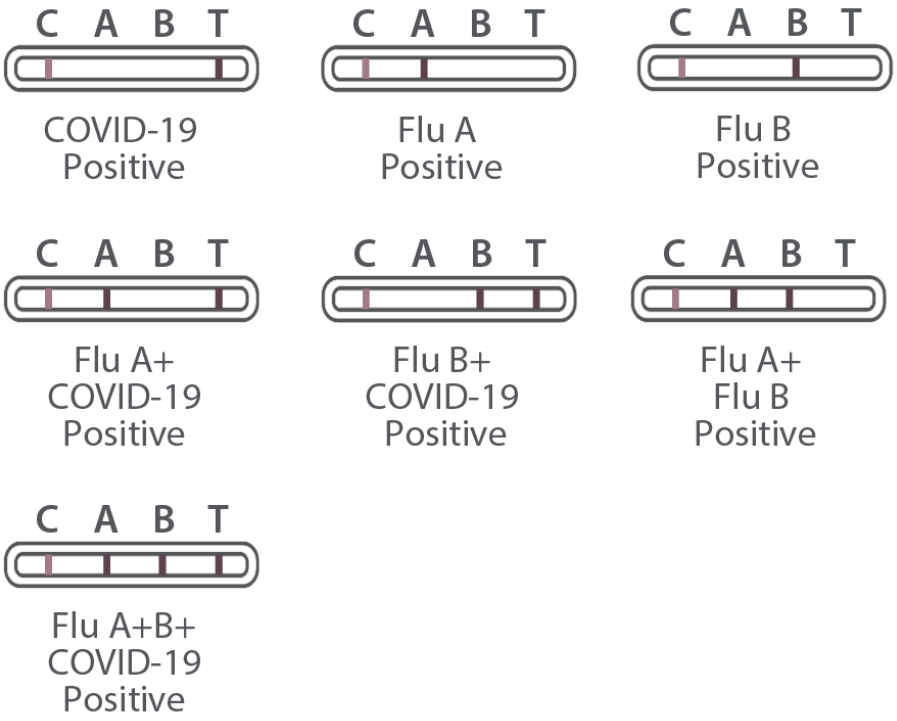
A negative test result indicates that the virus that causes COVID-19, Flu A, and/or Flu B was not detected in the sample. A negative result does not mean that the patient does not have COVID-19, Flu A, and/or Flu B infection. There is a higher chance of false negative results with antigen tests compared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

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.

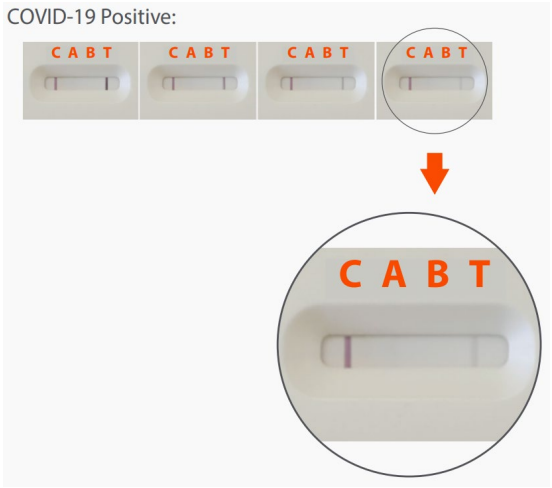
If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

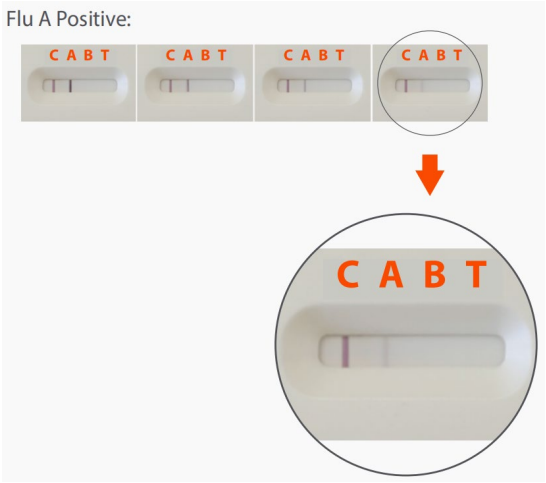
Positive Results

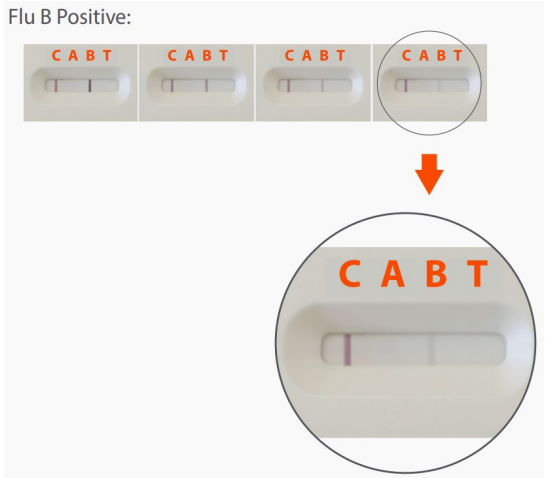
If the control line at “C” is visible and any other single line or multiple lines on ‘A’, ‘B’, and/or ’T’ appear, the test is positive.



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.







It is possible to have more than one positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2, the virus that causes COVID-19. If more than one positive Test Line is observed, retest with a new patient sample, Test Card and Test Tube. A differing result should be followed by confirmatory testing with another test method, such as PCR.

UNDERSTANDING TEST RESULTS:

COVID-19 Positive (+) Result

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus(es) that cause COVID-19, Flu A, and/or Flu B were detected in the patient's sample. It is very likely that the patient has the respective infection(s) and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local

guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

A positive result does not rule out co-infections with other pathogens or identify any specific influenza A subtype, influenza B lineage, or SARS-CoV-2 variant. The agent detected may not be the definite cause of disease. Individuals who test positive with the iHealth COVID-19/Flu A&B Rapid Test Pro should self-isolate and seek follow up care with their 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.

SERIAL TESTING

Repeat Testing is needed 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. Repeat testing is needed to improve test accuracy for SARS-CoV-2. 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	YES	SARS-CoV-2(+) Influenza A	Positive for COVID-19 Positive for Influenza A and/or B

and/or B(+)		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

LIMITATIONS

- 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 SARS-CoV-2 and influenza as compared to a molecular test, especially in samples with low viral load.

- 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.
- All antigen test negative results, for SARS-CoV-2 or influenza, are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have SARS-CoV-2 infection, however additional follow-up may be needed.
- If the test is positive, then proteins from the viruses that cause COVID-19 or influenza infection have been found in the sample and the individual likely has a respiratory infection with SARS-CoV-2 or influenza.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- The iHealth® COVID-19/Flu A&B Rapid Test Pro has been evaluated for use with human direct anterior nasal swab specimens only.
- The performance of the iHealth® COVID-19/Flu A&B Rapid Test Pro has not been evaluated for use in patients who do not show signs and symptoms of respiratory infection.
- 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.
- Use of iHealth COVID-19/Flu A&B Rapid Test Pro is limited to laboratory personnel and CLIA waived users. This test is not for home use.
- The contents of this kit are to be used for the qualitative detection of influenza type A and B antigens as well as SARS-CoV-2 antigen from direct anterior nasal swab samples only.
- This test detects viable (live) and non-viable influenza A, influenza B, and SARS- CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture or molecular results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not identify specific influenza A subtypes, influenza B lineages, or SARS-CoV-2 variants.

- Negative test results cannot rule out diseases caused by other bacterial or viral pathogens.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low viral activity when prevalence is moderate to low.
- Individuals who received nasally administered influenza vaccine may have positive test results for up to 3 days after vaccination.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza viruses that have undergone minor amino acid changes in the target epitope region.
- If the differentiation of specific influenza A, influenza B, or SARS subtypes or variants is needed, additional testing, in consultation with state or local public health departments, is required.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The iHealth COVID-19/Flu A&B Rapid Test Pro Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

However, to assist in using the iHealth COVID-19/Flu A&B Rapid Test Pro ("your product" in the conditions below). the relevant Conditions of Authorization are listed below:

• Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.

• Authorized laboratories using your product must use your product as outlined in iHealth COVID-19/Flu A&B Rapid Test Pro Instructions for Use and Quick Reference Guide. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

• Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

• Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

• Authorized laboratories must collect information on the performance of your product and report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and iHealth by contacting Technical Services (via email at support@iHealthlabs.com or via phone at (855) 816-7705).

• All operators using your product must be appropriately trained in performing and

interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

- iHealth, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The Letter of Authorization refers to "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests.
This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation" as "Authorized Laboratories".

PERFORMANCE CHARACTERISTICS

Limit of Detection (LOD)

The limit of detection (LoD) for the iHealth COVID-19/Flu A&B Rapid Test Pro 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 negative clinical matrix. 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	Stock Concentration ($TCID_{50}$/mL)	LoD concentration ($TCID_{50}$/mL)	$TCID_{50}$/S wab	#Positive /#total Tested	Percent Detected (%)
SARS-CoV-2 (UV inactivated, USA-WA1/2020)	3.16×10^6	1.58×10^3	7.9×10^1	20/20	100%
Influenza A A/Victoria/4897/2022(H1N1)	2.02×10^5	5.05×10^2	2.53×10^1	20/20	100%
Influenza A A/Darwin/6/2021(H3N2)	4.17×10^5	4.17×10^2	2.09×10^1	20/20	100%

Influenza B Victoria/Washington/02/2019	3.16 x 10^6	3.16×10^3	1.58×10^2	20/20	100%
Influenza B Yamagata/Florida/4/2006	1.17×10^5	5.85×10^1	2.93×10^0	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 Pro 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 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	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 Pro. 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 samples.
Testing showed no evidence of cross-reactivity at the concentrations tested.

In silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was conducted to assess the degree of 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 (Species C)	1.02×10^6 $TCID_{50}$/mL	0/3	0/3	0/3
Adenovirus Type 7, Type 7A (Species B)	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 Type (e.g. 68), Species D Type 68	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 sp. diphtheriae Z116	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
Hemophilus influenzae, type b; Eagan	9.68×10^6 cfu/mL	0/3	0/3	0/3
Lactobacillus sp., Lactobacillus Acidophilus	1.21×10^7 cfu/mL	0/3	0/3	0/3
Legionella spp 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

Microorganism Introduced	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
Mycobacterium tuberculosis avirulent	3.03×10^5 cfu/mL	0/3	0/3	0/3
Neisseria meningitidis, serogroup A	3.43×10^6 cfu/mL	0/3	0/3	0/3
Neisseria sp. Elongata Z071	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 Protein A producer, e.g., Cowan strain, NCTC 8530 [S11]; Cowan's serotype 1	2.60×10^8 cfu/mL	0/3	0/3	0/3
Staphylococcus epidermidis (MRSE; RP62A)	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, Strain Edmonston	8.48×10^5 $TCID_{50}$/mL	0/3	0/3	0/3
Mumps (Isolate 1)	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 or 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	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)
	$TCID_{50}$/mL			
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 (Species C)	1.02×10^6 $TCID_{50}$/mL	3/3	3/3	3/3
Adenovirus Type 7, Type 7A (Species B)	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
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 Type (e.g. 68), Species D Type 68	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 sp. diphtheriae Z116	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
Hemophilus influenzae, type b; Eagan	9.68×10^6 cfu/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)
Lactobacillus sp., Lactobacillus Acidophilus	1.21×10^7 cfu/mL	3/3	3/3	3/3
Legionella spp 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 avirulent	3.03×10^5 cfu/mL	3/3	3/3	3/3
Neisseria meningitidis, serogroup A	3.43×10^6 cfu/mL	3/3	3/3	3/3
Neisseria sp. Elongata Z071	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 Protein A producer, e.g., Cowan strain, NCTC 8530 [S11]; Cowan's serotype 1	2.60×10^8 cfu/mL	3/3	3/3	3/3
Staphylococcus epidermidis (MRSE; RP62A)	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, Strain Edmonston	8.48×10^5 $TCID_{50}$/mL	3/3	3/3	3/3
Mumps (Isolate 1)	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 Pro. 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
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 alcohol	5% v/v	3/3	3/3	3/3
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 Pro 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 Pro 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 x 10^5	Yamagata	1.75 x 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. The other nasal swab sample was collected by a healthcare professional in UTM, at least 15 minutes before or after each subject/tester completed sample collection and testing on the investigational test. The HCP collected specimens were sent for testing by the reference methods, FDA-cleared molecular comparator tests, 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=523)**
Age			
Mean (SD)	8.1 (5.2)	34.6 (17.8)	20.1 (18.2)
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	Comparators Positives	Comparators 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.

ASSISTANCE

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

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REORDER

iHealth COVID-19/Flu A&B Rapid Test Pro (Model: ICF-3000P)
iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit (Model: CSW-ANSCF)

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 damage

 Manufacturer

 Contains sufficient for <n> tests

 Use-by date

 Batch code

℞ONLY Caution: Federal law restricts this device to sale by or on the order of a physician

Device for near-patient testing

Device not for self-testing

QTY Quantity

CONTROL - Negative control

CONTROL + Positive control

Uncontaminated recycled content-packaging, kit box, Instructions for Use is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program

Manufactured for iHealth Labs, Inc.
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Rev.05/31/2024

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

Instructions for Use

Model: CSW-ANSCF

For in vitro diagnostic use
For prescription use only
For use under Emergency Use Authorization (EUA) only

INTENDED USE

The iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit is intended for in vitro diagnostic use in quality control testing with the iHealth COVID-19/Flu A&B Rapid Test Pro.

SUMMARY

The iHealth COVID-19/Flu A&B Rapid Test Pro Control kit includes one COVID-19/Flu A&B Positive Control Swab and one COVID-19/Flu A&B Negative Control Swab for external quality control testing. Use the iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit to help ensure that the iHealth COVID-19/Flu A&B Rapid Test Pro is functioning properly and to demonstrate proper performance by the test operator. External controls are intended to monitor substantial device failure.
If External Quality Control testing fails, repeat the testing of the failed control or contact iHealth Technical Services at (855) 816-7705 or support@iHealthlabs.com before running patient samples.
External quality control requirements should be established in accordance with local, state, and federal regulations or accreditation requirements. Minimally, iHealth recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

KIT CONTENTS

1 - COVID-19/Flu A&B Positive Control Swab coated with non-infectious recombinant influenza A, influenza B, and SARS-CoV-2 antigen
1 - COVID-19/Flu A&B Negative Control Swab
1 - iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

• iHealth COVID-19/Flu A&B Rapid Test Pro
• Timer or Clock

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. 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 and influenza A/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.
3. Caution: Federal law restricts this device to sale by or on the order of a physician.
4. DO NOT use the iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit past the expiration date.
5. Not for patient use.
6. Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
7. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
8. The control swab and test device should be discarded in a proper biohazard container after testing.

KIT STORAGE AND STABILITY

The iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit must be stored at room temperature 36-86°F (2-30°C).
Shelf life: The expiration date is labeled on the package.

EXTERNAL QUALITY CONTROL TESTING PROCEDURE

To perform a positive or negative control test, complete the steps in the Test Procedure section of the assay Instructions for Use treating the control swab in the same manner as a patient swab (refer to iHealth COVID-19/Flu A&B Rapid Test Pro Instructions for Use, available on the website: https://support.ihealthlabs.com/3-in-1-POC-IFU).

EXPECTED RESULTS

A Positive External Control Result

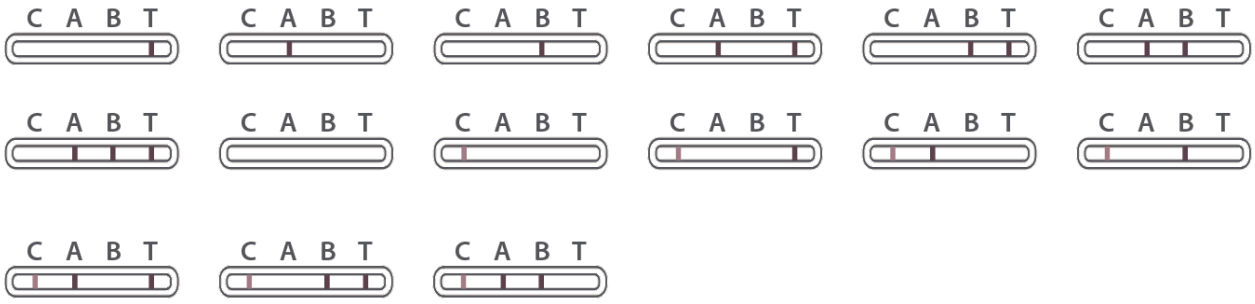
When the COVID-19/Flu A&B Positive Control Swab is tested, the appearance of ANY shade of a very light or faint pink or purple line at the “A” Test Line, “B” Test Line, and “T” Test Line, along with a “C” Control Line indicates that the influenza and SARS-CoV-2 antigen binding properties of the Test Card are functional.

A Negative External Control Result

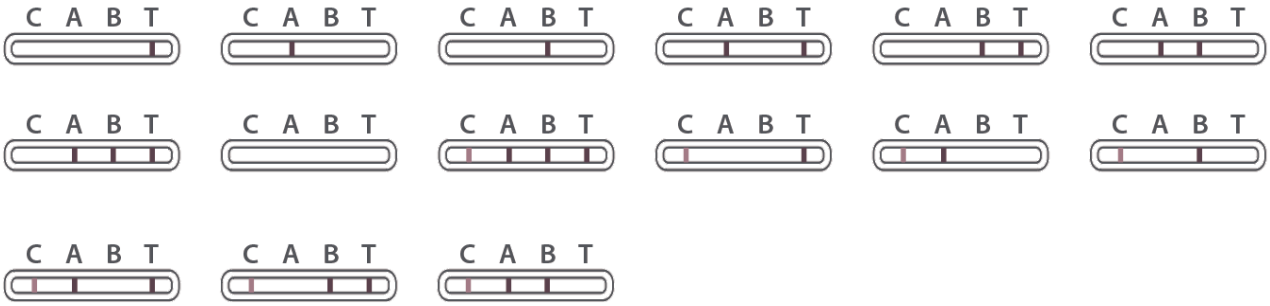
When the COVID-19/Flu A&B Negative Control Swab is tested, there should only be the appearance of the “C” Control Line without lines at the “A” Test Line, “B” Test Line, nor the “T” Test Line to indicate that there is no non-specific antigen binding and the Test Card is functional.

Invalid Result

When any other results occur for Positive External Control, it is considered that the test kit is invalid.



When any other results occur for Negative External Control, it is considered that the test kit is invalid.



If invalid results happens either on Negative Control Swab or on Positive Control Swab, the associated test kit may be invalid and do NOT proceed with testing any clinical samples.

Note: Results inconsistent with the illustrations are considered invalid. Please retest using a new positive and/or negative quality control swab. If you receive invalid results more than two consecutive times from the same batch, please contact technical support.

Refer to the iHealth COVID-19/Flu A&B Rapid Test Pro Instructions for Use for a complete description of the assay procedure and interpretation of results.

DISPOSING OF MATERIALS

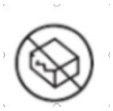
Dispose of hazardous or biologically contaminated materials according to your institution's practices. Discard all materials in a safe and acceptable manner that is in compliance with all
country, state, and local requirements.

REORDER

iHealth COVID-19/Flu A&B Rapid Test Pro (Model: ICF-3000P)
iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit (Model: CSW-ANSCF)

SYMBOLS

Caution

	Do not re-use
	Consult Instructions for Use
IVD	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
LOT	Batch code
$\mathbf{R_x}$ ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
	Device for near-patient testing
	Device not for self-testing
QTY	Quantity
CONTROL –	Negative control
CONTROL +	Positive control

Uncontaminated recycled content-packaging, kit box, Instructions for Use is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program

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