iHealth®

COVID-19/Flu A&B Rapid Test

QUICK REFERENCE INSTRUCTIONS

For use under Emergency Use Authorization (EUA) only

For in vitro diagnostic use.

For use with anterior nasal swab specimens.

Carefully read all instructions 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.**

An anterior nasal swab sample can be self-collected by an individual aged 14 years or older. Children aged 2-13 years should be tested by an adult.

STORAGE AND STABILITY

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

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:

1x Swab

1x Test Card in Pouch

1x Test Tube with Extraction Solution

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.

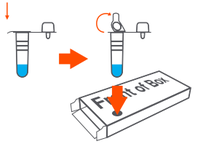
DO NOT open the individual pouches until instructed to do so.

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.

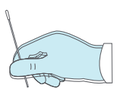
Remove the Test Card from its foil pouch.

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).

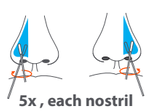
9.

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.**

REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.



5x , each nostril

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.

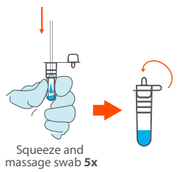
Place the swab into the extraction solution making sure the swab head is completely immersed.

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.

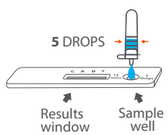


Close the dropper cap that is attached to the tube.

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.

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.

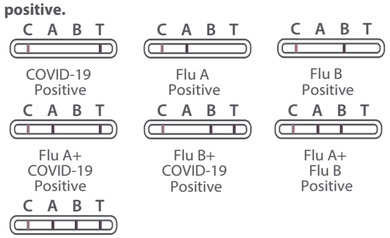
NEGATIVE RESULTS

If the control line at "C" is visible and you do not see a line at 'A', 'B', or 'T', it means the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours.

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.

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

UNDERSTANDING YOUR RESULTS

INVALID RESULT:

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.

NEGATIVE RESULT:

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 RESULT:

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.

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.

iHealth

COVID-19/Flu A&B Rapid Test

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.

HOW TO USE THIS TEST

Serial testing should be performed in all individuals with SARS-CoV-2 negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

If you test SARS-CoV-2 negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.

If your test is SARS-CoV-2 positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

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 and hand sanitizer 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	Concentrations
Triton X-100	Harmful if swallowed (H302) Causes skin irritation (H315) Causes 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-respose/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 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 60 minutes. It is recommended to use the test kit immediately after opening. The expiration date is on the package.

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.

FREQUENTLY ASKED QUESTIONS

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Warnings and Result Interpretation sections for more information).

Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 and flu to the family of the tested individual and others in your community.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the viruses that cause COVID-19 and the flu. Molecular tests detect genetic material from the virus. Antigen tests, such as the iHealth COVID-19/Flu A&B Rapid Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

Q: WHAT IF I HAVE A COVID-19 POSITIVE TEST RESULT?
A: A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self isolate from others and contact a healthcare provider for medical advice about your positive result.

Q: WHAT IF I HAVE A COVID-19 NEGATIVE TEST RESULT?
A: A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: HOW ACCURATE IS THIS TEST?
A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at https://support.ihealthlabs.com/3-in-1-IFU.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: An invalid result means the test was not able to tell if you have COVID-19 and influenza infection or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

IMPORTANT: Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

SYMBOLS

	Manufacturer	IVD	*In vitro* diagnostic medical device		Use-by Date
	Consult instructions for use	REF	Catalog number		Do not re-use
	Temperature limit	LOT	Batch code	OTC	Over-the-Counter

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.

iHealth

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

Revision Date:
05/07/2024

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®

Rapid Self-Test

Results In 15 Mins

Insert tube here

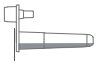
1 TEST

COVID-19 Flu A&B 3-in-1

iHealth

Components

COVID-19/Flu A&B Test Card



Tube

Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

IVD OTC 2℃ 36℉ 30℃ 86℉

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

1 × COVID-19/Flu A&B Test Card; **1** × Tube; **1** × Swab

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

UDI

UPC

Model: ICF-3000

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®

Rapid Self-Test

Results In 15 Mins

Insert tube here

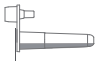
2 TESTS

COVID-19 Flu A&B 3-in-1

iHealth

Components

COVID-19/Flu A&B Test Card



Tube

Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

IVD OTC 2℃ 36℉ 30℃ 86℉

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

2 × COVID-19/Flu A&B Test Card; **2** × Tube; **2** × Swab

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

UDI

UPC

Model: ICF-3000

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®
Rapid Self-Test
Results In 15 Mins

Insert tube here

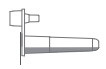
3 TESTS

COVID-19 Flu A&B 3-in-1

iHealth

Components


COVID-19/Flu A&B Test Card


Tube


Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

IVD OTC 2℃ 36℉ 30℃ 86℉

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

3 × COVID-19/Flu A&B Test Card; **3** × Tube; **3** × Swab

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

UDI

UPC

Model: ICF-3000

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®
Rapid Self-Test
Results In 15 Mins

Insert tube here

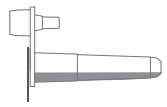
4 TESTS

COVID-19 Flu A&B 3-in-1

iHealth

Components

COVID-19/Flu A&B Test Card



Tube

Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

IVD OTC 2℃ 36℉ 30℃ 86℉

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

4 × COVID-19/Flu A&B Test Card; **4** × Tube; **4** × Swab

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

UDI

Model: ICF-3000

UPC

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®
Rapid Self-Test
Results In 15 Mins

Insert tube here

5 TESTS

COVID-19 Flu A&B 3-in-1

iHealth

Components

COVID-19/Flu A&B Test Card

Tube

Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

IVD OTC 2℃ 36℉ 30℃ 86℉

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

5 × COVID-19/Flu A&B Test Card; **5** × Tube; **5** × Swab

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

UDI

Model: ICF-3000

UPC

iHealth®

Rapid Self-Test

Results In 15 Mins

25 tests

COVID-19 Flu A&B 3-in-1

Insert Tube Here

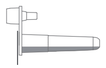
- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.

IVD OTC

2℃ 36℉ 30℃ 86℉

Components

COVID-19/Flu A&B Test Card



Tube

Swab

iHealth

COVID-19/Flu A&B Rapid Test

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www.fda.gov/covid-tests

Contents

25 × COVID-19/Flu A&B Test Card; **25** × Tube; **25** × Swab

Manufactured for iHealth Labs, Inc.
880 W Maude Ave, Sunnyvale, CA 94085 USA

Made in China
1-855-816-7705

www.ihealthlabs.com

UDI

Model: ICF-3000

UPC

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.

IVD OTC 2℃ 36℉ 30℃ 86℉

Components

COVID-19/Flu A&B Test Card

Tube

Swab

iHealth

COVID-19/Flu A&B Rapid Test

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

For more information about current expiration dates for at-home OTC COVID-19/Influenza diagnostic tests, please visit: http://www.fda/gov/covid-tests

Contents

40 × COVID-19/Flu A&B Test Card; **40** × Tube; **40** × Swab

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

UDI

Model: ICF-3000

UPC

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®

Rapid Self-Test

Results In 15 Mins

Insert tube here

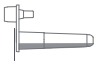
1 TEST

COVID-19 Flu A&B 3-in-1

iHealth

Components

COVID-19/Flu A&B Test Card



Tube

Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

IVD OTC 2℃ 36℉ 30℃ 86℉

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

1 × COVID-19/Flu A&B Test Card; **1** × Tube; **1** × Swab

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

UDI

Model: ICF-3000

iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706

UPC

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®

Rapid Self-Test

Results In 15 Mins

Insert tube here

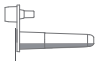
2 TESTS

COVID-19 Flu A&B 3-in-1

iHealth

Components

COVID-19/Flu A&B Test Card



Tube

Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

IVD OTC 2℃ 36℉ 30℃ 86℉

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

2 × COVID-19/Flu A&B Test Card; **2** × Tube; **2** × Swab

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

UDI

Model: ICF-3000

iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706

UPC

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®
Rapid Self-Test
Results In 15 Mins

Insert tube here

3 TESTS

COVID-19 Flu A&B 3-in-1

iHealth

Components

COVID-19/Flu A&B Test Card

Tube

Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

IVD OTC 2℃ 36℉ 30℃ 86℉

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

3 × COVID-19/Flu A&B Test Card; **3** × Tube; **3** × Swab

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

UDI

Model: ICF-3000

iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706

UPC

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®
Rapid Self-Test
Results In 15 Mins

Insert tube here

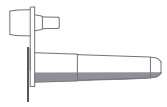
4 TESTS

COVID-19 Flu A&B 3-in-1

iHealth

Components

COVID-19/Flu A&B Test Card



Tube

Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

IVD OTC 2℃ 36℉ 30℃ 86℉

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

4 × COVID-19/Flu A&B Test Card; **4** × Tube; **4** × Swab

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

iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706

UDI

UPC

Model: ICF-3000

iHealth COVID-19/Flu A&B Rapid Test

iHealth

iHealth®
Rapid Self-Test
Results In 15 Mins

Insert tube here

5 TESTS

COVID-19 Flu A&B 3-in-1

iHealth

Components

COVID-19/Flu A&B Test Card

Tube

Swab

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

IVD OTC 2℃ 36℉ 30℃ 86℉

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.
- For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www/fda/gov/covid-tests

Contents

5 × COVID-19/Flu A&B Test Card; **5** × Tube; **5** × Swab

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

iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706

UDI

Model: ICF-3000

UPC

iHealth®

Rapid Self-Test

Results In 15 Mins

25 tests

COVID-19 Flu A&B 3-in-1

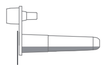
Insert Tube Here

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.

IVD OTC 2℃ 36℉ 30℃ 86℉

Components

COVID-19/Flu A&B Test Card



Tube

Swab

iHealth

COVID-19/Flu A&B Rapid Test

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www.fda.gov/covid-tests

Contents

25 × COVID-19/Flu A&B Test Card; **25** × Tube; **25** × Swab

iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706

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

Model: ICF-3000

UDI

UPC

COVID-19
Flu A&B
3-in-1

Insert tube here

iHealth®

Rapid Self-Test

Results In 15 Mins

40 Tests

- **Items necessary to use the test but not provided in the test kit:** timer or clock.
- Use immediately after opening the foil pouch.
- Avoid contact of the extraction solution in the Test Tube with skin and eyes.

IVD OTC 2℃ 36℉ 30℃ 86℉

Components

COVID-19/Flu A&B Test Card

Tube

Swab

iHealth

COVID-19/Flu A&B Rapid Test

iHealth

For use under Emergency Use Authorization (EUA) only.

Do not use if you have had symptoms longer than 4 days or no symptoms at all.

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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.

Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

For more information about current expiration dates for at-home OTC COVID-19/Influenza diagnostic tests, please visit: http://www.fda/gov/covid-tests

Contents

40 x COVID-19/Flu A&B Test Card; **40** x Tube; **40** x Swab

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

iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706

UDI

Model: ICF-3000

UPC